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[Continued on next page]

(54) **Title:** SLEEP APNEA DEVICE AND METHOD

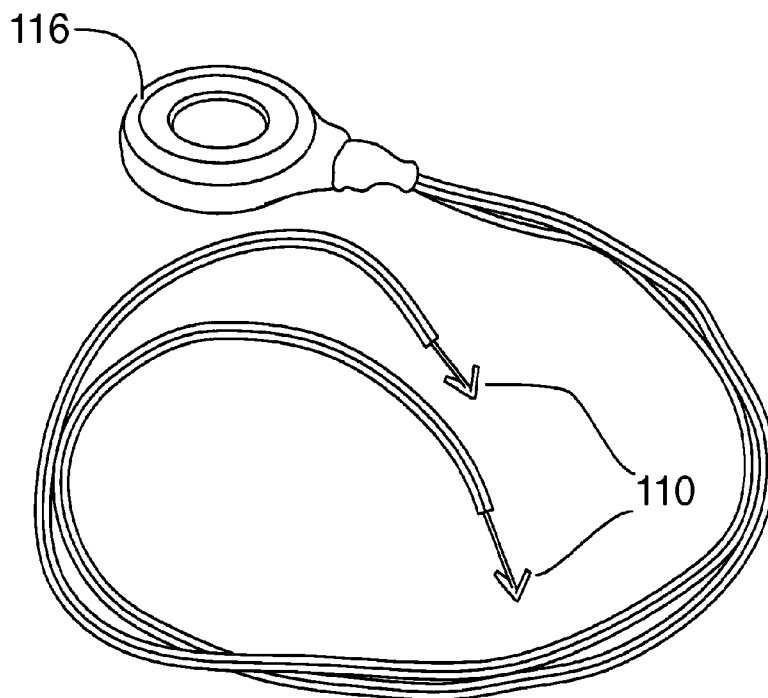


FIG. 5

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(57) Abstract: A device and method is described for the treatment of obstructive sleep apnea. This method involves the implantation of a muscle stimulation electrode directly into the muscle of the genioglossus that advances the posterior aspect of the tongue anteriorly thus relieving the obstruction of the tongue in sleep apnea. The device is powered by an implanted stimulator that receives its energy in turn from a radio frequency transmitted transcutaneous device that is applied to the patient at the time of sleep.

PATENT APPLICATION
FOR
SLEEP APNEA DEVICE AND METHOD

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CROSS REFERENCE TO RELATED APPLICATIONS

Not applicable.

BACKGROUND

Field of the Invention

[001] This present invention is generally directed toward the implantation of a medical device for treating patients with a specific physiologic dysfunction and in particular, treating patients with obstructive sleep apnea.

Background of the Invention

[002] Obstructive sleep apnea (OSA) is a disorder that affects more than 12 million people in the United States alone. (American Lung Association. "Obstructive sleep apnea (OSA) or sleep disordered breathing (SDB): in-depth.")(http://www.lungusa.org). Obstructive sleep apnea is a condition where the airway of an individual is temporarily obstructed during sleep. This most commonly occurs at the level of the soft palate and/or the base of the tongue and pharynx. Its causes are complex and multifactorial but appear to be due to the relaxation of muscles of the soft palate, tongue and pharynx that occur when one falls asleep.

[003] OSA causes the cessation of breathing which eventually awakens the patient at which point muscle tone is temporarily restored allowing breathing to resume. This sleep disturbance can occur more than 100 times per night in severe cases. The physiologic consequences of a lack of a sound night sleep and the stress on the body during these apneic spells are becoming more apparent. Besides the potential affects on the incidence and severity of hypertension, heart disease, and stroke there are also social consequences, reduced work productivity and deterioration of quality of life (Arch. Intern. Med. 152:538-541, 1992. J. Sleep Res. 4:183-188. 1995.)

[004] Recently, there has been more attention in the medical literature directed to the problems resulting from OSA and methods to help treat it. OSA is usually diagnosed by a sleep study. Patients found to have OSA are offered treatments ranging from weight loss and increase in exercise, dental appliances, continuous positive airway pressure (CPAP) to ablative surgical techniques. Weight loss and increased exercise have not been found to be a

sustainable solution in most OSA patients. Noncompliance with CPAP has been reported in 46-83% of patients (Proc. Of the American Thoracic Society 5:173-178, 2008.) Ablative surgery is effective in only about 32% of patients with severe with severe OSA (Laryngoscope 105:311-314, 1995.) Obstruction of the airway by the tongue appears to be the most problematic as it has a ball valve affect on the airway. The harder one tries to breath with the tongue obstructing, the more wedged the obstruction becomes. Eventually the patient awakens, regains muscles tone and can breathe again.

[005] Recent studies (J. Appl. Physiol. 103:1662-1668, 2007) have identified the areas of the Genioglossus muscle in human subjects that when stimulated move the base of the tongue forward thus relieving the obstruction. Selective stimulation of the genioglossus muscle in humans has been shown to decrease the number of obstructive events in OSA patients (J. Appl. Physiol. 81(2):643-652, 1996). The proposed device to assist OSA patients would provide periodic stimulation of the tongue muscles to prevent the airway from obstructing. The device would eliminate the need to wear a CPAP mask or undergo a painful oblotion procedure in an operating room with post operative hospitalization. Because of the ease of use with this device, patient compliance would significantly improve.

