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United States Patent Application Publication 20250261965
Kind Code A1
Publication Date August 21, 2025
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Atherectomy Devices and Methods

Abstract

Rotational atherectomy devices and systems can remove or reduce stenotic lesions in blood vessels by rotating an abrasive element within the vessel. The abrasive element can be attached to a distal portion of an elongate flexible drive shaft that extends from a handle assembly.

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Family ID: **1000008576647**

Appl. No.: **19/191602**

Filed: **April 28, 2025**

Related U.S. Application Data

parent US continuation 18816314 20240827 parent-grant-document US 12310617 child US 19191602
parent US continuation 18440651 20240213 parent-grant-document US 12096956 child US 18816314
parent US continuation 18386124 20231101 parent-grant-document US 11931065 child US 18440651
parent US continuation 18231998 20230809 parent-grant-document US 11839400 child US 18386124
parent US continuation 18132728 20230410 parent-grant-document US 11759229 child US 18231998
parent US continuation 16827105 20200323 parent-grant-document US 11627983 child US 18132728
parent US continuation 16198425 20181121 parent-grant-document US 10639064 child US 16827105

parent US continuation 16197125 20181120 parent-grant-document US 10639063 child US 16198425
parent US continuation 15091919 20160406 parent-grant-document US 10639062 child US 16197125

Publication Classification

Int. Cl.: **A61B17/3207** (20060101); **A61B17/00** (20060101); **A61B17/22** (20060101); **A61B17/32** (20060101)

U.S. Cl.:

CPC **A61B17/320758** (20130101); A61B2017/00057 (20130101); A61B2017/00075 (20130101); A61B2017/00553 (20130101); A61B2017/00557 (20130101); A61B2017/00778 (20130101); A61B2017/22069 (20130101); A61B2017/320004 (20130101); A61B2017/320008 (20130101); A61B2017/320766 (20130101)

Background/Summary

CLAIM OF PRIORITY [0001] This application is a continuation of U.S. application Ser. No. 18/816,314, filed on Aug. 27, 2024, which is a continuation of U.S. application Ser. No. 18/440,651 filed on Feb. 13, 2024 (now U.S. Pat. No. 12,096,956), which is a continuation of U.S. application Ser. No. 18/386,124 filed on Nov. 1, 2023 (now U.S. Pat. No. 11,931,065), which is a continuation of U.S. application Ser. No. 18/231,998 filed on Aug. 9, 2023 (now U.S. Pat. No. 11,839,400), which is a continuation of U.S. application Ser. No. 18/132,728 filed on Apr. 10, 2023 (now U.S. Pat. No. 11,759,229), which is a continuation of U.S. application Ser. No. 16/827,105 filed on Mar. 23, 2020 (now U.S. [0002] U.S. Pat. No. 11,627,983), which is a continuation of U.S. application Ser. No. 16/198,425 filed on Nov. 21, 2018 (now U.S. Pat. No. 10,639,064), which is a continuation of 16/197,125 filed on Nov. 20, 2018 (now U.S. Pat. No. 10,639,063), which is a continuation of U.S. patent application Ser. No. 15/091,919 filed on Apr. 6, 2016 (now U.S. Pat. No. 10,639,062), the entire contents of which are hereby incorporated by reference.

TECHNICAL FIELD
[0003] 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
[0004] Atherosclerosis, the clogging of arteries with plaque, is often a cause 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.
[0005] 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.
[0006] 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

[0007] Some embodiments of rotational atherectomy systems described herein can remove or reduce stenotic lesions in blood vessels by rotating an abrasive element to abrade and breakdown the lesion. In some embodiments, the abrasive element is attached to a distal portion of an elongate flexible drive shaft that extends from a handle assembly. In particular embodiments, the handle assembly includes a rotatable turbine member that drives rotation of the drive shaft (for example, in response to pressurized gas or other fluid being controllably delivered to act on the turbine member). In various embodiments, the turbine member is rotatably attached to a carriage that is longitudinally translatable in relation to a housing of the handle assembly (so that the turbine member translates longitudinally with the carriage relative to the housing). Optionally, the handle assembly can include a latch mechanism that can be actuated to allow the carriage to translate to a first position (e.g., a proximal-most position in some embodiments described below) relative to the housing. The first position of the carriage may be a guidewire advancing/withdrawing position in that, while the carriage is in the first position, a guidewire pathway is opened so that a guidewire can be slidably passed through the handle assembly and a lumen of the drive shaft. In some cases, while the carriage is shifted away from the first position (e.g., not in the proximal-most position in some embodiments described below) to an operative position, the guidewire pathway is closed by a seal that hinders liquid egress from a proximal end of the drive shaft.

