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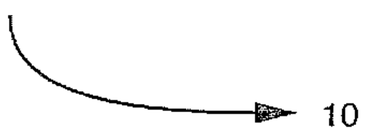
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(54) Title: CATHETER CLIP



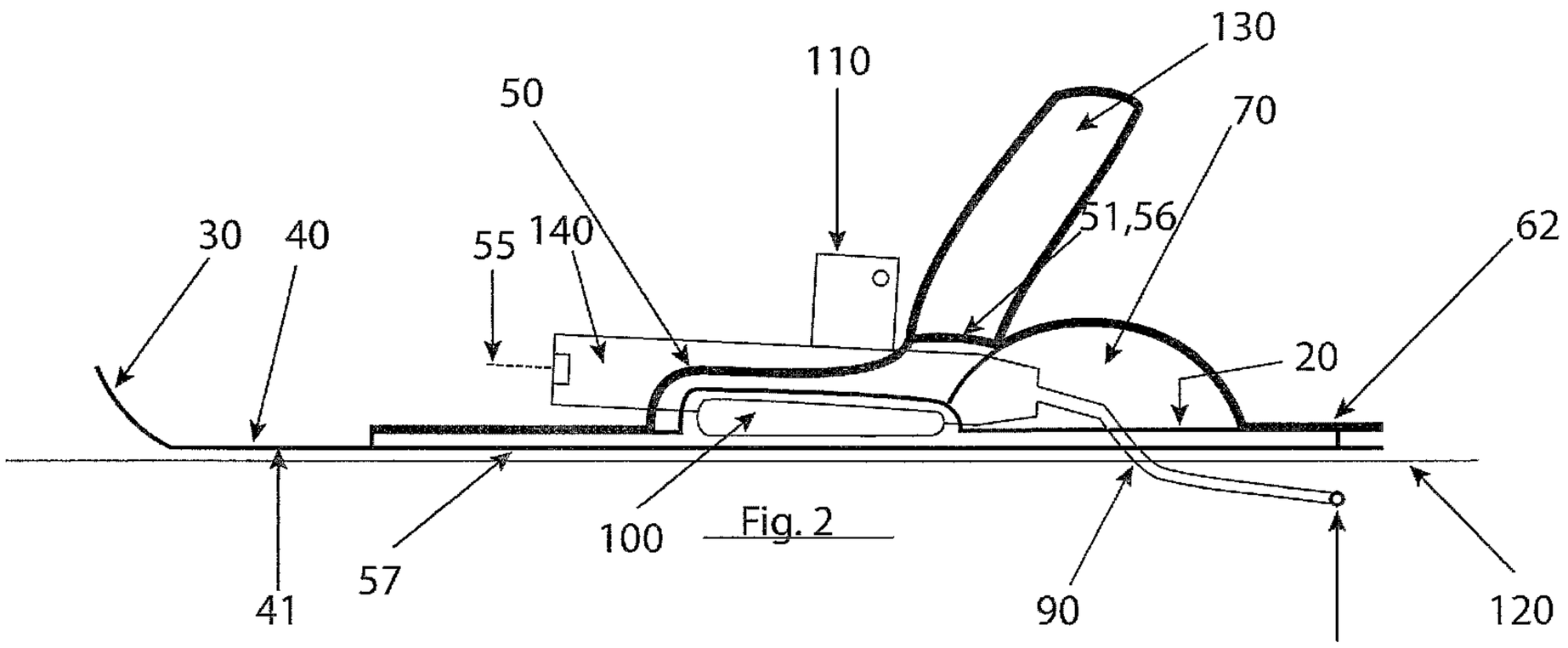


Fig. 2

(57) Abrégé/Abstract:
The invention provides a device for securing an invasive medical implementation such as a catheter to a patient. The device generally combines (1) an adherent surface that attaches the device to the skin and (2) a flexible clasping means to grasp the catheter and reversibly secure it to the device.

