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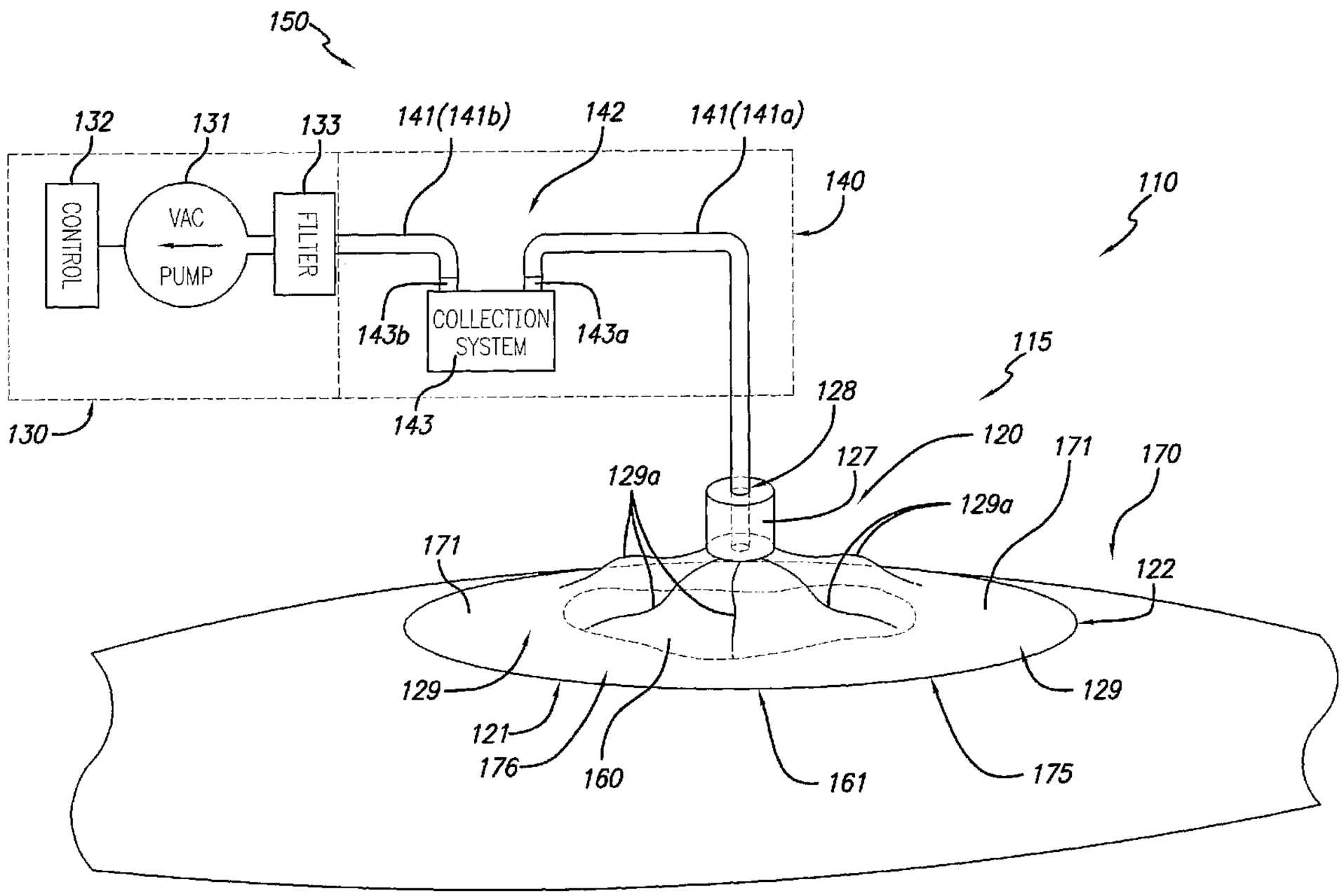

(57) Abrégé/Abstract:
A wound treatment appliance is provided that generally comprises a gas-impermeable flexible overlay that covers all or a portion of a wound for purposes of applying a reduced pressure to the covered portion of the wound. When reduced pressure is applied to the flexible overlay, it collapses in the approximate direction of the wound, producing an approximately hermetic seal between the flexible overlay and the body in the area of the wound. In addition, the appliance may further comprise a collection chamber to collect and store exudate from the wound. The appliance may also comprise a vacuum system to supply reduced pressure to the wound in the area under the flexible overlay. Further, the appliance may include wound packing means to assist in wound healing. The appliance may also include a suction drain. Finally, methods are provided for using the appliance.

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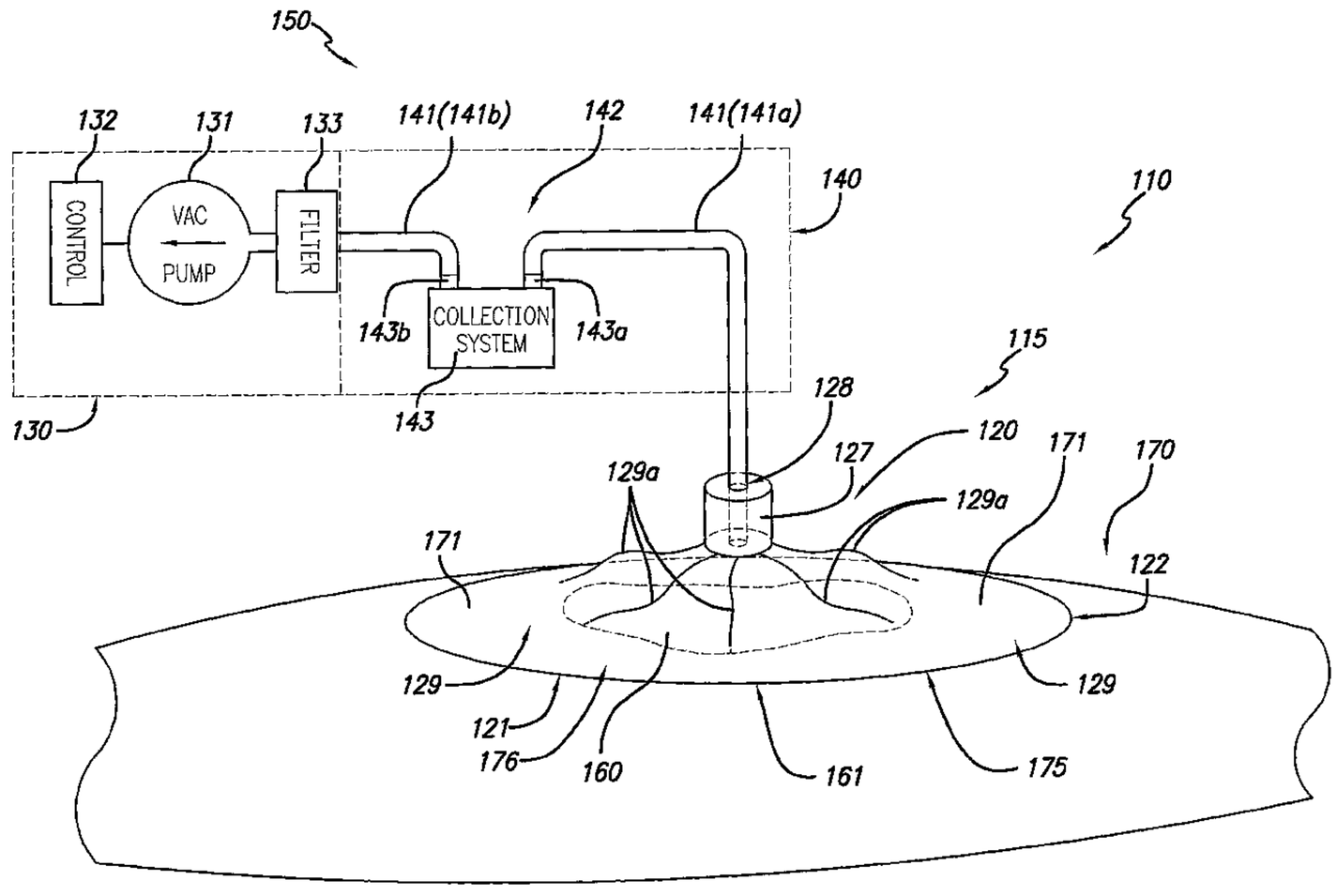
(54) Title: IMPROVED FLEXIBLE REDUCED PRESSURE TREATMENT APPLIANCE



(57) Abstract: A wound treatment appliance is provided that generally comprises a gas-impermeable flexible overlay that covers all or a portion of a wound for purposes of applying a reduced pressure to the covered portion of the wound. When reduced pressure is applied to the flexible overlay, it collapses in the approximate direction of the wound, producing an approximately hermetic seal between the flexible overlay and the body in the area of the wound. In addition, the appliance may further comprise a collection chamber to collect and store exudate from the wound. The appliance may also comprise a vacuum system to supply reduced pressure to the wound in the area under the flexible overlay. Further, the appliance may include wound packing means to assist in wound healing. The appliance may also include a suction drain. Finally, methods are provided for using the appliance.

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IMPROVED FLEXIBLE REDUCED PRESSURE TREATMENT APPLIANCE

by

Richard Scott Weston

TECHNICAL FIELD

The present invention generally relates to treatment of wounds, and more specifically to an improved apparatus and method for treating all or a portion of a wound on a body by applying reduced pressure to the portion of the wound for which treatment is desired. In this context, the terms "wound" and "body" are to be interpreted broadly, to include any body part of a patient that may be treated using reduced pressure.

BACKGROUND ART

The treatment of wounds by means of applying reduced pressure to the site of the wound is well known in the art. Systems of this type are disclosed in U.S. Patent Application Nos. 10/652,100, filed on August 28, 2003, and 11/026,733, filed on December 30, 2004, by the present inventor with the U.S. Patent and Trademark Office. Yet other systems are disclosed in U.S. patent nos. 5,636,643 (Argenta and Morykwas), 5,645,081 (Argenta and Morykwas), and 4,969,880 (Zamierowski), and U.S published patent application nos. 2002/0065494 (Lockwood, et al.), 2002/0068913 (Fleishmann), 2002/0161346 (Lockwood, et al.), 2002/0183702 (Henley, et al.), 2002/019503 (Risk and Petrosenko), 2002/019504 (Risk and Petrosenko), 2003/0040687 (Boynton, et al.), and 2003/0050594 (Zamierowski). These references are not necessarily prior art.

Reduced pressure wound treatment systems currently known in the art commonly involve placing a cover that is impermeable to liquids over the wound, using various means to seal the cover to the tissue of the patient surrounding the wound, and connecting a source of reduced pressure (such as a vacuum pump) to the cover in a manner so that an area of reduced pressure is created under the cover in the area of the wound. However, the covers currently known and used in the art have a number of disadvantages. For example, in one version they tend to be in the form of a flexible sheet of material that is placed over the wound and sealed to the surrounding tissue using an adhesive, adhesive tape, or other similar means. As tissue swelling in the area of the wound decreases during the healing process, the adhesive may begin to stretch the surrounding tissue, as well as tissue within the wound, resulting in discomfort and pain to the patient and possibly more frequent cover changes. In addition, these types of

covers can typically only be used where there is normal tissue adjacent to the wound to which the adhesive seal can be attached. Otherwise, the seal must be made in a portion of the area of the wound, and exudate from the wound tends to break the seal so that reduced pressure cannot be maintained beneath the wound cover. Thus, such covers (and many other covers requiring adhesive seals) may typically only be used to treat an entire wound, as opposed to only a portion of a wound. Further, the adhesive seal creates discomfort for the patient when the sheet cover is removed. In other versions, the covers tend to be rigid or semi-rigid in nature so that they are held away from the surface of the wound. In these versions, the covers are sometimes difficult to use because the shape and contour of the patient's body in the area of the wound do not readily adapt to the shape of the cover. In addition, it is also often necessary to use an adhesive, adhesive tape, or other similar means to seal the rigid or semi-rigid cover to the tissue surrounding the wound. In these instances, the same disadvantages discussed above with respect to the sheet-type covers also apply to these covers. In still other cases, the rigid and semi-rigid covers must be used with padding in the area where the cover is adjacent to the patient to prevent the edges of the cover from exerting undue pressure on the tissue surrounding the wound. Without the padding, the patient may experience pain and discomfort. These covers may also have the problem of placing tension on the surrounding tissue as swelling in the area of the wound decreases during the healing process. In yet another version, covers are constructed of combinations of flexible materials and rigid materials. In these versions, a flexible member, such as a flexible sheet, is typically supported by a rigid or semi-rigid structure that is either placed between the flexible member and the wound or in the area above and outside the flexible member. In either case, the flexible member must usually be sealed to the tissue surrounding the wound using an adhesive, adhesive tape, or other similar means. This seal creates the same problems described above. In addition, the same problems described above with respect to rigid and semi-rigid structures are also often present. In all of the versions described above, it may be difficult to tell if reduced pressure in the area of the wound under the cover has been lost because the cover itself does not generally provide a visual clue of such loss.

Therefore, there is a need for a reduced pressure wound treatment system that has a means to enclose all or a portion of a wound without the need for an adhesive seal. There is also a need for such enclosing means to be flexible, so that it adapts to changing shapes and contours of the patient's body as wound healing progresses. Further, there is a need for an enclosing means that is adaptable to a wide variety of patient body shapes and contours. There

is also a need for an enclosing means that is simple to apply to the patient's body, and simple to remove from the patient's body. There is also a need for an enclosing means that is relatively inexpensive, while meeting the needs described above. In addition, there is a need for an enclosing means that may be used within the wound (or a portion thereof), without the need to seal the enclosing means to normal tissue surrounding the wound. Further, there is a need for an enclosing means that flexes with movement of the portion of the body surrounding the wound, without the need for an adhesive seal or rigid or semi-rigid structure. Finally, there is a need for an enclosing means that provides a visual clue of loss of reduced pressure in the area of the wound under the enclosing means.

DISCLOSURE OF INVENTION

In accordance with the present invention, a wound treatment appliance is provided for treating all or a portion of a wound by applying reduced pressure (i.e., pressure that is below ambient atmospheric pressure) to the portion of the wound to be treated in a controlled manner for a selected time period in a manner that overcomes the disadvantages of currently existing apparatus. The wound treatment appliance is generally comprised of a flexible overlay and reduced pressure supply means, which are used to connect the flexible overlay to a reduced pressure supply source that provides a supply of reduced pressure to the flexible overlay. The flexible overlay is adapted to be placed over and enclose all or a portion of a wound on the surface of the body of a patient. The flexible overlay is also adapted to maintain reduced pressure under the flexible overlay in the area of the wound. The flexible overlay is drawn downward, collapsing in the approximate direction of the area of the wound to be treated, when reduced pressure is supplied to the volume under the flexible overlay in the area of the wound. As the flexible overlay collapses, the portions of the flexible overlay positioned adjacent to the surface of the body at the wound site are at (or can be deformed to be at) a relatively acute angle relative to such surface of the body and are drawn tightly against the surface of the body at the wound site, forming an approximately hermetic seal. References to an "approximately hermetic seal" herein refer generally to a seal that is gas-tight and liquid-tight for purposes of the reduced pressure treatment of the wound, which may provide for a relatively small degree of leakage, so that outside air may enter the volume under the flexible overlay in the area of the wound, as long as the degree of leakage is small enough so that the vacuum system can maintain the desired degree of reduced pressure in the volume under the flexible overlay in the area of the wound. In some cases where the collapsing flexible overlay may not produce an approximately hermetic seal that is solely capable of maintaining the

reduced pressure in the volume under the flexible overlay in the area of the wound, it may be necessary to provide supplemental sealing means, which are described in more detail below, to provide a seal between the portions of the flexible overlay and the body where the approximately hermetic seal is not adequate. In some cases, at least one fold forms in the surface of the flexible overlay when it collapses, so that fluids aspirated by the wound flow along the at least one fold to the reduced pressure supply means, where they are removed from the flexible overlay by the reduced pressure supply means cooperating with the reduced pressure supply source.

In some embodiments of the present invention, the wound treatment appliance is further comprised of a collection chamber and collection chamber attachment means to operably connect the collection chamber to the flexible overlay. In these embodiments, the reduced pressure supply means is attached to the collection chamber, rather than the flexible overlay. The collection chamber attachment means allows fluid to flow from the volume under the flexible overlay into the collection chamber, where it may be collected and retained until disposal. The collection chamber attachment means may also provide flow control means, such as one or more valves, that permit fluid to flow from the volume under the flexible overlay into the collection chamber, but not in the opposite direction. The appliance may also further comprise the reduced pressure supply source, which may be further comprised of a vacuum pump or a suction bulb system described in more detail below. The reduced pressure supply source and the reduced pressure supply means, together with a fluid collection system that may be a part of the reduced pressure supply means, are sometimes together referred to as the "vacuum system." The appliance may also further comprise tissue protection means to protect and strengthen the body tissue that is adjacent to the flexible overlay at the wound site or wound packing means that are placed in or over the wound to assist in wound healing. The present invention also includes a method, which is described in more detail below, of treating a wound on a body using the wound treatment appliance.