[006] Others have also tried to address this problem. Some have proposed implanting a cuff electrode around the hypoglossal nerve (U.S. Patent 5,522,862, U.S. patent 5,549,655, U.S. patent 5,540,733, incorporated by reference herein in their entirety). However, this requires a major surgical operation and there is great risk since there is a vital vein immediately adjacent the target nerve. Others have proposed more diffuse electrical stimulation (U.S. patent 6,212,435, U.S. published patent application 2008/0021506, incorporated by reference herein in their entirety) . However, this results in such a significant jolt that, rather than a non-awakening but effective stimulation, the patient is often indeed awakened, causing a sleep deprivation disorder by a different mechanism.

BRIEF SUMMARY OF THE INVENTION

[007] In preferred embodiments, there are provided method and devices for treating obstructive sleep apnea by direct wire stimulation to a specific set of muscle fibers.

[008] In one embodiment, there is provided a method for treating obstructive sleep apnea in a patient comprising the steps of: applying direct intramuscular electrical stimulation to a specific set of muscle fibers in a muscle of the patient's airway, wherein the electrical

stimulation is provided by an implanted electrode assembly, wherein the electrode assembly comprises one or more electrodes connected to an implanted receiver, and wherein the implanted electrode assembly is in operative association with an external electromagnetic frequency transmitting antenna located on or near a patient's body, such that said electrical stimulation is provided when the antenna transmits an electromagnetic frequency to the implanted electrode assembly, wherein upon receiving the frequency the implanted electrode assembly generates an electrical current in the one or more electrodes, and wherein the electrical current is delivered directly by wire to specific set of muscle fibers.

[009] In another embodiment, the method further comprises alternatively the step of implanting the electrode(s) using a 20 gauge needle, and/or implanting the receiver unit in the submental area in a patient who is somewhat obese as this would not be cosmetically apparent, and/or the step of implanting the receiver subcutaneously in the pectoral region which would remove any appearance of the receiver from view in a normally clothed individual, and/or the step of having the device implanted in the patient in the operating room in which case implantation over the pectoralis muscle would become far more comfortable under general anesthetic and this can be done while the patient may be undergoing some other operative procedure such as a septoplasty, turbinate reduction, or uvulectomy.

[0010] In another preferred embodiment, the method further comprises the step of having the power source on a timer to allow the stimulation to begin at some time period after the patient has gone to sleep, and/or the step of allowing the patient to adjust the length of stimulation based upon the quality of sleep and/or any sensation they may experience when the stimulator is turned on, and/or the step of allowing the patient to adjust the strength of the stimulation as the patient's physical condition or body habitus may change with time, and/or the step of utilizing sound activated stimulation, thereby allowing the power unit to turn on when the sound of snoring is received from the patient thus allowing the device to be utilized only during times when the patient may actually experience the apneic episodes, and/or the step of having the device turn on when the patient's oxygen concentration as measured by a transcutaneous receiver placed on the antenna over the patient's skin would detect an oxygen concentration of less than 96%, and/or the step of activating the receiver directly with Witricity which would be applied to the patient from a power source on a bedside table and through the wireless activation of the stimulator, and/or the step of having the stimulator implanted in the constrictor muscles of the pharynx to aid in opening the airway.

[0011] In a preferred embodiment, there is provided a medical device for treating a patient for obstructive sleep apnea comprising an implanted electrode assembly, wherein the electrode assembly comprises one or more electrodes connected to an implanted receiver, and wherein the implanted electrode assembly is in operative association with an external electromagnetic frequency transmitting antenna located on or near a patient's body, such that electrical stimulation is directly provided by wire to a specific set of muscle fibers in a muscle of the patient's airway when the antenna transmits an electromagnetic frequency to the implanted electrode assembly, wherein upon receiving the frequency the implanted electrode assembly generates an electrical current in the one or more electrodes, and wherein the electrical current is delivered directly by wire to the specific set of muscle fibers.

[0012] In another preferred embodiment, the device further comprises wherein the electrode(s) of the electrode assembly are made from wire having a dimension of 0.007 inches, and/or further comprises wherein the electrode(s) (wire) is sized to fit within a 20-gauge needle (about 0.0230 inches internal diameter), and/or wherein the medical device further comprises a needle for implantation means where the needle may range from 27 ga to 10 ga, with 20 gauge being optimal. Note that for a specific diameter wire having a 4-way folded barb at its terminus for attaching to tissue (a barb-like four-way fold of a wire can be seen in cross-section to have a central wire with three adjacent wires in a triangular formation around the central wire, and thus requiring an implantation needle of an appropriate size.

[0013] In another preferred embodiment, the device further comprises alternatively timer-means for having the power source on a timer to allow the stimulation to begin at some time period after the patient has gone to sleep, and/or length-adjustment-means for allowing the patient to adjust the length of stimulation based upon the quality of sleep and/or any sensation they may experience when the stimulator is turned on, and/or strength-adjustment-means for allowing the patient to adjust the strength of the stimulation as the patient's physical condition or body habitus may change with time.

