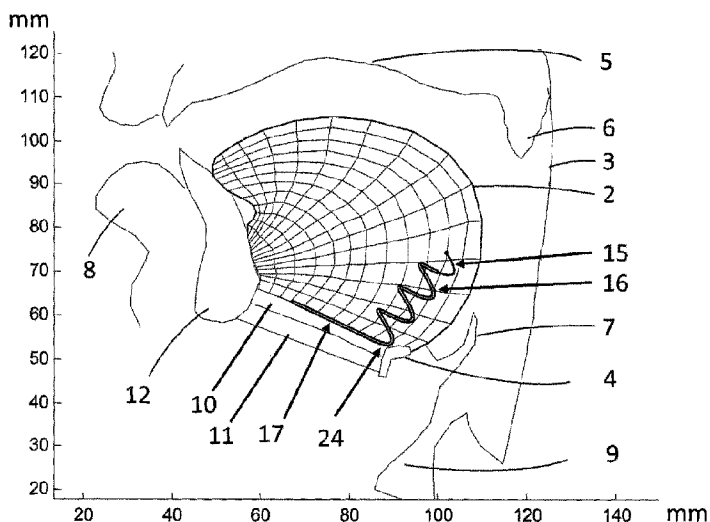




(86) Date de dépôt PCT/PCT Filing Date: 2014/03/17
 (87) Date publication PCT/PCT Publication Date: 2014/09/18
 (45) Date de délivrance/Issue Date: 2021/06/29
 (85) Entrée phase nationale/National Entry: 2015/08/25
 (86) N° demande PCT/PCT Application No.: IB 2014/000364
 (87) N° publication PCT/PCT Publication No.: 2014/140777
 (30) Priorités/Priorities: 2013/03/15 (US61/787,006);
 2013/12/11 (US61/914,444)

(51) Cl.Int./Int.Cl. *A61F 5/56* (2006.01)
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(54) Titre : **IMPLANT DE DEFORMATION DE LANGUE**
 (54) Title: **TONGUE DEFORMATION IMPLANT**



(57) **Abrégé/Abstract:**

There is provided a method and apparatus for a tongue implant to induce deformation of the tongue made of Nitinol in superelastic state at body temperature for the treatment of obstructive sleep apnea. In one embodiment the implant has a function of a V shaped spring, one leg helically inserted into the tongue, the other leg beneath the root of the tongue, to permanently compress the tongue. In another embodiment, there is provided a method and apparatus for placement of a helical implant to permanently compress the tongue by deforming it and stiffening it to maintain tongue stability for the treatment of obstructive sleep apnea.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau(10) International Publication Number
WO 2014/140777 A1(43) International Publication Date
18 September 2014 (18.09.2014)(51) International Patent Classification:
A61F 5/56 (2006.01)(21) International Application Number:
PCT/IB2014/000364(22) International Filing Date:
17 March 2014 (17.03.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/787,006 15 March 2013 (15.03.2013) US
61/914,444 11 December 2013 (11.12.2013) US

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ausgasse 1, CH-9320 Arbon (CH).(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR,
KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM,
ZW.(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

Published:

— with international search report (Art. 21(3))

(54) Title: TONGUE DEFORMATION IMPLANT

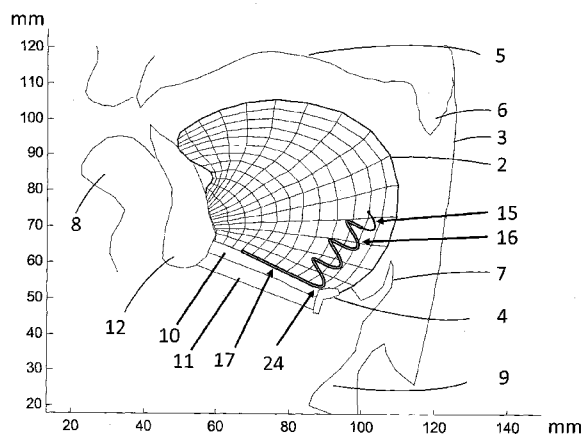


FIG. 1

(57) Abstract: There is provided a method and apparatus for a tongue implant to induce deformation of the tongue made of Nitinol in superelastic state at body temperature for the treatment of obstructive sleep apnea. In one embodiment the implant has a function of a V shaped spring, one leg helically inserted into the tongue, the other leg beneath the root of the tongue, to permanently compress the tongue. In another embodiment, there is provided a method and apparatus for placement of a helical implant to permanently compress the tongue by deforming it and stiffening it to maintain tongue stability for the treatment of obstructive sleep apnea.



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TONGUE DEFORMATION IMPLANT

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10 entitled to antedate such material by virtue of prior invention.

Field of the invention

 The present invention relates generally to the treatment of obstructive sleep apnea and snoring.
15

Background of the Invention

 Obstructive sleep apnea (OSA) is defined as recurrent cessation of breathing with upper airway
obstruction occurring during sleep, resulting in substantially reduced (hypopnea) or complete cessation
20 (apnea) of airflow despite ongoing breathing efforts. By convention, the patient must experience more
than 30 episodes lasting more than 10 seconds or more than five abnormal breathing disturbances
(hypopneas or apneas) per hour of sleep. In most cases the person is unaware

that a disturbance is taking place. Referring now to **FIG. 1**, the human upper airway anatomy consists of the mandible bone **12**, tongue **2**, pharynx **3**, hyoid bone **4**, palate **5**, uvula **6**, epiglottis **7**, lips **8**, larynx **9**, geniohyoid **10**, mylohyoid **11**, and adjacent facial structures. This anatomy plays a central role in speaking, breathing, mastication and swallowing. The airway is composed of numerous muscles and soft tissue but lacks rigid or bony support. Most notably, it contains a collapsible portion that extends from the hard palate **5** to the larynx **9**. Although the ability of the upper airway to change shape and momentarily close is essential for speech and swallowing during an awake state, this feature also provides the opportunity for collapse at inopportune times such as during sleep. Although non-obese individuals may suffer from OSA, obesity is the main epidemiologic risk factor. It can influence both the structure and function of skeletal muscles. The interplay and correlated movements between all the anatomical structures is complex. These various physiological traits and the potential for each to influence sleep apnea pathophysiology have been described in detail in review articles. The pathophysiological causes of OSA likely vary considerably between individuals. Important components likely include upper airway anatomy, the ability of the upper airway dilator muscles to respond to respiratory challenge during sleep, the propensity to wake from increased respiratory drive during sleep (arousal threshold), the stability of the respiratory control system (loop gain), and the potential for state-related changes in lung volume to influence these factors. Ultimately, the maintenance of pharyngeal patency depends on the equilibrium between occluding and dilating forces. Upper airway dilator muscle activity is crucial to the counteraction of the negative intraluminal pressure generated in the pharynx during inspiration. Diminution of this activity during sleep is thought to play a central role in pharyngeal collapse and obstruction in patients with OSA.

The development of occlusion in this disorder has been related to “prolapsing” of the tongue into the pharynx. The tongue being prolapsed has been attributed to diminished neuromuscular activity in the genioglossus muscle inside the tongue which protrudes it forward, when it is activated. Activation of the genioglossus (GG), the main tongue protruder, has been shown to reduce pharyngeal resistance and collapsibility by far more than all other upper airway dilators.

There are a variety of treatments for OSA, but continuous positive airway pressure (CPAP), in which a nose mask is attached via a tube to a machine to blow pressurized air into the pharynx and push the collapsed section open, is still the gold standard in treatment. Surgical procedures

aiming for tissue reduction or stiffening to widen the pharynx have proven to be unreliable or to have adverse effects. However, as most patients dislike or refuse to use a mask for CPAP treatment, new procedures involving implants are needed. Multiple trials attempting to relieve OSA by functional electric stimulation of upper airway dilators during sleep resulted in modest and/or inconsistent results.

5 Numerous attempts have been made towards treating OSA by placing implants into the tongue and are known in prior art, for example, the Pavad Medical tongue stabilization device U.S. Pat. No. 7,909,037 and U.S. Pat. No. 7,909,038, both dated March 22, 2011. Another implant for treating OSA is the Restore Medical implant disclosed in U.S. Pat. No. 7,401,611 dated July 22, 2008, or the Revent Medical implant disclosed in U.S. Pat. No. 8,167,787 dated May 1, 2012 and U.S. Pat. No. 8,327,854 dated December

10 11, 2012. Another implant for treating OSA is disclosed in U.S. Pat. No. 8,220,466. This '466 patent describes a spring attached to the mandible bone, which pulls the tongue anteriorly. All of the mentioned patents involve surgical procedures, which may not be suitable for some patients and/or which are extremely time consuming for inserting or are not minimal invasive or show unsatisfying success rates.

15 What is needed therefore is a surgically fast and minimally invasive tongue implant to treat OSA, which can deform like the tongue to comply with physiological tasks, but changing its rigidity to reliably and safely open up the pharyngeal airway blocked by the tongue. The implant should stiffen the tongue along the base into the body of the tongue and protrude it. Furthermore, it must minimize relative movement between implanted member and surface area in contact with the tongue to avoid abrasion of

20 the implant.

Summary of the Invention

A method and apparatus for the treatment of OSA are disclosed which protrudes the tongue and

25 hence enlarges the pharyngeal cross-sectional area by implanting a Nitinol device in superelastic state at body temperature having the function of a V shaped spring, one leg inserted helically directly from the root of the tongue near the hyoid bone, along and near the base of the tongue into the body of the tongue, the apex leaving the root of the tongue providing a torque moment, the other leg acting as a force distributor placed between the root of the tongue and the

geniohyoid, or between geniohyoid and mylohyoid. Another embodiment shows placement of a helical Nitinol device in superelastic state at body temperature along and near the base of the tongue to permanently compress the tongue, hence protruding the tongue to enlarge the pharyngeal cross-sectional to prevent obstructions of the airway.

5

Brief Description of the Drawings

- FIG. 1 is a midsagittal plane view of the pharynx with an implant helically inserted inside the tongue and the force distribution section between root of the tongue and geniohyoid muscle.
- FIG. 2 is a midsagittal plane view of the pharynx of the Perrier (2003) tongue model showing a preferred site for tongue implantation and associated deformations of that section induced by the three main muscles and rest position.
- FIG. 3 is a midsagittal plane view of the pharynx of the Perrier (2003) tongue model showing a helical pathway and associated deformations of that section induced by the three main muscles and the rest position.
- FIG. 4A is a top view on the tongue showing a helical implant inside the tongue in undeformed state when inserting it.
- FIG. 4B is a top view on the tongue showing the deformation of a helical implant inside the tongue with associated change in length of the tongue.
- FIG. 5 is a front view of a tongue implant showing all sections.
- FIG. 6A shows a bottom view of the implant with the mandibulohyoid section for force distribution shaped in serpentine way without the flexible distal end section.
- FIG. 6B shows a side view of the implant with the mandibulohyoid section for force distribution shaped in serpentine way without the flexible distal end section.
- FIG. 6C shows a perspective view of the implant with the mandibulohyoid section for force distribution shaped in serpentine way without the flexible distal end section.

