US 20200016390A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2020/0016390 A1**

KLEPAC (43) **Pub. Date: Jan. 16, 2020**

(54) **VASCULAR ACCESS PORT AND CATHETER**

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(21) Appl. No.: **16/536,375**

(22) Filed: **Aug. 9, 2019**

Related U.S. Application Data

(63) Continuation of application No. 13/222,462, filed on Aug. 31, 2011, now Pat. No. 10,406,340.

(60) Provisional application No. 61/411,270, filed on Nov. 8, 2010.

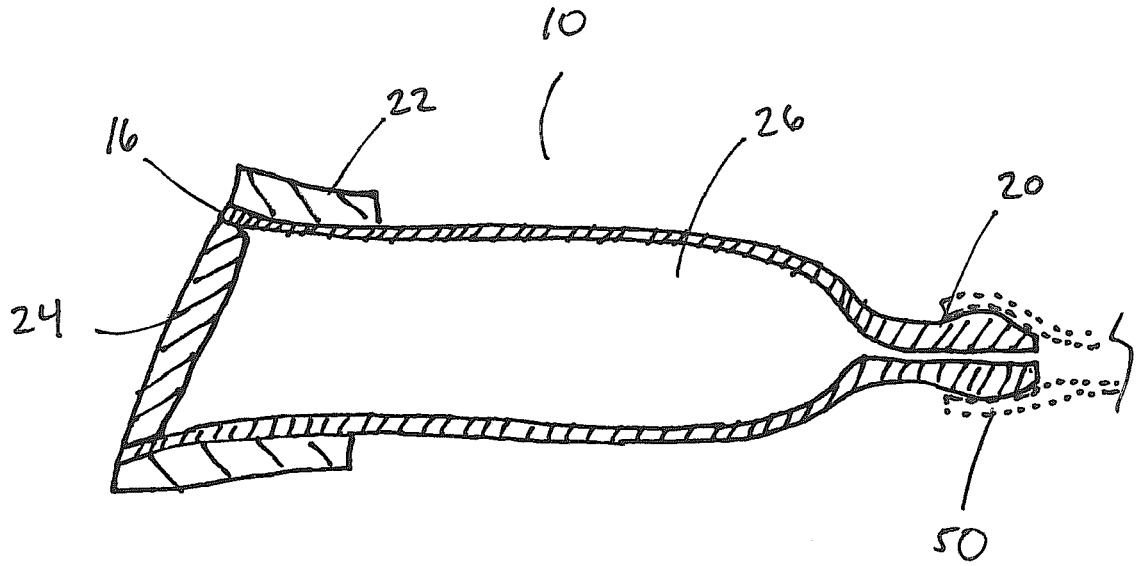
Publication Classification

(51) **Int. Cl.**
A61M 39/02 (2006.01)
A61M 39/06 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 39/0247*** (2013.01); *A61M 25/0097* (2013.01); ***A61M 39/06*** (2013.01)

(57) **ABSTRACT**

A vascular access port and catheter for use in association with same. The port has a length greater than its height and an access face that is angled with respect to the longitudinal axis of the port. The catheter has a first end for association with a port, and a second end with an angled intra-vascular flange. Apart from the flange is an extra-vascular retaining ring. The wall of the vessel is disposed between the intra vascular flange and extra vascular retaining ring to hold the catheter in place without the need of sutures.



