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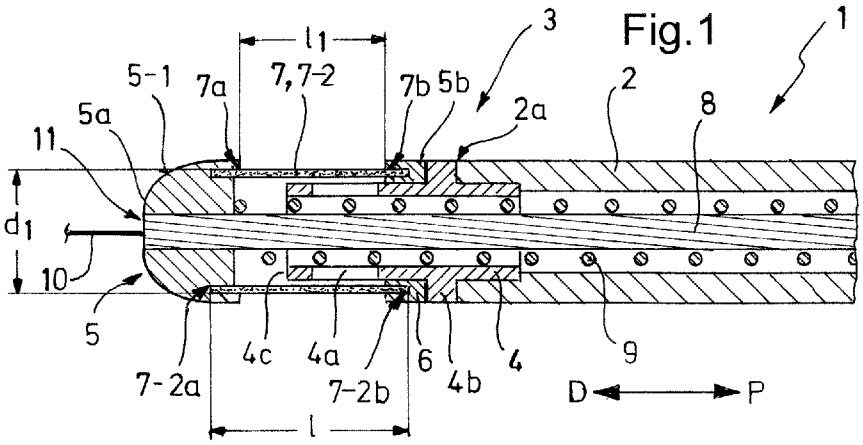
(54) Title: ATHERECTOMY CATHETER AND ATHERECTOMY SYSTEM

Fig.1



(57) Abstract: The disclosure relates to a catheter (1) comprising a tube (2) having a proximal and a distal tube end (2a) and a distal head (3) protruding from the distal tube end (2a) in the distal direction (D). The distal head (3) comprises a stator (4) which is stationary relative to the tube (2) and connected to the distal tube end (2a), and a rotor (5) which is rotatable relative to the stator (4) and to the tube (2), and has a proximal end (5b) and a distal tip (5a). The rotor (5) is located outside the stator (4), and the stator (4) and the rotor (5) are configured such that the rotor (5) is rotatable at a speed of at least 5.000 rpm relative to the stator (4). The rotor (5) comprises a bearing (6) at the proximal end (5b) of the rotor for rotatable support relative to the stator (4), the distal tip (5a) comprising at least partially an abrasive surface (5-1) for removing clot and/or calcifications from a vessel wall. A functional section (7) is configured such that the rotor (5) can assume a low-profile configuration in which the functional section (7) is substantially straight and has a first diameter (d1) and a first length (l1), and a large-profile configuration in which the functional section has a second length (l2) and at least in one part a second diameter (d2), wherein the first diameter (d1) is smaller than the second diameter (d2), and the first length (l1) is longer than the second length (l2), wherein the catheter is configured such that transition from the low-profile configuration to the large-profile configuration is initiated by a reduction of the length from the first length to the second length, and such that said transition represents, at the same time, an enlargement from the first diameter to the second diameter.

[Continued on next page]

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STRAUB MEDICAL AG

Atherectomy Catheter and Atherectomy System

Background

In atherectomy procedures, it may be desired to increase the lumen of a vessel, i.e. the cross-section of the vessel (also referred to as the so-called luminal gain). It may be necessary during a procedure to change the catheter to a bigger size, i.e. use a larger head/tip of a catheter for a subsequent pass, so as to increase the luminal gain. For example, a smaller access puncture may be preferable in terms of closure after the procedure or because of restrictions on access dimensions, e.g. due to scarring. For various reasons, it may be desired or necessary to use a relatively small catheter size for access and/or different catheter sized during the same procedure, with different head/tip sizes.

Summary of the Invention

The present disclosure provides an atherectomy catheter having a functional section that can selectively assume a low-profile configuration and a protruding/extended/enlarged, i.e. large-profile configuration. The low-profile configuration has a lower profile than the large-profile configuration. Accordingly, the large-profile configuration has a larger profile than the low-profile configuration.

An atherectomy catheter of the disclosure comprises a tube having a proximal and a distal tube end, and a distal head protruding from the distal tube end in the distal direction, wherein the distal head comprises a stator which is stationary relative to the tube and connected to the distal tube end, and a rotor which is rotatable relative to the

stator and to the tube and has a proximal end and a distal tip. The rotor is at least partially located outside the stator or the stator is at least partially received inside the rotor (but this may not be necessary). The stator and the rotor are configured such that the rotor is rotatable at least at a speed of 5000 rpm relative to the stator. The rotor comprises a bearing, a distal tip and a functional section. The bearing is provided, optionally at the proximal end of the rotor, for rotatable support relative to the stator. The distal tip may optionally comprise at least partially an abrasive surface for removing clot and/or calcifications from a vessel wall. The functional section is configured such that the rotor can assume a low-profile configuration in which the functional section has a first diameter and a first length, and a large-profile configuration in which the functional section has a second length and at least in one part a second diameter, wherein the first diameter is smaller than the second diameter, and the first length is greater than the second length.

The catheter may be configured such that the transition from the low-profile configuration to the large-profile configuration is initiated by a reduction of the length from the first length to the second length and such that said transition represents, at the same time, and enlargement from the first diameter to the second diameter.

Alternative or additional wording for the last section of claim 1 may be as follows: The catheter is configured such that the functional structure is urged/forced to shorten the length of the functional section and to bend/bulge outwardly into the large-profile configuration by retraction of an actuator (drive shaft) in the low-profile configuration.

In some embodiments, the distal tip is movable relative to the drive shaft along the distal/proximal, i.e. axial, direction. While the bearing remains at a constant axial

position (when comparing the low-profile and large-profile configurations, relative to the tube), the distal tip is distal to the bearing and is movable in the longitudinal direction. The bearing supports rotation of the rotor relative to the stator at high rotational speeds.

