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(54) **Title**: A TONGUE MANIPULATION DEVICE AND ANCHOR FOR USE IN SUCH DEVICES

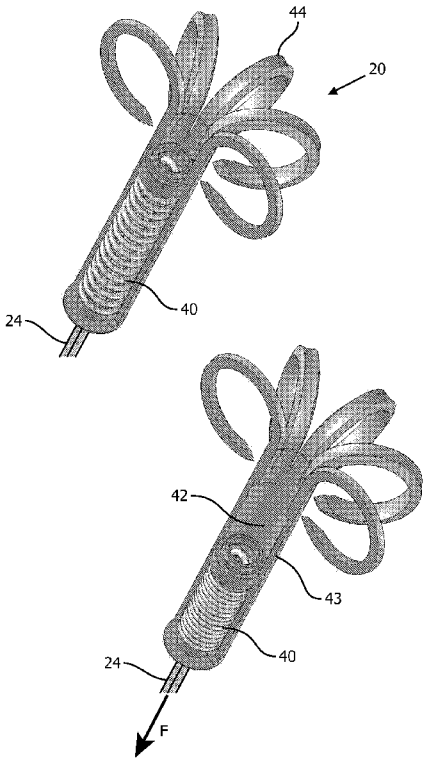


FIG. 4

(57) **Abstract**: An anchor for a tongue manipulation device comprises an outer housing (43), within which is housed a compressible elastic member (40) for applying a biasing force to a tether line (24) and for allowing the distance between a tissue anchor (20) and a bone anchor (22) to be increased when a loading force exceeds the biasing force. Extension of the tether line is accompanied by compression of the elastic member. This design results in minimal irritation and potential inflammatory response triggered by the constant movement of the elastic member, and it is prevented from overstretching thus reducing wear and tear.

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TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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A tongue manipulation device and anchor for use in such devices

FIELD OF THE INVENTION

This invention relates to a tongue manipulation device, and particularly to the design of the soft tissue anchor or bone fixing used in such devices.

BACKGROUND OF THE INVENTION

It is known to use a tongue manipulation device to treat upper airway obstruction and sleep disordered breathing.

Respiratory disorders during sleep are recognized as a common problem with significant clinical consequences. Obstructive Sleep Apnoea (OSA) causes an intermittent cessation of airflow. When these obstructive episodes occur, an affected person will transiently arouse. Because these arousal episodes typically occur 10 to 60 times per night, sleep fragmentation occurs which produces excessive daytime sleepiness. Some patients with OSA experience over 100 transient arousal episodes per hour. OSA may also lead to cardiovascular and pulmonary disease.

Various approaches are known which aim to maintain the airway passage during sleep. Oral appliances aimed at changing the position of the soft palate, jaw or tongue are available, but patient discomfort has limited their use. Continuous Positive Airway Pressure (CPAP) devices are often used as first-line treatments for OSA. These devices use a sealed mask which produces airflow at a slightly elevated pressure and acts to maintain positive air pressure within the airway.

This invention relates to an approach by which a tongue manipulation device is surgically applied to a patient. Aspire Medical was the originator of the "Advance", implantable tongue suspension technology.

The technology and various embodiments are described in detail in US2008/0023012 for example, Figs. 1 to 3 give examples of these embodiments.

The complete device comprises three essential parts:

(i) a tissue anchor which is surgically placed inside the tongue;

(ii) a bone anchor which is typically attached to the mandible; and

(iii) a tether line which fixes the tissue anchor to the bone anchor.

The bone anchor comprises a spool, enabling the surgeon to spool the tether into the bone anchor. This process is called titration or adjustment and stabilizes the tongue as well as advances the tongue in the direction of the mandible (or prevents the tongue moving back), preventing blocking of the airway. The spool arrangement comprises an indexing part and a spool part, so that a tangible as well as an audible sound is made during titration so that the degree of tightening can be judged. The indexing part can also retain the spool in a fixed position after adjustment or a separate lock can be used.

Clinical studies have shown that the "Advance" technology is able to significantly reduce the number of apnoeic events in moderate and severe apnoea patients.

Generally, the implant is placed in the midline of the tongue at the base of the tongue and the device provides stabilization and advancement of the tongue base, so that the tongue can no longer move freely back. Instead, it is blocked by the stretched wire between the bone and tissue anchor. The tissue area, which is the target zone for the implant, moves by physiological events such as swallowing, yawning and speech up and down and forwards and backwards. The leads to a pulling force at the wire causing both a mechanical loading of the implant in the tongue and the bone anchor. In very extreme loading situations, this mechanical load might harm the device itself and/or irritate the tissue that may lead to a slippage of the implant through the tongue tissue or a long term tissue remodelling.

