

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
14 April 2011 (14.04.2011)

(10) International Publication Number  
**WO 2011/044421 A1**

- (51) International Patent Classification:  
A61N 7/02 (2006.01)
- (21) International Application Number:  
PCT/US2010/051917
- (22) International Filing Date:  
8 October 2010 (08.10.2010)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
61/249,850 8 October 2009 (08.10.2009) US  
61/372,044 9 August 2010 (09.08.2010) US
- (71) Applicant (for all designated States except US): **C. R. BARD, INC.** [—/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **BURNSIDE, Eddie, K.** [US/US]; 436 East Premier Lane, Grantsville, UT

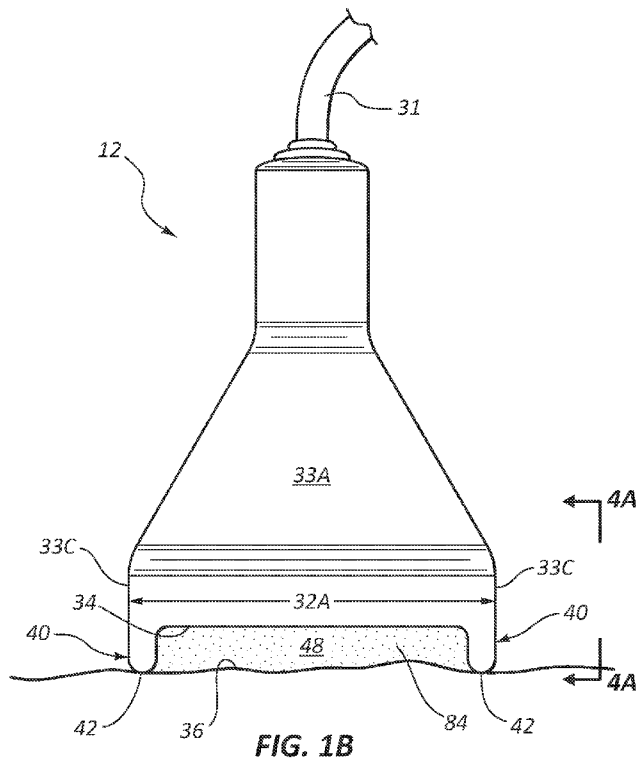
84029 (US). **LINDEKUGEL, Eric, W.** [US/US]; 1381 Hudson Avenue, Salt Lake City, UT 84106 (US). **COX, Jeremy, B.** [US/US]; 685 Eighth Avenue, Salt Lake City, UT 84103 (US). **BLANCHARD, Daniel, B.** [US/US]; 4507 Summerwood Drive, Bountiful, UT 84010 (US). **MORGAN, Paul, D.** [US/US]; 353 Bellevue Way, Draper, UT 84020 (US). **STINGER, Kevin, W.** [US/US]; 963 Mary Margret Drive, Kaysville, UT 84037 (US).

(74) Agent: **WIGHT, Todd, W.**; Rutan & Tucker LLP, 611 Anton Boulevard, Suite 1400, Costa Mesa, CA 92626 (US).

(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,

[Continued on next page]

(54) Title: SPACERS FOR USE WITH AN ULTRASOUND PROBE



(57) Abstract: A probe cap for use with an ultrasound probe including a head portion and an acoustic surface is disclosed. In one embodiment, the probe cap includes a body that defines a cavity sized for releasably receiving the head portion of the probe therein. The probe cap body further defines a hole that is proximate the acoustic surface of the head portion. A compliant spacer component is disposed in the hole. The spacer component can include a hydrogel and provides an acoustic path between the acoustic surface and a tissue surface of a patient. The spacer component includes a skin contact surface that defines a concavity and is deformable against the tissue surface.

WO 2011/044421 A1

SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

**(84) Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Declarations under Rule 4.17:**

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- of inventorship (Rule 4.17(iv))

**Published:**

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

**SPACERS FOR USE WITH AN ULTRASOUND PROBE****CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 61/249,850, filed October 8, 2009, and entitled "Ultrasound Probe Spacers," and U.S. Provisional Patent Application No. 61/372,044, filed August 9, 2010, and entitled "Support and Cover Structures for an Ultrasound Probe Head." Each of these applications is incorporated herein by reference in its entirety.

**BRIEF SUMMARY**

[0002] Briefly summarized, embodiments of the present invention are directed to a probe cap for use with an ultrasound probe including a head portion and an acoustic surface. In one embodiment, the probe cap includes a body that defines a cavity sized for releasably receiving the head portion of the probe therein. The probe cap body further defines a hole that is proximate the acoustic surface of the head portion. A compliant spacer component is disposed in the hole. The spacer component can include a hydrogel and provides an acoustic path between the acoustic surface and a tissue surface of a patient. The spacer component further includes a skin contact surface that defines a concavity and is deformable against the tissue surface. The skin contact surface can further define a spacer element adjacent the concavity.

[0003] In another embodiment, an ultrasound imaging system for imaging a subcutaneous structure of a patient is disclosed and includes a display, an ultrasound probe including an acoustic surface from which ultrasound signals are emitted, and first and second spacer elements. The spacer elements are positioned proximate opposite ends of the acoustic surface and are configured to provide a gap between the acoustic surface and a tissue surface of the patient. So configured, the spacer elements prevent compression of the subcutaneous structure of the patient.

[0004] These and other features of embodiments of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of embodiments of the invention as set forth hereinafter.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0005] A more particular description of the present disclosure will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0006] FIGS. 1A and 1B are perspective and side views, respectively, of an ultrasound probe including spacer elements configured in accordance with one embodiment;

[0007] FIG. 2 is a simplified cross sectional view of the ultrasound probe of FIGS. 1A and 1B used to image a vessel of a patient;

[0008] FIG. 3 is a side view of the ultrasound probe of FIGS. 1A and 1B enclosed within a sheath in accordance with one embodiment;

[0009] FIGS. 4A and 4B are side views of a portion of an ultrasound probe including spacer elements and further showing examples of possible acoustic surface configurations in accordance with one embodiment;

[00010] FIG. 5 is a side view of a portion of an ultrasound probe including a spacer element in accordance with one embodiment;

[00011] FIG. 6 shows ultrasound spacer elements configured in accordance with one embodiment;

[00012] FIG. 7 shows ultrasound spacer elements configured in accordance with one embodiment;

[00013] FIG. 8 shows ultrasound spacer elements configured in accordance with one embodiment;

[00014] FIGS. 9A and 9B show spacer elements configured in accordance with one embodiment;

[00015] FIG. 10 is a side view of an ultrasound probe including spacer elements configured in accordance with one embodiment;

[00016] FIG. 11 is a side view of an ultrasound probe including a cap including spacer elements and a sheath in accordance with one embodiment;

[00017] FIG. 12 is a perspective view of a spacer component in accordance with one embodiment;

[00018] FIGS. 13A-13C show use of the spacer component of FIG. 12 in accordance with one embodiment;

[00019] FIG. 14 is a side view of a spacer component in accordance with one embodiment;

[00020] FIGS. 15A-15B show use of the spacer component of FIG. 14 in accordance with one embodiment;

[00021] FIG. 16 is an exploded perspective view of an ultrasound probe and a probe cap in accordance with one embodiment;

[00022] FIGS. 17A-17D are various views of the probe cap of FIG. 16;

[00023] FIGS. 18A and 18B are an exploded perspective view and cross sectional side view of an ultrasound probe/probe cap and a spacer component, respectively;

[00024] FIG. 19 is a cross sectional view of a head portion of the ultrasound probe of FIG. 16;

[00025] FIG. 20 is a cross sectional view of the probe cap of FIG. 16;

[00026] FIG. 21 is a cross sectional view of a head portion of the ultrasound probe of FIG. 16 received within the probe cap of FIG. 16;

[00027] FIG. 22 is another cross sectional view showing a head portion of the ultrasound probe of FIG. 16 received within the probe cap of FIG. 16; and

[00028] FIG. 23 is a perspective view of a mated configuration of the ultrasound probe and probe cap of FIG. 16.

### **DETAILED DESCRIPTION OF SELECTED EMBODIMENTS**

[00029] Reference will now be made to figures wherein like structures will be provided with like reference designations. It is understood that the drawings are diagrammatic and schematic representations of exemplary embodiments of the present invention, and are neither limiting nor necessarily drawn to scale.

[00030] For clarity it is to be understood that the word “proximal” refers to a direction relatively closer to a clinician using the device to be described herein, while the word “distal” refers to a direction relatively further from the clinician. For example, the end of a catheter placed within the body of a patient is considered a distal end of the catheter, while the catheter end remaining outside the body is a proximal end of the catheter. Also, the words “including,” “has,” and “having,” as used herein, including the claims, shall have the same meaning as the word “comprising.”

[00031] FIGS. 1-23 depict various features of embodiments of the present invention, which are generally directed to various components for spacing an acoustic surface of an ultrasound probe from a tissue surface of a patient during ultrasound procedures to image subcutaneous tissues of the patient. Such ultrasound procedures are employed, for instance, in connection with the placement of a catheter within a vessel of the patient. As will be described, the components for spacing the acoustic surface in one embodiment prevent undesired compression of subcutaneous vessels, especially superficial vessel, which in turn improves the imaging of such vessels by the probe.

[00032] Reference is first made to FIGS. 1A and 1B, which depict an ultrasound imaging system 10 according to one embodiment, including an ultrasound probe 12 and a console 20 including a display 30 for depicting an image produced by the probe. In the present embodiment, the probe 12 is operably connected to the console 20 via a cable 31, though in one embodiment the probe can be wirelessly connected thereto.

[00033] The probe 12 includes a head 32 defined by a longitudinal length 32A and a width 32B. The body of the probe generally defines a front face 33A, a rear face 33B, and side faces 33C. It should be appreciated that the preceding description of the probe is not meant to limit application of the principles described herein in any way. The probe head 32 includes an acoustic surface 34 extending along at least a portion of a longitudinal length 32A of the probe head from which ultrasonic impulses are emitted in

order to penetrate and image subcutaneous portions of the patient. Note that the size, shape and configuration of both the probe and acoustic surface can vary from what is described herein while still residing within the principles of the present disclosure. Note also that FIG. 1A shows just one example of an ultrasound imaging system; other systems including other components can also benefit from the principles described herein.

**[00034]** As depicted in FIGS. 1A and 1B, in accordance with one embodiment the probe head 32 includes two spacer elements, generally depicted at 40, disposed adjacent the probe acoustic surface 34 at each end of the longitudinal length 32A. Each spacer element 40 acts as an extended surface to provide a gap 48 between the acoustic surface 34 and the skin 36 or other tissue surface of the patient, as further described below, when the probe 12 is placed on the patient's skin for use in subcutaneous imaging.

**[00035]** In greater detail, each spacer element 40 in the present embodiment defines a blade-like extended surface that includes a contact surface 42 for contacting the tissue/skin 36 of the patient. The contact surface 42 can be shaped in one of several configurations, as will be discussed further below.

**[00036]** Reference is now made to FIG. 2. When no spacers are present on an ultrasound probe, the acoustic surface thereof directly contacts the patient's skin during imaging, which can cause a downward pressure sufficient to undesirably compress a subcutaneous vessel disposed beneath the probe. Further, the proximity of the probe acoustic surface to the patient's skin can cause the focal point of the probe to reside below the vessel to be imaged, resulting in less than optimal image resolution of superficial vessels or other objects residing relatively close to the skin surface.

**[00037]** In contrast to the above, FIG. 2 shows the probe 12 including the spacer elements 40 disposed at each longitudinal end of the probe head 32 and adjacent the acoustic surface 34. So configured, the acoustic surface 34 is spaced apart from the patient's skin 36 during probe use, and only the contact surfaces 42 of the spacer elements 40 are in contact therewith. The gap 48 is thus defined between the acoustic surface 34 and the patient's skin 36, which can be filled with an ultrasonic gel 84 or other acoustically transparent substance to improve imaging, in one embodiment.

**[00038]** Because the acoustic surface 34 of the ultrasound probe head 32 is not in direct contact with the patient's skin 36 during probe use, pressure on the skin imposed by the acoustic surface is avoided, which in turn prevents a vessel 50 underneath the probe 12 from being compressed by the probe during use. Instead, any downward force provided by the probe 12 is directed through the spacer elements 40. As such, the vessel 50 below the acoustic surface 34 remains patent and can be accurately imaged. Further, the increased distance between the acoustic surface 34 and the patient's skin 36 provided by the gap 48 moves the focal spot of the probe 12 to a location relatively close below the skin surface, which enables superficial vessels and other objects residing near the skin surface to be brought more closely to the focal point of the probe and be sharply imaged.