The functional section is configured accordingly. Specifically, the functional section of an atherectomy catheter of the disclosure is configured to selectively assume the low-profile configuration and the large-profile configuration. As such, the functional structure may be regarded as an expandable structure, as it can be expanded as to its diameter.

The invention is based on the idea of the inter-/counter-play between the diameter and the length of the functional section. For example, the larger the second diameter in the large-profile configuration, the shorter the second length. The second length and the second diameter are inversely related.
Hence, the shorter the length of the functional section, the larger the radial extension of the functional section. Accordingly, the radial dimension/extension, e.g. the diameter, of the head/functional section is indirectly coupled to the longitudinal dimension/length of the functional section. The functional section may be regarded as expandable (in the radial direction). The radial expansion may be continuous along the circumference. In other words, the same angular expansion may be obtained.

In particular, the present disclosure may be characterised by the functional section and the high-speed rotation of the rotor, and optionally the abrasive surface of the distal tip of the rotor.

As such, the catheter may be suitable for various vessel diameters, i.e. for versatile use. Further, if the

requirements as to the catheter size change during a procedure, the catheter can be adjusted by way of the selection of the configuration, so that a change of the catheter may possibly be avoided. Accordingly, an additional luminal gain can be achieved without the need to change the catheter or possibly to increase the passes made.

The catheter of the disclosure may allow to adjust the diameter of the functional section in the large-profile configuration in real time, and specifically adjust it to the anatomy in which the rotor of the atherectomy catheter is at one moment in time during a procedure. This provides the advantage that the catheter does not need to be confined to predetermined radial dimensions. Rather, according to need, the second diameter of the large-profile configuration can be adapted as needed.

At the same time, the large-profile configuration may represent a robust and strong structure so as to allow for removal of calcifications, not only of soft tissue clot. In this regard, in particular an abrasive coating, e.g. a diamond coating on the rotor may be beneficial.

The low-profile configuration and the large-profile configuration relate to the radial extension of the functional section (in the transverse direction), i.e. in the direction orthogonal to the distal/proximal direction.

There may be more than a single large-profile configuration, but multiple large-profile configurations, wherein the protruding bulge increases in its size towards a "maximum" large-profile configuration.

The transition between the low-profile and the large-profile configurations may be continuous. As such, a stepless change/shift from the low-profile configuration to the large-profile configuration may be possible. Vice versa, this

applies to a transition from the large-profile configuration to the low-profile configuration. Changing between the low-profile configuration and the large-profile configuration may be regarded as a reversible procedure.

The rotor may be regarded as a rotor head. During a procedure, the functional section, which is part of the rotor, rotates at a relatively high speed, namely at a speed of at least 5000 rpm relative to the stator and to the remaining catheter. Upon rotation of the rotor relative to the stator, no shearing effect may occur between the rotor and the stator, at least in some embodiments.

The second diameter is larger than the first diameter, and this may be supported by the stator being at least partially beneath the rotor, for the following reason: Once the functional section is shortened, the "surplus" part of the functional section may be prone to folding/bending. As the functional section is, on the inner side supported by the stator, the stator may hinder the "surplus" of the functional section to bend inwardly. Therefore, the overlap of the functional section on the stator may support the desired bending/bulging towards the outside, so as to increase the diameter of the functional section in the large-profile configuration.

The tube may comprise a braiding, so as to form a braided catheter shaft. The tube material may be … a combination of a stiffer outer layer (such as polyamide) and a friction reducing inner layer (such as PTFE or polyimide). A stainless steel or Aramid fibre braiding in between the other and inner layers may be provided. It may support the catheter in stiffness for better push and torque ability.

Optionally, the stator comprises at least one window for allowing for entry of clot and/or calcifications into the tube. The functional section may have openings to allow clot

and/or calcifications to pass through. The stator and the rotor may be configured such that the at least one window of the stator and the openings of the rotor intermittently overlap during rotation of the rotor so as to allow for aspiration of clot and/or calcifications from outside of the rotor to the inside of the stator and the tube. By way of the intermittent overlap between the opening in the stator and openings in the rotor, a suction port is created, so that suction of clot/calcifications through the rotor and stator can take place.

Optionally, the functional section is configured to be engaged with the vessel wall and/or to scratch or abrade clot/calcifications from the vessel wall. Specifically, an outer surface of the rotor may, during rotation, be in close contact with the vessel wall.

Optionally, the catheter further comprises a drive shaft, which may be a torque cable, extending along the tube and connected to the distal tip of the rotor for rotatably driving the rotor. The rotor may be driven by the drive shaft. At its proximal end, the torque cable may be connected at the proximal end of the catheter shaft to a drive motor. This allows for an efficient driving of the rotor.

Optionally, the drive shaft has a lumen to receive a guidewire. This allows for an over-the-wire atherectomy catheter.

Further optionally, the drive shaft may serve as an actuator for changing between the low-profile and large-profile configurations and/or wherein the catheter is configured such that retraction of the drive shaft in the proximal direction renders the functional section in the large-profile configuration and pushing of the drive shaft in the distal direction renders the functional section in the low-profile configuration. When pulling back the drive shaft/torque

cable, the low-profile configuration is changed to the large-profile configuration. The actuation includes an axial translation of torque cable. This may be initiated by the user/operator. Accordingly, a mechanically reliable configuration which may be easy to operate is obtained. In the low-profile configuration, the actuator may be in its distal position. In the large-profile configuration, the actuator may be in its proximal position.

When the driveshaft/torque cable is retracted, i.e. pulled by the user, the functional section is reduced as to its length, i.e. shortened, so that the distal tip of the rotor and the bearing are closer to each other and their distance is reduced. During a procedure, the driveshaft/torque cable may be advanced, i.e. pushed forward, so that the low-profile configuration is resumed.

