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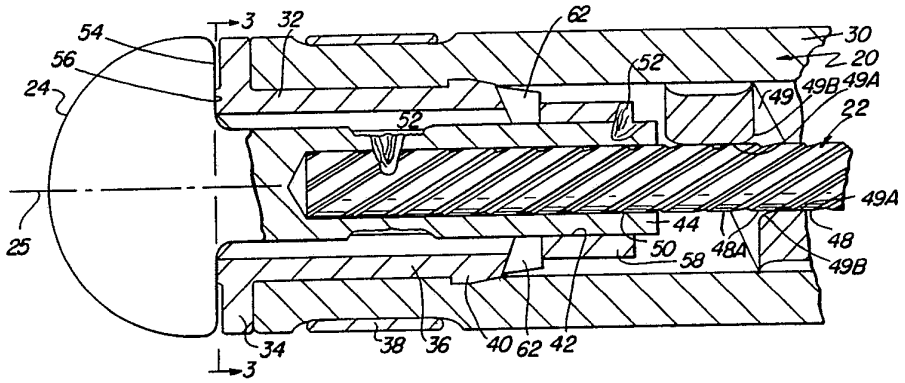

(57) Abstract

Flexible, small diameter catheter (20, 200) for effecting various surgical procedures, such as opening a restriction formed of an undesirable material, e.g., atherosclerotic plaque, in a lumen, e.g., an artery, of a living being, dilating a duct or tube, e.g., a fallopian tube, eustachian tube, bile duct, etc., in a living being and destroying a stone, e.g., kidney stone, gall stone, in the body of a living being. One embodiment of the catheter (20) includes a working head (24) having at least one non-sharp impacting surface (24A, 24B) arranged to be moved, e.g., rotated, at a high rate of speed by an associated drive means (22) within the catheter. The catheter with the moving working head is brought into engagement to effect the opening of the restriction by dilating the artery and/or removing undesirable material therefrom. The removal of undesirable material results from the impacting surface impacting the material of the restriction repeatedly. A fluid (27) is provided through the catheter to the working head and a portion is thrown radially outward. The fluid at the working head also flows in a vortex (31) to carry any particles broken off from the restriction back to the moving working head where they are impacted again and again to further reduce their size. Such action creates particles of sufficiently small size that they may be enabled to flow distally without significant deleterious effects to distally located tissue. One can effect the in situ valvulectomy of a section of vein within a living being using the catheters of this invention. In still another method, another embodiment of the catheter is used to disintegrate a stone, such as a kidney or gall stone, in the body of a living being. In another method, the catheters of this invention are used to stop spasm in a lumen in a living being.

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CATHETER WITH HIGH SPEED MOVING WORKING HEAD FOR IN-BODY SURGICAL PROCEDURES

Field of the Invention

This invention relates generally to medical devices and more particularly to flexible, power-driven catheters for intravascular surgery and other in-body surgical procedures.

Background Art

Heretofore, the only interventional methods for treating atherosclerotic disease involves surgery for bypassing or remolding obstructive atherosclerotic material. Lasers have been suggested and are under investigation for transluminal revascularization. However, such devices have not been found common acceptance in medical practice because of various technical difficulties, the most serious of which being their tendency to perforate arterial tissue.

In United States Patent No. 4,445,509 (Auth) there is disclosed a recanalization catheter designed specifically for cutting away hard, abnormal deposits, such as atherosclerotic plaque, from the inside of an artery, and while supposedly preserving the soft arterial tissue. That recanalization catheter includes a sharp edged, multi-fluted, rotary cutting tip mounted at the distal end of the catheter and arranged to be rotated by a flexible drive shaft extending down the center of the catheter. The rotation of the cutting head is stated as producing a "differential cutting" effect whereupon relatively hard deposits are cut away from relatively soft tissue. Suction ports are provided in the cutting tips to pull the hard particles produced by the cutting action into the catheter for removal at the proximal end thereof so that such particles do not flow distally of the catheter where they could have an adverse effect on the patient's body.

It has been determined that the use of sharp rotary cutting blades in a revascularization catheter can have various adverse effects on the arterial tissue, e.g., snagging, cutting or otherwise damaging the tissue of the artery wall.

Disclosure of the Invention

In accordance with one preferred embodiment the invention comprises a catheter and method of its use for introduction into a lumen in a living being to open a restriction formed of an undesirable material in a portion of the lumen. That catheter comprises an elongated flexible member having a longitudinal axis, a working head located adjacent the distal end thereof and drive means therefor. The working head comprises at least one, non-sharp, impacting surface. The drive means is arranged for effecting the high speed movement of the working head to impact the undesirable material and thereby open said restriction.

In accordance with another aspect of the invention the catheter and its method of use increases the diameter of a lumen within the body of the living being. To that end, the catheter is inserted into the lumen from a remote location and the drive means operated to cause the working head to move at the high rate of speed whereupon the action of the working head causes the lumen to be enlarged. The lumen may be a blood vessel having a restriction therein caused by some material, e.g., atherosclerotic plaque, or may be a constricted duct, tube, or other passageway, e.g., a fallopian tube.

In accordance with another aspect of the invention the catheter and its method of use renders the valves in a section of vein inoperative in situ. To that end the catheter is inserted into the vein section from a remote location and the drive means operated to cause the working head to move at a high rate of speed so that it contacts the valve, whereupon the mechanical action of the working head renders the valve inoperative.

