US Patent & Trademark Office
Patent Public Search | Text View

United States Patent Application Publication	20250261963
Kind Code	A1
Publication Date	August 21, 2025
Inventor(s)	Casiraro; Matthew R. et al.

Catheters, Catheter Assemblies, & Methods

Abstract

The present disclosure relates to catheters for use in removing an occlusion in a vessel. The catheter includes a cannula with a sidewall that defines a cannula lumen, and a distal portion, disposed at a distal end of the cannula, with a body that defines a body lumen. The catheter also includes a helix member that is rotatably disposed, at least partially, in the cannula lumen and body lumen. A longitudinally-oriented blade is attached to the helix member and at least a portion of the blade is intermittently exposed at the lateral opening. In operation, catheters according to the present disclosure generate negative pressure, which aspirates the occlusive material from the vessel through the catheter. In embodiments, while the occlusive material is being aspirated, the catheter causes the occlusive material to contact the clot fragmentation components, causing the occlusive material to break into smaller fragments.

Inventors:	**Casiraro; Matthew R. (Tempe, AZ), Chanduszko; Andrzej J. (Chandler, AZ)**
Applicant:	**Bard Peripheral Vascular, Inc.** (Franklin Lakes, NJ)
Family ID:	**1000008586085**
Assignee:	**Bard Peripheral Vascular, Inc. (Franklin Lakes, NJ)**
Appl. No.:	**18/702979**
Filed (or PCT Filed):	**December 29, 2021**
PCT No.:	**PCT/US2021/065501**

Publication Classification

Int. Cl.: **A61B17/3207** (20060101); **A61B17/00** (20060101)

U.S. Cl.:

CPC **A61B17/320758** (20130101); A61B2017/00893 (20130101); A61B2017/320716 (20130101); A61B2217/005 (20130101); A61B2217/007 (20130101)

Background/Summary

TECHNICAL FIELD

[0001] The present specification generally relates to catheters, catheter assemblies, and methods for aspirating, fragmenting and removing blood clots, fatty deposits, or other extractable material in medical procedures such as atherectomy and thrombectomy.

BACKGROUND

[0002] Cardiovascular diseases are a leading cause of death worldwide. Vascular occlusions refer to blockages of blood vessels. Thrombosis is a specific type of vascular occlusion caused by a thrombus (i.e. a blood clot). Thrombi are formed from aggregated platelets, red blood cells, and fibrin proteins, but also may also include plaque and other blood-borne substances such as fat, cholesterol, and calcium.

[0003] Thrombi can form in both arteries and veins. Venous thrombosis leads to congestion of the affected part of the body, while arterial thrombosis affects the blood supply to tissue and can lead to ischemia or necrosis. Additional complications can arise when a piece of either an arterial or a venous thrombus breaks off. This piece of thrombus, called an embolus, can travel through the circulation and lodge somewhere else as an embolism.

[0004] Medical procedures such as thrombectomy can be used to remove thrombi from a blood vessel. One method of thrombectomy is mechanical aspiration. As a thrombus ages, it may become more fibrous and therefore more resistant to aspiration and mechanical fragmentation. This may result in blockages of existing aspiration devices due to a large clot burden. If the thrombectomy device is blocked, the procedure may be extended or an additional device may be required. When a thrombus is fragmented into smaller pieces, it is easier to transport the particles through the catheter and out of the patient without blockage of the device.

[0005] Accordingly, a need exists for devices to improve performance of occlusion removal by enhancing fragmentation and aspiration.

BRIEF SUMMARY

[0006] Embodiments of the present disclosure are directed to catheter assemblies with enhanced aspiration and clot fragmentation components that assist in reducing the size of material removed from hollow anatomical structures, such as a vessel or the like. In operation, catheter assemblies according to the present disclosure generate negative pressure, which aspirates the occlusive material from the vessel through the catheter. In embodiments, catheter assemblies according to the present disclosure also operate to increase fragmentation of the occlusive material. While the occlusive material is being aspirated, the catheter assembly causes the occlusive material to contact the clot fragmentation components, causing the occlusive material to break into smaller fragments. The smaller fragments of the occlusive material are able to be aspirated through the cannula lumen of the catheter more effectively, thereby preventing blockage or clogging of the catheter according to the present disclosure.

[0007] According to one embodiment of the present disclosure, a catheter for use in removing an occlusion in a body lumen includes a cannula having a sidewall that defines a cannula lumen, and a distal portion, disposed at a distal end of the cannula, the distal portion comprising a body, said body defining a body lumen and said body further defining a lateral opening extending through the body and into the body lumen. The catheter also includes a helix member that is rotatably disposed, at least partially, in the cannula lumen and body lumen. A longitudinally-oriented blade is attached to the helix member and at least a portion of the blade is intermittently exposed at the lateral opening.

[0008] According to another embodiment of the present disclosure, a catheter assembly for use in removing an occlusion in a body lumen includes a cannula having a sidewall that defines a cannula lumen, and a distal portion, disposed at a distal end of the cannula. The distal portion has a body defining a body lumen, and a cylinder comprising a cylinder wall configured to define a cylinder opening. The catheter assembly includes a helix member rotatably disposed in the cannula lumen and the body lumen. The helix member has a distal terminal end and a rotational axis. The cylinder is coupled to the distal terminal end of the helix member. The cylinder opening longitudinally extends along the rotational axis. The cylinder also has a plurality of cantilevered blade members that extend inwardly from the cylinder wall toward the rotational axis.

[0009] According to another embodiment of the present disclosure, a method for removing occlusive material from a vessel, includes advancing a catheter to the occlusive material within the vessel; receiving the occlusive material within a lateral opening of a distal portion of the catheter; rotating a helix member positioned at least partially within the cannula lumen and the body lumen and rotatable with respect to a sidewall of the catheter, wherein a longitudinally-oriented blade is coupled to the helix and offset from a longitudinal axis of the catheter; fragmenting the occlusive material with the longitudinally-oriented blade as the occlusive material enters the lateral opening; and transporting the occlusive material from the lateral opening of the distal portion to a proximal portion of the catheter via the helix member.

