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Smith et al.

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(54) **DILATING INTRODUCER DEVICES AND METHODS FOR VASCULAR ACCESS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(22) Filed: **Sep. 18, 2023**

(51) **Int. Cl.**

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A61B 17/34	(2006.01)
A61F 2/24	(2006.01)
A61M 25/09	(2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/3421*** (2013.01); ***A61F 2/2436*** (2013.01); ***A61M 25/09041*** (2013.01); ***A61M 29/02*** (2013.01)

(58) **Field of Classification Search**
CPC A61M 29/02; A61M 25/09041; A61M 25/0668; A61M 2025/0675; A61F 2/2436; A61B 17/3421; A61B 17/3439; A61B 17/3423; A61B 17/0482; A61B 17/0483; A61B 2017/06052; A61B 17/02
See application file for complete search history.

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Assistant Examiner — Mikail A Mannan
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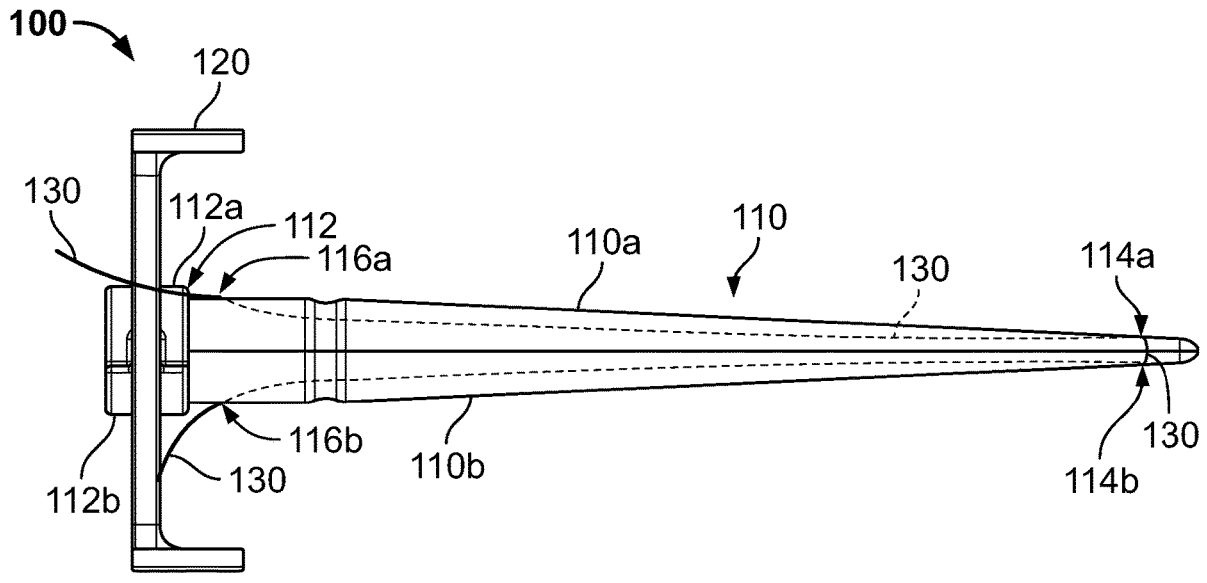
(57) **ABSTRACT**

Devices used to deploy transvascular medical device systems and methods for using such devices are described in this document. For example, this document describes dilating introducer devices used for the percutaneous vascular deployment of catheter-based medical devices such as structural heart medical devices. Such dilating introducer devices can facilitate the percutaneous vascular deployment of catheter-based medical devices without an additional introducer sheath.

13 Claims, 12 Drawing Sheets



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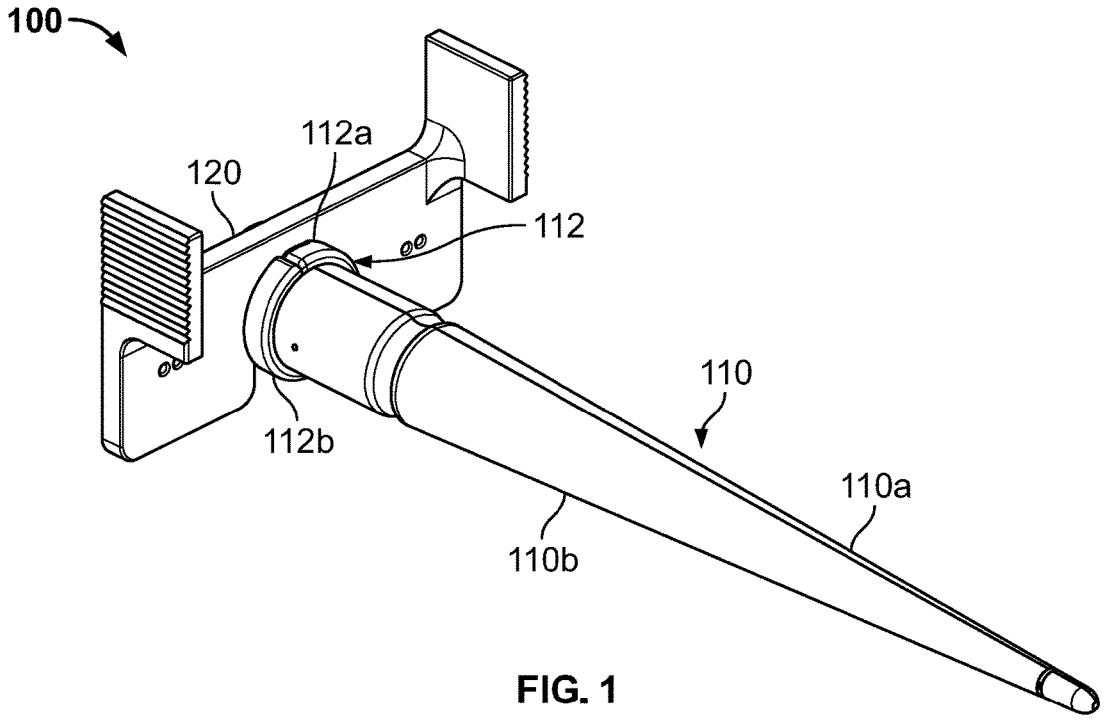
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FIG. 1

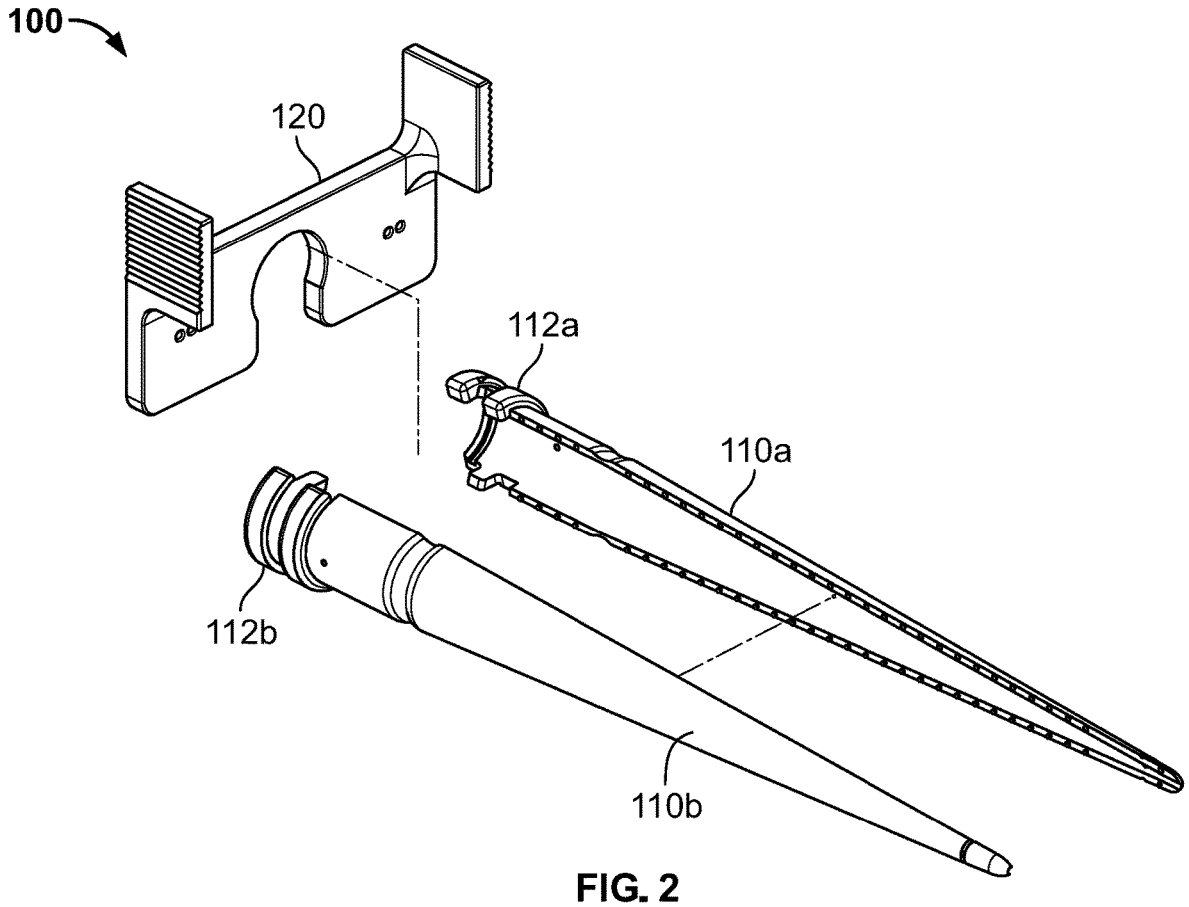
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FIG. 2

