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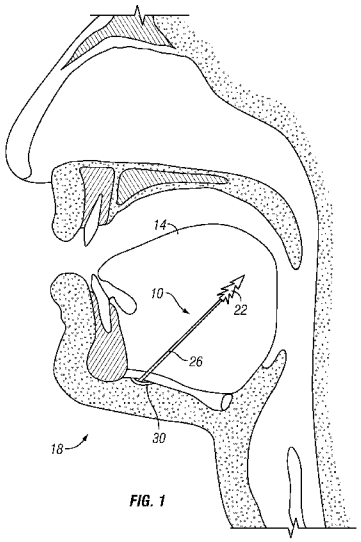


FIG. 1

(57) Abstract: Tongue- stabilization device (10) for treatment and/or reduction of symptoms of obstructive sleep apnea (OSA).

WO 2011/068952 A1

DEVICES FOR TONGUE STABILIZATION

DESCRIPTION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application Serial No. 61/266,035 (filed December 2, 2009), incorporated by reference herein.

BACKGROUND

1. Field of the Invention

[0002] The present invention relates generally to devices and methods for stabilizing the tongue of a mammal, such as a human, and, more particularly, but not by way of limitation, to devices and methods for stabilizing the tongue to prevent and/or alleviate symptoms of obstructive sleep apnea (OSA).

2. Description of Related Art

[0003] Obstructive sleep apnea (OSA) is disease that affects up to 20% of the adult population. OSA generally occurs during sleep when soft tissue obstructs the airway and creates cessation of or impedes breathing. Obstruction can occur at one or more levels including the retropalatal and retrolingual areas. Surgical correction of such obstructions remains a challenge, specifically for the retrolingual area. Removal or ablation of tongue tissue has been utilized with poor results due to complications, such as severe bleeding, abscess formation, and/or the inability to move the tongue anterior enough to relieve the obstruction.

[0004] A number of devices and methods have been developed and/or are in use in the art for the treatment, and/or alleviation of symptoms of obstructive sleep apnea (OSA). The following references involve examples of methods or devices related to OSA, and may facilitate understanding of background information and possible application-specific information for this and related fields of endeavor: **(1)** US Patent Application No. 10/597,590, filed February 28, 2005, and published as Pub. No. US 2009/0014012; **(2)** US Patent Application No. 12/011,782, filed January 29, 2008, and published as Pub. No. US 2008/0188947; **(3)** US Patent Application No. 11/762,642, filed June 13, 2007, and published as Pub. No. US 2008/0023012; **(4)** US Patent Application No. 11/835,931, filed August 8, 2007, and published as Pub. No. US 2008/006769; **(5)** US Patent Application No. 11/820,168, filed June 18, 2007, and published as Pub. No. US 2008/0066864; **(6)** US Patent Application No. 11/762,

752, filed June 13, 2007, and published as Pub. No. US 20008/0058584; **(7)** US Patent Application No. 11/835,966, filed August 8, 2007, and published as Pub. No. US 2008/0083461; **(8)** US Patent Application No. 11/598,220, filed November 9, 2006, and published as Pub. No. US 2007/0144539; **(9)** US Patent Application No. 11/107,160, filed April 15, 2005, and published as Pub. No. US 2006/0235264; **(10)** US Patent Application No. 11/334,216, filed January 18, 2006, and published as Pub. No. US 2007/0163603 **(11)** US Patent Application No. 10/746,707, filed December 23, 2003, and published as Pub. No. US 2005/0133026; and **(12)** US Patent No. 6,408,851, filed October 1, 1991. The foregoing references numbered (1) through (12) are hereby incorporated by reference in their entireties.

SUMMARY

[0005] The present disclosure includes various embodiments of devices and methods for tongue stabilization, such as, for example, for treatment and/or alleviation of symptoms of OSA.

[0006] Some embodiments of the present tongue stabilization devices, comprise: an anchor having an anterior penetration point, a posterior end, and a plurality of barbs each having a point extending away from the penetration point; a suture connected to the anchor; and a counter-tension member configured to be slidably disposed on the suture. In some embodiments, the counter-tension member is configured to freely slide relative to the suture in a first direction, and to resist sliding relative to the suture in a second direction. In some embodiments, at least one of the anchor, suture, and counter-tension member comprises a bio-absorbable material. In some embodiments, each of the anchor, suture, and counter-tension member each comprise a bio-absorbable material.

[0007] Unlike existing tongue stabilization devices, embodiments of the present tongue stabilization devices do not require attachment to the mandible. As explained in more detail below, during use of exemplary embodiments the removal or incision in the tongue can cause either reduction of tongue tissue or the reorientation of the incision by creating tension on the suture and pulling the posterior aspect of the tongue anteriorly. The creation of a wound can allow the tongue to heal in the new orientation so tension is only needed during the healing process and not permanently. The temporary nature of the use of exemplary embodiments can allow for its

components (*e.g.* the anchor, suture, and counter-tension member) to be constructed from bioabsorbable material.

[0008] Certain existing devices that are configured to be anchored to the mandible can require constant and permanent tension to effectively reposition or stabilize the tongue. Such configurations are susceptible to breakage due to the constant and permanent tension placed on the components. Exemplary embodiments of the present disclosure do not require anchoring to the mandible and are not as susceptible to breakage because the tongue can be stabilized or repositioned without permanent tension. In certain exemplary embodiments, multiple devices can be placed in the tongue, spreading the tension among the different implants and sculpting the base of tongue, thereby further reducing the likelihood of breakage.

[0009] In exemplary embodiments, the device is entering through a clean wound, reducing the risk of infection and abscess formation (in contrast to existing methods of using on radio frequency ablation on the base of tongue through the surface). With exemplary embodiments, the closure of the wound can also help create hemostasis which can reduce the possible complication of a hematoma formation. Furthermore, since the surface of the tongue is not penetrated, pain may be greatly reduced.

[00010] Some embodiments of the present methods of stabilizing a tongue of a patient, comprise: providing a tongue-stabilization device (e.g., comprising: an anchor configured such that if the anchor is inserted into soft tissue of a patient the anchor will resist removal from the soft tissue; a suture having a first end connected to the anchor, and a second end extending from the anchor; and a counter-tension member configured to be slidably disposed on the suture); creating an incision through the skin in the submental (under the mandible) area; inserting the tongue-stabilization device through the incision such that the anchor is disposed near a posterior portion of the tongue and the suture extends through the anterior portion of the tongue and through the incision; positioning the counter-tension member along the suture outside the tongue adjacent a lower surface of the tongue; and tensioning the suture between the anchor and the counter-tension member.

[00011] In some embodiments, inserting comprises: disposing at least a portion of the tongue-stabilization device in a needle; inserting the needle through the incision such that the anchor is disposed near a posterior portion of the tongue and the needle

extends through the anterior portion of the tongue and through the incision; and removing the needle from the tongue.

[00012] Certain embodiments may further comprise: creating a void in the tongue proximal to the anchor, where the void is oriented generally parallel to an axis extending from the posterior portion of the tongue to the anterior portion of the tongue prior to tensioning the suture; and the void is oriented generally perpendicular to an axis extending from the posterior portion of the tongue to the anterior portion of the tongue after tensioning the suture.

[00013] In some embodiments, inserting comprises: disposing at least a portion of the tongue-stabilization device in an insertion device, wherein the insertion device comprises an ablation mechanism; inserting the insertion device through the incision such that the anchor is disposed near a posterior portion of the tongue and the insertion device extends through the anterior portion of the tongue and through the incision; ablating tissue with the ablation mechanism; and

removing the insertion device from the tongue. In certain embodiments, the ablative tissue is anterior to the anchor such that when the counter-tension member is placed in the suture the wound is closed by moving the posterior tongue anteriorly. The ablation of tissue can be accomplished by an energy source such as ultrasound, radio frequency, electricity, etc. The ablation may create the reduction of tongue tissue, or an anterior to posterior (AP) incision. When tension is placed on the suture the wound may close in a posterior to anterior orientation or the AP incision may change orientation to lateral. The closure or reorientation of the wound can result in anterior movement of the base of tongue. In certain embodiments, the movement can become permanent once the tissue heals in the new orientation.

[00014] In some embodiments, the step of tensioning the suture is performed before the step of positioning the counter tension member. In some embodiments, the step of positioning the counter-tension member comprises sliding the counter-tension member along the suture. In some embodiments, the counter-tension member is configured such that if the counter-tension member is disposed on the suture the counter-tension member will freely slide relative to the suture in a first direction, and resist sliding relative to the suture in a second direction. In some embodiments, the anchor has an anterior penetration point, a posterior end, a longitudinal axis extending from the, and a plurality of barbs each having a point extending away from the penetration point. In some embodiments, the suture comprises a plurality of barbs

extending away from the anchor. In some embodiments, the anchor, suture, and counter-tension member each comprise a bio-absorbable material.

[00015] Some embodiments of the present tongue-stabilization devices, comprise: a body having an elongated portion with a coupling end and an enlarged end, the body configured to be inserted into a hole through the tongue of a human patient, and the enlarged end configured to resist being pulled through the hole; and a retention member having a coupling portion and a tooth portion, the coupling portion configured to be coupled to the coupling end of the body, and the tooth portion configured to fit between a set of two laterally-adjacent teeth of the patient. In certain embodiments, the retention member may be configured to attach or couple to the teeth or on the teeth. In specific embodiments, the retention member may be a custom-fitted, removable dental appliance that fits over the teeth, a permanent appliance that is cemented or otherwise affixed directly to the teeth or any device that rests between the teeth or slips around one tooth or multiple teeth.

[00016] In some embodiments, the coupling end of the body comprises an opening, the coupling portion of the retention member comprises a ring configured to be coupled to the opening. In some embodiments, the ring is configured to be removably coupled to the opening. In some embodiments, the retention member comprises a narrow portion configured to fit between two laterally-adjacent teeth, and an enlarged portion configured to not fit between the two laterally-adjacent teeth. As noted above, in certain embodiments, the retention member may be configured to attach or couple to the teeth or on the teeth.

[0010] In some embodiments, the retention member comprises two tooth portions each configured to fit between a different set of two laterally-adjacent teeth of the patient. In some embodiments, each tooth portion comprises a narrow portion configured to fit between two laterally-adjacent teeth, and an enlarged portion configured to not fit between the two laterally-adjacent teeth. In some embodiments, the retention member is configured is configured such that if worn by a patient at least a portion of the retention member extends linearly across the lower jaw of the patient substantially perpendicular to the elongated portion of the body. In some embodiments, the two tooth portions of the retention member are unitary, and the coupling portion is the midpoint between the enlarged portions of the two tooth portions.

[0011] In some embodiments, the body and the retention member are unitary. In some embodiments, the coupling portion of the body comprises an enlarged portion configured to resist movement of the tongue of a patient relative to the body. In some embodiments, the coupling end of the body has a maximum transverse dimension that is substantially the same as or less than the maximum transverse dimension as the elongated portion of the body. Some embodiments further comprise: a coupling member configured to be coupled to the coupling end of the body and the coupling portion of the retention member. In some embodiments, the coupling member comprises chain.

[0012] In some embodiments, the body is configured to extend through at least two portions of the tongue of a patient. In some embodiments, the elongated portion and coupling end of the body are each flexible. In some embodiments, the elongated portion and coupling end of the body are unitary. In some embodiments, the elongated portion and coupling end of the body comprise chain. In some embodiments, the retention member comprises chain.

[0013] Some embodiments of the present methods of stabilizing a tongue of a patient, comprise: providing a tongue-stabilization device (e.g., comprising: a body having an elongated portion with a coupling end and an enlarged end, the body configured to be inserted into a hole through the tongue of a human patient, and the enlarged end configured to resist being pulled through the hole; and a retention member having a coupling portion and a tooth portion, the coupling portion configured to be coupled to the coupling end of the body, and the tooth portion configured to couple to one or more teeth or to fit between a set of two laterally-adjacent teeth of the patient); positioning the body of the tongue-stabilization device through a hole in the tongue of a patient; coupling the coupling portion of the retention member to the coupling end of the body of the tongue-stabilization device; and positioning each of the one or more tooth portions of the retention member between a set of two laterally-adjacent teeth of the patient such that the tongue-stabilization device resists posterior motion of the tongue. Other embodiments may comprise attaching the retention member directly to the teeth or on the teeth.

[0014] Some embodiments of the present tongue-shaping devices comprise: a bar configured to extend transversely across the tongue of a patient through two holes in the tongue..

[0015] Any embodiment of any of the present methods can consist of or consist essentially of – rather than comprise/include/contain/have – any of the described steps, elements, and/or features. Thus, in any of the claims, the term "consisting of" or "consisting essentially of" can be substituted for any of the open-ended linking verbs recited above, in order to change the scope of a given claim from what it would otherwise be using the open-ended linking verb.

[0016] Details associated with the embodiments described above and others are presented below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The following drawings illustrate by way of example and not limitation. For the sake of brevity and clarity, every feature of a given structure is not always labeled in every figure in which that structure appears. Identical reference numbers do not necessarily indicate an identical structure. Rather, the same reference number may be used to indicate a similar feature or a feature with similar functionality, as may non-identical reference numbers.

[0018] **FIG. 1** depicts a side cross-sectional view of a human patient having one embodiment of the present tongue-stabilization devices implanted the tongue of the patient.

[0019] **FIG. 2A** depicts an anchor and suture of the embodiment of **FIG. 1** with an insertion needle.

[0020] **FIG. 2B** depicts an anchor and suture of the embodiment of **FIG. 1** with an insertion needle.

[0021] **FIG. 3** depicts an anchor of the embodiment of **FIG. 1**.

[0022] **FIG. 4** depicts a counter-tension device of the embodiment of **FIG. 1**.

[0023] **FIG. 5** depicts perspective view of a barbed suture suitable for use with or in some embodiments of the present tongue-stabilization devices and methods.

[0024] **FIGS. 6A-6E** depicts certain aspects of some embodiments of the present tongue-stabilization methods and methods of implanting the present tongue-stabilization devices.

[0025] **FIGS. 7** and **8** depict side views of portions of two embodiments of tongue-stabilization devices in the tongue of a human patient.

[0026] **FIGS. 9-23** depict various views of embodiments of the present tongue-stabilization devices.

[0027] **FIG. 24** depicts a front view of one of the present tongue-shaping devices.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0028] The term "coupled" is defined as connected, although not necessarily directly, and not necessarily mechanically; two items that are "coupled" may be integral with each other. The terms "a" and "an" are defined as one or more unless this disclosure explicitly requires otherwise. The terms "substantially," "approximately," and "about" are defined as largely but not necessarily wholly what is specified, as understood by a person of ordinary skill in the art.

[0029] The terms "comprise" (and any form of comprise, such as "comprises" and "comprising"), "have" (and any form of have, such as "has" and "having"), "include" (and any form of include, such as "includes" and "including") and "contain" (and any form of contain, such as "contains" and "containing") are open-ended linking verbs. As a result, a system that "comprises," "has," "includes" or "contains" one or more elements possesses those one or more elements, but is not limited to possessing only those elements. Likewise, a method that "comprises," "has," "includes" or "contains" one or more steps possesses those one or more steps, but is not limited to possessing only those one or more steps. For example, in a method that comprises providing a tongue-stabilization device, the method includes the specified steps but is not limited to having only those steps. For example, such a method could also include inserting the device through an incision into the tongue of a patient.

