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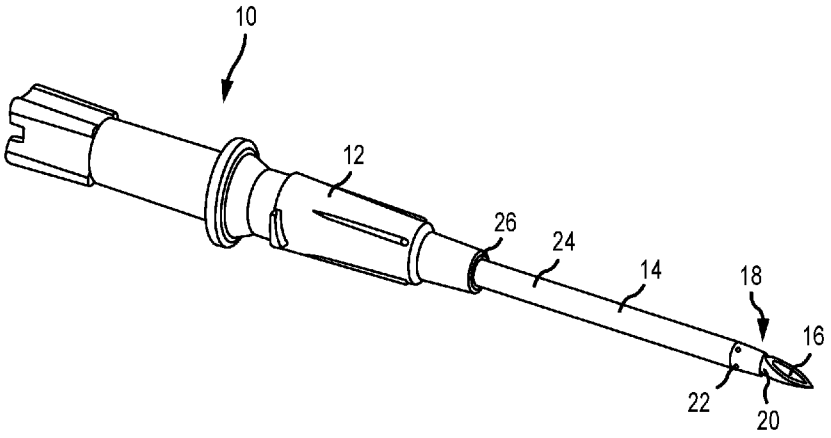


FIG.1

(57) Abstract: The present disclosure describes various catheters that address potential recoil issues. Such catheter may contain multiple lumens that allow for the discharge of infusants a various points on the catheter distal end. Further, multiple openings may be present on the distal end of the catheter. The openings can be covered with a membrane that ruptures at a designated flow pressure. The catheter tip can contain blind holes that remain covered, and are only opened to become active when required. Such catheters can allow for multiple infusant flow exits, rather than a singular steady jet exiting the distal end of the catheter.

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RECOIL BALANCING CATHETER

BACKGROUND

The present disclosure relates to catheter assemblies. In particular, the present disclosure relates to catheters having features that balance against recoil forces.

Intravascular catheters are used for infusing fluid into a patient, withdrawing fluid from a patient, or monitoring various parameters of the vascular system of a patient. Typically, a needle is used to introduce the catheter into a blood vessel of the patient. A catheter is mounted over a needle that has a sharp distal tip, with at least the distal portion of the catheter tightly engaging the outer surface of the needle to prevent peel-back of the catheter during insertion into the blood vessel.

A clinician inserts the needle through the skin of the patient and into the blood vessel. Once a flashback of blood is seen within a flashback chamber, the catheter is threaded over the needle and inserted completely into the blood vessel. The needle is then withdrawn from the catheter leaving the catheter in place.

Some procedures using a catheter require a high rate of infusion, thus increasing the pressure associated with the discharge of fluids through the catheter. For example, some imaging procedures, such as angioplasty, require a high pressure discharge of contrast fluid into the patient. A clinician inserts a catheter and injects contrast fluid through the catheter into a vein or artery of a patient. The area of the injection with the contrast fluid is imaged using x-ray energy or magnetic fields (as used in magnetic resonance imaging) and the resulting image is recorded and/or displayed on a monitor. The images can be used for many purposes, including diagnostic activities as well as interventional procedures such as angioplasty, wherein a balloon is inserted into a vascular system and inflated to open a stenosis.

During the injection procedure, fluid typically flows out of the open distal end of the catheter tip. However, the fluid dynamics associated with some catheter designs often cause the catheter to be pushed back or to recoil as a result of the speed of the fluid as it exits the distal tip. In effect, the recoil force of the catheter is directly proportional to the fluid speed at the tip.

Such recoil can create undesirable movement of the catheter tube. Catheters may be prone to recoil if fluid flow out of the tip is of sufficient speed. Catheter designs

incorporating valves or openings located along the distal portion of the catheter wall have been considered in an attempt to better facilitate control of the fluid flow. However, while the prior art design of catheters used during high pressure/high speed discharge of fluids offer control of fluid flow and recoil, the designs do not address other peripheral issues associated with the insertion and use of catheters.

Further, catheters, such as indwelling catheters, may be susceptible to clotting and infection when used in vivo. Clotting and infection might also occur in in vitro applications that mimic in vivo environments. It is estimated that 20% to 40% of catheters used in vivo develop thrombi. Once catheter thrombus occurs, the patient may be predisposed to infection; similarly, catheter infection increases the risk of thrombosis. Such infections serve to increase health care costs, including the costs of antibiotics, new catheters, possible hospital stays, ICU care, and any follow-up procedures.

SUMMARY

A catheter in accordance with the present disclosure includes an elongated tubular structure having a proximal end and a distal end, wherein the distal end of said tubular structure having a main opening at the distal edge. The catheter also has a plurality of auxiliary openings, wherein each of the plurality of auxiliary openings is covered by a respective rupturable membrane.

A catheter assembly in accordance with the present disclosure includes a catheter with a central lumen having a proximal end and a distal end, and a distal tip attached to the central lumen at the distal end. The distal tip has a plurality of openings that are covered by a membrane that is capable of being ruptured at a designated pressure. A catheter hub is attached to the proximal end of the catheter.

A catheter in accordance with the present disclosure includes a main lumen having a proximal end, a distal tip, and a central axis. The distal tip of the main lumen contains a main outlet. The catheter also has a plurality of auxiliary lumens secured to the main lumen. Each of the plurality of auxiliary lumen have a proximal end and a distal end. The plurality of auxiliary lumens are secured to the main lumen in a coaxial arrangement, and the each of the plurality of auxiliary lumens contain a respective auxiliary outlet proximal to the main outlet.

A catheter assembly in accordance with the present disclosure has a main lumen having a proximal end with an inlet, and a distal tip with an outlet at a distal end. The assembly also includes at least one auxiliary lumen attached to the main lumen that has a proximal end and a distal end, and a hub attached to the proximal end of the main lumen and

the proximal end of the auxiliary lumen. The main lumen and at least one auxiliary lumen share an opening at the hub.

A vascular access and infusion device including a catheter in accordance with the present disclosure can comprise an elongated tubular structure having a proximal end, a distal end, and a lumen extending there between, and a tip at the distal end of the elongated tubular structure having a main opening and at least one auxiliary opening being formed through a wall thickness of the elongated tubular structure and in communication with the lumen, wherein at least a portion of the catheter comprises an anti-thrombogenic agent. The anti-thrombogenic agent can be disposed on the distal end of the elongated tubular structure. The anti-thrombogenic agent comprises at least one of a heparin-based drug or agent, hirudin, a protein, a peptides, and a fluoropolymer additive. Further, at least a portion of an inner surface of the elongated tubular structure can comprise a lubricious coating and/or at least one of a phosphorylcholine additive and a polyethyleneoxide additive.