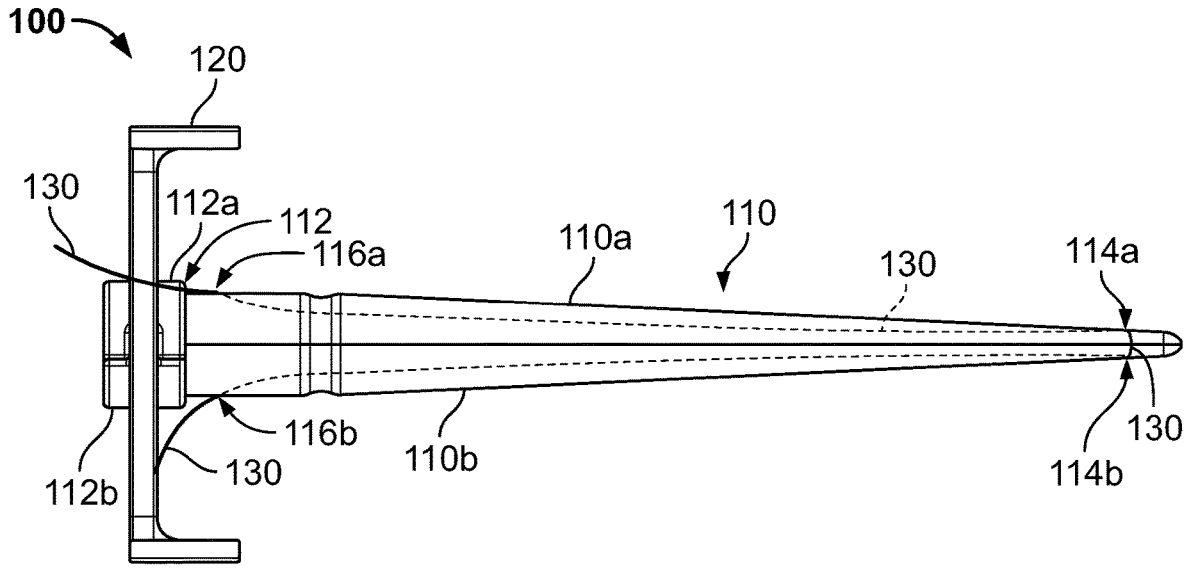
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FIG. 3

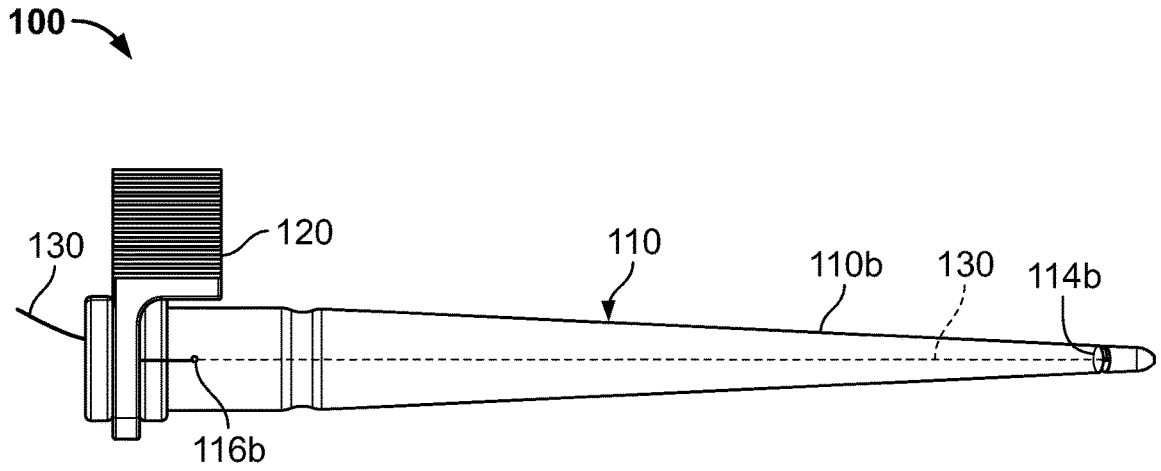
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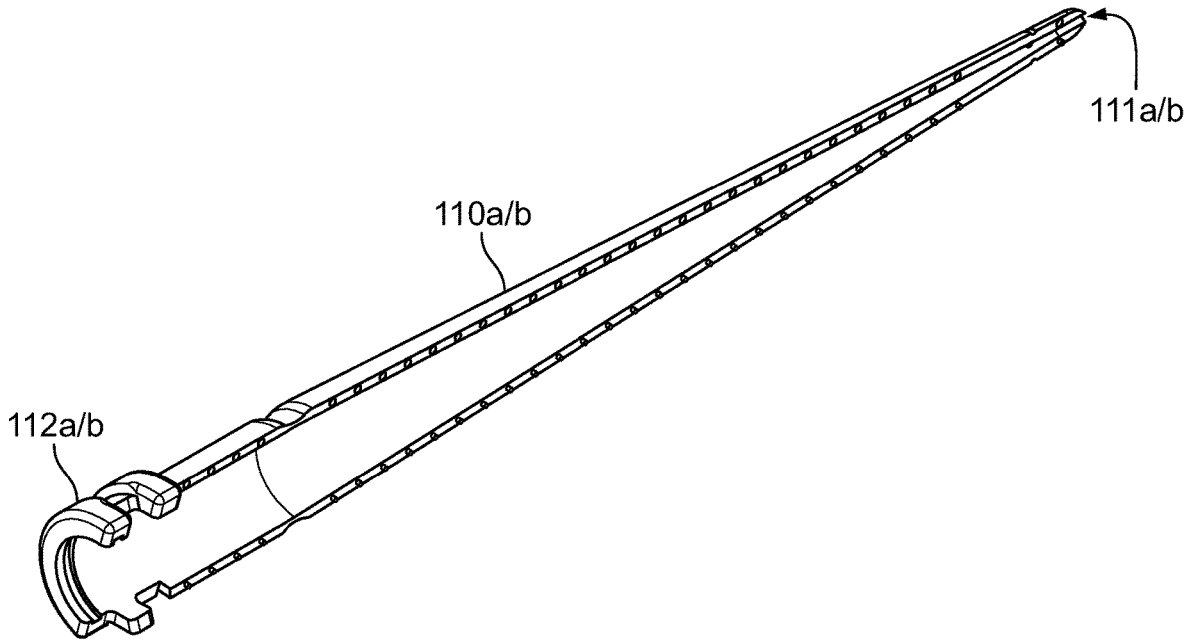
FIG. 4



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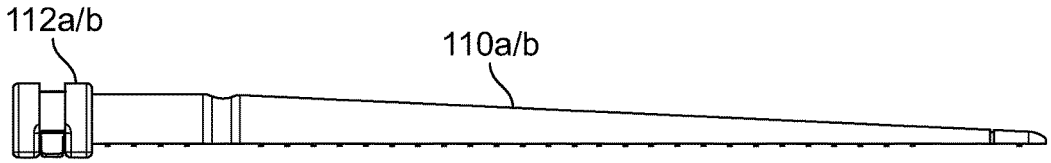

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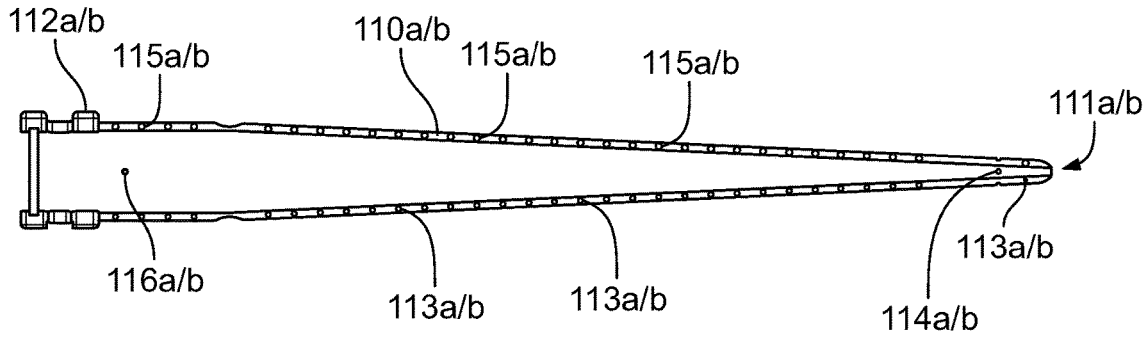

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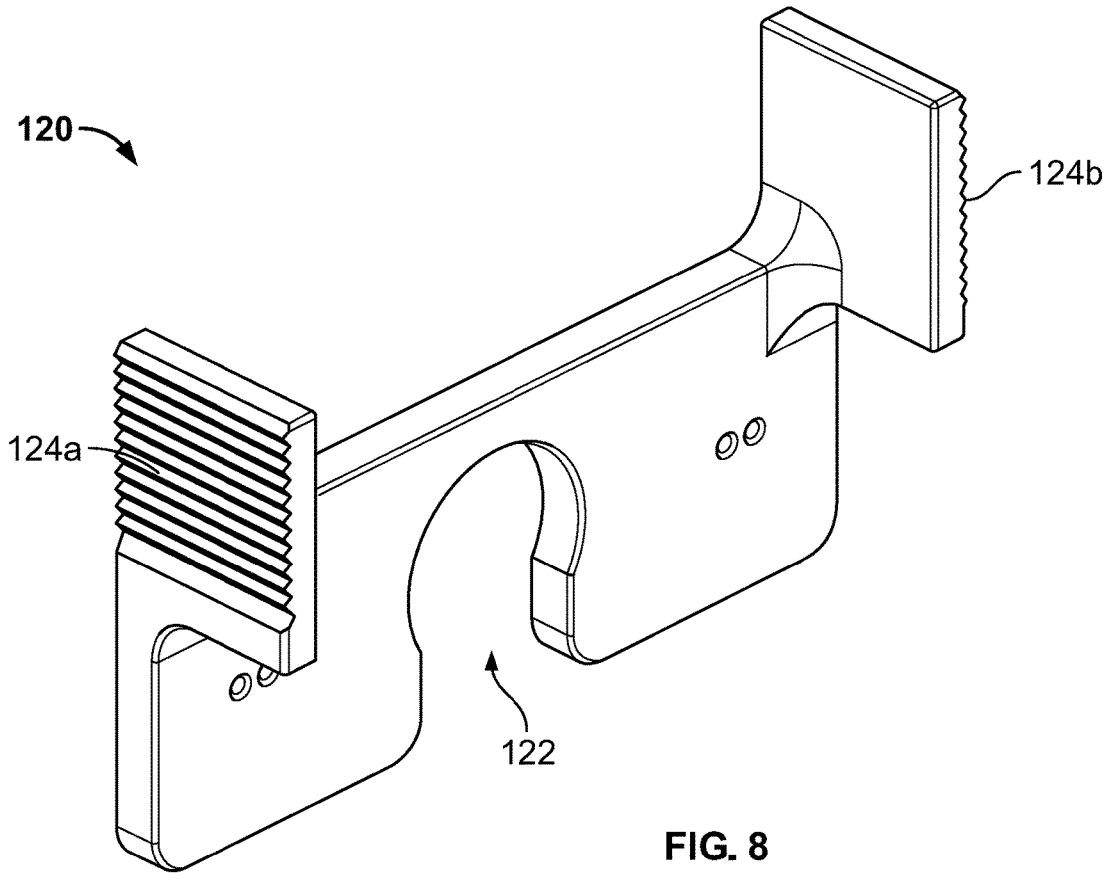