[0030] Further, a device or structure that is configured in a certain way is configured in at least that way, but it can also be configured in other ways than those specifically described.

[0031] Referring now to the drawings, and more particularly to **FIG. 1**, shown therein and designated by the reference numeral **10** is one of the present tongue-stabilization devices. More specifically, device **10** is shown implanted in a tongue **14** of a human patient **18**. In the embodiment shown, device **10** comprises an anchor **22**, a suture **26**, and a counter-tension member **30**. Anchor **22** is configured such that if the anchor is inserted into soft tissue (e.g., of tongue **14**) of a patient the anchor will resist removal from the soft tissue (e.g., of tongue **14**). Device **10** can be (and is shown) configured to take advantage of the tongue being naturally anchored anteriorly to the mandible. For example, device **10** can be implanted to compress the

tongue in an anterior-posterior direction such that the natural tethering between the tongue and mandible will pull the tongue anteriorly (forward).

[0032]

[0033] Referring now to **FIGS. 2A**, **2B, 3**, and **4**, anchor **22**, suture **26**, and counter-tension member **30** are shown in more detail. Anchor **22** has an anterior penetration point **34**, a posterior end **38**, and a plurality of barbs **42** each having a point **46** extending away from the penetration point **34**. In the embodiment shown in **FIG. 2A,** suture **26** extends through an insertion needle **80** and is coupled (e.g., connected) to anchor **22**, such as, for example, at posterior end **38** of anchor **22** (e.g., by way of a knot, adhesive, and/or the like).

[0034] The embodiment shown in **FIG. 2B** is similar to that shown in **FIG. 2A**, with the exception that suture **26** extends through an insertion device **81** that comprises a tissue ablation mechanism **83**. Tissue ablation mechanism **83** may comprise any one of a number of mechanisms configured to ablate tissue, including for example, an transmitter of radio or ultrasonic frequency electromagnetic waves. In other non-limiting examples of tissue ablation mechanism **82** may comprise a laser transmitter, or mechanical devices (*e.g.*, a microdebrider).

[0035] Counter-tension member **30** is configured to be slidably disposed on suture **26**, such as, for example, by way of an opening **50** configured such that suture **26** fits through opening **50** of counter-tension member **30**. In the embodiment shown in **FIG. 5**, counter-tension member **30** is configured to freely slide relative to the suture in a first direction **54**, and to resist sliding relative to the suture in a second direction **58**. In this way, as is described in more detail below, counter-tension member **30** can be slid along suture **26** into an installed position (e.g., as in **FIG. 1**) and counter-tension member **30** will resist sliding out of the installed position (e.g., will resist releasing any tension in suture **26** between counter-tension member **30** and anchor **22**). The counter-tension member can be configured (with or by any suitable structure, assembly, or the like) to freely slide relative to the suture in a first direction **54**, and to resist sliding relative to the suture in a second direction **58**. For example, counter-tension member **30** can include a tapered cone structure having aperture **50** through it that is configured to increase the size of aperture **50** when a force is applied to counter-tension member **30** in first direction **54**, and to decrease the size of aperture **50** and thereby pinch suture **22** (to resist sliding) when a force is applied to counter-tension member **30** in second direction **58**. In other embodiments, suture **26** can be

wrapped or tied around counter-tension member **30** once counter-tension member **30** is in a desired position relative to suture **26** and/or tongue **14** (e.g., to maintain a tension in suture **26**). In some embodiments, counter-tension member **30** is provided with a protrusion, notch, spool, or other structure (not shown) to facilitate wrapping and/or tying of the suture to the counter-tension member.

[0036] In some embodiments, one or more (e.g., one, all, etc.) of anchor **22**, suture **26**, and/or counter-tension member **30** each comprises a bio-absorbable material. Anchor **22**, suture **26**, and/or counter-tension member **30** can comprise any suitable biocompatible material. In certain exemplary embodiments, anchor **22**, suture **26**, and/or counter-tension member **30** comprise an absorbable copolymer comprising approximately 60 to 80 percent polyactide and approximately 20 to 40 percent polyglycolide. More specifically, anchor **22**, suture **26**, and/or counter-tension member **30** may comprise an absorbable copolymer comprising approximately 65 to 75 percent polyactide and approximately 25 to 35 percent polyglycolide. In a specific exemplary embodiment, anchor **22**, suture **26**, and/or counter-tension member **30** comprises an absorbable copolymer comprising approximately 70 percent polyactide and approximately 30 percent polyglycolide. In other embodiments, anchor **22**, suture **26**, and/or counter-tension member **30** may be non-absorbable (e.g., may comprise a non-absorbable material).

[0037] **FIG. 5** depicts a barbed suture **62** that can be used with various embodiments of the present tongue stabilization devices. In some embodiments, the barbed suture is integral to anchor **22**. Barbed suture **62** comprises a plurality of barbs **64**. In some embodiments, barbed suture is coupled to anchor **22** in place of suture **26** such that that barbs **64** extend away from anchor **22**. Barbed suture **62** can comprise any of the materials described above for anchor **22**, suture **26**, and/or counter-tension member **30**.

[0038] Referring now to **FIGS. 6A -6E**, one method of stabilizing a tongue of a patient is illustrated. In the embodiment illustrated, the method comprises: providing a tongue-stabilization device that comprises: an anchor **22** configured such that if the anchor is inserted into soft tissue (e.g., of tongue **14**) of a patient the anchor will resist removal from the soft tissue; a suture **26** having a first end **66** connected to anchor **22**, and a second end **70** extending from anchor **22**; and a counter-tension member **30** configured to be slidably disposed on suture **26**. The method can further comprise creating an incision **74** through the skin on the lower side of the patient's

jaw **78**, and inserting anchor **22** of the device **10** through incision **74** (e.g., with insertion needle **80** shown in **FIG. 2A** or insertion device **81** shown in **FIG. 2B**) and into an anterior portion **82** of tongue **14** toward a posterior portion **86** of tongue **14**. In some embodiments, anchor **14** is inserted into tongue **14** such that anchor **14** is disposed near posterior portion **86** of tongue **14** and suture **26** extends through anterior portion **82** of tongue **14** and through incision **78**. The method can further comprise positioning counter-tension member **30** along suture **26** outside tongue **14** adjacent a lower surface **90** of tongue **14** (e.g., by sliding counter-tension member **30** along suture **26** in direction **54** toward lower surface **90** of tongue **14**). The method can further comprise tensioning suture **26** between anchor **22** and counter-tension member **30**. Stated another way, once counter-tension member **30** is positioned adjacent lower surface **90** of tongue **14**, suture **26** can be pulled through counter-tension member **30** to pull posterior portion 86 of the tongue forward to, for example, open the airway, shape the rear of the tongue, stabilize the tongue, or the like.

[0039] Stated another way, device **10** can be placed minimally invasively by making a small incision **74** under the mandible, inserting a placement device (e.g., needle with suture internal, etc.) such that suture **26** extends out of the tongue anteriorly (e.g., through an anterior portion **82** of the tongue); and placing a counter-tension member **30** on suture **26** that can only move along suture **26** in an anterior to posterior direction. By placing tension on suture **26** while pushing counter-tension member **30** in a posterior direction (toward posterior portion **86** of the tongue) against the tissue of the tongue, suture **26** will compress the tongue between anchor **22** and counter-tension member **30** and pull at least a portion of the tongue in an anterior direction. Multiple barbs **42** on anchor **22** (and/or barbed suture **62**) can spread the forces of the tension in the suture, and multiple anchors **22** can spread the forces of the tension on the suture among multiple regions of the tongue so that each barb has a relatively minimal amount of tension.

[0040] In some embodiments of the present methods, inserting anchor **22** comprises: disposing at least a portion of the anchor (e.g., posterior end **38**) in a needle; inserting the needle through incision **74** such that the anchor is disposed near posterior portion **86** of the tongue and the needle extends through anterior portion **82** of the tongue and through incision **74**; and removing the needle from the tongue. For example, insertion needle **80** comprises a distal end **92** configured to be temporarily coupled to anchor **22** for insertion of anchor **22** into soft tissue (e.g., tongue **14**) of the

patient. Needle **80** also comprises a proximal or base end (not shown) that can be coupled to any suitable handle, actuator, or the like, such as, for example, that can be configured to decouple or eject anchor **22** from distal end **92** of needle **80**. In the embodiment shown, distal end **92** stops short of penetration point **34** of anchor **22** such that penetration point **34** facilitates or enables penetration during insertion of anchor **22**, and/or such that upon insertion of anchor **22** into tongue **14**, barbs **42** are permitted to engage the soft tissue of the tongue such that needle **80** can be removed from tongue **14** while anchor **22** will resist removal from the soft tissue (e.g., such that anchor **22** will remain inserted or embedded in the soft tissue of the tongue). In other embodiments, distal end **92** can be configured to extend past penetration point **34** of anchor **22** (and/or distal end **92** can be angled and/or sharpened as in a traditional hypodermic needle) such that distal end **92** facilitates or enables insertion of needle **80** and anchor during insertion of anchor **22**. In some embodiments, needle **80** can be configured to cover and/or at least partially compress barbs **42** while anchor **22** is coupled to and/or disposed within needle **80** (e.g., during insertion of a anchor **22** into tongue **14**. In the embodiment shown, needle **80** is configured such that if anchor **22** is coupled to or disposed within needle **80** then suture **26** extends through at least a portion (and/or the entire length of) needle **80**. In other embodiments, needle **80** can comprise a notch or opening configured to permit suture **26** to pass through the notch or opening rather than extending the length of the needle.

[0041] Referring now to **FIGS. 6D** and **6E**, the orientation of a void **84** in tongue **14** is altered as tension is placed on suture **26** via anchor **22** and counter-tension member **30**. In certain embodiments, void **84** can be formed in tongue **14** at least partially circumferentially around device **10** and proximal to anchor **22.** In specific embodiments void **84** can be formed via an incision in tongue **14** or by ablating tissue in tongue **14** (*e.g.*, via issue ablation mechanism **83**). In specific embodiments, void **84** may be formed via tissue ablation and suction. Upon initial placement of device **10** into tongue **14,** void **84**, is oriented generally parallel to an axis extending from posterior portion **86** of tongue **14** to anterior portion **82** of tongue **14**. This configuration is shown in **FIG. 6D**.

[0042] After tension is placed on suture (*e.g.*, by pushing counter-tension member **30** in a posterior direction toward posterior portion **86** the orientation of void **84** is altered so that it is generally perpendicular to an axis extending from posterior portion **86** of tongue **14** to anterior portion **82** of tongue **14.** This configuration is

shown in **FIG. 6E**. In addition to altering the orientation of void **84**, the tension on suture **26** also increases the width of tongue **14** (*e.g.*, the dimension illustrated by dimension "W" in **FIGS. 6D** and **6E)**. Furthermore, the tension on suture **26** may also decrease the thickness of tongue **14** (*e.g.* the dimension of tongue **14** measured in the same direction of suture **26** as shown in **FIG. 6B**) and move posterior portion **86** of tongue **14** in the direction indicated by arrow **87** in **FIG. 6E**.

[0043] In certain embodiments, a suture passer may be utilized to create a continuous (*e.g.* running) suture by passing needle **80** between the arms of the suture passer. In still other embodiments, suture **26** may be welded together to maintain a low profile and reduce the patient's sensation of suture **26**.

[0044] In some embodiments of the present methods, insertion device **81** shown in **FIG. 2B**, rather than needle **80,** may be utilized to insert anchor **22** and suture **26**. Insertion device **81** can be inserted into tongue **14** in a manner similar to that of previously described embodiments (*e.g.*, through a submental incision). Ablation mechanism **83** can then be used to ablate tissue of tongue **14** (*e.g.*, via a radio or ultrasound frequency electromagnetic wave transmitter, laser transmitter, microdebrider, shaver, or any other suitable mechanism).

[0045] Once the tissue is ablated, insertion device **81** can be withdrawn leaving suture **26** in place. Suture **26** can be pulled, while anchor **22** (and counter-tension member **30**) keep tension on suture **26**. This can collapse the ablated area, pulling tongue **14** tissue anteriorly, *e.g.* so that the thickness of tongue **14** in the ablated area is decreased while the width (measured across the mandible) is increased. In certain embodiments, insertion device **81** may also be configured to provide suction to remove the ablated tissue. In specific embodiments, ablation mechanism **83** is sufficiently spaced from anchor **22** so that, after installation, anchor **22** will be located in tissue that has not been ablated. The above-described technique does not require an anchor to mandible, allowing multiple sutures to be placed in the tongue. In specific embodiments, anchor **22**, suture **26**, and counter-tension member **30** may be absorbable since the tissue will heal in the new configuration and there is no need to rely on continued tension to cause the desired effect.

[0046] The above-described technique can also provide several advantages over other known ablative techniques, which generally require penetrating through the surface and seeding the area with bacteria. Such techniques generally require the

surgeon to wait for the tissue to remodel to create the desired effect after the ablation is completed.

[0047] In some embodiments of the present methods, barbed suture **62** can be used in place of suture **26**, or in place of a portion of suture **26**. For example, device **10** can comprise a length of barbed suture **62** adjacent anchor **22**, and a length of suture **26** coupled to (e.g., unitary with) the length of barbed suture **62**, such that the length of barbed suture **62** is configured to assist anchor **22** in maintaining the position of anchor **22** relative to tongue **14**, and the length of suture **26** is configured to permit retention member **30** to slide on the length of suture **26**. In some embodiments, the step of tensioning the suture is performed before the step of positioning the counter tension member. That is, in some embodiments, after anchor **22** is inserted into tongue **14**, suture **26** is tensioned before counter-tension member **30** is positioned adjacent lower surface **90** of the tongue. In this way, counter-tension member **30** can be positioned once the suture is tensioned.

[0048] In some embodiments of the present methods, the anchor can comprise anchor **22** of **FIGS. 1-3**. In other embodiments, the anchor can comprise any suitable anchor that is configured to resist removal once inserted into soft tissue. In some embodiments, the present methods can comprise a plurality of tongue-stabilization devices (e.g., **10**) to shape and/or stabilize the tongue of a patient in a suitable and/or desired way. For example, **FIG. 6C** depicts a tongue **14** with three separate devices **10** inserted into the tongue.

[0049] Referring now to **FIG. 7**, shown therein and designated by the reference numeral **100a** is a portion of a tongue-stabilization device. Device **100a** comprises a body **104a** configured to be coupled to a retention member (described below). Body **104a** has an elongated portion **112** with a coupling end **116** and an enlarged end **120**, and is configured to be inserted into a hole **124** through a tongue **14** of a human patient (e.g., **18**). Enlarged end **120** is configured to resist being pulled through hole **124** (e.g., enlarged end **120** is larger than hole **124**). In the embodiment shown, enlarged end **120** has a rounded, flattened shape that is larger than hole **124**. Enlarged end **120** can also be configured to resist chafing, scraping, and/or cutting the tongue and/or other portions of a patient's mouth. More specifically, enlarged portion **120** (and/or other portions, members, or parts of device **100a**) can be formed without sharp corners, with smooth surfaces, and/or of flexible or resilient materials to reduce the likelihood of any damaging interaction with the patients tongue or mouth. In the

embodiment shown, coupling end **116** includes a connection member **130** to permit body **104a** to be coupled to retention member (described below). In the embodiment shown, connection member **130a** comprises a loop. In other embodiments, connection member **130a** can comprise any suitable structure or shape configured to be coupled (e.g., removably) to any of the present retention members (described below). In the embodiment shown, loop **130a** is larger than hole **124**, but does not necessarily need to be larger than hole **124**. Body **104a** can be placed (e.g., hole **124** can be formed in tongue and/or body **104a** inserted in hole **124**) under local anesthesia, such that, for example, any of the present retention members **108c-108o** (shown in FIGS. 9-21, discussed below) can be coupled to body **104a** (e.g., at night) to anchor tongue **14** to the mandibular teeth to prevent the tongue from collapsing or falling posteriorly and/or impeding the airway (e.g., during sleep).