A method of manufacturing a catheter in accordance with the present disclosure comprises compounding a catheter polymer material with an anti-thrombogenic additive and extruding a tubular catheter body from the catheter polymer material, wherein the anti-thrombogenic additive migrates to a surface of the tubular catheter body imparting the surface with anti-thrombogenic properties. The anti-thrombogenic additive can comprise at least one of a heparin-based drug or agent, hirudin, a protein, a peptides, and a fluoropolymer additive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a simplified schematic for a catheter assembly;

FIG.2 is a perspective view of a catheter and catheter hub;

FIG. 3 is a cross sectional view of a catheter tube in a vein;

FIG. 4 is a schematic cross sectional views of catheter tubes illustrating various potential flow outlet patterns;

FIG. 5 is a perspective wireframe view of a multiple lumen catheter;

FIG. 6 is a perspective view of the distal end of the multiple lumen catheter;

FIG. 7 is a perspective view of the proximal end of the multiple lumen catheter;

FIG. 8 is a perspective view of a catheter tube with rupturable membranes;

FIG. 9 is a cross sectional view of the catheter tube end of FIG. 8;

FIG. 10 is a cross sectional view of an alternate embodiment of the catheter tube end of FIG. 8;

FIG. 11 is a cross sectional view of another alternate embodiment of the catheter tube end of FIG. 8; and

FIGS. 12A, 12B, and 12C are cross sectional side views of a catheter tube in various stages of in vivo deployment in accordance with the present disclosure.

DETAILED DESCRIPTION

The present disclosure relates to various embodiments of catheters to address potential recoil issues, as well as other noted issues. In various embodiments, the catheter contains multiple lumens that allow for the discharge of infusants at various points on the catheter. In other embodiments, multiple openings are present on the distal end of the catheter. The openings are covered with a membrane that ruptures a designated pressure of flow through the catheter. The catheter tip contains blind holes that remain covered, and are only opened to become active when required.

Various features and benefits of the present disclosure will be further appreciated in view of the description that follows and the accompanying drawings.

FIG. 1 illustrates an embodiment of a catheter assembly 10, such as a diagnostic catheter used during angiography or other procedures. Catheter assembly 10 includes hub 12 having catheter 14 with needle 16 extending through tip 18 at the distal end. FIG. 2 illustrates a portion of the catheter assembly including catheter 14 and hub 12. The distal tip 18 contains a main outlet 20, as well as auxiliary outlets 22. The arrangement of the auxiliary outlets 22 on distal tip 18 allow for improved management of fluid forces that better stabilize the distal tip 18 of catheter 14 over a wide range of injection parameters.

As shown in FIG. 1, catheter 14 includes a central lumen 24, with distal tip 18 and a proximal end 26 that extends to join hub 12. Central lumen 24 communicates with distal tip 18 for the passage fluids. Attached to the proximal end 26 of the catheter 14 is the hub 12. Hub 12 provides a standard interface for syringes, injectors, pumps, and other similar devices and affords access to catheter 14. In one embodiment, the hub 12 has a frustro-conically shaped distal portion connected to a cylindrical portion. Other appropriate hub 12 geometries, such as tubular, frustro-spherical, funnel-shaped, or the like, are also common in the art. The overall hub design is such to allow the hub to be compatible with injection equipment. Secondary structures known in the art are also not illustrated, but are envisioned to cooperate with the base structures disclosed. For example, the catheter may also contain a needle tip protector, flashback chamber for identifying when a blood vessel has been pierced by the needle, or a multiple-piece catheter hub. The proximal end of needle 16 may be

attached to various structures that facilitate the clinicians control and movement of the needle while in the catheter assembly as well as when needle is removed from the catheter assembly for disposal.

Hub 12 may be constructed from any number of plastics or polymers known in the art. Similarly, catheter 14 is constructed from polymers known in the art. For example, catheter 14 may be fabricated from biocompatible material such as polypropylene, polystyrene, polyvinylchloride, polytetrafluoroethylene, and the like. In other embodiments, catheter may contain a metallic material, such as surgical steel, titanium, cobalt steel, and the like, or radiopaque materials that assist in locating and identifying catheter 14 in imaging procedures.

Catheter assembly 10 is generally designed for use in combination with a vascular infusion system capable of rapidly delivering an infusant to the vascular system of a patient, as opposed to a low pressure/low flow system that may rely on gravity feed of fluids. High volume flow infusion systems are commonly configured to operate at internal pressures up or exceeding 300 psi (pounds per square inch). Many systems operate in the range of 75 to 500 psi, while specific devices of this type operate at 100, 200, and 300 psi. To achieve the desired speed of fluid injection, a fluid pumping apparatus is configured to rapidly deliver an infusant, such as blood, medicaments, and CT scan contrast agents to the vascular system of a patient. Desirable infusants may also include various fluids often of high viscosity as required for medical and diagnostic procedures. For example, a trend in diagnostic imaging procedures is to utilize contrast media enhancement, which requires more viscous contrast media to be pushed into a patient at a higher flow rate, thereby resulting in increased image quality. Thus, catheter assembly 10 is designed to achieve the desired infusion flow rate.

High volume infusion via catheter through the catheter tip results in a recoil force that may cause the catheter tip to shift within the blood vessel of the patient thereby displacing the catheter and/or damaging the vessel and/or injection site on the patient. As illustrated in FIG. 3, fluid leaves catheter 14 through main outlet 20 created by pumping force Fp. This results in a counter recoil force Fr that tends to push catheter 14 in the opposite direction of pumping force Fp. Higher volume discharges of infusants may result in movement of the catheter within blood vessel 28 of the patient. The addition of auxiliary outlets 22 in distal tip 18 of catheter 14 compensates for some of the recoil force, thus preventing the catheter 14 from moving or damaging the vessel of the patient. Auxiliary outlets 22 allow for the flow of infusants to be distributed in multiple directions, thus counteracting some of the pumping force Fp.

