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Nordgren et al.

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(54) **STERILE COVERS FOR ULTRASOUND PROBE**

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This patent is subject to a terminal disclaimer.

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(60) Provisional application No. 62/097,477, filed on Dec. 29, 2014.

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A61B 8/00 (2006.01)

(52) **U.S. Cl.**
CPC **A61B 8/4422** (2013.01)

(58) **Field of Classification Search**
CPC A61B 8/4422
See application file for complete search history.

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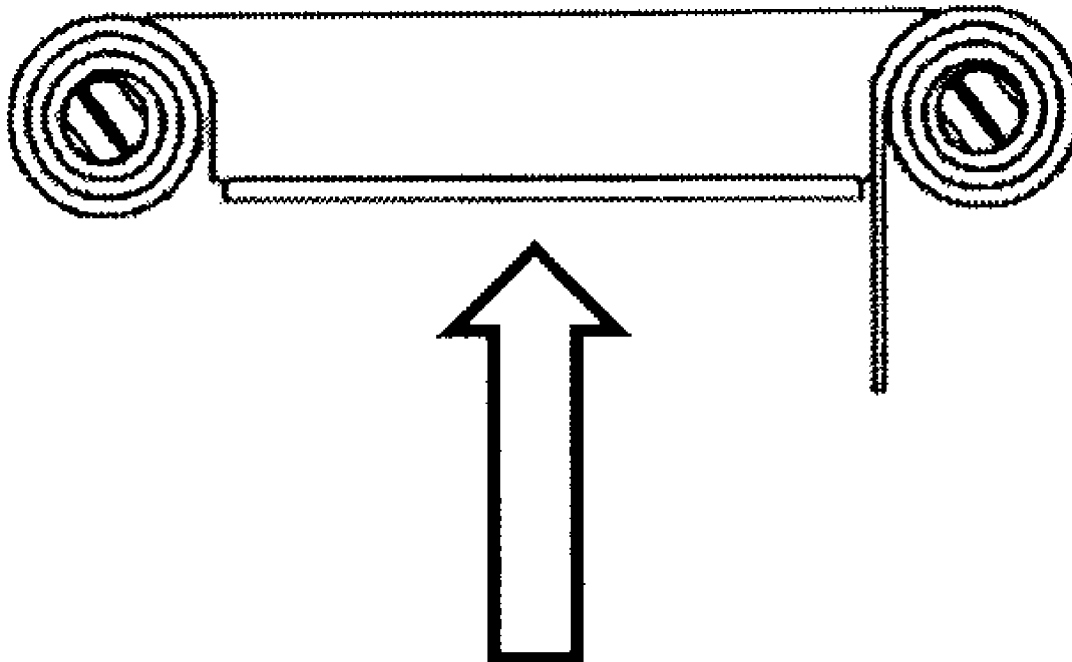
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(57) **ABSTRACT**

A flexible cover for an ultrasound probe is described, comprising a folded-over flexible sheath which is then rolled, incorporating in the roll a flexible band and designed to facilitate easy application of a sterile sheath over an ultrasound probe.

