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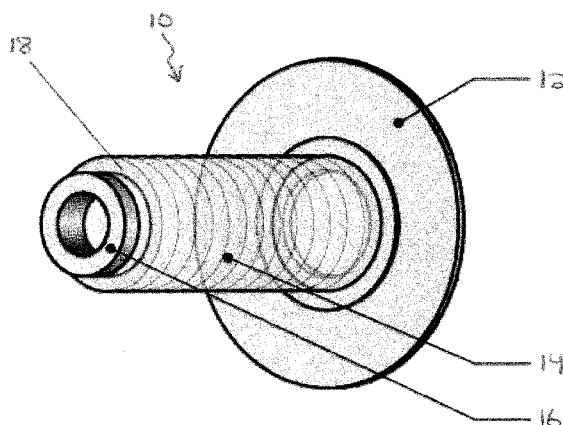
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- (54) **Title:** SEALED STERILE CATHETER DRESSINGS

FIG. 1



- (57) **Abstract:** Devices and methods are provided for sealing a catheter insertion site to maintain sterility. In one embodiment, a catheter dressing is provided that includes an adhesive plate configured for attachment to the skin of a patient and a flexible sheath that extends proximally from the adhesive plate. The sheath can be capable of longitudinal extension from a compressed to an extended state and can be configured in its extended state to surround an external segment of a catheter implanted in the patient and circumferentially seal to a portion of the external segment at a distance from the adhesive plate. The dressing can also be configured to restrict longitudinal movement of the catheter while at the same time permitting non-longitudinal movement. One-piece rigid or semi-rigid dressing bodies are also disclosed, as are various methods and devices for facilitating removal and or replacement of a catheter dressing.



SEALED STERILE CATHETER DRESSINGS

RELATED APPLICATIONS

5 This application claims priority to United States Provisional Patent Application No. 61/255,927 filed on October 29, 2009 and entitled "SEALED STERILE CATHETER DRESSINGS," which application is incorporated herein by reference in its entirety.

10 FIELD OF THE INVENTION

 The present invention relates to methods and devices for sealing medical devices, and in particular to methods and devices for sealing and maintaining sterility at a catheter insertion site.

15 BACKGROUND OF THE INVENTION

 The insertion of a catheter into a body cavity, duct, or vessel to allow drainage, injection of fluids, and/or access by surgical instruments is a common procedure in the practice of medicine. Catheters come in a variety of shapes and forms and can be used for a variety of tasks, including chemotherapy, fluid drainage, hemodialysis, and
20 administering intravenous fluids, anesthesia, or other medications. A peripheral intravascular catheter can be used to administer medication, nutrition, and various other intravenous fluids via peripheral blood vessels, to perform hemodynamic measurements, and to provide access for procedures and devices affecting the cardiovascular system. A central venous catheter can be used to deliver medications or fluids to vessels near the
25 heart or into the heart itself. It is estimated that more than 100 million peripheral venous catheters and more than 250,000 central venous catheters are placed in patients in the United States each year. Other intravascular catheters include those used for hemodialysis, peripheral central access (PIC), interventional procedure access, cardiac ventricular assist device access, and other long term vascular access support. These can
30 be both arterial and venous in respect to the type of vessel in which they are inserted. For these many intravascular catheter uses, the catheter insertion site is traditionally and universally dressed by pressing the round, tubular catheter against the skin of the patient with a sterile adhesive patch-type dressing or with sterile gauze and adhesive tape,

which are the two dressing types recommended by the United States Centers for Disease Control and Prevention (“CDC”).

One major problem with intravascular catheterization methods is the risk of infection. For example, infections related to central venous catheters alone occur up to 80,000 times per year in the U.S., leading to 28,000 deaths and costing as much as 2.3 billion dollars per year. The rise of multi-drug resistant organisms has further compounded the magnitude of the problem of intravascular catheter infection, and the lay press and medical literature have paid increasing attention to this problem. As a very significant marker of this concern, the Centers for Medicare and Medicaid recently ruled that costs associated with catheter-related infection will no longer be reimbursed. Because of this, there has been a very strong push by clinicians, hospitals, and insurers to address the problem of catheter related infection. Several improved strategies for catheter care have been introduced, such as using rigorous interval dressing change protocols, applying optimal catheter care techniques, using antibiotic impregnated catheters, using improved dressing materials, and/or supplying antimicrobial additives to the dressing composition.

All of these strategies, however, still have the fundamental drawback of working within the mechanical constraints of the “traditional” patch-type covering dressing. This dressing strategy, which has been used since the first intravascular catheter was placed more than 100 years ago, acts, as stated above, by pressing the tubular catheter against the skin with a flat adhesive dressing that serves to cover both the catheter-skin insertion site and a portion of the catheter external to the body. The fundamental shortcoming of this traditional dressing strategy is that it precludes the creation of a sterile seal at the catheter-skin insertion site, as a gap between the round contour of the catheter and the skin is always left. The size of this gap is larger if the dressing is attached to wider diameter points of the catheter device, such as a catheter hub or an intermediate connector. Inflow of contaminants to the catheter insertion site along these open channels is always a possibility with such methods and devices, and therefore true sterility can never be achieved. In addition, over time, movement of the skin and catheter relative to one another and relative to the dressing can increase the size of the catheter-dressing gap. Furthermore, these dressings cannot be exposed to water or other

liquids as these liquids will flow directly to the catheter-skin insertion site, thereby further contaminating this site.

Accordingly, there is a need for catheter dressing methods and devices that provide for improved sealing at the catheter-dressing junction and/or improved sterility at the catheter insertion site. The devices and methods disclosed herein represent a paradigm shift in intravascular catheter care from a non-sterile, non-sealing dressing to a fully sealed and durably-sterile solution.

SUMMARY OF THE INVENTION

Methods and devices are disclosed for dressing and/or sealing a catheter insertion site.

In one aspect, a catheter dressing is provided that can include an adhesive plate configured for attachment to the skin of a patient and a flexible sheath having a proximal end and a distal end and extending proximally from the adhesive plate. The sheath is capable of longitudinal extension from a compressed to an extended state and configured in its extended state to surround an external segment of a catheter implanted in the patient and circumferentially seal to a portion of the external segment at a distance from the adhesive plate. The sheath can define a sealed chamber around the external segment of the catheter and a portion of the patient. In one embodiment, movement of the catheter with respect to the patient does not disrupt a seal formed between the sheath and the catheter. The sheath can optionally be coupled to the catheter. The sheath can include a splittable seam formed therein and can be capable of being opened along the seam such that the catheter dressing can be removed from a catheter around which the dressing is installed. In one embodiment, the seam can include a non-full-thickness perforation.

The sheath can include an attachment mechanism, such as a friction coupler, a threaded coupler, an inflation coupler, an electromagnetic coupler, and/or an adhesive. In one embodiment, the attachment mechanism can be attached to the adhesive plate. The sheath can also include a stretchable gasket ring at its proximal end for sealing to the portion of the external segment of the catheter and the portion of the external segment of the catheter can include an annular groove for receiving the stretchable gasket ring. At least a portion of the sheath can be transparent and the sheath can

include an access portal and/or an absorbent member disposed therein. In one embodiment, the sealed chamber can be sterile. In certain embodiments, the sheath can be formed integrally with the catheter. In one embodiment, the external segment of the catheter can include one or more of a catheter body, a catheter hub, a MicroCLAVE-type needleless connector, and/or a Luer-type connector. The sheath can be formed of at least one of an antibiotic-impregnated material and an antimicrobial-impregnated material and/or at least one of an antibiotic secreting member and an antimicrobial secreting member can be disposed within the sheath.

In another exemplary embodiment, the catheter dressing can include a clamp configured to secure at least one of the sheath and the external segment of the catheter to the patient. The clamp can also be configured to apply a compressive force to the gasket ring of the sheath and/or to increase the integrity of a seal formed between the sheath and the external segment of the catheter.

In another embodiment, the dressing can include a coupling member configured for coupling to a terminal end of the external segment of the catheter, the coupling member having at least one lumen to provide a fluid flow path to or from the catheter. The sheath can be extendable between the adhesive plate and the coupling member to surround a longitudinal segment of the catheter. In one embodiment, the sheath is configured to restrict longitudinal movement of the external segment of the catheter relative to the patient while permitting non-longitudinal movement of the external segment of the catheter relative to the patient. The sheath can also be formed integrally with the coupling member, and/or the coupling member can be directly attached to the adhesive plate. The coupling member can be any of a valve, a catheter body, a catheter hub, a Luer-type connector, a MicroCLAVE-type connector, a threaded fitting, and/or a friction fitting. In one embodiment, a kit is provided that includes the catheter dressing and a catheter having a mating feature for attachment of the catheter to the catheter dressing.

In another aspect, a catheter dressing assembly is provided that can include an adhesive plate configured for attachment to the skin of a patient, a coupling member configured for coupling to an external end of a catheter implanted in the patient, the coupling member having at least one lumen to provide a fluid flow path to or from the catheter, and a flexible sheath extendable between the adhesive plate and the coupling

member to surround a longitudinal segment of the catheter. The sheath can include an attachment mechanism for attaching the sheath to the coupling member, such as a friction coupler, a threaded coupler, an inflation coupler, an electromagnetic coupler, and/or an adhesive. In one embodiment, the attachment mechanism can be attached to the adhesive plate. The sheath can also include a stretchable gasket ring at its proximal end for sealing to the coupling member and the coupling member can include an annular groove for receiving the stretchable gasket ring. At least a portion of the sheath can be transparent and the sheath can include an access portal. The dressing assembly can also include an absorbent member disposed within the sheath. The sheath can define a sealed chamber around the end of the catheter and a portion of the patient. In one embodiment, the sealed chamber can be sterile. The sheath can be formed integrally with the coupling member and/or the coupling member can be directly attached to the adhesive plate. In such embodiments, movement of the catheter with respect to the patient does not disrupt a seal formed between the sheath and the coupling member.

The sheath can be formed of at least one of an antibiotic-impregnated material or an antimicrobial-impregnated material capable of secreting an antibiotic or antimicrobial agent.

In another embodiment, the dressing assembly can include a clamp configured to secure at least one of the sheath and the coupling member to the patient. The clamp can also be configured to apply a compressive force to the gasket ring of the sheath and/or to increase the integrity of a seal formed between the sheath and the external segment of the catheter.

In another exemplary embodiment, the coupling member can include a valve, a catheter body, a catheter hub, a Luer-type connector, a MicroCLAVE-type connector, a threaded fitting, and/or a friction fitting.

In another aspect, a method for circumferentially sealing a catheter insertion site is provided. The method can include inserting a distal end of a catheter into a patient at an insertion site, connecting a proximal end of the catheter to a coupling member having a flexible sheath extendable therefrom, extending the sheath along an external segment of the catheter to the patient, and adhesively sealing a distal end of the sheath circumferentially around the catheter insertion site. The method can also include

unsealing the distal end of the sheath and disconnecting the proximal end of the catheter from the coupling member.

5 The method can further include moving the catheter with respect to the patient without disrupting a seal formed between the sheath and the catheter or coupling member. The method can also include effecting and maintaining a sterile seal around the insertion site and/or securing at least one of the sheath and the external segment of the catheter to the patient. The method can include moving the catheter with respect to the patient without disrupting a seal formed between the sheath and the coupling
10 member, applying a sterilizing agent to an interior volume of the sheath through an access portal formed in a sidewall of the sheath, and/or applying sterilizing radiation to an internal volume of the sheath. The sterilizing agent can include at least one of an antibiotic solution, an antimicrobial solution, and a sterilization gas. The method can also include removing a sample from the internal volume of the sheath through an access
15 portal formed in a sidewall of the sheath and testing the sample. The method can also include separating the dressing along a non-full-thickness perforation formed in a sidewall of the dressing.

 In another aspect, a method is provided for circumferentially sealing a catheter insertion site. The method includes inserting a distal end of a catheter into a patient at
20 an insertion site, the catheter having a flexible sheath extendable therefrom, extending the sheath along an external segment of the catheter to the patient, and sealing a distal end of the sheath circumferentially around the catheter insertion site.

 In yet another aspect, a catheter and dressing assembly is provided that includes a catheter and an integrated dressing comprising an adhesive plate and a flexible sheath
25 having a proximal end joined to the catheter and a distal end joined to the adhesive plate. The sheath is capable of longitudinal extension from a compressed to an extended state and configured in its extended state to surround an external segment of the catheter when implanted in the patient and the adhesive plate is configured for attachment to the patient's skin to provide a circumferential seal.

30 In one embodiment, movement of the catheter with respect to the patient does not disrupt a seal formed between the sheath and the catheter. The sheath can also include a stretchable gasket ring at its proximal end for sealing to the portion of the external segment of the catheter. The sheath can also include an attachment mechanism,

such as a friction coupler, a snap-fit coupler, a threaded coupler, an inflation coupler, an electromagnetic coupler, or an adhesive. The external segment of the catheter can be any of a catheter body, a catheter hub, a MicroCLAVE-type connector, and a Luer-type connector, and can include an annular groove for receiving the stretchable gasket ring. At least a portion of the sheath can be transparent, and an absorbent member can be disposed within the sheath. The sheath can define a sealed chamber around the external segment of the catheter and a portion of the patient and the sealed chamber can be sterile. The sheath can include an access portal and can be formed integrally with the catheter. The assembly can also include a clamp configured to secure at least one of the sheath and the external segment of the catheter to the patient. The clamp can be configured to increase the integrity of a seal formed between the sheath and the external segment of the catheter. The sheath can also include a stretchable gasket ring at its proximal end for sealing to the portion of the external segment of the catheter and the clamp can be configured to apply a compressive force to the gasket ring. In one embodiment, the attachment mechanism is attached to the adhesive plate.

In another aspect, a removable catheter dressing is provided that includes an adhesive plate configured for attachment to the skin of a patient and a flexible sheath having a proximal end and a distal end and extending proximally from the adhesive plate, the flexible sheath having a longitudinal seam formed therein. The sheath is capable of being opened along the seam such that the catheter dressing can be removed from a catheter around which the dressing is installed. In one embodiment, the seam can be a non-full-thickness perforation.

In yet another aspect, a method is provided for removing a catheter dressing from a catheter that is at least partially inserted into a patient. The method includes separating the dressing from the tether, e.g., along a longitudinal non-full-thickness perforation formed in a sidewall of the dressing.

In another aspect, a catheter dressing is provided that includes an adhesive plate configured for attachment to the skin of a patient and a flexible sheath having a proximal end and a distal end and extending proximally from the adhesive plate, the flexible sheath having a longitudinal opening formed therein. The sheath is capable of being placed around an installed catheter and closed along the opening to circumferentially seal an external portion of the installed catheter at a distance from the adhesive plate.

5 The dressing can also include a mating mechanism configured to selectively mate first and second free edges of the sheath to one another along the opening. The mating mechanism can include any of a friction-based closure, an adhesive closure, a latch-type closure, and a male-female closure.

10 In yet another aspect, a method is provided for replacing a catheter dressing. The method includes removing a first catheter dressing circumferentially sealed around an external portion of a catheter that is at least partially inserted into a patient, placing a second catheter dressing having a longitudinal opening around the external portion of the catheter, and sealing the opening of the second catheter dressing to circumferentially seal the external portion of the catheter. The method can also include securing the external portion of the catheter to the patient with the second catheter dressing such that longitudinal movement of the external portion of the catheter relative to the patient is restricted and non-longitudinal movement of the external segment of the catheter relative to the patient is permitted. The method can also include at least one of sterilizing and cleaning a site at which the catheter is inserted into the patient after removing the first catheter dressing and before placing the second catheter dressing. In one embodiment, sealing the opening includes joining first and second free edges of the second catheter dressing, which can optionally include mating at least one of a friction-based closure, an adhesive closure, a latch-type closure, and a male-female closure formed thereon. The method can also include clamping a sheath portion of the second catheter dressing to an exterior surface of a catheter hub with a circumferential support ring and/or reinforcing a seal between an adhesive plate portion of the second catheter dressing and a skin of the patient by applying a circular adhesive ring, the circular adhesive ring having an outer diameter that is greater than an outer diameter of the adhesive plate portion.

25 In another aspect, a catheter dressing is provided that includes a unitary body having a planar distal adhesive surface defining a distal opening, a proximal portion defining a proximal opening, and an interior chamber extending from the proximal opening to the distal opening. The proximal opening is configured to form a circumferential seal around a catheter that is at least partially inserted into a patient and the distal adhesive surface is configured to adhere to the patient's skin to form a circumferential seal around a skin site at which the catheter is inserted. The body includes a splittable seam along which the body can be selectively opened and resealed.

The body can be rigid or semi-rigid such that the body restricts movement of the catheter relative to the patient and the body can include an access portal. The proximal opening can be formed perpendicular to the planar distal adhesive surface.

5 In yet another aspect, a catheter is provided that includes an elongate tubular body having proximal and distal ends and defining a central lumen. The body includes a mating feature for mating to a catheter dressing such that a sheath portion of the dressing can be coupled to the mating feature and extended towards a patient to create a circumferential sterile seal around an opening in the patient through which at least a
10 portion of the body is inserted.

 In another aspect, the methods and devices can be used to achieve a sterile seal when placing a catheter using a Seldinger technique. For example, the dressing can be placed over a catheter tip, and the proximal end of the dressing can be attached to the catheter hub prior to insertion of the catheter over a guide wire. Once the catheter is
15 positioned, the dressing can be unfurled and an adhesive plate at the distal end of the dressing can be attached to the skin around the catheter insertion site to provide a circumferential seal. The dressing can also be either pre-attached to the catheter or can be formed integrally therewith.

 In another aspect, the sealed chamber can be accessed via one or more sheath
20 access portals to introduce cleaning, sanitizing and/or antimicrobial agents. In one embodiment, a sterilizing agent such as an antibiotic solution or a sterilization gas can be applied to an interior volume of the sheath through an access portal formed in a sidewall of the sheath.