Optionally, a helix may surround the drive shaft and/or may extend along an outer surface of the drive shaft. By way of the helix, clot and/or calcifications may be conveyed proximally. The helix may rotate together with the drive shaft. The helix may be provided on an outer surface of the torque cable/drive shaft. Rotation of the torque cable rotates the helix, which creates suction so as to aspirate atherosclerotic material, i.e. clot and/or calcifications. Hence, the helix serves for transport of clot and/or calcifications. As such, aspiration is created by the rotating helix, and represents an Archimedes screw to transport the material towards the proximal end of the catheter.

Optionally, an outer surface of the functional section is at least partially coated with an abrasive coating. By way of the abrasive coating, removal of clot and/or calcifications may be improved. Additionally or alternatively, an abrasive surface may be provided on the distal tip of the rotor.

Optionally, an outer surface of the stator is at least partially coated with a durable coating to reduce friction between the rotor and the stator. In some embodiments, the bearing is at least partially coated with such coating on a bearing surface. This may reduce wear. E.g., ADLC coating may be provided on stainless steel. The bearing may be located at the proximal end of the rotor and/or may be ring-shaped.

Optionally, the functional section may comprise a functional structure, optionally the functional structure comprising cutting edges configured to cut clot and/or calcifications from a vessel wall and/or the functional structure may be a metal structure.

Further optionally, the functional structure is inelastic, while allowing for bending, i.e. while being bendable. This means that the length of the functional structure remains constant.

In some embodiments, the functional structure may comprise metal, optionally memory metal, such as nitinol.
An advantage of using memory metal may be that … the characteristics (super elasticity) of this material may allow for better resistance to (constant) bending forces.

Optionally, a distal end of the functional structure is captured by the distal tip of the rotor (5) and/or a proximal end of the functional structure is captured by the bearing.

Optionally, the functional structure (section) may comprise struts, optionally woven and/or perforated struts. Further optionally, woven nitinol struts are comprised. Optionally, the struts of the functional structure are not movable relative to each other. The functional section (structure) and its struts may be inelastic, i.e. not resilient.

The struts may be provided in a pattern such that openings in the functional structure allow for clot and/or calcifications to pass through.

Optionally, the distal tip may be made of stainless steel and/or may be hood-shaped. Stainless steel may supply sufficient stiffness to the tip and may, at the same time, serve as an appropriate basis for the abrasive coating. The hood-shape of the tip may support passing of the catheter through an occlusion or vessel having a reduced diameter.

Optionally, the distal tip may comprise a through-hole for receiving the drive shaft and/or a guidewire. By way of the through-hole, the drive shaft can be connected to the distal tip of the rotor, so as to rotatably drive the rotor. Additionally or alternatively, a guidewire may extend through the through-hole, optionally through an inner lumen of the torque cable/drive shaft.

In some embodiments, the distal tip and the bearing are connected by means of the functional section. The functional section is positioned between the distal tip and the bearing of the rotor. More specifically, the functional section is provided proximal to the distal tip and distal to the bearing of the rotor.

In the low-profile configuration, the functional section may basically be cylindrical. In some embodiments, in the low-profile configuration, the functional section is substantially straight/extended. In this low-profile configuration, the functional section has its maximum length.

Optionally, in the large-profile configuration, the functional section comprises an outward bulge and/or at least in part, protrudes outwardly from the distal tip and or is bulged outwardly. By way of the protrusion of the functional section in the radial direction from the remaining rotor, the

luminal gain can be increased. The bulge may be formed in the centre of the functional section/structure in the longitudinal direction.

Optionally, the stator comprises an abutment, further optionally, a ring-shaped abutment, and the distal tube end abuts a proximal surface of the abutment, and the bearing abuts a distal surface of the abutment. By way of the abutment, improved connection between the distal tube end and the rotor, part of which is the bearing, is obtainable.

In some embodiments, the stator may comprise a stop against which an inner surface of e.g. the distal tip of the rotor abuts when the functional section is in the large-profile configuration. The stop may be a distal end of the stator. The distal tip of the rotor abuts the distal part of the stator when the functional section is brought into the large-profile configuration. In some embodiments, this may define the maximum diameter of the functional section in the large-profile configuration. Put differently, this may define the minimum length of the functional section. For example, the distal tip can be retracted by an operator until it abuts the stop, which defines the maximum retraction.

The present disclosure is also directed to an atherectomy system comprising a catheter of any of the preceding claims.

Brief Description of the Drawings

Figure 1 schematically depicts a cross-sectional view of a distal part of an atherectomy catheter in the low-profile configuration.

Figure 2 schematically depicts a cross-sectional view of distal part of an atherectomy catheter in the large-profile configuration.

Figure 3 schematically depicts a rotor of the disclosure.

Figure 4 schematically depicts an atherectomy system of the disclosure.

Detailed Description

Figure 1 depicts an atherectomy catheter 1 having a tube 2 having a proximal end and a distal end 2a. The catheter 1 further comprises a distal head 3 protruding from the distal tube end 2a in the distal direction D. The distal direction is opposite the proximal direction P. Both directions may be referred to as axial or longitudinal direction.

The distal head 3 comprises a stator 4 which is stationary relative to the tube 2 and connected to the distal tube end 2a, and a rotor 5. The stator 4 protrudes in the distal direction D from the distal tube end 2a. The rotor 5 is rotatable relative to the stator 4 and to the tube 2. The rotor 5 has a proximal end 5b and a distal tip 5a. The rotor 5 is located outside the stator 4. Hence, the stator is, at least partially, received inside the rotor 5. The stator 4 and the rotor 5 are configured such that rotor is rotatable at a speed of at least 5.000 rpm around the stator 4. By way of the rotation of the rotor 5, clot and/or calcifications can be removed, e.g. scratched, from a vessel wall (not shown). Hence, the outer surface of the rotor 5 may be considered to be in direct contact with a vessel (not shown) during a procedure.