10 Claims, 24 Drawing Sheets



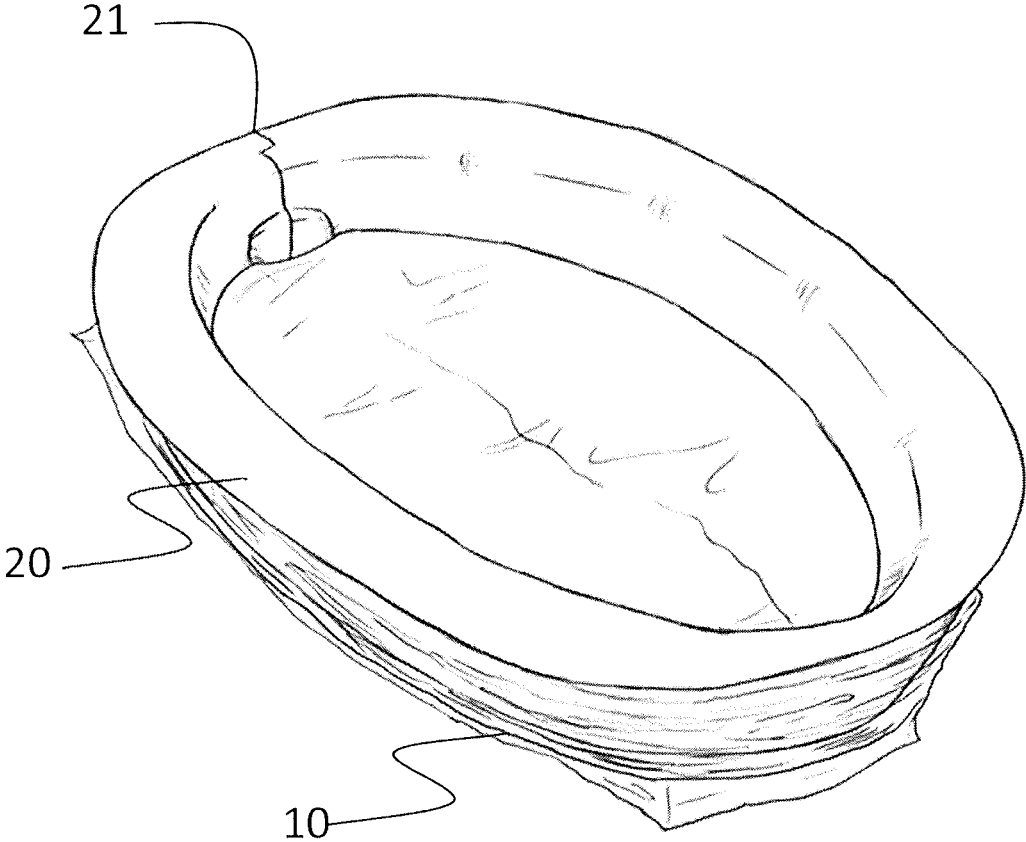


Figure 1

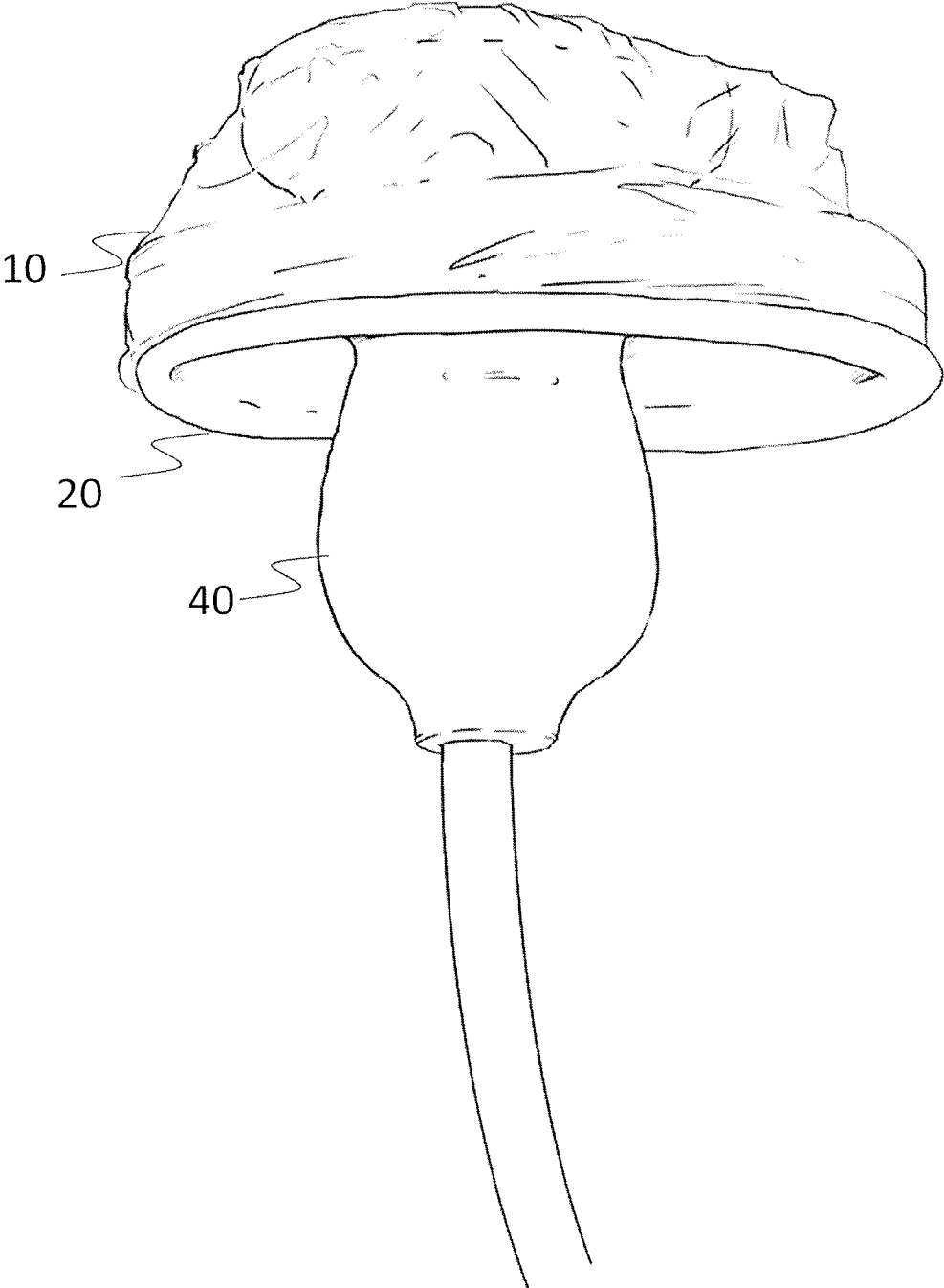


Figure 2

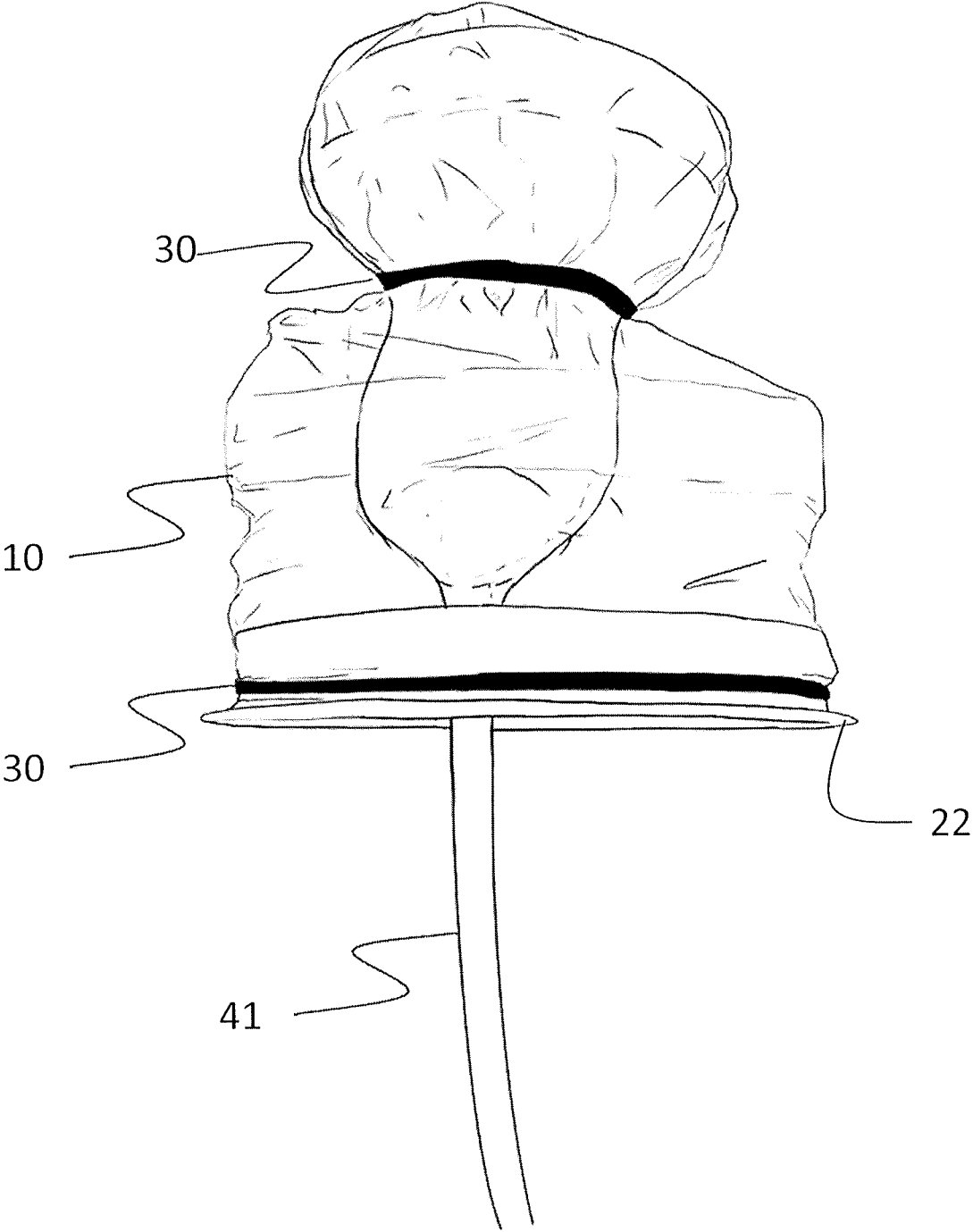


Figure 3

