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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	NA001KR_US2
First Named Inventor	Na
Title	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
Express Mail Label No.	via EFSWEB

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [ ] **Fee Transmittal Form** (PTO/SB/17 or equivalent)
2. [X] **Applicant asserts small entity status.** See 37 CFR 1.27.
3. [ ] **Applicant certifies micro entity status.** See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
4. [X] **Specification** [*Total Pages* 26] Both the claims and abstract must start on a new page *(See MPEP § 608.01(a)) for information on the preferred arrangement)*
5. [X] **Drawing(s)** *(35 U.S.C. 113)* [*Total Sheets* 21]
6. **Inventor's Oath or Declaration** [*Total Sheets* 1] *(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))*
   a. [ ] Newly executed (original or copy)
   b. [X] A copy from a prior application (37 CFR 1.63 (d))
7. [X] **Application Data Sheet** **See Note Below.* See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
8. [ ] **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)*
   [ ] Landscape Table on CD
9. **Nucleotide and/or Amino Acid Sequence Submission.** (*if applicable, items a. – c. are required*)
   a. [ ] Computer Readable Form (CRF)
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ACCOMPANYING APPLICATION PAPERS

10. [ ] **Assignment Papers** (cover sheet & document(s))
    Name of Assignee
11. [ ] **37 CFR 3.73(c) Statement** [ ] **Power of Attorney** (*when there is an assignee*)
12. [ ] **English Translation Document** *(if applicable)*
13. [ ] **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    [ ] Copies of citations attached
14. [X] **Preliminary Amendment – 8 pages**
15. [ ] **Return Receipt Postcard** *(MPEP § 503) (Should be specifically itemized)*
16. [ ] **Certified Copy of Priority Document(s)** *(if foreign priority is claimed)*
17. [ ] **Nonpublication Request** under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
18. [X] **Other:**
    Replacement drawings pages (6 pages)
    Marked Up Specification (24 Pages)
    Clean copy of amended Specification (24 Pages)

***Note:** (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS

[X] The address associated with Customer Number: 26338 ***OR*** [ ] Correspondence address below

Name					
Address					
City		State		Zip Code	
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Signature	/mwresq/	Date	October 3, 2017
Name (Print/type)	*Merle Richman*	Registration No. (Attorney/Agent)	38282

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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SUBSTITUTE SPECIFICATION – CLEAN

UNITED STATES PATENT APPLICATION

METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

INVENTOR

Jongju Na of Republic of Korea

Prepared by:

Merle W. Richman, Esq.
P.O. Box 3333
La Jolla, CA 92038-3333
ATTORNEY DOCKET NA001KR_US3

METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

Cross Reference to Related Applications

[0001] The present application is a continuation of US Application Number 15096686, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT", Attorney Docket No. NA001KR_US2 filed on April 12, 2016, which is a continuation of US Application Number 13/825,083, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMALOGICAL TREATMENT", Attorney Docket No. NA001KR_US filed on January 20, 2014 now US Patent 9320536, which is a National Stage entry of PCT/KR2012/001335, filed on February 22, 2012, which claims priority to US Application Number 61/449,080, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMALOGICAL TREATMENT", Attorney Docket No. NA001US1 filed on March 3, 2011 and US Application Number 13/060,274, Patent No. 8979912, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMALOGICAL TREATMENT", Attorney Docket No. NA001US filed on February 22, 2011, which is a National Stage entry of PCT Application Number PCT/US2008/074131, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMALOGICAL TREATMENT", Attorney Docket No. NA001PCT filed on August 22, 2008, which claims priority to Republic of Korea Application Number 10-2008-0076993, entitled "Electrical system, skin, skin care and cosmetic electricity," filed on August 6, 2008, the entirety of each is incorporated by reference.

Technical Field

[0002] Various embodiments described herein relate generally to treating dermatological tissue, including systems, and methods used in treating dermatological tissue.

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Background Information

[0003] It may be desirable to treat dermatological tissue; the present invention provides such treatment.

Brief Description of the Drawings

[0004] FIG. 1A is a simplified isometric diagram of a dermatological treatment apparatus according to various embodiments.

[0005] FIG. 1B is a simplified, side diagram of the dermatological treatment apparatus according to various embodiments.

[0006] FIG. 1C is a simplified, exploded layer view of the dermatological treatment apparatus according to various embodiments.

[0007] FIG. 1D is a simplified view of a layer of a dermatological treatment apparatus according to various embodiments.

[0008] FIG. 2A is a simplified isometric diagram of a dermatological treatment architecture according to various embodiments.

[0009] FIG. 2B is a simplified cross-sectional diagram of a dermatological treatment apparatus according to various embodiments.

[0010] FIG. 2C is a simplified cross-sectional diagram of another dermatological treatment apparatus according to various embodiments.

[0011] FIG. 2D is a simplified cross-sectional diagram of another dermatological treatment apparatus according to various embodiments.

[0012] FIG. 2E is a simplified view of a layer of a dermatological treatment apparatus according to various embodiments.

[0013] FIG. 2F is a simplified, exploded view of layers of the dermatological treatment apparatus according to various embodiments.

[0014] FIG. 3A is a simplified isometric diagram of a dermatological treatment apparatus according to various embodiments.

[0015] FIG. 3B is a simplified isometric diagram of another dermatological treatment apparatus according to various embodiments.

[0016] FIG. 4A is a simplified view of a layer of a dermatological treatment apparatus according to various embodiments.

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[0017] FIG. 4B is a simplified view of a layer and apparatus of a dermatological treatment system according to various embodiments.

[0018] FIG. 4C is a simplified view of a layer and apparatus of a dermatological treatment system according to various embodiments.

[0019] FIGs. 5A-6 are diagrams of signals that may be applied to one or more dermatological treatment systems according to various embodiments.

[0020] FIG. 7A-7C are flow diagrams illustrating dermatological treatment system processing algorithms according to various embodiments.

[0021] FIG. 8 is a block diagram of an article according to various embodiments.

[0022] FIG. 9A is a simplified block diagram of a dermatological treatment architecture according to various embodiments.

[0023] FIG. 9B is a block diagram of an article according to various embodiments that may be employed in architecture of FIG. 9A.

[0024] FIG. 9C is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus with the needles retracted according to various embodiments.

[0025] FIG. 9D is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus with the needles deployed according to various embodiments.

[0026] FIG. 10A-10D are simplified, partial, cross-sectional diagrams of a cartridge in various stages of attachment to a dermatological treatment apparatus according to various embodiments.

[0027] FIG. 10E is a simplified, partial, cross-sectional diagram of a dermatological treatment apparatus with needles deployed according to various embodiments.

[0028] FIG. 10F is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus cartridge interface according to various embodiments.

[0029] FIG. 11A is a simplified, partial, cross-sectional diagram of a dermatological treatment apparatus cartridge coupled to a handle with needles deployed according to various embodiments.

[0030] FIG. 11B is a simplified, cross-sectional diagram of a cartridge needle assembly according to various embodiments.

[0031] FIG. 11C is a simplified, cross-sectional, exploded diagram of a cartridge needle assembly according to various embodiments.

[0032] FIG. 12 is a flow diagram illustrating a dermatological treatment system processing algorithms according to various embodiments.

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Detailed Description

[0033] FIG. 1A is a simplified isometric diagram and FIG. 1B is a simplified side view of a dermatological treatment apparatus 10 according to various embodiments. The apparatus 10 may include a user handle 220 coupled to an acupuncture plate 200. In an embodiment the plate 200 may be elastically coupled to the handle segment 222 via an elastomeric section 210. The elastomeric section may be comprised of a combination of elastomeric materials and non-elastomeric materials. The elastomeric materials may include plastics, rubber (synthetic or natural), and spring(s).

[0034] FIG. 1C includes a simplified exploded view of an embodiment of an acupuncture plate 200 according to various embodiments. The plate 200 may include an upper, substantially rigid section or layer 290, deformable or elastic section 270 or layer, and acupuncture section or layer 250. The acupuncture section 250 may include a plurality of acupuncture pins or needles 230. FIG. 1D is a simplified bottom view of the plate 200 showing the location or holes 212 for the pins or needles 230. In an embodiment the plate 200 may have a rectangular cross section having a dimensional about 1 to 4 cm in width and about 1 to 6 cm in length. The plate 200 may any shape including circular, elliptical, polygon, or other shape where the shape may be particular to a dermatological area to be treated.

[0035] In an embodiment the plate may include about 140 pins or needles 230 uniformly separated. Each needle may be about 0.1 to 0.4 mm in diameter and 0.2 mm to 1.4 mm in length including 0.3 mm diameter and 0.8 mm in length in an embodiment. The elastic section or layer 270 may be comprised of a combination of elastomeric materials and non-elastomeric materials. The elastomeric materials may include plastics, rubber (synthetic or natural), and spring(s). The pin section 250 may be coupled directly or indirectly to the upper section 290 via the elastic section 270, including via glues, screws, welds, or other connection. In an embodiment the pin section 250 may include elastomers to enable at least partial deformation of the pin section 250 about the pins 230.

[0036] In operation a user may employ the apparatus 10 to create a plurality of micro-wounds or holes in dermatological layers of a mammal's 20 skin or dermis. The micro-wound or hole creation may improve the absorption or application of one or more chemicals applied on or about the micro-wounds or holes.

[0037] FIG. 2A is a simplified diagram of a dermatological treatment architecture 310 according to various embodiments. Architecture 310 includes an acupuncture apparatus 320 and an

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electrical signal generation system 300. The electrical signal generation system 300 may be electrically coupled to the acupuncture apparatus 320 via one or more wires 300A and to a mammal 20 to be treated via one or more wires 300B. FIG. 2B is a simplified cross-sectional diagram of the acupuncture apparatus 320 according to various embodiments. The apparatus 320 may include a handle 330, elastic section 333, electrical interface 340, internal wire(s) 331and plate 350. The pins 351 may have a length A (0.3 mm to 2.1 mm in an embodiment) where at least one pin 351 is electrically coupled to the electrical interface 340 via the internal wire 331. The electrical interface 340 may be removably connected to the system 300 wire 300A.

[0038] The electrical signal generation system 300 may generate a variety of signals (such as shown in FIGS. 5A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and lead 300A. A pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351. FIG. 2C is a simplified cross-sectional diagram of an acupuncture apparatus 360 according to various embodiments. The apparatus 360 may include a handle 330, an elastic section 333, an electrical conductive interface 390, internal wire(s) 331, signal generator 370, switch 375, and plate 350. The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to the conductive interface 390.

[0039] The signal generator or module 370 may generate a variety of signals (such as shown in FIGS. 5A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and the conductive interface 390. In operation a user 20 may touch the conductive interface 390 and place one or more electrically coupled pins 351 in contact with their dermis to form an electrical pathway from the pin 351 to the electrical conductive interface 390. The signal generator 370 may include a battery to supply energy to generate one or more electrical signals. The switch 375 coupled to the generator 370 may cause the generator to produce one or more electrical signals for a predetermined time interval or until the switch 375 is triggered again. As noted a pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351.

[0040] FIG. 2D is a simplified cross-sectional diagram of an acupuncture apparatus 362 according to various embodiments. The apparatus 362 may include a handle 330, an elastic section 333, internal wire(s) 331, 332, signal generator 370, switch 375, and plate 350. The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to at least one other pin 352 via internal wire 332. When active the pins 351, 352 may form at least one dipole pair. The

signal generator or module 370 may generate a variety of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins 351, 352.

[0041] FIG. 2F includes a simplified exploded view of an embodiment of an acupuncture plate 350 including at least one electrically coupled pin 351 according to various embodiments. The plate 350 may include an upper, substantially rigid section or layer 357, deformable or elastic section 355 or layer, and acupuncture section or layer 353. The acupuncture section 353 may include a plurality of acupuncture pins or needles 351 where at least one pin 351 is electrically coupled to the wire 331. In a bipolar configuration a second wire 332 may be coupled to at least one other pin 351. FIG. 2E is a simplified bottom view of the plate 350 showing the pins or needles 359, 357 where the pins may be electrically coupled to a first wire 331 and a second wire 332 to form dipole pair (bipolar pins).

[0042] In an embodiment the plate 350 may have a rectangular cross section having a dimensional about 1 to 4 cm in width and about 1 to 6 cm in length. The plate 350 may any shape including circular, elliptical, polygon, or other shape where the shape may be particular to a dermatological area to be treated.

[0043] In an embodiment the plate may include about 140 pins or needles 351 uniformly separated. Each needle may be about 0.1 to 0.4 mm in diameter and 0.2 mm to 1.4 mm in length including 0.3 mm diameter and 0.8 mm in length in an embodiment. The elastic section or layer 355 may be comprised of a combination of elastomeric materials and non-elastomeric materials. The elastomeric materials may include plastics, rubber (synthetic or natural), and spring(s). The pin section 353 may be coupled directly or indirectly to the upper section 357 via the elastic section 355, including via glues, screws, welds, or other connection. In an embodiment the pin section 353 may include elastomers to enable at least partial deformation of the pin section 353 about the pins 351.

[0044] FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus 400, 460 including at least one pin 451 that may be coupled to an electrical signal via an internal wire 458. Each apparatus 400, 460 includes curved roller 450 having a plurality of acupuncture pins 451 where the pins 451 may be similar to pins 351. In apparatus 400, the electrical lead wire 300A may be coupled to an electrical interface 410 in the apparatus handle 430 where the interface 410 is electrically coupled to the internal wire 458. In apparatus 460, the handle 430 may include a signal generator 470 similar to generator 370, switch 475, and conduction surface 490. Apparatus 460 may

operate similar to apparatus 360 in operation other than the rolling capability of the apparatus 460, 400. In an embodiment the rollers 450 may have various configurations to conform to a dermal area to be treated.

[0045] In any of the above apparatus 10, 320, 350, 360, 400, 460, the plate or roller 200, 350, 450 may include a plurality of embedded LEDs 32A, 32B, a battery 52, a controller 54, and an antenna 56 as shown in FIG. 4A. In an embodiment the LED 32A may be configured to emit energy of a first particular frequency range and the LED 32B may be configured to emit energy of a second particular frequency range. The surface 22 of a roller 450, plate 200, 350, 450 may also be embedded with a chemical 22A that may be used to treat dermatological cells. The chemical 22A may be reactive to the first and the second frequency ranges. Further dermatological cells may be reactive to the first and the second frequency ranges. In addition, the combination of the chemical 22A and the application of the first and the second frequency ranges to the chemical 22A and dermatological cells may have a synergetic effect.

[0046] In an embodiment the chemical 22A may be applied directly to the dermatological cells to be treated. In a further embodiment a chemical 22A may not be employed in addition to the apparatus 10, 320, 350, 360, 400, 460. In an embodiment the pin section 250, 353, may be translucent and comprised of polyurethane, medical silicon, or other pliable, translucent, hypoallergenic material.

[0047] In an embodiment the local controller 54 and battery 52 may also be embedded in the upper section 290, 357, pin section 230, 351, or the handle 220, 330, or separately between these sections. The controller 54 may be electrically coupled to the one or more LEDs 32A, 32B. The controller 54 may also be coupled to a battery 52. The controller 54 may generate one or more signals for LEDs 32A, 32B as a function of a user switch 75, 56. The signals may vary as a function of the first and second frequency ranges. The controller 54 may include one or more timers 58 that may limit the application of energy to the LEDs 32A, 32B to predetermined time intervals. In an embodiment the controller may also be coupled to an antenna 56 to receive or transmit one or more signals related to the transmission of energy to one or more LEDs 32A, 32B. In an embodiment the system 10 may be configured to treat a particular segment of dermatological cells such as a face. The apparatus 10 may be configured to conform to a user's anatomy so that emitted light is focused on dermatological cells. In another embodiment 200, the system 200 may be configured to treat

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another anatomical region including dermatological cells on an arm, leg, chest, hands, feet, neck, or other region.

[0048] In an embodiment 510 shown in FIG. 4B, a controller 54, an antenna 104, and a power source 60 may be located external to the apparatus 10, 320, 360. The power source 60 may be coupled to the controller 54. The controller 54 may be coupled to one or more LEDs 32A, 32B via one or more electric wires 106. The controller 54 may generate one or more signals for LEDs 32A, 32B as a function of the user switch 56. The signals may vary as a function of the first and second frequency ranges. The controller 54 may include one or more timers 58 that may limit the application of energy to the LEDs 32A, 32B to predetermined time intervals. In an embodiment the controller may also be coupled to an antenna 104 to receive or transmit one or more signals related to the transmission of energy to one or more LEDs 32A, 32B.

[0049] As shown in FIG. 4C, in any of the above apparatus 10, 320, 350, 360, 400, 460, the plate or roller 200, 350, 450 may include a plurality of embedded LED lens 536, a fiber optic pathway 534, and an LED 532. In this embodiment, system 530 LED 532 shown in FIG. 4C may be coupled to lens 536 via the fiber optic pathway 534. The controller 540 may generate an LED signal via the LED 532 that is transmitted to dermatological cells via the lens 536 and the fiber optic pathway 534.

[0050] FIGS.5A-5B are diagrams of electrical signal waveforms 650, 630, 640 that may be applied to one or more LEDs 32A, 32B, 532 and to the pins 230, 351, 451 according to various embodiments. The signal waveform 650 includes several square-wave pulses 652, 654, 656 that may be applied to an LED 32A, 32B, 532. Each pulse 652, 654, 656 may a have a similar magnitude and envelope. The waveform 650 may be used to energize an LED 32A, 32B, 532 and to the pins 230, 351, 451 periodically P1 for a predetermined interval T1 where each pulse 652, 654, 656 has a amplitude A1. In an embodiment, A1 may be about 0.1 milliamperes (mA) to 10 mA, the pulse width T1 may be about 100 microseconds (μs) to 500 μs and the period P1 may from 100 ms to 500 ms as a function of the energy required to create capacitance in a liquid. In another embodiment, A1 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width T1 may be about 200 microsecond (μs) and the period P1 may about 250 ms as a function of the energy to drive an LED or cause one or more pins 230, 351, 451 to vibrate.

[0051] In FIG. 5B a signal waveform 630 may be applied to a first LED 32A, 32B, 532 module or group and to the pins 230, 351, 451 and a second waveform 640 may be applied or used

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to energize a second LED 32A, 32B, 532 module and the pins 230, 351, 451, 352. The signal waveform 630 includes several square-wave pulses 632, 634, and 636 and the signal waveform 640 includes several square-wave pulses 642, 644, and 646. Each pulse 632, 634, 636, 642, 644, 646 may a have a similar magnitude and envelope. The waveform 630 may be used to energize a first LED 32A, 32B, 332 module and the pins 230, 351, 451 periodically P1 for a predetermined interval T1 where each pulse 632, 634, 636 has an amplitude A1. The waveform 640 may be used to energize a second LED 32A, 32B, 332 module and the pins 230, 351, 451 periodically P2 for a predetermined interval T2 where each pulse 642, 644, 646 has an amplitude B1. The pulse width T1, T2 may be about 100 microseconds (μs) to 500 μs and the period P1, P2 may from 100 ms to 500 ms as a function of the energy to affect dermatological cells or chemicals 22A. In another embodiment, A1, A2 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width T1, T2 may be about 200 microsecond (μs) and the period P1, P2 may about 250 ms as a function of the energy required to affect dermatological cells or chemicals 22A. In an embodiment the pulses 632, 634, 636 do not substantially overlap the pulses 642, 644, 646. In an embodiment T1 > T2 and P2 is an integer multiple of P1.

[0052] FIG. 6 depicts a waveform 670 that includes multiple pulses 672, 674, 676, 678, 682, and 684 that may not overlap in the time or the frequency domain. In an embodiment each pulse 672, 674, 676, 678, 682, and 684 may have a pulse width T3, and frequency spectrum width F1 and period P3. The pulse 672 is frequency offset from the pulse 674, the pulse 676 is frequency offset from the pulse 678, and the pulse 682 is frequency offset from the pulse 684. The pulses 672, 674, 676, 678, 682, and 684 may be applied to an LED module to affect dermatological cells or chemicals 22A and the pins 230, 351, 451. Pulses 672, 674 having different frequency spectrums may enable different LED stimulation. In an embodiment the pulses 672, 676, 682 may be applied to a first LED module and the pulses 674, 678, 684 may be applied to a second LED module. The frequency separation between the respective pulses may enable simultaneous energization of a first and a second LED module and the pins 230, 351, 451 and subsequent and independent spectrum generation.

[0053] In an embodiment the invention may employ the algorithm 740 shown in FIG. 7A to apply therapy to dermatological cells. A user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermatological cells to be treated (activity 741) including pressing the apparatus against the cells firmly enough to embed one or more pins 251, 351, 451 in the cells. A

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first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a first LED module or group (32A) and the pins 230, 351, 451 of a dermatological apparatus 10, 320, 360, 360, 400, 460 (activity 742) for a predetermined time period (activity 744). A second signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a second LED module or group (32B) and the pins 230, 351, 451 of a dermatological apparatus 10, 320, 360, 360, 400, 460 (activity 746) for a predetermined time period (activity 748). The signals applied to the groups may be selected to stimulate dermatological cells or chemicals 22A or cause vibration of one or more pins 251, 351, 451.

[0054] In another embodiment the invention may employ the algorithm 750 shown in FIG. 7B to apply therapy to dermatological cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermatological cells to be treated (activity 751). The user, clinician, or equipment may place apparatus 10, 320, 360, 360, 400, 460 on dermatological cells to be treated (activity 752). A signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a LED module or group (32A or 32B) and the pins 230, 351, 451 (activity 354) for a predetermined time period (activity 356).

[0055] In another embodiment the invention may employ the algorithm 760 shown in FIG. 7C to apply therapy to dermatological cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermatological cells to be treated (activity 761). The user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermatological cells to be treated (activity 762). A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a first LED module or group (32A) and one or more pins 251, 351, 451 of a dermatological apparatus 10, 320, 360, 360, 400, 460 (activity 763) for a predetermined time period (activity 764). A second signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a second LED module or group (32B) and one or more pins 251, 351, 451 of a dermatological apparatus 10, 320, 360, 360, 400, 460 (activity 766) for a predetermined time period (activity 768).

[0056] The apparatus 10, 320, 360, 360, 400, 460 may be used to employ cosmetic or medications or other chemicals directly on dermatological cells such as skin with the addition of light of specific frequencies for treatment and healing of epidermal cells of the skin or tissue below the skin with the object of assisting the agents used in delivery, uptake, action and function more effectively. The LEDs 32A, 32B may create the specific frequencies of light. The apparatus 10, 320, 360, 360, 400, 460, light application may enable cosmetic or medication or other active chemicals 22A on dermatological cells for longer time periods while preventing dehydration of the

applied substances. Such light application may improve the efficacy of cosmetic or medication or other active chemical as a function of the selected wavelengths or frequencies.

[0057] Further the dermatological system application may increase cellular activity and help heal tissue faster and facilitate the delivery, uptake and use in the cell of the cosmetics, medications, or chemicals 22A used. The LED light of specific frequencies may increase fibroblast production and collagen as well as other activities of the cell including stimulating the organelles and mitochondria to produce ATP for cell energy for functioning, decreasing treatment time and facilitate healing. The apparatus 10, 320, 360, 360, 400, 460 make the agents used on the body more efficacious and useful to the body on a cellular level.

[0058] The apparatus 10, 320, 360, 360, 400, 460 may stimulate the basic energy processes in the mitochondria (energy compartments) of each cell, particularly when near-infrared light is used to activate the color sensitive chemicals (chromophores, cytochrome systems) inside but not limited to these spectrum alone as the UV, other visible and IR spectrums may also be usable. In an embodiment optimal LED wavelengths for skin repair may include 640, 680, 730 nanometers (nm) wavelengths to IR 880 nm. Further application of blue light 400 nm to 490 via the apparatus 10, 320, 360, 360, 400, 460 may inhibit the growth and kill bacteria, fungus in and on dermatological cells. The apparatus 10, 320, 360, 360, 400, 460 may be employed to apply cosmetics, medications and/or other actives directly to the skin and maintain their presence long-term while using LED or other actinic light to increase their effect on the cells and tissue in the body. The apparatus 10, 320, 360, 360, 400, 460 are also highly portability and enable user mobility during treatment.

[0059] Chemicals 22A may include cosmetics, medications and other actives appropriate for dermatological cells including AHA's (alpha hydroxy acid), natural oils, aloe vera compounds, collagen boosters, bt, chitosan, daeses, endorphins, photodynamic drugs (PDT) like (Photofrin or ALA), vitamins A, C E or others, kojic acid, retinols or other exfoliant, salicylic acid, anti oxidants or other youth boosters and anti aging cosmetic or medications, antiseptic, antibiotics, anti-cancer agents, aroma therapy agents, fruit and vegetable extracts, anti-inflammatory agents, pain relievers, hormones, depilatories, and others, but the scope of this invention is not limited to these alone but can include any helpful medication, herbal formula or active compound for the skin and/or other tissues.

[0060] FIG. 8 is a block diagram of an article 780 according to various embodiments. The article 780 shown in FIG. 8 may be used in various embodiments as a part of apparatus 10, 320,

360, 360, 400, 460 where the article 780 may be any computing device including a personal data assistant, cellular telephone, laptop computer, or desktop computer. The article 780 may include a central processing unit (CPU) 782, a random access memory (RAM) 784, a read only memory (ROM") 806, a display 788, a user input device 812, a transceiver application specific integrated circuit (ASIC) 816, a digital to analog (D/A) and analog to digital (A/D) convertor 815, a microphone 808, a speaker 802, and an antenna 804. The CPU 782 may include an OS module 814 and an application module 813. The RAM 784 may include switches 56 and timers 58.

[0061] The ROM 806 is coupled to the CPU 782 and may store the program instructions to be executed by the CPU 782. The RAM 784 is coupled to the CPU 782 and may store temporary program data, overhead information, and the queues 798. The user input device 812 may comprise an input device such as a keypad, touch pad screen, track ball or other similar input device that allows the user to navigate through menus in order to operate the article 780. The display 788 may be an output device such as a CRT, LCD, LED or other lighting apparatus that enables the user to read, view, or hear user detectable signals.

[0062] The microphone 808 and speaker 802 may be incorporated into the device 780. The microphone 808 and speaker 802 may also be separated from the device 780. Received data may be transmitted to the CPU 782 via a bus 796 where the data may include signals for an LED 32A, 32B, 332 or optical module or wires 331, 458. The transceiver ASIC 816 may include an instruction set necessary to communicate data, screens, or signals. The ASIC 816 may be coupled to the antenna 804 to communicate wireless messages, pages, and signal information within the signal. When a message is received by the transceiver ASIC 816, its corresponding data may be transferred to the CPU 782 via the serial bus 796. The data can include wireless protocol, overhead information, and data to be processed by the device 780 in accordance with the methods described herein.

[0063] The D/A and A/D convertor 815 may be coupled to one or more optical modules to generate a signal to be used to energize one of the optical modules. The D/A and A/D convertor 815 may also be coupled to one devices such as LEDs 32A, 32B and the pins 251, 351, 451. Any of the components previously described can be implemented in a number of ways, including embodiments in software. Any of the components previously described can be implemented in a number of ways, including embodiments in software. Thus, the LEDs 32A, 32B, pins 251, 351, 451, controllers 54, switch 56, timers 58, controller 320 may all be characterized as "modules" herein. The modules may include hardware circuitry, single or multi-processor circuits, memory circuits, software

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program modules and objects, firmware, and combinations thereof, as desired by the architect of the system 10, 30, 50, 60 and as appropriate for particular implementations of various embodiments.

[0064] FIG. 9A is a simplified block diagram of a dermatological treatment architecture (DTA) 900 according to various embodiments. As shown in FIG. 9A, architecture 900 includes a signal generation and control module (SGC) 910, a handle module 920, and an actuator module 930. In an embodiment the handle module 920 may include a deployable needle module 924 and a motor and LED module 922. In an embodiment the deployable needle module 924 may be releasably coupled to the motor and LED module 922. In a further embodiment the deployable needle module 924 may be a disposable cartridge module 924 to be removed and disposed after one or more treatments or for each patient, client, or user.

[0065] The SGC 910 may include one or more displays 912A, user input device 912B, handle module interface 914A, and actuator module interface 914C, electrical energy storage module 913, and one or more wheels 916A, 916B. In an embodiment the SGC 910 may be moveable and the wheels 916A, 916B may be lockable to prevent unintentional movement of the SGC 910 once positioned where desired by a user. In another embodiment the SGC 910 may also be coupled to the external power source including an alternating current (AC) grid source.

[0066] In an embodiment the displays 912A may indicate operational parameters for a hand module 920 to be coupled or coupled to the SGC 910. The displays 920 may be touch sensitive so a user may configure one or more operational parameters. In an embodiment the operational parameters may include electrical energy signal intensity to be applied the hand module 920, timing of such energy application, needle deployment timing and depth(s), LED intensity and timing, and number of cycles or shots to be conducted for each actuation via the actuator 930. In an embodiment the actuator 930 may be integral to the SGC 910 or a separate device wireless coupled or wired to the SGC 910 via a cable 914D and the SGC 910 actuator module interface 914C.

[0067] In an embodiment the actuator 930 may a mechanical device including a foot actuator or hand based actuator. The actuator 930 may also be an electronic device having an ASIC or running an application on a device (such as a computer, laptop, PDA, cellphone, or other electronic device) such as the module 780 shown in FIG. 8. In an embodiment the application may enable a user to set or control any of the possible operational parameters of the SGC 910 and initiate actuation a device 920 coupled to the SGC 910. FIG. 9B is a block diagram of a CPU module 911 that may be employed in the SGC 910 according to various embodiments.

[0068] The CPU module 911 may include a radio frequency (RF) signal generator (RFSG) module 911A, a needle deployment motor controller (NDMC) module 911B, and a photonic signal generator module (PSG) 911C. In an embodiment the photonic signal generator module 911C may be an LED signal generator or controller module 911C. In an embodiment a hand module 920 may include one or more photonic generation devices or modules (922I in FIG. 10A, 10B) where the PSG 911C may generate control or energy signals that cause the photonic modules 922I to generate photons of one or more frequencies with a desired intensity.

[0069] The NDMC 911B may control the deployment of one or more needles 924A of a deployable needle module 924 (FIG. 9C) based on one or more user selected operational parameters. The parameters may determine the depth and duty cycle related to the needle(s) 924A deployment in an embodiment. The signals generated by the NDMC 911B to control needle deployment may vary as a function of motor(s) (922A, FIG. 9C) employed to drive one or more needles 924A. As described above an electrical signal may also be applied to the needle(s) 924A to cause vibration of the needles or enable cutting, blending, and coagulation of the tissue in which the needles 924A are deployed. The RFSG 911A may generate one or more electrical signals to be applied to one or more needles 924A based on the selected operational parameters. An electrical signal may be applied to a single needle 924A, group of needles 924A (mono-polar configuration) or pair(s) of needles 924A (bipolar configuration) in an embodiment. In an embodiment the RFSG 911A may apply signals 650, 630, 640, 670 shown in FIGs. 5A, 5B, and 6, a combination thereof, or other signals.

[0070] In an embodiment the CPU module 911 via the RFSG 911A, NDMC 911B, and PSG 911C may create various therapy solutions including various combinations of photonic, electrical, and mechanical (needle deployment) therapy. In a further embodiment the CPU module 911 may control the generation of photonic energy to particular modules 922I, individual or group of needle(s) 924A deployment via one or more motors 922A, and control electrical signal(s) applied to individual or group of needles 924A. Accordingly the DTA 900 may apply various therapies based on user selections via the displays 912A, user selection device 912B, and actuator 930. The CPU 911 may employ the algorithm 930 (FIG. 12) or variations thereof to control the operation of the DTA 900.

[0071] FIG. 9C is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus or hand module 920 with one or more needles 924A retracted according to

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various embodiments. FIG. 9D is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus or hand module 920 with one or more needles 924A deployed according to various embodiments. The handle module 920 may include a deployable needle module (DNM) 924 and a motor and LED module (MLM) 922. In an embodiment the DLM 924 may be a releasably couplable cartridge module. In a further embodiment the DLM 924 may be a detachable cartridge module (DCM) 924 where the DCM may be changed between therapy application(s) or client(s). In a further embodiment, the DCM 924 may be disposed after usage or cleaned via an autoclave or chemical process.

[0072] As shown in FIGs. 9C and 9D, the MLM 922 may include one or more motors 922A, longitudinally extendable drive arms 922B, drive shaft 922C, outer casing 922D, signal interface 922E, photonic generator module 922H, and DCM 924 interface 925 (shown in FIGs. 10A to 10F). The motor(s) 922A and photonic generator module 922H may be electrically coupled to the signal interface 922E to received control signals and energy to operate one or more motors 922A and photonic devices or modules 922I of the photonic generator module 922H. The drive arm(s) 922B may be coupled to one or more drive shafts 922C so the drive shafts may be moved longitudinally to deploy and retract one or more needles 924A when the MLM 922 is operatively coupled to the DNM 924.

[0073] As shown in FIGs. 9C and 9D the deployable needle module 924 may include at least one deployable needle 924A, MLM connecting arm and drive coupling tabs 924B, and MLM connecting/locking arms 924C. The MLM connecting/locking arms 924C may be configured to engage and lock to DCM 924 interface 925 recesses 925D (FIG. 10F). The MLM connecting arm and drive coupling tabs 924B may be configured to disengage connecting/locking arms 924C from the MLM interface 925 when the tabs 924B are depressed inward in an embodiment (as shown in FIG. 10B). The tabs 924B may further displace drive shaft connecting arms 924D (FIG. 10A) inward or centrally when the tabs 924B are depressed inwardly (as also shown in FIG. 10B). When the connecting/locking arms 924C are depressed inwardly or centrally (FIG. 9C and 9D) from an outward position (FIG. 10B). The arms 924C may engage the interface 925 recesses 925D to securely hold the DNM 924 to the MLM 922. The arms 924C may also displace the tabs 924B outwardly and cause the drive shaft connecting arms 924D to return outwardly.

[0074] The drive shaft connecting arms 924D may securely engage the drive shaft 922C tip 922F (FIG. 10E) recess 922G (FIG. 10E) when they return to an outward position as shown in FIG.

10D and 10E. In this configuration the DNM 924 is securely coupled to the MLM 922 via the arms 924C and 924D. In this configuration the motor(s) 922A via drive shaft(s) 922C coupled to the motor 922A shaft 922B may reliably drive one or more needles 924A of the DNM 924 (from a retracted or deployed position such as shown in FIGs. 9C and 9D, respectively). Further the motor(s) 922A may include steps or infinite drive extension 922B control to enable precise needle deployment depth or extension beyond the DNM 924 shell (924E, Fig. 10A).

[0075] FIG. 10A-10D are simplified, partial, cross-sectional diagrams of the DNM 924 in various stages of attachment to the MLM 922 via the arms 924C and 924D according to various embodiments. As shown in FIG. 10A the DNM or DCM 924 is decoupled from the MLM 922. The MLM 922 includes the photonic generator module (PGM) 922H, interface 925, and drive shaft tip 922F in a distal portion. As shown in FIG. 10A the PGM 922H may include one or more photon modules 922I. The photon modules 922I may be LED modules and emit photon with various frequencies and intensities based on the PSG 911C control signal.

[0076] As shown in FIG. 10A the DNM or DCM 924 may include the connecting arms 924C, deflecting tabs 924B, drive shaft coupling arms 924D, outer shell 924E, and one or more needles 924A. In an embodiment the drive shaft coupling arms 924D may include tabs that may securely engage the drive shaft tip 922F recess 922G. The drive shaft coupling arms 924D may be returnably deflectable inwardly (as shown in FIG. 10B) via inward depression of the tabs 924B. Such inward depression of the tabs 924B may deflect the coupling arms 924C outward. Similarly, inward depression of the coupling arms 924C to engage the interface 925 recesses 925D securely may deflect the tab arms 924B outwardly (relative the central axis of the DNM 920). Such outward movement may enable the drive shaft coupling arms 924D to return to a non-deflected state as shown in FIG. 10A.

[0077] In an embodiment a DNM or DCM 924 may be securely coupled to a MLM 922 by first completely compressing the arms or tabs 924B as shown in FIG. 10B. As noted above such inward compression may cause the coupling arms 924C to deflect outwardly and the drive shaft coupling arms 924D to be deflected inwardly towards each other. The drive shaft coupling arms 924D may be compressed so they may fit within the drive shaft 922C tip 922F recess 922G as the DNM or DCM 924 is advanced toward the MLM 922 distal end to securely couple the DNM 924 to the MLM 922 (as shown in FIG. 10D). After the DNM or DCM 924 is placed over the MLM 922 distal end so the drive shaft coupling arms 924D are located within the drive shaft 922C tip 922F

recess 922G and the coupling arms 924C are adjacent the MLM 922 interface 925 recesses 925D as shown in FIG. 10C.

[0078] To complete the coupling of a DNM 924 to the MLM 922, the coupling arms 924C may compressed inwardly as shown in FIG. 10D. The compression of the coupling arms 924C may deflect the tabs or arms 924B outwardly. Such outward deflection of the arms 924B may enable the drive shaft coupling arms 924D to return to a non-deflected state and securely engage the MLM 922 drive shaft 922C tip 922F recess 922G (as shown in FIG. 10D). In an embodiment a single coupling arm 924C, drive shaft coupling arm 924D, and tab 924B may be employed in an DNM 924. After the secure coupling of the DNM 924 to the MLM 922, the MLM 922 via the motor(s) 922A may controllably deploy one or more needles 924A as shown in FIG. 10E. FIG. 10F is a simplified cross-sectional diagram of a DNM interface 925 according to various embodiments.

[0079] As noted the interface 925 may include one or more recesses 925D to be securely engaged to DNM 924 coupling arms 924C. The interface 925 may also include several fenestrations or openings 925A, 925B, 925C (FIG. 10F). The central fenestration 925A may be sized to enable passage of the MLM 922 drive shaft 922C tip 922F. The fenestrations 925C may be sized and located above one or more photon modules 922I to enable photons generated by the photon modules 922I to pass into the DNM 924. In an embodiment the DNM 924 outer casing 924E may be translucent and act as a waveguide to communicate photons to the needle area of the DNM 924. The fenestrations 925B may be sized and configured to enable electrical coupling pins 924G (FIG. 11A) passage from the DNM 924 to electrical couplings of the MLM 922. The pins 924G may communicate electrical signals from the RFSG 911A to one or more needles 924A via the wires 914B and MLM 922.

[0080] FIG. 11A is a simplified, partial, cross-sectional diagram of DNM 924 coupled to a MLM 922 with needles 924A deployed according to various embodiments. As shown in FIG. 11A, the DNM 924 may further include electrical coupling pins 924G set with a spring loaded base 924H (in an embodiment). As noted the pins 924G may extend to electrical contacts in the MLM 922 via the interface 925 fenestrations 925B. Although a pair of pins 924G is shown, one or more pins 924G may be employed in a DNM 924 according to various embodiments. A drive shaft coupling arm 924D may include an offset 924I where the offset may be configured to engage a tab or arm 924B.

[0081] As shown in FIG. 11A when the needle array or assemble 924F is deployed depression of the tabs 924B inwardly will not engage the drive shaft coupling arms 924D (via the offsets 924I). Such a configuration may prevent unintentional decoupling of the DNM 924 to the MLM 922 when the needle assembly 924F is at least partially deployed. As shown in FIG. 11A, the electrical contact pin 924G is sized to fit within the spring loaded based 924H. In an embodiment the internal spring 924M (FIG. 11C) may force extension of the pin 924G to maintain electrical conduction with the MLM 922 as the needle assembly 924F is moved (recessed and deployed to various depths). FIG. 11B is a simplified, cross-sectional diagram of a DNM 924 needle assembly 924F according to various embodiments. FIG. 11C is a simplified, cross-sectional, exploded diagram of the DNM 924 needle assembly 924F according to various embodiments. As shown in FIGs. 11B and 11C, the needle assembly 924F may include a pin cover 924J, drive arm module 924L, needles 924A, pins 924G with bases 924H, and needle printed circuit board (PCB) 924K.

[0082] In an embodiment the PCB 924K may couple one or more needles 924A to a first pin 924G base 924H and another one or more needles 924A to another pin 924G based 924H. The first pin 924G and second pin 924H may couple alternating rows or columns of needles 924A to form one or more dipoles between such needles 924A. The drive shaft coupling arms 924D may have a base 924L where the cover 924J includes fenestrations for the needles 924A, a recess for the PCB 924K, and an outer recess for the coupling arm base 924L (as shown assembled in FIG. 11B).

[0083] FIG. 12 is a flow diagram illustrating a DTA 900 processing algorithms 930 according to various embodiments. As noted the DTA 900 SGC 911 RFSG 911A, NDMC 911B, and PSG 911C may enable a user or clinician to select a variety of operational parameters to deliver a desired combination of electrical, light (photonic), and mechanical (needle) therapy to dermatological tissue. In the algorithm 930, a user may select different operational modes including cut (activities 932A to 932F), blend (activities 934A to 934F), and coagulation (activities 936A to 936F) in an embodiment. In a cut operational mode, a user may select the electrical signal intensity (activity 932B) and application time (activity 932C). The CPU 911 may determine the total energy that will be applied for each activation based on the selected intensity and time (total fluence – activity 932D). Then, upon activation (activity 932E, 932F) the DTA 900 may energize the MLM 922 based on the operational parameters.

[0084] In a blend operational mode (activity 934A), a user may select the electrical signal intensity, start delay, and duty cycle (activity 934B) and needle deployment depth and number of

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shots per activation (activity 934C). The duty cycle may include the delay before energy and needle deployment, the time the energy and needles are deployed, and the subsequent off or rest time before the next possible duty cycle. As noted above the motor(s) 922A may enable precise needle extension (effective depth) control. In an embodiment the motor(s) 922A may include a transverse motor that converts rotational force to longitudinal force. The motor may be a Haydon model number: 21H4AB-05-049 having a motor speed of about 0.005mm/msec and motor power of about 1000 Hz approximately 40N (Newton) (described in detail at www.haydonkerk.com and whose specifications are incorporated by reference).

[0085] The CPU 911 may determine the total energy that will be applied for each activation based on the selected intensity and duty cycle (total fluence – activity 934D). Then, upon activation (activity 934E, 934F) the DTA 900 may energize the MLM 922 based on the operational parameters and deploy the needle assembly 924F to a desired extension beyond the DNM 924 shell 924E to enable a desired depth of needle 924A penetration within tissue when the shell 924E is placed adjacent the tissue.

[0086] In a coagulation operational mode (activity 936A), a user may select the electrical signal intensity and start delay (activity 936B) and needle deployment depth and number of shots per activation (activity 936C). As noted above the motor(s) 922A may enable precise needle extension (effective depth) control. The CPU 911 may determine the total energy that will be applied for each activation based on the selected intensity (total fluence – activity 936D). Then, upon activation (activity 936E, 936F) the DTA 900 may energize the MLM 922 based on the operational parameters and deploy the needle assembly 924F to a desired extension beyond the DNM 924 shell 924E to enable a desired depth of needle 924A penetration within tissue when the shell 924E is placed adjacent the tissue.

[0087] Applications that may include the novel apparatus and systems of various embodiments include electronic circuitry used in high-speed computers, communication and signal processing circuitry, modems, single or multi-processor modules, single or multiple embedded processors, data switches, and application-specific modules, including multilayer, multi-chip modules. Such apparatus and systems may further be included as sub-components within a variety of electronic systems, such as televisions, cellular telephones, personal computers (e.g., laptop computers, desktop computers, handheld computers, tablet computers, etc.), workstations, radios,

video players, audio players (e.g., mp3 players), vehicles, medical devices (e.g., heart monitor, blood pressure monitor, etc.) and others. Some embodiments may include a number of methods.

[0088] It may be possible to execute the activities described herein in an order other than the order described. Various activities described with respect to the methods identified herein can be executed in repetitive, serial, or parallel fashion.

[0089] A software program may be launched from a computer-readable medium in a computer-based system to execute functions defined in the software program. Various programming languages may be employed to create software programs designed to implement and perform the methods disclosed herein. The programs may be structured in an object-orientated format using an object-oriented language such as Java or C++. Alternatively, the programs may be structured in a procedure-orientated format using a procedural language, such as assembly or C. The software components may communicate using a number of mechanisms well known to those skilled in the art, such as application program interfaces or inter-process communication techniques, including remote procedure calls. The teachings of various embodiments are not limited to any particular programming language or environment.

[0090] The accompanying drawings that form a part hereof show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. The embodiments illustrated are described in sufficient detail to enable those skilled in the art to practice the teachings disclosed herein. Other embodiments may be utilized and derived therefrom, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. This Detailed Description, therefore, is not to be taken in a limiting sense, and the scope of various embodiments is defined only by the appended claims, along with the full range of equivalents to which such claims are entitled.

[0091] Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is in fact disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other

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embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

[0092] The Abstract of the Disclosure is provided to comply with 37 C.F.R. §1.72(b), requiring an abstract that will allow the reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims. In the foregoing Detailed Description, various features are grouped together in a single embodiment for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted to require more features than are expressly recited in each claim. Rather, inventive subject matter may be found in less than all features of a single disclosed embodiment. Thus the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separate embodiment.

METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

Abstract of the Disclosure

Embodiments of dermatological cell treatment are described generally herein. Other embodiments may be described and claimed.

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SUBSTITUTE SPECIFICATION – MARKED UP

UNITED STATES PATENT APPLICATION

METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

INVENTOR

Jongju Na of Republic of Korea

Prepared by:

Merle W. Richman, Esq.
P.O. Box 3333
La Jolla, CA 92038-3333
ATTORNEY DOCKET NA001KR_US3

METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

Cross Reference to Related Applications

[0001] The present application is a continuation of US Application Number 15096686, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT", Attorney Docket No. NA001KR_US2 filed on April 12, 2016, which is a continuation of US Application Number 13/825,083, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMALOGICAL TREATMENT", Attorney Docket No. NA001KR_US filed on January 20, 2014 now US Patent 9320536,, which is a National Stage entry of PCT/KR2012/001335, filed on February 22, 2012, which claims priority to US Application Number 61/449,080, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMALOGICAL TREATMENT", Attorney Docket No. NA001US1 filed on March 3, 2011 and US Application Number 13/060,274, Patent No. 8979912, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMALOGICAL TREATMENT", Attorney Docket No. NA001US filed on February 22, 2011, which is a National Stage entry of PCT Application Number PCT/US2008/074131, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMALOGICAL TREATMENT", Attorney Docket No. NA001PCT filed on August 22, 2008, which claims ~~the benefit of~~ priority to Republic of Korea Application Number 10-2008-0076993, entitled "Electrical system, skin, skin care and cosmetic electricity," filed on August 6, 2008, ~~PCT Application Number PCT/US2008/074131, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT", Attorney Docket No. NA001PCT filed on August 22, 2008, and US Application Number 13/060,274, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT", Attorney Docket No. NA001US filed on February 22, 2011,~~ the entirety of each is incorporated by reference.

Technical Field

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[0002] Various embodiments described herein relate generally to treating dermatological tissue, including systems, and methods used in treating dermatological tissue.

Background Information

[0003] It may be desirable to treat dermatological tissue; the present invention provides such treatment.

Brief Description of the Drawings

[0004] FIG. 1A is a simplified isometric diagram of a dermatological treatment apparatus according to various embodiments.

[0005] FIG. 1B is a simplified, side diagram of the dermatological treatment apparatus according to various embodiments.

[0006] FIG. 1C is a simplified, exploded layer view of the dermatological treatment apparatus according to various embodiments.

[0007] FIG. 1D is a simplified view of a layer of a dermatological treatment apparatus according to various embodiments.

[0008] FIG. 2A is a simplified isometric diagram of a dermatological treatment architecture according to various embodiments.

[0009] FIG. 2B is a simplified cross-sectional diagram of a dermatological treatment apparatus according to various embodiments.

[0010] FIG. 2C is a simplified cross-sectional diagram of another dermatological treatment apparatus according to various embodiments.

[0011] FIG. 2D is a simplified cross-sectional diagram of another dermatological treatment apparatus according to various embodiments.

[0012] FIG. 2E is a simplified view of a layer of a dermatological treatment apparatus according to various embodiments.

[0013] FIG. 2F is a simplified, exploded view of layers of the dermatological treatment apparatus according to various embodiments.

[0014] FIG. 3A is a simplified isometric diagram of a dermatological treatment apparatus according to various embodiments.

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[0015] FIG. 3B is a simplified isometric diagram of another dermatological treatment apparatus according to various embodiments.

[0016] FIG. 4A is a simplified view of a layer of a dermatological treatment apparatus according to various embodiments.

[0017] FIG. 4B is a simplified view of a layer and apparatus of a dermatological treatment system according to various embodiments.

[0018] FIG. 4C is a simplified view of a layer and apparatus of a dermatological treatment system according to various embodiments.

[0019] FIGs. 5A-6 are diagrams of signals that may be applied to one or more dermatological treatment systems according to various embodiments.

[0020] FIG. 7A-7C are flow diagrams illustrating dermatological treatment system processing algorithms according to various embodiments.

[0021] FIG. 8 is a block diagram of an article according to various embodiments.

[0022] FIG. 9A is a simplified block diagram of a dermatological treatment architecture according to various embodiments.

[0023] FIG. 9B is a block diagram of an article according to various embodiments that may be employed in architecture of FIG. 9A.

[0024] FIG. 9C is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus with the needles retracted according to various embodiments.

[0025] FIG. 9D is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus with the needles deployed according to various embodiments.

[0026] FIG. 10A-10D are simplified, partial, cross-sectional diagrams of a cartridge in various stages of attachment to a dermatological treatment apparatus according to various embodiments.

[0027] FIG. 10E is a simplified, partial, cross-sectional diagram of a dermatological treatment apparatus with needles deployed according to various embodiments.

[0028] FIG. 10F is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus cartridge interface according to various embodiments.

[0029] FIG. 11A is a simplified, partial, cross-sectional diagram of a dermatological treatment apparatus cartridge coupled to a handle with needles deployed according to various embodiments.

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[0030] FIG. 11B is a simplified, cross-sectional diagram of a cartridge needle assembly according to various embodiments.

[0031] FIG. 11C is a simplified, cross-sectional, exploded diagram of a cartridge needle assembly according to various embodiments.

[0032] FIG. 12 is a flow diagram illustrating a dermatological treatment system processing algorithms according to various embodiments.

Detailed Description

[0033] FIG. 1A is a simplified isometric diagram and FIG. 1B is a simplified side view of a dermatological treatment apparatus 10 according to various embodiments. The apparatus 10 may include a user handle 220 coupled to an acupuncture plate 200. In an embodiment the plate 200 may be elastically coupled to the handle segment 222 via an elastomeric section 210. The elastomeric section may be comprised of a combination of elastomeric materials and non-elastomeric materials. The elastomeric materials may include plastics, rubber (synthetic or natural), and spring(s).

[0034] FIG. 1C includes a simplified exploded view of an embodiment of an acupuncture plate 200 according to various embodiments. The plate 200 may include an upper, substantially rigid section or layer 290, deformable or elastic section 270 or layer, and acupuncture section or layer 250. The acupuncture section 250 may include a plurality of acupuncture pins or needles 230. FIG. 1D is a simplified bottom view of the plate 200 showing the location or holes 212 for the pins or needles 230. In an embodiment the plate 200 may have a rectangular cross section having a dimensional about 1 to 4 cm in width and about 1 to 6 cm in length. The plate 200 may any shape including circular, elliptical, polygon, or other shape where the shape may be particular to a dermatological area to be treated.

[0035] In an embodiment the plate may include about 140 pins or needles 230 uniformly separated. Each needle may be about 0.1 to 0.4 mm in diameter and 0.2 mm to 1.4 mm in length including 0.3 mm diameter and 0.8 mm in length in an embodiment. The elastic section or layer 270 may be comprised of a combination of elastomeric materials and non-elastomeric materials. The elastomeric materials may include plastics, rubber (synthetic or natural), and spring(s). The pin section ~~230~~ 250 may be coupled directly or indirectly to the upper section 290 via the elastic section ~~250~~270, including via glues, screws, welds, or other connection. In an embodiment the pin section 250 may include elastomers to enable at least partial deformation of the pin section 250 about the pins 230.

[0036] In operation a user may employ the apparatus 10 to create a plurality of micro-wounds or holes in dermatological layers of a mammal's 20 skin or dermis. The micro-wound or hole creation may improve the absorption or application of one or more chemicals applied on or about the micro-wounds or holes.

[0037] FIG. 2A is a simplified diagram of a dermatological treatment architecture 310 according to various embodiments. Architecture 310 includes an acupuncture apparatus 320 and an

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electrical signal generation system 300. The electrical signal generation system 300 may be electrically coupled to the acupuncture apparatus 320 via one or more wires 300A and to a mammal 20 to be treated via one or more wires 300B. FIG. 2B is a simplified cross-sectional diagram of the acupuncture apparatus 320 according to various embodiments. The apparatus 320 may include a handle 330, elastic section 333, electrical interface 340, internal wire(s) 331and plate 350. The pins 351 may have a length A (0.3 mm to 2.1 mm in an embodiment) where at least one pin 351 is electrically coupled to the electrical interface 340 via the internal wire 331. The electrical interface 340 may be removably connected to the system 300 wire 300A.

[0038] The electrical signal generation system 300 may generate a variety of signals (such as shown in FIGS. 5A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and lead 300A. A pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351. FIG. 2C is a simplified cross-sectional diagram of an acupuncture apparatus 360 according to various embodiments. The apparatus 360 may include a handle 330, an elastic section 333, an electrical conductive interface 390, internal wire(s) 331, signal generator 370, switch 375, and plate 350. The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to the conductive interface 390.

[0039] The signal generator or module 370 may generate a variety of signals (such as shown in FIGS. 5A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and the conductive interface 390. In operation a user 20 may touch the conductive interface 390 and place one or more electrically coupled pins 351 in contact with their dermis to form an electrical pathway from the pin 351 to the electrical conductive interface 390. The signal generator 370 may include a battery to supply energy to generate one or more electrical signals. The switch 375 coupled to the generator 370 may cause the generator to produce one or more electrical signals for a predetermined time interval or until the switch 375 is triggered again. As noted a pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351.

[0040] FIG. 2D is a simplified cross-sectional diagram of an acupuncture apparatus 362 according to various embodiments. The apparatus 362 may include a handle 330, an elastic section 333, internal wire(s) 331, 332, signal generator 370, switch 375, and plate 350. The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to at least one other pin 352 via internal wire 332. When active the pins 351, 352 may form at least one dipole pair. The

signal generator or module 370 may generate a variety of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins 351, 352.

[0041] FIG. 2F includes a simplified exploded view of an embodiment of an acupuncture plate 350 including at least one electrically coupled pin 351 according to various embodiments. The plate 350 may include an upper, substantially rigid section or layer 357, deformable or elastic section 355 or layer, and acupuncture section or layer 353. The acupuncture section 353 may include a plurality of acupuncture pins or needles 351 where at least one pin 351 is electrically coupled to the wire 331. In a bipolar configuration a second wire 332 may be coupled to at least one other pin 351. FIG. 2E is a simplified bottom view of the plate 350 showing the pins or needles 359, 357 where the pins may be electrically coupled to a first wire 331 and a second wire 332 to form dipole pair (bipolar pins).

[0042] In an embodiment the plate 350 may have a rectangular cross section having a dimensional about 1 to 4 cm in width and about 1 to 6 cm in length. The plate 350 may any shape including circular, elliptical, polygon, or other shape where the shape may be particular to a dermatological area to be treated.

[0043] In an embodiment the plate may include about 140 pins or needles 351 uniformly separated. Each needle may be about 0.1 to 0.4 mm in diameter and 0.2 mm to 1.4 mm in length including 0.3 mm diameter and 0.8 mm in length in an embodiment. The elastic section or layer 355 may be comprised of a combination of elastomeric materials and non-elastomeric materials. The elastomeric materials may include plastics, rubber (synthetic or natural), and spring(s). The pin section 353 may be coupled directly or indirectly to the upper section 357 via the elastic section ~~353~~355, including via glues, screws, welds, or other connection. In an embodiment the pin section 353 may include elastomers to enable at least partial deformation of the pin section 353 about the pins 351.

[0044] FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus 400, 460 including at least one pin 451 that may be coupled to an electrical signal via an internal wire 458. Each apparatus 400, 460 includes curved roller 450 having a plurality of acupuncture pins 451 where the pins 451 may be similar to pins 351. In apparatus 400, the electrical lead wire ~~400A~~ 300A may be coupled to an electrical interface 410 in the apparatus handle 430 where the interface 410 is electrically coupled to the internal wire 458. In apparatus 460, the handle 430 may include a signal generator 470 similar to generator 370, switch 475, and conduction surface 490. Apparatus 460 may

operate similar to apparatus 360 in operation other than the rolling capability of the apparatus 460, 400. In an embodiment the rollers 450 may have various configurations to conform to a dermal area to be treated.

[0045] In any of the above apparatus 10, 320, 350, 360, 400, 460, the plate or roller 200, 350, 450 may include a plurality of embedded LEDs 32A, 32B, a battery 52, a controller 54, and an antenna 56 as shown in FIG. 4A. In an embodiment the LED 32A may be configured to emit energy of a first particular frequency range and the LED 32B may be configured to emit energy of a second particular frequency range. The surface 22 of a roller 450, plate 200, 350, 450 may also be embedded with a chemical 22A that may be used to treat dermatological cells. The chemical 22A may be reactive to the first and the second frequency ranges. Further dermatological cells may be reactive to the first and the second frequency ranges. In addition, the combination of the chemical 22A and the application of the first and the second frequency ranges to the chemical 22A and dermatological cells may have a synergetic effect.

[0046] In an embodiment the chemical 22A may be applied directly to the dermatological cells to be treated. In a further embodiment a chemical 22A may not be employed in addition to the apparatus 10, 320, 350, 360, 400, 460. In an embodiment the pin section 250, 353, may be translucent and comprised of polyurethane, medical silicon, or other pliable, translucent, hypoallergenic material.

[0047] In an embodiment the local controller 54 and battery 52 may also be embedded in the upper section 290, 357, pin section 230, 351, or the handle 220, 330, or separately between these sections. The controller 54 may be electrically coupled to the one or more ~~LEDS~~ LEDs 32A, 32B. The controller 54 may also be coupled to a battery 52. The controller 54 may generate one or more signals for LEDs 32A, 32B as a function of a user switch 75, 56. The signals may vary as a function of the first and second frequency ranges. The controller 54 may include one or more timers 58 that may limit the application of energy to the LEDs 32A, 32B to predetermined time intervals. In an embodiment the controller may also be coupled to an antenna 56 to receive or transmit one or more signals related to the transmission of energy to one or more LEDs 32A, 32B. In an embodiment the system 10 may be configured to treat a particular segment of dermatological cells such as a face. The apparatus 10 may be configured to conform to a user's anatomy so that emitted light is focused on dermatological cells. In another embodiment 200, the system 200 may be configured to treat

another anatomical region including dermatological cells on an arm, leg, chest, hands, feet, neck, or other region.

[0048] In an embodiment 510 shown in FIG. 4B, a controller 54, an antenna 104, and a power source 60 may be located ~~in~~ external to the apparatus 10, 320, 360. The power source 60 may be coupled to the controller 54. The controller 54 may be coupled to one or more LEDs 32A, 32B via one or more electric wires 106. The controller 54 may generate one or more signals for LEDs 32A, 32B as a function of the user switch 56. The signals may vary as a function of the first and second frequency ranges. The controller 54 may include one or more timers 58 that may limit the application of energy to the LEDs 32A, 32B to predetermined time intervals. In an embodiment the controller may also be coupled to an antenna 104 to receive or transmit one or more signals related to the transmission of energy to one or more LEDs 32A, 32B.

[0049] ~~In~~ As shown in FIG. 4C, in any of the above apparatus 10, 320, 350, 360, 400, 460, the plate or roller 200, 350, 450 may include a plurality of embedded LED lens 536, a fiber optic pathway 534, and an LED 532. In this embodiment, system 530 ~~the~~ LED 532 shown in FIG. 4C may be coupled to lens 536 via the fiber optic pathway 534. The controller 540 may generate an LED signal via the LED 532 that is transmitted to dermatological cells via the lens 536 and the fiber optic pathway 534.

[0050] FIGS.5A-5B are diagrams of electrical signal waveforms 650, 630, 640 that may be applied to one or more LEDs 32A, 32B, 532 and to the pins 230, 351, 451 according to various embodiments. The signal waveform 650 includes several square-wave pulses 652, 654, 656 that may be applied to an LED 32A, 32B, 532. Each pulse 652, 654, 656 may a have a similar magnitude and envelope. The waveform 650 may be used to energize an LED 32A, 32B, 532 and to the pins 230, 351, 451 periodically P1 for a predetermined interval T1 where each pulse 652, 654, 656 has a amplitude A1. In an embodiment, A1 may be about 0.1 milliamperes (mA) to 10 mA, the pulse width T1 may be about 100 microseconds (μs) to 500 μs and the period P1 may from 100 ms to 500 ms as a function of the energy required to create capacitance in a liquid. In another embodiment, A1 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width T1 may be about 200 microsecond (μs) and the period P1 may about 250 ms as a function of the energy to drive an LED or cause one or more pins 230, 351, 451 to vibrate.

[0051] In FIG. 5B a signal waveform 630 may be applied to a first LED 32A, 32B, 532 module or group and to the pins 230, 351, 451 and a second waveform 640 may be applied or used

to energize a second LED 32A, 32B, 532 module and the pins 230, 351, 451, 352. The signal waveform 630 includes several square-wave pulses 632, 634, and 636 and the signal waveform 640 includes several square-wave pulses 642, 644, and 646. Each pulse 632, 634, 636, 642, 644, 646 may a have a similar magnitude and envelope. The waveform 630 may be used to energize a first LED 32A, 32B, 332 module and the pins 230, 351, 451 periodically P1 for a predetermined interval T1 where each pulse 632, 634, 636 has an amplitude A1. The waveform 640 may be used to energize a second LED 32A, 32B, 332 module and the pins 230, 351, 451 periodically P2 for a predetermined interval T2 where each pulse 642, 644, 646 has an amplitude B1. The pulse width T1, T2 may be about 100 microseconds (μs) to 500 μs and the period P1, P2 may from 100 ms to 500 ms as a function of the energy to affect dermatological cells or chemicals 22A. In another embodiment, A1, A2 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width T1, T2 may be about 200 microsecond (μs) and the period P1, P2 may about 250 ms as a function of the energy required to affect dermatological cells or chemicals 22A. In an embodiment the pulses 632, 634, 636 do not substantially overlap the pulses 642, 644, 646. In an embodiment T1 > T2 and P2 is an integer multiple of P1.

[0052] FIG. 6 depicts a waveform 670 that includes multiple pulses 672, 674, 676, 678, 682, and 684 that may not overlap in the time or the frequency domain. In an embodiment each pulse 672, 674, 676, 678, 682, and 684 may have a pulse width T3, and frequency spectrum width F1 and period P3. The pulse 672 is frequency offset from the pulse 674, the pulse 676 is frequency offset from the pulse 678, and the pulse 682 is frequency offset from the pulse 684. The pulses 672, 674, 676, 678, 682, and 684 may be applied to an LED module to affect dermatological cells or chemicals 22A and the pins 230, 351, 451. Pulses 672, 674 having different frequency spectrums may enable different LED stimulation. In an embodiment the pulses 672, 676, 682 may be applied to a first LED module and the pulses 674, 678, 684 may be applied to a second LED module. The frequency separation between the respective pulses may enable simultaneous energization of a first and a second LED module and the pins 230, 351, 451 and subsequent and independent spectrum generation.

[0053] In an embodiment the invention may employ the algorithm 740 shown in FIG. 7A to apply therapy to dermatological cells. A user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermatological cells to be treated (activity 741) including pressing the apparatus against the cells firmly enough to embed one or more pins 251, 351, 451 in the cells. A

first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a first LED module or group (32A) and the pins 230, 351, 451 of a dermatological apparatus 10, 320, 360, 360, 400, 460 (activity 742) for a predetermined time period (activity 744). A second signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a second LED module or group (32B) and the pins 230, 351, 451 of a dermatological apparatus 10, 320, 360, 360, 400, 460 (activity 746) for a predetermined time period (activity 748). The signals applied to the groups may be selected to stimulate dermatological cells or chemicals 22A or cause vibration of one or more pins 251, 351, 451.

[0054] In another embodiment the invention may employ the algorithm 750 shown in FIG. 7B to apply therapy to dermatological cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermatological cells to be treated (activity 751). The user, clinician, or equipment may place apparatus 10, 320, 360, 360, 400, 460 on dermatological cells to be treated (activity 752). A signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a LED module or group (32A or 32B) and the pins 230, 351, 451 (activity 354) for a predetermined time period (activity 356).

[0055] In another embodiment the invention may employ the algorithm 760 shown in FIG. 7C to apply therapy to dermatological cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermatological cells to be treated (activity 761). The user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermatological cells to be treated (activity 762). A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a first LED module or group (32A) and one or more pins 251, 351, 451 of a dermatological apparatus 10, 320, 360, 360, 400, 460 (activity 763) for a predetermined time period (activity 764). A second signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a second LED module or group (32B) and one or more pins 251, 351, 451 of a dermatological apparatus 10, 320, 360, 360, 400, 460 (activity 766) for a predetermined time period (activity 768).

[0056] The apparatus 10, 320, 360, 360, 400, 460 may be used to employ cosmetic or medications or other chemicals directly on dermatological cells such as skin with the addition of light of specific frequencies for treatment and healing of epidermal cells of the skin or tissue below the skin with the object of assisting the agents used in delivery, uptake, action and function more effectively. The LEDs 32A, 32B may create the specific frequencies of light. The apparatus 10, 320, 360, 360, 400, 460, light application may enable cosmetic or medication or other active chemicals 22A on dermatological cells for longer time periods while preventing dehydration of the

applied substances. Such light application may improve the efficacy of cosmetic or medication or other active chemical as a function of the selected wavelengths or frequencies.

[0057] Further the dermatological system application may increase cellular activity and help heal tissue faster and facilitate the delivery, uptake and use in the cell of the cosmetics, medications, or chemicals 22A used. The LED light of specific frequencies may increase fibroblast production and collagen as well as other activities of the cell including stimulating the organelles and mitochondria to produce ATP for cell energy for functioning, decreasing treatment time and facilitate healing. The apparatus 10, 320, 360, 360, 400, 460 make the agents used on the body more efficacious and useful to the body on a cellular level.

[0058] The apparatus 10, 320, 360, 360, 400, 460 may stimulate the basic energy processes in the mitochondria (energy compartments) of each cell, particularly when near-infrared light is used to activate the color sensitive chemicals (chromophores, cytochrome systems) inside but not limited to these spectrum alone as the UV, other visible and IR spectrums may also be usable. In an embodiment optimal LED wavelengths for skin repair may include 640, 680, 730 nanometers (nm) wavelengths to IR 880 nm. Further application of blue light 400 nm to 490 via the apparatus 10, 320, 360, 360, 400, 460 may inhibit the growth and kill bacteria, fungus in and on dermatological cells. The apparatus 10, 320, 360, 360, 400, 460 may be employed to apply cosmetics, medications and/or other actives directly to the skin and maintain their presence long-term while using LED or other actinic light to increase their effect on the cells and tissue in the body. The apparatus 10, 320, 360, 360, 400, 460 are also highly portability and enable user mobility during treatment.

[0059] Chemicals 22A may include cosmetics, medications and other actives appropriate for dermatological cells including AHA's (alpha hydroxy acid), natural oils, aloe vera compounds, collagen boosters, bt, chitosan, daeses, endorphins, photodynamic drugs (PDT) like (Photofrin or ALA), vitamins A, C E or others, kojic acid, retinols or other exfoliant, salicylic acid, anti oxidants or other youth boosters and anti aging cosmetic or medications, antiseptic, antibiotics, anti-cancer agents, aroma therapy agents, fruit and vegetable extracts, anti-inflammatory agents, pain relievers, hormones, depilatories, and others, but the scope of this invention is not limited to these alone but can include any helpful medication, herbal formula or active compound for the skin and/or other tissues.

[0060] FIG. 8 is a block diagram of an article 780 according to various embodiments. The article 780 shown in FIG. 8 may be used in various embodiments as a part of apparatus 10, 320,

360, 360, 400, 460 where the article 780 may be any computing device including a personal data assistant, cellular telephone, laptop computer, or desktop computer. The article 780 may include a central processing unit (CPU) 782, a random access memory (RAM) 784, a read only memory (ROM") 806, a display 788, a user input device 812, a transceiver application specific integrated circuit (ASIC) 816, a digital to analog (D/A) and analog to digital (A/D) convertor 815, a microphone 808, a speaker 802, and an antenna 804. The CPU 782 may include an OS module 814 and an application module 813. The RAM 784 may include switches 56 and timers 58.

[0061] The ROM 806 is coupled to the CPU 782 and may store the program instructions to be executed by the CPU 782. The RAM 784 is coupled to the CPU 782 and may store temporary program data, overhead information, and the queues 798. The user input device 812 may comprise an input device such as a keypad, touch pad screen, track ball or other similar input device that allows the user to navigate through menus in order to operate the article 780. The display 788 may be an output device such as a CRT, LCD, LED or other lighting apparatus that enables the user to read, view, or hear user detectable signals.

[0062] The microphone 808 and speaker 802 may be incorporated into the device 780. The microphone 808 and speaker 802 may also be separated from the device 780. Received data may be transmitted to the CPU 782 via a bus 796 where the data may include signals for an LED 32A, 32B, 332 or optical module or wires 331, 458. The transceiver ASIC 816 may include an instruction set necessary to communicate data, screens, or signals. The ASIC 816 may be coupled to the antenna 804 to communicate wireless messages, pages, and signal information within the signal. When a message is received by the transceiver ASIC 816, its corresponding data may be transferred to the CPU 782 via the serial bus 796. The data can include wireless protocol, overhead information, and data to be processed by the device 780 in accordance with the methods described herein.

[0063] The D/A and A/D convertor 815 may be coupled to one or more optical modules to generate a signal to be used to energize one of the optical modules. The D/A and A/D convertor 815 may also be coupled to one devices such as LEDs 32A, 32B and the pins 251, 351, 451. Any of the components previously described can be implemented in a number of ways, including embodiments in software. Any of the components previously described can be implemented in a number of ways, including embodiments in software. Thus, the LEDs 32A, 32B, pins 251, 351, 451, controllers 54, switch 56, timers 58, controller 320 may all be characterized as "modules" herein. The modules may include hardware circuitry, single or multi-processor circuits, memory circuits, software

program modules and objects, firmware, and combinations thereof, as desired by the architect of the system 10, 30, 50, 60 and as appropriate for particular implementations of various embodiments.

[0064] FIG. 9A is a simplified block diagram of a dermatological treatment architecture (DTA) 900 according to various embodiments. As shown in FIG. 9A, architecture 900 includes a signal generation and control module (SGC) 910, a handle module 920, and an actuator module 930. In an embodiment the handle module 920 may include a deployable needle module 924 and a motor and LED module 922. In an embodiment the deployable needle module 924 may be releasably coupled to the motor and LED module 922. In a further embodiment the deployable needle module 924 may be a disposable cartridge module 924 to be removed and disposed after one or more treatments or for each patient, client, or user.

[0065] The SGC 910 may include one or more displays 912A, user input device 912B, handle module interface 914A, and actuator module interface 914C, electrical energy storage module 913, and one or more wheels 916A, 916B. In an embodiment the SGC 910 may be moveable and the wheels 916A, 916B may be lockable to prevent unintentional movement of the SGC 910 once positioned where desired by a user. In another embodiment the SGC 910 may also be coupled to the external power source including an alternating current (AC) grid source.

[0066] In an embodiment the displays 912A may indicate operational parameters for a hand module 920 to be coupled or coupled to the SGC 910. The displays 920 may be touch sensitive so a user may configure one or more operational parameters. In an embodiment the operational parameters may include electrical energy signal intensity to be applied the hand module 920, timing of such energy application, needle deployment timing and depth(s), LED intensity and timing, and number of cycles or shots to be conducted for each actuation via the actuator 930. In an embodiment the actuator 930 may be integral to the SGC 910 or a separate device wireless coupled or wired to the SGC 910 via a cable 914D and the SGC 910 actuator module interface 914C.

[0067] In an embodiment the actuator 930 may a mechanical device including a foot actuator or hand based actuator. The actuator 930 may also be an electronic device having an ASIC or running an application on a device (such as a computer, laptop, PDA, cellphone, or other electronic device) such as the module 780 shown in FIG. 8. In an embodiment the application may enable a user to set or control any of the possible operational parameters of the SGC 910 and initiate actuation a device 920 coupled to the SGC 910. FIG. 9B is a block diagram of a CPU module 911 that may be employed in the SGC 910 according to various embodiments.

[0068] The CPU module 911 may include a radio frequency (RF) signal generator (RFSG) module 911A, a needle deployment motor controller (NDMC) module 911B, and a photonic signal generator module (PSG) 911C. In an embodiment the photonic signal generator module 911C may be an LED signal generator or controller module 911C. In an embodiment a hand module 920 may include one or more photonic generation devices or modules (922I in FIG. 10A, 10B) where the PSG 911C may generate control or energy signals that cause the photonic modules 922I to generate photons of one or more frequencies with a desired intensity.

[0069] The NDMC 911B may control the deployment of one or more needles 924A of a deployable needle module 924 (FIG. 9C) based on one or more user selected operational parameters. The parameters may determine the depth and duty cycle related to the needle(s) 924A deployment in an embodiment. The signals generated by the NDMC 911B to control needle deployment may vary as a function of motor(s) (922A, FIG. 9C) employed to drive one or more needles 924A. As described above an electrical signal may also be applied to the needle(s) 924A to cause vibration of the needles or enable cutting, blending, and coagulation of the tissue in which the needles 924A are deployed. The RFSG 911A may generate one or more electrical signals to be applied to one or more needles 924A based on the selected operational parameters. An electrical signal may be applied to a single needle 924A, group of needles 924A (mono-polar configuration) or pair(s) of needles 924A (bipolar configuration) in an embodiment. In an embodiment the RFSG 911A may apply signals 650, 630, 640, 670 shown in FIGs. 5A, 5B, and 6, a combination thereof, or other signals.

[0070] In an embodiment the CPU module 911 via the RFSG 911A, NDMC 911B, and PSG 911C may create various therapy solutions including various combinations of photonic, electrical, and mechanical (needle deployment) therapy. In a further embodiment the CPU module 911 may control the generation of photonic energy to particular modules 922I, individual or group of needle(s) 924A deployment via one or more motors 922A, and control electrical signal(s) applied to individual or group of needles 924A. Accordingly the DTA 900 may apply various therapies based on user selections via the displays 912A, user selection device 912B, and actuator 930. The CPU 911 may employ the algorithm 930 (FIG. 12) or variations thereof to control the operation of the DTA 900.

[0071] FIG. 9C is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus or hand module 920 with one or more needles 924A retracted according to

various embodiments. FIG. 9D is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus or hand module 920 with one or more needles 924A deployed according to various embodiments. The handle module 920 may include a deployable needle module (DNM) 924 and a motor and LED module (MLM) 922. In an embodiment the DLM 924 may be a releasably couplable cartridge module. In a further embodiment the DLM 924 may be a detachable cartridge module (DCM) 924 where the DCM may be changed between therapy application(s) or client(s). In a further embodiment, the DCM 924 may be disposed after usage or cleaned via an autoclave or chemical process.

[0072] As shown in FIGs. 9C and 9D, the MLM 922 may include one or more motors 922A, longitudinally extendable drive arms 922B, drive shaft 922C, outer casing 922D, signal interface 922E, photonic generator module 922H, and DCM 924 interface 925 (shown in FIGs. 10A to 10F). The motor(s) 922A and photonic generator module 922H may be electrically coupled to the signal interface 922E to received control signals and energy to operate one or more motors 922A and photonic devices or modules 922I of the photonic generator module 922H. The drive arm(s) 922B may be coupled to one or more drive shafts 922C so the drive shafts may be moved longitudinally to deploy and retract one or more needles 924A when the MLM 922 is operatively coupled to the DNM 924.

[0073] As shown in FIGs. 9C and 9D the deployable needle module 924 may include at least one deployable needle 924A, MLM connecting arm and drive coupling tabs 924B, and MLM connecting/locking arms 924C. The MLM connecting/locking arms 924C may be configured to engage and lock to DCM 924 interface 925 recesses 925D (FIG. 10F). The MLM connecting arm and drive coupling tabs 924B may be configured to disengage connecting/locking arms 924C from the MLM interface 925 when the tabs 924B are depressed inward in an embodiment (as shown in FIG. 10B). The tabs 924B may further displace drive shaft connecting arms 924D (FIG. 10A) inward or centrally when the tabs 924B are depressed inwardly (as also shown in FIG. 10B). When the connecting/locking arms 924C are depressed inwardly or centrally (FIG. 9C and 9D) from an outward position (FIG. 10B). The arms 924C may engage the interface 925 recesses 925D to securely hold the DNM 924 to the MLM 922. The arms 924C may also displace the tabs 924B outwardly and cause the drive shaft connecting arms 924D to return outwardly.

[0074] The drive shaft connecting arms 924D may securely engage the drive shaft 922C tip 922F (FIG. 10E) recess 922G (FIG. 10E) when they return to an outward position as shown in FIG.

10D and 10E. In this configuration the DNM 924 is securely coupled to the MLM 922 via the arms 924C and 924D. In this configuration the motor(s) 922A via drive shaft(s) 922C coupled to the motor 922A shaft 922B may reliably drive one or more needles 924A of the DNM 924 (from a retracted or deployed position such as shown in FIGs. 9C and 9D, respectively). Further the motor(s) 922A may include steps or infinite drive extension 922B control to enable precise needle deployment depth or extension beyond the DNM 924 shell (924E, Fig. 10A).

[0075] FIG. 10A-10D are simplified, partial, cross-sectional diagrams of the DNM 924 in various stages of attachment to the MLM 922 via the arms 924C and 924D according to various embodiments. As shown in FIG. 10A the DNM or DCM 924 is decoupled from the MLM 922. The MLM 922 includes the photonic generator module (PGM) 922H, interface 925, and drive shaft tip 922F in a distal portion. As shown in FIG. 10A the PGM 922H may include one or more photon modules 922I. The photon modules 922I may be LED modules and emit photon with various frequencies and intensities based on the PSG 911C control signal.

[0076] As shown in FIG. 10A the DNM or DCM 924 may include the connecting arms 924C, deflecting tabs 924B, drive shaft coupling arms 924D, outer shell 924E, and one or more needles 924A. In an embodiment the drive shaft coupling arms 924D may include tabs that may securely engage the drive shaft tip 922F recess 922G. The drive shaft coupling arms 924D may be returnably deflectable inwardly (as shown in FIG. 10B) via inward depression of the tabs 924B. Such inward depression of the tabs 924B may deflect the coupling arms 924C outward. Similarly, inward depression of the coupling arms 924C to engage the interface 925 recesses 925D securely may deflect the tab arms 924B outwardly (relative the central axis of the DNM 920). Such outward movement may enable the drive shaft coupling arms 924D to return to a non-deflected state as shown in FIG. 10A.

[0077] In an embodiment a DNM or DCM 924 may be securely coupled to a MLM 922 by first completely compressing the arms or tabs 924B as shown in FIG. 10B. As noted above such inward compression may cause the coupling arms 924C to deflect outwardly and the drive shaft coupling arms 924D to be deflected inwardly towards each other. The drive shaft coupling arms 924D may be compressed so they may fit within the drive shaft 922C tip 922F recess 922G as the DNM or DCM 924 is advanced toward the MLM 922 distal end to securely couple the DNM 924 to the MLM 922 (as shown in FIG. 10D). After the DNM or DCM 924 is placed over the MLM 922 distal end so the drive shaft coupling arms 924D are located within the drive shaft 922C tip 922F

recess 922G and the coupling arms 924C are adjacent the MLM 922 interface 925 recesses 925D as shown in FIG. 10C.

[0078] To complete the coupling of a DNM 924 to the MLM 922, the coupling arms 924C may compressed inwardly as shown in FIG. 10D. The compression of the coupling arms 924C may deflect the tabs or arms 924B outwardly. Such outward deflection of the arms 924B may enable the drive shaft coupling arms 924D to return to a non-deflected state and securely engage the MLM 922 drive shaft 922C tip 922F recess 922G (as shown in FIG. 10D). In an embodiment a single coupling arm 924C, drive shaft coupling arm 924D, and tab 924B may be employed in an DNM 924. After the secure coupling of the DNM 924 to the MLM 922, the MLM 922 via the motor(s) 922A may ~~controllable~~ controllably deploy one or more needles 924A as shown in FIG. 10E. FIG. 10F is a simplified cross-sectional diagram of a DNM interface 925 according to various embodiments.

[0079] As noted the interface 925 may include one or more recesses 925D to be securely engaged to DNM 924 coupling arms 924C. The interface 925 may also include several fenestrations or openings 925A, 925B, 925C (FIG. 10F). The central fenestration 925A may be sized to enable passage of the MLM 922 drive shaft 922C tip 922F. The fenestrations 925C may be sized and located above one or more photon modules 922I to enable photons generated by the photon modules 922I to pass into the DNM 924. In an embodiment the DNM 924 outer casing 924E may be translucent and act as a waveguide to communicate photons to the needle area of the DNM 924. The fenestrations 925B may be sized and configured to enable electrical coupling pins 924G (FIG. 11A) passage from the DNM 924 to electrical couplings of the MLM 922. The pins 924G may communicate electrical signals from the RFSG 911A to one or more needles 924A via the wires 914B and MLM 922.

[0080] FIG. 11A is a simplified, partial, cross-sectional diagram of DNM 924 coupled to a MLM 922 with needles 924A deployed according to various embodiments. As shown in FIG. 11A, the DNM 924 may further include electrical coupling pins 924G set with a spring loaded base 924H (in an embodiment). As noted the pins 924G may extend to electrical contacts in the MLM 922 via the interface 925 fenestrations 925B. ~~Along~~ Although a pair of pins 924G is shown, one or more pins 924G may be employed in a DNM 924 according to various embodiments. A drive shaft coupling arm 924D may include an offset 924I where the offset may be configured to engage a tab or arm 924B.

[0081] As shown in FIG. 11A when the needle array or assemble 924F is deployed depression of the tabs 924B inwardly will not engage the drive shaft coupling arms 924D (via the offsets 924I). Such a configuration may prevent unintentional decoupling of the DNM 924 to the MLM 922 when the needle assembly 924F is at least partially deployed. As shown in FIG. 11A, the electrical contact pin 924G is sized to fit within the spring loaded based 924H. In an embodiment the internal spring 924M ~~is~~ (FIG. 11C) may force extension of the pin 924G to maintain electrical conduction with the MLM 922 as the needle assembly 924F is moved (recessed and deployed to various depths). FIG. 11B is a simplified, cross-sectional diagram of a DNM 924 needle assembly 924F according to various embodiments. FIG. 11C is a simplified, cross-sectional, exploded diagram of the DNM 924 needle assembly 924F according to various embodiments. As shown in FIGs. 11B and 11C, the needle assembly 924F may include a pin cover 924J, drive arm module 924L, needles 924A, pins 924G with bases 924H, and needle printed circuit board (PCB) 924K.

[0082] In an embodiment the PCB 924K may couple one or more needles 924A to a first pin 924G base 924H and another one or more needles 924A to another pin 924G based 924H. The first pin 924G and second pin 924H may couple alternating rows or columns of needles 924A to form one or more dipoles between such needles 924A. The drive shaft coupling arms 924D may have a base 924L where the cover 924J includes fenestrations for the needles 924A, a recess for the PCB 924K, and an outer recess for the coupling arm base 924L (as shown assembled in FIG. 11B).

[0083] FIG. 12 is a flow diagram illustrating a DTA 900 processing algorithms 930 according to various embodiments. As noted the DTA 900 SGC 911 RFSG 911A, NDMC 911B, and PSG 911C may enable a user or clinician to select a variety of operational parameters to deliver a desired combination of electrical, light (photonic), and mechanical (needle) therapy to dermatological tissue. In the algorithm 930, a user may select different operational modes including cut (activities 932A to 932F), blend (activities 934A to 934F), and coagulation (activities 936A to 936F) in an embodiment. In a cut operational mode, a user may select the electrical signal intensity (activity 932B) and application time (activity 932C). The CPU 911 may determine the total energy that will be applied for each activation based on the selected intensity and time (total fluence – activity 932D). Then, upon activation (activity 932E, 932F) the DTA 900 may energize the MLM 922 based on the operational parameters.

[0084] In a blend operational mode (activity 934A), a user may select the electrical signal intensity, start delay, and duty cycle (activity 934B) and needle deployment depth and number of

shots per activation (activity 934C). The duty cycle may include the delay before energy and ~~need~~ needle deployment, the time the energy and needles are deployed, and the subsequent off or rest time before the next possible duty cycle. As noted above the motor(s) 922A may enable precise needle extension (effective depth) control. In an embodiment the motor(s) 922A may include a transverse motor that converts rotational force to longitudinal force. The motor may be a Haydon model number: 21H4AB-05-049 having a motor speed of about 0.005mm/msec and motor power of about 1000 Hz approximately 40N (Newton) (described in detail at www.haydonkerk.com and whose specifications are incorporated by reference).

[0085] The CPU 911 may determine the total energy that will be applied for each activation based on the selected intensity and duty cycle (total fluence – activity 934D). Then, upon activation (activity 934E, 934F) the DTA 900 may energize the MLM 922 based on the operational parameters and deploy the needle assembly 924F to a desired extension beyond the DNM 924 shell 924E to enable a desired depth of needle 924A penetration within tissue when the shell 924E is placed adjacent the tissue.

[0086] In a coagulation operational mode (activity 936A), a user may select the electrical signal intensity and start delay (activity 936B) and needle deployment depth and number of shots per activation (activity 936C). As noted above the motor(s) 922A may enable precise needle extension (effective depth) control. The CPU 911 may determine the total energy that will be applied for each activation based on the selected intensity (total fluence – activity 936D). Then, upon activation (activity 936E, 936F) the DTA 900 may energize the MLM 922 based on the operational parameters and deploy the needle assembly 924F to a desired extension beyond the DNM 924 shell 924E to enable a desired depth of needle 924A penetration within tissue when the shell 924E is placed adjacent the tissue.

[0087] Applications that may include the novel apparatus and systems of various embodiments include electronic circuitry used in high-speed computers, communication and signal processing circuitry, modems, single or multi-processor modules, single or multiple embedded processors, data switches, and application-specific modules, including multilayer, multi-chip modules. Such apparatus and systems may further be included as sub-components within a variety of electronic systems, such as televisions, cellular telephones, personal computers (e.g., laptop computers, desktop computers, handheld computers, tablet computers, etc.), workstations, radios,

video players, audio players (e.g., mp3 players), vehicles, medical devices (e.g., heart monitor, blood pressure monitor, etc.) and others. Some embodiments may include a number of methods.

[0088] It may be possible to execute the activities described herein in an order other than the order described. Various activities described with respect to the methods identified herein can be executed in repetitive, serial, or parallel fashion.

[0089] A software program may be launched from a computer-readable medium in a computer-based system to execute functions defined in the software program. Various programming languages may be employed to create software programs designed to implement and perform the methods disclosed herein. The programs may be structured in an object-orientated format using an object-oriented language such as Java or C++. Alternatively, the programs may be structured in a procedure-orientated format using a procedural language, such as assembly or C. The software components may communicate using a number of mechanisms well known to those skilled in the art, such as application program interfaces or inter-process communication techniques, including remote procedure calls. The teachings of various embodiments are not limited to any particular programming language or environment.

[0090] The accompanying drawings that form a part hereof show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. The embodiments illustrated are described in sufficient detail to enable those skilled in the art to practice the teachings disclosed herein. Other embodiments may be utilized and derived therefrom, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. This Detailed Description, therefore, is not to be taken in a limiting sense, and the scope of various embodiments is defined only by the appended claims, along with the full range of equivalents to which such claims are entitled.

[0091] Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is in fact disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other

embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

[0092] The Abstract of the Disclosure is provided to comply with 37 C.F.R. §1.72(b), requiring an abstract that will allow the reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims. In the foregoing Detailed Description, various features are grouped together in a single embodiment for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted to require more features than are expressly recited in each claim. Rather, inventive subject matter may be found in less than all features of a single disclosed embodiment. Thus the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separate embodiment.

METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

Abstract of the Disclosure

Embodiments of dermatological cell treatment are described generally herein. Other embodiments may be described and claimed.

ENDYMED EXHIBIT 1002 - 49/733

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Filer:	Merle W. Richman
Attorney Docket Number:	NA001KR_US3

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	70	70
UTILITY SEARCH FEE	2111	1	300	300
UTILITY EXAMINATION FEE	2311	1	360	360
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**730**

Electronic Acknowledgement Receipt

EFS ID:	30558655
Application Number:	15724261
International Application Number:	
Confirmation Number:	3803
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Customer Number:	26338
Filer:	Merle W. Richman
Filer Authorized By:	
Attorney Docket Number:	NA001KR_US3
Receipt Date:	03-OCT-2017
Filing Date:	
Time Stamp:	23:35:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	na001kr_us3-ads.pdf	1503789 5d3f2bb9f917ac8fa92c0efb4953ef305b7b7ffe	no	7

Warnings:

ENDYMED EXHIBIT 1002 - 52/733

Information:					
2	Oath or Declaration filed	na001kr_us2_declaration_executed.pdf	107251 e7df63cecdabf63e26e7a1767c6d0d37a56d43d5	no	1
Warnings:					
Information:					
3	Drawings-only black and white line drawings	na001kr_us3-drawings.pdf	4430191 3c55b76110e8a13f08b4a5dd9bf315abc80ddefc	no	21
Warnings:					
Information:					
4	Specification	na001kr_us3-application.pdf	166265 e84768863d40a60464f64490568091140a328cbd	no	26
Warnings:					
Information:					
5	Preliminary Amendment	na001kr_us3-preliminary-amendment.pdf	90908 b0c447ec8e9d7904b18e236d50fd3f8931cab295	no	5
Warnings:					
Information:					
6	Transmittal of New Application	na001kr_us3-transmittal.pdf	122579 e4def06150f564e71aec3b1ebda104ba71b0b047	no	1
Warnings:					
Information:					
7	Specification	na001kr_us3-application-clean.pdf	163199 27a55a41041717744b7d3c339af5586e7857f5ab	no	24
Warnings:					
Information:					
8	Specification	na001kr_us3-application-marked-up.pdf	165158 6fb221831026bc726100a4d694aba024bf682eab	no	24
Warnings:					
Information:					

9	Fee Worksheet (SB06)	fee-info.pdf	35000 fcaef63435601ba833bec631977b155428bf046c	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	6784340

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/14 (03-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NA001KR_US3
	Application Number	
Title of Invention	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
Mr	Jongju		Na	

Residence Information (Select One) US Residency ● Non US Residency Active US Military Service

City	Songpa-Gu	Country of Residence i	KR

Mailing Address of Inventor:

Address 1	17145 Von Karman Ave.		
Address 2	Scarlet RF Inc		
City	Irvine	**State/Province**	CA
Postal Code	92614	**Country** i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	26338		
Email Address	merle@mwresq.com	Add Email	Remove Email

Application Information:

Title of the Invention	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT		
Attorney Docket Number	NA001KR_US3	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	21	**Suggested Figure for Publication (if any)**	9A

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NA001KR_US3
	Application Number	
Title of Invention	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT	

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	◯ Limited Recognition (37 CFR 11.9)
Customer Number	26338		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	15096686	2016-04-12
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15096686	Continuation of	13825083	2013-03-19	9320536	2016-04-26

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13825083	a 371 of international	PCTKR2012001335	2012-02-22
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCTKR2012001335	non provisional of	61449080	2011-03-03
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
PCTKR201200133	Continuation of	13060274	2011-02-22	8979412	2015-03-17

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NA001KR_US3
	Application Number	
Title of Invention	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT	

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13060274	a 371 of international	PCTUS2008074131	2008-08-22

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)
10-2008-0076993	KR	2008-08-06	

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

X This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

Authorization to Permit Access:

X Authorization to Permit Access to the Instant Application by the Participating Offices

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NA001KR_US3
	Application Number	
Title of Invention	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT	

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date o f filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NA001KR_US3
	Application Number	
Title of Invention	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT	

Mailing Address Information For Applicant:			
Address 1			
Address 2			
City		**State/Province**	
Country[i]		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Non-Applicant Assignee Information:

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Assignee 1

Complete this section only if non-applicant assignee information is desired to be included on the patent application publication in accordance with 37 CFR 1.215(b). Do not include in this section an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest), as the patent application publication will include the name of the applicant(s).

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If the Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Non-Applicant Assignee:			
Address 1			
Address 2			
City		**State/Province**	
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Phone Number		Fax Number	
Email Address			

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	NA001KR_US3
	Application Number	
Title of Invention	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT	

Signature:

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Signature	/mwresq/			Date (YYYY-MM-DD)	2017-10-03
First Name	Merle	Last Name	Richman	Registration Number	38282

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This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Co o p eration Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/AIA/01 (06-12)
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATIONS USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

As the below named inventor, I hereby declare that:

This declaration is directed to:

[ ] The attached application, or

[X] United States application or PCT international application number 15096686 filed on 4/12/2016.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published applications or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Jongju Na Date (Optional): 09/17/2016

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comment on the amount of time you required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

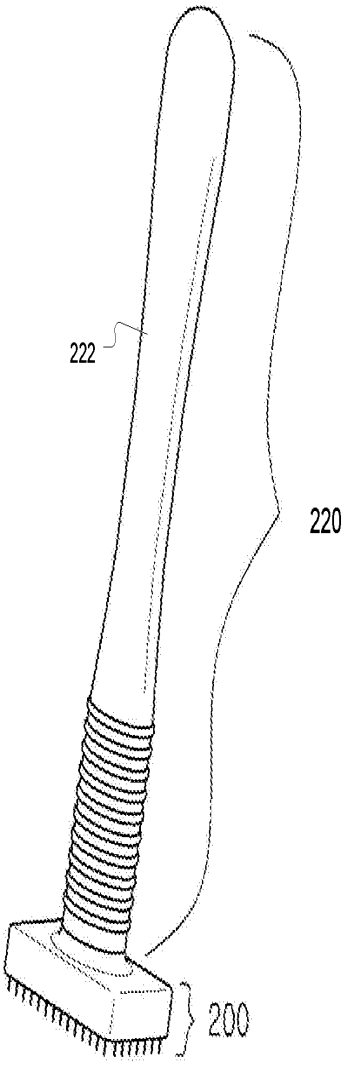


FIGURE 1A

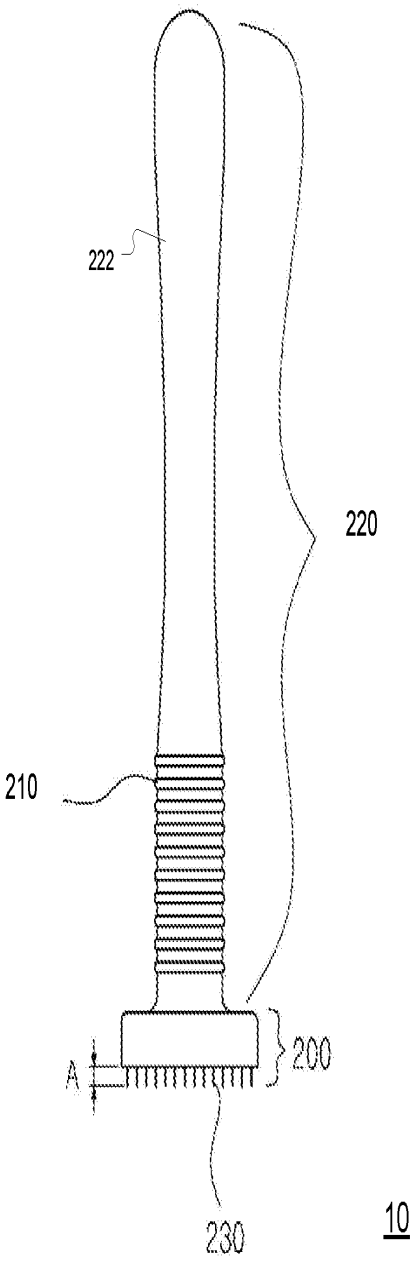


FIGURE 1B

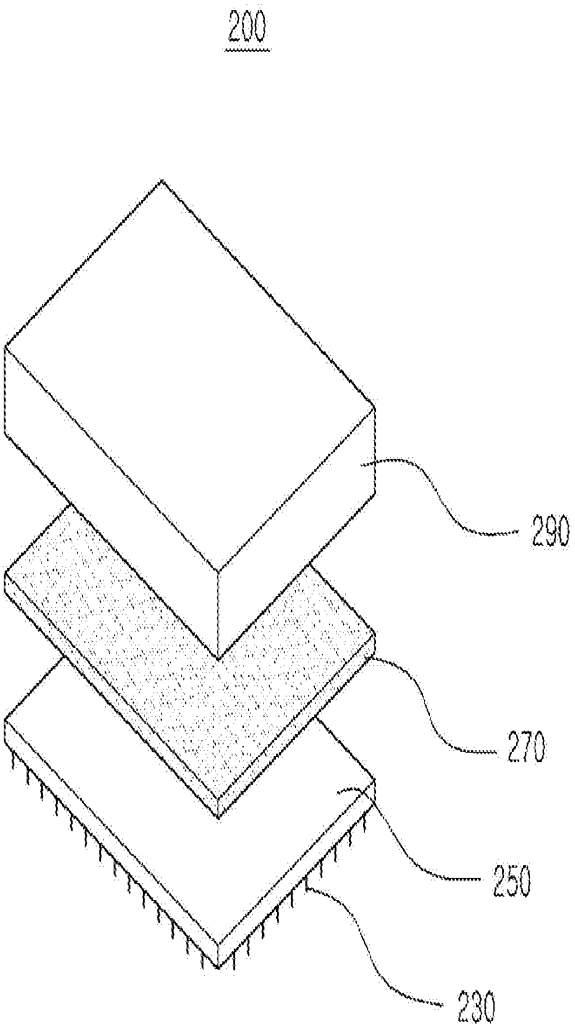


FIGURE 1C

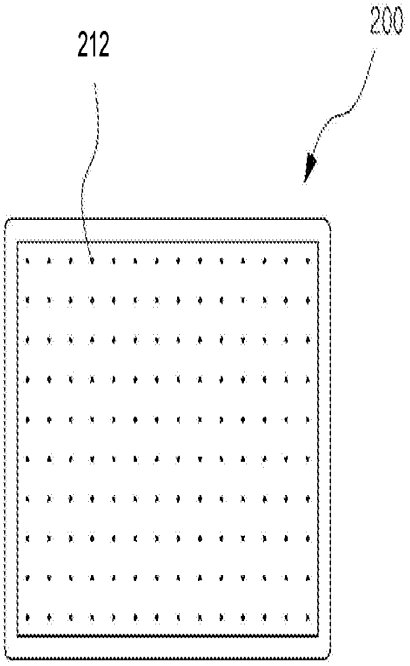


FIGURE 1D

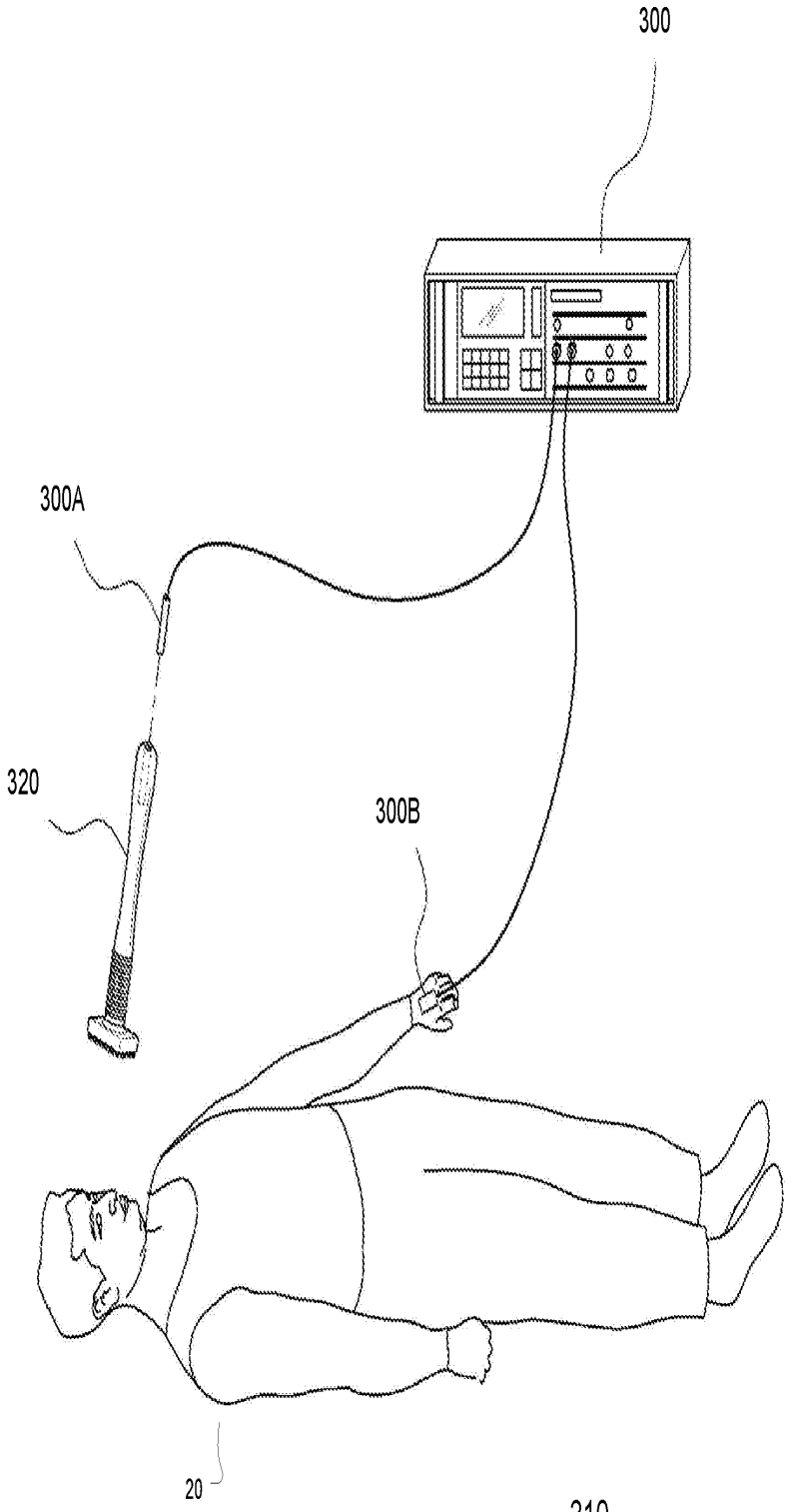


FIGURE 2A

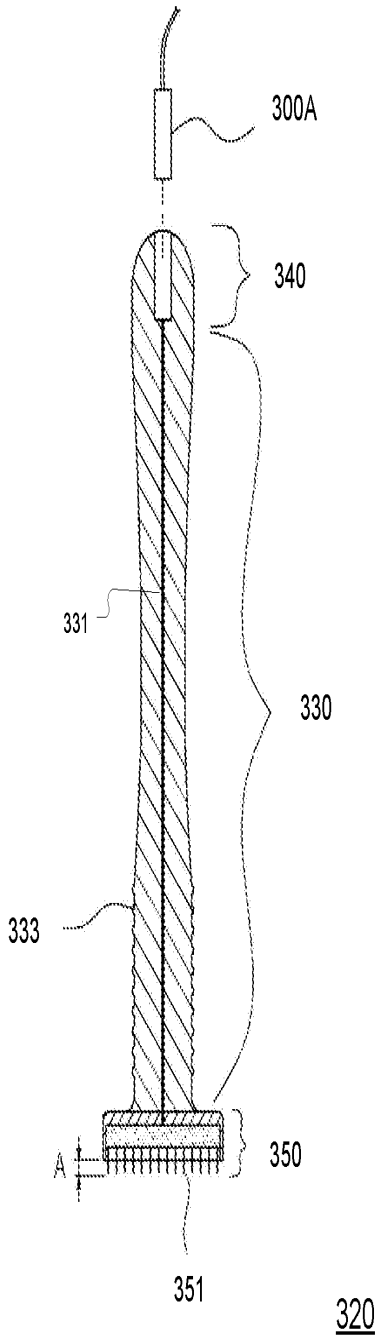


FIGURE 2B

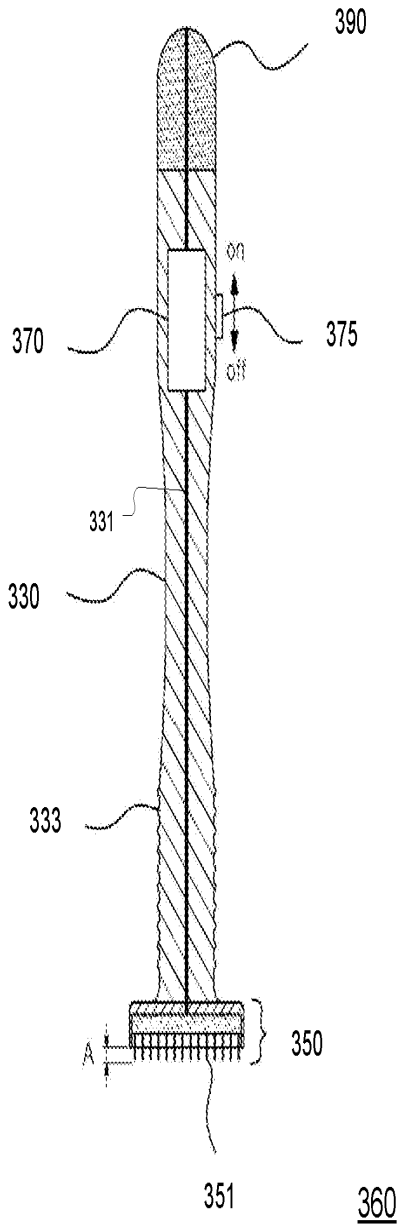


FIGURE 2C

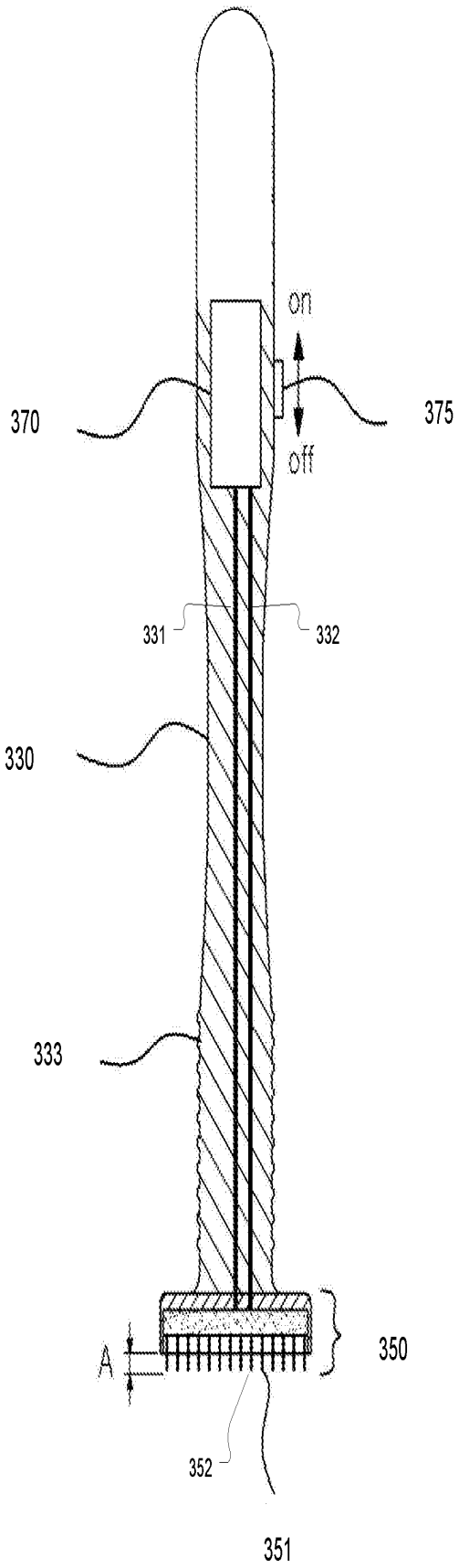


FIGURE 2D

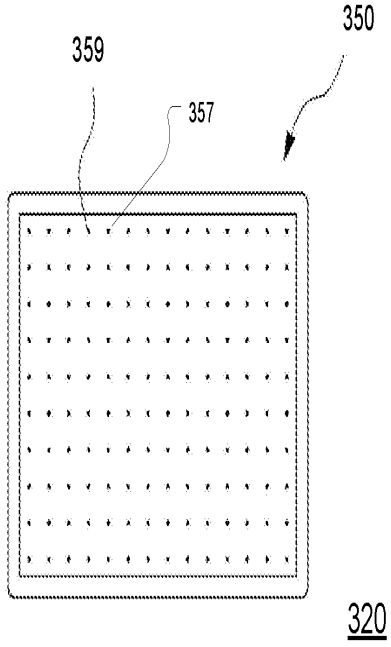


FIGURE 2E

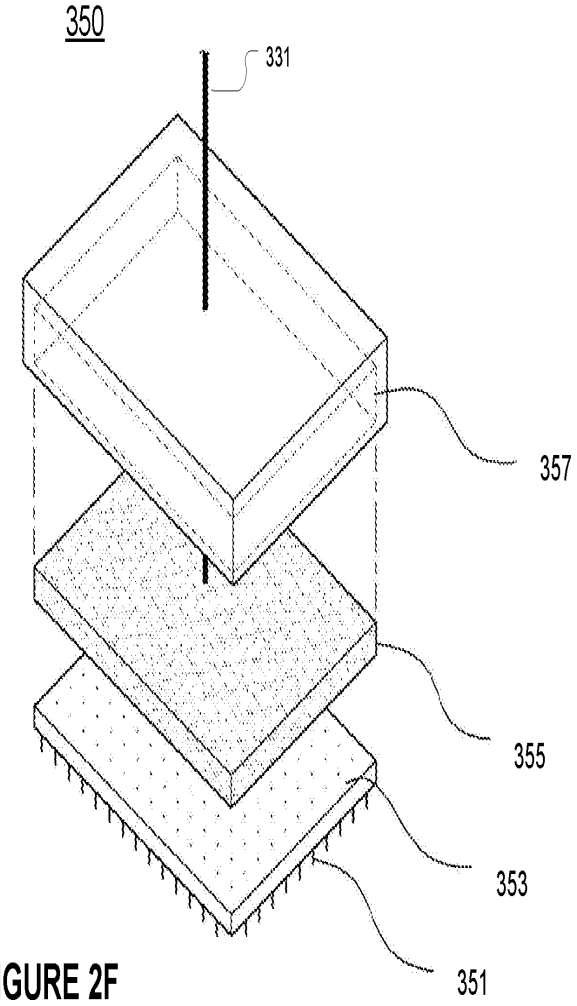


FIGURE 2F

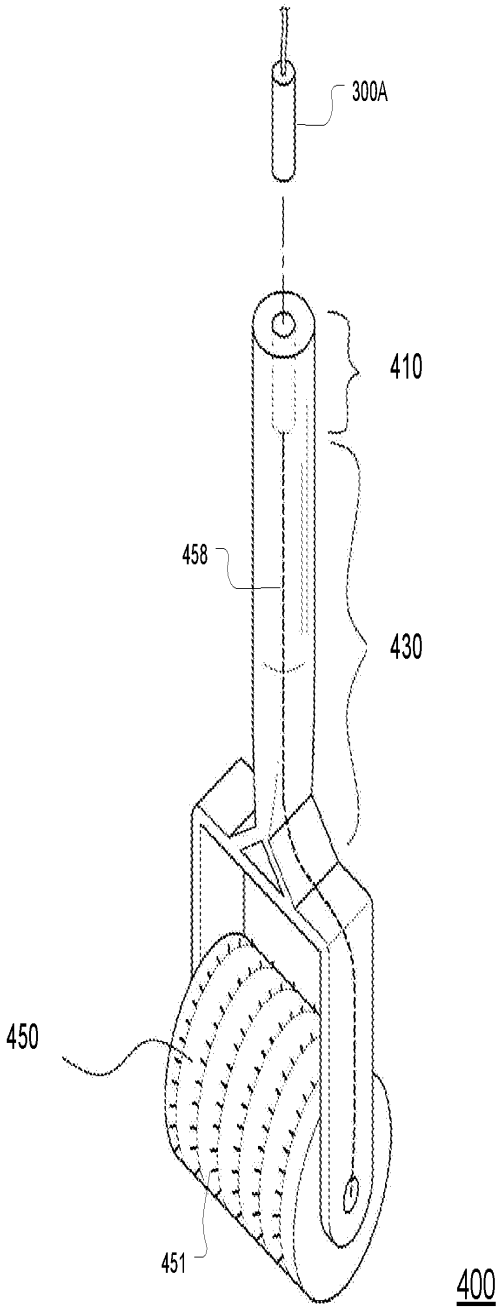


FIGURE 3A

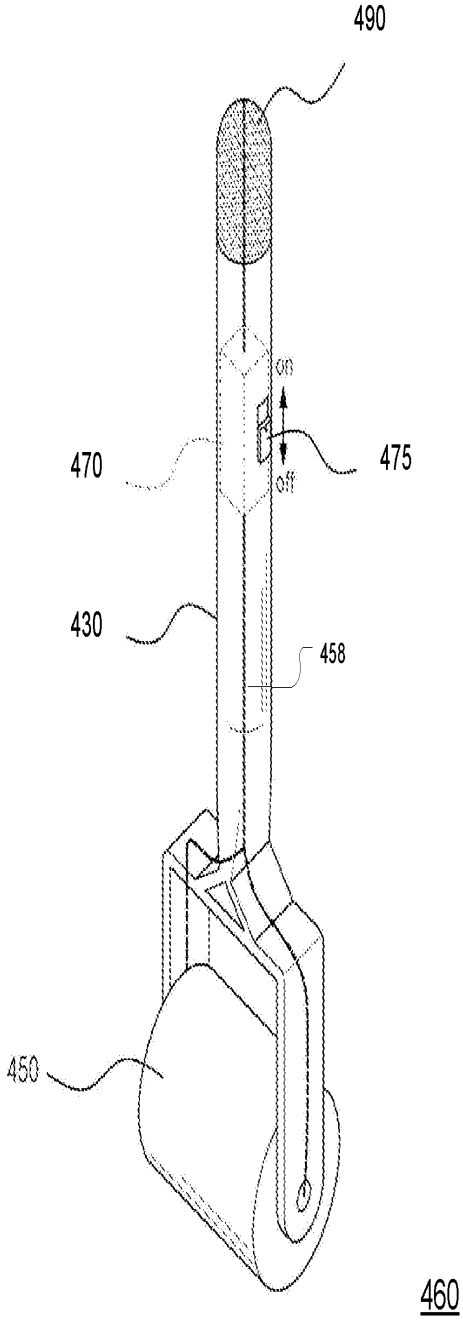


FIGURE 3B

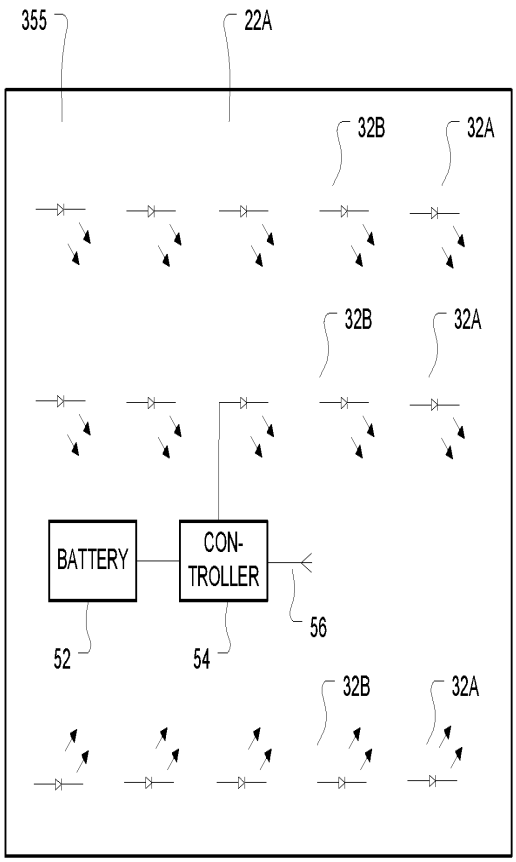


FIGURE 4A 520

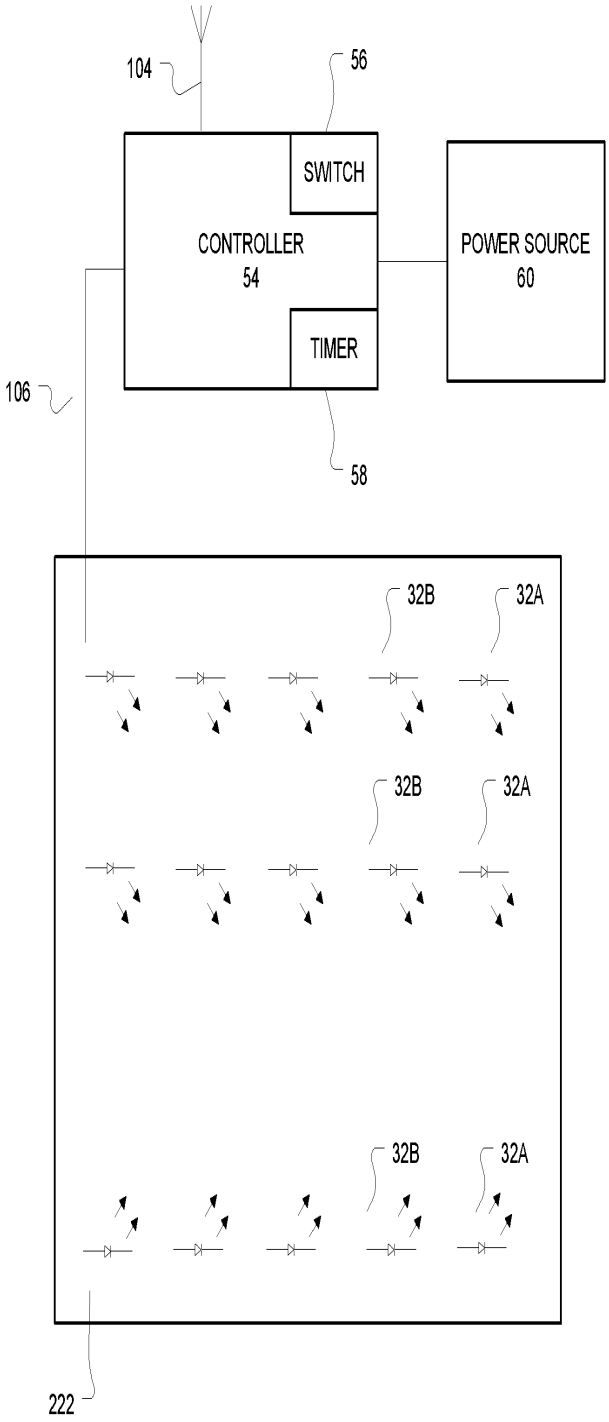
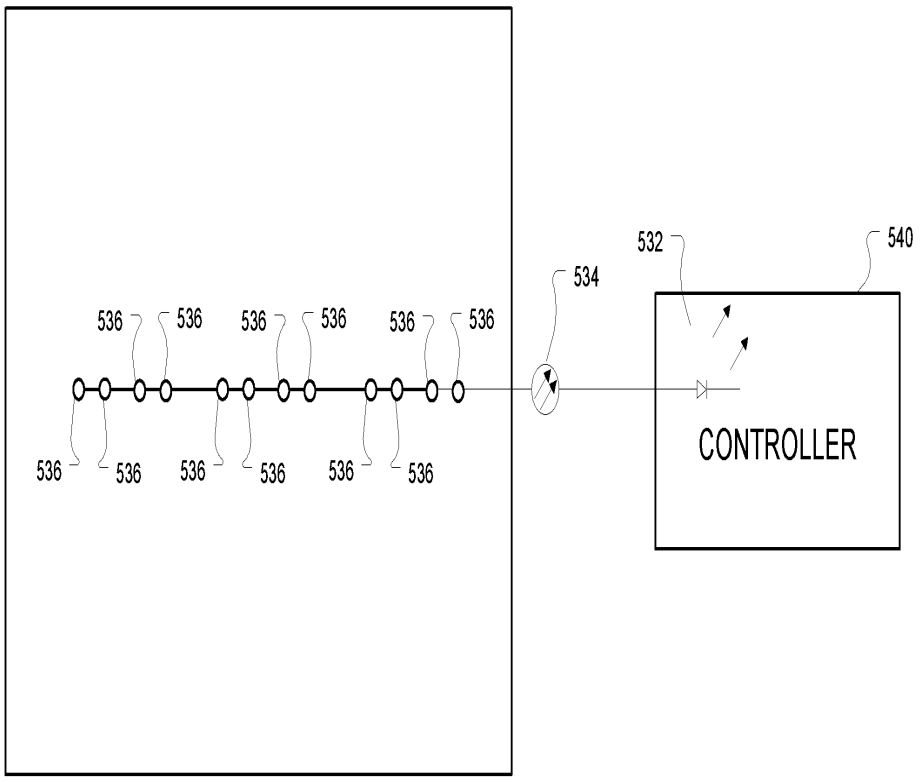


FIGURE 4B 510


532
540
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536
CONTROLLER
530

FIGURE 4C

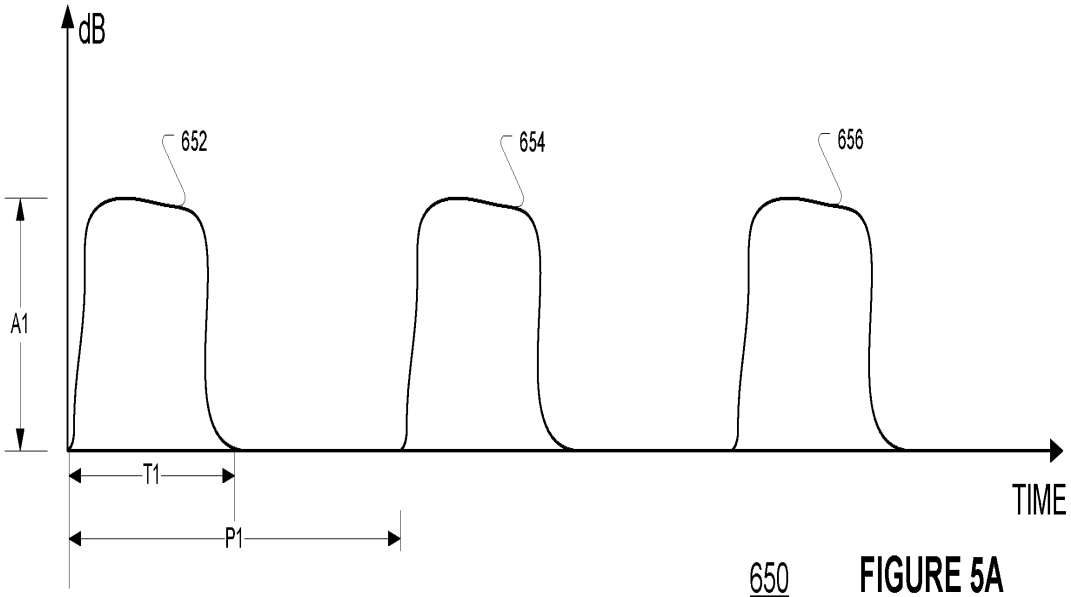
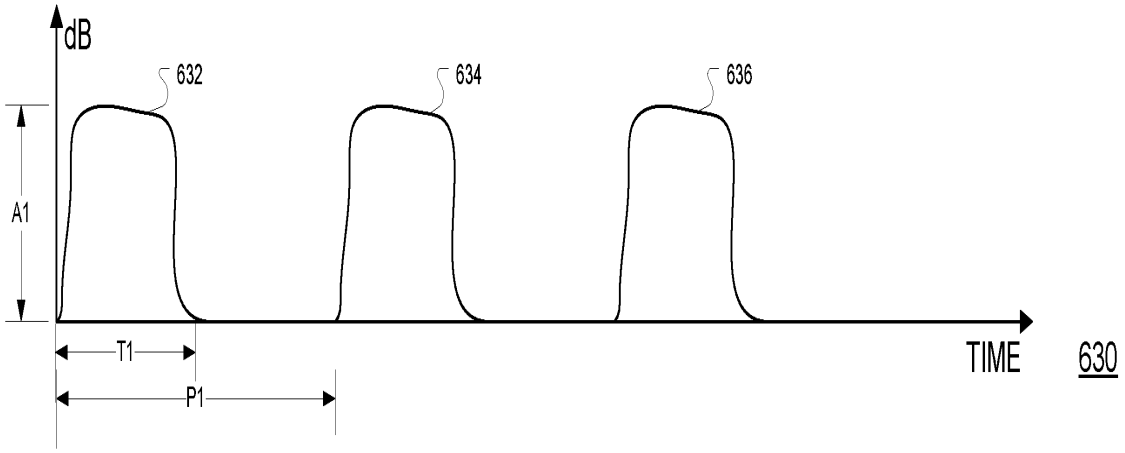


FIGURE 5A



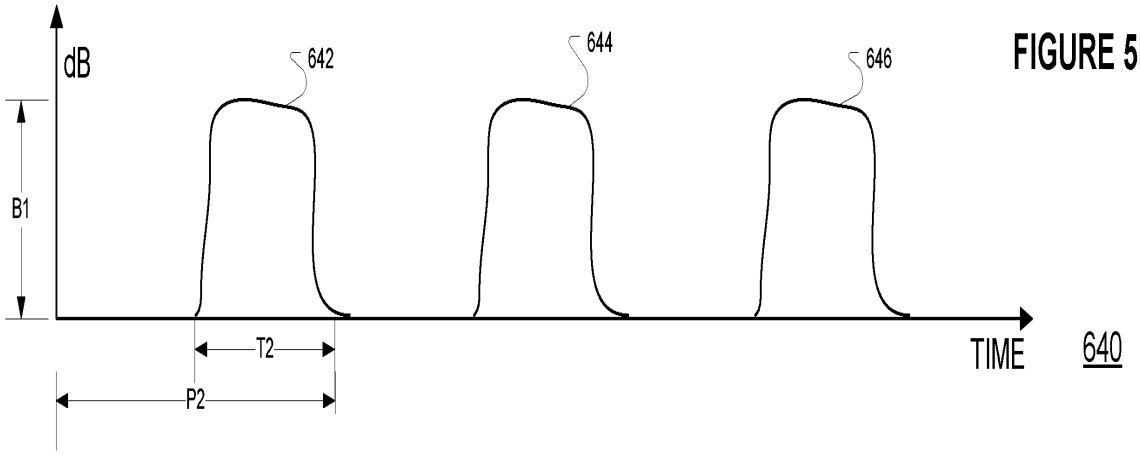


FIGURE 5B

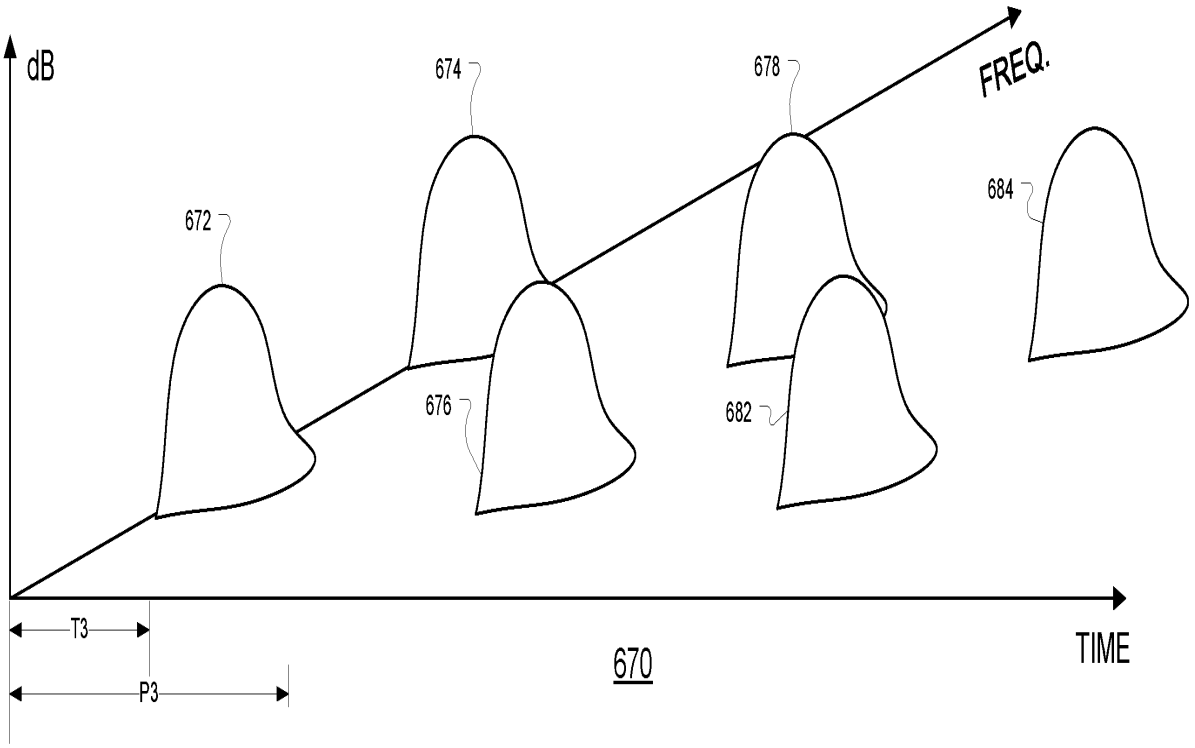


FIGURE 6

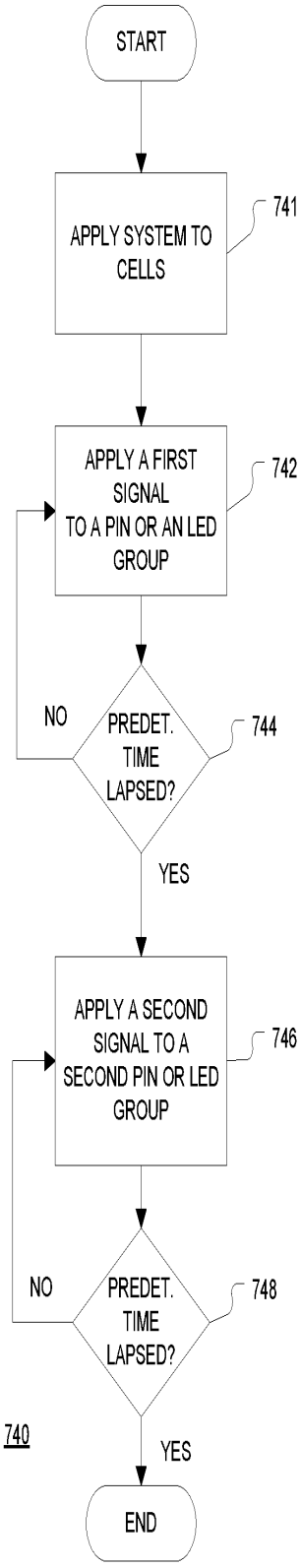


FIGURE 7A

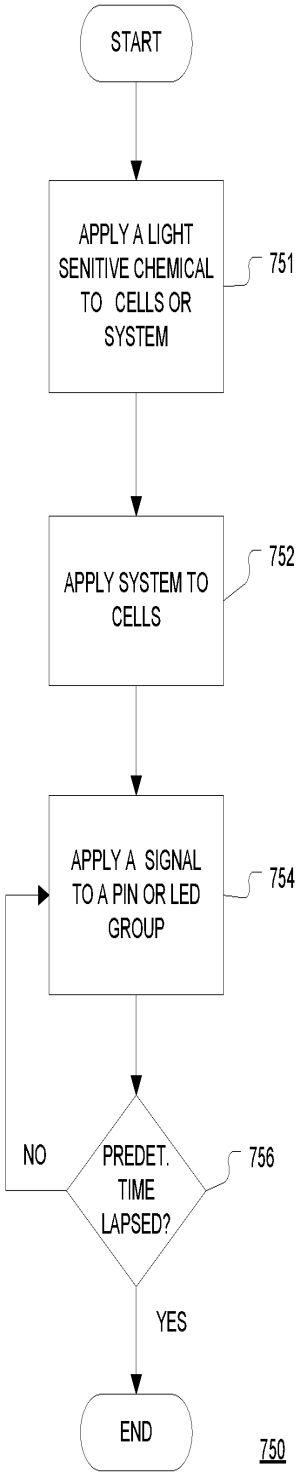


FIGURE 7B

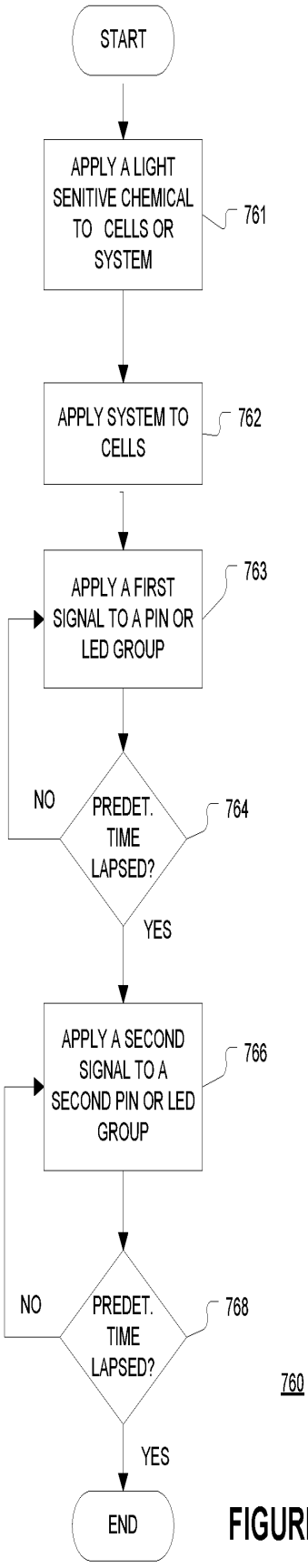


FIGURE 7C

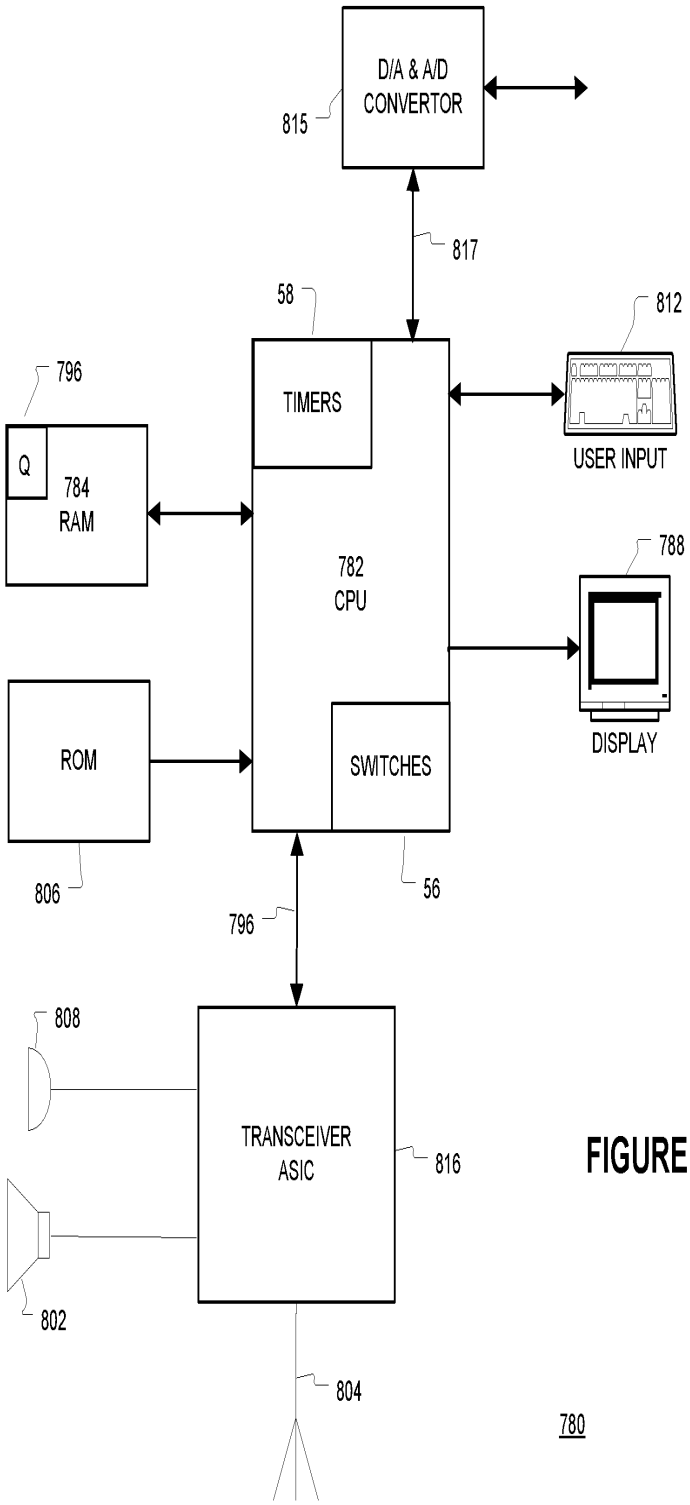

D/A & A/D
CONVERTOR
815
817
58
812
796
TIMERS
USER INPUT
Q
784
RAM
782
CPU
788
ROM
SWITCHES
DISPLAY
806
56
796
808
TRANSCEIVER
ASIC
816
802
804
780

FIGURE 8

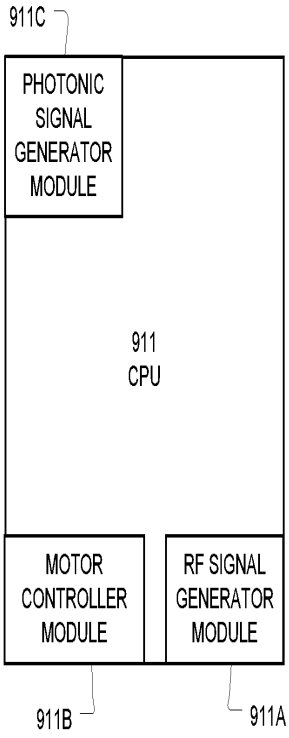


FIGURE 9B

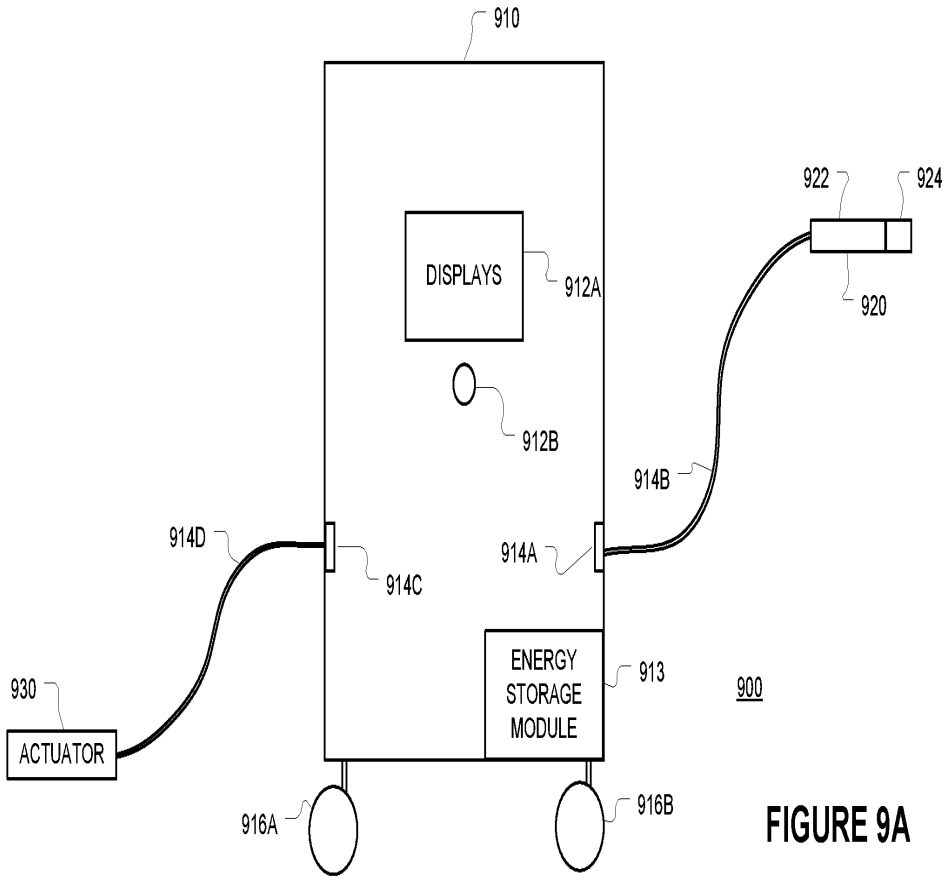


FIGURE 9A

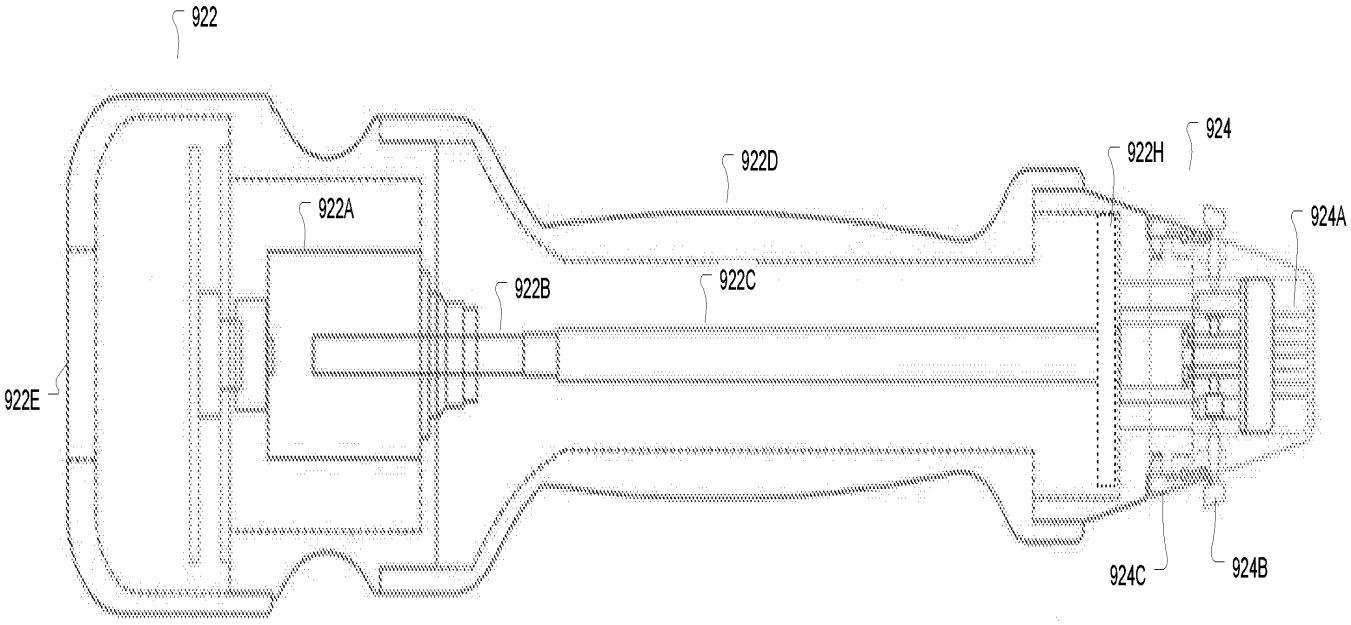


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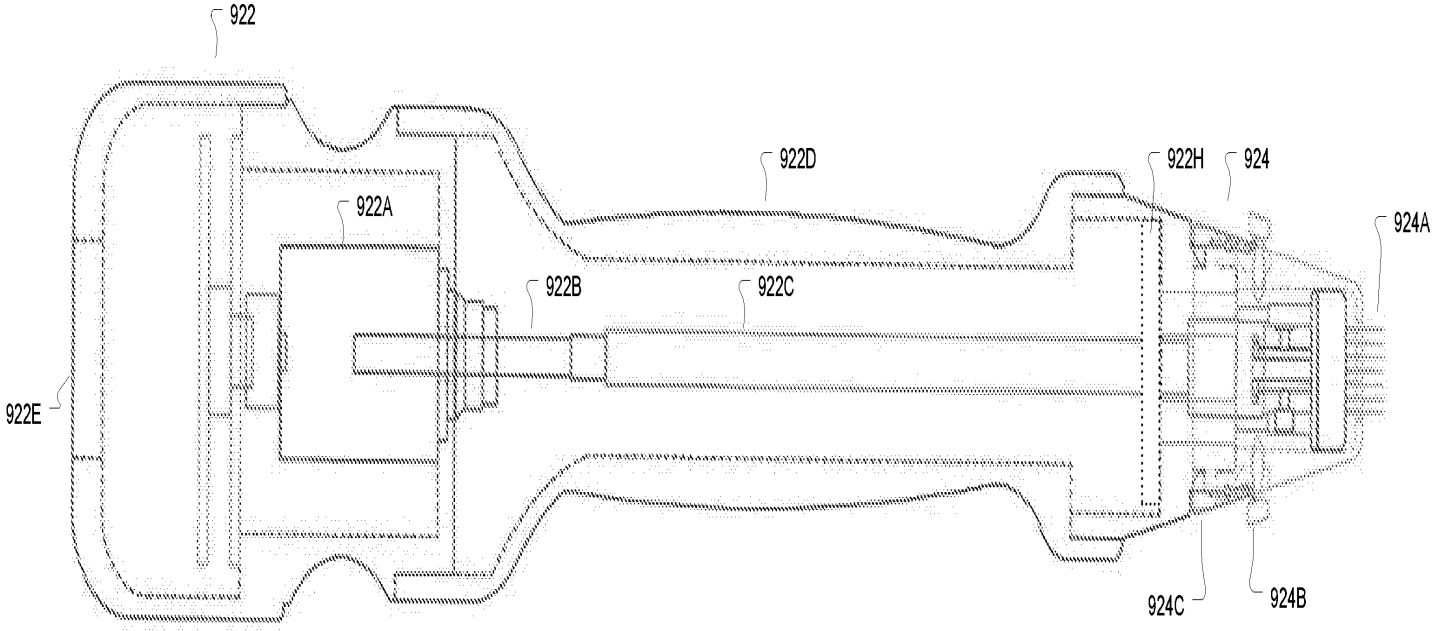
FIGURE 9C



920

FIGURE 9D

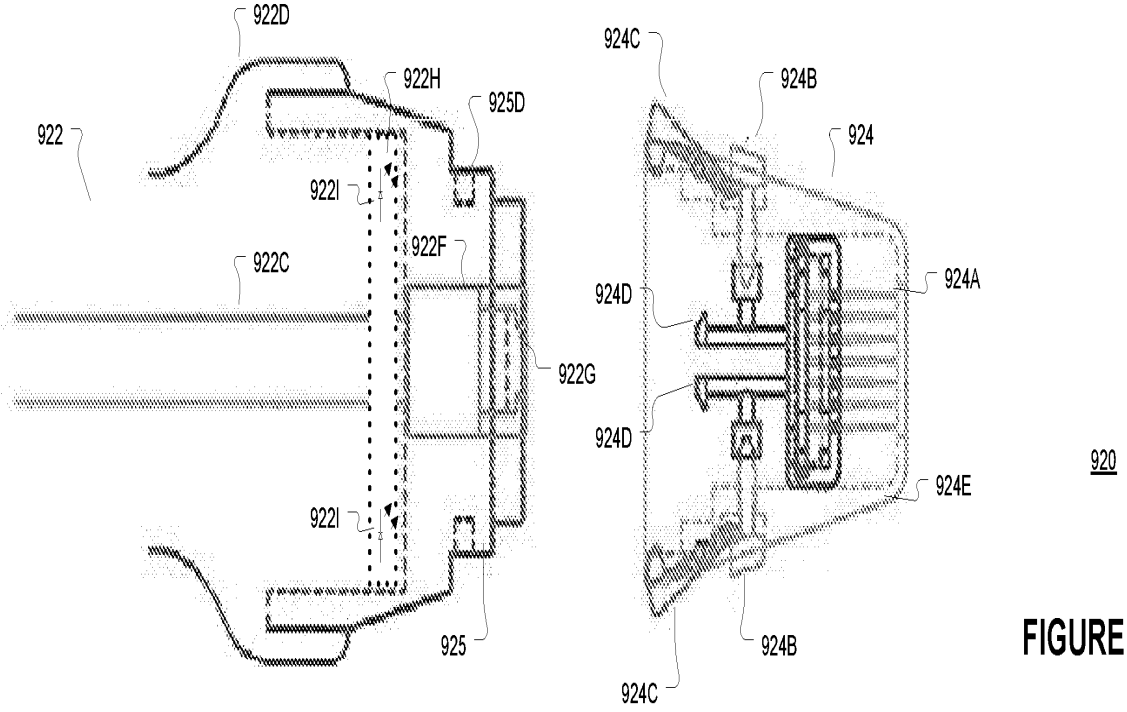


FIGURE 10A

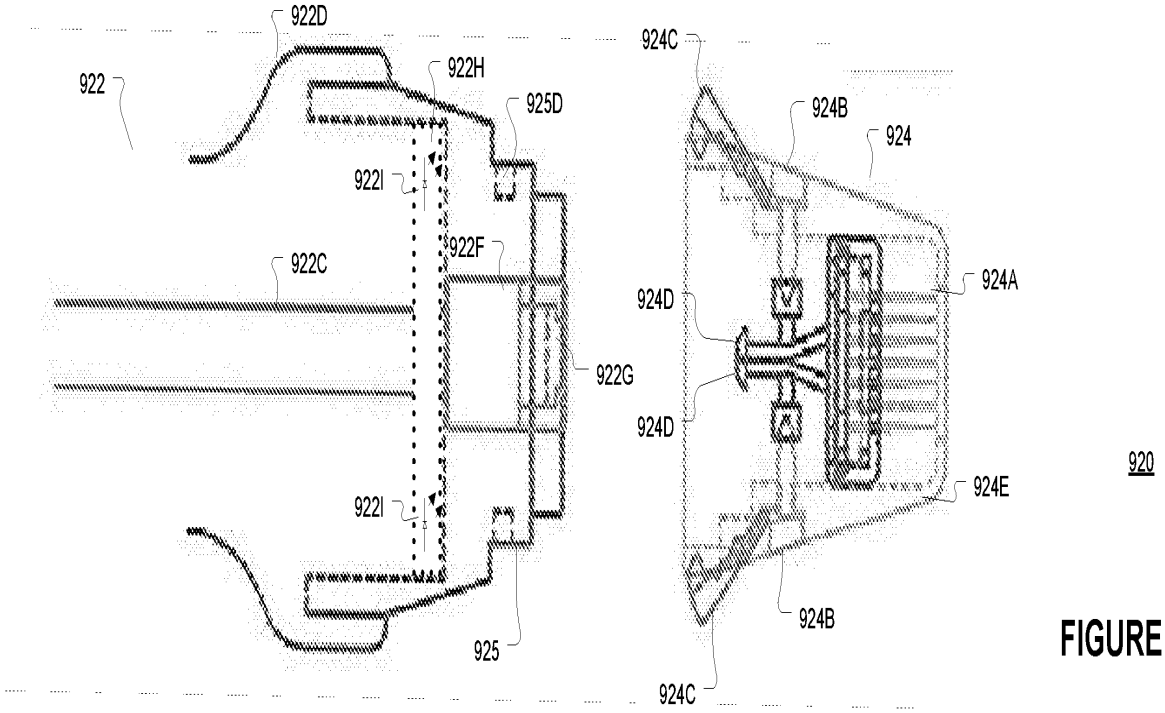


FIGURE 10B

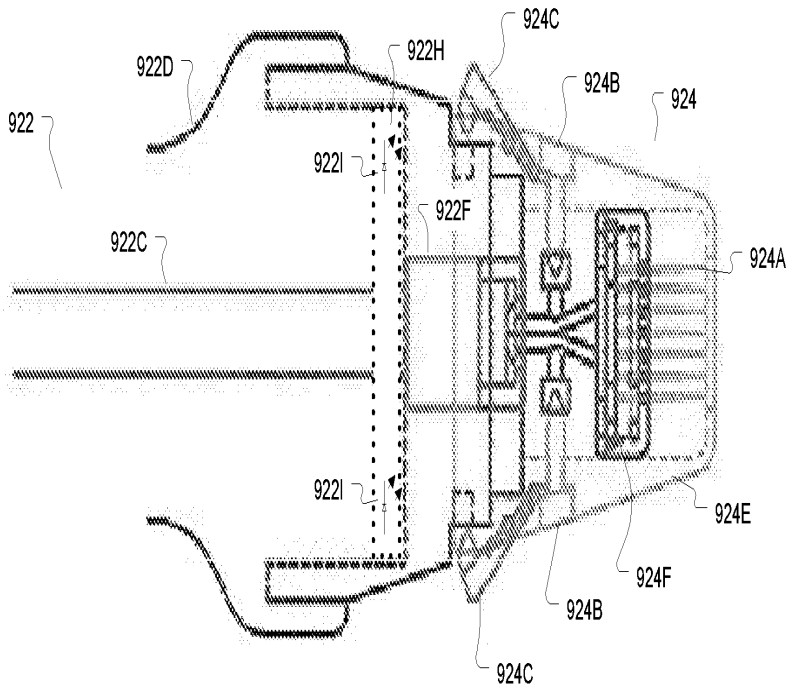


FIGURE 10C

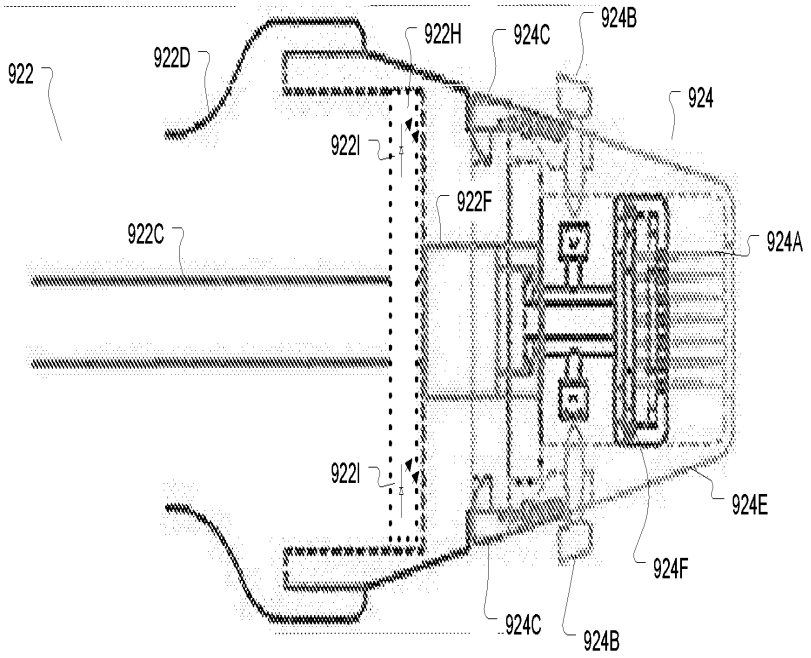


FIGURE 10D

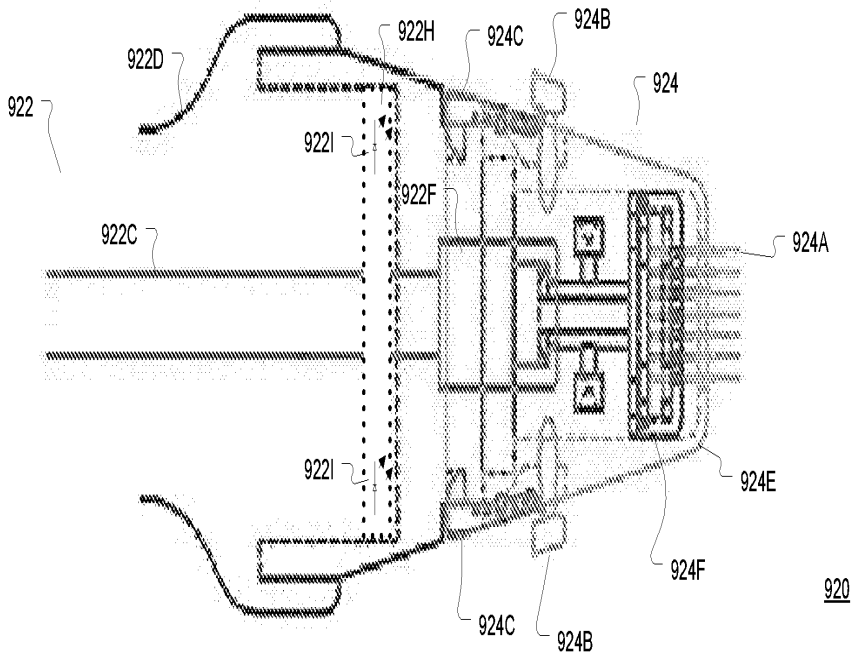


FIGURE 10E

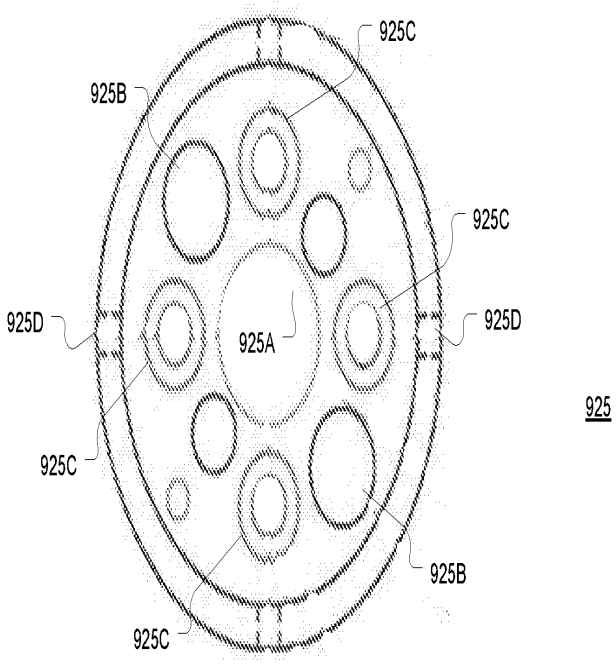
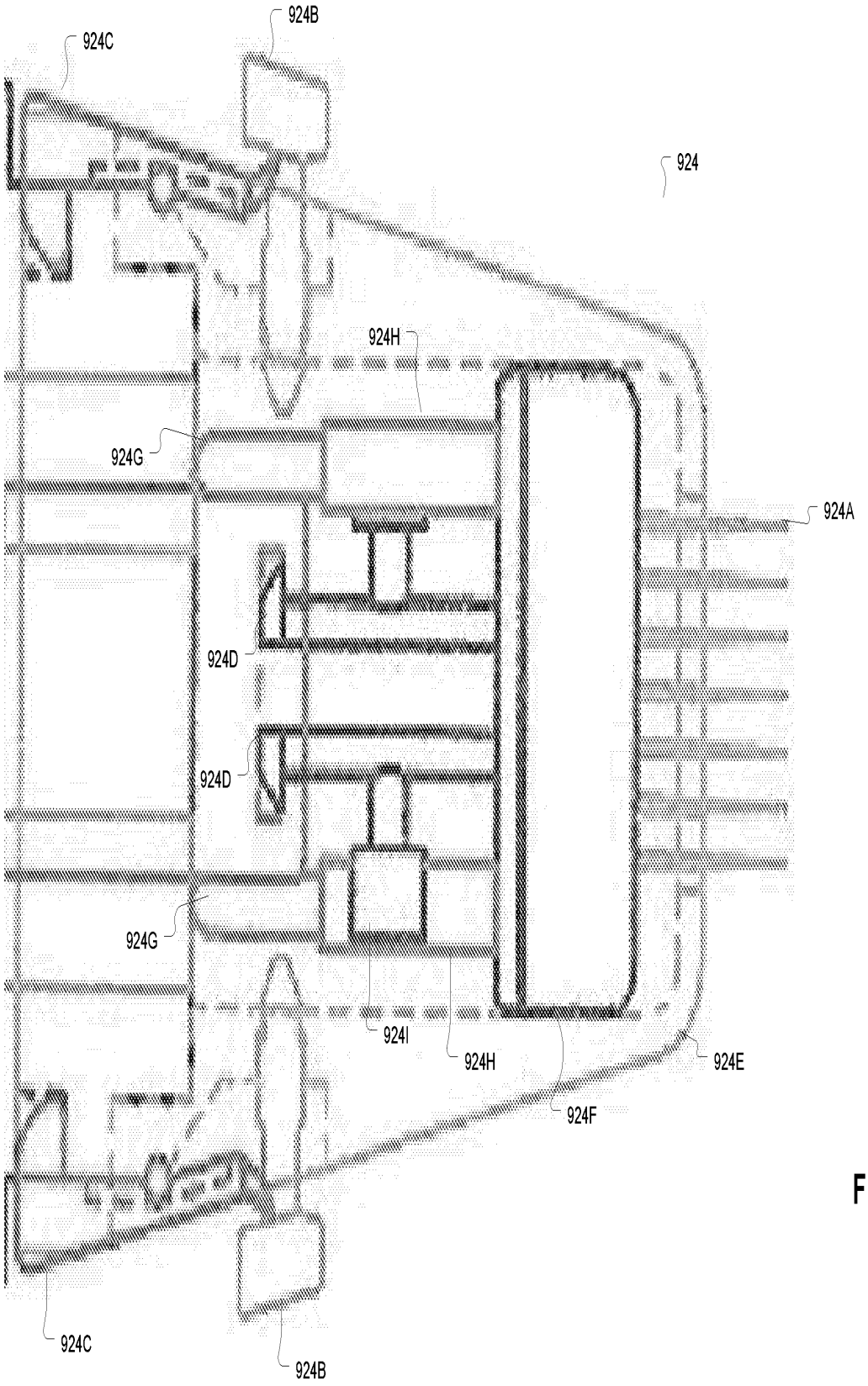


FIGURE 10F


924B
924C
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924D
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924B

FIGURE 11A

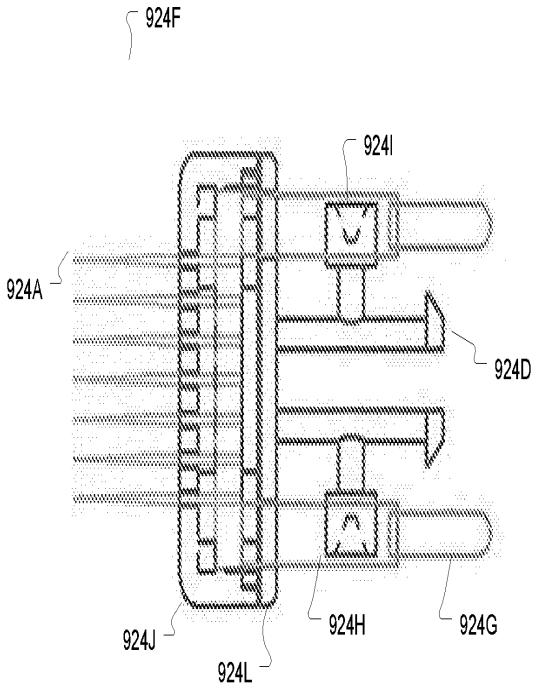

FIGURE 11B

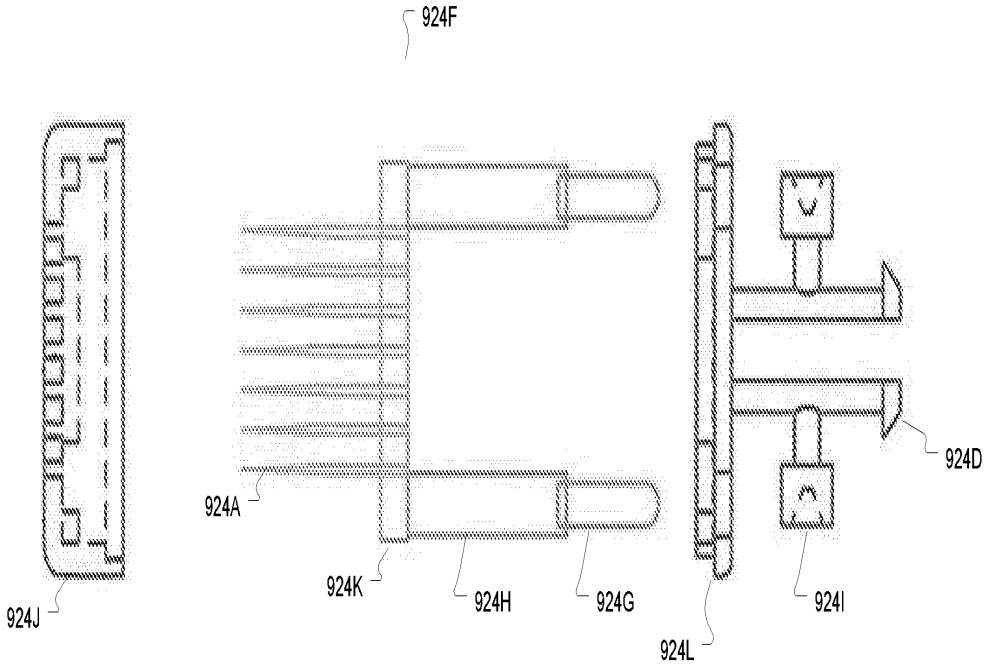

FIGURE 11C

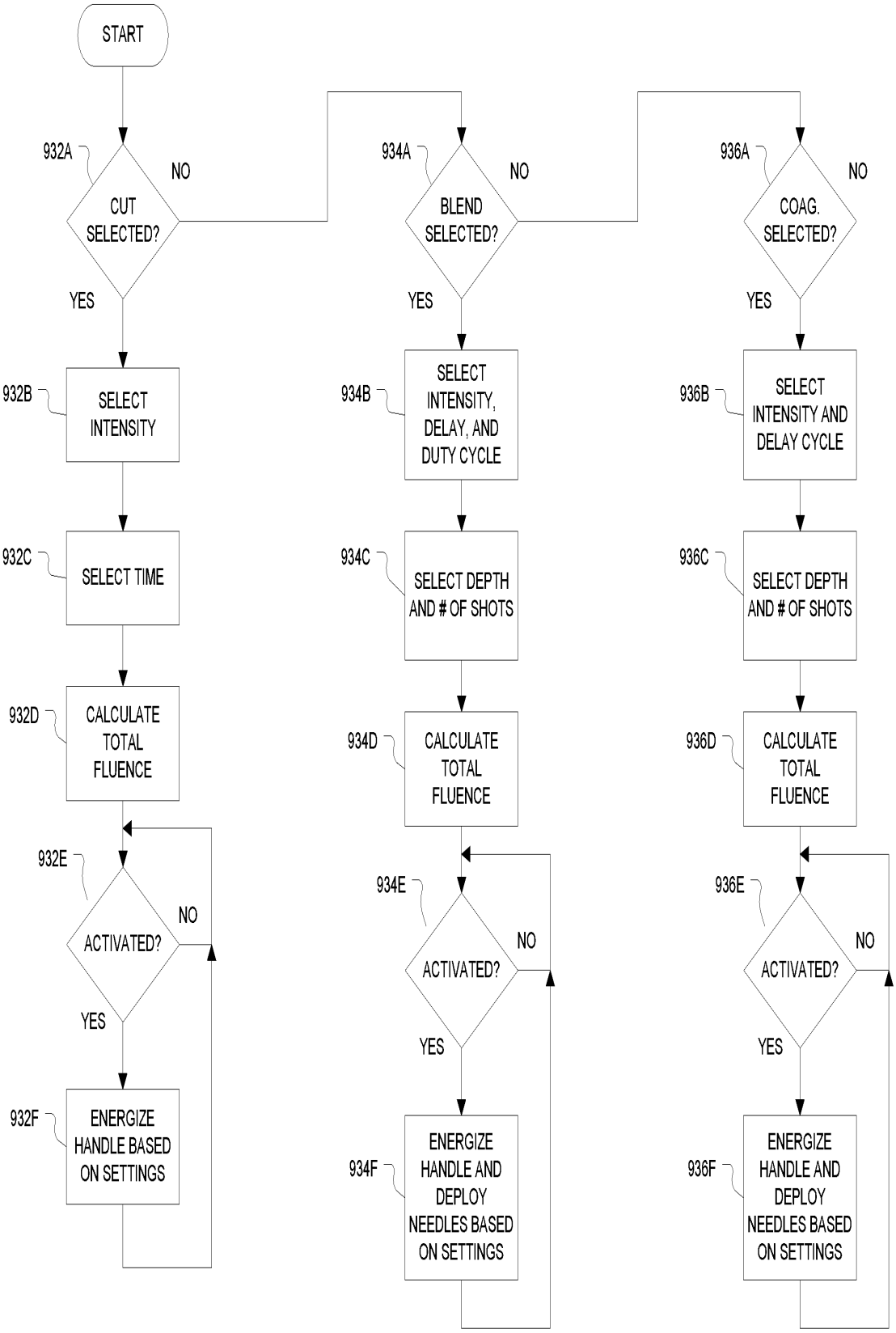
START
932A
CUT SELECTED?
NO
YES
932B
SELECT INTENSITY
932C
SELECT TIME
932D
CALCULATE TOTAL FLUENCE
932E
ACTIVATED?
NO
YES
932F
ENERGIZE HANDLE BASED ON SETTINGS
934A
BLEND SELECTED?
NO
YES
934B
SELECT INTENSITY, DELAY, AND DUTY CYCLE
934C
SELECT DEPTH AND # OF SHOTS
934D
CALCULATE TOTAL FLUENCE
934E
ACTIVATED?
NO
YES
934F
ENERGIZE HANDLE AND DEPLOY NEEDLES BASED ON SETTINGS
936A
COAG. SELECTED?
NO
YES
936B
SELECT INTENSITY AND DELAY CYCLE
936C
SELECT DEPTH AND # OF SHOTS
936D
CALCULATE TOTAL FLUENCE
936E
ACTIVATED?
NO
YES
936F
ENERGIZE HANDLE AND DEPLOY NEEDLES BASED ON SETTINGS
930

FIGURE 12

UNITED STATES PATENT APPLICATION

METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

INVENTOR

Jongju Na of Republic of Korea

Prepared by:

Merle W. Richman, Esq.
P.O. Box 3333
La Jolla, CA 92038-3333
ATTORNEY DOCKET NA001KR_US3

METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

Cross Reference to Related Applications

[0001] The present application claims the benefit of priority to Republic of Korea Application Number 10-2008-0076993, entitled "Electrical system, skin, skin care and cosmetic electricity," filed on August 6, 2008, PCT Application Number PCT/US3008/074131, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT", Attorney Docket No. NA001PCT filed on August 22, 2008, and US Application Number 13/060,274, entitled "METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT", Attorney Docket No. NA001US filed on February 22, 2011, the entirety of each is incorporated by reference.

Technical Field

[0002] Various embodiments described herein relate generally to treating dermatological tissue, including systems, and methods used in treating dermatological tissue.

Background Information

[0003] It may be desirable to treat dermatological tissue; the present invention provides such treatment.

Brief Description of the Drawings

[0004] FIG. 1A is a simplified isometric diagram of a dermatological treatment apparatus according to various embodiments.

[0005] FIG. 1B is a simplified, side diagram of the dermatological treatment apparatus according to various embodiments.

[0006] FIG. 1C is a simplified, exploded layer view of the dermatological treatment apparatus according to various embodiments.

ENDYMED EXHIBIT 1002 - 85/733

[0007] FIG. 1D is a simplified view of a layer of a dermatological treatment apparatus according to various embodiments.

[0008] FIG. 2A is a simplified isometric diagram of a dermatological treatment architecture according to various embodiments.

[0009] FIG. 2B is a simplified cross-sectional diagram of a dermatological treatment apparatus according to various embodiments.

[0010] FIG. 2C is a simplified cross-sectional diagram of another dermatological treatment apparatus according to various embodiments.

[0011] FIG. 2D is a simplified cross-sectional diagram of another dermatological treatment apparatus according to various embodiments.

[0012] FIG. 2E is a simplified view of a layer of a dermatological treatment apparatus according to various embodiments.

[0013] FIG. 2F is a simplified, exploded view of layers of the dermatological treatment apparatus according to various embodiments.

[0014] FIG. 3A is a simplified isometric diagram of a dermatological treatment apparatus according to various embodiments.

[0015] FIG. 3B is a simplified isometric diagram of another dermatological treatment apparatus according to various embodiments.

[0016] FIG. 4A is a simplified view of a layer of a dermatological treatment apparatus according to various embodiments.

[0017] FIG. 4B is a simplified view of a layer and apparatus of a dermatological treatment system according to various embodiments.

[0018] FIG. 4C is a simplified view of a layer and apparatus of a dermatological treatment system according to various embodiments.

[0019] FIGs. 5A-6 are diagrams of signals that may be applied to one or more dermatological treatment systems according to various embodiments.

[0020] FIG. 7A-7C are flow diagrams illustrating dermatological treatment system processing algorithms according to various embodiments.

[0021] FIG. 8 is a block diagram of an article according to various embodiments.

[0022] FIG. 9A is a simplified block diagram of a dermatological treatment architecture according to various embodiments.

[0023] FIG. 9B is a block diagram of an article according to various embodiments that may be employed in architecture of FIG. 9A.

[0024] FIG. 9C is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus with the needles retracted according to various embodiments.

[0025] FIG. 9D is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus with the needles deployed according to various embodiments.

[0026] FIG. 10A-10D are simplified, partial, cross-sectional diagrams of a cartridge in various stages of attachment to a dermatological treatment apparatus according to various embodiments.

[0027] FIG. 10E is a simplified, partial, cross-sectional diagram of a dermatological treatment apparatus with needles deployed according to various embodiments.

[0028] FIG. 10F is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus cartridge interface according to various embodiments.

[0029] FIG. 11A is a simplified, partial, cross-sectional diagram of a dermatological treatment apparatus cartridge coupled to a handle with needles deployed according to various embodiments.

[0030] FIG. 11B is a simplified, cross-sectional diagram of a cartridge needle assembly according to various embodiments.

[0031] FIG. 11C is a simplified, cross-sectional, exploded diagram of a cartridge needle assembly according to various embodiments.

[0032] FIG. 12 is a flow diagram illustrating a dermatological treatment system processing algorithms according to various embodiments.

