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(71) Demandeur/Applicant:
BOSTON SCIENTIFIC SCIMED, INC., US
(72) Inventeurs/Inventors:
SCOTT, SERENA, US;
HANSEN, KATRINA, US;
ELLIS-RECH, DAVID SHLOMO RAFAEL, US;
CALLAGHAN, DAVID, US;
TASSONI, ANTHONY FRANK, JR., US;
STORBECK, GENE THOMAS, US
(74) Agent: SMART & BIGGAR LLP

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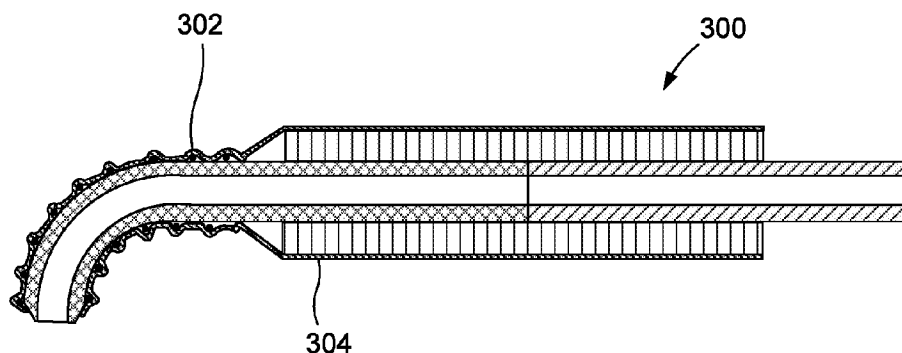


FIG. 4

(57) **Abrégé/Abstract:**

A device may include a catheter and a support tube. The catheter includes a lumen extending therethrough. The catheter is sized and shaped to extend through an endoscopic shaft to a target tissue within a living body. The lumen is sized and shaped for receiving a puncturing device therethrough. The catheter includes a first catheter portion distal to a second catheter portion. The first and second catheter portions are formed from different materials. The first catheter portion has a flexible curved distal end. The tube is fixed about an outer surface of a proximal end of the first catheter portion and an outer surface of a distal end of the second catheter portion.

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(71) Applicant: **BOSTON SCIENTIFIC SCIMED, INC.**
[US/US]; One Scimed Place, Maple Grove, Minnesota
55311 (US).

(72) Inventors: **SCOTT, Serena**; 71 Harley Dr, # 10,
Worcester, Massachusetts 01606 (US). **HANSEN, Ka-
trina**; 15R Edgemere Blvd, Shrewsbury, Massachusetts
01545 (US). **ELLIS-RECH, David Shlomo Rafael**; 111
South Main Street, Sharon, Massachusetts 02067 (US).
CALLAGHAN, David; 6 Voyagers Lane, Ashland, Mass-

achusetts 01721 (US). **TASSONI, Anthony Frank, Jr.**;
14416 Hummingbird St NW, Andover, Minnesota 55304
(US). **STORBECK, Gene Thomas**; 2104 Mill Pond Drive,
South Windsor, Connecticut 06174 (US).

(74) Agent: **KAPLUN, Oleg F.** et al.; 150 Broadway, Suite 702,
New York, New York 10038 (US).

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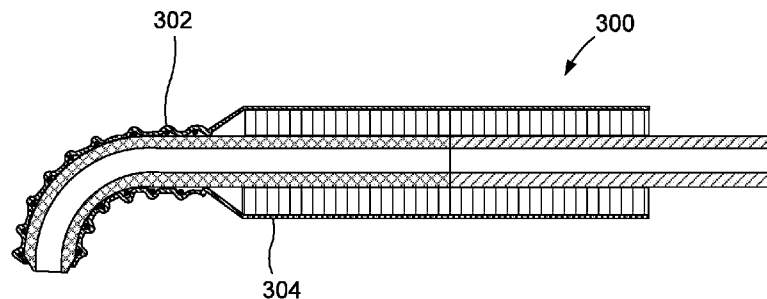


FIG. 4

(57) Abstract: A device may include a catheter and a support tube. The catheter includes a lumen extending therethrough. The catheter is sized and shaped to extend through an endoscopic shaft to a target tissue within a living body. The lumen is sized and shaped for receiving a puncturing device therethrough. The catheter includes a first catheter portion distal to a second catheter portion. The first and second catheter portions are formed from different materials. The first catheter portion has a flexible curved distal end. The tube is fixed about an outer surface of a proximal end of the first catheter portion and an outer surface of a distal end of the second catheter portion.