To avoid high loading situations, it is known to provide some flexibility (stretchability). For example, it is known to add flexible members such as springs into the tether line.

A disadvantage of such a construction can be that the flexible member is not shielded from the biological environment. As such, the flexible member can cause irritation and potential inflammatory response. The flexible member can also be prone to wear or damage, for example by overstretching so that the function deteriorates over time.

SUMMARY OF THE INVENTION

According to the invention, there is provided a device as claimed in the independent claim.

In one aspect, the invention provides an anchor for a tongue manipulation device which device comprises a tissue anchor for attachment to the tongue, a bone anchor and a tether line which fixes the tissue anchor to the bone anchor,

wherein the anchor comprises an outer housing which defines a chamber, and a compressible elastic member housed within the chamber, the elastic member having a tether line end and an anchor end which is movable within the chamber, wherein an end of the tether line is connected to the anchor end of the elastic member,

wherein the elastic member is adapted to apply a biasing force to the tether line and to allow the distance between the tissue anchor and the bone anchor to be increased when a loading force exceeds the biasing force.

In this design, a compressible elastic member, such as a spring is integrated either into the structure which anchors into the tongue tissue or into the bone anchor. One advantage of such a construction is that the elastic member is shielded from the biological environment. As such, the spring results in minimal irritation and potential inflammatory response triggered by the constant movement of the spring. The elastic member provides a restraining force which is intended to be functional while the user sleeps, but allows additional extension under a greater load, when the user speaks, eats or drinks (for example).

The design of the elastic member, with the tether line connected to the end of the elastic member on the anchor side rather than the tether line side, means that extension of the tether line is accompanied by compression. The elastic member is thus prevented from overstretching. The stretching of the elastic member is limited by the interaction between the elastic member and the chamber, and this elastic member stretching is not induced by the forces applied by the user.

The length of the elastic member varies in use according to the load applied. An elongate compressible spring for example can easily be integrated into the anchor, along the axis of the tether line - so that there is an end of the spring on the tether line side and an end of the spring on the anchor side.

The elastic member can be a coil spring, and the tether line can extend through the central opening of the spring so that the spring extends back from the end of the tether line.

The biasing force is preferably selected to be greater than the gravitational force applied to the tether line by the tongue.

The elastic member can allow a maximum distance between the tissue anchor and the bone anchor when a threshold force is reached.

The biasing force can comprise a spring preload of between 1N and 10N (more preferably 2N to 4N, for example 3N), and the threshold force can be between 2N and 20N (more preferably 3N to 15N, such as 6N).

The elastic member preferably provides a maximum distance variation of between 3mm and 20mm (such as 5mm).

The invention also provides a tongue manipulation system, comprising a tissue anchor and a bone anchor for attachment to the mandible, wherein one or both anchors have the elastic member design of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Examples of the invention will now be described in detail with reference to the accompanying drawings, in which:

Fig. 1 shows generally how a known tongue manipulation device is used;

Fig. 2 shows the known tongue manipulation device in more detail;

Fig. 3 shows how the tension in the tether line is adjusted in the device of Figs. 1 and 2; and

Fig. 4 shows a tissue anchor to which the invention has been applied; and

Fig. 5 shows a bone anchor to which the invention has been applied and shows the spring in more detail.

DETAILED DESCRIPTION OF THE EMBODIMENTS

The invention relates to tongue manipulation devices having a tissue anchor for attachment to the tongue, a bone anchor typically for attachment to the mandible and a tether line which fixes the tissue anchor to the bone anchor. One or both anchors comprises an outer housing, within which is housed a compressible spring for applying a biasing force to the tether line and for allowing the distance between the tissue anchor and the bone anchor to be increased when a loading force exceeds the biasing force. Extension of the tether line is accompanied by spring compression. The spring results in minimal irritation and potential inflammatory response triggered by the constant movement of the spring, and is prevented from overstretching.

The invention can be applied as a modification to known devices, for example of the type described in detail in US2008/0023012, which is hereby incorporated by reference.

The relevant parts of the known device will first be described, with reference to Figs. 1 to 3 which are adapted from US2008/0023012.

Fig. 1 shows a tongue manipulation device 10 attached to a securing assembly 12 located on the inferior surface of the mandible 14. The tongue is shown as 16.

