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(54) METHOD AND APPARATUS FOR MICRO-NEEDLE ARRAY ELECTRODE TREATMENT OF TISSUE

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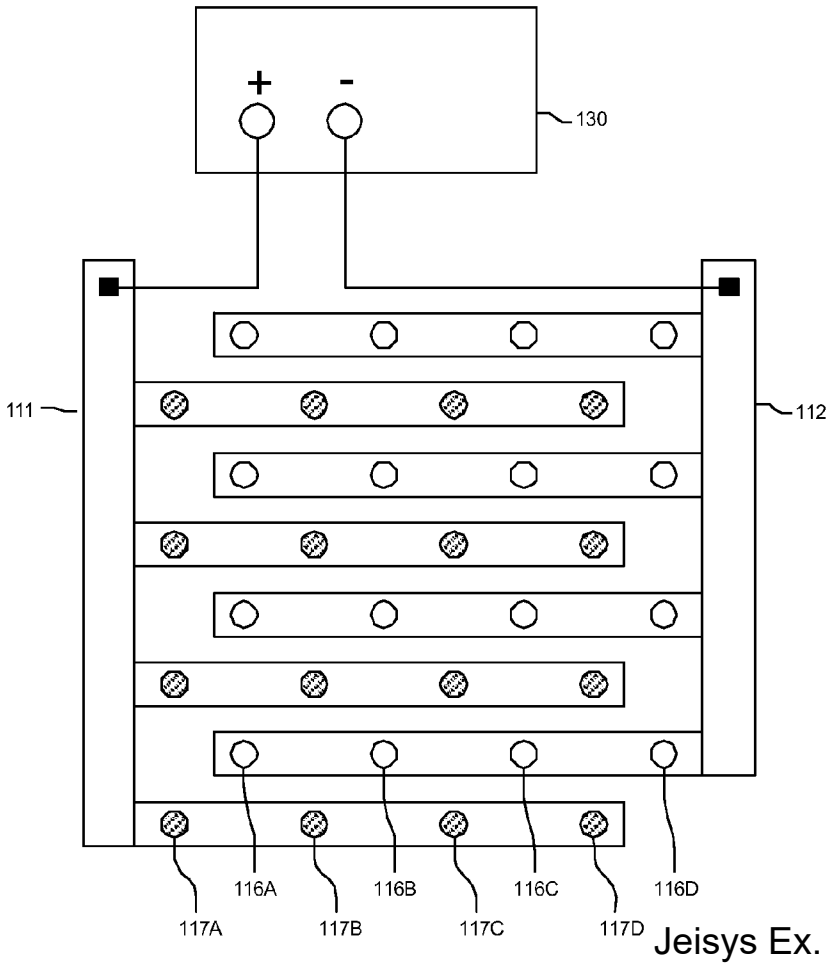
(57) **ABSTRACT**

The invention describes a system and method for revitalizing aging skin using electromagnetic energy that is delivered using a plurality of needles that are capable of penetrating the skin to desired depths. A particular aspect of the invention is the capability to spare zones of tissue from thermal exposure. This sparing of tissue allows new tissue to be regenerated while the heat treatment can shrink the collagen and tighten the underlying structures. Additionally, the system is capable of delivering therapeutically beneficial substances either through the penetrating needles or through channels that have been created by the penetration of the needles.