[0050] **FIG. 8** depicts an alternate embodiment **104b** of body **104a**. Body **104b** is substantially similar to body **104a**, with the primary exception that body **104b** comprises a clasp **130b** that is configured to be coupled (e.g., removably) to a corresponding structure (e.g., a loop or ring) of a retention member (described below). For example, clasp **130b** can be configured to be opened and/or closed by a user (e.g., a patient).

[0051] Referring now to **FIGS. 9-21**, various views are shown of embodiments of the present tongue-stabilization devices. The various embodiments shown in **FIGS. 9-21** are similar to one another in various respects, and the differences are therefore primarily described.

[0052] **FIG. 9** depicts a side cross-sectional view of one of the present tongue-stabilization devices **100c**, and **FIG. 10** depicts a front view of device **100c**. Device **100c** comprises a body **104a** (having an elongated portion with a coupling end and an enlarged end, the body configured to be inserted into a hole through the tongue of a human patient, and the enlarged end configured to resist being pulled through the hole, as described with reference to **FIG. 7**). Device **100c** further comprises a retention member **108c** having a coupling portion **134** and one or more (e.g., two) tooth portions **138**. Coupling portion **134** is configured to be coupled to coupling end **116** of body **104a**, and each tooth portion **138** is configured to fit between a set of two laterally-adjacent teeth of the patient (e.g., **142a** and **142b**, or **142c** and **142d**). Each tooth portion **138** comprises a narrow portion **146** configured to fit between two laterally-adjacent teeth (e.g., **142a** and **142b**, or **142c** and **142d**), and an enlarged

portion **150c** configured to not fit between the two laterally-adjacent teeth (e.g., configured to be larger than the space between two laterally adjacent teeth and/or otherwise shaped such that enlarged portion **150c** will not fit between the laterally-adjacent teeth). In the embodiment shown, retention member **108c** comprises two tooth portions **138**, each configured to fit between a different set of two laterally-adjacent teeth of the patient (e.g., **142a** and **142b**, or **142c** and **142d**). In this way, each tooth portion **138** is configured such that a user can slide narrow portion **146** between two laterally-adjacent teeth such that enlarged portion **150c** is near or in contact with the respective laterally-adjacent teeth (e.g., **142a** and **142b**). Tooth portions **138** can be unitary (e.g., formed of a single piece) with one another and/or with coupling portion **134**. In this way, when device **100a** is installed as shown, body **104a** and retention member **108c** cooperate to hold tongue **14** in a forward position (e.g., to prevent the tongue from moving rearward beyond a predetermined position, such as, for example, as may be predetermined by the position of hole **124** in tongue **14** and the size of device **100a**).

[0053] Coupling portion **134** can comprise one or more of a ring, clasp, or the like configured to be coupled (e.g., removably) to coupling end **116** of body **104a**. In the embodiment shown, coupling end **116** of body **104a** comprises an opening (e.g., has an opening defined therethrough, such as, for example, in a ring, or a hole formed through coupling end **116** of body **108c**), and coupling portion **134** of retention member **108c** comprises a ring configured to be coupled (e.g., removably) to the opening (in the coupling end of the body).

[0054] Body **104a** and/or retention member **108c** can comprise any suitable biocompatible and/or hypoallergenic material or materials, such as, for example, stainless steel, titanium, polymer, composite, or the like. Body **104a** and retention member **108c** need not comprise the same material or materials. For example, body **104a** can comprise a substantially rigid material such as stainless steel, and/or retention member **108c** can comprise a resilient material such as a resilient polymer (or retention member **108c** can comprise a substantially rigid material such as stainless steel, and body **104a** can comprise a resilient material such as a resilient polymer). In this way, stress and/or wear on teeth can be limited and/or reduced.

[0055] It is understood that the embodiments shown in FIGS. 9-11 are merely exemplary embodiments of the present disclosure. Other embodiments for example, may comprise variations or alterations to the components illustrated. For example, in

certain embodiments, the retention member may be configured to attach or couple to the teeth or on the teeth. In specific embodiments, the retention member may be a custom-fitted, removable dental appliance that fits over the teeth, a permanent appliance that is cemented or otherwise affixed directly to the teeth or any device that rests between the teeth or slips around one tooth or multiple teeth.

[0056] **FIG. 11** depicts another embodiment **100d** of the present tongue-stabilization devices. Device **100d** comprises a body **104a** and a retention member **108d** having a coupling portion **134** and a single tooth portion **138** (configured to fit between a single set of two laterally-adjacent teeth **142b** and **142c**). As shown, enlarged portion **150d** of tooth portion **138** of device **100d** comprises a ring that is configured to not fit between laterally-adjacent teeth **142a** and **142b**.

[0057] **FIG. 12** depicts another embodiment **100e** of the present tongue-stabilization devices. Device **100e** comprises a body **104e** that is similar to body **104a** with the primary exception that body **104e** comprises a ring **130e** that is substantially larger than elongated portion **112**. In the embodiment shown, body **104e** can comprise a flexible and/or resilient material, such that ring **130e** can be compressed to fit through hole **124** in tongue **14**; and such that once through hole **124**, ring **130e** will relax or expand to an enlarged and relaxed state in which ring **130e** is larger than hole **124** to resist ring **130e** being pulled through hole **124** (e.g., resists to a lesser degree than enlarged end **120** of body **104e** resists being pulled through hole **124**. Additionally, enlarged portion **150e** of tooth portion **138** of body **104e** comprises a flattened tab that extends laterally a distance (e.g., greater than half the width of an adjacent tooth **142b** or **142c**) in each of left and right directions.

[0058] **FIG. 13** depicts another embodiment **100f** of the present tongue-stabilization devices. Device **100f** comprises a body **104f** that is similar to body **104a** with the primary exception that body **104f** comprises a connection structure **130f** that does not comprise a ring. In the embodiment shown, connection structure **130f** has a diamond shape. In some embodiments connection structure **130f** comprises an axial (axially aligned with elongated portion **112**) opening (e.g., threaded, or knurled) into which coupling portion **134** of retention member **108f** can be inserted. For example, in such embodiments, coupling portion **134** can be elongated and/or can be configured (e.g., can be threaded or knurled) to correspond to the threads or knurls of an axial opening. In other embodiments, connection structure **130f** (and therefore body **104f**) can be unitary with retention member **108f**, such that, for example, the enlarged

connection structure **130f** merely comprises an enlarged portion configured to resist motion of body **104f** relative to tongue **14** when body **104f** is disposed in tongue **14**, as shown. Stated another way, connection structure **130f** is configured to resist movement of tongue **14** relative to body **104f**. In some embodiments, connection structure **130f** is configured to at least partially collapse when pressed through hole **124**, and to relax or de-compress (e.g., enlarge) when connection structure **130** is pushed out of hole **124**. In other embodiments, connection structure **130f** is substantially rigid such that as connection structure **130f** is pushed through hole **124**, the soft tissue of the tongue is pushed apart such that hole **124** temporarily expands, and then hole **124** contracts once coupling portion **130f** is pushed out of hole **124**. Enlarged portion **150f** is substantially similar to enlarged portion **150e** of device **100e**.

[0059] **FIG. 14** depicts another embodiment **100g** of the present tongue-stabilization devices. Device **100g** comprises a body **104g** that is similar to body **104a** with the primary exception that body **104g** does not have a connection structure, and is instead unitary with retention member **108g**. In particular, there is no enlarged or other structure designating or demarcating a border or distinction between body **104g** and retention member **108g**. Retention member **108g** comprises an enlarged portion **150g** of tooth portion **138** that comprises a flattened tab that extends laterally a distance (e.g., about the width of an adjacent tooth **142b** or **142c**) in each of left and right directions. Enlarged portion **150** can be shaped to contour to an outer surface of each tooth **142b**, **142c**.

[0060] **FIG. 15** depicts another embodiment **100h** of the present tongue-stabilization devices. Device **100h** comprises a body **104h** that is similar to body **104f**, and a retention member **108h** that is substantially similar to retention member **108f**, with the primary exceptions that body **104h** comprises a connection structure **130h** that has a square shape, and retention member **108h** has an enlarged end **150h** that comprise a ring (e.g., substantially similar to that of retention member **108d**).

[0061] **FIG. 16** depicts another embodiment **100i** of the present tongue-stabilization devices. Device **100i** comprises a body **104i** that is similar to body **104f**, and a retention member **108i** that is substantially similar to retention member **108f**, with the primary exceptions that body **104i** comprises a connection structure **130i** that has a round or circular shape.

[0062] **FIGS. 17** and **18** depict a another embodiment **100j** of the present tongue-stabilization devices. Device **100j** comprises a body **104j** that is similar to

body **104a**, with the primary exceptions that the connection end **116** of body **104j** has a maximum transverse dimension (e.g., diameter or width perpendicular to the length of elongated portion **112**) that is substantially the same as or less than the maximum transverse dimension (e.g., diameter or width) as elongated portion **112** of the body. Connection structure **130j** comprises an opening extending through connection end **116** of body **104j**, and a coupling member **154** configured to be coupled to coupling end **116** (e.g., through opening **130j**) of body **104j** and coupling portion **134** of retention member **108j**. For example, in the embodiment shown, coupling portion **134** of retention member **108j** comprises an opening through which coupling member **154** can be passed to couple body **104j** to retention member **108j**, or through which a second coupling member **158** can be passed such that second coupling member **158** can be coupled to coupling member **154**. In some embodiments, coupling member **154** and/or coupling member **158** can comprise a small chain (e.g., comprising stainless steel, titanium, or the like). Enlarged portion **150j** is substantially similar to enlarged portion **150e** of device **100e**.

[0063] **FIG. 19** depicts another embodiment **100k** of the present tongue-stabilization devices. Device **100k** comprises a body **104j**. Device **100k** further comprises a retention member **108k** that is substantially similar to retention member **108e**, with the primary exception that enlarged portion **150k** is substantially similar to enlarged portion **150g** of device **100g**. In some embodiments, coupling portion **134** of retention member **108k** can comprise a clasp or the like that is configured to be removably coupled to opening **130j**. In other embodiments coupling portion **134** (e.g., ring) of retention member **108k** is permanently or non-removably (without destroying retention member **108**) coupled to body **104j**.

[0064] **FIG. 20** depicts another embodiment **100L** of the present tongue-stabilization devices. Device **100L** comprises a body **104j**. Device **100L** further comprises a retention member **108L** that is substantially similar to retention member **108c**, with the primary exception that retention member **108L** comprises a coupling portion **134** (e.g., rather than a ring) that is the midpoint between the enlarged portions **150L** of the two tooth portions **138**. In the embodiment shown, the two tooth portions **138** of retention member **108L** are unitary.

[0065] In some embodiments of the present tongue-stabilization devices, elongated portion **112** an/or connection end **116** of the body comprise chain. In some embodiments, the retention member comprises chain. For example, **FIG. 21** depicts

another embodiment **100m** of the present tongue-stabilization devices. Device **100m** comprises a body **104m** and a retention member **108m** that are substantially similar to body **104e** and retention member **108e**, with the primary exceptions that elongated portion **112** and connection end **116** of body **104m** comprise a chain looped from (and back to) enlarged end **120**, and retention member **108m** comprises a chain extending between tooth portion **138** and coupling portion **134**. Coupling portion **134** can comprise a ring through which the chain of connection end **116** can extend through, or coupling portion **134** can comprise a clasp or the like for coupling (e.g., removably) to connection **116** end of body **104m**. In some embodiments, coupling portion **134** can comprise a ring through which the chain of connection end **116** can extend through, or coupling portion **134** can comprise a clasp or the like for coupling (e.g., removably) to connection **116** of body **104m**.

[0066] By way of another example, **FIG. 22** depicts another embodiment **100n** of the present tongue-stabilization devices. Device **100n** comprises a body **104j**. Device **100n** further comprises a retention member **108n** that is similar to retention member **108L**, with the primary exceptions that coupling portion **134** comprises a length of chain configured to be coupled to body **104j** (e.g., by a ring **162** through opening **130j**) and to be coupled to tooth portion **138** (e.g., by a ring **166)**, and that tooth portion **138** comprises a piece of chain having an enlarged portion **150n** at either end. In some embodiments coupling portion **134** is coupled directly (e.g., non-removably to tooth portion **138**). Stated another way, and as shown in **FIG. 22**, retention member **108n** is configured such that if worn by a patient at least a portion of retention member **108n** (e.g., tooth portion **138**) extends linearly across the lower jaw of the patient substantially perpendicular to elongated portion **112** of body **104j**).

[0067] By way of another example, **FIG. 23** depicts another embodiment **100o** of the present tongue-stabilization devices. Device **100o** comprises a body **104m**. Device **100o** further comprises a retention member **108o** that is substantially similar to retention member **108L**, with the primary exception that retention member **108o** comprises a length of chain extending between tooth portions **138** (e.g., enlarged portions **150o**).

[0068] Some of the present methods of stabilizing a tongue comprise: providing a tongue-stabilization device (e.g., **100a-100o**) comprising a body and a retention member; positioning the body through a hole (e.g., **124**) in the tongue (e.g., **14**) of a patient (e.g., **18**); coupling a coupling portion of the retention member to a

coupling end of the body; and positioning each of the one or more tooth portions of the retention member between a set of two laterally-adjacent teeth (e.g., **142a** and **142b**, or **142c** and **142d**) of the patient (e.g., **18**) such that the device **100a** resists posterior motion of the tongue.

[0069] Referring now to **FIG. 24**, an embodiment **200** is shown of one of the present tongue-shaping devices. Device **200** comprises: a bar **204** configured to extend transversely across tongue **14** of a patient through two holes **208a**, **208b** in the tongue. In the embodiment shown, device **200** further comprises enlarged ends **212a** and **212b** that are larger than (have a diameter or other maximum transverse dimension that is larger than) the diameter or other corresponding dimension of holes **208a**, **208b** such that if device **200** is installed in a tongue as shown in **FIG. 23**, enlarged ends **212a**, **212b** will resist being pulled through holes **208a**, **208b**. In the embodiment shown, holes **208a** and **208b** extend through the tongue from (and through) a lower surface of the tongue to (and through) an upper surface of the tongue. As shown, in some methods of shaping a tongue with device **200**, device **200** is disposed through the tongue such that bar **204** extends across an upper surface of the tongue and such that enlarged ends **212a**, **212b** are disposed below the lower surface of the tongue. In other embodiments, device **200** can be disposed relative to the tongue such that enlarged ends **212a**, **212b** are disposed on or above an upper surface of the tongue and bar **204** extends below the lower surface of the tongue. In some embodiments, enlarged ends **212a**, **212b** each have a maximum transverse dimension (e.g., diameter) that is larger than the corresponding maximum transverse dimension (e.g., diameter) of each of holes **208a**, **208b** such that enlarged ends **212a and 212b** resist motion of bar **204** relative to the tongue. In this way, device **200** can be inserted through holes **208a**, **208b** to compress tongue **14**, such as, for example, to compress and/or shape the tongue to prevent the tongue from blocking an airway of a patient and/or reduce blockage of the airway by the tongue. One or both of enlarged ends **212a**, **212b** can be configured to thread or screw into and/or out of bar **204** such that an enlarged end (e.g., **212a**) can be removed from bar **204**, bar **204** inserted through holes **208a** and **208b**, and the enlarged end (e.g., **212a**) re-attached or re-coupled to bar **204** to prevent bar **204** from pulling out of holes **208a**, **208b**. Device **200** can comprise any suitable materials and/or be configured to have any suitable characteristics, such as, for example, any of the materials and/or characteristics described above for devices **10** and/or **100a-100o**.