 In yet another embodiment, the sheath can be transparent to sterilizing radiation,
25 such as UV radiation, and the method can further comprise sterilizing or maintaining the sterility of the dressing's sealed chamber before, during, or after deployment of the dressing.

 In a further embodiment a method for circumferentially sealing a catheter
insertion site is provided that can include inserting a distal end of a catheter into a
30 patient at an insertion site, the catheter having a flexible sheath extendable therefrom and extending the sheath along an external segment of the catheter to the patient. The method can also include adhesively sealing a distal end of the sheath circumferentially around the catheter insertion site.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

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FIG. 1 is a perspective view of one embodiment of a catheter dressing according to the invention;

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FIG. 2A is a plan view of the catheter dressing of FIG. 1 in a compressed state;

FIG. 2B is a plan view of the catheter dressing of FIG. 1 in an extended state;

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FIG. 3 is a plan view of a catheter implanted in a patient and sealed using the catheter dressing of FIG. 1;

FIG. 4A is a cross-sectional profile view of one embodiment of an attachment plate according to the invention;

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FIG. 4B is a plan view of the attachment plate of FIG. 4A;

FIG. 5A is a plan view of one embodiment of a catheter dressing according to the invention sealed to a catheter hub;

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FIG. 5B is a plan view of another catheter hub showing a catheter dressing according to the invention in phantom;

FIG. 5C is a plan view of the catheter dressing and catheter hub of FIG. 5B;

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FIG. 5D is a plan view of a MicroCLAVE-type connector showing a catheter dressing according to the invention in phantom;

FIG. 5E is a plan view of a Luer-type connector likewise showing a catheter dressing according to the invention in phantom;

FIG. 5F is a plan view of the catheter dressing and connector of FIG. 5D;

FIG. 5G is a plan view of the catheter dressing and connector of FIG. 5E;

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FIG. 6A is a partial cross-sectional plan view of a catheter dressing sealed to a catheter hub having an integral attachment mechanism according to the invention;

FIG. 6B is a partial cross-sectional plan view of a catheter dressing sealed to another catheter hub likewise having an integral attachment mechanism according to the invention;

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FIG. 6C is a phantom view of a catheter dressing sealed to a MicroCLAVE-type connector having an integral attachment mechanism according to the invention;

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FIG. 6D is a phantom view of a catheter dressing sealed to a Luer-type connector having an integral attachment mechanism according to the invention;

FIG. 7A is a top view of an implanted catheter dressed with a catheter dressing and a catheter hub secured to a patient with one embodiment of a securement device;

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FIG. 7B is a side view of the implanted catheter and catheter dressing of FIG. 7A;

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FIG. 7C is a plan view of the securement device of FIGS. 7A-7B;

FIG. 7D is a profile view of the securement device of FIGS. 7A-7C;

FIG. 8A is a partial cross-sectional profile view of a catheter implanted in a patient and dressed with another embodiment of a dressing device according to the invention;

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FIG. 8B is a partial cross-sectional plan view of the catheter and dressing device of FIG. 8A;

5 FIG. 8C is a plan view of one embodiment of a folding plate for use in a catheter dressing according to the invention;

FIG. 8D is a partial cross-sectional profile view of one embodiment of a dressing device that includes the folding plate of FIG. 8C;

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FIG. 9A is a plan view of a catheter, a catheter hub, and one embodiment of a catheter dressing according to the invention;

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FIG. 9B is a plan view of the catheter dressing of FIG. 9A sealed to the catheter hub of FIG. 9A;

FIG. 9C is a plan view of the catheter, catheter dressing, and catheter hub of FIGS. 9A-9B after the catheter has been partially implanted in a patient;

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FIG. 9D is a plan view of the catheter dressing of FIGS. 9A-9C sealed to a patient's skin;

FIG. 10A is a plan view of a catheter, a catheter hub, and another embodiment of a catheter dressing according to the invention;

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FIG. 10B is a plan view of the catheter dressing of FIG. 10A sealed to the catheter hub of FIG. 10A;

FIG. 10C is a plan view of the catheter, catheter dressing, and catheter hub of FIGS. 10A-10B after the catheter has been partially implanted in a patient;

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FIG. 10D is a plan view of the catheter dressing of FIGS. 10A-10C sealed to a patient's skin;

FIG. 11A is a plan view of a coupling member and yet another embodiment of a catheter dressing according to the invention;

5 FIG. 11B is a plan view of the catheter dressing of FIG. 11A sealed to the coupling member of FIG. 11A;

 FIG. 11C is a plan view of a catheter coupled to the coupling member of FIGS. 11A-11B and partially implanted in a patient;

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 FIG. 11D is a plan view of the catheter dressing of FIGS. 11A-11C sealed to a patient's skin;

 FIG. 12 is a plan view of another embodiment of a catheter dressing according to the invention capable of cleavage for removing the dressing from an installed catheter;

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 FIG. 13A is a plan view of another embodiment of a catheter dressing according to the invention in an unsealed configuration, the dressing having a friction-fit closure mechanism;

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 FIG. 13B is a cross-section taken along the line A-A in FIG. 13A;

 FIG. 13C is a plan view of the catheter dressing of FIG. 13A in a sealed configuration;

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 FIG. 14A is a plan view of another embodiment of a catheter dressing according to the invention in an unsealed configuration, the dressing having an adhesive closure mechanism;

30 FIG. 14B is a cross-section taken along the line A-A in FIG. 14A;

 FIG. 14C is a plan view of the catheter dressing of FIG. 14A in a sealed configuration;

FIG. 15A is a plan view of another embodiment of a catheter dressing according to the invention in an unsealed configuration, the dressing having a friction-fit closure mechanism and an adhesive closure mechanism;

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FIG. 15B is a cross-section taken along the line A-A in FIG. 15A;

FIG. 15C is a plan view of the catheter dressing of FIG. 15A in a sealed configuration;

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FIG. 16A is a perspective view of another embodiment of a catheter dressing according to the invention having an angled base plate;

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FIG. 16B is a profile view of the dressing of FIG. 16A sealed at its proximal end to a catheter hub;

FIG. 16C is a profile view of the dressing of FIG. 16A sealed at its proximal end to a catheter hub and at its distal end to a patient;

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FIG. 16D is a profile view of one embodiment of a sealing element according to the invention;

FIG. 16E is a profile view of one embodiment of a securement device according to the invention;

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FIG. 17A is a perspective view of another embodiment of a catheter device according to the invention having a re-sealable seam and an angled base plate;

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FIG. 17B is a profile view of the dressing of FIG. 17A sealed to a catheter hub and to a patient;

FIG. 17C is a profile view of another embodiment of a securement device according to the invention;

FIG. 18A is a plan view of one embodiment of a rigid or semi-rigid catheter dressing body according to the invention;

5 FIG. 18B is a profile view of the dressing body of FIG. 18A;

FIG. 18C is a plan view of the dressing body of FIG. 18A sealed to a catheter and a patient;

10 FIG. 18D is a partial cross-sectional profile view of the dressing body of FIG. 18A taken along the line A-A when the dressing is sealed to a catheter and a patient;

FIG. 18E is a partial cross-sectional profile view of the dressing body of FIG. 18A taken along the line A-A when the dressing is sealed to a catheter hub and a patient;

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FIG. 19A is a plan view of one embodiment of a catheter seal support device according to the invention;

FIG. 19B is a profile view of the catheter seal support device of FIG. 19A;

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FIG. 19C is a profile view of another embodiment of the catheter seal support device of FIG. 19A;

FIG. 20A is a plan view of one embodiment of plate seal support device according to the invention;

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FIG. 20B is a perspective view of the plate seal support device of FIG. 20A;

FIG. 20C is a perspective view of one embodiment of a re-sealable catheter dressing according to the invention; and

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FIG. 20D is a perspective view of the plate seal support device of FIG. 20A installed over the dressing of FIG. 20C.

DETAILED DESCRIPTION OF THE INVENTION

Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those skilled in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the present invention.

A person skilled in the art will appreciate that, while methods and devices are described herein in connection with catheters implantable in humans, the methods and devices can also be used in any instance in which a seal is desired around an elongate device implanted into or otherwise extending from a plant, an animal, and/or any non-living machine, structure, or system.

In general, devices and methods are provided for circumferentially sealing a catheter insertion site with improved sterility. The devices and methods can also involve securing a catheter in various ways. For example, a dressing can be provided to restrict longitudinal movement (e.g. inward or outward migration) of a catheter relative to a patient while at the same time permitting free non-longitudinal movement of the catheter (e.g., up, down, left, right, lateral, and/or rotational), all without disrupting or disturbing the sterile circumferential seal. In other words, once sealed, the catheter can be restricted or prevented by the dressing from being further withdrawn from, or inserted into, the patient but can remain otherwise freely movable. Alternatively, the dressing can be configured to completely secure the catheter such that all movement of the catheter relative to the patient is restricted. A catheter dressing is provided in one embodiment that includes an adhesive plate configured for attachment to the skin of a patient and a flexible sheath that extends proximally from the adhesive plate. The sheath is capable of longitudinal extension from a compressed to an extended state and configured in its extended state to surround an external segment of a catheter implanted in the patient and circumferentially seal thereto at a distance from the adhesive plate.

When installed, the catheter dressing can define a sterile sealed chamber around the catheter insertion site. The catheter dressing can restrict longitudinal movement of the catheter relative to the patient (e.g., prevent such movement altogether or restrict such movement to a range commensurate with the range over which the sheath can be compressed and extended). At the same time, the catheter can be moved left, right, up, down, etc. relevant to the patient without disrupting the sterile sealed chamber.

FIG. 1 illustrates one exemplary embodiment of a catheter dressing 10. As shown, the dressing 10 is generally in the form of a plate 12 configured to be attached to the skin of a patient around a catheter insertion site and a flexible sheath 14 extending proximally from the plate 12. As used herein “proximal” refers to a direction or location away from a patient and “distal” refers to a direction or location towards or into the patient. A sealing element 16 can be provided at the proximal end 18 of the sheath 14 for sealing to a catheter inserted through the sheath 14. As used herein, “catheter” refers not only to a catheter body itself, but also includes, without limitation, peripheral IV catheters, central line catheters, intra-arterial catheters, intra-arterial access sheaths, catheter hubs, catheter connection and/or coupling devices, catheters having a specially modified connection point, and/or any other associated structures or devices. The plate 12 is configured to provide a sterile, 360 degree seal with a surface to which it is attached, for example a skin surface of a patient. Thus, the plate 12 can provide a seal that completely surrounds a catheter insertion site. As shown in FIGS. 2A and 2B, the sheath 14 is capable of longitudinal extension from a compressed state (FIG. 2A) to an extended state (FIG. 2B). In either state, and anywhere in between, the dressing 10 provides at least two distinct seal regions 20, 22. A first seal region 20 is formed between the plate 12 and a patient 26. A second seal region 22 exists at the proximal end 18 of the sheath 14, where the sheath can be sealed to a catheter. Thus, the sheath 14 is extendable proximally from the plate 12 and is configured to surround and circumferentially seal to a catheter, thereby defining a sealed, sterile chamber around the catheter and the catheter insertion site.

As used herein, the terms “circumferential seal,” “circumferentially sealed”, and any related terms or variations thereof should not be construed as being limited only to a seal formed around a round or circular object. Rather, these terms refer also, without

limitation, to a seal formed all the way around or substantially all the way around the perimeter of any object, regardless of shape.

As shown in FIG. 3, a catheter 24 can be inserted into a patient 26 through a skin surface 28. The dressing 10 can be installed over the catheter 24 such that the two are substantially coaxial. The plate 12 can be adhered to the skin surface 28, thereby forming a first seal region 20 that surrounds the catheter insertion site. The sheath 14 can be extended a distance longitudinally along the catheter 24 to a second seal region 22, where the sealing element 16 can create a sterile seal between the sheath 14 and the catheter 24. Once installed, the dressing 10 is effective to define a sealed, sterile region around the catheter insertion site and at least a portion of the catheter.

The plate 12 can have a variety of configurations. In one embodiment, as shown in FIG. 4A, the plate includes a flexible structural layer 32, an adhesive layer 34, and a peel-away backing layer 36. The backing layer 36 covers and protects the adhesive layer 34 until just before the dressing 10 is to be installed. During installation, the backing layer 36 can be removed, thereby exposing the adhesive layer 34 for attachment to the patient's skin. Any of a variety of adhesives known in the art can be used for attaching the plate 12 to the patient's skin and the adhesive can be chosen based on a variety of factors, including for example the quality, sterility, and durability of the seal created, the biocompatibility of the adhesive with human skin or with a particular skin type, and/or cost.

Although illustrated as being an adhesive plate, the plate 12 can be attached to the patient in a variety of ways. For example, the plate can include hooks, tabs, and/or apertures through which a suture or other tie-down mechanism can be received, or a suture can be threaded directly through the plate material. The plate can also be attached using an adhesive tape such that the tape partially overlaps the proximal surface of the plate 12 and partially overlaps the patient's skin. Various combinations of the attachment techniques described herein can also be employed. In addition, as discussed in further detail below, a secondary plate seal support device can be employed to augment the plate-skin seal.

The plate 12 can be made from a variety of materials known in the art such as various semi-rigid/flexible materials, including polyurethanes such as Pellethane (available from The Dow Chemical Company of Midland, MI, USA), thermoplastic

elastomers such as Santoprene (available from ExxonMobil Chemical of Houston, TX, USA), polyisoprene elastomers, medium to high durometer silicone elastomers, and/or any combination thereof. The plate can also be formed of various polymers, including polycarbonates and polyetheretherketone (PEEK), metals such as titanium or stainless steel, composites such as carbon-fiber reinforced PEEK, various ceramic materials, and/or any combination thereof. The plate can also be formed from any other suitable fabrics, foams, plastics, and/or metals known in the art.

As illustrated in FIG. 4B, the plate is generally in the form of a thin annular ring having an inner diameter D1 and an outer diameter D2. Although the illustrated embodiment is of a generally circular shape, the plate 12 can also be constructed in virtually any other shape, such as rectangular or elliptical. In general, the plate 12 is sized in accordance with the catheter to which it will be applied. Specifically, the inner diameter D1 of the plate 12 can be sized such that it is slightly larger than the diameter of the catheter. In the case of an adhesive attachment means, the outside diameter D2 of the plate 12 can be chosen based in part on the strength of the adhesive used to ensure that an adequate surface area of the plate 12 is adhered to the patient to maintain a strong and stable seal. In one exemplary embodiment, the plate can be in the form of an annular ring having an inner diameter of approximately 0.5 mm to approximately 20 mm and an outer diameter of approximately 2 mm to approximately 100 mm.

The sheath 14 can be formed integrally with the plate 12 or it can be attached thereto using a variety of techniques, so long as a sterile seal exists therebetween. For example, the distal end of the sheath 14 can be sandwiched between multiple layers of the plate 12, or it can be attached to the plate 12 using an adhesive. A variety of other methods known in the art can also be employed, such as sonic welding, frictional engagement, etc.

As shown in FIG. 5A, the sheath 14 is generally in the form of an elongate flexible tube. While the illustrated sheath 14 is flexible, the sheath 14 and/or dressing 10 can also be rigid or semi-rigid, which can advantageously permit longitudinal or other movement of the catheter relative to the patient to be further restricted by the dressing. The surface of the sheath can be pleated or folded in an accordion-like fashion such that the sheath 14 is extendible from a compressed state to an expanded state (see FIGS. 2A-2B). Alternatively, or in addition, the sheath can be formed from a stretchable material

to facilitate longitudinal extension. Exemplary materials from which the sheath can be formed include a clear flexible plastic, similar to that used for other medical-surgical grade materials and devices. Many options for this plastic material are available and that
5 chosen for the sheath can have a combination of optimal attributes such as flexibility, strength, durability, breathability, microbial resistance, etc. Other exemplary sheath materials include silicone, polyisoprene, other elastomers or rubbers, and/or any combination thereof. Any other suitable material known in the art can also be used.

The distal end 38 of the sheath 14 is configured to sealably attach to the plate 12,
10 as describe above. The proximal end 40 of the sheath 14 is configured to seal around a catheter and can optionally include a sealing element 16. In the illustrated embodiment, the sealing element 16 is in the form of a flexible gasket ring. The sheath 14 can be molded around the sealing element 16, can be bonded thereto using an adhesive, or can be attached thereto using any other suitable method known in the art. The sealing
15 element 16 and the sheath 14 can sealably mate to a catheter. In the illustrated embodiment, the sheath 14 is shown advanced proximally along a catheter 24 and over a portion of the nose 42 of a 3-into-1 catheter hub 44. As shown, the nose 42 of the catheter hub 44 has a generally conical tapered surface. The sealing element 16 is stretched over the nose 42 such that the resilient properties of the sealing element 16
20 cause it to exert a radially inward force against the nose 42. When advanced far enough along the nose 42, this force can create a sealing engagement between the hub 44 and the sheath 14 and/or the sealing element 16. Although a sealing element 16 in the form of a stretchable gasket ring is illustrated, such structure is not necessarily required. For example, the sheath 14 itself can have flexible and resilient properties that would
25 facilitate sealing engagement with a catheter. Furthermore, a seal between the sheath 14 and a catheter can be effected in a variety of other ways, including for example adhesive bonding, clamping, balloon pressure inflation, and/or magnetic coupling.

The catheter dressing 10 can also include an absorbent element 48 disposed within the sheath 14. In one embodiment the absorbent element 48 can be a strip of
30 sterile gauze material positioned adjacent to the skin surface 28 of the patient. In such embodiments, the absorbent element 48 can absorb any moisture, condensation, or fluid seepage emanating from the catheter insertion site, from the patient's skin, or otherwise present within the sealed catheter dressing 10. An antimicrobial-containing or

antibiotic-containing element can also be disposed within the sheath 14 and can optionally be configured to release one or more cleansing/sterilizing agents over time. Alternatively, or in addition, the sheath 14 or dressing 10 itself can be formed from an antibiotic or antimicrobial impregnated material and can release said antibiotic or antimicrobial over time.