The rotor 5 comprises a bearing 6, the distal tip 5a and a functional section 7. The bearing 6 is provided at a proximal end 5b of the rotor 5 and rotatably supports the rotor 5 relative to the stator 4. The distal tip 5a comprises an abrasive surface 5-1 to remove clot and/or calcifications from the vessel wall. Specifically, the abrasive surface may comprise a diamond coating. The abrasive surface may be directed in the distal direction D

and/or may be directed in a transverse direction orthogonal to the distal direction D. The longitudinal direction runs in between the distal and proximal directions.

The functional section 7 is configured such that the rotor 5 assumes a low-profile configuration or a large-profile configuration, per the user's choice based on the anatomy's requirements.

Specifically, in the low-profile configuration, which is shown in Figure 1, the functional section 7 is substantially straight and has a first diameter d1 and a first length l1. The large-profile configuration of the functional section 7 is shown in Figure 2, in which the functional section 7 has a second length l2 and at least in one part of the functional section a second diameter d2. The second diameter d2 is the maximum diameter of the functional section 7 at one moment in time. Hence, from one moment in time to another moment in time, the large-profile configuration and in particular the second diameter d2 may change, so that the second diameter d2 being the maximum diameter per moment in time may change over time. The first diameter d1 is smaller than the second diameter d2, and the first length l1 is longer than the second length l2. When comparing Figures 1 and 2, it is evident that the length l1 of the functional section 7 is longer than the length l2 of the functional section 7 in the large-profile configuration, wherein the diameter d1 in the low-profile configuration is smaller than the diameter d2 in the large-profile configuration. The catheter 1 is configured such that transition from the low-profile configuration, as shown in Figure 1, to the large-profile configuration, as shown in Figure 2, is initiated by a reduction of the length from the first length d1 to the second length d2, and such that the transition represents, at the same time, and enlargement from the first diameter d1 to the second diameter d2.

The functional section 7 comprises a functional structure 7-2. The functional structure 7-2 has a length l which remains the same in the low-profile and large-profile configurations. Specifically, the overall length of the functional structure 7-2 is the same in the large-profile configuration as well as in the low-profile configuration. The functional structure 7-2 is inelastic. As can be taken from Figure 1, in the low-profile configuration, the functional structure 7-2 (the functional section 7) is straight and extended. In Figure 2, however, the functional structure 7-2 (the functional section 7) has an outward bulge, so that the functional section 7 comprising the outward bulge has a shorter length l2. In the large-profile configuration, the functional section protrudes from the remaining catheter and forms an outward bulge. Specifically, in the large-profile configuration, the functional section protrudes from the remaining catheter 1, e.g. from the maximum diameter of the distal tip 5a in a radial/transverse direction. For example, the additional diameter in the large-profile configuration shown in Figure 2 corresponds to the difference between d2 and d1.

As shown in Figures 1 and 2, a distal end 7a of the functional structure 7-2 is captured by the distal tip 5a of the rotor 5. As the bearing 6 (e.g. a ring) captures a proximal end 7-2b of the functional structure, both ends of the functional structure 7-2 are captured by parts of the rotor.

The functional structure has a constant length l. In the low-profile configuration having a straight extension of the functional structure 7-2, the length l1 of the functional section may correspond to the length of the functional structure l without the distal and proximal ends of the functional structure which are covered by the outer surface of the rotor. The length l1/l2 of the functional section may be defined by the length of the functional structure l which can contribute to the function - which is the outer surface

of the functional structure 7 which is exposed by the remaining parts of the rotor 5.

Figures 1 and 2 show that the stator 4 comprises at least one window 4a for entry of clot and/or calcifications into the tube 2. Also the rotor 5 has openings 7-1, namely in the functional section 7. The openings 7-1 to allow clot and/or calcification to pass through. Once the window 4a in the stator and the openings 7-1 in the functional section of the rotor 5 overlap during rotation of the rotor 5, a suction opening allowing for aspiration of clot and/or calcifications inside the stator and the rotor is formed. The at least one window 4a of the stator 4 and the openings 7-1 of the rotor 5 intermittently overlap during rotation of the rotor 5.

This allows for direct aspiration of clot/calcifications, namely at the location at which the clot/calcification is removed. Possibly, the bulge of the functional structure 7-2 and the suction opening formed by the overlapping window 4a of the stator 4 and the openings 7-1 of the functional structure 7-2 are at the same angular/circumferential positions. This may be achieved if the metal struts 7-5 have openings inbetween, these openings serving as openings in the rotor 5.

Figures 1 and 2 show a drive shaft 8 representing a torque cable. The drive shaft 8 extends along the tube 2, i.e. in the longitudinal direction, and connects to the distal tip 5a of the rotor 5. The drive shaft 8 is driven by a motor 15 which is proximal to the proximal end of the catheter tube 2 and is thereby rotated. Accordingly, the drive shaft 8, which is connected to the rotor 5, rotatably drives the rotor 5.

The drive shaft 8 has a lumen to receive a guidewire 10. The drive shaft 8 and the guidewire 10 extend through a through-hole 11 formed in the distal tip 5a of the rotor 5. A helix

9 surrounds the drive shaft 8 and extends along an outer surface of the drive shaft 8 along the longitudinal direction.

The drive shaft 8 serves as an actuator for changing between the low-profile configuration of Figure 1 and the large-profile configuration of Figure 2. Specifically, the catheter 1 allows for retraction of the drive shaft 8 in the proximal direction P (longitudinal direction) so as to bring the functional section 7 in the large-profile configuration. Vice versa, advancing the drive shaft 8, i.e. pushing the drive shaft in the distal direction D, brings the functional section 7 in the low-profile configuration shown in Figure 2.