**[00039]** Note that the gap 48 shown in FIGS. 1A-2 is bounded during probe use by the acoustic surface 34, the skin 36, and the spacer elements 40. As such, the gap 48 remains open below the front and rear faces 33A, 33B of the probe 12. Note that additional spacers could be employed to further define the gap 48, if desired.

**[00040]** Reference is now made to FIG. 3 in describing one embodiment, wherein a sheath 52 is placed over the probe 12 to provide a sterile field about the probe. The sheath 52 can be disposed about the probe 12 such that a relatively close fit is defined between the sheath and the side faces 33C and front/rear faces 33A, 33B of the probe so that the ultrasound gel 84 can be included in and confined within the gap 48 by the sheath and the spacer elements 40. Note that sheaths or barriers of many different styles or configurations may be used.

**[00041]** FIGS. 4A and 4B show example surface configurations for the acoustic surface 34. In FIG. 4A, the acoustic surface 34 is flat as to be substantially parallel with the patient's skin 36 during probe use. In FIG. 4B, the acoustic surface 34 defines a concave shape with respect to the skin 36. This configuration can assist in trapping a volume of ultrasound gel within the gap 48. Of course, other acoustic surface configurations can be employed.

**[00042]** FIG. 5 gives one example of a possible configuration for the contact surface 42 of the spacer element 40, wherein the contact surface defines a convex shape for engagement with the patient's skin or other tissue surface. Note this is in contrast to the



relatively flat contact surface 42 shown in FIGS. 4A and 4B, for instance. Other spacer contact surface shapes can be employed, including straight, rounded, angled, etc.

[00043] FIG. 6 shows that a height “H” of each spacer element 40 can be defined according to a particular need or application in order to define a particular separation between the acoustic surface 34 and the patient’s skin 36 during use of the probe 12. Note that in one embodiment, the spacer elements are integrally formed with the probe housing. In another embodiment, the spacer elements are removably attached to the probe. The spacer elements can include materials similar to or different from those materials included in the probe housing.

[00044] Reference is now made to FIGS. 7 and 8, wherein FIG. 7 shows that in one embodiment the spacer elements 40 can be configured to extend longitudinally a distance “E” past the side surfaces 33C of the probe 12. In FIG. 8, each of the spacer elements 40 is inset a distance “I” from the probe side surfaces 33C.

[00045] FIGS. 9A and 9B depict yet another possible spacer element configuration according to one embodiment, wherein each spacer element 40 is included at an end of an extension arm 48 that extends from a corresponding one of the front and rear faces 33A, 33B of the probe 12. Such a configuration may be useful, for instance, in advancing the probe 12 along the patient skin 36 in a direction parallel to the longitudinal length of the acoustic surface 34. These and other spacer configurations are therefore contemplated as residing with the spirit of the present disclosure.

[00046] FIG. 10 shows a height-adjustable spacer element 40 so as to allow variation in the set-off distance of the acoustic surface 34 from the skin 36. In the illustrated embodiment, a bracket 60 that slidably receives the spacer element 40 is included on the side face 33C of the probe 12 and includes a depression or hole 62. Corresponding protuberances 64 are included on the spacer element 40 and are configured to be selectively received into the hole 62 so as to removably lock the spacer element in place at a specified height. The protuberances 64 are distributed along the length of the spacer element 40 such that one of multiple spacer heights may be selected. A similarly adjustable spacer element is included on the opposite side face of the probe 12. Of course, other adjustable spacer element configurations can be included on the probe in addition to that explicitly described here.

[00047] FIG. 11 shows details of yet another embodiment, wherein the spacer elements 40 are included on a cap 70 that is removably attachable to the probe head 32. In the present embodiment, the cap is snapped on to the probe head 32 via an interference fit, but in other embodiments other attachment schemes can be employed, including inter-engaging surfaces on the probe and cap, for example. A sheath 72 is attached to the cap 70 so as to provide a sterile barrier for the ultrasound probe 10. In one embodiment the cap 70 and sheath 72 are disposable.

[00048] It should be appreciated that the number, size, height, shape, etc., of the spacer elements can vary from what is explicitly described herein. For instance, one, three, or more spacers can be included. Or the relative heights of the spacers can differ one from another so as to produce an angled probe-to-skin configuration. The probe can include one of many different shapes, designs, etc. These and other modifications are thus considered part of the present disclosure.

[00049] FIG. 12 depicts details of a spacer component 78 configured for attachment to the probe head 32, as shown in FIG. 13A, according to one embodiment. The spacer component 78 includes a body of compliant material, such as a hydrogel, in one embodiment, which generally maintains its intended shape when deforming forces are absent. The compliant material in one embodiment can include AQUAFLEX<sup>®</sup> ultrasound gel from Parker Laboratories, Inc., Fairfield, New Jersey. The spacer component 78 further defines spacer elements 80 on each longitudinal end thereof, with a concavity 82 defined between the spacer elements. It is appreciated that other suitable materials can be employed for the compliant material of the spacer component, including acoustically transparent, sufficiently solid materials such as soft silicone, rubber, etc. In one embodiment, the compliant material is thermoformable, sterilizable, and shelf stable for at least one year.

[00050] As shown in FIGS. 13A-13C, the spacer component 78 due to its compliant nature can deform so as to conform to the shape of the surface of the patient's skin 36 during use of the probe 12. For example, the probe 12 including the spacer component 78 can be placed on a patient's arm. So positioned, the spacers 80 of the spacer component 78 can deform as needed as to match the cross sectional curvature of the arm surface and maintain contact with the skin 36 thereof. FIGS. 13B and 13C show such deformation of the spacer component 78 for relatively larger arms. Thus, the spacer

component 78 provides an acoustic path between the acoustic surface and the skin surface without need of a flowable ultrasound gel. It is appreciated that the spacer component can be used in connection with imaging other portions of the patient's body and that the spacer component can define other shapes for contacting differently shaped body portions. Further, in one embodiment, an ultrasound gel can be included between the spacer component and the skin, such as in the concavity thereof.

**[00051]** FIG. 14 depicts a spacer component 90 according to another embodiment, including a flexible casing 92 that can operably attach to the probe head 32, as shown. The casing 92 includes arms 92A that contain a compliant insert 94, such as hydrogel in one embodiment. As shown in FIGS. 15A and 15B, the spacer component 90 is positioned on the probe head 32 so as to provide both spacing and an acoustic path between the acoustic surface 34 and the surface of the skin 36 or other tissue surface such that flowable ultrasound gel is not needed. So configured, the insert 94 thereof defines a contact surface 96 for contacting the surface of the skin 36 during ultrasound probe use. In one embodiment, the arms 92A of the casing 92 can be pressed inward to modify the shape of the contact surface 96. For instance, FIG. 15A shows that the contact surface 96 of the insert 94 defines a relatively shallow concavity 98 when the arms 92A of the casing 92 are allowed to flex outward. When the arms 92A are pressed inward as in FIG. 15B, however, the insert 94 is compressed by the arms and the concavity 98 of the contact surface 96 becomes relatively more pronounced. Such a configuration of the contact surface 96 may be desirable to stabilize a position of the subcutaneous vessel while preventing its collapse. The arms 92A can be biased to restore themselves to a given position when not being pressed by a user.

**[00052]** FIG. 16 shows details of a probe cap 110 for use with the probe 12 according to one embodiment. The cap 110 is configured to receive therein the head 32 of the probe 12 and to provide a spacer component 118 for providing desired spacing between the acoustic surface 34 of the probe head 32 and the skin 36.

**[00053]** As shown in FIGS. 17A-17D, the cap 110 defines a cavity 112 that is sized to receive therein the head 32 of the probe 12. An engagement feature 114 is included with the cap 110 to releasably and mechanically attach the cap to the probe 12, though it is appreciated that various designs can be employed to accomplish the same functionality. The cap 110 further includes a needle guide base 116 on which a

detachable needle guide can be placed so as to assist a clinician in placing a needle through the skin 36 after a vessel has been located through use of the ultrasound system 10 (FIG. 1A).

**[00054]** With continuing reference to FIGS. 17A-17D, reference is made to FIGS. 18A and 18B, which depict various details of the spacer component 118, which is disposed in a hole 130 defined in the cap 110, best seen in FIGS. 17A and 17C. As shown, the spacer component 118 includes a skin contact surface 126 that defines two spacer elements 120 and a concavity 122 disposed therebetween. The spacer component includes 118 a compliant material, such as hydrogel in one embodiment, though it is appreciated that other suitable materials can also be employed. The spacer component 118 thus requires no use of flowable ultrasound gel to be applied to the skin 36 in order to provide an acoustic path between the acoustic surface 134 and the patient's skin. The spacer component 118 further defines a lip 128 about a perimeter thereof to assist in its retention within the hole 130 of the cap 110, as seen in FIG. 18B. As shown, in the present embodiment the lip 128 is shaped so as to be sandwiched between the cap 110 and probe head 32, thus preventing its unintended removal from the cap.

**[00055]** FIG. 19 shows that in the present embodiment the acoustic surface 134 of the probe head 32 defines a convex shape. Correspondingly, FIG. 20 shows that a probe contact surface 136 of the compliant spacer component 118 also defines a convex surface. FIG. 21 shows that when the probe head 32 is received into the cavity 112 of the cap 110, the convexly shaped probe contact surface 136 of the spacer component 118 deformably engages the convexly shaped acoustic surface 134 of the probe head 32 so as to ensure adequate contact therebetween and to provide a suitable acoustic path through the spacer component. Of course, other complementary shapes can be employed on the acoustic surface and probe contact surface of the spacer component.

**[00056]** FIG. 22 shows another view of the engagement between the probe head 32 and the cap 110, according to the present embodiment. A recess 138 is included on the cap 110 to receive therein an orientation nub 140 on the probe head 32, which nub provides a landmark for orienting an ultrasound image on the display 30 (FIG. 1A) with the orientation of the probe 12 as held by the clinician. FIG. 23 shows the cap 110, including the spacer component 118, removably attached to the probe 12. Note that in one embodiment the cap provides a sterile barrier for the probe head, and is disposable.

[00057] Embodiments of the invention may be embodied in other specific forms without departing from the spirit of the present disclosure. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the embodiments is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

## CLAIMS

1. An ultrasound imaging system for imaging a subcutaneous structure of a patient, comprising:
  - a display;
  - an ultrasound probe including an acoustic surface from which ultrasound signals are emitted; and
  - first and second spacer elements positioned proximate to opposite ends of the acoustic surface to provide a gap between the acoustic surface and a tissue surface of the patient so as to prevent compression of the subcutaneous structure of the patient below the acoustic surface.
2. The imaging system as defined in claim 1, wherein the first and second spacer elements include blade-like extensions.
3. The imaging system as defined in claim 1, wherein the first and second spacer elements are integrally formed with the ultrasound probe and wherein each spacer element is coincident with a side surface of the ultrasound probe.
4. The imaging system as defined in claim 1, wherein the gap is configured to include an ultrasound gel therein.
5. The imaging system as defined in claim 4, wherein the acoustic surface is concavely shaped to assist in retention of the ultrasound gel within the gap.
6. The imaging system as defined in claim 4, further comprising a sheath that is disposed over the probe so as to cover the first and second spacer elements and provide a barrier for retaining the ultrasound gel within the gap.
7. The imaging system as defined in claim 1, wherein a tissue contact surface of each spacer element is rounded.
8. The imaging system as defined in claim 1, wherein each spacer element is height-adjustable to allow for altering the size of the gap between the acoustic surface and a tissue surface of the patient.

9. The imaging system as defined in claim 1, wherein the spacer elements are included on a cap that is removably attached to the probe and wherein a sheath is attached to the cap to cover the ultrasound probe.

10. The imaging system as defined in claim 1, wherein the spacer elements enable superficial vessels of the patient to fall within a focal point of the ultrasound probe.

11. A spacer component for use with an ultrasound probe, the probe including an acoustic surface, the spacer component comprising:

a compliant member attachable to the probe to provide an acoustic path between the acoustic surface of the probe and a tissue surface of the patient, the compliant member including a tissue contact surface that defines a concavity.