[0008] In one implementation, a rotational atherectomy device includes: an elongate flexible drive shaft comprising a torque-transmitting coil (the drive shaft defining a central lumen and a longitudinal axis); an abrasive element attached to a distal portion of the drive shaft such that a center of mass of the abrasive element is offset from the longitudinal axis; a turbine member coupled to a proximal portion of the drive shaft such that rotation of the turbine member rotates the drive shaft about the longitudinal axis; and an adjustable seal positioned proximally of the turbine member to hinder liquid egress from a proximal end of the central lumen. The adjustable seal has a self-closing portion that is openable to slidably receive a guidewire through the adjustable seal and that is closable to provide a seal of the proximal end of the central lumen.

[0009] Such a rotational atherectomy device may optionally include one or more of the following features. The rotational atherectomy device may also include a handle assembly in which the turbine member is housed. The rotational atherectomy device may also include a sheath having a proximal end attached to the handle assembly. The sheath may define a sheath lumen therethrough in which the drive shaft is slidably disposed. In some embodiments, the sheath includes an inflatable member surrounding a distal end portion of the sheath. The inflatable member may define one or more perfusion openings configured to allow fluid flow between a proximal end of the inflatable member and a distal end of the inflatable member. The rotational atherectomy device may also include a carriage to which the turbine member is coupled. In some embodiments, the carriage is longitudinally translatable in relation to a housing of the handle assembly. Such longitudinal translations of the turbine member may result in corresponding longitudinal translations of the drive shaft.

[0010] In another implementation, a rotational atherectomy device includes: a handle assembly; an elongate flexible drive shaft comprising a torque-transmitting coil extending from the handle assembly (the drive shaft defining a central lumen and a longitudinal axis); an abrasive element attached to the drive shaft such that a center of mass of the abrasive element is offset from the longitudinal axis; a turbine member disposed within the handle assembly and coupled to the drive shaft such that rotation of the turbine member drives rotation of the drive shaft about the longitudinal axis; and a valve coupled to the handle assembly to control rotation of the turbine member between a rotationally stopped state and a rotationally moving state.

[0011] Such a rotational atherectomy device may optionally include one or more of the following features. The rotational atherectomy device may also include a carriage to which the turbine member is rotatably attached. In some embodiments, the carriage may be longitudinally translatable in relation to a housing of the handle assembly. In particular embodiments, the valve may be coupled to the carriage. The valve may be spring biased to a closed configuration resulting in the turbine member being in the rotationally stopped state. In some cases, the valve may be manually actuatable to an open configuration resulting in the turbine member being in the rotationally moving state. The rotational atherectomy device may also include a sheath having a proximal end attached to the handle assembly. Such a sheath may define a sheath lumen therethrough in which the drive shaft is slidably disposed. The sheath may include an inflatable member surrounding a distal end portion of the sheath. In some embodiments, the inflatable member may define one or more perfusion openings configured to allow fluid flow between a proximal end of the inflatable member and a distal end of the inflatable member.

[0012] In another implementation, a rotational atherectomy device includes: a handle assembly including a housing; an elongate flexible drive shaft comprising a torque-transmitting coil extending from the housing (the drive shaft defining a central lumen and a longitudinal axis); an abrasive element attached to the drive shaft such that a center of mass of the abrasive element is offset from the longitudinal axis; a turbine member disposed within the housing and coupled to the drive shaft such that rotation of the turbine member rotates the drive shaft about the longitudinal axis; a carriage to which the turbine member is rotatably attached, wherein the carriage is longitudinally translatable in relation to the housing; and a latch mechanism coupled to the housing. Activation of the latch mechanism allows the carriage to translate to a first position in which the handle assembly positions the drive shaft to receive or withdrawn a guidewire.

[0013] Such a rotational atherectomy device may optionally include one or more of the following features. When the carriage is located in the first position, an access port defined by the housing may be in fluid communication with the central lumen of the drive shaft. When the carriage is shifted away from the first position, an access port defined by the housing may be disconnected from fluid communication with the central lumen of the drive shaft. The first position may be a proximal-most position of the carriage. When the carriage is located in the proximal-most position and the latch mechanism is deactivated, the carriage may be detained in the proximal-most position. The rotational atherectomy device may also include a valve coupled to the carriage and operable to direct fluid to the turbine member for driving rotation of the turbine member and the drive shaft.