Detailed Description

[0033] FIG. 1A is a simplified isometric diagram and FIG. 1B is a simplified side view of a dermatological treatment apparatus 10 according to various embodiments. The apparatus 10 may include a user handle 220 coupled to an acupuncture plate 200. In an embodiment the plate 200 may be elastically coupled to the handle segment 222 via an elastomeric section 210. The elastomeric section may be comprised of a combination of elastomeric materials and non-elastomeric materials. The elastomeric materials may include plastics, rubber (synthetic or natural), and spring(s).

[0034] FIG. 1C includes a simplified exploded view of an embodiment of an acupuncture plate 200 according to various embodiments. The plate 200 may include an upper, substantially rigid section or layer 290, deformable or elastic section 270 or layer, and acupuncture section or layer 250. The acupuncture section 250 may include a plurality of acupuncture pins or needles 230. FIG. 1D is a simplified bottom view of the plate 200 showing the location or holes 212 for the pins or needles 230. In an embodiment the plate 200 may have a rectangular cross section having a dimensional about 1 to 4 cm in width and about 1 to 6 cm in length. The plate 200 may any shape including circular, elliptical, polygon, or other shape where the shape may be particular to a dermatological area to be treated.

[0035] In an embodiment the plate may include about 140 pins or needles 230 uniformly separated. Each needle may be about 0.1 to 0.4 mm in diameter and 0.2 mm to 1.4 mm in length including 0.3 mm diameter and 0.8 mm in length in an embodiment. The elastic section or layer 270 may be comprised of a combination of elastomeric materials and non-elastomeric materials. The elastomeric materials may include plastics, rubber (synthetic or natural), and spring(s). The pin section 230 may be coupled directly or indirectly to the upper section 290 via the elastic section 250, including via glues, screws, welds, or other connection. In an embodiment the pin section 250 may include elastomers to enable at least partial deformation of the pin section 250 about the pins 230.

[0036] In operation a user may employ the apparatus 10 to create a plurality of micro-wounds or holes in dermatological layers of a mammal's 20 skin or dermis. The micro-wound or hole creation may improve the absorption or application of one or more chemicals applied on or about the micro-wounds or holes.

[0037] FIG. 2A is a simplified diagram of a dermatological treatment architecture 310 according to various embodiments. Architecture 310 includes an acupuncture apparatus 320 and an

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electrical signal generation system 300. The electrical signal generation system 300 may be electrically coupled to the acupuncture apparatus 320 via one or more wires 300A and to a mammal 20 to be treated via one or more wires 300B. FIG. 2B is a simplified cross-sectional diagram of the acupuncture apparatus 320 according to various embodiments. The apparatus 320 may include a handle 330, elastic section 333, electrical interface 340, internal wire(s) 331and plate 350. The pins 351 may have a length A (0.3 mm to 2.1 mm in an embodiment) where at least one pin 351 is electrically coupled to the electrical interface 340 via the internal wire 331. The electrical interface 340 may be removably connected to the system 300 wire 300A.

[0038] The electrical signal generation system 300 may generate a variety of signals (such as shown in FIGS. 5A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and lead 300A. A pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351. FIG. 2C is a simplified cross-sectional diagram of an acupuncture apparatus 360 according to various embodiments. The apparatus 360 may include a handle 330, an elastic section 333, an electrical conductive interface 390, internal wire(s) 331, signal generator 370, switch 375, and plate 350. The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to the conductive interface 390.

[0039] The signal generator or module 370 may generate a variety of signals (such as shown in FIGS. 5A to 6) to vibrate one or more pins 351 electrically coupled to the system 300 via the internal wire 331 and the conductive interface 390. In operation a user 20 may touch the conductive interface 390 and place one or more electrically coupled pins 351 in contact with their dermis to form an electrical pathway from the pin 351 to the electrical conductive interface 390. The signal generator 370 may include a battery to supply energy to generate one or more electrical signals. The switch 375 coupled to the generator 370 may cause the generator to produce one or more electrical signals for a predetermined time interval or until the switch 375 is triggered again. As noted a pin vibration 351 may increase the micro-wound or cut formed in dermis by the pin 351.

[0040] FIG. 2D is a simplified cross-sectional diagram of an acupuncture apparatus 362 according to various embodiments. The apparatus 362 may include a handle 330, an elastic section 333, internal wire(s) 331, 332, signal generator 370, switch 375, and plate 350. The signal generator 370 may be coupled to at least one pin 351 via internal wire 331 and coupled to at least one other pin 352 via internal wire 332. When active the pins 351, 352 may form at least one dipole pair. The

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signal generator or module 370 may generate a variety of signals (such as shown in FIGS. 5A to 6) to vibrate one or more dipole pair or bipolar pins 351, 352.

[0041] FIG. 2F includes a simplified exploded view of an embodiment of an acupuncture plate 350 including at least one electrically coupled pin 351 according to various embodiments. The plate 350 may include an upper, substantially rigid section or layer 357, deformable or elastic section 355 or layer, and acupuncture section or layer 353. The acupuncture section 353 may include a plurality of acupuncture pins or needles 351 where at least one pin 351 is electrically coupled to the wire 331. In a bipolar configuration a second wire 332 may be coupled to at least one other pin 351. FIG. 2E is a simplified bottom view of the plate 350 showing the pins or needles 359, 357 where the pins may be electrically coupled to a first wire 331 and a second wire 332 to form dipole pair (bipolar pins).

[0042] In an embodiment the plate 350 may have a rectangular cross section having a dimensional about 1 to 4 cm in width and about 1 to 6 cm in length. The plate 350 may any shape including circular, elliptical, polygon, or other shape where the shape may be particular to a dermatological area to be treated.

[0043] In an embodiment the plate may include about 140 pins or needles 351 uniformly separated. Each needle may be about 0.1 to 0.4 mm in diameter and 0.2 mm to 1.4 mm in length including 0.3 mm diameter and 0.8 mm in length in an embodiment. The elastic section or layer 355 may be comprised of a combination of elastomeric materials and non-elastomeric materials. The elastomeric materials may include plastics, rubber (synthetic or natural), and spring(s). The pin section 353 may be coupled directly or indirectly to the upper section 357 via the elastic section 353, including via glues, screws, welds, or other connection. In an embodiment the pin section 353 may include elastomers to enable at least partial deformation of the pin section 353 about the pins 351.

[0044] FIGS. 3A and 3B are simplified isometric diagrams of acupuncture apparatus 400, 460 including at least one pin 451 that may be coupled to an electrical signal via an internal wire 458. Each apparatus 400, 460 includes curved roller 450 having a plurality of acupuncture pins 451 where the pins 451 may be similar to pins 351. In apparatus 400, the electrical lead wire 400A may be coupled to an electrical interface 410 in the apparatus handle 430 where the interface 410 is electrically coupled to the internal wire 458. In apparatus 460, the handle 430 may include a signal generator 470 similar to generator 370, switch 475, and conduction surface 490. Apparatus 460 may

operate similar to apparatus 360 in operation other than the rolling capability of the apparatus 460, 400. In an embodiment the rollers 450 may have various configurations to conform to a dermal area to be treated.

[0045] In any of the above apparatus 10, 320, 350, 360, 400, 460, the plate or roller 200, 350, 450 may include a plurality of embedded LEDs 32A, 32B, a battery 52, a controller 54, and an antenna 56 as shown in FIG. 4A. In an embodiment the LED 32A may be configured to emit energy of a first particular frequency range and the LED 32B may be configured to emit energy of a second particular frequency range. The surface 22 of a roller 450, plate 200, 350, 450 may also be embedded with a chemical 22A that may be used to treat dermatological cells. The chemical 22A may be reactive to the first and the second frequency ranges. Further dermatological cells may be reactive to the first and the second frequency ranges. In addition, the combination of the chemical 22A and the application of the first and the second frequency ranges to the chemical 22A and dermatological cells may have a synergetic effect.

[0046] In an embodiment the chemical 22A may be applied directly to the dermatological cells to be treated. In a further embodiment a chemical 22A may not be employed in addition to the apparatus 10, 320, 350, 360, 400, 460. In an embodiment the pin section 250, 353, may be translucent and comprised of polyurethane, medical silicon, or other pliable, translucent, hypoallergenic material.

[0047] In an embodiment the local controller 54 and battery 52 may also be embedded in the upper section 290, 357, pin section 230, 351, or the handle 220, 330, or separately between these sections. The controller 54 may be electrically coupled to the one or more LEDS 32A, 32B. The controller 54 may also be coupled to a battery 52. The controller 54 may generate one or more signals for LEDs 32A, 32B as a function of a user switch 75, 56. The signals may vary as a function of the first and second frequency ranges. The controller 54 may include one or more timers 58 that may limit the application of energy to the LEDs 32A, 32B to predetermined time intervals. In an embodiment the controller may also be coupled to an antenna 56 to receive or transmit one or more signals related to the transmission of energy to one or more LEDs 32A, 32B. In an embodiment the system 10 may be configured to treat a particular segment of dermatological cells such as a face. The apparatus 10 may be configured to conform to a user's anatomy so that emitted light is focused on dermatological cells. In another embodiment 200, the system 200 may be configured to treat

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another anatomical region including dermatological cells on an arm, leg, chest, hands, feet, neck, or other region.

[0048] In an embodiment 510 shown in FIG. 4B, a controller 54, an antenna 104, and a power source 60 may be located in external to the apparatus 10, 320, 360. The power source 60 may be coupled to the controller 54. The controller 54 may be coupled to one or more LEDs 32A, 32B via one or more electric wires 106. The controller 54 may generate one or more signals for LEDs 32A, 32B as a function of the user switch 56. The signals may vary as a function of the first and second frequency ranges. The controller 54 may include one or more timers 58 that may limit the application of energy to the LEDs 32A, 32B to predetermined time intervals. In an embodiment the controller may also be coupled to an antenna 104 to receive or transmit one or more signals related to the transmission of energy to one or more LEDs 32A, 32B.

[0049] In any of the above apparatus 10, 320, 350, 360, 400, 460, the plate or roller 200, 350, 450 may include a plurality of embedded LED lens 536, a fiber optic pathway 534, and an LED 532. In this embodiment the LED 532 may be coupled to lens 536 via the fiber optic pathway 534. The controller 540 may generate an LED signal via the LED 532 that is transmitted to dermatological cells via the lens 536 and the fiber optic pathway 534.

[0050] FIGS.5A-5B are diagrams of electrical signal waveforms 650, 630, 640 that may be applied to one or more LEDs 32A, 32B, 532 and to the pins 230, 351, 451 according to various embodiments. The signal waveform 650 includes several square-wave pulses 652, 654, 656 that may be applied to an LED 32A, 32B, 532. Each pulse 652, 654, 656 may a have a similar magnitude and envelope. The waveform 650 may be used to energize an LED 32A, 32B, 532 and to the pins 230, 351, 451 periodically P1 for a predetermined interval T1 where each pulse 652, 654, 656 has a amplitude A1. In an embodiment, A1 may be about 0.1 milliamperes (mA) to 10 mA, the pulse width T1 may be about 100 microseconds (μs) to 500 μs and the period P1 may from 100 ms to 500 ms as a function of the energy required to create capacitance in a liquid. In another embodiment, A1 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width T1 may be about 200 microsecond (μs) and the period P1 may about 250 ms as a function of the energy to drive an LED or cause one or more pins 230, 351, 451 to vibrate.

[0051] In FIG. 5B a signal waveform 630 may be applied to a first LED 32A, 32B, 532 module or group and to the pins 230, 351, 451 and a second waveform 640 may be applied or used to energize a second LED 32A, 32B, 532 module and the pins 230, 351, 451, 352. The signal

waveform 630 includes several square-wave pulses 632, 634, and 636 and the signal waveform 640 includes several square-wave pulses 642, 644, and 646. Each pulse 632, 634, 636, 642, 644, 646 may a have a similar magnitude and envelope. The waveform 630 may be used to energize a first LED 32A, 32B, 332 module and the pins 230, 351, 451 periodically P1 for a predetermined interval T1 where each pulse 632, 634, 636 has an amplitude A1. The waveform 640 may be used to energize a second LED 32A, 32B, 332 module and the pins 230, 351, 451 periodically P2 for a predetermined interval T2 where each pulse 642, 644, 646 has an amplitude B1. The pulse width T1, T2 may be about 100 microseconds (μs) to 500 μs and the period P1, P2 may from 100 ms to 500 ms as a function of the energy to affect dermatological cells or chemicals 22A. In another embodiment, A1, A2 may be about 0.5 milliamperes (mA) to 5 mA, the pulse width T1, T2 may be about 200 microsecond (μs) and the period P1, P2 may about 250 ms as a function of the energy required to affect dermatological cells or chemicals 22A. In an embodiment the pulses 632, 634, 636 do not substantially overlap the pulses 642, 644, 646. In an embodiment T1 > T2 and P2 is an integer multiple of P1.

[0052] FIG. 6 depicts a waveform 670 that includes multiple pulses 672, 674, 676, 678, 682, and 684 that may not overlap in the time or the frequency domain. In an embodiment each pulse 672, 674, 676, 678, 682, and 684 may have a pulse width T3, and frequency spectrum width F1 and period P3. The pulse 672 is frequency offset from the pulse 674, the pulse 676 is frequency offset from the pulse 678, and the pulse 682 is frequency offset from the pulse 684. The pulses 672, 674, 676, 678, 682, and 684 may be applied to an LED module to affect dermatological cells or chemicals 22A and the pins 230, 351, 451. Pulses 672, 674 having different frequency spectrums may enable different LED stimulation. In an embodiment the pulses 672, 676, 682 may be applied to a first LED module and the pulses 674, 678, 684 may be applied to a second LED module. The frequency separation between the respective pulses may enable simultaneous energization of a first and a second LED module and the pins 230, 351, 451 and subsequent and independent spectrum generation.

[0053] In an embodiment the invention may employ the algorithm 740 shown in FIG. 7A to apply therapy to dermatological cells. A user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermatological cells to be treated (activity 741) including pressing the apparatus against the cells firmly enough to embed one or more pins 251, 351, 451 in the cells. A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a first LED module or group

(32A) and the pins 230, 351, 451 of a dermatological apparatus 10, 320, 360, 360, 400, 460 (activity 742) for a predetermined time period (activity 744). A second signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a second LED module or group (32B) and the pins 230, 351, 451 of a dermatological apparatus 10, 320, 360, 360, 400, 460 (activity 746) for a predetermined time period (activity 748). The signals applied to the groups may be selected to stimulate dermatological cells or chemicals 22A or cause vibration of one or more pins 251, 351, 451.

[0054] In another embodiment the invention may employ the algorithm 750 shown in FIG. 7B to apply therapy to dermatological cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermatological cells to be treated (activity 751). The user, clinician, or equipment may place apparatus 10, 320, 360, 360, 400, 460 on dermatological cells to be treated (activity 752). A signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a LED module or group (32A or 32B) and the pins 230, 351, 451 (activity 354) for a predetermined time period (activity 356).

[0055] In another embodiment the invention may employ the algorithm 760 shown in FIG. 7C to apply therapy to dermatological cells. A user, clinician, or equipment may apply a light sensitive chemical on an apparatus 10, 320, 360, 360, 400, 460 or on dermatological cells to be treated (activity 761). The user, clinician, or equipment may place an apparatus 10, 320, 360, 360, 400, 460 on dermatological cells to be treated (activity 762). A first signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a first LED module or group (32A) and one or more pins 251, 351, 451 of a dermatological apparatus 10, 320, 360, 360, 400, 460 (activity 763) for a predetermined time period (activity 764). A second signal such as shown in FIGS. 5A, 5B, and 6 may be applied to a second LED module or group (32B) and one or more pins 251, 351, 451 of a dermatological apparatus 10, 320, 360, 360, 400, 460 (activity 766) for a predetermined time period (activity 768).

[0056] The apparatus 10, 320, 360, 360, 400, 460 may be used to employ cosmetic or medications or other chemicals directly on dermatological cells such as skin with the addition of light of specific frequencies for treatment and healing of epidermal cells of the skin or tissue below the skin with the object of assisting the agents used in delivery, uptake, action and function more effectively. The LEDs 32A, 32B may create the specific frequencies of light. The apparatus 10, 320, 360, 360, 400, 460, light application may enable cosmetic or medication or other active chemicals 22A on dermatological cells for longer time periods while preventing dehydration of the

applied substances. Such light application may improve the efficacy of cosmetic or medication or other active chemical as a function of the selected wavelengths or frequencies.

[0057] Further the dermatological system application may increase cellular activity and help heal tissue faster and facilitate the delivery, uptake and use in the cell of the cosmetics, medications, or chemicals 22A used. The LED light of specific frequencies may increase fibroblast production and collagen as well as other activities of the cell including stimulating the organelles and mitochondria to produce ATP for cell energy for functioning, decreasing treatment time and facilitate healing. The apparatus 10, 320, 360, 360, 400, 460 make the agents used on the body more efficacious and useful to the body on a cellular level.

[0058] The apparatus 10, 320, 360, 360, 400, 460 may stimulate the basic energy processes in the mitochondria (energy compartments) of each cell, particularly when near-infrared light is used to activate the color sensitive chemicals (chromophores, cytochrome systems) inside but not limited to these spectrum alone as the UV, other visible and IR spectrums may also be usable. In an embodiment optimal LED wavelengths for skin repair may include 640, 680, 730 nanometers (nm) wavelengths to IR 880 nm. Further application of blue light 400 nm to 490 via the apparatus 10, 320, 360, 360, 400, 460 may inhibit the growth and kill bacteria, fungus in and on dermatological cells. The apparatus 10, 320, 360, 360, 400, 460 may be employed to apply cosmetics, medications and/or other actives directly to the skin and maintain their presence long-term while using LED or other actinic light to increase their effect on the cells and tissue in the body. The apparatus 10, 320, 360, 360, 400, 460 are also highly portability and enable user mobility during treatment.

[0059] Chemicals 22A may include cosmetics, medications and other actives appropriate for dermatological cells including AHA's (alpha hydroxy acid), natural oils, aloe vera compounds, collagen boosters, bt, chitosan, daeses, endorphins, photodynamic drugs (PDT) like (Photofrin or ALA), vitamins A, C E or others, kojic acid, retinols or other exfoliant, salicylic acid, anti oxidants or other youth boosters and anti aging cosmetic or medications, antiseptic, antibiotics, anti-cancer agents, aroma therapy agents, fruit and vegetable extracts, anti-inflammatory agents, pain relievers, hormones, depilatories, and others, but the scope of this invention is not limited to these alone but can include any helpful medication, herbal formula or active compound for the skin and/or other tissues.

[0060] FIG. 8 is a block diagram of an article 780 according to various embodiments. The article 780 shown in FIG. 8 may be used in various embodiments as a part of apparatus 10, 320,

360, 360, 400, 460 where the article 780 may be any computing device including a personal data assistant, cellular telephone, laptop computer, or desktop computer. The article 780 may include a central processing unit (CPU) 782, a random access memory (RAM) 784, a read only memory (ROM") 806, a display 788, a user input device 812, a transceiver application specific integrated circuit (ASIC) 816, a digital to analog (D/A) and analog to digital (A/D) convertor 815, a microphone 808, a speaker 802, and an antenna 804. The CPU 782 may include an OS module 814 and an application module 813. The RAM 784 may include switches 56 and timers 58.

[0061] The ROM 806 is coupled to the CPU 782 and may store the program instructions to be executed by the CPU 782. The RAM 784 is coupled to the CPU 782 and may store temporary program data, overhead information, and the queues 798. The user input device 812 may comprise an input device such as a keypad, touch pad screen, track ball or other similar input device that allows the user to navigate through menus in order to operate the article 780. The display 788 may be an output device such as a CRT, LCD, LED or other lighting apparatus that enables the user to read, view, or hear user detectable signals.

[0062] The microphone 808 and speaker 802 may be incorporated into the device 780. The microphone 808 and speaker 802 may also be separated from the device 780. Received data may be transmitted to the CPU 782 via a bus 796 where the data may include signals for an LED 32A, 32B, 332 or optical module or wires 331, 458. The transceiver ASIC 816 may include an instruction set necessary to communicate data, screens, or signals. The ASIC 816 may be coupled to the antenna 804 to communicate wireless messages, pages, and signal information within the signal. When a message is received by the transceiver ASIC 816, its corresponding data may be transferred to the CPU 782 via the serial bus 796. The data can include wireless protocol, overhead information, and data to be processed by the device 780 in accordance with the methods described herein.

[0063] The D/A and A/D convertor 815 may be coupled to one or more optical modules to generate a signal to be used to energize one of the optical modules. The D/A and A/D convertor 815 may also be coupled to one devices such as LEDs 32A, 32B and the pins 251, 351, 451. Any of the components previously described can be implemented in a number of ways, including embodiments in software. Any of the components previously described can be implemented in a number of ways, including embodiments in software. Thus, the LEDs 32A, 32B, pins 251, 351, 451, controllers 54, switch 56, timers 58, controller 320 may all be characterized as "modules" herein. The modules may include hardware circuitry, single or multi-processor circuits, memory circuits, software

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program modules and objects, firmware, and combinations thereof, as desired by the architect of the system 10, 30, 50, 60 and as appropriate for particular implementations of various embodiments.

[0064] FIG. 9A is a simplified block diagram of a dermatological treatment architecture (DTA) 900 according to various embodiments. As shown in FIG. 9A, architecture 900 includes a signal generation and control module (SGC) 910, a handle module 920, and an actuator module 930. In an embodiment the handle module 920 may include a deployable needle module 924 and a motor and LED module 922. In an embodiment the deployable needle module 924 may be releasably coupled to the motor and LED module 922. In a further embodiment the deployable needle module 924 may be a disposable cartridge module 924 to be removed and disposed after one or more treatments or for each patient, client, or user.

[0065] The SGC 910 may include one or more displays 912A, user input device 912B, handle module interface 914A, and actuator module interface 914C, electrical energy storage module 913, and one or more wheels 916A, 916B. In an embodiment the SGC 910 may be moveable and the wheels 916A, 916B may be lockable to prevent unintentional movement of the SGC 910 once positioned where desired by a user. In another embodiment the SGC 910 may also be coupled to the external power source including an alternating current (AC) grid source.

[0066] In an embodiment the displays 912A may indicate operational parameters for a hand module 920 to be coupled or coupled to the SGC 910. The displays 920 may be touch sensitive so a user may configure one or more operational parameters. In an embodiment the operational parameters may include electrical energy signal intensity to be applied the hand module 920, timing of such energy application, needle deployment timing and depth(s), LED intensity and timing, and number of cycles or shots to be conducted for each actuation via the actuator 930. In an embodiment the actuator 930 may be integral to the SGC 910 or a separate device wireless coupled or wired to the SGC 910 via a cable 914D and the SGC 910 actuator module interface 914C.

[0067] In an embodiment the actuator 930 may a mechanical device including a foot actuator or hand based actuator. The actuator 930 may also be an electronic device having an ASIC or running an application on a device (such as a computer, laptop, PDA, cellphone, or other electronic device) such as the module 780 shown in FIG. 8. In an embodiment the application may enable a user to set or control any of the possible operational parameters of the SGC 910 and initiate actuation a device 920 coupled to the SGC 910. FIG. 9B is a block diagram of a CPU module 911 that may be employed in the SGC 910 according to various embodiments.

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[0068] The CPU module 911 may include a radio frequency (RF) signal generator (RFSG) module 911A, a needle deployment motor controller (NDMC) module 911B, and a photonic signal generator module (PSG) 911C. In an embodiment the photonic signal generator module 911C may be an LED signal generator or controller module 911C. In an embodiment a hand module 920 may include one or more photonic generation devices or modules (922I in FIG. 10A, 10B) where the PSG 911C may generate control or energy signals that cause the photonic modules 922I to generate photons of one or more frequencies with a desired intensity.

[0069] The NDMC 911B may control the deployment of one or more needles 924A of a deployable needle module 924 (FIG. 9C) based on one or more user selected operational parameters. The parameters may determine the depth and duty cycle related to the needle(s) 924A deployment in an embodiment. The signals generated by the NDMC 911B to control needle deployment may vary as a function of motor(s) (922A, FIG. 9C) employed to drive one or more needles 924A. As described above an electrical signal may also be applied to the needle(s) 924A to cause vibration of the needles or enable cutting and coagulation of the tissue in which the needles 924A are deployed. The RFSG 911A may generate one or more electrical signals to be applied to one or more needles 924A based on the selected operational parameters. An electrical signal may be applied to a single needle 924A, group of needles 924A (mono-polar configuration) or pair(s) of needles 924A (bipolar configuration) in an embodiment. In an embodiment the RFSG 911A may apply signals 650, 630, 640, 670 shown in FIGs. 5A, 5B, and 6, a combination thereof, or other signals.

[0070] In an embodiment the CPU module 911 via the RFSG 911A, NDMC 911B, and PSG 911C may create various therapy solutions including various combinations of photonic, electrical, and mechanical (needle deployment) therapy. In a further embodiment the CPU module 911 may control the generation of photonic energy to particular modules 922I, individual or group of needle(s) 924A deployment via one or more motors 922A, and control electrical signal(s) applied to individual or group of needles 924A. Accordingly the DTA 900 may apply various therapies based on user selections via the displays 912A, user selection device 912B, and actuator 930. The CPU 911 may employ the algorithm 930 (FIG. 12) or variations thereof to control the operation of the DTA 900.

[0071] FIG. 9C is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus or hand module 920 with one or more needles 924A retracted according to

various embodiments. FIG. 9D is a simplified cross-sectional diagram of a cartridge based dermatological treatment apparatus or hand module 920 with one or more needles 924A deployed according to various embodiments. The handle module 920 may include a deployable needle module (DNM) 924 and a motor and LED module (MLM) 922. In an embodiment the DLM 924 may be a releasably couplable cartridge module. In a further embodiment the DLM 924 may be a detachable cartridge module (DCM) 924 where the DCM may be changed between therapy application(s) or client(s). In a further embodiment, the DCM 924 may be disposed after usage or cleaned via an autoclave or chemical process.

[0072] As shown in FIGs. 9C and 9D, the MLM 922 may include one or more motors 922A, longitudinally extendable drive arms 922B, drive shaft 922C, outer casing 922D, signal interface 922E, photonic generator module 922H, and DCM 924 interface 925 (shown in FIGs. 10A to 10F). The motor(s) 922A and photonic generator module 922H may be electrically coupled to the signal interface 922E to received control signals and energy to operate one or more motors 922A and photonic devices or modules 922I of the photonic generator module 922H. The drive arm(s) 922B may be coupled to one or more drive shafts 922C so the drive shafts may be moved longitudinally to deploy and retract one or more needles 924A when the MLM 922 is operatively coupled to the DNM 924.

[0073] As shown in FIGs. 9C and 9D the deployable needle module 924 may include at least one deployable needle 924A, MLM connecting arm and drive coupling tabs 924B, and MLM connecting/locking arms 924C. The MLM connecting/locking arms 924C may be configured to engage and lock to DCM 924 interface 925 recesses 925D (FIG. 10F). The MLM connecting arm and drive coupling tabs 924B may be configured to disengage connecting/locking arms 924C from the MLM interface 925 when the tabs 924B are depressed inward in an embodiment (as shown in FIG. 10B). The tabs 924B may further displace drive shaft connecting arms 924D inward or centrally when the tabs 924B are depressed inwardly (as also shown in FIG. 10B). When the connecting/locking arms 924C are depressed inwardly or centrally (FIG. 9C and 9D) from an outward position (FIG. 10B). The arms 924C may engage the interface 925 recesses 925D to securely hold the DNM 924 to the MLM 922. The arms 924C may also displace the tabs 924B outwardly and cause the drive shaft connecting arms 924D to return outwardly.

[0074] The drive shaft connecting arms 924D may securely engage the drive shaft 922C tip 922F (FIG. 10E) recess 922G (FIG. 10E) when they return to an outward position as shown in FIG.

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10D and 10E. In this configuration the DNM 924 is securely coupled to the MLM 922 via the arms 924C and 924D. In this configuration the motor(s) 922A via drive shaft(s) 922C coupled to the motor 922A shaft 922B may reliably drive one or more needles 924A of the DNM 924 (from a retracted or deployed position such as shown in FIGs. 9C and 9D, respectively). Further the motor(s) 922A may include steps or infinite drive extension 922B control to enable precise needle deployment depth or extension beyond the DNM 924 shell (924E, Fig. 10A).

[0075] FIG. 10A-10D are simplified, partial, cross-sectional diagrams of the DNM 924 in various stages of attachment to the MLM 922 via the arms 924C and 924D according to various embodiments. As shown in FIG. 10A the DNM or DCM 924 is decoupled from the MLM 922. The MLM 922 includes the photonic generator module (PGM) 922H, interface 925, and drive shaft tip 922F in a distal portion. As shown in FIG. 10A the PGM 922H may include one or more photon modules 922I. The photon modules 922I may be LED modules and emit photon with various frequencies and intensities based on the PSG 911C control signal.

[0076] As shown in FIG. 10A the DNM or DCM 924 may include the connecting arms 924C, deflecting tabs 924B, drive shaft coupling arms 924D, outer shell 924E, and one or more needles 924A. In an embodiment the drive shaft coupling arms 924D may include tabs that may securely engage the drive shaft tip 922F recess 922G. The drive shaft coupling arms 924D may be returnably deflectable inwardly (as shown in FIG. 10B) via inward depression of the tabs 924B. Such inward depression of the tabs 924B may deflect the coupling arms 924C outward. Similarly, inward depression of the coupling arms 924C to engage the interface 925 recesses 925D securely may deflect the tab arms 924B outwardly (relative the central axis of the DNM 920). Such outward movement may enable the drive shaft coupling arms 924D to return to a non-deflected state as shown in FIG. 10A.

[0077] In an embodiment a DNM or DCM 924 may be securely coupled to a MLM 922 by first completely compressing the arms or tabs 924B as shown in FIG. 10B. As noted above such inward compression may cause the coupling arms 924C to deflect outwardly and the drive shaft coupling arms 924D to be deflected inwardly towards each other. The drive shaft coupling arms 924D may be compressed so they may fit within the drive shaft 922C tip 922F recess 922G as the DNM or DCM 924 is advanced toward the MLM 922 distal end to securely couple the DNM 924 to the MLM 922 (as shown in FIG. 10D). After the DNM or DCM 924 is placed over the MLM 922 distal end so the drive shaft coupling arms 924D are located within the drive shaft 922C tip 922F

recess 922G and the coupling arms 924C are adjacent the MLM 922 interface 925 recesses 925D as shown in FIG. 10C.

[0078] To complete the coupling of a DNM 924 to the MLM 922, the coupling arms 924C may compressed inwardly as shown in FIG. 10D. The compression of the coupling arms 924C may deflect the tabs or arms 924B outwardly. Such outward deflection of the arms 924B may enable the drive shaft coupling arms 924D to return to a non-deflected state and securely engage the MLM 922 drive shaft 922C tip 922F recess 922G (as shown in FIG. 10D). In an embodiment a single coupling arm 924C, drive shaft coupling arm 924D, and tab 924B may be employed in an DNM 924. After the secure coupling of the DNM 924 to the MLM 922, the MLM 922 via the motor(s) 922A may controllable deploy one or more needles 924A as shown in FIG. 10E. FIG. 10F is a simplified cross-sectional diagram of a DNM interface 925 according to various embodiments.

[0079] As noted the interface 925 may include one or more recesses 925D to be securely engaged to DNM 924 coupling arms 924C. The interface 925 may also include several fenestrations or openings 925A, 925B, 925C. The central fenestration 925A may be sized to enable passage of the MLM 922 drive shaft 922C tip 922F. The fenestrations 925C may be sized and located above one or more photon modules 922I to enable photons generated by the photon modules 922I to pass into the DNM 924. In an embodiment the DNM 924 outer casing 924E may be translucent and act as a waveguide to communicate photons to the needle area of the DNM 924. The fenestrations 925B may be sized and configured to enable electrical coupling pins 924G (FIG. 11A) passage from the DNM 924 to electrical couplings of the MLM 922. The pins 924G may communicate electrical signals from the RFSG 911A to one or more needles 924A via the wires 914B and MLM 922.

[0080] FIG. 11A is a simplified, partial, cross-sectional diagram of DNM 924 coupled to a MLM 922 with needles 924A deployed according to various embodiments. As shown in FIG. 11A, the DNM 924 may further include electrical coupling pins 924G set with a spring loaded base 924H (in an embodiment). As noted the pins 924G may extend to electrical contacts in the MLM 922 via the interface 925 fenestrations 925B. Along a pair of pins 924G is shown, one or more pins 924G may be employed in a DNM 924 according to various embodiments. A drive shaft coupling arm 924D may include an offset 924I where the offset may be configured to engage a tab or arm 924B.

[0081] As shown in FIG. 11A when the needle array or assemble 924F is deployed depression of the tabs 924B inwardly will not engage the drive shaft coupling arms 924D (via the offsets 924I). Such a configuration may prevent unintentional decoupling of the DNM 924 to the

MLM 922 when the needle assembly 924F is at least partially deployed. As shown in FIG. 11A, the electrical contact pin 924G is sized to fit within the spring loaded based 924H. In an embodiment the internal spring 924M is may force extension of the pin 924G to maintain electrical conduction with the MLM 922 as the needle assembly 924F is moved (recessed and deployed to various depths). FIG. 11B is a simplified, cross-sectional diagram of a DNM 924 needle assembly 924F according to various embodiments. FIG. 11C is a simplified, cross-sectional, exploded diagram of the DNM 924 needle assembly 924F according to various embodiments. As shown in FIGs. 11B and 11C, the needle assembly 924F may include a pin cover 924J, drive arm module 924L, needles 924A, pins 924G with bases 924H, and needle printed circuit board (PCB) 924K.

[0082] In an embodiment the PCB 924K may couple one or more needles 924A to a first pin 924G base 924H and another one or more needles 924A to another pin 924G based 924H. The first pin 924G and second pin 924H may couple alternating rows or columns of needles 924A to form one or more dipoles between such needles 924A. The drive shaft coupling arms 924D may have a base 924L where the cover 924J includes fenestrations for the needles 924A, a recess for the PCB 924K, and an outer recess for the coupling arm base 924L (as shown assembled in FIG. 11B).

[0083] FIG. 12 is a flow diagram illustrating a DTA 900 processing algorithms 930 according to various embodiments. As noted the DTA 900 SGC 911 RFSG 911A, NDMC 911B, and PSG 911C may enable a user or clinician to select a variety of operational parameters to deliver a desired combination of electrical, light (photonic), and mechanical (needle) therapy to dermatological tissue. In the algorithm 930, a user may select different operational modes including cut (activities 932A to 932F), blend (activities 934A to 934F), and coagulation (activities 936A to 936F) in an embodiment. In a cut operational mode, a user may select the electrical signal intensity (activity 932B) and application time (activity 932C). The CPU 911 may determine the total energy that will be applied for each activation based on the selected intensity and time (total fluence – activity 932D). Then, upon activation (activity 932E, 932F) the DTA 900 may energize the MLM 922 based on the operational parameters.

[0084] In a blend operational mode (activity 934A), a user may select the electrical signal intensity, start delay, and duty cycle (activity 934B) and needle deployment depth and number of shots per activation (activity 934C). The duty cycle may include the delay before energy and need deployment, the time the energy and needles are deployed, and the subsequent off or rest time before the next possible duty cycle. As noted above the motor(s) 922A may enable precise needle

extension (effective depth) control. In an embodiment the motor(s) 922A may include a transverse motor that converts rotational force to longitudinal force. The motor may be a Haydon model number: 21H4AB-05-049 having a motor speed of about 0.005mm/msec and motor power of about 1000 Hz approximately 40N (Newton) (described in detail at www.haydonkerk.com and whose specifications are incorporated by reference).

[0085] The CPU 911 may determine the total energy that will be applied for each activation based on the selected intensity and duty cycle (total fluence – activity 934D). Then, upon activation (activity 934E, 934F) the DTA 900 may energize the MLM 922 based on the operational parameters and deploy the needle assembly 924F to a desired extension beyond the DNM 924 shell 924E to enable a desired depth of needle 924A penetration within tissue when the shell 924E is placed adjacent the tissue.

[0086] In a coagulation operational mode (activity 936A), a user may select the electrical signal intensity and start delay (activity 936B) and needle deployment depth and number of shots per activation (activity 936C). As noted above the motor(s) 922A may enable precise needle extension (effective depth) control. The CPU 911 may determine the total energy that will be applied for each activation based on the selected intensity (total fluence – activity 936D). Then, upon activation (activity 936E, 936F) the DTA 900 may energize the MLM 922 based on the operational parameters and deploy the needle assembly 924F to a desired extension beyond the DNM 924 shell 924E to enable a desired depth of needle 924A penetration within tissue when the shell 924E is placed adjacent the tissue.

[0087] Applications that may include the novel apparatus and systems of various embodiments include electronic circuitry used in high-speed computers, communication and signal processing circuitry, modems, single or multi-processor modules, single or multiple embedded processors, data switches, and application-specific modules, including multilayer, multi-chip modules. Such apparatus and systems may further be included as sub-components within a variety of electronic systems, such as televisions, cellular telephones, personal computers (e.g., laptop computers, desktop computers, handheld computers, tablet computers, etc.), workstations, radios, video players, audio players (e.g., mp3 players), vehicles, medical devices (e.g., heart monitor, blood pressure monitor, etc.) and others. Some embodiments may include a number of methods.

[0088] It may be possible to execute the activities described herein in an order other than the order described. Various activities described with respect to the methods identified herein can be executed in repetitive, serial, or parallel fashion.

[0089] A software program may be launched from a computer-readable medium in a computer-based system to execute functions defined in the software program. Various programming languages may be employed to create software programs designed to implement and perform the methods disclosed herein. The programs may be structured in an object-orientated format using an object-oriented language such as Java or C++. Alternatively, the programs may be structured in a procedure-orientated format using a procedural language, such as assembly or C. The software components may communicate using a number of mechanisms well known to those skilled in the art, such as application program interfaces or inter-process communication techniques, including remote procedure calls. The teachings of various embodiments are not limited to any particular programming language or environment.

[0090] The accompanying drawings that form a part hereof show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. The embodiments illustrated are described in sufficient detail to enable those skilled in the art to practice the teachings disclosed herein. Other embodiments may be utilized and derived therefrom, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. This Detailed Description, therefore, is not to be taken in a limiting sense, and the scope of various embodiments is defined only by the appended claims, along with the full range of equivalents to which such claims are entitled.

[0091] Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is in fact disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

[0092] The Abstract of the Disclosure is provided to comply with 37 C.F.R. §1.72(b), requiring an abstract that will allow the reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims. In the foregoing Detailed Description, various features are grouped together in a single embodiment for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted to require more features than are expressly recited in each claim. Rather, inventive subject matter may be found in less than all features of a single disclosed embodiment. Thus the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separate embodiment.

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Claims

What is claimed is:

1. A method of treating dermatological tissue, comprising:

placing a device including a distal end including a plurality of extendable needles from a device distal end surface on or near dermatological tissue to be treated;

energizing a motor coupled to the extendable needles to cause at least one needle to extend a desired distance from the distal end surface; and

energizing the at least one needle via a signal generator electrically coupled to the at least one needle to cause vibration of the at least one needle.

2. The method of claim 1, further comprising placing a dermatological chemical one of on at least a portion of the dermatological tissue, at least a portion of the inner surface, and the at least one needle.

3. The method of claim 1, wherein the device further includes a proximal handle and a releasably couplable deployable needle assembly, the extendable needles located in the needle assembly.

4. The method of claim 3, wherein the proximal handle includes the needle deploying motor.

5. The method of claim 4, wherein the proximal handle further includes at least one embedded LED therein and further including energizing the LED when the signal generator is energized.

6. The method of claim 5, comprising energizing the LED to generate one of a blue and an infra-red photonic signal.

7. The method of claim 4, wherein the needle deploying motor is coupled the needle assembly via a drive shaft.

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8. The method of claim 5, wherein the releasably couplable deployable needle assembly includes a translucent section to communicate the photon signal to the at least one needle.

9. The method of claim 3, further comprising employing an RF signal generator electrically coupled to the at least one needle to generate a signal that causes vibration of the at least one needle.

10. The method of claim 3, wherein tissue penetration by the at least one needle creates a micro-wound and further comprising employing an RF signal generator electrically coupled to the at least one needle to generate a signal that causes vibration of the at least one needle sufficient to increase the tissue micro-wound.

11. An apparatus for treating dermatological tissue, comprising:

a device including a distal end and a plurality of extendable needles, at least one needle extendable from the device distal end surface;

a motor coupled to at least one needle that causes the at least one needle to extend a desired distance from the distal end surface when energized with a particular signal; and

a signal generator electrically coupled to the at least one needle to cause vibration of the at least one needle when the at least one needle energized with a particular signal.

12. The apparatus of claim 11, wherein the device includes a proximal end couplable to the signal generator.

13. The apparatus of claim 11, wherein the device further includes a proximal handle and a releasably couplable deployable needle assembly, the extendable needles located in the needle assembly.

14. The apparatus of claim 12, wherein the proximal handle includes the motor.

15. The apparatus of claim 14, wherein the proximal handle further includes at least one embedded LED therein and further including a photonic signal generator electrically coupled to the least one embedded LED.

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16. The apparatus of claim 15, wherein the at least one embedded LED generates one of a blue and an infra-red photonic signal.

17. The apparatus of claim 14, further comprising a drive shaft coupling the motor to the at least one needle.

18. The apparatus of claim 15, wherein the releasably couplable deployable needle assembly includes a translucent section that communicates photon signals.

19. The apparatus of claim 13, further comprising an RF signal generator electrically coupled to the at least one needle, the RF signal generator causing vibration of the at least one needle when the needle is energized with a particular signal.

20. The apparatus of claim 13, wherein tissue penetration by the at least one needle creates a micro-wound and further comprising an RF signal generator electrically coupled to the at least one needle, the RF signal generator causing vibration of the at least one needle when the needle is energized with a particular signal sufficient to increase the tissue micro-wound.

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METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

Abstract of the Disclosure

Embodiments of dermatological cell treatment are described generally herein. Other embodiments may be described and claimed.

ENDYMED EXHIBIT 1002 - 109/733

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Na	
Application No.: not yet assigned	Art Unit: Unknown
Filed: Herewith	Examiner: Unknown
Title: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT	
Attorney Docket No.: NA001KR_US3	

PRELIMINARY AMENDMENT UNDER 37 CFR 1.115

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Please amend this application as follows, where amendments to specification start on page 2, claims on page 10, and drawings on page 14 and remarks start on page 15:

In the Title:

METHOD, SYSTEM, AND APPARATUS FOR ~~DERMALOGICAL~~ DERMATOLOGICAL TREATMENT

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In the Specification:

The many minor and grammatical changes to the specification are shown in the attached marked up and clean version of the specification. Entry is respectfully requested.

ENDYMED EXHIBIT 1002 - 111/733

In the claims:

1. (Cancelled).
2. (Cancelled).
3. (Cancelled).
4. (Cancelled).
5. (Cancelled).
6. (Cancelled).
7. (Cancelled).
8. (Cancelled).
9. (Cancelled).
10. (Cancelled).
11. (Cancelled).
12. (Cancelled).
13. (Cancelled).
14. (Cancelled).
15. (Cancelled).
16. (Cancelled).
17. (Cancelled).
18. (Cancelled).
19. (Cancelled).
20. (Cancelled).

21. (Newly Added) A method of treating dermatological tissue, comprising:

placing a device surface on or near dermatological tissue to be treated, the surface including a plurality of needles one of extending or extendable a desired distance from the surface; and

directing a signal generator electrically coupled to the plurality of extended needles to produce pulsed radio frequency signals across the plurality of needles to affect dermatological tissue near the plurality of needles.

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In the drawings:

Please replace pages 8 and 16-20 of the drawings with attached replacement pages. In the drawings, FIG. 4A reference 56 has been changed to 104. In FIG. 11 springs (reference 924M) has been added. Support for the spring addition is present in paragraph 0081 of the specification as filed.

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REMARKS

Claims 1-20 were pending. Claims 1-20 have been cancelled and claim 21 has been added. Upon entry of this preliminary amendment, claim 21 will be pending. Entry of this preliminary amendment is respectfully requested. Applicant has also amended the specification to correct minor grammatical or reference errors as shown in the marked up and clean copies of the specification and replaced five drawings to correct errors and improve their quality. No new matter has been added. Entry of the preliminary amendments is respectfully requested.

.

Respectfully Submitted,

10/3/2017 /mwresq/_____
Date Merle Richman
Patent Attorney
Reg. No. 38282

Merle Richman
Patent Attorney
Customer ID - 26338
PO Box 3333
La Jolla, CA 92038-3333

Tel. 858 551-2030

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Application Number: 15724261 Document Date: 10/03/2017

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Application Number	15724261
Filing Date	2017-10-03
First Named Inventor	Jongju Na
Art Unit	
Examiner Name	
Attorney Docket Number	NA001KR_US3

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7824394	B2	2010-11-02	Manstein, Dieter	
	2	7618429	B2	2005-12-22	Mulholland, R. Stephen	
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	4	9320536	B2	2016-04-26	Na, Jongju	
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	Application Number	15724261
	Filing Date	2017-10-03
	First Named Inventor	Jongju Na
	Art Unit	
	Examiner Name	
	Attorney Docket Number	NA001KR_US3

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	1	20090312691	A1	2009-12-17	Kim et al.	
	2	20080269666	A1	2008-10-30	Wang et al.	
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	7	20080082090	A1	2008-04-03	MANSTEIN, DIETER	paragraphs [0002] and [0036], claims 1, 3-5, 16, 19 and 22-24 and figures 3-5

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	Application Number	15724261
	Filing Date	2017-10-03
	First Named Inventor	Jongju Na
	Art Unit	
	Examiner Name	
	Attorney Docket Number	NA001KR_US3

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Examiner Name	
Attorney Docket Number	NA001KR_US3

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	10-2011-0002210	KR	A	2011-01-07	YANG, WON DONG	paragraphs [0024], [0055], [0057], [0062], [0071], [0073]-[0075], [0078], [0095], [0099]-[0100], [0103],	
	2	10-2010-001828	KR	A	2010-02-17	NA, JONG JU	paragraphs [0030]-[0037] and [0043], claims 3-4 and figures 4-6	
	3	2009-506873	JP	A	2009-02-19	THE FOUNDRY, INC	paragraphs [0053], [0085] and [0088], claims 1-4 and 14-17 and figures 8A-8C	
	4	00/74763	WO	A2	2000-12-14	Georgia Tech Research		
	5	2005/058407	WO	A1	2005-06-05	IN-OMICROTEC LTD		
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	8	10-2006-0027194	KR	A	2006-03-25	SHIN Hyun Sun		
	9	10-2010-0055292	KR	A	2010-05-26	JEJOONG MEDICAL CO		

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Examiner Name	
Attorney Docket Number	NA001KR_US3

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	1	Translated WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY FOR International application No. PCT/KR2012/001335 mailed 28.09.2012 (7 pages)	
	2	Translated International Search report for International application No. PCT/KR2012/004695 mailed 28.09.2012 (3 pages) PCT/KR2012/001335 mailed 28.09.2012 (3 pages)	
	3	Translated WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY FOR International application No. PCT/KR2012/004695 mailed 02.01.2013 (7 pages)	
	4	Translated International Search report for International application No. PCT/KR2012/004695 mailed 31.12.2012 (2 pages)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15724261
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First Named Inventor	Jongju Na
Art Unit	
Examiner Name	
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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/mwresq/	Date (YYYY-MM-DD)	2017-10-24
Name/Print	Merle W Richman	Registration Number	38282

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(65) 공개번호
(43) 공개일자

(73) 특허권자 신현순
서울 서초구 잠원동 69번지 137-030

(72) 발명자 신현순
서울 서초구 잠원동 69번지 137-030

(74) 대리인 김수진
윤의섭

(56) 선행기술조사문헌
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(54) 피부치료 전극봉

(57) 요약

본 발명은 본체의 시스템 제어부에 의해 주파수가 제어되는 전류가 공급되는 전류공급부를 가지는 피부치료 시스템의 전극봉에 있어서, 피부와 접촉하는 복수의 침봉; 상기 전류공급부에서 공급되는 전류가 흐르는 관통부; 상기 관통부를 비접촉으로 둘러싸도록 내부에 홀이 형성된 핸들부; 상기 관통부와 연결되어 전류가 흐르며, 상기 복수의 침봉이 삽입되도록 전면부에 다수의 홀을 구비하며, 상기 침봉을 끼워 고정하도록 고무재질의 한쌍의 침봉지지봉을 구비한 침봉지지부; 및 상기 핸들부의 길이방향의 끝단에 끼워져 결합되어 상기 침봉지지부와 접촉되는 절연캡; 을 포함하여 구성되는 것을 특징으로 하는 피부치료 전극봉에 관한 것이다.

본 발명에 의해 피부 미용 및 치료 시간을 감축하고 넓은 부위의 피부범위를 치료대상으로 선택할 수 있어 효율적인 임상효과를 얻을 수 있다.

대표도

도 4

특허청구의 범위

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청구항 1.

본체의 시스템 제어부에 의해 주파수가 제어되는 전류가 공급되는 전류공급부를 가지는 피부치료 시스템의 전극봉에 있어서,

피부와 접촉하는 복수의 침봉;

상기 전류공급부에서 공급되는 전류가 흐르는 관통부;

상기 관통부를 비접촉으로 둘러싸도록 내부에 홀이 형성된 핸들부;

상기 관통부와 연결되어 전류가 흐르며, 상기 복수의 침봉이 삽입되도록 전면부에 다수의 홀을 구비하며, 상기 침봉을 끼워 고정하도록 고무재질의 한쌍의 침봉지지봉을 구비한 침봉지지부; 및

상기 핸들부의 길이방향의 끝단에 끼워져 결합되어 상기 침봉지지부와 접촉되는 절연캡; 을 포함하여 구성되는 것을 특징으로 하는 피부치료 전극봉.

청구항 2.

제 1항에 있어서,

상기 전류공급부에서 공급된 전류가 유입되며, 상기 관통부와 나사결합되면서 상기 핸들부와 접촉하는 절연부재로 형성된 입력부를 구비한 것을 특징으로 하는 피부치료 전극봉.

청구항 3.

삭제

청구항 4.

삭제

청구항 5.

삭제

명세서

발명의 상세한 설명

발명의 목적

발명이 속하는 기술 및 그 분야의 종래기술

본 발명은 피부치료 시스템에 관한 것으로서, 특히 피부치료시에 전원제어 시스템으로부터 공급되는 주파수에 따른 미세전류를 모공에 가하여 전류를 피부 내부에 침투시켜 실질적인 에너지를 주름이나 여드름 흉터부위에 전달해 주어서 환자 본인 자신의 생리작용으로 인한 활동으로 콜라겐과 엘라스틴의 재생과 리프팅(피부를 당겨주고 강화하는 것)을 유도해 주는 피부치료용 전극봉에 관한 것이다.

도 1은 종래의 피부치료 시스템의 사용 상태도를 나타내는 도면이다. 도면에 도시한바와 같이 종래의 피부치료 시스템의 경우, 제어부(40)를 가진 시스템 본체(30)에 장착된 전류공급부(50)를 통해 이온삼투 전극봉(20)과 피부치료 전극봉(10)의 양단에 각종 주파수에 따라 각각 다른 극성의 전류를 가하고, 이온삼투 전극봉(20)의 타단은 치료받는 자의 손에 쥐게

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하고, 피부치료 전극봉(10)의 타단을 얼굴부위의 주름에 접촉하게 하면 피부에서 이온활동이 일어남과 함께 조직마다 삼투압의 차이를 만들어지고, 이에 따라 인체의 생리작용으로 인한 열에너지와 분자들의 활동으로 인해 콜라겐과 엘라스틴의 재생과 리프팅을 유도하게 된다.

그러나 상기 피부치료 전극봉(10)의 경우 한개의 침이 형성된 전극봉을 사용함에 인해서 피부의 주름살 부위를 치료함에 많은 시간이 요구될 뿐만 아니라 정확한 부위에 피어싱이 어려운 문제점이 있었다.

또한 피부치료 전극봉(10)에 부착되어지는 침의 경우 일반적인 금속을 사용할 수도 있으나, 금속 알레르기가 있는 경우에는 피부치료를 받고 난 후 금속 알레르기 현상을 유발하여 치료부위에 부작용을 일으키는 등의 문제점이 있을 수 있다.

발명이 이루고자 하는 기술적 과제

상기의 문제점을 해결하기 위해 본 발명은 복수의 침이 형성될 수 있는 피부치료 전극봉을 제공하여 넓은 부위의 피부범위를 치료대상으로 선택하여 피부치료 시간을 감축하도록 하며 또한 피부에 주파수에 따른 전기적인 자극을 가함으로써 피부를 활성화하여 피부를 보호하는것을 목적으로 한다. 사용되는 침은 스테인레스로 된 금속을 사용할 수도 있으며, 금속 알레르기가 있는 경우에는 금,은 또는 백금으로 도금하여 구성함으로써 금속알레르기로 인한 부작용을 방지하는 것도 또 다른 목적이다.

발명의 구성

상술한 목적을 달성하기 위하여, 본 발명은 본체의 시스템 제어부에 의해 제어되는 각종 주파수에 따른 전류공급부를 가지는 피부치료시스템에 있어서, 상기 전류공급부와 연결되며 홀을 가진 절연부재로 구성된 입력부; 상기 입력부와 나사결합이 되며 내부에 길이방향으로 홀이 형성된 금속재질의 관통부; 상기 입력부와 접촉되며, 길이방향으로 홀이 형성되어 상기 관통부를 비접촉으로 둘러싸는 핸들부; 상기 핸들부의 길이방향의 끝단에 끼움 결합되는 홀을 가진 절연캡; 상기 관통부의 길이방향의 끝단에 나사 결합되며 양단에 홀을 가지는 금속재질의 롤러지지부; 상기 홀에 결합되는 금속재질의 회전지지봉; 상기 회전지지봉에 끼움결합되는 방사형태로 배열된 침이 형성된 금속재질의 롤러를 포함하여 구성되는 피부치료 전극봉을 특징으로 한다.

또한 본 발명은 상기 롤러는 금속 알레르기가 있는 경우를 대비하여 금, 은 또는 백금으로 도금처리된 침이 형성된 롤러를 포함하여 구성되는 피부치료 전극봉을 특징으로 할 수 있다.

또한 본 발명은 상기 회전지지봉은 상기 롤러를 교체할 수 있도록 분리가능하게 홀에 나사 결합되는 회전지지봉을 포함하여 구성되는 피부치료 전극봉을 특징으로 한다.

또한 본 발명은 본체의 시스템 제어부에 의해 주파수가 제어되는 전류가 공급되는 전류공급부를 가지는 피부치료 시스템의 전극봉에 있어서, 피부와 접촉하는 복수의 침봉; 상기 전류공급부에서 공급되는 전류가 흐르는 관통부; 상기 관통부를 비접촉으로 둘러싸도록 내부에 홀이 형성된 핸들부; 상기 관통부와 연결되어 전류가 흐르며, 상기 복수의 침봉이 삽입되도록 전면부에 다수의 홀을 구비하며, 상기 침봉을 끼워 고정하도록 고무재질의 한쌍의 침봉지지봉을 구비한 침봉지지부; 및 상기 핸들부의 길이방향의 끝단에 끼워져 결합되어 상기 침봉지지부와 접촉되는 절연캡; 을 포함하여 구성되는 피부치료 전극봉을 특징으로 한다.

또한, 본 발명은 상기 침봉은 금속 알레르기가 있는 경우를 대비하여 금,은 또는 백금으로 도금처리된 침봉을 포함하여 구성되는 피부치료 전극봉을 특징으로 한다.
또한, 상기 전류공급부에서 공급된 전류가 유입되며, 상기 관통부와 나사결합되면서 상기 핸들부와 접촉하는 절연부재로 형성된 입력부를 구비한 것을 특징으로 한다.

이하, 본 발명에 의한 피부치료 전극봉을 도 2, 3, 4 를 참고하여 설명하면 다음과 같다.

도 2는 본 발명의 제 1실시예에 의한 피부치료 전극봉의 분해사시도로서 도시한 바와 같이, 피부치료 전극봉은 입력부(310), 관통부(320), 핸들부(330), 절연캡(340), 롤러지지부(120), 회전지지봉(130), 롤러(110)로서 구성되어진다.

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상기 입력부(310)는 도 1에서 도시한 바와 같은 피부치료 시스템의 전류공급부(50)와 연결되며 홀을 가지며 중심부에 나사선이 형성된다. 치료시에 피부치료 전극봉을 잡는 의술자의 손부위에 전류가 흘러 자극을 받지 못하도록 절연부재로 구성되고, 상기 전류공급부(50)의 전류는 상기 입력부(310)를 통해 입력부(310)와 결합하는 관통부(320)로만 흘러갈 수 있도록 구성된다.

상기 입력부(310)와 나사결합이 되며 내부에 길이방향으로 홀이 형성된 관통부(320)를 구성한다. 상기 관통부(320)는 금속재질로서 상기 전류공급부(50)의 전류가 흘러들어가는 통로의 역할을 한다.

상기 입력부(310)와 접촉되며, 길이방향으로 홀이 형성되고 상기 관통부(320)를 비접촉으로 둘러싸는 핸들부(330)를 구성한다. 상기 핸들부(330)는 의술자가 피부 치료를 할 때 손으로 잡는 부위로서 의술자의 손에 전극이 가해져서는 안되고, 핸들부(330)로 전류가 흐른다면 피부 부위에 자극의 강도를 약화하는 원인이 되므로 관통부(320)와 직접적인 접촉을 이루어서는 안된다

따라서 상기 핸들부(330)는 절연부재로 구성된 상기 입력부(310)와 절연캡(340)에만 접촉을 하며, 상기 관통부(320)와의 접촉방지를 위해 핸들부(330)의 구경을 관통부(320)보다 크게 구성하면서 관통부(320)를 둘러싸도록 구성된다.

상기 핸들부(330)의 길이방향의 끝단에 끼움 결합되는 홀을 가진 절연캡(340)을 구성한다. 상기 절연캡(340)은 핸들부(330)와 롤러지지부(120)사이에 위치하여 롤러지지부(120)에 흐르는 전류가 핸들부(330)에 흐르지 못하도록 하는 작용을 하게 된다.

상기 관통부(320)의 길이방향의 끝단에 나사 결합되며 양단에 홀을 가지는 금속재질의 롤러지지부(120)가 구성된다. 상기 전류공급부(50)로부터의 전류는 상기의 관통부(320)를 따라 흐르며 롤러지지부(120)로 흐르게 된다.

상기 롤러지지부(120)는 'ㄷ'자형상으로 구성되는 것이 롤러(110)가 끼움결합되는 구조를 만들수 있어 바람직하며, 상기 'ㄷ'자형상의 롤러지지부(120)의 마주보는 양단에 홀이 형성되도록 구성된다.

상기 롤러지지부(120)의 마주보는 양단의 홀에 금속재질의 회전지지봉(130)이 결합되며, 상기 회전지지봉(130)에 방사형태로 배열된 침(140)이 형성된 금속재질의 롤러(110)가 끼움결합하게 되도록 구성된다. 상기 회전지지봉(130)은 결합되는 롤러(110)와의 유격을 조정해서 롤러(110)의 탈조를 방지하고 잘 회전하도록 구성되어진다.

상기 롤러(110)는 일반적인 금속으로 제작할 수 있으나, 스텐레스 재질을 사용하여 구성하는 것이 바람직하고, 외부에 금, 은 또는 백금으로 도금처리된 침(140)을 형성함으로써 피부와 접촉시에 금속 알레르기를 방지하도록 구성할 수 있다.

상기 롤러지지부(120)의 마주보는 양단의 홀에 회전지지봉(130)이 나사결합을 하게 되도록 구성하여 치료부위나 피부의 민감도를 고려하여 상기 롤러(110)를 교체할 수 있도록 구성된다.

도 3a는 본 발명에 의한 롤러의 제 1실시예에 의한 사시도로서 도시한 바와 같이, 롤러(110a)에 방사형태의 배열된 침의 간격을 넓게 형성하여 구성되어진다.

상기와 같은 침의 배열간격이 넓게 형성된 롤러(110a)의 경우 피부접촉시에 각각의 침의 강도가 더 강하게 느껴짐에 따라 민감하지 않은 피부에 적합하다.

도 3b는 본 발명에 의한 롤러의 제 2실시예에 의한 사시도로서 도시한 바와 같이, 롤러(110b)의 크기를 작게하여 구성할 수 있다. 상기와 같은 작은 크기의 롤러(110b)는 눈썹 부근같은 좁은 공간의 피부치료에 적합하게 작용할 수 있다.

도 4는 본 발명의 제 2실시예에 의한 피부치료 전극봉의 분해사시도로서 도시된 바와 같이, 피부치료 전극봉은 입력부(310), 관통부(320), 핸들부(330), 절연캡(340), 침봉지지부(220), 침봉지지봉(230), 복수의 침봉(210)으로 구성되어진다.

상기의 구성요소중 입력부(310), 관통부(320), 핸들부(330), 절연캡(340)등의 구성요소는 본발명에 의한 제 1실시예의 구성요소와 일치하므로 이하에서는 본 발명에 의한 제 1실시예와 다른 특징부를 중심으로 설명하면 다음과 같다.

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상기 관통부(320)에 나사 결합되며 전면부에 복수의 홀을 가지며 양측면에 두개의 홀을 가지는 금속재질의 침봉지지부(220)가 구성된다.

상기 침봉지지부(220)의 양측면의 두개의 홀사이에 침봉지지봉(230)이 각각 끼움결합된다. 상기 복수의 침봉(210)은 상기 침봉지지부(220)의 전면부를 통해 삽입되고, 상기 침봉지지봉(230) 사이에 끼움결합되어 구성되어지며 피부의 주름부라인을 따라 일렬로 자극을 가할 수 있는 구조적 특징을 가진다.

상기 침봉(210)은 주름라인을 정확하게 피어싱할 수 있도록 긴 선재형으로 구성되는 것이 바람직하다.

상기 침봉지지봉(230)은 고무재질로 구성되어 삽입된 복수의 침봉(210)이 고정되도록 하는 역할을 한다.

상기 침봉(210)은 금속재질로 만들어지나, 스테인레스강을 사용함이 바람직하고, 금,은 또는 백금으로 도금처리하여 구성함으로써 피부와 접촉시에 금속 알레르기를 방지하도록 구성할 수 있다.

발명의 효과

이상에서 설명한 바와 같이, 본 발명에 의한 피부치료 전극봉은 다음과 같은 효과가 있다.

한개의 침이 부착된 전극봉을 개선하여 방사형태로 침을 배열한 로울러가 회전함에 따라 전극이 일정하게 피부를 자극할 수 있는 피부치료 전극봉을 제공하여 넓은 부위의 피부범위를 치료대상으로 선택할 수 있어 피부치료 시간을 감축할 수 있게 된다.

또한 로울러에 배열된 침은 일반적인 금속 재질로 만들어질 수 있지만 금,은 또는 백금으로 도금하여 구성함으로서 금속알레르기로 인한 부작용을 방지할 수 있어 피부를 보호할 수 있는 효과도 있다.

또한 피부의 부위와 민감도에 따라 롤러를 교체할 수 있어 효율적인 피부 치료 및 피부나 두피 보호 등의 피부보호 효과를 얻을 수 있다.

또한 복수의 침봉으로 구성된 피부치료 전극봉을 통해 주름라인을 단시간내에 제거할 수 있어 탁월한 주름제거효과를 얻을 수 있다.

또한 본 발명은 일정한 자극을 피부에 줌으로써 피부노화 방지 및 튼살을 회복하는 데에 유용하게 사용되어질 수 있는 효과가 있다.

도면의 간단한 설명

도 1은 종래기술에 의한 피부치료 전극봉의 사용상태도.

도 2는 본 발명의 제 1실시예에 의한 피부치료 전극봉의 분해사시도.

도 3a는 본 발명에 의한 롤러의 제 1실시예에 의한 사시도.

도 3b는 본 발명에 의한 롤러의 제 2실시예에 의한 사시도.

도 4는 본 발명의 제 2실시예에 의한 피부치료 전극봉의 분해사시도.

도면중 주요 부분에 사용된 부호의 설명

10; 피부치료 전극봉

20; 이온삼투 전극봉

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30; 피부치료 시스템 본체

40; 시스템 제어부

50; 전류공급부

110, 110a, 110b; 롤러

120; 롤러지지부

130; 회전지지봉

140; 침

210; 침봉

220; 침봉지지부

230; 침봉지지봉

310; 입력부

320; 관통부

330; 핸들부

340; 결연캡

도면

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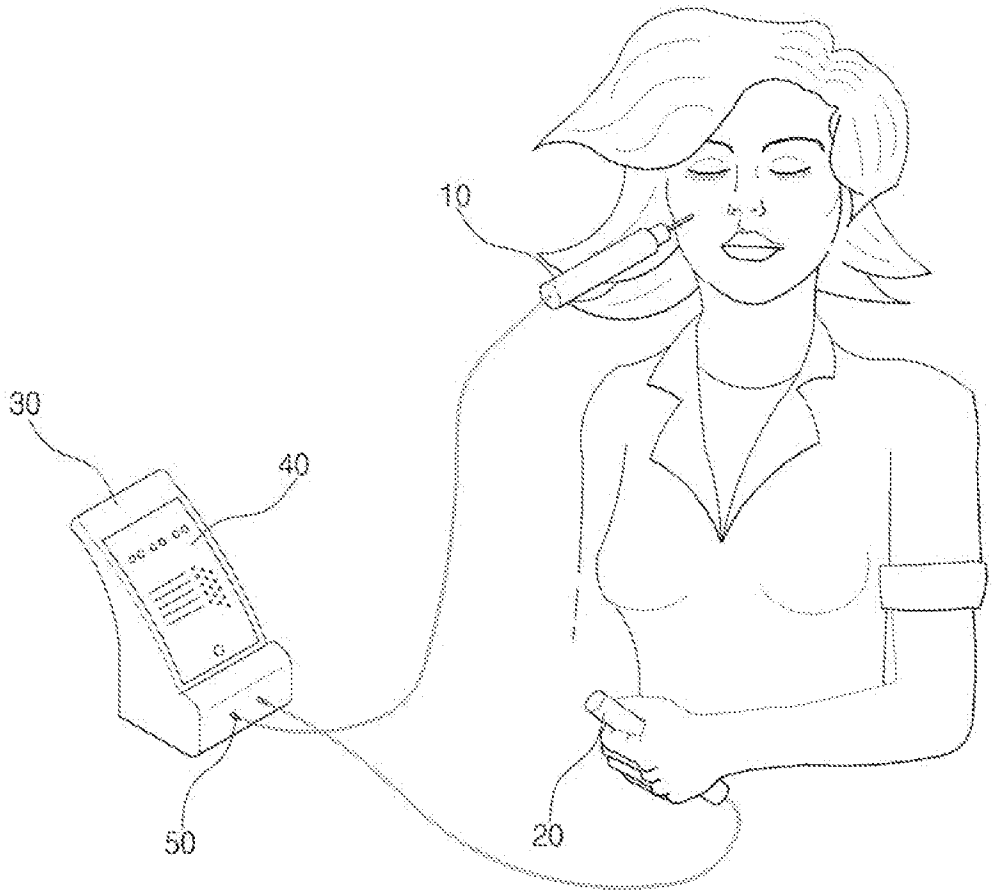
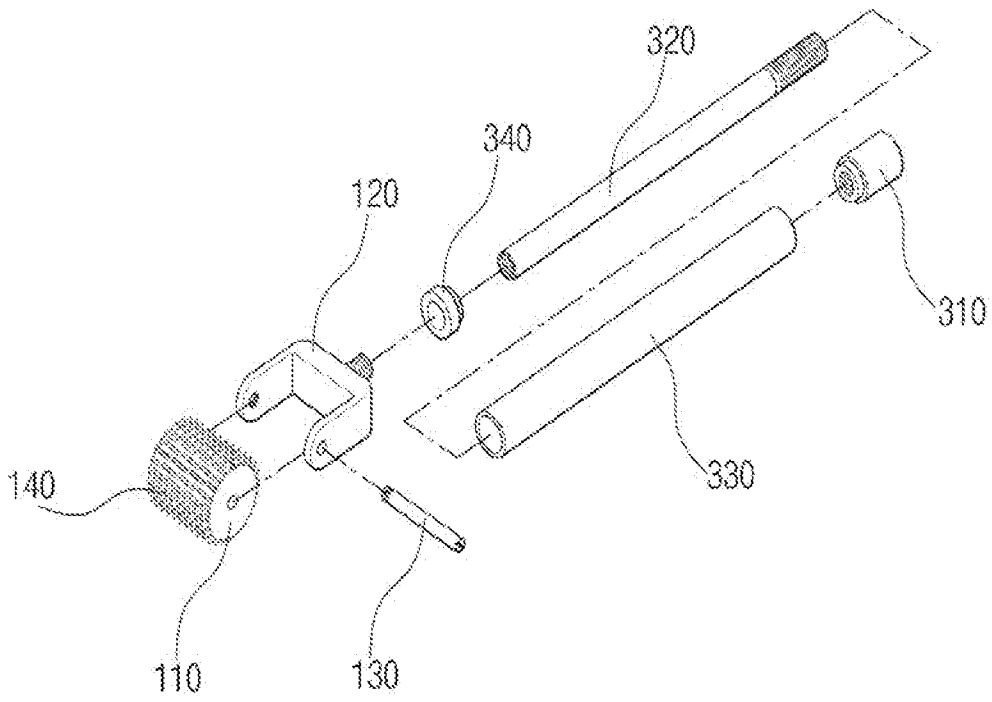
도면1



도면2



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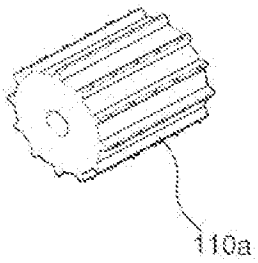
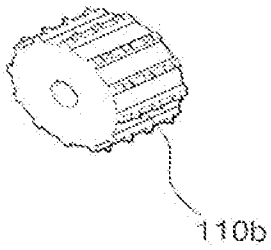
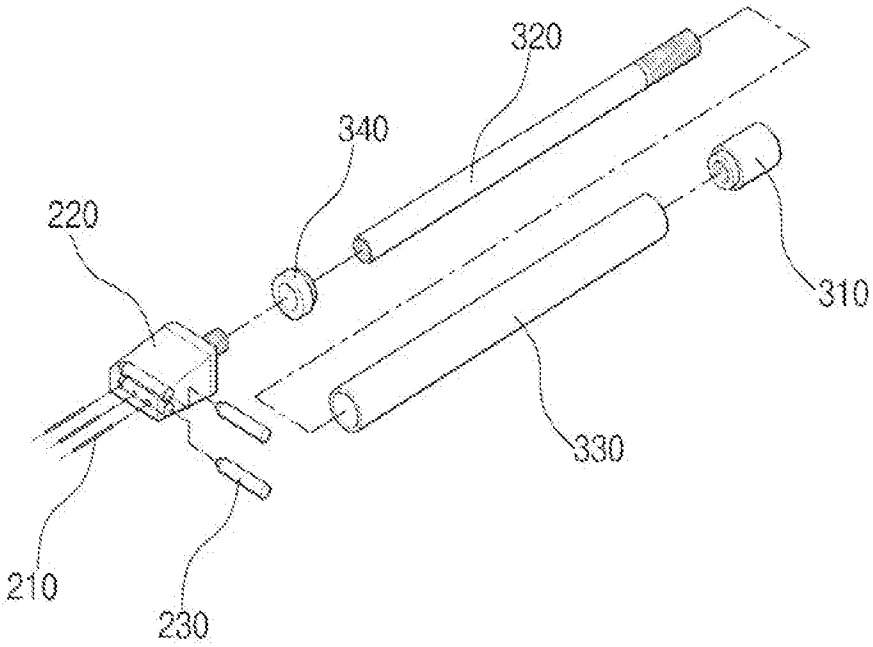
도면3a



도면3b



도면4



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(73) 특허권자
라종주
충남 천안시 쌍용2동 889-2 대우빌딩2층
(72) 발명자
라종주
충남 천안시 쌍용2동 889-2 대우빌딩2층
(74) 대리인
특허법인맥

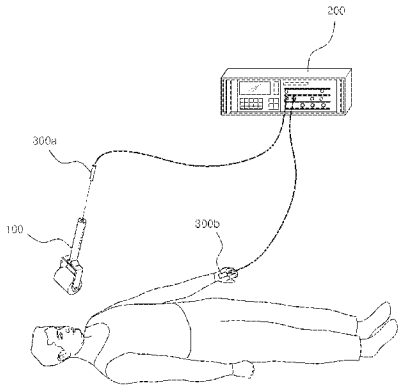
전체 청구항 수 : 총 5 항 심사관 : 양성연

(54) 전기 피부 미용기

(57) 요 약

전기 피부 미용기 및 전기 피부 미용 시스템이 개시된다. 본 발명은, 환자의 피부에 접촉되어 회전되는 롤러부, 롤러부를 환자의 피부상에서 가압할 수 있도록, 롤러부에 결합되는 손잡이부, 및 손잡이부에 결합되며, 롤러부에 전기가 도통되도록 전기발생 장치로부터의 연결단자와 접속되는 전기 입력부를 포함한다. 본 발명에 따르면, 피부층에서의 이온 자극 및 소정 주파수의 전기적인 진동 자극을 가함으로써, 피부층에서의 용액, 크림, 젤, 연고제 등의 흡수율을 획기적으로 높여 피부조직의 효과적인 재생이 가능하게 된다.

대 표 도 - 도1



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특허청구의 범위

청구항 1

환자의 피부에 접촉되어 회전되는 롤러부;

상기 롤러부를 환자의 피부상에서 가압할 수 있도록, 상기 롤러부에 결합되는 손잡이부;

상기 롤러부에 전기가 도통되도록 상기 롤러부에 전압을 공급하는 전원 공급부; 및

상기 손잡이부의 외부에 결합되며, 상기 롤러부에 공급된 전압과 반대 극성의 전압을 상기 전원 공급부로부터 공급받는 접지부

를 포함하는 전기 피부 미용기.

청구항 2

삭제

청구항 3

일면에 복수개의 금속성 침체가 삽입된 평판부;

상기 평판부의 중심축 상에서 상기 평판부에 결합되는 손잡이부; 및

상기 복수개의 금속성 침체에 전기가 도통되도록 상기 복수개의 금속성 침체에 전압을 공급하는 전원 공급부

를 포함하며,

피시술자의 피부에서의 피부 개선용 물질의 흡수율을 높이기 위해, 상기 복수개의 금속성 침체는 상기 피시술자의 피부에 마이크로 홀을 형성하고, 상기 복수개의 금속성 침체는 상기 전원 공급부로부터의 전기에 의해 상기 피시술자의 피부 진피층에 전기적 자극을 가하는 것인 전기 피부 미용기.

청구항 4

삭제

청구항 5

제3항에 있어서,

상기 복수개의 금속성 침체의 끝에는 상기 전원 공급부에 의해 이온, 라디오파, 초음파, 고주파, 중주파, 및 저주파 중 어느 하나가 발생하는 것인 전기 피부 미용기.

청구항 6

삭제

청구항 7

제3항에 있어서,

상기 손잡이부의 외부에 결합되며, 상기 금속성 침체에 공급된 전압과 반대 극성의 전압을 상기 전원 공급부로부터 공급받는 접지부를 더 포함하는 전기 피부 미용기.

청구항 8

삭제

청구항 9

제3항에 있어서,

상기 손잡이부는 내부에 적어도 하나의 탄성체를 포함하는 것인 전기 피부 미용기.

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명 세 서

발명의 상세한 설명

기 술 분 야

[0001] 본 발명은 전기 피부 미용기 및 전기 피부 미용 시스템에 관한 것으로, 더욱 상세하게는 피부조직의 효과적인 재생을 위한 전기 피부 미용기 및 전기 피부 미용 시스템에 관한 것이다.

배 경 기 술

[0002] 피부조직의 노화, 흉터, 여드름 자국 등을 개선하기 위한 방법으로서, 종래에는 단순히 피부재생을 위한 용액, 크림, 젤, 연고제 등의 의약품을 단순히 피부에 도포하는 방식에 의한 치료만이 이루어졌다. 그러나, 피부에 도포된 용액, 크림, 젤, 연고제 등의 양에서 피부의 진피층으로 흡수되어 치료에 유효하게 작용하는 용액, 크림, 젤, 연고제 등의 양은 상대적으로 그 비율이 매우 작으며, 그 결과 효과적인 피부조직의 개선을 위한 치료가 이루어지지 않는다는 문제점이 있었다. 따라서, 피부조직의 효과적인 재생을 위해 피부층에서의 용액, 크림, 젤, 연고제 등의 흡수율을 획기적으로 높일 수 있는 방법이 필요하게 되었다.

발명의 내용

해결 하고자하는 과제

[0003] 따라서, 본 발명의 목적은, 피부조직의 효과적인 재생을 위한 전기 피부 미용기 및 전기 피부 미용 시스템을 제공함에 있다.

과제 해결수단

[0004] 상기 목적을 달성하기 위한 본 발명에 따른 전기 피부 미용기는, 환자의 피부에 접촉되어 회전되는 롤러부; 상기 롤러부를 환자의 피부상에서 가압할 수 있도록, 상기 롤러부에 결합되는 손잡이부; 및 상기 손잡이부에 결합되며, 상기 롤러부에 전기가 도통되도록 전기발생 장치로부터의 연결단자와 접속되는 전기 입력부를 포함한다.

[0005] 한편, 본 발명에 따른 전기 피부 미용 시스템은 환자의 피부에 접촉되어 회전되는 롤러부, 상기 롤러부를 환자의 피부상에서 가압할 수 있도록, 상기 롤러부에 결합되는 손잡이부, 및 상기 손잡이부에 결합되며, 상기 롤러부에 전기가 도통되도록 전기발생 장치로부터의 연결단자와 접속되는 전기 입력부를 구비하는 전기 피부 미용기; 및 상기 전기 피부 미용기의 상기 전기 입력부와 접속되는 연결단자를 통해 상기 전기 피부 미용기의 상기 롤러부에 전기가 도통되도록 하는 전기발생 장치를 포함한다.

[0006] 한편, 본 발명에 따른 전기 피부 미용기는, 환자의 피부에 접촉되어 회전되는 롤러부; 상기 롤러부를 환자의 피부상에서 가압할 수 있도록, 상기 롤러부에 결합되는 손잡이부; 및 상기 롤러부에 전기가 도통되도록 상기 롤러부에 전압을 공급하는 전원 공급부를 포함한다.

[0007] 바람직하게는, 상기 환자가 손으로 잡을 수 있도록 상기 손잡이부의 외부에 결합되며, 상기 롤러부에 공급된 전압과 반대 극성의 전압을 상기 전원 공급부로부터 공급받는 접지부를 더 포함한다.

[0008] 한편, 본 발명에 따른 전기 피부 미용기는, 일면에 복수개의 금속성 침체가 삽입된 평판부; 상기 평판부의 중심축 상에서 상기 평판부에 결합되는 손잡이부; 및 상기 금속성 침체에 전기가 도통되도록 상기 금속성 침체에 전압을 공급하는 전원 공급부를 포함한다.

[0009] 바람직하게는, 상기 손잡이부의 외부에 결합되며, 상기 금속성 침체에 공급된 전압과 반대 극성의 전압을 상기 전원 공급부로부터 공급받는 접지부를 더 포함한다.

[0010] 또한, 상기 복수개의 금속성 침체의 끝에는 상기 전원 공급부에 의해 이온, 라디오파, 초음파, 고주파, 중주파, 및 저주파 중 어느 하나가 발생하는 것을 특징으로 한다.

효 과

[0011] 이상 설명한 바와 같이, 본 발명에 따르면, 피부층에서의 이온 자극 및 소정 주파수의 전기적인 진동 자극을 가함으로써, 피부층에서의 용액, 크림, 젤, 연고제 등의 흡수율을 획기적으로 높여 피부조직의 효과적인 재생이

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가능하게 된다.

발명의 실시를 위한 구체적인 내용

[0012] 이하에서는 도면을 참조하여 본 발명을 보다 상세하게 설명한다. 도면들 중 동일한 구성요소들은 가능한 한 어느 곳에서든지 동일한 부호들로 나타내고 있음에 유의해야 한다. 또한 본 발명의 요지를 불필요하게 흐릴 수 있는 공지 기능 및 구성에 대한 상세한 설명은 생략한다.

[0013] 도 1은 본 발명의 일실시예에 따른 전기 피부 미용 시스템을 이용한 시술 장면을 나타내는 도면이다. 도 1을 참조하면, 본 발명에 따른 전기 피부 미용 시스템은 전기 피부 미용기(100), 전기발생 장치(200), 및 연결단자(300a,300b)를 포함한다.

[0014] 여기서, 전기 피부 미용기(100)는 연결단자(300a)를 통해서 공급받은 전기발생 장치(200)에서 생성된 전기를 이용하여 환자의 치료부위에 전기자극을 가하며, 전기발생 장치(200)는 연결단자(300a)를 통해서 전기 피부 미용기(100)에 전기를 공급하고, 연결단자(300a,300b)는 전기발생 장치(200)의 (+),(-)극에 각각 연결되어 있으며, 전기발생 장치(200)의 (-)극에 연결된 연결단자(300a)는 전기 피부 미용기(100)에 접속되어, 전기 피부 미용기(100)에 전기발생 장치(200)로부터의 전기가 도통되도록 하고, 전기발생 장치(200)의 (+)극에 연결된 연결단자(300b)는 환자의 신체에 부착된다.

[0015] 즉, 시술자는 전기발생 장치(200)의 (-)극에 연결된 연결단자(300a)를 전기 피부 미용기(100)에 접속하고, 전기발생 장치(200)의 (+)극에 연결된 연결단자(300b)를 환자의 신체에 부착시킴으로써, 전기 피부 미용기(100)를 통하여 시술을 하는 동안에 환자의 치료부위에 전기자극이 가해지도록 한다.

[0016] 이러한 과정 중에 시술자는 환자의 치료부위에 비타민C 원액 또는 콜라겐 등을 반복적으로 도포함으로써, 피부조직의 재생이 효율적으로 이루어지게 한다. 한편, 본 발명을 실시함에 있어서, 전기발생 장치(200)의 (+)극에 연결된 연결단자(300a)를 전기 피부 미용기(100)에 접속하고, 전기발생 장치(200)의 (-)극에 연결된 연결단자(300b)를 환자의 신체에 부착할 수도 있을 것이다.

[0017] 본 발명을 실시함에 있어서, 전기발생 장치(200)는 교류전류를 발생시킬 수도 있을 것이며, 주파수에 따라 전기 피부 미용기(100) 상의 금속성 침체의 끝에는 라디오파, 초음파, 고주파, 중주파, 및 저주파 등이 발생할 수 있을 것이다. 한편, 전기발생 장치(200)는 (+)전류와 (-)전류가 일정 주기로 교번되는 펄스 전류를 발생시킬 수도 있을 것이다.

[0018] 도 2는 본 발명의 일실시예에 따른 전기 피부 미용기를 도시한 도면이다. 도 2를 참조하면, 본 발명의 일실시예에 따른 전기 피부 미용기(100)는 전기 입력부(110), 손잡이부(130), 및 롤러부(450)를 포함한다.

[0019] 여기서, 전기 입력부(110)에는 전기발생 장치(200)로부터의 연결단자(300a)가 삽입되며, 전기 피부 미용기(100)를 이용한 시술에 필요한 전기가 전기발생 장치(200)로부터 연결단자(300a)를 통해 전기 입력부(110)로 입력된다.

[0020] 한편, 손잡이부(130)는 시술자가 본 발명에 따른 전기 피부 미용기(100)로 환자에게 시술을 하는 경우에 손으로 잡는 부분이며, 롤러부(450)는 환자의 시술부위에 직접 가압을 하는 부분으로서, 환자의 피부에 접촉된 상태에서 회전될 수 있도록 제작된다.

[0021] 또한, 롤러부(450)는 금속 재질로 제작되어, 전기 입력부(110)를 통해 입력된 전기가 롤러부(450)를 통해 환자의 피부에 전달된다.

[0022] 즉, 시술자는 환자의 시술부위 상에서 전기 피부 미용기(100)의 손잡이부(130)를 잡고 적당한 압력을 가하여 롤러부(450)를 굴림으로써, 환자의 시술부위에 이온 자극 및 전기 자극을 가할 수 있게 된다.

[0023] 도 3은 본 발명의 다른 실시예에 따른 전기 피부 미용기의 구조를 나타낸 도면이다. 도 3을 참조하면, 본 발명의 다른 실시예에 따른 전기 피부 미용기(100)는 손잡이부(130), 롤러부(450), 전원 공급부(170), 스위칭부(175), 및 접지부(190)를 포함한다.

[0024] 손잡이부(130), 및 롤러부(450)는 도 2에서의 본 발명의 일실시예에 따른 전기 피부 미용기(100)에서의 손잡이부(130), 및 롤러부(450)와 기능 및 작용이 동일하다.

[0025] 도 2에서의 본 발명의 일실시예에 따른 전기 피부 미용기(100)는 전기 입력부(110)가 구비되어 외부의 전기발생 장치(200)로부터의 전기가 입력되었으나, 도 3에서의 본 발명의 다른 실시예에 따른 전기 피부 미용기(100)는

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휴대용으로 제작된 것으로서, 내부에 자체 전원 공급부(170)를 구비하고 있다.

[0026] 즉, 전원 공급부(170)에 연결된 스위칭부(175)를 'on'으로 하는 경우에, 전원 공급부(170)는 롤러부(450)에 전압을 공급하여 롤러부(450)에는 전기가 흐르게 된다.

[0027] 한편, 도 3에서의 전기 피부 미용기(100)의 손잡이부(130)의 외부에는 금속 재질의 접지부(190)가 결합되어 있으며, 접지부(190)는 롤러부(450)에 공급된 전압과 반대 극성의 전압을 전원 공급부(170)로부터 공급받는다.

[0028] 그에 따라, 도 3에서의 전기 피부 미용기(100)를 이용하여 환자가 직접 시술하는 경우에 (+)전압이 공급되는 롤러부(450)는 시술부위 피부에 접촉한 상태에서 (-)전압이 공급되는 접지부(190)를 손으로 파지함으로써 치료부위에 전기자극이 가해지게 된다.

[0029] 즉, 도 3에서의 전기 피부 미용기(100)에 의하면, 환자는 전기 피부 미용기(100)를 휴대하고 다니면서, 스위칭부(175)를 'on'으로 한 뒤, 손잡이부(130)에 결합된 접지부(190)를 손으로 파지한 상태에서 전기가 흐르는 롤러부(450)를 자신의 얼굴 등의 피부에 직접 문지르는 동작을 통해 직접 시술을 할 수 있게 된다.

[0030] 도 4는 본 발명의 또 다른 실시예에 따른 전기 피부 미용기의 구조를 나타낸 도면이다. 도 4를 참조하면, 본 발명의 또 다른 실시예에 따른 전기 피부 미용기(100)는 도 3에서의 롤러부(450) 대신에 평판부(150)를 구비한다.

[0031] 도 4에서의 본 발명의 또 다른 실시예에 따른 전기 피부 미용기는 도 3에서의 전기 피부 미용기(100)에서와 같이 휴대용으로 제작된 것으로서, 내부에 자체 전원 공급부(170)를 구비하고 있다.

[0032] 한편, 도 4에서의 평판부(150)는 환자의 시술부위에 직접 가압을 하는 부분으로서, 평판부(150)의 하측면에는 다수의 극미세 침체(micro needle:151)가 구비되어 있다.

[0033] 여기서, 극미세 침체(151)는 평판부(150)에 형성된 다수의 홀에 삽입되어 고정되어 있으며, 평판부(150)를 기준으로 일정한 길이(A)만큼 돌출되어 있다. 극미세 침체(151)의 돌출길이(A)는 0.8㎜ 또는 2.1㎜ 또는 0.24㎜인 것이 바람직하며, 극미세 침체(151)의 지름은 0.3㎜로 함이 바람직할 것이나, 본 발명을 실시함에 있어서, 극미세 침체(151)의 돌출길이(A) 및 극미세 침체(151)의 지름은 시술부위 및 시술용도에 따라 다양한 변경 및 조합이 가능할 것이다.

[0034] 또한, 전원 공급부(170)로부터 발생된 전기는 손잡이부(130)의 내부에 구비되어 있는 전기 전달체를 통하여 극미세 침체(151)에 전달되며, 극미체 침체(151)는 시술자에 의해 피부 진피층에 삽입된 상태에서 피부조직에 이온 자극 및 소정 주파수의 전기 자극을 가하게 된다.

[0035] 한편, 본 발명에 따른 전기 침슬기의 손잡이부(130)의 내부에는 시술의 용이성을 확보하기 위한 탄성절편(133)이 적어도 하나 이상 형성되어 있는 것이 바람직하다. 손잡이부(130)의 내부에 삽입된 탄성절편(133)에는 탄성특성이 우수한 고무절편이 사용될 수도 있고, 기타 판형 스프링 등이 사용될 수도 있을 것이다.

[0036] 손잡이부(130)의 내부에 삽입된 탄성절편(133)은 극미세 침체(151)가 시술부위의 진피층으로 부드럽게 삽입되어 이온 자극 및 소정 주파수의 진동 자극을 가하도록 하는 기능을 하게 된다.

[0037] 전원 공급부(170)에 구비된 스위칭부(175)를 'on'으로 하는 경우에, 전원 공급부(170)는 극미세 침체(151)에 전압을 공급하며, 손잡이부(130)의 외부에 결합된 금속성의 접지부(190)에는 극미세 침체(151)에 공급된 전압과 반대 극성의 전압이 공급된다.

[0038] 즉, 환자는 도 4에서의 전기 피부 미용기(100)를 직접 시술하는 경우에 (+)전압이 공급되는 극미세 침체(151)를 시술부위 피부 진피층에 삽입한 상태에서 (-)전압이 공급되는 접지부(190)를 손으로 파지함으로써 치료부위에 전기자극이 가해지도록 한다.

[0039] 도 5는 도 4에서의 전기 피부 미용기의 저면도로서 평판부의 하측면을 도시하는 도면이다. 도 5를 참조하면, 본 발명에 따른 전기 피부 미용기(100)의 평판부(150)는 직사각형의 형상을 하고 있으며, 그 내부에는 다수의 홀(hole)(159)이 형성되어 있다. 본 발명을 실시함에 있어서, 평판부(150)의 형상은 직사각형, 마름모형, 원형, 타원형 등의 시술자의 편리에 따른 다양한 형상(예를 들어, 환자의 시술 부위의 형상과 유사한 형상 등)으로 이루어질 수 있을 것이다.

[0040] 평판부(150)에 형성된 홀(159)은 가로방향으로 14개의 행을 따라 동일한 간격으로 위치하고 있으며, 세로방향으로는 10개의 행을 따라 동일한 간격으로 위치하고 있다. 그 결과, 평판부(150)에는 등간격의 격자형상으로 총 140개의 홀(159)이 형성된다. 이와 같이 평판부(150)에 형성된 다수의 홀(159)에는 환자의 시술부위에 미세상처

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를 내기 위한 극미세 침체(151)가 삽입되어 고정된다.

[0041] 다만, 본 발명을 실시함에 있어서, 평판부(150)에 형성된 홀(159)의 개수 및 간격은 시술목적에 따라 적절하게 조정될 수 있을 것이다.

[0042] 도 6은 도 4에서의 전기 피부 미용기의 평판부의 분해 사시도이다. 도 4 내지 도 6을 참조하면 본 발명에 따른 전기 피부 미용기(100)의 평판부(150)는 복수개의 극미세 침체(151), 하면부(153), 전기 전도부(155), 및 상면부(157)를 포함한다.

[0043] 복수개의 극미세 침체(151)는 하면부(153)에 형성된 복수개의 홀(159)을 통해 하면부(153)와 결합되어 있으며, 하면부(153)는 전기 전도부(155)와 결합되어 있다. 여기서, 복수개의 극미세 침체(151)는 하면부(153)를 관통하여, 전기 전도부(155)에 전기적으로 결합되어 있다.

[0044] 전기 피부 미용기(100)의 전원 공급부(170)에서 발생된 전기는 손잡이부(130) 내의 도전성의 전기 전달체를 통하여 전기 전도부(155)로 전해지며, 최종적으로는 전기 전도부(155)에 전기적으로 결합되어 있는 복수개의 극미세 침체(151)에 전달된다. 그 결과 극미체 침체(151)는 시술자에 의해 피부 진피층에 삽입된 상태에서 피부조직에 이온 자극 및 소정 주파수의 전기 자극을 가하게 된다.

[0045] 한편, 전기 전도부(155)는 상면부(157)와 결합되어 있으며, 상면부(157)는 전기 피부 미용기(100)의 손잡이부(130)와 일체로서 연결되어 있거나, 나사방식에 의해서 결합되어 있을 수도 있을 것이다.

[0046] 도 4에서의 본 발명의 또 다른 실시예에 따른 전기 피부 미용기(100)의 시술과정을 설명하면, 환자는 전기 피부 미용기(100)의 손잡이부(130)를 잡고서, 다수의 극미세 침체(151)를 환자의 시술부위에 대고 압력을 가한다. 이러한 과정의 반복을 통해 환자의 시술부위에는 무수히 많은 미세상처(즉, 마이크로 홀)가 생기게 되고, 이러한 마이크로 홀 내의 극미세 침체(151) 끝에서는 소정의 주파수의 전류가 주위의 피부조직으로 전도되며, 이에 따라 극미세 침체(151) 주변의 피부조직의 이온을 흥분시키거나 전기적 진동 자극에 의한 열을 일으키게 된다.

[0047] 이와 같은 피부 진피층에서의 이온 자극 및 소정 주파수의 전기적인 진동 자극을 통해서, 피부조직의 효과적인 재생을 위해 피부층에서의 용액, 크림, 젤, 연고재 등의 흡수율을 획기적으로 높여 환자의 피부 조직은 빠른 속도로 새로운 조직을 형성하게 된다.

[0048] 이상에서는 본 발명의 바람직한 실시예 및 응용예에 대하여 도시하고 설명하였지만, 본 발명은 상술한 특정의 실시예 및 응용예에 한정되지 아니하며, 청구범위에서 청구하는 본 발명의 요지를 벗어남이 없이 당해 발명이 속하는 기술분야에서 통상의 지식을 가진자에 의해 다양한 변형실시가 가능한 것은 물론이고, 이러한 변형실시들은 본 발명의 기술적 사상이나 전망으로부터 개별적으로 이해되어져서는 안될 것이다.

도면의 간단한 설명

[0049] 도 1은 본 발명의 일실시예에 따른 전기 피부 미용 시스템을 이용한 시술 장면을 나타내는 도면,

[0050] 도 2는 본 발명의 일실시예에 따른 전기 피부 미용기를 도시한 도면,

[0051] 도 3은 본 발명의 다른 실시예에 따른 전기 피부 미용기의 구조를 나타낸 도면,

[0052] 도 4는 본 발명의 또 다른 실시예에 따른 전기 피부 미용기의 구조를 나타낸 도면,

[0053] 도 5는 도 4에서의 전기 피부 미용기의 저면도로서 평판부의 하측면을 도시하는 도면, 및

[0054] 도 6은 도 4에서의 전기 피부 미용기의 평판부의 분해 사시도이다.

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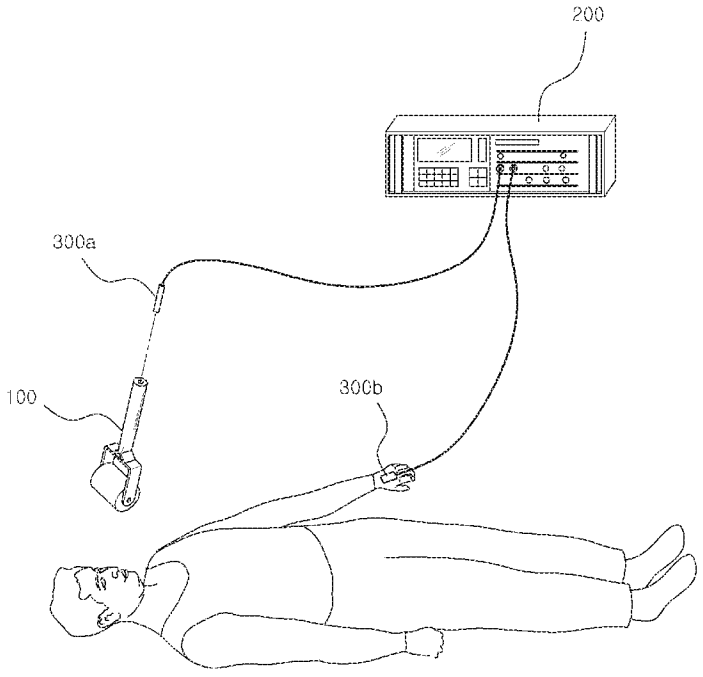
도면

도면1



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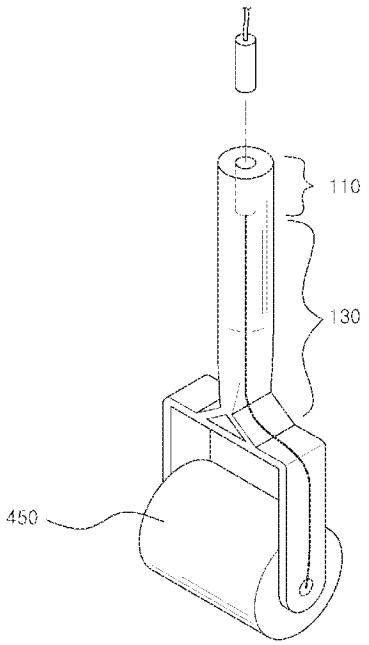

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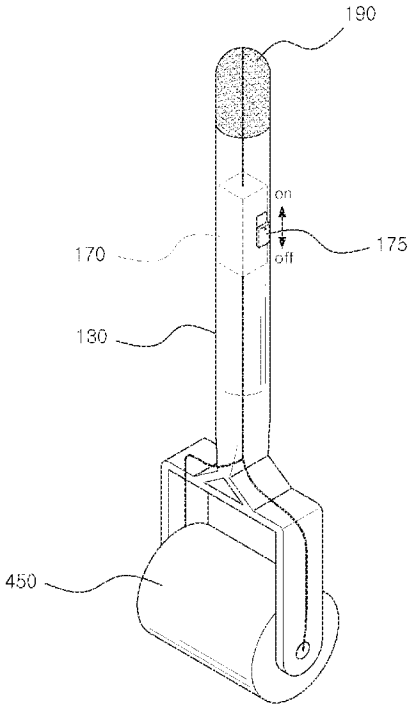
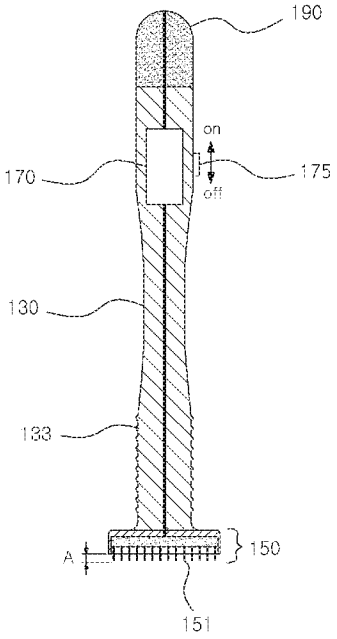
도면3



도면4



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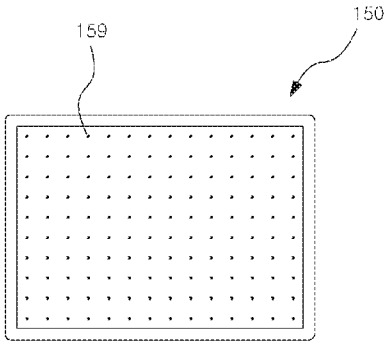
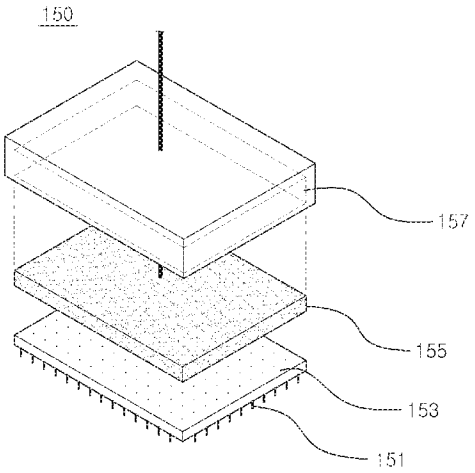
도면5



도면6



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(73) 특허권자
(주)제중메디칼
강원도 원주시 태장2동 1720-26 의료기기산업단지 1동 111호
(72) 발명자
김인수
강원 원주시 개운동 380-44
(74) 대리인
민혜정

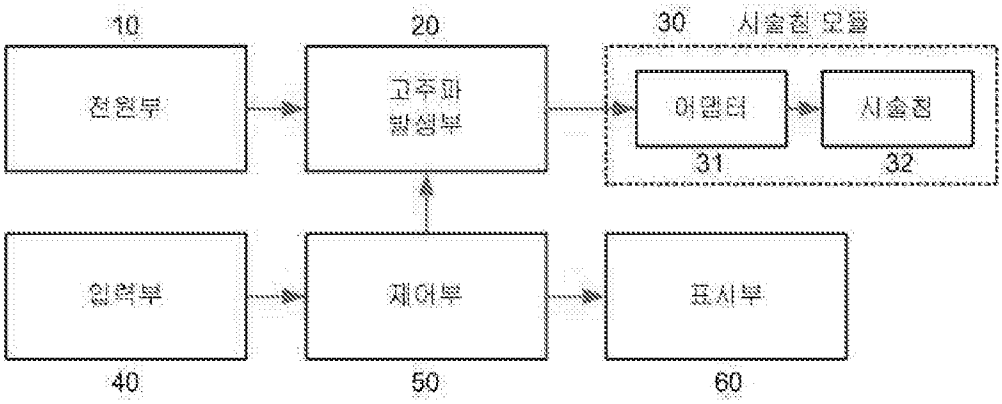
전체 청구항 수 : 총 16 항 심사관 : 전창익

(54) 고주파 침봉기

(57) 요 약

본 발명은 피부 재생 및 치료 등을 위한 고주파 침봉기에 관한 것이다. 본 발명은, 전원부; 상기 전원부로부터 구동전원을 공급받고, 제어부의 제어에 따라 고주파를 발생시키는 고주파 발생부; 상기 고주파 발생부로부터 발생된 고주파를 시술침에 전달하는 시술침 모듈; 상기 고주파 발생부를 제어하여 발생되는 주파수의 크기 및 주기를 제어하는 제어부; 상기 제어부에 사용자의 조작명령을 입력하는 입력부; 및 상기 제어부의 처리 결과 및 기기의 동작 상태를 표시하는 표시부를 포함하는 것을 특징으로 한다. 따라서, 피부에 삽입되는 침에 고주파를 공급하여 피부 재생 및 치료 효과를 더욱 향상시키고, 상기 고주파를 바이폴라 구동방식으로 공급하여 피부 재생 및 치료 효과를 더욱 향상시키고, 상기 고주파를 단 펄스 또는 복합 펄스로 공급하여 피부 재생 및 치료 효과를 더욱 향상시킨다.

대 표 도 - 도1



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특허청구의 범위

청구항 1

전원부;

상기 전원부로부터 구동전원을 공급받고, 제어부의 제어에 따라 고주파를 발생시키는 고주파 발생부;

상기 고주파 발생부로부터 발생된 고주파를 시술침에 전달하는 시술침 모듈; 및

상기 고주파 발생부를 제어하여 발생되는 주파수의 크기 및 주기를 제어하는 제어부를 포함하는 고주파 침봉기에 있어서,

상기 시술침은 적어도 2개 이상으로 구성되어 어댑터에 의하여 소정 높이가 돌출되도록 고정되는 것을 특징으로 하는 고주파 침봉기.

청구항 2

삭제

청구항 3

제 1 항에 있어서,

상기 다수개의 시술침들이 상기 어댑터에 일정 간격으로 배열되는 것을 특징으로 하는 고주파 침봉기.

청구항 4

제 3 항에 있어서,

상기 어댑터는

상기 시술침들의 배열 간격이 1㎜ 이상 5㎜ 이하인 것을 특징으로 하는 고주파 침봉기.

청구항 5

제 1항에 있어서,

상기 어댑터는

상기 시술침의 돌출 높이를 조절하는 노브가 형성된 것을 특징으로 하는 고주파 침봉기.

청구항 6

제 5항에 있어서,

상기 어댑터는

상기 시술침의 돌출 높이는 0.5㎜ 이상 3.5㎜ 이하로 설정하되, 상기 노브에 의하여 0.5㎜ 단위로 조절되는 것을 특징으로 하는 고주파 침봉기.

청구항 7

제 1 항에 있어서,

상기 시술침의 직경은

0.16㎜ 이상 0.3㎜ 이하인 것을 특징으로 하는 고주파 침봉기.

청구항 8

제 1 항에 있어서,

상기 시술침은

금, 은 및 텅스텐 중의 어느 한 재질로 이루어지거나 또는 이들의 조합으로 이루어진 것을 특징으로 하는 고주

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파 침봉기.

청구항 9

제 1 항에 있어서,

상기 고주파 발생부는

바이폴라 구동방식인 것을 특징으로 하는 고주파 침봉기.

청구항 10

제 1 항에 있어서,

상기 고주파 발생부는

복합 펄스 방식인 것을 특징으로 하는 고주파 침봉기.

청구항 11

제 1 항에 있어서,

상기 고주파 발생부는

복변조 방식인 것을 특징으로 하는 고주파 침봉기.

청구항 12

제 10 항에 있어서,

상기 고주파 발생부는

100㎑ 이상 50㎒ 이하 대역의 고주파를 10Hz 이상 120Hz 이하로 FM변조하여 복변조 하는 것을 특징으로 하는 고주파 침봉기.

청구항 13

전원부;

상기 전원부로부터 구동전원을 공급받고, 제어부의 제어에 따라 고주파를 발생시키는 고주파 발생부;

다수개의 시술침들이 일정 간격으로 배열되고, 상기 고주파 발생부로부터 발생된 고주파를 상기 시술침들에 전달하되,

상기 고주파 발생부로부터 발생된 고주파는 중앙부의 시술침으로부터 외부의 시술침 방향으로 순차적으로 전달하는 시술침 모듈; 및

상기 고주파 발생부를 제어하여 발생되는 주파수의 크기 및 주기를 제어하는 제어부를 포함하는 것을 특징으로 하는 고주파 침봉기.

청구항 14

전원부;

상기 전원부로부터 구동전원을 공급받고, 제어부의 제어에 따라 고주파를 발생시키는 고주파 발생부;

상기 고주파 발생부로부터 발생된 고주파를 시술침에 전달하는 시술침 모듈;

상기 고주파 발생부를 제어하여 발생되는 주파수의 크기 및 주기를 제어하는 제어부;

상기 제어부에 사용자의 조작명령을 입력하는 입력부; 및

상기 제어부의 처리 결과 및 기기의 동작 상태를 표시하는 표시부를 포함하는 고주파 침봉기에 있어서,

상기 시술침은 적어도 2개 이상으로 구성되어 어댑터에 의하여 소정 높이가 돌출되도록 고정되는 것을 특징으로 하는 고주파 침봉기.

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청구항 15

제 14 항에 있어서,

상기 입력부는

상기 제어부에 사용자의 조작명령을 입력하고, 이에 따라 상기 고주파 발생부에서 발생되는 주파수의 크기 및 주기를 변경시키는 것을 특징으로 하는 고주파 침봉기.

청구항 16

제 15 항에 있어서,

상기 입력부는 유선 또는 무선 리모콘으로 구성된 것을 특징으로 하는 고주파 침봉기.

청구항 17

제 15 항에 있어서,

상기 표시부는

상기 제어부의 처리 결과 및 기기의 동작 상태를 문자, 도형, 기호로 표시하는 화면 디스플레이용 모니터인 것을 특징으로 하는 고주파 침봉기.

명 세 서

발명의 상세한 설명

기 술 분 야

[0001] 본 발명은 고주파 침봉기에 관한 것으로, 더욱 상세하게는 피부 재생 및 치료 등을 위한 고주파 침봉기에 관한 것이다.

배 경 기 술

[0002] 최근 침을 이용한 미용도구 또는 의료기 들의 사용이 증가되고 있는 실정이다.

[0003] 예로서, MTS 또는 더마롤러는 마이크로 니들 테라피 라고도 불리우며, 여러개의 바늘이 달린 간단한 미용도구이며 독일에서 처음 개발되었다.

[0004] 이러한 침을 이용한 기기(이하 침봉기라 한다.)는 여드름 및 흉터의 움푹 들어간 부위의 피부 콜라겐을 자극하여 피부재생이 이루어진다.

[0005] 또한, 바늘이 피부 밑 콜라겐층을 자극하게 되며 새로운 콜라겐 형성을 촉진하게 되어 주름살 제거 및 피부 탄력을 회복하게 된다.

[0006] 또한, 피부 미백 효과도 있다.

[0007] 그러나 이러한 종래의 침봉기는 피부에 단순히 침을 삽입하는 물리적인 힘만을 가하여 자극을 주거나 일정 세포를 파괴하기 때문에 그 이상으로 효과를 향상시킬 수 없는 문제점이 있었다.

발명의 내용

해결 하고자하는 과제

[0008] 따라서 본 발명은 상술한 종래의 문제점을 극복하기 위한 것으로서, 피부에 삽입되는 침에 고주파를 공급하여 피부 재생 및 치료 효과를 더욱 향상시킨 고주파 침봉기를 제공하는 것을 그 목적으로 한다.

[0009] 또한, 상기 고주파를 바이폴라 구동방식으로 공급하는 것을 다른 목적으로 한다.

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[0010] 또한, 상기 고주파를 단 펄스 또는 복합 펄스로 공급하는 것을 또 다른 목적으로 한다.

과제 해결수단

[0011] 상기 목적을 달성하기 위하여 본 발명에 따른 고주파 침봉기는, 전원부; 상기 전원부로부터 구동전원을 공급받고, 제어부의 제어에 따라 고주파를 발생시키는 고주파 발생부; 상기 고주파 발생부로부터 발생된 고주파를 시술침에 전달하는 시술침 모듈; 및 상기 고주파 발생부를 제어하여 발생되는 주파수의 크기 및 주기를 제어하는 제어부를 포함하는 것을 특징으로 한다.

[0012] 상기 시술침은 적어도 2개 이상으로 구성되어 어댑터에 의하여 소정 높이가 돌출되도록 고정된다.

[0013] 상기 다수개의 시술침들이 상기 어댑터에 일정 간격으로 배열될 수 있다.

[0014] 상기 어댑터는 상기 시술침들의 배열 간격이 1㎜ 이상 5㎜ 이하인 것이 바람직하다.

[0015] 상기 어댑터는 상기 시술침의 돌출 높이를 조절하는 노브가 형성된다.

[0016] 상기 어댑터는 상기 시술침의 돌출 높이는 0.5㎜ 이상 3.5㎜ 이하로 설정하되, 상기 노브에 의하여 0.5㎜ 단위로 조절된다.

[0017] 상기 시술침의 직경은 0.16㎜ 이상 0.3㎜ 이하인 것이 바람직하다.

[0018] 상기 시술침은 금, 은 및 텅스텐 중의 어느 한 재질로 이루어지거나 또는 이들의 조합으로 이루어진다.

[0019] 상기 고주파 발생부는 바이폴라 구동방식인 것이 바람직하다.

[0020] 상기 고주파 발생부는 복합 펄스 방식인 것이 더욱 바람직하다.

[0021] 상기 고주파 발생부는 복변조 방식으로서, 상기 고주파 발생부는 100㎑ 이상 50㎒ 이하 대역의 고주파를 10㎐ 이상 120㎐ 이하로 FM변조하여 복변조 하는 것이 바람직하다.

[0022] 본 발명의 다른 특징은, 전원부; 상기 전원부로부터 구동전원을 공급받고, 제어부의 제어에 따라 고주파를 발생시키는 고주파 발생부; 다수개의 시술침들이 일정 간격으로 배열되고, 상기 고주파 발생부로부터 발생된 고주파를 상기 시술침들에 전달하되, 상기 고주파 발생부로부터 발생된 고주파는 중앙부의 시술침으로부터 외부의 시술침 방향으로 순차적으로 전달하는 시술침 모듈; 및 상기 고주파 발생부를 제어하여 발생되는 주파수의 크기 및 주기를 제어하는 제어부를 포함하는 것을 특징으로 한다.

[0023] 본 발명의 또 다른 특징은, 전원부; 상기 전원부로부터 구동전원을 공급받고, 제어부의 제어에 따라 고주파를 발생시키는 고주파 발생부; 상기 고주파 발생부로부터 발생된 고주파를 시술침에 전달하는 시술침 모듈; 상기 고주파 발생부를 제어하여 발생되는 주파수의 크기 및 주기를 제어하는 제어부; 상기 제어부에 사용자의 조작명령을 입력하는 입력부; 및 상기 제어부의 처리 결과 및 기기의 동작 상태를 표시하는 표시부를 포함하는 것을 특징으로 한다.

[0024] 상기 입력부는 상기 제어부에 사용자의 조작명령을 입력하고, 이에 따라 상기 고주파 발생부에서 발생되는 주파수의 크기 및 주기를 변경시킨다. 상기 입력부는 유선 또는 무선 리모콘으로 구성된다.

[0025] 상기 표시부는 상기 제어부의 처리 결과 및 기기의 동작 상태를 문자, 도형, 기호 등으로 표시하는 화면 디스플레이용 모니터인 것이 바람직하다.

효 과

[0026] 본 발명에 따른 고주파 침봉기에 의하면, 피부에 삽입되는 침에 고주파를 공급하여 피부 재생 및 치료 효과를 더욱 향상시킨 효과가 있다.

[0027] 또한, 상기 고주파를 바이폴라 구동방식으로 공급하여 피부 재생 및 치료 효과를 더욱 향상시킨 효과도 있다.

[0028] 또한, 상기 고주파를 단 펄스 또는 복합 펄스로 공급하여 피부 재생 및 치료 효과를 더욱 향상시킨 효과도 있다.

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발명의 실시를 위한 구체적인 내용

[0029] 이하, 본 발명의 일 실시예에 의한 구성 및 동작을 첨부한 도면을 참조하여 상세히 설명한다.

[0030] 본 명세서 및 청구범위에 사용된 용어나 단어는 통상적이거나 사전적인 의미로 한정 해석되지 아니하며, 발명자는 그 자신의 발명을 가장 최선의 방법으로 설명하기 위해 용어의 개념을 적절하게 정의할 수 있다는 원칙에 입각하여 본 발명의 기술적 사상에 부합하는 의미와 개념으로 해석되어야만 한다. 따라서, 본 명세서에 기재된 실시예와 도면에 도시된 구성은 본 발명의 가장 바람직한 일 실시예에 불과할 뿐이므로, 본 출원시점에 있어서 이들을 대체할 수 있는 다양한 균등물과 변형예들이 있을 수 있음을 이해하여야 한다.

[0031] 본 발명은 함몰된 피부, 끊긴 피부 및 이상 돌출 피부 흔히 말하는 주름 등의 노화 피부 재거 그리고 그에 따른 피부 세포의 재생을 위하여 예로서, 인체에 무해한 0.16mm-0.3mm의 시술침을 0.5-3.5mm 정도의 미세한 깊이와 1mm-5mm 폭으로 환부에 침투시킨 후 아주 짧은 시간 동안 RF의 출력을 설정된 침의 침투 깊이와 폭만큼 피부에 인가하여 노화되거나 병변을 가진 세포를 괴사시킴으로써 새로운 피부 세포를 재생하는 것이다. 이때 괴사 면은 각각의 피부 병변에 따라 다양한 형태로 구성된 침을 선택하여 시술하게 된다.

[0032] 도 1은 본 발명에 따른 고주파 침봉기를 나타낸 블록 구성도이다.

[0033] 도시된 바와 같이, 본 발명은 전원부(10), 고주파 발생부(20), 시술침 모듈(30), 어댑터(31), 시술침(32), 노브(33), 입력부(40), 제어부(50) 및 표시부(60)를 포함한다.

[0034] 전원부(10)는 통상의 110~220V 상용교류전압(AC)을 인가받아 장치에 필요한 크기의 교류 또는 직류전압(DC)을 변환하여 공급한다.

[0035] 고주파 발생부(20)는 상기 전원부(10)로부터 구동전원을 공급받고, 제어부(50)의 제어에 따라 고주파를 발생시킨다.

[0036] 시술침 모듈(30)은 상기 고주파 발생부(20)로부터 발생된 고주파를 시술침(32)에 전달한다.

[0037] 이를 위하여 상기 시술침(32)은 적어도 2개 이상으로 구성되어 어댑터(31)에 의하여 소정 높이가 돌출되도록 고정된다.

[0038] 또한, 상기 다수개의 시술침(32)들이 상기 어댑터(31)에 일정 간격으로 배열되는 것이 바람직하다. 이때, 상기 어댑터(31)는 상기 시술침(32)들의 배열 간격이 1mm 이상 5mm 이하가 되도록 형성한다.

[0039] 상기 어댑터(31)는 상기 시술침(32)의 돌출 높이를 조절하는 노브(33)가 형성된다.

[0040] 상기 어댑터(31)는 상기 시술침(32)의 돌출 높이는 0.5mm 이상 3.5mm 이하로 설정하되, 상기 노브(33)에 의하여 0.5mm 단위로 조절되는 것이 가능하다.

[0041] 상기 시술침(32)의 직경은 0.16mm 이상 0.3mm 이하인 것이 바람직하다.

[0042] 또한, 상기 시술침(32)은 금, 은 및 텅스텐 중의 어느 한 재질로 이루어지거나 또는 이들의 조합으로 이루어질 수 있다.

[0043] 제어부(50)는 상기 고주파 발생부(20)를 제어하여 발생되는 주파수의 크기 및 주기를 제어한다.

[0044] 이를 위하여 상기 제어부(50)는 연산, 비교 및 판단 기능을 갖는 마이크로컴퓨터(MICOM) 또는 CPU, MPU 등의 중앙처리장치가 적용될 수 있다.

[0045] 상기 고주파 발생부(20)는 바이폴라 구동방식인 것이 바람직하다.

[0046] 상기 고주파 발생부(20)는 복합 펄스 방식인 것이 더욱 바람직하다.

[0047] 또한, 상기 고주파 발생부(20)는 복변조 방식인 것이 가능하다. 이때, 상기 고주파 발생부(20)는 100㎑ 이상 50㎒ 이하 대역의 고주파를 10㎐ 이상 120㎐ 이하로 FM변조하여 복변조 한다.

[0048] 또한, 상기 다수개의 시술침(32)들이 일정 간격으로 배열되고, 상기 고주파 발생부(20)로부터 발생된 고주파를 상기 시술침(32)들에 전달하되, 상기 고주파 발생부(20)로부터 발생된 고주파는 중앙부의 시술침(32)으로부터 외부의 시술침(32) 방향으로 순차적으로 전달한다.

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[0049] 또한, 입력부(40)는 상기 제어부(50)에 사용자의 조작명령을 입력한다.

[0050] 상기 입력부(40)는 상기 제어부(50)에 사용자의 조작명령을 입력하고, 이에 따라 상기 고주파 발생부(20)에서 발생되는 주파수의 크기 및 주기를 변경시킨다.

[0051] 이를 위하여, 상기 입력부(40)는 유선 또는 무선 리모콘으로 구성된다.

[0052] 표시부(60)는 상기 제어부(50)의 처리 결과 및 기기의 동작 상태를 표시한다.

[0053] 상기 표시부(60)는 상기 제어부(50)의 처리 결과 및 기기의 동작 상태를 문자, 도형, 기호 등으로 표시하는 화면 디스플레이용 모니터인 것이 바람직하다.

[0054] 도 2는 본 발명에 따른 시술침 모듈의 구조를 나타낸 사시도이다.

[0055] 도시된 바와 같이, 본 발명에 따른 시술침 모듈(30)은 적어도 2개 이상으로 구성된 상기 시술침(32)이 어댑터(31)에 의하여 소정 높이가 돌출되도록 고정된다.

[0056] 상기 어댑터(31)의 노브(33)는 상기 시술침(32)의 돌출 높이를 조절한다. 이때, 상기 시술침(32)의 돌출 높이는 0.5㎜ 이상 3.5㎜ 이하로 설정하되, 상기 노브(33)에 의하여 0.5㎜ 단위로 조절된다.

[0057] 또한, 상기 시술침(32)의 직경은 0.16㎜ 이상 0.3㎜ 이하이고, 재질은 금, 은 및 텅스텐 중의 어느 한 재질로 이루어지거나 또는 이들의 조합으로 이루어진다.

[0058] 도 3은 본 발명에 따른 시술침의 배열 구조를 나타낸 평면도이다.

[0059] 도시된 바와 같이, 본 발명의 상기 다수개의 시술침(32)들이 상기 어댑터(31)에 일정 간격으로 배열되되, 상기 어댑터(31)는 상기 시술침(32)들의 배열 간격이 1㎜ 이상 5㎜ 이하가 되도록 형성한다.

[0060] 도 4는 도 3의 시술침 배열에 따른 바이폴라 구동방식을 설명하기 위한 도면이다.

[0061] 도시된 바와 같이, 상기 고주파 발생부(20)는 바이폴라 구동방식으로 상기 시술침(32)을 동작시킨다.

[0062] 여기서, 본 발명이 플레이트 패드를 이용하지 않고 바이폴라 구동방식을 적용하는 이유는 도시된 모든 시술침(32)에 동시에 출력을 보낼 경우 전기적 특성상 가장 통전률이 좋은 시술침(32) 쪽으로 치우치게 고주파가 흘러 편중되는 것을 막기 위하여 바이폴라 구동방식을 적용한 것이다. 따라서, 모든 시술침(32)에 골고루 고주파를 흘려보낼 수 있다.

[0063] 또한, 상기 고주파 발생부(20)는 출력 시간은 깊이에 따라 시술자의 판단에 의하여 입력부(40)를 통하여 설정되어 지며, 대략 출력 시간은 10msec이상 100msec 이하이며 이는 단 펄스 혹은 복합 펄스 방식으로 구성될 수 있다.

[0064] 또한, 상기 고주파 발생부(20)는 100㎑ 이상 50㎒ 이하 대역의 고주파를 10Hz 이상 120Hz 이하로 FM변조하여 복변조 한다. 즉, 구성 주파수는 100khz -5MHz대역의 고주파가 이용되며, 이를 다시 FM변조하여 10Hz-120Hz로 복변조 하여 사용한다.

[0065] 또한, 일정 간격으로 배열된 상기 다수개의 시술침(32)들에 상기 고주파 발생부(20)로부터 발생된 고주파를 상기 시술침(32)들에 전달하되, 상기 고주파 발생부(20)로부터 발생된 고주파는 중앙부의 시술침(32)으로부터 외부의 시술침(32) 방향으로 순차적으로 전달한다.

[0066] 즉, 통전 방식은 핀 투 핀(pin to the pin) 방식으로 예를 들면 B 와 d 에 고주파 양극성을 출력시 16번핀과 22번핀에 고주파가 순간 흘러 치료되는 형식으로 전류를 중앙 부위부터 바깥부위로 조사하는 방식이다. 중앙에서 외곽부분으로 조사하는 이유는 발생되는 열의 분포를 균일화하기 위함이다(잠열 축척에 따른 불균등 치료 제거).

[0067] 도 5는 본 발명에 따른 고주파 침봉기의 제어과정을 나타낸 순서도이다.

[0068] 도시된 바와 같이, 본 발명의 동작이 개시되면, 전원부(10)가 온되어 통상의 110~220V 상용교류전압(AC)을 장치에 필요한 크기의 직류전압(DC)으로 변환하여 공급한다(S100).

[0069] 이후, 제어부(50)의 제어에 따라 시스템의 초기화 명령을 수행하고(S110), 사용자는 입력부(40)를 통하여 전압 선택, 시간 및 횟수를 설정하는 모드 선택 단계를 수행한다(S120).

[0070] 이후, 시작키가 입력되면(S130), 상기 단계에서 설정된 값에 따른 동작 모드가 실행된다(S140).

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[0071] 따라서, 고주파 발생부(20)는 상기 전원부(10)로부터 구동전원을 공급받고, 제어부(50)의 제어에 따라 고주파를 발생시키고, 시술침 모듈(30)은 상기 고주파 발생부(20)로부터 발생된 고주파를 시술침(32)에 전달한다.

[0072] 이때, 제어부(50)는 상기 고주파 발생부(20)를 제어하여 발생되는 주파수의 크기 및 주기를 제어한다.

[0073] 한편, 상기 입력부(40)는 상기 제어부(50)에 사용자의 조작명령을 입력하고, 이에 따라 상기 고주파 발생부(20)에서 발생되는 주파수의 크기 및 주기를 변경시킬 수 있다(S150).

[0074] 이후, 동작 시간 및 횟수가 종료되면 상기 고주파 발생부(20)의 동작을 정지시킨다(S160~S170).

[0075] 이때, 표시부(60)는 상기 제어부(50)의 처리 결과 및 기기의 동작 상태를 표시할 수 있다.

[0076] 이상과 같이 본 발명은 비록 한정된 실시예와 도면에 의해 설명되었으나, 본 발명은 상기의 실시예에 한정되는 것은 아니며, 이는 본 발명이 속하는 분야에서 통상의 지식을 가진 자라면 이러한 기재로부터 다양한 수정 및 변형이 가능하다. 따라서, 본 발명 사상은 아래에 기재된 특허청구범위에 의해서만 파악되어야 하고, 이의 균등 또는 등가적 변형 모두는 본 발명 사상의 범주에 속한다고 할 것이다.

도면의 간단한 설명

[0077] 도 1은 본 발명에 따른 고주파 침봉기를 나타낸 블록 구성도.

[0078] 도 2는 본 발명에 따른 시술침 모듈의 구조를 나타낸 사시도.

[0079] 도 3은 본 발명에 따른 시술침의 배열 구조를 나타낸 평면도.

[0080] 도 4는 도 3의 시술침 배열에 따른 바이폴라 구동방식을 설명하기 위한 도면.

[0081] 도 5는 본 발명에 따른 고주파 침봉기의 제어과정을 나타낸 순서도.

[0082] <도면의 주요 부분에 대한 부호의 설명>

[0083] 10 : 전원부 20 : 고주파 발생부

[0084] 30 : 시술침 모듈 31 : 어댑터

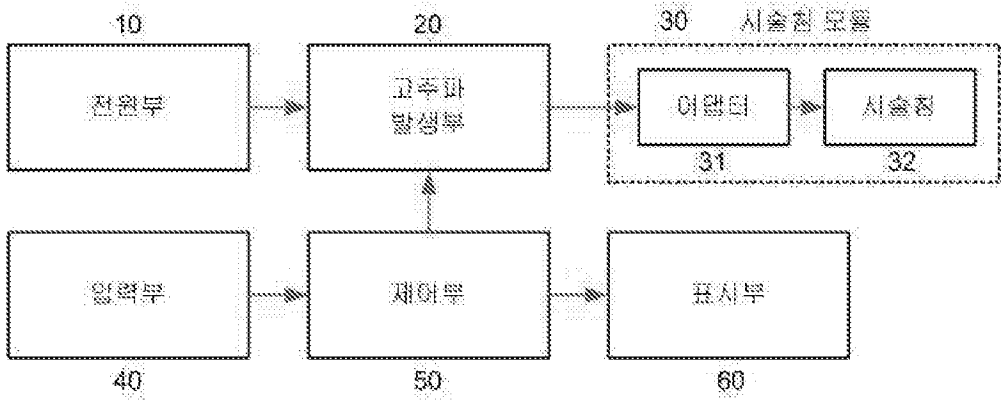
[0085] 32 : 시술침 33 : 노브

[0086] 40 : 입력부 50 : 제어부

[0087] 60 : 표시부

도면

도면1



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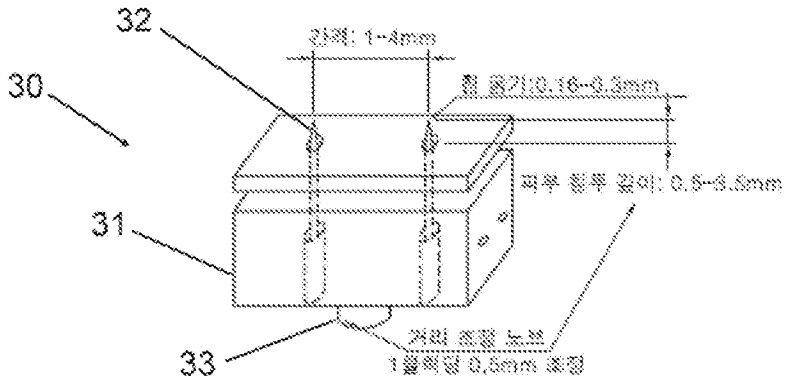
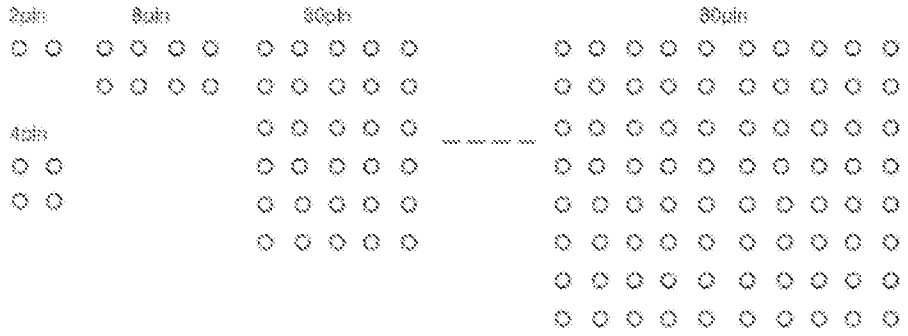
도면2



도면3



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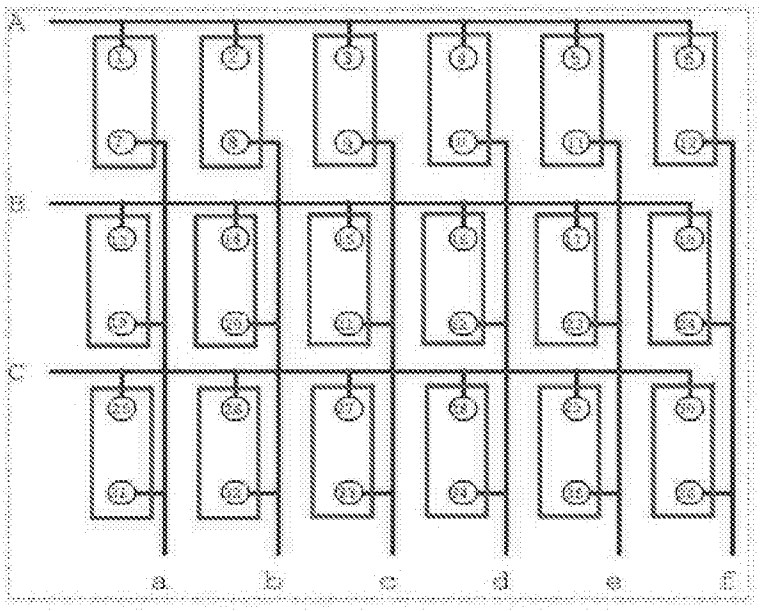
도면4



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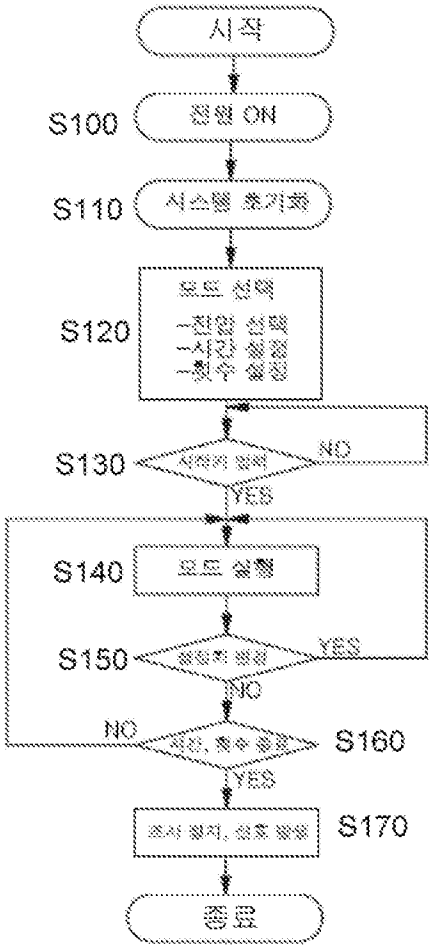
도면5



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(19) 대한민국특허청(KR)
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(71) 출원인
양원동
서울시 관악구

(72) 발명자
양원동
서울시 관악구

(74) 대리인
김건우

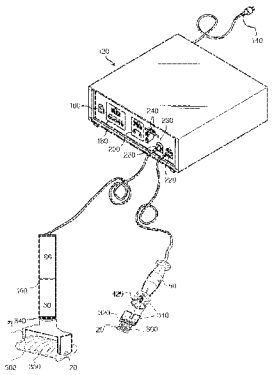
전체 청구항 수 : 총 15 항

(54) 기능성 침체

(57) 요 약

본 발명은 피부미용, 탈모치료, 비만치료 등을 위한 다중천공 시술 장치 및 방법에 관한 것으로서, 더욱 상세하게는 여러 개의 침이 식립된 침체로 인체의 피부에 구멍을 뚫을 수 있으며 시술시간을 단축할 수 있고 시술시의 통증을 최소화할 수 있는 등 시술의 효과를 극대화할 수 있고 특히 다양한 전기파로 이루어진 전기 자극 침체가 인설되어 미세전류 발생장치로부터 발생한 미세전류인 전기파를 이용하여 인체를 자극하여 통증완화와 치료효과를 증진할 수 있는 전기 자극 침체가 인설된 기능성 침체에 관한 것이다.

대 표 도 - 도6



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특허청구의 범위

청구항 1

다수의 침이 식립된 침채부(300)에 인설된 전기 자극 침채 몸체(20)와 전기파를 발생하는 제어부 몸체(120)와 사용자가 파지하는 손잡이 부(60)로 구성되며,

상기 제어부 몸체(120) 또는 손잡이부(60)에는 전기파 발생부(40)와 이를 작동하는 작동 스위치(160)와 조절 스위치(180)와 표시부(200)와 모드 선택 스위치(240)와,

압축기를 통한 에어 발생기(20)와 이를 상기 전기 자극 침채 몸체(20)로 연결하여주는 연결 케이블(260) 또는 에어 분출구(220)가 제어부 몸체(120)에 인설되는 것을 특징으로 기능성 침채.

청구항 2

침채부(300)는 침채가 탈 부착되는 침채 탈 부착부(340)가 구성되고 회전 작용 또는 왕복작용을 하는 침채부(300)상에 식립되어 침채 헤드 탈 부착부(260)에 의해 손잡이부(60)가 탈 부착되며 상기 침채부(300)를 고정해주는 침채 고정부재(220)로 구성되는 것을 특징으로 기능성 침채.

청구항 3

제2항에 있어서,

상기 침채부(300) 또는 침 삽입 홀(360)에 전기파가 통전 되도록 전기파 발생부(40)로부터의 연결단자(280) 또는 접속단이 설치되며 상기 전기 자극 침채에서 발생하는 전기파의 세기와 종류를 설정하는 조절 스위치(180)와 상기 설정된 특성들을 표시하는 표시부(200)와 컨트롤러의 작동을 제어하기 위한 작동스위치(160)와 모드 선택 스위치(240)가 제어부 몸체(120) 또는 손잡이부(60)에 부착되는 것을 특징으로 기능성 침채.

청구항 4

제3항에 있어서,

상기 전기파 발생부(40)는 트랜스포머의 전기파 발생 회로부(PCB)상의 코일로부터 스파이크 펄스를 출력하는 스파이크 펄스 발생 회로 부가 제어부 몸체(120) 또는 손잡이부(60) 내부에 인설되며, 상기 스파이크 펄스 발생 회로로부터 제공되는 한쪽의 전극이 되는 복수의 침채부(300)를 갖는 양 전극부 또는 상기 스파이크 펄스가 제공되는 다른 쪽의 전극이 되는 음 전극부를 구비하여 상기 침채부(300)와 연통 되어진 것을 특징으로 기능성 침채.

청구항 5

전기 자극 침채 몸체(20)의 치료 전기인 스파이크 펄스의 주파수는 9.0±0.2Hz, 펄스 폭은 100~800㎲ 범위이며 펄스 폭 기간의 양의 피크 전압치가 1.5~100V가 되며 상기 펄스 폭 기간에서 양전극부 전압이 소정 전압치 이상을 유지하도록, 상기 출력 트랜스포머의 코일의 감은 수의 비를 설정하여 전기파가 발생하는 것을 특징으로 기능성 침채.

청구항 6

제1항 내지 제5항 중 어느 한 항에 있어서,

손잡이부(60)에 연결 케이블(260)을 통해 침채부(300)의 침채로 전기파가 전달되는 연결 단자(280)가 구비되고, 상기 제어부 몸체(120) 또는 손잡이부(60) 내부에 인설되어 공급되는 전원을 미세 직류전류로 변환시키는 전기파 발생부(40)가 구비되며, 상기 제어부 몸체(120) 또는 손잡이 부(60)상에 전기파 발생부(40)로 공급되는 전원을 제어할 수 있는 작동 스위치(160) 및 상기 작동 표시부(200)가 구비된 것을 특징으로 기능성 침채.

청구항 7

제1항에 있어서,

전기 자극 침채 몸체(20)에 공급되는 전원은 콘덴서와 저항과 트랜지스터 및 가변저항과 연결되며 상기 작동 스위치(160)가 켜(on)지면 상기에서 공급된 전원이 상기 콘덴서를 충전시키기 위하여 가변 저항 측으로 흐름과

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동시에 트랜지스터의 컬렉터에 인가되고, 콘덴서가 충전될 때까지 가변저항 측으로 흐르는 전류는 저항과 저항에서 발생하는 전압 강하분 만큼만 트랜지스터의 베이스 측으로 흐르고, 이후 콘덴서의 충전이 끝나면 콘덴서는 디커플링 콘덴서의 역할을 하게 되어 전류는 트랜지스터의 베이스에 그대로 인가됨으로써 미세 전기파가 침체부(300)에 발생 되어 표피에 전달되는 것을 특징으로 기능성 침체.

청구항 8

제7항에 있어서,

전기 자극 침체 몸체(20)의 전기파를 발생시키는 전기파 발생부(40)는 적어도 하나의 전기파 발생부(40)를 포함하는 것을 특징으로 기능성 침체.

청구항 9

제8항에 있어서,

상기 전기 자극 침체 몸체(20)의 침체부(300)에 형성된 침체 일측에 양극(+) 및 음극(-)의 전극이 맞개 장착되어 상기 침체부(300)에 전기파를 전달하는 것을 특징으로 하는 기능성 침체.

청구항 10

제9항에 있어서,

상기 침체부(300)는 피시술자의 피부 상에서 가압할 수 있도록, 상기 침체부(300)에 탈부착 되는 손잡이부(60)가 구성되고 상기 다수개의 침체부(300)에 전기파가 통전 되도록 전기파발생 장치로부터의 연결단자(280)와 접속되는 전기파 입력부를 포함하는 것을 특징으로 하는 기능성 침체.

청구항 11

제10항에 있어서,

상기 침체부(300)에는 형성된 다수개의 침체부(300)의 끝에는 상기 전기파 발생 장치에 의해 라디오파, 초음파, 고주파, 중주파, 저주파 중 선택된 어느 하나가 전기파가 전기파 발생부(40)에 의하여 발생하여 피부 표면에 전달되는 것을 특징으로 하는 기능성 침체.

청구항 12

제11항에 있어서,

상기 전기파 발생부(40)를 갖는 제어부 몸체(120)에는 출력단에 각기 연결되는 +/- 도전판과, 상기 침체부(300)와 결합하면서 상기 +/- 도전판에 각각 연결되며 인체에 접촉시 전류를 발생시키는 전극이 구성된 것을 특징으로 하는 기능성 침체.

청구항 13

제12항에 있어서,

상기 자극기 본체(20), 해드 부(40)와,손잡이부 (60)와 ,작동스위치(160)로 이루어지고 다수의 침(100)이 식립된 침 다발(120)과 이를 고정하는 침 다발 고정부(140)와 상기 침 다발이 부착된 침 결합 판(160)과 이와 연통된 진동판(200)과 이를 전원에 의하여 회전 유동하는 구동 부재(180)가 부착되고 상기 구동부재(180)의 회전운동을 직선운동으로 바꿔주는 크랭크부(400) 및 캠 축으로 구성되어 상기 침체가 피부 및 두피에 왕복 자극하는 것을 특징으로 하는 기능성 침체.

청구항 14

제13항에 있어서,

상기 침체 구동부재(420)는 전동모터, 에어 터빈, 초음파 중 선택된 어느 하나이고 상기 크랭크 부(380)는 침체 구동 부재(420)에 의한 회전운동을 캠 부(400)를 통하여 왕복 운동하는 것을 특징으로 하는 피부자극기.

청구항 15

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제14항에 있어서,

상기 침체부(300) 에는 자력이 발생하는 자석으로 된 것을 특징으로 하는 피부자극기.

명 세 서

발명의 상세한 설명

기 술 분 야

[0001] 본 발명은 상기하였듯이 피부 자극 및 치료용으로 사용되는 침체의 일측부에 부착된 전기 자극 침에 관한 것으로서, 더욱 자세하게는 통증을 완화하고 제거하는 치료 효과를 보다 높일 수 있는 침체에 인설된 전기 치료기를 침체에 부여할 수 있는 기능성 침체를 제공하는 데 있다.

[0002] 본원발명의 침체의 시술법으로는 한방에서 시술하는 시침방법과 양방병원 피부과에서 시술하는 탄산가스 및 레이저를 이용한 탄산 요법, 프락셀 레이저 치료법이 있으나, 고가의 시술비용과 시술 후 부작용과 더불어서 치료기간 동안 일상생활에 규제가 따른다는 점에서 최근에는 의료기관이 아닌 가정에서 상기의 침이 박힌 롤러를 이용하여 피부미용을 실시하고 있다.

[0003] 본원에서 사용하는 침체 헤드부에 부착되는 침은 종류가 매우 다양하여 가장 가는 것은 그 지름이 0.1㎜ 이하이며 가장 두꺼운 것은 지름이 0.5㎜ 이상이 되는 것도 시중에 판매가 되고 있고 가는 것일수록 피부자극이 덜하여 사용시 고통이 감소하고 상기 침의 구경의 두께가 굵을수록 삽입시 통증이 증가하는 한편 피부에 더 많은 자극을 주므로 효과가 뛰어나다 할 수 있으며 침의 길이도 길이가 짧은 0.5㎜부터 2㎝ 이상이 되는 기다란 롤러 침이 시중에 출시되고 있다.

[0004] 종래의 예리한 다량의 침이 식립된 침체는 고가이다 보니 대부분의 사용자가 하나를 구입하여 사용하는데 상기의 롤러를 피부에 사용하다 보면 인체의 방어기전의 원리로 외부 침투 물질로부터 피부가 저항하는 인체 인체표피층과의 충격이나 피부의 마찰 또는 사용중 주위의 물리적인 충격으로 상기 침 끝이 휘거나 마모되는 문제점이 발생하였으며 특히 상기의 롤러 침을 장기간에 걸쳐서 사용하다 보면 상기의 롤러 침을 가정에서 재아무리 살균이나 소독을 한다 하여도 상기의 롤러 침의 사용시에 접촉되는 인체의 혈액이나 분비물과 고름 등이 묻게 되어 자칫하다가는 교차 감염이 발생할 수 있는 문제점이 대두하였다.

[0005] 결국에는 이를 해결하려면 상기 침체 전체를 교환하는 비용지출과 경제적 손실이 발생하였다.

[0006] 본원 발명은 상기와 같은 문제점을 보완하여 사용중 침 끝이 마모나 파손된 침이 식립된 침체를 간편하게 분리하고 상기의 새로운 침체를 간단하게 부착하고 침 시술시 전기 자극 침체를 작동하여 고통 없이 효과 있게 시술하는데 그 목적이 있다.

[0007] 상기 목적을 달성하기 위하여, 본 발명은, 전기파 치료기에 있어서, 전기파를 발생시키는 전기파 발생부와; 상기 전기파 발생부를 수용하며, 파지할 수 있는 손잡이부를 갖는 본체와 전기파 발생부로부터 발생된 전기파가 출력되는 적어도 하나의 전기파 발생부를 포함하는 것을 특징으로 하는 전기파 치료기를 제공한다.

[0008] 또한, 상기 본체에는 상기 전기파 발생부로 전원을 공급하는 전원 공급부와, 상기 전기파 발생부의 작동을 제어하는 제어부가 마련되어 있는 것이 바람직하다.

[0009] 본원에서는 전기파 침은 일면에 다수개의 침체가 삽입된 침체부의 중심축 상에서 상기 침체부에 결합하는 손잡이부, 및 손잡이부에 결합하며, 다수개의 금속성침체에 전기파가 통전 되도록 전기발생 장치로부터의 연결단자와 접속되는 전기 입력부를 구비한다.

[0010] 또한, 본원에서 사용되는 전기자극은 흔히 일반적으로 간섭파(Interference)라고 부르며 간섭파란, 서로 다른 중주파를 교차시킬 때에 인체 안에서 만들어지는 파형을 말하며 이러한 것을 고전적 간섭파형(Classic Interference) 혹은 4극 간섭파(4-pole IF)라고 부르며 독일의 네멕(Nemec)이라는 사람이 가장 먼저 발견하였다고 하여 네멕간섭이라고도 부르는데 용어적인 차이는 있지만, 이러한 파형은 모든 간섭파 치료기 기들이 다 갖고 있는 기본적인 파형이다.

[0011] 이러한 파형을 대각선으로 교차시키면, 흔히 말하는 클로버형태의 간섭파 형이 몸 안에서 만들어지게 되는데, 이러한 간섭파는 주로 4000Hz 이상의 중주파(혹은 5000 Hz) 혹은 그 이상의 주파수를 사용하며, 이러한 높은 주파수는 피부 저항이 적기 때문에 상대적으로 많은 전류를 인체 내에 효과적으로 보낼 수가 있는 것이다.

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[0012] 또한, 인체 내에서 발생하는 간섭파로 치료하기 때문에, 경피 신경만을 자극하는 일반 저주파 치료기보다 침투 깊이가 더욱 깊으며 더욱 넓은 부위를 자극할 수가 있다.

[0013] 한편, 인간은 나이가 들어감에 따라 안면근육은 자연스러운 탄탄함과 탄력을 잃게 되어 주름살이 생기거나 피부의 처짐이 발생하게 되므로, 가장 눈에 잘 띄는 얼굴의 주름살과 처짐을 방지하기 위한 피부관리에 신경을 쓰게 된다. 특히, 얼굴의 주름살과 처짐 등을 방지하기 위한 가장 쉬운 방법으로 화장품을 이용하여 안면 피부관리를 수행하고 있다. 이때, 화장품을 이용하여 피부를 관리하는 경우에는 피부 인체 표피의 각질층 밑에는 두꺼운 단백질 보호층으로 방어벽이 형성되어 있고, 이 단백질 보호층에 의해 피부의 인체 표피와 진피층이 분리되어 있으므로 피부보호 효과가 우수한 화장품을 사용하더라도 진피층에 쌓인 노폐물을 제거하지 못하고, 화장품의 영양이 진피층까지 깊숙하게 침투되지 못하여 피부보호의 효과가 미흡한 등의 한계가 있었다.

[0014] 그러나 전기자극을 하여주면 시술시 통증을 줄여주고 콜라겐과 탄성섬유의 생산을 증가시키고 피부 세포를 재생시키는 기능뿐 아니라 세포재생과 혈류증가로 인해 피부를 건강하고 탄력 있게 하여 주어 피부 보호 및 관리에 탁월한 효과를 인정받고 있다.

[0015] 종래의 침체는 피부에 기공만 형성하는데 비하여 본 발명은 상기 침체에 의하여 피부를 일차적으로 천공함과 동시에 전기파 펄스가 인체 내부 깊숙하게 공급될 수 있도록 전기적 자극을 가능하도록 하고 또 한편으로는 신경계통을 자극함으로 통증을 완화하는 기능적 목적을 이룰 수 있는 효과가 있는 것이다.

발명의 실시

[0016] 일반적으로 다중천공 시술 방법은 주로 주름, 여드름 제거, 각질 제거 등과 같은 피부 미용 및 두발 건강을 위한 치료법으로서, 피부에 구멍을 낸 후 그 위에 약물 또는 화장품을 발라 약물 침투가 빠르고 많이 침투하게 하여 약효를 극대화하는 방법과, 피부에 바늘로 자극을 주어 이에 따른 인체의 반사작용으로 콜라겐이 형성되는 것을 유도하는 방법이 있으며, 주요 시술부위는 얼굴과 두피이다.

[0017] 예를 들면, 인체의 피부에 수백~수만 개의 미세한 구멍을 냄으로써, 미세한 구멍을 내는 과정에서 손상된 피부 조직의 자생력을 이용하여 새살이 돋아나게 하고, 미세한 구멍이 생긴 부위에 치료용 약물을 도포하여 이 약물이 미세한 구멍을 통해 피부 속으로 빠르게 침투할 수 있도록 하여 시술의 효과를 극대화할 수 있는 방법이다.

[0018] 본원발명에서 사용되는 전기 자극 침체는, 침체로 인체의 표피에 수많은 기공을 형성하고 인체에 전류를 흐르게 하는 작용에 의해 치료를 행하기 때문에, 인체의 생리적 매커니즘과 밀접하게 관계되며 통상, 통증은, 통증의 원인이 되는 자극에 의해서, 말초 신경으로부터 중추 신경인 척수를 경유하여, 대뇌에 이르러 통증을 자각하는 것이 이미 신경 면역학에 의해 명백하게 되어 있다. 이때, 척수 레벨에서 자극이 전달되었을 때, 운동 신경이 흥분하여, 근육의 긴장이 일어난다.

[0019] 또한, 교감신경이 작동하고, 부신으로부터 카테콜아민이라고 하는 물질이 분비되며 다음으로, 혈관의 수축이 일어나고, 세포 조직에 혈액 부족이 발생한다.

[0020] 이 이상한 대사가 계속되었을 때에 통증 발생 물질로 알려진 브라디키닌이나 세로토닌이 분비된다. 그리고 이들의 물질이 말초 신경으로부터 척수를 경유하여 대뇌에서 재차 통증이 인식되는 메커니즘이 작용한다.

[0021] 한편, 인체는, 신경의 작용과 이온에 의한 전기 신호에 의해서 밸런스가 조정되고, 고유의 주파수가 존재하는 것도 알려져 있다. 예를 들면, 심장으로부터는 심장 전류, 뇌로부터는 뇌파, 신경이나 근육으로부터는 동작 전류, 부상을 당한 부위에서는 손상 전류 등이 생기고 있고, 이것은 미약 전류 이론이라고 불리고 있다. 구체적으로는, 세포의 내측에는 플러스의 전하가, 외측의 세포막에는 마이너스의 전하가 많아지고, 균등하게 이온 균형을 잡음으로써 건강이 유지된다.

[0022] 일반적으로 이온 밸런스는, 칼륨 이온과 나트륨 이온에 의해서 행해지고, 세포막의 내측은 칼륨 이온이 많고, 역으로 세포막의 외측에서는 칼륨 이온이 적고 나트륨 이온이 많아지고, 이것이 대뇌나 신경 세포의 말단의 정보에 의해서 조정되고 있다.

[0023] 또, 뇌파에 있어서도, 일상생활이나 긴장 상태 시에는 13Hz 이상의 베타파가 되고, 적당한 릴랙스 상태일 때에는 7Hz ~13Hz의 알파 파가 되고, 명하니 있는 상태나 졸음이 있을 때에는 4Hz ~7Hz의 세타파가 발생한다.

[0024] 본 발명은 상기하였듯이 피부 자극기로 사용되는 침체에 부착된 침의 제조방법에 관한 것으로, 더욱 자세하게는 침체에 부착되는 다수개의 침이 부착된 어셈블리를 간단하게 단턱이나 끼움식, 자석 등으로 탈부착 설치할 수 있으며 작업공정을 개선하여 생산성이 향상되고 소비자의 사용시 비용이 적게 드는 전기 자극 침체에 관한 것이

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다.

[0025] 상기의 침은 인체 인체표피층을 상하지 않게 하면서도 레이저 박피나 필링 시술 때와 같은 자연치유적 콜라겐 생성 유도로 노화된 피부를 환원시킬 수 있으며, 피부 표면에 국소 마취제를 도포한 후 병변 부위에 롤러를 이용한 시술을 함으로써 흉터나 튼 살, 주름개선 및 여드름 흉터 개선에 효과적이며 특히 미세한 바늘이 피부에 침투되면서 진피조직을 섬유계 구성하고 재배열 시켜주기 때문에 모낭의 파열을 최소화하고, 피부의 변형이나 세포의 괴사를 막아주며 인체의 피부 면을 자극하여 콜라겐 합성과 흉터 회복을 촉진시켜 주는 기법이라 할 수 있다.

[0026] 본원 발명의 유사 선행기술로는 먼저 일본국 특허 출원번호: 10-1994-0001485, 공개번호: 10-1995-0023388, 등록번호: 10-0143375-0000, 발명의 명칭: 초음파미용, 건강 장치가 있는데, 상기 기술은 손잡이부를 가진 본체의 일단 부에 중공 원통 롤러를 회전이 자유롭게 지지하고, 이 중공 원통 롤러의 내부에 초음파 발생 부를 설치하고, 이 중공 원통 롤러 자체가 상기 초음파 발생부에 의해 진동되는 초음파 진동체를 이루고 있는 것으로 하는 초음파 미용, 건강 장치로서, 단순 회전 원통형 롤러 내부에 초음파장치를 담지하는 기술로 본원 발명과는 기술적 구성이 전혀 다르고;

[0027] 대한민국특허 출원번호: 20-2003-0002185, 출원일자: 2003년01월23일, 고안의 명칭: 피부미용기구는 초음파로 인해 진동하는 압전소자가 부착된 진동판이 피부 면을 따라 슬라이딩 되면서 피부표면을 세정할 수 있도록 된 것으로, 하나 이상의 압전소자와; 금속재질의 막판 형상을 이루되, 케이스 안으로 내장되는 일단 부에는 압전소자가 접착 부재를 매개로 부착되고, 타단 부는 외부로 돌출되어 피부와 접촉돼 는 진동판 및 진동판의 일단 부를 감싸 보호하고 손잡이부 기능을 갖는 케이스로 이루어진 피부미용기구로 통상의 초음파가 부착되고 피부와 접촉되는 진동판; 및, 진동판의 일단 부를 감싸 보호하고 손잡이부 기능을 갖는 케이스로 이루어진 피부미용기구로 본원과는 그 기술적 특징과 구성이 각별하고;

[0028] 출원번호: 10-1999-0019723, 공개번호: 특2000-0075228, 고안의 명칭: 초음파를 이용한 미용기기는 각 장치들에 직류전원을 공급하는 전원공급장치와, 트리트먼트를 위한 시간, 초음파 출력레벨, 웨이스/바디 및 아온/크린 선택을 입력하는 키 입력부와, 상기 키 입력 부로부터 입력된 설정 값에 따라 복수의 디스플레이와 초음파 출력부위 동작을 제어하는 마이컴 제어부와, 상기 마이컴 제어부의 제어신호에 따라 웨이스 무버의 제 1 초음파 진동자 또는 제 2 초음파 진동자 중의 어느 하나에 해당하는 전기파의 초음파 신호를 출력하는 것으로 구성되어있으며;

[0029] 다음으로, 출원번호: 10-2003-0039255, 공개번호: 10-2004-0108504, 등록번호: 10-0507453-0000, 발명의 명칭: 피부미용기기의 안정된 전력관리 방법 및 장치, 그리고 이를 이용한 휴대용 피부 미용기는 전원부 충전 전원을 승압하기 위한 DC-DC 컨버터 부; 초음파 소자 또는 이온 도입을 행하는 피부미용기 구동부; 전원 스위치 및 작동스위치의 스위치 부; 작동상태를 표시하는 디스플레이 부; 및 전원부 충전 전원을 승압하기 위한 DC-DC 컨버터 부; 초음파 소자 또는 이온 도입을 행하는 피부미용기 구동부; 전원 스위치 및 작동스위치의 스위치 부; 작동상태를 표시하는 디스플레이부호 구성되어 상기 선행기술과 유사한 것을 특징으로 하는 피부미용기기의 안정된 전력관리방법으로 기술되어 있으며;

[0030] 출원번호/일자: 10-1999-0037517(1999.09.04), 공개번호/일자: 10-2000-0000074(2000.01.15), 등록번호/일자: 10-0319493-0000(2001.12.19), 발명의 명칭: 피부 미용기는, 마이크로 컨트롤러를 이용하여 저주파 또는 이온의 작용으로 피부를 관리하는 미용기에 있어서, 전체 회로를 제어하는 마이크로 컨트롤러를 포함하는 중앙처리부와, 상기 중앙처리부에 외부 신호를 입력시키는 다수의 키 스위치를 갖는 스위치 입력 부와, 상기 입력된 외부 신호에 기초하여 상기 중앙처리부의 제어하에 출력 강도가 상이한 제1의 출력과 제2의 출력을 발생하는 초음파 출력 부와, 직류 전원을 공급하는 전원부를 포함하여 이루어지는 것을 특징으로 하는 피부 미용기와;

[0031] 출원번호/일자: 10-2003-0026413(2003.04.25), 공개번호/일자: 10-2004-0092184(2004.11.03), 등록번호/일자: 10-0507442-0000(2005.08.02), 발명의 명칭: 피부미용장치는, 모드 선택 스위치, 프로그램작동 스위치, 업다운 레벨작동 스위치와 모드 선택 스위치 및 온/오프 작동 스위치에 의한 각종 제어 및 선택신호를 컨트롤러나 침체에 입력하기 위한 제어부와, 상기 제어부에 의한 각종 제어 및 모드 선택 입력에 따라 전원의 온/오프 제어신호를 생성하고 출력레벨제어를 위한 다단계의 듀티를 갖는 제어펄스를 생성하고 다양한 리프팅 전압 출력을 위한 프로그램별 펄스신호와 각 모드별 출력단자 선택신호를 생성하고 표시부의 각 프로그램 및 모드 표시용 LED 구동신호를 생성하도록 구성하는 것을 특징으로 하는 피부미용장치와;

[0032] 출원번호 10-2007-0010701, 등록번호 10-0794640에는, 발명의 명칭이 전기 자극 침체의 롤러 제조방법인 발명이

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개시되어 있는데, 상기의 침채는 침을 롤러나 침채에 식립하기 위하여 화학약품으로 부식한 후 접착제를 도포하여 고정시켰던바 상기의 화학물질이나 접착제가 신체에 영향을 미칠 수 있으며 제조공정이 복잡하여 시간이 오래 걸리고 사용시 침이 빠지거나 들어가는 현상이 발생할 수 있는 문제점이 발생하였다.

[0033] 이처럼 상기의 다수의 저주파나 미용기 관련 기술이 출원 또는 등록되어있음을 알 수 있으며 각기 저마다 특정된 기술로 기재되었지만 본원에서처럼 피부 자극 및 천공을 위하여 사용하는 다양한 침이 식립 되어 있는 침채부 및 침채 구동 부재 및 손잡이부를 회전 몸체 결합요 홈 또는 단턱 및 자석이나 나사 산을 통하여 간편하게 탈부착하여 사용자의 선택에 따라서 종류별로 사용할 수 있으며 무엇보다 신체에 부착하는 패드를 사용하지않는 전기 자극 침채는 아직 개시되지 않았다.

[0034] 상기에서 말했듯이 처음에는 예리하였던 롤러나 침채에 부착된 침 끝이 점차 무뎌지게 되거나 세균에 노출되어 장기간에 걸쳐서 사용을 할 수 없고 결국에는 상기 침채 전체를 교환하는 비용지출과 경제적 손실이 발생하였다.

[0035] 이러한 다중천공 시술 방법은 피부를 벗겨내어 손상된 피부가 재생되는 것을 이용하여 주름이나 색소침착이 치료되는 기존의 시술법(레이저, 박피 등)과는 달리 인체 표피를 제거하거나 손상시키지 않고 자체 콜라겐 생성을 유도하는 신개념 세포 복원 방법이라 할 수 있다.

[0036] 부작용없이 간편하고 안전한 다중천공 시술 방법은 다수의 침이 피부에 침투되면서 발생하는 자연적 상처치유(Wound healing)작용으로 진피조직이 새로이 구성되고 재배열되기 때문에 흉터가 얇아지고, 피부가 팽팽하게 당겨지면서 잔주름이 감소하고 색소침착이 개선되어 건강하고 깨끗한 피부로 되돌아갈 수 있다.

[0037] 또한, 수백 개의 침이 몇 분 동안에 수백~수만 개의 엄청난 통과 통로를 제공하여 최신 활성 펩타이드 등의 유효성분을 전달함으로써 치료 효과를 더욱 극대화시킬 수 있다.

[0038] 인체의 피부에 다중천공을 형성하는 방법으로는 상기한 롤러(Multi roller needle)를 이용하는 방법과 다수의 침채가 식립된 침채를 왕복 운동하거나 레이저를 이용하는 다양한 방법 등이 있다.

[0039] 한편, 메조테라피 시술은 비만치료, 튼살, 주름제거, 탈모치료 등을 위하여 치료용 약물을 침채를 통해 인체에 주입하는 시술로서, 먹는 약 또는 바르는 약보다 정확한 효과를 낼 수 있는 치료 방법이다.

[0040] 이와 같이 다중천공 시술은 인체 피부에 구멍을 내고 나서 그 위에 약물을 도포하는 방법으로서, 롤러를 이용하는 방법, 침채를 왕복 운동하는 방법, 레이저를 이용하는 방법, 니들건을 하는 방법 등이 있으나, 이러한 시술법들은 구멍을 낸 후, 약물을 도포함으로써 시술시간이 길고, 또한 도포한 약물이 100% 인체에 흡수되지 않으므로 많은 양의 약물을 사용해야하는 단점이 있다.

[0041] 또한, 메조테라피 시술의 경우 침채를 1개 사용하여 약물을 주사하기 때문에 비만치료, 탈모치료 등과 같이 많은 횟수의 주사가 필요한 경우에는 시술시간이 길어지고, 또한 주사에 수반되는 통증이 커지는 문제가 있다.

[0042] 본원 발명은 상기와 같은 문제점을 보완하여 사용중 침 끝이 마모나 파손된 침이 식립된 침채의 침채가 간편하게 분리하고 새로운 침채부를 부착하여 안전하고 고통 없이 전기자극을 동반하여 인체에 편리하고 효과 있게 시술하는데 그 목적이 있다.

발명의 내용

해결 하고자하는 과제

[0043] 본 발명은, 침채부에 전기파를 부여하는 기능성 침채에 관한 것으로서, 더욱 상세하게는, 휴대가 간편하며, 신체의 모든 부위에 사용할 수 있는 전기파를 부여하는 침채에 관한 것이다.

[0044] 일반적으로 전기파 치료기는 전기파를 이용하여 신체의 자극점을 자극함으로써, 각종 질환을 예방하거나 치료하는데 널리 사용되고 있다.

[0045] 근래에는, 신체에 부착되는 접착 패드를 마련하고, 접착 패드에 전기파를 흘려 신체의 자극점을 자극하는 전기파 치료기가 널리 보급되어 있다.

[0046] 이러한 접착 패드를 이용하는 전기파 치료기는, 접착 패드가 부착되는 신체 부위에 전기파가 잘 흐르도록 접착력이 있는 물질이나 물파스 등과 같은 약제를 도포하여 사용하게 된다.

[0047] 그런데 종래의 전기파 치료기에 있어서는, 전기파를 발생시키는 전기파 발생부와 접착 패드가 분리되어 있어 휴

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대가 간편하지 않을 뿐만 아니라 접착력이 있는 물질과 젤 등을 신체에 도포하여 사용하여야 하므로, 특히 머리카락이 있는 머릿부분 이외에 털이 있는 신체 부위에 접착 패드를 부착하는 것이 곤란하므로 간편하게 사용할 수 없는 문제점이 있다. 즉, 신체의 특정 부위를 사용하는 데 있어 제약이 따르는 문제점이 있다.

[0048] 따라서, 본 발명의 목적은, 휴대가 간편하며, 신체의 모든 부위에 간편하게 사용할 수 있는 전기파 치료기를 제공하는 것이다.

[0049] 또한, 본 발명의 다른 목적은, 근육을 이완시키고 혈액순환을 촉진시켜 인체의 건강을 증진시킬 수 있는 전기파 치료기를 제공하는 것이며 전원 또는 충전전지를 전원으로 사용하여 미세전류 발생장치로부터 발생된 미세 전기파를 이용하여 인체를 자극하여 통증완화와 치료효과를 증진할 수 있는 전기 자극 침체가 인설된 기능성 침체에 관한 것이다.

[0050] 본원의 다수의 침이 식립된 침체는 크게 2가지 작용에 의해서 피부의 문제점들이 해결되는데 하나는 침의 피부 자극에 의해 문제부위에 자가치유능력을 이끌어내기 위해 병원에서는 롤러를 1주에 한번 또는 1달에 두 번 사용하고 가정에서는 매일 또는 주2회 마사지하듯 가볍게 사용하게 되고 이로 이해 탈모, 흉터, 주름, 여드름자국, 색소, 모공, 대머리, 튼 살 및 피부재생능력이 감소하여 동반되는 피부 문제점들을 자연적인 방법으로 어느 정도 해결하게 된다.

[0051] 또 하나는 상기의 피부문제를 치료해줄 약물을 함께 사용하여 피부 각질층에만 발려있던 주요성분(펩티드)들을 피부가 요구하는 깊이 층까지 다수의 침을 이용해 기공을 만들어 신속하게 넣어주는 작용으로 아무리 고가의 화장품 또는 발모 성분들일지라도 피부 인체표피층이나 각질층에만 발라지는 효과가 있었다면 상기 침은 피부 필요 물질을 전기파와 함께 직접 피부 깊숙이 넣어주어 그 효과를 극대화하는 방법으로 미세한 침으로 인체의 피부 면을 자극하여 콜라겐 합성과 흉터 회복을 촉진시켜 주며 동통을 완화해주는 기법을 말한다.

[0052] 또한, 종래의 예리한 다량의 침이 식립된 롤러용 침체는 고가이다 보니 대부분의 사용자가 하나를 구입하여 사용하며 이를 여러 사람이 공동으로 사용하기도 하는데 상기의 롤러를 피부에 사용하다 보면 인체의 방어기전의 원리로 외부 침투 물질로부터 피부가 저항하는 인체 표피층과의 충격이나 피부의 마찰 또는 사용중 주위의 물리적인 충격으로 상기 침 끝이 휘거나 마모되는 문제점이 발생하였으며; 특히 상기의 롤러 침을 장기간에 걸쳐서 사용하다 보면 상기의 롤러 침을 가정에서 재아무리 살균이나 소독을 한다 하여도 상기의 롤러 침의 사용시에 접촉되는 인체의 혈 은이나 분비물과 고름 등이 묻게 되어 타인 사용시에는 자칫하다가는 교차 감염이나 포도상구균과 간염 더 나아가 AIDS 같은 무서운 전염성 병원균에 노출이나 감염될 수 있는 문제점이 대두하였고 결국에는 이를 해결하려면 상기 침체 전체를 교환하는 고 비용의 지출과 경제적 손실이 발생하였다.

[0053] 본원 발명은 상기와 같은 여러 문제점을 보완하여 사용중 침 끝이 마모나 파손된 침이 식립된 침체를 간편하게 분리하고 상기의 새로운 침체를 간단하게 부착하여 새로운 침과 인체의 생리적 매커니즘에 대응하는 주파수, 전압 등의 물리량을 더욱 정밀하게 설정하는데 더하여, 파형의 동적 변화에 대해서도 최적의 설정을 행하여, 통증을 완화하고 제거하는 치료 효과를 보다 높일 수 있는 전기 자극 침체를 제공하는 데 있다.

[0054] 또, 본 발명의 다른 목적은, 종래의 전기 치료기에 비하여, 특히, 대폭적인 추가 부품이나 구조적 변경을 동반하는 일 없이 용이하게 실시할 수 있고, 저 비용화 및 소형 콤팩트 화에 기여할 수 있는 전기 자극의 기능을 갖는 기능성 침체를 제공하는 데 있다.

과제 해결수단

[0055] 상기 목적을 달성하기 위해, 본 발명의 전기파 자극기가 인설된 침체에는 출력 트랜스포머의 코일로부터 스파이크 펄스를 출력하는 스파이크 펄스 발생 회로부와 손으로 쥘 수 있는 손잡이부와 이 손잡이부의 내부에 상기 전기 자극장치를 설치하게 된다.

[0056] 또한, 스파이크 펄스 발생 회로로부터 출력하는 스파이크 펄스가 제공되는 한쪽의 전극이 되는 복수의 침 도전체를 갖는 양전극부 및 상기 스파이크 펄스가 제공되는 다른 쪽의 전극이 되는 음 전극부를 구비하여 이루어진 전기파 치료기를 구성할 때에, 스파이크 펄스의 주파수를 바람직하게는 9.0±0.2Hz, 펄스 폭을 100~800㎲ 중 선택된 어느 하나의 상태로 설정하는 동시에, 인체의 부하 저항에 대응하는 10~400KΩ 부하로 인가하는 스파이크 펄스의 펄스 폭 기간의 양의 피크 바람직하게는 전압치가 1.5V~100V가 되고, 또한 펄스 폭 기간에서 양의 전압이 소정 전압치 이상을 유지하도록, 출력 트랜스포머의 코일의 감은 수의 비를 설정하여 이루어지는 것을 특징으로 한다.

[0057] 본원의 침체와 연통되어 전기파를 공급하는 제어부 몸체 및 전기 자극 침체부 내에 삽설된 전기파 자극기는 인

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체에 부착되는 패드 사용이 없이 전원을 통하여 발생시킨 전기파 펄스를 침체에 공급함으로써 인체 시술시에 통증 완화와 더불어서 주무름, 두드림, 진동효과 등의 전기적인 자극을 가하는데 목적이 있는 것이다.

효 과

[0058] 이상, 설명한 바와 같이, 본 발명에 따른 전기 자극 침체가 부착된 침체에 의하면, 종래의 침이 식립된 롤러용 침체는 분해 및 착탈이 안 되는 단 일체이고 일체형이다 보니 분업이 어려워 제조공정이 까다롭고 구입비용이 고가이다 보니 대부분의 사용자가 하나를 구입하여 사용하고 고장시나 침의 마모시는 전체를 폐기해야하는 문제점으로 특히 상기의 롤러를 피부에 사용하다 보면 인체의 방어기전의 원리로 외부 침투 물질로부터 피부가 저항하는 인체 인체표피층과의 충격이나 피부의 마찰 또는 사용중 주위의 물리적인 충격으로 상기 침 끝이 휘거나 마모되는 문제점이 발생하였으며; 특히 상기의 롤러 침을 장기간에 걸쳐서 사용하다 보면 상기의 롤러 침을 가정에서 제아무리 살균이나 소독을 한다 하여도 상기의 롤러 침의 사용시에 접촉되는 인체의 혈액이나 분비물과 고름 등이 묻게 되어 자칫하다가는 교차 감염이 발생할 수 있는 문제점이 대두하였고 결국에는 이를 해결하려면 상기 침체 전체를 교환하는 비용지출과 경제적 손실이 발생하였다.

[0059] 또한, 종래의 전기파 치료기에 있어서는, 전기파를 발생시키는 전기파 발생부와 접촉 패드가 분리되어 있어 휴대가 간편하지 않을 뿐만 아니라 접착력이 있는 물질과 젤 등을 신체에 도포하여 사용하여야 하므로, 특히 머리카락이 있는 머릿부분 이외에 털이 있는 신체 부위에 접착 패드를 부착하는 것이 곤란하므로 간편하게 사용할 수 없는 문제점이 있었고 "즉" 신체의 특정 부위를 사용하는 데 있어 제약이 따르는 문제점이 있다.

[0060] 본원 발명은 상기와 같은 문제점을 보완하여 사용중 침 끝이 마모나 파손된 침이 식립된 침체를 간편하게 분리하고 상기의 새로운 침체를 간단하게 부착하여 새로운 침으로 고통 없이 효과 있게 시술하는데 그 목적과 효과가 있는 것이다.

[0061] 또한, 본 발명의 전기적인 펄스에 의해, 인체의 생리적 메커니즘에 대응하는 주파수, 전압 등의 물리량을 더욱 정밀하게 설정하는데 더하여, 파형의 동적 변화에 대해서도 최적의 설정을 행하여, 통증을 완화하고 제거하는 치료 효과를 보다 높일 수 있다.

[0062] 이와 같이 본 발명은 다수 개의 침체로 인체의 피부에 구멍을 내고 이와 동시에 약물을 주입함으로써, 시술시간을 줄일 수 있고, 시술시 통증을 최소화할 수 있으며, 약물의 침투 효과를 높일 수 있는 저렴한 비용으로 다중 천공 시술 및 매조테라피 시술할 수 있는 장점이 있으며 깊은 부위의 시술이 가능하여 부위별 시술 또한 가능한 장점이 있다.

[0063] 또한, 본 발명의 다른 목적은, 근육을 이완시키고 혈액순환을 촉진시켜 인체의 건강을 증진시킬 수 있는 전기파 치료기를 제공하는 것이다.

발명의 실시를 위한 구체적인 내용

[0064] 본원발명은 피부 표피에 사용하여 기공을 형성하고 여기에 더불어서 전기 자극이 되는 기능성 침체에 관한 것으로, 더욱 상세하게는 피부조직의 효과적인 치료 및 재생을 위한 전기파 자극기가 부착된 침체에 관한 것이다.

[0065] 다양한 전기파로 이루어진 전기 자극 침체가 인설된 침체는 한의학에 주로 사용하는 다양한 침을 원통형 또는 라운드 및 다각형 형태의 롤러나 일정형상의 침체에 삽입하고 여기에 소정의 전기파를 인가시켜 피부보호, 노화방지 등을 위한 피부를 관리함에 있어 시술하는 침체에 미세전류 발생장치로부터 발생된 미세전류인 전기파를 이용하여 인체를 자극하여 통증완화와 치료효과를 증진할 수 있는 전기 자극 침체부(300)가 인설된 침체에 관한 것이다.

[0066] 본원발명에서 사용하는 전기자극 요법은 전기자극 원리 중에서 MPS 초미세전류 자극(Microcurrent Pulse Stimulation)이라는 전기파 자극 요법으로 인체의 자극 부위에 패드를 사용하지 않고 다양한 전극으로 미세한 생체전류를 흘려서 신경과 근육의 활동을 자극하는 원리이다.