As is illustrated in the detailed descriptions herein, the wound treatment appliance of the present invention meets the needs discussed above in the Background Art section. The application of reduced pressure to a wound by the appliance provides such benefits as faster healing, increased formation of granulation tissue, closure of chronic open wounds, reduction of bacterial density within wounds, inhibition of burn penetration, and enhancement of flap and graft attachment. Wounds that have exhibited positive response to treatment by the

application of negative pressure include infected open wounds, decubitus ulcers, dehisced incisions, partial thickness burns, and various lesions to which flaps or grafts have been attached. The present invention may also be used to prevent wounds by increasing circulation of blood and lymph. In addition, when the flexible overlay is enclosing all or a portion of the wound, the portions of the flexible overlay positioned adjacent to the surface of the body at the wound site form an approximately hermetic seal, which may not require supplemental sealing means, such as an adhesive, in many cases. As a result, the flexible overlay is simple to apply to the patient. In addition, there is often no need for any other sealing means, so that there is often no need for medical staff to take the time to make a separate seal. Even where the geometry of the surface of the body surrounding the wound may require that supplemental sealing means be used to provide some limited assistance to ensure a seal, the amount of such assistance (such as by applying an adhesive) is limited, especially when compared to current covers in the art. In addition, as swelling of tissue at the wound site decreases, the flexible nature of the flexible overlay allows it to further deform to conform to the changing shape and contours at the wound site. This prevents the patient from being discomforted as the swelling decreases. It may also reduce the need to change the covering over the wound as healing progresses. The flexible overlay may also be used for unusual geometries of the body at or surrounding the wound because of the overlay's flexible nature and relatively large surface area. The flexible overlay may also be used within the perimeter of a wound in many cases because there is not typically a need to seal the flexible overlay to normal tissue surrounding the wound. Further, because there is typically no need for an adhesive seal, removal of the flexible overlay merely requires removal of the reduced pressure from the area under the flexible overlay. It is thus simple to remove from the patient. In addition, there is usually no pain and discomfort for the patient when the flexible overlay is removed. Even if a limited amount of supplemental sealing means (such as an adhesive) are required to provide a seal at a portion of the flexible overlay that is adjacent to the surface surrounding the wound, the reduced amount of supplemental sealing means should cause a corresponding reduction in the amount of such pain and discomfort. Further, the preferred embodiments of the collapsed flexible overlay will have folds in its surface while in the collapsed state, so that fluid aspirated by the wound may flow along the folds to be removed from under the flexible overlay. In addition, if reduced pressure is lost under the flexible overlay, the flexible overlay will expand outward from the wound, providing a visual indication that reduced pressure has been lost. Finally, in its preferred embodiments, the flexible overlay should be relatively inexpensive to manufacture, while meeting the described needs.

BRIEF DESCRIPTION OF DRAWINGS

The details of the present invention will be described in conjunction with the appended drawings, in which: **FIG. 1A** is a perspective view of an embodiment of a flexible overlay; **FIG. 1B** is a perspective view of another embodiment of a flexible overlay; **FIG. 1C** is a perspective view of another embodiment of a flexible overlay; **FIG. 2A** is a view of an embodiment of a wound treatment appliance comprising a flexible overlay covering a wound, shown in perspective view, and a vacuum system, depicted generally and shown in schematic elevation view; **FIG. 2B** is a sectional elevational detailed view of an embodiment of a collection container and the shutoff mechanism portion of the collection system of **FIG. 2A**; **FIG. 3** is a view of an embodiment of a wound treatment appliance comprising a flexible overlay with wound packing means covering a wound, shown in cross-sectional elevational view, and an embodiment of a vacuum system, shown in perspective view; **FIG. 4** is a perspective view of another embodiment of a wound treatment appliance; **FIG. 5** is a view of an embodiment of a wound treatment appliance comprising an embodiment of a flexible overlay with a collection chamber covering a wound, shown in perspective view, and a vacuum system, depicted generally and shown in schematic elevation view; and **FIG. 6** is a view of another embodiment of a wound treatment appliance comprised of a flexible overlay with a collection chamber, shown in partially broken away perspective view, and a vacuum system, depicted generally and shown in schematic elevation view.

BEST MODE FOR CARRYING OUT THE INVENTION

In accordance with the present invention, a wound treatment appliance is provided for treating all or a portion of a wound by applying reduced pressure (i.e., pressure that is below ambient atmospheric pressure) to the portion of the wound to be treated in a controlled manner for a selected time period in a manner that overcomes the disadvantages of currently existing apparatus. One embodiment of a first aspect of a first version of the invention is a wound treatment appliance **10** that is comprised of the liquid impermeable flexible overlay **20** illustrated in **FIG. 1A** and reduced pressure supply means, which are described in more detail below. In this embodiment, the flexible overlay **20** has an approximately elongated conical shape, having an opening **21** with an opening perimeter **22** adjacent to the opening **21** (at the base of the elongated conical shape) that is approximately elliptical in shape. The flexible overlay **20** illustrated in **FIG. 1A** is in its natural shape, as it exists prior to being applied to a patient for treatment of all or a portion of a wound. In other embodiments, the flexible overlay

20 may have other shapes. For example, the flexible overlay **20** may be approximately conical in shape, rather than the approximately elongated conical shape illustrated in **FIG. 1A**. As another example, as illustrated in **FIG. 1B**, only the bottom portion **23a** of the flexible overlay **20a** may have an approximately elongated conical shape. In this embodiment, and in the same manner as illustrated in **FIG. 1A**, the bottom portion **23a** has an opening **21a** with an opening perimeter **22a** adjacent to the opening **21a** (at the base of the elongated conical shape) that is approximately elliptical in shape. In the embodiment of the flexible overlay illustrated in **FIG. 1B**, the top portion **24a** is flatter than the comparable portion of the flexible overlay **20** in the embodiment illustrated in **FIG. 1A**. In other embodiments, the top portion **24a** of the flexible overlay **20a** may have almost any shape that is adaptable to a bottom portion **23a** having an approximately elongated conical shape. In addition, in yet other embodiments of this first aspect of the first version of the invention, the bottom portion **23a** of the flexible overlay **20a** may be in the approximate shape of a cone, rather than the elongated conical shape illustrated in **FIG. 1B**. In yet another embodiment, as illustrated in **FIG. 1C**, the flexible overlay **20b** is comprised of six cover portions **23b**, **23b'**, where the cover portions **23b** are viewable in **FIG. 1C** and the cover portions **23b'** are illustrated by phantom lines. In this embodiment, each of such cover portions **23b**, **23b'** is approximately triangular in shape, and one point of each of the at least three cover portions **23b**, **23b'** is joined to form an apex **24b** of the impermeable flexible overlay **20b**. One side of each cover portion **23b**, **23b'** adjacent to the apex **24b** is joined to an adjacent side of another of such cover portions **23b**, **23b'** so that the bases **22b**, **22b'** of the cover portions **23b**, **23b'**, respectively, form an opening **21b** sized to be placed over and enclose the area of the wound to be treated. In other embodiments, the flexible overlay **20b** may have a different number of cover portions **23b**, **23b'**. Preferably, in these embodiments, there are at least three cover portions **23b**, **23b'**. In addition, in yet other embodiments, the flexible overlay **20b** may have cover portions **23b**, **23b'** having a different shape, such as trapezoidal or parabolic. In still other embodiments, the flexible overlay **20**, **20a**, **20b** may be of almost any shape that may be adaptable for treating all or a portion of a wound, as long as the flexible overlay **20**, **20a**, **20b** is flexible, as described in more detail below, and the interior surface of the flexible overlay **20**, **20a**, **20b** is adapted to make an approximately hermetic seal with the body of the patient at the site of the wound, as described in more detail below. Referring again to **FIG. 1A** as an example, in some embodiments of this first aspect of the first version of the invention, the interior surface of the flexible overlay **20** is adapted to make an approximately hermetic seal with the body of the patient at the site of the wound by having a surface area larger than the surface area of the portion of the body of the

patient covered by the flexible overlay **20**, as described in more detail below.

The preferred shape and size of the flexible overlay **20**, **20a**, **20b** is dependent upon the size of the portion of the wound to be treated, the shape and contour of the portion of the body that is to be covered by the flexible overlay **20**, **20a**, **20b** at the site of the wound, the magnitude of the reduced pressure to be maintained under the flexible overlay **20**, **20a**, **20b**. More preferred, as illustrated in **FIG. 1B**, the flexible overlay **20a** has an approximately elongated conically shaped bottom portion **23a**. Most preferred, as illustrated in **FIG. 1A**, the flexible overlay **20** is shaped approximately as an elongated cone. The preferred thickness of the portion **25**, **25a**, **25b** of the flexible overlay **20**, **20a**, **20b** adjacent to the open end **21**, **21a**, **21b** of the flexible overlay **20**, **20a**, **20b** is dependent upon the size and shape of the flexible overlay **20**, **20a**, **20b**, the shape and contour of the portion of the body that is to be covered by the flexible overlay **20**, **20a**, **20b** at the site of the wound, the magnitude of the reduced pressure to be maintained under the flexible overlay **20**, **20a**, **20b**, and other factors, such as the depth of the wound and the amount of the desired collapse of the flexible overlay **20**, **20a**, **20b**. For example, in the embodiment illustrated in **FIG. 1A**, for a flexible overlay **20** constructed of silicone and having an approximately elongated conical shape with an opening **21** having a major diameter of approximately 7 inches (17.8 cm) and a minor diameter of approximately 4 inches (10.2 cm), the preferred thickness of the portion **25** of the flexible overlay **20** adjacent to the open end **21** of the flexible overlay **20** is in the range from 1/32 inches (0.079 cm) to 3/32 inches (0.238 cm). More preferred in this embodiment, the thickness of the portion **25** of the flexible overlay **20** adjacent to the open end **21** of the flexible overlay **20** is approximately 1/16 inches (0.159 cm). It is to be noted that in other embodiments the thickness of the flexible overlay **20**, including the portion **25** of the flexible overlay **20** adjacent to the open end **21** of the flexible overlay **20**, may vary from location to location on the flexible overlay **20**.

In the embodiment of the flexible overlay **20** illustrated in **FIG. 1A**, the flexible overlay **20** has a series of raised beads **26** on the outside surface of the flexible overlay **20**. In this embodiment, the raised beads **26** are generally parallel to the perimeter **22** of the opening **21** of the flexible overlay **20**. The same is also true of the raised bead **26b** of the flexible overlay **20b** of the embodiment illustrated in **FIG. 1C**. In other embodiments, such as that illustrated in **FIG. 1B**, the raised beads **26a** may have a different orientation. In still other embodiments, the raised beads **26**, **26a**, **26b** may be in almost any orientation desired by the

user of the wound treatment appliance **10**, **10a**, **10b**. In various embodiments of this first aspect of the first version of the invention, as illustrated in **FIG. 1A**, the raised beads **26** may provide a guide for the user administering the reduced pressure treatment to cut away a portion of the flexible overlay **20**, so that the perimeter **22** of the opening **21** of the flexible overlay **20** is smaller than it was originally. For example, by cutting along the parallel raised beads **26** of the flexible overlay **20** of **FIG. 1A**, the size of the opening **21** of the flexible overlay **20** can be made smaller while the shape of the perimeter **22** remains approximately the same. It is to noted, however, that in various embodiments of this first aspect of the first version of the invention, as described in more detail below, the flexible overlay **20** may be cut into different shapes in order to adapt the flexible overlay **20** for use with different shapes and contours of the surface of the body at the site of the wound.

In the various embodiments of this first aspect of the first version of the invention, the flexible overlay **20**, **20a**, **20b** may be comprised of almost any medical grade flexible material that is currently known in the art or that may be developed in the art in the future, as long as such material is fluid-impermeable, suitable for purposes of wound treatment (e.g., can be sterilized and does not absorb significant amounts of wound exudate), and is capable of forming an approximately hermetic seal with the surface of the body at the site of the wound, as described in more detail below. For example, the flexible overlay **20**, **20a**, **20b** may be comprised of rubber (including neoprene), and flexible polymer materials, such as silicone, silicone blends, silicone substitutes, polyester, vinyl, polyimide, polyethylene napthalate, polycarbonates, polyester-polycarbonate blends, or a similar polymer, or combinations of all such materials. Preferably, the flexible overlay **20**, **20a**, **20b** is comprised of silicone. Although the raised beads **26**, **26a**, **26b** may be constructed of a material different from the material comprising the remainder of the flexible overlay **20**, **20a**, **20b** in various embodiments of the invention, the raised beads **26**, **26a**, **26b** are preferably constructed from the same material comprising the remainder of the flexible overlay **20**, **20a**, **20b**. In other embodiments, the raised beads **26**, **26a**, **26b** may be placed on the flexible overlay **20**, **20a**, **20b** by means of a mark, such as indelible ink, on the surface of the flexible overlay **20**, **20a**, **20b**. It is to be noted that in various embodiments of this first aspect of the first version of the invention, the flexible overlay **20**, **20a**, **20b** may be constructed in whole or in part of gas-permeable materials, allowing limited amounts of oxygen to penetrate the flexible overlay **20**, **20a**, **20b** so that the area of the wound under the flexible overlay **20**, **20a** can "breathe." It is also to be noted that all portions of the flexible overlay **20**, **20a**, **20b** are preferably constructed of one

type of polymer material, such as silicone. The flexible overlay **20**, **20a**, **20b** may be constructed using any suitable means currently known in the art or that may be developed in the art in the future. For example, a flexible overlay **20**, **20a**, **20b** constructed of silicone may be manufactured by means of injection molding.

In the embodiments of the flexible overlay **20, 20a**, **20b** illustrated in **FIG. 1A**, **FIG. 1B**, and **FIG. 1C**, respectively, each of the flexible overlays **20**, **20a**, **20b** further comprises a port **27, 27a**, **27b** adapted to receive a reduced pressure supply means to supply reduced pressure to the area of the wound under the flexible overlay **20, 20a**, **20b**. Although the port **27** is positioned at approximately the apex of the elongated cone-shaped flexible overlay **20** in the embodiment illustrated in **FIG. 1A**, and the port **27b** is positioned at approximately the apex **24b** of the triangular-shaped cover portions **23b, 23b'** in the embodiment illustrated in **FIG. 1C**, which is the preferred location, the port may be located at another location on the flexible overlay in other embodiments. In such embodiments, and referring to **FIG. 1B** as an example, the port **27a** (and alternate port **27a'**) may be located at almost any location on the surface of the flexible overlay **20a** as long as the port **27a**, **27a'** does not adversely affect the ability of the flexible overlay **20a** to make an approximately hermetic seal with the surface of the body at the wound site, as described in more detail below. For example, the port **27a**, **27a'** may not be located too close to the perimeter **22a** of the opening **21a** of the flexible overlay **20a** because the approximately hermetic seal with the surface of the body is typically formed at that location. In the embodiment of the flexible overlay **20a** illustrated in **FIG. 1B**, the alternate port **27a'** may preferably be located at any location on the top portion **24a** of the flexible overlay **20a**, and more preferably, the port **27a** is located at the center of the top portion **24a** of the flexible overlay **20a**. Referring again to **FIG. 1A** as an example, although the port **27** may be constructed of a material different from the material comprising the remainder of the flexible overlay **20** in various embodiments of the invention, the port **27** is preferably constructed from the same material comprising the remainder of the flexible overlay **20**. In the embodiments of the flexible overlay **20, 20a, 20b** illustrated in **FIG. 1A**, **FIG. 1B**, and **FIG. 1C**, respectively, the ports **27**, **27a**, **27b** are generally cylindrical in shape and are further comprised of an approximately cylindrical channel **28**, **28a**, **28b**, respectively, that extends from the top of each of the ports **27**, **27a**, **27b**, respectively, to the bottom of the ports **27**, **27a**, **27b**, respectively. The ports **27**, **27a**, **27b** of these embodiments are thus able to receive a vacuum system or reduced pressure supply means, which are described in more detail below, adapted to be connected to this shape of port **27**, **27a**, **27b**, respectively, and

channel **28**, **28a**, **28b**, respectively. In other embodiments of this first aspect of the first aspect of the first version of the invention, the ports **27**, **27a**, **27b** or the channels **28**, **28a**, **28b**, respectively, or both may have different shapes and configurations as may be desired to adapt and connect the ports **27**, **27a**, **27b**, respectively, and the channels **28**, **28a**, **28b**, respectively, to the vacuum system or reduced pressure supply means, which are described in more detail below.

An embodiment of a second aspect of the first version of the present invention is the wound treatment appliance **110** illustrated in **FIG. 2A**. In this embodiment, the wound treatment appliance **110** is comprised of a wound treatment device **115** and a vacuum system, generally designated **150**, that is operably connected to, and provides a supply of reduced pressure to, the wound treatment device **115**. Also in this embodiment, the wound treatment device **115** is comprised of a flexible overlay **120**. In addition, in this embodiment, the vacuum system **150** is further comprised of a reduced pressure supply source, generally designated **130**, which is illustrated schematically and described in more detail below, and reduced pressure supply means, generally designated **140**, which are illustrated schematically and described in more detail below. Also in this embodiment, the reduced pressure supply means **140** are used to connect the reduced pressure supply source **130** to the flexible overlay **120** in a manner so that reduced pressure is supplied to the volume under the flexible overlay **120** in the area of the wound **160**, as described in more detail below. In the embodiment of the second aspect of the first version of the invention illustrated in **FIG. 2A**, the flexible overlay **120** has substantially the same structure, features, characteristics and operation as the flexible overlay **20** described above and illustrated in connection with **FIG. 1A**. It is to be noted, however, that in other embodiments of this second aspect of the first version of the invention, the flexible overlay **120** may have substantially the same structure, features and characteristics as any embodiment of all of the flexible overlays **20**, **20a, 20b** of the first aspect of the first version of the invention described above and illustrated in connection with **FIG. 1A**, **FIG. 1B**, and **FIG. 1C**. **FIG. 2A** also illustrates an example of how the embodiment of the flexible overlay **20** illustrated in **FIG. 1A** may be used to provide reduced pressure treatment for a wound **160** on the body **170** of a patient. In this example, the flexible overlay **120** is placed over and encloses the entire wound **160**, as described in more detail below. In other embodiments, the flexible overlay **120** need not enclose the entire wound **160**.

