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(58) **Field of Classification Search**
None
See application file for complete search history.

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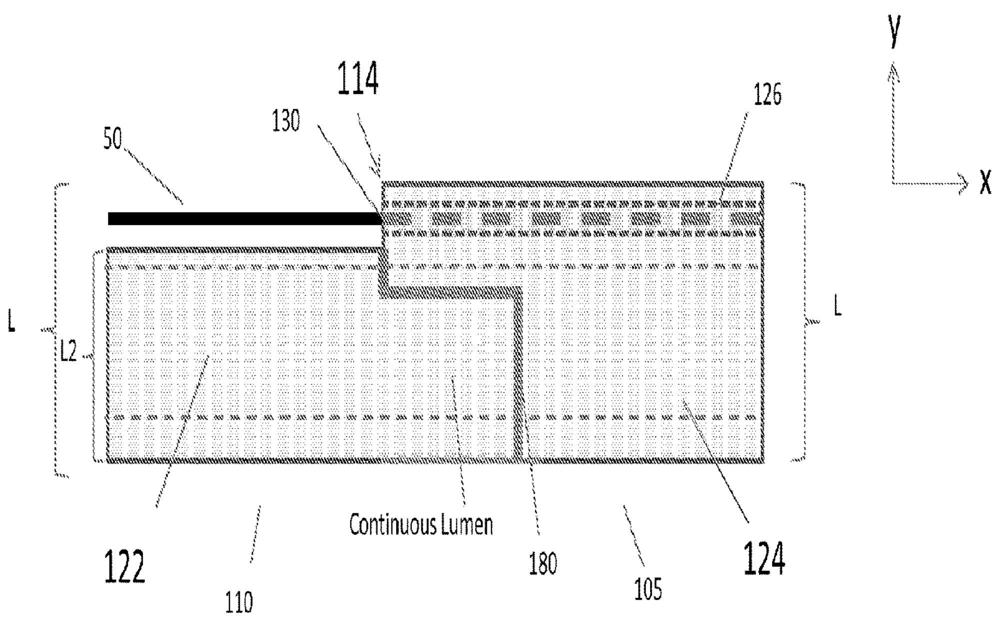
(57) **ABSTRACT**

The present invention generally relates to a rapid exchange configuration that reduces the profile of a catheter riding on a guidewire and minimizes guidewire resistance. According to certain embodiments, a body of the catheter includes a distal portion and a proximal portion. The distal portion defines a guidewire lumen and includes a guidewire exit port being open in a proximal direction and leading to the guidewire lumen. A proximal section of the guidewire lumen is straight.

11 Claims, 9 Drawing Sheets



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(Prior Art)

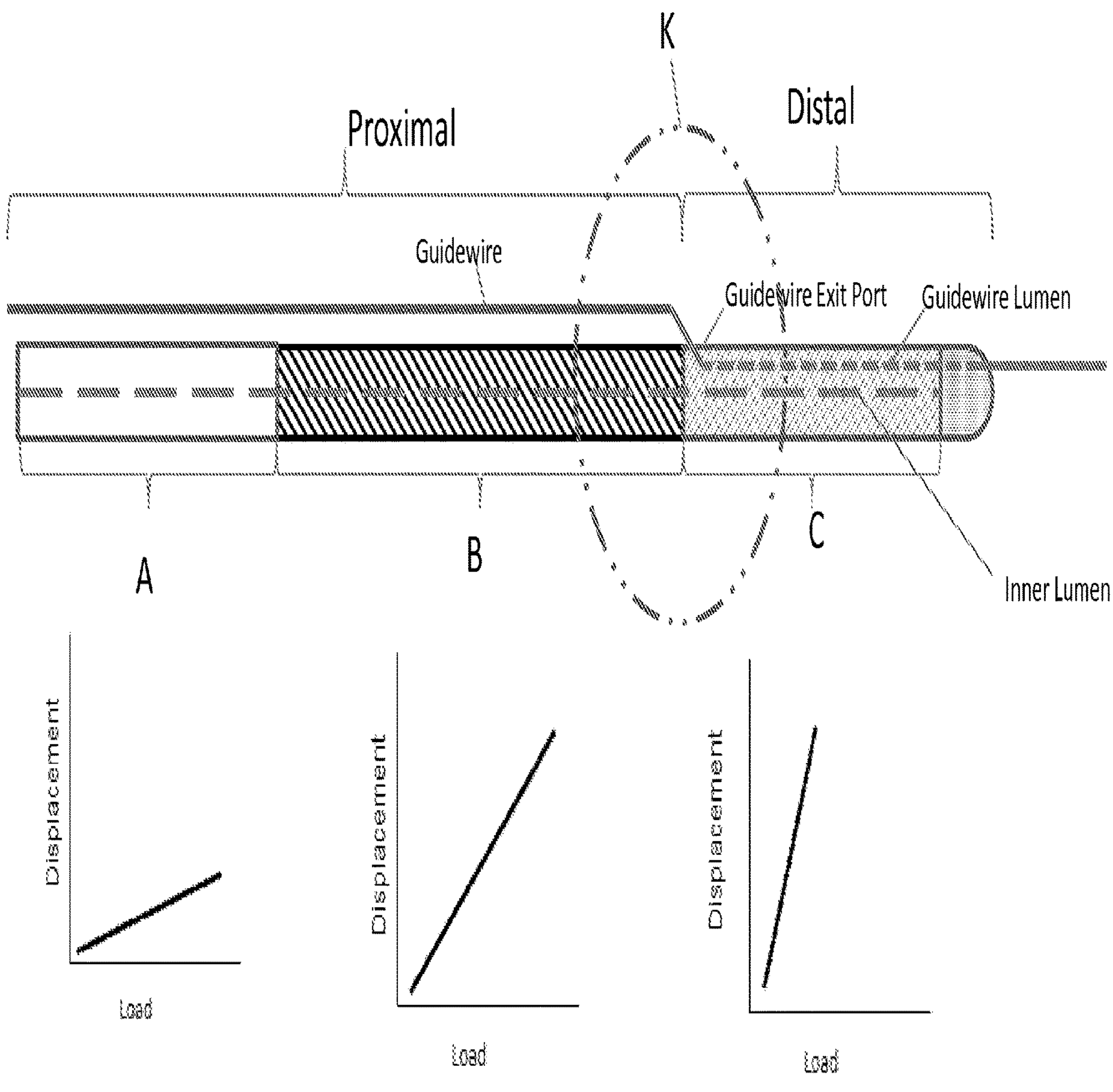


Figure 1

(Prior Art)

FIG. 2A

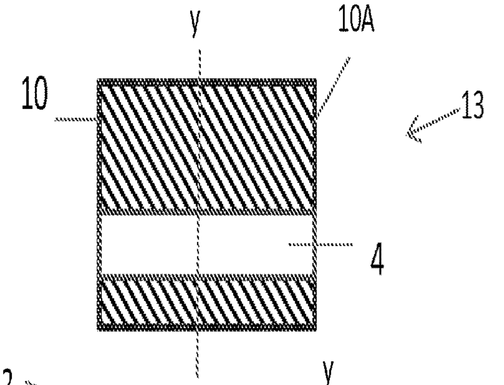


FIG. 2B

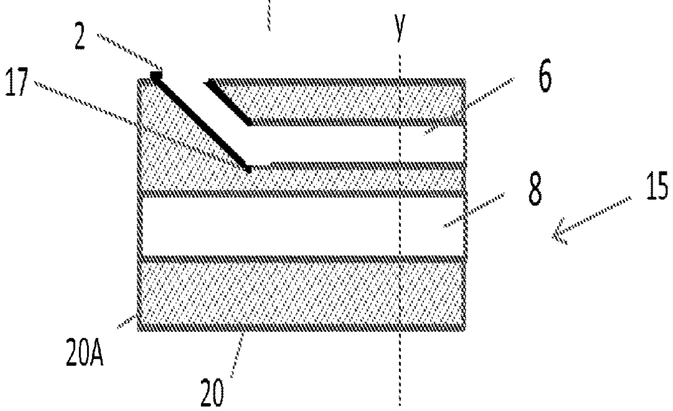


FIG. 2C

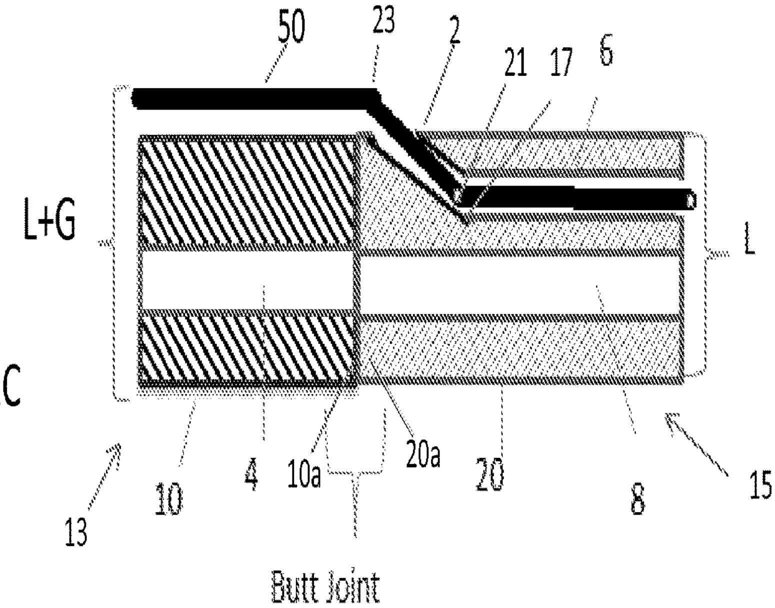


FIG. 2D

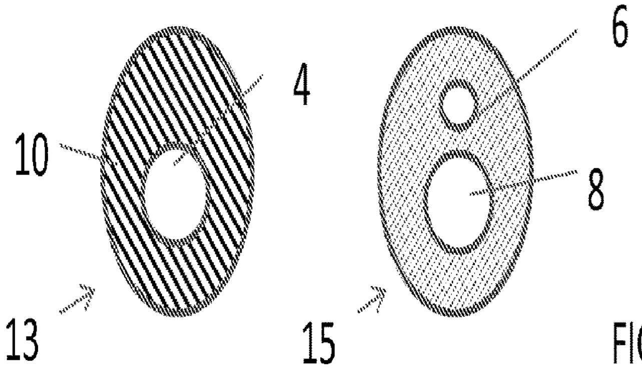


FIG. 2E

(Prior Art)