As illustrated in FIG. 4, various arrangements of auxiliary outlets 22 may be incorporated into distal tip 18 of catheter 14. Auxiliary outlets 22 allow for the creation of auxiliary force Fa that is generally perpendicular to pumping for Fp. Furthermore, the presence of auxiliary outlets 22 at distal tip 18 of catheter 14 can reduce the speed of a fluid jet exiting main outlet 20, thus reducing impact and potential for damage to blood vessel walls. Additionally, the presence of auxiliary outlets 22 can reduce pressure loss and reduce the overall system pressure while permitting higher injection rates for high volume power injector systems due to the presence of modified flow forces. As shown in FIG. 4, auxiliary outlets are placed in a symmetric pattern about the center of main outlet 20. The arrangement allows for insertion of catheter 14 into blood vessel 28 without requiring a specific orientation of catheter 14.

In various embodiments, auxiliary openings 22 of catheter 14 are angled toward the proximal end of the catheter 14. This particular angle configuration causes the fluid exiting the catheter 14 to flow in a retrograde direction to the injection fluid stream. The resulting direction and magnitude of the fluid flow exiting main outlet 20 of catheter 14 supplies forces urging the catheter 14 in a forward or distal direction. By properly spacing the auxiliary openings 22 along the periphery of distal tip 18 of catheter 14, the lateral or radial forces generated by the rearward motion of the fluid as it exits the catheter 14 through angle openings are ideally balanced. As a result, the design of catheter 14 with auxiliary openings 22 substantially reduces or prevents a recoil, or excessive movement of distal tip 18 of catheter 14 during an injection.

FIG. 5 is a perspective wireframe of a multiple lumen catheter 40. FIG. 6 is a perspective view of distal end 42 of the multiple lumen catheter, and FIG. 7 is a perspective view of proximal end 44. Multiple lumen catheter 40 contains main lumen 46 and auxiliary lumens 48, and is fabricated from materials previously noted for catheter 14 by manufacturing methods know in the art such as extrusion.

As illustrated, multiple lumen catheter 40 is a single construct, and may be fabricated as a single extrusion. The outer periphery of multiple lumen catheter 40 is cylindrical and contains a smooth cylindrical surface so as not to irritate a patient when inserted into a blood vessel. Auxiliary lumens 48 are symmetrically space about the inner surface of multiple lumen catheter 40. Auxiliary lumens 48 are much smaller than main lumen 46, and are illustrated as being ovular in shape, although other geometries such as cylindrical is envisioned. Auxiliary lumens 48 share a portion of their respective outer peripheries with the wall of main lumen 46. Auxiliary lumens are sized to still allow needle 16 (See FIG. 1) to be

inserted within main lumen 46 for placing of multiple lumen catheter 40 within a patient. In alternate embodiments, auxiliary lumens 48 are created on the outer surface of multiple lumen catheter 40.

Multiple lumen catheter 40 may be fabricated from a single material, or multiple materials. In one embodiment, auxiliary lumens 48 are translucent, thus allowing for a clinician to quickly visualize when flashback (blood return) occurs. In another embodiment, main lumen 46 is constructed from a radiopaque material to assist in locating the catheter during imaging of the patient.

Referring to FIG. 6, distal tip 18 of multiple lumen catheter 40 is tapered, and contains auxiliary openings 22, which are the termination of auxiliary lumens 48. In one embodiment, auxiliary openings 22 are created by beveling to outer periphery of multiple lumen catheter 40 to create the taper thereon. In alternate embodiments, auxiliary openings 22 are created by the extrusion process, or fabricating the apertures through manufacturing techniques known in the art. Main opening 20 is located distal to auxiliary openings 22.

As illustrated in FIG. 7, proximal end 44 contains main inlet 50 and auxiliary inlets 52. Proximal end 44 is connected to hub 12. Main inlet 50 and auxiliary inlets 52 share a common entrance within hub 12, thus allowing for infusants to be simultaneously introduced into both main lumen 46 and auxiliary lumens 48. The simultaneous introduction allow for infusants to exit both main outlet 20 and auxiliary outlets 22, which will counteract recoil forces as previously noted.

FIG. 8 is a perspective view of catheter 60 having distal tip 18 with main opening 20 and auxiliary openings 22. In this embodiment, auxiliary openings are arranged in an array, having linear sets of openings arranged about the periphery of distal tip 18. Although illustrated as three linear openings equally spaced apart on the axis, and located at ninety degree intervals about the circumference of distal tip 18, any number of openings in the linear direction as well as any number of rows circumferentially may be utilized.

FIG. 9 is a cross sectional view of catheter 60. In the embodiment illustrated, auxiliary openings 22 are covered with membranes 62. The membrane material is rupturable at a designated pressure, such as 100 psi. Once a high volume flow at the designated pressure is introduced into catheter 60, membranes 62 will separate from wall 66 of distal tip 18, thus creating auxiliary openings 22. Ideally, membranes 62 will not separate at pressures present during insertion of distal tip 18 and the rest of catheter 60, nor at gravity feed pressure (typically pressures below 100 psi). Upon introduction of a pressurized infusant at the designated pressure break point, membranes 62 will separate to create auxiliary openings 22.

Catheters containing flow holes present a potential problem of blood clotting in the tip. When the catheter is not in use and to maintain catheter patency, a saline or heparin lock is applied in practice. That is, the catheter is filled with the aforementioned solution(s) to prevent the catheter from getting blocked due to blood clotting. However, if the catheter contains flow holes, the fluid lock is ineffective since the fluid can escape out of the flow holes into the bloodstream and the section of the catheter between the flow holes and the tip eventually gets filled with blood. The blood can eventually clot and can potentially leading to thromboembolism. Membranes 62 covering auxiliary openings 22 allow for a fluid lock to stay effective, and prevent clot formation. Membranes 32 open only under the designated pressure. Prior to application of the pressurized infusant, auxiliary openings 22 are closed, thus preventing blood clotting in distal tip 18

Membranes 62 may be made of the same or similar material as the rest of distal tip 18 or the rest of catheter 60. In alternate embodiments, distal tip 18 is constructed from a first material and the rest of catheter 60 is constructed from a second material. Similarly, in some embodiments Membrane 62 is constructed from a different material than the rest of distal tip 18. Membranes 62 of distal tip 18 may be designed to contain differing break or rupture pressures. For example, the most distal membranes may break at 100 psi, with more proximal membranes breaking at 200 psi and 300 psi, respectively. Alternatively, the break points of the membranes may be reversed, such that the most distal membrane had the highest break point pressure.