In accordance with yet another aspect of the invention the catheter and its method of use disintegrates a stone or other loose body (e.g., a body containing calcium) located within a living being. To that end, the catheter is inserted into the body from a remote location and the drive means operated to cause the working head to move at the high rate of speed so that when the working head is brought into contact with the stone, its mechanical action pulverizes the stone to result in its disintegration.

Brief Description of the Drawing

Fig. 1 is a perspective view, partially in section, showing the operation of one embodiment of the catheter of the subject invention in an artery restricted by occlusive atherosclerotic disease and illustrating the dilation and restriction opening properties of the catheter;

Fig. 2 is a side elevational view, partially in section, showing the distal end of the catheter shown in Fig. 1;

Fig. 3 is a sectional view taken along Line 3-3 of Fig. 2;

Fig. 4 is an end view of the catheter shown in Fig. 2;

Fig. 5 is a side elevational view of a portion of the distal end of the catheter of Fig. 1 and showing the expulsion of fluid therefrom during operation of the catheter;

Fig. 6 is a front elevational view of the working head or tip of the catheter shown in Fig. 1;

Fig. 7 is a side elevational view of the tip shown in Fig. 6;

Fig. 8 is another side elevational view of the tip shown in Fig. 6;

Fig. 9 is a side elevational view of a catheter like that shown in Fig. 1 located within a bodily lumen, e.g., artery, and illustrating the creation of vortex flow adjacent the working head during the operation of the catheter;

Fig. 10 is an enlarged front elevational view of an alternative working head or tip to that shown in Fig. 6;

Fig. 11 is an enlarged side elevational view of the alternative working tip shown in Fig. 10;

Fig. 12 is a side elevational view partially in section, showing the distal end of another catheter constructed in accordance with this invention and for carrying out methods of this invention;

Fig. 13 is a reduced, exploded perspective view of a portion of the distal end of the catheter of Fig. 12;

Fig. 14 is a reduced side elevational view of the impaction member forming a portion of the catheter of Fig. 12; and

Fig. 15 is a front elevational view of the impaction member shown in Fig. 14.

Description of the Invention

Referring now in greater detail to the various figures of the drawing wherein like reference characters refer to like parts, there is shown in Fig. 1 the distal end of one embodiment of a catheter 20 for intravascular or other surgical/medical applications, e.g., fallopian tube dilation. The catheter 20 is an elongated flexible member, approximately 180cm long and of small outside diameter e.g., 8 French(F) or 2.68mm, and including a flexible drive assembly or system 22 (only a portion of which can be seen in Fig. 2) located therein. That drive system will be described later and is particularly suited for in-body surgical applications, but can be used for other applications requiring the transmission of power at high speed and low torque, through a very narrow path, including bends of small, e.g., .75 inches (1.9 cm) radius of curvature. Located at the distal end portion of the catheter 20 is a working head or tool 24. The working head is arranged to be moved at a high speed with respect to the catheter by the drive means to effect the surgical procedure to be carried out by the catheter. The proximal end of the drive means of the catheter and which is located outside the patient's body is adapted to be connected to a source of rotary power, e.g., an electric motor (not shown). In the preferred embodiment disclosed herein, the drive means 22 effects the rotary movement of the working head 24 under the power provided from the remote power source (motor).

When the catheter 20 is used for treating occlusive atherosclerotic disease, such as opening a restriction in an artery formed by atherosclerotic plaque, the catheter is introduced into the vascular system of the patient, such as through an opening in the femoral artery at a point in the groin. The catheter is then guided through the vascular system of the patient to the site of

the vascular occlusion or blockage that has been determined to exist so that its working head 24 is located immediately adjacent the restriction. In the illustration in Fig. 1, the working head 24 is shown in position in a coronary artery 26 immediately adjacent a restriction 28, e.g., partial occlusion or full occlusion, which is to be opened to the freer flow of blood therethrough.

As will be recognized by those skilled in the art, such arterial restrictions are formed by the deposit of atherosclerotic plaque or some other material(s), such as wax and/or calcified athoroma, thickened and/or ulcerated intima, etc. Once in position, the catheter 20 is arranged to transluminally recatherize the diseased artery by dilating the stenotic or occluded area (which may or may not be covered by fibrous plaque) and/or selectively removing calcified thrombotic, or fatty tissue unprotected by fibrous plaque while alowing the artery wall to remain intact.

The details of the construction and operation of the catheter will be described later. Suffice now to state that the working head 24 includes a pair of non-sharp impacting surfaces 24A and 24B for impacting the material forming the restriction. The impacting surfaces 24A and 24B are formed by rounded or radiused edges of a respective pair of cam surfaces 24C and 24D. The cam surfaces are clearly shown in Figs. 2, 4 and 6 and are formed by those convex outer surface portions of the working head located between a pair of relieved, e.g., flat, surfaces 24E and 24F. The working head 24 is arranged to be rotated about the longitudinal axis 25 (Fig. 2) of the catheter at a high rate of speed, e.g., from 10,000 rpm to 200,000 rpm. At the same time, fluid 27 (Fig. 5) is passed through the catheter and out of the base of the working head at the distal end of the catheter adjacent the central longitudinal axis thereof as shown in Fig. 5. The opening of the restriction to allow freer flow of blood is effected by the dilation and/or selective emulsification properties of the catheter's working head. In this connection, during the operation of the catheter 20 (to be described in