[0014] In another implementation, a rotational atherectomy system includes a rotational atherectomy device and a controller operatively connected with the rotational atherectomy device. The rotational atherectomy device includes: a handle assembly including a housing; an elongate flexible drive shaft comprising a torque-transmitting coil extending from the housing (the drive shaft defining a central lumen and a longitudinal axis); an abrasive element attached to the drive shaft such that a center of mass of the abrasive element is offset from the longitudinal axis; a sheath having a proximal end attached to the housing, the sheath defining a longitudinal sheath lumen therethrough in which the drive shaft is slidably disposed; a turbine member disposed within the housing and coupled to the drive shaft such that rotation of the turbine member rotates the drive shaft about the longitudinal axis; an optical sensor configured for detecting rotation of the turbine member; and a carriage to which the turbine member is rotatably attached, wherein the carriage is longitudinally translatable in relation to the housing. The controller is configured for supplying a pressurized gas for rotating the turbine member. In some embodiments, the controller will not supply the pressurized gas unless the optical sensor is in electrical communication with the controller.

[0015] Such a rotational atherectomy system may optionally include one or more of the following features. In some embodiments, the controller will not supply the pressurized gas unless a pressure of a flush fluid supplied to the sheath lumen is above a threshold limit value.

[0016] In another implementation, a method of performing a rotational atherectomy is provided. The method includes: (i) advancing a drive shaft of a rotation atherectomy device along a guide wire so that an eccentric abrasive element of the drive shaft is directed toward a targeted vessel (the drive shaft comprising torque-transmitting coil extending from a handle assembly and being configured to rotate in response to rotation of a turbine member housed within the handle assembly); (ii) withdrawing the guidewire from a proximal end of the central lumen of the drive shaft and through an adjustable seal positioned proximal of the turbine member (the adjustable seal having a self-closing portion that shifts from an open configuration to a closed configuration that provides a seal); and (iii) after withdrawing the guidewire from the drive shaft and through the adjustable seal, rotating the turbine member coupled to the proximal portion of the drive shaft to drive rotation of the drive shaft about a longitudinal axis of the drive shaft.
[0017] In another implementation, another method of performing a rotational atherectomy is provided. The method includes: advancing a drive shaft assembly of a rotation atherectomy device along a guide wire disposed within a vasculature of the patient so that a distal end of the drive shaft assembly is advanced toward the targeted lesion. The drive shaft assembly includes: a sheath comprising an elongate tubular member defining a lumen therethrough and an inflatable member disposed about a distal end portion of the tubular member; a torque-transmitting coil slidably disposed within the lumen and extending distally from a handle assembly (the torque-transmitting coil configured to rotate in response to rotation of a turbine member housed within the handle assembly); and one or more abrasive elements attached to a distal end portion of the torque-transmitting coil. The method also includes: inflating the inflatable member while the inflatable member is positioned at the targeted lesion (wherein the inflating results in compression of the targeted lesion); and rotating the turbine member to drive rotation of the torque-transmitting coil such that the one or more abrasive elements contact the targeted lesion.
[0018] 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 after the guidewire is withdrawn from the drive shaft (and, optionally, from the handle assembly too). Accordingly, in some embodiments the handle assemblies provided herein include features that allow the drive shaft to be positioned over a guidewire, and that allow the guidewire to be retracted from the drive shaft prior to rotational operations of the drive shaft. In addition, a seal mechanism is provided in particular embodiments that seals the proximal end of the drive shaft lumen after the guidewire has been retracted. Rotational operations of the drive shaft without engagement with a guidewire provides operational advantages such as, but not limited to, providing greater flexibility of the drive shaft, and reducing frictional resistance.
[0019] 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.
[0020] Third, some embodiments of the rotational atherectomy devices and systems include a controller that interfaces with a handle assembly. The controller can be operable, for example, for supplying compressed gas (or other power source) for the turbine member of the handle assembly, and to adjustably control the rotational speed of the turbine member. In some embodiments, the controller can include one or more fail-safe mechanisms that discontinue/prevent the supply of the compressed gas (or other power source) for the turbine member in particular circumstances. For example, in some embodiments the controller will supply the compressed gas to the turbine

member (or otherwise drive rotation of the drive shaft) only if a sensor device configured to detect the rotation speed of the turbine member or drive shaft is in electrical communication with the controller. In another example, in various embodiments the controller will supply the compressed gas to the turbine member (or otherwise drive rotation of the drive shaft) only if a detected fluid pressure of a sheath flush fluid (to be delivered into the sheath that carries the drive shaft) is above a threshold limit. Such fail-safe mechanism can, in particular implementations, advantageously maintain safe and effective performance of the rotational atherectomy system.
[0021] 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