In one embodiment, membranes 62 may contain a partial cut therethrough. The cut will extend from the inner surface towards the outer surface, and be located central to the auxiliary opening to be utilized. The cut will act as a weak point to assist in allowing the material to rupture and separate. Similarly, membranes 62 may contain more material adjacent the edge of auxiliary opening 22 being covered. The extra material will prevent the membrane from completely detaching from the wall of distal tip 18.

FIG. 9 illustrates an embodiment wherein membranes 62 are on the inner surface of distal tip 18. FIG. 10 illustrates an alternate embodiment wherein membranes 62 are attached at the outer surface of distal tip 18. Auxiliary openings 22 are illustrated as being angled, for the purposes previously noted. FIG. 11 illustrates an embodiment wherein membranes 62 are part of sleeve 64 that has been secured to the inner surface of distal tip 18. When infusants are introduced at the designated pressure, the portions of sleeve 64 adjacent auxiliary opening 22 will rupture to allow fluid to flow therethrough.

For catheters that utilize flow holes (such as auxiliary openings 22), blood may clot in or around the tip of the catheter, especially when the catheter must remain in place for an extended time, even after 24 hours. Therefore, improving the anti-thrombogenic properties of such indwelling vascular access devices, including catheters, may result in lower healthcare costs and increased patient comfort.

Typically, when a catheter is not in use, and to maintain catheter patency, a saline or heparin lock can be applied, i.e., the catheter is filled with such fluids to prevent blood clots from forming and blocking the catheter. If the catheter contains auxiliary openings, however, a fluid lock is generally ineffective because the fluid can escape from the auxiliary openings and into the bloodstream. Thus, the section of the catheter between the tip and the auxiliary openings may eventually fill with blood, which can create blood clots and potentially lead to thromboembolism, infection, or other undesirable clinical outcomes.

In various embodiments, a catheter including auxiliary openings can include anti- and/or non-thrombogenic coatings or other lubricious materials to reduce the formation of thrombi in or around such indwelling catheters.

With initial reference to Figs. 12A-12C, a catheter 14 comprising auxiliary openings 22 may be more susceptible to thrombus formation because traditional remedies, like introducing a lock solution 70 into the catheter, are mitigated by the escape of lock solution 70 through auxiliary openings 22. Blood may enter and coagulate within catheter 14 such as, for example, between mail outlet 20 and auxiliary openings 22 within tip 18.

In various embodiments, catheter 14 can comprise an anti-thrombogenic additive that is extruded along with the polymer comprising the catheter body during the manufacturing process. Such additives may migrate to the polymer surface and impart at least a portion of the surface of catheter 14 with anti-thrombogenic properties. For example, suitable additives can include fluoropolymer additives, which include fluorocarbon-based polymers, including oligomers, having carbon-fluorine bonds. After formation of catheter 14, auxiliary openings 22 extending from the lumen of catheter 14 to the outer surface. In such embodiments, the catheter surface, the catheter lumen, and the surface area of the flow holes extending from the lumen into the bloodstream may comprise anti-thrombogenic properties.

Further, for example, heparin or heparin sulfate can be applied to the part or all of catheter 14. In various embodiments, heparin or heparin sulfate is added to the distal end of catheter 14, which is in contact with a patient's blood or other biologic environment. Although heparin is a suitable anti-thrombogenic agent, it may cause reactions in patients that have allergies to certain animal-based reagents because it is usually made from animal

products. In such cases, hirudin is a suitable alternative because it does not tend to induce allergic reactions similar to heparin, yet functions much like heparin. Still other suitable anti-thrombogenic agents include proteins or peptides.

In addition to using coatings that elute anti-thrombogenic agents like heparin-based coatings and hirudin, coatings that include non-thrombogenic polymers, like phosphorylcholine for example, may be utilized. Such materials differ from drug eluting coatings in that the polymer itself acts to prevent platelets from depositing on surfaces of catheter 14, thereby arresting blood clot formation. Other substances that help prevent clot formation include amalgamating a dense layer of polyethyleneoxide chains to the catheter surface. Such non-thrombogenic polymer coatings can include an active biologic that helps turn off the foreign body response and is highly non-thrombogenic.

In various embodiments, a catheter polymer material or matrix is compounded with an anti-thrombogenic additive and then extruded into the catheter tubes. In such embodiments, the anti-thrombogenic additive can migrate to the polymer surface, imparting the entire catheter surface with anti-thrombogenic properties.

In various embodiments, an anti-thrombogenic coating is applied to a surface of a catheter in one or more of the following manners: the coating is applied only to a portion of the length of the catheter so that only the surfaces distal and including the flow holes of the catheter are coated; or only to the distal portion of the catheter excluding the flow holes; or only to the distal portion of the catheter that is in contact with body fluids or blood. Further, a portion or all of the inside and/or outside surfaces of any portion of the catheter can be coated with an anti-thrombogenic coating to reduce blood platelet adhesion and thrombus formation.

In various embodiments, a micro-pattern of an anti-thrombogenic agent can be applied to a length of an interior and/or exterior surface of the tubular body member. The anti-thrombogenic agent can comprise any suitable material that inhibits blood platelet adhesion, thrombus formation and/or infection, including but not limited to those disclosed herein.

Any relative terms or terms of degree used herein, such as "substantially", "essentially", "generally" and the like, should be interpreted in accordance with and subject to any applicable definitions or limits expressly stated herein. In all instances, any relative terms or terms of degree used herein should be interpreted to broadly encompass any relevant disclosed embodiments as well as such ranges or variations as would be understood by a person of ordinary skill in the art in view of the entirety of the present disclosure, such as to

encompass ordinary manufacturing tolerance variations, incidental alignment variations, intermittent pressure variations, and the like.

While the present disclosure has been described with reference to an exemplary embodiment(s), it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted for elements thereof without departing from the scope of the present disclosure. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the present disclosure without departing from the essential scope thereof. Therefore, it is intended that the present disclosure not be limited to the particular embodiment(s) disclosed, but that the disclosure will include all embodiments falling within the scope of the appended claims. For example, features described with respect to any given embodiment can be utilized in conjunction with any other disclosed embodiment. Also, the present disclosure can be implemented in conjunction with other structures or steps not specifically discussed, as would be understood by a person of ordinary skill in the art.

