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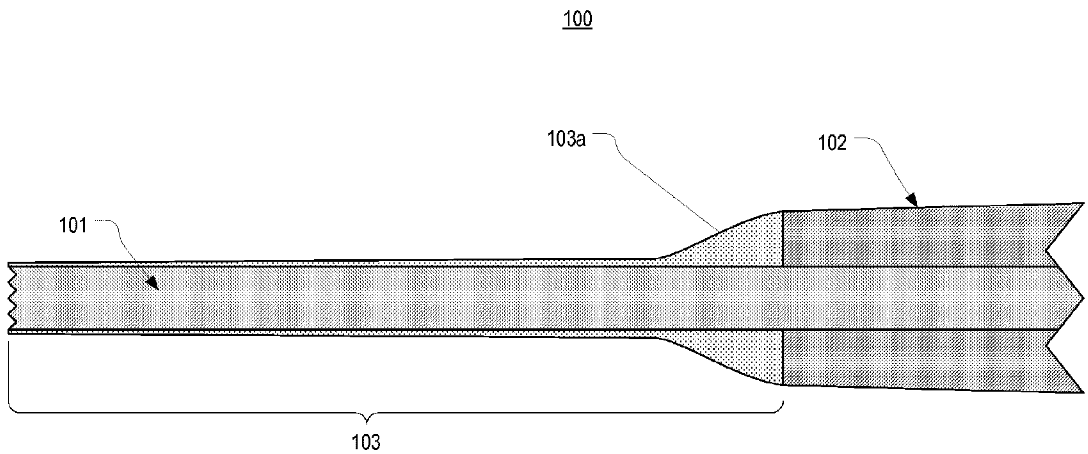
(54) Title: ANTIMICROBIAL COATING FORMING KINK RESISTANT FEATURE ON A VASCULAR ACCESS DEVICE



(57) Abrégé/Abstract:
A vascular access device includes an antimicrobial coating that provides kink resistance to a catheter. The antimicrobial coating can extend along a length of the catheter to provide antimicrobial protection when the catheter is inserted into the patient's vasculature. The antimicrobial coating can also increase the effective diameter of the catheter to minimize the likelihood that the catheter will become kinked.

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(54) Title: ANTIMICROBIAL COATING FORMING KINK RESISTANT FEATURE ON A VASCULAR ACCESS DEVICE

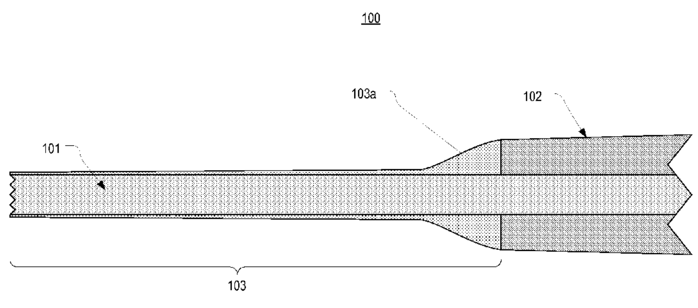

FIG. 2

(57) Abstract: A vascular access device includes an antimicrobial coating that provides kink resistance to a catheter. The antimicrobial coating can extend along a length of the catheter to provide antimicrobial protection when the catheter is inserted into the patient's vasculature. The antimicrobial coating can also increase the effective diameter of the catheter to minimize the likelihood that the catheter will become kinked.

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ANTIMICROBIAL COATING FORMING KINK RESISTANT FEATURE ON A VASCULAR ACCESS DEVICE

BACKGROUND OF THE INVENTION

[0001] The present invention relates generally to vascular access devices that include an antimicrobial coating. In particular, the present invention is directed to an antimicrobial coating that forms a kink resistant feature on a vascular access device.

[0002] It is becoming more common for vascular access devices such as catheters to include an antimicrobial coating to minimize the occurrence of infections caused by the use of the vascular access device. For example, catheters oftentimes include an antimicrobial lubricant that provides lubrication during insertion of the catheter into the patient's vasculature and then provides antimicrobial protection while the catheter is inserted.

[0003] One problem that exists with the use of current antimicrobial coatings is the risk of toxicity caused when excess antimicrobial agents enter the bloodstream or are distributed to a confined location. In order to obtain antimicrobial protection for a substantial duration of time (e.g. for the entire time that the catheter is inserted), a significant amount of antimicrobial lubrication must be present on the catheter. With the use of significant amounts of lubrication, there is a risk that too high of a concentration of antimicrobial agents will be distributed.

[0004] Another problem that exists with the use of catheters is kinking. For example, when a peripheral intravenous catheter is inserted into the patient's vasculature, it will typically be bent at the point where the catheter exits the catheter adapter (e.g. due to catheter adapter being placed flat on the patient's skin) and possibly where the catheter enters through the patient's skin or vasculature. This bending can oftentimes result in kinks that limit or prevent fluid flow through the catheter.

BRIEF SUMMARY OF THE INVENTION

[0005] The present invention extends to vascular access devices that include an antimicrobial coating that provides kink resistance to a catheter. The antimicrobial coating can extend along a length of the catheter to provide antimicrobial protection when the catheter is inserted into the patient's vasculature. The antimicrobial coating can also increase the effective diameter of the catheter to minimize the likelihood that the catheter will become kinked.

[0006] In one embodiment, the present invention is implemented as a vascular access device. The vascular access device includes a catheter adapter, a catheter that extends distally from the catheter adapter, and an antimicrobial coating. The antimicrobial coating is applied to at least a portion of the catheter adapter and comprises a base material that releases one or more antimicrobial agents when the antimicrobial coating is inserted within a patient's skin. The base material also provides kink resistance to the catheter.