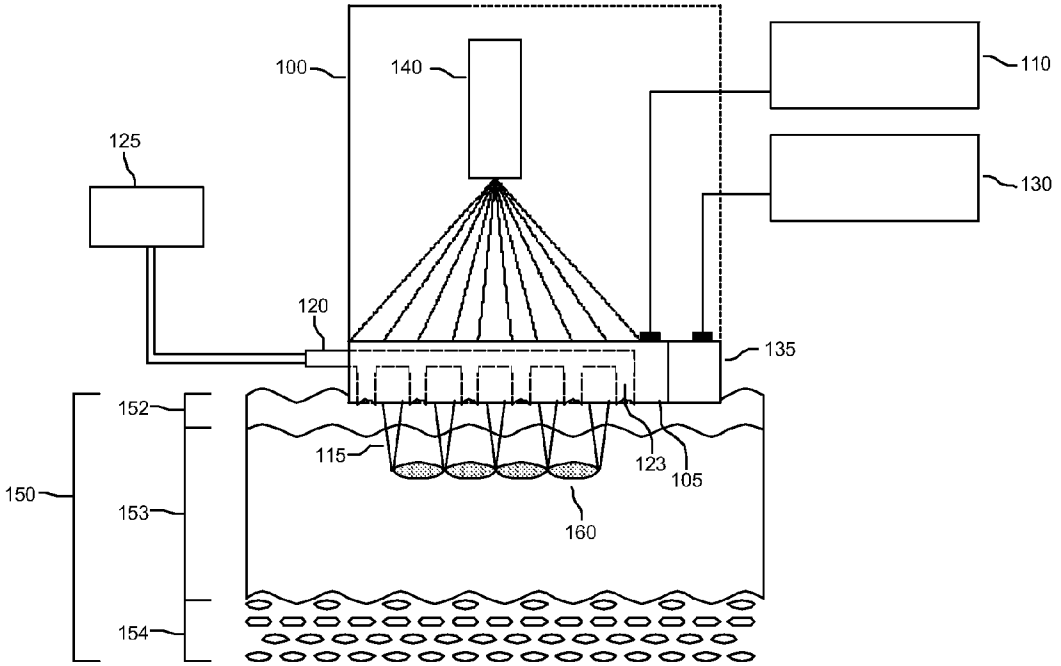


Figure 1

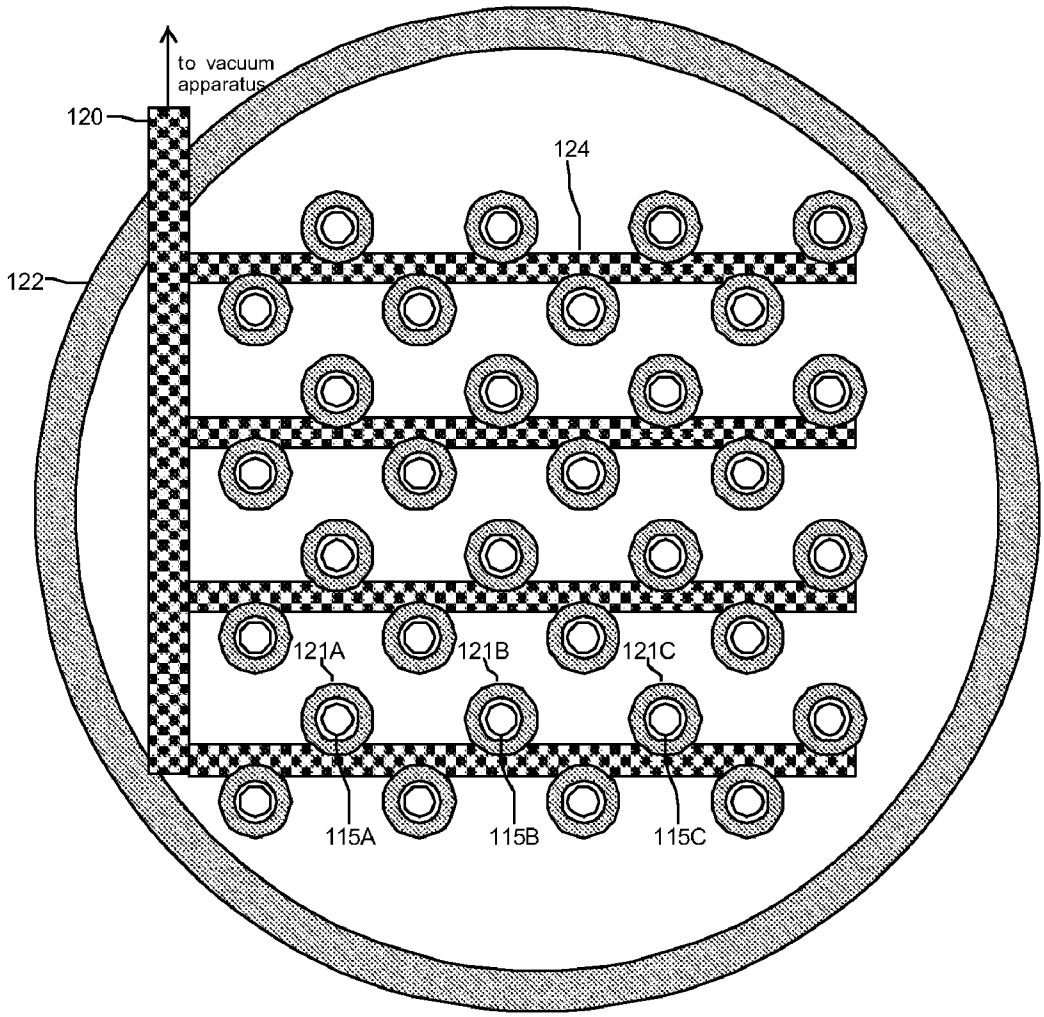

to vacuum apparatus
120
122
124
121A
121B
121C
115A
115B
115C

Figure 2

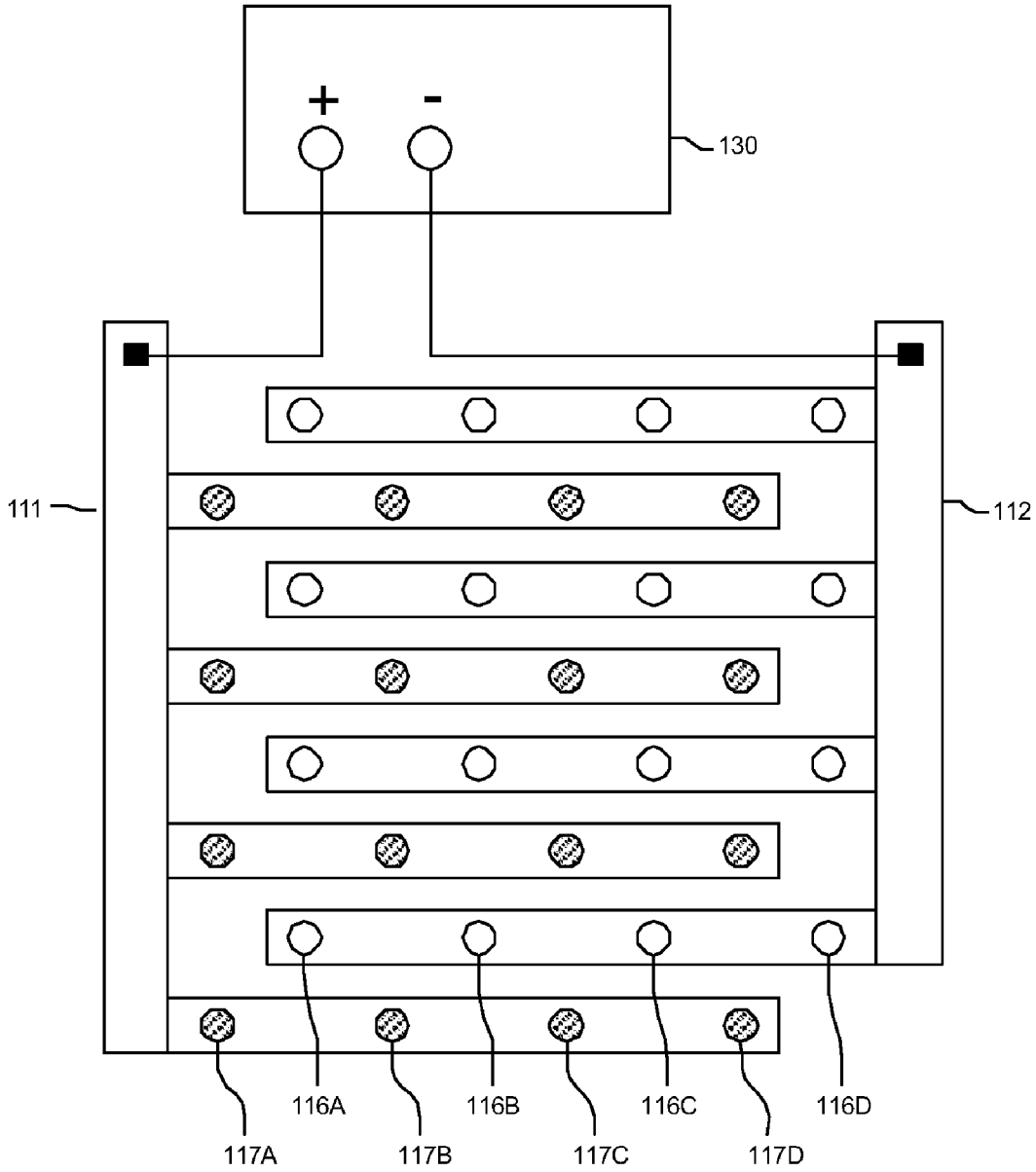


Figure 3A

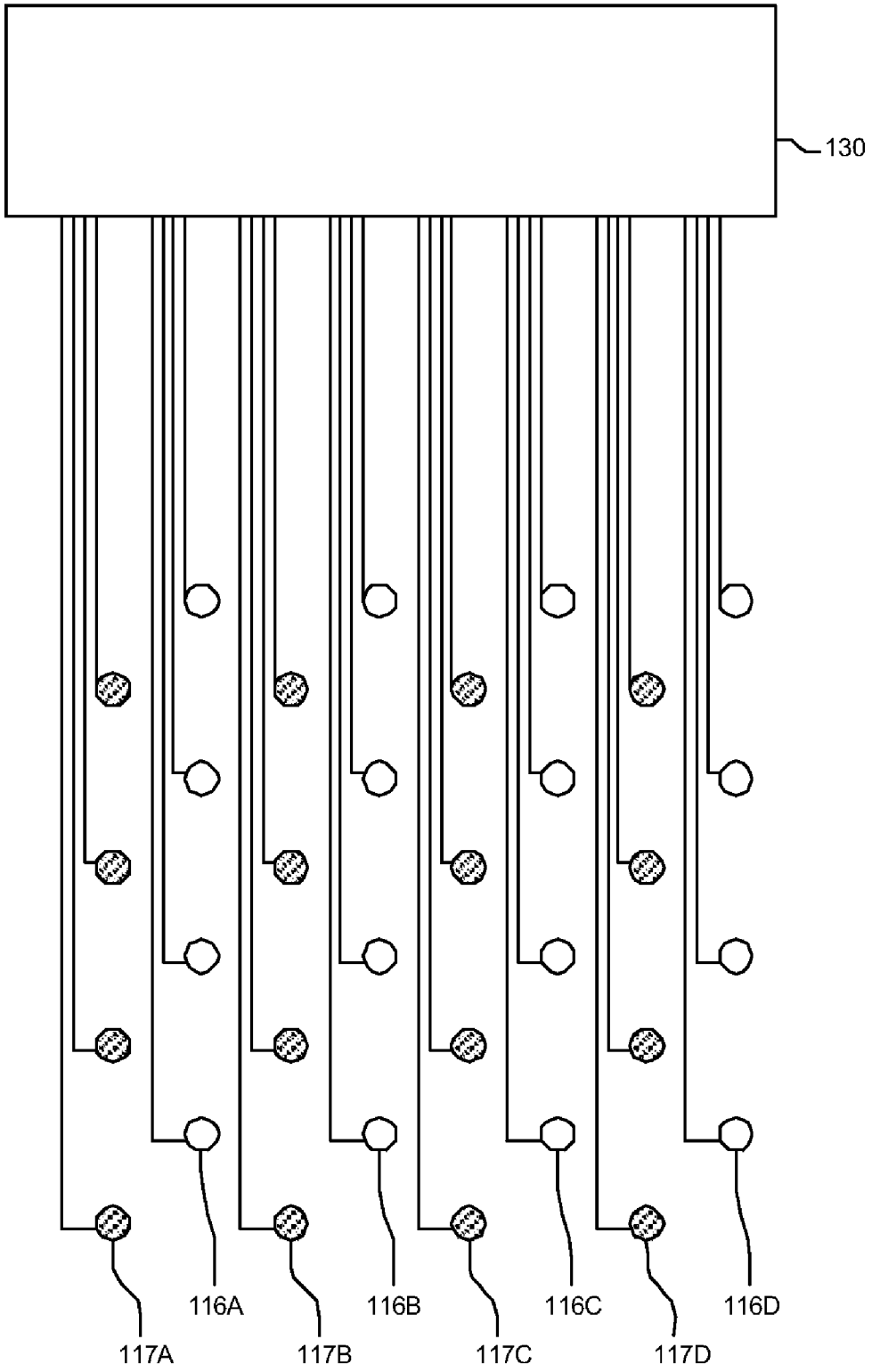


Figure 3B

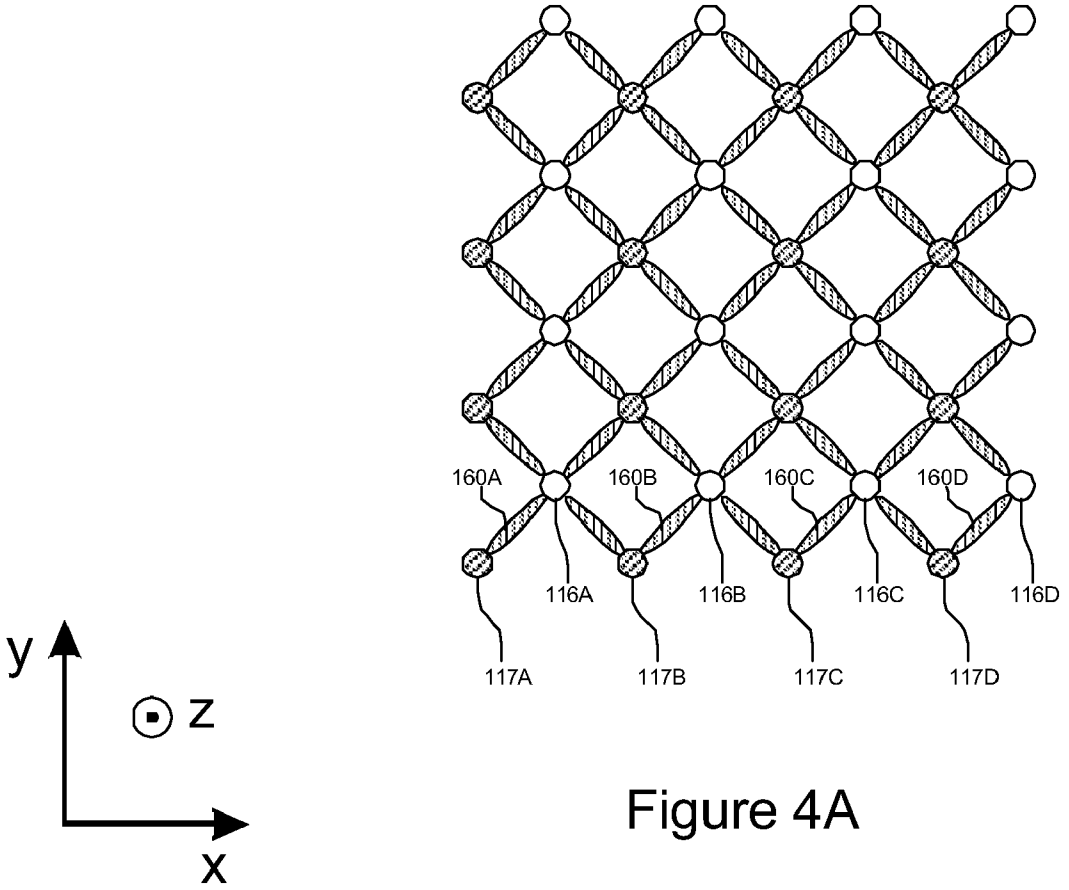


Figure 4A

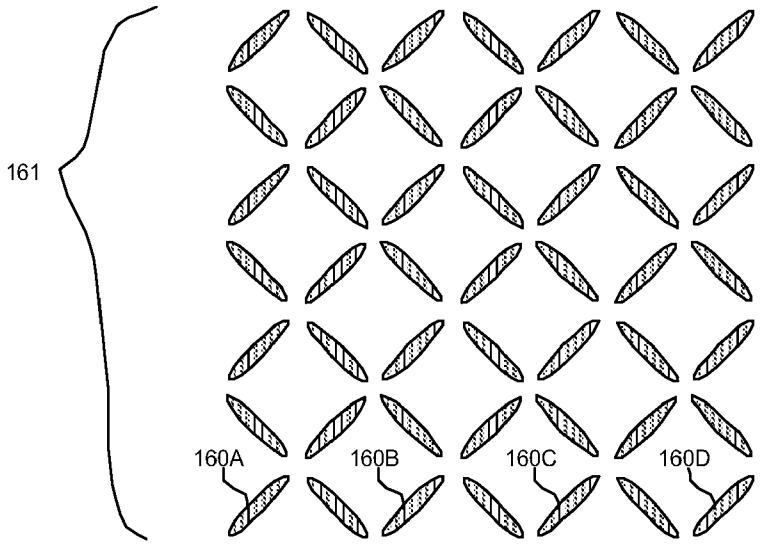


Figure 4B

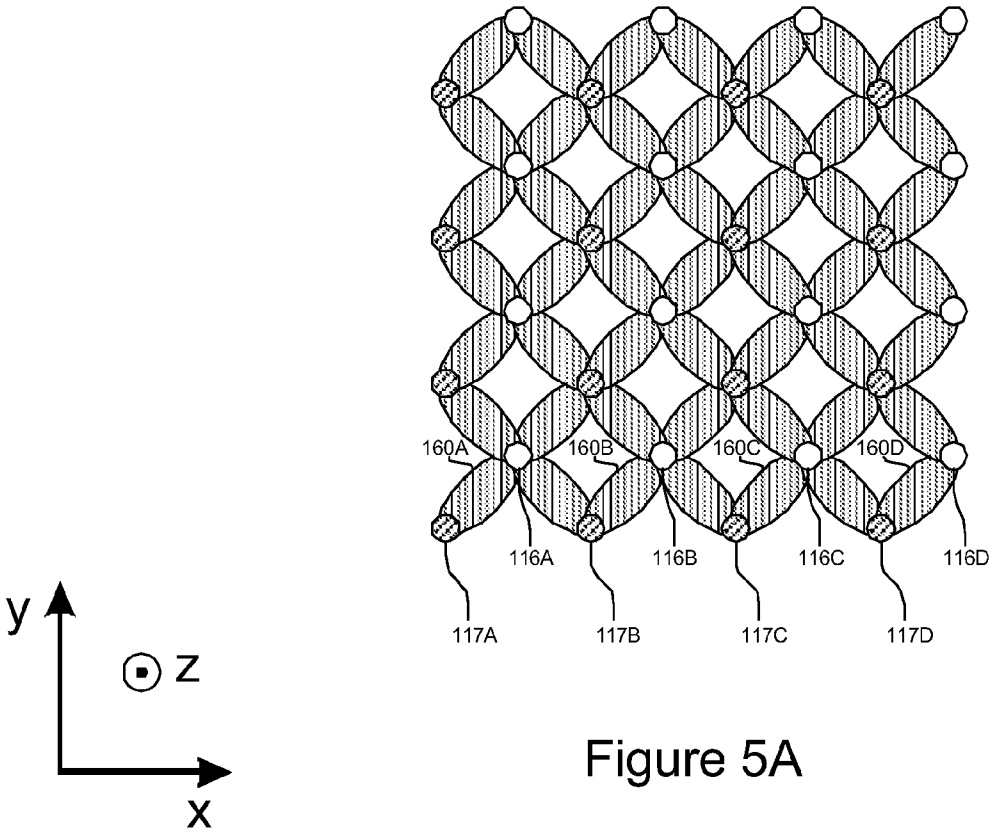


Figure 5A

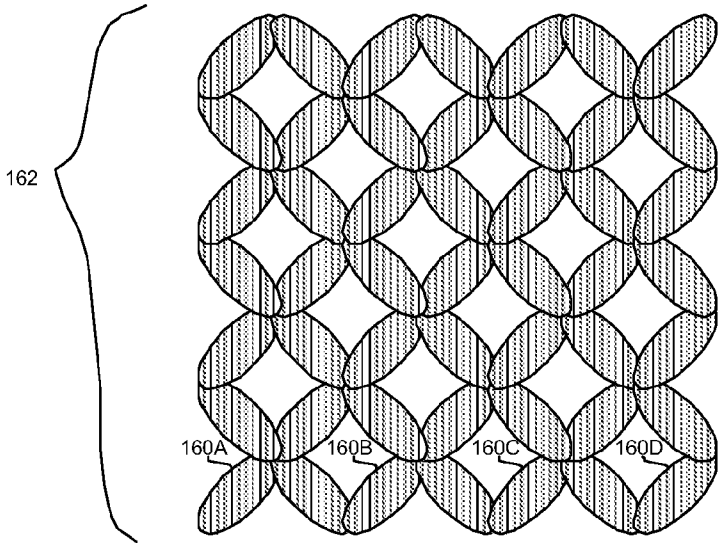


Figure 5B

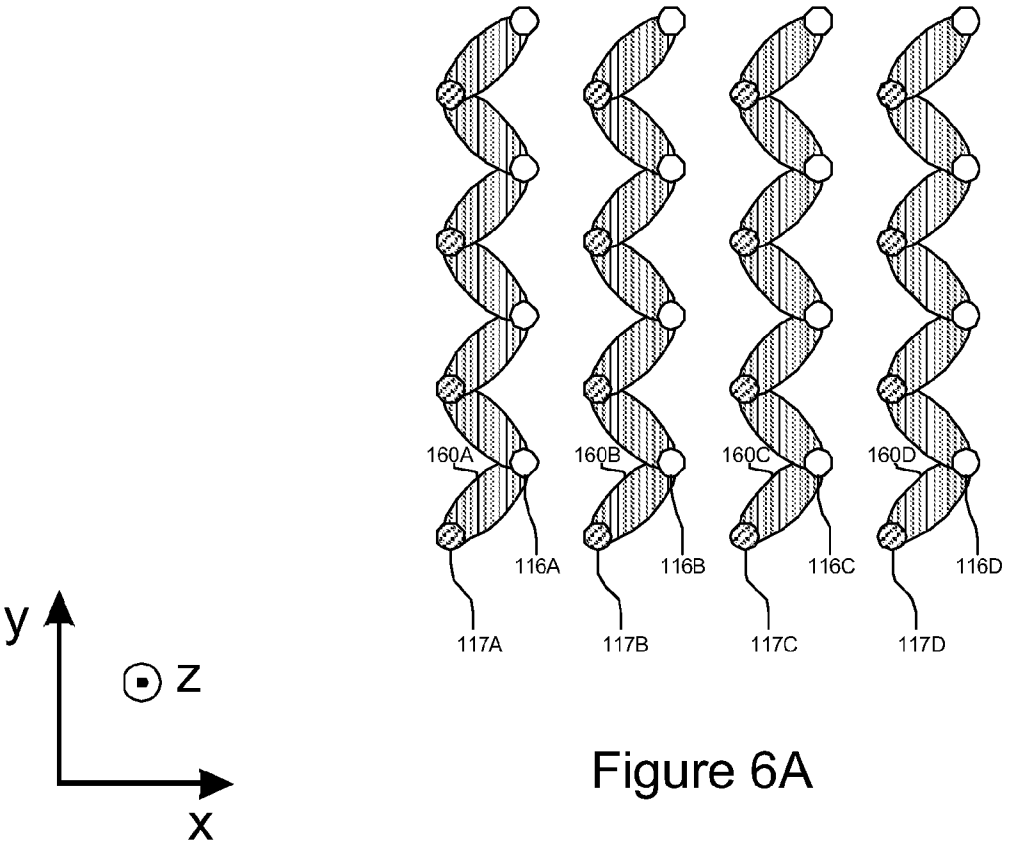


Figure 6A

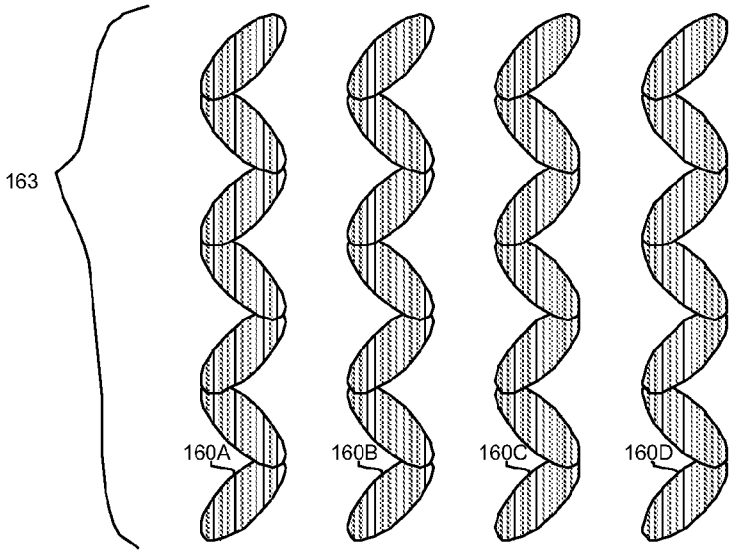


Figure 6B

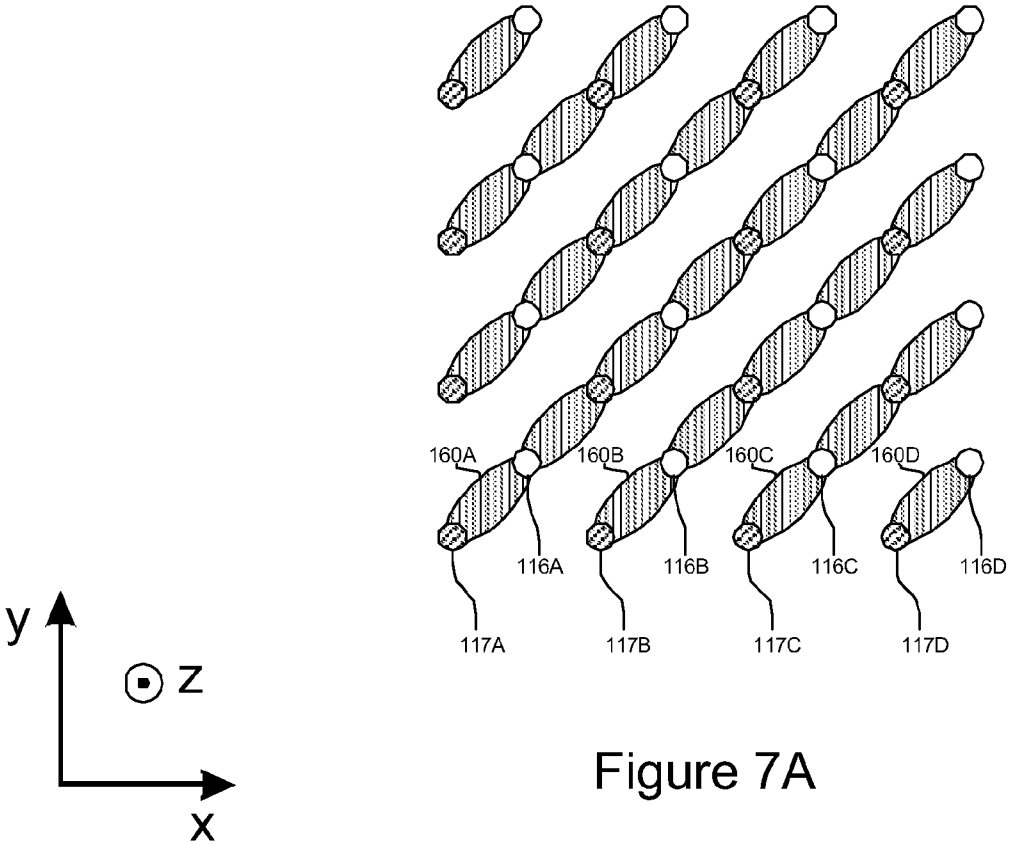


Figure 7A

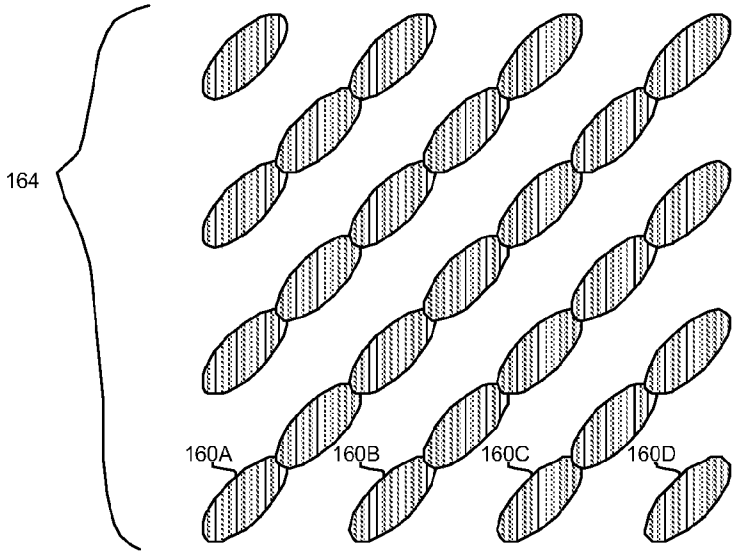


Figure 7B

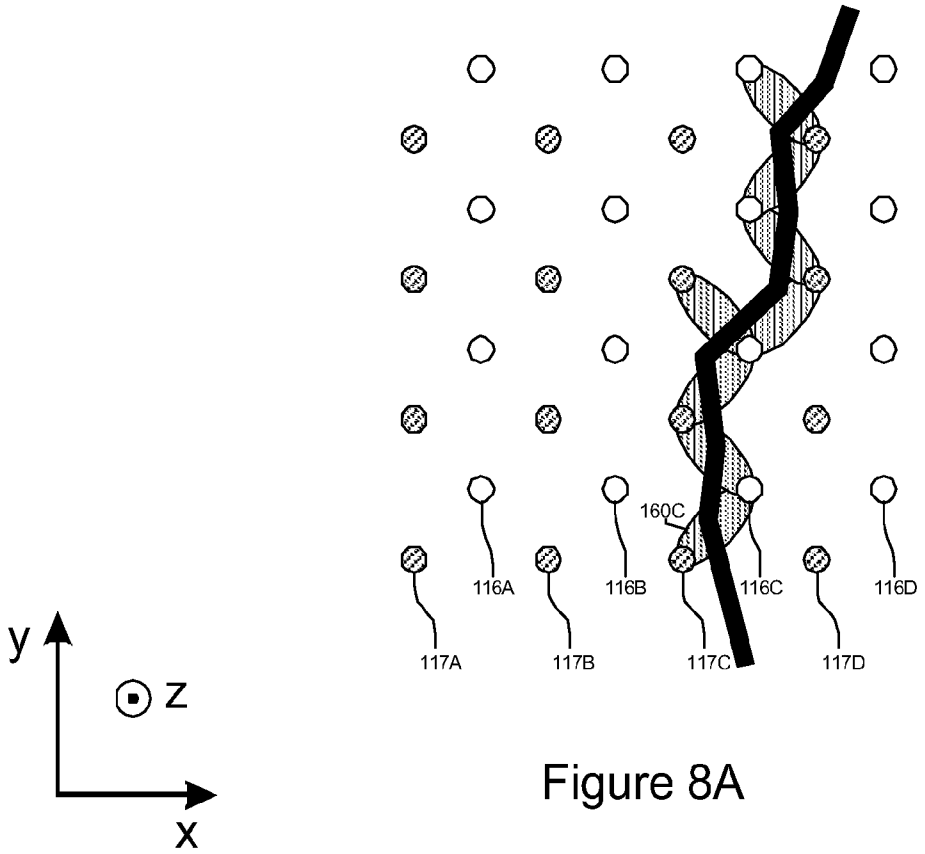


Figure 8A

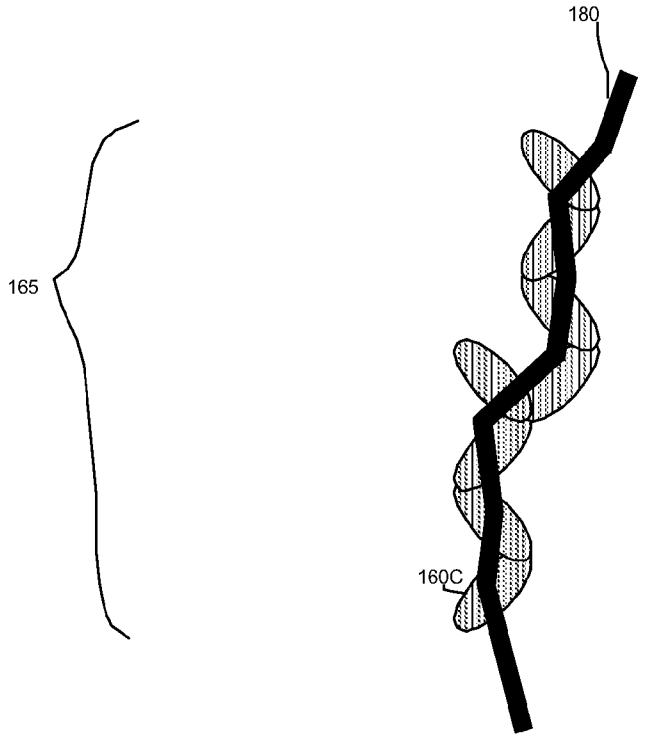


Figure 8B

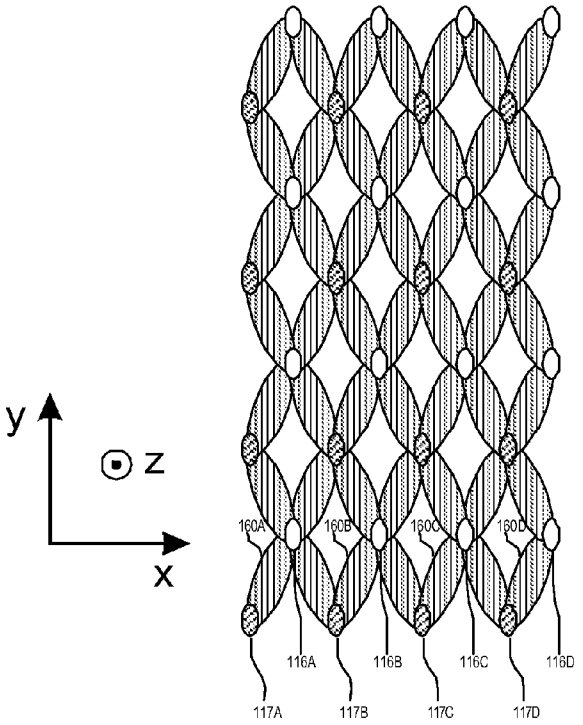


Figure 9A

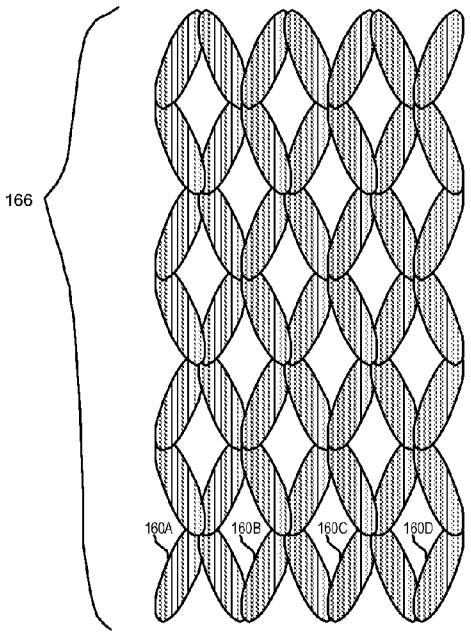


Figure 9B

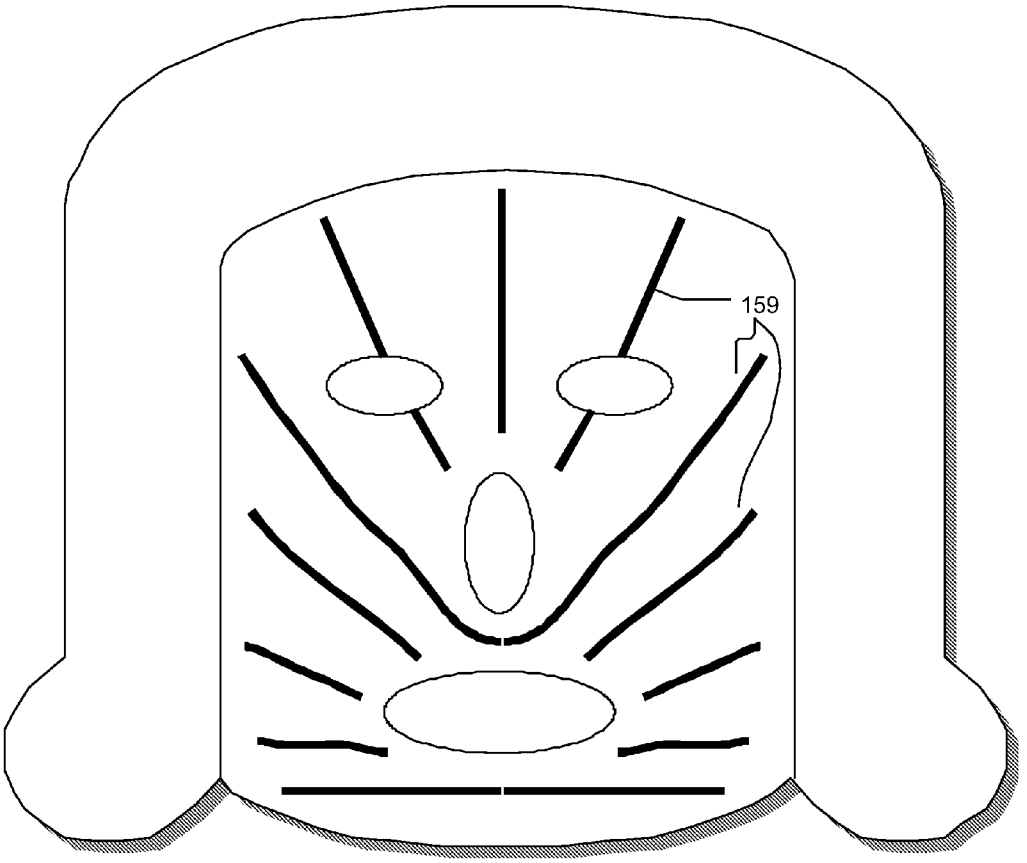


Figure 10

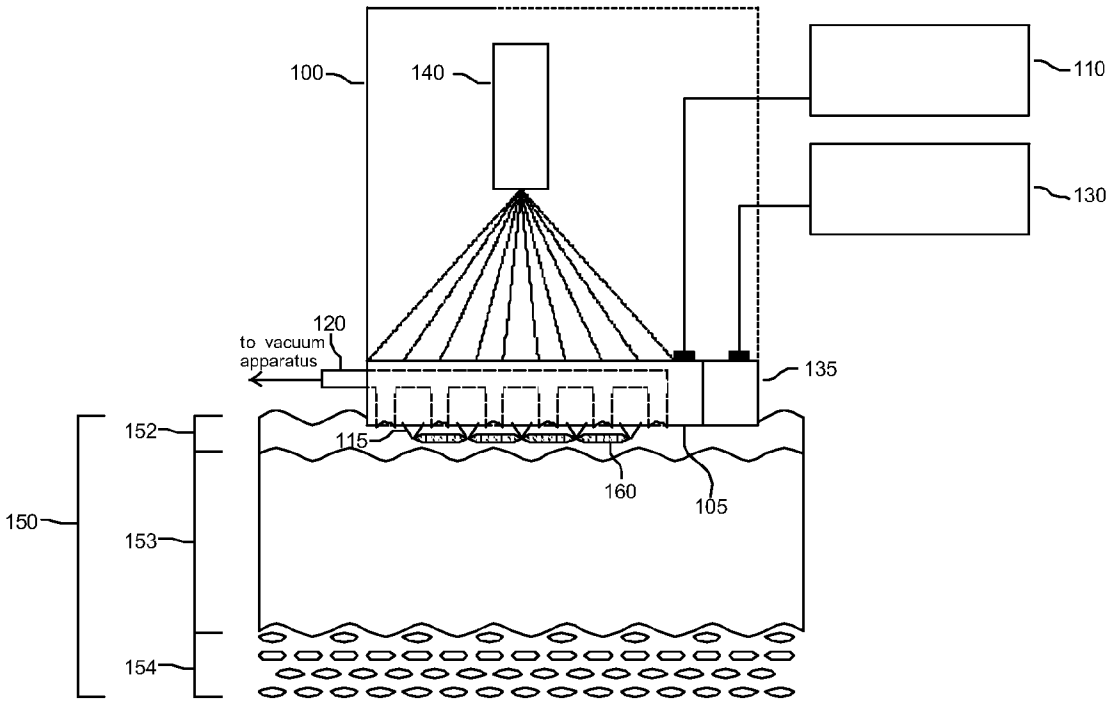

100
140
110
130
120
to vacuum apparatus
135
152
115
160
105
150
153
154

Figure 11

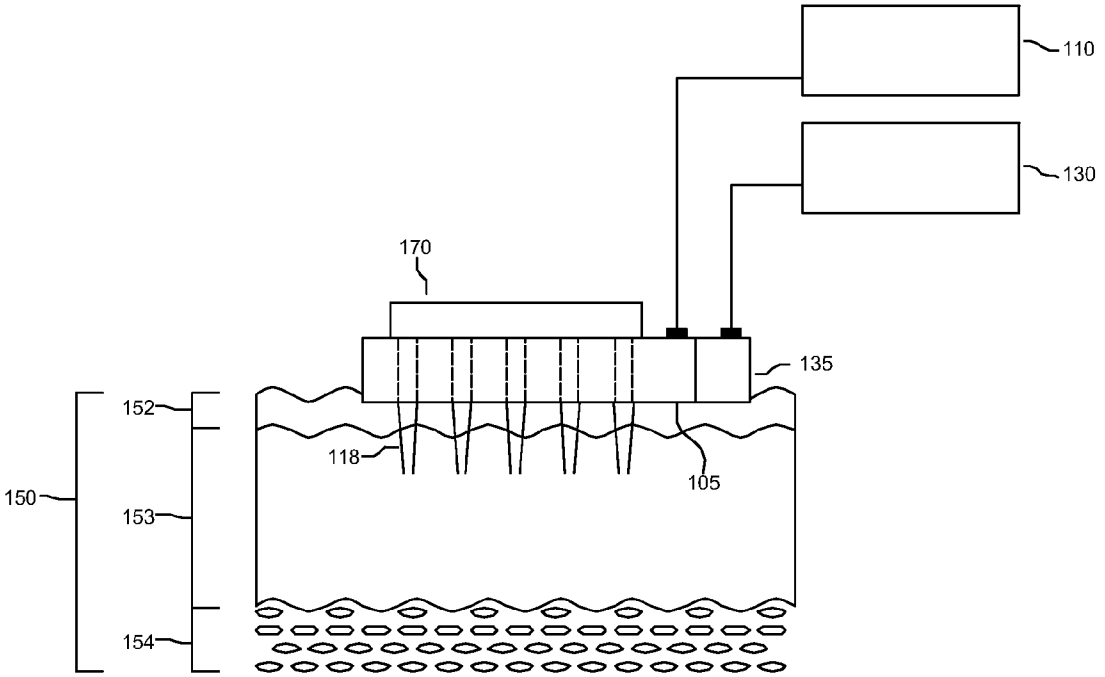


Figure 12

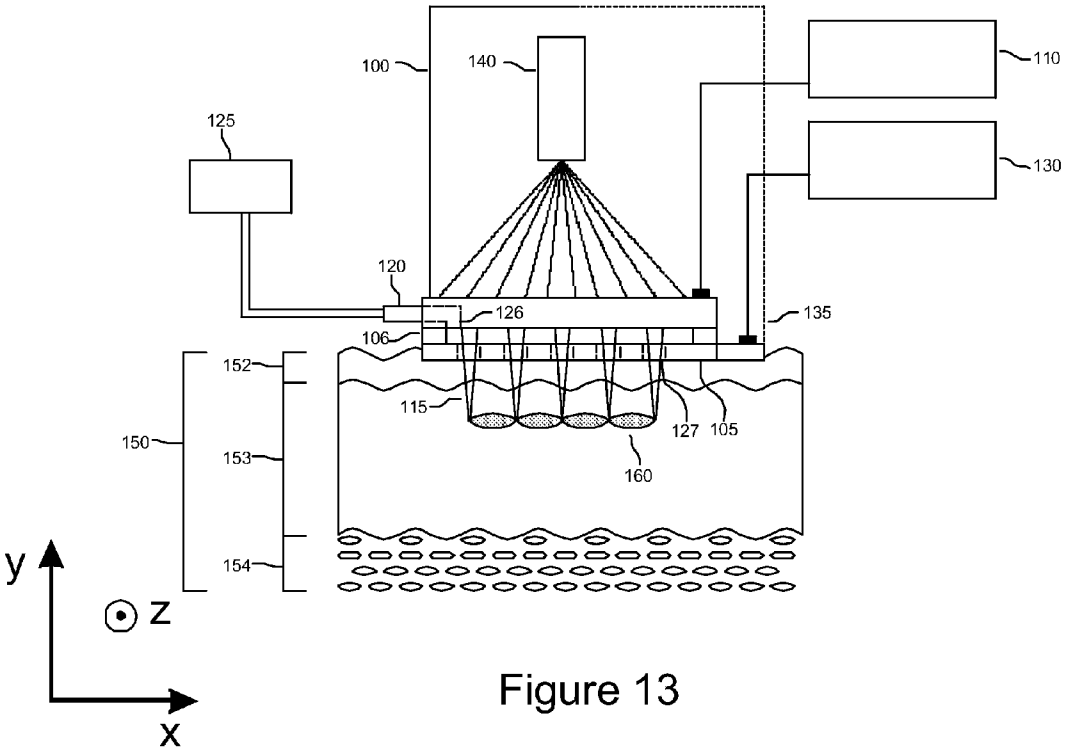

100
140
110
125
130
120
126
135
106
152
115
127
105
150
153
160
154
y
z
x

Figure 13

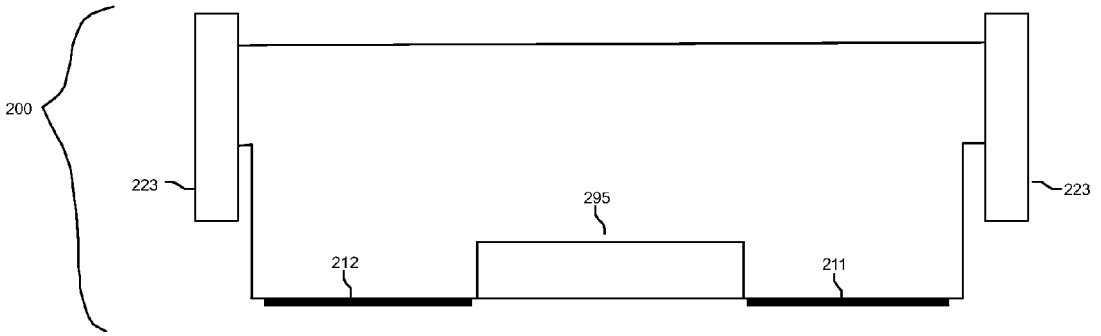


Figure 14A

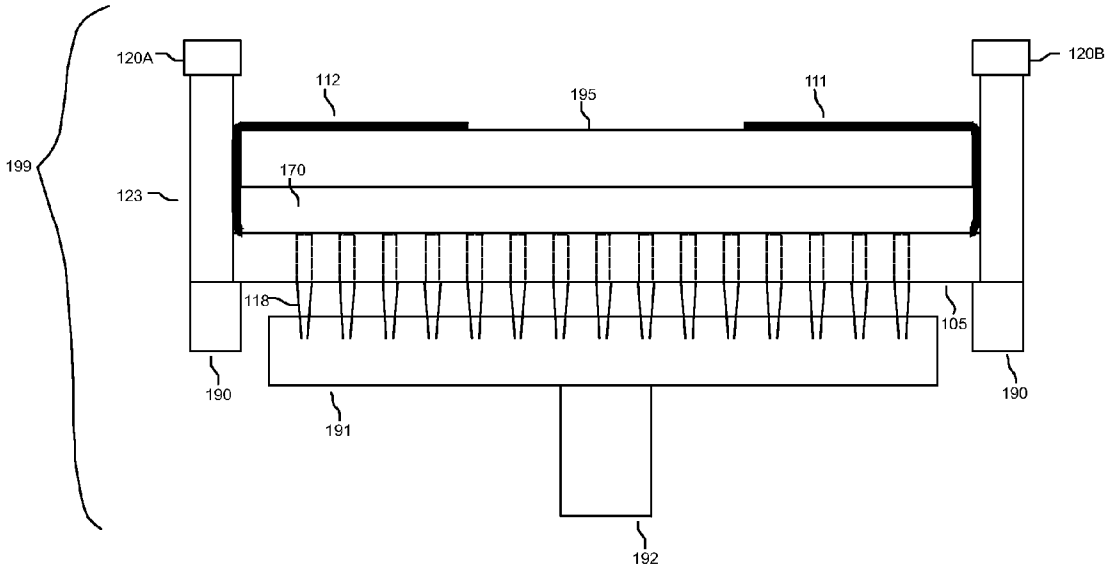


Figure 14B

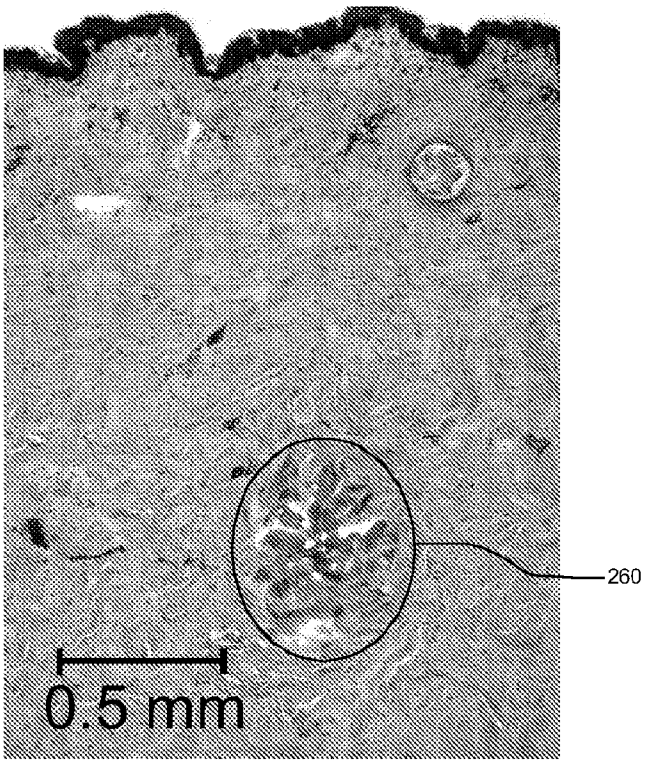


Figure 15A

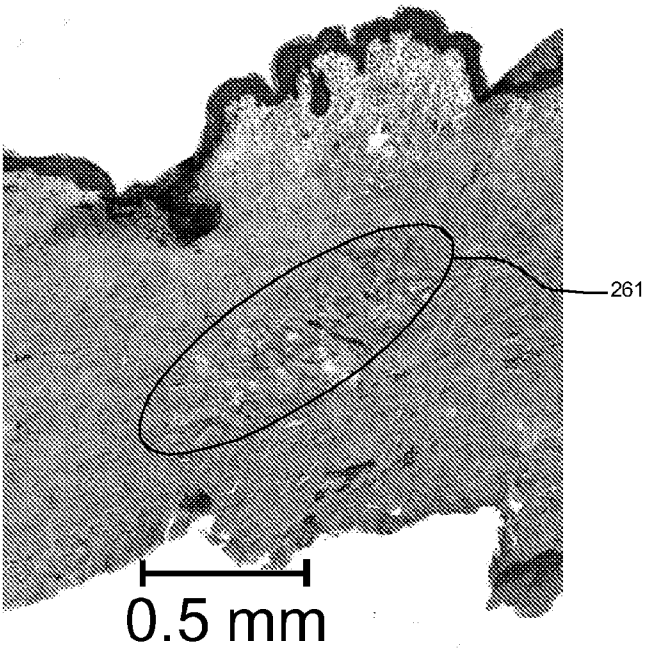


Figure 15B