FIG. 3A

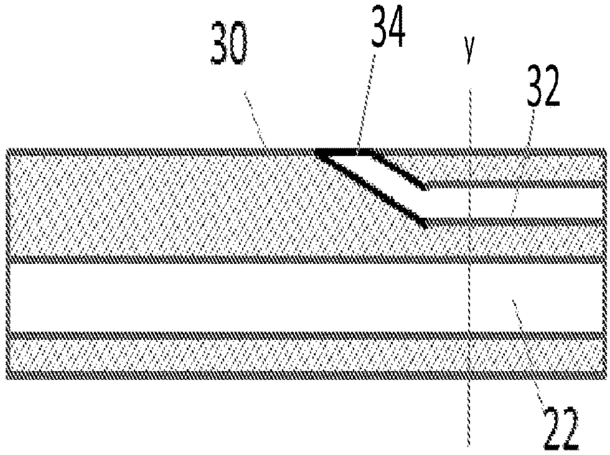


FIG. 3B

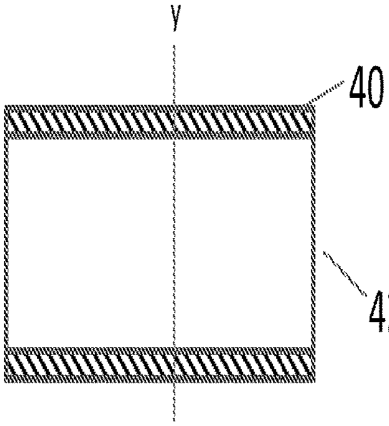
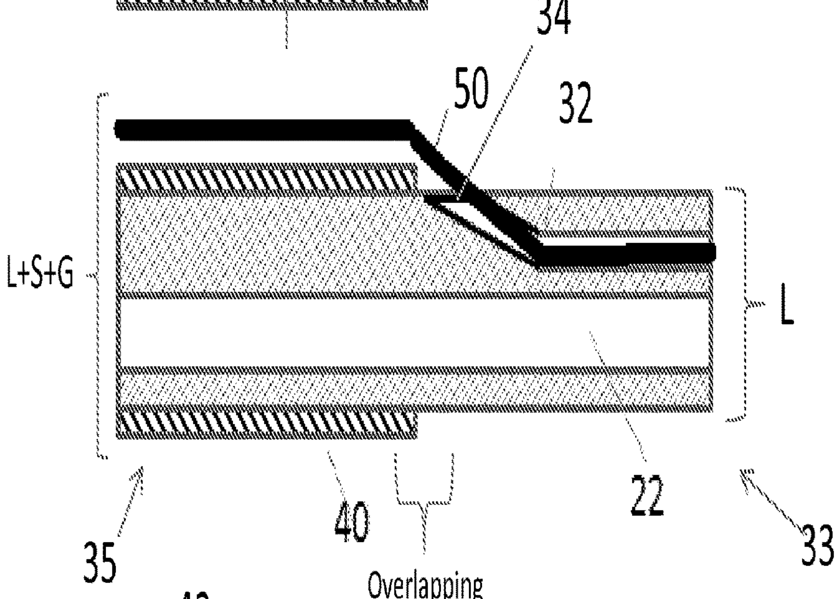


FIG. 3C



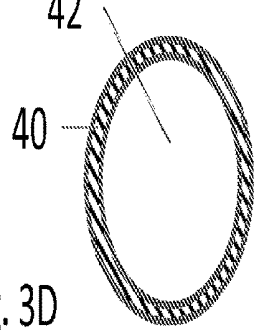


Fig. 3D

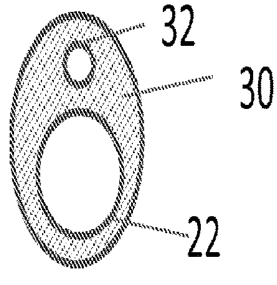
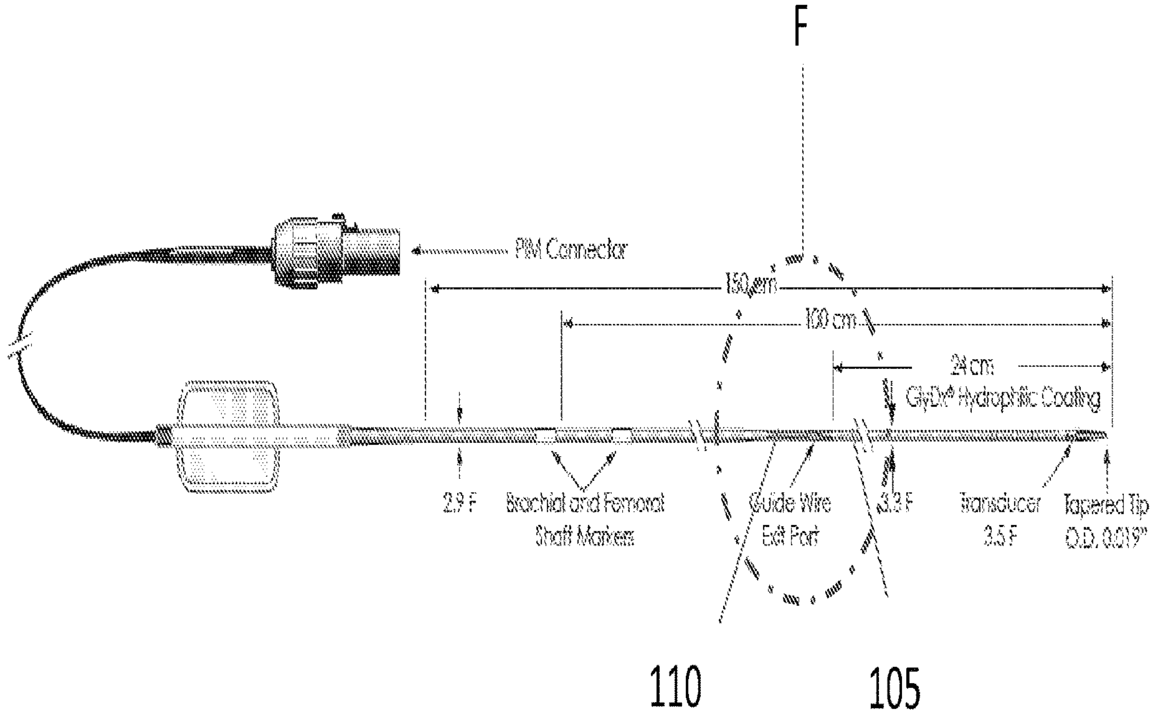


FIG. 3E

FIG. 4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PIM Connector
150 cm
100 cm
24 cm
GlyDx® Hydrophilic Coating
2.9 F
Brachial and Femoral
Shaft Markers
Guide Wire
Exit Port
3.3 F
Transducer
3.5 F
Tapered Tip
O.D. 0.019"
110
105