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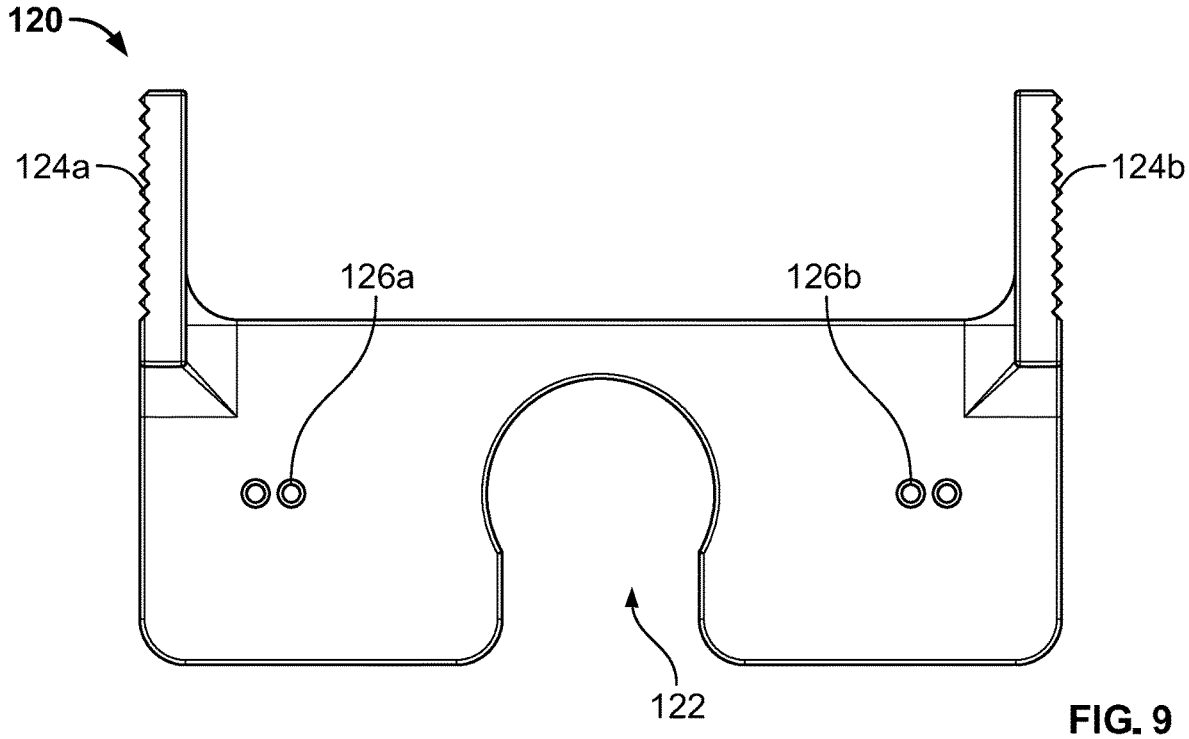

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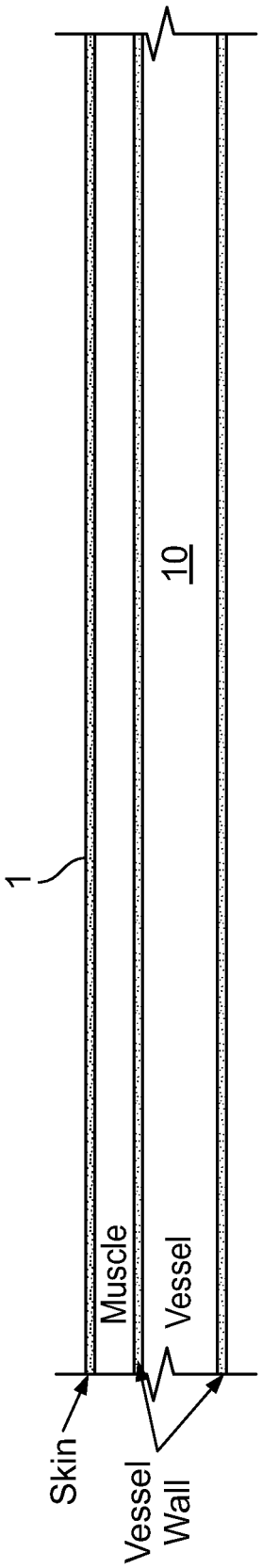
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Vessel
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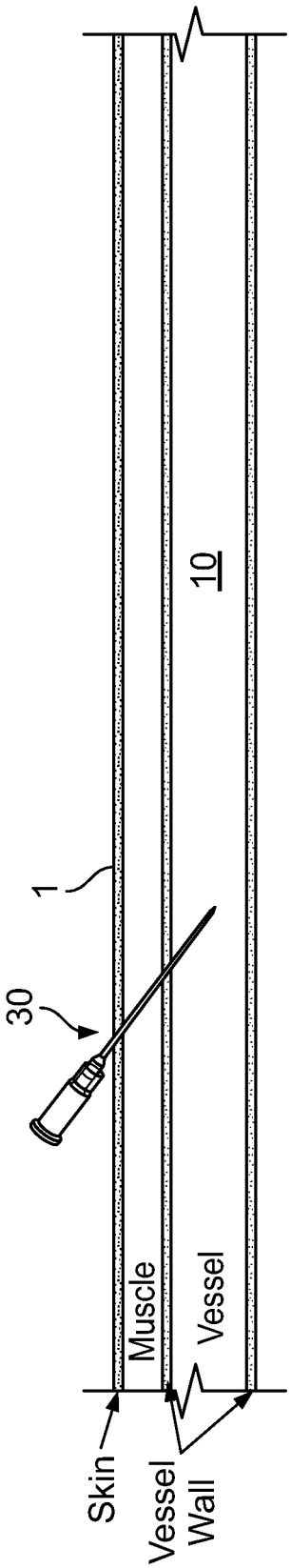
FIG. 10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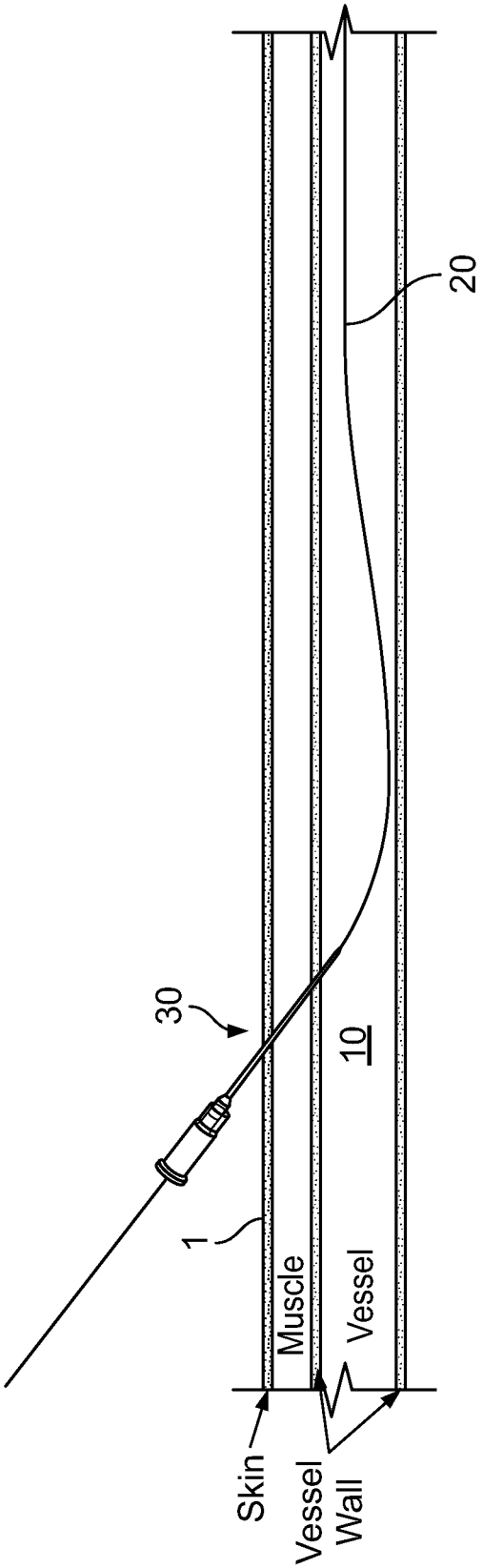
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Muscle
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FIG. 12