[0014] In another preferred embodiment, the medical device further comprises alternatively sound-activation-means for allowing the power unit to turn on when the sound of snoring is received from the patient thus allowing the device to be utilized only during times when the patient may actually experience the apneic episodes, and/or oxygen-sensing means and auto-start means for having the device turn on when the patient's oxygen concentration as measured by a transcutaneous receiver placed on the antenna over the

patient's skin would detect an oxygen concentration of less than 96%.

[0015] In another preferred embodiment, the medical device further comprises wireless electricity means for activating the receiver directly with "Witricity" which would be applied to the patient from a power source on a bedside table and through the wireless activation of the stimulator.

[0016] In another preferred embodiment, the medical device further comprises one or more electrodes implanted in the constrictor muscles of the pharynx to aid in opening the airway.

[0017] In another preferred embodiment, the medical device further comprises any of the above claims further comprising microprocessor electronics to process the devices activities.

[0018] Another preferred embodiment provided herein comprises a specific surgically implantable electrode having an atraumatic removal feature, comprising an electrically conductive wire connected to a stainless steel deformable barb, wherein the deformable barb comprises two operative positions, the first position comprising a pointed hook shape for attachment to tissue, and a second position comprising a straightened shape, wherein upon removal of the deformable barb from the tissue, the deformable barb changes from the first to the second position.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] **Figure 1.** Shows a lateral sagittal view of the oropharynx showing the location of the tongue in proximity to the posterior pharyngeal wall. The location of the hyoid bone and the chin portion of the mandibular bone and the approximate areas at which the electrodes would be introduced into that muscle.

[0020] **Figure 2.** Shows a frontal view of a patient whose head is tilted up revealing the site of the incision in the submental region and also the site of the incision just anterior to the sternocleidomastoid muscle in the neck.

[0021] **Figure 3.** Shows the proposed power source which would be able to be clipped to patient's night clothes and be powered by AA replaceable or rechargeable batteries.

[0022] **Figure 4.** Shows the antenna which delivers the radiofrequency to the receiver and is to be placed over the receiver on the skin and held in place with a small adhesive dressing.

[0023] **Figure 5.** Shows the receiver with the 2 electrodes present.

[0024] **Figure 6.** Fig. 6A Shows the point of the muscle stimulator which is at the end of

Teflon coated stainless steel wire. Fig. 6B shows detail indicating the wire is sufficiently flexible to allow deformation of the tip if the stimulator needs to be removed.

[0025] **Figure 7.** Shows the stimulator and the stimulator insertion device which is a 20 or 22 gauge 1 ¼ inch needle. The larger of the barbs of the stimulator tip would be placed in the barrel of the needle as shown. This coupled device would then be introduced into the genioglossus muscle and the needle removed leaving the stimulator device in place.

[0026] **Figure 8.** Shows the transformation of the needle tip as it is withdrawn from the tissue of the patient if necessary and illustrates the atraumatic way in which the stimulator can be removed.

DETAILED DESCRIPTION OF THE INVENTION

[0027] The proposed device and method for treating OSA is a significant improvement in that it allows implantation of the device in an office setting with a very brief procedure. This will allow stimulation of existing tissue and avoids the current methods of treatment which are quite uncomfortable such as surgical ablative treatment, uvulopalatopharyngoplasty, or additive treatment such as wearing a CPAP mask at night. The patient would then be able to control this device through the application of the antenna over the receiver at night.

[0028] Referring now to the figures, FIG. 1 shows a cross section of the upper airway in particular the tongue (genioglossus muscle) 20. FIG. 1 also shows the locations, L1 and L2, of the specific placements for the electrodes 110.

[0029] The device itself consists of 4 parts. First is a power source 120 (Fig. 3). Second is an antenna 118 (Fig. 4). Third is a receiver 116 and fourth is the stimulating electrode 110 (Fig. 5). The power source provides the power for the device and is of small size so that it can be clipped to the upper nightwear of the patient being treated. This is connected to the antennae which deliver the radio frequency to the receiver which has been implanted in the neck of the patient with the stimulating electrodes emanating from the receiver and entering into specific muscle sites in the tongue of the patient. The antennae is held in place via an adhesive and this is applied over the receiver on the patient's neck at the time the patient would be going to sleep. It is then removed in the morning.

[0030] The receiver includes an electrical pulse source, or pulse generator. The electrodes impart electrical pulses, generated by the pulse generator, directly by wire to the genioglossus muscle to stimulate the specific muscle fibers to a point where the patient's tongue is moved

anteriorly to maintain upper airway patency. The pulse generator has an output that provides electrical pulses having selectable properties of mode, polarity, amplitude, current, pulse width, and frequency. The pulse mode may be direct current; and, the polarity may be negative or positive. The polarity of the electrical pulses may be periodically reversed according to predetermined criteria for balanced electrical current flows through the genioglossus muscle. Commercially available pulse generators provide pulses having many of the previously mentioned variables and may include microprocessor and electronics for signal processing and cooperation with apnea detection devices. The stimulator may be variably set to provide direct current pulses having an amplitude, a frequency, and a duration to provide a non-awakening stimulation directly by wire to the specific muscle fibers.