[0067] 이는 주기적인 펄스를 가하여 침처럼 깊숙이 꼽히는 느낌의 자극을 주는 것으로 자극의 강도는 종래의 침술요법보다 월등한 효과를 제공하며 이 요법은 생체전류를 기본으로 한 서양의학과 동양의학인 침과 뜸의 원리에 대한 한의학이 결합한 것이다.

[0068] 전기요법은 인체에 미세한 전기파를 통하게 하여 그 자극으로 근육을 직접 마사지하고, 신경을 진정시키고 혈행을 촉진시켜 결림 등에 의한 급성 및 만성 통증 등의 완화, 회복을 도와주는 물리치료 요법으로 근육의 수축운동을 일으켜서 신체 기능의 쇠약이나 비만, 질병을 치료하기도 하며 진동(Hz-1초당 진동수)을 시켜 신경 진정

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작용, 근육절환치료, 혈액순환촉진, 마사지, 지방세포 축소 효과로 나눌 수 있는 것이다.

[0069] 이하, 본 발명의 구성을 첨부된 도면을 참조하여 상세하게 설명하면 다음과 같고 아래에서는 본 발명을 설명함에 있어, 관련된 공지 기능 또는 구성에 대한 구체적인 설명이 본 발명의 요지를 복잡하게 하거나 불필요하게 흐릴 수 있다고 판단되는 경우에는 그 상세한 설명은 생략할 것이다.

[0070] 도 1은 종래의 전기 자극 침채의 일실시 예를 나타낸 사시도를 나타낸 것으로 손가락에 전극을 연결하고 목 부위에 전기자극을 기능성 침채를 사시도로 나타낸 것이다.

[0071] 도 2는 본원 발명의 기능성 침채에 있어 침채의 일실시 예를 나타낸 사시도로서 이를 참조하면, 본 발명에 따른 전기 자극 침채의 구성으로는 전기 자극 침체 몸채(20)와 전기파 발생부(40)에는 사용자가 파지하는 손잡이부(60) 및 침체부(300)를 포함하며 이를 상세하게 설명하면 다음과 같다.

[0072] 여기서, 전기파 발생부(40)에는 전기발생 장치로부터의 연결 케이블(260)을 통한 연결 단자(280)가 삽입되며, 전기 자극 침채를 이용한 시술에 필요한 전기가 상기 전기 발생장치로부터 연결단자(280)를 통해 전기 입력부로 입력된다.

[0073] 한편, 손잡이부(60)는 시술자가 본 발명에 따른 전기 자극 침채로 환자에게 시술을 하는 경우에 손으로 잡는 부분으로 손잡이 상부 케이스(80)와 하부케이스(100)로 이루어지며 상기 제어부 몸채(120)에는 전기파 발생부(40)와 이를 작동하는 작동 스위치(160)와 조절 스위치(180)와 표시부(200)와 압축기 등을 통한 에어 발생기(20)와 이를 상기 전기 자극 침채 몸채(20)로 연결하여주는 에어 분출구(220)가 제어부 몸체(120)에 인설되게 된다.

[0074] 또한, 침채부(300)는 시술자가 직접 가압을 하는 부분으로 다수의 예리한 침들이 침삽입홀(360)에 식립 되어 있으며 침채 탈부착부(340)에 의하여 상기 침채부(300)가 자유롭게 탈부착이 되는 것이다.

[0075] 여기서, 상기 침체부(300)는 형성된 전도성 금속소재로 이루어진 침 삽입홀(360)에 삽입되어 고정되어 있으며, 침채부(300)를 기준으로 일정한 길이만큼 돌출되어 있다.

[0076] 이러한 침채는 시술자에 의해 피부 진피층에 삽입된 상태에서 피부조직에 자극 및 소정 전기파의 전기파 자극을 가하게 된다.

[0077] 한편, 본 발명에 따른 전기 자극 침체의 제어부 몸체(120)에는 시술의 용이성을 확보하기 위한 탄성 절편이 적어도 하나 이상 형성되어 있는 것이 바람직하며 제어부 몸채(120)에 삽입된 탄성 절편에는 탄성 특성이 우수한 고무 절편이 사용될 수도 있고, 기타 판형 스프링 등이 사용될 수도 있으며 바람직하게는 시술 용도에 따라 제어부 몸채(120)에 무탄성 절편을 삽입할 수도 있을 것이다.

[0078] 또한, 제어부 몸체(120)에 삽입된 탄성 절편은 예리한 침채가 시술부위의 진피층으로 부드럽게 삽입되어 자극 및 소정 전기파의 진동 자극을 가하도록 하는 기능을 하게 되며 바람직하게는 침의 상태를 자력이 발생하는 자석으로 하여 자기장의 효과까지 볼 수 있게 할 수도 있다.

[0079] 또한, 본 발명에 따른 전기 자극 침채의 침채부(300)는 원통형 또는 타원형 및 다각형 등의 다양한 형상을 하고 있으며, 그 내부 또는 외부에는 다수의 전도성 금속 소재로 이루어진 침 삽입홀(360)이 형성되며 침체가 탈부착되는 침채 탈 부착부(340)가 구성되며 시술부위에 미세상처를 내기 위한 예리한 침채가 삽입되어 고정된다.

[0080] 다만, 본 발명을 실시함에 있어서,침채부(300)에 형성된 전도성 금속소재로 이루어진 침 삽입홀(360)의 개수 및 간격은 시술목적에 따라 적절하게 조정될 수 있을 것이다.

[0081] 또한, 상기 전기파 발생부(40)는 조절 스위치(180)에 인설 되는데 전원(140)을 개폐하는 전원 버튼과 전기파 전류의 강약을 단계적으로 증감, 조절하는 기능이 구성된 작동 스위치(160)와 라디오파, 초음파, 고주파, 중주파, 및 저주파 등의 전기 자극을 선택하여 출력하는 모드 선택 스위치(240)와 전원 버튼의 ON/OFF상태와 현재의 작동 상태를 알리는 램프가 구성된 표시부(200)로 이루어진 것을 사시도로 나타낸 것으로 상기의 전기 자극 침체, 헤드에 결합하고 전기파 발진회로기판(PCB)의 출력단에 단자로 연결된 도전판과, 침채부(300)와 결합 및 해체되고 도전판에 각기 연결된 다수의 전극으로 구성된다.

[0082] 본 발명의 전기 자극 침채는 전기파 발생부(40) 및 타이머 등이 상기 제어부 몸채(120) 내부에 설치되고, 조작 패널이 외부에 설치된 제어부 몸체(120)가 구비된다.

[0083] 여기서 상기 본체의 상부 면에는 상기 본체의 내측 공간부와 연통 됨과 동시에 상기 조작 패널에 연결되는 연결

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케이블(260)이 내측에 배선되어 구비된다.

[0084] 아울러 상기의 조작 패널에 구비된 조작버튼과의 상호 연결을 알리는 숫자 또는 기호 등이 표시된 표시부가 형성된다.

[0085] 또한, 침채 부(300)에 끼워지는 접속부가 구비되어 상기 본체에서 발생하는 전기파를 침으로 전달하는 연결 케이블(260)이 더 구비된다.

[0086] 아울러, 상기 채결 부재에는 바람직하게는 나사 결합되는 커버 부재가 구비되며, 상기 커버 부재는 하부가 개방된 연질의 용기 형상으로 형성되고, 외주 면에 내측과 연통 되는 관통구멍이 형성되며, 상부에는 상기 채결 부재에 나사 결합하도록 나사 산이 형성된다.

[0087] 또한, 상기 커버부는 상기 접속부가 형성된 타측 끝단 부에서 약간 이격되게 하여 외측에 나사 산이 형성되어 손으로 이를 회동하여 채결 부재가 작동되는 것도 바람직하다.

[0088] 또한, 상기 연결 케이블(260)의 끝단 부에는 시술된 침에 연결하는 연결 단자(280)가 구비되며, 상기 채결 부재와 연결 단자(280)의 사이에 연결 케이블(260)이 구비되고, 그리고, 상기 연결 단자(280)는 하부가 개방되게 내측에 삽입공이 형성되고, 외주면 상단의 소정 위치에는 버튼 공이 형성되며, 상부 면에는 상기 연결 케이블(260)이 연결 결합하는 연결단자(280)가 구비되는 것이다.

[0089] 여기서, 상기 몸체의 삽입공에는 고정구가 형성된 고정체가 내주 면에 고정되고, 상기 고정체의 타측부에 대응되는 유동체가 구비되며, 상기 유동체는 상기 고정구에 힌지결합되고, 상기 고정체의 하부와 접촉된 상태를 유지하도록 힌지 결합부에 탄성 부재가 구비되며, 상기 유동체의 상부에는 상기 버튼 공에 채결되어 상기 유동체의 상부를 밀어주어 하부가 고정 체로부터 이탈되어 벌어지도록 하는 버튼이 구비된다.

[0090] 이렇게 상기 커버 부재를 피부에 고정한 후에 연결 케이블(260)의 접속부를 상기 제어부 몸체(120)의 포트에 꺼운 후 본체의 조작패널의 작동스위치(160)와 조절스위치(180)를 조작하게 되면 상기 연결 케이블(260)을 통하여 전기파가 침체부(300)의 구비된 침으로 전달되게 되며 인체의 표피에 전달되게 된다.

[0091] 이때, 상기 커버 부재는 연결 케이블(260)의 채결 부재에 나사 결합 되어 있는 것으로, 사용자의 선택에 따라 커버 부재는 채결 부재에 나사 결합시켜 사용할 수도 있고, 채결 부재로부터 커버 부재를 완전히 분리시켜 제거하여 바람직하게 사용될 수도 있다.

[0092] 상기와 같은 동일한 방법에 의해 다수 개가 시술된 침에 연결 케이블(260)을 연결시켜 전기파를 인가시키게 된다.

[0093] 따라서, 전기파를 침으로 인가시켜줌으로써, 시술자의 피부에 목적하는 시술하게 되어 소정의 치료 효과를 얻을 수 있게 됨으로써, 피부 보호와 피부가 노화되는 것을 방지 등 피부를 건강하게 관리할 수 있게 된다.

[0094] 도 3은 본원 발명의 기능성 침채에 있어 침채의 또 다른 일실시 예를 나타낸 사시도.

[0095] 도 4는 본원 발명의 기능성 침채에 있어 침채와 구동부재의 일실시 예를 나타낸 사시도로서, 본원의 전기 자극 침채 몸체 (20)에는 전기파가 발생하는 전기파 발생부(40)와 사용시 사용자가 파지하는 손잡이부(60)와 상기 손잡이를 개폐하는 손잡이 상부케이스(80)와 손잡이 하부 케이스(100)가 구성된다.

[0096] 한편, 제어부 몸체(120)에는 전원(140)이 입력되는 전원부와 상기 전기 자극 침채 몸체 (20)를 동작하는 작동스위치(160)와 이를 조절하는 조절스위치(180)가 형성된다.

[0097] 또한, 상기 제어부 몸체(120)에는 기기의 작동을 사용자가 육관으로 파악할 수 있는 표시부(200)가 구성되며 기기의 강약이나 시간을 조절하는 모드 선택스위치(240)가 구성되게 된다.

[0098] 제어부 몸체(120)에는 소형 압축기가 인설되어 압축공기를 에어 분출구(220)를 통하여 전기 자극 침채 몸체(20)에 전달하여 상기 침채부(300)가 상하로 유동하거나 회전하게 되는 것이다.

[0099] 한편, 전기 자극 침채 몸체 (20)에는 연결 케이블(260)이 연결단자(280)로 연결되어 침채부(300)가 구동하게 되며 상기 침채부(300)에는 침이 식립되는 침 삽입 홀(360)과 다수의 침을 일정형상의 침채에 고정하는 침채 고정부재(320)와 상기 침채부(300)를 손잡이(60)에서 탈부착하는 침채 탈 부착부(340)가 구성되게 된다.

[0100] 또한, 상기 전기 자극 침채 몸체 (20)의 상부에는 상기 침채부(300)를 유동하는 크랭크 부(380)와 캠부(400)를 구비하는 침채 구동 부재(420)가 인설되어 상기 침채부(300)를 회전 또는 왕복 작용을 하여 표피에 천공을 하게

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되는 것을 사시도로 나타낸 것이다.

[0101] 상기한 목적을 달성하기 위한 본 발명에 따르면, 케이스 내부에 전원을 공급하는 전원(140) 및 상기에서 공급되는 전원을 미세 직류전류로 변환시키는 전기파 발생부(40)가 구비되며, 케이스 외부로 상기에서 전기파 발생부(40)로 공급되는 전원을 제어할 수 있는 스위치를 비롯한 버튼과 상기 본체와 적어도 하나의 패치가 전기적으로 연결되어 케이스의 일면을 통해 외부로 돌출되며, 상기 패치의 중심에 이마나 얼굴을 미세전류로 자극할 수 있는 것을 특징으로 하는 미세전류 자극기를 제공하는 데 있다.

[0102] 한편, 본 발명에 따른 전기 자극 침채는 표면에 다수개의 침채가 삽입된 상기

[0103] 침채부(300)를 피시술자의 피부 상에서 가압할 수 있도록, 침채부(300)에 결합하는 손잡이(60)부에 결합하며, 제어부 몸채(120)에는 다수개의 침채에 전기파가 상기 침채부(300)에 통전 되도록 전기파 발생 장치로부터의 연결단자와 접속되는 전기파 입력부를 구비한다.

[0104] 본 발명에 따르면, 다수개의 예리한 침채를 통하여 인체의 피부면에 이온, 라디오파, 초음파, 고주파, 중주파, 및 저주파 중 선택된 어느 하나의 전기 자극을 가함으로써, 피부조직의 효과적인 치료 및 재생할 수 있게 된다.

[0105] 피부조직의 노화, 흉터, 여드름 자국 등을 개선하기 위한 방법으로서, 종래에는 단순히 피부치료 및 재생을 위한 용액, 크림, 젤, 연고제 등의 의약품을 단순히 피부에 도포하는 방식에 의한 치료만이 이루어졌으나 상기 약제의 침투비율의 양은 상대적으로 그 비율이 매우 작으며, 그 결과 효과적인 피부조직의 개선을 위한 치료가 이루어지지 않는다는 문제점이 있었으며 피부조직의 효과적인 치료 및 재생을 위한 침채부(300)를 제공함에 있다.

[0106] 상기 목적을 달성하기 위한 본 발명에 따른 전기 자극 침채는, 표면에 다수개의 침체가 삽입된 침채부(300)와 상기 침채부(300) 피시술자의 피부 상에서 가압할 수 있도록, 상기 침채부(300)에 결합하는 손잡이부(60), 및 상기 손잡이부(60)에 결합하며, 상기 다수개의 침체에 전기파가 통전 되도록 상기 제어부 몸체(120)에는 전기파 발생부(40)로부터의 연결단자와 접속되는 전기파 입력부를 포함한다.

[0107] 또한, 바람직하게는, 상기 다수개의 침채의 끝에는 상기 전기파 발생 장치에 의해 이온, 라디오파, 초음파, 고주파, 중주파, 및 저주파 중 선택된 어느 하나의 전기파가 발생하는 것을 특징으로 한다.

[0108] 또한, 본 발명은 침채만 별도로 휴대용으로 사용할 수 있는 전기 자극 침체에 관한 것으로, 제어부 몸채(120)에 전기파 발생부(40)를 갖는 전기파를 제어하는 조절 스위치(180)를 구비하고, 손잡이부(60) 일단에 침채부(300)를 형성하며, 상기 침채부(300) 에는 상호 이격되고 전기파 발생부(40)의 양측 출력단에 단자로 연결된 도전판과, 상기 침채부(300) 외면에 결합하고 도전판에 각기 접속된 다수의 전극을 구비한 것으로, 사용이 편리한 것은 물론, 안면을 비롯한 피부 마사지시나 피부 자극시 전기파에 의해 피부의 혈행을 촉진함과 동시에 피부조직을 부드럽고 탄력 있게 개선하며, 또한 안면의 질환이나 문제성 피부를 개선할 수 있도록 된 것이다.

[0109] 일반적으로 피부조직은 최외층인 인체 표피로부터 진피, 피하조직으로 이루어져 있으며, 인체 표피와 진피층에는 모낭공을 포함하는 피지선과 땀구멍이 형성되어 있어 과다하게 분비되는 피지선과 땀으로 인하여 피부를 오염시키기 쉽다.

[0110] 사람의 몸은 60%가량이 수분으로 이루어져 있음과 아울러 물과 전해질(電解質)로 생긴 조직체이다.

[0111] 몸에 전기가 통한다는 것은 체내에서 전해질 이온의 이동에 의해 전기파가 흐르기 때문이며, 이러한 현상을 이용하여 피부에 전기자극을 준다는 것은 전류의 이동에 의해 신체조직에 흥분이 일어나는 것으로 표현할 수 있다.

[0112] 이때의 흥분이란 이온(전기)을 지닌 분자가 원자의 전극 밑에 모이기도 하고 흩어지기도 하는 현상이다. 전기파를 이용한 치료요법은 이러한 생체의 전기 에너지를 이용한 것으로 전류자극을 가하여 흥분을 일으키기 위해서는 전류의 강도(전압의 높이)를 결정하는 통전량, 통전시간과 주파수를 결정하는 전류작용시간 및 전압의 변화를 결정하는 파형(wave form)을 주로 고려해야 한다.

[0113] 사람의 피부는 절연상태에 가깝게 되어 있어 쉽게 전기를 통하지는 않으나, 어느 정도 전압을 높여가면 전류가 피부조직을 통해 흐르기 시작하며, 이 상태에서 더욱 높은 전압으로 자극을 주면 많은 이온이 함께 움직이면서 흥분을 증가시킨다.

[0114] 그러나 높은 전압이라도 단시간에 작용한다면 자극이 되지 않으므로, 자극은 일정시간 이상 유지되어야 하며, 전류의 자극효과는 전압에 따라 달라진다.

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[0115] 즉, 전압이 높으면 통전시간은 비교적 짧아도 좋으나, 전압이 낮으면 통전시간은 길어도 체내의 흥분작용은 발생하지 않는다.

[0116] 피부에 자극작용은 전류의 변화하는 속도에 따라 크게 달라지는데, 전류변화가 완만하면 자극작용이 적어지고, 반대로 전류변화가 급속하면 자극작용도 강하게 일어나며 인체에는 또한 어느 정도의 전류가 흐르면 역으로 기전력이 발생하여 전류의 유입을 차단하려 하는 분극 작용이 있으며, 이러한 분극 작용을 방지하면서 체내의 흥분작용을 일으키기 위해서는 전압의 적합한 변화 즉, 파형 값을 정확히 산출해야 한다.

[0117] 주지된 바와 같이 전기파는 경혈 마사지로 자극을 줌과 동시에 혈행을 촉진하고, 영양크림 또는 팩 등과 함께 이용할 경우 체내의 대사개선과 다양한 피부 마사지효과를 얻을 수 있으며, 안면의 기미, 검버섯, 주름, 여드름, 주근깨 등 각종 피부질환의 완화, 예방 및 개선에 주로 이용되고 있다.

[0118] 그러나 전기파를 이용한 종래의 시스템은 장치의 규모가 크고 구조가 복잡하고 패드를 사용하여야 한다는 단점이 있었다.

[0119] 본 발명의 또 다른 목적은, 매우 저렴한 비용으로 전기파에 의한 높은 효과를 얻을 수 있는 전기파 침체부(300)를 제공함에 있다.

[0120] 본 발명은 상기의 제반 목적을 달성하기 위하여, 제어부 몸체(120) 내부에 전기파 발생부(40)를 구비하고, 손잡이부(60) 일단부와 탈부착 되는 상기 침체부(300)를 형성하며, 상기 침체부(300)에 상기 전기파 발생부(40)로부터 발진된 전기파 펄스가 인가 되도록 전기파를 전달할 수 있는 상기 침체부(300)를 구비한다.

[0121] 또한, 전기파 발생부(40)에는 본체에서 발생하는 전기파를 제어하는 제어부를 포함시켜 전원의 개폐 및 전류, 전압의 가변에 의한 펄스의 주기의 조정 또는 펄스의 강도 등을 조정할 수 있도록 구성한다.

[0122] 손잡이부(60)는 손으로 충분히 파지할 수 있는 길이로 하고, 헤드는 손잡이부(60)로부터 둔각으로 형성하되, 각도범위가 지나치게 증가하지 않도록 하는 것이 바람직하다.

[0123] 또한, 전기파 발생부(40)에는 전기파 조절 스위치(180)를 포함시켜 전원의 개폐 및 전류, 전압의 가변에 의한 펄스의 주기조정 또는 펄스의 강도 등을 조정할 수 있도록 구성한다.

[0124] 상기 전기파 발생부(40)는, 바람직하게는 제어부 몸체(120)에 형성된 가이드 리브 및 그 가이드 리브에 결합한 전기파 발진회로기판(PCB)과, 가이드 리브에 형성된 걸림 후크 및 전기파 발진회로기판(PCB)과 이격되도록 걸림 후크를 통해 가이드 리브에 탄력적으로 결합되게 구성한다.

[0125] 상기 전기파 조절 스위치(180)는 상기 제어부 몸체(120)에 내설된 상기 전기파 발진회로기판(PCB)에 연결되어 전원을 개폐하는 전원 버튼과 전기파 전류의 강약을 단계적으로 증감, 조절하는 주파수 조정버튼으로 이루어지며 상기 전원 버튼의 ON/OFF 상태에서 점등 및 소등 상태를 유지하는 램프로 구성한다.

[0126] 또한, 상기 전원 버튼과 주파수 조정버튼은 손잡이부(60)를 통해 돌출되어 조작할 수도 있으며 상기 버튼의 안내를 위한 커버를 손잡이부(60)에 결합한다.

[0127] 상기 전기 자극 침체는 침체부(300)의 내부 또는 외부에 상호 이격 하여 결합하고 전기파 발진 회로기판의 양측 출력단에 단자로 연결된 도전판과, 침체부(300)로부터 결합하고 도전판에 각기 접속, 연결된 다수의 전극으로 구성한다.

[0128] 즉, 전원 버튼이 ON 되면, 전원(140)으로부터 전기파 발생부(40) 및 전기파 조절 스위치(180)에 전원이 공급되고, 상기 전기파 발생 부로부터 발생하는 전기파 펄스가 단자를 통해 침체부(300)의 도전판에 인가되며, 도전판에 접속된 플러스 및 마이너스 침체가 피부에 접촉되면서 피하조직에 전기파 전류를 흘림과 동시에 전류의 흐름에 의해 인체 표피, 진피, 피하지방층의 이온 분자를 유동시켜 흥분작용을 일으키거나 진통, 진정작용을 행하게 된다.

[0129] 여기서 피부조직에 통증 또는 여드름 등이나 염증이 있을 경우에는 주파수 범위를 낮게 설정하고, 통증이 없을 때는 전기파의 주파수 범위를 상대적으로 높이는 것이 바람직하다.

[0130] 또한, 전기 자극 침체의 최초 사용시는 비교적 낮은 단계의 전기파 전류를 공급하고 점차 전류의 강도를 높여가는 것이 바람직하다.

[0131] 본원에서 사용되는 전기파라 함은 초장파, 초자장, 음전위, 고주파, 자주파, 중주파 등 인체에 유익한 모든 주파수를 포함하며 상기 전기파 중에서 바람직하게 선택하여 사용되는 것이다.

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[0132] 또한, 전도성 금속소재로 이루어진 침 삽입홀(360)이 구성되어 다수의 침체가 각기 상부에 돌출되도록 설치되는 몸체와; 침체 일측에 전기파를 발생시키기 위한 전기파 발생부(40)와; 상기 침체 일측에 있는 전기파 발생부(40)를 통해 치료받고자 하는 표피에 침체부(300)를 통하여 전달되는 전기파의 강, 중, 약을 설정하고 전기파의 종류 등을 설정할 수 있는 전기파 설정 조절 스위치(180)와; 상기 전기파 설정조절 스위치(180)와 표시부와; 전기파의 강, 중, 약 및 전기파 종류 등을 컨트롤러부터 제어하여 전기파 발생부(40)를 통해 발생시키게 하는 컨트롤러; 그리고, 상기 컨트롤러의 작동을 제어하는 작동스위치를 구비하는 것을 특징으로 한다.

[0133] 또한, 침체부(300) 에 식립된 침체의 일측에는 각기(+)와(-)가 맞게 장착되어 사용자가 희망하는 전기파를 상기 조절 스위치(180)의 컨트롤러에서 제어하여 상기 침체부(300)에 식립된 침체에 치료용 전기파를 전달하는데 이때 사용자가 치료에 상기 침체에 사용자의 피부가 닿게 된다.

[0134] 이때 상기 침체의 일측에 장착된 전기 자극 침체로부터 상기 컨트롤러가 제어한 전기파를 발생시켜 침체와 닿은 표피에 작용시킴으로써 침체에 식립된 침체를 통해 환부에 전기파를 전달하여 전기파 치료가 가능하도록 한다.

[0135] 또한, 상기 몸체 내부에 구성된 전기파 발생부(40)를 통하여 침체가 사용자의 두피나 피부 등에 닿지 않아도 전기파가 두피나 피부 등에 작용할 수 있는 전기파가 있는데 이때의 대표적인 주파수는 초자장이나 초장파이다.

[0136] 한편, 상기 전기 자극 침체가 상기 몸체 내부에 장착되고 사용자가 희망하는 초자장이나 초장파를 상기 컨트롤러에서 제어하여 전기파 발생부(40)를 통해 발생하게 하는데 이때 사용자가 치료에 상기 침체를 통하여 치료 주파수를 두피나 피부 등에 작용시키지 아니하여도 상기 몸체 내부의 전기파 발생부(40)를 통해 발생된 초 자장이나 초장파의 영역에 사용자의 피부나 두피 등이 들어오게 되면 상기 피부나 안면, 두피 등에 작용하게 됨으로써 전기파를 통한 치료가 가능하도록 된다.

[0137] 일례로는 상기 몸체에 내설되는 전원(140)로 구성되며, 상기 전원 공급부 출력단은 전원스위치 및 전자 장치 등을 차례로 경유하여 상기 각 전기 자극 침체에 (+)와(-)로 접속된다. 즉, 상기 전원 스위치가 온 스위칭 되는 동안에만 상기 전기 자극 침체에 전원 공급부의 전압이 컨트롤러의 명령에 따라 공급되도록 구성되는 것이다.

[0138] 이때 전기 자극 침체의 작동방법 중에 각 전자장치가 없이 전원스위치에 의하여 전원공급 부에서 바로 전기 자극 침체로 전압을 인가하여 작동할 수 있음은 물론이다.

[0139] 그리고 상기 전원스위치의 작동과 동시에 상기 발광램프를 설치하고, 상기 전원스위치의 작동과 동시에 상기 발광램프가 점등되도록 구성함으로써, 사용자가 전원스위치가 온 스위칭 된 상태임을 용이하게 확인할 수 있도록 구성하는 것이 바람직할 것이다.

[0140] 상기 컨트롤러는, 상기 전기파 조절 스위치(180)에 의해 사용자가 시술자의 신체조건에 따라 치료 주파수 세기 및 전기파의 종류를 설정하여 작동스위치를 누르면 전기파가 전기 자극 침체에 의해 침체로 전달되어 전기파의 종류를 제어하여 치료파 발생기에 전기파가 발생하게 하는 역할도 하게 된다 그리고, 상기 작동스위치(160)를 상기 컨트롤러의 작동 여부를 제어하기 위하여 상기 몸체 일측에 설치되며, 상기 조절 스위치(180)에 위치한 컨트롤러에 연결된다.

[0141] 또한, 상기 몸체 일측에는 상기 컨트롤러에 각기 전기적으로 연결되는 시간조정부와 시간표시부가 구비될 수 있는데 상기 시간조정부에는 바람직하게는 10분 단위버튼, 1분 단위버튼 및 시작과 정지버튼이 구비되며, 상기 10분 단위버튼 및 1분 단위 버튼이 작동됨에 따라 10분씩 또는 1~5분씩 증가한 시간이 상기 시간표시부에 설정되도록 구성된다.

[0142] 그리고 상기 시작과 정지버튼이 한번 눌러지면 상기 시간표시부에 설정된 시간이 카운트 다운되어 감소하며, 상기 시작과 정지버튼이 두 번째 눌러지면 상기 타임표시부에 설정된 시간이 제로로 리셋 되도록 구성된다.

[0143] 더불어, 상기 시간조정부에 설정된 시간이 카운트 다운되어 제로에 도달하게 되면, 이를 감지한 상기 컨트롤러에서 오프 시킴으로써, 상기 전원 공급부(Vcc)로부터 상기 각 전기파 조절 스위치(180)로 입력되던 전압이 차단되도록 구성된다.

[0144] 상기 시간 표시부는 상기 시간조정부에 의해 설정된 시간을 표시하도록 몸체 외면에 설치되는 LED및 LED 및 LCD 등의 램프와, 상기 컨트롤러로부터 설정된 시간에 대응되는 제어신호를 입력받고 상기 설정된 상기 LED및 LCD와 디스플레이되도록 하는 LED 및 LCD와 조절 스위치(180)로 구성될 수 있다.

[0145] 한편, 상기 침체는 치료 주파수가 잘 전달될 수 있는 금속재질과 특수 섬유 등으로 전기파가 잘 통하는 물질 등으로 구성시키는 것이 바람직할 것이며 또한 침의 상태를 자력이 발생하는 자석으로 하여 자기장의 효과까지 볼

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수 있게 할 수도 있다.

[0146] 또한, 상기 전기파 조절 스위치(180)에서 전기파 강약 세기를 조절하는데 세기를 약하게 하려면 전기파 등의 세기 약 버튼을 누르면 그 동작 정도가 전기파 표시부(200)에 나타나게 되고 전기파 세기 강 버튼을 누르면 그 동작 정도가 전기파 표시부(200)에 나타나게 되므로 사용자의 원하는 강, 중, 약을 선택한 다음 전기파 조절 스위치(180)의 버튼 여를 통해 전기파의 종류를 설정하면 그 설정된 전기파의 종류가 전기파 제어표시부에 나타나게 된다.

[0147] 이와 같은 상태에서, 상기 작동 스위치(160)를 작동시키면, 이를 감지한 컨트롤러에서 상기 전원 공급부의 전압 이상기 전기 자극 침체에 컨트롤러의 명령대로 인가되어 전기 자극 침체를 통하여 발생된 전기파를 통해 본원의 전기 자극 침체의 작동을 하게 된다.

[0148] 그리고 상기 시간 조정부의 이용시, 상기 작동스위치(160)를 작동시킴과 동시에 상기 타임조정부의 시작과 정지 버튼을 작동시키면, 상기 표시부는 LCD에 설정되어 있는 시간이 타이머에 의하여 카운트 다운되기 시작한다.

[0149] 상기 타임표시부가 카운트 다운되는 동안에는 상기 컨트롤러가 타임표시부의 LED및 LCD에 설정되어 있는 시간이 종료되면, 상기 컨트롤러가 상기 전원공급을 오프시킴으로써, 상기 침체에 의한 전기파 치료를 종료하게 되는 것이다.

[0150] 이러한 구성에 의하여, 전원공급 부로부터 전원이 공급되면, 조절 스위치(180)는 작동 스위치(160)와 모드 선택 스위치(240)의 조작에 따라 메모리에 저장된 정보에 의거하여 전기파 발생부(40)를 작동시킨다. 전기파 발생부(40)가 작동함과 동시에, 전기파 발생부(40)로부터 전기파가 출력되고, 사용자는 본체의 손잡이부(60)를

[0151] 파지한 상태에서 원하는 신체 부위에 전기파 발생부(40)를 밀착시켜 전기파로 자극함으로써, 근육을 이완시키고 혈액순환을 촉진시켜 인체의 건강을 증진시킬 수 있게 된다. 특히, 전기파 발생부(40)는 본체에 수용되어 있으며 전기파 발생부(40)가 본체로부터 돌출되어 있어 신체 모든 부위에도 간편하게 사용할 수 있게 된다.

[0152] 한편, 전술한 실시 예에서는, 전기파 발생부(40)가 침 형상을 가지는 것으로 설명하고 있지만, 전기파 발생부(40)는 반구형 또는 다각형, 타원형의 단면형상을 가지며 돌출되거나 봉형상을 가질 수도 있는 것이다.

[0153] 도 5는 본원 발명의 기능성 침체에 있어 침체와 제어부 몸체의 일실시 예를 나타낸 사시도로서, 도 5를 참조하면 본 발명에 따른 전기 자극 침체의 침체부(300)는 다수개의 예리한 침체부(300)가 삽입되는데 상기의 침체부(300)에 내부 또는 외부에 형성된 다수개의 전도성 금속소재로 이루어진 침 삽입홀(360)에 상기 침체부(300)가 접촉이나 결합하게 되어 있으며, 이 침체는 본체 손잡이부(60)의 전기파 발생기로부터 발생한 전기파와 연결된 전기 전도부와 결합하여 있다.

[0154] 한편, 상기 침체부(300) 내부 또는 외부에 형성된 침체의 삽입 홀(360)은 전기 전도와 전성이 우수한 은, 동, 티탄 등의 금속으로 상기 침체의 전도부로 사용되는 것이 바람직할 것이다.

[0155] 한편, 바람직하게는 전기 전도부와 다수개의 예리한 침체와의 전기적인 결합 특성이 양호해지도록, 전기 전도부와 다수개의 예리한 침체의 사이에는 도전성의 합성수지 소재의 전도체가 포함될 수도 있을 것이다.

[0156] 이처럼 전기 자극 침체의 전기 입력부를 통해 전기발생 장치로부터 입력된 전기는 손잡이부(60) 내의 연결 케이블(260)을 통하여 제어부 몸체(120)에 형성된 침체의 전기 전도부로 전해지며, 최종적으로는 전기 전도부에 전기적으로 결합하여 있는 다수개의 예리한 침체에 전달되어 인체에 작용되게 되는 것이며 상기 침체는 시술자에 의해 인체의 피부 면에 삽입된 상태에서 피부조직에 이온 자극 및 소정 전기파의 전기 자극을 가하게 된다.

[0157] 본 발명에 따른 전기 자극 침체의 시술과정을 설명하면, 시술자는 전기 자극 침체의 손잡이부(60)를 손으로 파지하고서 상기 침체를 시술부위에 대고 회전하면서 압력을 가하게 되고 이러한 시술을 통하여 시술부위에는 많은 미세상처가 생김과 동시에 상기 침체 끝에서는 소정의 전기파의 전류가 주위의 피부조직으로 전도되며, 이에 따라 예리한 침체 주변의 피부조직의 이온을 흥분시키거나 전기적 진동 자극에 의한 열을 일으키게 된다.

[0158] 이와 같은 인체의 피부 면에 이온 자극 및 소정 전기파의 전기적인 진동 자극을 통해서, 피부조직의 효과적인 재생을 위해 피부층에서의 용액, 크림, 젤, 연고제 등의 흡수율을 획기적으로 높여 시술자의 피부 조직은 빠른 속도로 새로운 조직을 형성하게 되는 것이다.

[0159] 도 6은 본원 발명의 기능성 침체에 있어 침체와 제어부 몸체의 연결의 일실시 예를 나타낸 사시도로서, 도 6을 참조하면, 본 발명의 일실시예에 따른 전기 자극 침체는 전기 입력부, 손잡이부(60), 및 침체부(300)를 포함한다.

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[0160] 여기서, 전기 입력부 및 손잡이부(60)의 구성 및 기능은 상기의 전기 자극 침체에서 설명한 바와 동일하다.

[0161] 본 발명에 따른 전기 자극 침체는, 전기파를 발생하는 전기파 발생부(40)와, 전기파 발생부(40)를 수용하며 파지할 수 있는 손잡이부(60)를 갖는 본체와, 본체의 착달되는 침체부(300)에 인설된 전기파 발생부(40)로부터 발생된 전기파가 출력되는 다수의 전기파 발생부(40)를 가진다.

[0162] 상기 제어부 몸체(120)에는 상기 전기파 발생부(40)로부터 발생하는 전기파의 강약을 조절하는 작동 스위치(160)와 모드 선택 스위치(240)와,전기파의 출력시간을 설정하는 타이머 등을 포함하며 기기의 작동을 조작하는 작동 스위치(160)가 마련되어 있으며, 이러한 조작부의 작동 등에 관한 정보를 표시하는 디스플레이부인 표시부(200)가 마련되어 있다.

[0163] 아울러 상기 손잡이부(60)는 손잡이 상부케이스(80)와 손잡이 하부 케이스(100)의 사이에는 전기파 발생부(40)가 수용되어 있으며 전기파 발생부(40)는 제어부 몸체(120)에 구성되며 마이컴으로 이루어진 조절 스위치(180)에 의해 작동되며, 인쇄회로 기판상(PCB)에 마련되어 조절 스위치(180)의 작동에 의해 소정의 전기파로 발진하는 발진용 트랜스를 더 포함하게 되는 것이다.

[0164] 상기 전기파 출력 부에서 발생한 전기파는 침체에 전달되며 전기파 발생부(40)로부터 발생된 전기파가 치료받고자 하는 신체부위에 전달 가능하도록 전기파 발생부(40)와 통전 가능하게 설치되어 있다.

[0165] 또한, 손잡이부(60)와 손잡이 하부케이스(100)의 사이에는 조절 스위치(180)로 전원을 공급하는 전원 공급부가 수용되어 있으며 또한, 손잡이 상부 케이성(80)과 손잡이 하부 케이스(100)는 상호 결합함으로써 파지할 수 있는 손잡이부(60)를 형성함이 바람직하다.

[0166] 한편, 본 발명에 따른 전기파 치료기는, 도 3, 4에 도시된 바와 같이, 작동 스위치(160)와 모드 선택 스위치(240)를 조작하면 조절 스위치(180)는 입력된 신호를 파악하고, 메모리에 미리 저장된 정보에 따라 전기파 발생부(40)를 작동시킨다.

[0167] 여기서, 조절 스위치(180)는 전기파 발생부(40)로부터 발생하는 전기파의 강약을 조절할 수 있을 뿐만 아니라, 조절 스위치(180)에 내장된 타이머에 의해 정해진 시간만큼, 또는 정해진 시간에만 작동하도록 전원을 가변시킬 수도 있게 된다.

[0168] 이러한 구성에 의하여, 전원 공급부인 전원(140)으로부터 전원이 공급되면, 조절 스위치(180)는 작동 스위치(160)와 모드 선택 스위치(240)의 조작에 따라 메모리에 저장된 정보에 의거하여 전기파 발생부(40)를 작동시키게 되는 것이다.

[0169] 이처럼 전기파 발생부(40)가 작동함과 동시에, 전기파 발생부(40)로부터 전기파가 출력되고, 사용자는 본체의 손잡이부(60)를 파지한 상태에서 원하는 신체 부위에 전기파 발생부(40)를 밀착시켜 전기파로 자극함으로써, 근육을 이완시키고 혈액순환을 촉진시켜 인체의 건강을 증진시킬 수 있게 된다.

[0170] 한편, 전술한 실시한 예에서는, 전기파 발생부(40)가 상기 침체부(300)에 식립된 침 형상을 가지는 것으로 설명하고 있지만, 바람직하게는 상기 침체부(300)에 자극용인 침 끝이 무딘 침을 삽입하거나 피부에 마사지나 약재를 흡수시키거나 바르기 위한 침이 삽입되지않는 밋밋한 침체부(300)를 탈부착하는 것도 바람직하다.

[0171] 또한, 상기 전기파 발생부(40)의 일실시 예에 의한 바람직한 전기파 발생상태를 개략적으로 설명하면 상기에서 공급되는 전원이 콘덴서와 저항과 트랜지스터 및 가변저항과 전기적으로 연결되어, 상기 작동 스위치(160) 켜(on)지면 상기에서 공급된 전원이 상기 콘덴서를 충전시키기 위하여 가변저항 측으로 흐름과 동시에 트랜지스터의 컬렉터에 인가되고, 콘덴서가 충전될 때까지 가변저항 측으로 흐르는 전류는 저항과 저항에서 발생하는 전압이 강하되는 만큼만 트랜지스터의 베이스 측으로 흐르고, 이후 콘덴서의 충전이 끝나면 상기 콘덴서는 디커플링 콘덴서의 역할을 하게 되어 전류는 트랜지스터의 베이스에 그대로 인가됨으로써 미세 전기파를 발생시키어 상기 침체부(300)의 침체부(300)에 전달되는 것이 바람직하다.

[0172] 그리고 바람직하기로 상기 전기 자극 침체 몸체(20)는 전원(140)을 교체할 수 있도록 케이스가 구비되며 전원인가를 확인할 수 있는 엘이디 다이오드가 배치되어 작동 스위치(160) 점등(turn-on)되면 엘이디 다이오드가 일정한 주기로 발광 되며, 여기서 상기 전기파 발생부(40)는 전기 자극으로써 유용한 정도의 미세전류인 수 마이크로 암페어 이상의 전류를 발생시키는 것이 필요하고 그 이유는 다음과 같다.

[0173] 전류의 경우 인체에서는 약 0.06㎃ 정도의 미세전류가 흐른다고 알려져 있으며, 건강 상태에 따라 이러한 미세전류의 강도가 다르다고 알려져 있으며, 통상적으로 건강 상태가 나빠지면 미세전류의 양이 훨씬 적게 흐르는

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것이 임상적으로 알려져 있다.

[0174] 따라서 이러한 신체에 자극이 될 수 있는 정도의 크기를 가지는 미세 전기파를 외부에서 자극함으로써 신체 내부의 밸런스에 기여할 수 있게 된다.

[0175] 또한, 신체의 감각 수준에 따라 약간씩 정도의 차이는 있으나, 통상적으로 1㎃ 정도의 전류는 충분히 지각할 수 있다고 알려져 있으며, 장시간 전류의 통전은 별로 바람직하지 않다고 알려져 있다.

[0176] 따라서 이마나 얼굴을 통해 공급되는 전류는 1㎃보다는 적은 수~수백 마이크로 암페어(㎂) 정도의 크기면 족할 것이고, 바람직하기로 이러한 전류는 지속적 흐름이 아닌 일정시간 동안 단속적으로 흘러 자극으로써 역할을 수행하는 것이 바람직하다.

[0177] 그리고 가장 바람직하게는 순간 전류가 인체 내부전류인 300㎂ 이하로 전달되어 예민한 부분에 사용하거나 장시간 사용되더라도 신체에 부작용이 없는 정도의 미세전류가 흐르는 것이 좋다.

[0178] 또한 상기에서 도시된 바와 같이, 상기 전기파 발생부(40)는 콘덴서와 저항과 트랜지스터 및 가변저항을 연결하며 이에 스위치 버튼의 온-오프에 의해 전원(140)을 미세 직류전류로 변환하여 후술 되는 침체부(300)로 인가되도록 구성된다.

[0179] 바람직하게는 상기 침체부(300)로 인가되는 스파이크 펄스(Ps)의 주파수를 9.0±0.2Hz, 펄스 폭을 100~800㎲로 설정하는 동시에, 인체의 부하 저항에 대응하는 10~400KΩ 부하로 인가하는 스파이크 펄스의 펄스 폭 기간의 양의 피크 전압치가 1.5~100V가 되고, 또한 펄스 폭 기간에서의 양의 전압이 소정 전압치 이상을 유지하도록, 출력하는데 트랜스포머의 코일의 감은 수의 비를 설정함이 바람직하며 전원(140)으로부터 직류전원이 공급되고, 저항과 가변저항을 통하여 1~300㎂ 이하의 적정한 미세 전기파가 생기도록 하여 패치로 전도가 이루어지도록 한다.

[0180] 여기서 상기 전원(140) 전원은 1.5~12V의 직류전원을 공급하여도 무방할 것이며 이에 따라 가변저항의 폭이 달라지면 1~300㎂ 이하의 적정한 미세 전기파를 공급할 수 있게 되는 것이다.

[0181] 이러한 상기 전기자극 발생부의 작동은 다음과 같다.

[0182] 전기 자극 침체 몸체(20)에 인설된 작동 스위치(160)가 점등되면 최초로 공급된 1.5~12V의 직류전원이 상기 콘덴서를 충전시키기 위하여 가변저항 측으로 흐름과 동시에 패치를 통하여 트랜지스터의 컬렉터에 인가된다.

[0183] 그리고 상기 콘덴서가 충전될 때까지 가변 저항 측으로 흐르는 전류는 저항과 저항에서 발생하는 전압 강하 분만큼만 트랜지스터의 베이스 측으로 흐르게 트랜지스터는 아주 작게 통전된다.

[0184] 이후 상기 콘덴서의 충전이 끝나면 콘덴서는 디커플링 콘덴서의 역할을 하게 되어 전류는 트랜지스터의 베이스에 그대로 인가된다.

[0185] 따라서 트랜지스터가 점등(turn-on)되어 패치에 미세 전기파를 흐리게 된다.

[0186] 여기서 도시된 저항은 전기파의 값에 따라 회로에 배치될 수도 있다.

[0187] 따라서 필요로 하는 수십 마이크로 암페어의 전류를 생성하기 위해서는 상기 침체부(300)의 내부저항은 다음과 같은 일실시예에 의한 조건을 고려하였다.

[0188] 패치의 내부저항값은, R = V / I(1V의 전압을 가했을 때 1A의 전류가 흐르는 경우의 저항을 1Ω이라고 한다)로 구해질 수 있다.

[0189] 예를 들어 전원(140)에서 공급되는 전원이 3V라 가정할 때, 60㎂의 미세전류가 흐르기 위해서는 50kΩ의 내부저항값을 가지는 침체부(300)를 형성하면 되고 이에 따라 침체부(300)의 내부저항값이 달라지면 1~300㎂ 이하의 적정한 미세 전기파를 공급할 수 있게 되는 것이다.

[0190] 상기 펄스 발생 회로의 제1포트는 기본 펄스를 출력하는 출력 포트이며, 기본 펄스는, 주파수가 8.0Hz, 펄스 전압(Vo)이 -5V, 펄스 폭이 100~800㎲로 설정됨이 바람직하다.

[0191] 상기 주파수는 8.0Hz이 최적이지만, 9.0±0.2Hz의 범위로도 허용됨이 바람직하다.

[0192] 또, 펄스 폭은 변경하는 것에 의해, 자극(에너지)의 강약 조합을 수시로 바꿀 수 있는 것이며 강약 전환 회로는, 펄스 폭을 변경하여, 자극의 강약 조합을 바꾸기 위한 회로로, 전술한 모드 선택 스위치(240)를 구비한다.

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[0193] 이 경우, 모드 선택 스위치(240)의 가동 접점은, 펄스 발생 회로의 제2포트에 접속하는 동시에, 제1고정 접점은 무 접속으로 하고, 제2고정 접점은 저항을 통해 어스 라인에 접속하고, 제3고정 접점은 어스 라인에 직접 접속한다.

[0194] 이것에 의해, 모드 선택 스위치(240)를 제1고정 접점으로 바꾸면, 제2포트에는, 저항을 통해 전원 전압을 제공 가능하게 되기 때문에, 펄스 폭은, 500㎲가 되고, 자극은 "강"이 된다.

[0195] 또 바람직하게는 상기 모드 선택 스위치(240)를 제2고정 접점으로 바꾸면, 제2포트에는, 분압된 전원 전압을 제공 가능하게 되기 때문에, 펄스 폭은, 400㎲이 되고, 자극은 "중"이 된다. 또한, 모드 선택 스위치(240)를 제3고정 접점으로 바꾸면, 제2포트에 제공되는 전압은 "0(제로)"이 되기 때문에, 펄스 폭은, 200㎲가 되고, 자극은 "약"이 된다. 또한, 이와 같이 펄스 폭이 설정되고, 또한 주파수가 8.0Hz로 설정되는 것에 의해, 무 펄스 기간은, 대략 100msec 이상이 된다.

[0196] 한편, 펄스 발생 회로의 제1포트(출력 포트)는, 출력 트랜지스터를 통해 출력 트랜스포머의 코일의 한 끝에 접속한다.

[0197] 또한, 코일의 다른 한끝은, 작동 스위치(160)를 통해 양극에 접속되며 음극은, 어스 라인에 접속함이 바람직하다.

[0198] 이 경우, 출력 트랜스포머의 코일의 감은 수의 비는, 스파이크 펄스를 얻는 데에 중요한 설정 요소가 되고, 양호한 스파이크 펄스를 얻을 수 있다.

[0199] 이것에 의해, 인체의 부하 저항에 대응할 수 있는 예컨대 300kΩ의 부하 저항을 접속했을 때에는, 최적의 파형 형상의 스파이크 펄스를 얻을 수 있으며, 이 경우, 얻어지는 스파이크 펄스의 펄스 폭의 기간에서의 양의 피크 전압치는, 1.5~100V 사이에서 이루어짐이 바람직하고, 또한 펄스 폭(Tp)의 기간에서의 양의 전압은, 소정 전압치 이상을 유지하는 파형이 얻어짐이 바람직하다.

[0200] 또, 출력 트랜스 포머의 코일의 한 끝은 양 전극부에 접속하는 동시에, 코일의 다른 한 끝은, 음 전극부를 구성하는 전극 플레이트 및 접속 잭에 각각 접속한다.

[0201] 한편, 전원 레귤레이터는, 입력단자를, 작동 스위치를 통해 양극에 접속하는 동시에, 출력 단자를, 전원입력 회로의 입력측에 접속한다.

[0202] 통상, 인체의 부하 저항발생은 10~400kΩ이고, 코일의 양단 간에도 10~400kΩ 정도에서 부하 저항이 접속되며 이 결과, 침체부(300)의 침체부(300)로부터 치료하고자 하는 피부의 피부면 에 대하여 소정의 스파이크 펄스가 인가되는데 서서히 작동스위치를 올려서 따갑지않게 사용하는 것이 효과적이다.

[0203] 따라서, 이와 같은 전기 자극 침체의 사용에 의해, 특히, 인체의 생리적 매커니즘에 대응하는 주파수, 전압 등의 물리량은 보다 정밀하게 설정되는 것에 더하여, 파형의 동적 변화에 대해서도 최적의 설정이 행해지기 때문에, 피부자극이나 치료시 통증을 완화하고 치료 효과가 보다 높아진다.

[0204] 도 7은 본원 발명의 기능성 침체에 있어 침체와 제어부가 하나로 된 것의 일실시 예를 나타낸 사시도로서, 본 발명의 전기 자극 침체에 있어 제어부 몸체(120)와 관련 없이 독립된 전기 자극침체를 구성하는데 상기 침체에는 탈착 요 홈과 나사 산으로 탈착되는 롤러 손잡이부(60)의 일실시 예를 나타낸 사시도를 나타낸 것으,로 상기 침체부(300)는 침체 결합 나사 산과 이를 고정하는 고정패킹으로 침체부(300)와 손잡이부(60)가 분리 및 탈착되는 것 또한 바람직하다.

[0205] 또한, 상기 침체부(300)는 탈착 요 홈과 탈부착 버튼 또는 나사 산으로 바람직하게는 단 턱이나 자석, 꺼움 부재로 상기의 전기 자극 침체가 인설된 손잡이부(60)와 분리 및 탈착되거나 또는 상기 손잡이부(60)와 침체부(300)는 상기 침체 몸체 어느 일측단에 일체로 돌출 설치된 일정 크기의 탈착 요홈 또는 끼움 편에 단 턱이나 끼움식, 자석 등으로 착탈 되게 끼울 수 있는 것을 특징으로 하는 침이 형성된 롤러를 사시도로 나타낸 것이다.

[0206] 이처럼 상기의 전기파 발생부(40)가 발생하는 침체부(300)는, 상기 제어부 몸체(120)에는 침체부(300)에 상기 전기파 발생부(40)와 전원(140)부와 조절 스위치(180)가 부착되며 사용자의 선택에 따라서 여러 가지의 실시예에 의하여 침체가 자유롭게 분리 및 착탈 되게 되는 것이며 예컨대 얼굴의 기미나 작은 점, 모공 등을 제거하기 위해서는 침의 지름 0.12㎜에 침 길이 2.0㎜가 바람직하고 얼굴의 여드름 자국을 없애기 위해서는 침의 지름 0.15㎜에 침 길이 2.3㎜가 바람직하고 이보다 큰 주름살을 없애는 데는 침의 지름 0.18㎜에 침 길이 2.5㎜가 바람직하고 인체에 형성된 흉터를 치유하기 위해서는 침의 지름 0.30~4㎜에 침 길이 5㎜가 바람직한데 상기하였듯

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이 침의 지름이 작고 길이가 짧을수록 통증은 줄고 이와 반대로 침의 지름이 넓고 길이가 길수록 처음 사용하는 사람은 고통이 심하여 사용자가 아를 두려워하여 지름과 길이가 길은 침을 사용하여야 하는 사람인대도 통증 때문에 지름이 작고 길이가 짧은 침을 사용하고 있는 현실이며 상기의 침채부(300)가 부착된 미용기를 사용함에 있어 피부에 천공을 시키는 처음 과정에 침의 지름 0.30~4mm 에 침 길이 5mm 이상의 침을 사용하는 것은 고통으로 인한 무리가 따르므로 처음에는 피부의 단련을 위해서 침의 지름 0.12mm에 침 길이 2.0mm를 사용하고 점차 피부가 단련되고 고통을 차단하는 물질이나 면역 물질 및 콜라겐이 인체에 생성되면 그때부터 자신의 증상에 맞는 두껍고 긴 침을 사용하면 되는 것이며 일례로 여드름 자국과 주름, 기미 등을 한꺼번에 치료하고자하면 각기 사용되는 침의 굵기나 길이가 상이하므로 여러 대의 침채를 사용해야하는 문제점이 발생한바 본원의 전기파 발생부(40)가 발생하는 침채부(300)에는 침채 고정부재(320)를 통하여 상기 침채부(300)가 간편하게 탈부착하여 증상에 따라서 청결하고 요긴하게 사용할 수 있는 장점이 있는 것이다.

[0207] 한편, 상기 침채부(300)는 탈착 요 홈 또는 돌기 및 손잡이부(60)와 아를 탈착하는 탈부착 버튼으로 구성되어 상기의 침채 탈 부착부(340)와 손잡이부(60)를 단 턱이나 자석 또는 결합 돌기로 조립 및 해체하여 사용하는 것 또한 바람직하며 상기 침채부(300)는 침채 결합 나사 산과 이를 고정 하는 고정패킹으로 침채부(300)와 손잡이부(60)가 분리 및 탈착되는 회동식 연결부를 갖는 것 또한 바람직하다.

[0208] 이처럼 상기 침채부(300)는 침채 탈부착부(340)를 통하여 탈착 요홈과 탈부착 버튼으로 또는 단 턱과 탈착 요홈으로 분리 및 탈착되거나 또는 상기 손잡이부(60)와 침채부(300)는 상기 침채 몸체 어느 일 측 단에 일체로 돌출 설치된 일정 크기의 탈착 요 홈 및 그 끼움 편에 단 턱으로 착탈 되게 끼울 수 있는 것을 특징으로 하는 전기 자극 부가 구성된 침이 형성된 침채를 개시하게 되는 것이다.

[0209] 상기 침채부(300)는 침채 탈부착부(340)인 탈착 요 홈과 탈부착 버튼으로 탈부착 되거나 또는 단 턱과 탈착 요홈으로 분리 및 탈착되거나 또는 상기 손잡이부(60)와 침채부(300)는 어느 일 측 단에 일체로 돌출 설치된 일정 크기의 탈착요 홈 및 그 끼움 편에 단 턱으로 착탈 되게 되며 바람직하게는 탄력을 가지는 끼움 부를 밀착시키면 끼움 결합부가 걸림 공이 걸림 턱에 걸리게 되어 견고하게 밀착 고정됨으로써 상기 침채를 단단하게 사용할 수 있게 되는 것이다.

[0210] 이에 의하여, 침채부(300)만 별도로 휴대용으로 사용이 가능하며, 얼굴이나 이마를 비롯하여 신체의 모든 부위에 간편하게 사용할 수 있으며, 또한 근육을 이완시키고 혈액순환을 촉진시켜 인체의 건강을 증진시킬 수 있다.

[0211] 또한, 상기 침채부(300)를 구동하는 침채 구동 부재(420)의 구동수단은 크랭크 부(380)는 침채 구동 부재(420)인 모터나 에어의 힘으로 구동하게 되는데, 회전운동을 캠 부(400)를 통하여 왕복 운동하여 피부 및 두피를 자극하는데 본체 내부에 인설된 PCB부내에 부착된 컨트롤러에 의하여 속도와 강도를 조절할 수 있고 상기 PCB부는 이와 연통 된 전원을 연결 및 해체해주는 릴레이 부와 본체를 동작하는 작동스위치(160)로 구성되고 이를 연결 케이블(260)을 통하여 침채 구동부재(420)인 모터 및 압축기나 컴프레서 등을 이용한 에어 터빈을 작동하게 되는데, 상기 침채 구동 부재(420)는 모터나 에어 터빈 대신에 초음파 진동자를 사용함도 바람직하다.

[0212] 그리고 상기 제조방법에 의해 제조된 침채부(300)는 종래와 같이 손잡이부(60)가 형성된 침채에 침채 탈 부착부(340)를 통하여 결합 및 탈착시켜 본원의 침채부(300)를 제조하게 되는 것이다.

[0213] 상기 본 발명의 명세서는 일 실시 예에 의한 바람직한 실시 예에 대하여 도시하고 설명하였으나 본 발명은 상기한 실시 예에 한정되지 아니하며, 특허청구범위에서 청구하는 본 발명의 요지를 벗어남이 없이 다양한 변형이 가능할 것이며 상기에 기재된 본원 발명은 명세서 및 청구범위에 사용된 용어나 단어는 통상적이거나 사전적인 의미로 한정해서 해석되어서는 아니 되며, 본원 발명자는 그 자신의 발명을 가장 최선의 방법으로 설명하기 위해 용어의 개념을 적절하게 정의할 수 있다는 원칙에 입각하여 본 발명의 기술적 사상에 부합하는 의미와 개념으로 해석되어야만 한다.

[0214] 따라서, 상기 명세서에 기재된 실시 예와 도면에 도시된 구성은 본 발명의 가장 바람직한 하나의 일실시 예에 불과할 뿐이고 본 발명의 기술적 사상을 모두 대변하는 것은 아니므로, 본 출원시점에 있어서 이들을 대체할 수 있는 다양한 균등물과 변형 예들이 있을 수 있음을 당업자는 이해하여야 한다.

[0215] 그리고 후술 되는 용어들은 본 발명에서의 기능을 고려하여 간략하게 정의된 용어들로서 이는 당업자의 의도 또는 관례 등에 따라 달라질 수 있으며 본원의 침 제조 방식은 통상의 바람직한 제조방법에 모두 포함될 수 있는 것이며 그러므로 그 정의는 본 명세서 전반에 걸친 내용을 토대로 내려져야 할 것이다.

도면의 간단한 설명

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[0216] 도 1은 종래의 전기 자극 침채의 일실시 예를 나타낸 사진이다.

[0217] 도 2는 본원 발명의 기능성 침채에 있어 침체의 일실시 예를 나타낸 사시도이다.

[0218] 도 3은 본원 발명의 기능성 침채에 있어 침체의 또 다른 일실시 예를 나타낸 사시도이다.

[0219] 도 4는 본원 발명의 기능성 침채에 있어 침체와 구동부재의 일실시 예를 나타낸 사시도이다.

[0220] 도 5는 본원 발명의 기능성 침채에 있어 침체와 제어부 몸체의 일실시 예를 나타낸 사시도이다.

[0221] 도 6은 본원 발명의 기능성 침채에 있어 침체와 제어부 몸체의 연결의 일실시 예를 나타낸 사시도이다.

[0222] 도 7은 본원 발명의 기능성 침채에 있어 침체와 제어부가 하나로 된 것의 일실시 예를 나타낸 사시도이다.

[0223] *도면의 주요 부분에 대한 부호의 설명*

[0224] 20: 전기 자극 침채 몸체 40: 전기파 발생부

[0225] 60: 손잡이부 80: 손잡이 상부케이스

[0226] 100: 손잡이 하부 케이스 120: 제어부 몸체

[0227] 140: 전원 160: 작동스위치

[0228] 180: 조절스위치 200: 표시부

[0229] 220: 에어 분출구 240: 모드 선택스위치

[0230] 260: 연결 케이블 280: 연결단자

[0231] 300: 침체부 320: 침채 고정부재

[0232] 340: 침체 탈 부착부 360: 침 삽입 홀

[0233] 380: 크랭크 부 400: 캡부

[0234] 420: 침체 구동 부재

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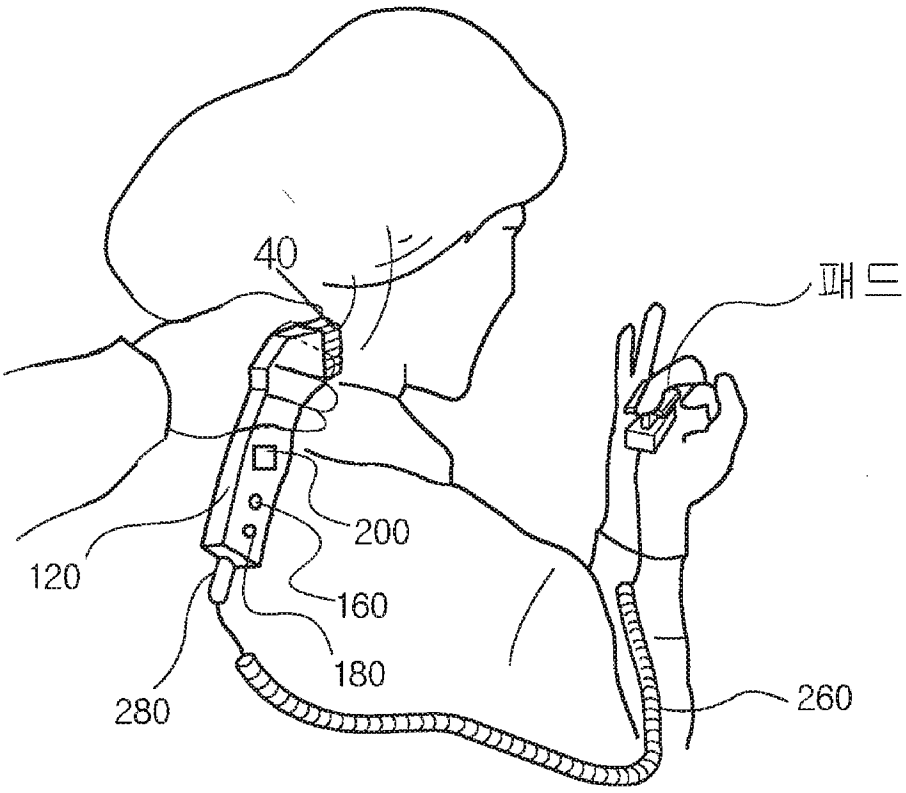
도면

도면1



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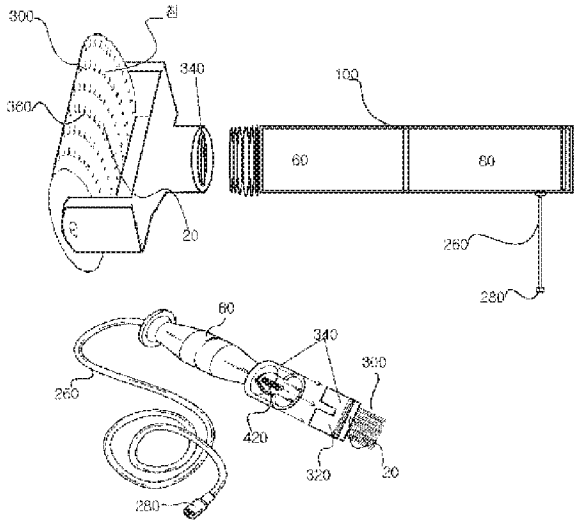

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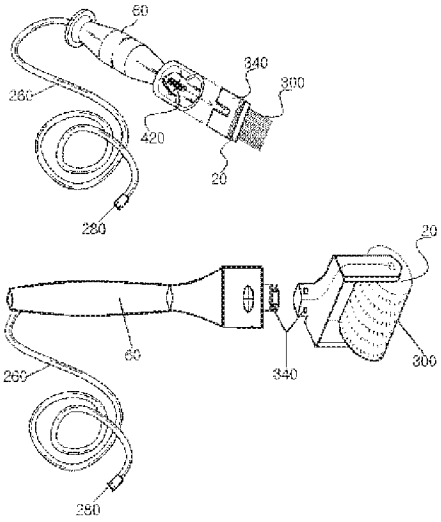

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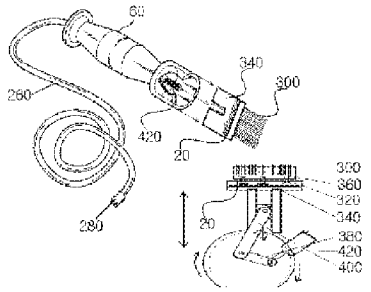

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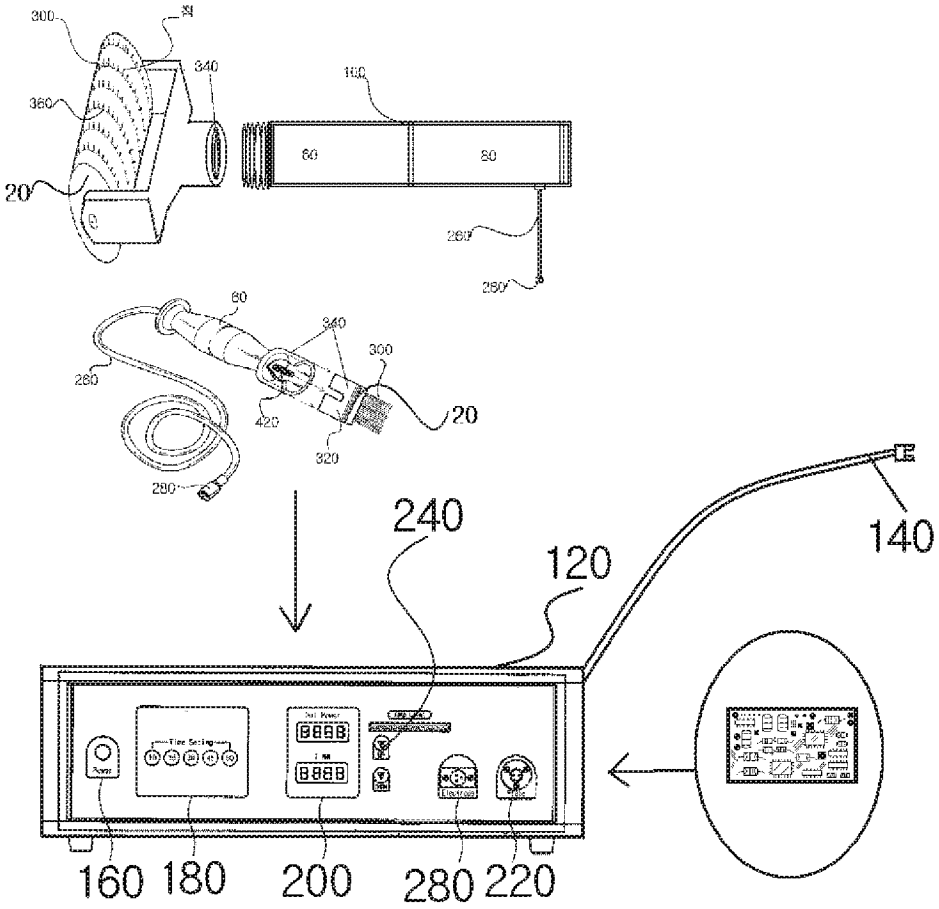
도면5



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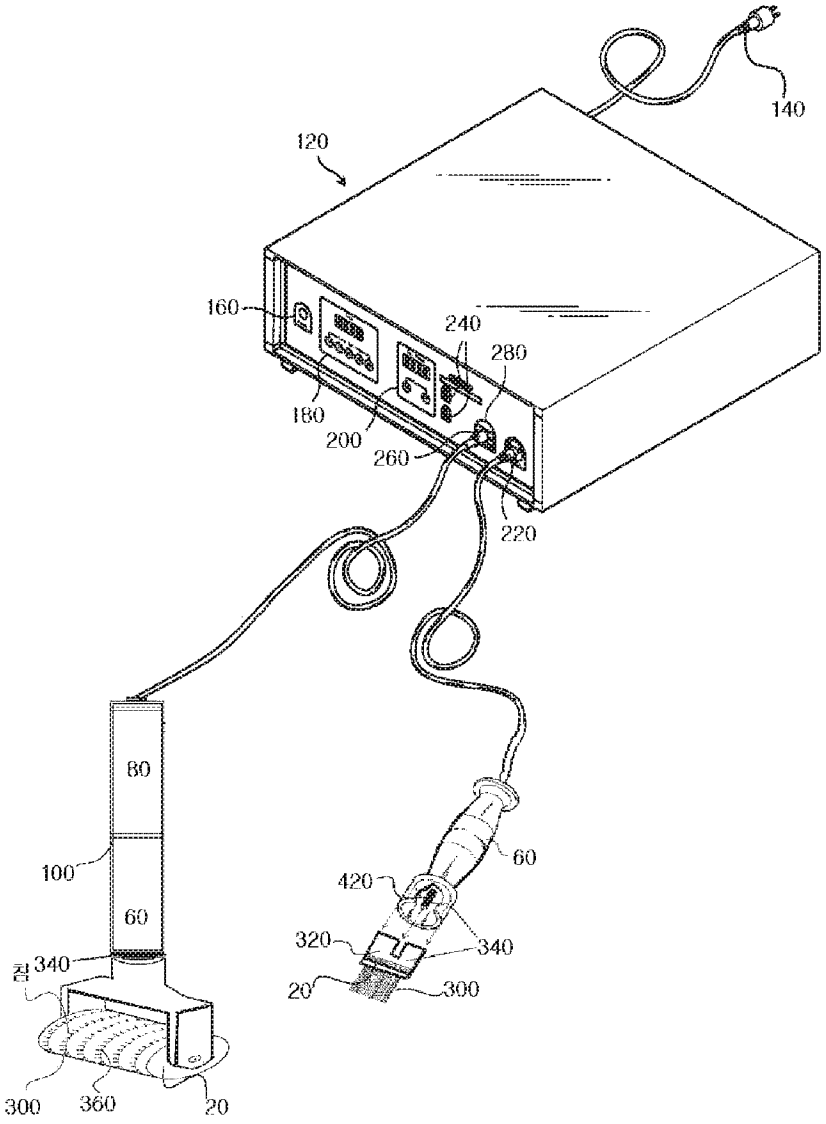
도면6



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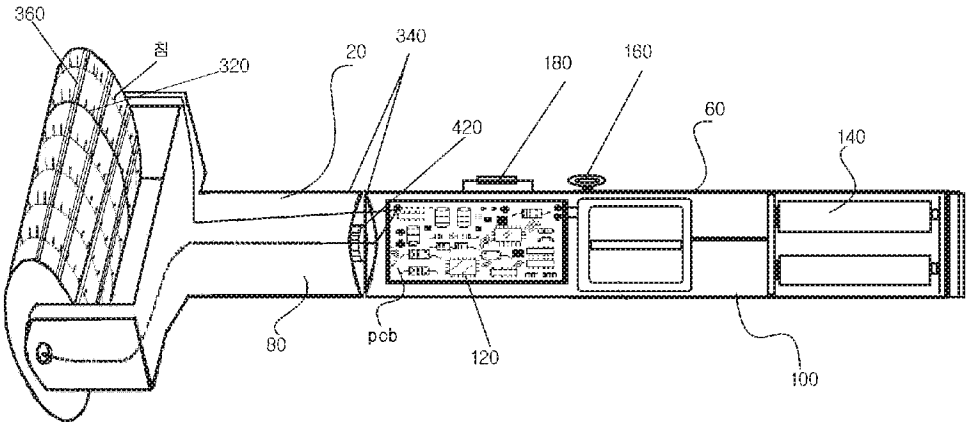
도면7



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(71) Applicant: GEORGIA TECH RESEARCH CORPORATION [US/US]; 400 Tenth Street, Centennial Research Building, Atlanta, GA 30332-0414 (US).

(72) Inventors: PRAUSNITZ, Mark, R.; 417 West Howard Avenue, Decatur, GA 30030 (US). ALLEN, Mark, G.; 425 Spalding Drive, Atlanta, GA 30328 (US). HENRY, Sebastien; 1511 Vinings Parkway, Smyrna, GA 30080 (US). MCALLISTER, Devin, V.; 49 Geddes Street, Holley, NY 14470 (US). ACKLEY, Donald, E.; 2033 Cambridge Avenue, Cardiff, CA 92007 (US). GUJRAL, Inder-Jeet; 111-9 Trowbridge Street, Cambridge, MA 02138 (US). JACKSON, Thomas; 7135 Olivetas Avenue, La Jolla, CA 92037 (US).

(74) Agents: PABST, Patrea, L. et al.; Arnall Golden & Gregory, LLP, 2800 One Atlantic Center, 1201 West Peachtree Street, Atlanta, GA 30309-3450 (US).

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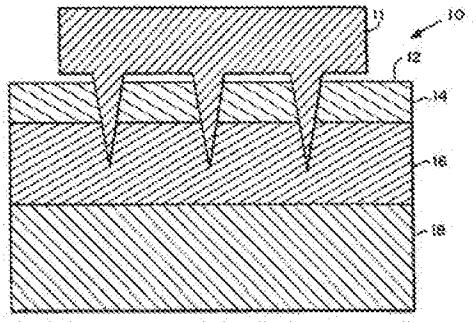

(57) Abstract: Microneedle devices are provided for delivery of drugs across biological tissue and for controlled sampling of biological fluids in a minimally-invasive, painless, and convenient manner. The devices permit 1) drug delivery at clinically relevant rates across or into skin or other tissue barriers, and/or 2) *in vivo* sensing or withdrawal of biological fluids from the body, particularly from or through the skin or other tissue barriers. Drug delivery devices preferably include a plurality of hollow microneedles attached to or integrated into a substrate, and at least one reservoir (containing drug) selectably in communication with the microneedles, wherein the amount of drug to be delivered can be selectively altered. Withdrawal or sensing microneedle devices preferably include microneedles attached to or integrated into a substrate, and at least one collection chamber and or sensor in communication with the microneedles. Preferred embodiments further include a means for inducing biological fluid, such as interstitial fluid, to be drawn through the microneedles and into the collection chamber for analysis. Also provided are microneedle devices and methods for the enhanced transport of molecules across tissue by improving the interaction of an array of microneedles and a deformable, elastic biological barrier, such as human skin. The devices and methods act to 1) limit the elasticity, 2) adapt to the elasticity, 3) utilize alternate ways of creating the holes for the microneedles to penetrate the biological barrier, other than the simply direct pressure of the microneedle substrate to the barrier surface, or 4) combination of 1)-3).

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DEVICES AND METHODS FOR ENHANCED MICRONEEDLE PENETRATION OF BIOLOGICAL BARRIERS

Background Of The Invention

This invention is generally in the field of devices for the transport of therapeutic or biological molecules across tissue barriers, such as for drug delivery or for the withdrawal and sensing of biological fluids, such as in the analysis of blood glucose levels.

A frequent limitation of drugs and therapeutic agents is their delivery: how to transport drugs across biological barriers in the body (e.g., the skin, the oral mucosa, the blood-brain barrier), which normally do not transport drugs at rates that are therapeutically useful or optimal.

Drugs commonly are administered orally as pills or capsules. Many drugs, however, cannot be effectively delivered in this manner, due to degradation in the gastrointestinal tract and/or elimination by the liver. Moreover, some drugs cannot effectively diffuse across the intestinal mucosa. Patient compliance may also be a problem in therapies requiring, for example, that pills be taken at particular intervals over a prolonged time.

Another common technique for delivering drugs across a biological barrier is the use of a needle, such as those used with standard syringes or catheters, to transport drugs across (through) the skin. While effective for this purpose, needles generally cause pain; local damage to the skin at the site of insertion; bleeding, which increases the risk of disease transmission; and a wound sufficiently large to be a site of infection. Needle techniques also generally require administration by one trained in its use, and are not preferred for frequent routine use due to the vascular damage caused by repeated punctures, nor are they desirable for long term, controlled continuous drug delivery.

Similarly, current methods of sampling biological fluids are invasive and suffer from the same disadvantages. For example, the extraction of analytes through the skin is critical to diabetic patients, who typically must measure blood glucose several times per day in order to optimize insulin treatment and thereby reduce the severe long-term complications of the disease. Currently, diabetics do this by pricking the highly vascularized fingertips with a lancet to perforate the skin, then

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milking the skin with manual pressure to produce a drop of blood, which is then assayed for glucose using a disposable diagnostic strip and a meter into which the strip fits. This method of glucose measurement has the major disadvantage that it is painful, so diabetics do not like to obtain a glucose measurement as often as is medically indicated. It would therefore be highly useful to be able to obtain a sample of blood, lymph, or interstitial fluid more quickly, using an easier procedure, and relatively noninvasively. It also would be advantageous to be able to repeatedly or continually extract analyte transdermally over a period of time.

An alternative delivery technique is the transdermal patch, which usually relies on diffusion of the drug across the skin. However, this method is not useful for many drugs, due to the poor permeability (i.e. effective barrier properties) of the skin. The rate of diffusion depends in part on the size and hydrophilicity of the drug molecules and the concentration gradient across the stratum corneum. Few drugs have the necessary physiochemical properties to be effectively delivered through the skin by passive diffusion. Iontophoresis, electroporation, ultrasound, and heat (so-called active systems) have been used in an attempt to improve the rate of delivery. While providing varying degrees of enhancement, these techniques are not suitable for all types of drugs, failing to provide the desired level of delivery. In some cases, they are also painful and inconvenient or impractical for continuous controlled drug delivery over a period of hours or days. Some proposed alternatives to the needle require the use of (1) lasers or heat to create a hole in the skin, which is inconvenient, expensive, or undesirable for repeated use; (2) electric fields or ultrasound, which also is inconvenient and expensive; or (3) chemical or biological penetration enhancing agents, which can be irritating to the tissue and undesirable for repeated use. Attempts have been made to design alternative devices for active transfer of drugs, or analyte to be measured, through the skin.

For example, U.S. Patent No. 5,879,326 to Godshall et al. and PCT WO 96/37256 by Silicon Microdevices, Inc. disclose a transdermal drug delivery apparatus that includes a cutter portion having a plurality of microprotrusions, which have straight sidewalls, extending from a substrate that is in communication with a drug reservoir. In operation, the microprotrusions penetrate the skin until limited by a stop region of the substrate and then are moved parallel to the skin to create incisions. Channels in the substrate adjacent to the microprotrusions allow drug

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from the reservoir to flow to the skin near the area disrupted by the microprotrusions. Merely creating a wound, rather than using a needle which conveys drug through an enclosed channel into the site of administration, creates variability in dosage.

U.S. Patent No. 5,250,023 to Lee *et al.* discloses a transdermal drug delivery device, which includes a plurality of needles having a diameter in the range of 50 to 400 μm. The needles are supported in a water-swellable polymer substrate through which a drug solution permeates to contact the surface of the skin. An electric current is applied to the device to open the pathways created by the needles, following their withdrawal from the skin upon swelling of the polymer substrate.

PCT WO 93/17754 by Gross *et al.* discloses another transdermal drug delivery device that includes a housing having a liquid drug reservoir and a plurality of tubular elements for transporting liquid drug into the skin. The tubular elements may be in the form of hollow needles having *inner* diameters of less than 1 mm and an outer diameter of 1.0 mm.

While each of these devices has potential use, there remains a need for better drug delivery devices, which make smaller incisions, deliver drug with greater efficiency (greater drug delivery per quantity applied) and less variability of drug administration, and/or are easier to use. In view of these needs, microneedle devices have been developed, which are described in PCT WO 99/64580. Certain embodiments of the device were found to readily penetrate skin samples in *in vitro* experiments, but not always provide uniform or complete insertion of the microneedles into some areas of the skin *in vivo*, as the stratum corneum and underlying tissues are highly deformable and elastic over much of the body.

It is therefore an object of the present invention to provide a microneedle device for relatively painless, controlled, safe, convenient transdermal delivery of drugs.

It is a further object of the present invention to provide a microneedle device controlled sampling or sensing of biological fluids in a minimally-invasive, painless, and convenient manner.

It is another object of the present invention to provide methods and devices for improving the control of microneedle insertion into the body of a patient.

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Summary Of The Invention

Microneedle devices are provided for delivery of drugs across or into biological tissue and for controlled sampling of biological fluids in a minimally-invasive, painless, and convenient manner. The microneedle devices permit (1) drug delivery at clinically relevant rates across or into skin or other tissue barriers, and (2) *in vivo* sensing or withdrawal of biological fluids from the body, particularly from or through the skin or other tissue barriers.

In a preferred embodiment for drug delivery, the devices include a plurality of hollow microneedles, which are attached to or integrated into a substrate, and at least one reservoir selectably in communication with the microneedles, wherein the volume or amount of drug to be delivered can be selectively altered. The reservoir contains the drug to be delivered, and can be formed of a deformable, preferably elastic, material. The device also can include means for compressing the reservoir to drive the drug from the reservoir through the microneedles. The means can include a plunger or osmotic pump. In one embodiment, the reservoir is a syringe or pump connected to the substrate. The device also can include a sealing mechanism to contain the drug in one or more of the reservoirs until it is ready to be delivered or mixed with a liquid carrier. In one embodiment, the sealing mechanism is a fracturable barrier interposed between the reservoir and the substrate. The device also can include a means for providing feedback, such as color change, to the user to indicate that delivery has been initiated and/or completed. In another embodiment, the microneedle device further includes a rate control means, such as a semi-permeable membrane, to regulate the rate or extent of drug which flows through the microneedles.

In a preferred embodiment for withdrawal or sensing, the microneedle device includes one or more microneedles, preferably in a three-dimensional array, a substrate to which the microneedles are connected, and at least one collection chamber and/or sensor in communication with the microneedles. Preferred embodiments further include a means for inducing biological fluid, such as blood, lymph, or interstitial fluid, to be drawn through the microneedles and into the collection chamber for analysis. This induction preferably is accomplished by use of a pressure gradient, which can be created for example by selectively increasing the interior volume of the collection chamber, which includes an elastic or movable

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portion engaged to a rigid base. In a preferred embodiment, the microneedle device further comprises means for transduction, storage, transmission, and display of measured values. The microneedle device also preferably includes means for securing the device to a biological barrier during withdrawal or sensing.

The microneedle devices preferably are provided with means for preventing undesired reuse of or contact with the microneedles. These means can include protective packaging, such as a peelable liner that temporarily covers the tips of the microneedles. The packaging also can be used to shear off the microneedles following their intended use, thereby preventing their reuse.

Also provided are microneedle devices and methods of use thereof for the enhanced transport of molecules, including drugs and biological molecules, across tissue by improving the interaction of an array of microneedles and a deformable, elastic biological barrier, such as human skin. The devices and methods act to (1) limit the elasticity, (2) adapt to the elasticity, (3) utilize alternate ways of creating the holes for the microneedles to penetrate the biological barrier, other than the simply direct pressure of the microneedle substrate to the barrier surface, or (4) combinations of (1)-(3).

In preferred embodiments for limiting the elasticity of skin, the microneedle device includes features suitable for stretching, pulling, or pinching the skin to present a more rigid, less deformable, surface in the area to which the microneedles are applied (i.e. penetrate). For example, a vacuum can be applied to the area of the skin at the site of microneedle application to pull it taut and/or pull the skin onto the tips of the microneedles. Alternatively or in addition, the elasticity of skin can be reduced by applying a thin film or membrane over the skin surface at the site of application, so as to keep the skin tight, limiting the ability of the skin to stretch at the application site. The microneedles are then pushed through the film or membrane and into the skin.

In preferred embodiments for adapting the device to the elasticity of skin, the microneedles of the device include individual extensions or are provided in a curved three dimensional array, for example, by using a flexible substrate and/or varying the height of the microneedles in the array. In another embodiment, the microneedles are applied to the skin surface at an increased velocity, thereby

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reducing the time available for the stratum corneum and underlying tissues to deform from contact with the tips or entire length of the microneedles.

In a preferred embodiment for creating holes in the skin for microneedles, tiny holes are burned into the skin, for example, by heating of the tips of the microneedles and/or by using a laser. In another embodiment, a focused blast of high pressure gas is used to create the holes.

Brief Description Of The Drawings

Figures 1a-e are side cross-sectional views of a method for making hollow microneedles.

Figures 2a-g are side cross-sectional views of a method for making a hollow microneedle.

Figures 3a-d are side cross-sectional views illustrating a preferred method for making hollow microneedles.

Figures 4a-d are side cross-sectional views illustrating a preferred method for making hollow silicon microtubes.

Figures 5a-e are side cross-sectional views illustrating a preferred method for making hollow metal microtubes.

Figures 6a-d are side cross-sectional views illustrating a preferred method for making tapered metal microneedles.

Figures 7a-d are side cross-sectional views illustrating a method for making tapered microneedles using laser-formed molds.

Figures 8a-f are side cross-sectional views illustrating a second method for making tapered microneedles using laser-formed molds.

Figure 9 is a side elevational view of a schematic of an embodiment of the microneedle device inserted into undeformed skin.

Figures 10a-d are illustrations of microneedle devices having various embodiments of microneedle extensions.

Figures 11a-c are cross-sectional views illustrating microneedle devices having curved substrates (11a), varying microneedle height (11b), and linear microneedle arrays (11c).

Figures 12a-e are cross-sectional views illustrating preferred microneedle devices inserted into skin with altered elasticity.

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Figures 13a-c are cross-sectional views illustrating preferred embodiments of microneedle devices which can apply suction to skin at the site of insertion.

Figures 14a-c are cross-sectional (14a-b) and perspective (14c) views illustrating preferred embodiments of microneedle devices which stretch the skin at the site of insertion.

Figures 15a-c are cross-sectional views illustrating examples of microneedle devices which pinch the skin at the site of insertion.

Figure 16 is a cross-sectional view of a preferred embodiment of a microneedle device for use in localized heating of skin.

Figure 17 is a cross-sectional view of a preferred embodiment of a microneedle device having a microneedle reinforcing layer.

Figures 18a-b are cross-sectional views of a preferred embodiment of a microneedle device having a flexible substrate in an unactivated position (18a) and an activated position (18b).

Figure 19 is a cross-sectional view a preferred embodiment of a microneedle device having arrays of microneedles with spaces between the arrays.

Figures 20a-c are cross-sectional views of preferred embodiments of a microneedle drug delivery device. The device of Figure 20a includes a reservoir and is suitable for transdermal drug delivery. The device of Figures 20a and 20b includes a deformable reservoir, wherein delivery is activated by manual, e.g., finger or thumb, pressure applied to compress the reservoir directly (20b) or indirectly (20c).

Figure 21 is a cross-sectional view of another preferred embodiment of a microneedle drug delivery device, wherein delivery is activated by manual pressure applied via a plunger to compress the reservoir.

Figure 22 is a cross-sectional view of another preferred embodiment of a microneedle drug delivery device, wherein delivery is activated by releasing a compressed spring which forces the plunger to compress the reservoir.

Figures 23a-b are cross-sectional views of preferred embodiments of a microneedle drug delivery device having a multiple chambered reservoirs.

Figure 24 is a cross-sectional view of a preferred embodiment of the microneedle drug delivery device, which incorporates an osmotic pump to force the drug contents from the reservoir.

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Figure 25 is a cross-sectional view of a preferred embodiment of a microneedle device for fluid withdrawal.

Figure 26 is a cross-sectional view of another preferred embodiment of a microneedle device for fluid withdrawal.

Figures 27a-c are cross-sectional views of preferred embodiments of a microneedle device in which a sensor is included on the external surface of a hollow needle (27a), on the internal bore surface of a hollow needle (27b), and within the pores of a porous, hollow needle (27c).

Detailed Description Of The Invention

1. Biological Barriers

The devices disclosed herein are useful in transport of material into or across biological barriers including the skin (or parts thereof); the blood-brain barrier; mucosal tissue (e.g., oral, nasal, ocular, vaginal, urethral, gastrointestinal, respiratory); blood vessels; lymphatic vessels; or cell membranes (e.g., for the introduction of material into the interior of a cell or cells). The biological barriers can be in humans or other types of animals, as well as in plants, insects, or other organisms, including bacteria, yeast, fungi, and embryos. The microneedle devices can be applied to tissue internally with the aid of a catheter or laparoscope. For certain applications, such as for drug delivery to an internal tissue, the devices can be surgically implanted.

In a preferred embodiment, the microneedle device disclosed herein is applied to skin. The stratum corneum is the outer layer, generally between 10 and 50 cells, or between 10 and 20 μm thick. Unlike other tissue in the body, the stratum corneum contains "cells" (called keratinocytes) filled with bundles of cross-linked keratin and keratohyalin surrounded by an extracellular matrix of lipids. It is this structure that is believed to give skin its barrier properties, which prevents therapeutic transdermal administration of many drugs. Below the stratum corneum is the viable epidermis, which is between 50 and 100 μm thick. The viable epidermis contains no blood vessels, and it exchanges metabolites by diffusion to and from the dermis. Beneath the viable epidermis is the dermis, which is between 1 and 3 mm thick and contains blood vessels, lymphatics, and nerves.

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As used herein, references to using the microneedle devices on "skin" also include using the microneedle devices with other biological barriers unless expressly limited to only skin.

2. The Microneedle Device

The microneedle devices disclosed herein include a substrate, one or more microneedles, and optionally (i) a reservoir for delivery of drugs, (ii) a fluid collection chamber for collection of biological fluid, and/or (iii) a sensor for sensing an analyte, all or any of which (i-iii) can be selectably in communication with at least one microneedle. The devices also can include one or more pumps, sensors, and/or microprocessors to control the interaction of the foregoing. The microneedle device preferably includes penetration enhancing features to alter or adapt to deformable and elastic biological barriers, such as the skin over much of the human body. Preferably, the microneedles are provided as a multi-dimensional array, in contrast to a device with a single microneedle or single row of microneedles. The microneedle device can be adapted to be a single-use, disposable device, or can be adapted to be fully or partially reusable.

In one embodiment for delivery of drugs, the microneedle device includes at least three components: a plurality of microneedles; a substrate to which the base of the microneedles are secured or integrated; and at least one reservoir that is selectably in fluid connection with one or more of the microneedles.

a. Substrate

The substrate of the device can be constructed from a variety of materials, including metals, ceramics, semiconductors, organics, polymers, and composites. The substrate includes the base to which the microneedles are attached or integrally formed. A reservoir and/or fluid collection chamber also may be attached to, or integrally formed with, the substrate. The substrate can be adapted to fit a Luer-Lock syringe or other conventionally used drug delivery or fluid withdrawal device that currently uses hypodermic needles as the barrier penetration method. A fluid collection chamber and/or sensor can be attached to the substrate or formed (e.g., as part of the substrate) to communicate directly with the base of the microneedles.

In one embodiment of the device, the substrate is formed from a thin, rigid material that is sufficiently stiff so as to force the attached microneedles through the

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biological barrier in such areas where the barrier resists deformation by the microneedles.

In a preferred embodiment of the device, the substrate, and possibly other components, is formed from flexible materials, or have appropriate materials so as to be flexible, to allow the device to fit the contours of the biological barrier (such as the skin, vessel walls, or the eye) to which the device is applied and to adapt to barrier deformations that may occur when the microneedle device is applied. A flexible device further facilitates more consistent penetration during use, since penetration can be limited by deviations in the attachment surface. For example, the surface of human skin is not flat due to dermatoglyphics, i.e. tiny wrinkles, and hair, and is highly deformable. The flexible substrate can be deformed mechanically (for example, using an actuator or simply by fluid pressure) in order to pierce the biological barrier. Conformality of the flexible device to the skin can be further enhanced by using an external force, such as a uniform pressure, to aid insertion of the microneedles into the biological barrier. However, for some biological barriers or applications, a rigid substrate may be preferred.

b. Microneedle

The microneedles of the device can be constructed from a variety of materials, including metals, ceramics, semiconductors, organics, polymers, and composites. Representative materials of construction include pharmaceutical grade stainless steel, gold, titanium, nickel, iron, gold, tin, chromium, copper, palladium, platinum, alloys of these or other metals, silicon, silicon dioxide, and polymers. Representative biodegradable polymers include polymers of hydroxy acids such as lactic acid and glycolic acid polylactide, polyglycolide, polylactide-co-glycolide, and copolymers with PEG, polyanhydrides, poly(ortho)esters, polyurethanes, poly(butyric acid), poly(valeric acid), and poly(lactide-co-caprolactone). Representative non-biodegradable polymers include polycarbonate, polymethacrylic acid, ethylenevinyl acetate, polytetrafluoroethylene (TEFLON^{TM}), and polyesters.

Generally, the microneedles should have the mechanical strength to remain intact for delivery of drugs, or serve as a conduit for the collection of biological fluid, while being inserted into the skin, while remaining in place for up to a number of days, and while being removed. In embodiments where the microneedles are formed of biodegradable polymers, however, this mechanical requirement is less

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stringent, since the microneedles or tips thereof can break off, for example in the skin, and will biodegrade. Nonetheless, even a biodegradable microneedle still needs to remain intact at least long enough for the microneedle to serve its intended purpose (e.g., its conduit function). Therefore, biodegradable microneedles can provide an increased level of safety, as compared to nonbiodegradable ones. The microneedles generally should be sterilizable using standard methods such as ethylene oxide or gamma irradiation.

The microneedles can be formed of a nonporous solid, a porous solid (with or without a sealed coating or exterior portion), or hollow. As used herein, the term "porous" means having pores or voids throughout at least a portion of the microneedle structure, sufficiently large and sufficiently interconnected to permit passage of fluid and/or solid materials through the microneedle. As used herein, the term "hollow" means having one or more substantially annular bores or channels through the interior of the microneedle structure, having a diameter sufficiently large to permit passage of fluid and/or solid materials through the microneedle. The annular bores may extend throughout all or a portion of the needle in the direction of the tip to the base, extending parallel to the direction of the needle or branching or exiting at a side of the needle, as appropriate. A solid or porous microneedle can be hollow. One of skill in the art can select the appropriate porosity and/or bore features required for specific applications. For example, one can adjust the pore size or bore diameter to permit passage of the particular material to be transported through the microneedle device. The inner surface of the bore of hollow microneedles can be made rough to enhance cell membrane disruption for those applications in which cell disruption is useful.

The microneedles can have straight or tapered shafts. A hollow microneedle that has a substantially uniform diameter, which needle does not taper to a point, is referred to herein as a "microtube." As used herein, the term "microneedle" includes both microtubes and tapered needles unless otherwise indicated. In one embodiment, the diameter of the microneedle is greatest at the base end of the microneedle and tapers to a point at the end distal the base. The microneedle can also be fabricated to have a shaft that includes both a straight (untapered) portion and a tapered portion.

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In a preferred embodiment for drug delivery, the microneedles are hollow; that is, each contains at least one substantially annular bore or channel having a diameter large enough to permit passage of a drug-containing fluid and/or solid materials through the microneedle. The bores may be linear, i.e. extend upwardly from needle base to needle tip, or they may take a more complex path, e.g. extend upwardly from the needle base, but then lead to one or more 'portholes' or 'slits' on the sides of the needles, rather than an opening at the needle tip.

The microneedles can be formed with shafts that have a circular cross-section in the perpendicular, or the cross-section can be non-circular. For example, the cross-section of the microneedle can be polygonal (e.g. star-shaped, square, triangular), oblong, or another shape. The shaft can have one or more bores. The cross-sectional dimensions typically are between about 10 nm and 1 mm, preferably between 1 and 500 μm, and more preferably between 10 and 200 μm. The outer diameter is typically between about 10 μm and about 100 μm, and the inner diameter is typically between about 3 μm and about 80 μm.

The length of the microneedles typically is between about 10 μm and 1 mm, preferably between 100 and 1 mm, more preferably between 100 and 500 μm, and more preferably between 150 and 350 μm. An array of microneedles can include a mixture of microneedles having, for example, various lengths, outer diameters, inner diameters, cross-sectional shapes, and spacing between the microneedles. Preferably, the microneedles are sized to avoid or minimize contact with nerve endings in the biological tissue, such as the dermis, thereby eliminating or reducing pain when the microneedles are inserted, for example into the skin.

The microneedles can be oriented perpendicular or at an angle to the substrate. Preferably, the microneedles are oriented perpendicular to the substrate to provide structural strength and to permit ease of insertion into the tissue. An array of microneedles can include a mixture of microneedle orientations, heights, spacings, or other parameters. This variation in an array can be useful, for example, if different microneedles are to provide different sensing or insertion functions.

In embodiments for sensing and/or withdrawal, the microneedles function as a conduit, a sensing element, or a combination thereof. In one embodiment, one or more of the microneedles are coated (if solid, porous, or hollow) and/or at least

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partially filled (if porous or hollow) with a sensing or diffusion-modifying material. In one embodiment, the microneedle can have one or more holes (ports) or slits positioned on the sides of the shaft of a hollow microneedle having a blunt, open, or closed tip. This design may reduce blockage of the conduit, for example, due to tissue or cells when the microneedles are inserted.

c. Reservoir

In some embodiments, particularly those for drug delivery and fluid extraction, the microneedle device includes a reservoir in communication, preferably selectably so, with the microneedles. The reservoir can be attached to the substrate by any suitable means. In a preferred embodiment, the reservoir is attached to the back of the substrate (opposite the microneedles) around the periphery, using an adhesive agent (e.g., glue). A gasket may also be used to facilitate formation of a fluid-tight seal.

In a preferred embodiment, the reservoir contains drug, for delivery through the microneedles. The reservoir may be a hollow vessel, a porous matrix, or a solid form including drug which is transported therefrom. The reservoir can be formed from a variety of materials that are compatible with the drug or biological fluid contained therein. Preferred materials include natural and synthetic polymers, metals, ceramics, semiconductors, organics, and composites. In one embodiment, the reservoir is a standard syringe.

The microneedle device can include one or a plurality of chambers for storing materials to be delivered. In the embodiment having multiple chambers, each can be in fluid connection with all or a portion of the microneedles of the device array. In one embodiment, at least two chambers are used to separately contain drug (e.g., a lyophilized drug, such as a vaccine) and an administration vehicle (e.g., saline) in order to prevent or minimize degradation during storage. Immediately before use, the contents of the chambers are mixed. Mixing can be triggered by any means, including, for example, mechanical disruption (i.e. puncturing or breaking), changing the porosity, or electrochemical degradation of the walls or membranes separating the chambers. In another embodiment, a single device is used to deliver different drugs, which are stored separately in different chambers. In this embodiment, the rate of delivery of each drug can be independently controlled.

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In a preferred embodiment, the reservoir should be in direct contact with the microneedles and have holes through which drug could exit the reservoir and flow into the interior of hollow or porous microneedles. In another preferred embodiment, the reservoir has holes which permit the drug to transport out of the reservoir and onto the skin surface. From there, drug is transported into the skin, either through hollow or porous microneedles, along the sides of solid microneedles, or through pathways created by microneedles in the skin.

In a preferred embodiment for drug delivery, the reservoir is selectably in connection with the microneedle bore, such that the reservoir contents can flow from the reservoir and out through the microneedle tip, into the target tissue. Typically, it is attached to, or integrated into, the substrate, either integrally (as in a one-piece device) or at the moment of drug delivery (as with a Luer-lock type device). The reservoir is to provide suitable, leak-free storage of the drug composition before it is to be delivered. The reservoir should keep the drug composition free of contaminants and degradation-enhancing agents. For example, the reservoir should exclude light when the drug composition contains photo-sensitive materials, and should include an oxygen barrier material in order to minimize exposure of drugs sensitive to oxidation. Also, the reservoir should keep volatile materials inside the reservoir, for example, to prevent water from evaporating, causing the drug composition to dry out and become undeliverable.

The drug reservoir can be substantially rigid or readily deformable. The reservoir can be formed from one or more polymers, metals, ceramics, or combinations thereof. In a preferred embodiment, the reservoir includes a volume surrounded by one or more walls, or includes a porous material, such as a sponge, which can retain, for example, the drug liquid until the material is compressed.

In a preferred embodiment, the reservoir is formed of an elastic material, such as an elastomeric polymer or rubber. For example, the reservoir can be a balloon-like pouch that is stretched (in tension) when filled with a fluid drug composition to be delivered.

The reservoir of a single microneedle device can include a plurality of compartments that are isolated from one another and/or from a portion of the microneedles in an array. The device can, for example, be provided to deliver different drugs through different needles, or to deliver the same or different drugs at

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different rates or at different times (Figure 23a). Alternatively, the contents of the different compartments can be combined with one another, for example, by piercing, or otherwise removing, a barrier between the compartments, so as to allow the materials to mix. In a preferred embodiment, one compartment contains a saline solution or another delivery vehicle, while another compartment contains lyophilized drug (Figure 23b). In a preferred embodiment, the reservoir is a standard or Luer-Lock syringe adapted to connect to a microneedle array.

d. Collection Chamber

In embodiments for extraction, the device preferably includes a fluid collection chamber. The fluid collection chamber is selectably in connection with the microneedle bores or pores, such that a biological fluid can flow from the tissue surrounding the microneedle, through the microneedle, and into the collection chamber. Typically, the collection chamber is attached to, or integrated into, the substrate. The chamber should function to contain a biological fluid sample so as to permit analysis within the microneedle device or following transfer to a separate analytical device.

The collection chamber can be substantially rigid or readily deformable. The collection chamber can be formed from one or more polymers, metals, ceramics, semiconductor, or combinations thereof. In a preferred embodiment, the collection chamber contains a porous or absorbent material, such as a sponge, gel, or paper or polymeric strip. The material can be permanently contained or removable, and can function as a diagnostic element or substrate for use in analytical devices. The chamber can initially be empty or can contain a gas or one or more reagents in any form (e.g., liquid or solid particles). In one embodiment, at least a portion of the interior walls of the chamber are coated with a reagent for assaying the biological fluid.

In a preferred embodiment, the collection chamber is formed of an elastic material, such as an elastomeric polymer or rubber. For example, the collection chamber can be a collapsed balloon-like pouch that expands when the biological fluid is drawn into the collection chamber.

The collection chamber of a microneedle device can include a plurality of compartments that are temporarily or permanently isolated from one another and/or from a portion of the microneedles in an array. The device can, for example, be

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provided to collect or sense through different needles at different rates or at different times into the different compartments. Alternatively, some of the different compartments can contain analytical reagents which can be combined with the biological fluid sample, for example, by piercing, or otherwise removing, a barrier between the compartments, so as to allow the materials to mix for analysis.

In another preferred embodiment, the collection chamber is adapted to receive and use standard glucose sensing strips, which can be loaded into the microneedle device before, during, or after the biological fluid is extracted.

Two embodiments of the microneedle device are shown in Figures 25-26. In Figure 25, microneedle device **610** includes substrate **612** from which a three-dimensional array of microneedles **614** protrude. As shown, the annular bore of the microneedles **614** extends through the substrate **612**. The device **610** also includes fluid collection chamber **616** which is in fluid connection with the microneedles **614**. Fluid collection chamber **616** includes an access port **618** through which collected fluid can be withdrawn from collection chamber **616**, and/or through which a withdrawing force, such as a vacuum, can be applied. In Figure 26, microneedle device **620** includes substrate **612** from which a three-dimensional array of microneedles **614** protrude, and fluid collection chamber **616**, as well as elastic cap **622** and one-way valve **624**. The interior of elastic cap **622** is in communication with, or open to, fluid collection chamber **616**.

e. Transport Control Components

The microneedle device also must be capable of transporting material across the barrier at a useful rate. For example, the microneedle device must be capable of delivering drug across the skin at a rate sufficient to be therapeutically useful. The device may include a housing with microelectronics and other micromachined structures to control the rate of delivery either according to a preprogrammed schedule or through active interface with the patient, a healthcare professional, or a biosensor. The rate can be controlled by manipulating a variety of factors, including the characteristics of the drug formulation to be delivered (e.g., its viscosity, electric charge, and chemical composition); the dimensions of each microneedle (e.g., its outer diameter and the area of porous or hollow openings); the number of microneedles in the device; the application of a driving force (e.g., a concentration gradient, a voltage gradient, a pressure gradient); and the use of a valve.

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The rate also can be controlled by interposing between the drug in the reservoir and the opening(s) at the base end of the microneedle polymeric or other materials selected for their diffusion characteristics. For example, the material composition and layer thickness can be manipulated using methods known in the art to vary the rate of diffusion of the drug of interest through the material, thereby controlling the rate at which the drug flows from the reservoir through the microneedle and into the tissue.

Transportation of molecules through the microneedles can be controlled or monitored using, for example, various combinations of valves, pumps, sensors, actuators, and microprocessors. These components can be produced using standard manufacturing or microfabrication techniques. Actuators that may be useful with the microneedle devices disclosed herein include micropumps, microvalves, and positioners. In a preferred embodiment, a microprocessor is programmed to control a pump or valve, thereby controlling the rate of delivery.

Flow of molecules through the microneedles can occur based on diffusion, capillary action, or can be induced using conventional mechanical pumps or nonmechanical driving forces, such as electroosmosis or electrophoresis, or convection. For example, in electroosmosis, electrodes are positioned on the biological barrier surface, one or more microneedles, and/or the substrate adjacent the needles, to create a convective flow which carries oppositely charged ionic species and/or neutral molecules toward or into the biological barrier. In a preferred embodiment, the microneedle device is used in combination with another mechanism that enhances the permeability of the biological barrier, for example by increasing cell uptake or membrane disruption, using electric fields, ultrasound, chemical enhancers, vacuum viruses, pH, heat and/or light.

Passage of the microneedles, or drug to be transported via the microneedles, can be manipulated by shaping the microneedle surface, or by selection of the material forming the microneedle surface (which could be a coating rather than the microneedle per se). For example, one or more grooves on the outside surface of the microneedles can be used to direct the passage of drug, particularly in a liquid state. Alternatively, the physical surface properties of the microneedle can be manipulated to either promote or inhibit transport of material along the microneedle surface, such as by controlling hydrophilicity or hydrophobicity.

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The flow of molecules can be regulated using a wide range of valves or gates. These valves can be the type that are selectively and repeatedly opened and closed, or they can be single-use types. For example, in a disposable, single-use drug delivery device, a fracturable barrier or one-way gate may be installed in the device between the reservoir and the opening of the microneedles. When ready to use, the barrier can be broken or gate opened to permit flow through the microneedles. Other valves or gates used in the microneedle devices can be activated thermally, electrochemically, mechanically, or magnetically to selectively initiate, modulate, or stop the flow of molecules through the needles. In a preferred embodiment, flow is controlled by using a rate-limiting membrane as a "valve."

The microneedle devices can further include a flowmeter or other means to monitor flow through the microneedles and to coordinate use of the pumps and valves.

f. Sensors

The sensing/analyzing function can occur in the microneedle or body of the device (e.g., in the fluid collection chamber), or external to the device following removal of a sample. The sensing device can be in or attached to one or more microneedles, integrated into the substrate, or within or in communication with the fluid collection chamber. Biosensors can be located on the microneedle surface, inside a hollow or porous microneedle, or inside a device in communication with the body tissue via the microneedle (solid, hollow, or porous).

In a preferred embodiment, the microneedle device provides a single-use collection means. In this design, the microneedle array is used to extract a single measurement and then is detached from a reusable base portion, if any, and disposed.

In one embodiment, the microneedle device is adapted to work with "laboratory-on-a-chip" devices, such as made by Caliper Technologies, Palo Alto, California (*see, e.g.*, U.S. Patent No. 5,852,495 to Parce and U.S. Patent No. 5,876,675 to Kennedy); Aclara Biosciences, Hayward, California (*see, e.g.*, U.S. Patent No. 5,858,188 to Soane et al. and U.S. Patent No. 5,883,211 to Sassi et al.); and Nanogen, San Diego, California (*see, e.g.*, U.S. Patent Nos. 5,605,662 and 5,632,957 to Heller et al.).

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(i). Types of Sensors

Useful sensors may include sensors of pressure, temperature, chemicals, pH, and/or electro-magnetic fields. These microneedle biosensors can include four classes of principal transducers: potentiometric, amperometric, optical, and physiochemical. An amperometric sensor monitors currents generated when electrons are exchanged between a biological system and an electrode. Blood glucose sensors frequently are of this type.

Sensing information or signals can be transferred optically (e.g., refractive index) or electrically (e.g., measuring changes in electrical impedance, resistance, current, voltage, or combination thereof). For example, it may be useful to measure a change in the resistance of tissue to an electrical current, wherein different resistances are calibrated to signal that withdrawal has been completed.

In a preferred embodiment, the microneedle device may include an integrated sensor, such as a chemical sensor, biosensor, or other measurement system to form a complete extraction/ measurement system. The unit can be constructed to function as a closed loop drug delivery unit, including drug delivery means, analyte recovery means, sensing means to measure the analyte, and control means to provide a signal to the drug delivery means. In a preferred embodiment, the unit would include subunits to withdraw fluid and calculate the concentration of glucose, for example, to determine the amount of insulin needed and deliver that amount of insulin.

The device can include means for assaying the amount of analyte extracted. For example, an assay method that results in a color change could be used. The change in color could be detected using a light beam that enters into a disposable collection chamber through a window on top. The analyte may also be detected in the chamber through the use of an enzyme electrode or biosensor. The analyte sensing system can include enzymes that react with the analyte of interest and either electrochemical or optical transducers that measure the content of reaction. Examples of such enzymes are glucose oxidase and glucose dehydrogenase.

An example of an enzyme electrode for glucose is a screen-printed electrode on the surface of which is immobilized glucose oxidase and an electron mediator such as ferrocene or its derivatives. Electrons generated by the oxidation of glucose are transferred from glucose oxidase to the electrode via the mediator. Thus, the

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concentration of glucose in the analyte solution is proportional to the current generated. Yet another detection mechanism may be used based on near-infrared spectroscopy. In this method, concentration of extracted glucose in a gel is detected by the absorption of the near-infrared light that passes through the chamber through two windows.

(ii). Microneedle as Sensing Element

In one embodiment, the microneedle is adapted to be the sensing element. For example, an assay material, such as glucose oxidase, can be (i) coated onto the external surface of hollow or solid microneedles, (ii) distributed within the pores of porous microneedles, or (iii) line or fill the bore(s) of hollow microneedles. See Figure 27 which illustrates a cross sectional view of a preferred embodiment of a microneedle device **630** including microneedle **632**, attached to substrate **634** and having hollow bore **636**. In Figure 27a, sensor material **638** is coated on the external surface of microneedle **632**. In Figure 27b, sensor material **638** is coated on the internal surface of hollow bore **636**. In Figure 27c, sensor material **638** is located within the pores of a porous microneedle **632**. Solid microneedles can also hold or contain sensor material as in Figure 27a, or as in Figure 27c if the microneedles are porous. These various microneedle types and sensors can be used in different combinations within a device array.

In this embodiment, the assay material contacts the analyte for which it is selective and undergoes a change, such as an oxidation reaction. This change is communicated, either directly or indirectly, to the user. For example, change may be indicated optically (change in color or refractive index) or electrically. Alternatively, the change may induce a shift in pH that can be measured and communicated using conventional techniques. In more complex embodiments, the analyte may be adsorbed to the microneedle or a coating thereon, such that mechanical sensing can be used, for example, by measuring vibration changes caused by the adsorption.

The microneedle may function as a conduit for fluids, solutes, electric charge, light, or other materials. In one embodiment, hollow microneedles can be filled with a substance, such as a gel, that has a sensing functionality associated with it. In an application for sensing based on binding to a substrate or reaction mediated by an enzyme, the substrate or enzyme can be immobilized in the needle interior,

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which would be especially useful in a porous needle to create an integral needle/sensor.

(iii). Sensor Electronics

In a preferred embodiment, the sensors are selectively in communication with an electronics package. The electronics package typically includes a power source (e.g., a battery), as well as electronic hardware and software for the transduction, storage, transmission, and display of measured values. The electronics package can be selectively fixed to the microneedle device, for example, so that the electronics package can be reused with a new, disposable microneedle device. The electronics package can include a mechanism for wireless or wire-based transmission of measured values to a remote device for analysis and/or display. The electronics also may include mathematical manipulation of the sensed data, for example, to average measured values or eliminate outlying datapoints so as to provide more useful measurements.

The electronics package also can include software and hardware to initiate or automate the sensing and analysis processes. It may be desirable to design a microneedle device capable of taking multiple measurements to withdraw/sense samples on a preprogrammed schedule (e.g., periodic or random), for example, to monitor the blood plasma levels of an illegal drug. Such a device could be adapted for use with a transmitter designed to lock onto the wrist or ankle of a drug offender or other probationer. The device would then be able to randomly test the wearer without his knowledge in order to assess his compliance with orders to abstain from drug or alcohol use.

In an alternative embodiment, the electronics package includes a device for controlling the withdrawal or sensing process. For example, sensing could be activated based on elapsed time, body temperature, or in response to an external trigger (e.g., motion sensor or push-button). The electronics package, for example, could provide substantially instantaneous readings of glucose levels by depressing a button, or in a microneedle device (e.g., adapted to be worn for an extended period of time), the electronics could it could display a summary of intermittent glucose measurements taken automatically throughout the day. Such a microneedle device would be highly useful to diabetic patients to routinely monitor their blood glucose levels following insulin dosing, between or following meals, and at other times

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throughout the day.

Wave guides can be incorporated into the microneedle device to direct light to a specific location, or for detection, for example, using means such as a pH dye for color evaluation. Similarly, heat, electricity, light or other energy forms may be precisely transmitted to directly stimulate, damage, or heal a specific tissue or intermediary (e.g., tattoo removal for dark skinned persons), or diagnostic purposes, such as measurement of blood glucose based on IR spectra or by chromatographic means, measuring a color change in the presence of immobilized glucose oxidase in combination with an appropriate substrate.

(iv). Single Unit Multiple Sensing

A single microneedle device can be designed to provide multiple, preferably sequential, measurements. In a preferred embodiment, the device includes a plurality of discrete fluid collection chambers, each of which is in communication with a defined subset of microneedles in an array of microneedles. The sensing unit of the device can sense each of the collection chambers independently. The sensing can be triggered manually or device electronics can be preprogrammed to automatically trigger, for example at specific time intervals. The device can include a means for storing, displaying, or transmitting the multiple measured values as needed.

(v). Sensor Calibration

Calibration of the sensor can be accomplished using the concentration of a second analyte or the same analyte measured by another means. The primary analyte can be normalized, lowering extraction to extraction and site to site variability, by the concentration of the second analyte or same analyte from a separate measurement. Normalization may be a linear or non-linear relationship.

In a preferred embodiment for glucose sensing, a reusable sensor, which assays glucose concentration in interstitial fluid, can be calibrated daily by correlating interstitial fluid glucose values with values obtained from glucose measurements obtained from blood, similar to the approach used by Cygnus Inc.'s "Gluco-Watch."

g. Attachment Features

A collar or flange also can be provided with the device, for example, around the periphery of the substrate or the base. It preferably is attached to the device, but

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alternatively can be formed as an integral part of the substrate, for example by forming microneedles only near the center of an "oversized" substrate. The collar can also emanate from other parts of the device. The collar can provide an interface to attach the microneedle array to the rest of the device, and can facilitate handling of the smaller devices.

In a preferred embodiment, the microneedle device includes an adhesive to temporarily secure the device to the surface of the biological barrier. The adhesive can be essentially anywhere on the device to facilitate contact with the biological barrier. For example, the adhesive can be on the surface of the collar (same side as microneedles), on the surface of the substrate between the microneedles (near the base of the microneedles), or a combination thereof.

The device can be integrated into an adhesive patch or an elastic band, which may be worn, for example, around the user's arm or ankle. The arm band can be conveniently worn by a patient for drug delivery, sampling of biological fluids, or both over a prolonged period of time, such as several hours.

Care must be taken so that any adhesive agent does not plug the bores of hollow microneedles. For example, the adhesive agent can be applied in a liquid solution by flooding the top of the substrate below the tips of the microneedles, such as from the side of an array of microneedles, or by using a three-dimensional printing process. The solvent can then be evaporated from the adhesive agent solution, thereby precipitating or gelling the adhesive agent to yield a tacky surface. An alternate method of keeping the tips free of an applied adhesive agent is to choose materials of construction having a hydrophobicity or hydrophilicity to control the wetting of the surface to the microneedle tips.

Where a vacuum is used to induce fluid flow into the device, it may be necessary to provide means for creating a gas-tight seal around the edge of the device so that air is not drawn in through the microneedles at the biological barrier hole/microneedle shaft periphery. The attachment collar or adhesive material can be adapted to provide this function using techniques common to the those skilled in the art. One example is to design the attachment collar to function as a "suction-cup" and wet the interface of the skin and attachment collar with water or another physiologically acceptable sealant.

h. Transdermal Microneedle Device

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Figure 9 is a side elevational view of a schematic of an embodiment of the microneedle device inserted into undeformed skin. The device **10** includes an upper portion or substrate **11** from which a plurality of microneedles **12** protrude. The height of the upper portion **11** is between about 1 μm and 1 cm, and the width of the upper portion is between about 1 mm and 10 cm. The upper portion **11** of the device can be solid or hollow, and may include multiple compartments. In a preferred embodiment for drug delivery, the upper portion **11** contains one or more drugs to be delivered. It is also preferred that the upper portion include one or more sensors and/or an apparatus (e.g., pump or electrode) to drive (provide/direct the force) transport of the drug or other molecules.

The height (or length) of the microneedles **12** generally is between about 1 μm and 1 mm. The diameter and length both affect pain as well as functional properties of the needles. In one embodiment for transdermal applications, the "insertion depth" of the microneedles **12** is less than about 100 μm, more preferably about 30 μm, so that insertion of the microneedles **12** into the skin through the stratum corneum **14** does not penetrate through the epidermis **16** into the dermis **18** (as described below), thereby avoiding contacting nerves and reducing the potential for causing pain. In such applications, the actual length of the microneedles may be longer, since the portion of the microneedles distal the tip may not be inserted into the skin; the uninserted length depends on the particular device design and configuration. The actual (overall) height or length of microneedles **12** should be equal to the insertion depth plus the uninserted length. Other embodiments using sufficiently small microneedles may penetrate into the dermis without causing pain.

The diameter of each microneedle **12** generally is between about 10 nm and 1 mm, and preferably leaves a residual hole (following microneedle insertion and withdrawal) of less than about 1 μm, to avoid making a hole which would allow bacteria to enter the penetration wound. The actual microneedle diameter should be larger than 1 μm, since the hole likely will contract following withdrawal of the microneedle. The diameter of microneedle **12** more preferably is between about 1 μm and 100 μm. Larger diameter and longer microneedles are acceptable, so long as the microneedle can penetrate the biological barrier to the desired depth and the hole remaining in the skin or other tissue following withdrawal of the microneedle is

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sufficiently small, preferably small enough to exclude bacterial entry. The microneedles **12** can be solid or porous, and can include one or more bores connected to upper portion **11**.

1. Microneedle Penetration Enhancing Features

In a preferred embodiment, the microneedle devices include features which improve penetration of the microneedles into deformable, elastic biological barriers, such as human skin. As used herein, "improved penetration" refers to providing more uniform, better controlled insertion of microneedles, for example, as compared to manual insertion of a microneedle or array of microneedles into skin without compensation (in the device design or site preparation or both) for deformation of the skin at the intended site of insertion. This is particularly critical for devices which include a three dimensional array of the microneedles. These features typically function to (1) adapt to the deformation, (2) limit the deformation, and/or (3) utilize alternate ways of creating the holes in the biological barrier for the microneedles to enter. These penetration enhancing techniques generally can be used with solid, porous, or hollow microneedles. Examples of penetration enhancing features include the following:

(i). Microneedle Extensions

In a preferred embodiment for adapting the device to the elasticity of skin, the microneedles of the device include extensions, also called protrusion enhancers. One solution to enhance microneedle penetration would be to make the microneedles much longer. However, very tall, small diameter microneedles would tend to be structurally fragile. Therefore, a relatively wider, yet tall base is provided between the substrate and the microneedle to increase the length while maintaining structural integrity of the microneedles. The extensions can be fabricated using the same microfabrication techniques described herein or other conventional fabrication techniques, and typically are made integrally with the substrate and microneedles. The extensions can be of any cross-sectional shape, are typically between about 500 μm and 10 mm in height, and generally are at least about 200 μm in diameter for a single needle/single extension configuration. A single extension can support one or more microneedles.

The extensions also can be designed to function as a penetration stop or limiter, to limit the depth of microneedle penetration.

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Figures 10a-c illustrate several non-limiting embodiments of the extensions. Device **110** includes substrate **112**, extension **114**, and microneedle(s) **116**. The figures show a single needle/single extension configuration (10a), a multiple needle/single extension configuration (10b), and a multiple needle/multiple extension configuration (10c). The microneedle devices can include arrays of microneedles and extensions in essentially any combination and number.

Figure 10d illustrates an embodiment of a microneedle device **180** having extension **182** terminating in microneedle array **184**. The device also includes shoulder **186** and key (cutout) **188**, which serve to control stretching of the skin at the site of microneedle insertion to enhance penetration. The skin stretches in key **188** as microneedle device **180** is pushed in, while shoulder **186** simultaneously limits the area of skin being stretched.

(ii). Optimized Microneedle Spacing

In another embodiment to adapt to the deformability of skin, the microneedle device includes arrays of microneedles having spaces between the microneedles or between arrays of microneedles, wherein the spacings permit areas of the skin to fill the spaces in order to enhance microneedle contact with adjacent areas of the skin. The spacing is designed to adapt to the skin's radius of curvature to overcome the penetration problem.

Figure 19 illustrates a microneedle device **300** having arrays of microneedles **302** with spaces **304** between the arrays. Spaces **304** have a size between about one and ten times, preferably between about one and two times, the size of the arrays **302**. This spacing effect can be achieved using some configurations of the microneedle extensions described above.

(iii). Linear and Curved Arrays of Microneedles

In another embodiment for adapting the device to the elasticity of skin, the microneedles are provided in a curved three dimensional array. For example, the microneedle device can have a rigid substrate which forms a curved, rather than planar, surface. The substrate can be, for example, hemispherical or elliptical. The device, by presenting the needles with a curved surface, can provide improved uniformity of penetration among the microneedles of an array, as illustrated in Figure 11a. This same effect also can be achieved by varying the height of the microneedles in the array having a planar substrate, as shown in Figure 11b.

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In a preferred embodiment, two dimensional (i.e. linear) arrays are used. A preferred embodiment of a linear array microneedle device is shown in Figure 11c. Device **220** includes substrate **222**, which is formed into a U-shape, and an array of microneedles **224** at the apex of substrate **222**. The substrate/microneedle portion is mounted over the end of a slotted holder **226**. Molecules for transport through the microneedles **224** flow through one or more slots **228** positioned at the end of the slotted holder **226**. The device also includes a fitting portion **230** which is integral with or attached to the slotted holder **226**. The fitting portion **230** can be, for example, a female Luer lock for attachment to a conventional syringe. The use of a linear array such as in this device readily deforms the skin at a sharp radius over the tips of the microneedles **224**, greatly facilitating their penetration into the skin.

In a variation of this embodiment, several linear arrays of microneedles can be combined onto a single fitting portion or holder in order to increase the area of injection. By spacing the arrays on the holder widely enough, the correct skin deformation can be maintained. The spacing is selected to be sufficient to allow the skin or other barrier to reach a relaxed state in the region between the arrays, thus facilitating the correct deformation over each needle array in a manner independent of other arrays.

These microneedle devices are fabricated using or adapting the same microfabrication techniques described herein. In one embodiment, microneedle arrays can be fabricated on flexible substrates, which then are mounted onto rigid spherical, cylindrical, or elliptical surfaces.

(iv). Flexible Substrates

The substrate also can be flexible so that it deforms with the skin or other barrier upon application of the microneedle array.

Figures 18a-b illustrate a preferred embodiment of a microneedle device having a flexible substrate. In this case, device **250** include microneedles **252**, which are fabricated on a flexible substrate **254**. The substrate is laminated to a preformed membrane bubble **256**, such as those which are used as a membrane switch. This laminated structure is attached to holder **258**.

The molecules to be delivered, e.g., drug, are contained in a chamber **260** formed between the membrane bubble **256** and the substrate **254**. The molecules are sealed inside the chamber either at the laminating step or are filled after lamination.

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for example, by injection through the membrane. A sponge or similar device (not shown) may be incorporated into the chamber **260** to contain the molecules before insertion and delivery. The sponge device is compressed by the bubble membrane as it turns to its downward position (*see* Figure 18b).

In operation, the device **250** is pressed against the skin, wherein the holder **258** positions the microneedles **252** against the skin, as shown in Figure 18a. Then, force is applied to the membrane bubble **256**, flipping it through its transition state to the down position. This action applies pressure to the molecules in the chamber **260**, expanding the substrate **254** of the microneedle array and pushing the microneedles **252** through the skin. Subsequently, the pressure forces the molecules through the microneedles **252** and into the skin. It The change in pressure upon the membrane bubble must occur faster and be larger than can be relieved by the flow of molecules through the microneedles, in order to achieve effective delivery.

In an alternative embodiment, the chamber **260** may include an intermediate septum or equivalent divider (not shown) which can be ruptured or moved to permit the molecules to flow through the microneedles **252**. For example, the user applies pressure to the membrane bubble, which pressure first forces the microneedles into the skin, as shown in Figure 18b, and then ruptures the septum to deliver drugs through the needle and into the skin.

(v). *High Velocity Insertion*

In another embodiment, the microneedles are applied to the skin surface at an increased velocity, thereby reducing the time available for the stratum corneum and underlying tissues to deform from contact with the tips of the microneedles. The insertion can be by forcing the microneedles into the skin, forcing the skin into the microneedles, or a combination thereof. This more rapid microneedle/skin contact can occur, for example, by releasing a compressed spring or other elastic device that pushes or pulls the microneedles, or by a rapid burst release of compressed gas against the back of the substrate. Alternatively, the skin could be forced by rapidly pulling a vacuum or pushing the skin from the sides (pinching) at the site of microneedle administration to cause the skin to be pulled up against an array of microneedles. Various combinations of these mechanisms can be used together, and typically are integrated into the microneedle device.

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(vi). Limiting Biological Barrier Elasticity

In preferred embodiments for limiting the elasticity/deformation of tissue, the microneedle device includes features suitable for stretching, pulling, or pinching the tissue, particularly skin, to present a more rigid surface in the area to which the microneedles are applied (i.e. penetrate) as illustrated in Figures 12a-c.

It may also be useful to cool the stratum corneum to reduce its elasticity and/or to apply chemicals to the skin surface to "tighten" the skin and reduce its elasticity. For example, the skin surface may be cooled by directing a flow of cold gas through the microneedles onto the skin surface. The flow of cold gas can be generated, for example, from a liquefied gas source such as nitrogen, carbon dioxide, or a refrigerant such as FREON™. The skin also can be cooled by contact with a cooling (e.g., refrigerated) element, such as a plate, or the microneedles themselves can function as the cooling element. The cooling element should provide sufficient local cooling of the stratum corneum so as to stiffen the stratum corneum in the vicinity of each needle sufficiently to enhance penetration. These cooling means can be used independently or in combination with chemical means to tighten the skin. Examples of chemical means include biocompatible organic solvents, such as isopropanol or acetone, which tend to dry out and stiffen the skin surface, or such astringent chemicals that can be topically applied to the skin before microneedle insertion.

(a). suction

Suction can be used to hold the skin in place during the insertion of the microneedle, limiting the deflection and deformation of skin in contact with the tips of the microneedles. Suction also can be used to bring skin in contact with stationary microneedles, and if sufficiently great, can cause the skin to be pierced by the microneedles. The suction may also enhance systemic delivery of drug by increasing blood flow in the area of administration via the microneedles, or may enhance withdrawal of interstitial fluid or blood for analysis/sensing. The suction typically is induced by creating a vacuum on the skin at the site of microneedle application. The vacuum induced is between about 10 and 2000 mm Hg, preferably between about 50 and 300 mm Hg, at the site of application. The suction typically can occur before, simultaneously with, or following insertion of the microneedles.

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Examples of microneedle devices adapted to create a vacuum are shown in Figures 13a-c. Figure 13a shows device **120** which includes substrate **122**, microneedle array **124**, and reservoir **126**, which is partially enclosed by outer chamber **128**. Outer chamber **128** includes a port **127** through which air or other fluids within the chamber are withdrawn following, and/or before, contact of the opening rim **129** to the skin surface. The outer chamber **128** can be made of flexible or rigid material, and generally is gas impermeable. A source of vacuum, e.g., a vacuum pump, typically is adapted to be in fluid communication with port **127**. A micro-battery-powered vacuum pump can be integrated into the device to provide this function. In another embodiment, device **128** can be evacuated, so that when triggered, the skin at the site of administration is exposed to the vacuum and is pulled up into the device. This embodiment effects a short pulse of vacuum, without requiring extra equipment. In another embodiment, a tool can be used to mechanically create the necessary vacuum upon manual activation.

Figure 13b is a variation of the device shown in Figure 13a, wherein device **130** includes two coaxial cylinders, outer cylinder **132** and inner cylinder **134**. Vacuum is induced in the space between the cylinders. Inner cylinder **134** terminates with reservoir **136**, substrate **138**, and microneedles **140**. Outer cylinder **132** and its rim **139** function as the outer chamber **128** and opening rim **129** in Figure 13a. Optionally, an overpressure can be applied in the inner cylinder **134** to facilitate flow, e.g. of drug, from reservoir **136** through the microneedles **140**. The device can be designed to have the inner cylinder **134** and microneedles **140** in a position fixed or movable with respect to the outer cylinder **132**, as appropriate. In other embodiments, the device can have a non-cylindrical shape.

A preferred embodiment of a suction device for use with a microneedle array is shown in Figure 13c. The suction device **200** includes body portion **202** having an inner vacuum ring **204** and an outer vacuum ring **206**, separated by a ring-shaped microneedle array (not shown). The use of coaxial suction rings provides a uniform deformation force on the skin. The amount of deformation can be controlled by varying the absolute and relative sizes of the annular vacuum rings, and by controlling the amount of vacuum pulled, for example, by a suction pump. The relative height of the inner and outer rings, and their height relative to the microneedle array, can be varied to change the skin deformation and consequent

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pressure onto the microneedle array. In the device shown, molecules, typically as a fluid, are delivered through a port **208** in the annular ring holding the microneedles, and to the whole ring-shaped array through a circular fluidics channel **210** adjacent the substrate of the microneedles. The device shown includes a female Luer lock **212** for attachment to a conventional syringe, as well as tubing section **214** that can be used to connect the device to a vacuum pump of some kind, either manually or power driven.

(b). stretching

Stretching can also be used to limit the deflection and deformation of skin in contact with the tips of the microneedles. The stretching can be effected by a separate device or incorporated as a feature of the microneedle device itself.

Figures 14a-b shows one embodiment of a microneedle device that includes a stretching component. Microneedle device **150** includes flexible stretching cone **152**, which includes circular outer rim **156** and surrounds microneedles **154**. Figure 14a shows device **150** with the stretching cone **152** in its normal, relaxed form and shape (i.e. no net forces applied to it) resting on the skin surface, with the tips of microneedles **154** terminating inside stretching cone **152**. Figure 14b shows device **150** following application of pressure (e.g., manual pressure) on device **150** toward the skin. As the force is applied, outer rim **156** begins to "flatten" and frictionally engages the skin surface, stretching the skin away from and perpendicular to the central axis of the stretching cone **152**, while the microneedles **154** move into contact with and then penetrate the skin. The outer rim **156** should be roughened, knurled, have teeth, or be formed of or coated with a sticky or non-slippery material so as to provide the necessary engagement between the surfaces. Examples of suitable materials include rubbers and synthetic polymers.

In another embodiment, the device includes an aperture or other means of allowing gas trapped between the barrier and the device to escape. Examples of such apertures include one or more vent holes or slits, for example, through the side of the stretching cone **152**.

A preferred embodiment is shown in Figure 14c, wherein stretching cone **152** is replaced with a plurality of, e.g., four, hinged stretching elements **153**. The stretching elements stretch the skin laterally as device **150** is pressed down against the skin. The skin deflection is determined by the length of the stretcher element

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153 relative to the length of the central cylinder 155. Like outer rim 156, the ends of the stretching elements 153 (distal the hinge end) preferably are roughened or knurled, have teeth, or are formed of or coated with a sticky or non-slippery material so as to control the friction between the skin and the stretching elements 153, thereby providing an additional means of controlling the stretching force. The device shown in Figure 14c is connected to a standard female Luer lock 157, for attachment to a standard syringe. In a preferred embodiment, microneedles 154 are aligned in columns and rows substantially parallel to the stretching element 153, so as to optimize the stretching force fore effective microneedle penetration.

In another embodiment, stretching of the skin is accomplished using a separate ring device, which can be pressed against the skin and then concentrically expanded to stretch the skin within the ring. For example, the ring device can be a rubber-coated metal band (having diameter x), which is compressed into a coil (having a diameter less than x). The coiled ring is then pressed against the skin and allowed to uncoil (i.e. expand to diameter x again), while frictionally engaging the skin, thereby stretching it. In a further embodiment, the ring device is configured as an iris that expands to stretch the skin upon mechanical actuation by engaging an actuation lever or rotary motion.

(c). pinching

Pinching can also be used to limit the deflection and deformation of skin in contact with the tips of the microneedles. In a preferred embodiment, the microneedle device includes jaws, typically one or more pair, which can be pressed against the skin surface and triggered to close against a segment of skin, as illustrated in Figures 15a-b. The size of the jaw opening can be selected based on the area of skin to be pinched to facilitate penetration of the microneedle array selected for use.

In Figures 15a-b, microneedle device 160 includes a pair of jaws 164 having flex or hinge points 168 and tips 166, positioned around microneedles 162. The Figures show the jaws 164 in the open position (Fig. 15a) and in the closed position (Fig. 15b), pinching an area of skin which is drawn against the microneedle 162, causing the microneedles to penetrate the skin.

An alternative embodiment of the clamping device and method is illustrated in Figure 15c, wherein clamping device 170 is used to pinch the skin and provide a

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rigid support **172** behind a pinched section of skin, in order to present a surface of limited deformability for insertion of the microneedles **174**. Clamping device **170** can be a separate device from the microneedle device **176**, or the devices can be integrated into a single unit.

(d). adhesive film assist

The deformation of skin can be reduced by applying a thin, adhesive film over the skin surface at the site of application. The film keeps the skin taut and limits deformation at the site of microneedle insertion as the microneedles are pushed through the film and into the skin. This is analogous to the use of a surgical tape that is applied to the skin before making a surgical incision.

The adhesive film can include an expandable or shrinkable material that is triggered to change size or shape prior to microneedle application, so as to stretch the skin thereby further limiting its deformability. For example, the material can be water-swellable, and wetted (triggering event) prior to microneedle application. In another example, the material can change form in response to a change in temperature (triggering event).

The adhesive film must be thin enough for the microneedles to penetrate both the film and the stratum corneum. If hollow microneedles are used, then the film should fracture upon penetration without substantial clogging of the hollow bore of the microneedles. Alternatively, the film could be formed of a woven or porous material so that the microneedles substantially penetrate gaps or pores in the adhesive film rather than the fibers or matrix of the film material. Examples of suitable films include ethylene-tetrafluoroethylene (ETFE) copolymer mesh (available from Goodfellow PLC) and porous films such as GORETEXTM (available from William H. Gore, Inc.) coupled with an appropriate acrylic adhesive.

(vii). Creating Holes for the Microneedles

Another method of improving the penetration of biological barriers with microneedles involves producing holes or pathways in the barrier through which the microneedles can traverse, other than the pathway created solely by forcing the microneedle into barrier. A variety of techniques can be adapted for use with the microneedle devices described herein. For example, U.S. Patent No. 5,885,211 to Eppstein, et al. discloses several methods of selectively removing the stratum corneum to enhance permeability of human skin. Some of these so-called

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microporation techniques disclosed can be adapted to promote penetration of microneedles into the viable epidermis. In a preferred embodiment, holes are created by vaporizing the stratum corneum, for example, by using a laser or by heating of the tips of the microneedles.

Laser techniques are described, for example, in U.S. patents No. 5,885,211 to Eppstein, et al. and No. 4,775,361 to Jacques et al. The laser, or pulsed light source, preferably is used in conjunction with a dye which substantially absorbs over the emission range of the light. The dye is applied to the skin and the laser or light is focused on the dye, heating it. Then, the stratum corneum adjacent to the dye is heated by conduction, elevating the temperature of tissue-bound water and other vaporizable substances in the selected area above the vaporization point of the water and other vaporizable substances. This vaporization results in degradation of the stratum corneum at one or more select, i.e. pinpoint, areas, through which the microneedles can readily penetrate. One of skill in the art can readily select the appropriate dye, laser (e.g., Helium-Neon) or light source, and parameters of use, based, in part, on the particular microneedle array, drug to be delivered, and/or analyte to sample. In one embodiment, the light is focused, in part, by passing the light through the internal bore of a hollow microneedle.

Thermal ablation of the stratum corneum can be achieved by radiant heating (using a light/laser as described above) or by using conductive heating. For example, U.S. Patent No. 5,885,211 to Eppstein, et al. describes contacting human skin with a heat source (conductive heating) ablate the stratum corneum. The microneedle devices described herein can be applied to the ablated skin and/or can be configured to provide the ablation of the stratum corneum, in particularly by heating the microneedles to serve as the heat source which contacts the skin. Heating of the microneedles can be accomplished, for example, by (1) contacting the needles with an ohmic heating element, (2) providing microneedles formed of or coated with a conductive material, through which a modulated electrical current is passed to induce resistive heating of the microneedles, or (3) providing microneedles positioned in a modulatable alternating magnetic field of an excitation coil such that energizing the excitation coil with alternating current produces eddy currents sufficient to heat the microneedles by internal ohmic losses. The microneedles should be able to rapidly heat the skin surface at select spots to above 100 °C,

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preferably above 123 °C, to induce flash vaporization of the water content of the stratum corneum, as described in U.S. Patent No. 4,775,361 to Jacques et al. The heating preferably is done using an on/off cycling technique and/or adjacent cooling to minimize damage to tissues adjacent the target area. In embodiments in which the microneedles are heated, the substrate preferably includes an insulating material, as shown in Figure 16, which illustrates two hollow microneedles and substrate in cross-section.

Other embodiments include applying a jet or focused blast of high pressure fluid to hydraulically puncture the stratum corneum and form a micropore into which the microneedle is inserted. The micropore preferably is slightly larger than the diameter of the microneedle. The microneedle device can be designed to utilize hollow microneedles to direct the jet of high pressure fluid. Various devices and techniques for high velocity introduction of fluids and particles into skin for delivery of drugs or genes are described, for example, in U.S. Patents No. 5,919,159 and No. 5,599,302 to Lilley, et al. (Medi-Ject, Inc.), U.S. Patent No. 5, 899,880 to Bellhouse, et al. (PowderJect Research Ltd.), and U.S. Patent No. 5,865,796 to McCabe (PowderJect Vaccines, Inc.). Creation of the holes and penetration can be enhanced by select cooling/freezing of the surface of the skin, e.g., cryoablation (see U.S. Patent No. 5,147,355 to Friedman, et al.). For example, the microneedle device can be adapted to create a local Joule-Thompson effect (see U.S. Patent No. 5,758,505 to Dobak III, et al.).

In another embodiment, chemical agents, such as certain keratin reducing agents (see U.S. Pat. No. 5,911,223 to Weaver et al.), can be applied at the site of administration to degrade the keratin of the skin's stratum corneum, rendering it more porous. Examples of suitable chemicals include sodium thiosulfate and urea.

(viii). Lubricated Microneedles

In one embodiment, the microneedles include a lubricating material, such as TEFLON™ (polytetrafluoroethylene), coated onto the microneedles. In a preferred embodiment, the lubricating material is incorporated into metal microneedles, for example, by plating the lubricating material with the metal during the manufacture of the microneedles.

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(x). Vibrating the Microneedles

Essentially all of the microneedle devices and methods described herein can be adapted to vibrate the microneedles and/or the skin to further facilitate penetration. The vibration can be effected to move the microneedles perpendicular and/or parallel to the surface of the biological barrier, and/or at an orientation thereinbetween. The vibration motion can be induced using known techniques, the most common of which is coupling the microneedle or array thereof to a piezoelectric transducer that can provide the vibratory motion. Such a transducer can be bonded directly to the array or can be bonded to a reservoir, thereby utilizing the acoustic transmission properties of the reservoir contents (e.g., an aqueous drug solution) to transmit vibration to the microneedles. Alternatively, electromechanical actuation can be used to vibrate the microneedles, such electromechanical actuation means include miniature motors and speaker coils.

3. Methods of Making Microneedle Devices

The microneedle devices are made by microfabrication processes, by creating small mechanical structures in silicon, metal, polymer, and other materials. These microfabrication processes are based on well-established methods used to make integrated circuits, electronic packages and other microelectronic devices, augmented by additional methods used in the field of micromachining. The microneedle devices can have dimensions as small as a few nanometers and can be mass-produced at low per-unit costs.

a. Microfabrication Processes

Microfabrication processes that may be used in making the microneedles disclosed herein include lithography; etching techniques, such as wet chemical, dry, and photoresist removal; thermal oxidation of silicon; electroplating and electroless plating; diffusion processes, such as boron, phosphorus, arsenic, and antimony diffusion; ion implamation; film deposition, such as evaporation (filament, electron beam, flash, and shadowing and step coverage), sputtering, chemical vapor deposition (CVD), epitaxy (vapor phase, liquid phase, and molecular beam), electroplating, screen printing, lamination, stereolithography, laser machining, and laser ablation (including projection ablation). *See generally* Jaeger, Introduction to Microelectronic Fabrication (Addison-Wesley Publishing Co., Reading MA 1988); Runyan, *et al.*, Semiconductor Integrated Circuit Processing Technology (Addison-

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Wesley Publishing Co., Reading MA 1990); *Proceedings of the IEEE Micro Electro Mechanical Systems Conference 1987-1998*; Rai-Choudhury, ed., Handbook of Microlithography, Micromachining & Microfabrication (SPIE Optical Engineering Press, Bellingham, WA 1997).

The following methods are preferred for making microneedles.

(i). Electrochemical Etching of Silicon

In this method, electrochemical etching of solid silicon to porous silicon is used to create extremely fine (on the order of 0.01 μm) silicon networks which can be used as piercing structures. This method uses electrolytic anodization of silicon in aqueous hydrofluoric acid, potentially in combination with light, to etch channels into the silicon. By varying the doping concentration of the silicon wafer to be etched, the electrolytic potential during etching, the incident light intensity, and the electrolyte concentration, control over the ultimate pore structure can be achieved. The material not etched (i.e. the silicon remaining) forms the microneedles. This method has been used to produce irregular needle-type structures measuring tens of nanometers in width.

(ii). Plasma Etching

This process uses deep plasma etching of silicon to create microneedles with diameters on the order of 0.1 μm or larger. Needles are patterned directly using photolithography, rather than indirectly by controlling the voltage (as in electrochemical etching), thus providing greater control over the final microneedle geometry.

In this process, an appropriate masking material (e.g., metal) is deposited onto a silicon wafer substrate and patterned into dots having the diameter of the desired microneedles. The wafer is then subjected to a carefully controlled plasma based on fluorine/oxygen chemistries to etch very deep, high aspect ratio trenches into the silicon. *See, e.g.*, Jansen, *et al.*, "The Black Silicon Method IV: The Fabrication of Three-Dimensional Structures in Silicon with High Aspect Ratios for Scanning Probe Microscopy and Other Applications," *IEEE Proceedings of Micro Electro Mechanical Systems Conference*, pp. 88-93 (1995). Those regions protected by the metal mask remain and form the needles. This method is further described in Example 1 below.

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(iii). Electroplating

In this process, a metal layer is first evaporated onto a planar substrate. A layer of photoresist is then deposited onto the metal to form a patterned mold which leaves an exposed-metal region in the shape of needles. By electroplating onto the exposed regions of the metal seed layer, the mold bounded by photoresist can be filled with electroplated material. Finally, the substrate and photoresist mold are removed, leaving the finished microneedle array. The microneedles produced by this process generally have diameters on the order of 1 μm or larger. *See, e.g.*, Frazier, *et al.*, "Two dimensional metallic microelectrode arrays for extracellular stimulation and recording of neurons", *IEEE Proceedings of the Micro Electro Mechanical Systems Conference*, pp. 195-200 (1993).

(iv). Other Processes

Another method for forming microneedles made of silicon or other materials is to use microfabrication techniques such as photolithography, plasma etching, or laser ablation to make a mold form (A), transferring that mold form to other materials using standard mold transfer techniques, such as embossing or injection molding (B), and reproducing the shape of the original mold form (A) using the newly-created mold (B) to yield the final microneedles (C). Alternatively, the creation of the mold form (A) could be skipped and the mold (B) could be microfabricated directly, which could then be used to create the final microneedles (C).

Another method of forming solid silicon microneedles is by using epitaxial growth on silicon substrates, as is utilized by Containerless Research, Inc. (Evanston, Illinois, USA) for its products.

b. Hollow or Porous Microneedles

In a preferred embodiment, microneedles are made with pores or other pathways through which material may be transported. The following descriptions outline representative methods for fabricating either porous or hollow microneedles.

(i). Porous Microneedles

Rather than having a single, well-defined hole down the length of the needle, porous needles are filled with a network of channels or pores which allow conduction of fluid or energy through the needle shaft. It has been shown that by appropriate electrochemical oxidation of silicon, pore arrays with high aspect ratios

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and a range of different pore size regimes can be formed; these pore regimes are defined as (1) microporous regime with average pore dimensions less than 2 nm, (2) mesoporous regime with average pore sizes of between 2 nm and 50 nm, and (3) macroporous regime with pores greater than 50 nm. The mesoporous and macroporous regimes are expected to be most useful for drug delivery. Two approaches to porous needles are generally available, either (a) the silicon wafer is first made porous and then etched as described above to form needles or (b) solid microneedles are etched and then rendered porous, for example, by means of electrochemical oxidation, such as by anodization of a silicon substrate in a hydrofluoric acid electrolyte. The size distribution of the etched porous structure is highly dependent on several variables, including doping kind and illumination conditions, as detailed in Lehmann, "Porous Silicon--A New Material for MEMS", *IEEE Proceedings of the Micro Electro Mechanical Systems Conference*, pp. 1-6 (1996). Porous polymer or metallic microneedles can be formed, for example, by micromolding a polymer containing a volatilizable or leachable material, such as a volatile salt, dispersed in the polymer or metal, and then volatilizing or leaching the dispersed material, leaving a porous polymer matrix in the shape of the microneedle.

(ii). Hollow Microneedles

Three-dimensional arrays of hollow microneedles can be fabricated, for example, using combinations of dry etching processes (Laermer, et al., "Bosch Deep Silicon Etching: Improving Uniformity and Etch Rate for Advanced MEMS Applications," *Micro Electro Mechanical Systems*, Orlando, Fl, USA, (Jan. 17-21, 1999); Despont et al., "High-Aspect-Ratio, Ultrathick, Negative-Tone Near-UV Photoresist for MEMS", *Proc. of IEEE 10th Annual International Workshop on MEMS*, Nagoya, Japan, pp. 518-22 (Jan. 26-30, 1997)); micromold creation in lithographically-defined and/or laser ablated polymers and selective sidewall electroplating; or direct micromolding techniques using epoxy mold transfers.

One or more distinct and continuous pathways are created through the interior of microneedles. In a preferred embodiment, the microneedle has a single annular pathway along the center axis of the microneedle. This pathway can be achieved by initially chemically or physically etching the holes in the material and then etching away microneedles around the hole. Alternatively, the microneedles and their holes can be made simultaneously or holes can be etched into existing

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microneedles. As another option, a microneedle form or mold can be made, then coated, and then etched away, leaving only the outer coating to form a hollow microneedle. Coatings can be formed either by deposition of a film or by oxidation of the silicon microneedles to a specific thickness, followed by removal of the interior silicon. Also, holes from the backside of the wafer to the underside of the hollow needles can be created using a front-to-backside infrared alignment followed by etching from the backside of the wafer.

(a). silicon microneedles

One method for hollow needle fabrication is to replace the solid mask used in the formation of solid needles by a mask that includes a solid shape with one or more interior regions of the solid shape removed. One example is a "donut-shaped" mask. Using this type of mask, interior regions of the needle are etched simultaneously with their side walls. Due to lateral etching of the inner side walls of the needle, this may not produce sufficiently sharp walls. In that case, two plasma etches may be used, one to form the outer walls of the microneedle (i.e., the 'standard' etch), and one to form the inner hollow core (which is an extremely anisotropic etch, such as in inductively-coupled-plasma "ICP" etch). For example, the ICP etch can be used to form the interior region of the needle followed by a second photolithography step and a standard etch to form the outer walls of the microneedle. Figure 1a represents a silicon wafer **82** with a patterned photoresist layer **84** on top of the wafer **82**. The wafer **82** is anisotropically etched (Figure 1b) to form a cavity **86** through its entire thickness (Figure 1c). The wafer **82** is then coated with a chromium layer **88** followed by a second photoresist layer **90** patterned so as to cover the cavity **86** and form a circular mask for subsequent etching (Figure 1d). The wafer **82** is then etched by a standard etch to form the outer tapered walls **92** of the microneedle (Figure 1e).

Alternatively, this structure can be achieved by substituting the chromium mask used for the solid microneedles described in Example 1 by a silicon nitride layer **94** on the silicon substrate **95** covered with chromium **96**, deposited as shown in Figure 2a and patterned as shown in Figure 2b. Solid microneedles are then etched as described in Example 1 as shown Figure 2c, the chromium **96** is stripped (Figure 2d), and the silicon **95** is oxidized to form a thin layer of silicon dioxide **97** on all exposed silicon surfaces (Figure 2e). The silicon nitride layer **94** prevents

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oxidation at the needle tip. The silicon nitride **94** is then stripped (Figure 2f), leaving exposed silicon at the tip of the needle and oxide-covered silicon **97** everywhere else. The needle is then exposed to an ICP plasma which selectively etches the inner sidewalls of the silicon **95** in a highly anisotropic manner to form the interior hole of the needle (Figure 2g).

Another method uses the solid silicon needles described previously as 'forms' around which the actual needle structures are deposited. After deposition, the forms are etched away, yielding the hollow structures. Silica needles or metal needles can be formed using different methods. Silica needles can be formed by creating needle structures similar to the ICP needles described above prior to the oxidation described above. The wafers are then oxidized to a controlled thickness, forming a layer on the shaft of the needle form which will eventually become the hollow microneedle. The silicon nitride is then stripped and the silicon core selectively etched away (e.g., in a wet alkaline solution) to form a hollow silica microneedle.

In a preferred embodiment, an array of hollow silicon microtubes is made using deep reactive ion etching combined with a modified black silicon process in a conventional reactive ion etcher, as described in Example 3 below. First, arrays of circular holes are patterned through photoresist into SiO_2, such as on a silicon wafer. Then the silicon can be etched using deep reactive ion etching (DRIE) in an inductively coupled plasma (ICP) reactor to etch deep vertical holes. The photoresist was then removed. Next, a second photolithography step patterns the remaining SiO_2 layer into circles concentric to the holes, leaving ring shaped oxide masks surrounding the holes. The photoresist is then removed and the silicon wafer again deep silicon etched, such that the holes are etched completely through the wafer (inside the SiO_2 ring) and simultaneously the silicon is etched around the SiO_2 ring leaving a cylinder.

This latter process can be varied to produce hollow, tapered microneedles. After an array of holes is fabricated as described above, the photoresist and SiO_2 layers are replaced with conformal DC sputtered chromium rings. The second ICP etch is replaced with a SF_6/O_2 plasma etch in a reactive ion etcher (RIE), which results in positively sloping outer sidewalls. Henry, et al., "Micromachined Needles for the Transdermal Delivery of Drugs," *Micro Electro Mechanical Systems*, Heidelberg, Germany, pp. 494-98 (Jan. 26-29, 1998).

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(b). metal microneedles

Metal needles can be formed by physical vapor deposition of appropriate metal layers on solid needle forms, which can be made of silicon using the techniques described above, or which can be formed using other standard mold techniques such as embossing or injection molding. The metals are selectively removed from the tips of the needles using electropolishing techniques, in which an applied anodic potential in an electrolytic solution will cause dissolution of metals more rapidly at sharp points, due to concentration of electric field lines at the sharp points. Once the underlying silicon needle forms have been exposed at the tips, the silicon is selectively etched away to form hollow metallic needle structures. This process could also be used to make hollow needles made from other materials by depositing a material other than metal on the needle forms and following the procedure described above.

A preferred method of fabricating hollow metal microneedles utilizes micromold plating techniques, which are described as follows and in Examples 4 and 5. In a method for making metal microtubes, which does not require dry silicon etching, a photo-defined mold first is first produced, for example, by spin casting a thick layer, typically 150 μm, of an epoxy (e.g., SU-8) onto a substrate that has been coated with a thin sacrificial layer, typically about 10 to 50 nm. Arrays of cylindrical holes are then photolithographically defined through the epoxy layer, which typically is about 150 μm thick. (Despont, et al., "High-Aspect-Ratio, Ultrathick, Negative-Tone Near-UV Photoresist for MEMS," *Proc. of IEEE 10th Annual International Workshop on MEMS*, Nagoya, Japan, pp. 518-22 (Jan. 26-30, 1997)). The diameter of these cylindrical holes defines the outer diameter of the tubes. The upper surface of the substrate, the sacrificial layer, is then partially removed at the bottom of the cylindrical holes in the photoresist. The exact method chosen depends on the choice of substrate. For example, the process has been successfully performed on silicon and glass substrates (in which the upper surface is etched using isotropic wet or dry etching techniques) and copper-clad printed wiring board substrates. In the latter case, the copper laminate is selectively removed using wet etching. Then a seed layer, such as Ti/Cu/Ti (e.g., 30 nm/200 nm/30 nm), is conformally DC sputter-deposited onto the upper surface of the epoxy mold and onto the sidewalls of the cylindrical holes. The seed layer should be electrically

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isolated from the substrate. Subsequently, one or more electroplatable metals or alloys are electroplated onto the seed layer. Representative suitable metals and alloys include Ni, NiFe, Au, Cu, Cr, Pt, Pd, and Ti. The surrounding epoxy is then removed, leaving microtubes which each have an interior annular hole that extends through the base metal supporting the tubes. The rate and duration of electroplating is controlled in order to define the wall thickness and inner diameter of the microtubes. In one embodiment, this method was used to produce microtubes having a height of between about 150 and 250 μm, an outer diameter of between about 40 and 120 μm, and an inner diameter of between about 30 and 110 μm (i.e., having a wall thickness of 10 μm). In a typical array, the microtubes have a tube center-to-center spacing of about 150 μm, but can vary depending on the desired needle density.

A variation of this method is preferred for forming tapered microneedles. As described above, photolithography yields holes in the epoxy which have vertical sidewalls, such that the resulting shafts of the microneedles are straight, not tapered. This vertical sidewall limitation can be overcome by molding a preexisting 3D structure, i.e., a mold-insert. The subsequent removal of the mold-insert leaves a mold which can be surface plated similarly to the holes produced by photolithography described above.

Alternatively, non-vertical sidewalls can be produced directly in the polymeric mold into which electroplating will take place. For example, conventional photoresists known in the art can be exposed and developed in such as way as to have the surface immediately adjacent to the mask be wider than the other surface. Specialized greyscale photoresists in combination with greyscale masks can accomplish the same effect. Laser-ablated molds can also be made with tapered sidewalls, e.g., by optical adjustment of the beam (in the case of serial hole fabrication) or of the reticle or mold during ablation (in the case of projection ablation).

To form hollow tapered microneedles, the mold-insert is an array of solid silicon microneedles, formed as described in Henry, et al., "Micromachined Needles for the Transdermal Delivery of Drugs," *Micro Electro Mechanical Systems*, Heidelberg, Germany, Jan. 26-29, pp. 494-98 (1998). First, a layer of a material, such as an epoxy (e.g., SU-8 or a polydimethylsiloxane ("PDMS")), is spin cast onto

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the array of silicon needles to completely blanket the entire array. The epoxy settles during pre-bake to create a planar surface above the silicon needle tips; the material is then fully pre-baked, photolithographically cross-linked, and post-baked.

The upper surface of the epoxy is then etched away, for example with an O_2/CHF_3 plasma, until the needle tips are exposed, preferably leaving between about 1 and 5 μm of tip protruding from the epoxy. The silicon is then selectively removed, for example by using a SF_6 plasma or a HNO_3/HF solution. The remaining epoxy micromold is the negative of the microneedles and has a small diameter hole where the tip of the microneedle formerly protruded.

After the removal of the silicon, a seed layer, such as Ti-Cu-Ti, is conformally sputter-deposited onto the epoxy micromold. Following the same process sequence described for hollow metal microtubes, one or more electroplatable metals or alloys, such as Ni, NiFe, Au, or Cu, are electroplated onto the seed layer. Finally, the epoxy is removed, for example by using an O_2/CHF_3 plasma, leaving an array of hollow metal microneedles. An advantage of using PDMS in this application is that the micromold can be physically removed from the silicon mold insert by mechanical means, such as peeling, without damaging the silicon mold insert, thus allowing the silicon mold insert to be reused. Furthermore, the electroplated microneedles can be removed from the PDMS mold by mechanical means, for example by peeling, thereby allowing the PDMS to also be reused. In a preferred embodiment, this method is used to produce microneedles having a height of between about 150 and 250 μm, an outer diameter of between about 40 and 120 μm, and an inner diameter of between about 50 and 100 μm. In a typical array, the microtubes have a tube center-to-center spacing of about 150 μm, but can vary depending on the desired needle density. The microneedles are 150 μm in height with a base diameter of 80 μm, a tip diameter of 10 μm, and a needle-to-needle spacing of 150 μm.

(c). silicon dioxide microneedles

Hollow microneedles formed of silicon dioxide can be made by oxidizing the surface of the silicon microneedle forms (as described above), rather than depositing a metal and then etching away the solid needle forms to leave the hollow silicon dioxide structures. This method is illustrated in Figures 3a-d. Figure 3a shows an

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array **24** of needle forms **26** with masks **28** on their tips. In Figure 3b, the needle forms **26** have been coated with a layer **30** of metal, silicon dioxide or other material. Figure 3c shows the coated needle forms **26** with the masks **28** removed. Finally, in Figure 3d, the needle forms **26** have been etched away, leaving hollow needles **30** made of metal, silicon dioxide, or other materials.

In one embodiment, hollow, porous, or solid microneedles are provided with longitudinal grooves or other modifications to the exterior surface of the microneedles. Grooves, for example, should be useful in directing the flow of molecules along the outside of microneedles.

(d). polymer microneedles

In a preferred method, polymeric microneedles are made using microfabricated molds. For example, the epoxy molds can be made as described above and injection molding techniques can be applied to form the microneedles in the molds (Weber, et al., "Micromolding - a powerful tool for the large scale production of precise microstructures", *Proc. SPIE - International Soc. Optical Engineer* 2879:156-67 (1996); Schift, et al., "Fabrication of replicated high precision insert elements for micro-optical bench arrangements" *Proc. SPIE - International Soc. Optical Engineer*. 3513:122-34 (1998)). These micromolding techniques are preferred over other techniques described herein, since they can provide relatively less expensive replication, i.e. lower cost of mass production. In a preferred embodiment, the polymer is biodegradable.

Microneedles, particularly hollow ones and ones formed of relatively brittle materials, may break at the juncture of the microneedle and substrate due to mechanical stresses at the sharp angle formed there. It has been found that the integrity of such microneedles can be improved by reinforcing the base of the microneedles with an additional layer of material (e.g., silicon) applied onto the face of the substrate face adjacent the base end of the microneedles as shown in Figure 17.

4. Microneedle Device Applications

The device may be used for single or multiple uses for rapid transport across a biological barrier or may be left in place for longer times (e.g., hours or days) for long-term transport of molecules. Depending on the dimensions of the device, the application site, and the route in which the device is introduced into (or onto) the

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biological barrier, the device may be used to introduce or remove molecules at specific locations.

As discussed above, Figure 9 shows a side elevational view of a schematic of a preferred embodiment of the microneedle device **10** in a transdermal application. The device **10** is applied to the skin such that the microneedles **12** penetrate through the stratum corneum and enter the viable epidermis so that the tip of the microneedle at least penetrates into the viable epidermis. In a preferred embodiment, drug molecules in a reservoir within the upper portion **11** flow through or around the microneedles and into the viable epidermis, where the drug molecules then diffuse into the dermis for local treatment or for transport through the body.

To control the transport of material out of or into the device through the microneedles, a variety of forces or mechanisms can be employed. These include pressure gradients, concentration gradients, electricity, ultrasound, receptor binding, heat, chemicals, and chemical reactions. Mechanical or other gates in conjunction with the forces and mechanisms described above can be used to selectively control transport of the material.

In particular embodiments, the device should be "user-friendly." For example, in some transdermal applications, affixing the device to the skin should be relatively simple, and not require special skills. This embodiment of a microneedle may include an array of microneedles attached to a housing containing drug in an internal reservoir, wherein the housing has a bioadhesive coating around the microneedles. The patient can remove a peel-away backing to expose an adhesive coating, and then press the device onto a clean part of the skin, leaving it to administer drug over the course of, for example, several days.

a. Drug Delivery

Essentially any drug or other bioactive agents can be delivered using these devices. Many drugs can be delivered at a variety of therapeutic rates. The rate can be controlled by varying a number of design factors, including the outer diameter of the microneedle, the number and size of pores or channels in each microneedle, the number of microneedles in an array, the magnitude and frequency of application of the force driving the drug through the microneedle and/or the holes created by the microneedles. For example, devices designed to deliver drug at different rates might have more microneedles for more rapid delivery and fewer microneedles for less

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rapid delivery. As another example, a device designed to deliver drug at a variable rate could vary the driving force (e.g., pressure gradient controlled by a pump) for transport according to a schedule which was pre-programmed or controlled by, for example, the user or his doctor. The devices can be affixed to the skin or other tissue to deliver drugs continuously or intermittently, for durations ranging from a few seconds to several hours or days.

One of skill in the art can measure the rate of drug delivery for particular microneedle devices using *in vitro* and *in vivo* methods known in the art. For example, to measure the rate of transdermal drug delivery, human cadaver skin mounted on standard diffusion chambers can be used to predict actual rates. *See* Hadgraft & Guy, eds., Transdermal Drug Delivery: Developmental Issues and Research Initiatives (Marcel Dekker, New York 1989); Bronaugh & Maibach, Percutaneous Absorption, Mechanisms--Methodology--Drug Delivery (Marcel Dekker, New York 1989). After filling the compartment on the dermis side of the diffusion chamber with saline, a microneedle array is inserted into the stratum corneum; a drug solution is placed in the reservoir of the microneedle device; and samples of the saline solution are taken over time and assayed to determine the rates of drug transport.

In an alternate embodiment, biodegradable or non-biodegradable microneedles can be used as the entire drug delivery device, where biodegradable microneedles are a preferred embodiment. For example, the microneedles may be formed of a biodegradable polymer containing a dispersion of an active agent for local or systemic delivery. The agent could be released over time, according to a profile determined by the composition and geometry of the microneedles, the concentration of the drug and other factors. In this way, the drug reservoir is within the matrix of one or more of the microneedles.

In another alternate embodiment, these microneedles may be purposefully sheared off from the substrate after penetrating the biological barrier. In this way, a portion of the microneedles would remain within or on the other side of the biological barrier and a portion of the microneedles and their substrate would be removed from the biological barrier. In the case of skin, this can involve inserting an array into the skin, manually or otherwise breaking off the microneedles tips and then removing the base of the microneedles. The portion of the microneedles which

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remains in the skin or other biological barrier can then release drug over time according to a profile determined by the composition and geometry of the microneedles, the concentration of the drug and other factors. In a preferred embodiment, the microneedles are made of a biodegradable polymer. The release of drug from the biodegradable microneedle tips can be controlled by the rate of polymer degradation. The tips can release drugs for local or systemic effect, or other agents, such as perfume, insect repellent and sun block.

Microneedle shape and content can be designed to control the breakage of microneedles. For example, a notch can be introduced into microneedles either at the time of fabrication or as a subsequent step. In this way, microneedles would preferentially break at the site of the notch. Moreover, the size and shape of the portion of microneedles which break off can be controlled not only for specific drug release patterns, but also for specific interactions with cells in the body. For example, objects of a few microns in size are known to be taken up by macrophages. The portions of microneedles that break off can be controlled to be bigger or smaller than that to prevent uptake by macrophages or can be that size to promote uptake by macrophages, which can be desirable for delivery of vaccines.

(i). Drugs to be Delivered

Essentially any drug can be delivered using the microneedle devices. As used herein, the term "drug" refers to an agent which possesses therapeutic, prophylactic, or diagnostic properties *in vivo*, for example when administered to an animal, including mammals, such as humans. The drug can be for local treatment or for regional or systemic therapy.

Representative examples of suitable therapeutic and/or prophylactic active agents include proteins, such as hormones, antigens, and growth factors; nucleic acids, such as antisense molecules; and smaller molecules, such as antibiotics, steroids, decongestants, neuroactive agents, anesthetics, and sedatives. Examples of suitable diagnostic agents include radioactive isotopes and radioopaque agents, metals, gases, labels including chromatographic, fluorescent or enzymatic labels.

The drug can be or include a peptide, protein, carbohydrate (including monosaccharides, oligosaccharides, and polysaccharides), nucleoprotein, mucoprotein, lipoprotein, glycoprotein, nucleic acid molecules (including any form of DNA such as cDNA, RNA, or a fragment thereof, oligonucleotides, and genes),

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nucleotide, nucleoside, lipid, biologically active organic or inorganic molecules, or combination thereof.

Drugs can be selected, for example, from enzymes, polysaccharides, polynucleotide molecules, and synthetic organic and inorganic compounds. Representative agents include anti-infectives, hormones, such as insulin, growth regulators, drugs regulating cardiac action or blood flow, and drugs for pain control. The following are representative examples, and disorders they are used to treat: Calcitonin, osteoporosis; Enoxaprin, anticoagulant; Etanercept, rheumatoid arthritis; Erythropoietin, anemia; Fentanyl, postoperative and chronic pain; Filgrastin, low white blood cells from chemotherapy; Heparin, anticoagulant; Insulin, human, diabetes; Interferon β 1a, multiple sclerosis; Lidocaine, local anesthesia; Somatropin, growth hormone; and Sumatriptan, migraine headaches.

The amount of drug can be selected by one of skill in the art based, for example on the particular drug, its desired effect at the planned release levels, and the time span over which the drug should be released.

(ii). Examples of Drug Delivery Devices

Preferred embodiments of the microneedle device are shown in Figures 20a-c. The device **510** includes substrate **512** from which a three-dimensional array of microneedles **514** protrude. As shown, the annular bore of the microneedles **514** extends through the substrate **512**. The device **510** also includes a reservoir **516** secured to substrate **512** via a sealing mechanism **518**. Figure 20a shows how the reservoir can be accessed directly by application to the skin, for example, for simple transdermal delivery of an agent. The device in Figure 20b includes a deformable bubble reservoir **516**. Manual pressure can be used to expel its contents at the site of application. Figure 20c shows a separate reservoir **516** from means **519** for expelling the contents of the reservoir **516** at the site of administration. The expelling means **519** can be simply a flexible bag. The expelling means **519** may also contain a vacuum so that it expands when vented, to create pressure on the reservoir, or it may be elastic so that it deforms when released from one position (not shown). Alternatively, reservoir **516** could be formed of an elastic material which deforms when released.

The sealing mechanism **518** can be, for example, an adhesive material or gasket. The sealing mechanism **518** can further function as or include a fracturable

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barrier or rate controlling membrane overlaying the surface of the substrate. In this embodiment, nothing can be released until a seal or peel-off strip covering is removed.

Another preferred embodiment of the microneedle device is shown in Figure 21. The device **520** includes substrate **512** from which a three-dimensional array of microneedles **514** protrude. The device **520** also includes plunger **522** that is slidably secured to the upper surface of substrate **512** by plunger guide frame **524** using a restraint such as a Leur-lock interface **523**. The substrate **512** can be attached or detached to a syringe **526** via a connector such as a Luer-lock type attachment **523**. The plunger **522**, guide frame **524**, and connector **523** connect to, form or contain reservoir **516**. A Luer-lock type attachment could alternatively be used to secure the device to means for controlling flow or transport through the device such as a pump.

A further preferred embodiment of the microneedle device is shown in Figure 22. Like the device in Figure 21, the device **530** includes substrate **512**, microneedles **514**, plunger **522**, plunger guide frame **524**, and reservoir **516**. Device **530** further includes plunger housing **532**, which is attached to, or integrally formed with, plunger guide frame **524**. A compressed spring or other tension-based mechanism **534** is positioned between plunger housing **532** and plunger **522**. The device **530** further includes spring hold/release mechanism **536**, which keeps the plunger up (spring compressed) until triggered to compress reservoir **516**.

(iii). Initiating Delivery

In a preferred embodiment, delivery of the drug from the reservoir is initiated by applying a force, such as by pressing the top of the reservoir, to cause the reservoir contents (i.e. a drug containing composition) to flow out through the microneedles—an active or dynamic process. For example, the user can apply finger-pressure directly to a deformable reservoir "bubble." (Figure 20) or to a plunger mechanism (Figure 21) or a Luer-lock type syringe that in turn causes the drug composition to be forced from the reservoir. The plunger also can be adapted to activate by application of a constant, reproducible force, for example, a spring (e.g., under compression) (Figure 22) or elastic band (e.g., in tension).

A variation of this embodiment utilizes a balloon-like reservoir in tension to provide the force. Then, when an opening is formed in the balloon reservoir, the

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contents are forced out of the reservoir as the balloon contracts to its relaxed state. The contraction is selectively triggered to provide the driving force for delivery.

In a preferred embodiment, the force ruptures a fracturable barrier between the reservoir contents and the inlet of the microneedle. Representative barriers include thin foil, polymer, or laminant films. In another preferred embodiment, the microneedles tips are blocked until immediately before use. The blocking material can be, for example, a peelable adhesive or gel film, which will not clog the openings in the microneedle tip when the film is removed from the device.

Delivery also can be initiated by opening a mechanical gate or valve interposed between the reservoir outlet and the microneedle inlet. For example, a thin film or plate can be slid or peeled away from the back of the substrate.

In an alternate embodiment, delivery is initiated by changing the physical or chemical properties of the drug composition and/or of a barrier material. For example, the barrier can be a porous membrane having a porosity that can be selectably altered to permit flow, or the drug composition can be selected to change from a solid or semi-solid state to a fluid state, for example as the temperature is increased from ambient to that of body temperature. Such a drug composition can be prepared, for example, by combining the drug with a biodegradable polymeric material.

A preferred embodiment of the microneedle device is shown in Figure 23a. Figure 23a shows a device **540** in which microneedles **514** attached to a substrate **512** which is attached to multiple compartments **516a**, **516b**, **516c**, and **516d**. Each compartment can contain or function as a reservoir. Material can be expelled from each compartment through all or a subset of microneedles **514**.

Figure 23b depicts a device **550** in which microneedles **514** are attached to a substrate **512** which is attached to reservoir **558** containing, for example, lyophilized drug **554**. The reservoir **558** is attached to a fracturable barrier **552** which is attached to another reservoir **556** containing, for example, saline. If the barrier **552** is fractured, the two reservoirs **554** and **556** are in fluid communication with each other and their contents can mix.

Delivery also can be initiated by activating an osmotic pump, as described, for example, in U.S. Patent No. 4,320,758 to Eckenhoff, which has been adapted to the substrate of the microneedle device. For example, the reservoir/osmotic pump

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includes an inner flexible bag that holds the drug charge, an intermediate layer of an osmotically effective solute composition, such as an inorganic salt, that encapsulates the bag, and an outer shape-retaining membrane that is at least in part permeable to water and that encapsulates both the layer of osmotically effective solute composition and the bag. In operation, the bag filled with the fluid drug compositions is exposed to an aqueous environment, so that water is imbibed from the environment by the osmotically effective solute through the membrane into the space between the inner flexible bag and the membrane. Since the bag is flexible and the membrane is rigid, the imbibed water squeezes the bag inwardly, thereby displacing drug out the microneedles.

Figure 24 shows a device **560** in which microneedles **514** are attached to a substrate **512** which is attached to a drug reservoir **562**. This reservoir is surrounded at least partially by a flexible, impermeable membrane **564**. The drug reservoir is connected to another reservoir **566** which contains, for example, an inorganic salt. The two reservoirs **562** and **566** are separated by the impermeable membrane **564**, which is impermeable to the contents of both reservoirs **562** and **566**. The reservoir **566** is also connected to another reservoir **568** which contains, for example, an aqueous solution in which the organic salt is at least partially soluble. The two reservoirs **566** and **568** are separated by a rigid, semi-permeable membrane **570**, which is partially or completely impermeable to the salt in reservoir **566** and partially or fully permeable to the solution in reservoir **568**. There is also an optional fill port or vent **572** in communication with the reservoir **568**, through which material can be added to or removed from the reservoir **568**. Using this device **560**, water can be drawn from the reservoir **568** across the semi-permeable membrane **570** into the reservoir **566** due to osmosis caused by the presence of salt in the reservoir **566**. The flow of water will cause the volume of reservoir **566** to increase and thereby force the volume of reservoir **562** to decrease, which causes material to expel from reservoir **562** through microneedles **514**.

In an alternate embodiment, delivery is initiated by opening the pathway between the reservoir and the microneedle tip, or unblocking the tip openings, and simply allowing the drug to be delivered by diffusion, that is, a passive process.

(iv). Controlling the Delivery Rate

The microneedle device must be capable of transporting drug across or into

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the tissue at a useful rate. For example, the microneedle device must be capable of delivering drug at a rate sufficient to be therapeutically useful. The rate of delivery of the drug composition can be controlled by altering one or more of several design variables. For example, the amount of material flowing through the needles can be controlled by manipulating the effective hydrodynamic conductivity (the volumetric through-capacity) of a single device array, for example, by using more or fewer microneedles, by increasing or decreasing the number or diameter of the bores in the microneedles, or by filling at least some of the microneedle bores with a diffusion-limiting material. It is preferred, however, to simplify the manufacturing process by limiting the needle design to two or three "sizes" of microneedle arrays to accommodate, for example small, medium, and large volumetric flows, for which the delivery rate is controlled by other means.

Other means for controlling the rate of delivery include varying the driving force applied to the drug composition in the reservoir. For example, in passive diffusion systems, the concentration of drug in the reservoir can be increased to increase the rate of mass transfer. In active systems, for example, the pressure applied to the reservoir can be varied, such as by varying the spring constant or number of springs or elastic bands.

In either active or passive systems, the barrier material can be selected to provide a particular rate of diffusion for the drug molecules being delivered through the barrier at the needle inlet.