The sheath can also optionally include an access portal 46 for accessing and manipulating the internal volume and contents of the sheath 14. For example, the access portal 46 can permit infusion of cleansing, sanitizing, and/or antimicrobial type solutions, to clean or replace the absorbent element 48, or to permit the infusion of sterilizing gas or use of another sterilizing material. When appropriate, the access portal 46 can also be used to expose the sealed volume of the dressing and the catheter insertion site to ultraviolet or other sanitizing radiation, or to remove a sample or specimen from the dressing 10 for testing. The access portal 46 can also be used to alter various conditions within the sealed dressing 10, such as pH, temperature, humidity, sterility, etc.

In one embodiment, at least a portion of the sheath 14 can be transparent to allow for visualization and monitoring of the internal condition and contents of the sealed volume and the catheter insertion site. For example, the entire sheath 14 can be formed of a transparent material as illustrated in FIG. 5A, or the sheath can include one or more transparent windows at various points along an outer surface thereof.

In addition to central line catheter hubs like the one illustrated in FIG. 5A, the sheath 14 and/or the sealing element 16 can also be effective to circumferentially seal around an external surface of various other catheter components. For example, FIGS. 5B and 5C illustrate a standard catheter hub 50. As shown, the hub 50 includes a first, proximal end 52 for coupling to a fluid conveying device such as a syringe or IV line. The hub further includes a second, distal end 54 that is in fluid communication with the proximal end 52 and that is configured to couple to an implantable catheter 24. Much like the central line catheter hub 44 discussed above, the standard catheter hub 50 can be circumferentially sealed by advancing the sheath 14 and/or sealing element 16 proximally along a tapered outer surface of the hub 50.

As shown in FIGS. 5D-5E, the catheter dressing 10 can be part of a catheter dressing assembly that can further include an intermediate coupling member. In general, the coupling member has a distal end that is in fluid communication with an implantable catheter. The proximal end of the coupling member can include a valve such as a Luer-type connector, a MicroCLAVE-type connector, a threaded fitting, and/or a friction fitting. The valve can also be a blunt injection site or can be configured to couple to a variety of fluid conveying devices, such as syringes, IV lines, catheter extensions, and the like. FIG. 5D illustrates one embodiment of a coupling member in the form of a MicroCLAVE-type connector 56. The connector 56 includes fittings 58, 60 at either end configured to couple the connector to various fluid conveying devices known in the art, including for example implantable catheters. The main body of the connector 56 includes a tapered outer surface 62 over which the sheath 14 and/or sealing element 16 can be advanced to form a sterile seal. FIG. 5E shows another embodiment of a coupling member in the form of a Luer-type connector 64. The Luer-type connector includes fittings 66, 68 at either end configured to couple the connector 64 to various fluid conveying devices known in the art, including for example implantable catheters. The main body of the connector 64 includes an outer surface over which the sheath 14 and/or sealing element 16 can be advanced to form a sterile seal. While MicroCLAVE-type and Luer-type connectors are specifically illustrated and described herein, a person having ordinary skill in the art will appreciate that any suitable fluid conveying structure can be used as a coupling member.

FIG. 5F illustrates a catheter dressing 10 sealed around an implanted catheter 24 that is coupled to a MicroCLAVE-type connector 56. As shown, an adhesive plate 12 circumferentially surrounds a catheter insertion site and is adhered to the skin 28 of a patient. A sheath 14 extends proximally from the adhesive plate 12 to the connector 56. A sealing element 16 at the proximal end of the sheath 14 is drawn distally against the tapered surface of the connector 56, resulting in a sterile seal between the sheath 14 and the connector 56. FIG. 5G shows a similar catheter dressing 10 sealed around a Luer-type connector 64. As shown, the sealing element 16 at the proximal end of the sheath 14 frictionally engages the central body of the connector 64, forming a sterile seal therewith.

The catheter dressing assembly can also include a variety of catheter components that are specifically tailored for receiving the sheath 14 and/or the sealing element 16 of the catheter dressing 10. By way of non-limiting example, catheter bodies, catheter hubs, MicroCLAVE-type connectors, Luer-type connectors, and/or any intermediate-type connector directly attached in luminal continuity with the catheter can all be modified to include an attachment mechanism to enhance the integrity and stability of the dressing seal. For example, as shown in FIGS. 6A-6D, a catheter hub 50', a catheter hub 44', a MicroCLAVE-type connector 56', and/or a Luer-type connector 64' can each be modified to include an annular groove 70 formed in an outer surface thereof configured to receive the sealing element 16 and/or a portion of the sheath 14 therein. As will be appreciated by a person having ordinary skill in the art, inclusion of such a groove can provide for a more durable and tighter seal between the catheter components 50', 44', 56', 64' and the sheath 14.

In order to achieve optimal patient comfort, optimal catheter stability, and minimal damage to internal patient vessels and structures, it can be desirable to orient the catheter such that it lies substantially flat against the patient's skin. In one embodiment, the dressing can be configured to secure the catheter in such a position, and to prevent inadvertent movement of the catheter relative to the patient. Alternatively, or in addition, securement devices can be provided that are configured to further secure the catheter and/or the catheter dressings and dressing assemblies described herein to the patient. In certain embodiments, the securement device can also provide additional strength and stability to the seal between the sheath and the catheter.

As shown in FIGS. 7A-7D, a securement device in the form of a clamp 72 can be used to anchor the catheter 24 and/or catheter dressing 10 to the patient 26. As particularly shown in FIG. 7D, the clamp 72 includes a planar base portion 78 and an upright clamping portion 88. The clamping portion 88 includes first and second levers 80, 82 and a ratchet and pawl mechanism 84, 86. Squeezing the first and second levers 80, 82 towards each other causes the inner diameter of the clamping portion 88 to decrease as the pawl 86 rides over one or more ratchet teeth 84. As the first and second levers 80, 82 are advanced toward one another, the ratchet and pawl mechanism 84, 86 is effective to prevent movement of the first and second levers 80, 82 away from each other and thus to prevent diametrical expansion of the upright clamping portion 88.

When necessary to release or open the clamp, the first lever 80 can be actuated to disengage the pawl 86 from the ratchet teeth 84, thereby permitting the inner diameter of the clamping portion 88 to expand and ultimately open. To ensure optimal operation of the clamp 72, it can be formed from any flexible yet semi-rigid material known in the art.

Referring now to FIGS. 7A and 7B, an implanted catheter 24 is shown lying substantially flat against the patient 26 and dressed with a catheter dressing 10 as described herein. An adhesive pad 74, which can have a construction similar or identical to that of the adhesive plate 12, is used to attach the central line catheter hub 44 and the clamp 72 to the patient. The planar base portion 78 of the clamp and the lateral ears 90, 92 of the hub 44 can be affixed to the adhesive pad 74 using a variety of techniques known in the art. As shown, the clamp 72 can be positioned with respect to the hub 44 such that the upright clamping portion 88 is substantially aligned with the seal region 22 defined by the sheath 14, hub 44, and/or sealing element 16. Thus, squeezing the first and second levers 80, 82 of the clamp 72 towards each other and locking the levers 80, 82 using the ratchet and pawl mechanism 84, 86 is effective to apply a force radially inward against the seal region 22, resulting in a tighter and more secure seal.

As shown particularly in FIG. 7D, the clamp 72 can further include an inner gasket ring 76 configured to prevent abrasion of the sheath 14 and/or sealing element 16 by the clamp 72. The gasket ring 76 can also ensure that the radial force applied by the clamp 72 is substantially uniform about the circumference of the seal region 22.

While the catheter dressing 10, clamp 72, and/or catheter 24 are generally described herein as being attached directly to the skin of a patient, other indirect attachment means are also possible. For example, any of these structures could instead be attached first to a wrap, pad, bandage, or the like which can then in turn be attached to the patient. In addition, the clamp 72 can optionally be free floating (e.g., can be provided without the base portion 78) and can be applied to the dressing after it is installed around a catheter, as discussed in greater detail below.

In another exemplary embodiment, the plate, sheath, coupling member, and clamp can be provided as a single unitary dressing device 110. As illustrated in FIG. 8A, the device 110 generally includes a folding adhesive plate 112, a coupling member

or coupling body 100, and a flexible sheath 114. The folding adhesive plate 112 is configured to attach to the skin 28 of a patient 26 and includes an aperture 113 formed therein for receiving an implantable catheter 24 therethrough. The coupling body 100
5 can be fixedly attached to the adhesive plate 112 such that the flexible sheath 114 can extend from a ramped surface 102 of the coupling body 100 to a proximal surface of the folding plate 112 to form a sealed volume around the aperture 113. Thus, by placing the folding plate 112 such that the aperture 113 surrounds a catheter insertion site, a sterile sealed volume is created around the site.

10 The coupling body 100 can include an access portal 146 for accessing the sealed volume of the device. The coupling body 100 can also include a first fitting 104 disposed within the sealed volume and configured to couple to an implanted catheter 24. A second fitting 106 can also be provided to facilitate insertion or removal of fluids from the implanted catheter 24.

15 In use, the dressing device 110 is effective to create a circumferential seal around a catheter insertion site and an implanted catheter 24 and to prevent movement (e.g., longitudinal, lateral, and/or rotational) of the implanted catheter 24. As shown in FIG. 8D, the device can be placed on a skin surface 28 adjacent to a catheter insertion site with the adhesive plate 112 in a folded position. Using appropriate sterile procedures,
20 the external portion of the implanted catheter 24 can be coupled to the first fitting 104 of the coupling body 100. The adhesive plate can then be lowered to an unfolded position in which it lies substantially flat against the patient's skin surface 28 and is adhered thereto, thereby surrounding the catheter insertion site and enclosing it within the aperture 113. When installed, the dressing device 110 defines a sealed volume around
25 the implanted catheter 24 and the catheter insertion site beneath the sheath 114. The sealed volume is accessible via the access port 146 and the catheter is accessible via the second fitting 106 of the coupling body 100.

Various methods for circumferentially sealing a catheter insertion site are also provided herein, for example by using the catheter dressings and systems described
30 above. FIGS. 9A-9D illustrate one exemplary method for sealing an implantable catheter 24 that is coupled to a catheter hub 50. As shown in FIG. 9A, a catheter dressing 10 is configured with the flexible sheath 14 in a compressed state and a catheter 24 is inserted therethrough. The dressing 10 is advanced proximally along the catheter

24 and the catheter hub 50 until the sealing element 16 of the sheath 14 forms a satisfactorily tight seal with the hub 50, as shown in FIG. 9B. As shown in FIG. 9C, the catheter can then be inserted into a patient 26 at a catheter insertion site. The sheath 14 can then be longitudinally extended along the implanted catheter 24 such that the adhesive plate 12 can be attached to the patient's skin surface 28, thereby forming a sterile circumferential seal around the catheter 24, a portion of the catheter hub 50, and the catheter insertion site.

FIGS. 10A-10D illustrate a similar method wherein a central line catheter hub 44 and an associated catheter insertion site are circumferentially sealed using a catheter dressing 10. As shown, a catheter dressing 10 is advanced proximally over a catheter 24 and the catheter hub 44 until the sealing element 16 of the dressing 10 is stretched sufficiently over the hub 44 to create a sterile seal. The catheter 24 can be partially inserted into a patient 26 and the sheath 14 can be longitudinally extended to a state in which the adhesive plate 12 can be attached and sealed to a skin surface 28 of the patient 26.

FIGS. 11A-11D illustrate an exemplary method for sealing an implanted catheter 24 using a catheter dressing 10 and an intermediate coupling member. As shown in FIG. 11A, one example of an intermediate coupling member – a Luer-type connector 64 – can be passed through the sheath 14 and adhesive plate 12 of a catheter dressing 10 while the sheath 14 is in a compressed state, thereby sealing the sheath 14 and/or the sealing element 16 circumferentially around the body of the Luer-type connector 64, as shown in FIG. 11B. The connector 64 can then be coupled to the proximal end of a catheter 24, either before or after the catheter is inserted into a patient, as illustrated in FIG. 11C. The sheath 14 can then be longitudinally extended along the connector 64 and catheter 24 to an extended state in which the adhesive plate 12 can be attached to the skin surface 28 of the patient 26, as shown for example in FIG. 11D. In an alternative embodiment, the adhesive plate 12 can be omitted or formed integrally with the sheath 14 such that the sheath 14 itself is directly attachable to the patient.

After a catheter insertion site is sealed using the methods or devices disclosed herein, it can be desirable to remove and/or replace the catheter dressing. Accordingly, dressings and related methods are provided that include a mechanism for removing and/or replacing the dressing.

FIG. 12 illustrates one embodiment of a catheter dressing 210 that can be removed from an inserted catheter without requiring the catheter itself to be removed from the patient. As shown, the dressing 210 includes an adhesive plate 212, a sheath 214, and a sealing element 216, each of which have one or more pre-specified break-points 215. Together, the break points 215 define a longitudinal, linear seam 231 or path along which the dressing 210 can be separated when sufficient stress is applied. Thus, when it is desired to remove an installed dressing 210, the plate 212, the sheath 214, and the sealing element 216 can be separated along the seam 231 defined by the break points 215 to create an opening through which the installed catheter can pass as the dressing 210 is removed. Once the dressing 210 is removed, the exposed catheter and skin entrance site can be cleaned and/or sterilized as desired. A new dressing can then be installed, as described below.

An indwelling intravascular catheter that is already in place and has either not had a dressing placed, or has had its dressing removed, can have a new dressing installed. FIGS. 13A-15C and 17A-18E illustrate various exemplary embodiments of catheter dressings that can be installed around a catheter that is already inserted into a patient. These dressings generally have an open configuration in which they can be placed around an inserted catheter or can be removed from an inserted catheter. During installation, the opened dressing is placed around the catheter and reconstituted into a generally tubular shape using one or more of a variety of attachment mechanisms, including without limitation a friction fit, a male-female snap fit, an adhesive coupling, and/or a latch-type closure, thereby establishing a circumferential seal around the catheter.

In FIG. 13A, a dressing 310 is shown having a plate 312, a sheath 314, and a sealing element 316. The dressing 310 is shown in an opened or unfolded configuration in which the free edges 317, 319 of the sheath 314 are separated such that the sheath 314 does not form a complete tube. A first edge 317 of the sheath 314 is provided with a longitudinal female groove 321. A second edge 319 of the sheath 314 is provided with a longitudinal male tab 323. Together, the female groove 321 and the male tab 323 form a friction-fit seal along the length of the sheath 314. The plate 312 and the sealing element 316 are similarly provided with female receptacles 325 and male projections 327 which can be selectively mated to form a friction-fit seal at the breakpoints of the

plate 312 and the sealing element 316. FIG. 13B illustrates a cross-section of the sheath 314. As shown, the female groove 321 and the male tab 323 can be separated such that the sheath 314 can be installed around a catheter that has already been placed. It will thus be appreciated that the male components 319, 327 of the dressing 310 and the female components 317, 325 of the dressing 310 can be mated (as shown in FIG. 13C) to form a circumferential sterile seal around a catheter that has already been placed, or can be separated to facilitate removal of the dressing 310 from such catheters.

FIGS. 14A-14C illustrate another exemplary embodiment of a catheter dressing 410 that can be installed around an already-placed catheter. As shown, the dressing 410 includes a plate 412, a sheath 414, and a sealing element 416. The dressing 410 is shown in an opened or unfolded configuration in which opposed free edges 417, 419 of the dressing 410 are separated such that the dressing 410 does not form a complete tube. A first edge 417 of the dressing 410 is provided with an adhesive flap 429. When installed around a catheter, the first edge 417 can be placed adjacent the second edge 419 and the adhesive flap 429 can be folded across the gap between the edges 417, 419 to form a circumferential sterile seal around the catheter. It will be appreciated that the edges 417, 419 and the adhesive flap 429 extend the full length of the dressing 410 (e.g., across the plate 412 and the sealing member 416 as well). FIG. 14B illustrates a cross-section of the sheath 414. As shown, the first edge 417 and the second edge 419 can be separated such that the sheath 414 can be installed around a catheter that has already been placed. Once placed around the catheter, the edges 417, 419 can be mated as shown in FIG. 14C by folding over and adhering the adhesive flap 429 to form a circumferential sterile seal around a catheter that has already been placed. To facilitate removal of the dressing 410 from an already-placed catheter, the flap 429 can be peeled back and the edges 417, 419 separated to form an opening through which the catheter can pass as the dressing 410 is removed.

FIGS. 15A-15C illustrate another exemplary embodiment of a catheter dressing 510 that can be installed around an already-placed catheter. As shown, the dressing 510 includes a plate 512, a sheath 514, and a sealing element 516 and generally combines the friction-fit features of the catheter dressing 310 of FIGS. 13A-13C and the adhesive flap features of the catheter dressing 410 of FIGS. 14A-14C. The dressing 510 is shown in an opened or unfolded configuration in which opposed free edges 517, 519 of the

5 dressing 510 are separated such that the dressing 510 does not form a complete tube. A first edge 517 of the sheath 514 is provided with an adhesive flap 529 and a longitudinal female groove 521. A second edge 519 of the sheath 514 is provided with a longitudinal male tab 523. When installed around a catheter, the male tab 523 can form a friction-fit seal with the female groove 521. The adhesive flap 529 can be folded over the second edge 519 of the sheath and adhered to an exterior thereof to reinforce the sealing engagement. The plate 512 and the sealing element 516 are similarly provided with female receptacles 525 and male projections 527 which can be selectively mated to form a friction-fit seal at the breakpoints of the plate 512 and the sealing element 516. In addition, the adhesive flap 529 can extend the full length of the dressing 510 (e.g., across the plate 512 and the sealing member 516 as well). FIG. 15B illustrates a cross-section of the sheath 514. As shown, the first edge 517 and the second edge 519 can be separated such that the sheath 514 can be installed around a catheter that has already been placed. Although the adhesive flap 529 is shown as being formed on the same edge 517 of the sheath 514 as the female groove 521, it can also be formed on the opposite edge 519 of the sheath 514 (e.g., adjacent the male tab 523). Once placed around the catheter, the edges 517, 519 can be mated as shown in FIG. 15C by engaging the male tab 523 and the female groove 521 and folding over and adhering the adhesive flap 529 to form a circumferential sterile seal around a catheter that has already been placed. To facilitate removal of the dressing 510 from an already-placed catheter, the flap 529 can be peeled back and the edges 517, 519 separated to form an opening through which the catheter can pass as the dressing 510 is removed.