[0031] Referring to Fig. 2, the preferred method of implantation of the device would be performed in a physician's office under local anesthesia and is expected to take approximately 15-20 minutes. The area under the patient's chin in the midline is infiltrated with local anesthetic as is the area just anterior to the sternocleidomastoid muscle in the mid portion of the neck. A line connecting these two points is also infiltrated with the same local anesthetic. The area is cleansed with beta dyne. A 1 centimeter horizontal incision 210 (Fig. 2) is then made in the anesthetized area just anterior to the sternocleidomastoid muscle. A small pocket is created subcutaneously and the receiver is placed in this pocket. The second incision 220 measuring approximately 1 centimeter is made in the mid portion of the submental region approximately half way between the hyoid bone and the chin.

[0032] Referring now to FIGS. 7 and 8, a common surgical tunneling device is then used to connect these two pockets. The electrodes are then attached to the tunneling device and pushed or pulled through the subcutaneous tunnel emanating in the submental incision. The electrodes are then attached as in Fig. 7 to the electrode positioning device 140 (a 20 gauge needle).

[0033] The electrode(s) of the electrode assembly are made from biocompatible wire having a dimension ranging from about 0.005 to about 0.010 inches, with preferred thickness being about 0.007 inches. The tip (barb) 112 is made of medical grade stainless steel. Alternatively it may be made of other functionally equivalent materials. The wire has a biocompatible coating 160, which may include silastic, Teflon ® and the like.

[0034] The electrode(s) (wire) is sized to fit within a 20-gauge needle (about 0.0230 inches internal diameter), but the implantation or insertion needle may range from 27 ga to 10

ga, with 20 gauge being optimal. The wire is 0.007 inch platinum and has a 4-way folded barb shown in Fig. 7 at its terminus for attaching to tissue. Alternative configurations for attaching to tissue are contemplated as within the scope of the invention. The barb may be housed within (internal to) the needle, either entirely or partially as shown in Fig. 7.

Alternately the barb may be external to the implantation needle where only the wire is disposed within the needle. For a barb housed entirely within the needle, upon insertion, the wire may be threaded down the needle such that the barb expands into the space of the needle being withdrawn from the tissue. A barb-like four-way fold of the wire can be seen in cross-section to have a central wire with three adjacent wires in an approximate triangular formation around the central wire, and thus requiring an implantation needle that has at least about 0.021 inches in diameter for a 0.007 inch wire. For a barb completely external to the needle having the attached trailing wire housed within the needle, the internal diameter of the needle need only be large enough to accommodate the width of the electrode wire.

[0035] One electrode is placed through the stab incision in the submental area just anterior to the midline and is slowly advanced with the introducer until located just behind the front portion of the mandible in the genioglossus muscle. In a preferred embodiment, the depth ranges from about 0.5 cm to about 2.0 cm, and more preferably from about 1.0 cm to about 1.75 cm, and more preferably from about 1.5 cm to about 1.75 cm.

[0036] Referring again to FIG. 1, the location L2 of the second electrode is initially determined by inserting a non-barbed probe to identify the optimal placement by depth and angle. Although the depth varies from patient to patient, it is contemplated that an average depth of about 1.5 to about 1.75 cm within the genioglossus muscle 20. The second electrode is placed, parallel to the non-barbed probe, to the same depth and angle, through the same stab incision site but placed anterior to the hyoid bone but posterior to the first electrode, the stimulator being used intermittently while the tongue is observed through a flexible laryngoscope or dental mirror for appropriate movement. After this has been placed in it's position and stimuli is applied, the location L2 is finally determined as it causes the base of the tongue to move forward. After this has been completed the underlying tissues are closed over the electrodes and wires using ...sutures of 4-0 chromic or vicryl and the skin incisions are closed with interrupted sutures of 5-0 or 6-0 fast absorbing gut. A small amount of bacitracin or antibiotic ointment is applied. The patient is then given oral antibiotics for 3 days postoperatively. The wounds are kept clean during the healing period which would be

approximately 14 days. The patient then returns to the office where the antennae is placed over the receiver in the neck and the intensity of voltage is calibrated to achieve adequate tongue movement clearing the back of the throat and not causing the patient to experience any pain. After this is accomplished the patient is instructed on how to apply the antennae 118 and how to turn on the device when they will be sleeping.

[0037] By having the device implanted in an office setting under a local anesthetic, and the application of the stimulus being administered transdermally through the antennae 118, patient compliance should be vastly improved as this is a far more comfortable way to open the oral pharynx than with either surgery or CPAP.

[0038] A second modification of the implant includes implanting the receiver 116 in the submental area in a patient who is somewhat obese as this would not be cosmetically apparent.

[0039] A third application of implanting the receiver 116 subcutaneously in the pectoral region which would remove any appearance of the receiver from view in a normally clothed individual.

[0040] A fourth application would be to have the device implanted in the patient in the operating room or on an outpatient basis. In the case of implantation in the operating room, implantation over the pectoralis muscle would become far more comfortable under general anesthetic and this can be done while the patient may be undergoing some other operative procedure such as a septoplasty, turbinate reduction, tonsillectomy, or uvullectomy. In the case of outpatient implantation, complications are minimized. It is contemplated that implantation may also be performed using ultrasound imaging to assist with targeting the locations L1 and L2, and with verifying implant location and functionality.