CLAIMS:

1. A catheter comprising:

an elongated tubular structure having a proximal end and a distal end, wherein the distal end of the elongated tubular structure comprises a main opening at a distal edge; and

a plurality of auxiliary openings, wherein each of the plurality of auxiliary openings is covered by a respective rupturable membrane.

2. The catheter of claim 1, wherein the respective rupturable membranes are secured to an inner portion of the distal end.

3. The catheter of claim 1, wherein the respective rupturable membranes are secured to an outer portion of the distal end.

4. The catheter of claim 1, wherein the proximal end of the elongated tubular structure comprises a first material, and the distal end comprises a second material.

5. The catheter of claim 1, further comprising a sleeve secured to the distal end, wherein the sleeve contains the respective rupturable membranes.

6. The catheter of claim 1, wherein at least a portion of elongated tubular structure comprises a polymeric material with an anti-thrombogenic agent.

7. The catheter of claim 6, wherein the anti-thrombogenic agent is disposed on a surface of at least a portion of the elongated tubular structure.

8. The catheter of claim 6, wherein the distal end of the elongated tubular structure comprises the anti-thrombogenic agent.

9. The catheter of claim 6, wherein the anti-thrombogenic agent comprises at least one of a heparin-based agent, hirudin, a protein, a peptide, and a fluoropolymer additive.

10. The catheter of claim 1, wherein an inner surface of the elongated tubular structure comprises a lubricious coating.

11. The catheter of claim 1, wherein at least a portion of the elongated tubular structure comprises at least one of a phosphorylcholine additive and a polyethyleneoxide additive.

12. A catheter assembly comprising:

a catheter comprising a central lumen having a proximal end and a distal end, and a distal tip attached to the central lumen at the distal end, the distal tip comprising a plurality of openings that are covered by a membrane that is capable of being ruptured at a designated pressure; and a catheter hub attached to the proximal end of the catheter.

13. The catheter assembly of claim 12, wherein the membrane is secured to an inner portion of the distal tip.

14. The catheter assembly of claim 12, wherein the membrane is secured to an outer portion of the distal tip.

15. The catheter assembly of claim 12, wherein the designated pressure is equal to or greater than 100 pounds per square inch.

16. The catheter assembly of claim 12, wherein the plurality of openings are angled with respect to a central axis of the central lumen.

17. A catheter comprising:

a main lumen having a proximal end, a distal tip, and a central axis, wherein the distal tip of the main lumen contains a main outlet; and

a plurality of auxiliary lumens secured to the main lumen, each of the plurality of auxiliary lumens having a proximal end and a distal end, wherein the plurality of auxiliary lumens are secured to the main lumen in a coaxial arrangement, and wherein the each of the plurality of auxiliary lumens contain a respective auxiliary outlet proximal to the main outlet.

18. The catheter of claim 17 wherein the distal tip is tapered.

19. The catheter of claim 17 wherein the main lumen shares a common wall with each of the plurality of auxiliary lumens.

20. The catheter of claim 17 wherein the main lumen and each of the plurality of auxiliary lumens share a common opening adjacent the proximal end.

21. The catheter of claim 17 wherein the plurality of auxiliary lumens comprise a translucent material.

22. A catheter assembly comprising:

a main lumen having a proximal end with an inlet and a distal tip with an outlet at a distal end;

at least one auxiliary lumen attached to the main lumen, the at least one auxiliary lumen having a proximal end and a distal end; and

a hub attached to the proximal end of the main lumen and the proximal end of the at least one auxiliary lumen, wherein the main lumen and the at least one auxiliary lumen share an opening at the hub.

23. The catheter assembly of claim 22, wherein the at least one auxiliary lumen comprises a translucent material.

24. The catheter assembly of claim 22, wherein the at least one auxiliary lumen contains an auxiliary outlet in communication with the distal tip proximal the outlet of the main lumen.

25. The catheter assembly of claim 22, further comprising a plurality of auxiliary lumens attached to the main lumen.

26. The catheter assembly of claim 22, wherein each of the plurality of auxiliary lumens shares a common wall with the main lumen.

27. A vascular access and infusion device, including a catheter, comprising:

an elongated tubular structure having a proximal end, a distal end, and a lumen extending there between; and

a tip at the distal end of the elongated tubular structure having a main opening and at least one auxiliary opening being formed through a wall thickness of the elongated tubular structure and in communication with the lumen,

wherein at least a portion of the catheter comprises an anti-thrombogenic agent.

28. The device of claim 27, wherein the anti-thrombogenic agent is disposed on the distal end of the elongated tubular structure.

29. The device of claim 27, wherein at least a portion of an inner surface of the elongated tubular structure comprises a lubricious coating.

30. The device of claim 27, wherein the anti-thrombogenic agent comprises at least one of a heparin-based drug or agent, hirudin, a protein, a peptides, and a fluoropolymer additive.

31. The device of claim 27, wherein the elongated tubular structure comprises at least one of a phosphorylcholine additive and a polyethyleneoxide additive.

32. A method of manufacturing a catheter comprising:

compounding a catheter polymer material with an anti-thrombogenic additive; and

extruding a tubular catheter body from the catheter polymer material, wherein the anti-thrombogenic additive migrates to a surface of the tubular catheter body imparting the surface with anti-thrombogenic properties.

33. The method of claim 32, wherein the anti-thrombogenic additive comprises at least one of a heparin-based drug or agent, hirudin, a protein, a peptides, and a fluoropolymer additive.

