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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 April 2010 (22.04.2010)

PCT

(10) International Publication Number
WO 2010/043043 A2

(51) International Patent Classification:
G09B 9/00 (2006.01) *A61B 19/00* (2006.01)
G09B 19/00 (2006.01)

(21) International Application Number:
PCT/CA2009/001467

(22) International Filing Date:
14 October 2009 (14.10.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/105,418 14 October 2008 (14.10.2008) US

(71) Applicant *(for all designated States except US)*: **PYNG MEDICAL CORPORATION** [CA/CA]; #7 - 13511 Crestwood Place, Richmond, British Columbia V6V 2E9 (CA).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **STOCK, Lawrence** [US/US]; c/o #7 - 13511 Crestwood Place, Richmond, British Columbia V6V 2E9 (CA). **RUMSEY, Royce** [US/US]; c/o #7 - 13511 Crestwood Place, Richmond, British Columbia V6V 2E9 (CA). **RANGER, Nicole** [CA/CA]; c/o #7 - 13511 Crestwood Place, Richmond, British Columbia V6V 2E9 (CA).

(74) Agent: **MORRISON, Lesley M.**; c/o Fasken Martineau DuMoulin LLP, 2900 - 550 Burrard Street, Vancouver, British Columbia V6C 0A3 (CA).

(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, 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, IS, JP, KE, KG, KM, 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, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (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, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

(54) **Title**: TRAINING DEVICE FOR MEDICAL PROCEDURES

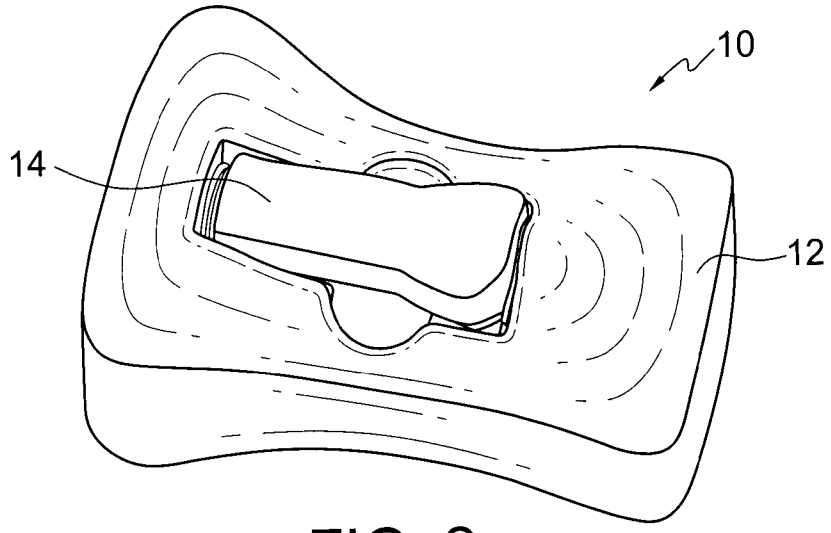

FIG. 2

(57) **Abstract**: A training device includes a tracheal module for simulating a trachea of a mammal, the tracheal module being flexible and including a pair of severable membranes for receiving an incision to simulate a medical procedure and being selectively receivable in a base unit.

WO 2010/043043 A2

TRAINING DEVICE FOR MEDICAL PROCEDURES

Technical Field

[0001] The present invention relates to medical training devices, in particular, training devices for use in simulating emergency medical procedures.

Background

[0002] In certain emergency situations, first responders must perform medical procedures to stabilize an individual's key physiological functions. These medical procedures are often invasive and are typically administered in less than ideal weather and lighting conditions. Examples of medical procedures that may be performed by first responders include: tracheotomies, cricothyrotomies, installation of nasopharyngeal airways and installation and administration of solutions such as blood, plasma and saline via intraosseous and/or intravenous routes. When the air passages leading to an individual's trachea from their mouth and/or nose are obstructed or seriously damaged, a tracheotomy or cricothyrotomy may have to be performed immediately in order to open an alternative airway and maintain the supply of oxygen to the lungs.

[0003] Tracheotomies and cricothyrotomies are surgical procedures that are performed on an individual's throat by making an incision into the airway. Once the incision has been made, a tracheotomy tube may be installed in the airway. These procedures allow for respiration to be maintained in emergency situations in which the individual's airway is blocked by foreign objects, by swelling, or as a consequence of major facial trauma and damage to the nasal and oral passages leading into the trachea.

[0004] Tracheotomy and cricothyrotomy procedures are typically performed by skilled medical personnel including paramedics, emergency physicians, and surgeons. Related surgical procedures involving dissection with scalpels typically result in blood release and are difficult for first responders to administer in emergency field situations. Cricothyrotomies are considered easier and faster than tracheotomies. However, precision is required during the incision into the trachea via the cricothyroid membrane, which is located just underneath the thyroid cartilage. As a result, these procedures are generally performed as last resorts under emergency situations.

[0005] First responders typically undergo training in order to prepare for emergency situations in which access to an airway of an individual must be achieved. Training is typically performed using human cadavers or pig cadavers, which allow first responders to become sufficiently familiar with physical landmarks associated with the thyroid-critoid-tracheal cartilage to facilitate rapid identification of target incision sites. Other devices and methods for training first responders and medical personnel are needed.

Summary

[0006] There is disclosed herein a training device including a tracheal module for simulating a trachea of a mammal, the tracheal module being flexible and including a pair of severable membranes for receiving an incision to simulate a medical procedure.

[0007] There is disclosed herein a method for training an individual to perform a medical procedure, the method including: providing a tracheal module, the tracheal module including a pair of severable membranes for receiving an incision to simulate a medical procedure; and providing instructions for performing the medical procedure; wherein the tracheal module is flexible to simulate a trachea of a mammal.

Drawings

[0008] The following figures set forth embodiments of the invention in which like reference numerals denote like parts. Embodiments of the invention are illustrated by way of example and not by way of limitation in the accompanying figures.

[0009] Figure 1 is a cross-sectional side view of an example of an installation of a tracheotomy tube after a tracheotomy procedure;

[0010] Figure 2 is an isometric view of a training device according to an embodiment of the invention;

[0011] Figure 3 is an isometric view of a base of the training device of Figure 2;

[0012] Figure 4 is a side view of the base of Figure 3;

[0013] Figure 5 is a side view of a base according to another embodiment of the invention;

[0014] Figure 6 is an isometric view of a tracheal module of the training device of Figure 2;

[0015] Figure 7 is a side sectional view of the tracheal module of Figure 6;

[0016] Figure 8 is an end view of the tracheal module of Figure 6;

[0017] Figure 9 is a side view of the tracheal module of Figure 6;

[0018] Figure 10 is an end view of a membrane of the tracheal module of Figure 6;

[0019] Figure 11 is an isometric view of a cover of the tracheal module of Figure 6;

[0020] Figure 12 is an isometric view of a tube of the tracheal module of Figure 6;

[0021] Figure 13 is an end view and a side view of another membrane of the tracheal module of Figure 6;

[0022] Figure 14 is an isometric view of portions of the tracheal module of Figure 6 illustrating the flexibility thereof;

[0023] Figure 15 is top view of portions of a tracheal module according to another embodiment of the invention;

[0024] Figure 16 is an isometric view of the training device of Figure 2 showing the tracheal module partially received in the base;

[0025] Figure 17 is an isometric view of the training device of Figure 2, a percutaneous cricothyrotomy device and a tracheotomy tube;

[0026] Figure 18 is an isometric view of the training device of Figure 2 showing a trainee locating a target incision site;

[0027] Figure 19A is an isometric view of the training device of Figure 2 showing an incision being performed using the percutaneous cricothyrotomy device;

[0028] Figure 19B is a side view of portions of Figure 20A;

[0029] Figure 20 is an isometric view of the training device of Figure 2 showing an individual spreading a portion of the tracheal module;

[0030] Figure 21 is an isometric view of the training device of Figure 2 showing a further incision being performed;

[0031] Figure 22 is an isometric view of the training device of Figure 2 showing jaws of the percutaneous cricothyrotomy device spreading apart an opening formed by the incisions;

[0032] Figure 23 is an isometric view of the training device of Figure 2 showing the tracheotomy tube being inserted into the opening;

[0033] Figure 24 is an isometric view of the training device of Figure 2 showing the tracheotomy tube fully inserted into the opening; and

[0034] Figures 25-28 show isometric views of the training device of Figure 2 being operated on using a scalpel and retractors.

Detailed Description of Embodiments of the Invention

[0035] Referring to Figure 1, an example of an installation of a tracheotomy tube into a trachea in between the upper tracheal cartilages is shown. In order to properly install the tracheotomy tube, a first responder makes an incision through the skin 1 and epidermal layers and through an opening in the tracheal cartilage below the thyroid cartilage 2 and the cricoid cartilage 3. The incised opening is then spread sufficiently wide to insert the tracheotomy tube 5 into the trachea 4. The tracheotomy tube 5 is secured to the throat of the individual.