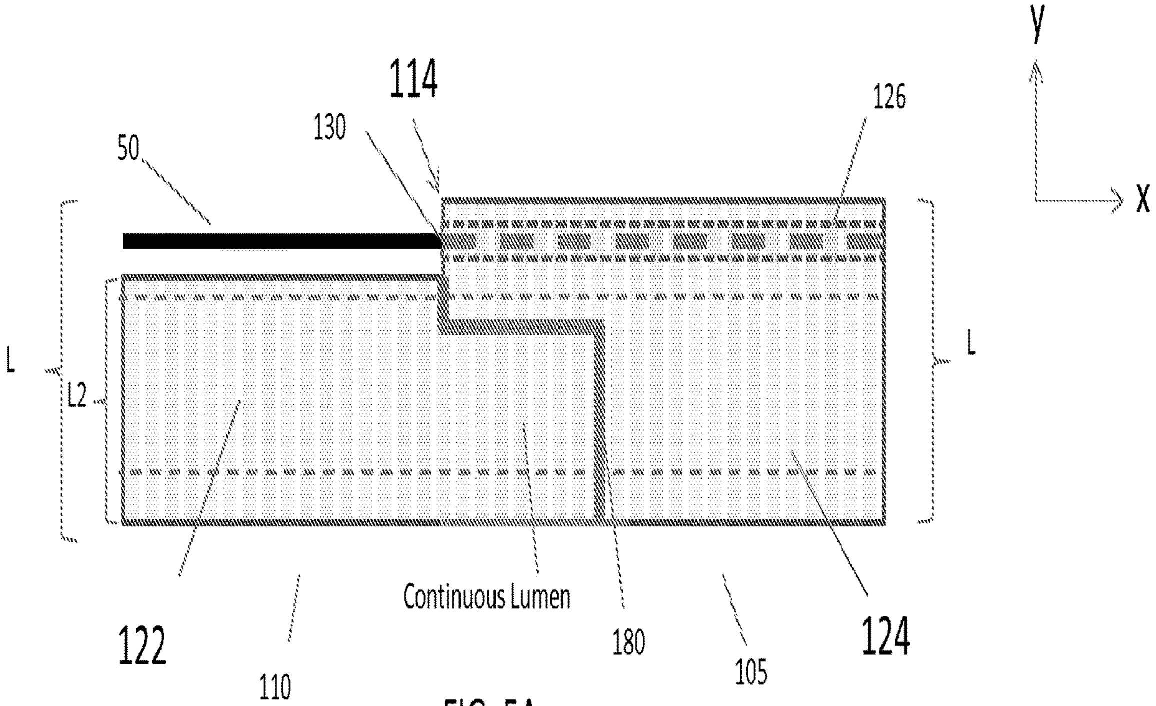

FIG. 5A

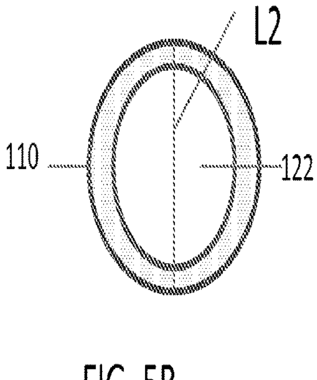

FIG. 5B

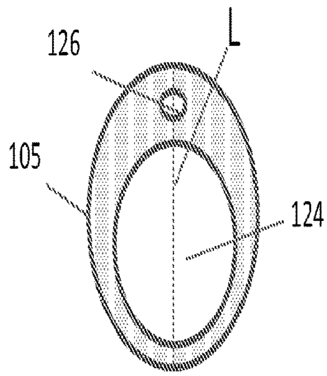

FIG. 5C

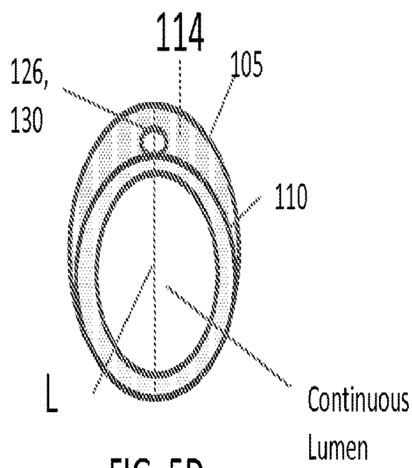

FIG. 5D

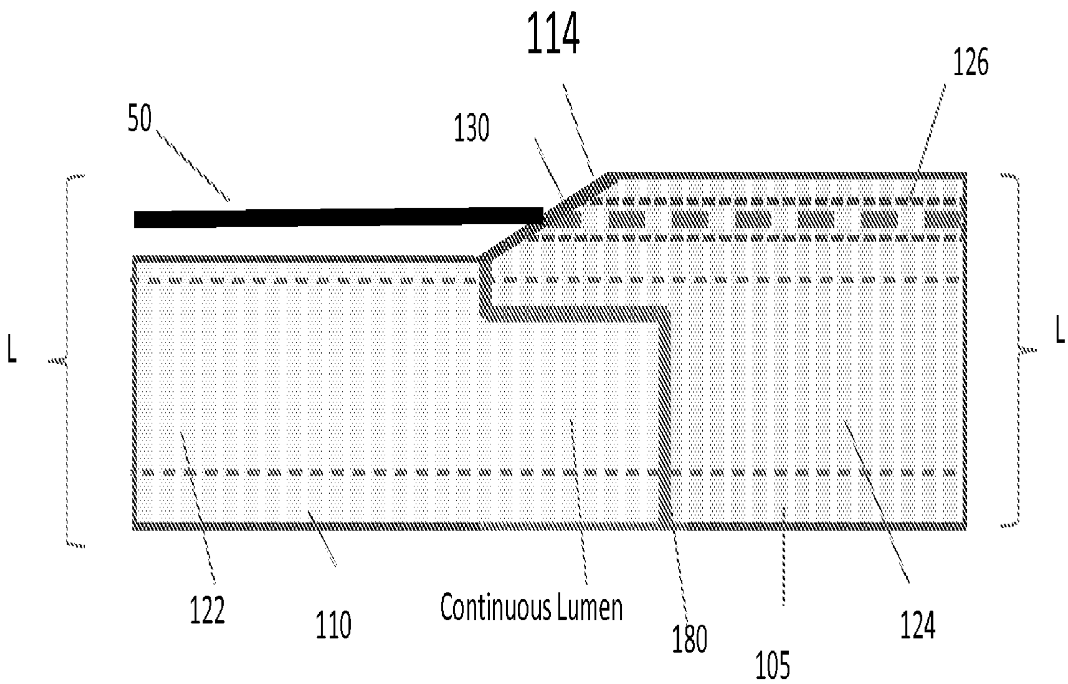

FIG. 5E

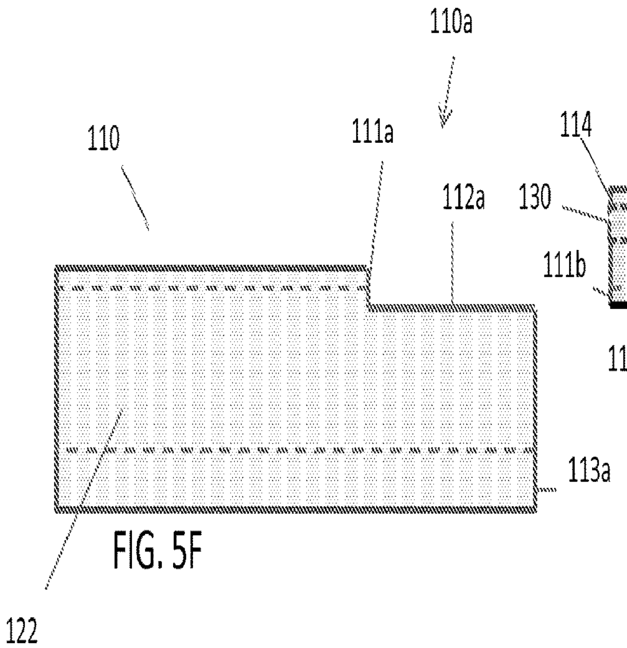

FIG. 5F

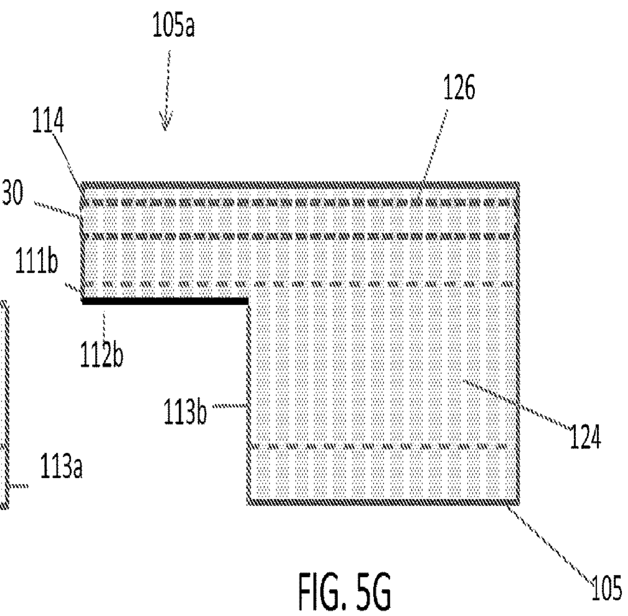

FIG. 5G

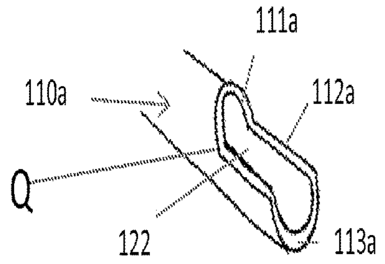

FIG. 5H

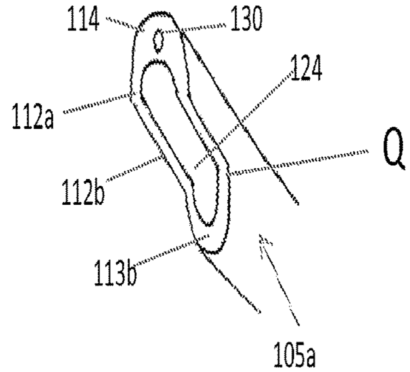

FIG. 5I

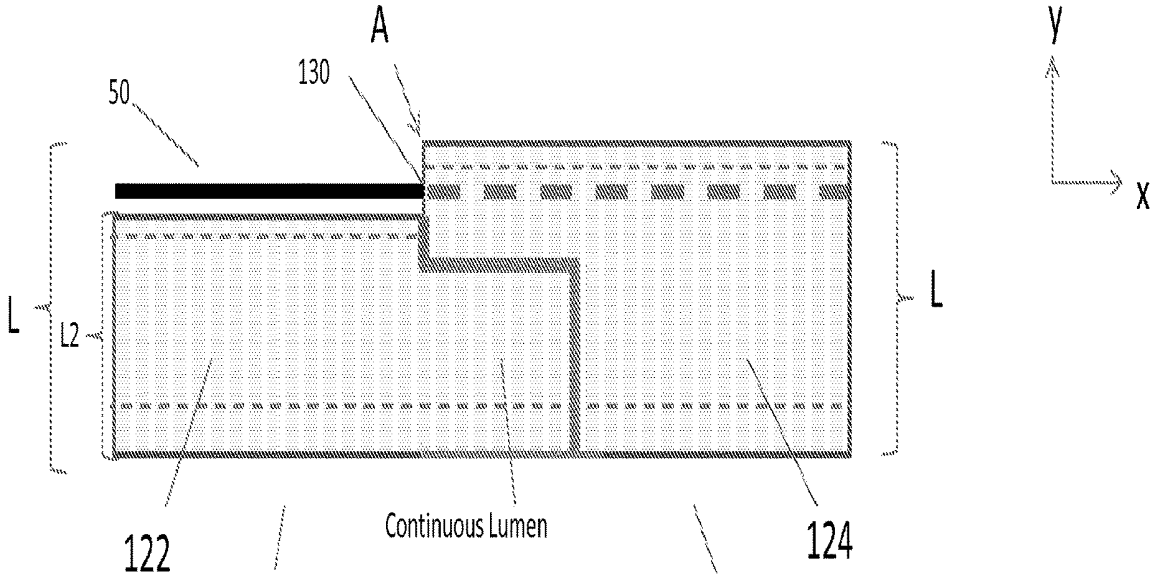

FIG. 6A

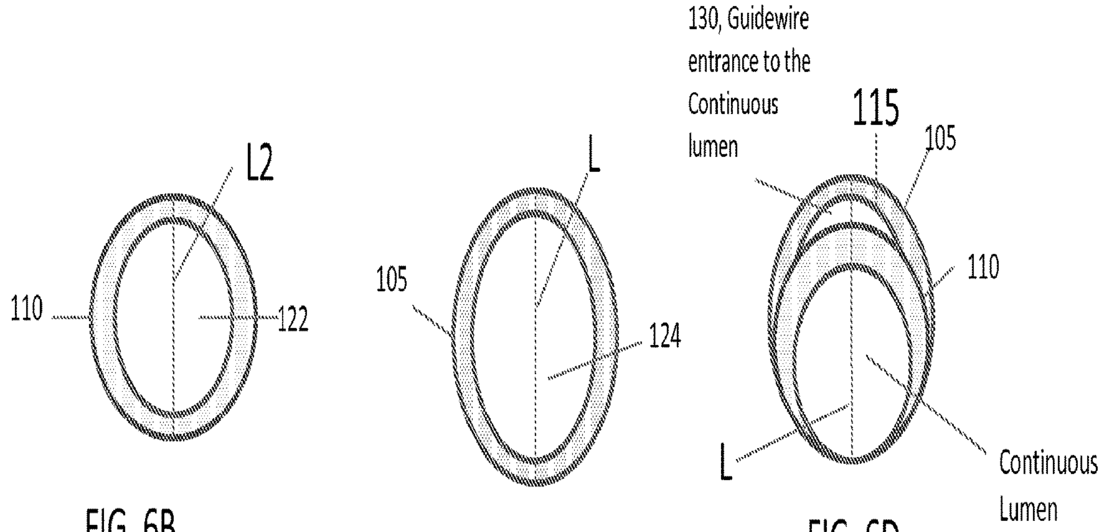

FIG. 6B

FIG. 6C

FIG. 6D

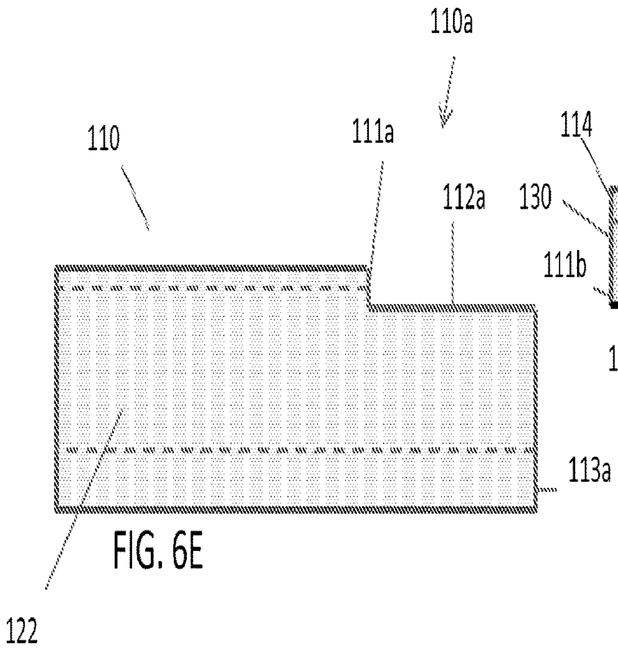

FIG. 6E

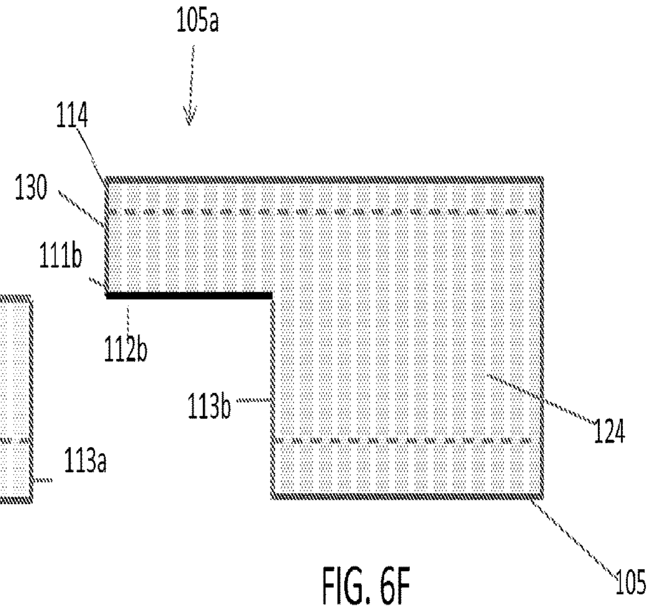

FIG. 6F

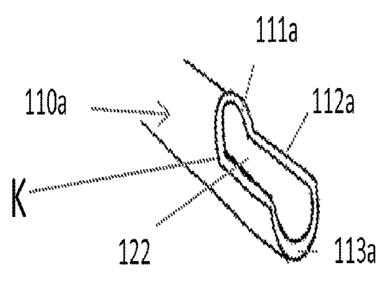

FIG. 6G

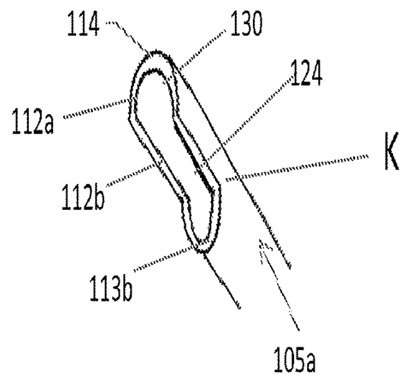

FIG. 6H

SMOOTH TRANSITION CATHETERS

RELATED APPLICATION

This application claims the benefit of and priority to U.S. Provisional Ser. No. 61/739,855, filed Dec. 20, 2012, which is incorporated by reference in its entirety.

TECHNICAL FIELD

The present application generally relates rapid exchange configuration for catheters. The invention provides enhanced designs that improve transitions between components of catheter.

BACKGROUND

Intraluminal devices, such as guidewires and catheters, allow for a variety of disorders of the endovascular to be evaluated and treated without creating an open surgical field. Endovascular procedures typically include passing a guidewire through an access artery (e.g. brachial, femoral, radial) and to a vessel of interest within the vasculature. Once the guidewire is in place, a catheter is guided over the guidewire to perform an intraluminal procedure at the vessel of interest. An intraluminal procedure may require the introduction and exchange of several specialized catheters into the vasculature, which can lead to lengthy procedure times. As a result, changes have been made to the design of the catheters in order to improve their exchangeability and reduce procedure length.

A known catheter design for reducing procedure time is a rapid exchange configuration, which includes a guidewire lumen that only extends through the distal portion of the catheter. Prior to rapid exchange guidewire lumens, catheters often included an over-the-wire lumen that extended the entire length of the catheter device. Due to the long lumen, an over-the-wire catheter requires a guidewire more than twice the length of the catheter. This allows a physician to maintain a grip on the ex vivo portion of the guidewire when exchanging catheters. The long guidewire is cumbersome to handle, causes clutter, and often slows down an already lengthy procedure.