[0007] In some embodiments, the antimicrobial coating can be positioned adjacent the catheter adapter and/or can include an increased diameter portion. In some embodiments, the increased diameter portion is positioned adjacent the catheter adapter.

[0008] In some embodiments, the length of the antimicrobial coating can be configured so that the distal end of the antimicrobial coating is positioned near an intimal layer of a vein when the catheter is inserted into the vein. In some embodiments, this length can be between 7 mm and 12 mm.

[0009] In some embodiments, the base material can be hydroscopic to enhance the release of the antimicrobial agents when the antimicrobial coating is positioned within the patient's skin. In some embodiments, the base material can be a UV cured acrylate-urethane or a heat-cured polyurethane. In some embodiments, the base material may have a hardness that slightly exceeds a hardness of the catheter.

[0010] In some embodiments, the vascular access device can also include an antimicrobial lubricant that is applied to the catheter. In some embodiments, the antimicrobial lubricant can be applied to a portion of the catheter that does not include the antimicrobial coating.

[0011] In another embodiment, the present invention is implemented as a vascular access device. The vascular access device includes a catheter adapter, a catheter that extends distally from the catheter adapter, and an antimicrobial coating. The antimicrobial coating extends from the catheter adapter towards a distal end of the catheter and has an increased diameter portion adjacent the catheter adapter.

[0012] In another embodiment, the present invention is implemented as a catheter that comprises an antimicrobial coating applied to a portion of the catheter. The antimicrobial coating has a proximal end and a distal end. The proximal end comprises an increased diameter portion. The antimicrobial coating also comprises a base material that releases one or more antimicrobial agents when the antimicrobial coating is positioned within a patient's skin.

[0013] This summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter.

[0014] Additional features and advantages of the invention will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by the practice of the invention. The features and advantages of the invention may be realized and obtained by means of the instruments and combinations particularly pointed out in the appended claims. These and other features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] In order to describe the manner in which the above-recited and other advantages and features of the invention can be obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered to be limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0016] Figure 1 is a perspective view of a vascular access device that includes an antimicrobial coating that functions as a kink resistant feature on the catheter.

[0017] Figure 1A is a perspective view of the vascular access device of Figure 1 showing the antimicrobial coating along a length of the catheter.

[0018] Figure 2 illustrates a cross-sectional view of a portion of a vascular access device.

[0019] Figure 3 illustrates a cross-sectional view of the vascular access device of Figure 2 when it has been inserted into the vasculature of a patient.

[0020] Figure 3A is a detailed cross-sectional view of the antimicrobial coating in contact with dermal layers of the skin, the primary source of resident bacteria.

[0021] Figure 4 is a cross-sectional view of a vascular access device with the addition of an antimicrobial lubricant on a distal portion of the catheter.

[0022] Figure 5 is a cross-sectional view of a vascular access device when the antimicrobial coating extends along a full length of the catheter.

DETAILED DESCRIPTION OF THE INVENTION

[0023] Figure 1 illustrates an example vascular access device 100 that includes an antimicrobial coating 103 in accordance with one or more embodiments of the invention. Vascular access device 100 includes a catheter adapter 102 and a catheter 101 that extends distally from the catheter adapter. Although vascular access device 100 is shown as including extension tubing, a vascular access device in accordance with the present invention need not include extension tubing. Further, vascular access device 100 is an example of a peripheral intravenous catheter. However, an antimicrobial coating in accordance with the present invention can be applied on other types of catheters including central venous catheters and peripherally inserted central catheters. In short, any device that includes a flexible component that is inserted into the vasculature of a patient can include an antimicrobial coating on the component in accordance with one or more embodiments of the present invention.

[0024] The antimicrobial coating may comprise any material that has anti-pathogenic properties which may be applied to the surface of a catheter and that has sufficient rigidity to minimize the likelihood that the catheter will become kinked when it is bent. For example, in some embodiments, the antimicrobial coating can comprise a base material matrix and one or more antimicrobial agents. In some embodiments, the base material matrix can be a UV curable, hydrophilic material that contains an antimicrobial agent with controlled release (elution) characteristics. Alternatively, a base material can be coated with an antimicrobial coating from which an antimicrobial agent will elute when subject to a fluid.

[0025] For example, the base material, in some embodiments, can be a water softening UV cure matrix such as UV cured acrylate-urethanes, or heat-cured polyurethanes. Water softening materials can be preferred in many implementations over non-softening materials as such materials become more flexible when inserted into the patient and exposed to fluid. Catheters are oftentimes formed of such water softening materials. Therefore, using an antimicrobial coating that also consists of a water softening material can match the properties of the coating to the catheter to minimize any negative impact the coating may have on the performance of the catheter and on patient comfort. For example, in some embodiments, the hardness of the antimicrobial coating may only slightly exceed that of the catheter. This increased hardness minimizes the likelihood that the catheter will become kinked while minimally affecting the patient's comfort during catheter use because the catheter remains substantially elastic.

[0026] Examples of materials that could be used to form the antimicrobial coating of the present invention includes those disclosed in U.S. Patent No.: 8,512,294 titled Vascular Access Device Antimicrobial Materials And Solutions; U.S. Patent Application No.: 12/397,760 titled Antimicrobial Compositions; U.S. Patent Application No.: 12/476,997 titled Antimicrobial Coating Compositions; U.S. Patent Application No.: 12/490,235 titled Systems And Methods For Applying An Antimicrobial Coating To A Medical Device; and U.S. Patent

[0027] In one particular embodiment, the antimicrobial agent used to form the antimicrobial coating can be chlorhexidine including chlorhexidine diacetate (CHA) and/or chlorhexidine gluconate (CHG). However, any other antimicrobial agent that will elute from a base material or from a coating on a base material could be used.

