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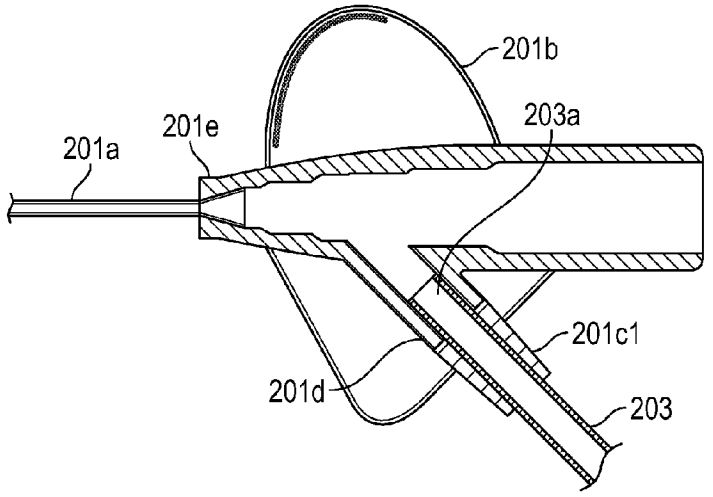
(54) Title: EXTENSION TUBING STRAIN RELIEF



(57) Abrégé/Abstract:
A vascular access device (200) includes strain relief features to minimize the likelihood of the extension tubing (203) becoming kinked during use. These strain relief features can be configured at both ends of the extension tubing to minimize the likelihood of kinking at the interfaces to the catheter adapter (201) and luer adapter (204). To provide strain relief at the catheter adapter end of the extension tubing, an interface (201c1) formed of a flexible material can be aligned with an extension (201d) of the catheter adapter into which the extension tubing inserts. The interface can be integrated into a stabilization platform or formed separately from a stabilization platform. To provide strain relief at the luer adapter end of the extension tubing, a flexible spacer (206) can be coupled to a distal end of the adapter and have a distal portion (206a) that is positioned around the extension tube.

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(54) Title: EXTENSION TUBING STRAIN RELIEF

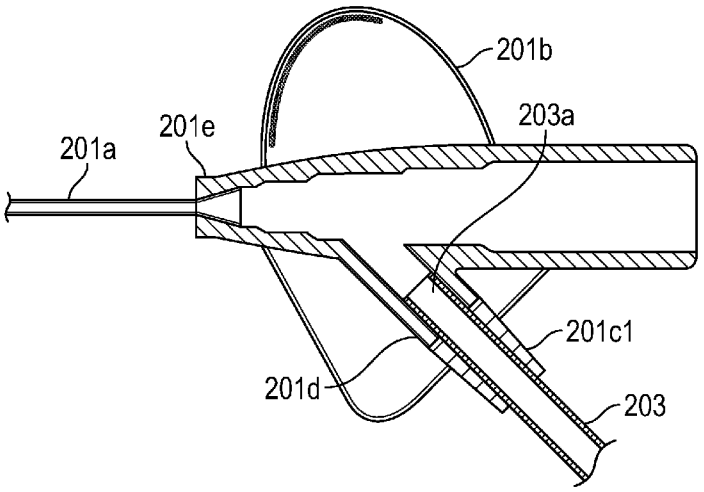

FIG. 4

(57) Abstract: A vascular access device (200) includes strain relief features to minimize the likelihood of the extension tubing (203) becoming kinked during use. These strain relief features can be configured at both ends of the extension tubing to minimize the likelihood of kinking at the interfaces to the catheter adapter (201) and luer adapter (204). To provide strain relief at the catheter adapter end of the extension tubing, an interface (201c1) formed of a flexible material can be aligned with an extension (201d) of the catheter adapter into which the extension tubing inserts. The interface can be integrated into a stabilization platform or formed separately from a stabilization platform. To provide strain relief at the luer adapter end of the extension tubing, a flexible spacer (206) can be coupled to a distal end of the adapter and have a distal portion (206a) that is positioned around the extension tube.

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EXTENSION TUBING STRAIN RELIEF

BACKGROUND

[0001] When a vascular access device is identified as being "closed" or "integrated," it generally refers to the fact that the device is configured to prevent blood from escaping the device during insertion of the catheter. Typically, such IV access devices accomplish this by integrating an extension set with the catheter adapter.

[0002] Figure 1 illustrates an example of a prior art closed vascular access device 100. Device 100 includes a catheter adapter 101 from which a catheter 101a extends, a needle hub 102 from which a needle 102a extends, extension tubing 103 that is coupled to catheter adapter 101 at one end and includes a Y-adapter 104 coupled to the other end, and a clamp 107 for blocking or limiting fluid flow through extension tube 103. Y-adapter 104 includes a port 105 and a vent plug 106. Although a Y-adapter is shown, any type of luer adapter could be used. Device 100 can be a closed system by incorporating fluid flow blocking components (e.g., a septum or vent) into each external opening of the device such as into a proximal end of catheter adapter 101 and into any ports in adapter 104.

[0003] Catheter adapter 101 includes a stabilization platform that is comprised of a first side 101b and a second side 101c. Catheter adapter 101 also includes an extension 101d that extends from a main body portion 101e of catheter adapter 101. Access device 100 can be referred to as "integrated" because an end of extension tubing 103 inserts into and is secured within extension 101d such that extension tubing 103 is fluidly coupled to catheter 101a via a lumen of catheter adapter 101.

[0004] In access device 100, extension tubing 103 may kink at the interface between extension tubing 103 and extension 101d. Similarly, extension tubing 103 may also kink at the interface between extension tubing 103 and luer adapter 104.