METHOD AND APPARATUS FOR MICRO-NEEDLE ARRAY ELECTRODE TREATMENT OF TISSUE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Ser. No. 60/741,031, "Method and apparatus for micro-needle array electrode treatment of tissue," filed Nov. 29, 2005.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention relates generally to biological tissue treatment using electromagnetic energy delivered through an array of needle electrodes. More particularly, it relates to using radio frequency energy through an array of micron-needles for rejuvenating human skin by a fractional treatment.

[0004] 2. Description of the Related Art

[0005] Skin is the primary barrier that withstands environmental impact, such as sun, cold, wind, etc. Along with aging, environmental factors cause the skin to lose its youthful look and develop wrinkles. Human skin is made of epidermis, which is about 100 μm thick, followed by the dermis, which can extend up to 4 mm from the surface and finally the subcutaneous layer. These three layers control the overall appearance of the skin (youthful or aged). The dermis is made up of elastin, collagen, glycosoaminoglycans, and proteoglycans. The subcutaneous layer also has fibrous vertical bands that course through it and represent a link between dermal collagen and the subcutaneous layer. The collagen fibers provide the strength and elasticity to skin. With age and sun exposure, collagen loses its elasticity (tensile strength) and skin loses its youthful, tight appearance. Not surprisingly, numerous techniques have been described for rejuvenating the appearance of skin.

[0006] One approach to skin rejuvenation is to physically inject collagen into the skin. This gives an appearance of fullness or plumpness and the offending lines are smoothened. Bovine collagen has been used for this purpose. Unfortunately, this is not a long-lasting or complete fix for the problem and there are frequent reports of allergic reactions to the collagen injections.