[0010] According to another embodiment of the present disclosure, a method for removing occlusive material from a vessel, includes advancing a catheter assembly to the occlusive material within the vessel; rotating a helix member positioned at least partially within and rotatable with respect to a sidewall of the catheter assembly; receiving the occlusive material within a distal end opening of a distal portion of the catheter, wherein the distal end opening is coaxial with a cylinder opening defined by a cylinder wall of a cylinder, wherein the cylinder is connected to a distal terminal end of the helix member; fragmenting occlusive material with a plurality of cantilevered blade members that extend inwardly from the cylinder wall as the occlusive material enters the cylinder opening; and transporting the occlusive material from the cylinder opening to a proximal portion of the catheter assembly via the helix member.

[0011] Additional features and advantages of the technology disclosed in this disclosure will be set forth in the detailed description which follows, and in part will be readily apparent to those skilled in the art from the description or recognized by practicing the technology as described in this disclosure, including the detailed description which follows, the claims, as well as the appended drawings.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The embodiments set forth in the drawings are illustrative and exemplary in nature and not intended to limit the subject matter defined by the claims. The following detailed description of the illustrative embodiments can be understood when read in conjunction with the following drawings, where like structure is indicated with like reference numerals and in which:

[0013] FIG. **1** schematically depicts a catheter including a helical member, according to one or more embodiments shown and described herein;

[0014] FIG. **2**A schematically depicts the catheter of FIG. **1** with a lateral opening including one or more teeth, according to one or more embodiments shown and described herein;

[0015] FIG. **2**B schematically depicts the catheter of FIG. **1** with a lateral opening including one or more teeth, according to one or more embodiments shown and described herein;

[0016] FIG. **2**C schematically depicts the catheter of FIG. **1** with an alternative lateral opening and

a distal end opening, according to one or more embodiments shown and described herein;
[0017] FIG. **2**D schematically depicts the catheter of FIG. **1** with a maceration bar extending across the lateral opening, according to one or more embodiments shown and described herein;
[0018] FIG. **3**A schematically depicts the helical member of FIG. **1** in isolation, according to one or more embodiments shown and described herein;
[0019] FIG. **3**B depicts another embodiment of a helical member, according to one or more embodiments shown and described herein;
[0020] FIG. **4** schematically depicts use of a catheter to remove occlusive material from a body lumen, according to one or more embodiments described herein;
[0021] FIG. **5**A schematically depicts the internal components of a catheter including a cylinder, according to one or more embodiments shown and described herein;
[0022] FIG. **5**B schematically depicts the internal components of the catheter of FIG. **5**A, having a lateral opening distal to the cylinder, according to one or more embodiments shown and described herein;
[0023] FIG. **5**C schematically depicts an axial view of the cylinder positioned within the catheter of FIG. **5**A, according to one or more embodiments shown and described herein;
[0024] FIG. **5**D schematically depicts a perspective view of the cylinder of FIG. **5**A in isolation, according to one or more embodiments shown and described herein;
[0025] FIG. **6** schematically depicts use of the catheter of FIG. **5**A to remove occlusive material from a body lumen, according to one or more embodiments shown and described herein;
[0026] FIG. **7**A schematically depicts the internal components of a catheter according to one or more embodiments shown and described herein;
[0027] FIG. **7**B schematically depicts the internal components of a catheter according to one or more embodiments shown and described herein.

DETAILED DESCRIPTION

[0028] Embodiments of the present disclosure are generally directed to catheter assemblies with enhanced aspiration and clot fragmentation components that assist in reducing the size of occlusions during removal from a body lumen. In operation, catheter assemblies according to the present disclosure generate negative pressure, which aspirates the occlusion from the body lumen through the catheter. In embodiments, catheter assemblies according to the present disclosure also operate to increase fragmentation of the occlusion. While the occlusive material is being aspirated, the catheter assembly causes the occlusive material to contact the clot fragmentation components, causing the occlusion to break into smaller fragments. The smaller fragments of the occlusive material are able to be aspirated through the cannula lumen of the catheter more effectively, thereby preventing blockage or clogging of the catheter according to the present disclosure.
[0029] The enhanced aspiration and clot fragmentation components of the present disclosure are structured to facilitate smaller pieces of occlusive material moving through the catheter, thereby providing predictable and continuous performance. Moreover, reducing the size of fragments of extractable material reduces stress on the helix member or other components of the catheter that may be caused by trying to aspirate large particles and enables better transport of the occlusion particles through the catheter. These and other embodiments of catheters are disclosed in greater detail herein with reference to the appended figures.
[0030] Now referring to FIG. **1**, a catheter **100** is schematically depicted. In embodiments, the catheter **100** includes a cannula **102** having a sidewall **104**. The sidewall **104** may define a cannula lumen **106** extending through the cannula **102**, such as depicted in FIG. **5**. The cannula **102** may be any material suitable for advancing through a vessel, such as, but not limited to, polyurethanes, polyamides, fluoropolymers, polyolefins, PVC, polyimides, polyetheretherketone, or the like. In embodiments, the sidewall **104** of the cannula **102** may be reinforced by any means suitable to preserve the flexibility of the cannula **102** while increasing stability, such as but not limited to, multilayered plastics, braided wire mesh, or the like.

[0031] The catheter **100** extends axially between a distal end and a proximal end. The catheter **100** may be sized to be advanced axially through a body lumen, such as a blood vessel, or the like. In some embodiments, a guidewire **114** may be inserted into a blood vessel, and the catheter **100** may be inserted into the blood vessel over the guidewire **114**. For example, the guidewire **114** may extend axially through the cannula lumen **106**. In some embodiments, there may not be a guidewire **114**.