In the embodiment illustrated in **FIG. 2A**, the reduced pressure supply source **130** of

the vacuum system **150**, which produces a source of reduced pressure or suction that is supplied to the flexible overlay **120**, is comprised of a vacuum pump **131**, a control device **132**, and a filter **133**. Although the preferred means of producing the reduced pressure or suction is a vacuum pump **131** in this embodiment, in other embodiments of this second aspect of the first version of the invention other means may be used, such as an outlet port of a centralized hospital vacuum system. In the illustrated embodiment, predetermined amounts of suction or reduced pressure are produced by the vacuum pump **131**. The vacuum pump **131** is preferably controlled by a control device **132**, such as a switch or a timer that may be set to provide cyclic on/off operation of the vacuum pump **131** according to user-selected intervals. Alternatively, the vacuum pump **131** may be operated continuously without the use of a cyclical timer. In addition, in some embodiments the control device **132** may provide for separate control of the level of reduced pressure applied to the wound **160** and the flow rate of fluid aspirated from the wound **160**. In these embodiments, relatively low levels of reduced pressure may be maintained in the area of the wound **160** under the wound treatment device **115**, while still providing for the removal of a relatively large volume of exudate from the wound **160**. A filter **133**, such as a micropore filter, is preferably attached to the inlet of the vacuum pump **131** to prevent potentially pathogenic microbes or aerosols from contaminating, and then being vented to atmosphere by, the vacuum pump **131**. In other embodiments, the filter **133** may also be a hydrophobic filter that prevents any exudate from the wound from contaminating, and then being vented to atmosphere by, the vacuum pump **131**. It is to be noted that in other embodiments of the invention, the reduced pressure supply source **130** may not have a filter **133** or a control **132** or any combination of the same.

In the embodiment of the second aspect of the first version of the invention illustrated in **FIG. 2A**, the reduced pressure supply means **140** of the vacuum system **150**, which are used to connect the reduced pressure supply source **130** to the flexible overlay **120** so that reduced pressure is supplied to the volume under the flexible overlay **120** in the area of the wound **160** is comprised of at least one tubing member **141**. In this embodiment, the at least one tubing member **141** is sufficiently flexible to permit movement of the at least one tubing member **141**, but is sufficiently rigid to resist constriction when reduced pressure is supplied to the flexible overlay **120** or when the location of the wound **160** is such that the patient must sit or lie upon the at least one tubing member **141** or upon the wound treatment device **115**. In the embodiment illustrated in **FIG. 2A**, the at least one tubing member **141** is connected to the flexible overlay **120** by inserting one end of the at least one tubing member **141** into the

opening **128** of the port **127** of the flexible overlay **120**. In this embodiment, the at least one tubing member is held in place in the opening **128** by means of an adhesive. It is to be noted that in other embodiments of this second aspect of the first version of the invention, the at least one tubing member **141** may be connected to the port **127** of the flexible overlay **120** using any suitable means currently known in the art or developed in the art in the future. Examples include variable descending diameter adapters (commonly referred to as "Christmas tree" adapters), luer lock fittings and adapters, clamps, and combinations of such means. Alternatively, the port **127** and the at least one tubing member **141** may be fabricated as a single piece. Similar means may be used to connect the other end of the at least one tubing member **141** to the vacuum pump **131** or other reduced pressure supply source **130** providing the reduced pressure.

In the embodiment illustrated in **FIG. 2A**, the reduced pressure supply means **140** further comprises a fluid collection system, generally designated **142**, that is interconnected between the suction pump **131** and the flexible overlay **120** to remove and collect any exudate that may be aspirated from the wound **160** and collected by the flexible overlay **120**. The flexible overlay **120** functions to actively draw fluid or exudate from the wound **160**. Collection of exudate in a fluid collection system **142** intermediate the pump **131** and the flexible overlay **120** is desirable to prevent clogging of the pump **131**. The fluid collection system **142** is comprised of a fluid-impermeable collection container **143** and a shutoff mechanism **144**, which are described in more detail below in connection with **FIG. 2B**. The container **143** may be of any size and shape capable of intercepting and retaining a predetermined amount of exudate. Many examples of such containers are available in the relevant art. Referring to **FIG. 2B**, which is an enlarged elevational cross-sectional view of the preferred embodiment of the container **143**, the container **143** includes a first port **143a** at the top opening of the container **143** for sealed connection to tubing member **141a**, where the other end of the tubing member **141a** is connected to the flexible overlay **120**. The first port **143a** enables suction to be applied to the flexible overlay **120** through the tubing **141a** and also enables exudate from the portion of the wound **160** covered by the flexible overlay **120** to be drained into the container **143**. The container **143** provides a means for containing and temporarily storing the collected exudate. A second port **143b** is also provided on the top of the container **143** to enable the application of suction from the vacuum pump **131**. The second port **143b** of the collection system **142** is connected to the vacuum pump **131** by tubing member **141b**. The collection system **142** is sealed generally gas-tight to enable the suction

pump **131** to supply suction to the flexible overlay **120** through the collection system **142**.

The embodiment of the collection system **142** illustrated in **FIG. 2B** also includes a shutoff mechanism for halting or inhibiting the supply of the reduced pressure to the flexible overlay **120** in the event that the exudate aspirated from the wound **160** exceeds a predetermined quantity. Interrupting the application of suction to the flexible overlay **120** is desirable to prevent exsanguination in the unlikely event a blood vessel ruptures under the flexible overlay **120** during treatment. If, for example, a blood vessel ruptures in the vicinity of the wound **160**, a shut-off mechanism would be useful to prevent the vacuum system **150** from aspirating any significant quantity of blood from the patient. In the preferred embodiment of the shutoff mechanism **144**, as illustrated in **FIG. 2B**, the shutoff mechanism **144** is a float valve assembly in the form of a ball **144a** which is held and suspended within a cage **144b** positioned below a valve seat **144c** disposed within the opening at the top of the container below the second port **143b** that will float upon the exudate and will be lifted against the valve seat **144c** as the container **143** fills with exudate. When the ball **144a** is firmly seated against the valve seat **144c**, the float valve blocks the second port **143b** and thereby shuts off the source of suction from the vacuum system **150**. In other embodiments of the container **143**, other types of mechanisms may also be employed to detect the liquid level within the container **143** in order to arrest operation of the vacuum system **50**. In addition, in various embodiments of this second version of the invention, the shutoff mechanism **144** may be comprised of any means that enables the vacuum system **150** to halt the supply of reduced pressure to the flexible overlay **120** at any time that the volume of exudate from the wound **160** exceeds a predetermined amount. Such means may include mechanical switches, electrical switches operably connected to the vacuum system controller **132**, optical, thermal or weight sensors operably connected to the vacuum system controller **132**, and any other means that are currently known in the relevant art or that may be developed in the art in the future.

In some embodiments of this second version of the invention, the wound treatment appliance **110** further comprises tissue protection means **175** to protect and strengthen the body tissue **171** that is adjacent to the flexible overlay **120** at the wound site **161**. The tissue protection means **175** protects the tissue **171** by preventing abrasion and maceration of the tissue. Preferably, the tissue protection means **175** is a hydrocolloid material, such as COLOPAST Hydrocolloid 2655, anhydrous lanoline, or any combination of such hydrocolloid materials. More preferably, the tissue protection means **175** is COLOPAST Hydrocolloid

2655. The tissue protection means **175** may be applied to the body tissue **171** to be protected, or it may be applied to the surface of the flexible overlay **120** that is to be in contact with the body tissue **171**, or both, prior to placing the flexible overlay **120** on the surface of the body **170** at the wound site **161**. It is to be noted that application of the tissue protection means **175** to the body tissue **171** that is adjacent to the flexible overlay **120** at the wound site **161** may only entail application of the tissue protection means **175** to the portion of the body tissue **171** adjacent to the flexible overlay **120** that requires such protection.

FIG. 2A also illustrates an example of how the embodiment of the flexible overlay **20** illustrated in **FIG. 1A** (which is flexible overlay **120** in **FIG. 2A**) may be used to provide reduced pressure treatment for a wound **160** on the body **170** of a patient. In this example, the flexible overlay **120** is removed from an aseptic package in which it is stored. The flexible overlay **120** is then placed over and encloses the portion of the wound **160** to be treated, which is the entire wound **160** in this example. The flexible overlay **120** is also connected to the vacuum system **150** by means of the port **127** on the flexible overlay **120** either before, after or during the placement of the flexible overlay **120** over the wound **160**. Where it is deemed necessary by the user of the wound treatment appliance **110**, tissue protection means **175**, as described above, may be placed on a portion of the flexible overlay **120**, on the body tissue **171** to be protected, or both, prior to placing the flexible overlay **120** over the wound **160**. In the example illustrated in **FIG. 2A**, the interior surface portions **129** of the flexible overlay **120** positioned around and adjacent to the perimeter **122** of the opening **121** of the flexible overlay **120** are at (or can be deformed to be at) a relatively acute angle relative to the surrounding surface of the body **170**. Such deformation may be caused by the user of the wound treatment appliance **110** exerting mild pressure on the portions **129** of the flexible overlay **120** positioned around and adjacent to the perimeter **122** of the opening **121** of the flexible overlay **120** so that they are in contact with the surface of the body **170** surrounding the wound **160**. Reduced pressure is then supplied to the flexible overlay **120** by the vacuum system **150**. When reduced pressure is applied to the volume under the flexible overlay **120** in the area of the wound **160**, the flexible overlay **120** is drawn downward by the reduced pressure, collapsing the flexible overlay **120** in the approximate direction of the wound **160**. As the flexible overlay **120** collapses, the portions **129** of the flexible overlay **120** adjacent to the perimeter **122** of the opening **121** of the flexible overlay **120** are drawn tightly against the surface of the body **170** surrounding the wound **160**, thus forming an approximately hermetic seal between the portions **129** of the flexible overlay **120** adjacent to the perimeter **122** of the opening **121**

of the flexible overlay **120** and the portion of the body **170** adjacent to such portions **129**. References to an "approximately hermetic seal" herein refer generally to a seal that may be made gas-tight and liquid-tight for purposes of the reduced pressure treatment of the wound **160**. It is to be noted that this seal need not be entirely gas-tight and liquid-tight. For example, the approximately hermetic seal may allow for a relatively small degree of leakage, so that outside air may enter the volume under the flexible overlay **120** in the area of the wound **160**, as long as the degree of leakage is small enough so that the vacuum system **150** can maintain the desired degree of reduced pressure in the volume under the flexible overlay **120** in the area of the wound **160**. As another example, the approximately hermetic seal formed by the collapsing flexible overlay **120** may not be solely capable of maintaining the reduced pressure in the volume under the impermeable overlay **120** in the area of the wound **160** due to the shape of the body **170** at the site of the wound **160** or for other reasons. In these cases, it may be necessary to provide supplemental sealing means, which are used to provide a seal between the portions of the flexible overlay **120** and the body **170** where the approximately hermetic seal is not adequate to permit reduced pressure to be maintained in the volume under the flexible overlay **120** in the area of the wound **160**. For example, in the illustrated embodiment, the supplemental sealing means **176** may be an adhesive applied to a portion of the impermeable overlay **120** or a portion of the body **170** in a manner similar to the application of the tissue protection means **175** described above. In other embodiments, the supplemental sealing means **176** may be comprised of almost any suitable means to provide an adequate seal. For example, the supplemental sealing means **176** may be comprised of an adhesive, an adhesive tape, a stretch fabric that covers the wound treatment device **115** and is wrapped around a portion of the body **170** of the patient in the area of the wound **160**, lanoline, or any combination of such means. It is also to be noted that in this embodiment at least one fold **129a** forms in the surface of the flexible overlay **120** when it collapses, so that fluids aspirated by the wound **160** flow along the at least one fold **129a** to the port **127**, where the fluid is removed from the flexible overlay **120** by means of the reduced pressure supply means **140** cooperating with the reduced pressure supply source **130**. Thus, in the preferred embodiments, the impermeable overlay **120** is constructed of a material, and has a size, shape and thickness, that permits the flexible overlay **120** to collapse in the direction of the wound **160** and form an approximately hermetic seal with the body **170** when reduced pressure is applied to the volume under the flexible overlay **120** in the area of the wound **160**, while still being rigid enough to support the approximately hermetic seal with the body **170** and to support the at least one fold **129a**. It is also to be noted that the volume under the

impermeable overlay **120** in the area of the wound **160** may be minimal while the impermeable overlay **120** is in its collapsed state over the wound **160**. In the preferred embodiments of this second aspect of the first version of the invention, the reduced pressure maintained in the volume under the flexible overlay **120** in the area of the wound **160** is in the range from approximately 20 mm of Hg below atmospheric pressure to approximately 125 mm of Hg below atmospheric pressure. In yet other embodiments, the reduced pressure is applied to the flexible overlay **120** in a cyclic nature, the cyclic nature providing alternating time periods of application of reduced pressure and non-application of reduced pressure. In all of these embodiments, the reduced pressure is maintained in the volume under the flexible overlay **120** in the area of the wound **160** until the wound **160** has progressed toward a selected stage of healing.

An embodiment of a third aspect of the first version of the invention is the wound treatment appliance **210** illustrated in **FIG. 3**. In this embodiment, the wound treatment appliance **210** is comprised of a wound treatment device **215** and a vacuum system, generally designated **250**, that is operably connected to, and provides a supply of reduced pressure to, the wound treatment device **215**. In addition, in this embodiment, the vacuum system **250** is further comprised of a reduced pressure supply source, generally designated **280**, which is described in more detail below, and reduced pressure supply means, generally designated **240**, which are described in more detail below. Also in this embodiment, the wound treatment device **215** is further comprised of a flexible overlay **220**, wound packing means **278**, and a suction drain **245**. In the embodiment of the third aspect of the first version of the invention illustrated in **FIG. 3**, the flexible overlay **220** has substantially the same structure, features, characteristics and operation as the flexible overlay **20** described above and illustrated in connection with **FIG. 1A**. It is to be noted, however, that in other embodiments of this third aspect of the first version of the invention, the flexible overlay **220** may have substantially the same structure, features, characteristics and operation as any embodiment of all of the flexible overlays **20, 20a, 20b** of the first aspect of the first version of the invention described above and illustrated in connection with **FIG. 1A, FIG. 1B,** and **FIG. 1C**, respectively. In the embodiment illustrated in **FIG. 3**, the flexible overlay **220** is placed over and encloses the entire wound **260** and is illustrated in a state of partial collapse, with the portion **229** of the flexible overlay **220** adjacent to the opening **221** in the perimeter **222** of the flexible overlay **220** forming an approximately hermetic seal with the adjacent portions **271** of the body **270**. It is to be noted that in various embodiments of this third aspect of the first version of the

invention, the wound treatment appliance **210** may also be comprised of tissue protection means **275**, which may be substantially the same as the tissue protection means **175** of the second aspect of the first version of the invention described above and illustrated in connection with **FIG. 2A**.

In the embodiment of the third aspect of the first version of the invention illustrated in **FIG. 3**, the wound treatment device **215** is further comprised of wound packing means **278**, which is placed in the area of the wound **260** under the flexible overlay **220**. In this embodiment, the flexible overlay **220** is placed over the area of the wound **260** to be treated and the wound packing means **278** when the flexible overlay **220** is positioned on the surface of the body **270** at the site of the wound **260**. In some embodiments of this third aspect of the first version of the invention, the wound packing means **278** may be placed within the wound **260** to prevent overgrowth of the tissue in the area of the wound **260**. For example, and preferably in these cases, the wound packing means **278** may comprised of absorbent dressings, antiseptic dressings, nonadherent dressings, water dressings, or combinations of such dressings. More preferably, the wound packing means **278** may be comprised of gauze or cotton or any combination of gauze and cotton. In still other embodiments of this third aspect of the first version of the invention, the wound packing means **278** may be comprised of an absorbable matrix adapted to encourage growth of the tissue in the area of the wound **260** into the matrix. In these embodiments, the absorbable matrix (as wound packing means **278**) is constructed of an absorbable material that is absorbed into the epithelial and subcutaneous tissue in the wound **260** as the wound **260** heals. The matrix (as wound packing means **278**) may vary in thickness and rigidity, and it may be desirable to use a spongy absorbable material for the patient's comfort if the patient must lie upon the wound treatment device **215** during treatment. The matrix (as wound packing means **278**) may also be perforated and constructed in a sponge-type or foam-type structure to enhance gas flow and to reduce the weight of the matrix. Because of the absorbable nature of the absorbable matrix (as wound packing means **278**), the matrix should require less frequent changing than other dressing types during the treatment process. In other circumstances, the matrix (as wound packing means **278**) may not need to be changed at all during the treatment process. In some embodiments of this third aspect of the first version of the invention, the absorbable matrix (as wound packing means **278**) may be comprised of collagens or other absorbable materials or combinations of all such materials. U.S. Patent Application Serial No. 10/652,100, which was filed by the present inventor with the U.S. Patent and Trademark Office on August 28, 2003, also discloses various

embodiments of an absorbable matrix that may be utilized with various embodiments of the third aspect of the first version of the present invention. For example, the wound packing means **278** may be comprised of multiple types of absorbable material that have different rates of absorption into the tissue surrounding the wound. The different types of material may be positioned concentrically, in layers, or in other orientations within the wound packing means **278**. It is to be noted, however, that wound packing means **278** may not be utilized in other embodiments of this third aspect of the first version of the invention.