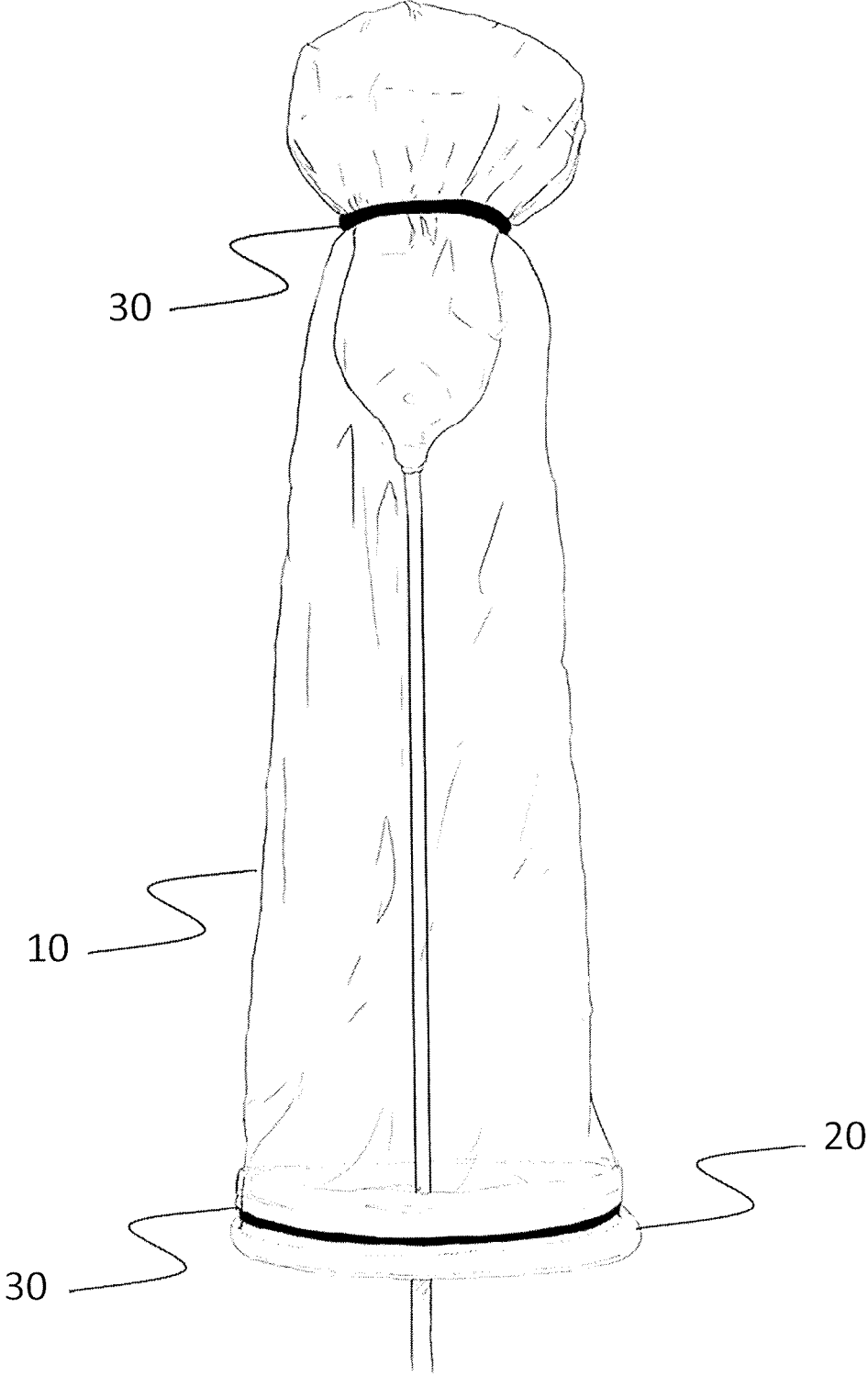


Figure 4

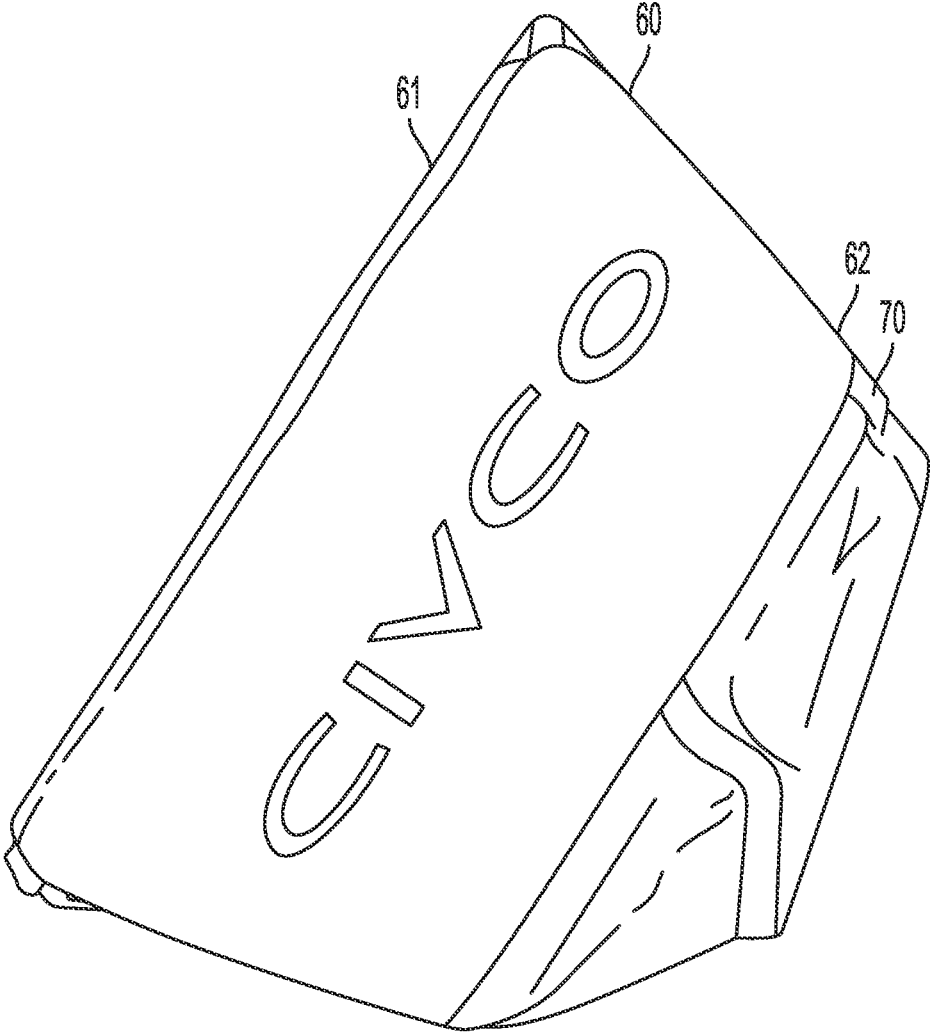


Figure 5

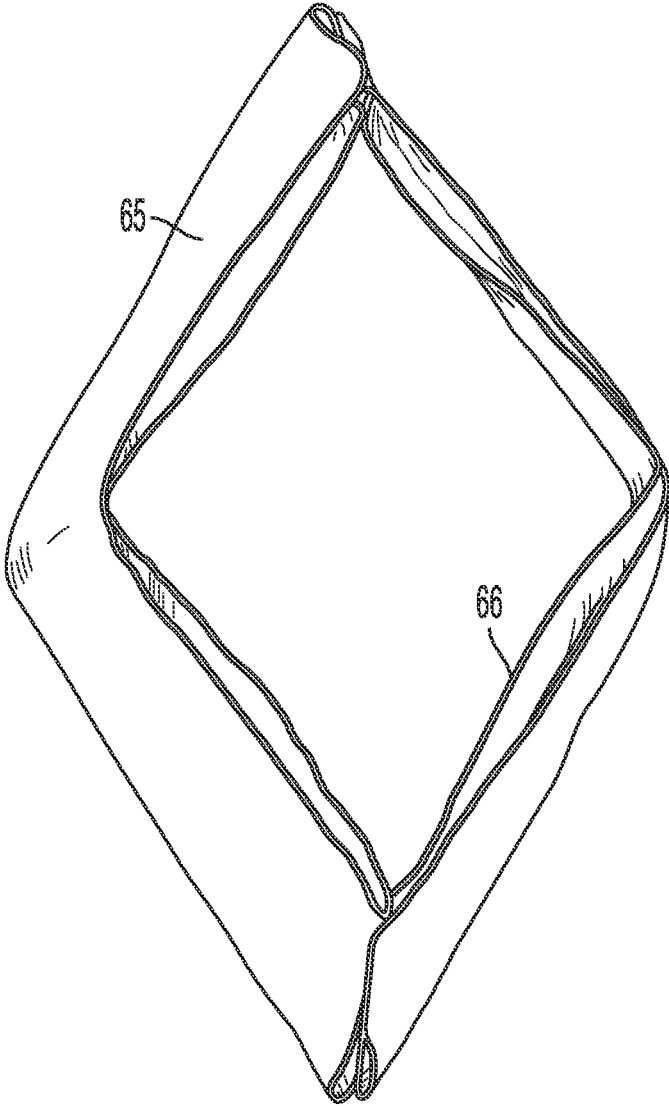


Figure 6

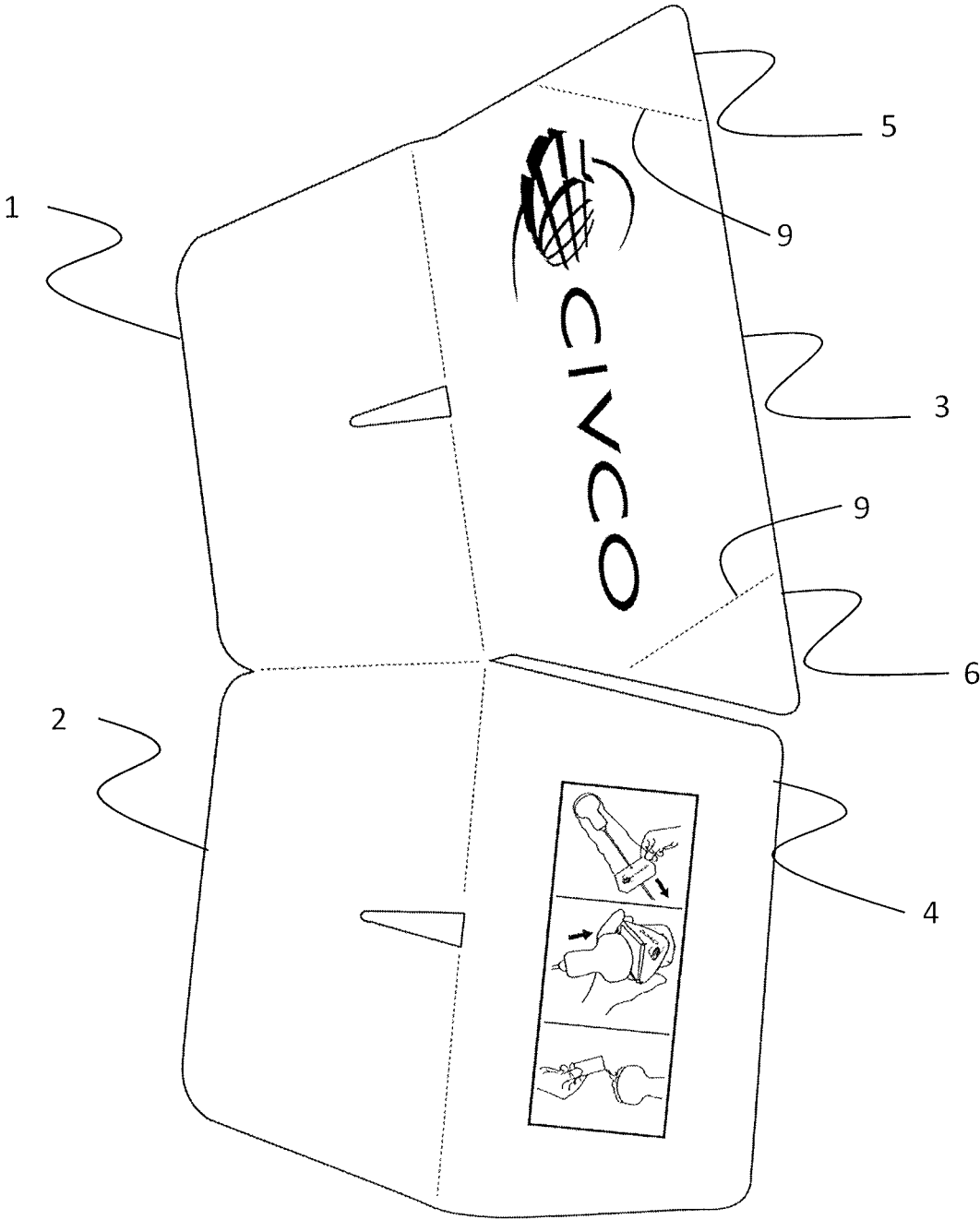


Figure 7