[0032] In embodiments, the catheter **100** includes distal portion **108** disposed at the distal end of cannula **102**. In embodiments, the distal portion **108** may generally include a body **113**. The body **113** may define a body lumen **117**, which may be coaxial with the cannula lumen **106**. The body **113**, in some embodiments, may define a lateral opening **112** into the body lumen **117**. In some embodiments, the lateral opening **112** may have a first section **112**A that extends generally axially and a second section **112**B that extends circumferentially, meeting at transition point **119** (e.g., to provide a generally L-shaped or J-shaped opening). In other embodiments, the lateral opening **112** can be generally triangular, with the width tapering towards the proximal end of the cannula **102**. In some embodiments, the lateral opening **112** may be generally rectangular. Other shapes are contemplated and possible (e.g., circular, oval, or any polygonal or non-polygonal, regular, or irregular shape). For example, in embodiments, there may be more than one lateral opening. For example, multiple lateral openings may be disposed approximately diametrically from one another on the body **113**. In embodiments, one or more portions of the lateral opening **112** extends along the body in the axial direction. In embodiments, one or more portions of the lateral opening **112** extend circumferentially about a longitudinal axis of the catheter **100**. In some embodiments, the lateral opening **112** may be one or more circular holes. In embodiments, the circular holes can be arranged in axial succession. In some embodiments, the circular holes can be placed such that the circumferences of the holes overlap (such as depicted in FIG. **2**C). The lateral opening **112** may be formed using conventional tools or techniques, such as drilling, milling, punching, erosion, water jet cutting, or the like. In some embodiments, the lateral opening **112** may be molded into the body during formation.

[0033] The distal portion **108** may be generally cylindrical and may taper toward the distal end. Tapering may improve advancement of the catheter **100** through a lumen. The distal portion **108** may also be made from different materials than cannula **102**. Distal portion **108** may be any material suitable for advancing through a vessel and supporting clot fragmentation components, such as, but not limited to, metals (stainless steel, titanium, etc.) plastics, or composite materials.

[0034] Still referring to FIG. **1**, the catheter **100** may also include a helix member **110** that is disposed in the cannula lumen **106** of catheter **100** and may extend into the body lumen **117** of the distal portion **108**. For example, the helix member **110** may extend past the lateral opening **112** such that occlusive material entering through the lateral opening is met and directed proximally through the catheter **100** via the helix member **110**. The helix member **110** may extend axially through catheter **100** so as to be substantially coaxial with the cannula lumen **106** and the body lumen **117**. The helix member **110** may be coupled at a proximal end to a rotational actuator (e.g., a motor) which causes the helix member **110** to rotate about the longitudinal axis of the catheter **100** relative to the cannula **102**. In some embodiments, the helix member **110** may be coupled to distal portion **108**, such that rotation of the helix member **110** rotates the distal portion **108**. For example, the helix member **110** may be welded, brazed, adhered, fastened, or otherwise fixedly attached to the distal portion. In some embodiments, the helix member **110** is not coupled to the distal portion **108**, and the distal portion is not rotatable relative to the cannula **102**. The helix member may generally be a wire or sheet wound into a helical shape (e.g., a helical spring shape). Accordingly, the helix member **110** may define a central lumen extending therethrough along the longitudinal axis of the catheter. Helix member **110** may be made from any suitable material, such as, but not limited to, stainless steel, titanium, or the like. In embodiments, the helix member **110** can be coated with any suitable biocompatible coatings, thereby reducing adhesion of blood to the helix member. Examples of suitable coatings may include, but are not limited to, hydrophilic coatings or pharmacologic coatings such as heparin, and the like.

[0035] Still referring to FIG. **1**, in embodiments, a longitudinally-oriented blade **116** may be attached to rotational helix member **110**. Referring to FIG. **3**A and **3**B, in embodiments, longitudinally-oriented blade **116** may be welded, brazed, adhered, fastened, or otherwise fixedly attached to the rotational helix member **110**. For example, in embodiments, longitudinally-oriented blade **116** may be attached to the rotational helix member **110** through one or more perforations **109** in rotational helix member **110**. The longitudinally-oriented blade **116** may be oriented substantially parallel to a longitudinal axis of the catheter **100**. A portion of the longitudinally-oriented blade **116** may be intermittently exposed at lateral opening **112**, depicted in FIG. **1**, during rotation of the rotational helix member **110**. Intermittent exposure may refer to exposure of at least a portion of the longitudinally-oriented blade **116** at the lateral opening **112** depending on the rotational state of the rotational helix member **110**. The longitudinally-oriented blade **116** may rotate with the helix member **110**, helping to increase fragmentation and maceration of the occlusion as the occlusion particles enter through the lateral opening **112**. The longitudinally-oriented blade **116** may be configured to cut tissue and/or occlusion particles. That is, in embodiments, the longitudinally-oriented blade **116** provides an additional cutting mechanism in addition to the rotational helix member **110** itself. In some embodiments, the longitudinally-oriented blade **116** may define a sharp cutting edge. In other embodiments, the longitudinally-oriented blade **116** may be substantially blunt-edged. In embodiments, the longitudinally-oriented blade **116** is formed of a metallic wire or ribbon. For example, longitudinally-oriented blade **116** may be any material suitable for attachment to helix member **110** and fragmentation of the occlusion, such as, but not limited to, stainless steel, titanium, and the like. In embodiments, a plurality of blades may attached to the helix and spaced approximately equidistant from each other.