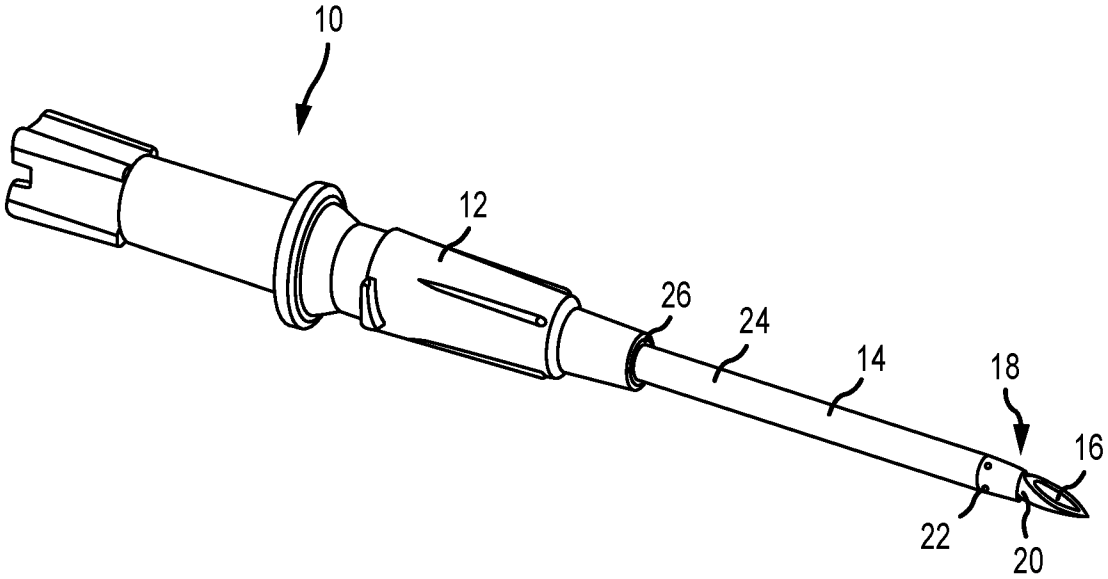


FIG.1

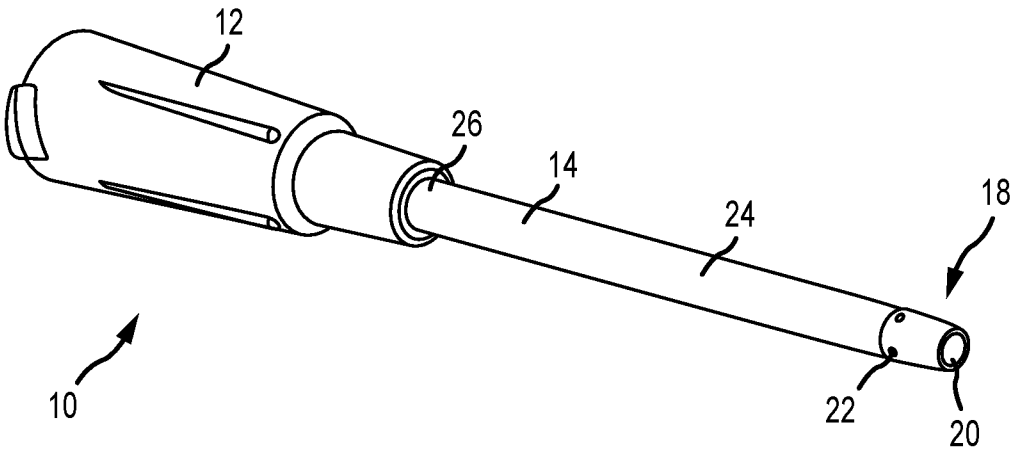


FIG.2

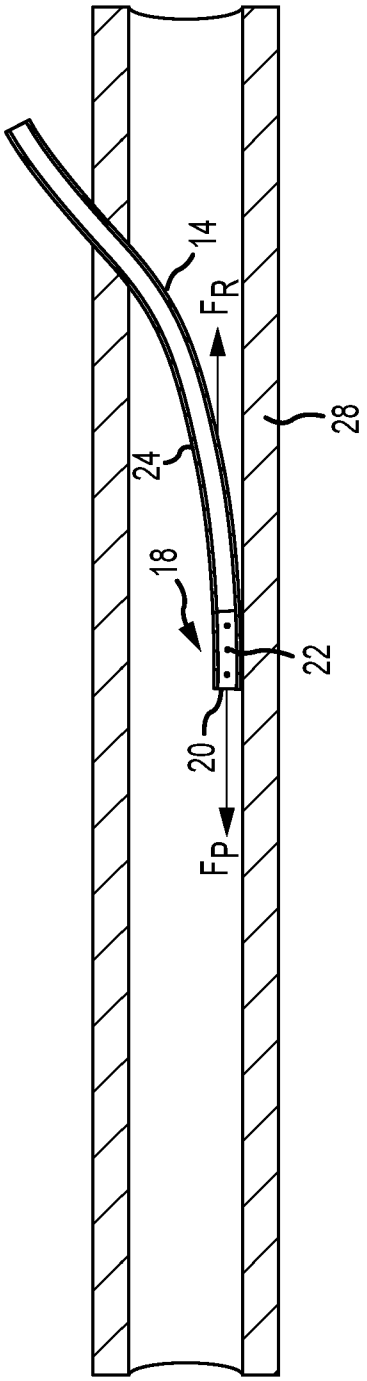


FIG.3

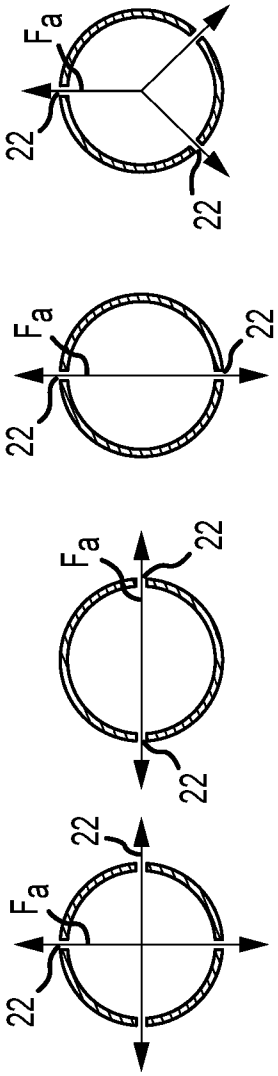


FIG.4

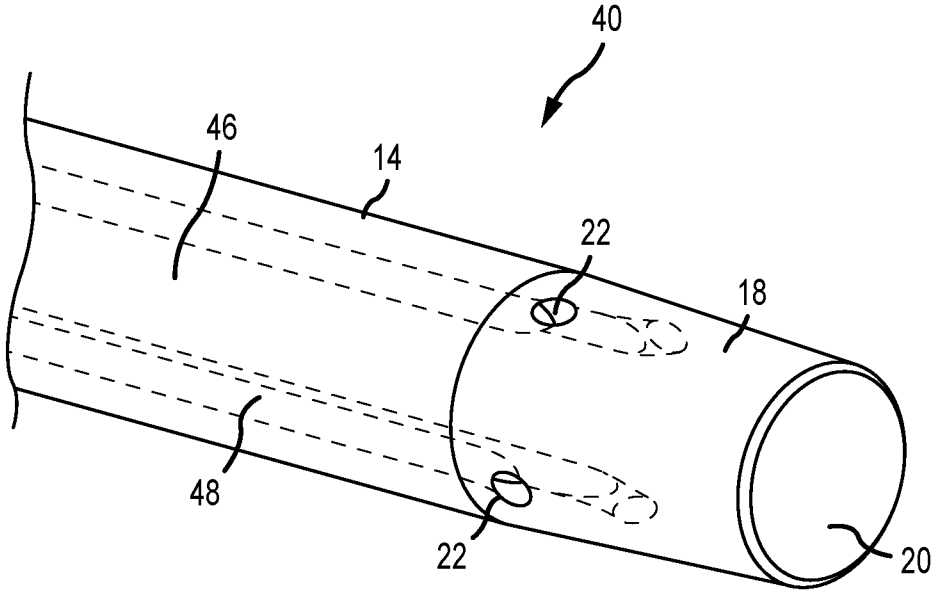