DESCRIPTION OF DRAWINGS
[0022] FIG. **1** is a perspective view of an example rotational atherectomy system in accordance with some embodiments.
[0023] FIG. **2** shows an example rotational atherectomy device in use within a target vessel that includes a lesion. An abrasive element of the rotational atherectomy device is being rotated at a first longitudinal position.
[0024] FIG. **3** shows the rotational atherectomy device of FIG. **2** with the abrasive element being rotated at a second longitudinal position that is distal of the first longitudinal position.
[0025] FIG. **4** shows the rotational atherectomy device of FIG. **2** with the abrasive element being rotated at a third longitudinal position that is distal of the second longitudinal position.
[0026] FIG. **5** is a schematic diagram of an example rotational atherectomy system including a drive shaft with an abrasive element, a handle assembly, and a controller.
[0027] FIG. **6** shows the schematic diagram of FIG. **5** with a carriage of the handle assembly and the abrasive element in distal-most positions.
[0028] FIG. **7** shows the schematic diagram of FIG. **5** with the carriage of the handle assembly and the abrasive element in positions that are proximal of the positions shown in FIG. **6**.
[0029] FIG. **8** shows the schematic diagram of FIG. **5** with the carriage of the handle assembly and the abrasive element in proximal-most positions.
[0030] FIG. **9** shows an exploded perspective view of an example handle assembly in accordance with some embodiments.
[0031] FIG. **10** shows a longitudinal cross-sectional view of the handle assembly of FIG. **9**.
[0032] Like reference symbols in the various drawings indicate like elements.
DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS
[0033] Referring to FIG. **1**, in some embodiments a rotational atherectomy system **100** for removing or reducing stenotic lesions in blood vessels can include 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 control the rotational atherectomy procedure.
[0034] 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 the handle assembly **110**. The flexible drive shaft **136** is slidably and rotatably disposed within a lumen of the sheath **132**. Hence, as described further below, during a rotational atherectomy procedure the flexible drive shaft **136** is in motion (e.g., rotating and translating) while the sheath **132** is generally stationary.
[0035] In the depicted embodiment, an inflatable member **134** surrounds a distal end portion of the

sheath **132**. The inflatable member **134** is selectively expandable between a deflated low-profile configuration and an inflated deployed configuration. In some embodiments, the inflatable member **134** can be selectively inflated or deflated by injecting or extracting an inflation fluid (e.g., saline) into the inflatable member **134**. Accordingly, in some embodiments the sheath **132** includes an inflation lumen through which the inflation fluid can pass (to and from the inflatable member **134**). The inflatable member **134** 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 **134** can be inflated so that the outer diameter of the inflatable member **134** contacts the wall of the vessel. In that arrangement, the inflatable member **134** advantageously stabilizes the drive shaft assembly **130** in the vessel during the rotational atherectomy procedure.

[0036] In some embodiments, the inflatable member **134** or the sheath **132** may define one or more passageways that facilitate on-going perfusion in the vessel even while the inflatable member **134** is expanded and in contact with the wall of the vessel. Such passageways may be around the perimeter of the inflatable member **134**, through the inflatable member **134** in one or more areas within the periphery defined by the inflatable member **134**, or through the sheath **132**.

[0037] 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 inflatable member **134** such that the distal end portion of the driveshaft **136** is exposed (i.e., not within the sheath **132**). The exposed distal end portion of the driveshaft **136** includes one or more abrasive elements **138**, a 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** between the inflatable member **134** and the distal stability element **140**. 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**. The distal drive shaft extension portion **142** extends distally from the distal stability element **140** and terminates at a free end.

[0038] 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** have a center of mass that is axially offset from central longitudinal axis of the drive shaft **136**. As the drive shaft **136** is rotated about its longitudinal axis, centrifugal force will cause the one or more abrasive elements **138** to follow a transverse circular orbit around the longitudinal axis. The orbiting one or more abrasive elements **138** will contact the stenotic lesion to ablate the lesion to a reduced size. The 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 further below, contemporaneous with the rotation of the drive shaft **136**, the drive shaft **136** can be translated along the longitudinal axis of the drive shaft **136**. Hence, lesions can be ablated radially and longitudinally by virtue of the orbital rotation and translation of the one or more abrasive elements **138**, respectively.

[0039] 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** 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 abrasive elements **138**. In this embodiment, the drive shaft **136** comprises one or more helically wound wires (or filars). 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.

[0040] In this embodiment, the drive shaft **136** has a hollow core. That is, the drive shaft **136** defines a longitudinal lumen running therethrough. The lumen can be used to slidably receive a guidewire 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.

[0041] In some embodiments, the drive shaft **136** includes a 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 at least a portion of drive shaft **136** (e.g., a distal portion of the drive shaft **136** extending from the free end to a location proximal to the inflatable member **134**). In some embodiments, a portion of the drive shaft **136** is uncoated (e.g., from the location proximal to the inflatable member **134** to the handle **110**). 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 coated portions of the drive shaft **136**.

[0042] 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 the 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**.

[0043] In the depicted embodiment, the distal stability element **140** is a 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 in relation to the center of mass of the one or more abrasive elements **138**.

[0044] 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 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 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**.