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Endoscopic Catheter Device

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Priority Claim

[0001] The present disclosure claims priority to U.S. Provisional Patent Application Serial No. 62/928,082 filed October 30, 2019; the disclosure of which is incorporated herewith by reference.

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Field

[0002] The present disclosure relates to endoscopic catheter devices, and, in particular, to microcatheters for use in endoscopic ultrasound access procedures.

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Background

[0003] Endoscopic ultrasound (EUS) access procedures are often used to gain access to patient anatomy such as a bile duct, pancreatic duct, or pancreatic fluid collection to e.g. insert a stent and relieve a blockage. These procedures often rely on curved (J-tip) catheters that can be rotated so that the curved distal end of the catheter faces in a desired direction, e.g., down the lumen of the duct, to deliver a guide wire to a target site within the body. However, existing catheters may display limitations making them unsuitable for certain applications. For example, some catheters may be prone to compression along their length due to insufficient column strength for effective puncturing.

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Summary

[0004] The present disclosure relates to a device may include a catheter. The catheter includes a lumen extending therethrough. The catheter is sized and shaped to extend through an endoscopic shaft to a target tissue within a living body. The lumen is sized and shaped for receiving a

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puncturing device therethrough. The catheter includes a first catheter portion distal to a second catheter portion. The first and second catheter portions are formed from different materials. The first catheter portion has a flexible curved distal end.

5 [0005] In an embodiment, the device may also include a support tube. The tube is fixed about an outer surface of a proximal end of the first catheter portion and an outer surface of a distal end of the second catheter portion.

[0006] In an embodiment, the first catheter portion is formed of a braided polymer and the
10 second catheter portion is formed of nitinol.

[0007] In an embodiment, the support tube is formed of a flexible laser-cut steel.

[0008] In an embodiment, the device further includes a layer of electrical insulation surrounding
15 the support tube.

[0009] In an embodiment, the first and second catheter portions meet at a butt joint and are joined to the support tube.

20 [0010] In an embodiment, the device further includes an echogenic material on the flexible distal end and/or the support tube.

[0011] In an embodiment, the echogenic material is a coating comprising particles suspended in an acoustically transparent material.

25 [0012] In an embodiment, the echogenic material is a wire or a polymer that is coiled or braided over the distal end.

[0013] In an embodiment, the device further includes a puncturing device sized and shaped to
30 extend through the lumen of the catheter and distally out the curved distal end, the puncturing device straightening the curved distal end when the puncturing device extends therethrough so

that, when the puncturing device punctures an access hole in the target tissue, the straightened distal end follows the puncturing device into the access hole.

[0014] In an embodiment, the device further includes an electrosurgical sheath longitudinally
5 slidable along an exterior of the catheter and the support tube, the electrosurgical sheath having an electrosurgical tip for electrosurgically dilating the access hole when the electrosurgical sheath is slid over the curved distal end and an electrical current is applied.

[0015] In an embodiment, the proximal end of the first catheter portion has a reduced outer
10 diameter relative to an outer diameter of a distal end of the first catheter portion.

[0016] In an embodiment, the second catheter portion has an outer diameter substantially equal to the reduced outer diameter of the proximal end of the first catheter portion.

[0017] In an embodiment, the support tube has an outer diameter substantially equal to the outer
15 diameter of the distal end of the first catheter portion.

[0018] In an embodiment, the device further includes a polymer surrounding one of the outer
20 surface of the proximal end of the first catheter portion and the outer surface of the distal end of the second catheter portion when the outer surfaces do not align.

[0019] In an embodiment, an edge of one of an inner surface of the proximal end of the first
catheter portion and an inner surface of the distal end of the second catheter portion is
chamfered.

[0020] In an embodiment, the device further includes a metal hypotube surrounding the outer
25 surface of the first catheter portion immediately proximal of the curved distal end.

[0021] In an embodiment, the device may further include a polymer having a first diameter
30 surrounding the outer surface of the proximal end of the first catheter portion and the polymer having a second diameter surrounding the outer surface of the distal end of the second catheter

portion. The second diameter is larger than the first diameter.

Brief Description

5 [0022] Fig. 1 shows an endoscopic access assembly for use during EUS-guided procedures.

[0023] Fig. 2 shows a distal end of the catheter of the endoscopic access assembly of Fig. 1.