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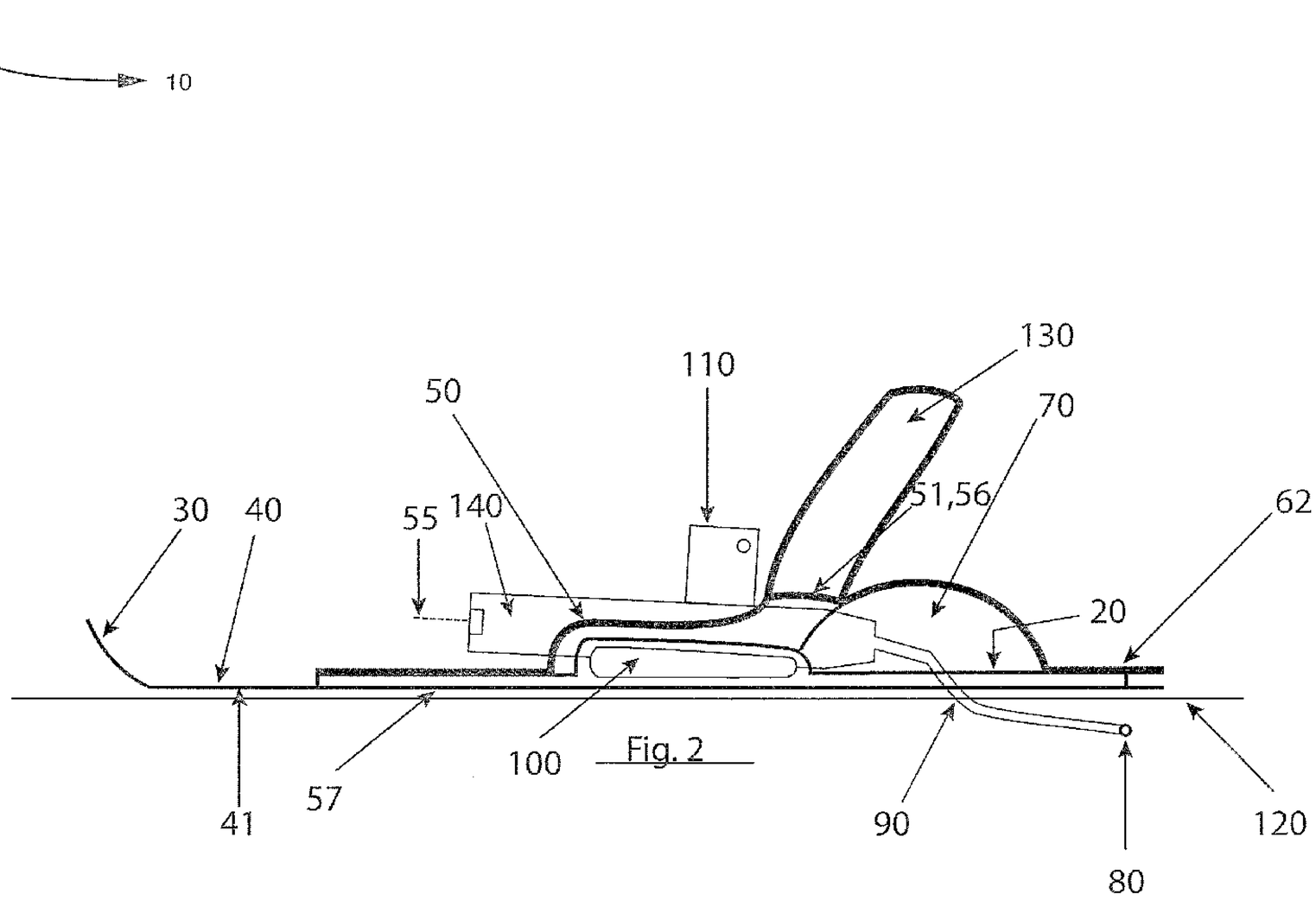


Fig. 2

(57) Abstract: The invention provides a device for securing an invasive medical implementation such as a catheter to a patient. The device generally combines (1) an adherent surface that attaches the device to the skin and (2) a flexible clasping means to grasp the catheter and reversibly secure it to the device.

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CATHETER CLIP

FIELD OF THE INVENTION

The invention generally relates to a device for securing an invasive medical implementation to a subject. Specific embodiments allow a user to secure a catheter to a patient rapidly and without the aid of prior surgical tapes, glues, dressings and/or foams.

BACKGROUND

Medical implementations such as catheters, medical lines, tubing and like articles are routinely used to move fluids to and from patients. A catheter typically includes a hard part which remains exterior to the patient, and a soft part, at least a portion of which is inserted into the patient. The hard part can include a connection point (sometimes called a hub) to which other medical implementations (eg., a syringe, fluid supply tube) can be joined. Following installation and securement ("catheterization"), the catheter is a convenient means for administering fluids such as drugs or withdrawing blood or other body fluids from the patient.

According to prior practice, a caregiver uses glue, foam, surgical tape, dressing or a combination thereof to secure the catheter against the skin of the patient. Typically, the caregiver covers the catheter insertion site with a dressing after swabbing the area with antiseptic. The entire procedure can take several minutes or more. In addition, catheterization can require frequent disconnection between of the catheter as new medical lines are added or replaced, thereby stressing securing tapes, glues or foams. In settings involving long-term catheter use, the caregiver must frequently clean the insertion site about the inserted (indwelling) catheter, change the dressings, and apply fresh antiseptic.

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There has been increasing recognition that caregivers spend too much time securing catheters to patients. Moreover, prior practice has not been able to prevent catheter dislodgement and/or infection near insertion sites. Catheters that are taped or glued in place are readily pulled out during "routine" dressing changes. Surgical tapes and foams can be uncomfortable or irritating for some. Many patients cannot rest comfortably knowing that a secured catheter may dislodge from the insertion time during sleep. Young or elderly patients are especially vulnerable to these and related shortcomings.

It is becoming clear that prior catheter securement devices and procedures have not optimally served patients. These and other drawbacks have created a need for a more rapid and reliable device for securing catheters to patients. Accordingly, it would be desirable to have a device that can be used to secure a catheter to the skin of a patient that does not rely on use of prior tapes, glues, dressings and/or foams. It would be further desirable to have methods of using such a device so that the catheter can be rapidly and reliably secured to the patient.

