(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
30 August 2018 (30.08.2018)

WIPO | PCT

(10) International Publication Number
WO 2018/156771 A1

(51) International Patent Classification:
A61B 17/22 (2006.01) *A61B 17/3205* (2006.01)
A61B 17/32 (2006.01) *A61B 17/3207* (2006.01)

(21) International Application Number:
PCT/US2018/019238

(22) International Filing Date:
22 February 2018 (22.02.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
15/440,402 23 February 2017 (23.02.2017) US

(71) Applicant: **CARDIO FLOW, INC.** [US/US]; P.O. Box 120018, St. Paul, Minnesota 55112 (US).

(72) Inventors: **BENJAMIN, Albert Selden**; 2674 Elm St, St. Paul, Minnesota 55109 (US). **SVENDSEN, Cassandra Ann Piippo**; 11892 Isanti St NE, Blaine, Minnesota 55449 (US). **PLOWE, Charles Anthony**; 12320 Lever Street NE, Blaine, Minnesota 55449 (US). **ROBINSON, Paul Joseph**; 888 East Avenue, Mahtomedi, Minnesota 55115 (US).

(74) Agent: **KIM, Grace J.** et al.; Fish & Richardson P.C., P.O. Box 1022, Minneapolis, Minnesota 55440 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(54) Title: ATHERECTOMY DEVICES AND METHODS

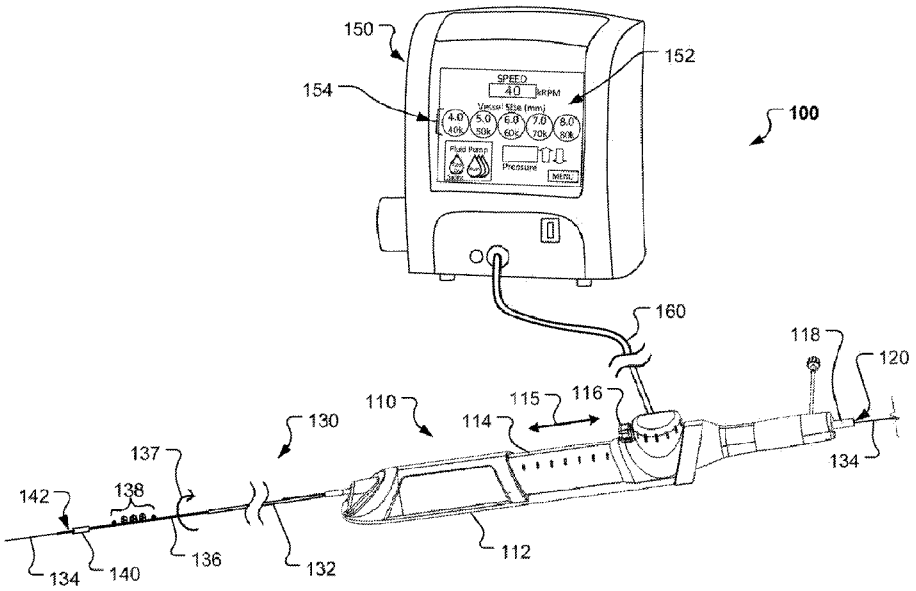


FIG. 1

(57) Abstract: Rotational atherectomy devices and systems can remove or reduce stenotic lesions in blood vessels by rotating one or more abrasive elements within the vessel. The abrasive elements can be attached to a distal portion of an elongate flexible drive shaft that extends from a handle assembly that includes a driver for rotating the drive shaft. In particular implementations, individual abrasive elements are attached to the drive shaft at differing radial angles in comparison to each other (e.g., configured in a helical array). The centers of mass of the abrasive elements can define a path that fully or partially spirals around the drive shaft. In some embodiments, a distal stability element with a center of mass aligned with the longitudinal axis is fixedly mounted to the drive shaft.

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[Continued on next page]

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *with international search report (Art. 21(3))*

Atherectomy Devices and Methods

TECHNICAL FIELD

This document relates to rotational atherectomy devices and systems for removing or reducing stenotic lesions in blood vessels, for example, by rotating an abrasive element within the vessel to partially or completely remove the stenotic lesion material.

BACKGROUND

Atherosclerosis, the clogging of arteries with plaque, is often a result of coronary heart disease or vascular problems in other regions of the body. Plaque is made up of fat, cholesterol, calcium, and other substances found in the blood. Over time, the plaque hardens and narrows the arteries. This limits the flow of oxygen-rich blood to organs and other parts of the body.

Blood flow through the peripheral arteries (e.g., carotid, iliac, femoral, renal etc.), can be similarly affected by the development of atherosclerotic blockages. Peripheral artery disease (PAD) can be serious because without adequate blood flow, the kidneys, legs, arms, and feet may suffer irreversible damage. Left untreated, the tissue can die or harbor infection.

One method of removing or reducing such blockages in blood vessels is known as rotational atherectomy. In some implementations, a drive shaft carrying an abrasive burr or other abrasive surface (e.g., formed from diamond grit or diamond particles) rotates at a high speed within the vessel, and the clinician operator slowly advances the atherectomy device distally so that the abrasive burr scrapes against the occluding lesion and disintegrates it, reducing the occlusion and improving the blood flow through the vessel.

SUMMARY

Some embodiments of rotational atherectomy systems described herein can remove or reduce stenotic lesions in blood vessels by rotating one or more abrasive elements to abrade and breakdown the lesion. Some embodiments can abrade stenotic lesions in blood vessels by rotating the abrasive element(s) according to a stable and predictable orbiting profile. In some embodiments, the abrasive element(s) are attached to a distal portion of an elongate flexible drive shaft that extends from a

handle assembly. In particular embodiments, a rotational atherectomy device comprises an elongate flexible drive shaft with multiple eccentric abrasive elements that are attached to the drive shaft, and one or more weighted stability elements are attached to the drive shaft such that at least one stability element is distal of the abrasive element. Optionally, the stability elements have a center of mass that is axially aligned with a central longitudinal axis of the drive shaft while the eccentric abrasive element(s) has a center of mass that is axially offset from central longitudinal axis of the drive shaft.

In some embodiments, multiple abrasive elements are coupled to the drive shaft and are offset from each other around the drive shaft such that the centers of the abrasive elements are disposed at differing radial angles from the drive shaft in relation to each other. For example, in some embodiments a path defined by the centers of mass of the abrasive elements defines a spiral around a length of the central longitudinal axis of the drive shaft. A flexible polymer coating may surround at least a portion of the drive shaft, including the stability element(s) in some embodiments. Also, in some optional embodiments, a distal extension portion of the drive shaft may extend distally beyond the distal-most stability element.

In one aspect, this disclosure is directed to a rotational atherectomy device for removing stenotic lesion material from a blood vessel of a patient. In some embodiments, the rotational atherectomy device includes: (i) an elongate flexible drive shaft comprising a torque-transmitting coil and defining a longitudinal axis, the drive shaft being configured to rotate about the longitudinal axis; (ii) first and second abrasive elements attached to a distal end portion of the drive shaft and each having a center of mass offset from the longitudinal axis, the center of mass of the first abrasive element being offset from the longitudinal axis at a first radial angle, the center of mass of the second abrasive element being offset from the longitudinal axis at a second radial angle that differs from the first radial angle; and (iii) a distal stability element fixedly mounted to the drive shaft and having a center of mass aligned with the longitudinal axis, the distal stability element being distally spaced apart from the first and second abrasive elements.

Such a rotational atherectomy device may optionally include one or more of the following features. The device may also include a third abrasive element attached to the distal end portion of the drive shaft. The center of mass of the third abrasive

element may be offset from the longitudinal axis along a third radial angle that differs from the first radial angle and the second radial angle. The second radial angle may differ from the first radial angle by at least 15 degrees. The third radial angle may differ from the first radial angle and the second radial angle by at least 15 degrees. The distal stability element may comprise a metal cylinder surrounding the torque-transmitting coil of the drive shaft and having a maximum diameter smaller than the first and second abrasive elements, and wherein the distal stability element has an abrasive outer surface. The device may also include an array of abrasive elements including the first and second abrasive elements and additional abrasive elements attached to the distal end portion of the drive shaft. In some embodiments, a proximal-most one of the array of abrasive elements and a distal-most one of the array of abrasives element are each smaller than intermediate ones of the array of abrasive elements. A path defined by the centers of mass of the array of abrasive elements may define at least a portion of a helical path around the longitudinal axis. The device may also include a flexible polymer coating along the drive shaft such that the coating surrounds an outer diameter of at least a portion of drive shaft.

In some embodiments, the rotational atherectomy device also includes: (iv) an actuator handle assembly configured to drive rotation of the drive shaft about the longitudinal axis, the actuator handle assembly comprising a carriage assembly that is movable in relation to other portions of the actuator handle assembly to translate the drive shaft along the longitudinal axis; and (v) a sheath extending from the actuator handle assembly, the drive shaft slidably disposed within a lumen defined by the sheath.

In another aspect, this disclosure is directed to a rotational atherectomy device for removing stenotic lesion material from a blood vessel of a patient. In some embodiments, the rotational atherectomy device includes: (a) an elongate flexible drive shaft comprising a torque-transmitting coil and defining a longitudinal axis, the drive shaft being configured to rotate about the longitudinal axis; (b) a helical array of abrasive elements attached to a distal end portion of the drive shaft, each of the abrasive elements having a center of mass that is offset from the longitudinal axis, the centers of mass of the abrasive elements being noncollinear; and (c) a distal stability element affixed to the drive shaft and having a center of mass aligned with the

longitudinal axis, the distal stability element distally spaced apart from the plurality of abrasive elements.

Such a rotational atherectomy device may optionally include one or more of the following features. The device may also include a flexible polymer coating along the drive shaft such that the coating surrounds an outer diameter of at least a portion of drive shaft. The drive shaft may include a distal-most extension portion that extends distally of the distal stability element for a distal extension distance. The drive shaft may have a central lumen configured to receive a guidewire extending along the longitudinal axis. The distal stability element may comprise a metal cylinder surrounding the torque-transmitting coil, and wherein the metal cylinder has an abrasive outer surface. The plurality of abrasive elements may be spaced apart from each other by at least 50% of an outer diameter of a largest one of the abrasive elements. A proximal-most one of the abrasive elements and a distal-most one of the abrasives element may each be smaller than intermediate ones of the abrasive elements. A path defined by the centers of mass of sequential abrasive elements of plurality the abrasive elements may spiral around the longitudinal axis. The plurality of abrasive elements may include at least five abrasive elements.

In another aspect, this disclosure is directed to a system for performing rotational atherectomy to remove stenotic lesion material from a blood vessel of a patient. In some embodiments, the system includes: 1) an elongate flexible drive shaft comprising a torque-transmitting coil and defining a longitudinal axis, the drive shaft being configured to rotate about the longitudinal axis; 2) one or more abrasive elements attached to a distal end portion of the drive shaft, each of the abrasive elements having a center of mass that is offset from the longitudinal axis; 3) a distal stability element fixed to the drive shaft and having a center of mass aligned with the longitudinal axis, the distal stability element distally spaced apart from the plurality of abrasive elements; 4) an actuator handle assembly configured to drive rotation of the drive shaft about the longitudinal axis, the actuator handle assembly comprising a carriage assembly that is movable in relation to other portions of the actuator handle assembly to translate the drive shaft along the longitudinal axis; 6) a sheath extending from the actuator handle assembly, the drive shaft slidably disposed within a lumen defined by the sheath; and 7) a controller operably coupleable to the actuator handle assembly, the controller configured to provide output to the actuator handle assembly

that causes the actuator handle assembly to drive the rotation of the drive shaft about the longitudinal axis. The controller can include a user interface with a plurality of selectable inputs corresponding to a plurality of vessel sizes. The controller may be configured to provide a respective output to the actuator handle assembly that differs for each of the vessel sizes.

Such a system for performing rotational atherectomy to remove stenotic lesion material from a blood vessel of a patient may optionally include one or more of the following features. A center of mass of a first one of the abrasive elements may be transversely offset from the longitudinal axis along a first angle. A center of mass of a second one of the abrasive elements may be transversely offset from the longitudinal axis along a second angle that differs from the first angle by at least 15 degrees. The system may also include a flexible polymer coating along the drive shaft such that the coating surrounds an outer diameter of at least a portion of drive shaft. In some embodiments, the distal stability element has an abrasive outer surface.