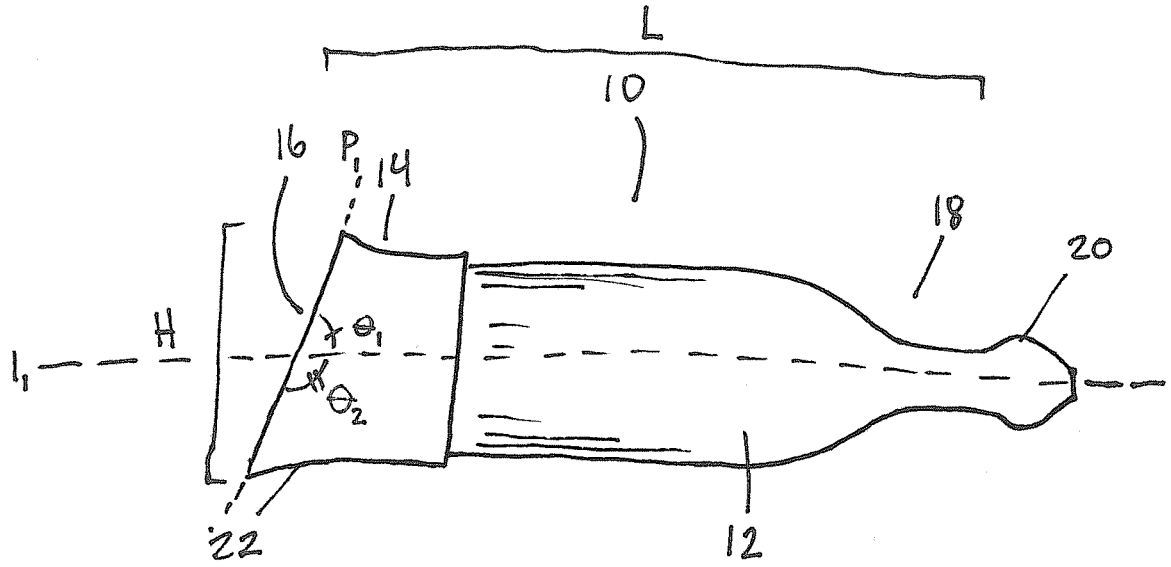


FIG. 1

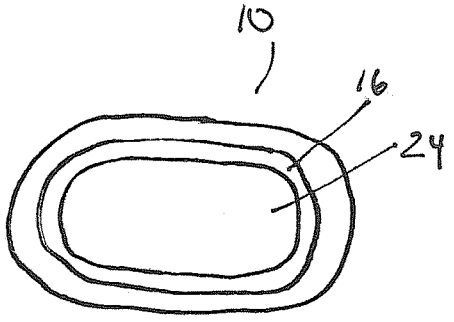


FIG. 2

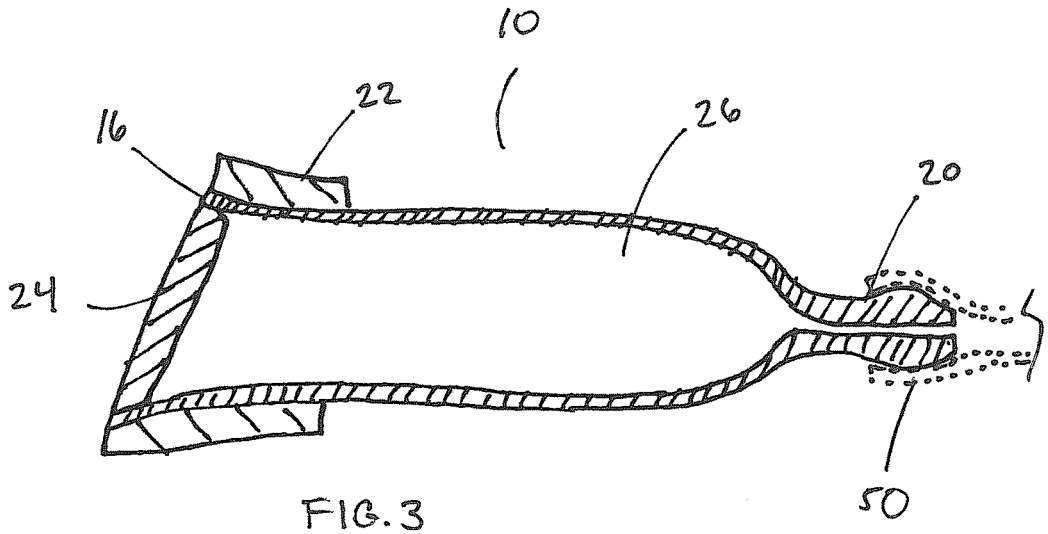


FIG. 3

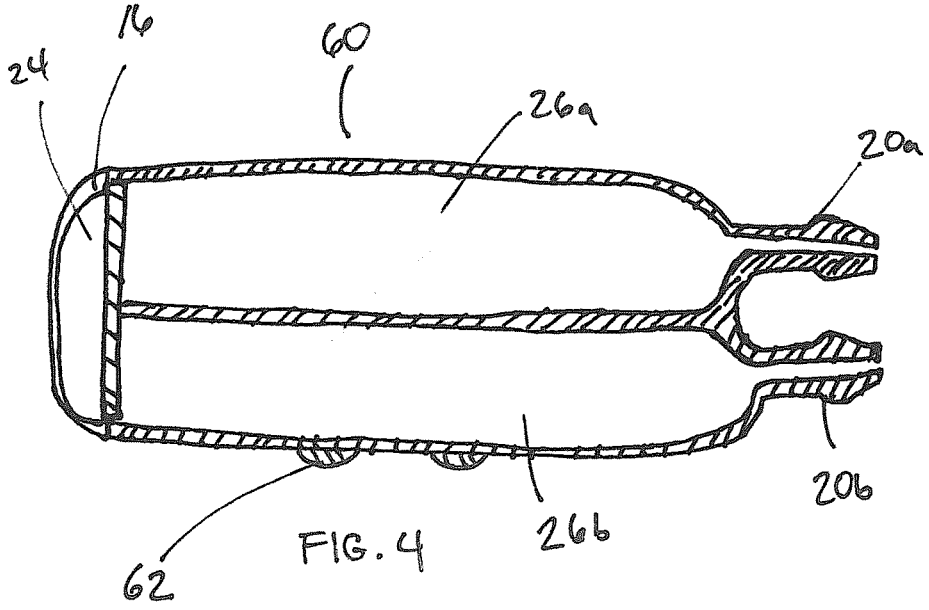


FIG. 4

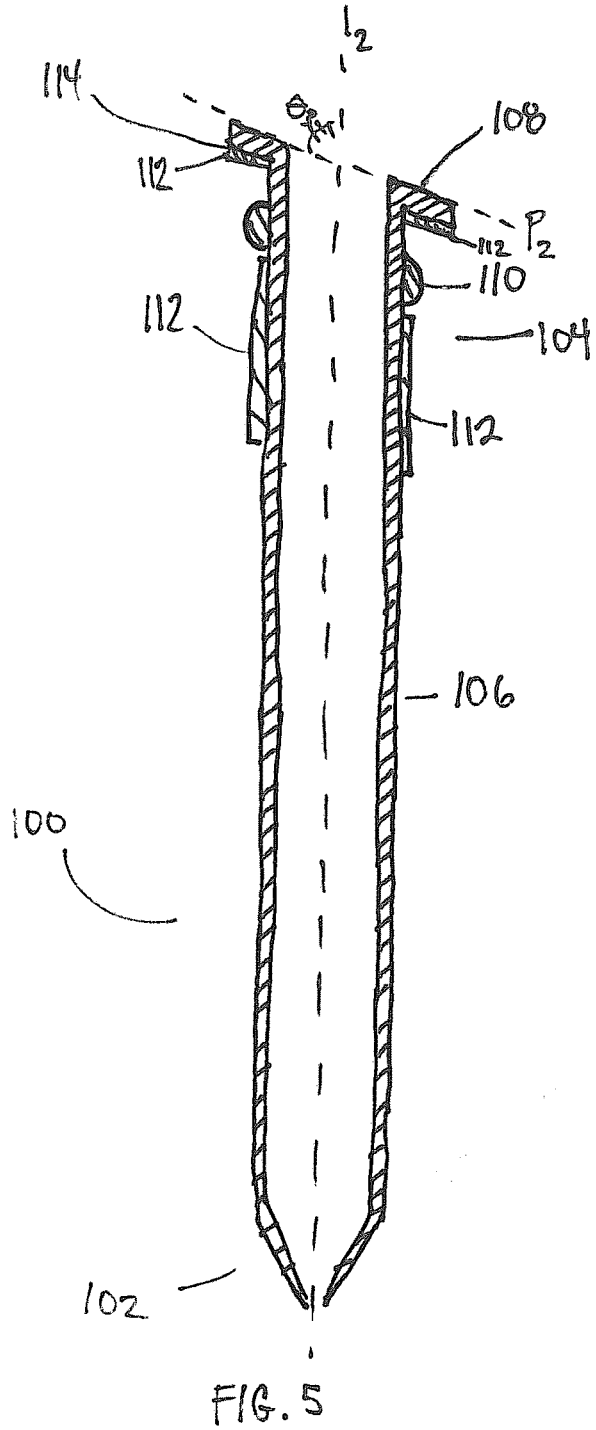

l_2
114
θ_{int}
108
112
P_2
112
110
112
104
112
106
100
102

FIG. 5

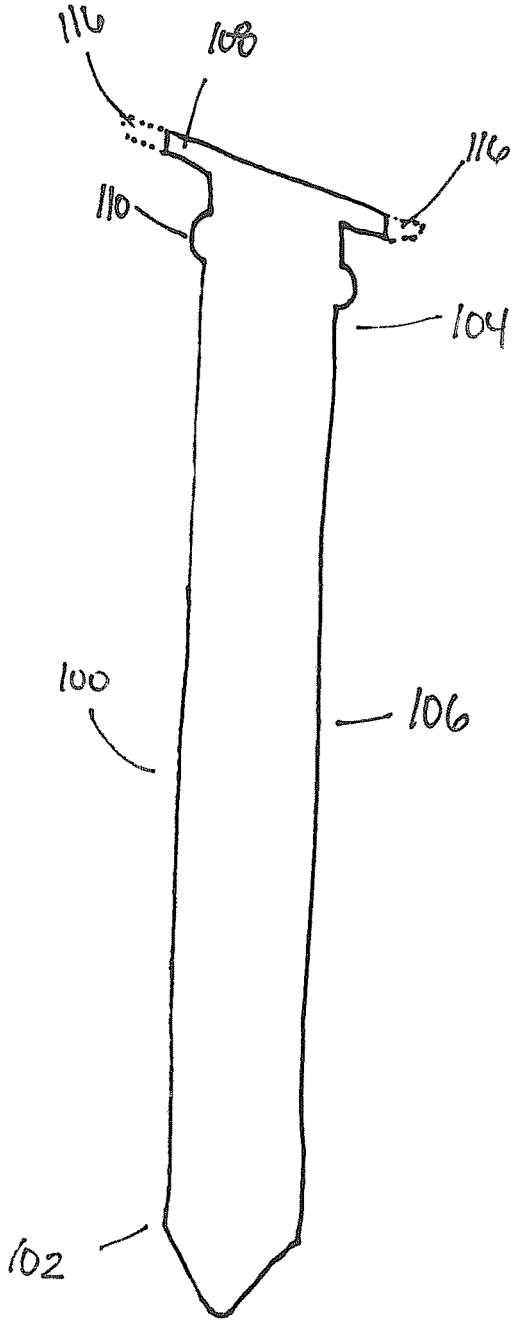

116
108
116
110
104
100
106
102

FIG. 6

VASCULAR ACCESS PORT AND CATHETER

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation application of U.S. patent application Ser. No. 13/222,462, filed Aug. 31, 2011, which claims priority from U.S. Provisional Application No. 61/411,270 filed Nov. 8, 2010, the entireties of which are incorporated herein.

FIELD OF THE INVENTION

[0002] The invention relates to a vascular access port and catheters that are used in association with same.

BACKGROUND OF THE INVENTION

[0003] Vascular access ports are useful in the treatment of certain diseases that can require the infusion of drugs, blood products, nutritional fluids, or other fluids into a patient's venous or arterial system.