BRIEF SUMMARY OF THE INVENTION

[0005] The present invention is generally directed to an integrated vascular access device that includes strain relief features to reduce the likelihood of the extension tubing becoming kinked during use. These strain relief features can be configured at both ends of the extension tubing to minimize the likelihood of kinking at the interfaces to the catheter adapter and luer adapter.

[0006] To provide strain relief at the catheter adapter end of the extension tubing, an extension of the catheter adapter into which the extension tubing inserts can be integrated into a side of a stabilization platform. Various components and/or surfaces of the present

invention may comprise a soft, flexible material to assist the user in gripping the components, and/or to provide strain relief to a desired component. In some embodiments, a flexible material comprises a soft polymer having a durometer hardness of from approximately 30 Shore A to approximately 90 Shore D. In some embodiments, a flexible material comprises a soft polymer having a durometer hardness from approximately 50 Shore A to approximately 90 Shore D.

[0007] In some embodiments, the stabilization platform is formed of a flexible material. This flexible material can also be used to form an end portion of the extension. In this way, the end portion of the extension, which forms the interface between the extension tubing and the catheter adapter, is allowed to flex to minimize the likelihood that the extension tubing will become kinked. Alternatively, this interface can be formed separately from the stabilization platform including in embodiments where the catheter may or may not include a stabilization platform.

[0008] To provide strain relief at the luer adapter end of the extension tubing, a spacer comprising a flexible material can be positioned around the extension tubing and coupled to an end of the luer adapter. The flexible spacer therefore provides reinforcement at the interface between the extension tubing and the luer adapter and is allowed to flex to minimize the likelihood of kinking. In some embodiments, the flexible spacer can also be sized to block a clamp from extending overtop or contacting the rigid portion of the luer adapter. This further minimizes the likelihood of kinking due to the clamp bending against the luer adapter.

[0009] In one embodiment, the present invention is implemented as a vascular access device that includes: a catheter adapter comprising a main body portion from which a catheter extends distally and an extension that extends outwardly from the main body portion; extension tubing having a distal end that inserts into and is secured within the extension; and an interface formed of a flexible material that is positioned in-line with the extension such that the extension tubing extends through the interface and into the extension.

[0010] In another embodiment, the present invention is implemented as a vascular access device that includes: a catheter adapter; an adapter; extension tubing having a distal end coupled to the catheter adapter and a proximal end coupled to the adapter; and a flexible spacer having a proximal portion that is coupled to a distal end of the adapter and a distal portion that is positioned around the extension tubing.

[0011] In another embodiment, the present invention is implemented as a vascular access device that includes: a catheter adapter comprising a main body portion from which a

catheter extends distally and an extension that extends outwardly from the main body portion; extension tubing having a distal end that inserts into and is secured within the extension; an adapter coupled to a proximal end of the extension tubing; and a first strain relief feature formed at a catheter adapter end of the extension tubing and a second strain relief feature formed at an adapter end of the extension tubing. The first and second strain relief feature are one of: an interface formed of a flexible material that is positioned in-line with the extension or a distal end of the adapter such that the extension tubing extends through the interface and into the extension or distal end of the adapter; or a flexible spacer having a first end that is coupled to the extension or distal end of the adapter and a second end that is positioned around the extension tubing.

[0012] These and other features and advantages of the present invention may be incorporated into certain embodiments of the invention and 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. The present invention does not require that all the advantageous features and all the advantages described herein be incorporated into every embodiment of the invention.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0013] In order that the manner in which the above-recited and other features and advantages of the invention are obtained will be readily understood, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. These drawings depict only typical embodiments of the invention and are not therefore to be considered to limit the scope of the invention.

[0014] Figure 1 illustrates a prior art IV access device.

[0015] Figure 2 illustrates a vascular access device configured in accordance with one or more embodiments of the present invention.

[0016] Figure 3 illustrates a catheter adapter of the vascular access device shown in Figure 2.

[0017] Figure 4 provides a cross-sectional view of the catheter adapter shown in Figure 3.

[0018] Figure 5 provides a cross-sectional view of one embodiment of the luer adapter of the vascular access device shown in Figure 2.

[0019] Figure 6 provides a cross-sectional view of another embodiment of the luer adapter of the vascular access device shown in Figure 2.

DETAILED DESCRIPTION OF THE INVENTION

[0020] Figure 2 illustrates an example of a vascular access device 200 that is configured in accordance with one or more embodiments of the present invention. Access device 200 includes a catheter adapter 201 from which a catheter 201a extends distally, a needle hub 202 from which a needle 202a extends distally, extension tubing 203 having a distal end 203a that is coupled to catheter adapter 201 and a proximal end 203b coupled to an adapter 204, and a clamp 205 for restricting the flow of fluid through extension tubing 203. Adapter 204 can typically be a luer adapter which is configured to allow other access devices to be coupled to access device 200.

[0021] Catheter adapter 201 can include a stabilization platform formed by sides 201b and 201c which extend outwardly from opposite sides of catheter adapter 201. As shown in Figure 2, in some embodiments access device 200 is configured for right-hand use in that extension tubing 203 couples to the left side of catheter adapter 201 such that stabilization platform side 201b is fully exposed. This can facilitate gripping stabilization platform side 201b with the thumb of the right hand. Of course, in an access device designed for left-hand use, stabilization platform sides 201b, 201c and extension tubing 203 would be on opposite sides of catheter adapter 201 from what is shown in Figure 2.

[0022] Needle hub 202 includes a paddle grip 202b that extends outwardly from the right side of needle hub 202 and has a shape that generally corresponds to the shape of stabilization platform side 201b. Accordingly, paddle grip 202b can be positioned directly beneath stabilization platform side 201b so that stabilization platform side 201b and paddle grip 202b can be sandwiched between the clinician's thumb and index finger during insertion of catheter 201a. By configuring paddle grip 202b in this manner, the clinician can easily withdraw needle hub 202 from catheter adapter 201 by simply sliding the index finger backwards with respect to the thumb thereby causing the paddle grip 202b to slide backward away from stabilization platform side 201b.