[0036] Referring to Figure 2, a training device 10 according to an embodiment is generally shown. The training device 10 anatomically simulates a neck and throat area of an adult human in order to allow trainees to perform medical procedures thereon for training purposes. The training device 10 is manufactured using selected components and materials that are assembled in a manner that provides the "feel" of the neck and throat area to trainees. The training medical device 10 is suitable for performing training medical procedures thereon that include gaining access to an airway of an individual. In particular, cricothryrotomy and tracheotomy procedures may be performed. The training medical procedures may further include the rapid installation of tracheal air tubes, i.e., tracheal intubations, through a subject's throat into their trachea.

[0037] The training device 10 includes a base unit 12 and a tracheal module 14. Referring to Figures 3 and 4, the base unit 12 includes a generally flat bottom surface 16 that can be placed onto a work surface (not shown) to allow the training medical procedure to be safely performed. The dimensions of the base unit 12 generally approximate the neck and throat area of an adult human. The base unit 12 includes a cavity 18 that is formed in a top surface 22 of the base unit 12 for receiving the tracheal module 14, as shown in Figure 4A. The cavity 18 is sized to limit movement of the

tracheal module 14 relative to the base unit 12 during performance of the training medical procedure.

[0038] The cavity 18 includes a pair of recesses 20 that are sized to allow a trainee's fingers to be received therein when gripping the tracheal module 14 along a length thereof. Gripping of the tracheal module 14 occurs during performance of the training medical procedure in order to allow the trainee to identify landmarks and stabilize the tracheal module 14 during an incision. Gripping of the tracheal module 14 further occurs during insertion of the tracheal module 14 into the base unit 12 in preparation for a training session, as shown in Figure 17, and removal of the tracheal module 14 from the base unit 12 upon completion of the training session

[0039] The base unit 12 is made of a resilient material selected to closely resemble the properties of a human throat. As shown in Figure 5, the base unit 12 may be hyper-extended upward in order to approximate a human subject during the *in vivo* performance of medical procedures.

[0040] Referring to Figures 6 and 7, the tracheal module 14 includes a tube 50 for simulating a trachea tube, a first membrane 60 for simulating a membrane overlay of the trachea tube, a cover 24 for simulating interconnections of a thyroid cartilage, a cricoid cartilage and a plurality of tracheal cartilages, and a second membrane 44 for simulating the skin and epidermal layers overlying the throat. End caps 46 are provided on opposite ends of the tracheal module 14 to facilitate the attachment of hoses that allow for simulation of lung inflation during training.

[0041] As shown in Figure 11, the cover 24 includes a channel 26 that is sized to receive the tube 50. First protrusions 30 are provided on an outer surface 32 of the cover 24 and are spaced along the cover 24 to simulate tracheal cartilage. Slots 34 are provided between some of the first protrusions 30 to simulate tracheal openings. A second protrusion 36 is provided adjacent to the first protrusions 30 to simulate the cricoid cartilage. An opening 38, which simulates the cricothyroid opening, is provided between the second protrusion 36 and a raised portion 40 that is shaped to simulate the thyroid cartilage. Flexing relief slots 42 are provided at regular intervals along the side edges of the cover 24 to accommodate flexing of the tracheal module 14. In one embodiment, the slots 34 are provided between each of the first protrusions 30.

[0042] The cover 24 may be produced by injection molding or, alternatively, cast molding. Suitable materials for the cover 24 include ABS (Acrylonitrile Butadiene Styrene), polyurethane or any resilient material that enable the cover 24 to provide a tactile sensation of a human trachea to a trainee.

[0043] Referring also to Figure 12, the tube 50 includes outwardly extending ribs 52, which are provided on an outer surface 54 thereof. The ribs 52 approximate the physical structure of a human trachea. An opening 56, which simulates a cricothyroid opening, and a slot 58, which simulates a tracheal opening, are provided in the tube 50. In one embodiment, the tube is a respiratory tube. As will be appreciated by a person skilled in the art, the tube 50 may be any suitable tube that is flexible and made of a resilient material.

[0044] Referring to Figure 13, the first membrane 60 is generally a flexible material that is sized to receive the tube 50. The first membrane 60 fits snugly over the tube 50 to simulate the cricothyroid membrane. Together, the tube 50 and the first membrane 60 provide a tube assembly that is received in the channel 26 of the cover 24.

[0045] Referring to Figures 7 and 9, the second membrane 44 is generally a flexible material that is sized to receive the cover 24 and tube assembly. The second membrane 44 fits snugly over the tracheal cover 24 to simulate skin and epidermal layers overlaying the tracheal cartilages and trachea. In one embodiment, the second membrane 44 includes an adhesive underside that secures the second membrane 44 to the cover 24 and tube assembly. In another embodiment, the end caps 46 maintain the second membrane 44 in position.

[0046] The first membrane 60 and second membrane 44 are made of a thin mylar or vinyl film. In one embodiment, the film has a thickness of 2 to 3 mm. The first and second membranes 60, 44 may be produced as a cylinder or, alternatively, mechanically formed into a cylinder using an adhesive or a fusing process. In one embodiment, the first membrane 60 is not formed into a cylinder and instead is sized to cover the openings 56, 58 of the tube 50. In this embodiment, the first membrane 60 is coupled to the tube 50 by an adhesive or in another suitable manner that would be understood by a person skilled in the art. Materials of both membranes 60, 44 are selected for their surface and structural properties to provide a tactile response that is

comparable to the human body surface and the underlying epidermal and endodermal layers. Suitable materials include latex compositions, polythelene compositions, polypropylene compositions, non-latex materials including Nitril and materials comprising multiple layers of one or more such compositions, for example. The first membrane 60 and the second membrane 44 may be made of the same material or, alternatively, may be made of different materials.

[0047] Referring to Figure 14, the tracheal module 14 is capable of flexing as shown. In Figure 14, the second membrane 44 has been removed in order to more clearly illustrate the flexibility of the tracheal module 14. The tracheal module 14 is assembled as follows: 1) the first membrane 60 slides over the tube 50; 2) the tube assembly is then inserted into the cover 24 such that opening 38 of the cover 24 is aligned with opening 56 of the tube 50 and the slot 34 nearest to the opening 38 of the cover 24 is aligned with opening 58 of the tube 50. Once the tube assembly and cover 24 are properly aligned, an O-ring 46 is used to secure the components in position; 3) the second membrane 44 then slides over the cover 24 and tube assembly; and finally, 4) end caps 48 slide onto the ends of the tracheal module 14. Assembly and disassembly of the tracheal module 14 may be achieved rapidly to allow for easy replacement of severed first and second membranes 60, 44 following a training medical procedure, for example.

[0048] In one embodiment, which is shown in Figure 15, the cover 24 includes grooves 66 that are provided near the ends of the cover 24. In this embodiment, a pair of O-rings 64 that are received in the grooves 66 of the cover 24 replace the end caps 48 toe secure the tracheal module components to one another.

[0049] In use, the tracheal module 14 is first assembled and then inserted into the base unit 12 in preparation for a training medical procedure, as shown in Figures 16 and 17. In this example, a percutaneous cricothyrotomy device 6 (CRIC™ Cricothyrotomy System, Pyng Medical Corp., Richmond, BC, Canada) is used to perform a cricothryrotomy procedure on the training device 10. Referring to Figure 18, a trainee first locates a target incision site using anatomical references on the tracheal module 14. The target incision site for the cricothryrotomy procedure is through openings 38 and 56 of the cover 24 and tube 50, respectively, which simulate the cricothyroid

opening. The location of anatomical references will not be discussed herein, a person skilled in the art of cricothryrotomy procedures would readily understand how to locate the target incision site.

[0050] Referring to Figures 19A and 19B, the trainee makes an incision through the second membrane 44 of the tracheal module 14 at the target incision site using a blade 7 of the percutaneous cricothyrotomy device 6. The trainee then spreads the incision as shown in Figure 20 and makes a further incision through the first membrane 60, as shown in Figure 21. As shown in Figure 22, the trainee then manipulates the percutaneous cricothyrotomy device 6 to insert the spreaders thereof into the incision. The spreaders open the incision to allow for the insertion of the tracheotomy tube 5 into the incision, as shown in Figure 23. The tracheotomy tube 5 is then fully inserted into the incision to complete the training medical procedure, as shown in Figure 24.

[0051] In another example, which is illustrated by Figures 25 to 28, a scalpel and retractors are used to perform a cricothryrotomy procedure on the training device 10. The training medical procedure is performed in the same manner as has been previously described in relation to Figures 18 to 24.

[0052] In another example (not shown), a tracheotomy procedure is performed on the training device 10. In this example, the incisions through the second membrane 44 and first membrane 60 are performed through a tracheal opening.

[0053] Instructions for performing the training medical procedures are provided to the trainees prior to commencing a training medical procedure by qualified training personnel .

[0054] It will be appreciated by a person skilled in the art that prior to performance of a second training medical procedure on the training device 10. The tracheal module 14 is disassembled and the membranes 44, 60 are replaced with intact membranes.

[0055] It will be appreciated by a person skilled in the art that the tracheal module 14 may be received in any base that supports the tracheal module 14 and allows for the performance of a training medical procedure thereon.