25

- FIG. 7 is a coronal plane cross section of the mandible showing placement of the mandibulohyoid section including a fin.
- FIG. 8 is a helical section with an exaggerated schematic view of an implant showing a profile distribution of a helical section.
- 5 FIG. 9 shows a cross section of the helical section of a Nitinol tube.
- FIG.10A shows a cross section of the helical section a Nitinol wire embedded in silicone rubber and having a fluoropolymer coating.
- FIG. 10B shows a cross section of the helical section a Nitinol wire embedded in silicone rubber having a fluoropolymer coating and an outer hull of a UHMWPE fabric.
- 10 FIG. 11A-C shows different views of the flexible distal end section.
- FIG. 12A&B shows the distal end section reacting to a small dislocation of the distal end of the helical section inside the tissue.
- FIG. 13 shows a longitudinal cross section of a different flexible distal end.
- FIG. 14 is another embodiment for a force distributing mandibulohyoid section without the
15 flexible distal end section.

Detailed Description of the Preferred Embodiment

The following descriptions are of exemplary embodiments of the invention and the
20 inventors' conception of the best mode and are not intended to limit the scope, applicability or configuration of the invention in any way. Rather, the following description is intended to provide convenient illustrations for implementing various embodiments of the invention. As will become apparent, changes may be made in the function and/or arrangement of any of the elements described in the disclosed exemplary embodiments without departing from the spirit and scope of the
25 invention.

The tongue is a unique and complex motor organ in the human body, but highly constrained inside the mouth. Its base is attached to the mandible and to the hyoid bone, while its upper and lateral surfaces are often in contact with the palate and the teeth. It is composed almost entirely of muscle and containing no skeleton. There are two different types of tongue muscles: intrinsic fibers, which originate and terminate within the tongue, and extrinsic fibers, those which arise externally from rigid bony surfaces. A detailed anatomical study has been described in Takemoto (2001). Activities of these muscles result in subtle movements of muscular structure and produce large deformations of the tongue's soft tissues. This is crucial for multiple physiological tasks, such as speech, mastication and swallowing. In speech, the tongue assumes stereotyped configurations which determine overall vocal tract shape, whereas in mastication and swallowing, the tongue acts to contain and propel a bolus of food. In each instance, regional activation of specific lingual muscles results in prototypical tissue deformation.

Tissue incompressibility is commonly assumed as the tissue is highly aqueous, giving the tongue its capability to behave as a muscular hydrostat, which is an organ, whose musculature creates motion and supplies skeletal support for that motion as well (like the elephant trunk or squid tentacle). This incompressibility enables quick and efficient alteration of its form while maintaining original volume. Because of the complexity of lingual anatomy and its material attributes, the relationship between tongue structure and mechanical function is difficult to understand. Owing to incompressibility and complex fiber structure, lingual mechanics cannot be readily studied from changes of overall tissue shape. It requires an analysis of the complex organization of the human tongue musculature and internal muscle dynamics to understand the occurring deformations of the tongue, which is a necessary and critical requirement in order to fully understand the scope of this invention for a permanently implanted tongue actuator or a passive tongue compressing implant to treat OSA. Biomechanical models of the tongue and vocal tract have been in use since the 1960's to study articulation. Their complexity has increased with the acquisition of new knowledge about anatomical, neurophysiological and physical characteristics of the tongue, as well as with the vast growth in the computational capacities. All these models have significantly contributed to the increase in knowledge about tongue behavior and tongue control during speech production, and more specifically about the relations between muscle recruitments and tongue shape or acoustic signal (see in particular for 2D models Perkell, 1996, using his model presented in Perkell (1974);

Kiritani *et al.*, 1976, Dang and Honda, 2004; Hashimoto and Suga, 1986;; Payan and Perrier, 1997; Sanguineti *et al.*, 1998; For 3D models, see Buchaillard, S., Perrier, P., Payan, Y., 2009; Wilhelms-Tricarico, 1995; Kakita *et al.*, 1985)

5 The tongue implant should not limit movements in absolute terms like hyoid or tongue suspension for the treatment of OSA do, nor should it negatively influence speaking, mastication or swallowing. Out of these three tasks, not to influence speaking is the most difficult to cope with when placing an artificial member directly into the tongue. The production of speech involves complex muscles patterns. Some of these patterns are very fast, e.g. from a vowel to [k] about 30ms, but doesn't involve strong muscle activation. Levels of forces generated by real speakers
10 produced by the main muscles are in between 0.5 and 1.5 N. It must be noted, that these values measured are the force resultant. Inside the tongue accumulated forces are higher due to hydrostatic function of the tongue (Buchaillard and Perrier 2009). Since the production of speech is the fastest task with the lowest force production resultant, any device put directly into the tongue may create too much rigidity making it harder for the tongue to deform.

15 Other muscles activities, mainly mastication and swallowing, are deformations with stronger muscle activation. If the device makes swallowing or mastication movements harder in terms of necessary deformation forces, the increase would not be noted as easily or felt discomforting, because of stronger and slower muscle activation than in the production of speech. Regarding force levels, force distribution and deformations, these findings are essential to develop
20 an implant to be placed directly inside the muscles of the tongue. The device must neither restrict movements of the tongue nor make speaking noticeably harder.

To simplify the complexity of the deformation analysis as well as to enhance the visual understanding, the 2D tongue deformation model of Perrier et al. (2003) has been chosen representing tongue characteristics that are relevant for speech and not the latest 3D models.
25 Limiting the tongue model to the midsagittal plane is an acceptable simplification. In 2002 Badin et al. stated that «most 3D geometry of tongue, lips and face can be – at least for speech – predicted from their midsagittal contours.» It was verified in 2006 as Badin and Serrurier teach that “The error made in the prediction of the 3D tongue shapes from their midsagittal contours can finally be quantified by the difference between the overall full 3D RMS errors for the model (0.22 cm) and
30 for the inversion based on the midsagittal error (0.25 cm): the mere 0.03 cm (13.6 %) increase of

this error testifies to the very good predictability of the 3D tongue surface mesh from its 2D midsagittal contour.”

Accounting for tissue incompressibility would require measuring tissue deformations in 3D space, which obviously can't be done in a planar model. For that reason, tongue deformations in the direction orthogonal to the midsagittal plane were assumed to be negligible in comparison to the geometrical changes in this plane (*plane strain hypothesis*). Tissue quasi-incompressibility of the tongue is equivalent to area conservation and can be modeled with a Poisson's ratio value close to 0.5. This hypothesis is well supported by 3D measurements of tongue deformation during speech production, such as the ultrasound data published by Stone *et al.* (1997) or the MRI data analyzed by Badin *et al.* (2002). It can therefore be assumed, that for better understanding of midsagittal deformations during speech production, the model is fairly accurate and can serve as a basic model to address the underlying problem and solution. It is important to analyze extreme deformation patterns occurring inside the tongue in order to understand how and why it is crucial to insert a member helically from the root of the tongue, along and near the base of the tongue into the body of the tongue.

The intrinsic muscles as well as some extrinsic muscles contribute to a lesser extent to the sagittal tongue shape than the three major extrinsic muscles: the *genioglossus*, the *styloglossus*, and the *hyoglossus*, which are responsible for the main displacement and shaping of the overall tongue structure (Perkell, 1996). This has been reconfirmed in Perrier *et al.* 2003 and Buchaillard/Perrier 2009. The deformations produced by the three main muscles are by far the most extreme prototypical deformations patterns. Since deformations produced in speech are always activations of several muscles, the deformations never reach the extreme of these muscles activated solely. But if a helical pathway can fit into these extremes, deformation patterns of *styloglossus*, *hyoglossus*, posterior *genioglossus* and the tongue in rest position can be analyzed and with that the deformations between these extremes should be covered as well.

The problem with inserting a flexible, but in its longitudinal direction unelongatable member into the tongue in a straight or curved way is that the length of the pathway changes with the deformations of the tongue and that change could lead to a displacement and/or will definitely cause abrasion of the member due to relative movement between member and muscle fibers. To keep the member in place, a pathway which doesn't change its length needs to be found, which

will also minimize relative movement. A well-adapted helical pathway, submentally pierced near the root of the tongue, along and near the base of the tongue into the body of the tongue can fulfill that criterion. The pierced helical pathway must have nearly equal length in all the extreme deformations of the tongue.

5

Now referring to **FIG. 2** tongue deformations induced by each modeled main extrinsic muscle are plotted with the tongue model of Perrier (2003). Direction and amplitude of the simulated deformations were verified to be compatible with data measured (Badin *et al.*, 1995) The tongue shapes **2** shown in the figure are similar to those seen in a number of cineradiographic studies of speech movements (e.g., Perkell, 1969, Bothorel *et al.*, 1986, Napadov, 1999 and 2002). The darkened section changes in length **13**, width **14** and curvature as muscle are being activated. By piercing an helical pathway into that section and putting an implant inside, said implant can also change length and width, because it can substitute an increase in pitch with a decrease in diameter and vice versa. If the right pathway orientation and helical specifications are adequately defined, it could therefore deform and
15 behave like the tongue with minimal relative movement between implant and tongue.

To achieve this, submental helical piercing is performed with the tongue in deformed state, like the deformation produced by styloglossus activation. As explained in International Patent Application PCT/IB2011/002878 entitled Helical Inserter, a Miller laryngoscope is put into the oral cavity down the pharynx to level of the epiglottis and the tongue is slightly pulled anteriorly (not shown in drawings),
20 such that the base of the tongue is straightened before piercing the tongue helically. Such a pathway for the helical section **16** is shown in **FIG. 3** for the deformation induced by the three main extrinsic muscles and the rest position. For simplicity of measuring length, a zigzag line is chosen to represent the helix, as it is a reasonable approximation in 2D.

25

Now referring to **FIGs. 4 A&B**, the helical section inside the body of the tongue **2** has four different portions: two widening portions **20** anteriorly and posteriorly and two compressing portions **21** creating an oval shape of the helix in top view, which deforms the tongue in a protruding way, as indicated with $-\Delta L$ in **FIG. 4B**. It must be explicitly noted that the helical section is not acting like a spring, which always pulls in direction of the axis when being expanded, as for example that disclosed in U.S. Pat. No. 8,220,466. The helical section in this implant compresses the tissue towards the axis of the helix in midsagittal plane and it is inserted through helical piercing with the axis in close to parallel orientation to the spine in midsagittal plane view.