[0070] The various illustrative embodiments of devices, systems, and methods described herein are not intended to be limited to the particular forms disclosed. Rather, they include all modifications and alternatives falling within the scope of the claims.

[0071] The claims are not intended to include, and should not be interpreted to include, means-plus- or step-plus-function limitations, unless such a limitation is explicitly recited in a given claim using the phrase(s) "means for" or "step for," respectively.

REFERENCES

[0072] The following references, to the extent that they provide exemplary procedural or other details supplementary to those set forth herein, are specifically incorporated herein by reference.

[0073] US Patent No. 5,245,023 "Method for producing novel polyester biopolymers" by Peoples and Sinskey, issued September 14, 1993.

[0074] US Patent No. 5,250,430 "Polyhydroxyalkanoate polymerase" by Peoples and Sinskey, issued October 5, 1993.

[0075] US Patent No. 5,534,432 "Polyhydroxybutyrate polymerase" by Peoples and Sinskey, issued July 9, 1996.

[0076] US Patent No. 5,663,063 "Method for producing polyester biopolymers" by Peoples and Sinskey, issued September 2, 1997.

[0077] US Patent No. 6,245,537 "Removing endotoxin with an oxidizing agent from polyhydroxyalkanoates produced by fermentation" by Williams, Martin, Horowitz and Gerngross, issued June 12, 2001.

[0078] US Patent No. 6,316,262 "Biological systems for manufacture of polyhydroxyalkanoate polymers containing 4-hydroxyacids" by Huisman, Skraly, Martin and Peoples, issued November 13, 2001.

[0079] US Patent No. 6,514,515 "Bioabsorbable, biocompatible polymers for tissue engineering" by Williams, issued February 4, 2003.

[0080] US Patent No. 6,548,569 "Medical devices and applications of polyhydroxyalkanoate polymers" by Williams, Martin, and Skraly, issued April 15, 2003.

[0081] US Patent No. 6,555,123 "Polyhydroxyalkanoate compositions for soft tissue repair, augmentation, and viscosupplementation, by Williams and Martin, issued April 29, 2003.

[0082] US Patent No. 6,585,994 "Polyhydroxyalkanoate compositions for soft tissue repair, augmentation, and viscosupplementation, by Williams and Martin, issued July 1, 2003.

[0083] US Patent No. 6,592,892"Flushable disposable polymeric products" by Williams, issued July 15, 2003.

[0084] US Patent No. 6,593,116 "Transgenic microbial polyhydroxyalkanoate producers" by Huisman, Peoples, and Skraly, issued July 15, 2003.

[0085] US Patent No. 6,610,764 "Polyhydroxyalkanoate compositions having controlled degradation rates" by Martin, Skraly, and Williams, issued August 26, 2003.

[0086] US Patent No. 6,623,749 "Medical device containing polyhydroxyalkanoate treated with oxidizing agent to remove endotoxin" by Williams, Martin, Gerngross and Horowitz, issued September 23, 2003.

[0087] US Patent No. 6,689,589 "Biological systems for manufacturing of polyhydroxyalkanoates polymers containing 4-hydroxyacids" by Huisman, Skraly, Martin and Peoples, issued February 10, 2004.

[0088] US Patent No. 6,746,685 "Bioabsorbable, biocompatible polymers for tissue engineering" by Williams, issued June 8, 2004.

[0089] US Patent No. 6,828,357 "Polyhydroxyalkanaote compositions having controlled degradation rates" by Martin , Skraly, and Williams, issued December 7, 2004.

[0090] US Patent No. 6,838,493 "Medical devices and applications of polyhydroxyalkanoate polymers" by Williams, Martin, and Skraly, issued January 4, 2005.

[0091] US Patent No. 6,867,247 "Medical devices and applications of polyhydroxyalkanoate polymers" by Williams, Martin, Skraly, issued March 15, 2005.

[0092] US Patent No. 6,867,248 "Polyhydroxyalkanoate compositions having controlled degradation rates" by Martin, Skraly, and Williams, issued March 15, 2005.

[0093] US Patent No. 6,878,758 "Polyhydroxyalkanoate compositions having controlled degradation rates" by Martin, Skraly and Williams, issued April 12, 2005.

[0094] US Pub App. No. 20020164729 "Production of polyhydroxyalkanoates from polyols" by Skraly and Sholl, published November 7, 2002.

[0095] US Pub. App. No. 20040234576 "Polyhydroxyalkanoate medical textiles and fibers" by Martin, Rizk, Ahuja, and Williams, published November 25, 2004.

CLAIMS

1. A tongue stabilization device, comprising:

an anchor having an anterior penetration point, a posterior end, and a plurality of barbs each having a point extending away from the penetration point;

a suture connected to the anchor; and

a counter-tension member configured to be slidably disposed on the suture.

2. The tongue-stabilization device of claim 1, where the counter-tension member is configured to freely slide relative to the suture in a first direction, and to resist sliding relative to the suture in a second direction.

3. The tongue-stabilization device, where at least one of the anchor, suture, and counter-tension member comprises a bio-absorbable material.

4. The tongue-stabilization device of claim 3, where each of the anchor, suture, and counter-tension member each comprise a bio-absorbable material.

5. A method of stabilizing a tongue of a patient, the method comprising:

providing a tongue-stabilization device comprising:

an anchor configured such that if the anchor is inserted into soft tissue of a patient the anchor will resist removal from the soft tissue;

a suture having a first end connected to the anchor, and a second end extending from the anchor; and

a counter-tension member configured to be slidably disposed on the suture;

creating an incision through the skin in a submental area of the patient;

inserting the tongue-stabilization device through the incision such that the anchor is disposed near a posterior portion of the tongue and the suture extends through the anterior portion of the tongue and through the incision;

positioning the counter-tension member along the suture outside the tongue adjacent a lower surface of the tongue; and

tensioning the suture between the anchor and the counter-tension member.

6. The method of claim 5, where inserting comprises:

disposing at least a portion of the tongue-stabilization device in a needle;

inserting the needle through the incision such that the anchor is disposed near a posterior portion of the tongue and the needle extends through the anterior portion of the tongue and through the incision; and

removing the needle from the tongue.

7. The method of claim 6 further comprising:

creating a void in the tongue proximal to the anchor, wherein the void is oriented generally parallel to an axis extending from the posterior portion of the tongue to the anterior portion of the tongue prior to tensioning the suture; and

the void is oriented generally perpendicular to an axis extending from the posterior portion of the tongue to the anterior portion of the tongue after tensioning the suture.

8. The method of claim 5, where inserting comprises:

disposing at least a portion of the tongue-stabilization device in an insertion device, wherein the insertion device comprises an ablation mechanism;

inserting the insertion device through the incision such that the anchor is disposed near a posterior portion of the tongue and the insertion device extends through the anterior portion of the tongue and through the incision;

ablating tissue with the ablation mechanism; and

removing the insertion device from the tongue.

9. The method of claim 5, where the step of tensioning the suture is performed before the step of positioning the counter tension member.

10. The method of claim 5, where the step of positioning the counter-tension member comprises sliding the counter-tension member along the suture.

11. The method of claim 10, where the counter-tension member is configured such that if the counter-tension member is disposed on the suture the counter-tension member will freely slide relative to the suture in a first direction, and resist sliding relative to the suture in a second direction.

12. The method of claim 5, where the anchor has an anterior penetration point, a posterior end, a longitudinal axis extending from the, and a plurality of barbs each having a point extending away from the penetration point.

13. The method of claim 5, where the suture comprises a plurality of barbs extending away from the anchor.

14. The method of claim 5, where the anchor, suture, and counter-tension member each comprise a bio-absorbable material.

15. A tongue-stabilization device, comprising:

a body having an elongated portion with a coupling end and an enlarged end, the body configured to be inserted into a hole through the tongue of a human patient, and the enlarged end configured to resist being pulled through the hole; and

a retention member having a coupling portion and a tooth portion, the coupling portion configured to be coupled to the coupling end of the body, and the tooth portion configured to couple to one or more teeth of the patient.

16. The tongue-stabilization device of claim 15, where the coupling end of the body comprises an opening, the coupling portion of the retention member comprises a ring configured to be coupled to the opening.

17. The tongue-stabilization device of claim 15, where the ring is configured to be removably coupled to the opening.

18. The tongue-stabilization device of claim 15, where the retention member comprises a narrow portion configured to fit between two laterally-adjacent teeth, and an enlarged portion configured to not fit between the two laterally-adjacent teeth.

19. The tongue-stabilization device of claim 15, where the retention member comprises two tooth portions each configured to fit between a different set of two laterally-adjacent teeth of the patient.

20. The tongue-stabilization device of claim 19, where each tooth portion comprises a narrow portion configured to fit between two laterally-adjacent teeth, and an enlarged portion configured to not fit between the two laterally-adjacent teeth.

21. The tongue-stabilization device of claim 19, where the retention member is configured is configured such that if worn by a patient at least a portion of the retention member extends linearly across the lower jaw of the patient substantially perpendicular to the elongated portion of the body.

22. The tongue-stabilization device of claim 21, where the two tooth portions of the retention member are unitary, and the coupling portion is the midpoint between the enlarged portions of the two tooth portions.

23. The tongue-stabilization device of claim 15, where the body and the retention member are unitary.

24. The tongue stabilization device of claim 15, where the coupling portion of the body comprises an enlarged portion configured to resist movement of the tongue of a patient relative to the body.

25. The tongue-stabilization device of claim 15, where the coupling end of the body has a maximum transverse dimension that is substantially the same as or less than the maximum transverse dimension as the elongated portion of the body.

26. The tongue-stabilization device of claim 25, further comprising:

a coupling member configured to be coupled to the coupling end of the body and the coupling portion of the retention member.

27. The tongue-stabilization device of claim 26, where the coupling member comprises chain.

28. The tongue-stabilization device of claim 15, where the elongated portion and coupling end of the body are each flexible.

29. The tongue-stabilization device of claim 28, where the elongated portion and coupling end of the body are unitary.

30. The tongue-stabilization device of claim 29, where the elongated portion and coupling end of the body comprise chain.

31. The tongue-stabilization device of any of claims 15-30, where the retention member comprises chain.

32. A method of stabilizing a tongue of a patient, the method comprising:

providing a tongue-stabilization device comprising:

a body having an elongated portion with a coupling end and an enlarged end, the body configured to be inserted into a hole through the tongue of a human patient, and the enlarged end configured to resist being pulled through the hole; and

a retention member having a coupling portion and a tooth portion, the coupling portion configured to be coupled to the coupling end of the body, and the tooth portion configured to couple to one or more teeth of the patient;

positioning the body of the tongue-stabilization device through a hole in the tongue of a patient;

coupling the coupling portion of the retention member to the coupling end of the body of the tongue-stabilization device; and

positioning each of the one or more tooth portions of the retention member between a set of two laterally-adjacent teeth of the patient such that the tongue-stabilization device resists posterior motion of the tongue.