[0045] Still referring to FIG. **1**, the one or more abrasive elements **138**, which may also be referred to as a burr, 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 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, six, seven, eight, or more than eight 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 are smaller in diameter than the three inner abrasive elements.

[0046] The center of mass of the one or more abrasive elements **138** is offset from the longitudinal axis of the drive shaft **136**. Therefore, as the eccentric one or more abrasive elements **138** are rotated in 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 drive shaft **136** using a biocompatible adhesive, welding, press fitting, and the like. 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).

[0047] 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 1:1, 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.

[0048] 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**. 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.

[0049] The carriage assembly **114** includes a valve actuator **116**. In the depicted embodiment, the valve actuator **116** is a button that can be depressed to actuate a compressed gas control valve (FIGS. **9** and **10**) 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 (FIG. **10**) 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**).

[0050] 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 (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.

[0051] In the depicted embodiment, the handle assembly **110** also includes a carriage docking latch actuator **118**. As described further below, the carriage docking latch actuator **118** can be actuated (e.g., depressed) to allow the carriage assembly **114** to translate to a proximal-most position in which an access port **120** defined by the housing **112** is put into fluid communication with the lumen of the drive shaft **136**. In that proximal-most position, a guidewire can be readily installed or removed from the lumen of the drive shaft **136** via the access port **120**. While the carriage assembly **114** is in the proximal-most position, the carriage docking latch actuator **118** can be released and the carriage assembly **114** will remain releasably latched in the proximal-most position. Thereafter, actuation of the carriage docking latch actuator **118** will allow the carriage assembly **114** to be translated distally away from the proximal-most position. While the carriage assembly **114** is located in any position other than the proximal-most position, the carriage docking latch actuator **118** will not allow the carriage assembly **114** to be moved into the proximal-most position unless the carriage docking latch actuator **118** is actuated.

[0052] Still referring to FIG. **1**, the rotational atherectomy system **100** also includes the controller **150**. 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**.

[0053] 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 a user interface **152**. If a speed adjustment is desired, the clinician can increase or decrease the rotational speed of the drive shaft **136** using an RPM adjustment device **154** on the controller **150**. 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 the drive shaft **136**.

[0054] 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.

[0055] Referring also to FIGS. **2-4**, 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**.

[0056] Briefly, in some implementations the following activities may occur to achieve the deployed arrangement shown in FIGS. **2-4**. An introducer sheath (not shown) can be percutaneously advanced into the vasculature of the patient. A guidewire (not shown) 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 and other atherectomy system components during placement. Next, the rotational atherectomy system **100** can be inserted over the guidewire.

For example, an opening to the lumen of the drive shaft **136** at the distal free end of the drive shaft **136** can be placed onto the guidewire, and then the drive shaft assembly **130** and handle assembly **110** can be gradually advanced over the guidewire to the position in relation to the lesion **14** as shown. The inflatable member **134** is configured in its deflated, low-profiled configuration during the advancing. 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. Preferably, the carriage assembly **114** is latched in its proximal-most docking position during the advancement of the drive shaft assembly **130**, and handle assembly **110** over the guidewire. Eventually, after enough advancing, the proximal end of the guidewire will extend proximally from the handle assembly **110** (via the access port **120** defined by the handle housing **112**). Next, the guidewire can be withdrawn from the patient by pulling the guidewire out from the access port **120** defined by the handle housing **112**. After withdrawing the guidewire, the carriage docking latch actuator **118** can be activated to allow the carriage assembly **114** to move from its proximal-most position. The inflatable member **134** can be inflated so that it contacts the inner wall **12** of the vessel **10**. Then, the rotation and translational motions of the drive shaft **136** and one or more abrasive elements **138** (as depicted by FIGS. **2-4**) can be commenced to perform ablation of the lesion **14**.

[0057] In some implementations, prior to the ablation of the lesion **14** by the one or more abrasive elements **138**, the inflatable member **134** can be used as an angioplasty balloon. That is, sheath **132** can be advanced to a position that places the inflatable member **134** within the lesion **14**. The inflatable member **134** can then be 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, the inflatable member **134** 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 the inflatable member **134** or another balloon member associated with the drive shaft assembly **130** after the rotational atherectomy procedure is performed.

[0058] In some implementations, the guidewire is withdrawn completely out of the lumen of the drive shaft **136** prior to ablation of the lesion **14** (as described above). 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 the portion that is not subject to the significant orbital path in the area of the one or more abrasive elements **138**. After the guidewire is withdraw (fully or partially), the drive shaft **136** is then 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**.

[0059] Still referring to FIGS. **2-4**, 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 motion of a “jump rope.” As shown, some portions of the drive shaft **136** (e.g., a portion that is just distal of the inflatable member **134** 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**).