[0007] It is now well established that collagen is sensitive to heat treatment and denatures when heated above its transition temperature. This denaturing is accompanied by shrinking of the collagen fibers and this shrinking can provide sagging or wrinkled skin with a tightened youthful appearance. Both heat and chemical based approaches have been described and used to shrink collagen.

[0008] Peeling most or all of the outer layer of the skin is another known method of rejuvenating the skin. Peeling can be achieved chemically, mechanically or photothermally. Chemical peeling is carried out using chemicals such as trichloroacetic acid and phenol. An inability to control the depth of the peeling, possible pigmentary change, and risk of scarring are among the problems associated with chemical peeling.

[0009] All the above methods suffer from the problem of being invasive and involve significant amount of pain. As these cosmetic procedures are all generally elective procedures, pain and the occasional side effects have been a significant deterrent to many, who would otherwise like to undergo these procedures.

[0010] To overcome some of the issues associated with the invasive procedures, laser and radio frequency energy based wrinkle reduction treatments have been proposed. For example, U.S. Pat. No. 6,387,089 describes using pulsed light for heating and shrinking the collagen and thereby restoring the elasticity of the skin. Since collagen is located within the dermis and subcutaneous layers and not in the epidermis, lasers that target collagen must penetrate through the epidermis and through the dermal epidermal junction. Due to Bier's Law absorption, the laser beam is typically the most intense at the surface of the