[0036] Referring now to FIGS. **2**A-**2**C, the catheter **100** is depicted without the guidewire **114** and with the lateral opening **112** including one or more additional features or elements (e.g., corners, grooves, sharpened edges, bumps, protrusions, cavities, and the like) to further facilitate fragmentation of the occlusive material as it is drawn into the body lumen **117** through the lateral opening **112**. For example, an edge of the lateral opening **112** may be formed as a cutting edge **115**, thus ensuring improved fragmentation of the material aspirated by the catheter **100**. In embodiments, the cutting edge **115** may be aligned with the body **113** of the distal portion **108**. In embodiments, the cutting edges **115** may be disposed inwards or recessed relative to the body **113**. In embodiments, the cutting edges **115** may have a structured shape, e.g. zigzagged. In embodiments, the cutting edge **115** may protrude into lateral opening **112**. For example, extending from an edge of the lateral opening may be one or more teeth **120** defining at least a portion of the cutting edge **115**. As depicted in FIG. **2**A, the one or more teeth **120** may extend in a circumferential direction across the lateral opening **112**. In other embodiments, such as depicted in FIG. **2**B, the one or more teeth **120** may extend along an axial direction across the lateral opening **112**. In other embodiments, there may be a combination of the laterally and circumferentially extending teeth. Although in each embodiment, there is only depicted a single tooth, there may be a plurality of teeth, e.g., two or more teeth, three or more teeth, etc. Additionally, wherein the lateral opening forms a “J” or “L” shape, the one or more teeth may be at a transition point **119**, depicted in FIG. **1**, between the first section **112**A and the second section **112**B. The cutting edge **115** of the one or more teeth **120** may be curved or straight.

[0037] As noted above, in some embodiments, the lateral opening **112** may include one or more circular holes. In embodiments, the circular holes can be arranged in axial succession. In some embodiments, as depicted in FIG. **2**C, the circular holes can be placed such that the circumferences of the holes overlap. In embodiments, the overlap of the holes can be configured to form one or more cutting edges **115**. In some embodiments, the distal portion **108** may further include a distal end opening **118**. In embodiments, the distal end opening **118** may be sized and shaped to provide entry and/or egress into the body lumen **117** of the body **113**. In embodiments, distal end opening **118** may be coaxial with body lumen **117** and cannula lumen **106**. In embodiments, as occlusive material is drawn through lateral opening **112** and distal end opening **118** into the body lumen **117**, the occlusive material is fragmented by longitudinally-oriented blade **116** and/or the helix member **110**. In some embodiments, distal end opening **118** may allow for additional aspiration of occluding material.

[0038] In embodiments, such as depicted in FIG. **2**D, the catheter **100** may include a maceration bar **121**, extending across the lateral opening **112**. In embodiments, the maceration bar **121** may be welded, brazed, adhered, fastened, or otherwise fixedly attached to the body **113**. In embodiments, the maceration bar **121** may be molded into the body **113** during formation. In embodiments, the maceration bar **121** may extend circumferentially about a longitudinal axis of the catheter **100**. The maceration bar **121** may be configured to cut tissue and/or occlusion particles. That is, in embodiments, the maceration bar **121** facilitates fragmentation of the occlusive material as it is drawn into the body lumen **117** through the lateral opening **112**. Stated another way, as occlusive material is drawn through lateral opening **112**, the occlusive material is fragmented by the maceration bar **121**. The fragmented material may be then aspirated into the body lumen **117**, where the longitudinally-oriented blade **116** and/or the helix member **110** may facilitate further fragment the occlusive material. In some embodiments, the maceration bar **121** may define a sharp edge to assisting in cutting and/or fragmentation. In other embodiments, the maceration bar **121** may be substantially blunt-edged. The maceration bar **121** may be included in any of the embodiments described herein.

[0039] FIG. **3**A schematically depicts an embodiment of a distal portion of the rotational helix member **110** and the guidewire **114** in isolation from the cannula **102** and the distal portion **108**. As depicted and noted above, the longitudinally-oriented blade **116** may be attached to a distal portion of the rotational helix member **110** that is positioned in the distal portion **108** of the catheter **100**. In embodiments, the longitudinally-oriented blade **116** may be attached to one or more loops **111** of the rotational helix member (e.g., two or more loops, three or more loops etc.) such that the longitudinally oriented blade may extend across an entirety of the lateral opening in the axial direction. For example, in the depicted embodiment, the longitudinally-oriented blade **116** is coupled to three consecutive loops **111***a*, **111***b*, **111***c*. As noted above, in embodiments, the longitudinally-oriented blade **116** may be attached to the rotational helix member **110** through a perforation in rotational helix member **110**. Accordingly, each of the consecutive loops **111***a*, **111***b*, **111***c*, may each include a perforation **109***a*, **109***b*, **109***c*, or opening sized to receive the longitudinally-oriented blade **116**. The perforations may be positioned between an inner diameter and an outer diameter of the rotational helix member **110**, such that the longitudinally-oriented blade **116** is completed surround by material of the rotational helix member **110** at each perforation through which it extends.

[0040] As depicted in FIG. **3**B, in embodiments, longitudinally-oriented blade **116** may instead attach to a circumferential periphery of rotational helix member **110**. That is, the longitudinally-oriented blade **116** may connect to the outer perimeter of the helix member **110**. As in the embodiment above, the longitudinally-oriented blade **116** may be coupled to the helix member **110** at one or more locations. For example, the longitudinally-oriented blade **116** may be coupled to one or more loops **111** of the helix member **110** (e.g., two or more loops, three or more loops, etc.) such that the longitudinally-oriented blade may extend across an entirety of the lateral opening in the axial direction. In some embodiments, the longitudinally-oriented blade **116** may not be coupled to consecutive loops and may be coupled to non-consecutive loops, while simply extending past any intervening loops.

[0041] As noted above, the helix member **110** may be operatively coupled to a motor (not shown). Rotation of the helix may be controlled by user input. In embodiments, the user input may include a foot pedal, push-button, slider, toggle, switch, touch screen, or the like that can be actuated by a user. The rotation of the helix member **110** generates negative pressure in the catheter **100**. In embodiments, the helix member rotates from about 10,000 to about 200,000 rpm, though other rotational speeds are contemplated and possible based on the particular application. The negative pressure produced by the rotation of the helix member **110** is strong enough to aspirate fragments of occlusive material into the body lumen **117** through the lateral openings **112**. For example, the aspiration rate may be about 45 ml/min or more, about 75 ml/min or more, or about 130 ml/min or more, though other rates are contemplated and possible. The negative pressure generated by the rotation of rotational helix member **110** carries the fragmented material through the body lumen **117**, through the cannula lumen **106** from the distal end of the catheter **100** to the proximal end and into a collection receptacle (not shown). In embodiments, an external vacuum (not shown) may be added to increase the negative pressure inside the catheter **100**.