[0004] The ports are beneficial in that they allow for repeated access to a patient's venous or arterial system through catheters attached to the port.

[0005] Since the ports are often implanted for an extended period of time, the manner of attachment, the comfort of the patient, and decreasing the rates of infections are all concerns that need to be adequately addressed by such a port.

[0006] With respect to the catheters used with the port, the catheters are typically attached to vessels using sutures or other invasive means that penetrate the vessel walls and can cause permanent damage to the vessel.

[0007] The present invention is directed to resolving these and other matters.

SUMMARY OF THE INVENTION

[0008] In one embodiment of the invention, the invention is directed to a port for allowing vascular access. The port may include a body having a length with a longitudinal axis and a height, the length being greater than the height, a first end having an access face and a second end with a connecting member, and, a retaining cuff disposed on the body at the first end, wherein the access face lies in a plane being at an angle with respect to the longitudinal axis of the body.

[0009] The port may include two fludically separated chambers, and each chamber may be associated with a connecting member.

[0010] The port may include a perimeter about the longitudinal axis, and the perimeter may be an oval, or it may be a circle.

[0011] A port according to this embodiment allows for repeated access to the vessels, while providing increased stabilization of the position of the port. Moreover, the overall design is believed to provide for better patient comfort. Finally, such a port decreases the risk of infection as it is intended to be subcutaneously placed.

[0012] Further, it is believed that a port according to one or more of these embodiments allows the device to have a flatter (lower profile) position under the patient's skin. Moreover, such a port does not leave the access face outwardly exposed. In addition, it is believed to provide a better connection with a catheter, as the connection can be in line with the longitudinal axis of the port—as opposed to an angle.

[0013] In another embodiment of the invention, the invention is directed to a catheter having a first end capable of receiving a connecting member, a second end, and, a tubular extension disposed between the first end and second end and having a longitudinal axis, wherein the second end includes an intra-vascular flange, and a extra-vascular retaining ring being spaced apart from the intravascular flange, and, wherein the intra-vascular flange is in a plane located at an angle to the longitudinal axis.

[0014] The extra-vascular retaining ring may be integral with the tubular extension.

[0015] Further, the extra-vascular retaining ring may be movable with respect to the intra-vascular flange.

[0016] The catheter may also include a stent material disposed adjacent the second end.

[0017] The intra-vascular flange may also include a stent material, and may include a stent material on an upper-side of the intra-vascular flange.

[0018] The edges of the intra-vascular flange may be tapered.

[0019] A catheter according to one or more of these embodiments is believed to provide many benefits. For example, a catheter according to the present invention does not need to be sutured to a vessel. Rather, the vessel wall is placed between the intra-vascular flange and the extra-vascular retaining ring. This holds the catheter in place. Since the catheter does not require sutures, or other invasive attaching means, less damage is done to vessel wall.

[0020] Moreover, since no continuous arterial venous fistula is created, the return vein will not develop pressure induced intimal hyperplasia or stenosis. While, some fibrin deposition will occur from the presence of the catheter material at the anastomotic site, this should progress in a much slower manner.

[0021] In addition, lack of a continuous fistula also minimizes the possibility of the patient developing an arterial steal phenomena or extremity swelling from passive venous congestion.

[0022] The maintenance of the port and catheters can also easily be achieved with such a port and/or catheter.

[0023] Moreover the port and catheters allow for central vascular access can be obtained for antegrade arterial and retrograde venous cannulation to perform thrombectomy and angioplasty. When a catheter needs to be exchanged, secondary sites can be utilized in close proximity to the original anastomosis. This extends the life of the accessed vessel and thus markedly extends the time an extremity can be used for dialysis.

[0024] It is contemplated, but not necessarily required, that a port according to the present invention is utilized in association with a catheter according to the present invention.

[0025] It is to be understood that the aspects and objects of the present invention described above may be combinable and that other advantages and aspects of the present invention will become apparent upon reading the following description of the drawings and detailed description of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] The present invention will become more fully apparent from the following description and appended claims, taken in conjunction with the accompanying drawings.

