PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 :		(11) International Publication Number:
A61B 17/00	A1	WO 00/54659
		(43) International Publication Date: 21 September 2000 (21.09.00)

(21) International Application Number: PCT/US00/06494

(22) International Filing Date: 10 March 2000 (10.03.00)

(30) Priority Data:

60/124,419	15 March 1999 (15.03.99)	US
09/338,302	22 June 1999 (22.06.99)	US

(71) Applicant: PROLIFIX MEDICAL, INC. [US/US]; Suite 2, 680 West Maude Avenue, Sunnyvale, CA 94086 (US).

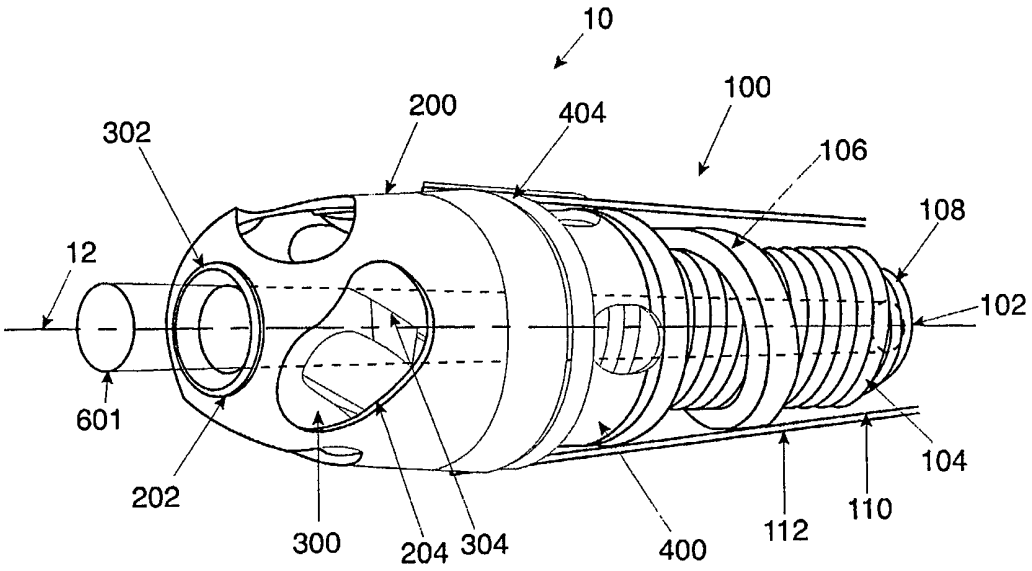
(72) Inventors: TO, John; 38158 Iris Court, Newark, CA 94560 (US). MCFANN, Tim; 7 No. View Way, Redwood City, CA 94062 (US). FORSTER, David; 630 Starhill Road, Woodside, CA 94062 (US).

(74) Agents: HESLIN, James, M. et al.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th floor, San Francisco, CA 94111 (US).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: SHIELDED ATHERECTOMY DEVICE



(57) Abstract

This invention is a traumatic arthro-ectomy device (10) having a shear body (300) contained within a substantially form fitting housing (200), the housing (200) having apertures (204) through which occlusive tissue may protrude into the interior of the housing (204), and be engaged by a rotating shearing body (300) within. The shearing body (300) has teeth (304), flutes which are helical in design, and have a cutting line.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

SHIELDED ATHERECTOMY DEVICE

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is a continuation-in-part of a regular U.S. Patent Application No. 09/338,302, filed June 22, 1999, which claims benefit under 35 USC §119(e) from U.S. Provisional Patent Applications Nos. 60/124,419, filed March 15, 1999, 60/120,663, filed February 19, 1999; and 60/113,651, filed December 23, 1998; the complete disclosures of which are hereby incorporated herein by reference in their entirety for all purposes.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to apparatus for treating and removing occluding material from a body lumen, such as blood vessels. In particular, the present invention relates to apparatus and methods for guided atherectomy, using a catheter having a shearing body, the shearing body being enclosed in a housing or screen.

2. Description of the Background Art

A number of methods and devices are currently available for removing stenotic or occluding material from a blood vessel, and for restoring adequate blood flow to the blood vessel. One common procedure is known as percutaneous transluminal angioplasty (PTA), in which a catheter that is provided with a dilatation balloon at its distal end is positioned in a blood vessel at the site of the stenosis. The balloon is then expanded to dilate the blood vessel in order to restore adequate blood flow to regions beyond the stenosis.

While often effective PTA suffers from certain limitations. For example, PTA can be effective only if the occluding material in the blood vessel has a sufficiently large opening to allow the balloon to be positioned inside the occluding material. Where the blood vessel is almost completely occluded, it is difficult if not impossible to position the balloon of a catheter inside the occluding material. In addition, PTA suffers from multiple intra-procedural and post-procedural problems: abrupt closure, elastic recoil, and restenosis. Abrupt closure is the rapid re-occlusion of the blood vessel within hours of the initial treatment. Abrupt closure can result from rapid thrombus formation which

occurs in response to injury of the vessel wall from the PTA procedure. Elastic recoil is the elastic recovery of the dilated vessel approaching its pre-procedural diameter. Restenosis is the re-narrowing of the blood vessel over the weeks or months following an initial apparently successful PTA procedure. Restenosis occurs in up to 50% of all PTA patients and results from smooth muscle cell proliferation and migration and remodeling.

To address the problems of abrupt closure, elastic recoil, and restenosis described above, PTA procedures have been followed by implanting vascular stents inside the blood vessel at the treatment site. These stents are thin-walled scaffolds which are expanded at the treatment site to act as a mechanical support for the luminal wall of the blood vessel, thereby inhibiting elastic recoil. Although the stent diminishes the contribution of remodeling to vessel narrowing, restenosis still occurs frequently at the stented regions of blood vessels. This is because most stents comprise an open lattice, and cell proliferation (often referred to as hyperplasia) can occur in the interstices between the support elements of the lattice. As a result, instead of forming a barrier to hyperplasia and restenosis, the stent can become embedded within an accumulated mass of thrombus and tissue, and the treatment site becomes stenosed again.

Because a stent is an open lattice or scaffold type device, the deployment of a guidewire through a stented region must be undertaken with particular care so the guidewire is not threaded through the open lattice of the stent. In such event the atherectomy device which travels down the path of the guidewire will be directed into the stent and do great damage to the stent, as well as traumatize the blood vessel. Assuming the guidewire is properly deployed in the blood vessel, the use of an atherectomy device inside stented region must be undertaken with particular care to avoid positioning the atherectomy device in proximity to the stent so as to damage the stent, and once again traumatize the blood vessel.

Treatment of an occluded stent faces all the difficulties discussed above with respect to treatment of initial occlusions and is further complicated by the need to avoid damaging the stent during the removal of the hyperplasia occluding material.

Devices such as rotational atherectomy devices (e.g., the Transluminal Extraction Catheter made by Interventional Technologies of San Diego, California, and the Rotablator, made by Boston Scientific of Bellevue, Washington) enjoy a limited amount of success in a stented blood vessel, but face additional challenges in removing stenotic tissue without interacting with the stent itself. The interaction of a rotating

removal mechanism on a thin metal scaffolding can produce severe complications during a medical procedure.

Thus, there remains a need for improved methods and apparatus for treating and removing occluding material from a blood vessel. In particular, it would be desirable to provide apparatus and methods which can remove material from vessels which are almost fully occluded, which can treat vessels having a stent deployed within the lumen without damaging the vessel, and able to remove stenotic tissue, or restonotic tissue as quickly as can be safely achieved. It is also desirous to be able to operate within a stented blood vessel with an atherectomy device so that the atherectomy device will not damage the stent in the event of incidental or intentional contact with the stent during an atherectomy procedure. Desirably, the apparatus and methods of the present invention will be easy to implement, present acceptable risks to the patient, and be readily performed by physicians who are familiar with balloon angioplasty and other conventional intravascular treatments. At least some of these objectives will be met by the embodiments of the present invention described below.

SUMMARY OF THE INVENTION

The present invention for the removal of stenotic material within a stent, as well as the removal of stenotic material from a unstented blood vessel. The apparatus has a longitudinal axis, and a defined proximal and distal end. For purposes of discussion, the proximal end is the side of the device which is closer to the physician using the device and the distal end is the side which is going away from the physician. The apparatus comprises a rotatable shearing body and a housing that acts as a sheath for the rotating shearing body. The shearing body is held in place by a series of bearing surfaces between the shearing body and the housing and a restraining collar. The present invention relates solely to an atherectomy device located at the distal tip of a catheter. The apparatus is designed for use at the tip of a catheter, principally for interventional cardiology procedures. The atherectomy devices described herein, in several embodiments, all relate to a shielded atherectomy device, or a screen for use with an atherectomy device.

The rotatable shearing body has a curved distal end. The distal end has a center in the form of a collar or ring depression. The proximal end is generally cylindrical. A lumen extends along the longitudinal or central axis from the distal end to the proximal end. The curved distal end has a bearing surface along the center and distal curved end. Slightly back from the center, a plurality of helical flutes are formed between

the teeth of the shearing body. The helical flutes are designed to act as an impeller during the rotation of the shearing body. Preferably the helical teeth have a positive rake angle. The torque transmission device translates rotational energy directly to the shearing body, producing the active moving element of the invention.

The housing has a curved distal end and a generally cylindrical proximal end. The housing is designed to sheathe the rotatable shearing body. The housing has a receptacle for engaging the center of the shearing body, or itself has a center which the shearing body can receive. The distal end has a smooth interior that functions as a distal bearing surface to carry part of the load of the shearing body. The center also carries a portion of the load of the shearing body. On the proximal end, a restraining collar maintains the proper alignment of the shearing body proximal end, and acts as a proximal bearing surface for the shearing body proximal end. The restraining collar may be a lip or step on the interior of the proximal end of the housing, or an additional component such as a ferrule. The exterior of the housing proximal region is tapered to receive a catheter. Alternatively the ferrule or equivalent component may serve to receive the catheter, and then the ferrule can be joined to the housing. The housing has at least one aperture through which occlusive tissue may protrude into the interior of the housing. The apertures of the housing are angled to be roughly 45 degrees off the main axis of the removal mechanism.

The apertures are aligned to work in cooperation with the teeth of the shearing body. The minor axis of the apertures is designed to be too narrow for a stent strut or guidewire to protrude through the aperture when the strut or guidewire is essentially parallel to the minor axis. Because of this relationship, the teeth of the shearing body may have a long leading edge which is parallel to the minor axis and not ever come into contact with a medical device, thus eliminating the threat of accidental severance of a stent strut or guidewire. The major axis of the apertures is sufficient for a stent strut or guidewire to come into contact with the shearing body by protruding parallel to the major axis. However, the shearing body operates in a circular path about the main axis of the shearing body, the leading edges of the teeth act as bumpers to push other medical devices, such as stent struts or guidewires, out of the apertures instead of cutting them. In this way the present invention can safely operate within the envelope defined by a stent, and can safely remove tissue that engulfs a stent. Tissue removal occurs when the leading edge of the teeth either shear off tissue protruding into the housing, or cooperate with the aperture edge to "scissors" tissue from the body lumen.

The principles utilized in forming the principle embodiment have also yielded several viable alternative embodiments.

In a second preferred embodiment, a screen for connecting to a rotating shearing body is disclosed. The screen has a distal end, a proximal end, and a gap zone defined by the space between the distal and proximal ends. The screen is made of a substantially inflexible housing which is concentric with the rotating shearing body when the screen is connected to the rotating shearing body. The screen has an inner chamber with an inner wall shaped to closely cover the shearing body. The gap zone of the screen has a plurality of apertures in order to expose the shearing surface of the shearing body. The screen has a first bearing surface on its distal side, and a second bearing surface on its proximal side. The first and second bearing surfaces cooperate with matching bearing surfaces on the shearing body to maintain the screen in a fixed concentric alignment relative to the shearing body. To prevent the screen from rotating, the second shearing surface has an extended lip or ring for attaching the screen to the catheter.