[0023] Needle hub 202 also includes a flash chamber 210 that is coupled to the proximal end of needle hub 202. Flash chamber 210 can include a plug 210a that allows air to escape through a proximal opening in needle hub 202 while preventing blood from escaping. Also, a proximal end of needle 202a can extend into flash chamber 210 and can include an opening to allow blood to flow out of needle 202a and into flash chamber 210.

[0024] In accordance with embodiments of the present invention and as shown in Figures 3 and 4, a main body portion 201e of catheter adapter 201 can include an extension 201d that is integrated into stabilization platform side 201c. Extension 201d can be

configured to receive and secure a distal end 203a of extension tubing 203. Both main body portion 201e and extension 201d can be molded from the same material.

[0025] Stabilization platform side 201c can be formed around (e.g., molded around) extension 201d in a manner that produces an interface 201c1 around extension tubing 203. Interface 201c1 can be (but is not required to be) formed of the same material as stabilization platform side 201c which is more flexible than the material used to form main body portion 201e and extension 201d. Once formed, interface 201c1 can function as an end portion of extension 201d. In other words, the combination of extension 201d and interface 201c1 can form a continuous structure through which distal end 203a of extension tubing 203 extends. One of skill in the art will appreciate that interface 201c1 may be incorporated into any stabilization platform of any compatible catheter adapter comprising an integrated extension tube and respective extension. For example, in one embodiment interface 201c1 may be incorporated into or onto extension 101d of prior art device 100 of Figure 1.

[0026] Because interface 201c1 is formed of a more flexible material than extension 201d, kinking is less likely to occur at the interface between extension tubing 203 and extension 201d. In particular, extension tubing 203 can be formed of a material that is substantially flexible to allow adapter 204 to be positioned at any suitable location with respect to catheter adapter 201. Interface 201c1 (as well as stabilization platform side 201c) can be less flexible than extension tubing 203 but more flexible than extension 201d so that the portion of extension tubing 203 within interface 201c1 can bend to some degree, but not enough to form a kink. This transition in flexibility substantially reduces the likelihood that extension tubing 203 will kink.

[0027] Figure 4 provides a cross-sectional view of catheter adapter 201. In this figure, the cross-section is taken along a plane that is just above the top surface of stabilization platform sides 201b and 201c and that extends through main body portion 201e and extension 201d. As shown, main body portion 201e and extension 201d can be molded as a single component. Stabilization platform side 201b, stabilization platform side 201c, and interface 201c1 may also be molded as a single component around catheter adapter 201. Alternatively, stabilization platform side 201c and interface 201c1 could be molded as a single component that is separate from stabilization platform side 201b. In either case, interface 201c1 is an integral portion of stabilization platform side 201c that forms a sleeve-like structure through which extension tubing 203c extends. Figure 4 also shows that the distal end 203a of extension tubing 203 inserts into extension 201d so that it is secured to catheter adapter 201.

Extension 201d and interface 201c1 can therefore form a continuous lumen through which extension tubing 203 inserts.

[0028] In other embodiments, interface 201c1 may be formed independently of a stabilization platform. For example, interface 201c1 could be molded around or against extension 201d independently of (e.g., above) stabilization platform side 201b. Alternatively, interface 201c1 could be molded around or against extension 201d on catheter adapters that do not include a stabilization platform or that include only a stabilization platform side on an opposite side of the catheter adapter (e.g., only stabilization platform side 201b).

[0029] It is noted that needle hub 202 is not shown in Figures 3 and 4. Also, catheter adapter 201 may typically include a septum (not shown) positioned proximal to extension 201d to prevent blood or fluid from flowing proximally out through the proximal opening of catheter adapter 201. Extension 201d is shown as not extending up to or beyond an edge of stabilization platform side 201c. However, in some embodiments, extension 201d may extend farther than what is shown in Figures 3 and 4. For example, extension 201d could extend up to and even beyond the edge of stabilization platform side 201c. In such cases, interface 201c1 could be configured to encapsulate a portion of extension 201d as well as to extend beyond an edge of extension 201d in the manner shown in Figures 3 and 4.

[0030] Figures 5 and 6 illustrate cross-sectional views of embodiments of a luer adapter 204 that includes a flexible spacer 206. As shown, a proximal end 203b of extension tubing 203 extends into and is secured within luer adapter 204. Flexible spacer 206 has a sleeve shape with an inner diameter that is sufficient to allow flexible spacer 206 to be placed around extension tubing 203. Flexible spacer 206 can also be sufficiently elastic to allow a proximal portion 206b to be placed around a distal end of luer adapter 204. With proximal portion 206b placed around luer adapter 204, flexible spacer 206 will be secured to luer adapter 204 with a distal portion 206a being positioned around extension tubing 203. Distal portion 206a can provide reinforcement at the interface between luer adapter 204 and extension tubing 203 thereby minimizing the likelihood that extension tubing 203 will become kinked at the interface.

[0031] In some embodiments, such as is shown in Figures 5 and 6, the distal opening of luer adapter 204 can include a chamfered surface 204a. Chamfered surface 204a allows extension tubing 203 to bend slightly prior to contacting the distal edge of luer adapter 204. As shown in Figure 6, in some embodiments, the inner diameter of flexible spacer 206 can be greater than the outer diameter of extension tubing 203 and substantially equal to the

diameter at the distalmost point of chamfered surface 204a. In such cases, a space 206a1 will exist between extension tubing 203 and distal portion 206a.