Fig. 2 shows a possible design of the tongue manipulation device in more detail.

It comprises a tissue anchor 20 for attachment (in particular implantation) to the tongue and a bone anchor 22 for attachment to the mandible. A tether line 24 fixes the tissue anchor to the bone anchor.

The bone anchor 22 comprises a tether line spool arrangement 26. This enables the tether line to be wound onto the spool to take up slack in the tether line so that the line can provide a desired restricted movement of the tongue.

Fig. 3 shows how adjustment of the spool is made, and shows a cross section through the lower part of the head of a patient. The bone anchor 22 is attached to the lower mandible 30 as shown. To tighten the tether line 24, a rotary drive shaft 32 (known as a "titration needle" or “adjustment tool”) is inserted into an opening in the spool part of the bone anchor, and adjustment is judged based on an indexed function.

The invention provides an arrangement in which some flexibility is provided in the line between the tongue and the mandible. A biasing force needs to be overcome to extend the tether line, and this is designed so that the weight of the tongue during sleep is insufficient to cause significant extension of the tether line length. However, discomfort of the patient is reduced during waking hours, as increased forces (for example resulting from swallowing, speaking, drinking) are cushioned by the spring, which also allows some additional freedom of movement of the tongue.

Fig. 4 shows a first embodiment of the invention, in which the tissue anchor 20 incorporates a compressible spring element in the form of a coil spring. Two images are shown in Fig. 4 for different degrees of spring compression.

This first embodiment makes use of a compressible spring 40 integrated in the tissue anchor. The spring is located within a chamber 42 defined by the outer housing 43 of the anchor 20. This chamber is closed apart from an opening through which the tether line 10 is received. The spring extends parallel to the tether line, and can be considered to have a tether line end (i.e. facing the tether line - the lower part of the spring in Fig. 4) and an anchor end (i.e. facing the bone or tongue - the upper part of the spring in Fig. 4). The chamber is directly adjacent the gripping part 44 of the anchor and it therefore is situated comfortably under the tongue in use.

The tether line extends through a central channel within the coil spring so that the end of the tether line is connected to the end of the spring nearer the tissue anchor. As explained below and as seen in Fig. 4, this means that the extension of the tether line is

accompanied by compression rather than expansion of the spring. The rest position of the spring is thus an extended state, and a force is needed to the compress the spring. This compression is limited because the spring will reach a fully compressed state when adjacent coils are in contact with each other. The shape of the chamber 42 prevents the coil spring crumpling or overlapping, so that damage of the spring when a large force is applied can be avoided.

The extension of the spring is also limited by the size of the chamber 42, because the end of the spring to which the tether line is attached reaches a stop defined by the chamber, as shown in the top part of Fig. 4. In this maximum spring extension state (corresponding to a shortest tether line length) the spring is preloaded. In other words, the spring is not allowed to extend fully to its relaxed state, and is held in a state of partial compression.

This preload is intended to overcome the gravitational force from the tongue during sleep. If the load (force F applied to the tether line 24 as shown) is higher than the preload the wire elongates by compressing the spring 40 as shown in the lower image of Fig. 4.

When the spring is fully compressed as shown, the maximum amount of additional tether line length is obtained.

By the design of the spring and the chamber, the threshold preload force and the force when the spring is fully compressed can be defined. This design thus provides a limited stroke of the spring whilst loaded. Typical values are 3N preload, 6N fully compressed spring, 5mm stroke. These levels of force enable the spring to be compact with a small outer diameter. For example the outer diameter of the housing 43 around the chamber can be in the range of 2mm to 4mm.

Fig. 5 shows a second embodiment in which a different implementation of the invention is applied to the bone anchor, and it shows the spring in more detail.

This second embodiment makes use of a torsional spring 50 (also known as a leg-spring) connected to the spool in the bone anchor. The bone anchor again has an outer housing 52 and the torsional spring is located within a chamber 54.

The torsional spring is preloaded. It applies a torsional force to the spool of the bone anchor which is fixed to the tether line.

This preload again is designed to overcome the gravitational force of the tongue during sleep.