[0041] A fifth application would be to have the power source 120 on a timer. This would allow the stimulation to begin at some time period after the patient has gone to sleep.

[0042] A sixth application would be to allow the patient to adjust the parameters of stimulation based upon the quality of sleep and/or any sensation they may experience when the stimulator is turned on. Parameters contemplated herein include without limitation length of time of stimulation, strength of stimulation, and so forth.

[0043] A seventh application would be to allow the patient to adjust the parameters of the stimulation as the patient's physical condition or body habitus may change with time.

[0044] An eighth application would be sound activated stimulation. This would allow the

power unit to turn on when the sound of snoring is received from the patient. This would allow the device to be utilized only during times when the patient may actually experience the apneic episodes.

[0045] A ninth application would be to have the device turned on when the patient's oxygen concentration as measured by a transcutaneous receiver placed on the antenna over the patient's skin would detect an oxygen concentration of less than 96%.

[0046] A tenth application would be activation of the receiver directly with Witricity which would be applied to the patient from a power source on a bedside table and through the wireless activation of the stimulator.

[0047] An eleventh application is to have the stimulators implanted in the constrictor muscles of the pharynx to aid in opening the airway.

[0048] In use, the device as described herein and/or the method as described herein provides for alternating on/off "intermittent" treatment wherein the tissue is stimulated for a given period, and then the tissue is allowed to rest for a given period. In one preferred embodiment, the device or method applies stimulation for 5 seconds, and then stimulation is turned off for 5 seconds. In another preferred embodiment, the period of stimulation ranges from 1 to 20 seconds, with varying rest periods. In another preferred embodiment, the period of stimulation is 20 seconds and the rest period is 5 seconds. In yet another preferred embodiment, the period is 60 seconds on with 60 seconds off. On periods may range, without limitations from 1 to 120 seconds, and off periods similarly. On/off intermittent periods include from 5/5, 20/5, 10/10, 5/60, 60/5, 20/20, 30/30, 40/40, 50/50, 60/60, and so forth.

[0049] In addition to the alternating intermittent embodiments, in yet another preferred embodiment, the period is 60 seconds on and 60 seconds off, with sub-intervals of 5 seconds on and 5 seconds off during the 60 seconds "on" stimulation period. Accordingly, alternating intermittent periods can be optionally used with sub-intervals in ranges of on/of periods from 1 to 300 seconds.

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- [0062] The references recited herein are incorporated herein in their entirety, particularly

as they relate to teaching the level of ordinary skill in this art and for any disclosure necessary for the commoner understanding of the subject matter of the claimed invention. It will be clear to a person of ordinary skill in the art that the above embodiments may be altered or that insubstantial changes may be made without departing from the scope of the invention. Accordingly, the scope of the invention is determined by the scope of the following claims and their equitable Equivalents.

I claim:

1. A method for treating obstructive sleep apnea in a patient comprising the steps of:
applying direct electrical stimulation to a specific set of muscle fibers in a muscle of the patient's airway, wherein the electrical stimulation is provided by an implanted electrode assembly, wherein the electrode assembly comprises one or more electrodes connected to an implanted receiver, and wherein the implanted electrode assembly is in operative association with an external electromagnetic frequency transmitting antenna located on or near a patient's body, such that said electrical stimulation is provided when the antenna transmits an electromagnetic frequency to the implanted electrode assembly, wherein upon receiving the frequency the implanted electrode assembly generates an electrical current in the one or more electrodes, and wherein the electrical current is delivered directly by wire to specific set of genioglossus muscle fibers.
2. The method of claim 1, further comprising the step of implanting the receiver in the submental area in a patient.
3. The method of claim 1, further comprising the step of implanting the receiver subcutaneously in the pectoral region.
4. The method of claim 1, further comprising the step of having the device implanted in the patient in the operating room in combination with another operative procedure.
5. The method of claim 1, further comprising the step of having the power source on a timer to allow the stimulation to begin at some time period after the patient has gone to sleep.
6. The method of claim 1, further comprising the step of allowing the patient to adjust the parameters of stimulation based upon the quality of sleep and/or any sensation they may experience when the stimulator is turned on.
7. The method of claim 1, further comprising the step of allowing the patient to adjust the parameters of the stimulation as the patient's physical condition or body habitus may change with time.
8. The method of claim 1, further comprising the step of utilizing sound activated stimulation, thereby allowing the power unit to turn on when the sound of snoring is

received from the patient thus allowing the device to be utilized only during times when the patient may actually experience the apneic episodes.