In another aspect, this disclosure is directed to a method for performing rotational atherectomy to remove stenotic lesion material from a blood vessel of a patient. In some embodiments, the method includes: delivering a rotational atherectomy device into the blood vessel and rotating the drive shaft about the longitudinal axis such that the abrasive elements orbit around the longitudinal axis. In some embodiments, the rotational atherectomy device includes: (a) an elongate flexible drive shaft comprising a torque-transmitting coil and defining a longitudinal axis, the drive shaft being configured to rotate about the longitudinal axis; (b) a helical array of abrasive elements attached to a distal end portion of the drive shaft, each of the abrasive elements having a center of mass that is offset from the longitudinal axis, the centers of mass of the abrasive elements arranged along a path that spirals around the longitudinal axis; and (c) a distal stability element affixed to the drive shaft and having a center of mass aligned with the longitudinal axis, the distal stability element distally spaced apart from the plurality of abrasive elements.

Some of the embodiments described herein may provide one or more of the following advantages. First, some embodiments of the rotational atherectomy system are configured to advance the drive shaft and the handle assembly over a guidewire, and to drive the rotation of the drive shaft while the guidewire remains within the drive shaft. Accordingly, in some embodiments the handle assemblies provided

herein include features that allow the drive shaft to be positioned over a guidewire. Thereafter, the guidewire can be detained in relation to the handle so that the guidewire will not rotate while the drive shaft is being rotated.

Second, some embodiments of the rotational atherectomy devices and systems provided herein include a handle assembly with a carriage that is manually translatable during rotation of the drive shaft, resulting in longitudinal translation of the rotating abrasive element in relation to a target lesion. In particular embodiments, a valve (or other connector) is mounted on the carriage and operable to control a supply of compressed gas (or other power source) to a carriage-mounted turbine member. The turbine member rotationally drives the drive shaft of the atherectomy device. Hence, in some embodiments the valve for actuating the rotational operation of the drive shaft is conveniently located on the translatable carriage of the handle assembly. Alternatively, in some embodiments an electric motor is used to drive rotations of the drive shaft.

Third, some embodiments of the rotational atherectomy devices and systems operate with a stable and predictable rotary motion profile for enhanced atherectomy performance. That is, when the device is being rotated in operation, the eccentric abrasive element(s) follows a predefined, consistent orbital path (offset from an axis of rotation of the device) while the stability element(s) and other portions of the device remain on or near to the axis of rotation for the drive shaft in a stable manner. This predictable orbital motion profile can be attained by the use of design features including, but not limited to, stability element(s) that have centers of mass that are coaxial with the longitudinal axis of the drive shaft, a polymeric coating on at least a portion of the drive shaft, a distal-most drive shaft extension portion, and the like. Some embodiments of the rotational atherectomy devices and systems provided herein may include one or more of such design features.

Fourth, some embodiments of the rotational atherectomy devices and systems provided herein can be used to treat large-diameter vessels (including renal and iliac arteries having an internal diameter that is multiple time greater than the outer diameter of the abrasive element) while requiring only a small introducer sheath size. In other words, in some embodiments the rotating eccentric abrasive element(s) traces an orbital path that is substantially larger than the outer diameter of the rotational atherectomy device in the non-rotating state. This feature improves the ability of the

rotational atherectomy devices provided herein to treat very large vessels while still fitting within a small introducer size. In some embodiments, this feature can be at least partially attained by using a helical array of abrasive elements that has a high eccentric mass (e.g., the centers of mass of the abrasive elements are significantly offset from the central longitudinal axis of the drive shaft). Further, in some embodiments this feature can be at least partially attained by using multiple abrasive elements that are offset from each other around the drive shaft such that the centers of the abrasive elements are not coaxial with each other.

Fifth, in some embodiments the rotational atherectomy devices include a distal stability element that has an abrasive outer surface. In some cases, while the rotational atherectomy device is being advanced within the vasculature of a patient, the distal end of the rotational atherectomy device may encounter lesions that occlude or substantially occlude the vessel. In such a case, the abrasive outer surface on the distal stability element may help facilitate passage of the distal stability element through lesions that occlude or substantially occlude the vessel. In some such cases the drive shaft may be used to rotate the distal stability element to help facilitate boring of the distal stability element through such lesions in a drill-like fashion.

Sixth, in some embodiments rotational atherectomy systems described herein include user controls that are convenient and straight-forward to operate. In one such example, the user controls can include selectable elements that correspond to the diametric size of the vessel to be treated. When the clinician-user selects the particular vessel size, the system will determine an appropriate rpm of the drive shaft to obtain the desired orbit of the abrasive element(s) for the particular vessel size. Hence, in such a case the clinician-user conveniently does not need to explicitly select or control the rpm of the drive shaft. In another example, the user controls can include selectable elements that correspond to the speed of drive shaft rotations. In some such examples, the user can conveniently select “low,” “medium,” or “high” speeds.

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

DESCRIPTION OF DRAWINGS

FIG. 1 is a perspective view of an example rotational atherectomy system in accordance with some embodiments.

FIG. 2 shows a guidewire being advanced through a lesion in a blood vessel.

FIG. 3 shows an example rotational atherectomy device being advanced over the guidewire of FIG. 2 and into region of the lesion.

FIG. 4 shows the example rotational atherectomy device of FIG. 3 in use at a first longitudinal position in the region of the lesion. A multi-portion abrasive element of the rotational atherectomy device is being rotated along an orbital path to abrade the lesion.

FIG. 5 shows the rotational atherectomy device of FIG. 3 with the abrasive element being rotated at a second longitudinal position that is distal of the first longitudinal position.

FIG. 6 shows the rotational atherectomy device of FIG. 3 with the abrasive element being rotated at a third longitudinal position that is distal of the second longitudinal position.

FIG. 7 is a longitudinal cross-sectional view of a distal portion of an example rotational atherectomy device showing a multi-portion abrasive element and a distal stability element with an abrasive coating.

FIG. 8 is a side view of a distal portion of another example rotational atherectomy device showing a multi-portion abrasive element and a distal stability element with an abrasive coating. The individual portions of the multi-portion abrasive element are offset from each other around the drive shaft such that the centers of mass of the abrasive element portions define a spiral path around the drive shaft axis.

FIG. 9 is a transverse cross-sectional view of the rotational atherectomy device of FIG. 8 taken along the cutting-plane line 9—9.

FIG. 10 is a transverse cross-sectional view of the rotational atherectomy device of FIG. 8 taken along the cutting-plane line 10—10.

FIG. 11 is a transverse cross-sectional view of the rotational atherectomy device of FIG. 8 taken along the cutting-plane line 11—11.

FIG. 12 is a transverse cross-sectional view of the rotational atherectomy device of FIG. 8 taken along the cutting-plane line 12—12.

FIG. 13 is a transverse cross-sectional view of the rotational atherectomy device of FIG. 8 taken along the cutting-plane line 13—13.

FIG. 14 shows an example user control unit of a rotational atherectomy system that is being operated by a clinician-user to perform a rotational atherectomy procedure below the knee of a patient.

FIG. 15 shows the example user control unit of FIG. 14 being operated to perform a rotational atherectomy procedure above the knee of a patient.

FIG. 16 shows an example user control unit with another type of user interface.

Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

Referring to **FIG. 1**, in some embodiments a rotational atherectomy system 100 for removing or reducing stenotic lesions in blood vessels can include a guidewire 134, an actuator handle assembly 110, an elongate flexible drive shaft assembly 130, and a controller 150. The drive shaft assembly 130 extends distally from the handle assembly 110. The controller 150 is connected to the handle assembly 110 via a cable assembly 160. The handle assembly 110 and controller 150 can be operated by a clinician to perform and control the rotational atherectomy procedure.

In the depicted embodiment, the elongate flexible drive shaft assembly 130 includes a sheath 132 and a flexible drive shaft 136. A proximal end of the sheath 132 is fixed to a distal end of the handle assembly 110. The flexible drive shaft 136 is slidably and rotatably disposed within a lumen of the sheath 132. The flexible drive shaft 136 defines a longitudinal lumen in which the guidewire 134 is slidably disposed. In this embodiment, the flexible drive shaft 136 includes a torque-transmitting coil that defines the longitudinal lumen along a central longitudinal axis, and the drive 136 shaft is configured to rotate about the longitudinal axis while the sheath 132 remains generally stationary. Hence, as described further below, during a rotational atherectomy procedure the flexible drive shaft 136 is in motion (e.g., rotating and longitudinally translating) while the sheath 132 and the guidewire 134 are generally stationary.

In some optional embodiments, an inflatable member (not shown) can surround a distal end portion of the sheath 132. Such an inflatable member can be

selectively expandable between a deflated low-profile configuration and an inflated deployed configuration. The sheath 132 may define an inflation lumen through which the inflation fluid can pass (to and from the optional inflatable member). The inflatable member can be in the deflated low-profile configuration during the navigation of the drive shaft assembly 130 through the patient's vasculature to a target location in a vessel. Then, at the target location, the inflatable member can be inflated so that the outer diameter of the inflatable member contacts the wall of the vessel. In that arrangement, the inflatable member advantageously stabilizes the drive shaft assembly 130 in the vessel during the rotational atherectomy procedure.

Still referring to FIG 1, the flexible driveshaft 136 is slidably and rotatably disposed within a lumen of the sheath 132. A distal end portion of the driveshaft 136 extends distally of the distal end of the sheath 132 such that the distal end portion of the driveshaft 136 is exposed (e.g., not within the sheath 132, at least not during the performance of the actual rotational atherectomy).

In the depicted embodiment, the exposed distal end portion of the driveshaft 136 includes one or more abrasive elements 138, a (optional) distal stability element 140, and a distal drive shaft extension portion 142. In the depicted embodiment, the one or more abrasive elements 138 are eccentrically-fixed to the driveshaft 136 proximal of the distal stability element 140. In this embodiment, the distal stability element 140 is concentrically-fixed to the driveshaft 136 between the one or more abrasive elements 138 and the distal drive shaft extension portion 142. As such, the center of mass of the distal stability element 140 is aligned with the central axis of the drive shaft 136 while the center of mass of each abrasive element 138 is offset from the central axis of the drive shaft 136. The distal drive shaft extension portion 142, which includes the torque-transmitting coil, is configured to rotate about the longitudinal axis extends distally from the distal stability element 140 and terminates at a free end of the drive shaft 136.

In some optional embodiments, a proximal stability element (not shown) is included. The proximal stability element can be constructed and configured similarly to the depicted embodiment of the distal stability element 140 (e.g., a metallic cylinder directly coupled to the torque-transmitting coil of the drive shaft 136 and concentric with the longitudinal axis of the drive shaft 136) while being located proximal to the one or more abrasive elements 138.

In the depicted embodiment, the distal stability element 140 has a center of mass that is axially aligned with a central longitudinal axis of the drive shaft 136, while the one or more abrasive elements 138 (collectively and/or individually) have a center of mass that is axially offset from central longitudinal axis of the drive shaft 136. Accordingly, as the drive shaft 136 is rotated about its longitudinal axis, the principle of centrifugal force will cause the one or more abrasive elements 138 (and the portion of the drive shaft 136 to which the one or more abrasive elements 138 are affixed) to follow a transverse generally circular orbit (e.g., somewhat similar to a "jump rope" orbital movement) relative to the central axis of the drive shaft 136 (as described below, for example, in connection with FIGS. 4-6). In general, faster speeds (rpm) of rotation of the drive shaft 136 will result in larger diameters of the orbit (within the limits of the vessel diameter). The orbiting one or more abrasive elements 138 will contact the stenotic lesion to ablate or abrade the lesion to a reduced size (i.e., small particles of the lesion will be abraded from the lesion).