As in the example above, the end of the tether line is connected to one of the legs of the spring so that tether line extension causes torsional compression of the spring. The term "compression" should be understood accordingly, in that compression can apply to a coil spring, a torsional spring or indeed any other block of elastic material. In the case of a spring, a compression is a biasing of the spring into a more tightly wound or compressed state. In the case of a torsion spring, the tether line can be considered to be attached to the remote leg of the spring to ensure that tether line extension causes torsional spring compression. This again means that the extension of the tether line is limited when the torsional spring is fully wound. In the same way as above, the torsional spring applies a preload, and it reaches its limit of torsional winding when the spring is fully torsionally wound.

To perform titration, a titration tool is engaged into the bone anchor housing. Before turning the spool by the titration tool, the bone anchor is switched (by a locking feature in the titration tool) from a locked state to an unlocked state so that the spring is decoupled from the spool. In this unlocked state the spring is disabled by blocking the elasticity, and the spool can be turned by the titration tool, with the tether line spooled onto the spool. After titration, the tool switches back the bone anchor from the unlocked into the locked state so that the spring is enabled again. The torsional spring then allows for a limited angle of rotation of the spool when the threshold force is reached. One spring leg can be fixed in position and the other can be able to rotate over a limited angular range when a sufficient (linear) force is applied to the spool by the tether line.

As in first the example above, the torsional spring will alleviate the forces acting on the implant as well as on the tongue tissue. In this design, the spring can be integrated into the spooling and indexing arrangement with little or no additional space required.

In the first example above, an enclosed coil spring design is applied to the tissue anchor. The same enclosed coil spring design may equally be applied to the bone anchor, again with the housing of the bone anchor having a portion containing the coil spring where the tether line exits the bone anchor casing. ThE same design of compressible coil spring can thus be applied to the bone anchor and to the tissue anchor. The length of the housing (along the axis of the tether line) required to provide the required amount of tether line length adjustment can then be shared between the two anchors.

Alternatively, the tissue anchor design of the first example above, and the bone anchor design of the second example above can be combined, so that the two anchors again share the function of providing tether line elasticity.

The two examples above make use of compressible spring designs. However, other compressible elastic members can be used, such as a pneumatic spring using a compressed gas, a hydraulic spring using a compressed liquid, or a compressible elastomer.

The invention provides a limited stroke of the spring to prevent spring damage, and this improves clinical applicability as well as mechanical feasibility.

Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practicing the claimed invention, from a study of the drawings, the disclosure, and the appended claims. In the claims, the word "comprising" does not exclude other elements or steps, and the indefinite article "a" or "an" does not exclude a plurality. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measured cannot be used to advantage. Any reference signs in the claims should not be construed as limiting the scope.

CLAIMS:

1. An anchor for a tongue manipulation device (10) which device comprises a tissue anchor (20) for attachment to the tongue (16), a bone anchor (22) and a tether line (24) which fixes the tissue anchor to the bone anchor,

wherein the anchor comprises an outer housing (43) which defines a chamber (42), and a compressible elastic member (40) housed within the chamber (42), the elastic member having a tether line end and an anchor end which is movable within the chamber, wherein an end of the tether line is connectable to the anchor end of the elastic member,

wherein the elastic member (40) is adapted to apply a biasing force to the tether line (24) and to allow the distance between the tissue anchor and the bone anchor to be increased when a loading force exceeds the biasing force

wherein the anchor is arranged as the tissue anchor or the bone anchor.

2. An anchor as claimed in claim 1, wherein the elastic member comprises a compressible spring.

3. An anchor as claimed in claim 2, wherein the compressible spring comprises a coil spring and the tether line extends through the coil spring.

4. An anchor as claimed in claim 1, wherein the elastic member comprises a torsional spring.

5. An anchor as claimed in claim 1, wherein the biasing force is selected to be greater than the gravitational force applied to the tether line by the tongue.

6. An anchor as claimed in claim 5, wherein the elastic member (40) allows a maximum distance between the tissue anchor and the bone anchor when a threshold force is reached.

7. An anchor as claimed in claim 6, wherein the biasing force comprises a spring preload of between 1N and 10N, and the threshold force is between 2N and 20N.

8. An anchor as claimed in claim 1, wherein the spring (40) provides a maximum distance variation of between 3mm and 20mm.

9. An anchor as claimed in claim 3, comprising a tissue anchor.

10. A tongue manipulation system, comprising a tissue anchor as claimed in claim 9, and a bone anchor (22) for attachment to the mandible.

11. A system as claimed in claim 10 further comprising a tether line (24) which couples the tissue anchor to the bone anchor.