[0060] 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) along the longitudinal axis of the drive shaft **136** and the handle assembly **110** 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. **2-4**.

[0061] In some embodiments, the inflatable member **134** or the sheath **132** may define one or more passageways **141** that facilitate on-going perfusion in the vessel even while the inflatable member **134** is expanded and in contact with the wall of the vessel. Such passageways **141** may be around the perimeter of the inflatable member **134** (between the inflatable member **134** and the inner wall **12** of the vessel **10**), through the inflatable member **134** in one or more areas within the periphery defined by the inflatable member **134**, or through the sheath **132** (as depicted). In the depicted arrangement, blood in the vessel **10** can continue to flow by passing through the sheath **132** between the one or more passageways **141** and the distal end opening **143** of the sheath **132**.

[0062] Referring to FIG. **5**, the rotational atherectomy system **100** can be depicted schematically to allow for further description of the system **100**. Here, the sheath **132** is shown in partial longitudinal cross-section to allow for visualization of the features therein, and the boundary of the handle assembly **110** is shown in dashed lines. As described above, the rotational atherectomy system **100** includes the handle assembly **110**, the drive shaft assembly **130**, and the controller **150**.

[0063] The drive shaft assembly **130** includes the sheath **132** (with the inflatable member **136**) and the drive shaft **136**. The drive shaft **136** is slidably and rotatably disposed within a longitudinal lumen defined by the sheath **132**. A clearance exists between the drive shaft **136** and the inner diameter of the longitudinal lumen defined by the sheath **132**. A flush fluid can be supplied via a flush fluid port **133** into the clearance between the drive shaft **136** and the inner diameter of the longitudinal lumen defined by the sheath **132**. The flush fluid can provide lubrication and cooling between the drive shaft **136** and the inner diameter of the longitudinal lumen defined by the sheath **132**. Additionally, the flush fluid can inhibit blood ingress into the drive shaft assembly **130**. In some embodiments, the flush fluid port **133** can be used for aspiration.

[0064] The drive shaft assembly **130** also includes an inflation fluid port **131**. The inflation fluid port **131** is in fluid communication with a lumen defined within the wall of the sheath **132** and with the inflatable member **134**. Hence, by supplying a fluid via the inflation fluid port **131** (e.g., using a syringe, pump, etc.) the inflatable member **134** can be inflated to its expanded configuration. Conversely, by withdrawing a fluid via the inflation fluid port **131**, the inflatable member **134** can be deflated to its collapsed, low-profile configuration.

[0065] The proximal end of the sheath **132** is fixed to the housing **112** of the handle assembly **110**. In some embodiments, pig tails are coupled to the inflation fluid port **131** and or the flush fluid port **133**.

[0066] The handle assembly **110** includes the turbine member **119**. The turbine member **119** can be driven by compressed gas supplied through a valve **126** and a nozzle **128**. The turbine member **119**, valve **126**, and nozzle **128** are mounted to the carriage assembly **114** (FIG. **1**). The turbine member **119** rotates on bearings **117**.

[0067] In the depicted configuration, the valve **126** is closed. Therefore, the turbine member **119** and the drive shaft **136** are not rotating in the depicted configuration.

[0068] The handle assembly **110** also includes an RPM sensor **120**. In some embodiments, the RPM sensor **120** is an optical sensor that detects the passage of each vane of the turbine member **119** as the turbine member **119** is rotating.

[0069] In the depicted embodiment, a proximal end portion of the drive shaft **136** is coupled with the turbine member **119** using an intermediary tubular member **113**. The tubular member **113** can be a stainless steel tube, for example. In some embodiments, the proximal end portion of the drive shaft **136** is bonded within a lumen of the intermediary tubular member **113** using an adhesive (e.g., a cyanoacrylate type of adhesive, and the like). A seal **135** exists between the outer diameter of the intermediary tubular member **113** and the inner diameter of the proximal end of the sheath **132**. The seal **135** inhibits the egress of the flush fluid supplied via the flush fluid port **133**.

[0070] The arrangement of the proximal end portion of the drive shaft **136**, the intermediary tubular member **113**, and the turbine member **119** is such that an opening to the lumen of the drive shaft **136** is located proximal of the turbine member **119**. An adjustable seal **121** is positioned at the location of the opening. The adjustable seal **121** includes a self-closing portion. While the self-closing portion is closed, the adjustable seal **121** hinders liquid egress from the proximal end of the lumen defined by the drive shaft **136** (and the lumens defined by the intermediary tubular member **113** and the turbine member **119**). While the self-closing portion is opened, a guidewire can be slidably received through the adjustable seal **121**, and into the lumens defined by the proximal end portion of the drive shaft **136**, the intermediary tubular member **113**, and the turbine member **119**. The operations of the adjustable seal will be described further below (in reference to FIG. **8**).