(v). Feedback about Delivery

In a preferred embodiment, the microneedle device includes a feedback means so that the user can (1) determine whether delivery has been initiated; and/or (2) confirm that the reservoir has been emptied, that is delivery complete. Representative feedback means include a sound, a color (change) indicator, or a change in the shape of a deformable reservoir. In a preferred embodiment, the feedback for completion of delivery is simply that the reservoir is pressed flat against the back of the substrate and cannot be further deformed.

(vi). Feedback about Penetration of Microneedles into Tissue

The user of the microneedle device typically can determine if the microneedles have been properly inserted into the skin or other tissue through visual or tactile means, that is assessing whether the substrate has been pressed essentially

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flush to the tissue surface. For example, if a puddle of liquid drug composition appears near the device, then the user may infer that the microneedles are not fully inserted, suggesting that the device needs to be reapplied. The liquid drug compositions can include a coloring agent to enhance the visual feedback.

In a more complex embodiment, an electrical or chemical measurement is adapted to provide the feedback. For example, penetration can be determined by measuring a change in electrical resistance at the skin or other tissue, or a pH change. Alternately, needle-to-needle electrical resistance can be measured. In a preferred embodiment, the microneedle device includes a disposable cartridge containing the microneedles. In these devices, an LED (e.g. green light/red light) or liquid crystal display can be provided with the reusable portion of the device.

(vii). Multi-Cartridge Microneedle Device

A modification of the disposable, single use microneedle device utilizes a reusable triggering device (e.g., a plunger) in combination with a cartridge containing one or more, preferably a plurality, of single-use microneedle devices. For example, the cartridge can be a circular disk having 10 or 12 microneedle arrays connected to a single-dose reservoir, wherein the cartridge can be loaded into and unloaded from the triggering device. The triggering device can, for example, be designed to move a new dose into position for delivery, compress the reservoir to deliver the drug, and then eject or immobilize the used array. This type of reusable triggering device also can include a power source, such as a battery, used to operate a built-in measurement device, for example, for analyte measurement of interstitial fluids or electrical verification of needle penetration into skin.

(viii). Microneedle Device Packaging

In a preferred embodiment following manufacture of the microneedle device, it is packaged for storage, shipment, and sale before use. The packaging should prevent contamination and damage. The packaging also should prevent premature triggering or release of any drug or vehicle contents from the reservoir.

It is particularly important that, the microneedle device is provided with a removable protective cover or cushion that protects the microneedles from damage. The protective cover also can function to keep the drug material from prematurely leaking out of the microneedles. In a preferred embodiment, an adhesive material or gel film used to selectively secure the cover over the microneedles. In an alternate

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embodiment, the film is antiseptic, and following removal can serve as a wipe to prepare the skin surface before insertion of the microneedles.

The packaging also can be adapted to serve as a vessel for safely disposing of the used microneedle device. In a preferred embodiment, the single-use microneedles are provided a device or material to shear the needles from the substrate or plug the microneedles, so as to prevent undesirable reuse of the device. In one embodiment, the inner back of the reservoir is provided with a tacky substance. When the reservoir is compressed against the back of the substrate following delivery of the reservoir contents, the tacky substance is driven into the opening of the microneedles, plugging them. In one embodiment of this device, the tacky material dries and hardens so that the substance cannot readily be removed.

b. Diagnostic Sensing of Body Fluids (Biosensors)

The device is applied to the skin or other biological barrier at the site where the sample is to be collected or measured. Then, biological fluid, or a component thereof, is drawn into or through the pores or bores of the microneedles, and optionally collected in the collection chamber. Alternatively, where the microneedles function as the sensor, sensing occurs without transfer of biological fluid into a collection chamber. One embodiment of the devices described herein may be used to remove material from the body across a biological barrier, i.e. for minimally invasive diagnostic sensing. For example, fluids can be transported from interstitial fluid in a tissue into a reservoir in the upper portion of the device. The fluid can then be assayed while in the reservoir or the fluid can be removed from the reservoir to be assayed, for diagnostic or other purposes. For example, interstitial fluids can be removed from the epidermis across the stratum corneum to assay for glucose concentration, which should be useful in aiding diabetics in determining their required insulin dose.

The sensing device can be in or attached to one or more microneedles, or in a housing adapted to the substrate. Sensing information or signals can be transferred optically (e.g., refractive index) or electrically (e.g., measuring changes in electrical impedance, resistance, current, voltage, or combination thereof). For example, it may be useful to measure a change as a function of change in resistance of tissue to an electrical current or voltage, or a change in response to channel binding or other

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criteria (such as an optical change) wherein different resistances are calibrated to signal that more or less flow of drug is needed, or that delivery has been completed.

In one embodiment, one or more microneedle devices can be used for (1) withdrawal of interstitial fluid, (2) assay of the fluid, and/or (3) delivery of the appropriate amount of a therapeutic agent based on the results of the assay, either automatically or with human intervention. For example, a sensor delivery system may be combined to form, for example, a system which withdraws bodily fluid, measures its glucose content, and delivers an appropriate amount of insulin. The sensing or delivery step also can be performed using conventional techniques, which would be integrated into use of the microneedle device. For example, the microneedle device could be used to withdraw and assay glucose, and a conventional syringe and needle used to administer the insulin, or *vice versa*.

In an alternate embodiment, microneedles may be purposefully sheared off from the substrate after penetrating the biological barrier, as described above. The portion of the microneedles which remain within or on the other side of the biological barrier could contain one or more biosensors. For example, the sensor could change color as its output. For microneedles sheared off in the skin, this color change could be observed through the skin by visual inspection or with the aid of an optical apparatus.

The microneedles can also be used for aerosolization or delivery for example directly to a mucosal surface in the nasal or buccal regions or to the pulmonary system.

The microneedle devices disclosed herein also should be useful for controlling transport across tissues other than skin. For example, microneedles can be inserted into the eye across, for example, conjunctiva, sclera, and/or cornea, to facilitate delivery of drugs into the eye. Similarly, microneedles inserted into the eye can facilitate transport of fluid out of the eye, which may be of benefit for treatment of glaucoma. Microneedles may also be inserted into the buccal (oral), nasal, vaginal, or other accessible mucosa to facilitate transport into, out of, or across those tissues. For example, a drug may be delivered across the buccal mucosa for local treatment in the mouth or for systemic uptake and delivery. As another example, microneedle devices may be used internally within the body on, for example, the lining of the gastrointestinal tract to facilitate uptake of

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orally-ingested drugs or the lining of blood vessels to facilitate penetration of drugs into the vessel wall. For example, cardiovascular applications include using microneedle devices to facilitate vessel distension or immobilization, similarly to a stent, wherein the microneedles/substrate can function as a "staple-like" device to penetrate into different tissue segments and hold their relative positions for a period of time to permit tissue regeneration. This application could be particularly useful with biodegradable devices. These uses may involve invasive procedures to introduce the microneedle devices into the body or could involve swallowing, inhaling, injecting or otherwise introducing the devices in a non-invasive or minimally-invasive manner.

(i) Biological Fluids for Withdrawal and Sensing

The microneedle devices are useful in the transport of biological fluids from within or across a variety of biological barriers including the skin (or parts thereof); the blood-brain barrier; mucosal tissue; blood vessels; lymphatic vessels; cell membranes; epithelial tissue; and endothelial tissue. The biological barriers can be in humans or other types of animals, as well as in plants, insects, or other organisms, including bacteria, yeast, fungi, and embryos. In preferred embodiments, biological fluids are withdrawn from skin, more preferably human skin, for minimally invasive diagnostic sensing.

Biological fluids useful with the devices described herein include blood, lymph, interstitial fluid, and intracellular fluid. A preferred biological fluid to be withdrawn or sensed is interstitial fluid.

A variety of analytes are routinely measured in the blood, lymph or other body fluids. Examples of typical analytes that can be measured include blood sugar (glucose), cholesterol, bilirubin, creatine, various metabolic enzymes, hemoglobin, heparin, hematocrit, vitamin K or other clotting factors, uric acid, carcinoembryonic antigen or other tumor antigens, and various reproductive hormones such as those associated with ovulation or pregnancy. Other substances or properties desirable to detect include lactate (important for athletes), oxygen, pH, alcohol, tobacco metabolites, and illegal drugs (important for both medical diagnosis and law enforcement).

In a preferred embodiment, interstitial fluids are removed from the dermis or epidermis across the stratum corneum to assay for glucose concentration, which is

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useful in aiding diabetics in determining their required insulin dose.

(ii). Feedback about Microneedle Penetration into Tissue

The user of the microneedle device typically can determine if the microneedles have been properly inserted into the skin or other tissue through visual or tactile means, that is assessing whether the substrate has been pressed essentially flush to the tissue surface. A coloring agent can be used to enhance the visual feedback by indicating a color change triggered by biological fluid filing the collection chamber.

In a more complex embodiment, an electrical or chemical measurement is adapted to provide the feedback. For example, penetration can be determined by measuring a change in electrical resistance at the skin or other tissue, or a pH change. Alternately, needle-to-needle electrical resistance can be measured. In a preferred embodiment, the microneedle device includes a disposable cartridge containing the microneedles. In these devices, an LED (e.g., green light/red light) or liquid crystal display can be provided with the reusable portion or the device.

(iii). Feedback about Withdrawal

In a preferred embodiment, the microneedle device includes a feedback means so that the user can determine whether withdrawal and/or sensing has been completed. Representative feedback means include a sound, a color (change) indicator, or a change in the position or shape of a reservoir or collection chamber.

(iv). Initiating and Controlling Fluid Withdrawal

In a preferred embodiment, the microneedle device is capable of transporting molecules across or from the tissue at a useful rate. That rate will, of course, depend on the particular application. For assaying blood glucose, for example, the device preferably withdraws at least between about 5 and 10 μl of interstitial fluid, preferably in about a minute or less time. For other applications, it may be desirable to apply the device to the barrier for several hours or more in order to monitor the changing blood plasma level of a particular analyte, such as an exogenous drug or hormone level, for example on a real-time basis or to obtain a time-averaged value.

The rate of withdrawal can be controlled by altering one or more of several design variables. For example, the amount of material flowing through the needles can be controlled by manipulating the volumetric through-capacity of a single device array, e.g., by using more or fewer microneedles, by increasing or decreasing the

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number or diameter of the bores in the microneedles, by filling at least some of the microneedle bores with a diffusion-limiting material, or by varying the driving force applied to the biological fluid. It is preferred, however, to simplify the manufacturing process by limiting the needle design to two or three "sizes" of microneedle arrays to accommodate, for example small, medium, and large volumetric flows, for which the withdrawal rate is controlled by other means.

The flow of biological fluid from the tissue through the microneedle and into the collection chamber or into contact with the sensors occurs due to capillary action, diffusion, or is induced using conventional mechanical pumps or nonmechanical driving forces, such as electroosmosis or electrophoresis, thermal gradients, or convection. For example, in electroosmosis, electrodes are positioned on the biological barrier surface, on one or more microneedles, and/or on the substrate adjacent the needles, to create a convective flow which carries charged ionic species and/or neutral molecules toward and/or through at least one of the microneedles.

Transportation of molecules through the microneedles can be controlled or monitored using, for example, various combinations of semi-permeable membranes, valves, pumps, sensors, actuators, and microprocessors. These components can be produced using standard manufacturing or microfabrication techniques. Actuators that may be useful with the microneedle devices disclosed herein include micropumps, microvalves, and positioners.

In preferred embodiments, the microneedle device is used with another mechanism that enhances the permeability of the biological barrier, such as by increasing cell membrane disruption, using electric fields, ultrasound, chemical enhancers, vacuum, viruses, pH, heat, and/or light. Chemical and/or physical enhancers can be applied to the biological barrier at the insertion site of the device before or during the withdrawal of the device, for example, to draw analyte closer to the skin surface.

(a). bulk flow extraction

A preferred microneedle device is shown in Figure 26 and described above. Microneedle device **620** preferably is operated as follows. After or simultaneously with the insertion of device **620** into, for example, the skin, manual pressure is applied to elastic cap **622** so as to deform (compress) it and reduce the interior

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volume of elastic cap **622** and fluid collection chamber **616**. The deformation causes gas within the cap and chamber to be purged from the device via one-way valve **624**. As elastic cap **622** returns to its undeformed (uncompressed) shape, pressure is reduced within the interior volume, creating a pressure differential or vacuum, which causes the interstitial fluid, to be drawn through the microneedles **614** and into fluid collection chamber **616**, until the pressure is equalized. Once in the collection chamber **616**, the fluid sample can be analyzed by withdrawing device **620** from the skin, again depressing elastic cap **622**, to force the sample out of the chamber either through the microneedles **614** or one-way valve **624**, and, for example, onto a diagnostic strip or into a container adapted for the particular analytical method to be employed.

Other spring means can be adapted to cause a change in the volume, and thus internal pressure, of the collection chamber. For example, the fluid collection chamber can be adapted to have a movable, rigid top with fixed, rigid side walls, wherein the interface between the walls and top form a gas-tight seal (such as by using a gasket). The volume of the piston-like apparatus can be expanding by activating one or more compressed springs to move the top of the chamber as desired, thereby reducing the pressure in the collection chamber.

In an alternative embodiment, withdrawal can be initiated by activating an osmotic pump, as described, for example, in U.S. Patent No. 4,320,758 to Eckenhoff, which has been engineered to create a volume expansion/pressure reduction in the collection chamber to draw biological fluid to be drawn into the collection chamber.

In a preferred embodiment, withdrawal is conducted using a microneedle device fitted to a Luer-Lock syringe or similar conventionally-used devices that currently uses hypodermic needles in the barrier penetration method.

(b). diffusion-based extraction

One preferred embodiment uses diffusion to move the analyte fluid into the fluid collection chamber. A microneedle device using this method generally includes microneedle bores or pores, and/or a fluid collection chamber, that are filled with a diffusion medium, such as water, a saline solution, or a gel, which is physiologically compatible with the biological barrier tissue. Once the needle is inserted into the biological barrier (e.g., the skin), the diffusion medium contacts the

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biological fluid. Typically, the diffusion medium in the microneedles initially contains none of the analyte to be measured; therefore, analyte at a higher concentration in the biological fluid diffuses into the diffusion medium in the microneedle until a detectable level of analyte in collected or measured. This should be achieved rapidly due to the very small size/length of the microneedles, thereby providing an analyte concentration for sensing that is rapidly response to that in the tissue.

(c). hybrid bulk flow/diffusion

In another embodiment, the microneedle device is designed to employ a combination of forces to drive the analyte into the collection chamber. A preferred hybrid design includes the preferred bulk flow microneedle device described above, but with two primary differences. First, the fluid collection chamber has no one-way valve and contains a fluid diffusion medium, preferably physiological saline. Second, a temporary barrier is interposed between the fluid collection chamber and the base of the microneedles. The temporary barrier can be a fracturable membrane, mechanical gate, or other means for containing the diffusion medium within the device until the barrier is broken or removed at a selected time to permit flow of molecules between the microneedles and fluid collection chamber.

In a preferred embodiment, the temporary barrier is an easily fracturable membrane. The device can function as follows: The microneedles first are inserted into the skin of the user. Then the user depresses the elastic cap, causing the fluid diffusion medium to fracture the membrane and fill the bores or pores of the microneedles and contact the biological fluid. After the user releases the elastic cap, it partially or fully returns to its undeformed shape, reducing the pressure in the interior and causing a mixture of the biological fluid and diffusion medium to be drawn through the microneedles and into fluid collection chamber. Once bulk fluid flow ceases, diffusion may continue until the concentration of biological fluid or analyte equilibrates. The mixture can be assayed as described herein, considering the dilution effect induced by the presence of the diffusion medium.

Any of these embodiments of the microneedle device can be adapted to function a series of micro-assays (e.g., as can be provided with an electronics package) or single assays (e.g., standard glucose strips).

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(v). Multi-Cartridge Microneedle Device

A modification of the disposable, single use microneedle device utilizes a reusable portion providing the withdrawal force (e.g., suction) or electronics package in combination with a cartridge containing one or more, preferably a plurality, of single-use, disposable microneedle devices for collection and/or sensing. For example, the cartridge can be a circular disk having 10 or 12 microneedle arrays connected to a single-assay element, wherein the cartridge can be loaded into and unloaded from the reusable portion. The triggering device can, for example, be designed to move a new microneedle array into position, withdraw or sense the sample of biological fluid, and then eject or immobilize the used microneedle array. This type of reusable triggering device also can include a power source, such as a battery, used to operate a built-in measurement device, for example, for analyte measurement of interstitial fluids. In one embodiment, the devices are provided in a multipack (e.g., six or twelve pack) form of complete devices, that is, each device is fully sufficient for use. Individual devices can be separated as needed for each sensing measurement.

e. Delivery of Energy

Other than transport of drugs and biological molecules, the microneedles may be used to transmit or transfer other materials and energy forms, such as light, electricity, heat, or pressure. The microneedles, for example, could be used to direct light to specific locations within the body, in order that the light can directly act on a tissue or on an intermediary, such as light-sensitive molecules in photodynamic therapy.

The present invention will be further understood with reference to the following non-limiting examples.

Example 1: Fabrication of Solid Silicon Microneedles

A chromium masking material was deposited onto silicon wafers and patterned into dots having a diameter approximately equal to the base of the desired microneedles. The wafers were then loaded into a reactive ion etcher and subjected to a carefully controlled plasma based on fluorine/oxygen chemistries to etch very deep, high aspect ratio valleys into the silicon. Those regions protected by the metal mask remain and form the microneedles.

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<100>-oriented, prime grade, 450-550 μm thick, 10-15 Ω-cm silicon wafers (Nova Electronic Materials Inc., Richardson, TX) were used as the starting material. The wafers were cleaned in a solution of 5 parts by volume deionized water, 1 part 30% hydrogen peroxide, and 1 part 30% ammonium hydroxide (J.T. Baker, Phillipsburg, NJ) at approximately 80°C for 15 minutes, and then dried in an oven (Blue M Electric, Watertown, WI) at 150°C for 10 minutes. Approximately 1000 Å of chromium (Mat-Vac Technology, Flagler Beach, FL) was deposited onto the wafers using a DC-sputterer (601 Sputtering System, CVC Products, Rochester, NY). The chromium layer was patterned into 20 by 20 arrays of 80 μm diameter dots with 150 μm center-to-center spacing using the lithographic process described below.

A layer of photosensitive material (1827 photoresist, Shipley, Marlborough, MA) was deposited onto the chromium layer covering the silicon wafers. A standard lithographic mask (Telic, Santa Monica, CA) bearing the appropriate dot array pattern was positioned on top of the photoresist layer. The wafer and photoresist were then exposed to ultraviolet (UV) light through the mask by means of an optical mask aligner (Hybralign Series 500, Optical Associates, Inc., Milpitas, CA). The exposed photoresist was removed by soaking the wafers in a liquid developer (354 developer, Shipley, Marlborough, MA) leaving the desired dot array of photoresist on the chromium layer. Subsequently, the wafers were dipped into a chromium etchant (CR-75; Cyanteck Fremont, CA), which etched the chromium that had been exposed during the photolithography step, leaving dot arrays of chromium (covered with photoresist) on the surface of the silicon wafer. The photoresist still present on the chromium dots formed the masks needed for fabrication of the microneedles, described below.

The microneedles were fabricated using a reactive ion etching techniques based on the Black Silicon Method developed at the University of Twente. The patterned wafers were etched in a reactive ion etcher (700 series wafer/batch Plasma Processing System, Plasma Therm, St. Petersburg, FL) with means for ensuring good thermal contact between the wafers and the underlying platen (Apiezon N, K.J. Lesker, Clairton, PA). The wafers were etched using the following gases and conditions: SF_6 (20 standard cubic centimeters per minute) and O_2 (15 standard cubic centimeters per minute) at a pressure of 150 mTorr and a power of 150 W for

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a run time of approximately 250 minutes. These conditions caused both deep vertical etching and slight lateral underetching. By controlling the ratio of flow rates of the SF_6 and O_2 gases used to form the plasma, the aspect ratio of the microneedles could be adjusted. The regions protected by the chromium masks remained and formed the microneedles. Etching was allowed to proceed until the masks fell off due to underetching, resulting in an array of sharp silicon spikes.

Example 2: Transdermal Transport Using Solid Microneedles

To determine if microfabricated microneedles could be used to enhance transdermal drug delivery, arrays of microneedles were made using a deep plasma etching technique. Their ability to penetrate human skin without breaking was tested and the resulting changes in transdermal transport were measured.

Arrays of microneedles were fabricated having extremely sharp tips (radius of curvature less than 1 μm), and are approximately 150 μm long. Because the skin surface is not flat due to dermatoglyphics and hair, the full length of these microneedles will not penetrate the skin. All experiments were performed at room temperature (23±2 °C).

The ability of the microneedles to pierce skin without breaking was then tested. Insertion of the arrays into skin required only gentle pushing. Inspection by light and electron microscopy showed that more than 95% of microneedles within an array pierced across the stratum corneum of the epidermis samples. Moreover, essentially all of the microneedles that penetrated the epidermis remained intact. On those very few which broke, only the top 5-10 μm was damaged. Microneedle arrays could also be removed without difficulty or additional damage, as well as re-inserted into skin multiple times.

To quantitatively assess the ability of microneedles to increase transdermal transport, calcein permeability of human epidermis with and without inserted microneedle arrays was measured. Calcein crosses skin very poorly under normal circumstances and therefore represents an especially difficult compound to deliver. As expected, passive permeability of calcein across unaltered skin was very low, indicating that the epidermis samples were intact.

Insertion of microneedles into skin was capable of dramatically increasing permeability to calcein. When microneedles were inserted and left embedded in the skin, calcein permeability was increased by more than 1000-fold. Insertion of

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microneedles for 10 s, followed by their removal, yielded an almost 10,000-fold increase. Finally, insertion of a microneedle array for 1 h, followed by its removal, increased skin permeability by about 25,000-fold. Permeabilities for skin with microneedles inserted and then removed are higher than for skin with microneedles remaining embedded probably because the microneedles themselves or the silicon plate supporting the array may block access to the microscopic holes created in the skin. Light microscopy showed that the holes which remained in the skin after microneedles were removed were approximately 1 μm in size.

To confirm *in vitro* experiments which showed that skin permeability can be significantly increased by microneedles, studies were conducted with human volunteers. They indicated that microneedles could be easily inserted into the skin of the forearm or hand. Moreover, insertion of microneedle arrays was never reported to be painful, but sometimes elicited a mild "wearing" sensation described as a weak pressure or the feeling of a piece of tape affixed to the skin. Although transport experiments were not performed *in vivo*, skin electrical resistance was measured before and after microneedle insertion. Microneedles caused a 50-fold drop in skin resistance, a drop similar to that caused by the insertion of a 30-gauge "macroneedle." Inspection of the site immediately after microneedle insertion showed no holes visible by light microscopy. No erythema, edema, or other reaction to microneedles was observed over the hours and days which followed. This indicates that microneedle arrays can permeabilize skin in human subjects in a non-painful and safe manner.

Example 3: Fabrication of Silicon Microtubes

Three-dimensional arrays of microtubes were fabricated from silicon, using deep reactive ion etching combined with a modified black silicon process in a conventional reactive ion etcher. The fabrication process is illustrated in Figures 4a-d. First, arrays of 40 μm diameter circular holes **32** were patterned through photoresist **34** into a 1 μm thick SiO_2 layer **36** on a two inch silicon wafer **38** (Figure 4a). The wafer **38** was then etched using deep reactive ion etching (DRIE) (Laermer, et al., "Bosch Deep Silicon Etching: Improving Uniformity and Etch Rate for Advanced MEMS Applications," *Micro Electro Mechanical Systems*, Orlando, Florida, USA (Jan. 17-21, 1999)), in an inductively coupled plasma (ICP) reactor to etch deep vertical holes **40**. The deep silicon etch was stopped after the holes **40** are

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approximately 200 μm deep into the silicon substrate **38** (Figure 4b) and the photoresist **34** was removed. A second photolithography step patterned the remaining SiO_2 layer **36** into circles concentric to the holes, thus leaving ring shaped oxide masks **34** surrounding the holes (Figure 4c). The photoresist **34** was then removed and the wafer **38** was again deep silicon etched, while simultaneously the holes **40** were etched completely through the wafer **38** (inside the SiO_2 ring) and the silicon was etched around the SiO_2 ring **38** leaving a cylinder **42** (Figure 4d). The resulting tubes were 150 μm in height, with an outer diameter of 80 μm, an inner diameter of 40 μm, and a tube center-to-center spacing of 300 μm.

Example 4: Micromold Fabrication of Metal Microtubes

Hollow metal microtubes were prepared without dry silicon etching, using a thick, photo-defined mold of epoxy. The sequences are illustrated in Figures 5a-e. First, a thick layer of SU-8 epoxy **44** was spin cast onto a silicon or glass substrate **46** that had been coated with 30 nm of titanium **48**, the sacrificial layer. Arrays of cylindrical holes **49** were then photolithographically defined through an epoxy layer **44**, typically 150 μm thick (Figure 5a). The sacrificial layer then was partially removed using a wet etching solution containing hydrofluoric acid and water at the bottom of the cylindrical holes in the SU-8 photoresist **46** (Figure 5b). A seed layer of Ti/Cu/Ti (30 nm/200 nm/30 nm) **39** was then conformally DC sputter-deposited onto the upper surface of the epoxy mold and onto the sidewalls of the cylindrical holes **49** (Figure 5c). As shown in Figure 5c, the seed layer **39** was electrically isolated from the substrate. Subsequently, NiFe was electroplated onto the seed layer **39** (Figure 5d), the epoxy **44** was removed from the substrate, and the surrounding epoxy **44** was removed (Figure 5e). The resulting microtubes are 200 μm in height with an outer diameter of 80 μm, an inner diameter of 60 μm, and a tube center-to-center spacing of 150 μm. The holes in the interior of the microtubes protrude through the base metal supporting the tubes.

Example 5: Micromold Fabrication of Tapered Microneedles

A micromold having tapered walls was fabricated by molding a preexisting 3-D array of microneedles, i.e. the mold-insert, and subsequently removing the mold insert. The micromold was then surface plated in a manner similar to that for the

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microtubes described in Example 4. The fabrication sequence is illustrated in Figures 6a-d.

First, an array of solid silicon microneedles **50** were prepared as described in Henry, et al., "Micromachined Needles for the Transdermal Delivery of Drugs," *Micro Electro Mechanical Systems*, Heidelberg, Germany, Jan. 26-29, pp. 494-98 (1998). Then, a layer of epoxy **52** (SU-8) was spin cast onto the microneedle array to completely blanket the array (Figure 6a). The epoxy **52** settled during pre-bake to create a planar surface above the tips of the microneedles **50**. The epoxy **52** was then fully pre-baked, photolithographically cross-linked, and post-baked.

Then, the upper surface of the epoxy **52** was etched away using an O_2/CHF_3 plasma until approximately 1 to 2 μm of the needle tips **54** were exposed, protruding from the epoxy **52** (Figure 6b). The silicon was then selectively removed by using a SF_6 plasma (Figure 6c). The remaining epoxy mold **52** provided a negative of the microneedles with a small diameter hole where the tip of the silicon needle protruded. After the removal of the silicon, a seed layer of Ti-Cu-Ti **54** was conformally sputter-deposited onto the top and sidewalls of the epoxy micromold **52**. Following the same process sequence as described in Example 4, NiFe was then electroplated onto the seed layer **54** (Figure 6c). Finally, the epoxy was removed using an O_2/CHF_3 plasma, leaving a 20 x 20 array of NiFe hollow metal microneedles **54** (Figure 6d). The microneedles **54** were 150 μm in height with a base diameter of 80 μm, a tip diameter of 10 μm, and a needle-to-needle spacing of 150 μm.

Micromold-based microneedles also have been successfully manufactured using a process in which the epoxy mold material was replaced with PDMS. In this case, it was possible to remove the mold from the mold insert, as well as the microneedles from the mold, using only physical techniques such as peeling. This approach advantageously requires no dry etching and allows one to reuse both the mold and the mold insert.

Example 6: Micromold Fabrication of Tapered Microneedles Using Laser-Formed Molds

A micromold having tapered walls was fabricated by use of laser ablation techniques, as shown in Figures 7a-d. A laser-ablatable polymer sheet **60** such as KAPTON™ polyimide approximately 150 μm in thickness was optionally

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laminated to a thin (10-30 μm) metal sheet **62** such as titanium (Figure 7a). A tapered hole **64** was formed in the metal/polymer laminate **60/62** using a laser technique such as excimer laser ablation (Figure 7b). The entry hole of the laser spot was on the metal side **62**, and a through hole was made through both the metal sheet and the polymer film. The through hole **64** was tapered in combination with either defocusing or appropriate substrate motion to create a taper such that the wide end of the hole **64** (typically 40-50 μm) was on the metal side **62** and the narrow end of the hole **64** (typically 10-20 μm) was on the polymer **60** side. A thin layer of metal **66**, e.g. titanium, of thickness 0.1 μm was then deposited, e.g., using a sputter-deposition technique, in such a way that the metal **66** deposited on the metal film side and coated the polymer sidewalls, but did not coat the polymer **60** side of the laminate (Figure 7c). Electrodeposition of metal **68**, e.g., gold, to a thickness of 1 to 5 μm was then performed on the titanium-coated metal surface **66**, and polymer sidewalls curved section of **60** next to **64**. Finally, the polymer **60** was removed, using e.g. an oxygen plasma, to form the completed microneedles (Figure 7d).

Alternate polymer removal methods, such as thermal, solvent, aqueous, or photo-degradation followed by solvent or aqueous removal, are also possible if the polymer material is chosen appropriately (e.g., a photoresist resin).

Example 7: Formation of Microneedles by Embossing

Formation of a microneedle by embossing is shown in Figures 8a-f. A polymeric layer **70** (Figure 8a) is embossed by a solid microneedle or microneedle array **72** (Figure 8b). The array **72** is removed (Figure 8c), and the layer **70** is etched from the non-embossed side **74** until the embossed cavity **76** is exposed (Figure 8d). A metallic layer **78** is then deposited on the embossed side and the sidewalls, but not on the non-embossed side **74** (Figure 8e). This layer **78** is optionally thickened by electrodeposition of an additional metal layer **80** on top of it (Figure 8e). The polymer layer **70** is then removed to form the microneedles **78/80** (Figure 8f).

Example 8: Transdermal Application of Hollow Microneedles

The bore of hollow microneedles must provide fluid flow with minimal clogging in order to be suitable to transport material, such as in transdermal drug delivery. Therefore, microneedles and microtubes were evaluated to determine their suitability for these functions.

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Hollow metal and silicon microneedles, produced as described in Examples 3-5, were inserted through human skin epidermis with no apparent clogging of the needle bores. Scanning electron microscopy of a hollow metal (NiFe) microneedle penetrating up through the underside of human epidermis showed the microneedle remains intact, with the tip free of debris. Similarly, silicon microneedles, metal microneedles, and metal microtubes were successfully inserted through human skin. Also, the hollow microneedles were shown to permit the flow of water through their bores.

Example 9: Drug Transport Through Microneedles Inserted Into Skin

Studies were performed with solid and hollow microneedles to demonstrate transport of molecules and fluids. As shown in Table 1, transport of a number of different compounds across skin is possible using microneedles. These studies were performed using either solid silicon microneedles or using hollow silicon microneedles made by methods described in this patent. Transport was measured across human cadaver epidermis *in vitro* using Franz diffusion chambers at 37 °C using methods described in Henry, et al., "Microfabricated microneedles: A novel method to increase transdermal drug delivery" *J. Pharm. Sci.* 87: 922-25 (1998).

The transdermal delivery of calcein, insulin, bovine serum albumin ("BSA"), and nanoparticles was measured. Delivery refers to the ability to transport these compounds from the stratum corneum side of the epidermis to the viable epidermis side. This is the direction of transport associated with delivering drugs into the body. Removal of calcein was also measured. Removal refers to the ability to transport calcein from the viable epidermis side of the epidermis to the stratum corneum side. This is the direction of transport associated with removing from the body compounds found in the body, such as glucose.

In all cases shown in Table 1, transport of these compounds across skin occurred at levels below the detection limit when no needles were inserted into the skin. Intact skin provides an excellent barrier to transport of these compounds. In all cases examined, when solid microneedles were inserted into the skin and left in place, large skin permeabilities were measured, indicating that the microneedles had created pathways for transport across the skin. Furthermore, in all cases, when solid microneedles were inserted into the skin and then removed, even greater skin permeabilities resulted. Finally, when hollow microneedles were inserted into the

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skin and left in place, still greater skin permeabilities resulted for those compounds tested. These studies show that microneedles can dramatically increase skin permeability and can thereby increase transport of a number of different compounds across the skin. They also shows that when solid microneedles are used, a preferred embodiment involves inserting and then removing microneedles, rather than leaving them in place. They also shows that using hollow microneedles are a preferred embodiment over the use of solid microneedles.

Table 1: Transport of Drugs Through Microneedles Inserted Into Skin

Compound	No needles	Solid needles inserted	Solid needles inserted and removed	Hollow needles inserted
Calcein delivery	**	4×10^{-5}	1×10^{-4}	1×10^{-4}
Calcein removal	**	2×10^{-5}	1×10^{-4}	n.a.
Insulin delivery	**	1×10^{-4}	1×10^{-4}	n.a.
BSA delivery	**	9×10^{-7}	8×10^{-7}	9×10^{-7}
Nanoparticle delivery	**	n.a.	3×10^{-5}	n.a.

** means that the transport was below the detection limit.
n.a. means that the data are not available.
Nanoparticles were made of latex with a diameter of approximately 100 nm.

Example 10: Flow of Water Through Hollow Microneedles

To demonstrate that fluid can be forced through hollow microneedles at meaningful rates, the flow rate of water through a microneedle array was measures as a function of pressure. The array used contained 100 hollow silicon microneedles having an inner diameter of 50 μm and an outer diameter of 80 μm. The results, which are shown in Table 2, demonstrate that significant flow rates of water through microneedles can be achieved at modest pressures. The measured flow rates are comparable to flow rates through hypodermic needles attached to syringes.

Table 2: Flow Rate of Water Through Hollow Silicon Microneedles as a Function of Applied Pressure

Pressure (psi)	Flow rate (ml/min)
1.0	16
1.5	24
2.0	31
2.5	38
3.0	45

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Modifications and variations of the methods and devices described herein will be obvious to those skilled in the art from the foregoing detailed description. Such modifications and variations are intended to come within the scope of the appended claims.

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We claim:

1. A device for transport of a material across or into a biological barrier comprising

a) a plurality of hollow microneedles each having a base end and a tip, with at least one hollow pathway disposed at or between the base end and the tip,

b) a substrate to which the base ends of the microneedles are attached or integrated, and

c) at least one reservoir which is in connection with the base ends of at least one of the microneedles, either integrally or separably until the moment of use,

wherein the volume or amount of material to be transported can selectively be altered.

2. The device of claim 1 wherein the reservoir is formed of a material which is deformable.

3. The device of claim 2 wherein the reservoir is elastic.

4. The device of claim 1 wherein the reservoir further comprises a therapeutic, prophylactic, or diagnostic agent.

5. The device of claim 4 wherein the agent is selected from the group consisting of peptides, proteins, carbohydrates, nucleic acid molecules, lipids, organic molecules, biologically active inorganic molecules, and combinations thereof.

6. The device of claim 1 further comprising a plunger movably secured to the substrate, wherein the plunger can compress the reservoir.

7. The device of claim 6 further comprising a spring engaged with the plunger.

8. The device of claim 1 wherein the diameter of the microneedles is between about 10 μm and about 200 μm.

9. The device of claim 1 wherein the length of the microneedles is between about 100 μm and 1 mm.

10. The device of claim 1 wherein the microneedles are adapted to provide an insertion depth of less than about 100 to 150 μm.

11. The device of claim 1 comprising a three dimensional array of microneedles.

12. The device of claim 1 further comprising an adhesive material for

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securing the device during delivery.

13. The device of claim 1 wherein the reservoir is a syringe or pump connected to the substrate.

14. The device of claim 1 comprising an attachment means for securing the device to a syringe or pump.

15. The device of claim 13 wherein the substrate is adapted to removably connect to a standard or Luer-lock syringe.

16. The device of claim 1 further comprising a sealing mechanism which is interposed between the reservoir and the substrate or which is secured to the tips of the microneedles.

17. The device of claim 16 wherein the sealing mechanism is a fracturable barrier interposed between the reservoir and the substrate.

18. The device of claim 1 further comprising a means for providing feedback to indicate that delivery has been initiated or completed.

19. The device of claim 1 wherein at least the microneedles are manufactured for single use as a disposable reagent.

20. The device of claim 1 wherein the device further comprises means for stopping delivery.

21. The device of claim 1 further comprising an osmotic pump to move agent.

22. The device of claim 1 wherein the microneedle is at an angle other than perpendicular to the substrate.

23. The device of claim 1 wherein the substrate is formed of a flexible material.

24. The device of claim 1 comprising multiple compartments or reservoirs.

25. The device of claim 24 wherein the compartments or reservoirs can be connected or in communication with each other.

26. The device of claim 24 wherein one or more reservoirs contain a solid formulation and one or more reservoirs contains a liquid carrier for the solid formulation.

27. The device of claim 1 in a packaging that protects the device from damage and/or contamination.

28. The device of claim 1 further comprising a removable liner that covers

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the microneedle tips and that can be used to protect and/or seal access to or from the microneedles.

29. The device of claim 1 wherein the device comprises rate control means, which can be used to regulate the rate or extent at which materials flow through the microneedles.

30. The device of claim 29 wherein the rate control means is a membrane at one end of the microneedles through which agent or fluid must pass.

31. The device of claim 29 wherein the rate control means is a material positioned within the hollow pathway of the microneedles.

32. The device of claim 1 comprising multiple microneedle arrays in combination with means for accessing one or more arrays at a time.

33. The device of claim 1 comprising means for preventing undesired contact with or use of the microneedles.

34. The device of claim 33 wherein the means is packaging that covers the microneedles.

35. The device of claim 33 wherein the means is packaging that shears off the microneedles, or tips thereof, after use.

36. The device of claim 33 wherein the means are materials which are delivered into the hollow pathways to seal the microneedles.

37. A method for delivering a therapeutic, prophylactic or diagnostic agent across or into tissue comprising

inserting into the tissue one or more microneedles that are in fluid connection with at least one reservoir containing the agent to be delivered, and

reducing the volume or amount of the agent in the reservoir by driving the agent through at least one of the microneedles.

38. The method of claim 37 wherein the reservoir is formed of a material which is deformable.

39. The method of claim 37 wherein the volume or amount of the agent in the reservoir is reduced by depressing a plunger that is movably secured to the substrate.

40. A kit of parts for delivering a therapeutic, prophylactic or diagnostic agent across or into tissue comprising

(a) one or more microneedle devices which comprise a plurality of hollow

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microneedles, a substrate to the microneedles are attached or integrated, and at least one reservoir which is selectably in communication with the microneedles, wherein at least one of the reservoirs contains the therapeutic, prophylactic or diagnostic agent to be delivered; and

(b) a triggering device which is adapted to activate delivery of the agent from reservoir through the microneedles of one of the devices at a time.

41. A device for collecting a sample of a biological fluid comprising:

(a) one or more hollow or porous microneedles having a base end and a tip,

(b) a substrate to which the base of the microneedle is attached or integrated, and

(c) at least one collection chamber which is selectably in fluid communication with the base end of the microneedle.

42. The device of claim 41 further comprising

(d) a means for inducing transport of the biological fluid or component thereof into the collection chamber.

43. The device of claim 42 wherein the pressure within the collection chamber can selectively be reduced.

44. The device of claim 43 wherein the pressure reduction is induced by expanding the internal volume of the collection chamber.

45. The device of claim 44 wherein the collection chamber is a standard or Luer-lock syringe.

46. The device of claim 43 wherein the collection chamber comprises an upper portion which is formed of a material which is deformable.

47. The device of claim 43 further comprising a plunger movably secured to the substrate, wherein the plunger can deform the collection chamber.

48. The device of claim 46 further comprising a one-way valve.

49. The device of claim 41 wherein the collection chamber comprises a plurality of compartments.

50. The device of claim 41 comprising a three dimensional array of microneedles.

51. The device of claim 41 further comprising an adhesive material for securing the device to the biological barrier surface during fluid withdrawal or sensing.

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52. The device of claim 41 further comprising a means for controlling flow through the microneedle.

53. The device of claim 42 wherein the means for controlling flow is a fracturable or removable barrier which is interposed between the collection chamber and base of the microneedle.

54. The device of claim 41 further comprising a sensor in communication with the collection chamber.

55. A device for sensing an analyte in a biological fluid, the device comprising:

(a) one or more microneedles having a base end and a tip,

(b) a substrate to which the base of the microneedle is attached or integrated,

(c) at least one sensor which is selectably in communication with the microneedle.

56. The device of claim 55 wherein the sensor comprises

a chemical or biochemical agent that react with the analyte, and

electrochemical or optical transducers which measure the reaction of the agent and analyte.

57. The device of claim 56 wherein the agent is an enzyme selected from the group consisting of glucose oxidase, glucose dehydrogensase, and combinations thereof.

58. The device of claim 55 further comprising an electronics package in communication with the sensor.

59. The device of claim 55 for insertion of the microneedles in skin and sensing of glucose.

60. A device for sensing an analyte in a biological fluid, the device comprising:

(a) one or more microneedles having a base end and a tip,

(b) a substrate to which the base of the microneedle is attached or integrated,

wherein at least one of the microneedles is or comprises a sensor.

61. The device of claim 60 wherein the sensor comprises

a chemical or biochemical agent that react with the analyte, and

electrochemical or optical transducers which measure the reaction of the agent and analyte.

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62. The device of claim 60 further comprising an electronics package in communication with the sensor.

63. The device of claim 60 for insertion of the microneedles in skin and sensing of glucose.

64. The device of claim 41 wherein the collection chamber is adapted to receive and use glucose strips.

65. The device of claim 41 wherein the microneedle is hollow and comprises at least one opening in the side of the microneedle.

66. The device of claim 41 wherein the microneedle has a hollow bore containing a material to modulate the flow of biological fluid through the microneedles into the collection chamber.

67. A method for collecting a sample of a biological fluid or analyte therein, comprising the steps:

providing a device comprising (i) one or more hollow or porous microneedles having a base end and a tip, (ii) a substrate to which the base of the microneedle is attached or integrated, (iii) at least one collection chamber which is selectably in fluid connection with the base end of the microneedle, and (iv) a means for inducing transport of the biological fluid or component thereof into the collection chamber;

inserting the microneedles into a biological barrier comprising biological fluid; and

triggering the induction means to permit the transport of the biological fluid or a component thereof through the microneedles and into the collection chamber.

68. The method of claim 67 wherein the induction means is selected from capillary action, diffusion, mechanical pumps, electroosmosis, electrophoresis, convection, and combinations thereof.

69. The method of claim 67 wherein the induction means utilizes a pressure gradient in which the pressure within the microneedles and/or collection chamber is less than the pressure of the biological fluid adjacent the tip of the microneedle.

70. The method of claim 67 wherein the analyte to be collected or sensed is selected from the group consisting of glucose, cholesterol, bilirubin, creatine, metabolic enzymes, hemoglobin, heparin, clotting factors, uric acid, tumor antigens, reproductive hormones, oxygen, pH, alcohol, tobacco metabolites, and illegal drugs.

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71. A method sensing an analyte in a biological fluid, comprising the steps:

(a) providing a device comprising (i) one or more hollow or porous microneedles having a base end and a tip, (ii) a substrate to which the base of the microneedle is attached or integrated, and (iii) at least one sensor which is in communication with one or more of the microneedles;

(b) inserting the microneedles into a biological barrier comprising biological fluid; and

(c) contacting the sensor with the biological fluid.

72. The method of claim 71 wherein the device further comprises (iv) at least one collection chamber which is selectably in fluid connection with the base end of the microneedle, and (v) a means for inducing transport of the biological fluid or component thereof into the collection chamber, and

wherein, after step (b), the induction means is triggered to draw the biological fluid or a component thereof through the microneedles and into the collection chamber.

73. The method of claim 72 wherein the induction means utilizes a pressure gradient in which the pressure within the microneedles and/or collection chamber is less than the pressure of the biological fluid adjacent the tip of the microneedle.

74. The method of claim 73 wherein the pressure gradient is created by increasing the volume within the collection chamber.

75. The method of claim 71 wherein the analyte to be collected or sensed is selected from the group consisting of glucose, cholesterol, bilirubin, creatine, metabolic enzymes, hemoglobin, heparin, clotting factors, uric acid, tumor antigens, reproductive hormones, oxygen, pH, alcohol, tobacco metabolites, and illegal drugs.

76. The method of claim 27 or 31 for sensing glucose wherein the biological barrier is human skin.

77. A device for transport of material or energy across or into an elastic biological barrier comprising

a microneedle having a tip end and a base end,

a substrate connected to the base end of the microneedle, and

a means for improving penetration of the biological barrier by the microneedle.

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78. The device of claim 77 wherein the biological barrier is human or other mammalian skin.

79. The device of claim 77 wherein the means comprises one or more extensions (i) interposed between the substrate and the base end of the microneedle or (ii) extending from the side of the substrate distal to the base end of the microneedle.

80. The device of claim 79 wherein the extension is between about 500 μm and about 10 mm in height.

81. The device of claim 79 wherein the extension has a cross-sectional dimension of at least about 200 μm.

82. The device of claim 79 wherein the extension includes an array of microneedles extending therefrom.

83. The device of claim 79 wherein the extension is composed of a material which is different from the material forming the microneedles.

84. The device of claim 79 wherein the microneedle is hollow and wherein the extension includes at least one aperture in communication with the bore of the microneedle.

85. The device of claim 79 further comprising a rigid surface positioned apart from an array of the microneedles and oriented to contact an elastic biological barrier substantially at the same time as the microneedles when the microneedles are applied to the barrier.

86. The device of claim 77 wherein the substrate is curved.

87. The device of claim 77 comprising a plurality of microneedles of varying lengths.

88. The device of claim 87 comprising

four or more microneedles wherein the tip ends of the microneedles collectively define a curvilinear surface.

89. The device of claim 77 comprising a plurality of hollow microneedles in a linear array, wherein the substrate is mounted on a holder having one or more apertures through the holder in communication with the microneedles.

90. The device of claim 77 wherein the substrate is flexible.

91. The device of claim 90 wherein the substrate is deformable by fluid pressure or mechanical means.

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92. The device of claim 91 wherein the substrate is mounted onto a flexible membrane bubble.

93. The device of claim 92 further comprising a second membrane bubble positioned to define a chamber between the flexible membrane bubble and the second membrane bubble.

94. The device of claim 93 wherein the chamber contains molecules which flow through the microneedle.

95. The device of claim 94 wherein the molecules are drug molecules.

96. The device of claim 77 wherein the means reduces the elasticity of the biological barrier.

97. The device of claim 96 wherein the means physically manipulates the biological barrier to present a more rigid surface in the area of the biological barrier to be penetrated by the microneedle.

98. The device of claim 97 wherein the manipulation is selected from the group consisting of stretching, pulling, pinching, and a combination thereof.

99. The device of claim 98 wherein the manipulation includes pulling by reducing the atmospheric pressure over the area of the biological barrier to be penetrated by the microneedles.

100. The device of claim 99 further comprising a body portion defining a first vacuum region and a second vacuum region.

wherein an array of microneedles separates the first and second regions.

101. The device of claim 100 wherein the body portion comprises an annular ring which holds the microneedles.

102. The device of claim 101 wherein the microneedle is hollow and wherein the body portion further comprises a means for attachment to a syringe, a conduit for connection to a vacuum pump, or both.

103. The device of claim 98 wherein the means for physically manipulating comprises a stretching cone or expandable ring around the microneedles.

104. The device of claim 98 wherein the means comprises a body portion from which a plurality of stretching elements are pivotally attached.

105. The device of claim 104 wherein the stretching elements have ends provided with a non-slip feature for engagement with the biological barrier.

106. The device of claim 98 wherein the means comprises jaws for pinching

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a portion of the biological barrier for contact with the microneedles.

107. The device of claim 97 wherein the means comprises an adhesive film applied over the area of the biological barrier to be penetrated by the microneedle.

108. The device of claim 79 wherein the means for improving penetration creates holes in the stratum corneum, wherein the microneedle can be inserted into the holes.

109. The device of claim 108 wherein the means for creating holes is selected from the group consisting of thermal ablation, high pressure fluid puncturing, cryoablation, and application of degradation agents.

110. The device of claim 77 wherein the means for improving penetration accelerates the tips of the microneedles into the biological barrier, accelerates the biological barrier into contact with the tips of the microneedles, or a combination thereof.

111. The device of claim 110 wherein the means for accelerating the tip of the microneedle comprises releasing a spring or gas under compression.

112. The device of claim 77 wherein a lubricating material is incorporated into or coated onto the microneedle.

113. The device of claim 77 further comprising a collar to limit the depth of microneedle penetration.

114. The device of claim 77 further comprising a means for attaching the device to the skin of a patient, wherein the means is not the microneedle.

115. The device of claim 114 wherein the means is an adhesive film.

116. The device of claim 114 wherein the means is an arm band.

117. The device of claim 77 wherein the microneedle is hollow and wherein the device further comprises a reservoir selectably in communication with the hollow microneedle.

118. The device of claim 77 wherein the means for enhancing penetration comprises an apparatus for vibrating the microneedle.

119. The device of claim 118 wherein the apparatus comprises a piezoelectric transducer or an electromechanical actuator.

120. A kit of parts for use in transport of material or energy across or into an elastic biological barrier, comprising

(i) a device comprising one or more microneedles having a tip end and a

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base end, and a substrate connected to the base end of the microneedle, and

(ii) an adhesive film or barrier-tightening chemical, either of which can be applied over an area of the biological barrier to be penetrated by the microneedle.

121. A method for transport of material or energy across or into an elastic biological barrier comprising using the device of any of claims 77-119.

122. The device of any of claims 1-36 and 41-66 further comprising a means for improving penetration of the biological barrier by the microneedles.

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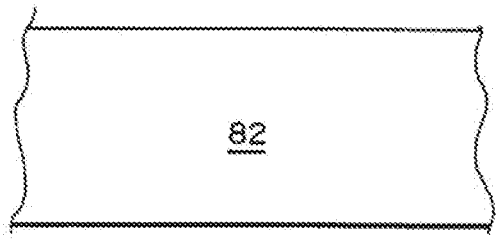

FIG. 1A

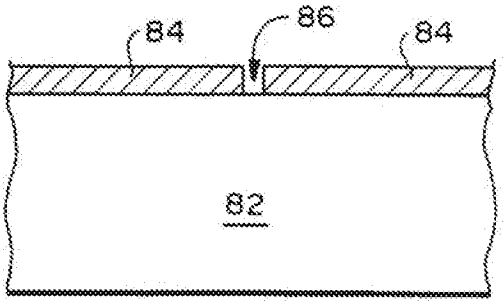

FIG. 1B

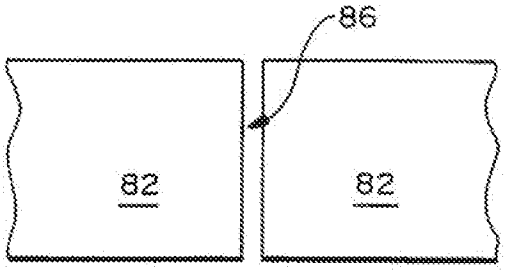

FIG. 1C

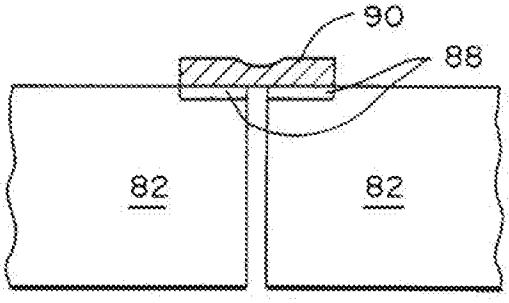

FIG. 1D

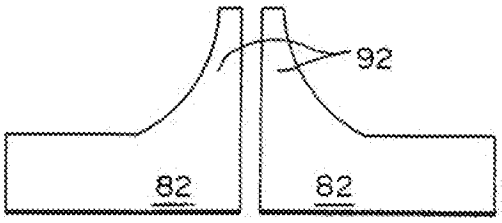

FIG. 1E

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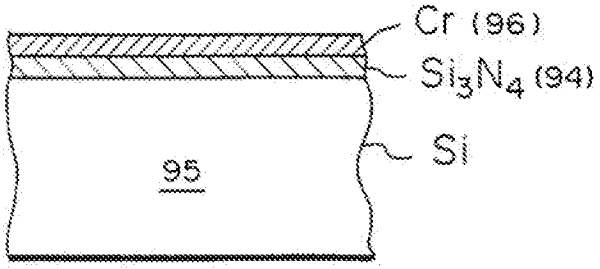

FIG. 2A

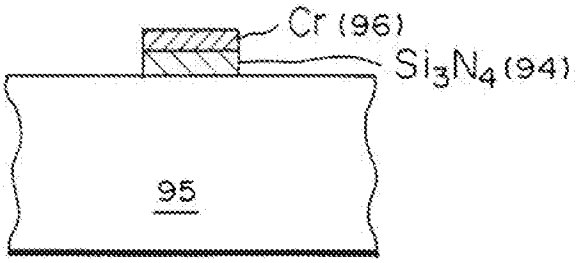

FIG. 2B

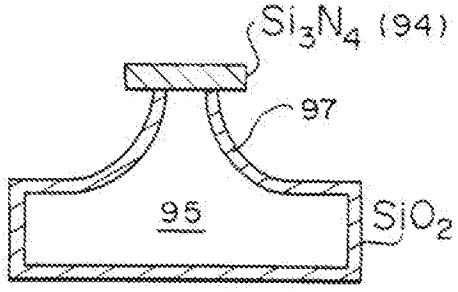

FIG. 2E

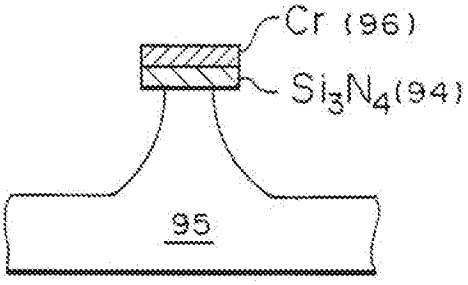

FIG. 2C

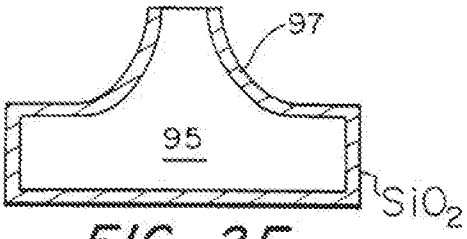

FIG. 2F

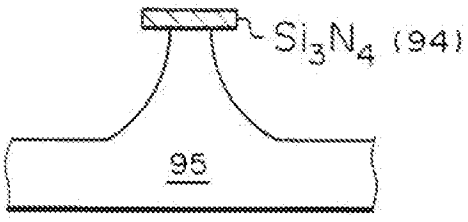

FIG. 2D

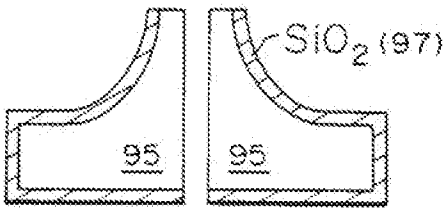

FIG. 2G

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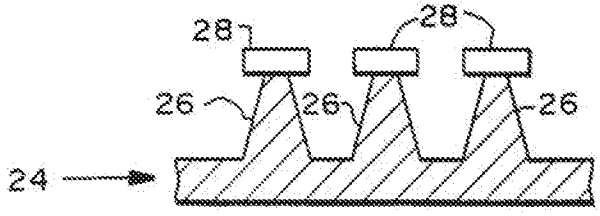

FIG. 3A

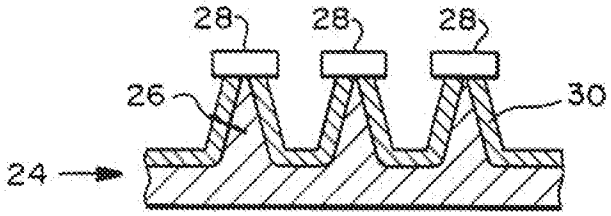

FIG. 3B

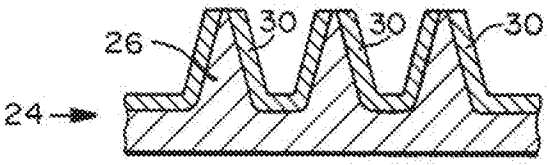

FIG. 3C

FIG. 3D

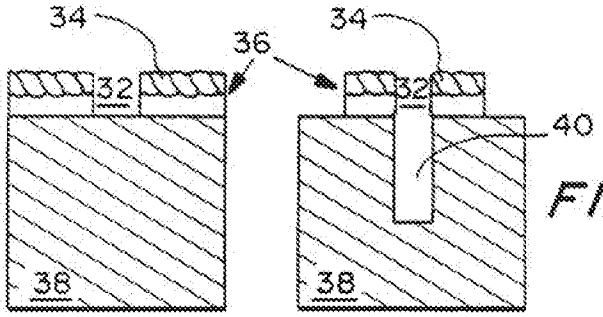

FIG. 4A

FIG. 4C

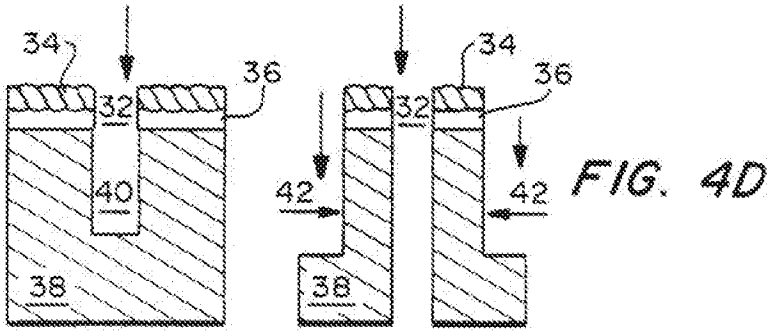

FIG. 4B

FIG. 4D

ENDYMED EXHIBIT 1002 - 262/733

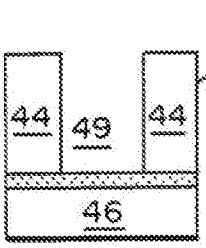

FIG. 5A

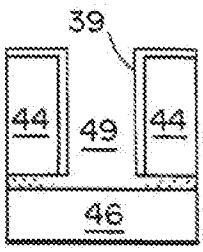

FIG. 5C

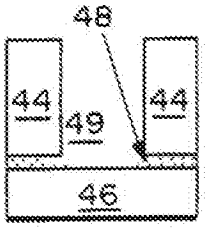

FIG. 5B

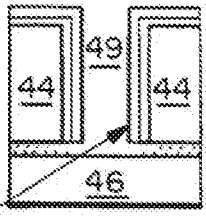

FIG. 5D

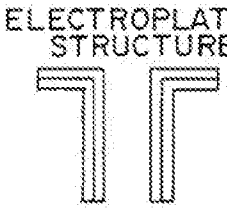

FIG. 5E

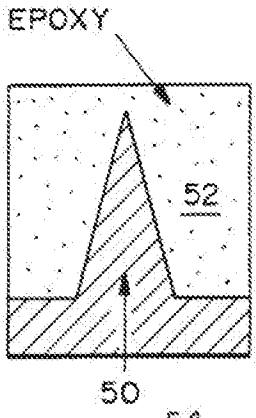

FIG. 6A

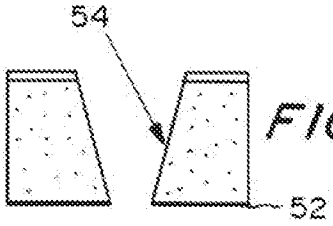

FIG. 6C

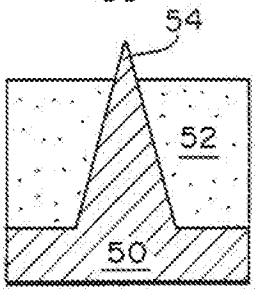

FIG. 6B

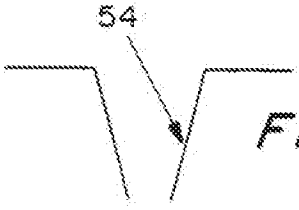

FIG. 6D

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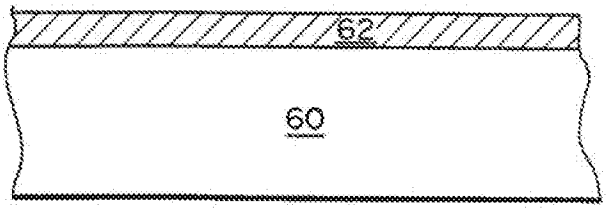


FIG. 7A

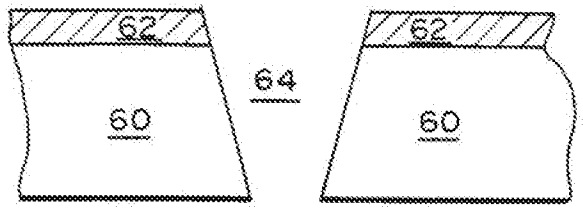


FIG. 7B

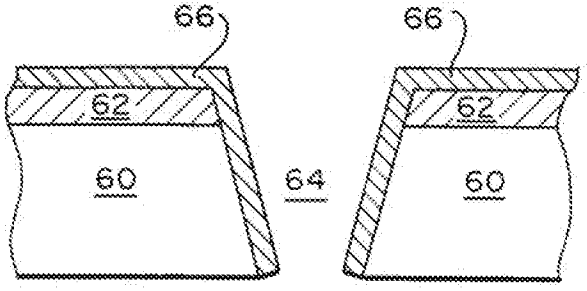


FIG. 7C

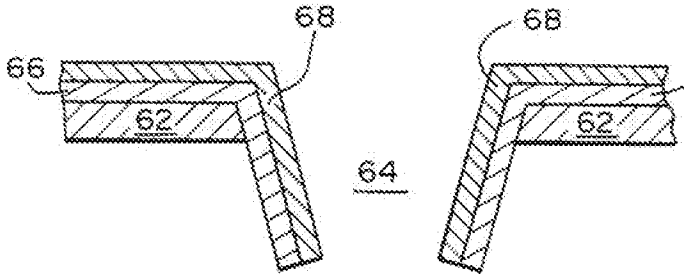


FIG. 7D

ENDYMED EXHIBIT 1002 - 264/733

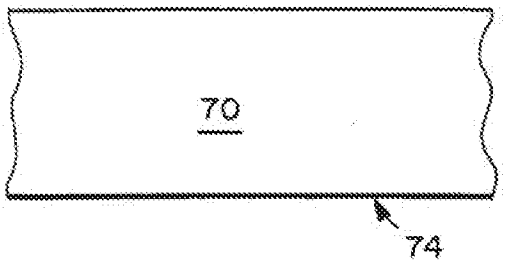


FIG. 8A

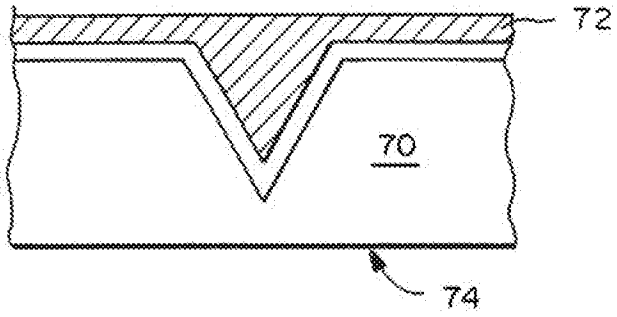


FIG. 8B

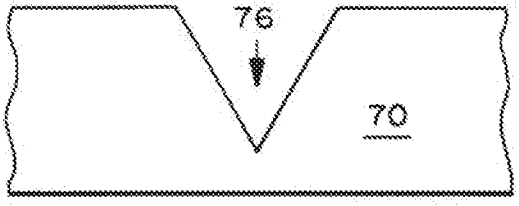


FIG. 8C

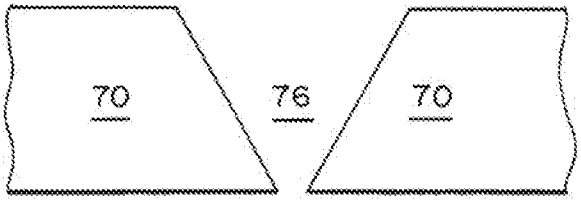


FIG. 8D

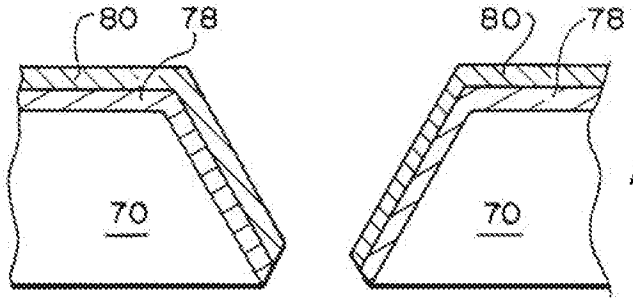


FIG. 8E

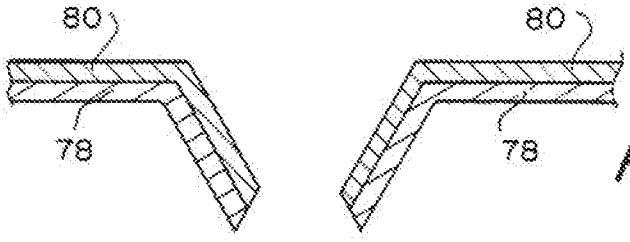
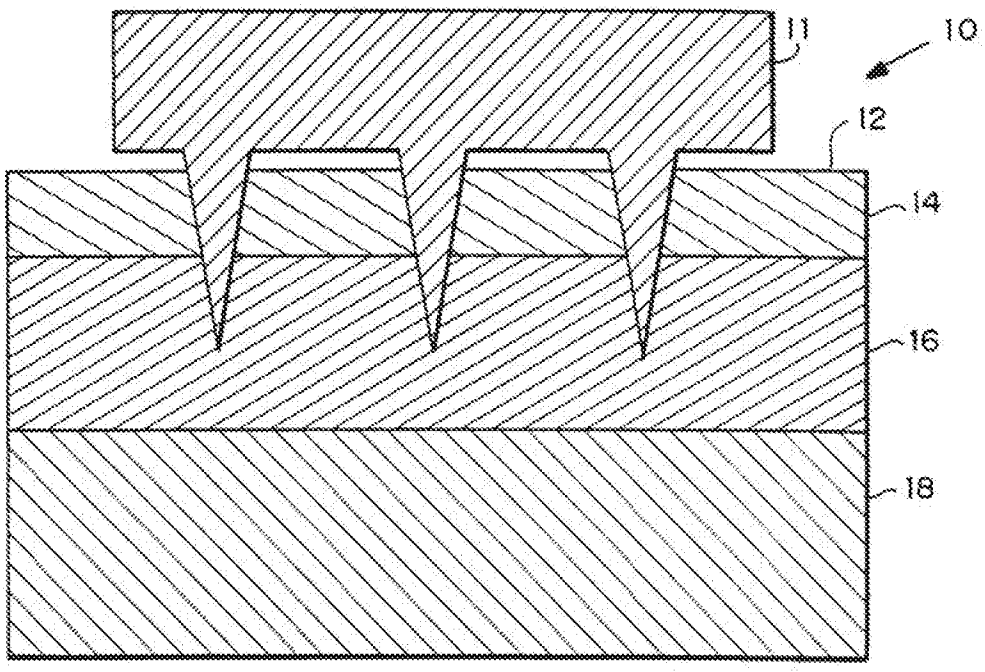


FIG. 8F

ENDYMED EXHIBIT 1002 - 265/733

FIG. 9



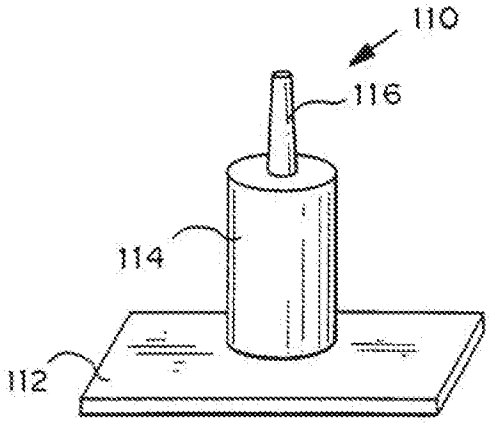


FIG. 10A

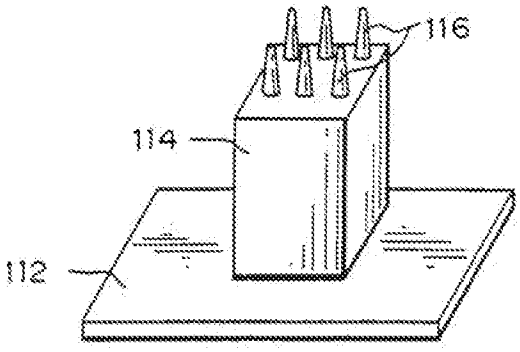


FIG. 10B

ENDYMED EXHIBIT 1002 - 266/733

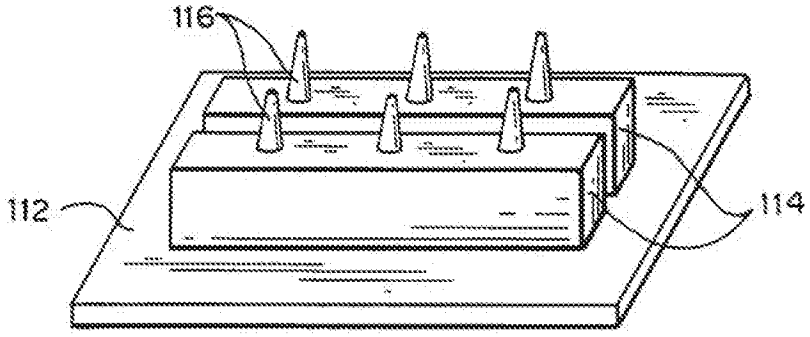


FIG. 10C

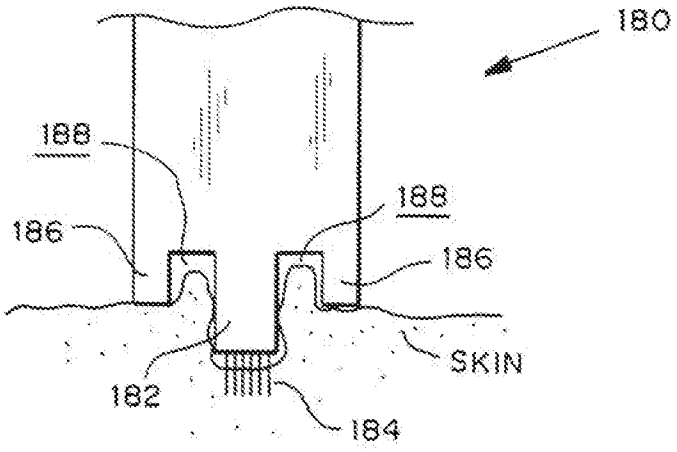


FIG. 10D

ENDYMED EXHIBIT 1002 - 267/733

FIG. 11A

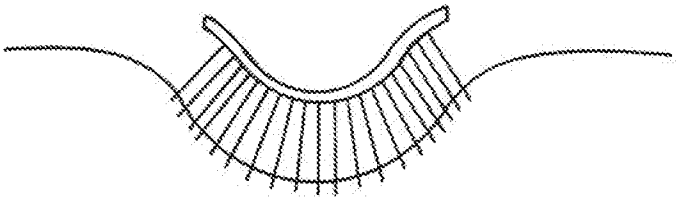


FIG. 11B

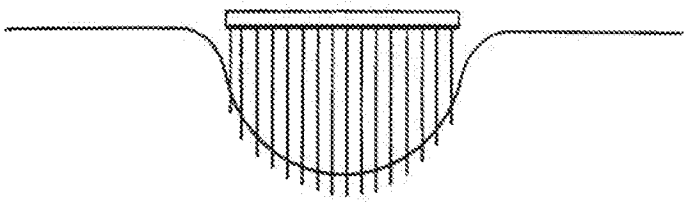
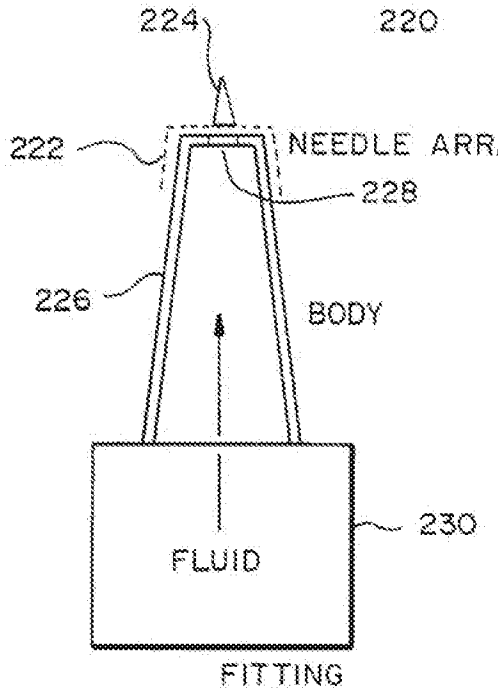


FIG. 11C



ENDYMED EXHIBIT 1002 - 268/733

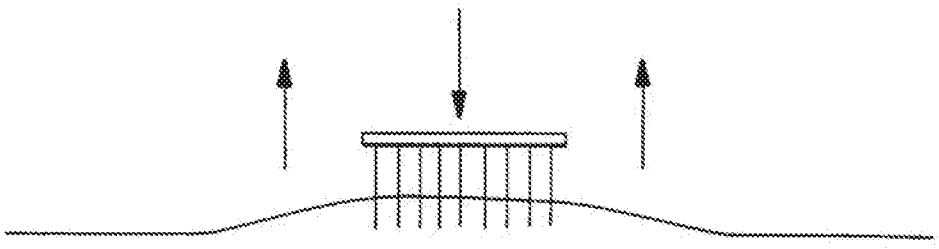


FIG. 12A

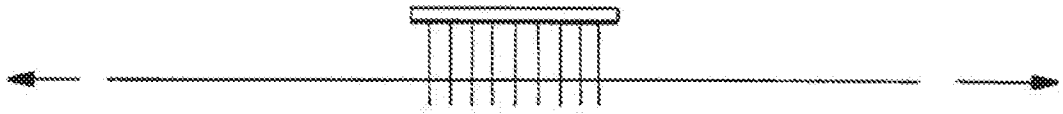


FIG. 12B

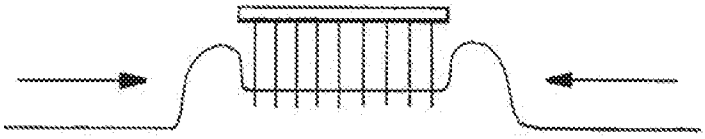


FIG. 12C

ENDYMED EXHIBIT 1002 - 269/733

FIG. 13A

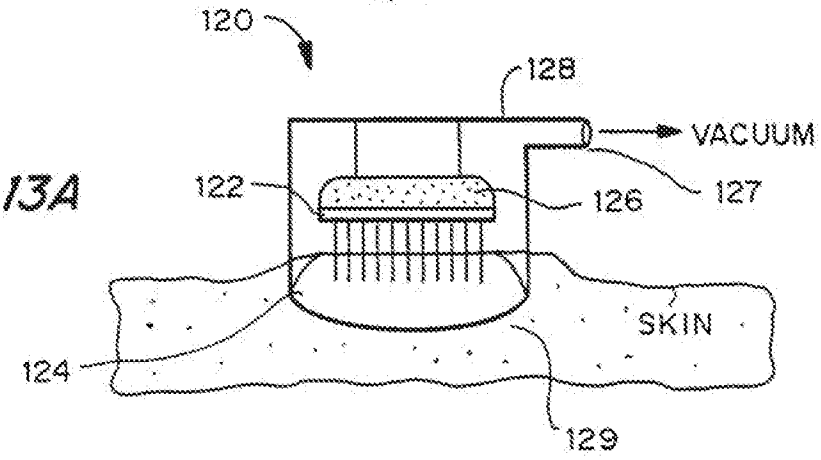


FIG. 13B

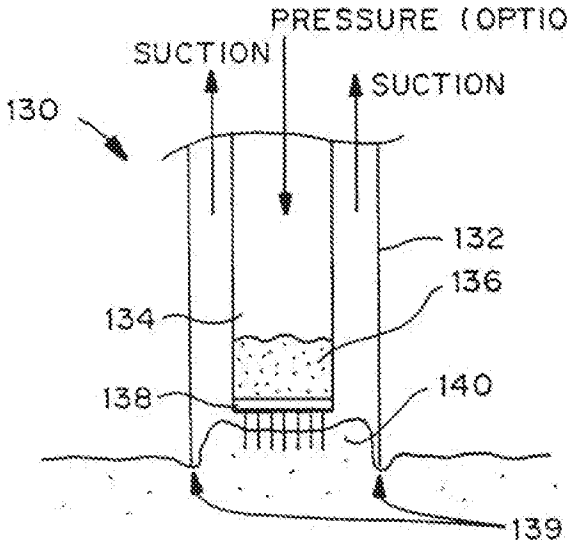
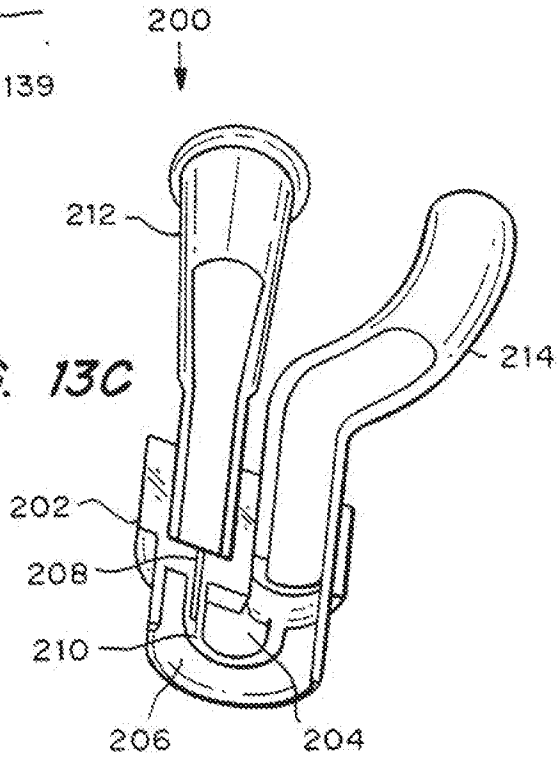


FIG. 13C



ENDYMED EXHIBIT 1002 - 270/733

DEVICE RESTING ON SKIN SURFACE

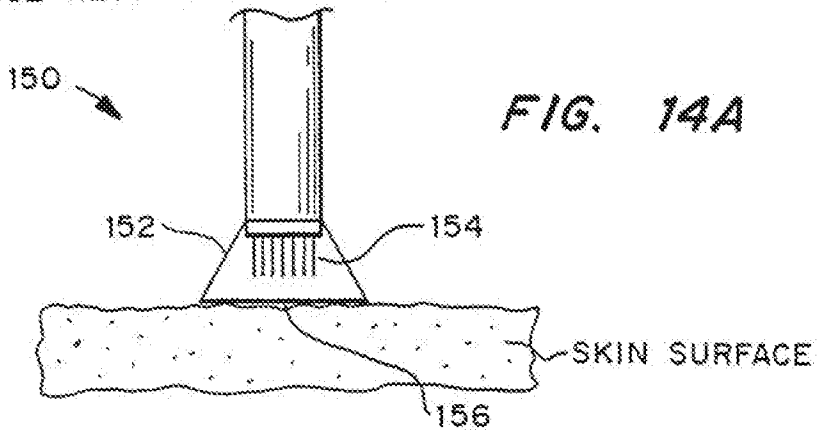


FIG. 14A

FORCE APPLIED TO MICRONEEDLE / STRETCHING DEVICE

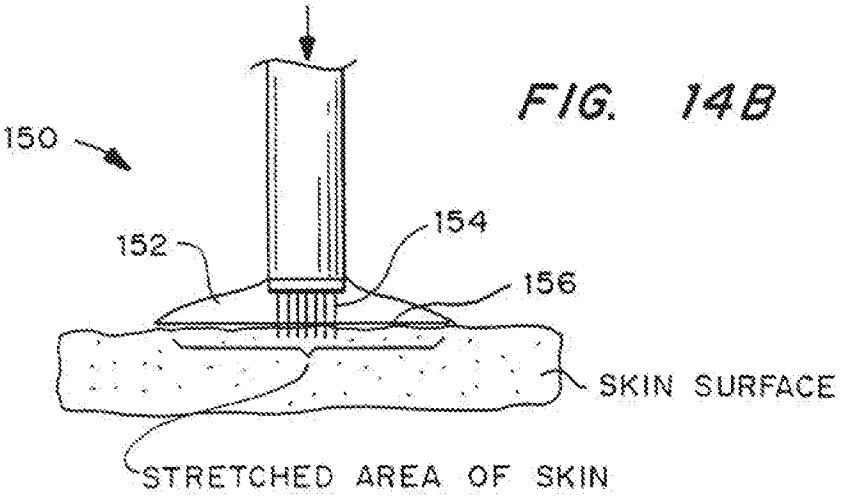


FIG. 14B

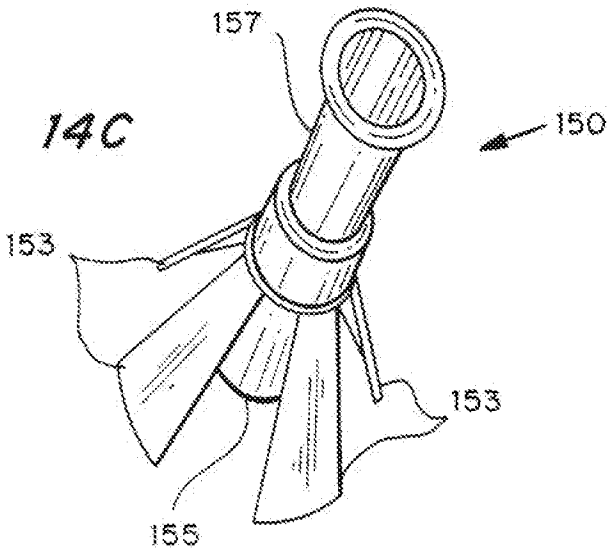


FIG. 14C

ENDYMED EXHIBIT 1002 - 271/733

DEVICE RESTING ON SKIN SURFACE - JAWS OPEN

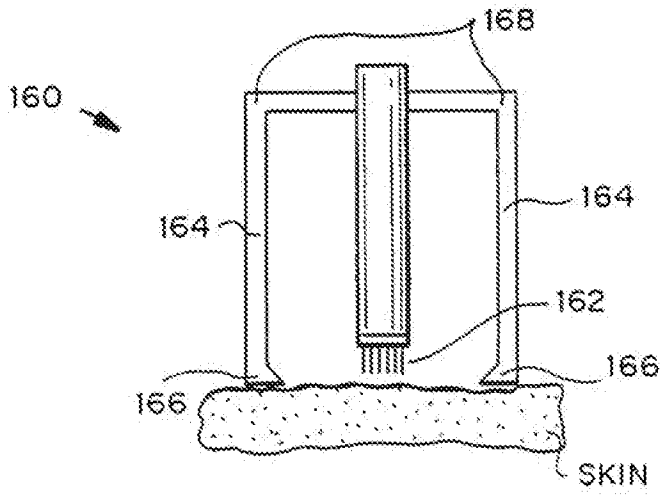


FIG. 15A

DEVICE PINCHING SKIN - JAWS CLOSED

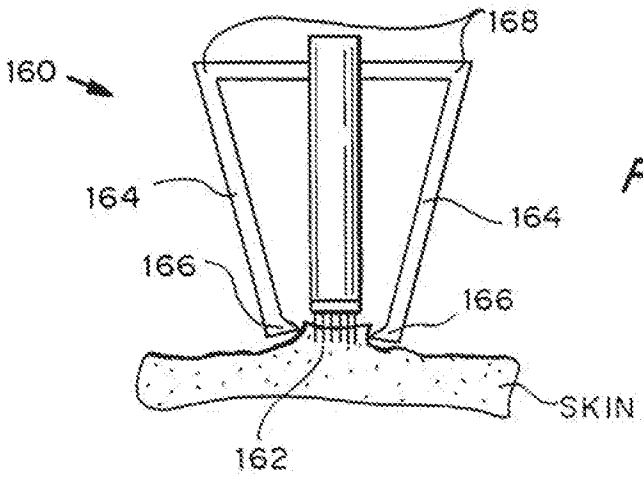


FIG. 15B

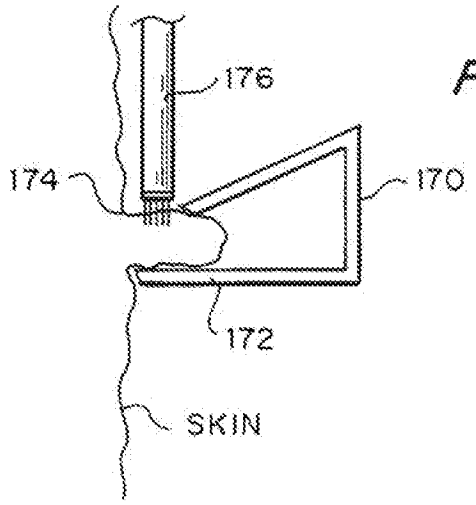


FIG. 15C

ENDYMED EXHIBIT 1002 - 272/733

FIG. 16

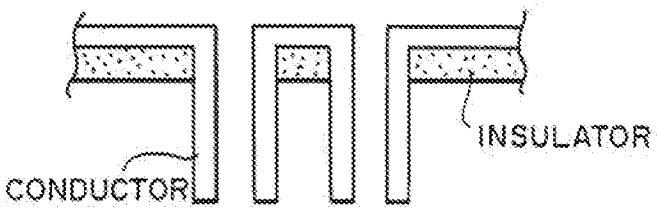


FIG. 17

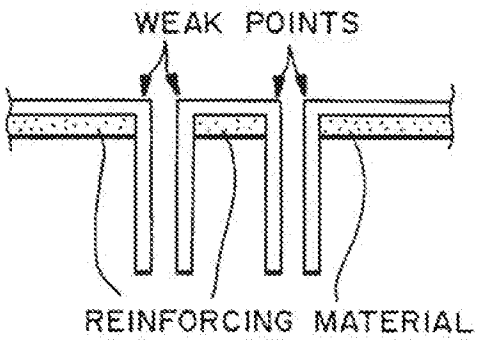


FIG. 18A

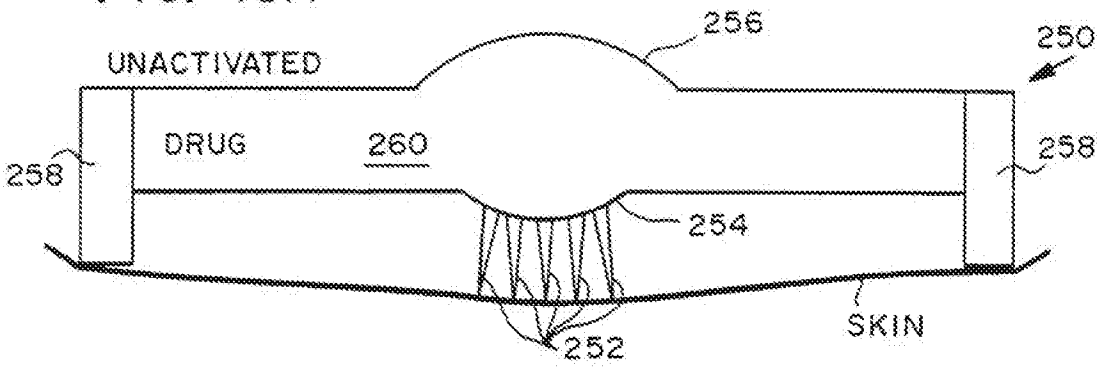
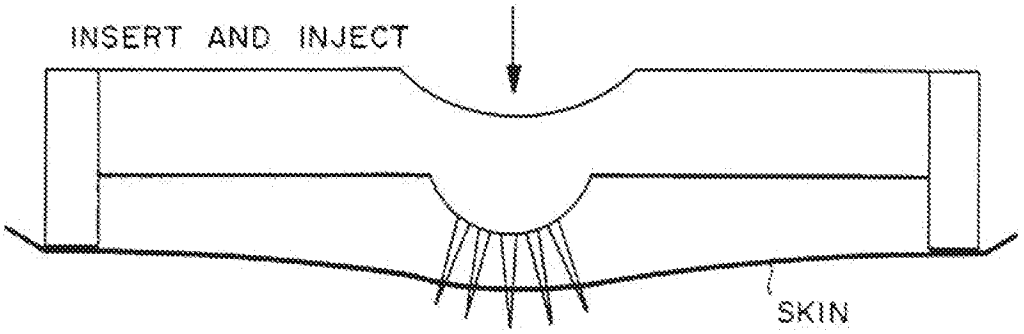


FIG. 18B



ENDYMED EXHIBIT 1002 - 273/733

FIG. 19

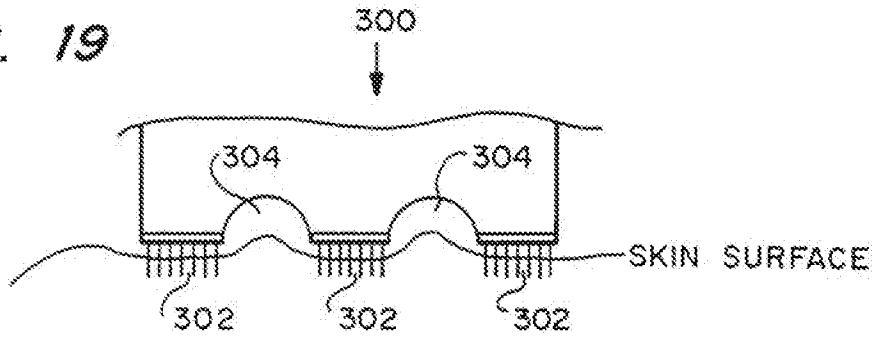


FIG. 20A

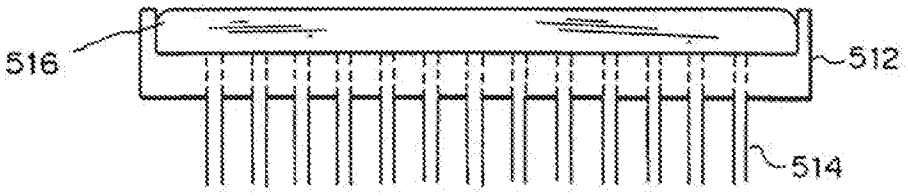


FIG. 20B

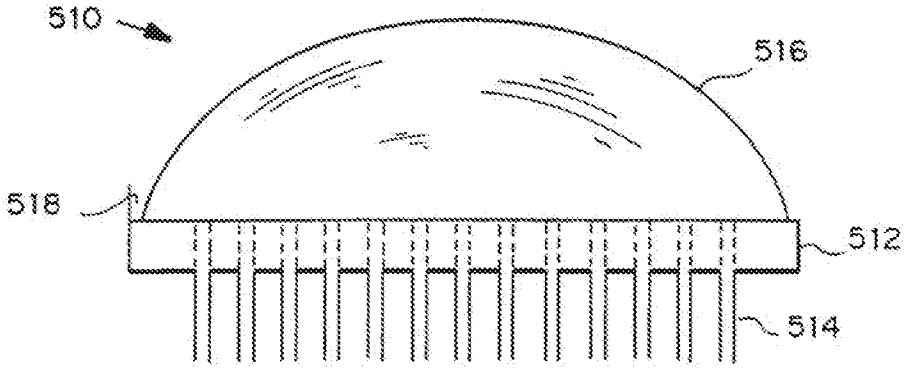
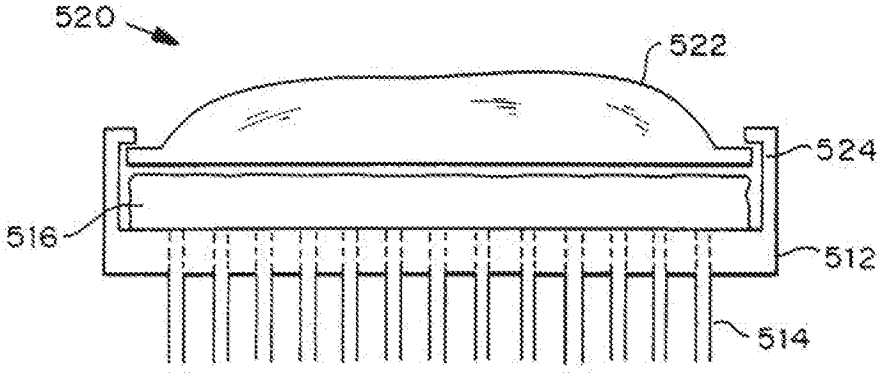


FIG. 20C



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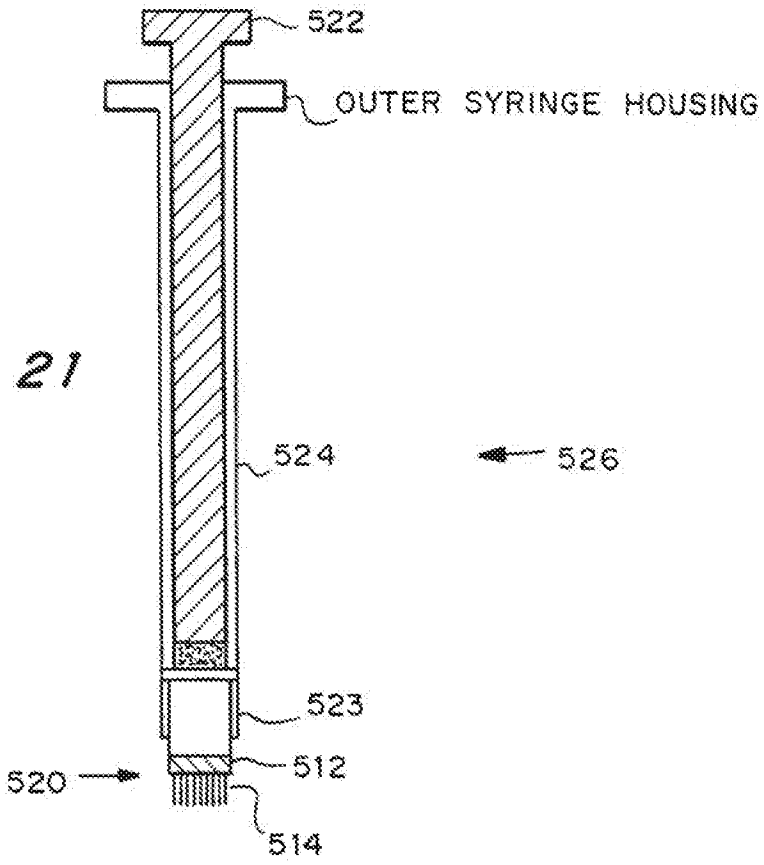

FIG. 21

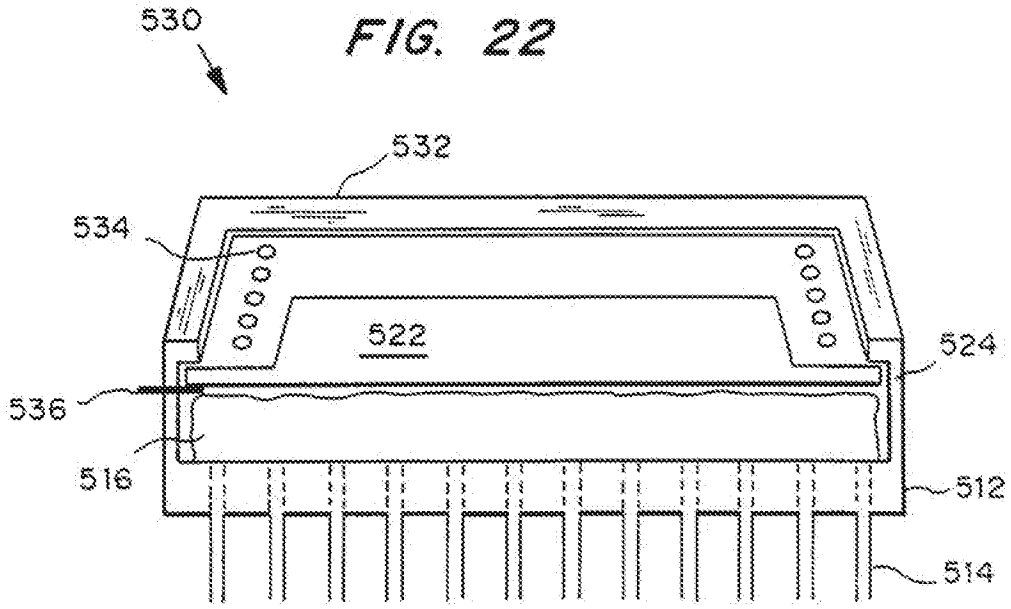

FIG. 22

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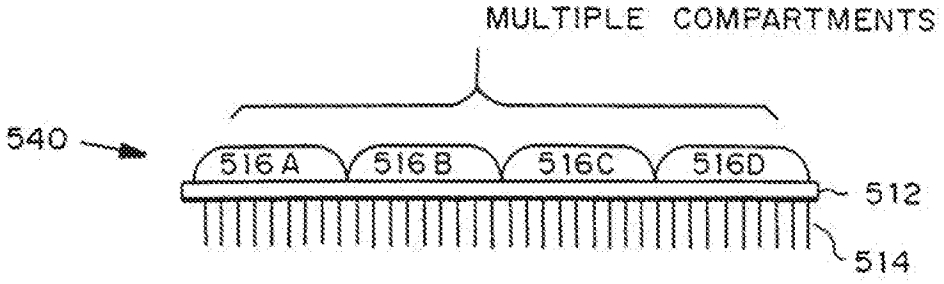

FIG. 23A

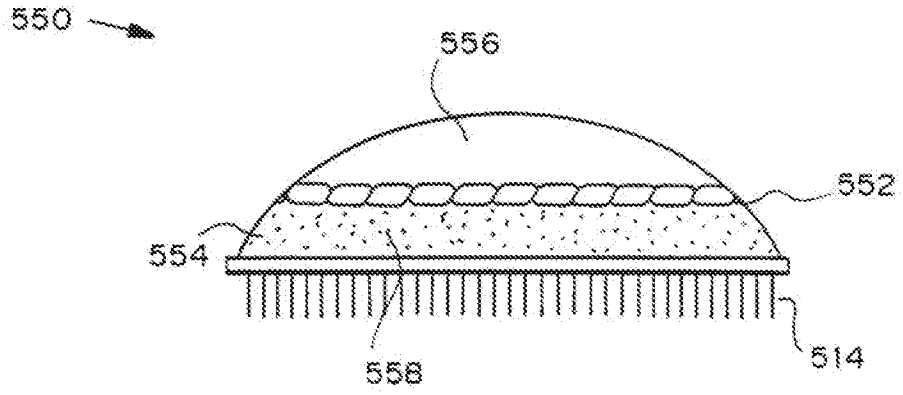

FIG. 23B

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FIG. 24

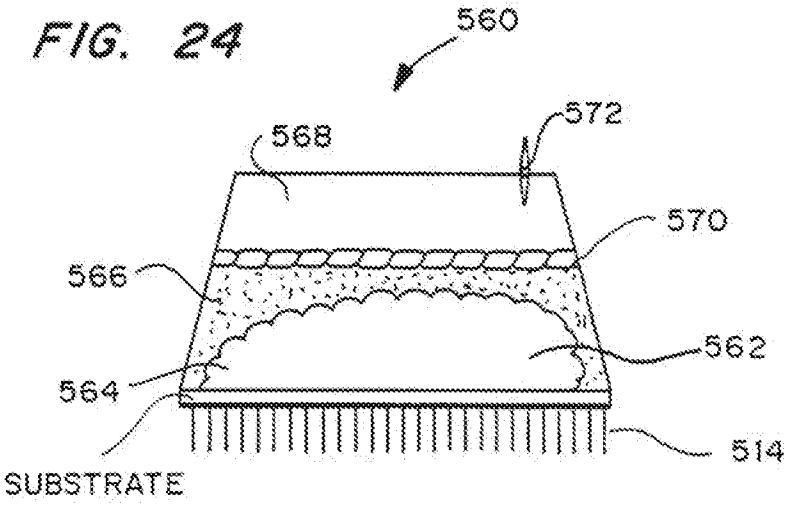


FIG. 25

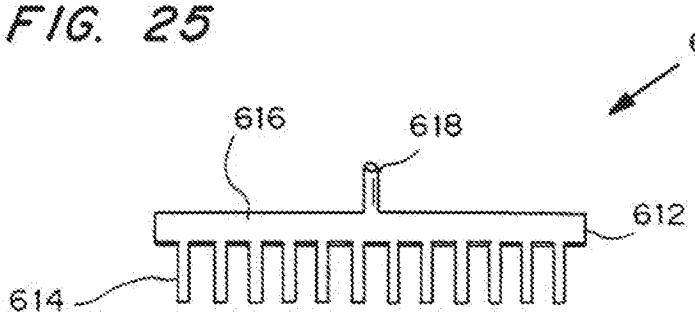
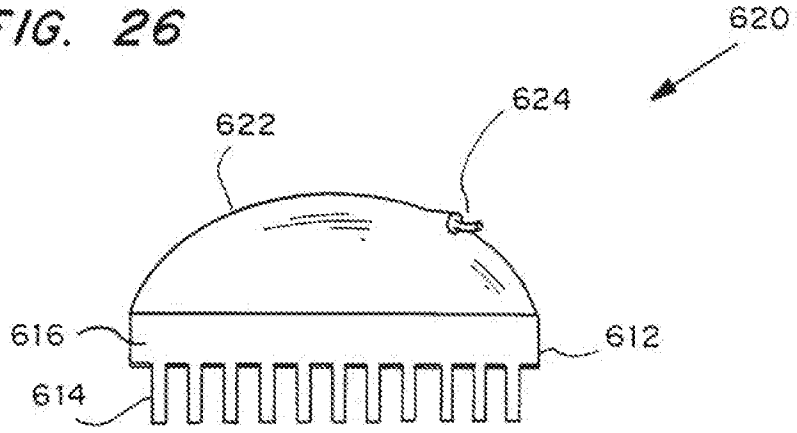


FIG. 26



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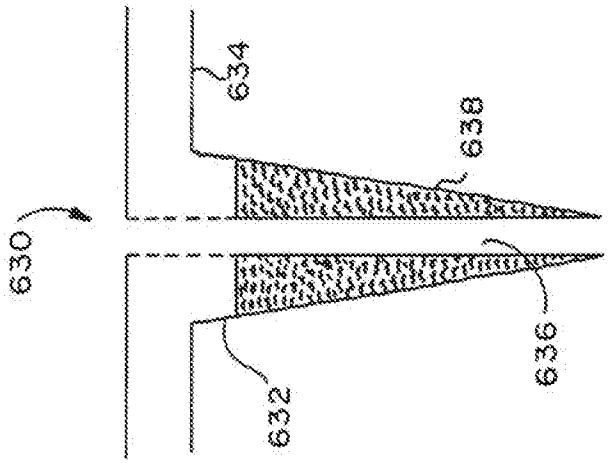

FIG. 27C

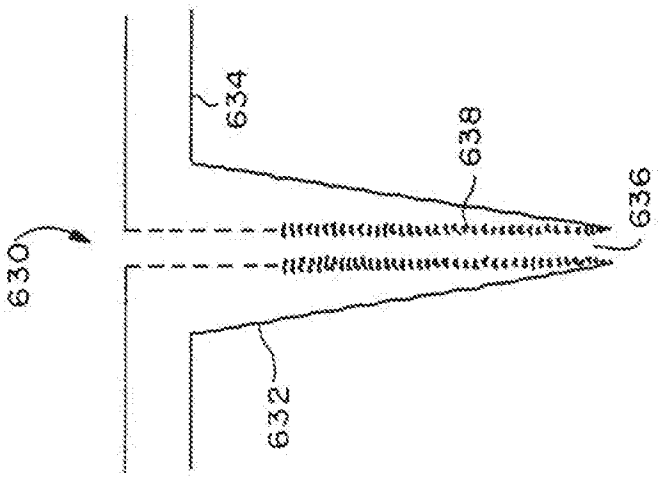

FIG. 27B

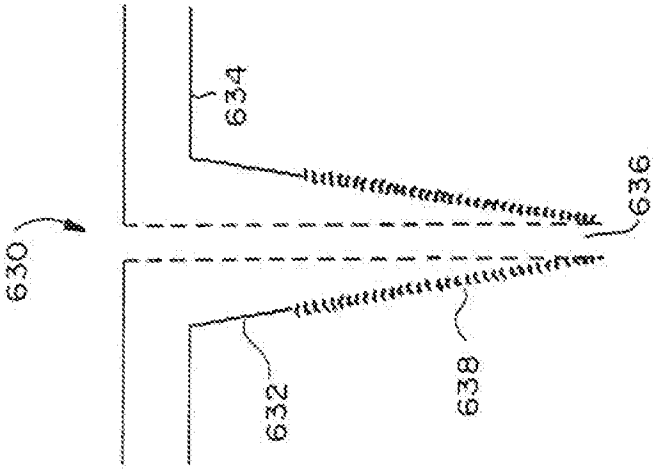

FIG. 27A

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(71) Applicant *(for all designated States except US)*: **INOMICROTEC LTD** [IL/IL]; 6 Izmargad St., 45045 Hod Hasharon (IL).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **GORDON, Michael** [IL/IL]; 6 Izmargad St., 45045 Hod Hasharon (IL). **GERDON, Shmuel** [IL/IL]; 7 Itamar Ben-avi St., Kefar Aharon, Nes- Ziona (IL).

(74) Agent: **BRESSLER, Eyal**, DR. Eyal BRESSLER, 8 Hamarpe st., POB 45220, 91450 Jerusalem (IL).

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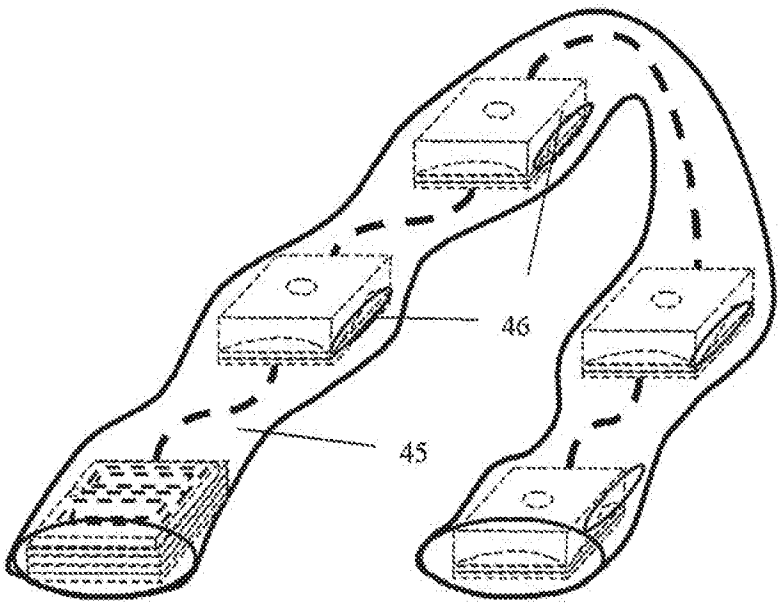

(57) Abstract: The presen invention discloses a novel photochemical emitter (PCE) useful for releasing products of photochemical reactions to its surroundings. This implantable PCE comprising at least one chemical or biological matrix; said matrix is capable of releasing at least one product of photochemical reaction; and at least one light emitting device in communication with a sufficient power source; said emitter is adapted to emit light at a specific wave length and intensity so said photochemical reaction is provided and said photochemical product is obtained. The present invention also discloses a method for releasing products of photochemical reactions into the surroundings of a PCE device, comprising the step of emitting light of a specific wave length and intensity over a biological or chemical matrix by means of at least one light emitting device, so said photochemical reaction is provided and a photochemical product is obtained.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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A METHOD AND DEVICE FOR CONTROLLED RELEASE OF CHEMICALS AND BIOLOGICAL SUBSTANCES BY PHOTOCHEMICAL REACTIONS

FIELD OF THE INVENTION

The present invention generally relates to a method for controlled release of chemical and biological substances by photochemical reactions and to a device for said release. According to one embodiment, the present invention relates to an implantable device adapted for *in vivo* administration of drugs and medications.

BACKGROUND OF THE INVENTION

Controlled release of chemical substances, such as in drug in situ administration systems, and the in vivo delivery of biological molecules is approaching accelerated research and development efforts. The administration of biologically active agents (e.g., a drug) to the body is usually characterized by a means adapted to answer one or both of the following requirements: to be delivered in response to a biofeedback mechanism; to be administrated to their target organs at relatively low volumes due to drugs' significant systematic toxicity when circulating in the blood. Hence, various implantable medical devices for in vivo drug delivery were disclosed in the art. One such technology is an implantable infusion pump, comprising a pressurized drug reservoir and means for fluid flow control. These systems are not capable of accurately controlling the dosage of drugs delivered to the patient.

Another approach is an apparatus containing two compartments separated by a moveable partition, such as the implantable device disclosed in U.S. Pat. No. 5,876,741 to Ron et al. These systems are designed in such a manner that volume expansion of a composition located in one compartment causes a biologically active compound located in the second compartment to be discharged into the biological environment through the passageway. A similar approach, as shown in U.S. Pat. No. 6,485,462 to Kriesel, presents an implantable fluid delivery device, containing a heat responsive polymer gel material that, upon being

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heated by a heating coil, functions as an internal energy source for expelling the medicinal fluids from the device.

Another drug delivery system is described in U.S. Patents. No. 5,797,898, 6,123,861 and 6,551,838 to Santini, Jr. et al. These devices comprise switches provided on a microchip to control the delivery of drugs or liquid chemicals from reservoirs having reservoir caps or barriers that actively or passively disintegrate. The permeability of such a barrier layer solely by molecules or energy is controlled by applying a stimulus such as an electric field or current, magnetic field, change in pH, or by thermal, photochemical, chemical, electrochemical, or mechanical means. This 'Slide Door' approach is suitable only for a few systems. Moreover, the quanta of released drugs or liquid chemicals is predetermined in the manufacturing process, and is definitively limited to the volume of the reservoir compartment. Extended external dimensions thus characterize this implant, whereat a compact low volume implant, containing a fast reacting, solid-based, high accuracy chemical release is a long felt need.

SUMMARY OF THE INVENTION

It is hence one object of the present invention to provide a cost- effective photochemical emitter (PCE) useful for releasing products of photochemical reactions to its surroundings. This PCE is essentially comprised of (a) at least one chemical or biological matrix; said matrix is capable of releasing at least one product of photochemical reaction; and (b), at least one light emitting device in communication with a sufficient power source; said emitter is adapted to emit light at a specific wave length and intensity, thus said photochemical reaction is provided and said photochemical product is obtained.

The aforementioned PCE may additionally comprise one or more modules selected from a programmable chemical selection, adapted to set activation signals to specific light emitters within the PCE; a programmable chemical release timer, adapted to load chemical release schedules; a chemical release message processor, adapted to decode the received spectral signal into a series of control and data bits, so a multi chemical and multi profile release pattern is obtained; at least one thin film rechargeable energy cell,

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providing an energy source; a radio frequency receiver; adapted to convert low-power high-frequency signals into base-band signals; a thin-film antenna (e.g., a thin-film printed antenna); adapted to receive a weak electro-magnetic waves, and translate them into electric radio frequency signals or any combination thereof.

The PCE defined above may comprise a stack of accessories and auxiliaries selected from the group of a programmable chemical selection; programmable chemical release timer; a chemical release message processor; a thin film rechargeable energy cell; a radio frequency receiver; a thin-film antenna or any combination thereof. It is in the scope of the present invention wherein the light emitting devices emits ultraviolet light; visible light; infrared radiation or any combination thereof.

It is further in the scope of the present invention wherein the aforementioned PCE comprises at least one sensor. This sensor may be adapted to determine one or more environmental inputs selected from physical, chemical and/or biological parameters in such a manner that correlating outputs or reactions are provided. Alternatively; said sensor may be adapted to determine one or more physiological inputs selected from physical, chemical and/or biological parameters in such a manner that correlating outputs or reactions are provided. The inputs are potentially determined adjacent to the PCE, in any remote location or in combination thereof. The PCE hereto-defined may hence be adapted to a feedback operational mode; wherein the releasing parameters of the photochemical reaction products are in correlation with the obtained inputs. The releasing parameters may be selected from any of the group of release rate or flux; release onset or offset; type, number, location or identity of the light emitting device or devices; light wavelength and/or light intensity. At least one detector may be in communication with an additional one or more implanted PCEs. The sensor may thus be in inline, offline and/or mediated communication with the PCE. Alternatively or additionally, the said PCE may additionally comprise an interface adapted for a remote operation; wherein the said PCE's operation is regulated by at least one remote user, processor, sensor or any combination thereof.

It is another object of the present invention to present an implantable PCE. Hence, it is in the scope of the present invention wherein the photochemical product is adapted for *in*

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vivo administration of drugs and medications. Moreover, the photochemical product may be adapted for *in vivo* administration of drugs and medications and said administration may be provided as a feedback to predetermined physiological parameters.

It is yet another object of the present invention to present a useful method for releasing products of photochemical reactions into the surroundings of a PCE device. This method comprises emitting light of a specific wave length and intensity over a biological or chemical matrix by means of at least one light emitting device, so said photochemical reaction is provided and a photochemical product is obtained. This method may be also adapted for *in vivo* administration of photochemical products by means of an implantable PCE. Alternatively, the method may be adapted for administration of photochemical products by feedback by means of an implantable PCE , additionally comprising the steps of (a) obtaining a plurality of physiological inputs selected from physical, chemical and/or biological parameters by means of at least one sensor; (b) providing for a plurality of correlated output signals; and (c) emitting light of a specific wave length and intensity over a biological or chemical matrix so the administration of photochemical product is obtained; in such a manner that that said administration is provided in correlation to said predetermined physiological parameters.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be implemented in practice, a plurality of embodiments will now be described, by way of non-limiting example only, with reference to the accompanying drawing, in which

figure 1 schematically illustrates the lateral and top view of the photochemical emitter (PCE) according to one embodiment of the present invention comprising inter alia solid chemical block and a UV light source matrix;

figure 2 schematically illustrates the chemical substrate, as viewed by the UV source matrix;

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figure 3 schematically illustrates the Programmable Chemical Selection (PCS) which is programmed to set activation signals to specific UV cells within the PCE, depending on the chemical code numbers in its input;

figure 4 schematically illustrates the Programmable Chemical Release Timer (PCRT), which enables loading of complex chemical release schedules;

figure 5 schematically illustrates the Chemical Release Message Processor (CRMP) responsible for decoding the received spectral signal into a series of control and data bits, enabling multi chemical and multi profile release pattern;

figure 6 schematically illustrates the Thin Film Rechargeable Energy Cell (TFREC); which is an optional energy source;

figure 7 schematically illustrates the Radio Frequency Receiver/Transmitter of the RFRP, responsible for converting low-power high-frequency signals into base-band signals entering the Processor and converting- up base-band signals to transmittable RF signals;

figure 8 schematically illustrates a thin-film Antenna, used to receive weak electro-magnetic waves, translate them into electric radio frequency signals and transmit the same;

figure 9 schematically illustrates the principle of a thin-film printed antenna pattern;

figure 10 schematically illustrates the integration of the antenna, receiver, processor and thin-film energy cell functions;

figure 11 schematically illustrates one possible approach to integrating the chemical layer, the light source layer and the programmable chemical select layer; these subunits are adapted to be in a cascade;

figure 12 schematically illustrates the cascaded configuration of the PCE based units of figure 11, and the leading receiver cell, connected using a possible flexible printed conductor; and,

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figure 13 schematically illustrates a flexible tube, housing and protecting the cascade and the surrounding tissue from negative interaction.

DETAILED DESCRIPTION OF THE INVENTION

The following description is provided, alongside all chapters of the present invention, so as to enable any person skilled in the art to make use of said invention and sets forth the best modes contemplated by the inventor of carrying out this invention. Various modifications, however, will remain apparent to those skilled in the art, since the generic principles of the present invention have been defined specifically to provide a method for controlled release of chemical and biological substances by photochemical reactions and a device adapted for said purpose.

The term 'photochemical emitter', denoted hereto as PCE, generally refers' according to the present invention' to any device, which is adapted to release products of photochemical reactions to its surroundings. This PCE is schematically comprised of at least one chemical or biological matrix and at least one light-emitting device. The said matrix is capable of releasing at least one product of photochemical reaction. The said light-emitting device is in communication with a sufficient power source; and is further adapted to emit light at a specific wave length and intensity so said photochemical reaction is provided and said photochemical product is obtained. The term 'PCE' also refers according to the present invention to any device as defined above, further adapted for either integrated or non-integrated mode of operation. Said PCE may thus be a stand-alone product or an ingredient of a communicated assembly or mechanism. This device may be further adapted to indoor or outdoor operation; to be implanted in other system or systems, to be implanted in living bodies, such as the human body or to be adapted to any topical or cosmetic uses. Said device may be operated by any known means, e.g., remote control, feedback, continuous action, discontinuous action, delayed operational mode etc.

Reference is made now to figure 1, illustrating one embodiment of the present invention wherein the photochemical emitter (PCE, 100) is schematically described. The PCE is adapted to emit a UV light of a specific spectra range over a predetermined chemical or

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biological substrate, or over a plurality of those substrates. It is well in the scope of the present invention wherein said emitter is in communication with a plurality of optional accessories, such as a wireless remote control auxiliary, a self thin-film energy source etc.

According to yet another embodiment of the present invention, said PCE comprises a miniature light emitting assembly (6). This assembly is preferably comprised of an array of light emitting diodes (LEDs) and may be selected from blue light-emitting gallium nitride (GaN) LED; a UV-emitting LED; a UV-emitting LED additionally comprising a converter material or device for converting said UV light into a visible spectral range; a visible LED-phosphor, LEDs providing a relatively high-energy photon from a blue LED in such a manner that phosphorescence is obtained in a number of materials; or any combination thereof.

Reference is still made to figure 1, presenting a top view of a micro LED array, where the miniature light emitting assembly (6) is a sapphire with *n* X *p*-doped GaN layers. Photolithographic and microelectronic metal deposition methods are used to pattern metal conductors (7) and metal bonding pads (9). All *n*-pads of the LEDs are arranged on the top and bottom edge of the diode matrix and designated diode column numbers (8), and all *p*-pads of the diodes could be arranged on the left and right edges of the matrix designated row numbers. This column/row addressing technique enables the illumination of one or multiple LEDs simultaneously.

Still referring to figure 1, a cross section of one embodiment of a PCE (100) is presented in a perspective view. This PCE is comprised of a base portion with the miniature light emitting assembly (6) as defined above, and an upper portion (1). Said base portion is comprised of a base member (6A) and the array of LEDs (6B), potentially covered by means of a transparent glass top (4). On top of said LEDs (6B) and/or the glass top (4), a chemical or biological matrix (1) is located. Said sandwich-like packaging (100) is affixed firmly by reversible or irreversible means, comprising one or more mechanical fastening members, e.g., screws, zips, lockable reinforcement devices etc, securing the package through the continuous bore (10A) and (10B). Alternatively or additionally, it is acknowledged in this respect that the packaging my be secured by chemical means, such as glues etc. Moreover, a plurality of fastening auxiliaries such as attachments (5) is

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possibly used. It is in the scope of the present invention wherein said auxiliaries are selected in a non limiting manner from magnets, magnetic films or ferromagnetic thin films located at the rim of the device. Alternatively, for some applications, flexible tubing, firmly gripping chemical substrate and LED matrix may be used.

According to yet another embodiment of the present invention, controlling and/or processing means are further attached to the aforementioned PCE (100). Hence for example, a Ball Grid Array (BGA), which is preferably located adjacent to base (6A), enables soldering to standard electronic Printed Circuit Boards (PCBs). As was set forth above, it is also in the scope of the present invention wherein the aforementioned PCE additionally comprises means for remote control, timing abilities, variable energy sources, encoding facilities etc. These means are described in the art and most of them are commercially available, so they fit to the hereto-defined PCE with no intensive alterations.

It is acknowledged in this respect that the aforementioned chemical or biological matrix (10) may be selected from any matrix which is comprised of at least one biological, non-biological, organic, inorganic composition, or a combination of any of these compositions or mixtures. Said matrix is either in a continuous, discontinuous form or any combination thereof, and is either homogenous or heterogeneous. It may further be possessed of either isotropic or anisotropy characteristics. This matrix may be comprised of monomers, polymers or any combination thereof. According to one preferred embodiment of the present invention, the said matrix is sensitive to a light emitted by any internal or external source at a predetermined range and intensity in such a manner that said light causes the matrix to release, activate or to trigger at least one biological or chemical species, which is further transferred actively or diffused passively to a remote target location. Said release, activation or triggering of the said species is provided in a simultaneous on-line manner and/or in a delayed off-line manner; *in vivo*, *ex vivo*, *in vitro*, *in situ* or *ex situ* or any combination thereof. For example, an S-S enriched matrix is useful for releasing sulfur containing active agents in response to a sufficient light emission. Another example is an N-N enriched matrix.

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It is further in the scope of the present invention wherein the released agent was previously immobilized, encapsulated or entrapped into the said matrix. Additionally or alternatively, the released agent was adsorbed or affixed onto the surface of the matrix.

It is also well in the scope of the present invention wherein a plurality of chemical agents or biological agents are immobilized by methods known in the art into and/or onto a supporting matrix, wherein a light is emitted in a predetermined manner and hence selectively controls the release of a specific agent. It also controls the specific location on the matrix wherein the agent begins to be released and further regulates the kinetics of its release.

An example is provided in a non limiting manner, wherein agents of two different species are absorbed: one is anchored by means of forming N-N bonds with the supporting matrix and the other is immobilized by means of forming S-S bonds with said matrix. By emitting a light beam effective for breaking those N-N bonds, said first agent is subsequently desorbed from the bulk of the matrix, and slowly released to the surroundings. Additionally or alternatively, by emitting a different light beam effective for breaking S-S bonds, said second agent is rapidly desorbed from the said matrix surface in such a manner that a large initial concentration is provided. A hormone or hormone-like regulating agent is suitable for such an immobilization by said N-N bonds; wherein a biocide (e.g., bactericide, antibiotics, fungicide) is especially useful for being immobilized by said S-S adsorbing bonds.

The aforementioned matrix may be selected from a bulk material; a conglomerate, a mosaic or a multi-laminar structure of various ingredients; and/or a film, preferably a thin film; e.g., a film characterized by an average thickness of micrometers or less. Many thin films are possible, such as wafer sheet-like structures.

It is acknowledged in this respect that the aforementioned PCE (100) is comprised of a plurality of *N* thin mosaics, wherein *N* is an integer number equal to one or more; each of which is characterized by a continuous array of different matrices. Most preferably, a correlation is made between the locations of the light emitting devices (e.g., LEDs) and the location of said thin matrices, in such a manner that the light is effectively illuminated

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on a significant portion of the matrix, and/or in such a manner that the matrix is illuminated by the proper light emitting device; at the proper light wavelength -.

It is further acknowledged in this respect that the aforementioned PCE (100) is characterized by a laminar structure, wherein a base portion comprises two or more faces. Each face comprises its own light emitting devices, adapted to emit light towards an adjacent matrix. Referring to the above-mentioned example, a coin-like PCE is provided, one face comprising an S-S bonded matrix and the other face comprising an N-N bonded matrix in such a manner that the first light-emitting device is powered to release the biocide, and *vice versa*, the second light-emitting device is used to release the hormone-like regulating agent,.

Reference is made now to Fig. 2., presenting a perspective view of the aforementioned wafer-like matrix (2). Said wafer is possibly made utilizing a multiple set of lithography masks with a step-and-repeat square pattern. -. The optional alignment bore (3), located at the center of each chip, is either laser drilled or photo cleaved.

It is also in the scope of the present invention wherein these thin films are provided on a silicon wafer or other suitable substrate. These films can then be patterned using photolithographic techniques and suitable etching techniques. Suitable materials include silicon dioxide, silicon nitride, polycrystalline silicon etc.

According to another embodiment of the present invention, a novel Programmable Chemical Selection (i.e., PCS) option is hereto provided. It enables the user to program and re-program predetermined characterizations and thus to enable a specific release rate and substance combination; to combine such release with a given operating code number etc. Reference is made now to figure 3, presenting a PCS which is programmed to set activation signals to specific UV cells within the PCE, depending on the chemical code numbers in its input. The chemical substrate surface may exhibit a multiple of chemical sites. Each site could then be sub-divided into smaller sites according to the minimum dose requiring release. Each site is then designated by a code number. Activating said code number is adapted to set all rows and column LEDs in that site, to the "on" state. This code is programmed into a programmable device; one of which may be a standard

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Electronically Programmable Logic Device (i.e., EPLD), referenced by ALTERA Classic EPLDs.

The signals setting rows and columns to "on" are captured in a row/column standard logic latch device. This enables the decoding serial processing of multiple chemical sights activation. The actual activation and release will be triggered at the precise timing required.

The triggered row/column signal feeds into current driving transistors, able to supply the LED matrix with the variable current required. This logic/current handshake enables significant power saving in the digital circuitry, through the use of micro-power logic.

Bond pads are designed at the periphery of the PCS, enabling external sidewall connections to further options of the PCE, or connections to a BGA, should no further options be required.

Reference is made now to figure 4, schematically illustrating the Programmable Chemical Release Timer (PCRT, 18), which enables loading of complex chemical release schedules. The PCRT enables the user to program the PCE to release chemicals at predetermined intervals ranging from seconds to years. A non-limiting example of such a timer is based on a digital oscillator utilizing a resistor – capacitor (i.e., RC) time constant, such as the referenced LM555 data sheet. Several counters may then be dedicated to counting seconds, minutes, hours, days and weeks. Several more counters, may be programmed, according to user settings, for as many chemical release cycles required. Typical counter circuitry is described in reference "Binary Counter with Asynchronous Clear".

Reference is made now to figure 5, schematically illustrating the Chemical Release Message Processor (CRMP, 16) responsible for decoding the received spectral signal into a series of control and data bits, enabling a multi chemical and multi profile release pattern. The processor enables the user to use a composition of complex chemical release profiles, for multi chemical substrate. The processor is adapted to receive a series of information bits including the unique Implant ID number, the number of dose cycles, the

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chemicals released in each dose, the duration release of each chemical and the amount released.

Prior to storing the programmed dose cycles, the processor is adapted to transmit the instructions to the RF Transceiver, for confirmation. The processor may perform additional functions such as control and report, according to specific application requirements.

Reference is made now to figure 6, schematically illustrating the Thin Film Rechargeable Energy Cell (i.e., TFREC, 60); which is an optional energy source. The default energy source is adapted to be an implanted lithium energy cell with connecting leads to the PCE and built-in short-circuit protection.

A variation to this may be a rechargeable lithium battery, integrated with a charging unit. The charger unit receives energy from a coil transmitter external to the body. The energy cell may be implanted under the skin, similarly to a pacemaker. However, the TFREC is an option that depends heavily on work done on an invention of an implanted charger unit, not available to date. The TFREC technology is described in the art and may be used with no significant alternations. The cathode film (21), the electrolyte film (22) and the anode (23) are all schematically illustrated in figure 6.

Reference is made now to figure 7, schematically illustrating the Radio Frequency Transceiver (70) of the RFRP, responsible for bi-directional conversion of low-power high-frequency signals into base-band signals entering the Processor. The transceiver's main function is to enable reliable wireless transmission of the chemical release cycles from an external controller into the PCE implanted near the therapy-requiring organ of the human body. The aforementioned transceiver would suffice for most utilizations. Nevertheless, it is acknowledged in this respect that due to increasing RF signals surrounding us, unintentional trigger of the activation of the PCE may occur. To minimize this hazard, the transceiver may be adapted to request confirmation and/or verification for each chemical or biological release programming session.

Both receive and transmit functions adapted for implant devices have been realized at various frequency bands, modulation schemes and signal bandwidth. One of the primary

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concerns is the power consumption of the transceiver. It is acknowledged in this respect that for a frequent and high dosage chemical release, the transceiver may consume a high percentage of the total PCE's power requirements. Higher power consumption impacts the battery size, location and lifetime span between replacements. The least power-consuming transceiver configuration, would be the Amplitude Shift Keying (i.e., ASK) whereby transmitted RF energy would represent a logic "1" and no RF would be a logic "0". Assuming an equal statistical distribution of ones and zeros, half the time the transmitter is off, saving power. The transceiver circuitry is very simple, and therefore compact and low cost.

It is also acknowledged in this respect that RF wireless devices may operate in high cost protected licensed RF bands or non-licensed "free-to-all" RF bands. The non-licensed bands are increasingly dense in RF applications, and therefore increasingly vulnerable to mutual interference. The interference is mostly interpreted as high-level noise. In order to extract signals equal to or lower than the received noise, the information data bits are multiplied by a known coding sequence, thereby increasing signal bandwidth and hence denoted in the term spread-spectrum. The received signal is multiplied by the same code, thereby creating a processing gain only for the known code signals and not for the general noise signals. This gain differentiates the information signal from the noise.

Many RF transceiver chips are commercially available for the ASK or the coded spread spectrum architectures and their variations, Phase Shift Keying (i.e., PSK) and Frequency Shift Keying (i.e., FSK). Selecting the most suitable available will be done individually for each application of the PCE.

Reference is made now to figure 8, schematically illustrating a thin-film Antenna, used to receive weak electro-magnetic waves, and translate them into electric radio frequency signals. The antenna (31) is usually a printed conductor proportional in length to the wireless frequency band chosen for the PCE application. The printed antenna is on the outward facing surface of the chip, enabling electro-magnetic signal reception on the actual conductor side.

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Reference is made now to figure 9, schematically illustrating the principle of a thin-film printed antenna pattern. Printing the antenna (31) on a substrate is one useful option. In applications utilizing low frequency bands, it may be more practical to attach a coated antenna wire to the PCE and fold the antenna wire alongside the implanted components.

Reference is made now to figure 10, schematically illustrating one embodiment adapted to integrate antenna, receiver, processor and thin-film energy cell functions in one device (1000). This configuration is successfully adapted to minimize the components adjacent to the attended organ. The device according to this embodiment is hence comprised of an antenna (35), an RFTR (26), a TFREC (20), a PCRT (18) and a CRMP (16).

Reference is made now to figure 11, schematically illustrating another embodiment of the present invention, wherein chemical or biological thin layer, light source layer and programmable chemical select layer are integrated in one possible cascade. The transceiver and energy source are potentially separated from the PCE, the chemical release package is adapted to include a suitable chemical substrate (1), UV diode matrix (6) etc.

Reference is made now to figure 12, schematically illustrating the cascaded configuration of the PCE cells and the leading receiver cell, connected via flexible printed conductors. Here for example, the chemical release is provided in a relatively narrow, long and curved enclosure, comprising a multiple of PCE's (1), which are interconnected in a cascade formation with a standard flexible multi conductor substrate (40), forming a tree structure. PCEs are interconnected to a single transceiver, processor and energy unit (35).

It is also in the scope of the present invention wherein the PCE or the PCE cascade or any of the photochemical emitter defined or described above is comprised of at least one detector. The term 'detector' refers in the present invention to any sensor, or other detecting means adapted to analyze, screen, acquiring images, physiological or environmental parameters, including physical (e.g., temperature, RGB values, radiation etc), chemical, biological or medical quantitive or qualitive inputs. The aforementioned detector may be also in communication with one or more additional implanted PCEs

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and/or with external devices, adapted to process said inputs to correlated outputs, and then to deliver said outputs towards one or more PCEs.

It is also in the scope of the present invention wherein said PCE is adapted to provide for a feedback operational mode; wherein the releasing parameters of the photochemical reaction products or any other measurable parameter, are in correlation with the obtained physiological or environmental inputs. It is acknowledged in this respect that at least a portion of said releasing parameters or feasibly measurable parameters, are selected in a non limiting manner from any of the reactions to the released substance or the group of the rate of said release or its flux; release onset or offset; the type, number, location or identity of the light emitting device or devices; light wavelength and/or light intensity. It is further acknowledged that the aforementioned detector may also be in communication with one or more additional implanted PCEs, so a communication network is provided comprising one or more detectors and one or more PCEs. This communication is provided by means known in the art inline, offline and/or in a mediated manner, e.g., by a supporting means of a transmitter, operator, processor etc., wherein said means are integrated or non-integrated with one or more of said PCEs or detectors.

As set forth above, the present invention relates to a method for releasing products of photochemical reactions into the surroundings of a PCE device. This method comprises emitting light of a specific wave length and intensity over a biological or chemical matrix by means of at least one light emitting device, so said photochemical reaction is provided and a photochemical product is obtained. Additionally or alternatively, the said method is especially useful for administrating photochemical products by feedback means of an implantable PCE I. This method additionally comprises the three steps of (a) obtaining a plurality of either environmental or physiological inputs selected from physical, chemical and/or biological parameters by means of at least one sensor; (b) providing for a plurality of correlated output signals; and then (c) emitting light of a specific wave length and intensity over a biological or chemical matrix so the administration of photochemical product is obtained; in such a manner that that said administration is provided in correlation to said predetermined physiological or environmental parameters.

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Reference is made now to figure 13, schematically illustrating a flexible tube, housing and protecting the cascade and the surrounding tissue from negative interactions. Hence, according to another embodiment of the present invention, the PCE aforementioned tree configuration is housed in a highly flexible, specifically punctured tube or hose (45), designed to assist in applying force on both ends of each PCE, thereby forcing the released chemical molecules, out through a plurality of holes (see 46 for example). The elasticity constant and the size of the tube relative to the PCE, determine the force at which the chemical molecules are propelled out.

It is lastly in the scope of the present invention wherein said flexible housing is biocompatible, flexible and adapted to be impermeable, isolated and/or sealed to any liquids of the body. It is acknowledged in this respect that said flexible housing is adapted to provide enhanced diffusion of the photochemical product. Hence for example, it is comprised of passive transferring means, such as holes, prosive portions, lipophilic or hydrophilic portions, selective membranes etc; and/or active transferring means, such as pumps, impellers, busters etc.

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CLAIMS

1. A photochemical emitter (PCE) useful for releasing products of photochemical reactions to its surroundings, comprising;
   a. at least one chemical or biological matrix; said matrix is capable of releasing at least one product of photochemical reaction; and,
   b. at least one light emitting device in communication with a sufficient power source; said emitter is adapted to emit light at a specific wave length and intensity so said photochemical reaction is provided and said photochemical product is obtained.

2. The PCE according to claim 1, additionally comprising a programmable chemical selection, adapted to set activation signals to specific light emitters within the PCE.

3. The PCE according to claim 1, additionally comprising a programmable chemical release timer, adapted to load chemical release schedules.

4. The PCE according to claim 1, additionally comprising a chemical release message processor, adapted for decoding the received spectral signal into a series of control and data bits, so a multi chemical and multi profile release pattern is obtained.

5. The PCE according to claim 1, additionally comprising at least one thin film rechargeable energy cell, providing an energy source.

6. The PCE according to claim 1, additionally comprising a radio frequency receiver; adapted for converting low-power high-frequency signals into base-band signals.

7. The PCE according to claim 1, additionally comprising a thin-film antenna; adapted for receiving weak electro-magnetic waves, and translating them into electric radio frequency signals.

8. The PCE according to claim 7, wherein the antenna is a thin-film printed antenna.

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9. The PCE according to claim 1, comprising a stack of accessories and auxiliaries selected from the group of a programmable chemical selection; programmable chemical release timer; a chemical release message processor; a thin film rechargeable energy cell; a radio frequency receiver; a thin-film antenna or any combination thereof.

10. The PCE according to claim 1, wherein the light emitting devices emits ultraviolet light.

11. The PCE according to claim 1, wherein the light emitting devices emits visible light.

12. The PCE according to claim 1, wherein the light emitting devices emits infrared radiation.

13. The PCE as defined in claim 1 or in any of its dependent claims, additionally comprising at least one sensor.

14. The PCE according to claim 13, wherein the sensor is adapted to determine one or more environmental inputs selected from physical, chemical and/or biological parameters in such a manner that correlating outputs or reactions are provided.

15. The PCE according to claim 13, wherein the sensor is adapted to determine one or more physiological inputs selected from physical, chemical and/or biological parameters in such a manner that correlating outputs or reactions are provided.

16. The PCE according to any of claims 14 or 15, wherein the inputs are determined adjacent to the PCE, in any remote location or in combination thereof.

17. The PCE according to any of claims 14 or 15, adapted to a feedback operational mode; wherein the releasing parameters of the photochemical reaction products are in correlation with the obtained inputs.

18. The PCE according to claim 17, wherein the releasing parameters are selected from any of the group of release rate or flux; release onset or offset; type, number,

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location or identity of the light emitting device or devices; light wavelength and/or light intensity.

19. The PCE according to claim 17, wherein the at least one detector is in communication with one or more additional implanted PCEs.

20. The PCE according to claim 13; wherein the sensor is in inline, offline and/or mediated communication with the PCE.

21. The PCE as defined in claim 1 or in any of its dependent claims, additionally comprising an interface adapted for remote operation; wherein the said PCE's operation is regulated by at least one remote user, processor, sensor or any combination thereof.

22. An implantable PCE as defined in claim 1 or in any of its dependent claims.

23. The implantable PCE according to claim 22, wherein the photochemical product is adapted for *in vivo* administration of drugs and medications.

24. The implantable PCE according to claim 22, wherein the photochemical product is adapted for *in vivo* administration of drugs and medications and further wherein said administration is provided as a feedback to predetermined physiological parameters.

25. A method for releasing products of photochemical reactions into the surroundings of a PCE device, comprising the step of emitting light of a specific wave length and intensity over a biological or chemical matrix by means of at least one light emitting device, so said photochemical reaction is provided and a photochemical product is obtained.

26. The method according to claim 25, adapted for *in vivo* administration of photochemical products by means of an implantable PCE.

27. The method according to claim 25, adapted for administration of photochemical products by feedback means of an implantable PCE, additionally comprising the steps of;

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a. obtaining a plurality of physiological inputs selected from physical, chemical and/or biological parameters by means of at least one sensor;
b. providing for a plurality of correlated output signals;
c. emitting light of a specific wave length and intensity over a biological or chemical matrix so the administration of photochemical product is obtained; in such a manner that that said administration is provided in correlation to said predetermined physiological parameters.

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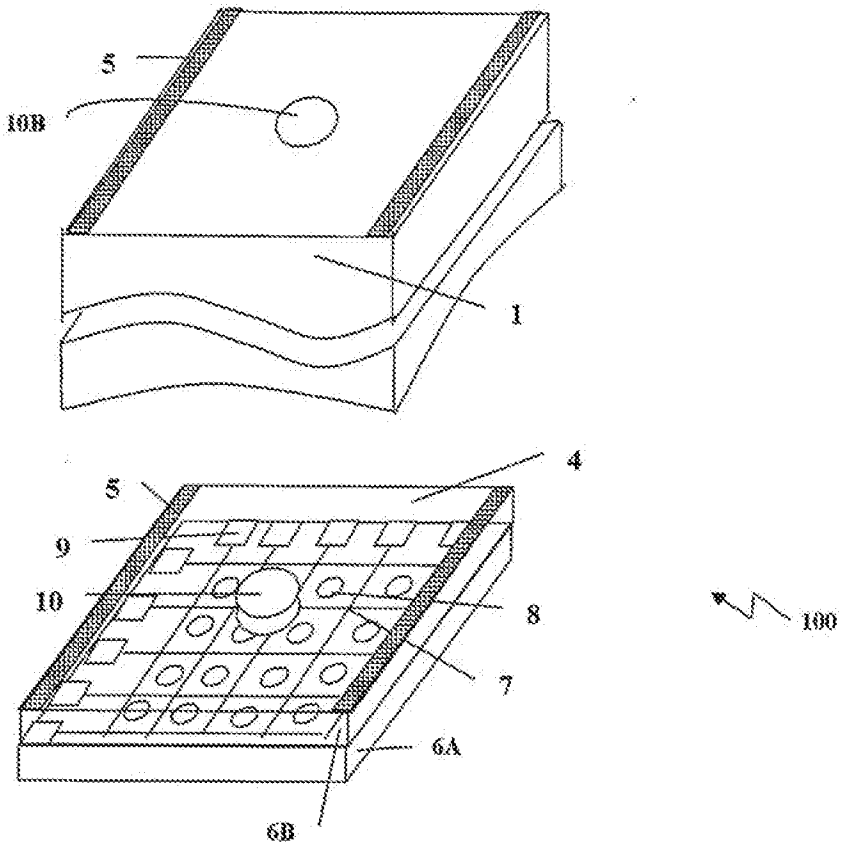

FIGURE 1

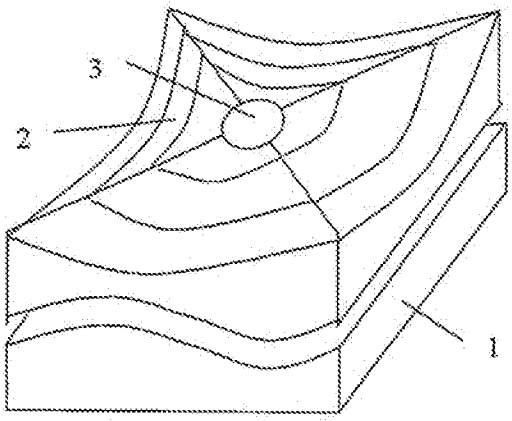

FIGURE 2

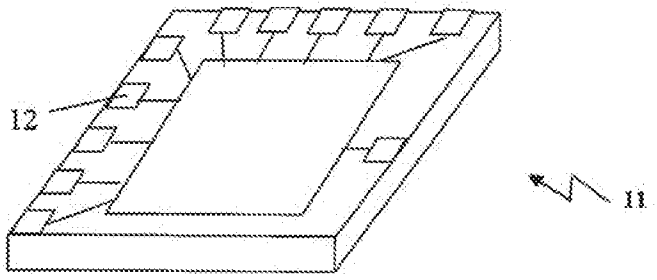

FIGURE 3

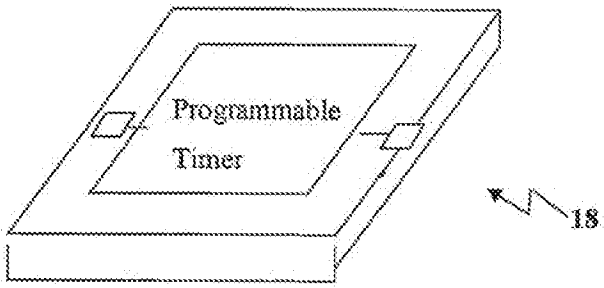

FIGURE 4

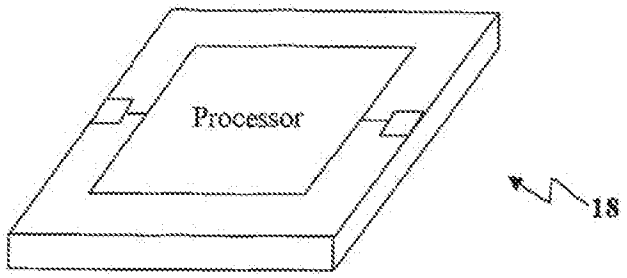

FIGURE 5

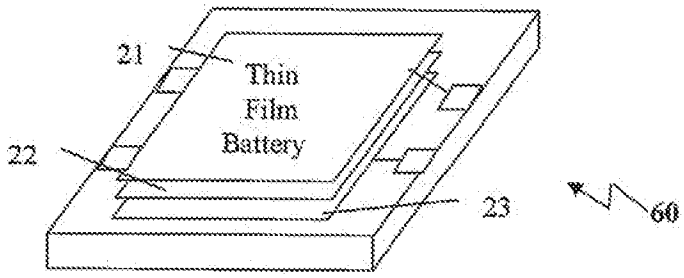

FIGURE 6

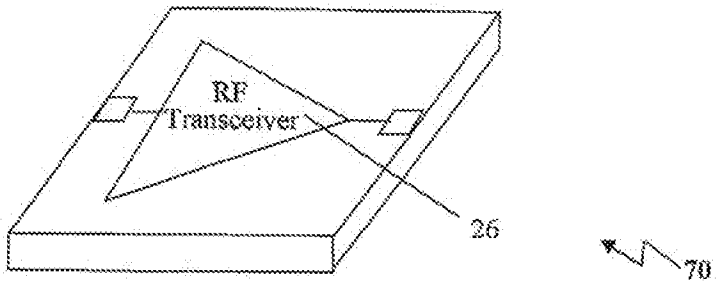

FIGURE 7

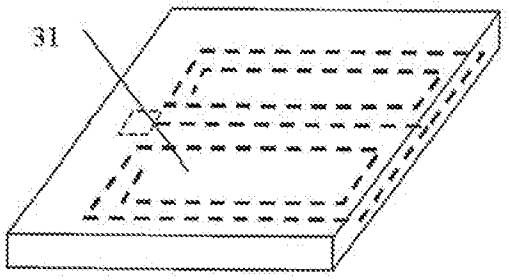

FIGURE 8

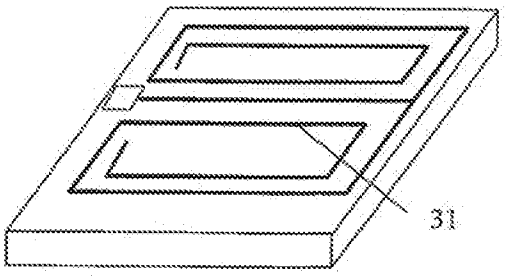

FIGURE 9

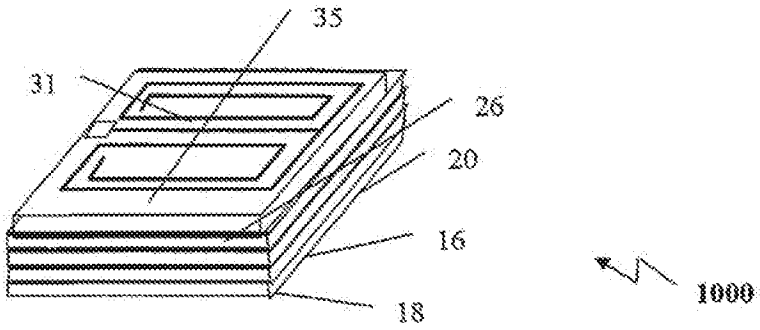

FIGURE 10

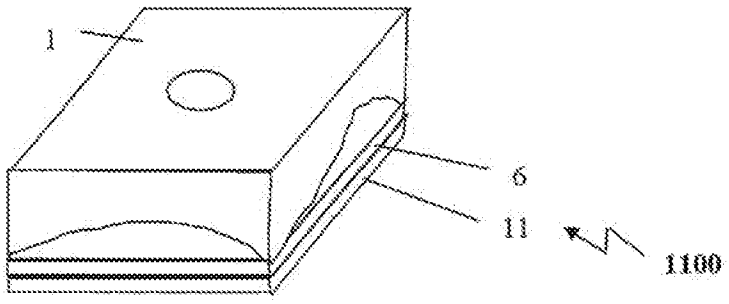

FIGURE 11

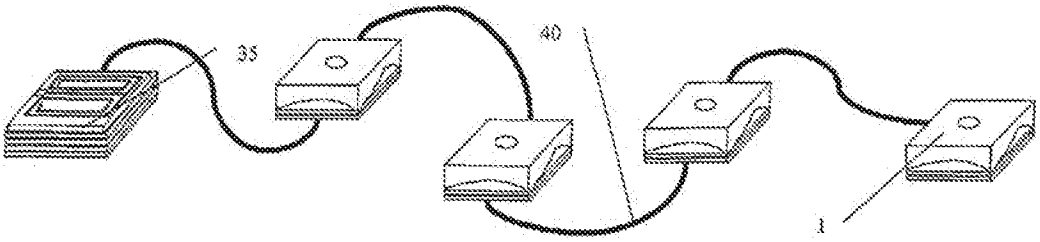

FIGURE 12

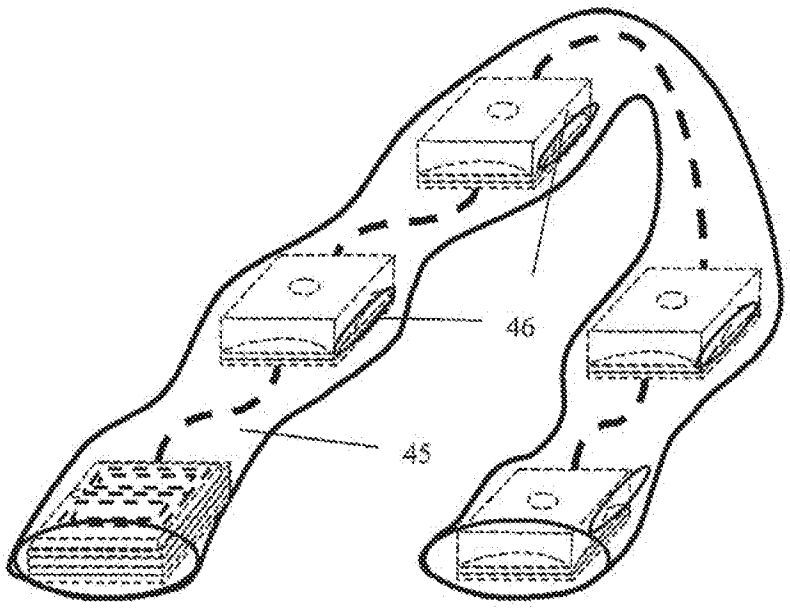

FIGURE 13

INTERNATIONAL SEARCH REPORT

national Application No
PCT/IL2004/001135

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M37/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N A61M A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/97899 A (WAYNE STATE UNIVERSITY; IEZZI, RAYMOND; AUNER, GREG; MCALLISTER, JAMES) 27 December 2001 (2001-12-27) page 4, line 4 - line 26 page 6, line 9 - page 13, line 31	1-25
X	WO 96/23543 A (ANGIOMEDICS II INCORPORATED) 8 August 1996 (1996-08-08) page 2, line 35 - page 7, line 9	1,2, 10-25
X	US 5 470 307 A (LINDALL ET AL) 28 November 1995 (1995-11-28) column 5, line 58 - column 10, line 34	1,2, 10-25
X	US 5 482 719 A (GUILLET ET AL) 9 January 1996 (1996-01-09) column 1, line 50 - column 3, line 58	1,2, 10-25

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 April 2005	04/05/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Petter, E

Form PCT/ISA/210 (second sheet) (January 2004)

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 273 904 B1 (CHEN JAMES C ET AL) 14 August 2001 (2001-08-14) column 9, line 5 - line 21 column 6, line 43 - column 7, line 65	5,7,8
A	US 2002/188327 A1 (STRUBLE CHESTER) 12 December 2002 (2002-12-12) abstract	15,24
A	US 2002/038137 A1 (STEIN MARC T) 28 March 2002 (2002-03-28) abstract	15,24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2004/001135

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 26, 27
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery and therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

national Application No
PCT/IL2004/001135

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US 2002038137 A1	28-03-2002	NONE	

ENDYMED EXHIBIT 1002 - 310/733

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 October 2005 (20.10.2005)

PCT

(10) International Publication Number
WO 2005/096979 A1

(51) International Patent Classification[7]: A61B 18/14, A61N 1/00

(21) International Application Number: PCT/US2005/011096

(22) International Filing Date: 1 April 2005 (01.04.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/558,476 1 April 2004 (01.04.2004) US

(71) Applicant *(for all designated States except US)*: **THE GENERAL HOSPITAL CORPORATION** [US/US]; 55 Fruit Street, Boston, MA 02114 (US).

(72) Inventor: **MANSTEIN, Dieter**; 4 Longfellow Place, Apt. 2005, Boston, MA 02114 (US).

(74) Agents: **KOWALSKI, Thomas, J.** et al.; Frommer Lawrence & Haug LLP, 745 Fifth Avenue, New York, NY 10151 (US).

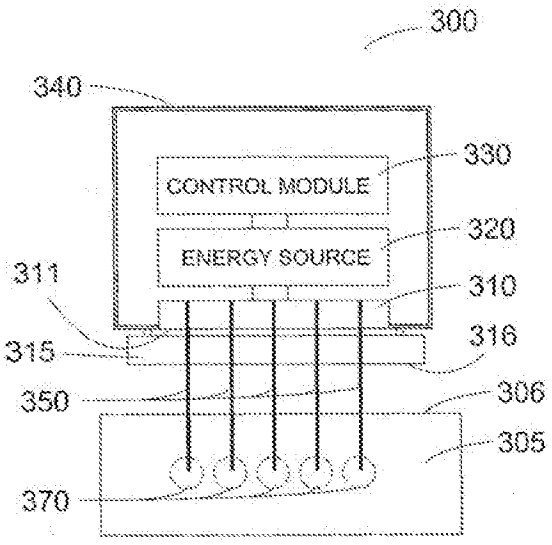
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING



(57) Abstract: The present invention provides improved methods and apparatus for skin treatment and tissue remodeling. The apparatus includes an array of needles that penetrate the skin and serve as electrodes to deliver radio frequency current or other electrical or optical energy into the tissue being treated, causing thermal damage in controlled patterns. The damaged regions promote beneficial results such as uniform skin tightening by stimulation of wound healing and collagen growth.

WO 2005/096979 A1

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TITLE OF THE INVENTION

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

RELATED APPLICATION

This application claims priority to U.S. Provisional Application Serial No. 60/558,476, filed on April 1, 2004.

INCORPORATION BY REFERENCE

The foregoing applications, and all documents cited therein or during their prosecution ("appln cited documents") and all documents cited or referenced in the appln cited documents, and all documents cited or referenced herein ("herein cited documents"), and all documents cited or referenced in herein cited documents, together with any manufacturer's instructions, descriptions, product specifications, and product sheets for any products mentioned herein or in any document incorporated by reference herein, are hereby incorporated herein by reference, and may be employed in the practice of the invention.

FIELD OF THE INVENTION

The present invention is directed to an improved method for treatment of skin and other tissues. More specifically, it is directed to a method of fractional wounding using arrays of needles to damage selected regions of the skin or subdermal tissue and thereby promote beneficial results including skin tightening and tissue remodeling.

BACKGROUND OF THE INVENTION

Skin is primarily made of two layers. The outer layer, or epidermis, has a depth of approximately 100 μm. The inner layer, or dermis, has depth of approximately 3000 μm from the outer surface of the skin and is primarily composed of a network of fibrous protein known as collagen.

There is an increasing demand for repair of skin defects, which can be induced by aging, sun exposure, dermatological diseases, traumatic effects, and the like. Aging skin tends to lose its elasticity, leading to increased formation of wrinkles and sagging. Other causes of undesirable wrinkles in skin include excessive weight loss and pregnancy. There are several well-known surgical approaches to improving the appearance of skin that involve incisions being made in the skin followed by the removal of some tissue and rejoining of the remaining tissue. These surgical approaches include facelifts, brow lifts, breast lifts, and "tummy tucks." Such approaches have many negative side effects including scar formation, long healing times, displacement of skin from its original location relative to the underlying bone structure, and nonuniform skin tightening.

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Many treatments have been developed that use electromagnetic radiation to improve skin defects by inducing a thermal injury to the skin, which results in a complex wound healing response of the skin. This leads to a biological repair of the injured skin and may be accompanied by other desirable effects. Various techniques providing this objective have been introduced in recent years. The different techniques can be generally categorized in two groups of treatment modalities: ablative laser skin resurfacing ("LSR") and non-ablative collagen remodeling ("NCR"). The first group of treatment modalities, LSR, includes causing fairly extensive thermal damage to the epidermis and/or dermis, while the second group, NCR, is designed to avoid thermal damage of the epidermis.

LSR is considered to be an effective laser treatment for repairing skin. In a typical LSR procedure, shown schematically in Fig. 1, a region of the epidermis 100 and a corresponding region of the dermis 110 beneath it are thermally damaged to promote wound healing. Electromagnetic energy 120 is directed towards a region of skin, ablating the skin and removing both epidermal and dermal tissue in region 130. LSR with pulsed CO_2 or Er:YAG lasers, which may be referred to in the art as laser resurfacing or ablative resurfacing, is considered to be an effective treatment option for signs of photo aged skin, chronically aged skin, scars, superficial pigmented lesions, stretch marks, and superficial skin lesions. However, patients may experience major drawbacks after each LSR treatment, including edema, oozing, and burning discomfort during first fourteen (14) days after treatment. These major drawbacks can be unacceptable for many patients. A further problem with LSR procedures is that the procedures are relatively painful and therefore generally require an application of a significant amount of analgesia. While LSR of relatively small areas can be performed under local anesthesia provided by injection of an anestheticum, LSR of relatively large areas is frequently performed under general anesthesia or after nerve blockade by multiple injections of anesthetic.

A limitation of LSR is that ablative resurfacing in areas other than the face generally have a greater risk of scarring because the recovery from skin injury within these areas is not very effective. Further, LSR techniques are better suited for correction of pigmentation defects and small lesions than for reducing or eliminating wrinkles.

In an attempt to overcome the problems associated with LSR procedures, several types of NCR techniques has emerged. These techniques are variously referred to in the art as non-ablative resurfacing, non-ablative subsurfacing, or non-ablative skin remodeling. NCR techniques generally utilize non-ablative lasers, flashlamps, or radio frequency current to damage dermal tissue while sparing damage to the epidermal tissue. The concept behind

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NCR techniques is that thermal damage of the dermal tissue is thought to induce collagen shrinkage, leading to tightening of the skin above, and stimulation of wound healing which results in biological repair and formation of new dermal collagen. This type of wound healing can result in a decrease of structural damage related to photoaging. Avoidance of epidermal damage in NCR techniques decreases the severity and duration of treatment-related side effects. In particular, post-procedural oozing, crusting, pigmentary changes and incidence of infections due to prolonged loss of the epidermal barrier function can usually be avoided by using NCR techniques.

In the NCR method of skin treatment, illustrated schematically in Fig. 2, selective portions of dermal tissue 135 within the dermal layer 110 are heated to induce wound healing without damaging the epidermis 100 above. Selective dermal damage that leaves the epidermis undamaged can be achieved by cooling the surface of the skin and focusing electromagnetic energy 120, which may be a laser beam, onto dermal region 135 using lens 125. Other strategies are also applied using nonablative lasers to achieve damage to the dermis while sparing the epidermis in NCR treatment methods. Nonablative lasers used in NCR procedures generally have a deeper dermal penetration depth as compared to ablative lasers used in LSR procedures. Wavelengths in the near infrared spectrum can be used. These wavelengths cause the non-ablative laser to have a deeper penetration depth than the very superficially-absorbed ablative Er:YAG and CO_2 lasers. Examples of NCR techniques and apparatus are disclosed by Anderson et al. in U.S. Patent Publication No. 2002/0161357.

While it has been demonstrated that these NCR techniques can assist in avoiding epidermal damage, one of the major drawbacks of these techniques is their limited efficacies. The improvement of photoaged skin or scars after the treatment with NCR techniques is significantly smaller than the improvements found when LSR ablative techniques are utilized. Even after multiple treatments, the clinical improvement is often far below the patient's expectations. In addition, clinical improvement is usually several months delayed after a series of treatment procedures. NCR is moderately effective for wrinkle removal and is generally not effective for dyschromia. One advantage of NCR is that it does not have the undesirable side effects that are characteristic of the LSR treatment, such as the risk of scarring or infection.

Another limitation of NCR procedures relates to the breadth of acceptable treatment parameters for safe and effective treatment of dermatological disorders. The NCR procedures generally rely on an optimum coordination of laser energy and cooling parameters, which can result in an unwanted temperature profile within the skin leading to

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either no therapeutic effect or scar formation due to the overheating of a relatively large volume of the tissue.

Another approach to skin tightening and wrinkle removal involves the application of radio frequency ("RF") electrical current to dermal tissue via a cooled electrode at the surface of the skin. Application of RF current in this noninvasive manner results in a heated region developed below the electrode that damages a relatively large volume of the dermis, and epidermal damage is minimized by the active cooling of the surface electrode during treatment. This treatment approach can be painful, and can lead to short-term swelling of the treated area. Also, because of the relatively large volume of tissue treated and the need to balance application of RF current with surface cooling, this RF tissue remodeling approach does not permit fine control of damage patterns and subsequent skin tightening. This type of RF technique is monopolar, relying on a remote grounding of the patient to complete the current flow from the single electrode. The current in monopolar applications must flow through the patient's body to the remote ground, which can lead to unwanted electrical stimulation of other parts of the body. In contrast, bipolar instruments conduct the current between two relatively nearby electrodes through a more localized pathway.

In view of the shortcomings of the above methods of dermatological treatment and tissue remodeling, there is a need to provide a procedure and apparatus that combine safe and effective treatment for tissue remodeling, skin tightening, and wrinkle removal with minimal side effects, such as intra-procedural discomfort, post-procedural discomfort, lengthy healing time, and post-procedural infection.

Citation or identification of any document in this application is not an admission that such document is available as prior art to the present invention.

SUMMARY OF THE INVENTION

It is therefore one of the objects of the present invention to provide an apparatus and method that combines safe and effective treatment for an improvement of dermatological disorders with minimum side effects. Another object of the present invention is to provide an apparatus and method that promotes skin tightening and wrinkle removal by creation of a pattern of small localized regions of thermal damage within the dermis. Still another object of the present invention is to provide a method and apparatus for skin tightening or other forms of tissue remodeling by using an array of electrode needles to controllably deliver electrical or thermal energy to predetermined locations within the dermis or other tissue.

These and other objects can be achieved with an exemplary embodiment of the apparatus and method according to the present invention, in which portions of a target area of

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tissue are be subjected electromagnetic radiation, such as radio frequency pulses, or thermal energy. Electromagnetic radiation is directed to portions of a target area within the skin or deeper tissue using minimally invasive methods, causing fractional wounding of the portions of the target area. The electromagnetic radiation may be generated by an electromagnetic radiation source, which is configured to deliver heat, radio frequency pulses, electrical current, or the like to a plurality of target areas.

In yet another exemplary embodiment according to the present invention, an electromagnetic radiation source is configured to generate electromagnetic radiation, and a delivery device comprising an array of needles, coupled to the electromagnetic radiation source, is configured to penetrate the skin to a desired depth to deliver the electromagnetic radiation directly to a plurality of target areas.

One method in accordance with the present invention comprises inserting an array of needles into a region of skin to a predetermined depth. Radio frequency pulses of electrical current are then applied to one or more of the needles, which can function as electrodes in monopolar or bipolar modes to create regions of thermal damage and/or necrosis in the tissue surrounding the tips of the needles.

In an alternate aspect of the invention, one or more of the needles in the array may be hollow and used to deliver small amounts of analgesic or anesthetic into the region of skin being treated. These hollow needles may be interspersed among the electrode needles in the array, and they may also function as electrodes.

In another embodiment of the invention, the electrode needles may also be connected to a second source of electrical current in the milliampere range. Detection of a nerve close to any of the inserted needles of the array is achieved by sequential application of small currents to the needles in the array and observation of any visible motor response. If a nerve is detected, the nearby needle or needles can be deactivated during the subsequent application of RF current to other electrode needles in the array to avoid damaging the nerve.

In yet another embodiment of the invention, the methods and apparatus described herein can be used to heat portions of cartilage, such as that located in the nose, using a minimally invasive technique, allowing reshaping of the pliant heated cartilage to a desired form.

A further understanding of the nature and advantages of the present invention will become apparent by reference to the remaining portions of the specification and drawings.

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BRIEF DESCRIPTION OF THE DRAWINGS

The following detailed description, given by way of example, but not intended to limit the invention solely to the specific embodiments described, may best be understood in conjunction with the accompanying drawings, in which:

Fig. 1 is a schematic drawing of a cross section of a tissue treated using the ASR method.

Fig. 2 is a schematic drawing of a cross section of a tissue treated using the NSR method.

Fig. 3 is a schematic illustration of an apparatus for conducting tissue reshaping using electromagnetic energy according to one embodiment of the present invention.

Fig. 4 is a schematic illustration of portions of an apparatus for conducting tissue reshaping according to one embodiment of the present invention.

Throughout the drawings, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components, or portions of the illustrated embodiments. Moreover, while the present invention will now be described in detail with reference to the Figures, it is done so in connection with the illustrative embodiments and is not limited by the particular embodiments illustrated in the Figures.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to methods and apparatus for improvement of skin defects including, but not limited to, wrinkles, stretch marks, and cellulite. In one embodiment, skin tightening or tissue remodeling is accomplished by creating a distribution of regions of necrosis, fibrosis, or other damage in the tissue being treated. The tissue damage is achieved by delivering localized concentrations of electrical current that is converted into heat in the vicinity of the tips of the electrode needles. Inducing regions of local thermal damage within the dermis results in an immediate shrinking of collagen, leading to beneficial skin tightening response. Additionally, the thermal damage tends to stimulate the formation of new collagen, which makes the local skin tissue fuller and gradually leads to additional skin tightening and reduction of wrinkles.

In an exemplary embodiment of the present invention, tissue treatment apparatus 300 shown in Fig. 3 may be used to create regions of damage within the tissue being treated. The tissue reshaping apparatus may comprise a plurality of needles 350 attached to a base 310. The base is attached to housing 340 or formed as a part of the housing. A source of RF current 320 is electrically connected to each of the needles 350. A control module 330 permits variation of the characteristics of the RF electrical current, which can be supplied

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individually to one or more of the needles. Optionally, energy source 320 and/or control module 330 may be located outside of the housing.

In one exemplary embodiment, the energy source 320 is a radio frequency (RF) device capable of outputing signals having frequencies in a desired range. In another exemplary embodiment, the energy source is capable of outputting an AC or DC electric current. The control module 330 provides application-specific settings to the energy source 320. The energy source 320 receives these settings, and generates a current directed to and from specified needles for selectable or predetermined durations, intensities, and sequences based on these settings.

In yet another embodiment of the present invention, a spacer substrate 315 containing a pattern of small holes through which the array of needles protrudes may optionally be provided between the base 310 and the surface of the skin 306. This spacer substrate may be used to provide mechanical stability to the needles. Optionally, this substrate may be movably attached to the base 310 or housing 340 and adjustable with respect to base 310, supporting the array of needles to control the depth of the needles protruding from the lower surface 316 of spacer substrate 315, and thus controlling the depth to which the needles are inserted into the skin.

In practicing a method in accordance with the present invention, the sharp distal ends of needles 350 pierce the surface 306 of skin tissue 305 and are inserted into the tissue until the bottom surface 316 of spacer substrate 315 (or the bottom surface 311 of base 310 if a spacer substrate 315 is not used) contacts the surface 306 of the skin 305. This configuration permits reliable insertion of the array of needles to a predetermined depth within the tissue being treated. Control module 330 is then configured to deliver controlled amounts of RF current to one or more needles 350.

Base 310 and/or spacer substrate 315, if used, can be planar or they may have a bottom surface that is contoured to follow the shape of the region of tissue being treated. This permits penetration of the needle array to a uniform depth within the targeted tissue even if the surface of the skin is not planar, e.g., along the eye sockets.

In another embodiment, base 310 and/or a spacer substrate 315, if used, may be cooled by any suitable means (such as by embedded conduits containing circulating coolant or by a Peltier device) to cool the surface of the skin when the needle array penetrates the skin to reduce or eliminate pain. The surface region of the skin being treated and/or the needles themselves may also be precooled by separate means, including convective or conductive means, prior to penetration of the skin by the array of needles.

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In a preferred embodiment of the present invention, the shafts of conductive needles 350 are electrically insulated except for the portion of the needle near the tip. In the apparatus of Fig. 3, application of RF current to the needles 350 causes heating in the exposed tip region, inducing thermal damage regions 370 around the tip of each needle. Thermal damage regions 370 result from operation of the apparatus in monopolar configuration, in which a remote grounding electrode, not shown in Fig. 3, is attached to a remote part of the patient's body to complete the circuit of electricity conveyed to needles 350 by energy source 320. In this monopolar configuration, RF current causes heating of the tip regions of the needles 350, generating thermal damage in tissue regions 370 adjacent to the needle tips that are approximately spherical or slightly elongated in shape.

In one embodiment of the invention, current may be delivered simultaneously to all needles in the array to produce a pattern of thermal damage around the tip of each needle. In alternative embodiments, control module 330 and energy source 320 can be configured to supply electrical current to individual needles, to specific groups of needles within the array, or to any combination of individual needles in any desired temporal sequence. Providing current to different needles at different times during treatment (instead of heating all needles in the array at once) may help to avoid potential local electrical or thermal interactions among needles that can lead to excessive local damage.

In yet another embodiment of the present invention one or more vibrating means, such as a piezoelectric transducer or a small motor with an eccentric weight fixed to the shaft, may be mechanically coupled to housing 340 and/or base 310 that supports the array of needles 350. Vibrations conductively induced in needles 350 by such vibrating means can facilitate the piercing of the skin by the needle tips and subsequent insertion of the needles into the tissue. The vibrating means can have an amplitude of vibration in the range of about 50-500 μm or, more preferably, between about 100-200 μm. The frequency of the induced vibrations can be from about 10 hz to about 10 khz, more preferably from about 500 hz to about 2 khz, and even more preferably about 1 khz. The particular vibration parameters chosen may depend on the size and material of the needles, the number of needles in the array, and the average spacing of the needles. The vibrating means may further comprise an optional controller capable of adjusting the amplitude and/or frequency of the vibrations.

Additional details and embodiments of the present invention are shown in Figure 4. Conductive needles 410 and 415 are shown attached to base 310. Insulation 420 covers the shaft of needles 410 and 415 protruding from base 310 except for the region near the lower tip, and electrically insulates each conductive needle shaft from surrounding tissue 305.

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Electrical conductors 430 and 431, which may be wires or the like, extend from an upper portion of needles 410 and 415 respectively, and are connected to the energy source (not shown here). Suitable insulating materials for insulation 420 include, but are not limited to, Teflon®, polymers, glasses, and other nonconductive coatings. A particular material may be chosen as an insulator to facilitate penetration and insertion of needles 410 and 415 into tissue 305.

Needles 410 and 415 are shown operating in bipolar mode in another embodiment of the present invention. Needle 410 is a positive electrode delivering RF or other current to the tip region of the needle from the energy source via conductor 430. Needle 415 functions as a grounding electrode that is connected to the ground of the energy source via conductor 431. In this configuration the applied current will travel through the tissue between the tips of needles 410 and 415, generating an elongated region of thermal damage 425 around and between the tips of the two needles.

An elongated region of damaged tissue 425 can be created between any two adjacent or nearby needles in the array through proper configuration of control module 330 and energy source 320. In an embodiment of the present invention, elongated damage regions 425 are formed between several pairs of needles within the array of needles to form a desired damage pattern in the tissue 305. The regions of thermal damage 325 created in bipolar operation of the apparatus may be formed simultaneously or, alternatively, sequentially, using any combinations of proximate needles in the array to form each region. A wide variety of thermal damage patterns can be created using a single array of needles through appropriate configuration of energy source 320 and control module 330 to deliver predetermined amounts of current between selected pairs of needles. This apparatus thus allows for the creation of complex damage patterns within the tissue 305 that may be macroscopically elongated in preferred directions to produce anisotropic shrinkage and reshaping.

In practicing the methods and apparatus of the present invention, the needles can have a width of about 500-1000 μm or preferably about 700-800 μm. Needles less than 500 μm in diameter may also be used if they are mechanically strong enough. Needles thicker than about 1000 μm in diameter may be undesirable because of the difficulty in forcing larger needles to penetrate the skin and because of the increased propensity for pain and scarring. The length of the needles extending into the skin will depend on the targeted depth for damagng the tissue. A typical depth for targeting collagen in the dermis is about about 1500-2000 μm, although shallower or deeper distances may be preferred for different treatments

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and regions of the body being treated. Needles within a single array may protrude by different lengths from the base 310 or spacer substrate 315. This will cause the tips of the needles to be positioned at different depths within the tissue being treated, and allow creation of damaged tissue at more than one depth. This variation in needle depth can achieve formation of damaged tissue over a larger volume within the tissue being treated.

The needle arrays may have any geometry appropriate for the desired treatment being performed. The spacing between adjacent needles is preferably greater than about 1mm apart, and may be as large as about 2 cm. The spacing between needles in an array need not be uniform, and can be closer in areas where a greater amount of damage or more precise control of damage in the target area of tissue is desired. In one embodiment, the array of needles may comprise pairs of needles separated from adjacent pairs by larger distances. This geometry may be well-suited for inducing damage in bipolar mode between pairs of needles. Needles may also be arranged in a regular or near-regular square or triangular array. In any array geometry, the pattern of damage and resultant tissue reshaping may be controlled with some precision by adjusting the intensity and duration of power transmitted to single needles or pairs of needles.

The amount of energy directed to a given needle will vary depending on the tissue being treated and the desired extent of thermal damage to induce. For typical needle spacings noted above, the energy source should be configured to deliver about 1-1 00 mJ per needle or pair of needles in the array. It may be preferable to initially use lower amounts of energy and perform two or more treatments over the same target area to better control the damage pattens and extent of reshaping.

In yet another embodiment of the present invention, one or more of the needles in the array may be hollow, such as needle 440 in Fig. 4. Center channel 450 may be used to deliver a local analgesic such as lidocaine 2% solution from a source (not shown) located within or above base 310 into the tissue 305 to reduce or eliminate pain caused by the thermal damage process.

In yet another embodiment of the present invention, hollow needle 440 is bifunctional, capable of conducting RF current or other energy via conductor 432 and also capable of delivering a local analgesic or the like through center channel 450. Similar to needles 410 and 415, bifunctional needle 440 has insulation 445 covering the shaft extending from base 310 except for the region near the lower tip. Analgesic may be supplied to the tissue either before or during application of RF or other current to the needle 450.

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In one embodiment of the invention, one or more of the needles in the array may be bifunctional like needle 440. Alternatively, one or more needles may be hollow and optionally nonconductive, suitable only for delivering a local analgesic or the like. The array of needles used for a given application may comprise any combination of solid electrodes, bifunctional needles, or hollow nonconductive needles. For example, one type of needle array may comprise pairs of electrode needles operating in bipolar mode, with a hollow needle located between each pair. In this configuration, the hollow needle can deliver analgesic to the tissue between the tips of the electrode needles prior to applying current to the electrodes and causing thermal damage in the numbed tissue.