[0032] Flexible spacer 206 can be a separate component from extension tubing 203 and luer adapter 204. As a separate component, flexible spacer 206 can be formed of a suitable elastic material that is different than the material used to form luer adapter 204. In some embodiments, flexible spacer 206 can have an outer diameter that is greater than an inner diameter of the channel or opening in clamp 205 through which extension tubing 203 extends. In this way, flexible spacer 206 can function to prevent clamp 205 from being positioned too close to luer adapter 204. In particular, if clamp 205 clamps extension tubing 203 at the interface between extension tubing 203 and luer adapter 206, it would cause extension tubing 203 to be more likely to kink at the interface when it is bent against the distal end of the luer adapter 204. Flexible spacer 206 can also be employed to ensure that clamp 205 cannot clamp extension tubing 203 near the interface.

[0033] Although the above description describes forming interface 201c1 only at the catheter adapter end of the extension tubing and describes incorporating flexible spacer 206 only at the luer adapter end of the extension tubing, these techniques could be applied on the opposite ends of the extension tubing. For example, an interface similar to interface 201c1 could be formed on a distal end of luer adapter 204 around extension tubing 203 in place of flexible spacer 206. This could be accomplished by separately molding an interface from a flexible material around the distal end of luer adapter 204 (e.g., with reference to the figures, extension 201d could be viewed as the distal end of luer adapter 204). Alternatively, in embodiments where luer adapter 204 includes a component that is molded of a flexible material, the interface could be integrally formed within the component in a similar manner as interface 201c1 can be integrally formed within stabilization platform side 201c. For example, if luer adapter 204 includes a soft grip feature, this soft grip feature could be extended to form an interface at the distal end of luer adapter 204.

[0034] Similarly, a flexible spacer could be employed at the catheter adapter end of the extension tubing in place of interface 201c1. This could be accomplished by placing a distal portion of a flexible spacer around (or otherwise secured to) extension 201d. In such cases, extension 201d could be configured with a chamfer similar to what is shown in Figures 5 and 6. As described above, a flexible spacer could be employed in this manner in any configuration of a catheter adapter that includes extension 201d including those with or without a stabilization platform.

[0035] Various embodiments of the present invention further comprise a safety mechanism configured to secure the sharpened, distal tip of the introducer needle following removal and separation of the needle hub from the catheter adapter. A safety mechanism may include any compatible device known in the art. In some instances, the safety mechanism is configured to interact with a needle feature, such as a ferrule, notch, crimp or bump on the cannula. The crimp or bump formed in the cannula causes a slight out of round configuration that can be used to activate a safety mechanism. In some instance, the safety mechanism comprises an arm or lever that is actuated to capture the needle tip within the mechanism and prevent the tip from emerging prior to safe disposal.

[0036] The safety mechanism is attached to the body of the needle and is capable of sliding along the length thereof. In some instances, an initial or assembled position of the safety mechanism is located in proximity to the base or proximal end of the catheter adapter prior to catheterization. For some configurations, the assembled position of the safety mechanism is between the proximal end of the needle hub and the proximal end of the catheter adapter or stabilization platform, wherein the safety mechanism does not overlap the catheter adapter or stabilization platform. In some instances, a portion of the safety mechanism is positioned within the catheter adapter, with the balance of the safety mechanism being positioned external to the catheter adapter, such as within the needle hub. In some embodiments, a portion of the catheter adapter or stabilization platform is extended proximally to provide a housing in which at least a portion of the safety mechanism is housed. In some instances, the entire safety mechanism is housed within the housing of the catheter adapter or stabilization platform prior to catheterization.

[0037] In some embodiments, the assembled position of the safety mechanism positions the proximal end of the catheter adapter between the distal end of the safety mechanism and a distal end of a paddle grip of the needle hub. In some instances, the assembled position of the safety mechanism positions the proximal end of the catheter adapter between the distal end of the safety mechanism and a proximal end of a paddle grip of the needle hub. In some instances, a portion of the safety mechanism overlaps a portion of a paddle grip of the needle hub. In some embodiments, at least some portion of at least one of the catheter adapter and the paddle grip overlaps at least some portion of the safety mechanism. In some embodiments, no portion of the catheter adapter or paddle grip overlaps any portion of the safety mechanism.

[0038] In some embodiments, a defeatable mechanical connection is provided between the safety mechanism and at least one other component of the access device. In some

embodiments, a distal end of the safety mechanism is selectively coupled to a proximal end of the catheter adapter. In one embodiment, the safety mechanism interlocks internally to the proximal end of the catheter adapter. In one embodiment, the safety mechanism interlocks externally to the proximal end of the catheter adapter. In some embodiments, a distal end of the safety mechanism is selectively coupled to a proximal end of the stabilization platform. In some embodiments, a surface of the safety mechanism is selectively coupled to at least one surface of at least one of the catheter adapter, a blood control valve, an extension tube, and the stabilization platform. In some instances, the mechanical connection is defeated upon securement of the needle tip within the safety mechanism.

[0039] The present invention may be embodied in other specific forms without departing from its structures, methods, or other essential characteristics as broadly described herein and claimed hereinafter. 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 that 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 comprising a main body portion, an extension, and a catheter, wherein the main body portion comprises a proximal end and a distal end aligned with the proximal end, wherein the catheter extends distally from the distal end, wherein the extension extends outwardly from the main body portion and is disposed between the proximal end and the distal end, wherein the extension is constructed of a first material;

a stabilization platform extending outwardly from the catheter adapter, wherein the stabilization platform comprises a wing;

extension tubing having a distal end that inserts into and is secured within the extension; and

an interface coupled to a proximal-most surface of the extension and formed of a second material, wherein the second material is more flexible than the first material, wherein the extension tubing extends through and proximally from the interface, wherein the interface is an integral portion of the stabilization platform.