[0028] Figure 1A illustrates a detailed view of catheter 101 and antimicrobial coating 103. As shown, antimicrobial coating 103 can extend from catheter adapter 102 along a portion of catheter 101. In this example, antimicrobial coating 103 extends along about half the length of catheter 101. However, in some embodiments, antimicrobial coating 103 can extend along a larger or smaller length of catheter 101, including extending to the distal tip.

[0029] As best seen in Figure 1A, the proximal end of antimicrobial coating 103 can have a diameter that increases towards catheter adapter 102. Catheter 101 is most likely to kink as it exits from catheter adapter 102. Therefore, increasing the diameter of antimicrobial coating 103 towards catheter adapter 102 provides additional kink resistance where kinks would otherwise be most likely to occur. In some embodiments, such as is shown in Figure 1A, the increase in the diameter of antimicrobial coating 103 can be gradually increased to the point that the antimicrobial coating has the same diameter as the nose of catheter adapter 102.

[0030] Although in Figures 1 and 1A antimicrobial coating 103 is shown as extending only up to catheter adapter 102, in some embodiments, the antimicrobial coating can extend proximally onto a portion of the catheter adapter. Also, in some embodiments, the diameter of the antimicrobial coating at the point where it meets the catheter adapter can be configured to be less than the diameter of the catheter adapter at that point. Further, in some embodiments, rather than having a gradually increasing diameter, the diameter may step up from a smaller diameter to a larger diameter at some distance from the catheter adapter. Accordingly, the present invention encompasses many different types of increases in the diameter of the antimicrobial coating as the coating approaches the catheter adapter.

[0031] Figure 1A also shows that the diameter of antimicrobial coating 103 decreases to a minimal amount at the distal end of the coating. Having a minimal diameter at the distal end of the coating can minimize any discomfort caused to the patient when catheter 101 is inserted.

[0032] Figure 1A also illustrates that, in some embodiments, an antimicrobial lube 104 can be applied to any portion of the catheter that does not include the antimicrobial coating.

However, the present invention encompasses embodiments where only an antimicrobial coating is applied to a catheter regardless of whether the antimicrobial coating extends only along a portion of the length of the catheter.

[0033] Figure 2 provides a cross-sectional view of vascular access device 100 to better illustrate the increase in the diameter of antimicrobial coating 103. As shown, towards a distal end of antimicrobial coating 103, the diameter of the coating is minimal. In some embodiments, the diameter at this distal end may be between 10 and 100 microns. Then, as antimicrobial coating 103 approaches catheter adapter 102, the diameter gradually increases to form an increased diameter portion 103a. Increased diameter portion 103a can provide increased kink resistance to the catheter as it exits catheter adapter 102. For example, because of the increased diameter of portion 103a, the catheter will be unlikely to bend sufficiently at the point that it exits catheter adapter 102 to cause a kink. In other words, increased diameter portion 103a will tend to cause catheter 101 to bend more gradually as it exits catheter adapter 102 rather than bending sharply at the exit point. Similarly, the other (smaller diameter) portions of antimicrobial coating 103 can provide additional rigidity to catheter 101 to minimize the likelihood of any sharp bends that may result in kinks.

[0034] Figure 3 illustrates how antimicrobial coating 103 can provide kink resistance to catheter 101. As shown, catheter adapter 102 is positioned generally flat on the patient's skin 300. Because of this, catheter 101 will be angled downward from the point where it exits catheter adapter 102 to the point where it enters through the patient's skin 300. Antimicrobial coating 103, and more particularly, increased diameter portion 103a causes catheter 101 to bend more gradually between the insertion point and catheter adapter 102 thereby minimizing the likelihood of kinking.

[0035] Figure 3 also illustrates an example where the length of antimicrobial coating 103 is configured so that the coating extends through the dermal layers of skin 300 and into the entrance to vein 301. In this way, antimicrobial agents can be released from antimicrobial coating 103 directly to the dermal layers and at the insertion points into skin 300 and into vein 301. These locations, and particularly the dermal layers, are the primary source of bacteria that may enter vein 301. For this reason, the length of antimicrobial coating 103 can be configured to ensure that antimicrobial agents are targeted to these locations.

[0036] Figure 3A provides a detailed view of a portion of Figure 3 to illustrate the dermal layers 302 of skin 300 where catheter 101 is inserted. As shown, antimicrobial coating 103 has a sufficient length to ensure that the coating is in contact with the dermal layers. By employing an antimicrobial coating that elutes antimicrobial agents (e.g. a coating that is hydroscopic), the antimicrobial agents can be distributed to the dermal layers (and surrounding areas) in a controlled manner to minimize the possibility of toxicity from the agents.

[0037] As addressed above, when an antimicrobial lubricant is used to provide antimicrobial protection to these dermal layers, there is a greater risk of toxicity because it is difficult to ensure that the antimicrobial agents will be localized to the dermal layers and not introduced into the patient's vasculature at toxic levels. In contrast, by employing an antimicrobial coating comprising a base material that elutes antimicrobial agents, the antimicrobial agents can be accurately distributed to the dermal layers 302 and released at a rate that provides long term antimicrobial protection. In other words, antimicrobial coating 103 can limit the total amount of a particular antimicrobial agent that elutes throughout the life of the device, and concentrate the agent in the area of maximum benefit.

[0038] To ensure proper positioning of antimicrobial coating 103 when vascular access device 100 is used, antimicrobial coating 103 can be configured with an appropriate length. For example, the depth of tissue between the outer layers of skin and the intimal layers of the vein is commonly between 3 mm and 6 mm. Also, it is typical for 4 mm to 6 mm of the catheter to remain outside of the skin. Therefore, in some embodiments, the length of antimicrobial coating 103 can extend from 7 mm to 12 mm from the catheter adapter to ensure that the distal end of the coating is positioned at least at, if not beyond, the intimal layers of the vein.