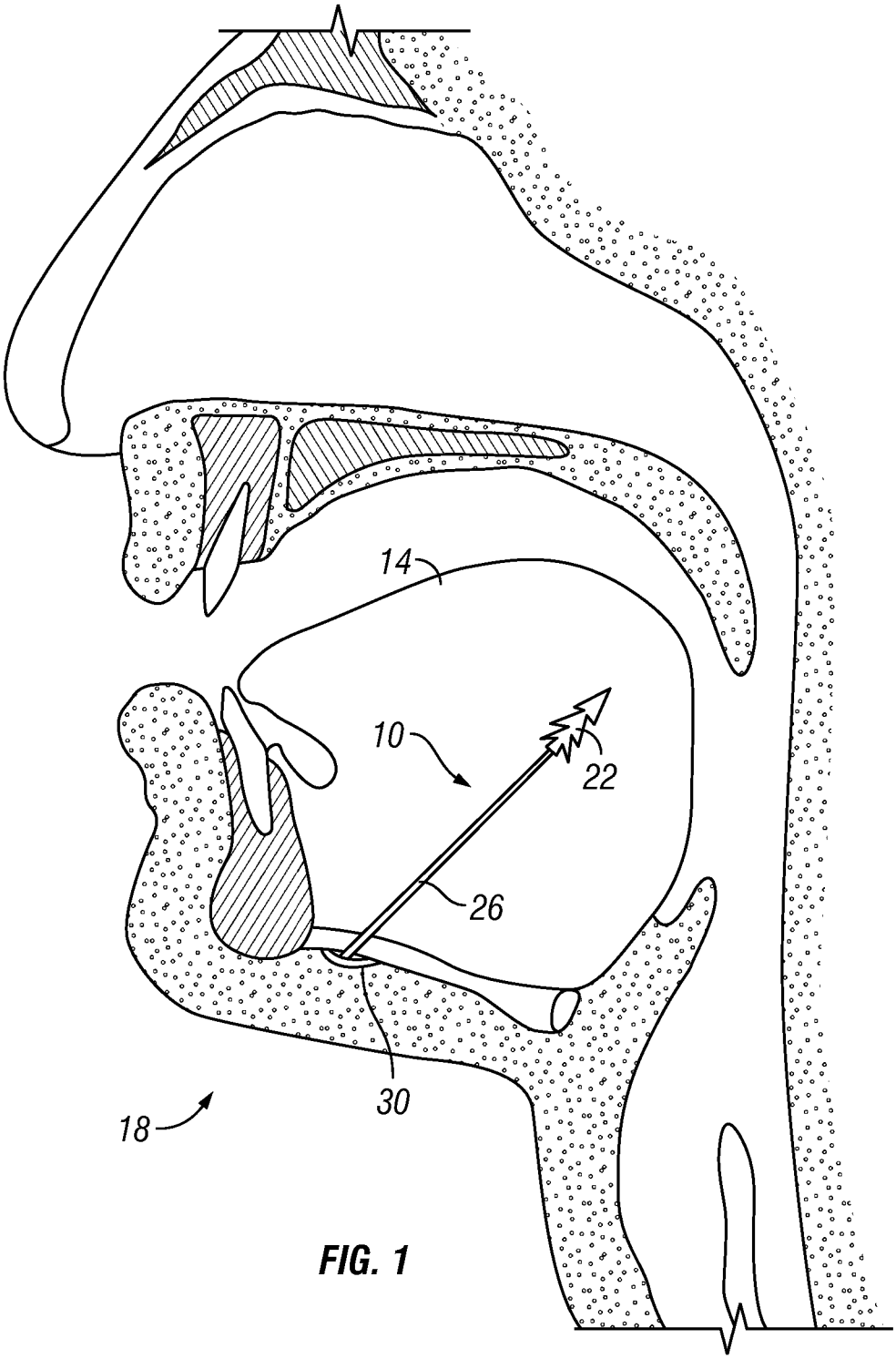


FIG. 1

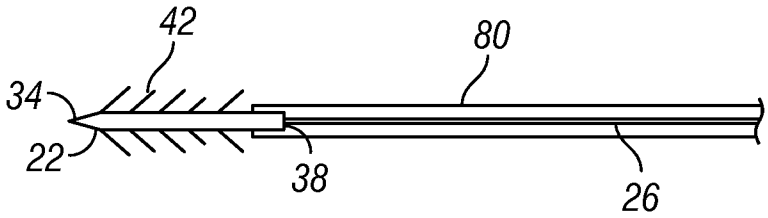


FIG. 2A

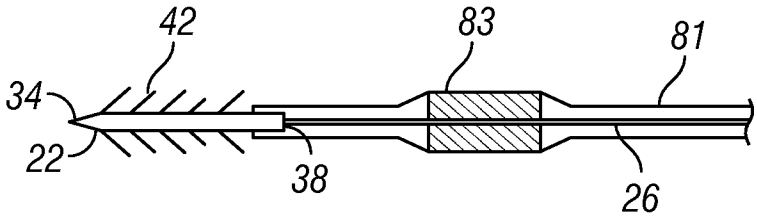


FIG. 2B

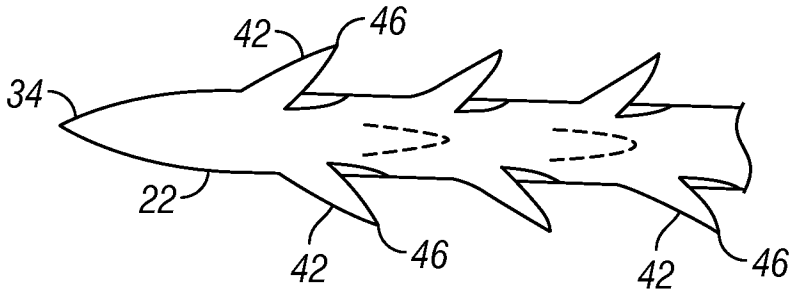


FIG. 3

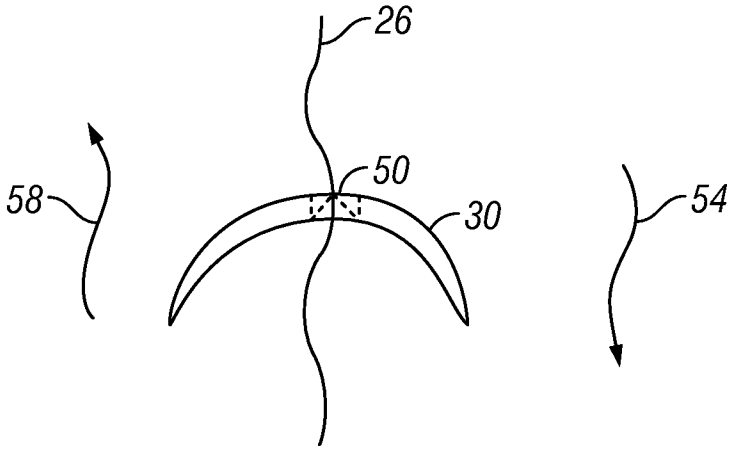


FIG. 4

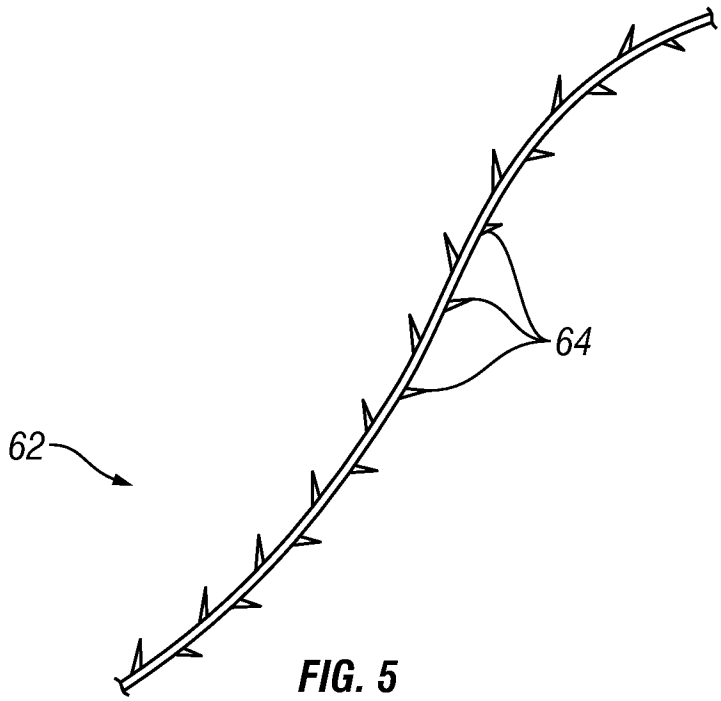


FIG. 5

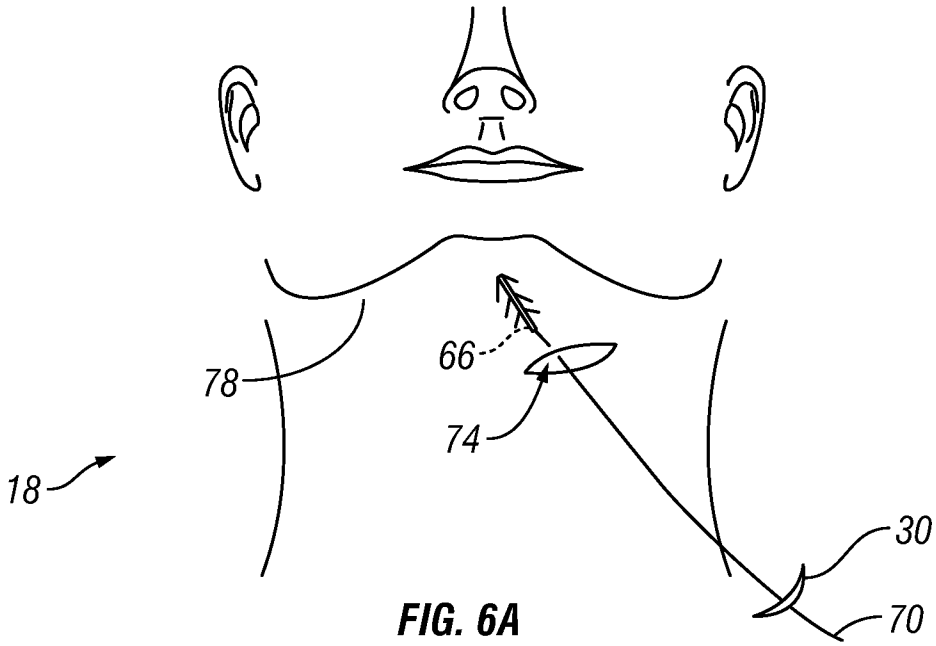


FIG. 6A

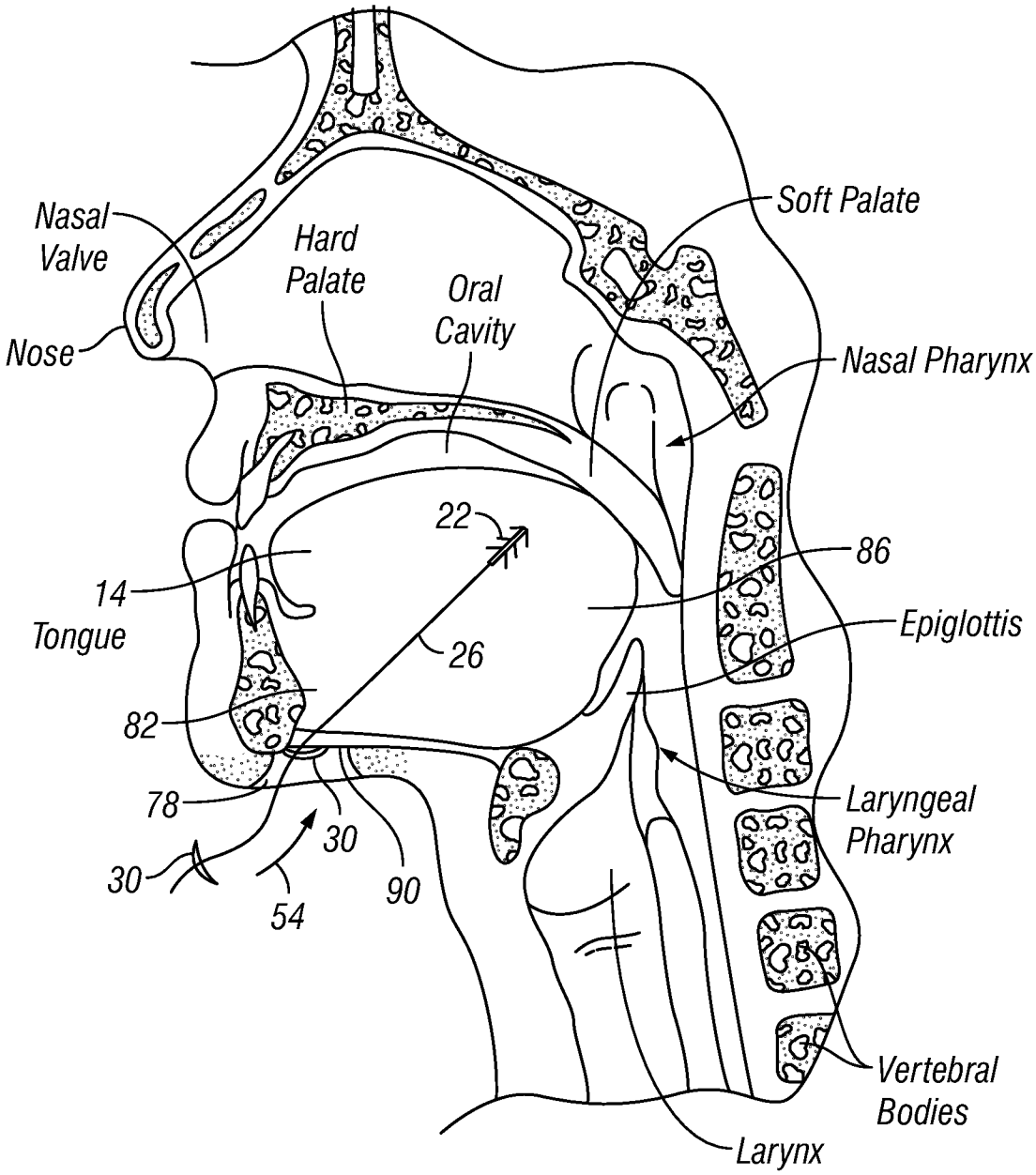

Nasal Valve
Nose
Hard Palate
Oral Cavity
Soft Palate
Nasal Pharynx
22
86
14
Tongue
26
Epiglottis
82
78
30
30
54
90
Laryngeal Pharynx
Vertebral Bodies
Larynx