9. The method of claim 1, further comprising the step of having the device turn on when the patient's oxygen concentration as measured by a transcutaneous receiver placed on the antenna over the patient's skin would detect an oxygen concentration of less than 96%.
10. The method of claim 1, further comprising the step of activating the receiver directly with Witricity which would be applied to the patient from a power source on a bedside table and through the wireless activation of the stimulator.
11. The method of claim 1, further comprising the step of having the stimulator implanted in the constrictor muscles of the pharynx to aid in opening the airway.
12. The method of claim 1, further comprising wherein the step of applying electrical stimulation is performed intermittently.
13. The method of claim 12, further comprising wherein the intermittent stimulation is applied for 5 to 300 seconds followed by a rest period.
14. A medical device for treating a patient for obstructive sleep apnea comprising an implanted electrode assembly, wherein the electrode assembly comprises one or more electrodes connected to an implanted receiver, and wherein the implanted electrode assembly is in operative association with an external electromagnetic frequency transmitting antenna located on or near a patient's body, such that electrical stimulation is provided to a specific set of muscle fibers in a muscle of the patient's airway when the antenna transmits an electromagnetic frequency to the implanted electrode assembly, wherein upon receiving the frequency the implanted electrode assembly generates an electrical current in the one or more electrodes, and wherein the electrical current is delivered directly by wire to the specific set of muscle fibers.
15. The medical device of claim 12, further comprising timer means for having the power source on a timer to allow the stimulation to begin at some time period after the patient has gone to sleep.
16. The medical device of claim 12, further comprising parameter adjustment means for allowing the patient to adjust a quality parameter of stimulation based upon the quality of sleep and/or any sensation they may experience when the stimulator is turned on.

17. The medical device of claim 12, further comprising condition parameter adjustment means for allowing the patient to adjust a parameter of the stimulation as the patient's physical condition or body habitus may change with time.
18. The medical device of claim 12, further comprising sound activation means for allowing the power unit to turn on when the sound of snoring is received from the patient thus allowing the device to be utilized only during times when the patient may actually experience the apneic episodes.
19. The medical device of claim 12, further comprising oxygen-sensing means and auto-start means for having the device turn on when the patient's oxygen concentration as measured by a transcutaneous receiver placed on the antenna over the patient's skin would detect an oxygen concentration of less than 96%.
20. The medical device of claim 12, further comprising wireless electricity means for activating the receiver directly with "Witricity" which would be applied to the patient from a power source on a bedside table and through the wireless activation of the stimulator.
21. The medical device of claim 12, further comprising one or more electrodes implanted in the constrictor muscles of the pharynx to aid in opening the airway.
22. The medical device of claim 12, further comprising a timer and control mechanism for intermittent application of the electrical stimulation.
23. The medical device of any of claims 12-19, further comprising microprocessor electronics in operative association with the device to process the device's activities.
24. The medical device of any of claim 12-20, further comprising wherein the electrode(s) of the electrode assembly are made from wire having a dimension ranging from about 0.005 to about 0.010 inches.
25. The medical device of any of claim 12-20 , further comprising wherein the electrode(s) (wire) is sized to fit within a 20-gauge syringe needle (about 0.0230 inches internal diameter).
26. The medical device of any of claim 12-20 , further comprising an implantation needle ranging from 27 ga to 10 ga in size, wherein the electrode comprises a barb attached to a wire, and the implantation needle is in operative association with the barb to facilitate attachment of the barb to the target tissue.
27. The medical device of any of claim 12-20 , further comprising wherein the electrode

comprises a stainless steel barb attached to a biocompatible wire.

28. A surgically implantable electrode having an atraumatic removal feature, comprising an electrically conductive wire connected to a stainless steel deformable barb, wherein the deformable barb comprises two operative positions, the first position comprising a pointed hook shape for attachment to tissue, and a second position comprising a straightened shape, wherein upon removal of the deformable barb from the tissue, the deformable barb changes from the first to the second position.



FIG. 1

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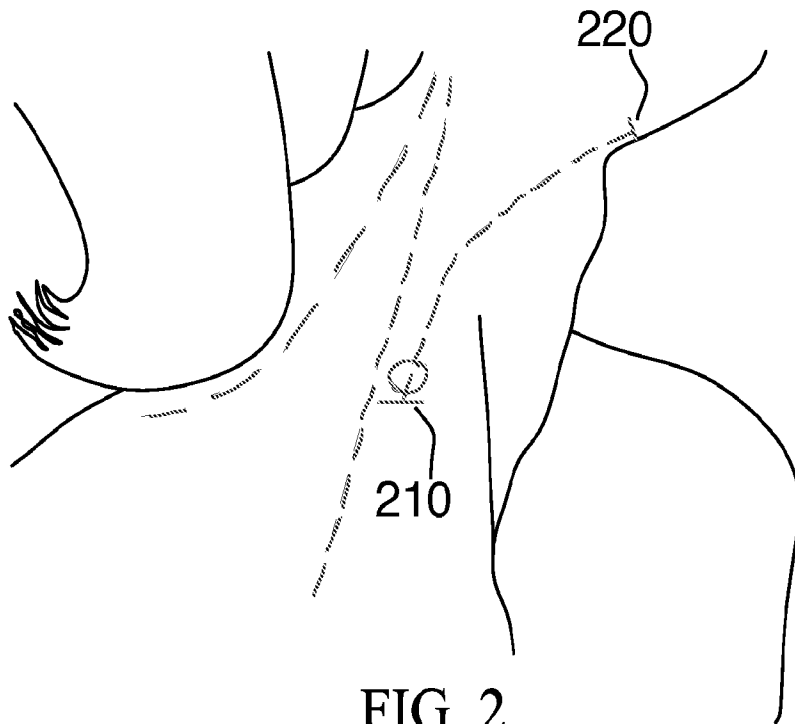