30

Now referring to **FIG 5**, which describes the basic V spring setup, one embodiment comprises four sections: the flexible distal end section **15**, the helical section **16** inside the body of the tongue **2**, the torque providing section **24** at entry of the root of tongue, and the mandibulohyoid section **17** for force distribution. The flexible distal end section **15** provides means for stabilization of the member distally inside the body of the tongue allowing small displacement of the helical section **16** to avoid poking of the tissue as the tongue is performing its physiological tasks, which might be noted as tingling sensation. The helical section **16** providing means to exert a force on the tongue towards the axis of the helix, essentially stiffening and compressing it along the base of the tongue and protruding the tongue. The mandibulohyoid section **17** providing means for force distribution of the torque produced **24**. Now referring to **FIG. 6**, there is provided a force distribution section placed between geniohyoid **10** and root of tongue having a shape of a serpentine line **22** to better distribute the force produced by the torque section **24** and compress the body of the tongue stiffening and protruding it. Now referring to **FIG. 7**, to prevent dislocation laterally of the mandibulohyoid section, a fin **25** can be shaped for placement without attachment between the two geniohyoid muscles **10**. Now referring to **FIG. 14**, explaining another embodiment of the mandibulohyoid section **17'**, instead of creating a shape like a serpentine line for force distribution of the torque producing section **24**, a force distributing part **26** could be placed between geniohyoid **10** and body of tongue or between mylohyoid **11** and geniohyoid **10**, preferably made of a polymer. This part would be slipped into the target site and then attached to the member as indicated by the arrow, for example by an aperture **28** with a corresponding distal end **29** of the member. Again, to prevent dislocation laterally, a fin **27** is added to be placed between the two geniohyoid muscles **10**.

In another embodiment, only the helical section and the flexible distal end section are used, thus only compressing the tongue along the base of the tongue, the implant not acting like a V shaped spring.

Superelastic Nickel-Titanium (Nitinol or NiTi) has become the material of choice for self-expanding, stents, stent grafts, filter, baskets and other devices for interventional procedures. With the demand for high precision NiTi material in different forms, especially wire and tubes, immense progress has been made in the manufacturing processes, making it possible to get material in a wide range of geometries and sizes.

What makes Nitinol unique is its ability to exist in two different temperature-dependent crystal structures (phases) called martensite (lower temperature) and austenite (higher temperature); superelastic Nitinol is fully in austenite state.

While most metals can be deformed by slip or dislocation, NiTi responds to stress by simply changing the orientation of its crystal structure through the movement of twin boundaries. A NiTi specimen will deform until it consists only of the correspondence variant, which produces maximum strain. However, deformation beyond this will result in classical plastic deformation by slip, which is irrecoverable and therefore has no 'memory effect'. If the deformation is halted midway, the specimen will contain several different correspondence variants. If such a specimen is heated above A_f , a parent phase with an orientation identical to that existing prior to the deformation is created from the correspondence variants in accordance with the lattice correspondences between the original parent phase and each variant.

The austenite crystal structure is a simple cubic structure, while martensite has a more complex rhombic structure. This phenomenon causes the specimen to revert completely to the shape had before the deformation. The above phenomenon is the basis of such special properties as the shape memory effect and superelasticity. The properties of Nitinol rely on this dynamic crystalline structure. The molecular structure is sensitive to external stress and temperature. The alloy has three defined temperature phases.

1. Austenite Phase (superelastic state). Temperature is above transition temperature. The transition temperature varies depending upon the exact composition of the Nitinol alloy; today it can be fine-tuned to a specific temperature. The yield strength with which the material tries to return to its original shape is considerable; 35,000 to 70,000 psi. The Crystalline structure is cubic.

2. Martensitic Phase. Low temperature phase. The crystal structure is needle-like and collected in small domains. Within the small domains the needle-like crystals are aligned. The alloy may be bent or formed easily and will remain in that shape. Deformation pressure is 10,000 to 20,000 psi. Bending transforms the crystalline structure of the alloy producing an internal stress.

5 **3. Annealing Phase.** High temperature phase. The alloy will reorient its (cubic) crystalline structure to "remember" its present shape. The annealing phase for the Nitinol wire is about 540°C. A CNC torsion spring coiler machine like the FMU series of German producer Wafios could be used to produce a tube, for example a stainless steel tube, having the desired shape which the Nitinol should have. The Nitinol tube or wire will be pulled into the formed tube for annealing.

10 Due to the high cyclic deformation load the implant is subjected to as the tongue performs its physiological task, the strain should be kept low, at best below 0.5% to avoid early fatigue of the Nitinol to enhance longevity. This can be influenced by choosing the helical pathway pierced through the tongue well. The pierced pathway should have a diameter between 4mm to 30mm with a pitch between 3mm to 20mm. The orientation of piercing in midsagittal plane should be almost
15 parallel to the spine. The common mechanical properties of austenitic NiTi are presented in Table 1.

Table 1.

Selected mechanical properties of NiTi	Austenite
Ultimate tensile strength (MPa)	800–1500
Tensile yield strength(MPa)	100–800
Modulus of elasticity (GPa)	70–110
Elongation at failure (%)	1–20

20

It is feasible to vary the critical transition temperatures either by small variations of the Ti/Ni composition or by substituting metallic cobalt for nickel.

Referring to **FIG. 8**, a tube having a constant diameter could be used, but this might create too much rigidity towards the distal end inside the tongue body. Another basic shape would be cone like because the most force for deformation of the tongue is need at the root of the tongue and less force is required towards the flexible distal end of the member inside the tongue body.

5 However, since it isn't necessary to have the same amount of force exerted along the whole length of the member, the Nitinol tube or wire can be grinded, laser cut or structured laser ablated to a profile such that with every half turn it is thinner (the widening portion **20**) than the compressing portion **21** in between. The smaller profile **20** is used so that the tongue can deform at these sections, the member only requiring minimal deformation forces when the tongue is performing its

10 physiological tasks during daytime. The thicker sections are needed to deform the tongue at night when OSA occurs with muscles inactive. Since the force that the member can exert on the tongue is directly dependent on its square area, this is the section which is deforming and changing the stiffness of the tongue. The compression portion of the helix facing posteriorly (towards the pharynx) must be stronger than the ones facing anteriorly (towards the front teeth). This creates

15 segments between each pitch and deforms the tongue in a protruding way. Pressure exerted should be between 2kPa and 25kPa. The diameter of the Nitinol wire should be between 50 μ m to 700 μ m or for a tube, the ID about 600 μ m and OD about 1.2mm.

Now referring to **FIG. 9** and **10A&B**, showing three cross sections of the helical section **16**, the problem with putting a force exerting Nitinol implant into soft tissue like muscles of the

20 tongue is that the modulus of elasticity of Nitinol in superelastic state is very high (70-110GPa) and the modulus of elasticity of muscles is low (a few kPa) creating a great mismatch between these two materials. The Nitinol might therefore "cut" through soft tissue as observed in with the Repose System to treat apnea. To avoid this behavior, the modulus of elasticity of the Nitinol implant device may be lowered by increasing the surface area where the force is exerted and

25 combining it with a material having a low modulus of elasticity.

To increase the surface area, wings **30** are added to the device oriented perpendicular to the force exerted, which means the wings are in parallel orientation to the axis of the helix. Further the Nitinol is combined with silicone rubber or the like having a low modulus of elasticity.

Now referring to **FIG. 9**, a Nitinol tube **33** with a silicone rubber core **31** and an outer hull

30 a fluoropolymer **32** having wings **30** is produced by following the steps of:

1. Producing a stainless steel tube having the desired shape the Nitinol should have with an ID slightly larger than the OD of the Nitinol tube;
2. Pulling the Nitinol tube inside the stainless steel tube;
3. Annealing;
- 5 4. Pulling Nitinol out of stainless steel tube;
5. Closing one end of the Nitinol tube by putting a short Nitinol wire (0.5mm length) into the distal end of the tube and laser weld both parts together;
6. Cooling the Nitinol tube down to its martensite phase;
7. Pulling the Nitinol tube inside a straight stainless steel tube having a slightly larger ID than
10 the OD of the Nitinol tube;
8. Increasing the ID of the Nitinol tube by pressurizing it with air or water inside the stainless steel tube (the increased diameter will remain as long as the Nitinol tube is in martensite);
9. Cutting of the closed distal end of the Nitinol tube;
10. Pulling a prefabricated silicone wire having an OD corresponding to the original ID of the
15 Nitinol tube inside;
11. Heating the Nitinol tube up to change the phase to austenite which will cause the Nitinol to shrink to its original size creating form fit between the two materials;
12. Cooling the Nitinol down to martensite and straighten it without twisting;
13. Placing the Nitinol tube to the infeed of a ram extrusion machine to create the
20 fluoropolymer outer hull having wings, push or draw through a die of the desired cross-section;
14. Thermal curing the fluoropolymer; and
15. Cutting of residual material on both ends;

25 In case of using silicone instead of silicone rubber for the core **31**, the silicone is filled inside the Nitinol tube **33**, and the end of the tube is closed with a short Nitinol wire (0,5mm) having an OD corresponding the ID, then laser weld the two parts together.

Now referring to **FIG. 10A&B**, a Nitinol wire **35** is embedded in silicone rubber **36** of the desired cross section and later coated with a melt processable fluoropolymer **34** by following the steps of:

1. Producing a stainless steel tube having the desired shape the Nitinol should have with an ID slightly larger than the OD of the Nitinol wire;
2. Pulling the Nitinol wire inside the stainless steel tube;
3. Annealing;
- 5 4. Pulling Nitinol out of stainless steel tube;
5. Cooling the Nitinol down to martensite and straighten it without twisting;
6. Placing the Nitinol wire to the infeed of a ram extrusion machine to create the silicone rubber outer hull, push or draw through a die of the desired cross-section;
7. Vulcanizing;
- 10 8. Cutting of residual material on both ends;

The above-stated materials of making the Nitinol tube **33** and Nitinol wire **35** are part of the invention and are intended to be claimed as such in a later filed divisional application.

15 Now referring to **FIG. 10B**, to further protect the fluoropolymer coating **34** from wear inside the tongue due to small relative movements, a woven or braided fabric **37** surface can be created with a ultra-high-molecular-weight polyethylene (UHMWPE) fiber, for example like Dyneema of Royal DSM N.V., having the advantage of very high wear resistance. Since the UHMWPE can't be joined with the fluoropolymer, only the tension created of the woven fabric
20 holds it in place. Therefore, wings cannot be formed because it would create a void, but instead, an equilateral triangle can be formed on both sides of the wire.

For both production techniques described, the Nitinol tube or wire must be aligned before placing it to the infeed of the ram extrusion, so that the wings or increased surface area is in the desired orientation before pushing it through the die of the ram extrusion. This could be achieved
25 by laser marking the Nitinol tube or wire. For example, the stainless steel tube needed for shape setting of the Nitinol could have several small drill holes at predetermined places so that the laser marking can be done after annealing, before the Nitinol is pulled out the stainless steel tube. These markings are later used to keep the orientation when placing the Nitinol into the infeed of the ram extrusion.

