

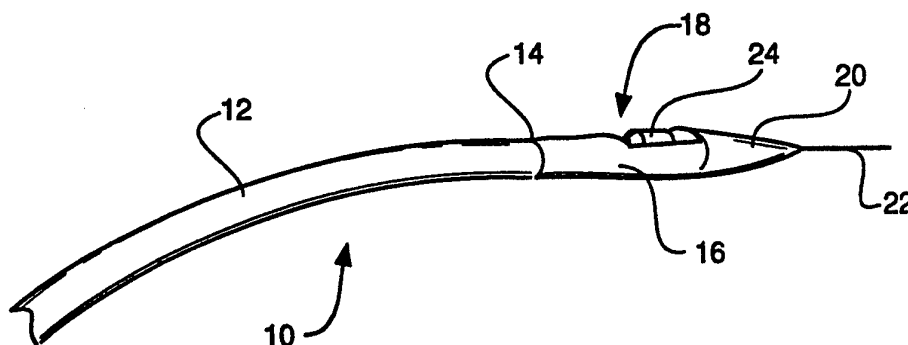


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(54) Title: IMPROVED CUTTER DEVICE**(57) Abstract**

Disclosed herein is a cutter for removing soft and hard tissue when used with an atherectomy catheter (10) of the type having a cutter housing (16) attached to the distal end of a catheter member (12) having a torque cable (26). A circular (5) cutting blade (24) is disposed within the housing (16) and is secured to the distal end of a rotatable torque cable (26). An elongated aperture (18) formed along one side of the housing (16) allows the intrusion of stenotic material which may then be severed by rotating and axially translating the cutting blade (24). The cutting blade may be made from a cemented tungsten carbide compound of 90 percent (10) tungsten carbide (WC) and 10 percent cobalt (Co) which is heated, injection molded and sintered to produce a hard, durable cutting edge (28). The cutting edge (28) is coated with titanium carbonitride using a physical vapor deposition process to further increase durability and resistance to fragmentation. Cutting edge hardness is further increased by application of an ion implantation (15) of nitrogen using an ion-beam assisted deposition process. A variety of alternative cutter materials, coatings and geometries are devined which improve cutter performance in removing soft and hard lesions.



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IMPROVED CUTTER DEVICE

Technical Field:

This invention relates to biological tissue cutters for use with atherectomy devices inserted into a biological conduit for removal of diseased tissue, and specifically relates to cutters adapted for removal of calcified tissue.

Background Art:

Atherosclerosis is a condition characterized by fatty deposits (atheromas) in the intimal lining of a patient's blood vessels. Atherosclerosis can present in a variety of ways including angina, hypertension, myocardial infarction, strokes, and the like. Regions of the blood vessel which are blocked by atheroma, plaque, or other material are generally referred to as stenoses, and the blocking material as stenotic material. The atheromas deposited on the blood vessel walls are often relatively soft and tractable. However, in many cases the atheromic material is a calcified and hardened plaque. Removal of the calcified tissue by current atherectomy is extremely difficult.

Atherectomy is a procedure which has been developed for removing stenotic material from the vascular system, usually before substantial calcification has occurred. Atherectomy procedures utilize a variety of special catheters having tissue cutting members (cutters) located at a distal end. In use, the catheter is inserted into a biological conduit of the vascular system so that the cutter is adjacent to the stenotic region. The cutter is then manipulated to excise a portion of the stenotic material. The severed material is captured to prevent the release of emboli into the blood stream.

The cutter on an atherectomy catheter can take a variety of forms, including fixed blades (requiring movement of the entire catheter to effect cutting) and movable blades which are manipulated within a stationary housing at the distal end of the catheter.

Of particular interest to the present invention are atherectomy catheters of the type described in copending U.S. continuation-in-part application, serial no. 08/091,160, filed July 13, 1993 by Milo et al., entitled "Imaging Atherectomy Apparatus," hereby incorporated by reference. These atherectomy catheters
5 include a cutter housing attached to the distal end of a torquable catheter body. A circular cutting blade is disposed within the housing and is secured to the distal end of a rotatable drive shaft (torque cable). An elongated aperture (window) formed along one side of the housing allows the intrusion of stenotic material which may then be severed by rotating and axially translating the cutting blade.

10 Such atherectomy catheters have enjoyed substantial success and acceptance in the medical community where their use has been limited primarily to removal of non-calcified stenotic material. Not infrequently however, an interventionist (physician) is confronted with a need to remove tissue including calcified deposits. These deposits are extremely hard, their hardness
15 comparable to that of the material used to make the cutting blade.

Attempts to use atherectomy catheters to remove calcified tissue result in the cutting edge becoming rounded and dulled. A dulled blade can be ineffective for removing non-calcified (soft) tissue.

What is needed is a cutting blade which is effective for cutting soft tissue.

20 What is also needed is a cutting blade hard enough to retain its soft tissue cutting ability when used to remove calcified tissue.

Finally, what is needed is a cutting blade that is biocompatible.

Disclosure of Invention:

It is an object of this invention to provide a cutter which is hard enough to cut calcified tissue, and retains a cutting edge which can effectively remove soft tissue.

- 5 It is an additional object of this invention to provide a cutting blade which is biocompatible.

In accordance with the above objects and those that will be mentioned and will become apparent below, the invention provides a cutter for use in a biological catheter as a remover of plaque from a biological conduit, the cutter
10 comprising:

a body having a cutting edge and an exterior portion, and being adaptable for attachment to a torque cable;

the body being made of a material selected from the group consisting of tungsten carbide, cermet, carbide-based cermets, polycrystalline cubic boron
15 nitride, aluminum oxide, and silicon nitride; and

the exterior portion of the cutter body being biocompatible;
whereby the cutting edge cuts calcified tissue and soft tissue.