In the embodiment of the third aspect of the first version of the invention illustrated in **FIG. 3**, the wound treatment device **215** is also comprised of a suction drain **245** and suction drain connection means, which are described in more detail below, to operably connect the reduced pressure supply means **240** to the suction drain **245** so that the suction drain **245** is in fluid communication with the reduced pressure supply means **240** and reduced pressure is supplied to the volume under the flexible overlay **220** in the area of the wound **260** by means of the suction drain **245**. In this embodiment, the suction drain **245** is further comprised of a bottom drain portion **245a** extending into the area of the wound **260** under the impermeable overlay **220** from a top drain portion **245b** positioned within the port **227**. In various embodiments, the top drain portion **245b** may be permanently or removably attached to the interior surface of the opening **228** of the port **227** using any suitable means, such as an adhesive, or by the top drain portion **245b** having a shape adapted so that all or a portion of it fits tightly against all or a portion of the interior surface of the opening **228** in the port **227**. It is to be noted that the top drain portion **245b** must be sufficiently sealed against the surface of the port **227** in a manner so that reduced pressure can be maintained in the volume under the impermeable overlay **220** in the area of the wound **260**. In the embodiment illustrated in **FIG. 3**, the top drain portion **245b** and the bottom drain portion **245a** of the suction drain **245** are comprised of polymer tubing that is flexible enough to allow the tubing to easily bend, but rigid enough to prevent the tubing from collapsing during use. In other embodiments, portions of the top drain portion **245b** and the bottom drain portion **245a** of the suction drain **245** may be comprised of other materials, such as flexible or semi-rigid polymers, plastics, rubber, silicone, or combinations of such materials. In yet other embodiments, the suction drain **245** may have different cross-sectional shapes, such as elliptical, square, rectangular, pentagonal, hexagonal, or other shapes, as long as the suction drain **245** is adapted to provide an approximately hermetic seal with the port **227**, as described in more detail above. In still other embodiments, the bottom drain portion **245a** of the suction drain **245** may be further

comprised of wound suction means that may be used to remove debris, exudate and other matter from the wound **260**. In the embodiment illustrated in **FIG. 3**, the wound suction means is comprised of a distal end portion **245a'** of the tubing comprising the bottom drain portion **245a** having a plurality of perforations **245a"** in the surface of the distal end portion **245a'**. In other embodiments, the distal end portion **245a'** of the bottom drain portion **245a** may have almost any shape or combination of shapes (e.g., circular, elliptical, square, pentagonal, or hexagonal), including a shape different from the remaining portion of the bottom drain portion **245a**, may be of almost any size relative to the remaining bottom drain portion **245a** (e.g., may be longer or shorter than the remaining bottom drain portion **245a** or have a cross-section smaller or larger than the remaining bottom drain portion **245a**, or both), may have more or fewer perforations **245a"**, may have different sizes and shapes of perforations **245a"**, may extend along different portions of the bottom drain portion **245a**, and may be constructed in whole or in part of materials that are not flexible. In embodiments that have a distal end portion **245a'**, the distal end portion **245a'** may be attached to the remaining portion of the bottom drain portion **245a** in almost any manner, as long as the remaining bottom drain portion **245a** is in fluid communication with the wound suction means **245a'**. Examples include an adhesive in some embodiments and a fastening collar in other embodiments. In still other embodiments, the distal end portion **245a'** may be fused or welded to the remaining portion of the bottom drain portion **245a**. In yet other embodiments, the distal end portion **245a'** and the remaining portion of the bottom drain portion **245a** may be fabricated as a single piece.

In some embodiments of this first version of the invention, as illustrated in **FIG. 3**, the top drain portion **245b** may extend beyond the top of the port **227** into the area outside the volume of the flexible overlay **220**. In some of these embodiments, as is also illustrated in **FIG. 3**, the suction drain connection means, which may be used to removably connect the reduced pressure supply means **240** to the top drain portion **245b** of the suction drain **245** is a variable descending diameter adapter **246** (commonly referred to as a "Christmas tree" adapter) that is placed into the interior volume of the top drain portion **245b** at its distal end. In other embodiments, the suction drain connection means may be clamps, fastening collars, or other fasteners or combinations thereof. In yet other embodiments, the top drain portion **245b** may be fused or welded to the reduced pressure supply means **240**. In still other embodiments, the top drain portion **245b** and the portion of the reduced pressure supply means **240** adjacent to the top drain portion **245b** may be fabricated as a single piece. In other embodiments, the

top drain portion **245b** may not extend beyond the top of the port **227** and the reduced pressure supply means **240** may connect directly to the port **227** using any suitable means, such as an adhesive, welding, fusing, clamps, collars or other fasteners, or any combination of such means.

In the embodiment of this third aspect of the first version of the invention illustrated in **FIG. 3**, the distal end portion **245a'** of the suction drain **245** extends into the interior volume of the wound packing means **278**. In this embodiment, the wound packing means **278** and the suction drain **245** may be fabricated by snaking the distal end portion **245a'** of the suction drain **245** through an internal passageway in the wound packing means **278**, such as by pulling the distal end portion **245a'** of the suction drain **245** through the passageway using forceps. Alternatively, the wound packing means **278** and the suction drain **245** may be manufactured as a single piece in sterile conditions and then be stored in an aseptic package until ready for use. In other embodiments, the distal end portion **245a'** of the suction drain **245** may be placed adjacent or close to the wound packing means **278** in the area of the wound **260**. The preferred means of placement of the suction drain **245** relative to the wound packing means **278** is dependent upon the type of wound **260**, the wound packing means **278**, and the type of treatment desired. Referring to **FIG. 3** as an example, it is therefore to be noted that in some embodiments of this third aspect of the first version of the invention, the wound treatment device **215** may utilize a suction drain **245** without utilizing wound packing means **278**, while in other embodiments a suction drain **245** may be utilized with wound packing means **278**. In addition, in other embodiments of this first version of the invention, the wound treatment device **215** may utilize wound packing means **278** without utilizing a suction drain **245**, while in other embodiments wound packing means **278** may be utilized with a suction drain **245**.

In the embodiment of the first version of the invention illustrated in **FIG. 3**, the vacuum system **250**, which in conjunction with the wound treatment device **215** also represents a fourth aspect of this first version of the invention, is generally comprised of a suction bulb **281** having an inlet port **282** and an outlet port **283**, a bulb connection tubing member **284**, an exhaust tubing member **285**, an exhaust control valve **286**, a filter **287**, and a supplemental vacuum system (illustrated schematically and generally designated **250a**). In this embodiment, the suction bulb **281** is a hollow sphere that may be used to produce a supply of reduced pressure for use with the wound treatment device **215**. In addition, the suction bulb **281** may also be used to receive and store fluid aspirated from the wound **260**. The inlet port

282 of the suction bulb **281** is connected to one end of the bulb connection tubing member **284**, which is also the reduced pressure supply means **240** in this embodiment. The connection tubing member **284** is connected by suction drain connection means to the top drain portion **245b** at its other end in a manner so that the interior volume of the suction bulb **281** is in fluid communication with the suction drain **245**. In this embodiment, the bulb connection tubing member **284** is sufficiently flexible to permit movement of the bulb connection tubing member **284**, but is sufficiently rigid to resist constriction when reduced pressure is supplied to the suction drain **245** or when the location of the wound **260** is such that the patient must sit or lie upon the bulb connection tubing member **284** or upon the wound treatment device **215**. The outlet port **283** of the suction bulb **281** is connected to the exhaust tubing member **285**. In this embodiment, the exhaust tubing member **285** is sufficiently flexible to permit movement of the exhaust tubing member **285**, but is sufficiently rigid to resist constriction when reduced pressure is supplied to the suction drain **245**. The inlet port **282** of the suction bulb **281** may be connected to the bulb connection tubing member **284** and the outlet port **283** of the suction bulb **281** may be connected to the exhaust tubing member **285** using any suitable means, such as by welding, fusing, adhesives, clamps, or any combination of such means. In addition, in some embodiments, which are the preferred embodiments, the suction bulb **281**, the bulb connection tubing member **284**, and the exhaust tubing member **285** may be fabricated as a single piece. In the illustrated embodiment, the exhaust control valve **286** and the filter **287** are operably connected to the exhaust tubing member **285**. In this embodiment, the exhaust control valve **286** is used to regulate the flow of fluids (gases and liquids) to and from the suction bulb **281** and the supplemental vacuum system **250a**. In embodiments of the invention that do not have a supplemental vacuum system **250a**, the exhaust control valve **286** regulates flow of fluids to and from the suction bulb **281** and the outside atmosphere. Generally, the exhaust control valve **286** allows fluids to flow out of the suction bulb **281** through the outlet port **283**, but not to flow in the reverse direction unless permitted by the user of the appliance **210**. Any type of flow control valve may be used as the exhaust control valve **286**, as long as the valve is capable of operating in the anticipated environment involving reduced pressure and wound **260** exudate. Such valves are well known in the relevant art, such as sprung and unsprung flapper-type valves and disc-type valves. In this embodiment, the filter **287** is operably attached to the exhaust tubing member **285** between the outlet port **283** of the suction bulb **281** and the exhaust control valve **286**. The filter **287** prevents potentially pathogenic microbes or aerosols from contaminating the exhaust control valve **286** (and supplemental vacuum system **250a**), and then being vented to atmosphere. The filter **287** may be any

suitable type of filter, such as a micropore filter. In other embodiments, the filter **287** may also be a hydrophobic filter that prevents any exudate from the wound **260** from contaminating the exhaust control valve **286** (and the supplemental vacuum system **250a**) and then being vented to atmosphere. In still other embodiments, the filter **287** may perform both functions. It is to be noted, however, that the outlet port **283**, the exhaust control valve **286**, the filter **287**, or any combination of the exhaust control valve **286** and the filter **287**, need not be utilized in connection with the vacuum system **250** in other embodiments of the invention.

In some embodiments of these third and forth aspects of the first version of the invention illustrated in **FIG. 3** that do not utilize a supplemental vacuum system **250a**, the suction bulb **281** may be used to produce a supply of reduced pressure in the following manner. First, the user of the appliance **210** appropriately seals all of the component parts of the appliance **210** in the manner described herein. For example, the impermeable overlay **220** is sealed (or placed adjacent) to the body **170** and the suction drain **245** is sealed to the bulb connection tubing member **284** and the surface of the port **227**. The user then opens the exhaust control valve **286** and applies force to the outside surface of the suction bulb **281**, deforming it in a manner that causes its interior volume to be reduced. When the suction bulb **281** is deformed, the gas in the interior volume is expelled to atmosphere through the outlet port **283**, the exhaust tubing member **285**, the filter **287**, and the exhaust control valve **286**. The user then closes the exhaust control valve **286** and releases the force on the suction bulb **286**. The suction bulb **281** then expands, drawing fluid from the area of the wound **260** under the wound treatment device **215** into the suction bulb **281** through the suction drain **245** and causing the pressure in such area to decrease. To release the reduced pressure, the user of the appliance **210** may open the exhaust control valve **286**, allowing atmospheric air into the interior volume of the suction bulb **281**. The level of reduced pressure may also be regulated by momentarily opening the exhaust control valve **286**.

The suction bulb **281** may be constructed of almost any fluid impermeable flexible or semi-rigid material that is suitable for medical use and that can be readily deformed by application of pressure to the outside surface of the suction bulb **281** by users of the appliance **210** and still return to its original shape upon release of the pressure. For example, the suction bulb **281** may be constructed of rubber, neoprene, silicone, or other flexible or semi-rigid polymers, or any combination of all such materials. In addition, the suction bulb **281** may be of almost any shape, such as cubical, ellipsoidal, or polygonal. The suction bulb **281** may also

be of varying size depending upon the anticipated use of the suction bulb **281**, the size of the wound treatment device **215**, use of a supplemental vacuum system **250a**, the level of reduced pressure desired, and the preference of the user of the appliance **210**. In the embodiment of the invention illustrated in **FIG. 3**, the supplemental vacuum system **250a** is connected to the exhaust tubing member **285** and is used to provide a supplemental supply of reduced pressure to the suction bulb **281** and wound treatment device **215**. In this embodiment, the supplemental vacuum system **250a** may have substantially the same structure, features, characteristics and operation of the various embodiments of the vacuum system **50** of the first version of the invention described above and illustrated in connection with **FIG. 2A** and **FIG. 2B**. It is to be noted, however, that the supplemental vacuum system **250a** need not be used in connection with the vacuum system **280** in other embodiments of the invention.

Except as described below, the wound treatment appliance **210** described above and illustrated in connection with **FIG. 3** may generally be used in a manner similar to the wound treatment appliance **110** described above and illustrated in connection with **FIG. 2A** and **FIG. 2B**. As a result, except as described below, the example of how the embodiment of the wound treatment appliance **110** and the flexible overlay **120** described above and illustrated in connection **FIG. 2A** may be used in treatment of a wound **160** also applies to the embodiment of the appliance **210** of the third aspect of the first version of the invention described above and illustrated in connection with **FIG. 3**. In the case of the embodiment illustrated in **FIG. 3**, however, the wound packing means **278** is placed into the wound **260** prior to placement of the flexible overlay **220** over the portion of the wound **260** to be treated. In addition, the flexible overlay **220** is placed over the wound packing means **278**. In embodiments where the distal end portion **245a'** of a suction drain **245** is placed into the interior volume of, or adjacent to, the wound packing means **278**, the distal end portion **245a'** of the suction drain **245** is also placed in the appropriate position before the flexible overlay **220** is placed over the wound **260**. In embodiments utilizing a suction drain **245** without wound packing means **278**, the suction drain **245** is installed in the flexible overlay **220** before the flexible overlay **220** is placed over the wound **260**.

Another embodiment of the first version of the invention is the wound treatment appliance **310** illustrated in **FIG. 4**. **FIG. 4** also illustrates another example of how the embodiment of the flexible overlay **20** described above and illustrated in connection with **FIG. 1A** may be used to provide reduced pressure treatment for a wound **360** on the body **370** of a

patient. In this embodiment, the wound treatment appliance **310** is comprised of a flexible overlay **320** and a vacuum system, generally designated **350**, that is operably connected to, and provides a supply of reduced pressure to, the flexible overlay **320**. In addition, in this embodiment, the vacuum system **350** is further comprised of a reduced pressure supply source, generally designated **330**, which is described in more detail below, and reduced pressure supply means, generally designated **340**, which are described in more detail below. In this embodiment, the reduced pressure supply means **340** are used to connect the reduced pressure supply source **330** to the flexible overlay **320** in a manner so that reduced pressure is supplied to the area under the flexible overlay **320**, as described in more detail below. In the embodiment of the first version of the invention illustrated in **FIG. 4**, the flexible overlay **320** has substantially the same structure, features and characteristics as the flexible overlay **20** described above and illustrated in connection with **FIG. 1A**. It is to be noted, however, that in other embodiments of this first version of the invention, the flexible overlay **320** may have substantially the same structure, features and characteristics as any embodiment of all of the flexible overlays **20, 20a, 20b** of the first version of the invention described above and illustrated in connection with **FIG. 1A**, **FIG. 1B**, and **FIG. 1C**, respectively. In this example, the flexible overlay **320** is placed over and encloses the entire wound **360**, which is at the distal end of an amputated limb. It is to be noted that in other embodiments, the appliance **310** may also be comprised of tissue protection means **375**, which may be substantially the same as the tissue protection means **175** of the first version of the invention described above and illustrated in connection with **FIG. 2A**. In other embodiments, the appliance **310** may also be comprised of wound packing means (not illustrated), which may be substantially the same as the wound packing means **278** of the first version of the invention described above and illustrated in connection with **FIG. 3**.