[0039] Of course, other lengths of antimicrobial coating may be used in other embodiments. In short, the length of the antimicrobial coating can be selected for a particular vascular access device based at least partially on the typical length of the catheter that remains outside of the skin when the particular vascular access device is used. For example, many catheters include a line or other indication that identifies how deep the catheter should be inserted. In some embodiments, the length of antimicrobial coating 103 can be based on the length of the catheter between the catheter adapter and this type of indication. Similarly, the length of the antimicrobial coating may also be based on the distance from the outer layers of the skin and the intimal layers of a vein where the catheter will be inserted (i.e. the length can be based on the intended location where the catheter will typically be inserted).

[0040] The antimicrobial coating of the present invention can be particularly beneficial on a vascular access device that is used to draw blood. It is becoming more common to draw blood samples through vascular access devices that have previously been used primarily to inject fluids into the patient's vasculature. When fluids are being injected, there is less concern for kinking because the pressure of the fluid tends to open any kinks that may otherwise occur in the catheter. However, when these same devices are employed to draw blood, kinking is more likely because of the reduced pressures and flow rates used when drawing blood. The antimicrobial coating of the present invention can therefore be particularly beneficial to prevent kinks during blood draw.

[0041] Figure 4 illustrates an alternate embodiment of the vascular access device depicted in Figure 3. Figure 4 differs from Figure 3 in that an antimicrobial lubricant 310 has been applied to the portion of catheter 101 that does not include antimicrobial coating 103. Antimicrobial lubricant 310, in some embodiments, may also extend at least partially over antimicrobial coating 103. Antimicrobial lubricant 310 can provide lubrication to catheter 101 to assist in insertion and can also provide additional antimicrobial protection throughout the insertion site. For example, as catheter 101 is inserted, antimicrobial lubricant 310 can rub off on the dermal layers of the skin to provide immediate and concentrated antimicrobial protection. Then, antimicrobial coating 103, once positioned within the dermal layers, can continue to provide antimicrobial protection in a controlled release and targeted manner. Antimicrobial lubricant 310 can also assist in preventing clots from forming on and in catheter 101, particularly in the distal opening or openings of catheter 101.

[0042] Figure 5 illustrates another alternate embodiment of the vascular access device depicted in Figure 3. Figure 5 differs from Figure 3 in that antimicrobial coating 103 extends to the distal end of catheter 101. In such cases, an antimicrobial lubricant, although not depicted, may also be used.

[0043] In accordance with one or more embodiments of the invention, an antimicrobial coating can be applied to a vascular access device by dispensing an uncured base material on the catheter adjacent the catheter adapter. This base material can be applied while spinning the catheter slowly (e.g. between 20 and 120 rpm). The catheter can continue to be spun while a die is used to draw the base material over the desired length of the catheter. In some embodiments, a clamshell die may be used. Then, the coating can be cured. In some embodiments, the catheter can continue to be spun while the coating is cured.

[0044] The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS

1. A vascular access device comprising:

a catheter adapter;

a catheter that extends distally from the catheter adapter and comprises a material; and

an antimicrobial coating comprising one or more antimicrobial agents applied to at least a portion of the catheter, the antimicrobial coating comprising a base material that releases the one or more antimicrobial agents when the antimicrobial coating is inserted within the skin of a patient, wherein the base material is UV cured, wherein the antimicrobial coating is uniform in thickness along a first portion of the catheter, wherein the antimicrobial coating increases in thickness along a second portion of the catheter adjacent the catheter adapter, wherein when the catheter is inserted into a vein of the patient, the first portion is configured to be positioned at least at an intimal layer of the vein and the second portion is configured to be disposed outside a body of the patient at least proximate the outer layers of the skin.

2. The vascular access device of claim 1, wherein the distal end of the antimicrobial coating is positioned proximal to the distal end of the catheter.

3. The vascular access device of claim 1, wherein the length of the antimicrobial coating is between 7 mm and 12 mm.

4. The vascular access device of claim 1, wherein the base material is hydroscopic.

5. The vascular access device of claim 1, wherein the base material is UV cured acrylate-urethane.

6. The vascular access device of claim 1, wherein the thickness of the antimicrobial coating at the distal end of the antimicrobial coating is between 10 microns and 100 microns.

7. The vascular access device of claim 1, further comprising:

an antimicrobial lubricant applied to the catheter.

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8. The vascular access device of claim 7, wherein the antimicrobial lubricant is applied to a portion of the catheter that does not include the antimicrobial coating.

9. A vascular access device comprising:

a catheter adapter;

a catheter that extends distally from the catheter adapter; and

an antimicrobial coating on the catheter extending from the catheter adapter towards the distal end of the catheter, wherein the antimicrobial coating comprises a base material that releases one or more antimicrobial agents when the catheter is inserted within the skin of a patient, wherein the base material is cured, the antimicrobial coating having a diameter portion adjacent the catheter adapter, wherein the antimicrobial coating increases in thickness from the distal portion of the catheter to the proximal portion of the catheter proximate the distal end of the catheter adapter.

10. The vascular access device of claim 9, wherein the antimicrobial coating has a hardness greater than the hardness of the catheter.

11. The vascular access device of claim 9, wherein the distal end of the antimicrobial coating is positioned at a length from the catheter adapter that corresponds with a length of the catheter that is intended to exist between an intimal layer of a vein and the catheter adapter when the catheter is inserted into the vein.