A third embodiment includes a screen for connection to a catheter having an axially moveable shearing mechanism. The screen has a distal end, a proximal end and a gap zone between the distal and proximal ends. The screen is made of a substantially inflexible housing having a central axis parallel to that of a catheter to which it is attached. The screen has an inner chamber with an inner wall shaped to closely cover the shearing mechanism. The gap zone has a plurality of apertures in it to expose the shearing mechanism. A first attachment surface is located on the screen distal to the shearing mechanism, and a second attachment surface is located proximal to the shearing mechanism. The first and second attachment surfaces hold the screen to the catheter while the shearing mechanism slides within the screen inner chamber.

Additional alternate designs of the present invention as well as a system including the present invention, methods of manufacture and methods of use are also disclosed. A more thorough understanding of the present invention can be obtained through review of the detailed description of the invention and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A shows a profile view of the present invention attached to the distal end of a catheter.

Figure 1B shows a cut away perspective view of the present invention with a catheter and guidewire.

Figure 1C is a cut away profile view of the present invention and a catheter.

Figure 2A shows the angles of the various cooperating cutting elements.

Figure 2B shows the minimum operating angle.

Figure 2C shows the maximum operating angle.

Figures 2D-2F show three alternative designs for the housing aperture.

Figures 3A – 3C show a perspective, plan and profile view of the shearing body, and its main elements.

Figures 3D-3G show four alternative shearing body designs.

Figure 4A shows a ferrule for use in combination with a separate restraining device.

Figure 4B shows a unibody housing design.

Figure 5 presents an assembly view of all the elements of the invention, plus torque shaft, needed to put together the apparatus.

Figure 6A-B shows a screen.

Figure 6C-D illustrate two alternative screens

Figure 7A-B is a blow up of the fitted screen and shearing body assembly.

Figure 8A-B illustrate a system utilizing the present invention.

Figure 9A-C illustrate two alternative embodiments of the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The following detailed descriptions are the best presently contemplated modes of carrying out the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating general principles of embodiments of the invention. The scope of the invention is best defined by the appended claims. In certain instances, detailed descriptions of well-known devices, compositions, components, mechanisms and methods are omitted so as to not obscure the description of the present invention with unnecessary detail.

The terms "occlusive" and "stenotic" material, as used in the present invention refers to any proliferative or anomalous tissue or substances that occupy a lumen and represent a blockage that impedes the lumen's normal function. "Occlusive" and "Stenotic" material can include, but are not limited to thrombus, emboli, atheroma, atherosclerosis or smooth muscle cell hyperplasia.

A "medical device" is considered to be any artificial structure intentionally placed into a body lumen. Generally medical devices used in conjunction with atherectomy procedures include stents, guidewires, and various types of catheters. The design of the present invention is intended to be able to safely remove occlusive tissue in a body lumen in the presence of any of these other medical devices, in particular the present invention is particularly well suited for the removal of occlusive tissue that engulfs a stent. Discussion herein includes references to a "stent loop" or "stent loops". The reference applies to the orientation of the wire framework used to make a stent. When a stent is deployed within a blood vessel, usually by balloon angioplasty, the balloon scaffolding expands to conform to the outer diameter of the balloon used to deploy it. The expanded lattice has a structure where the wire frame or scaffolding is arranged in loops. The width of these loops are referred to within the present application as "stent loops" and are used to determine the appropriate aperture size.

Many terms used in the present description can be found in any machinists handbook. The terms used to describe the preferred embodiment are the same terms generally used to describe a fluted cutter such as a dental burr.

The following additional definitions are specific to the present invention, they are discussed in brief here, and used in context throughout the rest of the description and claims.

The "Gap Zone" is the area between the distal bearing or attachment surface and the proximal attachment or bearing surface. It is the part of the screen having the apertures that expose the shearing body with in the screen to the blood vessel or body lumen. During the operation of the present invention, atherosclerotic tissue invaginates through the apertures of the gap zone and is removed from the body lumen by the shearing body within the screen or housing. The gap zone is readily identifiable by the numerous openings or windows giving this area of the screen or housing the appearance similar to that of a cheese grater.

The "effective shearing surface" or "shearing surface area" refers to the area of the shearing body which is exposed to the tissue as it invaginates through the apertures in the gap zone. The effective shearing surface includes areas of the shearing body which may not do any removal of tissue that invaginates through the apertures. However if these areas are exposed to the apertures of the gap zone, the area is considered part of the effective surface area.

The "profile" of the shearing body is defined by the shape of the shearing body along its largest or greatest dimension while rotating. In the case of a fluted cutter, for example, the profile of the shearing body is the profile of the area the cutter makes while rotating from tooth to tooth. Not while stationary (from tooth to flute).

The "gap space" is the space between the inner wall of the screen or housing and the profile of the shearing body.

A "fitted screen" is a screen or housing which has an outer profile approximately the same shape as the shearing body it encloses.

1. Shearing Body with Opposing Angled Slotted Housing

Turning now to the drawings, Figure 1A shows an overview of the invention. The present invention provides an apparatus 10 for use in treating and removing occluding material from a blood vessel or other body lumen of an animal or human. The apparatus 10 comprises a rotating shearing body 300 secured within a housing 200. Apertures 204 in the housing 200 are shaped and angled to permit tissue to protrude into the interior of the housing 200 while restricting the alignment of medical device protrusion to a single axis. In this manner the shearing body 300 avoids striking a medical device in a manner that may lead to severing or damaging the medical device while still allowing the removal of protruding tissue. The non-parallel alignment of the leading tooth edge (see below) and the apertures 204 main axis 14 produce a novel aspect of the design referred to as the operating angle 150. The shearing body 300 has a center 302 which fits through a receptacle 202 in the housing 200. The contact area of the center 302 and receptacle 202 are preferably electro-polished or electroplated to reduce friction. The center 302 and receptacle 202 must have an extremely tight tolerance so the shearing body 300 may rotate in the housing 200, yet the tolerance must be sufficient to prevent the shearing body 300 from oscillating off the central axis 12 during operation. The proximal end of the shearing body 300 has a counter bore 322 (see below) for receiving a torque shaft 104. The counter bore 322 is designed to have an extremely tight tolerance with the torque shaft 104 so there is little play in the axial movement of the shearing body 300 during operation. Because the actual length of a torque shaft 104 can vary under operational conditions, a restraining collar 405 is preferred to limit the movement of the shearing body 300 along the axis 12, while the proximal end of the housing 200 prevents the shearing body 300 from oscillating side to side. All surfaces where the shearing body actually contacts the housing 200 or restraining collar 405 are considered bearing

surfaces. Bearing surfaces are preferably electro-polished or electroplated to reduce friction, however the present invention is known to operate without such features. The restraining collar 405 may be substituted for a ferrule 400, or a unibody housing 2004 (see below) to control the axial movement of the shearing body 300. A catheter jacket 112 is attached to the proximal side of the apparatus 10, whether it be the proximal end of the housing 200, or a separate ferrule 400 attached to the proximal end of the housing. The appended drawings include a main axis indicator 12 with the arrowhead always pointing toward the distal end of each component.

Figure 1B is a three dimensional cut away perspective view of the present invention. The apparatus 10 comprises three elements. A housing 200 which contains a shearing body 300 and a ferrule 400 acting as a restraining collar. The housing 200 has a plurality of apertures 204 through which occlusive material in a body lumen may protrude to the interior of the housing 200. Occlusive material (not shown) that protrudes through the apertures 204 will be sheared off by the teeth 304 or the cooperation of the teeth 304 with the edge of the aperture 204. A catheter 100 is attached on the proximal end of the ferrule 400 up to the annular lip 404. The catheter has a torque shaft 104, and has a mechanism for removing tissue such as a screw pump 106, or a vacuum pump. The catheter lining 110 and polymer jacket 112 assist in securing the outer surfaces of the catheter 100 to the ferrule 400 by any means known in the art. A guidewire 601 extends from the lumen 102 of the torque shaft 104 through the shearing body lumen 320 (see below) along the main axis 12. Preferably the torque shaft 104 has a liner 108 to insulate the guidewire 601 from friction when the torque shaft 104 is spinning. The housing 200 has a receptacle 202 for engaging a center 302 from the shearing body 300. However the relative position of the two components could be switched without altering the effectiveness of the apparatus 10.

Figure 1C shows a catheter 100 can be mated to the apparatus 10 by securing the proximal end of the housing 200. The catheter 100 is made up of several layers. A torque shaft 104 runs axially through the catheter 100 and has a polymer jacket 112 over the exterior. The torque shaft 104 is shown running through the central lumen of the apparatus 10. The torque shaft 104 passes through the proximal end of the housing 200 and through the ferrule 400 (or a restraining collar 405) to engage the shearing body 300. It is important that the torque shaft 104 be able to freely rotate within the housing 200 and the ferrule 400, but be fixed to the shearing body 300.

It can be seen the shearing body 300 is located at the distal interior of the housing 200, and the ferrule 400 appears to abut the shearing body 300 within the ferrule 400. In fact there is a small gap 50 between the shearing body 300 and the ferrule 400. The gap 50 is the spacing which develops during operation. A torque shaft 104 will most likely not maintain a perfectly fixed length in operation. Therefore a small space is to be expected between the shearing body 300 and the ferrule 400. The gap 50 is preferably about 0.002" but can be larger or smaller depending on the length change in the torque shaft 104. The shearing body has a lumen 320 extending through it which widens out step wise on the proximal side into a counter bore 322 for fittingly engaging a torque shaft 104. The counter bore 322 may be any fitting or connecting means which can secure the torque shaft 104 to the shearing body 300. The means for such a connection is not an inventive concept in the apparatus 10 and there are many ways well known in the art to make this connection. At the distal end of the apparatus 10, the shearing body 300 has a center 302 which extends at least partially through the housing receptacle 202. The combined fit with the center 302 and the counter bore 322 should have an extremely tight tolerance so that the shearing body 300 remains in proper alignment while rotating. The annular space 44 on either side should be no more than 0.050" and is preferably less than 0.002" per side. Thus the tolerance for oscillation is no more than the annular space 44. The combination of the center 302 and receptacle 202, the ferrule 400 (or restraining collar) and the torque shaft 104 all contribute to maintaining the position of the shearing body 300. It should be noted here that perfect alignment of the shearing body within the housing 200 during operation is impossible. The change in length in the torque shaft 104 automatically creates a gap 50 in which the bearing surface may not be able to engage the shearing body. Therefore it must be understood in the present invention that any variance up to that of the annular space 44 is considered normal. Occasionally oscillation will exceed the annular space 44 and the apparatus 10 will still function.

Figure 2A shows the angular positioning of the main axis 12, the aperture angle 148 of the major axis 14 of the aperture 204, and the cutting angle 149 of the cutter axis 16 of the teeth 304. Here, the sum of the aperture angle 148 and the cutting angle 149 comprises the operating angle 150. In the preferred embodiment the operating angle 150 is between 15 and 90 degrees. The aperture angle 148 does not have to be equal to the cutting angle 149. Thus the relative operating angle 150 to the main axis 12 may not be centered. Figures 2B and 2C show variations where the operating angle is as small as 15 degrees, and as large as 165 degrees. The preferred embodiment has the operating

angle at a close to 90 degrees as can be made. The shallower angles and wider angles between the range of 15-165 degrees are operational, however not as effective. The actual shape of the aperture 204 may vary from device to device, but in general must have a long axis identified as the major axis 14. The major axis 14 will be that line which can be drawn through the aperture 204, regardless of its shape, that identifies its major axis of orientation on the housing. Figures 2D-2F show three variations of the aperture shape, and the major axis 14 of each aperture 204. The short axis of the aperture 204, or the minor axis can be no greater than the tangent line of the inner diameter of the housing 200 across the outer diameter of the housing 200. This prevents a straight lying object, across the minor axis, from protruding into the housing unless the straight lying object is soft relative to the hardness of the housing 200.