FIG. 2

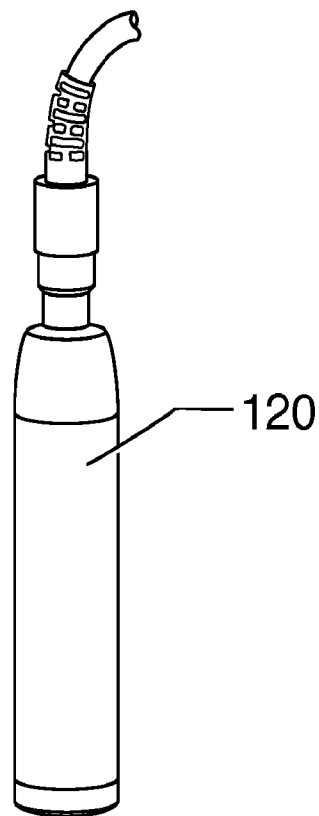


FIG. 3

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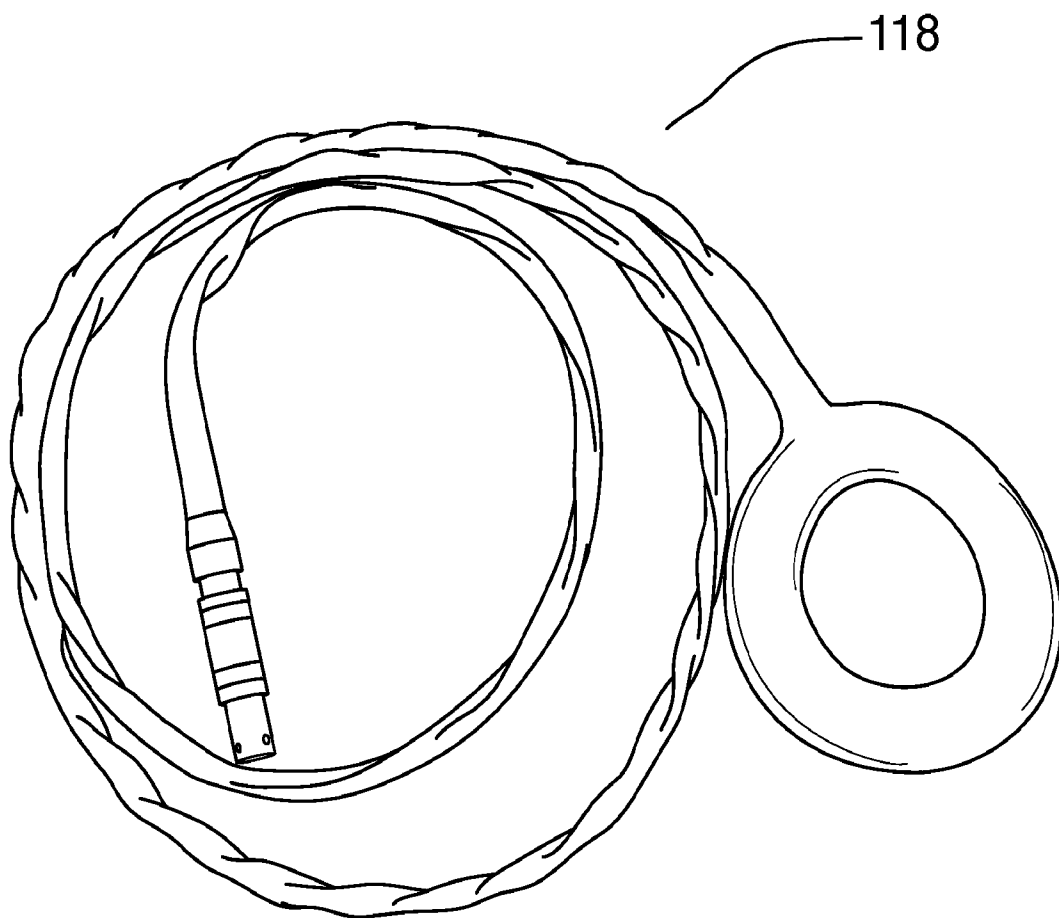