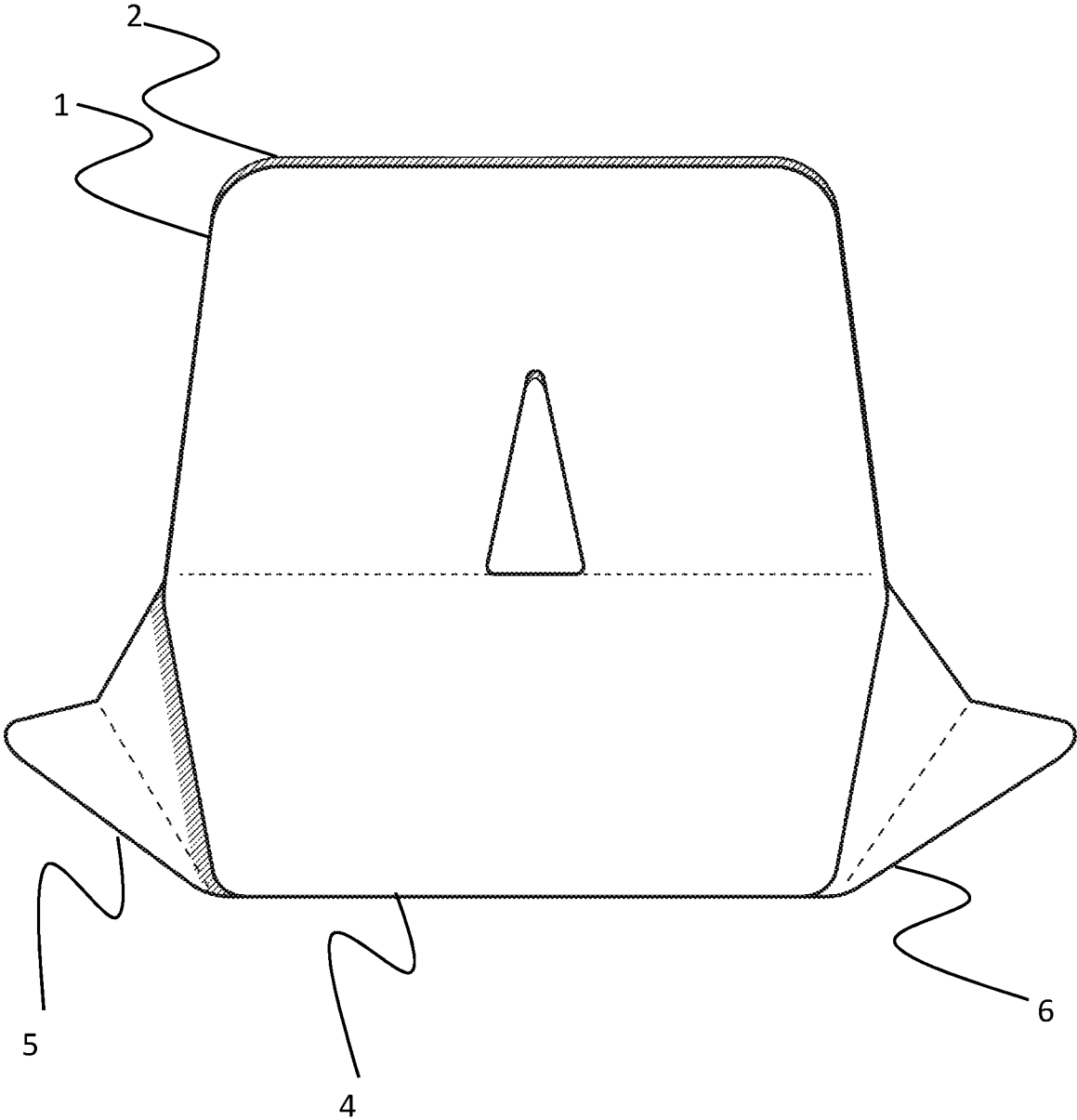


Figure 8

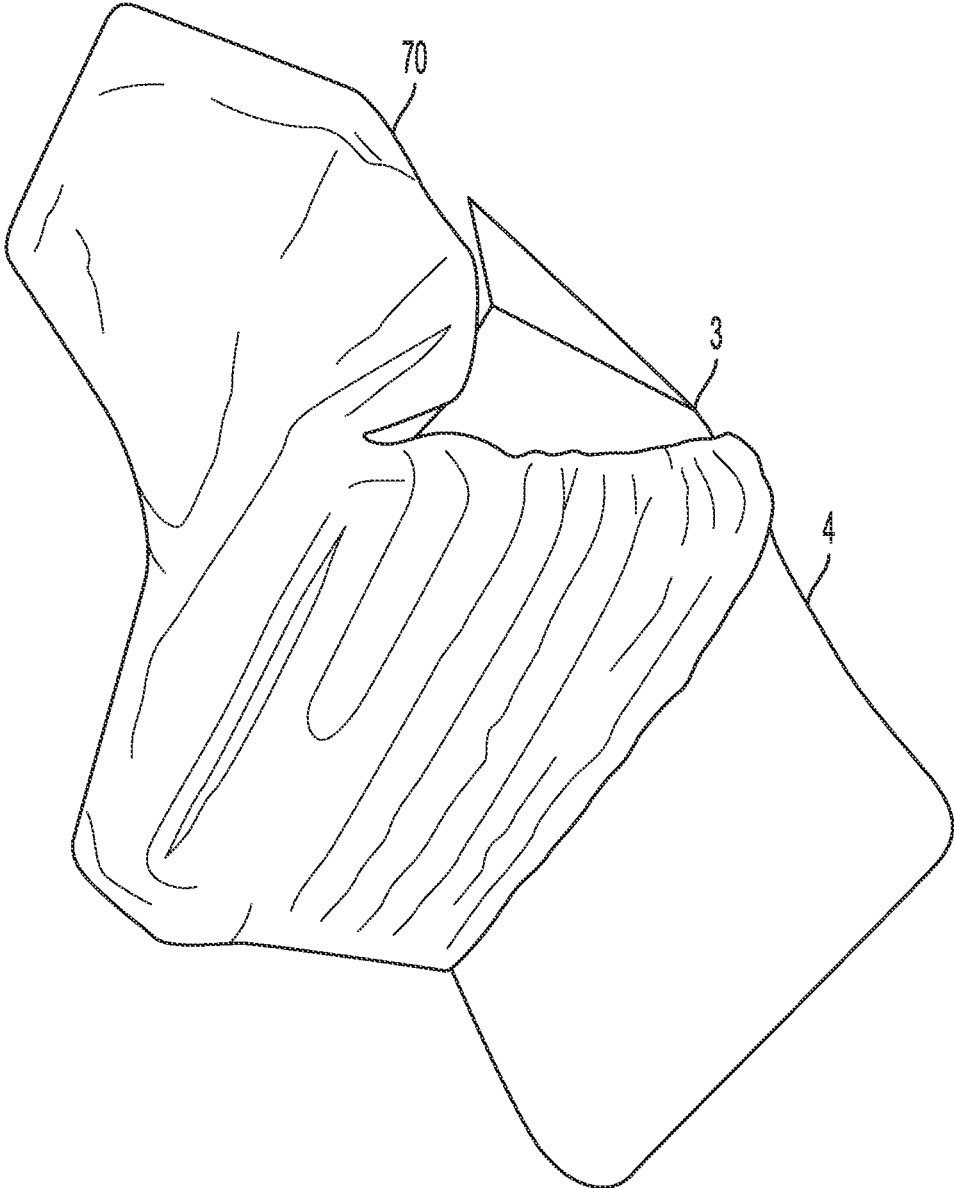


Figure 9

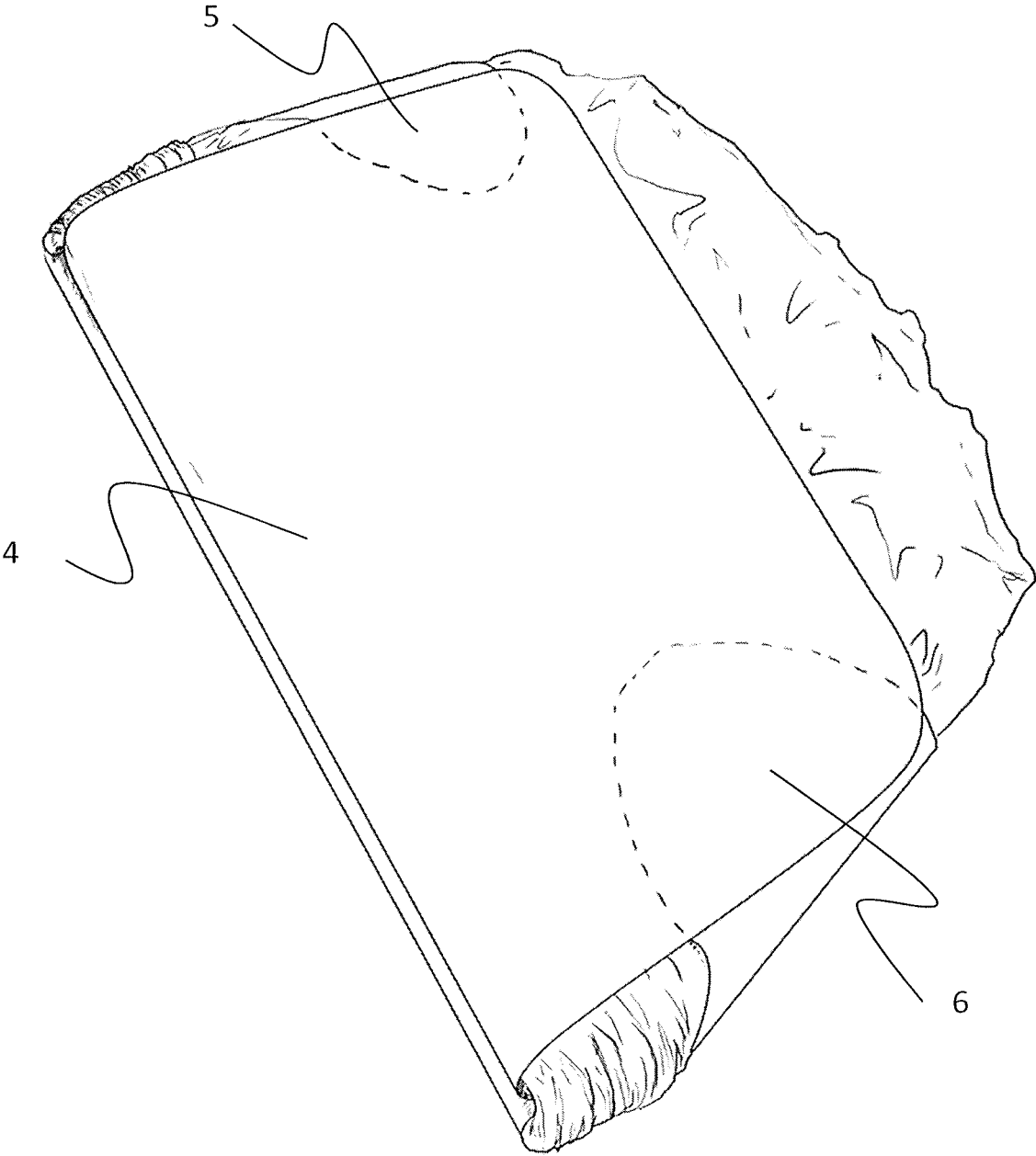


Figure 10

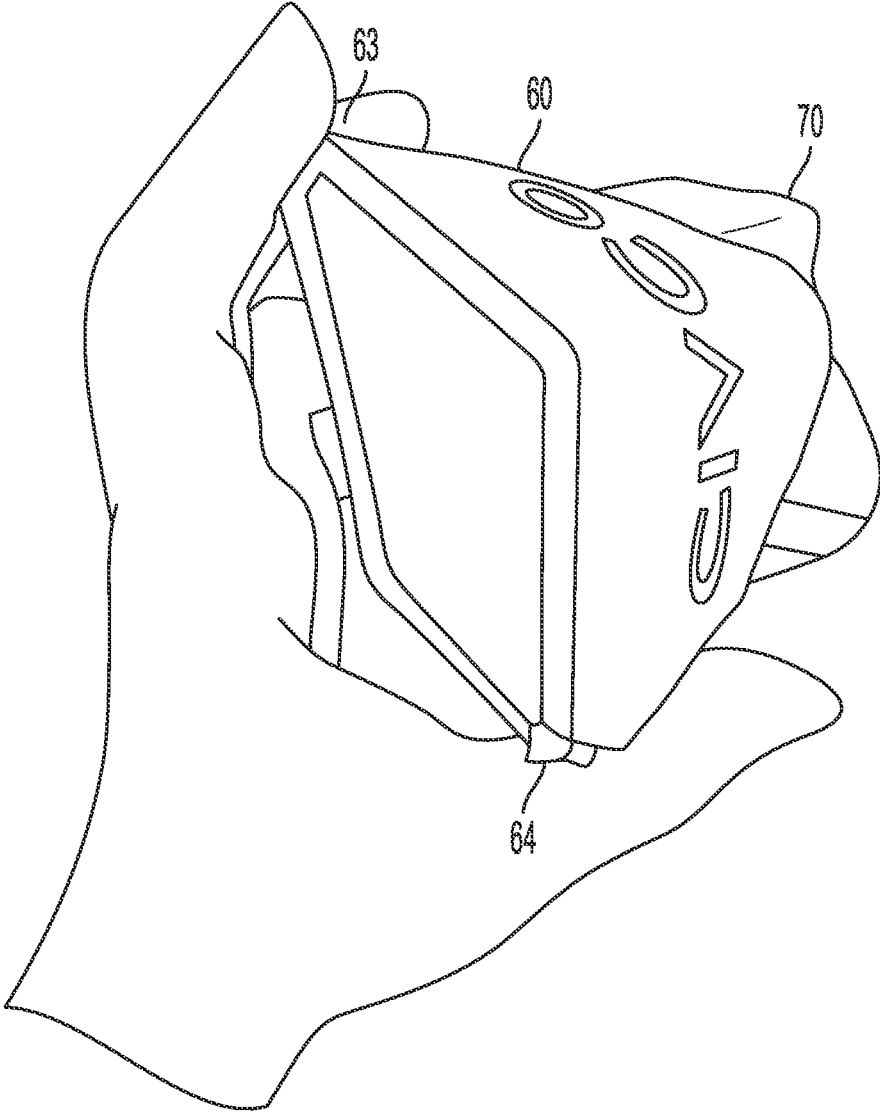


Figure 11