[0024] Fig. 3 shows a cross-sectional view of the catheter of Fig. 2

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[0025] Fig. 4 shows a catheter with an echogenic material on the outer surface of the J-tip.

[0026] Fig. 5 shows a catheter with a polymer portion having a varying outer diameter.

15 [0027] Fig. 6 shows a catheter with an extended hypotube.

Detailed Description

[0028] The present disclosure may be further understood with reference to the following
20 description and the appended drawings, wherein like elements are referred to with the same
reference numerals. The exemplary embodiments describe to endoscopic catheter devices, and,
in particular, microcatheters for use during EUS-guided procedures, e.g., pancreaticobiliary
access procedures, having high column strength for making smooth punctures when used with a
sharp puncturing tip (sharp) extending out the lumen of the catheter. Some embodiments have
25 electrical insulation and heat resistance for electrosurgical dilation. Each of the described
embodiments may have an echogenic material added for improving a view of the device under
ultrasound guidance during the procedure.

[0029] Fig. 1 shows an endoscopic access assembly 100 for use during EUS-guided procedures
30 according to an exemplary embodiment. The endoscopic access assembly 100 has a
microcatheter 200, to be described in greater detail below with respect to Fig. 3. The

microcatheter 200 has a flexible tip 202. In an exemplary embodiment, the tip 202 may be configured to assume (in an unstressed state) a curved shape (e.g., J-tip), as shown in Fig. 2. The curve shape may take the shape of an arc, a J, or another shape. In the exemplary embodiment, the curve shape is a J.

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[0030] The microcatheter 200 further has an outer support tube 210, to be described in greater detail below. In Fig. 1, a puncturing element with a rigid, sharp tip (sharp) 102 extends through the lumen and out the tip 202 of the microcatheter 200. The sharp 102 is generally straight when in an unstressed state, so that, as the sharp 102 is advanced through the lumen of the microcatheter 200 to the distal end of the tip 202, the tip 202 is straightened. In this straightened configuration, i.e., with the sharp 102 extending out the distal end of the J-tip 202 (but prior to extending the sharp 102 and the tip 202 distally out the electrosurgical sheath 104), the combined sharp/J-tip is advanced (e.g., through an endoscope) to a target location within the body. The user may then puncture a target site in the anatomy to a given depth with the sharp 102 while advancing the tip 202 along with the sharp 102 so that the tip 202 follows the sharp 102 through the tissue to a target location (e.g., through a wall of the small intestine into a target bile duct). When the tip 202 is at a desired position within the bile duct, the sharp 102 is withdrawn from the tip 202, permitting the tip 202 to revert to its curved shape. The tip 202 may then be rotated to a desired orientation so that the distal hook of the tip 202 aims the distal opening of the tip 202 in a direction along which a guidewire is to be advanced into the bile duct.

[0031] The guidewire is then inserted through the microcatheter 200 and the tip 202 to extend distally out of the tip 202 and moved further into the bile duct until a desired length of the guidewire is received within the bile duct. Once the guidewire has been positioned as desired, a flexible electrosurgical sheath 104 with an electrosurgical tip 106 is advanced over the catheter 200 and the tip 202 while applying an RF current from the electrosurgical tip 106 through the tissue to dilate the access hole(s) made by the sharp 102 and the tip 202. This ensures the integrity of these openings, after which the catheter 200 may be withdrawn from the body leaving the guidewire in place within the bile duct. A stent or other treatment and/or diagnostic devices may then be inserted over the guidewire through the access holes to the target site within the bile duct as would be understood by those skilled in the art.

[0032] Fig. 3 shows a cross-section of the catheter 200 in greater detail. The catheter 200 exhibits increased column strength based in part on the construction of an outer support tube 210 and a metal hypotube portion 206 fashioned for strength and flexibility, to be explained in detail below. The catheter 200 also shows increased heat resistance, radiopacity, rotational control, water tightness and flexibility.

[0033] The catheter 200 comprises a two-part catheter shaft having a distal braided polymer portion 204 including the tip 202, the proximal end of the polymer portion 204 butted against the hypotube 206 proximal to the polymer portion 204. The proximal end of the polymer 204 and the distal end of the hypotube 206 meet at a butt joint 208. The outer support tube 210 is affixed to the outer diameters of both the polymer portion 204 and the hypotube 206, a part of the support tube 210 covering and providing support for the joint 208 between the portions of tube. The outer support tube 210 may extend a full length of the catheter 200.