The rotating distal stability element 140 will remain generally at the longitudinal axis of the drive shaft 136 as the drive shaft 136 is rotated (as described below, for example, in connection with FIGS. 4-6). In some optional embodiments, two or more distal stability elements 140 are included. As described further below, contemporaneous with the rotation of the drive shaft 136, the drive shaft 136 can be translated back and forth along the longitudinal axis of the drive shaft 136. Hence, lesions can be abraded radially and longitudinally by virtue of the orbital rotation and translation of the one or more abrasive elements 138, respectively.

The flexible drive shaft 136 of rotational atherectomy system 100 is laterally flexible so that the drive shaft 136 can readily conform to the non-linear vasculature of the patient, and so that a portion of the drive shaft 136 at and adjacent to the one or more abrasive elements 138 will laterally deflect when acted on by the centrifugal forces resulting from the rotation of the one or more eccentric abrasive elements 138. In this embodiment, the drive shaft 136 comprises one or more helically wound wires (or filars) that provide one or more torque-transmitting coils of the drive shaft 136 (as described below, for example, in connection with FIGS. 7-8). In some embodiments, the one or more helically wound wires are made of a metallic material such as, but not limited to, stainless steel (e.g., 316, 316L, or 316LVM), nitinol, titanium, titanium alloys (e.g., titanium beta 3), carbon steel, or another suitable metal or metal alloy. In

some alternative embodiments, the filars are or include graphite, Kevlar, or a polymeric material. In some embodiments, the filars can be woven, rather than wound. In some embodiments, individual filars can comprise multiple strands of material that are twisted, woven, or otherwise coupled together to form a filar. In some embodiments, the filars have different cross-sectional geometries (size or shape) at different portions along the axial length of the drive shaft 136. In some embodiments, the filars have a cross-sectional geometry other than a circle, e.g., an ovular, square, triangular, or another suitable shape.

In this embodiment, the drive shaft 136 has a hollow core. That is, the drive shaft 136 defines a central longitudinal lumen running therethrough. The lumen can be used to slidably receive the guidewire 134 therein, as will be described further below. In some embodiments, the lumen can be used to aspirate particulate or to convey fluids that are beneficial for the atherectomy procedure.

In some embodiments, the drive shaft 136 includes an optional coating on one or more portions of the outer diameter of the drive shaft 136. The coating may also be described as a jacket, a sleeve, a covering, a casing, and the like. In some embodiments, the coating adds column strength to the drive shaft 136 to facilitate a greater ability to push the drive shaft 136 through stenotic lesions. In addition, the coating can enhance the rotational stability of the drive shaft 136 during use. In some embodiments, the coating is a flexible polymer coating that surrounds an outer diameter of the coil (but not the abrasive elements 138 or the distal stability element 140) along at least a portion of drive shaft 136 (e.g., the distal portion of the drive shaft 136 exposed outwardly from the sheath 132). In some embodiments, a portion of the drive shaft 136 or all of the drive shaft 136 is uncoated. In particular embodiments, the coating is a fluid impermeable material such that the lumen of the drive shaft 136 provides a fluid impermeable flow path along at least the coated portions of the drive shaft 136.

The coating may be made of materials including, but not limited to, PEBEX, PICOFLEX, PTFE, ePTFE, FEP, PEEK, silicone, PVC, urethane, polyethylene, polypropylene, and the like, and combinations thereof. In some embodiments, the coating covers the distal stability element 140 and the distal extension portion 142, thereby leaving only the one or more abrasive elements 138 exposed (non-coated) along the distal portion of the drive shaft 136. In alternative embodiments, the distal

stability element 140 is not covered with the coating, and thus would be exposed like the abrasive element 140. In some embodiments, two or more layers of the coating can be included on portions of the drive shaft 136. Further, in some embodiments different coating materials (e.g., with different durometers and/or stiffnesses) can be used at different locations on the drive shaft 136.

In the depicted embodiment, the distal stability element 140 is a metallic cylindrical member having an inner diameter that surrounds a portion of the outer diameter of the drive shaft 136. In some embodiments, the distal stability element 140 has a longitudinal length that is greater than a maximum exterior diameter of the distal stability element 140. In the depicted embodiment, the distal stability element 140 is coaxial with the longitudinal axis of the drive shaft 136. Therefore, the center of mass of the distal stability element 140 is axially aligned (non-eccentric) with the longitudinal axis of the drive shaft 136. In alternative rotational atherectomy device embodiments, stability element(s) that have centers of mass that are eccentric in relation to the longitudinal axis may be included in addition to, or as an alternative to, the coaxial stability elements 140. For example, in some alternative embodiments, the stability element(s) can have centers of mass that are eccentric in relation to the longitudinal axis and that are offset 180 degrees (or otherwise oriented) in relation to the center of mass of the one or more abrasive elements 138.

The distal stability element 140 may be made of a suitable biocompatible material, such as a higher-density biocompatible material. For example, in some embodiments the distal stability element 140 may be made of metallic materials such as stainless steel, tungsten, molybdenum, iridium, cobalt, cadmium, and the like, and alloys thereof. The distal stability element 140 has a fixed outer diameter. That is, the distal stability element 140 is not an expandable member in the depicted embodiment. The distal stability element 140 may be mounted to the filars of the drive shaft 136 using a biocompatible adhesive, by welding, by press fitting, and the like, and by combinations thereof. The coating may also be used in some embodiments to attach or to supplement the attachment of the distal stability element 140 to the filars of the drive shaft 136. Alternatively, the distal stability element 140 can be integrally formed as a unitary structure with the filars of the drive shaft 136 (e.g., using filars of a different size or density, using filars that are double-wound to provide multiple filar layers, or the like). The maximum outer diameter of the distal

stability element 140 may be smaller than the maximum outer diameters of the one or more abrasive elements 138.

In some embodiments, the distal stability element 140 has an abrasive coating on its exterior surface. For example, in some embodiments a diamond coating (or other suitable type of abrasive coating) is disposed on the outer surface of the distal stability element 140. In some cases, such an abrasive surface on the distal stability element 140 can help facilitate the passage of the distal stability element 140 through vessel restrictions (such as calcified areas of a blood vessel).

In some embodiments, the distal stability element 140 has an exterior cylindrical surface that is smoother and different from an abrasive exterior surface of the one or more abrasive elements 138. That may be the case whether or not the distal stability element 140 have an abrasive coating on its exterior surface. In some embodiments, the abrasive coating on the exterior surface of the distal stability element 140 is rougher than the abrasive surfaces on the one or more abrasive elements 138.

Still referring to FIG. 1, the one or more abrasive elements 138 (which may also be referred to as a burr, multiple burrs, or (optionally) a helical array of burrs) can comprise a biocompatible material that is coated with an abrasive media such as diamond grit, diamond particles, silicon carbide, and the like. In the depicted embodiment, the abrasive elements 138 includes a total of five discrete abrasive elements that are spaced apart from each other. In some embodiments, one, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, or more than fifteen discrete abrasive elements are included as the one or more abrasive elements 138. Each of the five discrete abrasive elements can include the abrasive media coating, such as a diamond grit coating.

In the depicted embodiment, the two outermost abrasive elements are smaller in maximum diameter than the three inner abrasive elements. In some embodiments, all of the abrasive elements are the same size. In particular embodiments, three or more different sizes of abrasive elements are included. Any and all such possible arrangements of sizes of abrasive elements are envisioned and within the scope of this disclosure.

Also, in the depicted embodiment, the center of mass of each abrasive element 138 is offset from the longitudinal axis of the drive shaft 136. Therefore, as the

eccentric one or more abrasive elements 138 are rotated (along an orbital path), at least a portion of the abrasive surface of the one or more abrasive elements 138 can make contact with surrounding stenotic lesion material. As with the distal stability element 140, the eccentric one or more abrasive elements 138 may be mounted to the filars of the torque-transmitting coil of the drive shaft 136 using a biocompatible adhesive, high temperature solder, welding, press fitting, and the like. In some embodiments, a hypotube is crimped onto the driveshaft and an abrasive element is laser welded to the hypotube. Alternatively, the one or more abrasive elements 138 can be integrally formed as a unitary structure with the filars of the drive shaft 136 (e.g., using filars that are wound in a different pattern to create an axially offset structure, or the like).

In some embodiments, the spacing of the distal stability element 140 relative to the one or more abrasive elements 138 and the length of the distal extension portion 142 can be selected to advantageously provide a stable and predictable rotary motion profile during high-speed rotation of the drive shaft 136. For example, in embodiments that include the distal driveshaft extension portion 142, the ratio of the length of the distal driveshaft extension 142 to the distance between the centers of the one or more abrasive elements 138 and the distal stability element 140 is about 1:0.5, about 1:0.8, about 1:1, about 1.1:1, about 1.2:1, about 1.5:1, about 2:1, about 2.5:1, about 3:1, or higher than 3:1.

Still referring to FIG. 1, the rotational atherectomy system 100 also includes the actuator handle assembly 110. The actuator handle assembly 110 includes a housing 112 and a carriage assembly 114. The carriage assembly 114 is slidably translatable along the longitudinal axis of the handle assembly 110 as indicated by the arrow 115. For example, in some embodiments the carriage assembly 114 can be translated, without limitation, about 8 cm to about 12 cm, or about 6 cm to about 10 cm, or about 4 cm to about 8 cm, or about 6 cm to about 14 cm. As the carriage assembly 114 is translated in relation to the housing 112, the drive shaft 136 translates in relation to the sheath 132 in a corresponding manner.

In the depicted embodiment, the carriage assembly 114 includes a valve actuator 116. In some embodiments, an electric motor for driving rotations of the drive shaft 136 is coupled to the carriage assembly 114 such that the valve actuator 116 is an electrical switch instead. In the depicted embodiment, the valve actuator

116 is a button that can be depressed to actuate a compressed gas control valve (on/off; defaulting to off) mounted to the carriage assembly 114. While the valve actuator 116 is depressed, a compressed gas (e.g., air, nitrogen, etc.) is supplied through the valve to a turbine member that is rotatably coupled to the carriage assembly 114 and fixedly coupled to the drive shaft 136. Hence, an activation of the valve actuator 116 will result in a rotation of the turbine member and, in turn, the drive shaft 136 (as depicted by arrow 137). It should be understood that the rotational atherectomy system 100 is configured to rotate the drive shaft 136 at a high speed of rotation (e.g., 20,000-160,000 rpm) such that the eccentric one or more abrasive elements 138 revolve in an orbital path to thereby contact and remove portions of a target lesion (even those portions of the lesion that are spaced farther from the axis of the drive shaft 136 than the maximum radius of the one or more abrasive elements 138).

To operate the handle assembly 110 during a rotational atherectomy procedure, a clinician can grasp the carriage assembly 114 and depress the valve actuator 116 with the same hand. The clinician can move (translate) the carriage assembly 114 distally and proximally by hand (e.g., back and forth in relation to the housing 112), while maintaining the valve actuator 116 in the depressed state. In that manner, a target lesion(s) can be ablated radially and longitudinally by virtue of the resulting orbital rotation and translation of the one or more abrasive elements 138, respectively.

During an atherectomy treatment, in some cases the guidewire 134 is left in position in relation to the drive shaft 136 generally as shown. For example, in some cases the portion of the guidewire 134 that is extending beyond the distal end of the drive shaft 136 (or extension portion 142) is about 10 inches to about 12 inches (about 25 cm to about 30 cm), about 6 inches to about 16 inches (about 15 cm to about 40 cm), or about 2 inches to about 20 inches (about 5 cm to about 50 cm). In some cases, the guidewire 134 is pulled back to be within (while not extending distally from) the drive shaft 136 during an atherectomy treatment. The distal end of the guidewire 134 may be positioned anywhere within the drive shaft 136 during an atherectomy treatment. In some cases, the guidewire 134 may be completely removed from within the drive shaft during an atherectomy treatment. The extent to which the guidewire 134 is engaged with the drive shaft 136 during an atherectomy treatment may affect

the size of the orbital path of the one or more abrasive elements 138. Accordingly, the extent to which the guidewire 134 is engaged with the drive shaft 136 may be situationally selected to be well-suited for a particular patient anatomy, physician's preference, type of treatment being delivered, and other such factors.