Figure 3A is a perspective view of the preferred shearing body 300 used in the present invention. The main axis 12 defines the distal end of the shearing body 300. A center 302 is used to engage the receptacle 202 of the housing 200. The distal end 310 is curved and is a bearing surface for the shearing body 300. The shearing body 300 has a plurality of flutes 308 which are helical in shape. The leading edge of the teeth 304 engage any tissue which protrudes into the housing and shears such tissue off. The top of the teeth 304 have a radial land 306 which helps to push a medical device out of the path of the next tooth that comes during rotation. In addition the teeth 304 themselves may act as a sort of bumper to push a medical device out of the aperture and thus avoid cutting the medical device. There is a step down region 314 near the proximal end of the teeth 304 to increase the annular space 44 between the shearing body 300 and the housing 200.

Figure 3B shows a proximal view of the shearing body 300. The main axis 12 can be seen at the center of the part. The helical flutes and teeth have a positive rake angle 334 in the preferred embodiment. The rake angle 334 is determined by the relative lines drawn through the radius 330 of the shearing body, and the extension line from the edge of each tooth 332. While both neutral and negative rake angles are operative, it is believed at the current time the best mode uses the positive rake angle. A guidewire lumen 320 can be seen at the center of the shearing body 300, along with an enlarged opening which serves as the counter bore 322.

Figure 3C shows a cross section profile of the shearing body 300. The guidewire lumen 320 can be seen as widening out to reveal the counter bore 322 where the torque shaft 104 would be fixedly attached.

Figure 3D is a clean profile of the shearing body used in the majority of the appended drawings. Figure 3E shows a shearing body with steeper helical pitch in the flutes, and 3F shows a shearing body with few teeth 304. The helical pitch of the shearing body can vary from 0.010" to 1.000" (inches). The pitch being the length along the cylinder the path of the flute is drawn until one complete revolution of the cylinder is made. Figure 3G shows an alternative design of the present invention where the shearing body has an abrasive surface on its distal end.

Figure 4A shows an enlarged view of the ferrule 400. It can be seen the annular lip 404 separates the proximal and distal side of the ferrule, the flow ports 414 being located on the proximal side.

Figure 4B shows a unibody housing 2004 with an interior restraining collar 405. All other elements match to corresponding features in the housing 200 or ferrule 400..

Figure 5 shows a separated assembly view of the apparatus 10 before final assembly. The distal end of each piece follows the axis line 12. The torque shaft 104 extends through the ferrule 400 and engages the shearing body 300. The shearing body 300 is pushed into the distal interior of the housing 200 where bearing surfaces help maintain the shearing body's position. A polyester heat shrink tubing 115 is placed over the annular lip 404 of the ferrule 400 to secure the catheter 100 to the ferrule 400 and the housing 200.

2. Screen for use with Rotating Shearing Body

Figure 6A is a plan view of a screen 500 for closely covering a shearing body. The screen 500 follows a central axis 12 with the distal end 520 pointed in the same direction as the central axis 12. The screen 500 has a distal end 520 and a proximal end 530 with a gap zone 540 located between the distal end 520 and proximal end 530. Within the region of the gap zone 540 a plurality of apertures 504 are arranged in a series of transverse rings about the center axis 12. While the apertures 504 may be arranged in almost any conceivable fashion, the preferred embodiment uses a first transverse ring 506 of apertures 504 located as close to the distal end 520 as possible. If additional transverse rings of apertures are desired, they are referred to as second ring, third ring, etc. The nomenclature used here refers to the most distal transverse ring as the first ring, and all subsequent rings following in natural progression. The subsequent transverse rings of apertures 508, 510, 512 are staggered to maximize the number of apertures 504 which can

be fit into the gap zone 540. The number of transverse rings or apertures is not fixed, and the pattern of apertures 504 may be any desired that will physically fit in the gap zone 540 without critically compromising the strength of the screen 500. It is also contemplated to have staggered or uneven spacing between the transverse rings. Generally the first transverse ring 506 should be located as close to the distal end as possible to ensure as much occlusive material as possible will invaginate into the inner chamber 550 as the catheter 100 is advanced.

The placement and proximity of the apertures 504 must be balanced with the strength of the screen 500 in the gap zone 540 and the struts 514 which separate each aperture 504. Each strut 514 also has a region of narrowest width 516 where the apertures 504 are closest together and the structural integrity of the screen 500 is weakest. The integrity of the screen 500, particularly in the gap zone 540 can be improved by making the screen 500 of a harder material. Preferably stainless steel is used to make the screen 500. However other materials such as tungsten carbide, titanium and ceramics (natural and synthetically created such as sapphire) can be used. Ultimately the hardness of the screen 500 depends on the hardness of the shearing body 300.

To improve the life of the screen 500 and reduce the risk of a break down of the screen 500 during operation, the relative hardness of the shearing body 300 preferably will not exceed the hardness of the screen 500. It is more preferable the hardness of the screen 500 will be equal to or greater than the hardness of the shearing body 300.

The size of the apertures 504 will reflect the environment the screen 500 is intended to be used in. There is no limit to the maximum size of the apertures 504 except as to what the gap zone 540 can accommodate. However for coronary applications with in a body lumen 320 having a deployed stent, the aperture 504 should be sized so that the maximum diameter of the aperture 504 is smaller than the stent loop which make up the basic scaffolding structure of the stent. The preferred embodiment at the present time uses apertures 504 that are sized 0.001" (one thousands of one inch) smaller than the width of a deployed stent loop.

In the preferred embodiment the screen has a first traverse row 506 of apertures of 0.010" diameter. There are eleven apertures in the first traverse ring. Following are three traverse rows with eleven apertures in each ring. To maintain the strut width at the narrowest point between apertures, the apertures of the second, third and fourth traverse rows are 0.012" diameter. The aperture 504 size is based on two

competing criteria. The first is the need to provide sufficient gap area for tissue to invaginate into the inner chamber 550 to be removed by the shearing body 300. Second is the need to keep the stent loops out of the inner chamber 550 so the stent loop cannot interact with the shearing body 300. It is impossible to fully detail the width of every stent loop available or possible, however in view of those stents with a significant portion of market share, the aperture size selected to balance the two competing interests for the preferred embodiment is to use apertures 504 of 0.015" diameter or less. The wall thickness of the screen 500 along the gap zone is 0.002" with a tolerance of +/- 0.001". The distal end has a bearing surface including a stickout receptacle 502 for receiving the distal bearing surface of a shearing body 300 as previously described. To maintain the general width of a coronary catheter, the diameter of the screen is generally 0.06" +/- 0.02". The diameter of the shearing body 300 disposed within the screen 500 is necessarily adapted to conform to the inner chamber of the screen 500.

In the present embodiment the distal end has a length of 0.004" +/- 0.003" and is roughly the same length as the center 502 for receiving the shearing body 300 bearing surface. The length of the proximal end varies with the number of transverse rings in the gap zone 540. There is no minimum length for the proximal end so long as sufficient surface area exists to permit the proximal bearing surface of the shearing body 354 (or ferrule 400 attached to the shearing body 300) to center the shearing body 300 with respect to the screen 500.

Figure 6C shows an alternative embodiment of the screen 500 having three transverse rows of apertures, where the apertures sizes are 0.015" in the first transverse ring, and 0.020" in the second and third rows. Figure 6D shows yet another embodiment having eight transverse transverse rings, the first transverse ring having apertures of 0.004" diameter. The second transverse row having apertures of 0.005" diameter, the third transverse ring having apertures of 0.006" diameter and the remaining transverse rings 512x having apertures of 0.007" diameter. Once again each transverse ring is offset from the ring directly distal of it in order to maximize the available aperture space 504 and expose the effective shearing surface 350 of the shearing body 300. The screen strut 316 width in this embodiment has been reduced to 0.001" and the material of this housing is preferably tungsten carbide or titanium.

Figure 7A shows a cut away view of the screen 500 and a shearing body 300 displaced within. The screen 500 has an inner chamber 550 that closely covers the shearing body 300. The shearing body 300 has a distal bearing surface 352 and a

proximal bearing surface 354. Between the distal bearing surface 352 and the proximal bearing surface 354 is the effective shearing surface 350. The gap zone 540 of the screen 500 may have the same dimension over the shearing body 300 as the effective shearing surface 350. However the present invention operates equally well if the effective shearing surface 350 is smaller than the gap zone 540, or larger. A small degree of overlap of the distal end 520 or the proximal end 530 over the effective bearing surface 350 is also permitted.

Figure 7B illustrates a blow up of the cross section of the screen 500 and the shearing body 300. The gap defined by the space between the effective shearing surface 350 and the inner wall 552 of the gap zone 540 is the gap space 554. The gap space 554 is preferably as small as possible to allow the shearing body 300 to rotate within the screen 500 without interacting with the inner wall 552 of the gap zone, while at the same time maintaining a close proximity to effectively "scissor" tissue which invaginates into the inner chamber 550 during operation. In the present invention the gap space 554 is preferably less than 0.002" radially. For purposes of the screen 500 the shearing body 300 may be of the type which has teeth and flutes as previously described in figures 3A-G, or it can be of the type shown in figure 9A-B (below). The outside shape of the screen 500 should follow the profile of the shearing body 300. Where the shearing body 300 may be tapered on its proximal bearing surface 354, the screen 500 should also taper down on the proximal end 530.

3. Systems with Safety Screen and Angled Housing

Figure 8A-B illustrate a system 800 of the present invention. The system 800 includes a catheter 100 having a shearing body 300 at its distal end, and a screen 500 covering the shearing body 300. A guidewire 601 is shown as well. The distal end of the catheter 100 may use any of the embodiments of the shearing body and housing or shearing body and screen described herein. The use of most atherectomy devices includes a motor drive unit MDU, a vacuum pump VP and a receptacle R for removed occlusive material. These additional elements are provided here merely as illustration and should not be considered as part of the present invention.

4. Prophetic Embodiments

Figure 9 illustrates several prophetic examples of a screen 500 used to closely cover alternative shearing bodies. Fig 9A illustrates an oblong shaped rotary burr

having a screen 500a fitted to it. The screen can be manufactured according to the methods described herein with the use of a swaging machine to provide the curvature on the proximal end of the screen 500a. The process permits the screen to be precisely fitted to the rotating shearing body 300a. If necessary, and depending on the curvature of the rotary burr/cutter, relief slots may be made in the screen 500a prior to swaging. Fig 9B illustrates a screen 500b being fixedly attached to a catheter 100 at the distal and proximal locations of a shearing mechanism. The screen 500b has a plurality of apertures arranged in a rectangular pattern, simulating a window. In this manner the screen 500b simulates a window of a directional atherectomy device. Figure 9C illustrates a shearing body having flutes and a screen attached directly to the shearing body along the radial land of each tooth.