[0042] FIG. **4** schematically illustrates aspiration of occlusive material **750** by the catheter **100**. It is noted that while the embodiment of FIG. **1** is illustrated, any of the embodiments may be used. As shown in FIG. **4**, when the distal portion **108** encounters occlusive material **750** within a vessel **700** (e.g. a vein, an artery, etc.), the occlusive material **750** can be aspirated through the catheter **100** via negative pressure generated by rotation of the rotational helix member **110**. In embodiments, the catheter **100** can be positioned in a vessel **700** and advanced in an axial direction, substantially parallel to vessel wall **702**. As noted above, in embodiments, when the distal portion **108** encounters the occlusive material **750**, the rotation of the rotational helix member **110** generates negative pressure within the body lumen **117** and cannula lumen **106**. In some embodiments, as depicted, the occlusive material **750** may be aspirated into the body lumen **117** through the lateral opening **112** (or an end opening as described above). As occlusive material **750** is drawn into the body lumen **117** through the lateral opening **112**, the longitudinally-oriented blade **116** assists in fragmenting the occlusive material **750** into smaller particle sizes. The fragmented material is then transported away from lateral opening **112** in a proximal direction through catheter **100** via helix member **110**.

[0043] Referring now to FIGS. **5**A-D, another embodiment of a catheter **200** is schematically depicted, showing internal components. The catheter **200** is similar to catheter **100** as described above. In particular, the catheter **200** includes a cannula **202** having a sidewall **204**. The sidewall **104** may define a cannula lumen **206** extending through the cannula **202**. The cannula **202** is substantially the same as the cannula **102**, as described above.

[0044] In embodiments, the catheter **200** includes a distal portion **208** disposed at the distal end of the cannula **202**. In embodiments, the distal portion **208** may generally include a body **213**. The body **213** may define a body lumen **217**, which may be coaxial with the cannula lumen **206**. The distal portion **208** is substantially similar to the distal portion **108**, described above. For example, the distal portion **208** may be generally cylindrical. Additionally, though not depicted, the distal portion **208** may taper toward the distal end. Tapering may improve advancement of the catheter **200** through a vessel. The distal portion **208** may also be made from different materials than the cannula **202**. In some embodiments, the distal portion **208** may further include a distal end opening **218**. In embodiments, the distal end opening **218** may be sized and shaped to provide entry and/or egress into the body lumen **217** of the body **213**. In embodiments, the distal end opening **218** may be coaxial with the body lumen **217** and the cannula lumen **206**. In some embodiments, the distal end opening **218** may allow for aspiration of occluding material. It is noted that while the present embodiment, only depicts a distal end opening **218**, a lateral opening, such as in the embodiments described above, may be included without departing from the scope of the present disclosure.

[0045] In the present embodiment, the distal portion **208** may include a cylinder **220**, as further illustrated in FIGS. **5**C and **5**D, positioned within the body **213**. In embodiments, the cylinder **220** may be a hollow cylinder, with a cylinder wall **222** defining a cylinder opening **219**. In embodiments, the cylinder opening **219** may be coaxial with the body lumen **217** and the cannula lumen **206**. In embodiments, cylinder opening **219** may be coaxial with distal end opening **218**. In some embodiments, such as depicted in FIG. 5B, the body **213** of the distal portion **208** may in place of or in addition to the distal end opening **218** may define a lateral opening **212** into the body lumen **217**. As noted above, the lateral opening **212** is substantially similar to the lateral opening **112**, described in detail above. In some embodiments, the lateral opening **212** may allow for additional aspiration of occluding material. In such embodiments, the cylinder **220** may be positioned proximally to the lateral opening **212**.

[0046] The cylinder **220** may include one or more features to aid in macerating occlusive material as it enters the catheter **200**. For example, and with reference to FIG. 5C and 5D, the cylinder **220** may include a plurality of cantilevered blade members **500** that extend inwardly from the cylinder wall **222** toward a longitudinal axis (or the rotational axis) of the catheter **200**. In embodiments, the cylinder **220** may include a single cantilevered blade member **500**. In embodiments, the blade members **500** may be triangularly shaped, though other shapes are contemplated and possible (e.g., rectangular, square, leaf, etc.). In some embodiments, the blade members **500** may be staggered longitudinally along the cylinder wall **122** so that at least one blade member is positioned proximally to another blade member. In embodiments, the blade members **500** may be randomly staggered along cylinder wall **222** or the blade members **500** may be staggered at regular intervals along the cylinder wall **222**. In embodiments, the blade members **500** may be angled in the proximal or distal directions. Cantilevered blade members **500** may fragment the occlusive material as it is aspirated into the body lumen **217**. It is noted that the cylinder **220** and cantilevered blade members **500** may be included in any of the embodiments described herein. It is further contemplated that though the plurality of cantilevered blade members **500** are illustrated as extending inwardly from the cylinder wall **222**, in some embodiments, the plurality of cantilevered blade members **500** may extend outwardly from the cylinder wall **222**.

[0047] Referring again to FIG. 5A, in embodiments, the catheter **200** may also include a helix member **210** that is disposed in the cannula lumen **206** and may extend into the body lumen **217** of the distal portion **208**. The helix member **210** is substantially the same as the helix member **110** described in detail above. The helix member **210** may extend axially through catheter **200** so as to be substantially coaxial with the cannula lumen **206** and the body lumen **217**. The helix member **210** may be coupled at a proximal end to a rotational actuator (e.g., a motor) which causes the helix member **210** to rotate about the longitudinal axis of the catheter **200** relative to the cannula **202**.