In the depicted embodiment, the handle assembly 110 also includes a guidewire detention mechanism 118. The guidewire detention mechanism 118 can be selectively actuated (e.g., rotated) to releasably clamp and maintain the guidewire 134 in a stationary position relative to the handle assembly 110 (and, in turn, stationary in relation to rotations of the drive shaft 136 during an atherectomy treatment). While the drive shaft 136 and handle assembly 110 are being advanced over the guidewire 134 to put the one or more abrasive elements 138 into a targeted position within a patient's vessel, the guidewire detention mechanism 118 will be unactuated so that the handle assembly 110 is free to slide in relation to the guidewire 134. Then, when the clinician is ready to begin the atherectomy treatment, the guidewire detention mechanism 118 can be actuated to releasably detain/lock the guidewire 134 in relation to the handle assembly 110. That way the guidewire 134 will not rotate while the drive shaft 136 is rotating, and the guidewire 134 will not translate while the carriage assembly 114 is being manually translated.

Still referring to FIG. 1, the rotational atherectomy system 100 also includes the controller 150. In the depicted embodiment, the controller 150 includes a user interface 152 that includes a plurality of selectable inputs 154 that correspond to a plurality of vessel sizes (diameters). To operate the rotational atherectomy system 100, the user can select a particular one of the selectable inputs 154 that corresponds to the diameter of the vessel being treated. In response, the controller 150 will determine the appropriate gas pressure for rotating the drive shaft 136 in a vessel of the selected diameter (faster rpm for larger vessels and slower rpm for smaller vessel), and supply the gas at the appropriate pressure to the handle assembly 110.

In some embodiments, the controller 150 is pole-mounted. The controller 150 can be used to control particular operations of the handle assembly 110 and the drive shaft assembly 130. For example, the controller 150 can be used to compute, display, and adjust the rotational speed of the drive shaft 136.

In some embodiments, the controller 150 can include electronic controls that are in electrical communication with a turbine RPM sensor located on the carriage

assembly 114. The controller 150 can convert the signal(s) from the sensor into a corresponding RPM quantity and display the RPM on the user interface 152. If a speed adjustment is desired, the clinician can increase or decrease the rotational speed of the drive shaft 136. In result, a flow or pressure of compressed gas supplied from the controller 150 to the handle assembly 110 (via the cable assembly 160) will be modulated. The modulation of the flow or pressure of the compressed gas will result in a corresponding modulation of the RPM of the turbine member and of the drive shaft 136.

In some embodiments, the controller 150 includes one or more interlock features that can enhance the functionality of the rotational atherectomy system 100. In one such example, if the controller 150 does not detect any electrical signal (or a proper signal) from the turbine RPM sensor, the controller 150 can discontinue the supply of compressed gas. In another example, if a pressure of a flush liquid supplied to the sheath 132 is below a threshold pressure value, the controller 150 can discontinue the supply of compressed gas.

Referring also to **FIGS. 2–6**, the rotational atherectomy system 100 can be used to treat a vessel 10 having a stenotic lesion 14 along an inner wall 12 of the vessel 10. The rotational atherectomy system 100 is used to fully or partially remove the stenotic lesion 14, thereby removing or reducing the blockage within the vessel 10 caused by the stenotic lesion 14. By performing such a treatment, the blood flow through the vessel 10 may be thereafter increased or otherwise improved. The vessel 10 and lesion 14 are shown in longitudinal cross-sectional views to enable visualization of the rotational atherectomy system 100.

Briefly, in some implementations the following activities may occur to achieve the deployed arrangement shown in FIGS. 2–6. In some embodiments, an introducer sheath (not shown) can be percutaneously advanced into the vasculature of the patient. The guidewire 134 can then be inserted through a lumen of the introducer sheath and navigated within the patient's vasculature to a target location (e.g., the location of the lesion 14). Techniques such as x-ray fluoroscopy or ultrasonic imaging may be used to provide visualization of the guidewire 134 and other atherectomy system components during placement. In some embodiments, no introducer sheath is used and the guidewire 134 is inserted without assistance from a sheath. The resulting arrangement is depicted in FIG. 2.

Next, as depicted in FIG. 3, portions of the rotational atherectomy system 100 can be inserted over the guidewire 134. For example, an opening to the lumen of the drive shaft 136 at the distal free end of the drive shaft 136 (e.g., at the distal end of the optional distal drive shaft extension portion 142) can be placed onto the guidewire 134, and then the drive shaft assembly 130 and handle assembly 110 can be gradually advanced over the guidewire 134 to the position in relation to the lesion 14 as shown. In some cases, the drive shaft 136 is disposed fully within the lumen of the sheath 132 during the advancing. In some cases, a distal end portion of the drive shaft 136 extends from the distal end opening 143 of the sheath 132 during the advancing. Eventually, after enough advancing, the proximal end of the guidewire 134 will extend proximally from the handle assembly 110 (via the access port 120 defined by the handle housing 112).

In some cases (such as in the depicted example), the lesion 14 may be so large (i.e., so extensively occluding the vessel 10) that it is difficult or impossible to push the distal stability element 140 through the lesion 14. In some such cases, an abrasive outer surface on the distal stability element 140 can be used to help facilitate passage of the distal stability element 140 into or through the lesion 14. In some such cases, the drive shaft 136 can be rotated to further help facilitate the distal stability element 140 to bore into/through the lesion 14.

Next, as depicted by FIGS. 4–6, the rotation and translational motions of the drive shaft 136 (and the one or more abrasive elements 138) can be commenced to perform ablation of the lesion 14.

In some implementations, prior to the ablation of the lesion 14 by the one or more abrasive elements 138, an inflatable member can be used as an angioplasty balloon to treat the lesion 14. That is, an inflatable member (on the sheath 132, for example) can be positioned within the lesion 14 and then inflated to compress the lesion 14 against the inner wall 12 of the vessel 10. Thereafter, the rotational atherectomy procedure can be performed. In some implementations, such an inflatable member can be used as an angioplasty balloon after the rotational atherectomy procedure is performed. In some implementations, additionally or alternatively, a stent can be placed at lesion 14 using an inflatable member on the sheath 132 (or another balloon member associated with the drive shaft assembly 130) after the rotational atherectomy procedure is performed.

The guidewire 134 may remain extending from the distal end of the drive shaft 136 during the atherectomy procedure as shown. For example, as depicted by FIGS. 4-6, the guidewire 134 extends through the lumen of the drive shaft 136 and further extends distally of the distal end of the distal extension portion 142 during the rotation and translational motions of the drive shaft 136 (refer, for example, to FIGS. 4-6). In some alternative implementations, the guidewire 134 is withdrawn completely out of the lumen of the drive shaft 136 prior to during the rotation and translational motions of the drive shaft 136 for abrading the lesion 14. In other implementations, the guidewire is withdrawn only partially. That is, in some implementations a portion of the guidewire remains within the lumen of the drive shaft 136 during rotation of the drive shaft 136, but remains only in a proximal portion that is not subject to the significant orbital path in the area of the one or more abrasive elements 138 (e.g., remains within the portion of the drive shaft 136 that remains in the sheath 132).

To perform the atherectomy procedure, the drive shaft 136 is rotated at a high rate of rotation (e.g., 20,000-160,000 rpm) such that the eccentric one or more abrasive elements 138 revolve in an orbital path about an axis of rotation and thereby contacts and removes portions of the lesion 14.

Still referring to FIGS. 4–6, the rotational atherectomy system 100 is depicted during the high-speed rotation of the drive shaft 136. The centrifugal force acting on the eccentrically weighted one or more abrasive elements 138 causes the one or more abrasive elements 138 to orbit in an orbital path around the axis of rotation 139. In some implementations, the orbital path can be somewhat similar to the orbital motion of a "jump rope." As shown, some portions of the drive shaft 136 (e.g., a portion that is just distal of the sheath 132 and another portion that is distal of the distal stability element 140) can remain in general alignment with the axis of rotation 139, but the particular portion of the drive shaft 136 adjacent to the one or more abrasive elements 138 is not aligned with the axis of rotation 139 (and instead orbits around the axis 139). As such, in some implementations, the axis of rotation 139 may be aligned with the longitudinal axis of a proximal part of the drive shaft 136 (e.g., a part within the distal end of the sheath 132) and with the longitudinal axis of the distal extension portion 142 of the drive shaft 136.

In some implementations, as the one or more abrasive elements 138 rotates, the clinician operator slowly advances the carriage assembly 114 distally (and,

optionally, reciprocates both distally and proximally) in a longitudinal translation direction so that the abrasive surface of the one or more abrasive elements 138 scrapes against additional portions of the occluding lesion 14 to reduce the size of the occlusion, and to thereby improve the blood flow through the vessel 10. This combination of rotational and translational motion of the one or more abrasive elements 138 is depicted by the sequence of FIGS. 4–6.

In some embodiments, the sheath 132 may define one or more lumens (e.g., the same lumen as, or another lumen than, the lumen in which the drive shaft 136 is located) that can be used for aspiration (e.g., of abraded particles of the lesion 14). In some cases, such lumens can be additionally or alternatively used to deliver perfusion and/or therapeutic substances to the location of the lesion 14, or to prevent backflow of blood from vessel 10 into sheath 132.

Referring to **FIG. 7**, a distal end portion of the drive shaft 136 is shown in a longitudinal cross-sectional view. The distal end portion of the drive shaft 136 includes the one or more abrasive elements 138 that are eccentrically-fixed to the driveshaft 136, the distal stability element 140 with an abrasive outer surface, and the distal drive shaft extension portion 142.

In the depicted embodiment, the one or more abrasive elements 138 includes a total of five discrete abrasive elements that are spaced apart from each other. In some embodiments, one, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, or more than fifteen discrete abrasive elements are included as the one or more abrasive elements 138. Each of the five discrete abrasive elements can include the abrasive media coating.

In the depicted embodiment, the two outermost abrasive elements of the abrasive elements 138 are smaller in maximum diameter than the three inner abrasive elements of the abrasive elements 138. In some embodiments, all of the abrasive elements are the same size. In particular embodiments, three or more different sizes of abrasive elements are included. Any and all such possible arrangements of sizes of abrasive elements are envisioned and within the scope of this disclosure.

The one or more abrasive elements 138 can be made to any suitable size. For clarity, the size of the one or more abrasive elements 138 will refer herein to the maximum outer diameter of individual abrasive elements of the one or more abrasive elements 138. In some embodiments, the one or more abrasive elements 138 are

about 2 mm in size (maximum outer diameter). In some embodiments, the size of the one or more abrasive elements 138 is in a range of about 1.5 mm to about 2.5 mm, or about 1.0 mm to about 3.0 mm, or about 0.5 mm to about 4.0 mm, without limitation. Again, in a single embodiment, one or more of the abrasive elements 138 can have a different size in comparison to the other abrasive elements 138. In some embodiments, the two outermost abrasive elements are about 1.5 mm in diameter and the inner abrasive elements are about 2.0 mm in diameter.

In the depicted embodiment, the one or more abrasive elements 138, individually, are oblong in shape. A variety of different shapes can be used for the one or more abrasive elements 138. For example, in some embodiments the one or more abrasive elements 138 are individually shaped as spheres, discs, rods, cylinders, polyhedrons, cubes, prisms, and the like. In some embodiments, such as the depicted embodiment, all of the one or more abrasive elements 138 are the same shape. In particular embodiments, one or more of the abrasive elements 138 has a different shape than one or more of the other abrasive elements 138. That is, two, three, or more differing shapes of individual abrasive elements 138 can be combined on the same drive shaft 136.

In the depicted embodiment, adjacent abrasive elements of the one or more abrasive elements 138 are spaced apart from each other. For example, in the depicted embodiment the two distal-most individual abrasive elements are spaced apart from each other by a distance 'X'. In some embodiments, the spacing between adjacent abrasive elements is consistent between all of the one or more abrasive elements 138. Alternatively, in some embodiments the spacing between some adjacent pairs of abrasive elements differs from the spacing between other adjacent pairs of abrasive elements.