5. Method of Manufacture

The following manufacturing method applies generally to both the screen 500 and the housing 200 used in making the apparatus 10. Subtle variations in the manufacture of either the screen 500 or the housing 200 will be pointed out at each particular step. For reference purposes the methods described herein refer to the creation of the apparatus 10, which for this section includes both the housing 200 with shearing body 300 described in section 1, and the screen 500 used to closely cover a shearing body 300 described in section 2. The term "screen" is used below generically to mean either the screen 500 or the housing 200. The apparatus 10 of the present invention may be manufactured in numerous ways. Presently the best contemplated manner of making the screen is described in the following steps.

a. First Step -- Creating a Dimensioned Screen

The screen 500 can be made from a mandrel or rod of stainless steel or other sufficiently hard material. Preferably the mandrel is chosen with a diameter matching the desired outside diameter of the screen 500 to be made. The mandrel is cut to length corresponding to the length of the screen 500 along the main axis 12 creating a blank. The blank is secured to a fixture for holding it in place, and loaded into the chuck of a lathe or CNC machine while a customized radius tool is used to shape the distal end of the blank. Once the distal end has been formed the blank is reversed so a customized end mill with a desired radius can be used to shape the inner chamber 550. The screen 500 may have a center 502 which can be created simultaneously with the inner chamber 550, or separately using a different end mill after the inner chamber 550 is completed.

b. Second Step -- Creation of the Apertures

Once the inner chamber 550 is completed, the screen 500 is remounted on to a new mandrel having a profile to match the inner chamber and bear the load of the aperture creating process. With the new mandrel secured in the stock of a lathe or CNC machine, a properly dimensioned drill bit is used to create the apertures (204 or 504)of the desired pattern and size. The aperture size is predetermined depending on the specific environment the screen will be used in (e.g. A stented lumen vs. native coronary disease). A CNC device is preferred for a more precise control of the aperture spacing and orientation. Once the apertures are created, the screen is removed from the support mandrel and deburred by placing a second end mill into the inner chamber and gently rotating the second end mill to remove burrs or other particulates inside the inner chamber 550 without deforming the screen. Optionally the screen 500 may be placed into a support frame while the de-burr process is done. Finally the screen is electro-polished to smooth out any remaining rough edges. While the present method uses classic machining to produce the apertures of the screen, other techniques are also possible, such as laser machining, EDM (Electrical Discharge Machining) and photo-etching to name a few.

c. Third Step -- Assembly of the Screen and Shearing Body

Once the screen 500 is completed, a ferrule 400 is slipped over the torque shaft 104. The screen 500 is then attached directly to the end of the torque shaft 104, with the shearing body receiving the torque shaft 104 in the counter bore 322 of the shearing body. The Ferrule 400 is then advanced to the distal end of the torque shaft until it comes into contact with the shearing body 300. Ideally the shearing body 300 has a proximal bearing surface 354 that has an outer diameter which matches the diameter of the ferrule 400 on the distal side of the restraining collar 405. The ferrule 400 is joined to the screen 500 while the shearing body and torque shaft are free to rotate within the inner chamber of the screen. The distal bearing surface 352 and proximal bearing surface 354 must maintain the shearing body in a concentric alignment with the screen 500, while permitting the shearing body to freely rotate within the screen at high speed. The screen and ferrule may be joined by solder, epoxy, laser welding or any other acceptable method.

d. Fourth Step -- Completion of the Catheter

A polymer jacket 112 is melted over the exterior of the ferrule 400 along the proximal end 408 of the ferrule 400. The polymer preferably seeps into the flow ports 414 to help secure the polymer jacket 112 to the ferrule 400. In one aspect of

the invention a shrink heat tube 115 is melted over the joint where the polymer jacket 112 is joined to the apparatus 10. The heat shrink tubing 115 provides added hoop strength to the joint and helps secure the catheter 100 to the screen 500. The joining of the polymer jacket 112 to the housing 200 helps prevent rotational torque from being transferred from the shearing body 300 to the screen 500 during operation. The catheter jacket 112 can be secured to the housing 200 by any means understood in the art. The ferrule 400 has an annular lip 404 used to improve the hoop strength of the ferrule 400. The completed assembly (see figure 1A) completes the assembly of all aspects of the present invention.

It will be readily apparent to one skilled in the art of machining and CNC processing that there are many alternative methods to making the present invention. The methods previously described are not to be considered limiting as the only way to make the present invention.

While the description above refers to particular embodiments of the present invention, it will be understood that many modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true scope and spirit of the present invention.

WHAT IS CLAIMED IS:

1. An apparatus for the removal of occlusive material in a stent comprising a rotating shearing body maintained in a near fixed axial alignment within a stiff housing and a restraining collar, the housing having a plurality of angled apertures for allowing occlusive material to protrude through said apertures when the housing is pressed against a body lumen, the shearing body having a plurality of teeth for cleaving the occlusive material which protrudes into the housing, the teeth having an alignment that is not parallel to the angled apertures to prevent the cutting of a medical device.

2. The apparatus of claim 1, wherein the shearing body further comprises:

a curved distal end having a center, a generally cylindrical proximal end and a lumen extending therethrough;

a bearing surface formed on said distal end;

an outer surface having a plurality of helical flutes between the teeth, said flutes formed with a pitch angle to act as an impeller when the shearing body is rotating; and

a mating juncture for attaching the shearing body to a torque shaft.

3. The apparatus of claim 1, wherein the housing further comprises:

a curved distal end with a receptacle for fittingly engaging the center of the shearing body;

a smooth interior bearing surface; and

a generally cylindrical proximal end having an outer surface, and inner surface, and a tapered region near the proximal edge for fittingly receiving a catheter.

4. The apparatus of claim 1, wherein the teeth are aligned substantially perpendicular to the major axis of the apertures.

5. The apparatus of claim 1, wherein said angled apertures are preferably aligned approximately 45 degrees from the central axis.

6. The apparatus of claim 1, where in the cutting axis is preferably aligned approximately 45 degrees from the central axis opposite the angled apertures.

7. The apparatus of claim 1, wherein the operating angle is preferably 90 (ninety) degrees.

8. The apparatus of claim 1, wherein the operating angle is not less than 15 degrees from each other.

9. The apparatus as in claim 1, wherein the housing has a thickness of less than 0.050" (five-hundredths of an inch).

10. The apparatus as in claim 1, wherein the housing has a thickness which is preferably between 0.0015" and 0.0025".

11. The apparatus of claim 1, wherein the housing has an inner diameter less than 0.500" (half an inch).

12. The apparatus of claim 1, wherein the housing is made of stainless steel.

13. The apparatus of claim 1, wherein the housing is made of titanium.

14. The apparatus of claim 1, wherein the housing is made of a ceramic material.

15. The apparatus of claim 1, wherein the housing is made of plastic.

16. The apparatus of claim 1, wherein the housing is made of a composite material.

17. The apparatus of claim 1 wherein the teeth of the shearing body have a positive radial rake angle.

18. The apparatus of claim 1, wherein the shearing body is spaced apart from the housing along the length of the flutes of the shearing body by an annular space not greater than 0.050" (fifty thousandths of an inch).

19. The apparatus of claim 1, wherein an annular space separates the shearing body and the housing, said annular space being preferably between 0.0005" and 0.0015".

20. The apparatus of claim 2, wherein the flutes of the shearing body have a pitch between 0.010" and 1.000".

21. The apparatus of claim 1, wherein the shearing body and housing are of different material hardness.

22. The apparatus of claim 2, wherein the shearing body is soldered to the torque shaft.

23. The apparatus of claim 2, wherein the shearing body is chemically bonded to the torque shaft.

24. The apparatus of claim 2, wherein the shearing body is laser welded to the torque shaft.

25. The apparatus of claim 2, wherein the shearing body is secured to the torque shaft with an interference fitting.

26. The apparatus of claim 1, wherein the housing is made of stainless steel.

27. The apparatus of claim 1, wherein the housing is made of titanium.

28. The apparatus of claim 1, wherein the housing is made of a ceramic material.

29. The apparatus of claim 1, wherein the housing is made of plastic.

30. The apparatus of claim 1, wherein the housing is made of a composite material.

31. The apparatus of claim 1, wherein the shearing body cooperates with the apertures to remove stenotic material from a region defined by a stent.

32. The apparatus of claim 1, wherein the restraining collar is a ferrule having an outer surface with a proximal end and a distal end separated by an annular lip, said distal end being fixedly attached within said distal orifice and said proximal end

being fixedly attached to a catheter, said ferrule further comprising an inner surface defining a lumen through which the torque shaft may rotate.

33. The apparatus of claim 1, wherein the housing is made of stainless steel.

34. The apparatus of claim 1, wherein the housing is made of titanium.

35. The apparatus of claim 1, wherein the housing is made of a ceramic material.

36. The apparatus of claim 1, wherein the housing is made of plastic.

37. The apparatus of claim 1, wherein the housing is made of a composite material.

38. The apparatus of claim 32, wherein the ferrule is integrated onto the proximal end of the housing.

39. The apparatus of claim 32, wherein the ferrule is fixedly attached to the catheter wherein the catheter has a sheath of a polymeric material which is melted on to the ferrule.

40. The apparatus of claim 2, wherein the torque shaft comprises a braided tubing.

41. The apparatus of claim 2, wherein the torque shaft is a plurality of counter wound coils.

42. The apparatus of claim 2, wherein the torque shaft further comprises a Teflon tube incorporating a wire braid and a polymer laminate.

43. The apparatus of claim 1, wherein the medical device is an artificial structure.

44. A removal mechanism for the removal of stenotic material within a stent having a longitudinal axis, a proximal end, and a distal end, said apparatus comprising:

an axially rotatable shearing body having at least one flute aligned in a helical fashion with respect to the longitudinal axis, a lumen extending there through for passage of a guidewire, a center guide at said distal end and a means for mating the shearing body to a torque transmission device;

a housing to sheathe the rotatable shearing body and having a generally cylindrical shape with a distal receptacle for receiving the center of the shearing body, the housing having at least one aperture for occlusive material to protrude into the interior of the housing, the apertures being aligned at an angle in partial opposition with the flutes; and

a connection means for attaching a catheter to the housing such that the shearing body and the torque shaft may freely rotate within the housing and be properly maintained in axial position relative to the housing.

45. The removal mechanism as in claim 44, wherein the housing has a thickness of less than 0.050" (five-hundredths of an inch).

46. The removal mechanism as in claim 44, wherein the housing has a thickness which is preferably between 0.0015" and 0.0025".

47. The removal mechanism of claim 44, wherein the housing has an inner diameter between 0.500" and 0.040".

48. The apparatus of claim 44, wherein the housing is made of stainless steel.

49. The apparatus of claim 44, wherein the housing is made of titanium.

50. The apparatus of claim 44, wherein the housing is made of a ceramic material.

51. The apparatus of claim 44, wherein the housing is made of plastic.

52. The apparatus of claim 44, wherein the housing is made of a composite material.

53. The removal mechanism of claim 44 wherein the teeth of the shearing body have a positive radial rake angle.

54. The removal mechanism of claim 44, wherein the removal mechanism is spaced apart from the outer shell along the length of the flutes of the removal mechanism by an annular spacing not greater than 0.005" (five thousandths of an inch).

55. The removal mechanism of claim 44, wherein an annular space separates the shearing body and the housing, said annular space being preferably between 0.0005" and 0.0015".

56. The removal mechanism of claim 44, wherein the housing is at least as hard as the shearing body.

57. The removal mechanism of claim 44, wherein the housing is harder than the shearing body.

58. The removal mechanism of claim 44, wherein the helical flutes and apertures are at a 90 (ninety) degree angle with respect to each other.

59. The removal mechanism of claim 44, wherein the helical flutes and apertures are at an angle of not less than 15 degrees from each other.

60. The removal mechanism of claim 44, wherein the shearing body is soldered to the torque shaft.

61. The removal mechanism of claim 44, wherein the shearing body is chemically bonded to the torque shaft.

62. The removal mechanism of claim 44, wherein the shearing body is joined to the torque shaft with a laser weld.

63. The removal mechanism of claim 44, wherein the shearing body mechanism has an interference fit with the torque shaft.

64. The apparatus of claim 44, wherein the housing is made of stainless steel.

65. The apparatus of claim 44, wherein the housing is made of titanium.

66. The apparatus of claim 44, wherein the housing is made of a ceramic material.

67. The apparatus of claim 44, wherein the housing is made of plastic.

68. The apparatus of claim 44, wherein the housing is made of a composite material.

69. The removal mechanism of claim 44, wherein the shearing body cooperates with the aperture to remove stenotic material from a region defined by a stent.

70. The removal mechanism of claim 44, wherein the connection means for attaching the catheter and the housing is located at the proximal end of the housing.

71. The removal mechanism of claim 44, wherein the connection means is a ferrule having an outer surface with a proximal end and a distal end separated by an annular lip, said distal end being fixedly attached within said proximal end of the housing and said proximal end being fixedly attached to a catheter, said ferrule further comprising an inner surface defining a lumen through which the torque shaft may rotate.

72. The apparatus of claim 44, wherein the housing is made of stainless steel.

73. The apparatus of claim 44, wherein the housing is made of titanium.

74. The apparatus of claim 44, wherein the housing is made of a ceramic material.

75. The apparatus of claim 44, wherein the housing is made of plastic.

76. The apparatus of claim 44, wherein the housing is made of a composite material.

77. The removal mechanism of claim 71, wherein the ferrule is integrated onto the proximal end of the housing.

78. The removal mechanism of claim 71, wherein the ferrule is fixedly attached to the catheter wherein the catheter has a sheath of a polymeric material which is melted on to the ferrule.