[0034] As would be understood by those skilled in the art, the polymer used in the braided polymer portion 204 is selected to have a relatively high melting temperature (to prevent melting or deformation during electrosurgical dilation), shape memory (to allow the J-tip to naturally revert to the curved shape) and good dielectric strength (to electrically insulate the internal braid in the exposed tip). The polymer may be, for example, Arnitel, Pebax, nylon, polyurethane, etc. Some polymers may be more suitable for higher temperature applications, while others may be more suitable for lower temperature applications. The braid within the polymer may be round wire or ribbon made from thin stainless steel, steel, nitinol, more radiopaque materials such as tungsten or platinum, or other metals. The braid may also include a high strength non-metallic braid reinforcement such as a liquid-crystal polymer (LCP), PEEK, etc. The braided polymer may have a thin innermost layer made of e.g. PTFE, FEP, HDPE or other polymers with a lubricious additive to provide a surface to braid onto and to reduce friction, thereby reducing the force required to remove the sharp therefrom and/or to insert a guidewire therethrough.

[0035] The tip 202 of the polymer portion 204 of this embodiment may be set into the J-shape using heat. As would be understood by those skilled in the art, the curved shape allows for the

insertion of a guidewire into a target lumen (e.g., a bile duct) in a desired direction as the J-tip 202 is rotated to face the distal opening of the tip 202 lumen in the desired direction after the J-tip 202 has entered the targeted anatomy. The braid provides durability, kink resistance, torque transmission and tensile strength.

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[0036] Additionally, the distal end of the braided polymer portion 204 of the tapered tip 202 may be beveled or tapered to reduce the force required to penetrate target tissue during initial puncture. The tip 202 may have a short, unbraided portion at its distal-most end to allow for the tapering. The unbraided portion may be a different material suited to withstanding compressive forces during tip entry, e.g. a harder material such as vestamid nylon. The tip 202 may further have a radiopaque (RO) marker 214 at the distal end of the braid to help terminate the braid and/or provide radiopacity (for more easily visualizing the marker 214 and thus the tip 202 via e.g. X-ray).

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[0037] The metal hypotube 206 may be made, e.g., of nitinol for providing flexibility, column strength and torque transmission. The distal end of the hypotube 206 (abutting the polymer portion 204) may be chamfered on the inner diameter thereof to prevent guidewire skiving along the inner edge as would be understood by those skilled in the art.

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[0038] The outer support tube 210 in this embodiment may be made of laser-cut steel to provide flexibility, although other means for making the support tube 210 flexible, such as mechanical cutting or coiling, may be used. The steel material for the support tube 210 is less prone to cracking than nitinol, improving durability. The outer support tube 210 may have a short portion that is not laser cut and is positioned at the joint 208 to prevent bending at the joint 208, where such bending could also lead to guidewire skiving at the butt joint 208 between the polymer 204 and the hypotube 206. To further prevent bending, the joint 208 between the polymer 204 and the hypotube 206 may be set far enough proximally from the distal tip so that the joint 208 does not advance into through the tissue openings into the target anatomy, so that it may supported by the electrosurgical sheath 104 at all times.

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[0039] The support tube 210 is fixed to the outer diameters of a proximal end of the polymer 204

and a distal end of the hypotube 206 and provides additional column strength, kink resistance, torsional rigidity and twist resistance to the polymer portion 204. The support tube 210 may be fixed to the polymer 204 and hypotube 206 via, e.g., glue, which may also provide a chamfer or taper at the distal end of the hypotube 206 for smoother passage into tissue during the initial
5 puncture using a sharp. The support tube 210 is covered with a thin layer of electrical insulation 212 to prevent the burning of non-targeted tissue adjacent to the support tube 210 as the electrosurgical dilation tip 106 is advanced over the support tube 210.

[0040] In an alternate embodiment, the catheter 200 may form part of a cold device that provides
10 puncture and directional guidewire access, but not cauterization or electrosurgical dilation. In this embodiment, the microcatheter does not need to be heat resistant or electrically insulated. Thus, the braided polymer may be made of arnitel, Pebax, PEEK, or another material. No electrical insulation is necessary in this embodiment. The cold device may be used in e.g. rendezvous EUS access procedures in which the guidewire is fed down the duct and out the
15 papilla. If used in transmural stenting procedures, an exchange may be needed to introduce an additional dilating tool, or a taper could be added to the electrosurgical tip 106 for cold dilation.