In some embodiments, the spacing distance X in ratio to the maximum diameter of the abrasive elements 138 is about 1:1. That is, the spacing distance X is about equal to the maximum diameter. The spacing distance X can be selected to provide a desired degree of flexibility of the portion of the drive shaft 136 to which the one or more abrasive elements 138 are attached. In some embodiments, the ratio is about 1.5:1 (i.e., X is about 1.5 times longer than the maximum diameter). In some embodiments, the ratio is in a range of about 0.2:1 to about 0.4:1, or about 0.4:1 to about 0.6:1, or about 0.6:1 to about 0.8:1, or about 0.8:1 to about 1:1, or about 1:1 to

about 1.2:1, or about 1.2:1 to about 1.4:1, or about 1.4:1 to about 1.6:1, or about 1.6:1 to about 1.8:1, or about 1.8:1 to about 2.0:1, or about 2.0:1 to about 2.2:1, or about 2.2:1 to about 2.4:1, or about 2.4:1 to about 3.0:1, or about 3.0:1 to about 4.0:1, and anywhere between or beyond those ranges.

In the depicted embodiment, the center of mass of each one of the one or more abrasive elements 138 is offset from the longitudinal axis of the drive shaft 136 along a same radial angle. Said another way, the centers of mass of all of the one or more abrasive elements 138 are coplanar with the longitudinal axis of the drive shaft 136. If the size of each of the one or more abrasive elements 138 is equal, the centers of mass of the one or more abrasive elements 138 would be collinear on a line that is parallel to the longitudinal axis of the drive shaft 136.

Referring to **FIG. 8**, according to some embodiments of the rotational atherectomy devices provided herein, one or more abrasive elements 144 are arranged at differing radial angles in relation to the drive shaft 136. In such a case, a path defined by the centers of mass of the one or more abrasive elements 144 spirals along the drive shaft 136. In some cases (e.g., when the diameters of the one or more abrasive elements 144 are equal and the adjacent abrasive elements are all equally spaced), the centers of mass of the one or more abrasive elements 144 define a helical path along/around the drive shaft 136. It has been found that such arrangements can provide a desirably-shaped orbital rotation of the one or more abrasive elements 144.

It should be understood that any of the structural features described in the context of one embodiment of the rotational atherectomy devices provided herein can be combined with any of the structural features described in the context of one or more other embodiments of the rotational atherectomy devices provided herein. For example, the size and/or shape features of the one or more abrasive elements 138 can be incorporated in any desired combination with the spiral arrangement of the one or more abrasive elements 144.

Referring also to **FIGS. 9–13**, the differing radial angles of the individual abrasive elements 144a, 144b, 144c, 144d, and 144e can be further visualized. To avoid confusion, each figure of FIGS. 9–13 illustrates only the closest one of the individual abrasive elements 144a, 144b, 144c, 144d, and 144e (i.e., closest in terms of the corresponding cutting-plane as shown in FIG. 8). For example, in FIG. 10,

abrasive element 144b is shown, but abrasive element 144a is not shown (so that the radial orientation of the abrasive element 144b is clearly depicted).

It can be seen in FIGS. 9–13 that the centers of mass of abrasive elements 144a, 144b, 144c, 144d, and 144e are at differing radial angles in relation to the drive shaft 136. Hence, it can be said that the abrasive elements 144a, 144b, 144c, 144d, and 144e are disposed at differing radial angles in relation to the drive shaft 136.

In the depicted embodiment, the radial angles of the abrasive elements 144a, 144b, 144c, 144d, and 144e differ from each other by a consistent 37.5 degrees (approximately) in comparison to the adjacent abrasive element(s). For example, the center of mass of abrasive element 144b is disposed at a radial angle B that is about 37.5 degrees different than the angle at which the center of mass of abrasive element 144a is disposed, and about 37.5 degrees different than the angle C at which the center of mass of abrasive element 144c is disposed. Similarly, the center of mass of abrasive element 144c is disposed at a radial angle C that is about 37.5 degrees different than the angle B at which the center of mass of abrasive element 144b is disposed, and about 37.5 degrees different than the angle D at which the center of mass of abrasive element 144d is disposed. The same type of relative relationships can be said about abrasive element 144d.

While the depicted embodiment has a relative radial offset of 37.5 degrees (approximately) in comparison to the adjacent abrasive element(s), a variety of other relative radial offsets are envisioned. For example, in some embodiments the relative radial offsets of the adjacent abrasive elements is in a range of about 0 degrees to about 5 degrees, or about 5 degrees to about 10 degrees, or about 10 degrees to about 15 degrees, or about 15 degrees to about 20 degrees, or about 20 degrees to about 25 degrees, or about 25 degrees to about 30 degrees, or about 30 degrees to about 35 degrees, or about 10 degrees to about 30 degrees, or about 20 degrees to about 40 degrees, or about 20 degrees to about 50 degrees.

While in the depicted embodiment, the relative radial offsets of the abrasive elements 144a, 144b, 144c, 144d, and 144e in comparison to the adjacent abrasive element(s) are consistent, in some embodiments some abrasive elements are radially offset to a greater or lesser extent than others. For example, while angles B, C, D, and E are all multiples of 37.5 degrees, in some embodiments one or more of the angles B, C, D, and/or E is not a multiple of the same angle as the others.

The direction of the spiral defined by the centers of mass of the abrasive elements 144a, 144b, 144c, 144d, and 144e can be in either direction around the drive shaft 136, and in either the same direction as the wind of the filars or in the opposing direction as the wind of the filars.

Referring to **FIG. 14**, the rotational atherectomy system 100 also includes the controller 150. In the depicted embodiment, the controller 150 includes a user interface 152 that includes a plurality of selectable inputs 154 that correspond to a plurality of vessel sizes (diameters). Other types of user interfaces are also envisioned (e.g., refer to FIG. 16). To operate the rotational atherectomy system 100, the user can select a particular one of the selectable inputs 154 that corresponds to the diameter of the vessel being treated. In response, the controller 150 will determine the appropriate gas pressure for rotating the one or more abrasive elements 138 in a vessel of the selected diameter (faster rpm for larger vessels and slower rpm for smaller vessel), and supply the gas at the appropriate pressure to the handle assembly 110. In some embodiments, the driver for rotation of the one or more abrasive elements 138 is an electrical motor rather than the pneumatic motor included in the depicted example.

In the depicted example, the vessel to be treated is in a leg 10 of a patient. In particular, the vessel is below a knee 12 (e.g., an tibial artery, without limitation). Such a vessel can tend to be relatively small in diameter. Therefore, in this illustrative example, the clinician user is inputting a vessel size of 4.0 mm. In response, the controller 150 will determine the appropriate gas pressure for rotating the one or more abrasive elements 138 in a 4.0 mm vessel. For example, that speed may be about 40,000 rpm. The corresponding gas pressure will be supplied to the handle assembly 110 via cable assembly 160 (FIG. 1).

Referring to **FIG. 15**, in another example, the vessel to be treated is above the knee 12. For example, without limitation, the vessel may be an iliac or femoral artery. Such a vessel will tend to be relatively large in diameter. Therefore, in this illustrative example, the clinician user is inputting a vessel size of 8.0 mm. In response, the controller 150 will determine the appropriate gas pressure for rotating the one or more abrasive elements 138 in an 8.0 mm vessel. For example, that speed may be about 80,000 rpm. The corresponding gas pressure will be supplied to the handle assembly 110 via cable assembly 160 (FIG. 1).

Referring to **FIG. 16**, in some embodiments the rotational atherectomy systems described herein can include a controller 250 that has is configured with an example user interface 252. The user interface 252 includes readily understandable and convenient-to-use selectable inputs 254 that correspond to the rotational speed at which the drive shaft will be driven by the controller 250.

In this example, the user interface 252 is configured such that the user can simply select either "LOW," "MED," or "HIGH" speed via the selectable inputs 254. Based on the user's selection of either "LOW," "MED," or "HIGH," the controller 250 will provide a corresponding output for rotating the drive shaft at a corresponding rotational speed. It should be understood that the user interfaces 152 (e.g., FIGS. 14 and 15) and 252 are merely exemplary and non-limiting. That is, other types of user interface controls can also be suitably used, and are envisioned within the scope of this disclosure.

A number of embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the invention. For example, design features of the embodiments described herein can be combined with other design features of other embodiments described herein. Accordingly, other embodiments are within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A rotational atherectomy device for removing stenotic lesion material from a blood vessel of a patient, the device comprising:

an elongate flexible drive shaft comprising a torque-transmitting coil and defining a longitudinal axis, the drive shaft being configured to rotate about the longitudinal axis;

first and second abrasive elements attached to a distal end portion of the drive shaft and each having a center of mass offset from the longitudinal axis, the center of mass of the first abrasive element being offset from the longitudinal axis at a first radial angle, the center of mass of the second abrasive element being offset from the longitudinal axis at a second radial angle that differs from the first radial angle; and

a distal stability element fixedly mounted to the drive shaft and having a center of mass aligned with the longitudinal axis, the distal stability element being distally spaced apart from the first and second abrasive elements.

2. The device of claim 1, further comprising a third abrasive element attached to the distal end portion of the drive shaft, wherein the center of mass of the third abrasive element is offset from the longitudinal axis along a third radial angle that differs from the first radial angle and the second radial angle.

3. The device of claim 1 or claim 2, wherein the second radial angle differs from the first radial angle by at least 15 degrees, and wherein the third radial angle differs from the first radial angle and the second radial angle by at least 15 degrees.

4. The device of any one of claims 1-3, wherein the distal stability element comprises a metal cylinder surrounding the torque-transmitting coil of the drive shaft and having a maximum diameter smaller than the first and second abrasive elements, and wherein the distal stability element has an abrasive outer surface.

5. The device of any one of claims 1-4, further comprising an array of abrasive elements including the first and second abrasive elements and additional abrasive elements attached to the distal end portion of the drive shaft, wherein a proximal-most

one of the array of abrasive elements and a distal-most one of the array of abrasives element are each smaller than intermediate ones of the array of abrasive elements.

6. The device of claim 5, wherein a path defined by the centers of mass of the array of abrasive elements define at least a portion of a helical path around the longitudinal axis.

7. The device of any one of claims 1-6, further comprising a flexible polymer coating along the drive shaft such that the coating surrounds an outer diameter of at least a portion of drive shaft.

8. A rotational atherectomy device for removing stenotic lesion material from a blood vessel of a patient, the device comprising:

an elongate flexible drive shaft comprising a torque-transmitting coil and defining a longitudinal axis, the drive shaft being configured to rotate about the longitudinal axis;

a helical array of abrasive elements attached to a distal end portion of the drive shaft, each of the abrasive elements having a center of mass that is offset from the longitudinal axis, the centers of mass of the abrasive elements being noncollinear; and

a distal stability element affixed to the drive shaft and having a center of mass aligned with the longitudinal axis, the distal stability element distally spaced apart from the plurality of abrasive elements.

9. The device of claim 8, further comprising a flexible polymer coating along the drive shaft such that the coating surrounds an outer diameter of at least a portion of drive shaft.

10. The device of claim 8 or claim 9, wherein the drive shaft comprises a distal-most extension portion that extends distally of the distal stability element for a distal extension distance.

11. The device of any one of claims 8-10, wherein the drive shaft has a central lumen configured to receive a guidewire extending along the longitudinal axis.

12. The device of any one of claims 8-11, wherein the distal stability element comprises a metal cylinder surrounding the torque-transmitting coil, and wherein the metal cylinder has an abrasive outer surface.

13. The device of any one of claims 8-12, wherein the plurality of abrasive elements are spaced apart from each other by at least 50% of an outer diameter of a largest one of the abrasive elements.

14. The device of any one of claims 8-13, wherein a proximal-most one of the abrasive elements and a distal-most one of the abrasives element are each smaller than intermediate ones of the abrasive elements.

15. The device of any one of claims 8-14, wherein a path defined by the centers of mass of sequential abrasive elements of the plurality of abrasive elements spirals around the longitudinal axis.

16. The device of any one of claims 8-15, wherein the plurality of abrasive elements comprises five abrasive elements.

17. The device of any one of the preceding claims, further comprising:

an actuator handle assembly configured to drive rotation of the drive shaft about the longitudinal axis, the actuator handle assembly comprising a carriage assembly that is movable in relation to other portions of the actuator handle assembly to translate the drive shaft along the longitudinal axis; and

a sheath extending from the actuator handle assembly, the drive shaft slidably disposed within a lumen defined by the sheath.