SUMMARY

In broad terms, the invention provides a device for securing an invasive medical implementation such as a catheter to a patient. The device generally combines (1) an adherent surface that attaches the device to the skin and (2) a flexible clasping means to grasp the catheter and secure it to the device. Securement is typically reversible. Preferred practice of the invention avoids use of prior tapes, glues, dressings and/or foams to secure the medical implementation to the patient. Use of the invention can substantially reduce catheter securement times, thereby enhancing the reliability, comfort, and safety of catheterization. The invention is relatively simple to use and can be employed by experienced and inexperienced caregivers alike.

Accordingly, and in one aspect, the invention provides a device for securing a catheter to an insertion site of a patient. In one embodiment, the device includes at least one of and preferably all of the following as operably linked components:

(a) a flexible base comprising a sealed patient contacting surface,

(b) a solid portion joined to the flexible base and comprising a clasping means for securing the catheter; and

(c) a handle adapted to remove, with one digit (finger or thumb), a seal from the patient contacting surface. Preferably, the handle is joined to the seal which seal protects the adhesive on at least part of the surface sufficient to attach the secured catheter to the patient insertion site. In a particular invention embodiment, the device will be referred to herein as a "catheter clip" or like phrase.

In another aspect, the invention provides a unitary package that includes the device wherein the device is preferably sterile and includes a packing material substantially resistant to penetration by microorganisms, viruses and the like.

In yet another aspect, the invention provides a method of securing a catheter to an insertion site of a patient. In one embodiment, the method includes at least one of and preferably all of the following steps:

(a) providing a device comprising:

(i) a flexible base comprising a sealed patient contacting surface,

(ii) a solid portion joined to the flexible base and comprising a clasping means for securing the catheter to the device,

(iii) a handle region joined to the flexible portion and adapted to remove, with one hand, a seal from the patient contacting surface, thereby exposing the adhesive for releasably securing the catheter to the insertion site of the patient,

(b) removing, with at least one digit, the seal from the patient contacting surface of the flexible portion to expose the adhesive,

(c) guiding the device over the catheter,

(d) contacting the flexible base (patient contacting surface) to the patient sufficient to adhere the device thereto; and

(e) actuating the clasping means to grasp the catheter (preferably at or around the solid part), thereby securing the catheter to insertion site of the patient.

Further uses and advantages of the invention will be apparent from the following Drawings and discussion.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A is a drawing (top view) showing a catheter clip of the invention.

Figure 1B is a drawing (top view) showing the catheter clip securing a catheter having lateral wings for stabilizing the catheters and connecting hubs.

Figure 2 is a drawing (cross-sectional view) of the catheter clip securing a catheter against the skin of a patient.

DETAILED DESCRIPTION

In the present section, the invention is illustrated with regard to one or more particular embodiments. These embodiments are intended merely to illustrate certain principles of the invention and not to limit the invention or use thereof in any way.

Figure 1A shows a particular embodiment of the invention ("catheter clip") for securing a catheter to a skin insertion site of a patient. The catheter clip **10** includes a solid portion **50** joined to a flexible base **20.** The flexible base **20** includes an underlying patient contacting surface **41** (see Fig. 2) that is at least partially sealed with a suitable sealing medium such as paper or a plastic. The solid portion **50** includes a clasping means **51** adapted to grasp and securing the catheter to the catheter clip **10**. The clasping means **51** may include or consist of nearly any suitable plastic material provided it flexibly resists extension by a user. A cover **40** is in actuating contact with a handle **30** attached to the flexible base **20.** The handle **30** and the cover **40** are in sealing contact with a seal formed on at least part of the patient contacting surface **41**. Preferably, the seal will protect an adhesive on at least part of the patient contacting surface **41**, preferably substantially all of it. The amount of adhesive on the patient contacting surface **41** is not critical provided it is sufficient to attach the catheter clip **10** to the patient.

Referring again to Figure 1A, the solid portion **50**, flexible base **20** and the handle **30** together define an open chamber **52** that includes a distal end **53** (shown contacting a first centerpoint) for receiving the catheter and a proximal end **54** (shown contacting a second centerpoint) for accepting the catheter from the distal end **53**

toward the skin insertion site 90 (see Fig.1B). The first centerpoint of the distal end **53** and the second centerpoint of the proximal end define an axis **55** surrounded by the open chamber **52**. In preferred use, a catheter (typically the hard part) is placed along the axis **55** for securement to the catheter clip **10** by the clasping means **51**. As shown, the open chamber **52** further includes a top **56** defined by at least part of the solid portion **50** and a bottom **57** (see Fig. 2) opposite the top **56** and defined by the handle **30** and the flexible base **20**. In the embodiment shown, the top **56** is in actuating contact with the clasping means **51**, wherein actuation of the top **56** is sufficient to flex the clasping means **51** so that it grasps and secures the hard part of a catheter to the catheter clip **10**.

The flexible base **20** and optionally the solid portion **50** further define a compartment **70** positioned at or near the insertion site **90**. The compartment **70** is typically adapted to at least partially surround the patient insertion site including completely surrounding it. According to Fig. 1A, the top **56** substantially extends from the clasping means **51** to the compartment **70**. Optionally, the compartment **70** is in sealing contact with the seal of the patient contacting surface **41**. In one embodiment, the compartment **70** will include an effective amount of an antimicrobial (antiseptic) agent sufficient to minimize or eliminate infection at the insertion site. Suitable examples include certain alcohols and phenols known to have antiseptic properties (eg., isopropyl alcohol, phenol), iodine tinctures, chlorhexidine, povidone-iodine (Betadine®) and the like. Preferably, the agents are provided in the compartment **70** in a liquid, semi-liquid or cream format. Topical use antibiotics (eg., bacitracin zinc, polymysin B sulfate, and/or neomycin sulfate), preferably in cream form, can also be used alone or in combination with other antimicrobial agents.