79. The removal mechanism of claim 44, wherein the torque shaft comprises a braided tubing.

80. The removal mechanism of claim 44, wherein the torque shaft is a plurality of counter wound coils.

81. The removal mechanism of claim 44, wherein the torque shaft further comprises a Teflon tube incorporating a wire braid and a polymer laminate.

82. An removal mechanism for the removal of stenotic material within a stented body lumen having a longitudinal axis, a proximal end, and a distal end, said apparatus comprising:

a rotatable removal mechanism having an abrasive surface, a lumen extending there through for passage of a guidewire, a center guide at said distal end and a housing for mating to a torque transmission device;

a housing formed into a generally cylindrical cross section and shaped to sheath the rotatable shearing body within, said housing having at least one aperture for exposing the helical flutes of the rotatable shearing body and the apertures being aligned at an angle in opposition with the flutes, a distal orifice for receiving the center guide and a proximal orifice; and

a connection means for attaching a catheter to the housing such that the shearing body and the torque transmission device may freely rotate within the housing and be properly maintained in axial position to the housing.

83. A screen for connection to a rotating shearing body of a catheter, said screen having a distal end, a proximal end, and a gap zone located between the distal end and the proximal end, said screen comprising:

(a) a substantially inflexible housing being concentric with said rotating shearing body when the screen is connected thereto, having an inner chamber with an inner wall shaped to closely cover the shearing body, and having a plurality of apertures in the gap zone to substantially expose an effective shearing surface area of the rotating shearing body;

(b) a first bearing surface located on the distal end; and

(c) a second bearing surface located at the proximal end;

wherein said first and second bearing surfaces maintain the screen in a fixed concentric alignment relative to the rotating shearing body.

84. The screen of claim 83, wherein the inflexible housing is made of stainless steel.

85. The screen of claim 83, wherein the inflexible housing is made of titanium.

86. The screen of claim 83, wherein the inflexible housing is made of a ceramic material.

87. The screen of claim 83, wherein the inflexible housing is made of a refractory metal.

88. The screen of claim 83, wherein the housing is bell shaped.

89. The screen of claim 83, wherein the housing is roughly football shaped.

90. The screen of claim 83, wherein the housing is a hemisphere.

91. The screen of claim 83, wherein the housing is bullet shaped.

92. The screen of claim 83, wherein the apertures in the gap zone are arranged in transverse rings about the circumference of the gap zone.

93. The screen of claim 83, wherein the apertures in the gap zone are arranged in a spiral pattern about the circumference of the gap zone.

94. The screen of claim 83, wherein the apertures in the gap zone are spaced apart not less than 0.001".

95. The screen of claim 83 wherein the apertures are preferably less than 0.015" diameter.

96. The fitted screen of claim 83, wherein the apertures are more preferably less than 0.0125" diameter.

97. The screen of claim 83, wherein the apertures of the gap zone are circular.

98. The screen of claim 83, wherein the apertures of the gap zone are oval.

99. The screen of claim 83, wherein the apertures are slots.

100. A screen for connection to a catheter having a axially moveable shearing mechanism, said screen having a distal end, a proximal end, and a gap zone between the distal end and the proximal end, said screen comprising:

(a) a substantially inflexible housing having a central axis parallel to a long axis of the catheter when the screen is connected thereto, having an inner chamber with an inner wall shaped to closely cover the shearing mechanism, and having a plurality of apertures in the gap zone to substantially expose the shearing mechanism;

(b) a first attachment surface located on the distal end of the screen for fixedly attaching said screen to the catheter at a point distal of said shearing mechanism; and

(c) a second attachment surface located on the proximal end of the screen for fixedly attaching said screen to the catheter at a point proximal of said shearing mechanism.

101. The screen of claim 100, wherein the inflexible housing is made of stainless steel.

102. The screen of claim 100, wherein the inflexible housing is made of titanium.

103. The screen of claim 100, wherein the inflexible housing is made of a ceramic material.

104. The screen of claim 100, wherein the inflexible housing is made of a refractory metal.

105. The screen of claim 100, wherein the housing is bell shaped.

106. The screen of claim 100, wherein the housing is roughly football shaped.

107. The screen of claim 100, wherein the housing is a cylinder.

108. The screen of claim 100, wherein the housing is bullet shaped.

109. The screen of claim 100, wherein the apertures in the gap zone are arranged in equidistant rings about the circumference of the gap zone.

110. The screen of claim 100, wherein the apertures in the gap zone are arranged in a spiral pattern about the circumference of the gap zone.

111. The screen of claim 100, wherein the apertures in the gap zone are spaced apart not less than 0.001".

112. The screen of claim 100 wherein the apertures are preferably less than 0.015" diameter.

113. The fitted screen of claim 100, wherein the apertures are more preferably less than 0.0125" diameter.

114. The screen of claim 100, wherein the apertures of the gap zone are circular.

115. The screen of claim 100, wherein the apertures of the gap zone are oval.

116. The screen of claim 100, wherein the apertures are slots.

117. The screen of claim 116, wherein the aperture slots are aligned substantially parallel to the axis of the catheter.

118. A shielded shearing body for use with a catheter comprising:

(a) a shearing body having a shearing surface, the shearing body having distal end, a proximal end and a lumen extending therethrough;

(b) a screen being fixedly attached to the shearing body, said screen having a distal end, a proximal end, and a gap zone defined by the space between said distal end and said proximal end, the gap zone having a plurality of apertures and closely covering the shearing body, and having an inner chamber for closely covering the shearing body;

wherein the inner chamber of the screen and the shearing surface define a gap space.

119. The shielded shearing body of claim 118, wherein the screen has an outer profile that is bullet shaped.

120. The shielded shearing body of claim 119, wherein the outer profile substantially follows the profile of the shearing body.

121. The shielded shearing body of claim 118, wherein the screen has a wall thickness less than 0.005".

122. The shielded shearing body of claim 118, wherein the inflexible housing is made of stainless steel.

123. The shielded shearing body of claim 118, wherein the inflexible housing is made of titanium.

124. The shielded shearing body of claim 118, wherein the inflexible housing is made of a ceramic material.

125. The shielded shearing body of claim 118, wherein the inflexible housing is made of a refractory metal.

126. The shielded shearing body of claim 118, wherein the apertures in the gap zone are arranged in equidistant rings about the circumference of the gap zone.

127. The shielded shearing body of claim 118, wherein the apertures in the gap zone are arranged in a spiral pattern about the circumference of the gap zone.

128. The shielded shearing body of claim 118, wherein the apertures in the gap zone are spaced apart not less than 0.001".

129. The shielded shearing body of claim 118 wherein the apertures are preferably less than 0.015" diameter.

130. The shielded shearing body of claim 118, wherein the apertures are more preferably less than 0.0125" diameter.

131. The shielded shearing body of claim 118, wherein the apertures of the gap zone are circular.

132. The shielded shearing body of claim 118, wherein the apertures of the gap zone are oval.

133. The shielded shearing body of claim 118, wherein the apertures are slots.

134. The shielded shearing body of claim 133, wherein the aperture slots are aligned substantially parallel to the axis of the catheter.

135. The shielded shearing body of claim 118, wherein the gap space between the screen and the shearing body is less than 0.0005".

136. A system, comprising:

(a) a catheter having a distal end, a proximal end, and a lumen extending longitudinally therethrough;

(b) a torque member extending longitudinally through the lumen of the catheter, and having a lumen and a distal end;

(c) a rotating shearing body secured to the distal end of the torque member; and

(d) a fitted screen for connection to the rotating shearing body, said screen having a distal end, a proximal end, and a gap zone located between the distal end and the proximal end, said screen comprising a substantially inflexible housing being concentric with said rotating shearing body when the screen is connected thereto, having an inner chamber with an inner wall shaped to closely cover the shearing body, and having a plurality of apertures in the gap zone to substantially expose an effective shearing surface area of the rotating shearing body, the fitted screen further comprising a first bearing surface located on the distal end, a second bearing surface located at the proximal end, wherein said first and second bearing surfaces maintain the fitted screen in a fixed concentric alignment relative to the rotating shearing body.

137. The system of claim 136, further comprises:

(e) a guidewire.

138. The system of claim 137, wherein said guidewire has a guide section which defines a curved three-dimensional profile that is diametrically larger than a width of the shearing body, the guide section providing a curved path along which the shearing body can be advanced, the guide section being made from a shape memory material having sufficient flexibility to assume a generally straightened profile when the guide section extends through the lumen of the torque member.

139. The system of claim 136, wherein the torque member may be axially advanced through the catheter.

140. The system of claim 136, wherein the torque member and the shearing body are separated by a ferrule adapted to bind the torque member and shearing body together.

141. The system of claim 140, wherein the ferrule act as proximal concentric bearing surfaces to the fitted screen.

142. The system of claim 140, wherein the ferrule acts as proximal concentric attachment surfaces to the fitted screen.

143. The system of claim 136, wherein the gap space is less than 0.002" radially.

144. The system of claim 136, wherein the gap space is preferably less than 0.001" radially.

145. The system of claim 136, wherein the gap space is more preferably less than 0.0005" radially.

146. The system of claim 136, wherein the fitted screen the shearing body are made of materials having the same hardness.

147. The system of claim 136, wherein the fitted screen has a material hardness greater that the hardness of the shearing body.

148. A method of making a fitted screen adapted to closely cover a shearing body of a catheter comprising the steps of:

(a) determining the dimensional configuration of the shearing body;

(b) determining the effective shearing surface area of the shearing body;

(c) forming a housing of at least one piece capable of fitting said shearing body and having an inner profile that closely matches the outer dimensional profile of the shearing body;

(d) creating a distal bearing surface;

(e) creating a proximal bearing surface:

(f) creating a screen from said housing by making a plurality of apertures in said housing in the area of the housing which corresponds to the effective shearing surface area of the shearing body; and

(g) attaching the screen to said catheter such that said shearing body can operate as intended without interfering with the fitted screen.

149. The method according to claim 148, wherein the housing of step (c) is more than one piece.

150. The method according to claim 148, wherein the apertures of step (f) are formed by conventional machining.

151. The method according to claim 148, wherein the apertures of step (f) are formed by a laser.

152. The method according to claim 148, wherein the apertures of step (f) are formed by electrical discharge machining.

153. The method according to claim 148, wherein the apertures of step (f) are formed by water-jet machining.

154. The method according to claim 148, wherein step (g) is replaced with steps:

(h) polishing the apertures;

(i) attaching the screen to said catheter such that said shearing body can operate as intended without interfering with the fitted screen.