considerable detail later), the fluid jets exiting the distal end of the catheter at the rotating working head are immediately accelerated laterally by the relieved, e.g., flatted, surfaces. The fluid stream is thus broken up into small segments, bullets or slugs 29 (Fig. 5) that develop considerable momentum as they are flung radially outward toward the wall of the artery. These liquid slugs transfer their momentum to the artery wall, helping to force the artery wall outward laterally in all directions, thereby dilating it. The liquid also serves as a lubricant for the working head-tissue interface, a coolant to maintain the tissue temperature within acceptable limits, and a carrier for radiopaque media and/or other medications. The rotating working head with its non-sharp impacting surfaces 24A and 24B also serves to differentiate atherosclerotic tissue from normal tissue through the inherent differences in the tissue's physical properties and organizational patterns. Therefore, when the catheter is passed transluminally through a diseased artery, the device's working head serves to emulsify occlusive lesions not covered with fibrous plaque by repeatedly impacting the material forming the restriction as the working head is rotated and with minimal risk of puncture or perforation of the contiguous arterial wall.

The non-sharp impacting surfaces 24A and 24B of the rapidly rotating working head removes atherosclerotic tissue by emulsification and differentiates the diseased tissue from the relatively undiseased tissue by using two properties found in normal tissue that is not found in most, if not all, atherosclerotic tissue. In this connection, when an artery wall is in contact with the high rotary speed working head, its most important protective property is its viscoelasticity. Simply stated, the artery wall tissue yields repeatedly under stress of the cam surfaces of rotating working head and returns to its original shape only after some delay, (i.e., the relieved surface following the cam surface pass the tissue so that the stress is removed, whereupon the tissue is enabled to recover as a function of viscoelastic memory). That stress is applied to the artery

wall by the rounded edge of each cammed surface of the rotating working head with each revolution. As will be appreciated from the discussion to follow, the degree of deformation of the artery wall is affected by the height and profile of the cam surfaces and contiguous radiused impacting surfaces, and the axial load applied thereto by the operator. The degree of deformation and the frequency at which it takes place in turn define the energy the arterial tissue absorbs and, hence, the damage created. Damage to the artery wall can thus be reduced several ways, namely, keeping the height of the tissue engaging surfaces relatively small, making the cam profile a gentle rise, utilizing a high speed (frequency) revolution (tissue will essentially remain in its deformed state, touching only the outermost rounded edges of the working head adjacent each cam surface), and by keeping the axial load low to limit the stress on the artery wall. By appropriate selection of these parameters, the working head will do little or no damage to non-diseased tissue and will not puncture or otherwise perforate the artery wall except under excessive force or where the artery wall is totally diseased (e.g., non-viscoelastic, as occurs in the case of a Monckeberg's sclerosis).

Fibrous plaque, unlike most diseased tissue, is viscoelastic and is undamaged when the rotating working head with its cam surfaces pass over it. The rounded edged cam surfaces have great difficulty in penetrating the fibrous plaque. Therefore, in a stenotic or occlusive lesion where fibrous plaque lines the obstructive lesion, dilation rather than selective emulsification plays the major role in reestablishing blood flow.

In contrast, atherosclerotic tissue is not viscoelastic. If calcific, fatty, thrombotic or a combination of all three exist and are not protected by fibrous plaque, such material will not yield under the stress induced by the rotating working head. Instead, such material absorbs the high frequency energy transmitted by the work head's impacting surfaces and the material is emulsified. The emulsification process is accomplished by the repeated impaction of the non-sharp impacting surfaces on the

restriction forming material. Such action causes the material to be broken away in small particles. The catheter of the subject invention produces a powerful vortex flow illustrated diagrammatically and identified by the reference numeral 31 in Fig. 9. This vortex works in conjunction with the rotating working head so that the particles produced by the impacting action are repeatedly impacted over and over, so that upon each impaction their size is reduced further until the resulting particle size is sufficiently small that the particles can be permitted to flow downstream tissue without causing any significant deleterious effects to the patient. In this connection, it has been determined that in a typical operation 95% of the particles created during the impacting or emulsification process have a surface area smaller than that of a red blood cell.

A second important protective property inherent in nondiseased artery walls is its highly organized fibrous structure. Thus, as can be seen in Fig. 1, the fibers 33 of an artery wall 26 run circumferential to the lumen of the artery and generally perpendicular to the impacting surfaces 24A and 24B of the working head where they meet. This perpendicular line between those impacting surfaces and the arterial wall fibers is protective. Thus, the rotating working head does not separate the fibers. Instead, they remain organized in parallel, resisting separation and penetration. The energy absorped from the rotating working head is distributed through the many fibers, thereby reducing the destructive force applied per fiber. Accordingly, individual fibers are undamaged and the artery wall remains intact.

Like most pathologic tissue, atherosclerotic tissue is distinctively different from non-diseased tissue in one major respect, lack of unified organization. Thus, when such tissue is engaged by the rotating working head, minute portions of the atherosclerotic tissue must absorb the impacting surfaces' energy alone. Accordingly, a particle of the material breaks off from the adjacent tissue. As mentioned earlier and as will be described in detail later, the operation of the rotary working

head creates a vortex flow 31 adjacent the working head which causes the particles broken away by the action of the working head to be repeatedly impacted by the non-sharp, impacting surfaces 24A and 24B, thereby breaking those particles into smaller and smaller particles until they become part of what is effectively a highly emulsified solution.