In yet another embodiment of the present invention, one or more of the needles in the array may be further connected to an electronic detection apparatus and perform the additional function of a probe to detect the presence of a nerve near the tip. The electronic detection apparatus may comprise a source of electrical current in the milliampere range and control means to send small currents on the order of a milliamp to specific needles in the array. Detection of a nerve close to any of the inserted needles of the array is performed by sequential application of small currents to the needles in the array and observation of any visible motor response. If a nerve is detected, control module 330 can be configured to deactivate the needle or needles close to the nerve during the subsequent treatment to avoid damaging the nerve. A nerve detection method based on principles similar to those described herein is disclosed by Urmey et al. in Regional Anesthesia and Pain Medicine 27:3 (May-June) 2002, pp. 261-267.

In still another embodiment, one or more of the needles may be hollow, and a light fiber or light guide is inserted into the hollow needle such that one end of it extends to or slightly protrudes from the needle tip. The other end of the light fiber or light guide in communication with a source of optical energy. Optical energy supplied to the tip of the light guide or light fiber may then be used to heat the tip, which then heats the surrounding tissue, i.e., the target area, to cause fractional wounding at the needle tip. An array of needles used in accordance with the present invention may comprise a mix of electrode needles and light-guide needles. Alternatively, each needle may carry a light guide and all of the energy used to cause thermal damage may be generated by the optical energy source instead of using RF or other electrical current. A portion of the light guide or light fiber, such as the portion at the tip of the needle, may be configured to absorb energy and facilitate conversion of the optical energy to heat. In these embodiments, the optical energy source may comprise, but is not limited to, a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG

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laser, an argon-ion laser, a He-Ne laser, a carbon dioxide laser, an eximer laser, or a ruby laser. The optical energy conveyed by a light guide or light fiber may optionally be continuous or pulsed.

Treatments performed in accordance with the present invention may be used to target collagen in the dermis. This can lead to immediate tightening of the skin and reduction of wrinkles overlying the damaged tissue arising from contraction of the heated collagen. Over time, the thermal damage also promotes the formation of new collagen, which serves to smooth out the skin even more.

An alternative application of the methods of the present invention may be to reduce or eliminate the appearance of cellulite. To achieve this, the arrays of needles are configured to target the dermis and optionally the upper layer of subcutaneous fat directly. Creating dispersed patterns of small thermally-damaged regions in these layers can tighten the networked collagen structure and suppress the protrusion of the subcutaneous fat into the dermal tissue that causes cellulite.

Yet another application of the methods and apparatus of the present invention is to reshape cartilage. It is known that cartilage softens upon heating, and heating it to about 70 degrees C can soften the cartilage sufficiently to permit reshaping that persists upon cooling. Currently, specialized lasers are used to heat and soften cartilage in the nasal passages for reshaping. Using the methods and apparatus described herein, cartilage can be targeted by an array of needles and heated in a suitably gradual way, using lower power densities and longer times, to provide relatively uniform heating. Shaping of the cartilage is thus possible using a minimally invasive technique that can be used where laser heating may not be feasible.

Any of the thermal damaging and tissue reshaping methods practiced in accordance with the present invention may be performed in a single treatment, or by multiple treatments performed either consecutively during one session or at longer intervals over multiple sessions. Individual or multiple treatments of a given region of tissue can be used to achieve the appropriate thermal damage and desired cosmetic effects.

Having thus described in detail preferred embodiments of the present invention, it is to be understood that the invention defined by the above paragraphs is not to be limited to particular details set forth in the above description as many apparent variations thereof are possible without departing from the spirit or scope of the present invention.

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WHAT IS CLAIMED IS:

1. A tissue reshaping apparatus comprising:

a plurality of needles attached to a base, wherein the base is attached to a housing or part of the housing;

an energy source in communication with one or more of the needles; and

optionally comprising a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.

2. The apparatus of claim 1 wherein one or more of the needles are electrically conductive and the energy source is configured to supply RF current individually to one or more of the needles.

3. The apparatus of claim 2 wherein the energy source and/or control module is located outside of the housing.

4. The appratus of any one of claims 1 to 3 wherein the energy source is a radio frequency (RF) device capable of outputing signals having frequencies in a desired range.

5. The apparatus of any one of claims 1 to 4 wherein the energy source is capable of outputting an AC or DC electric current.

6. The apparatus of any one of claims 1 to 5 wherein the control module provides application-specific settings to the energy source, and wherein the energy source receives the settings, and generates a current directed to and optionally from specified needles for selectable or predetermined durations, intensities, and sequences based on the settings.

7. The apparatus of any one of claims 1 to 6 wherein the needles comprise sharp distal ends capable of piercing the surface of skin tissue and penetrating into the tissue until the lower side of the base contacts the surface of the skin.

8. The apparatus of any one of claims 1 to 7 wherein the control module is configured to deliver controlled amounts of RF current to one or more of the needles.

9. The apparatus of any one of claims 1 to 8 further comprising a spacer substrate comprising a pattern of small holes through which the plurality of needles protrudes.

10. The apparatus of claim 9 wherein the substrate is movably attached to the base or the housing and wherein the position of the substrate is adjustable relative to that of the base to control the depth of the needles protruding from the lower surface of the spacer substrate.

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11. The apparatus of any one of claims 1 to 10 wherein the base and/or optionally, the spacer substrate, is planar or has a lower surface that is contoured to follow the shape of the region of tissue being treated.

12. The apparatus of any one of claims 1 to 11 wherein the base and/or a spacer substrate further comprises cooling means configured to cool a skin surface to reduce or eliminats pain when the plurality of needles penetrates the skin surface.

13. The apparatus of claim 12 wherein said cooling comprises embedded conduits containing circulating coolant or a Peltier device.

14. The apparatus of any one of claims 1 to 13 wherein said apparatus is configured to deliver RF energy to one or more needles in a monopolar configuration.

15. The apparatus of any one of claims 1 to 13 wherein said apparatus is configured to deliver RF energy to one or more needles in a bipolar configuration.

16. The apparatus of any one of claims 1 to 15 further comprising a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft.

17. The apparatus claim of 16 wherein the vibrational frequency of said vibrating means is between about 10 hz to about 10 khz, between about 500 hz to about 2 khz, or is about 1 khz.

18. The apparatus claim 17 wherein the vibrational amplitude of said vibrating means is between about 50-500 μm or between about 100-200 μm.

19. The apparatus of any one of claims 1 to 18 wherein the energy source and the control module are configured to deliver energy to a plurality of pairs of needles in bipolar mode..

20. The apparatus of any one of claims 1 to 19 wherein the diameter of the needles is between about 500-1000 μm or between about 700-800 μm.

21. The apparatus of any one of claims 1 to 20 wherein the average spacing of needles is between about 1 mm and 2 cm, and wherein the needles optionally are not uniformly spaced.

22. The apparatus of any one of claims 1 to 21 wherein one or more of the needles are hollow and are configured to deliver a local analgesic to the tissue surrounding the tip of the needle.

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23. The apparatus of any of claims 1 to 22 further comprising an electronic detection device in electrical communication with one or more of the needles that is configured to detect the presence of a nerve near the tip of one or more of the needles.

24. The apparatus of claim 23 wherein the detection device is in communication with the control module and the control module is configured to prevent the energy source from supplying energy to any needle if a nerve has been detected near that needle.

25. The apparatus of any of claims 1 to 24 further comprising a source of optical energy and one or more hollow needles containing light fibers or light guides, wherein the apparatus is configured to deliver a controlled amount of electromagnetic energy through the light fiber or light guide and into the tissue surrounding the tip of the hollow needle.

26. The apparatus of claim 25 wherein the optical energy source comprises a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG laser, an argon-ion laser, a He-Ne laser, a carbon dioxide laser, an eximer laser, or a ruby laser, and wherein the electromagnetic energy conveyed by the light guide or light fiber is continuous or pulsed.

27. A method of treating skin comprising the steps of:

providing a plurality of needles attached to a base;

providing an energy source in communication with one or more of the needles;

inserting the needles into the skin to a predetermined depth; and

supplying energy to more than one of the needles to induce a pattern of damage in the tissue surrounding the needles.

28. The method of claim 27 further comprising:

providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.

29. The method of claim 28 further comprising:

providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin.

30. The method of claim 29 wherein the energy is RF current and the needles are insulated except near their tips.

31. The method of claim 30 further comprising:

providing a detection device in communication with one or more of the needles;

supplying low current to one or more of the needles sequentially to detect the presence of a nerve near the needles; and

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preventing the energy source from supplying energy to any needle if a nerve has been detected near that needle.

32. The method of claim 27 further comprising:

providing one or more hollow needles attached to the base and injecting an analgesic through the hollow needles into the surrounding tissue after the needles are inserting into the skin.

33. The method of claim 29 further comprising:

providing hollow needles containing light fibers or light guides in communication with the energy source, wherein the energy source is a source of optical energy;

supplying energy to the light fibers or light guides to induce thermal damage in a portion of the tissue surrounding the hollow needles.

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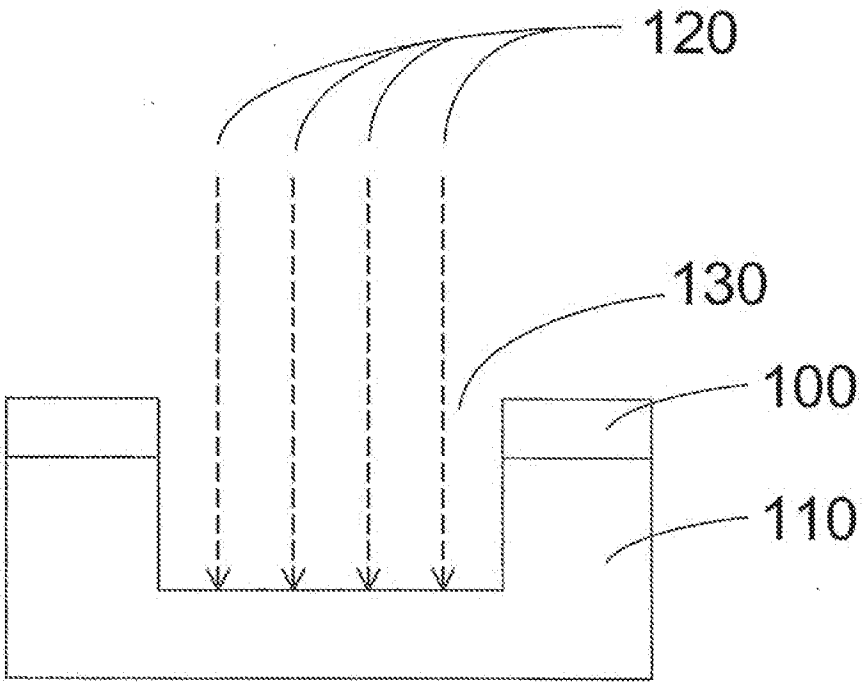

FIG. 1

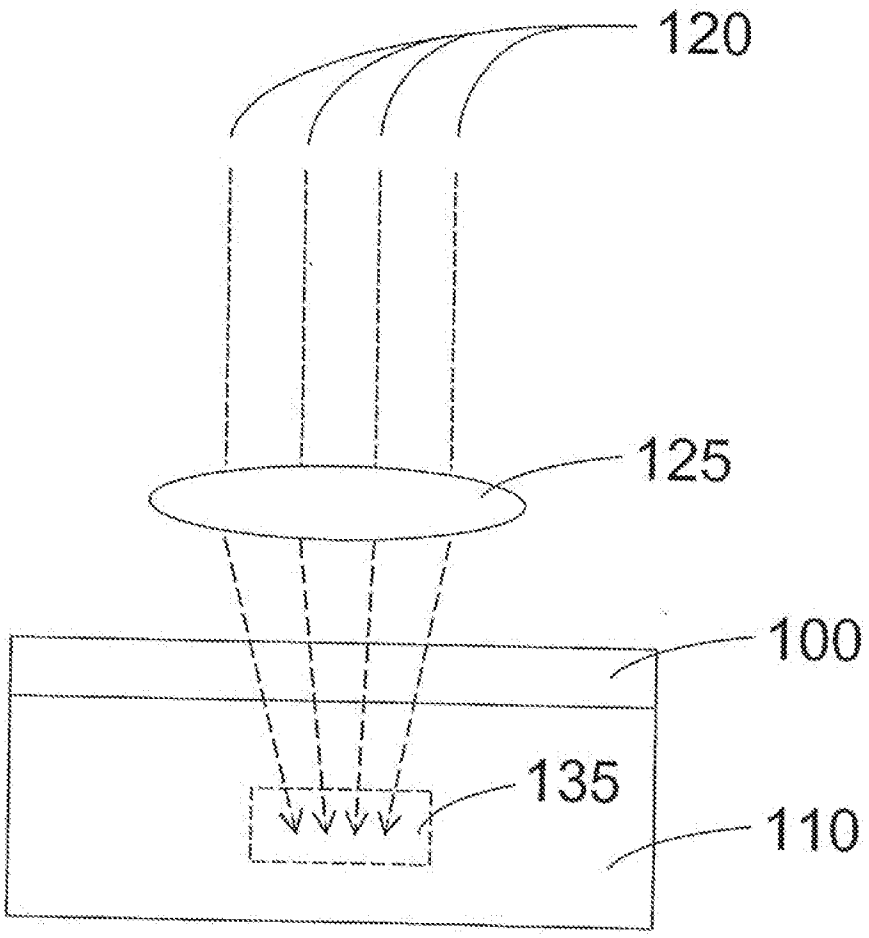

FIG. 2

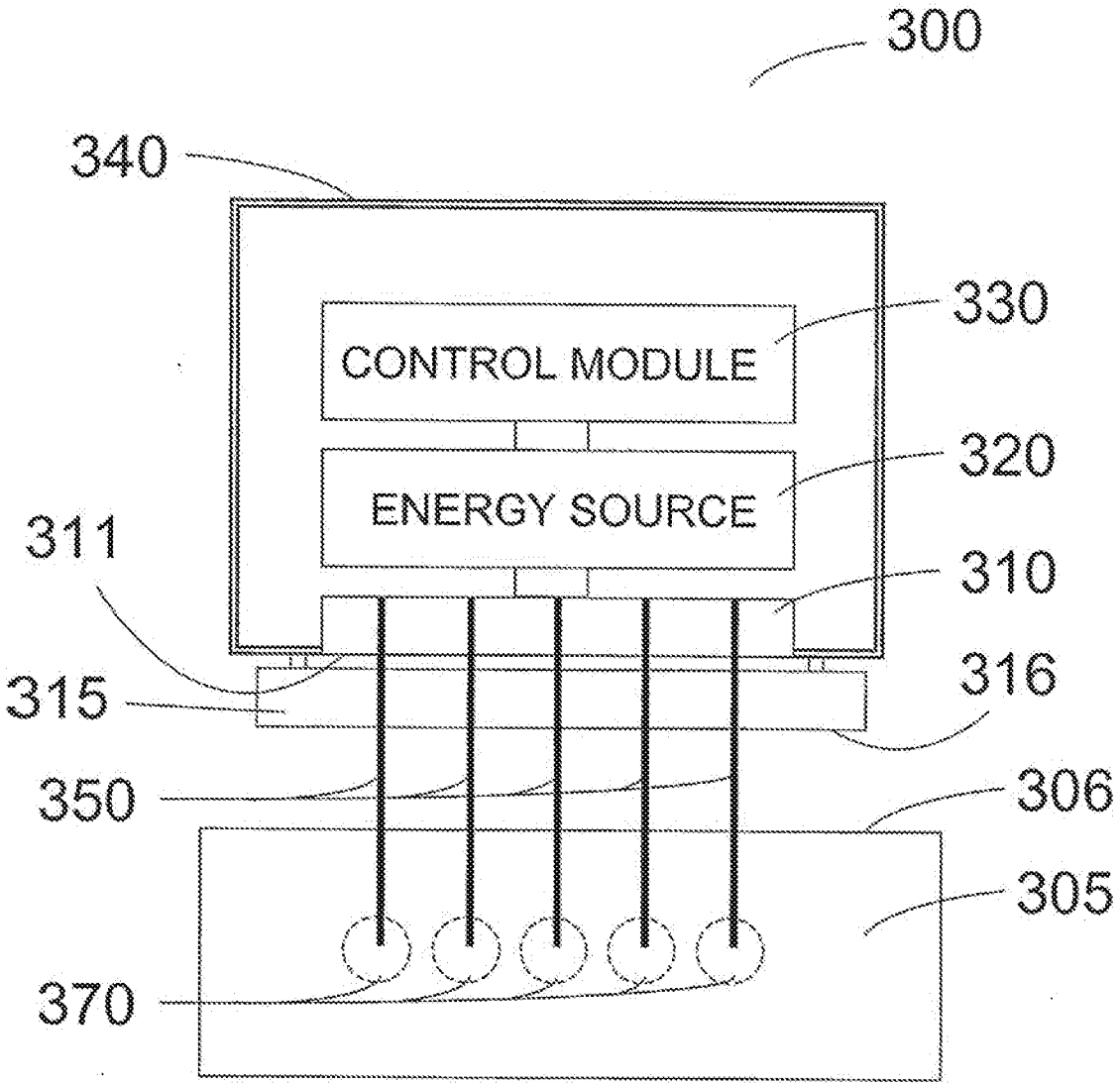
300
340
330
CONTROL MODULE
320
ENERGY SOURCE
311
310
316
315
350
306
305
370

FIG. 3

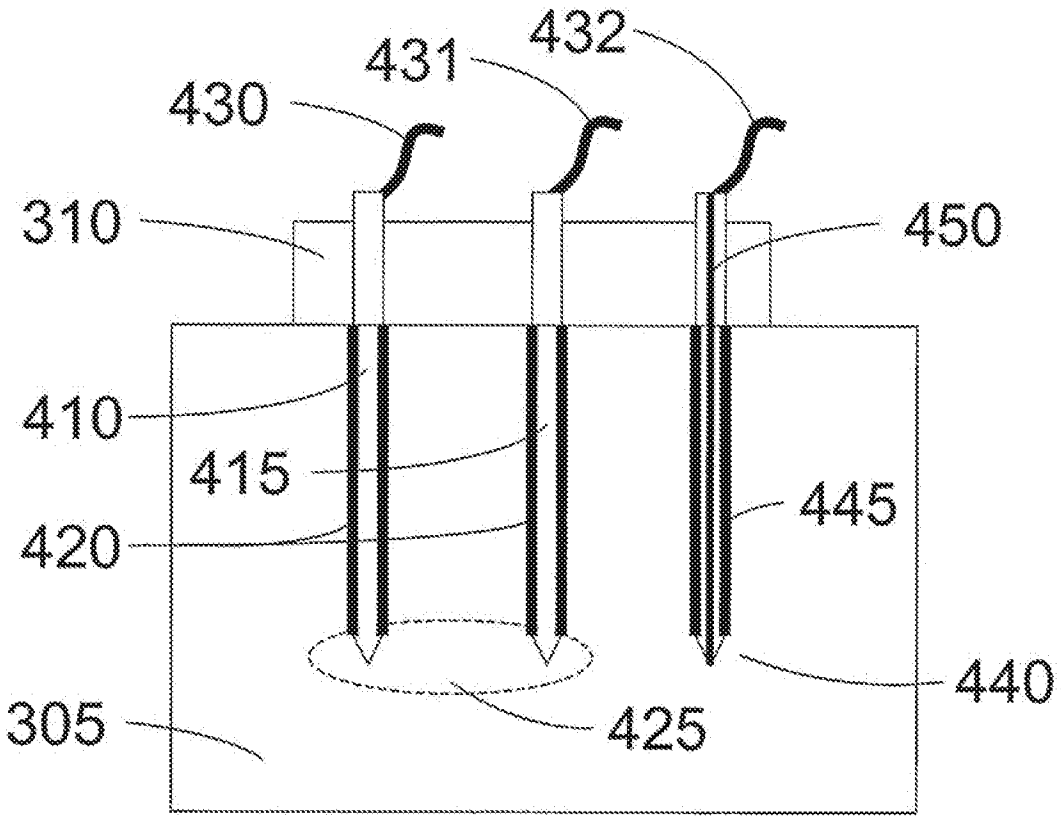

FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/011096

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14 A61N1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 277 116 B1 (UTELY DAVID ET AL) 21 August 2001 (2001-08-21) abstract; figures 6-9 column 3, line 49 - column 5, line 30	1-15, 19-22
Y	column 7, line 38 - column 10, line 9	16-18, 23-26
X	US 2002/128641 A1 (UNDERWOOD RONALD A ET AL) 12 September 2002 (2002-09-12) abstract; figures 5-8 paragraph '0032! - paragraph '0040! paragraph '0051! - paragraph '0056!	1-10, 12-15, 19-21
Y	WO 02/060523 A (BROWN, TONY, R; NGUYEN, HEIN; WADHWANI, SURESH; ADAME, OCTAVIO, V; LAU) 8 August 2002 (2002-08-08) paragraph '0063!; claims 19,20	16-18

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 July 2005	15/07/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Beck, E

Form PCT/ISA/210 (second sheet) (January 2004)

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/011096

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	W.F. URMEY: "Percutaneous electrode guidance: A noninvasive technique for prelocation of peripheral nerves to facilitate peripheral plexus or nerve block" REGIONAL ANESTHESIA AND PAIN MEDICINE, vol. 27, no. 3, 2002, pages 261-267, XP002334726 cited in the application abstract page 262 - page 263	23,24
Y	US 5 861 002 A (DESAI ET AL) 19 January 1999 (1999-01-19) column 16, line 51 - column 17, line 20	25,26

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

MED-EXHIBIT 1002 - 333/733
ENDYMED EXHIBIT 1002 - 333/733

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/011096

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 27-33
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery,Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2005/011096

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 5395312 A	07-03-1995
		US 5490836 A	13-02-1996

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(71) Applicants *(for all designated States except US)*: **HONAM PETROCHEMICAL CORP.** [KR/KR]; 395-67, Shindaebang-dong, Dongjak-gu, Seoul 156-010 (KR). **KOREA ADVANCED INSTITUTE OF SCIENCE AND TECHNOLOGY** [KR/KR]; 373-1, Guseong-dong, Yuseong-gu, Daejeon-si 305-701 (KR).

(72) Inventors; and

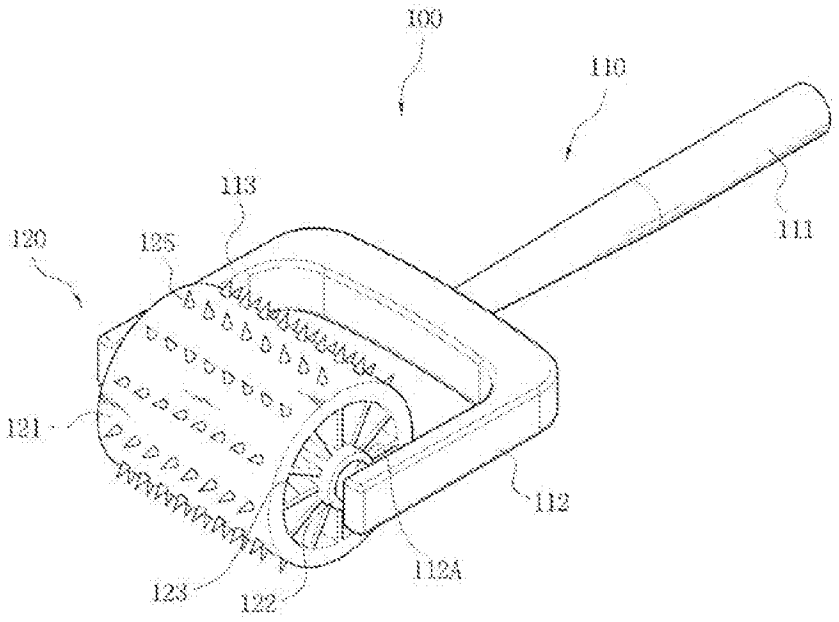
(75) Inventors/Applicants *(for US only)*: **KIM, Chang-Hyun** [KR/KR]; # 109-1102, Daelim Dure Apt., Sinseong-dong, Yuseong-gu, Daejeon-si 305-720 (KR). **HYUN, Dong-Hun** [KR/KR]; # 109-104, Daelim Dure Apt., Sinseong-dong, Yuseong-gu, Daejeon-si 305-720 (KR). **LEE, Seung-Sup** [KR/KR]; Mechanical engineering, Korea, Advanced Institute of Science and, Technology, 373-1, Guseong-dong, Yuseong-gu, Daejeon-si 305-701 (KR). **HAN, Man-Hee** [KR/KR]; Mechanical engineering, Korea, Advanced Institute of Science and, Technology, 373-1, Guseong-dong, Yuseong-gu, Daejeon 305-701 (KR).

(74) Agents: **JIN, Hee-Dong** et al.; 701, BYC Bldg., 648-1, Yeoksam-Dong, Gangnam-Gu, Seoul 135-080 (KR).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, MG, MK, MN, MW, MX, MY,

[Continued on next page]

(54) Title: MICRO NEEDLE ROLLER ASSEMBLY



(57) Abstract: The present invention provides a micro needle roller assembly comprising a roller head including an external cylindrical member having a plurality of micro needles mounted on a surface thereof and an internal member placed in the external member and supported to the external member by supporting piece; and a handling member coupled to the internal member for rotating the internal member of the roller head, the micro needles, the external cylindrical member and the internal member being made of polymer resin.

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MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Description

MICRO NEDDLE ROLLER ASSEMBLY

Technical Field

[1] The present invention relates to a micro needle roller assembly, more particularly, to a micro needle roller assembly utilized for delivering drug through a skin tissue.

[2]

Background Art

[3] In general, in the method for transdermal delivery of drug, drug is difficult to penetrate stratum corneum, and so an absorptance of drug is extremely low. In particular, the larger a molecular weight of drug is, the less a drug absorptance becomes. In order to remove the aforementioned problem, the technology utilizing micro needles has been proposed. In this technology, channels penetrating a portion or all of epidermis of the skin are formed by the micro needles and drug is then delivered to the epidermis of the skin or a underlayer of the epidermis through the channels.

[4]

[5] According to the above technology utilizing micro needles, the drug having a large molecular weight, such as insulin, hormone medicine and the like can be easily delivered. In addition, once the micro needles penetrate and stimulate the dermis of the skin, a burn or a scar can be naturally healed. Also, a generation of the collagen is induced so that it is possible to improve the skin tone and maximize an anti-aging effect.

[6]

[7] In current, a micro needle roller is utilized as a channel forming means. The micro needle roller comprises a cylindrical roller head on which a plurality of micro needles are formed, the micro needles form a plurality of channels on the skin when the roller head is rotated. Examples of the micro needle roller are disclosed in WO02/47555, WO02/49711.

[8]

[9] In the above conventional micro needle roller, however, the micro needles are made of stainless steel. And, the micro needles are protruded from an inside of the roller head, and so a space in which the needles can be disposed is limited. Consequently, there is a limit to a reduction of a distance between the needles.

[10]

[11] In general, a linear distance between the needles are approximately 2 mm, it is difficult to reduce the distance between the needles to maximize the treatment effect. In addition, to utilize repeatedly the needle roller, the needle roller should be sterilized.

Also, since the needle roller is made of stainless steel, its manufacturing cost and selling price become high.

[12]

[13] As another related art, the tool for forming channel on skin for delivery drug comprising circular shaped thin plates, each of which having a plurality of skin needles formed at an end portion thereof, spacers, each of which being disposed between the thin plates, a central axis on which the thin plates and the spacers are assembled and reinforcing members mounted to both ends of the central axis is disclosed in Korean Utility Registration No. 115807.

[14]

[15] However, the above tool has the problem that the process for manufacturing this device is complicated so that it is difficult to manufacture the device in large quantities at extremely low cost. For example, the circular shaped thin plates should be alternatively assembled, and so there is a difficulty manufacturing this tool due to the above condition. Accordingly, there are drawbacks that the above tool can not be manufactured through one shot process and a manufacturing time becomes lengthened.

[16]

Disclosure of Invention

Technical Problem

[17] Accordingly, the present invention is conceived to solve the aforementioned problems of the conventional micro roller assembly, an object of the present invention is to provide a micro roller assembly which has a simple structure and is able to shorten a manufacturing time and can be manufactured in a mass production manner with a low manufacturing cost.

[18]

[19] Another object of the present invention is to provide a micro needle roller assembly which can enhance the drug transdermal delivery efficiency due to a narrow distance between needles.

[20]

Technical Solution

[21] In order to achieve the above objects, a micro needle roller assembly according to the present invention comprises a roller head including an external cylindrical member having a plurality of micro needles mounted on a surface thereof and an internal member placed in the external member and supported to the external member by supporting piece; and a handling member coupled to the internal member for rotating the internal member of the roller head; the micro needles, the external cylindrical member and the internal member being made of polymer resin.

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[22]

[23] Here, the internal member is a hollow cylindrical member and the supporting pieces are extended in a radial direction of the internal member. Also, the internal member has cylindrical shaped receiving spaces formed at both end portions thereof.

[24]

[25] The micro needles, the external cylindrical member and the internal member are made of polymer resin such thermosetting resin or thermoplastic resin and can be formed integrally with each other.

[26]

[27] On the other hand, the handling member comprises a gripper; first and second connecting arms extended from the gripper; and protrusions formed on inner surfaces of the first and second connecting arms, the protrusions being received in the receiving spaces formed at both end portions of the internal member of the roller head.

[28]

[29] Also, the external member of the roller head has grooves formed on a surface thereof, the roller head comprises needle blocks having needles formed thereon, and the needle blocks are received in the grooves.

[30]

[31] Here, the groove is extended in the longitudinal direction of the external member and has an upper portion and a lower portion having a width larger than that of the upper portion, and the needle block has a sectional shape that is the same as that of the groove.

[32]

[33] In particular, the grooves can be formed in parallel to an axis of the external cylindrical member. On the contrary, the grooves are inclined at a certain angle with respect to an axis of the external cylindrical member.

[34]

[35] The micro needle roller assembly according to the present invention can further comprises side covers fixed to both side ends of the roller head, each side cover has an opening corresponding to the internal member.

[36]

[37] The micro needle roller assembly according to the present invention can further comprises a vibration generating means and a power electric source received in a space formed in the gripper of the handling member.

[38]

[39] The micro needle roller assembly according to the present invention may further comprise a cover fixed to the gripper and placed on the roller head.

[40]

Advantageous Effects

[41] Since all structural members, that is, the cylindrical external member and a plurality of needles formed on an outer surface of the external member and the internal member coupled to the external member by the supporting pieces are made of polymer resin and formed integrally with each other, the micro needle roller assembly according to the present invention can be simply manufactured by only once injection forming process.

[42]

[43] In addition, in the micro needle roller assembly according to the present invention, the needle blocks on which the micro needles are formed and the roller head are separately manufactured and then assembled to each other. Accordingly, after the needle blocks that were contacted with the user's skin are detached from the roller head, new needle blocks are be then mounted to the roller head so that the roller head and the handling member can be repeatedly utilized.

[44]

[45] Further, a plurality of needles having the different size (diameter and height) can be formed the needle blocks, respectively, and so the user can select the needle block having a desired sized needles on the basis of the kind of drug, a dosage of drug and a part of the body to which the drug is applied, and then mount the selected needle block to the roller head.

[46]

[47] In particular, since the micro needle roller assembly according to the present invention comprises a vibration generating means, the micro needles pierces effectively skin due to a vibration transmitted to the roller head so that the drug delivery effect is increased, the skin tissue is activated and a circulation of blood can be expedited.

[48]

[49] In addition, when the micro needles pierce the skin, blood spurted from channels formed by the needles is blocked by the cover placed on the roller head, and so the use can use sanitarily the micro roller assembly.

[50]

[51] In particular, the skin can become soft by infrared ray radiated from the infrared ray-generating device to stimulate the skin contacted with the micro needles. Accordingly, the drug may be delivered in the skin to enhance remarkably a treatment effect.

[52]

Brief Description of the Drawings

[53] The above and other objects, features and advantages of the present invention will

become apparent from the following description of preferred embodiments given in conjunction with the accompanying drawings, in which:

[54] FIG. 1 is a perspective view of a micro needle roller assembly according to the first embodiment of the present invention;

[55] FIG. 2 is an exploded perspective view of the micro needle roller assembly according to the first embodiment of the present invention;

[56] FIG. 3 is a perspective view of the micro needle roller assembly according to the second embodiment of the present invention;

[57] FIG. 4 is an exploded perspective view of the micro needle roller assembly according to the second embodiment of the present invention;

[58] FIG. 5 is a perspective view of a needle block to be coupled with a roller head shown in FIG. 4;

[59] FIG. 6 is a perspective view of a modified example of the roller head shown in FIG. 4;

[60] FIG. 7 is a perspective view of the micro needle roller assembly according to the third embodiment of the present invention;

[61] FIG. 8 is a sectional view of a handling member shown in FIG. 7;

[62] FIG. 9 is a perspective view of a motor and a vibration generating member utilized in the micro needle roller assembly according to the third embodiment of the present invention;

[63] FIG. 10 is a perspective view of the micro needle roller assembly and shows that the cover is mounted to the roller head shown in FIG. 7;

[64] FIG. 11 is a partial perspective view showing a state where the cover is detached from the roller head shown in FIG. 10;

[65] FIG. 12 and FIG. 13 are perspective views of the micro needles assemblies and shows the cover having the different shapes is mounted to the roller head; and

[66] FIG. 14 is a plane view of the handling member in which an infrared ray-generating device is provided.

[67]

Best Mode for Carrying Out the Invention

[68] Hereinafter, the micro needle roller assembly according to the preferred embodiments of the present invention will be described in more detail with reference to the accompanying drawings.

[69]

[70] First embodiment

[71] FIG. 1 is a perspective view of a micro needle roller assembly according to the first embodiment of the present invention and FIG. 2 is an exploded perspective view of a

micro needle roller assembly according to the first embodiment of the present invention.

[72]

[73] Referring to FIG. 1 and FIG. 2, a micro needle roller assembly 100 (hereinafter, referred to as "needle roller assembly" comprise a roller head 120 and a handling member 110.

[74]

[75] The roller head 120 comprises an external hollow cylindrical member 121 (hereinafter, referred to as "external member") and an internal hollow member 122 (hereinafter, referred to as "internal member") placed in the external member 121. The internal member 122 is supported to the external member 121 by a plurality of supporting pieces 123 fixed thereto and extended in a radial direction. The number of the supporting pieces 123 and a length of each supporting piece are not limited. However, it is preferred that a length of each supporting piece 123 is the same as that of the external member 121 so as to prevent the external member 121 from being transformed when the force is applied to the external member.

[76]

[77] The external member 121 and the internal member 122 are coaxially disposed and a shape of the internal member is not limited to a specific one. A receiving space 124 of the internal member 122 is utilized as a space for receiving a specific member constituting the handling member 110 described below.

[78]

[79] A plurality of micro needles 125 (hereinafter, referred to as "needle" are formed on an outer surface of the external member 121. Preferably, the external member 121and the needles 125 of the roller head 120 are formed integrally with each other and made of polymer resin such as thermosetting resin including epoxy resin, phenol resin, polyurethane resin or thermoplastic resin including PC (polycarbonate), PEI (polyetherimide), PMMA (polymethylmethacrylate), POM (polyacetal), PLA (polylatide), PSU (polysulfone) and the like.

[80]

[81] Here, it is preferred to use biodegradable polymer, for example PLA (polylatide), PLGA (poly lactic-co-glycolic acid) as polymer resin. Due to the above material, if the needle 125 is remained in the skin, the needle made of the above mentioned material does not harm human being and can be dissolved in short time,

[82]

[83] Each needle 125 is protruded from an outer surface of the external member 121 with a certain height. A height of the needle 125 may be varied according to a usage of the micro needle assembly 100. For example, if the needle 125 penetrates an epidermis to

form a channel reaching a corium layer, a height of the needle 125 is in the range from 200 ㎛ to 750㎛.In general, a height of the needle 125 is determined in the range from 20 ㎛ to 2,000㎛, however, a height of the needle can be out of the above range, if necessary.

[84]

[85] On the other hand, the needles 125 can be disposed on an outer surface of the external member 121 with lines at regular intervals. Due to the above structure, the uniform channel distribution can be obtained on a specific area of the skin. However, in order to form a great number of the channels on a specific area of the skin through the needles 125, it is desirable to make narrow a distance between the lines constituting the needles 125 on an outer surface of the external member 121 within the limits of the possible.

[86]

[87] In addition, FIG. 2 shows that each needle 125 has a conical shape. However, a shape of the needle is not limited thereto.

[88]

[89] Unlike the roller head shown in FIG. 3, on the other hand, the roller may be constituted by using only one cylindrical member having a cylindrical space formed at a central portion thereof. However, it is inevitable that the roller head having the above structure has a large volume, and so material mentioned previously is significantly influenced by heat during a forming process for manufacturing the roller head

[90]

[91] In view of the above, the roller head 120 according to this embodiment consists of the internal member 122, the external member 121 and a plurality of supporting pieces 123 connecting both members, and so an entire volume of the roller head is remarkably reduced, whereby it is possible to reduce significantly a transformation caused by heat in the forming process.

[92]

[93] In particular, in micro needle roller assembly according to this embodiment of the present, the cylindrical external member, a plurality of needles formed on an outer surface of the cylindrical external member and the internal member are made of polymer resin and formed integrally with each other, and the roller head can be formed by performing only once injection forming process.

[94]

[95] On the other hand, the handling member 110 comprises a gripper 111 and first and second connecting arms 112 and 113 extended from one end of the gripper to both sides. Free ends of the first and second connecting arms 112 and 113 correspond to both side ends of the internal member 122 of the roller head 120. Cylindrical protrusions 112A and 113A with a certain length are protrudely formed on inner

surfaces of the free end portions of the first and second connecting arms 112 and 113, respectively,

[96]

[97] By inserting the cylindrical protrusions 112A and 113A formed on inner surfaces of the free end portions of the first and second connecting arms 112 and 113 into both side ends of the receiving space 124 of the internal member 122 of the roller head 120, an assembling of the handling member 110 and the roller head 120 is completed.

[98]

[99] A diameter of each of the protrusions 112A and 113A is smaller than that of the receiving space 124 of the internal member 122, and so each of the protrusions 112A and 113A can be rotated in the receiving member of the internal member 122.

[100]

[101] On the other hand, in order to insert easily the protrusions 112A and 113A into the receiving space 124 of the internal member 122 and to inhibit the protrusions 112A and 113A from being taken out of the receiving space 124 after the protrusions are inserted in the receiving space, it is preferred that the first and second arms 112 and 113 of the handling member 110 are made of material having an elasticity.

[102]

[103] Below, the function of the needle roller assembly 100 according to this embodiment constructed as described above is described with reference to the drawings.

[104]

[105] As described above, the protrusions 112A and 113A formed on the first and second connecting arms 112 and 113 of the handling member 110 are inserted into both end portions of the receiving space 124 of the internal member 122 of the roller head 120 to assemble the handling member 110 and the roller head 120.

[106]

[107] Then, the user grips the griper 111 of the handling member 110 and places the exter nal member 121 of the roller head 120 on a skin. At this time, the transdermal drug is already applied on the skin.

[108]

[109] In this state, once the user exerts a force on the gripper 111, the roller head 120 is rotated about the protrusions 112A and 113A received in the receiving space 124 and moved on the skin.

[110]

[111] Due to a rotation and movement of the roller head 120 on the skin, the needles 125 formed on the external member 121 penetrate a portion of epidermis or entire epidermis constituting the skin to form delivery paths (channels) for the transdermal drug. In the above process, the transdermal drug applied on the skin penetrates the skin

through the channel formed by the needles 125.

[112]

[113] On the other hand, as described above, the internal member 122 of the roller head 120 does not have to be formed into a cylindrical shape if the receiving space 124 in which the protrusions 112A and 113A formed on the first and second connecting arms 112 and 113 is received and rotated has a cylindrical shape. In addition, although the above description illustrates that the receiving space 124 is formed along the entire length of the internal member 122, the space can be formed in each of both end portions of the internal member 122.

[114]

[115] Second embodiment

[116] FIG. 3 and FIG. 4 are perspective view and exploded perspective view of a micro needle roller assembly according to the second embodiment of the present invention and show the structure of each of the members constituting the micro needle roller assembly according to the second embodiment of the present invention. .

[117]

[118] Referring to FIG. 3 and FIG. 4, a micro needle roller assembly 200 (hereinafter, referred to as "needle roller assembly") also comprise a roller head 220 and a handling member 210.

[119]

[120] The handling member 210 comprises a gripper 211 and first and second connecting arms 212 and 213 extended from one end of the gripper to both sides. Free ends of the first and second connecting arms 212 and 213 correspond to both side ends of an internal member 222 of the roller head 220. Cylindrical protrusions 212A and 213A with a certain length are protrudely formed on inner surfaces of the free end portions of the first and second connecting arms 212 and 213, respectively,

[121]

[122] A structure and function of each element constituting the handling member 210 are the same as those of each element constituting the handling member 110, and so the description thereof is omitted.

[123]

[124] The roller head 220 in the needle roller assembly 200 according to the present embodiment comprises an external hollow cylindrical member 221 (hereinafter, referred to as "external member" and an internal hollow member 222 (hereinafter, referred to as "internal member" placed in the external member 221. The internal member 222 is supported to the external member 221 by a plurality of supporting pieces 223 fixed thereto and extended in a radial direction.

[125]

[126] A structure and relation of the external member 221 and the internal member 222 in this embodiment are the same as those of the external member and the internal member in the first embodiment, and so the description thereof is omitted.

[127]

[128] In addition, a plurality of needle blocks 230 are mounted on an outer surface of the external member 221 of the roller head 220. Structures of the roller head 200 and needle block are concretely described with reference to FIG. 4 and FIG. 5 as follows.

[129]

[130] As shown in FIG. 4, the roller head 220 consists of the external hollow cylindrical member 221 and the internal hollow member 222, a plurality of grooves 222-1 having a certain length are formed on an outer surface of the external member 121. Both ends of each groove 221-1 are opened, and a width of an upper portion of each groove is smaller than that of a lower portion.

[131]

[132] FIG. 5 is a perspective view of one needle block 230 mounted to needle head 220

[133]

[134] The needle block 230 as shown in FIG. 5 is mounted to on the external cylindrical member 221 constituted as described above.

[135]

[136] The needle block 230 is received in each groove 221-1 formed on an outer surface of the external cylindrical member 221. Accordingly, the needle block 230 and the groove 221-1 formed on the external cylindrical member 221 have the same general cross-sectional shape. That is, a width W2 of a lower portion of the needle block 230 is larger than a width W1 of an upper portion, and so the needle block 230 of the groove 221-1 may not be separated in the radial direction of the external cylindrical member 221. On the other hand, a height of each needle block 230 is the same as a depth of each groove 221-1 and a plurality of needles 225 are disposed on an upper surface of the needle block 230.

[137]

[138] The needle block 230 and the needles 225 can be formed integrally with each other and made of polymer resin such as epoxy resin, phenol resin, polyurethane resin or thermoplastic resin such as PC (polycarbonate), PEI (polyetherimide), PMMA (polymethylmethacrylate), POM (polyacetal), PLA (polylatide), PSU (polysulfone) and the like.

[139]

[140] Here, it is preferred to use biodegradable polymer, for example PLA (polylatide), PLGA (poly lactic-co-glycolic acid) as polymer resin. Due to the above material, if the needle 225 separated from the needle block 230 is remained in the skin, the needle

made of the above mentioned material does not harm human being and can be dissolved in short time,

[141]

[142] Each needle 225 is protruded from an outer surface of the needle block 230 with a certain height. A height of the needle 225 may be varied according to a usage of the micro needle assembly 200. For example, if the needle 225 penetrates an epidermis to form a channel reaching a corium layer, a height of the needle 225 is in the range from 200 □ to 750□.In general, a height of the needle 225 is determined in the range from 20 □ to 2,000□, however, a height of the needle can be out of the above range, if necessary.

[143]

[144] Here, the needles 225 can be disposed on the needle block 230 at regular intervals. Due to the above structure, the uniform channel distribution can be obtained on a specific area of the skin. However, in order to form a great number of the channels on a specific area of the skin through the needles 225, it is desirable to make narrow a distance between the needles 225 on the needle block 225. In addition, FIG. 5 shows that each needle 225 has a conical shape. However, a shape of the needle is not limited thereto.

[145]

[146] As shown in FIG. 4, on the other hand, side covers 240 and 250 are mounted to both sides of the external member 221 for preventing the needle blocks 230 from being separated in an axial direction of the external member 221. Diameter of the side covers 240 and 250 are the same as that of the external member 221.

[147]

[148] Once the side covers 240 and 250 are fixed to both sides of the external member 221, both end portions of the internal member 224 are exposed through openings 241 and 251 formed at central portions of the side covers 240 and 250 and both opened side ends of each groove 221-1 correspond to the side covers 240 and 250, respectively. In this state, the needle blocks 230 received in the grooves 221-1 can not be separated from the grooves by the side cover 240 or 250.

[149]

[150] Below, an assembling process and a function of the needle roller assembly 200 according to this embodiment are described with reference to the drawing.

[151]

[152] First, each of the needle blocks 230 is slid and inserted in respective groove 221-1 through an opened end of the groove 221-1 by pushing the needle block 230, and the side covers 240 and 250 are then fixed to both side end portions of the external member 221, respectively, after all the needle blocks are inserted in the grooves.

[153]

[154] In this state, the protrusions 212A and 213A formed on the first and second connecting arms 212 and 213 of the handling member 210 are inserted into both end portions of the receiving space 224 of the internal member 222 of the roller head 120 exposed out of the side covers 240 and 250 to assemble the handling member 210 and the roller head 220.

[155]

[156] Thereafter, the user grips the gripper 211 of the handling member 210 and places the external member 221 of the roller head 220 on a skin. In this state, once the users exerts a force to the gripper 221, the external member 221 is rotated about the protrusi ons 212A and 213A received in the receiving space 224 and moved on the skin.

[157]

[158] The subsequent process and the function are the same as those of the needle roller assembly 100 according to the first embodiment, and so a detailed description thereto is omitted.

[159]

[160] On the other hand, in a state where only one side cover (for example, 250) is fixed to one side end portion of the external member 221, the needle blocks 230 can be slid and inserted in the grooves 221-1 through opened ends of the groove 221-1 to which the side cover is not fixed. Then, another side cover (for example, 240) can be fixed to the other end portion of the external member 221 to complete an assembly of the roller head.

[161]

[162] FIG. 6 is a perspective view of the modified example of the roller head shown in FIG. 4. Unlike the roller head 220 consisting of the external member 221 and the internal member 222 as shown in FIG. 4, single cylindrical member 221A having an axial through-passage 224A is formed at a central portion thereof can be utilized as the roller head 220A.

[163]

[164] In a case where single cylindrical member 221A is used as the roller head 220A, a plurality of grooves 221A-1 are formed on an outer surface of the cylindrical member 221A.

[165]

[166] At this time, although the grooves 221A-1 can be formed in parallel to an axis of the cylindrical member 221A, each groove 221A-1 can be inclined at a certain angle with respect to an axis of the cylindrical member 221A as shown in FIG. 6. The needle blocks 230 are mounted to the needle block 200A having the structure as described above.

[167]

[168] In the roller head 220A having the structure as shown in FIG. 6, on the other hand, due to a curved outer surface of the cylindrical member 221A, the grooves 221A-1 inclined at a certain angle with respect to an axis of the cylindrical member 221A has a longitudinal sectional shape which is rounded along the entire length thereof. As described above, however, since the needle block 230 is made of flexible resin material, although the groove 221A-1 has any shape, the needle block 230 having the elasticity can be smoothly inserted and received in the groove 221A-1.

[169]

[170] Here, in the roller head 220 shown in FIG. 4, since the needle blocks 230 are disposed on the external member 221 at regular intervals, rows of the needles 225 are also disposed at regular intervals. In the roller head 220A having the structure shown in FIG. 6, however, each needle block 230 is inclinedly disposed with respect to the axis of the cylindrical member 221A so that the needles 225 are irregularly arranged on the roller head 220A.

[171]

[172] Due to the above arrangement of the needles, in the needles formed on the same needle block 230, some of the needles penetrate the skin and the rest of the needles do not penetrate the skin. Accordingly, the roller head 220A can be smoothly rotated without generating a large resistance between the needle block and the skin.

[173]

[174] Although not shown in the drawing, on the other hand, the side covers 240 and 250 shown in FIG. 4 are fixed to both sides of the roller head 200A to prevent the needle block 230 from be separated from the roller head 200A.

[175]

[176] Third embodiment

[177] A micro needle roller assembly (hereinafter, referred to as "needle roller assembly" according to the third embodiment of the present invention is described as follows.

[178]

[179] FIG. 7 is a perspective view of a needle roller assembly according to the third embodiment of the present invention, a needle roller assembly 300 according the third embodiment of the present invention also comprises a roller head 320 and a handling member 310.

[180]

[181] A structure and function of the roller head 320 in this embodiment are the same as those of the roller heads 220 and 220A according to the second embodiment, and so the description thereof is omitted.

[182]

[183] In addition, a structure and function of needles 325 mounted to the roller head 320 in

this embodiment are the same as those of the needles 125 and 225 mounted to the roller heads 120, 220 and 220A of the needle roller assemblies 100 and 200 according to the first and second embodiments, and so the description thereof is omitted.

[184]

[185] Major feature of the needle roller assembly 300 according to the third embodiment of the present invention is the structure which can apply a vibration to the roller head 320 contacted with a skin to enhance the ability to penetrate the skin.

[186]

[187] Below, the needle roller assembly 300 having the above function is described in more detail.

[188]

[189] FIG. 8 is a sectional view of the handling member 310 shown in FIG. 7, the handling member 310 comprises a gripper 411 and first and second connecting arms 412 and 413 extended from one end of the gripper 311 to both sides. Free ends of the first and second connecting arms 312 and 313 correspond to both side ends of the roller head 320. Cylindrical protrusions 312A and 313A (shown in FIG. 15) with a certain length are protrudely formed on inner surfaces of the free end portions of the first and second connecting arms 312 and 313, respectively,

[190]

[191] As shown in FIG. 8, an end portion of the gripper 311, that is, a portion adjacent to the first and second connecting arms 312 and 313 is inclined upward, a recess 311-A with a certain depth is formed on the inclined portion. When the user uses the needle roller assembly 300, the user s finger is placed in the recess 311-1 formed on a front end portion of the gripper 311 so that the user can stably apply a force to the gripper 311.

[192]

[193] As shown in FIG. 8, a space 311-2 with a certain volume can be formed in the gripper 311, a vibration generating means 330, a circuit section 340 and an electric power source 350 are accommodated in this space 311-2. A structure and function of the vibration generating means, the circuit section and the electric power source are described below.

[194]

[195] FIG. 9 is a view illustrating the vibration generating means constituting the needle roller assembly according to the third embodiment of the present invention, the vibration generating means 330 comprises a driving motor 331 and an eccentric weight 333.

[196]

[197] As shown in FIG. 9, a connecting aperture 333-1 of the eccentric weight 333 to

which a driving shaft 3331-1 of the driving motor 331 is biased to one side, and so a vibration is generated when the eccentric weight 333 is rotated according to a drive of the driving motor 331.

[198]

[199] The vibration caused by the eccentric weight 333 is transmitted to the roller head 320 connected to the gripper 311 through the first and second connecting arms 312 and 313. Accordingly, the vibration is transmitted to the needles 325 mounted to the roller head 320 to make the needles 325 pierces easily the skin. Consequently, the drug penetrates effectively the skin.

[200]

[201] In addition, the vibrating needles 325 stimulate the skin to activate a skin tissue and expedite a circulation of the blood, and so the drug penetrating in the skin can be effectively spread.

[202]

[203] The circuit section 340 provided in the space 311-2 of the gripper 311 is electrically connected to the driving motor 331, a switch 341 (for example, a slide switch) connected to the circuit section 340 is slidably installed on an outer surface of the gripper 311. Thus, according to a movement of the switch 341, a flow of electric power to the driving motor 331 of the vibration generating means 330 is controlled through the circuit section 340.

[204]

[205] The electric power source 350 (for example, a battery) is provided in the space 311-2 of the gripper 311, this electric power source 350 is electrically connected to the circuit section 340. According to an operation of the switch 341 described above, an electric power of the electric power source 350 is applied to the driving motor 331 of the vibration generating means 330 via the circuit section 340.

[206]

[207] On the other hand, the needle roller assembly 300 according to the third embodiment of the present invention can further comprises a light emitting diode (LED) 360 provided on an outer surface of the gripper 311. For example, the LED 360 is electrically connected to the circuit section 340 and the driving motor 331 in series. Once the electric power is applied to the driving motor 331 through the circuit section 340, the LED 360 emits the light, and so the user can visually verify that the electric power is supplied to the driving motor 331.

[208]

[209] FIG. 10 is a perspective view of the needle roller assembly showing that a cover 380 is mounted to the roller head 320 shown in FIG. 7 and FIG. 11 is a partial perspective view showing a state where the cover 380 is detached from the roller head 320 shown

in FIG. 10.

[210]

[211] As described above, when the roller head 320 to which the needles 325 are mounted pressurizes the skin and is moved, blood can be spurted from channels formed by the needles 325. The cover 380 provided on the roller head 320 prevents blood from being splashed to an outside.

[212]

[213] As shown in the drawing, the cover 380 comprises a hollow semi-cylindrical sheet 382, an extension piece 384 extended from the sheet 382 and a bending piece 386 formed at a rear end portion of the extension piece 384. A width of the sheet 382 is the same as that of the roller head 320.

[214]

[215] On the other hand, a slit 311-3 with a certain width is formed on a front portion of the gripper 311 adjacent to the first and second connecting arms 312 and 313, the bending piece 386 of the cover 380 is inserted in this slit 311-3. Accordingly, the hollow semi-cylindrical sheet 382 of the cover 380 covers a portion of the roller head 320 except a lower side corresponding to the user's skin.

[216]

[217] FIG. 12 is a perspective view of the micro needles assembly and shows that a cover 380A is mounted to the roller head 320.

[218]

[219] The cover 380A shown in FIG. 12 comprises a hollow semi-cylindrical sheet 382A, an extension piece 384A extended from the sheet 382A and a bending piece (not shown) formed at a rear end portion of the extension piece 384A. Supporting bars 388A with a certain length are fixed to both sides of the sheet 382A, the supporting bars 388A are contacted with upper surfaces of the first and second connecting arms 312 (in FIG. 12, only one supporting bar 388A and only one connecting arm 312 are shown).

[220]

[221] The supporting bars 388A prevents the sheet 382A of the cover 380A from being contacted with the roller head 320, and so the roller head 320 can be smoothly rotated and moved without any obstruction caused by the sheet 382A.

[222]

[223] FIG. 13 is a perspective view of the micro needles assembly and shows that a cover 380B is mounted to the roller head 320. The cover 380B shown in FIG. 13 also comprises a hollow semi-cylindrical sheet 382B, an extension piece 384B extended from the sheet 382B and a bending piece (not shown) formed at a rear end portion of the extension piece 384B.

[224]

[225] Hooks 388B with a certain length are fixed to both sides of the sheet 382B, the hooks 388B are coupled to the first and second connecting arms 312 (in FIG. 13, only one hook 388B and only one connecting arm 312 are shown).

[226]

[227] The hooks 388B prevents the sheet 382B of the cover 380B from being contacted with the roller head 320, and so the roller head 320 can be smoothly rotated and moved without any obstruction caused by the sheet 382B.

[228]

[229] On the other hand, grooves (not shown in the drawing) with a certain depth can be formed on upper surfaces of the first and second connecting arms 312, respectively, and each of these grooves corresponds to each hook. When the cover 380B is coupled to the roller head 320, the hooks 388B are received in the grooves formed on the upper surfaces of the first and second connecting arms 312, respectively, and so the hooks 388B can not be separated from the first and second connecting arms 312. Consequently, the cover 380B is stably placed on the roller head 320.

[230]

[231] It is preferably that the covers 380, 380A and 380B described above is made of transparent material for enabling the user to verify visually whether blood is oozing from the channel formed by the needles or not. Polycarbonate (PC), polyethylene terephthalate (PET), polymethylmethacrylate (PMMA) and the like can be used as the material for the covers 380, 380A and 380B. Also, the cover can be formed integrally with the gripper.

[232]

[233] On the other hand, the needle roller assembly according to the present invention can further comprise at least one infrared ray-generating device. FIG. 14 is a plane view of the handling member in which the infrared ray-generating devices are mounted. For the convenience's sake, the roller head is not shown in FIG. 14.

[234]

[235] The infrared ray-generating devices 392 and 393 are provided on inner surfaces of the first and second connecting arms 312 and 313 to be coupled to the roller head (320 in FIG. 7 to FIG. 13), the infrared ray-generating devices 392 and 393 are electrically connected to the electric power source 350 via the circuit section 340 described above.

[236]

[237] Here, the circuit section 340, the vibration generation means 350 and the infrared ray-generating devices 392 and 393 are electrically and sequentially connected to each other and the circuit section 340 is connected to the vibration generation means 350 through the switch, and so the vibration generation means 350 and the infrared ray-

generating devices 392 and 393 can be simultaneously controlled (that is, turned on/ turned of) by an operation of the switch.

[238]

[239] It is preferable to utilize the infrared ray-generating device radiating far infrared ray with a wavelength of 250 or more as the infrared ray-generating devices 392 and 393. As is generally known, far infrared ray has a high heat action and strong penetration force, and so it is possible to obtain an excellent fomentation effect for circulation of blood by means of far infrared ray. In addition, due to far infrared ray, skin can become soft so that the skin contacted with the needles is stimulated and the drug applied on the skin can easily penetrate the skin.

[240]

[241] In general, far infrared ray radiating material discharged from the infrared ray-generating devices 392, 393 radiates more far infrared ray under a condition of a high temperature, and so it is desirable that the infrared ray-generating devices are heated to a temperature of 40 to 50℃ and then radiate the far infrared ray.

[242]

[243] If far infrared ray of a temperature of 50℃ or more is radiated, it is apprehended that user can get burn in the skin. Accordingly, it is preferable that a temperature sensing sensor (not shown) is provided to control a temperature of far infrared ray to a predetermined value or less.

[244]

[245] Although embodiments have been described with reference to a number of illustrative embodiments thereof, it should be understood that numerous other modifications and embodiments can be devised by those skilled in the art that will fall within the spirit and scope of the principles of this disclosure. More particularly, various variations and modifications are possible in the component parts and/or arrangements of the subject combination arrangement within the scope of the disclosure, the drawings and appended claims. In addition to variations and modifications in the component parts and/or arrangements, alternative uses will also be apparent to those skilled in the art.

[246]

Industrial Applicability

[247] Since all structural members, that is, the cylindrical external member and a plurality of needles formed on an outer surface of the external member and the internal member coupled to the external member by the supporting pieces are made of polymer resin and formed integrally with each other, the micro needle roller assembly according to the present invention can be simply manufactured by only once injection forming

process.

[248]

[249] In addition, in the micro needle roller assembly according to the present invention, the needle blocks on which the micro needles are formed and the roller head are separately manufactured and then assembled to each other. Accordingly, after the needle blocks that were contacted with the user's skin are detached from the roller head, new needle blocks are be then mounted to the roller head so that the roller head and the handling member can be repeatedly utilized.

[250]

[251] Further, a plurality of needles having the different size (diameter and height) can be formed the needle blocks, respectively, and so the user can select the needle block having a desired sized needles on the basis of the kind of drug, a dosage of drug and a part of the body to which the drug is applied, and then mount the selected needle block to the roller head.

[252]

[253] In particular, since the micro needle roller assembly according to the present invention comprises a vibration generating means, the micro needles pierces effectively skin due to a vibration transmitted to the roller head so that the drug delivery effect is increased, the skin tissue is activated and a circulation of blood can be expedited.

[254]

[255] In addition, when the micro needles pierce the skin, blood spurted from channels formed by the needles is blocked by the cover placed on the roller head, and so the use can use sanitarily the micro roller assembly.

[256]

[257] In particular, the skin can become soft by infrared ray radiated from the infrared ray-generating device to stimulate the skin contacted with the micro needles. Accordingly, the drug may be delivered in the skin to enhance remarkably a treatment effect.

[258]

[259]

Claims

[1] A micro needle roller assembly, comprising;
a roller head including an external cylindrical member having a plurality of micro needles mounted on a surface thereof and an internal member placed in the external member and supported to the external member by supporting pieces; and
a handling member coupled to the internal member for rotating the internal member of the roller head;
the micro needles, the external cylindrical member and the internal member being made of polymer resin.

[2] The micro needle roller assembly according to claim 1, wherein the internal member is a hollow cylindrical member and the supporting pieces are extended in a radial direction of the internal member.

[3] The micro needle roller assembly according to claim 1, wherein the internal member has cylindrical shaped receiving spaces formed at both end portions thereof.

[4] The micro needle roller assembly according to claim 1, wherein the supporting piece has the length that is the same as that of the external member to prevent the external member from being transformed.

[5] The micro needle roller assembly according to claim 1, wherein polymer resin is one of thermosetting resin and thermoplastic resin.

[6] The micro needle roller assembly according to claim 1, wherein polymer resin is biodegradable polymer.

[7] The micro needle roller assembly according to claim 1, wherein the micro needles, the external member, the supporting pieces and the internal member are formed integrally with each other.

[8] The micro needle roller assembly according to claim 1, wherein the handling member comprises;
a gripper;
first and second connecting arms extended from the gripper; and
protrusions formed on inner surfaces of the first and second connecting arms, the protrusions being received in the receiving spaces formed at both end portions of the internal member of the roller head.

[9] The micro needle roller assembly according to claim 1, wherein the external member of the roller head has grooves formed on a surface thereof, the roller head comprises needle blocks having needles formed thereon, and the needle blocks are received in the grooves.

[10] The micro needle roller assembly according to claim 9, wherein the groove is

extended in the longitudinal direction of the external member and has an upper portion and a lower portion having a width larger than that of the upper portion, and the needle block has a sectional shape that is the same as that of the groove.

[11] The micro needle roller assembly according to claim 9, wherein the needles and the needle block are formed integrally with each other and made from the same material from which the external member is made.

[12] The micro needle roller assembly according to claim 10, wherein the grooves are formed in parallel to an axis of the external cylindrical member.

[13] The micro needle roller assembly according to claim 10, wherein the grooves are inclined at a certain angle with respect to an axis of the external cylindrical member.

[14] The micro needle roller assembly according to any one of claim 9 to claim 13, further comprising side covers fixed to both side ends of the roller head, each of the side covers having an opening corresponding to the internal member.

[15] The micro needle roller assembly according to claim 1, further comprising a vibration generating means and a power electric source received in a space formed in the gripper of the handling member.

[16] The micro needle roller assembly according to claim 15, wherein the vibration generating means comprises a driving motor connected electrically to the power electric source and an eccentric weight coupled to a driving shaft of the driving motor.

[17] The micro needle roller assembly according to claim 15, further comprising a switch for controlling an electrical connection between the vibration generating means and the power electric source.

[18] The micro needle roller assembly according to claim 17, further comprising at least one infrared ray-generating device being connected to the power electric source via the switch and provided on an inner surface of at least one of the first and second connecting arms.

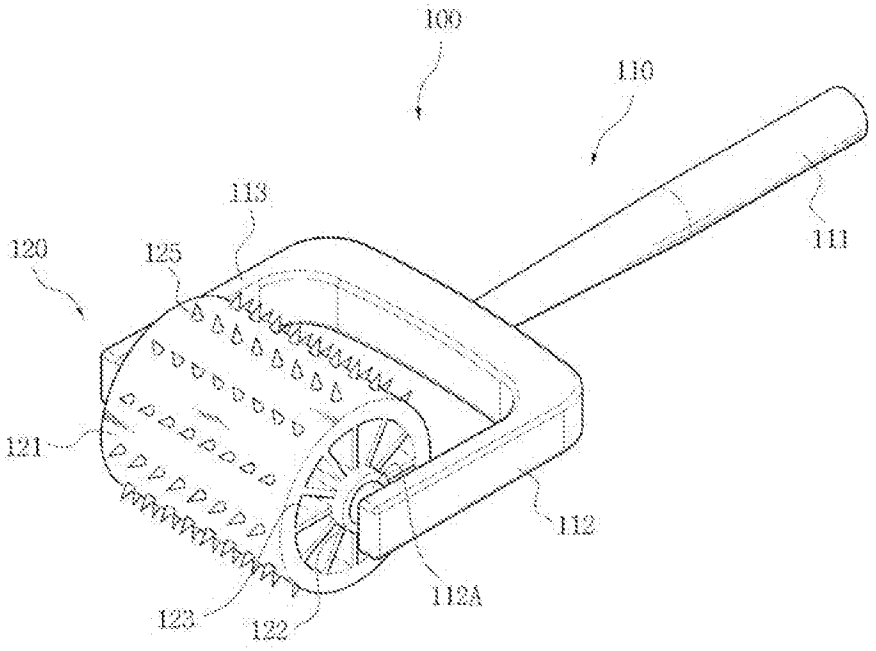
[19] The micro needle roller assembly according to claim 1, wherein the gripper has a recess formed on a surface thereof adjacent to the first and second connecting arms.

[20] The micro needle roller assembly according to claim 1, further comprising a cover fixed to the gripper and placed on the roller head.

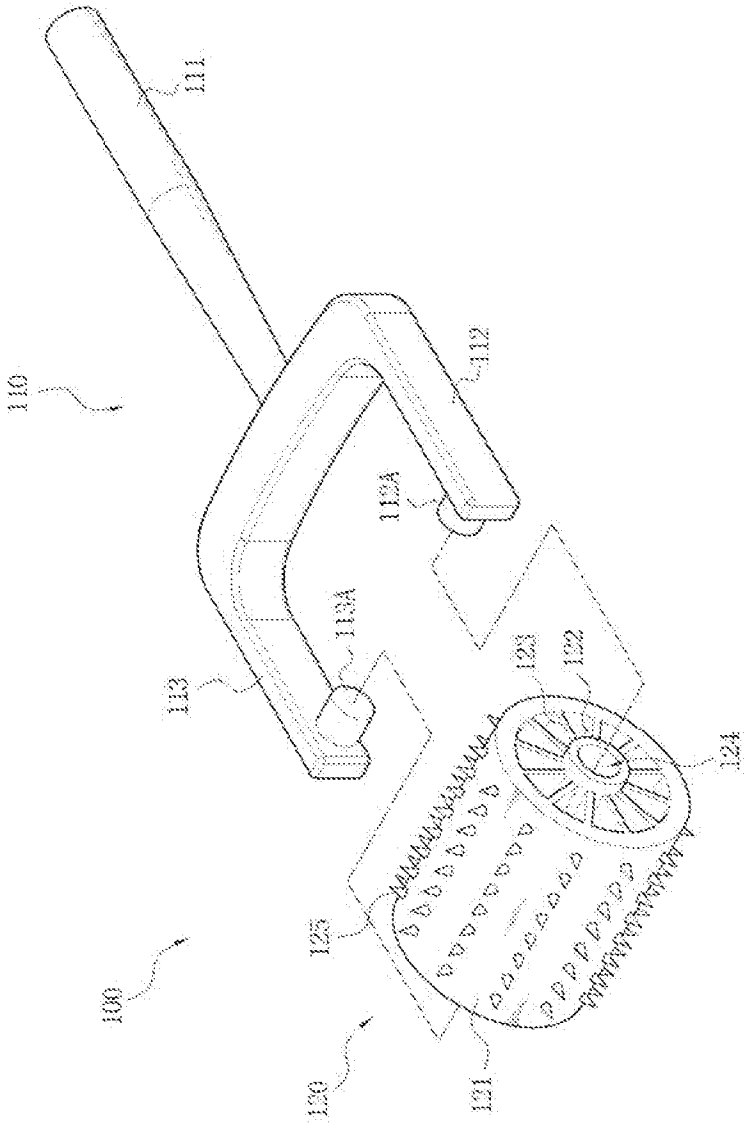
[21] The micro needle roller assembly according to claim 20, wherein the gripper has a slit formed at a portion thereof and the cover comprises a hollow semi-cylindrical sheet, an extension piece extended from the sheet and a bending piece formed at one end portion of the extension piece and inserted in the slit of the gripper.

[22] The micro needle roller assembly according to claim 21, wherein the sheet of the cover has a width which is the same as that of the roller head.

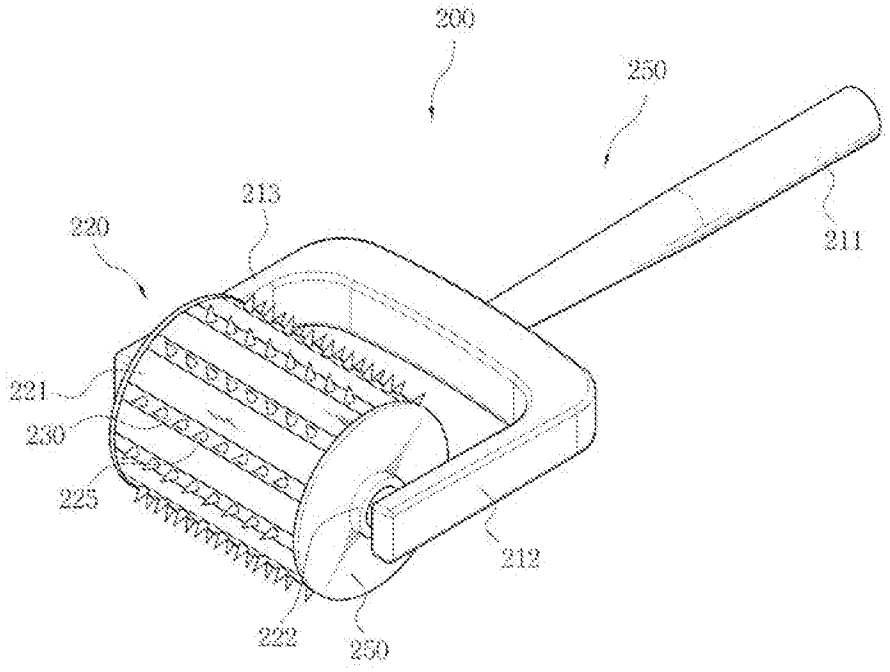
[Fig. 1]



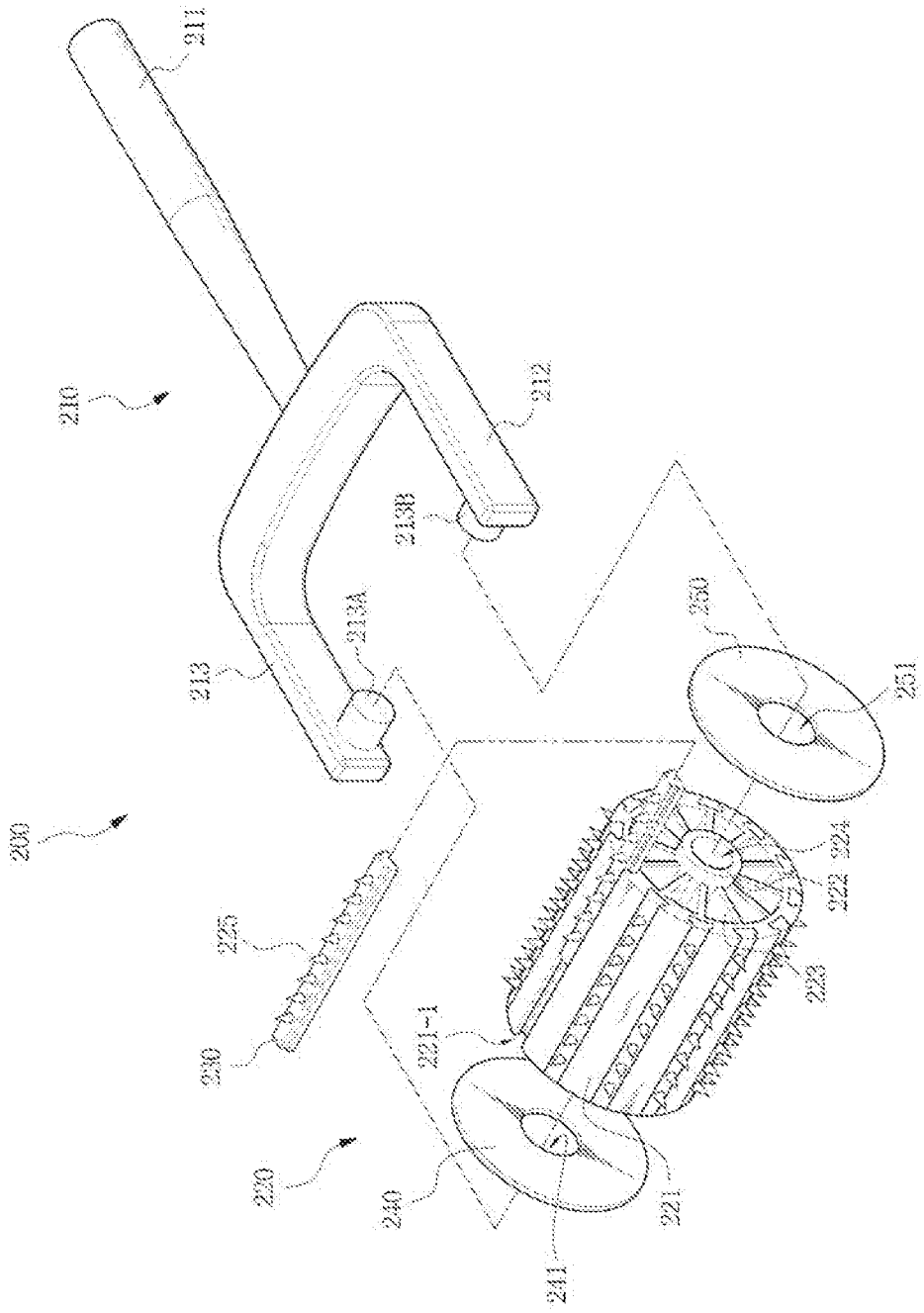
[Fig. 2]



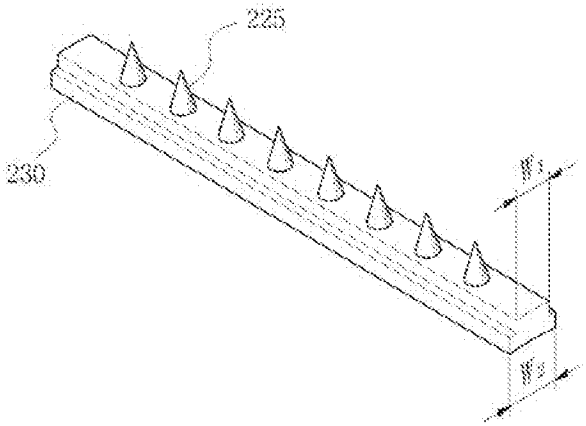
[Fig. 3]



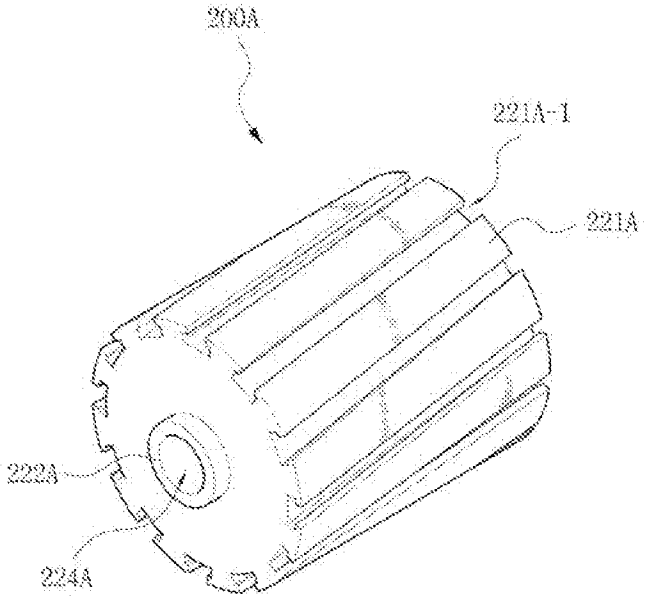
[Fig. 4]


211
210
212
213B
213A
213
250
251
200
224
222
225
223
221-1
230
220
240
221
241

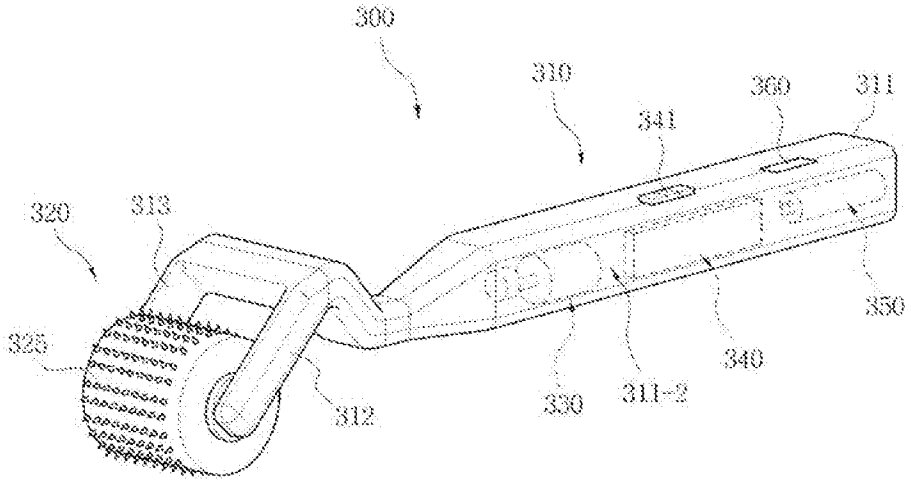
[Fig. 5]



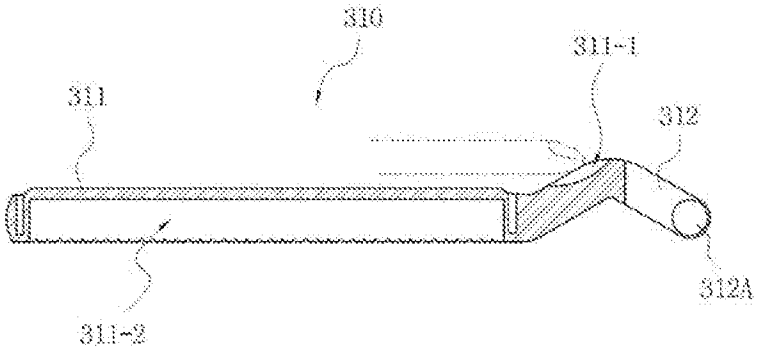
[Fig. 6]



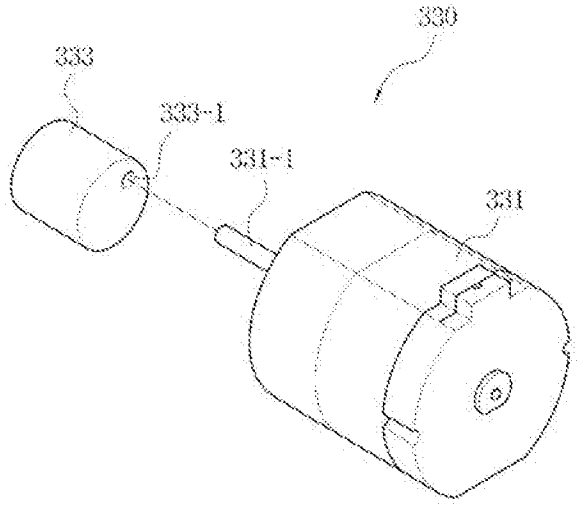
[Fig. 7]



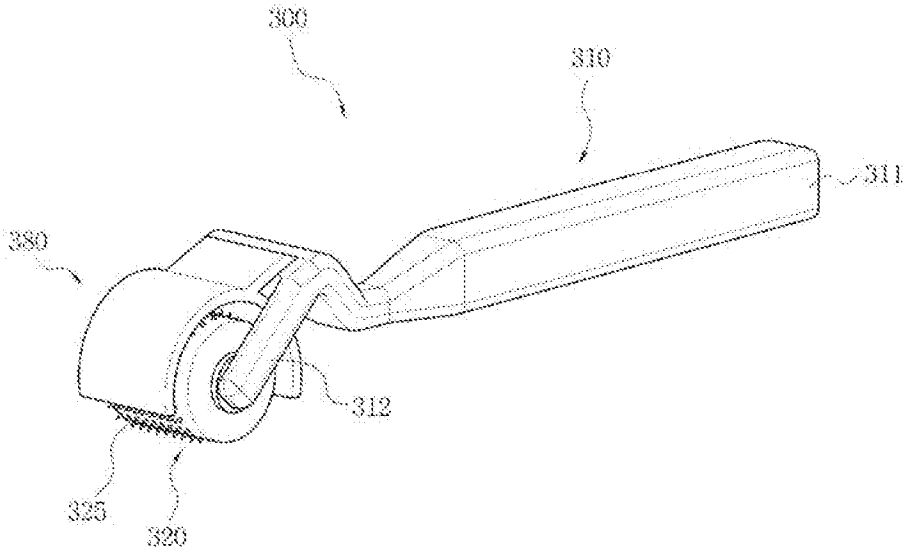
[Fig. 8]



[Fig. 9]



[Fig. 10]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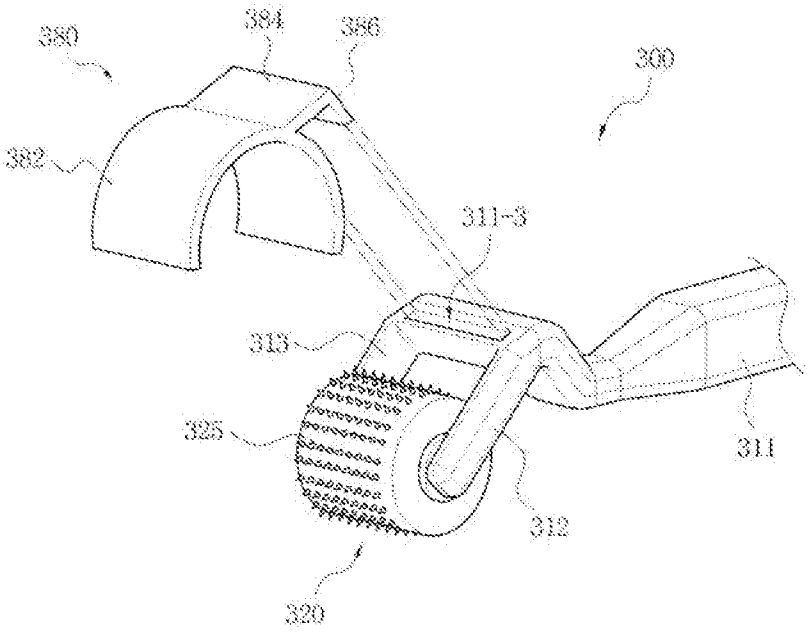
325
320

[Fig. 11]


380
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300
382
311-3
313
325
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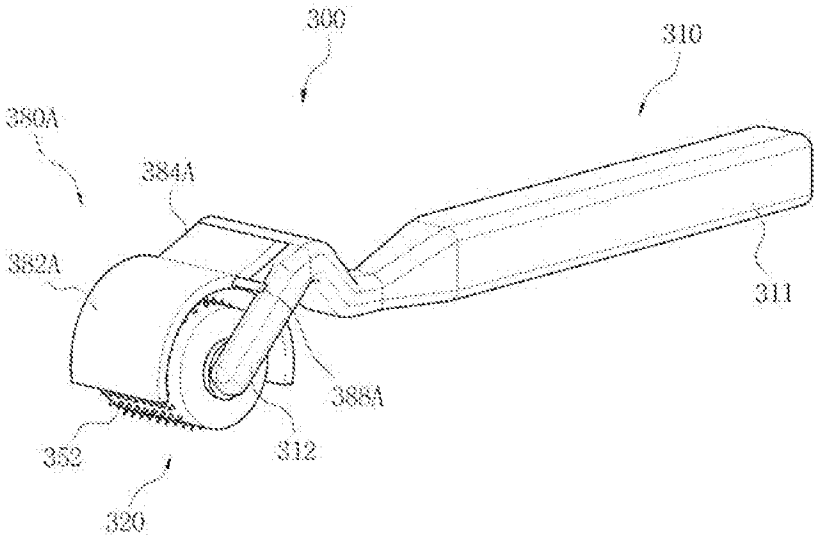
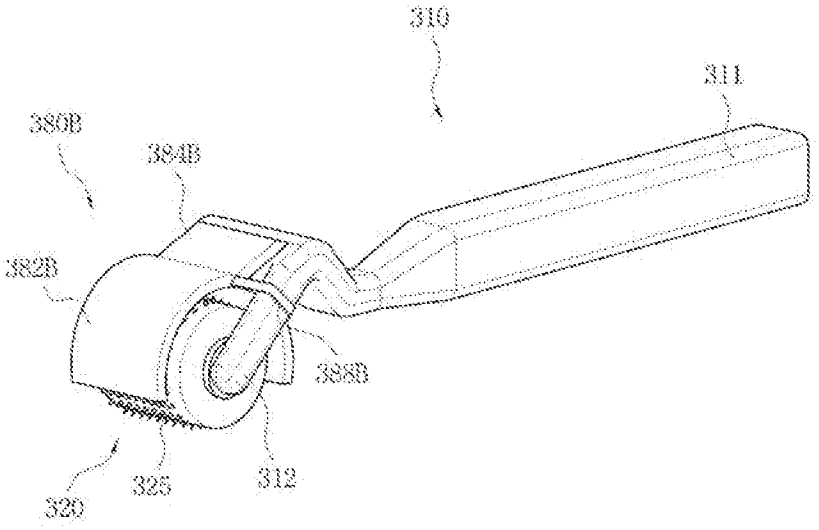
312
320

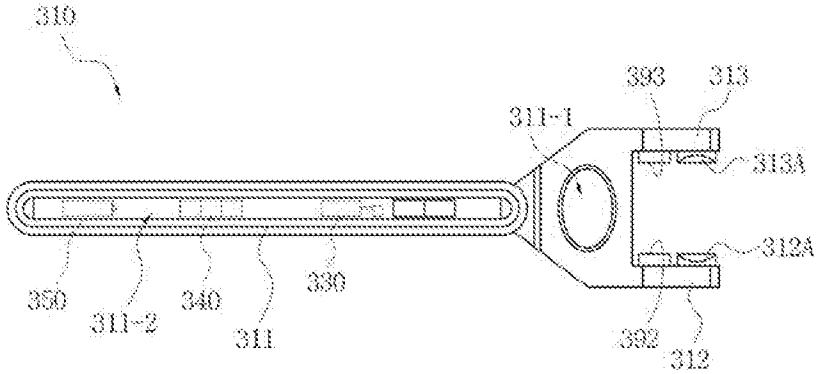
[Fig. 12]



[Fig. 13]



[Fig. 14]



ENDYMED EXHIBIT 1002 - 367/733

INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2007/003121

A. CLASSIFICATION OF SUBJECT MATTER

A61M 37/00(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 8 A61B, A61H 15/00, A61H 15/02

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean Utility Models and Applications for Utility Models since 1975
Japanese Utility Models and Applications for Utility Models since 1975

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKIPASS(KIPO internal), esp@cenet, Delphion "needle, pin, skin, epidermis, drug, and ingredient"

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 02/047555 A3 (FERNANDES, DESMOND, BRIAN) 20 June 2002 See Abstract, Claims 1-16 (Cited in the applications).	1-22
A	WO 02/49711 A1 (UEBL, HORST) 27 June 2002 See Abstract, Fig. 1a-Fig. 3 (Cited in the applications).	1-22
A	WO 2005/082596 A1 (BOONE, MARY, E. et al.) 9 September 2005 See Abstract, Fig. 1A-Fig. 3B.	1-22
A	KR 20-0418106 Y1 (SHIN, HYUN SUGN) 9 June 2006 See Abstract, Fig. 1-Fig. 4.	1-22
P, A	KR 20-0428914 Y1 (HWANG, DEUK SAENG) 17 October 2006 See Abstract, Fig. 1-Fig. 5.	1-22

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 SEPTEMBER 2007 (27.09.2007)	**27 SEPTEMBER 2007 (27.09.2007)**

Name and mailing address of the ISA/KR	Authorized officer
Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea	KIM, Jun Kyung
Facsimile No. 82-42-472-7140	Telephone No. 82-42-481-5558

Form PCT/ISA/210 (second sheet) (April 2007)

ENDYMED EXHIBIT 1002 - 368/733

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/KR2007/003121

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 02/047555 A3	20.06.2002	AU2002225241A1	24.06.2002
		DE20180242U1	02.10.2002
		WO0247555A2	20.06.2002
		WO2002047555B1	06.03.2003
WO 02/49711 A1	27.06.2002	AU2002217113A5	01.07.2002
		DE10063634A1	11.07.2002
		DE10063634B4	12.01.2006
		DE20023722U1	24.11.2005
WO 2005/082536 A1	09.09.2005	EP1716452A1	08.11.2006
		US20060159396A1	20.07.2006
		US2007019176 1A1	16.08.2007
KR 20-0418106 Y1	09.06.2006	None	
KR 20-0428914 Y1	17.10.2006.	None	

Form PCT/ISA/210 (patent family annex) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2012/001335

A. CLASSIFICATION OF SUBJECT MATTER

A61N 1/30(2006.01)i, A61H 23/02(2006.01)i, A61M 37/00(2006.01)i, A61N 5/06(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N 1/30; A61B 18/00; A61H 15/00; A61B 18/20; A61H 39/08; A61N 1/00; A61N 1/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean Utility models and applications for Utility models: IPC as above
Japanese Utility models and applications for Utility models: IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS (KIPO internal) & Keywords: skin, beauty appliance, protrusion, needle, motor, distance, signal, electricity, vibration.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	KR 10-2011-0002210 A (YANG, WON DONG) 07 January 2011 See paragraphs [0024], [0055], [0057], [0062], [0071], [0073]-[0075], [0078], [0095], [0099]-[0100], [0103], [0107] and [0211], claims 1-3, 11 and 14 and figure 4.	1-20
Y	US 2008-0082090 A1 (MANSTEIN, DIETER) 03 April 2008 See paragraphs [0002] and [0036], claims 1, 3-5, 16, 19 and 22-24 and figures 3-5.	1-20
A	KR 10-2010-0018288 A (NA, JONG JU) 17 February 2010 See paragraphs [0030]-[0037] and [0043], claims 3-4 and figures 4-6.	1-20
A	JP 2009-506873 A (THE FOUNDRY, INC.) 19 February 2009 See paragraphs [0053], [0085] and [0088], claims 1-4 and 14-17 and figures 8A-8C.	1-20

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 SEPTEMBER 2012 (28.09.2012)	**28 SEPTEMBER 2012 (28.09.2012)**
Name and mailing address of the ISA/KR Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer Telephone No.

Form PCT/ISA/210 (second sheet) (July 2009)

ENDYMED EXHIBIT 1002 - 370/733

Patent document cited in search report	Publication date	Patent family member	Publication date
KR 10-2011-0002210 A	07.01.2011	NONE	
US 2008-0082090 A1	03.04.2008	AU 2005-231443 A1	20.10.2005
		AU 2005-231470 A1	20.10.2005
		AU 2005-231470 B2	06.10.2011
		CA 2579145 A1	20.10.2005
		CA 2579146 A1	20.10.2005
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		EP 2301471 A1	30.03.2011
		JP 2007-531578 A	08.11.2007
		JP 2007-537781 A	27.12.2007
		JP 4971133 B2	11.07.2012
		US 2005-0222565 A1	06.10.2005
		US 2007-0264288 A1	15.11.2007
		US 2011-0046615 A1	24.02.2011
		US 7824394 B2	02.11.2010
		US 8268332 B2	18.09.2012
		WO 2005-096979 A1	20.10.2005
		WO 2005-096981 A2	20.10.2005
		WO 2005-096981 A3	20.10.2005
		WO 2005-107848 A2	17.11.2005
KR 10-2010-0018288 A	17.02.2010	NONE	
JP 2009-506873 A	19.02.2009	AU 2006-267633 A1	15.03.2007
		AU 2006-267676 A1	15.03.2007
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		EP 1940300 A2	09.07.2008
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		US 2008-0200863 A1	21.08.2008
		US 2008-0200864 A1	21.08.2008
		US 2008-0246654 A1	09.10.2008

ENDYMED EXHIBIT 1002 - 371/733

Patent document cited in search report	Publication date	Patent family member	Publication date
		US 2009-0093737 A1	09.04.2009
		US 2009-0275879 A1	05.11.2009
		US 2009-0275899 A1	05.11.2009
		US 2009-0326439 A1	31.12.2009
		US 2010-0010420 A1	14.01.2010
		US 2010-0228182 A1	09.09.2010
		US 2010-0228207 A1	09.09.2010
		US 2011-0028898 A1	03.02.2011
		US 7588547 B2	15.09.2009
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		WO 2007-030367 A2	15.03.2007
		WO 2007-030367 A3	15.03.2007
		WO 2007-030415 A2	15.03.2007
		WO 2007-030415 A3	20.09.2007
		WO 2009-005980 A2	08.01.2009
		WO 2009-005982 A1	08.01.2009
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		WO 2009-006006 A1	08.01.2009
		WO 2009-006009 A1	08.01.2009
		WO 2009-048969 A1	16.04.2009
		WO 2011-017663 A1	10.02.2011
		WO 2011-149980 A1	01.12.2011
		WO 2011-149984 A1	01.12.2011

ENDYMED EXHIBIT 1002 - 372/733

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	28.09.2012
Applicant's or agent's file reference IP117107-PCT	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/KR2012/001335	22.02.2012	03.03.2011

International Patent Classification (IPC) or both national classification and IPC
A61N1/30(2006.01)i, A61H23/02(2006.01)i, A61M37/00(2006.01)i, A61N5/06(2006.01)i

Applicant
NA, Jongju

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [x] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/KR	Date of completion of this opinion	Authorized officer
Facsimile No		Telephone No

ENDYMED EXHIBIT 1002 - 373/733

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/KR2012/001335

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

ENDYMED EXHIBIT 1002 - 374/733

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/KR2012/001335

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-20	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	None	NO

2. Citations and explanations:

Reference is made to the following documents:

D1: KR 10-2011-0002210 A (YANG, Won Dong) 07 January 2011
D2: US 2008-0082090 A1 (MANSTEIN, Dieter) 03 April 2008
D3: KR 10-2010-0016288 A (LA, Jong Ju) 17 February 2010
D4: JP 2009-506873 A (THE FOUNDRY, INC.) 19 February 2009

(Notice)
The expression of claim 11 of "power is applied by a needle" is interpreted and determined to be expressed as "power is applied to a needle".

2.1. Novelty and Inventive Step

2.1.1. Independent Claims: Claims 1 and 11

Document D1, which is considered to be the closest prior art to the invention as set forth in claims 1 and 11, discloses an electromagnetic wave skin stimulator (see paragraphs [0024], [0055], and [0057]), comprising: a needle body part (300; see paragraphs [0074], [0075] and [0095] and figure 4) having a plurality of needle bodies protruding toward a lower end surface; a needle body

ENDYMED EXHIBIT 1002 - 375/733

driving member (420; see paragraphs [0100] and [0211]) which enables a reciprocating operation by moving the needle body part and is composed of a motor and the like; and an electromagnetic wave generation unit (see paragraphs [0078] and [0103]) for enabling the needle bodies to vibrate by applying electromagnetic waves to the needle bodies. Said electromagnetic wave skin stimulator corresponds to a skin tissue care device comprising a tool, a motor, and a signal generator. Claim 1 pertains to a method for caring skin by driving the skin tissue care device. Thus, claim 1 substantially comprises the same technical feature as claim 11.

The invention of claims 1 and 11 differs from the invention disclosed in document D1 in that a needle is protruded as much as a desired distance from an end surface of the tool by the motor. However, document D2 discloses a skin treatment device for controlling a needle (350) so that the needle protrudes at a required length from a bottom surface of a spacer substrate (315) according to the depth of the needle to be inserted into the skin (see paragraphs [0002] and [0036] and figure 3).

The invention as set forth in claims 1 and 11 would be obviously derived by a person skilled in the art from the combination between the invention disclosed in document D1 and the feature disclosed in document D2. Thus, the invention as set forth in claims 1 and 11 is novel under PCT Article 33(2), but lacks an inventive step under PCT Article 33(3).

2.1.2. Dependent Claims: Claims 2 to 10 and 12 to 20

ENDYMED EXHIBIT 1002 - 376/733

Claims 2 and 3 are dependent on claim 1 and claims 12 and 13 are dependent on claim 11.

A step of loading a cosmetic article on a skin tissue in claim 2 is the same as a step of drilling the skin using the needle body and injecting a drug therein in document D1 (see paragraph [0062]).

An upper knob and a developing type needle assembly coupled detachably with the upper knob in claims 3 and 13, are substantially the same as a knob unit (60) and a needle body attaching/detaching unit (340) in document D1 (see figure 4 and paragraphs [0073], [0074] and [0093]).

Claims 4, 9, and 10 are dependent on claim 3 and claims 14, 19, and 20 are dependent on claim 13.

A needle developing motor and a driving shaft as set forth in claim 4, claim 7 which is dependent on claim 4, claim 14, and claim 17 which is dependent on claim 14, are substantially the same as the motor for constituting the needle body driving member and a crank part/cam part in document D1 (see paragraphs [0100] and [0211]).

A built-in LED as set forth in claim 5, which is dependent on claim 4, and claim 15, which is dependent on claim 14, is substantially the same as an LED and an electromagnetic wave radiation source in document D2 (see claims 16 and 24). Blue and infrared optical signals as set forth in claim 6, which is dependent on claim 5, and claim 16, which is dependent on claim 15, could be simply selected according to an application area for treatment.

A transparent part for transferring the optical signals

ENDYMED EXHIBIT 1002 - 377/733

to the needle in claim 8, which is dependent on claim 5, and claim 18, which is dependent on claim 15, is substantially the same as an optical fiber for playing a role of an optical guide in document D2 (see claims 4 and 5).

A radio frequency (RF) signal generator in claims 9, 10, 19, and 20 is substantially the same as the electromagnetic wave generation unit for generating radio waves in document D1 (see paragraph [0107] and claim 11).

An upper end capable of being coupled with the signal generator in claim 12 is substantially the same as the knob part (60) comprising the electromagnetic wave generation unit in document D1 (see paragraph [0071]).

Thus, the invention as set forth in claims 2 to 10 and 12 to 20 is novel under PCT Article 33(2), but lacks an inventive step under PCT Article 33(3).

2.2. Industrial Applicability

The invention as set forth in claims 1 to 20 is industrially applicable under PCT Article 33(4).

ENDYMED EXHIBIT 1002 - 378/733

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/KR2012/001335

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 11 sets forth the feature in which "power is applied by a needle". However, the feature of providing an electrical signal by supplying power to a needle is set forth in the entire part of the description. The feature in which the power is applied by the needle is not supported by the description and does not meet the requirement of PCT Article 6.

ENDYMED EXHIBIT 1002 - 379/733

INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2012/004695

A. CLASSIFICATION OF SUBJECT MATTER

A61N 1/32(2006.01)i, A61N 1/06(2006.01)i, A61H 39/08(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N 1/32; A61B 18/00; A61N 1/04; A61N 1/00; A61N 1/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean Utility models and applications for Utility models: IPC as above
Japanese Utility models and applications for Utility models: IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS (KIPO internal) & Keywords: noodle, skin, insertion, alternating current, high frequency, bipolar, solidification, Na-effect, NaPlus-effect.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2011-0046615 A1 (MANSTEIN, DIETER) 24 February 2011 See paragraphs [0019], [0031]-[0032], [0039]-[0042], [0056]-[0060], [0062]-[0063], [0073], [0075], and [0077]-[0079]; claims 16 and 25; and figures 3-4.	1-16
A	US 2008-0281389 A1 (KNOPP, PETER G. et al.) 13 November 2008 See paragraphs [0069], [0072], [0092], [0098] and [0121]; claim 96; and figures 2D-2F, 8C-8F and 13A-13B.	1-16
A	US 2006-0293725 A1 (RUBINSKY, BORIS et al.) 28 December 2006 See paragraphs [0062], [0065] and [0085]-[0087]; claims 36, 39-40 and 53-56; and figures 2(c)-2(d).	1-16
A	KR 10-2010-0055292 A (JEJOONG MEDICAL CO., LTD.) 26 May 2010 See paragraphs [0031], [0034]-[0041], [0045] and [0060]-[0066]; claims 1-4, 9 and 12; and figures 1-4.	1-16

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 DECEMBER 2012 (31.12.2012)	**02 JANUARY 2013 (02.01.2013)**
Name and mailing address of the ISA/KR Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer Telephone No.

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PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*: 02.01.2013	
Applicant's or agent's file reference: PCT12-14	FOR FURTHER ACTION: See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/KR2012/004695	14.06.2012	14.06.2011

International Patent Classification (IPC) or both national classification and IPC
A61N1/32(2006.01)i, A61N1/06(2006.01)i, A61H39/08(2006.01)i

Applicant
NA, Jong Ju

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/KR	Date of completion of this opinion	Authorized officer
Facsimile No.		Telephone No.

Form PCT/ISA/237 (cover sheet) (July 2011)

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/KR2012/004695

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/KR2012/004695

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-16	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-16	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-16	YES
	Claims	None	NO

2. Citations and explanations:

Reference is made to the following documents:

D1: US 2011-0046615 A1 (MANSTEIN, DIETER) 24 February 2011

D2: US 2008-0281389 A1 (KNOPP, PETER G., and 1 other individual) 13 November 2008

D3: US 2006-0293725 A1 (RUBKINSKY, BORIS, and 2 other individuals) 28 December 2006

D4: KR 10-2010-0055292 A (JEJOONG MEDICAL CO., LTD.) 26 May 2010

(Comments)

1) In claims 1-7, the term "the plurality of needles" [as Korean transliteration of the term 'needles'] shall be construed as "the plurality of needles", the term "the electricity applied" shall be construed as "the electricity applied to the needles", and the term "the area of the skin treated by the components" shall be construed as "the area of the treated skin subsequent to the treatment".

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2) Claims 13-16 shall be construed to be dependent on claim 5 or claim 7 which discloses application of electricity.

2.1. Novelty and Inventive Step

The invention as set forth in claims 1-7 differs from the inventions as disclosed in the cited documents D1-D4 in that the area of the treated skin achieves the appearance of being burnt by a Ra-effect or Ra plus-effect; and even if the cited documents D1-D4 are taken into consideration, this difference would not have been obvious to a person having ordinary skill in the art to which the present invention pertains. Therefore, it is deemed that the invention as set forth in claims 1-7 is novel and involves an inventive step pursuant to PCT Article 33(2) and (3).

Claims **8-12** are dependent on any one of claims 1-7, and claims **13-16** are dependent on claim 5 or claim 7, and as such, it is deemed that the invention as set forth therein is novel and involves an inventive step pursuant to PCT Article 33(2) and (3).

2.2. Industrial Applicability

It is deemed that the invention as set forth in claims 1-16 of the present application is industrially applicable (PCT Article 33(4)).

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

1) Since the specification of the present application contains incorrect descriptions regarding the drawings as discussed below, the provisions of PCT Rule 5.1(a)(iv) are not complied with.

1)-1. In paragraph [28] of the specification, it is stated that figure 10 shows an example in which a Ra plus-effect is achieved; however, figure 10 shows a method for arranging needles.

1)-2. In paragraphs [39] and [78] of the specification, it is stated that figure 6 shows a configuration in which the skin is burnt by a Ra-effect; however, figure 6 indicates one example of a bipolar electrode arrangement; and in paragraph [78], it is stated that figure 10 shows a configuration in which the skin is burnt; however, figure 10 indicates one example of a bipolar electrode arrangement.

1)-3. In paragraph [80] of the specification, it is stated that figure 7 is related to a polar arrangement of needles; however, figure 7 indicates one example of a configuration of the skin being burnt by a Ra plus-effect.

1)-4. In paragraph [83] of the specification, it is stated that figure 11 is an example of expressing an arrangement of needles; however, figure 11 is a drawing for defining the interval between the needles.

1)-5. In paragraph [105] of the specification figure 12

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Box No. VII Certain defects in the international application

is discussed; however, figure 12 is not a drawing that is appended.

2) According to the provisions of PCT Rule 11.13(l), reference signs not mentioned in the specification shall not appear in the drawings; however, despite the fact that the reference signs 919, 929, 939 are not mentioned in the specification, they appear in figures 7-9. Therefore, the present application does not comply with the provisions of PCT Rule 11.13(l).

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1) Claims 1-7 contain both the recitation "a plurality of needles" and the recitation "the plurality of needles"; however, it is indefinite as to whether the recitations "needles" [as Korean transliteration of the term 'needles'] and "needles" refer to the same constitution or mutually different constitutions, whereby the claimed invention is not definitely defined, and as such, the provisions of PCT Article 6 are not complied with.

2) Claims 1-7 contain the term "the electricity applied" and "to the components"; however, it is indefinite as to what is being referred to thereby, whereby the claimed invention is not definitely defined, and as such, the provisions of PCT Article 6 are not complied with.

3) Claims 13-16 are dependent on any one of claims 1-7, and contain the recitation "the voltage of the electricity applied" or "the application time of the electricity applied"; however, since claims 1-4 and 6 do not contain the recitation of applying electricity, it is indefinite as to what is being referred to thereby, whereby the claimed invention is not definitely defined, and as such, the provisions of PCT Article 6 are not complied with.

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(19)日本国特許庁(JP)　(12)公表特許公報(A)　(11)特許出願公表番号
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(43)公表日　平成21年2月19日(2009.2.19)

(51)Int.Cl.		F I			テーマコード（参考）
A61N 1/06	(2006.01)	A61N	1/06		4C053
A61B 18/00	(2006.01)	A61B	17/36	330	4C160

審査請求 未請求　予備審査請求 未請求　（全 34 頁）

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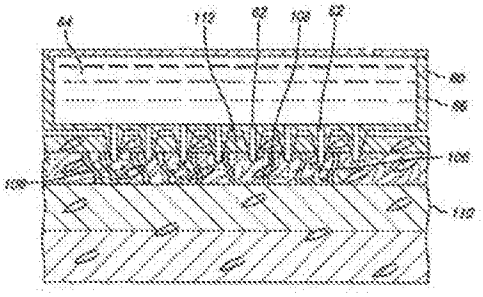
(71)出願人　505418308
ザ　ファウンドリー、　インコーポレイテッド
アメリカ合衆国　カリフォルニア　９４０２５、　メンロパーク、　ジェファーソン　ドライブ　１９９
(74)代理人　100075812
弁理士　吉武　賢次
(74)代理人　100091982
弁理士　永井　浩之
(74)代理人　100096895
弁理士　岡田　淳平
(74)代理人　100117787
弁理士　勝沼　宏仁

最終頁に続く

(54)【発明の名称】皮下構造を破壊するための装置および方法

(57)【要約】
肌の凹凸および過剰な脂肪組織、セルライトおよび瘢痕化のような他の疾患を治療するために、哺乳類の身体の皮下構造を崩壊／破壊するための方法および装置が提供される。この装置および方法は、肌を介して非侵襲的に、より肌を介してより少ない侵襲性で、あるいは皮下アプローチを介して最小限に侵襲的に治療を行うための、エネルギーを伝達する印加装置、極微針、カテーテルおよび皮下の治療装置を備える。手技を援助してかつ改良する様々な薬剤もまた開示されている。



【特許請求の範囲】
【請求項１】
電界発生装置と、
前記電界発生装置と電気的に接続された少なくとも２つの電極と、
治療する皮下組織に治療促進剤の溶液を注入するように構成された注入モジュールと、
を備えることを特徴とする皮下組織を崩壊させるための医療装置。
【請求項２】
少なくとも１つの電極が治療する皮下組織に挿入されるように構成されるとともに、少なくとも１つの他の電極が治療する患者の表皮に当てられるように構成されていることを特徴とする請求項１に記載の医療装置。
【請求項３】
少なくとも２つの電極が治療する患者の表皮に当てられるように構成されていることを特徴とする請求項１に記載の医療装置。
【請求項４】
少なくとも２つの電極が治療する皮下組織に挿入されるように構成されていることを特徴とする請求項１に記載の医療装置。
【請求項５】
少なくとも２つの電極のうちの１つが接地電極として構成されていることを特徴とする請求項１に記載の医療装置。
【請求項６】
少なくとも２つの電極が双極電極として構成されていることを特徴とする請求項１に記載の医療装置。
【請求項７】
少なくとも２つの電極のうちの１つが略トロイド形状であることを特徴とする請求項１に記載の医療装置。
【請求項８】
少なくとも２つの電極のうちの１つが略円柱形に形作られていることを特徴とする請求項１に記載の医療装置。
【請求項９】
前記電界発生装置が電気穿孔発生装置であることを特徴とする請求項１に記載の医療装置。
【請求項１０】
ハウジングをさらに備え、
少なくとも２つの電極のうちの１つが前記ハウジングの内側に配設されていることを特徴とする請求項１に記載の医療装置。
【請求項１１】
少なくとも一つの電極が前記ハウジングの内側に配設された中央治療要素として構成されるとともに、
前記中央治療要素と前記ハウジングの間に環状領域が配設されていることを特徴とする請求項１０に記載の医療装置。
【請求項１２】
前記環状領域は、負圧供給源と接続されるように構成され、それによって前記ハウジングが治療する領域の上に重なっている肌と接触するように構成されていることを特徴とする請求項１１に記載の医療装置。
【請求項１３】
前記中央治療要素が前記ハウジングの内側に埋め込まれていることを特徴とする請求項１１に記載の医療装置。
【請求項１４】
前記中央治療要素は、治療する患者の肌の上で転動するように構成されていることを特徴とする請求項１１に記載の医療装置。

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【請求項１５】
注入モジュールに接続された極微針を有するパッドをさらに備え、
このパッドは治療する患者の肌に追従するように構成されていることを特徴とする請求項１に記載の医療装置。
【請求項１６】
前記パッドは、リザーバおよび極微針を配置するための作動要素を更に有していることを特徴とする請求項１５に記載の医療装置。
【請求項１７】
前記極微針の少なくとも１つが、少なくとも２つの電極のうちの１つとして構成されていることを特徴とする請求項１５に記載の医療装置。
【請求項１８】
治療する皮下の領域に枝を配置するように構成されたカテーテルデバイスを更に備えることを特徴とする請求項１５に記載の医療装置。
【請求項１９】
前記枝は、針、電極および切断要素からなるグループより選択されることを特徴とする請求項１８に記載の医療装置。
【請求項２０】
第１の近位端、皮下組織への挿入に適合した第２の遠位端、およびそれらの間で縦方向に配置されたチャネルを有する管状要素と、
第１の近位端および第２の遠位端を有して前記チャネルの内側に配設されるとともに、前記チャネルの内側に引き込まれた第１の状態から前記チャネルの外に延びた第２の状態へと動くことができる、複数の伸長可能な細長い要素と、
を備え、
前記細長い要素の遠位端は、延びた状態のときに、引き込まれた状態におけるよりも互いに遠くに離間していることを特徴とする皮下組織を破壊する装置。
【請求項２１】
前記複数の伸長可能な細長い要素は、針，電極および切断要素からなるグループより選択されることを特徴とする請求項２０に記載の皮下組織を破壊する装置。
【請求項２２】
複数の伸長可能な細長い要素は、生物組織を破壊する効果のために、エネルギー場を形成するように幾何学的に構成されていることを特徴とする請求項２０に記載の皮下組織を破壊する装置。
【請求項２３】
第１の電極および第２の電極を設け、
治療する組織に隣接させて第１の電極を配置し、
前記第１および第２の電極の間に電流を生じさせるように構成されたエネルギー供給システムに前記第１の電極および前記第２の電極を接続し、
前記第１の電極と前記第２の電極との間に電流を提供し、それによって少なくとも一つの細胞の透過性を増大させることを特徴とする皮下構造を選択的に破壊する方法。
【請求項２４】
少なくとも前記第１の電極が、生物組織を破壊する効果のためのエネルギー場を作る幾何学的形状に構成されていることを特徴とする請求項２３に記載の皮下構造を選択的に破壊する方法。
【請求項２５】
ハウジングの内側に配設された中央治療要素を治療する組織の上で転動させることをさらに含み、
前記第１の電極が前記中央治療要素に配設されていることを特徴とする請求項２３に記載の皮下構造を選択的に破壊する方法。
【請求項２６】
前記中央治療要素の周りに配設された環状領域に大気より低い圧力を提供することをさ

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らに含むことを特徴とする請求項２５に記載の皮下構造を選択的に破壊する方法。
【発明の詳細な説明】
【技術分野】
【０００１】
（関連出願の相互参照）
本出願は、２００５年９月７日に出願された米国仮特許出願第６０／７１５，３９８号に基づく優先権を主張する。なお、この参照によってその内容の全体が本願明細書に組み込まれるものとする。
本発明は、表皮および皮下における皮膚の凹凸を治療するための方法および装置に関し、より詳しくは、過剰な脂肪組織、セルライトおよび瘢痕化のような皮膚の凹凸および他の疾患を治療するために、哺乳類の身体の皮下構造を崩壊／破壊する方法および装置を提供するものである。
この明細書において言及する全ての出版物および特許あるいは特許出願は、個々の出版物、特許あるいは特許出願があたかも具体的にかつ個別的に組み込まれるかのように、その参照により同一範囲で本願明細書に組み込まれるものとする。
【背景技術】
【０００２】
女性型の脂肪栄養障害は、皮膚の表面（肌）の組織分布の変化、あるいは皮下のある領域において増大した流体保持力あるいは脂肪組織の増量によって生じる陥凹形成効果につながる。皮下組織の限局性の代謝異常である。このような状態は、一般にセルライトとして公知であるが、思春期後の女性の９０％およびいくらかの男性に影響を及ぼす。セルライトは一般に尻、臀部および脚部に出現するが、一般的に認識されているように必ずしも太りすぎによって生じるというわけではない。セルライトは、表皮および真皮層の下にある皮下レベルの組織に形成される。この領域において、脂肪細胞は、セプタムと呼ばれている結合組織のバンドによって取り囲まれた室の内部に配置される。水分が保持されると、これらの線維性セプタムによって定められる周辺部の内側に保持されている脂肪細胞が伸張し、かつセプタムおよび取り囲んでいる結合組織を伸張させる。最終的には、この結合組織が収縮しかつ硬化（硬化症）して柔軟性を持たない長さで肌を保持する一方、セプタム間の室が重量の増加および水分の増加によって伸張し続ける。このことは肌の領域が引き下げられることに帰着するが、その一方で他の部分が外側に膨張するので、皮膚表面上につぶつぶのある「ゆず肌」あるいは「カテージチーズ」のような外観をもたらす。
【０００３】
肥満はセルライトの根本的な原因であるとは考えられないけれども、その領域における脂肪細胞の数の増大により、それは間違いなくセルライト領域における陥凹状の外観を悪化させる。深部の脂肪および解剖学的組織のより大きな領域を目標とする脂肪吸引のような従来の脂肪摘出技術は、時にはセルライトの外観を悪化させることがある。皮下の脂肪ポケットが残存するとともに、その領域の下方に横たわっている塊（深部の脂肪）の喪失によって目立つことになるからである。脂肪吸引を何度実行しても、患者はなお残存しているセルライトのような肌の凹凸の治療を要求する。
【０００４】
セルライトのような肌の凹凸を治療するための様々なアプローチ、および不必要な脂肪組織の除去が提案されてきた。例えば、様々な局所的な薬剤の付加に加えた、吸引とマッサージの組合せあるいは吸引、マッサージおよびエネルギの適用によって患部に機械的なマッサージを提供する方法および装置が現在は利用可能である。１９５０年代に開発されたメソセラピーは、スポーツ傷害から慢性の痛みにおよぶ疾病のために肌を介して様々な治療溶液を注入するものであり、しわおよびセルライトを治療するための美容整形手技としてヨーロッパにおいて広く用いられてきた。この治療は、アミノフィリン、ヒアルロン酸、ノボカイン、植物エキスおよび他のビタミンといった様々な薬剤の肌を介しての注入あるいは移入を含み、血行および脂肪酸化の可能性の増大をもたらす。Acthyders（Tuswood International，オンタリオ，カナダ）と名付けられた治療は、ビタミン、抗繊維化薬

、脂肪分解薬(lypolitics)、抗炎症剤といった様々なメソセラピー薬剤の塗布に続いて、真皮に小さなチャネルを開けるために角質層を電気穿孔するローラシステムを用いる。

【０００５】

リンパの排液を改善するマッサージ技術が１９３０年代の初期に試みられた。米国特許第５，８８５，２３２号および第５，９６１，４７５号に記載されている"Endermologie"装置（LPG Systems、フランス）、米国特許公開２００５／００４９５４３号に記載されている"Synergie"装置（Dynatronics，ソルトレークシティ、ユタ州）および"Silklight"装置（Lumenis、テルアビブ、イスラエル）のような機械的なマッサージ装置あるいはプレソテラピーもまた開発されてきたが、これらの全てが吸引および機械的なローラによる皮下マッサージを用いるものである。なお、これらの文献の全体がこの参照によって本願明細書に組み込まれるものとする。他のアプローチは様々なエネルギー源を含んでいるが、Cynosureの"TriActive"装置（Cynosure，ウェストフォード、マサチューセッツ州）は機械的なマッサージに加えて半導体レーザのパルスを用いるし、"Cellulux"装置（Palomar Medical，Burlington，マサチューセッツ州）は冷却されたチラーを介して目標とする皮下脂肪組織に赤外光を放射する。米国特許第６，８８９，０９０号、第６，７０２，８０８号および第６，６６２，０５４号に詳述されている"VelaSmooth"システム（Syneron，Inc.，Yokneam Illit，イスラエル）は、脂肪組織の代謝を増大させる吸引と共に双極性の高周波エネルギーを用いる。なお、これらの文献の内容の全体がこの参照によって本願明細書に組み込まれるものとする。米国特許第５，７５５，７５３号，第６，７４９，６２４号、第５，９４８，０１１号、第６，３８７，３８０号、第６，３８１，４９７号、第６，３８１，４９８号，第５，９１９，２１９号、第３，３７７，８５４号、第６，３７７，８５５号、第６，２４１，７５３号、第６，４０５，０９０号、第６，３１１，０９０号、第５，８７１，５２４号、第６，４１３，２５５号、第６，４６１，３７８号，第６，４５３，２０２号、第６，４３０，４４６号に詳述されている，"Thermacool"装置（Thermage，Inc.，Hayward，カリフォルニア州）は、皮下の線維性セプタムを縮小させてしわおよび他の肌欠陥を治療するために高周波エネルギーを用いる。なお、これらの文献の内容の全体がこの参照によって本願明細書に組み込まれるものとする。それらの全部において本願明細書に引用したものとする。いくつかの針の組を用いて低周波割込み電磁場を印加することにより循環の排液を助ける、脂肪電気泳動のような他のエネルギベースの治療法もまた開発されてきた("Cellulite. Aspects of Cliniques et Morpho-histologiques"，J. med. Esth. Et Chir Derm (1983)；10(40)，229-223)。なお、この文献の内容の全体がこの参照によって本願明細書に組み込まれるものとする。同様に"Dermosonic"装置（Sysedex Medical、ミネアポリス、ミネソタ州）においては，保持された流体および毒素の再吸収および排液を促進するために無侵襲性の超音波が用いられる。さらに、米国特許出願第２００４／００１９３７１号は、組織を改質して肌の凹凸を治療するためにエネルギーを付加することを記載している。また、米国特許出願第２００３／０２２０６７４号ははセルライトを治療するために冷却の使用を記載している。

【０００６】

瘢痕化および陥凹形成といった肌の凹凸の治療における他のアプローチは、サブシジョンと呼ばれる技術である。この技術は、陥凹形成あるいは瘢痕化の領域において比較的大きい寸法の針を皮膚下に挿入し，次いで肌の下において機械的に針を操作して皮下領域の線維性セプタムをバラバラにする。"Subcision: A treatment for cellulite"，International Journal of Dermatology (2000) 39:539-544に詳述されているように、目標領域に局所麻酔薬を注入し、１８サイズの針を皮膚表面の１０～２０ミリメートル下方に挿入する。次いで，針を表皮に平行に案内して肌の下に剥離平面を作り出し、陥凹形成あるいは瘢痕化を生じさせている締め付けられたセプタムを殆ど完全に引き裂き、あるいは「自由に引き上げる」。それから、出血を制御するために圧力を負荷し、次いで手技に続けて圧縫布を使用する。いくらかの患者には臨床的な効果がある反面、痛み，挫傷、出血および瘢痕化に帰着することもあり得る。米国特許第６，９１６，３２８号は、サブシジョンのために横方向に配置される切削機構を記載している。なお、この文献の内容の全体がこの

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参照によって本願明細書に組み込まれるものとする。また、超音波で支援されたサブシジョン技術を用いる技術が、"Surgical Treatment of Cellulite and its Results", American Journal of Cosmetic Surgery, (1999)16:4 299-303に詳述されている。なお、その内容はこの参照によって本願明細書に組み込まれるものとする。

【０００７】

脂肪吸引、腫脹性脂肪の吸引、リポローシス(lypolosis)として公知の技術は、身体皮下および深部脂肪領域の脂肪組織を目標としている。これらの技術はまた、脂肪細胞を崩壊させてから取り除くこと、および身体の免疫／リンパシステムによる再吸収のためにそれらを残すことを含む。従来の脂肪吸引は、取り除かれる脂肪の部位に配置される外科的なカニューレの使用、流体の注入および脂肪組織をバラバラにするカニューレの機械的な動き、崩壊させた脂肪組織を患者から直接吸引するための吸入を含む。"Lysonix"システム（Mentor Corporation、サンタバーバラ、カリフォルニア州）は、米国特許第４，８８６，４９１号および第５，４１９，７６１号に詳述されているように、（目標部位の組織の空洞化によって）組織分裂を援助するために、吸引カニューレのハンドピース上にある超音波振動子を用いる。なお、これらの文献の内容の全体がこの参照によって本願明細書に組み込まれるものとする。加えて、米国特許第６，０４１，７８７号および第６，０３２，６７５号に詳述されているように、脂肪組織を破壊するために低温冷却することが提案されてきた。なお、これらの文献の内容の全体がこの参照によって本願明細書に組み込まれるものとする。腫脹性の脂肪吸引として公知の従来の脂肪吸引技術の変形例は１９８５年に導入されたが、現在では米国における標準的な治療となっている。それは、吸引カニューレによる機械的な破壊および除去の前における、目標領域への腫脹性の流体の注入を伴う。この流体は、機械的な破壊に伴う痛みの緩和を助けるとともに、組織を膨張させて機械的な除去の作用を受けやすくする。リドカインのような局所麻酔薬、エピネフリン、食塩水、カリウム等の血管収縮剤を含む様々な組合せの流体を腫脹性の溶液として用いることができる。そのようなアプローチの利点は、以下の論文に詳述されている。"Laboratory and Histopathologic Comparative Study of Internal Ultrasound- Assisted Lipoplasty and Tumescent Lipoplasty" Plastic and Reconstructive Surgery, Sept. 15, (2002) 110:4, 1158-1164、および"When One Liter Does Not Equal 1000 Milliliters: Implications for the Tumescent Technique" Dermatol. Surg. (2000) 26:1024-1028、なお、これらの文献の内容の全体がこの参照によって本願明細書に明白に組み込まれるものとする。

【０００８】

Liposonix（Bothell,ワシントン州）および、Ultrashape（テルアビブ、イスラエル）は、脂肪組織を非侵襲的に破壊するために焦点を合わせた超音波を用いる。米国特許第６，６０７，４９８号、米国特許公開２０００４／０１０６８６７号および２００５／０１５４４３１号は、これらのシステムを記載している。なお、これらの文献の内容の全体がこの参照によって本願明細書に組み込まれるものとする。

【０００９】

皮膚科的クリーム、化粧水、ビタミンおよびハーブサプリメントを用いる様々な他のアプローチもまた提案されてきた。個人的な温泉場およびサロンは、身体のこすり洗い、圧覚点マッサージを含むセルライトマッサージ治療を提供するが、植物性揮発油、海草、トクサ、クレマチスおよびツタのような植物化学種から抽出されたハーブ製品の使用もまた提案されてきた。多数の治療が存在するけれども、それらの殆どは肌の凹凸に対して永続的な効果を提供しないし、いくつかは（脂肪吸引が瘢痕化あるいはセルライトのより顕著な外観を生じさせるように）一つの治療が他のものを悪化させ、あるいはその採用を制限するマイナスの副作用を有している。ほとんどの治療は、継続する複数の治療を必要とし、それらの効果を維持するためにはかなりの出費がかかり、かつ結果もまちまちである。

【発明の開示】

【発明が解決しようとする課題】

【００１０】

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前述したことを考慮すると、肌の凹凸を治療するための最小限に侵襲性のあるいは無侵襲性の方法および装置を提供すること、および顔面、首、腕、脚部、大腿、臀部、胸部、腹部および他の目標領域のような人体の部位に継続する美的な結果を提供することが望ましい。

【００１１】

また、肌の凹凸を治療するための、従来技術を改良して侵襲性がより少なくかつ副作用の少ない方法および装置を提供することが望ましい。

【課題を解決するための手段】

【００１２】

前述したことに鑑みて、本発明の一態様は、皮膚および皮下の凹凸、より詳しくは過剰な脂肪組織、セルライト、瘢痕化および関連した疾患を治療する、最小限に侵襲的あるいは非侵襲的で、制御されかつ選択的な、より耐久性のある効果を提供する方法および装置を提供する。

【００１３】

本発明の一態様においては、（皮膚の表面に）非侵襲的に、（皮膚表面下３～１０ミリメートルの間で）より低侵襲的に、あるいは（深部脂肪層に対して６ミリメートルよりも浮く）最小限に侵襲性の装置を適用し、電気、超音波あるいは他のエネルギー場を用いて哺乳類の身体の皮下構造を崩壊／破壊する、そのような状態を治療するための方法および装置が提供される。

【００１４】

本発明の更なる態様において、そのようなエネルギー場は、標的細胞膜の透過化処理(poreabilization)を介して細胞レベルで組織を崩壊させるための、指定された持続期間および振幅の一つのパルスあるいは複数のパルスによって発生させることができる。本発明の更なる態様においては、標的皮下構造の細胞膜に孔を生成することにより、細胞の死滅に帰着する不可逆的な細胞損傷を生じさせることが望ましい。

【００１５】

本発明の他の態様においては、高周波エネルギー、直流、電気抵抗による熱エネルギー、超音波エネルギー、マイクロ波エネルギーあるいはレーザエネルギーを印加する本発明の装置および方法を用いて皮下の構造を破壊することが望ましい。

【００１６】

本発明の別の態様においては、標的組織（結合組織、コラーゲン、脂肪組織等）への電気的な手技は、細胞膜の可逆的なあるいは不可逆的な電気穿孔を生じさせることにより細胞レベルの組織を破壊して印加された電界の作用を受けやすくするべく、低張塩水、カリウム等の促進剤の注入あるいは付加による細胞内の環境あるいはまた細胞膜の変化によって改良することができる。

【００１７】

本発明の別の態様において、標的組織（結合組織、コラーゲン、脂肪組織等）の破壊は、微小な泡、攪拌された塩水、商業的に入手可能な超音波造影剤等のような促進剤を注入あるいは付加し、その領域に供給されたエネルギーを増大させ、空洞化等によって治療効果を高めることにより改良することができる。

【００１８】

本発明の更なる態様において、エネルギー伝達部材は、標的部位へのエネルギー供給の改良に適するように、皮膚に、経皮的にあるいは皮下に配置することができる。

【００１９】

本発明の更なる態様は、リドカイン、エピネフリン、低張塩水、カリウム、緩衝塩水、微小な泡、商業的に入手可能な超音波造影剤、微小球体等のような治療促進剤の治療部位への付加と共に、本発明のエネルギーアプローチを用いることにより、肌の凹凸および他の関係する疾患を治療する方法および装置を提供することにある。

【００２０】

加えて、本発明の別の態様では、本発明の治療を施した後に、全体的な所望の効果を改

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良する必要に応じて、脂肪細胞、脂肪、ＰＬＬＡ、コラーゲン、ヒドロキシアパタイト、ヒアルロン酸等の充填剤を付加する。

【００２１】

本発明の更なる態様において、体内の複数の位置から安全に適用することができる治療を提供するために、ある種の型の細胞は選択的に破壊するがそれ以外については破壊しない方法および装置を提供することが望ましい。

【００２２】

本発明の一態様は、皮下組織を破壊するための医療装置であって、電界発生装置、この電界発生装置と電気的に接続された少なくとも２つの電極、および治療する皮下組織に治療促進剤の溶液を注入するように構成された注入モジュールを備える。少なくとも一つの電極は治療する皮下組織に挿入されるように構成され、かつ少なくとも一つの他の電極は治療する患者の表皮に当てられるように構成される。本発明の更に別の態様において、少なくとも２つの電極が治療する患者の表皮に当てられるように構成される。少なくとも２つの電極を、治療する皮下組織に挿入されるように構成してもよい。少なくとも２つの電極のうちの１つは接地電極として構成することができる。少なくとも２つの電極は双極電極として構成することができる。少なくとも２つの電極のうちの少なくとも１つは、概ね環状の形状である。少なくとも２つの電極のうちの少なくとも１つは概ね円柱の形である。さらに別の態様において、電界発生装置は電気穿孔（エレクトロポレーション）発生装置である。

【００２３】

この医療用機器は、ハウジングを更に含み、少なくとも２つの電極のうちの１つがこのハウジングの内側に配設される。少なくとも１つの電極はハウジングの内側に配設される中央治療要素として構成することができ、この中央治療要素とハウジングとの間に環状領域を配設することができる。この環状領域は、負圧供給源に接続されるように構成することができ、それによってハウジングは治療する領域の上に垂なっている肌と接触するように構成される。中央治療要素はハウジングの内側に埋め込むことができる。中央治療要素は、治療する患者の肌の上を転動するように構成することができる。

【００２４】

本発明の更なる態様において、この装置は、注入モジュールに接続された極微針を有したパッドを備え、このパッドは治療する患者の肌に追従するように構成される。このパッドは、リザーバおよび極微針を配置させるための作動要素を含むことができる。なお本発明の更なる態様において、少なくとも極微針の１つが、少なくとも２つの電極のうちの１つとして構成される。

【００２５】

本発明の更なる態様において、カテーテルデバイスは、治療する皮下領域に枝を配置するように構成することができる。これらの枝は、針、電極および切断要素からなるグループより選択される。

【００２６】

本発明の更に別の態様は、皮下組織を破壊する装置であって、第１の近位端、皮下組織への挿入に適合した第２の遠位端、およびそれらの間で縦方向に配置されたチャネルを有した管状要素を備える。複数の伸長可能な細長い要素は、第１の近位端および第２の遠位端を有してチャネルの内側に配設されるとともに、チャネルの内側に引き込まれた第１の状態からチャネルの外に延びた第２の状態へと動くことができ、細長い要素の遠位端は、延びた状態のときに、引き込まれた状態におけるよりも遠くへと互いに離間する。複数の伸長可能な細長い要素は、針、電極および切断要素からなるグループより選択することができる。本発明の更なる態様においては、複数の伸長可能な細長い要素は、生物組織を破壊する効果のために、エネルギー場を形成するように幾何学的に構成される。

【００２７】

本発明の一態様は皮下構造を選択的に破壊する方法であり、第１の電極および第２の電極を設け、治療する組織に隣接させて第１の電極を配置し、第１の電極および第２の電極

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をエネルギー供給システムに接続し、このエネルギー供給システムは第１および第２の電極の間に電流を生じさせるように構成され、第１の電極と第２の電極との間に電流を提供し、それによって少なくとも一つの細胞の透過性を増大する。少なくとも、第１の電極は、生物組織を破壊する効果のために、エネルギー場を作る幾何学的に構成することができる。この方法は、ハウジングの内側に配設された中央治療要素を治療組織上で転動させることを含むが、第１の電極は中央治療要素に配設される。本発明の更に別の態様においては、大気より低い圧力が、中央治療要素の周りに配設された環状領域に与えられる。

【００２８】

本発明の更なる特徴、その本質および様々な利点は、添付の図面および以下の説明から明らかとなる。

【発明を実施するための最良の形態】

【００２９】

本発明は、コラーゲン、結合組織、脂肪組織（脂肪細胞）等の皮下構造（あわせて「標的組織」あるいは「皮下構造」）を標的として破壊する方法および装置に関する。本発明は、標的とする領域の美的な外観の改善に有用である。この標的領域は、人体において改善が望まれる、顔面、あご、首、胸部、乳房、腕、胴、腹部（骨盤領域を含む）、大腿、臀部、膝および脚部を含む任意の表面あるいは輪郭から成る。標的組織には、その領域の結合組織あるいはセプタム、または皮下および深部脂肪の沈殿あるいは層のような、その下に横たわっていて望ましくない身体の輪郭を悪化させ得る組織が含まれる。

【００３０】

肌の凹凸は、セルライトや瘢痕化、あるいは首、あご、乳房、尻、腹部、脚等の領域における脂肪の沈殿あるいは過剰な脂肪といった、外側の様相に対する人の満足感を減少させる状態を指す。

【００３１】

ここで図１Ａおよび 図１Ｂを参照すると、治療すべき皮膚組織あるいはまた皮下組織の目標領域１００の断面が示されているが、表皮１０２、真皮１０４、皮下脂肪１０６、線維性のセプタム１０８、微小循環、リンパ排液、およびより深部脂肪層１１０が含まれている。真皮は、実質的に線のセプタムあるいは膠原線維を介して皮層に付着した脂肪皮下結合組織に接続されている。この皮下脂肪組織は、セプタムの繊維によって分離されて、脂肪組織あるいは脂肪の室１１２に区画されている。これらの室は増大した脂肪細胞あるいは保持されている流体の存在に起因して膨張し、脂肪領域が膨張してセプタムが張力下で厚くなると、セプタム上に張力を生じさせて最終的には皮膚表面に陥凹を形成する。次いで微小循環およびリンパ排液が弱まり、さらには局部的な代謝性の症状を悪化させる。図１Ａは、肌の凹凸を呈していない全く通常の肌の断面を示している。図１Ｂは、膨張してセプタムに締め付けられて、不規則な皮膚表面の特徴につながる皮下脂肪層を示している。

【００３２】

蓄えられたあるいは深部脂肪層１１０は、皮下脂肪層１０６の下位に配設されて肌の凹凸の一因となる。そのため、この開示においては「皮下の構造」として考慮する。少なくとも一つの実施形態において、本発明の装置は、上述したような目標領域１００に向けることができる。いくつかの特定の実施形態には、エネルギー支援サブシジョン、線維性セプタム１０８の破壊、陥凹形成の原因となる皮膚表面上の外側の圧力を少なくするための皮下脂肪１０６の細胞の破壊、あるいは全体的な表面輪郭のためより深部脂肪層１１０の破壊が含まれる。

【００３３】

本発明の目的を達成するためには、電気穿孔（可逆性あるいはまたは不可逆性）、パルス電界、高周波エネルギー、マイクロ波エネルギー、レーザエネルギー、超音波エネルギ等を含む様々なエネルギー形態を用いて皮下構造１０６、１０８、１１０の破壊を達成する方法および装置を用いることが望ましい。例えば、パルス電界の適用、あるいはまた目標領域１００に直接的にあるいは目標領域に近接させた電気穿孔の適用は、所望の破壊を

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生じさせることができる。この開示においては、「電気穿孔（エレクトロポレーション）」という用語はパルス電界（PEFs）、ナノ秒パルス電界（nsPEFs）、イオン浸透、電気泳動法、電子透過化処理、音響穿孔、あるいはまたその組合せの、恒久的なあるいは一時的な、可逆的なあるいは不可逆的な、補助的な薬剤を使用しあるいは使用しない、熱影響の存在を必要としない使用を含む。同様に、本願明細書において用いる「電極」という用語は、アンテナ、例えば極超短波送信装置や超音波要素を含む、種々のタイプのエネルギーを生み出す装置の使用を包含する。

【００３４】

可逆的な電気穿孔は１９７０年代の初期に初めて認められたが、電子化学療法、遺伝子導入、経皮薬物送達、ワクチン等のような様々な目的のために、目標とする細胞への化学製品、薬物、遺伝子および他の微粒子を移入させるべく，医学および生物学において広範囲にわたって用いられてきた。不可逆性の電気穿孔は、電気穿孔技術を用いるときには歴史的にほとんどの場合に回避されてきたが、水および食品の細菌除去(debacterilization)、幹細胞強化および癌細胞パージ（Mangano、米国特許第６，０４３，０６６号）、腫瘍性前立腺組織の統制された切除（Chomenky、ＵＳ２００３／００６０８５６）、身体血管の再狭窄の治療（Jaafar、ＵＳ２００１／００４４５９６），脂肪細胞の選択的不可逆性電気穿孔法（Jaafar，ＵＳ２００４／００１９３７１）および腫瘍切除(Davalos，et al Tissue Ablation with Irreversible Electroporation，Annals of Biomedical Engineering 33:2，pp. 223-231（２００５年２月）の用途における細胞分離のために近年提案されてきている。

【００３５】

さらに、超短パルスあるいはナノ秒パルス電界（nsPEFs）に適用されるエネルギー場も，本発明に用途を有している。そのような技術は，外膜を永久的に崩壊させることなしに細胞下の構造を目標とするために超短波パルス長を用いる。この技術の実例は、Schoenbach et al. In Intracellular Effect of Ultrashort Electrical Pulses in J. Bioelectromagnetics 22:440-448 (2001)に記載され，かつ、米国特許６，３２６，１７７に記載されている。なお，その内容はこの参照によって本願明細書に明白に組み込まれるものとする。短いパルスは細胞内の器官を目標とし、細胞膜に電気穿孔効果を呈するが、そのような効果は可逆的であるため恒久的な膜破壊につながることはない。ナノ秒パルスの適用に続いて細胞内の内容物における細胞自滅が誘起され、細胞の生存度（例えば再生能力）に影響を及ぼす。

【００３６】

一般的に、電気穿孔は、電極の組あるいは電極の列を活性化させて電界を生じさせるように構成された装置を用いて達成することができる。そのような場は，多極、双極、あるいは単極の電極配置において発生させることができる。細胞に印加されると、印加されたパルスの持続期間および強度に応じて，この場は、細胞膜の透過化を増大させるように作用し、そして，１）細胞脂質二重層に孔が形成されるようにして短い期間の間細胞膜を可逆的に開き，様々な治療上の成分あるいは微粒子が侵入できるようにし，その後、エネルギーの印加が停止すると、細胞を殺すことなく孔が自然発生的に閉じるか、あるいは，２）より高い強度（より長い、より高いエネルギー）のパルスを用いて，不可逆的に細胞膜を開きあるいは孔を開けて細胞の不安定性を生じさせ、細胞死を引き起こすか，あるいは、３）ナノ秒パルスのエネルギーを印加して、細胞膜の不可逆的な穿孔を生じさせることなく、細胞自滅および細胞死につながる細胞内の基質の破壊を引き起こす。Weaver，Electroporation: A General Phenomenon for Manipulating Cells and Tissues Journal of Cellular Biochemistry，51 : 426-435 (1993)によって特徴づけられるように、短い（１－１００マイクロ秒）およびより長い（１～１０ミリ秒）パルスが様々な型の細胞電気穿孔を生じさせる。なお、この文献の全体がこの参照によって本願明細書に組み込まれるものとする。単一の細胞モデルにおいては、ほとんどの細胞は、細胞全体に印加される１～１，５Ｖの範囲（膜電位）において電気的な穿孔を呈する。細胞容積に電気穿孔を適用するために、１０Ｖ／ｃｍ～１０，０００Ｖ／ｃｍおよび１．０ナノ秒～０．１秒にわたる

パルス持続時間を印加することができる。

【００３７】

ある種の要因は、供給された電界が目標を定めた細胞にどの様に作用するかについて影響を及ぼすが、これらの要因には細胞のサイズ、細胞の形状、印加された電界に関する細胞の配向、細胞の温度、細胞間の距離（細胞と細胞の分離）、細胞の種類、組織の不均一性、細胞膜の特性などが含まれる。より大きい細胞は、損傷に対してより脆弱であり得る。例えば、骨格筋細胞が、すぐ近くの結合組織細胞よりも電気的な損傷の作用を受けやすいことが指摘されている（Gaylor et al. Tissue Injury in Electrical Trauma. J. Theor. Biol. (1988) 133, 223-237)。なお、その全体がこの参照によって本願明細書に組み込まれるものとする。脂肪組織あるいは脂肪細胞は、それらの断熱的な特性に起因して損傷に対し脆弱ではないため、細胞膜が損傷の作用を受けやすくするためには前処理あるいはエネルギーを印加する間の処理が必要である。

【００３８】

この領域における研究によると、低張溶液は人間の脂肪細胞のセル直径をかなり増大させることができる。注入から１５分以内では、４分の１の通常生理食塩溶液がセル直径に対してかなりの効果を有することが既に報告されている。低張溶液を超音波脂肪吸引と共に使用することの科学的な根拠は、(Jennifer M. Bennett, MS, abstract presented at Plastic Surgery 2004)に記載されている。例えば、脂肪細胞が本発明の標的組織である場合には、低張塩水のような溶液をその領域に注入する必要があるが、それは翻って脂肪細胞の腫大を生じさせて細胞膜上の応力の増加を引き起こし、電気穿孔あるいは超音波エネルギーの印加または他のエネルギー形態の印加によってより破壊の作用を受けやすくする。そのような増強効果は、細胞サイズの変化、増大した細胞伝導率、増大した細胞外伝導率、増大した壁応力であり、増大した透過性につながる。加えて、塩水、カリウムおよび他の溶液成分の濃度の変更は細胞膜の透過化に影響を及ぼす。

【００３９】

それに加えて、細胞は、印加された場の中でどのように方向付けられているかによって、より損傷の作用を受けやすくなる。例えば、非球形細胞の長軸が電界に沿って方向付けられていると、より破壊の作用を受けやすい（Lee et al, Electrical Injury Mechanisms: Electrical Breakdown of Cell Membranes, Plastic and Reconstructive Surgery, November 1987, 672-679）。なお、この文献の全体がこの参照によって本願明細書に組み込まれるものとする。例えば、本発明の前後関係においては、結合組織の方向付けに応じて、場の方向によっては印加されたエネルギー場の作用を受けやすくなる。使用するパルス発生器、あるいは所望の効果に応じて電気穿孔を達成するために正弦波のＡＣパルス、ＤＣパルス、方形波パルス、指数関数的に減衰する波形、組み合わせられたＡＣ／ＤＣパルス、あるいはCell Poration and Cell Fusion using an Oscillating Electric Field, Biophysical Journal October 1989, Volume 56 pgs 641-652のChangに記載されているＤＣシフトされたＲＦ信号のような他のパルス波形を含む、パルスの様々な波形あるいは形状のパルスを適用することができる。なお、上記の文献の全体がこの参照によって本願明細書に組み込まれるものとする。印加されるエネルギーのパラメータは変更することができるが、それらには以下の全てあるいはそのいくつかが含まれる：波形形状、振幅、パルス持続時間、パルスの間隔、パルスの数、波形等の組合せ。本発明の電気穿孔カテーテルシステムは、Cytopulse Sciences, Inc.（Columbia, メリーランド州）、あるいはGene Pulser Xcell (Bio-Rad, Inc.)、ICEA（Carpi、イタリア）、またはInovio（San Diego、カリフォルニア州）から入手可能な、表面電極あるいはカテーテル電極のようなエネルギー印加装置に電気的に接続されたパルス発生装置を備える。この発生装置は、不可逆性の電気穿孔を引き起こすべく、より高い電圧、増大したパルス電気容量あるいは他の変更を生じさせるように変更することができる。一つの実施形態において、この発生装置は、電界(e-field)がより長くとどまり、それによって脂肪組織の細胞電気穿孔が高められ、あるいはまた筋組織の破壊が最小化されるように、その電流を制限することができる。

【００４０】

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本発明の一実施形態によると、所望の効果に応じて、様々なエネルギー形態の適用と共に様々な治療促進剤５４を用いることができるが、そのいくつかについては以下に詳述する。例えば薬剤は、治療装置から直接的にあるいは遠く離れた注射部位から、静脈内供給を含めて、経皮的にあるいは皮下注射によって伝達することができる。治療促進剤には、リドカインのような麻酔薬、エピネフリンのような血管収縮の薬剤、低張塩水、カリウム、撹拌された塩水、微小な泡、商業的に入手可能な超音波造影剤、微小球体、脂肪細胞、脂肪、自己由来の組織（例えば、身体からの敵対的な反応を最小化するための組織移植片を形成するきれいな脂肪細胞を生み出す崩壊された脂肪細胞）、ＰＬＬＡ、ヒドロキシアパタイト(hydroxyappetite)が含まれる。治療促進剤は、本発明のエネルギー印加治療の前に、間に、あるいは後に供給することができる。

【００４１】

本発明の装置は（皮膚表面あるいは表皮１０２に対して）非侵襲的に適用されるもの、（表皮表面１０２の下の約３～１０ミリメートル下方の肌を介した）より侵襲的でないもの、および（深部皮下領域１０６および深部脂肪層１１０に対して約８ミリメートルあるいはより深い）最小限に侵襲的なもの、を含む。所望の効果に応じて、選択されたエネルギーおよび電極の設計は、効率よく目標が定められた組織のタイプに影響を与える開示のために、ある種のエネルギー形態および電極を組み合せるが、本発明の範囲を制限することは意図していない。

【００４２】

ここで図２を参照すると、本発明の一実施形態に係る装置３０は、ハウジング３２および中央治療要素３４を有している。ハウジングと中央治療要素の間には環状領域３６が配設されている。この環状領域は、ハウジングから中央治療要素までの寸法が約５～２０ミリメートルの開口３８を有している。一つの実施形態においては、中央治療要素はハウジングの内部に回転自在に接続されたローラとして構成され、ハウジングが肌の表面１０２（図１）上を移動するときに回転できるようにしている。さらに他の実施形態においては、中央治療要素は、ハウジングの内部に部分的に例えば約５～３０ミリメートルにわたって埋め込まれるが、皮膚表面に当てられると肌を押して電気的な接続のためのより良好な接触をもたらすように充分な距離で延びる。一つの実施形態においては、中央治療要素あるいはハウジングが電極となり、患者の身体のどこかに接地パッド（図示せず）の形態でアース（図示せず）が配置され、あるいは、ハウジングおよび中央の治療要素の両方が二極性のシステムを形成する活性電極となる。一つの実施形態においては、ハウジングおよび中央治療要素の両方が、電力が供給されている間にほぼ同時に肌あるいは表皮１０２に接触する。後に詳述するように、環状領域に関連させて管腔を挿入し、この装置を吸引性の管腔に接続することにより、この装置を肌に当てるときに吸引できるようにすることが有益である。例えば、少なくとも一つの実施形態において、医療的な吸引あるいは負圧を環状領域３６に接続し、目標領域１００（図１）とこの装置３０が互いに引っ張り合うようにする。このようにして、肌あるいは表皮１０２との接触が維持されて所望の加圧が達成される。治療装置による様々な組織層の加圧は、治療効果を達成するために必要なエネルギー量に影響を与える。

【００４３】

中央治療要素３４あるいはハウジング３２は、多くの形状に構成することができる。少なくとも一つの実施形態において、中央治療要素３４は円柱、環状体、楕円等として形付けることができる。ある用途において、治療要素の一つの領域にエネルギーを供給して集中させるときには、少なくとも一つの曲率半径を有する幾何学的形状が「エッジ効果」を最小化するために望ましい。

【００４４】

ここで図３を参照すると、本発明の他の実施形態は、目標とする組織１００の領域のいずれかの側に配置されたクランプ４０を含んでいる。一つの実施形態において、このクランプは、表皮１０２と接触する第１電極４１および第２電極４２を有した二極性の構造に構成されている。治療する皮下組織１０６は、これらの電極の間に配設される。第１電極

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が電圧を供給し、第２電極はアースである。

【００４５】

ここで図３Ｂを参照すると、クランプ脚あるいは電極４０の鋭い縁部における「エッジ効果」すなわち電流の集中が増大したエネルギー密度を呈するので、より一様なエネルギーの供給が最も有益である本発明の所期の効果にとっては望ましくない。エネルギーのより一様な供給は早すぎたインピーダンス上昇の可能性を減少させて、供給されるエネルギーの総計および持続期間あるいは表皮１０２（図１）のような取り囲んでいる構造への意図しない組織損傷を減少させる。

【００４６】

図４は、本発明の他の実施形態の断面を表しているが、略円柱状の要素５１，５２を有したクランプ５０が採用されて、「エッジ効果」を少なくするとともにより一様な電流を印加するようになっている。この実施形態においては、クランプの脚５１が活性電極（アクティブな電極）として、かつクランプの他の脚５２がアースとして示されている。しかしながら、実際には、両方のクランプアーム５１、５２を活性電極およびアース（図示せず）として、治療する領域１００の近傍にあるいは治療する領域から離して患者の組織上に配置することができる。

【００４７】

図５Ａは、形状が環状で球面の直径が例えば４５ミリメートルである中央治療要素３４を用いた単極構造の図２の装置３０の適用を示している。この実施形態においては、中央治療要素は正に帯電した活性電極であり、所望の標的組織は皮下脂肪１０６および線維性のセプタム１０８および筋肉層まで至る深部脂肪１１０（図１）を含む結合組織である。中央治療要素として様々な直径、例えば１０ミリメートル～５０ミリメートルの球形を用いることができる。ここで図５Ｂを参照すると、中央治療要素の曲率半径により、皮下の層１０６、１０８、１１０（図１）の内部に目標が定められたエネルギーに加えて「エッジ効果」は存在していない。

【００４８】

例示的な意味では、図２Ａ～図５Ｂに描かれている装置は様々なエネルギー源を用いて利用することができるが、実際には前述したような電気穿孔発生装置を用いる。５～２００ボルトの範囲で、目標を定める組織の厚みおよび細胞のタイプに応じて５０～１０，０００Ｖ／ｃｍの範囲、例えば１００～３，０００Ｖ／ｃｍの範囲の電界強度の様々な電力を供給することができる。そのようなエネルギーの供給はまた、目標組織に対する破壊的な効果を最大にする一方で筋収縮を最小化するためにパルスとしあるいは切替えることができる。

【００４９】

本発明のエネルギー印加装置は、本願明細書の他の部分で詳述する注射可能な促進剤５４と共に用いることができる。ここで図６を参照すると、本発明の少なくとも一つの実施形態は、治療促進剤５４の皮下注射と共に用いられる中央治療要素３４を有した、非侵襲性のエネルギー供給システムを含んでいる。この実施形態においては、エネルギー供給システム３３は上述した電気穿孔発生装置であり、中央治療要素３４が電極であるが、それはSiemens/Acuson（Malvern、ペンシルバニア州）によって製作されるシステムのような超音波振動子に作動的に接続される超音波発生装置とすることができる。注入は、皮下脂肪１０６、深部脂肪１１０（図１）、線維性のセプタム１０８あるいは破壊する他の結合組織を含む破壊すべき皮下構造の任意の位置に目標を定めることができる。このシステムは、皮膚表面から印加されたエネルギーに接触すると激増する泡やその他の形態の増大したエネルギーポテンシャルを治療部位に生み出すために、注入の前に溶液を「泡立たせ」あるいは攪拌する注射器５６を含むことができる。

【００５０】

図７Ａ～７Ｂおよび図８Ａ～図８Ｃを参照すると、本発明の更なる実施形態においては、ハンドピース２６８は、患者の皮膚表面に追従するパッド６０を含んでいる。このパッドは、そこから延びる複数の極微針（マイクロニードル）６２を含むとともに、リザーバ

６４と連通している。この装置は、空気あるいは流体によって膨張し、患者の肌の皮層を介して極微針を配置させる、ブラダのような作動要素６６を更に備えている。肌を介した針の挿入は目標組織の抵抗を実質的に減少させ、目標組織を、印加されたエネルギーの作用をより受けやすいものとする。極微針は、治療する目標組織に応じて０．５ミリメートル～２０ミリメートルの距離で肌の内部に延びるが、いずれの場合も角質層を通過する。例えば、セルライトを治療するためには１～５ミリメートルの針入深さが望ましいが、より深い皮下脂肪のためには３～２０ミリメートル、例えば５～１０ミリメートルの深さが望ましい。一つの実施形態においては、肌を不必要な組織損傷から保護するために極微針の作動部分以外は絶縁され、例えば最初の０．５ミリメートル～１ミリメートルは絶縁体を支持することができる。さらに他の実施形態において、針は完全に絶縁することができる。別の実施例では針は絶縁されない。極微針は、上述した電気穿孔発生装置あるいは超音波発生装置のようなエネルギー源３３（図６）に作動的に接続することができる。さらに、極微針を介して治療促進剤５４を注入することができる。

【００５１】

極微針６２は、列の間で二極式とすることもできるし、あるいは患者のどこかに配置された接地パッド（図示せず）と共に単極式に作動させることもできる。ラスター走査の仕方で電力を印加して、様々な対あるいは対のセットをある間隔で活性化させることができる。極微針の列の間の間隔は、最大浸界が均一となるように、例えば０．５～５．０ミリメートルの範囲の間隔に設定される。

【００５２】

さらに他の実施例においては、ハンドピース２６８のベース２６６は、大気より低い圧力を用いて患者の肌１０２をベースに向かって上方に吸引するための吸引部材２６４を含むことができる。この吸引部材は、機械ポンプ（図示せず）、ハンドポンプ（図示せず）あるいは大気より低い圧力の他の供給源に接続できる、少なくとも一つの吸引管２７０を含んでいる。

【００５３】

一つの実施形態においては、肌１０２は、肌に吸引を負荷する前にハンドピース２６８の外に配置されている針６２に向かって上方に吸引される。その後、肌に吸引が負荷されると、肌はハンドピースのベース２６６に向かって上方に吸引され、針は治療する患者の少なくとも表皮１０２を貫通する。他の実施形態においては、ハンドピースは第１の状態で患者の上に配置されるが、このときには針の遠位端はハンドピースの内部にある。それから、ハンドピースのベースに対して肌を上方に引っ張るために吸引が負荷される。その後、針の遠位端がハンドピースの外側にある第２の状態に針を配置すると、針は治療する患者の少なくとも表皮を貫通する。一つの実施形態においては、針の遠位端は注入部材から自動的に配置される。第１の状態と第２の状態との間での針の移動は制御装置によって制御される。少なくとも一つの実施形態においては、第１の状態と第２の状態との間での針の自動的な配置のために、モータをハンドピースに含めることができる。

【００５４】

図８Ａ～図８Ｂは、治療促進剤５４を注入できるとともに、皮層１０４（角質層）を通って治療が望まれる皮下層１０６、１０８、１１０（図１）の内部へと延びるように構成された、一連の極微針６２を示している。例えば、本発明による極微針６２を介したエネルギーの印加は、皮下層のセプタム１０８を破壊することができ、エネルギー支援のサブシジョンおよびそれに続く肌の平滑化を生じさせる。加えて、極微針は、その直径および針入の深さに応じて、皮下脂肪１０６の細胞を破壊するために、治療促進剤が細胞に入ってその機能を破壊することができるように細胞膜の透過処理を生じさせるのに十分な、あるいは細胞死に結びつく不可逆性の電気穿孔を生じさせるのに十分なエネルギーを供給することができる。図８Ｂは、治療促進剤５４を注入できる追従可能なパッド６０あるいはリザーバ６４上にある極微針６２の配列を描いている。一つの実施形態においては、針は二極式の構造に配置することができる。他の実施形態においては、針が単極式の構造に配置され、かつ接地パッドが治療する組織から間隔を開けて患者に装着される。

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【００５５】
環状体電極５１、５２およびクランプ電極４１（図２～図６）を極微針６２と共に構成することは本発明の範囲内であるが，この極微針６２は、ユーザーによって、または装置３０の環状領域３６（図２）あるいは吸引部材２６４に負荷される負圧によって患者の肌の皮層１０４に押し込まれる。さらに、ユーザーが治療することを望む距離および位置に極微針を置くことができるようにすることは有益である。この際、それによってユーザーが別々の針６２を配置できるテンプレート９０（図１５）を設けるとともに、選択された配置に応じたエネルギーのアルゴリズムを提供することは、本発明の範囲内である。
【００５６】
ここで図９を参照すると、本発明の他の実施形態においては、針６２、電極７２あるいは電極列７４を配置するように構成されたカテーテルデバイス７０を、肌１０２、１０４を通して目標である皮下構造１０６、１０８、１１０に挿入するために設けることができる。例えば、扇形に広がった電極配列７４を複数の延伸要素あるいは枝６２、７２と共に設けることができる。
【００５７】
枝６２、７２は、メインカテーテルシャフト７６を介して肌１０２、１０４を通して配置することができ、実質的に皮膚表面１０２と水平（平行）な配向で「扇形に展開する」、枝がまた電極７２である実施形態においては、枝を皮膚表面に実質的に平行であるように配置してエネルギーを印加すると、皮下脂肪１０６あるいは線維性のセプタム１０８のような皮下の構造を破壊することができる。複数の枝を用いると、今日の装置によって予測されるよりも大きな領域をより短い時間で治療することが可能である。電極装置７０の枝は、治療促進剤５４の注入を可能にするために中空に構成することができる。中空の枝は、その全長に沿ってそしてその遠位端７９に複数の流出口７８を有することができる。
【００５８】
一つの実施形態においては、扇形に広がる枝の配列７４は、第１の近位端７６ｐ，皮下組織への挿入のために適合した第２の遠位端７６ｄ、およびそれらの間で長手方向に配設されたチャネル７６ｃを有した，細状要素７０を含むことができる。第１の近位端（図示せず）および第２の遠位端７９を有した複数の伸長可能な細長い要素７２、７４は、チャネルの中に配設されるとともに、チャネルの内部に引き込まれた第１の状態からチャネルの外に延びる第２の状態へと動くことができ、細長い要素の遠位端は延び出た状態においては引き込まれた状態よりも互いに離れている。一つの実施形態においては、高周波メスをこの配列に用いることができる。さらに他の実施形態においては、機械的なメスあるいは切断要素をこの配列に用いることができる。
【００５９】
ここで図１０を参照すると、本発明のさらに他の実施形態においては、枝はエネルギーを供給しない単に鋭利な切断要素８０であるが、これらの枝を皮膚表面１０２に平行に配置してカテーテルシャフト７６の縦軸７７（図９）の周りに回転させ、あるいは肌に対して実質的に平行な配向で引き込ませると、この装置７０は一度の回転あるいは引き込みにおいて複数のセプタム１０８を効率的に破壊することができる。さらに他の実施形態においては、少なくとも一つのカテーテルシャフト７６を、治療する組織の内部への治療促進剤５４の注入のために構成することができる。さらに他の実施形態においては，針の先端の幾何学的形状は，特定の組織を破壊する効果のためのエネルギー場を形作る構成とすることができる。
【００６０】
ここで図１１を参照すると、さらに他の実施形態においては，作動要素８０、例えば切断要素をカテーテルシャフト７６の中心軸７７に対して鋭角に配置することができる。この装置の作動領域８０は、カテーテルシャフトに挿入するために折り畳むとともに，皮下のスペース１０６、１０８、１１０に配置するときには伸張させることができる。切断する状態に配置されると、図１１に示したように、カテーテルシャフトは皮膚表面１０２に平行に方向付けられ、装置７０を引き戻すと、そのチャネルにおいてセプタム１０８を捕

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抜して切断する。装置７０の作動領域８０は、例えば、鈍い解剖器具、機械的なカッター、あるいはエネルギー支援された装置とすることができる。高周波エネルギーあるいは電気抵抗の熱エネルギーを含む、任意の適用可能なエネルギーの物理療法を利用することができる。

【００６１】

ここで図１２～図１４を参照すると、少なくとも一つの実施形態においては、皮下注射用針６２あるいは電極７２を組織破壊装置３０と共に用いることができる。一つの実施形態においては、組織破壊装置３０、例えば図２～図６に示して上述した装置のような、ハウジング３２および転動する中央治療要素３４、クランプ４０あるいはトロイド形の電極５０と共に、扇形に広がる電極７４が配置される。さらに他の実施形態においては、扇形に広がる電極７４を、装置３０、例えば転動する中央治療要素３４とは独立させて配置することができる。

【００６２】

一つの実施形態においては、線維性のセプタム１０８のような結合組織に目標を定めるために、それらが生み出す電界を有利に配置できるように、扇形に広がる針電極７４を方向付けることができる。図１２～図１３を参照すると、少なくとも一つの実施形態においては、中央治療要素３４が正に帯電し、かつ針電極６２、７２、７４は負に帯電する。図１３に示した一実施形態は、トロイド形の中央治療要素３４の中心を通って扇型の電極７４の配備を含めることができる。扇形に広がる電極は、治療する組織のエネルギーによる破壊を助けるために機械的に回転させることができる。図１４に示した他の実施形態は、ハウジング３２の内部に配置されるとともにトロイド形の中央治療要素３４の周縁に配置された、真っ直ぐな針電極６２、７２を含むことができる。これらの針は、電界線がセプタムに対して垂直にあるいは平行に方向付けられるように皮下に形付けられあるいは構成され、セプタムは電気的に崩壊させられる。図１４を参照すると、針電極６２、７２は、その近位側が電気的に絶縁されるとともに、電気的に活性な遠位端が露出している。少なくとも一つの実施形態においては、中央治療要素３４が負に帯電し、かつ針電極６２、７２、７４が正に帯電する。ここで図１４Ａを参照すると、正に帯電する中央治療要素３４とそれを取り囲んで負に帯電している電極６２、７２、７４との間の距離「Ｄ」は、形状に治療する組織に対する破壊的なエネルギーの分布を形付けるために変更することができる。

【００６３】

ここで図１５を参照すると、少なくとも一つの実施形態においては、ハウジング３２は、真っ直ぐな針電極６２、７２の挿入を案内するチャネル３５を有したテンプレート９０として構成することができる。様々なサイズのテンプレートを設けることができ、それによって針電極の様々な挿入パターンが可能となる。これらのテンプレート９０は、瘢痕化した領域、あるいは重症なセルライトの場合には特定の凹みあるいは凹みの集合体といった、特定の領域に焦点を合わせたサイズとすることができる。大型のセルライトの凹みはより大型のテンプレートで治療することができ、より小さいセルライトの凹みはより小さいテンプレートで治療することができる。エネルギーは、患者を治療するために用いる特定のテンプレートに合わせて調整することができる。

【００６４】

一つの実施形態においては、中央治療要素３４は、有効な治療領域を最大化するために、少なくとも一つの針電極６２、７２と共に作用することができる。さらに、針電極は、装置３０のハウジング３２の周囲に配置して、一緒にエネルギーを印加し、あるいは多重化することができる。ここで図１６を参照すると、少なくとも一つの実施形態においては、中央治療要素を正に帯電する電極として構成し、かつ周囲に分配される複数の針電極７２を負に帯電する電極として構成することができる。このような極性は、単なる例示であって、供給されるエネルギーのタイプおよび所望の効果に応じて電極の極性を切り替えあるいは変更できることは理解されなければならない。ユーザによる電極７２あるいは針６２の配置を案内するために、テンプレート９０を用いることができる。先に言及したよう

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に、治療する組織の望ましい容量に応じて、様々に異なって寸法決めされかつ形作られたテンプレートを提供することができる。

【００６５】

ここで図１６をより詳しく参照すると、一つの実施形態においては、中心電極３４から連続的にエネルギーを供給することができるが、周囲の接地電極７２Ａ～７２Ｒは時間的な順番で活性化される。したがって、周辺電極７２Ａ～７２Ｒは順番に活性化される。このことは、エネルギー供給を一定にすることによって筋肉刺激を減少させるとともに、単一の接地電極の高いインピーダンスに起因して供給される総エネルギーを減少させる。各組織部分にはわずかな時間だけエネルギーが印加され、それによって組織の加熱および温熱損傷を最小化する。この電極配列が治療領域全体の上でゆっくり移動すると、低エネルギーの治療となる。一つの実施形態においては、中央の正電極とそれを取り囲んでいる周辺電極との間の距離は１０．０ミリメートルである。少なくとも一つの実施形態においては、エネルギーが１０オーム、２００ボルト、０．５アンペアあるいはまた１００ワットで供給される。さらに他の実施形態においては、２０分の１のデューティーサイクルが一つの領域に用いられる。さらに他の実施形態においては、より高いインピーダンスおよびより低い電力が用いられる。

【００６６】

ここで図１７Ａ～図１７Ｂを参照すると、本発明のさらに他の実施形態においては、超音波エネルギーを印加することによって皮下の構造を崩壊させるために、超音波装置１２０、例えばハンドピース１２２および治療シャフト１２４を有した超音波カテーテルが用いられる。この超音波装置は、例えば高周波メスを含み、あるいは針カニューレの先端に超音波振動子を取り付けることができる。この装置１２０は、治療シャフトの開口１２５あるいは別個の注入装置５６（図６）を介した、治療領域、例えば皮下脂肪１０６に向けての治療促進剤５４の注入と共に用いることができる。エネルギー印加の前における治療促進溶液の注入を保証するために、選択的な制御装置１２８をいることができる。さらに、治療領域に微小な泡１３２（撹拌した塩水等）を注入するために、上述したものに類似した注入および泡立ち装置５６，１３０を用いることができる。一つの実施形態においては、高周波針あるいは超音波治療シャフトは、治療する皮下組織あるいはセルライト凹みの下方で前後方向に動かされるように構成する。

【００６７】

少なくとも一つの実施形態において、本発明は、哺乳類の患者の皮下構造１０６、１０８（図１）を崩壊させる装置を含む。この装置は、その表面に配設された１つ若しくは複数のエネルギー伝達部材３４、４０、５０あるいは電極７２、７４を有する印加装置３０、７０（図２、図９）を備えることができる。一つの実施形態において、この印加装置はカテーテル７０（図９）として構成される。電極は、電気パルスを伝達するように構成される。この装置は、印加装置に作動的に接続されるとともに約１０Ｖ～３０００Ｖの電気パルスを供給するように構成されたパルス発生器３３（図６）を更に備える。印加装置および発生装置は、膠原性の皮下構造、例えば線維性のセプタム１０８を破壊するように構成することができる。

【００６８】

他の実施形態（図９～図１３）においては、この印加装置は、治療する皮下の構造１０６，１０８に隣接する領域へと哺乳類の患者の肌１０２、１０４を介して挿入されるように構成されたカテーテルデバイス７０である。このカテーテルあるいは印加装置は、治療する目標膠原性構造１０８に対しある角度に配置することができる。

【００６９】

少なくとも一つの実施形態（図４）において、この印加装置５０は、少なくとも一つの曲率半径および少なくとも一つの表面を有したトロイド形の形状を有する。

【００７０】

再び図２を参照すると、さらに他の実施形態において、この印加装置３４は、ハウジング３２の内側に取り付けられるとともに、ハウジングに対して動くように構成される。さ

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らに他の実施形態においては、ハウジングが活性電極であり、この印加装置がリターン電極あるいはアースである。他の実施形態においては、ハウジングがリターン電極あるいはアースであり、この印加装置が活性電極である。一つの実施形態において、この印加装置は、ハウジングに回転自在に接続されて複数の方向に回転できるようになっている。

【００７１】

再び図７Ａ～図８Ｃを参照すると、他の実施形態においては、この印加装置の少なくとも一つの表面は、哺乳類の患者の肌を貫通できる極微針６２を更に含む。これらの極微針は、エネルギー伝達要素を含むことができる。さらに他の実施形態において、この印加装置は、追従可能なパッド６０として構成される。この追従可能なパッドは、哺乳類の患者の肌１０２、１０４を貫通できる、そこから延びる極微針を更に含む。この印加装置は、１つ若しくは複数の電極が、哺乳類の患者の肌を貫通することができる極微針を含むように構成することができる。

【００７２】

さらに他の実施例において、本発明はまた、哺乳類の身体の肌の凹凸の一因となる皮下構造を選択的に破壊する方法を含む。この方法は、第１電極４１および第２電極４２を有したエネルギー伝達装置を提供することを含む。第１および第２の電極の間に電界を生み出すように構成された、パルス発生器３３が提供される。このエネルギー伝達装置は、治療する皮下組織１０６、１０８に隣接した領域に配置され、皮下構造を破壊するために少なくとも一つの細胞の透過化を生じさせるべく、この皮下構造に細胞レベルでエネルギーを与える。一つの実施例において、この細胞の透過化は可逆的である。他の一実施例において、この細胞の透過化は不可逆的である。さらに他の実施形態において、不可逆的な細胞の透過化は、細胞内の基質の細胞自滅の生成を介して達成される。

【００７３】

再び図６を参照すると、さらに他の実施形態において、本発明の皮下組織を治療する方法は、治療促進剤５４を準備し、第１電極３４と第２電極３２の間の電界活性化と共に例えば注射器５６により治療促進剤を供給することを含む。治療促進剤は、リドカインのような麻酔薬、エピネフリンのような血管収縮薬、低張溶液、低張塩水、カリウム、攪拌された塩水、微小な泡、あるいはまた微小球体、リドカイン、あるいは膠質性溶液を含む。

【００７４】

なお他の実施形態において、セルライトを治療する方法は、患者の皮下領域にある線維性セプタム１０８の細胞への局所的なエネルギーの供給を含む。このエネルギーは、セプタムを破壊するのに十分な程度に線維性セプタムの細胞膜を透過化させるために、選択された条件の下で細胞に供給される。

【００７５】

再び図１２を参照すると、少なくとも一つの実施形態において、哺乳類の患者の皮下構造を破壊するための装置は、その表面上に配設された１つ若しくは複数のエネルギー伝達部材３４を有する印加装置３０を備え、このエネルギー伝達部材はエネルギー場を伝達するように構成されている。エネルギー場の伝達と共に、治療促進剤５４を治療する組織１００に付加することができる。エネルギー伝達部材および治療促進剤は、膠原性の皮下構造１０８を破壊するように作動する。この皮下構造は、印加装置に対し実質的にある角度で方向付けることができる。

【００７６】

本願明細書において議論する方法および装置は、肌の凹凸を治療するための、および過剰な脂肪組織、セルライトおよび瘢痕化といった他の疾患を治療するための、哺乳類の身体における皮下構造１０６、１０８の破壊あるいはまた破壊にとって有益である。この装置および方法は、エネルギーを伝える印加装置、極微針、カテーテル、および肌を介した非侵襲的な、肌を介したより侵襲的でない、あるいは最小限に侵襲的な皮下アプローチによる治療を適用するための皮下治療装置を含む。この分野の公知でありかつ本願明細書において議論する様々な薬剤は、皮下組織を治療するためのこれらの手技を支援しあるいは改良する。

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【００７７】
一つの実施形態において、本発明は、軟組織を治療するための装置を含む。他の実施形態において、本発明は、線維組織を治療するための方法を含む。一つの実施形態において、本発明は、脂肪細胞およびセプタム１０８を含む皮下脂肪層１０６を治療するための方法および装置を更に含む。一つの実施形態において、本発明は、セルライトを治療するための方法および装置を更に含む。本発明は、セルライトの外観の一時的な減少、あるいはセルライトの恒久的な減少のために有益である。本発明はまた、脂肪吸引の補助的な手段として用いることができる。さらに本発明は、セルライトの外観を一時的に改善するための、皮下への流体の注入および分散を提供する。本発明はまた、良性新生物、例えば脂肪腫の除去のために有益である。

【００７８】
少なくとも一つの実施形態において、本発明は、標的領域の美的な外観を改善するために、コラーゲン、結合組織、脂肪組織（脂肪細胞）等といった皮下の構造（あわせて「標的組織」あるいは「皮下構造」）に目標を定めて破壊する方法および装置を指向している。この標的領域は、人体において改善が望まれる、顔面、あご、首、胸部、乳房、腕、脚、腹部（骨盤領域を含む）、大腿、臀部、膝および脚部を含む任意の表面あるいは輪郭から成る。目標とする組織には、その領域の結合組織あるいはセプタム、または皮下およびより深い脂肪の沈澱あるいは層のような、その下に横たわっていて望ましくない身体の輪郭を悪化させ得る組織が含まれる。肌の凹凸は、セルライトや線維化、あるいは首、あご、乳房、尻、腹部、腕等の領域における脂肪の沈澱あるいは過剰な脂肪といった、外側の様相に対する人の満足感を減少させる状態を指す。

【００７９】
本願明細書において使用する促進剤５４という用語は、外因性のガス、液体、混合物、溶液、化学薬品のうちの少なくとも一つ、または組織に適用されたときにエネルギー供給システム３３の破壊的な生物学効果を改良する材料を指す。促進剤の一つの実例は、促進溶液である。一つの実施形態において、この促進溶液は、外因性の気体、例えば微小な泡１３２を含む。促進剤あるいは促進溶液は、例えば、塩水、通常生理食塩溶液、低張塩水、低張溶液、高張液、リドカイン、エピネフリン、膠質性溶液、あるいはまた微小な泡溶液を含むことができる。他の促進剤は、本願明細書において更に詳細に説明される。一つの実施形態において、本発明は、促進溶液を撹拌しあるいはまた混合するように構成された撹拌システム５６、および溶液を注入するように構成された注入部材５６、１２２を備える組立体である。少なくとも一つの実施形態において、この組立体は、また、溶液を格納するための容器、例えばその内部に溶液を格納するためのリザーバ６４を備える。このリザーバは、従来技術において周知の点滴バッグとすることができる。

【００８０】
ここで図１８を参照すると、一つの実施形態において、組立体２００はエネルギー供給システム３３を備える。医師が促進溶液２１０を調製して吊り下げると、この組立体は、前もってプログラムされたあるいはユーザが定めたアルゴリズムに基づいて混合し、注入し、かつ治療する組織にエネルギーを付加する。このアルゴリズムは、制御装置２２８にプログラムすることができる。この制御装置は、他の構成部分を含む単一構造の組立体に含めることもできるし、あるいはこの組立体の他の構成部分と連絡するように構成された別個のユニットとすることもできる。少なくとも一つの実施形態において、この制御装置はプロセッサおよびメモリーを含む。少なくとも一つの実施形態において、この制御装置は、また、入力装置２３６、例えば電気スイッチ、ボタン、あるいはキーパッドを含むことができる。少なくとも一つの実施形態において、この制御装置はまた、出力装置２３８、例えば従来技術において周知のＬＥＤライト、液晶画面、計器、あるいは他のスクリーンおよび出力表示器を含むことができる。他の実施形態において、入力装置２３６および出力装置２３８は制御装置から分離することができるが、制御装置と電気的に通信する。組立体は、促進溶液２１０をリザーバ２２０から撹拌機２０８へと搬送し、そこにおいて溶液が混合されかつ撹拌されるように構成される。撹拌機２０８は単一構造のハンドピー

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ス２４２に含めることができる。組立体は、その後、注入部材２１４を用いて患者に溶液を注入するように構成される。組立体はまた、ハンドピースに含まれるエネルギー供給装置２０４を用いて、治療のために注入した組織１００にエネルギーを印加するように構成される。このハンドピースは、中央治療要素３４を有したハウジング３２、例えば図２に示した組織破壊装置３０として構成することができる。一つの実施形態においては、少なくとも一つの皮下注射針６２が溶液注入部材２１４に配設される。さらに他の実施形態において、溶液注入部材は、格納式の針６２と共に構成することができる。