[0048] In embodiments, cylinder **220** may be coupled to a distal terminal end **211** of rotational helix member **210** via any conventional joining technique (e.g., loop connectors, brazing, welding, adhesives, or the like). Accordingly, as the rotational helix member **210** rotates, the cylinder **220** would also rotate, enhancing fragmentation of the occlusive material as it enters the body lumen **217** through distal end opening **218**. In some embodiments, it is contemplated that the cylinder **220** may be coupled to the body **213** (e.g., via, brazing, welding, or the like), such that the cylinder **220** rotates with the body **220**. In either case, as the cylinder **220** rotates, particles going through the cylinder may be macerated and particularized via the plurality of cantilevered blade members **500**.

[0049] FIG. **6** schematically illustrates aspiration of occlusive material **750** by the catheter **200**. It is noted that while the embodiment of FIG. 5A is illustrated; any of the embodiments may be used. As shown in FIG. **6**, the catheter **200** can be positioned in a vessel (e.g. a vein, an artery, etc.) **700** and advanced in an axial direction, substantially parallel to a vessel wall **702** until the distal portion **208** encounters occlusive material **750**. As noted above, in embodiments, when the distal portion **208** encounters occlusive material **750**, the rotation of the rotational helix member **210** generates negative pressure within the body lumen **217** of the distal portion **208**. In embodiments, the occlusive material **750** may be aspirated into the body lumen **217** of the distal portion **208** through distal end opening **218** (or the lateral side opening **212**, where include). As occlusive material **750** is drawn into the body lumen **217**, the occlusive material **750** moves proximally toward the cylinder **220** positioned in the body **213** of the distal portion **208**. The plurality of cantilevered blade members **500** extending inwardly from cylinder wall **222** of cylinder **220** assists in fragmenting the occlusive material **750** into smaller particle sizes. The fragmented material is then transported away from the cylinder **220** in a proximal direction through the catheter **200** via helix member **210**.

[0050] Referring now to FIGS. **7**A and **7**B, another embodiment of a catheter **300** is schematically depicted showing internal components. The catheter **300** is similar to catheters **100** and **200** as described above. In particular, the catheter **300** includes a cannula **302** that is substantially the same as the cannula **102** and the cannula **202**, as described in detail above.

[0051] In embodiments, the catheter **300** includes a distal portion **308** disposed at the distal end of a cannula. In embodiments, the distal portion **308** may generally include a body **313**. The body **313** may define a body lumen **317**. The distal portion **308** is substantially similar to the distal portion **108** and the distal portion **208** as described in detail above. The distal portion **308** may be generally cylindrical. As in embodiments above, though not shown, the distal portion **308** may taper toward the distal end. In embodiments, the catheter **300** may also include a helix member **310** that is disposed in the catheter **300** and may extend into the body lumen **317** of the distal portion **308**. The helix member **310** is substantially the same as the helix member **110** and the helix member **210** described in detail above. The helix member **310** may extend axially through the catheter **300** so as to be substantially coaxial with the body lumen **317**. The helix member **310** may be coupled at a proximal end to a rotational actuator (e.g., a motor) which causes the helix member **310** to rotate about the longitudinal axis of the catheter **300**. In some embodiments, the body **313** of the distal portion **308** may define a lateral opening **312** into the body lumen **317**. The lateral opening **312** is substantially similar to the lateral opening **112**, described in detail above. In some embodiments, the lateral opening **312** may allow for aspiration of the occlusive material as it is drawn into the body lumen **317** through the lateral opening **312**.

[0052] In embodiments, the catheter **300** may further include an irrigation assembly **600** configured to dispense or pump fluid through a plurality of fluid delivery ports **602** into the body lumen **317**. In embodiments, the fluid is pumped at a rate of about 60 cc/min, though other rates are contemplated and possible. Fluid delivery ports **602** are configured to deliver pressurized fluid into the body lumen **317**. In embodiments, the fluid can be any suitable sterile liquid. Examples of suitable liquids may include, but are not limited to, saline, water, thrombolytic agents, and the like. In embodiments, the fluid is pressurized at about 10,000 psi, though other rates are contemplated and possible. Negative pressure generated from the rotation of the helix member **310** aspirates the fluid and fragmented occlusive material into a proximal portion of catheter **100** and to a collection receptacle (not shown).

[0053] In embodiments, as depicted in FIG. **7**A the irrigation assembly **600** is disposed in the body lumen **317**, so as to be positioned coaxially within the helix member **310**. In embodiments, the irrigation assembly **600** may be coupled to the distal portion **308** (e.g., via, brazing, welding, or the like). The irrigation assembly **600** may extend axially through the catheter **300** along the longitudinal axis of the catheter **300**. In embodiments, as an occlusion is aspirated through the lateral opening **312**, the fluid delivery ports **602** deliver fluid into the body lumen **317**, causing increased fragmentation of the occlusion. In embodiments, the fluid delivery ports **602** may be disposed to deliver fluid at a desired angle. For example, fluid delivery ports **602** may deliver fluid orthogonally or non-orthogonally to the irrigation assembly. In embodiments, the fluid may be delivered through the fluid delivery ports **602** continuously. In embodiments, the fluid may be delivered through the fluid delivery ports **602** in pulses. In embodiments, the catheter **300** may include a longitudinally-oriented blade **316**. The longitudinally oriented-blade **316** is substantially similar to the longitudinally-oriented blade **116** described in detail above. The longitudinally-oriented blade is coupled to rotational helix member **310** as described above. As an occlusion is aspirated through the lateral opening **312**, the occlusive material encounters longitudinally-oriented blade **316**, causing increased fragmentation of the clot. Then, the fluid delivery ports **602** may deliver fluid into the body lumen **317**, causing further increased fragmentation of the occlusion.