In the embodiment of the first version of the invention illustrated in **FIG. 4**, the reduced pressure supply source **330** of the vacuum system **350**, which produces a source of reduced pressure or suction that is supplied to the flexible overlay **320**, includes a small, portable vacuum pump **331**, a filter **333**, and a power source (not illustrated) that is contained within the housing for the portable vacuum pump **331**. In the illustrated embodiment, predetermined amounts of suction or reduced pressure are produced by the portable vacuum pump **331**. The portable vacuum pump **331** is preferably controlled by a control device (not illustrated) that is also located within the housing for the portable vacuum pump **331**, which may provide substantially the same functions as the control device **132** of the first version of

the invention described above and illustrated in connection with **FIG. 2A** and **FIG. 2B**. Except for its smaller size, the portable vacuum pump **331** may operate in substantially the same manner as the vacuum pump **131** of the first version of the invention described above and illustrated in connection with **FIG. 2A** and **FIG. 2B**. In the embodiment illustrated in **FIG. 4**, the filter **333** may have the same structure, features, characteristics and operation, and provide substantially the same functions, as the filter **133** of the first version of the invention described above and illustrated in connection with **FIG. 2A** and **FIG. 2B**. The power source may be any source of energy currently known in the art or that may be developed in the art in the future that may be used to power the portable vacuum pump **331**. For example, in some embodiments, the power source may be a fuel cell or battery. In the illustrated embodiment, the filter **333** is rigidly connected to the portable vacuum pump **331**. It is to be noted that in other embodiments of the first version of the invention, the reduced pressure supply source **330** may not have a filter **333**.

In the embodiment of the first version of the invention illustrated in **FIG. 4**, the reduced pressure supply means **340** of the vacuum system **350**, which is used to connect the reduced pressure supply source **330** to a port **327** on the flexible overlay **320** so that reduced pressure is supplied to the area of the wound **360** under the flexible overlay **320**, is comprised of at least one tubing member **341**. In this embodiment, the at least one tubing member **341** is a rigid tubing member. In other embodiments, the at least one tubing member **341** may be sufficiently flexible to permit movement of the at least one tubing member **341**, but is sufficiently rigid to resist constriction when reduced pressure is supplied to the port **327** or when the location of the wound **360** is such that the patient must sit or lie upon the at least one tubing member **341** or upon the flexible overlay **320**. In the embodiment illustrated in **FIG. 4**, the at least one tubing member **341** is connected to the port **327** by inserting one end of the at least one tubing member **341** into an opening **328** in the port **484** and sealing (such as with an adhesive) the at least one tubing member **341** to the port **327**. It is to be noted that in other embodiments, the at least one tubing member **341** may be connected to the port **327** using any suitable means currently known in the relevant art or developed in the relevant art in the future. Examples include the suction drain connection means of the first version of the invention discussed above and illustrated in connection with **FIG. 3**. Similar means may be used to connect the other end of the at least one tubing member **341** to the reduced pressure supply source **330** providing the reduced pressure. In other embodiments of this first version of the invention, the reduced pressure supply means **340** may further comprise a fluid

collection system (not illustrated), which may generally have the same structure, features, characteristics and operation, and perform the same functions, as the fluid collection system **142** of the first version of the invention described above and illustrated in connection with **FIG. 2A** and **FIG. 2B**.

An embodiment of a second version of the invention is the wound treatment appliance **410** illustrated in **FIG. 5**. In this embodiment, the appliance **410** is comprised of a wound treatment device **415**, which is further comprised of a flexible overlay **420**, a collection chamber **490** to receive and hold fluid aspirated from the wound **460**, collection chamber attachment means to operably attach the collection chamber **490** to the flexible overlay **420**, as described in more detail below, and reduced pressure supply means, generally designated **440**, which are described in more detail below. In this embodiment, the flexible overlay **420** is adapted to be placed over and enclose all or a portion of the wound **460** in the same manner as the flexible overlay **20** described in detail above and illustrated in connection with **FIG. 1A**. It is to be noted, however, that the flexible overlay **420** illustrated in **FIG. 5** is shown in position on the body **470** over the wound **460**, but not in its collapsed state. In the illustrated embodiment, and except as described in more detail below, the flexible overlay **420** has substantially the same structure, features and characteristics as the flexible overlay **20** described in detail above and illustrated in connection with **FIG. 1A**. In the various embodiments of this second version of the invention, except as described in more detail below, the flexible overlay **420** may have substantially the same structure, features, characteristics and operation as the embodiments of the flexible overlays **20, 20a, 20b, 120, 220** described in more detail above and illustrated in connection with **FIG. 1A**, **FIG. 1B**, **FIG. 1C**, **FIG. 2A**, and **FIG. 3**, respectively. In the illustrated embodiment, reduced pressure supply means, generally designated **440**, which are described in more detail below, are used to operably connect the collection chamber **490** to a reduced pressure supply source, generally designated **430**, which is described in more detail below, that provides a supply of reduced pressure to the collection chamber **490**, so that the volume within the collection chamber **490** and under the flexible overlay **420** in the area of the wound **460** to be treated are supplied with reduced pressure by the reduced pressure supply source **430**. Together, the reduced pressure supply means **440** and the reduced pressure supply source **430** comprise a vacuum system, generally designated **450**. In the various embodiments of this second version of the invention, except as described in more detail below, the reduced pressure supply means **440** used to connect the reduced pressure supply source **430** to the collection chamber **490** may have substantially the

same structure, features, characteristics and operation as the reduced pressure supply means **140, 240, 340** described above and illustrated in connection with **FIG. 2A**, **FIG. 2B**, **FIG. 3**, and **FIG. 4**, respectively. In addition, in the various embodiments of this second version of the invention, except as described in more detail below, the reduced pressure supply source **430** used to provide the supply of reduced pressure to the collection chamber **490** may have substantially the same structure, features, characteristics and operation as the reduced pressure supply source **130, 280, 330** described above and illustrated in connection with **FIG. 2A**, **FIG. 2B**, **FIG. 3**, and **FIG. 4**, respectively.

In the embodiment of the appliance **410** illustrated in **FIG. 5**, the collection chamber **490** is approximately cylindrical in shape. In other embodiments, the collection chamber **490** may have other shapes. For example, the collection chamber may be shaped approximately as a sphere, ellipsoid, cube, polyhedron, or other shape or combination of such shapes, as long as the collection chamber **490** has an interior volume to receive and hold fluid aspirated from the wound **460**. The collection chamber **490** may also be of almost any size. For example, the collection chamber **490** may be relatively small where the wound **460** is expected to aspirate only a small volume of fluid. On the other hand, the collection chamber **490** may be relatively large where it is expected that the wound **460** will aspirate a large volume of fluid. As a result, the preferred size of the collection chamber **490** is dependent upon the size of the wound **460** to be treated, the size of the flexible overlay **420**, the type of wound **460** to be treated, and the preference of the user of the appliance **410**. In the various embodiments of this second version of the invention, the collection chamber **490** may be comprised of almost any medical grade material that is currently known in the art or that may be developed in the art in the future, as long as such material is fluid-impermeable and suitable for purposes of wound treatment (e.g., can be sterilized and does not absorb significant amounts of wound **460** exudate). For example, the collection chamber **490** may be comprised of rubber (including neoprene) and polymer materials, such as silicone, silicone blends, silicon substitutes, polyvinyl chloride, polycarbonates, polyester-polycarbonate blends, or a similar polymer, or combinations of all such materials. It is to be noted that the collection chamber **490** may have a rigid or semi-rigid structure in some embodiments. In other embodiments, the collection chamber **490** may be more flexible so that it can be squeezed in a manner similar to the suction bulb **281**, as described above and illustrated in connection with **FIG. 3**. Although the collection chamber **490** may be constructed of a material different from the material comprising the flexible overlay **420** in various embodiments of the invention, the collection chamber **490** is preferably

constructed from the same material comprising the flexible overlay **420**. The collection chamber **490** may be constructed using any suitable means currently known in the art or that may be developed in the art in the future. For example, a collection chamber **490** constructed of silicone may be manufactured by means of injection molding.

In the various embodiments of this second version of the invention, the collection chamber attachment means operably attaches the collection chamber **490** to the flexible overlay **420** in a manner so that exudate and reduced pressure are permitted to flow between the collection chamber **490** and the volume under the flexible overlay **420** in the area of the wound **460**. Also, in the various embodiments of the second version of the invention, as illustrated by the appliance **410** in **FIG. 5**, the collection chamber **490** is positioned approximately adjacent to the flexible overlay **420** on the side of the flexible overlay **420** opposite the wound **460**. Although the collection chamber **490** and the collection chamber attachment means are positioned approximately at the apex of the flexible overlay **420** in the illustrated embodiment, in other embodiments the collection chamber **490** and collection chamber attachment means may be positioned at almost any location on the surface of the flexible overlay **420** opposite the wound **460**, as long as the collection chamber **490** and collection chamber attachment means do not materially interfere with the operation of the flexible overlay **420**. As illustrated in **FIG. 5**, the collection chamber attachment means may be a rigid or semi-rigid connecting member **491** between the collection chamber **490** and the flexible overlay **420**. In this embodiment, the connecting member **491** is approximately cylindrical in shape and has a port **492** therein, which is also approximately cylindrical in shape and extends between the collection chamber **490** and the flexible overlay **420** so that fluids can flow between the collection chamber **490** and the flexible overlay **420**. In other embodiments, the connecting member **491** and the port **492** may be of almost any shape or combination of shapes. For example, the connecting member **491** and the port **492** may be shaped approximately as a sphere, ellipsoid, cube, polygon, paraboloid, or any other shape or combination of shapes, as long as the connecting member **491** provides a rigid or semi-rigid connection between the collection chamber **490** and the flexible overlay **420** that is adequate to support the collection chamber **490** when it is filled with exudate from the wound **460**, and the port **492** is of a size and shape adequate to allow the flow of exudate from the wound **460** between the collection chamber **490** and the flexible overlay **420**. For example, the collection chamber **490** in some embodiments may have approximately the same outside diameter as the connecting member **491**, as illustrated by the phantom lines **493** in **FIG. 5**. The connecting

member **491** may generally be constructed of any material that is suitable for construction of the collection chamber **490** or the flexible overlay **420**, and is preferably constructed from the same materials as the collection chamber **490** and the flexible overlay **420**. In various embodiments, the collection chamber **490** and the flexible overlay **420** may be connected to the connecting member **491** using any suitable means, such as by adhesives, welding, fusing, clamps, and other fastening means or combinations of such means. In yet other embodiments, the collection chamber **490**, the flexible overlay **420**, and the connecting member **491** may be fabricated as a single piece. In still other embodiments, one or more of the connections between the collection chamber **490**, the flexible overlay **420**, and the connecting member **491** may provide for removing one component from another to empty fluid from the collection chamber **490**. For example, the collection chamber **490**, the flexible overlay **420**, and the connecting member **491** may each be threaded at their points of connection so that they can be screwed together and then unscrewed when desired. In still other embodiments, the collection chamber **490** and the flexible overlay **420** may be directly connected together without a connecting member **491**, as long as the connection allows fluid to flow between the collection chamber **490** and the flexible overlay **420**. Such connection may be made using any of the means described above in this paragraph.

In some embodiments of this second version of the invention, as illustrated in **FIG. 5**, the connecting member **491**, as the collection chamber attachment means, may be further comprised of a flow control means, which is described in more detail below, operably positioned between the collection chamber **490** and the flexible overlay **420**. In these embodiments, the flow control means permits fluid aspirated from the wound **460** to flow from the volume under the flexible overlay **420** in the area of the wound **460** through the port **492** into the collection chamber **490**, but not in the opposite direction. In the illustrated embodiment, the flow control means is comprised of a flapper-type valve **494**. In this embodiment, the valve **494** has two flapper members **494a** that are hinged at their distal end to a portion of the connecting member **491**, and the flapper members **494a** are of a shape and size adapted to substantially close the port **492** when they are positioned in the closed position. In other embodiments, the flow control means may be comprised of a disc-type valve, wherein the disc of the valve moves with the flow of fluids and contacts a seat disposed around the perimeter of the port when the flow of fluids is misdirected, so that the port is sealed closed and prevents fluid flow in the wrong direction. In some embodiments, as illustrated in **FIG. 5**, the collection chamber **490** may be further comprised of a shroud **495** (illustrated by the

phantom lines) that extends from a portion of the collection chamber **490** to the flexible overlay **420**. In these embodiments, the shroud **495** is approximately tubular in shape. In other embodiments, the shroud **495** may have other shapes. The shroud **495** generally provides additional support for the collection chamber **490** and may also provide for a more aesthetically pleasing appearance for the appliance **410**. In addition, in the embodiment of the appliance **410** illustrated in **FIG. 5**, the reduced pressure supply means **440** is connected to the collection chamber **490** by means of a stopper **445** adapted to fit into an opening **496** in the collection chamber **490**. The stopper **445** forms a seal with the portion of the collection chamber **490** adjacent to the opening **496** so that reduced pressure can be maintained within the interior volume of the collection chamber **490**. In this embodiment, the reduced pressure supply means is comprised of a tubular member **441** that is positioned in a port **446** in the stopper **445** at one end and is connected to the reduced pressure supply source **430** at the other end.

The embodiment of the appliance **410** illustrated in **FIG. 5** may be used to treat a wound **460** on a body **470** using a method comprising the following steps. First, the wound treatment device **415** is positioned on the body **470** over the area of the wound **460** to be treated. Next, the vacuum system **450** is operably connected to the collection chamber **490**. The flexible overlay **420** may then be collapsed in the approximate direction of the wound **460** when reduced pressure is supplied to the volume under the flexible overlay **420** in the area of the wound **460** so that an approximately hermetic seal (as illustrated and described in more detail above in connection with **FIG. 2A**) is formed between the flexible overlay **420** and the body **470** in the area of the wound **460**. Next, reduced pressure is maintained in the volume of the flexible overlay **420** in the area of the wound **460** until the area of the wound **460** being treated has progressed toward a selected stage of healing. In other embodiments, the method may further comprise the step of placing tissue protection means **475**, which may be substantially the same as the tissue protection means **175**, as described above and illustrated in connection with **FIG. 2A**, on the tissue **471** of the body **470** that is to be approximately adjacent to the flexible overlay **420**, such step being performed prior to positioning the flexible overlay **420** over the area of the wound **460** to be treated. In yet other embodiments, the method further comprises the step of placing wound packing means (not illustrated), which may be substantially the same as the wound packing means **278**, as described above and illustrated in connection with **FIG. 3**, between the wound **460** and the flexible overlay **420** in the area of the wound **460** to be treated, such step being performed prior to positioning the

flexible overlay **420** over the area of the wound **460** to be treated. In still other embodiments, the reduced pressure under the flexible overlay **420** in the area of the wound **460** is in the range from approximately 20 mm of Hg below atmospheric pressure to approximately 125 mm of Hg below atmospheric pressure. In other embodiments, the reduced pressure is applied in a cyclic nature, the cyclic nature providing alternating time periods of application of reduced pressure and without application of reduced pressure. In yet other embodiments, the method is further comprised of the step of emptying any fluid collected in the collection chamber **490**. This step may be performed after the flexible overlay **420** is collapsed in the approximate direction of the wound **460** and may also be performed before or after the area of the wound **460** being treated has progressed toward a selected stage of healing.

Another embodiment of the second version of the invention is the wound treatment appliance **510** illustrated in **FIG. 6**. In this embodiment, the appliance **510** is comprised of a flexible overlay **520**, a collection chamber **590** to receive and hold fluid aspirated from a wound (not shown), collection chamber attachment means to operably attach the collection chamber **590** to the flexible overlay **520**, as described in more detail below, and reduced pressure supply means, generally designated **540**, which are described in more detail below. In this embodiment, the flexible overlay **520** is adapted to be placed over and enclose all or a portion of a wound in the same manner as the flexible overlay **20a** described in detail above and illustrated in connection with **FIG. 1B**. It is to be noted that the flexible overlay **520** illustrated in **FIG. 6** is not shown in its collapsed state. In the illustrated embodiment, and except as described in more detail below, the flexible overlay **520** has substantially the same structure, features and characteristics as the flexible overlay **20a** described in detail above and illustrated in connection with **FIG. 1B**. In other embodiments, the flexible overlay **520** may be of other shapes and have other features. For example, the flexible overlay **520** may be of the shape and have the features illustrated and described above in connection with the appliance **10b** of **FIG. 1C**. In the embodiment illustrated in **FIG. 6**, the reduced pressure supply means **540**, which are described in more detail below, may be used to operably connect the collection chamber **590** to a reduced pressure supply source (not shown), which is described in more detail below, that provides a supply of reduced pressure to the collection chamber **590**, so that the volume within the collection chamber **590** and under the flexible overlay **520** in the area of the wound to be treated are supplied with reduced pressure by the reduced pressure supply source. Together, the reduced pressure supply means **540** and the reduced pressure supply source comprise a vacuum system, generally designated **550**. In this

embodiment of the second version of the invention, except as described in more detail below, the reduced pressure supply means **540** used to connect the reduced pressure supply source to the collection chamber **590** may have substantially the same structure, features, characteristics and operation as the reduced pressure supply means **140, 240, 340** described above and illustrated in connection with **FIG. 2A**, **FIG. 2B**, **FIG. 3**, and **FIG. 4**, respectively. In addition, in this embodiment of the second version of the invention, except as described in more detail below, the reduced pressure supply source used to provide the supply of reduced pressure to the collection chamber **590** may have substantially the same structure, features, characteristics and operation as the reduced pressure supply source **130, 280, 330** described above and illustrated in connection with **FIG. 2A**, **FIG. 2B**, **FIG. 3**, and **FIG. 4**, respectively. The embodiment of the appliance **510** illustrated in **FIG. 6** may be used to treat a wound on a body using substantially the same method described above in connection with the appliance **410** illustrated in **FIG. 5**.