[0071] Referring to FIG. **6**, the valve **126** can be opened by actuation of the valve actuator **116**, resulting in flow of compressed gas from the controller **150**, through the valve **126** and the nozzle **128**, and rotation of the turbine member **119**. The rotation of the turbine member **119**, in turn, results in a rotation of the drive shaft **136** as depicted by arrow **137**. The clinician operator can view the measured RPM of the turbine/drive shaft via the user interface **152**, and adjust the speed of the rotation via the RPM adjustment device **154** on the controller **150**.

[0072] Additionally, the clinician operator can translate the carriage assembly **114** (FIG. **1**) and the drive shaft **136** as depicted by arrow **115**. In the depicted arrangement, the carriage assembly **114** has been translated to a distal-most position.

[0073] Referring also to FIG. **7**, the clinician operator can also translate the carriage assembly **114** (FIG. **1**) and the drive shaft **136** (as depicted by arrow **115**) to a proximal position. In some cases, the clinician operator may oscillate the carriage assembly **114** between the distal position of FIG. **6** and the proximal position of FIG. **7** (or to one or more intermediate positions therebetween) multiple times while the drive shaft **136** is rotating so as to ablate a lesion.

[0074] Referring to FIG. **8**, the carriage assembly **114** (FIG. **1**) can also be translated to a proximal-most position as illustrated. While the carriage assembly **114** is located in the proximal-most position (in relation to the housing **112** of the handle assembly **110**), a guidewire can be readily withdrawn from (or inserted into) the rotational atherectomy system **100**.

[0075] To facilitate positioning of the carriage assembly **114** in the proximal-most position, the clinician operator first actuates the carriage docking latch actuator **118**. Then, while the carriage docking latch actuator **118** is actuated, the carriage assembly **114** can be translated to the proximal-most position. In some embodiments, unless the carriage docking latch actuator **118** is actuated the carriage assembly **114** is mechanically prevented from translating to the proximal-most position. In some embodiments, while the carriage assembly **114** is in the proximal-most position, the carriage assembly **114** is releasably latched in the proximal-most position. A second actuation of the carriage docking latch actuator **118** can unlatch the carriage assembly **114** so that it can be translated distally away from the proximal-most position.

[0076] In the depicted embodiment, the act of positioning of the carriage assembly **114** in the proximal-most position results in forcing a seal puncture member **124** distally into engagement with the adjustable seal **121**. Said another way, the seal puncture member **124** penetrates the self-closing portion of the adjustable seal **121** when the carriage assembly **114** is translated to the proximal-most position. A lumen defined by the seal puncture member **124** becomes aligned with (and in fluid communication with) the lumen defined by the drive shaft **136**. Therefore, in that arrangement a passageway is created from the access port **120** defined in the proximal end of the housing **112** to the lumen of the drive shaft **136**.

[0077] While the carriage assembly **114** is located in the proximal-most position, a guidewire can be readily withdrawn from (or inserted into) the rotational atherectomy system **100**. For example, when installing the rotational atherectomy system **100** over a guidewire, the proximal end of the guidewire can first be threaded into the open distal tip of the drive shaft **136**. Then the drive shaft assembly **130** (and handle assembly **110**) can be pushed distally over the guidewire. Eventually, as the drive shaft assembly **130** (and handle assembly **110**) continue to be pushed distally over the

guidewire, the proximal end of the guidewire will emerge from the access port **120** defined in the proximal end of the housing **112**. That is the case because, while the carriage assembly **114** is located in the proximal-most position, a passageway is opened all the way from the distal tip of the drive shaft **136** to the access port **120** defined in the proximal end of the housing **112**. To remove the guidewire from engagement with the rotational atherectomy system **100**, while the carriage assembly **114** is located in the proximal-most position the guidewire can be pulled proximally out from the access port **120** defined in the proximal end of the housing **112**. After withdrawing the guidewire from the drive shaft **136** (through the adjustable seal **121**), the rotational atherectomy system **100** can be operated by supplying compressed gas to the turbine member **119** to drive the rotation of the drive shaft **136**.
[0078] Referring to FIGS. **9** and **10**, the handle assembly **110** is illustrated in exploded and longitudinal cross-sectional views for additional visibility of the components of the handle assembly **110**. The components and functionality of the handle assembly **110** have been described above in reference to FIGS. **1-8**.
[0079] 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.