The exact physiological reaction of the artery to the action of the working head is not known at this time. What is known is that the walls of the artery itself become dilated and remain dilated even after the catheter and its working head is withdrawn. In particular, it has been determined by angiogram and other testing procedures that after one has passed the working head of a catheter past the restriction that the walls of the artery have become stretched or dilated and remain such. More particularly, it has been found that the adventicia and media portions of the artery are stretched, while the intima (lining portion, which is most commonly the diseased portion) is fractured and fissured. Such action ensures that the restriction is thus "opened" to freer blood flow therethrough. Based on experience with balloon angioplasty the fracturing or fissuring of the intima enables renewed blood flow and naturally bodily processes to remodel and shrink the lesion in many cases.

Among the factors which may play a part in the restriction opening process is the changing or rearrangement of the vessel structure, e.g., vessel fibers, etc., due to any one or more of the following: Mechanical stretching of the lumen structure resulting from the size of the working head (a static effect) and/or the dynamic effect of cyclical high speed mechanical movement, e.g., rotation of the working head; increase in temperature of the lumen structure resulting from the mechanical cycling of the viscoelastic properties of the lumen tissue, bombardment with liquid propelled at the lumen wall by the rapid movement, e.g., rotation, of the working head, whereupon the head pressure of the liquid impacting the walls exceeds the normal local blood pressure; forcing or wedging of liquid into the lumen walls by mechanically induced film pressure as the working head's

cammed and impacting surfaces slide over the lumen surface, whereupon the tissue fibers are forced apart; and forcing of liquid into the lumen walls by the local dynamic or hydrostatic pressure induced by the injected liquid and/or the moving working head. Other, as yet undetermined, factors may also play a part in the dilation process.

Referring to Fig. 2, the details of the distal end of a preferred embodiment of the catheter 20 will now be described. As can be seen the catheter 20 basically comprises an elongated, flexible tubular member or jacket 30 which is formed of a suitable material, e.g., plastic, and which has a small outside diameter, e.g., 8F or less. In a preferred embodiment shown herein the outside diameter is approximately 1.7 mm (5 F) or less. This size catheter is merely exemplary. Thus, in accordance with this invention, the catheter can be constructed as small as 2 F (.67 mm).

At the distal end of the catheter 20 there is secured a sleeve-like bushing 32. The bushing includes a flanged end face 34 arranged to abut the end of the catheter's jacket 30 and a tubular portion 36. The outside diameter of portion 36 is approximately that of the inside diameter of the catheter's jacket 30 so that it is snugly fit therein. The bushing is held firmly in place by a retaining band 38 which tightly encircles the periphery of the catheter jacket 30 so that plural gripping teeth 40 located about the periphery of the tubular portion 36 dig into the interior surface of the catheter jacket 30 and hold the bushing tightly in place therein. The bushing 32 also includes a through bore 42 (Figs. 2 and 3) extending therethrough and aligned with the longitudinal central axis 25 of the catheter.

The working head 24 includes a mounting shank or axle 44 projecting proximally and passing through the bore 42 in the bushing 32. The flexible drive system comprises an elongated drive cable 48 preferably formed of plural elongated wires, i.e., a central wire (not shown) surrounded by six helical wires. The outer surface of the helical wires is swaged or hammered to form

a generally large area cylindrical surface 48A (Fig. 2). The central wire of the cable 48, may, if desired, be tube. The cable 48 extends down the interior in the catheter's jacket 30 coaxial with axis 25 from a remote, proximally located point (not shown) at which it is connected to a source of power, e.g., an electric motor, to the working head. Thus, the distal end of the cable 48 terminates at and is disposed within a longitudinal extending bore 50 in the axle 44 of the working head 24. The end of the drive cable 48 is secured in place in the bore 50 via a laser weld joint 52. The shape of the working head 24 will be described later. Suffice now to state that it includes a generally planar rear surface 54 which engages the front surface 56 of the bushing flange 34. The working head 24 is prevented from axial movement within the bushing 32 by virtue of a retaining ring 58 mounted on the proximal end of the working head axle 44 contiguous with the proximal end of the bushing. The retaining ring 58 is secured to the proximal end of the working head axle 44 via another laser weld 52.

The drive cable 48 is supported in the central position along axis 25 by means of a spiral bearing 49 (Fig. 2) so that the cable can rotate about that axis within the bearing. That bearing member thus comprises a helical or spiral cylindrical coil of wire surrounding the multistrand drive cable 48. The spiral bearing 49 is preferably constructed of a wire having a rectangular cross section. When such a wire is bent into a helix, it forms a central passageway defined by a large area cylindrical surface 49A and with the inside corners of the wire forming each helical convolution being convex at 49B. The bearing 49 extends substantially the entire length of the catheter from a proximately located point adjacent the drive motor (not shown) to the distal end of the catheter. The outer diameter of the helical bearing coil is sufficiently great so that its loops just clear the interior surface of the catheter's jacket 30 to hold the bearing securely in place therein. The inside diameter of the central passageway 49A extending down the length of the helical bearing is just slightly greater than the

outside diameter of the drive cable 48, that is, the diameter of cylindrical surface 48A, so that the drive cable can freely rotate therein.