In a preferred embodiment, the cutter body is made from a cemented tungsten carbide mixture of 90 percent tungsten carbide and 10 percent cobalt
20 (90WC-10Co). The cutter body is cylindrical, has proximal and distal ends and an axis extending between the ends. The distal end has a cup shaped recess, the recess being generally symmetrical about the axis. The cylinder has an outer surface which includes an outer wall portion adapted to fit compatibly within a cylindrical housing of the catheter. The body and the cutting edge of the 90WC-
25 10Co cutter are coated with a biocompatible material selected from the group consisting of titanium carbonitride and titanium nitride. This coating increases resistance to abrasion (erosion), hardness, and to fragmentation (durability).

In another embodiment, the cutting edge of a coated 90WC-10Co cutter is treated by ion implantation of nitrogen. This implantation further increases the
30 performance of the cutting edge.

In another embodiment, the cutter is made of a stainless steel and is coated with a biocompatible substance which increases the hardness of the cutting edge.

In another embodiment, the cutter is made of a stainless steel and the surface is treated by a process such as ion implantation to increase the hardness and the overall cutting performance of the cutting edge.

A number of alternative cutting edge geometries are defined, and a method for hardening the stainless steel cutting edge by heat treating is presented.

10 It is an advantage of the present invention to provide a cutter capable of effectively removing both calcified (hard) and non-calcified (soft) tissue.

It is a further advantage of the present invention to provide a cutter having a cutting edge durable enough to resist fragmentation when used to remove hard lesions.

15 It is also an advantage of this invention to provide a cutter which is biocompatible.

Brief Description of Drawings:

For a further understanding of the objects and advantages of the present invention, reference should be had to the following detailed description, taken in conjunction with the accompanying drawing, in which like parts are given like reference numerals and wherein:

Fig. 1 is a partial perspective view of an atherectomy catheter which uses a cutter in accordance with the present invention.

Fig. 2 is a partial perspective view of a torque cable and attached cutter of 25 the atherectomy catheter of Fig. 1.

Fig. 3 is an end view of the cutter of Fig. 2 and having a cup shaped single arcuate cutting edge.

Fig. 4 is a side sectional view taken along line 4-4 of Fig. 3 and looking in the direction of the arrows.

30 Fig. 5 is a perspective view of the cutter of Figs. 3, 4.

Fig. 6 is an end view of an alternative embodiment of the cutter of Figs. 3-5 and having a serrated cutting edge.

Fig. 7 is a side sectional view of the cutter of Fig. 6 taken along line 7-7 and looking in the direction of the arrows.

5 Fig. 8 is a perspective view of the cutter of Figs. 6, 7.

Fig. 9 is an end view of another alternative embodiment of the cutter of Fig. 2 and having a cup shaped compound angle single arcuate cutting edge.

Fig. 10 is a side sectional view of the cutter of Fig. 9 taken along the line 10-10 and looking in the direction of the arrows.

10 Fig. 11 is a perspective view of the cutter of Figs. 9, 10.

Fig. 12 is an end view of another alternative embodiment of the cutter of Fig. 2 and having a flat-lapped, abrasive cutting surface.

Fig. 13 is a side sectional view of the cutter of Fig. 12 taken along the line 13-13 and looking in the direction of the arrows.

15 Fig. 14 is a perspective view of the cutter of Figs. 12, 13.

Fig. 15 is an end view of another alternative embodiment of the cutter of Figs. 12-14 and including cutting teeth along the abrasive, flat-lapped cutting surface.

Fig. 16 is a side sectional view of the cutter of Fig. 15 taken along the line 20 16-16 and looking in the direction of the arrows.

Fig. 17 is a perspective view of the cutter of Figs. 15, 16.

Fig. 18 is an end view of another alternative embodiment of the cutter of Fig. 2 and including a flat-lapped, single cutting edge.

Fig. 19 is a side sectional view of the cutter of Fig. 18 taken along the line 25 19-19 and looking in the direction of the arrows.

Fig. 20 is a perspective view of the cutter of Figs. 18, 19.

Fig. 21 is an end view of another alternative embodiment of the cutter of Fig. 2 and having a curvilinear varying height cutting edge.

Fig. 22 is a side sectional view of the cutter of Fig. 21 taken along the line 30 22-22 and looking in the direction of the arrows.

Fig. 23 is a perspective view of the cutter of Figs. 21, 22.

Fig. 24 is an end view of another alternative embodiment of the cutter of Fig. 2 and having a spiral varying height cutting edge.

Fig. 25 is a side sectional view of the cutter of Fig. 24 taken along the line 5 25-25 and looking in the direction of the arrows.

Fig. 26 is a perspective view of the cutter of Figs. 24, 25.

Modes for Carrying Out the Invention:

With respect to Figs. 1 and 2, there is shown a partial perspective view of 10 an atherectomy catheter 10 illustrating an elongated catheter member 12 having a distal end 14, a cylindrical housing 16 including an opening 18 along one side, a nose cone 20, a guide wire 22, a torque cable 26, and a biological tissue cutter 24 with a cutting edge 28.

The distal end 14 of the elongated catheter member 12 is connected to 15 the cylindrical housing 16. The nose cone 20 provides an atraumatic termination. The flexible torque cable 26 extends within the catheter member 12 and into the housing 16. The cutter 24 is attached to the torque cable 26 and is able to rotate and slide freely within the cylindrical housing 16. The guide wire 22 extends through the torque cable 26, through the cutter 24 and extends distally beyond 20 the end of the nose cone 20.