skin. This results in unacceptable heating of the upper layers of the skin. Various approaches have been described to cool the upper layers of the skin while maintaining the layers underneath at the desired temperature. One approach is to spray a cryogen on the surface so that the surface remains cools while the underlying layers (and hence collagen) are heated. Such an approach is described in U.S. Pat. No. 6,514,244. Another approach described in U.S. Pat. No. 6,387,089 is the use of a cooled transparent substance, such as ice, gel or crystal that is in contact with the surface the skin. The transparent nature of the coolant would allow the laser beam to penetrate the different skin layers.

[0011] To overcome some of the problems associated with the undesired heating of the upper layers of the skin (epidermal and dermal), U.S. Pat. No. 6,311,090 describes using RF energy and an arrangement comprising RF electrodes that rest on the surface of the skin. A reverse thermal gradient is created that apparently does not substantially affect melanocytes and other epithelial cells. However, even such non-invasive methods have the significant limitation that energy cannot be effectively focused in a specific region of interest, say, the dermis.

[0012] Other approaches have been described to heat the dermis without heating more superficial layers. These involve using electrically conductive needles that penetrate the surface of the skin into the tissue and provide heating. U.S. Pat. Nos. 6,277,116 and 6,920,883 describe such systems. Unfortunately, such an approach results in widespread heating of the subcutaneous layer and potentially melting the fat in the subcutaneous layer. This leads to undesired scarring of the tissue.