[0041] In still another embodiment, the tip 202 of the catheter 200 is made sufficiently long and flexible to be advanced through the duct and up to or through a stricture. As would be
20 understood by those skilled in the art, having the tip 202 adjacent to a stricture provides additional support and ease of use when advancing a guidewire through the stricture during a rendezvous procedure. In some procedures, a stent may be placed over this guidewire. The laser cut steel design provides additional flexibility for passage through the pancreaticobiliary tree. Permanent changes in the shape of the microcatheter 200 while passing it down the duct are
25 acceptable because shape changes are detrimental only to rotation and puncture, which have already been completed at that point during the use of this single use device.

[0042] The exemplary embodiments also describe microcatheters with echogenic materials added for improved viewing via ultrasound during the procedure. An echogenic material may be
30 added to any of the embodiments described herein.

[0043] Fig. 4 shows a catheter 300 with an echogenic material 302 on the outer surface of the J-tip. The echogenic material may, in this embodiment, be a coating of rigid, echogenic particles suspended in a soft, acoustically transparent material. Alternately, the echogenic material may be a wire or polymer that is coiled or braided over the J-tip. The wire may be e.g. nitinol, steel, tungsten, or another material, which may be radiopaque as well as echogenic to increase the radiopacity of the catheter 300. The wire may be round or ribbon and may be e.g. $\sim 1 - 5$ thousandths of an inch in diameter. An extended electrical insulator 304 may cover both the outer support tube and the echogenic material 302 when the echogenic material 302 is a wire or coil on the tip surface. If, however, the catheter 300 is a cold device, no electrical insulation would be necessary.

[0044] The exemplary embodiments also describe microcatheters that, despite having a laser cut support tube included thereon, have a relatively small outer diameter. The reduced outer diameter microcatheter may be desirable to physicians to reduce the size of the puncture hole created in the tissue.

[0045] Fig. 5 shows a catheter 400 with a polymer portion 402 having a varying outer diameter. The catheter 400 has a larger outer diameter at the curved distal end, comparable to the earlier described embodiments, and a smaller outer diameter at a proximal end where it is surrounded by an outer support tube 408. The outer support tube 408 may have a thickness that essentially fills in the difference between the curved distal end diameter and the smaller proximal end, giving the catheter 400 a substantially uniform outer diameter from the support tube portion to the distal tip, although this uniform diameter is not required.

[0046] The hypotube 404 has a cross-sectional area substantially similar to that of the reduced diameter proximal end of the polymer portion 402 and which, similarly to the previously described embodiments, is joined to the polymer portion at a joint 406. The support tube 408 protects the joint 406 in a manner similar to that described in regard to the previous embodiments. The reduced cross-sectional area allows for more precise puncturing of the anatomy. The braid wires in the polymer portion 402 may be partially exposed on the proximal end of the polymer portion 402 where these exposed braid wires will be covered by the support

tube 408 and/or electrical insulation 412. The catheter 400 may also include an echogenic material 410 covered by the electrical insulation 412 for electrosurgical dilation applications.

[0047] In another embodiment, the inner and outer diameters of the polymer portion and the hypotube may not precisely line up. If such an imprecise line-up for the inner diameters is used, the portion with the smaller diameter may be chamfered or tapered to prevent skiving of items e.g., guidewires inserted therethrough. Alternatively, when the outer diameters do not line up skiving may be prevented by including a layer of another material over the polymer or hypotube (whichever is smaller) to fill a gap between it and the support tube. This material may, e.g., be a heat shrink.

[0048] In still another embodiment, the outer support tube may be excluded from the design, with the hypotube replacing its function. This embodiment may be desirable for applications in which a less flexible or smaller device is acceptable, such as urology applications. If used in less tortuous paths, or in applications where the device is smaller overall, it may be able to rotate easily without excessive whipping.

[0049] Fig. 6 shows a catheter 500 with an extended hypotube 504. The catheter 500 includes the polymer portion 502 where, similar to Fig. 4, the polymer portion 502 has a larger outer diameter at the curved distal end and a smaller outer diameter at a proximal end. However, rather than being surrounded by an outer support tube, the smaller diameter proximal end is surrounded by the hypotube 504. Alternatively, the polymer may have a constant outer diameter, as in Fig. 4. In this embodiment, the polymer portion 502 extends proximally the full length of the catheter, albeit at a smaller diameter, with the hypotube 504 providing support along the length of the catheter up to the joint 506 where the hypotube 504 terminates. The polymer 502 and the hypotube 504 may be attached using adhesives, a polymer reflow, or other means. The joint 506 may be located further distally than in previously described embodiments. For example, the hypotube 504 may extend into the puncture site.