FIGS. 16A-16E illustrate another embodiment of a catheter dressing 610 that generally includes a flexible sheath 614 that is formed at a non-ninety-degree angle relative to an adhesive plate 612. The angle between the sheath 614 and the plate 612 can advantageously make the dressing 610 easier to install and can reduce forces that tend to separate the plate 612 from the patient's skin 628. An access portal 646 can be provided in a sidewall of the sheath 614 as described above for accessing and manipulating the internal volume and contents of the sheath 614.

As shown in FIG. 16B, a sealing element 616 formed at a proximal end of the sheath 614 can be sealably mated to a catheter 624 and/or a specially-designed catheter hub 644. In the illustrated embodiment, the sealing element 616 is advanced proximally

over the nose 642 of the catheter hub 644 until it engages an annular groove 670 formed thereon. Once the dressing 610 is mated to the catheter 624 or catheter hub 644 as described above, the sheath 614 can be unfurled or unfolded distally and the adhesive plate 612 can be adhered to the patient's skin 628, as shown in FIG. 16C. It will be appreciated that, when installed as shown, the dressing 610 provides a sterile circumferential seal around the catheter 624, the catheter hub 644, and the catheter-skin insertion site. A variety of techniques can be used to effect a sealing engagement between the sheath 614 and the catheter 624 or catheter hub 644. As shown in FIG. 16D, a sealing element 616 in the form of a stretchable gasket ring can be employed to form a sealing engagement with a corresponding groove 670 formed on an outer surface of the catheter hub 644. The resilient properties of the sealing element 616 can cause it to exert a radially inward force against the groove 670, thereby forming a sterile seal.

Alternatively, or in addition, a securement device such as a clamp 672 shown in FIG. 16E can be used to hold the sealing element 616 in position around the catheter hub 644 or to reinforce the seal formed therebetween. The clamp 672 operates substantially in the same manner as the clamping portion 88 shown in FIGS. 7A-7D. An adhesive pad 674 can be provided to attach the catheter hub 644 to the patient's skin 628, and the clamp 672 can optionally include a base portion (not shown) which can be coupled to the adhesive pad 674 as described above.

FIGS. 17A-17C illustrate another embodiment of a catheter dressing 610' that is substantially identical to the catheter dressing 610 shown in FIGS. 16A-16C except that it includes features for removing the dressing from, and installing the dressing around, an already-placed catheter. As shown, the dressing 610' includes a sheath 614' coupled to an adhesive plate 612' at a non-ninety-degree angle. The dressing 610' is provided with a longitudinal seam 631' that extends the entire length of the sheath 610', the adhesive plate 612', and a sealing member 616' (shown in FIG. 17C). The dressing 610' can be selectively separated and attached at the seam 631' to facilitate installation of the dressing 610' around a catheter that has already been inserted into a patient or to facilitate removal of the dressing 610' from such catheters. For example, the seam 631' can be formed with a friction-fit arrangement (e.g., as shown in FIGS. 13A-13C), with an adhesive flap arrangement (e.g., as shown in FIGS. 14A-14C), or with a combination thereof (e.g., as shown in FIGS. 15A-15C).

As shown in FIG. 17A, the seam 631' can be formed on a side of the sheath 614' that intersects the plate 612' at an obtuse angle. This can advantageously permit joining of the free edges of the sheath 614', the free edges of the adhesive plate 612', and the free edges of the sealing member 616' to occur almost in a single plane, which can ease installation and removal of the dressing 610'. A plate seal support device 633' can optionally be provided to reinforce and support the seal formed between the adhesive plate 612' and a patient's skin, as discussed in further detail below.

In use, as shown in FIG. 17B, the dressing 610' can be placed around an inserted catheter 624' and catheter hub 644'. The dressing 610' can then be joined along the seam 631' and the adhesive plate 612' can be affixed to the patient's skin 628'. A C-shaped gasket sealing element 616' and an associated clamp 672' as shown in FIG. 17C can then be installed around the hub 644' and the dressing 610' to complete a sterile circumferential seal around the catheter 624', the hub 644', and the catheter-skin insertion site.

FIGS. 18A-18E illustrate another embodiment of a catheter dressing 710 that permits a rigid or semi-rigid snap-fit seal to be formed with a catheter or a catheter hub. The dressing 710 includes a unitary body 700 having an adhesive base portion 712 configured to be adhered to a patient's skin circumferentially around a catheter-skin insertion site. The base portion 712 is generally ring-shaped and defines a distal opening 715 sized to surround the insertion site. The base portion 712 can also include a re-sealable seam 731 to facilitate installation of the dressing 710 around a catheter that is already inserted into a patient.

A rigid or semi-rigid proximal portion 714 extends vertically upward from a surface of the base portion 712 opposite to the surface that is adhered to the patient. The proximal portion 714 defines a proximal opening 713. An inner lumen 717 extends between the proximal opening 713 of the proximal portion 714 and the distal opening 715 of the base portion 712, defining a chamber in which a catheter can be positioned. The re-sealable seam 731 can also extend along the proximal portion 714 to allow the entire body 700 to be selectively separated and reattached in a sealable fashion (e.g., when it is necessary to remove or install the dressing 710 from an already-inserted catheter). The seam 731 can be formed by any of the aforementioned mechanisms, including a friction-fit, an adhesive flap, a latch-type engagement, or any combination

thereof. In the illustrated embodiment, the opposed free edges of the sheath 714 are provided with corresponding male tabs 725 and female receptacles (not shown) to facilitate a friction-fit seal therebetween. The proximal portion 714 can also include one or more access portals 746 for accessing and manipulating the interior and contents of the dressing 710.

In addition, the dressing 710 can include an annular groove 771 formed in an interior surface thereof, adjacent to the proximal opening 713, that is configured to receive a corresponding annular projection 773 formed on a catheter line 724 (as shown in FIG. 18D) or on a catheter hub 744 (as shown in FIG. 18E). The annular groove 771 and the proximal opening 713 can also be seen as forming an annular lip which can engage a corresponding slot or groove 770 formed in the catheter hub 744. This groove-projection interface provides a snap-fit sealing engagement between the dressing 710 and the catheter 724 or the hub 744, which can advantageously secure the catheter 724 in position and prevent movement (e.g., longitudinal, lateral, and/or rotational) of the catheter 724 relative to the patient.

As noted above, a variety of adjuncts to the dressings disclosed herein can be provided to support, reinforce, and otherwise supplement the sterile seals at the proximal and distal ends of the dressing. FIGS. 19A-19C illustrate one exemplary embodiment of a catheter seal support device 800 for forming or reinforcing a seal at the dressing-catheter junction. The support device 800 is configured to circumferentially surround a catheter having a dressing disposed therearound. The support device 800 can be effective to squeeze and clamp the dressing around the catheter, holding it firmly in place and reinforcing or forming a sterile seal. As shown, the support device 800 generally includes a clamping portion 888 and an inner gasket ring 876.

The clamping portion 888 includes first and second levers 880, 882 and a ratchet and pawl mechanism 884, 886. Squeezing the first and second levers 880, 882 towards each other causes the inner diameter of the clamping portion 888 to decrease as the pawl 886 rides over one or more ratchet teeth 884. As the first and second levers 880, 882 are advanced toward one another, the ratchet and pawl mechanism 884, 886 is effective to prevent movement of the first and second levers 880, 882 away from each other and thus to prevent diametrical expansion of the clamping portion 888. When necessary to release or open the clamp, the first lever 880 can be actuated to disengage the pawl 886

from the ratchet teeth 884, thereby permitting the inner diameter of the clamping portion 888 to expand and ultimately open. To ensure optimal operation of the support device 800, it can be formed from any flexible yet semi-rigid material known in the art.

5 The gasket ring 876 can be positioned about an inner circumference of the clamping portion 888 and can be configured to prevent abrasion of a dressing around which the clamping portion 888 is placed. The gasket ring 876 can also ensure that the radial force applied by the support device 800 is substantially uniform about the circumference of the dressing. As shown in FIG. 19C, the gasket ring 876 can have an
10 opening 877 such that the gasket ring 876 is substantially C-shaped and thus can be installed around an already-dressed or already-inserted catheter. When used with a dressing having a longitudinal seam formed therein for separating the dressing, it is preferred that the opening 877 in the gasket ring 876 be placed on the opposite side of the dressing (e.g., such that the opening 877 is disposed 180 degrees from the seam in
15 the dressing). This can desirably provide a more stable, reliable seal.

 FIGS. 20A-20D show one embodiment of a plate seal support device 900. The support device 900 generally comprises a circular adhesive ring 901. The ring 901 has a break 903 formed therein such that the ring 901 can be opened, placed around an already-installed dressing, and then closed (e.g., reconstituted as a circle). The ring 901
20 can include an overlap region 905 such that the free ends of the ring overlap one another. In one embodiment, the overlap region 905 can extend between 30 and 60 degrees around the ring 901.

 In use, the support device 900 can be placed to further seal the outer edge of a catheter dressing's adhesive plate to a patient's skin and to prevent the plate of the
25 dressing from inadvertently separating at a re-sealable seam. FIG. 20C illustrates an exemplary catheter dressing 910 with which the support device 900 can be used. The dressing 910 is adhered to a patient's skin 928 via a circular adhesive plate 912. A longitudinal seam 931 is formed in the dressing 910 (including in the plate 912) to allow the dressing to be installed on or removed from an already-placed catheter. As shown in
30 FIG. 20D, the support device 900 can be opened at the break 903, positioned around the dressing 910, and closed such that the overlap portion 905 adheres to a top surface of an opposed free end of the adhesive ring 901. It will be appreciated that the inner diameter of the support device 900 is smaller than the outer diameter of the adhesive plate 912

and the outer diameter of the support device 900 is larger than the outer diameter of the adhesive plate 912. Accordingly, the support device 900 overlaps a portion of the adhesive ring 912 and a portion of the patient's skin 928, thereby reinforcing and/or forming a circumferential seal between the dressing 910 and the skin 928. As shown, the break 903 and overlap portion 905 of the support device 900 can be positioned on a side of the dressing 910 opposite to the seam 931 such that the two do not overlap. For example, the break 903 in the support device 900 can be positioned 180 degrees from the seam 931 in the dressing 910, which can provide a more stable and reliable seal.

The catheter dressings and dressing assemblies described herein can also be packaged in the form of a kit including dressings and/or assemblies of various sizes for use with various sized catheters. Such kits can also include catheters of various sizes and types, including customized or modified catheters designed specifically to interface with the dressings and dressing assemblies described herein.

The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a caregiver immediately prior to a catheterization procedure. Those skilled in the art will appreciate that reconditioning of a device can utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

Preferably, the invention described herein will be processed before use. First, a new or used device is obtained and if necessary cleaned. The device can then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and device are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the device and in the container.

The sterilized device can then be stored in the sterile container. The sealed container keeps the device sterile until it is opened in the medical field.

5 It is preferred that the device is sterilized. This can be done by any number of ways known to those skilled in the art including beta or gamma radiation, ethylene oxide, steam, and/or a liquid bath (e.g., cold soak).

One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by
10 the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

What is claimed is:

CLAIMS:

1. A catheter dressing comprising:
5 an adhesive plate configured for attachment to the skin of a patient; and
a flexible sheath having a proximal end and a distal end and extending
proximally from the adhesive plate;
wherein the sheath is capable of longitudinal extension from a compressed to an
extended state and configured in its extended state to surround an external segment of a
10 catheter implanted in the patient and circumferentially seal to a portion of the external
segment at a distance from the adhesive plate.
2. The catheter dressing of claim 1, wherein the sheath defines a sealed chamber
around the external segment of the catheter and a portion of the patient and, optionally,
15 wherein the sealed chamber is sterile.
3. The catheter dressing of claim 1, wherein movement of the catheter with respect
to the patient does not disrupt a seal formed between the sheath and the catheter.
- 20 4. The catheter dressing of claim 1, wherein the sheath further comprises a
stretchable gasket ring at its proximal end for sealing to the portion of the external
segment of the catheter and, optionally, wherein the portion of the external segment of
the catheter further comprises an annular groove for receiving the stretchable gasket
ring.
- 25 5. The catheter dressing of claim 1, wherein the sheath further comprises an
attachment mechanism selected from the group consisting of a friction coupler, a
threaded coupler, an inflation coupler, an electromagnetic coupler, and an adhesive.
- 30 6. The catheter dressing of claim 1, wherein the portion of the external segment of
the catheter is selected from the group consisting of a catheter body, a catheter hub, a
MicroCLAVE-type connector, and a Luer-type connector.

7. The catheter dressing of claim 1, wherein at least a portion of the sheath is transparent and, optionally, wherein the sheath is formed of at least one of an antibiotic-impregnated material and an antimicrobial-impregnated material and, optionally,
5 wherein the sheath comprises an access portal.

8. The catheter dressing of claim 1, further comprising at least one of an antibiotic secreting member, an antimicrobial secreting member, and an absorbent member disposed within the sheath.
10

9. The catheter dressing of claim 1, wherein the sheath is formed integrally with the catheter.

10. The catheter dressing of claim 1, further comprising a clamp configured to secure at least one of the sheath and the external segment of the catheter to the patient and, optionally, wherein the clamp is configured to increase the integrity of a seal formed between the sheath and the external segment of the catheter and, optionally, wherein the sheath further comprises a stretchable gasket ring at its proximal end for sealing to the portion of the external segment of the catheter and wherein the clamp is configured to
15 apply a compressive force to the gasket ring.
20

11. The catheter dressing of claim 1, further comprising a coupling member configured for coupling to a terminal end of the external segment of the catheter, the coupling member having at least one lumen to provide a fluid flow path to or from the catheter and, optionally, wherein the sheath is extendable between the adhesive plate and the coupling member to surround a longitudinal segment of the catheter.
25

12. The dressing assembly of claim 11, wherein the sheath is formed integrally with the coupling member and, optionally, wherein the coupling member is directly attached to the adhesive plate and, further optionally, wherein the coupling member is selected from the group consisting of a valve, a catheter body, a catheter hub, a Luer-type connector, a MicroCLAVE-type connector, a threaded fitting, and a friction fitting.
30

13. The catheter dressing of claim 1, wherein the sheath has a splittable seam formed therein and is capable of being opened along the seam such that the catheter dressing can be removed from a catheter around which the dressing is installed and, optionally,
5 wherein the seam comprises a non-full-thickness perforation.

14. A kit comprising:
the catheter dressing of claim 1; and
a catheter having a mating feature for attachment of the catheter to the catheter
10 dressing.

15. The catheter dressing of claim 1, wherein the sheath is configured to restrict longitudinal movement of the external segment of the catheter relative to the patient while permitting non-longitudinal movement of the external segment of the catheter
15 relative to the patient.

16. A catheter dressing comprising:
a unitary body having a planar distal adhesive surface defining a distal opening, a proximal portion defining a proximal opening, and an interior chamber extending from
20 the proximal opening to the distal opening;
wherein the proximal opening is configured to form a circumferential seal around a catheter that is at least partially inserted into a patient,
the distal adhesive surface is configured to adhere to the patient's skin to form a circumferential seal around a skin site at which the catheter is inserted, and
25 the body includes a splittable seam along which the body can be selectively opened.

17. The catheter dressing of claim 16, wherein the body is rigid or semi-rigid such that the body restricts movement of the catheter relative to the patient.
30

18. The catheter dressing of claim 16, wherein the proximal opening is formed perpendicular to the planar distal adhesive surface.

19. A catheter, comprising:
an elongate tubular body having proximal and distal ends and defining a central lumen;
- 5 wherein the body includes a mating feature for mating to a catheter dressing such that a sheath portion of the dressing can be coupled to the mating feature and extended towards a patient to create a circumferential sterile seal around an opening in the patient through which at least a portion of the body is inserted.
- 10 20. A catheter and dressing assembly comprising:
a catheter; and
an integrated dressing comprising an adhesive plate and a flexible sheath having a proximal end joined to the catheter and a distal end joined to the adhesive plate;
- 15 wherein the sheath is capable of longitudinal extension from a compressed to an extended state and configured in its extended state to surround an external segment of the catheter when implanted in the patient and the adhesive plate is configured for attachment to the patient's skin to provide a circumferential seal.
- 20 21. The assembly of claim 20, wherein the sheath further comprises a stretchable gasket ring at its proximal end for sealing to the portion of the external segment of the catheter.
- 25 22. The assembly of claim 21, wherein the portion of the external segment of the catheter further comprises an annular groove for receiving the stretchable gasket ring and, optionally, wherein the external segment of the catheter is selected from the group consisting of a catheter body, a catheter hub, a MicroCLAVE-type connector, and a Luer-type connector.

23. A catheter dressing comprising:
an adhesive plate configured for attachment to the skin of a patient; and
a flexible sheath having a proximal end and a distal end and extending
5 proximally from the adhesive plate, the flexible sheath having a longitudinal opening
formed therein;
wherein the sheath is capable of being placed around an installed catheter and
closed along the opening to circumferentially seal an external portion of the installed
catheter at a distance from the adhesive plate.
- 10
24. The catheter dressing of claim 23, further comprising a mating mechanism
selected from the group consisting of a friction-based closure, an adhesive closure, a
latch-type closure, and a male-female closure, the mating mechanism being configured
to selectively mate first and second free edges of the sheath to one another along the
15 opening.