155. The method of claim 148, wherein step (g) further comprises attaching the screen to the shearing body.

156. The method of claim 148, wherein step (g) is accomplished by swaging.

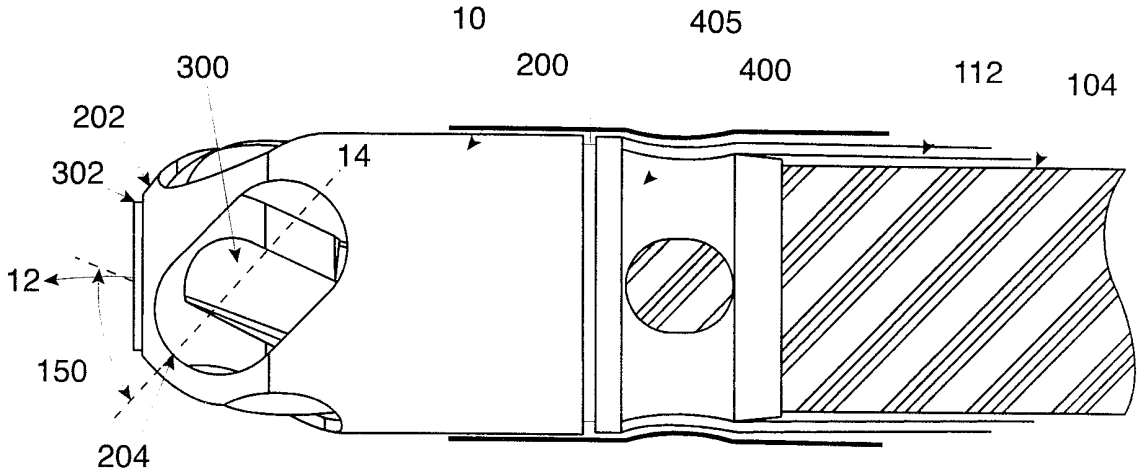

10
405
300
200
400
112
104
202
14
302
12
150
204

FIG.1A

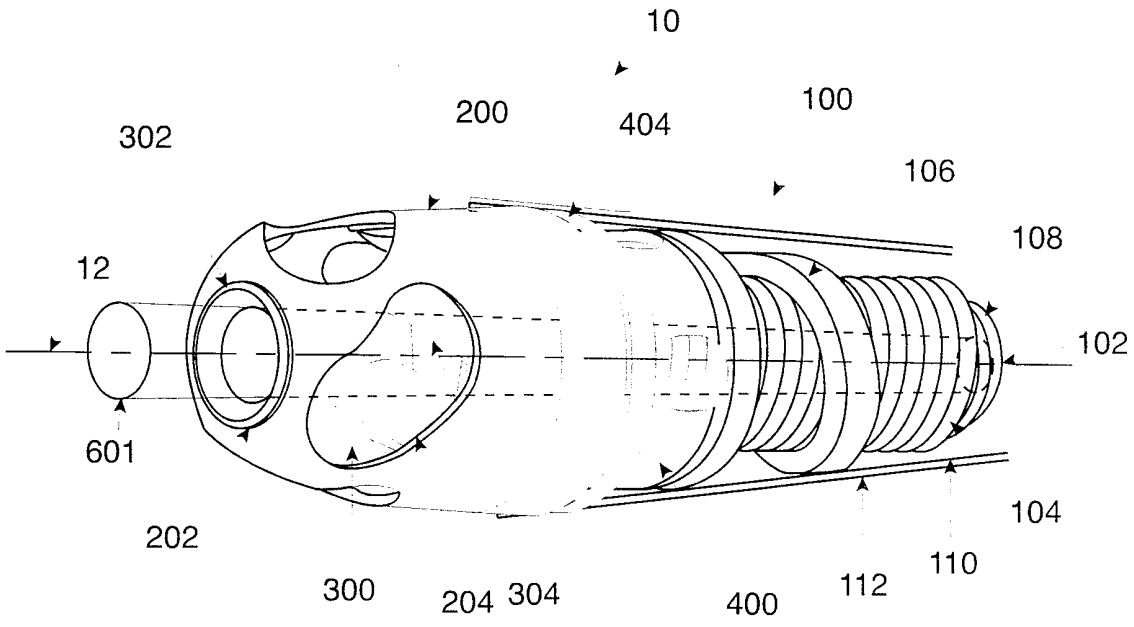

10
200
404
100
302
106
108
12
102
601
104
202
110
300
204
304
400
112

FIG.1B

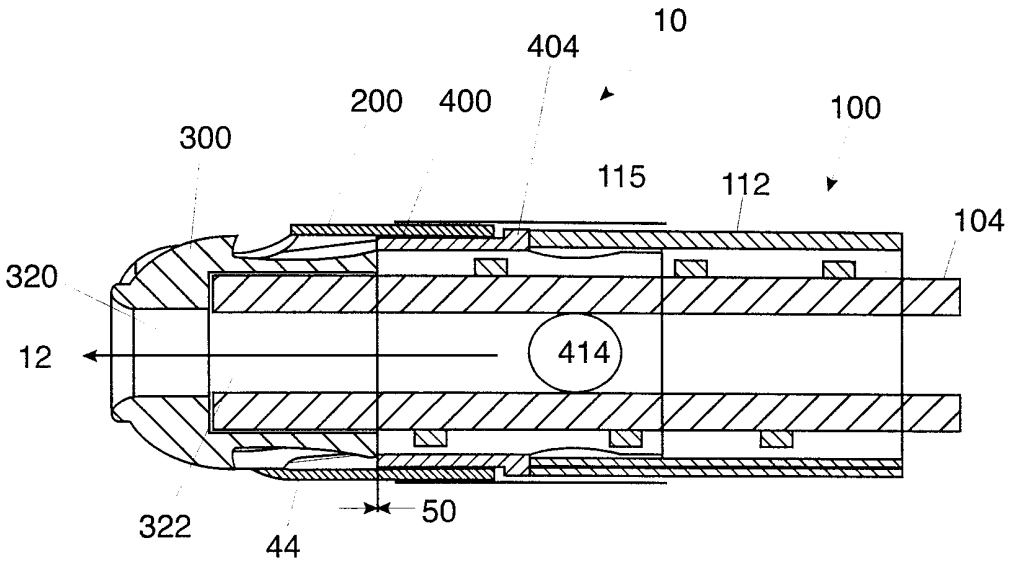

10
404
200
400
100
300
115
112
104
320
12
414
322
44
50

FIG. 1C

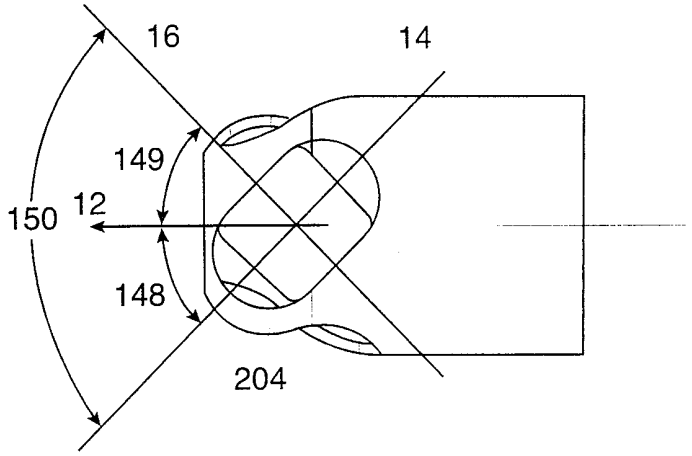

16
14
149
150
12
148
204

FIG. 2A

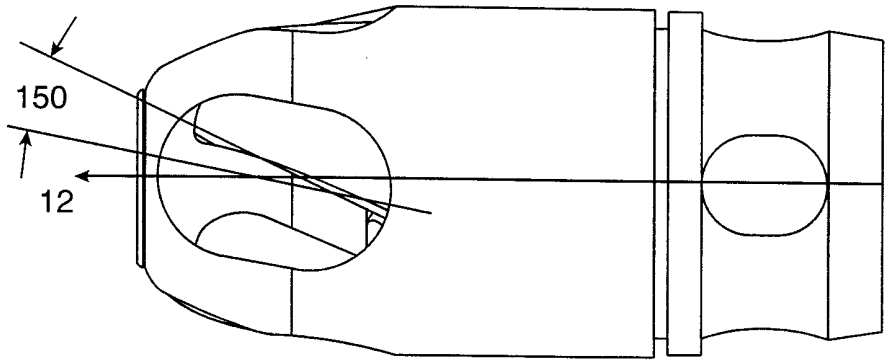


FIG. 2B

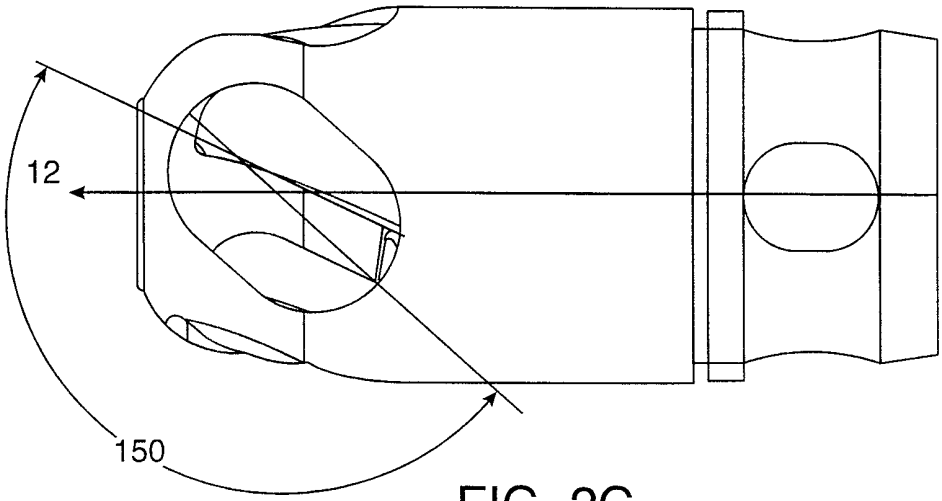
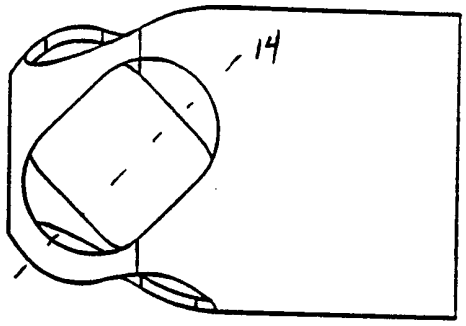


FIG. 2C



2D

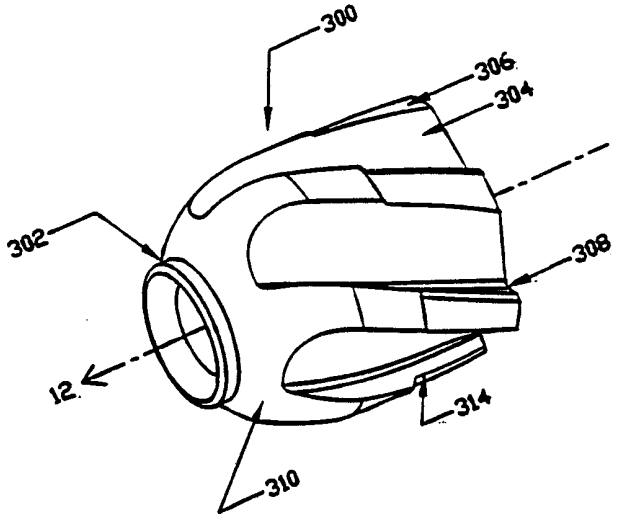
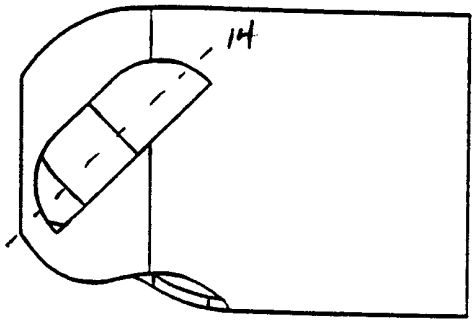


Fig. 3A



2E

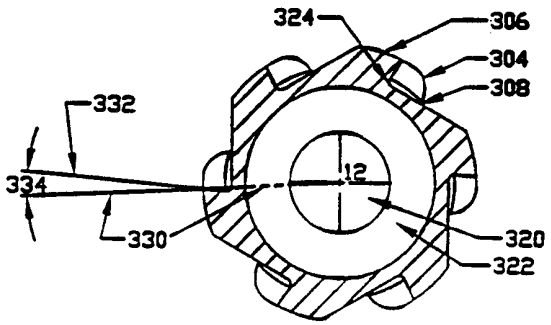
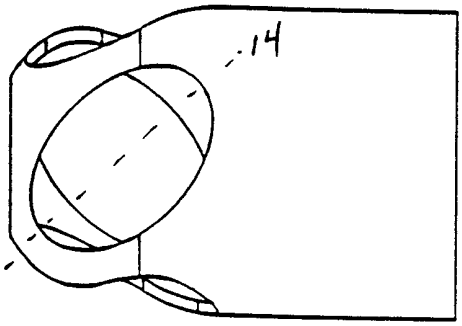