12. A vascular access device comprising:

a catheter adapter;

a catheter that extends distally from the catheter adapter; and

an antimicrobial coating, comprising one or more antimicrobial agents, applied to a portion of the catheter, the antimicrobial coating having a proximal end and a distal end, the antimicrobial coating comprising a base material that releases the one or more antimicrobial agents when the antimicrobial coating is positioned within the skin of a patient, wherein the base material is cured, wherein the antimicrobial coating is uniform in thickness along a first portion of the catheter, wherein the antimicrobial coating increases in thickness along a second portion of the catheter adjacent the catheter adapter, wherein the outer diameter of the

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antimicrobial coating at the proximal end of the second portion equals the outer diameter at the distal end of the catheter adapter.

13. The vascular access device of claim 1, wherein the length of the second portion is less than 6 mm.

14. The vascular access device of claim 1, wherein the thickness of the antimicrobial coating increases gradually along the second portion of the catheter.

15. The vascular access device of claim 1, wherein the thickness of the antimicrobial coating steps up from a smaller diameter to a larger diameter at some point along the second portion of the catheter.

16. The vascular access device of claim 1, wherein the antimicrobial coating extends beyond the distal end of the catheter adapter onto only a portion of the catheter adapter.

17. The vascular access device of claim 1, wherein the diameter of the antimicrobial coating at the point where the antimicrobial coating meets the catheter adapter is less than the diameter of the catheter adapter at the point.

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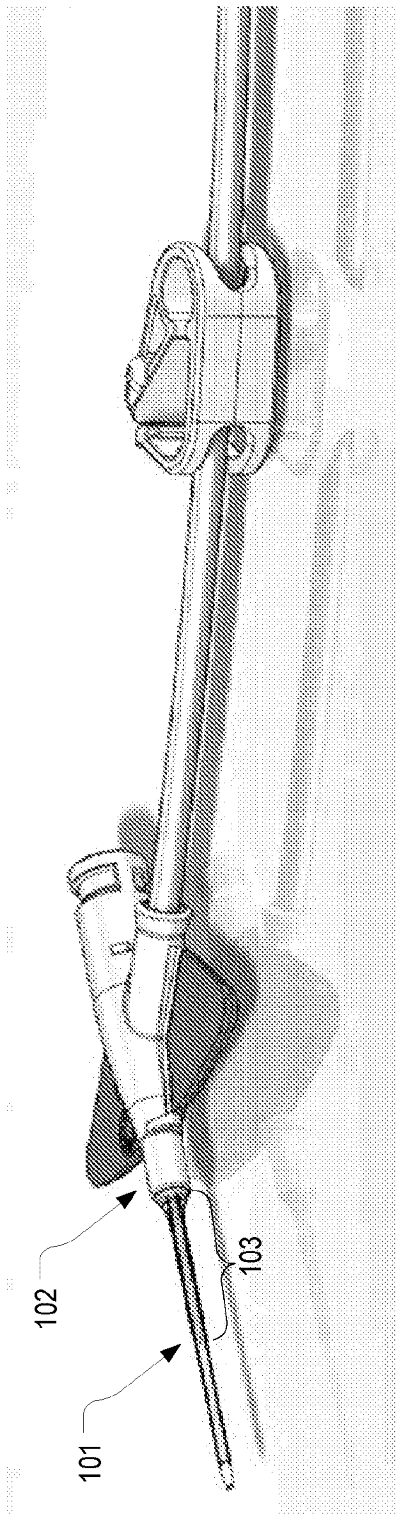