Now referring to **FIGS. 11-13**, the flexible distal end section **15** must be designed that the member can neither be displaced nor can it poke tongue tissue. But it must leave the option of extraction of the implant without cutting the whole tongue open, but rather just by pulling it out of the body of the tongue. A polymeric fiber **51**, for example a polyamide, substantially smaller in diameter, for example
5 30 μ m, is attached at the flexible distal end **44** of the helical section **16**. At the distal end **52** of the distal end section **15**, a sphere could be attached to the fiber **51** having the same diameter as the helical section **16**, but it could have other shapes. The pressure inside the tongue tissue **56** will hold in place. Another option shown in **FIG. 13** would be to shape the distal end **44** of the helical section **16** like a cone and to shape the distal end of **15** like a cone **54** as well, but facing reverse direction. This allows for small
10 displacement, but the cone shape will make it slide back to an initial position. This could be further enhanced by shaping the distal end of the distal end section **53** in concave form. The distal end section and the helical section can be joined together for example by means of laser welding **55** or pressfitting it to the Nitinol.

15 In an advantage, a tongue implant for the treatment of OSA is provided which is easy to install in a minimally invasive manner.

In another advantage, a tongue implant is provided which can deform the tongue to comply with physiological tasks, but changes its rigidity to reliably and safely open up the pharyngeal airway blocked
20 by the tongue.

In another advantage, the implant stiffens the tongue along its base into the body of the tongue and protrudes it.

25 In another advantage, the implant once installed, minimizes relative movement between itself and the surface area of the tongue in contact with it, to minimize abrasion.

In an advantage, the implant and method of the invention allow for the use of a Nitinol material while having a lower overall modulus of elasticity, to protect the tongue.

Other characteristics and modes of execution of the invention are described in the appended claims.

Further, the invention should be considered as comprising all possible combinations of every feature described in the instant specification, appended claims, and/or drawing figures which
5 may be considered new, inventive and industrially applicable.

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10 distribute copies, display, or otherwise use this patent specification, inclusive of the appendix hereto and any computer program comprised therein, except as an appendix to a patent issuing hereon.

Multiple variations and modifications are possible in the embodiments of the invention described here. Although certain illustrative embodiments of the invention have been shown and
15 described here, a wide range of modifications, changes, and substitutions is contemplated in the foregoing disclosure. While the above description contains many specifics, these should not be construed as limitations on the scope of the invention, but rather as exemplifications of one or another preferred embodiment thereof. In some instances, some features of the present invention may be employed without a corresponding use of the other features. Accordingly, it is appropriate
20 that the foregoing description be construed broadly and understood as being given by way of illustration and example only, the spirit and scope of the invention being limited only by the claims which ultimately issue in this application.

CLAIMS:

1. An implant for treating obstructive airway disorders comprising an element forming a helix having a helix axis in a helical section of the implant wherein, at body temperature, the helical section is elastic and exhibits an oval shape as seen along the helix axis, such that, when implanted along a helically pierced pathway in a tongue, the implant compresses the tongue by a force directed toward the helix axis.
2. The implant of claim 1, wherein the element is adapted such that the force deforms the helically pierced pathway to an oval shape in a plane transverse to the helically pierced pathway.
3. The implant of claim 2, wherein the oval shape has a larger diameter directed along a coronal plane of the tongue.
4. The implant of claim 1, wherein the element in the helical section comprises compression portions and widening portions for producing the force towards the axis of the helix.
5. The implant of claim 4, wherein a cross section of the widening portions is smaller than a cross section of the compression portions.
6. The implant of claim 4, wherein the compression portions and widening portions alternate every quarter turn of the helical section.
7. The implant of claim 1, wherein the element in the helical section is shaped as a cone such that an end of the element to be inserted first has a smaller cross section than an opposite end of the element.

8. The implant of claim 7, wherein the element in the helical section is shaped as a profiled cone with alternate fibered parts having larger and smaller cross-sections.
9. The implant of claim 1, wherein the element comprises NiTi adapted to be in a superelastic state at body temperature.
10. The implant of claim 9, wherein the element comprises a NiTi wire having an elastomeric outer hull comprising a silicone rubber.
11. The implant of claim 10, wherein the silicone rubber is formed to increase a surface area perpendicular to the force exerted, in order to decrease a pressure at a given force on soft tissue.
12. The implant of claim 10, wherein the outer hull has wings.
13. The implant of claim 1, wherein the implant further comprises a flexible distal end section positioned adjacent the helical section.
14. The implant of claim 1, wherein the implant further comprises a torque-producing section and a force distributing section, wherein the torque producing section and force distributing section are adapted such that when implemented into a patient's tongue the implant biases the tongue to return toward a second deformed shape without requiring tissue attachment.
15. The implant of claim 14, wherein the force distributing section is adapted for placement between a root of the tongue and the geniohyoid muscle, or is adapted for placement between the geniohyoid and the mylohyoid muscle.

16. The implant of claim 14, wherein the force distributing section is adapted to be attachable to the mandible bone for exerting a pulling force and/or is adapted to be attachable to the hyoid bone.

17. The implant of claim 14, wherein the force distributing section further comprises an axially compliant fin adapted to be placed between the two geniohyoid muscles thereby preventing dislocation.

18. The implant of claim 7, wherein forces exerted vary along the implant ranging between 0 and 25kPa, variable through a defined variation in diameter of the implant.

19. The implant of claim 13, wherein a distal end of the flexible distal end section has a spherical shape or a conical shape.

20. An implant for treating obstructive airway disorders comprising an element forming a helix in a helical section of the implant adapted such that the implant is helically insertable along a base of a tongue along a helically pierced pathway, wherein the element in the helical section comprises compression portions and widening portions for producing a force towards an axis of the helix when implanted.

21. The implant of claim 20, wherein the helical section is of round shape, on a plane transverse to the axis.

22. The implant of claim 20, wherein the element is adapted such that the force deforms the helically pierced pathway to an oval shape in a plane transverse to the helically pierced pathway.

23. The implant of claim 20, wherein the element in the helical section is shaped as a cone such that an end of the element to be inserted first into tissue has a smaller cross section than an opposite end of the element.

24. The implant of claim 20, wherein a cross section of the widening portions is smaller than a cross section of the compression portions.
25. The implant of claim 20, wherein the compression portions and widening portions alternate every quarter turn of the helical section.
26. The implant of claim 20, wherein the element comprises a temperature dependent shape memory alloy adapted to be in superelastic state at body temperature.
27. The implant of claim 26, wherein the temperature dependent shape memory alloy comprises NiTi.
28. The implant of claim 26, wherein the temperature dependent shape memory alloy forms a NiTi wire comprising a protective coating.
29. The implant of claim 28, wherein the protective coating comprises a fluoropolymer.
30. The implant of claim 29, wherein the fluoropolymer comprises ETFE or FEP.
31. The implant of claim 20, wherein the implant further comprises a torque-producing section and a force distributing section, wherein the torque producing section and force distributing section are adapted such that when implemented into a patient's tongue the implant compresses a body of the tongue stiffening and protruding it.
32. The implant of claim 31, wherein the force distributing section is adapted for placement between a root of the tongue and the geniohyoid muscle, or is adapted for placement between the geniohyoid and the mylohyoid muscle.
33. The implant of claim 32, wherein the force distributing section further comprises a fin adapted to be placed between the two geniohyoid muscles thereby preventing dislocation.

34. The implant of claim 31, wherein the force distributing section is arranged to be attachable to the mandible bone or the torque producing section is arranged to be attachable to the hyoid bone.
35. The implant of claim 31, wherein the force distributing section is shaped as a serpentine line.
36. The implant according to claim 20, wherein the force exerted by the element creates a pressure on the tongue between 2 and 25kPa.
37. The implant according to claim 20, wherein the implant comprises a polymer.
38. An implant for treating obstructive airway disorders comprising an element forming a helix in a helical section of the implant adapted such that the implant is helically insertable along a base of a tongue along a helically pierced pathway, wherein the element, when implanted, is arranged to form an oval shape in a plane transverse to the helically pierced pathway, wherein the oval shape has a larger diameter directed along a coronal plane of the tongue.
39. The implant of claim 38, wherein the implant comprises nitinol adapted to be in superelastic state at body temperature.