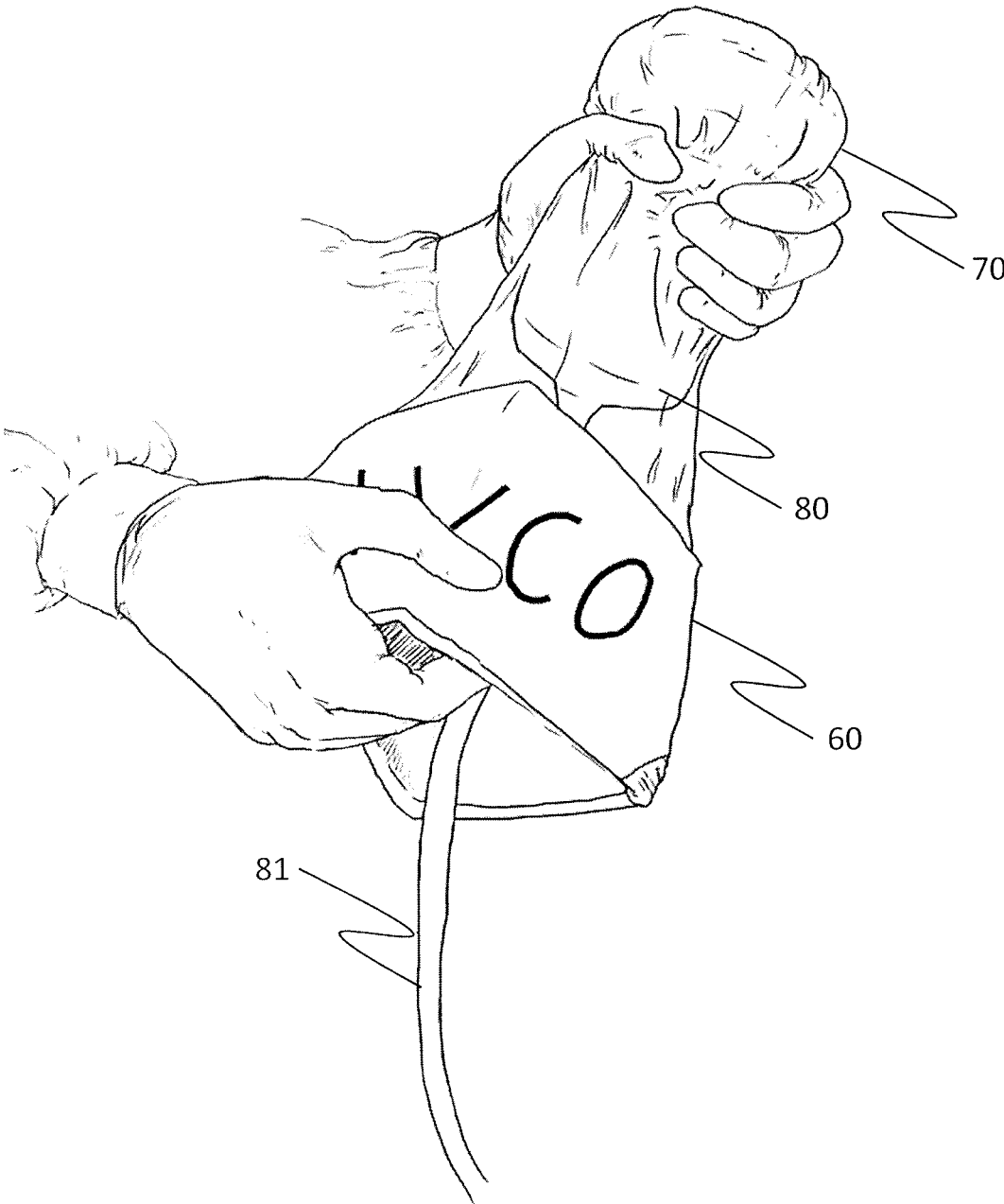


Figure 12



Figure 13

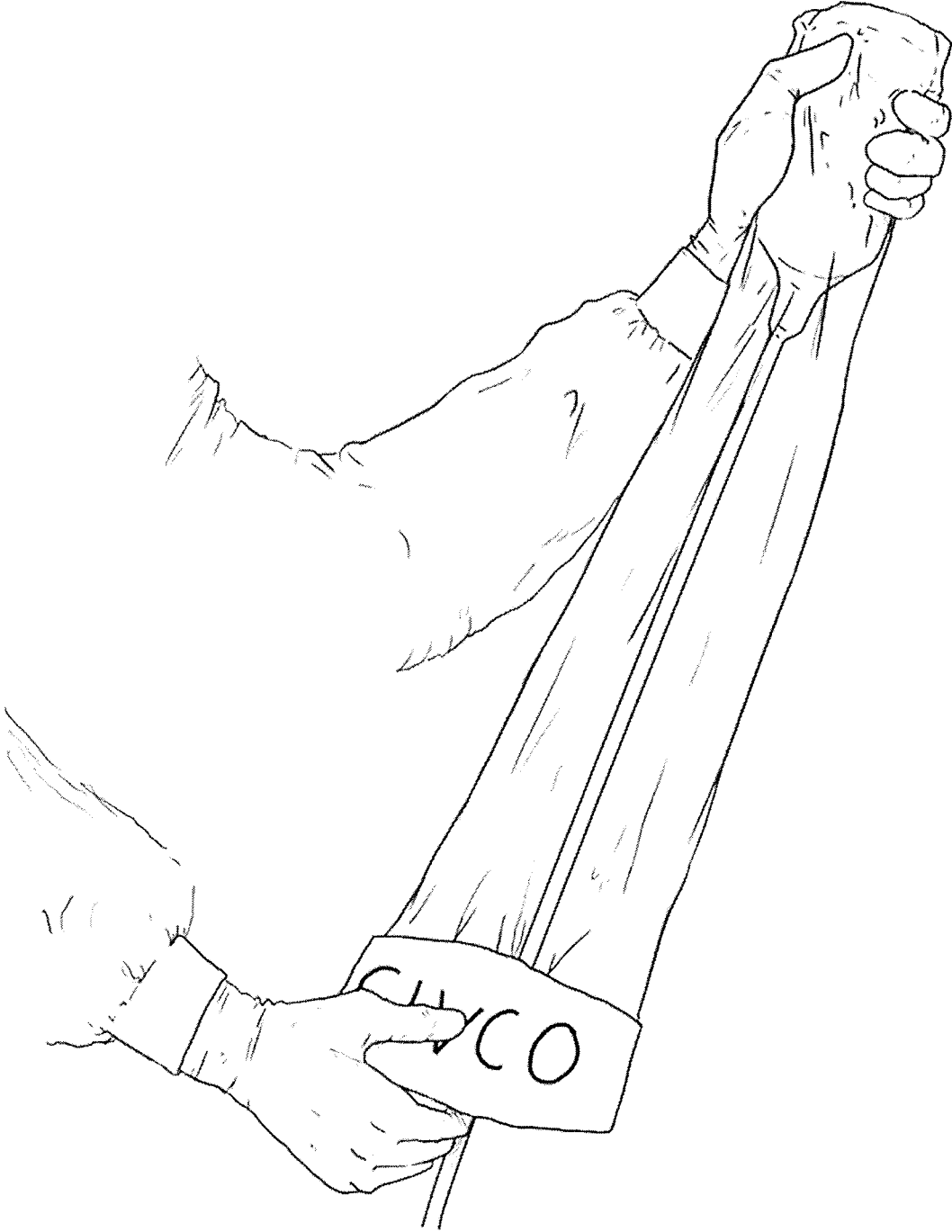


Figure 14

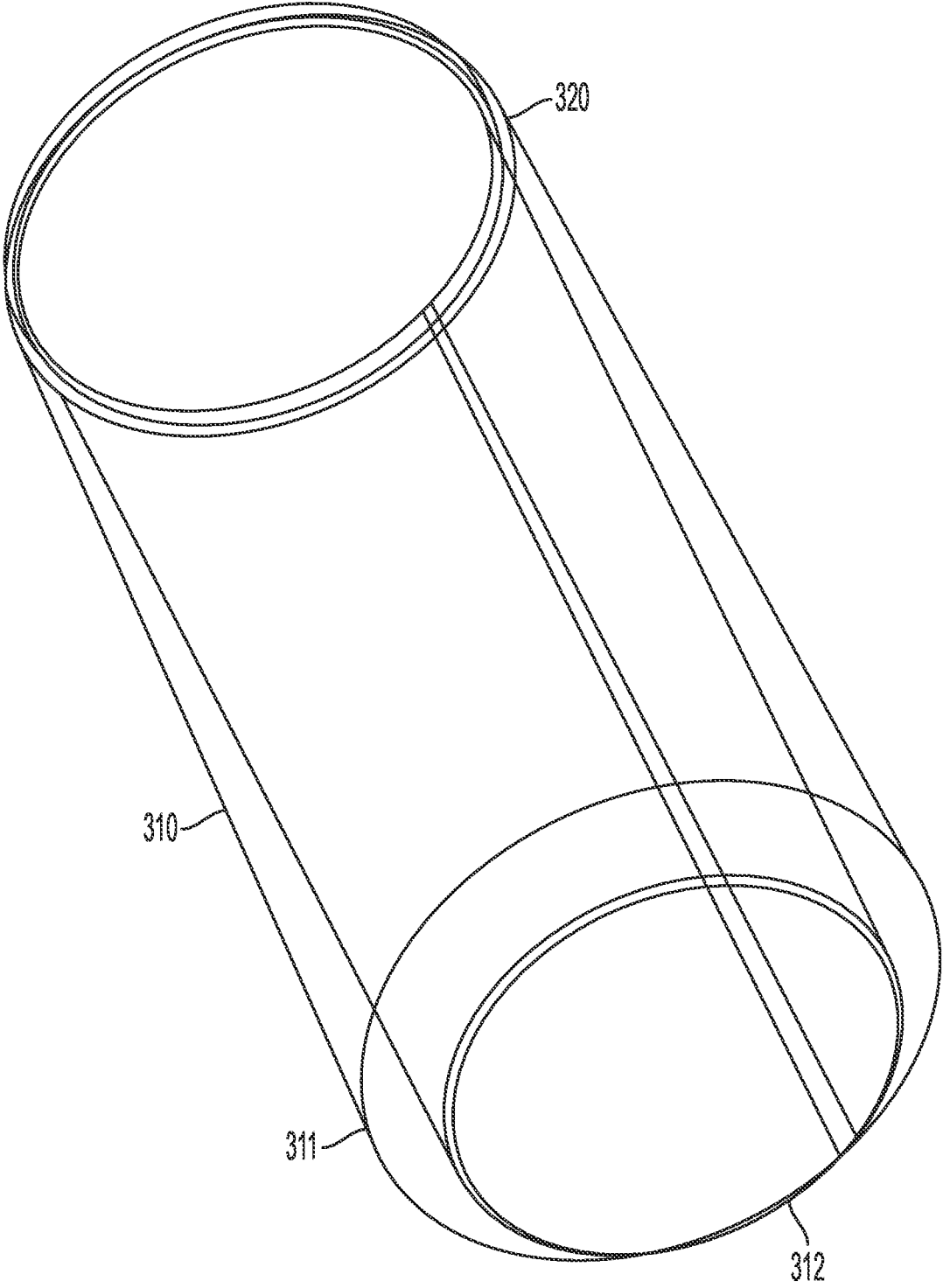


Figure 15

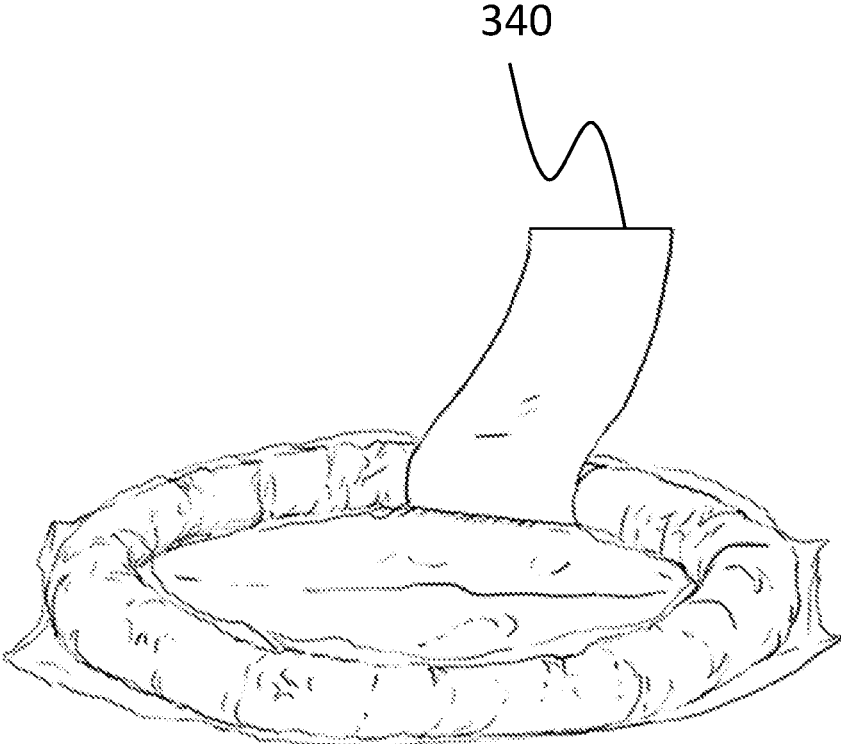