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FIG. 1

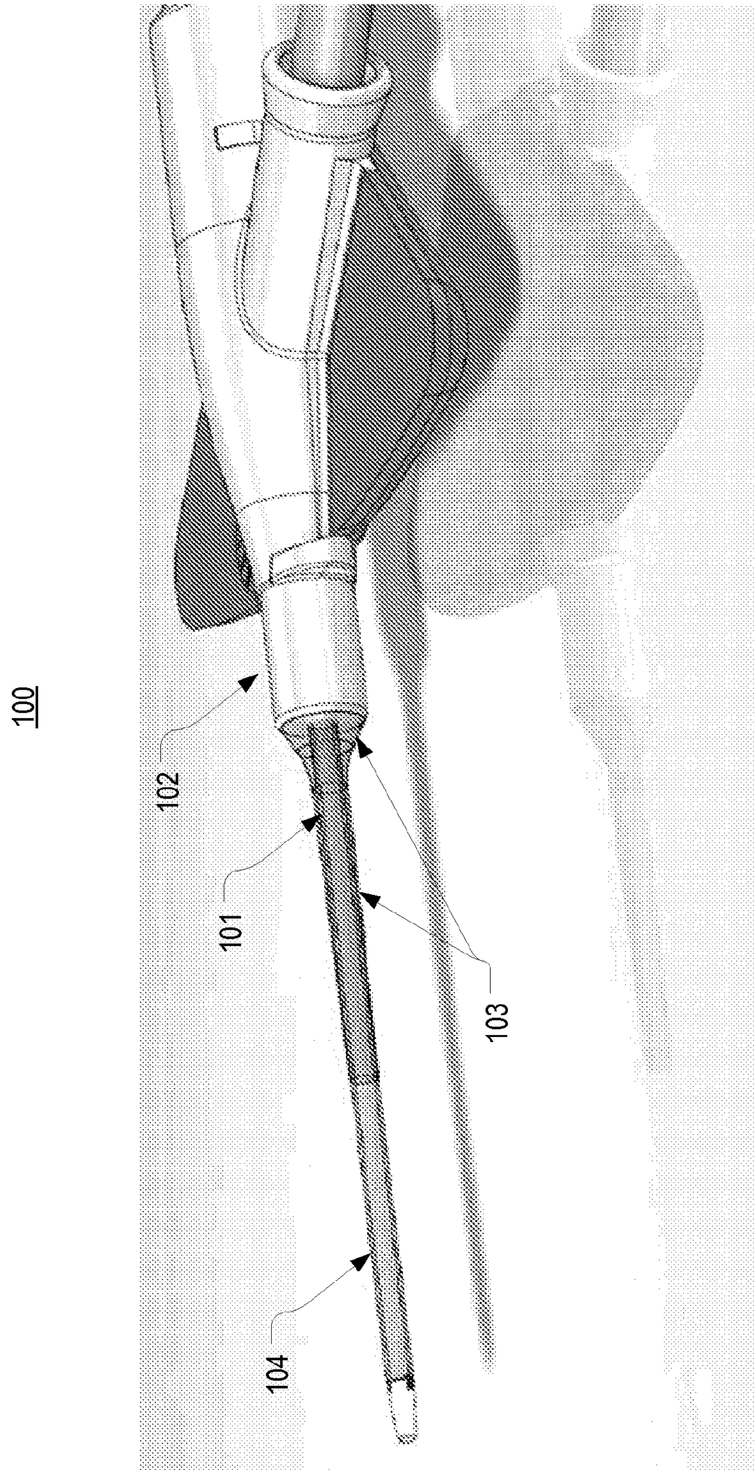

FIG. 1A

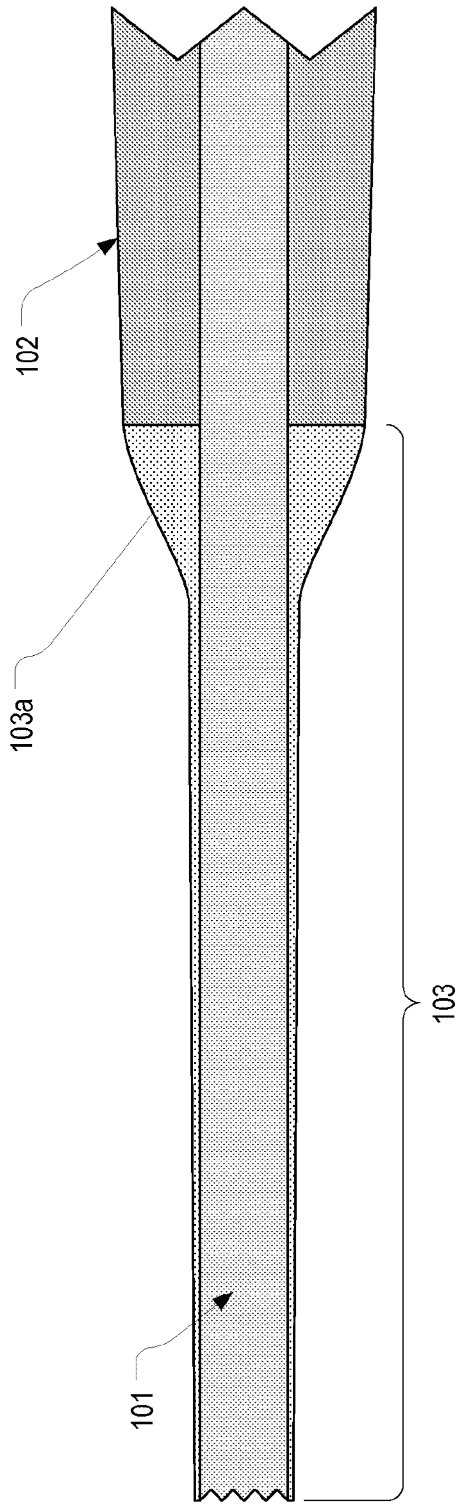