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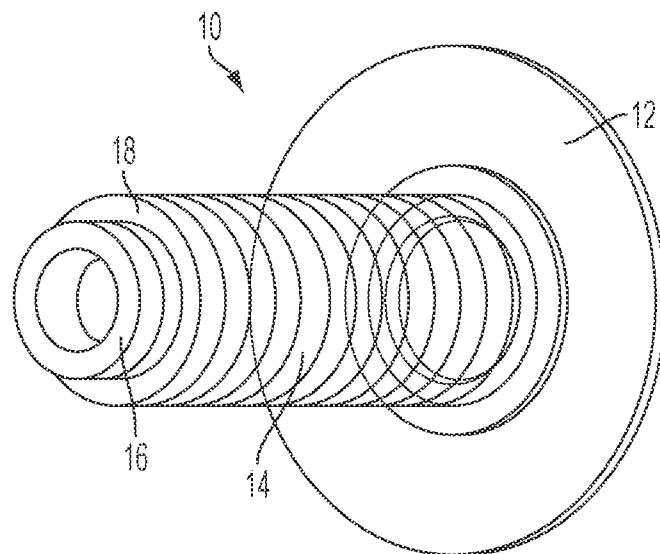


FIG. 1

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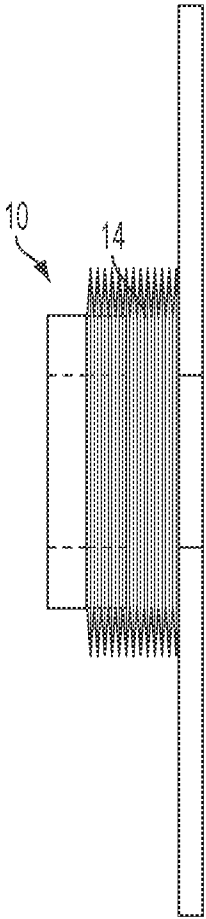


FIG. 2A

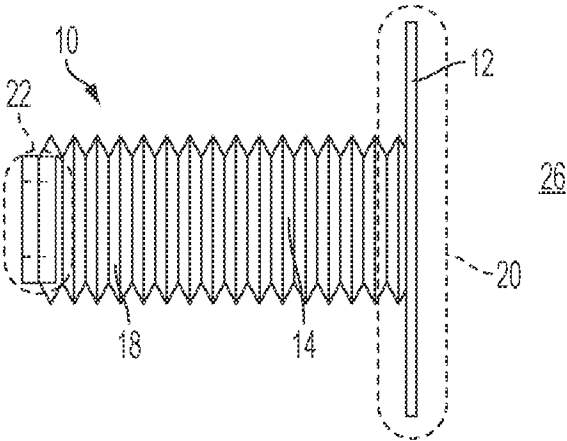


FIG. 2B

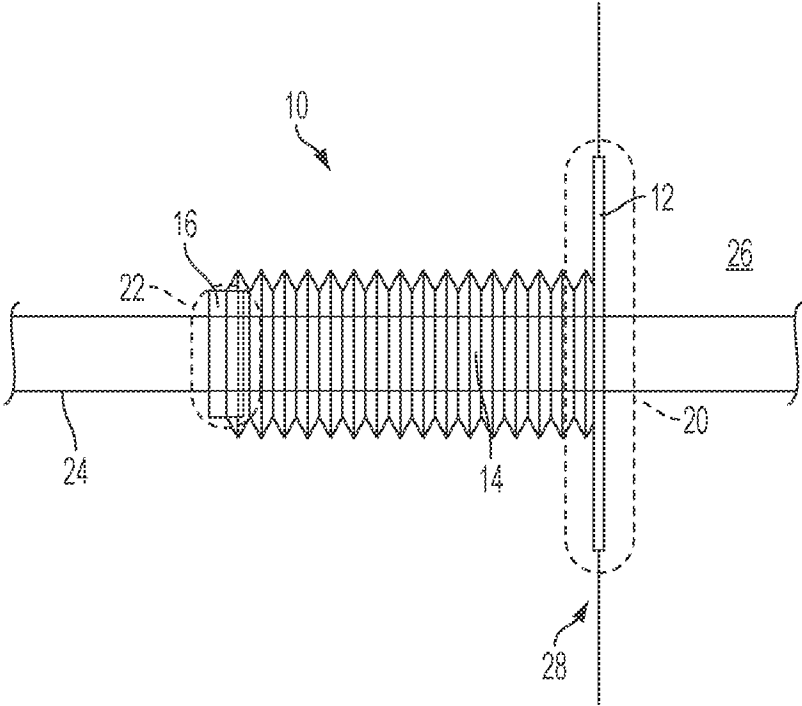


FIG. 3

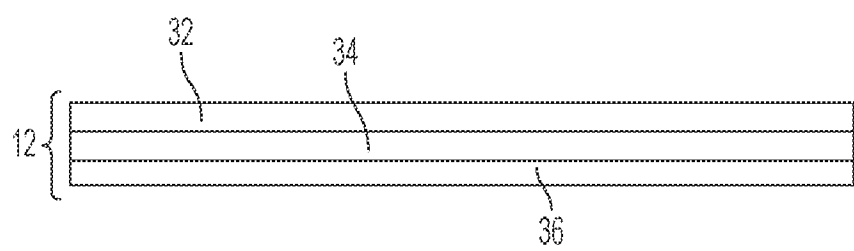


FIG. 4A

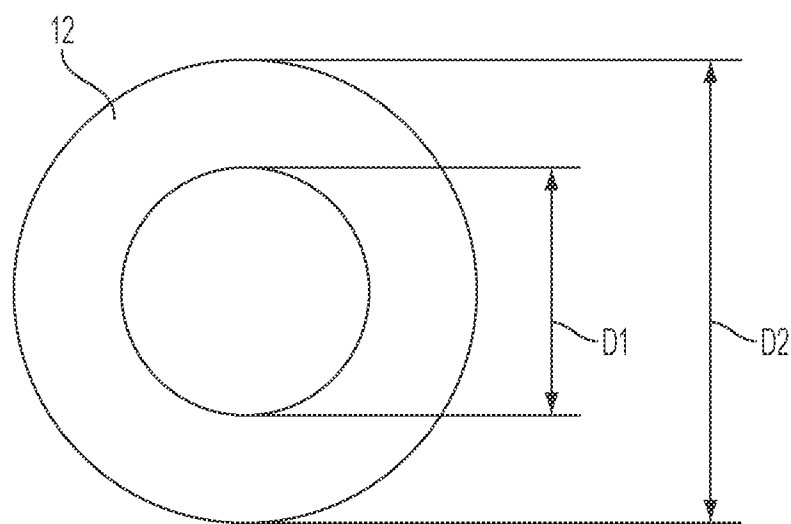


FIG. 4B

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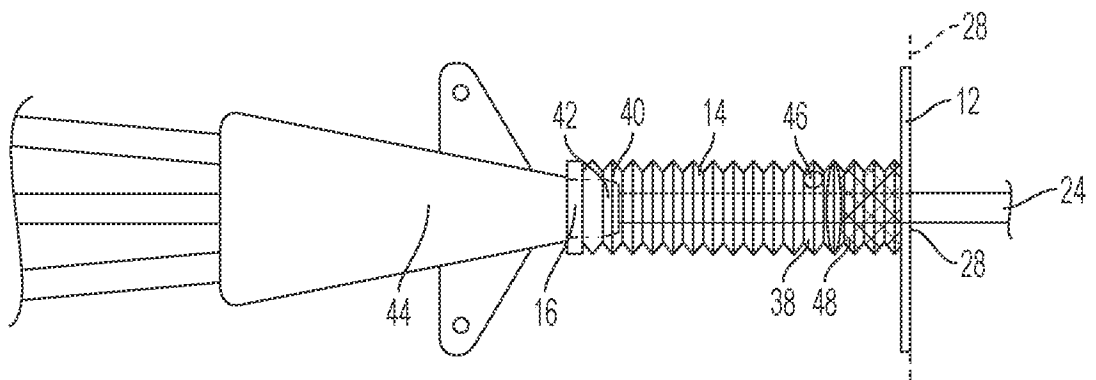


FIG. 5A

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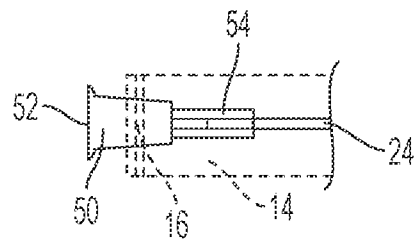


FIG. 5B

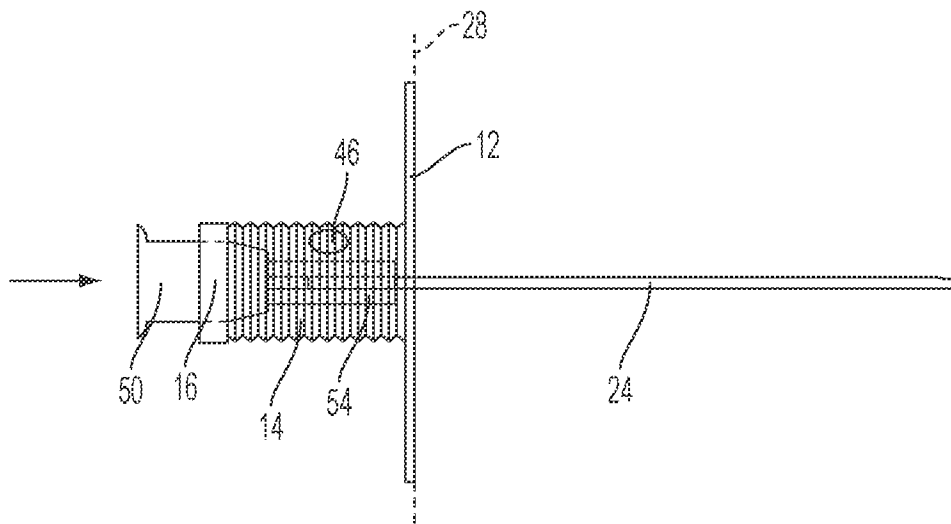


FIG. 5C

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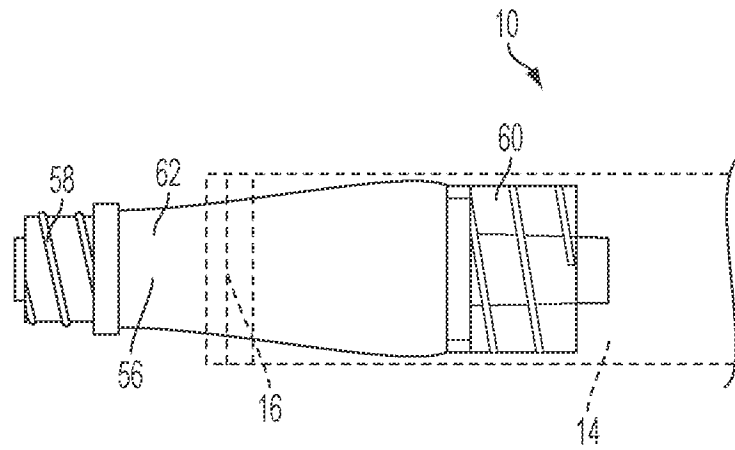


FIG. 5D

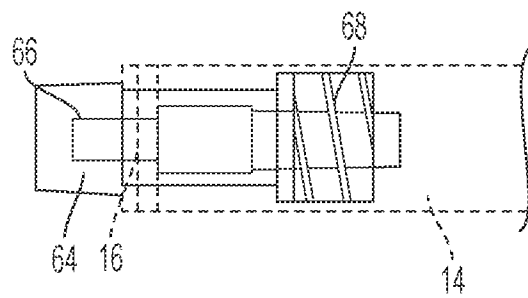


FIG. 5E

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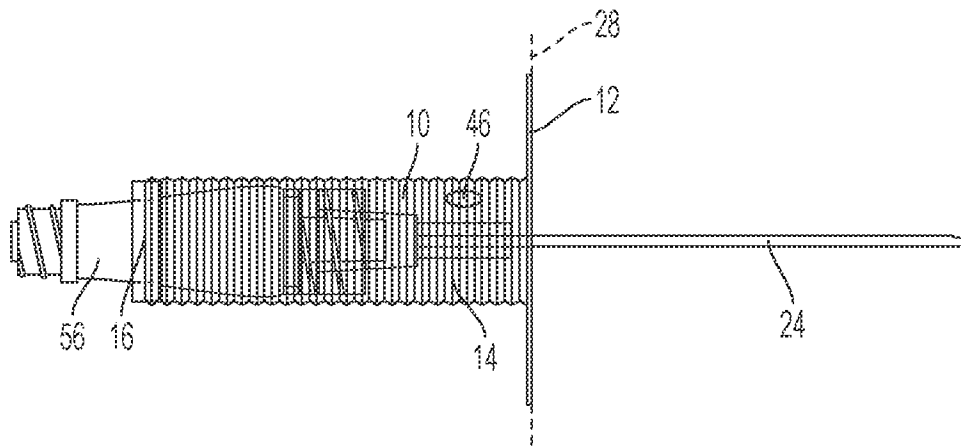


FIG. 5F

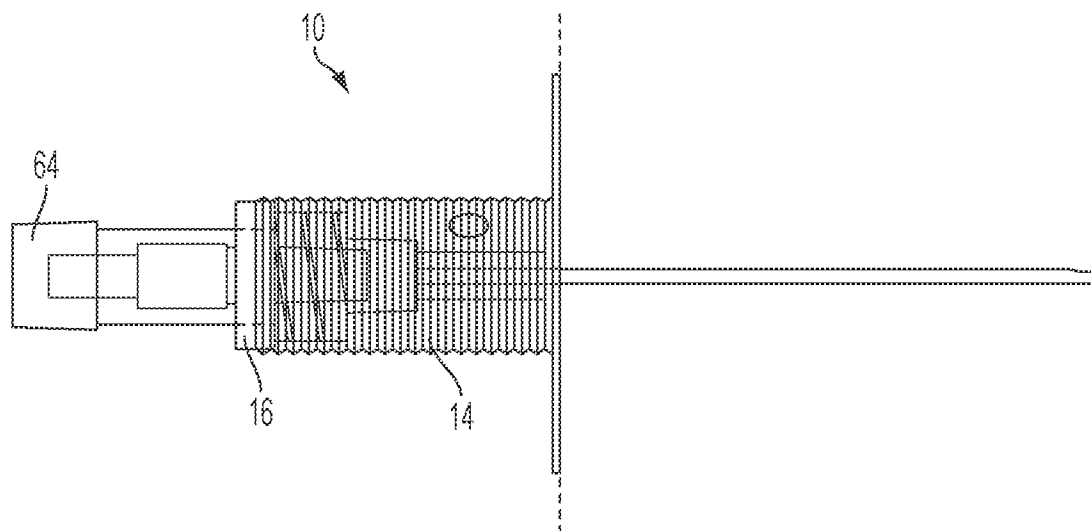


FIG. 5G

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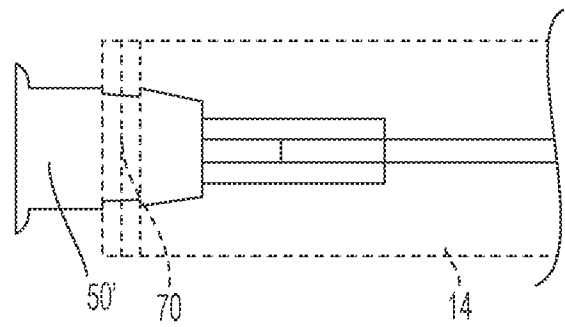


FIG. 6A

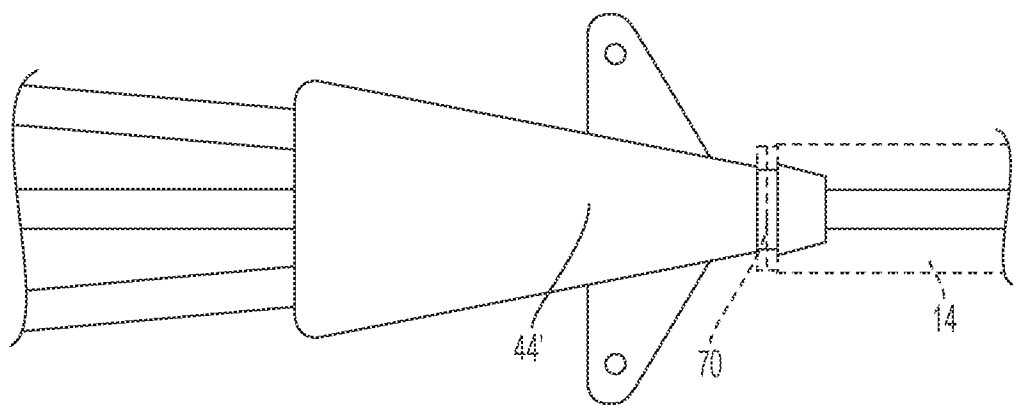


FIG. 6B

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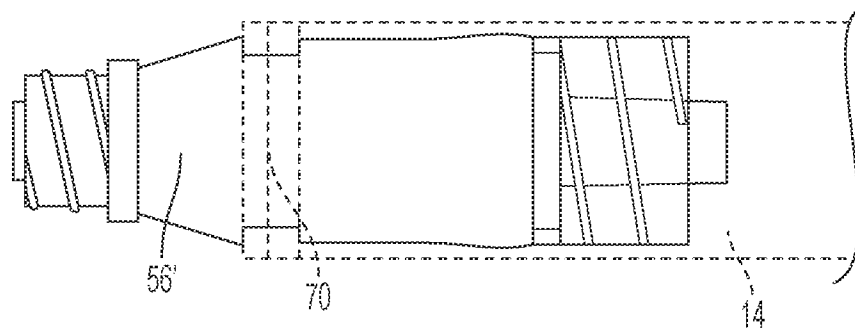