In the embodiment illustrated in **FIG. 6**, the collection chamber **590** is positioned approximately adjacent to the flexible overlay **520** on the side of the flexible overlay **520** opposite the wound. In this embodiment, the collection chamber attachment means, as described in more detail below, is comprised of a membrane **591**. In this embodiment, the membrane **591** acts as a barrier separating the collection chamber **590** and the flexible overlay **520**, so that the membrane **591** acts as a portion of the surface of the collection chamber **590** and a portion of the surface of the flexible overlay **520**. In addition, the membrane **591** has at least one port **592** therein so that the volume within the collection chamber **590** is in fluid communication with the volume under the flexible overlay **520** in the area of the wound. It is to be noted that there may be more than one port **592** in other embodiments. The number of ports **492** is generally dependent upon the size and shape of the collection chamber **590**, the size and shape of the flexible overlay **520**, the anticipated amount of exudate to be aspirated from the wound, the level of reduced pressure to be utilized, and the individual preference of the user of the appliance **510**. In embodiments where the flexible overlay **520** has an approximately elongated conical shape, as illustrated in **FIG. 6**, the flexible overlay **520** may have a base end opening **521** and a top end opening **524** opposite the base end opening **521**. In these embodiments, the base end opening **521** may have an either approximately circular shape or approximately elliptical shape sized to be placed over and enclose the area of the wound to be treated. The top end opening **524** may have either an approximately circular shape or approximately elliptical shape. In the illustrated embodiments, the membrane **591** is adapted

to be of the same shape and size as the top end opening **524** and the membrane **591** is positioned so that it is attached to the entire perimeter of the top end opening **524** and covers the entire top end opening **524**. The membrane **591** may be attached to the perimeter of the top end opening **524** by any suitable means currently known in the relevant art or developed in the art in the future. Examples of such means include welding or fusing the membrane **591** to the perimeter of the top end opening **524**. Alternatively, the membrane **591** may be fabricated as a single piece with the flexible overlay **520**.

In the embodiment of the appliance **510** illustrated in **FIG. 6**, the collection chamber **590** has an approximately elongated conical shape, a chamber bottom end opening **593**, and a reduced pressure supply port **596** positioned at the apex of the collection chamber **590** opposite the chamber bottom end opening **593**. The reduced pressure supply port **596** may be used to operably connect the reduced pressure supply means **540** to the collection chamber **590**. In some embodiments, a micropore or hydrophobic filter or both (not shown) may be operably positioned within the reduced pressure supply port **596** or the connection with the reduced pressure supply means **540** to retain the exudate from the wound within the collection container **590** or to prevent exudate from contaminating portions of the vacuum system **550**, or both. In the illustrated embodiment, the chamber bottom end opening **593** is adapted to be of approximately the same size and shape as the top end opening **524** of the flexible overlay **520**. In other embodiments, the collection chamber **590** may be of other shapes and sizes and its bottom end opening **593** may not necessarily be of the same size and shape as the top end opening **524** of the flexible overlay **520**. In all embodiments, however, the collection chamber **590** is attached to the membrane **591** in a manner so that the membrane **591** acts as a portion of the surface of the collection chamber **590** and so that the volume within the collection chamber **590** is airtight, except for the at least one port **592** and the reduced pressure supply port **596**. In the preferred embodiment, the collection chamber **590** and the flexible overlay **520** have the shapes illustrated in **FIG. 6**. The membrane **591** may be attached to the perimeter of the chamber bottom end opening **593** by any suitable means currently known in the relevant art or developed in the art in the future. Examples of such means include welding or fusing the membrane **591** to the perimeter of the chamber bottom end opening **593**. Alternatively, the membrane **591** or the flexible overlay **520**, or both, may be fabricated as a single piece with the collection chamber **590**. The preferred shapes and sizes of the collection chamber **590** and the flexible overlay **520** are dependent upon the size and type of wound to be treated, the area of the body on which the wound is positioned, the level of reduced pressure to be utilized, the

amount of collapse of the flexible overlay **520** desired, and the preference of the user of the appliance **510**. In this embodiment of the second version of the invention, the collection chamber **590** may be comprised of almost any medical grade material that is currently known in the art or that may be developed in the art in the future, as long as such material is fluid-impermeable and suitable for purposes of wound treatment (e.g., can be sterilized and does not absorb significant amounts of wound exudate). For example, the collection chamber **590** may be comprised of rubber (including neoprene) and flexible polymer materials, such as silicone, silicone blends, silicone substitutes, polyvinyl chloride, polycarbonates, polyester-polycarbonate blends, or a similar polymer, or combinations of all such materials. It is to be noted that the collection chamber **590** may have a rigid or semi-rigid structure in some embodiments. In other embodiments, the collection chamber **590** may be more flexible so that it can be squeezed in a manner similar to the suction bulb **281**, as described above and illustrated in connection with **FIG. 3**. Although the collection chamber **590** may be constructed of a material different from the material comprising the flexible overlay **520** in various embodiments of the invention, the collection chamber **590** is preferably constructed from the same material comprising the flexible overlay **520**. The collection chamber **590** may be constructed using any suitable means currently known in the art or that may be developed in the art in the future. For example, a collection chamber **590** constructed of silicone may be manufactured by means of injection molding.

In the embodiment of the second version of the invention illustrated in **FIG. 6**, the membrane **591** and its means of being sealed to the perimeters of the top end opening **524** and the chamber bottom end opening **593**, together as collection chamber attachment means, operably attach the collection chamber **590** to the flexible overlay **520** in a manner so that exudate and reduced pressure are permitted to flow between the collection chamber **590** and the volume under the flexible overlay **520** in the area of the wound. In the embodiment illustrated in **FIG. 6**, the at least one port **592** is approximately cylindrical in shape and extends between the collection chamber **590** and the flexible overlay **520** so that fluids can flow between the collection chamber **590** and the flexible overlay **520**. In other embodiments, the at least one port **592** may be of almost any shape or combination of shapes. In some embodiments of this second version of the invention, as illustrated in **FIG. 6**, the membrane **591** comprising the collection chamber attachment means may be further comprised of a flow control means, which is described in more detail below, operably connected with the at least one port **592** and positioned between the collection chamber **590** and the flexible overlay **520**.

In these embodiments, the flow control means permits fluid aspirated from the wound to flow from the volume under the flexible overlay **520** in the area of the wound **560** through the at least one port **592** into the collection chamber **590**, but not in the opposite direction. In the illustrated embodiment, the flow control means is comprised of a flapper-type valve **594**. In this embodiment, the valve **594** has two flapper members **594a** that are hinged at their distal end to a portion of the membrane **491** or supporting structure surrounding the at least one port **492** and the flapper members **594a** are of a shape and size adapted to substantially close the at least one port **592** when they are positioned in the closed position. In other embodiments, the flow control means may be comprised of a disc-type of valve.

The reader's attention is directed to all papers and documents which are filed concurrently with this description and which are open to public inspection with this description, and the contents of all such papers and documents are incorporated herein by reference. All of the features disclosed in this description (including the accompanying claims, abstract, and drawings) may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features. In this respect, it is to be understood that the invention is not limited in its application to the details of construction and to the arrangements of the components set forth in this description (including the claims and abstract) or illustrated in the accompanying drawings. This invention may be embodied in the form illustrated in the accompanying drawings, but the drawings are illustrative only and changes may be made in the specific construction illustrated and described within the scope of the appended claims. The invention is capable of other embodiments and of being practiced and carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of the description and should not be regarded as limiting.

INDUSTRIAL APPLICABILITY

The reader is directed to the other sections of this description for matters related to industrial applicability of the present invention.

CLAIMS

What is claimed is:

1. An appliance for administering reduced pressure treatment to a wound on a body, the appliance comprising:
   (a) a gas-impermeable flexible overlay sized to be placed over and enclose the area of the wound to be treated and adapted to maintain reduced pressure in the volume under the gas-impermeable flexible overlay in the area of the wound; and
   (b) reduced pressure supply means to operably connect the gas-impermeable flexible overlay to a reduced pressure supply source that provides a supply of reduced pressure to the gas-impermeable flexible overlay, so that the volume under the gas-impermeable flexible overlay in the area of the wound to be treated is supplied with reduced pressure by the reduced pressure supply source;
   (c) wherein the gas-impermeable flexible overlay collapses in the approximate direction of the area of the wound to be treated when reduced pressure is supplied to the volume under the gas-impermeable flexible overlay in the area of the wound, such collapse causing the formation of an approximately hermetic seal between the gas-impermeable flexible overlay and the body in the area of the wound.

2. The appliance of claim 1, wherein the gas-impermeable flexible overlay is further comprised of an interior surface facing the area of the wound to be treated and the surface area of the interior surface is greater than the surface area of the portion of the body to be enclosed by the gas-impermeable flexible overlay.

3. The appliance of claim 2, wherein the gas-impermeable flexible overlay has an approximately elongated conical shape with an approximately elliptically-shaped open end at the base of the elongated conical shape, wherein the approximately elliptically-shaped open end at the base is sized to be placed over and enclose the area of the wound to be treated.

4. The appliance of claim 2, wherein:
   (a) the gas-impermeable flexible overlay is comprised of at least three cover portions, each of such cover portions being approximately triangular in shape; and
   (b) one point of each of the at least three triangular-shaped cover portions are joined to

form an apex of the gas-impermeable flexible overlay and one side of each at least three triangular-shaped cover portions adjacent to the apex is joined to an adjacent side of another of such at least three triangular-shaped cover portions so that the bases of the at least three triangular-shaped cover portions form an opening sized to be placed over and enclose the area of the wound to be treated.

5. The appliance of claim 1, further comprising supplemental sealing means to form a seal between the gas-impermeable flexible overlay and the body in the area of the wound.

6. The appliance of claim 1, further comprising tissue protection means operably positioned between the body and the portion of the gas-impermeable flexible overlay adjacent to the body at the wound site, the tissue protection means being to protect and strengthen the tissue of the body adjacent to the gas-impermeable flexible overlay at the wound site.

7. An appliance for administering reduced pressure treatment to a wound on a body, the appliance comprising:

(a) a gas-impermeable flexible overlay sized to be placed over and enclose the area of the wound to be treated and adapted to maintain reduced pressure in the volume under the gas-impermeable flexible overlay in the area of the wound;

(b) a collection chamber to receive and hold fluid aspirated from the wound;

(c) collection chamber attachment means to operably attach the collection chamber to the gas-impermeable flexible overlay, wherein reduced pressure and the fluid are permitted to flow between the collection chamber and the gas-impermeable flexible overlay; and

(d) reduced pressure supply means to operably connect the collection chamber to a reduced pressure supply source that provides a supply of reduced pressure to the collection chamber, so that the volume within the collection chamber and under the gas-impermeable overlay in the area of the wound to be treated are supplied with reduced pressure by the reduced pressure supply source;

(e) wherein the gas-impermeable flexible overlay collapses in the approximate direction of the area of the wound to be treated when reduced pressure is supplied to the volume under the gas-impermeable flexible overlay in the area of the wound, such collapse causing the formation of an approximately hermetic seal between the gas-impermeable flexible overlay and the body in the area of the wound.

8. The appliance of claim 7, wherein

(a) the gas-impermeable flexible overlay has an approximately conical or elongated conical shape with an approximately circularly or elliptically-shaped open end at the base of the conical or elongated conical shape wherein the approximately circularly or elliptically-shaped open end at the base is sized to be placed over and enclose the area of the wound to be treated; and

(b) the collection chamber and the collection chamber attachment means are positioned approximately at the apex of the conical or elongated conically shaped gas-impermeable flexible overlay on the side of the gas-impermeable flexible overlay opposite the wound.

9. The appliance of claim 7, wherein:

(a) the collection chamber is positioned approximately adjacent to the gas-impermeable flexible overlay on the side of the gas-impermeable flexible overlay opposite the wound; and

(b) the collection chamber attachment means is comprised of a membrane, wherein:

(i) the membrane acts as a barrier separating the collection chamber and the gas-impermeable flexible overlay, so that the membrane acts as a portion of the surface of the collection chamber and a portion of the surface of the gas-impermeable flexible overlay; and

(ii) the membrane has at least one port therein so that the volume within the collection chamber is in fluid communication with the volume under the gas-impermeable flexible overlay in the area of the wound.

10. The appliance of claim 8 or claim 9, wherein the collection chamber attachment means is further comprised of flow control means operably positioned between the collection chamber and the gas-impermeable flexible overlay, wherein the flow control means permits the fluid to flow from the volume under the gas-impermeable flexible overlay in the area of the wound to the collection chamber, but not in the opposite direction.

11. The appliance of claim 8 or claim 9, wherein the collection chamber further comprises:

(a) a reduced pressure supply port, wherein the reduced pressure supply means is connected to the collection chamber by means of the reduced pressure supply port; and

(b) a micropore filter, a hydrophobic filter, or both, operably disposed within the reduced

pressure supply port.

12. An appliance for administering reduced pressure treatment to a wound on a body, the appliance comprising:

(a) a wound treatment device, wherein the wound treatment device is further comprised of:

(i) a gas-impermeable flexible overlay sized to be placed over and enclose the area of the wound to be treated and adapted to maintain reduced pressure in the area of the wound to be treated;

(ii) wherein the gas-impermeable flexible overlay collapses in the approximate direction of the area of the wound to be treated when reduced pressure is supplied to the volume under the gas-impermeable flexible overlay in the area of the wound, such collapse causing the formation of an approximately hermetic seal between the gas-impermeable flexible overlay and the body in the area of the wound; and

(b) a vacuum system, wherein the vacuum system is comprised of:

(i) a reduced pressure supply source that provides a supply of reduced pressure; and

(ii) reduced pressure supply means to operably connect the gas-impermeable flexible overlay to the reduced pressure supply source, so that the volume under the gas-impermeable flexible overlay in the area of the wound is supplied with reduced pressure by the reduced pressure supply source.

13. The appliance of claim 12, wherein the reduced pressure supply source is comprised of a vacuum pump.

14. The appliance of claim 13, wherein the vacuum pump is comprised of a portable vacuum pump.

15. The appliance of claim 13 or claim 14, wherein the reduced pressure supply source further comprises a control system, wherein the control system controls the operation of the vacuum pump.

16. The appliance of claim 13 or claim 14, wherein:

(a) the reduced pressure supply source further comprises a filter operably positioned between the vacuum pump and the reduced pressure supply means; and

(b) the filter prevents the venting of and contamination of the vacuum pump by micro-

organisms aspirated from the wound or fluids aspirated from the wound or both.

17. The appliance of claim 12, wherein the reduced pressure supply means is comprised of a collection system that is operably positioned between the gas-impermeable flexible overlay and the reduced pressure supply source and the collection system comprises a container to receive and hold fluid aspirated from the wound.

18. The appliance of claim 12, wherein the reduced pressure supply source is comprised of a suction bulb.

19. The appliance of claim 18, wherein:

(a) the suction bulb is further comprised of an inlet port and an outlet port, wherein the inlet port is operably connected to the reduced pressure supply means;

(b) the vacuum system further comprises an exhaust tubing member operably connected to the outlet port; and

(c) the vacuum system further comprises an exhaust control valve operably connected to the exhaust tubing member.

20. The appliance of claim 19, wherein the vacuum system is further comprised of a filter operably connected to the exhaust tubing member, wherein the filter prevents the venting of micro-organisms aspirated from the wound or fluids aspirated from the wound, or both.

21. The appliance of claim 12, further comprising wound packing means, wherein the wound packing means is positioned between the wound treatment device and the portion of the wound to be treated.

22. The appliance of claim 12, further comprising:

(a) a suction drain extending from the reduced pressure supply means into the volume under the gas-impermeable flexible overlay in the area of the wound; and

(b) suction drain connecting means to operably connect the reduced pressure supply means to the suction drain so that the suction drain is in fluid communication with the reduced pressure supply means and reduced pressure is supplied to the volume under the gas-impermeable flexible overlay in the area of the wound by means of the suction drain.

23. A method of treating a wound on a body, such method comprising the steps of:

(a) positioning a gas-impermeable flexible overlay on the body over the area of the wound to be treated, wherein the gas-impermeable flexible overlay is sized to be placed over and enclose the area of the wound to be treated and adapted to maintain reduced pressure in the area of the wound to be treated;

(b) operably connecting the gas-impermeable flexible overlay with a vacuum system for producing reduced pressure in the volume under the gas-impermeable flexible overlay in the area of the wound to be treated;

(c) collapsing the gas-impermeable flexible overlay in the approximate direction of the wound when reduced pressure is supplied to the volume under the gas-impermeable flexible overlay in the area of the wound so that an approximately hermetic seal is formed between the gas-impermeable flexible overlay and the body in the area of the wound; and

(d) maintaining the reduced pressure until the area of the wound being treated has progressed toward a selected stage of healing.

24. The method of claim 23, wherein the reduced pressure under the gas-impermeable overlay in the area of the wound is in the range from approximately 20 mm of Hg below atmospheric pressure to approximately 125 mm of Hg below atmospheric pressure.

25. The method of claim 23, wherein the reduced pressure is applied in a cyclic nature, the cyclic nature providing alternating time periods of application of reduced pressure and without application of reduced pressure.