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FIG. 2

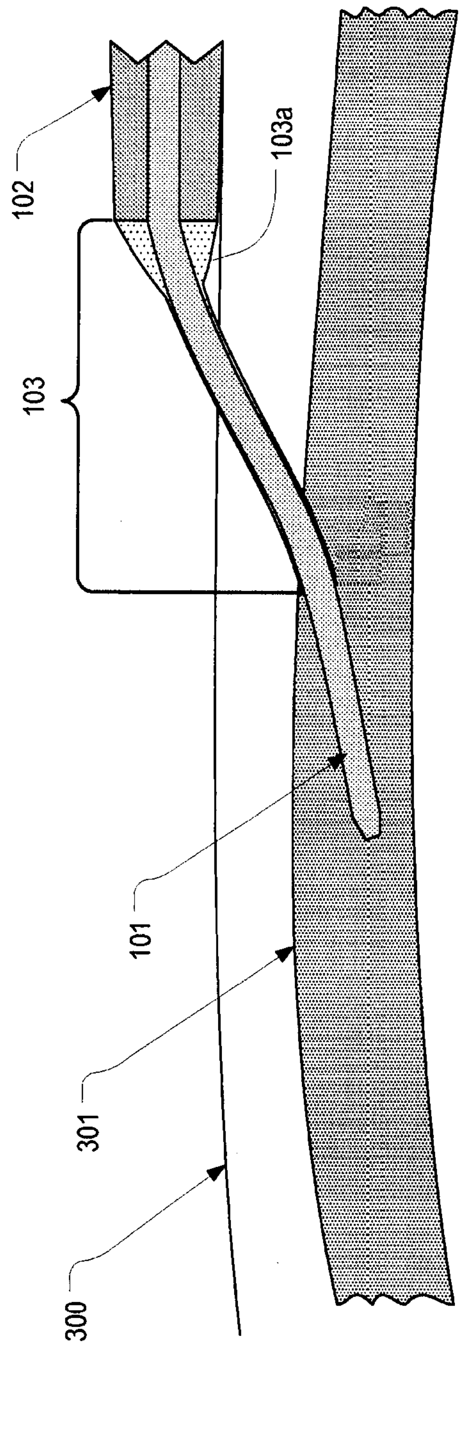


FIG. 3

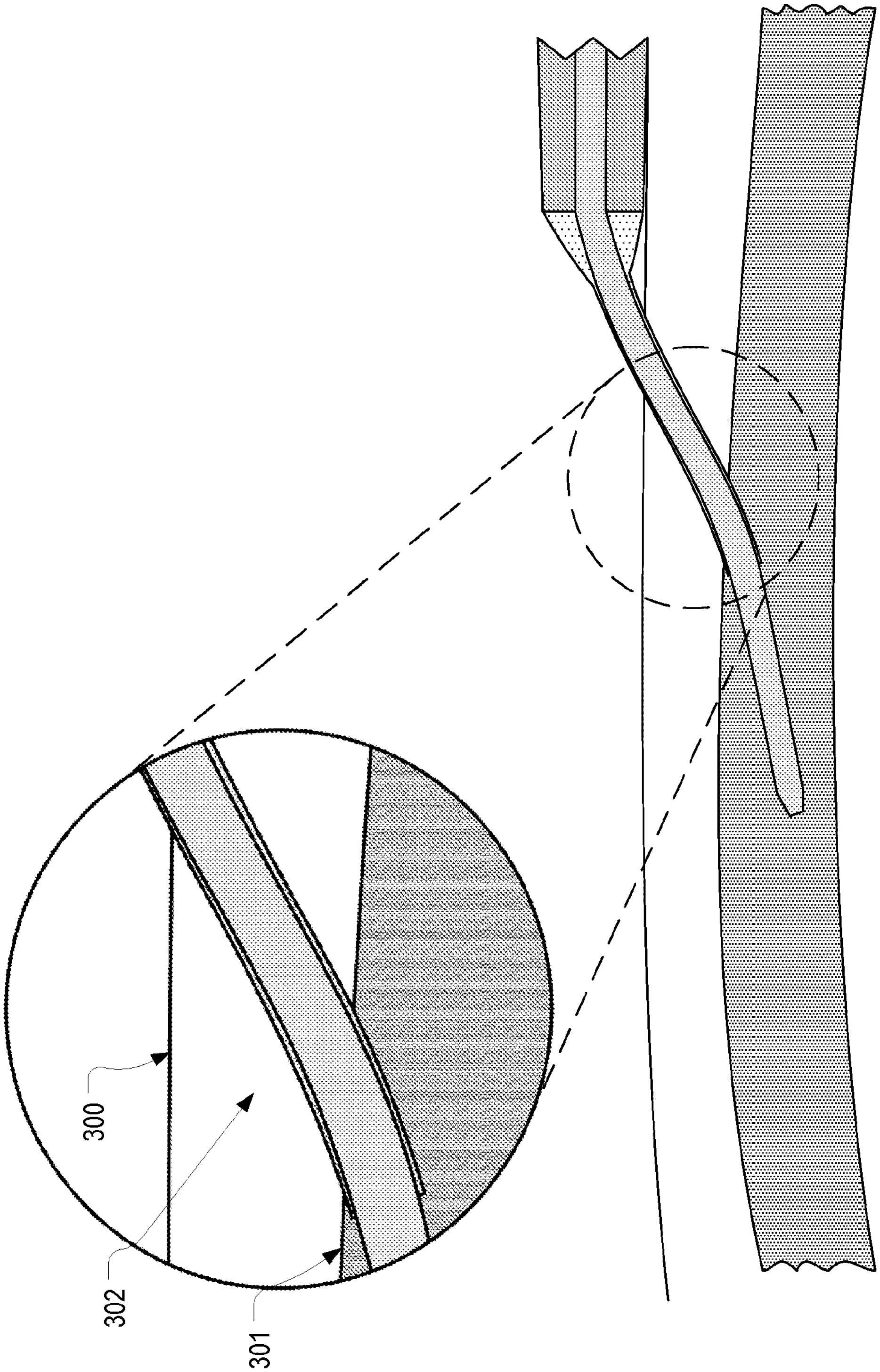


FIG. 3A

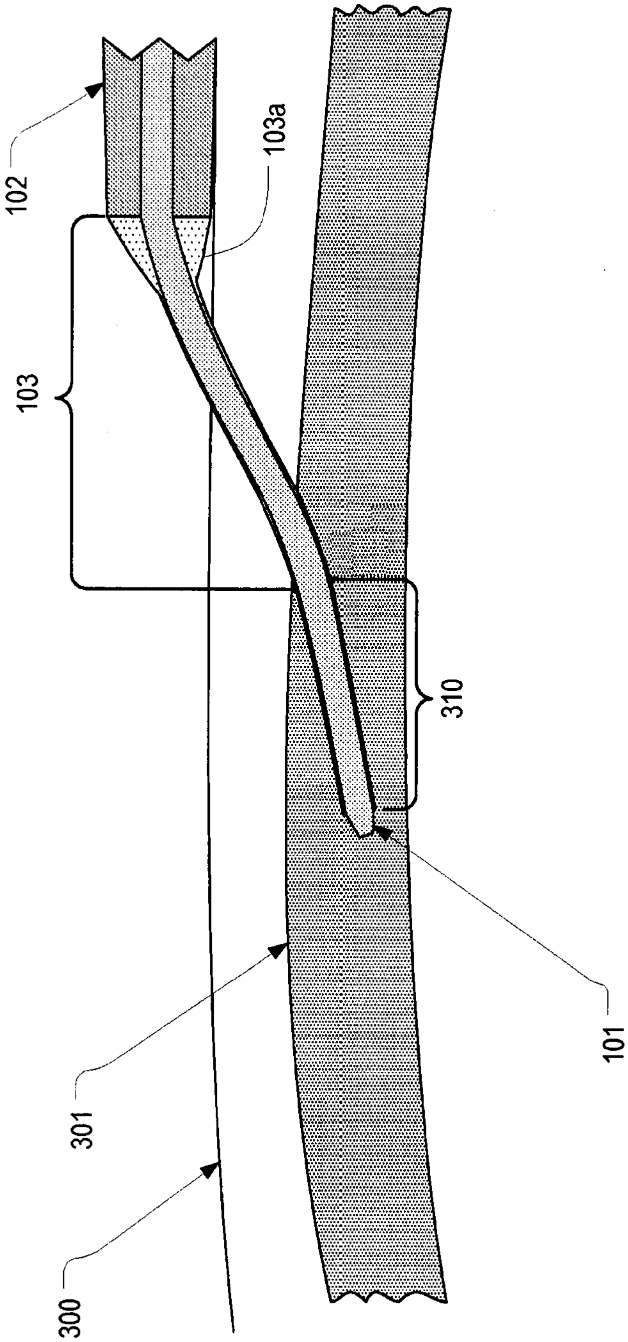