[0050] In another embodiment, the metal hypotube may be excluded from the design. In this embodiment, the polymer runs the length of the catheter, with the outer support tube extending

proximally for a greater length. This embodiment may be particularly suited for applications where the device length may be short, such as in urology or pulmonology applications. In these cases, the axial compression of the laser cut support tube and polymer would be multiplied over a shorter overall length, resulting in less axial compression overall during puncture.

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[0051] It will be appreciated by those skilled in the art that changes may be made to the embodiments described above without departing from the inventive concept thereof. It should further be appreciated that structural features and methods associated with one of the embodiments can be incorporated into other embodiments. It is understood, therefore, that this invention is not limited to the particular embodiment disclosed, but rather modifications are also covered within the scope of the present invention as defined by the appended claims.

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Claims

1. A device, comprising:
a catheter including a lumen extending therethrough, the catheter being sized and shaped
5 to extend through an endoscopic shaft to a target tissue within a living body, the lumen being
sized and shaped for receiving a puncturing device therethrough, the catheter including a first
catheter portion distal to a second catheter portion, the first and second catheter portions being
formed from different materials, the first catheter portion having a flexible curved distal end.
- 10 2. The device of claim 1, wherein the first catheter portion is formed of a braided polymer
and the second catheter portion is formed of nitinol.
3. The device of any of claims 1-2, further comprising:
a support tube fixed about an outer surface of a proximal end of the first catheter portion
15 and an outer surface of a distal end of the second catheter portion.
4. The device of claim 3, further comprising:
a layer of electrical insulation surrounding the support tube.
- 20 5. The device of any of claims 3-4, wherein the first and second catheter portions meet at a
butt joint and are joined to the support tube.
6. The device of any of one of claims 3-5, further comprising:
an echogenic material on the flexible distal end and/or the support tube.
25
7. The device of claim 6, wherein the echogenic material is a coating comprising particles
suspended in an acoustically transparent material.
8. The device of claim 6, wherein the echogenic material is a wire or a polymer that is
30 coiled or braided over the distal end.

9. The device of any of one of claims 1-8, further comprising:

a puncturing device sized and shaped to extend through the lumen of the catheter and distally out the curved distal end, the puncturing device straightening the curved distal end when the puncturing device extends therethrough so that, when the puncturing device punctures an access hole in the target tissue, the straightened distal end follows the puncturing device into the access hole.

10. The device of any of one of claims 1-9, further comprising:

an electrosurgical sheath longitudinally slidable along an exterior of the catheter and the support tube, the electrosurgical sheath having an electrosurgical tip for electrosurgically dilating the access hole when the electrosurgical sheath is slid over the curved distal end and an electrical current is applied.

11. The device of any of one of claims 1-10, wherein the proximal end of the first catheter portion has a reduced outer diameter relative to an outer diameter of a distal end of the first catheter portion.

12. The device of claim 11, wherein the second catheter portion has an outer diameter substantially equal to the reduced outer diameter of the proximal end of the first catheter portion and wherein the support tube has an outer diameter substantially equal to the outer diameter of the distal end of the first catheter portion.

13. The device of any of one of claims 1-12, further comprising:

a polymer surrounding one of the outer surface of the proximal end of the first catheter portion and the outer surface of the distal end of the second catheter portion when the outer surfaces do not align.

14. The device of any of one of claims 1-13, wherein an edge of one of an inner surface of the proximal end of the first catheter portion and an inner surface of the distal end of the second catheter portion is chamfered.

15. The device of any of one of claims 1-14, further comprising:
a metal hypotube surrounding the outer surface of the first catheter portion immediately proximal of the curved distal end.

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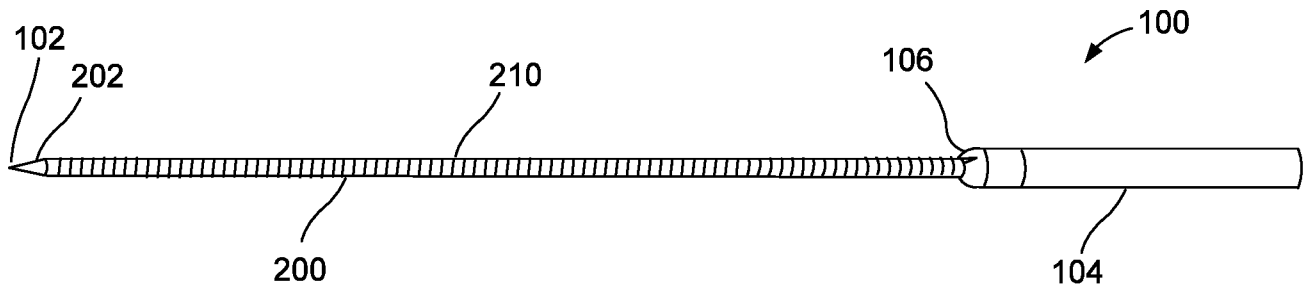