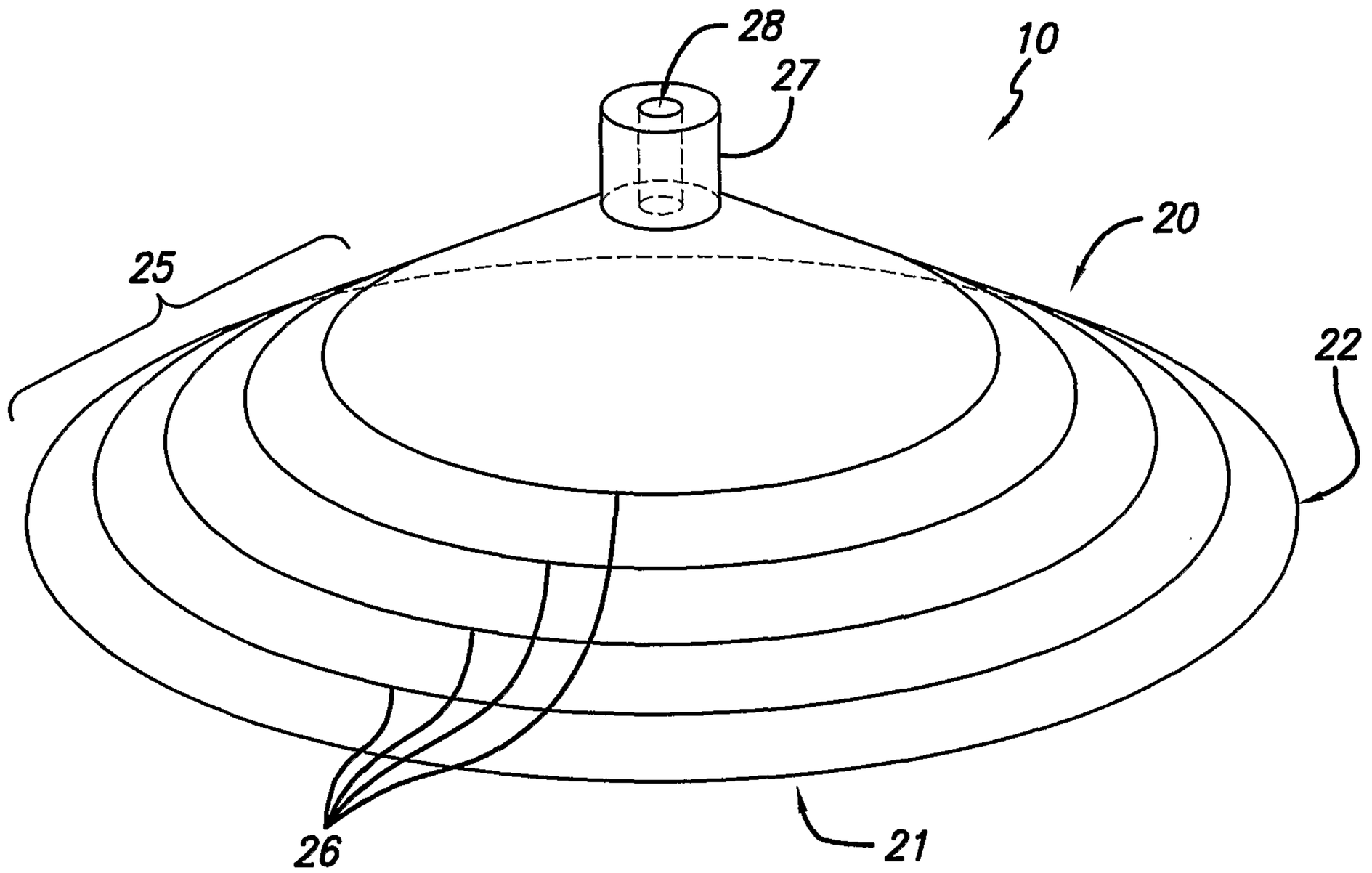
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FIG. 1A

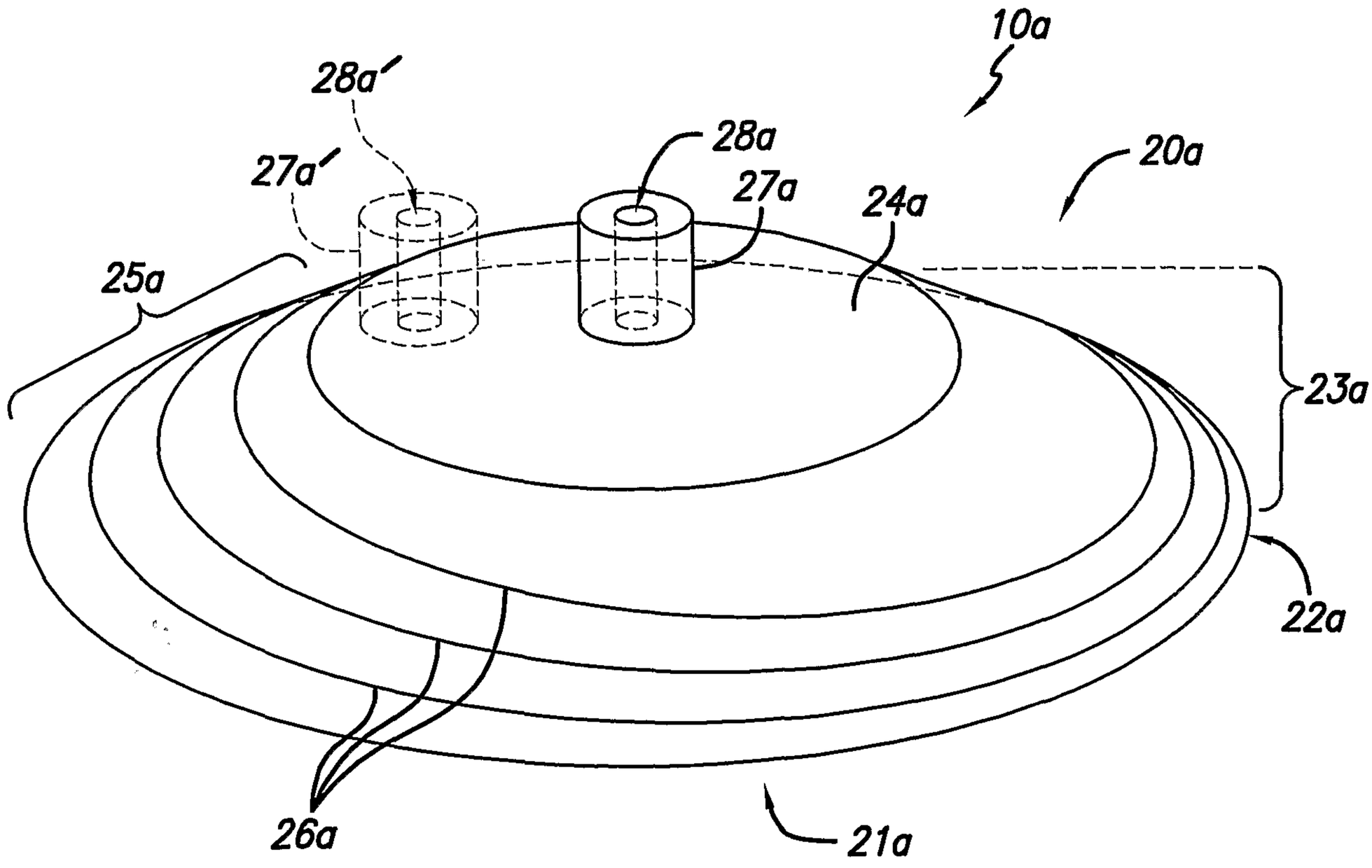
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FIG. 1B

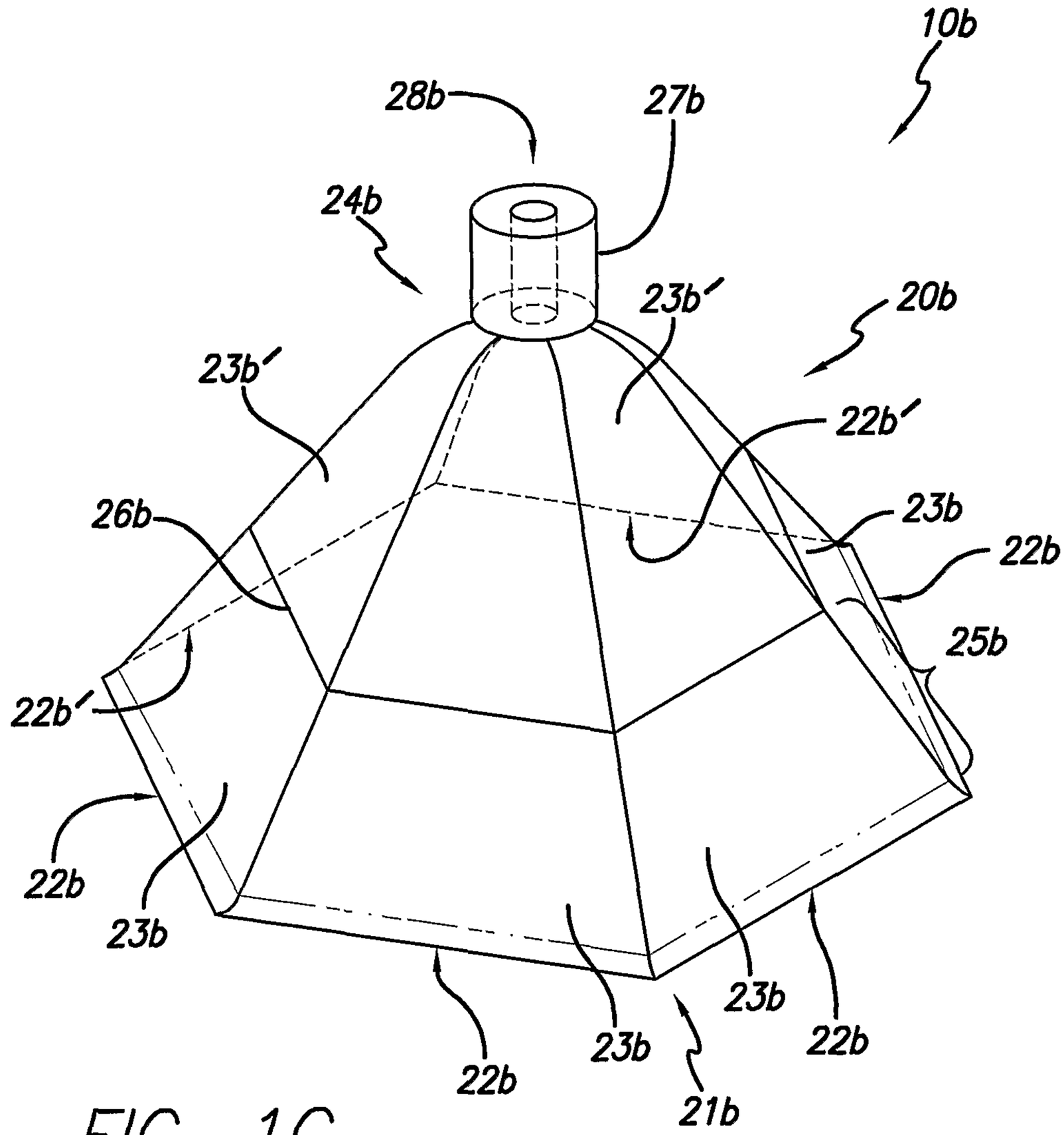
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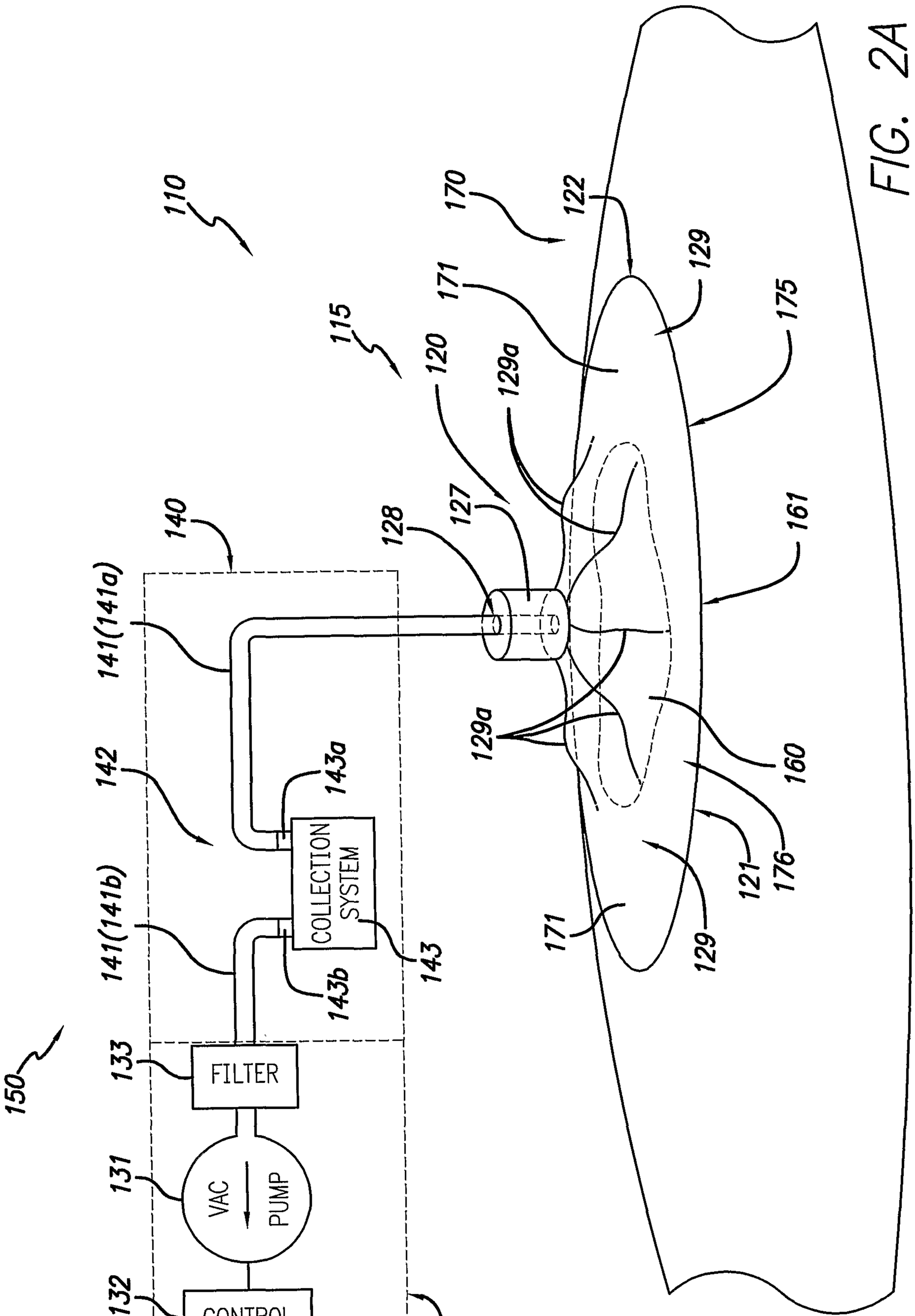
FIG. 1C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VAC PUMP
CONTROL
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176