FIG. 6C

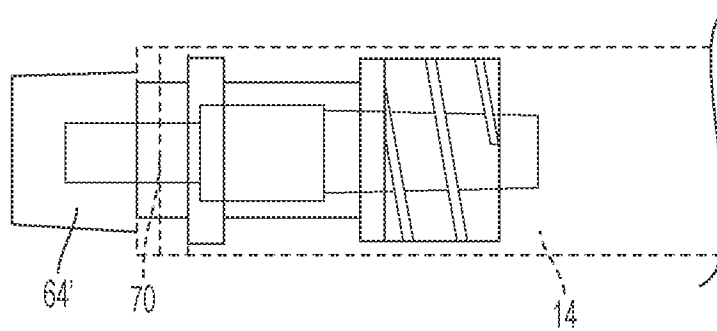


FIG. 6D

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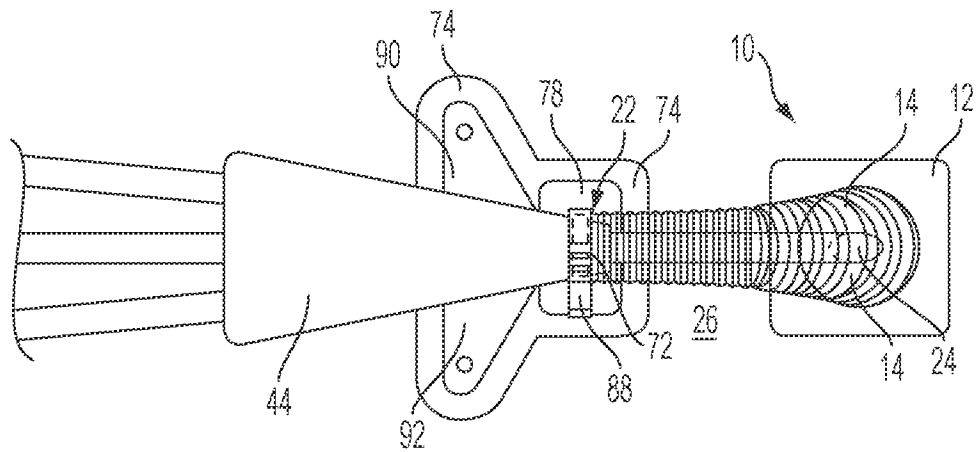


FIG. 7A

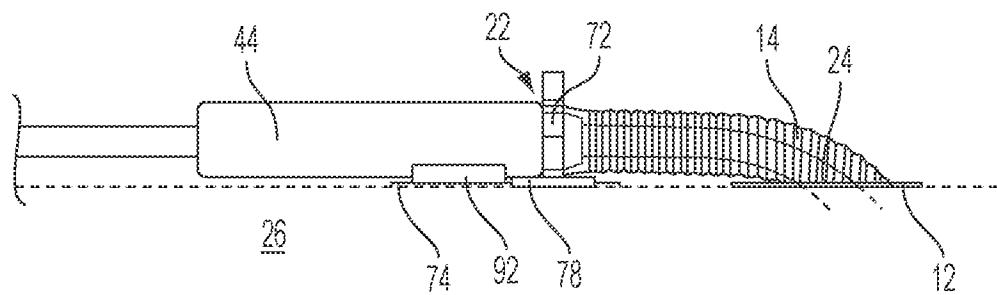


FIG. 7B

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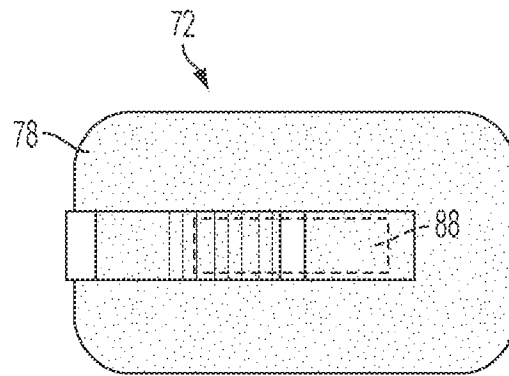


FIG. 7C

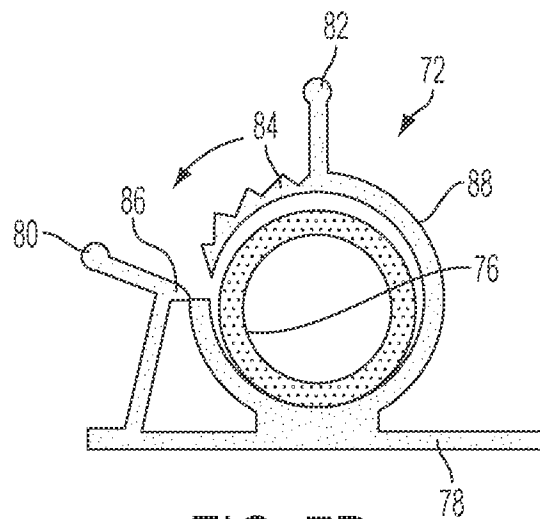


FIG. 7D

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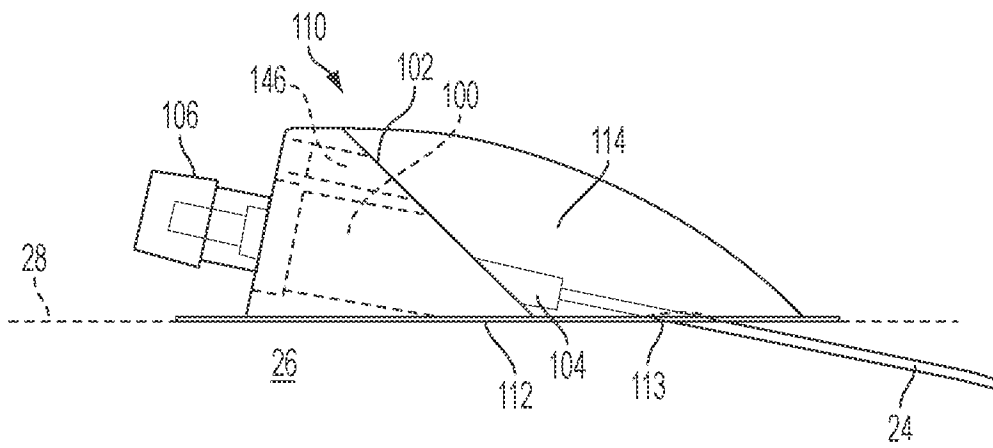


FIG. 8A

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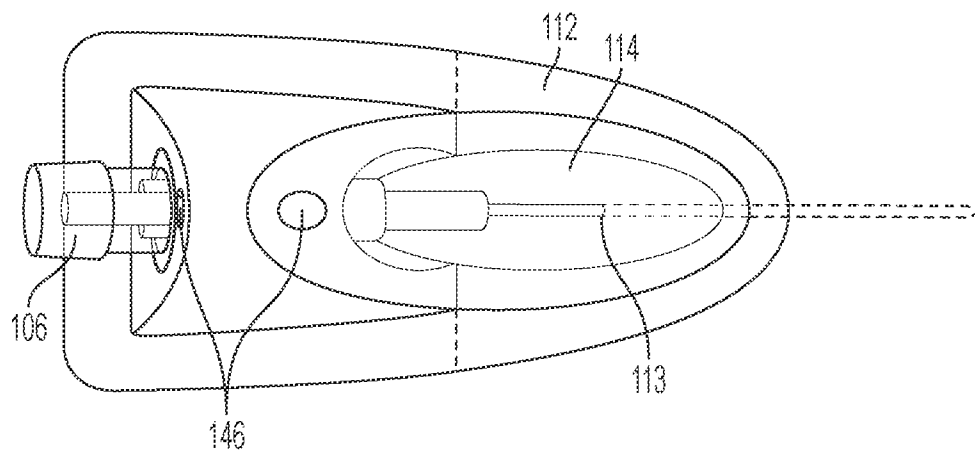


FIG. 8B

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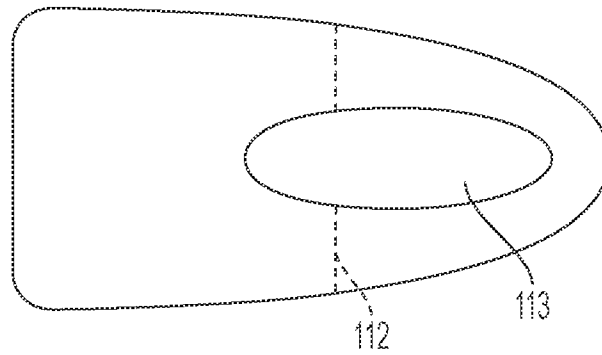


FIG. 8C

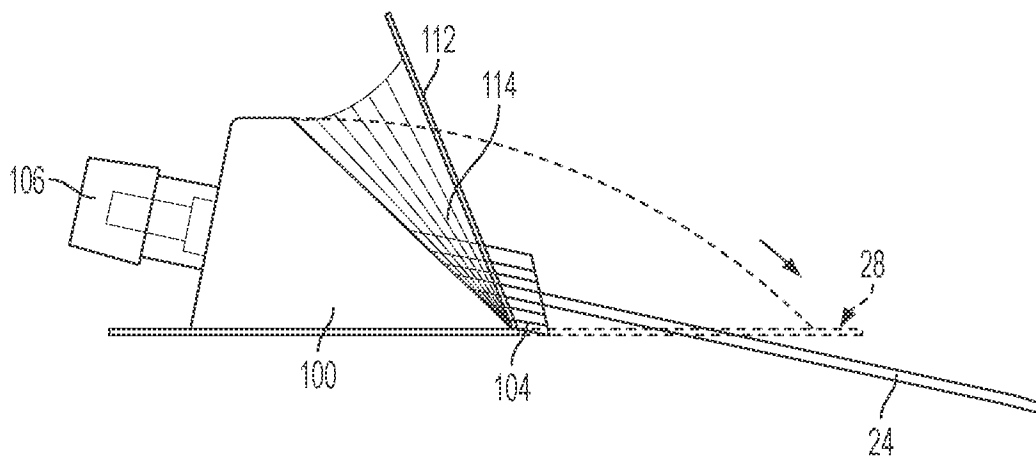


FIG. 8D

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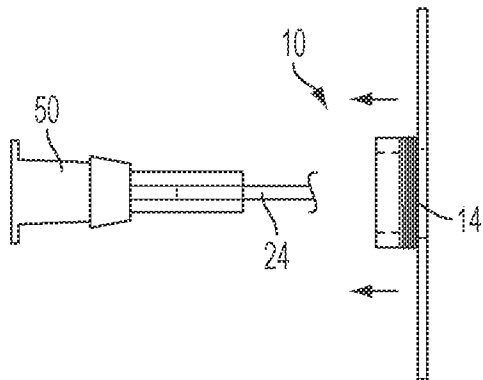


FIG. 9A

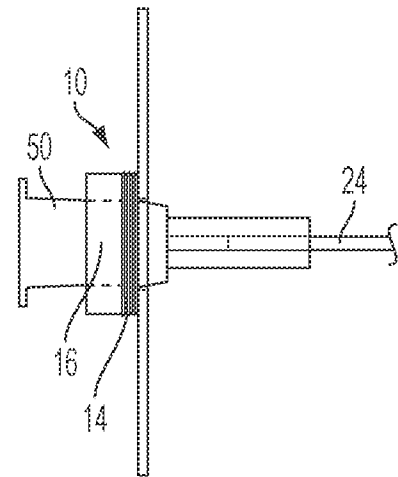


FIG. 9B

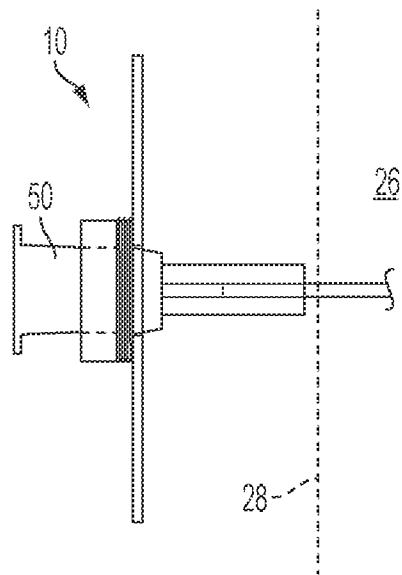


FIG. 9C

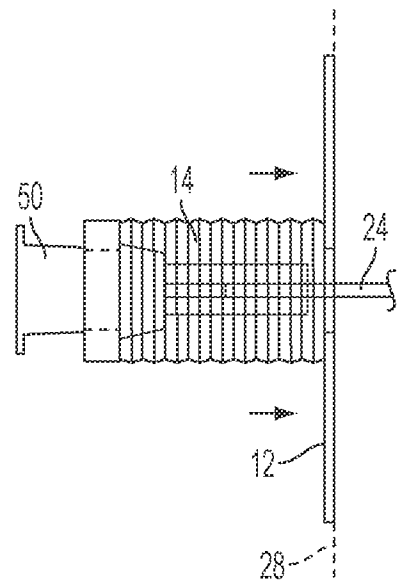


FIG. 9D

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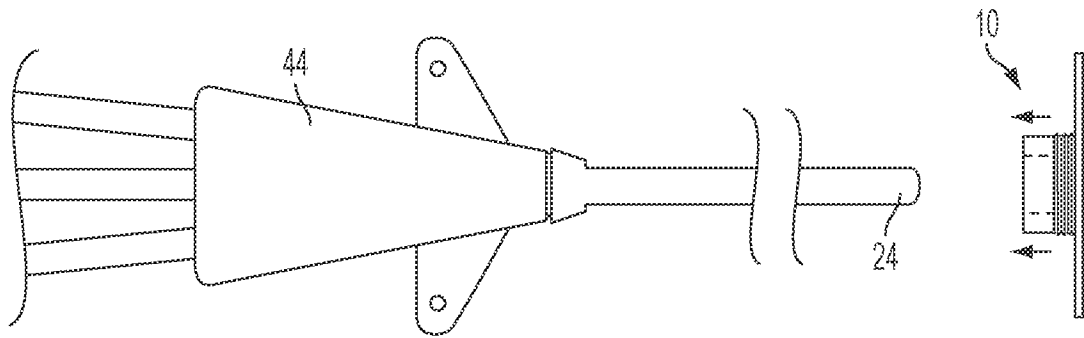


FIG. 10A

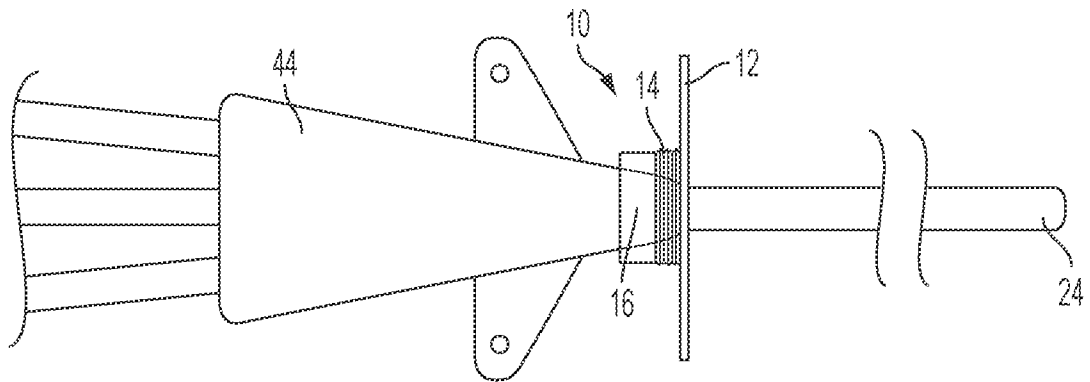


FIG. 10B

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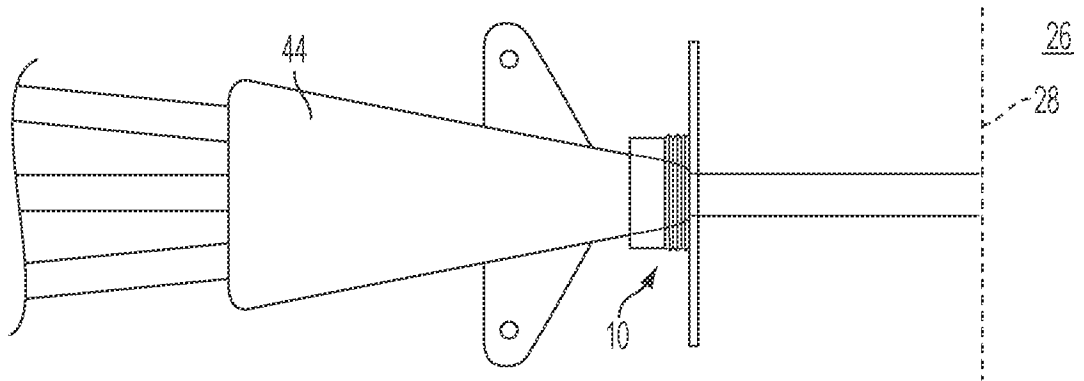