[0027] FIG. **1** is a side perspective view of a vascular access port according to an embodiment of the present invention.

[0028] FIG. **2** is a front perspective view of a vascular access port according to an embodiment of the present invention.

[0029] FIG. **3** is a side perspective cutaway view of a vascular access port according to an embodiment of the present invention.

[0030] FIG. **4** is a top perspective cutaway view of a vascular access port according to an embodiment of the present invention.

[0031] FIG. **5** is a side cutaway view of a catheter according to the present invention.

[0032] FIG. **6** is a side view of a catheter according to the present invention.

[0033] Understanding that the accompanying drawings depict only typical embodiments, and are, therefore, not to be considered to be limiting of the scope of the present disclosure, the embodiments will be described and explained with specificity and detail in reference to the accompanying drawings.

DETAILED DESCRIPTION OF THE DRAWINGS

[0034] While this invention is susceptible of embodiment in many different forms, there is shown in the drawings and will herein be described in detail one or more embodiments with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the invention to the embodiments illustrated.

[0035] Reference throughout this description to features, advantages, objects or similar language does not imply that all of the features and advantages that may be realized with the present invention should be or are in any single embodiment of the invention. Rather, language referring to the features and advantages is understood to mean that a specific feature, advantage, or characteristic described in connection with an embodiment is included in at least one embodiment of the present invention. Thus, discussion of the features and advantages, and similar language, throughout this specification may, but do not necessarily, refer to the same embodiment.

[0036] A preferred embodiment of the port **10** according to an aspect of the present invention includes a body **12** having a first end **14** and a second end **18**. The body **12** may be constructed out of plastic, titanium, or any other suitable material.

[0037] Measuring from the first end **14** to the second end **18** provides a measurement for a length L. The body **12** also includes a height H. The length L is greater than the height H. Depending on the configuration of the body **12**, the length L may range between 2.5 cm-3.8 cm and the height H may range from 1.3 cm-1.9 cm. This configuration allows for the port **10** to be implanted in a patient, such that the length L of the body **12** is relatively parallel to the body part in the patient where the port **10** is being implanted. For example, if the port **10** is implanted in an arm, the length L of the body **12** would extend in the same direction as the length of the patient's arm.

[0038] The first end **14** includes an access face **16** that lies in a plane P_1 that is at an angle with respect to the longitudinal axis $\mathbf{1}_1$ of the body **12**. It is preferred that the acute angle θ_1 of the access face **16** be disposed adjacent the patient's skin (or laterally), and the obtuse angle θ_2 be disposed away from the skin (or medially). At the second end **18**, it is preferred that the body **12** is tapered to a connecting member **20**. The connecting member allows for a catheter **50** or other device to be attached to the body **12** of the port **10** in order to, for example, transport liquids deposited by needle.

[0039] The access face **16** may include a septum **24** for allowing access to a chamber **26** inside of the body **12**. In this manner, the septum **24** can be penetrated, for example, by a needle and allow for delivery of liquid. The septum **24** provides for a fludically sealed chamber **26**. The septum **24** may be made from silicone or other suitable materials.

[0040] In order to maintain the placement of the port **10**, disposed about the first end **14** is a retaining cuff **22**. The retaining cuff **22** allows for tissue to grow and attach itself to the retaining cuff **22**, and thus the port **10**. This will maintain the position of the port **10** within the patient's body. For example, the retaining cuff **22** may be Dacron®, a polyester weave material, or any other known material. Other retaining methods known in the art, such as sutures, etc, may be employed to assist in maintaining the position of the port **10**.

[0041] In one embodiment contemplated, a port **60** may include two fludically separated chambers **26***a*, **26***b*, and each chamber **26***a*, **26***b* may be associated with a connecting member **20***a*, **20***b*. (See, FIG. **4**). In such a configuration, it is contemplated that nipples **62**, ridges, studs, or other structures are provided such that the structure indicates the appropriate configuration. In other words, nipples **62** may be placed on the external surface of the body on the medial side so that after subcutaneous implantation, so that a person can feel the nipples **62** and easily discern which chamber **26***a*, **26***b* is disposed medially.