12. The spacer component as defined in claim 11, wherein the compliant member further includes first and second spacer elements disposed on opposite ends of the concavity, the spacer elements including extended surfaces that are deformable against the tissue of the patient during use of the probe.

13. The spacer component as defined in claim 11, wherein the compliant member includes a hydrogel and wherein spacer compliant provides a complete acoustic path between the acoustic surface and the tissue surface such that no flowable ultrasound gel is required for use of the probe.

14. The spacer component as defined in claim 11, wherein the compliant member is disposed within a casing, the casing being attachable to the ultrasound probe.

15. The spacer component as defined in claim 14, wherein the casing includes flexible side arms, the side arms being movable by a clinician to modify a shape of the tissue contact surface.

16. The spacer component as defined in claim 15, wherein an inward squeezing of the flexible arms causes the concavity of the tissue contact surface to decrease in width.

17. A probe cap for use with an ultrasound probe, the probe including a head portion and an acoustic surface on the head portion, the probe cap comprising:

a body defining a cavity sized for releasably receiving the head portion of the probe therein, the body defining a hole proximate the acoustic surface;

a compliant spacer component disposed in the hole, the spacer component providing an acoustic path between the acoustic surface and a tissue surface of a patient, the spacer component including a skin contact surface that defines a concavity.

18. The probe cap as defined in claim 17, wherein the spacer component includes a hydrogel and wherein the tissue contact surface defines at least one spacer element adjacent the concavity, the tissue contact surface being deformable against the tissue surface.

19. The probe cap as defined in claim 18, wherein the acoustic surface of the probe head defines a convex surface and wherein a probe head contact surface of the spacer component includes a convex surface such that the probe head contact surface substantially engages the acoustic surface of the probe head when the probe cap is attached to the probe head portion.

20. The probe cap as defined in claim 19, wherein the spacer component further includes a lip portion configured to retain the spacer component within the hole of the probe cap body.

21. The probe cap as defined in claim 20, further including:

at least one engagement feature for releasably attaching the probe cap to the probe head portion; and

a needle guide base for receiving a needle guide thereon.