2. The vascular access device of claim 1, wherein

the stabilization platform has a first stabilization platform side that is coupled to the catheter adapter and extends outwardly from the main body portion.

3. The vascular access device of claim 2, wherein the interface is an integral part of the first stabilization platform side.

4. The vascular access device of claim 2, wherein the first stabilization platform side is molded around a portion of the extension.

5. The vascular access device of claim 1, wherein the interface:

extends around a portion of the extension; or

is molded to the extension.

6. The vascular access device of claim 2, wherein the first stabilization platform side and the extension are formed of the same flexible material.

7. The vascular access device of claim 2, wherein the first stabilization platform side extends outwardly from the main body portion farther than the extension.

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

an adapter coupled to a proximal end of the extension tubing; and

a flexible spacer having a proximal portion that is coupled to a distal end of the adapter and a distal portion that is positioned around the extension tubing.

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9. The vascular access device of claim 8, wherein the flexible spacer is a separate component from the adapter.

10. The vascular access device of claim 8, wherein a distal opening of the adapter includes a chamfered surface.

11. The vascular access device of claim 10, wherein an inner diameter of the flexible spacer is substantially equal to a diameter at the distal-most portion of the chamfered surface.

12. The vascular access device of claim 8, further comprising:

a clamp having an opening through which the extension tubing extends to secure the clamp to the extension tubing, the opening having a diameter, and wherein an outer diameter of the flexible spacer is greater than the diameter of the opening to prevent the clamp from extending overtop the flexible spacer.

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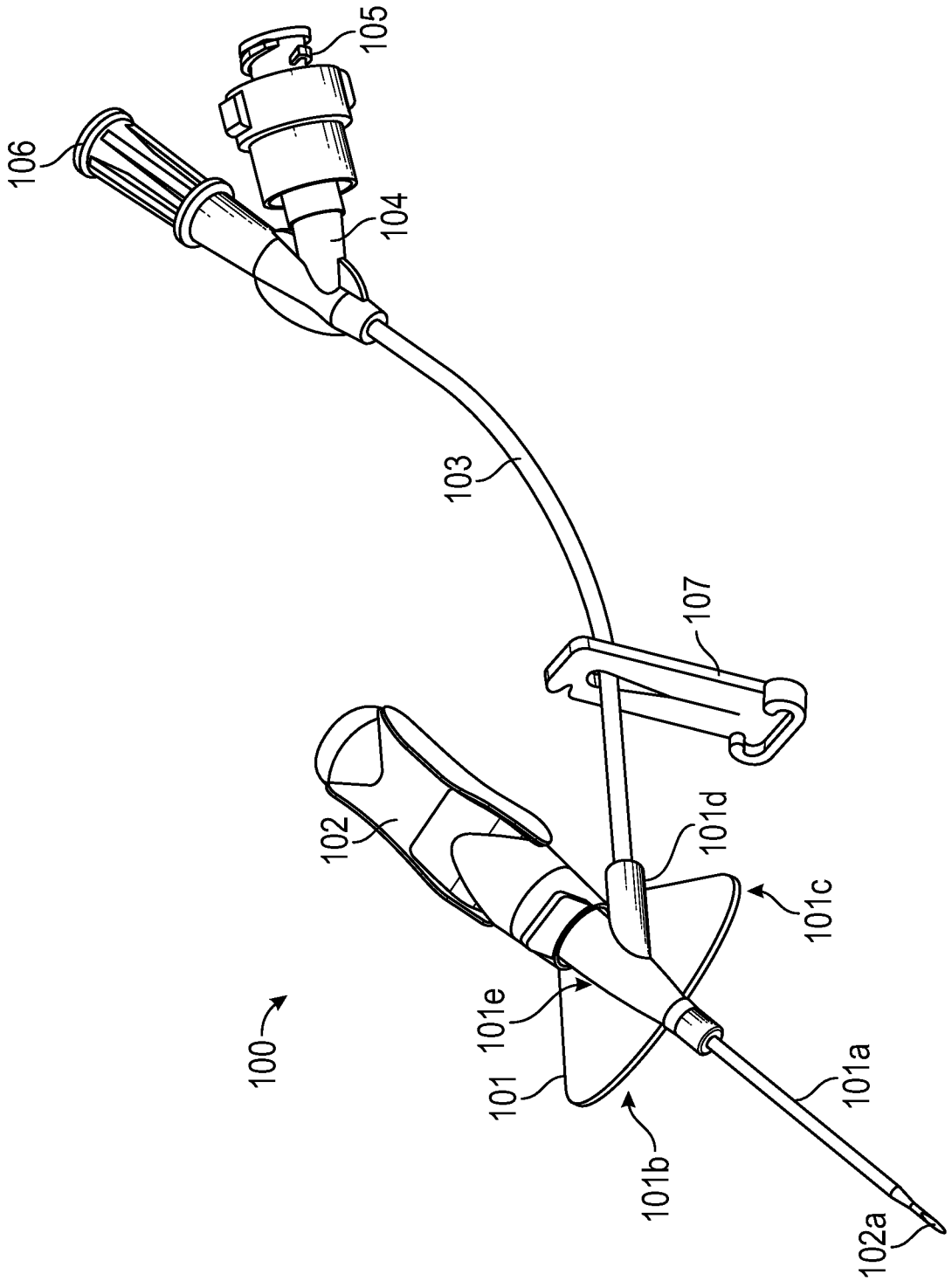
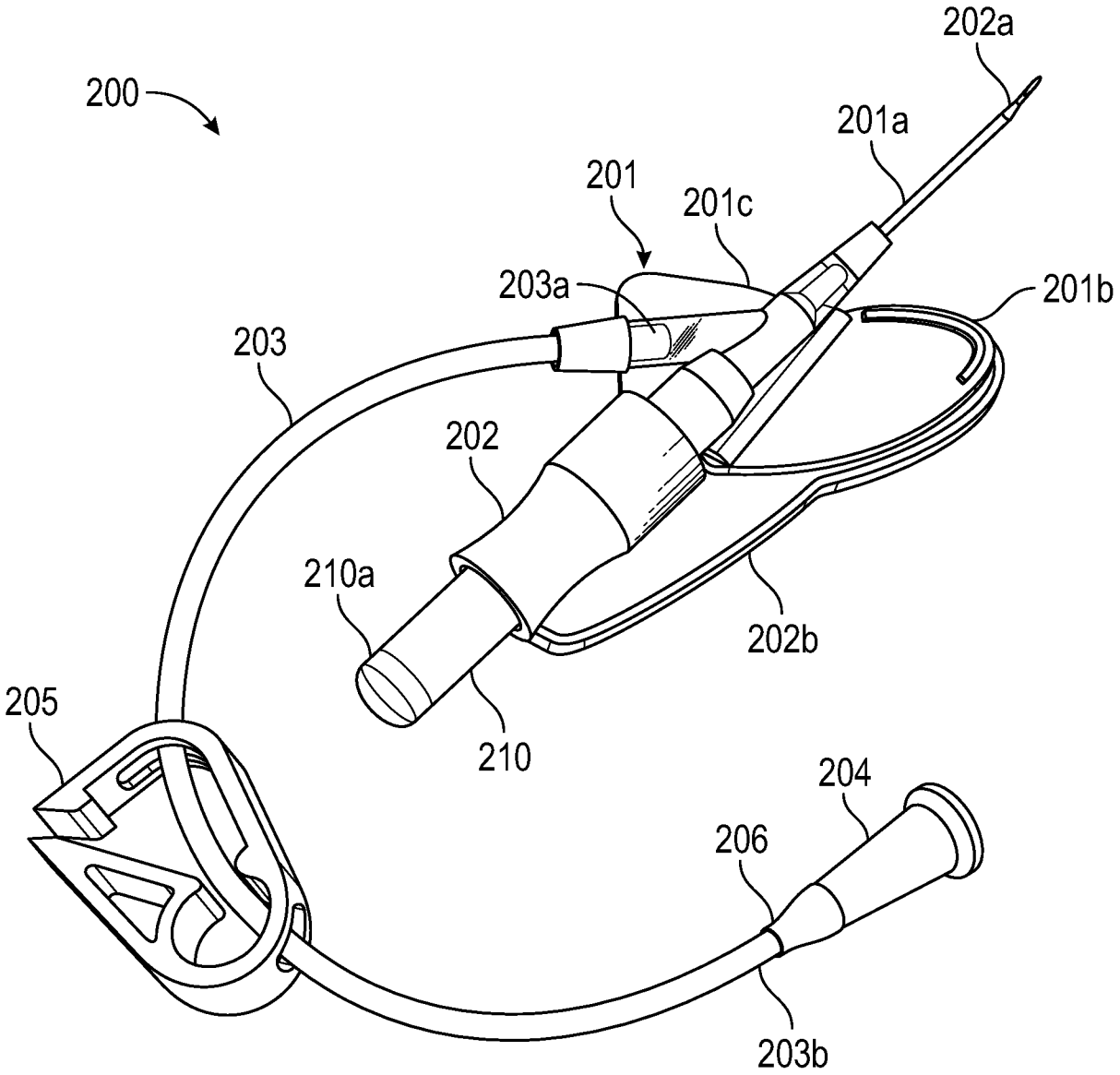