As indicated in Figure 3, the functional structure 7-2, which is comprised in the functional section 7, comprises a memory metal, such as Nitinol. The functional section, i.e. the functional structure 7-2, comprises struts 7-5. The struts 7-5 may be woven and/or perforated. The struts 7-5 comprise cutting edges 7-3 which are configured to cut clot and/or calcifications from the vessel wall (not shown). The functional structure 7-2 is inelastic and represents a metal structure. The metal structure has openings 7-1 as discussed above and cutting edges 7-4.

In Figure 3, the functional section 7, i.e. the functional structure 7-2, is in the low-profile configuration, which corresponds to Figure 1. The distal tip 5a of the rotor 5 has an abrasive surface 5-1, such as a diamond coating.

Multiple openings 7-1 are regularly distributed along the functional structure 7-2. At the edges of a strut 7-5 of the functional structure 7-2, a cutting edge 7-4 is formed. The cutting edges 7-4 are configured to engage the clot/calcifications in the vessel wall and act as cutters upon rotation of the rotor 5.

The bearing 6 is at least partially coated with ADLC on an inner bearing surface. The opposite part, namely the part of the stator 4 around which the rotor 5 and the bearing 6 rotate, may also comprise ADLC, so as to reduce wear and friction. The bearing 6 may be made of stainless steel.

The distal tip 5a may be made of stainless steel. As can be taken from the Figures, the distal tip 5a is hood-shaped. Specifically, the tip of the hood points in the distal direction D. This may help to advance the catheter 1 in the distal direction D.

The bearing 6 captures a distal end of the functional structure 7-2, wherein the distal tip 5a captures the proximal end of the functional structure 7-2. As such, the distal tip 5a and the bearing 6 are connected by means of the functional structure 7-2. As can be taken from Figures 1 and 3, in the low-profile configuration, the functional section 7 is basically cylindrical. On the other hand, in the large-profile configuration, as shown in Figure 2, the functional section 7 represents an outward bulge. The centre of the bulge may indicate the second diameter d2, i.e. the diameter of the functional section 2 in the large-profile configuration.

The stator 4 comprises an abutment 4b, as shown in Figures 1 and 2. The abutment 4b may be ring-shaped, and the distal tube end 2a abuts a proximal surface of the abutment 4b, while the bearing 6 abuts a distal surface of the abutment 4b. The abutment 4b may represent a proximal attachment or fixation of the rotor 5 relative to the catheter tube 2 as well as to the stator 4. The abutment 4b allows for fixing the proximal end of the rotor 5, while allowing for rotation of the rotor 5.

The stator 4 further comprises a stop 4c, which represents, as shown in Figures 1 and 2, a distal end of the stator 4.

The rotor 5, specifically an inner surface of a distal tip of the rotor 5, abuts against the stop 4c, when the functional section 7 is in the large-profile configuration or retracted so as to be brought in the large-profile configuration. Hence, the stop 4c may be seen as a delimiter for delimiting the maximum retraction of the torque cable 8 and, hence, for determining the minimum length l2 of the functional section in the large-profile configuration.

Figure 4 depicts an atherectomy system 12 of the disclosure. The atherectomy system 12 comprises the atherectomy catheter 1 as described above, as well as a handle 13 having a housing 14 accommodating the motor 15 for rotatably driving the drive shaft 8 of the catheter 1 at its proximal end. Fig. 4 also shows a collection bag 16 for collecting the removed clot/calcifications/bodily fluid and an optional foot switch 17 for controlling the system 12.

During a procedure, when crossing a lesion, the abrasive surface on the distal tip 5a may help to advance the catheter 1 in the longitudinal direction D. To increase the luminal gain, when the catheter 1 is stationary in the vasculature, the drive shaft 8 can be retracted gradually, i.e. a gradual movement to obtain the large-profile configuration, up to the maximum large-profile configuration. For example, during access into the vasculature, the low profile configuration may be beneficial, and during the procedure, the large-profile configuration (or successively larger diameters of large-profile configurations) may be useful. This transformation from the low-profile to the large-profile configuration can be achieved by initiating the longitudinal movement (retraction) of the drive shaft 8 by manipulation on the catheter handle 13.
When treating a chronic total occlusion (CTO), the catheter 1 may be used in a first step in its low-profile configuration to cross the lesion. In a second step of the procedure, the large-profile configuration may be used to achieve additional

luminal gain before subsequent treatments, such as balloon dilation or stenting.

Reference signs

1	atherectomy catheter
2	tube
2a	distal tube end
3	distal head
4	stator
4a	window
4b	abutment
4c	stop
5	rotor
5-1	abrasive surface
5a	distal tip of rotor
5b	proximal end of rotor
6	bearing
7	functional section
7a	distal end of functional section
7b	proximal end of functional section
7-1	opening
7-2	functional structure
7-2a	distal end of functional structure
7-2b	proximal end of functional structure
7-3	bulge
7-4	cutting edge
7-5	strut
8	drive shaft (torque cable)
9	helix
10	guidewire
11	through-hole
12	atherectomy system
13	handle
14	housing
15	motor
16	collection bag
17	foot switch
18	control unit

d1, d2 first, second diameter of functional section
l1, l2 first, second length of functional section
l length of functional structure