FIG.5

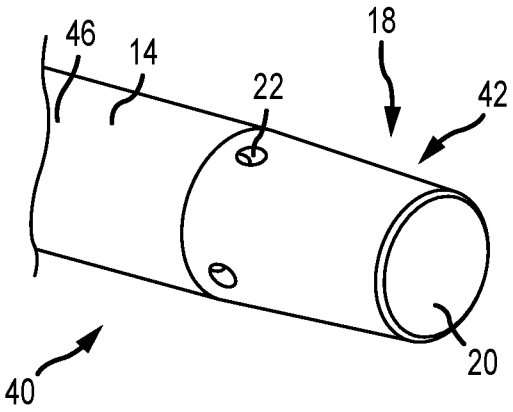


FIG.6

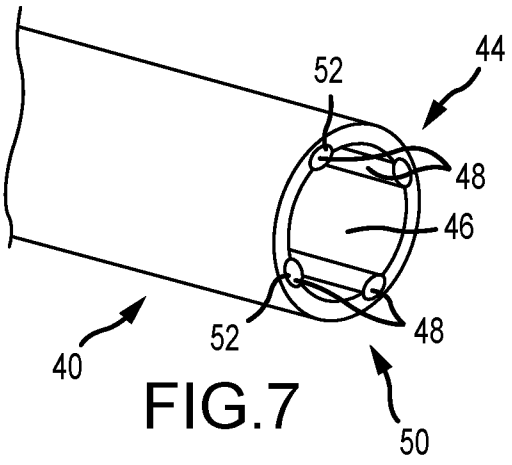


FIG.7

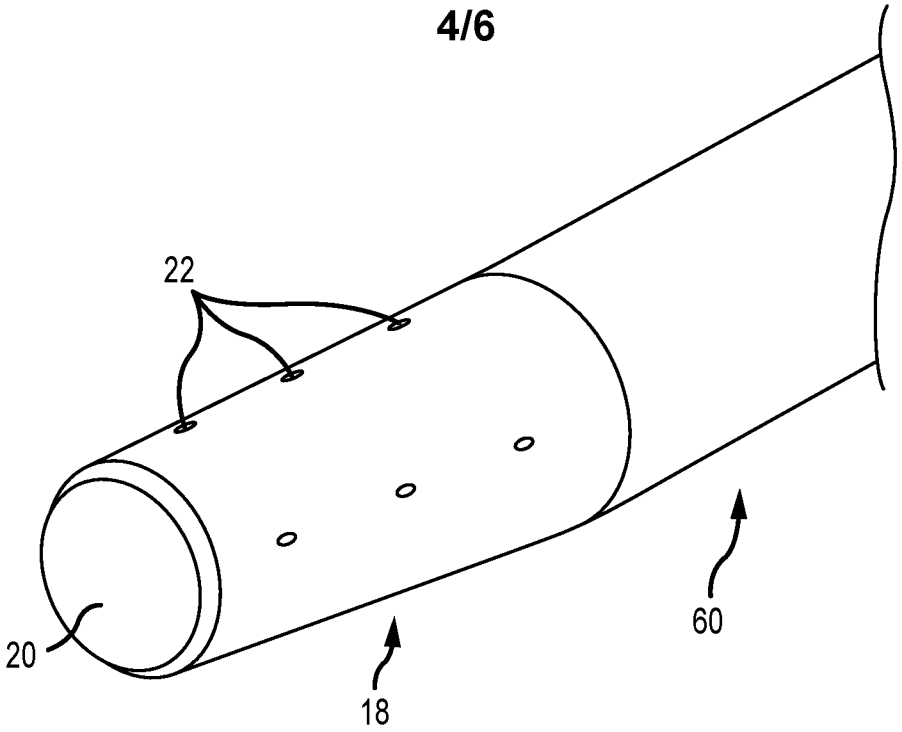


FIG.8

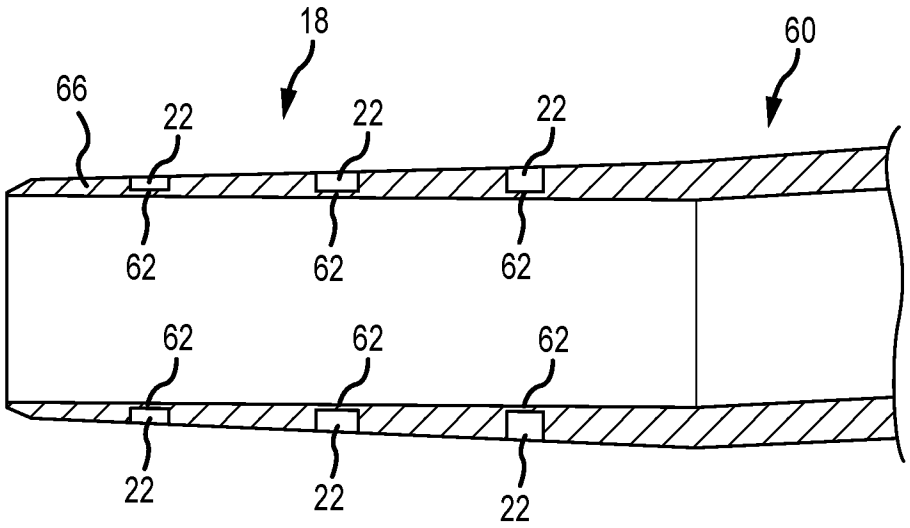


FIG.9