In contrast, a rapid exchange catheter has a guidewire lumen that only extends through the distal portion of the catheter. A typical known rapid exchange configuration includes a substantially L-shaped lumen that begins at a distal tip of the catheter and ends at a guidewire exit port, which is located on a side of the distal portion of the catheter and faces the vessel surface. In this configuration, the guidewire passes through the catheter shaft only for a segment of the length of the shaft, and the catheter can be moved along the guidewire in "monorail" fashion. Because the guidewire lumen is considerably shorter than the overall length of the catheter, a shorter guidewire can be used. For easy handling, the guidewire simply has to be long enough so that the length of the guidewire protruding from the patient is longer than the length of the guidewire lumen of the catheter. This ensures a portion of the guidewire is exposed at all times and may be grasped by the physician.

The current rapid exchange configuration suffers from some drawbacks, however. The rapid exchange design requires a portion of the guidewire to bend within the L-shaped guidewire lumen to exit the guidewire exit port located on the side of the catheter. In addition, the guidewire must bend again once out of the guidewire exit port in order to extend parallel to the proximal portion of the catheter.

Because the guidewire exits the side of the catheter and then extends in parallel to the catheter, this configuration increases the vessel diameter requirements (i.e. the vessel must fit the combined diameters of the catheter and the guidewire).

In addition, the various bending of the guidewire may provide push issues or track issues with the catheter as it is being driven over the guidewire. A push issue arises when a proximal portion of a catheter is pushed further into the entry vessel and a distal end does not move the corresponding distance. A track issue arises when the proximal portion is torqued and the distal end does not rotate as expected. Pushing and tracking properly are crucial in negotiating the difficult curves or obstructions in the vasculature.

Thus, there is a need for a rapid exchange catheter with a low profile that reduces guidewire resistance.

SUMMARY

The invention provides catheters having a guidewire exit port that is open in the proximal direction and a substantially straight guidewire lumen. Catheters of the invention allow rapid guidewire exchange and minimal guidewire resistance. Because the guidewire lumen is substantially straight, the guidewire is not required to bend in order to exit the guidewire lumen or bend in order to extend along the proximal portion of the catheter within the vessel. This eliminates guidewire resistance as the catheter is being guided on the guidewire and provides better push and tracking characteristics. In addition, with the rapid exchange configuration of the invention, the exposed guidewire extends parallel to the proximal portion of the catheter without increasing the profile of the combined catheter and guidewire.

According to certain aspects, a catheter with the rapid exchange configuration of the invention includes a proximal portion and a distal portion. The distal portion defines a guidewire lumen, in which a proximal portion of the guidewire lumen is substantially straight. The distal portion also includes a guidewire exit port being open in a proximal direction and leading to the guidewire lumen. The guidewire exit port is configured to receive a guidewire running parallel to the proximal portion. In some embodiments, the distal portion has a cross-section larger than a cross-section of the proximal portion. In this manner, the combined profile of the guidewire and the proximal portion is the same as or smaller than the profile of the distal portion of the catheter. As a result, the portion of the guidewire exiting the distal portion does not increase the vessel diameter requirements.

A catheter with the rapid exchange configuration according to certain embodiments is constructed from a first shaft coupled to a second shaft. The coupled first shaft and second shaft form at least part of the catheter body. The first shaft includes a skived proximal portion and defines a first lumen. The skived proximal portion includes a guidewire exit port being open in the proximal direction. The second shaft includes a skived distal portion and defines a second lumen. The skived distal portion of the second shaft is coupled to the skived proximal portion of the first shaft such that the first lumen and the second lumen form a continuous lumen. In some embodiments, the continuous lumen includes the guidewire lumen, and the guidewire exit port leads to a portion of the continuous lumen. In other embodiments, the first shaft includes a guidewire lumen separate from the continuous lumen, and the guidewire exit port leads to the guidewire lumen.

Concepts of the invention can be applied to any type of catheter. Suitable catheters include, for example, imaging catheters, delivery catheters, and interventional catheters. In particular embodiments, a catheter including concepts of the invention is an imaging catheter. The imaging catheter may include an imaging element positioned on the distal portion of the catheter. The imaging element is a component of an imaging assembly. The imaging assembly can be an ultrasound assembly or an optical coherence tomography assembly.

Other and further aspects and features of the invention will be evident from the following detailed description and accompanying drawings, which are intended to illustrate, not limit, the invention.

BRIEF DESCRIPTION OF DRAWINGS

FIG. **1** depicts a prior art catheter.

FIG. **2**A depicts the distal end of a proximal portion of a catheter.

FIG. **2**B depicts the proximal end of a distal portion of a catheter.

FIG. **2**C depicts a proximal portion of FIG. **2**A coupled to the distal portion of FIG. **2**B via a butt joint.

FIG. **2**D depicts a cross-sectional view of the proximal portion of FIG. **2**A.

FIG. **2**E depicts a cross-sectional view of the distal portion of FIG. **2**B.

FIG. **3**A depicts a section of a foundation hypotube of a catheter.

FIG. **3**B depicts a section of an intermediate hypotube of a catheter.

FIG. **3**C depicts the intermediate hypotube of FIG. **3**B overlapping the foundation hypotube of FIG. **3**A to form the distal and proximal portions of varying flexibility.

FIG. **3**D depicts a cross-sectional view of the proximal portion of FIG. **3**A.

FIG. **3**E depicts a cross-sectional view of the distal portion of FIG. **3**B.

FIG. **4** depicts an exemplary phased-array IVUS catheter with the rapid exchange configuration of the invention according to certain embodiments.

FIG. **5**A shows the transition between a distal portion and a proximal portion of a catheter having the rapid exchange configuration of the invention according to certain embodiments.

FIG. **5**B illustrates a cross-sectional view of the proximal portion shown in FIG. **5**A.

FIG. **5**C illustrates a cross-sectional view of the distal portion shown in FIG. **5**A.

FIG. **5**D illustrates a distal-facing view of the proximal portion extending proximally from the distal portion as shown in FIG. **5**A.

FIG. **5**E shows an alternative embodiment of the transition between the distal portion and proximal portion of the catheter shown in FIG. **5**A.

FIG. **5**F shows the distal end of the proximal portion of a catheter according to certain embodiments of the invention.

FIG. **5**G shows the proximal end of the distal portion of a catheter according to certain embodiments of the invention.

FIG. **5**H illustrates a skive cut of a proximal portion of the invention according to certain embodiments.

FIG. **5**I illustrates a skive cut of a distal portion of the invention according to certain embodiments.

FIG. **6**A shows the transition between a distal portion and a proximal portion of a catheter having the rapid exchange configuration of the invention according to other embodiments.

FIG. **6**B illustrates a cross-sectional view of the proximal portion shown in FIG. **6**A.

FIG. **6**C illustrates a cross-sectional view of the distal portion shown in FIG. **6**A.

FIG. **6**D illustrates a distal-facing view of the proximal portion extending proximally from the distal portion as shown in FIG. **6**A.

FIG. **6**E shows the distal end of the proximal portion of a catheter according to certain embodiments of the invention.

FIG. **6**F shows the proximal end of the distal portion of the catheter according to certain embodiments of the invention.

FIG. **6**G illustrates a skive cut of a proximal portion according to certain embodiments of the invention.

FIG. **6**H illustrates a skive cut of a distal portion according to certain embodiments of the invention.

DETAILED DESCRIPTION

The present invention discloses a rapid exchange configuration for catheters that provides the desired combination of a low profile catheter/guidewire system with minimal to no guidewire resistance. A catheter with the rapid exchange configuration of the invention generally includes a guidewire exit port being open in the proximal direction and leading to a substantially straight guidewire lumen. The proximally facing guidewire exit port and the substantially straight guidewire lumen allow the guidewire to remain straight as it passes through the guidewire lumen. This eliminates the bending of the required by contemporary rapid exchange guidewire lumens. Instead, with the rapid exchange configuration of the invention, the guidewire is able to smoothly transition into and out of the guidewire lumen. The smooth transition of the guidewire reduces guidewire resistance and improves catheter tracking and push capabilities.

As discussed in the Background, current rapid exchange configurations suffer from two major drawbacks. First, the guidewire is required to bend as it extends out of the guidewire exit port and along a proximal portion of the catheter. Second, because the guidewire exit port is located on the side of the catheter, a portion of the guidewire extending out of the guidewire exit port and next to the catheter body increases vessel diameter requirements. For example, the vessel must have a diameter sufficient to support both the full diameter of the catheter and the full diameter of the guidewire running in parallel to catheter. In order to better understand aspects and benefits of the current invention, a brief discussion of prior art rapid exchange catheters and the various mechanical elements thereof, in general, is provided below.

FIG. **1** depicts a prior art catheter. As shown in FIG. **1**, the catheter includes a proximal portion and a distal portion. The catheter is shown with a guidewire disposed therein. The catheter rides along the guidewire extending through the distal portion. A portion of the guidewire exits through a guidewire exit port and extends along the proximal portion of the catheter.