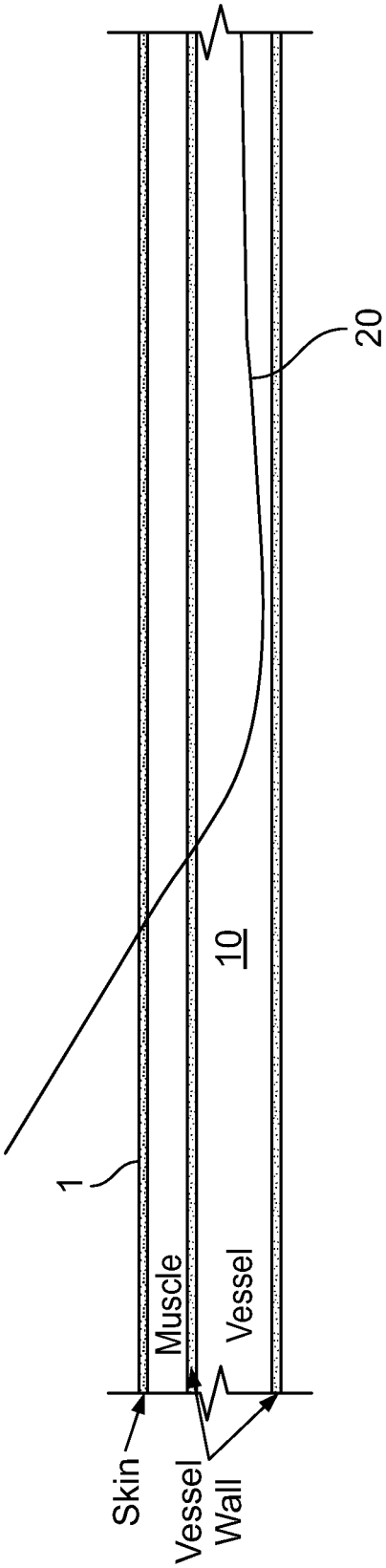
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FIG. 13

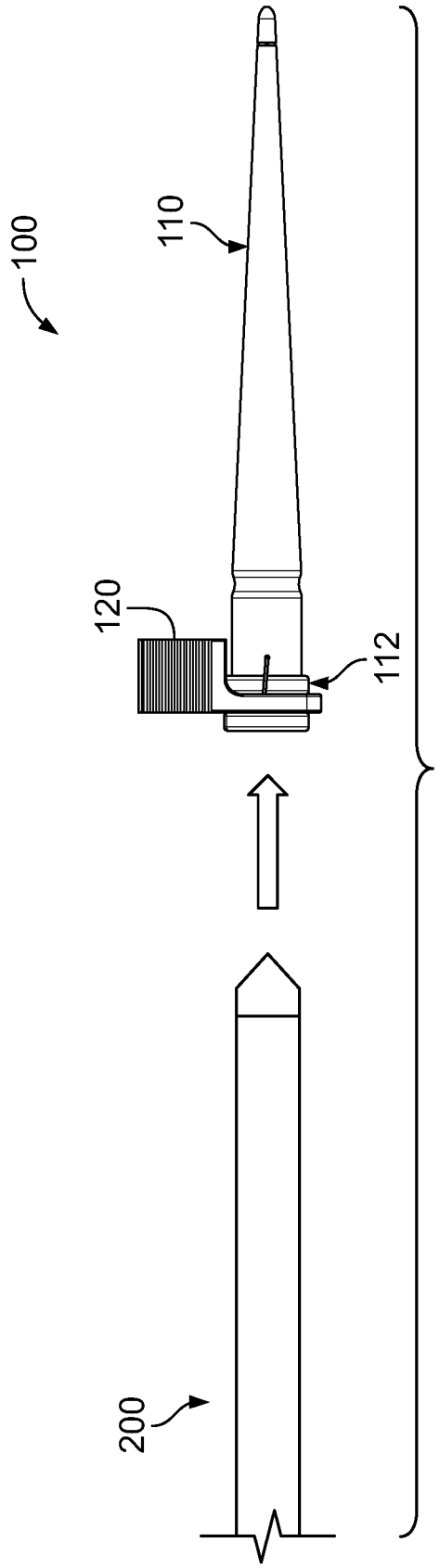

FIG. 14

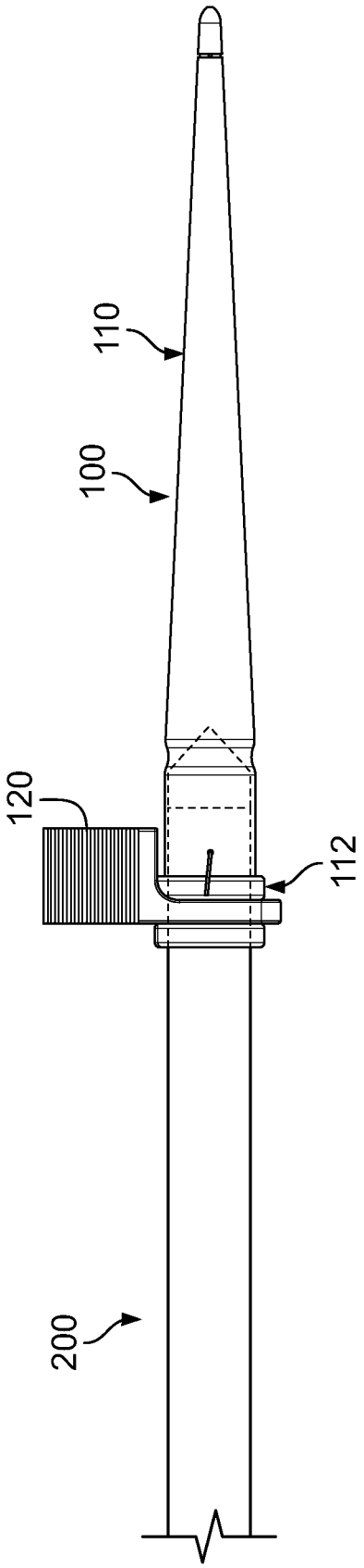

FIG. 15

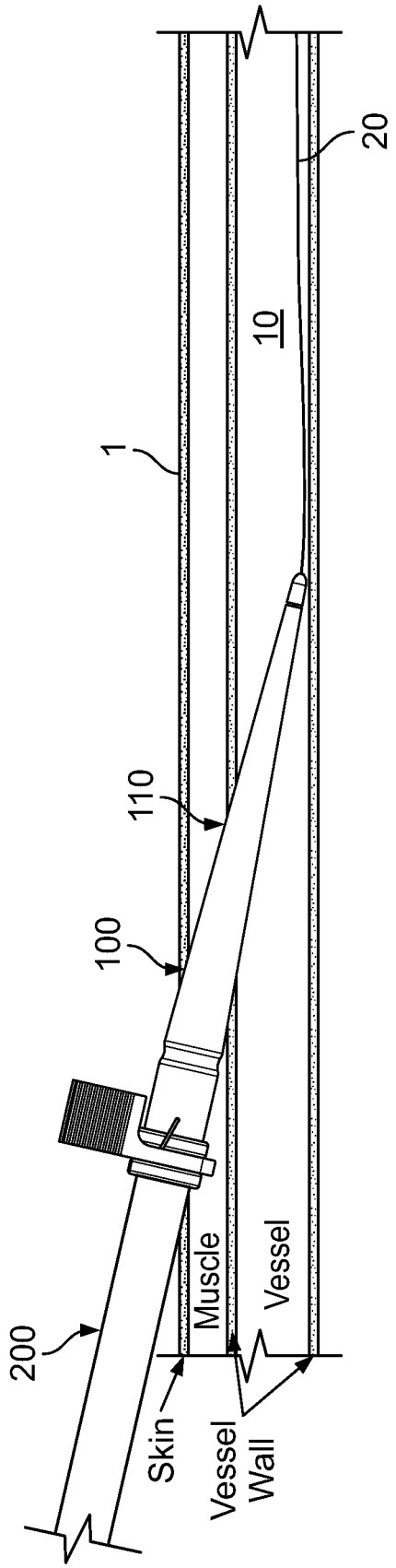
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FIG. 16

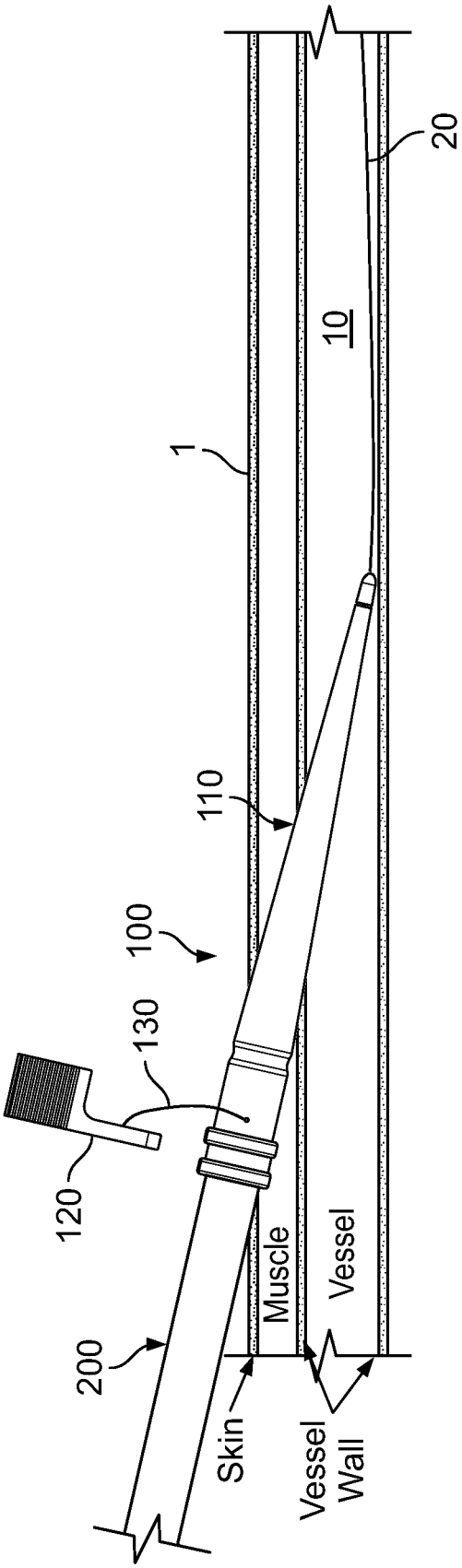
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FIG. 17