P proximal direction
D distal direction

Claims

1. Atherectomy catheter (1) comprising
a tube (2) having a proximal and a distal tube end (2a),
a distal head (3) protruding from the distal tube end (2a) in the distal direction (D),
the distal head (3) comprising
a stator (4) which is stationary relative to the tube (2) and connected to the distal tube end (2a),
a rotor (5) which is rotatable relative to the stator (4) and to the tube (2), and has a proximal end (5b) and a distal tip (5a),
wherein the rotor (5) is at least partially located outside the stator (4), and the stator (4) and the rotor (5) are configured such that the rotor (5) is rotatable at a speed of at least 5.000 rpm relative to the stator (4),
the rotor (5) further comprising
a bearing (6) for rotatable support of the rotor (5) relative to the stator (4), and
a functional section (7) configured such that the rotor (5) can assume a **low-profile configuration** in which the functional section (7) has a first diameter (d1) and a first length (l1), and a **large-profile configuration** in which the functional section has a second length (l2) and at least in one part a second diameter (d2), wherein the first diameter (d1) is smaller than the second diameter (d2), and the first length (l1) is longer than the second length (l2),
wherein the catheter is configured such that transition from the low-profile configuration to the large-profile configuration is initiated by a reduction of the length from the first length to the second length, and such that said transition represents, at the same time, an enlargement from the first diameter to the second diameter.

2. Atherectomy catheter (1) of claim 1, wherein

the stator (4) comprises at least one window (4a) for allowing for entry of clot and/or calcifications into the tube (2),

the functional section (7) has openings (7-1) to allow clot and/or calcifications to pass through, and

the stator (4) and the rotor (5) are configured such that the at least one window (4a) of the stator (4) and at least some of the openings (7-1) of the rotor intermittently overlap during rotation of the rotor (5), so as to allow for aspiration of clot and/or calcifications.

3. Atherectomy catheter (1) of claim 1 or 2, wherein the functional section (7) is configured to be engaged with the vessel wall and/or to scratch clot/calcifications from the vessel wall.

4. Atherectomy catheter (1) of any of the preceding claims, wherein the catheter (1) further comprises a drive shaft (8) extending along the tube (2) and connected to the distal tip (5a) of the rotor for rotatably driving the rotor (5).

5. Atherectomy catheter (1) of claim 4, wherein the drive shaft (8) has a lumen configured to receive a guidewire (10).

6. Atherectomy catheter (1) of claim 4 or 5, wherein the drive shaft (8) serves as an actuator for changing between the low-profile and large-profile configurations and/or wherein the catheter is configured such that retraction of the drive shaft (8) in the proximal direction (P) renders the functional section (7) in the large-profile configuration, and pushing of the drive shaft (8) in the distal direction (D) renders the functional section (7) in the low-profile configuration.

7. Atherectomy catheter (1) of any of the preceding claims, wherein a helix (9) at least partially surrounds the drive

shaft (8) and/or at least partially extends along an outer surface of drive shaft (8).

8. Atherectomy catheter (1) of any of the preceding claims, wherein an outer surface of the functional section (7) is at least partially coated with an abrasive coating and/or the distal tip (5a) comprising at least partially an abrasive surface (5-1) for removing clot and/or calcifications from a vessel wall.

9. Atherectomy catheter (1) of any of the preceding claims, wherein the bearing (6) is at least partially coated with ADLC and/or an outer surface of the stator (4) is at least partially coated with ADLC.

10. Atherectomy catheter (1) of any of the preceding claims, wherein the bearing (6) is located at the proximal end (5b) of the rotor (5) and/or is ring-shaped.

11. Atherectomy catheter (1) of claim 10, wherein the ring (6) is made of stainless steel.

12. Atherectomy catheter (1) of any of the preceding claims, wherein the functional section (7) comprises a functional structure (7-2), optionally wherein the functional structure (7-2) is inelastic.

13. Atherectomy catheter (1) of claim 12, wherein the functional structure (7-2) comprises cutting edges (7-3) configured to cut clot/calcifications from the vessel wall and/or the functional structure (7-2) being a metal structure.

14. Atherectomy catheter (1) of claim 12 or 13, wherein a distal end (7-2a) of the functional structure (7-2) is captured by the distal tip (5a) of the rotor (5) and/or a

proximal end (7-2b) of the functional structure (7-2) is captured by the bearing (6).

15. Atherectomy catheter (1) of any of the preceding claims 12 to 14, wherein the functional structure (7-2) comprises a metal, optionally memory metal, such as Nitinol.

16. Atherectomy catheter (1) of any of the preceding claims 12 to 15, wherein the functional structure (7-2) comprises struts (7-5), optionally woven and/or perforated struts, further optionally woven Nitinol struts (7-5).

17. Atherectomy catheter (1) of any of the preceding claims, wherein the distal tip (5a) of the rotor (5) is made of stainless steel and/or is hood-shaped.

18. Atherectomy catheter (1) of any of the preceding claims, wherein the distal tip (5a) comprises a through-hole (11) for receiving the drive shaft (8) and/or a guidewire.

19. Atherectomy catheter (1) of any of the preceding claims, wherein the distal tip (5a) and the bearing (6) are connected by means of the functional section (7).

20. Atherectomy catheter (1) of any of the preceding claims, wherein, in the low-profile configuration, the functional section (7) is basically cylindrical.

21. Atherectomy catheter (1) of any of the preceding claims, wherein, in the large-profile configuration, the functional section (7) comprises an outward bulge (7-3) and/or at least in part protrudes radially outwardly from the distal tip (5a) of the rotor (5) and/or is bulged outwardly.

22. Atherectomy catheter (1) of any of the preceding claims, wherein the stator (4) comprises an abutment (4b), which is optionally ring-shaped, wherein optionally the distal tube

end (2a) abuts a proximal surface of the abutment (4b), and/or the bearing (6) abuts a distal surface of the abutment (4b).