A common problem of prior art catheters is their rapid exchange configuration, which is highlighted in the area enclosed by circle K of FIG. **1**. The rapid exchange configuration includes the shape of the rapid exchange guidewire lumen and the location of the guidewire exit port. Because the guidewire exit port is located on a side of the catheter body, the guidewire lumen requires a bend to direct the guidewire from the distal tip to the guidewire exit port. The bend ultimate causes a guidewire extending through the lumen to bend. In addition, the location of the guidewire exit port requires the guidewire to bend again upon exiting the guidewire exit port so that the guidewire extends parallel and alongside catheter body. FIG. **2**C highlights the contemporary guidewire lumen and guidewire exit port. The distal portion **15** includes guidewire lumen **6**. The guidewire lumen **6** includes bend **17** and leads to guidewire exit port **2** located on the side of the distal portion **15**. The guidewire **50** extending through the lumen **6** and out of the guidewire exit port **2** must bend twice **21** and **23** in order to run alongside the proximal portion **13**. This bending of the guidewire can cause resistance against the catheter as it is pushed distally along or rotated with respect to the guidewire, which may result in push and tracking issues.

Most catheters include at least one inner lumen, in which one or more functional elements are housed or driven there through. For example, imaging catheters often utilize the inner lumen to house transmission lines that connect an imaging element located on the distal end of the catheter to an imaging instrument connected to a proximal end of the catheter. Delivery catheters, on the other hand, often use the inner lumen to contain an implant deployment mechanism. For example, a push rod can be driven through the inner lumen to distally deploy an implant out of a distal end of the catheter and into a vessel. Aspiration catheters utilize the inner lumen as an aspiration channel, through which debris and blood clots can be removed from the vessel.

The proximal portion and the distal portion of most catheters act to create a catheter body of variable stiffness and flexibility. The distal portion is typically quite flexible. The proximal portion, as shown in FIG. **1**, may include a stiff section A and an intermediate section B, which has flexibility somewhere between the stiff portion and a flexible distal portion. Alternatively, the proximal portion may be a hypotube of uniform flexibility. The stiffness/flexibility is shown graphically next to each section as correlation between load and lateral displacement. The stiff portion A includes a small correlation between load and lateral displacement. In other words, when a transverse force is exerted on the proximal end, the proximal end only flexes a small amount. In contrast, the distal end is quite flexible and experiences a large amount of lateral displacement with a relatively small amount of applied load.

In order to create the catheter body of varying stiffness and flexibility, the catheter is generally formed from a combination of components fused together or overlapping. That, the stiff portion, intermediate section, and the distal portion are often separate individual tubes or parts that are fused together or overlapped to form the elongate catheter body with desired mechanical properties. For example, the stiff portion of many catheters includes a stiff hollow tube (hypotube) that is only slightly flexible and has excellent compressional strength, allowing a physician to deliver force laterally along the catheter. Hypotubes may be constructed from standard metals, such as stainless steel, or from memory metals, such as nitinol, an alloy of nickel and titanium. Hypotubes may also be constructed from polymers such as the polymer sold under the trademark PEBAX®, nylon, HDPE, and the polymer sold under the trademark PEEK™. The intermediate sections are often also hypotubes and are constructed from polymers with moderate stiffness, such as polyamides, to provide transitional flexibility between the proximal and distal ends. The distal end of the intraluminal device is typically constructed from a flexible polymer hypotube with good kink resistance, such as a fluoropolymer.

A common design consideration for joining portions of a catheter includes aligning lumens of the individual sections. For example, in order to create a continuous inner lumen extending the entire length of the catheter, the lumens of the individual sections must be aligned. Another design consideration is the tensile strength of catheter at the joint between two different portions. A catheter design having insufficient tensile strength can result in catheter failure. For example, when catheter is under tension while being proximally retracted from within the patient's body lumen, a catheter body having insufficient tensile strength may partially or completely tear at the joint between two portions. This can result in the potentially lethal dislocation of the catheter distal portion.

Another design consideration for joining the distal and proximal portions of the catheter includes the rapid exchange profile of the catheter. The rapid exchange profile is the combined profile of both the guidewire and catheter having a rapid exchange configuration. One must consider the catheter diameter and the diameter of the guidewire when determining whether the system can enter a vessel of interest. Vessels of interest are often inherently small and can have further reduced diameters due to the build up of atheroma material such as plaque. As such, it is desirable to have a small rapid exchange profile, so that the catheter can access more vessels. The type of transition can affect the overall rapid exchange profile of the catheter.

The following describes common ways for transitioning between the distal and proximal portions of varying flexibility, which is also the portion of the catheter enclosed by the circled K of FIG. **1**. The resulting rapid exchange profile is also discussed.

One known way to transition between the distal and proximal portions of a catheter is to form a butt joint. A butt joint is formed by abutting the flat ends of the distal and proximal portions squarely together. Generally, an intermediate hypotube of the proximal portion is coupled directly coupled to a flexible hypotube of the distal portion and then fused together to form a continuous elongate catheter body. FIGS. **2**A-**2**E depict formation of a butt joint between a flexible distal portion and a stiffer proximal portion of a catheter. FIG. **2**A shows the distal end **10** of a proximal portion **13** with an inner lumen **4**. FIG. **2**D shows a cross-sectional view of the proximal portion **13** at the y-axis of FIG. **2**A. FIG. **2**B shows a proximal end **20** of the distal portion **15** with an inner lumen **8** and a guidewire lumen **6**. FIG. **2**E shows a cross-sectional view of the distal portion **15** at the y-axis of FIG. **2**B. The guidewire lumen **6** includes a bend **17** that leads to a guidewire exit port **2** on a side of the distal portion **20**. To form the butt joint, a distal surface **10***a* of the proximal portion **13** is placed flush against a proximal surface **20***a* of the distal portion **15**, as shown in FIG. **2**C. The inner lumen **4** of the proximal portion **13** is matched up against the inner lumen **8** of the proximal portion **10**. Once properly abutted, the proximal portion **13** is fused to the distal portion **15** using known catheter fusing techniques.

FIG. **2**C also shows the rapid exchange profile of the catheter with the butt joint configuration. As shown, a portion of the guidewire **50** is extending through the guidewire lumen **6**. Another portion of the guidewire **50** exits through the guidewire exit port **2** and is extending parallel to the proximal portion **13**. Because the guidewire **50** exits the side of the distal portion, the rapid exchange profile includes the diameter of both the guidewire and the catheter. That is, the rapid exchange profile includes the diameter (L) of the catheter plus the diameter (G) of the guidewire (L+G).

A problem associated with the butt joint design is that the butt joint has a low tensile strength, and therefore poses a risk of joint failure and dislocation of the distal portion. An alternative design for transitioning between the distal and proximal portions that provides variable flexibility and a high tensile strength is an overlapping design. The overlapping design includes overlapping hypotubes or applying coating layers to create the flexible distal portion and the stiffer proximal portion. For example, a flexible hypotube extending the fully length of the catheter is provided as a foundation. To create an intermediate proximal section (Section B in FIG. **1**), a polymer coating or hypotube is placed over a portion of the flexible hypotube leaving only the distal portion exposed. This creates the flexible distal portion and an intermediate proximal portion. To create the stiff proximal section (Section A in FIG. **1**), an additional polymer coating or hypotube is placed over the proximal end of the proximal portion leaving the intermediate proximal section B exposed.

FIGS. **3**A-**3**E depict formation of an overlapping transition between a flexible distal portion and a stiffer proximal portion of a catheter. FIG. **3**A shows a foundation hypotube **30**. Although not shown, the foundation hypotube **30** extends the entire length of the catheter body. The foundation hypotube **30** includes an inner lumen **22** and a guidewire lumen **32**. FIG. **3**E shows a cross-sectional view of the foundation hypotube **30** at the y-axis of FIG. **3**A. FIG. **3**B shows an intermediate hypotube **40**. The intermediate hypotube **40** can be used to create the intermediate section B of the proximal portion (See FIG. **1**). The intermediate hypotube **40** includes a center lumen **42**. FIG. **3**D shows a cross-sectional view of the intermediate hypotube **40**. To form the catheter with varying flexibility, the foundation hypotube **30** is disposed within the center lumen **42** of the intermediate hypotube **40**, leaving the distal portion of the foundation hypotube **30** exposed, as shown in FIG. **3**C. The foundation hypotube **30** and the intermediate hypotube **40** can be fused together with heat or by adhesive. The exposed foundation hypotube **30** forms flexible distal portion **33** and the overlapping hypotubes **30** and **40** form the intermediate proximal portion **35**. Instead of the using an intermediate hypotube **40**, the intermediate proximal portion **35** can be formed by applying a polymer coating to the foundation tube **30**, leaving the distal portion exposed.

FIG. **3**C also shows the rapid exchange profile of the catheter with the overlapping configuration. Like the butt-joint design, the catheter guidewire **50** exits the side of the distal portion and extends along the length of the proximal portion of the catheter. However, the overlapping catheter body has a larger diameter as compared to the butt-joint configuration because the profile of the proximal portion includes the diameter (L) of the foundation catheter body plus the thickness (S) of the intermediate hypotube. Thus, the overall rapid exchange profile includes the diameter (L) of the foundation hypotube **30**, the thickness (S) of the intermediate hypotube **40**, and the diameter (G) of the guidewire **50**.

While the overlapping design provides a catheter having variable flexibility with high tensile strength, the overlapping configuration undesirably increases the rapid exchange profile. Because of the increased rapid exchange profile, the overlapping design limits the accessibility of the catheter within the vasculature.

Catheters of the invention overcome the shortcomings of the prior art by providing a substantially straight guidewire lumen and a proximally facing guidewire exit port. In addition, some embodiments of the present invention include a smaller rapid exchange profile than possible with the prior art catheters. Furthermore, certain embodiments achieve the smaller rapid exchange profile while also maintaining the high tensile strength between a flexible distal portion and a stiffer proximal portion.