It should be pointed out at this juncture that the drive cable 48 need not be drawn or swaged. Moreover, the drive element need not be a cable, but can be a single wire. Further still, the spiral bearing need not be formed of a rectangular wire and thus can be of any shape, e.g., circular, oval, etc. The use of the swaged multistrand drive cable with a rectangular section bearing wire is preferred to provide a system exhibiting a high degree of flexibility and which does not tend to produce a significant amount of wear particles. In that connection, the large engaging surfaces 48A and 49A tend to minimize the creation of any wear particles caused by the rotation of cable 48 within bearing 49.

It should also be pointed out at this juncture that the spiral wire 49 may serve as the drive member (it would be secured to the working head) while the component 48 serves as the bearing.

With a drive system constructed as shown and described, the drive cable 48 can be rotated at a high rate of speed, e.g., from 10,000 to 200,000 rpm, while the catheter is bent through a small radius of curvature, e.g., .75 inches (1.9 cm), yet maintaining positional neutrality (centering) of the drive cable and without the creation of any standing waves (without the cable going into "critical whirl") which could result in unwanted vibration to the catheter.

The spacing between the convolutions of the spiral bearing 49, the inner surface of the catheter jacket 30 and the outer surface of the drive cable 48 form a fluid passageway which a fluid (liquid) can flow from the proximal end of the catheter to the distal end. This liquid is utilized to cool or lubricate the bearing system and also serves to cool the tissue-working head interface. Moreover, as will be described in detail later, and as mentioned earlier, this liquid is expelled at the rotating working head to aid in the dilation of the arterial tissue at the

working head. Moreover, the liquid which is passed down the catheter can, if desired, be oxygenated to eliminate distal ischemia during the restriction opening procedure by the catheter. Also, if desired, nitrates, contrast media or other drugs can be added to the liquid as needed during the procedure.

In order to insure that the catheter is sufficiently flexible to negotiate short radii of curvature, while not presenting an undue impediment to the flow of cooling fluid through the fluid passageway in the catheter, the width of the rectangular wire making up the helical coil 48 and the pitch of its loops are appropriately selected. In the embodiment shown and described herein the width (the dimension measured in the direction of axis 25) of the wire making up the helical coil is approximately .009 inch (.22mm) for a 5F catheter, while its thickness is approximately .0065 inch (.16mm) and the helix of the angle coils is approximately 30° measured from the axis 25. The outside diameter of the swaged drive cable 48 for a 5F catheter is .015 inch (.38mm). This construction optimizes bending, flexibility, torsional strength and fluid flow passage. It must be pointed out that the wire width (diameter, if the wire is of circular cross section) and/or helix angle of the helical bearing may be other dimensions, if desired, and depending upon the application. As will be appreciated, of course, the smaller the helix angle the more convolutions of the helix and hence the greater distance through which fluid must flow.

In accordance with the preferred embodiment of the catheter the helical coil bearing 49 is formed of a strong, yet flexible, low friction material, such as heat treated beryllium-copper.

The means for enabling the liquid to exit the catheter at the distal end will now be described with reference to Figs. 2, 4 and 5.

Thus, as can be seen therein, extending down the central bore 42 of the bearing 32 are four, equidistantly spaced, grooves 60. The distal end of each groove 60 terminates at a fluid exit port 61 located at the distal end flange 34 of the bushing, while

the proximal end of each groove 60 terminates in a respective, generally radially extending, relief groove 62. The fluid (liquid) 27 passing down the interior of catheter tube 30 flows under pressure (denoted by the character P in Fig. 5) into the relief grooves 62, through the associated longitudinal grooves 60 and out through the ports 61 at the end face of the catheter closely adjacent to the longitudinal axis 25.

The details of the working head 24 will now be discussed. As can be seen in Figs. 2, 4, 6, 7 and 8, the working head 24 basically comprises a convex shaped tip of a generally hemispherical shape and having a pair of generally planar diametrically disposed side faces heretofore referred to as relieved surfaces 24C and 24D. Thus, the cam surfaces formed therebetween are sections of the surface of a sphere. The interface of the cam surfaces 24C and 24D with the relieved surfaces 24E and 24F are rounded (radiussed) so that each interface surface is not sharp (although in the scale of the drawings herein it may appear to be a sharp line). As can be seen in Fig. 8, the relieved surfaces 24E and 24F taper toward each other in the direction toward the distal end of the working head, with the maximum spacing between the relieved surfaces being approximately the diameter of the working head shaft 44. Thus, the flatted or relieved surfaces are at a negative rake angle to the cam surfaces. Further details of the working head will be described later.

As can be seen in Fig. 4, by virtue of the shape of the working head as described above the fluid exit ports 61 at the distal end of two diametrically disposed grooves 40 are uncovered or exposed by the relieved surfaces 24E and 24F to enable fluid 27 passing through those grooves to exit the ports 61. As will be appreciated by those skilled in the art, since the working head rotates, the relieved surfaces of the working head sequentially cover and uncover diametrically opposed ports 61 at the distal ends of the grooves. This action breaks up the fluid streams 27 exiting from those ports into the previously mentioned segments or slugs 29.