In the embodiment shown in Figure 1A, the flexible base **20** is substantially planar. Preferably, the flexible base **20** is composed of a material (or composite) of sufficient rigidity so that self-folding is minimized or eliminated. To further minimize self-folding, the catheter clip **10** includes extensions **60**, **61**, and **62** of the solid portion **50** which are positioned to help keep the flexible base **20** substantially extended. Additional rigidity is provided by firming contact between the extensions **60**, **61** and **62** and the flexible base **20**.

Figure 1B shows the catheter clip **10** with a catheter **140** secured to the patient insertion site **90** which catheter **140** is composed of a catheter hard part **110** with a connecting hubs **111**, **112**, lateral wings **100** for stabilizing the catheter and a catheter soft part **80** extending from the insertion site **90** toward and under the skin **120**. The catheter **140** is secured to the catheter clip **10** by actuation of clasping means **51** as previously described. The catheter clip **10** is secured to the patient through the adhesive of the patient contacting surface **41**.

Referring now to Figure 2, the catheter clip **10** is shown in cross-section with the catheter **140** secured to the patient insertion site **90**. Also shown is the top **56** of the solid portion **50** with a protrusion **130** that extends acutely from the axis **55** (see also Fig. 1A) and is in actuating contact with the clasping means **51**. The protrusion **130** is adapted to receive at least one digit from a user which digit engages protrusion **130** to flex the clasping means **51**, grasp the catheter **140** (preferably along the hard part **110**), and secure it to the catheter clip **10**.

According to one use of the catheter clip **10**, a caregiver inserts the soft part **80** of the catheter **140** under the skin **120** at the patient insertion site **90**. Subsequently, the caregiver uses a finger to remove cover **40** and the handle **30** in sealing contact with the adhesive along the patient contacting surface **41** of the flexible base **20**, thereby removing the seal and exposing the adhesive. The catheter clip **10** is then guided around the patient insertion site **90** to reversibly attach the invention to the skin **120** of the patient. Using the same or different finger, the caregiver engages the protrusion **130** to flex the clasping means **51** and grasp the hard part **110** of the catheter **140**, thereby releasably securing the catheter **140** to the catheter clip **10**. The procedure is readily reversible. In one approach, the patient contacting surface **41** is removed from the patient. The clamping means **51** is flexed by the user to allow removal of the catheter **140** from the invention.

Manufacture

The invention can be readily made using one or a combination of approaches. In one method, the hard part of the catheter clip **10** is molded as a single-piece system with the clasping means **51** capable of convenient and repeated flexure. The hard part of the catheter clip **10** can be molded from a single polymer material in a one-shot

injection molding operation. Many suitable materials could be used such as nearly any moldable plastic that is capable of being formed as provided herein and retaining its shape during use. More specific materials include, but are not limited to, many acrylic and polycarbonate materials, styrenes, and ABS. Other suitable materials include certain polyesters, nylons, and other polymer materials such as certain polyethylenes and polypropylenes. Certain memory plastics may also be used provided intended results are achieved. If two different materials are used, the device can be made by a two-shot process whereby both materials are injected at different gates into the mold cavity. Other processes are also feasible, such as insert molding. MRI compatible materials may be suitable for some invention applications.

Once the hard part of the catheter clip **10** is made, it can be joined using standard approaches to the soft part of the device which generally includes the flexible base **20**.

The flexible base **20** can be made using one or a combination of conventional approaches. In one method, the flexible base **20** comprises a relatively thin film, such as a thin urethane or silicone film, adhered to the handle **30** and cover **40.** The handle **30** and cover **40** can be made somewhat stiffer than the flexible base **20** facilitate handling. The handle **30** and the cover **40** may extend beyond an edge or edges of the thin film, so that the flexible base **20** can be handled relatively easily. In one embodiment, substantially all of the undersurface of the flexible base **20** (ie., the patient contacting surfacem41) is adhesively coated and contacted with a separate release seal which extends beyond the perimeter of the thin film and is in sealing contact with the handle **30** and cover **40**. Nearly any adhesive suitable for topical medical use can be applied to the thin film using standard methods. Examples include, but are not limited to, an acrylic adhesive containing an acrylic acid alkyl ester as a main component, a rubber adhesive containing a natural rubber and/or a synthetic rubber as a main component, as well as "pressure sensitive adhesives" (PSAs). See also U.S. Pat. Nos. 7,094,944; 6,936,661; and 6,805,961 and references disclosed therein for other suitable adhesives.

As will be apparent, the seal may protect the adhesive on at least part of the patient contacting surface 41 (e.g., less than about 50%, for instance, about 5%, 10%, 20% or about 30%), preferably substantially all of the surface (e.g., about 80%, 90%,

95% up to about 100%). The amount of adhesive on the patient contacting surface is not critical provided intended results are achieved.