The concepts of the invention may be applied to any intraluminal catheter, which may include intravascular catheters and urological catheters. In certain embodiments, the concepts of the invention are applied to rapid exchange catheters, which have guidewire lumens only extending in the distal portion. A catheter of the invention may be an imaging catheter, a delivery catheter, or an interventional catheter. Delivery catheters typically deliver a medical device (e.g. stent, filter, or plug) into the body. Interventional catheters are often used to morcellate or ablate diseased tissue. Catheter bodies intended for intravascular introduction, will typically have a length in the range from 50 cm to 200 cm and an outer diameter in the range from 1 French to 12 French (0.33 mm: 1 French), usually from 3 French to 9 French. In the case of coronary catheters, the length is typically in the range from 125 cm to 200 cm, the diameter is preferably below 8 French, more preferably below 7 French, and most preferably in the range from 2 French to 7 French. A distal portion of a catheter may range from 5 cm to 25 cm and a proximal portion may range from 50 to about 200 cm. Intermediate sections of the proximal portion may range from 25-125 cm.

In some embodiments, the catheter will be an imaging or sensing catheter. Imaging catheters allow a physician to acquire images of tissues from within a lumen, e.g., a blood vessel. Often it is instructive to image a tissue prior to treatment, e.g., with angioplasty or drugs. The image may be obtained with acoustic waves, i.e., ultrasound, or the image may be obtained with light. Thus, the invention includes intravascular ultrasound (IVUS), optical coherence tomography (OCT), and intravascular magnetic resonance imaging (IVMRI), in addition to other intravascular imaging techniques. Systems for IVUS are discussed in U.S. Pat. No. 5,771,895; U.S. Pub. 2009/0284332; U.S. Pub. 2009/0195514 A1; U.S. Pub. 2007/0232933; and U.S. Pub. 2005/0249391, the contents of each of which are hereby incorporated by reference in their entirety. The imaging catheters may use any configuration, such as phased array, forward-looking, rotational pullback, etc. Sensing catheters, such as flow (Doppler), pressure, temperature, or blood oxygenation-sensing catheters will also benefit from variable stiffness midsections.

An exemplary phased-array IVUS catheter with the improved rapid exchange configuration of the invention is illustrated in FIG. **4**. The area enclosed by circle F highlights the transition between the distal portion and proximal portion and a rapid exchange configuration of the invention. Various embodiments of the transition between the distal portion and the proximal portion and embodiments of the rapid exchange configuration of the invention are described hereinafter.

FIG. **5**A shows the transition between a distal portion **105** and a proximal portion **110** of a catheter having the rapid exchange configuration according to one embodiment. The distal portion **105** and the proximal portion **110** can be formed from one continuous shaft or two shafts coupled (e.g. fused) together at a joint. As shown, the distal portion **105** and the proximal portion **110** are two separate shafts coupled together to form the catheter body. Preferably, the distal portion **105** is a flexible hypotube fabricated from a flexible polymer (as discussed previously), and the proximal portion **110** is a hypotube of moderate stiffness (such as the previously discussed hypotubes for the intermediate section B).

As discussed, certain aspects of the invention involve forming a joint between a shaft of the distal portion **105** and a shaft of the proximal portion **110** to create the rapid exchange configuration shown in FIG. **5**A. FIG. **5**F shows a distal end **110***a* of the shaft of the proximal portion **110** according to certain embodiments. The proximal portion **110** defines an inner lumen **122** and includes a distal end **110***a*. FIG. **5**G shows a proximal end **105***a* of the shaft of the distal portion **105** according to certain embodiments. The distal portion **105** defines an inner lumen **124** and a guidewire lumen **126**. To form the catheter body, the distal end **110***a* of the proximal portion **110** is coupled to the proximal end **105***a* of the distal portion **105**. Preferably, the distal portion **105** and the proximal portion **110** are joined so that the inner lumen **124** of the distal portion **105** and the inner lumen **122** of the proximal portion **110** align to form the continuous lumen shown in FIG. **5**A.

A diameter L**2** of the proximal portion **110** is smaller than the diameter L of the distal portion **105**. This orientation allows a section of the distal portion **105** to extend vertically (in the y-direction) beyond the proximal portion **110** as joined to the distal portion **105**. The extended section of the distal portion **105** forms the proximal face **114** of the distal portion **105**. FIG. **5**B illustrates a cross sectional view of the proximal portion **110** as shown in **5**A. FIG. **5**C illustrates a cross sectional view of the distal portion **105** as shown in FIG. **5**A. FIG. **5**D illustrates a distal-facing view of the proximal portion **110** extending proximally from the distal portion **105** as shown in **5**A. As shown in FIG. **5**D, the cross-section of the proximal portion **110** completely aligns with a section of the distal portion **105**. In this manner, the maximum diameter of the combined proximal and distal portions is the diameter L of the distal portion **105**.

As discussed, the section of the distal portion **105** extending vertically above the proximal portion **110** (i.e. the section of the distal portion **105** that is not directly aligned with and facing the proximal portion **110**) forms the proximal face **114** of the distal portion **105**. The proximal face **114** defines a guidewire exit port **130**, which leads to guidewire lumen **126**. FIG. **5**E depicts another embodiment of the proximal face **114** that has been angled to provide a smoother device profile.

As shown in FIG. **5**A, the guidewire exit port **130** is open in the proximal direction and leads to a guidewire lumen **126**. In certain embodiments, at least the proximal portion of the guidewire lumen **126** is substantially straight. In certain embodiments, the entire length of the guidewire lumen is substantially straight **126**. Alternatively, a distal portion of the guidewire lumen may slight curve to, for example, combine the guidewire lumen **126** with the continuous lumen or provide a guidewire entry port at the center of a distal tip of the device.

A benefit of the proximally facing guidewire exit port **130** leading to a substantially straight guidewire lumen **126**, as shown in FIGS. **5**A and **5**E, is that the guidewire **50** does not have to bend to exit the guidewire lumen **126**. In addition, the guidewire **50** does not have to bend after exiting the guidewire exit port to extend alongside the proximal portion **110**. Rather, the guidewire **50** maintains a substantially straight shape as it extends through the guidewire lumen **126** and out of the guidewire exit port **130**. This configuration reduces resistance of the guidewire **50** as the catheter is driven over the guidewire **50** in the distal or proximal directions.

Another benefit of the catheter design shown in FIGS. **5**A and **5**E is the rapid exchange profile (i.e. the combined profile of the catheter and guidewire). Because the rapid exchange configuration does not require the guidewire **50** to exit through a guidewire exit port located on the side of the distal portion **105**, the guidewire **50** does not increase the rapid exchange profile of the device. Rather, the guidewire **50** exits proximally from the guidewire exit port **130** in a linear fashion and runs parallel and along the proximal portion **110**. Thus, the rapid exchange profile of the device equals the diameter L of the distal portion **110**. As a result, devices having this rapid exchange configuration of the invention have an overall lower profile than the prior art rapid exchange catheters shown in FIGS. **1**, **2**C and **3**C. The lower profile allows a physician to access the smaller vessels of the vasculature with ease.

In addition, the distal portion **105** and the proximal portion **110** of the embodiment shown in FIGS. **5**A and **5**B, define at least one inner lumen that extends continuously between the distal portion and the proximal portion **110**. The inner continuous lumen may extend the entire length of the catheter. The continuous lumen may provide any function, such as housing the transmission lines to provide energy to an imaging element, sensor, or ablation element located at the distal end of the device and to return signals from any of those elements. As another example, the continuous lumen can be used to house a morcellating tool that can be extended out of the distal end of the catheter to morcellate diseased tissue.

FIG. **6**A shows the transition between a distal portion **105** and a proximal portion **110** of a catheter having the rapid exchange configuration according to another embodiment. The distal portion **105** and the proximal portion **110** can be formed from one continuous shaft or two shafts coupled (e.g. fused) together at a joint. As shown, the distal portion **105** and the proximal portion **110** are two separate shafts coupled together to form the catheter body. Preferably, the distal portion **105** is a flexible hypotube fabricated from a flexible polymer (as discussed previously), and the proximal portion **110** is a hypotube of moderate stiffness (such as the previously discussed hypotubes for the intermediate section).

As discussed, certain aspects of the invention involve forming a joint between a shaft of the distal portion **105** and a shaft of the proximal portion **110** to create the rapid exchange configuration shown in FIG. **6**A. FIG. **6**E shows the shaft of the proximal portion **110** according to certain embodiments. The proximal portion **110** defines an inner lumen **122** and includes a distal end **110***a*. FIG. **6**F shows the shaft of the distal portion **110** according to certain embodiments. The distal portion **105** defines an inner lumen **124**. In this aspect, the inner lumen **124** is the guidewire lumen and forms the continuous lumen between the distal portion **105** and proximal portion **120**. In addition, the distal portion **105** includes a proximal end **105***a*. To form the catheter body, the distal end **110***a* of the proximal portion **110** is coupled to the proximal end **105***a* of the distal portion **105**.