[0013] One approach that has been described to limit the general, uniform heating of the tissue is fractional treatment of the tissue, as described in published U.S. Patent Application 20050049582. This application describes the use of laser energy to create treatment zones of desired shapes in the skin, where untreated, healthy tissue lies between the regions of treated tissue. This enables the untreated tissue to participate in the healing and recovery process.

[0014] Hence, it will be desirable to accomplish the fractional or patterned heat generation in the epidermis, dermis or subcutaneous layers of the skin using needles or micron-needles that could be located at the desired depth in the skin.

SUMMARY OF THE INVENTION

[0015] The invention describes improved methods and systems for rejuvenating aging skin to achieve cosmetically

desirable outcomes by shrinking collagen using radio frequency energy that is delivered to the target sites using a microneedle electrode array.

[0016] The invention provides a dermatological treatment apparatus for selectively treating zones of tissue within the skin. Such selective tissue treatment is achieved using an array of electrically conductive microneedles that are connected to a radio frequency energy source. The RF energy source is operated by a controller unit, which is programmable and is capable of activating a selected group of needle electrodes. This programmable selectivity leads to a desired pattern of microneedle electrodes treating zones of tissue at the desired location in the skin and simultaneously sparing tissue that is surrounding the targeted zones.

[0017] The controller unit has the capability of monitoring changes in the tissue parameters, such as conductivity and temperature, and uses these measurements to determine when treatment should be terminated. Additionally, the tissue property measurements can identify sensitive zones, such as nerves, to be excluded from the thermal treatment.

[0018] The microneedles can also be hollow and thereby are capable of delivering desirable therapeutic agents to the treated zones. The therapeutic agents could include anesthetics, growth factors, stem cells, botulinum toxin, etc.

[0019] In another embodiment, the microneedles are driven into the tissue using mechanical energy, where such driving force could be vibration or pressure. In another aspect of this invention, the treatment device has a suction coupling such that the each microneedle penetration depth could be individually controlled. This is highly desirable in anatomical regions containing uneven contours, such as the face and the transition areas from the face to the neck.

[0020] In yet another embodiment of this invention, the controller has algorithms embedded in it, which identifies the appropriate needle pair(s) that needs to be activated so that there is enough thermal relaxation time at the treated zones and thereby avoiding overheating of the treated zones and maintaining the desired temperature of the untreated tissue surrounding the treated zones.

[0021] Additional features and advantages of the invention described in the drawings and the description below and in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] The invention has other advantages and features which will be more readily apparent from the following detailed description of the invention and the appended claims, when taken in conjunction with the accompanying drawings, in which:

[0023] FIG. **1** is a diagram showing an embodiment of the invention wherein a handpiece is placed in contact with the skin. Vacuum channels are used to make reproducible contact with the skin surface and to force the needles into the skin. RF energy is delivered to the skin through the needles to form fractional treatment zones. Cryogenic spray is used to cool the needles and/or the contact plate to prevent overheating of selected tissue.

[0024] FIG. **2** is a diagram showing details of the vacuum channel in the area around the needle array.

[0025] FIG. **3** shows wiring diagrams of the needle electrode array for two embodiments of the invention. FIG. **3**A shows a wiring pattern where only two source electrodes are used. FIG. **3**B shows a wiring pattern where multiple source electrodes are used such that each electrode is wired individually.

[0026] FIGS. **4** and **5** are treatment patterns that can be created using either of the wiring patterns shown in FIGS. **3**A and **3**B. FIGS. **4**A and **5**A show treatment patterns and the electrodes. FIGS. **4**B and **5**B show the corresponding treatment patterns after the electrodes have been removed from the skin. The treatment pattern in FIG. **4**B is discontinuous. The treatment pattern in FIG. **5**B is continuous.

[0027] FIGS. **6** and **7** show treatment patterns that can be created using the wiring pattern shown in FIG. **3**B. FIGS. **6**A and **7**A show treatment patterns and the electrodes. FIGS. **6**B and **7**B show the corresponding treatment patterns after the electrodes have been removed from the skin.

[0028] FIGS. **8** and **8**A show a treatment pattern that is used to treat an unwanted blood vessel.

[0029] FIGS. **9**A and **9**B show a treatment pattern that can be created using either of the wiring patterns shown in FIGS. **3**A and **3**B, if the device is elongated in one direction of the array relative to the other. FIG. **9**A shows a treatment pattern and the electrodes. FIG. **9**B shows the corresponding treatment pattern after the electrodes have been removed from the skin.

[0030] FIG. **10** is a diagram of the lines of maximum extensibility for the face. Treatment can be performed along the lines of maximum extensibility to enhance the treatment appearance.

[0031] FIG. **11** is a diagram of an embodiment of the invention wherein the micro needles have shallow penetration.

[0032] FIG. **12** is a diagram of an embodiment of the invention wherein the micro needles are hollow to allow delivery of a substance into the skin tissue.

[0033] FIG. **13** is a diagram of an embodiment of the invention wherein the depth of the needles can be adjusted by adjusting the space between two plates. In this embodiment, the needles may be pushed into the skin with the assistance of vacuum.

[0034] FIGS. **14**A and **14**B show an embodiment of the invention that comprises a removable tip that attaches to a handpiece.

[0035] FIGS. **15**A and **15**B show histology sections of human skin stained with hemotoxylin and eosin following ex vivo treatment with RF energy delivered using a microneedle electrode array. FIG. **15**A and **15**B represent different pulse conditions for the pulse source and the needle positions.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0036] FIG. **1** illustrates an embodiment of the invention. In this embodiment, a radio frequency (RF) source **110** is connected to an array of needles **115** that are mounted on a contact plate **105**. The RF source **110** generates energy that is delivered to the tissue to create treatment zones **160** within

the skin **150**. A vacuum apparatus or suction apparatus **125** is attached to a vacuum port **120** of the contact plate **105**. A handpiece **100** is used by the practitioner to control the location of the device on the skin and deliver RF energy to the desired location for treatment. A cryogenic spray **140** is used to cool the contact plate **105** and/or the needles **115**. A vibrating element **135** is mechanically coupled to the contact plate **105**. A vibration power source **130** is preferably located external to the handpiece **100** and is connected to the vibrating element **135** to power the vibrating element **135**, which in turn would drive the needles **115** into the skin, as the vibrating element **135** is mechanically coupled to the contact plate **105** on which the needles are mounted.

[**0037**] The handpiece **100** can be applied to the surface of the skin **150**. This causes the needles **115** to penetrate the surface of the skin **150**. The skin **150** may have significant wrinkles or other topology. Therefore, the needles may not all penetrate to the same depth within the skin. In some embodiments of the invention, it is preferable that all of the needles penetrate to a predetermined depth within the skin **150**. Preferably, the needles are arranged to primarily deliver treatment in the papillary dermis and/or the upper reticular dermis. A vacuum port **120** can be attached to a vacuum apparatus **125**. The vacuum apparatus **125** creates a negative pressure within the vacuum channels **123** (as shown in FIG. **1**) so that the surface of the skin **150** is drawn into contact with the contact plate **105** and the needles **115** penetrate into the skin **150** to a predetermined depth beneath the surface of the skin **150**. The vibrating element **135** can be powered by the vibration power source **130** to help the needles **115** penetrate into the skin **150** more easily by vibrating the contact plate **105** and/or the needles **115**. While the needles **115** are located within the skin **150**, they can be powered by the RF source **110** to create an array of treatment zones **160** through resistive heating of the tissue. In some embodiments, it may be desirable to avoid or limit treatment of the epidermis **152** or selected upper layers of the skin **150**, which can be accomplished by cooling the back of the contact plate **105** with a cryogenic spray **140**. It may also be desirable to limit the penetration depth of the needles such that the needles do not penetrate into the layer of subcutaneous fat **154** because melting of the fat layer can lead to scarring due to fat atrophy. Melting of the subcutaneous fat **154** also reduces the skin thickness which may not be desirable. The contact plate **105** can be thermally conductive to carry the heat away from the skin **150** during or following treatment.

[**0038**] Cryogenic spray cooling **140** may be used to actively cool the contact plate **105** to enhance the cooling of the skin **150**. A cryogenic spray cooling **140** may also be used to cool the surface of the skin **150** directly by spraying cryogen onto the surface of the skin **150**. The cryogenic spray **140** could be a container containing a cryogen, such as, for example, compressed tetrafluoroethane.

[**0039**] In an alternate embodiment (not shown), the contact plate **105** may be cooled by circulating a liquid at room-temperature or chilled liquid to make thermal contact to the contact plate **105**. The cooling fluid can conductively cool the needles **115** and/or the contact plate **105**, which lowers the temperature of the skin **150** relative to the temperature that would be achieved without cooling. Cooling of the skin **150**, when desired, can thus be used to avoid heating or over heating of the epidermis **152** or upper layers of the skin **150**.

[**0040**] In a preferred embodiment, the needles **115** are **36**-gauge electrically conductive needles that are connected to the RF source **110**. The needles **115** could be prepared by cutting commercially available long hypodermic needles. The needles **115** can be soldered onto a circuit board where the circuit board is patterned, as shown in the patterns of FIG. **3**, to create an array of wired needles **115** that can be used according to this invention. The circuit board can be single or multilayered.

[**0041**] Preferably, the needles **115** are pointed and made of a solid conductive material such as, for example, metal. The needles **115** may also be hollow or made of an electrically nonconductive material that has a conductive coating. In some embodiments, each of the needles **115** can comprise an electrically conductive shaft or coating that is coated on the surface with an electrically non-conductive material such as, for example, Teflon. An electrically non-conductive coating material can be patterned in order to channel the RF treatment energy to a particular location where the electrically conductive shaft or coating contacts the skin through a gap in the patterned electrically non-conductive coating. In a preferred embodiment, the needles **115** are 50 to 300 μm in diameter. The diameter of the needles **115** is preferably at least 50 μm to reduce breakage of the needles **115**. The diameter of the needles **115** is preferably less than 300 μm to allow close packing of the needles **115** and to reduce disruption to the skin **150** and purpura, as the needles **115** penetrate into the skin **150**. The needles are also described as microneedles and when connected to an RF energy source as a microneedle electrode array.

[**0042**] The RF source **110** can be a radio frequency or microwave source that is used to create a temperature increase in the tissue when used with the needles **115**. The RF source **110** may be bipolar or monopolar. Preferably, these sources operate in a frequency range used for industrial applications so that cheaper electromagnetic sources are available. For example, the frequency of the RF source can be chosen to be about 6.78 MHz or about 13.56 MHz. In some preferred embodiments, the frequency range is from 0.1 to 10 MHz or from 0.4 to 3 MHz. The resistance of the skin varies with the frequency of RF source. The frequency range of the RF source can be chosen based on the desired treatment zone profile including for example treatment zone size, treatment zone shape, treatment zone aspect ratio, and treatment zone spacing.

[**0043**] In a preferred embodiment, the vacuum channels **123** are machined into the contact plate **105**. The contact plate **105** is preferably electrically-insulating to prevent shorting between the needles while providing physical support for the needles. An electrically insulating material that could be used in some embodiments is alumina. A vacuum port **120** connects to the vacuum channels **123** to create a negative pressure in the vacuum channels **123** when the vacuum port **120** is connected to the vacuum apparatus **125**. In a preferred embodiment, the vacuum port **120** is a hose fitting to which a vacuum hose is attached to connect the vacuum channels **123** to the vacuum apparatus **125**. The vacuum apparatus **125** can be, for example, a vacuum pump.

[**0044**] In a preferred embodiment, the vibrating element **135** is a piezo-electric vibrating unit or an electrical buzzer

and the vibration power source **130** is an electrical source that is matched to the vibrating element **135**.

[**0045**] The treatment zones **160** are shown in FIG. **1** to be located within the dermis **153**, but these treatment zones may also be located within the epidermis **152**, at the dermal-epidermal junction, or treatment zones may include regions in both the epidermis **152** and dermis **153**.

[**0046**] The treatment pattern created by the treatment zones **160** can depend, for example, on the distribution of the needles **115**, on the wiring patterns for the needles **115**, and/or on the firing pattern of the needles **115** by the RF source **110**. The array of treatment zones **160** that is created according to the invention may be regular or irregular. It will typically be easier to design and build an apparatus using automated manufacturing techniques if the array of treatment zones **160** is regular. Creating irregular arrays of treatment zones **160** will reduce the visual impact due to treatment by making the treatment appear more natural since many natural features vary in an irregular manner within the skin **150**.