Fig. 3B



2F

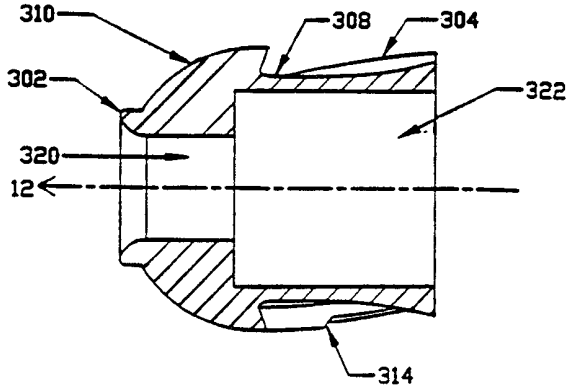


Fig. 3C

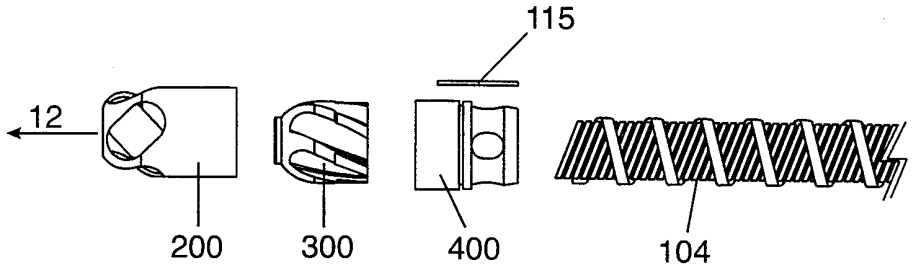


FIG. 5

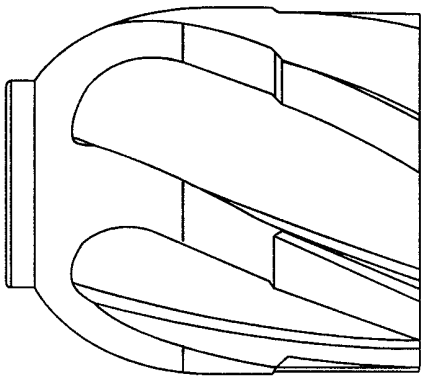


FIG. 3D

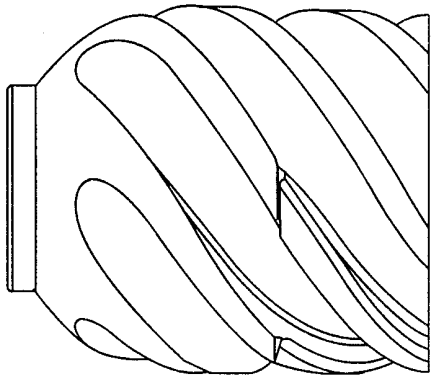


FIG. 3E

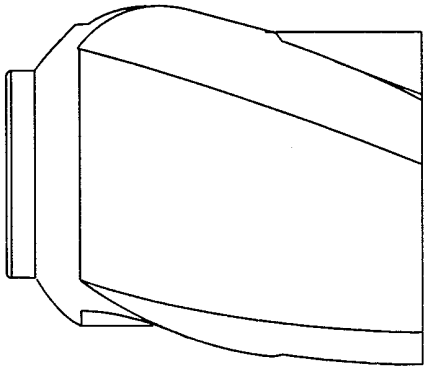


FIG. 3F

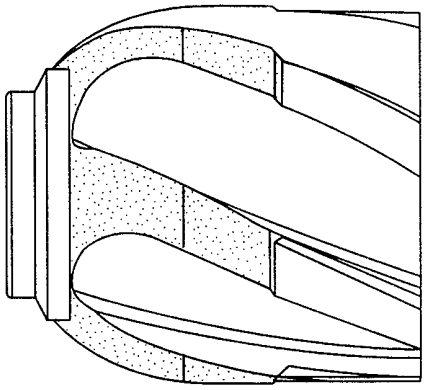


FIG. 3G

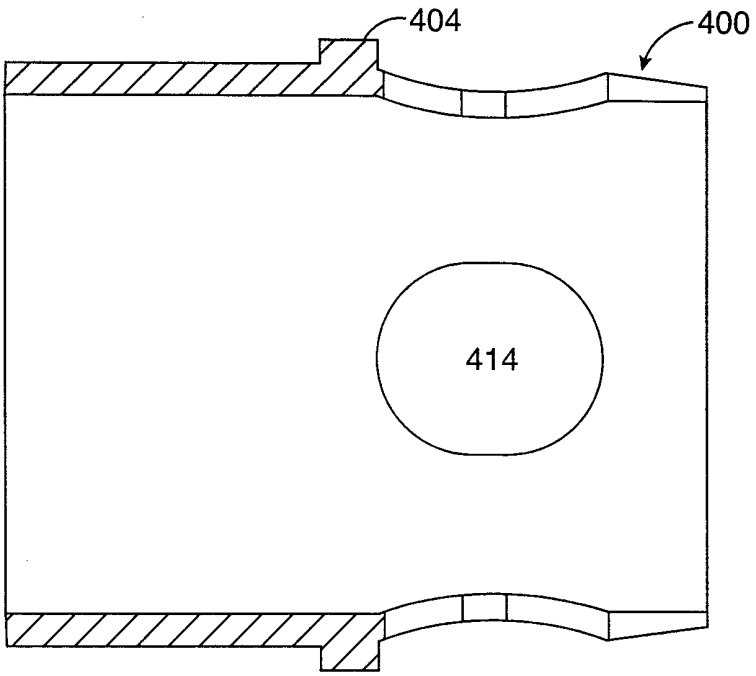


FIG. 4A

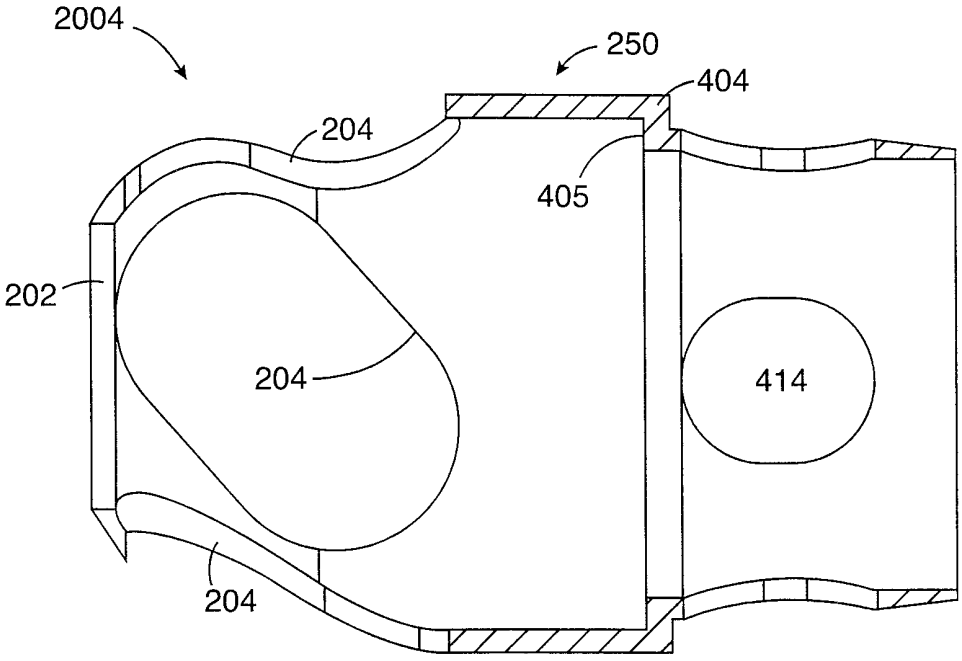


FIG. 4B

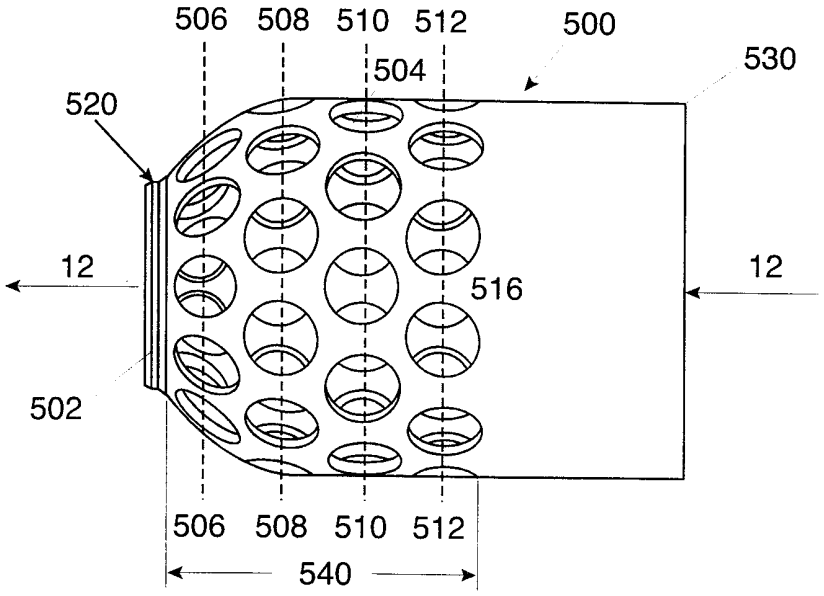

506
508
510
512
500
504
530
520
12
516
12
502
506
508
510
512
540

FIG. 6A

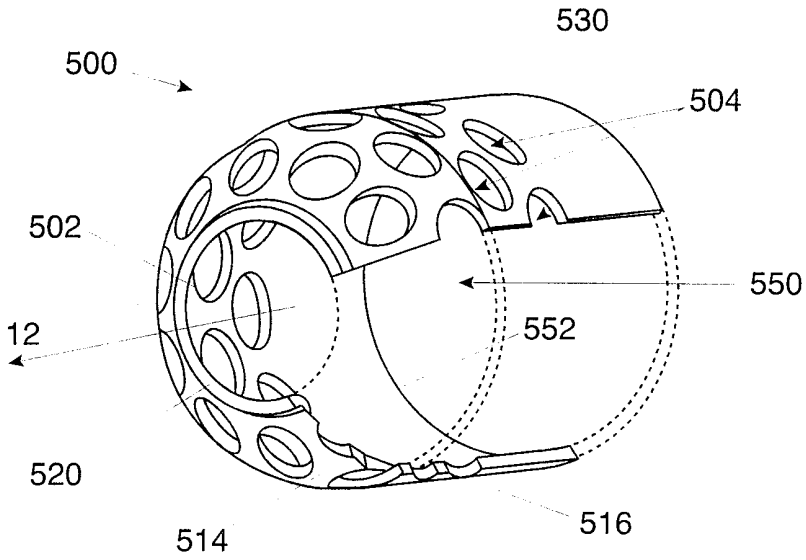

530
500
504
502
550
12
552
520
516
514

FIG. 6B

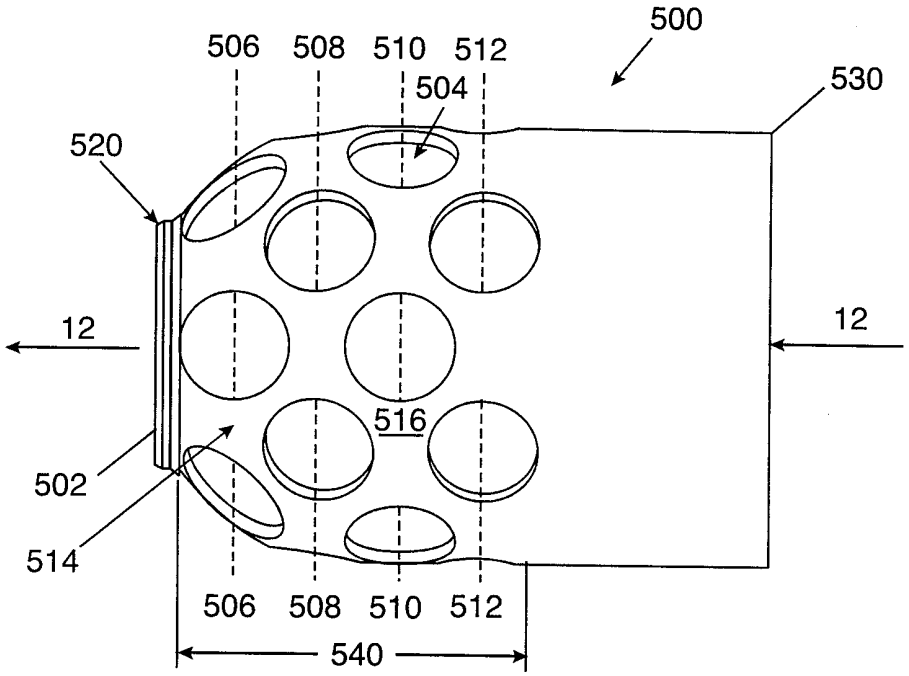

500
506
508
510
512
504
530
520
12
12
516
502
514
506
508
510
512
540

FIG. 6C

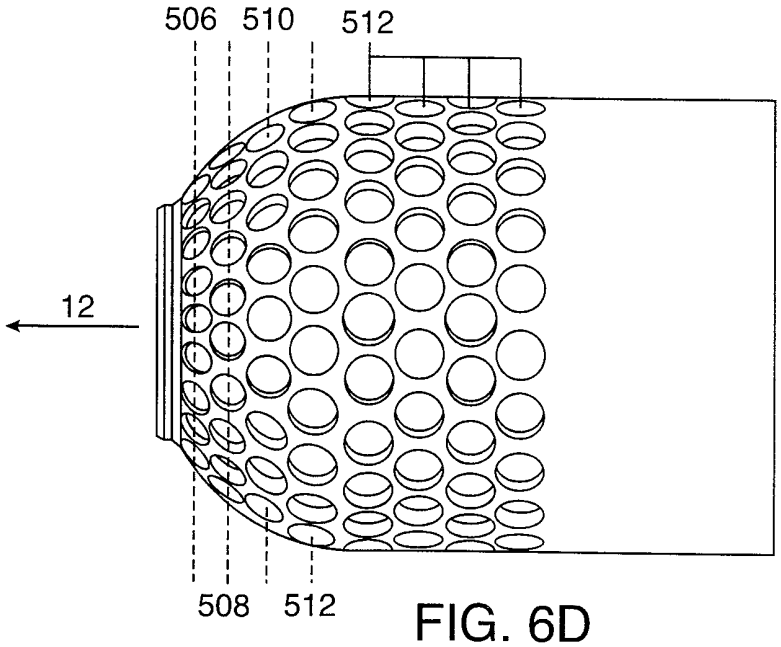

506
510
512
12
508
512

FIG. 6D

Figure 7B

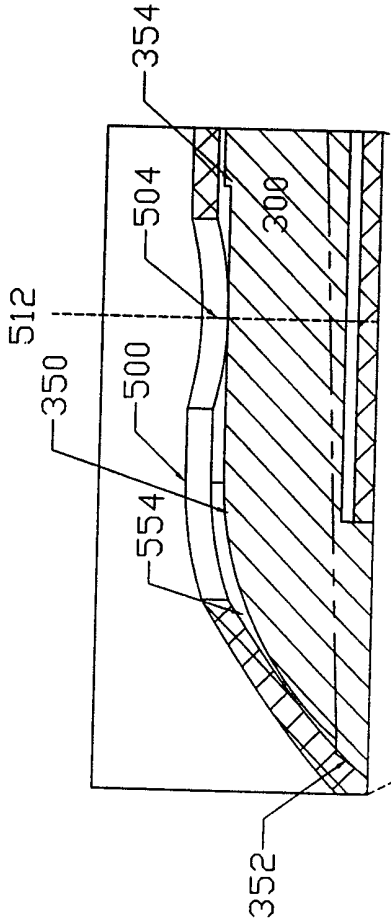
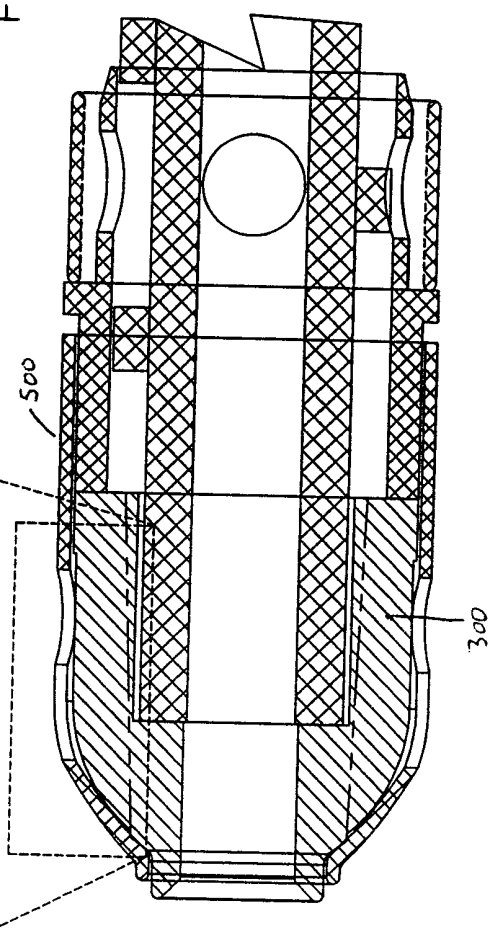