FIG. 2A

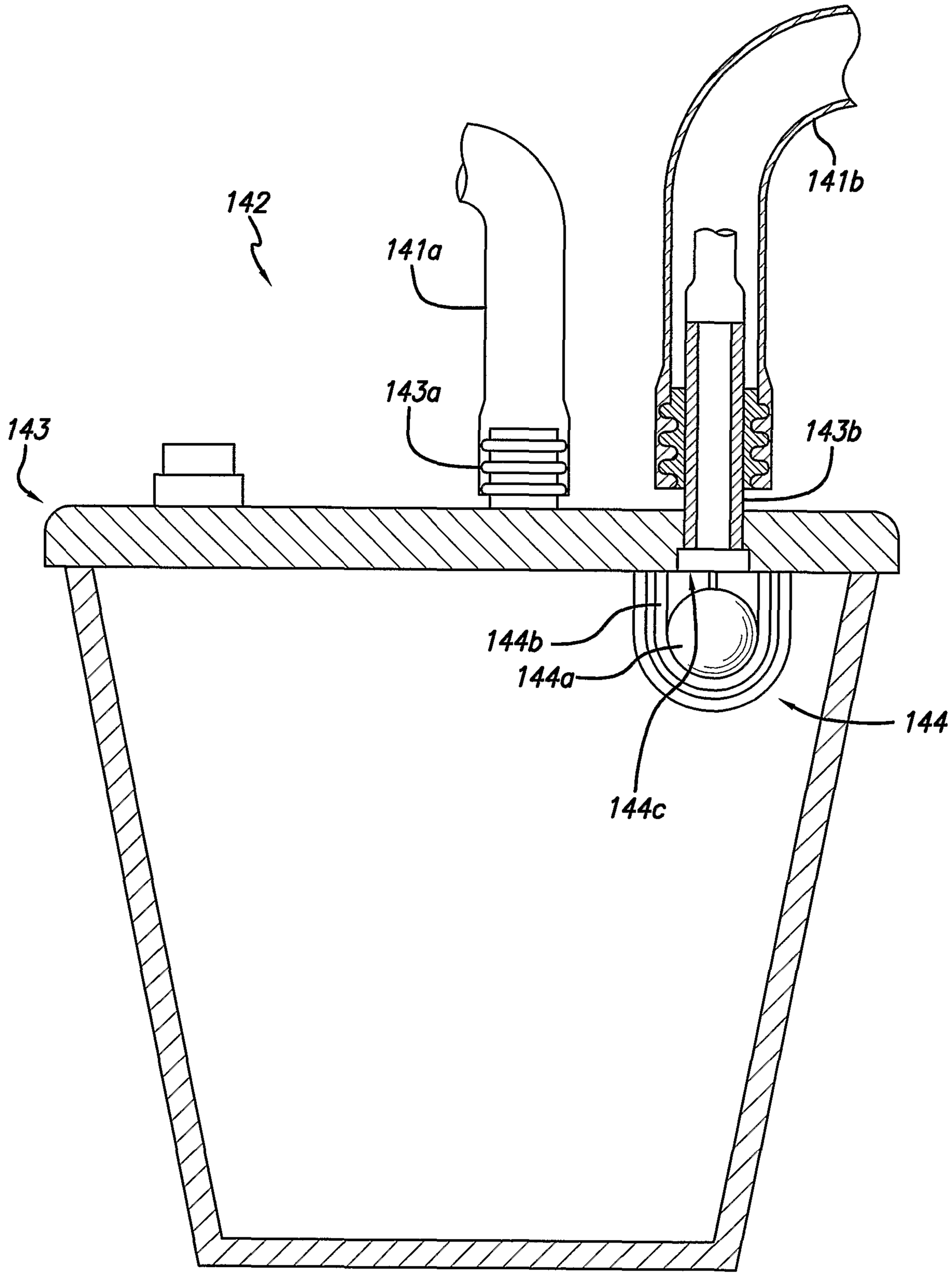
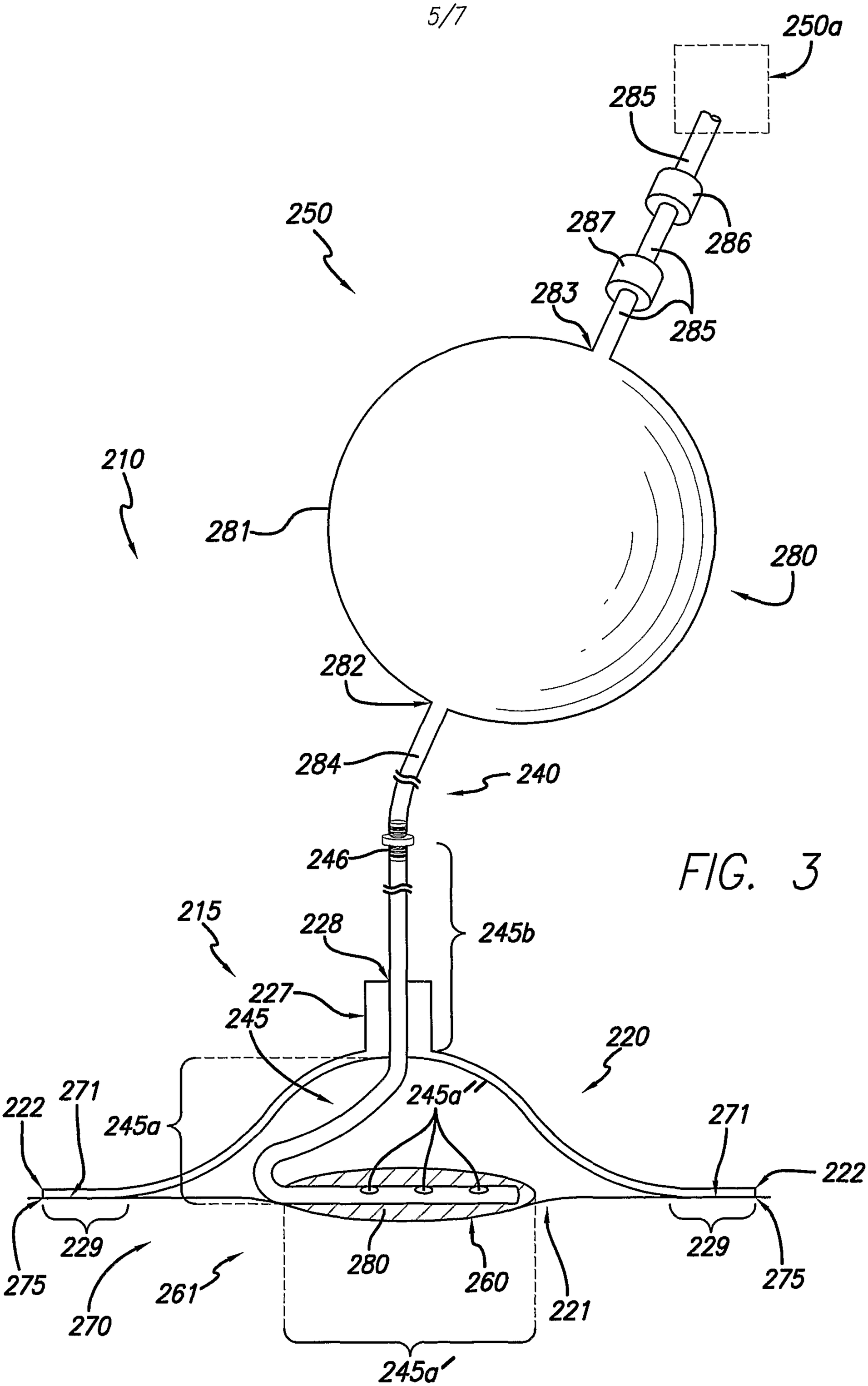


FIG. 2B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245a'

FIG. 3

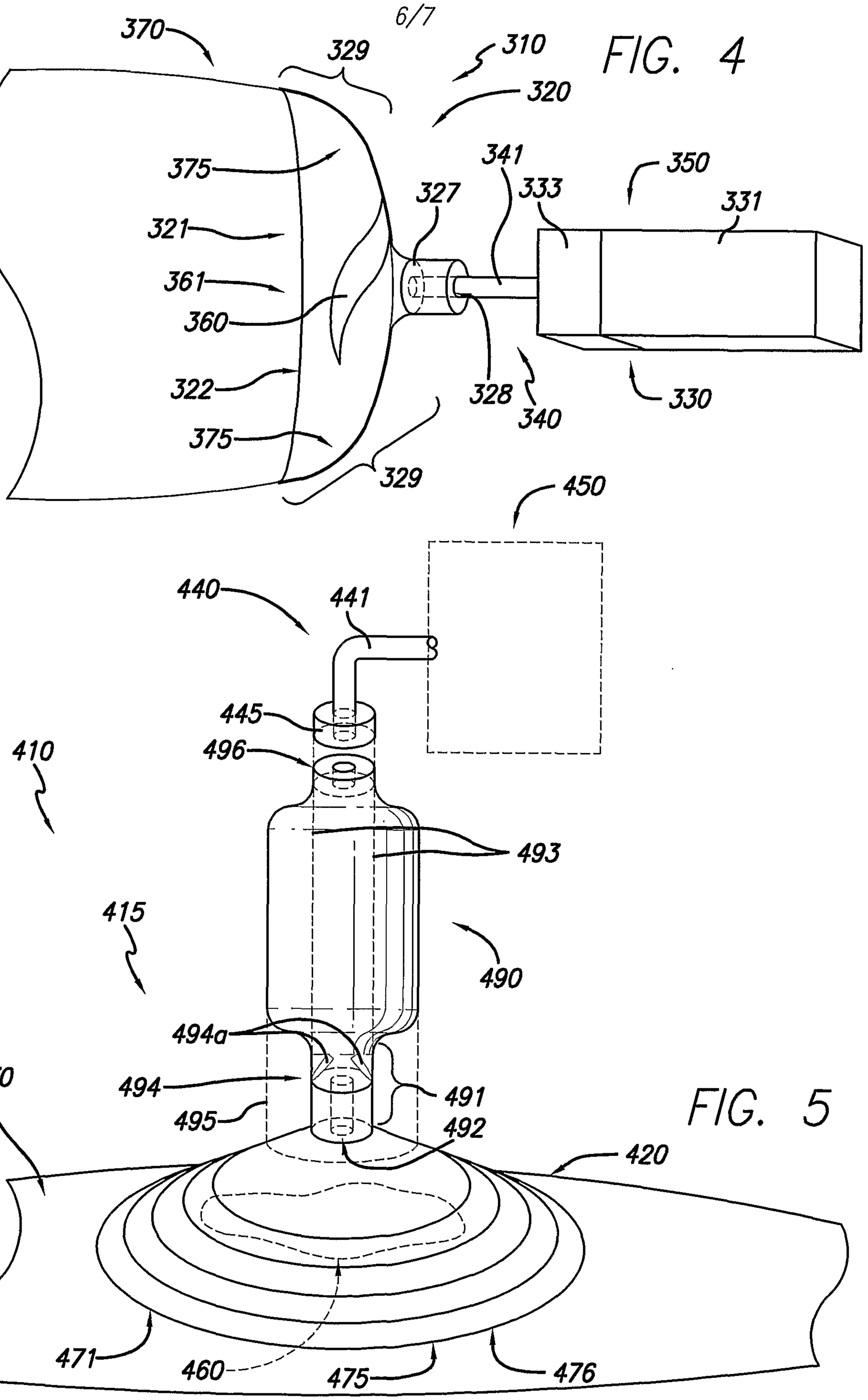
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FIG. 4

FIG. 5

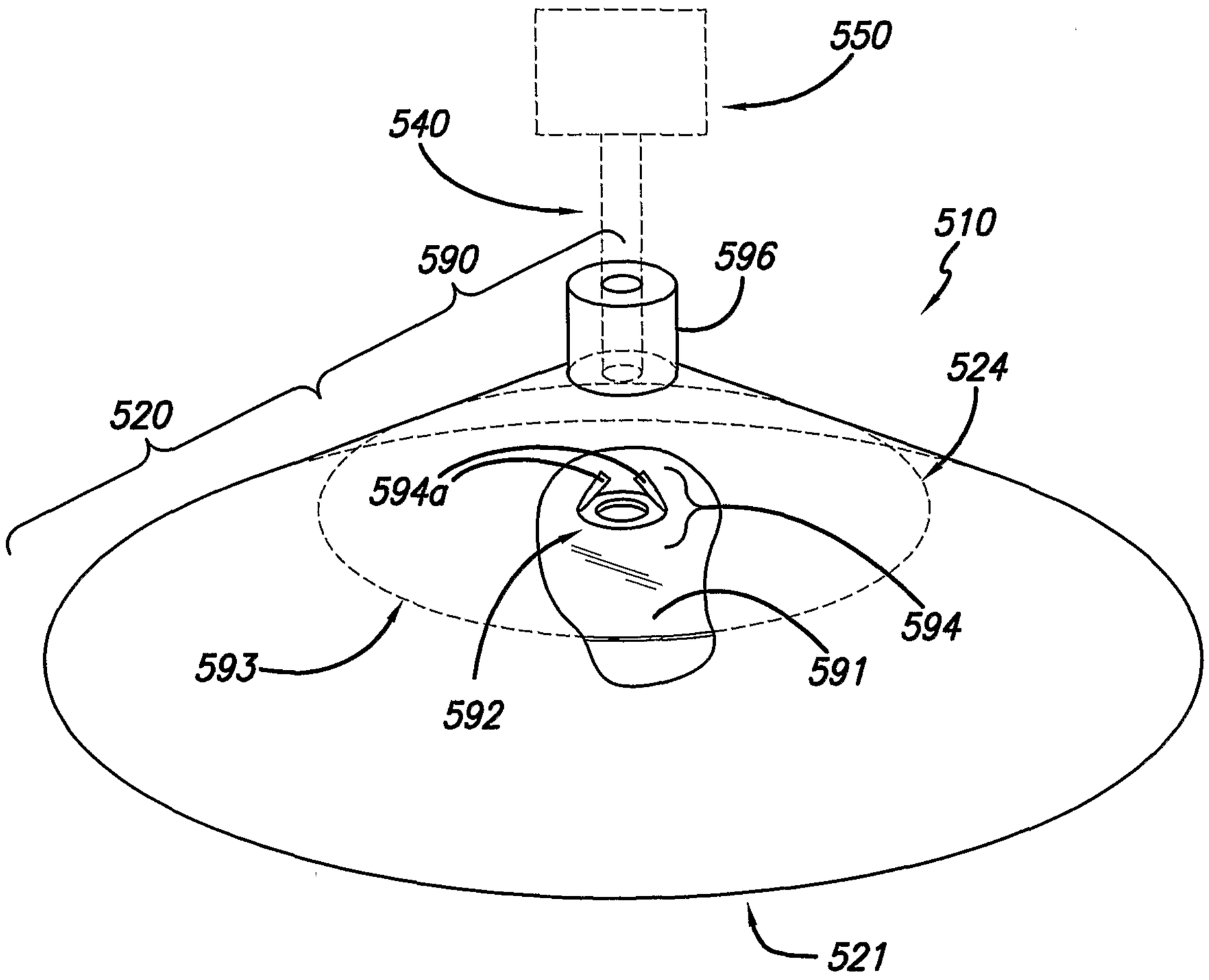
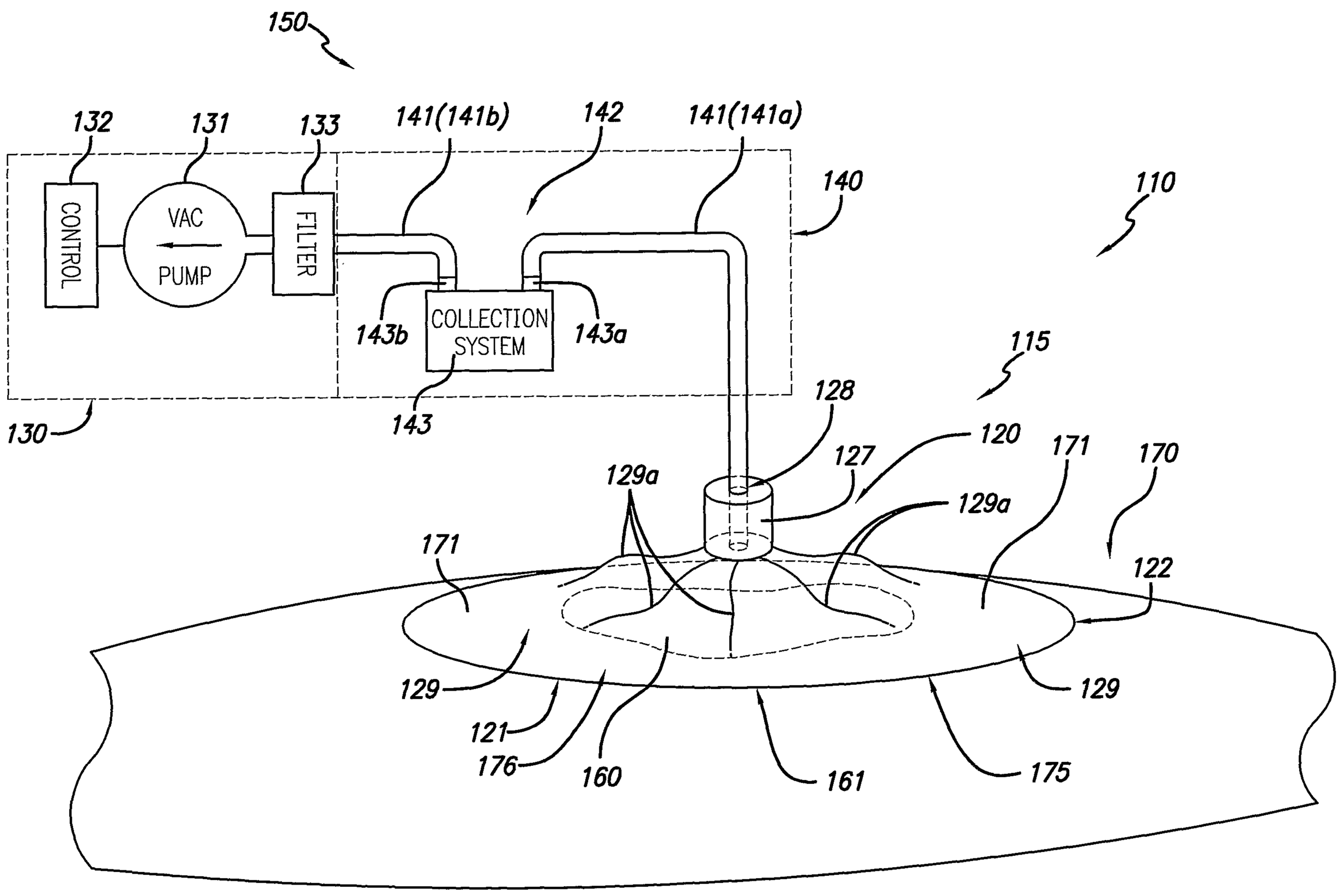


FIG. 6


150
132
131
133
141(141b)
142
141(141a)
140
110
CONTROL
VAC
PUMP
FILTER
143b
COLLECTION SYSTEM
143a
115
128
130
143
120
127
129a
171
170
129a
171
122
129
129
121
176
160
161
175