[**0047**] The vacuum channels **123** shown in FIG. **1** can be arranged according to the desired treatment application. A preferred embodiment for the geometry of the vacuum channels **123** of FIG. **1** is shown in FIG. **2**. In this embodiment, the vacuum channels **123** comprise an outer vacuum ring **122**, vacuum feeder lines **124**, and individual needle-specific vacuum rings **121**. In FIG. **2**, negative pressure created within the outer vacuum ring **122** holds the skin to the contact plate **105** shown in FIG. **1** to hold the skin **150** and contact plate **105** in contact as shown in FIG. **1**. The outer vacuum ring **122** creates a more uniform application of force by the individual needle-specific vacuum rings **121**. In this embodiment, the vacuum feeder lines **124** are not typically in contact with the skin **150**, but they can be. The vacuum feeder lines **124** are used to connect the vacuum port **120** to the outer vacuum ring **122** and to the individual needle-specific vacuum rings **121**.

[**0048**] Individual needle-specific vacuum rings **121**A-C wrap around each of the needles **115**A-C in the array. The negative pressure created within each of the needle-specific vacuum rings **121** forces the skin **150** onto the encircled needle such that the encircled needle penetrates to a predetermined depth in the skin **150**.

[**0049**] The RF source **110** shown in FIG. **1** may be wired to the needles **115** in different patterns that may be chosen based on the desired application. A preferred embodiment of the wiring pattern is shown in FIG. **3**A. In FIG. **3**A, the RF source **110** has two output terminals. One of the output terminals is labeled with a plus sign (active) and the other with a minus sign (return) to indicate two poles of the RF source **110**. Alternate interleaved rows of the array are wired to either the plus or the minus electrode through the common wiring buses **111** and **112**. Thus, two interleaved arrays of regularly spaced needles **115** are formed. One array includes all of the negative polarity needles **116** (return electrodes) and the other includes all of the positive polarity needles **117** (active electrodes). In FIG. **3**, the negative needles **116** are open and the positive needles **117** are shaded.

[**0050**] The spacing between the negative needles **116** and the positive needles **117** can be chosen, for example, based on the resistance of the skin at the frequency of the RF source **110** such that the pulsing of the RF source **110** creates a treatment zone **160** between nearest neighbors within the array of needles **115**.

[**0051**] Note that needles **115** can be described generally as needles **115** or they can be further categorized as positive polarity needles **117** (shaded in FIGS. **3-9**) and negative polarity needles **116** (unshaded in FIGS. **3-9**). Positive needles **117** and negative needles **116** are subsets of the general category of needles **115**. Positive and negative polarities refer to opposite poles of the RF source.

[**0052**] In an embodiment, the array of needles **115** comprises at least sixteen needles **115**. The use of at least sixteen needles makes the treatment proceed faster than with fewer needles and also helps to reduce the torque that may be applied to each needle which could tear the skin **150**.

[**0053**] FIGS. **4**A and **4**B show a treatment pattern **161** of treatment zones **160** that can be produced from either of the wiring patterns shown in FIG. **3**A or **3**B. FIG. **4**A shows the treatment zones **160** that are created between nearest neighbor needles **115** that are connected to opposite poles of the RF source **110**. FIG. **4**B shows the corresponding treatment pattern **161** of FIG. **4**A after the needles have been removed from the skin **150**. The treatment pattern **161** is an example of a discontinuous treatment pattern **161** of treatment zones **160**.

[**0054**] With the proper choice of parameters, the treatment can be self limiting to create treatment zones **160** of approximately uniform size across the treatment pattern **161**. The self limiting nature of the treatment can be achieved by choosing the frequency of the RF source **110** to be a frequency for which the tissue resistivity (impedance) increases as the tissue is treated. As skin **150** is treated, the water content of the treatment zone **160** is reduced, which typically increases the resistivity of the treatment zone **160** relative to the surrounding skin **150**.

[**0055**] At high RF pulse energies and/or close spacing of the array of needles **115**, the treatment zones **160** can be created such that the treatment zones **160** merge together to form a continuous treatment pattern **162** as shown in FIGS. SA and **5**B. The continuous treatment pattern **162** can be created using either the wiring pattern shown in FIG. **3**A or **3**B.

[**0056**] FIGS. **6** and **7** show other treatment patterns **163** and **164** that can be created using the wiring pattern shown in FIG. **3**B. In these embodiments, not all of the electrode pairs are activated. The treatment patterns **163** and **164** differ in the timing between pulsing of electrode pairs to create each treatment zone **160** and in which electrode pairs are pulsed.

[**0057**] In an alternate embodiment, the needles are connected to an RF switching network such that the polarity of each needle **115** can be selected for each pulse of the RF source **110**. Selected needles **115** may also be floated or grounded by the switching network to create other treatment patterns. The array of needles **115** can thus be reconfigurable. A reconfigurable array of needles **115** can be used to actively target features within tissue. For example, a CCD camera or visual observation port can be used to identify the position of a blood vessel **180** to be treated within the skin **150**. As shown in FIGS. **8**A and **8**B, once the blood vessel **180** has been identified, selected needle pairs can be fired to

treat or to spare the identified blood vessel **180**. Other identifiable objects within or on the skin **150** can be targeted or spared using a reconfigurable array of needles **115**. For example, sebaceous glands, tattoos, wrinkles, scars, hairs, hair follicles, and pigmented lesions may be targeted using reconfigurable arrays of needles **115**. Another example of a reconfigurable array of needles **115** is an individually addressable needle system as shown in FIG. **3**B where the RF source **110** can individually address each needle or selected sets of needles within in the array. Apart from visual identification, structures such as blood vessels could also be identified by commonly known techniques. One such technique would be an impedance sweep of the tissue.

[**0058**] FIG. **9** shows an arrangement of the needles **115** in which the treatment pattern **165** is elongated due to a different arrangement of the needles **115**. Also illustrated in this example is the use of needles **115** with oval cross sections, which can be used to create more localized electrical field profiles within the tissue or to create a discontinuous treatment pattern **161** as shown in FIG. **4**B. Oval cross sections can also be used to reduce local fields and thus reduce charring and over-treatment.

[**0059**] Each treatment zone **160** can be created by electrically connecting the needles **116** and **117** at the opposite ends of each local region of skin **150** to be treated to different poles of the RF source **110**. One or more treatment zones **160** within any of the treatment patterns **161-166** can be created either sequentially or simultaneously depending on the desired application. Sequential creation of treatment zones **160** is useful in situations where minimizing thermal crosstalk is important or where the power of the RF source **110** is limited. Simultaneous creation of treatment zones **160** is useful in situations where treatment speed is important.

[**0060**] Each of the treatment patterns **161-166** desirably spares healthy tissue between the treatment zones **160**. Sparing of healthy tissue between treatment zones **160** reduces the incidence of scarring and promotes rapid healing by allowing nutrients, cells, and cytokines to flow more quickly to the wounded areas to stimulate the wound healing response. The spared tissue also allows transport to the dermal-epidermal junction and the epidermis so that the epidermis can remain healthy or heal quickly following treatment.

[**0061**] The treatment patterns **161-166** are shown here as examples of treatments that can be created performed according to the invention. Other patterns can be used to create different effects based on particular applications.

[**0062**] The treatment pattern **164** shown in FIGS. **7**A and **7**B is particularly useful because it can create a line of tension within the skin **150** due to collagen denaturation. Collagen denaturation causes collagen fibers to shrink in length by up to approximately 60% or 70% and thus can provide considerable tension along a particular direction. To enhance the appearance of shrinkage on the skin, the treatment can preferably be aligned to cause shrinkage along the directions of maximum extensibility. The lines of maximum extensibility **159** are illustrated in FIG. **10**. Arranging treatment along the lines of maximum extensibility **159** will be helpful for reducing the visibility of wrinkles.

[**0063**] FIG. **11** shows an embodiment of the invention in which needles **115** penetrate primarily to predetermined depths within the epidermis **152** such that treatment zones **160** are created in the epidermis **152** and/or along the dermal-epidermal junction located at the base of the epidermis **152**. To limit the penetration to only the epidermis, it may be desirable to limit the predetermined needle penetration depth to 5-50 μm.

[**0064**] FIG. **12** shows an embodiment of the invention in which delivery needles **118** are hollow and open at the distal end. Delivery needles **118** can be physically connected to a fluid filled reservoir **170** that contains a therapeutic substance that is to be delivered beneath the surface of the skin into, for example, the epidermis **152**, dermis **153**, subcutaneous fat **154**, or muscular layers (not shown). Examples of therapeutic substances that can be delivered are anesthetics (such as lidocaine), vitamins (such as vitamin C), minerals, growth factors, pro-drugs, hormones, stem cells, vasoconstrictors, steroids, botulinum toxin, and photosensitive toxins. In an alternate embodiment, the needles can be made to be permeable so that therapeutic substances can be delivered through the permeable needles.

[**0065**] Since the primary barrier for many topically applied therapeutic substances is the stratum corneum, which is the outermost layer of the epidermis, the delivery needles **118** can significantly enhance delivery of a therapeutic substance even if the delivery needles **118** only penetrate into the epidermis **152** and not into the dermis **153**.

[**0066**] The delivery of botulinum toxin in combination with the RF treatment using a microneedle area is one embodiment, whereby the combination treatment of fractional RF tightening of tissue and local temporary paralysis of the underlying muscles through the use of botulinum toxin is effective for treatment of wrinkles and the delay of recurrence of wrinkles.

[**0067**] In an alternate embodiment, therapeutic substances can be applied to the surface of the skin **150** after treatment to cause the therapeutic substances to penetrate into the pores or channels created by needles **115** or **118**.

[**0068**] In some embodiments, it may be desirable to use a high level of treatment to create large treatment zones or allow a large needle separation. In such embodiments, the skin may be charred or over-treated due to the local concentration of the electric field that occurs, for example, near the ends of the needles where the electric field may be highest. As shown in FIG. **13**, the incidence of over-treatment or charring can be reduced by cooling the needles **115** using the cryogenic spray **140** by spraying directly onto a thermal mounting plate **107** that is thermally connected to the needles **115**. The embodiments that use this cooled needle approach can also reduce the occurrence of the skin **150** adhering to the surface of the needles **115** when the RF treatment is performed. The contact plate **105** may be thermally insulating or thermally conductive depending on the desired thermal profile for treatment. Chilling the needles **115** will help to reduce purpura in some applications.

[**0069**] The contact plate **105** may be in thermal contact with the thermal mounting plate **107** to cool the surface of the skin **150** instead of or in addition to cooling the needles **115**. In another embodiment, the cryogenic spray **140** may also be directed to cool both the contact plate **105** and the thermal mounting plate **107** by patterning a first plate, which

is either the contact plate or the thermal mounting plate **107**, such that part of the cryogen emanating from the cryogen spray **140** passes through patterned regions in the first plate to cool the second plate that lies beyond the first plate.

[**0070**] In some embodiments, it may be desirable to use vacuum force to push the needles **115** into the skin **150** after good contact has been established between the contact plate **105** and the skin **150**. The embodiment shown in FIG. **1** is a preferred embodiment, as it does not have many moving parts that can wear out. An alternate embodiment shown in FIG. **13** provides better contact between the contact plate **105** and the skin **150** prior to the activation of the vacuum apparatus **125**.

[**0071**] In FIG. **13**, the vacuum apparatus **125** draws a negative pressure to create a force between the thermal mounting plate **107** and the contact plate **105**. The vacuum apparatus **125** is connected to the chamber between the thermal mounting plate **107** and the contact plate **105** via the vacuum port **120** and the vacuum feeder line **126**. The needles **115** can be attached to the thermal mounting plate **107**. As the chamber is pumped to a negative pressure, the force between the thermal mounting plate **107** and the contact plate **105** can be used to force needles **115** to a predetermined depth within the skin **150**. The adjustable spacer **106** may comprise bellows that can be expanded or compressed to create the desired offset to control the penetration depth of the needles. By adjusting the height of the adjustable spacer **106**, the predetermined depth of penetration of the needles **115** in the skin **150** can be adjusted.