Figure 16

Fig. 17 a

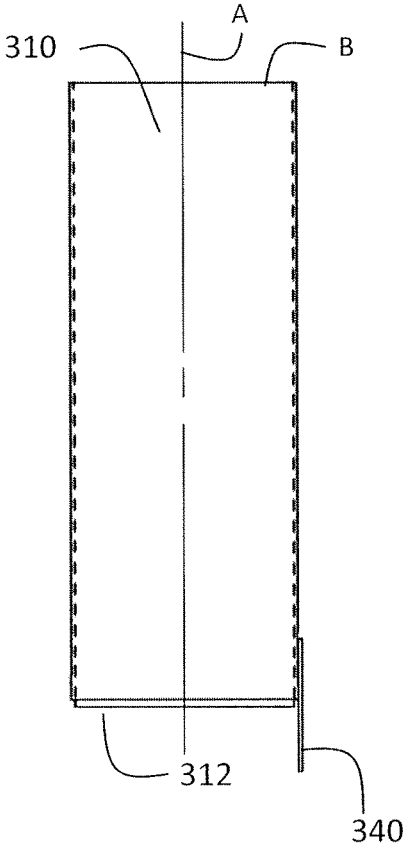


Fig. 17 b

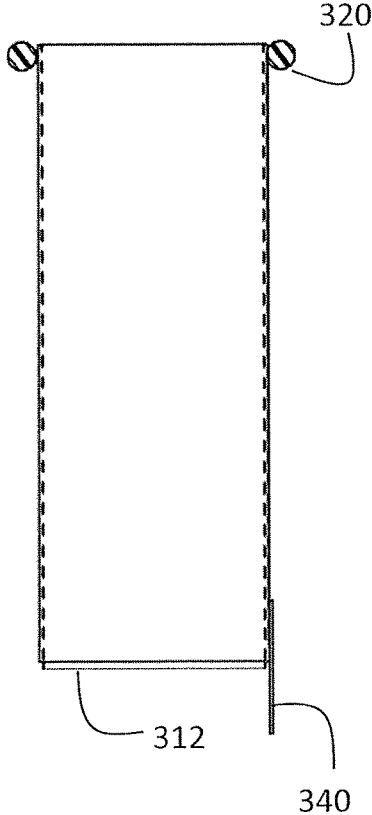


Fig. 17 c

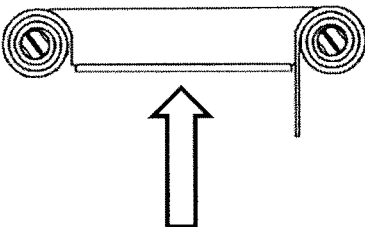
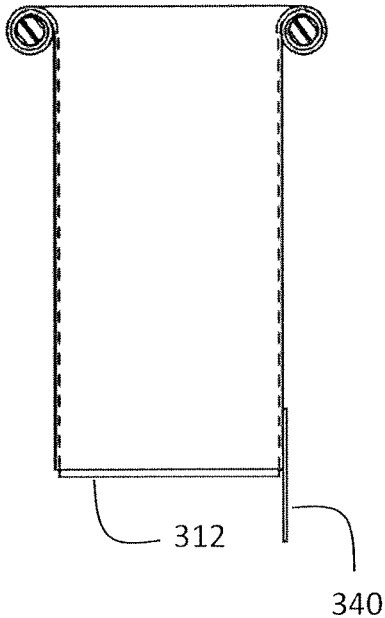