【００８１】

本発明はまた、患者の皮下脂肪１０６に対する皮下注射に対して生体適合性を有した様々な治療促進剤５４を含む。一つの実施形態において、溶液は腫脹性の溶液である。腫脹性の溶液は、局所麻酔の適用をもたらすために特に適合させたものであり、周知の技術である。腫脹性の溶液は、様々な医薬用溶液を含むことができる。腫脹性溶液の一つの実施例は、２％のリドカインを含有した１０００ｍｌの通常生理食塩溶液、３０ｍｌ（６００ｍｇ）のエピネフリン、および１モル（１２．５ｍｌあるいは１２．５ｍｇ）の重炭酸ナトリウムを含む溶液である。腫脹性溶液の少なくとも一つの他の実施例は、１０００ｍｌの通常生理食塩溶液、５０ｍｌの１％のリドカイン、１ｃｃの１：１０００エピネフリンを含む溶液である。これらの添加物は商業的に入手可能である。腫脹性溶液は、治療部位の出血を減少させるとともに、手技の間および後における痛みを減少させる局所麻酔効果を提供する。

【００８２】

一つの実施形態において、促進溶液５４は正常食塩溶液である。さらに他の実施形態において、促進溶液は低張溶液である。さらに他の実施形態において、溶液は微小な泡あるいはナノサイズの泡を含む溶液である。この溶液は、微小な泡を含む溶液を生じさせるために、２つの注射器の間で１回若しくは複数回撹拌される。本願明細書の他の部分で詳細に説明するように、微小な泡あるいはナノサイズの泡を含むいくつかの溶液は商業的に入手可能である。

【００８３】

促進剤は所望する効果に応じるが、その幾つかは以下に詳述される。例えば促進剤は、経皮的にあるいは治療する組織への注入により伝達することができる。治療促進剤には、リドカインのような麻酔薬、界面活性剤、エピネフリンのような血管収縮の薬剤、低張塩水、カリウム、撹拌された塩水、微小な泡、商業的に入手可能な超音波造影剤、微小球体、脂肪細胞、脂肪、自己由来の組織（例えば、身体からの敵対的な反応を最小化するための組織移植片を形成するきれいな脂肪細胞を生み出す崩壊された脂肪細胞）、ＰＬＬＡ、ヒドロキシアパタイトが含まれる。治療促進剤は、皮下組織への音波の負荷の前に、間に、あるいはその後に供給することができる。

【００８４】

一つの実施形態において、溶液注入部材２１４に対する電源は、溶液注入部材に含まれる。他の実施形態において、溶液注入部材の電源は溶液注入部材の外部に配置される。例えば、溶液注入部材の電源は制御装置２２８によって供給することができる。少なくとも一つの実施形態において、注入容量、深さ、タイミング、および注入と超音波の負荷との同期を制御するアルゴリズムは、溶液注入部材に含まれているメモリあるいはまたプロセッサに含めることができる。少なくとも他の実施形態においては、注入容量、深さ、タイミング、および注入と超音波の負荷との同期を制御するアルゴリズムは、溶液注入部材の外部に配置された、例えば制御装置に含めることができる。

【００８５】

一つの実施形態において、溶液注入部材２１４は少なくとも一つの皮下注射針６２を含む。皮下注射針は、溶液注入部材に接続された近位端、および治療のために標的領域１００に貫通するように構成された遠位端を有している。針の遠位端は、周知のように、肌に対するより外傷的でない貫入のために、斜めに切断（図示せず）することができる。一つの実施形態において、針は極微針を含むことができる。少なくとも一つの実施形態におい

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て、針は角錐状（図示せず）に形付けることができる。さらに他の実施形態において、溶液注入部材は複数の皮下注射針を含む。皮下注射針は、溶液が針を通って組織に流入するように構成された中央管腔を具備した、管状のチャネルを有している。一つの実施形態において、溶液注入部材は、溶液注入部材の内部の位置から針が表皮１０２を介して治療する皮下組織に貫通する位置へと、皮下注射針を移動させるための作動要素（図示せず）を有している。一つの実施形態において、針は、少なくとも皮下脂肪１０６を貫通するように構成される。さらに他の実施形態において、針は、深部脂肪層１１０を貫通するように構成される。

【００８６】

注射針の直径は４０ゲージから７ゲージのサイズにわたる。一つの実施形態において、注射針は３０ゲージのサイズである。さらに他の実施形態において、注射針は２８ゲージのサイズである。さらなる実施形態において、注射針は２５ゲージのサイズである。追加の実施形態において、注射針は２２ゲージのサイズである。さらに他の実施形態において、注射針は２０ゲージのサイズである。さらに一つの実施形態において、注射針は１８ゲージのサイズである。針の全てを一つの長さとすることもできるし、あるいは異なる長さすることもでき。一つの実施形態において、針の全長は２．０ミリメートル～１０．０ｃｍである。一つの実施形態においては、針の全長は５ミリメートル未満である。他の実施形態において、針の全長は５．０ミリメートル～２．０ｃｍの範囲である。他の一つの実施形態において、針の全長は１．０ｃｍ～３ｃｍの範囲である。さらに他の実施形態において、針の全長は２．０ｃｍ～５ｃｍの範囲である。他の実施形態においては、針の全長は３．０ｃｍ～１０．０ｃｍの範囲である。

【００８７】

少なくとも一つの実施形態において、注射針６２は極微針を含む。一つの実施形態において、極微針の直径は２０ミクロン～５００ミクロンの範囲である。一つの実施形態において、極微針の全長は１００ミクロン～２０００ミクロンの範囲である。少なくとも一つの実施形態において、針は表皮１０２から深部脂肪層１１０に到達するのに十分な長さである。少なくとも一つの他の実施形態において、針は表皮から筋肉層２６に到達するのに十分な長さである。少なくとも一つの実施形態において、患者の快適性を増大させるために、局所的な麻酔クリームあるいはゲル、局所冷却法あるいは局所ブロックを用いて、更なる麻酔を治療領域に付加することができる。局所麻酔薬は、唯一必要な麻酔薬とすることもできるし、促進剤として用いられる任意のリドカインに代えることもできる。

【００８８】

一つの実施形態において、針６２は、治療する標的組織に応じて、皮膚表面から０．２ミリメートル～４０ミリメートルの距離にある皮下組織１０６に延びるのに十分な長さとすることができる。針は、針の遠位端２２６が少なくとも角質層を通って延びることができるように十分に長い。例えば、セルライトを治療するためには１．０ミリメートル～５．０ミリメートルの針入の深さが望しく、より深い皮下脂肪のためには３．０ミリメートル～４０ミリメートルの針入深さが望ましい。１つ若しくは複数の皮下注射針が、手動であるいは制御装置２２８によって自動的に、様々な深さに移動することができる。少なくとも一つの実施形態において、針は表皮１０２から深部脂肪層１１０に到達するのに十分な長さである。少なくとも一つの他の実施形態において、針は表皮１０２から筋肉層２６に到達するのに十分な長さである。

【００８９】

少なくとも一つの実施形態において、本発明の装置は、より深い組織層からより表面的な組織層へと、各段階の注入の間に組織に対してエネルギーを負荷しつつ、段階的な深さの注入を提供するように構成される。１つ若しくは複数の皮下注射針が、手動であるいは制御装置２２８によって自動的に様々な深さに移動することができ、更に後述するように組織は段階的な深さで治療される。

【００９０】

組立体２００は、注入部材２１４による溶液の注入の後に、様々な回数でエネルギー供

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給システム３３を活性化できるように構成されている。少なくとも一つの実施形態において、治療する組織への溶液の注入に続いて、組織へのエネルギー負荷のタイミングに同期させるために、制御装置２２８を用いることができる。一つの実施形態において、注入部材は、少なくとも治療する組織への溶液の注入を開始させるためのスイッチを有するように構成される。少なくとも一つの実施形態において、注入部材は、注入を停止させあるいはまた患者から針６２を引き抜くための停止ボタンを有するように構成することができる。

【００９１】

本発明のさらに他の実施形態において、組立体２００は冷却モジュール（図示せず）を含む。患者の肌への注入は、一般的に不快感、腫大、出血、瘢痕化あるいは他の望まれない効果といった副作用を伴う。さらにまた、本発明によって治療される皮下組織の破壊は、多くの美容整形あるいは皮膚科的治療に一般的ないくつかの副作用に結びつく。冷却モジュールの使用は本発明による治療の副作用を減少させる。組織の冷却は、出血、腫大および不快感を減少させる。この冷却モジュールは、従来技術において公知の多くの冷却方式のいずれかを含むことができる。少なくとも一つの実施形態において、冷却モジュールの一部はハンドピース２４２に含めることができる。冷却モジュールの一つの利点は、本発明の治療に伴う不快感、腫大、瘢痕化および他の望まれない効果の治療あるいは予防を援助することにある。少なくとも一つの他の実施形態において、この冷却モジュールは別個のモジュールとして組立体に含めることができる。さらに他の実施形態において、促進溶液は、治療する組織への注入の前に冷却することができる。

【００９２】

ハンドピース２４２は，異なる皮下異常あるいは異なる重症度の皮下異常を治療するように構成された、異なるサイズに設けることができる。一つのハンドピースは、他のものよりも高い針６２の密度を有する。例えば、セルライトのより重症な領域は、針の密度がより高いパターンのハンドピースによって治療することができる。使い捨てのハンドピースを有する少なくとも一つの実施形態においては、そのハンドピースの他の患者への再利用を防止するために安全対策チップ（図示せず）をハンドピースに設けることができ、それによって例えば肝炎あるいはエイズといった疾患の拡散を防止することができる。安全対策チップは、偽造のハンドピースが流通して患者に用いられることを防止するために含めることができる。

【００９３】

安定した結果を生み出すためのさらに他の要因は、治療する部位の肌表面積に対する注入溶液の容量である。一つの実施形態において、注入容量は、治療する部位の肌表面領域について約０．１ｃｃ／平方ｃｍ～治療する部位の肌表面領域について約２．０ｃｃ／平方ｃｍの範囲である。他の実施形態において、注入容量は、治療する部位の肌表面領域について約０．２５ｃｃ／平方ｃｍ～治療する部位の肌表面領域について約１．５ｃｃ／平方ｃｍの範囲である。さらに他の実施形態において，注入容量は、治療する部位の肌表面領域について約０．５ｃｃ／平方ｃｍ～治療する部位の肌表面領域について約１．０ｃｃ／平方ｃｍの範囲である。しかしながら、上述した注入容量は例示のためだけのものであり、治療する個々の患者の耐痛限界および治療する位置の脂肪層の深さに応じて変更することができる。

【００９４】

安定した結果を生み出すためのさらに別の要因は、治療する組織への溶液の噴射率である。一つの実施形態において、溶液の噴射率は約０．０１ｃｃ／秒～約１．０ｃｃ／秒の範囲である。他の一実施形態において、溶液の噴射率は約０．０２ｃｃ／秒～約０．５ｃｃ／秒の範囲である。別の実施形態において、溶液の噴射率は約０．０５ｃｃ／秒～約０．２ｃｃ／秒の範囲である。しかしながら、前述した噴射率は例示のためだけのものであり、治療する個々の患者の耐痛限界および治療する位置の脂肪層の症状に応じて変更することができる。

【００９５】

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本発明は、皮下組織を崩壊させる方法を含む。この方法は、治療する皮下組織１００に少なくとも一つの促進剤５４を配設することを含む。促進剤には溶液を含めることができる。この溶液は、少なくとも一つの皮下注射針６２を介して皮下脂肪１０６に注入することができる。それから、しばらくの間皮下組織に配設される促進剤を残して針を引き抜くことができる。エネルギー供給システム３３は治療する組織にエネルギーを供給することができ、促進剤に近接する皮下脂肪１０６あるいはまた線維性のセプタム１０８は崩壊する。

【００９６】

組織に伝達するエネルギー量および組織における生物学的な効果の一つの要因は、破壊的なエネルギーを組織に印加する前に注入された溶液が組織内に存在する時間の長さである。一つの実施形態において、注入された溶液は、破壊的なエネルギーを印加する前の約１０分～約３０分で組織内に浸透する。さらに他の実施例において、注入された溶液は、破壊的なエネルギーを印加する前の約１分～約１０分で組織内に浸透する。さらに他の実施例において、注入された溶液は、破壊的なエネルギーを印加する前の約１秒～約１分で組織内に浸透する。少なくとも一つの他の実施形態において、注入された溶液は、破壊的なエネルギーを印加する前の約５０ミリ秒～約１０００ミリ秒で組織内に浸透する。少なくとも一つの他の実施形態において、破壊的なエネルギーは溶液の注入とほとんど同時に治療する組織に印加される。

【００９７】

破壊的エネルギー照射の持続期間もまた、組織に対する破壊的エネルギーの生物学的な効果を決定し得る。一つの実施形態において、破壊的エネルギーは約１０秒の持続期間で治療する組織１００に印加される。他の実施形態において、破壊的エネルギーは約３０秒の持続期間で治療する組織１００に印加される。さらに他の実施形態において、破壊的エネルギーは約１分の持続期間で治療する組織１００に印加される。さらに他の実施形態において、破壊的エネルギーは約２分の持続期間で治療する組織１００に印加される。少なくとも一つの他の実施形態において、破壊的エネルギーは約５分の持続期間で治療する組織１００に印加される。さらに他の実施形態において、破壊的エネルギーは約５分～２０分の間の持続期間で治療する組織１００に印加される。なお他のひとつ実施形態において、破壊的エネルギーは約２０分～１時間の持続期間で治療する組織１００に印加される。

【００９８】

腫脹性の溶液は、例えば脂肪吸引手技の間に局所麻酔の適用を提供する、特に構成された溶液である。腫脹性の溶液は周知の技術である。腫脹性の溶液は様々な医薬用溶液を利用する。一つの実施形態において、腫脹性の溶液は、２％のリドカインを含有した１０００ｍｌの通常生理食塩溶液、３０ｍｌ（６００ミリグラム）のエピネフリン、および１モル（１２．５ｍｌあるいは１２．５ミリグラム）の重炭酸ナトリウムを含む。少なくとも一つの他の実施形態において、腫脹性の溶液は、１０００ｍｌの通常生理食塩溶液、５０ｍｌの１％リドカイン、および１ｃｃの１：１０００エピネフリンを含む溶液である。これらの添加物は、商業的に入手可能である。一つの実施形態においては、この腫脹性の溶液は撹拌機２０８に加えることができる。他の実施形態においては、予備混合されたあるいは商業的に入手可能な腫脹性の溶液を用いることができる。腫脹性の溶液は、治療部位の出血を減少させることができるとともに、手技の間および後における痛みを減少させる局所麻酔効果を提供することができる。少なくとも一つの実施形態において、促進剤はまた腫脹性の溶液を含むことができる。少なくとも一つの実施形態において、注入される促進溶液５４は低張溶液である。

【００９９】

少なくとも一つの他の実施形態において、様々な深さの皮下組織の治療は段階的に実行される。それぞれの注入に続いて、治療する組織への破壊的なエネルギーを負荷することができる。例えば、第１段階においては、深い位置への溶液の注入が実行されると、より深い層へ破壊的なエネルギーが印加される。第２段階においては、より表面的な位置への注入が実行されると、より表面的な層への破壊的なエネルギーが印加される。徐々に表面

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的となる深さにおける複数段階の溶液の注入は、破壊的なエネルギー、例えば溶液をそれぞれ注入した後における破壊的なエネルギーの印加と共に実行することができる。一つの実施形態において、各段階の注入は，その前段階の注入よりも約０．５～２．０ｃｍ浅い深さで実行される。一つの実施形態においては、各段階の注入は、その前段階の注入よりも約０．５ミリメートル浅い深さで実行される。他の実施例において，各段階の注入は、その前段階の注入よりも約１ミリメートル浅い深さで実行される。さらに追加的な一実施形態において、各段階の注入は、その前段階の注入よりも約２ミリメートル浅い深さで実行される。他の実施例において、各段階の注入は，その前段階の注入よりも約５ミリメートル浅い深さで実行される。さらに他の実施例において、各段階の注入は、その前段階の注入よりも約１．０センチメートル浅い深さで実行される。の他の実施形態、さらに一つの実施形態において，各段階の注入は、その前段階の注入よりも約１．５センチメートル浅い深さで実行される。さらに一つの実施形態において，各段階の注入は、その前段階の注入よりも約２．０センチメートル浅い深さで実行される。、さらに他の実施形態において、皮下組織の浸透は、約３０ミリメートル、約２５ミリメートル、および約２０ミリメートルの深さの段階において実行される。一つの他の実施形態において、皮下組織の浸透は、約１０ミリメートル，約５ミリメートル、および約２ミリメートルの深さの段階において実行される。少なくとも一つの実施形態においては、各段階の注入の間に破壊的なエネルギーを印加するのではなく、全ての深さにおける注入の後に一連の破壊的なエネルギーが組織に印加される。

【０１００】

一つの実施形態において、治療する組織は皮層１０４と深部脂肪層１１０との間において注入を受ける。他の実施例において、治療する組織は、表面的な脂肪層１０６と筋肉層２６との間において注入を受ける。さらに他の実施形態において、治療する組織は、皮層１０４と筋肉層２６との間において注入を受ける。一つの実施形態において、治療する組織は、約２ミリメートル～４．０センチメートルの深さにおいて注入を受ける。一つの実施形態においては、治療される組織は、約０．５ミリメートルの深さにおいて注入を受ける。少なくとも一つの実施形態において，治療される組織は、約１．０ミリメートルの深さにおいて注入を受ける。さらに追加的な一実施形態において、治療される組織は、約１．５ミリメートルの深さにおいて注入を受ける。一つの実施形態においては，組織は約２ミリメートルの深さにおいて注入を受けて治療される。他の一実施形態において、組織は約５ミリメートルの深さにおいて注入を受けて治療される。さらに他の実施例においては、組織は約１．０センチメートルの深さにおいて注入を受けて治療される。さらに一つの実施形態において、組織は約１．５センチメートルの深さにおいて注入を受けて治療される。さらに一つの実施形態において、組織は約２．０センチメートルの深さにおいて注入を受けて治療される。さらに一つの実施形態において，組織は約２．５センチメートルの深さにおいて注入を受けて治療される。さらに一つの実施形態において、組織は約３．０センチメートルの深さにおいて注入を受けて治療される。さらに一つの実施形態において，組織は約３．５センチメートルの深さにおいて注入を受けて治療される。さらに一つの実施形態において、組織は約４．０センチメートルの深さにおいて注入を受けて治療される。一つの実施形態においては，単一の深さの注入あるいは組織の浸透が実行される。少なくとも一つの他の実施形態においては，複数の深さにおける注入あるいは浸透が実行される。

【０１０１】

溶液の注入と破壊的なエネルギーの負荷との間の時間の経過は、約０秒～１時間の範囲とすることができる。溶液５４の注入に続く破壊的なエネルギーの印加のタイミングを同期させるために、自動制御装置２２８を用いることができる。一つの実施形態においては、破壊的なエネルギーの印加は溶液の注入とほぼ同時とすることができる。一つの実施形態においては、破壊的なエネルギーを印加する約５秒未満前に注入を実行することができる。他の実施例においては、破壊的なエネルギーを印加する約５秒～約２０秒前に注入が実行される。さらに一つの実施形態においては、破壊的なエネルギーを印加する約２０秒

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～約６０秒前に注入が実行される。さらに他の実施形態においては、破壊的なエネルギーを印加する約１分～５分前に注入が実行される。さらに一つの実施形態においては、破壊的なエネルギーを印加する約５分～１５分前に注入が実行される。もう一つの実施形態においては、破壊的なエネルギーを印加する約１５分～３０分前に注入が実行される。さらに他の実施例においては、破壊的なエネルギーを印加する約３０分～６０分前に注入が実行される。

【０１０２】

安定した結果を生じさせるさらに他の要因は、破壊的なエネルギーを印加する前に溶液をエネルギーによって組織内に分散させる期間である。一つの実施形態において、治療する組織に溶液を分散させるために超音波を用いることができる。一つの実施形態において、破壊的なエネルギーを印加する前に、エネルギーによって溶液を組織内に分散させる期間は約１秒～５秒である。他の実施形態において、破壊的なエネルギーを印加する前に、エネルギーによって溶液を組織内に分散させる期間は約５秒～３０秒である。さらに一つの実施形態において、破壊的なエネルギーを印加する前に、エネルギーによって溶液を組織内に分散させる期間は約３０秒～６０秒である。さらに他の実施形態において、破壊的なエネルギーを印加する前に、エネルギーによって溶液を組織内に分散させる期間は約１分～５分である。

【０１０３】

一つの実施形態においては、治療する組織の破壊に続いて、破壊された組織を患者の内部に残し、例えば患者の身体によって吸収させることができる。他の実施例においては、破壊した組織は、例えば脂肪吸引によって患者の身体から取り除くことができる。

【０１０４】

一つの実施形態において、電極は、肌の上に配置できるとともに、望まれない表面の火傷を回避するために最小限のエッジ効果を有するように構成される。さらに他の実施形態おいて、皮下の針電極は、少なくとも一つの針の遠位端に隣接した特定の位置にエネルギー電界強度を集中させるように構成することができる。例えば、ピラミッド状あるいは斜めに切断した遠位側を有する針は、その遠位端に隣接するきわめて高いエッジ効果を有する傾向がある。さらに他の実施形態においては、針の配列の配置、例えば針を並べて配置すると、複数の高い電界強度の組織治療箇所に結びつき、それによって治療する組織のより大きな領域の全体に局所性の組織剥離を生じさせる。身体が治療された組織を回復させてリモデリングすると、これらの組織の治療部位は再吸収され、破壊させた脂肪細胞は取り除かれる。このことは、局所性の火傷が健康な組織の島と共に治療された組織に作り出されて治癒および移動を容易にする、高い強度で焦点合わせされた超音波アレイを含む治療の後に生じるリモデリングに類似している。少なくとも一つの他の実施形態においては、鈍い針電極を含めることができ、それによって治療した組織におけるより大きな治療破壊効果領域に結びつく。

【０１０５】

本発明は、組織を治療する他の方法あるいは装置と組み合わせることができる。例えば、本発明は、肌を締める手技、例えばHayward（カリフォルニア州）のThermage Corporationから入手可能なThermage（商標）、Brisbane（カリフォルニア州）のCutera, Inc.から入手可能なCutera Titan(商標)、あるいは、Santa Clara（カリフォルニア州）のLumenis, Inc.から利用可能なAluma（商標）の使用を含むことができる。

【０１０６】

本発明は、その精神および必須の特徴から逸脱することなしに他の形態で具体化することができる。したがって、説明した実施形態はあらゆる観点において例示的なものであって限定的なものではないことが考慮されるべきである。ある好ましい実施形態について本発明を説明してきたが、当業者にとって明らかな他の実施形態もまた本発明の範囲内である。したがって、本発明の範囲は、添付の請求の範囲を参照することのみによって定められることが意図される。

【図面の簡単な説明】

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【０１０７】
【図１Ａ】皮膚および皮下組織の正常領域の様々な層を示す図。
【図１Ｂ】皮膚および皮下組織の病的な領域の様々な層を示す図。
【図２】非侵襲的にエネルギーを負荷する本発明の装置の一実施形態を示す図。
【図３Ａ】本発明のクランプの実施形態を模式的に示す図。
【図３Ｂ】図３Ａのクランプの実施形態における電流分布のモデルを模式的に示す図。
【図４】円柱状の電極を用いた図３Ａのクランプの実施形態を模式的に示す図。
【図５Ａ】本発明のローラボールの実施形態を模式的に示す図。
【図５Ｂ】図５Ａのローラボールの実施形態における電流分布を模式的に示す図。
【図６】外側に設けられたエネルギー負荷装置を有した治療促進剤と共に用いる本発明の注入システムの実施形態を示す図。
【図７Ａ】皮膚表面に当てられる極微針を具備したパッドを有するシステムを備えた本発明の実施形態を示す図。
【図７Ｂ】吸引が肌の表面をパッドに向けて上方に引っ張り上げたことにより極微針が肌表面を貫通している状態を示す図７Ａの実施形態を示す図。
【図８Ａ】目標とする組織に当てられた状態を示す図７Ａの実施形態の断面図。
【図８Ｂ】パッド上に配列として配設された極微針を有した本発明の装置の一実施形態を示す図。
【図８Ｃ】図８Ｂの装置の要部拡大図。
【図９】本発明の侵入型電極の配列の実施形態を示す図。
【図１０】本発明の侵入型電極の配列の実施形態を示す図。
【図１１】本発明の侵入型電極の配列の実施形態を示す図。
【図１２】皮膚表面に当てられる電極と共に用いられる、本発明の侵入型電極の配列の実施形態を示す図。
【図１３】皮膚表面に当てられる電極と共に用いられる、本発明の侵入型電極の配列の実施形態を示す図。
【図１４】皮膚表面に当てられる電極および提案する治療のレイアウトと共に用いられる、本発明の侵入型電極の配列の実施形態を示す図。
【図１４Ａ】電極治療のレイアウトの一例を示す図。
【図１５】個別に配置されるエネルギー伝達要素に使用するテンプレートを示す図。
【図１６】複数のエネルギー伝達要素に使用する治療アルゴリズムの一例を示す図。
【図１７Ａ】治療改善薬剤を注入するエネルギー負荷システムおよび装置を示す図。
【図１７Ｂ】治療する組織にハンドピースが挿入される図１７Ａのシステムおよび装置を示す図。
【図１８】皮下組織を治療するための組立体を示す図。

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【図１Ａ】

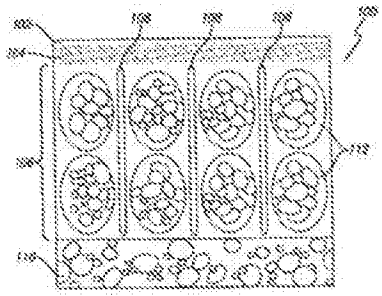


FIG. 1A

【図１Ｂ】

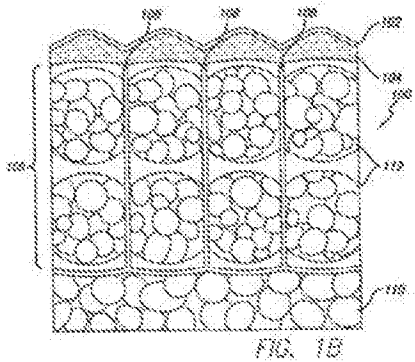


FIG. 1B

【図２】

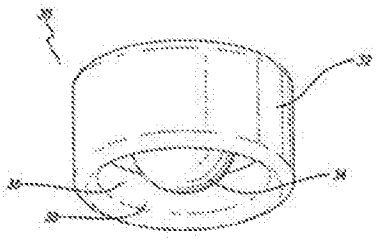


FIG. 2

【図３Ａ】

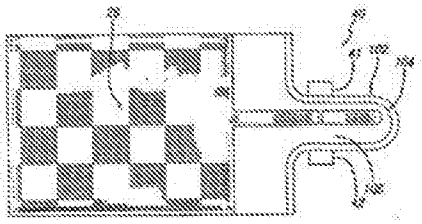
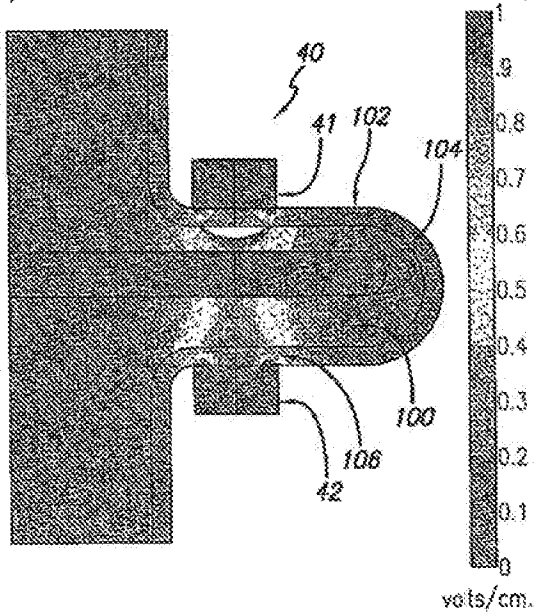


FIG. 3A

【図３Ｂ】

FIG. 3B



【図４】

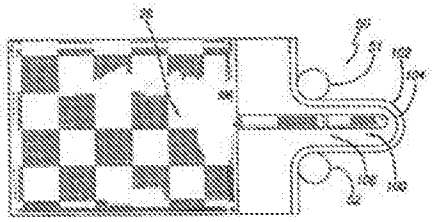


FIG. 4

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【図５Ａ】

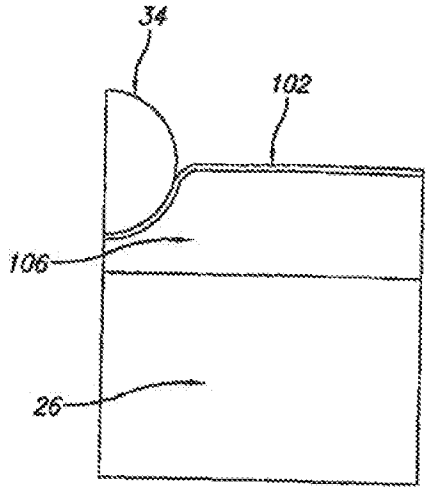
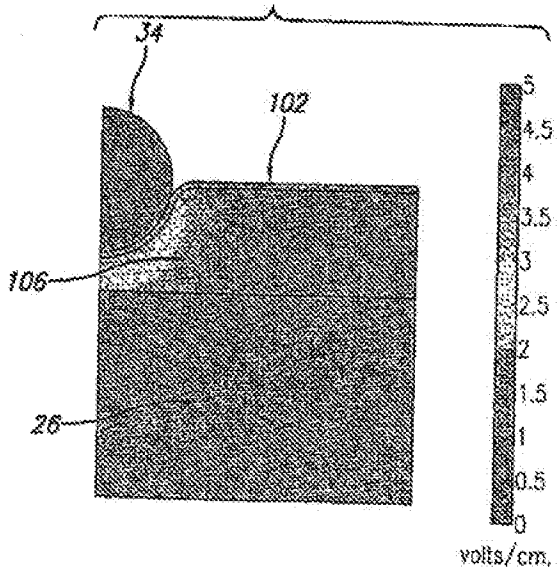


FIG. 5A

【図５Ｂ】

FIG. 5B



【図６】

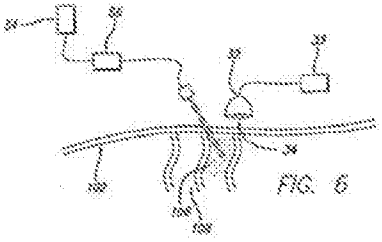


FIG. 6

【図７Ａ】

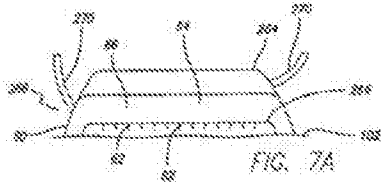


FIG. 7A

【図７Ｂ】

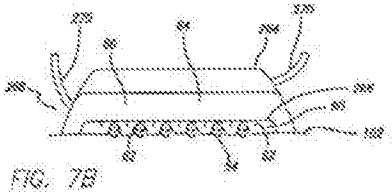


FIG. 7B

【図８Ａ】

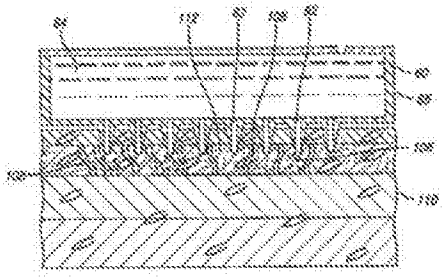


FIG. 8A

【図８Ｂ】

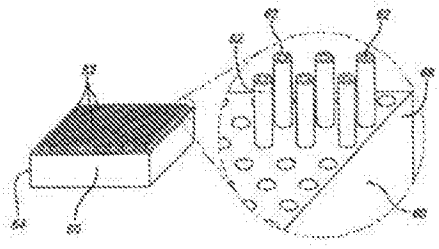


FIG. 8B FIG. 8C

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【図８Ｃ】

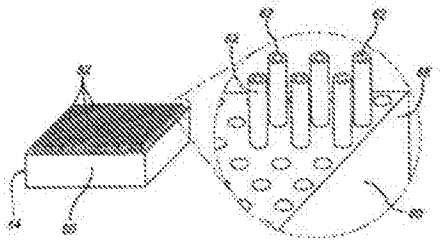

FIG. 8B FIG. 8C

【図９】

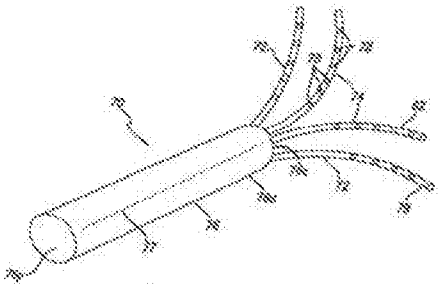

FIG. 9

【図１０】

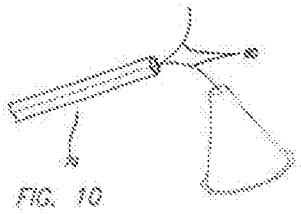

FIG. 10

【図１１】

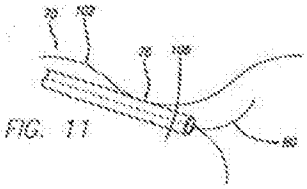

FIG. 11

【図１２】

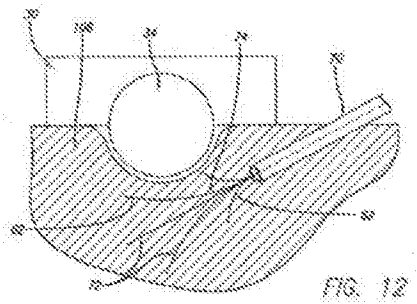

FIG. 12

【図１３】

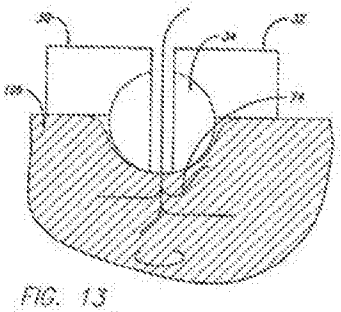

FIG. 13

【図１４】

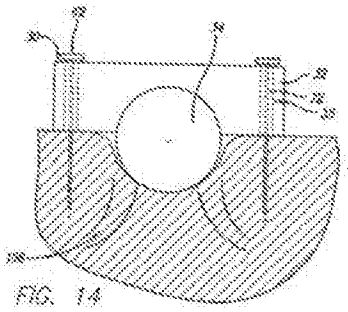

FIG. 14

【図１４Ａ】

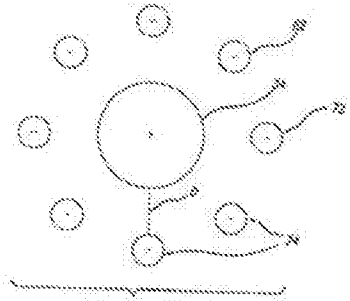

FIG. 14A

【図１５】

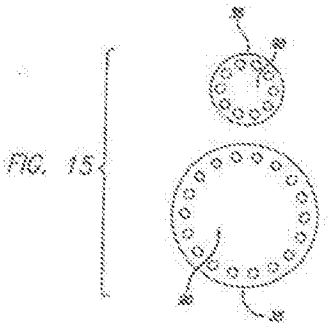

FIG. 15

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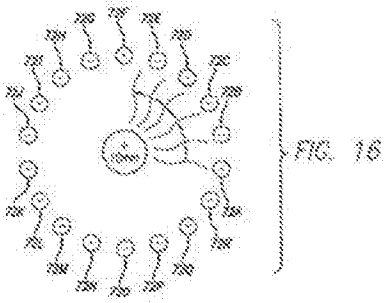
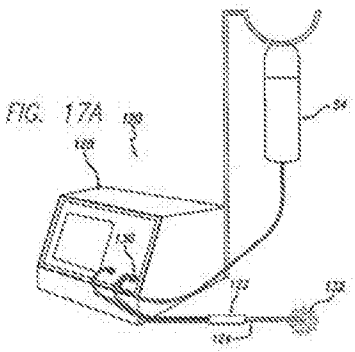
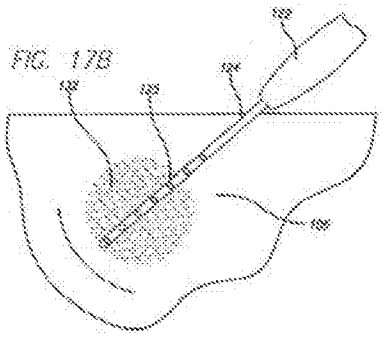
【図１６】



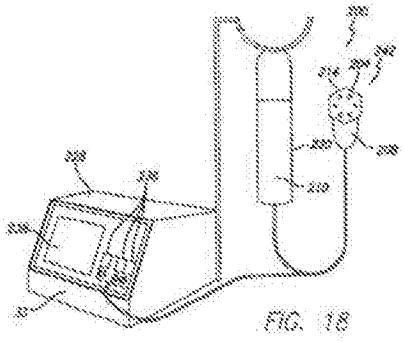
【図１７Ａ】



【図１７Ｂ】



【図１８】



【手続補正書】
【提出日】平成20年5月8日(2008.5.8)
【手続補正１】
【補正対象書類名】特許請求の範囲
【補正対象項目名】全文
【補正方法】変更
【補正の内容】
【特許請求の範囲】
【請求項１】
音波を発生させるための音波発生装置と、
前記音波発生装置に作動的に接続されるとともに患者の皮下組織に音波を印加するように構成された音波トランスデューサと、
ガス供給源と、
溶液供給源と、
前記溶液供給源および前記ガス供給源に作動的に接続された溶液注入部材と、
を備え、
前記溶液注入部材は、患者の皮下組織にガスおよび溶液を経皮的に注入するように構成され、
前記皮下組織に対する音波の印加は、前記皮下組織に注入された溶液内における皮下の空洞化による生物学効果を生み出し、
前記音波発生装置は、０．１ＭＰａ～１０．０ＭＰａの範囲のピーク負圧を有するとともに約０．２５ＭＨｚ～約２０ＭＨｚの範囲の振動数を有した音波を生じさせる皮下組織を治療するための組立体。
【請求項２】
前記ガス供給源が室内空気であることを特徴とする請求項１に記載の組立体。

【請求項３】
内部に前記ガス供給源を保持するように構成されたガスハウジングをさらに備えることを特徴とする請求項１に記載の組立体。
【請求項４】
内部に前記溶液供給源を保持するように構成された溶液ハウジングをさらに備えることを特徴とする請求項１に記載の組立体。
【請求項５】
前記溶液供給源および前記ガス供給源に作動的に接続された溶液撹拌機をさらに備え、
前記溶液撹拌機は溶液の微小な泡を作り出すように構成されていることを特徴とする請求項１に記載の組立体。
【請求項６】
前記溶液注入部材は、ハウジングおよび複数の中空の注入部材を含んでいることを特徴とする請求項１に記載の組立体。
【請求項７】
前記中空注入部材の少なくとも１つの遠位端は、溶液注入部材ハウジングの内側にある第１の状態と、前記遠位端が前記溶液注入部材ハウジングの外側に延びる第２の状態と、の間で動くことができることを特徴とする請求項６に記載の組立体。
【請求項８】
前記溶液注入部材は、扇形に広がる針の配列を有していることを特徴とする請求項１に記載の組立体。
【請求項９】
前記音波トランスデューサが平面トランスデューサであることを特徴とする請求項１に記載の組立体。
【請求項１０】
前記平面トランスデューサの焦点ゾーンは、表皮の下方において約１ミリメートル～約１５ミリメートルの組織深さで延びる近いゾーンから、表皮の下方において約１５ミリメートル～約３０ミリメートルの組織深さで延びる離れたゾーンへと延びていることを特徴とする請求項９に記載の組立体。
【請求項１１】
前記トランスデューサに作動的に接続されて所望の組織深さに平面トランスデューサの焦点ゾーンを配置する、音響的に連結された音響スタンドオフをさらに備えることを特徴とする請求項９に記載の組立体。
【請求項１２】
前記トランスデューサおよび前記注入部材の一つに作動的に接続されて、この組立体による美容整形あるいは皮膚科的治療に伴う不快感、腫大、瘢痕化あるいは他の望まれない効果を減少させる組織冷却モジュールをさらに備えることを特徴とする請求項１に記載の組立体。
【請求項１３】
前記溶液注入部材および前記音波発生装置に作動的に接続されるとともに溶液の注入と音波の印加とを協調させるように構成された制御モジュールをさらに備えることを特徴とする請求項１に記載の組立体。
【請求項１４】
前記制御モジュールは、音波の負荷と協調して様々な組織深さにおいて注入の段階的な順序を提供するように構成されていることを特徴とする請求項１３に記載の組立体。
【請求項１５】
前記溶液と前記ガスとを混ぜ合わせるように構成された溶液撹拌機と、
前記溶液の撹拌、前記溶液の皮下組織への注入、および前記皮下組織に対する音波の負荷を協調させるように構成された制御モジュールとをさらに備えることを特徴とする請求項１に記載の組立体。
【請求項１６】

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前記溶液撹拌機は、微小な泡を含んでいる溶液を生じさせるために前記溶液と前記ガスとを撹拌することを特徴とする請求項１５に記載の組立体。

【請求項１７】

約０．２５ＭＨｚ～約２０ＭＨｚの範囲の振動数および０．１Ｍｐａ～１０．０ＭＰａの範囲のピーク負圧を有した音波を生じさせるための音波発生装置と、

前記音波発生装置に作動的に連結されるとともに患者の皮下組織に音波を印加するように構成された音波トランスデューサと、

ガス供給源と、

前記ガス供給源に作動的に接続されるとともに前記ガスを前記溶液に混ぜ合わせて気体を含む溶液を生じさせるように構成された溶液撹拌機と、

前記溶液撹拌機に作動的に接続されるとともに気体を含んでいる溶液を患者の皮下組織に経皮的に注入するように構成された溶液注入部材と、

を備え、

前記音波が前記気体を含んでいる溶液と相互に作用する、皮下組織を治療するための組立体。

【請求項１８】

約０．２５ＭＨｚ～約２０ＭＨｚの範囲の振動数および０．１Ｍｐａ～１０．０ＭＰａの範囲のピーク負圧を有した超音波を生じさせるための超音波発生装置と、

前記超音波発生装置に作動的に接続されるとともに患者の皮下組織に超音波を印加するように構成された超音波トランスデューサと、

ガス供給源と、

溶液供給源と、

前記ガス供給源および前記溶液供給源に作動的に接続されるとともに前記ガスを前記溶液と混ぜ合わせて微小泡溶液を形成するように構成された溶液撹拌機と、

前記溶液撹拌機に作動的に接続されるとともに少なくとも一つの中空注入部材を有し、前記少なくとも一つの中空注入部材の遠位端は溶液注入部材ハウジングの内側にある第１の状態と前記注入部材の遠位端が前記溶液注入部材ハウジングの外側に延びる第２の状態との間で動くことができるようになっている溶液注入部材と、

微小な泡溶液の発生、治療する組織への微小な泡溶液の注入、治療する組織内における微小な泡溶液の分散、および治療する組織内の微小な泡溶液への超音波の照射を統合して協調させる制御モジュールと、

を備えることを特徴とする皮下組織を治療するための組立体。

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【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 06/34414

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8)- A61N 1/18 (2007.01)
USPC- 606/131
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 606/131

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 606/9, 32, 41, 191, 167; 604/22, 201, 288 (text search - see terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Electronic data base: PatWEST(USPT,PGPB,EPAB,JPAB); WIPO search
Search Terms Used: electrode; subcutaneous; needle etc.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	WO 2003/047689 A1 (JOSHI, A.V.) 12 June 2003 (12.06.2003) Entire document	1-9, 23 --- 10, 16-17
Y	US 2002/0120282 A1 (MORRIS et al) 29 August 2002 (29.08.2002) Entire document	10, 16-17
A	US 2004/0122483 A1 (Nathan et al.) 24 June 2004 (24.06.2004)	1-26

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 February 2007 (16.02.2007)	24 JUL 2007
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2005)

フロントページの続き

(81)指定国 AP(BW,GH,GM,KE,LS,MW,MZ,NA,SD,SL,SZ,TZ,UG,ZM,ZW),EA(AM,AZ,BY,KG,KZ,MD,RU,TJ,TM),EP(AT,BE,BG,CH,CY,CZ,DE,DK,EE,ES,FI,FR,GB,GR,HU,IE,IS,IT,LT,LU,LV,MC,NL,PL,PT,RO,SE,SI,SK,TR),OA(BF,BJ,CF,CG,CI,CM,GA,GN,GQ,GW,ML,MR,NE,SN,TD,TG),AE,AG,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BW,BY,BZ,CA,CH,CN,CO,CR,CU,CZ,DE,DK,DM,DZ,EC,EE,EG,ES,FI,GB,GD,GE,GH,GM,HN,HR,HU,ID,IL,IN,IS,JP,KE,KG,KM,KN,KP,KR,KZ,LA,LC,LK,LR,LS,LT,LU,LV,LY,MA,MD,MG,MK,MN,MW,MX,MY,MZ,NA,NG,NI,NO,NZ,OM,PG,PH,PL,PT,RO,RS,RU,SC,SD,SE,SG,SK,SL,SM,SV,SY,TJ,TM,TN,TR,TT,TZ,UA,UG,US,UZ,VC,VN,ZA,ZM,ZW

(74)代理人 100106655
弁理士 森 秀行
(72)発明者 マーク、イー. ディーム
アメリカ合衆国カリフォルニア州、マウンテン、ビュー、シエラ、アベニュ、６８５
(72)発明者 ハンソン、エス. ギフォード、ザ. サード
アメリカ合衆国カリフォルニア州、ウッドサイド、ウッドサイド、ロード、３１８０

Ｆターム(参考) 4C053 DD02 DD08
4C160 JJ33

Electronic Acknowledgement Receipt

EFS ID:	30749777
Application Number:	15724261
International Application Number:	
Confirmation Number:	3803
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Customer Number:	26338
Filer:	Merle W. Richman
Filer Authorized By:	
Attorney Docket Number:	NA001KR_US3
Receipt Date:	24-OCT-2017
Filing Date:	
Time Stamp:	19:27:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	na001kr_us3-ids.pdf	1037017 be73c05c5bb52976a0b60df3b4fa2a6b6468aaec	no	7

Warnings:

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Information:					
2	Foreign Reference	KR10-2006-0027194.pdf	287606 49f54e282248b6da82564b45e4e9d1fd8a52eb40	no	8
Warnings:					
Information:					
3	Foreign Reference	KR10-2010-001828.pdf	276342 aeb6122ed5d16814c76b2825a74fe7d4a119308c	no	9
Warnings:					
Information:					
4	Foreign Reference	KR10-2010-0055292.pdf	441739 93bb7e0ada2116fc3562d57bbb17d50c8af15ea8	no	11
Warnings:					
Information:					
5	Foreign Reference	KR10-2011-0002210.pdf	439029 9724db80340112806bdd62d8b69541f6445bd716	no	25
Warnings:					
Information:					
6	Foreign Reference	WO0074763A2.pdf	15800783 87bec0420e891a8485f031bdb514c5969e88fc7d	no	103
Warnings:					
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7	Foreign Reference	WO2005058407A1.pdf	4450919 70af817cdb8142893a46f5e5548588f973ed7043	no	32
Warnings:					
Information:					
8	Foreign Reference	WO2005096979A1.pdf	4255180 c29c7d59de64c77ceb43a4d9e863156a5b37d267	no	25
Warnings:					
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9	Foreign Reference	WO2008004781A1.pdf	4866550 55eb3e7af50ac9c8c4edb5ed9e66c6eaa1b6016a	no	34
Warnings:					
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10	Other Reference-Patent/App/Search documents	WO2012118293-ETISR-130.pdf	470980 12faa0c86c3ab94ab34a277423e7c9ec35ccd70c	no	3
Warnings:					
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11	Other Reference-Patent/App/Search documents	WO2012118293-ETWOS-971.pdf	890298 78b5b2cfbf6309996b675373093e493d646b0b58	no	7
Warnings:					
Information:					
12	Other Reference-Patent/App/Search documents	WO2012173405-tisr.pdf	344621 1a8afa944369175d9a99521af48901c3eadfbfa0	no	2
Warnings:					
Information:					
13	Other Reference-Patent/App/Search documents	WO2012173405-tsr.pdf	844107 f82333329000acf84f9aa244bd498771eb004484	no	7
Warnings:					
Information:					
14	Foreign Reference	JP2009-506873.pdf	16584231 899db36a727b598a763500d258a1fffa599fcf22	no	34
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/724,261

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	1 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/724,261	10/03/2017	3769	0.00	NA001KR_US3	1	1

CONFIRMATION NO. 3803

26338
MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

FILING RECEIPT

OC000000095234202

Date Mailed: 11/03/2017

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Jongju Na, Songpa-Gu, KOREA, REPUBLIC OF;

Applicant(s)

Jongju Na, Songpa-Gu, KOREA, REPUBLIC OF;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 15/096,686 04/12/2016 PAT 9775774
which is a CON of 13/825,083 01/20/2014 PAT 9320536 *
which is a 371 of PCT/KR2012/001335 02/22/2012
which claims benefit of 61/449,080 03/03/2011
and is a CON of 13/060,274 03/30/2011 PAT 8979912
which is a 371 of PCT/US08/74131 08/22/2008
(*)Data provided by applicant is not consistent with PTO records.

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REPUBLIC OF KOREA 10-2008-0076993 08/06/2008

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: No

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ENDYMED EXHIBIT 1002 - 428/733

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/724,261**
Projected Publication Date: To Be Determined - pending completion of Missing Parts
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

Preliminary Class

606

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: Yes

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/724,261	10/03/2017	Jongju Na	NA001KR_US3

CONFIRMATION NO. 3803

26338
MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

FORMALITIES LETTER

OC000000095234203

Date Mailed: 11/03/2017

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
- The application search fee must be submitted.
- The application examination fee must be submitted.
- Surcharge as set forth in 37 CFR 1.16(f) must be submitted.
  The surcharge is due for any one of:
  - late submission of the basic filing fee, search fee, or examination fee,
  - late submission of inventor's oath or declaration,
  - filing an application that does not contain at least one claim on filing, or
  - submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of this Notice to avoid abandonment is/are itemized below. Small entity discount is in effect. If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- $ **70** basic filing fee.
- $ **70** surcharge.
- $ **300** search fee.
- $ **360** examination fee.
- $(**0**) previous unapplied payment amount.
- $ **800** TOTAL FEE BALANCE DUE.

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Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

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Alexandria VA 22313-1450

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/jmilani/

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PTO/SB/08a (03-15)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15724261
Filing Date	2017-10-03
First Named Inventor	Jongju Na
Art Unit	
Examiner Name	
Attorney Docket Number	NA001KR_US3

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8666487	B2	2014-03-04	Kang	
	2	8540705	B2	2013-09-24	Mehta	
	3	5873840		1999-02-23	Bernard	
	4	9480836	B2	2016-11-01	Na	
	5	5993269		1999-11-30	Ito	
	6	6523420	B2	2003-02-25	Lee, Ho-Yeol	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15724261
	Filing Date	2017-10-03
	First Named Inventor	Jongju Na
	Art Unit	
	Examiner Name	
	Attorney Docket Number	NA001KR_US3

	1	20070066094	A1	2007-03-22	Jung-hye Kim	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	10-2006-0061011	KR	A	2006-06-07	CHU,KYOCHEOL		
	2	20-0172727	KR		1999-12-14	HYUNDAI MICRO ELEC		
	3	20-0176242	KR		2000-01-14	SK hynix Inc.		
	4	20-0201331Y1	KR	Y1	2000-08-19	HYUNDAI MICRO ELEC		
	5	10-0308121	KR	B1	2001-08-27	HYUNDAI MICRO ELEC		
	6	20-0268667	KR	Y1	2002-03-06	DONGBU ELECTRONIC		
	7	20-0284460	KR	Y1	2002-07-23	E Q ENG CO., LTD		
	8	10-0555713	KR	B1	2006-02-21	CHUNG,UN-YOUNG		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15724261
	Filing Date	2017-10-03
	First Named Inventor	Jongju Na
	Art Unit	
	Examiner Name	
	Attorney Docket Number	NA001KR_US3

	9	2000-039449	JP	A	2000-02-08	Seiko Epson Corp		
	10	2002-117926	JP	A	2002-04-19	HOSIDEN CORP		
	11	2005-351785	JP	A	2005-12-22	ATE SERVICE		
	12	08-088040	JP	A	1996-04-02	Hosiden		
	13	11-307161	JP	A	1999-11-05	Sony		
	14	25-43161	JP	Y2	1997-08-06	YOKOWO CO., LTD		

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
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Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15724261
	Filing Date	2017-10-03
	First Named Inventor	Jongju Na
	Art Unit	
	Examiner Name	
	Attorney Docket Number	NA001KR_US3

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15724261
Filing Date	2017-10-03
First Named Inventor	Jongju Na
Art Unit	
Examiner Name	
Attorney Docket Number	NA001KR_US3

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/mwresq/	Date (YYYY-MM-DD)	2017-11-07
Name/Print	Merle W Richman	Registration Number	38282

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(71)出願人　000194918
ホシデン株式会社
大阪府八尾市北久宝寺１丁目４番33号
(72)発明者　関口　茂美
群馬県伊勢崎市戸谷塚町329番地　ホシデン株式会社東京工場内
(74)代理人　弁理士　草野　卓　（外１名）

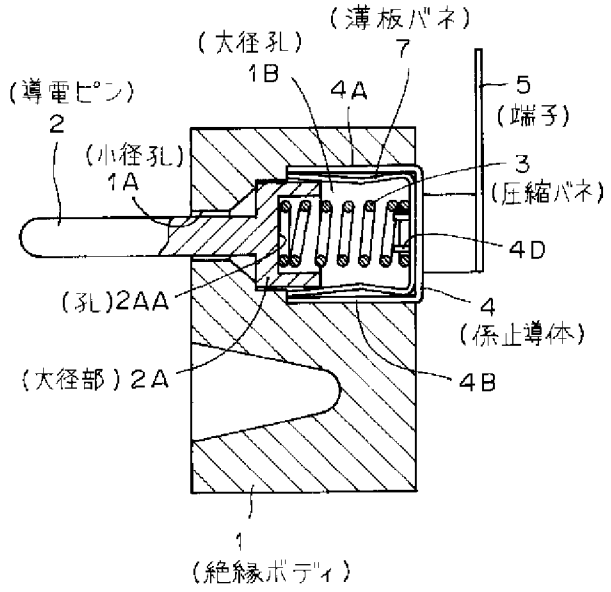
(54)【発明の名称】　スプリングピンコネクタ

(57)【要約】　（修正有）

【目的】　相手の接触体に大きな接触圧を与えることができ、電気的接触抵抗が小さいスプリングピンコネクタを提供する。

【構成】　導電ピン２の端部に大径部２Ａを有し、大径部を絶縁ボディ１に形成した大径孔１Ｂに挿入し、導電ピン２をこの大径部２Ａに連通する小径部を通じて絶縁ボディ１の外部に突出させ、大径部２４の開口端を係止導体４で塞ぐと共に、この係止導体４と大径部２４との間に圧縮バネ３を介挿し、圧縮バネ３の偏倚力によって相手の接触体に接触圧を与える構造のスプリングピンコネクタにおいて、係止導体４の内側に薄板バネ７を介挿し、この薄板バネ７によって導電ピン２と端子５との間の電気的導通性能を高める。

図１



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【特許請求の範囲】

【請求項１】　Ａ．一つの面に開口された複数の小径孔と、この小径孔に連通し上記一つの面と平行する他方の面に開口された複数の大径孔とが形成された絶縁ボディと、

Ｂ．上記小径孔を貫通し軸芯方向に移動自在に配置された導電性ピンと、

Ｃ．この導電ピンの上記大径孔側の端部に一体成形され、上記大径孔の直径より小さい直径を持つ大径部と、

Ｄ．この大径部の端面に形成された孔と、

Ｅ．上記大径部に形成した孔に一端が係合し、上記導電ピンに偏倚力を与える圧縮バネと、

Ｆ．コ字状に折曲形成された一対の脚を有し、この一対の脚が上記大径孔に沿って軸心方向に形成した溝に圧入されて上記圧縮バネを圧縮変形させて係止する係止導体と、

Ｇ．この係止導体から一体に延長されて形成された複数の端子と、

Ｈ．上記係止導体と圧縮バネとの間に介挿され、上記係止導体のコ字状の脚に沿って配置され、上記係止導体と上記可動接触子との間を電気的に導通させる薄板バネと、

によって構成したことを特徴とするスプリングピンコネクタ。

【請求項２】　請求項１記載の導電ピンに絶縁スリーブを導電ピンが内部で移動可能な状態で被せ、絶縁スリーブの端部は上記大径孔内に挿入され、この端部に形成されたフランジによって抜け止めされると共に、上記圧縮バネより弱い第２の圧縮バネを上記フランジと上記大径部との間に介挿したことを特徴とするスプリングピンコネクタ。

【発明の詳細な説明】

【０００１】

【産業上の利用分野】この発明は例えば電池によって動作する携帯用機器の電池と機器本体との間を電気的に接続する部分等に用いられるスプリングピンコネクタに関する。

【０００２】

【従来の技術】従来より、図１０に示すように絶縁ボディ１の一つの面に導電ピン２が複数突設され、この導電ピン２が絶縁ボディ１の内部に装着された圧縮バネ３（図１１参照）で弾性的に突出偏倚され、相手の接触体（特に図示しない）が各導電ピン２の先端に圧接されることにより導電ピン２が圧縮バネ３の偏倚力に抗して絶縁ボディ１内に後退し、相手の接触体の接触部分が多少凹凸方向にバラツキがあっても、被接触体の全ての端子が確実に各導電ピン２に接触できるように構成したスプリングピンコネクタが使用されている。

【０００３】また、図１２に示すように導電性チューブ６の内部にスプリング３と導電ピン２を収納させ、導電

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ピン２をスプリング３の偏倚力に従って導電ピン２を突出偏倚させるチューブ構造のスプリングピンコネクタもある。

【０００４】

【発明が解決しようとする課題】図１０及び図１２に示した従来の構造によれば、導電ピン２と端子５との間の導通は主に圧縮バネ３によって行われている。このため圧縮バネ３は例えばリン青銅のような良質な導電性とバネ性を持つバネ材を用いている。リン青銅は価格が高価なためコストの低減に障害となる。またリン青銅から成る圧縮バネ３のバネ性を確保する制限から圧縮バネ３の形状を小型化することがむずかしい。このためコネクタ全体の形状を小型化することもむずかしい。

【０００５】一方、図１２に示したチューブ構造のスプリングピンコネクタによれば、チューブ６の内径と導電ピン２の大径部分との間の寸法精度を高く保たなければならないから、この点で製造コストが高くなる欠点がある。

【０００６】

【課題を解決するための手段】この発明では小型化しても充分バネ力を得ることができるように圧縮バネをピアノ線によって形成する。ピアノ線の使用により増加した導電ピンと端子との間の抵抗値は、圧縮バネと端子との間に介挿した導電性の薄形バネによって低減させる。

【０００７】従って、この発明によれば圧縮バネの小型化によって全体として形状を小さくすることができる。また小型化したにも係わらず導電ピンと端子との間の電気抵抗が小さいスプリングピンコネクタを提供することができる。

【０００８】

【実施例】図１にこの発明の一実施例を示す。図１において図１０及び図１１と対応する部分には同一符号を付して示す。この発明では絶縁ボディ１の一つの面に小径孔１Ａを形成し、この小径孔１Ａに連通して大径孔１Ｂを形成する。大径孔１Ｂは絶縁ボディ１の他方の面に開放される。図示の例では図２に示すように絶縁ボディ１に５個の小径孔１Ａを形成した場合を示す。小径孔１Ａには導電ピン２が挿通される。導電ピン２の一端側には大径部２Ａを有し、大径部２Ａは絶縁ボディ１に形成した大径孔１Ｂに収納される。なお、図２は図１に示すＡ－Ａ線上の断面を示す。

【０００９】大径孔１Ｂは図３に示すように円孔１Ｂの側部に４本の溝１Ｃを有し、この溝１Ｃに図４に示す係止導体４を圧入し、大径孔１Ｂの開口面を閉塞する。つまり係止導体４は図４に示すように導電板をコ字状に折り曲げて形成した一対の脚４Ａ，４Ｂを有し、この脚４Ａ，４Ｂを溝１Ｃに圧入する。脚４Ａ，４Ｂの側辺には突起４Ｃを形成し、この突起４Ｃが溝１Ｃの側縁に喰い込んで係止導体４を抜け止めする。

【００１０】脚４Ａ，４Ｂの間には図５に示す薄板バネ

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７を介挿する。薄板バネ７は係止導体４と同様にコ字状に折り曲げて形成した一対の脚７Ａ，７Ｂを有する。脚７Ａ，７Ｂは途中で末広がりに開くように折目７Ｃを形成する。この薄板バネ７を係止導体４の脚４Ａと４Ｂの間に介挿することにより、薄板バネ７の脚７Ａと７Ｂが図１に示すように折目７Ｃの部分が内側に脹らんだ状態に装着される。

【００１１】従って導電ピン２と一体に移動する大径部２Ａはその外周面に薄板バネ７が摺接し、導電ピン２と係止導体４との間の接触を良好な状態に維持させる。係止導体４の天井面には図４に示すように一対の舌片４Ｄを内側に切り起こして突出させる。この舌片４Ｄは薄板バネ７に形成した孔７Ｄを通じて大径部２Ａの頭部と対向して配置され、圧縮バネ３の端部に係合させ圧縮バネ３の端部を大径孔１Ｂの軸芯位置に保持させる。圧縮バネ３の他端側は大径部２Ａに形成した孔２ＡＡに係合し、こちら側も大径孔１Ｂの軸芯位置に支持する。係止導体４の天井面の側辺から端子５が延長形成される。端子５は図２に示すように絶縁ボディ１の側面から突出され、この突出部分がプリント配線基板の孔に差し込まれて半田付けされる。

【００１２】この発明では上述したように薄板バネ７を設けたことにより、導電ピン２と係止導体４との間の接触が良好な状態に維持できる構造としたから、圧縮バネ３は特に良導体で構成しなくてよく、大きな偏倚力を得ることができるピアノ線によって構成することができる。ところで図２に示す符号８は導電ピン２に被せた絶縁スリーブを指す。絶縁スリーブ８は導電ピン２の外周を絶縁し、他の導電ピン２との間で導電性の異物によって短絡事故を起こさないようにするために設けられる。

【００１３】図６に図２に示したＢ－Ｂ線上の断面構造を示す。図６に示すように絶縁スリーブ８を装着すべき位置には図１に示した小径孔１Ａより大きく、大径孔１Ｂの直径より小さい中径孔１Ｃを形成し、この中径孔１Ｃに絶縁スリーブ８を挿通させる。絶縁スリーブ８の端部にはフランジ８Ａを形成し、このフランジ８Ａによって絶縁スリーブ８を抜け止めすると共に、フランジ８Ａと大径部２Ａとの間に第２の圧縮バネ９を介挿する。第２の圧縮バネ９は圧縮バネ３のバネ圧より弱いバネ圧の圧縮バネを用いるものとする。

【００１４】絶縁スリーブ８と大径部２Ａとの間にわずかなストロークＳＴが与えられる。圧縮バネ９のバネ圧が圧縮バネ３のバネ圧より小さいとすれば、絶縁スリーブ８はストロークＳＴの範囲で導電ピン２とは別に単独で移動することができる。この結果、相手の接触体が絶縁スリーブ８の先端に当接すると、絶縁スリーブ８は単独で絶縁ボディ１の中に入り込む方向に移動するから、相手の接触体は導電ピン２の先端に接触することができる。相手の接触体が図６の状態で更に右方向に移動すると、導電ピン２は圧縮バネ３を圧縮変形させながら絶縁

スリーブ８と共に右方向に移動することができる。この状態では導電ピン２は相手の接触体に圧縮バネ３の偏倚力に等しい力の接触圧を与える。

【００１５】なお、上述では絶縁スリーブ８を、５本ある導電ピン２の中の１本だけ設けた場合を説明したが、全ての導電ピン２に絶縁スリーブ８を付設してもよい。図７はこの発明の変形実施例を示す。この例では絶縁ボディ１の形状と、薄板バネ７の向きを係止導体４の脚４Ａ，４Ｂ（図９参照）と直交する向きに装着した点と、係止導体４から端子５を直接延長形成した点が図１に示した例と異なる点であり、その他の構成は図１の実施例と同じである。ここで薄板バネ７の向きを係止導体４の脚４Ａ，４Ｂの向きと直交する向きに選定することにより、大径部１Ｂの直径を薄板バネ７の板厚とたわみ量に相当する寸法だけ小さくすることができる。この結果、隣接する導電ピン２の相互間のピッチＰ（図８参照）を小さく採ることができる利点が得られる。その他の形状の違いは本質的なものでなく、この実施例でも図１に示した実施例と同等の作用効果を得ることができる。

【００１６】

【発明の効果】以上説明したように、この発明によれば薄板バネ７を導電ピン２と係止導体４との間に介挿し、この薄板バネ７によって導電ピン２と係止導体４との間の電気的な接触を維持させる構造としたから、圧縮バネ３に導通性能を要求しなくても導電ピン２と係止導体４との間の導通性能を良好な状態に保つことができる。

【００１７】この結果、圧縮バネ３としてリン青銅より抵抗値が高いピアノ線によって形成した圧縮バネを用いることができる。ピアノ線によって形成した圧縮バネはバネ圧が大きく得られるから、バネの径を小さくしても導電ピン２に大きいバネ圧を与えることができる。この結果、絶縁ボディ１の形状を小さくすることができ、全体の形状を小型化することができる。また相手の接触体に強い接触圧を与えることができるから、電池等に確実に接触させることができる利点が得られる。

【図面の簡単な説明】

【図１】この発明の一実施例を示す断面図。

【図２】図１に示した実施例の正面図。

【図３】図１に示した実施例に用いた大径孔の形状を説明するための拡大平面図。

【図４】図１に示した実施例に用いた係止導体と端子の構造を説明するための拡大斜視図。

【図５】図４と同様の薄板バネの構造を説明するための拡大斜視図。

【図６】図２に示したＢ－Ｂ線上の断面図。

【図７】この発明の変形実施例を示す断面図。

【図８】図７に示した実施例の正面図。

【図９】図７に示した実施例に用いた係止導体と端子の構造を説明するための拡大斜視図。

【図１０】従来の技術を説明するための斜視図。

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【図１１】図１０の断面図。

【図１２】従来の技術の他の例を示す断面図。

【符号の説明】

1　　絶縁ボディ
1A　　小径孔
1B　　大径孔
2　　導電ピン
2A　　大径部

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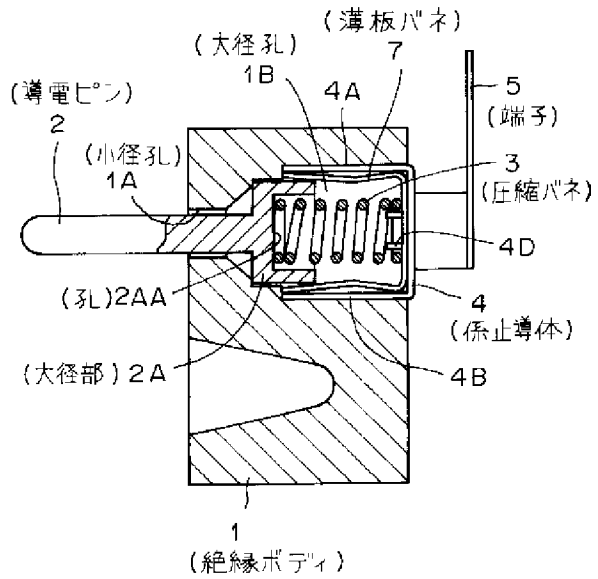
3　　圧縮バネ
4　　係止導体
4A，4B　　一対の脚
5　　端子
7　　薄板バネ
8　　絶縁スリーブ
9　　圧縮バネ

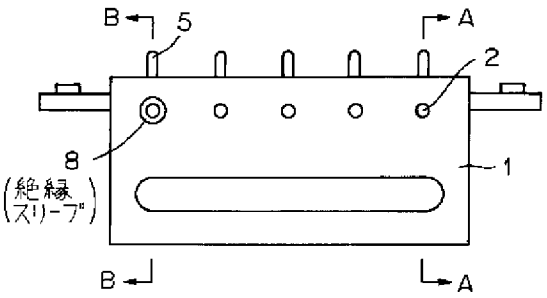
【図1】

図１



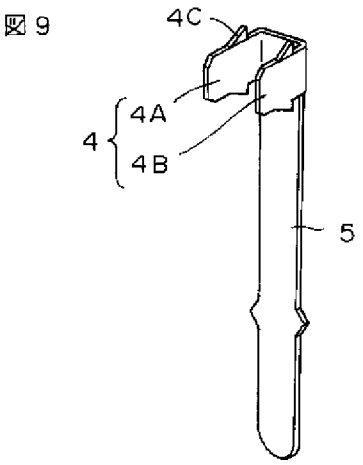
【図2】

図２



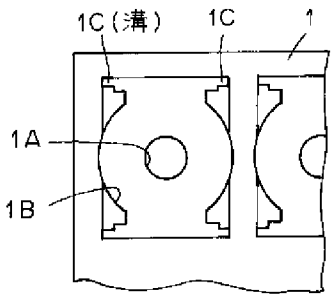
【図9】

図９



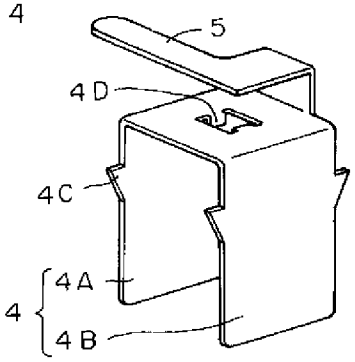
【図3】

図３



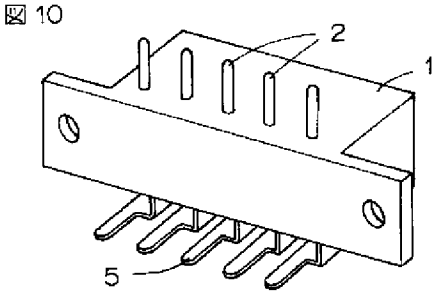
【図4】

図４



【図１０】

図10



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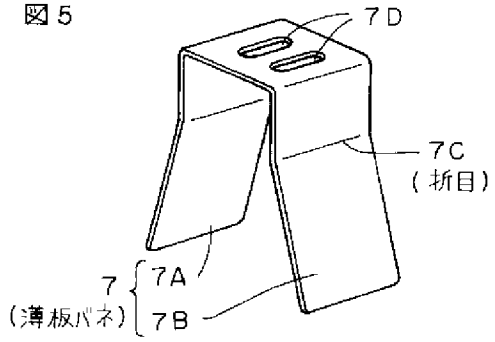
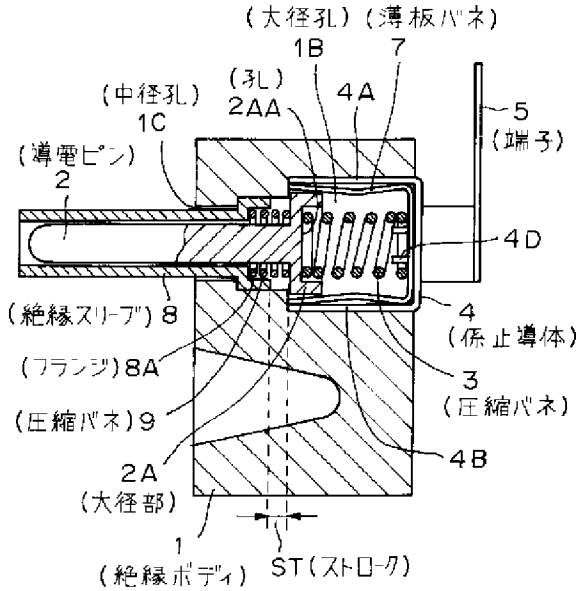
【図5】

図5



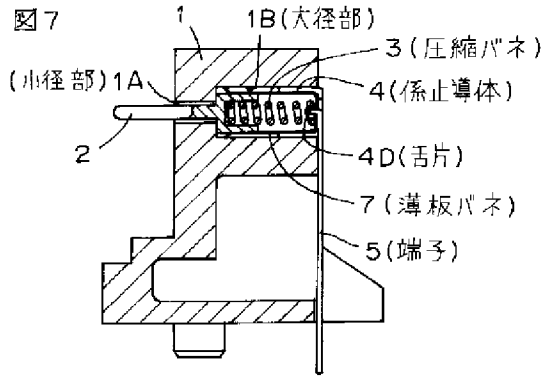
【図6】

図6



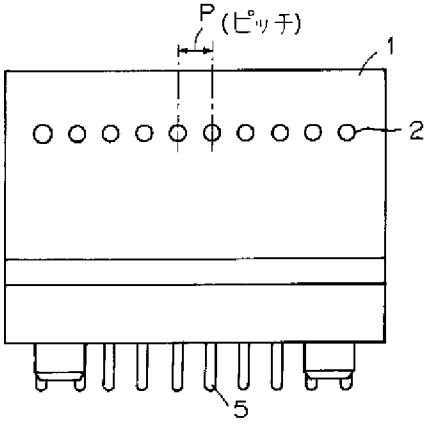
【図7】

図7



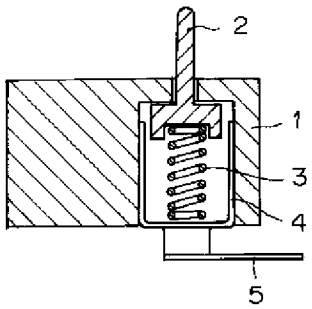
【図8】

図8



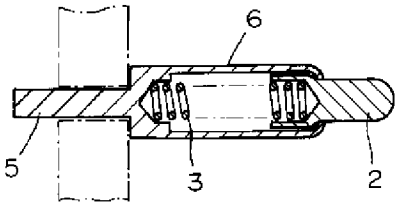
【図11】

図11



【図12】

図12



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23/02		23/02	Ｆ
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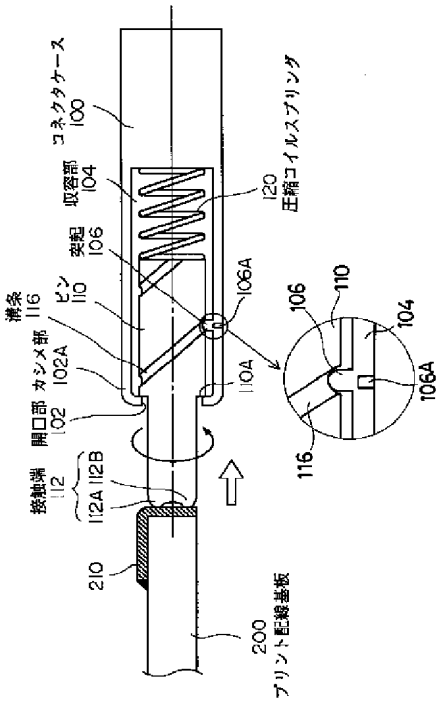
(71)出願人　000002185
ソニー株式会社
東京都品川区北品川６丁目７番35号
(72)発明者　山口　正人
東京都品川区北品川６丁目７番35号　ソニー株式会社内
(72)発明者　水野　智祥
東京都品川区北品川６丁目７番35号　ソニー株式会社内

(54)【発明の名称】　スプリングピンコネクタ

(57)【要約】
【課題】　人手等によらず、接点の接触不良を有効に防止することができるスプリングコネクタを提供する。
【解決手段】　コネクタケース１００とピン１１０と圧縮コイルスプリング１２０とを有し、ピン１１０の先端の接触端１１２をプリント配線基板２００に設けた接触板２１０に接触させる。コネクタケース１００は、円筒状の収容部１０４を有し、この収容部１０４内にピン１１０が軸方向にスライド自在に保持されている。ピン１１０の外周部には、螺旋状の溝条１１６が形成され、収容部１０４の内周部には、溝条１１６に係合する突起１０６が形成されている。したがって、ピン１１０が収容部１０４に対して軸方向にスライドした場合、突起１０６と溝条１１６の係合位置が変位し、ピン１１０が螺旋状に回転変位し、接触点の摺接による摩擦によりゴミや汚れが拭われ、良好な接触状態を維持できる。



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【特許請求の範囲】
【請求項１】　先端部が所定の接触部材に接触する接触端として形成されたピンと、
前記ピンを抜け止め状態で収容する収容部を有するとともに、前記ピンの接触端を前記収容部の外方に突出させる開口部を有し、前記ピンを軸方向にスライド自在に保持するコネクタケースと、
前記コネクタケースの収容部内に配置され、前記ピンをその接触端が前記開口部より突出する方向に付勢するスプリングとを具備したスプリングコネクタにおいて、
前記コネクタケースの収容部内に設けられ、前記ピンの軸方向のスライドに応じて、前記ピンを軸回り方向に変位させる回転ガイド手段を具備する、
ことを特徴とするスプリングピンコネクタ。
【請求項２】　前記ピンは略円柱状に形成され、前記収容部は、前記ピンの外周形状に対応した円筒状に形成されていることを特徴とする請求項１記載のスプリングピンコネクタ。
【請求項３】　前記回転ガイド手段は、前記コネクタケースの収容部の内周部に螺旋状に形成された溝条と、前記ピンの外周部に設けられ前記溝条に係合する突起とで構成されていることを特徴とする請求項２記載のスプリングピンコネクタ。
【請求項４】　前記回転ガイド手段は、前記ピンの外周部に螺旋状に形成された溝条と、前記コネクタケースの収容部の内周部に設けられ前記溝条に係合する突起とで構成されていることを特徴とする請求項２記載のスプリングピンコネクタ。
【請求項５】　前記ピンの接触端は、前記接触部材に対して複数の接触点を有することを特徴とする請求項１記載のスプリングピンコネクタ。
【請求項６】　前記ピンの接触端が凹凸を有することにより、前記接触部材に対して複数の接触点を有することを特徴とする請求項５記載のスプリングピンコネクタ。
【請求項７】　前記接触部材が凹凸を有することにより、前記ピンの接触端と前記接触部材とが複数の接触点を有することを特徴とする請求項５記載のスプリングピンコネクタ。
【請求項８】　前記接触部材は、プリント配線基板に信号の入出力端子として設けられていることを特徴とする請求項１記載のスプリングピンコネクタ。
【請求項９】　前記コネクタケースに複数の前記ピンを互いに並列に配置し、各ピンを複数の接触部材に同時に接触させるようにしたことを特徴とする請求項１記載のスプリングピンコネクタ。
【請求項１０】　電子機器の試験用の信号を入出力するためのプローブピンコネクタであることを特徴とする請求項１記載のスプリングピンコネクタ。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】本発明は、各種電子機器や、その試験用に利用されるスプリングピンコネクタに関する。
【０００２】
【従来の技術】従来より、例えば電子機器に設けられた接点にピンを接触させて各種信号を入出力するために、図４に示すようなスプリングコネクタが実用されている。図４において、ピン１０は、その先端部が例えばプリント配線基板に設けられた接点（接触部材）に接触する接触端１０Ａとして形成されており、コネクタケース２０に出没可能に保持されている。
【０００３】コネクタケース２０は、円柱状のピン１０に対して円筒状に設けられ、ピン１０を軸方向にスライド自在に保持しており、先端にピン１０の接触端１０Ａを突出させる開口部２０Ａを有する。なお、開口部２０Ａの周縁部は、内側にカシメられており、ピン１０の抜け止めが施されている。また、コネクタケース２０の基端部には、接続用のリード端子２０Ｂが設けられている。コネクタケース２０の内部には、圧縮コイルスプリング３０が設けられ、ピン１０を突出させる方向に付勢している。
【０００４】このようなスプリングコネクタでは、ピン１０の接触端１０Ａをプリント配線基板等に設けた接触部材に接触させることにより、圧縮コイルスプリング３０が自在に撓み、ピン１０の良好な接触状態を得るようになっている。
【０００５】
【発明が解決しようとする課題】しかしながら、上述したスプリングコネクタでは、ピン１０の接触端１０Ａと対象となる接触部材とが同じ位置で接触し、かつピン１０にクリーニング機能がないものであるため、この接触点の部分にゴミや汚れが付着しやすく、接触不良になりやすいという問題がある。特に、この種のスプリングコネクタにおいては、接点の接触、分離が繰り返し行われるため、ゴミや汚れが付着する機会が多くなることから、人手等によることなく、接触不良を防止する有効な対策が必要となる。
【０００６】そこで本発明の目的は、人手等によらず、接点の接触不良を有効に防止することができるスプリングコネクタを提供することにある。
【０００７】
【課題を解決するための手段】本発明は前記目的を達成するため、先端部が所定の接触部材に接触する接触端として形成されたピンと、前記ピンを抜け止め状態で収容する収容部を有するとともに、前記ピンの接触端を前記収容部の外方に突出させる開口部を有し、前記ピンを軸方向にスライド自在に保持するコネクタケースと、前記コネクタケースの収容部内に配置され、前記ピンをその接触端が前記開口部より突出する方向に付勢するスプリングとを具備したスプリングコネクタにおいて、前記コ

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ネクタケースの収容部内に設けられ、前記ピンの軸方向のスライドに応じて、前記ピンを軸回り方向に変位させる回転ガイド手段を具備することを特徴とする。

【０００８】本発明のスプリングピンコネクタでは、コネクタケースの収容部に保持されたピンの接触端を接触部材に押し当てることにより、その押圧力によってスプリングが撓み、ピンが軸方向にスライドして、ピンの接触端と接触部材とが良好な接触圧をもって接触する。また、ピンが軸方向にスライドした際に、回転ガイド手段によってピンが軸回り方向に変位し、接触端が回転しながら接触部材に接触する。したがって、この接触の際に、ピンの接触端にゴミや汚れが付着している場合には、一定の摩擦力を受けてゴミや汚れが拭われ、良好な接触状態を維持することができる。

【０００９】

【発明の実施の形態】以下、本発明によるスプリングコネクタの実施の形態について説明する。図１は、本発明によるスプリングコネクタの一例を示す断面図である。本例のスプリングコネクタは、コネクタケース１００と、ピン１１０と、圧縮コイルスプリング１２０とを有し、ピン１１０の先端の接触端１１２をプリント配線基板２００に設けた接触板（接触部材）２１０に接触させるようにしたものである。

【００１０】接触板２１０は、プリント配線基板２００の端部に臨む状態で設けられており、プリント配線基板２００上の配線に半田付け等によって接続されている。ピン１１０は、ほぼ円柱状に形成され、先端側が細径に形成され、基端側が太径に形成され、中途の段部１１０Ａがコネクタケース１００の開口部１０２の周縁部に形成されたカシメ部１０２Ａによって係止されることにより、基端側がコネクタケース１００に抜け止めされている。そして、ピン１１０の先端側が開口部１０２より突出している。そして、このピン１１０の先端側の接触端１１２は２つの山を有しており、２つの接触点１１２Ａ、１１２Ｂで接触板２１０に接触するようになっている。この２つの接触点１１２Ａ、１１２Ｂで接触することにより、より良好な接触状態を得るものである。

【００１１】コネクタケース１００は、円筒状の収容部１０４を有し、この収容部１０４内にピン１１０の基端側が収容されている。これにより、ピン１００は収容部１０４内で軸方向にスライド自在に保持されている。また、収容部１０４内には、圧縮コイルスプリング１２０が配置され、ピン１１０の基端部を押圧し、ピン１１０が突出する方向に付勢している。したがって、ピン１１０の接触端１１２を接触板２１０に接触させることにより、圧縮コイルスプリング１２０が自在に撓み、ピン１１０の接触端１１２が接触板２１０に一定の圧力で当接し、良好な接触状態を得ることができる。さらに、コネクタケース１００の基端部には、接続用のリード端子（図１には不図示）が設けられている。

【００１２】また、ピン１１０の基端側の外周部には、螺旋状の溝条１１６が形成されており、収容部１０４の内周部には、溝条１１６に係合する突起１０６が形成されている。溝条１１６は、断面がＵ字状に形成され、突起１０６を摺動自在に係合するものである。突起１０６は、コネクタケース１００に一体形成されたものであり、コネクタケース１００の外部には、突起１０６を成形する際の凹部１０６Ａが形成されている。そして、ピン１１０が収容部１０４に対して軸方向にスライドした場合、突起１０６と溝条１１６の係合位置が変位し、ピン１１０が螺旋状に回転変位することになる。すなわち本例では、溝条１１６と突起１０６とで、ピン１１０の回転ガイド手段を構成している。

【００１３】これにより、ピン１１０と接触板２１０との接触時に、ピン１１０が軸方向にスライドした際に、ピン１１０の接触端１１２における接触点１１２Ａ、１１２Ｂが軸回り方向に回転変位し、接触板２１０と接触点１１２Ａ、１１２Ｂの位置が軸回り方向に変位する。したがって、ピン１１０の接触端１１２や接触板２１０にゴミや汚れが付着した場合でも、両者の摺接による摩擦によって拭われるため、良好な接触状態を維持することができる。

【００１４】以上のように、本例のスプリングピンコネクタでは、ピン１１０の接触端１１２が接触板２１０に接触する際のピン１１０の回転による摺接によって接触点におけるゴミや汚れを除去でき、良好な接触状態を得ることができる。また、ピン１１０の接触端１１２に２つの接触点１１２Ａ、１１２Ｂを設けたことにより、ピン１１０の回転ともあいまって、より良好な接触状態を維持することができる。

【００１５】図２は、以上のようなスプリングコネクタを複数並列にモールドパッケージに収納した状態を示す斜視図である。モールドパッケージ３００内には、上述したコネクタケースが複数内蔵され、複数のピン１１０がモールドパッケージ３００より突出している。また、図３は、上述のようにピン１１０の接触端１１２に２つの接触点１１２Ａ、１１２Ｂを設ける代わりに、接触板側に２つの接触点を設けるようにした例を示している。すなわち、図３の例では、中央で屈曲した接触板２１２を設けることにより、屈曲部の両側の２つの接触点２１２Ａ、２１２Ｂで、ピン１１０のほぼ半球状の接触端１１４に２点で接触するようにしたものである。

【００１６】なお、以上のように必ずしも複数の接触点を設ける必要はなく、従来のような半球形の接触端を有するピンであっても、軸周り方向の回転により、従来に比して十分な効果を得ることが可能である。また、以上の例では、コネクタケース１００の内側に突起１０６を設け、ピン１１０の外周に溝条１１６を設けたが、反対にピン１１０の外周に突起を設け、コネクタケース１００の内側に溝条を設けてもよい。

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【００１７】

【発明の効果】以上説明したように本発明のスプリングコネクタでは、コネクタケースの収容部に保持されたピンの接触端を接触部材に押し当てる際に、ピンの軸方向のスライドに応じて、ピンを軸回り方向に変位させる回転ガイド手段を設けた。このため、ピンが軸方向にスライドした際に、回転ガイド手段によってピンが軸回り方向に変位し、接触端が回転しながら接触部材に接触するので、ピンの接触端にゴミや汚れが付着している場合には、一定の摺接による摩擦を受けてゴミや汚れが拭われ、良好な接触状態を維持することができる。

【図面の簡単な説明】

【図１】本発明によるスプリングコネクタの一例を示す断面図である。

【図２】図１に示すスプリングコネクタを複数並列にモールドパッケージに収納した状態を示す斜視図である。

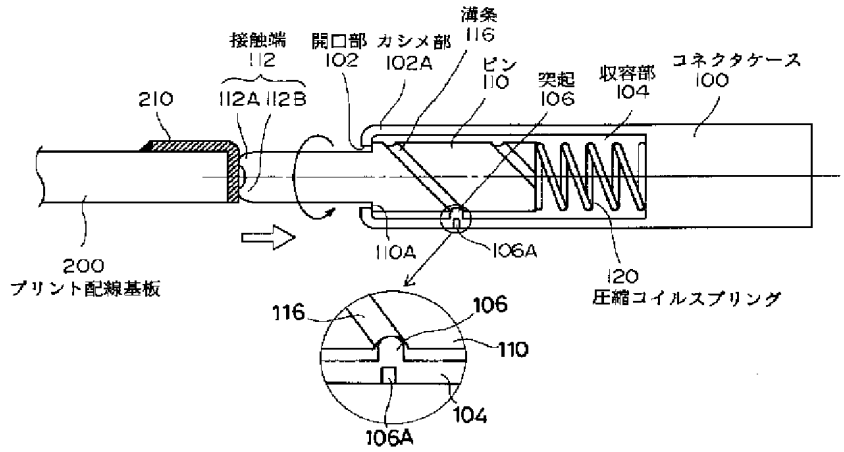
【図３】本発明によるスプリングコネクタの他の例を示す部分断面図である。

【図４】従来のスプリングコネクタの一例を示す断面図である。

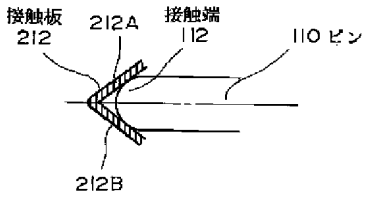
【符号の説明】

１００……コネクタケース、１０２……開口部、１０４……収容部、１０６……突起、１１０……ピン、１１２……接触端、１１２Ａ、１１２Ｂ……接触点、１１６……溝条、１２０……圧縮コイルスプリング、２００……プリント配線基板、２１０……接触板。

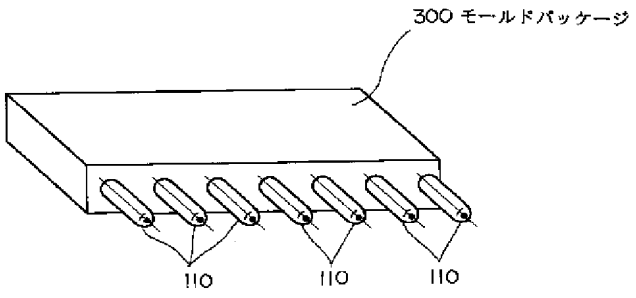
【図１】



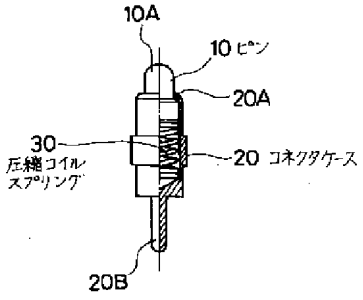
【図３】



【図２】



【図４】



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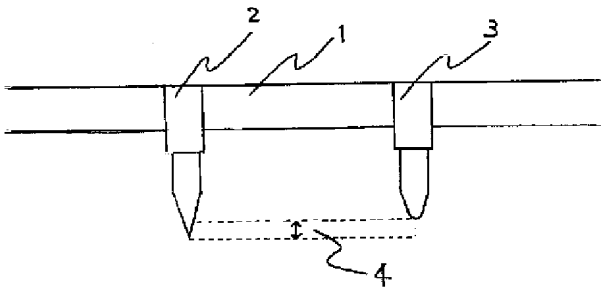
(71)出願人　000002369
セイコーエプソン株式会社
東京都新宿区西新宿２丁目４番１号
(72)発明者　遠田　寿直
長野県諏訪市大和３丁目３番５号　セイコーエプソン株式会社内
(74)代理人　100093388
弁理士　鈴木　喜三郎　（外２名）

Ｆターム(参考)　2G011 AA17 AB01 AC05 AC12 AC14 AE03
4M106 AA01 AA07 AD01 AD11 BA01 BA11 CA01 CA02 CA04 DD01 DD03 DD04 DD10 DD13 DD18

(54)【発明の名称】　ポゴピン構造のプローブ針を有するプローブカードとプローブ針の交換方法

(57)【要約】
【課題】プローブ針の高さや針位置の調整及び、プローブ針の交換作業に要する工数と時間は手作業の為、作業者の技能によりかなり差があり、上級者であってもかなりの工数と時間を必要とするという問題を有していた。
【解決手段】プローブカードのプローブ針をポゴピン構造とする。
【効果】多少の針高さバラツキが有っても安定して半導体ウエハのプロービングテストが可能となり、プローブカードテスター等の検査装置を使用したプローブ針高さ及び針位置調整等のメンテナンス回数を低減出来る。また、プローブ針寿命の延長にも繋がり、抜き差しのみでプローブ針交換が可能となるため作業の簡略化が実現でき、作業者の技能の優劣による差も少なくなる。よって、人的工数及び、作業時間の短縮が可能となる。



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【特許請求の範囲】
【請求項１】プローブカードのプローブ針をポゴピン構造とする特徴を有するプローブカード。
【請求項２】請求項１記載のプローブカードにおいて、プローブ針の交換を１ピン毎に抜き差しする事のみで可能とする特徴を有するプローブ針交換方法。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】本発明は、半導体ウエハプロービングテストで用いられるプローブカードに関する。
【０００２】
【従来の技術】プローブカードのプローブ針は、何回も半導体ウエハとコンタクトさせると摩耗等の原因により、プローブ針の高さバラツキや針位置のズレが発生し、コンタクト不良を引き起こす。現在はプローブカードと半導体ウエハとのコンタクト回数を管理し、定期的にプローブ針の調整、及び交換等のメンテナンス作業を実施しているのが一般的である。しかし、プローブ針の調整及び交換作業はプローブカードテスター等の検査装置を使用して針位置、針高さを確認しながらの手作業であり工数と時間を要していた。
【０００３】上記の問題を解決するため、特開平５－１１４６３０、特開平５－３０７０４９、特開平６－０２１１６８の例がある。
【０００４】特開平５－１１４６３０の例では、プローブカードにスルーホールを開け、スルーホールに硬軟化自在の溶剤を注入し、そのスルーホールにプローブ針を挿入する。プローブ針の調整及び交換は硬軟化自在の溶剤を軟化させ、自在にプローブ針を抜き差しして行う。
【０００５】特開平５－３０７０４９の例では、プローブカード基板の下にプローブ針を立てた針ブロックを設け、プローブ針の交換はプローブ針全ピンを針ブロックを着脱することによって行う。
【０００６】特開平６－０２１１６８の例では、プローブカード基板とプローブカードサブ基板と呼ぶ基板にプローブ針先端位置調整用貫通穴を設け、その2つのプローブ針先端位置調整用貫通穴をプローブ針を通す事により位置決めを行い、プローブ針の交換は、プローブ針を固定している半田付け部を溶解してプローブ針先端位置調整用貫通穴より抜き差しする事により行う。
【０００７】
【発明が解決しようとする課題】プローブ針の調整及び、交換作業に要する工数と時間は手作業の為、作業者の技能によりかなり差があり、上級者であってもかなりの工数と時間を必要とするという問題を有していた。
【０００８】そこで、本発明はプローブ針の調整及び、交換作業にかかる工数と時間を短縮し、作業者の技能の優劣による差があまり出ないプローブカードを提供する事を目的とする。
【０００９】
【課題を解決するための手段】上記課題を解決するため、請求項１、請求項２の発明はプローブカードのプローブ針をポゴピン構造とする事を特徴とする。
【００１０】
【作用】請求項１、請求項２記載の発明では、ポゴピンの特徴である上下方向のフレキシブルな動作及び、抜き差しのみでピン交換が出来る事により、プローブ針の高さバラツキが多少有っても安定してプロービングテストが実施でき、プローブ針の交換も抜き差しのみで可能となる。
【００１１】
【発明の実施の形態】以下本発明を図面に基づいて説明する。
【００１２】図１は本発明のプローブカードの構造を示したプローブカードの断面図である。図１で１はプローブカード基板、２はポゴピン構造プローブ針Ａ、３はポゴピン構造プローブ針Ｂ、４はプローブ針の段差である。図２に図１のプローブカードの動作を説明するための図を示す。図２において１はプローブカード基板、２はポゴピン構造プローブ針Ａ、３はポゴピン構造プローブ針Ｂ、５は半導体ＩＣチップのパッドである。図３は本発明のプローブ針の交換方法を説明するための図であり、１はプローブカード基板、６はポゴピン構造プローブ針のプローブ針部、７はポゴピン構造プローブ針のソケット部である。
【００１３】本発明のプローブカードは、図1のプローブカード基板１に上下方向にフレキシブルな動作ができ、抜き差しのみでプローブ針の交換が出来る事を特徴とするポゴピン構造プローブ針を立てた構成である。
【００１４】請求項１の発明のプローブカードの動作は、図1に示す様に摩耗等によりポゴピン構造プローブ針Ａ２とポゴピン構造プローブ針Ｂ３にプローブ針の段差４が生じた場合、ポゴピンの特徴である上下方向にフレキシブルな動作が可能という点を利用する。図２の様に半導体ＩＣチップのパッド５にポゴピン構造プローブ針Ａ２がコンタクトすると上方向にポゴピン構造プローブ針Ａ２がプローブ針の段差４の分だけスライドし、ポゴピン構造プローブ針Ｂ３と針高さが同じになる。よって、常に全ポゴピン構造プローブ針の針高さが同一になり、針高さのバラツキを気にせず半導体ＩＣチップのパッド５にコンタクト可能である事により、多少の針高さのバラツキが発生してもプローブ針の調整及び交換が不要となる。
【００１５】次に請求項２の発明を説明する。ポゴピン構造プローブ針が摩耗等の原因により交換をしなければならなかった場合、ポゴピンの特徴であるピン交換を抜き差しのみで行える事を利用し、図３に示した様にポゴピン構造プローブ針のプローブ針部６をポゴピン構造プローブ針のソケット部７より引き抜き、新しいポゴピン構造プローブ針のプローブ針部６をポゴピン構造プロー

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ブ針のソケット部７に差し込む事のみで交換作業を行う。よって、半田付け等の作業が無く、１ピン毎のプローブ針の交換を抜き差しする事のみで実施可能となる。

【００１６】従って、プローブ針をポゴピンタイプにする事により、プローブ針のメンテナンス回数の低減、プローブ針の交換作業の簡略化ができ、人的工数及び、作業時間の短縮が可能である。

【００１７】

【発明の効果】請求項１、請求項２記載の発明によれば、多少の針高さバラツキが有っても安定して半導体ウエハのプロービングテストが可能となり、プローブカードテスター等の検査装置を使用したプローブ針高さ及び針位置調整等のメンテナンス回数を低減出来る。また、プローブ針寿命の延長にも繋がり、抜き差しのみでプローブ針交換が可能となるため作業の簡略化が実現でき、作業者の技能の優劣による差も少なくなる。よって、人的工数及び、作業時間の短縮が可能となる。

【図面の簡単な説明】

【図１】本発明のプローブカードの構造を示したプローブカードの断面図。

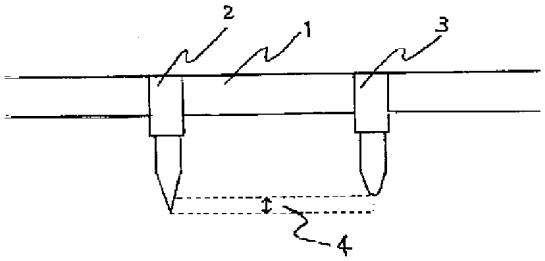
【図２】本発明のプローブカードの動作を説明するための図。

【図３】本発明のプローブ針の交換方法を説明するための図。

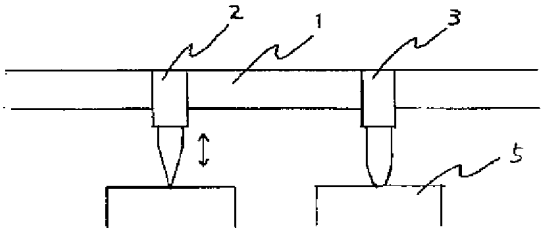
【符号の説明】

１・・・プローブカード基板
２・・・ポゴピン構造プローブ針Ａ
３・・・ポゴピン構造プローブ針Ｂ
４・・・プローブ針の段差
５・・・半導体ＩＣチップのパッド
６・・・ポゴピン構造プローブ針のプローブ針部
７・・・ポゴピン構造プローブ針のソケット部

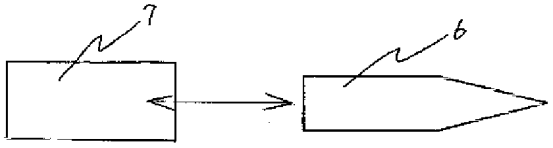
【図１】



【図２】



【図３】



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12/32		9/09	Ｂ	５Ｅ０７７
12/22		23/68	Ｐ	

審査請求　未請求　請求項の数２　ＯＬ　（全 ６ 頁）

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(71)出願人　000194918
ホシデン株式会社
大阪府八尾市北久宝寺１丁目４番33号
(72)発明者　関口　茂美
群馬県伊勢崎市戸谷塚町329番地　ホシデン株式会社東京工場内
(74)代理人　100066153
弁理士　草野　卓　（外１名）

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5E077 BB23 BB31 CC22 CC26 DD01 EE03 EE05 FF30 JJ07 JJ20

(54)【発明の名称】　スプリングピンコネクタ

(57)【要約】
【課題】製造工程を短縮でき、実装密度を上げることができる表面実装が可能なスプリングピンコネクタを提供する。
【解決手段】一つの面に開口された複数の小径孔11と、この小径孔に連通し一つの面と平行する他方の面に開口された複数の大径孔12とが形成された絶縁ボディ10と、小径孔を貫通し軸芯方向に移動自在に配置された導電性ピン２と、この導電性ピンの大径孔側の端部に一体成形された大径孔の直径より小さい直径を持つ大径部３と、この大径部の端面に形成された孔と、大径部に形成した孔に一端が係合し、導電性ピンに偏倚力を与える圧縮バネ４と、コ字状に折曲形成された一対の脚を有し、この一対の脚が大径孔に沿って軸芯方向に形成した溝に圧入された圧縮バネを圧縮変形させて係止する係止導体5Aと、係止導体の一対の脚を結合する面を端子部56Aとし、ほぼ中央部に外向きの凸部53Aを設ける。

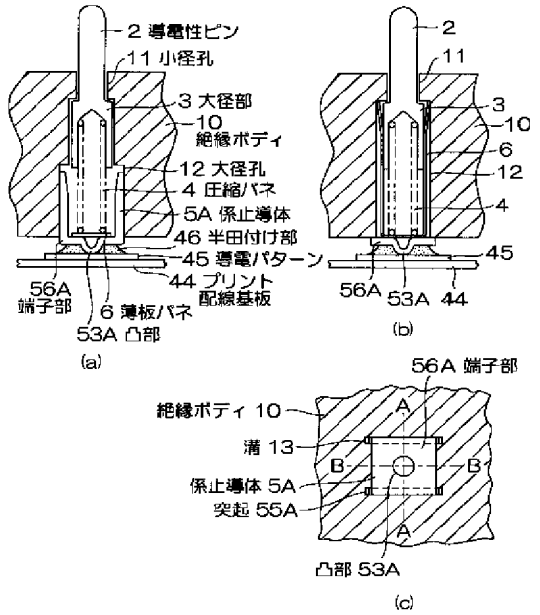

図1

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【特許請求の範囲】
【請求項１】一つの面に開口された複数の小径孔と、この小径孔に連通し上記一つの面と平行する他方の面に開口された複数の大径孔とが形成された絶縁ボディと、
上記小径孔を貫通し軸芯方向に移動自在に配置された導電性ピンと、
この導電性ピンの上記大径孔側の端部に一体成形され、上記大径孔の直径より小さい直径を持つ大径部と、
この大径部の端面に形成された孔と、
上記大径部に形成した孔に一端が係合し、上記導電性ピンに偏倚力を与える圧縮バネと、
コ字状に折曲形成された一対の脚を有し、この一対の脚が上記大径孔に沿って軸芯方向に形成した溝に圧入された上記圧縮バネを圧縮変形させて係止する係止導体と、
上記係止導体の一対の脚を結合する面を端子部とし、ほぼ中央部に外向きの凸部を設けたことを特徴とするスプリングピンコネクタ。
【請求項２】請求項１に記載のスプリングピンコネクタにおいて、
上記係止導体と圧縮バネとの間に介挿され、上記係止導体のコ字状の脚に沿って配置され、上記係止導体と上記導電性ピンとの間を電気的に導通させる薄板バネを備えたことを特徴とするスプリングピンコネクタ。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】この発明は、プリント配線基板の表面に実装するスプリングピンコネクタに関する。
【０００２】
【従来の技術】（従来例１）図３に従来例１のスプリングピンコネクタの断面図、図４にスプリングピンコネクタをプリント配線基板間に実装した構成図を示す。図５に５個のスプリングピンコネクタを絶縁被覆部で一体化した斜視図を示す。従来例１を図３～５を参照して説明する。
【０００３】図３に示すようにスプリングピンコネクタ１は一端部を他部に比して小径となるように絞り加工して取付基部31とした円筒状導体ピン30内に導体素材からなる圧縮バネ４を装着するとともに、この円筒状導体ピン内に先端が円錐状をなす導電性ピン２を挿入して前記圧縮バネに弾支されてその円錐状先端部が円筒状導体ピンの他端部の開口より突出した状態で進退自在となるようにしたものである。導電性ピン２の基部は中胴部に比してその径寸法を大きくして、円筒状導体ピンの開口縁に形成した内向フランジ32に係止して抜止される。また、圧縮バネの一端は、円筒状導体ピン内において小径の取付基部と中胴部との境界部に形成される段部面に係止する。
【０００４】図４に示すようにスプリングピンコネクタ１は一方のプリント配線基板40に設けた孔にスプリングピンコネクタの円筒状導体ピンの取付基部31を差し込んで立設し導電パターン45と半田付け46して固定した後、枠形のシャーシ60の下面側にこのプリント配線基板をねじ止め（ネジ挿通孔47、ネジ孔61、ネジ62）する。また、他方のプリント配線基板41の配線端子42が内側に向くように重ね合わせて導電ピンの先端部と接触させて、これら２枚のプリント配線基板間をスプリングピンコネクタにより接続する。
【０００５】また、図５に示すように複数のスプリングピンコネクタを絶縁被覆部35により導電性ピン２と取付基部31を突出させて被覆処理し一体化して２枚のプリント配線基板の複数の導電パターンと配線端子間を接続する。上記構成を備えることにより、プリント配線基板間の配線間隔にたわみなどによる寸法誤差がある場合でも接触不良を生じることなく良好な電気接続を行うことができ、また、組立・分解も容易に行える。
（実開昭５７－１０３６７５号公報　参照）
（従来例２）図６は従来例２のスプリングピンコネクタの図10Ｄ－Ｄ断面図、図７は絶縁ボディの底面図、図８は係止導体の斜視図、図９は薄板バネの斜視図、図10はスプリングピンコネクタの正面図を示す。
【０００６】従来例２を図６～10を参照して説明する。図６に示すようにスプリングピンコネクタ１は絶縁ボディ10の一つの面に小径孔11を形成し、この小径孔に連通して大径孔12を形成する。大径孔は絶縁ボディの他方の面に開放される。小径孔11には導電性ピン２が挿通される。導電性ピンの一端側には大径部３を有し、大径部は絶縁ボディに形成した大径孔に収納される。大径孔は図７に示すように円孔の側部に４本の溝13を備えている。
【０００７】図８に示すように係止導体５は導電板をコ字状に折り曲げて形成した一対の脚51を備え、溝間に係止導体の一対の脚を圧入し、大径孔の開口面を閉塞する。一対の脚の側辺には突起55を形成し、この突起が溝の側縁に食い込んで係止導体を抜け止めする。また、係止導体５の一対の脚を結合する面のほぼ中央に舌片52を内側に向けて突出させ、一体に延長して形成された端子53を設ける。図９に示すように薄板バネ６は係止導体と同様にコ字状に折り曲げて形成した一対の脚61を有する。脚は途中で末広がりに開くように折目62を形成する。
【０００８】係止導体の一対の脚の間には薄板バネ６を介挿する。この薄板バネを係止導体の脚間に介挿することにより、薄板バネの脚が図６に示すように折目の部分が内側に脹らんだ状態に装着される。係止導体に設けた舌片は薄板バネ６の脚間の面に形成した孔63を通じて大径部内に突出される。舌片は圧縮バネ４の端部に係合させて圧縮バネの端部を大径孔の軸芯位置に保持させる。
【０００９】図１０にスプリングピンコネクタの全体形状を示す。上記構成を備えることにより薄板バネを介して導電性ピンと係止導体相互が導通され圧縮バネとしてリン青銅よりバネ圧の高いピアノ線を用いることがで

き、バネ径を小さくしても導電性ピンに大きなバネ圧を与えることができるので全体として形状を小さくすることができる。（特開平８－８８０４０号公報　参照）

【００１０】

【発明が解決しようとする課題】（１）従来例１においてはスプリングピンコネクタを実装する場合にはプリント配線基板に孔を設け、この孔に取付基部を嵌合して半田付けすることにより固定する。したがって、プリント配線基板に孔を穿つ加工、この孔に嵌合するために円筒状導体ピンに取付基部を設ける加工を必要とし、また、導電ピンの大径部を抜け止めを行う内向フランジ加工を必要とし加工工程が複雑となる。

【００１１】さらに、図４に示すように個別に組み立てた複数のスプリングピンコネクタを絶縁被覆部で一体化とする別工程を必要とする。

（２）従来例２においては係止導体、薄板バネは高精度を必要としないでプレス加工により生産でき、また、絶縁ボディに係止導体を圧入することで複数の導電性ピンを備えたスプリングピンコネクタを組み立てることができ工程の短縮化を図ることはできるが係止導体から一体に延長して形成した端子をプリント配線基板の孔に挿入して半田付けすることから実装密度を上げることはできない。

【００１２】また、上記従来例１、２においてはスプリングピンコネクタをプリント配線基板の表面に実装できる構成は備えていない。本発明の目的は、従来例２のスプリングピンコネクタの構成の一部を変更することにより実装密度を上げることができ、表面実装を可能としたスプリングピンコネクタを提供することにある。

【００１３】

【課題を解決するための手段】上記課題を解決するために、請求項１の発明は、一つの面に開口された複数の小径孔と、この小径孔に連通し上記一つの面と平行する他方の面に開口された複数の大径孔とが形成された絶縁ボディと、上記小径孔を貫通し軸芯方向に移動自在に配置された導電性ピンと、この導電性ピンの上記大径孔側の端部に一体成形され、上記大径孔の直径より小さい直径を持つ大径部と、この大径部の端面に形成された孔と、上記大径部に形成した孔に一端が係合し、上記導電性ピンに偏倚力を与える圧縮バネと、コ字状に折曲形成された一対の脚を有し、この一対の脚が上記大径孔に沿って軸芯方向に形成した溝に圧入され上記圧縮バネを圧縮変形させて係止する係止導体を備えたスプリングピンコネクタにおいて、上記係止導体の一対の脚を結合する面を端子部とし、ほぼ中央部に外向きの凸部を設けたことを特徴とする。

【００１４】請求項２の発明は、請求項１のスプリングピンコネクタにおいて、上記係止導体と圧縮バネとの間に介挿され、上記係止導体のコ字状の脚に沿って配置され、上記係止導体と上記導電性ピンとの間を電気的に導通させる薄板バネを備えたことを特徴とする。

【００１５】

【発明の実施の形態】この発明は従来例２に記載されたスプリングピンコネクタの係止導体の構成を変更することにより実装密度を上げることができ、表面実装を可能としたスプリングピンコネクタを提供する。。従来例２に示されたスプリングピンコネクタは係止導体の脚を結合する面の側辺から延長して端子が形成され、この端子をプリント配線基板の孔に差し込み半田付けするのに対して、本発明のスプリングピンコネクタは係止導体の脚を結合する面を端子部としてプレス等により凸部を設け、この凸部を設けた端子部をプリント配線基板に半田付けをする。

【００１６】図１、２にこの発明の１実施例を示す。図１、２において、図６～10と対応する部分には同一符号を付して示す。図１は本発明のスプリングピンコネクタ断面図、底面図を示す。図１(a)は図１(c)Ａ－Ａ断面図、図１(b)は図１(c)Ｂ－Ｂ断面図、図１(c)はスプリングピンコネクタの底面図（係止導体方向から見た図）である。本発明の絶縁ボディ、導電性ピン、圧縮コイルバネ、薄板バネは図５～９に示された従来例２のものと同様であるので詳細な説明は省略する。

【００１７】図２に本発明の係止導体5Aの構成を示す。図２(a)は正面図、図２(b)は図２(a)Ｃ－Ｃ断面図を示す。係止導体5Aは図２に示すように導電板をコ字状に折り曲げて形成した一対の脚51Aとこの脚を結合する端子部56Aを有し、一対の脚を溝13に圧入する。脚の側辺には突起55Aを形成し、この突起が溝の側縁に食い込んで係止導体を抜け止めする。また、係止導体の端子部にはプレス等により外側に突出した凸部53Aを設ける。

【００１８】図１(a),(b)に示すようにスプリングピンコネクタ１はプリント配線基板44の導電パターン45上に垂直に配置されて端子部56Aと半田付けされ固定される。半田付けは端子部に設けた凸部により半田付け面と導電パターンの間に一定厚みの間隙を形成することにより、この間隙に多量の半田を介在せしめると共に端子部と半田の接合面積を増大させることができ接合強度を極めて大きくすることができる。また、凸部は端子部にプレス等により特別な部材を必要とすることなく簡単に加工することができる。凸部としては半球状に限らず、円錐状、角錐状、角柱状等のいずれの形状であってもよく、また、複数個設けてもよい。

【００１９】このような構成により底面積に比べて高さの高いスプリングピンコネクタをプリント配線基板の表面に実装することが可能となる。

【００２０】

【発明の効果】本発明は上記のとおり構成されているので次に記載の効果を奏する。

（１）スプリングピンコネクタを構成する個々の部品の寸法はそれほどの高精度を必要とせず、しかもハイサイ

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クルで生産が可能なプレス加工により生産ができるので部品価格を安価とすることができる。
（２）スプリングピンコネクタのプリント配線基板への端子部（半田付け部）はコネクタの軸方向下に納めることができるので実装面積を小さくでき、しかもフラックスや半田がコネクタ接触部に流入することがない。
（３）従来例２と同様に絶縁ボディに直接に他の部品を組み込んでいく工程をとることができ、工程の短縮化を図ることができる。
（４）全ての部品を絶縁ボディ内の所定の位置に固定するための部品である係止導体の端子部に凸部を一体に形成したので特別な材料を必要とすることなく、プレス等により簡単に加工できる。また、この凸部により端子部とプリント配線基板を強固に固定できる。
【図面の簡単な説明】
【図１】本発明のスプリングピンコネクタの断面図及び底面図。
【図２】本発明の係止導体の構成を示す正面図及び断面図。
【図３】従来例１のスプリングピンコネクタのの断面図。
【図４】従来例１のスプリングピンコネクタのプリント配線基板の実装状態を示す図。
【図５】従来例１のスプリングピンコネクタの複数個を絶縁被覆部で一体化した例を示す斜視図。
【図６】従来例２のスプリングピンコネクタの断面図。
【図７】従来例２の絶縁ボディの底面図。
【図８】従来例２の係止導体の斜視図。
【図９】従来例２の薄板バネの斜視図。
【図１０】従来例２のスプリングピンコネクタの正面図。
【符号の説明】
1　スプリングピンコネクタ
2　導電性ピン
4　圧縮バネ
5、5A　係止導体
6　薄板バネ
44　プリント配線基板
45　導電パターン
46　半田付け部
53A　凸部
56A　端子部

【図１】

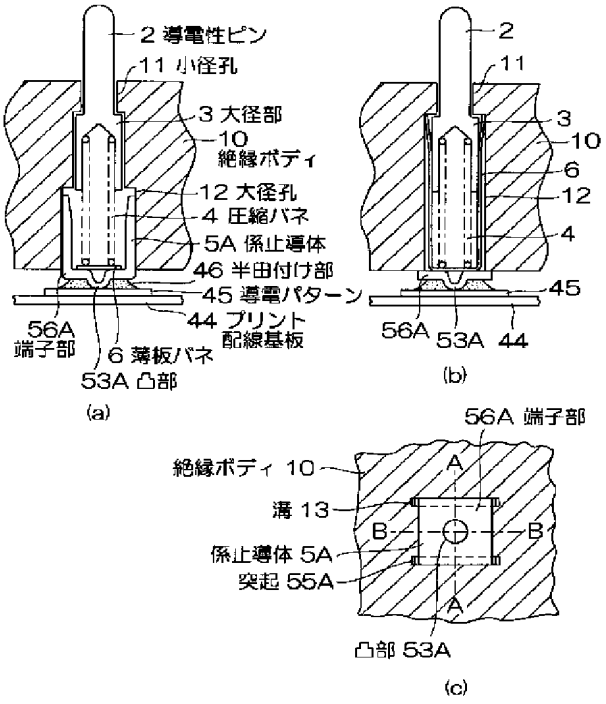


図1

【図２】

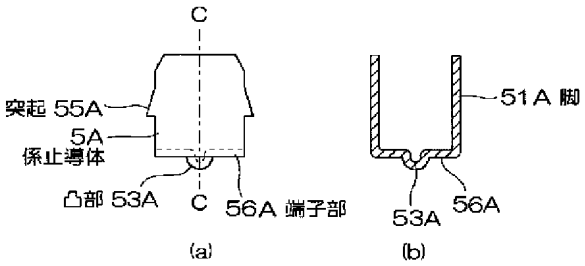
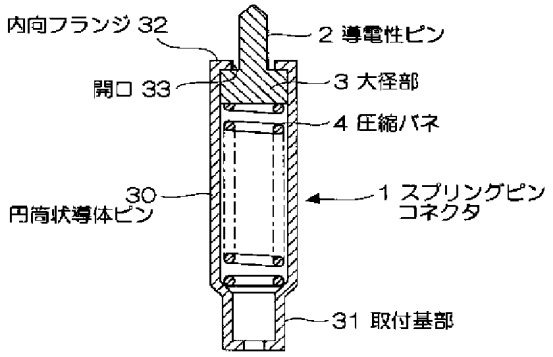


図2

【図3】



スプリングピンコネクタ 1

図3

【図7】

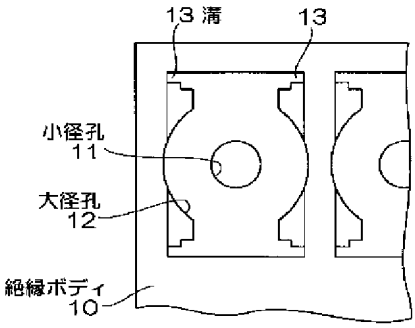


図7

【図4】

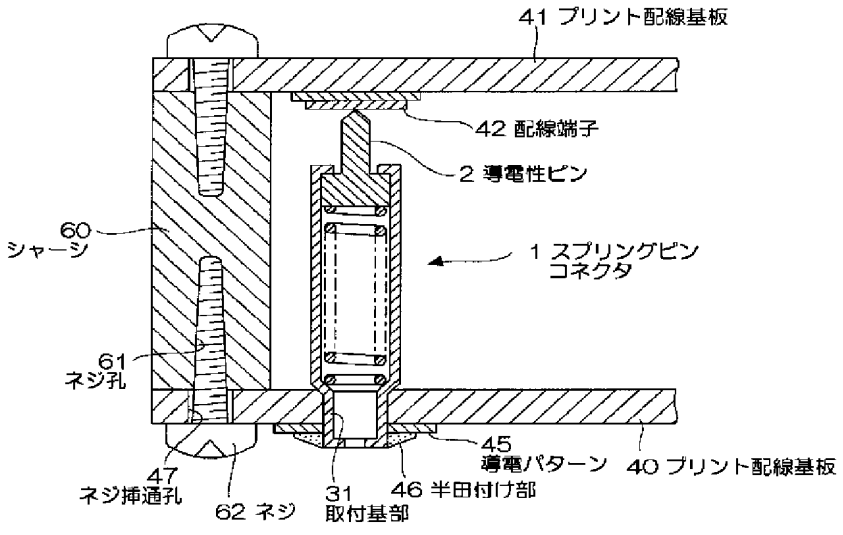


図4

【図５】

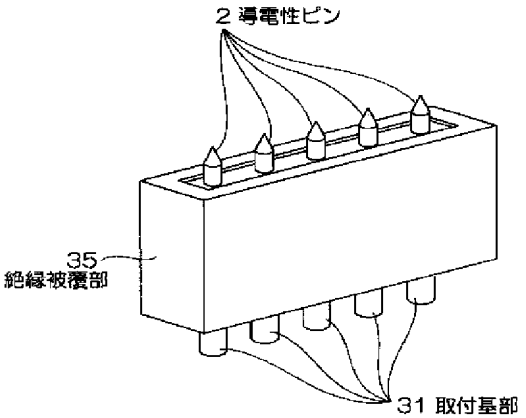
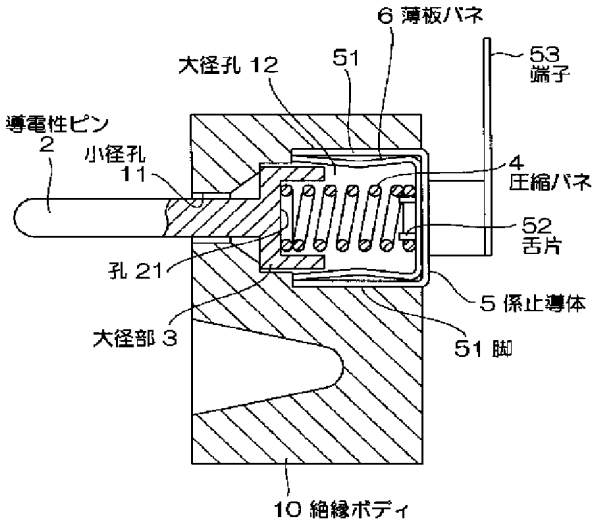


図5

【図６】



スプリングピンコネクタ 1

図6

【図８】

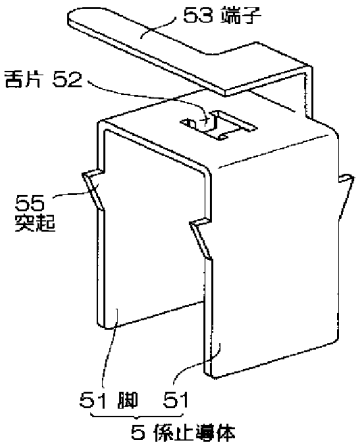


図8

【図９】

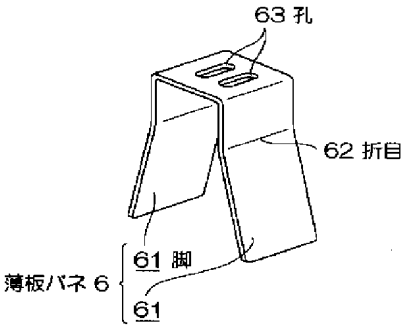
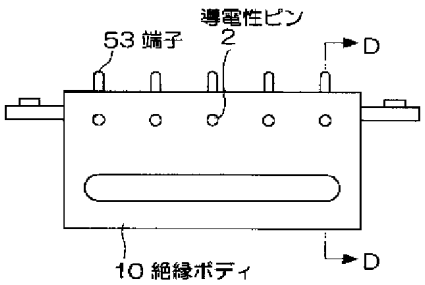


図9

【図１０】



スプリングピンコネクタ 1

図10

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---	---
(73) 특허권자	현대반도체 주식회사, 김영환
	대한민국
	361-480
	충북 청주시 흥덕구 향정동 1번지
(72) 발명자	임유식
	대한민국
	702-250
	대구광역시 북구 동천동 영남2차아파트 106/702
(74) 대리인	김용인
	강용복
(77) 심사청구	심사관: 오제욱

(54) 출원명 포고 핀(POGOPIN)의 이젝트(EJECT)장치

요약

본 발명은 포고 핀의 이젝트 장치에 관한 것으로 포고 핀을 이젝트하는 별도의 구조를 가진 포고 핀 이젝트 부재를 구비하여 상기 포고 핀 이젝트 수단에 의해 포고 핀의 이젝트시 다른 포고 핀의 손상을 방지하도록 함과 동시에 상기 포고 핀을 원활하게 이젝트하므로 작업효율이 향상되도록 한 것이다.

이를 위해, 본 발명은 보드(3)와 다른 부품이 밀착결합되도록 상기 보드(3)에 복수개의 포고 핀(1)이 결합된 것에 있어서, 상기 각 포고 핀(1)이 삽탈됨과 동시에 자동으로 벌어졌다 오무러 들었다 하면서 상기 각 포고 핀(1)을 하나씩 잡고 이젝트하도록 하는 포고 핀 이젝트 부재(101)가 구비된 것이다.

대표도

도3a

명세서

도면의 간단한 설명

도 1은 종래 포고 핀을 이젝트하는 상태를 나타낸 구조도.

도 2는 본 발명 포고 핀 이젝트 장치를 나타낸 분해 사시도.

도 3a 내지 도 3d는 본 발명 포고 핀 이젝트 장치가 작동되는 상태를 순차적으로 나타낸 작동상태도.

도 4a는 포고 핀 이젝트 장치의 포고 핀 집게부가 몸체의 내부로 삽입된 상태를 나타낸 저면도.

도 4b는 포고 핀 이젝트 장치의 포고 핀 집게부가 몸체의 외부로 나온 상태를 나타낸 저면도.

도면의 주요부분에 대한 부호의 설명

101: 포고 핀 이젝트 부재	102: 몸체
103: 가이드 공	104: 푸셔
105: 가이드 바	106: 핀 집게부
107: 분할핀	108: 탄성부재

발명의 상세한 설명

발명의 목적

발명이 속하는 기술 및 그 분야의 종래기술

본 발명은 포고 핀의 이젝트 장치에 관한 것으로써, 좀 더 구체적으로는 포고 핀을 원활하게 이젝트할 수 있도록 하는 포고 핀의 이젝트 장치에 관한 것이다.

종래의 포고 핀의 이젝트 장치는 도 1에서 도시한 바와 같이, 보드(3)에 결합되어 상기 보드(3)에 다른 부품과 밀착되어 결합될 수 있도록 하는 복수개의 포고 핀(1)과, 상기 각 포고 핀(1)을 보드(3)에서 이젝트(eject)시키는 핀세트(pincers)(2)로 구성되어 있다.

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이러한 구조의 포고 핀의 이젝트 장치는 보드(3)에 결합된 복수개의 포고 핀(1)를 상기 보드(3)에서 제거하기 위해 상기 보드(3)에서 각 포고 핀(1)을 빼낼 때에는 핀세트(2)나 롱 플라이어(plier)를 사용하여 포고 핀(1)를 각각 빼낸다.

즉, 보드(3)에 박혀 있는 각 포고 핀(1)의 상단부를 핀세트(2)로 잡은 다음 상기 핀세트(2)를 도면상 보드(3)의 상방으로 당기므로 상기 각 포고 핀(1)은 보드(3)에서 이젝트(eject)된다.

그러나, 이러한 종래 포고 핀의 이젝트 장치는 보드(3)에 박여 있는 복수개의 포고 핀(1) 중 어느 하나의 포고 핀(1) 상단부를 핀세트(2)나 롱 플라이어로 잡고 나서 보드(3)의 상방으로 잡아당기므로 상기 포고 핀(1)을 이젝트하게 되는데, 이 때 포고 핀(1)을 이젝트 하기 위해 핀세트(2)를 사용할 경우 포고 핀(1)과 핀세트(2)간에 미끄러짐이 발생되어 다른 포고 핀(1)를 건드리게 되어 상기 다른 포고 핀(1)이 손상될 수 있고, 상기 롱 플라이어를 사용할 경우 포고 핀(1)의 피치(pitch)가 적을 때에는 롱 플라이어를 사용할 수 없는 문제점이 있었다.

또한, 핀세트(2)나 롱 플라이어를 사용하여 포고 핀(1)을 이젝트 할 때 상기 이젝트하는 시간 및 힘이 많이 소요됨에 따라 작업효율이 저하되는 문제점도 있었다.

발명이 이루고자 하는 기술적 과제

본 발명은 상기의 제반 문제점을 해결하기 위해 안출한 것으로서, 포고 핀을 이젝트하는 별도의 구조를 가진 포고 핀 이젝트 부재를 구비하여 상기 포고 핀 이젝트 수단에 의해 포고 핀의 이젝트시 다른 포고 핀의 손상을 방지하도록 함과 동시에 상기 포고 핀을 원활하게 이젝트하므로 작업효율이 향상되도록 하는데 그 목적이 있다.

상기의 목적을 달성하기 위해, 본 발명은 보드와 다른 부품이 밀착결합되도록 상기 보드에 복수개의 포고 핀이 결합된 것에 있어서, 상기 각 포고 핀이 삽탈됨과 동시에 자동으로 벌어졌다 오무러 들었다 하면서 상기 각 포고 핀을 하나씩 잡고 이젝트하도록 하는 포고 핀 이젝트 부재가 구비된 것을 특징으로 하는 포고 핀의 이젝트 장치가 제공된다.

발명의 구성 및 작용

이하, 본 발명의 일 실시예를 첨부도면 도 2 내지 도 4b를 참조하여 상세히 설명하면 다음과 같다.

도 2는 본 발명 포고 핀 이젝트 장치를 나타낸 분해 사시도이고, 도 3a 내지 도 3d는 본 발명 포고 핀 이젝트 장치가 작동되는 상태를 순차적으로 나타낸 작동상태도이고, 도 4a는 포고 핀 이젝트 장치의 포고 핀 집게부가 몸체의 내부로 삽입된 상태를 나타낸 저면도이고, 도 4b는 포고 핀 이젝트 장치의 포고 핀 집게부가 몸체의 외부로 나온 상태를 나타낸 저면도이다.

본 발명은 보드(3)와 다른 부품이 밀착결합될 수 있도록 상기 보드(3)에 복수개의 포고 핀(1)이 결합되어 있고, 상기 각 포고 핀(1)이 삽탈됨과 동시에 자동으로 벌어졌다 오무러 들었다 하면서 상기 각 포고 핀(1)을 하나씩 잡고 이젝트하도록 하는 포고 핀 이젝트 부재(101)가 구비되어 있다.

상기 포고 핀 이젝트 부재(101)는 가이드 공(103)이 형성된 몸체(102)와, 상기 몸체(102)의 가이드 공(103) 내에 삽입되어 왕복 이동됨과 함께 끝단에 포고 핀(1)이 삽탈되는 핀 집게부(106)가 형성된 가이드 바(105)와, 상기 핀 집게부(106)의 반대편 가이드 바(105)에 결합되어 상기 가이드 바(105)를 왕복 이동시키도록 하는 푸셔(104)와, 상기 푸셔(104)와 몸체(102) 사이의 가이드 바(105) 외주연부에 감싸도록 설치되어 가이드 바(105)를 원위치로 복귀시키도록 하는 탄성부재(108)로 구성되어 있다.

상기 핀 집게부(106)는 몸체(102)의 가이드 공(103) 내로 삽입되면 오무러들고 상기 가이드 공(103)의 외부로 빠져 나오면 자체 탄성력에 의해 벌어지도록 복수개로 분할된 분할편(107)으로 형성되어 있다.

이와 같이 구성된 본 발명의 작용은 다음과 같다.

먼저, 보드(3)에 결합된 복수개의 포고 핀(1)의 상방에 포고 핀 이젝트 부재(101)를 위치시키고 나서 상기 핀 이젝트 부재(101)의 몸체(102)를 잡고 있는 상태에서 상기 몸체(102)의 상방에 위치된 푸셔(104)를 누르게 되면 상기 몸체(102)의 가이드 공(103) 내에 삽입되어 있는 가이드 바(105)가 상기 몸체(102)의 외부로 밀려 나오게 된다.

즉, 상기 가이드 바(105)의 끝단에 형성된 핀 집게부(106)가 몸체(102)의 외부로 밀려나와 상기 밀려나온 핀 집게부(106)의 복수개로 분할된 분할핀(107)이 자체 탄성력에 의해 벌어지게 되고, 상기 벌어진 각 분할핀(107) 사이 즉, 각 분할핀(107)의 중심부에 포고 핀(1)이 위치되도록 삽입된다.

상기 각 분할핀(107)의 중심부에 포고 핀(1)이 삽입된 상태에서 상기 푸셔(104)에 가해지는 힘을 제거하게 되면 상기 몸체(102)와 푸셔(104) 사이에 가이드 바(105)의 외주연부를 감싸는 탄성부재(108)의 탄성력에 의해 상기 푸셔(104)는 도면상 상방 측으로 이동됨과 함께 상기 몸체(102)가 보드(3) 측으로 이동된다.

이 때, 몸체(102)가 보드(3) 측으로 이동되면 상기 몸체(102)의 가이드 공(103) 내로 핀 집게부(106)가 삽입됨에 따라 핀 집게부(106)의 각 분할핀(107)이 모아지면서 포고 핀(1)을 견고하게 잡아주게 된다.

그리고, 상기 핀 집게부(106)의 각 분할핀(107)에 의해 포고 핀(1)이 견고하게 잡혀진 상태에서 상기 몸체(102)와 가이드 바(105)를 동시에 도면상 상방 측으로 잡아당기게 되면 상기 포고 핀 이젝트 부재(101)의 핀 집게부(106)에 의해 잡혀 있던 포고 핀(1)이 보드(3)에서 이젝트된다.

상기와 같은 방법으로 포고 핀 이젝트 부재(101)로 보드(3)에 결합된 복수개의 포고 핀(1)을 하나씩 이젝트시킨다.

발명의 효과

이상에서와 같이, 본 발명은 보드에 결합된 복수개의 포고 핀을 각각 이젝트 시키는 포고 핀 이젝트 부재를 설치함으로써, 상기 포고 핀을 이젝트할 때 다른 포고 핀에 영향을 미치지 않아 상기 다른 포고 핀의 손상을 방지할 수 있을 뿐만 아니라 상기 각 포고 핀을 힘들이지 않고 원활하게 이젝트 할 수 있어 작업효율이 향상되는 효과가 있다.

또한, 포고 핀 이젝트 부재에 의해 포고 핀의 이젝트 뿐만 아니라 상기 포고 핀의 장착에도 용이한 효과도 있다.

그리고, 포고 핀 이젝트 부재를 다른 작업에도 즉, 다른 물체의 착탈 등에도 응용할 수 있는 효과도 있다.

(57) 청구의 범위

청구항 1.

보드와 다른 부품이 밀착결합되도록 상기 보드에 복수개의 포고 핀이 결합된 것에 있어서,

가이드공이 형성된 몸체와, 상기 몸체의 가이드공 내에 삽입되어 왕복 이동됨과 함께 끝단에 포고 핀이 삽탈되는 핀 집게부가 형성된 가이드 바와, 상기 핀 집게부의 반대편 가이드 바에 결합되어 상기 가이드 바를 왕복 이동시키도록 하는 푸셔와, 상기 푸셔와 몸체 사이의 가이드 바의 외주연부에 감싸도록 설치되어 가이드 바를 원위치로 복귀시키도록 하는 탄성부재로 이루어져, 상기 각 포고 핀이 삽탈됨과 동시에 자동으로 벌어졌다 오무러 들었다 하면서 상기 각 포고 핀을 잡고 이젝트하도록 하는 것을 특징으로 하는 포고 핀의 이젝트 장치.

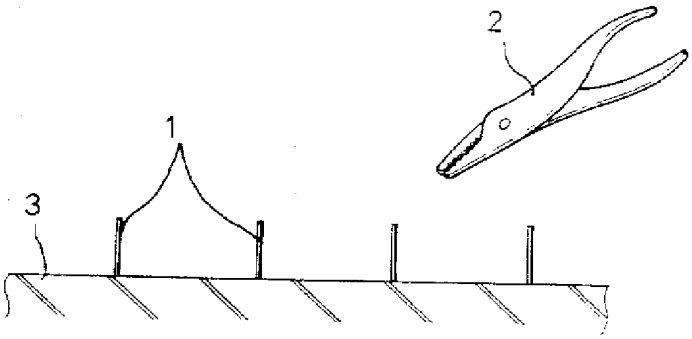
청구항 2.

제 1 항에 있어서,

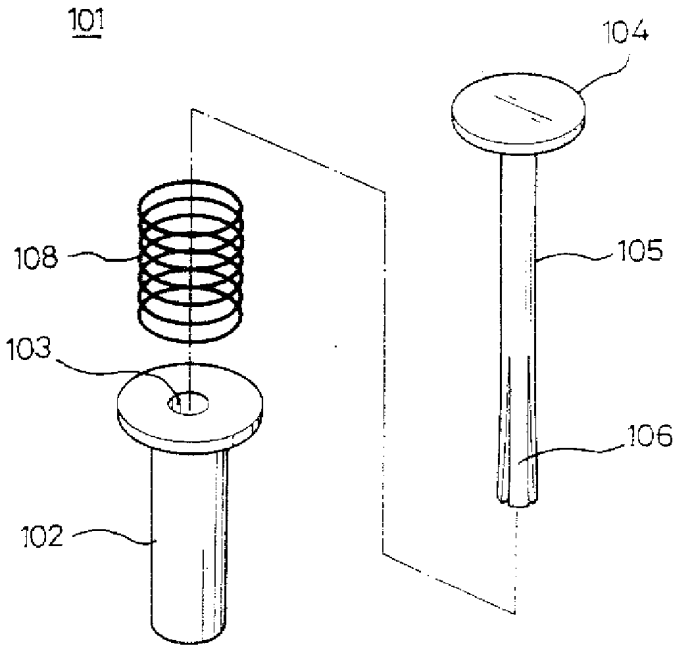
핀 집게부는 복수개로 분할된 분할편으로 형성하여 상기 핀 집게부가 가이드공 내로 삽입되면 상기 각 분할편은 오무러들고 상기 핀 집게부가 가이드공의 외부로 나오게 되면 자체 탄성력에 의해 상기 각 분할편은 벌어지도록 한 것을 특징으로 하는 포고 핀의 이젝트 장치.

도면

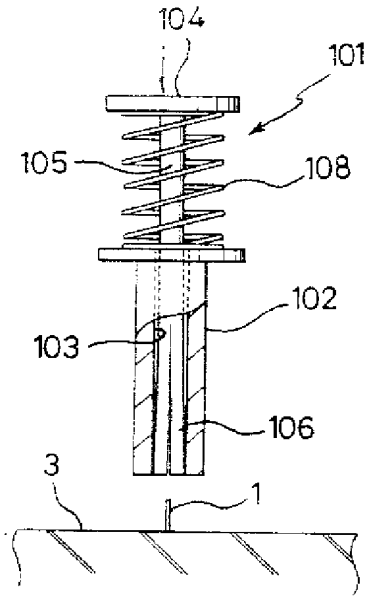
도면 1



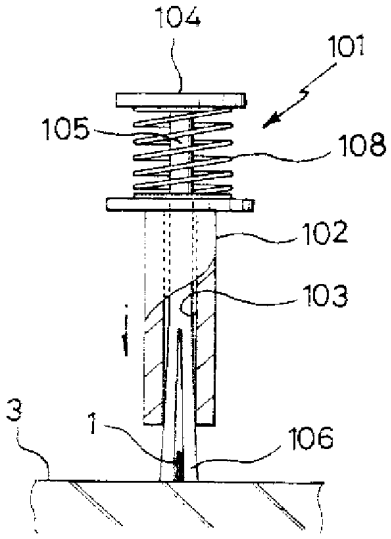
도면 2



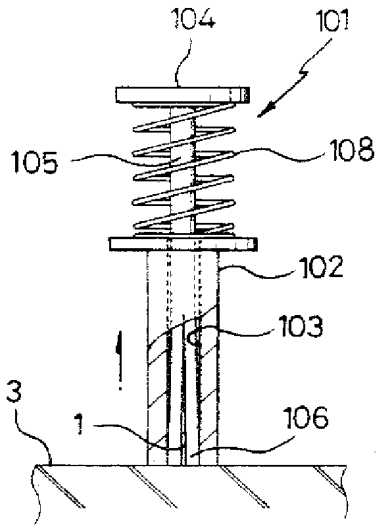
도면 3a



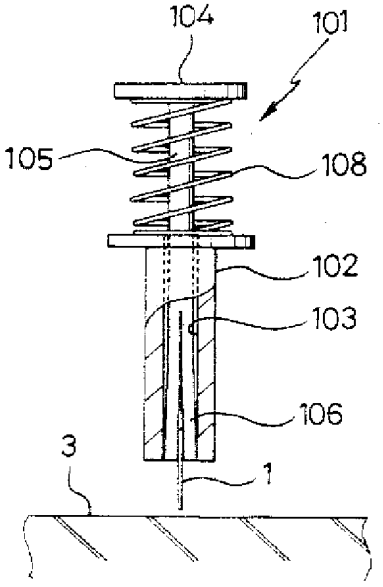
도면 3b



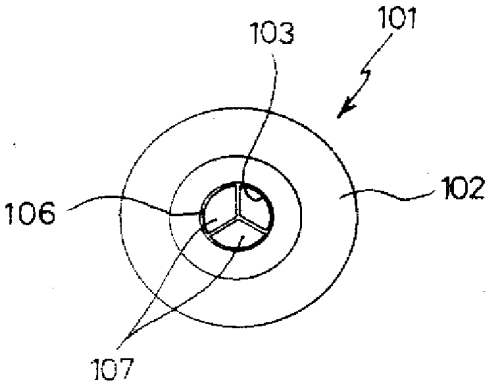
도면 3c



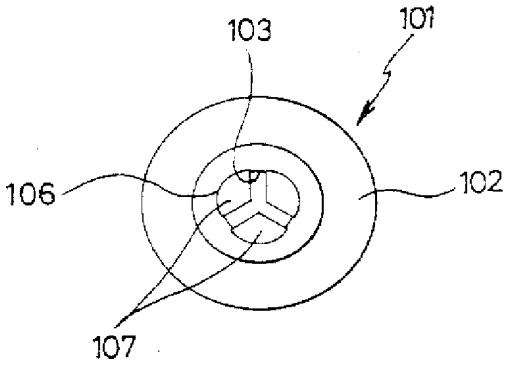
도면 3d



도면 4a



도면 4b



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(73) 특허권자 정운영
경기도 광주시 오포읍 문형리 100-1

(72) 발명자 정운영
경기도 광주시 오포읍 문형리 100-1

(74) 대리인 박장원

심사관 : 맹성재

(54) 포고핀 및 이를 이용한 테스트장치

요약

본 발명은 내부가 비어 있는 원통형 금속 몸체와, 상기 몸체의 중앙 외부면의 적어도 일부분에 나사산의 형태로 커팅된 스프링 구조가 일체로 형성되어 있는 것을 특징으로 하는 포고핀을 제공한다. 이와 같은 몸체상의 커팅은 레이저 가공에 의하여 매우 미세한 정도까지 가능하다. 본 발명에 따르면, 스프링과 접점부가 일체로 형성된 포고핀에 의하여 접촉 불량을 현저히 줄이고, 제조 및 조립이 용이한 테스트 장치를 개발할 수 있게 된다.

대표도

도 5a

색인어

포고핀, 테스트 장치, 레이저 커팅

명세서

도면의 간단한 설명

도 1은 종래의 테스트 장치의 단면을 보여주는 모식도.

도 2는 도 1의 부분확대도.

도 3은 종래의 포고핀의 단면도.

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도 4는 종래의 또 다른 포고핀의 단면도.

도 5a는 본 발명의 일실시예에 따른 포고핀의 측면도.

도 5b는 본 발명의 다른 일실시예에 따른 포고핀의 측면도.

도 6a는 본 발명의 또 다른 실시예에 따른 포고핀의 측면도.

도 6b는 본 발명의 또 다른 실시예에 따른 포고핀의 측면도.

도 7은 본 발명의 일실시예에 따른 포고핀을 사용한 테스트 장치의 단면도.

*** 도면의 주요부분에 대한 부호의 설명 ***

100:포고핀 101:윗부분(선단)

102:아랫부분(후단) 105:몸통 중앙부(스프링부)

126:(돌출된) 중앙부 136:(만입된) 중앙부

발명의 상세한 설명

발명의 목적

발명이 속하는 기술 및 그 분야의 종래기술

본 발명은 포고핀에 관한 것으로, 보다 상세하게는 접점부와 스프링이 일체적으로 형성된 개선된 포고핀 및 이를 이용한 테스트 장치에 관한 것이다.

웨이퍼 레벨의 제조공정이 완료된 웨이퍼 상의 각 칩들은 패키징공정을 수행하기 전에 EDS(Electrical DieSorting) 공정에서 테스트 설비에 의해 전기적인 특성 검사를 받게 된다. 또한, 패키징공정이 완료된 패키지들도 테스트설비에 의해 전기적인 특성 검사를 받게 된다. 이는 상기 웨이퍼의 각 칩들이나 패키지들이 반도체장치로서의 특정 기준에 적합하게 제조되었는지의 여부를 판단하기 위함이다.

최근에 들어, 반도체소자의 고집적화가 진행되면서 포고핀(Pogo Pin) 또는 스프링핀(Spring pin))이라는 탐침이 널리 사용되고 있다. 상기 포고핀을 적용한 블록은 테스터와 더트(Device Under Testing: DUT) 보드(또는 테스트 보드)를 전기적으로 접속한다.

도 1 및 도 2 에 도시된 바와 같이, 블록(10)에 원형 형상의 포고핀 안착 홀들(11)이 수직 관통하고, 상기 포고핀 안착홀들(11) 내에 원형 관통 형상의 포고핀 케이스들(20)이 각각 삽입 고정되고, 상기 포고핀 케이스들(20) 내에 포고핀들(30)이 하나씩 대응하여 삽입 설치된다. 더트 보드(40)가 상기 포고핀들(30)에 의해 테스터(60)의 케이블(50)에 전기적으로 연결된다.

여기서, 상기 블럭(10)은 상기 포고핀들(30)을 결합하는 결집판 기능을 하며, 주로 절연성 재질로 구성된다. 상기 포고핀 안착 홀들(11)이 상기 블록(10)의 상부면에 일정 간격을 두고 다수개 배치되고, 상기 포고핀 안착 홀들(11)의 하단부의 블럭(10)에는 상기 포고핀 케이스(20)가 더 이상 하강하지 못하고 걸리도록 하기 위한 포고핀 케이스 걸림턱(13)이 형성된다. 또한, 상기 포고핀 케이스 걸림턱(13)을 기준으로 한 상기 포고핀 안착 홀(11)의 상측 부분, 즉 더트 보드(40)를 대향하는 부분의 내경이 상기 포고핀 케이스 걸림턱(13)을 기준으로 한 상기 포고핀 안착 홀(11)의 하측 부분, 상기 테스터(50)의 케이블(60)에 연결된 부분의 내경보다 크다. 그리고, 상기 포고핀들(30)의 하우징(31)이 도전성 재질로 구성되며 상기 포고핀 안착 홀들(11)의 큰 내경과 동일한 외경을 갖는 원형 관통 형상으로 이루어진다. 접촉부(33)가 도전성 재질로 구성되며 상기 하우징(31)의 상측 부분 내에서 상기 하우징(31)에 밀착하며 이동하고 상기 더트 보드(40)의 도전성 패드(41)에 접촉한다. 지지부(35)가 도전성 재질로 구성되고, 상기 포고핀 안착 홀들(11)의 작은 내경과 동일한 외경을 가지며 상기 하우징(31)의 하측 부분에 결합된다. 스프링(37)이 상기 지지부(35)에 의해 지지되고, 상기 접촉부(33)와 상기 지지부(35)

사이에 배치되며 상기 접촉부(33)와 상기 패드(41)의 양호한 접촉을 위해 장력(Tension)을 가하여준다. 또한, 이동 제한부(31a)는 상기 하우징(31)의 일부분이 상기 하우징(31)의 내부 공간을 향해 절곡된 것으로, 상기 접촉부(33)가 상기 지지부(35)를 향해 일정 거리 이상 하향 이동하는 것을 제한하여 주도록 되어 있다.

상기 포고핀을 다른 일실시예인 도 3 을 참조하여 보다 자세히 알아보기로 한다. 도 3 은 반도체 제조장비용 포고핀 구조로서, 상부가 개방된 통형의 포고 가이드(2)와, 상기 포고 가이드의 내부에 설치된 스프링(3)과, 상기 스프링의 상부에 설치된 스프링 볼(4)과, 상기 스프링 볼(4)의 상부에 설치되는 포고팁(5)으로 구성되어 있다. 그리고, 상기 포고팁(5)은 상단이 뾰족한 형상으로 되어 상단 일부가 포고 가이드(2)로부터 노출되도록 설치되어 있으며, 하단에는 상기 포고팁(5)으로부터 이탈되는 것을 방지하기 위한 걸림턱(5a)이 형성되어 있다.

이와 같이 구성된 종래의 포고핀(1)중 포고팁(5)의 뾰족한 상단은 많은 접촉이 이루어져야 하므로 마모를 줄이기 위해 견고한 재질로 되어 있으며, 포고팁(5)은 스프링(3)에 의해 탄력지지되어 있으므로 도면상 상/하 방향으로의 탄성유동이 가능하다. 이 때, 상기 포고팁(5)의 하단에는 걸림턱(5a)이 형성되어 포고 가이드(2)의 상단에 걸려 있으므로 상/하 유동되더라도 포고 가이드(2)를 벗어날 수 없도록 되어 있다. 한편, 상기 포고팁(5)과 스프링(3)사이에 설치된 스프링 볼(4)은 스프링(3)의 탄성력을 고르게 포고팁(5)으로 전달하는 역할을 하므로써 포고팁(5)이 상/하 탄력 유동을 함에 있어서, 정확한 동작이 이루어지도록 하였다.

이와 같은 상기의 포고핀들을 도 4 를 토대로 종합해 보면, 상부의 일부분이 개방되며 내부가 중공이며 PCB에 고정된 하우징(71)과, 상기 하우징(71) 내부에 설치된 탄성체(스프링)(74)와, 스프링(74) 상단에 설치되며 상기 하우징(71)의 개방구의 내경보다 긴 직경을 갖는 걸림턱(73)과, 상기 걸림턱(73)과 일체형이며 일부가 하우징 밖으로 노출된 접촉삽입핀(72)과, 상기 접촉삽입핀의 상부에 도전성패드에 접촉하는 접촉부(75)으로 구성된다.

약간씩은 다르나 대부분의 포고핀은 이와 유사한 구성과 기능을 가지고 있다. 이와 같은 종래의 포고핀은 일단이 반도체 소자와 접촉하고, 타단은 테스트 장치의 PCB 금속 배선과 접촉하며, 포고핀 내부에서도 스프링과 접촉되는 등 많은 전기적인 접촉부위가 필요하며, 이에 따라 저항이 증가하거나 접촉 불량이 발생될 가능성이 크다. 또한 포고핀의 크기가 미세해질 수록 포고핀 제조 및 조립의 어려움이 있으며, 제조 단가도 상승하는 문제점이 있다.

발명이 이루고자 하는 기술적 과제

따라서, 본 발명의 목적은 포고핀이 갖는 전기적인 접촉점으로서의 역할과 탄성적인 완충장치로서의 역할을 동시에 수행할 수 있는 개선된 일체형 포고핀을 제공하는데 있다.

또한, 본 발명의 목적은 제조 및 조립이 용이하고 다양한 구조의 테스트 장치에 적용 가능한 새로운 포고핀을 제공하는 것이다.

발명의 구성 및 작용

상기 목적을 달성하기 위하여, 본 발명은 내부가 비어 있는 원통형 금속 몸체와, 상기 몸체의 중앙 외부면의 적어도 일부분에 나사산의 형태로 커팅된 스프링 구조가 일체로 형성되어 있는 것을 특징으로 하는 포고핀을 제공한다.

상기 몸체의 일측 끝단은 폭이 좁아져 경사진 형태일 수 있으며, 또한 상기 몸체의 일측 끝단에 산과 골이 형성된 톱니 형태가 되도록 할 수도 있다.

상기 몸체 중앙은 측방향으로 돌출되거나 만입되도록 하여 테스트 바디의 몸체와의 결합이 용이하도록 할 수 있다.

또한, 본 발명은 상부 몸체 및 하부 몸체로 구성되는 테스트 바디와; 상기 상부 몸체와 하부 몸체에 의하여 고정되어 테스트 바디에 삽입되며, 내부가 비어 있는 원통형 금속 몸체와, 상기 몸체의 중앙 외부면의 적어도 일부분에 나사산의 형태로 커팅된 스프링 구조가 일체로 형성되는 포고핀;을 포함하여 구성되는 테스트 장치를 제공한다.

본 발명에 따르면, 주사기 바늘과 같은 금속 파이프로서 내부가 비어 있는 원통형 몸체의 적어도 일부분이 원주상으로 나사산과 같이 스프링 형태로 커팅되어 몸체의 중앙부가 마치 코일과 같은 형태를 이루며, 접점부와 스프링이 일체형으로 형성된 포고핀을 제공하게 된다.

스프링 내지는 코일과 유사한 구조를 갖게 하기 위하여 수행되는 커팅 공정은 레이저를 이용하여 수행하는 것이 바람직하지만, 기타 절삭 가공도 가능할 것이다.

기존의 포고핀이 반도체 소자의 리드핀 또는 볼과 포고핀의 일단, 포고핀의 일단과 포고핀 내부의 코일, 코일과 포고핀의 타단, 포고핀의 타단과 테스터의 기판 배선으로 적어도 네 개의 전기적 접촉점이 필요한 반면, 본 발명의 경우, 반도체 소자의 리드핀 또는 볼과 포고핀의 일단, 그리고 포고핀의 타단과 테스터의 기판 배선의 단 두 곳의 접촉점만이 필요하므로 접촉 불량률이 현저하게 감소된다.

반도체 소자의 소형화에 따라 소자의 리드핀 또는 볼(BGA의 경우) 사이의 간격이 줄어들고 있으며, 이에 따라 포고핀의 크기 및 길이는 점차적으로 미세화되어 1mm이하의 두께, 예를 들면 0.35mm 정도의 매우 가는 바늘 형태가 되기도 한다. 이러한 상황에서 종래와 같이 몸체와 접점부 및 내부 스프링이 하나의 포고핀을 구성하는 경우, 각 구성요소들의 사이즈가 너무 작아 제조하기도 어려울뿐더러 각 구성요소를 하나의 포고핀으로 조립하는데 어려움이 있다.

본 발명의 경우 0.1mm 이하의 직경을 갖는 원통형의 파이프라도 외주면을 가공하여 스프링과 같은 코일 형태로 형성하므로 미세한 구성요소들을 하나의 조립체로 조립하는 번거로움이 없을 뿐만 아니라, 제조 단가도 줄어들게 된다. 레이저 가공의 경우 0.025mm 정도의 미세한 간격으로도 커팅이 가능하여 마이크로 포고핀의 제작도 기대할 수 있다.

또한, 파이프 형 포고핀의 어느 일단 또는 양단을 안으로 구부려 반도체 소자의 리드핀 또는 볼이나 테스터 장치의 기판 배선과의 접촉면을 크게 하여 저항을 더욱 줄일 수 있다.

한편, 본 발명의 포고핀은 파이프 형이므로 내부가 비어 있어, 이물질이 있더라도 낙하되고 포고핀에 이물질이 쌓이는 것을 방지할 수 있다. 따라서, 테스트 과정에서 반도체 소자와 테스트 장치간의 접촉 신뢰성을 더욱더 확보할 수 있다.

이하 도면을 참조하며 구체적인 실시예를 통하여 본 발명을 더욱 상세하게 설명한다.

도 5a는 본 발명에 따른 스프링형 포고핀의 일례를 보인 측면도이다. 포고핀(100)은 직경에 비하여 길이가 매우 긴 형태가 일반적이며, 도면에서는 상대적으로 직경이 크게 나타나 있으나 실제 제품에서는 적용되는 테스트 장치에 따라 길이에 대한 직경의 비가 더욱 큰 경우가 많을 것이다.

포고핀(100)의 몸체는 윗부분(101)과 아랫부분(102)을 제외한 중앙부(105)가 나사산의 형태로 커팅되어 있는 것을 볼 수 있다. 이와 같은 중앙부(105)는 마치 스프링 또는 코일처럼 탄성을 갖는 부위로서 포고핀(100) 자체에 외압에 대한 탄성력을 부여하게 된다. 스프링 구조를 이루는 중앙부(105)의 길이나 커팅 주기는 사용되는 테스트 장치의 용도에 따라 변화될 수 있다.

포고핀은 전기적인 접점 내지는 연결부위에 해당되므로 가급적 저항이 작은 소재가 사용되는 것이 바람직하며, 알루미늄이나 구리, 은, 백금, 금 등의 전기전도도가 우수한 금속이 사용될 수 있다.

포고핀(100)인 내부가 빈 원통형의 몸체에 몸체 중앙부의 외주면을 커팅 가공한 것이며, 이와 같은 커팅은 작업의 용이성 및 정밀한 가공을 위하여 레이저 가공이 바람직하다. 포고핀(100)의 윗부분(101)은 내부가 비어 있는 단순한 원통으로 일단으로서 표면이 평탄한 형태(101a)일 수 있다. 반면, 포고핀(100)의 아랫부분(102)은 테스트 장치의 PCB 상의 금속 배선과의 접촉 신뢰성을 확보하기 위하여 안으로 경사져 구부러진 형태가 될 수도 있다. 이와 같은 형태에 따라 접촉부(102a)가 상대적으로 큰 면적을 갖게 되고 내부 빈공간(102b)의 면적은 다소 줄어들게 된다.

도 5b는 도 5a의 실시예에 일부 변형을 가한 포고핀(110)으로서 다른 부위는 동일하나 포고핀의 윗부분(101')이 산과 골이 있는 형태를 취하고 있다. 이와 같은 변형은 포고핀에 접촉하는 반도체 소자의 접촉부위, 예를 들어 리드핀이나 볼의 접촉을 더욱 용이하게 하는 역할을 한다. 즉, 테스트시 표면의 평탄도가 일정치 않거나 소자에 따라 리드핀의 높이나 간격이 일정치 않을 때에도 포고핀과의 접촉 불량이 발생하지 않도록 한다.

이와 같은 포고핀의 윗부분(101')의 형태도 몸체 중앙부(105)와 마찬가지로 레이저 가공에 의하여 형성할 수도 있으며, 최초 원통형 포고핀 제조시 일부 끝단이 산과 골의 톱니형으로 형성되도록 할 수도 있을 것이다.

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이와 같이 본 발며에 따른 포고핀은 몸체 중앙부가 나사산과 유사한 스프링 형태를 취하고 있으므로 포고핀을 수용하는 테스트 몸체와의 결합시 별도의 결합수단 없이도 마찰에 의하여 결합 상태를 유지할 수 있다. 그러나 포고핀의 크기가 매우 미세하고 보다 정밀한 테스트가 요구되는 경우에는 포고핀과 포고핀을 수용하는 몸체와의 결합 상태 및 결합된 위치가 고정되어야 할 필요가 있다. 이와 같은 경우에는 다음과 같은 또 다른 변형된 형태의 포고핀이 바람직하다

도 6a는 도 5a의 실시예와 유사하게 원통형의 포고핀(120)의 몸통에 나사산 형태의 스프링 구조가 형성되어 있다. 그러나 중앙부(126)는 스프링 구조로 커팅되어 있는 부분(125a, 125b)과 비교할 때 상대적으로 측방향으로 돌출되어 있는 것을 볼 수 있다. 포고핀의 윗부분(121) 및 아랫부분(122)의 단면을 보인 그림에서는 원통형 몸체(121a 또는 122a) 측면으로 돌출부(126)가 형성되어 있는 모습을 볼 수 있다. 이렇게 돌출되어 있는 부분은 포고핀을 수용하는 테스트 몸체와의 결합 및 위치 고정을 위한 부분에 해당하며, 이에 대해서는 후술하기로 한다.

도 6a에 도시된 실시예는 비록 중앙부(126)위가 측방향으로 돌출되어 있더라도 중앙부 상부(125a) 및 하부(125b)로 스프링 구조가 형성되어 있어, 포고핀의 탄성적 움직임에는 전혀 영향이 없다. 이와 같이 돌출된 형태의 중앙부(126)는 원통형 포고핀의 중앙 부위를 포고핀의 길이방향과 동일하게 눌러서 형성할 수 있을 것이다.

도 6b는 도 6a의 실시예에서와는 달리 포고핀(130)의 중앙부(136)가 중앙부 상부(135a) 및 하부(135b)에 비하여 상대적으로 만입되어 있는 것을 볼 수 있다. 또한, 포고핀의 윗부분(131) 및 아랫부분(132)의 단면을 보인 그림에서는 원통형 몸체(131 또는 132a) 측면이 안으로 들어간 만입부(136)를 확인할 수 있다. 이와 같은 만입부 역시 포고핀과 포고핀을 수용하는 테스트 몸체와의 결합을 견고하게 하는 역할을 하며, 앞서 돌출된 형태의 중앙부(126)와는 달리 포고핀 몸체 안쪽으로 압력을 가하여 만입되도록 형성할 수 있을 것이다.

도 7은 본 발명에 따른 포고핀과 포고핀을 수용하는 테스트 몸체가 결합되어 있는 형태를 예시적으로 나타낸 것이다. 설명의 편의상 도 6a의 실시예에 따른 포고핀(120)과 태스트 몸체간의 결합을 설명한다. 포고핀(120)의 중앙부(126)는 측방향으로 돌출되어 있기 때문에 테스트 몸체(140a, 140b)는 이에 대응하여 일부분이 만입되어 있는 형태(142)를 볼 수 있다. 포고핀(120)은 중앙부(126)가 테스트 몸체의 만입부(142)에 끼워진 채로 고정되어 위치의 변화없이 안정적인 상태를 유지하게 된다. 한편, 중앙부 상부(125a) 및 하부(125b)의 스프링 구조에 의하여 상하로 탄성력을 발휘할 수 있으며, 윗부분(121)은 반도체 소자(미도시)와 접촉하게 되고 아랫부분(122)은 테스트 보드의 금속 배선(미도시)과 접촉하게 된다.

조립의 편의를 위하여 테스트 몸체는 윗몸체(140a)와 아랫몸체(140b)로 구성될 수 있으며, 윗몸체 및 아랫몸체의 결합 또는 다른 별도의 몸체와의 결합을 위하여 나사 결합을 위한 관통홀(150a, 150b)이 형성될 수 있다.

도 7의 실시예는 도 6a의 포고핀을 대상으로 하여 설명하였지만, 도 5a 또는 도 6b의 경우에도 도 7과 유사하거나 변형된 형태의 테스트 몸체와의 결합이 가능할 것이다.

발명의 효과

이상에서 살펴본 바와 같이, 본 발명은 간단한 구조의 포고핀을 제공하여, 테스트시 접점이 감소하고 따라서 테스트 불량이 크게 줄어들게 된다. 뿐만 아니라 포고핀의 제조가 용이하여 테스트 장치의 제조원가를 현저히 낮출 수 있다.

(57) 청구의 범위

청구항 1.

내부가 비어 있는 원통형 금속 몸체와, 상기 몸체의 중앙 외부면의 적어도 일부분에 나사산의 형태로 커팅된 스프링 구조가 일체로 형성되어 있는 것을 특징으로 하는 포고핀.

청구항 2.

제1항에 있어서, 상기 몸체의 일측 끝단은 폭이 좁아져 경사진 형태인 것을 특징으로 하는 포고핀.

청구항 3.

제1항에 있어서, 상기 몸체의 일측 끝단은 산과 골이 형성된 톱니 형태인 것을 특징으로 하는 포고핀.

청구항 4.

제1항에 있어서, 상기 몸체 중앙은 측방향으로 돌출되어 있는 것을 특징으로 하는 포고핀.

청구항 5.

제1항에 있어서, 상기 몸체 중앙은 측방향으로 만입되어 있는 것을 특징으로 하는 포고핀.

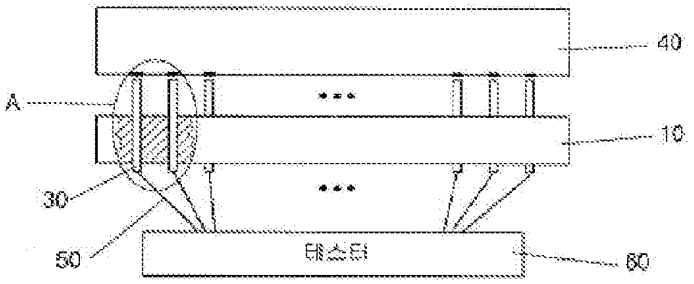
청구항 6.

상부 몸체 및 하부 몸체로 구성되는 테스트 바디와;

상기 상부 몸체와 하부 몸체에 의하여 고정되어 테스트 바디에 삽입되며, 내부가 비어 있는 원통형 금속 몸체와, 상기 몸체의 중앙 외부면의 적어도 일부분에 나사산의 형태로 커팅된 스프링 구조가 일체로 형성되는 포고핀;을 포함하여 구성되는 테스트 장치.

도면

도면1



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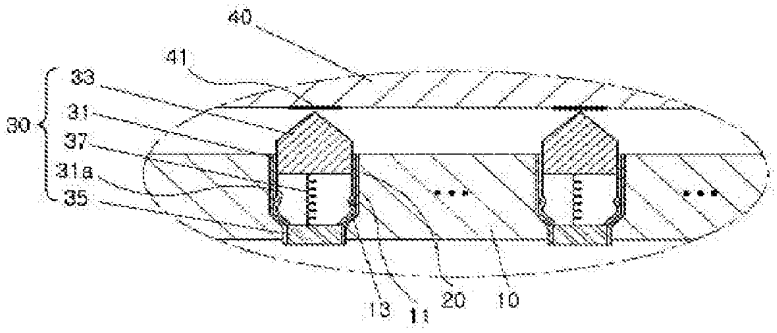
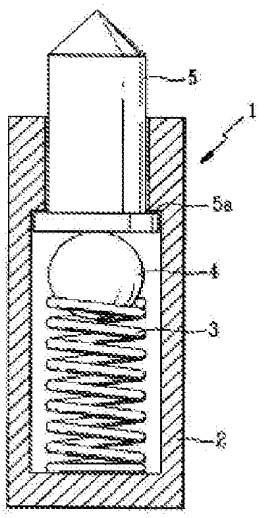
도면2



도면3



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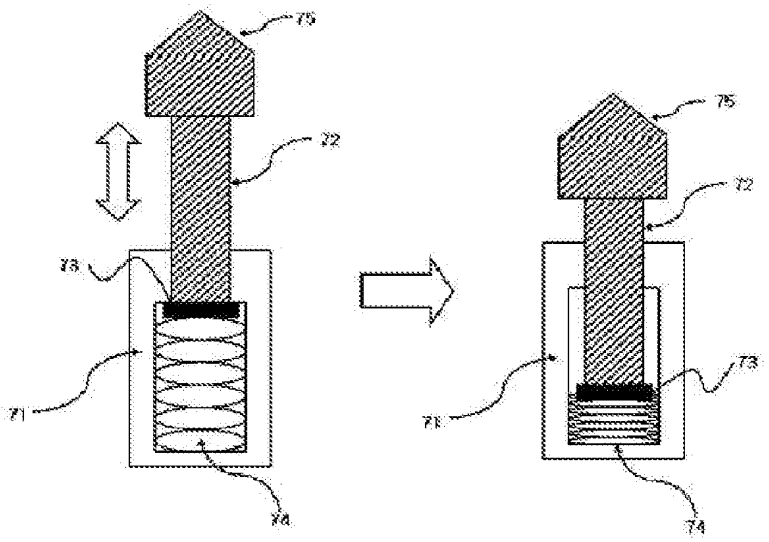
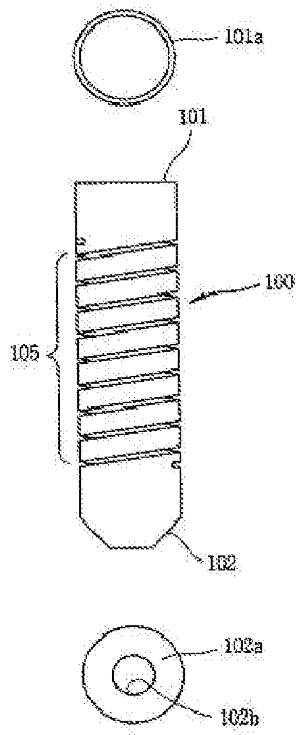
도면4



도면5a



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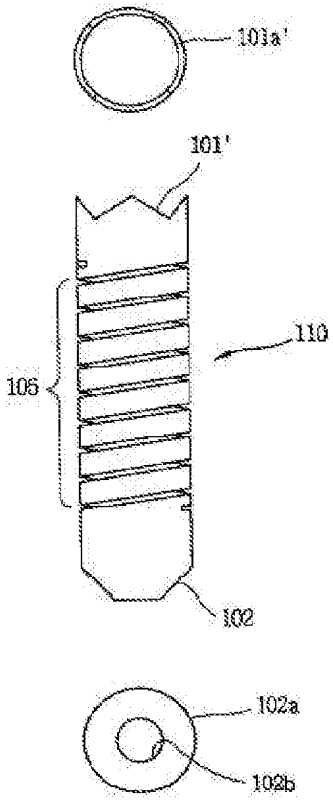
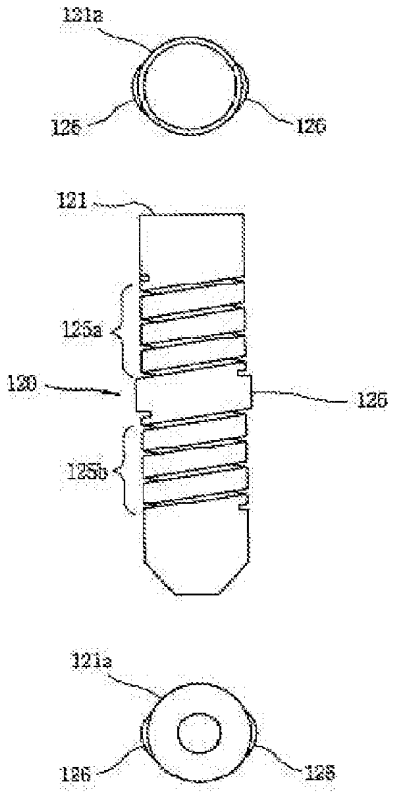
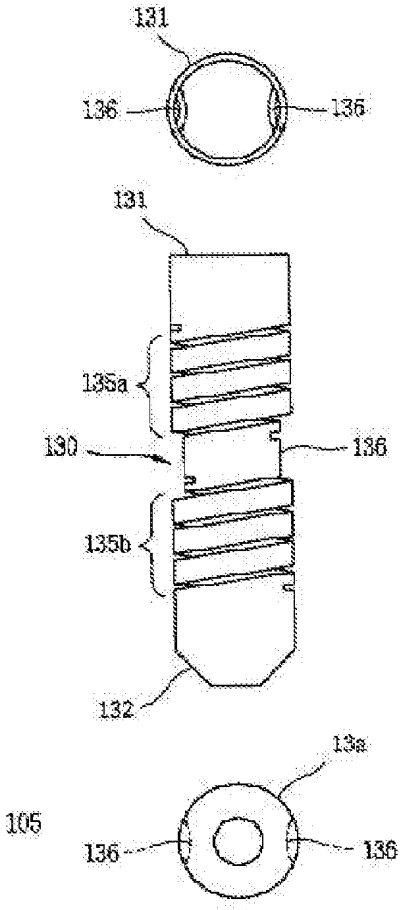
도면5b



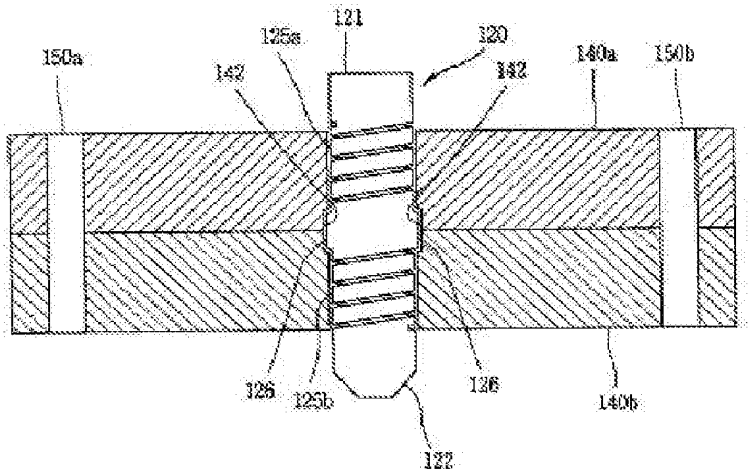
도면6a



도면6b



도면7



(19) 대한민국특허청(KR)
(12) 등록실용신안공보(Y1)

(51) Int. Cl.		(45) 공고일자	2000년03월02일
H01L 21/66		(11) 등록번호	20-0172727
		(24) 등록일자	1999년12월14일
(21) 출원번호	20-1997-0025828	(65) 공개번호	실1999-0012704
(22) 출원일자	1997년09월12일	(43) 공개일자	1999년04월15일
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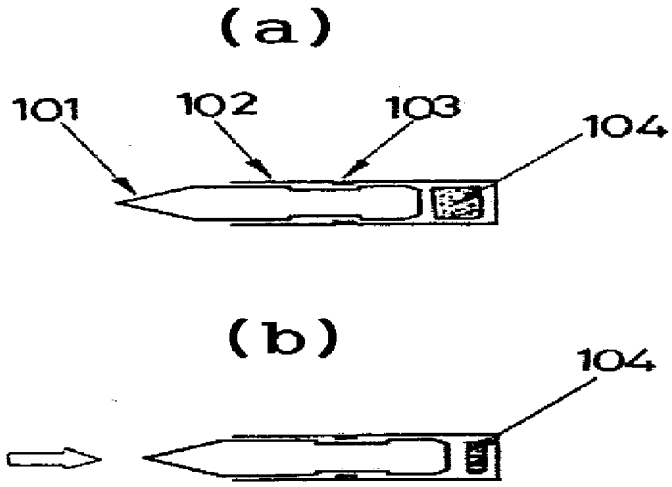
(73) 실용신안권자	현대반도체주식회사, 김영환
	대한민국
	361480
	충청북도 청주시 흥덕구 향정동 1번지
(72) 고안자	김도균
	대한민국
	충청북도 청주시 상당구 율량동 삼성 아파트 102-705
(74) 대리인	양순석
(77) 심사청구	심사관: 오제욱

(54) 출원명 포고 핀

요약

본 고안은 전기적 특성을 전달하고자 할 때 접촉수단으로 사용되는 포고 핀에 관한 것으로 직접 전기적인 접속을 하는 머리부분은 원뿔형태이며 이동하는 폭반큼 허리부분이 가늘게 형성된 핀과 상기 핀을 감싸고 있는 몸통과, 상기 몸통의 내부 중간에 형성되어 상기 핀이 몸통 외부로 이탈하는 것을 방지하는 빠짐방지 홈과, 상기 몸통의 하부에 위치하여 상기 핀을 지지하여 탄성력을 주는 탄성체로 구성되며 상기 탄성체는 도전성 고무를 사용하여 탄성력의 크기를 쉽게 조절할 수 있고 장기 사용에 의한 탄성력 약화를 방지할 수 있다.