12. An anchor as claimed in claim 4, comprising a bone anchor.

13. An anchor as claimed in claim 12, wherein an end of the torsional spring is rotationally movable within the chamber and coupled to an end of the tether line, and wherein the anchor further comprises a spool part for spooling of the tether line and the torsional spring (50) biases the spool part.

14. A tongue manipulation system, comprising a bone anchor as claimed in claim 13, and a tissue anchor for attachment to the tongue.

15. A tongue manipulation system comprising at least one anchor as claimed in claim 1.

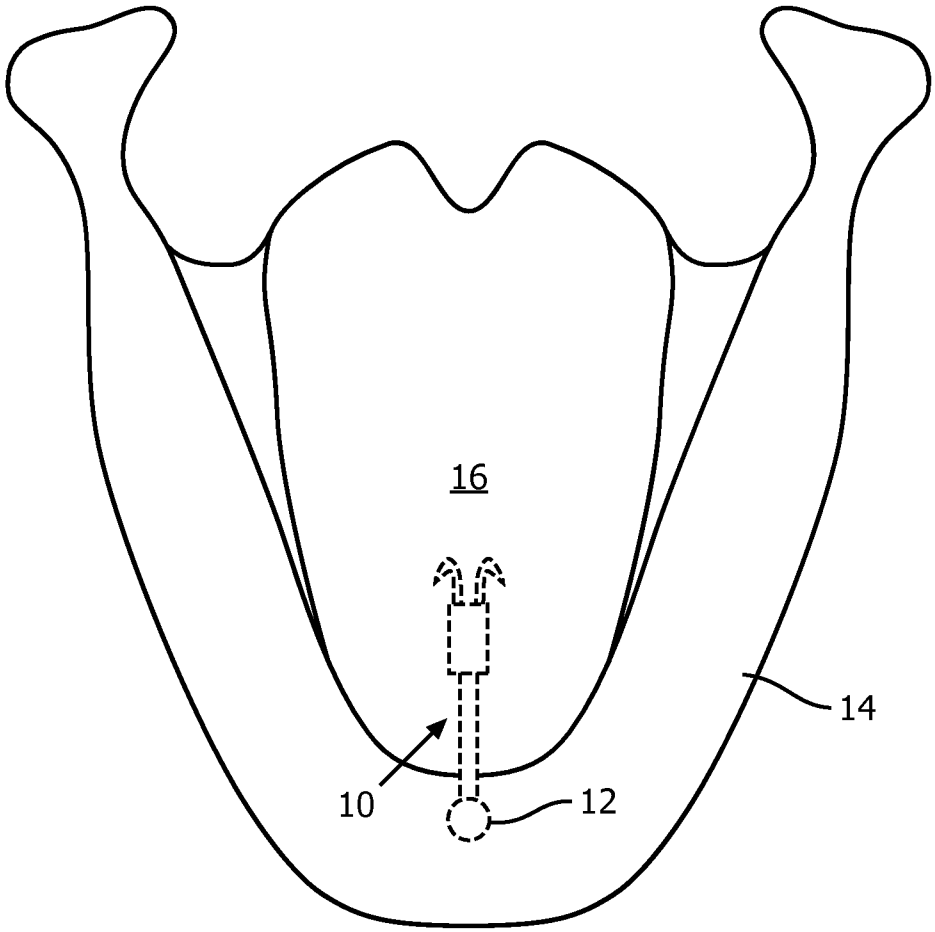


FIG. 1

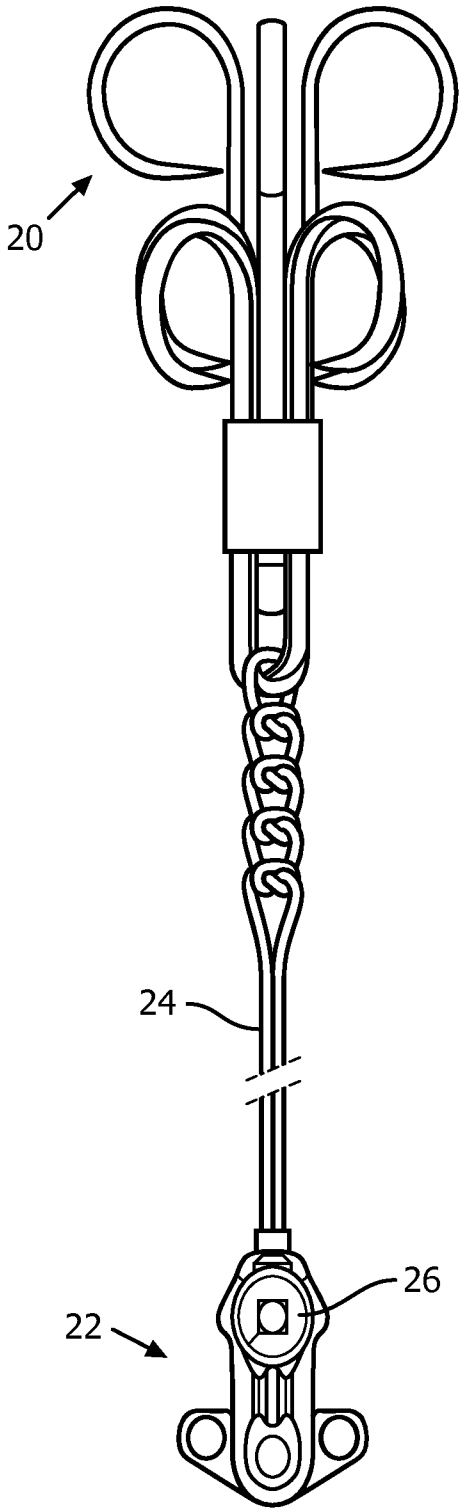


FIG. 2

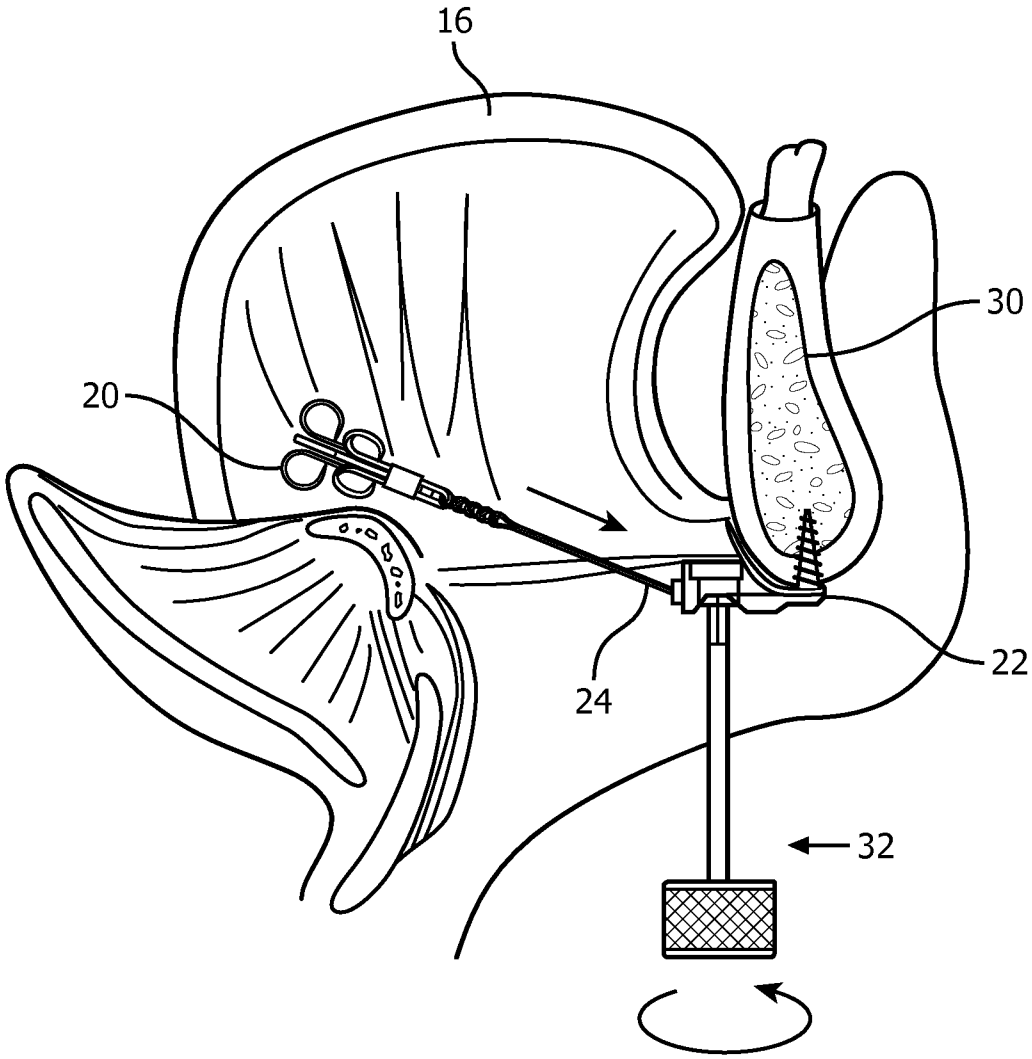


FIG. 3

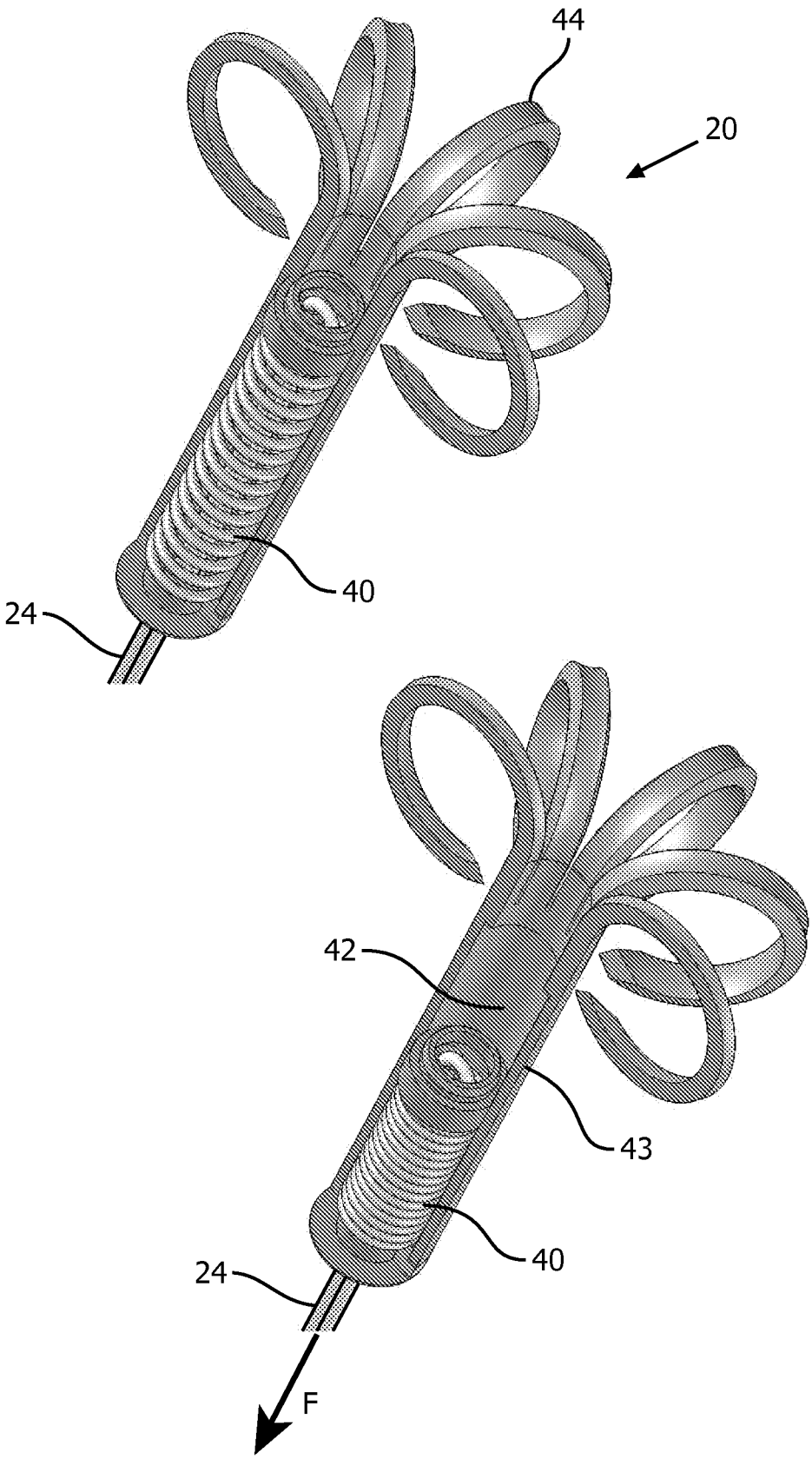
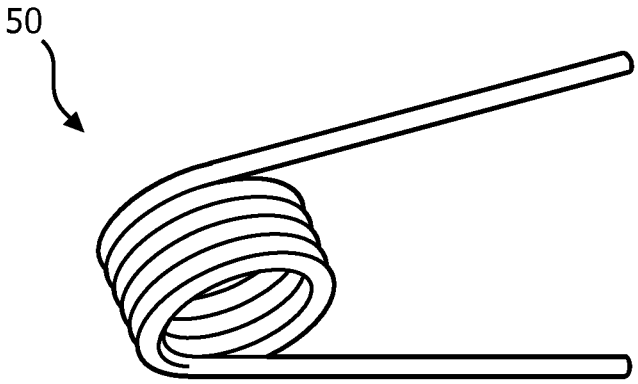