The fluid velocity is determined by the pressure at the point P in Fig. 5. For catheters of an 8F (French) size, and whose working head is of .05 inches radius a pressure of approximately 30 pounds per square inch is deemed sufficient to ensure that some liquid streams flow axially along axis 25 so that the exiting liquid is distributed in a generally hemispherical pattern about the working head. For catheters of 5F (French), a pressure of 100 PSI is sufficient. Accordingly, with sufficent fluid pressure applied some of the liquid streams reach the end of the tip contiguous with the longitudinal central axis 25 while other streams are cut off and accelerated at an acute angle thereto and still further streams are cut off and accelerated almost radially. Accordingly, with a working head and catheter constructed as described, the fluid exiting from the ports is distributed almost hemispherically around the tip without the need for a central hole therein.

In order to prevent heat induced injury to the artery, sufficient luquid should be expelled into the restriction at the working head. It has been found that 30 ccs per minute is suitable for an 8F (French) instrument while 20 ccs per minute is suitable for a 5F instrument.

As will be appreciated by those skilled in the art, many of the liquid slugs 29 have some radial component and develop tremendous momentum as they are flung outwards toward the artery wall. The momentum of the slugs is transferred to the artery wall, thereby forcing the wall laterally outward in all radial directions to dilate it, as described earlier.

Tests have shown that the radial pressure developed by the rotating working head is substantial and can raise local static pressure immediately adjacent the working head by approximately 100 to 200 millimeters of Hg. This increased pressure on the artery wall contiguous with the rotating working head is not due solely to the impact of the fluid slugs thereon, but is also due to the recirculation of the fluid surrounding the working head. In this connection, as noted earlier, the rotation of the working head about axis 25 produces a powerful, toroidal

shaped vortex 31 contiguous with the working head as shown in Fig. 9. The vortex 31 in addition to augmenting the application of increased pressure to the artery wall contiguous with the working head, also has the effect of recirculating any particles that may have been broken off from the restriction by the impact of the rotating working head with the material forming the restriction. Thus, if the material forming the restriction is such that particles are broken away they are circulated by the vortex and carried back into the rotating working head where they are progressively reduced in size. This progressive size reduction action has the result of producing particles which, as noted earlier, are safe to flow distally.

The impacting surfaces 24A and 24B, i.e., the interfacial areas at which the spherical section cam surfaces 24C and 24D meet the relieved surfaces 24E and 24F, are of sufficiently large radius to ensure that no damage to the healthy tissue of the artery occurs when those surfaces impact arterial tissue. In this regard, the viscoelastic nature of healthy tissue as well as diseased soft tissue is such that such soft materials can be stretched and negotiated by the rotating working head if its impacting surfaces are of sufficiently large radius that they allow the arterial tissue (in the form of a wave of tissue) to flow smoothly thereunder. At typical operating speeds the viscoelastic tissue wave is on the order of several thousands of an inch high. As long as the radius of the impacting surfaces 24A and 24B is of the order or greater than the tissue wave height, the tissue will not rupture during stretching. It has been found that for a working head like that shown herein and having two cam surfaces and running between 10,000 and 100,000 rpm a radius of .0015 for the impacting surfaces 24A and 24B is sufficient, providing the surgeon using the instrument is relatively skilled. A working head having an impacting surface whose radius is from .002 to .003 would be better to ensure that no damage results from the catheter's use by less skilled surgeons. Moreover the cam surface passing frequency, that is, the velocity of the cam surface coupled with the length of the

cam surface should be large enough that the tissue cannot recover substantially before the next impacting surface arrives. This allows quite aggressive instrument feed rates without puncture. In this connection, it is suggested that the velocity of the impacting surfaces 24A and 24B at their maximum distance from axis 25 be in the range from 100 to 2,000 centimeters per second. This speed range ensures that at the low end the impacting surfaces of the rotating working head always describe a fine helix in the artery even at high feed rates of the order of ten centimeters per second. This makes use of the protective nature of the tip travel along the axis of the circumferential arterial wall fibers. The radius of the impacting surfaces 24A and 24B should also not be too large. In this connection, as noted earlier, the rotating working head creates a powerful vortex for carrying any particles broken off from the material forming the restriction to be multiply impacted and subsequently reduced in size. Thus, in order not to compromise this action, it is necessary that the working head impacting surface radius not be too large to compromise such particle reduction action. For tips having an impacting surface radius of .002-.003 inches the progressive particle reduction action operates at tip rotational speeds of 30,000 to 90,000 rpm.

As just discussed, injury to soft tissue is controlled by the impacting surface radius and its passing velocity and to a lesser degree by its and the contiguous cam surface's clearance. However, hard tissue seems to be dramatically affected by clearance, with the smaller clearance, the less chance of injuring or perforating the arterial tissue. Directional protection control can also be achieved by varying the clearance of the working head's impacting surface radius. Hence, as can be seen in Figs. 6, 7 and 8, the portion of the working tip cam surfaces 24C and 24D contiguous with the rotational 25 is 45 is relieved by the formation of two diametrically opposed planar sections 24G and 24H. Thus, the radiussed impacting surfaces at the interface of the cam surfaces and the planar relieved surfaces have approximately zero degree clearance while the

radiused impacting surfaces at the interface of cam surfaces and the relieved surfaces form a ten degree clearance. Accordingly, the working head 24 of the subject invention has zero clearance at large radial distances from the rotational axis 25 and ten degree clearance at small radial distances. This feature compensates for the lower velocity of the impacting surfaces at smaller radial distances. Accordingly, in accordance with the subject invention, working heads can be produced to provide very small clearance at portions of the working head moving at high speed with respect to the material to be removed while providing some larger clearance at portions of the tip moving at lower speeds with respect to that material.