Fig. 17 d

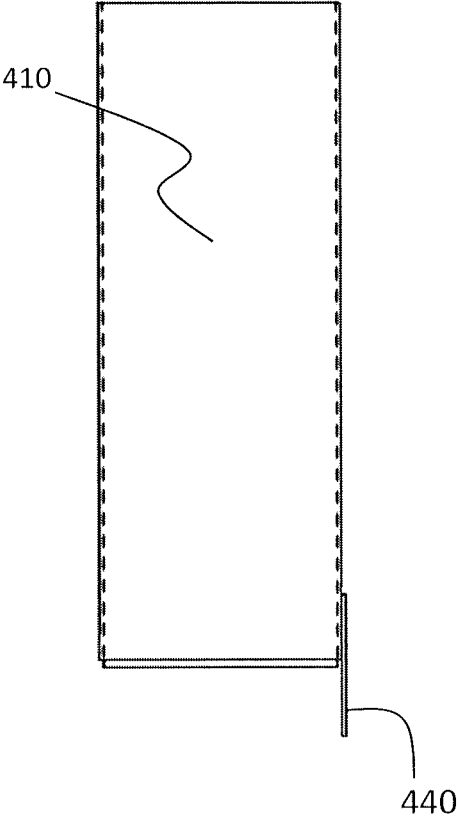


Fig. 18

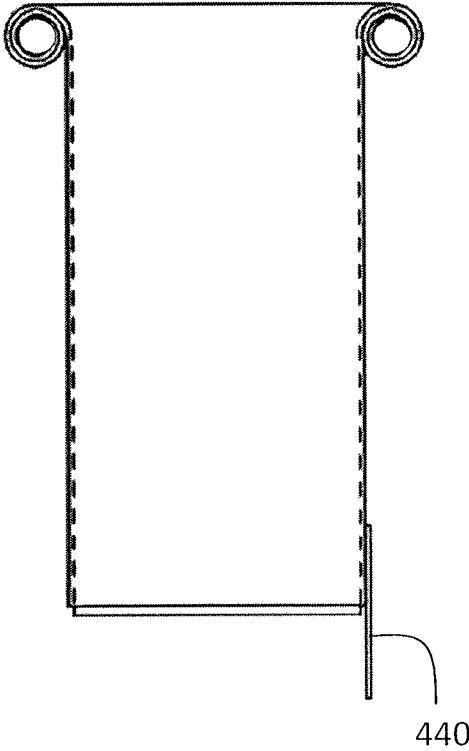


Fig. 19

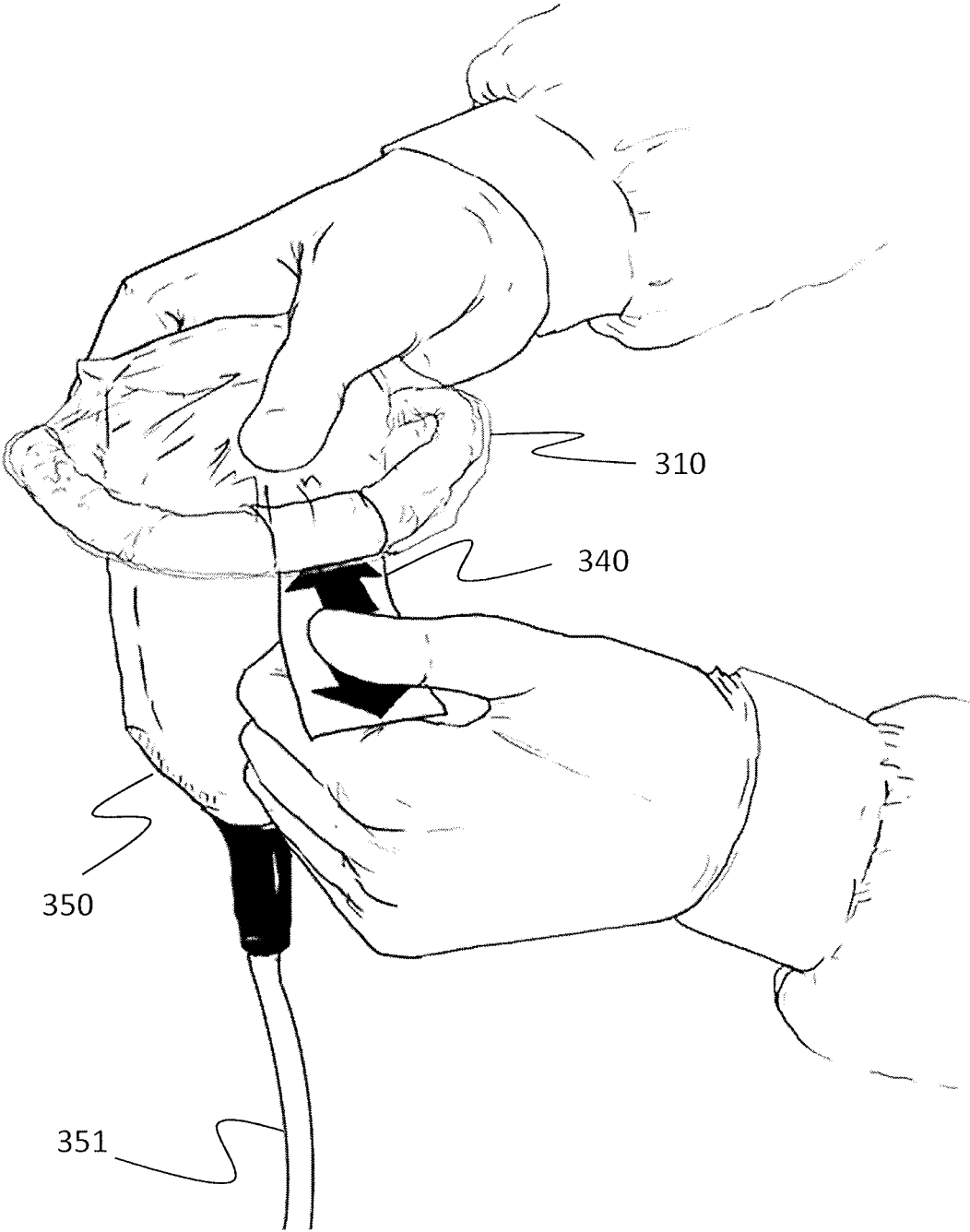


Figure 20



Figure 21



Figure 22

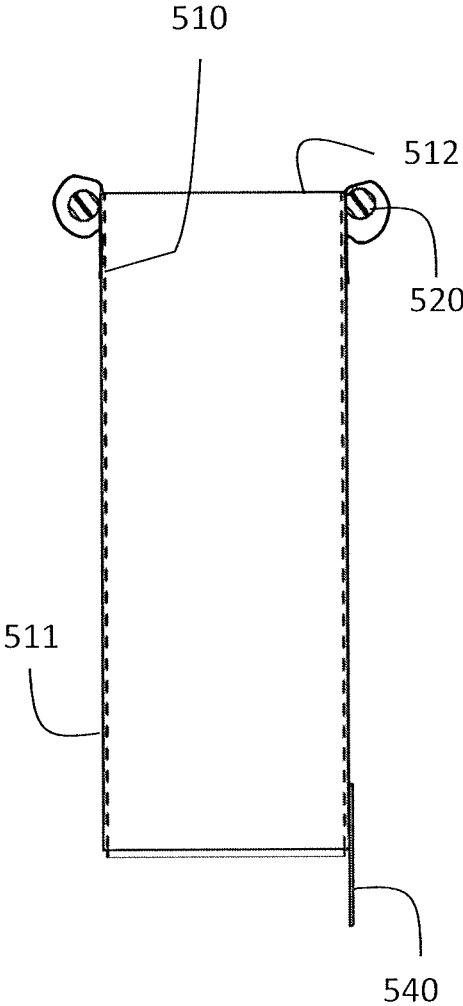


Fig. 23

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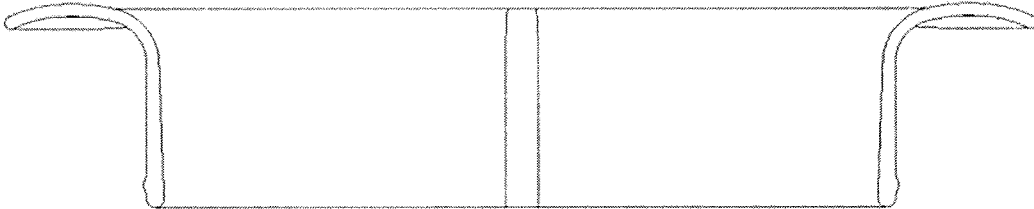


Fig. 24

STERILE COVERS FOR ULTRASOUND PROBE

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 14/982,288 filed Dec. 29, 2015, which claims priority under 35 U.S.C. § 119 to provisional Application No. 62/097,477 filed Dec. 29, 2014 and titled "Sterile Covers for Ultrasound Probe", the entire disclosures of which are incorporated by reference herein.

BACKGROUND OF THE INVENTION

This invention relates to medical devices and more particularly to ultrasound probes and devices for covering the probe for use in aseptic applications.

Ultrasound transducers are commonly used in sterile environments, yet it is impractical and expensive to keep the transducers and their accompanying signal cord sterile. Sterilization is time-consuming and not performed in the area where the ultrasound equipment is used. Because ultrasound transducers are expensive, maintaining sufficient numbers of available sterilized units is cost-prohibitive. Thus, common practice is to sheath the transducer and accompanying signal cord in a sterile sheath, with the outside of the sheath being sterile and the inside of the sheath being the only part that is in contact with the non-sterile transducer and cord. A number of patents have issued in this field, including: U.S. Pat. No. 4,593,699 (a sterile cover for a sonic probe); U.S. Pat. No. 5,910,113 (telescoping-collapsed polymeric tube with open-ended polygonal body mounted inside the tube to keep entryway of tube open, polygonal body is flat prior to use and can be popped open); U.S. Pat. No. 5,259,383 (sterile cover for ultrasound transducer and connection cable); and U.S. Pat. Nos. 7,850,664, 8,353,880 (sterile sheath for use in a biopsy system wherein biopsy needle pierces sheath). A collapsible device for single operator sheathing of an ultrasound probe is described in S. A. Lopez et al., "Design, prototyping and evaluation of a collapsible device for single-operator sheathing of ultrasound probes," *Mech. Sci.* 4, 1-7, 2013 doi: 10.5194/ms-4-1-2013. In a related field, a condom having deployment tabs is described in <http://www.sensicondoms.com/>.

All references cited herein are incorporated by reference as if fully set forth in this application. One of the problems that a user needs to be careful of when deploying the cover is not touching the non-sterile transducer cord when unfurling the cover. It is also difficult for an individual to apply a cover to a transducer probe by themselves without a high risk of contaminating the sterile field. Most prior art approaches require either two people or something physical to hold the ultrasound probe or the cover in place while applying and deploying the cover.

Further complicating the application of the sheath to the transducer is the fact that acoustic conductive gel must be applied to the transducer head before insertion into the sheath. It is difficult for the user to access the target surface for gel application and probe insertion with current fold methods, as the cover needs to be held open with a hand and the folded portion is not compact, causing the target surface to be several inches deep inside the cover. Keeping the gel, which is non-sterile, out of contact with the practitioner's hands, while also avoiding spreading the gel to other parts of the probe and the cord is a difficult task.

Thus, a need exists for a sheath and that can be easily applied to an ultrasound probe to achieve an easily repeatable process that maintains sterility of the outside of the sheath and the gloved hands of the practitioner who installs the sheath on the probe. The present invention addresses that need by providing three embodiments of a sheath that can be applied by one person easily and without risk of loss of sterility to the outside of the sheath.

SUMMARY OF THE INVENTION

One aspect of this invention is a ring sheath applicator with self-deploying elastic bands.

A second aspect of this invention is a semi-rigid sheath holder in which the flexible sheath is housed prior to use and from which it is dispensed.

A third aspect of this invention is a doubled over rolled flexible sheath.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a drawing of a first embodiment of a protective sheath having a ring applicator;

FIG. 2 a drawing of the protective sheath of FIG. 1 in a partially deployed state;

FIG. 3 a drawing of the protective sheath of FIG. 1 in a partially deployed state;

FIG. 4 a drawing of the protective sheath of FIG. 1 in a fully deployed state;

FIG. 5 is a drawing of a semi-rigid sheath dispenser with the sheath installed;

FIG. 6 is a bottom view of the sheath dispenser of FIG. 5, without the sheath installed;

FIG. 7 is a drawing of the sheath dispenser of FIG. 5 prior to assembly;

FIG. 8 is a drawing of the sheath dispenser of FIG. 5 partially assembled but without a sheath installed;

FIG. 9 is a further drawing of a semi-rigid sheath dispenser with the sheath installed;

FIG. 10 is a drawing of a semi-rigid sheath dispenser with the sheath installed;

FIG. 11 a drawing of the sheath dispenser of FIGS. 5 and 10, and flexed for insertion of an ultrasound probe;

FIG. 12 is a drawing of the sheath dispenser of FIGS. 5 and 10 partially deployed over an ultrasound transducer;

FIG. 13 is a further drawing of the sheath dispenser of FIGS. 5 and 10 partially deployed over an ultrasound transducer;

FIG. 14 is a drawing of the sheath dispenser of FIGS. 5 and 10 fully deployed over an ultrasound transducer;

FIG. 15 is a drawing of an exemplary rolled sheath prior to rolling;

FIG. 16 is a drawing of an exemplary rolled sheath prior to use;

FIG. 17a is a partial cross section view of an exemplary rolled sheath prior to rolling;

FIG. 17b is a further partial cross section view of an exemplary rolled sheath prior to rolling;

FIG. 17c is a partial cross section view of an exemplary rolled sheath partially rolled;

FIG. 17d is a partial cross section view of an exemplary rolled sheath;

FIG. 18 is a drawing of an exemplary rolled sheath prior to being rolled;

FIG. 19 is a drawing of the rolled sheath of FIG. 18 partially rolled;

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FIG. 20 is a drawing of an exemplary rolled sheath ready for application;

FIG. 21 is a drawing of an exemplary rolled sheath partially deployed;

FIG. 22 is a drawing of an exemplary rolled sheath fully deployed;

FIG. 23 is a cross section view of a further exemplary rolled sheath prior to being rolled; and

FIG. 24 is a cross section view of an exemplary embodiment of the ring applicator of FIG. 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the various figures wherein like reference characters refer to like parts there are described three embodiments of the invention.

First Embodiment: Ring Applicator with Self-Deploying Elastic Bands

With reference to FIGS. 1-4 and 24, in this first embodiment, the cover assembly consists of a sleeve-like sheath closed on one end and open on the other end 10, a ring-shaped applicator 20, and multiple elastic bands 30. The sheath is made with traditional flexible ultrasound transducer probe cover materials and dimensions. As shown in FIG. 1, the sheath 10 is folded accordion-style along its length to be retained on the outside of the rigid applicator ring 20. The elastic bands 30 shown in FIGS. 3 and 4, are stretched around the outside of the sheath as it is placed onto the ring 20. The elastic bands are placed at intervals from the closed-end to the open-end, and drawn together within the accordion fold, helping to retain the folded sheath onto the applicator ring.

With reference to FIGS. 2 and 3, to use the inventive sheath and ring installer, an applicator ring 20, having an extended lip 22 is applied over an ultrasound transducer 40 by the user. Once the sheath is on the distal end of the transducer, the sheath-covered portion of the transducer can be grasped and the open end of the sheath pulled along the length of the transducer 40 and transducer cord 41 by holding the ring applicator and pulling away from the transducer thus causing the sheath to unfold and be transferred from the applicator to the transducer. As the sheath unfurls over the transducer, the elastic bands are transferred one-by-one to the transducer handle and cord, both releasing the sheath from the ring applicator and securing the sheath to the transducer in a form-fitting manner along its length. The ultrasound transducer and cord may be temporarily mounted on a stand that allows a practitioner wearing sterile clothing and gloves to apply the sheath without directly touching the transducer or cord.

When the full length of the sheath has been deployed, the applicator ring can be removed from the transducer cord by flexing the ring apart at break 21 and pulling the applicator free past the cord.