18. A system for performing rotational atherectomy to remove stenotic lesion material from a blood vessel of a patient, the system comprising:

an elongate flexible drive shaft comprising a torque-transmitting coil and defining a longitudinal axis, the drive shaft being configured to rotate about the longitudinal axis;

one or more abrasive elements attached to a distal end portion of the drive shaft, each of the abrasive elements having a center of mass that is offset from the longitudinal axis;

a distal stability element fixed to the drive shaft and having a center of mass aligned with the longitudinal axis, the distal stability element distally spaced apart from the plurality of abrasive elements;

an actuator handle assembly configured to drive rotation of the drive shaft about the longitudinal axis, the actuator handle assembly comprising a carriage assembly that is movable in relation to other portions of the actuator handle assembly to translate the drive shaft along the longitudinal axis;

a sheath extending from the actuator handle assembly, the drive shaft slidably disposed within a lumen defined by the sheath; and

a controller operably coupleable to the actuator handle assembly, the controller configured to provide output to the actuator handle assembly that causes the actuator handle assembly to drive the rotation of the drive shaft about the longitudinal axis, the controller including a user interface with a plurality of selectable inputs corresponding to a plurality of vessel sizes, wherein controller is configured to provide a respective output to the actuator handle assembly that differs for each of the vessel sizes.

19. The system of claim 18, wherein a center of mass of a first one of the abrasive elements is transversely offset from the longitudinal axis along a first angle, and wherein a center of mass of a second one of the abrasive elements is transversely offset from the longitudinal axis along a second angle that differs from the first angle by at least 15 degrees.

20. The system of claim 18 or claim 19, further comprising a flexible polymer coating along the drive shaft such that the coating surrounds an outer diameter of at least a portion of drive shaft, and wherein the distal stability element has an abrasive outer surface.

21. A method for performing rotational atherectomy to remove stenotic lesion material from a blood vessel of a patient, the method comprising:

delivering a rotational atherectomy device into the blood vessel, wherein the rotational atherectomy device comprises:

an elongate flexible drive shaft comprising a torque-transmitting coil and defining a longitudinal axis, the drive shaft being configured to rotate about the longitudinal axis;

a helical array of abrasive elements attached to a distal end portion of the drive shaft, each of the abrasive elements having a center of mass that is offset from the longitudinal axis, the centers of mass of the abrasive elements arranged along a path that spirals around the longitudinal axis; and

a distal stability element affixed to the drive shaft and having a center of mass aligned with the longitudinal axis, the distal stability element distally spaced apart from the plurality of abrasive elements; and

rotating the drive shaft about the longitudinal axis such that the abrasive elements orbit around the longitudinal axis.

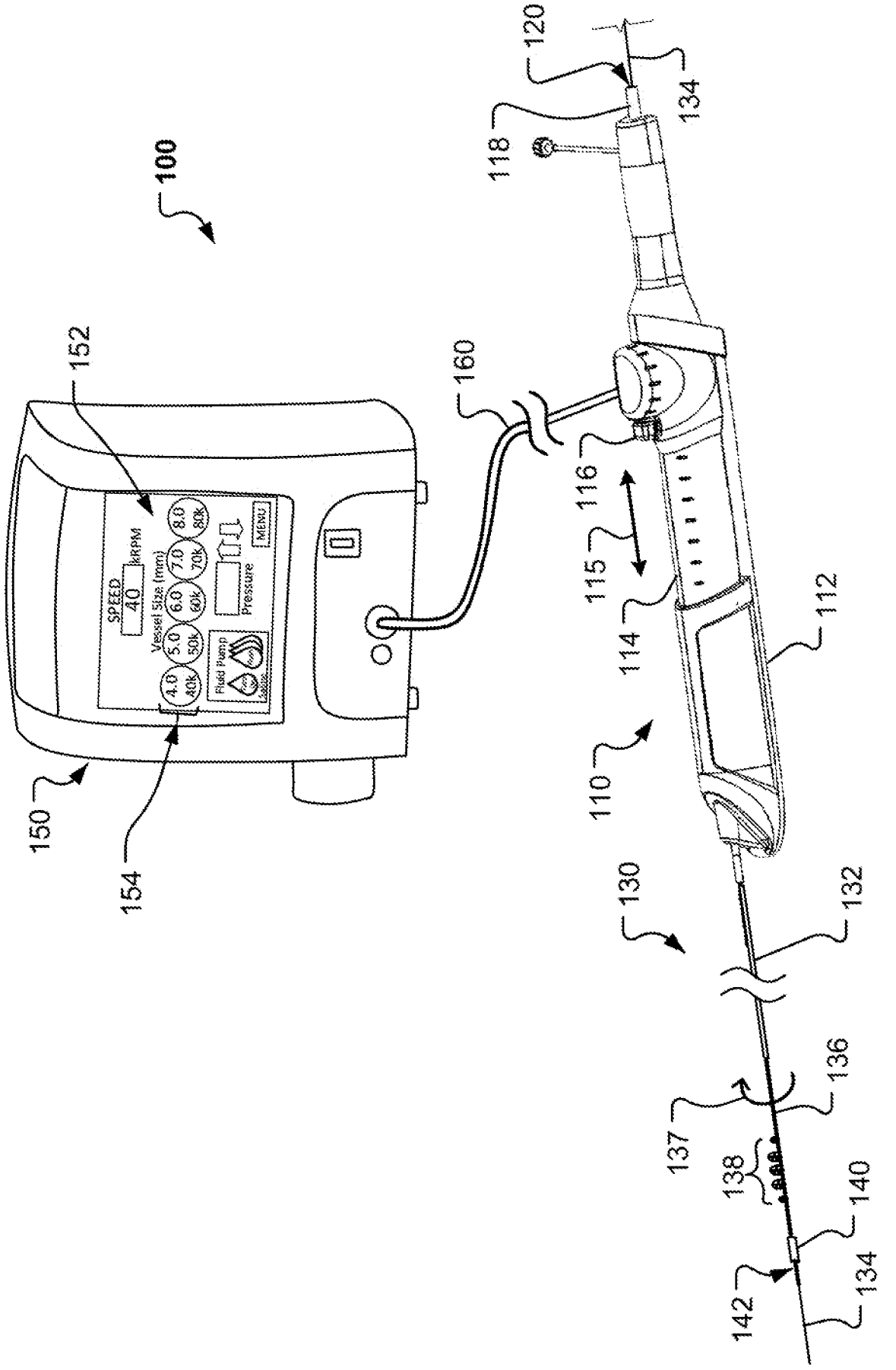

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SPEED
40
kRPM
Vessel Size (mm)
8.0
80k
7.0
70k
6.0
60k
5.0
50k
4.0
40k
Fluid Pump
Pressure
MENU