Fig 7A



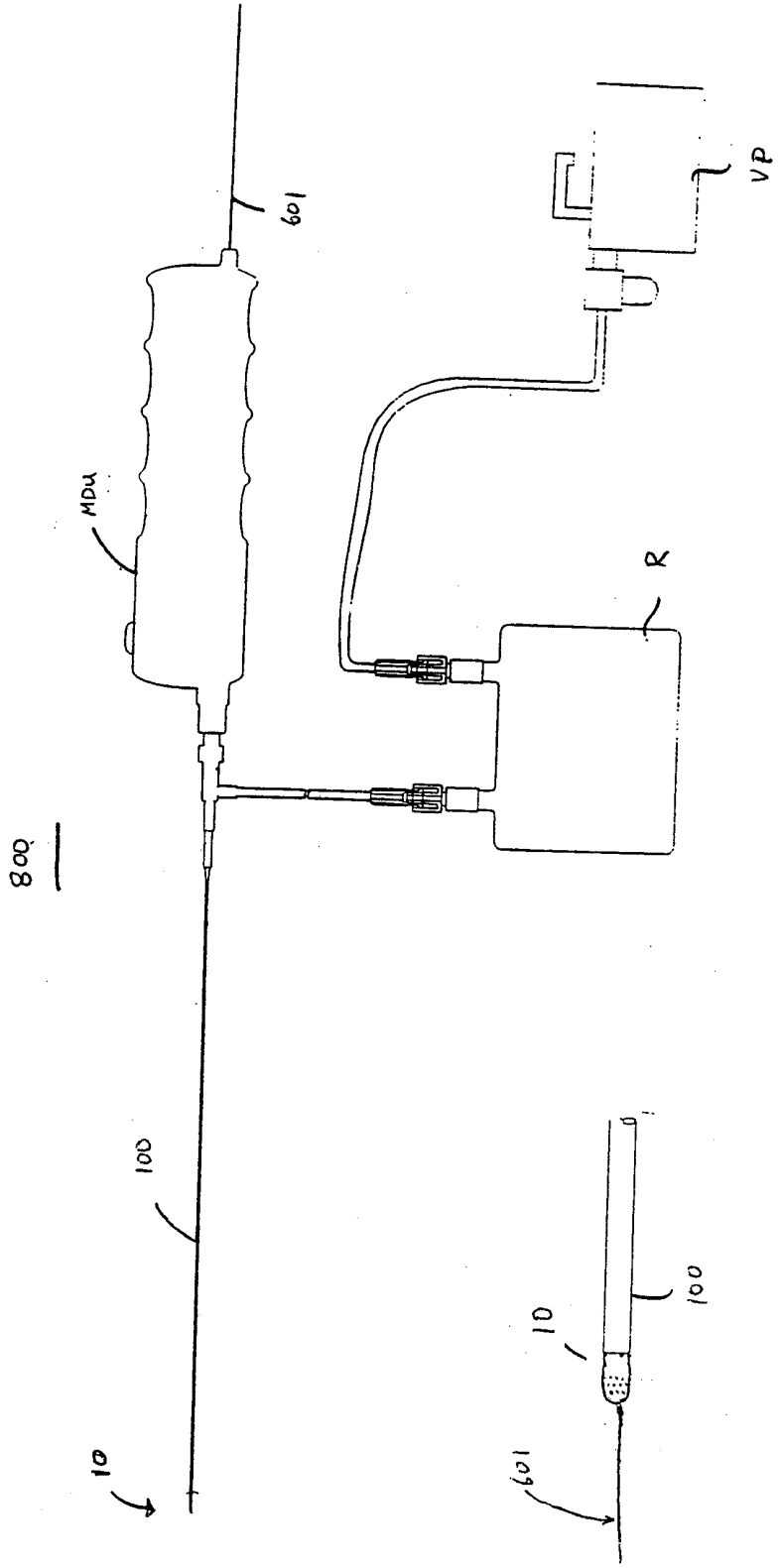


Fig 8A

Fig 8B

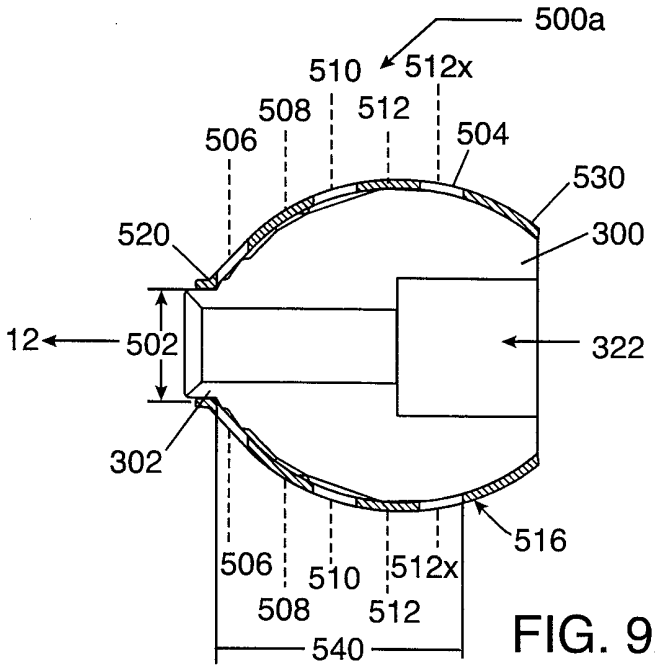


FIG. 9A

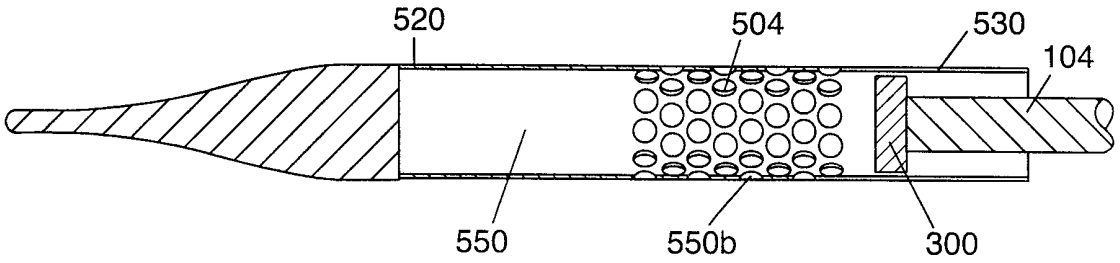


FIG. 9B

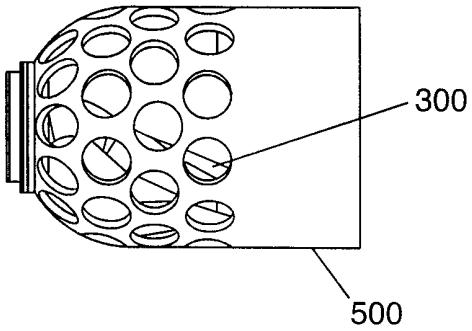


FIG. 9C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/06494

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/00
US CL : 606/159

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)

U.S. : 606/159, 167, 168, 170

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, E	US 6,053,923 A (VECA et al.) 25 April 2000, entire document.	11-44

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

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

Date of the actual completion of the international search 07 MAY 2000	Date of mailing of the international search report 08 JUN 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer VIKKI TRINH Telephone No. (703) 308-8238