The ring applicator solves the problem of the difficulty for the user to access the target surface of the ultrasound transducer for gel application and probe insertion with current fold methods, as the cover needs to be held open with a hand and the folded portion is not compact, causing the target surface to be several inches deep inside the cover. The ring applicator holds the cover in a wide-open fashion and contains the folded portion in a neat and compact state, further improving the ability of a single person to apply the

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cover and maintain sterility, as well as improving the ease of access for gel application and probe insertion.

Second Embodiment: Semi-Rigid Two-Walled Pouch Forming Protective Sheath Dispenser

A second embodiment of an improved sheath for an ultrasound probe is shown in FIGS. 5-14. In this embodiment as shown in FIG. 5, a semi-rigid dual-walled pouch 60 having two open ends 61, 62 houses an accordion-pleated protective sheath 70 between the dual walls 65, 66 of the pouch. The dual walls are clearly seen in FIG. 6, which is a bottom end view of the dispenser flexed for use. In operation, the sheath is dispensed from the bottom end of the pouch as shown in FIG. 12. The pouch can be made of cardboard or plastic or any other suitable material. The pouch is designed to house the sterile sheath and to snap open as shown in FIGS. 12 and 13 when grabbed at the corners 63, 64, as shown in FIG. 13. The protective sheath can be stuffed up inside the pouch as shown in FIG. 10 such that the pouch holds/encompasses or contains the sheath prior to use.

Assembly of an exemplary dual-walled pouch is as follows: An exemplary sheet is shown in FIG. 7. The sheet of FIG. 7 is first folded between parts 1 and 2, as shown in FIG. 8 such that parts 1 and 2 end up back-to-back. Next, parts 3 and 4 are folded to a 90 degree angle from their respective adjacent portions 1 and 2, to form a base as shown in FIG. 8, where parts 1 and 2 are vertical. The vertical parts of the pouch, 1 and 2 serve as guides onto which a protective sheath 70 is slid and pushed down to form accordion-like folds as shown in FIG. 9. Once the entire sheath is pushed fully down onto parts 1 and 2 of the dispenser, parts 3 and 4 are folded up alongside parts 1 and 2 respectively to form outer walls of the dispenser. Lastly, parts 5 and 6 are wrapped around and affixed to part 4 to complete the pouch/sheath assembly. The completed pouch, without a sheath installed is shown in FIG. 6 and is shown with a sheath installed in FIGS. 5 and 10.

Advantages of the pouch design are that it uses a cost-efficient method of "folding" the cover to minimize its size. Next, the pouch provides a protective support to the cover which is beneficial in deployment of cover as well as handling the cover if deployment is performed by a single user. The cover is "folded" into a pouch type protective holder which is rigid enough to hold the cover in its "folded" configuration and makes it easier for the user to handle and use.

The method of folding the sheath into this pouch is very easy for manufacturing which makes it possible to consider for the extra cost of the pouch cover holder. The pouch also provides a printable area onto which a manufacturer's logo or use information can be printed, as shown, for example, in FIG. 7.

Deployment of the exemplary sheath 70 out of the pouch 60 and over an ultrasound transducer 80 and cord 81 is shown in FIGS. 12-14.

Third Embodiment: Rolled Sheath

A third embodiment of a protective sheath for ultrasound probes is shown in FIGS. 15-23. In FIG. 15, the sheath 310 is a cylinder or other sleeve-like shaped container of flexible plastic or the like, having one open end 311 and one closed end 312. The sheath is rolled tightly around a flexible band 320, placing the folded portion in a compact state while leaving the closed end 312 that will go over the ultrasound

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probe fully accessible to the user. As shown in FIGS. 17a-17d, the sheath 310 is doubled over at the band, 320 such that the open end of the sheath 311 is substantially up to the closed end. This method of folding the cover is very fast and easy, and offers potential cost savings and excellent scalability for volume manufacturing.

FIG. 17a is a plan view of an exemplary cylindrical sheath having a longitudinal axis A and doubled over about its midsection at point B. The outer half of the length of the doubled over sheath is shown in full lines while the inner half of the length of the doubled over sheath is shown in hashed lines. The closed end of the sheath 312 is at the bottom of the two doubled over portions, as is the open end of the sheath, which in this view has a tab 340 attached for easy use as will be seen in the following explanation and figures. FIG. 17b shows the sheath of FIG. 17a with a flexible band 320 in cross section. FIG. 17c shows how the flexible band 320 shown in FIG. 17b is rolled down the length of the sheath, thus rolling up together both the inner and outer portions of the sheath. FIG. 17d shows a fully rolled sheath and a directional arrow pointing out the direction of insertion of an ultrasound probe.

In a preferred embodiment, shown in use FIG. 20, one or more pull tabs 340 are attached to the open end of the rolled sheath and left exposed after the sheath is fully rolled for easy access.

As shown in FIGS. 18 and 19, a doubled over sheath 410 can also be rolled about itself without a band and can optionally include a pull tab 440 for easy deployment.

As shown in FIGS. 20-22, the user places the sheath over the ultrasound probe 350 holding the probe through the closed end of the sheath. The user then pulls the tab 340 causing the sheath to un-roll along the length of the transducer and cord 351.

In an embodiment, the pull tab 340 can include a printed company logo, installation or expiry information.

In a further embodiment, shown in FIG. 23, a band 520 is placed between the inner 510 and outer portions 511 of the folded sheath at the fold point 512. In this embodiment, the sheath is rolled as described above and can be constructed with or without a pull tab 540, as described above.

Without further elaboration the foregoing will so fully illustrate the invention that others may, by applying current or future knowledge, adopt the same for use under various conditions of service.

What is claimed is:

1. A cover for an ultrasound probe, the probe having a distal end portion and a proximate end portion, said cover being formed of a flexible material and comprising:
 an elongated tubular sheath; and
 a flexible band,
 wherein the elongated tubular sheath comprises:
 a longitudinal axis,
 an inner surface,
 a closed end, and
 an open end,
 wherein the open end is located at an opposite end of the sheath from the closed end,
 wherein the sheath is folded over itself a single time such that the open end is disposed adjacent the closed end to form a folded-over sheath having a folded-over open end located distally from the closed end and the open end along the longitudinal axis,
 wherein the inner surface of the sheath between the folded-over open end and the open end forms an outer surface of the folded-over sheath,

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wherein the flexible band is disposed about the periphery of the outer surface of the folded-over sheath distally from the closed end and the open end and adjacent the folded-over open end,

wherein the folded-over sheath is rolled up about said band in a direction parallel to said longitudinal axis and toward the closed end and the open end, such that an entirety of the rolled up, folded-over sheath is provided proximate to the closed end and the open end, and

wherein unrolling the rolled up, folded-over sheath in a same direction as the roll-up direction causes the flexible band to self-deploy about an intermediate portion of the inner surface of the sheath.

2. The cover of claim 1, further comprising:
 a first tab secured to the sheath adjacent the open end, wherein the first tab is arranged to be pulled to unroll the sheath when the cover is disposed over the distal end portion of the ultrasound probe.

3. The cover of claim 2, further comprising:
 a second tab secured to the sheath adjacent the open end and opposite the first tab, wherein the second tab is arranged to be pulled to unroll the sheath when the cover is disposed over the distal end portion of the ultrasound probe.

4. A cover for an ultrasound probe, the probe having a distal end portion and a proximate end portion, said cover being formed of a flexible material and comprising:

an elongated tubular sheath; and
 a band,

wherein the sheath comprises:

a longitudinal axis,
 an inner surface,
 a closed end, and
 an open end,

wherein the open end is located at an opposite end of the sheath from the closed end,

wherein the sheath is folded over itself a single time such that the open end is disposed adjacent the closed end to form a folded-over sheath having a folded-over open end located distally from the closed end and the open end along the longitudinal axis,

wherein the inner surface of the sheath between the folded-over open end and the open end forms an outer surface of the folded-over sheath,

wherein the band is disposed inside the folded over sheath distally from the closed end and the open end and adjacent the folded-over open end,

wherein the folded-over sheath is rolled up about the band in a direction parallel to the longitudinal axis of the sheath and toward the closed end and the open end, such that an entirety of the rolled up, folded-over sheath is provided proximate to the closed end and the open end, and

wherein unrolling the rolled up, folded-over sheath in an opposite direction from the roll-up direction causes the flexible band to self-deploy about an intermediate portion of the inner surface of the sheath.

5. The cover of claim 4, further comprising:
 a first tab secured to the sheath adjacent the open end, wherein the first tab is arranged to be pulled to unroll the sheath when the cover is disposed over the distal end portion of the ultrasound probe.

6. The cover of claim 5, further comprising:
 a second tab secured to the sheath adjacent the open end and opposite the first tab,

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wherein the second tab is arranged to be pulled to unroll the sheath when the cover is disposed over the distal end portion of the ultrasound probe.

7. A method of preparing a cover for an ultrasound probe that includes a distal end portion, comprising:

folding an elongated tubular sheath having a closed end and an open end over itself a single time such that the open end is disposed adjacent the closed end to form a folded-over sheath having a folded-over open end located distally from the closed end and the open end;

disposing the folded-over sheath over a stand that substantially conforms to a perimeter of the open end of the sheath;

aligning a flexible band over the sheath near the folded-over open end and distally from the closed end and the open end; and

rolling the flexible band along with the sheath from the folded-over open end towards the closed end and the open end to form a rolled sheath, such that an entirety of the rolled up, folded-over sheath is provided proximate to the closed end and the open end, and such that unrolling the rolled sheath in a same direction as the roll-up direction causes the flexible band to self-deploy about an intermediate portion of the inner surface of the sheath.

8. The method of claim 7, further comprising:

disposing the rolled sheath over the distal end of the ultrasound probe and unrolling the sheath and flexible band towards a proximate end of the ultrasound probe.

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9. A method of preparing a cover for an ultrasound probe that includes a distal end portion, comprising:

folding an elongated tubular sheath having a closed end and an open end over itself a single time such that the open end is disposed adjacent the closed end to form a folded-over sheath having a folded-over open end located distally from the closed end and the open end;

disposing the folded-over sheath over a stand that substantially conforms to a perimeter of the open end of the sheath;

aligning a flexible band inside the folded-over open end and distally from the closed end and the open end;

rolling the flexible ring along with the sheath from the folded-over open end towards the closed end and the open end to form a rolled sheath, such that an entirety of the rolled up, folded-over sheath is provided proximate to the closed end and the open end, and such that unrolling the rolled sheath in an opposite direction from the roll-up direction causes the flexible band to self-deploy about an intermediate portion of the inner surface of the sheath.

10. The method of claim 9, further comprising:

disposing the rolled sheath over the distal end of the ultrasound probe and unrolling the sheath and flexible ring towards a proximate end of the ultrasound probe.

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