In use, the atherectomy catheter 10 is inserted into a biological vessel and positioned such that the opening 18 is adjacent to stenotic, calcified or diseased tissue. The torque cable 26 is manipulated to slide the cutter 24 into the proximal end of the housing 16. The torque cable 26 is then rotated and advanced in the 25 distal direction causing the attached cutter 24 to cut tissue which extends through opening 18 and into the cylindrical housing 16.

The distal end of the cutter 24 includes a sharpened, circular cutting edge 28. The cutting edge 28 slices through tissue which extends into the cylindrical housing 16.

Fig. 3 is an end view of a cutter 24 such as illustrated in Figs. 1, 2. Cutter 24 includes a cup shaped single arcuate cutting edge 28 and an axial bore 30.

A side sectional view through the line 4-4 of Fig. 3, looking in the direction of the arrows, is illustrated in Fig. 4. The cutter 24 includes the axial bore 30 whose diameter is adapted to accommodate the distal end 32 of the torque cable 26. The guide wire 22 is shown extending from the distal end 32 of the torque cable 26.

The cutter 24 is secured to the torque cable 26 by one of several methods including adhesive, press fit, or other methods of mechanical retention such as soldering, welding or brazing. In one embodiment, the torque cable 26 is made of a metal and is enclosed within a plastic covering. The plastic covering is removed near the distal end 32 of the torque cable 24 thereby exposing the metal. The distal end 32 is then soldered into the axial bore of the cutter 24.

Fig. 5 is a perspective view of the cutter 24 of Figs. 3 and 4 illustrating the cup shaped arcuate single cutting edge 28, the axial bore 30, a cup shaped distal recess 32 and an exterior portion or wall (outside diameter) 34. The intersection of the cup shaped recess 32 with the exterior wall 34 defines the single arcuate cutting edge 28.

Figs. 1 - 5 illustrate the cutter 24 which is the subject matter of the present invention. When the tissue being cut or removed is calcified, the circular cutting edge 28 can be easily damaged. A damaged cutting edge 28 is not effective for cutting calcified tissue, nor is it effective for cutting non-calcified (soft) stenotic tissue.

The present invention overcomes the problem of damage to the cutting edge 28 in a variety of ways. First to be considered is the use of tough, hard materials for making the cutter 24. The use of such materials provides a cutting edge 28 which can withstand much of the damage normally inflicted by calcified tissue while retaining the ability to effectively remove soft lesions.

Biocompatibility is assured by the use of coatings which also improve performance.

Second to be considered is a cutter 24 made of a stainless steel and coated with a biocompatible material to increase the surface hardness and lubricity. A secondary coating is applied to selected areas of the cutter 24 to provide an abrasive or grinding capability.

- 5 A third family of embodiments of the present invention relates to "engineered" surface treatments, such as ion implantation of selected materials. These are used to harden or to improve and maintain the cutting edge 28 during assembly and operation.

Next, a variety of cutting edge 28 geometries are defined which improve
10 the ability of the cutting edge 28 to remove or excise calcified tissue.

Finally, a method for hardening the stainless steel cutting edge by heat treating the cutter 24 is defined.

Materials

- 15 Testing has demonstrated that cutter base materials must meet the following requirements to be effective in removing calcified tissue. The cutter material must be *durable* enough to retain an effective soft tissue cutting edge while cutting hardened lesions. The cutter material must be *tough* (durable) enough to minimize fragmentation of the cutting edge. Finally, the material must
20 be *biocompatible*, at least where an exterior wall of the cutter is in contact with biological matter. The latter two requirements are unique to the atherectomy catheter application as compared with typical industrial cutting/machining requirements.

Tungsten carbide is a material which is capable of cutting hardened
25 lesions without significant degradation of the cutting edge. It retains its cutting edge and resists breakage. Other hard materials are known to possess similar properties.

Therefore, in one embodiment, the cutter body 24 is made of a material selected from the group including but not limited to tungsten carbide, cermets,

carbide- based cermets, polycrystalline cubic boron nitride, aluminum oxide and silicon nitride.

"Cermet" is an acronym used to designate a heterogeneous combination of metal(s) or alloy(s) with one or more ceramic phases in which there is relatively little solubility between metallic and ceramic phases at the preparation temperature. Carbide-based cermets constitute the bulk of the cermets. This group includes the cemented carbide cutting tools and wear parts based on tungsten carbide. These materials are described in Vol. 7, Metals Handbook, 9th edition, "Powder Metallurgy," American Soc. for Metals, 1984, which is specifically incorporated herein by reference.

Preferably the cutter body 24 is made of 90 percent tungsten carbide (WC) and 10 percent cobalt (Co) (by weight, designated herein as 90WC-10Co).

The tungsten carbide is in the form of a powder having particles of a diameter averaging 0.6 micron. The mixture of tungsten carbide powder and cobalt binder is placed in a mold and then pressed and heated ("sintering") in a well-defined process of producing cemented carbides. In most industrial applications, 6 percent cobalt is used for a similar purpose. The 10 percent cobalt mixture of the present invention makes the resulting material more durable and thus better able to resist breaking and chipping.

The 90 WC-10 Co cutter body 24 is only moderately biocompatible. When coated with titanium carbonitride or titanium nitride however, the 90 WC-10 Co body 24 becomes biologically inert.

Coatings

The cutter body 24, or a portion thereof, may be completely or selectively coated with materials which improve the cutting capabilities of the base material.