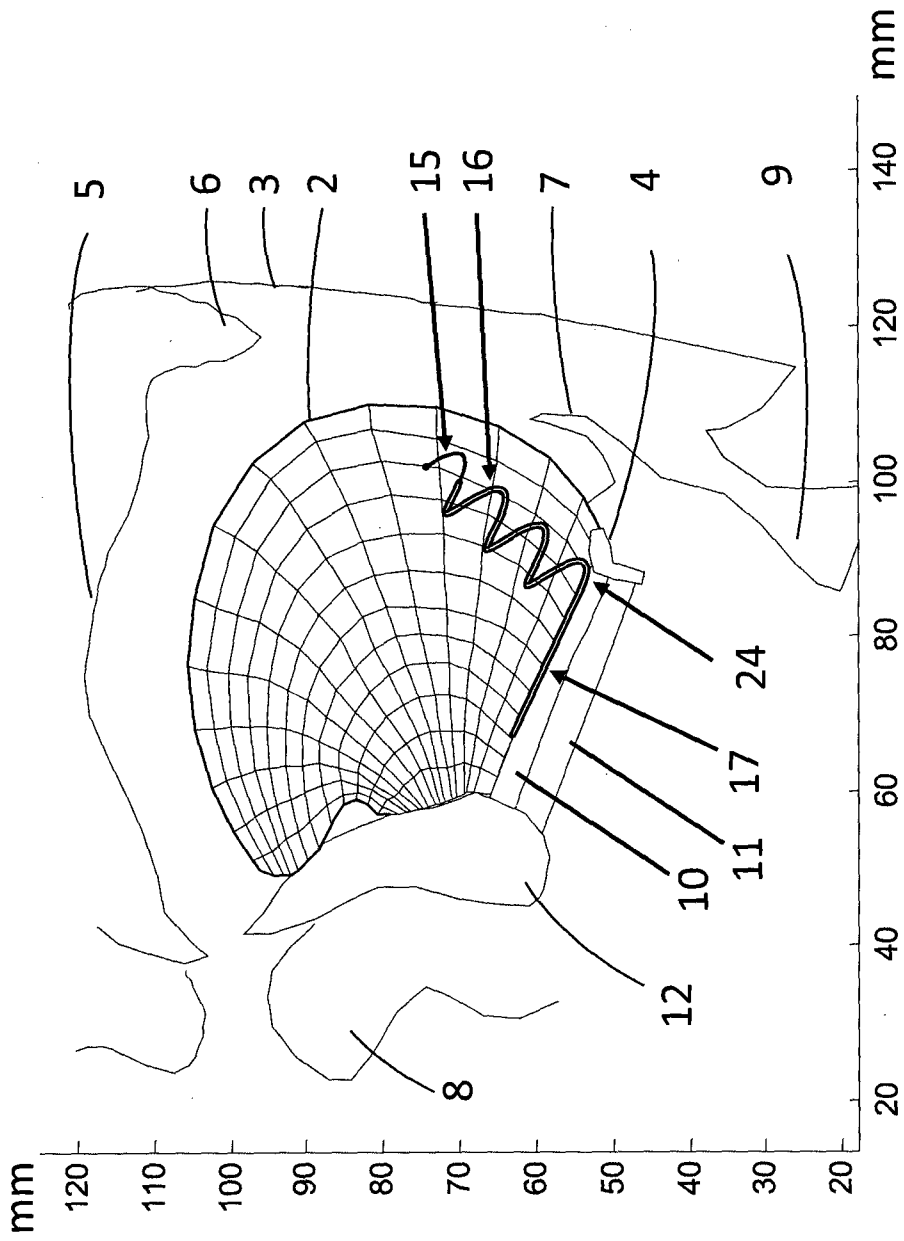


FIG. 1

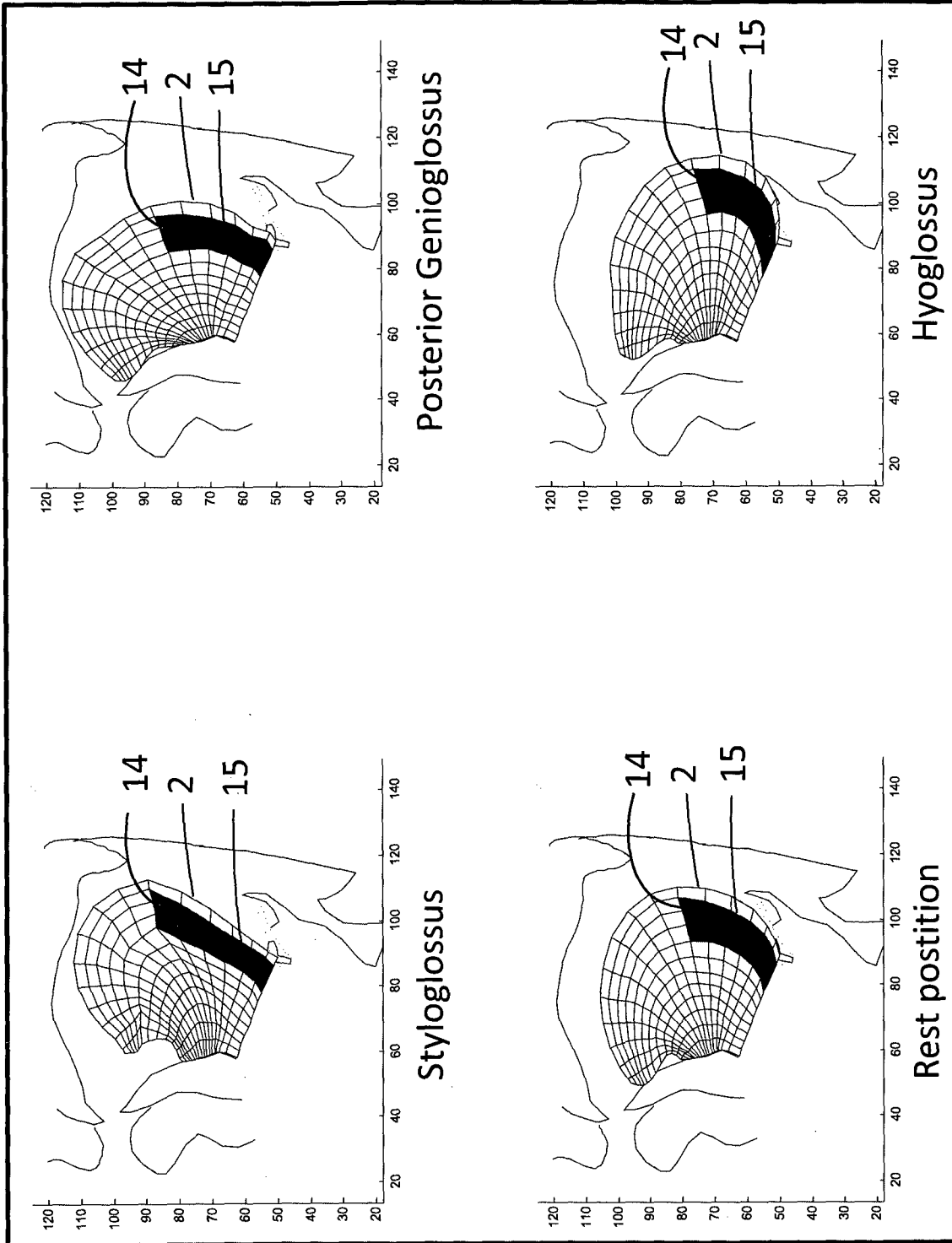


FIG. 2

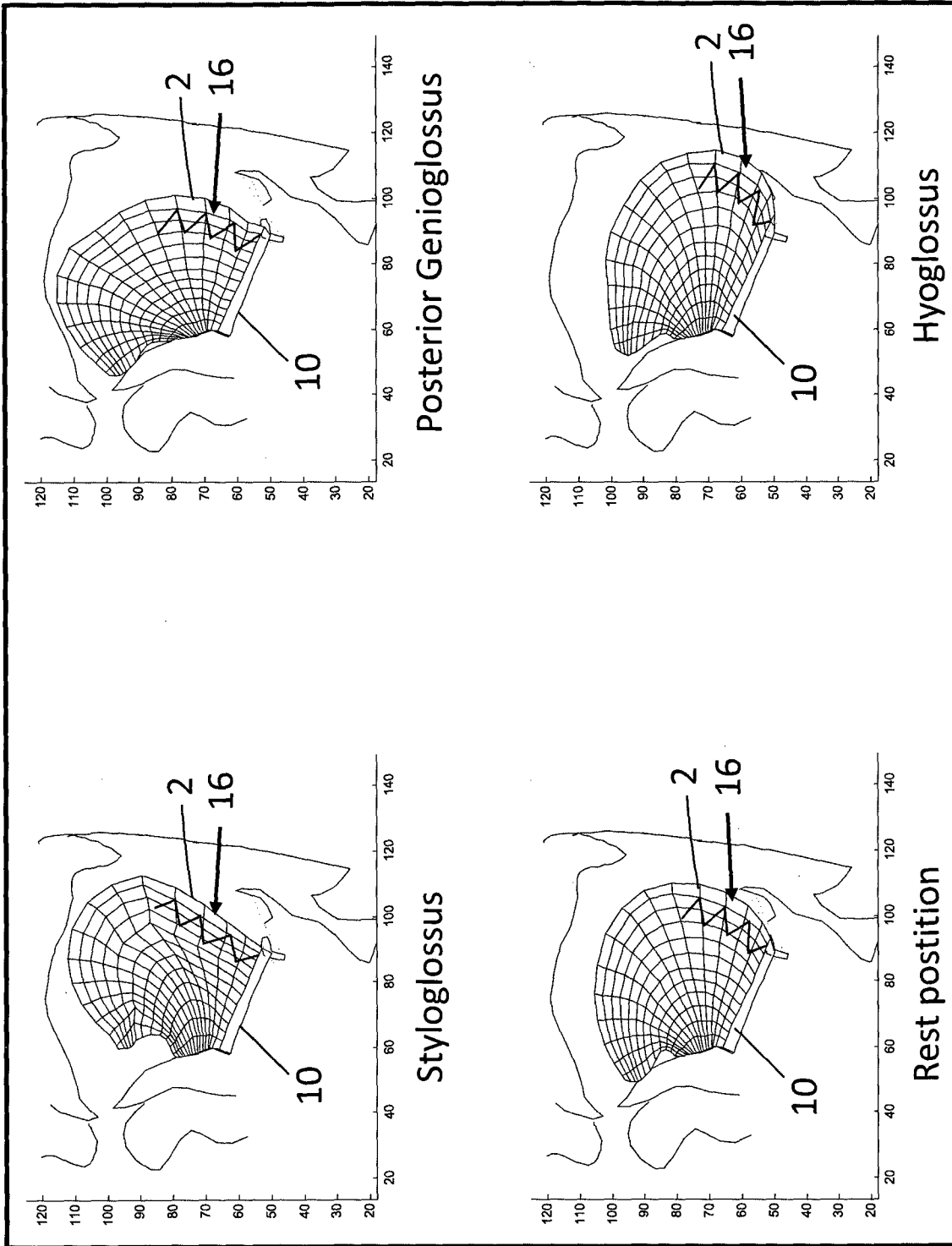


FIG. 3

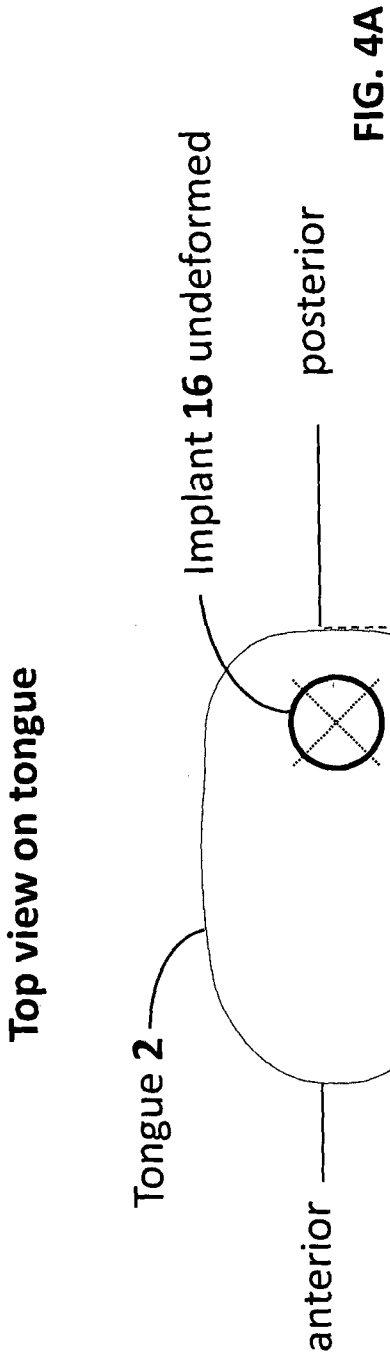


FIG. 4A