Negative pressure generated from the rotation of the helix member **310** aspirates the fluid and fragmented occlusive material into a proximal portion of catheter **300**.

[0054] In some embodiments, the irrigation assembly **600** may be coupled to an external circumferential periphery of distal portion **308** (e.g., via adhesives, welding, brazing, or the like), such as illustrated in FIG. **7**B. In this embodiment, the fluid delivery ports may extend through the distal portion **308** to inject fluid toward the longitudinal axis of the catheter **300**. In some embodiments, the longitudinally-oriented blade, such as depicted in FIG. **7**A may be included. However, in some embodiments, distal portion **308** includes a cylinder **320**. The cylinder **320** is substantially similar to the cylinder **220**, described in detail above. The cylinder **320** may include one or more features, such as the plurality of blade members described above, to aid in macerating occlusive material as it enters the catheter **300**. As an occlusion is aspirated into catheter **300**, the occlusive material encounters cylinder **320**, causing increased fragmentation of the clot. Then, the fluid delivery ports **602** may deliver fluid into the body lumen **317**, causing further increased fragmentation of the occlusion. Negative pressure generated from the rotation of the helix member **310** aspirates the fluid and fragmented occlusive material into a proximal portion of catheter **100**. The irrigation assembly **600** may be included in any of the embodiments described herein.

[0055] Embodiments can be further described with reference to the following numerical clauses:

[0056] 1. A catheter comprising: a cannula comprising a sidewall defining a cannula lumen; a distal portion, disposed at a distal end of the cannula, the distal portion comprising a body, said body defining a body lumen and said body further defining a lateral opening extending through the body and into the body lumen; a helix member positioned at least partially within (the body and the cannula) and rotatable with respect to the sidewall; and a longitudinally-oriented blade, attached to said helix member, wherein at least a portion of the blade is intermittently exposed at the lateral opening. The longitudinally-oriented blade may be configured to cut tissue and/or occlusion particles. [0057] 2. The catheter of the preceding clause, wherein the longitudinally-oriented blade is coupled to three or more loops of the helix member. [0058] 3. The catheter of any preceding clause, wherein the body comprises one or more cutting edges disposed at the lateral opening. [0059] 4. The catheter of any preceding clause, wherein the cutting edge is configured to extend across a portion of the lateral opening. [0060] 5. The catheter of any preceding clause, wherein the body defines a distal end opening. [0061] 6. The catheter of any preceding clause, further comprising an irrigation assembly, the irrigation assembly comprising a plurality of fluid delivery ports configured to dispense fluid into the body lumen and/or the cannula lumen. [0062] 7. The catheter of the preceding clause, wherein the fluid comprises saline or thrombolytic agents [0063] 8. The catheter of any preceding clauses 6 or 7, wherein the irrigation assembly is coupled to a circumferential periphery of the distal portion. [0064] 9. The catheter of any of preceding clauses 6-8, wherein the irrigation assembly is disposed in the cannula lumen. The catheter assembly of clauses 1 to 9 may also have features of the catheter assembly of clauses 10 to 15. [0065] 10. A catheter assembly comprising, a cannula comprising a sidewall defining a cannula lumen; a distal portion, disposed at a distal end of the cannula, the distal portion comprising: a body, said body defining a body lumen, and a cylinder comprising a cylinder wall configured to define a cylinder opening; a helix member rotatably disposed in the cannula lumen and the body lumen, the helix member having a distal terminal end and a rotational axis; wherein said cylinder is coupled to the distal terminal end of the helix member and said cylinder opening extends longitudinally along the rotational axis; and a plurality of cantilevered blade members that extend inwardly from the cylinder wall toward the rotational axis. [0066] 11. The catheter assembly of the preceding clauses 10, wherein the body defines a lateral opening in the distal portion. [0067] 12. The catheter assembly of the preceding clause 11, wherein the body comprises one or more cutting edges disposed at the lateral opening. [0068] 13. The catheter assembly of any preceding clauses 10 to 12, further comprising an irrigation assembly, said irrigation assembly comprising a plurality of fluid delivery ports configured to dispense fluid into the body lumen. [0069] 14. The catheter assembly of the preceding clause 13, wherein the irrigation assembly is coupled to a circumferential periphery of the distal portion. [0070] 15. The catheter assembly of any preceding clauses 12-14, wherein the fluid comprises saline and/or thrombolytic agents. The catheter assembly of clauses 10 to 15 may also have features of the catheter of clauses 1 to 10. [0071] 16. A method for removing occlusive material from a vessel, the method comprising: advancing a catheter to the occlusive material within the vessel; receiving the occlusive material within a lateral opening of a distal portion of the catheter; rotating a helix member positioned at least partially within the cannula lumen and the body lumen and rotatable with respect to a sidewall of the catheter, wherein a longitudinally-oriented blade is coupled to the helix and offset from a longitudinal axis of the catheter; fragmenting the occlusive material with the longitudinally-oriented blade as the occlusive material enters the lateral opening; and transporting the occlusive material from the lateral opening of the distal portion to a proximal portion of the catheter via the helix member. [0072] 17. The method of any preceding clause wherein the distal portion comprises one or more cutting edges disposed at the lateral opening. [0073] 18. The method of any preceding clause, wherein at least a portion of the longitudinally-oriented blade is intermittently exposed at the lateral opening. [0074] 19. The method of any preceding clause, further comprising dispensing fluid into a body lumen of the distal portion using an irrigation assembly, wherein said irrigation assembly comprises a plurality of fluid delivery ports. [0075] 20. A method for removing occlusive material from a vessel, the method comprising: advancing a catheter assembly to the occlusive material within the vessel; rotating a helix member positioned at least partially within and rotatable with respect to a sidewall of the catheter assembly; receiving the occlusive material within a distal end opening of a distal portion of the catheter, wherein the distal end opening is coaxial with a cylinder opening defined by a cylinder wall of a cylinder, wherein the cylinder is connected to a distal terminal end of the helix member; fragmenting occlusive material with a plurality of cantilevered blade members that extend inwardly from the cylinder wall as the occlusive material enters the cylinder opening; and transporting the occlusive material from the cylinder opening to a proximal portion of the catheter assembly via the helix member. [0076] 21. The method of any preceding clause, wherein the distal portion defines a lateral opening, positioned distal to the cylinder.