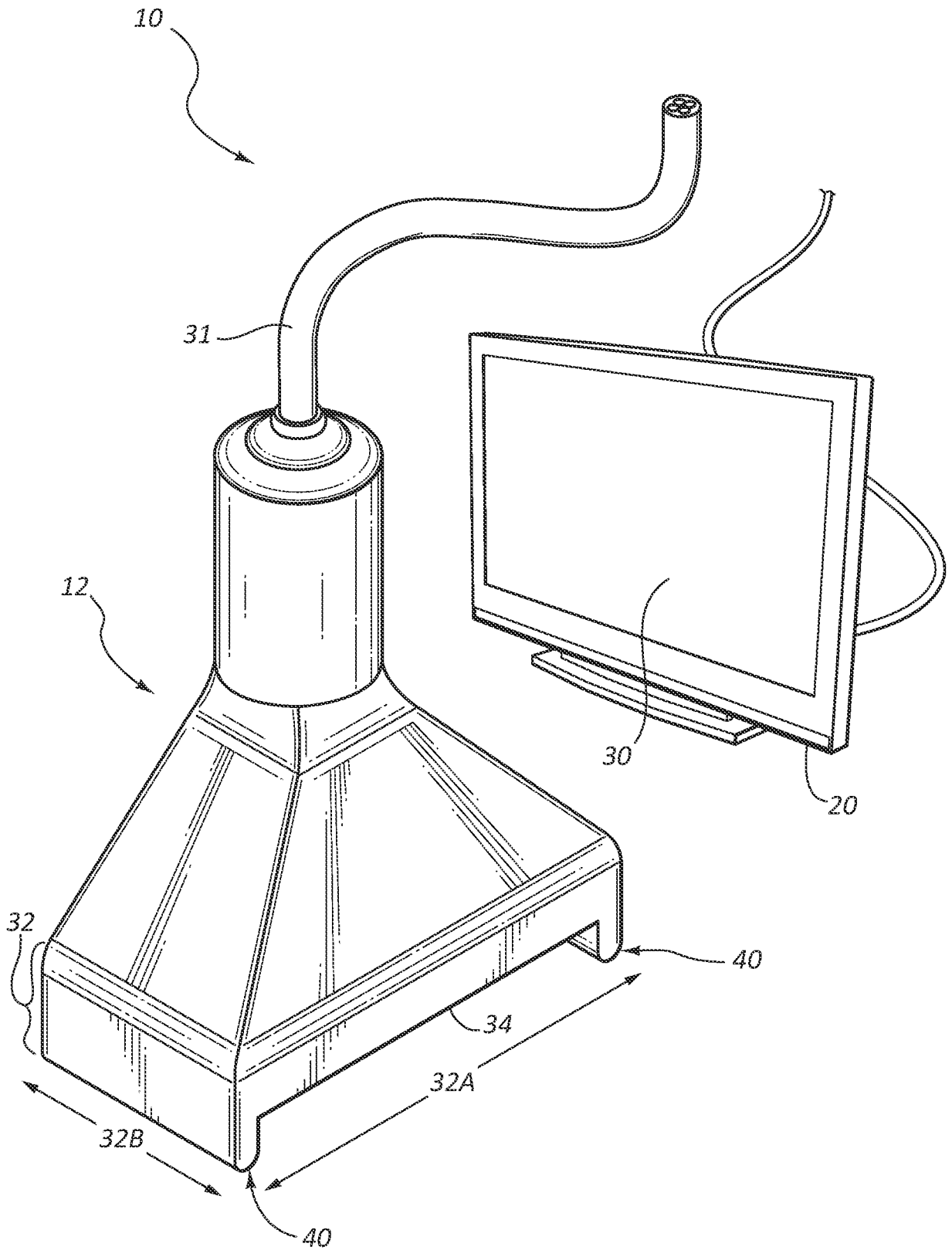


FIG. 1A

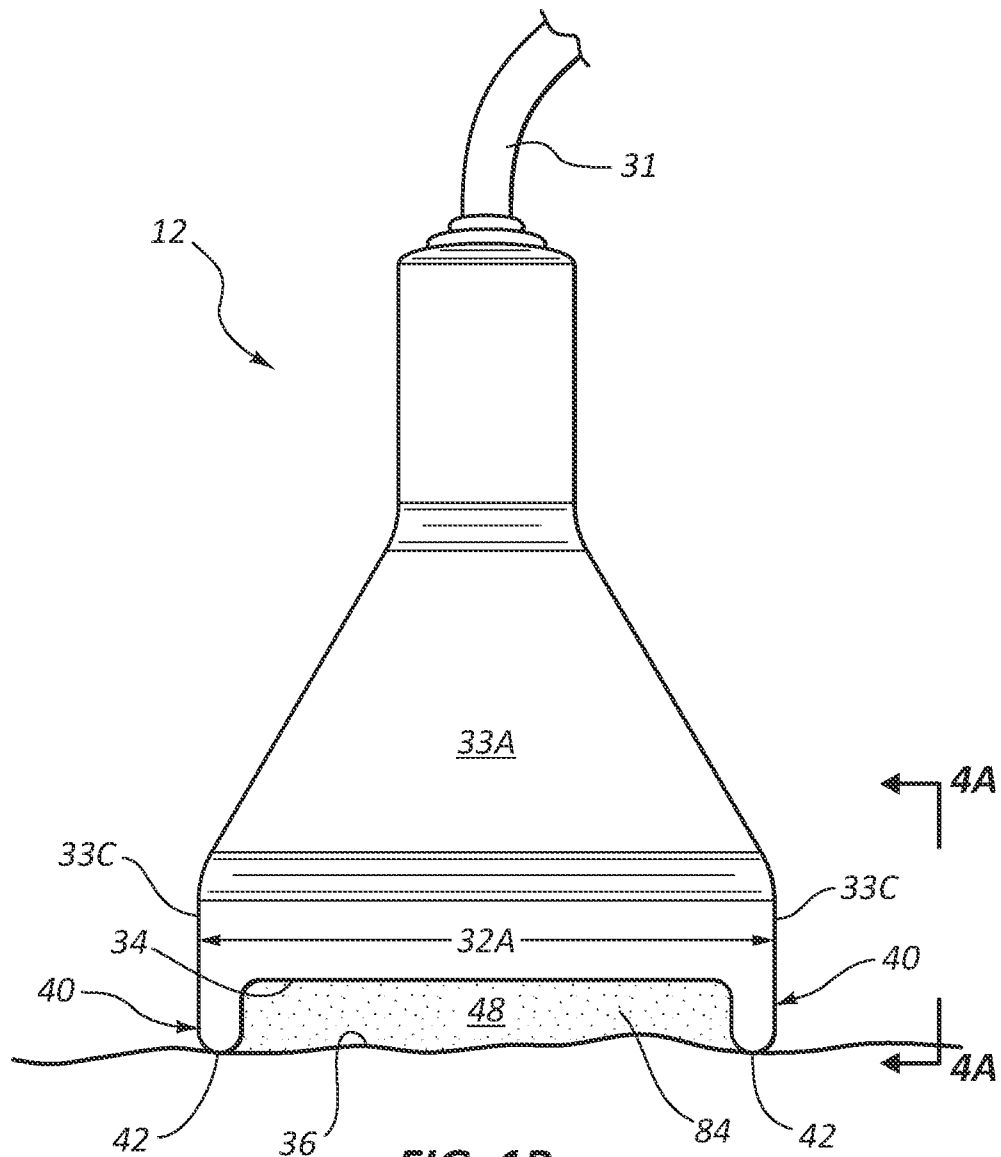


FIG. 1B

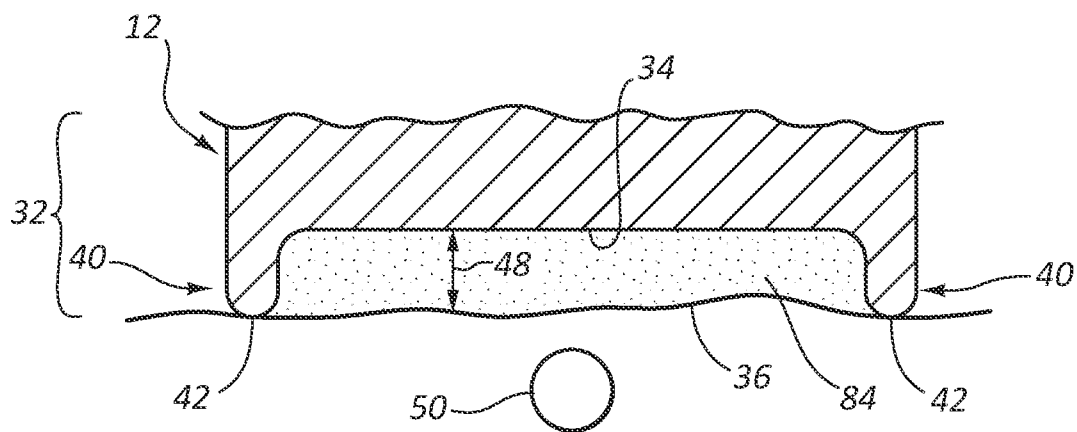


FIG. 2

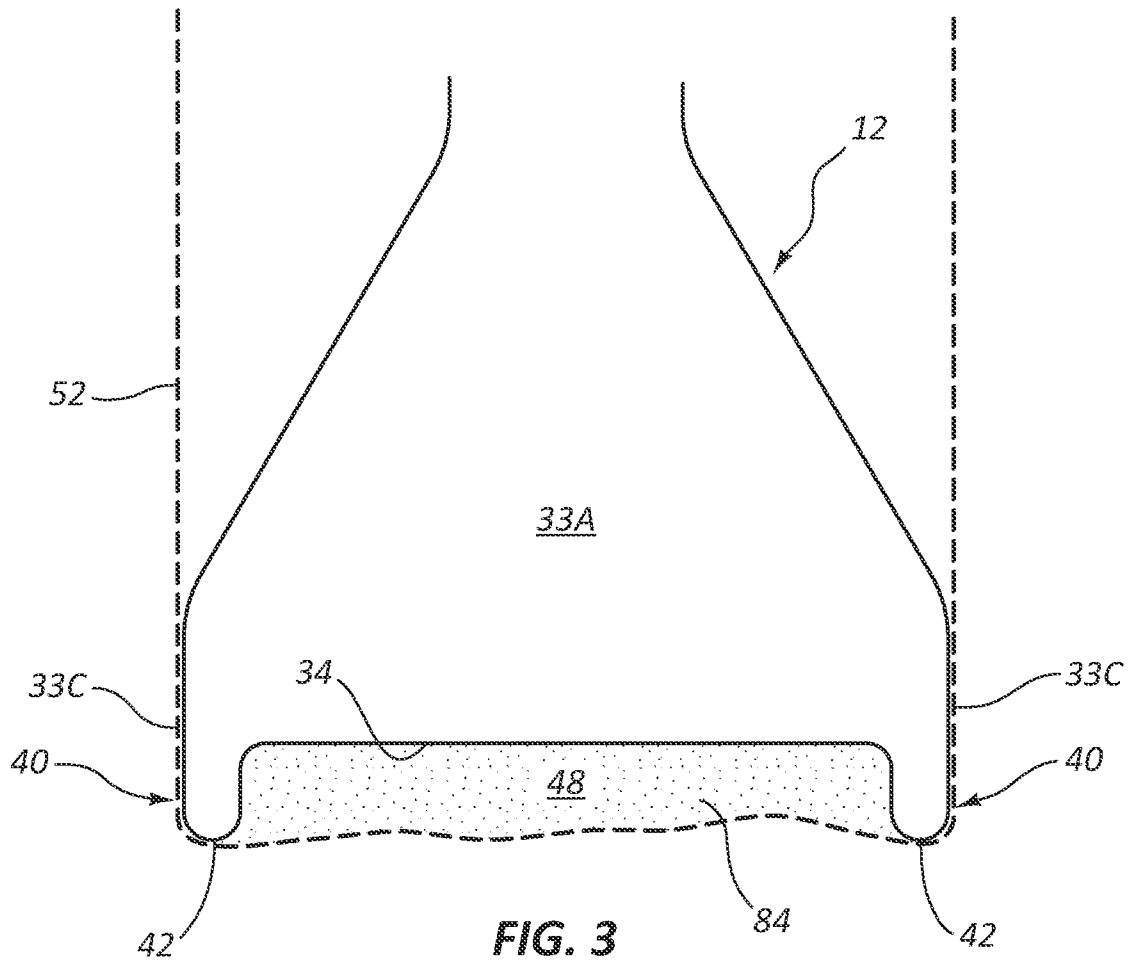


FIG. 3

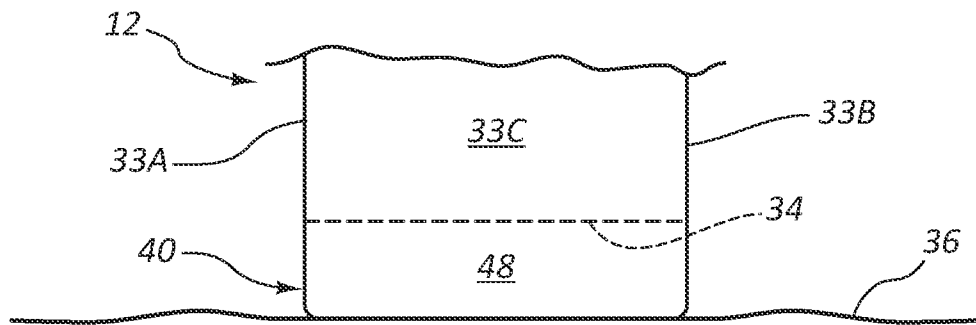


FIG. 4A

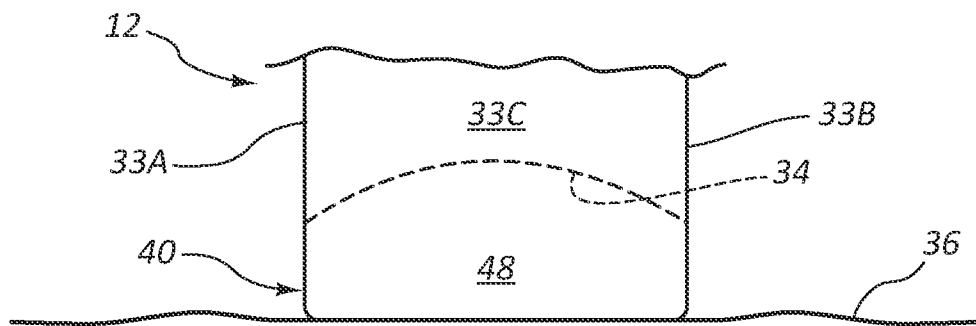
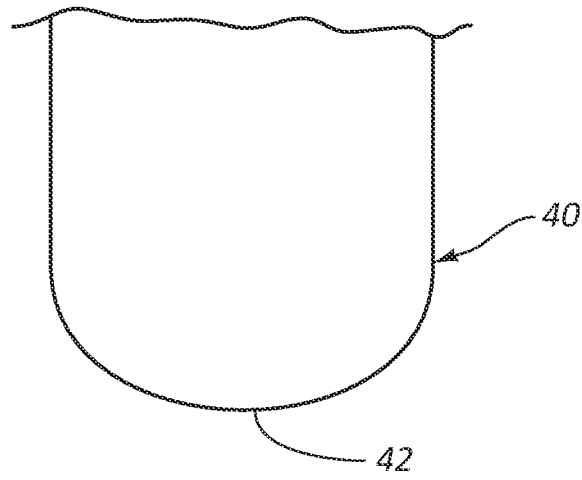
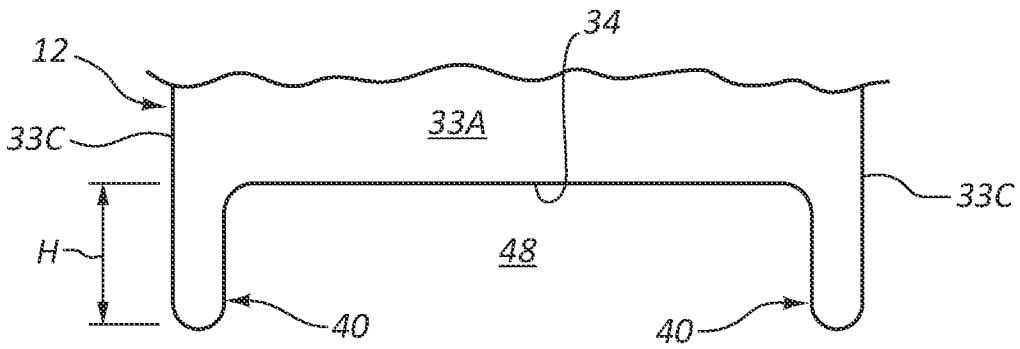