[0056] In one embodiment, the training device 10 does not include a separate base unit. Instead, the tracheal module 14 includes a flat bottom that can be placed onto a

work surface (not shown) to allow the training medical procedure to be safely performed.

[0057] It will further be appreciated by a person skilled in the art that while the present disclosure refers to a training device that provides a tactile representation of the throat and underlying tracheal system of an adult human, it is within the scope of the present invention to adjust the size of the base unit 12 and the tracheal module 14 to provide simulations of the throat areas of infants, adolescents, juveniles and adult humans. It is also within the scope of the present invention, for veterinary training purposes, to configure the base unit and the tracheal module to represent mammalian animal species such as canines, felines, equines, livestock, exotic animals and other species for which veterinary emergency tracheal intubation procedures are performed.

[0058] The training device 10 described herein provides a tracheal module 14 that anatomically, geometrically, texturally and dynamically simulates a human throat. The training device 10 provides a full scale model of a human throat that may be used in place of human or pig cadavers to train individuals how to perform medical procedures such as tracheotomies and cricothyrotomies, for example. The tube 50 of the tracheal module 14 geometrically and dynamically simulates a human airway passage, the first membrane 60 geometrically, texturally and dynamically simulates a human cricothyroid membrane, the cover 24 geometrically, texturally and dynamically simulates the human tracheal cartilage and the second membrane 44 geometrically, texturally and dynamically simulates the human skin in the tracheal area. The second membrane 44 and first membrane 60 are capable receiving incision and spreading of an incised area to simulate a medical procedure. The tracheal module 14 may be received in the base unit 12, which geometrically simulates the human anatomy relevant to the medical procedure. The training device 10 is provided for education and training purposes to help trainees learn how to locate landmarks and perform medical procedures.

[0059] Specific embodiments have been shown and described herein. However, modifications and variations may occur to those skilled in the art. All such modifications and variations are believed to be within the scope and sphere of the present invention.

Claims

1. A training device comprising:

a tracheal module for simulating a trachea of a mammal, said tracheal module being flexible and comprising a pair of severable membranes for receiving an incision to simulate a medical procedure.

2. A training device as claimed in claim 1, wherein said tracheal module comprises:

a flexible cover having a channel, a first opening and a second opening;

a flexible tube having a first opening and a second opening, said tube being received in said channel of said cover with first openings of said cover and said tube being aligned to simulate a cricothyroid opening and second openings of said cover and said tube being aligned to simulate a tracheal opening;

a first membrane covering said first opening and said second opening of said cover;

a second membrane covering said first opening and said second opening of said tube, said first membrane and said second membrane being severable to provide an air passage through said first openings; and

wherein an incision through said first membrane and said second membrane simulates a medical procedure.

3. A training device as claimed in claim 1, wherein said medical procedure is one of: a tracheotomy and a cricothyrotomy.

4. A training device as claimed in claim 2, comprising a base unit for receiving said tracheal module.

5. A training device as claimed in claim 4, wherein said base unit includes a lower surface for engaging a work surface and a cavity for receiving said tracheal module.

6. A training device as claimed in claim 5, wherein said base unit is made of a resilient material, said base unit for allowing user-engagement of the tracheal module during performance of said medical procedure.

7. A training device as claimed in claim 4, wherein said base unit is used with a plurality of tracheal modules.

8. A training device as claimed in claim 2, wherein said first membrane and said second membrane are removed following said medical procedure and replaced with intact membranes to allow for re-use of said training device.

9. A training device as claimed in claim 2, wherein side edges of said flexible cover includes flexing relief slots.

10. A method for training an individual to perform a medical procedure, said method comprising:

providing a tracheal module, said tracheal module comprising a pair of severable membranes for receiving an incision to simulate a medical procedure;

providing instructions for performing said medical procedure;

wherein said tracheal module is flexible to simulate a trachea of a mammal.

11. A method as claimed in claim 10, wherein said medical procedure is one of: a tracheotomy and a cricothyrotomy.

12. A method as claimed in claim 10, comprising providing another tracheal module for performing a second simulated medical procedure.

13. A method for training an individual to perform a medical procedure, said method comprising:

providing a tracheal module that anatomically, in geometric, textural, and dynamic aspects, replicates a human trachea, said tracheal module comprising:

a geometrically and dynamically accurate replication of the human airway passage;

a geometrically, texturally and dynamically accurate replication of a human cricythyroid membrane;

a geometrically, texturally and dynamically accurate replication of the human tracheal cartilage;

a geometrically, texturally and dynamically accurate replication of the human skin in the tracheal area, said human skin and cricythyroid membrane simulated components being capable of receiving incision and spreading of an incised area to simulate said medical procedure; and

providing instructions for performing said medical procedure.

14. A method as claimed in claim 13, wherein said tracheal module is selectively received in a base unit, said base unit geometrically replicates the human anatomy relevant to said medical procedure.

15. A method as claimed in claim 14, wherein said assembly of said tracheal module and said base unit provides for meaningful replication of the human anatomy and education and training as to locating landmarks for said medical procedure.