FIG. 4

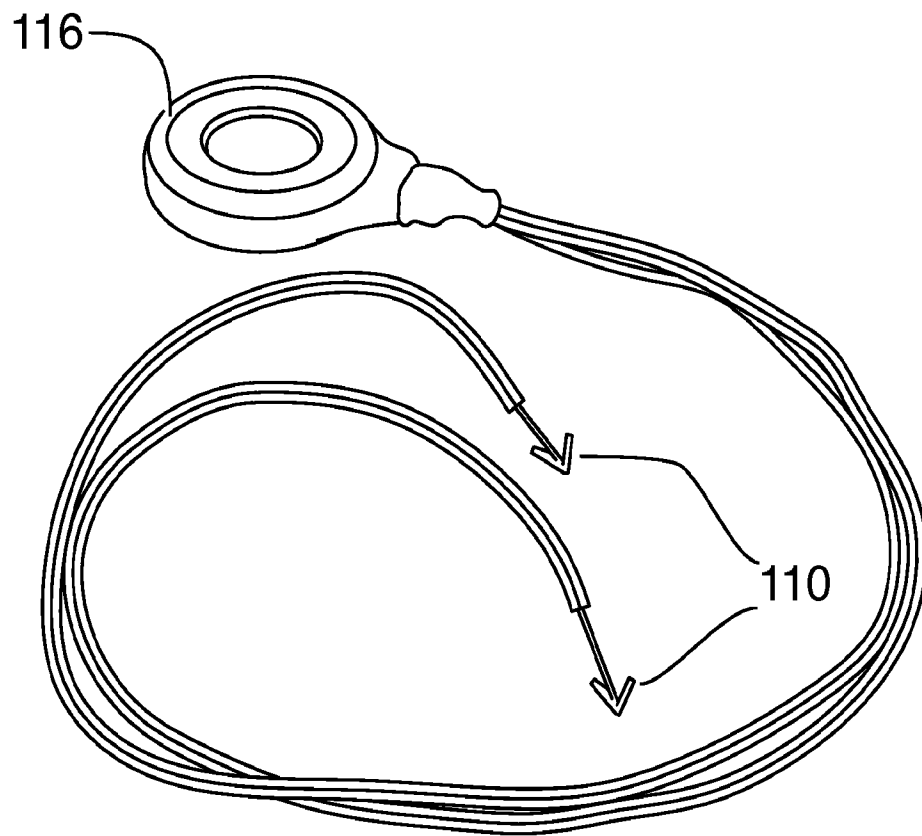


FIG. 5

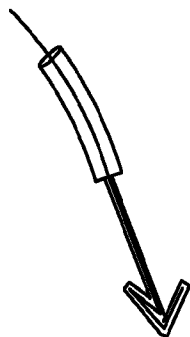


FIG. 6A

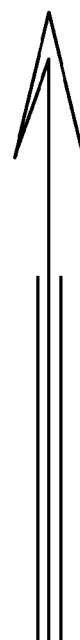


FIG. 6B

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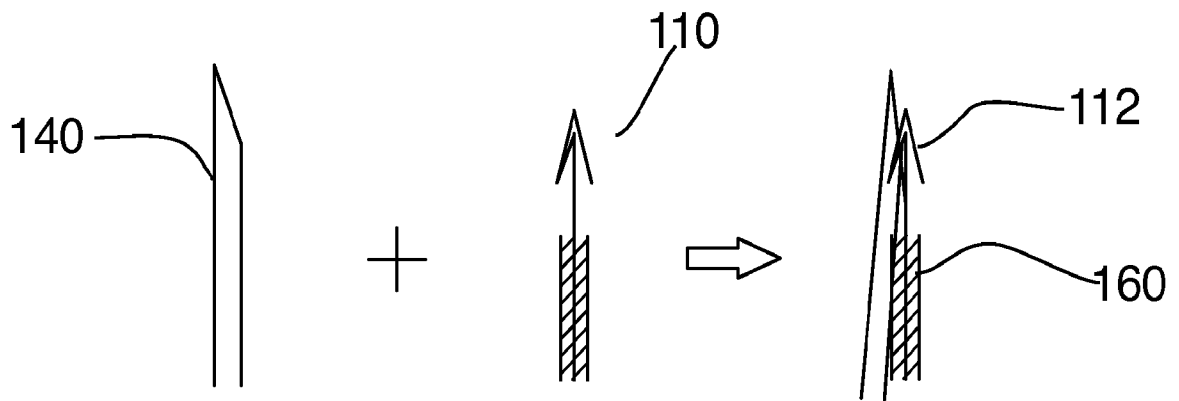


FIG. 7

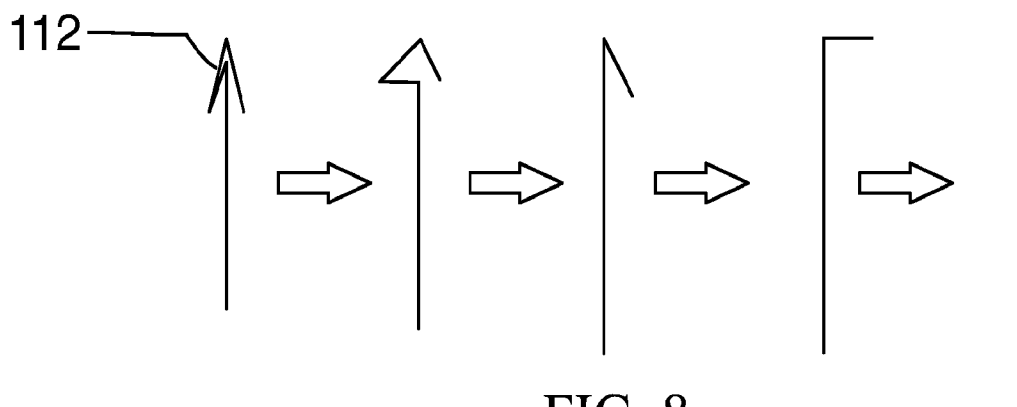


FIG. 8