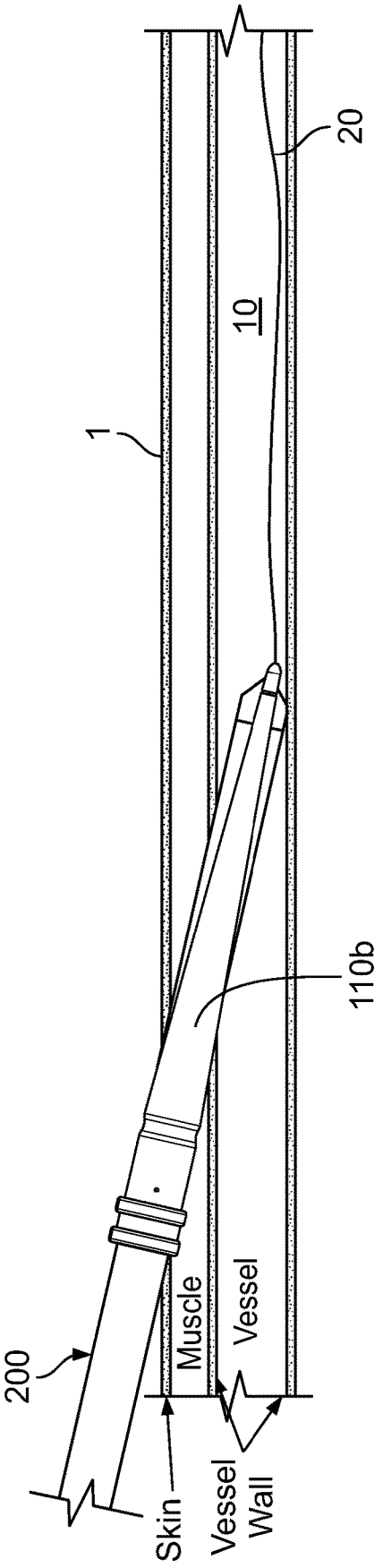
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FIG. 18

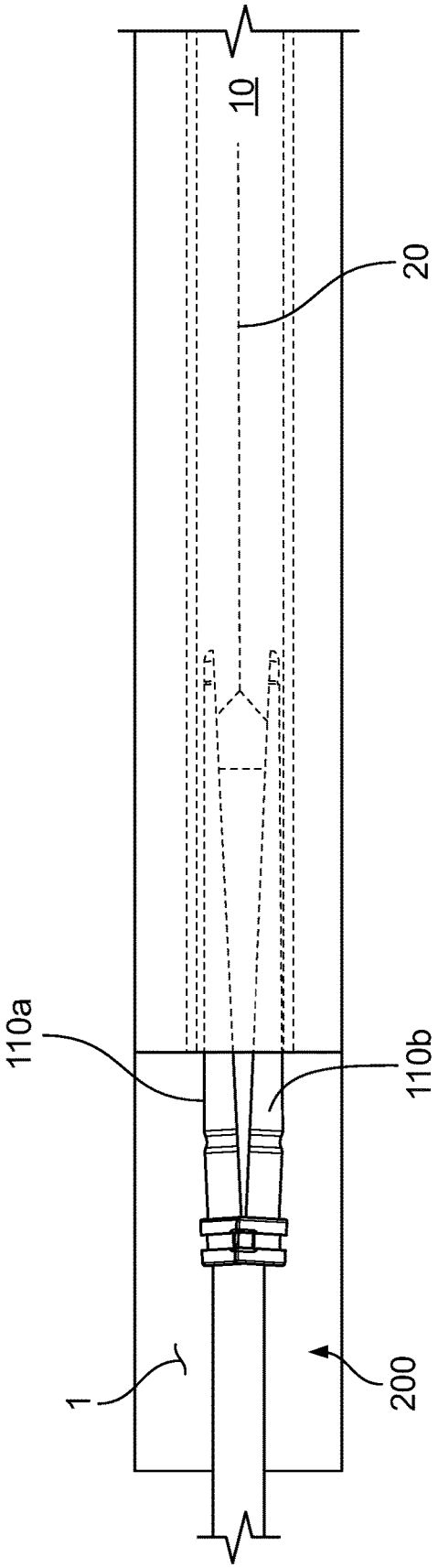
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FIG. 19

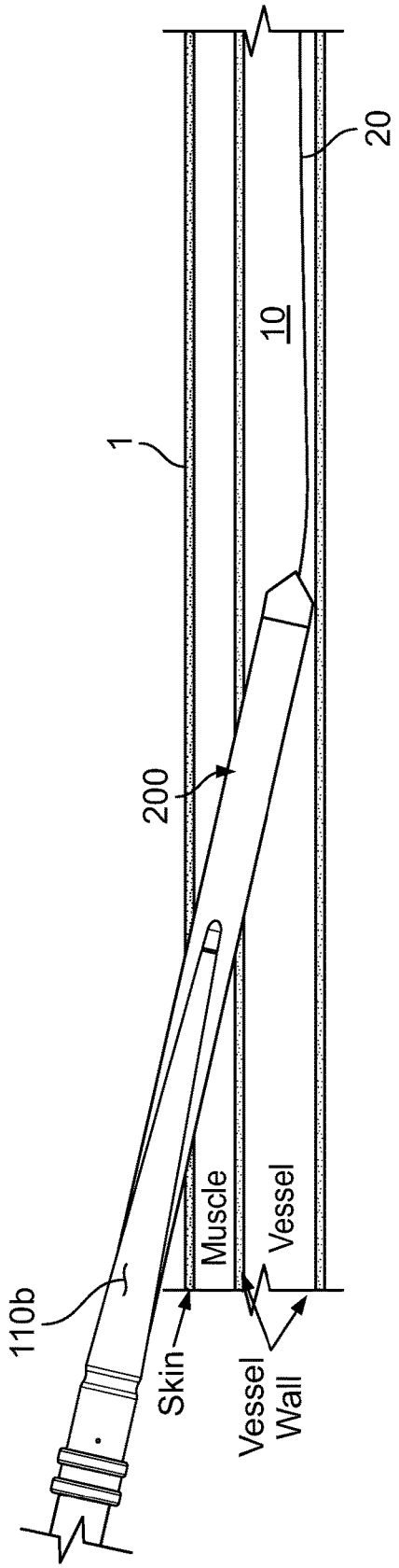
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FIG. 20

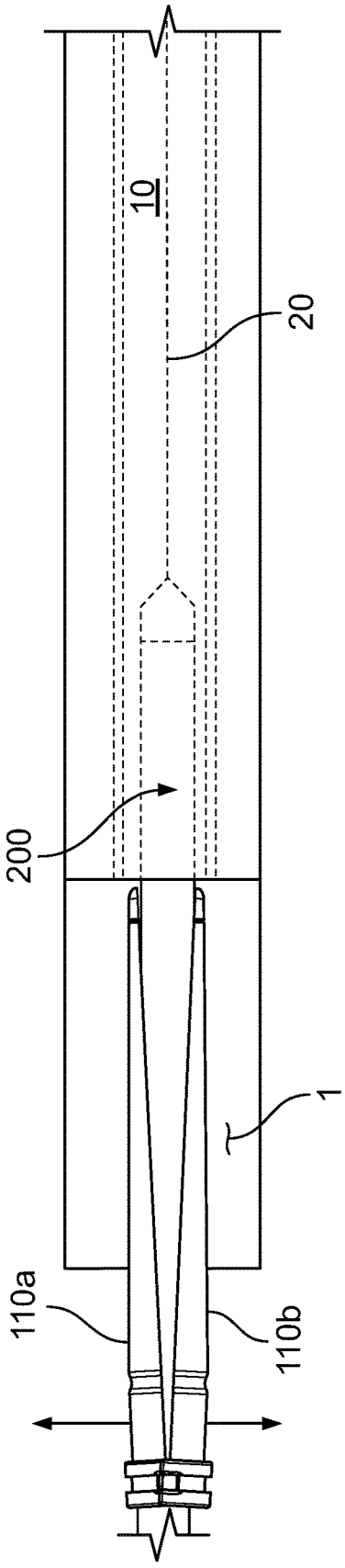
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FIG. 21