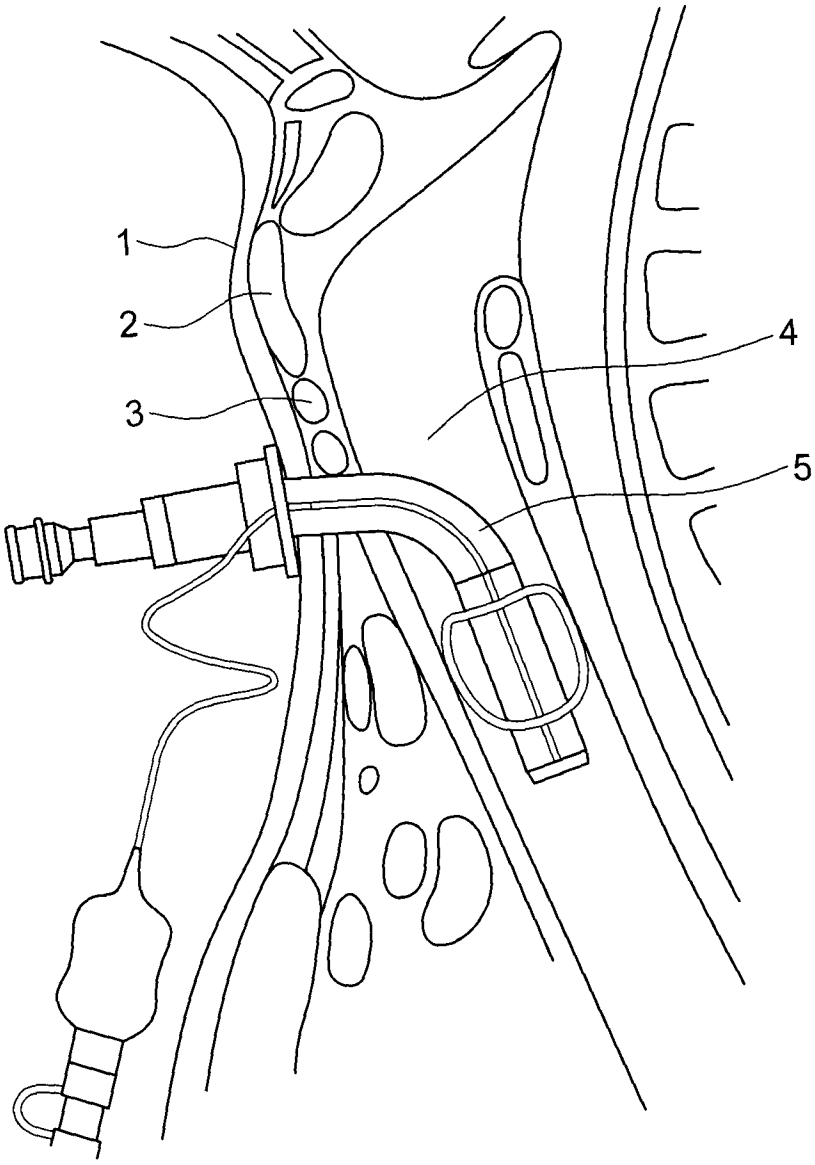

FIG. 1

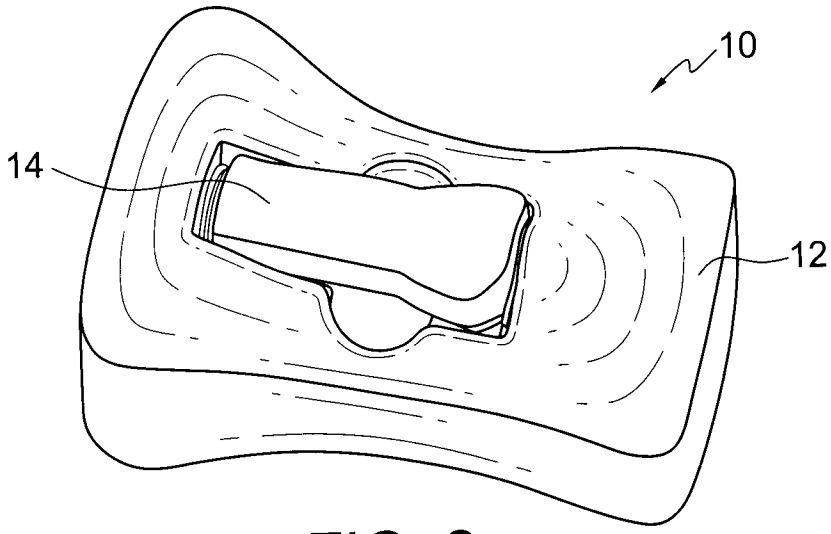

FIG. 2

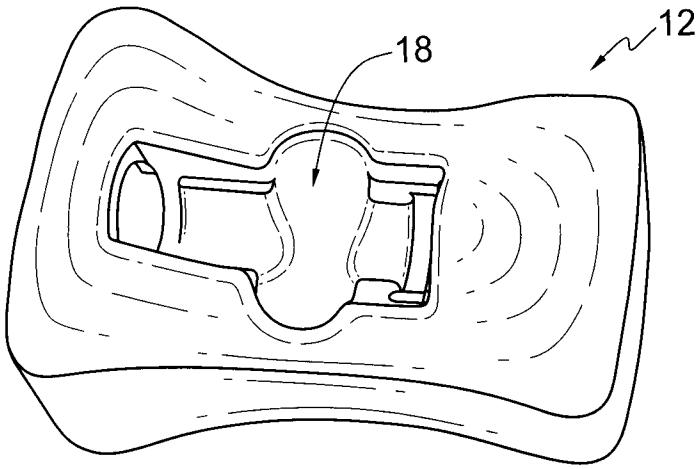

FIG. 3

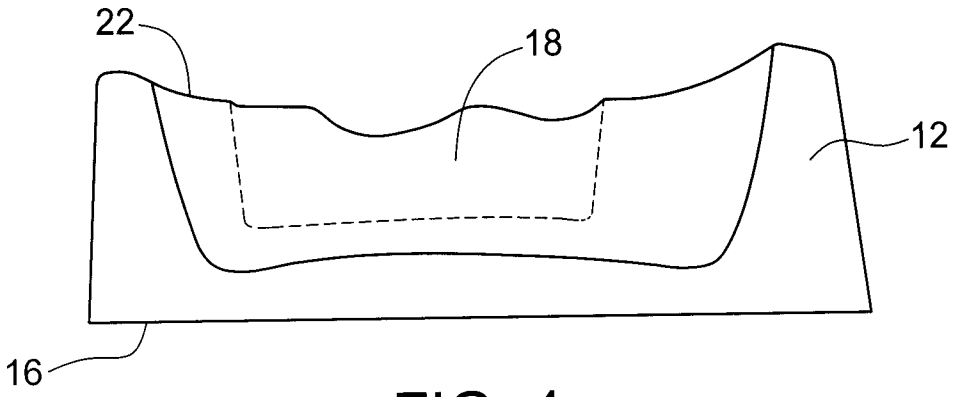

FIG. 4

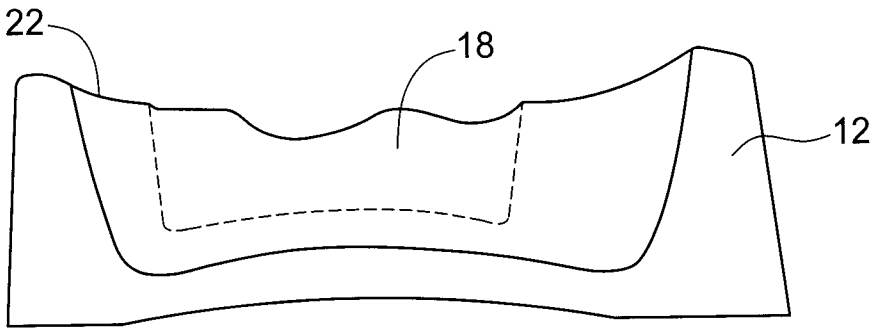

FIG. 5

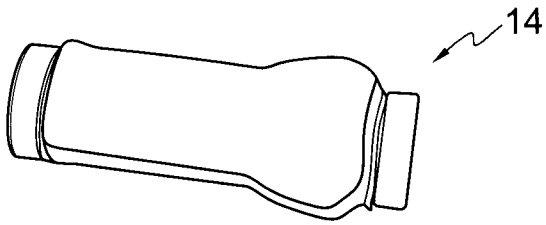