23. Atherectomy catheter (1) of any of the preceding claims, wherein the stator (4) comprises a distal stop (4c), against which the rotor (5), optionally an inner surface of the distal tip (5a) of the rotor (5), abuts in the large-profile configuration.

24. Atherectomy system (12) comprising the atherectomy catheter (1) of any of the preceding claims, a handle (13), a motor (15) for driving the drive shaft (8), and a control unit (18) for controlling the atherectomy system (12).

Fig.1

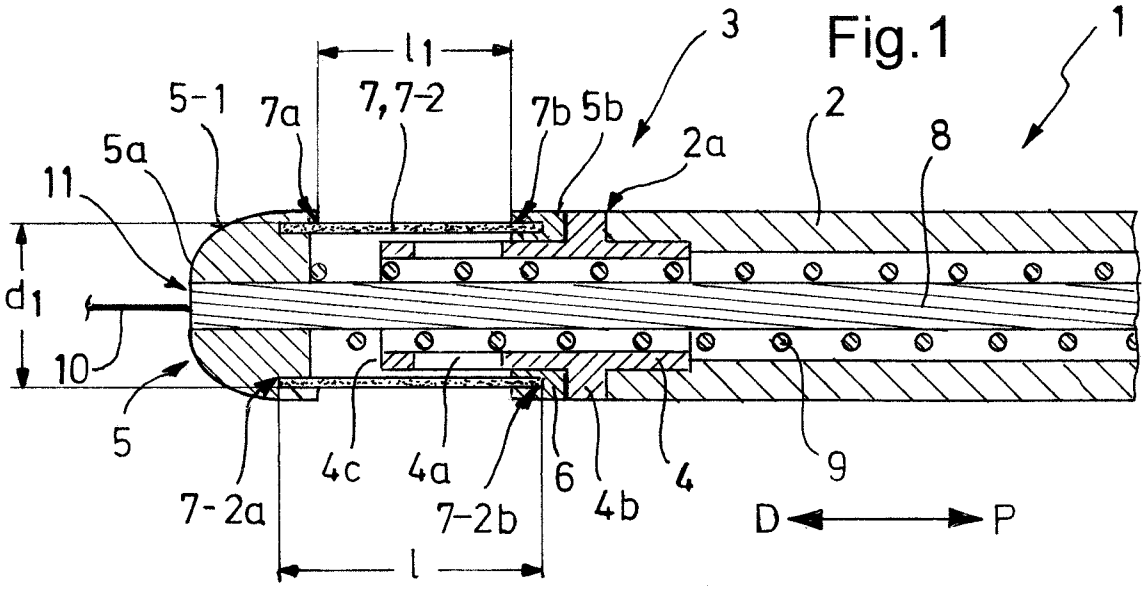


Fig. 2

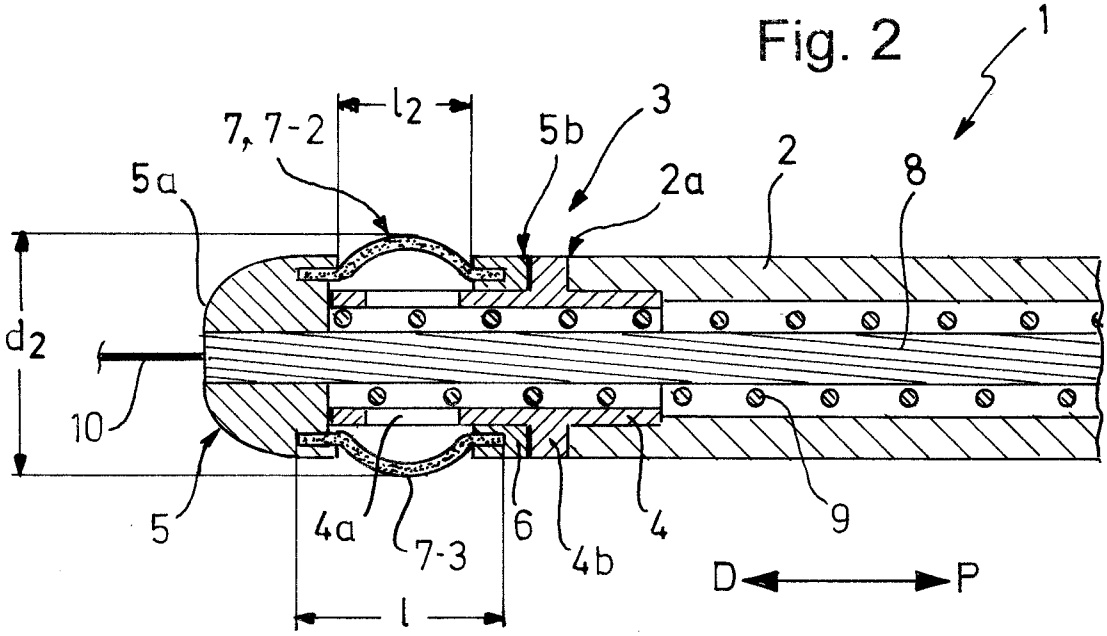


Fig. 3

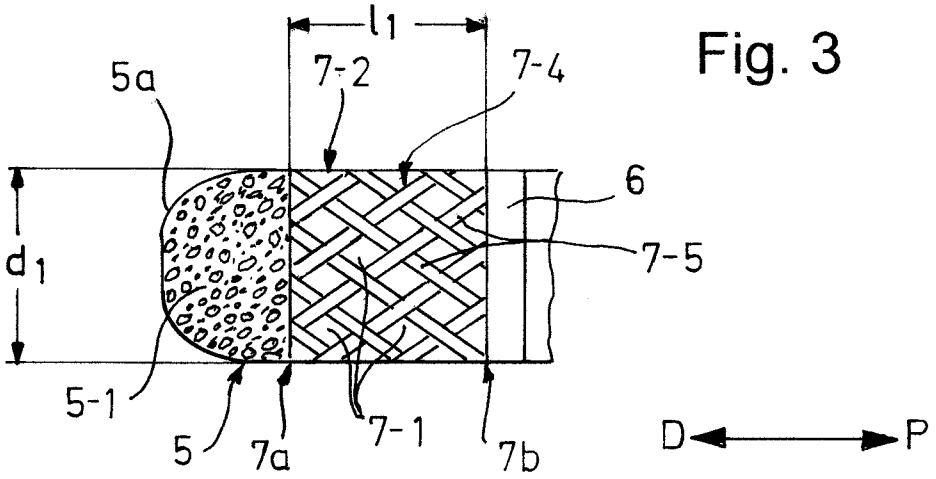
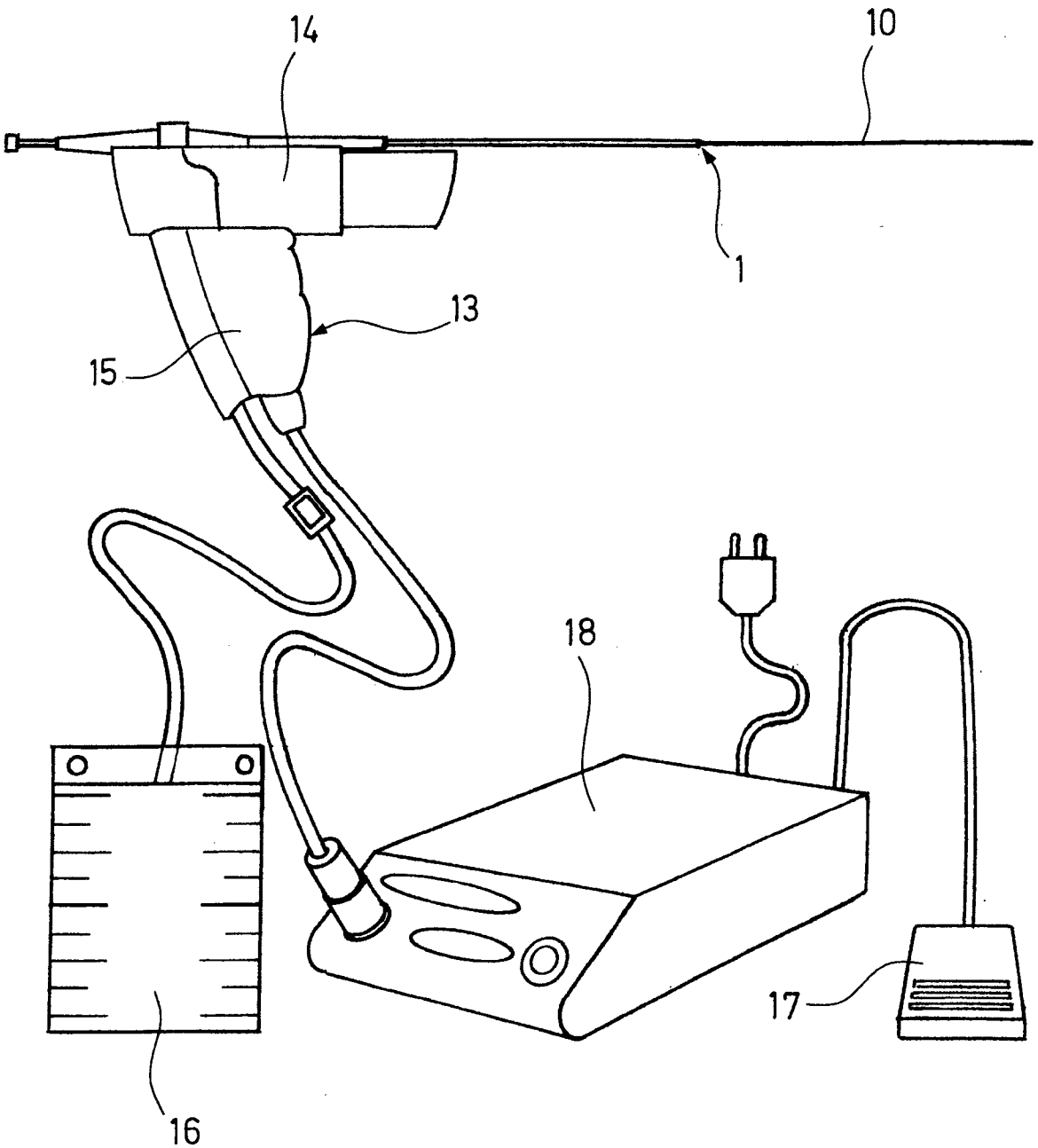


Fig. 4



INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2023/068207

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/3207
ADD. A61B17/32

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)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 836 868 A (RESSEMANN THOMAS V [US] ET AL) 17 November 1998 (1998-11-17) column 2, line 48 - column 4, line 16; figures 1-19 column 5, line 54 - column 42, line 14	1-24
A	EP 4 079 239 A1 (VETEX MEDICAL LTD [IE]) 26 October 2022 (2022-10-26) paragraph [0047] - paragraph [0113]; figures 1-18	1-24
A	US 2003/055445 A1 (EVANS MICHAEL A [US] ET AL) 20 March 2003 (2003-03-20) paragraph [0058] - paragraph [0067]; figures 1-18	1-24

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[x] Further documents are listed in the continuation of Box C.

[x] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 January 2024	29/01/2024

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2023/068207

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2006/229645 A1 (BONNETTE MICHAEL J [US] ET AL) 12 October 2006 (2006-10-12) paragraph [0062] - paragraph [0086]; figures 1-26	1-24

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