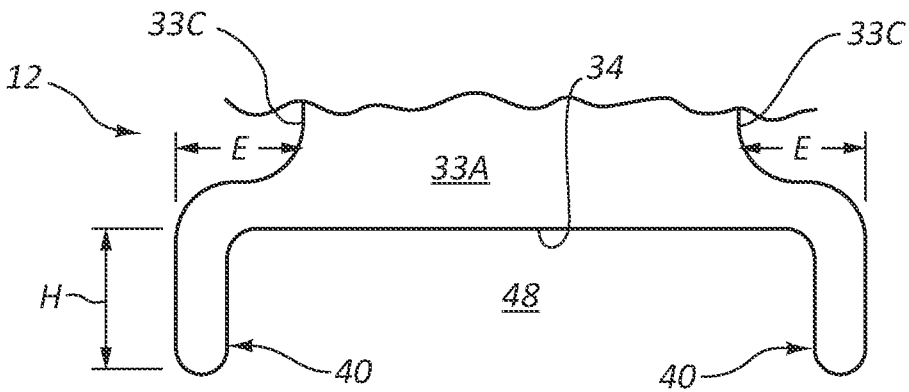
FIG. 4B



**FIG. 5**



**FIG. 6**



**FIG. 7**

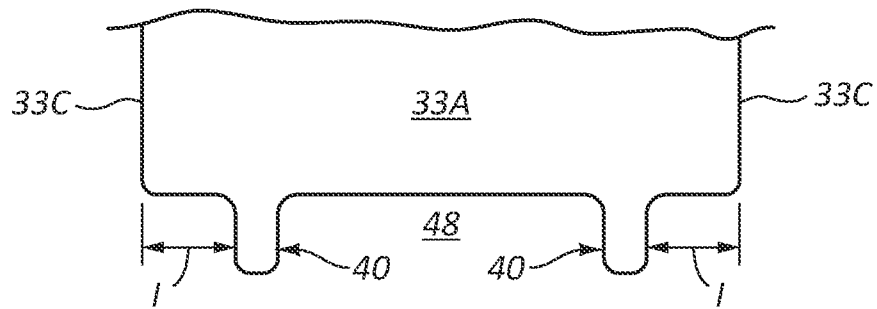


FIG. 8

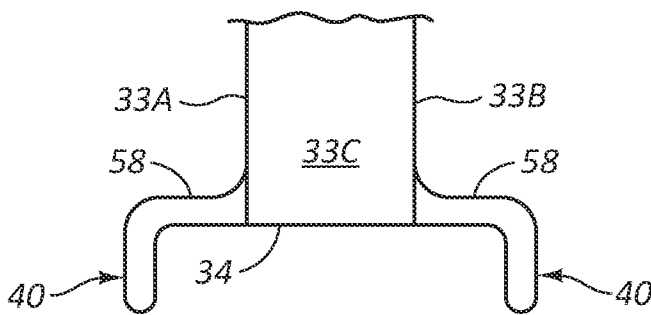


FIG. 9A

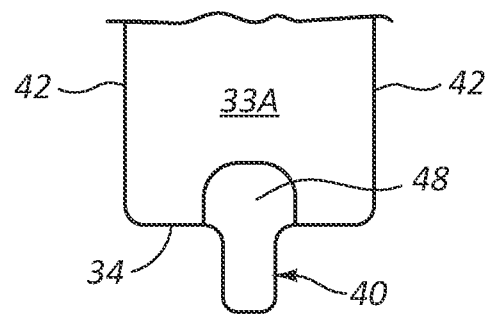


FIG. 9B

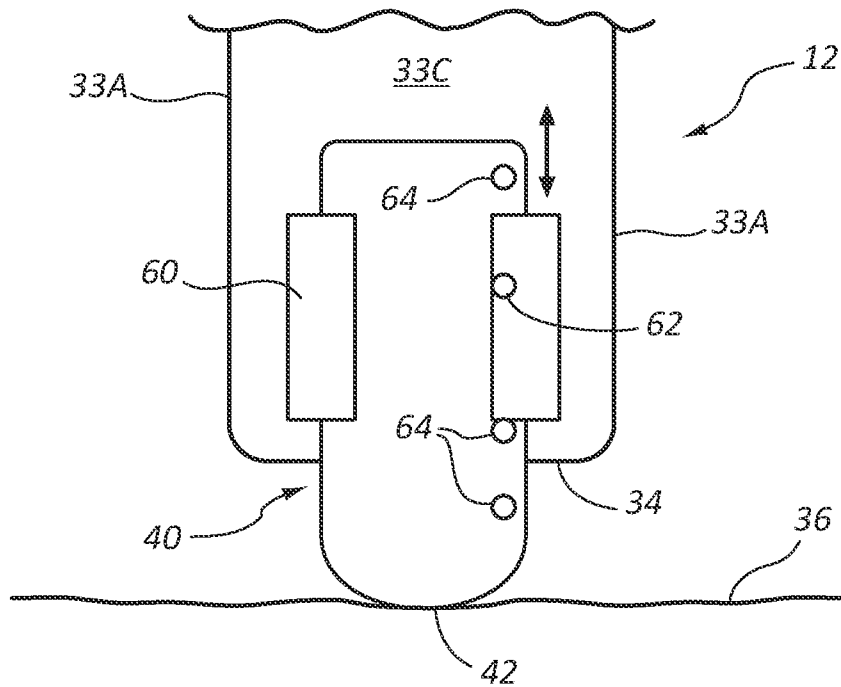
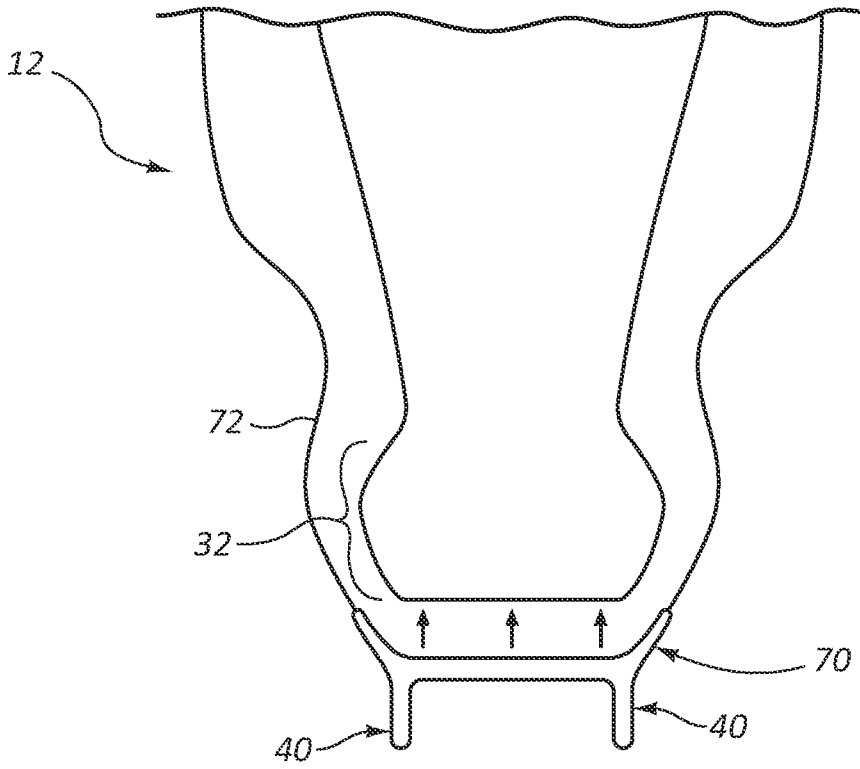
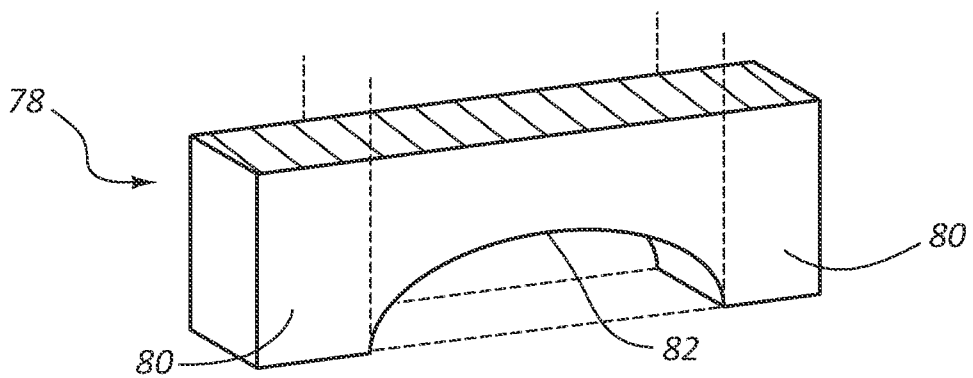