In order to produce an even more gentle action on the arterial tissue wave created by the rotating cammed working head, it can be constructed as shown in Figs. 10 and 11 and denoted by the reference numeral 100. Thus, in the working head 100 embodiment shown in Figs. 10 and 11, the convex cam surface is not of a constant radius of curvature. In this connection, as can be seen in Figs. 10 and 11, the working head 100 includes two quadraspherical section cam surfaces 100A and 100B, each of which has the same radius of curvature. The centers of generation of the quadraspheres are denoted by the reference numeral 101 and are spaced (offset) from each other by a distance D (Fig. 11). Accordingly, the surfaces 100A and 100B are separated from each other by an intermediate surface 100C whose width is D. As can be seen in Fig. 11, the surface 100C is tangential to the ends of the opposed quadraspherical surfaces 100A and 100B and is linear between the ends of those surfaces when viewed in the direction of lines 11-11 in Fig. 10 but circular and of the same radius as surfaces 100A and 100B measured around an axis 102 (Fig. 10). The plane in which the axes 25 and 102 lie includes the two centers of generation 101 and bisects the working head 100 into two halves. That plane will be hereinafter referred to as the working head bisecting plane. In the embodiment 100 shown herein, the flatted or relieved surfaces 100D and 100E are similar to relieved surfaces 24E and 24F of working head 24.

However, as can be seen in Fig. 10, the relieved surfaces 100D and 100E are oriented at an angle θ with respect to the working head bisecting plane. Thus, the working head 100 is bisected into two symmetric portions by the working head bisecting plane. This construction results in the creation of a long ramp cam surface 100AL between the leading radiused impacting surface 100G and the highest point 104. The ramp can be appreciated by viewing the difference between the path of maximum radius R generated by the rotation of head 24 and the surface 100AL while creating a short ramp surface 100AS between point 104 and the trailing radiused impacting surface 100H. By virtue of the relatively long ramp cam surface 100AL leading to the point of maximum cam surface radius a gentle cam action results when the surface 100AL makes contact with the material forming the restriction to result in lower acceleration (less aggression) applied to the particles produced by that impact. In alternative embodiments of the working head 100 the head bisecting plane can be oriented so that the angle θ is between zero degrees and any maximum angle. If the head bisecting plane is parallel to the relieved surfaces 100E and 100F so that the angle θ is zero degrees then the leading and trailing cam surfaces 100AL and 100AS will be the same length.

As should thus be appreciated by adjusting the orientation of the head bisecting angle, and hence the orientation of cam surfaces one can adjust the degree of aggression of the working head to a desired extent.

It should be pointed out at this juncture other shaped working heads in lieu of those disclosed herein can be constructed in accordance with this invention. Thus, the cam surfaces need not be portions of a spherical surface, but can be ovoidal, conical or any other suitable shape. Moreover, the relieved surfaces need not be planar, but can be arcuate, multiplanar (portions in different planes), etc. Furtherstill, the impacting surfaces need not be of a constant radius so long as they are sufficiently rounded or arcuate to be substantially equal to or larger than the tissue wave to be created by the rotation of the working head.

The vortex created by the rotation of the working head is effective in stopping large particles from passing downstream (distally). In this regard, it provides a very effective and important mechanism against macroembolization and distal infarction. Any particle that may break off distally or proximally to the rotating working head is immediately pulled into the vortex and its potential threat to a distal organ is terminated by its being reduced in size (repeatedly impacted to the point of emulsification).

The mechanical and fluid forces applied by the working head allow the catheter to track the point of least resistance in total occlusions. In this regard, the working head finds the area of least resistance by dissecting the tissue with fluid pressure as it moves forward. From observation, the point of least resistance is always in the lumen of the previously patent artery. It is therefore relatively easy and safe to open totally obstructed tortuous arteries with the subject catheter. In this connection, the working head finds the area of least resistance and serves to guide the catheter and not vice versa.

As will be appreciated by those skilled in the art, the catheter with its working head as disclosed and claimed herein has many properties useful in treating occulsive atherosclerotic disease. Moreover, the techniques for using the subject invention are simple and can be mastered easily and are moreover widely applicable to many organ systems relatively inexpensively and should be associated with low morbidity.

It should also be appreciated by those skilled in the art, that the catheter of the subject invention as well as its method of use enable coronary as well as peripheral, e.g., leg, revascularization of patients either intraoperatively or percutaneously, thereby providing methods of treatment which are less invasive, less expensive and less time consuming than prior art techniques. Moreover, the catheters of the subject invention enable revascularization of smaller arteries and longer lesions than otherwise possible. Thus, with the subject invention one can prophylactically treat coronary artery disease, perhaps one

of the most widespread diseases affecting Americans. It will also be appreciated by those skilled in the art that the subject catheters can be readily utilized to remove a thrombosis in a manner similar to the restriction opening process.

The subject catheters are also of significant utility for effecting tube or duct, such as eustachian tube, fallopian tube, etc., dilation. With regard to the latter, a substantial number of women in the United States are infertile due to fallopian tube malfunction or stricture. At present, there is no device or simple procedure to dilate or open the fallopian tube. In this connection, while microsurgical procedures to attempt to alleviate the occlusion or stenosis, the results have been poor, the technique difficult and expensive and of limited availability. By utilizing the catheters of this invention one can pass such catheters via the cervical os to the fallopian tube to effect the dilation of the stenosis or occlusion in the same manner as described with reference to revascularization of arteries.