[0077] It should now be understood that embodiments of the present disclosure pertain to catheters for use in removing an occlusion in a body lumen, which include a cannula having a sidewall that defines a lumen, and a distal portion. The distal portion includes openings to allow for occlusion aspiration. The catheter also includes a helix member that is rotatably disposed in the cannula lumen. The distal portion openings may be lateral or distal. Lateral openings may extend through the sidewall to the cannula lumen. The distal end portion of the helix member may include a longitudinally orientated blade attached to a circumferential periphery of the helix member. The blade may be intermittently exposed at the lateral opening.

[0078] It is noted that the terms “substantially” and “about” may be utilized herein to represent the inherent degree of uncertainty that may be attributed to any quantitative comparison, value, measurement, or other representation. These terms are also utilized herein to represent the degree by which a quantitative representation may vary from a stated reference without resulting in a change in the basic function of the subject matter at issue.

[0079] While particular embodiments have been illustrated and described herein, it should be understood that various other changes and modifications may be made without departing from the spirit and scope of the claimed subject matter. Moreover, although various aspects of the claimed subject matter have been described herein, such aspects need not be utilized in combination. It is therefore intended that the appended claims cover all such changes and modifications that are within the scope of the claimed subject matter.

Claims

1. A catheter comprising: a cannula comprising a sidewall defining a cannula lumen; a distal portion, disposed at a distal end of the cannula, the distal portion comprising a body, said body defining a body lumen and said body further defining a lateral opening extending through the body and into the body lumen; a helix member positioned at least partially within the cannula lumen and the body lumen and rotatable with respect to the sidewall; and a longitudinally-oriented blade, attached to said helix member, wherein at least a portion of the longitudinally-oriented blade is intermittently exposed at the lateral opening.
2. The catheter of claim 1, wherein the longitudinally-oriented blade is coupled to three or more loops of the helix member.
3. The catheter of claim 1, wherein the body comprises one or more cutting edges disposed at the lateral opening.
4. The catheter of claim 3, wherein the cutting edge is configured to extend across a portion of the lateral opening.
5. The catheter of claim 1, wherein the body defines a distal end opening.
6. The catheter of claim 1, further comprising an irrigation assembly, the irrigation assembly comprising a plurality of fluid delivery ports configured to dispense fluid into the body lumen.
7. The catheter of claim 6, wherein the fluid comprises saline or thrombolytic agents.
8. The catheter of claim 6, wherein the irrigation assembly is coupled to a circumferential periphery of the distal portion.
9. The catheter of claim 6, wherein the irrigation assembly is disposed in the cannula lumen.
10. A catheter assembly, comprising: a cannula comprising a sidewall defining a cannula lumen; a distal portion, disposed at a distal end of the cannula, the distal portion comprising: a body, said body defining a body lumen; and a cylinder comprising a cylinder wall configured to define a cylinder opening; a helix member rotatably disposed in the cannula lumen and the body lumen, the helix member having a distal terminal end and a rotational axis; wherein said cylinder is coupled to the distal terminal end of the helix member and said cylinder opening extends longitudinally along the rotational axis; and a plurality of cantilevered blade members that extend inwardly from the cylinder wall toward the rotational axis.
11. The catheter assembly of claim 10, wherein the body defines a lateral opening in the distal portion.
12. The catheter assembly of claim 11, wherein the body comprises one or more cutting edges disposed at the lateral opening.
13. The catheter assembly of claim 10, further comprising an irrigation assembly, said irrigation assembly comprising a plurality of fluid delivery ports configured to dispense fluid into the body lumen.
14. The catheter assembly of claim 13, wherein the irrigation assembly wherein the irrigation assembly is coupled to a circumferential periphery of the distal portion.
15. The catheter assembly of claim 13, wherein the fluid comprises saline or thrombolytic agents.
16. A method for removing occlusive material from a vessel, the method comprising: advancing a catheter to the occlusive material within the vessel; receiving the occlusive material within a lateral opening of a distal portion of the catheter; rotating a helix member positioned at least partially within the cannula lumen and the body lumen and rotatable with respect to a sidewall of the catheter, wherein a longitudinally-oriented blade is coupled to the helix member and offset from a longitudinal axis of the catheter; fragmenting the occlusive material with the longitudinally-oriented blade as the occlusive material enters the lateral opening; and transporting the occlusive material from the lateral opening of the distal portion to a proximal portion of the catheter via the helix member.
17. The method of claim 16, wherein the distal portion comprises one or more cutting edges disposed at the lateral opening.

18. The method of claim 16, wherein at least a portion of the longitudinally-oriented blade is intermittently exposed at the lateral opening.

19. The method of claim 16, further comprising dispensing fluid into a body lumen of the distal portion using an irrigation assembly, wherein said irrigation assembly comprises a plurality of fluid delivery ports.

20. A method for removing occlusive material from a vessel, the method comprising: advancing a catheter assembly to the occlusive material within the vessel; rotating a helix member positioned at least partially within and rotatable with respect to a sidewall of the catheter assembly; receiving the occlusive material within a distal end opening of a distal portion of the catheter, wherein the distal end opening is coaxial with a cylinder opening defined by a cylinder wall of a cylinder, wherein the cylinder is connected to a distal terminal end of the helix member; fragmenting occlusive material with a plurality of cantilevered blade members that extend inwardly from the cylinder wall as the occlusive material enters the cylinder opening; and transporting the occlusive material from the cylinder opening to a proximal portion of the catheter assembly via the helix member.

21. The method of claim 20, wherein the distal portion defines a lateral opening, positioned distal to the cylinder.