Additional Embodiments

As will be appreciated, other embodiments of the catheter clip **10** are within the scope of the invention. For instance, and referring now to Figure 1A, the clasping means **51** is shown as an integral part of the solid portion **50**. However in another embodiment, clasping means **51** may be joined to solid portion **50** through an elastic or semi-elastic polymer such as a memory plastic. Alternatively, the clasping means **51** can include or be joined to the solid portion **50** through a spring or related mechanism.

In another embodiment of the catheter clip **10**, the top **56** includes means (e.g., a spring or a rod) to position the clasping means **51** to a site desired by the user. It will be appreciated that in other embodiments, the top **56** and the clasping means **51** may be the same component.

In another embodiment, the compartment **70** can be quite small and be just sufficient to surround the insertion site of the catheter. In this embodiment, it will not be necessary to make the compartment **70** so that it is in sealing contact with other components of the device. Also in this embodiment, the use of an antimicrobial may not be necessary. Instead, it may be applied to the skin surface by the user.

Nearly any configuration of the protrusion **130** is acceptable provided intended results are achieved. For instance, and in one embodiment, the protrusion **130** will extend substantially perpendicular to the axis **55** of the open chamber **130**.

In yet another embodiment of the catheter clip **10**, only one or two of the extensions **60**, **61**, and **62** will be used to provide rigidity to the flexible base **20**. In yet another embodiment, the flexible base **20** will be of sufficient rigidity so that none of extensions **60, 61** and **62** are needed.

Incorporation by Reference

The contents of all references (including literature references, issued patents, published patent applications, and co-pending patent applications) cited throughout this application are hereby expressly incorporated herein in their entireties by reference.

Equivalents

It will be appreciated that those skilled in the art, upon consideration of this disclosure, may make modifications and improvements within the spirit and scope of the invention. Moreover, those skilled in the art will recognize, or be able to ascertain using no more than routine experimentation, many equivalents of the specific embodiments of the invention described herein. Such equivalents are intended to be encompassed by the following claims.

What is claimed is:

1. A device for securing a catheter to an insertion site of a patient comprising:

(a) a flexible base comprising a sealed patient contacting surface,

(b) a solid portion joined to the flexible base and comprising a clasping means for securing the catheter; and

(c) a handle adapted to remove, with one digit, a seal from the patient contacting surface, the handle being joined to the seal, the seal protecting an adhesive on at least part of the surface sufficient to attach the secured catheter to the patient insertion site.

2. The device of claim 1, wherein the solid portion, flexible base and the handle define an open chamber comprising a distal end for receiving the catheter and a proximal end for accepting the catheter from the distal end toward the patient insertion site.

3. The device of claim 2, wherein the distal end of the open chamber comprises a first centerpoint and the proximal end comprises a second centerpoint, the open chamber surrounding an axis defined by the first and second centerpoints.

4. The device of claims 2-3, wherein the open chamber further comprises: (1) a top defined by the solid portion, and (2) a bottom defined by the handle and the flexible base.

5. The device of claims 1-4, wherein the flexible base and optionally the solid portion further define a compartment at or near the patient insertion site, the compartment being adapted to at least partially surround the site.

6. The device of claims 4-5, wherein the top extends from the clasping means to the compartment.

7. The device of claim 6, wherein at least part of the top comprises a protrusion along an axis substantially perpendicular or acute to the axis of the open chamber.

8. The device of claim 7, wherein the protrusion is adapted to accept at least one digit from a user of the device.

9. The device of claim 8, wherein the top is in actuating contact with the clasping means of the solid portion, wherein actuation of the top is sufficient to secure the clasping means to the catheter.

10. The device of claims 6-9, wherein the top further comprises means to position the clasping means to a site desired by the user.

11. The device of claims 5-10, wherein the compartment is in sealing contact with the seal of the patient contacting surface.

12. The device of claim 11, wherein the compartment comprises a therapeutically effective amount of an antimicrobial agent to minimize infection at the insertion site.

13. The device of claims 1-12, wherein the flexible base is substantially planar and of sufficient rigidity to minimize self-folding.

14. The device of claim 13, wherein the rigidity is provided by firming contact with one or more extensions of the solid portion.

15. A unitary package comprising the device of claims 1-14, wherein the device is sterile and comprises a packing material substantially resistant to penetration by microorganisms.

16. A method of releasably securing a catheter to an insertion site of a patient comprising:

(a) providing a device comprising:

(i) a flexible base comprising a sealed patient contacting surface,

(ii) a solid portion joined to the flexible base and comprising a clasping means for securing the catheter to the device,

(iii) a handle region joined to the flexible portion and adapted to remove, with one hand, a seal from the patient contacting surface, thereby exposing the adhesive for releasably securing the catheter to the insertion site of the patient,

(b) removing, with at least one digit, the seal from the patient contacting surface of the flexible portion to expose the adhesive,

(c) guiding the device over the catheter,

(d) contacting the flexible base (patient contacting surface) to the patient sufficient to adhere the device thereto; and

(e) actuating the clasping means to grasp the catheter (catheter solid part), thereby securing the catheter to insertion site of the patient.