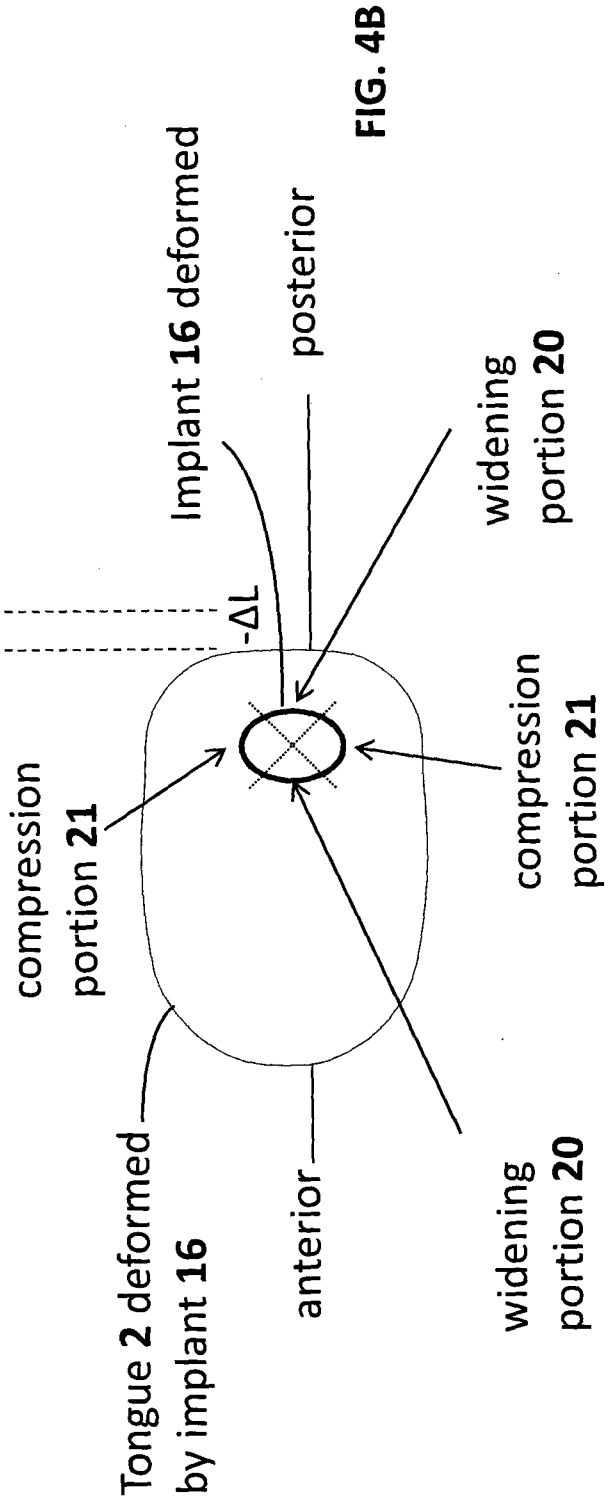


FIG. 4B

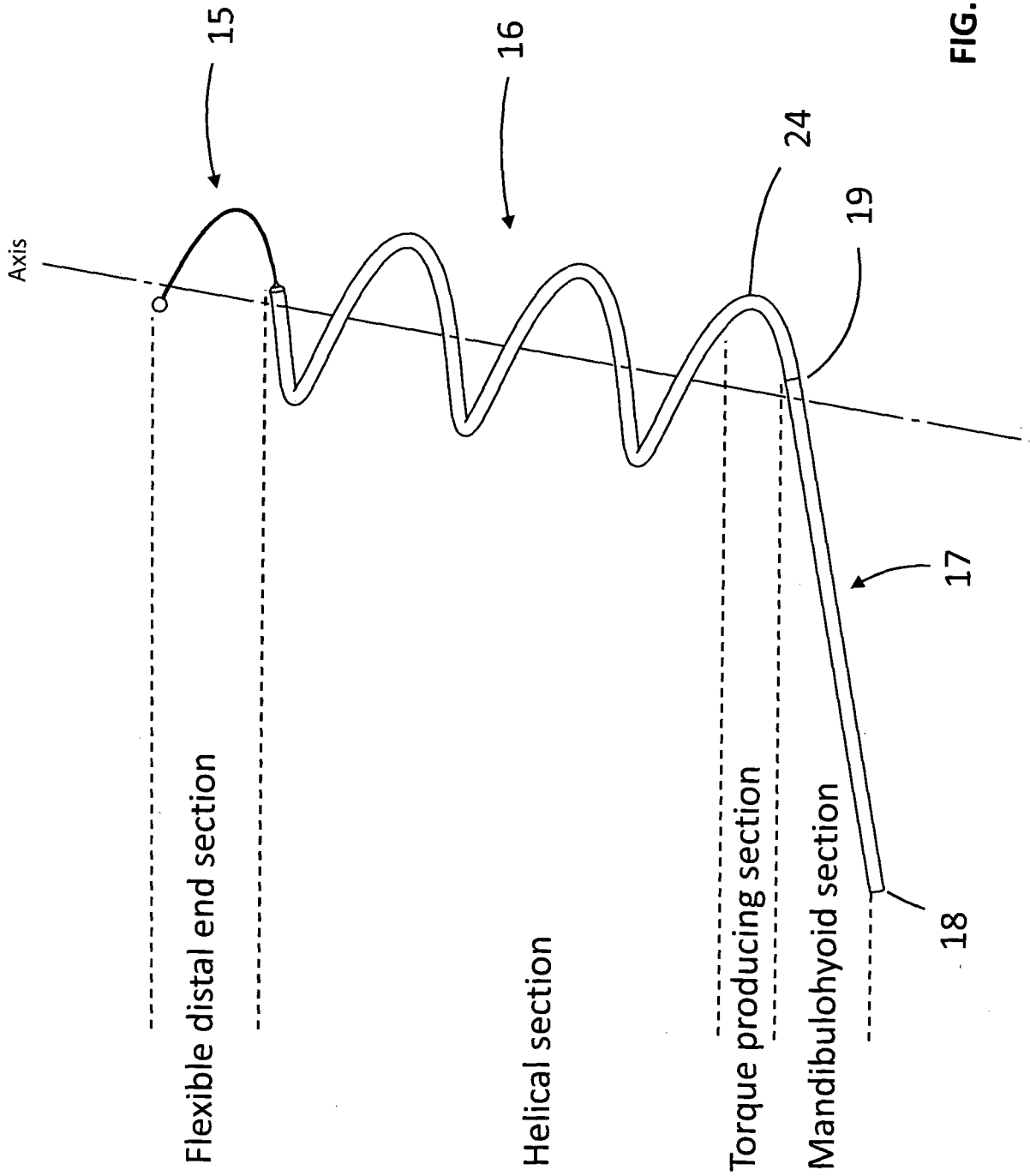


FIG. 5

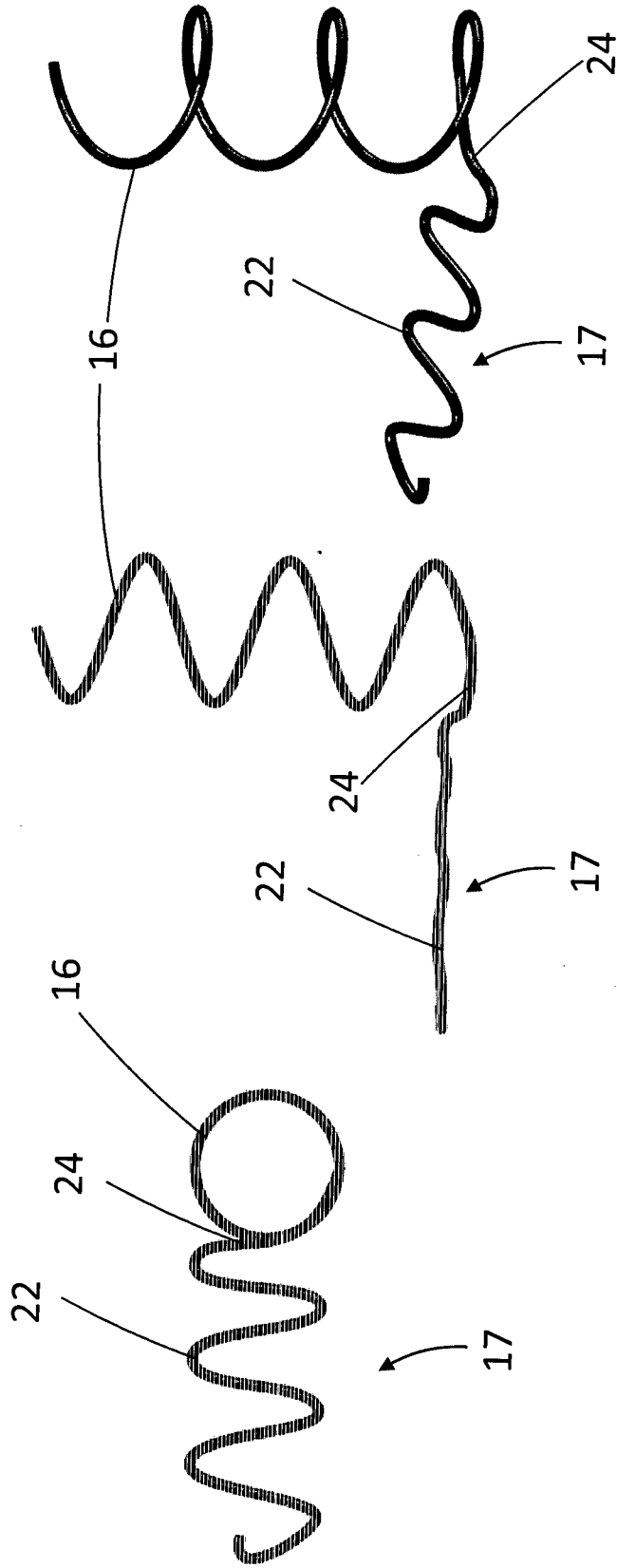


FIG. 6A

FIG. 6B

FIG. 6C

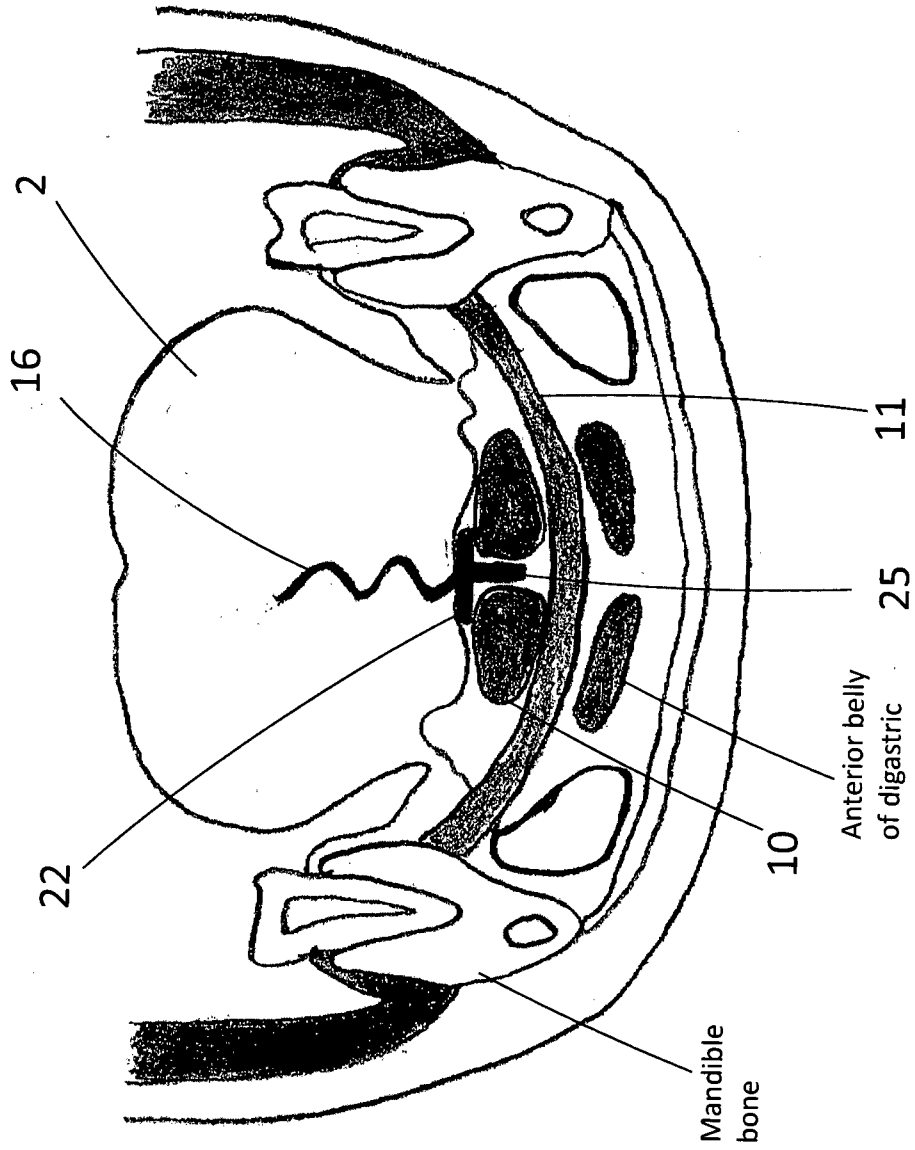



FIG. 7

1''' 