FIG. 6

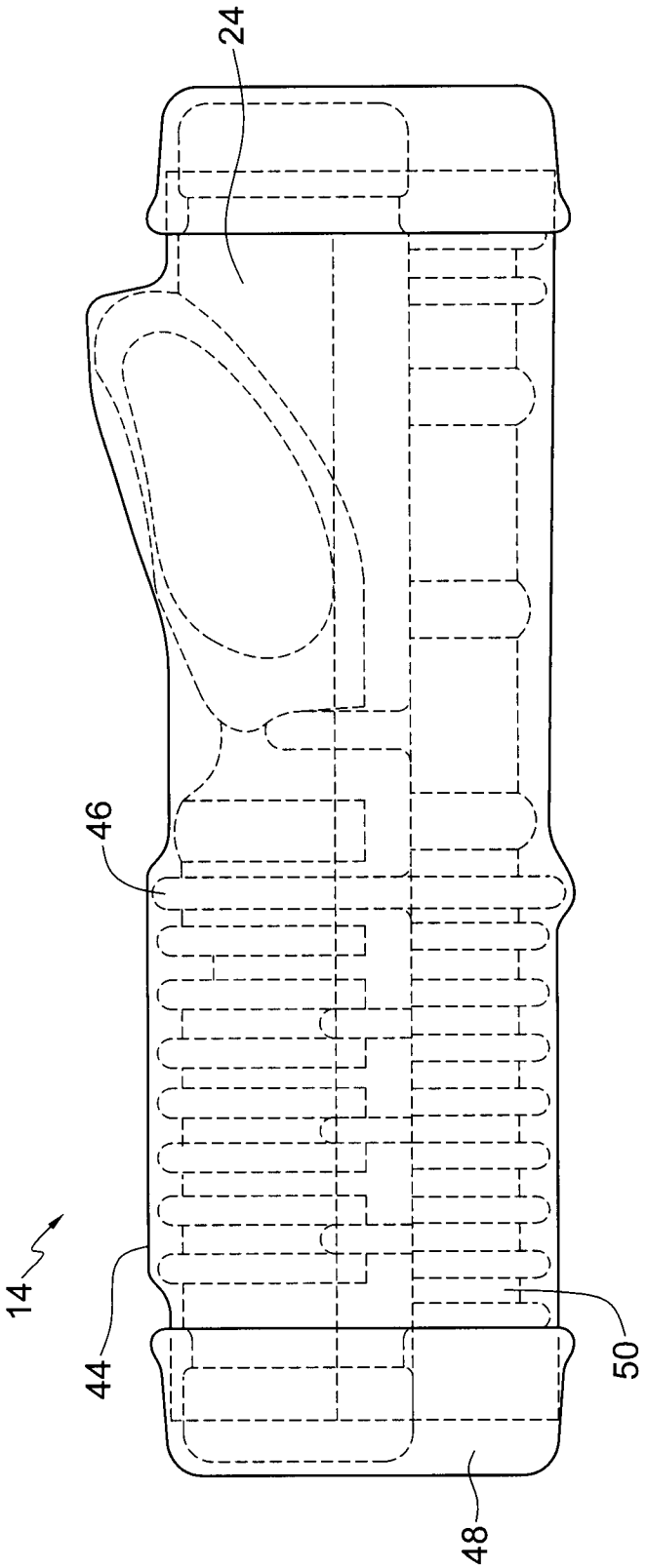

FIG. 7

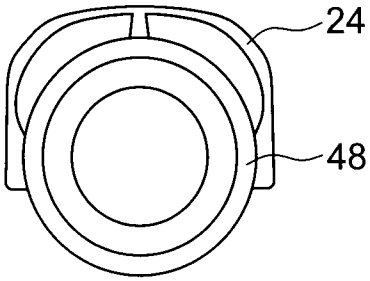

FIG. 8

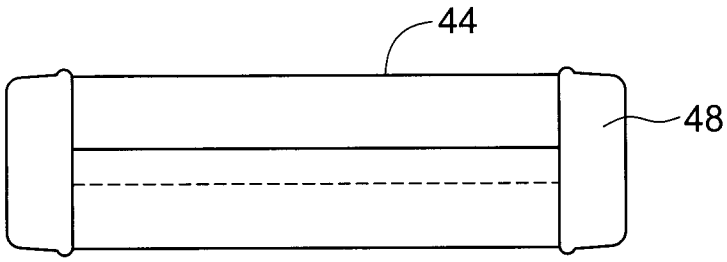

FIG. 9

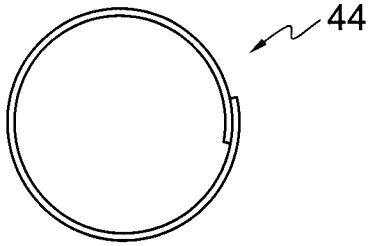

FIG. 10

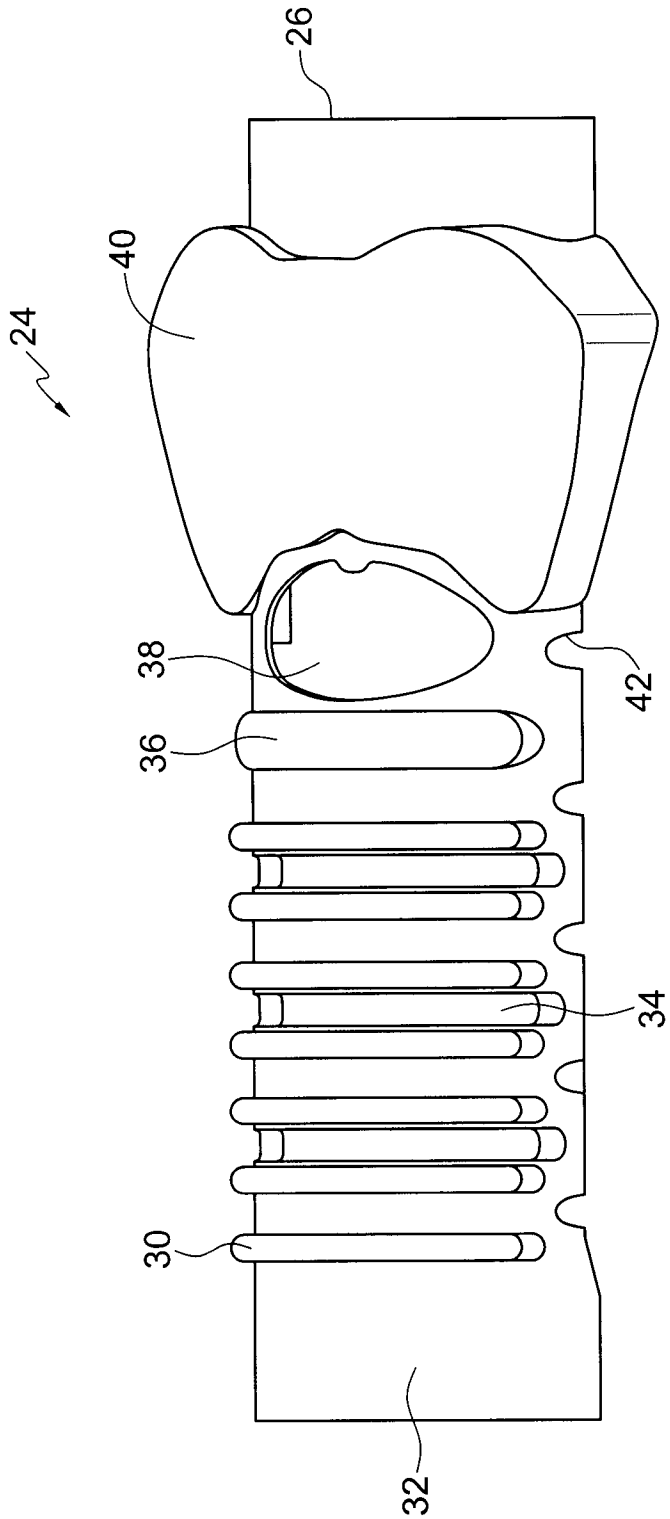

FIG. 11