FIG. 4

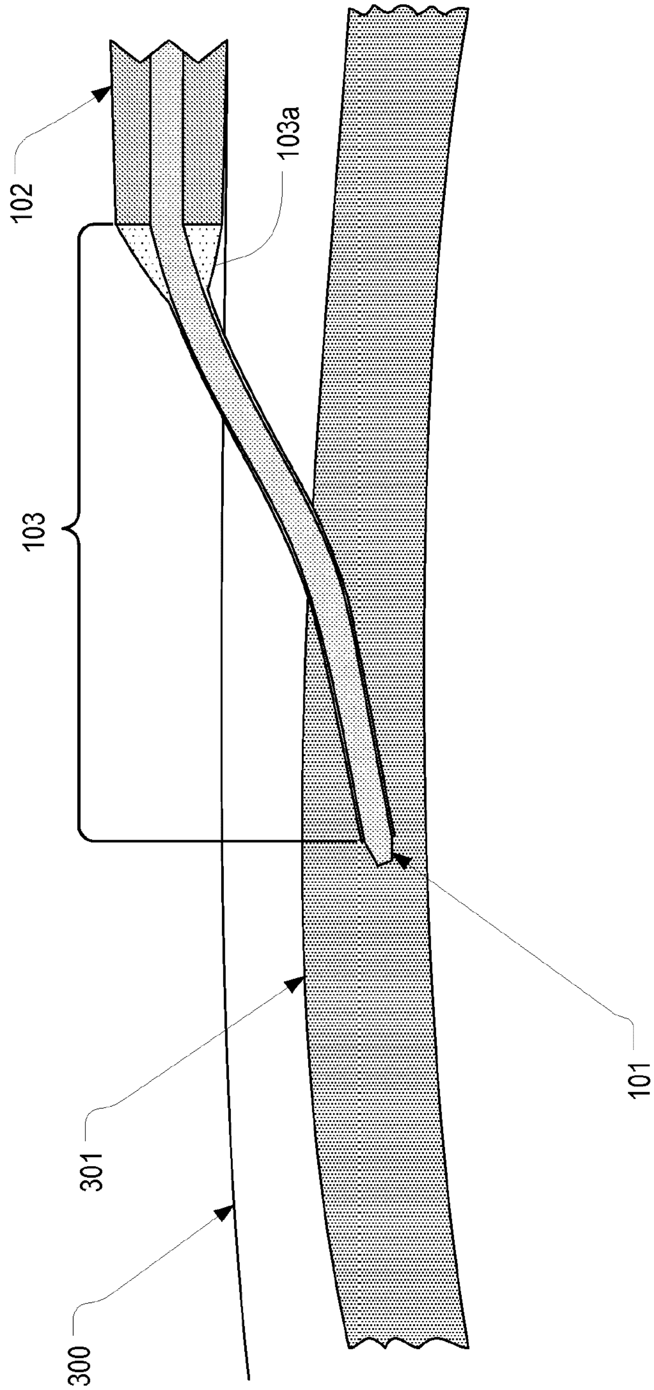
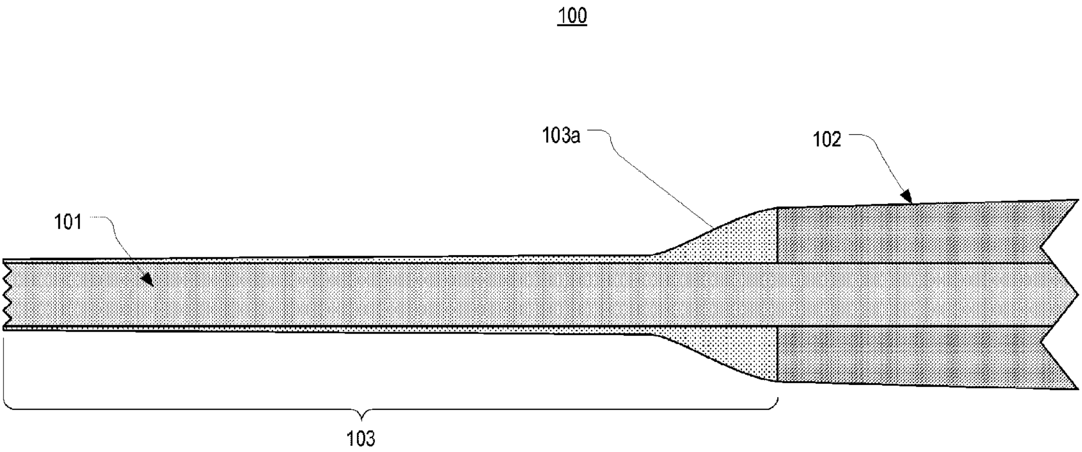


FIG. 5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