17. The device shown in Figures 1A, 1B and 2.

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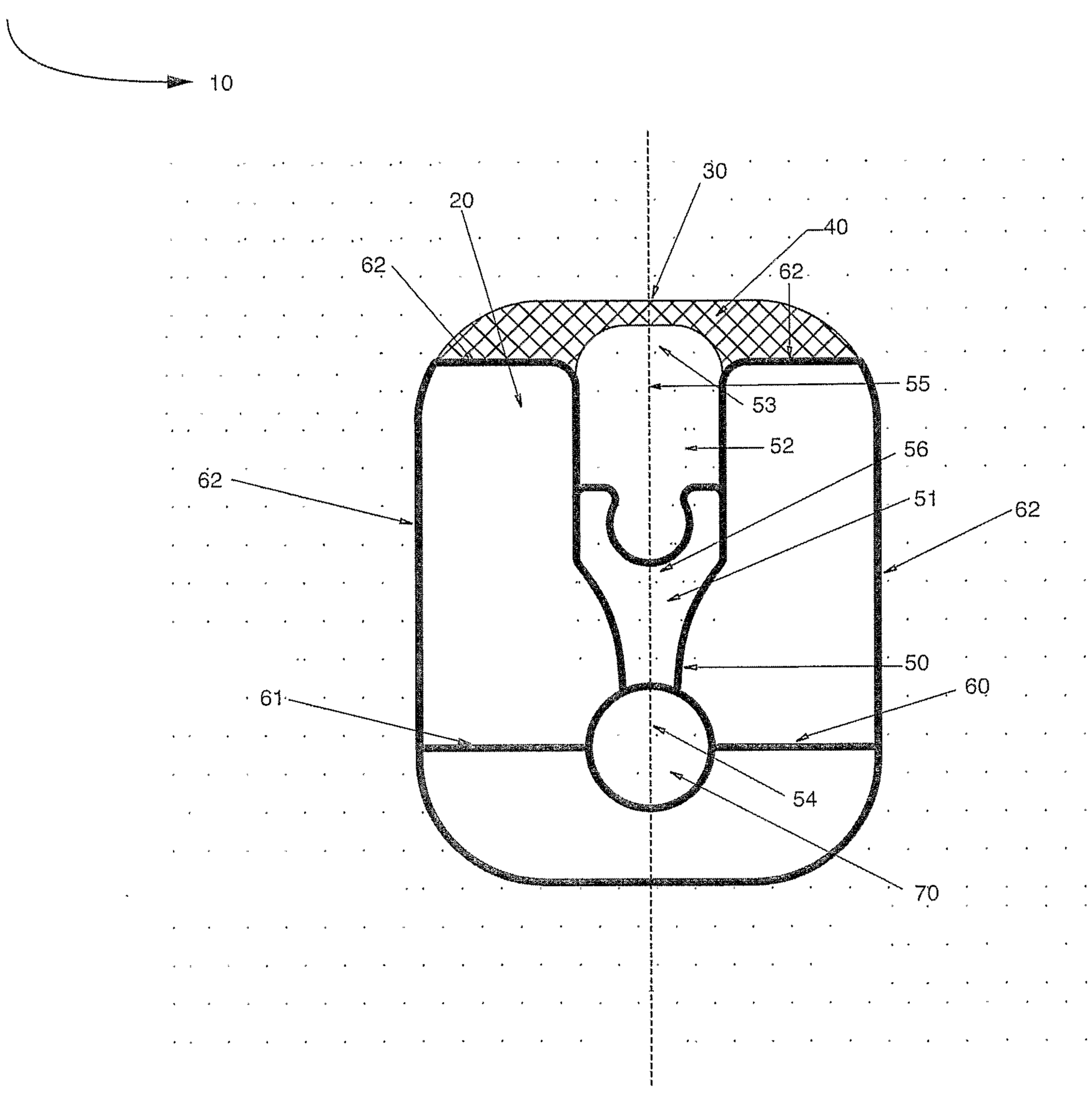