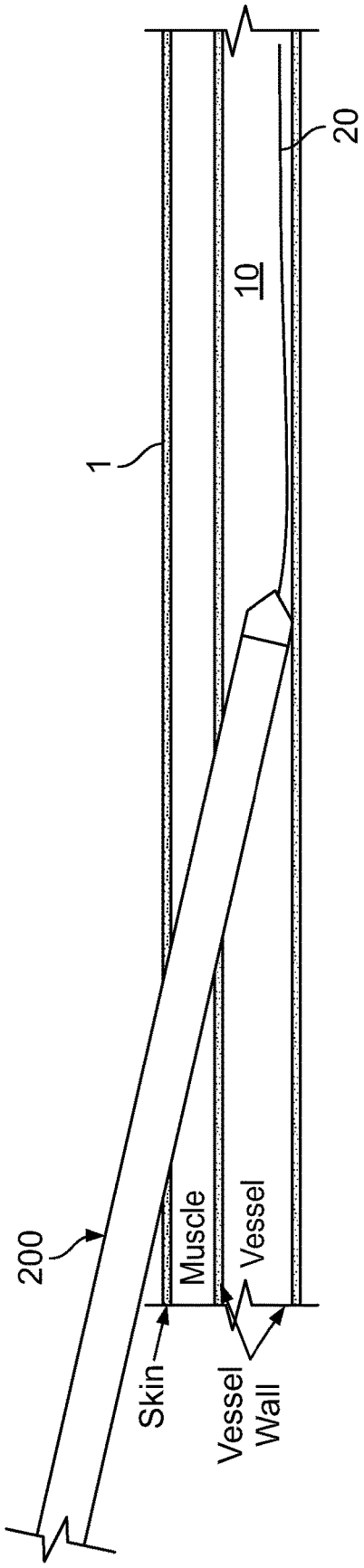
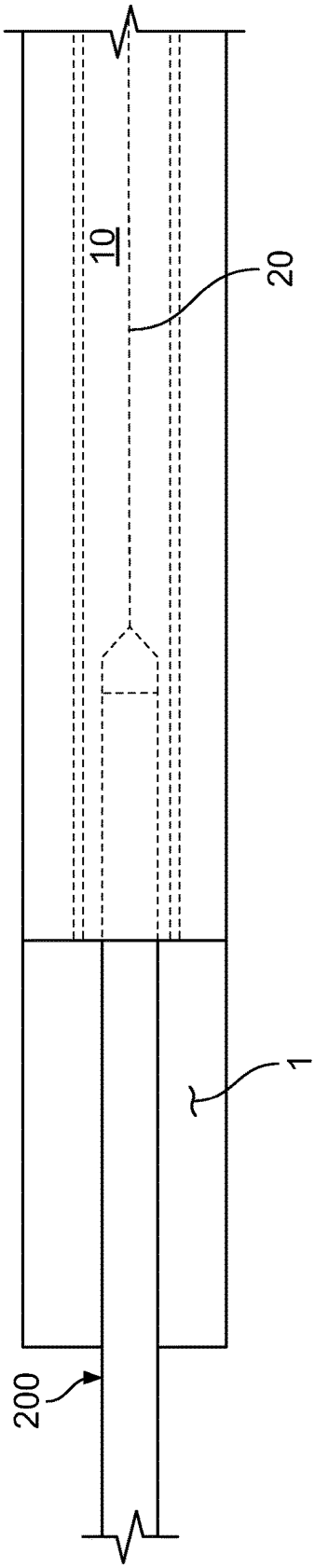


FIG. 22



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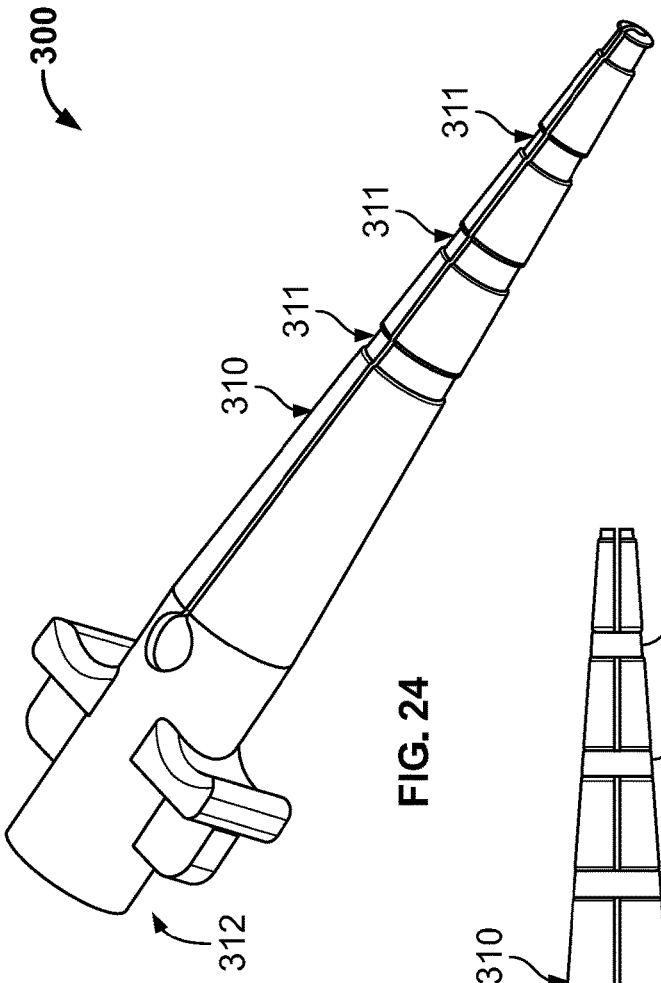

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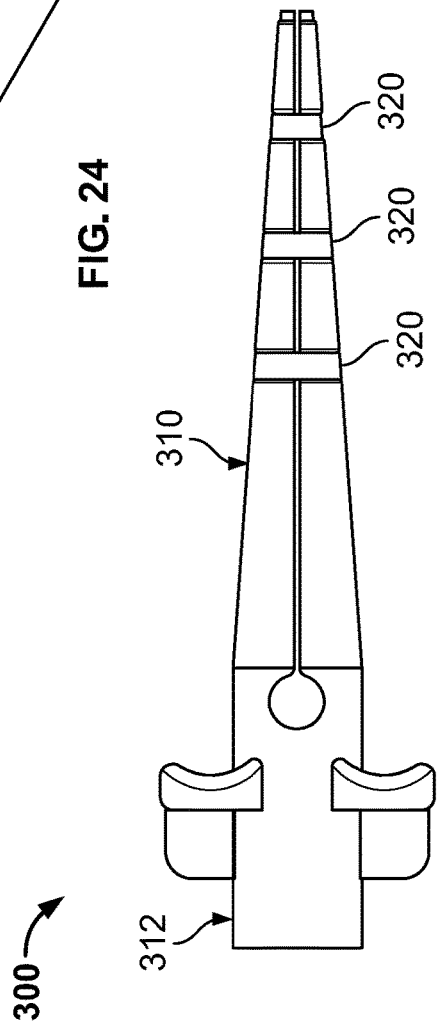

FIG. 25

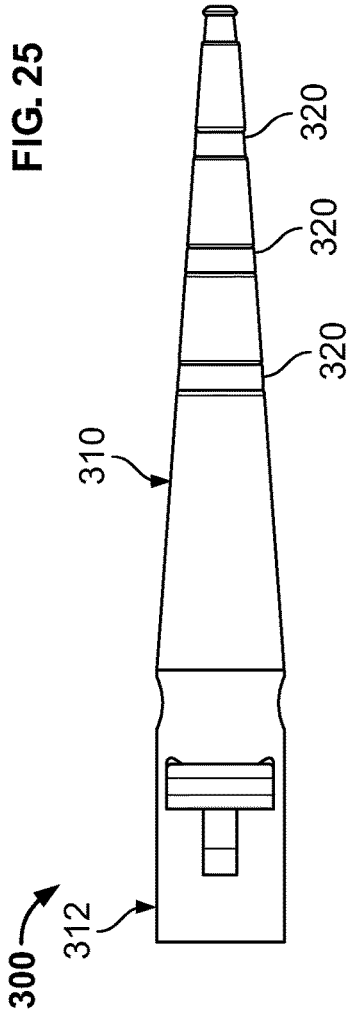

FIG. 26

DILATING INTRODUCER DEVICES AND METHODS FOR VASCULAR ACCESS

BACKGROUND

1. Technical Field

This document relates to devices used to deploy transvascular medical device systems and methods for using such devices. For example, this document relates to dilating introducer devices used for the percutaneous vascular deployment of catheter-based medical devices such as structural heart medical devices.

2. Background Information

Percutaneous sheath introducer devices are intended for use in settings such as the hospital catheterization laboratory for the percutaneous introduction of various medical devices into veins and/or arteries in a variety of diagnostic and therapeutic procedures.

Dilators are tubular devices used for dilating the percutaneous opening into a blood vessel. It has tapered distal end and proximal end comprising a hub.

SUMMARY

This document describes devices used to deploy transvascular medical device systems and methods for using such devices. For example, this document describes dilating introducer devices used for the percutaneous vascular deployment of catheter-based medical devices such as structural heart medical devices. Such dilating introducer devices can facilitate the percutaneous vascular deployment of catheter-based medical devices without an additional introducer sheath.

In one aspect this disclosure is directed to a dilating introducer device includes a conical tube comprising a first half releasably coupled to a second half, a clip releasably coupled to the first and second halves of the conical tube; and a suture removably extending through: (i) a first opening defined by the first half and (i) a first opening defined by the second half.

Such a dilating introducer device may optionally include one or more of the following optional features. In some embodiments, the suture extends through a first opening defined by the clip. In some such embodiments, the suture extends through a second opening defined by the clip. The suture may extend through: (i) a second opening defined by the first half and (i) a second opening defined by the second half. In some embodiments, the suture extends within a lumen of the conical tube between: (i) the first and second openings defined by the first half and (ii) the first and second openings defined by the second half. The first openings defined by the first and second halves may be at a tip portion of the conical tube. In some embodiments, the suture extends around an exterior of the conical tube between the first openings defined by the first and second halves of the conical tube. The clip may define an open-ended slot. The conical tube may include a hub that is releasably coupled in the open-ended slot. In some embodiments, the clip is flexible and is removable from the first and second halves of the conical tube by flexure of the clip. The first and second halves of the conical tube may be identical to each other. A guidewire opening may be defined at a distal-most tip of the conical tube. In some embodiments, the first and second halves of the conical tube comprise a plurality of protrusions and a plurality of complimentary recesses that releasably couple the first and second halves together.

In another aspect, this disclosure is directed to a method of introducing a catheter-based medical device into a blood vessel of a patient, the method comprising: (i) inserting a needle into the patient until a distal end portion of the needle is positioned in the blood vessel; (ii) insert a guidewire through the needle and into the blood vessel; (iii) removing the needle from the blood vessel; (iv) advancing a dilating introducer over the guidewire until a distal end portion of the dilating introducer is in the blood vessel, wherein at least a portion of the catheter-based medical device is in a lumen of the dilating introducer during the advancing; (v) advancing the catheter-based medical device through the lumen of the dilating introducer into the vessel; and (vi) removing the dilating introducer from the blood vessel.