FIG. 1

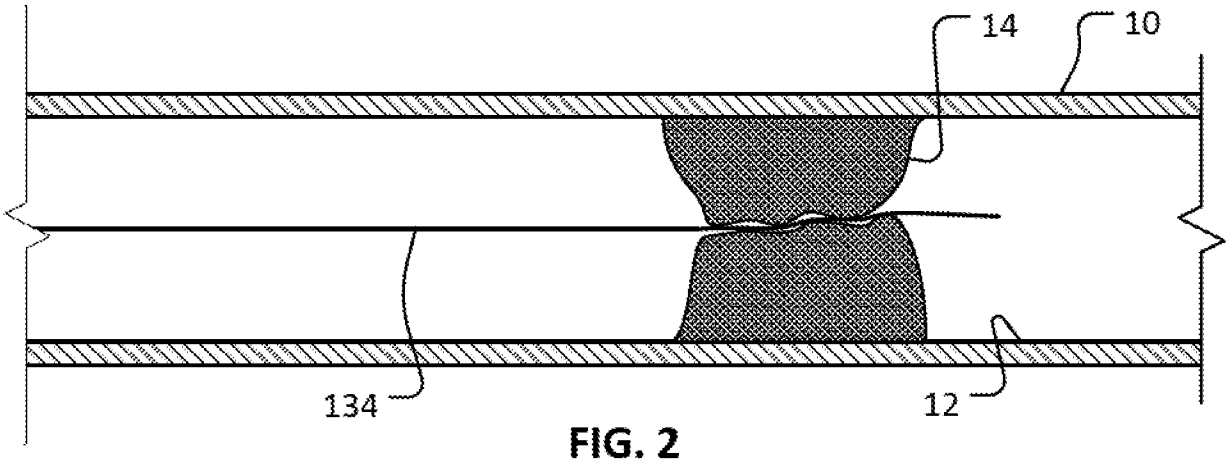


FIG. 2

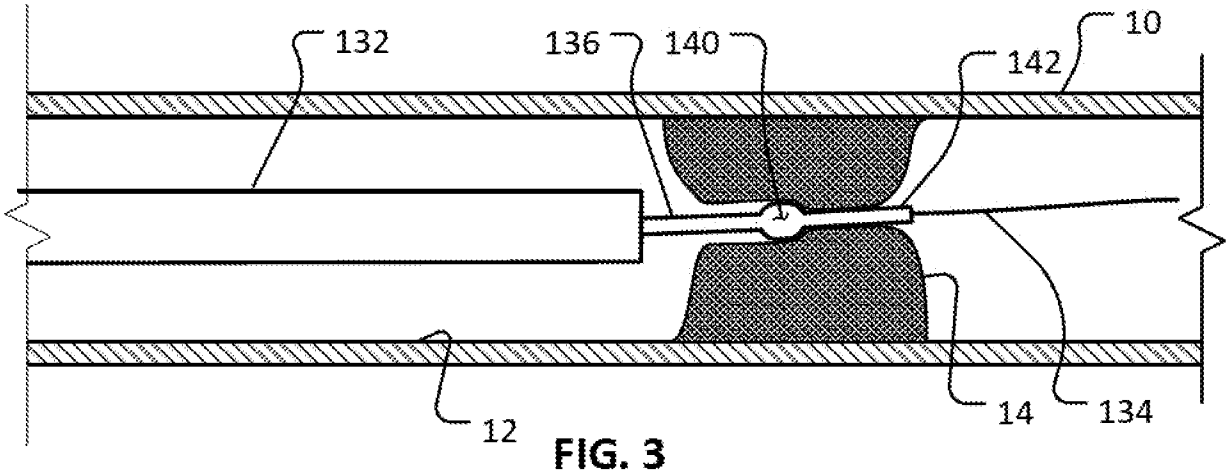


FIG. 3

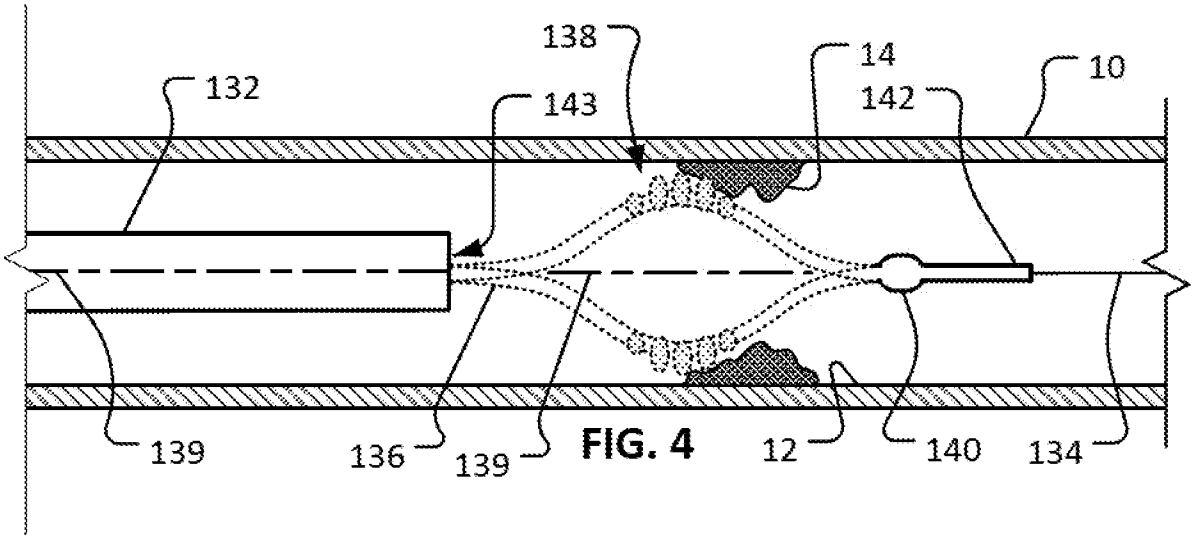


FIG. 4

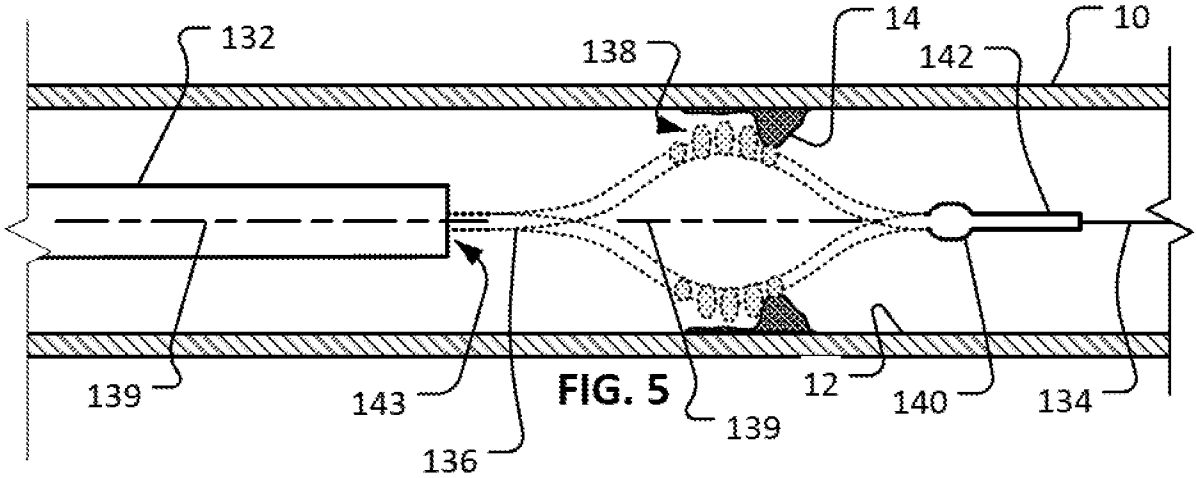


FIG. 5

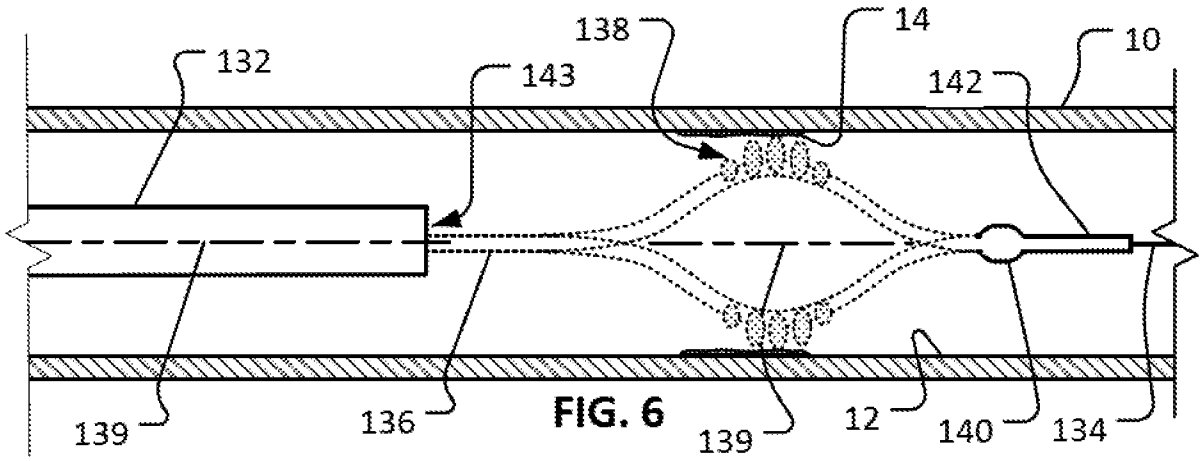


FIG. 6

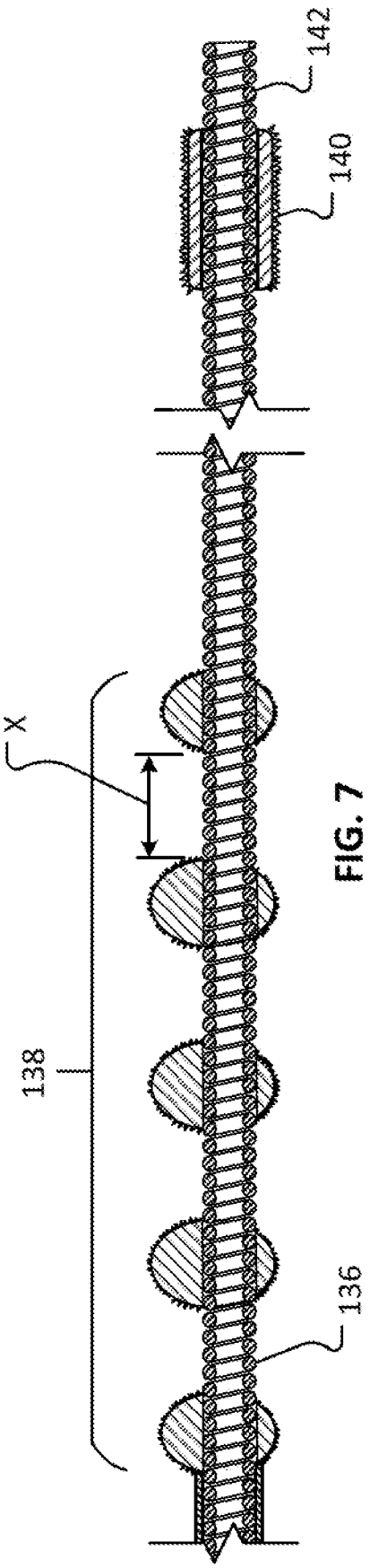

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FIG. 7

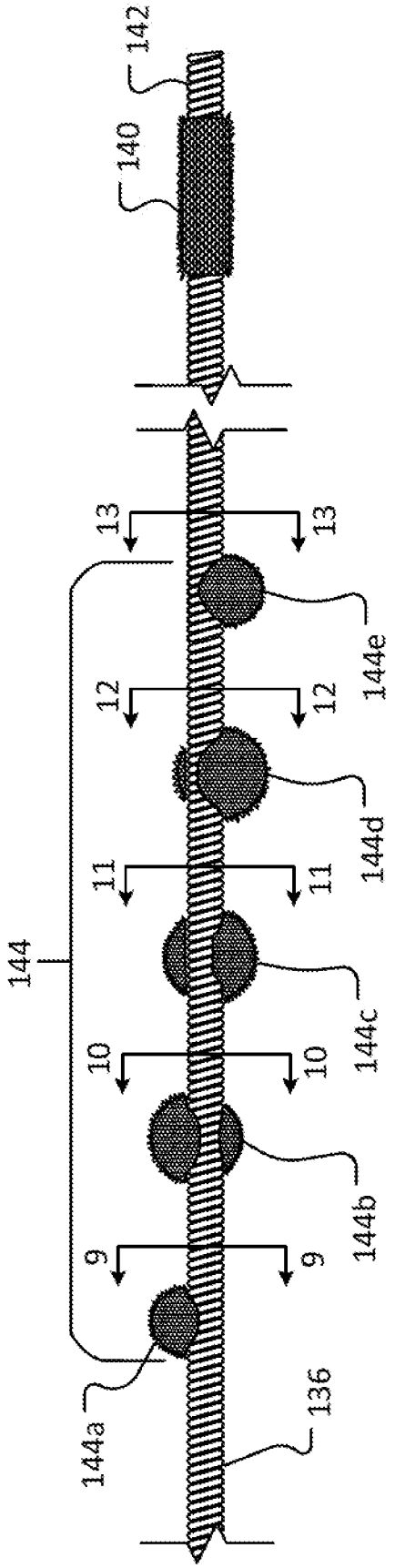

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144e
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144d
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144c
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144b
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144a
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FIG. 8