Relative to the harder materials which have been described above, a coated steel cutter has been shown to be easier to manufacture and has produced similar performance results. Stainless steel cutters made from either or both 440 FSe (free machining selenium, UNS designation S44023) or 440 C (USN

designation S44004) stainless steel, in combination with certain coatings, have been shown to cut through calcified material while retaining their edges.

Properties provided by the coatings include increased hardness (abrasive resistance) and improved surface finish (lubricity). Additive material shown to
5 improve performance include diamond-like carbon, alumina, titanium nitride, titanium carbonitride, zirconium nitride, boron nitride, cubic boron nitride and high chromium-composites such as ME-92 (Electrolyzing, Inc., Providence, RI), as well as other proven surface engineered treatments.

Selectively coating certain portions of the cutter 24 can be shown to
10 provide different functional zones on the cutter. For example, coating the cup-shaped recess 31 of the cutter 24 (Fig. 5) with an abrasive material such as polycrystalline diamond and coating the edge with a hard material, such as titanium nitride, will provide a cutter with the ability to cut the calcified material and also grind the calcified material as it bottoms out in the cup-shaped recess
15 31. This combination allows concurrent cutting and removal of the calcified material. Coating the outside diameter 34 of the cutter 24 with a hard, smooth coating can improve the bearing interface with the inside of the housing.

In a preferred embodiment, the cutting edge 28 of the 90 WC-10 Co cutter 24 is coated with a titanium carbonitride using a process such as the Balzers
20 TiCN coating process (Balzers Tool Coating Inc., North Tonawanda, New York). Alternatively, the cutter 24 is coated with a titanium nitride using a process such as the Balzers TiN process. The coating is a multiple layer thin film coating formed in a low temperature PVD (physical vapor deposition) process. The preferred coating thickness is approximately 2.5 microns. The resulting coating
25 edge has a thickness of approximately 5-10 microns.

Engineered Surfaces

Implantation of certain materials into the cutter base materials increases the hardness of the base material. Materials to be implanted include nitrogen,
30 boron and other elements that enhance the hardness, wear resistance ,

biocompatibility and general application efficiency. These other elements include chromium, carbon, titanium and nitrogen. The implantations are made using a surface engineered process such as ion-beam assisted deposition (IBAD) or ion implantation.

- 5 In one embodiment, an increase in cutting edge 28 hardness without significant decrease of durability has been noted for a 90 WC-10 Co base material coated with titanium carbonitride or titanium nitride and treated with an ion implantation of nitrogen.

10

Cutter Geometries

Figs. 3-5 define the basic cup shaped single arcuate cutting edge 28 which has been demonstrated to be an effective cutter geometry for the removal of heavily calcified stenotic tissue. Additional cutter geometries have been investigated for this purpose and are presented in Figs. 6 through 26.

- 15 A pair of variations of the single arcuate cutting edge cutter are illustrated in Figs. 6-11. Fig. 6 is an end view of a cutter 36 having a serrated cutting edge 38. The teeth of this cutting edge are effective at removing calcified tissue. Fig. 7 is a side sectional view taken through line 7-7 of Fig. 6 and looking in the direction of the arrows. Cutter 36 includes the axial bore 30 used for connection
20 of the cutter to the distal end of a torque cable. Fig. 8 is a perspective view of the cutter 36 illustrated in Figs. 6, 7. The serrated cutter 36 includes a cup shaped recess 31.

- Fig. 9 is an end view of a cup shaped compound angle single arcuate edged cutter 40. A side sectional view of the cutter 40 taken through the line 10-
25 10 of Fig. 9 and looking in the direction of the arrows is illustrated in Fig. 10. A cup shaped distal recess includes compound right frustrum sections 42 and 44. The compound arrangement allows significant cup depth while the body material near the cutting edge 46 retains a greater thickness than is possible with a simpler geometry. The increased thickness improves the ability to withstand
30 chipping and fragmentation of the cutting edge 46 when used to remove heavily

calcified material. Fig. 11 is a perspective view of the compound angle cutter 40 of Figs. 9 and 10. The cutter 40 includes the axial bore 30.

Figs. 12-17 illustrate cutters having a hollow cylindrical body and a flat-lapped abrasive cutting surface. The cutter having this geometry removes a calcified deposit by grinding it with the abrasive cutting surface. Fig. 12 is an end view of a cutter 48 having an abrasive cutting surface 50 which is coated with an abrasive material such as diamond grit. The abrasive material is applied to the cutting surface 50 using a physical vapor deposition process or the like or can be ion implanted as described above. Fig. 13 is a side sectional view along line 13-13 of Fig. 12 looking in the direction of the arrows. The cutter 48 includes a hollow interior 52 having a short axial bore 54 at the proximal end for attachment to a torque cable. The hollow interior 52 permits the collection of much removed tissue not possible with the more shallow cup shaped recess of other geometries.

Fig. 14 is a perspective view of the cutter 48 showing the abrasive cutting surface 50 and a portion of the hollow interior 52.

In Figs. 15-17, the flat-lapped abrasive cutting surface 50 includes a plurality of cutting teeth 56. Fig. 15 is an end view, Fig. 16 is a side sectional view along line 16-16 of Fig. 15, and Fig. 17 is a perspective view of the cutter.

Figs. 18-20 illustrate a cutter 58 having a flat-lapped single cutting edge 60. As illustrated in a side sectional view, Fig. 19, and in a perspective view, Fig. 20, the single cutting edge 60 includes a pair of spiral members 62 whose thickness decreases to a single arcuate cutting edge within 90 degrees of rotation. The distal surface of the spiral members 62 is flat lapped for grinding calcified material.