Such a method may optionally include one or more of the following features. The removing the dilating introducer from the blood vessel may comprise longitudinally splitting the dilating introducer into multiple pieces. The removing the dilating introducer from the blood vessel may comprise removing a suture from engagement with the dilating introducer prior to the longitudinally splitting the dilating introducer into multiple pieces. In some embodiments, the method is performed without using a conventional introducer sheath. In particular embodiments, a distal end portion of the catheter-based medical device is in the vessel prior to the removing the dilating introducer from the blood vessel. The catheter-based device may be a prosthetic heart valve coupled on a system of delivery catheters. The dilating introducer may be conically shaped.

Particular embodiments of the subject matter described in this document can be implemented to realize one or more of the following advantages. In some embodiments, various heart conditions such as valvular disease, cardiac fibrillation, diastolic heart failure and others can be treated using the devices and methods provided herein.

In some embodiments, various heart conditions can be treated in a minimally invasive fashion using the devices and methods provided herein. Such minimally invasive techniques can reduce recovery times, patient discomfort, and treatment costs.

The devices and methods described herein are designed and optimized to improve procedural efficiencies, costs, and patient outcomes in comparison to conventional methods that use multiple devices (such as a dilator and a separate introducer sheath) to perform the functions of the combined dilator and introducer as described herein.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention pertains. Although methods and materials similar or equivalent to those described herein can be used to practice the invention, suitable methods and materials are described herein. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description herein. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of an example vascular dilating introducer device in accordance with some embodiments provided herein.

FIG. **2** is an exploded perspective view of the vascular dilating introducer device of FIG. **1**.

FIG. **3** is a top view of the vascular dilating introducer device of FIG. **1**.

FIG. **4** is a side view of the vascular dilating introducer device of FIG. **1**.

FIG. **5** is a perspective view of a half conical tube of the vascular dilating introducer device of FIG. **1**.

FIG. **6** is a top view of the half conical tube of FIG. **5**.

FIG. **7** is a side view of the half conical tube of FIG. **5**.

FIG. **8** is a perspective view of a clip of the vascular dilating introducer device of FIG. **1**.

FIG. **9** is a front view of the clip of FIG. **8**.

FIG. **10** is a schematic cross-section view of a patient's skin, subcutaneous muscle layer, and blood vessel.

FIG. **11** shows the schematic cross-section view of FIG. **10** with an introducer needle installed by which percutaneous access to the blood vessel is attained.

FIG. **12** shows the schematic cross-section view of FIG. **11** with a guidewire installed into the blood vessel via the introducer needle.

FIG. **13** shows the schematic cross-section view of FIG. **12** with the introducer needle removed and the guidewire remaining installed in the blood vessel.

FIG. **14** shows a transvascular medical device system and the vascular dilating introducer device of FIG. **1**.

FIG. **15** shows a distal end portion of the transvascular medical device system of FIG. **14** inserted within a proximal end portion of the vascular dilating introducer device of FIG. **1**.

FIG. **16** shows the schematic cross-section view of FIG. **13** with the vascular dilating introducer device and transvascular medical device system of FIG. **15** after being percutaneously inserted into the blood vessel over the guidewire.

FIG. **17** shows the arrangement of FIG. **16** with the clip of the vascular dilating introducer device being removed therefrom.

FIG. **18** shows the arrangement of FIG. **17** with the two halves of the conical tube of vascular dilating introducer device being split apart and the transvascular medical device system being advanced therethrough.

FIG. **19** shows a top view of the arrangement of FIG. **18**.

FIG. **20** shows the arrangement of FIG. **18** with the halves of the conical tube of vascular dilating introducer device being withdrawn from the patient while the transvascular medical device system remains in place.

FIG. **21** shows a top view of the arrangement of FIG. **20**.

FIG. **22** shows the arrangement of FIG. **20** with the vascular dilating introducer device being completely withdrawn from the patient while the transvascular medical device system remains in place.

FIG. **23** shows a top view of the arrangement of FIG. **22**.

FIG. **24** is a perspective view of another example vascular dilating introducer device in accordance with some embodiments provided herein.

FIG. **25** is a top view of the vascular dilating introducer device of FIG. **24**.

FIG. **26** is a side view of the vascular dilating introducer device of FIG. **24**.

Like reference numbers represent corresponding parts throughout.

DETAILED DESCRIPTION

This document describes devices used to deploy transvascular medical device systems and methods for using such devices. For example, this document describes dilating introducer devices used for the percutaneous vascular deployment of catheter-based medical devices such as, but not limited to, structural heart medical devices. Such dilating introducer devices can facilitate the percutaneous vascular deployment of catheter-based medical devices without an additional introducer sheath.

A conventional percutaneous introduction of a transvascular medical device typically includes the following steps:

i) Percutaneous needle introduction into the blood vessel with the needle defining a lumen through which a guidewire is introduced into the blood vessel.

ii) Then, the needle is retracted, leaving the guidewire in place.

iii) Then, an introducer sheath along with a dilator inside its lumen is introduced over the guidewire.

iv) The dilator is then removed with the introducer sheath and guidewire remaining in place. At this instance, the introducer has a seal at the proximal end (handle) which creates a seal over the guidewire.

a. This seal is critical and if not proper, can result in air being introduced into the blood vessel or loss of a significant amount of blood.

b. The effectiveness of the seal may be affected by the difference between the inner diameter of the introducer and the outer diameter of the guidewire (typically 0.014" or 0.035"). The higher this difference, the engineering complexity of the achieving a proper seal is higher. This is especially pertinent in case of large transvascular medical devices that are:

i. 10 Fr-20 Fr: Transvascular medical device systems such as transcatheter aortic valve replacement, left atrial appendage closure devices, RF ablation catheters for A-Fib treatments, etc.

ii. 24 Fr-40 Fr: Transvascular medical device systems such as transcatheter mitral repair, transcatheter mitral replacement, transcatheter tricuspid repair, transcatheter tricuspid replacement, etc.

v) The transvascular medical device is then introduced through the introducer sheath over the guidewire. The seal (discussed in iv.b.ii above) should not only be effective between the introducer and the guidewire, but also be effective when a 10 Fr-40 Fr transvascular medical device is being introduced.

The dilating introducers described herein combine steps iii, iv, and v, and therefore reduces the number of steps. The dilating introducers described herein also ensure that there are no instances in the procedure where the risk of air introduction and/or blood loss is high. As such, it allows for a safer procedure. The dilating introducers described herein also allow for fewer devices and therefore could be more inexpensive.

FIG. **1** illustrates an example percutaneous introducer and vascular dilator device **100** (or "dilating introducer **100**" for short) in accordance with some embodiments described herein. As described further below (e.g., FIGS. **10-23**), the dilating introducer **100** can be used by a medical clinician to percutaneously insert a transvascular medical device system into a blood vessel of a patient. The dilating introducer **100** serves to both dilate the tissue opening and/or blood vessel and also to introduce the transvascular medical device system into the blood vessel through the dilating introducer **100**. That is, the dilating introducer **100** is a multifunctional device that can eliminate the need for a conventional introducer sheath that is commonly used when percutaneously inserting a transvascular medical device system into a blood vessel of a patient.

The dilating introducer **100** includes a conical tube **110** and a clip **120** that is releasably coupleable to, or on, the conical tube **110**. In particular, the clip **120** is releasably coupleable to a hub **112** located at a proximal end of the conical tube **110**. Even more particularly, in the depicted embodiment the clip **120** is releasably coupleable to the hub **112** by seating the clip **120** in an annular recess defined by the hub **112**.

Also referring to FIG. **2**, in the depicted embodiment the conical tube **110** is made of two halves, a first half **110***a* and a second half **110***b*. In other words, it can be said that the conical tube **110** is a two-part conical tube **110** that is made to be splitable (which serves a useful purpose when introducing a transvascular medical device system into a blood vessel of a patient, as described further below). The hub **112** is also made of two halves, a first hub portion **112***a* and a second hub portion **112***b*.

In the depicted embodiment, the two halves **110***a*/**112***a* and **110***b*/**112***b* that make up the conical tube **110** and hub **112** are identical to each other. That uniformity is advantageous from a manufacturing standpoint. However, it is not required in all embodiments for the conical tube **110** to be made of two identical halves.

Referring also to FIGS. **3** and **4**, the dilating introducer **100** also includes a suture **130**. The suture **130** is removably coupled with the conical tube **110** and with the clip **120**. The suture **130** serves to maintain the first half **110***a* and the second half **110***b* of the conical tube **110** in a coupled arrangement as depicted. In particular, the suture **130** serves to hold the distal tip portions of the first half **110***a* and the second half **110***b* in engagement with each other, while the clip **120** serves to hold the proximal portions of the first half **110***a* and the second half **110***b* in engagement with each other. However, when it is desired to allow the dilating introducer **100** to split when advancing a transvascular medical device system therethrough, the clip **120** and the suture **130** can be partially or fully removed from engagement with the conical tube **110**. When removed, the clip **120** will no longer hold the proximal portions of the first half **110***a* and the second half **110***b* in engagement with each other, and the suture **130** will no longer hold the distal tip portions of the first half **110***a* and the second half **110***b* of the conical tube **110** in engagement with each other. In that case, the first half **110***a* and the second half **110***b* of the conical tube **110** can be split apart from each other.

Referring also to FIGS. **5-7**, it can be seen (particularly in FIG. **7**) that the conical tube halves **110***a/b* each define a first opening **114***a/b* and a second opening **116***a/b* through a wall of the conical tube halves **110***a/b*. The openings **114***a/b* and **116***a/b* allow the suture **130** to pass therethrough. Accordingly, the suture **130** can be releasably coupled with the conical tube **110** by threading it through the openings **114***a/b* and **116***a/b* in a particular orientation or pattern.