FIG. 1
(Prior Art)


200
202a
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201c
203a
201b
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202b
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204
206
203b

FIG. 2

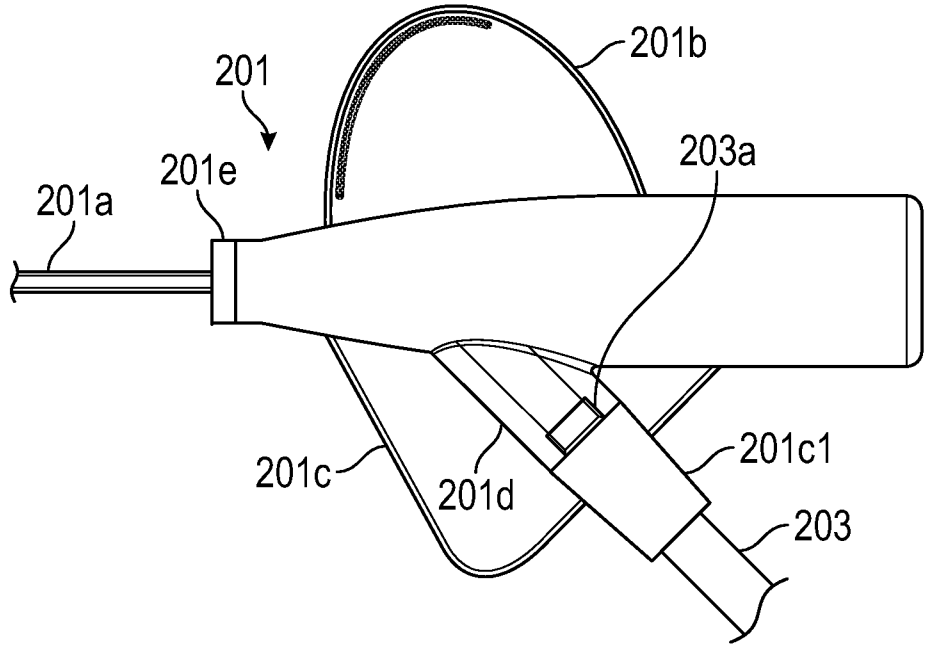

201
201b
203a
201e
201a
201c
201d
201c1
203

FIG. 3