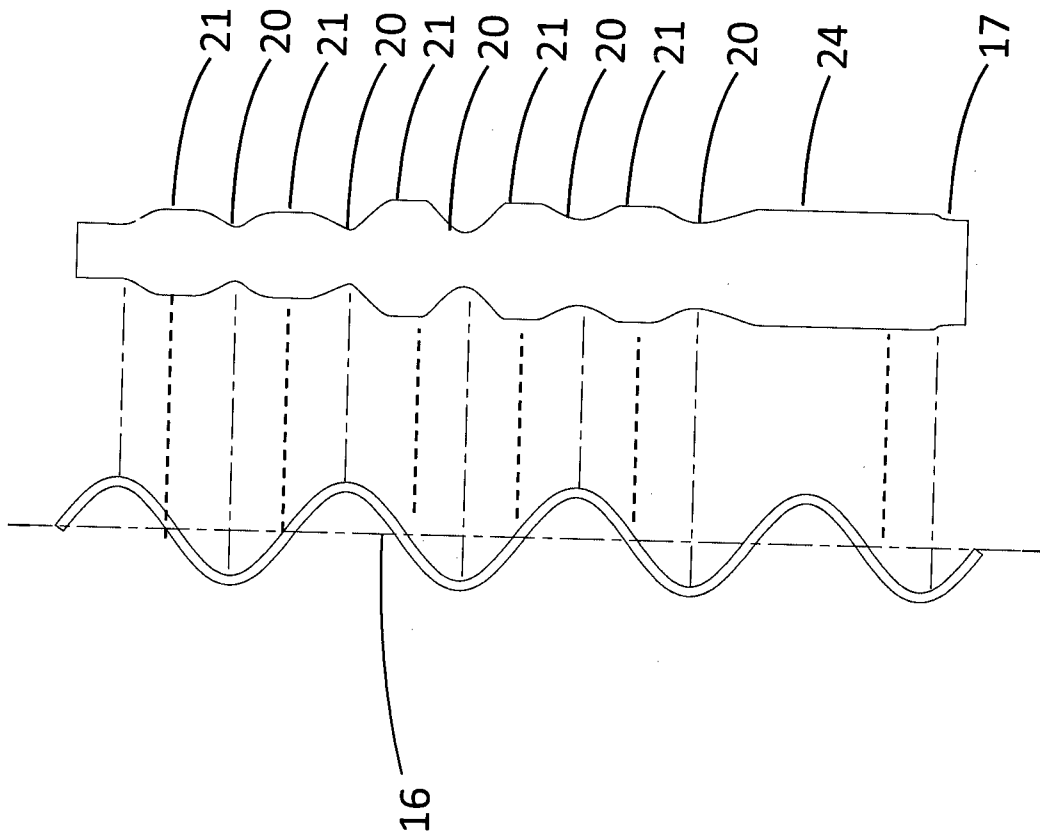


FIG. 8

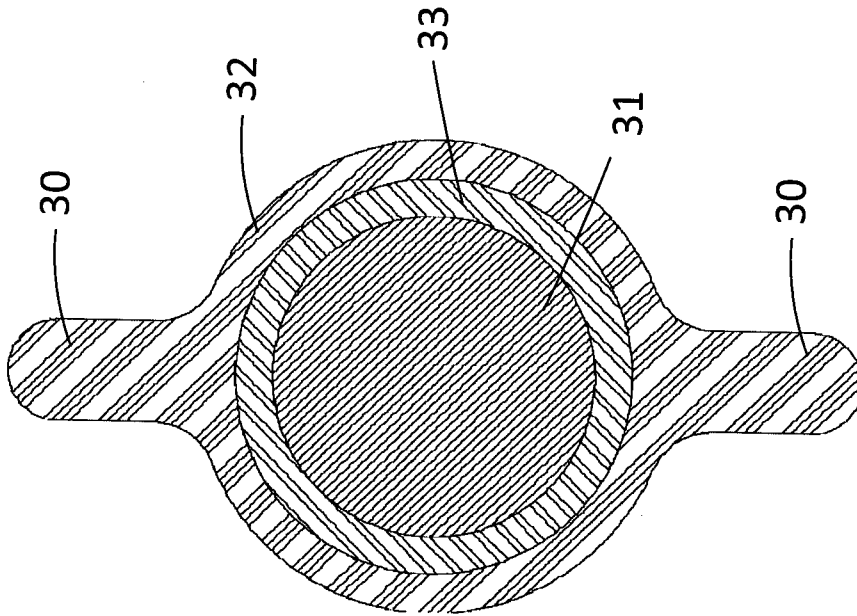


FIG. 9

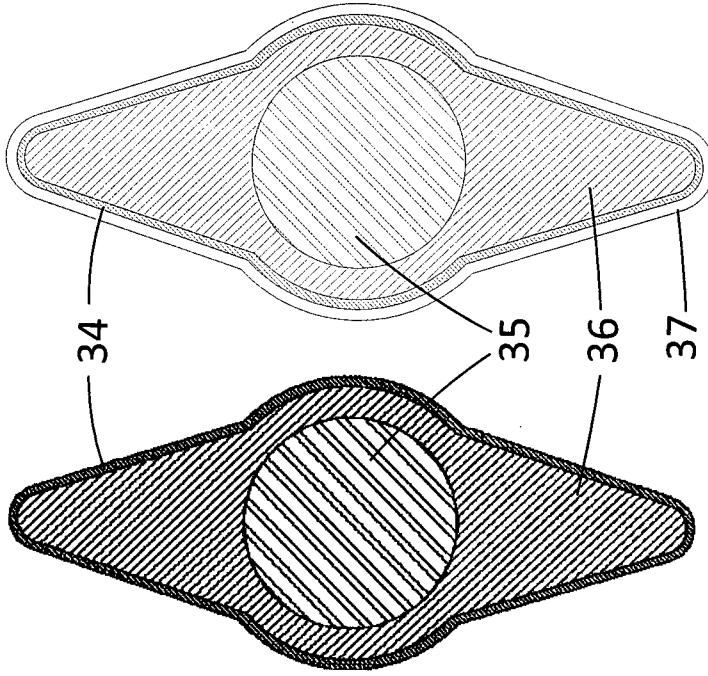


FIG. 10A

FIG. 10B

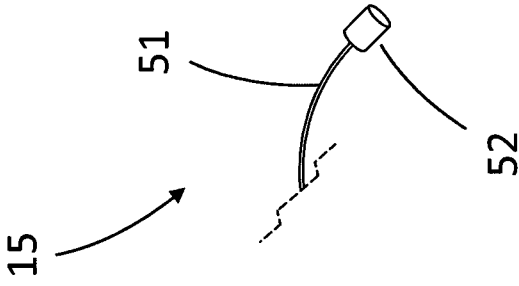


FIG. 11A

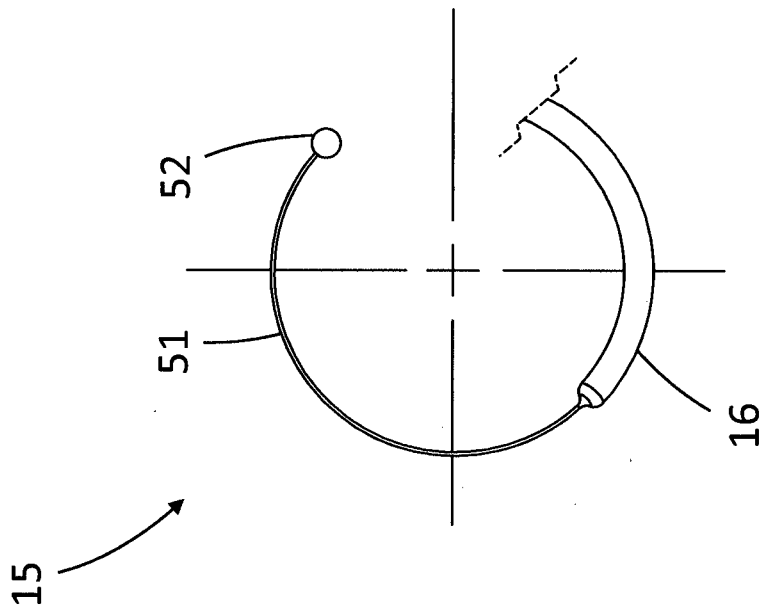


FIG. 11B