For example, in the depicted embodiment the suture **130** extends from the clip **120** and passes into the lumen defined by the conical tube **110** through the second opening **116***a*. Then the suture **130** extends distally and longitudinally in the lumen along the conical half **110***a* to the distal tip portion of the conical tube **110** where it exits the lumen through the first opening **114***a*. After exiting the lumen through the first opening **114***a*, the suture **130** wraps 180° around the outside of the distal tip portions of the conical tube halves **110***a/b*, and then reenters the lumen through the first opening **114***b*. From the distal end portion of the lumen, the suture extends proximally and longitudinally in the lumen along the conical half **110***b* until it exits the lumen through the second opening **116***b*. After exiting the second opening **116***b*, the suture **130** again extends to the clip **120**.

Adding tension to the suture **130** will hold the distal tip portions of the conical tube halves **110***a/b* securely together. In the depicted embodiment, the suture **130**, as it extends between the first opening **114***a* and the first opening **114***b*, resides in an annular groove/recess defined around an outer circumference of the distal tip portions of the conical tube halves **110***a/b*.

Still referring to FIGS. **5-7**, the conical tube halves **110***a/b* each define a semicircular guidewire opening **111***a/b* at the distal-most tips of the conical tube halves **110***a/b*. Accordingly, as described further below, the conical tube **110** can be advanced over a guidewire via the guidewire opening **111***a/b*.

A series of protrusions **113***a/b* extend from a first longitudinal wall surface of the each of the conical tube halves **110***a/b*. In addition, a corresponding series of recesses **115***a/b* are defined along a second longitudinal wall surface of the each of the conical tube halves **110***a/b*. Accordingly, when the two conical tube halves **110***a/b* are mated together to form the conical tube **110**, the series of protrusions **113***a/b* extend into the series of recesses **115***a/b*. In addition to the suture **130** holding the conical tube halves **110***a/b* together, this mating arrangement between the protrusions **113***a/b* and the recesses **115***a/b* further helps to hold the conical tube halves **110***a/b* together in the assembled form of the conical tube **110**.

Referring also to FIGS. **8** and **9**, the clip **120** defines an open-ended slot **122** in which the hub **112** of the conical tube **110** is slidably received. The clip **120** also includes two opposing finger pads **124***a* and **124***b*. When a clinician user desires to uncouple the clip **120** from the hub **112**, the clinician user can apply compression force by pinching the two opposing finger pads **124***a* and **124***b* to induce flexure of the clip **120** such that the open-ended slot **122** will widen. With the widened open-ended slot **122**, the clip **120** can be easily slipped off the hub **112** of the conical tube **110**.

The clip **120** also defines one or more first holes **126***a* and one or more second holes **126***b*. The one or more first holes **126***a* and one or more second holes **126***b* can be used for the suture **130** to extend through and/or to connect the suture **130** to the clip **120** as desired.

FIGS. **10-23** are a series of illustrations that depict how the dilating introducer **100** can be used to both dilate a tissue opening and/or blood vessel and also to introduce a transvascular medical device system into the blood vessel.

FIG. **10** shows a cross-sectional view of skin layer **1**, a subcutaneous muscle layer, and a blood vessel **10**.

In FIG. **11**, an introducer needle **30** has been percutaneously inserted such that its distal tip portion is positioned in the blood vessel **10**.

In FIG. **12**, a guidewire **20** has been inserted through the lumen of the introducer needle **30** such that the distal end portion of the guidewire **20** is positioned in the blood vessel **10**.

In FIG. **13**, the introducer needle **30** has been removed and the guidewire **20** is remaining percutaneously extending in the blood vessel **10**.

FIGS. **14** and **15** illustrate how an example transvascular system **200** can be engaged with the dilating introducer **100**. The distal end portion of the transvascular system **200** is positioned in the proximal end portion of the dilating introducer **100** (as shown in FIG. **15**). The clip **120** and suture **130** are on the conical tube **110** to hold the two-piece conical tube **110** together as a conical assembly.

The transvascular system **200** represents any type of medical device system that is deployed by advancement, using one or more catheters, along the vascular system of a patient.

FIG. **16** shows the dilating introducer **100** (with the transvascular system **200** coupled thereto) after its percutaneous advancement over the guidewire **20**. At least the distal tip portion of the dilating introducer **100** is positioned in the blood vessel **10**. As the dilating introducer **100** is percutaneously advanced to the depicted position, the dilating introducer **100** dilates (enlarges) the openings of the skin **1**, the muscle layer, and the blood vessel **10** in preparation for the later advancement of the transvascular system **200**.

FIG. **17** illustrates the removal of the clip **120** and the suture **130** from the two-piece conical tube **110**. Accordingly, the two-piece conical tube **110** is now free to longitudinally split apart.

FIGS. **18** and **19** show the advancement of the transvascular system **200** relative to the dilating introducer **100**, resulting in the splitting of the two-piece conical tube **110**. The advancement of the transvascular system **200** positions the distal end portion of the transvascular system **200** in the blood vessel **10**. The transvascular system **200** can be advanced over the guidewire **20**. In this manner, the dilating introducer **100** functions as an introducer sheath for the advancement of the transvascular system **200**.

FIGS. **20** and **21** illustrate the withdrawal of the split dilating introducer **100** from the patient. The transvascular system **200** on the guidewire **20** is remaining with the distal end portions thereof in the blood vessel **10**.

FIGS. **22** and **23** illustrate the transvascular system **200** on the guidewire **20** remaining in position relative to the patient, with their distal end portions in the blood vessel **10**. The dilating introducer **100** has been completely withdrawn. At this stage, the transvascular system **200** can be advanced via the blood vessel **10** as required for the performance of the medical procedure.

FIGS. **24-26** illustrate another dilating introducer **300**. The dilating introducer **300** can be used by a medical clinician to percutaneously insert a transvascular medical device system into a blood vessel of a patient. The dilating introducer **300** serves to both dilate the tissue opening and/or blood vessel and also to introduce the transvascular medical device system into the blood vessel through the dilating introducer **300**. That is, the dilating introducer **300** is a multifunctional device that can eliminate the need for a conventional introducer sheath that is commonly used when percutaneously inserting a transvascular medical device system into a blood vessel of a patient.

The dilating introducer **300** includes a conical tube **310**, a hub **312** attached at a proximal end of the conical tube **310**, and one or more elastic bands **320** coupled to the conical tube **310** to apply radially compressive hoop stress to the conical tube **310**. The elastic bands **320** are shown in FIGS. **25** and **26**, but are not shown in FIG. **24**.

The conical tube **310** is longitudinally split into two portions (all the way to the distal tip). The two portions of the conical tube **310** that are split apart from each other can flex radially outward, away from each other, as a transvascular medical device system is advanced through the dilating introducer **300**.

The conical tube **310** defines one or more annular recesses **311**. The one or more annular recesses **311** receive the one or more elastic bands **320**. In the depicted embodiment, there are three annular recesses **311** and three elastic bands **320**. In some embodiments, there are one, two, four, or more than four annular recesses **311** and corresponding elastic bands **320**.

The one or more elastic bands **320** are elastically stretchy. In some embodiments, the one or more elastic bands **320** are made of a material such as, but not limited to, a Pebax® elastomer or ChronoPrene™.

The elastic bands **320** function to bias the conical tube **310** to be configured in its conical shape as shown. However, when the transvascular medical device system is advanced through the dilating introducer **300**, the elastic bands **320** stretch to allow the splaying apart of the two portions of the conical tube **310**. In such a case, the two portions of the conical tube **310** flex radially outward away from each other in response to the passage of the larger diameter transvascular medical device system through the conical tube **310**.

While this specification contains many specific implementation details, these should not be construed as limitations on the scope of any invention or of what may be claimed, but rather as descriptions of features that may be specific to particular embodiments of particular inventions. Certain features that are described in this specification in the context of separate embodiments can also be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment can also be implemented in multiple embodiments separately or in any suitable subcombination. Moreover, although features may be described herein as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a subcombination or variation of a subcombination.

Similarly, while operations are depicted in the drawings in a particular order, this should not be understood as requiring that such operations be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results.

Particular embodiments of the subject matter have been described. Other embodiments are within the scope of the following claims. For example, the actions recited in the claims can be performed in a different order and still achieve desirable results. As one example, the processes depicted in the accompanying figures do not necessarily require the particular order shown, or sequential order, to achieve desirable results. In certain implementations, multitasking and parallel processing may be advantageous.

What is claimed is:

1. A dilating introducer device comprising:

a conical tube comprising a first half releasably coupled to a second half;

a clip releasably coupled to the first and second halves of the conical tube; and

a suture removably coupled directly with the conical tube and holding distal tip portions of the first and second halves in engagement with each other by extending through: (i) a first opening defined through a wall of the first half and (i) a first opening defined through a wall of the second half.

2. The device of claim **1**, wherein the suture extends through a first opening defined by the clip.

3. The device of claim **2**, wherein the suture extends through a second opening defined by the clip.

4. The device of claim **1**, wherein the suture extends through: (i) a second opening defined by the first half and (i) a second opening defined by the second half.

5. The device of claim 4, wherein the suture extends within a lumen of the conical tube between: (i) the first and second openings defined by the first half and (ii) the first and second openings defined by the second half.

6. The device of claim 1, wherein the first openings defined by the first and second halves are at the distal tip portions of the first and second halves of the conical tube.

7. The device of claim 6, wherein the suture extends around an exterior of the conical tube between the first openings defined by the first and second halves of the conical tube.

8. The device of claim 1, wherein the clip defines an open-ended slot.

9. The device of claim 8, wherein the conical tube comprises a hub that is releasably coupled in the open-ended slot.

10. The device of claim 1, wherein the clip is flexible and is removable from the first and second halves of the conical tube by flexure of the clip.

11. The device of claim 1, wherein the first and second halves of the conical tube are identical to each other.

12. The device of claim 11, wherein a guidewire opening is defined at a distal-most tip of the conical tube.

13. The device of claim 11, wherein the first and second halves of the conical tube comprise a plurality of protrusions and a plurality of complimentary recesses that releasably couple the first and second halves together.

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