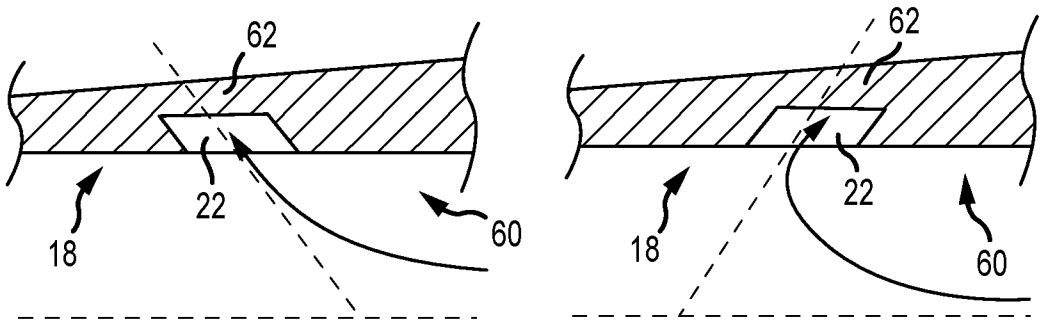


FIG.10

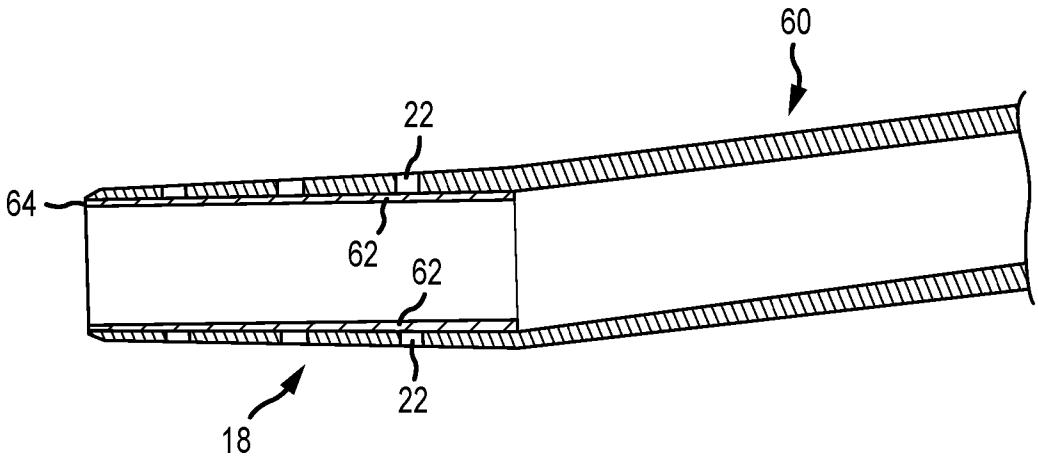


FIG.11

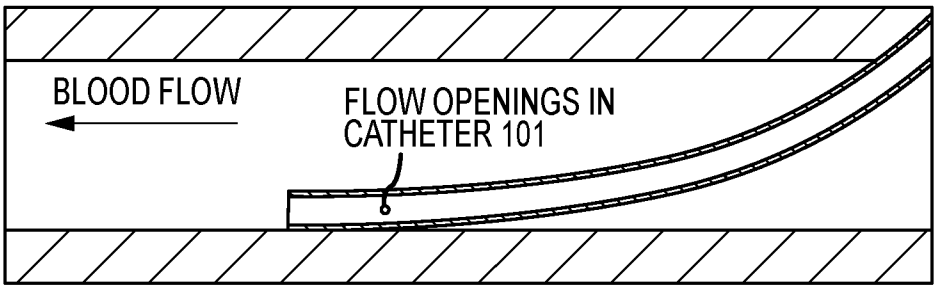


FIG.12A

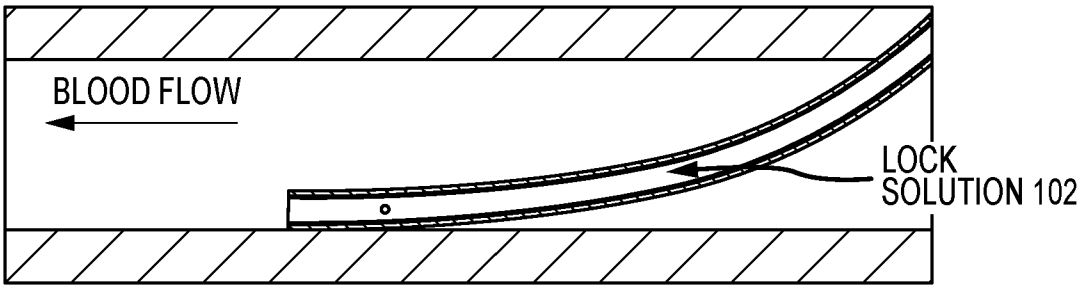


FIG.12B

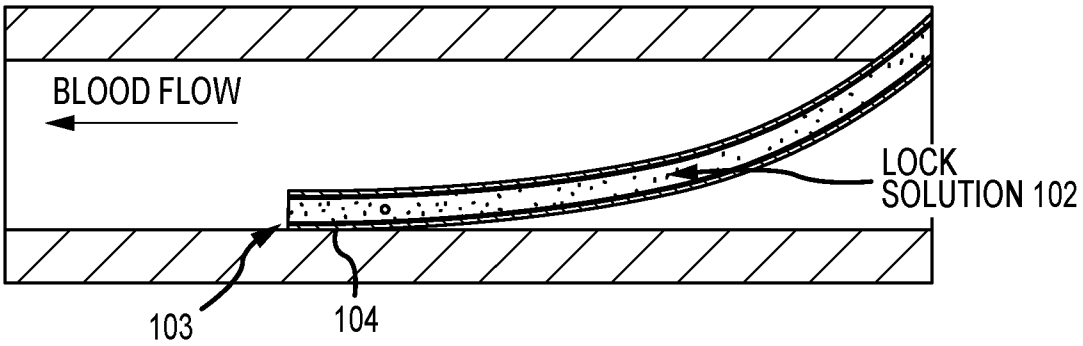


FIG.12C