Figs. 21-26 illustrate two cutters having non-uniform cutting heights. Figs. 21-23 show a cutter having a curvilinear cutting edge 66 whose height varies to reduce damage to the edge resulting from constant contact with calcified tissue. Figs. 24-26 illustrate a cutter 68 having a spiral varying height cutting edge 70. The cutting edge 70 is flat-lapped and decreases in width to a single cutting edge.

The cutters illustrated in Figs. 18-26 are manufactured by a process of metal injection molding. The cutters 58, 64, 68 can also be manufactured using processes such as electrical discharge machining (EDM), chemical etching, photo-laser etching, or assembled as composite structures using separate, joined 5 pieces.

Hardening by Heat Treatment

The cutting edge of each of the cutter geometries is typically sharpened. The edge retention of a sharpened cutting edge can also be improved by various 10 heat treating techniques. In one embodiment, a stainless steel cutter body is heat treated both before and after sharpening. Such treatment has been shown to improve performance in removing tissue. The hardened cutter 24 has been shown to maintain its narrow cutting edge better than a similar cutter which has not been hardened.

15 Suitable methods for heat treating stainless steel are provided in the ASM Handbook, Vol. 4, Heat Treating, "Heat Treating of Stainless Steels and Heat-Resistance Alloys," pages 77-782, ASM International, 1991, which is specifically incorporated herein by reference.

While the foregoing detailed description has described several 20 embodiments of the calcification cutter in accordance with this invention, it is to be understood that the above description is illustrative only and not limiting of the disclosed invention. Particularly, the specific geometry of the cutter may vary from those illustrated so long as the cutter retains a generally cylindrical configuration having a cutting edge at one end of the cylinder. Also, the manner 25 in which the torque cable is attached to the cutter may differ from those described. It will be appreciated that variations in the selection of the cutter body material, thickness and type of coating, the portion of the body coated, and the use of a surface implantation or heat treatment to increase hardness can be selected from the range of parameters described and the resulting cutter remains

within the scope and spirit of this invention. Thus the invention is to be limited only by the claims as set forth below.

Claims:

1. A cutter for use in a biological catheter as a remover of plaque from a biological conduit, the cutter comprising:
 - a body having a cutting edge and an exterior portion, and being adaptable
5 for attachment to a torque cable ;
 - the body being made of a material selected from the group consisting of tungsten carbide, cermet, carbide-based cermets, polycrystalline cubic boron nitride, aluminum oxide, and silicon nitride; and
 - the exterior portion of the cutter body being biocompatible;
- 10 whereby the cutting edge cuts calcified tissue and soft tissue.
2. A cutter for use with a catheter having a torque cable, the cutter comprising:
 - a body defining a cutting edge and adapted for attachment to the torque
cable;
 - 15 the body being made of a steel selected from the group consisting of 440 FSe steel and 440 C steel; and
 - a coating covering a predetermined portion of the body including the cutting edge, the coating being selected from the group consisting of polycrystalline diamond, diamond-like carbon, titanium aluminum nitride, titanium
20 nitride, titanium carbonitride, zirconium nitride, boron nitride, cubic boron nitride and high chromium-composites,
 - whereby the steel cutting edge, being coated with a hard, tough material, is capable of cutting calcified tissue.
3. A cutter for use with a catheter having a torque cable, the cutter
25 comprising:
 - a body defining a cutting edge, the body adapted for attachment to the torque cable;
 - the body being made of a steel selected from the group consisting of 440 FSe steel and 440 C steel; and

the body defining a surface, the surface, including the cutting edge being ion implanted with a material selected from the group consisting of nitrogen and boron,

whereby the cutting edge is capable of cutting calcified tissue.

- 5 4. The cutter of Claims 1, 2 or 3, wherein the cutting edge is sharpened.
5. The cutter of Claims 2 or 3, wherein the cutting edge is hardened by heat treating.
6. The cutter of Claims 2 or 3, wherein the cutting edge is hardened by heat treating and is sharpened.
- 10 7. The cutter of Claim 1, wherein the body is cylindrical, has a proximal end and a distal end, has an axis extending between the ends, and wherein the distal end includes a cup shaped recess, the recess being generally symmetrical about the axis, and wherein the body defines a surface having an outer wall.
8. The cutter of Claim 2, wherein the body is cylindrical, has a proximal end
15 and a distal end, has an axis extending between the ends, and wherein the distal end includes a cup shaped recess, the recess being generally symmetrical about the axis, and wherein the body defines a surface having an outer wall.
9. The cutter of Claim 3, wherein the body is cylindrical, has a proximal end and a distal end, has an axis extending between the ends, and wherein the distal
20 end includes a cup shaped recess, the recess being generally symmetrical about the axis, and wherein the surface includes an outer wall.
10. The cutter of Claims 7, 8 or 9, wherein the cylindrical body includes an axial bore extending therethrough.
11. The cutter of Claims 7, 8 or 9, wherein the cup shaped recess intersects
25 the outer wall and wherein the cutting edge is further defined by the intersection of the recess with the outer wall.
12. The cutter of Claim 11, wherein the cutting edge is a single arcuate edge.
13. The cutter of Claim 11, further including the cutting edge having serrated cutting teeth.
- 30 14. The cutter of Claim 11, having a single curvilinear cutting edge.