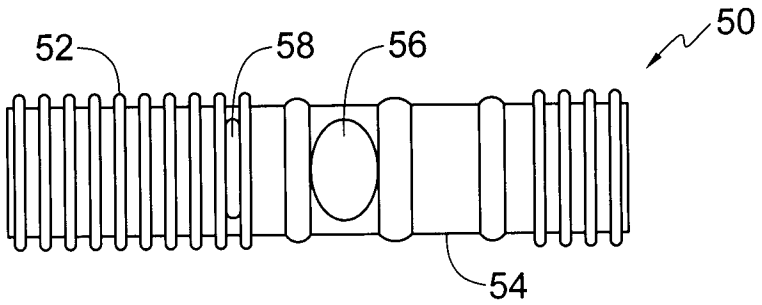

FIG. 12

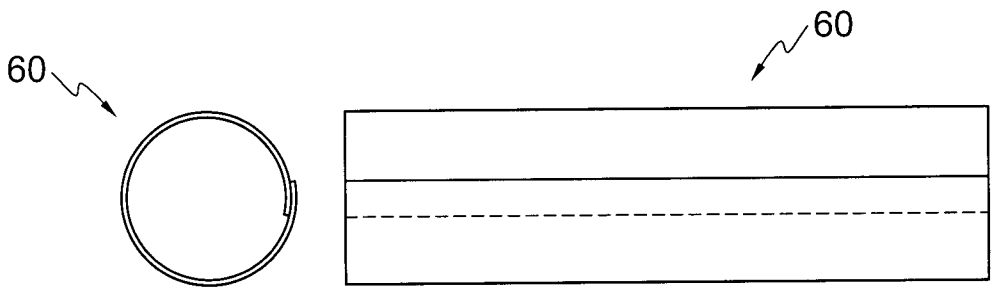

FIG. 13

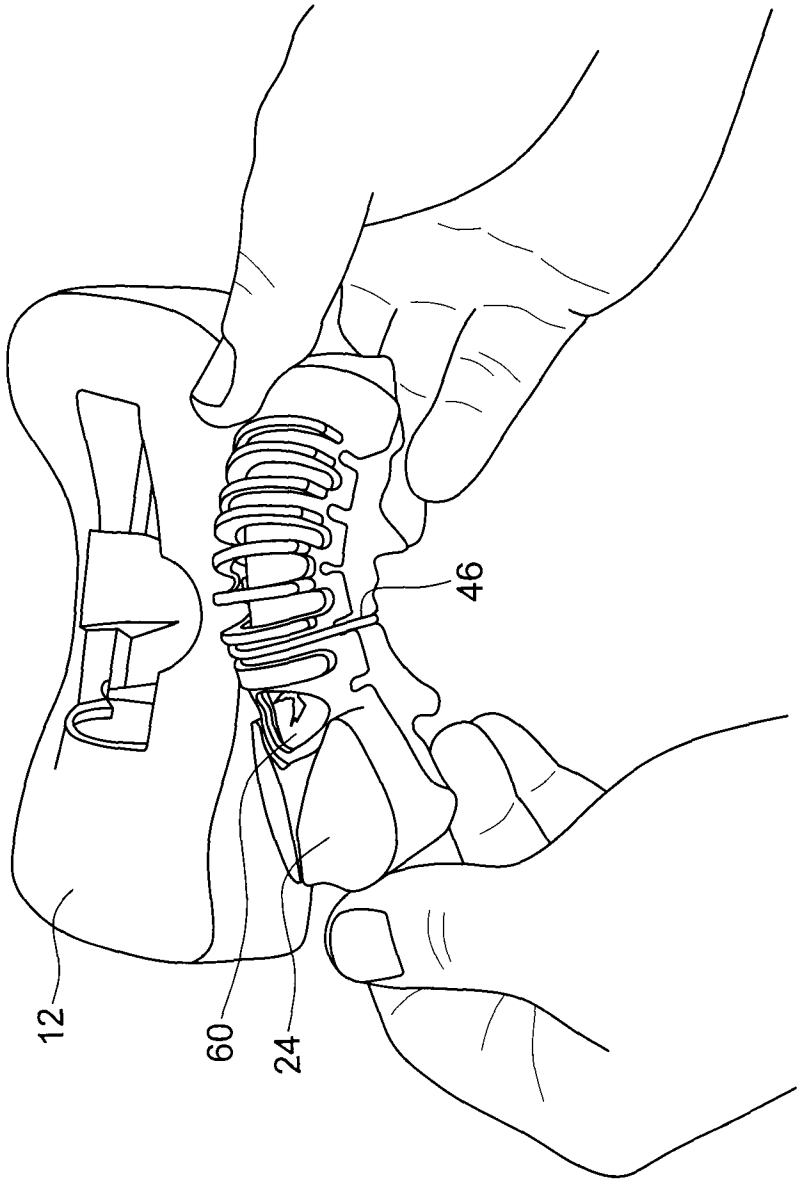

FIG. 14

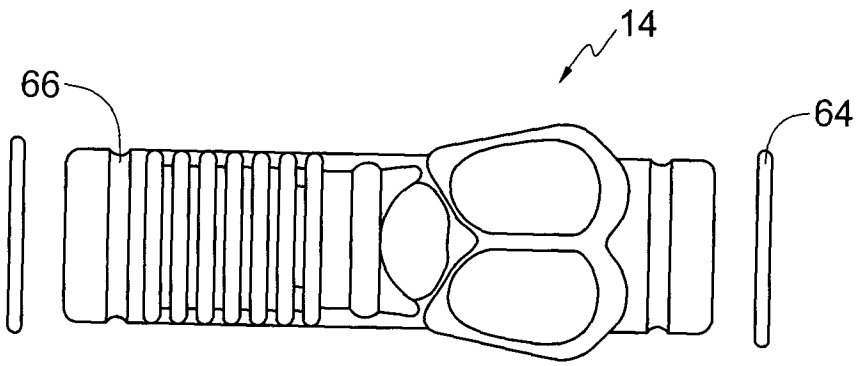

FIG. 15

FIG. 16

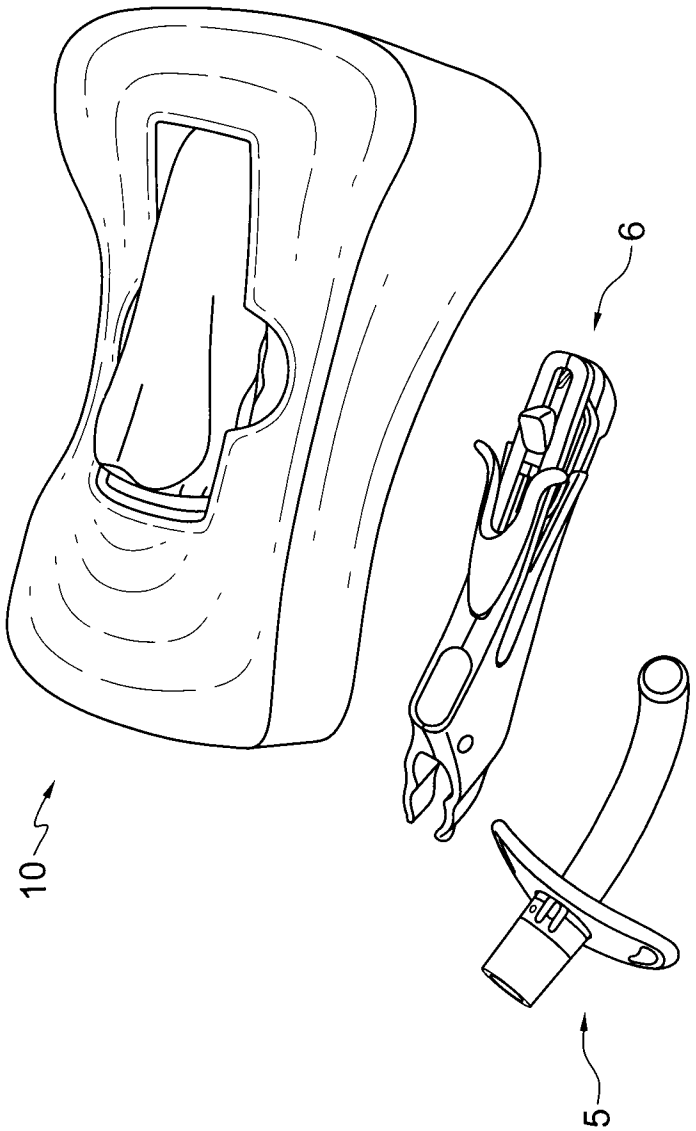

FIG. 17