Fig. 1A

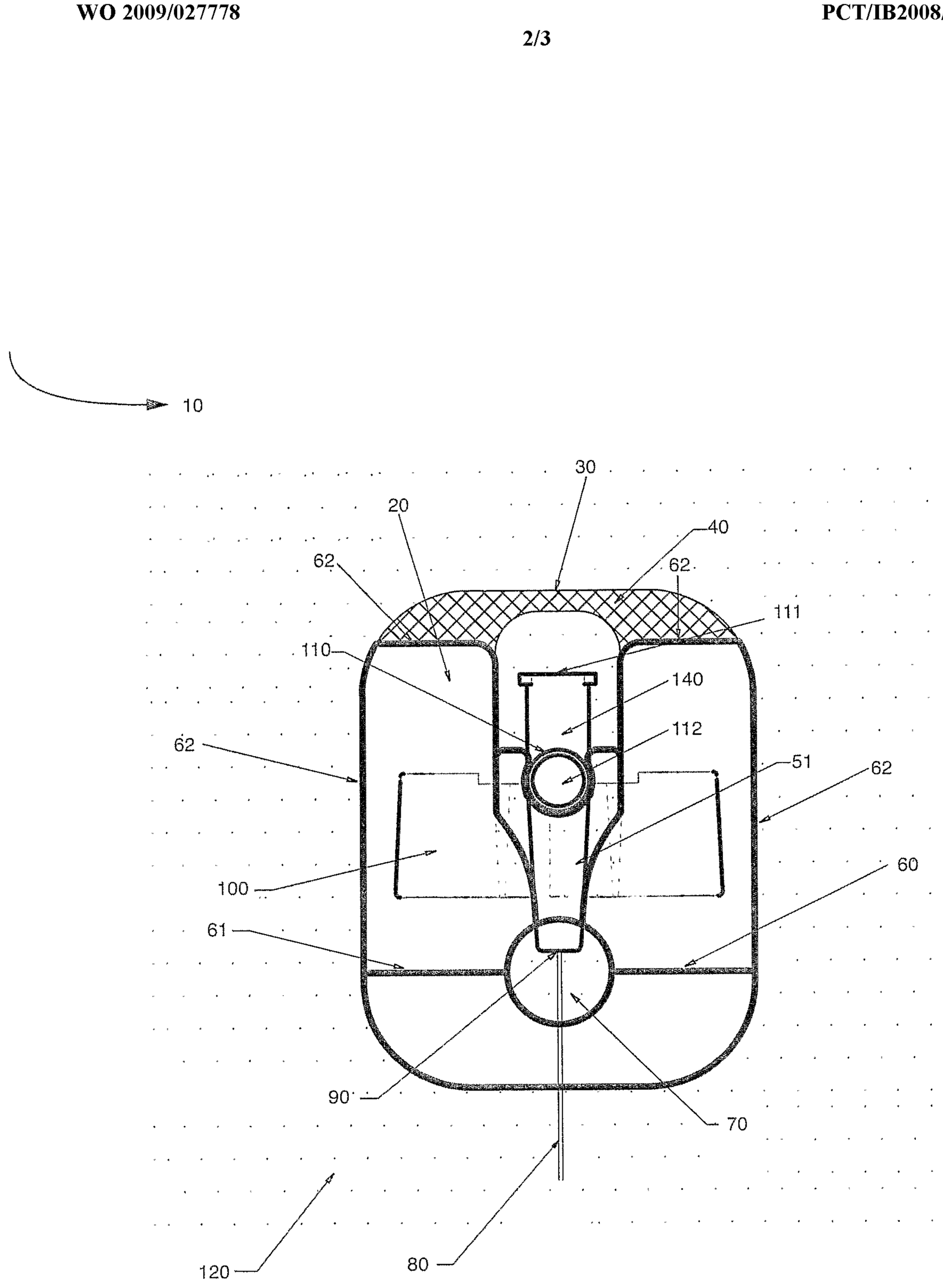


Fig. 1B