15. The cutter of Claims 7, 8 or 9, wherein the cutting edge is further defined by the intersection of an axial spiral with the outer wall, the defined cutting edge being a single flat-lapped edge having a width proportional to the distance from the distal end.
- 5 16. The cutter of Claim 11, wherein the cutting edge includes two radially opposed flat-lapped, single edged cutting members of uniform height, each member having an outside diameter coincident with the outer wall and having a width which varies uniformly radially.
17. The cutter of Claim 11, wherein the cylindrical body is hollow and wherein
10 the cutting edge is flat lapped and is coincident with the distal end.
18. The cutter of Claim 17, wherein the flat lapped cutting edge is abrasive.
19. The cutter of Claim 18, wherein the abrasive flat lapped cutting edge includes cutting teeth.
20. The cutter of Claim 8, wherein the cup shaped recess has an abrasive
15 coating and wherein the cutting edge has a lubricating and hardening coating selected from the group consisting of diamond-like carbon, alumina, titanium nitride, titanium carbonitride, zirconium nitride, boron nitride, cubic boron nitride and high chromium-composites.
21. The cutter of Claim 20, wherein the abrasive coating is polycrystalline
20 diamond and wherein the cutting edge is coated with titanium nitride.
22. The cutter of Claim 21, further including the outer wall having a coating selected from the group consisting of diamond-like carbon, alumina, titanium nitride, titanium carbonitride, zirconium nitride, boron nitride, cubic boron nitride and high chromium-composites.
- 25 23. A method for hardening a cutter for use with a catheter device to cut calcified tissue, the method comprising the steps of:
- providing a cutter including tissue cutting means for cutting the calcified tissue, the cutter being made of a material which can be hardened by heat treatment;

heat treating the cutter a first time to increase the hardness of the tissue cutting means;

sharpening the tissue cutting means; and

heat treating the cutter a second time to further increase the hardness of
5 the tissue cutting means.

24. A carbide cutter used with a catheter device for cutting calcified and soft tissue, the cutter comprising:

a hollow cylindrical body having a proximal end, a distal end, and a central axis extending through the body from one end to the other, the cylindrical body
10 having a surface including an outer wall;

the proximal end of the body being adapted for attachment to a cutter torque cable;

the distal end of the body having a cup shaped recess, the recess being generally symmetrical about the axis, the intersection of the recess with the outer
15 wall defining a tissue cutting edge;

the cutting edge being sharpened; and

the body being made of tungsten carbide.

25. The carbide cutter of Claim 24, wherein the body material is 90 percent tungsten carbide (WC) and is 10 percent cobalt (Co).

20 26. The carbide cutter of Claim 25, further including a biocompatible coating covering a predetermined portion of the body including the cutting edge, the coating being selected from the group consisting of titanium carbonitride and titanium nitride.

27. The carbide cutter of Claim 26, further including a predetermined portion
25 of the surface, including the cutting edge, being ion implanted with nitrogen.

28. The carbide cutter of Claim 25, further including means for increasing the hardness of the cutting edge to improve removal of calcified and non-calcified tissue.

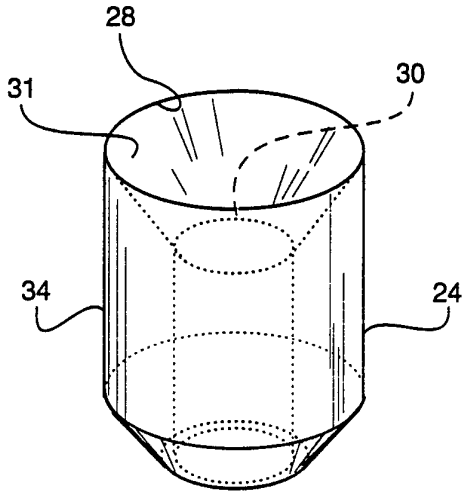
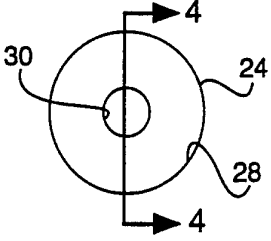
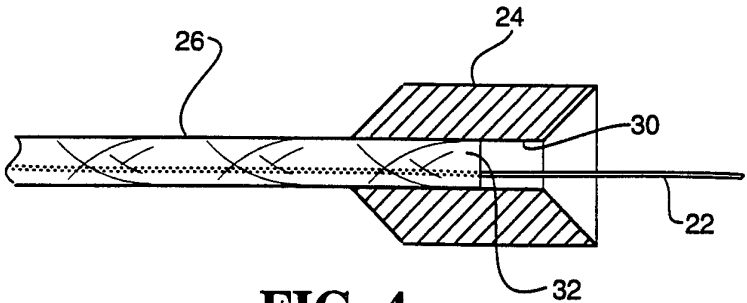
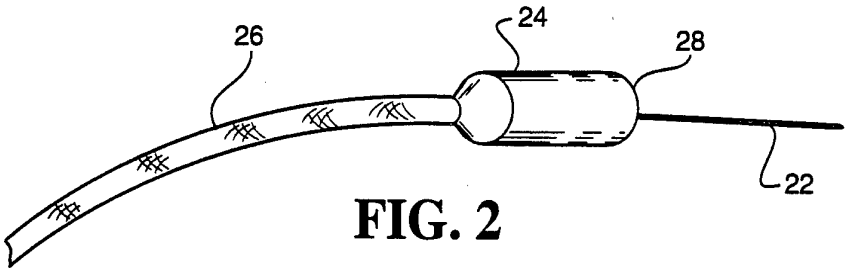
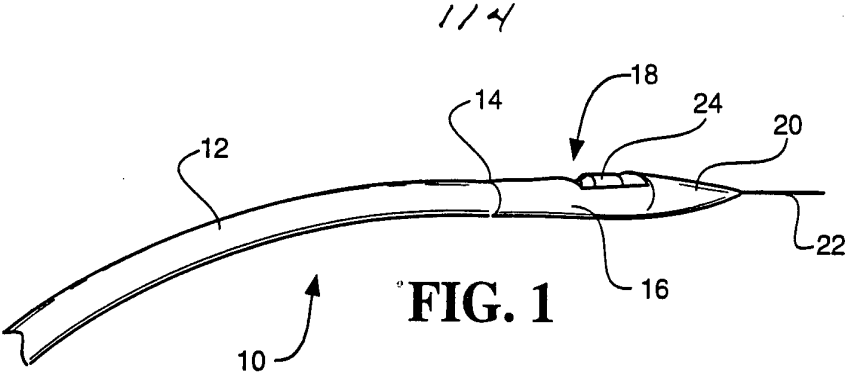
29. The carbide cutter of Claim 28, wherein the means for increasing hardness includes coating the cutting edge with a material selected from the group consisting of titanium carbonitride and titanium nitride.