A diameter L**2** of the proximal portion **110** is smaller than the diameter L of the distal portion **105**. In addition, the inner lumen **124** of the distal portion **105** is larger than the inner lumen **122** of the proximal portion **105**. Also, the distal portion **105** and the proximal portion **110** are joined so that the inner lumen **124** of the distal portion **105** at least partially aligns with the inner lumen **122** of the proximal portion **110** to form the continuous lumen shown in FIG. **6**A. This orientation allows a section of the distal portion **105**, which includes a section of the inner lumen **124**, to extend vertically (in the y-direction) beyond the proximal portion **110** as joined to the distal portion **105**. The extended section of the distal portion **105** forms the proximal face **114** of the distal portion **105**. An extended section of the inner lumen **124** forms a guidewire opening **130** on the proximal face **114**.

The guidewire opening **130** leads to the inner lumen **124** of the distal portion **124**, which is a part of the continuous lumen. Thus, in this embodiment, the inner lumen **124** of the continuous lumen is also the guidewire lumen. Merging the guidewire lumen with the inner lumen reduces the complexity of the shaft of the distal portion **105**. Instead of a shaft with a separate guidewire lumen and a separate inner lumen, a common hypotube with a single lumen can be used. In other words, the design shown in FIG. **6**A does not require that the distal portion **105** include a guidewire lumen separate from the inner lumen **124**, and the design can be made with standard commercially available hypotubes.

FIG. **6**B illustrates a cross sectional view of the proximal portion **110** shown in FIG. **6**A. FIG. **6**C illustrate a cross sectional view of the distal portion **105** shown in FIG. **6**A. FIG. **6**E shows a distal-facing view of the proximal portion **110** extending proximally from the distal portion **105** shown in FIG. **6**A. As shown in FIG. **6**D, the cross-sectional view of the proximal portion **110** completely aligns with a section the distal portion **105**. In this manner, the maximum diameter of the device is the diameter L of the distal portion **105**. As discussed, the section of the distal portion **105** extending vertically above the proximal portion **110** (i.e. the portion is not directly aligned with and facing the proximal portion **110**) forms the proximal face **114** of the distal portion **105**. The proximal face **114** defines a guidewire exit port **130**, which leads to inner lumen **124** of the continuous lumen. The proximal face **114** as shown in FIG. **6**A may be angled like the proximal face as shown in FIG. **5**E to provide a smoother device profile.

As shown in FIG. **6**A, the guidewire exit port **130** is open in the proximal direction and leads to inner lumen **124** of the continuous lumen. In certain embodiments, at least the proximal portion of the inner lumen **124** is substantially straight. In certain embodiments, the entire length of the inner lumen **124** is substantially straight. Alternatively, a distal portion of the inner lumen **124** may slight curve to provide a guidewire entry port at the center of a distal tip of the device.

A benefit of the proximally facing guidewire exit port **130** leading to the substantially straight inner lumen **124** of the continuous lumen, as shown in FIG. **6**A, is that the guidewire **50** does not have to bend to exit the inner lumen **124**. In addition, the guidewire **50** does not have to bend after exiting the guidewire exit port to extend alongside the proximal portion **110**. Rather, the guidewire **50** maintains a substantially straight shape as it extends through the inner lumen **124** and out of the guidewire exit port **130**. This configuration reduces resistance of the guidewire **50** as the catheter is driven over the guidewire **50** in the distal or proximal directions.

Another benefit of the catheter design shown in FIG. **6**A is the rapid exchange profile (i.e. the combined profile of the catheter and guidewire). Because the rapid exchange configuration does not require the guidewire **50** to exit through a guidewire exit port located on the side of the distal portion **105**, the guidewire **50** does not increase the rapid exchange profile of the device. Rather, the guidewire **50** exits proximally from the guidewire exit port **130** in a linear fashion and runs parallel and along the proximal portion **110**. Thus, the rapid exchange profile of the device equals the diameter L of the distal portion **110**. As a result, devices having this rapid exchange configuration of the invention have an overall lower profile than the prior art rapid exchange catheters shown in FIGS. **1**, **2**C and **3**C. The lower profile allows a physician to access the smaller vessels of the vasculature with ease.

In certain embodiments, the invention provides for joining the distal portion **105** and the proximal portion **110** in a segmented fashion. For example, the distal portion **105** and the proximal portion **110** are shown joined in a segmented fashion in FIGS. **5**A, **5**E, and **6**A. In order to produce a segmented joint of the invention, the distal portion **105** and the proximal portion **110** are skived in a complementary orientation that allows the proximal end **105***a* of the distal portion **105** to overlap with the distal end **110***a* of the proximal portion **110**. Skiving means cutting out a notch across the hypotube, and is best exemplified in FIGS. **5**H, **5**I, **6**G, and **6**H. Preferably and as shown, the notch is sliced off distal portion **105** and the proximal portion **105** at a 90° angle (shown as Q). However, other angles can be used, including 91°-135° angles.

Due to the skiving of the distal portion **105** and the proximal portion **110**, a plurality of complementary binding surfaces are formed that act to strengthen the joint between the distal portion **105** and proximal portion **110**. For example, skived distal end **110***a* of the proximal portion **110** includes binding surfaces **111***a*, **112***a*, and **113***a* that are complementary to the binding surfaces **111***b*, **112***b*, and **113***b* of the skived proximal end **105***a* of the distal portion **105**, respectively (See FIGS. **5**H, **5**I, **6**G, and **6**H). To form the segmented joint, the binding surfaces of the proximal portion **110** are coupled to their complementary binding surfaces of the distal portion **105**. The more complementary binding surfaces, the greater the tensile strength of the joint between the distal portion **105** and proximal portion **110**. The resulting joint of the distal portion **105** and the proximal portion **110** is shown as bolded line **180** in FIGS. **5**A, **5**E, and **6**A.

Any technique known in the art can be utilized to couple the proximal portion to the distal portion of the catheter. Typically, the various shafts of a catheter are coupled via heat fusing. An exemplary technique for fusing includes holding the shafts of the distal portion and the proximal portion together and placing one or more mandrels within the inner lumen and/or guidewire lumen. The mandrels are preferably the shape and size of the lumens and are coated with a non-stick coating. The non-stick coating can be a polytetrafluoroethylene (PTFE) or a paralene coating. With the distal and proximal portions held together along with the mandrels disposed therein, heat is applied to the joint of the distal and proximal portions, thereby fusing the shafts together. Once the shafts are fused together, the mandrels are removed, and the outer portion of the joint can be shaped as desired to form a smooth, consistent joint. One example of shaping includes angling the proximal end face of the distal portion as shown in FIG. **5**C.

INCORPORATION BY REFERENCE

References and citations to other documents, such as patents, patent applications, patent publications, journals, books, papers, web contents, have been made throughout this disclosure. All such documents are hereby incorporated herein by reference in their entirety for all purposes.

EQUIVALENTS

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The foregoing embodiments are therefore to be considered in all respects illustrative rather than limiting on the invention described herein. Scope of the invention is thus indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed is:

1. A catheter comprising:

a body including a first portion comprising proximal and distal ends and a second portion comprising proximal and distal ends, wherein the first portion comprises a first material and the second portion comprises a second material different from the first material,

wherein the first and second portions comprise an inner lumen extending through the first and second portions, wherein the first portion extends proximally from the proximal end of the second portion, and wherein the second portion includes an extended section,

wherein the proximal end of the second portion comprises an opening facing the proximal direction and leading to a guidewire lumen of the second portion,

wherein the guidewire lumen is straight along its entire length and extends through an entire length of the extended section,

wherein, along a longitudinal direction, the extended section has a first cross section different from a second cross section of a remainder of the second portion, wherein the first cross section and the second cross section comprise the guidewire lumen,

wherein the first portion includes a distal cut-out section comprising a first plurality of surfaces and the second portion includes a proximal cut-out section comprising a second plurality of surfaces, and

wherein the distal cut-out section and the proximal cut-out section fit together such that each of the first plurality of surfaces contacts a complementary surface in the second plurality of surfaces and that the extended section of the second portion extends over the distal cut-out section of the first portion.

2. The catheter of claim **1**, wherein the opening is configured to receive a guidewire running along and parallel to the first portion.

3. The catheter of claim **1**, wherein a diameter of the first portion is smaller than a diameter of the second portion.

4. The catheter of claim **1** wherein the opening is a guidewire exit port.

5. The catheter of claim **1**, wherein the inner lumen comprises the guidewire lumen.

6. The catheter of claim **1**, wherein the catheter is an imaging catheter.

7. The catheter of claim **6**, wherein the second portion comprises an imaging element.

8. The catheter of claim **7**, wherein the imaging element is a component of an imaging assembly, and the imaging assembly is selected from the group consisting of an ultrasound assembly and an optical coherence tomography assembly.

9. The catheter of claim **1**, wherein the first portion comprises a first flexibility and the second portion comprises a second flexibility different from the first flexibility.

10. The catheter of claim **1**, wherein the guidewire lumen and inner lumen form a single lumen.

11. The catheter of claim **1**, wherein the proximal end of the second portion comprising the opening is angled.

* * * * *

专利名称(译)	平滑过渡导管		
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摘要(译)

本发明总体上涉及一种快速交换构造，其减小了骑在导丝上的导管的轮廓并且使导丝的阻力最小化。 根据某些实施例，导管的主体包括远侧部分和近侧部分。 远端部分限定导丝管腔并且包括在近侧方向上敞开并通向导丝管腔的导丝出口。 导丝管腔的近端部分是笔直的。