대표도



명세서

도면의 간단한 설명

제1도는 종래의 포고 핀 단면도.

제2도는 본 고안의 포고 핀 단면도.

* 도면의 주요부분에 대한 부호의 설명

1,101 : 핀 2,102 : 몸통

3,103 : 핀 빠짐방지 홈 4 : 스프링

104 : 탄성체

고안의 상세한 설명

고안의 목적

고안이 속하는 기술 및 그 분야의 종래기술

본 고안은 전기적 특성을 전달하고자 할때 접촉수단으로 사용되는 포고 핀에 관한 것으로서, 특히 그 작은 크기의 형체를 가지고도 탄성력의 제약을 받지 않는 포고핀에 관한 것이다.

반도체 생산 공정에서 사용되는 모든 장비는 전기적인 신호를 전달하기 위한 수많은 전선을 가지고 있다. 이러한 장비내부의 한 모듈에서 다른 모듈로 신호를 전달하기 이해서는 반드시 전기적인 접속을 필요로 한다. 그 방법중의 하나가 포고 핀을 이용한 접속방법이다. 포고 핀은 전기적인 접속을 필요로 하는 패드형태와 효과적으로 접속 분리할 수 있는 장치이다.

제1도는 종래의 포고 핀 단면도이다.

종래의 포고 핀은 다른 패드형태의 장비와 직접 전기적인 접속을 하는 머리부분은 원뿔형태이며 이동하는 폭반큼 허리부분이 가늘게 형성된 핀(1)과, 상기 핀(1)을 감싸고 있는 몸통(2)과, 상기 몸통(2)의 내부 중간에 형성되어 상기 핀(1)이 몸통(2) 외부로 이탈하는 것을 방지하는 빠짐방지 홈(3)과, 상기 몸통(2)의 하부에 위치하여 상기 핀(1)를 지지하여 탄성력을 주는 스프링(4)으로 구성된다.

상기 종래의 포고 핀은 핀(1)의 머리부분이 다른 장비의 패드부분과 전기적인 접촉을 유지하도록 하기 위하여 스프링(4)이 탄성력을 제공한다.

그러나 좁고 협소한 부분과의 접속을 위하여 포고 핀을 작게 만들거나 핀이 몸통 내부로 밀려들어가는 간격이 작은 경우에 전기적인 접속이 정확히 이루어지려면 스프링의 굵기나 나선의 수를 조절하여 탄성력을 강화시켜야 하며 오래사용시 스프링의 탄설력이 약해지는 문제점을 가진다.

고안이 이루고자 하는 기술적 과제

따라서 본 고안은 상기 문제점을 해결하기 위하여 탄성력을 주는 스프링을 대신하여 도전성 고무를 사용한 포고 핀을 제공하는데 있다.
이하 도면을 참고하여 본 고안을 상세히 설명한다.

고안의 구성 및 작용

제2도는 본 고안에 따른 포고 핀 단면도이다.
본 고안은 포고 핀은 다른 패드형태의 장비와 직접 전기적인 접속을 하는 머리부분은 원뿔형태이며 이동하는 폭반큼 허리부분이 가늘게 형성된 핀(101)과, 상기 핀(101)을 감싸고 있는 몸통(102)과, 상기 몸통(102)의 내부 중간에 형성되어 상기 핀(101)이 몸통(102) 외부로 이탈하는 것을 방지하는 빠짐방지 홈(103)과, 상기 몸통(102)의 하부에 위치하여 상기 핀(101)를 지지하여 탄성력을 주는 탄성체(104)로 구성된다.
상기 본 고안의 포고 핀은 핀(101)의 머리부분이 다른 장비의 패드부분과 전기적인 접촉을 유지하도록 하기 위하여 탄성체(104)를 전도성 고무를 사용한다.

고안의 효과

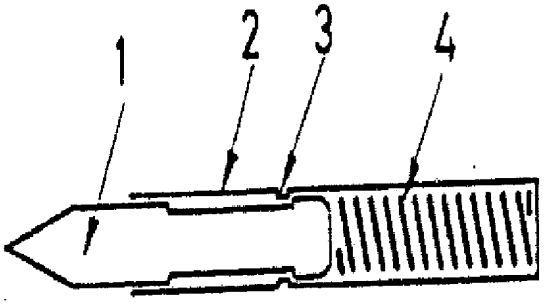
따라서 본 고안의 포고 핀은 탄성력의 크기를 고분자화합물인 고무 등을 특성에 따라 선택하여 탄성체로 사용함으로서 탄성력의 크기를 쉽게 조절할 수 있고 장기 사용에 의한 탄성력 약화를 방지할 수 있다.

(57) 청구의 범위

청구항 1.
전기적 특성을 전달하고자 할 때 접촉수단으로 사용되는 장치중 직접 전기적인 접속을 하는 머리부분은 원뿔형태이며 이동하는 폭반큼 허리부분이 가늘게 형성된 핀과 상기 핀을 감싸고 있는 몸통과, 상기 몸통의 내부 중간에 형성되어 상기 핀이 몸통 외부로 이탈하는 것을 방지하는 빠짐방지 홈과, 상기 몸통의 하부에 위치하여 상기 핀을 지지하여 탄성력을 주는 탄성체로 구성된 포고 핀에 있어서,
상기 탄성체가 전도성 고무로 형성된 것이 특징인 포고 핀.

도면

도면 1a



도면 1b

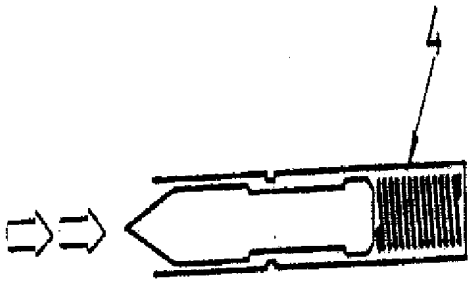


Fig. 2a

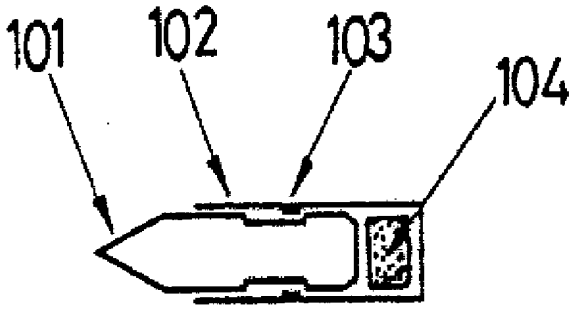
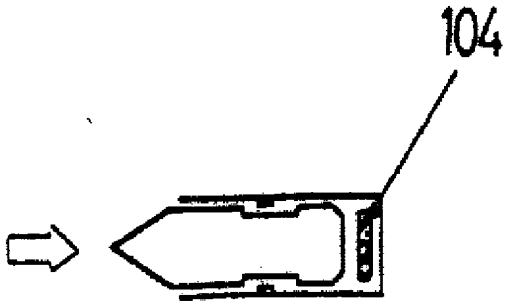


Fig. 2b



(19) 대한민국특허청(KR)
(12) 등록실용신안공보(Y1)

(51) Int. Cl.[7] H01L 21/66		(45) 공고일자	2000년04월15일
		(11) 등록번호	20-0176242
		(24) 등록일자	2000년01월14일
(21) 출원번호	20-1997-0040070	(65) 공개번호	실1999-0027477
(22) 출원일자	1997년12월23일	(43) 공개일자	1999년07월15일
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(73) 실용신안권자	현대전자산업주식회사, 김영환 대한민국 467701 경기도 이천시 부발읍 아미리 산 136-1
(72) 고안자	전경철 대한민국 467-080 경기도 이천시 대월면 부발읍 신하리 481-1 삼익아파트 103-152 윤용식 대한민국 467-000 경기도 이천시 안흥동 144-20 이천주공아파트 105동 1003호 홍정일 대한민국 467-010 경기도 이천시 이천우체국사서함 1010 현우관 1307 최순주 대한민국 467-080 경기도 이천시 대월면 사동4리 386-72 현대산업개발아파트 501동 903호
(74) 대리인	김동진 정은섭 허진석
(77) 심사청구	심사관: 오제욱

(54) 출원명 **포고핀의 리셉터클 접촉구조**

요약

본 고안은 포고핀과 리셉터클의 접속구조에 관한 것으로서, 특히, 포고핀의 몸체 후단으로 연이어서 형성된 리셉터클접촉부와; 상기 리셉터클접촉부의 외주면에 반구형상으로 환형으로 함몰 형성된 탄성홈부와; 상기 리셉터클접촉부에 끼움공을 통해 삽입되고, 탄성홈부에 탄성적으로 압입되는 탄성고정부가 형성된 리셉터클로 구성된 포고핀의 리셉터클 접촉구조인 바, 탄성홈부에 탄성적으로 밀착 삽입되는 탄성고정부를 리셉터클의 내측면에 형성하여 리셉터클을 통하여 포고핀으로 전달되는 전기적신호가 노이즈 없이 정확하게 전달되도록 하는 매우 유용하고 효과적인 고안이다.

대표도

도5

명세서

도면의 간단한 설명

도 1은 종래의 일반적인 포고핀과 그에 삽설되는 리셉터클의 분리 상태를 보인 도면.
도 2는 종래의 포고핀이 리셉터클에 삽설된 상태를 보이는 도면.
도 3은 본 고안에 따른 포고핀의 외관을 보인 사시도.
도 4는 본 고안에 따른 리셉터클을 보인 사시도.
도 5는 본 고안에 따른 포고핀이 리셉터클에 결합된 상태를 보인 도면.
-도면의 주요부분에 대한 부호의 설명-
20 : 포고핀 30 : 몸체

32 : 걸림홈부　　40 : 이동체
42 : 탐침부　　44 : 걸림턱
50 : 스프링　　60 : 리셉터클접촉부
62 : 탄성홈부　　64 : 가이드부
70 : 리셉터클　　72 : 끼움공
74 : 탄성고정부

고안의 상세한 설명

고안의 목적

고안이 속하는 기술 및 그 분야의 종래기술

본 고안은 모듈의 탭에 접속되는 포고핀에 관한 것으로, 특히, 탄성홈부에 탄성적으로 밀착 삽입되는 탄성고정부를 리셉터클의 내측면에 형성하여 리셉터클을 통하여 포고핀으로 전달되는 전기적신호가 노이즈 없이 정확하게 전달되도록 하는 포고핀의 리셉터클 접촉구조에 관한 것이다.

일반적으로, 모듈(module)이라는 것은 하나의 기능을 가진 소자의 집합 또는 프로그램의 집합을 일컫는 말로서, 컴퓨터와 같이 여러 가지 처리기능을 갖는 첨단 전자기기에 내장되어 여러 가지 언어프로세스 등을 처리하는 기능을 가지며, 인쇄회로기판(PCB)상에 여러 가지 반도체소자 등의 패키지장치가 탑재되어 다수의 접속핀에 의해 패널 등에 연결되어 설치된다.

이와 같이, 모듈을 제작한 후에 전기적특성이 제대로 되어 있는 지 여부를 판정하기 위하여 테스트시스템을 이용하여 모듈의 접속부분에 형성되고, 약간 돌출된 탭(Tab)에 포고핀(Pogo pin)이라는 탐침수단을 사용하여 테스트시스템과 모듈의 측정부위를 상호 도전된 상태로 연결하여 모듈의 전기적 특성을 측정하도록 하였다.

한편, 도 1은 종래의 일반적인 포고핀과 그에 삽설되는 리셉터클의 분리 상태를 보인 도면이고, 도 2는 종래의 포고핀이 리셉터클에 삽설된 상태를 보이는 도면으로서, 상기 포고핀(1)은 원통형상으로 일측이 개방되고, 내부에 슬라이딩홈부(7)가 형성되고, 이 슬라이딩홈부(7)에 연이어서 일정깊이 함몰된 걸림홈부(3)가 일정깊이 환상으로 형성된 몸체(2)와, 이 몸체(2)의 걸림홈부(3)에 걸려지는 걸림턱(6)이 형성되고, 끝단부에 모듈의 탭에 접촉되는 탐침부(5)를 구비하여 슬라이딩홈부(7)를 따라 전,후방으로 이동하는 이동체(4)와, 이 이동체(4)의 걸림턱(6)의 배면에 접촉되고, 슬라이딩홈부(7)내에 삽설되어 이동체(4)에 탄성력을 가하는 스프링(8)으로 구성된다.

이와 같이 구성된 상기 포고핀(1)은 테스트 시스템의 회로기판에 실리콘등에 의하여 고정되고, 전기적으로 접속되는 리셉터클(10)의 삽입홈(12)에 삽설되어 리셉터클(10)을 통하여 몸체(2)를 거쳐 포고핀(1)의 탐침부(5)로 도전되고, 이 탐침부(5)가 모듈의 탭에 접속됨으로써 테스터시스템이 모듈에 전기적으로 접속되는 것이다.

이와 같이, 실리콘에 의하여 고정된 리셉터클(10)의 삽입홈(12)내에 포고핀(1)의 몸체(2)를 빈번하게 삽입하여 접촉을 시키면서 모듈의 전기적 특성을 테스트시스템을 사용하여 측정하게 된다.

그런데, 상기한 바와 같이, 리셉터클(10)의 형상은 길이가 비교적 긴 원통형성으로서 내부가 밋밋한 형상으로 형성되어 있으며, 이 리셉터클(10)의 삽입홈(12)에 끼워지는 포고핀(1)의 몸체(2)부분 역시 외주면이 미끈한 형상으로 형성됨으로 인하여 포고핀(1)을 빈번하게 리셉터클(10)의 삽입홈(12)에 착탈되는 과정을 반복하다가 보면, 삽입홈(12)의 벽면과 몸체(2)의 외주면에 마모가 발생되어 접촉이 불량해져서 노이즈의 발생이 심해지고, 심한 경우에는 마모된 부분으로 이물질이 삽입되어져 전기적특성이 약화되어지는 문제점을 지니고 있었다.

고안이 이루고자 하는 기술적 과제

본 고안은 이러한 점을 감안하여 안출한 것으로서, 포고핀의 몸체 후방에 리셉터클이 접촉되는 리셉터클접촉부를 형성하고, 이 리셉터클접촉부에 반구홈 형상으로 일정깊이 함몰된 탄성홈부를 환형으로 형성하고, 이 탄성홈부에 탄성적으로 밀착 삽입되는 탄성고정부를 리셉터클의 내측면에 형성하여 리셉터클을 통하여 포고핀으로 전달되는 전기적신호가 노이즈 없이 정확하게 전달되도록 하는 것이 목적이다.

고안의 구성 및 작용

이러한 목적은 포고핀의 몸체 후단으로 연이어서 형성된 리셉터클접촉부와; 상기 리셉터클접촉부의 외주면에 반구형상으로 환형으로 함몰 형성된 탄성홈부와; 상기 리셉터클접촉부에 끼움공을 통해 삽입되고, 탄성홈부에 탄성적으로 압입되는 탄성고정부가 형성된 리셉터클로 구성된 포고핀의 리셉터클 접촉구조를 제공함으로써 달성된다.

이하, 첨부한 도면에 의거하여 본 고안의 구성에 대하여 상세히 설명한다.

우선, 도 3 내지 도 5에 도시된 바와 같이, 본 고안인 포고핀의 리셉터클 접촉구조의 구성을 살펴 보면, 포고핀(20)의 몸체(30) 후단으로 연이어서 형성된 리셉터클접촉부(60)와; 상기 리셉터클접촉부(60)의 외주면에 반구형상으로 환상으로 함몰 형성된 탄성홈부(62)와; 상기 리셉터클접촉부(60)에 끼움공(72)을 통해 삽입되고, 탄성홈부(62)에 탄성적으로 압입되는 탄성고정부(74)가 형성된 리셉터클(70)로 구성된다.

그리고, 상기 리셉터클접촉부(60)의 후방으로 작은 직경을 끝단부가 뾰족하게 돌출된 가이드부(64)가 형성되어 포고핀(20)이 리셉터클(70)의 끼움공(72)에 삽입될 때 안내역할을 하게 된다.

또한, 상기 포고핀(20)의 리셉터클접촉부(60)는 가이드부(64)에서 몸체(30)로 갈수록 직경이 약간 커지게 형성하여 리셉터클(70)의 끼움공(72)이 리셉터클접촉부(60)에 끼워질수록 견고하게 고정되도록 하므로 양자의 외측면과 내측면에 마모가 발생되더라도 결합력이 그대로 유지되어지게 구성하도록 한다.

이하, 본 고안의 작용을 개략적으로 살펴보도록 한다.

본고안의 실시예의 사용 상태를 살펴 보면, 먼저 도 5에 도시된 바와 같이, 먼저, 본 고안에 따른 리셉터클(70)을 테스터시스템의 회로기판에

실리콘등의 재료를 사용하여 고정 설치시키고, 이와 같이 설치된 리셉터클(70)에 포고핀(20)을 고정하여 모듈의 탭에 탐침부(42)를 접속시켜야 한다.
이와 같이, 포고핀(20)의 탐침부(42)를 모듈의 탭에 접속시키기 위하여 포고핀(20)의 가이드부(64)를 리셉터클(70)의 끼움공(72)으로 끼워서 리셉터클접촉부(60)에 끼움공(72)을 가압하여 강하게 밀어 넣게 되면, 탄성고정부(74)가 리셉터클접촉부(60)의 탄성홈부(62)에 압입되어 고정되면서 접속이 이루어지게 된다.
이러한 접속이 이루어진 후에 포고핀(20)을 이동시켜 이동체(40)의 탐침부(42)를 모듈의 탭에 접속시켜 테스트시스템과 모듈을 전기적으로 통전시키고, 이동체(40)의 걸림턱(44)은 몸체(30)의 걸림홈부(32)에 걸려져서 이탈이 방지된 상태로 슬라이딩홈부(34)를 따라 이동하고 스프링(50)의 탄성력을 받게 된다.
이와 같이, 리셉터클(70)의 탄성고정부(74)가 리셉터클접촉부(60)에 탄성적으로 가압고정된 상태로 있으므로 빈번하게 포고핀(20)이 리셉터클(70)에 착탈되더라도 접속성이 그대로 유지되므로 노이즈의 발생을 방지하게 되며, 이물질이 리셉터클(70)의 끼움공(72)으로 유입되더라도 양자의 접속성을 방해하지는 않게 된다.

고안의 효과

따라서, 상기한 바와 같이 본 고안에 따른 포고핀의 리셉터클 접촉구조를 사용하게 되면, 포고핀의 몸체 후방에 리셉터클이 접촉되는 리셉터클접촉부를 형성하고, 이 리셉터클접촉부에 반구홈 형상으로 일정깊이 함몰된 탄성홈부를 환형으로 형성하고, 이 탄성홈부에 탄성적으로 밀착 삽입되는 탄성고정부를 리셉터클의 내측면에 형성하여 리셉터클과 포고핀이 빈번하게 접속되어 마모가 발생되더라도 리셉터클을 통하여 포고핀으로 전달되는 전기적신호가 노이즈 없이 정확하게 전달되도록 하는 매우 유용하고 효과적인 고안이다.

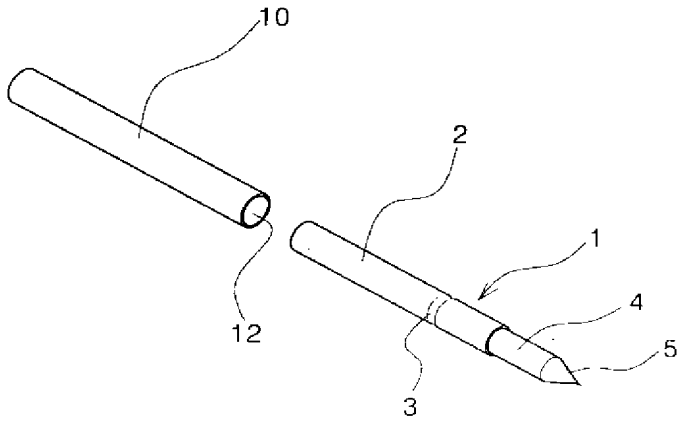
(57) 청구의 범위

청구항 1.
포고핀의 몸체 후단으로 연이어서 형성된 리셉터클접촉부와;
상기 리셉터클접촉부의 외주면에 반구형상으로 환형으로 함몰 형성된 탄성홈부와;
상기 리셉터클접촉부에 끼움공을 통해 삽입되고, 탄성홈부에 탄성적으로 압입되는 탄성고정부가 형성된 리셉터클로 구성된 것을 특징으로 하는 포고핀의 리셉터클 접촉구조.

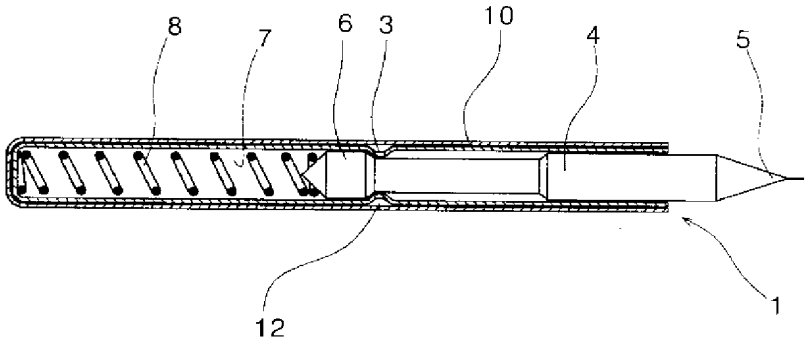
청구항 2.
제 1 항에 있어서, 상기 리셉터클접촉부의 후방으로 작은 직경으로 끝단부가 뾰족하게 돌출된 가이드부가 형성된 것을 특징으로 하는 포고핀의 리셉터클 접촉구조.

도면

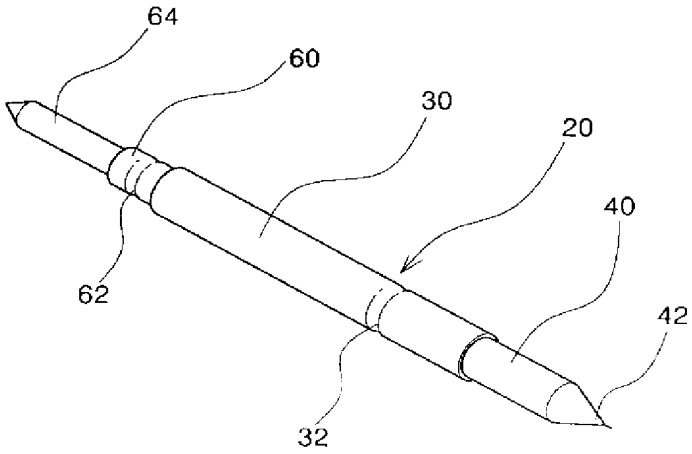
도면 1



도면 2



도면 3



도면 4

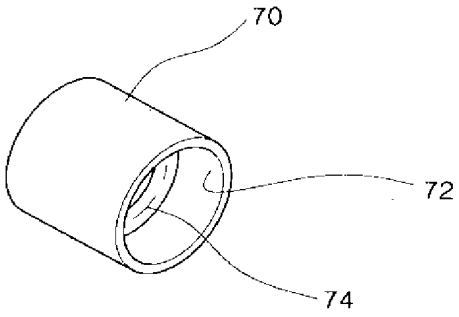
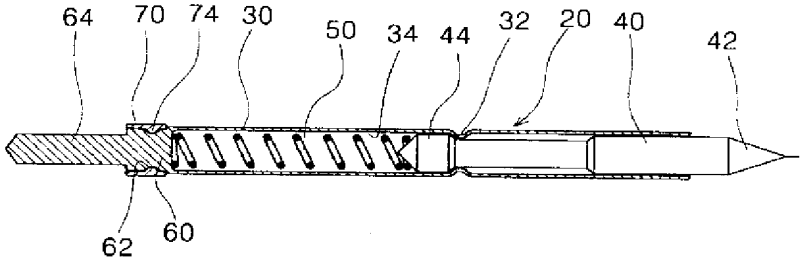


FIG. 5



(19) 대한민국특허청(KR)
(12) 등록실용신안공보(Y1)

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(73) 실용신안권자	현대반도체주식회사, 김영환
	대한민국
	361480
	충청북도 청주시 흥덕구 향정동 1번지
(72) 고안자	이세용
	대한민국
	361-010
	충청북도 청주시 흥덕구 수곡동 697
(74) 대리인	양순석
	한윤근
(77) 심사청구	심사관: 조현동

(54) 출원명 포고 핀

요약

본 고안은 포고핀이 포고핀 몸통내부에서 탄지되도록 상기 포고핀 몸통내부에 에어 또는 유체를 충진하여 포고핀의 접속시 접속 충격이 향상되고 장시간 사용시에도 균일한 탄성력을 유지하는 포고 핀에 관한 것으로 종래의 스프링이 내재된 포고핀은 장시간 사용할 때 스프링의 탄성력이 저하됨에 따라 접속유지력도 저하되고 이러한 탄성력의 변화로 인하여 포고핀 몸통 안에서 내부핀의 이동이 원활치 않아 상호 마찰되므로써 수명이 짧아지는 문제점이 있었던바 본 고안은 포고핀 몸통과 내부핀 사이에 개재되어 내부핀을 탄지하는 완충재로 에어 또는 유체를 사용하여 균일한 탄성력을 유지하므로써 접속시 충격이 완화되는 것은 물론 수명이 연장되는 잇점이 있는 포고핀이다.

대표도

도2a

명세서

도면의 간단한 설명

도 1a와 도 1b는 종래 포고 핀의 작동 전과 후의 상태를 개략적으로 도시한 사용상태도이고,

도 2a와 도 2b는 본 고안의 포고 핀의 작동 전과 후의 상태를 개략적으로 도시한 사용상태도이다.

* 도면의 주요 부분에 대한 부호의 설명 *

고안의 상세한 설명

고안의 목적

고안이 속하는 기술 및 그 분야의 종래기술

본 고안은 포고 핀(Pogo pin)에 관한 것으로 더욱 상세하게는 포고핀이 포고핀 몸통내부에서 탄지되도록 상기 포고핀 몸통내부에 에어 또는 유체를 충진하여 포고핀의 접속시 접속 충격이 향상되고 장시간 사용시에도 균일한 탄성력을 유지하는 포고 핀에 관한 것이다.

일반적으로 반도체 생산 공정에서 사용되는 모든 장비는 전기적인 신호를 전달하기 위한 수많은 전선을 가지고 있다. 이러한 장비 내부의 일측 모듈에서 타측 모듈로 신호를 전달하기 위해서는 반드시 전기적인 접속을 필요로한다.

이와같이 각 모듈을 전기적으로 접속하는 방법중의 하나가 포고 핀을 이용한 접속방법이다. 상기 포고 핀은 전기적인 접속을 필요로 하는 패드형태와 상호 효과적으로 접속 분리 할 수 있는 장치이다.

도 1a와 도 1b는 종래 포고 핀의 작동상태를 도시한 사용상태도로써 다른 패드형태의 장비와 상호 전기적인 접속을 하며 끝단에 요철(5)이 돌출된 접속패드부(3)를 일측단에 형성하는 내부핀(1)과, 상기 내부핀(1)을 감싸고 있는 포고핀 몸통(7)과, 상기 포고핀 몸통(7)과 내부핀(1) 사이에 개재되어 상기 내부핀(1)을 지지하는 스프링(9)과, 상기 내부핀 끝단이 상호 맞물려 포고핀 몸통에서의 이탈을 방지하는 걸림턱(11)으로 구성된다.

이러한 종래의 포고 핀은 접속하고자 하는 면에 접속패드부(3)를 밀착하여 일정한 힘으로 압착하면 포고핀 몸통(7)에 내설된 스프링(9)이

내부핀(1)을 가압하므로써 접속패드부(3)에 일정한 힘이 작용하여 상호 접속관계가 유지된다.
그러나, 종래의 스프링이 내재된 포고핀은 장시간 사용할 때 스프링의 탄성력이 저하됨에 따라 접속유지력도 저하되고 이러한 탄성력의 변화로 인하여 포고핀 몸통 안에서 내부핀의 이동이 원활치 않아 상호 마찰되므로써 수명이 짧아지는 문제점이 있다.

고안이 이루고자 하는 기술적 과제

본 고안의 목적은 포고핀 몸통과 내부핀 사이에 개재되어 내부핀을 탄지하는 완충재로 에어 또는 유체를 사용하여 균일한 텐션력을 유지하는 포고핀을 제공하는 데 있다.
따라서, 본 고안은 상기의 목적을 달성하고자, 다른 패드형태의 장비와 상호 전기적인 접속을 하는 접속패드부를 일측단에 형성하는 내부핀과, 상기 내부핀을 감싸고 있으며 끝단에 걸림턱이 내측으로 돌출된 포고핀 몸통과, 상기 포고핀 몸통과 내부핀 사이에 개재되어 상기 내부핀을 지지하는 완충재와, 상기 내부핀이 포고핀 몸통에 삽입되는 끝단 외주연에 형성되는 탄성재질로 이루어진 밀폐링으로 구성된다.

고안의 구성 및 작용

이하, 첨부된 도면을 참조하여 본 고안을 설명하면 다음과 같다.
도 2a와 도 2b는 본 고안의 포고 핀의 작동상태를 도시한 사용상태도이다.
접속하고자 하는 면과 상호 전기적으로 접속되는 접속패드부(103)가 일측단에 일체로 형성된 내부핀(101)과, 상기 내부핀(101)의 일단이 삽입되어 내주연에서 안내되는 포고핀 몸통(107)으로 이루어진다.
상기 접속패드부(103)의 끝단에는 요철(105)이 돌설되는 것이 바람직하다.
이때, 상기 포고핀 몸통(107)과 내부핀(101)이 상호 연결되는 사이에는 에어 또는 유체로 충진된 완충재(109)가 형성된다.
상기 내부핀(101)이 포고핀 몸통(107)에 삽입되는 일측단에는 탄성재질로 이루어진 밀폐링(113)이 일체로 형성된다.
이러한 밀폐링(113)은 내부핀(101)이 상기 포고핀 몸통(107) 안쪽에서 이동할 때 포고핀 몸통(107) 내측면과 내부핀(101) 사이에 형성되는 틈새를 밀폐하여 상기 완충재(109)가 외부로 누출되는 것을 방지한다.
또한 상기 밀폐링(113)은 포고핀 몸통(107)의 끝단에서 내측으로 절곡되어 형성된 걸림턱(111)과 맞물려 소정 힘 이하에서는 내부핀(101)이 포고핀 몸통(107)에서 이탈되지 않도록 한다.
본 고안의 포고 핀 작동과정을 알아보면 다음과 같다.
도면을 참조하면 다른 패드형태의 장비와 상호 전기적인 접속을 하기 위해서 접속하고자 하는 면에 포고 핀의 접속패드부(103)를 접촉한다.
이때 접속면의 상태에 따라 상기 접속패드부(103)의 끝단이 평평하거나 또는 요철(105)이 있는 접속패드부를 갖는 포고핀 중 적당한 것을 선택하여 사용한다.
이러한 상태에서 일정한 힘으로 포고핀 몸통(107)을 가압하면 포고핀 몸통(107)의 내측으로 내부핀(101)이 안내되면서 포고핀 몸통(107)과 내부핀(101) 사이에 개재된 완충재(109)에 의하여 내부핀(101)이 탄지되며 이 순간에 상기 탄지력이 접촉면방향으로 내부핀(101)을 가압하므로써 포고 핀이 접속된다.
이때 상기 포고핀 몸통(107)과 내부핀(101) 사이에 개재된 완충재(109)는 에어 또는 유체와 같이 밀도가 전체적으로 균일한 동시에 일정한 탄성력을 갖는 물체로 이루어져 접속시 접촉충격을 완화하는 동시에 균일한 탄성력이 작용하여 외부의 충격이 가해져도 접속면과 접속패드부(103)간의 접속력이 유지된다.

고안의 효과

상기에서 상술된 바와 같이, 본 고안은 포고핀 몸통과 내부핀 사이에 개재되어 내부핀을 탄지하는 완충재로 에어 또는 유체를 사용하여 균일한 탄성력을 유지하므로써 접속시 충격이 완화되는 것은 물론 수명이 연장되는 잇점이 있다.

(57) 청구의 범위

청구항 1.
다른 패드형태의 장비와 상호 전기적인 접속을 하는 접속패드부가 일측단에 형성된 내부핀과;
상기 내부핀을 감싸고 있으며 끝단에 상기 내부핀의 이탈을 방지하는 걸림턱이 내측으로 돌출된 포고핀 몸통과;
상기 포고핀 몸통과 내부핀 사이에 개재되며 균일한 밀도를 갖는 에어 또는 유체로 이루어져 상기 내부핀을 탄지하는 완충재와;
상기 내부핀이 포고핀 몸통에 삽입되는 끝단 외주연에 형성되어 상기 완충재의 누출을 방지하는 탄성재질로 이루어진 밀폐링으로 구성되는 것을 특징으로 하는 포고핀.

도면

Fig. 1a

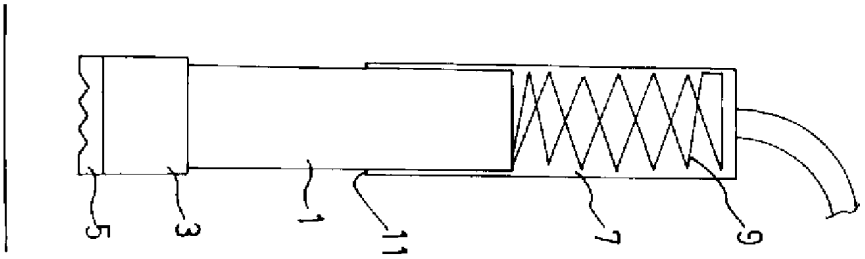


Fig. 1b

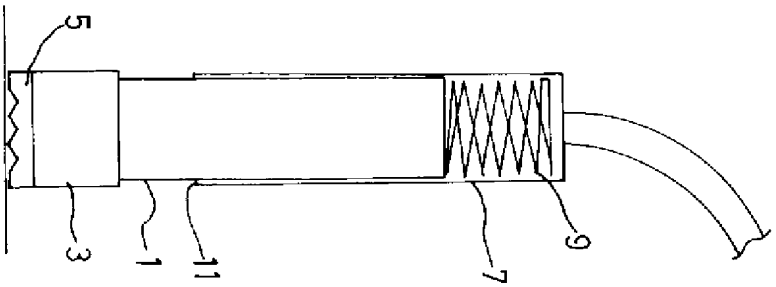


Fig. 2a

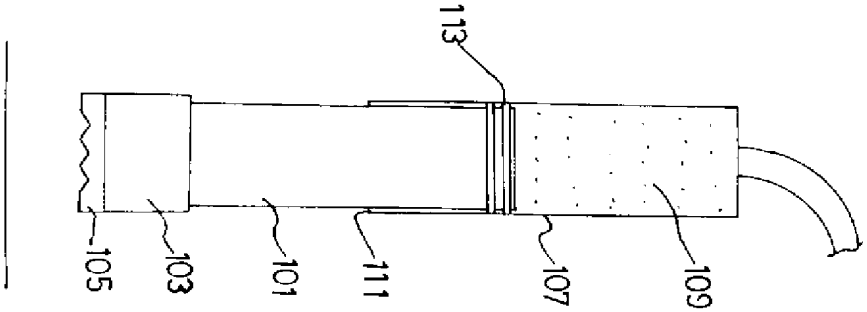
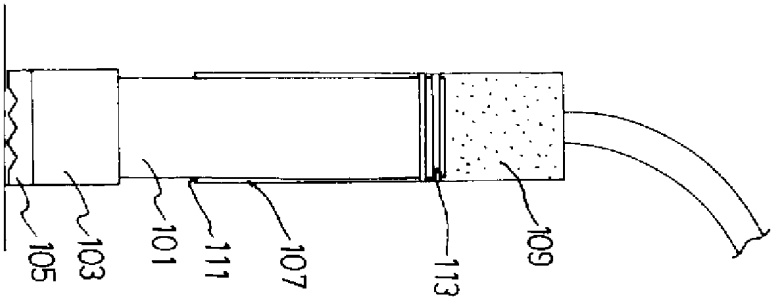


Fig. 2b



(19) 대한민국특허청(KR)
(12) 등록실용신안공보(Y1)

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(73) 실용신안권자 동부전자 주식회사
대한민국
135-937
서울 강남구 역삼1동 838
(72) 고안자 정일석
대한민국
361-260
충청북도청주시흥덕구가경동덕일한마음아파트104-607
(74) 대리인 김영철
김 순 영
이준서

(77) 심사청구 심사관: 여인홍
기술평가청구: 없음

(54) 출원명 포고핀

요약

본 고안은 포고핀(Pogo Pin)을 개시한다. 본 고안의 포고핀은 원통 형상의 하우징 내에 스프링이 배치되고, 상기 스프링을 사이에 두고 상기 하우징의 일측에 스프링 지지부가 배치되고, 상기 하우징의 타측에 접촉부가 배치되도록 구성된다. 또한, 상기 접촉부가 상기 하우징의 내경에 해당하는 직경을 가지며 상기 스프링에 접하는 원통부와, 상기 원통부의 상부면 중앙부에 일체로 돌출하는 선단부로 구성된다.

따라서, 상기 포고핀이 블록의 포고핀 케이스 내에 삽입, 설치된 후 더트 보드의 교체나 수리시에 작업상의 실수로 절단되더라도 상기 접촉부의 선단부만이 절단된다. 이때, 상기 접촉부의 원통부는 상기 포고핀 케이스의 상측부 보다 높게 위치한다. 따라서, 작업자가 상기 절단된 포고핀을 상기 포고핀 케이스로부터 용이하게 인출할 수가 있다.

대표도

도3

명세서

도면의 간단한 설명

도 1은 일반적인 보드간의 인터페이스를 위한 포고핀을 적용한 블록을 나타낸 구성도.

도 2는 종래의 포고핀을 나타낸 확대 단면도.

도 3은 본 고안에 의한 포고핀을 나타낸 확대 단면도.

고안의 상세한 설명

고안의 목적

고안이 속하는 기술 및 그 분야의 종래기술

본 고안은 포고핀(Pogo Pin)에 관한 것으로, 더욱 상세하게는 접촉부가 일부 절단되더라도 포고핀 케이스의 외부로 용이하게 인출할 수 있도록 한 포고핀에 관한 것이다.

일반적으로 웨이퍼 레벨의 제조공정이 완료된 웨이퍼 상의 각 칩들은 패키징공정을 수행하기 전에 EDS(Electrical Die Sorting) 공정에서 테스트 설비에 의해 전기적인 특성 검사를 받게 된다. 또한, 패키징공정이 완료된 패키지들도 테스트 설비에 의해 전기적인 특성 검사를 받게 된다. 이는 상기 웨이퍼의 각 칩들이나 패키지들이 반도체장치로서의 특정 기준에 적합하게 제조되었는 지의 여부를 판단하기 위함이다.

최근에 들어, 반도체소자의 고집적화가 진행되면서 포고핀(Pogo Pin)이라는 탐침이 널리 사용되고 있다. 상기 포고핀을 적용한 블록은 테스터와 더트(Device Under Testing: DUT) 보드(또는 테스트 보드)를 전기적으로 접속한다.

종래에는 도 1 및 도 2에 도시된 바와 같이, 블록(10)에 원형 형상의 포고핀 안착 홀들(11)이 수직 관통하고, 상기 포고핀 안착 홀들(11)

내에 원형 관통 형상의 포고핀 케이스들(20)이 각각 삽입 고정되고, 상기 포고핀 케이스들(20) 내에 포고핀들(30)이 하나씩 대응하여 삽입 설치된다. 더트 보드(40)가 상기 포고핀들(30)에 의해 테스터(50)의 케이블(60)에 전기적으로 연결된다.

여기서, 상기 블럭(10)은 상기 포고핀들(30)을 결합하는 결집판 기능을 하며, 주로 절연성 세라믹 재질로 구성된다. 상기 포고핀 안착 홀들(11)이 상기 블록(10)의 상부면에 일정 간격을 두고 다수개 배치되고, 상기 포고핀 안착 홀들(11)의 하단부의 블럭(10)에는 상기 포고핀 케이스(20)가 더 이상 하강하지 못하고 걸리도록 하기 위한 포고핀 케이스 걸림턱(13)이 형성된다.

또한, 상기 포고핀 케이스 걸림턱(13)을 기준으로 한 상기 포고핀 안착 홀(21)의 상측 부분, 즉 더트 보드(40)를 대향하는 부분의 내경이 상기 포고핀 케이스 걸림턱(13)을 기준으로 한 상기 포고핀 안착 홀(21)의 하측 부분, 상기 테스터(50)의 케이블(60)에 연결된 부분의 내경보다 크다.

그리고, 상기 포고핀들(30)의 하우징(31)이 도전성 재질로 구성되며 상기 포고핀 안착 홀들(11)의 큰 내경과 동일한 외경을 갖는 원형 관통 형상으로 이루어진다. 접촉부(33)가 도전성 재질로 구성되며 상기 하우징(31)의 상측 부분 내에서 상기 하우징(31)에 밀착하며 이동하고 상기 더트 보드(40)의 도전성 패드(41)에 접촉한다. 지지부(35)가 도전성 재질로 구성되고, 상기 포고핀 안착 홀들(11)의 작은 내경과 동일한 외경을 가지며 상기 하우징(31)의 하측 부분에 결합된다. 스프링(37)이 상기 지지부(35)에 의해 지지되고, 상기 접촉부(33)와 상기 지지부(35) 사이에 배치되며 상기 접촉부(33)와 상기 패드(41)의 양호한 접촉을 위해 장력(Tension)을 가하여준다.

또한, 이동 제한부(31a)는 상기 하우징(31)의 일부분이 상기 하우징(31)의 내부 공간을 향해 절곡된 것으로, 상기 접촉부(33)가 상기 지지부(35)를 향해 일정 거리 이상 하향 이동하는 것을 제한하여 준다.

이와 같이 구성되는 종래의 포고핀의 경우, 포고핀 케이스(20)에 포고핀(30)이 삽입, 설치되고, 상기 포고핀(30)의 지지부(35)가 접속수단(도시 안됨)에 의해 테스터(50)의 케이블(60)에 전기적으로 연결된 상태에서 상기 더트 보드(40)가 하향 이동하여 상기 더트 보드(40)의 패드(41)가 포고핀(30)의 접촉부(33)에 대응하여 가압하면, 상기 접촉부(33)의 하단부가 상기 이동 제한부(31a)까지 하향 이동하고 이에 따라 상기 포고핀(30)의 스프링(37)이 탄성적으로 압축되면서 상기 접촉부(33)가 상기 패드(41)에 강하게 접촉하게 된다.

따라서, 웨이퍼의 칩이나 패키지의 전기적인 테스트가 이루어질 수 있다.

고안이 이루고자 하는 기술적 과제

그런데, 반도체소자의 종류가 다양하기 때문에 테스트할 반도체소자가 변경될 때마다 해당 더트 보드를 교체하여야 하는 경우가 빈번하다. 또한, 상기 더트 보트의 수리를 수행하여야 하는 경우가 발생하기도 한다. 이러한 경우에는 작업자가 더트 보드의 교체나 수리를 수행하는 도중에 작업상의 부주의나 실수로 인해 상기 접촉부(33)의 원뿔형 선단부가 절단되는 경우가 발생한다.

이때, 작업자는 상기 파손된 포고핀을 새로운 포고핀으로 교체하기 위해 상기 절단된 포고핀(30)을 직접 손으로 상기 블록(10)의 포고핀 케이스(20)로부터 끄집어내고 있다.

그러나, 상기 포고핀(30)의 접촉부(33)는 원통 부분과, 상기 원통 부분에서부터 직경이 서서히 작아지는 원뿔 부분으로 이루어져 있고, 또한 상기 접촉부(33)의 절단 부위의 표면이 상기 포고핀 케이스(20)의 상측 단부와 거의 동일한 높이를 유지한다.

이로써, 상기 절단된 접촉부(33)가 상기 포고핀 케이스(20)의 상측 외부로 튀어나오지 않기 때문에 작업자가 상기 절단된 포고핀(30)을 직접 손으로 상기 포고핀 케이스(20)로부터 끄집어내기 어렵고, 심한 경우, 작업자가 상기 포고핀 케이스(20)를 뜯어낸 후 별도의 기구를 이용하여 상기 포고핀 케이스(20)의 하측부를 통해 밀어내어야 한다.

결국, 상기 절단된 포고핀의 교체 작업에 시간과 인력이 많이 소요된다. 뿐만 아니라 테스트 설비의 가동율이 저하되므로 테스트 설비의 생산성이 저하된다.

따라서, 본 고안의 목적은 접촉부가 일부 절단되더라도 포고핀 케이스로부터 인출해내는 작업의 편의성을 높이도록 한 포고핀을 제공하는데 있다.

본 고안의 다른 목적은 테스트 설비의 가도율을 높여 생산성을 높이도록 한 포고핀을 제공하는데 있다.

고안의 구성 및 작용

이와 같은 목적을 달성하기 위한 본 고안에 의한 포고핀은

블록의 포고핀 케이스 내에 설치되는 원통 형상의 하우징;

상기 하우징 내에 배치되는 스프링;

상기 스프링을 사이에 두고 상기 하우징 내의 일측 부분에 설치되어, 상기 스프링을 지지하는 스프링 지지부;

상기 하우징의 타측 개구 내에 설치되어 상기 스프링 지지부를 향해 이동 가능한 원통부와, 외부 패드와의 접촉을 하도록 하기 위해 상기 원통부의 상부면 중앙부에 일체로 돌출하는 선단부를 갖는 접촉부; 및

상기 하우징의 내부 공간을 향해 상기 하우징의 소정 부분에 절곡되어, 상기 원통부가 상기 스프링 지지부를 향해 일정 거리 이상 이동하는 것을 제한하는 이동 제한부를 포함하는 것을 특징으로 한다.

바람직하게는, 상기 접촉부의 원통부는 상기 선단부가 눌러지지 않는 평상시에 상기 포고핀 케이스의 상측부보다 높게 위치할 수 있다.

이하, 본 고안에 의한 포고핀을 첨부된 도면을 참조하여 상세히 설명하기로 한다. 종래의 부분과 동일 구성 및 동일 작용의 부분에는 동일 부호를 부여한다.

도 3은 본 고안에 의한 포고핀을 나타낸 확대 단면도이다. 도 3에 도시된 바와 같이, 블록(10)에 원형 형상의 포고핀 안착 홀들(11)이 수직 관통하고, 상기 포고핀 안착 홀들(11) 내에 원형 관통 형상의 포고핀 케이스들(20)이 각각 삽입 고정되고, 상기 포고핀 케이스들(20) 내에 포고핀들(130)이 하나씩 대응하여 삽입 설치된다.

여기서, 상기 블럭(10)은 상기 포고핀들(130)을 결합하는 결집판 기능을 하며, 주로 절연성 세라믹 재질로 구성된다. 상기 포고핀 안착 홀들(11)이 상기 블록(10)의 상부면에 일정 간격을 두고 다수개 배치되고, 상기 포고핀 안착 홀들(11)의 내부 하단부에는 상기 포고핀 케이스(20)가 더 이상 하강하지 못하고 걸리도록 하기 위한 포고핀 케이스 걸림턱(13)이 형성된다.

또한, 상기 포고핀 케이스 걸림턱(13)을 기준으로 한 상기 포고핀 안착 홀(21)의 상측 부분, 즉 더트 보드(40)를 대향하는 부분의 내경이 상기 포고핀 케이스 걸림턱(13)을 기준으로 한 상기 포고핀 안착 홀(21)의 하측 부분, 즉 테스터(도시 안됨)의 케이블에 연결된 부분의 내경보다 크다.

그리고, 상기 포고핀들(130)의 하우징(31)이 도전성 재질로 구성되며 상기 포고핀 안착 홀들(11)의 큰 내경과 동일한 외경을 갖는 원형 관통 형상으로 이루어진다. 접촉부(39)가 도전성 재질로 구성되며 상기 하우징(31)의 상측 부분 내에서 상기 하우징(31)에 밀착하며 이동하고 상기 더트 보드(40)의 도전성 패드(41)에 접촉한다. 지지부(35)가 도전성 재질로 구성되고, 상기 포고핀 안착 홀들(11)의 작은 내경과 동일한 외경을 가지며 상기 하우징(31)의 하측 부분 내에 결합된다. 스프링(37)이 상기 지지부(35)에 의해 지지되고, 상기 접촉부(39)와 상기 지지부(35) 사이에 배치되며 상기 접촉부(39)와 상기 패드(41)의 양호한 접촉을 위해 장력(Tension)을 가하여준다.

또한, 이동 제한부(31a)는 상기 하우징(31)의 내부 공간을 향해 상기 하우징(31)의 일부분이 절곡된 것으로, 상기 접촉부(39)가 상기 지지부(35)를 향해 일정 거리 이상 하향 이동하는 것을 제한하여 준다.

또한, 상기 접촉부(39)는 상기 하우징(31)의 내경과 동일한 직경을 가지며 상기 스프링(37)에 접하는 원통부(39a)와, 상기 원통부(39a)의 상부면의 중앙부로부터 상측으로 일체로 돌출 연결되며 상기 더트 보드(40)의 패드(41)에 접촉하는 선단부(39b)로 구성된다. 여기서, 상기 선단부(39b)가 상기 패드(40)에 의해 눌러지지 않는 평상시에는 상기 원통부(39a)의 상측부가 상기 포고핀 케이스(20)의 상측구보다 높게 위치하는 것이 바람직하다.

따라서, 작업자가 해당 더트 보드의 교체나 수리를 수행할 때, 작업상의 부주의나 실수로 인해 상기 접촉부(39)가 절단되는 경우가 발생하더라도 상기 접촉부(39)의 원통부(39a)가 일부 절단되는 대신에 상기 접촉부(39)의 선단부(39b)가 상기 원통부(39a)의 상부면의 중앙부로부터 절단되어버린다. 이때, 상기 원통부(39a)의 상측부가 상기 포고핀 케이스(20)의 상측으로 돌출하여 위치한다.

따라서, 작업자가 상기 포고핀 케이스(20)의 상측으로 돌출한, 절단된 원통부(39a)를 직접 손으로 잡을 수 있으므로 종래에 비하여 상기 포고핀(130)을 상기 포고핀 케이스(20)로부터 외부로 용이하게 인출할 수가 있다. 그 결과, 상기 포고핀의 교체 작업에 시간과 인력이 적게 소요되므로 포고핀의 교체 작업의 편의성이 높아진다. 뿐만 아니라 테스트 설비의 가동율이 높아지므로 테스트 설비의 생산성이 높아진다.

고안의 효과

이상에서 설명한 바와 같이, 본 고안에 의한 포고핀은 원통 형상의 하우징 내에 스프링이 배치되고, 상기 스프링을 사이에 두고 상기 하우징의 일측에 스프링 지지부가 배치되고, 상기 하우징의 타측에 접촉부가 배치되도록 구성된다. 또한, 상기 접촉부가 상기 하우징의 내경에 해당하는 직경을 가지며 상기 스프링에 접하는 원통부와, 상기 원통부의 상부면 중앙부에 일체로 돌출하는 선단부로 구성된다.

따라서, 상기 포고핀이 블록의 포고핀 케이스 내에 삽입, 설치된 후 더트 보드의 교체나 수리시에 작업상의 실수로 절단되더라도 상기 접촉부의 선단부만이 절단된다. 이때, 상기 접촉부의 원통부는 상기 포고핀 케이스의 상측부보다 높게 위치한다. 따라서, 작업자가 상기 절단된 포고핀을 상기 포고핀 케이스로부터 용이하게 인출할 수가 있다.

한편, 본 고안은 도시된 도면과 상세한 설명에 기술된 내용에 한정하지 않으며 본 고안의 사상을 벗어나지 않는 범위 내에서 다양한 형태의 변형도 가능함은 이 분야에 통상의 지식을 가진 자에게는 자명한 사실이다.

(57) 청구의 범위

청구항 1.

블록의 포고핀 케이스 내에 설치되는 원통 형상의 하우징;

상기 하우징 내에 배치되는 스프링;

상기 스프링을 사이에 두고 상기 하우징 내의 일측 부분에 설치되어, 상기 스프링을 지지하는 스프링 지지부;

상기 하우징의 타측 개구 내에 설치되어 상기 스프링 지지부를 향해 이동 가능한 원통부와, 외부 패드와의 접촉을 하도록 하기 위해 상기 원통부의 상부면 중앙부에 일체로 돌출하는 선단부를 갖는 접촉부; 및

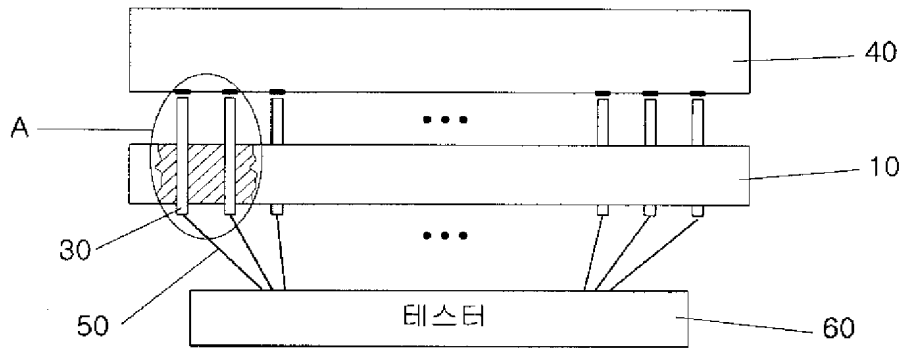
상기 하우징의 내부 공간을 향해 상기 하우징의 소정 부분에 절곡되어, 상기 원통부가 상기 스프링 지지부를 향해 일정 거리 이상 이동하는 것을 제한하는 이동 제한부를 포함하는 포고핀.

청구항 2.

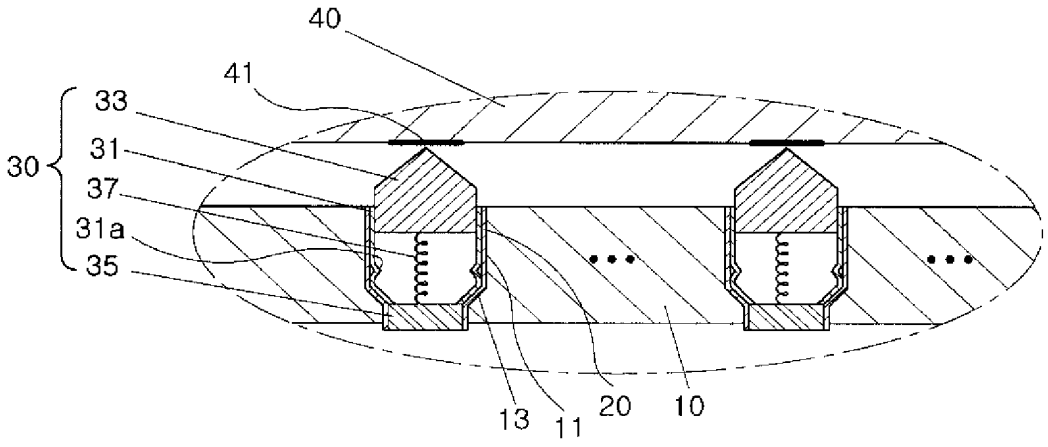
제 1 항에 있어서, 상기 접촉부의 원통부는 상기 선단부가 눌러지지 않는 평상시에 상기 포고핀 케이스의 상측부보다 높게 위치하는 것을 특징으로 하는 포고핀.

도면

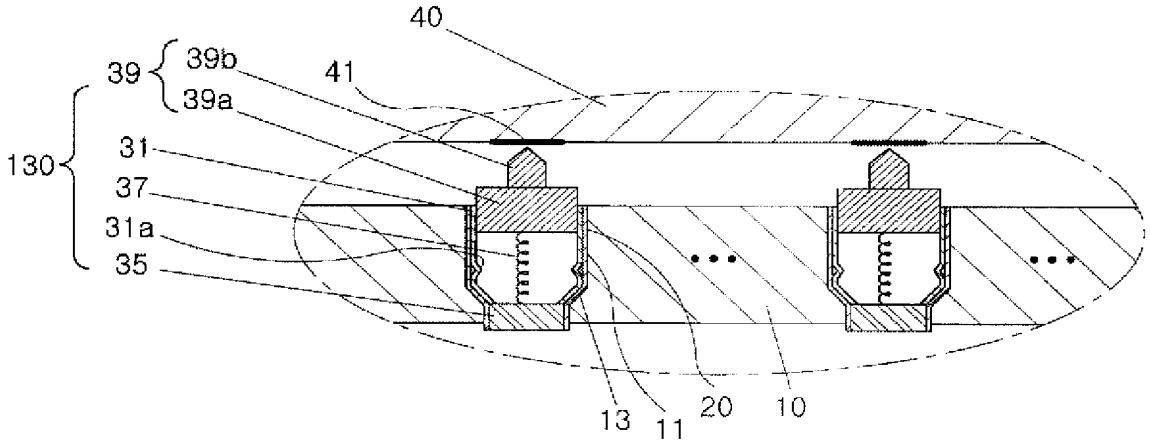
도면 1


40
A
10
30
50
테스터
60

도면 2


40
41
33
31
37
31a
35
30
13
11
20
10

도면 3


40
39
39b
39a
41
130
31
37
31a
35
13
11
20
10

(19) 대한민국특허청(KR)
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(73) 실용신안권자 (주)이큐엔지니어링
대한민국
463-070
경기도 성남시 분당구 야탑동 148 분당테크노파크 B-302
(72) 고안자 심민섭
대한민국
464-708
경기도광주시탄벌동40번지현대아파트102동1304호
(74) 대리인 황이남

(77) 심사청구 심사관: 오제욱
기술평가청구: 없음

(54) 출원명 포고핀

요약

본 고안은 포고핀에 관한 것으로, 보다 상세하게는 분진으로 인한 포고핀의 비작동을 해소하는 포고핀에 관한 것이다.

본 고안은 하부가 개방된 통형인 하우징(172)과,

상기 하우징 내부에 설치된 탄성체(174)와,

상기 탄성체(174)의 하부에 설치되며 상기 하우징(172)의 개방구의 내경보다 긴 직경을 가져 하우징(172) 밖으로 나오지 못하도록 걸쳐져 있는 걸림턱(173)과,

상부가 상기 하우징(172)의 개방구를 통과하여 상기 걸림턱(173)의 하부에 연결되며 PCB에 고정설치된 접촉삽입핀(171)으로 구성된다.

상기와 같이 접촉삽입핀의 상단면을, 접촉삽입핀의 상측에 있는 하우징의 하단면보다 작게 형성시켜 하우징내로 접촉삽입핀이 삽입되도록 함으로써 분진이 접촉삽입핀내로 들어가지 않고 아래로 떨어져서 제품의 수율이 향상되고 또한 포고핀의 수명을 연장되어 제조원가를 줄일수 있는 효과가 발생된다.

대표도

도5

색인어

포고핀, 탄성체

명세서

도면의 간단한 설명

도 1 은 일반적인 보드간의 인터페이스를 위한 포고핀을 적용한 블록을 나타낸 구성도

도 2 는 종래의 고안에 따른 일실시예1으로서, 도1의 A부분을 확대시킨 단면도

도 3 은 종래의 고안에 따른 일실시예2

도 4 는 종래의 고안에 따른 대표도

도 5 는 본 고안에 따른 포고핀의 구성도

※도면의 주요부분에 대한 부호의 설명※

1 : 포고핀 2 : 포고가이드
3 : 스프링 4 : 스프링볼
5 : 포고팁 5a : 걸림턱
10 : 블록 11 : 포고핀 안착홀
13 : 포고핀 케이스 걸림턱
20 : 포고핀 케이스 30 : 포고핀

31 ; 하우징 31a : 이동제한부
33 : 접촉부 35 : 지지부
37 : 탄성체(스프링) 40 : 더트보드 또는 테스트보드
50 : 케이블 60 : 테스터

71, 172 : 하우징 72, 171 : 접촉삽입핀
73, 173 : 걸림턱 74, 174 : 스프링(탄성체)
75, 175 : 접촉부

고안의 상세한 설명

고안의 목적

고안이 속하는 기술 및 그 분야의 종래기술

본 고안은 포고핀에 관한 것으로, 보다 상세하게는 분진으로 인한 포고핀의 비작동을 해소하는 포고핀에 관한 것이다.

일반적으로 웨이퍼 레벨의 제조공정이 완료된 웨이퍼 상의 각 칩들은 패키징공정을 수행하기 전에 EDS(Electrical DieSorting) 공정에서 테스트 설비에 의해 전기적인 특성 검사를 받게 된다. 또한, 패키징공정이 완료된 패키지들도 테스트설비에 의해 전기적인 특성 검사를 받게 된다. 이는 상기 웨이퍼의 각 칩들이나 패키지들이 반도체장치로서의 특정 기준에 적합하게 제조되었는지의 여부를 판단하기 위함이다.

최근에 들어, 반도체소자의 고집적화가 진행되면서 포고핀(Pogo Pin) 또는 스프링핀(Spring pin))이라는 탐침이 널리 사용되고 있다. 상기 포고핀을 적용한 블록은 테스터와 더트(Device Under Testing: DUT) 보드(또는 테스트 보드)를 전기적으로 접속한다.

도 1 및 도 2 에 도시된 바와 같이, 블록(10)에 원형 형상의 포고핀 안착 홀들(11)이 수직 관통하고, 상기 포고핀 안착 홀들(11) 내에 원형 관통 형상의 포고핀 케이스들(20)이 각각 삽입 고정되고, 상기 포고핀 케이스들(20) 내에 포고핀들(30)이 하나씩 대응하여 삽입 설치된다. 더트 보드(40)가 상기 포고핀들(30)에 의해 테스터(60)의 케이블(50)에 전기적으로 연결된다.

여기서, 상기 블럭(10)은 상기 포고핀들(30)을 결합하는 결집판 기능을 하며, 주로 절연성 재질로 구성된다. 상기포고핀 안착 홀들(11)이 상기 블록(10)의 상부면에 일정 간격을 두고 다수개 배치되고, 상기 포고핀 안착 홀들(11)의 하단부의 블럭(10)에는 상기 포고핀 케이스(20)가 더 이상 하강하지 못하고 걸리도록 하기 위한 포고핀 케이스 걸림턱(13)이 형성된다.

또한, 상기 포고핀 케이스 걸림턱(13)을 기준으로 한 상기 포고핀 안착 홀(11)의 상측 부분, 즉 더트 보드(40)를 대향하는 부분의 내경이 상기 포고핀 케이스 걸림턱(13)을 기준으로 한 상기 포고핀 안착 홀(11)의 하측 부분, 상기 테스터(50)의 케이블(60)에 연결된 부분의 내경보다 크다.

그리고, 상기 포고핀들(30)의 하우징(31)이 도전성 재질로 구성되며 상기 포고핀 안착 홀들(11)의 큰 내경과 동일한 외경을 갖는 원형 관통 형상으로 이루어진다. 접촉부(33)가 도전성 재질로 구성되며 상기 하우징(31)의 상측 부분 내에서 상기 하우징(31)에 밀착하며 이동하고 상기 더트 보드(40)의 도전성 패드(41)에 접촉한다. 지지부(35)가 도전성 재질로 구성되고, 상기 포고핀 안착 홀들(11)의 작은 내경과 동일한 외경을 가지며 상기 하우징(31)의 하측 부분에 결합된다.

스프링(37)이 상기 지지부(35)에 의해 지지되고, 상기 접촉부(33)와 상기 지지부(35) 사이에 배치되며 상기 접촉부(33)와상기 패드(41)의 양호한 접촉을 위해 장력(Tension)을 가하여준다.

또한, 이동 제한부(31a)는 상기 하우징(31)의 일부분이 상기 하우징(31)의 내부 공간을 향해 절곡된 것으로, 상기 접촉부(33)가 상기 지지부(35)를 향해 일정 거리 이상 하향 이동하는 것을 제한하여 주도록 되어 있다.

상기 포고핀을 다른 일실시예인 도 3 을 참조하여 보다 자세히 알아보기로 한다. 도 3 은 반도체 제조장비용 포고핀 구조로서,

상부가 개방된 통형의 포고 가이드(2)와, 상기 포고 가이드의 내부에 설치된 스프링(3)과, 상기 스프링의 상부에 설치된스프링 볼(4)과, 상기 스프링 볼(4)의 상부에 설치되는 포고팁(5)으로 구성되어 있다.

그리고, 상기 포고팁(5)은 상단이 뾰족한 형상으로 되어 상단 일부가 포고 가이드(2)로부터 노출되도록 설치되어 있으며,하단에는 상기 포고팁(5)으로부터 이탈되는 것을 방지하기 위한 걸림턱(5a)이 형성되어 있다.

이와 같이 구성된 종래의 포고핀(1)중 포고팁(5)의 뾰족한 상단은 많은 접촉이 이루어져야 하므로 마모를 줄이기 위해 견고한 재질로 되어 있으며, 포고팁(5)은 스프링(3)에 의해 탄력지지되어 있으므로 도면상 상/하 방향으로의 탄성유동이 가능하다.

이 때, 상기 포고팁(5)의 하단에는 걸림턱(5a)이 형성되어 포고 가이드(2)의 상단에 걸려 있으므로 상/하 유동되더라도포고 가이드(2)를 벗어날 수 없도록 되어 있다.

한편, 상기 포고팁(5)과 스프링(3)사이에 설치된 스프링 볼(4)은 스프링(3)의 탄성력을 고르게 포고팁(5)으로 전달하는 역할을 하므로써 포고팁(5)이 상/하 탄력 유동을 함에 있어서, 정확한 동작이 이루어지도록 하였다.

이와같은 상기의 포고핀들을 도 4 를 토대로 종합해 보면, 상부의 일부분이 개방되며 내부가 중공이며 PCB에 고정된 하우징(71)과, 상기 하우징(71) 내부에 설치된 탄성체(스프링)(74)와, 스프링(74) 상단에 설치되며 상기 하우징(71)의 개방구(開放口)의 내경보다 긴 직경을 갖는 걸림턱(73)과, 상기 걸림턱(73)과 일체형이며 일부가 하우징 밖으로 노출된 접촉삽입핀(72)과, 상기 접촉삽입핀의 상부에 도전성패드에 접촉하는 접촉부(75)으로 구성된다.

약간씩은 다르나 대부분의 포고핀은 이와 유사한 구성과 기능을 가지고 있다. 하지만 앞에서도 언급이 되어 있지만 하측에, PCB에 고정된 하우징(71)과 상측에 상하유동이 가능한 접촉삽입핀(72)이 접하는 부분에서, 하우징(71)의 직경이 접촉삽입핀(72)의 직경보다 크며 상기 접촉삽입핀이 상기 하우징의 개방구와 접하면서 개방구내로 상하유동이 이루어지므로 제품에서 발생하는 분진 또는 그외에서 발생하는 분진 등에 의해 접촉저항(마찰)이 생기며 또한 상기 하우징의 상단면에 상기 분진이 쌓이게 된다. 그래서 제품의 수율이 저하되고 또한 포고핀의 수명이 떨어져 제조원가가 높아지는 문제점이 발생한다.

고안이 이루고자 하는 기술적 과제

이에, 본 고안은 상기와 같은 문제점을 해결하기 위해 하우징과 접촉삽입핀이 접하는 부분에서 하우징의 직경을 접촉삽입핀의 직경보다 작게 형성시키며 상기 접촉삽입핀은 PCB에 고정되면서 상기 하우징이 상하유동되도록 하여 분지가 아래로 떨어질수 있도록 하는데 그 목적이 있다.

고안의 구성 및 작용

상기와 같은 목적을 이루기 위한 본 고안은, 종래의 접촉삽입핀을 절연체(PCB)에 고정시키며 접촉부는 종래의 하우징 하단에 형성시킨다. 즉 도시된 도5와 같이 하우징은 상기 접촉삽입핀의 상측에 위치되는데 그 구성은

하부가 개방된 통형인 하우징(172)과,

상기 하우징 내부에 설치된 탄성체(174)와,

상기 탄성체(174)의 하부에 설치되며 상기 하우징(172)의 개방구의 내경보다 긴 직경을 가져 하우징(172) 밖으로 나오지 못하도록 하우징내에 걸쳐져 있는 걸림턱(173)과,

상부가 상기 하우징(172)의 개방구를 통과하여 상기 걸림턱(173)의 하부에 연결되며 PCB에 고정설치된 접촉삽입핀(171)와,

상기 하우징(172)의 상측부분에 형성되어 도전성 패드와 접촉하는 접촉부(175)로 이루어진다.

상기 접촉부(175)는 도전성 재질로 구성되며 상기 하우징(1721)의 상측 부분 내에서 상기 하우징(172)에 밀착하며 이동하고 더트 보드의 도전성 패드에 접촉한다.

상기 하우징(172)은 내부가 중공이며 하부의 일부가 개방되어 있다. 이 개방된 구멍을 개방구라 한다.

상기 탄성체(174)는 탄성력을 가지며 스프링 등이 있으며 여기서는 하우징(172)의 내부에 있으며 밖으로 나오지 못하도록 상기 개방구의 내경보다 크다.

상기 걸림턱(173)은 상기 개방구의 내경보다 크며 상기 탄성체(174)의 하부에 위치한다.

상기 접촉삽입핀(빗금친 부분)(171)은 어떠한 형태든지 무관하나 단지 상부의 직경이 상기 개방구의 내경정도 되며 PCB에 고정된다는 것이다. 또한 접촉삽입핀(171)의 상부가 상기 걸림턱(173)과 연결되어 있어 스프링(174)에 의해 상하유동된다.

또한, 상기 하우징(172)의 내부에 그리스를 충진시키고 실링(sealing)시킴으로써 접촉삽입핀(171)과 하우징(172)의 접촉부분이 보다 원활해져 상하유동이 보다 잘 이루어진다.

고안의 효과

상기와 같이 접촉삽입핀의 상단면을, 접촉삽입핀의 상측에 있는 하우징의 하단면보다 작게 형성시켜 하우징내로 접촉삽입핀이 삽입되도록 함으로써 분진이 접촉삽입핀내로 들어가지 않고 아래로 떨어져서 제품의 수율이 향상되고 또한 포고핀의 수명을 연장되어 제조원가를 줄일수 있는 효과가 발생된다.

(57) 청구의 범위

청구항 1.

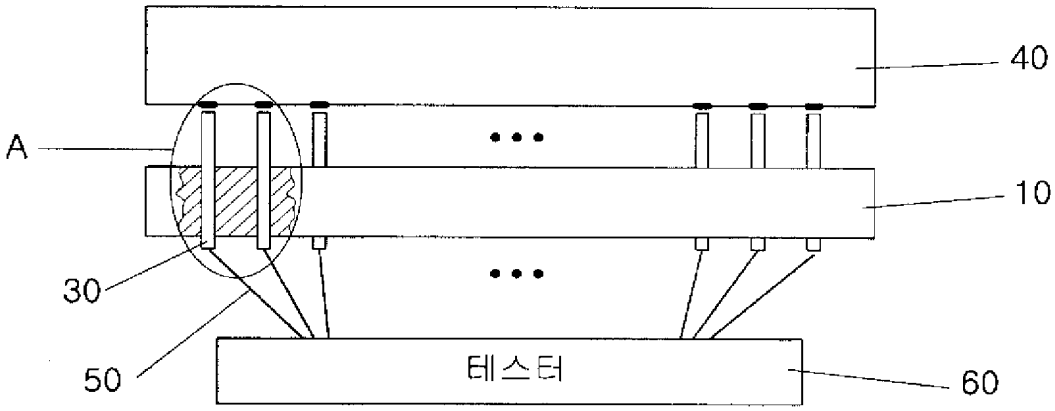
상측에는 하우징이, 하측에는 접촉삽입핀을 형성시키되, 상기 하우징은 하부의 일부가 개방된 개방구를 가진 통형이며 내부에 탄성체가 설치되며 탄성체 하부에 개방구의 직경보다 큰 걸림턱이 형성되며 상기 걸림턱이 접촉삽입핀의 상부면과 연결되어 있으며 상기 하우징의 상측부분에 도전성 패드와 접촉하는 접촉부가 형성됨을 특징으로 하는 포고핀

청구항 2.

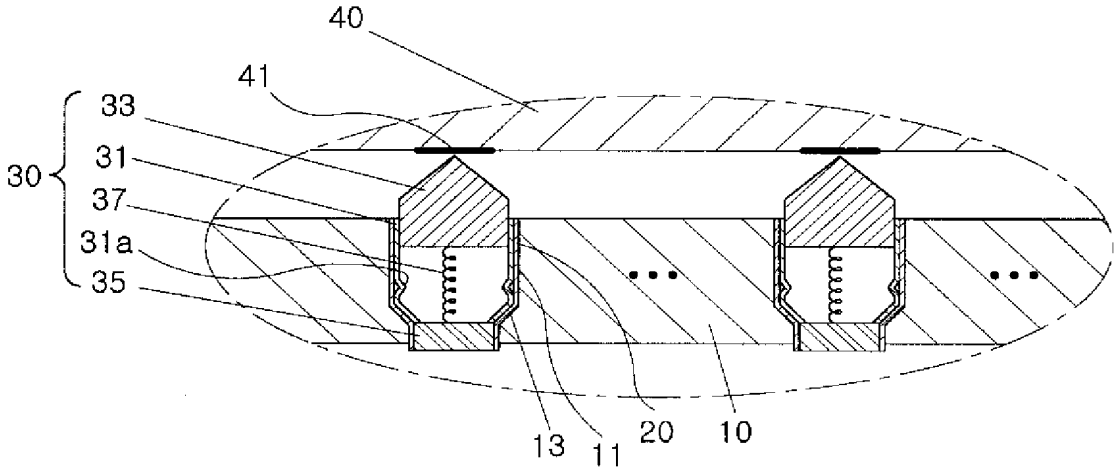
제 1 항에 있어서, 하우징의 내부에 그리스를 충진시키고 실링시킴으로써 하우징과 접촉삽입핀의 접촉부분이 보다 원활해짐을 특징으로 하는 포고핀.

도면

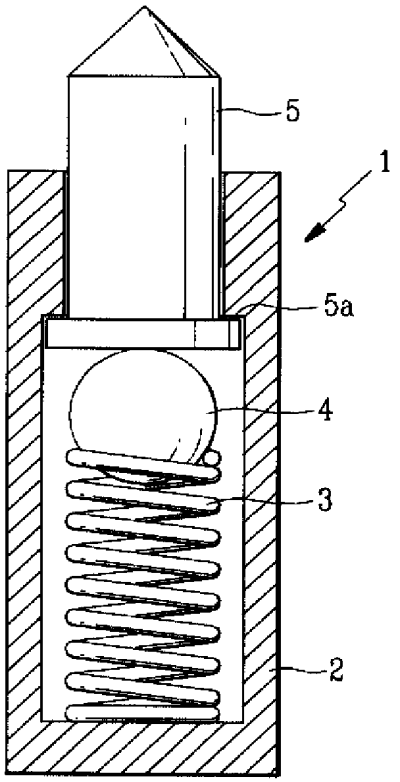
도면 1



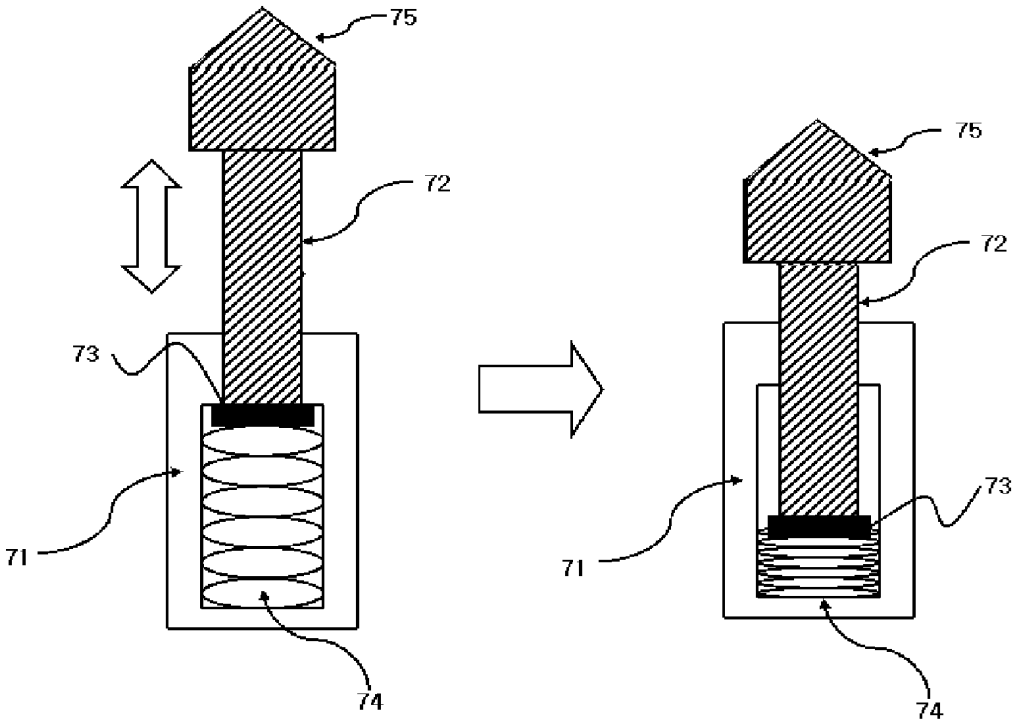
도면 2



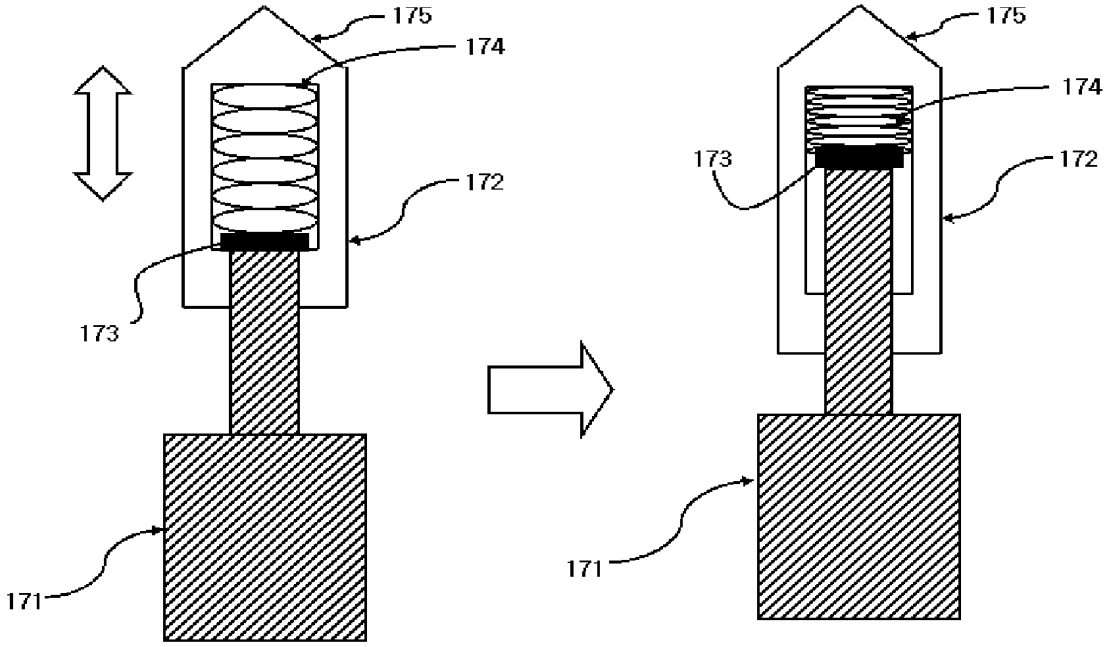
도면 3



도면 4



도면 5



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(71) 출원인 (주)티에스이
충청남도 천안시 직산면 군서리 134번지

(72) 발명자 추교철
충남 천안시 직산읍 수헐리 부영아파트 101동 1208호
오창수
충청남도 천안시 쌍용동 주공10단지 아파트 505동 102호
인치훈
충청남도 천안시 직산면 수헐리 부영아파트 102동 1007호

(74) 대리인 윤동열

심사청구 : 있음

(54) 스프링 핀을 갖는 연결 기판

요약

본 발명은 스프링 핀을 갖는 연결 기판에 관한 것으로, 컨택 기판과의 컨택 거리를 최소화하여 고주파 신호전달 특성을 향상시킬 수 있고, 컨택 기판과 안정적인 접촉을 구현할 수 있는 스프링 핀을 갖는 연결 기판을 제공한다. 즉, 본 발명은 상부면에 컨택 기판의 기판 패드에 대응되게 다수개의 연결 패드가 형성되고, 상기 연결 패드를 관통하여 소정의 깊이에 걸림턱을 갖는 비아 홀이 형성된 기판 몸체와; 하단부가 상기 비아 홀에 삽입되며 상기 하단부와 연결된 상단부가 상기 비아 홀 밖으로 돌출되는 스프링 핀;을 포함하며, 상기 스프링 핀은, 하단부가 상기 비아 홀에 삽입되고 상기 하단부와 연결된 상단부가 상기 비아 홀 밖으로 돌출된 컨택 핀과; 상기 컨택 핀의 상단부에 끼워져 상기 비아 홀에 삽입되어 상기 걸림턱에 지지되는 컨택 스프링;을 포함하며, 상기 컨택 기판으로 상기 스프링 핀을 가압하면, 상기 기판 몸체의 상부면으로 돌출된 스프링 핀의 상단부가 상기 비아 홀 안으로 삽입되어 상기 컨택 기판이 상기 기판 몸체의 상부면에 근접하게 위치할 수 있도록 하는 것을 특징으로 하는 스프링 핀을 갖는 연결 기판을 제공한다. 그리고 기판 몸체의 비아 홀에 컨택 스프링과 함께 컨택 핀의 일부가 삽입된 구조를 갖기 때문에, 제조 공정이 간단하고 고가의 포고 핀을 사용하는 것에 비해서 제조 비용이 저렴한 장점도 있다.

대표도

도 4

색인어

기판, 접촉, 포고 핀, 스프링, 삽입

명세서

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도면의 간단한 설명

도 1은 종래기술에 따른 포고 핀을 갖는 연결 기판을 보여주는 부분 단면도이다.

도 2 및 도 3은 도 1의 연결 기판에 컨택 기판이 접촉되는 상태를 보여주는 부분 단면도들이다.

도 4는 본 발명의 실시예에 따른 스프링 핀을 갖는 연결 기판을 보여주는 부분 단면도이다.

도 5는 도 4의 스프링 핀을 보여주는 분해 사시도이다.

도 6 및 도 7은 도 4의 연결 기판에 컨택 기판이 접촉되는 상태를 보여주는 부분 단면도들이다.

* 도면의 주요 부분에 대한 설명 *

20 : 컨택 기판 24 : 기판 패드

30 : 연결 기판 31 : 스프링 핀

32 : 기판 몸체 34 : 연결 패드

35 : 컨택 스프링 36 : 비아 홀

37: 컨택 핀 41 : 가이드 바

42 : 제 2 컨택 돌기 43 : 고정턱

44 : 제 1 컨택 돌기 45 : 제 1 접촉부

46 : 완충부 47 : 제 2 접촉부

발명의 상세한 설명

발명의 목적

발명이 속하는 기술 및 그 분야의 종래기술

본 발명은 기판 연결용 연결 기판에 관한 것으로, 더욱 상세하게는 컨택 기판과의 컨택 거리를 최소화하여 고주파 신호전달 특성을 향상시킬 수 있는 스프링 핀을 갖는 연결 기판에 관한 것이다.

기판과 기판의 전기적 연결에 있어서, 상대적으로 아래에 위치하는 연결 기판(10)으로, 도 1에 도시된 바와 같이, 상부면에 포고 핀(11)이 설치된 기판을 사용한다.

종래의 포고 핀(11)을 갖는 연결 기판(10)은 기판 몸체(12)와, 기판 몸체(12)의 상부면에 형성된 다수개의 연결 패드(14)와, 연결 패드(14)를 관통하여 기판 몸체(12)에 소정의 깊이로 설치 홈(16)이 형성되고, 그 설치 홈(16)에 삽입된 포고 핀(11)으로 구성된다.

포고 핀(11)은 핀 하우징(13)과, 핀 하우징(13) 내에 설치된 컨택 스프링(15)에 의해 가압되어 구속되는 컨택 핀(17)을 포함한다. 컨택 핀(17)의 상단은 핀 하우징(13)의 상단의 개방부(18)를 통하여 밖으로 돌출되며, 기판(20; 이하, "컨택 기판"이라 한다)에 안정적으로 접촉될 수 있도록 뾰족하게 형성되어 있다.

이와 같은 구조를 갖는 연결 기판(10)에 컨택 기판(20)이 탄성적으로 접촉되는 상태를, 도 2 및 도 3을 참조하여 설명하면, 컨택 기판(20)이 연결 기판(10)의 상부에 정렬된 상태에서 소정의 압력으로 컨택 기판(20)이 연결 기판(10)을 가압함으로

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써, 연결 기판의 포고 핀(11)이 컨택 기판(20)에 접촉하여 전기적으로 연결된다. 이때 컨택 기판(20)의 하부면에는 포고 핀(11)에 대응되는 위치에 기판 패드(24)가 형성되어 있으며, 그 기판 패드(24)에 포고 핀의 컨택 핀(17)이 탄성적으로 접촉하게 된다.

그리고 연결 기판(10)과 컨택 기판(20)의 접촉에 따른 컨택 기판의 기판 패드(24)에서 연결 기판의 연결 패드(14)까지의 전기적 연결 경로를 살펴보면, 컨택 기판의 기판 패드(24)에서 출발해서, 기판 패드(24)에 기계적으로 접촉한 컨택 핀(17)을 경유해서, 컨택 핀(17)과 기계적으로 접촉된 핀 하우징(13) 및 핀 하우징(13)이 접촉된 연결 패드(14)를 통하여 전기적으로 연결된다.

그런데 종래의 연결 기판(10)은 컨택 기판이 탄성적으로 접촉될 때, 연결 기판(10) 상부로 돌출된 핀 하우징(13)의 높이 보다는 적어도 높게 설치되기 때문에, 연결 기판(10)과 컨택 기판(20)의 사이의 컨택 거리(h1)만큼 신호 전송 길이가 길어져 고주파 신호전달 특성이 떨어질 수 있다.

종래의 연결 기판(10)은 포고 핀 접촉 방식으로 포고 핀(11)이 컨택 기판의 기판 패드(24)에 탄성적으로 접촉하게 되는데, 포고 핀(11)의 기판 패드(24)에 대한 접촉 정도에 따라서 접촉 저항의 변화의 폭이 큰 문제점을 안고 있다. 예컨대, 접촉 저항은 수십mΩ 내지 수백mΩ으로 변화의 폭이 크다. 상기한 문제는 포고 핀(11) 내부에서 컨택 핀(17)과 핀 하우징(13) 사이의 소프트 컨택(soft contact)을 하는 포고 핀(11) 자체의 특성으로 인해 발생되는 근원적인 문제이다.

그리고 고가의 포고 핀(11) 사용에 따른 연결 기판(10)의 제조 비용이 비싼 문제점도 안고 있다.

발명이 이루고자 하는 기술적 과제

따라서, 본 발명의 제 1 목적은 컨택 기판과의 컨택 거리를 최소화하여 고주파 신호전달 특성을 향상시킬 수 있는 연결 기판을 제공하는 데 있다.

본 발명의 제 2 목적은 컨택 기판과 안정적인 접촉을 구현할 수 있는 연결 기판을 제공하는 데 있다.

본 발명의 제 3 목적은 구조가 간단하면서 제조 비용을 낮출 수 있는 연결 기판을 제공하는 데 있다.

발명의 구성 및 작용

상기 목적을 달성하기 위하여, 본 발명은 컨택 기판 접촉용 연결 기판으로서, 상부면에 컨택 기판의 기판 패드에 대응되게 다수개의 연결 패드가 형성되고, 상기 연결 패드를 관통하여 소정의 깊이에 걸림턱을 갖는 비아 홀이 형성된 기판 몸체와; 하단부가 상기 비아 홀에 삽입되며 상기 하단부와 연결된 상단부가 상기 비아 홀 밖으로 돌출되는 스프링 핀;을 포함하며,

상기 스프링 핀은, 하단부가 상기 비아 홀에 삽입되고 상기 하단부와 연결된 상단부가 상기 비아 홀 밖으로 돌출된 컨택 핀과; 상기 컨택 핀의 상단부에 끼워져 상기 비아 홀에 삽입되어 상기 걸림턱에 지지되는 컨택 스프링;을 포함하며,

상기 컨택 기판으로 상기 스프링 핀을 가압하면, 상기 기판 몸체의 상부면으로 돌출된 스프링 핀의 상단부가 상기 비아 홀 안으로 삽입되어 상기 컨택 기판이 상기 기판 몸체의 상부면에 근접하게 위치할 수 있도록 하는 것을 특징으로 하는 스프링 핀을 갖는 연결 기판을 제공한다.

본 발명에 따른 기판 몸체의 비아 홀은 기판 몸체의 상부면에서 소정의 깊이로 형성된 제 1 비아 홀과, 제 1 비아 홀과 연통되어 있으며 제 1 비아 홀 보다는 내경이 작게 형성되어 기판 몸체의 하부면으로 관통된 제 2 비아 홀을 포함한다. 이때 걸림턱은 제 1 비아 홀과 제 2 비아 홀 경계의 단차면이다.

본 발명에 따른 컨택 핀은 제 1 비아 홀을 통하여 제 2 비아 홀에 삽입되어 컨택 핀의 상하이동을 안내하며, 컨택 핀의 하강시 제 2 비아 홀과 접촉하여 전기적으로 연결되는 가이드 바와, 가이드 바의 상단에 연결되며 가이드 바의 말단을 통하여 삽입된 컨택 스프링이 끼워져 고정되는 고정턱과, 고정턱 상단에 연결되며 컨택 기판과 기계적인 접촉으로 전기적으로 연결되는 제 1 컨택 돌기와, 고정턱 아래의 컨택 스프링이 삽입되는 부분에 가이드 바의 외경보다는 크게 형성되며 스프링 핀 압축시 컨택 스프링과 기계적인 접촉으로 전기적으로 연결되는 제 2 컨택 돌기를 포함한다.

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본 발명에 따른 컨택 스프링은 코일 스프링으로, 컨택 핀의 고정턱에 끼워져 고정되어 컨택 핀과 전기적 접속을 이루는 제 1 접촉부와, 제 1 접촉부와 연결되어 접촉될 컨택 기판이 가압하는 힘을 완충하는 완충부와, 완충부와 연결되며 걸림턱에 탑재되어 전기적 접속을 이루는 제 2 접촉부를 포함한다. 이때 컨택 스프링은 걸림턱을 지지점으로 해서 수축되거나 팽창된다.

그리고 본 발명에 따른 제 2 접촉부를 통하여 비아 홀로 바로 전기적 신호가 흐를 수 있도록 제 2 접촉부는 조밀하게 형성된다.

이하, 첨부 도면을 참조하여 본 발명의 실시예를 보다 상세하게 설명하고자 한다.

도 4는 본 발명의 실시예에 따른 스프링 핀(31)을 갖는 연결 기판(30)을 보여주는 부분 단면도이다. 도 5는 도 4의 스프링 핀(31)의 분해 사시도이다. 그리고 도 6 및 도 7은 도 4의 연결 기판(30)에 컨택 기판(20)이 접촉되는 상태를 보여주는 부분 단면도들이다.

도 4 내지 도 7를 참조하면, 본 발명의 실시예에 따른 연결 기판(30)은 상부면에 컨택 기판의 기판 패드(24)에 대응되게 다수개의 연결 패드(34)가 형성되고, 연결 패드(34)를 관통하여 소정의 깊이에 걸림턱(38)을 갖는 비아 홀(36)이 형성된 기판 몸체(32)와, 하단부가 비아 홀(36)에 삽입되며 상단부가 비아 홀(36) 밖으로 돌출되는 스프링 핀(31)을 포함한다. 특히 스프링 핀(31)은 하단부가 비아 홀(36)에 삽입되고 하단부와 연결된 상단부가 비아 홀(36) 밖으로 돌출된 컨택 핀(37)과, 컨택 핀(37)의 상단부에 끼워져 비아 홀(36)에 삽입되어 걸림턱(38)에 탑재되는 컨택 스프링(35)을 포함한다. 즉, 컨택 기판(20)이 연결 기판(30)에 접촉될 때, 기판 몸체(32)의 상부면으로 돌출된 스프링 핀(31)의 상단부가 비아 홀(36) 안으로 삽입되어 컨택 기판(20)이 기판 몸체(32)의 상부면에 근접하게 위치할 수 있도록 안내하기 때문에, 컨택 거리(h2)를 최소화할 수 있다. 구체적인 설명은 후술하도록 하겠다.

좀 더 상세히 설명하면, 비아 홀(36)은 연결 패드(34) 아래의 기판 몸체(32)를 수직으로 관통하여 형성되며, 비아 홀(36)의 내주면에는 연결 패드(34)와 전기적 접속을 이룰 수 있도록 도금층이 형성되어 있다. 특히 비아 홀(36)은 기판 몸체(32)의 상부면에서 소정의 깊이로 형성된 제 1 비아 홀(36a)과, 제 1 비아 홀(36a)과 연통되어 있으며 제 1 비아 홀(36a) 보다는 내경이 작게 형성되어 기판 몸체(32)의 하부면으로 관통된 제 2 비아 홀(36b)을 포함한다. 비아 홀(36)을 형성하는 방법은 먼저 제 2 비아 홀(36b)의 내경으로 기판 몸체(32)를 관통하게 구멍을 뚫은 다음, 다시 그 구멍에 걸림턱(38)이 형성될 위치까지 제 1 비아 홀(36a)의 내경으로 구멍을 형성한 후 구멍의 내주면에 무전해 도금법으로 도금층을 형성함으로써, 비아 홀(36)이 형성된다. 이때 걸림턱(38)은 제 1 비아 홀(36a)과 제 2 비아 홀(36b)의 경계의 단차면이다.

컨택 핀(37)은 전기 전도성이 양호한 도전성 금속으로 제조되거나, 표면이 도전성 물질로 도금된 핀으로, 제 1 비아 홀(36a)을 통하여 제 2 비아 홀(36b)에 삽입되며 컨택 핀(37)의 상하이동을 안내하는 가이드 바(41; guide bar)와, 가이드 바(41)의 상단에 연결되며 가이드 바(41)의 말단을 통하여 삽입된 컨택 스프링(35)이 끼워져 고정되는 고정턱(43)과, 고정턱(43) 상단에 연결되며 컨택 기판(20)과 기계적인 접촉으로 전기적으로 연결되는 제 1 컨택 돌기(44)와, 고정턱(43) 아래의 컨택 스프링(35)이 삽입되는 부분에 가이드 바(41)의 외경보다는 크게 형성되며 스프링 핀(31) 압축시 컨택 스프링(35)과 기계적인 접촉으로 전기적으로 연결되는 제 2 컨택 돌기(42)를 포함한다. 이때 컨택 기판(20)이 연결 기판(30)에 연결시 컨택 핀(37)이 하강할 때, 가이드 바(41)의 하단부는 제 2 비아 홀(36b)과 접촉하여 전기적으로 연결된다.

그리고 컨택 스프링(35)은 코일 스프링(coil spring)으로 컨택 핀(37)의 하단을 통하여 길이 방향으로 끼워져 설치되는데, 컨택 핀(37)의 고정턱(44)에 끼워져 고정되어 컨택 핀(37)과 전기적 접속을 이루는 제 1 접촉부(45)와, 제 1 접촉부(45)와 연결되어 접촉될 컨택 기판(20)이 가압하는 힘을 완충하는 완충부(46)와, 완충부(46)와 연결되며 걸림턱(38)에 탑재되어 전기적 접속을 이루는 제 2 접촉부(47)를 포함한다. 이때 컨택 스프링(35)은 걸림턱(38)을 지지점으로 해서 수축되거나 팽창된다. 제 2 접촉부(47)를 통하여 비아 홀(36)로 바로 전기적 신호가 흐를 수 있도록 제 2 접촉부(47)는 조밀하게 형성된다. 컨택 스프링(35), 컨택 핀(37)과 연결 패드(34) 사이에 전기적 신호가 원활하게 교환될 수 있도록, 컨택 스프링(35)의 표면은 전기 전도성이 양호한 전도성 물질로 도금처리하는 것이 바람직하다.

이때 기판 몸체(32)에 형성된 비아 홀(36)에 있어서, 제 2 비아 홀(36b)은 가이드 바(41)가 삽입되어 상하 이동할 수 있도록 가이드 바(41)의 외경보다는 적어도 큰 내경을 갖도록 형성하는 것이 바람직하며, 더욱 바람직하게는 스프링 핀(31) 가압시 가이드 바(41)의 하단부가 제 2 비아 홀(36b)의 내주면과 접촉할 수 있도록 가이드 바(41)의 외경보다는 너무 크지 않게 형성하는 것이다.

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이와 같은 구조를 갖는 본 발명에 따른 연결 기판(30)에 컨택 기판(20)이 접촉되는 상태를, 도 6 및 도 7을 참조하여 설명하면, 컨택 기판(20)이 연결 기판(30)의 상부에 정렬된 상태에서 소정의 압력으로 연결 기판(30)을 가압함으로써, 연결 기판의 스프링 핀(31)이 컨택 기판의 기판 패드(24)에 탄성적으로 접촉하여 전기적으로 연결된다. 물론 컨택 기판(20)의 하부면에는 스프링 핀(31)에 대응되는 위치에 기판 패드(24)가 형성되어 있으며, 그 기판 패드(24)에 스프링 핀의 컨택 핀(37)이 탄성적으로 접촉하게 된다.

이때 컨택 스프링(35)이 비아 홀(36)에 일정 부분이 삽입된 구조를 갖기 때문에, 연결 기판(30)에 컨택 기판(20)이 소정의 압력으로 접촉될 때, 연결 기판(30)의 상부면으로 돌출된 스프링 핀 (31)부분이 제 1 비아 홀(36a) 안으로 삽입되어 연결 기판(30)의 상부면에 거의 근접하게 컨택 기판(20)의 하부면이 위치할 수 있도록 안내함으로써 컨택 거리(h2)를 최소화할 수 있다. 즉 제 1 비아 홀(36a)과 제 2 비아 홀(36b) 사이의 걸림턱(38)에 컨택 스프링(35)이 지지된 구조를 갖기 때문에, 기판 몸체(32)의 상부로 돌출된 컨택 핀(37)과 함께 컨택 스프링(35)이 제 1 비아 홀(36a) 안으로 수축되어 삽입되어 연결 기판(30)의 상부면에 컨택 기판(20)이 근접하게 위치할 수 있도록 안내한다. 따라서 연결 기판(30)과 컨택 기판(20) 사이의 줄어든 컨택 거리(h2)만큼 연결 기판(30)과 컨택 기판(20) 사이의 신호 전송 길이를 줄일 수 있기 때문에, 고주파 신호 전달 특성을 향상시킬 수 있다.

한편 연결 기판(30)과 컨택 기판(20)의 접촉에 따른 컨택 기판의 기판 패드(24)에서 연결 기판의 비아 홀(36)까지의 전기적 연결 통로를 살펴보면, 컨택 기판의 기판 패드(24)에 기계적으로 접촉한 컨택 핀의 제 1 컨택 돌기(44)를 출발해서, 제 2 컨택 돌기(42)와 기계적으로 접촉된 컨택 스프링의 제 2 접촉부(47)와 전기적으로 연결된다. 이때 제 2 접촉부(47)는 걸림턱(38)에 지지되어 비아 홀(36)과 전기적으로 연결된다. 또는 제 2 비아 홀(36b)에 위치하는 가이드 바(41)의 하단부가 제 2 비아 홀(36b)의 내주면과 기계적으로 접촉하여 전기적으로 연결된다. 따라서 기판 패드(24)와 접촉된 제 1 컨택 돌기(44)를 출발해서, 제 2 컨택 돌기(42) 또는 가이드 바(41)가 비아 홀(36)과 기계적인 접촉에 의해 전기적으로 연결됨으로써, 컨택 기판(20)과 연결 기판(30)이 전기적으로 연결된다.

그리고 컨택 스프링(35)은 컨택 핀의 고정턱(43)과 걸림턱(38) 사이에 압축되어 소정의 가압력으로 컨택 핀(37) 및 걸림턱(38)에 기계적으로 직접 접촉되어 전기적으로 연결되기 때문에, 종래의 포고 핀 접촉 방식에 비해서 접촉 저항이 크기 않다.

한편, 본 명세서와 도면에 개시된 본 발명의 실시예들은 이해를 돕기 위해 특정 예를 제시한 것에 지나지 않으며, 본 발명의 범위를 한정하고자 하는 것은 아니다. 여기에 개시된 실시예들 이외에도 본 발명의 기술적 사상에 바탕을 둔 다른 변형예들이 실시 가능하다는 것은, 본 발명이 속하는 기술분야에서 통상의 지식을 가진 자에게 자명한 것이다.

발명의 효과

따라서, 본 발명의 구조를 따르면 연결 기판의 상부면으로 돌출된 스프링 핀 부분이 제 1 비아 홀 안으로 삽입되어 연결 기판의 상부면에 거의 근접하게 컨택 기판을 위치시킬 수 있기 때문에, 컨택 기판과 연결 기판 사이의 거리를 최소화하여 고주파 신호전달 특성을 향상시킬 수 있다.

그리고 기판 몸체에 설치된 스프링 핀의 컨택 스프링은, 컨택 기판이 연결 기판에 소정의 가압력으로 접촉할 때, 컨택 핀과 걸림턱 사이에 압축되어 소정의 가압력으로 컨택 핀과 걸림턱에 기계적으로 접촉하기 때문에, 종래의 포고 핀 접촉 방식에 비해서 접촉 저항을 줄일 수 있다.

또한 기판 몸체의 비아 홀에 스프링 핀이 삽입된 구조를 갖기 때문에, 스프링 핀의 구조가 간단하여 제조 공정이 간단하고 고가의 포고 핀 사용하는 것에 비해서 제조 비용이 저렴한 장점도 있다.

(57) 청구의 범위

청구항 1.

컨택 기판 접촉용 연결 기판으로서,

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상부면에 컨택 기판의 기판 패드에 대응되게 다수개의 연결 패드가 형성되고, 상기 연결 패드를 관통하여 소정의 깊이에 걸림턱을 갖는 비아 홀이 형성된 기판 몸체와;

하단부가 상기 비아 홀에 삽입되며 상기 하단부와 연결된 상단부가 상기 비아 홀 밖으로 돌출되는 스프링 핀;을 포함하며,

상기 스프링 핀은,

하단부가 상기 비아 홀에 삽입되고 상기 하단부와 연결된 상단부가 상기 비아 홀 밖으로 돌출된 컨택 핀과;

상기 컨택 핀의 상단부에 끼워져 상기 비아 홀에 삽입되어 상기 걸림턱에 지지되는 컨택 스프링;을 포함하며,

상기 컨택 기판으로 상기 스프링 핀을 가압하면, 상기 기판 몸체의 상부면으로 돌출된 스프링 핀의 상단부가 상기 비아 홀 안으로 삽입되어 상기 컨택 기판이 상기 기판 몸체의 상부면에 근접하게 위치할 수 있도록 하는 것을 특징으로 하는 스프링 핀을 갖는 연결 기판.

청구항 2.

제 1항에 있어서, 상기 비아 홀은,

상기 기판 몸체의 상부면에서 소정의 깊이로 형성된 제 1 비아 홀과;

상기 제 1 비아 홀과 연통되어 있으며, 상기 제 1 비아 홀 보다는 내경이 작게 형성되어 상기 기판 몸체의 하부면으로 관통된 제 2 비아 홀;을 포함하며,

상기 걸림턱은 상기 제 1 비아 홀과 제 2 비아 홀 경계의 단차면인 것을 특징으로 하는 스프링 핀을 갖는 연결 기판.

청구항 3.

제 1항에 있어서, 상기 컨택 핀은,

상기 제 1 비아 홀을 통하여 상기 제 2 비아 홀에 삽입되어 상기 컨택 핀의 상하이동을 안내하며, 상기 컨택 핀의 하강시 상기 제 2 비아 홀과 접촉하여 전기적으로 연결되는 가이드 바와;

상기 가이드 바의 상단에 연결되며, 상기 가이드 바의 말단을 통하여 삽입된 상기 컨택 스프링이 끼워져 고정되는 고정턱과;

상기 고정턱 상단에 연결되며, 컨택 기판과 기계적인 접촉으로 전기적으로 연결되는 제 1 컨택 돌기; 및

상기 고정턱 아래의 상기 컨택 스프링이 삽입되는 부분에 상기 가이드 바의 외경보다는 크게 형성되며, 상기 스프링 핀 압축시 상기 컨택 스프링과 기계적인 접촉으로 전기적으로 연결되는 제 2 컨택 돌기;를 포함하는 것을 특징으로 하는 스프링 핀을 갖는 연결 기판.

청구항 4.

제 3항에 있어서, 상기 컨택 스프링은 코일 스프링으로,

상기 컨택 핀의 고정턱에 끼워져 고정되어 상기 컨택 핀과 전기적 접속을 이루는 제 1 접촉부와;

상기 제 1 접촉부와 연결되어 접촉될 컨택 기판이 가압하는 힘을 완충하는 완충부; 및

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상기 완충부와 연결되며 상기 걸림턱에 탑재되어 전기적 접속을 이루는 제 2 접촉부;를 포함하며,

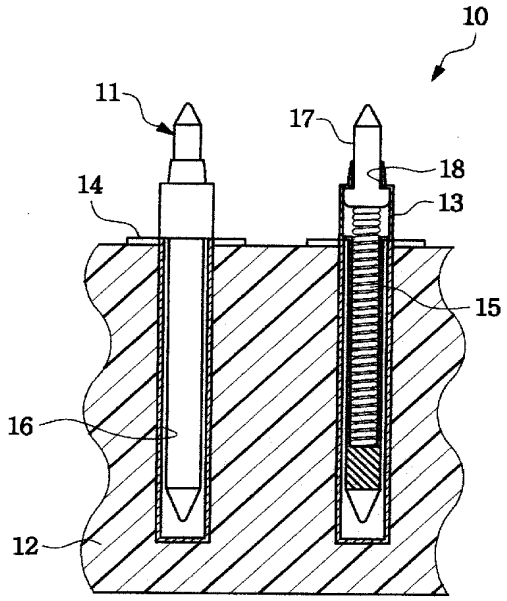
상기 컨택 스프링은 상기 걸림턱을 지지점으로 해서 수축되거나 팽창되는 것을 특징으로 하는 스프링 핀을 갖는 연결 기판.

청구항 5.

제 4항에 있어서, 상기 제 2 접촉부를 통하여 상기 비아 홀로 바로 전기적 신호가 흐를 수 있도록 상기 제 2 접촉부는 조밀하게 형성된 것을 특징으로 하는 스프링 핀을 갖는 연결 기판.

도면

도면1



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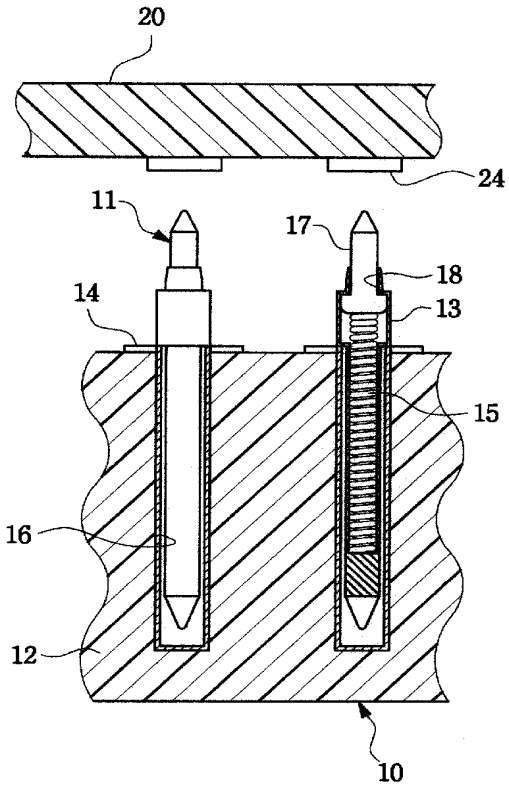
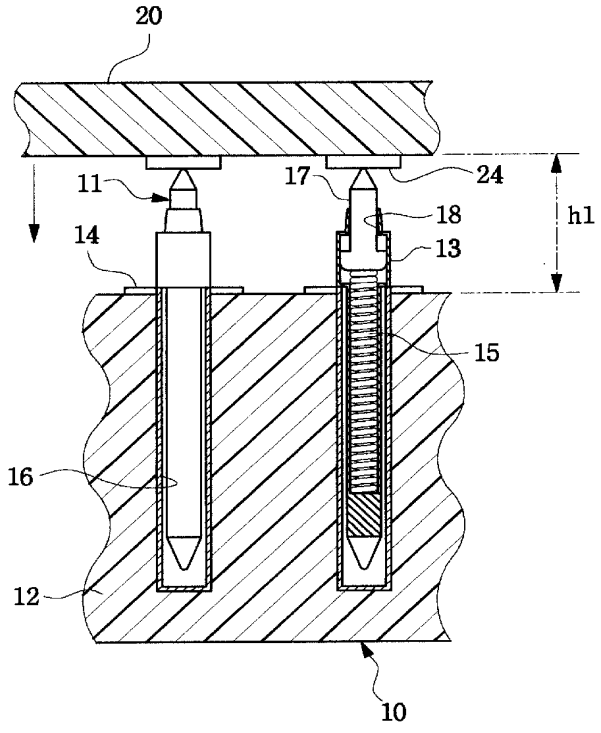
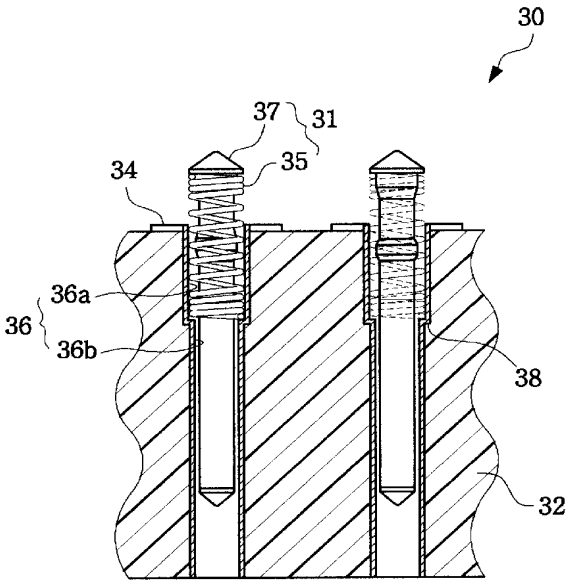
도면2



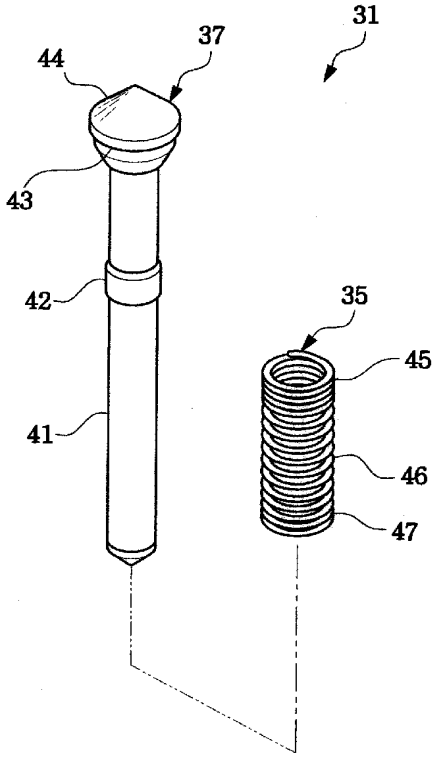
도면3



도면4



도면5



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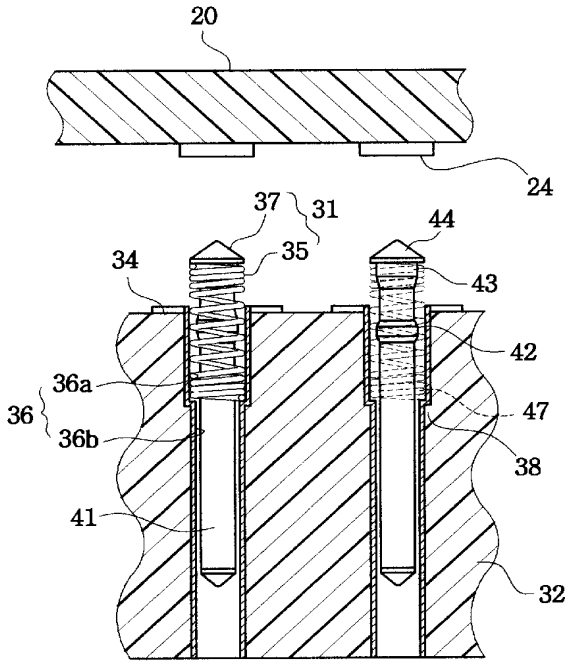
도면6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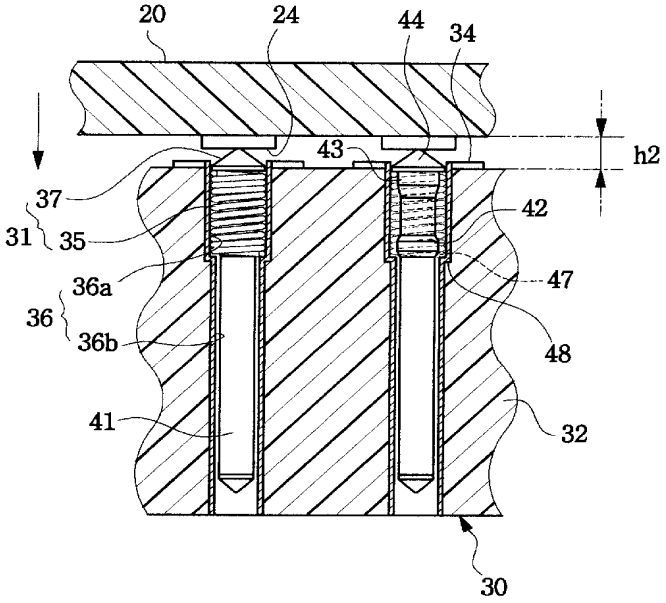
도면7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(73)実用新案権者　000006758
株式会社ヨコオ
東京都北区滝野川７丁目５番11号

(72)考案者　中　島　綱
東京都北区滝野川七丁目５番11号　株式会社ヨコオ内

(74)代理人　弁理士　佐藤　一雄　（外３名）

審査官　青山　待子

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実公　昭48−17990（ＪＰ，Ｙ１）
実公　昭48−22552（ＪＰ，Ｙ１）

(54)【考案の名称】　回路基板用コネクター

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(57)【実用新案登録請求の範囲】

【請求項１】コネクター本体に形成された嵌合溝と、この嵌合溝に挿入される回路基板を弾発的に挟持するように嵌合溝内に設けた板ばねとを備えた回路基板用コネクターにおいて、コネクター本体内部に上記嵌合溝に対して接近可能に嵌合溝に沿って押え駒部材を収容し、この押え駒部材に、前記板ばねの面に向かって突出する一連のスプリングピンを支持し、さらに、前記スプリングピンを前記板ばねの面に押圧して板ばねを回路基板面に押し付けるように、押え駒部材に板ばねへ向かう力を与える操作手段を設けたことを特徴とする回路基板用コネクター。

【考案の詳細な説明】

【０００１】

【産業上の利用分野】本考案は、例えば、テレビ、オーディオ、ＶＴＲ、ＯＡ機器等の回路基板を挟持して電気的な接続に使用される回路基板用コネクターに関する。

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【０００２】

【従来の技術】既に提案されているこの種の回路基板用コネクターは、図５に示されるように構成されている。

【０００３】即ち、図５において、細長い絶縁材で成型されたコネクター本体１の側壁には、嵌合溝２が水平に形成されており、この嵌合溝２には、回路基板３が端子を兼ねた板ばね４で弾発的に挟持して嵌装されている。又、この板ばね４の一端部４ａは上記コネクター本体１を貫通して外方へ突出して延設されており、この板ばね４の一端部４ａは、上記コネクター本体１に半田５で半田付けされている。

【０００４】従って、上述した回路基板用コネクターは、各板ばね４の各一端部４ａを上記コネクター本体１

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をそれぞれ貫通して外方へ突出して延設し、端子を兼ねた各板ばね４が上記回路基板３を弾発的に挟持して電気的に接続している。

【０００５】

【考案が解決しようとする課題】しかしながら、上述した回路基板用コネクターは、各板ばね４の各一端部４ａを上記コネクター本体１をそれぞれ貫通して外方へ突出して延設し、端子を兼ねた各板ばね４が上記回路基板３を弾発的に挟持して電気的に接続している関係上、上記板ばねの数が増えるにつれて、この各板ばね４と上記回路基板３との接触圧にばらつきが生じ、これに起因して、接触抵抗のばらつきが導通不良を生じる等の問題がある。

【０００６】本考案は、上述した問題を解消するために、板ばねの数が増えても、この各板ばねと回路基板との接触圧のばらつきを低減して安定化し、導通不良を解消して信頼性や安全性の向上を図るようにした回路基板コネクターを提供することを目的とする。

【０００７】

【課題を解決するための手段】本考案は、コネクター本体に嵌合溝を形成し、この嵌合溝に回路基板を板ばねで弾発的に挟持して嵌装する回路基板用コネクターにおいて、コネクター本体内部に、嵌合溝に対して接近可能に嵌合溝に沿って押え駒部材を収容し、この押え駒部材に、前記板ばねの面に向かって突出する一連のスプリングピンを支持し、さらに、前記スプリングピンを前記板ばねの面に押圧して板ばねを回路基板面に押し付けるように、押え駒部材に板ばねへ向かう力を与える操作手段を設けたことを特徴とする。

【０００８】

【作用】本考案では、上記コネクター本体内の板ばねを、押え駒部材に支持される一連のスプリングピンにより押圧することにより、板ばねの数が増えても、板ばねと回路基板との各接触圧を安定化してばらつきがなくなり、導通不良が解消する。

【０００９】

【実施例】以下、本考案を図示の一実施例について説明する。

【００１０】なお、本考案は、上述した公知例と同一の構成部材には、同じ符号を付して説明する。

【００１１】図１において、符号１は、細長い絶縁材で成型されたコネクター本体を示し、このコネクター本体１の側壁には、図２に示すように、嵌合溝２が長手方向に形成されており、この嵌合溝２には、回路基板３が端子を兼ねた板ばね４により弾発的に挟持された状態で嵌入されている。又、この板ばね４の一端部４ａは上記コネクター本体１を貫通して外方へ突出しており、この板ばね４の一端部４ａは、上記コネクター本体１に半田５で取り付けられている。さらに、上記嵌合溝２の位置する上記コネクター本体１の内部には、摺動溝６がコネクター本体１の長手方向に形成されており、この摺動溝６には、図１に示すように山形をなす複数（図では４個）の隆起カム部７ａを有する操作手段としてのスライド操作杆７が摺動自在に嵌装されている。さらに又、このスライド操作杆７の一端部には、つまみ７ｂが形成されており、このつまみ７ｂはスライド操作杆７を上記摺動溝６に沿ってコネクター本体１の長手方向に摺動するようになっている。又、このスライド操作杆７の各カム部７ａの位置する上記摺動溝６内には、複数（図２では１個のみ示す）に分割された押え駒部材８が緩く嵌装されており、この各押え駒部材８には、図３に拡大して示されるように、スプリングピン９が外方へ抜け出ないようにして、上記回路基板３の面に対し板ばね４を弾発的に押付けるように設けられている。

【００１２】即ち、このスプリングピン９は押え駒部材８の挿入穴８ａに接触ピン１０をコイルばね１１の弾力で外方へ突出するように付勢して設けられ、この接触ピン１０が上記回路基板３に対し板ばね４を弾発的に押付けるように作用する。

【００１３】上記各板ばね４の各一端部４ａは上記コネクター本体１をそれぞれ貫通して外方へ突出し、端子を兼ねた各板ばね４が上記回路基板３を弾発的に挟持して電気的な接続がなされる。

【００１４】他方、上記つまみ７ｂを指先で摘んで、これと一体の上記スライド操作杆７を摺動すると、このスライド操作杆７の各カム部７ａが上記各押え駒部材８を板ばね４の面へ向かって押動するので、この各押え駒部材８は上記各スプリングピン９を介して上記回路基板３に向かい上記板ばね４を弾発的に押付ける。

【００１５】従って、本考案は、板ばね４の数が増えても、この各板ばね４と回路基板３との接触圧のばらつきを低減して安定化し、導通不良を解消して信頼性や安全性の向上を図ることができる。

【００１６】図４に示す本考案の他の実施例としてのスプリングピン９は、各押え駒部材８の挿入孔８ａに有底筒体１２を固く嵌装し、この有底筒体１２内に接触ピン１０をコイルばね１１の弾力で外方へ突出するように付勢して設け、この接触ピン１０が上記板ばね４を回路基板３に向かって弾発的に押付けるようにしている。

【００１７】従って、図４に示される本考案の他の実施例は、多数のスプリングピン９を予め量産しておき、これらを上記各押え駒部材８の挿入孔８ａへ固く嵌装することにより、敏速に組立てることができるものである。

【００１８】

【考案の効果】以上述べたように、本考案によれば、コネクター本体に嵌合溝を形成し、この嵌合溝に回路基板を板ばねで弾発的に挟持して嵌入する形式の回路基板用コネクターにおいて、上記嵌合溝に沿う位置で、上記コネクター本体に、均一な押圧力をもつように製造し易いスプリングピンを上記回路基板の面に板ばねを押付ける

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ように設けているので、板ばねの数が増えても、この各板ばねと回路基板との接触圧のばらつきを低減して安定化し、導通不良を解消して信頼性や安全性の向上を図ることができる。また、回路基板を嵌合溝内に挿入した後、操作手段を操作することにより、スプリングピンを支持する押え駒部材が回路基板へ向かって変位するので、スプリングピンにより、板ばねを一斉に、均一な接触圧で回路基板に押し付けることができ、また操作手段の逆方向操作により板ばねの作用力を解くことができる。

【図面の簡単な説明】

【図１】本考案の回路基板用コネクターの正面図。

【図２】図１中の鎖線Ａ－Ａに沿う拡大断面図。

【図３】本考案に組込まれるスプリングピンの拡大断面＊図。

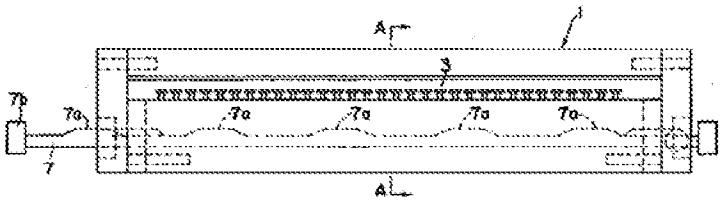
【図４】本考案で用いるスプリングピンの他の実施例を示す図。

【図５】既に提案されている回路基板用コネクターの断面図。

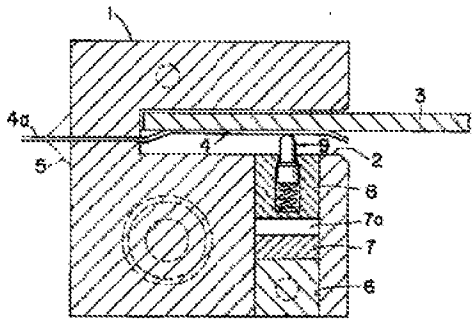
【符号の説明】

1　コネクター本体
2　嵌合溝
3　回路基板
4　板ばね
7　スライド操作杆
7ａ　カム部
8　押え駒部材
9　スプリングピン

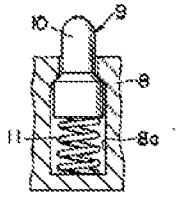
【図１】



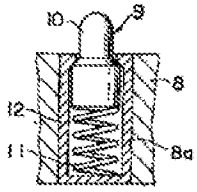
【図２】



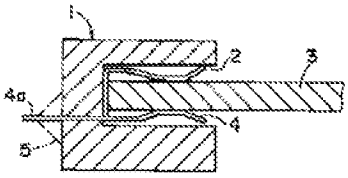
【図３】



【図４】



【図５】



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(71)出願人　501094845
エー・テイー・イー・サービス株式会社
東京都稲城市東長沼１９７番地
(74)代理人　100108338
弁理士　七條　耕司
(72)発明者　浅田　明
東京都稲城市東長沼１９７番地　エー・テイー・イー・サービス株式会社内
(72)発明者　佐々　裕一
東京都稲城市東長沼１９７番地　エー・テイー・イー・サービス株式会社内

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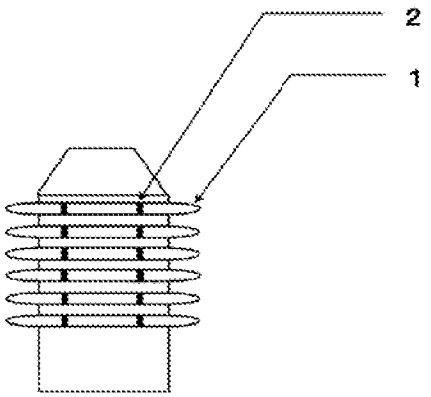
(54)【発明の名称】コンタクトピン及びポゴピン

(57)【要約】
【課題】ベローズ構造を採用して、バネ構造を本体部分に取り込み、構造的な簡素化を図り、さらにはベローズ構造にスリットを入れることにより、ストローク幅とコンタクト圧の調整を図り、全体として、ピンの全体長を短くし、ピンの太さを細くし、バネと本体との一体構造化により、各部品の接触抵抗を無くすことのできるコンタクトピン及びポゴピンを提供すること。
【解決手段】コンタクトピン（又はポゴピン）を一体構造化されたバネ機能を有するベローズ構造１で構成し、さらに、前記ベローズ構造１に、ベローズの突出部の周囲に複数個のスリット２が設けたことを特徴とする。
【選択図】　図１



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【特許請求の範囲】
【請求項１】
一体構造化されたバネ機能を有するベローズ構造からなることを特徴とするコンタクトピン。
【請求項２】
前記ベローズ構造は、ベローズの突出部の周囲に複数個のスリットが設けられていることを特徴とする請求項１に記載のコンタクトピン。
【請求項３】
一体構造化されたバネ機能を有するベローズ構造からなることを特徴とするポゴピン。
【請求項４】
前記ベローズ構造は、ベローズの突出部の周囲に複数個のスリットが設けられていることを特徴とする請求項３に記載のポゴピン。

【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、小型化された電子機器における、プリント基板と半導体集積回路等との電気的な接続を得るためのインターフェース部分の接触子として使用されるコンタクトピン、及び半導体検査装置・電子機器検査装置と被検査回路との電気的な接続を得るためのインターフェース部分の接触子として使用されるポゴピンに関する。
【背景技術】
【０００２】
近年は、電子機器、半導体検査装置・電子機器検査装置の高速・高機能化に伴い、半導体集積回路等の電子部品の高速・高機能化及び多ピン化が進み、これらに用いられるコンタクトピンやポゴピン等の接触子も、それに対応して、低容量、低抵抗、低コンタクト圧の性能が要求されている。
【０００３】
従来のコンタクトピンは、図５に示すように、プランジャ１１、バレル１２、スプリング１３等から構成されているのが一般的であり、またポゴピンも、図６に示すように、プランジャ２１、バレル２２、ボール２３、スプリング２４等から構成されているのが一般的である。
【０００４】
【特許文献１】特開２００２－３３４７６１号公報
【特許文献２】特開平１０－１８９０８７号公報
【発明の開示】
【発明が解決しようとする課題】
【０００５】
しかし、従来のコンタクトピンやポゴピンは、図５及び図６に示すように、複数個の部品群で構成されるため、ピンの全体長を短くしたり、ピンの太さを細くしたり、又は各部品の接触抵抗を低く抑えることが難しかった。さらに、多ピン対応の際に必要とする１ピン当たりのコンタクト圧を低くすることも困難であった。
【０００６】
本発明の目的は、上記の問題点に鑑み、ベローズ構造を採用して、バネ構造を本体部分に取り込み、構造を簡素化し、さらにはベローズ構造にスリットを入れることにより、ストローク幅とコンタクト圧の調整を図ることにより、全体として、ピンの全体長を短くし、ピンの太さを細くし、バネと本体との一体構造化により、各部品の接触抵抗を無くすことを可能にしたコンタクトピン及びポゴピンを提供することにある。
【課題を解決するための手段】
【０００７】

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本発明は、上記の課題を解決するために、次のような手段を採用した。
第１の手段は、一体構造化されたバネ機能を有するベローズ構造からなることを特徴とするコンタクトピンである。
【０００８】
第２の手段は、第１の手段において、前記ベローズ構造は、ベローズの突出部の周囲に複数個のスリットが設けられていることを特徴とするコンタクトピンである。
【０００９】
第３の手段は、一体構造化されたバネ機能を有するベローズ構造からなることを特徴とするポゴピンである。
【００１０】
第４の手段は、第３の手段において、前記ベローズ構造は、ベローズの突出部の周囲に複数個のスリットが設けられていることを特徴とするポゴピンである。
【発明の効果】
【００１１】
請求項１に記載の発明によれば、コンタクトピンが一体構造化されたバネ機能を有するベローズ構造から構成されているので、構造の簡素化、部品の一体化を図ることができ，さらに従来のものと比べて、コンタクトピンを短くかつ細くすることができる。
【００１２】
請求項２に記載の発明によれば、前記ベローズ構造は、ベローズの突出部の周囲に複数個のスリットを設けたので、請求項１に記載の発明の効果に加えて、ストローク幅の増加とコンタクト圧の調整が可能となり、これにより、ピン全体長が短くなり、ベローズ構造部分が短くなっても、必要なストローク幅を確保することができ、さらにはコンタクト圧を低減することができるようになる。その結果、コンタクトピンの低容量、低抵抗、低コンタクト圧化が可能となる。
【００１３】
請求項３に記載の発明によれば、ポゴピンが一体構造化されたバネ機能を有するベローズ構造から構成されているので、構造の簡素化、部品の一体化を図ることができ、さらに従来のものと比べて、ポゴピンを短くかつ細くすることができる。
【００１４】
請求項４に記載の発明によれば、前記ベローズ構造は、ベローズの突出部の周囲に複数個のスリットを設けたので、請求項３に記載の発明の効果に加えて、ストローク幅の増加とコンタクト圧の調整が可能となり、これにより，ピン全体長が短くなり、ベローズ構造部分が短くなっても、必要なストローク幅を確保することができ，さらにはコンタクト圧を低減することができるようになる。その結果、ポゴピンの低容量、低抵抗、低コンタクト圧化が可能となる。
【発明を実施するための最良の形態】
【００１５】
本発明の第１の実施形態を図１及び図２を用いて説明する。
図１は、本実施形態の発明に係るコンタクトピンの構成を示す図である。
同図において、１は一体構造化されたバネ機能を有するベローズ構造、２はベローズ構造１の突出部の周囲に設けられた複数個のスリットである。
【００１６】
図２（１）は、片面のみにプリント基板や電子部品と接触するための部分としての絞りを設けた場合のコンタクトピンの構成を示す図であり，また図２（２）は，両面にプリント基板や電子部品と接触するための部分としての絞りを設けた場合のコンタクトピンの構成を示す図である。
【００１７】
本実施形態の発明によれば，コンタクトピンは、図１及び図２に示すように、一体構造化されたバネ機能を有するベローズ構造から構成され、図５の従来例に示したコンタクトピンのように、プランジャ、バレル、スプリング等の部品群を必要としないので、簡素な

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一体構造のコンタクトピンを実現することができる。これにより、コンタクトピンを従来のものと比べて、短くかつ細くすることができる。

【００１８】

また、本実施形態の発明に係るコンタクトピンは、ベローズ構造１の突出部の周囲に複数個のスリット２を設けたので、ストローク幅の増加とコンタクト圧の調整が可能となり、これにより、ピン全体長が短くなり、ベローズ構造部分が短くなっても、必要なストローク幅を確保することができ、さらにはコンタクト圧を低減できるようになる。

【００１９】

本発明の第２の実施形態を図３及び図４を用いて説明する。

図３は、本実施形態の発明に係るポゴピンの構成を示す図である。

同図において、３は一体構造化されたバネ機能を有するベローズ構造、４はベローズ構造３の突出部の周囲に設けられた複数個のスリットである。

【００２０】

図４（１）は、片面のみにプリント基板や電子部品と接触するための部分としての絞りを設けた場合のポゴピンの構成を示す図であり、また図４（２）は、両面にプリント基板や電子部品と接触するための部分としての絞りを設けた場合のポゴピンの構成を示す図である。

【００２１】

本実施形態の発明によれば、ポゴピンは、図３及び図４に示すように、一体構造化されたバネ機能を有するベローズ構造から構成され、図６の従来例に示したポゴピンのようにプランジャ、バレル、ボール、スプリング等の部品群を必要としないので、簡素な一体構造のポゴピンを実現することができる。これにより、ポゴピンを従来のものと比べて、短くかつ細くすることができる。

【００２２】

また，本実施形態の発明に係るポゴピンは，ベローズ構造３の突出部の周囲に複数個のスリット４を設けたので，ストローク幅の増加とコンタクト圧の調整が可能となり，これにより、ピン全体長が短くなり、ベローズ構造部分が短くなっても、必要なストローク幅を確保することができ、さらにはコンタクト圧を低減できるようになる。

【図面の簡単な説明】

【００２３】

【図１】第１の実施形態の発明に係るコンタクトピンの構成を示す図である。

【図２】第１の実施形態の発明に係り、片面又は両面にプリント基板や電子部品と接触するための部分としての絞りを設けた場合のコンタクトピンを示す図である。

【図３】第２の実施形態の発明に係るポゴピンの構成を示す図である。

【図４】第２の実施形態の発明に係り、片面又は両面にプリント基板や電子部品と接触するための部分としての絞りを設けた場合のポゴピンを示す図である。

【図５】従来技術に係るコンタクトピンの構成を示す図である。

【図６】従来技術に係るポゴピンの構成を示す図である。

【符号の説明】

【００２４】

１　ベローズ構造
２　スリット
３　ベローズ構造
４　スリット

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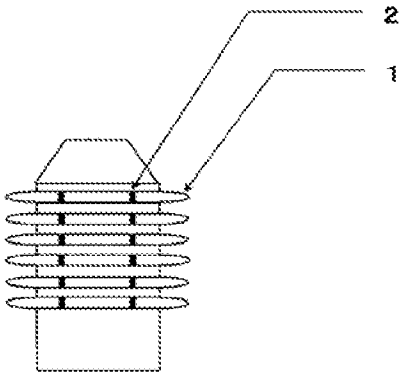
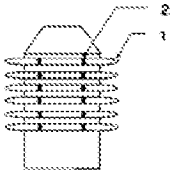
【図１】



【図２】

(1)



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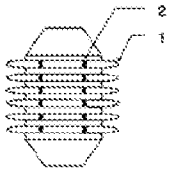
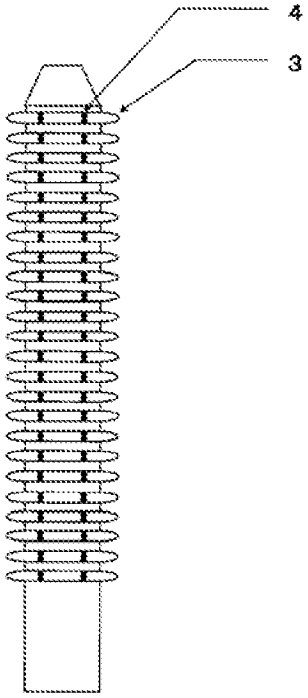


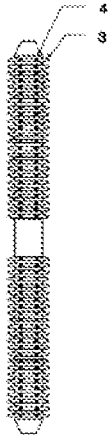
【図３】



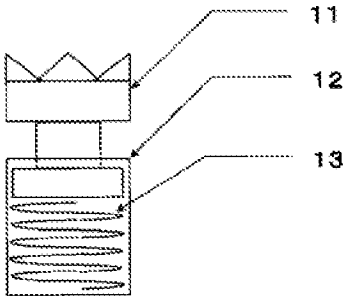
【図４】

(1)

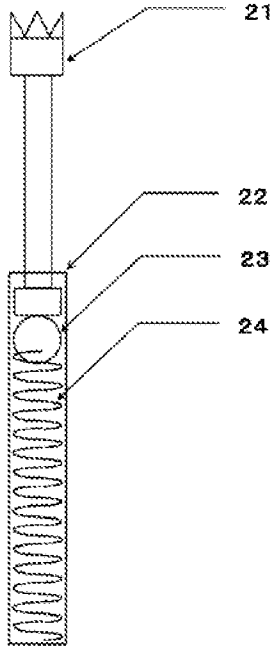
(2)



【図５】



【図６】



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12	Foreign Reference	KR200284460Y1.pdf	123604 a04028bbdc42cc3e13c31f2d2160aeff61804dfe	no	6
Warnings:					
Information:					
13	Foreign Reference	KR1020060061011A.pdf	307801 84bb286fa9786a7574cf37748d97837f14d4768c	no	10
Warnings:					
Information:					
14	Foreign Reference	JP2543161Y-image.pdf	1541901 800bc36e247e4d94f6a893db43de942b8106a978	no	3
Warnings:					
Information:					
15	Foreign Reference	JP2005351785A-image.pdf	1888412 8344f83d36aae77dfc6fb838aefe177db5afee4f	no	5
Warnings:					
Information:					
			Total Files Size (in bytes):	6115919	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Na Application No.: 15/724,261 Filed: 10/3/2017 Title: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT Attorney Docket No.: NA001KR_US3	Art Unit: Examiner:

PRELIMINARY AMENDMENT UNDER 37 CFR 1.115

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Please amend this application as follows, where amendments to specification start on page 2, claims on page 10, and drawings on page 14 and remarks start on page 15:

In the Title:

METHOD, SYSTEM, AND APPARATUS FOR ~~DERMALOGICAL~~ DERMATOLOGICAL TREATMENT

ENDYMED EXHIBIT 1002 - 520/733

In the Specification:

The many minor and grammatical changes to the specification are shown in previously submitted marked up and clean version of the specification. Entry is respectfully requested.

ENDYMED EXHIBIT 1002 - 521/733

In the claims:

1. (Cancelled).
2. (Cancelled).
3. (Cancelled).
4. (Cancelled).
5. (Cancelled).
6. (Cancelled).
7. (Cancelled).
8. (Cancelled).
9. (Cancelled).
10. (Cancelled).
11. (Cancelled).
12. (Cancelled).
13. (Cancelled).
14. (Cancelled).
15. (Cancelled).
16. (Cancelled).
17. (Cancelled).
18. (Cancelled).
19. (Cancelled).
20. (Cancelled).

ENDYMED EXHIBIT 1002 - 522/733

21. (Newly Added) A method of treating dermatological tissue, comprising:

placing a user holdable device releasably couplable deployable needle assembly end surface on or near dermatological tissue to be treated, the holdable device including a proximal end and the releasably couplable deployable needle assembly, the releasably couplable deployable needle assembly mechanically separatably from the proximal end and including a plurality of needles extendable from the releasably couplable deployable needle assembly end surface, one of the proximal end and the releasably couplable deployable needle assembly including at least one electrical contact and the other including at least one electrical contact couplable to the one of the proximal end and the releasably couplable deployable needle assembly at least one electrical contact; and

communicating electrical signals from the proximal end to releasably couplable deployable needle assembly via the electrical conductors.

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22. (Newly Added) The method of claim 21, further comprising energizing a motor coupled to a releasably couplable deployable needle assembly to cause a plurality of the extendable needles to extend a desired distance from the releasably couplable deployable needle assembly end surface.

23. (Newly Added) The method of claim 22, further comprising energizing the plurality of extended needles via a signal generator electrically coupled to the proximal end.

24. (Newly Added) The method of claim 21, wherein one of the least one electrical contacts includes a pin that is extendable in the same direction as the needles to maintain an electrical connection with the other of the at least one electrical contacts as the needles are deployed.

25. (Newly Added) The method of claim 21, wherein the proximal end includes a motor with a draft shaft releasably couplable to the releasably couplable deployable needle assembly and the method further including energizing the motor coupled to a releasably couplable deployable needle assembly to cause a plurality of the extendable needles to extend a desired distance from the releasably couplable deployable needle assembly end surface.

ENDYMED EXHIBIT 1002 - 523/733

26. (Newly Added) The method of claim 23, wherein the proximal end further includes at least one embedded LED therein and further including energizing the LED when the signal generator is energized, the at least one embedded LED illuminating the releasably couplable deployable needle assembly when energized.

27. (Newly Added) The method of claim 21, wherein one of the least one electrical contacts includes a pin that is extendable in the same direction as the needles.

28. (Newly Added) The method of claim 25, wherein the releasably couplable deployable needle assembly includes a translucent section to communicate illumination from the least one embedded LED to the plurality of extendable needles.

29. (Newly Added) The method of claim 21, wherein a first extendable electrical contact is coupled to a first plurality of the plurality of extendable needles and a second extendable electrical contact is coupled to a second, different plurality of the plurality of extendable needles.

30. (Newly Added) The method of claim 21, wherein one of the proximal end and the releasably couplable deployable needle assembly including at least two electrical contacts and the other including at least two electrical contacts couplable to the one of the proximal end and the releasably couplable deployable needle assembly at least two electrical contacts.

31. (Newly Added) The method of claim 23, further comprising energizing the motor to deploy the plurality of extendable needles to a predetermined depth and directing the signal generator to energize the plurality of extended needles to a predetermined intensity for a predetermined duty cycle.

ENDYMED EXHIBIT 1002 - 524/733

32. (Newly Added) An apparatus for treating dermatological tissue, comprising:

a user holdable device releasably couplable deployable needle assembly end surface on or near dermatological tissue to be treated, the holdable device including a proximal end and the releasably couplable deployable needle assembly, the releasably couplable deployable needle assembly mechanically separatably from the proximal end and including a plurality of needles extendable from the releasably couplable deployable needle assembly end surface, one of the proximal end and the releasably couplable deployable needle assembly including at least one electrical contact and the other including at least one electrical contact couplable to the one of the proximal end and the releasably couplable deployable needle assembly at least one electrical contact.

33. (Newly Added) The apparatus of claim 32, further including a motor coupled to the releasably couplable deployable needle assembly that causes the plurality of extendable needles to extend a desired distance from the releasably couplable deployable needle assembly end surface when the motor is energized with a particular signal.

34. (Newly Added) The apparatus of claim 33, further including a signal generator electrically coupled to the proximal end to energize the plurality of extended needles.

35. (Newly Added) The apparatus of claim 34, wherein the user holdable device proximal end includes an electrical connector couplable to the signal generator.

36. (Newly Added) The apparatus of claim 33, wherein the proximal end includes the motor, the motor including a draft shaft releasably couplable to the releasably couplable deployable needle assembly.

37. (Newly Added) The apparatus of claim 32, wherein the proximal end further includes at least one embedded LED therein and the apparatus further including a photonic signal generator electrically coupled to the least one embedded LED, the at least one embedded LED illuminating the releasably couplable deployable needle assembly when energized.

ENDYMED EXHIBIT 1002 - 525/733

38. (Newly Added) The apparatus of claim 32, the wherein one of the least one electrical contacts includes a pin that is extendable in the same direction as the needles.

39. (Newly Added) The apparatus of claim 32, wherein one of the proximal end and the releasably couplable deployable needle assembly including at least two electrical contacts and the other including at least two electrical contacts couplable to the one of the proximal end and the releasably couplable deployable needle assembly at least two electrical contacts.

40. (Newly Added) The apparatus of claim 32, wherein one of the least one electrical contacts includes a pin that is extendable in the same direction as the needles to maintain an electrical connection with the other of the at least one electrical contacts as the needles are deployed.

ENDYMED EXHIBIT 1002 - 526/733

In the drawings:

Please replace pages 8 and 16-20 of the drawings with replacement pages previously submitted. In the drawings, FIG. 4A reference 56 has been changed to 104. In FIG. 11 springs (reference 924M) has been added. Support for the spring addition is present in paragraph 0081 of the specification as filed.

ENDYMED EXHIBIT 1002 - 527/733

REMARKS

Claims 1-20 were pending. Claims 1-20 have been cancelled and claims 21-40 have been added. Upon entry of this preliminary amendment, claims 21-40 will be pending. Entry of this preliminary amendment is respectfully requested. Applicant has also amended the specification to correct minor grammatical or reference errors as shown in the marked up and clean copies of the specification and replaced five drawings to correct errors and improve their quality. No new matter has been added. Entry of the preliminary amendments is respectfully requested.

.

Respectfully Submitted,

11/15/2017 /mwresq/_____
Date Merle Richman
Patent Attorney
Reg. No. 38282

Merle Richman
Patent Attorney
Customer ID - 26338
PO Box 3333
La Jolla, CA 92038-3333

Tel. 858 551-2030

ENDYMED EXHIBIT 1002 - 528/733

Doc Code: TRAN.LET
Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FORM *(to be used for all correspondence after initial filing)*		Application Number	15724261
		Filing Date	Oct 3, 2017
		First Named Inventor	Na, Jongju
		Art Unit	
		Examiner Name	
Total Number of Pages in This Submission		Attorney Docket Number	NA001KR_US3

ENCLOSURES ***(Check all that apply)***

☐ Fee Transmittal Form	☐ Drawing(s)	☐ After Allowance communication to TC
☐ Fee Attached	☐ Licensing-related Papers	☐ Appeal Communication to Board of Appeals and Interferences
☒ Pre-Amendment / Reply (9 pages)	☐ Petition	☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
☐ After Final	☐ Petition to Convert to a Provisional Application	☐ Proprietary Information
☐ Affidavits/declaration(s)	☐ Power of Attorney, Revocation Change of Correspondence Address	☐ Status Letter
☐ Extension of Time Request	☐ Terminal Disclaimer	☐ Other Enclosure(s) (please identify below):
☐ Express Abandonment Request	☐ Request for Refund	
☐ Information Disclosure Statement	☐ CD, Number of CD(s) _____	
	☐ Landscape Table on CD	
☐ Certified Copy of Priority Document(s)		
☐ Reply to Missing Parts/ Incomplete Application	Remarks	
☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Merle W. Richman, Cust ID - 26338		
Signature	/mwresq/		
Printed name	Merle Richman		
Date	November 15, 2017	Reg. No.	38282

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being electronically transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Signature	/mwresq/		
Typed or printed name	Merle Richman	Date	November 15, 2017

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

In you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	30965278
Application Number:	15724261
International Application Number:	
Confirmation Number:	3803
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Customer Number:	26338
Filer:	Merle W. Richman
Filer Authorized By:	
Attorney Docket Number:	NA001KR_US3
Receipt Date:	15-NOV-2017
Filing Date:	03-OCT-2017
Time Stamp:	22:00:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Preliminary Amendment	na001kr_us3-preliminary-amendment-2nd.pdf	99345 4a924b7514323412e97e1341f96cff6a5c607c4a	no	9

Warnings:

ENDYMED EXHIBIT 1002 - 530/733

Information:					
2	Transmittal Letter	na001kr_us3-preliminary-amendment-transmittal.pdf	110761 e21b326b870bed69b9c1142796a427652ac8ca70	no	1
Warnings:					
Information:					
			Total Files Size (in bytes):	210106	

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/724,261	10/03/2017	Jongju Na	NA001KR_US3

CONFIRMATION NO. 3803

26338
MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

FORMALITIES LETTER

OC000000095523666

Date Mailed: 11/17/2017

NOTICE OF INCOMPLETE REPLY (NONPROVISIONAL)

Filing Date Granted

The U.S. Patent and Trademark Office has received your reply on to the Notice to File Missing Parts (Notice) mailed 11/03/2017 and it has been entered into the nonprovisional application. The reply, however, does not include the following items required in the Notice. A complete reply must be timely filed to prevent ABANDONMENT of the above-identified application. Replies should be mailed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

Applicant is given **TWO MONTHS** from the date of the Notice to File Missing Parts (Notice) mailed 11/03/2017 within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
- The application search fee was not received.
- The application examination fee was not received.
- Surcharge as set forth in 37 CFR 1.16(f) was not received.
  The surcharge is due for any one of:
  - late submission of the basic filing fee, search fee, or examination fee,
  - late submission of inventor's oath or declaration,
  - filing an application that does not contain at least one claim on filing, or
  - submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of the Notice to avoid abandonment is/are itemized below. Small entity discount is in effect. If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- $ **70** basic filing fee.
- $ **70** surcharge.
- $ **300** search fee.
- $ **360** examination fee.
- $(**0**) previous unapplied payment amount.
- $ **800** TOTAL FEE BALANCE DUE.

ENDYMED EXHIBIT 1002 - 532/733

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice". https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/agizaw/

ENDYMED EXHIBIT 1002 - 533/733

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/724,261

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Na	
Application No.: 15724261	
Filed: 10/3/2017	Art Unit: 3769
Title: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT	
Attorney Docket No.: NA001KR_US3	

RESPONSE TO NOTICE TO FILE MISSING PARTS OF APPLICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to a Notice to File Missing Parts of Application under 37 CFR 1.53(f). Enclosed is a copy of said Notice and the following documents and fees to complete the filing requirements of the above-identified application.

( ) Executed Declaration and Power of Attorney. The above-identified application is the same application which the inventor executed by signing the enclosed declaration.

(X) Statutory basic filing fee (X) Utility ( ) Design

(X) Missing Parts Surcharge $70.00

( ) A Petition for Extension of Time for reply to Notice of Missing Parts is attached.
- ( ) one month ($100.00)
- ( ) two months ($300.00)
- ( ) three months ($700.00)
- ( ) four months ($1100.00)

I hereby certify that this Correspondence is being deposited with the Unitec States Postal service with sufficient postage for first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or the correspondence is being electronically transmitted to the USPTO, on the date indicated below.

Date of Deposit: 11/17/2017

Typed Name: Merle W. Richman

Signature: /mwresq/_____

Respectfully submitted,

By /mwresq/
Merle Richman, Patent Attorney

Reg No. 38282

Date: 11/17/2017

Telephone No. 858 320-2030

Electronic Patent Application Fee Transmittal

Application Number:	15724261
Filing Date:	03-Oct-2017
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Filer:	Merle W. Richman
Attorney Docket Number:	NA001KR_US3

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	70	70
UTILITY SEARCH FEE	2111	1	300	300
UTILITY EXAMINATION FEE	2311	1	360	360
Pages:				
Claims:				
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	2051	1	70	70
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**800**

Electronic Acknowledgement Receipt

EFS ID:	30991384
Application Number:	15724261
International Application Number:	
Confirmation Number:	3803
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Customer Number:	26338
Filer:	Merle W. Richman
Filer Authorized By:	
Attorney Docket Number:	NA001KR_US3
Receipt Date:	18-NOV-2017
Filing Date:	03-OCT-2017
Time Stamp:	01:04:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Response to Pre-Exam Formalities Notice	na001kr_us3-missing-parts-response.pdf	75587 c06bd4e942f0eee3225df7b49eb12a30418d4a3d	no	1

Warnings:

ENDYMED EXHIBIT 1002 - 538/733

Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37095 e25d81a06c77af9c1f37dbedb0c3d287ec21529e	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	112682	

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New Applications Under 35 U.S.C. 111

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/724,261	10/03/2017	Jongju Na	NA001KR_US3

CONFIRMATION NO. 3803

26338
MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

FORMALITIES LETTER

OC000000095586125

Date Mailed: 11/22/2017

NOTICE OF INCOMPLETE REPLY (NONPROVISIONAL)

Filing Date Granted

The U.S. Patent and Trademark Office has received your reply on to the Notice to File Missing Parts (Notice) mailed 11/03/2017 and it has been entered into the nonprovisional application. The reply, however, does not include the following items required in the Notice. A complete reply must be timely filed to prevent ABANDONMENT of the above-identified application. Replies should be mailed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

Applicant is given **TWO MONTHS** from the date of the Notice to File Missing Parts (Notice) mailed 11/03/2017 within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
- The application search fee was not received.
- The application examination fee was not received.
- Surcharge as set forth in 37 CFR 1.16(f) was not received.
  The surcharge is due for any one of:
  - late submission of the basic filing fee, search fee, or examination fee,
  - late submission of inventor's oath or declaration,
  - filing an application that does not contain at least one claim on filing, or
  - submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of the Notice to avoid abandonment is/are itemized below. Small entity discount is in effect. If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- $ **70** basic filing fee.
- $ **70** surcharge.
- $ **300** search fee.
- $ **360** examination fee.
- $(**0**) previous unapplied payment amount.
- $ **800** TOTAL FEE BALANCE DUE.

ENDYMED EXHIBIT 1002 - 540/733

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice". https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/fasrat/

ENDYMED EXHIBIT 1002 - 541/733

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/724,261

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Na	
Application No.: 15724261	
Filed: 10/3/2017	Art Unit: 3769
Title: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT	
Attorney Docket No.: NA001KR_US3	

RESPONSE TO NOTICE TO FILE MISSING PARTS OF APPLICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to a Notice to File Missing Parts of Application under 37 CFR 1.53(f). Enclosed is a copy of said Notice and the following documents and fees to complete the filing requirements of the above-identified application.

( ) Executed Declaration and Power of Attorney. The above-identified application is the same application which the inventor executed by signing the enclosed declaration.

(X) Statutory basic filing fee (X) Utility ( ) Design

(X) Missing Parts Surcharge $70.00

(X) A Petition for Extension of Time for reply to Notice of Missing Parts is attached.
- (X) one month ($100.00)
- ( ) two months ($300.00)
- ( ) three months ($700.00)
- ( ) four months ($1100.00)

I hereby certify that this Correspondence is being deposited with the Unitec States Postal service with sufficient postage for first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or the correspondence is being electronically transmitted to the USPTO, on the date indicated below.

Date of Deposit: 1/10/2018

Typed Name: Merle W. Richman

Signature: /mwresq/_____

Respectfully submitted,

By /mwresq/
Merle Richman, Patent Attorney

Reg No. 38282

Date: 1/10/2018

Telephone No. 858 320-2030

Electronic Patent Application Fee Transmittal

Application Number:	15724261
Filing Date:	03-Oct-2017
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Filer:	Merle W. Richman
Attorney Docket Number:	NA001KR_US3

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	70	70
UTILITY SEARCH FEE	2111	1	300	300
UTILITY EXAMINATION FEE	2311	1	360	360
Pages:				
Claims:				
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	2051	1	70	70
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	2251	1	100	100
Miscellaneous:				
		Total in USD ($)		**900**

Electronic Acknowledgement Receipt

EFS ID:	31467277
Application Number:	15724261
International Application Number:	
Confirmation Number:	3803
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Customer Number:	26338
Filer:	Merle W. Richman
Filer Authorized By:	
Attorney Docket Number:	NA001KR_US3
Receipt Date:	10-JAN-2018
Filing Date:	03-OCT-2017
Time Stamp:	21:20:00
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$900
RAM confirmation Number	011118INTEFSW00006862601984
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Response to Pre-Exam Formalities Notice	na001kr_us3-missing-parts-response.pdf	76686 e689e54ed7242d4df264ec46eba1d5f446385911	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	39066 33e6a84d11fdc5b564d87ec6bddf110d3328f64b	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	115752		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/724,261	10/03/2017	3769	800	NA001KR_US3	20	2

CONFIRMATION NO. 3803

UPDATED FILING RECEIPT

26338
MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

OC000000098844256

Date Mailed: 01/12/2018

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Jongju Na, Songpa-Gu, KOREA, REPUBLIC OF;

Applicant(s)

Jongju Na, Songpa-Gu, KOREA, REPUBLIC OF;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 15/096,686 04/12/2016 PAT 9775774
which is a CON of 13/825,083 01/20/2014 PAT 9320536 *
which is a 371 of PCT/KR2012/001335 02/22/2012
which claims benefit of 61/449,080 03/03/2011
and is a CON of 13/060,274 03/30/2011 PAT 8979912
which is a 371 of PCT/US08/74131 08/22/2008
(*)Data provided by applicant is not consistent with PTO records.

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)
REPUBLIC OF KOREA 10-2008-0076993 08/06/2008

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: No

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

ENDYMED EXHIBIT 1002 - 548/733

Request to Retrieve - This application either claims priority to one or more applications filed in an intellectual property Office that participates in the Priority Document Exchange (PDX) program or contains a proper **Request to Retrieve Electronic Priority Application(s)** (PTO/SB/38 or its equivalent). Consequently, the USPTO will attempt to electronically retrieve these priority documents.

If Required, Foreign Filing License Granted: 11/02/2017
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/724,261**
Projected Publication Date: 04/19/2018
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

Preliminary Class

606

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: Yes

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative,

ENDYMED EXHIBIT 1002 - 549/733

this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

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technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

ENDYMED EXHIBIT 1002 - 551/733

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/724,261

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*	x 40 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*	x 210 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	730		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

대한민국 특허청
KOREAN INTELLECTUAL PROPERTY OFFICE

별첨 사본은 아래 출원의 원본과 동일함을 증명함.

This is to certify that the following application annexed hereto is a true copy from the records of the Korean Intellectual Property Office.

출 원 번 호 : 10-2008-0076993
Application Number

출 원 년 월 일 : 2008년 08월 06일
Filing Date AUG. 06, 2008

출 원 인 : 라종주
Applicant(s) NA Jong Ju

2018년 01월 15일

특 허 청
COMMISSIONER

제출 일자 : 2008-08-06

【서지사항】

【서류명】 특허출원서

【출원구분】 특허출원

【출원인】

【성명】 라종주

【특허고객번호】 4-2007-017445-9

【대리인】

【명칭】 특허법인 맥

【대리인번호】 9-2003-100064-5

【지정된변리사】 홍재일, 홍종원, 이은욱, 박천수, 박혜성, 김현호

【포괄위임등록번호】 2007-034893-7

【발명의 국문명칭】 전기 피부 미용기 및 전기 피부 미용 시스템

【발명의 영문명칭】 Electric Skin Treatment Device and Electric Skin Treatment System

【발명자】

【성명】 라종주

【특허고객번호】 4-2007-017445-9

【심사청구】 청구

【취지】 위와 같이 특허청장에게 제출합니다.

대리인 특허법인 맥 (인)

【수수료】

【출원료】	0	면	38,000 원
【가산출원료】	20	면	0 원
【우선권주장료】	0	건	0 원
【심사청구료】	5	항	269,000 원

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【합계】 307,000 원

【감면사유】 개인(70%감면)

【감면후 수수료】 92,100 원

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제출 일자 : 2008-08-06

【요약서】

【요약】

전기 피부 미용기 및 전기 피부 미용 시스템이 개시된다. 본 발명은, 환자의 피부에 접촉되어 회전되는 롤러부, 롤러부를 환자의 피부상에서 가압할 수 있도록, 롤러부에 결합되는 손잡이부, 및 손잡이부에 결합되며, 롤러부에 전기가 도통되도록 전기발생 장치로부터의 연결단자와 접속되는 전기 입력부를 포함한다. 본 발명에 따르면, 피부층에서의 이온 자극 및 소정 주파수의 전기적인 진동 자극을 가함으로써, 피부층에서의 용액, 크림, 젤, 연고제 등의 흡수율을 획기적으로 높여 피부조직의 효과적인 재생이 가능하게 된다.

【대표도】

도 1

【색인어】

피부, 전기, 롤러, 마사지

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제출 일자 : 2008-08-06

【발명의 설명】

【발명의 명칭】

전기 피부 미용기 및 전기 피부 미용 시스템{Electric Skin Treatment Device and Electric Skin Treatment System}

【발명의 상세한 설명】

【기술분야】

<1> 본 발명은 전기 피부 미용기 및 전기 피부 미용 시스템에 관한 것으로, 더욱 상세하게는 피부조직의 효과적인 재생을 위한 전기 피부 미용기 및 전기 피부 미용 시스템에 관한 것이다.

【배경기술】

<2> 피부조직의 노화, 흉터, 여드름 자국 등을 개선하기 위한 방법으로서, 종래에는 단순히 피부재생을 위한 용액, 크림, 젤, 연고제 등의 의약품을 단순히 피부에 도포하는 방식에 의한 치료만이 이루어졌다. 그러나, 피부에 도포된 용액, 크림, 젤, 연고제 등의 양에서 피부의 진피층으로 흡수되어 치료에 유효하게 작용하는 용액, 크림, 젤, 연고제 등의 양은 상대적으로 그 비율이 매우 작으며, 그 결과 효과적인 피부조직의 개선을 위한 치료가 이루어지지 않는다는 문제점이 있었다. 따라서, 피부조직의 효과적인 재생을 위해 피부층에서의 용액, 크림, 젤, 연고제 등의 흡수율을 획기적으로 높일 수 있는 방법이 필요하게 되었다.

【발명의 내용】

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【해결하고자 하는 과제】

<3> 따라서, 본 발명의 목적은, 피부조직의 효과적인 재생을 위한 전기 피부 미용기 및 전기 피부 미용 시스템을 제공함에 있다.

【과제 해결 수단】

<4> 상기 목적을 달성하기 위한 본 발명에 따른 전기 피부 미용기는, 환자의 피부에 접촉되어 회전되는 롤러부; 상기 롤러부를 환자의 피부상에서 가압할 수 있도록, 상기 롤러부에 결합되는 손잡이부; 및 상기 손잡이부에 결합되며, 상기 롤러부에 전기가 도통되도록 전기발생 장치로부터의 연결단자와 접속되는 전기 입력부를 포함한다.

<5> 한편, 본 발명에 따른 전기 피부 미용 시스템은 환자의 피부에 접촉되어 회전되는 롤러부, 상기 롤러부를 환자의 피부상에서 가압할 수 있도록, 상기 롤러부에 결합되는 손잡이부, 및 상기 손잡이부에 결합되며, 상기 롤러부에 전기가 도통되도록 전기발생 장치로부터의 연결단자와 접속되는 전기 입력부를 구비하는 전기 피부 미용기; 및 상기 전기 피부 미용기의 상기 전기 입력부와 접속되는 연결단자를 통해 상기 전기 피부 미용기의 상기 롤러부에 전기가 도통되도록 하는 전기발생 장치를 포함한다.

<6> 한편, 본 발명에 따른 전기 피부 미용기는, 환자의 피부에 접촉되어 회전되는 롤러부; 상기 롤러부를 환자의 피부상에서 가압할 수 있도록, 상기 롤러부에 결합되는 손잡이부; 및 상기 롤러부에 전기가 도통되도록 상기 롤러부에 전압을 공급

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하는 전원 공급부를 포함한다.

<7> 바람직하게는, 상기 환자가 손으로 잡을 수 있도록 상기 손잡이부의 외부에 결합되며, 상기 롤러부에 공급된 전압과 반대 극성의 전압을 상기 전원 공급부로부터 공급받는 접지부를 더 포함한다.

<8> 한편, 본 발명에 따른 전기 피부 미용기는, 일면에 복수개의 금속성 침체가 삽입된 평판부; 상기 평판부의 중심축 상에서 상기 평판부에 결합되는 손잡이부; 및 상기 금속성 침체에 전기가 도통되도록 상기 금속성 침체에 전압을 공급하는 전원 공급부를 포함한다.

<9> 바람직하게는, 상기 손잡이부의 외부에 결합되며, 상기 금속성 침체에 공급된 전압과 반대 극성의 전압을 상기 전원 공급부로부터 공급받는 접지부를 더 포함한다.

<10> 또한, 상기 복수개의 금속성 침체의 끝에는 상기 전원 공급부에 의해 이온, 라디오파, 초음파, 고주파, 중주파, 및 저주파 중 어느 하나가 발생하는 것을 특징으로 한다.

【효과】

<11> 이상 설명한 바와 같이, 본 발명에 따르면, 피부층에서의 이온 자극 및 소정 주파수의 전기적인 진동 자극을 가함으로써, 피부층에서의 용액, 크림, 젤, 연고제 등의 흡수율을 획기적으로 높여 피부조직의 효과적인 재생이 가능하게 된다.

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【발명의 실시를 위한 구체적인 내용】

<12> 이하에서는 도면을 참조하여 본 발명을 보다 상세하게 설명한다. 도면들 중 동일한 구성요소들은 가능한 한 어느 곳에서든지 동일한 부호들로 나타내고 있음에 유의해야 한다. 또한 본 발명의 요지를 불필요하게 흐릴 수 있는 공지 기능 및 구성에 대한 상세한 설명은 생략한다.

<13> 도 1은 본 발명의 일실시예에 따른 전기 피부 미용 시스템을 이용한 시술 장면을 나타내는 도면이다. 도 1을 참조하면, 본 발명에 따른 전기 피부 미용 시스템은 전기 피부 미용기(100), 전기발생 장치(200), 및 연결단자(300a,300b)를 포함한다.

<14> 여기서, 전기 피부 미용기(100)는 연결단자(300a)를 통해서 공급받은 전기발생 장치(200)에서 생성된 전기를 이용하여 환자의 치료부위에 전기자극을 가하며, 전기발생 장치(200)는 연결단자(300a)를 통해서 전기 피부 미용기(100)에 전기를 공급하고, 연결단자(300a,300b)는 전기발생 장치(200)의 (+),(-)극에 각각 연결되어 있으며, 전기발생 장치(200)의 (-)극에 연결된 연결단자(300a)는 전기 피부 미용기(100)에 접속되어, 전기 피부 미용기(100)에 전기발생 장치(200)로부터의 전기가 도통되도록 하고, 전기발생 장치(200)의 (+)극에 연결된 연결단자(300b)는 환자의 신체에 부착된다.

<15> 즉, 시술자는 전기발생 장치(200)의 (-)극에 연결된 연결단자(300a)를 전기 피부 미용기(100)에 접속하고, 전기발생 장치(200)의 (+)극에 연결된 연결단자

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(300b)를 환자의 신체에 부착시킴으로써, 전기 피부 미용기(100)를 통하여 시술을 하는 동안에 환자의 치료부위에 전기자극이 가해지도록 한다.

<16> 이러한 과정 중에 시술자는 환자의 치료부위에 비타민C 원액 또는 콜라겐 등을 반복적으로 도포함으로써, 피부 조직의 재생이 효율적으로 이루어지게 한다. 한편, 본 발명을 실시함에 있어서, 전기발생 장치(200)의 (+)극에 연결된 연결단자(300a)를 전기 피부 미용기(100)에 접속하고, 전기발생 장치(200)의 (-)극에 연결된 연결단자(300b)를 환자의 신체에 부착할 수도 있을 것이다.

<17> 본 발명을 실시함에 있어서, 전기발생 장치(200)는 교류전류를 발생시킬 수도 있을 것이며, 주파수에 따라 전기 피부 미용기(100) 상의 금속성 침체의 끝에는 라디오파, 초음파, 고주파, 중주파, 및 저주파 등이 발생할 수 있을 것이다. 한편, 전기발생 장치(200)는 (+)전류와 (-)전류가 일정 주기로 교번되는 펄스 전류를 발생시킬 수도 있을 것이다.

<18> 도 2는 본 발명의 일실시예에 따른 전기 피부 미용기를 도시한 도면이다. 도 2를 참조하면, 본 발명의 일실시예에 따른 전기 피부 미용기(100)는 전기 입력부(110), 손잡이부(130), 및 롤러부(450)를 포함한다.

<19> 여기서, 전기 입력부(110)에는 전기발생 장치(200)로부터의 연결단자(300a)가 삽입되며, 전기 피부 미용기(100)를 이용한 시술에 필요한 전기가 전기발생 장치(200)로부터 연결단자(300a)를 통해 전기 입력부(110)로 입력된다.

<20> 한편, 손잡이부(130)는 시술자가 본 발명에 따른 전기 피부 미용기(100)로

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환자에게 시술을 하는 경우에 손으로 잡는 부분이며, 롤러부(450)는 환자의 시술부위에 직접 가압을 하는 부분으로서, 환자의 피부에 접촉된 상태에서 회전될 수 있도록 제작된다.

<21> 또한, 롤러부(450)는 금속 재질로 제작되어, 전기 입력부(110)를 통해 입력된 전기가 롤러부(450)를 통해 환자의 피부에 전달된다.

<22> 즉, 시술자는 환자의 시술부위 상에서 전기 피부 미용기(100)의 손잡이부(130)를 잡고 적당한 압력을 가하여 롤러부(450)를 굴림으로써, 환자의 시술부위에 이온 자극 및 전기 자극을 가할 수 있게 된다.

<23> 도 3은 본 발명의 다른 실시예에 따른 전기 피부 미용기의 구조를 나타낸 도면이다. 도 3을 참조하면, 본 발명의 다른 실시예에 따른 전기 피부 미용기(100)는 손잡이부(130), 롤러부(450), 전원 공급부(170), 스위칭부(175), 및 접지부(190)를 포함한다.

<24> 손잡이부(130), 및 롤러부(450)는 도 2에서의 본 발명의 일실시예에 따른 전기 피부 미용기(100)에서의 손잡이부(130), 및 롤러부(450)와 기능 및 작용이 동일하다.

<25> 도 2에서의 본 발명의 일실시예에 따른 전기 피부 미용기(100)는 전기 입력부(110)가 구비되어 외부의 전기발생 장치(200)로부터의 전기가 입력되었으나, 도 3에서의 본 발명의 다른 실시예에 따른 전기 피부 미용기(100)는 휴대용으로 제작된 것으로서, 내부에 자체 전원 공급부(170)를 구비하고 있다.

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<26> 즉, 전원 공급부(170)에 연결된 스위칭부(175)를 'on'으로 하는 경우에, 전원 공급부(170)는 롤러부(450)에 전압을 공급하여 롤러부(450)에는 전기가 흐르게 된다.

<27> 한편, 도 3에서의 전기 피부 미용기(100)의 손잡이부(130)의 외부에는 금속 재질의 접지부(190)가 결합되어 있으며, 접지부(190)는 롤러부(450)에 공급된 전압과 반대 극성의 전압을 전원 공급부(170)로부터 공급받는다.

<28> 그에 따라, 도 3에서의 전기 피부 미용기(100)를 이용하여 환자가 직접 시술하는 경우에 (+)전압이 공급되는 롤러부(450)는 시술부위 피부에 접촉한 상태에서 (-)전압이 공급되는 접지부(190)를 손으로 파지함으로써 치료부위에 전기자극이 가해지게 된다.

<29> 즉, 도 3에서의 전기 피부 미용기(100)에 의하면, 환자는 전기 피부 미용기(100)를 휴대하고 다니면서, 스위칭부(175)를 'on'으로 한 뒤, 손잡이부(130)에 결합된 접지부(190)를 손으로 파지한 상태에서 전기가 흐르는 롤러부(450)를 자신의 얼굴 등의 피부에 직접 문지르는 동작을 통해 직접 시술을 할 수 있게 된다.

<30> 도 4는 본 발명의 또 다른 실시예에 따른 전기 피부 미용기의 구조를 나타낸 도면이다. 도 4를 참조하면, 본 발명의 또 다른 실시예에 따른 전기 피부 미용기(100)는 도 3에서의 롤러부(450) 대신에 평판부(150)를 구비한다.

<31> 도 4에서의 본 발명의 또 다른 실시예에 따른 전기 피부 미용기는 도 3에서의 전기 피부 미용기(100)에서와 같이 휴대용으로 제작된 것으로서, 내부에 자체

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전원 공급부(170)를 구비하고 있다.

<32> 한편, 도 4에서의 평판부(150)는 환자의 시술부위에 직접 가압을 하는 부분으로서, 평판부(150)의 하측면에는 다수의 극미세 침체(micro needle:151)가 구비되어 있다.

<33> 여기서, 극미세 침체(151)는 평판부(150)에 형성된 다수의 홀에 삽입되어 고정되어 있으며, 평판부(150)를 기준으로 일정한 길이(A)만큼 돌출되어 있다. 극미세 침체(151)의 돌출길이(A)는 0.8㎜ 또는 2.1㎜ 또는 0.24㎜인 것이 바람직하며, 극미세 침체(151)의 지름은 0.3㎜로 함이 바람직할 것이나, 본 발명을 실시함에 있어서, 극미체 침체(151)의 돌출길이(A) 및 극미세 침체(151)의 지름은 시술부위 및 시술용도에 따라 다양한 변경 및 조합이 가능할 것이다.

<34> 또한, 전원 공급부(170)로부터 발생된 전기는 손잡이부(130)의 내부에 구비되어 있는 전기 전달체를 통하여 극미세 침체(151)에 전달되며, 극미체 침체(151)는 시술자에 의해 피부 진피층에 삽입된 상태에서 피부조직에 이온 자극 및 소정 주파수의 전기 자극을 가하게 된다.

<35> 한편, 본 발명에 따른 전기 침술기의 손잡이부(130)의 내부에는 시술의 용이성을 확보하기 위한 탄성절편(133)이 적어도 하나 이상 형성되어 있는 것이 바람직하다. 손잡이부(130)의 내부에 삽입된 탄성절편(133)에는 탄성특성이 우수한 고무절편이 사용될 수도 있고, 기타 판형 스프링 등이 사용될 수도 있을 것이다.

<36> 손잡이부(130)의 내부에 삽입된 탄성절편(133)은 극미세 침체(151)가 시술부

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위의 진피층으로 부드럽게 삽입되어 이온 자극 및 소정 주파수의 진동 자극을 가하도록 하는 기능을 하게 된다.

<37> 전원 공급부(170)에 구비된 스위칭부(175)를 'on'으로 하는 경우에, 전원 공급부(170)는 극미세 침체(151)에 전압을 공급하며, 손잡이부(130)의 외부에 결합된 금속성의 접지부(190)에는 극미세 침체(151)에 공급된 전압과 반대 극성의 전압이 공급된다.

<38> 즉, 환자는 도 4에서의 전기 피부 미용기(100)를 직접 시술하는 경우에 (+)전압이 공급되는 극미세 침체(151)를 시술부위 피부 진피층에 삽입한 상태에서 (-)전압이 공급되는 접지부(190)를 손으로 파지함으로써 치료부위에 전기자극이 가해지도록 한다.

<39> 도 5는 도 4에서의 전기 피부 미용기의 저면도로서 평판부의 하측면을 도시하는 도면이다. 도 5를 참조하면, 본 발명에 따른 전기 피부 미용기(100)의 평판부(150)는 직사각형의 형상을 하고 있으며, 그 내부에는 다수의 홀(hole)(159)이 형성되어 있다. 본 발명을 실시함에 있어서, 평판부(150)의 형상은 직사각형, 마름모형, 원형, 타원형 등의 시술자의 편리에 따른 다양한 형상(예를 들어, 환자의 시술 부위의 형상과 유사한 형상 등)으로 이루어질 수 있을 것이다.