FIG. 10C

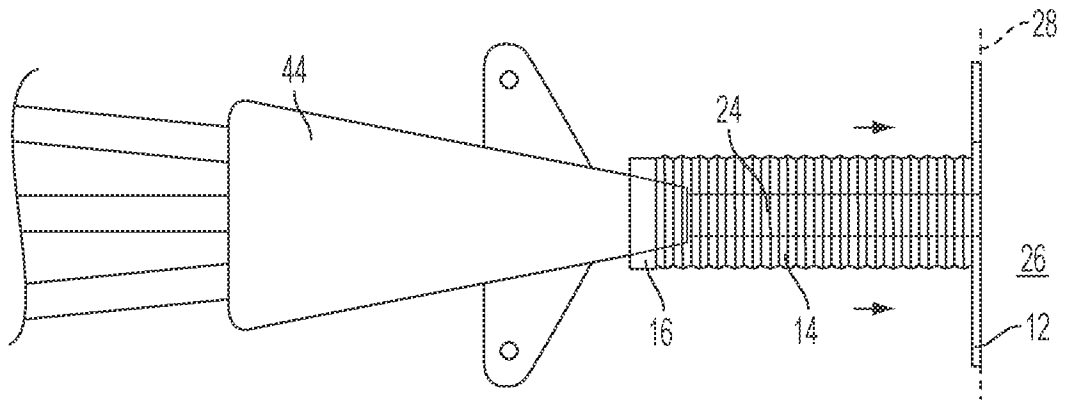


FIG. 10D

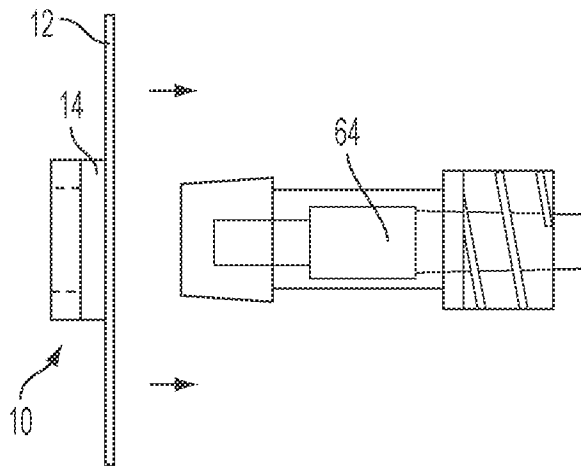


FIG. 11A

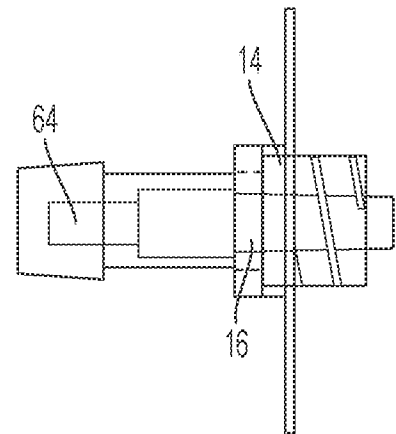


FIG. 11B

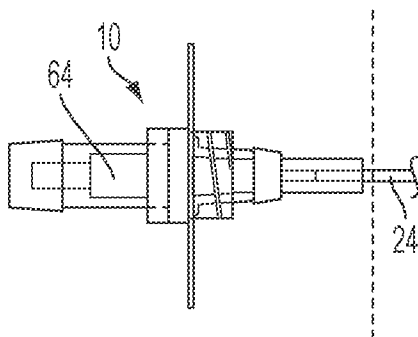


FIG. 11C

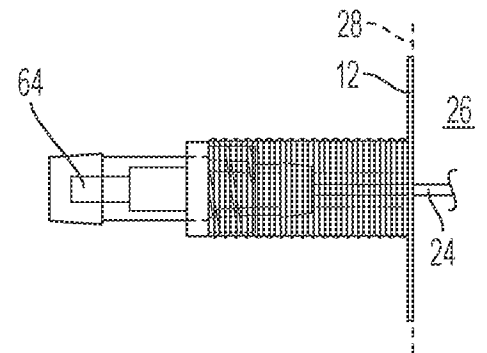


FIG. 11D

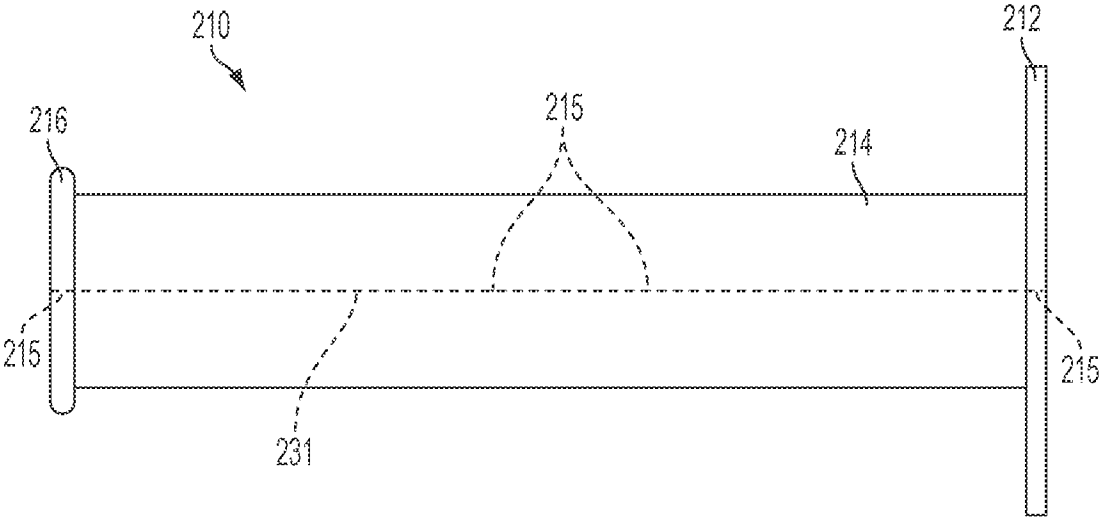


FIG. 12

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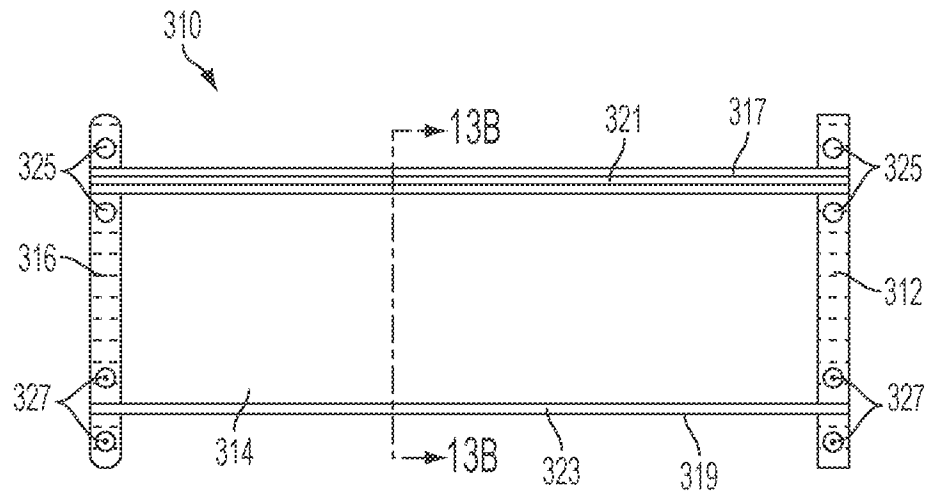


FIG. 13A

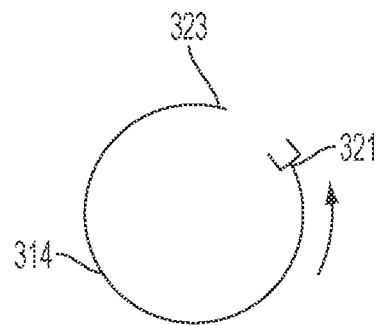


FIG. 13B

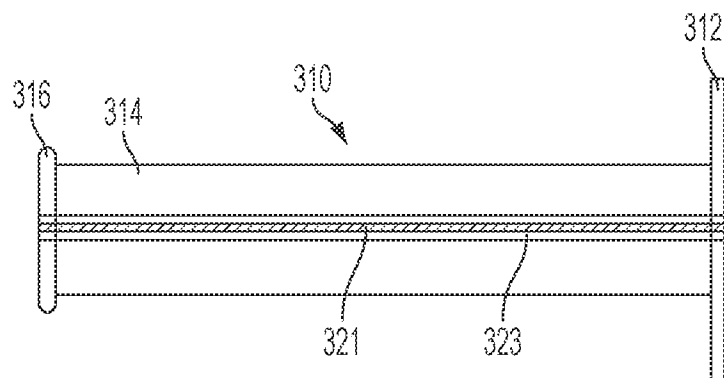


FIG. 13C

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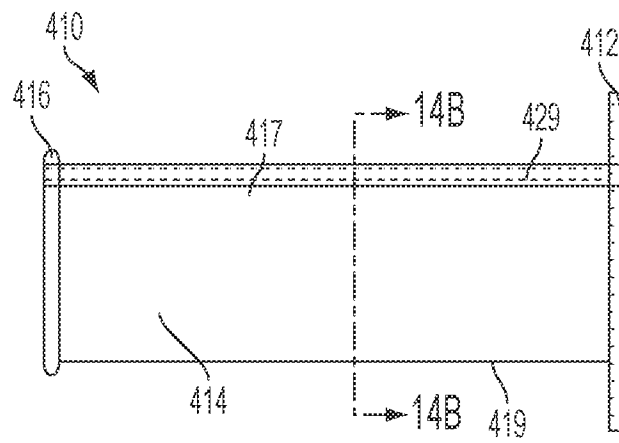


FIG. 14A

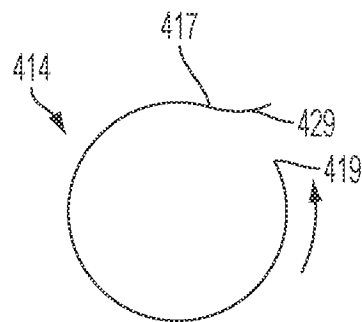


FIG. 14B

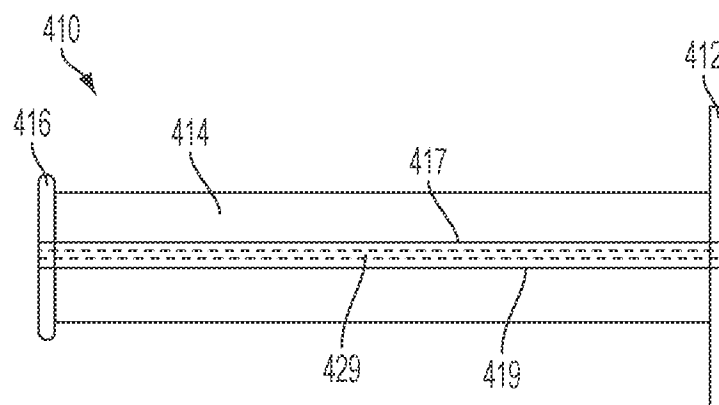


FIG. 14C

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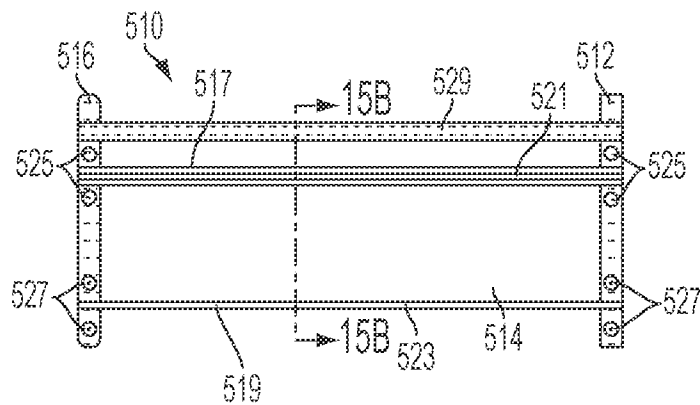


FIG. 15A

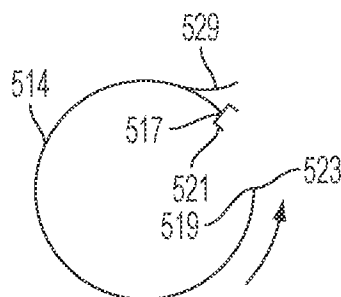


FIG. 15B

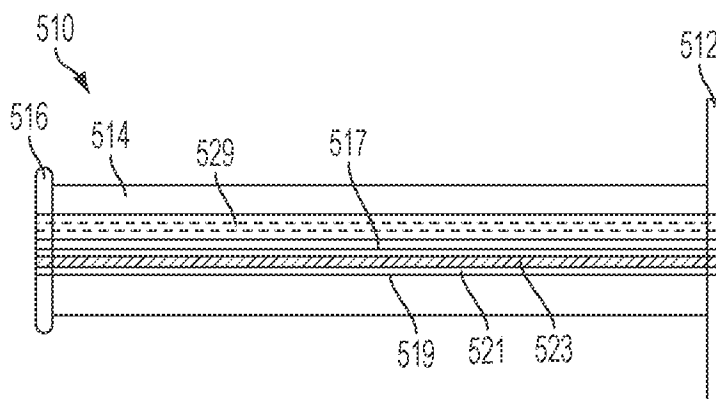


FIG. 15C

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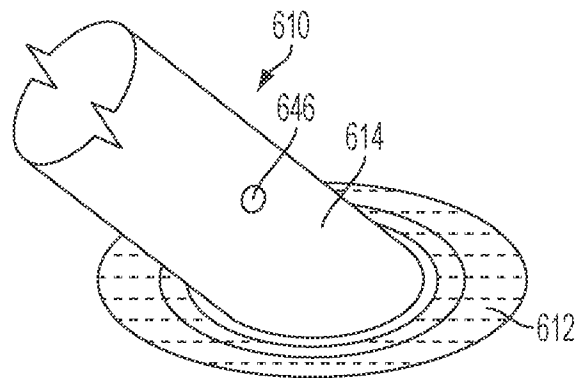


FIG. 16A

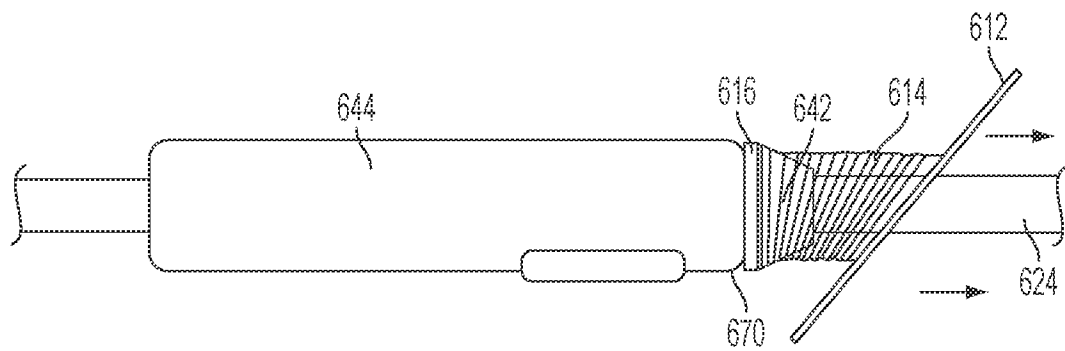


FIG. 16B

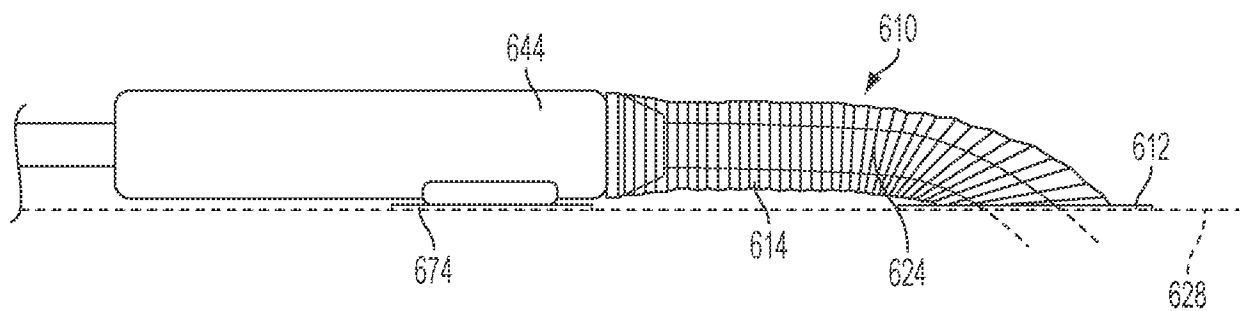


FIG. 16C

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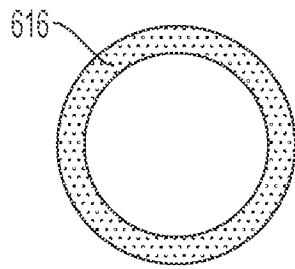