FIG. 10

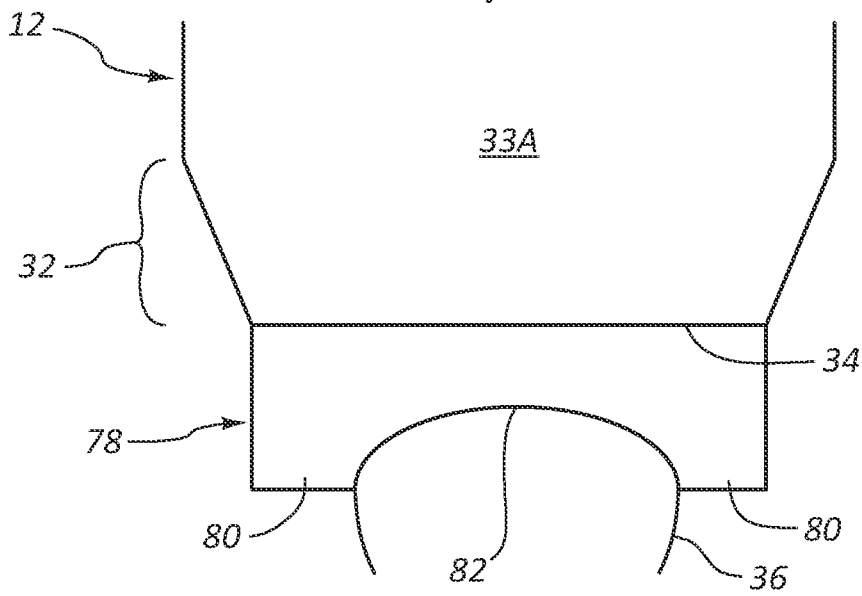


**FIG. 11**

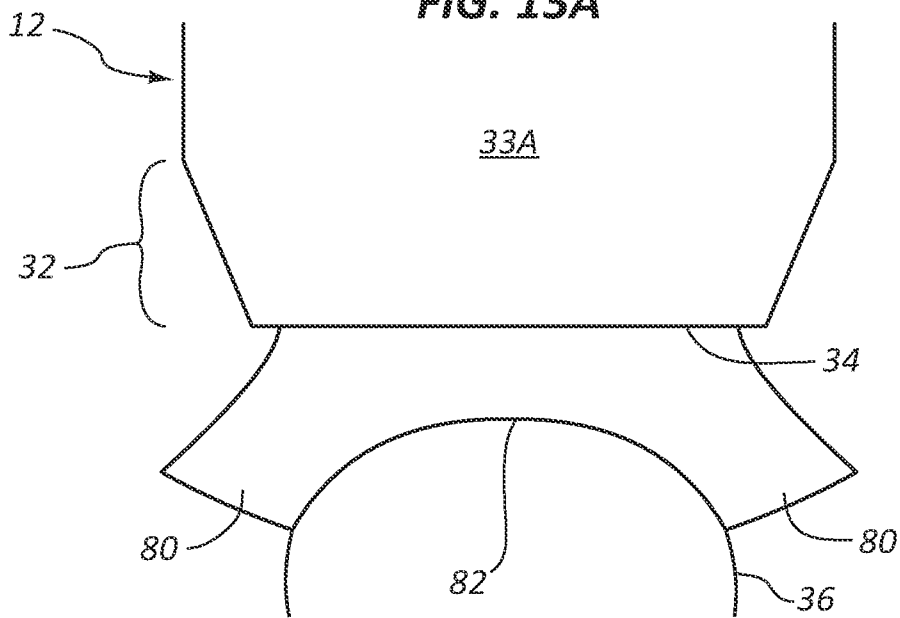


**FIG. 12**

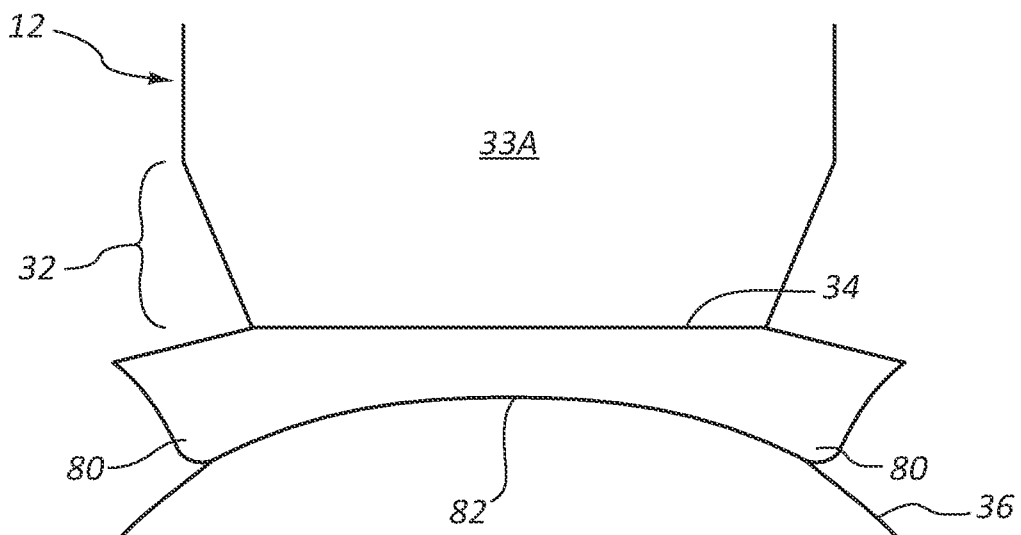
7/15



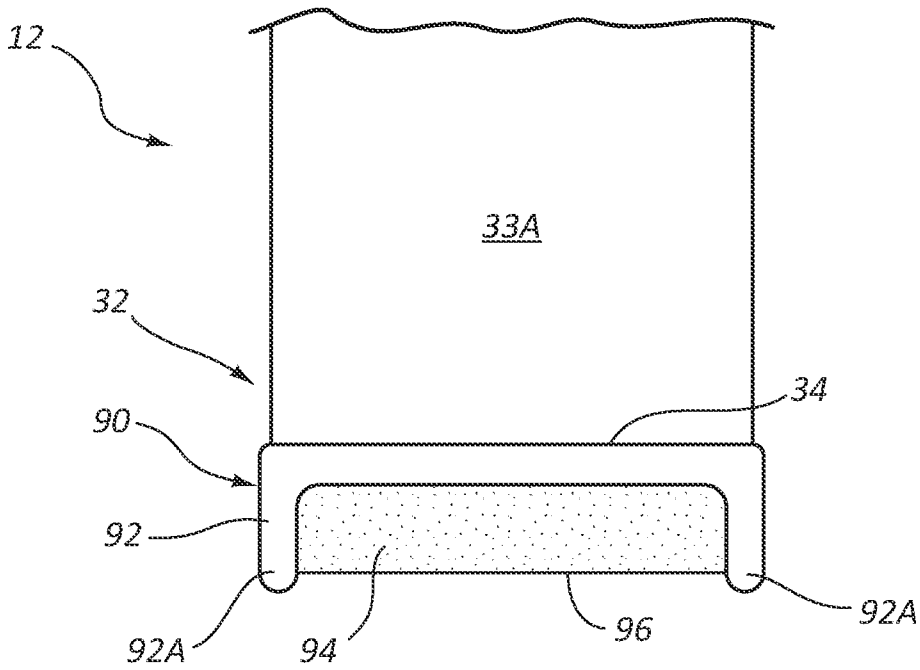
**FIG. 13A**



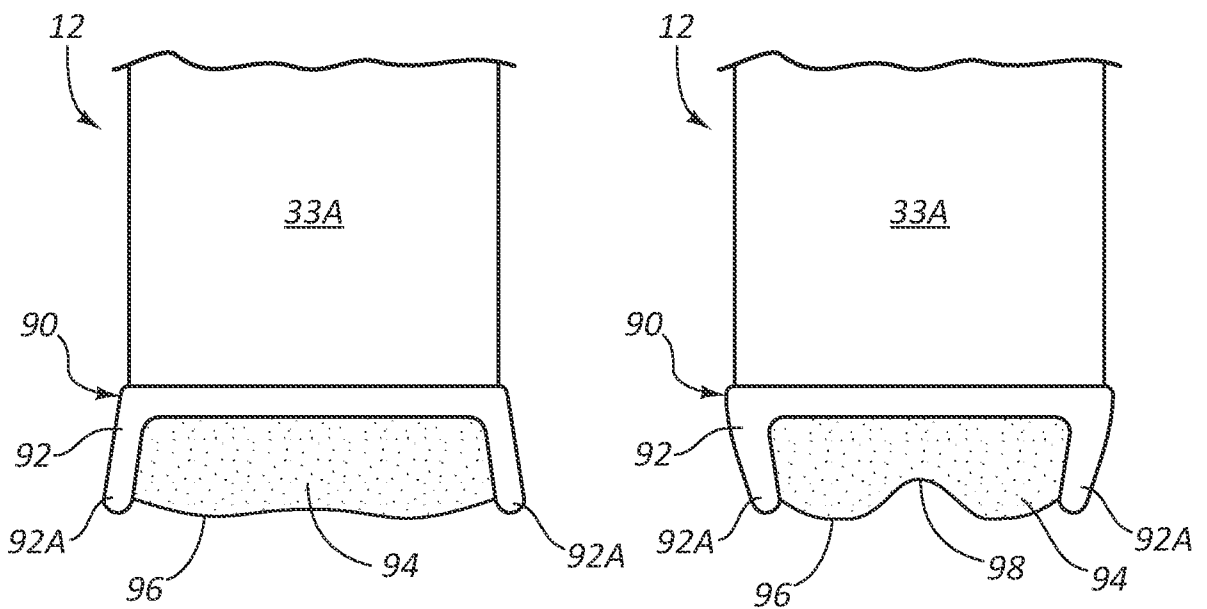
**FIG. 13B**



**FIG. 13C**



**FIG. 14**



**FIG. 15A**

**FIG. 15B**



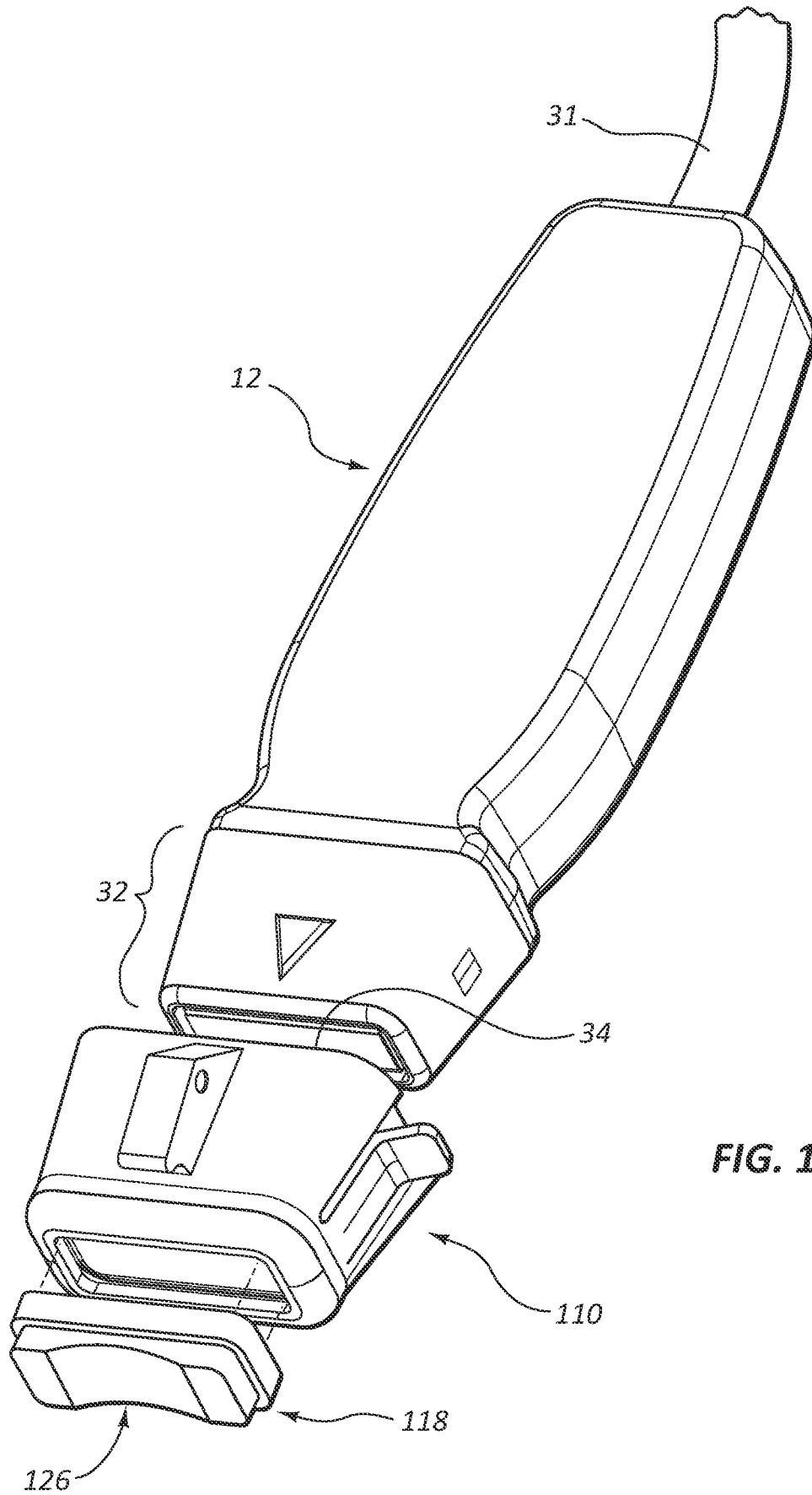