FIG. 1

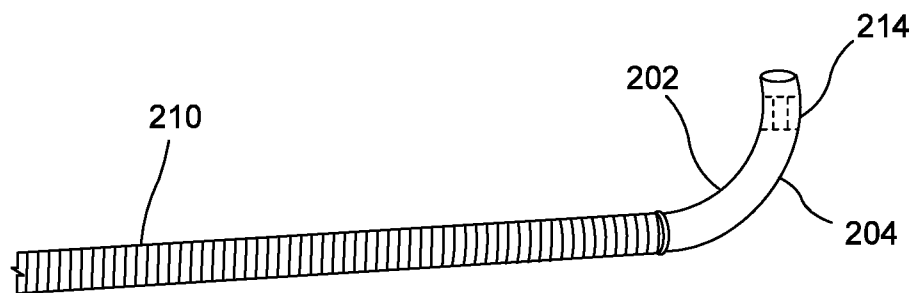


FIG. 2

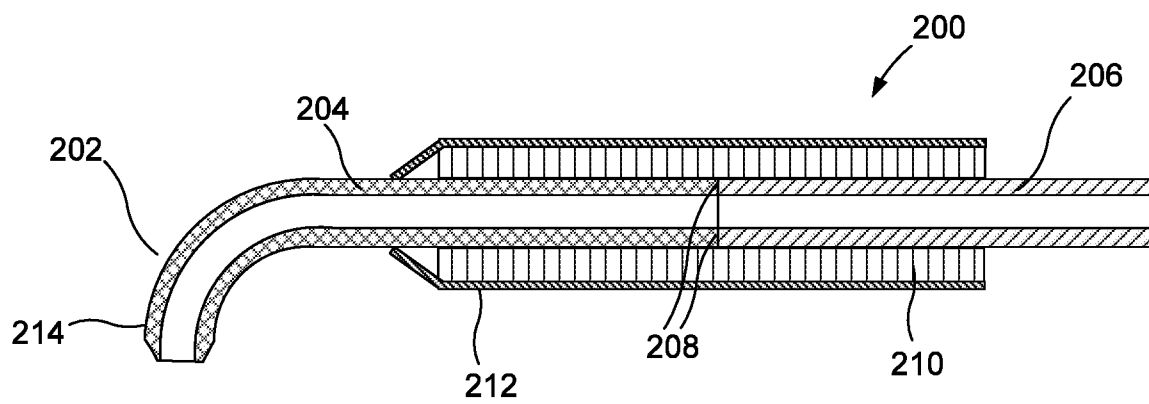


FIG. 3

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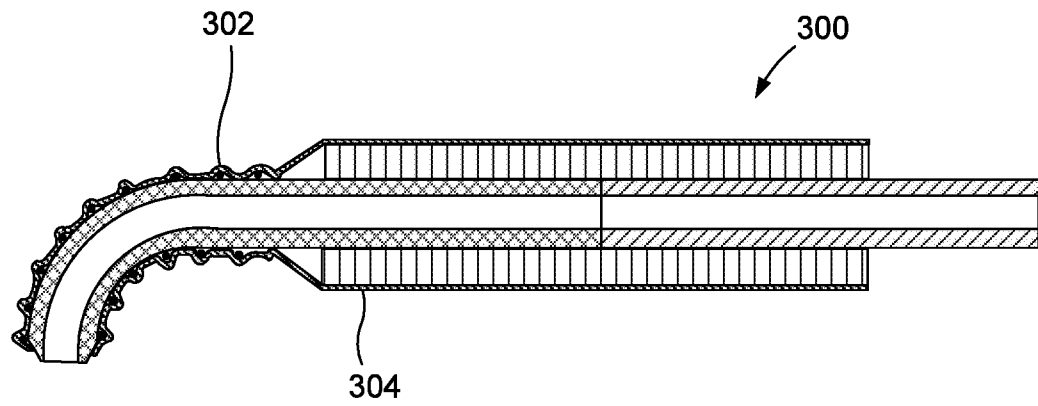