FIG. 6B

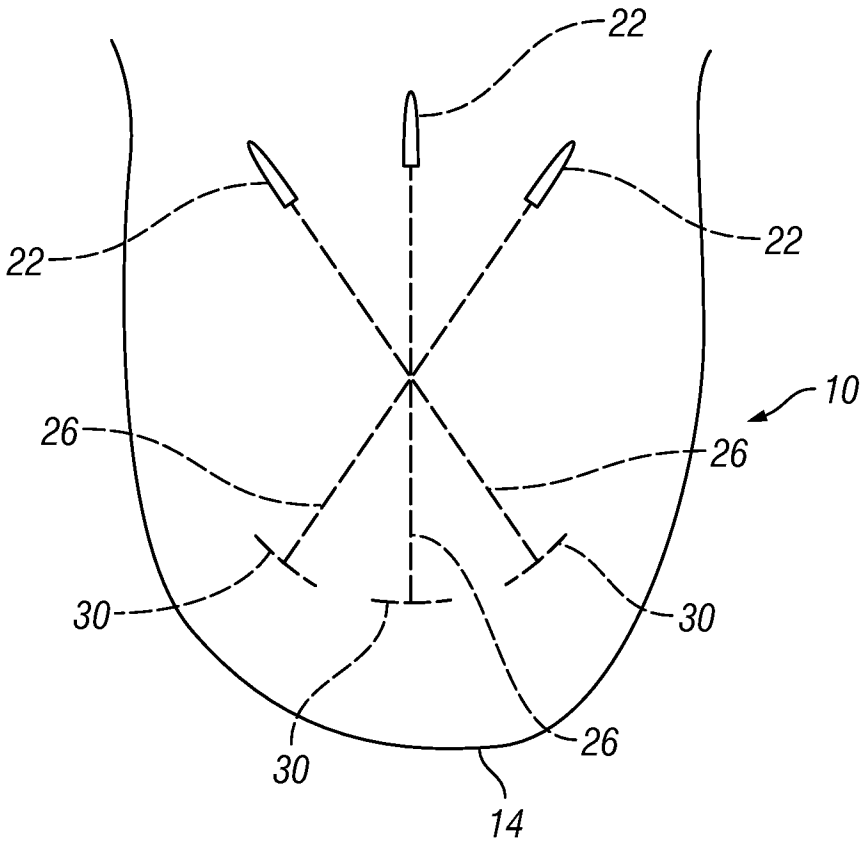


FIG. 6C

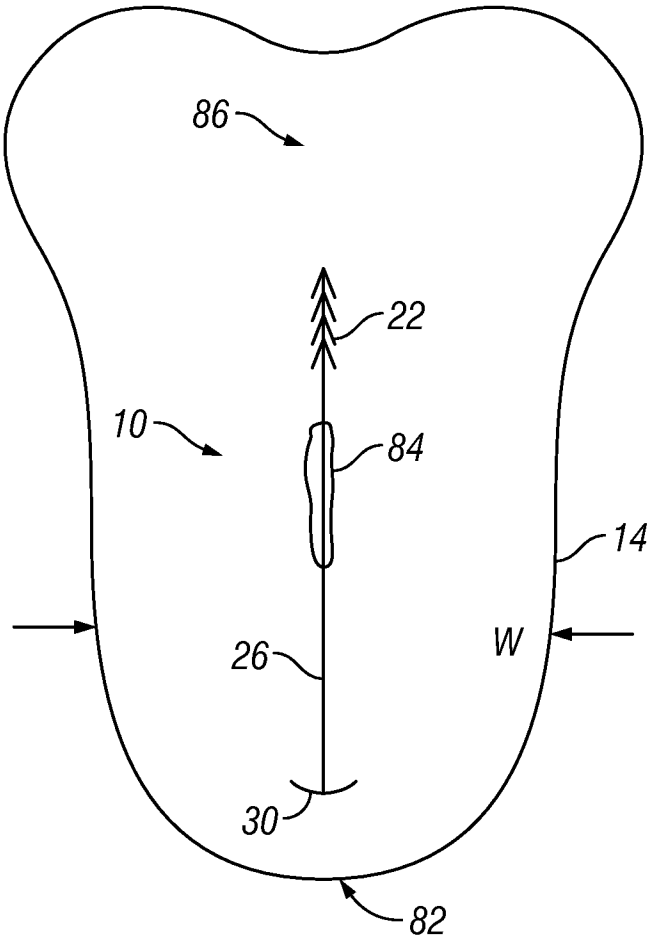


FIG. 6D

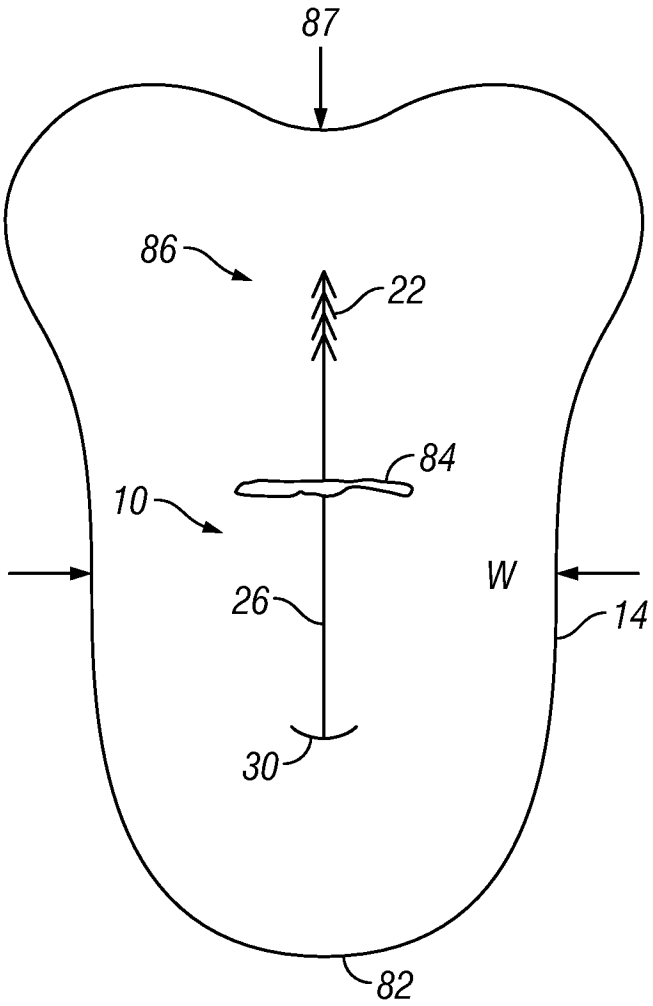


FIG. 6E

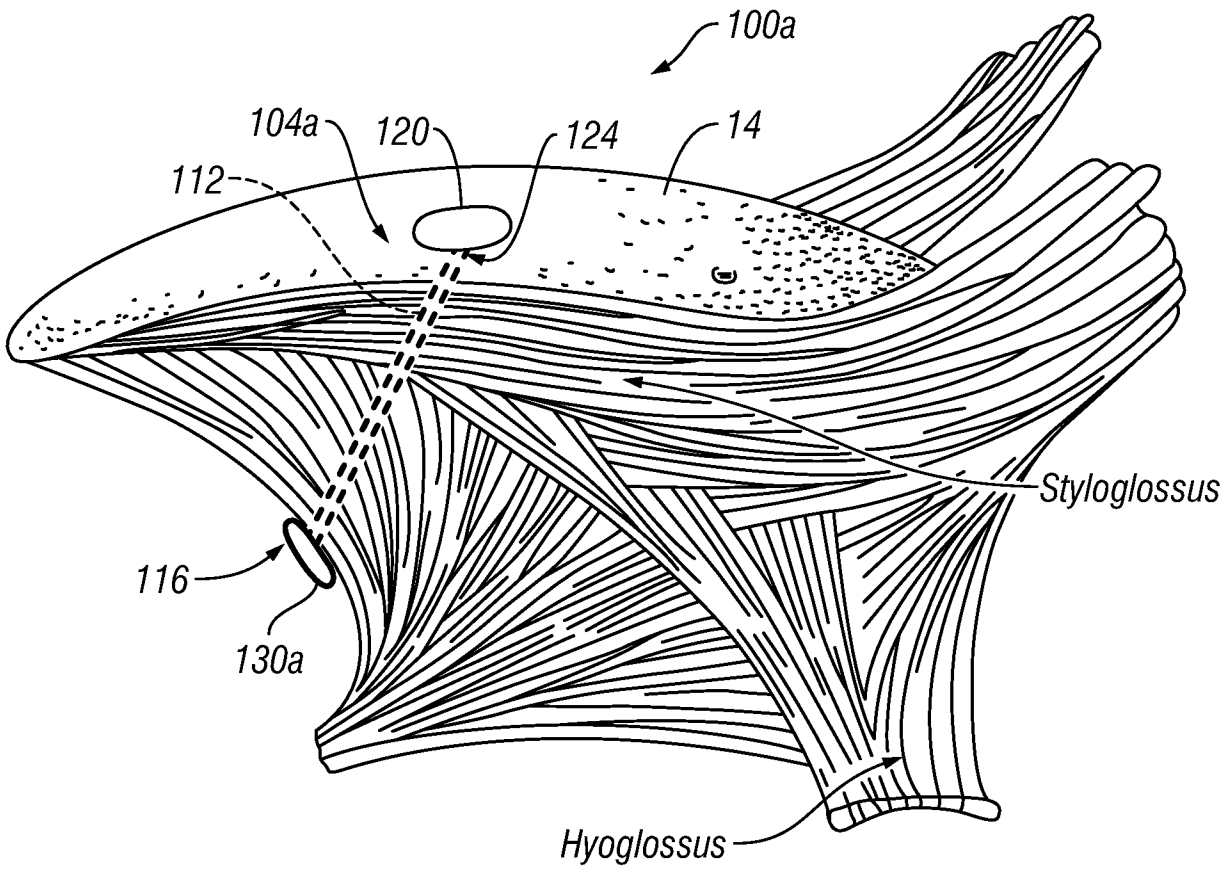


FIG. 7

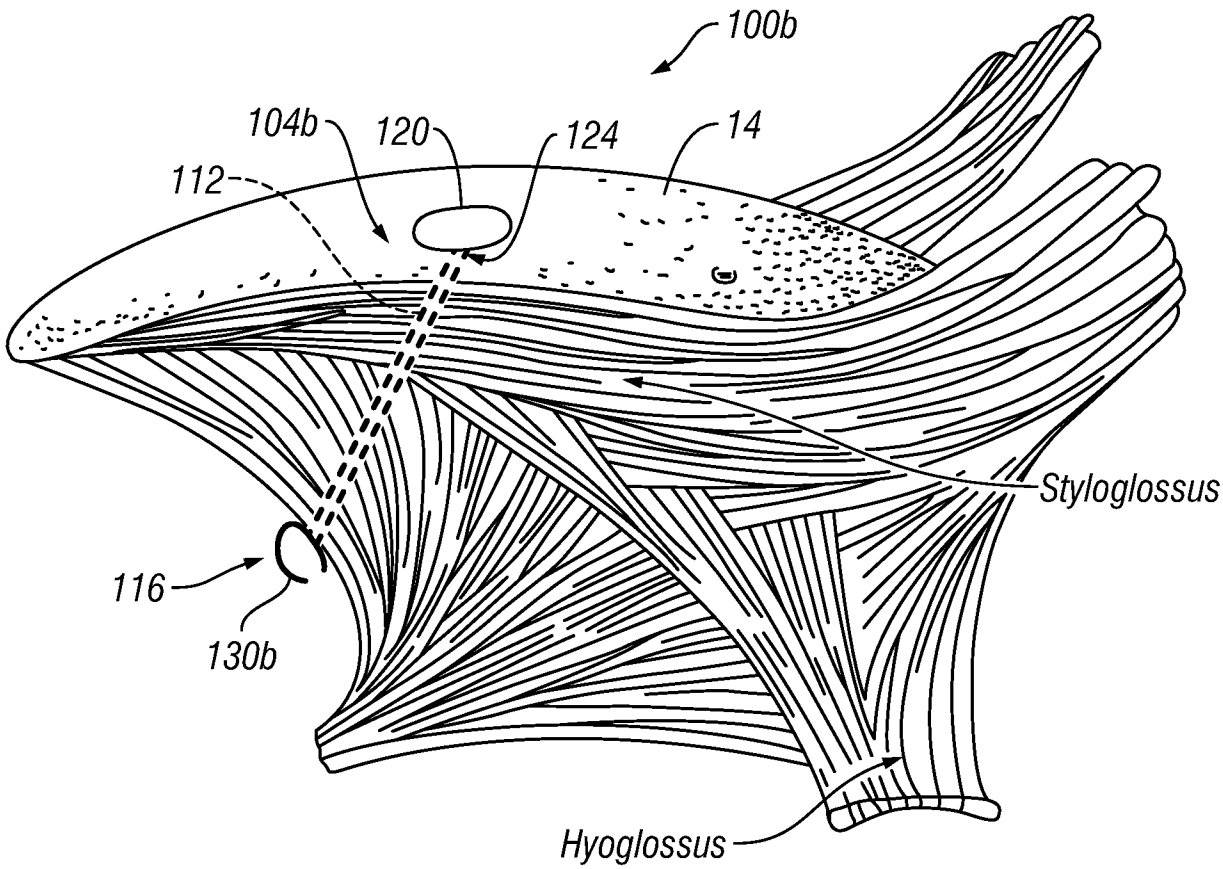


FIG. 8

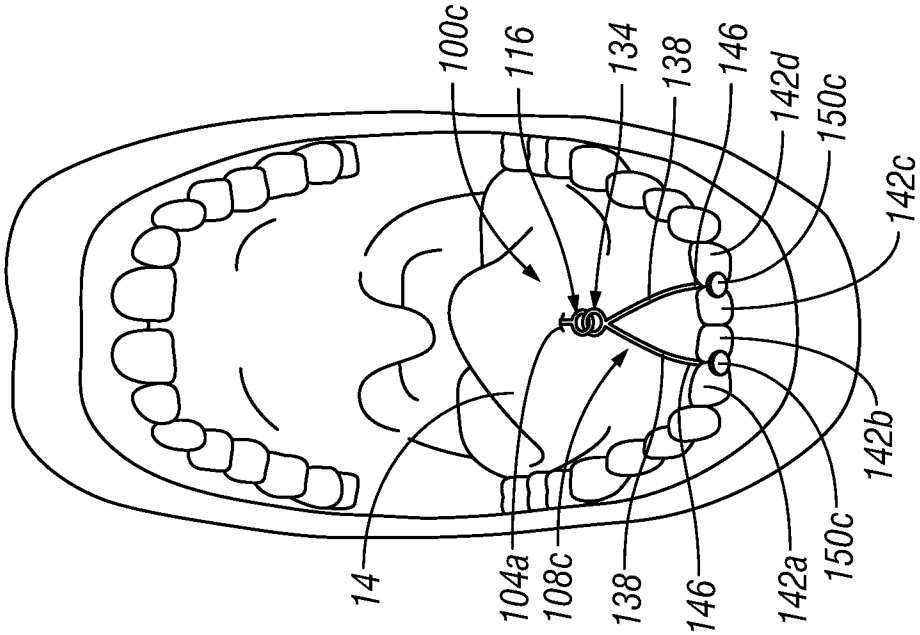
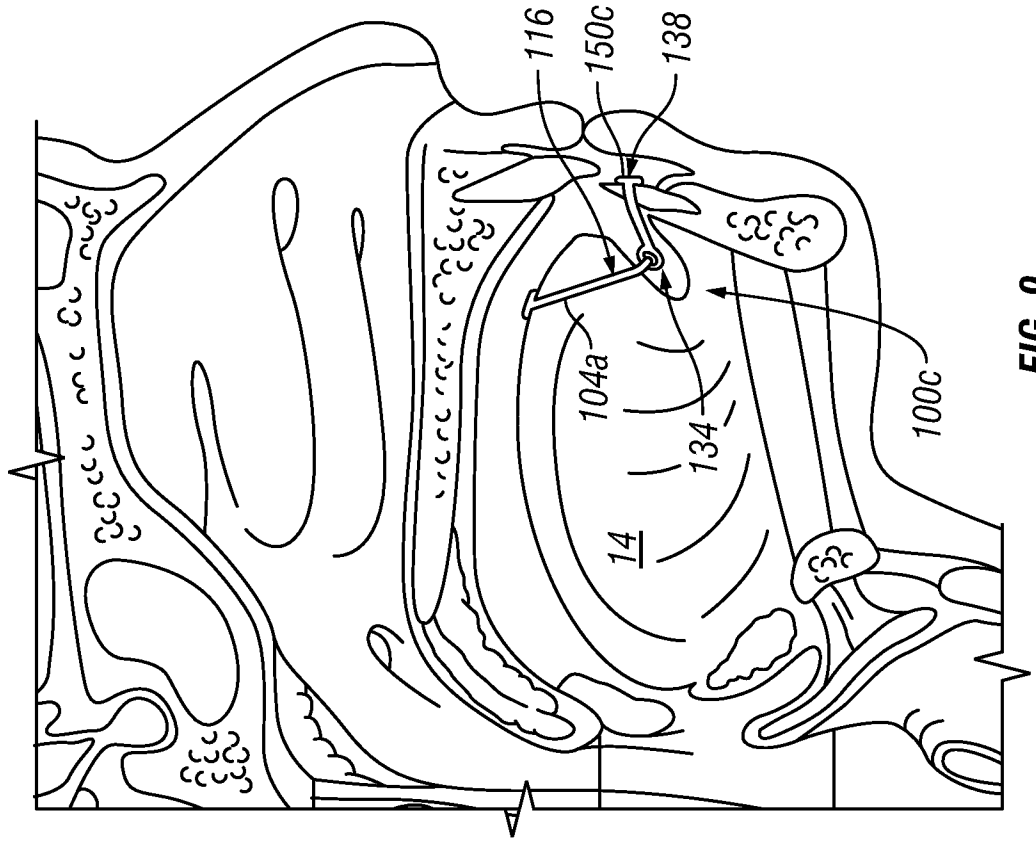

100c
116
134
138
146
142d
150c
142c
142b
150c
142a
146
138
108c
104a
14

FIG. 10


116
150c
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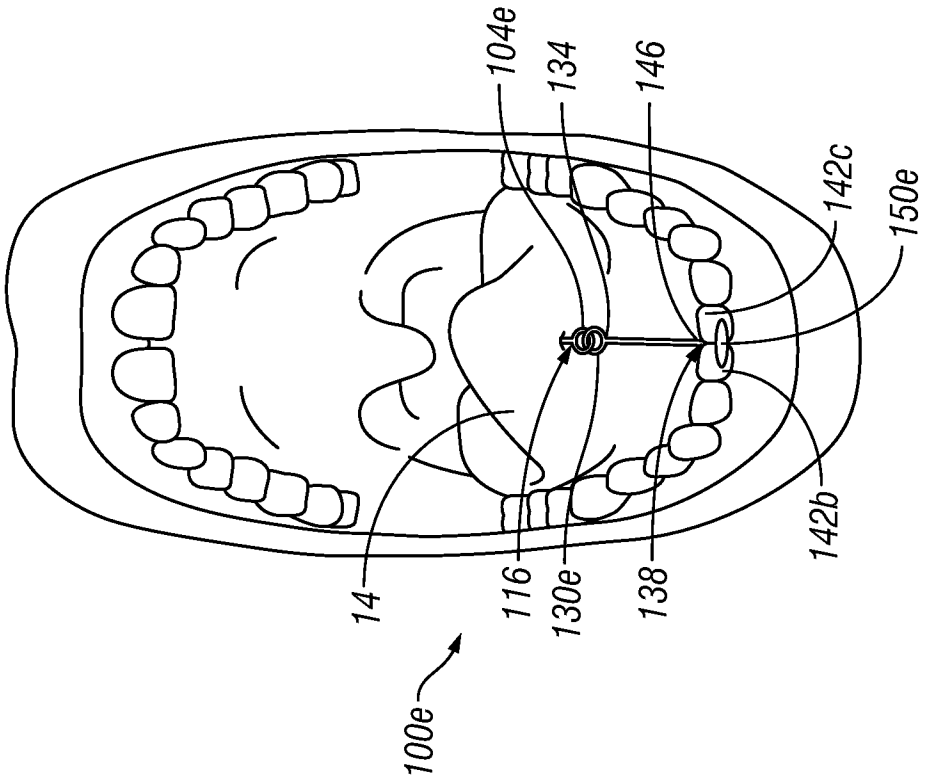
104a
134
14
100c