30. The carbide cutter of Claim 29, wherein the means for increasing
5 hardness further includes ion implanting the coated cutting edge with nitrogen.

31. The carbide cutter of Claim 25, further including means for increasing the durability of the cutting edge to minimize the potential for fragmentation of the cutting edge during removal of calcified tissue.

32. The carbide cutter of Claim 31, wherein the means for increasing durability
10 includes coating the cutting edge with a material selected from the group consisting of titanium carbonitride and titanium nitride.

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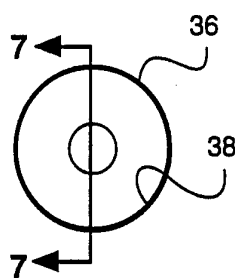


FIG. 6

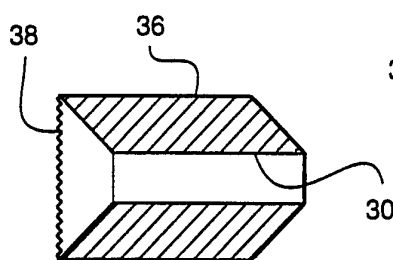


FIG. 7

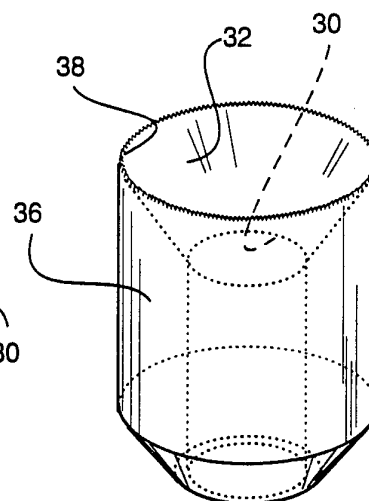


FIG. 8

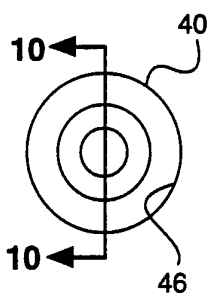


FIG. 9

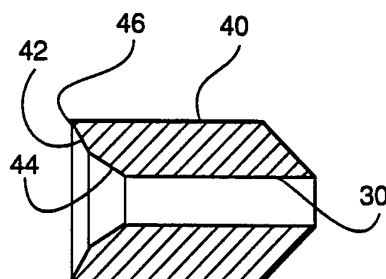


FIG. 10

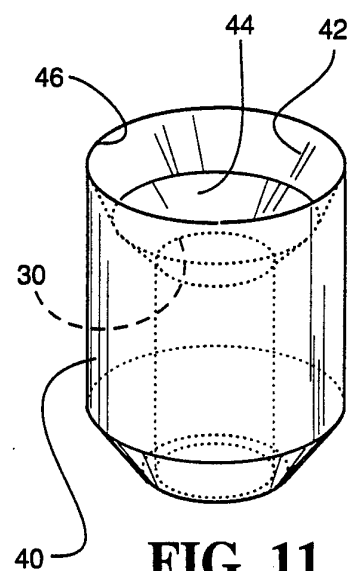


FIG. 11

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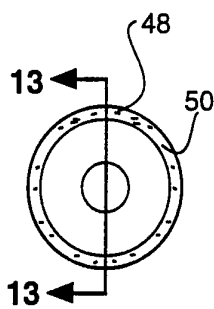