FIG. 4

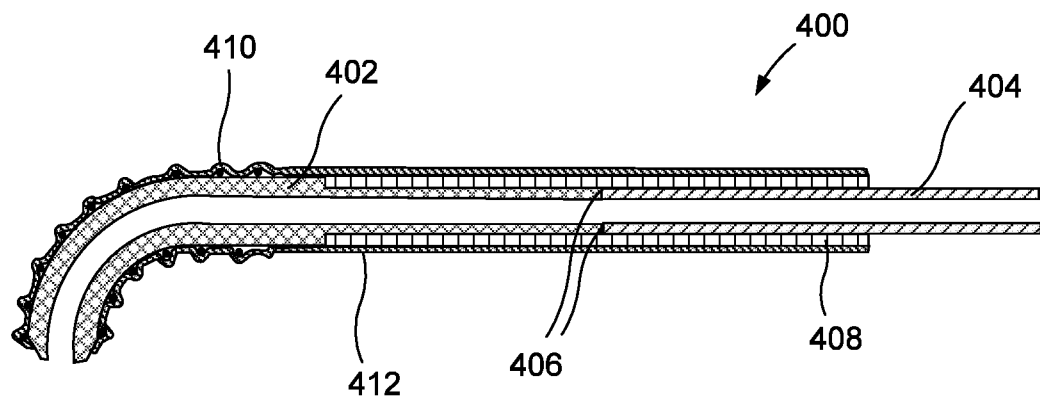


FIG. 5

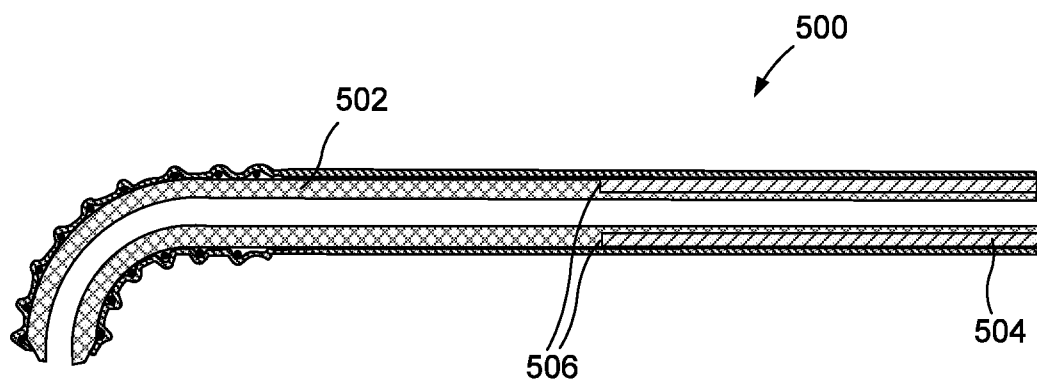


FIG. 6

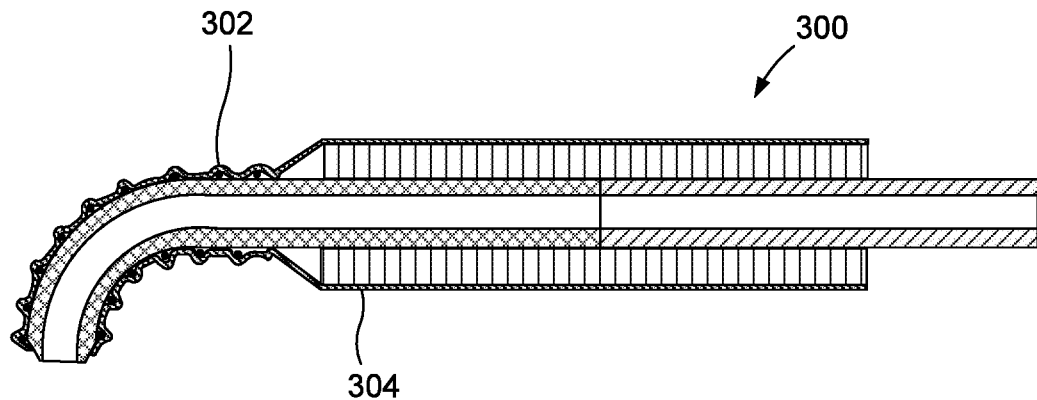


FIG. 4