FIG. 9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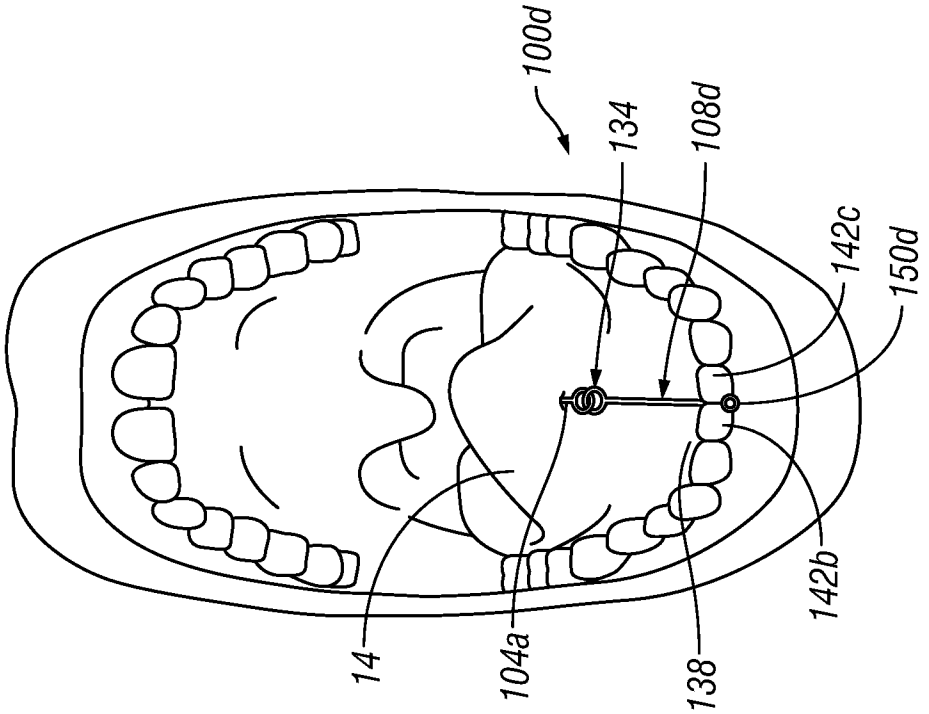
14
116
130e
138
142b
100e

FIG. 12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142c
150d
14
104a
138
142b