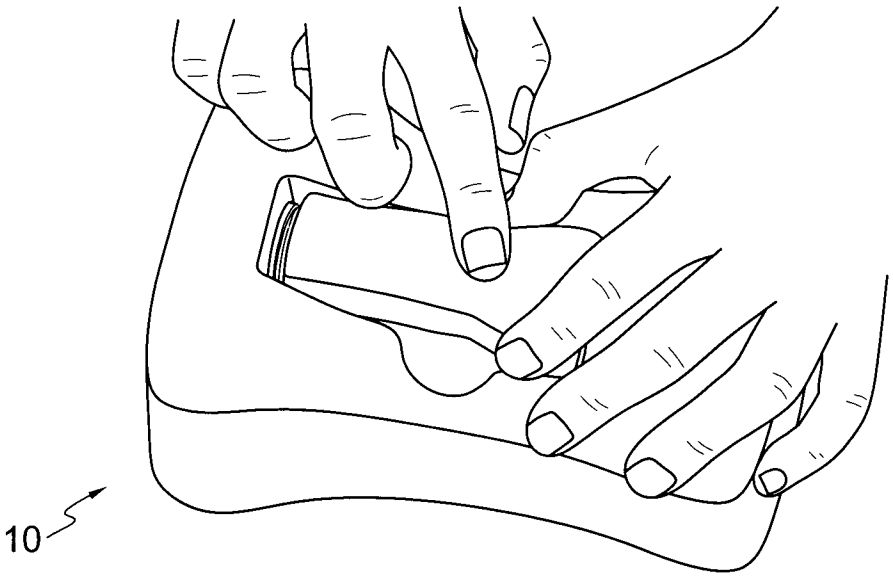

FIG. 18

FIG. 19A

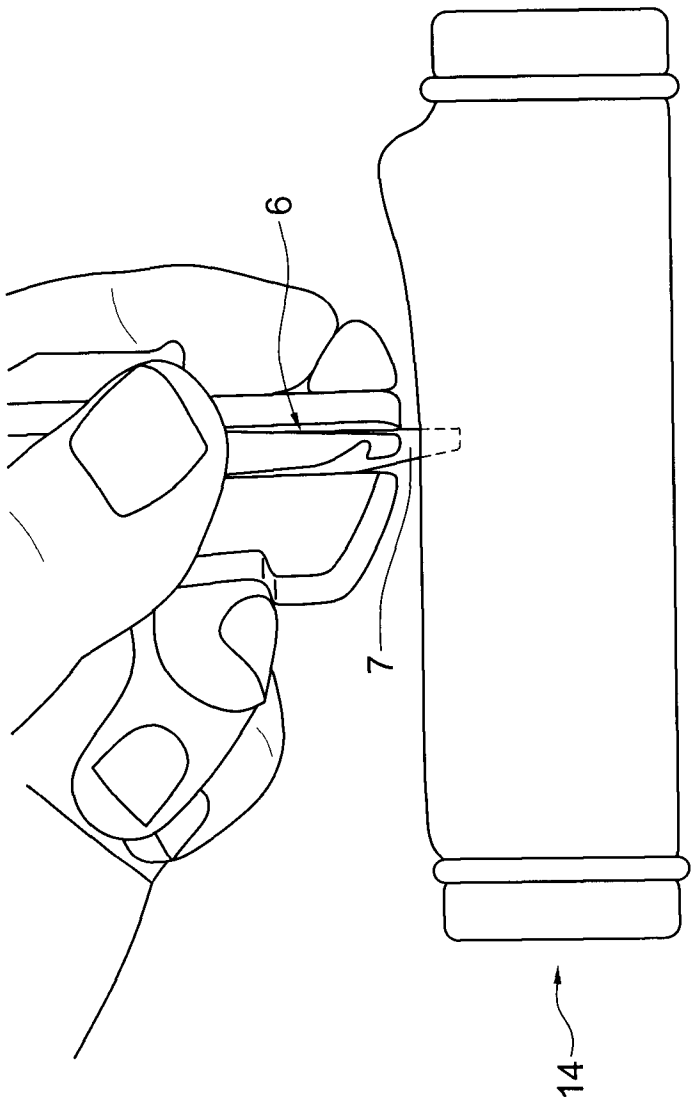

FIG. 19B

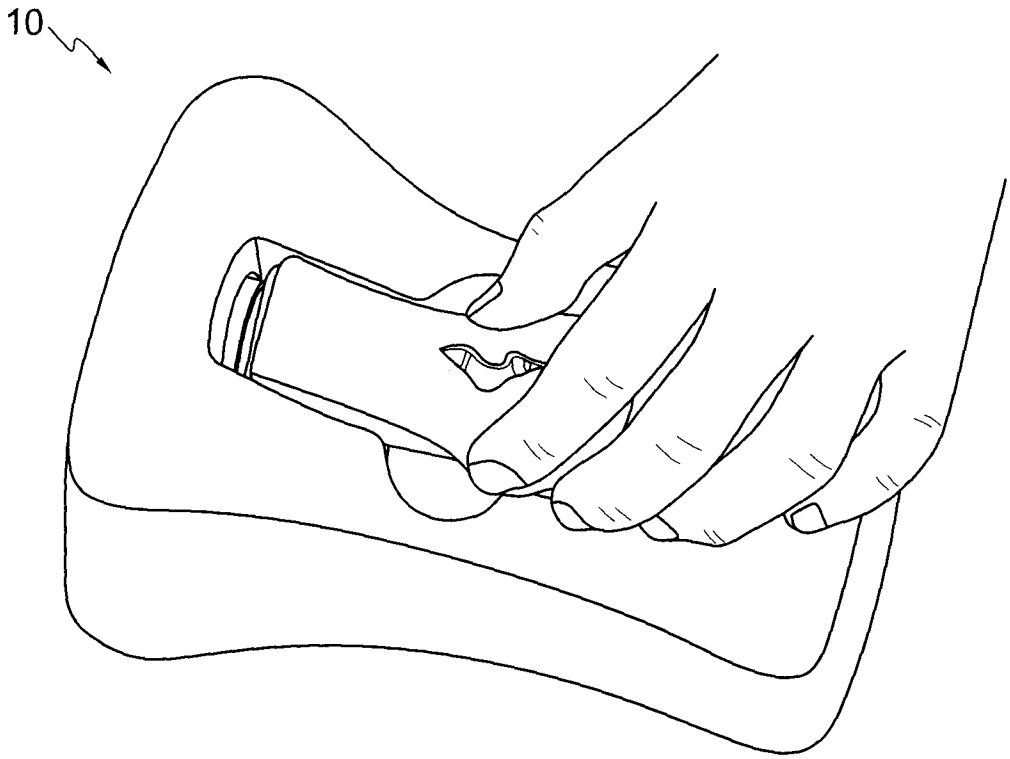

FIG. 20

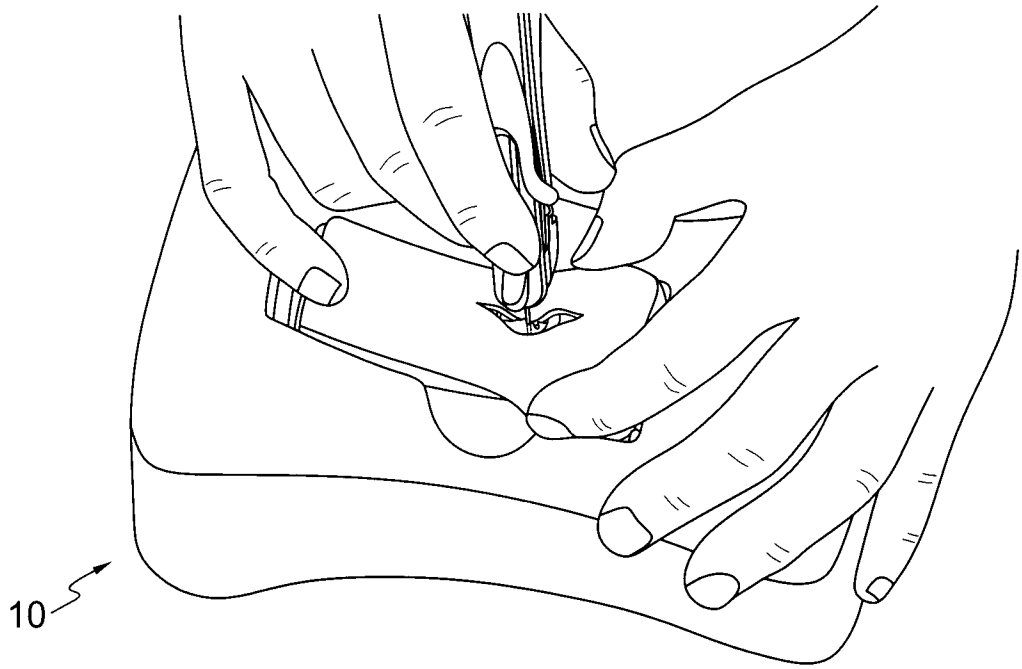

FIG. 21

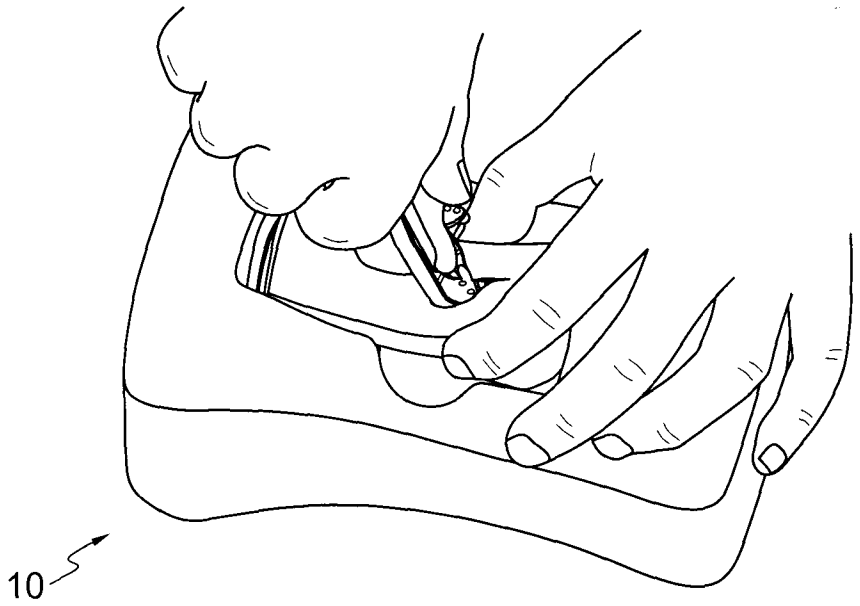

FIG. 22

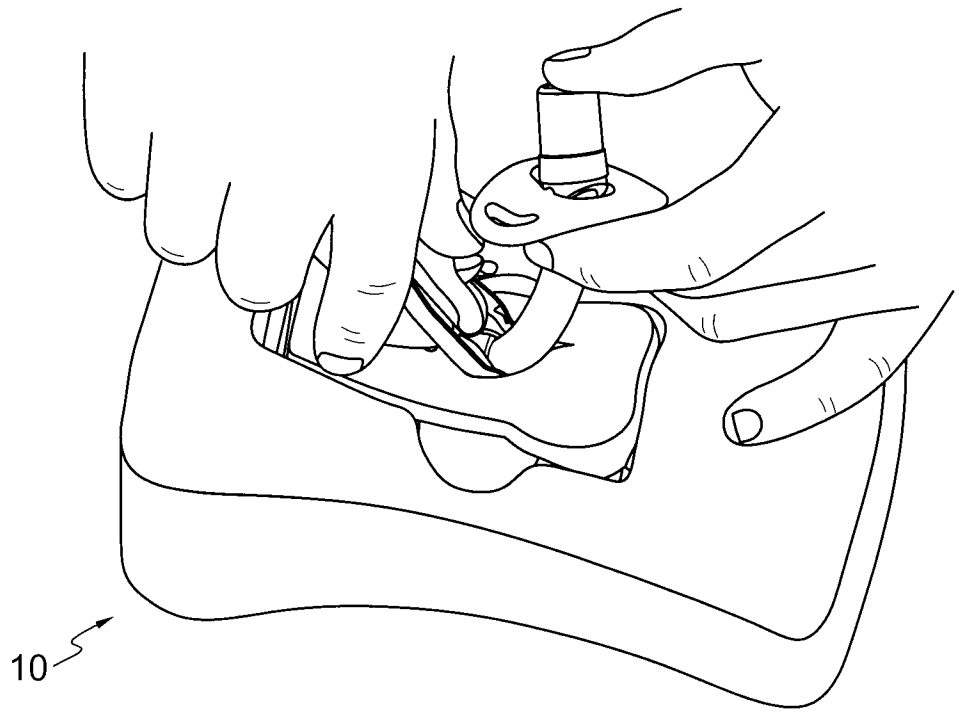