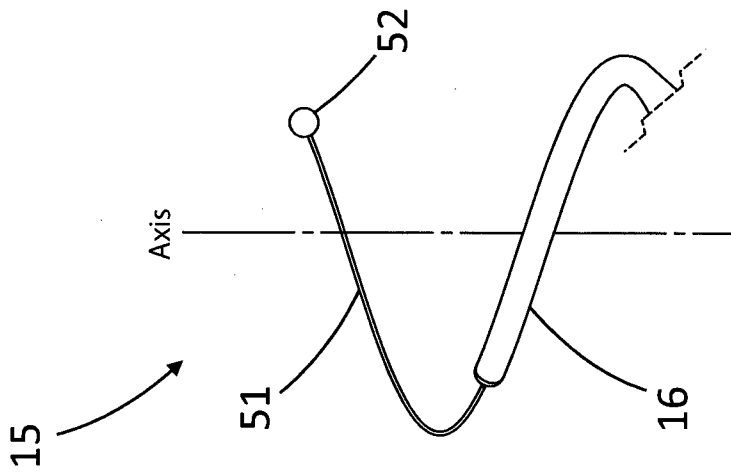


FIG. 11C

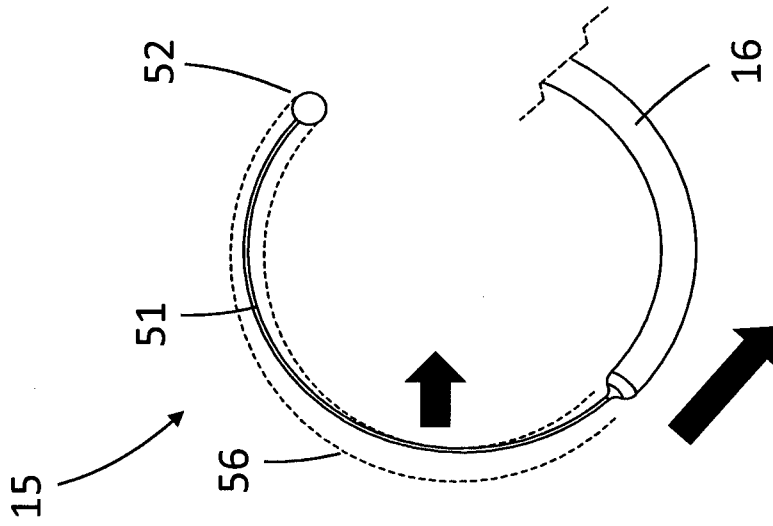


FIG. 12A

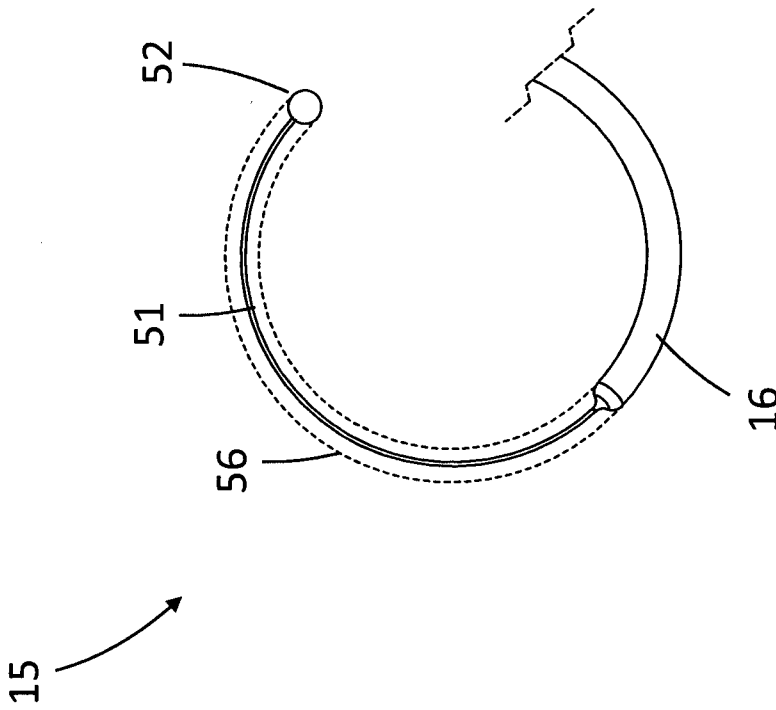


FIG. 12B

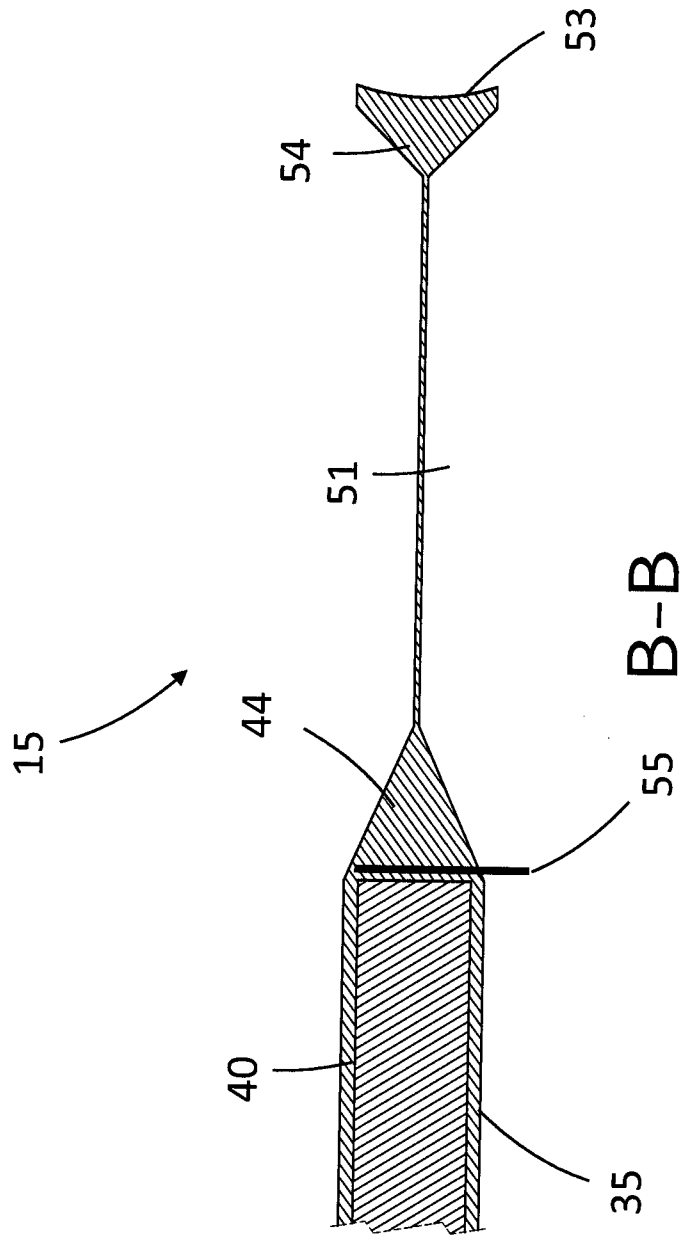


FIG. 13

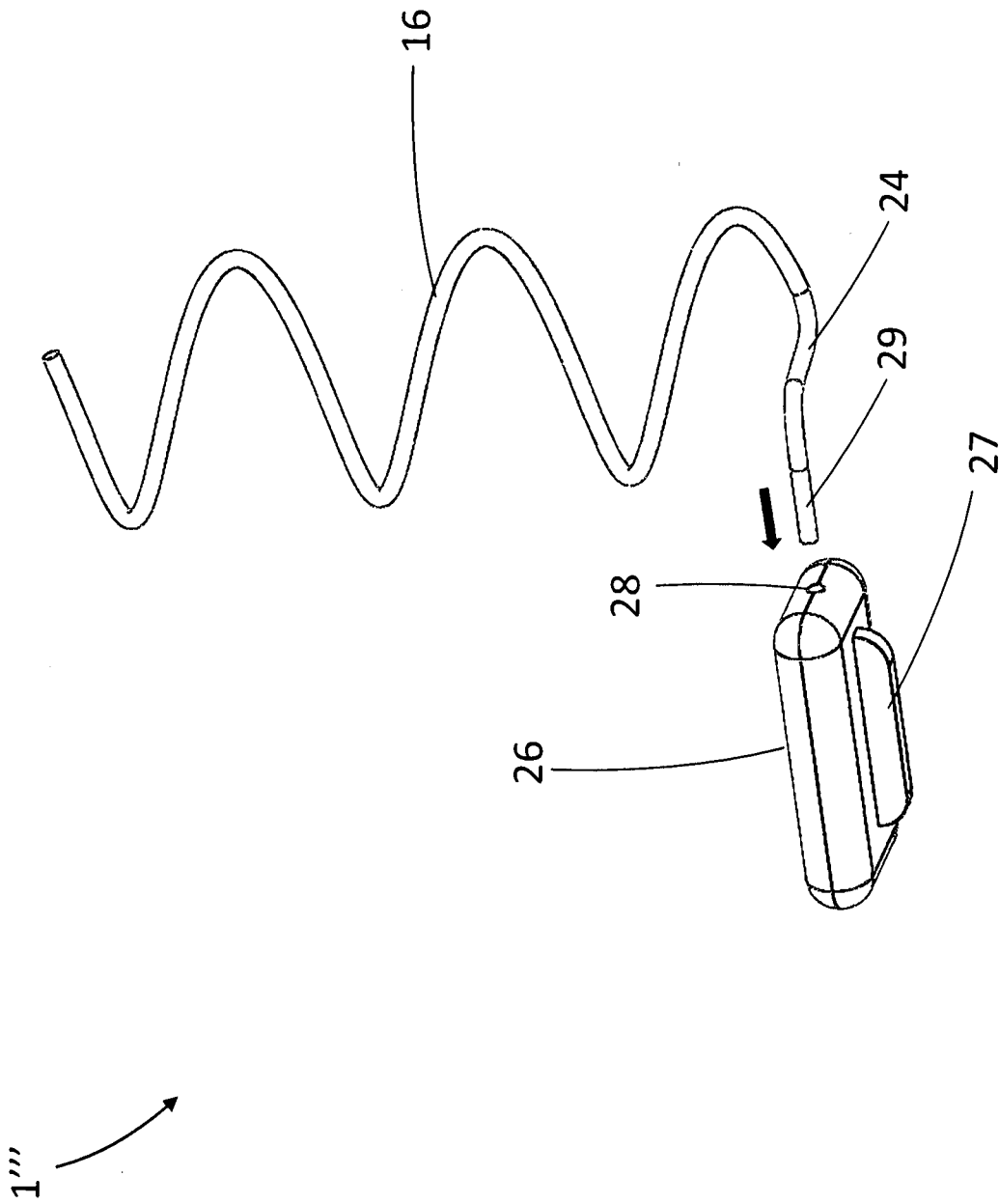


FIG. 14