[0042] The port **10**, **60** may include a perimeter about the longitudinal axis, and the perimeter may be an oval (FIG. **2**), or it may be a circle (FIG. **4**). Although depicted with a dual chamber port **60** having a circle perimeter and the single chamber port **10** having an oval perimeter, the present invention is not indented to be limited to such a shape, and the port **10**, **60** may have various shapes and still fall within the scope of the present invention.

[0043] As previously discussed, a port according to one or more aspects of the present invention is believed to provide, at a minimum, a port that minimizes the risk of infection, while providing an access point that accommodates the patient's comfort, as well as maintaining its implanted positioning.

[0044] As previously mentioned, the connecting member **20** allows the port **10**, **60** to be attached to, for example, a catheter **50**. It is preferred, but not required, that the catheter **100** be of the configuration depicted in FIGS. **5-6**.

[0045] In this aspect of the invention, the catheter **100** includes a first end **102** capable of receiving a connecting member, a second end **104**, and, a tubular extension **106** disposed between the first end **102** and second end **104**. The catheter **100** also includes a longitudinal axis $\mathbf{1}_2$. The catheter **100** may be made from polyurethane. Moreover, the size of the catheter **100** can range from 5 F to 8 F.

[0046] The second end **104** includes an intra-vascular flange **108**, and a extra-vascular retaining ring **110** being spaced apart from the intravascular flange **108**.

[0047] The intra-vascular flange **108** is in a plane P_2 located at an angle θ_3 to the longitudinal axis $\mathbf{1}_2$. In a

preferred embodiment, the intra-vascular flange **108** has an angle θ_3 between 30-45 degrees to the longitudinal axis 1_2.

[0048] The extra-vascular retaining ring **110** may be integral with the tubular extension **106**.

[0049] Further, the extra-vascular retaining ring **110** may be movable with respect to the intra-vascular flange **108**.

[0050] As shown in FIG. **5**, the catheter **100** may also include a sleeve of stent material **112** disposed adjacent the second end **104**. One such suitable stent material **112** is nitinol.

[0051] The intra-vascular flange **108** may also include a stent material **112**, and may include a stent material **112** on an upper-side **114** of the intra-vascular flange **108**. Another suitable stent material **112** may be stent barbs.

[0052] Further, the edges **116** of the intra-vascular flange **108** may be tapered to assist in the placement of same with guide wires. These guide wires may be removed prior to attachment of the catheter **100** to the port **10**.

[0053] The catheter **100** should have some structural rigidity which can be a property of the material of the catheter **100** (or thickness of same), or it may be imparted from an additional material, for example, wire mesh, or a coating such as silver oxide.

[0054] In order to aid in the placement of the catheter **100**, it is contemplated that the intra-vascular flange **108** and the extra-vascular retaining ring **110** are radio opaque. The catheter **100** may be positioned within vessels with the aide of a peel-away sheath of retractable stent deployment device.

[0055] As discussed above, the intra-vascular flange **108** and the extra-vascular retaining ring **110** function to hold the vessel wall, such that the catheter **100** may be placed without the need for suturing to the vessel wall. This will result in less damage done to the vessel.

[0056] It is to be understood that additional embodiments of the present invention described herein may be contemplated by one of ordinary skill in the art and that the scope of the present invention is not limited to the embodiments disclosed. While specific embodiments of the present invention have been illustrated and described, numerous modifications come to mind without significantly departing from the spirit of the invention, and the scope of protection is only limited by the scope of the accompanying claims.