[**0072**] FIGS. **14**A and **14**B show an embodiment of the invention that contains a disposable tip **199**. Delivery needles **118** are attached to a contact plate **105** for delivery of a therapeutic substance from the fluid filled reservoir **170**. Vacuum channels **123** are connected to two vacuum ports **120**A, and **120**B for connection to handpiece **200** that contains or attaches to a vacuum apparatus (not shown). The disposable tip **199** also comprises two electrical contact pads **111** and **112** for making electrical contact to two corresponding electrical contact pads **211** and **212** that are located on the handpiece **200**. The electrical contact pads **211** and **212** are connected to an RF source (not shown). The other end of the electrical contact pads **111** and **112** are connected to the delivery needles **118**. The tip **199** can be attached to a handpiece **200** using a magnetic latch **195** or by snap fitting or by other mechanical means. The needles **118** are surrounded by a vacuum curtain **190** that makes a vacuum seal with the skin (not shown) during treatment. Prior to use, the delivery needles **118** can be protected using a protective needle plug **191** that includes a plug handle **192** for removing the needle plug **191** from the delivery needles **118**.

[**0073**] To use the tip **199** shown in FIG. **14**B for treatment, the tip **199** is attached to the handpiece **200** using the magnetic latch **195**. The contact pads **111** and **112** make electrical contact to the corresponding electrical contact pads **211** and **212** on the handpiece **200**. The vacuum channels **223** attach to the vacuum ports **120** on the tip **199**. The protective needle plug **191** is removed using the plug handle **192**. The delivery needles **118** of the tip **199** are then applied to the skin (not shown) using manual pressure on the handpiece **200**. The vacuum curtain **190** would make an air tight seal with the skin. To help make the seal air tight, a vacuum compatible gel, grease, or sealant can be used. The vacuum apparatus (not shown) is activated to create a negative pressure between the contact plate **105** and the skin (not shown) to force the delivery needles **118** into the skin to a predetermined depth. The RF source (not shown) is then pulsed to create treatment zones (not shown) within the skin. Following treatment, the handpiece **200** is lifted from the skin to withdraw the delivery needles **118** and remove the tip **199** from the skin. The tip **199** can then be manually detached from the handpiece **200**.

[**0074**] The vacuum curtain **190** can be made of vinyl and should be thin enough to flex without breaking when applied to the skin so that a good vacuum seal can be created.

[**0075**] A fast-acting anesthetic in conductive saline solution can be added to the fluid-filled reservoir **170** for management of pain during or after the RF treatment. The use of conductive saline solution enlarges the electrical path for the RF treatment.

[**0076**] The tip **199** can be sterilized, if materials are chosen that are compatible with sterilizers, such as stainless steel and high melting temperature plastics.

[**0077**] FIG. **15** shows several treatment zones **260**, **261** created using an ex vivo human tissue model. Excised human abdominal skin **150** was placed on a hot plate to heat the skin **150** to approximately body temperature prior to treating using an RF source **110** connected to a pair of needle probes **115**. Saline soaked gauze sheets were used to keep the skin tissue moist as it was being heated prior to treatment. Two needles **115** were used to demonstrate the treatment zones created by each needle pair **116** and **117**.

[**0078**] Ex vivo tissue samples were frozen in optimal cutting temperature fluid (International Medical Equipment, Inc., San Marcos, Calif.) and were sliced with a cryostat into approximately 6-15 μm thick sections and stained with hematoxylin & eosin (Harris Hematoxylin and Eosin Y stains from International Medical Equipment, Inc.). The sliced sections were placed on glass microscope slides, dehydrated in 95% alcohol, and rehydrated in deionized water. Samples were then stained with hematoxylin to dye nuclei and cytoplasm within cells and with eosin to dye connective tissue. The concentration of alcohol was adjusted to optimize the contrast visible in the slide. Xylene was used to rinse the slides prior to mounting a glass coverslip.

[**0079**] FIG. **15**A shows the results of using of a needle pair that penetrated approximately 1-2 mm into the skin with a needle separation of 0.5 mm. A bipolar RF source operating at a frequency of 0.47 MHz, a power of 5W, and a pulse duration of 400 ms was used. The treatment zone **260** that was created has dimensions of approximately 500 μm width and 600 μm height. The aspect ratio of width to height of the treatment zone **260** is therefore approximately 5:6.

[**0080**] For FIG. **15**B, the conditions were similar to those for FIG. **15**A except the pulse duration was 200 ms, the separation between the needles **115** was 1 mm, and the depth of needle penetration was approximately 0.5-1 mm. The treatment zone **261** that was created has dimensions of approximately 900 μm width and 250 μm height. The aspect ratio of width to height for the treatment zone **261** is therefore approximately 3.6:1.

[**0081**] Other pulse parameters could be used. A preferred pulse source frequency is 0.47 MHz, but other frequencies

can be used as described above. Other frequencies are particularly useful to create treatment zones of different shapes because the material resistivity of the skin is frequency dependent. Therefore, different frequencies will create different treatment zone shapes for otherwise equivalent pulse conditions. For each electrode pair that is fired to create treatment zones between the electrode pair, the pulse energy from the RF source **110** is preferably 0.1 to 8.0 J and more preferably in the range of 0.5 to 2.0 J. Pulse energies in the range of 0.02 to 0.10 J can be used in cases where needles are spaced close together. Preferably, the aspect ratio of width to height for the treatment zones **160** is in the range of 1:2 to 5:1 and more preferably in the range 2:1 to 4:1. Treatment zones **160** with an aspect ratio of width to height of greater than 1:1 are called "lateral treatment zones." The height of the individual treatment zones **160** is preferably 0.1 to 0.5 mm. The preferred width of the individual treatment zones **160** is 0.1 to 2.0 mm, and more preferably 0.5 to 1.0 mm. The depth of the needle penetration into the skin **150** is preferably 0.025 to 2.0 mm and more preferably from 0.2 to 1.0 mm. Preferably the needles **115** penetrate into the dermis or epidermis to directly heat dermal or epidermal tissue through resistive heating. Larger or smaller treatment zones are within the scope of the invention and the size and location of the treatment zones will be application specific. There are some applications, such as for example, tattoo removal or fat removal that treatment will extend down into the subcutaneous fat or deeper. The pulse conditions outlined here produce substantial lateral tightening of skin tissue and treat substantial portions of the dermal tissue. These parameters can be used to coagulate collagen within the skin and to kill or injure cells to stimulate the wound healing response in surrounding healthy tissue.

[**0082**] Although the detailed description contains many specifics, these should not be construed as limiting the scope of the invention but merely as illustrating different examples and aspects of the invention. It should be appreciated that the scope of the invention includes other embodiments not discussed in detail above. For example, the disposable tip embodiment can also be used with needles that do not deliver a therapeutic substance. Various other modifications, changes and variations which will be apparent to those skilled in the art may be made in the arrangement, operation and details of the method and apparatus of the present invention disclosed herein without departing from the spirit and scope of the invention as defined in the appended claims. Therefore, the scope of the invention should be determined by the appended claims and their legal equivalents. Furthermore, no element, component or method step is intended to be dedicated to the public regardless of whether the element, component or method step is explicitly recited in the claims.

[**0083**] In the claims, reference to an element in the singular is not intended to mean "one and only one" unless explicitly stated, but rather is meant to mean "one or more." In addition, it is not necessary for a device or method to address every problem that is solvable by different embodiments of the invention in order to be encompassed by the claims.

What is claimed is:

1. A dermatological treatment apparatus for selectively treating zones of tissue comprising:

a plurality of mechanically coupled needles configured to penetrate a surface of a target area of human skin;

a handpiece mechanically connected to the plurality of mechanically coupled needles;

a radio frequency energy source operably connected to the plurality of needles such that the needles could be energized;

a controller operably connected to the radio frequency energy source;

wherein the needles are arranged so as to treat zones of tissue such that for selected treatment parameters tissue is spared around the treated zones.

2. An apparatus of claim 1, wherein the treatment zones are parallel to the surface of the skin.

3. An apparatus of claim 1, wherein the treatment zones are perpendicular to the surface of the skin.

4. An apparatus of claim 1, wherein the treatment zones extend laterally and vertically with respect to the surface of the skin.

5. An apparatus of claim 1, wherein the needles are made of an electrically conductive material.

6. An apparatus of claim 1, wherein the needles are coated with an electrically conductive material.

7. An apparatus of claim 5 or 6, wherein the needles have an electrically insulated exterior layer.

8. An apparatus of claim 7, wherein the insulating layer does not extend the entire length of the needle.

9. An apparatus of claim 8, wherein the insulating layer covers 10-95% of the length of the needle that is in the tissue.

10. An apparatus of claim 9, wherein the insulating layer covers 30-95% of the length of the needle.

11. An apparatus of claim 10, wherein the insulating layer covers 50-95% of the length of the needle.

12. An apparatus of claim 1, wherein the plurality of mechanically coupled needles includes at least 16 needles.

13. A device of claim 1, 2, **3**, **4**, **5**, or **6**, where the radio frequency energy source is bipolar.

14. A device of claim 1, 2, **3**, **4**, **5**, or **6**, where the radio frequency energy source is monopolar.

15. A device of claim 1, wherein needles are located on a grid.

16. A device of claim 15, wherein the needles are located equidistantly from each other.

17. A device of claim 15, wherein the needles are spaced further apart in one direction compared to the other direction on the grid.

18. A device of claim 1, wherein the penetrating the surface of the skin is accomplished using mechanical energy.

19. A device of claim 18, wherein the mechanical energy is in the form of negative pressure or vacuum.

20. A device of claim 18, wherein the mechanical energy is in the form of vibrations.

21. A device of claim 1, wherein the needles are configured to be cooled.

22. A device of claim 21, wherein the cooling is accomplished using a cryogen.

23. A device of claim 21, wherein the cooling is accomplished by thermal conduction.

24. A device of claim 1, wherein the needles are sterilizable.

25. A device of claim 1, wherein the needles are disposed after one use.

26. A device of claim 1, wherein the needles are configured to penetrate a predetermined depth into the target tissue.

27. A device of claim 26, wherein the depth of penetration of the needles is adjustable.

28. A device of claim 1, where the needles are hollow.

29. A device of claim 28, where the needles are configured to deliver one or more beneficial substances to into the target tissue.

30. A device of claim 29, where the beneficial substance is an anesthetic, growth factor, stem cells or botulinum toxin or combinations thereof.

31. A device of claim 1, wherein the controller terminates the treatment upon sensing a predetermined endpoint.

32. A device of claim 31, where the endpoint is temperature at the target area.

33. A device of claim 31, where the endpoint is impedance at the target area.

34. A device of claim 1, where the target tissue is human skin and the needles are configured to penetrate into the dermis.

35. A device of claim 1, where the needles are configured to penetrate about 0.2-1.0 mm into the target tissue.

36. A device of claim 1, where the needles are configured to penetrate about 5-50 μm into the target tissue.

37. A method of selectively treating zones of tissue comprising:

penetrating a plurality of mechanically coupled needles configured to penetrate the surface of a target area of human skin; wherein

a handpiece is mechanically connected to the plurality of mechanically coupled needles;

a RF energy source is operably connected to the plurality of needles such that the needles could be energized;

a controller is operably connected to the radio frequency pulse source;

wherein the needles are electrically conductive; and

treating zones of tissue such that for selected parameters tissue is spared around the treated zones.

38. A method of claim 37, where the treatment further comprises delivering a therapeutic substance to the tissue.

39. A method of claim 37, wherein the treatment comprises

creating a pattern of tightening in a subepidermal layer such that the pattern is dictated by configuration of the needles.

40. A method of claim 37, wherein the treatment comprises

creating a pattern of tightening in a dermal layer such that the pattern is dictated by configuration of the needles.

41. A method of claim 37, wherein the treatment comprises

creating a pattern of tightening in a dermal layer such that the pattern is preferentially aligned along the lines of maximum extensibility in the face.

42. A dermatological treatment apparatus for selectively treating zones of tissue comprising:

a plurality of mechanically coupled needles configured to penetrate a surface of a target area of human skin;

a handpiece mechanically connected to the plurality of mechanically coupled needles;

a radio frequency energy source operably connected to the plurality of needles such that the needles could be energized;

a controller operably connected to the radio frequency energy source;

wherein the needles are arranged so as to treat zones of tissue such that for selected treatment parameters tissue is spared around the treated zones to form discontinuous treated zones.

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