FIG. 16

10/15

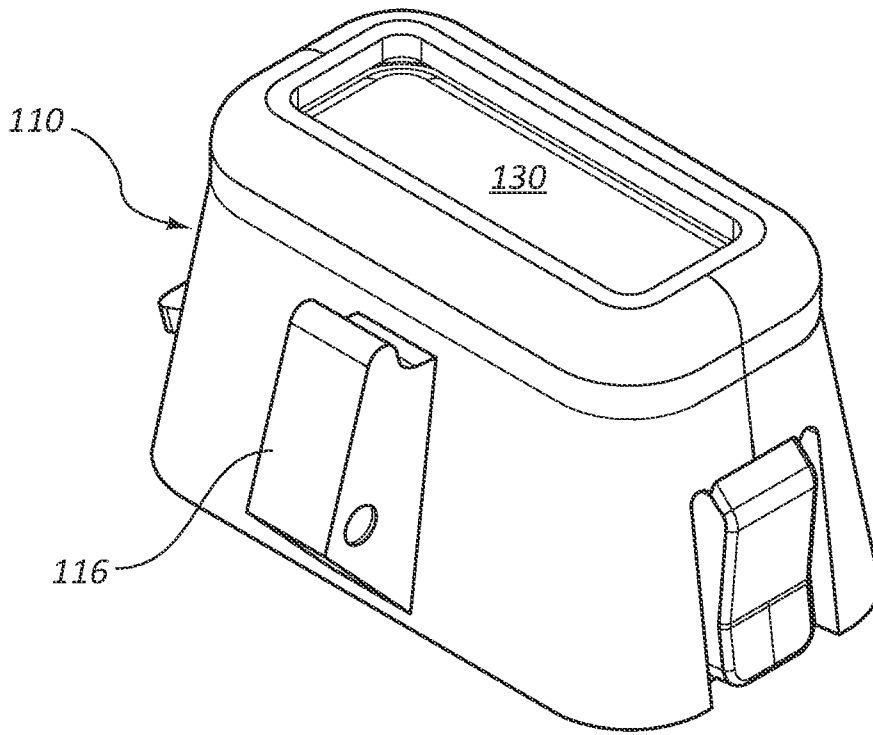


FIG. 17A

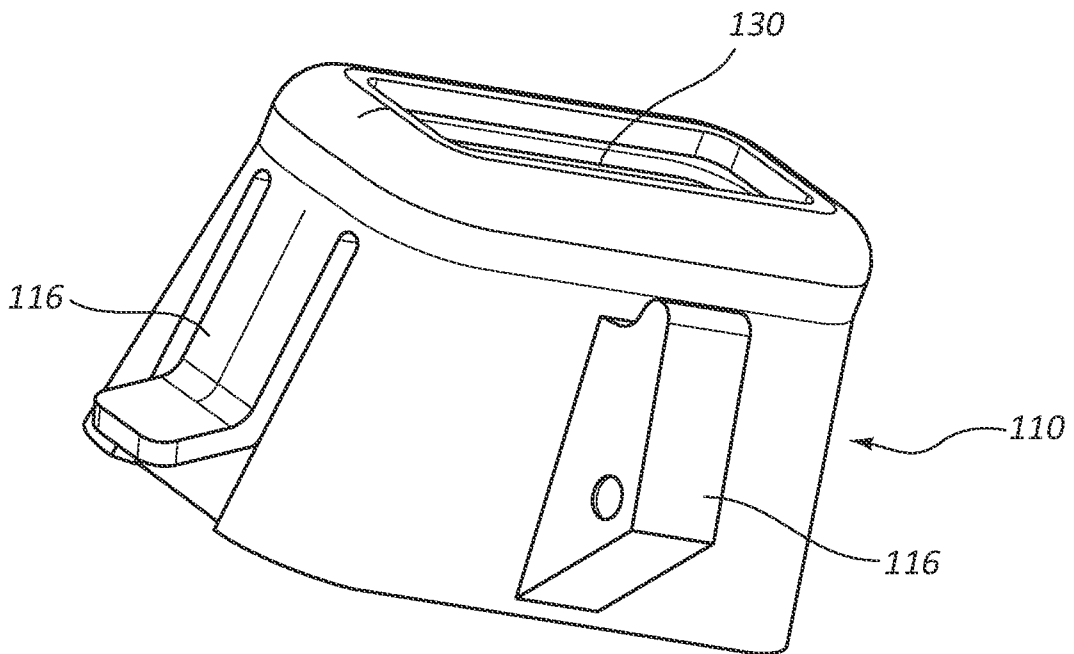


FIG. 17B

11/15

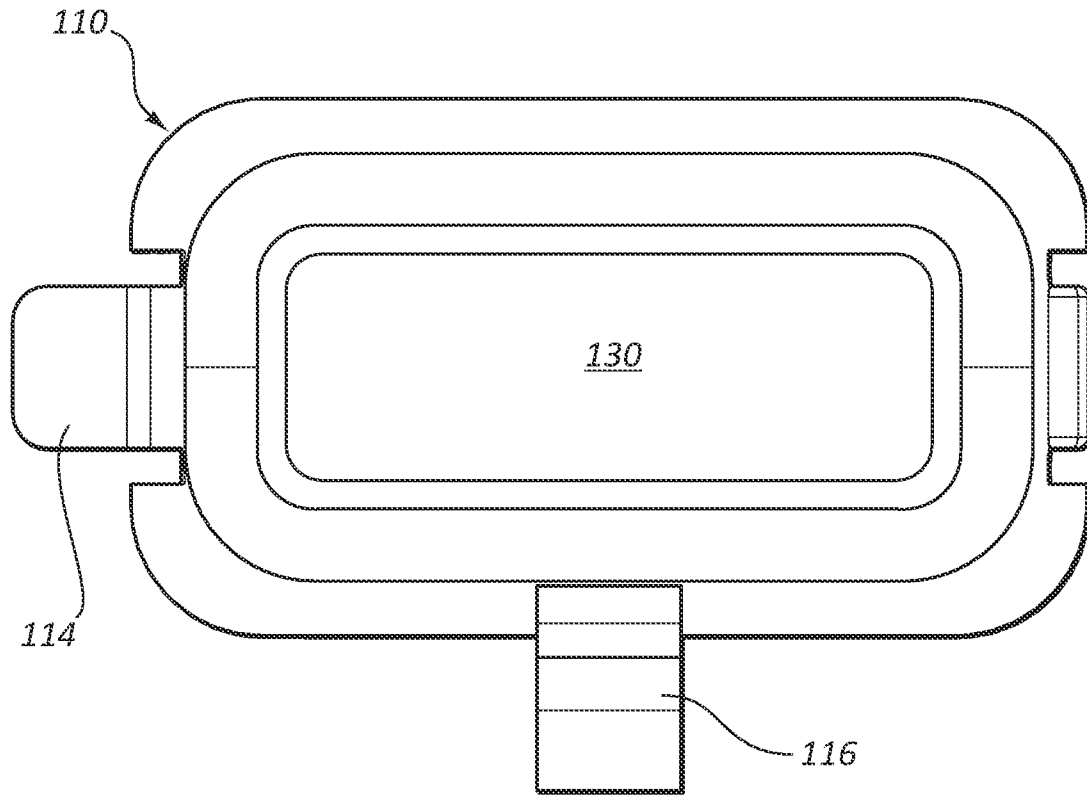


FIG. 17C

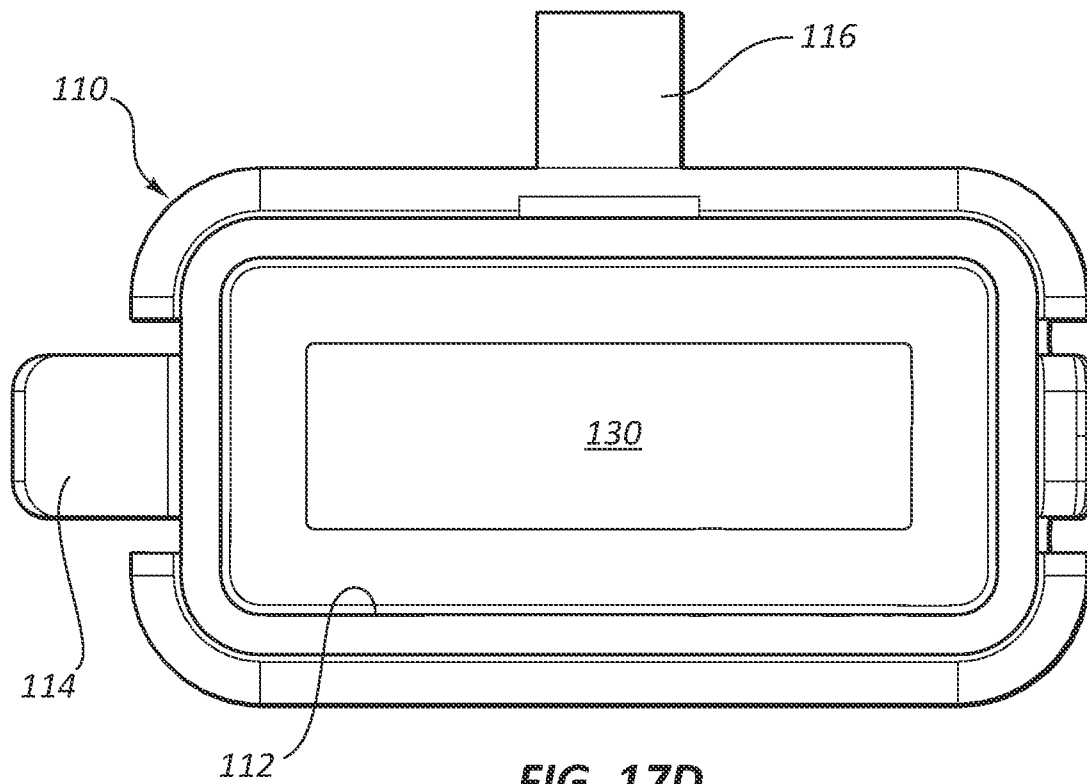


FIG. 17D

12/15

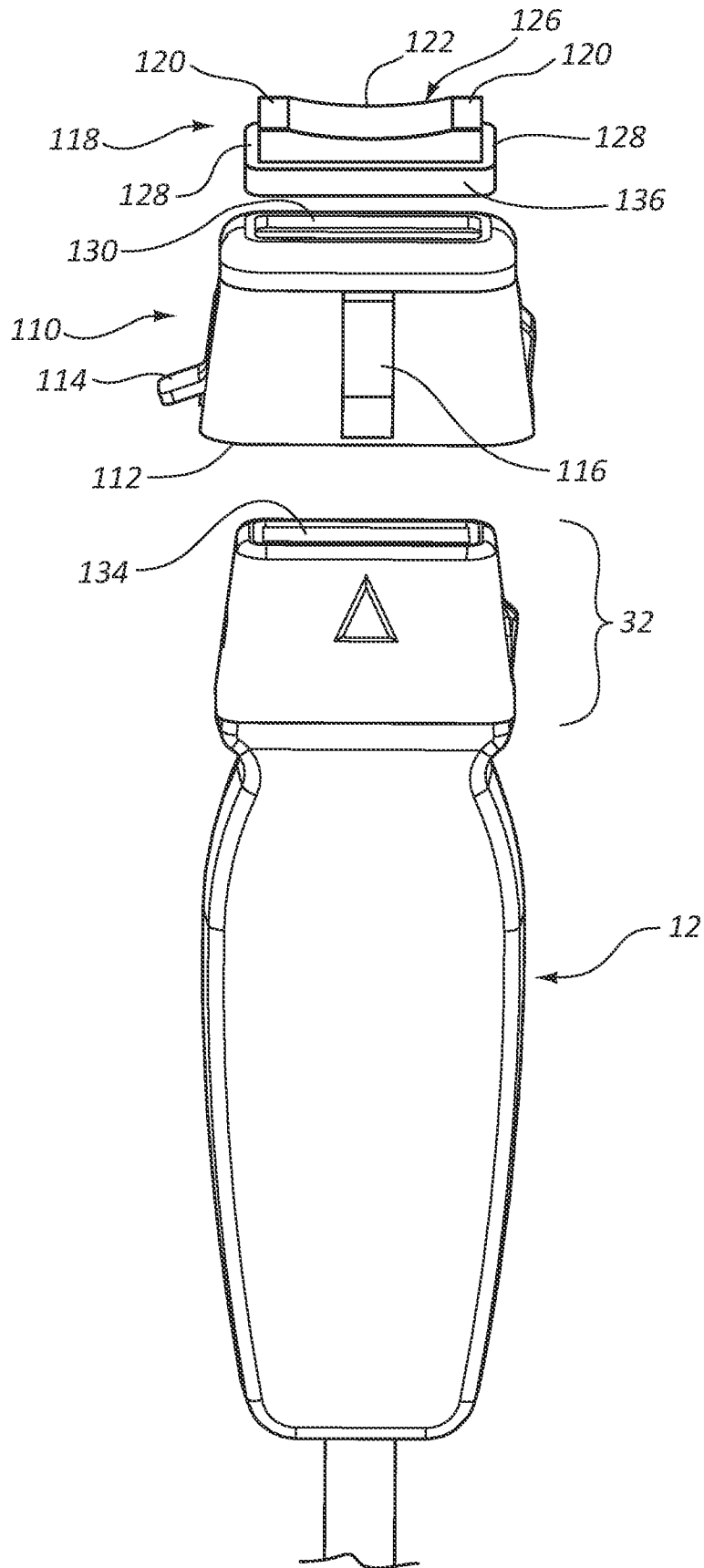
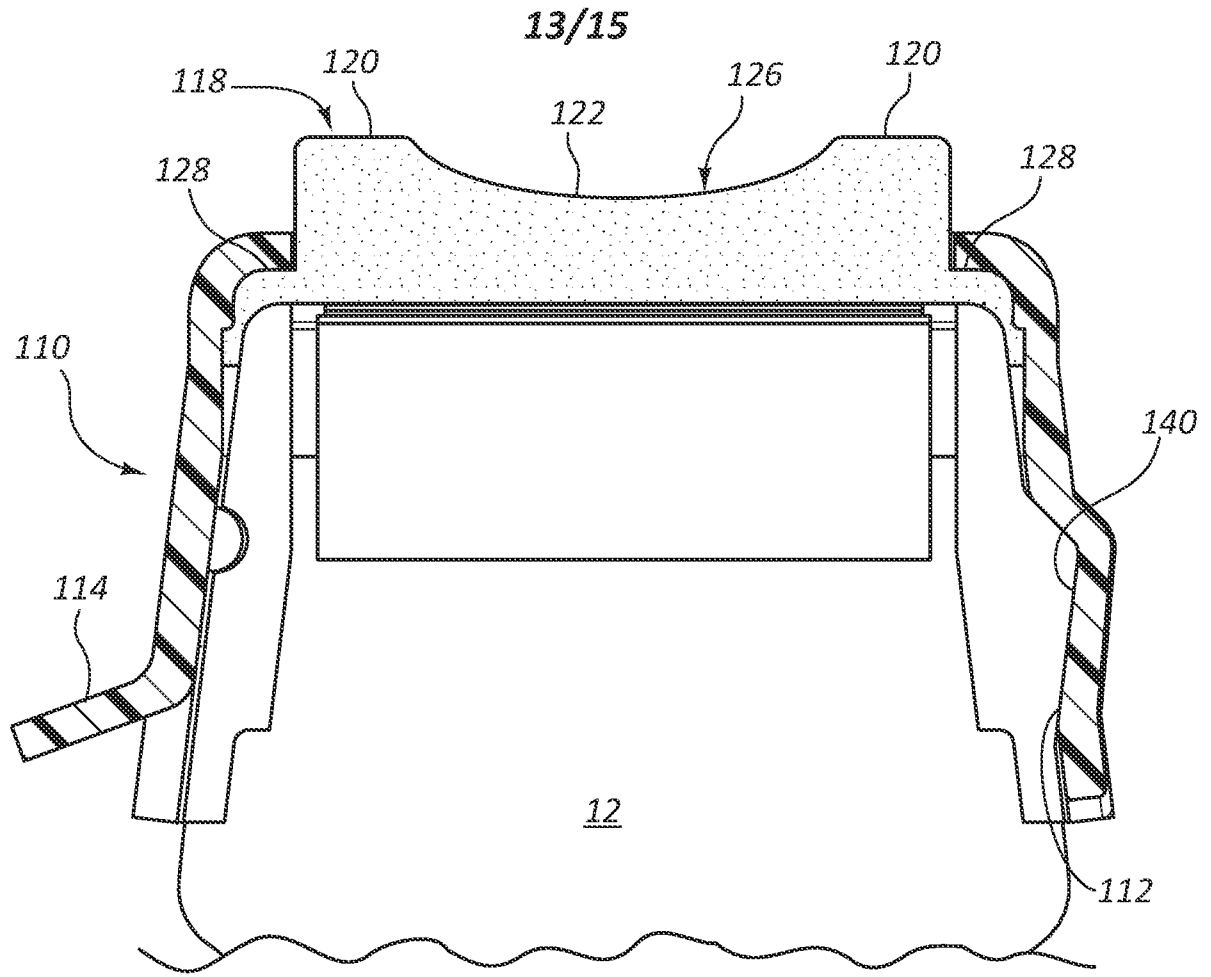
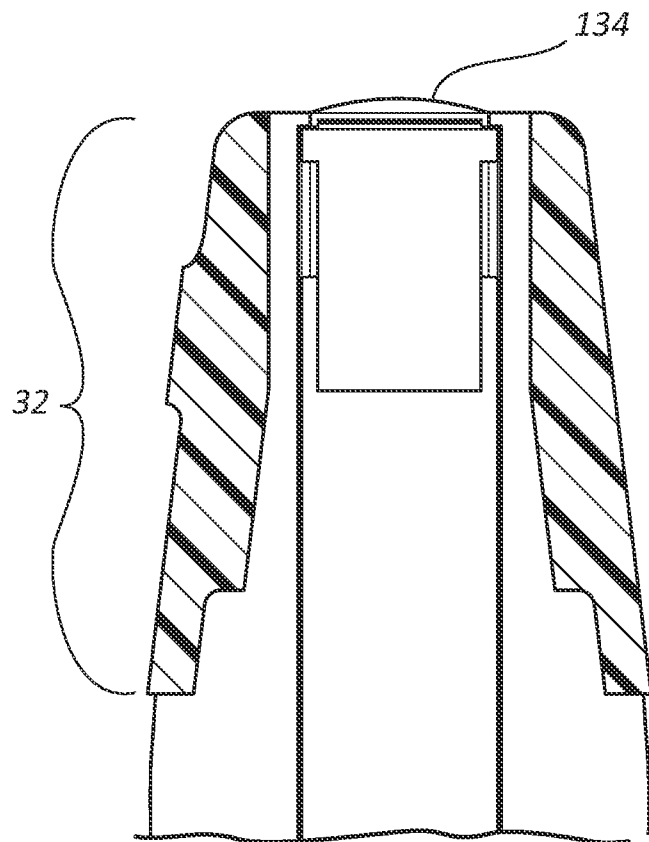