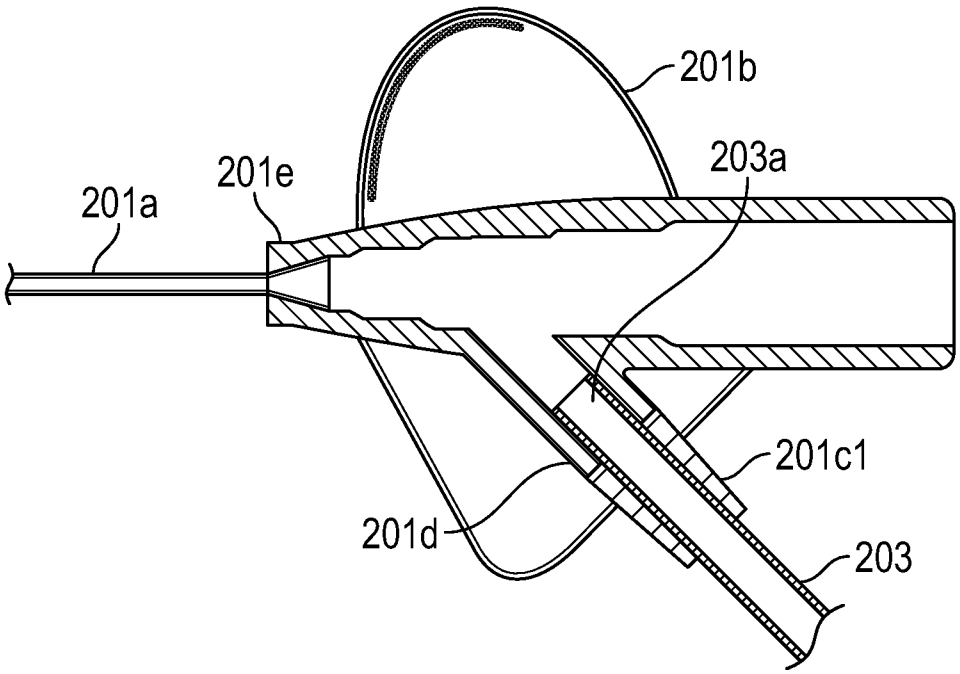

201b
203a
201e
201a
201c1
201d
203

FIG. 4

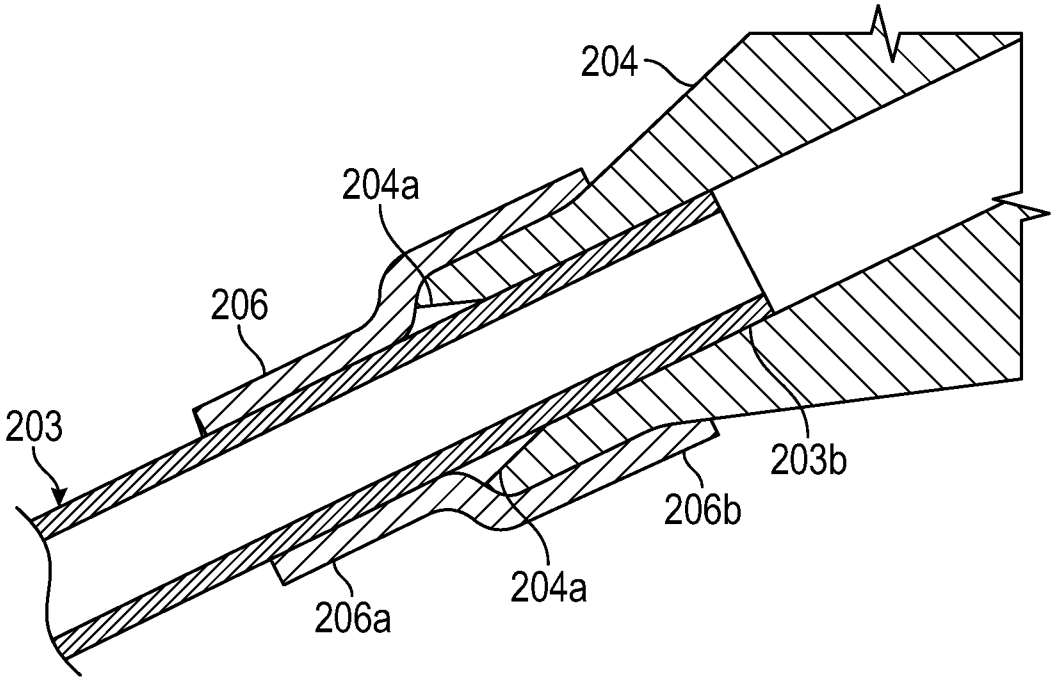

204
204a
206
203
203b
206b
204a
206a

FIG. 5

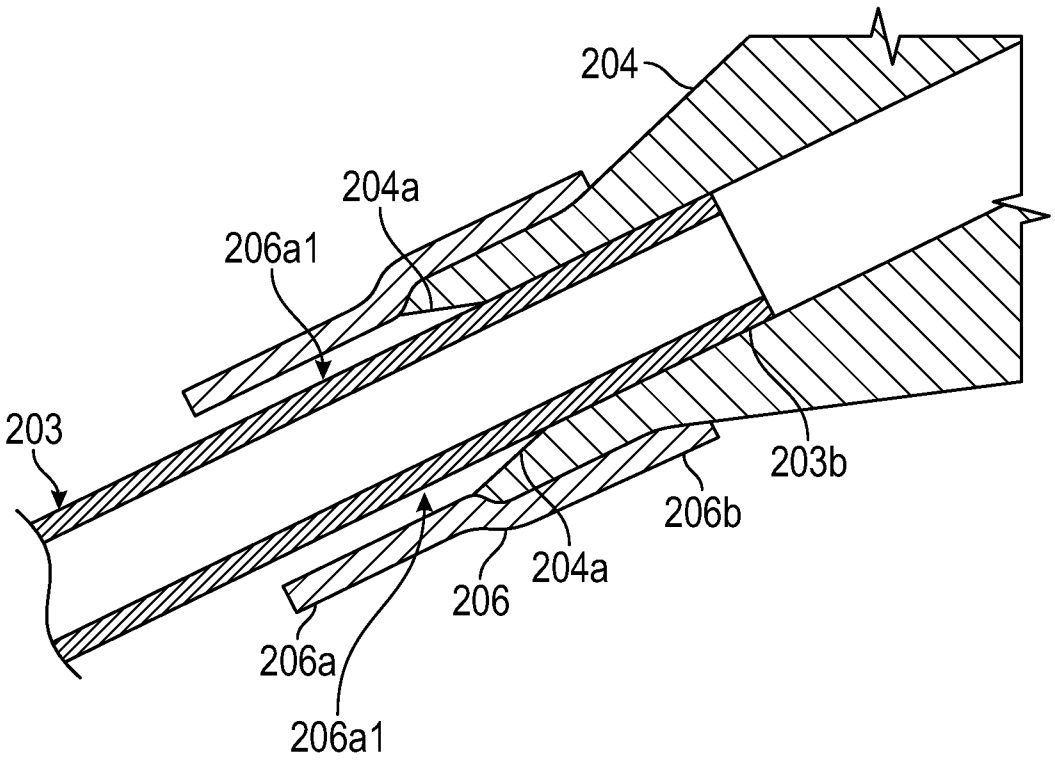
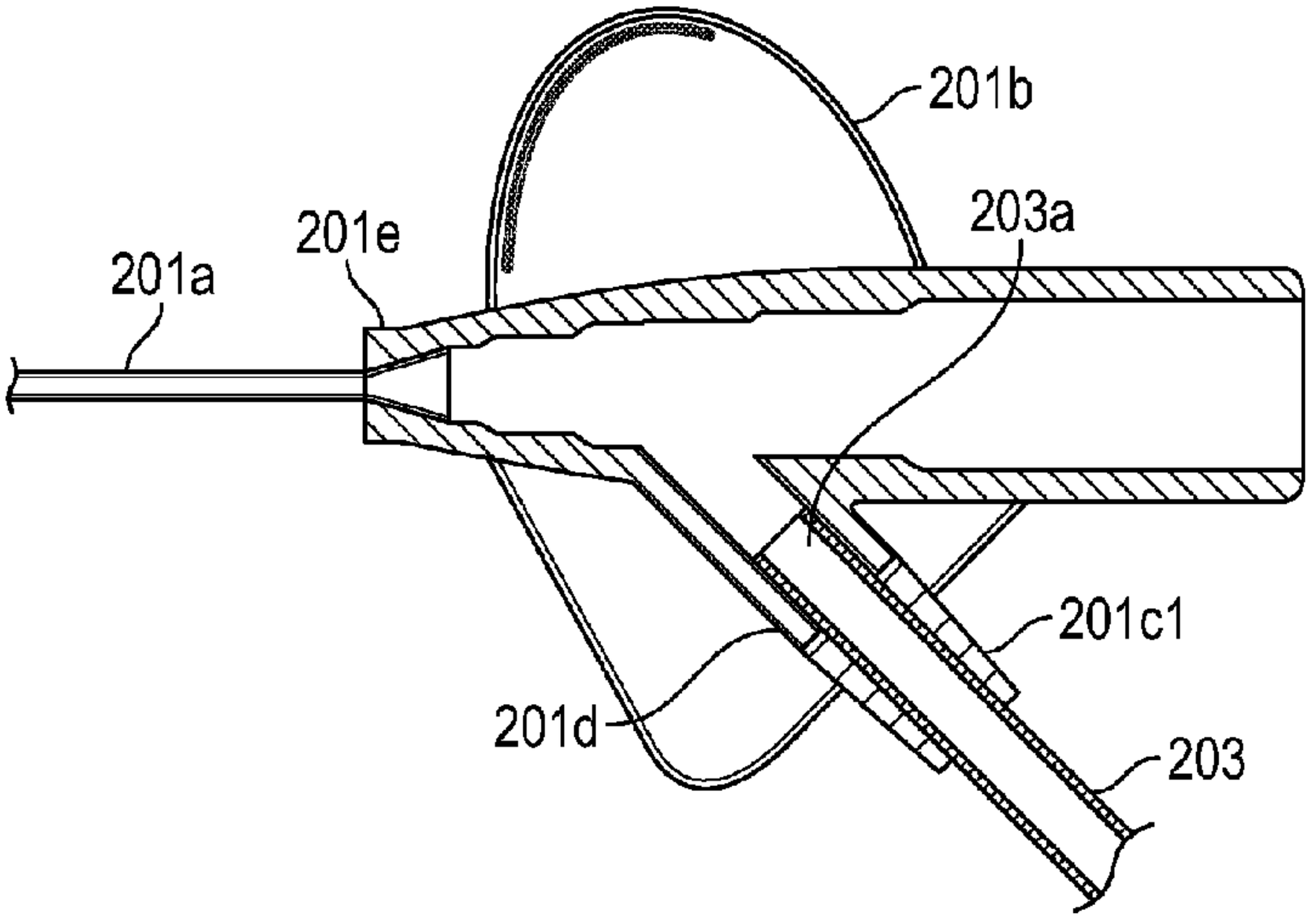

204
204a
206a1
203
203b
206b
204a
206
206a
206a1

FIG. 6


201b
203a
201e
201a
201c1
201d
203