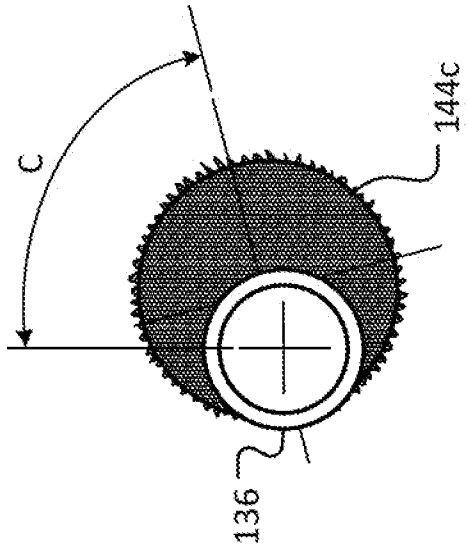


FIG. 11

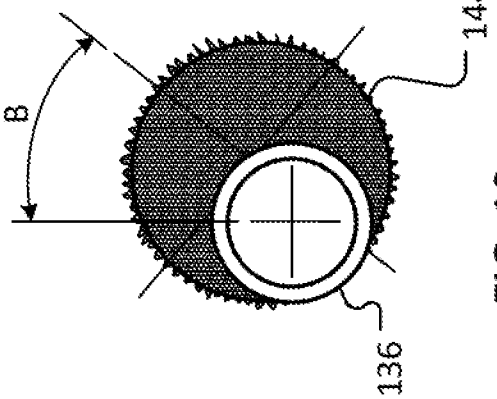


FIG. 10

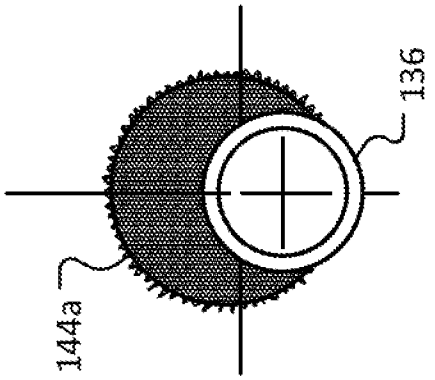


FIG. 9

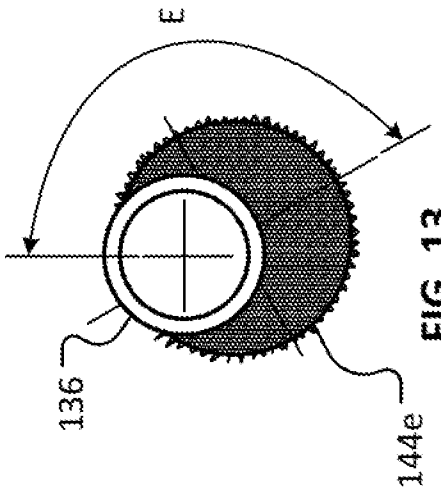


FIG. 13

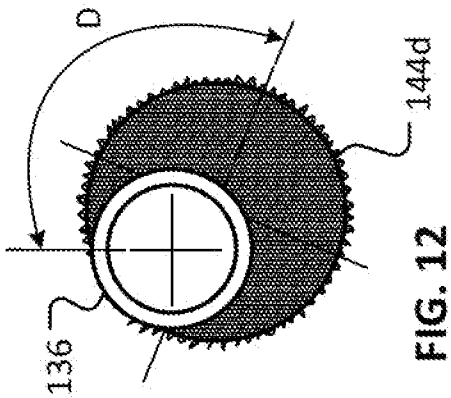


FIG. 12

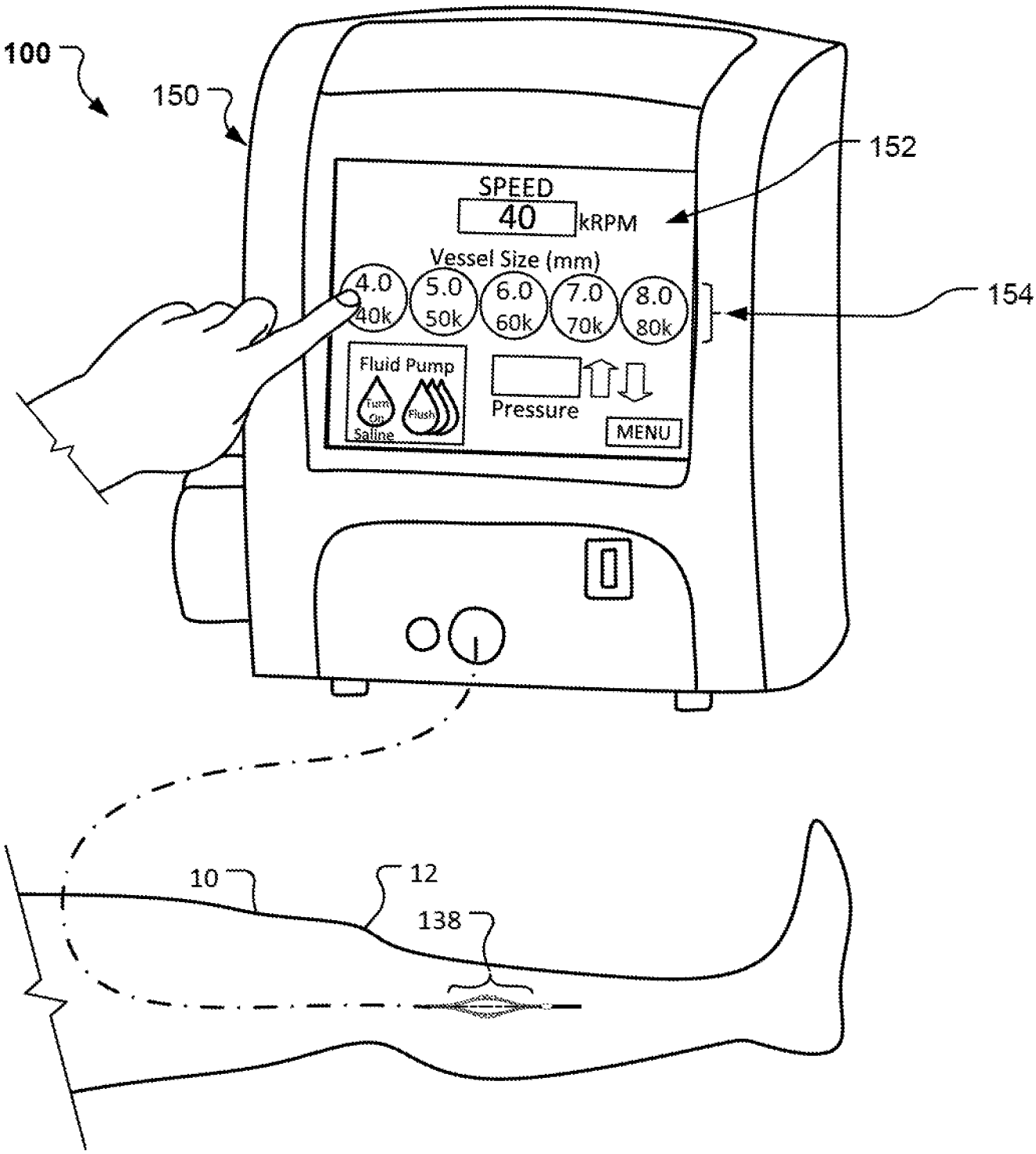

100
150
152
154
SPEED
40
kRPM
Vessel Size (mm)
4.0
40k
5.0
50k
6.0
60k
7.0
70k
8.0
80k
Fluid Pump
Turn On
Flush
Saline
Pressure
MENU
10
12
138

FIG. 14

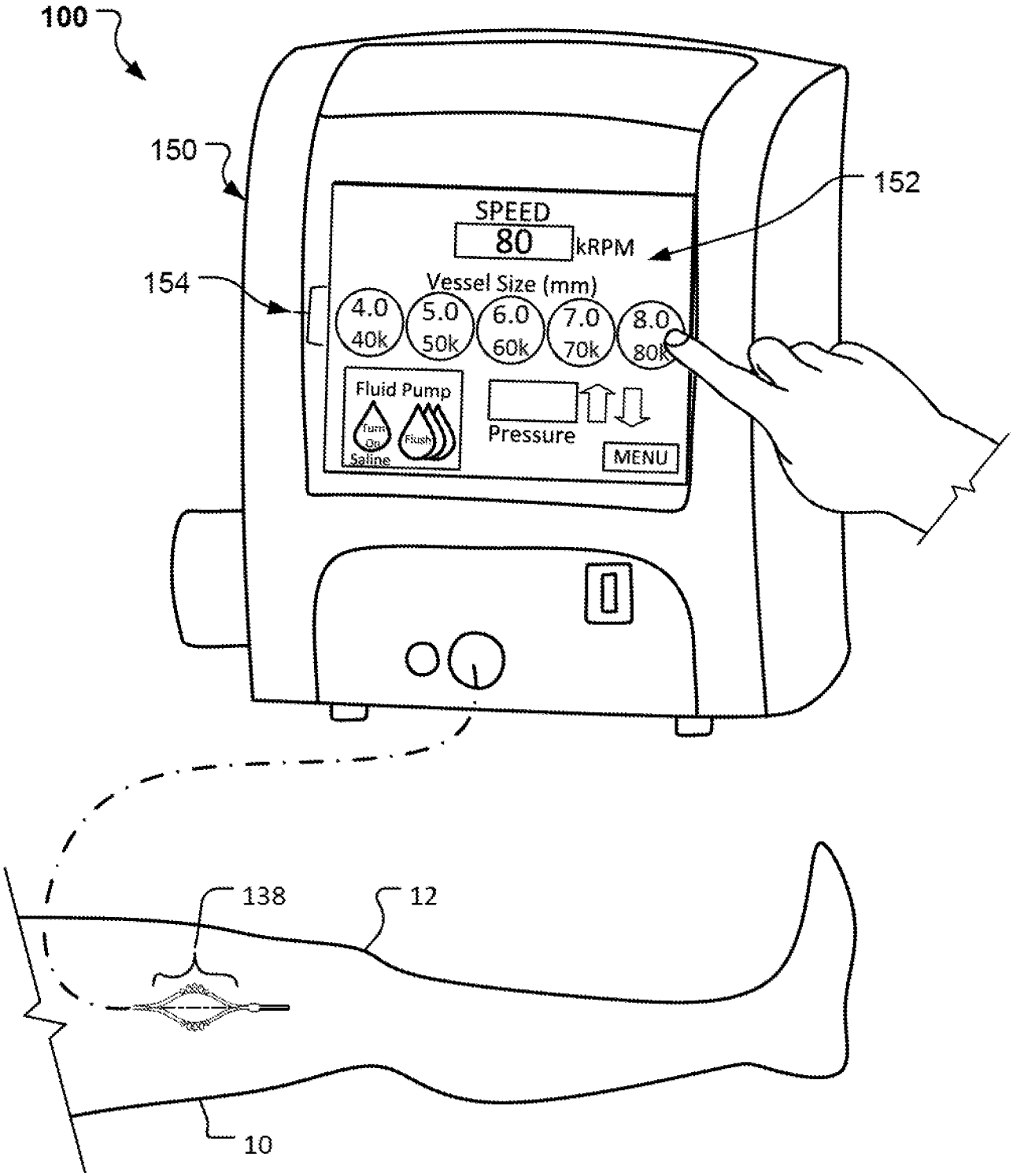

100
150
152
154
SPEED
80
kRPM
Vessel Size (mm)
4.0
40k
5.0
50k
6.0
60k
7.0
70k
8.0
80k
Fluid Pump
Turn On
Flush
Saline
Pressure
MENU
138
12
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FIG. 15

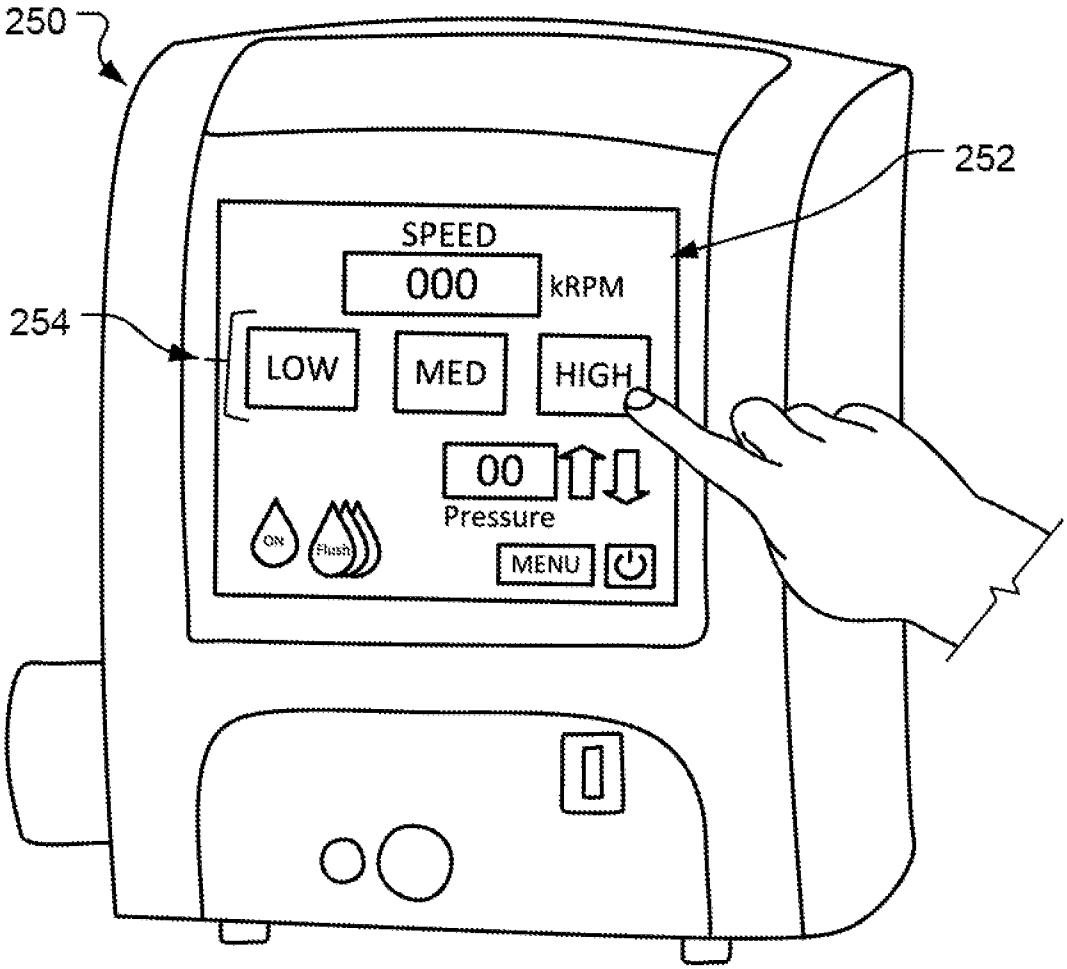


FIG. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/019238

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/22; A61B 17/32; A61B 17/3205; A61B 17/3207 (2018.01)
CPC - A61B 17/3205; A61B 17/3207; A61B 17/320758; A61B 2017/320766 (2018.02)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 604/93.01; 604/264; 604/523; 606/159 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2015/0196320 A1 (CARDIO FLOW INC.) 16 July 2015 (16.07.2015) entire document	1-3, 8-10, 18, 19, 21
Y	US 2014/0081298 A1 (CAMBRONNE) 20 March 2014 (20.03.2014) entire document	1-3, 8-10, 18, 19, 21
Y	US 2008/0161840 A1 (OSIROFF et al) 03 July 2008 (03.07.2008) entire document	18, 19

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 April 2018	08 MAY 2018
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/019238

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-7, 11-17
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.