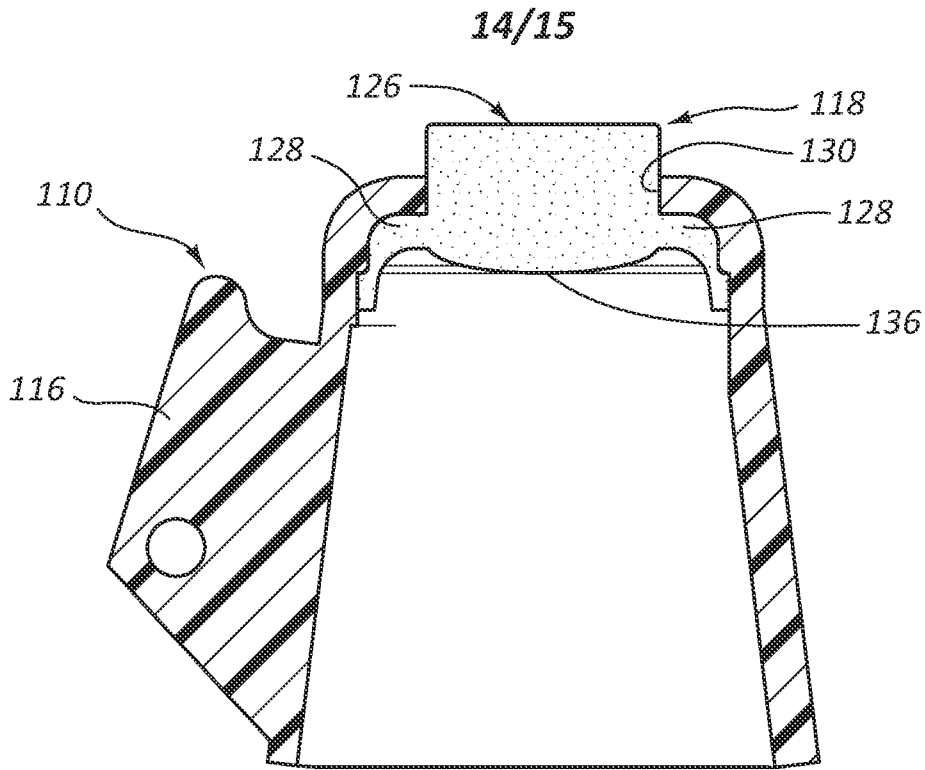
FIG. 18A



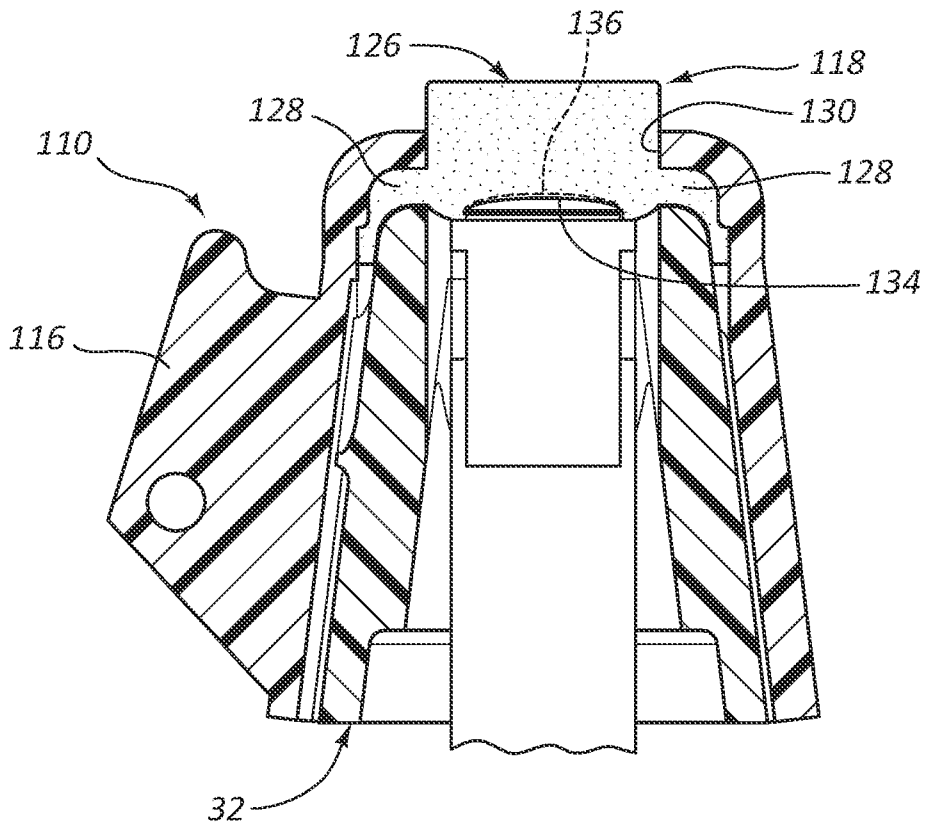
**FIG. 18B**



**FIG. 19**



**FIG. 20**



**FIG. 21**

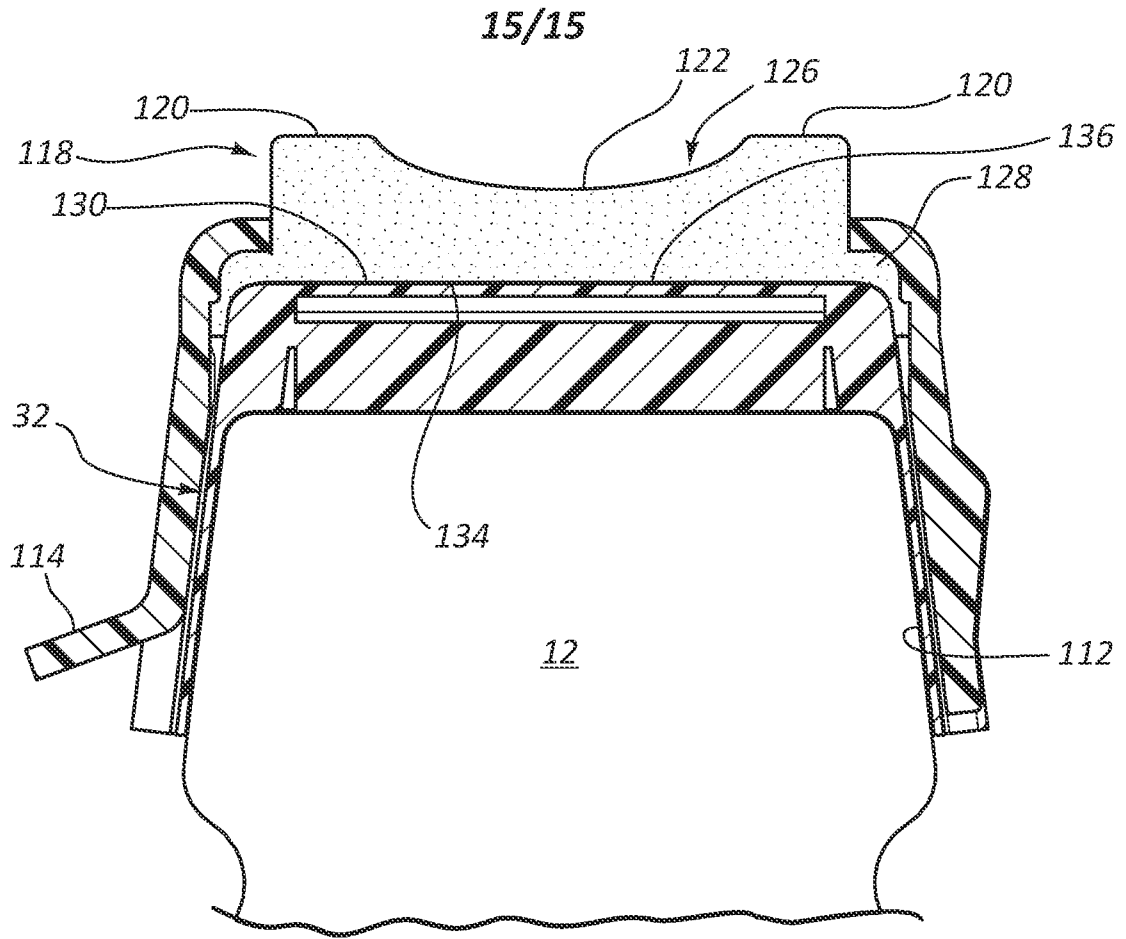


FIG. 22

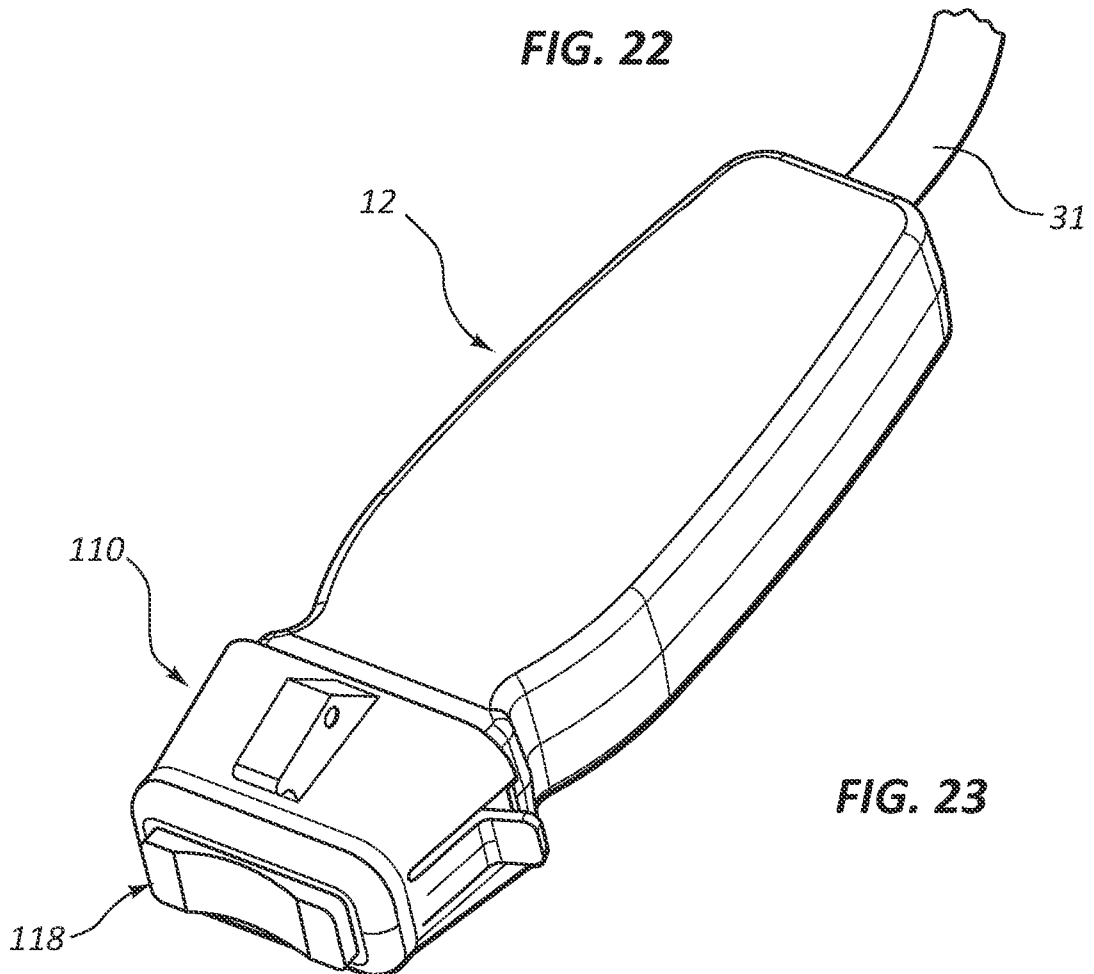


FIG. 23

INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2010/051917

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC(8) - A61N 7/02 (2010.01)  
 USPC - 600/459  
 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)  
 IPC(8) - A61N 7/02; G10K 11/02  
 USPC - 600/437, 444, 445, 446, 459, 463, 472; 604/22

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
 Minesoft PatBase, USPTO EAST System (US-PGPUB; USPAT), Google Patents

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 6,500,141 B1 (IRION et al) 31 December 2002 (31.12.2002) entire document	1-5, 7-8, 10 ----- 6, 9
X --- Y	US 5,394,877 A (ORR et al) 07 March 1995 (07.03.1995) entire document	11-16 ----- 17-21
Y	US 2005/0154308 A1 (QUISTGAARD et al) 14 July 2005 (14.07.2005) entire document	6, 9
Y	US 5,820,549 A (MARIAN JR) 13 October 1998 (13.10.1998) entire document	9, 17-21
Y	US 2006/0173329 A1 (IRIOKA et al) 03 August 2006 (03.08.2006) entire document	19-21
Y	US 7,241,267 B2 (FURIA) 10 July 2007 (10.07.2007) entire document	21
A	US 2005/0101869 A1 (BURBA et al) 12 May 2005 (12.05.2005) entire document	1-21
A	US 6,315,727 B1 (COLEMAN et al) 13 November 2001 (13.11.2001) entire document	1-21

Further documents are listed in the continuation of Box C.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"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
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 16 November 2010	Date of mailing of the international search report <b>29 NOV 2010</b>
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver  PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774