FIG. 23

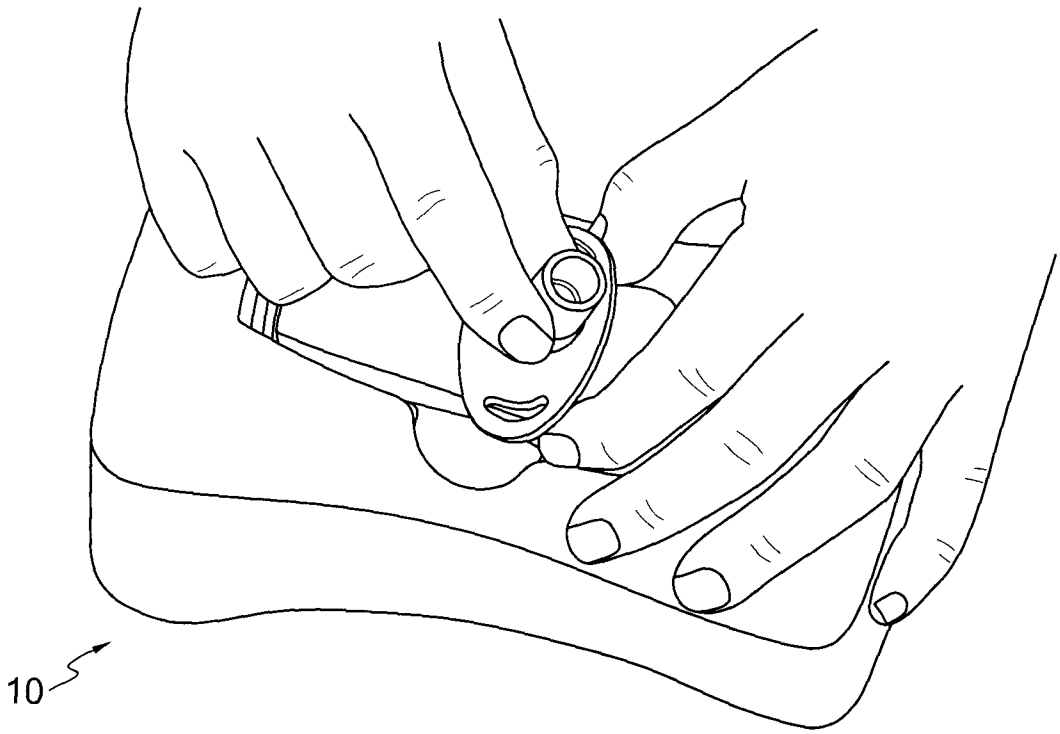

FIG. 24

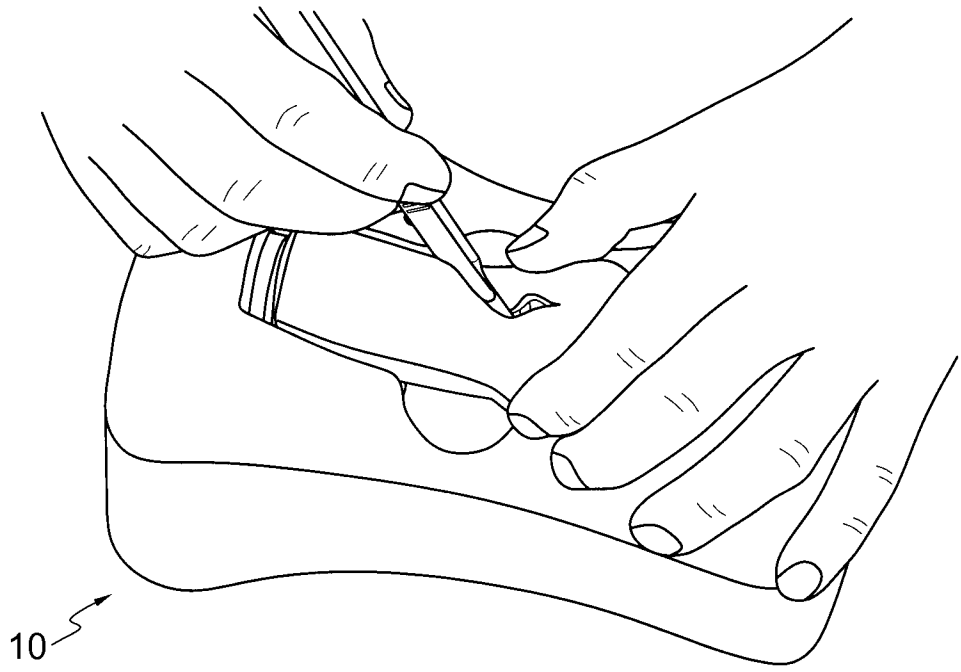

FIG. 25

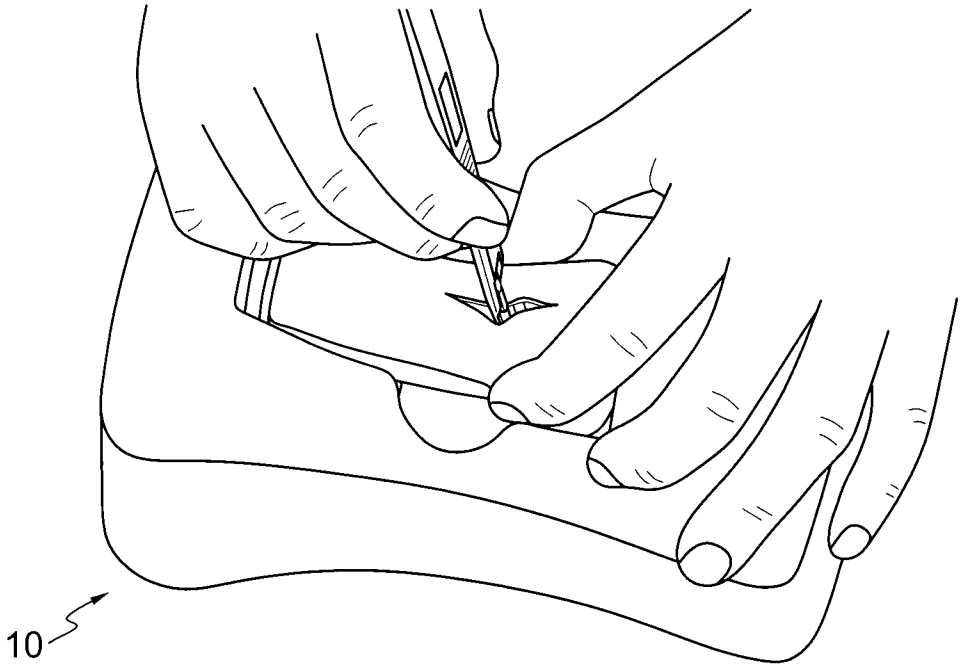

FIG. 26

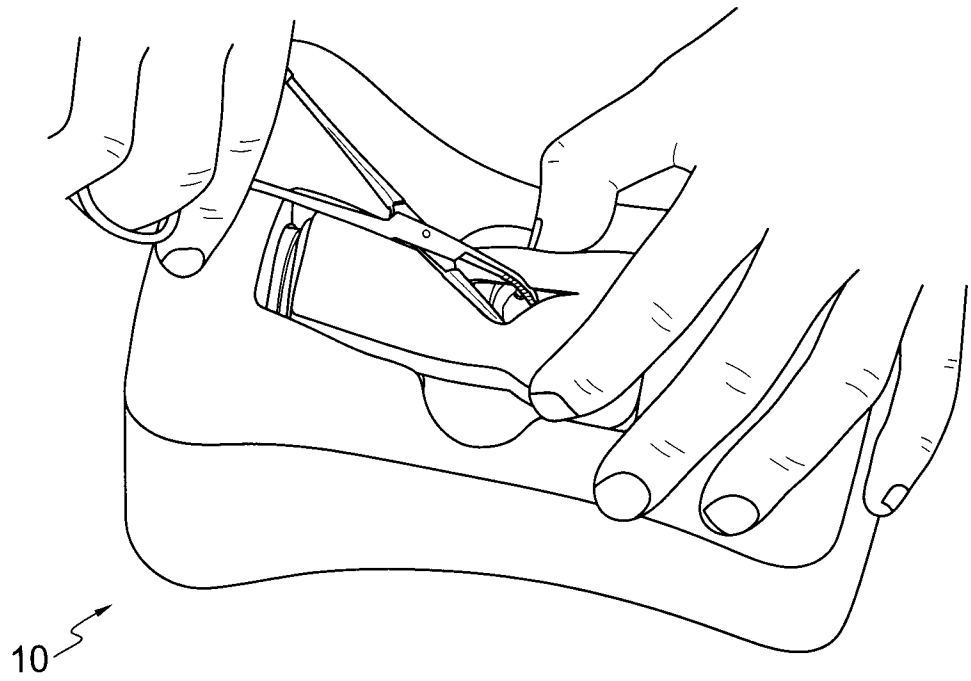

FIG. 27

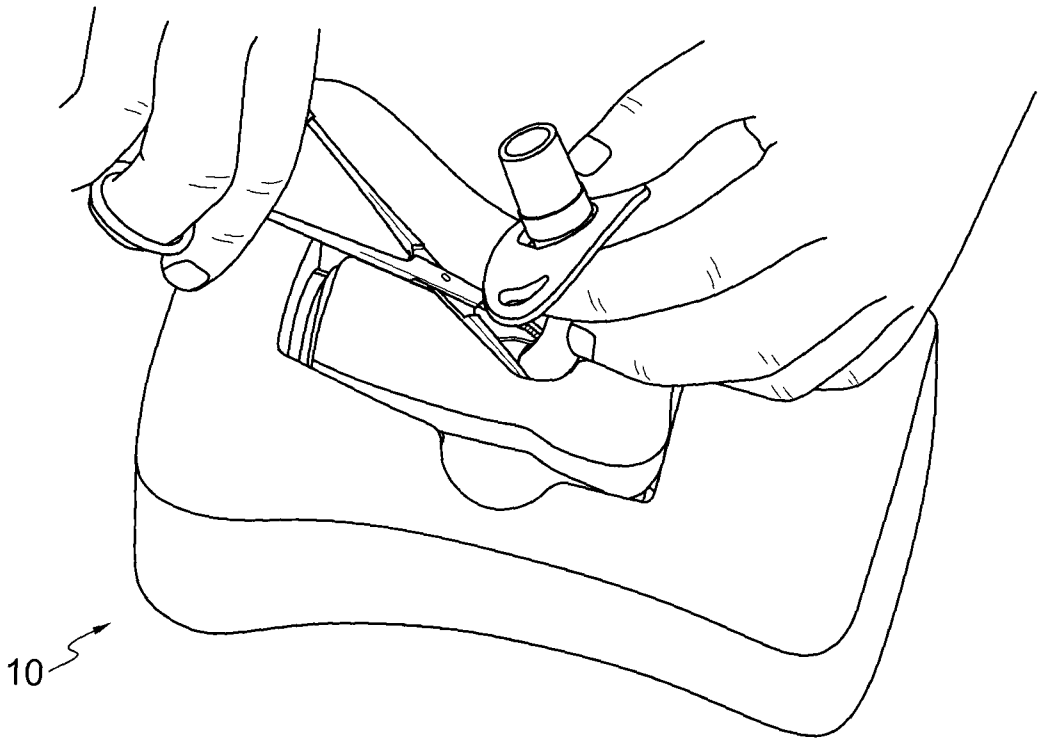

FIG. 28