FIG. 11

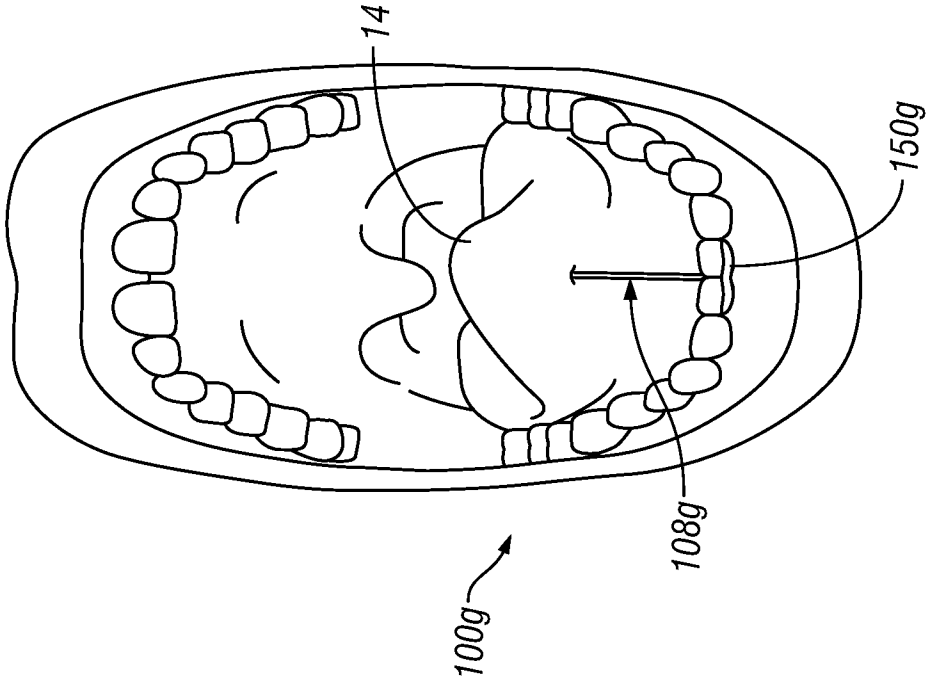


FIG. 14

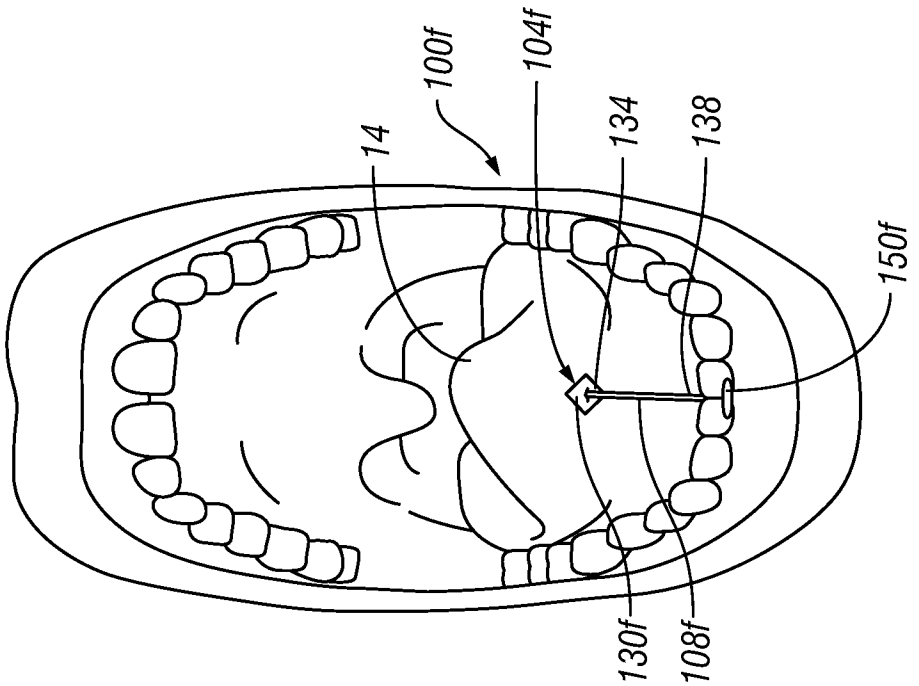


FIG. 13

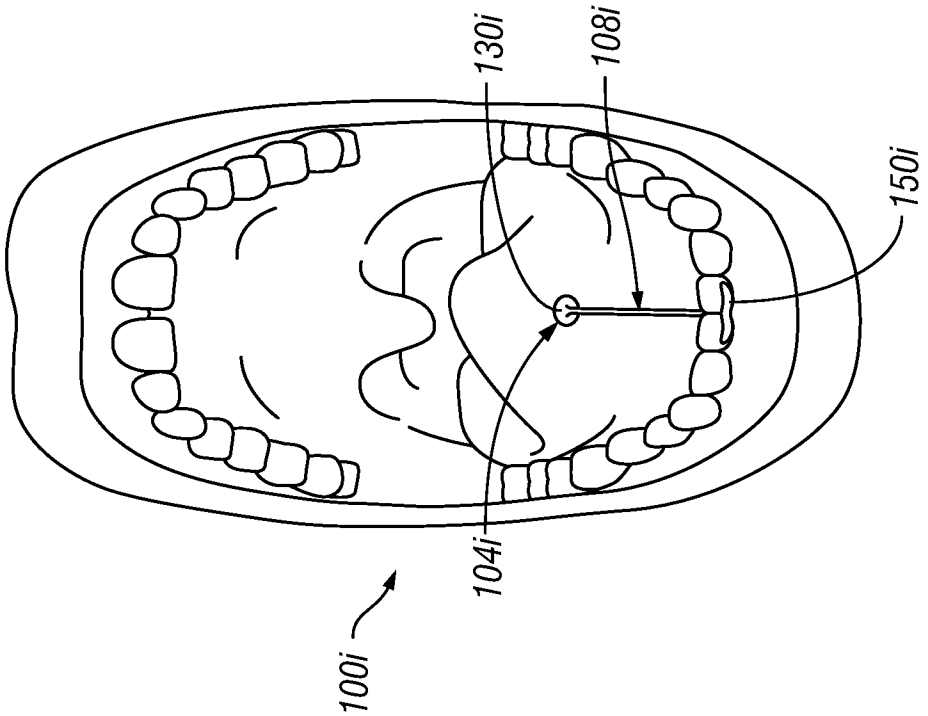


FIG. 16

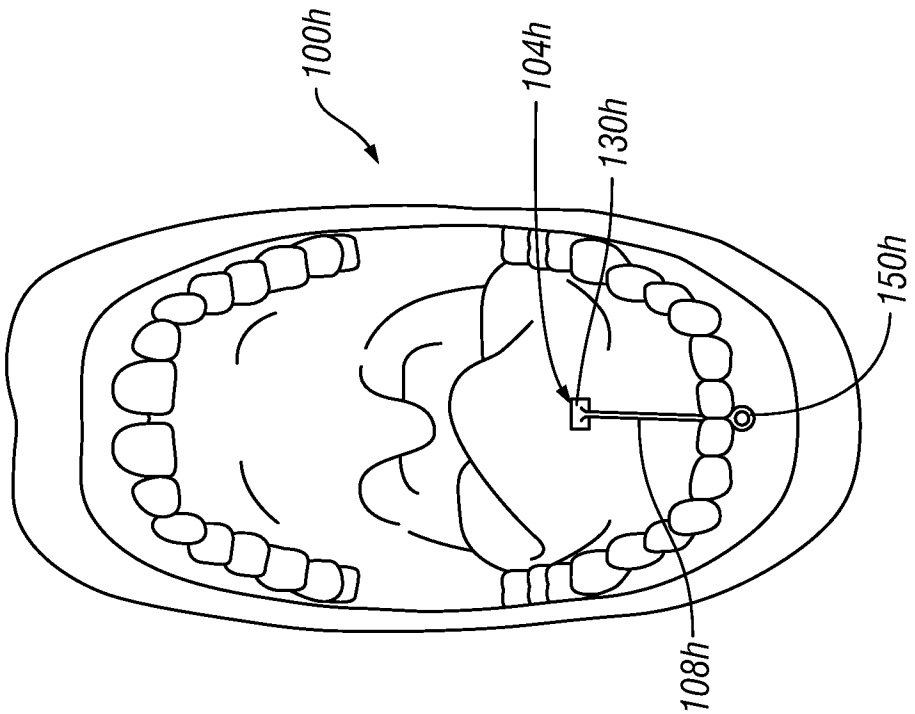


FIG. 15

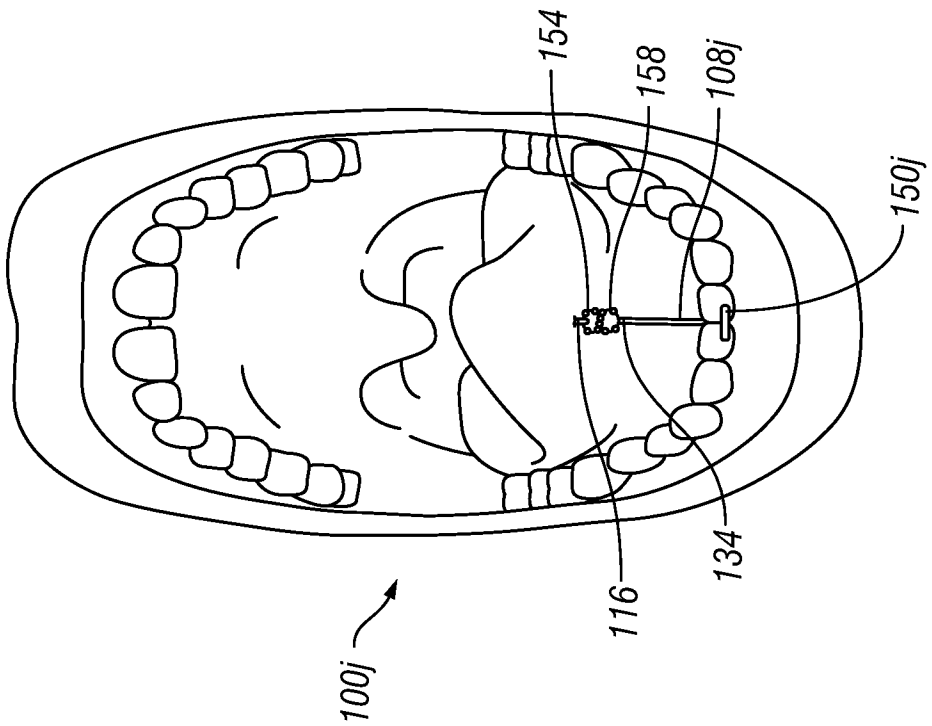


FIG. 18

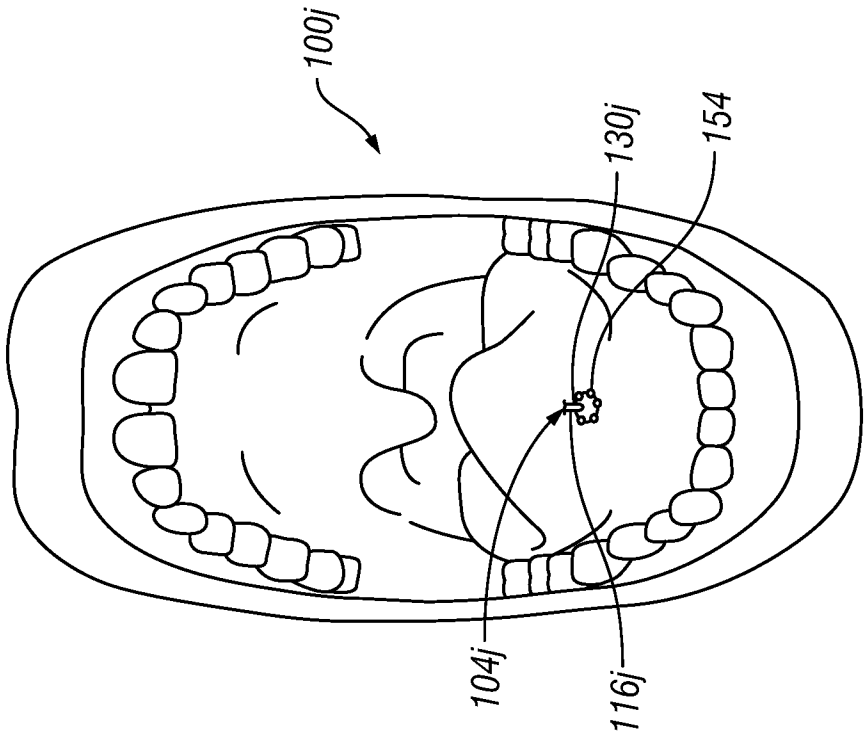


FIG. 17

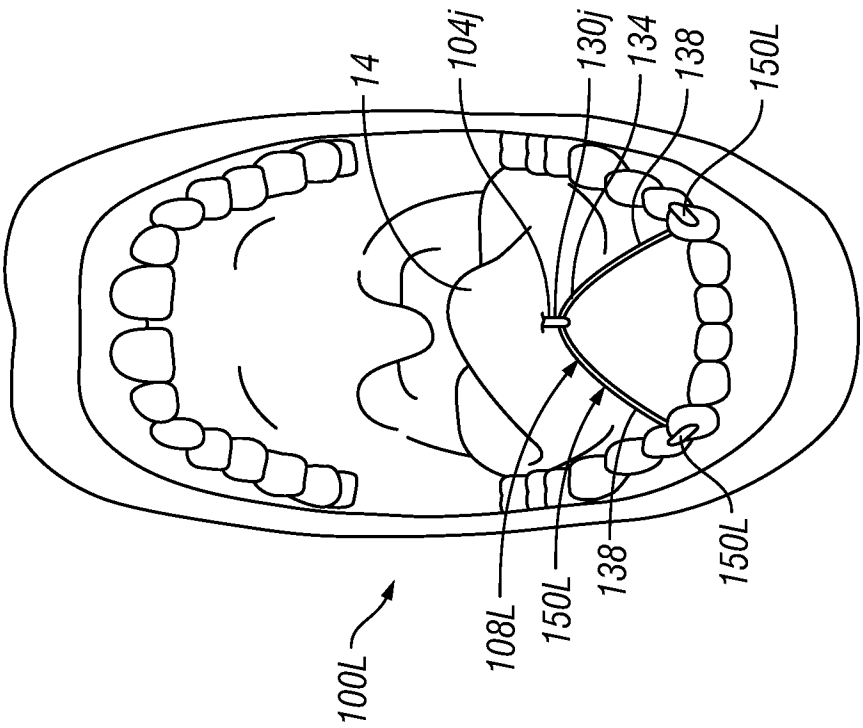
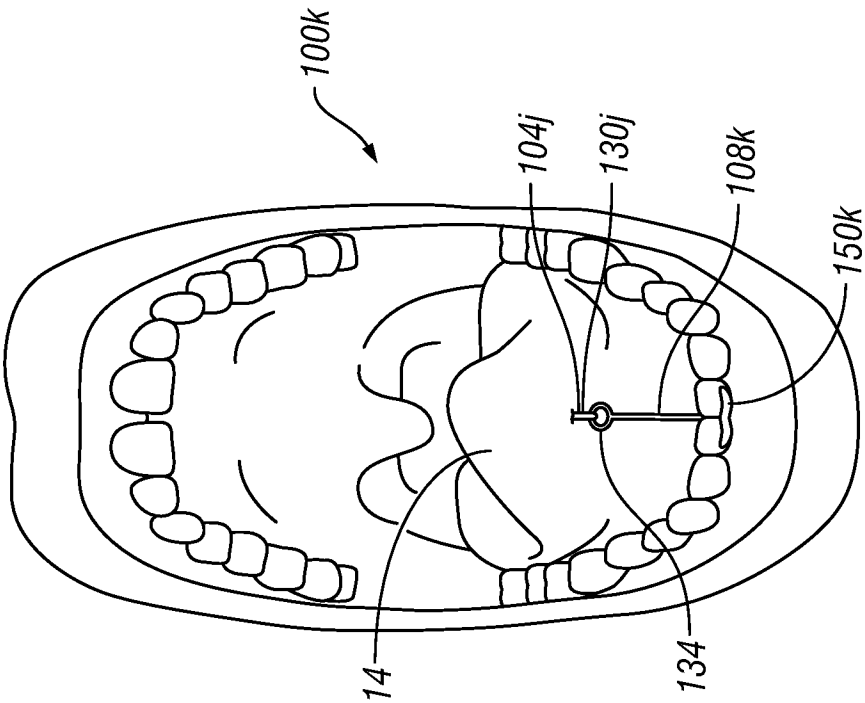

14
104j
130j
134
138
150L
100L
108L
150L
138
150L

FIG. 20


100k
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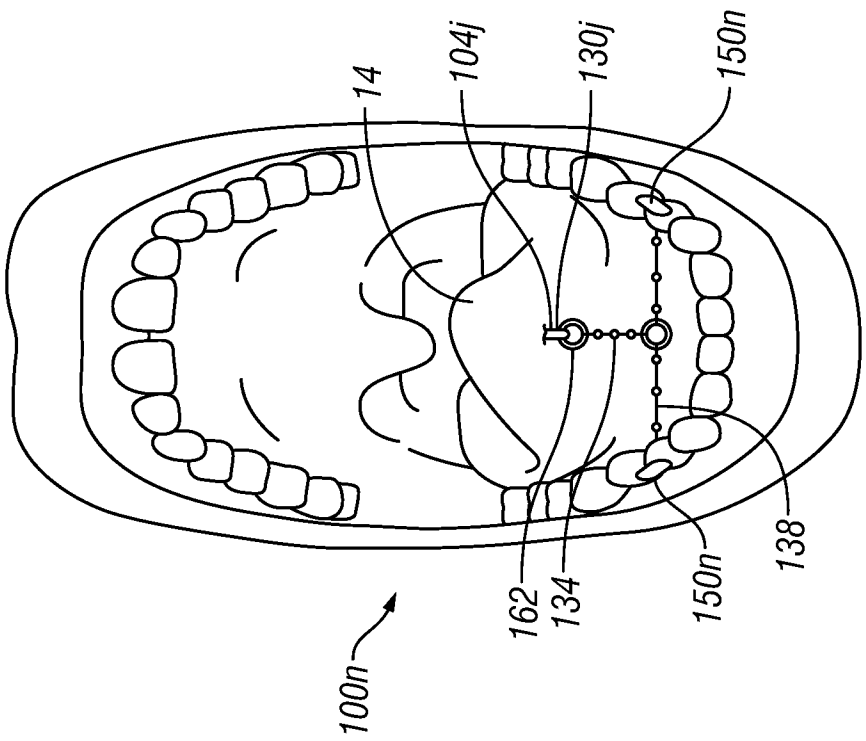
130j
108k
150k
14
134

FIG. 19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100n
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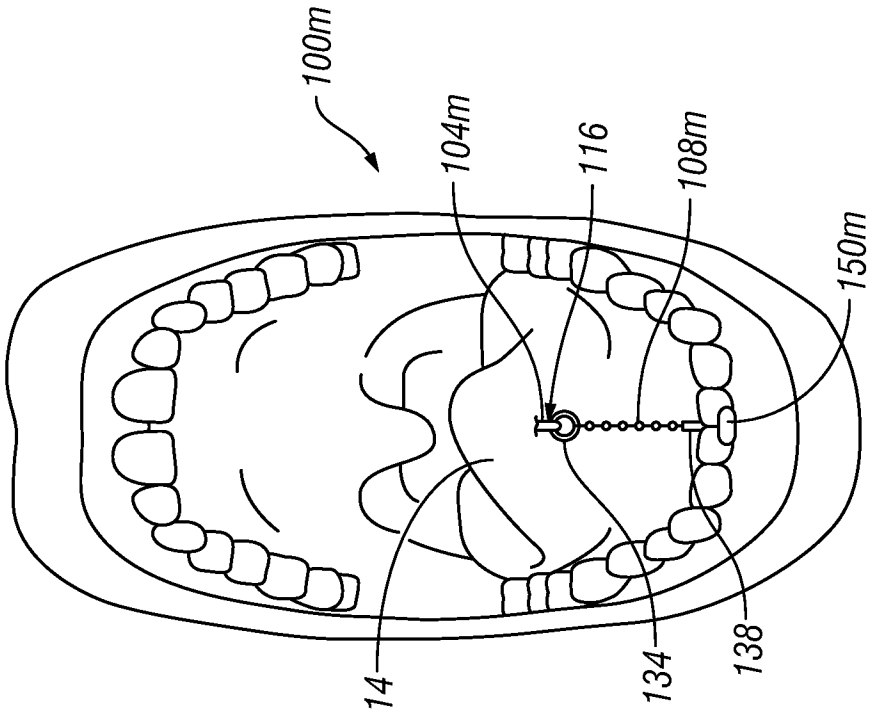
134
150n
138

FIG. 22


100m
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108m
150m
14
134
138

FIG. 21

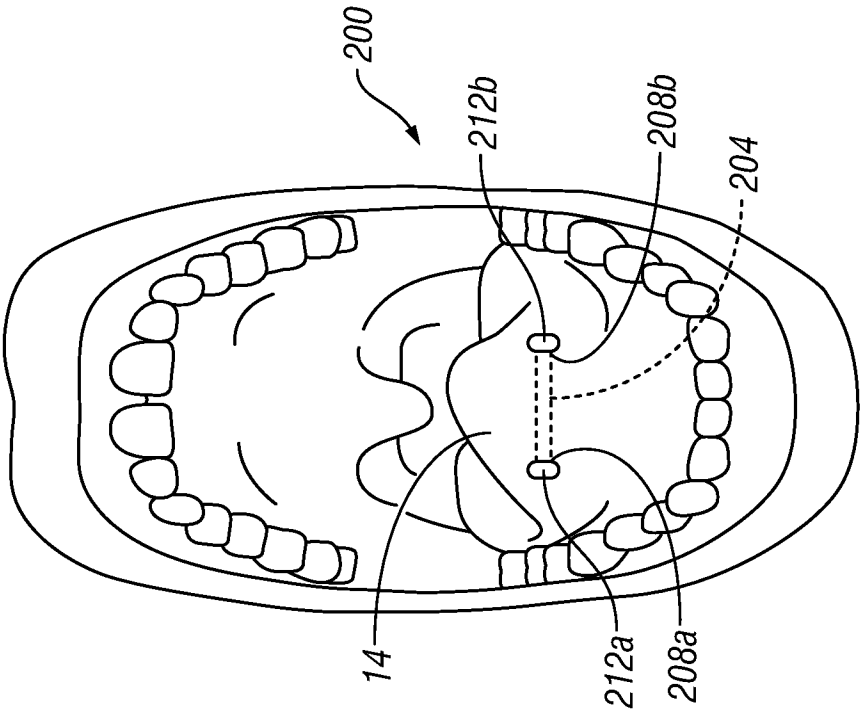
200
212b
208b
204
14
212a
208a

FIG. 24

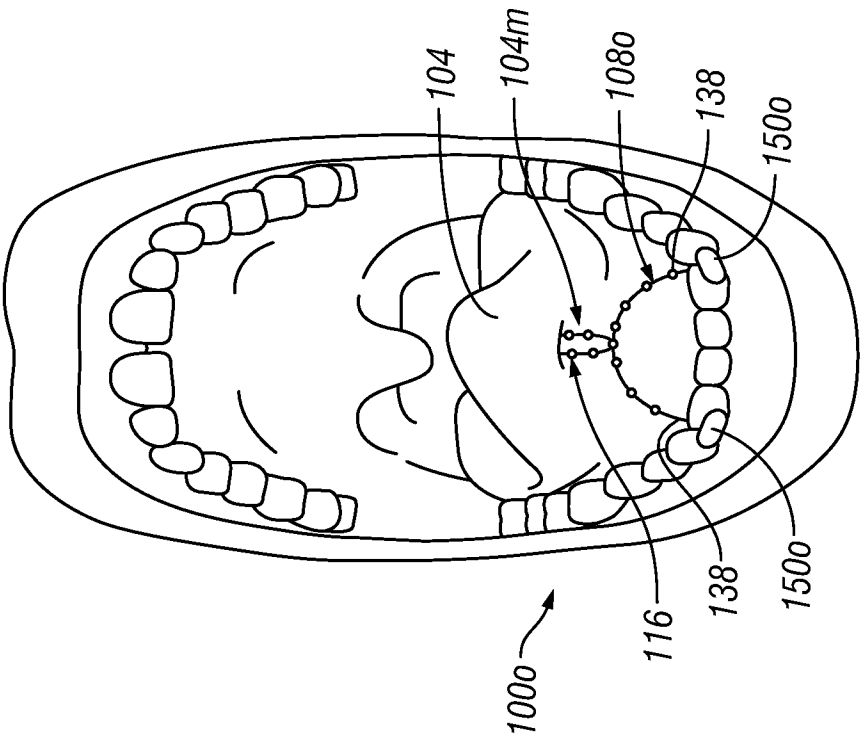
104
104m
108o
138
150o
100o
116
138
150o

FIG. 23

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/058700

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/56 A61B5/07 A61F2/02
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)
A61F A61B A61N

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/066769 A1 (DINEEN MICHAEL [US] ET AL) 20 March 2008 (2008-03-20)	1-4
A	* abstract; figures paragraphs [0024], [0055], [0057], [0062], [0066], [0067], [0072], [0073], [0075]	15-31

X	WO 2007/056583 A1 (ASPIRE MEDICAL INC [US]; VAN DER BURG ERIK [US]; DINEEN MICHAEL [US];) 18 May 2007 (2007-05-18)	1-4
A	* abstract; figures paragraphs [0018], [0024] - [0026], [0086] - [0098], [0100]	15-31

	-/--	

[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

"E" earlier document but published on or after the international filing date

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

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 February 2011	25/02/2011

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	Lager, Johan

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/058700

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/207608 A1 (HIROTSUKA MARK [US] ET AL) 21 September 2006 (2006-09-21)	15,23
A	* abstract; figures 37,38 paragraphs [0181], [0182]	1-4, 16-22, 24-31
A	US 2006/235264 A1 (VASSALLO CHARLES [US]) 19 October 2006 (2006-10-19) * abstract; figures paragraphs [0068] - [0073]	1-4, 15-31
A	US 2008/041398 A1 (HEGDE ANANT V [US] ET AL) 21 February 2008 (2008-02-21) * abstract; figures 44,46 paragraphs [0154] - [0165]	1-4, 15-31

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/058700

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 5-14, 32
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2010/058700

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008066769 A1	20-03-2008	NONE	
WO 2007056583 A1	18-05-2007	US 2007144539 A1	28-06-2007
US 2006207608 A1	21-09-2006	AT 465673 T	15-05-2010
		EP 1850728 A2	07-11-2007
		EP 2174584 A1	14-04-2010
		JP 2008529608 T	07-08-2008
		US 2006201519 A1	14-09-2006
		US 2006207606 A1	21-09-2006
		US 2006207607 A1	21-09-2006
		US 2006207612 A1	21-09-2006
		WO 2006101610 A2	28-09-2006
US 2006235264 A1	19-10-2006	NONE	
US 2008041398 A1	21-02-2008	EP 2200546 A1	30-06-2010
		WO 2009032625 A1	12-03-2009