FIG. 12

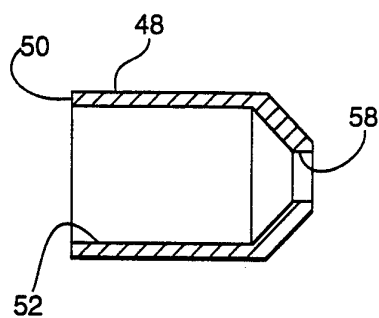


FIG. 13

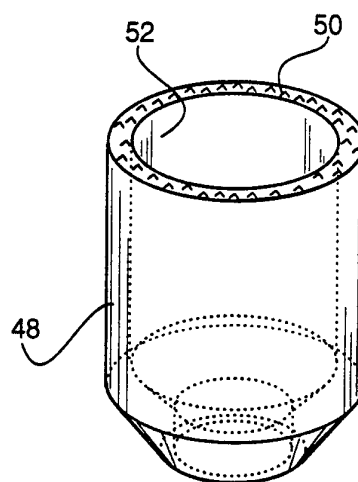


FIG. 14

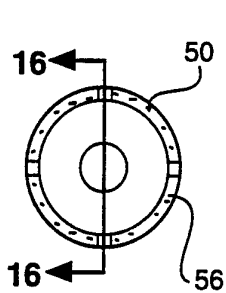


FIG. 15

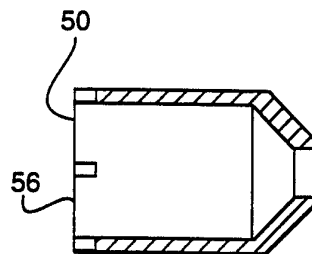


FIG. 16

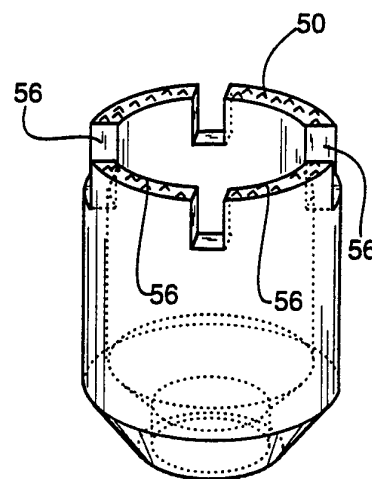


FIG. 17

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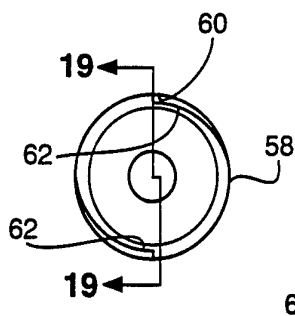


FIG. 18

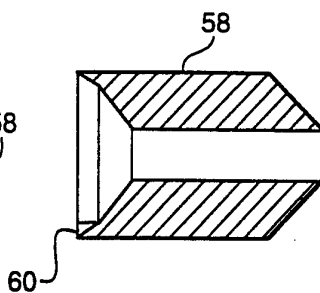


FIG. 19

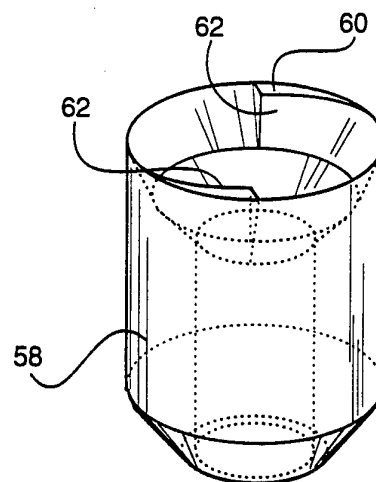


FIG. 20

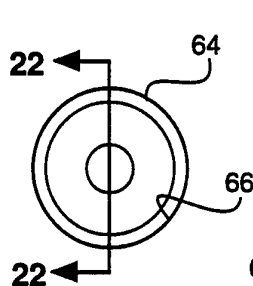


FIG. 21

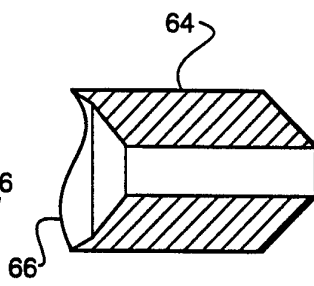


FIG. 22

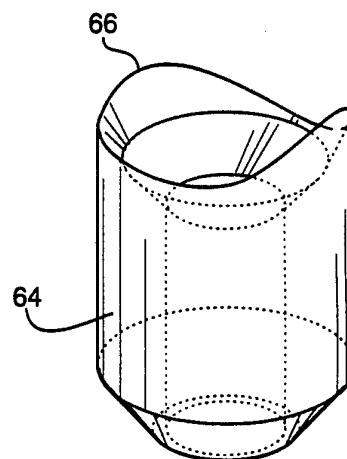


FIG. 23

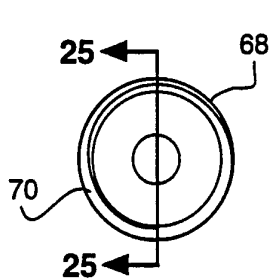


FIG. 24

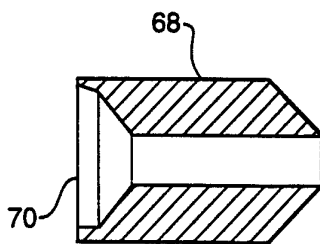


FIG. 25

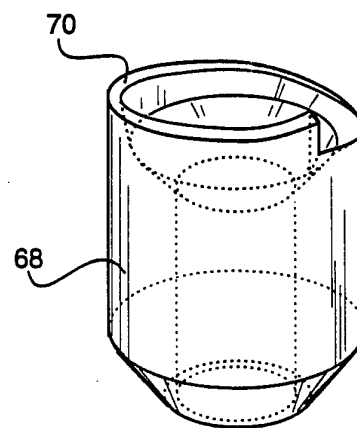


FIG. 26

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/12760

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/32

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

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 5,100,424, (JANG ET AL.), 31 March 1992. See entire document.	1, 7, 10/7, 11/7, 12/11/7, 24, 25
Y	US, A, 4,669,469, (GIFFORD, III ET AL.), 02 June 1987. See entire document.	2, 4/2, 5/2, 6/2, 8, 10/8, 11/8, 12/11/8
Y	US, A, 5,160,318, (SHULER), 03 November 1992. See entire document.	2, 4/2, 5/2, 6/2, 8, 10/8, 11/8, 12/11/8

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

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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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

"Z"

document member of the same patent family

Date of the actual completion of the international search

02 JANUARY 1995

Date of mailing of the international search report

13 FEB 1995

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