FIG. 4



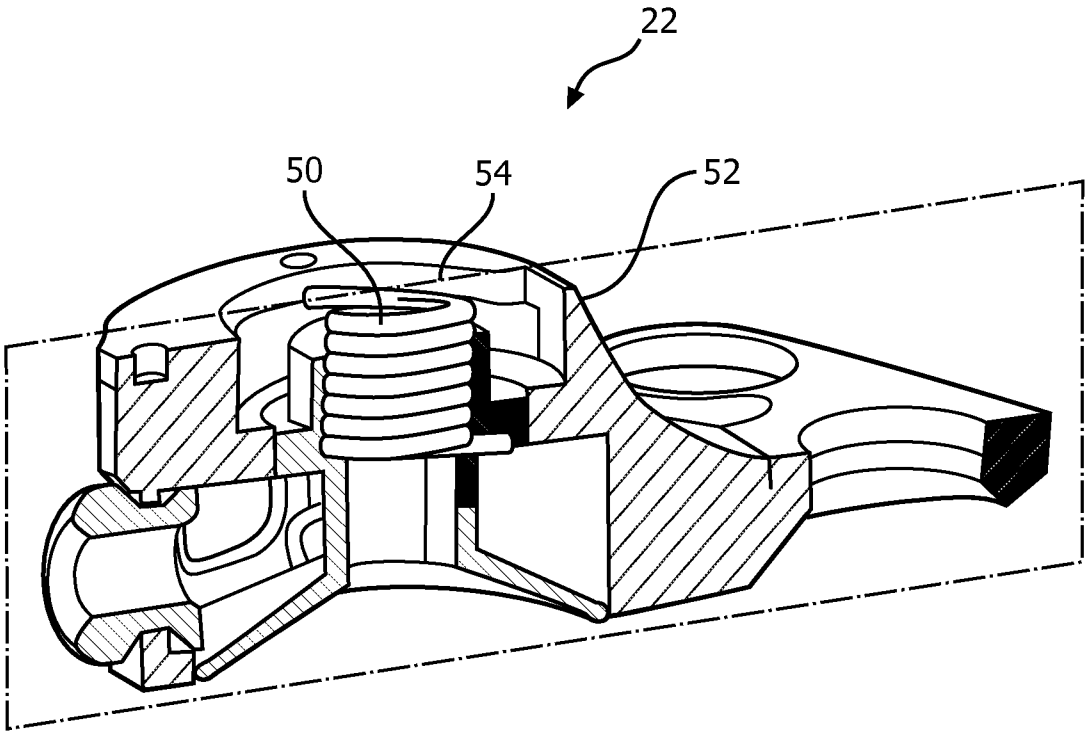


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/058422

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04 A61F5/56
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2011/151745 A1 (KONINKL PHILIPS ELECTRONICS NV [NL]; WITT ERIK KURT [US]; THOMAS CHARL) 8 December 2011 (2011-12-08) paragraph [0010] paragraph [0031] - paragraph [0045]; figures 4-8	1-15
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X	US 2012/130492 A1 (EGGLI STEFAN [CH] ET AL) 24 May 2012 (2012-05-24) paragraph [0042] - paragraph [0046]; figures 1-6	1-3

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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Date of the actual completion of the international search	Date of mailing of the international search report
27 January 2014	06/02/2014

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Roudaut, Tanguy

INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 2010/319710 A1 (PAVAD MEDICAL INC [US]; SHARKAWY ADAM [US]; SAHIN KORAY [US]; MCVICKER) 23 December 2010 (2010-12-23) paragraph [0109] - paragraph [0124]; figures 6A-7E	1-15
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A	EP 2 353 555 A1 (SOMNICS INC [US]) 10 August 2011 (2011-08-10) paragraph [0020] - paragraph [0027]; figures 1A-3	1-15

INTERNATIONAL SEARCH REPORT

Information on patent family members

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