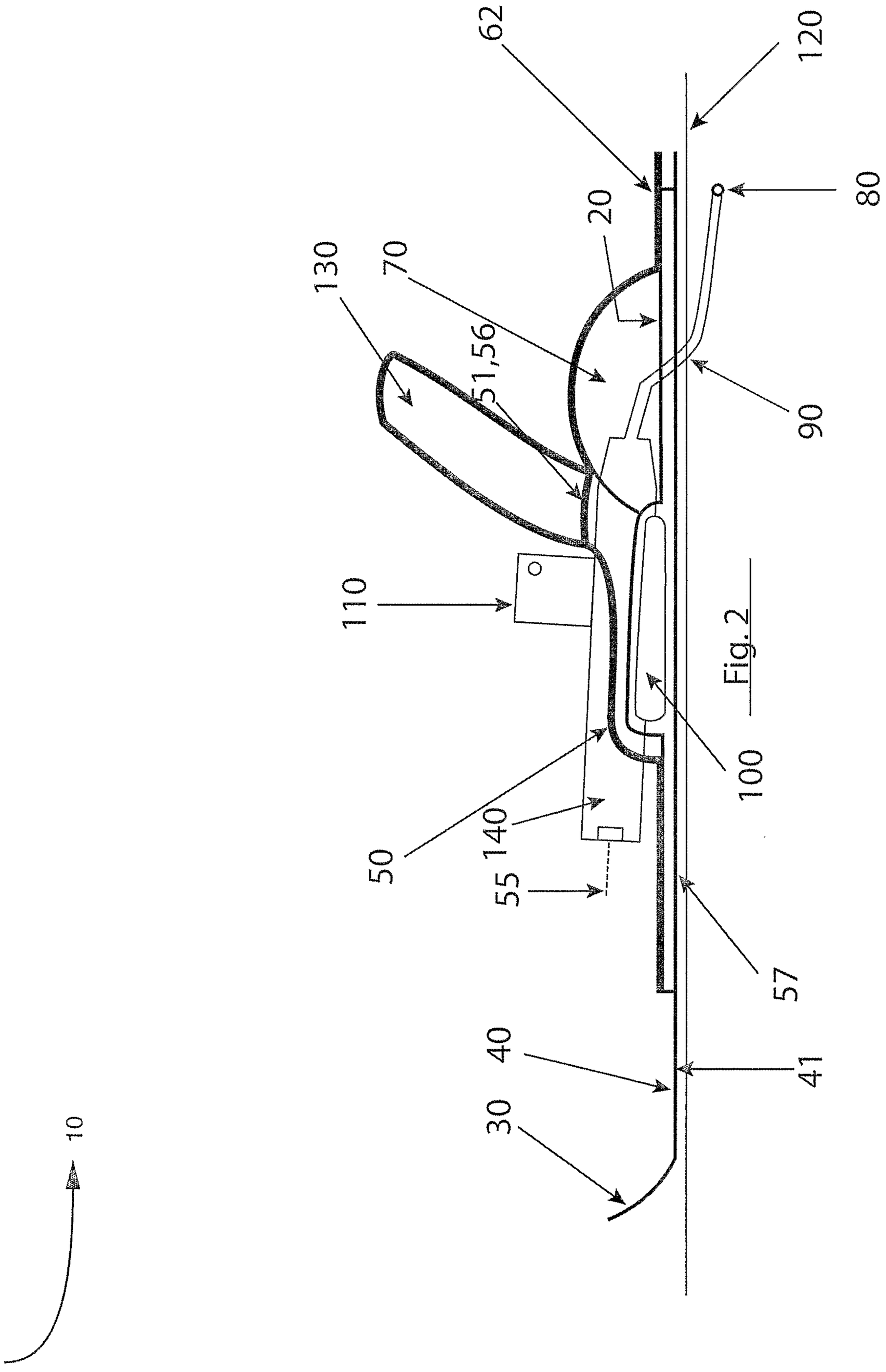


Fig. 2

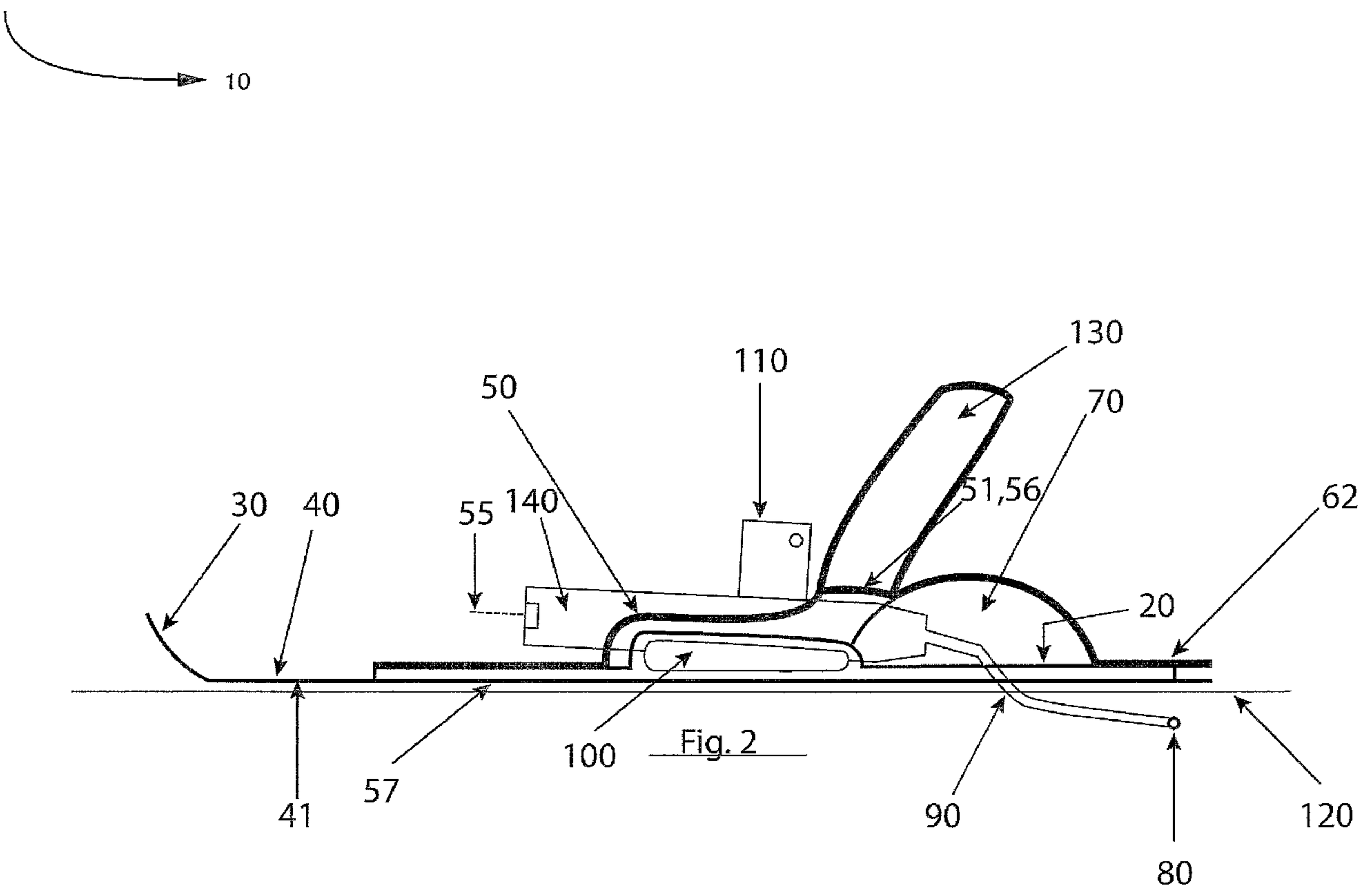


Fig. 2