<40> 평판부(150)에 형성된 홀(159)은 가로방향으로 14개의 행을 따라 동일한 간격으로 위치하고 있으며, 세로방향으로는 10개의 행을 따라 동일한 간격으로 위치하고 있다. 그 결과, 평판부(150)에는 등간격의 격자형상으로 총 140개의 홀(159)이 형성된다. 이와 같이 평판부(150)에 형성된 다수의 홀(159)에는 환자의 시술부

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위에 미세상처를 내기 위한 극미세 침체(151)가 삽입되어 고정된다.

<41> 다만, 본 발명을 실시함에 있어서, 평판부(150)에 형성된 홀(159)의 개수 및 간격은 시술목적에 따라 적절하게 조정될 수 있을 것이다.

<42> 도 6은 도 4에서의 전기 피부 미용기의 평판부의 분해 사시도이다. 도 4 내지 도 6을 참조하면 본 발명에 따른 전기 피부 미용기(100)의 평판부(150)는 복수개의 극미세 침체(151), 하면부(153), 전기 전도부(155), 및 상면부(157)를 포함한다.

<43> 복수개의 극미세 침체(151)는 하면부(153)에 형성된 복수개의 홀(159)을 통해 하면부(153)와 결합되어 있으며, 하면부(153)는 전기 전도부(155)와 결합되어 있다. 여기서, 복수개의 극미세 침체(151)는 하면부(153)를 관통하여, 전기 전도부(155)에 전기적으로 결합되어 있다.

<44> 전기 피부 미용기(100)의 전원 공급부(170)에서 발생된 전기는 손잡이부(130) 내의 도전성의 전기 전달체를 통하여 전기 전도부(155)로 전해지며, 최종적으로는 전기 전도부(155)에 전기적으로 결합되어 있는 복수개의 극미세 침체(151)에 전달된다. 그 결과 극미체 침체(151)는 시술자에 의해 피부 진피층에 삽입된 상태에서 피부조직에 이온 자극 및 소정 주파수의 전기 자극을 가하게 된다.

<45> 한편, 전기 전도부(155)는 상면부(157)와 결합되어 있으며, 상면부(157)는 전기 피부 미용기(100)의 손잡이부(130)와 일체로서 연결되어 있거나, 나사방식에 의해서 결합되어 있을 수도 있을 것이다.

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<46> 도 4에서의 본 발명의 또 다른 실시예에 따른 전기 피부 미용기(100)의 시술 과정을 설명하면, 환자는 전기 피부 미용기(100)의 손잡이부(130)를 잡고서, 다수의 극미세 침체(151)를 환자의 시술부위에 대고 압력을 가한다. 이러한 과정의 반복을 통해 환자의 시술부위에는 무수히 많은 미세상처(즉, 마이크로 홀)가 생기게 되고, 이러한 마이크로 홀 내의 극미세 침체(151) 끝에서는 소정의 주파수의 전류가 주위의 피부조직으로 전도되며, 이에 따라 극미세 침체(151) 주변의 피부조직의 이온을 흥분시키거나 전기적 진동 자극에 의한 열을 일으키게 된다.

<47> 이와 같은 피부 진피층에서의 이온 자극 및 소정 주파수의 전기적인 진동 자극을 통해서, 피부조직의 효과적인 재생을 위해 피부층에서의 용액, 크림, 젤, 연고제 등의 흡수율을 획기적으로 높여 환자의 피부 조직은 빠른 속도로 새로운 조직을 형성하게 된다.

<48> 이상에서는 본 발명의 바람직한 실시예 및 응용예에 대하여 도시하고 설명하였지만, 본 발명은 상술한 특정의 실시예 및 응용예에 한정되지 아니하며, 청구범위에서 청구하는 본 발명의 요지를 벗어남이 없이 당해 발명이 속하는 기술분야에서 통상의 지식을 가진자에 의해 다양한 변형실시가 가능한 것은 물론이고, 이러한 변형실시들은 본 발명의 기술적 사상이나 전망으로부터 개별적으로 이해되어져서는 안될 것이다.

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【특허청구범위】

【청구항 1】

환자의 피부에 접촉되어 회전되는 롤러부;

상기 롤러부를 환자의 피부상에서 가압할 수 있도록, 상기 롤러부에 결합되는 손잡이부; 및

상기 롤러부에 전기가 도통되도록 상기 롤러부에 전압을 공급하는 전원 공급부

를 포함하는 전기 피부 미용기.

【청구항 2】

제1항에 있어서,

상기 환자가 손으로 잡을 수 있도록 상기 손잡이부의 외부에 결합되며, 상기 롤러부에 공급된 전압과 반대 극성의 전압을 상기 전원 공급부로부터 공급받는 접지부를 더 포함하는 전기 피부 미용기.

【청구항 3】

일면에 복수개의 금속성 침체가 삽입된 평판부;

상기 평판부의 중심축 상에서 상기 평판부에 결합되는 손잡이부; 및

상기 금속성 침체에 전기가 도통되도록 상기 금속성 침체에 전압을 공급하는 전원 공급부

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를 포함하는 전기 피부 미용기.

【청구항 4】

제3항에 있어서,

상기 손잡이부의 외부에 결합되며, 상기 금속성 침체에 공급된 전압과 반대 극성의 전압을 상기 전원 공급부로부터 공급받는 접지부를 더 포함하는 전기 피부 미용기.

【청구항 5】

제1항 또는 제3항에 있어서,

상기 복수개의 금속성 침체의 끝에는 상기 전원 공급부에 의해 이온, 라디오파, 초음파, 고주파, 중주파, 및 저주파 중 어느 하나가 발생하는 것인 전기 피부 미용기.

【도면의 간단한 설명】

<49> 도 1은 본 발명의 일실시예에 따른 전기 피부 미용 시스템을 이용한 시술 장면을 나타내는 도면,

<50> 도 2는 본 발명의 일실시예에 따른 전기 피부 미용기를 도시한 도면,

<51> 도 3은 본 발명의 다른 실시예에 따른 전기 피부 미용기의 구조를 나타낸 도면,

<52> 도 4는 본 발명의 또 다른 실시예에 따른 전기 피부 미용기의 구조를 나타낸

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도면,

<53> 도 5는 도 4에서의 전기 피부 미용기의 저면도로서 평판부의 하측면을 도시하는 도면, 및

<54> 도 6은 도 4에서의 전기 피부 미용기의 평판부의 분해 사시도이다.

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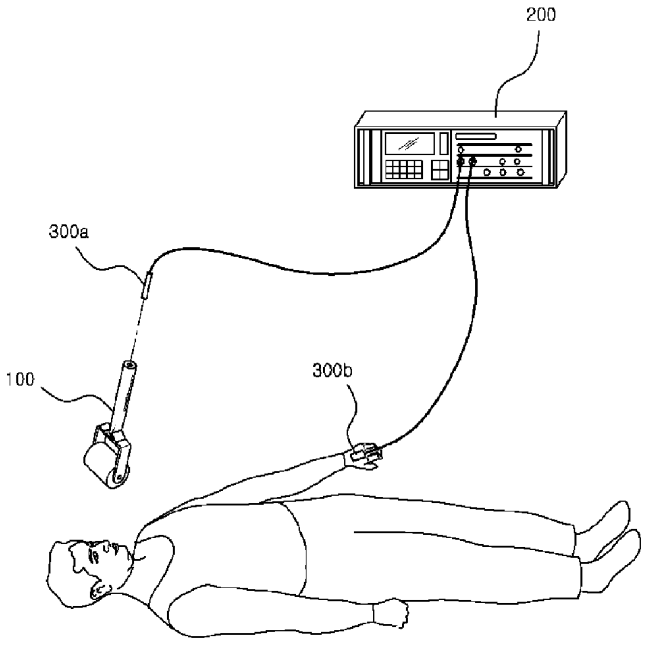
【도면】

【도 1】



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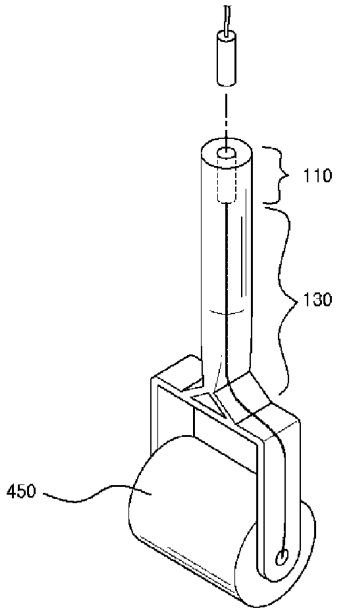
【도 2】



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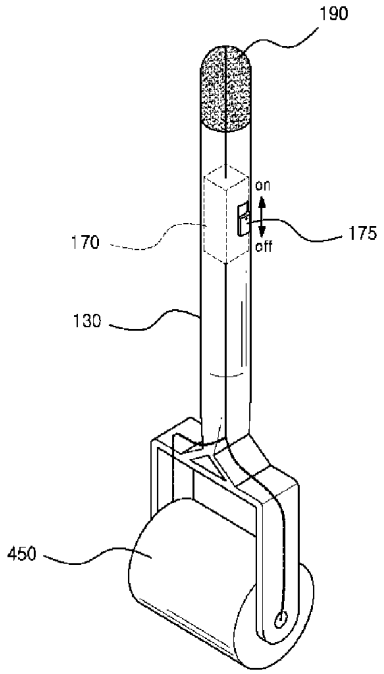
【도 3】



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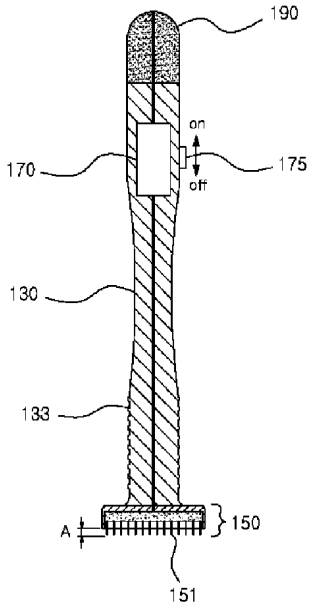
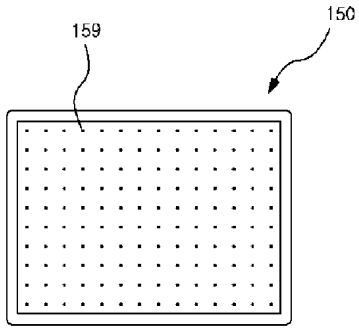
【도 4】



【도 5】



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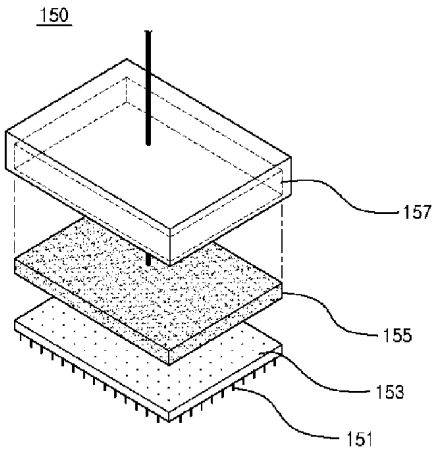
【도 6】



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MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

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MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

EXAMINER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Examiner DAVID C. COMSTOCK	Art Unit 3733	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2017*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *21-40* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *21-40* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *03 October 2017* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☒ All b)☐ Some** c)☐ None of the:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *24 OCT 2017, 07 NOV 2017*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-40 are rejected under 35 U.S.C. 103 as being unpatentable over The General Hospital ("General", WO 2005/096979 A1; cited by Applicant) in view of Yang, Won Dong ("Yang", KR 10-2011-00002210; cited by Applicant).

General discloses the claimed invention including a method of treating dermatological tissue, comprising: placing a user holdable device having coupled thereto a deployable needle assembly end surface on or near dermatological tissue to be treated, the holdable device including a proximal end and the couplable deployable needle assembly, the couplable deployable needle assembly assembled to the proximal end and including a plurality of needles extendable from the couplable deployable needle assembly end surface, one of the proximal end and the couplable deployable needle assembly including at least one electrical contact and the other including at least one electrical contact couplable to the one of the proximal end and the couplable deployable needle assembly at least one electrical contact; and communicating electrical signals from the proximal end to the couplable deployable needle assembly via

the electrical conductors. See, e.g. claims 1-33. The needles are attached to a base and the base is coupled to the housing. A motor extends the needles a desired amount relative to a substrate of the base (e.g. claim 10). The needles are energized with a signal via an electrical connection (e.g. claims 4 and 5). The device energizes a lighting source (e.g. claim 25). General discloses the claimed invention except for explicitly reciting the base portion being releasable and the LED lights. Yang shows a similar device wherein the needle assembly (e.g. 300) is releasable from the housing (e.g. 60). See Figs. Such a design allows for interchangeable heads for different patients and procedures. It would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to configure the device of General with a releasably coupled needle base assembly, in view of Yang, in order to make the assembly interchangeable to accommodate different patients and procedures. It is noted that the design incorporates an electrical contact (e.g. 420) that extends in the same direction as the needles, as well. It also would have been obvious to have used LED lights as the illumination source as merely an obvious design choice that is effective and inexpensive.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the

reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 21-40 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 9,320,536. Although the claims at issue are not identical, they are not patentably distinct from each other because the differences amount to minor changes in the arrangement and phraseology of the claims. The claims of both the patent and the present application are directed to the substantially same invention of a device and method for treating dermatological tissue comprising placing a user holdable device having a releasable assembly with deployable needles on or near tissue, the assembly including an electrical contact, and communicating electrical signals via the needles. The claims further recite energizing a motor to deploy the needles and maintaining electrical contact and illuminating an LED. Where differences exist, the issued patent includes more elements and is more specific. For example, in the issued patent, the independent claims further recite deploying the needles with the motor. In addition, the issued patent further recites the signal generator in the independent apparatus claim. Thus, the invention of the patent claims are in effect a “species” of the “generic” invention of the application claims. It has been held that the generic invention is “anticipated” by the

"species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the patent claims, they are not patentably distinct from the patent claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. The examiner can normally be reached Monday-Friday, 9 a.m. - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact* the examiner's supervisor, SPE, *at* (571) 272-4760**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID C COMSTOCK/
Examiner, Art Unit 3733
/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3733

Notice of References Cited	Application/Control No. 15/724,261	Applicant(s)/Patent Under Reexamination NA, JONGJU	
	Examiner DAVID C. COMSTOCK	Art Unit 3733	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-9,320,536 B2	04-2016	Na; Jongju	A61N1/30	1/1
*	B	US-2015/0217141 A1	08-2015	Barthe; Peter G.	A61N7/00	601/2
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15724261	NA, JONGJU
	Examiner	Art Unit
	DAVID C COMSTOCK	3733

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/06/2018								
	1	-								
	2	-								
	3	-								
	4	-								
	5	-								
	6	-								
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	8	-								
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	32	✓								
	33	✓								
	34	✓								
	35	✓								
	36	✓								

ENDYMED EXHIBIT 1002 - 584/733

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15724261	NA, JONGJU
	Examiner	Art Unit
	DAVID C COMSTOCK	3733

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/06/2018								
	37	✓								
	38	✓								
	39	✓								
	40	✓								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15724261	NA, JONGJU
	Examiner	Art Unit
	DAVID C COMSTOCK	3733

CPC- SEARCHED		
Symbol	Date	Examiner
A61H15/02.cpc. A61H 39/086,002.cpc. A61H37/00.cpc. A61N1/0502,328,36017.cpc. A61N5/0616,062,0624.cpc. A61B2017/3409.cpc. A61H23/02.cpc. A61H2015/0014.cpc. A61H2039/005.cpc.	8/6/2018	/DC/
A61H2201/0153,105,1207,1604,169,5007,5097.cpc. A61H2205/022,04,06,065,084,10,12.cpc. A61M2037/0007,0023.cpc. A61M2205/8206.cpc. A61N2005/0644,0652,0659,0661.cpc.	8/6/2018	/DC/

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	249	8/6/2018	/DC/
607	88, 102, 189	8/6/2018	/DC/
604	20, 46, 21, 117	8/6/2018	/DC/
606	9	8/6/2018	/DC/
601	2	8/6/2018	/DC/
424	1.11	8/6/2018	/DC/

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

SEARCH NOTES		
Search Notes	Date	Examiner
EAST text search--see EAST search history	8/6/2018	/DC/
Inventor name search--see EAST search history	8/6/2018	/DC/

/DAVID C COMSTOCK/ Examiner.Art Unit 3733	

INTERFERENCE SEARCH			
US Class/ CPC Symbol	**US Subclass / CPC Group**	**Date**	**Examiner**

/DAVID C COMSTOCK/ Examiner.Art Unit 3733	

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15724261
Filing Date	2017-10-03
First Named Inventor	Jongju Na
Art Unit	
Examiner Name	
Attorney Docket Number	NA001KR_US3

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8666487	B2	2014-03-04	Kang	
	2	8540705	B2	2013-09-24	Mehta	
	3	5873840		1999-02-23	Bernard	
	4	9480836	B2	2016-11-01	Na	
	5	5993269		1999-11-30	Ito	
	6	6523420	B2	2003-02-25	Lee, Ho-Yeol	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.C.C/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15724261
	Filing Date	2017-10-03
	First Named Inventor	Jongju Na
	Art Unit	
	Examiner Name	
	Attorney Docket Number	NA001KR_US3

	1	20070066094	A1	2007-03-22	Jung-hye Kim	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	10-2006-0061011	KR	A	2006-06-07	CHU,KYOCHEOL		
	2	20-0172727	KR		1999-12-14	HYUNDAI MICRO ELEC		
	3	20-0176242	KR		2000-01-14	SK hynix Inc.		
	4	20-0201331Y1	KR	Y1	2000-08-19	HYUNDAI MICRO ELEC		
	5	10-0308121	KR	B1	2001-08-27	HYUNDAI MICRO ELEC		
	6	20-0268667	KR	Y1	2002-03-06	DONGBU ELECTRONIC		
	7	20-0284460	KR	Y1	2002-07-23	E Q ENG CO., LTD		
	8	10-0555713	KR	B1	2006-02-21	CHUNG,UN-YOUNG		

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.C.C/

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	Filing Date	2017-10-03
	First Named Inventor	Jongju Na
	Art Unit	
	Examiner Name	
	Attorney Docket Number	NA001KR_US3

	9	2000-039449	JP	A	2000-02-08	Seiko Epson Corp		
	10	2002-117926	JP	A	2002-04-19	HOSIDEN CORP		
	11	2005-351785	JP	A	2005-12-22	ATE SERVICE		
	12	08-088040	JP	A	1996-04-02	Hosiden		
	13	11-307161	JP	A	1999-11-05	Sony		
	14	25-43161	JP	Y2	1997-08-06	YOKOWO CO., LTD		

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1		

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/DAVID C COMSTOCK/	Date Considered	08/06/2018

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.C.C/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15724261
	Filing Date	2017-10-03
	First Named Inventor	Jongju Na
	Art Unit	
	Examiner Name	
	Attorney Docket Number	NA001KR_US3

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.C.C/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15724261
	Filing Date	2017-10-03
	First Named Inventor	Jongju Na
	Art Unit	
	Examiner Name	
	Attorney Docket Number	NA001KR_US3

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/mwresq/	Date (YYYY-MM-DD)	2017-11-07
Name/Print	Merle W Richman	Registration Number	38282

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.C.C/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.C.C/

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L4	32252	A61H15/02.cpc. A61H 39/086,002.cpc. A61H37/00.cpc. A61N1/0502,328,36017.cpc. A61N5/0616,062,0624.cpc. A61B2017/3409.cpc. A61H23/02.cpc. A61H2015/0014.cpc. A61H2039/005.cpc. A61H2201/0153,105,1207,1604,169,5007,5097.cpc. A61H2205/022,04,06,065,084,10,12.cpc. A61M2037/0007,0023.cpc. A61M2205/8206.cpc. A61N2005/0644,0652,0659,0661.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2018/08/06 09:17
L5	14771	((600/249) or (607/88,102,189) or (604/20,46,21,117) or (606/9) or (601/2) or (424/1.11)).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/06 09:17
L6	924	(4 5) and needle and electric$3 and signal and (led or "l.e.d." or "light emitting diode") and (skin or dermis or dermatolog$4) and motor	US-PGPUB; USPAT; USOCR	OR	ON	2018/08/06 09:18
L7	505	6 and (releasabl$1 or detach$4)	US-PGPUB; USPAT; USOCR	OR	ON	2018/08/06 09:18
S1	32247	A61H15/02.cpc. A61H 39/086,002.cpc. A61H37/00.cpc. A61N1/0502,328,36017.cpc. A61N5/0616,062,0624.cpc. A61B2017/3409.cpc. A61H23/02.cpc. A61H2015/0014.cpc. A61H2039/005.cpc. A61H2201/0153,105,1207,1604,169,5007,5097.cpc. A61H2205/022,04,06,065,084,10,12.cpc. A61M2037/0007,0023.cpc. A61M2205/8206.cpc. A61N2005/0644,0652,0659,0661.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2018/08/06 02:11
S2	12	((("Na") near3 ("Jongju"))).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2018/08/06 02:13
S3	14771	((600/249) or (607/88,102,189) or (604/20,46,21,117) or (606/9) or (601/2) or (424/1.11)).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/08/06 02:15
S4	923	(S1 S3) and needle and electric$3 and signal and (led or "l.e.d." or "light emitting diode") and (skin or dermis or dermatolog$4) and motor	US-PGPUB; USPAT; USOCR	OR	ON	2018/08/06 02:39

8/6/2018 9:24:51 AM
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BIB DATA SHEET

CONFIRMATION NO. 3803

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
15/724,261	10/03/2017 RULE	600	3733	NA001KR_US3

APPLICANTS

INVENTORS

Jongju Na, Songpa-Gu, KOREA, REPUBLIC OF;

**** CONTINUING DATA ***************************

This application is a CON of 15/096,686 04/12/2016 PAT 9775774
which is a CON of 13/825,083 01/20/2014 PAT 9320536 *
which is a 371 of PCT/KR2012/001335 02/22/2012
which claims benefit of 61/449,080 03/03/2011
and is a CON of 13/060,274 03/30/2011 PAT 8979912
which is a 371 of PCT/US08/74131 08/22/2008
(*)Data provided by applicant is not consistent with PTO records.

**** FOREIGN APPLICATIONS ***************************

REPUBLIC OF KOREA 10-2008-0076993 08/06/2008

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
11/02/2017

Foreign Priority claimed ☑ Yes ☐ No 35 USC 119(a-d) conditions met ☑ Yes ☐ No Verified and Acknowledged /DAVID C COMSTOCK/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		KOREA, REPUBLIC OF	21	20	2

ADDRESS

MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038
UNITED STATES

TITLE

METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

FILING FEE RECEIVED		
800	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

ENDYMED EXHIBIT 1002 - 595/733

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15724261
Filing Date	2017-10-03
First Named Inventor	Jongju Na
Art Unit	
Examiner Name	
Attorney Docket Number	NA001KR_US3

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7824394	B2	2010-11-02	Manstein, Dieter	
	2	7618429	B2	2005-12-22	Mulholland, R. Stephen	
	3	6890319	B1	2005-10-10	Crocker, Peter John	
	4	9320536	B2	2016-04-26	Na, Jongju	
	5	7133717	B2	2006-11-07	Coston et al.	
	6	6931277	B1	2005-08-16	Yuhakov et al.	
	7	8979912	B2	2015-03-17	Na et al.	
	8	4180079	A	1979-12-25	Wing, Thomas	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.C.C/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15724261
	Filing Date	2017-10-03
	First Named Inventor	Jongju Na
	Art Unit	
	Examiner Name	
	Attorney Docket Number	NA001KR_US3

	9	5465593	A	1995-11-14	Takasu, Katsuya	
	10	5546954	A	1996-08-20	Yamada, Mamoru	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20090312691	A1	2009-12-17	Kim et al.	
	2	20080269666	A1	2008-10-30	Wang et al.	
	3	20070276318	A1	2007-11-29	Henley, Julian L.	
	4	20070231255	A1	2007-10-04	Barolet et al.	
	5	20070142885	A1	2007-06-21	Hantash et al.	
	6	20070073217	A1	2007-03-29	James, Terry L.	
	7	20080082090	A1	2008-04-03	MANSTEIN, DIETER	paragraphs [0002] and [0036], claims 1, 3-5, 16, 19 and 22-24 and figures 3-5

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.C.C/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15724261
	Filing Date	2017-10-03
	First Named Inventor	Jongju Na
	Art Unit	
	Examiner Name	
	Attorney Docket Number	NA001KR_US3

	8	20040058882	A1	2004-03-25	Eriksson et al.	
	9	20080014627	A1	2008-01-17	Merchant et al.	
	10	20070232962	A1	2007-10-04	Zumeris et al.	
	11	20080114298	A1	2008-05-15	Cantor et al.	
	12	20080091182	A1	2008-04-17	Mehta, Bankim	
	13	20070038181	A1	2007-02-15	Melamud; Alexander	
	14	20050222565	A1	2005-10-06	Manstein, Dieter	
	15	20110046615	A1	2011-02-24	Manstein, Dieter	
	16	20080281389	A1	2008-11-13	Knopp, Peter G.	
	17	20060293725	A1	2006-12-28	RUBINSKY, BORIS et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15724261
Filing Date	2017-10-03
First Named Inventor	Jongju Na
Art Unit	
Examiner Name	
Attorney Docket Number	NA001KR_US3

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	10-2011-0002210	KR	A	2011-01-07	YANG, WON DONG	paragraphs [0024], [0055], [0057], [0062], [0071], [0073]-[0075], [0078], [0095], [0099]-[0100], [0103],	
	2	10-2010-001828	KR	A	2010-02-17	NA, JONG JU	paragraphs [0030]-[0037] and [0043], claims 3-4 and figures 4-6	
	3	2009-506873	JP	A	2009-02-19	THE FOUNDRY, INC	paragraphs [0053], [0085] and [0088], claims 1-4 and 14-17 and figures 8A-8C	
	4	00/74763	WO	A2	2000-12-14	Georgia Tech Research		
	5	2005/058407	WO	A1	2005-06-05	IN-OMICROTEC LTD		
	6	2005/096979	WO	A1	2005-10-20	The General Hospital		
	7	2008/004781	WO	A1	2008-10-01	Honam Petrochemical Corp.		
	8	10-2006-0027194	KR	A	2006-03-25	SHIN Hyun Sun		
	9	10-2010-0055292	KR	A	2010-05-26	JEJOONG MEDICAL CO		

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NON-PATENT LITERATURE DOCUMENTS Remove

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15724261
	Filing Date	2017-10-03
	First Named Inventor	Jongju Na
	Art Unit	
	Examiner Name	
	Attorney Docket Number	NA001KR_US3

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Translated WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY FOR International application No. PCT/KR2012/001335 mailed 28.09.2012 (7 pages)	
	2	Translated International Search report for International application No. PCT/KR2012/004695 mailed 28.09.2012 (3 pages) PCT/KR2012/001335 mailed 28.09.2012 (3 pages)	
	3	Translated WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY FOR International application No. PCT/KR2012/004695 mailed 02.01.2013 (7 pages)	
	4	Translated International Search report for International application No. PCT/KR2012/004695 mailed 31.12.2012 (2 pages)	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/DAVID C COMSTOCK/	Date Considered	08/06/2018

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.C.C/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15724261
Filing Date	2017-10-03
First Named Inventor	Jongju Na
Art Unit	
Examiner Name	
Attorney Docket Number	NA001KR_US3

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/mwresq/	Date (YYYY-MM-DD)	2017-10-24
Name/Print	Merle W Richman	Registration Number	38282

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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UNITED STATES PATENT AND TRADEMARK OFFICE

USPTO Automated Interview Request (AIR)

Sep 16 2018

This paper requesting to schedule and/or conduct an interview is appropriate because:

This submission is requested to be accepted as an authorization for this interview to communicate via the internet. Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with the undersigned concerning scheduling of the interview via video conference, instant messaging, or electronic mail, and to conduct the interview in accordance with office practice including video conferencing.

Name(s):
Merle W Richman

S-signature:
/mwresq/

Registration Number:
38282

U.S. Application Number:
15724261

Confirmation Number:
3803

E-mail Address:
mrichman@ckrlaw.com

Phone Number:
8585512030

Proposed Time of Interview:
9-24-2018 11:00 AM ET

Alternative Proposed Time(s) of Interview:
9-25-2018 11:00 AM ET

Alternative Proposed Time(s) of Interview:
9-26-2018 11:00 AM ET

Prefered Interview Type:
Telephonic

I am the applicant or applicant's representative for this application.

Topic for Discussion:
proposed response to office action dated August 7, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/724,261	10/03/2017	Jongju Na	NA001KR_US3	3803

26338 7590 10/10/2018

MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

EXAMINER
COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
10/10/2018	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	15/724,261	NA, JONGJU	
	Examiner	Art Unit	
	DAVID C. COMSTOCK	3773	

All participants (applicant, applicant's representative, PTO personnel):

(1) *David Comstock*. (3)_____.

(2) *Merle Richman*. (4)_____.

Date of Interview: *04 October 2018*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *21-40*.

Identification of prior art discussed: *General (WO 2005/096979 A1), Yang, Won Dong ("Yang", KR 10-2011-00002210)*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant proposed adding the limitation "extendable" to the claimed electrical contacts (e.g., 924G extending from/into 924H, Fig. 11C). This allows the moving needle assembly to maintain electrical contact. It is unclear whether the applied art sets forth this feature. A machine translation of the Korean reference has been ordered, at which point, Applicant and Examiner will conduct a follow-up interview.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	/Pedro Philogene/ Primary Examiner, Art Unit 3773

ENDYMED EXHIBIT 1002 - 605/733

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

PTO/AIA/26 (04-14)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT

Docket Number (Optional)
NA001KR_US3

In re Application of: Na

Application No.: 15724261

Filed: 10/3/2017

For: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

The applicant, Na , owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term **prior patent** No. 9,320,536 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby knowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☒ The undersigned is an attorney or agent of record. Reg. No. 38282

/mwresq/ _____ October 30, 2018
Signature — Date

Merle Richman
Typed or printed name

Attorney of record — 858 551-2030
Title — Telephone Number

☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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Electronic Patent Application Fee Transmittal

Application Number:	15724261
Filing Date:	03-Oct-2017
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Filer:	Merle W. Richman
Attorney Docket Number:	NA001KR_US3

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	160	160
		Total in USD ($)		**160**

Electronic Acknowledgement Receipt

EFS ID:	34166696
Application Number:	15724261
International Application Number:	
Confirmation Number:	3803
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Customer Number:	26338
Filer:	Merle W. Richman
Filer Authorized By:	
Attorney Docket Number:	NA001KR_US3
Receipt Date:	30-OCT-2018
Filing Date:	03-OCT-2017
Time Stamp:	22:04:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$160
RAM confirmation Number	103118INTEFSW00006861601984
Deposit Account	
Authorized User	

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	na001kr_us3-roa-2018-08-07.pdf	91711 1b217b751aae19554394e5c7f3194f3e72983b85	no	9
Warnings:					
Information:					
2	Transmittal Letter	na001kr_us3-transmittal.pdf	112712 4ed82fd7a47d04566ddaa3d0bdf519b9b58e8078	no	1
Warnings:					
Information:					
3	Terminal Disclaimer Filed	na001_kr3-terminal-disclaimer.pdf	95346 224b4cf0bbf47fbb114545e29b14042641474171	no	1
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30583 8a831b79deeaa16a2a19f075a3680f586f91ddcb	no	2
Warnings:					
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		Total Files Size (in bytes):	330352		

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New Applications Under 35 U.S.C. 111

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National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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Doc Code: TRAN.LET
Document Description: Transmittal Letter

PTO/SB/21 (07-09)
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TRANSMITTAL FORM *(to be used for all correspondence after initial filing)*		Application Number	15724261
		Filing Date	Oct 3, 2017
		First Named Inventor	Na, Jongju
		Art Unit	3733
		Examiner Name	David C. Comstock
Total Number of Pages in This Submission		Attorney Docket Number	NA001KR_US3

ENCLOSURES *(Check all that apply)*

☐ Fee Transmittal Form	☐ Drawing(s)	☐ After Allowance Communication to TC
☐ Fee Attached	☐ Licensing-related Papers	☐ Appeal Communication to Board of Appeals and Interferences
☒ Amendment / Reply – 9 pages	☐ Petition	☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
☐ After Final	☐ Petition to Convert to a Provisional Application	☐ Proprietary Information
☐ Affidavits/declaration(s)	☐ Power of Attorney, Revocation Change of Correspondence Address	☐ Status Letter
☐ Extension of Time Request	☒ Terminal Disclaimer	☐ Other Enclosure(s) (please identify below):
☐ Express Abandonment Request	☐ Request for Refund	
☐ Information Disclosure Statement	☐ CD, Number of CD(s) _____	
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☐ Certified Copy of Priority Document(s)		
☐ Reply to Missing Parts/ Incomplete Application	Remarks	
☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	CKR Law - Customer ID - 151323		
Signature	/mwresq/		
Printed name	Merle Richman		
Date	October 30, 2018	Reg. No.	38282

CERTIFICATE OF TRANSMISSION/MAILING

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Signature	/mwresq/		
Typed or printed name	Merle Richman	Date	October 30, 2018

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Na Application No.: 15724261 Filed: 10/3/2017 Title: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT Attorney Docket No.: NA001KR_US3	Art Unit: 3733 Examiner: David C. Comstock

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE UNDER 37 CFR 1.111

Dear Sir:

In response to the Office Action of August 7, 2018 and interviews conducted on October 4, 2018 and October 30, 2018, please amend this application as follows.

Amendments to the claims begin on page 2.

Remarks begin on page 7.

ENDYMED EXHIBIT 1002 - 614/733

In the claims:

1. (Cancelled).
2. (Cancelled).
3. (Cancelled).
4. (Cancelled).
5. (Cancelled).
6. (Cancelled).
7. (Cancelled).
8. (Cancelled).
9. (Cancelled).
10. (Cancelled).
11. (Cancelled).
12. (Cancelled).
13. (Cancelled).
14. (Cancelled).
15. (Cancelled).
16. (Cancelled).
17. (Cancelled).
18. (Cancelled).
19. (Cancelled).
20. (Cancelled).

ENDYMED EXHIBIT 1002 - 615/733

21. (Currently Amended) A method of treating dermatological tissue, comprising:

placing a user holdable device releasably couplable deployable needle ~~assembly~~ module end surface on or near dermatological tissue to be treated, the user holdable device including a proximal end and the releasably couplable deployable needle ~~assembly~~module, the releasably couplable deployable needle ~~assembly~~ module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles, the needle assembly movable within the deployable needle module to ~~extendable~~ extend the plurality of needles from the releasably couplable deployable needle assembly end surface while ~~, one of the proximal end and the releasably couplable deployable needle assembly including~~ at least one extendable electrical contact of the needle assembly remains electrically coupled ~~and the other includingto~~ at least one electrical contact ~~couplable to the one~~ of the user holdable device proximal end ~~and the releasably couplable deployable needle assembly at least one electrical contact~~; and

communicating electrical signals from the user holdable device proximal end to ~~releasably couplable deployable~~the needle assembly via the electrical conductors.

22. (Currently Amended) The method of claim 21, further comprising energizing a motor coupled to the needle assembly ~~a releasably couplable deployable needle assembly~~ to cause ~~a~~ the plurality of the extendable needles to extend a desired distance from the releasably couplable deployable needle ~~assembly~~ module end surface.

23. (Currently Amended) The method of claim 22, further comprising energizing the plurality of ~~extended~~ needles via a signal generator electrically coupled to the user holdable device proximal end.

24. (Currently Amended) The method of claim 21, wherein one of the least one electrical ~~contacts~~ contact ~~includes a pin that~~ is extendable ~~in the same direction as the needles to maintain an electrical connection with the other of the at least one electrical contacts as the needles are deployed~~.

ENDYMED EXHIBIT 1002 - 616/733

25. (Currently Amended) The method of claim 21, wherein the user holdable device proximal end includes a motor with a draft shaft releasably couplable to the ~~releasably couplable deployable~~ needle assembly and the method further including energizing the motor coupled to ~~a~~ the ~~releasably couplable deployable~~ needle assembly to cause a plurality of the extendable needles to extend a desired distance from the releasably couplable deployable needle ~~assembly~~ module end surface.

26. (Currently Amended) The method of claim 23, wherein the user holdable device proximal end further includes at least one embedded LED therein and further including energizing the LED ~~when the signal generator is energized~~, the at least one embedded LED illuminating the releasably couplable deployable needle ~~assembly when energized~~module.

27. (Currently Amended) The method of claim 21, wherein one of the least one electrical contacts includes a pin that is extendable in the same direction as the needles.

28. (Currently Amended) The method of claim ~~25~~26, wherein the ~~releasably couplable deployable~~ needle assembly includes a translucent section to communicate illumination from the least one embedded LED to the plurality of extendable needles.

29. (Currently Amended) The method of claim 21, wherein a first ~~extendable~~ electrical contact is coupled to a first plurality of the plurality of extendable needles and a second ~~extendable~~ electrical contact is coupled to a second, different plurality of the plurality of extendable needles.

30. (Currently Amended) The method of claim 21, wherein one of the user holdable device proximal end and the ~~releasably couplable deployable~~ needle assembly ~~including~~ includes at least two extendable electrical contacts and the other ~~including~~ includes at least two electrical contacts couplable to the one of the user holdable device proximal end and the releasably couplable deployable needle assembly at least two extendable electrical contacts.

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31. (Previously Presented) The method of claim 23, further comprising energizing the motor to deploy the plurality of extendable needles to a predetermined depth and directing the signal generator to energize the plurality of extended needles to a predetermined intensity for a predetermined duty cycle.

32. (Currently Amended) An apparatus for treating dermatological tissue, comprising:

~~a user holdable device releasably couplable deployable needle assembly end surface on or near dermatological tissue to be treated, the~~a user holdable device including a proximal end and ~~the~~ a releasably couplable deployable needle ~~assembly~~ module, the releasably couplable deployable needle ~~assembly~~ module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles, the needle assembly movable within the deployable needle module to extend the plurality of needles ~~extendable~~ from the releasably couplable deployable needle assembly end surface while~~, one of the proximal end and the releasably couplable deployable needle assembly including~~ at least one electrical contact of the needle assembly remains electrically coupled to ~~and the other including~~ at least one electrical contact ~~couplable to the one~~ of the user holdable device proximal end ~~and the releasably couplable deployable needle assembly at least one electrical contact~~.

33. (Currently Amended) The apparatus of claim 32, further including a motor coupled to the ~~releasably couplable deployable~~ needle assembly ~~that causes~~to extend the plurality of extendable needles ~~to extend~~ a desired distance from the releasably couplable deployable needle assembly end surface when the motor is energized with a particular signal.

34. (Currently Amended) The apparatus of claim 33, further including a signal generator electrically coupled to the user holdable device proximal end to energize the plurality of extended needles.

35. (Previously Presented) The apparatus of claim 34, wherein the user holdable device proximal end includes an electrical connector couplable to the signal generator.

36. (Currently Amended) The apparatus of claim 33, wherein the user holdable device proximal end includes the motor, the motor including a draft shaft releasably couplable to the ~~releasably couplable deployable~~ needle assembly.

ENDYMED EXHIBIT 1002 - 618/733

37. (Currently Amended) The apparatus of claim 32, wherein the user holdable device proximal end further includes at least one embedded LED therein and the apparatus further including a photonic signal generator electrically coupled to the least one embedded LED, the at least one embedded LED illuminating the ~~releasably couplable deployable~~ needle assembly when energized.

38. (Currently Amended) The apparatus of claim 32, the wherein one of the least one extendable electrical ~~contacts~~ contact includes a pin that is extendable in the same direction as the needles.

39. (Currently Amended) The apparatus of claim 32, wherein one of the user holdable device proximal end and the ~~releasably couplable deployable~~ needle assembly ~~including~~ includes at least two extendable electrical contacts and the other including at least two electrical contacts couplable to the one of the user holdable device proximal end and the ~~releasably couplable deployable~~ needle assembly at least two electrical contacts.

40. (Currently Amended) The apparatus of claim 32, wherein one of the least one electrical contacts includes ~~a pin that~~ is extendable ~~in the same direction as the needles to maintain an electrical connection with the other of the at least one electrical contacts as the needles are deployed~~.

ENDYMED EXHIBIT 1002 - 619/733

REMARKS

Claim Status:

Pending claims prior to amendment:	21-40
Claims Amended:	21-30, 32-34, and 36-40
Claims Cancelled:	None
Claims Added:	None
Claims pending after entry:	21-40

Interview

During the interview on October 4, 2018, the cited references General and Yang were discussed. It was noted that Yang, a Korean language reference did not clearly recite certain feature relied upon for the section 103 rejection. The Examiner agreed to obtain a translation and then schedule a second interview. During the second interview on October 30, 2018, the translated Yang reference was discussed and its disposable section. The Examiner indicated that if the claims were amended to note the needles move independently of the entire disposable section, the may be allowable.

Prior Art Rejection:

The Examiner has rejected claims 21-40 under 35 U.S.C. 103 as being unpatentable over The General Hospital ("General", WO 2005/096979 A1) in view of Yang, Won Dong ("Yang", KR 10-2011-00002210).

As noted during the second interview on October 30, 2018, the Examiner indicated that if the claims were amended to note the needles move independently of the entire disposable section, the may be allowable. Applicants have amended the claims 21 and 32 to note that the disposable section termed a releasably couplable deployable needle module includes a needle assembly

ENDYMED EXHIBIT 1002 - 620/733

including a plurality of needles where the needle assembly is movable within the deployable needle module. The claims further state that during such movement at least one extendable electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end. Based on such amendments, Applicants respectfully contend that the claims are in condition for allowance.

Double Patenting Rejection:

The Examiner has rejected claims 21-40 on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 9,320,536. Applicants are filing a terminal disclaimer to U.S. Patent No. 9,320,536. Reconsideration is respectfully requested.

Applicants have made a diligent effort to place the claims in condition for allowance. However, should there remain unresolved issues that require adverse action, it is respectfully requested that the Examiner telephone Merle Richman, Applicants' Attorney at 858 551-2030 so that such issues may be resolved as expeditiously as possible.

For these reasons, and in view of the above amendments, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,

_10/30/2018_____	__/mwresq/_____
Date	Merle Richman
	Attorney/Agent for Applicant(s)
	Reg. No. 38282

Merle Richman
Partner
Customer ID - 151323
PO Box 3333

ENDYMED EXHIBIT 1002 - 621/733

La Jolla, CA 92038-3333
Tel. 858 551-2030

ENDYMED EXHIBIT 1002 - 622/733

PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/724,261	Filing Date 10/03/2017	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **10/30/2018**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $50 =	0
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $230 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

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Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	15/724,261	NA, JONGJU	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☐ APPROVED	☒ DISAPPROVED
Date Filed : 10/30/18	**This patent is subject to a Terminal Disclaimer**	

Approved/Disapproved by:

Td disapproved.

The terminal disclaimer identifies a party who is not the applicant (only for applications filed on or after September 16, 2012; See FP 14.26.10):

For cases filed on/after 9/16/12, 37 CFR 1.321 specifies that the applicant can disclaim, and the terminal disclaimer must specify the extent of the applicant's ownership.:

A request under 37 CFR 1.46(c) to change the applicant needs to be filed, which is (1) a request, signed by a 1.33(b) party, (2) a corrected ADS (37 CFR 1.76(c)) that identifies the "new" applicant in the applicant information, and is underlined since it is new, and (3) a 3.73(c) statement showing chain of title to the new applicant. Along with the § 1.46(c) request we need a POA that gives power to the attorney who is signing the TD, along with another copy of the TD, unless they file a TD that is signed by the applicant.

Please note the TD must be re-filed. No new fees are due.

Lawana Hixon

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/724,261	10/03/2017	Jongju Na	NA001KR_US3	3803

26338 7590 11/07/2018

MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

EXAMINER
COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
11/07/2018	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	15/724,261	NA, JONGJU	
	Examiner	Art Unit	
	DAVID C. COMSTOCK	3773	

All participants (applicant, applicant's representative, PTO personnel):

(1) *David Comstock*. (3)_____.

(2) *Merle Richman*. (4)_____.

Date of Interview: *30 October 2018*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *21 and 32*.

Identification of prior art discussed: *"General" (WO 2005/096979); "Yang" (KR 10-2011-00002210)*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

It was noted that in the device of Yang, the releasable portion moves together with the needle portion. Applicant's device has a design where the releasable portion remains stationary relative to the housing or handle portion, and the needle assembly moves relative thereto while maintaining electrical contact via telescoping/ collapsing spring-loaded leads. Applicant will amend the claims to further recite these distinguishing features. A machine translation of Yang is attached hereto .

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	/Pedro Philogene/ Primary Examiner, Art Unit 3773

ENDYMED EXHIBIT 1002 - 626/733

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Espacenet

Bibliographic data: KR20110002210 (A) — 2011-01-07

FUNCTIONAL NIDDLE

Inventor(s): YANG WON DONG [KR] ± (YANG, WON DONG)

Applicant(s): YANG WON DONG [KR] ± (YANG, WON DONG)

Classification: **- international:** ***A61H39/04; A61H39/08; A61N1/00***
- cooperative: **A61H23/02**; **A61H39/086**; **A61N1/18**; **A61N2/002**; A61H2201/10; A61H2201/5023; A61H2201/5043 more

Application number: KR20090059689 20090701 Global Dossier

Priority number(s): KR20090059689 20090701

Abstract of KR20110002210 (A)

PURPOSE: A functional needle system is provided, which can conveniently separated an implanted needle and simple attach a new needle. CONSTITUTION: A functional needle system comprises: an electrostimulation needle body(20) in which a plurality of needles are implanted; a controller body(120) generating electric wave; a handle part(60) that a user grips; an electric wave generating unit installed at the controller body or handle part; an operating switch(160) operating the electric wave generating unit; a control switch(180), a display unit(200), and a mode selection switch(240); a air generator; and a connecting cable or an air exhaust nozzle(220).

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Notice

This translation is machine-generated. It cannot be guaranteed that it is intelligible, accurate, complete, reliable or fit for specific purposes. Critical decisions, such as commercially relevant or financial decisions, should not be based on machine-translation output.

DESCRIPTION KR20110002210

Functional Downturn (FUNCTIONAL NIDDLE)

As described above, the present invention relates to an electric stimulation needle attached to one side of a stagnant used for skin irritation and treatment, and more particularly, to a stagnant electric therapy apparatus capable of enhancing a therapeutic effect of relieving pain and eliminating pain And to provide a functional stagnation that can be imparted to the stagnation. The method of stagnation according to the present invention includes an hour-hand method used in oriental medicine, carbonic acid therapy using carbon dioxide gas and laser, and Fraxel laser treatment performed in dermatology of both hospitals. However, in recent years, skin care has been carried out using a needle roller as described above in a home rather than a medical institution in that it is subject to regulations on life. There are many kinds of needles attached to the stagnation head used in the present invention. The most preferable ones are those having a diameter of 0.1 mm or less, the thickest ones having a diameter of 0.5 mm or more are sold in the market, The pain is reduced and the thickness of the needle of the needle is increased, the pain upon insertion is increased and the stimulation is given to the skin more, so that the effect is excellent. The length of the needle is 0.5 mm to 2 cm A long roller needle is on the market. Conventionally, a large amount of acupuncture stiffness is expensive, and most users purchase and use one. When the above roller is used on the skin, the skin of the human body skin layer In particular, when the roller needle is used over a long period of time, the roller needle may be sterilized or sterilized at home, The blood, secretions, and pus of the human body, which are brought into contact with the roller needle during the use of the roller needle, may be involved. In the end, to resolve this, there was cost and economic loss of exchanging the whole stagnation. The present invention has been made to solve the above-mentioned problems, and it is an object of the present invention to easily separate the stagnation where the needles or broken needles are placed during use, easily attach the new stagnation, and operate the electric stagnation during acupuncture, It has its purpose.

According to an aspect of the present invention, there is provided an electric wave therapy apparatus comprising: an electric wave generating unit generating an electric wave; A main body having a grip portion for receiving and holding the electric wave generating portion, and at least one electric wave generating portion for outputting an electric wave generated from the electric wave generating portion. The main body may further include a power supply unit for supplying power to the electric wave generator and a controller for controlling the operation of the electric wave generator. In the present invention, the electric dipstick includes a handle portion that is coupled to the recess portion on the center axis of the recess portion in which a plurality of recesses are inserted on one surface, and a connecting portion that is coupled to the handle portion, And an electric power input part connected to the control part. The electrical stimulation used in the present invention is generally called an interference wave. It refers to a waveform that is produced in the human body when an interference wave or a medium frequency is crossed. This is referred to as a classical interference wave or a quadrupole interference wave (4-pole IF), and Nemec, Germany, found it first. Nemec interference is also called the Nemec interference, but these waveforms are the basic waveforms of all the interference wave therapy devices. When these waveforms are crossed diagonally, the so-called clover-shaped interference waveforms are created in the body. These interference waves mainly use a medium frequency (or 5000 Hz) or more of 4000 Hz or more, Because it is small, it can send a relatively large current to the human body effectively. In addition, since it is treated with the interference wave generated in the human body, the depth of penetration is deeper than that of a general low-frequency treatment device for stimulating only the transcutaneous nerve, and it is possible to stimulate a wider area. On the other hand, as the person gets older, the facial muscles lose their natural strength and elasticity, causing wrinkles and skin sagging. Therefore, care for skin care to prevent wrinkles and sagging of the most prominent face It is written.

In particular, facial skin care is performed using cosmetics as the easiest way to prevent wrinkles and sagging of the face. In this case, when the skin is managed using cosmetics, a protective barrier is formed as a thick protein protective layer under the stratum corneum of the human skin, and since the skin of the human skin and the dermis layer are separated by the protein protective layer, Even when excellent cosmetics are used, the waste accumulated in the dermis layer can not be removed, and the nutrition of cosmetics can not penetrate deeply into the dermis layer, and the skin protection effect is insufficient. However, by stimulating electrical stimulation, it reduces pain during surgery, increases the production of collagen and elastic fibers, regenerates skin cells, and promotes cell renewal and blood flow to make skin healthy and elastic. The effect is recognized. Conventional stagnation forms pores only in the skin, whereas the present invention punctures the skin primarily by the stagnation and enables electric stimulation so that the electric pulse can be deeply supplied to the inside of the human body. On the other hand, Stimulation can have the effect of achieving a functional goal of relieving pain.

Generally, multi-perforating method is a treatment method for skin beauty and hair health such as wrinkles, acne removal, exfoliation, etc. It is a method of applying a drug or a cosmetic product on the skin after puncturing the skin, There is a method of maximizing and a method of stimulating the skin with a needle to induce collagen formation due to the reflection action of the human body. The main treatment part is the face and the scalp. For example, by making hundreds to tens of thousands of fine holes in the skin of a human body, it is possible to make the skin grow by using the self-sustaining force of the damaged skin tissue in the process of making fine holes, to apply the therapeutic drug to the site where the minute hole is formed, It is a way to maximize the effect of the procedure by making it penetrate quickly into the skin through this fine hole. The electric stagnation stagnation used in the present invention is closely related to the physiological mechanism of the human body, because the stagnation causes the formation of numerous pores on the epidermis of the human body and causes current to flow through the human body. Therefore, It is already evident by neuroimmunology that the pain from peripheral nerves is transmitted to the cerebrum via the spinal cord, which is the cause of the pain, through the nervous system. At this time, when the stimulus is delivered at the spinal cord level, the motor nerves become excited and the muscles tense. In addition, the sympathetic nervous system operates, the substance called catecholamine is secreted from the adrenal gland, the contraction of blood vessels occurs, and blood shortage occurs in the cell tissue. When this strange metabolism continues, bradykinin or serotonin, known as pain-causing substances, is secreted. And the mechanism of these substances is that the pain is recognized again in the cerebrum from the peripheral nerve via the spinal cord. On the other hand, the balance of the human body is adjusted by the action of the nerve and the electric signal by the ions, and it is also known that a unique frequency exists. For example, there are heart currents from the heart, brain waves from the brain, operating currents from the nerves and muscles, and damaged currents in the injured areas. This is called the weak current theory.

Concretely, the positive electric charge is increased in the inner side of the cell and the negative electric charge is increased in the outer side cell membrane, and health is maintained by uniformly balancing the ion balance. In general, the ion balance is carried out by potassium ion and sodium ion, and the inside of the cell membrane has a lot of potassium ions. Conversely, the outside of the cell membrane has less potassium ion and more sodium ions, . In EEG, the beta wave is 13 Hz or more at the time of daily life or tension, and the alpha wave is 7 Hz to 13 Hz when the relaxed state is appropriate, and a 4 to 7 Hz setta wave occurs when the ear is absent . The present invention relates to a method of manufacturing a needle attached to a stagnant used as a skin stimulator, and more particularly, to a method of manufacturing a needle having a plurality of stitches attached to a stagnant, And the electric stimulation stagnation which improves the work process to improve the productivity and low cost when the consumer uses it. The above-mentioned needle can reduce aged skin by inducing natural collagen production such as laser peeling or peeling treatment while not damaging the human body's skin layer. It is also possible to apply a local anesthetic to the skin surface, It is effective to improve scars, wrinkles, wrinkles, and acne scars. In particular, it minimizes the rupture of hair follicles by reorganizing and rearranging the dermis tissues as fine needle penetrates into skin, And stimulates the skin surface of the human body to promote collagen synthesis and scar recovery. Prior art similar to the present invention is disclosed in Japanese Patent Application No. 10-1994-0001485, Publication No. 10-1995-0023388, Registration No. 10-0143375-0000, entitled Ultrasound Beauty and Health Device , The technique is characterized in that a hollow cylindrical roller is rotatably supported at one end of a main body having a knob portion and an ultrasonic wave generating portion is provided inside the hollow cylindrical roller and the hollow cylindrical roller itself is ultrasonically oscillated by the ultrasonic wave generator As a ultrasonic cosmetic and health apparatus comprising a vibrating body, the ultrasonic apparatus is supported inside a simple rotating cylindrical roller, and its technical structure is completely different from that of the present invention. Korean Patent Application No. 20-2003-0002185 : January 23, 2003, design title: The skin beauty device is a device that vibrates due to ultrasonic waves, and the diaphragm with the piezoelectric element slides along the skin surface. And at least one piezoelectric element; A piezoelectric element is attached to one end of the case through a bonding member and the other end protrudes to the outside so as to cover and protect one end of the diaphragm and the diaphragm in contact with the skin, A diaphragm which is attached to a normal ultrasonic wave and contacts the skin; And a case having a function of holding and protecting one end of the diaphragm and having a handle function, and the technical features and configuration of the device are different from those of the present application, and Application No. 10-1999-0019723, Publication No. 2000-0075228 The ultrasound beauty device includes a power supply for supplying DC power to each device, a key input unit for

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inputting a time for treatment, ultrasonic output level, face / body and ion / clean selection, A microcomputer control unit for controlling the plurality of displays and the operation of the ultrasonic output part according to the set value input from the input unit, and a microcomputer control unit for controlling the plurality of displays and the ultrasonic output unit according to the control signal of the microcomputer control unit, An ultrasonic signal of an electric wave is outputted; next, an application number: 10-2003-0039255, a public number: 10-2004-0108504, etc. The present invention relates to a method and apparatus for stable power management of a skin beauty device, and a portable skin beauty device using the same, which includes a DC-DC converter unit for boosting a power source charge power; A skin beautifier driving unit for performing an ultrasonic wave or ion introduction; A switch portion of a power switch and an operation switch; A display unit for displaying an operating state; And a DC-DC converter unit for boosting the power source charging power; A skin beautifier driving unit for performing an ultrasonic wave or ion introduction; A switch portion of a power switch and an operation switch; And a display code for indicating an operating state of the skin care device is similar to that of the prior art, and is described as a stable power management method of a skin care device, wherein the application number / date: 10-1999-0037517 (September 04, 1999) The present invention relates to a skin beauty device, which uses a microcontroller to treat skin by the action of low frequency or ions, A central processing unit including a microcontroller for controlling an entire circuit; a switch input unit having a plurality of key switches for inputting an external signal to the central processing unit; An ultrasonic output section for generating a first output and a second output having different output intensities under the control of the processing section, and a power supply section for supplying a DC power supply And a skin cosmetic device to be used as a gingiva for a skin care product; 2005/02/02) Title of the Invention: The skin beauty device is a device for inputting various control and selection signals by a mode selection switch, a program operation switch, an up-down level operation switch, a mode selection switch and an on / A control unit for generating a control pulse having a multi-stage duty for output level control, a program-specific pulse for outputting various lifting voltages, And an output terminal selection signal for each mode, and generates an LED drive signal for each program and mode for display on the display unit. 701, and Registration No. 10-0794640 disclose an invention in which the invention is a method of manufacturing a roller for electric stagnation, wherein the stagnation is caused by corrosion with a chemical agent to apply the adhesive to the roller or stagnation, The above chemicals or adhesives may affect the body, and the manufacturing process is complicated and takes a long time, and there is a problem that the needle may be pulled out or enter during use.

As described above, various low-frequency and beauty device-related technologies have been filed or registered. Each of them has been described as a specific technology. However, as in the present invention, the various recesses and stagnation driving members And the handle portion can be easily detached and attached through a rotary body coupling groove or a step and a magnet or a screw thread so that it can be used according to the user's choice and the electric stagnation which does not use the pad attached to the body has not yet been disclosed. As mentioned above, initially, acupuncture points attached to sharpened rollers or stagnation gradually become dull or exposed to germs and can not be used over a long period of time, resulting in cost and economic loss of replacing the entire stagnation. Unlike conventional procedures (laser, peeling, etc.) in which wrinkles and pigmentation are treated by using the multi-piercing treatment method in which the skin is peeled off and the damaged skin is regenerated, the collagen production is induced without removing or damaging the human skin Which is a new conceptual cell reconstruction method. A simple and safe multi-perforation procedure without side effects is a natural wound healing process caused by the penetration of a large number of saliva into the skin, resulting in a new structure and rearrangement of the dermis, so that the scar becomes shallow and the skin is pulled tight Fine wrinkles can be reduced and pigmentation can be improved, leading to a healthy, clean skin. In addition, hundreds of saliva can provide hundreds to tens of thousands of massive passageways over a few minutes to maximize the therapeutic effect by delivering active ingredients such as the latest active peptides. As a method of forming multiple perforations on the skin of a human body, there are a method using the roller (multi roller needle) described above and a method using a laser to reciprocate a stagnant in which a plurality of stagnations are placed. On the other hand, mesotherapy is a treatment for injecting a therapeutic drug into a human body through stagnation for the treatment of obesity, stretch marks, wrinkle removal, hair loss, etc., and is a treatment method capable of obtaining more accurate effect than an eating medicine or a medicine to be applied.

As described above, the multi-perforating method is a method of applying a drug onto a human skin after puncturing the human skin, including a method using a roller, a method of reciprocating a stagnation, a method using a laser, and a method using a needle. A long time is required for applying the drug after the hole is made, and since the applied drug is not absorbed by the human body 100%, it is disadvantageous to use a large amount of drug. In the case of mesotherapy, since a drug is injected using one stagnation, when a large number of injections such as obesity treatment, hair loss treatment, etc. are required, the procedure time is long and the pain accompanying injection is increased . The present invention has been made to solve the above-mentioned problems, and it is an object of the present invention to provide a method and apparatus for easily and effectively separating stagnation of a stagnant stomach where a needle tip is worn or broken during use, It has its purpose.

TECHNICAL FIELD The present invention relates to a functional stagnant for applying electric waves to a stagnant portion, and more particularly, to a stagnation that is easy to carry and gives electric waves usable in all parts of the body. Generally, electric wave therapy devices are widely used to prevent or treat various diseases by stimulating stimulation points of the body by using electric waves. 2. Description of the Related Art In recent years, electric wave therapy devices have been widely used

END MED EXHIBIT 1002 - 631/733

which an adhesive pad attached to a body is provided and an electric wave is supplied to the adhesive pad to stimulate the stimulation points of the body. In the electric wave therapy device using such an adhesive pad, a drug such as a substance having an adhesive force or a water pesticide is applied to the body part to which the adhesive pad is attached so that the electric wave flows well. However, in the conventional electric wave therapy device, since the electric wave generating part for generating the electric wave and the adhesive pad are separated from each other, it is not easy to carry, and since a substance and a gel having adhesive strength are applied to the body and used, It is difficult to attach the adhesive pad to a hairy body part other than the part, so that it can not be used easily. That is, there is a problem in using a specific part of the body. Accordingly, an object of the present invention is to provide an electric wave therapy device which is easy to carry and which can be easily used in all parts of the body. It is another object of the present invention to provide a electric wave therapy device capable of relaxing muscles and promoting blood circulation to improve the health of a human body. The electric wave therapy device uses a power source or a rechargeable battery as a power source, To stimulate the human body to relieve pain and improve the therapeutic effect. In order to draw self-healing ability to the problem area by the skin irritation of acupuncture, the hospital puts roller at once or once per week in the hospital. It is used twice a month, and at home, it is lightly used as a daily or twice-a-week massage. Understanding the skin problems associated with hair loss, scarring, wrinkles, acne marks, pigmentation, pores, baldness, It is solved to some extent in a natural way.

The other is to use the drugs to treat the skin problems mentioned above, so that the main ingredients (peptides) applied only to the skin stratum corneum can be formed into the deep layer required by the skin by using a plurality of needles, Cosmetic or hair growth components, if the effect is applied only to the skin surface or stratum corneum of the skin, the needles penetrate deeply into the skin along with the electric wave, thereby stimulating the skin surface of the human body with a fine needle, It is a technique that promotes synthesis and scar recovery and alleviates pain. In addition, since the conventional stiff roller stagnant having a large amount of acupuncture is expensive, most users purchase and use one, and many people use it together. When the roller is used on the skin, As a result, there is a problem that the tip of the needle is bent or worn due to impact with the skin of the human body, which is skin-resistant from the external penetrating material, or friction of the skin or physical impact around the use; In particular, when the roller needle is used over a long period of time, even if the roller needle is sterilized or disinfected at home, the blood, secretion, pus, etc. of the human body, which is in contact with the roller needle, There have been problems such as cross infection, staphylococci and hepatitis, further exposure to infectious pathogens such as AIDS, and infectious diseases. In order to solve this problem, high cost expenditure and economic loss have occurred . The present invention has been made to solve the above-mentioned problems, and it is an object of the present invention to easily separate the stagnation in which the needles or broken needles are placed during use and to simply attach the new stagnation to adjust the frequency and voltage corresponding to the physiological mechanism of the new needles and the human body And the like, and also to provide an electric stimulation depression that can optimize the dynamic change of the waveform to further improve the therapeutic effect of alleviating and eliminating the pain. Another object of the present invention is to provide an electric stimulation device which can be easily carried out without accompanied by a great deal of additional parts or structural changes as compared with a conventional electric therapy device, And the like.

In order to achieve the above object, a stagnation of the electric-field stimulator of the present invention includes a spike pulse generation circuit for outputting a spike pulse from a coil of an output transformer, a handle for gripping by hand, . The electric wave therapy device further comprises a positive electrode portion having a plurality of needle conductors to be one electrode provided with a spike pulse output from the spike pulse generating circuit and a negative electrode portion serving as the other electrode to which the spike pulse is supplied The spike pulse frequency is preferably set to 9.0 ± 0.2 Hz and the pulse width is set to any one of the states selected from 100 to 800 μs and the spike applied to the load of 10 to 400 KΩ corresponding to the load resistance of the human body The ratio of the number of turns of the coil of the output transformer is set so that the positive peak of the pulse width period of the pulse is preferably 1.5 to 100 V and the positive voltage is maintained at the predetermined voltage value or more in the pulse width period . The electric body stimulator inserted in the body of the controller and the electric stagnation part communicating with the stagnation of the present invention to supply the electric wave supplies electric waves generated by the electric power to the stagnant without using the pad attached to the body, In addition, it is aimed to apply electric stimulation such as kneading, tapping, and vibration effect. As described above, according to the stagnation with the electric magnetic pole stagnation according to the present invention, since the conventional stagnant stagnation for the roller with the needle is not integrated, Since the purchase cost is high, most users purchase one and use it. In case of failure or acupuncture wear, the whole should be discarded. Especially when the roller is used on the skin, And the skin tip is warped or abraded due to friction with the skin or physical impact of the skin during use. Particularly, when the roller needle is used for a long period of time, even if the roller needle is sterilized or disinfected at home, blood, secretions, pus, etc. of the human body that is in contact with the roller needle are encountered Cross-contamination problems have arisen, and in order to solve them, there has been a cost incurred in exchanging the whole stagnation and an economic loss.

In addition, in the conventional electric wave therapy device, since the electric wave generating part for generating an electric wave and the contact pad are separated, it is not easy to carry, and since a substance and a gel having adhesive strength are applied to the body and used, There is a problem that it is not easy to use because it is difficult to attach the adhesive pad to a hairy body part

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hairy body part other than the head part, and there is a problem that the use of the specific part of the body is restricted. The present invention overcomes the above-mentioned problems and is intended to easily separate the stagnation where the needles or broken needles are placed during use and to simply attach the new stagnation and effectively perform the new needles without pain. It is. In addition to setting the physical quantities such as frequency and voltage corresponding to the physiological mechanism of the human body more precisely with the electric pulse of the present invention, it is also possible to optimize the dynamic change of the waveform to alleviate and remove the pain The therapeutic effect can be further enhanced. As described above, according to the present invention, it is possible to reduce the procedure time by puncturing the skin of the human body with a plurality of stagnation and injecting the drug at the same time, minimizing the pain during the procedure and lowering the cost It is advantageous to perform multi-perforation and mesotherapy, and it is also possible to perform deep part surgery and also to be able to perform part-by-part surgery. Another object of the present invention is to provide an electric wave therapy device which can relax muscles and promote blood circulation to promote health of the human body.

The present invention relates to a functional stagnant which is used in skin epidermis to form pores and which becomes an electric stimulus in addition to the stagnation. More specifically, the present invention relates to stagnation with an electric stimulator for effective treatment and regeneration of skin tissue. A stagnation in which electric striking downturn composed of various electric waves is inserted can be achieved by inserting various needles which are mainly used in Oriental medicine into cylindrical or round or polygonal rollers or stagnation of a certain shape and applying predetermined electric waves thereto to protect skin, The electric stimulation deceleration unit 300 that stimulates the human body by using an electric wave, which is a micro current generated from the micro-current generating unit, to improve the pain relief and the therapeutic effect, Lt; / RTI & gt; The electrical stimulation therapy used in the present invention is an electrical stimulation therapy called microcurrent pulse stimulation (MPS) among the electric stimulation principles, and a micro-current is applied to various electrodes without using a pad at the stimulation site of the human body, It is a principle that stimulates activity. It gives a stimulation feeling deep inside like a saliva by applying a periodic pulse. The intensity of the stimulus provides a superior effect than the conventional acupuncture therapy. This therapy is based on the principle of physiological electric current, Western medicine, oriental medicine, acupuncture and moxibustion is a combination of Oriental medicine. Electrotherapy is a physiotherapy which helps to relieve and recover the acute and chronic pain caused by stiffness by calming nerves and stimulating blood circulation by passing minute electric waves through the human body and stimulating the muscles. To treat weakness, obesity, and disease of the body's function. It can also be divided into nerve sedation, muscular disease treatment, blood circulation promotion, massage, and reduction of adipocytes by vibration (Hz-1 per second). Hereinafter, the present invention will be described in detail with reference to the accompanying drawings. In the following description of the present invention, a detailed description of known functions and configurations incorporated herein have been omitted for clarity and conciseness. The detailed description thereof will be omitted.

FIG. 1 is a perspective view showing an embodiment of a conventional electric-magnetic-pole stagnation in which an electrode is connected to a finger and an electric stimulus is applied to the neck, and a functional stagnation is shown in a perspective view. FIG. 2 is a perspective view illustrating one embodiment of the stagnation in the functional stagnation of the present invention. Referring to FIG. 2, the electric stagnation stagnation body according to the present invention includes an electric stagnation stagnation body 20 and an electric- And includes a grip portion 60 and a recessed portion 300, which will be described in detail as follows. The connection terminal 280 is inserted into the electric wave generator 40 through the connection cable 260 from the electricity generator and electric power required for the operation using the electric dipstick is transmitted from the electricity generator to the connection terminal 280. [To the electrical input unit. The handgrip 60 includes a handle upper case 80 and a lower case 100 as a hand gripping part when the operator performs an operation on a patient with an electric stimulation slump according to the present invention, An operation switch 160 for operating the electric wave generator 40, an adjustment switch 180, a display unit 200, an air generator 20 through a compressor or the like, The air blowing out port 220 is installed on the control unit body 120. A plurality of sharp needles are placed in the needle insertion holes 360 and the needle 300 is freely detached and attached by the denture attaching / detaching unit 340 will be. Here, the recess 300 is inserted and fixed in a needle insertion hole 360 made of a conductive metal material, and is protruded by a predetermined length based on the recess 300. Such a stagnation is applied to the skin tissue by stimulation and electric wave stimulation of a predetermined electric wave while the practitioner inserts it into the dermal layer of the skin. In the meantime, it is preferable that at least one elastic piece for securing ease of operation is formed on the control body 120 of the electric stimulation stagnation according to the present invention, and the elastic piece inserted into the control body 120 has excellent elasticity A rubber slice may be used, or a plate spring or the like may be used, and preferably, the non-elastic slice may be inserted into the control body 120 according to the intended use.

The elastic piece inserted into the body 120 of the control unit functions to smoothly insert a sharp stagnation into the dermis layer of the treatment area to apply a stimulus and a vibration stimulus of a predetermined electric wave. Preferably, The effect of the magnetic field can also be seen as a magnet. In addition, the recess 300 of the electric stagnation recess according to the present invention has various shapes such as a cylindrical shape, an elliptical shape, and a polygonal shape, and a needle insertion hole 360 made of a plurality of conductive metal materials is formed [illegible]

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dislocation portion 340 is formed in which a stagnation is detached and attached, and a sharp stagnation for causing micro-scratches is inserted and fixed. However, in the practice of the present invention, the number and spacing of the needle insertion holes 360 made of the conductive metal material formed in the recess 300 may be appropriately adjusted according to the purpose of the procedure. The electric wave generator 40 is installed in the control switch 180 and includes a power button for opening and closing the power source 140 and an operation switch 160 having a function for gradually increasing and decreasing intensity of the electric current, A mode selection switch 240 for selecting and outputting electric stimulation such as ultrasound, high frequency, medium frequency, and low frequency, and a display unit 200 including a lamp for notifying the ON / OFF state of the power button and the current operation state. A conductive plate coupled to the output terminal of the electric wave oscillation circuit board PCB and coupled to the head, and a plurality of electrodes connected to the conductive plate, respectively, coupled to and disassembled from the recess 300, do. The electric stagnation recess of the present invention includes a control body 120 provided with an electric wave generating unit 40 and a timer inside the control unit body 120 and an operation panel on the outside. Here, the upper surface of the main body is provided with a connection cable 260 which is connected to the inner space of the main body and connected to the operation panel, and is wired inward. In addition, a display unit displaying numerals, symbols, or the like indicating interconnection with operation buttons provided on the operation panel is formed.

The connection cable 260 is provided with a connecting portion to be inserted into the recess 300 and transmits the electric wave generated from the main body to the needle. In addition, the fastening member is preferably provided with a cover member which is screwed to the cover member, the cover member is formed in a soft container shape with its bottom opened, a through hole communicating with the inside thereof is formed on the outer peripheral surface, A screw thread is formed so as to be screwed to the fastening member. In addition, the cover portion may be slightly spaced from the other end of the connection portion, so that a screw thread is formed on the outer side, and the fastening member is operated by rotating the cover portion with the hand. A connection cable 280 is provided at an end of the connection cable 260 and a connection cable 260 is provided between the connection member 280 and the connection terminal 280. In addition, The connection terminal 280 is formed with an insertion hole at an inner side to open a lower portion and a button hole at a predetermined position at an upper end of an outer circumferential surface thereof and a connection terminal 280 to which the connection cable 260 is connected, will be. Here, the fixing hole formed in the inserting hole of the body is fixed to the inner circumferential surface, and a fluid corresponding to the other side of the fixing body is provided. The fluid is hinged to the fixing hole, An elastic member is provided on the hinge engaging portion so as to maintain the contact state, and a button is provided on the upper portion of the fluid body so that the upper portion of the fluid body is engaged with the button hole and the lower portion is released from the fixing body. After the cover member is fixed to the skin, after the connection portion of the connection cable 260 is inserted into the port of the control unit body 120, when the operation switch 160 of the operation panel of the main body and the control switch 180 are operated, The electric wave is transmitted through the cable 260 to the needle provided in the recess 300 and transmitted to the skin of the human body. At this time, the cover member is screwed to the fastening member of the connection cable 260, and the cover member may be screwed to the fastening member according to the user's choice, or the cover member may be completely removed from the fastening member May be preferably used.

By the same method as described above, a plurality of connecting cables 260 are connected to the acupuncture needle so that electric waves are applied. Therefore, by applying the electric wave to the needle, the intended treatment is performed on the skin of the practitioner, and a predetermined therapeutic effect can be obtained. Thus, it is possible to manage the skin in a healthy manner, such as protecting the skin and preventing aging of the skin. 3 is a perspective view showing still another embodiment of the stagnation in the functional stagnation of the present invention. FIG. 4 is a perspective view showing one embodiment of a stagnation and driving member in the functional stagnation of the present invention. In the electric stagnation stagnation body 20 of the present invention, the electric wave generating unit 40, in which electric waves are generated, A handle 60 and an upper case 80 and a lower case 100 for opening and closing the handle. The control unit 120 includes a power source to which the power source 140 is input and an operation switch 160 for operating the electric stimulation deceleration body 20 and an adjustment switch 180 for controlling the operation switch 160. In addition, the control unit body 120 includes a display unit 200 that allows the user to grasp the operation of the device, and a mode selection switch 240 is provided to adjust the intensity and time of the device. A small compressor is installed in the body 120 of the control unit, and the compressed air is delivered to the electric pole recessed body 20 through the air outlet 220 so that the recessed part 300 flows upward or downward or rotates. A connection cable 260 is connected to the electrical stimulation recessed body 20 to connect the recessed portion 300 to the recessed portion 300. A needle insertion hole 360 is formed in the recessed portion 300, A stagnation fixing member 320 for fixing the plurality of needles to a stagnation of a predetermined shape, and a stagnation removing unit 340 for detachably attaching the stagnation part 300 at the handle 60. A sloping drive member 420 having a crank portion 380 and a cam portion 400 flowing through the sloped portion 300 is installed on the upper portion of the electric stimulation sloped body 20, Which is rotated or reciprocated to perforate the epidermis.

According to an aspect of the present invention, there is provided a power supply apparatus including a power source for supplying power to a case and an electric wave generating unit for converting a [illegible]

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DC current, A button including a switch for controlling a power supplied to the electric wave generator 40, and at least one patch electrically connected to the main body and protruding to the outside through one surface of the case, And the face can be stimulated with a minute current. The electric stagnation recess according to the present invention is coupled to the handle 60 coupled to the stagnation part 300 so that the stagnation part 300 having a plurality of stagnations inserted on the surface thereof can be pressed on the skin of the client And an electric wave input unit connected to the connection terminal of the electric wave generator so that the electric wave is energized to the stagnant part 300 on the plurality of stagnation parts. According to the present invention, it is possible to effectively treat and regenerate the skin tissue by applying any one of electric stimulation selected from ion, radio wave, ultrasonic wave, high frequency, medium frequency and low frequency to the skin surface of the human body through a plurality of sharp stagnation . As a method for improving aging of skin tissue, scarring, acne scarring, etc., conventionally, only the treatment by simply applying the medicines such as solution, cream, gel and ointment for skin treatment and regeneration has been performed The amount of the penetration rate of the medicament is relatively small, and as a result, there is a problem that the treatment for improving the effective skin tissue is not performed, and the recess 300 for effective treatment and regeneration of the skin tissue is provided have. In order to accomplish the above object, the present invention provides an electric stimulation depression comprising: a depression (300) having a plurality of depressions inserted on a surface thereof; a depression (300) for depressing the depression (300) And a control unit body 120 coupled to the knob unit 60 and electrically connected to the connection terminals of the electric wave generator unit 40 so that electric waves are supplied to the plurality of stagnation units, And an input unit.

Preferably, at least one selected from among ions, radio waves, ultrasonic waves, high-frequency waves, mid-frequency waves, and low-frequency waves is generated by the electric wave generator at the ends of the plurality of stagnations. In addition, the present invention relates to an electric stagnation which can be used separately only in a stagnation state, and is provided with an adjustment switch (180) for controlling an electric wave having an electric wave generating part (40) in a control body (120) 60 and a recessed part 300 formed at one end of the recessed part 300. The recessed part 300 has a conductive plate spaced apart from each other and connected to both output ends of the electric wave generating part 40 by terminals, And is provided with a plurality of electrodes connected to the conductive plates, thereby facilitating the use of the skin, promoting blood circulation of the skin by electric waves during skin massage including the face, skin irritation, and soft and resiliently improving the skin tissue, It is possible to improve the facial diseases and problematic skin. Generally, skin tissue is composed of dermis and subcutaneous tissue from the outermost human skin, and sebaceous glands and pores including follicles are formed on the skin and dermis of the human body, so that it is easy to pollute skin due to excessive sebaceous glands and sweat. . Human body is composed of water and electrolyte (electrolytes) together with about 60% of water. The reason for the electricity to be transmitted to the body is that the electric wave flows due to the movement of the electrolytic ions in the body. Using this phenomenon, giving the electric stimulation to the skin can be expressed as the excitation of the body tissue due to the movement of the electric current. The excitement here is a phenomenon in which molecules with ions (electrons) gather and scatter under the electrodes of atoms. Therapeutic therapy using electric waves is based on the electrical energy of such a living body. In order to generate excitation by applying current stimulation, the amount of electric current that determines the intensity (voltage height) of the electric current, the current operation time to determine the energization time and frequency, The wave form that determines the frequency of the wave. The skin of a person is close to an insulated state and does not easily conduct electricity. However, when the voltage is raised to some extent, electric current starts to flow through the skin tissue. If stimulation is given at a higher voltage in this state, .

However, even if a high voltage is applied for a short time, the stimulus is not stimulated. Therefore, the stimulus should be maintained for a certain period of time, and the stimulating effect of the electric current depends on the voltage. That is, if the voltage is high, the energization time may be relatively short, but if the voltage is low, the energizing time does not occur in the body. The irritation effect on the skin varies greatly depending on the changing speed of the electric current. When the current change is gentle, the stimulus action is decreased. On the contrary, when the current change is rapid, the stimulus action is strongly occurred. And a polarizing action to block the flow of current. In order to prevent excitation action in the body while preventing such a polarization action, an appropriate change in voltage, that is, a waveform value, must be accurately calculated. As is well known, electric wave stimulates blood circulation while stimulating with a menstrual massage, and when used with a nutritional cream or pack, it improves the metabolism in the body and can obtain various skin massage effects. , Freckles and other various skin diseases are used to alleviate, prevent and improve. However, conventional systems using electric waves have a disadvantage in that the size of the apparatus is large, the structure is complicated, and pads must be used. Still another object of the present invention is to provide an electric wave precipitator 300 which can obtain a high effect by electric waves at a very low cost. In order to accomplish the above object, the present invention provides an electric wave generator (40) in a body (120) of a control unit, forming one end of a handle (60) and the depression (300) (300) capable of transmitting an electric wave so that an electric wave pulse oscillated from the electric wave generating part (40) is applied to the recessed part (300). The electric wave generating unit 40 includes a control unit for controlling the electric wave generated in the main body so as to be able to adjust the period of the pulse or the intensity of the pulse by varying the current and

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voltage. It is preferable that the grip portion 60 has a length enough to be gripped by the hand and the head is formed at an obtuse angle from the grip portion 60 so that the angular range is not excessively increased.

The electric wave generating unit 40 includes an electric wave adjusting switch 180 so as to be capable of adjusting the opening and closing of the electric power source, the period of the pulse by varying the current and the voltage, or the intensity of the pulse. The electric wave generating unit 40 preferably includes a guide rib formed on the control unit body 120 and an electric wave oscillating circuit board PCB coupled to the guide ribs. The electric wave generating unit 40 includes a hooking hook and an electric wave oscillating circuit board (PCB) So that the guide rib is elastically coupled to the guide rib through the engagement hawk. The electric wave control switch 180 is connected to the electric wave oscillation circuit board PCB installed in the controller body 120 and includes a power button for opening and closing a power source and a frequency control button for gradually increasing / And a lamp which maintains the ON and OFF states of the power button in the ON / OFF state. Also, the power button and the frequency adjusting button may be protruded through the knob 60, and the cover for guiding the button may be coupled to the knob 60. The electric-magnetic-pole stagnation is electrically connected to the inside or the outside of the stagnant part 300 and connected to both output terminals of the electric-wave oscillating circuit board. And a plurality of electrodes. That is, when the power button is turned on, power is supplied from the power source 140 to the electric wave generating unit 40 and the electric wave adjusting switch 180, and electric wave pulses generated from the electric wave generating unit are transmitted to the sink unit 300 through the terminals. And the positive and negative stagnation connected to the conductive plate are contacted with the skin to cause electric current to flow into the subcutaneous tissues and the ionic molecules of the human epidermis, dermis and subcutaneous fat layer are flowed by current flow. Causing pain, and sedation. Here, it is preferable to set the frequency range to be low when the skin tissue has pain, acne, or inflammation, and relatively increase the frequency range of the electric wave when there is no pain.

In addition, it is preferable to supply the electrical current of a relatively low level and gradually increase the intensity of the electric current during the initial use of the electrical stimulation recess. The electric parameter used in the present invention includes all frequencies useful for the human body such as superharmonic, superharmonic, negative electric potential, high frequency, low frequency, and mid-frequency, and is preferably selected among the electric waves. The body includes a needle insertion hole 360 made of a conductive metal material so that a plurality of recesses protrude from the upper portion. An electric wave generating unit (40) for generating electric waves on one side of the stagnation; An electric wave setting control switch (not shown) that can set the intensity, intensity, and intensity of the electric wave transmitted through the stagnant part 300 to the skin to be treated through the electric wave generating part 40 on the one side of the stagnation, 180; The electric wave setting switch 180 and the display unit; A controller for controlling the electric power, such as steel, medium, heavy, and electric wave types, from the controller through the electric wave generator 40; And an operation switch for controlling the operation of the controller. One side of the stagnant part mounted on the stagnant part 300 is fitted to each side of the stagnant part so that the electric waves desired by the user are controlled by the controller of the staggered switch 180, When the electric wave for treatment is delivered to the placed stagnation, the user's skin comes into contact with the stagnation of treatment. At this time, an electric wave controlled by the controller is generated from the electric stagnation stagnation mounted on one side of the stagnation so as to act on the skin touching the stagnation, so that the electric wave is transmitted to the affected part through the stagnant stagnation. In addition, there is an electric wave that can act on the scalp or skin even if the stagnation does not reach the user's scalp or skin through the electric wave generating part 40 formed inside the body. Typical frequencies at this time are supermagnetic fields and superficial waves. Meanwhile, the electric-magnetic-pole stagnation is mounted inside the body, and a supersonic magnetic field or a super-electric wave desired by the user is controlled by the controller to be generated through the electric-wave generating unit 40. At this time, If the user's skin or scalp enters the area of super-magnetic field or super-low frequency generated through the electric-wave generating part 40 inside the body even if it is not acted on the scalp or skin, the skin, the face, It is possible to treat by electric wave.

The output terminal of the power supply unit is connected to (+) and (-) of the electric stagnation recesses sequentially through a power switch, an electronic device, and the like. That is, the voltage of the power supply unit is supplied to the electric-magnetic-pole stagnant according to a command from the controller only while the power-supply switch is on-switching. In this case, it is needless to say that the operation of the electric stagnation stagnation can be performed by applying the voltage to the electric stagnation stagnation directly from the power supply unit by the power switch without using each electronic device. It is preferable that the light emitting lamp is provided at the same time as the operation of the power switch and the light emitting lamp is turned on simultaneously with the operation of the power switch so that the user can easily confirm that the power switch is on- something to do. When the user sets the treatment frequency intensity and the type of the electric wave according to the physical condition of the operator and presses the operation switch by the electric wave adjusting switch 180, the electric wave is transmitted to the stagnant state due to the electric stagnation, In addition, the operation switch 160 is installed on one side of the body to control whether the controller is operated or not, and a controller located in the control switch 180 . In addition, the body may be provided with a time adjusting unit and a time adjusting unit, each of which is electrically connected to the controller. The time adjusting unit preferably includes a 10-minute button, a 1-minute button and a start and stop button, The 10-minute unit button and the 1-minute unit button are operated so that the time increment [illegible]

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in the time display unit. When the start and stop buttons are pressed once, the time set on the time display unit is counted down and decreased. When the start and stop buttons are pressed a second time, the time set on the time display unit is reset to zero. In addition, when the time set in the time adjusting unit is counted down and reaches zero, the controller detects that the voltage input from the power supply unit Vcc to each of the electric wave adjusting switches 180 is cut off do.

The time display unit includes a lamp such as an LED, an LED, and an LCD installed on an outer surface of the body to display a time set by the time adjustment unit, a control signal corresponding to the set time from the controller, And an adjustment switch 180. The LCD and the LCD may be configured as described above. On the other hand, it is preferable that the stagnation is formed of a metal material and a special fiber which can transmit the treatment frequency well, and the like, It may be possible. In order to weaken the intensity of the electric wave intensity control by the electric wave intensity control switch 180, the degree of operation of the electric wave intensity button is displayed on the electric wave display unit 200 when the intensity of the electric wave or the like is pressed, If the type of the electric wave is set through the button of the electric wave control switch 180 after the user selects the desired strength, medium, and medicine, the type of the electric wave is displayed on the electric wave control display unit. In such a state, when the operation switch 160 is operated, the controller senses the voltage applied by the controller to the stagnation of the electric field of the voltage converter of the power supply unit, and the electric stimulus The operation of the stagnation occurs. When the time adjusting unit is used, when the operation switch 160 is operated and the start and stop buttons of the time adjusting unit are operated, the display unit starts counting down the time set on the LCD by the timer. While the time display unit is being counted down, when the time set in the LED and LCD of the time display unit is completed, the controller turns off the power supply to terminate the electric wave treatment due to the stagnation. With this configuration, when the power is supplied from the power supply unit, the adjustment switch 180 operates the electric wave generating unit 40 based on the information stored in the memory according to the operation of the operation switch 160 and the mode selection switch 240 .

The electric wave generating unit 40 is operated and an electric wave is output from the electric wave generating unit 40. The user holds the electric wave generating unit 40 on the desired body part in a state of holding the handle 60 of the main body By stimulating with electric waves, muscles are relaxed and blood circulation is promoted, so that the health of the human body can be improved. In particular, the electric wave generating part 40 is accommodated in the main body and the electric wave generating part 40 is protruded from the main body, so that it can be easily used in all parts of the body. In the above-described embodiment, the electric-wave generating portion 40 is described as having an acicular shape, but the electric-wave generating portion 40 may have a hemispherical, polygonal, or elliptical cross-sectional shape, . Referring to FIG. 5, the depression 300 of the electrical stimulation depression according to the present invention includes a plurality of sharp depression portions 300, The recess 300 is in contact with or coupled to a needle insertion hole 360 formed of a plurality of conductive metal materials formed inside or outside of the recess 300, Which is connected to an electric wave generated from the electric wave generator of the motor 60. Meanwhile, it is preferable that the recessed insertion hole 360 formed inside or outside of the recess 300 is used as a conductive portion of the recess by a metal such as silver, copper, or titanium, which is excellent in electrical conduction and electrical conductivity. Preferably, a conductive synthetic resin material may be included between the electrically conductive portion and the plurality of sharp recesses so that electrical coupling characteristics between the electrically conductive portion and the plurality of sharp recesses are improved. The electric power input from the electricity generating device through the electric input portion of the electric stagnation recess is transmitted to the electric conductive portion of the stagnant body formed in the control body 120 through the connecting cable 260 in the handle portion 60. Finally, And is applied to the human body. In the state where the stagnant body is inserted into the skin surface of the human body by the practitioner, ion stimulation and electrical stimulation of a predetermined electric wave are applied to the skin tissue.

The procedure of the electric stagnation stagnation according to the present invention is described as follows. The practitioner grasps the handle 60 of the electric stagnation recess by hand and applies pressure while rotating the stagnation against the treatment area. Through this procedure, At the end of the stagnation, the electric current of a predetermined electric wave is conducted to the surrounding skin tissue, thereby exciting the ions of the skin tissue around the sharp stagnation or causing heat by the electric vibration stimulus. In order to effectively regenerate the skin tissue through ion stimulation and electric vibration stimulation of a predetermined electric wave on the skin surface of the human body, the absorption rate of the solution, cream, gel, ointment agent and the like in the skin layer is drastically increased, It is the speed at which new organizations are formed. 6 is a perspective view illustrating one embodiment of the connection between the stagnation and the control body in the functional stagnation of the present invention. Referring to FIG. 6, the electric stagnation stagnation according to an embodiment of the present invention includes an electric input part,), And a stagnation part (300). Here, the configuration and function of the electric power input section and the handle section 60 are the same as those described above for the electric-magnetic-pole stagnation. The electric stagnation recess according to the present invention includes a main body having an electric wave generating portion (40) for generating an electric wave and a handle portion (60) for holding and holding the electric wave generating portion (40) And a plurality of electric wave generators 40 for outputting electric waves generated from the electric wave generators 40 installed in the main body 300. The controller body 120 includes an operation switch 160 for controlling the intensity of the electric wave generated from the electric wave generator 40, a mode selection switch 240, a timer

for setting the output time of the electric wave, And an operation switch 160 for operating the operation of the operation unit. The display unit 200, which is a display unit, displays information about operation of the operation unit. The handgrip 60 includes an electric wave generating part 40 between the upper handle case 80 and the lower handle case 100 and the electric wave generating part 40 is formed in the control body 120, And an oscillation transformer that is operated by an adjustment switch 180 formed on the printed circuit board (PCB) and oscillates with a predetermined electric wave by the operation of the adjustment switch 180.

The electric wave generated by the electric wave output unit is transmitted to the electric wave generating unit 40 so that electric waves generated from the electric wave generating unit 40 can be transmitted to a body part to be treated. A power supply unit for supplying power by an adjustment switch 180 is accommodated between the handle 60 and the lower case 100. The upper casing 80 and the lower casing 100 It is preferable to form the grip portion 60 which can be gripped by the engagement. 3 and 4, when the operation switch 160 and the mode selection switch 240 are operated, the control switch 180 grasps the input signal, And operates the electric wave generator 40 according to the previously stored information. The control switch 180 not only controls the intensity of the electric wave generated from the electric wave generator 40 but also controls the power supply to operate only for a predetermined time or a predetermined time by the timer built in the control switch 180 It can be varied. When the power is supplied from the power source 140 that is a power supply unit, the control switch 180 controls the operation of the electric wave generating unit 140 based on the information stored in the memory according to the operation of the operation switch 160 and the mode selection switch 240. [(40). The electric wave generating unit 40 is operated and an electric wave is output from the electric wave generating unit 40. The user holds the electric wave generating unit 40 in a desired body part while holding the handle 60 of the main body By stimulating with electric waves in close contact with each other, the muscles can be relaxed and blood circulation can be promoted, thereby improving the health of the human body. In the above-described embodiment, the electric wave generating part 40 has a needle shape that is placed in the recessed part 300. However, it is preferable that the recessed part 300 is provided with a needle- It is preferable to insert or detach a flat recess 300 in which a needle for inserting or applying a massage or a medicament to the skin is not inserted.

In addition, a preferable electric wave generating state according to an embodiment of the electric wave generating part 40 is as follows. The power source is electrically connected to a capacitor, a resistor, a transistor, and a variable resistor, When the capacitor is turned on, the power supplied to the capacitor flows to the collector of the transistor while flowing to the variable resistor to charge the capacitor. The current flowing to the variable resistor side until the capacitor is charged is the voltage generated in the resistor and the resistor The current flows to the base of the transistor as it is, thereby generating a minute electric wave, so that the current flowing through the recess 300 of the recess 300 is applied to the base of the transistor 300, . Preferably, the electric stimulation deceleration body 20 is provided with a case for replacing the electric power source 140 and an LED diode for confirming the power application is disposed. When the operation switch 160 is turned on, The diodes are caused to emit light at a constant cycle, and the electric wave generator 40 needs to generate a current of several microamperes or more, which is a minute current that is useful as an electric stimulus, for the following reason. It is known that micro currents of about 0.06 mA flow in the human body in the case of current, and it is known that the intensity of such micro currents differs according to the health condition. In general, when the health state deteriorates, It is known. Therefore, it is possible to contribute to the balance inside the body by stimulating the microwave having a magnitude enough to stimulate the body from the outside. In addition, although there is a slight difference depending on the sensory level of the body, it is generally known that a current of about 1 mA is sufficiently perceivable, and it is known that long-time current conduction is not preferable. Therefore, the current supplied through the forehead or face may be as small as several microamperes (μA) less than 1 mA, and preferably, the current flows intermittently for a certain period of time rather than continuous flow, .

Most preferably, the instantaneous current is delivered to the human body's internal current of 300 μA or less, and it is preferable that the microcurrent flowing through the body is not adversely affected even if it is used for a sensitive part or used for a long time. Also, as shown in the above, the electric wave generating unit 40 connects a capacitor, a resistor, a transistor, and a variable resistor, and converts the power source 140 into a fine DC current by turning on / off a switch button, (300). & Lt; / RTI & gt; Preferably, the frequency of the spike pulse Ps applied to the sink 300 is set to 9.0 ± 0.2 Hz, the pulse width is set to 100 to 800 μs, and a 10 to 400 KΩ load corresponding to the load resistance of the human body The ratio of the number of turns of the coil of the transformer to the output is set so that the positive peak voltage value in the pulse width period of the spike pulse becomes 1.5 to 100 V and the positive voltage in the pulse width period maintains the predetermined voltage value or more A DC power source is supplied from the power source 140 and an appropriate microelectric wave of 1 to 300 μA or less is generated through a resistor and a variable resistor so that the patch is conducted. Here, the power source 140 may supply a DC power of 1.5 to 12 V, and accordingly, when the width of the variable resistor is changed, it is possible to supply an appropriate microwave of 1 to 300 μA or less. The operation of the electric stimulation generating unit is as follows. When the operation switch 160 installed in the electric stimulation deceleration body 20 is turned on, a DC power source of 1.5 to 12 V initially supplied is applied to the collector of the transistor through the patch while flowing toward the variable resistance side to charge the capacitor. And the current flowing to the variable resistance side until the capacitor is charged flows to the base side of the transistor only by a voltage drop generated in the resistor and the resistor, so that the transistor is turned on.

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When the capacitor is completely charged, the capacitor serves as a decoupling capacitor, and the current is directly applied to the base of the transistor. Thus, the transistor is turned on and the micro-electric wave is blurred in the patch.

The resistors shown here may be arranged in the circuit according to the value of the electric wave. Therefore, in order to generate the required current of several tens of microamperes, the internal resistance of the recess 300 considers the conditions according to one embodiment as follows. The internal resistance value of the patch can be obtained by R = V / I (the resistance when a current of 1 A flows when a voltage of 1 V is applied is referred to as 1 OMEGA). For example, supposing that the power supplied from the power source 140 is 3V, in order to allow a fine current of 60 μA to flow, the sinker 300 having an internal resistance value of 50 k? It is possible to supply an appropriate minute electric wave of 1 to 300 μA or less. It is preferable that the first port of the pulse generation circuit is an output port for outputting a basic pulse, and the fundamental pulse is set to a frequency of 8.0 Hz, a pulse voltage Vo of -5 V, and a pulse width of 100 to 800 占 쏚. It is preferable that the frequency is 8.0 Hz, but it is also allowed to be in the range of 9.0 ± 0.2 Hz. In addition, by changing the pulse width, it is possible to change a strong combination of the magnetic poles (energy) from time to time. The strength changeover circuit is a circuit for changing the pulse width and changing the strength combination of the stimulation. 240). In this case, the movable contact of the mode selection switch 240 is connected to the second port of the pulse generating circuit, the first fixed contact is not connected, the second fixed contact is connected to the earth line through a resistor, The third fixed contact is connected directly to the earth line. As a result, when the mode selection switch 240 is changed to the first fixed contact, the power supply voltage can be supplied to the second port through the resistor, the pulse width becomes 500 μs, and the magnetic pole becomes "strong" do. Further, preferably, when the mode selection switch 240 is switched to the second fixed contact, the divided power supply voltage can be supplied to the second port, so that the pulse width becomes 400 [micro] s, do.

When the mode selection switch 240 is changed to the third fixed contact, the voltage supplied to the second port becomes & quot; 0 (zero) & quot ;, so that the pulse width becomes 200 μs and the stimulus becomes "weak" . Further, the pulse width is set as described above and the frequency is set to 8.0 Hz, whereby the non-pulse period becomes approximately 100 msec or more. On the other hand, the first port (output port) of the pulse generating circuit is connected to one end of the coil of the output transformer through the output transistor. It is preferable that the other end of the coil is connected to the anode through the operation switch 160 and the cathode is connected to the earth line. In this case, the ratio of the number of turns of the coil of the output transformer becomes an important factor for obtaining the spike pulse, and a good spike pulse can be obtained. Thus, when a load resistance of, for example, 300 k? Capable of coping with the load resistance of the human body is connected, an optimum waveform-shaped spike pulse can be obtained. In this case, it is preferable that the peak voltage value is in the range of 1.5 to 100 V and that the positive voltage in the period of the pulse width Tp is a waveform that maintains a predetermined voltage value or more. One end of the coil of the output transformer is connected to both electrode portions, and the other end of the coil is connected to the electrode plate and the connection jack constituting the negative electrode portion, respectively. On the other hand, the power regulator connects the input terminal to the anode through the operation switch and connects the output terminal to the input side of the power input circuit. Generally, the load resistance of the human body is 10 to 400 k OMEGA, and the load resistance is connected at about 10 to 400 KM across both ends of the coil. As a result, the dent of the skin 300 A predetermined spike pulse is applied to the surface, and it is effective to gradually use the spike pulse by raising the operation switch. Therefore, the use of such electrical stimulation depression makes it possible to set the physical quantities such as frequencies and voltages corresponding to physiological mechanisms of the human body more precisely, and also to optimize the dynamic changes of the waveform, Relieves pain during skin irritation or treatment and improves treatment effect.

FIG. 7 is a perspective view illustrating an embodiment in which the stagnation and the control unit are combined in the functional stagnation of the present invention. In the electric stagnation of the electric stagnation according to the present invention, The recessed portion 300 is formed by a recessed portion 300 and a recessed portion 300 with a recessed screw thread and a fixed packing for fixing the recessed recessed threaded portion. And the handle portion 60 are separated and removed. In addition, the recess 300 may be detached and detached from the handle 60 having the recess formed therein by a recess or a recess, a detachable button or screw thread, preferably a step, a magnet, or a fitting, The grip portion 60 and the recess portion 300 may be detachably attached to a detachment groove or a fitting having a predetermined size protruding integrally at one end of the recessed body by a step, a fitting, a magnet, or the like Is a perspective view of the needle roller. The stagnant part 300 where the electric wave generating part 40 is generated is connected to the electric wave generating part 40, the power source 140 and the control switch 180 In order to remove a stain, a small spot, a pore, etc. of a face, for example, a needle having a diameter of 0.12 mm and a needle length of 2.0 mm is required to be removed In order to eliminate facial acne marks, a needle length of 2.3 mm is preferable for a diameter of 0.15 mm of a needle, and a needle length of 2.5 mm is preferable for a needle diameter of 0.18 mm in order to remove a wrinkle larger than the needle. In order to heal a scar formed on the human body, The diameter of needle is 5mm in diameter and 0.30 ~ 4mm in diameter. As the diameter of needle is small and the length is short, the pain is decreased. On the contrary, when the diameter of needle is wide and the length is long, Although the user is afraid of the pain, he or she should use a needle with a long diameter and a long length. However, the user uses a needle having a small diameter and a short length due to pain and uses the [illegible] 308 holder.

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first step of perforating the skin, the use of a needle with a needle length of 5 mm or more at a needle diameter of 0.30 to 4 mm is accompanied by a discomfort due to pain. For the first time, for the training of the skin, If you use a thick, long-lasting acupuncture for your symptoms, then you should treat acne scars, wrinkles, and stains all at once. There is a problem in that a plurality of stagnation must be used because the thickness and the length of each needle used are different. It is that the electric wave generating unit 40 is caused slowdown unit 300 has advantages that may make the depression portion 300 is easily removable to clean and come in handy in accordance with the symptoms available through the slowdown holding member 320 for the original.

The recess 300 includes a recess or groove or protrusion and a handle 60 and a detachable button for detaching the recess 60. The recess 60 may be formed as a step or a magnet It is also preferable that the recess 300 is formed by a detachable coupling portion in which the recess 300 and the handle 60 are separated and detached from each other using a recessed screw thread and a fixing packing for fixing the recess. Is also preferable. As described above, the recess 300 is detached and detached from the recess 340 through the recess 340 and the recess 360, or the recess 360 is separated from the recess 360 by the recess and the release button, Wherein the recess is formed with a predetermined size of protruding indentation groove integrally protruding from one end of the body and the indentation can be inserted into and detached from the indentation with a step. The depressed portion 300 is detachably attached to or detached from the depressed / depressed portion 340, the depressed / depressed depressed portion 340 and the depressed / depressed depressed button, or the depressed / depressed depressed portion, or the depressed portion 300 and the depressed portion 300 And an engaging portion having a resilient force is brought into close contact with the engaging groove so that the engaging groove is caught by the engaging jaw, So that the stagnation can be firmly used. Accordingly, only the stagnant part 300 can be used separately, and it can be easily used on all parts of the body including the face and forehead, and can relax the muscles and promote blood circulation, thereby improving the health of the human body . The driving means of the stagnation driving member 420 driving the stagnation part 300 drives the crank part 380 by the force of the motor or the air as the stagnation driving member 420, 400 to regulate the speed and intensity by a controller attached to the inside of the PCB installed inside the main body to stimulate the skin and the scalp, and the PCB unit includes a relay unit for connecting and disassembling the power source connected thereto, and a main body And operates the motor and the air turbine using the compressor or the compressor, which is the stagnation driving member 420, through the connecting cable 260. The stagnation driving member 420 is driven by the motor It is also preferable to use ultrasonic vibrators instead of air turbines.

The recess 300 formed by the above manufacturing method is combined with and detached from the recess formed with the handle 60 through the recessed and unattached attaching portion 340 to manufacture the recessed portion 300 of the present invention will be. While the present invention has been particularly shown and described with reference to exemplary embodiments thereof, it is to be understood that the invention is not limited to the disclosed exemplary embodiments, and that various changes and modifications may be made without departing from the scope of the invention as defined in the appended claims. And the present invention described above should not be construed as limiting the terms or words used in the specification and claims to ordinary or dictionary terms. It should be construed as meaning and concept consistent with the technical idea of the present invention based on the principle that the concept can be properly defined. Therefore, the embodiments described in the above description and the configurations shown in the drawings are merely one preferred embodiment of the present invention and do not represent all the technical ideas of the present invention. Therefore, It should be understood by those skilled in the art that various equivalents and modifications may be made. It will be apparent to those skilled in the art that various modifications and variations can be made in the present invention without departing from the scope and spirit of the invention, Should be based on the contents of this specification.

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CLAIMS KR20110002210

1.

A control body 120 for generating an electric wave and a handle 60 for the user to grip the electric stimulation deceleration body 20 installed in the recessed part 300 having a plurality of needles, An operation switch 160, an adjustment switch 180, a display unit 200, a mode selection switch 240 and an air generator 20 through a compressor And a connecting cable 260 or an air blowing port 220 connecting the main body 200 and the main body 200 to the electric stagnation resting body 20 are installed in the control body 120.

2.

The stagnation part 300 is formed on the stagnation part 300 having the stagnation-disassembling part 340 where the stagnation is detached and is rotating or reciprocating, And a stagnation fixing member (220) for fixing the stagnation part (300).

3.

3. The apparatus according to claim 2, wherein a connection terminal (280) or a connection terminal is provided from the electric wave generating unit (40) so that electric wave is conducted to the sinking part (300) An operation switch 160 for controlling the operation of the controller, and a mode selection switch 240 are connected to the control body 120, Or the handle portion (60).

4.

The electric wave generator (40) according to claim 3, wherein the spike pulse generating circuit for outputting a spike pulse from the coil on the electric wave generating circuit part (PCB) of the transformer is installed inside the control part body (120) or the handle part And a negative electrode part serving as an electrode part having a plurality of recessed parts 300 to be one electrode provided from the spike pulse generation circuit or the other electrode provided with the spike pulse, And the functional stagnation.

5.

The frequency of the spike pulse, which is the therapy electric power of the electric stimulation drowning body 20, is 9.0 ± 0.2 Hz, the pulse width is in the range of 100 to 800 μs, the positive peak voltage value in the pulse width period is 1.5 to 100 V, And the electric wave is generated by setting the ratio of the number of turns of the coil of the output transformer so that the negative voltage maintains the predetermined voltage value or more.

6.

The portable terminal according to any one of claims 1 to 5, further comprising a connection terminal (280) through which an electric wave is transmitted to the handle (60) by a recess of the recess (300) through a connection cable (260) An electric wave

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generating unit 40 for converting the power supplied into the body 120 or the handle 60 into a fine DC current is provided and the electric wave is generated on the body 120 or the handle 60 An operation switch (160) for controlling power supplied to the unit (40) and the operation display unit (200).

7.

The power supply apparatus according to claim 1, wherein the power supplied to the electric field generator body (20) is connected to a capacitor, a resistor, a transistor and a variable resistor, and when the operation switch (160) is turned on, The current flowing to the variable resistor side and the current flowing to the variable resistor side until the capacitor is charged flows to the base side of the transistor only by the voltage drop caused by the resistor and the resistor, The capacitor serves as a decoupling capacitor, and the current is applied to the base of the transistor as it is, so that a minute electric wave is generated in the recess 300 and transferred to the epidermis.

8.

The functional stagnation according to claim 7, wherein the electric-wave generating unit (40) for generating electric waves of the electric-magnetic-field stagnating body (20) comprises at least one electric-wave generating unit (40).

9.

9. The method of claim 8, wherein positive and negative electrodes are mounted on one side of the stagnation part of the stagnation part (300) of the electric stagnant stagnation body (20) Wherein the functional stagnation occurs.

10.

10. The method according to claim 9, wherein the recessed part (300) comprises a grip part (60) detachably attached to the recessed part (300) so as to be pressed on the skin of the patient, And an electric wave input part connected to the connection terminal (280) from the electric wave generator so as to be energized.

11.

The electric wave generator as claimed in claim 10, wherein at least one of the radio wave, the ultrasonic wave, the high frequency, the medium frequency, and the low frequency is generated by the electric wave generator at the end of the plurality of recessed parts (300) 40) and is delivered to the surface of the skin.

12.

12. The plasma display panel as claimed in claim 11, wherein the controller body (120) having the electric wave generator (40) has a +/- conductive plate connected to the output terminal, And an electrode which is connected and generates a current upon contact with a human body.

13.

The hair dryer as set forth in claim 12, further comprising a needle bar (120) comprising a stimulator body (20), a head part (40), a handle part (60) And a vibration plate 200 communicating with the acupuncture board 160. The driving member 180 is rotated by a power source, A crank portion (400) for converting the rotational motion of the body (180) into a rectilinear motion, and a cam shaft, and the stagnant is reciprocated and stimulated on the skin and the scalp.

14.

The motorcycle according to claim 13, wherein the stagnation driving member (420) is any one selected from an electric motor, an air turbine, and an ultrasonic wave, and the crank unit (380) Wherein the elastic member is reciprocated through the elastic member.

15.

15. The skin stimulator of claim 14, wherein the depression (300) is made of a magnet generating a magnetic force

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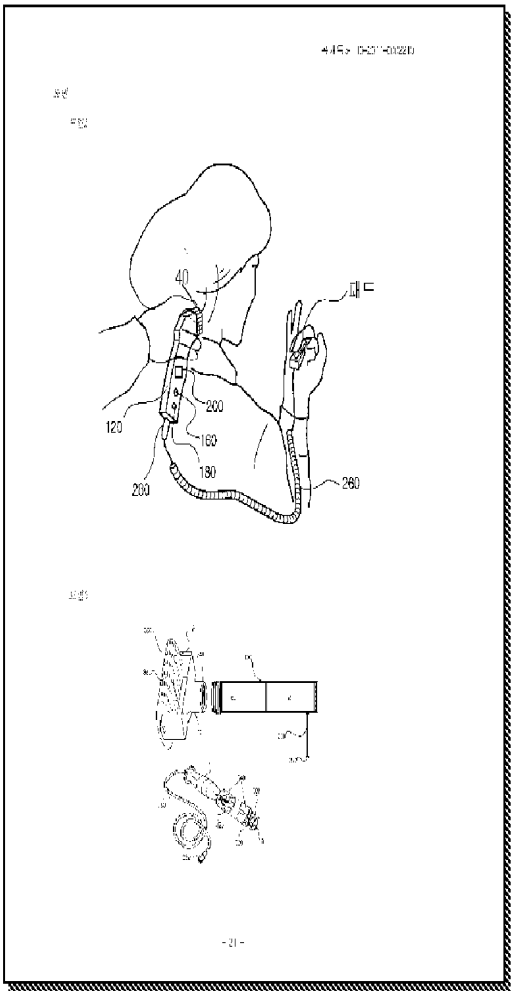

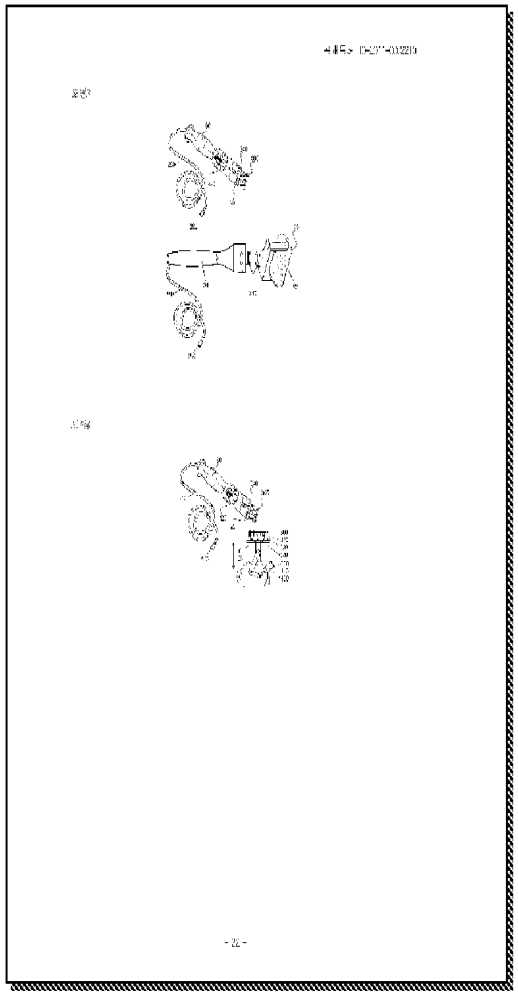

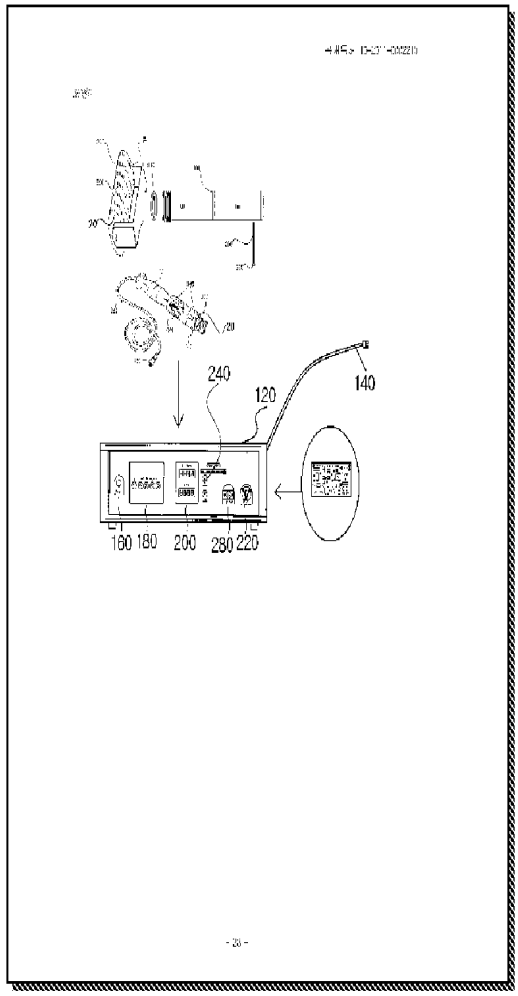

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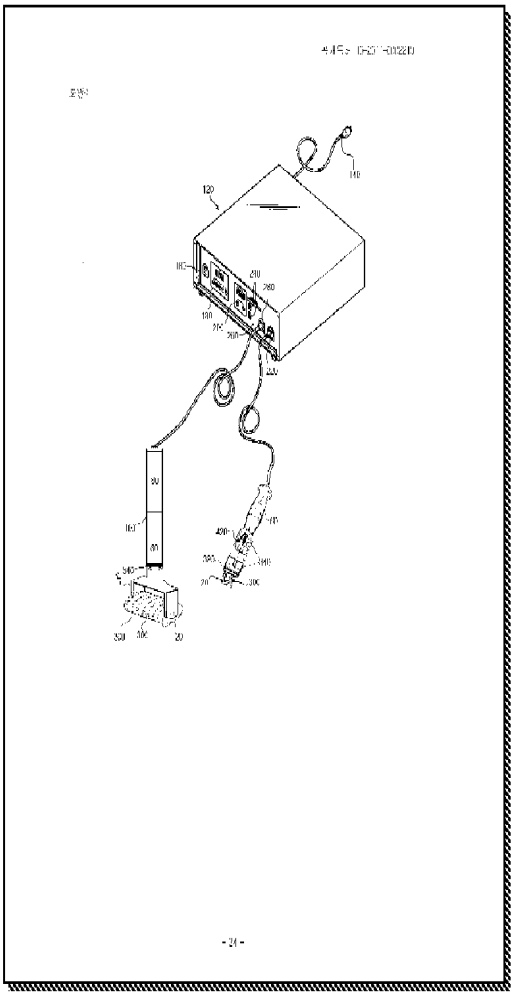

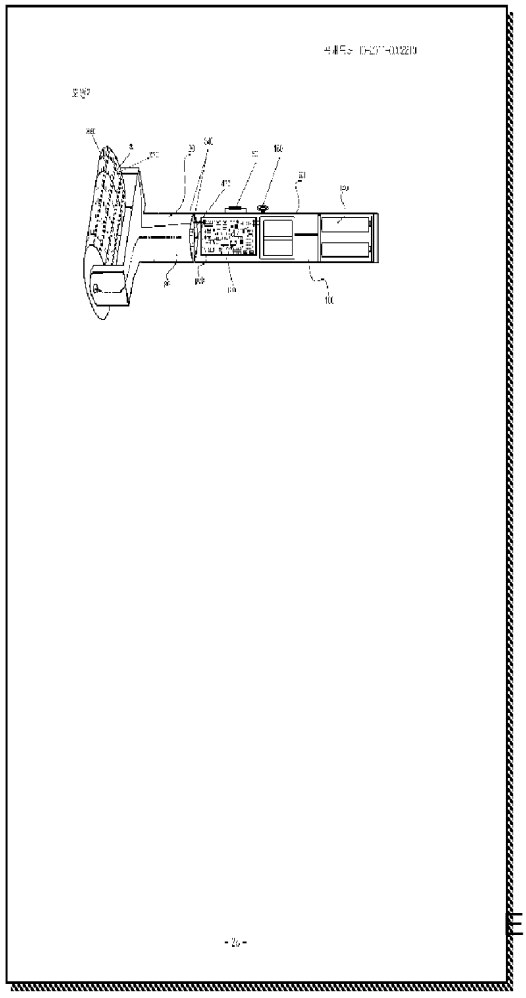

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/724,261	10/03/2017	Jongju Na	NA001KR_US3	3803

26338 7590 03/04/2019

MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

EXAMINER
COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
03/04/2019	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 15/724,261	Applicant(s) Na, Jongju	
	Examiner DAVID C COMSTOCK	Art Unit 3773	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 30 October 2018.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 21-40 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 21-40 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 03 October 2017 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☑ All b)☐ Some** c)☐ None of the:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

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DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Terminal Disclaimer

The terminal disclaimer does not comply with 37 CFR 1.321 because:

This application was filed on or after September 16, 2012. The party identified in the terminal disclaimer is not the applicant of record. A request to change the applicant under 37 CFR 1.46(c) must be filed and must include an application data sheet specifying the applicant in the applicant information section and comply with 37 CFR 3.71 and 3.73. To be reconsidered, the terminal disclaimer must be filed with the request under 37 CFR 1.46(c). If anyone other than the applicant, the person signing the terminal disclaimer must have appropriate power of attorney.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 21-40 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 9,320,536. Although the claims at issue are not identical, they are not patentably distinct from each other because the differences amount to minor changes in the arrangement and phraseology of the claims. The claims of both the patent and the present application are directed to the substantially same invention of a device and method for treating dermatological tissue comprising placing a user holdable device having a releasable assembly with deployable needles on or near tissue, the assembly including an electrical contact, and communicating electrical signals via the needles. The claims further recite energizing a motor to deploy the needles and maintaining electrical contact and illuminating an LED. Where differences exist, the issued patent includes more elements and is more specific. For example, in the issued patent, the independent claims further recite deploying the needles with the motor. In addition, the issued patent further recites the signal generator in the independent apparatus claim. Thus, the invention of the patent claims are in effect a "species" of the "generic" invention of the application claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the patent claims, they are not patentably distinct from the patent claims.

Response to Arguments

Applicant's arguments filed 30 October 2018 with respect to the amended claims have been fully considered and are persuasive. Therefore, the rejection under 35 USC 103 has been

withdrawn. However, Applicant must file a new terminal disclaimer as described above to overcome the double patenting rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. The examiner can normally be reached Monday-Friday, 9 a.m. - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact*** **the examiner's supervisor, SPE, *at* (571) 272-4760**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID C COMSTOCK/
Examiner, Art Unit 3773
/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3773

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/724,261	Na, Jongju
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61H15/02.cpc. A61H 39/086,002.cpc. A61H37/00.cpc. A61N1/0502,328,36017.cpc. A61N5/0616,062,0624.cpc. A61B2017/3409.cpc. A61H23/02.cpc. A61H2015/0014.cpc. A61H2039/005.cpc.	8/6/2018	/DC/
A61H2201/0153,105,1207,1604,169,5007,5097.cpc. A61H2205/022,04,06,065,084,10,12.cpc. A61M2037/0007,0023.cpc. A61M2205/8206.cpc. A61N2005/0644,0652,0659,0661.cpc.	8/6/2018	/DC/
Search updated	02/28/2019	/DC/

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
600	249	8/6/2018	/DC/
607	88, 102, 189	8/6/2018	/DC/
604	20, 46, 21, 117	8/6/2018	/DC/
606	9	8/6/2018	/DC/
601	2	8/6/2018	/DC/
424	1.11	8/6/2018	/DC/

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
EAST text search--see EAST search history	8/6/2018	/DC/
Inventor name search--see EAST search history	8/6/2018	/DC/
EAST text search updated--see EAST search history	02/28/2019	/DC/

	/DAVID C COMSTOCK/ Examiner.Art Unit 3733

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/724,261	Na, Jongju
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

	/DAVID C COMSTOCK/ Examiner.Art Unit 3733

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/724,261	Na, Jongju
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/06/2018	02/28/2019							
	1	-	-							
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	21	✓	✓							
	22	✓	✓							
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	30	✓	✓							
	31	✓	✓							
	32	✓	✓							
	33	✓	✓							
	34	✓	✓							
	35	✓	✓							
	36	✓	✓							
	37	✓	✓							
	38	✓	✓							
	39	✓	✓							
	40	✓	✓							

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	14770	((600/249) or (607/88,102,189) or (604/20,46,21,117) or (606/9) or (601/2) or (424/1.11)).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/02/28 23:56
L3	11180	A61H15/02.cpc. A61H39/086,002.cpc. A61H37/00.cpc. A61N1/0502,328,36017.cpc. A61N5/0616,062,0624.cpc. A61B2017/3409.cpc. A61H23/02.cpc. A61H2015/0014.cpc. A61H2039/005.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2019/03/01 00:00
L4	18739	A61H2201/0153,105,1207,1604,169,5007,5097.cpc. A61H2205/022,04,06,065,084,10,12.cpc. A61M2037/0007,0023.cpc. A61M2205/8206.cpc. A61N2005/0644,0652,0659,0661.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2019/03/01 00:01
L5	624	(1 2 3) and needle and electric$3 and signal and (led or "l.e.d." or "light emitting diode") and (skin or dermis or dermatolog$4) and motor	US-PGPUB; USPAT; USOCR	OR	ON	2019/03/01 00:02
L6	284	5 and (releasabl$1 or detach$4)	US-PGPUB; USPAT; USOCR	OR	ON	2019/03/01 00:02
L7	19	6 and @pd>"20180806"	US-PGPUB; USPAT; USOCR	OR	ON	2019/03/01 00:03
L8	31	5 and @pd>"20180806"	US-PGPUB; USPAT; USOCR	OR	ON	2019/03/01 00:03
L9	12	8 not 7	US-PGPUB; USPAT; USOCR	OR	ON	2019/03/01 00:03
L10	578	(1 2 3) and @pd>"20180806"	US-PGPUB; USPAT; USOCR	OR	ON	2019/03/01 00:04
L11	547	10 not (7 8)	US-PGPUB; USPAT; USOCR	OR	ON	2019/03/01 00:04

3/1/2019 12:10:01 AM
C:\Users\dcomstock\Documents\EAST\Workspaces\default.wsp

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/724,261	10/03/2017	Jongju Na	NA001KR_US3	3803

26338 7590 09/17/2019

MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

EXAMINER
COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
09/17/2019	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of Abandonment	Application No.	Applicant(s)
	15/724,261	Na, Jongju
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☑ Applicant's failure to timely file a proper reply to the Office letter mailed on 04 March 2019.
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 to the final rejection. (A proper reply under 37 CFR 1.113 to a final rejection consists only of:(1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) if this is utility or plant application, a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. Note that RCEs are not permitted in design applications.)
   (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
   (d) ☑ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $ _____ is insufficient. A balance of $ _____ is due.
   The issue fee required by 37CFR 1.18 is $ _____ . The publication fee, if required by 37 CFR 1.18(d), is $ _____ .
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record or other party authorized under 37 CFR 1.33 (b). See 37 CFR 1.138(b).

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34) upon the filing of a continuing application.

6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☐ The reason(s) below:

_____

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773

Petitions to revive under 37 CFR 1.137, or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

Doc Code: PA..
Document Description: Power of Attorney

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Application Number	15724261
Filing Date	10/3/2017
First Named Inventor	Na
Title	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
Art Unit	3733
Examiner Name	David C. Comstock
Attorney Docket Number	NA001KR_US3

SIGNATURE of Applicant or Patent Practitioner

Signature	mwresq/	Date (Optional)	04/10/2020
Name	Merle W Richman	Registration Number	38282
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc Code: PA..
Document Description: Power of Attorney

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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date
15724261	10/3/2017

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 26338

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

☑ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☐ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	
Name	Jongju Na		
Title			

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

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Name	Registration Number

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The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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Electronic Acknowledgement Receipt

EFS ID:	39127771
Application Number:	15724261
International Application Number:	
Confirmation Number:	3803
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Customer Number:	26338
Filer:	Merle W. Richman
Filer Authorized By:	
Attorney Docket Number:	NA001KR_US3
Receipt Date:	10-APR-2020
Filing Date:	03-OCT-2017
Time Stamp:	15:54:24
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	aia0082_DrNa.pdf	150079 727bf0fd1061a336757aeddd91f7d14333e782b7	no	4

Warnings:

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/AIA/26 (04-14)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) NA001KR_US3

In re Application of: Na

Application No.: 15724261

Filed: 10/3/2017

For: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

The applicant, Na , owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term **prior patent** No. 9,320,536 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

expires for failure to pay a maintenance fee;
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is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby knowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☒ The undersigned is an attorney or agent of record. Reg. No. 38282

/mwresq/ — Signature

April 10, 2020 — Date

Merle Richman — Typed or printed name

Attorney of record — Title

858 551-2030 — Telephone Number

☒ Terminal disclaimer fee under 37 CFR 1.20(d) previously paid.

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Electronic Acknowledgement Receipt

EFS ID:	39127911
Application Number:	15724261
International Application Number:	
Confirmation Number:	3803
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Customer Number:	26338
Filer:	Merle W. Richman
Filer Authorized By:	
Attorney Docket Number:	NA001KR_US3
Receipt Date:	10-APR-2020
Filing Date:	03-OCT-2017
Time Stamp:	15:59:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer Filed	na001_kr3-terminal-disclaimer.pdf	96453 e66cb1f0173cede5e6e248c632ed204457cf148c	no	1

Warnings:

ENDYMED EXHIBIT 1002 - 665/733

Information:	
Total Files Size (in bytes):	96453

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: PET.OP
Document Description: Petition for Review by the Office of Petitions

PTO/SB/64 (01-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(a)

Docket Number (Optional): NA001KR_US3

First named inventor: Na, Jongju

Application No.: 15/724,261 Art Unit: 3733

Filed: 10/3/2017 Examiner: David C. Comstock

Title: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

Attention: Office of Petitions
Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
FAX: (571) 273-8300

NOTE: If information or assistance is needed in completing this form, please contact the Office of Petitions at (571) 272-3282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the Office notice or action plus any extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION.

NOTE: A grantable petition requires the following items:
(1) Petition fee;
(2) Reply and/or issue fee;
(3) Terminal disclaimer with disclaimer fee -- required for all utility and plant applications filed before June 8, 1995; and for all design applications; and
(4) Statement that the entire delay was unintentional.

1. **Petition fee**

[X] Small entity fee $ 1000.00 Applicant claims small entity status. See 37 CFR 1.27.

[ ] Micro entity fee $ _____ (37 CFR 1.17(m)). Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

[ ] Undiscounted fee $ _____ (37 CFR 1.17(m)).

2. **Reply and/or fee**

A. The reply and/or fee to the above-noted Office notice or action in the form of _____ (identify the type of reply):

[ ] has been filed previously on _____.
[x] is enclosed herewith.

B. The issue fee and publication fee (if applicable) of $ _____.

[ ] has been paid previously on _____.
[ ] is enclosed herewith.

This collection of information is required by 37 CFR 1.137(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14 and 41.6. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: PET.OP
Document Description: Petition for Review by the Office of Petitions

PTO/SB/64 (01-18)
Approved for use through 11/30/2020. OMB 0651-0031
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(a)

3. **Terminal disclaimer with disclaimer fee**

[X] Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.

[ ] A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $_____) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. **STATEMENT:** The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(a) was unintentional. [NOTE: The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(a) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D)).]

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

/mwresq/ _____ April 10, 2020
Signature — Date

Merle Richman _____ 38282
Typed or Printed Name — Registration Number, if applicable

PO Box 3333 _____ (858)551-2030
Address — Telephone Number

La Jolla, California 92038
Address

Enclosures:

[ ] Fee Payment

[X] Reply

[ ] Terminal Disclaimer Form

[ ] Additional sheet(s) containing statements establishing unintentional delay

[ ] Other: _____

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

[ ] Deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

[X] Transmitted electronically on the date shown below to the United States Patent and Trademark Office at (571) 273-8300.

April 10, 2020 — Date

/mwresq/ — Signature

Merle Richman
Typed or printed name of person signing certificate

Electronic Patent Application Fee Transmittal

Application Number:	15724261
Filing Date:	03-Oct-2017
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Filer:	Merle W. Richman
Attorney Docket Number:	NA001KR_US3

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
PET. REVIVE ABANDON APP, DELAY PYMT-RESP	2453	1	1000	1000
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1000**

Electronic Acknowledgement Receipt

EFS ID:	39128242
Application Number:	15724261
International Application Number:	
Confirmation Number:	3803
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Customer Number:	26338
Filer:	Merle W. Richman
Filer Authorized By:	
Attorney Docket Number:	NA001KR_US3
Receipt Date:	10-APR-2020
Filing Date:	03-OCT-2017
Time Stamp:	16:15:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1000
RAM confirmation Number	E202040G16282567
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Arguments/Remarks Made in an Amendment	na001kr_us3-rfoa-2019-03-04.pdf	94972 c645dcd9c67711f41696139731d84417566 3c1be	no	8
Warnings:					
Information:					
2	Petition for review by the Office of Petitions	na001kr_us3-ptr-2019-03-04.pdf	105323 de2fce75872708e3e95df16eccf11aaf1ad80 f13	no	2
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30520 bb5b219e7c7a5b720fd664c689ceee2b1f5 07119	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	230815		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Na Application No.: 15724261 Filed: 10/3/2017 Title: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT Attorney Docket No.: NA001KR_US3	Art Unit: 3733 Examiner: David C. Comstock

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE UNDER 37 CFR 1.111

Dear Sir:

In response to the Final Office Action of March 4, 2019, please amend this application as follows.

Amendments to the claims begin on page 2.

Remarks begin on page 7.

ENDYMED EXHIBIT 1002 - 673/733

In the claims:

1. (Cancelled).
2. (Cancelled).
3. (Cancelled).
4. (Cancelled).
5. (Cancelled).
6. (Cancelled).
7. (Cancelled).
8. (Cancelled).
9. (Cancelled).
10. (Cancelled).
11. (Cancelled).
12. (Cancelled).
13. (Cancelled).
14. (Cancelled).
15. (Cancelled).
16. (Cancelled).
17. (Cancelled).
18. (Cancelled).
19. (Cancelled).
20. (Cancelled).

ENDYMED EXHIBIT 1002 - 674/733

21. (Currently Amended) A method of treating dermatological tissue, comprising:

placing a user holdable device releasably couplable deployable needle module end surface on or near dermatological tissue to be treated, the user holdable device including a proximal end and the releasably couplable deployable needle module, the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles, the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one ~~extendable~~ electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end; and

communicating electrical signals from the user holdable device proximal end to the needle assembly via the electrical ~~conductors~~contacts.

22. (Currently Amended) The method of claim 21, further comprising energizing a motor coupled to the needle assembly to cause the plurality of the ~~extendable~~ needles to extend a desired distance from the releasably couplable deployable needle module end surface.

23. (Previously Presented) The method of claim 22, further comprising energizing the plurality of needles via a signal generator electrically coupled to the user holdable device proximal end.

24. (Currently Amended) The method of claim 21, wherein one of the at least one electrical contacts is extendable.

25. (Currently Amended) The method of claim 21, wherein the user holdable device proximal end includes a motor with a ~~draft~~ drive shaft releasably couplable to the needle assembly and the method further including energizing the motor coupled via the draft shaft to the needle assembly to cause ~~a~~ the plurality of ~~the extendable~~ needles to extend a desired distance from the releasably couplable deployable needle module end surface.

ENDYMED EXHIBIT 1002 - 675/733

26. (Currently Amended) The method of claim 23, wherein the user holdable device proximal end further includes at least one embedded LED therein and further including energizing the at least one embedded LED~~,~~so the at least one embedded LED ~~illuminating~~ illuminates the releasably couplable deployable needle module.

27. (Currently Amended) The method of claim 21, wherein one of the at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles.

28. (Currently Amended) The method of claim 26, wherein the needle assembly includes a translucent section and further including energizing the least one embedded LED to ~~communicate illumination~~ illuminate ~~from the least one embedded LED to~~ the plurality of ~~extendable~~ needles via the needle assembly translucent section.

29. (Currently Amended) The method of claim 21, wherein a first electrical contact of the at least one electrical contact is electrically coupled to a first plurality of the plurality of ~~extendable~~ needles and a second electrical contact of the at least one electrical contact is electrically coupled to a second, different plurality of the plurality of ~~extendable~~ needles.

30. (Currently Amended) The method of claim 21, wherein one of the user holdable device proximal end and the needle assembly includes at least two extendable electrical contacts and the other includes at least two electrical contacts couplable to ~~the one of the user holdable device proximal end and the releasably couplable deployable needle assembly~~ at least two extendable electrical contacts.

31. (Currently Amended) The method of claim 23, further comprising energizing the motor to deploy the plurality of ~~extendable~~ needles to a predetermined depth and directing the signal generator to energize the plurality of ~~extended~~ needles ~~to~~ at a predetermined intensity for a predetermined duty cycle.

ENDYMED EXHIBIT 1002 - 676/733

32. (Currently Amended) An apparatus for treating dermatological tissue, comprising:

a user holdable device including a proximal end and

a releasably couplable deployable needle module, the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles, the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end.

33. (Currently Amended) The apparatus of claim 32, further including a motor coupled to the needle assembly to extend the plurality of ~~extendable~~ needles a desired distance from the releasably couplable deployable needle assembly end surface when the motor is energized with a particular signal.

34. (Currently Amended) The apparatus of claim 33, further including a signal generator electrically coupled to the user holdable device proximal end to energize the plurality of ~~extended~~ needles.

35. (Previously Presented) The apparatus of claim 34, wherein the user holdable device proximal end includes an electrical connector couplable to the signal generator.

36. (Currently Amended) The apparatus of claim 33, wherein the user holdable device proximal end includes the motor, the motor including a ~~draft~~ drive shaft releasably couplable to the needle assembly.

37. (Currently Amended) The apparatus of claim 32, wherein the user holdable device proximal end further includes at least one embedded LED therein and the apparatus further including a photonic signal generator electrically coupled to the least one embedded LED, the at least one embedded LED capable of illuminating the needle assembly when energized.

ENDYMED EXHIBIT 1002 - 677/733

38. (Currently Amended) The apparatus of claim 32, the wherein one of the at least one ~~extendable~~ electrical contacts includes a pin that is extendable in the same direction as the plurality of needles.

39. (Currently Amended) The apparatus of claim 32, wherein one of the user holdable device proximal end and the needle assembly includes at least two extendable electrical contacts and the other ~~including~~ includes at least two electrical contacts couplable to the ~~one of the user holdable device proximal end and the needle assembly~~ at least two extendable electrical contacts.

40. (Currently Amended) The apparatus of claim 32, wherein one of the at least one electrical contacts ~~includes~~ is extendable.

ENDYMED EXHIBIT 1002 - 678/733

REMARKS

Claim Status:

Pending claims prior to amendment:	21-40
Claims Amended:	21, 22, 24-34, and 36-40
Claims Cancelled:	None
Claims Added:	None
Claims pending after entry:	21-40

Claim Amendments:

Applicants have amended the claims to fix several minor errors in preparation for the allowance of the application given only a double patenting rejection remains. No new matter has been added and the claims have not been broadened. Entry after final is therefore requested.

Double Patenting Rejection:

The Examiner has rejected claims 21-40 on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 9,320,536. Applicants are re-filing a terminal disclaimer to U.S. Patent No. 9,320,536 along with power of attorney to address issues noted by the USPTO. Reconsideration is respectfully requested. Applicant request that Examiner contact undersigned Attorney if issues remain with this rejection.

Applicants have made a diligent effort to place the claims in condition for allowance. However, should there remain unresolved issues that require adverse action, it is respectfully requested that the Examiner telephone Merle Richman, Applicants' Attorney at 858 551-2030 so that such issues may be resolved as expeditiously as possible.

For these reasons, and in view of the above amendments, this application is now considered to be in condition for allowance and such action is earnestly solicited.

ENDYMED EXHIBIT 1002 - 679/733

Respectfully Submitted,

_04/10/2020_ __/mwresq/_____
Date Merle Richman
Attorney/Agent for Applicant(s)
Reg. No. 38282

Merle Richman
Partner
Customer ID - 26338
PO Box 3333
La Jolla, CA 92038-3333
Tel. 858 551-2030

ENDYMED EXHIBIT 1002 - 680/733

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/724,261	Filing Date 10/03/2017	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $40 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $210 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	04/10/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $230 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/KIMBERLY R WHITE/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
* 15/724,261 *	15/724,261	Na, Jongju	
	Examiner	**Art Unit**	
	COMSTOCK, DAVID C	3773	

Document Code - DISQ	**Internal Document - DO NOT MAIL**

TERMINAL DISCLAIMER	☐ APPROVED	☑ DISAPPROVED
Date Filed: 10 April 2020	**This patent is subject to a Terminal Disclaimer**	

Approved/Disapproved by:

Td disapprvoed.
See below for reasons.

Technology Center: OPLC

Telephone: (571)272-6074

The terminal disclaimer identifies a party who is not the applicant (only for applications filed on or after September 16, 2012; See FP 14.26.10):

For cases filed on/after 9/16/12, 37 CFR 1.321 specifies that the applicant can disclaim, and the terminal disclaimer must specify the extent of the applicant's ownership.:

A request under 37 CFR 1.46(c) to change the applicant needs to be filed, which is (1) a request, signed by a 1.33(b) party, (2) a corrected ADS (37 CFR 1.76(c)) that identifies the "new" applicant in the applicant information, and is underlined since it is new, and (3) a 3.73(c) statement showing chain of title to the new applicant. Along with the § 1.46(c) request we need a POA that gives power to the attomey who is signing the TD, along with another copy of the TD, unless they file a TD that is signed by the applicant.

Please note the TD must be re-filed. No new fees are due.
/Lawana Hixon/

Doc Code: DIST.E.FILE **Document Description: Electronic Terminal Disclaimer - Filed**	PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	15724261
Filing Date	03-Oct-2017
First Named Inventor	Jongju Na
Attorney Docket Number	NA001KR_US3
Title of Invention	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action

☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Jongju Na	100%

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

9320536

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

◯ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer Request

ENDYMED EXHIBIT 1002 - 683/733

◉	I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

◉ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Registration Number 38282

◯ A sole inventor

◯ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application

◯ A joint inventor; all of whom are signing this request

Signature	/mwresq/
Name	Merle W Richman

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Doc Code: DISQ.E.FILE
Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 15724261

Filing Date: 03-Oct-2017

Applicant/Patent under Reexamination: Na

Electronic Terminal Disclaimer filed on April 20, 2020

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt

EFS ID:	39205864
Application Number:	15724261
International Application Number:	
Confirmation Number:	3803
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Customer Number:	26338
Filer:	Merle W. Richman
Filer Authorized By:	
Attorney Docket Number:	NA001KR_US3
Receipt Date:	20-APR-2020
Filing Date:	03-OCT-2017
Time Stamp:	14:47:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	32090 7747458e25a7f1c58208bc492075d46354956445	no	2

Warnings:

Information:	
Total Files Size (in bytes):	32090

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/724,261	10/03/2017	Jongju Na	NA001KR_US3

CONFIRMATION NO. 3803

POA ACCEPTANCE LETTER

26338
MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

OC000000116297286

Date Mailed: 04/21/2020

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/10/2020.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/mmasfaw/

ENDYMED EXHIBIT 1002 - 688/733

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/724,261	10/03/2017	Jongju Na	NA001KR_US3	3803

26338 7590 07/13/2020

MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

EXAMINER	
COMSTOCK, DAVID C	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
07/13/2020	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Application of	:	
Na, Jongju	:	
Application No. 15/724,261	:	DECISION ON PETITION
Filed: October 3, 2017	:	
For: METHOD, SYSTEM, AND APPARATUS	:	
FOR DERMATOLOGICAL TREATMENT	:	
:		

This is a decision on the petition under the unintentional provisions of 37 CFR 1.137(a), filed April 10, 2020, to revive the above-identified application.

The petition is **GRANTED**.

The application became abandoned for failure to reply in a timely manner to the final Office action mailed, March 4, 2019, which set a shortened statutory period for reply of three (3) months. No extensions of time under the provisions of 37 CFR 1.136(a) were obtained. Accordingly, the application became abandoned on June 5, 2019. A Notice of Abandonment was mailed September 17, 2019.

The petition satisfies the requirements of 37 CFR 1.137(a) in that petitioner has supplied (1) the reply in the form of an amendment, (2) the petition fee of $1000, and (3) a proper statement of unintentional delay.

This application is being referred to Technology Center 3773 for appropriate action in the normal course of business on the reply received April 10, 2020.

Telephone inquiries concerning this decision should be directed to Felicia Jenkins at (571). 272-0986.

/JOANNE L BURKE/
Lead Paralegal Specialist, OPET

OK to enter upon revival

/DC/

06/23/2020

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Na	
Application No.: 15724261	Art Unit: 3733
Filed: 10/3/2017	Examiner: David C. Comstock
Title: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT	
Attorney Docket No.: NA001KR_US3	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE UNDER 37 CFR 1.111

Dear Sir:

In response to the Final Office Action of March 4, 2019, please amend this application as follows.

Amendments to the claims begin on page 2.

Remarks begin on page 7.

ENDYMED EXHIBIT 1002 - 691/733

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

26338 7590 08/20/2020

MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

EXAMINER
COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 08/20/2020

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/724,261	10/03/2017	Jongju Na	NA001KR_US3	3803

TITLE OF INVENTION: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	11/20/2020

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

ENDYMED EXHIBIT 1002 - 692/733

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26338 7590 08/20/2020

MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/724,261	10/03/2017	Jongju Na	NA001KR_US3	3803

TITLE OF INVENTION: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	11/20/2020

EXAMINER	ART UNIT	CLASS-SUBCLASS
COMSTOCK, DAVID C	3773	600-249000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/724,261	10/03/2017	Jongju Na	NA001KR_US3	3803

26338 7590 08/20/2020

MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

EXAMINER	
COMSTOCK, DAVID C	
ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 08/20/2020

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

ENDYMED EXHIBIT 1002 - 694/733

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ENDYMED EXHIBIT 1002 - 695/733

Notice of Allowability	Application No. 15/724,261	Applicant(s) Na, Jongju	
	Examiner DAVID C COMSTOCK	Art Unit 3773	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to amendment and terminal disclaimer filed 20 April 2020.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 21-40 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☑ All b) ☐ Some *c) ☐ None of the:

   1. ☑ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☑ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	/EDUARDO C ROBERT/ Supervisory Patent Examiner, Art Unit 3773

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. The amendment corrects obvious typographical errors. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Claim 25, line 3, "draft" has been changed to --drive--.

Claim 38, line 1, after "claim 32,", " the" has been deleted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. The examiner can normally be reached Monday-Friday, 9 a.m. - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact*** **the examiner's supervisor, SPE, *at* (571) 272-4719**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID C COMSTOCK/
Examiner, Art Unit 3773

/EDUARDO C ROBERT/
Supervisory Patent Examiner, Art Unit 3773

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/724,261	Na, Jongju
	Examiner	**Art Unit**
	DAVID C COMSTOCK	3773

CPC								
Symbol							**Type**	**Version**
A61H	/	39	/	086			F	2013-01-01
A61H	/	15	/	02			I	2013-01-01
A61M	/	37	/	00			I	2013-01-01
A61H	/	39	/	002			I	2013-01-01
A61N	/	5	/	0616			I	2013-01-01
A61N	/	1	/	0502			I	2013-01-01
A61N	/	1	/	328			I	2013-01-01
A61H	/	39	/	007			I	2013-01-01
A61N	/	1	/	36017			I	2013-01-01
A61N	/	5	/	062			I	2013-01-01
A61N	/	5	/	0624			I	2013-01-01
A61H	/	23	/	02			A	2013-01-01
A61H	/	2015	/	0014			A	2013-01-01
A61H	/	2039	/	005			A	2013-01-01
A61H	/	2201	/	0153			A	2013-01-01
A61H	/	2201	/	1604			A	2013-01-01
A61H	/	2201	/	169			A	2013-01-01
A61H	/	2201	/	5097			A	2013-01-01
A61H	/	2205	/	022			A	2013-01-01
A61H	/	2205	/	04			A	2013-01-01
A61H	/	2205	/	06			A	2013-01-01
A61H	/	2205	/	065			A	2013-01-01
A61H	/	2205	/	084			A	2013-01-01
A61H	/	2205	/	10			A	2013-01-01
A61H	/	2205	/	12			A	2013-01-01
A61N	/	2005	/	0644			A	2013-01-01
A61N	/	2005	/	0652			A	2013-01-01
A61B	/	2017	/	3409			A	2013-01-01
A61H	/	2201	/	5007			A	2013-01-01
A61M	/	2037	/	0023			A	2013-01-01
A61H	/	2201	/	105			A	2013-01-01

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	10 August 2020	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/EDUARDO C ROBERT/ Supervisory Patent Examiner, Art Unit 3773	12 August 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	10A

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/724,261	Na, Jongju
	Examiner	**Art Unit**
	DAVID C COMSTOCK	3773

CPC								
Symbol							**Type**	**Version**
A61H	/	2201	/	1207			A	2013-01-01
A61M	/	2037	/	0007			A	2013-01-01
A61M	/	2205	/	8206			A	2013-01-01
A61N	/	2005	/	0659			A	2013-01-01
A61N	/	2005	/	0661			A	2013-01-01

CPC Combination Sets									
Symbol							**Type**	**Set**	**Ranking**	**Version**
	/		/							

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	10 August 2020	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/EDUARDO C ROBERT/ Supervisory Patent Examiner, Art Unit 3773	12 August 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	10A

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/724,261	Na, Jongju
	Examiner	**Art Unit**
	DAVID C COMSTOCK	3773

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61H	/	39	/	08

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
607	115

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	10 August 2020	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/EDUARDO C ROBERT/ Supervisory Patent Examiner, Art Unit 3773	12 August 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	10A

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/724,261	Na, Jongju
	Examiner	**Art Unit**
	DAVID C COMSTOCK	3773

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		10		19	5	28	17	37						
	2		11		20	10	29	18	38						
	3		12	1	21	11	30	19	39						
	4		13	2	22	6	31	20	40						
	5		14	3	23	12	32								
	6		15	7	24	13	33								
	7		16	8	25	14	34								
	8		17	4	26	15	35								
	9		18	9	27	16	36								

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	10 August 2020	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/EDUARDO C ROBERT/ Supervisory Patent Examiner, Art Unit 3773	12 August 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	10A

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/724,261	Na, Jongju
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/06/2018	02/28/2019	08/10/2020						
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16	36	✓	✓	=						
17	37	✓	✓	=						
18	38	✓	✓	=						
19	39	✓	✓	=						
20	40	✓	✓	=						

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/724,261	Na, Jongju
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61H15/02.cpc. A61H 39/086,002.cpc. A61H37/00.cpc. A61N1/0502,328,36017.cpc. A61N5/0616,062,0624.cpc. A61B2017/3409.cpc. A61H23/02.cpc. A61H2015/0014.cpc. A61H2039/005.cpc.	8/6/2018	/DC/
A61H2201/0153,105,1207,1604,169,5007,5097.cpc. A61H2205/022,04,06,065,084,10,12.cpc. A61M2037/0007,0023.cpc. A61M2205/8206.cpc. A61N2005/0644,0652,0659,0661.cpc.	8/6/2018	/DC/
Search updated	02/28/2019	/DC/
Search updated	08/10/2020	/DC/
A61N1/328,36017	08/10/2020	/DC/

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
600	249	8/6/2018	/DC/
607	88, 102, 189, 115	8/6/2018	/DC/
604	20, 46, 21, 117	8/6/2018	/DC/
606	9	8/6/2018	/DC/
601	2	8/6/2018	/DC/
424	1.11	8/6/2018	/DC/
Search updated		08/10/2020	/DC/

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

	/DAVID C COMSTOCK/ Examiner.Art Unit 3733

ENDYMED EXHIBIT 1002 - 704/733

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/724,261	Na, Jongju
	Examiner	**Art Unit**
	DAVID C COMSTOCK	3773

Search Notes		
Search Notes	**Date**	**Examiner**
EAST text search--see EAST search history	8/6/2018	/DC/
Inventor name search--see EAST search history	8/6/2018	/DC/
EAST text search updated--see EAST search history	02/28/2019	/DC/
EAST text search updated--see EAST search history	08/10/2020	/DC/

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
See EAST interference search	N/A	08/10/2020	/DC/

	/DAVID C COMSTOCK/ Examiner.Art Unit 3733

Bibliographic Data

Application No: 15/724,261

Foreign Priority claimed: (•) Yes ( ) No

35 USC 119 (a-d) conditions met: [✓] Yes [ ] No [ ] Met After Allowance

Verified and Acknowledged: /DAVID C COMSTOCK/ Examiner's Signature [ ] Initials

Title: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
10/03/2017	600	3773	NA001KR_US3
RULE			

APPLICANTS

INVENTORS

Jongju Na, Songpa-Gu, KOREA, REPUBLIC OF

CONTINUING DATA

This application is a CON of 15096686 04/12/2016 PAT 9775774

15096686 is a CON of 13825083 01/20/2014 PAT 9320536

13825083 is a 371 of PCT/KR2012/001335 02/22/2012

PCT/KR2012/001335 is a CON of 13060274 03/30/2011 PAT 8979912

PCT/KR2012/001335 has PRO of 61449080 03/03/2011

13060274 is a 371 of PCT/US08/74131 08/22/2008

FOREIGN APPLICATIONS

KOREA, REPUBLIC OF KR10-2008-0076993 08/06/2008

IF REQUIRED, FOREIGN LICENSE GRANTED**

11/02/2017

** SMALL ENTITY **

STATE OR COUNTRY

KOREA, REPUBLIC OF

ADDRESS

MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038
UNITED STATES

FILING FEE RECEIVED

$900

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L4	1,314	(607/115).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/08/10 22:29
L6	296	4 and needle	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 22:29
S1	661	(600/249).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/08/10 17:47
S3	3,462	(607/88,102,109).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/08/10 17:49
S4	5,610	(604/20,46,21,117).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/08/10 17:50
S5	1,370	(606/9).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/08/10 17:51
S6	2,502	(601/2).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/08/10 17:51

S8	30,486	A61H15/02.cpc. A61H39/086,002.cpc. A61H37/00.cpc. A61N1/0502,328,36017.cpc. A61N5/0616,062,0624.cpc. A61B2017/3409.cpc. A61H23/02.cpc A61H2015/0014.cpc. A61H2039/005.cpc. A61H2201/0153,105,1207,1604,169,5007,5097.cpc. A61H2205/022,04,06,065,084,10,12.cpc. A61M2037/0007,0023.cpc. A61M2205/8206.cpc. A61N2005/0644,0652,0659,0661.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 18:37
S9	1,153	(S1 S3 S4 S5 S6 S7 S8) and needle and electric$3 and signal and (led or "l.e.d." or "light emitting diode") and (skin or dermis or dermatolog$4) and motor	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 18:39
S10	662	S9 and (releasabl$1 or detach$4)	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 18:39
S11	132	S10 and @pd>"20190301"	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 18:40
S12	191	S9 and @pd>"20190301"	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 18:49
S13	59	S12 not S11	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 18:49
S15	569	A61N1/328.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2020/08/10 19:16
S16	2,038	A61N1/36017.cpc.	US-PGPUB; USPAT	OR	ON	2020/08/10 19:40

			; USOCR			

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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8/10/2020 10:42:41 PM
C:\Users\dcomstock\Documents\EAST\Workspaces\15724261.wsp

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26338 7590 08/20/2020
MERLE W. RICHMAN, III
P.O. BOX 3333
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Merle W Richman	(Typed or printed name)
/mwresq/	(Signature)
11/19/2020	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/724,261	10/03/2017	Jongju Na	NA00IKR_US3	3803

TITLE OF INVENTION: METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$500	$0.00	$0.00	$500	11/20/2020

EXAMINER	ART UNIT	CLASS-SUBCLASS
COMSTOCK, DAVID C	3773	600-249000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Merle W. Richman, Esq.
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies .....

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

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5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☒ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /mwresq/ Date 11/19/2020

Typed or printed name Merle W. Richman, III Registration No. 38282

PTOL-85 Part B (08-18) Approved for use through 01/31/2020 OMB 0651-0033 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

ENDYMED EXHIBIT 1002 - 710/733

Electronic Patent Application Fee Transmittal

Application Number:	15724261
Filing Date:	03-Oct-2017
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Filer:	Merle W. Richman
Attorney Docket Number:	NA001KR_US3

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	500	500

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**500**

Electronic Acknowledgement Receipt

EFS ID:	41177529
Application Number:	15724261
International Application Number:	
Confirmation Number:	3803
Title of Invention:	METHOD, SYSTEM, AND APPARATUS FOR DERMATOLOGICAL TREATMENT
First Named Inventor/Applicant Name:	Jongju Na
Customer Number:	26338
Filer:	Merle W. Richman
Filer Authorized By:	
Attorney Docket Number:	NA001KR_US3
Receipt Date:	19-NOV-2020
Filing Date:	03-OCT-2017
Time Stamp:	23:48:05
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$500
RAM confirmation Number	E2020AIN48566169
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	na001kr_us3_issue-fee-transmittal-af.pdf	357946 98838a3270c07781d0a6b1c0c84c7a97686e1c17	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30330 483c5b7b1957ebc15855f988e213c42609a9ed5d	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	388276		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15724261
Filing Date	2017-10-03
First Named Inventor	Jongju Na
Art Unit	
Examiner Name	
Attorney Docket Number	NA001KR_US3

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7824394	B2	2010-11-02	Manstein, Dieter	
Change(s) applied to document, /C.L./ 9/30/2020	2	7618429	B2	11/2009 ~~2005-12-22~~	Mulholland, R. Stephen	
	3	6890319	B1	05/2005 ~~2005-10-10~~	Crocker, Peter John	
	4	9320536	B2	2016-04-26	Na, Jongju	
	5	7133717	B2	2006-11-07	Coston et al.	
	6	6931277	B1	2005-08-16	Yuhakov et al.	
	7	8979912	B2	2015-03-17	Na et al.	
	8	4180079	A	1979-12-25	Wing, Thomas	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.C.C/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/724,261	12/22/2020	10869812	NA001KR_US3	3803

26338 7590 12/02/2020

MERLE W. RICHMAN, III
P.O. BOX 3333
LA JOLLA, CA 92038

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

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APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Jongju Na, Songpa-Gu, KOREA, REPUBLIC OF;

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AO 120 (Rev. 08/10)

TO:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court for the Western District of Texas on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
6:21-cv-811	8/6/2021	for the Western District of Texas

PLAINTIFF	DEFENDANT
SYNKLOUD TECHNOLOGIES, LLC and SERENDIA, LLC	SUNG HWAN E&B CO., LTD.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	US 9,320,536 B2	4/26/2016	Serendia, LLC
2	US 9,480,836 B2	11/1/2016	Serendia, LLC
3	US 10,058,379 B2	8/28/2018	Serendia, LLC
4	US 10,869,812 B2	12/22/2020	Serendia, LLC
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

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AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
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☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
21cv4423(GRB)(ARL)	8/6/2021	Eastern District of New York

PLAINTIFF	DEFENDANT
Synkloud Technologies, LLC and Serendia, LLC	Cartessa Aesthetics, LLC

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	US 9,320,536 B2	4/26/2016	Serendia, LLC
2	US 9,480,836 B2	11/1/2016	Serendia, LLC
3	US 10,058,379 B2	8/28/2018	Serendia, LLC
4	US 10,869,812 B2	12/22/2020	Serendia, LLC
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
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In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
DOUGLAS C. PALMER	Deanna Rodin	8/9/2021

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AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
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☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
2:22-cv-00015-PHX-DLR	1/6/2022	for the District of Arizona

PLAINTIFF	DEFENDANT
SynKloud Technologies LLC, et al.	Aesthetics Biomedical Incorporated

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	US 9,320,536 B2	4/26/2016	Serendia, LLC
2	US 9,480,836 B2	11/1/2016	Serendia, LLC
3	US 10,058,379 B2	8/28/2018	Serendia, LLC
4	US 10,869,812 B2	12/22/2020	Serendia, LLC
5			

In the above--entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
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In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
Debra D Lucas	Rebecca E Lake	1/07/2022

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Trials@uspto.gov
571-272-7822

Paper 9
Entered: June 28, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CARTESSA AESTHETICS, LLC,
Petitioner,

v.

SERENDIA, LLC,
Patent Owner.

IPR2022-00377
Patent 10,869,812 B2

Before SHERIDAN K. SNEDDEN, CARL M. DEFRANCO, and TINA E. HULSE, *Administrative Patent Judges*.

DEFRANCO, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

Serendia, LLC ("Serendia") is the owner of U.S. Patent No. 10,869,812 B2 (Ex. 1001, "the '812 patent").[1] Cartessa Aesthetics, LLC

[1] Serendia identifies SynKloud Technologies, LLC as having the exclusive right to assert the '812 patent. *See* Paper 3.

("Cartessa") filed a Petition requesting *inter partes* review of claims 1–20 of the '812 patent.[2] Paper 1 ("Pet."). Serendia filed a Preliminary Response. Paper 8 ("Prelim. Resp."). Because Cartessa's Petition fails to demonstrate a reasonable likelihood that any of the challenged claims are unpatentable, we deny institution of *inter partes* review. *See* 35 U.S.C. § 314(a) (2018).

I. BACKGROUND

A. Related Matters

Also pending before the Office are petitions filed by Cartessa for *inter partes* review of two related patents, namely, U.S. Patent Nos. 9,775,774 B2 (IPR2022-00376) and 9,320,536 B2 (IPR2022-00378). Paper 7. Those patents, along with the '812 patent at issue here, are the subject of an infringement action filed August 6, 2021 in *SynKloud Techs., LLC v. Cartessa Aesthetics, LLC*, No. 2:21-cv-04423 (E.D.N.Y.) ("New York action"). Pet. 2; Papers 3, 7. According to the district court's docket, that action was subsequently stayed pending the outcome of our review of Cartessa's Petition here and in the related -00376 and -00378 proceedings.

The '812 patent is also the subject of two other infringement actions: (1) *SynKloud Techs., LLC v. Sung Hwan E&B Co., Ltd.*, No. 6:21-cv-00811 (W.D. Tex.) ("Texas action"), which appears to have been filed the same day as the New York action, and (2) *SynKloud Techs., LLC v. Aesthetics Biomedical, Inc.*, No. 2:22-cv-00015 (D. Ariz.) ("Arizona action"), filed January 4, 2022. Paper 7. We are not apprised of the status of either of those actions.

[2] Cartessa identifies Sung Hwan E&B Co., Ltd. and Aesthetics Biomedical, Inc. as also being real parties-in-interest. Paper 7.

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B. The '812 Patent

The '812 patent is directed to an apparatus and method "used in treating dermatological tissue." Ex. 1001, 1:33–35. As described and shown in the '812 patent, the "dermatological treatment apparatus" comprises "a user handle 220 coupled to an acupuncture plate 200." *Id.* at 2:63–67, Figs. 1A, 1B. The acupuncture plate includes "a plurality of acupuncture pins or needles 230." *Id.* at 3:6–12, Figs. 1B, 1C. In operation, a user employs the apparatus "to create a plurality of micro-wounds or holes in dermatological layers of a mammal's [] skin or dermis." *Id.* at 3:34–36. Creating such micro-wounds or holes in the skin "may improve the absorption or application of one or more chemicals applied on or about the micro-wounds or holes" (*id.* at 3:36–39) and "may increase cellular activity and help heal tissue faster and facilitate the delivery, uptake and use in the cell of the cosmetics, medications, or chemicals [] used" (*id.* at 8:6–9).

To assist in creating the micro-wounds or holes in the skin, "electrical signal generation system 300 may be electrically coupled to the acupuncture apparatus 320 via one or more wires 300A and to a mammal 20 to be treated via one or more wires 300B" so as to "generate a variety of signals . . . to vibrate one or more pins 351 electrically coupled to the system 300." *Id.* at 3:42–60, Figs. 2A–2C. In addition, the dermatological treatment apparatus may include "a disposable needle module 924 . . . to be removed and disposed after one or more treatments or for each patient, client, or user." *Id.* at 9:48–52, Figs. 9C–9D, 10A–10D.

C. The Sole Challenge

Claims Challenged	35 U.S.C. §	Basis
1–20	103	Morris[3] and Zhang[4]

In further support of this challenge, Cartessa submits the declaration of Robert E. Grove, Ph.D. *See* Ex. 1012. Serendia submits a rebuttal declaration from Paul Stauffer. *See* Ex. 2002.

D. The Challenged Claims

Two of the challenged claims are independent—claims 1 and 12. Claim 1 is a method claim, while claim 12 is an apparatus claim. In challenging these claims, Cartessa "starts with claim 12" (Pet. 25), which recites:

> 12. An apparatus for *treating dermatological tissue*, comprising:
>
> a user holdable device including a proximal end and
>
> a releasably couplable deployable needle module, the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles, the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end.

Ex. 1001, 16:45–59 (emphasis added).

[3] US 2002/0120260 A1, published Aug. 29, 2002 (Ex. 1002, "Morris").

[4] US 2006/0036210 A1, published Feb. 16, 2006 (Ex. 1003, "Zhang").

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II. ANALYSIS

A. Claim Construction

We apply the claim construction standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). That is, "the words of a claim 'are generally given their ordinary and customary meaning' . . . that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1312–13; *see also* 37 C.F.R. § 42.100(b).

1. "mechanically separatably" (claims 1 and 12)

Cartessa asks that we construe the terms "mechanically separatably," as recited by independent claims 1 and 12, "to mean 'mechanically *separable*.'" Pet. 24. Serendia responds by proposing a construction not only for that particular claim language, but for the entire limitation in which that language appears, namely, "a user holdable device including a proximal end and a releasably couplable deployable needle module, the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end." Prelim. Resp. 16–21. We do not perceive the need to construe that claim limitation, as the threshold question of institution in this case can be decided regardless of its construction. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (approving Board decision not to construe claim language where the construction is not material to the dispute).

2. "treating dermatological tissue" (preamble of claims 1 and 12)

The preamble of claims 1 and 12 recites that the claimed method and apparatus are for "treating dermatological tissue." Ex. 1001, 15:46, 16:45, respectively. Neither Cartessa nor Serendia addresses the limiting effect of

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that preamble in any meaningful fashion. For instance, Cartessa simply states that "[i]f the preamble is limiting, Morris discloses an apparatus for treating dermatological tissue." Pet. 26–27 (citing Ex. 1002 ¶¶ 2, 78). That approach by Cartessa—explaining how the prior art meets the preamble—appears to presume that the preamble is limiting. Serendia takes a similarly conclusory approach, quoting *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) that a claim preamble may be construed as limiting "if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim" (Prelim. Resp. 15) before asserting that the "treating dermatology tissue" limitation of claims 1 and 12 is "wholly absent from the combination of Morris and Zhang" (*id.* at 29).

It is beyond dispute that Cartessa, as petitioner, bears the burden of stating "[h]ow the challenged claim is to be construed." 37 C.F.R. § 42.104(b)(3). Nowhere do we discern, however, that Cartessa addresses the limiting effect of the preamble. Instead, Cartessa simply treats the preamble as an essential element of the claims in explaining that the prior art satisfies the preamble language of "[a]n apparatus for treating dermatological tissue." *See* Pet. 26–27 (claim 12), 72 (claim 1). And despite Serendia's clear position that the preamble is limiting (*see* Prelim. Resp. 15, 24–29), Cartessa did not seek leave to file a reply on the issue of the preamble's limiting effect (*see* 37 C.F.R. § 42.24(c)). Absent further discussion from Cartessa, we treat Cartessa's silence on this critical issue as a concession that the preamble of claims 1 and 12 is limiting. But even without that apparent concession, the record nonetheless supports that the preamble is limiting.

Whether to treat a preamble as a limitation is resolved "only on review of the entire[] . . . patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Catalina*, 289 F.3d at 808. "A claim's preamble may limit the claim when the claim drafter uses the preamble to define the subject matter of the claim." *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1284 (Fed. Cir. 2011). For instance, where the specification underscores the importance of the structure or steps recited in the preamble, the preamble may operate as a claim limitation. *Catalina*, 289 F.3d at 808. Further, "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." *Id.* at 808–09.

Here, the preamble of claims 1 and 12 recites essential elements of the claimed invention because it defines an important and distinguishing feature of the claimed "needle assembly," namely, that it is used to treat "dermatological tissue." Otherwise, without the preamble, the claims would be of unlimited scope, giving rise to countless user holdable devices having a needle-like assembly on their distal end surface. But the Specification makes clear that "the present invention" relates to a needle assembly used "to treat dermatological tissue." Ex. 1001, 1:39–40 ("It may be desirable to treat dermatological tissue; the present invention provides such treatment."). And all the embodiments described in the '812 patent "relate generally to treating dermatological tissue, including systems, and methods used in treating dermatological tissue." *Id.* at 1:33–35. Similarly, every figure of the '812 patent is described as depicting "a dermatological treatment

apparatus," "a dermatological treatment architecture," or "a dermatological treatment system." *Id.* at 1:43–2:59.

Those statements in the Specification underscore the pertinence of "dermatological tissue" to the claimed invention. *See Proveris Scientific Corp. v. Innovasystems, Inc.*, 739 F. 3d 1367, 1373 (Fed. Cir. 2014) ("[T]he preamble [provides] the only reference in any independent claim to the inventive concept . . . [and] [t]his fact alone is likely sufficient to support a conclusion that the preamble is limiting."). Indeed, where the specification refers to "the present invention" in terms only found in the preamble of the claim (rather than also in its body), which is the case here, it has been held that the preamble acts as a limitation on claim scope. *See Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1358 (Fed. Cir. 2012) (holding that the preamble phrase "rotary cutter deck" was a limitation where the specification referred to "the present invention" as "a rotary cutter deck"); *Poly–Am., LP v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004) (construing preamble as limiting where it disclosed a "fundamental characteristic of the claimed invention") (internal quotation marks and citation omitted).

The prosecution history of the '812 patent also highlights the relevance of the preamble's recitation of "dermatological tissue." For instance, the original version of independent claim 1 (then claim 21) *and independent claim 12* (then claim 32) included language in the body of the claim that the claimed invention be deployed "on or near dermatological tissue." Ex. 1007, at 526, 619. As such, the focus of the Examiner's prior art rejection of the independent claims was on needle assemblies for treating the skin, namely, that "pierce the surface 306 of skin tissue 305 and are

inserted . . . to a predetermined depth within the tissue being treated" (Ex. 1016, 7:18–23)) and "perforate the epidermis by allowing the needle . . . to rotate or reciprocate" (Ex. 1018 ¶ 100). Only after the Examiner recommended that both independent claims be amended to add that "the needle assembly [be] movable within the deployable needle module" was the reference to "on or near dermatological tissue" inexplicably dropped only from claim 12. *See* Ex. 1007, at 617, 619, 621–622, 627. The Examiner nonetheless allowed both claims to issue, thereby placing greater emphasis on the preamble's language of "treating dermatological tissue" than on similar language in the body of the claim. *See id.* at 650.

It is apparent from the Specification and prosecution history of the '812 patent that the preamble of claims 1 and 12 defines the subject matter of the claimed invention. In other words, the preamble is not merely limited to stating the intended use of the claimed invention, but rather provides an essential element—the treatment of "dermatological tissue"—as highlighted by the Specification and prosecution history. Thus, the preamble serves as a limitation that gives "life, meaning, and vitality to the claim[s]" as a whole. *Catalina*, 289 F.3d at 808.

B. Level of Ordinary Skill in the Art

Cartessa's declarant, Dr. Grove, testifies that one skilled in the art during the relevant time frame "would typically have had (1) seven to ten years of experience with development and/or use of treatment systems for delivery of electromagnetic radiation energy to skin or other tissues, and (2) a related graduate engineering degree or M.D." and "may have worked as part of a multidisciplinary team and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the

team when solving a technical problem." Ex. 1012 ¶ 27. Serendia does not contest Dr. Grove's articulation of the level of skill in the art. *See generally* Prelim. Resp. Nor do we see any reason to question it. Thus, for purposes of this decision, we analyze the asserted prior art with that level of skill in mind.

C. Independent Claim 12 (and its dependents)

As does Cartessa (*see* Pet. 25), we begin with claim 12, assessing whether the Petition supports a reasonable likelihood that the claimed "apparatus" is unpatentable as obvious over the asserted combination of Morris and Zhang. Cartessa maps the limitations of apparatus claim 12 to various teachings of Morris and Zhang (*see id.* at 26–49) and contends that one skilled in the art "would have recognized the benefits of Zhang's 'simple, modular and disposable' design" and understood that incorporation of Zhang's teachings "would not require changes to Morris's functionality or operability" (*id.* at 39–40). Although Cartessa's reason for combining the teachings of Morris and Zhang may find support in the record, we find that Cartessa fails to show that the asserted combination discloses or otherwise suggests an apparatus for "treating dermatological tissue," as required by the preamble of claim 12, which, as discussed above, serves as a limitation on the claim's scope.

For meeting the preamble limitation, Cartessa points to disclosures in Morris that concern *ablation of tumor tissue*, not treatment of dermatological tissue. Pet. 26–27 (citing Ex. 1002 ¶¶ 2, 78). In doing so, Cartessa acknowledges that "dermatological tissue" as recited in claim 12 "is skin." *Id.* at 26. But nowhere do we discern that the cited disclosures in Morris relate to the treatment of dermatological tissue, i.e., skin, as claimed.

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Rather, Morris is directed to an entirely different application, namely, the ablation of tumors.

In that regard, Morris focuses exclusively on "the minimally invasive treatment *and ablation of tissue masses such as tumors*" using "independently deployable electrodes configured to controllably *ablate a tumor* proximate or beneath a tissue surface." Ex. 1002 ¶ 2 (emphases added); *see also id.* ¶ 192 ("It will be appreciated that the applicants have provided a novel and useful apparatus and method for the treatment of tumors using surgical or minimally invasive methods."). Indeed, throughout Morris, the discussion centers on the apparatus's ability to ablate unhealthy tumor masses in target organs such as the liver and prostate while minimizing unwanted heating of surrounding healthy tissue. *See id.* ¶¶ 4–6, 78–79, 91, 122, 126–127, 155, 161, 178, 192. Likewise, all the features of Morris's apparatus, such as the configuration of the electrodes, depth of the deployed electrodes, and frequency and duty cycle of RF power supplied to the deployed electrodes, speak to treatment of the tumor mass by "ablation." *See id.* ¶¶ 7, 81, 91–92, 113, 124–127, 129, 144–147, 155, 170, 179–180, 191. Morris's clear and unequivocal focus on using the disclosed apparatus for the treatment and ablation of harmful tumor cells in target organs, in our view, negates the use of such an apparatus for the treatment and healing of skin cells.

That ablation of harmful tumor cells in a target organ does not equate to treatment of skin cells is further supported by Morris's disclosure that the electrodes are deployed "into a tumor or tissue mass so as . . . to precisely treat the tumor while avoiding adjacent critical anatomical structures such as vasculature (e.g. hepatic veins) and nerve plexi." *Id.* ¶ 79; *see also id.* ¶ 78

("deploy electrodes into the tumor while avoiding and minimizing injury to adjacent critical anatomical structures that are adjacent and underneath the target tumor mass"). To that end, the electrodes are positioned "to heat, necrose, or ablate any selected target tissue volume" and "to create a variety of different geometric ablation volumes or cell necrosis zones." *Id.* ¶¶ 114, 145. Notably, Morris further explains:

> The heating causes tissue temperature to rise sufficiently *to cause cell injury and death* particularly for temperatures in excess of 50-55° C. Increased amounts of power will result[] in higher temperature and greater magnitude of cell death it is desirable to be able to deliver a range of RF power levels depending upon a variety of parameters includ[ing] but not limited to tumor size, tissue type, tumor location and amount of tumor vascularization.

Id. ¶ 124 (emphasis added). Indeed, given the increased power levels used by Morris's apparatus in performing tumor ablation, Morris provides precautionary measures "to prevent any appreciable heating of the patient's skin." *Id.* ¶ 154.

Having reviewed Morris's disclosure as a whole, we highly doubt one skilled in the art would consider the claimed apparatus, where acupuncture needles are used for the treatment of skin, to be an obvious variant of Morris's apparatus, where ablation electrodes are used to cause "cell injury and death." *Compare* Ex. 1001, 3:6–14, 3:20–24, 3:34–62, Figs. 1B, 2A, *with* Ex. 1002 ¶¶ 124, 129, 145, Figs. 1, 22, 31. More likely than not, Morris's disclosure supports a clear distinction between tumor ablation and skin treatment such that one skilled in the art would not consider Morris's ablation apparatus to be suitable for skin treatment. *See, e.g.*, Ex. 2002 ¶¶ 15, 67–68, 71–73.

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Nor does Cartessa's addition of Zhang compensate for the deficiencies of Morris in the asserted combination. That is because Cartessa relies on Zhang for teaching something other than the "dermatological tissue" limitation of claim 12. *See* Pet. 25–26, 33–35, 37–42 (relying on Zhang only for teaching the "releasably couplable" and "mechanically separatably" limitations of the claimed needle module). Nor does Cartessa's reliance on the testimony of its declarant relieve our concerns with Cartessa's showing, as the testimony merely parrots, essentially verbatim, the arguments in the Petition. *Compare* Ex. 1012 ¶¶ 86–90, *with* Pet. 25–27, respectively.

In the end, because the asserted combination of Morris and Zhang lacks the "treating dermatological tissue" limitation of claim 12, we determine that Cartessa's Petition fails to support a reasonable likelihood that claim 12 is unpatentable as obvious over Morris and Zhang. And because Cartessa's challenge of dependent claims 13–20 suffers the same deficiency, we likewise determine that Cartessa falls short in demonstrating a reasonable likelihood that those dependent claims are unpatentable as obvious over Morris and Zhang.

D. Independent Claim 1 (and its dependents)

Like apparatus claim 12, method claim 1 recites limitations directed to treating "dermatological tissue." Ex. 1001, 15:46–49. Cartessa's challenge of claim 1 relies on the same challenge and essentially the same arguments as asserted against claim 12. *See* Pet. 72–73 (asserting that "[i]ndependent claim 1 is similar to independent claim 12" and "[t]hus, for sake of brevity, Petitioner refers back to the analysis of claim 12 for the overlapping limitations"). For the same reasons discussed above with respect to

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claims 12–20, we determine that Cartessa fails to demonstrate a reasonable likelihood that claims 1–11 are unpatentable as obvious over Morris and Zhang.

III. CONCLUSION

For the above reasons, we decline to institute *inter partes* review of any of the challenged claims of the '812 patent.

IV. ORDER

Accordingly, it is:

ORDERED that the Petition is *denied.*

For PETITIONER:

Richard LaCava
Taniel Anderson
Jasjit S. Vidwan
ARENT FOX LLP
richard.lacava@arentfox.com
taniel.anderson@arentfox.com
jasjit.vidwan@arentfox.com

For PATENT OWNER:

Gregory J. Gonsalves
Yeasun Yoon
CAPITOL IP LAW GROUP, PLLC
gonsalves@capitoliplaw.com
yoon@capitoliplaw.com

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