FIG. 16D

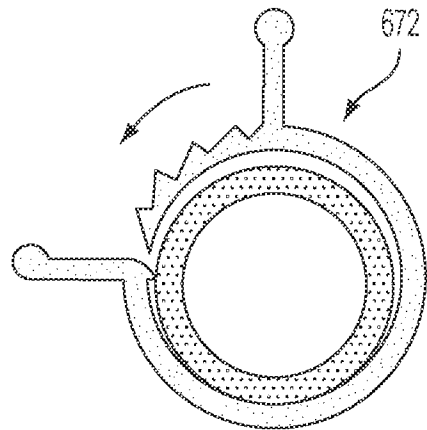


FIG. 16E

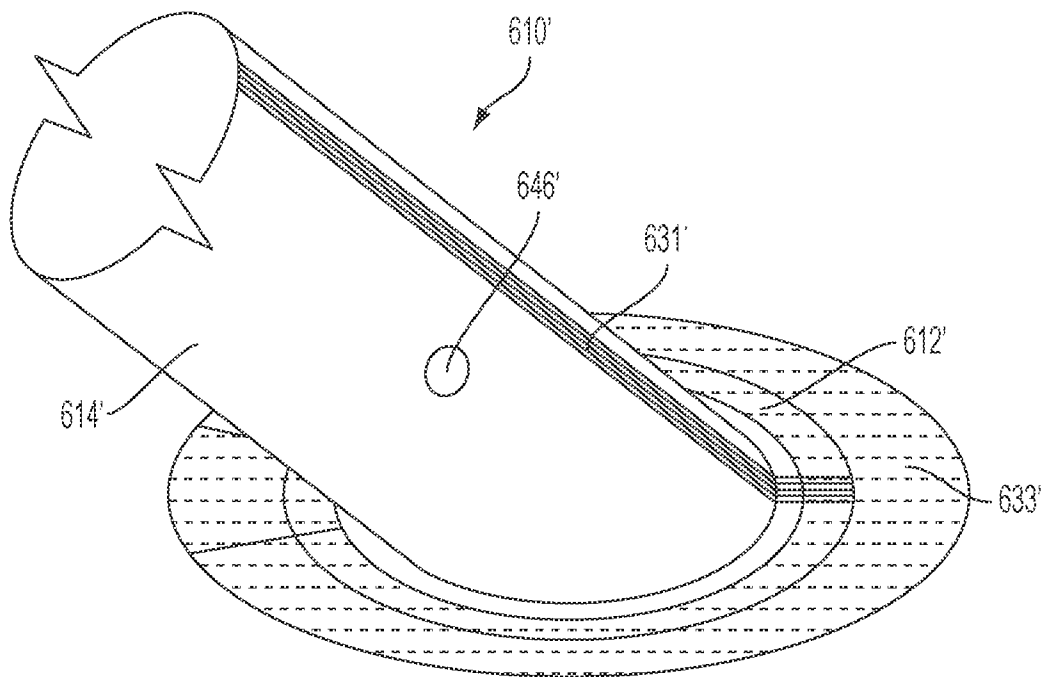


FIG. 17A

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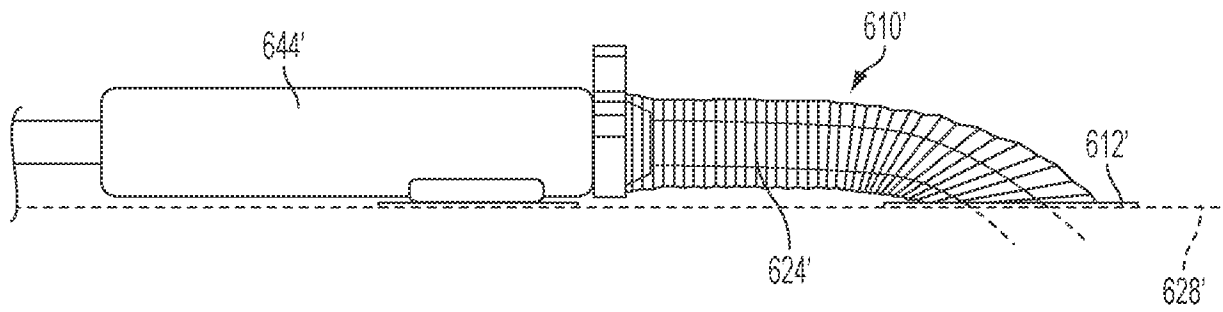


FIG. 17B

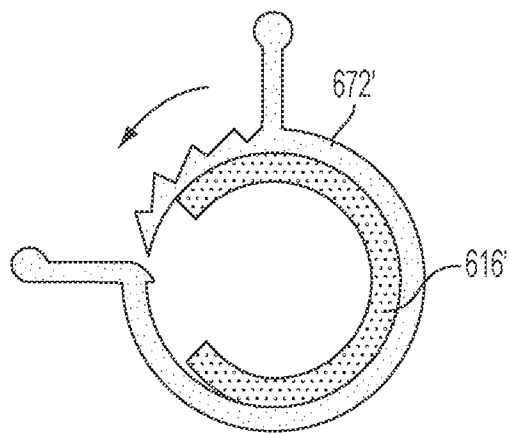


FIG. 17C

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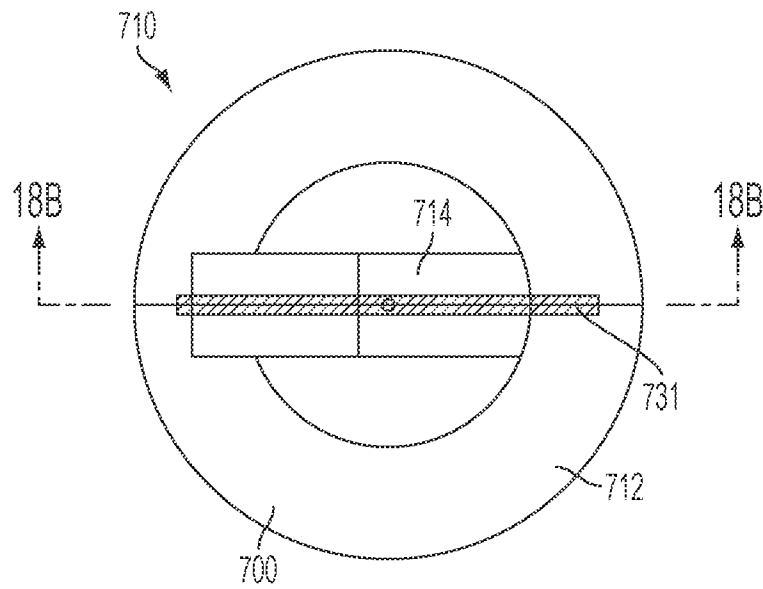


FIG. 18A

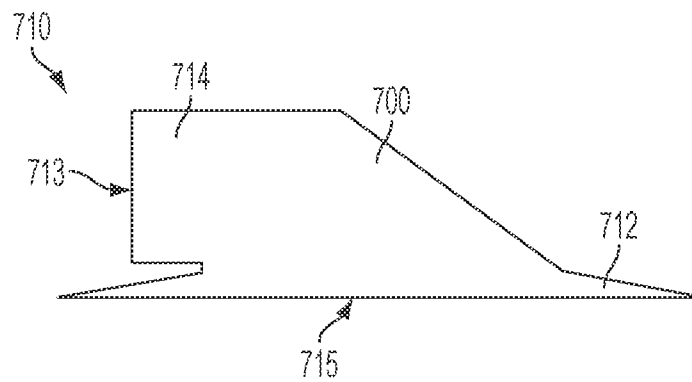


FIG. 18B

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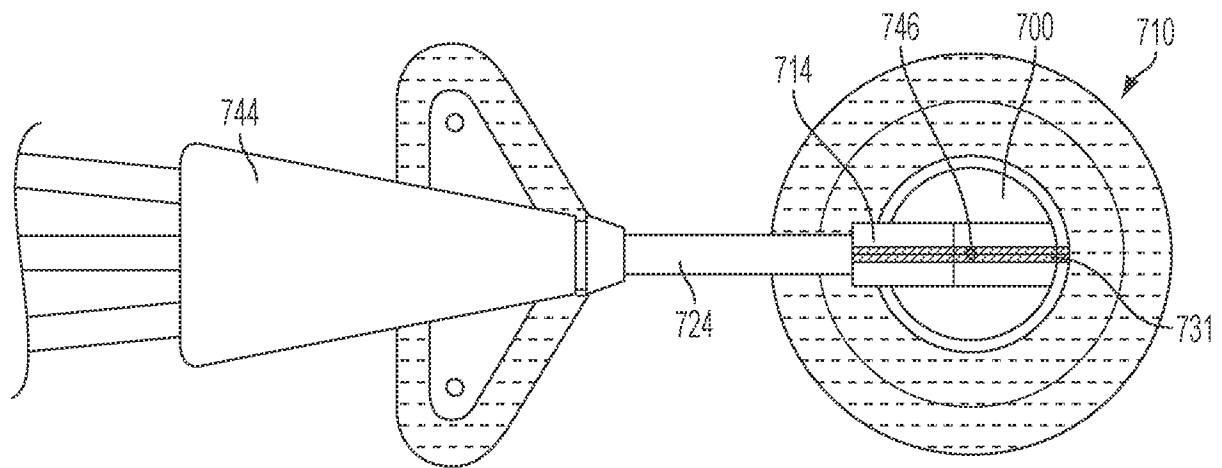


FIG. 18C

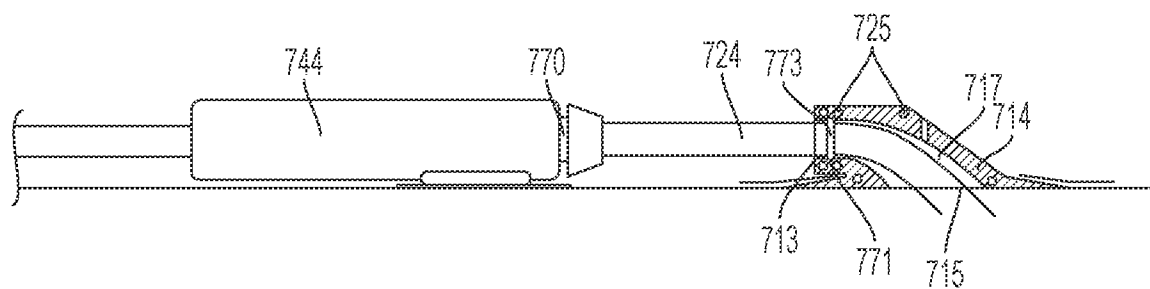


FIG. 18D

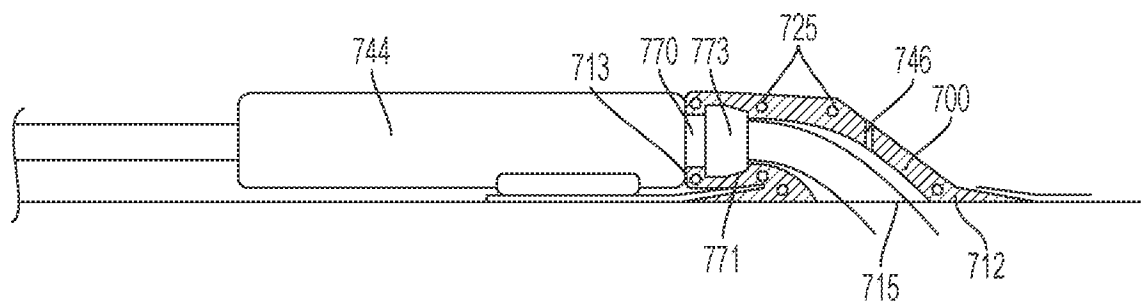


FIG. 18E

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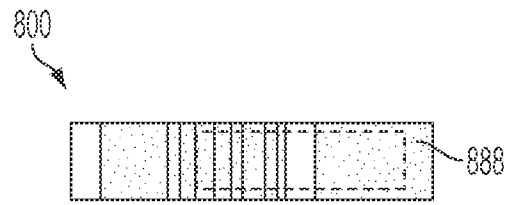


FIG. 19A

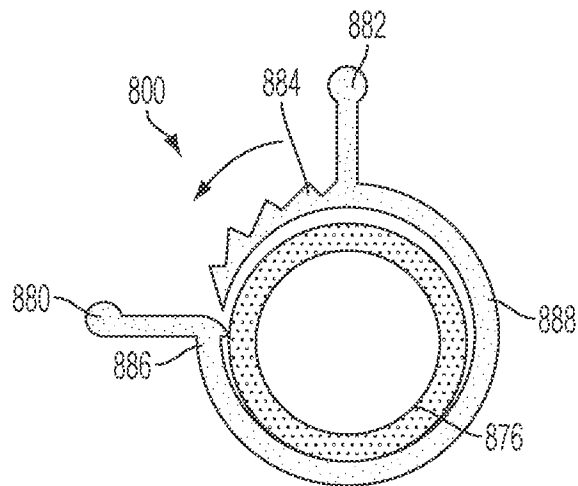


FIG. 19B

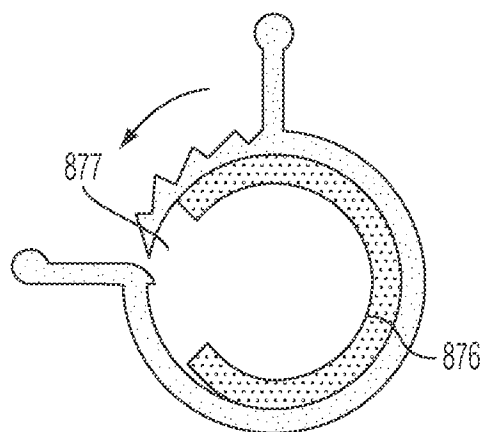


FIG. 19C

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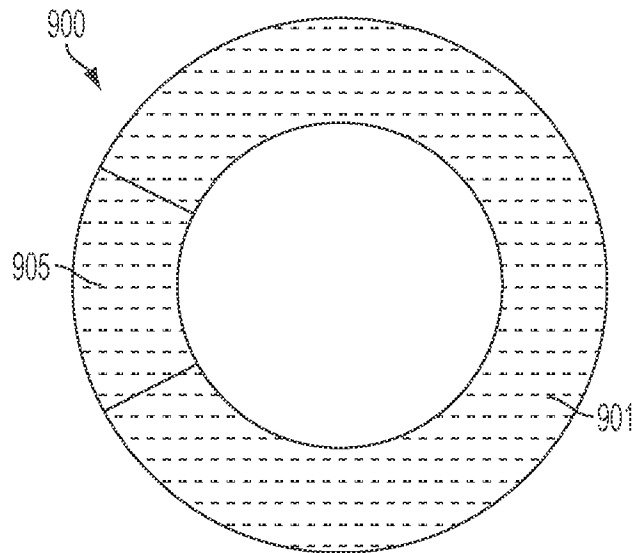


FIG. 20A

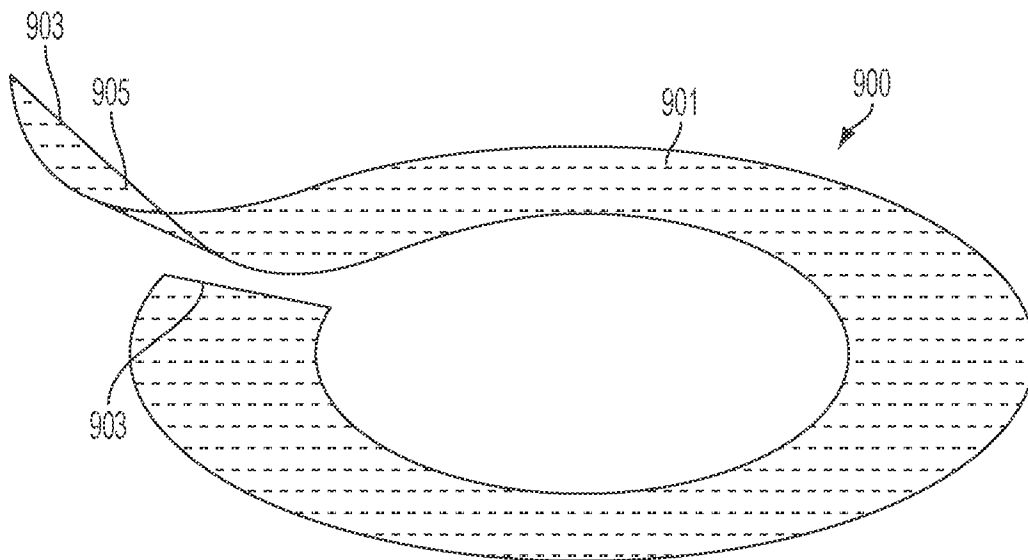


FIG. 20B

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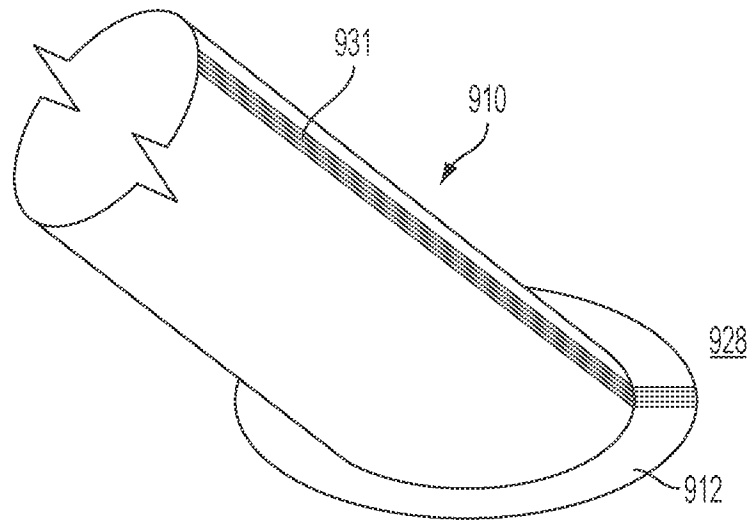


FIG. 20C

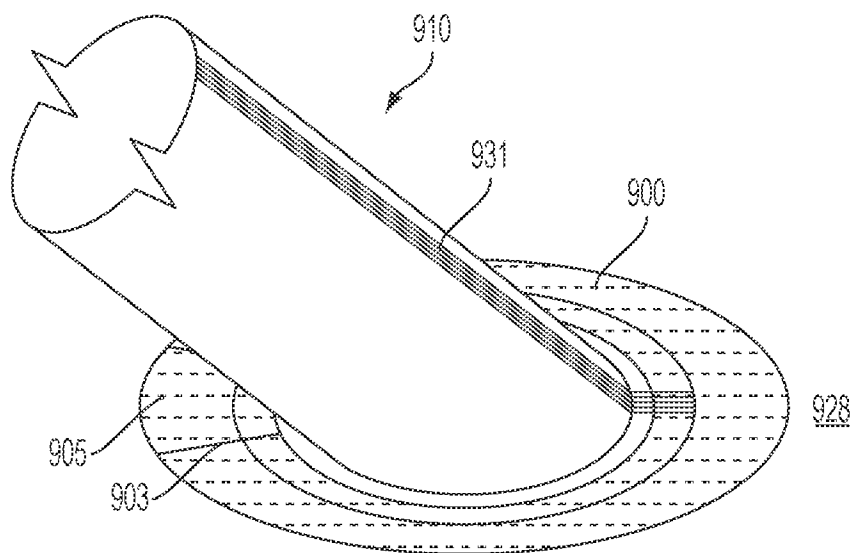


FIG. 20D