1-17. (canceled)

18. A catheter comprising:

a tubular extension extending from a first end to a second end and defining a longitudinal axis between the first end and the second end, wherein the first end is configured to receive a connecting member;

an intra-vascular flange formed from a first material and coupled to the tubular extension at the second end;

an extra-vascular retaining ring coupled to the tubular extension and spaced apart from the intra-vascular flange; and

a sleeve of stent material coupled to an outer surface of the tubular extension such that the sleeve terminates at a sleeve distal end and a sleeve proximal end whereby the entirety of the sleeve lies between the extra-vascular retaining ring and the first end of the tubular extension;

wherein the extra-vascular retaining ring and the intra-vascular flange are configured to hold the catheter in place when a wall of a peripheral vessel is positioned between them.

19. The catheter of claim **18**, wherein the extra-vascular retaining ring is a continuous ring in uninterrupted contact with the tubular extension around a circumference of the tubular extension.

20. The catheter of claim **18**, wherein the extra-vascular retaining ring is integrally formed with the tubular extension.

21. The catheter of claim **18**, wherein the extra-vascular retaining ring is movable along the tubular extension.

22. The catheter of claim **18**, further comprising an annular disk formed from a second material coupled to a planar upper face of the intra-vascular flange, the second material being different from the first material such that the annular disk is configured to increase the rigidity of the intra-vascular flange.

23. The catheter of claim **22**, wherein the annular disk is constructed of a stent material comprising stent barbs.

24. The catheter of claim **22**, wherein an inner face of the annular disk abuts the tubular extension and an outer face of the annular disk is adjacent an outer edge of the intra-vascular flange.

25. The catheter of claim **18**, wherein the extra-vascular retaining ring has a hemispherical cross-section.

26. The catheter of claim **18**, wherein the intra-vascular flange includes tapered edges.

27. The catheter of claim **18**, wherein the intra-vascular flange is disposed at an oblique angle with respect to the longitudinal axis.

28. The catheter of claim **18**, wherein the sleeve comprises a stent material comprising nitinol.

29. A catheter comprising:

a tubular extension extending from a first end to a second end and defining a longitudinal axis between the first end and the second end, wherein the first end is configured to receive a connecting member;

an intra-vascular flange formed from a first material and coupled to the tubular extension at the second end of the tubular extension, the intra-vascular flange being non-orthogonal to the longitudinal axis and having an upper face and a lower face, wherein the upper face is nearer the first end than is the lower face;

an extra-vascular retaining ring coupled to the tubular extension and spaced apart from the intra-vascular flange, the extra-vascular retaining ring being a continuous ring;

an annular disk coupled to the upper face of the intra-vascular flange; and

a sleeve of stent material coupled to an outer surface of the tubular extension such that the sleeve terminates at a sleeve distal end and a sleeve proximal end, whereby the sleeve lies between the extra-vascular retaining ring and the first end of the tubular extension;

wherein the extra-vascular retaining ring and the intra-vascular flange are configured to hold the catheter in place when a wall of a peripheral vessel is positioned between them.

30. The catheter of claim **29**, wherein a distal end of the sleeve is adjacent the extra-vascular retaining ring.

31. The catheter of claim **29**, wherein the sleeve comprises a stent material comprising nitinol.

32. The catheter of claim **29**, wherein the annular disk is constructed of a stent material comprising stent barbs.

33. The catheter of claim **29**, wherein an inner face of the annular disk abuts the tubular extension and an outer face of the annular disk is adjacent an outer edge of the intra-vascular flange.

34. A catheter, comprising:

a tubular extension extending from a first end to a second end, wherein the first end is configured to receive a connecting member;

an extra-vascular retaining ring coupled to the tubular extension, and

a sleeve of stent material coupled to an outer surface of the tubular extension such that the sleeve terminates at a sleeve distal end and a sleeve proximal end whereby the entirety of the sleeve lies between the extra-vascular retaining ring and the first end of the tubular extension.

35. The catheter of claim **34**, wherein the extra-vascular retaining ring is integrally formed with the tubular extension.

36. The catheter of claim **34**, wherein the extra-vascular retaining ring has a hemispherical cross-section.

37. The catheter of claim **34**, wherein the sleeve comprises a stent material comprising nitinol.

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