Claims

1. (canceled)
2. A method of rotational atherectomy comprising: advancing into a vessel at least one eccentric diamond-coated element fixedly mounted to a distal end portion of the torque-transmitting coil, wherein the torque-transmitting coil is slidably and rotatably disposed within a lumen of a sheath such that said at least one eccentric diamond-coated element is positioned distally of a distal end of the sheath, and wherein the torque-transmitting coil is coupled to a rotational atherectomy control handle configured to control rotation of the torque-transmitting coil, the rotational atherectomy control handle including: a handle housing having a front housing portion coupled to the sheath and a rear housing portion, the handle housing containing a slidable carriage that is coupled with the torque-transmitting coil, the slidable carriage being slidably translatable in a longitudinal direction relative to both the front housing portion of the handle housing and the sheath so as to longitudinally translate the torque-transmitting coil relative to both the front housing portion of the handle housing and the sheath; a user interface button configured to activate rotation of the torque-transmitting coil and being mounted with the slidable carriage such that both the user interface button and the slidable carriage are simultaneously translatable in the longitudinal direction while the user interface button is accessible along the upper side of the handle housing; a carriage lock actuator that is movable relative to the handle housing and is configured to releasably lock the slidable carriage in a locked position relative to the handle housing; a guidewire access port positioned at the rear housing portion of the handle housing; and a fluid delivery tube connected to the front housing portion of the handle housing at a location distal of the user interface button and proximal of the sheath, wherein the fluid delivery tube is in fluid communication with the lumen of the sheath; adjusting the carriage lock actuator so that the slidable carriage is unlocked from the locked position relative to the handle housing; and moving the slidable carriage and the user interface button mounted with the slidable carriage relative to the handle housing while the depressible button is in a depressed state to activate rotation of the torque-transmitting coil within the lumen of the sheath.
3. The method of claim 2, controlling the rotation of the torque-transmitting coil according to a speed control setting while the user interface button is in the depressed state.

4. The method of claim 3, wherein a control unit is configured to drive rotation of a rotatable member that is contained in the handle housing and that is coupled with the torque-transmitting coil so that the torque-transmitting coil rotates according to said speed control setting.
5. The method of claim 3, wherein the control unit is configured to drive rotation of the torque-transmitting coil only if a sensor configured to detect a rotation speed of the torque-transmitting coil is in electrical communication with the control unit.
6. The method of claim 3, wherein the control unit is configured to drive rotation of the torque-transmitting coil only if a fluid is delivered through the fluid delivery tube into the lumen of the sheath.
7. The method of claim 4, wherein the control unit is positioned external to the handle housing.
8. The method of claim 2, wherein after said adjusting the carriage lock actuator so that the slidable carriage is unlocked, the slidable carriage is manually translatable during rotation of the torque-transmitting coil so that the at least one eccentric diamond-coated element fixedly mounted to the distal end portion of the torque-transmitting coil is simultaneously movable both in longitudinal translation and in an orbital path.
9. The method of claim 2, wherein the at least one eccentric diamond-coated element fixedly mounted to the distal end portion of the torque-transmitting coil comprises an array of at least three same-shaped eccentric diamond-coated elements.
10. The method of claim 9, further comprising a distal concentric element fixedly mounted to the distal end portion of the torque-transmitting coil at a location that is distally spaced apart from a distal-most eccentric diamond-coated element in the array of at least three same-shaped eccentric diamond-coated elements.
11. The method of claim 10, wherein the distal concentric element comprises a metallic cylindrical element mounted to the torque-transmitting coil and axially aligned with the longitudinal axis of the torque-transmitting coil.
12. The method of claim 11, wherein the metallic cylindrical element has an axial length that is greater than each of the at least three same-shaped eccentric diamond-coated elements.
13. The method of claim 2, wherein a distal extension portion of the torque-transmitting coil extends distally of the at least one eccentric diamond-coated element fixedly mounted to the distal end portion of the torque-transmitting coil.
14. The method of claim 2, further comprising inserting a guidewire through the guidewire access port.
15. The method of claim 2, wherein the at least one eccentric diamond-coated element comprises a metallic burr welded to one or more filars along the distal end portion of the torque-transmitting coil.
16. The method of claim 2, wherein the torque-transmitting coil comprises a coating along at least a portion of an exterior of the torque-transmitting coil.
17. The method of claim 2, wherein the rotational atherectomy control handle further comprises a rotatable member positioned within the handle housing and coupled with the torque-transmitting coil.
18. The method of claim 17, wherein after said adjusting the carriage lock actuator so that the slidable carriage is unlocked, the slidable carriage is configured to longitudinally translate both the torque-transmitting coil and the rotatable member relative to the front housing portion of the handle housing.
19. The method of claim 17, wherein the rotatable member is a turbine member.
20. The method of claim 2, wherein the user interface button is a depressible button along an upwardly extending knob.
21. The method of claim 2, wherein while the depressible button is in the depressed state to activate rotation of the torque-transmitting coil, the torque-transmitting coil rotates at a rotational speed of 20,000 rpm to 160,000 rpm.