It has also been found that a catheter like those of this application can be utilized to stop spasm, i.e., uncontrolled constriction, in an artery or other lumen and for preventing it from going back into spasm. To that end, the catheter is inserted into the artery in spasm and operated, as described heretofore, whereupon the spasm immediately ceases and remains stopped even after the catheter is removed. While this effect, that is the stoppage and prevention of spasm, results from the use of catheters of this invention, the exact mechanism and exact physiological reaction of the lumen to the action of the catheter is unknown at this time. For example, the operation of the working head may cause the same effects discussed with respect to lumen dilation to occur to stop and prevent spasm. More particularly, the action of the working head may cause permanent change, e.g., damage to the neuromuscular junctions or muscles surrounding the lumen to prevent it from contracting. This antispasm technique is not limited to arterial or vascular applications. Hence, the technique can be used in any

application where spasm of a tubular body is a problem, e.g., bronchial tubes, the bowel, the esophagus, etc. To that end, the subject catheters can be used with any tubular structure which may go into spasm. Moreover, the diameter of the tubular structure in spasm can be substantially larger, e.g., more than double the diameter, of the catheter with the antispasm procedure still being effective.

As is known to those skilled in the art bypass surgery in the leg using the in situ approach for valvulectomies has proven superior to other methods to provide renewed blood circulation to the leg. However, in order to destroy or otherwise render inoperative the valves in the vein section so that the section can be used as an artery complex and lengthy surgical procedures are necessary. In this regard typical valvulectomies require complete exposure of the vein so that the valves thereof can be destroyed. Thus, heretofore in-situ valvulectomies have been primarily confined to "above-the-knee" applications. In accordance with the teaching of the invention the catheters as shown and/or discussed herein or with differently shaped working heads can be introduced into a vein section from a remote location and thereafter brought into contact with the valves to destroy the valves in a manner analgous to the revascularization of stenoic arteries. The advantage of such a method is that the vein need not be completely exposed and there is little danger of damage to the vein graft wall. Another significant advantage is that this technique can prepare veins for bypass to the level of an ankle and not merely in "above-the-knee" applications.

Kidney stones and other stones in the form of loose bodies having substantial calcium therein, e.g., gall bladder stones, bile stones, etc., affect the significant portion of the population in the United States and are the cause of great morbidity in those affected. Heretofore the techniques for removal of such stones have proven cumbersome, expensive and technically difficult to perform. While some apparatus such as the "Lithotripter" may prove a viable non-invasive approach to the removal or disintegration of such stones, such apparatus

appears to be of limited applicability, i.e., will be available only at large medical centers which can afford the high costs involved. Moreover, use of the "Lithotripter" may not be applicable to destruction of all types of stones. In accordance with this invention a catheter and its method of use is provided for effecting disintegration of hard bodily stones.

For example, in order to perform a cholecystecomy intraoperatively a flexible catheter, such as the preferred embodiment catheter 200 to be described hereinafter, is introduced through the cystic duct into the common bile duct. The working head of the catheter is a rotary impacting member which is rotated at a high rate of speed and brought into engagement with the stone. The catheter is constructed so that it creates a vortex fluid flow distally of the head to draw the stone toward working head. The rotation of the working head causes its plural impacting surfaces to batter the stone, thereby pulverizing the stone. This action results in the disintegration of the stone to the point where the resulting particles are sufficiently small so that natural bodily functions may flush them from the body. The catheter is removed through the cystic duct, thereby maintaining the integrity of the common bile duct.

Referring now to Figs. 12-15, the details of the catheter 200 having particular utility for effecting the disintegration of bodily stones or for accomplishing an in-situ valvulectomy will now be described.

The catheter 200 in many respects is identical in construction to the catheters 20 described heretofore. Hence the same reference numerals will be used for the common components. In particular the drive means and bearing means for the drive means can be the same as in either catheter 20, whereas the working head 202 is considerably different. In this regard the working head basically comprises a propeller-like impacting member 204 having a pair of blades 204A and 204B. The member 204 is threadedly engaged (not shown) onto a central mounting shaft 206 fixedly secured within an inner bushing 208. The inner bushing is disposed within an outer bushing 210. The outer

bushing is fixedly secured within a tubular shroud 212. The distal end of the drive cable 48 is secured within the shaft 206, whereupon the shaft and the inner bushing to which it is connected are arranged to rotate about central axis 25 under power from a remote motor (not shown). A plurality of slots 214 are provided along the outer bushing between it and the shroud 212. These slots serve as the fluid passageways (to be described later).

The shroud 212 serves to protect the surrounding bodily tissue(s), e.g., duct walls, from damage caused by the rotary motion of the blades 204A and 204B during the stone disintegration procedure. To that end the shroud is fixedly secured onto the distal end of the catheter jacket 30 by a retaining band (not shown) like that described with reference to Fig. 2. As can be seen clearly in Figs. 12 and 13, the shroud includes a plurality of generally rectangularly shaped windows 216 disposed about the periphery thereof adjacent its distal end (for reasons to be described later).

Each blade 204A and 204B of the impacting member 204 is curved and has a lead angle (Figs. 14 and 15) arranged so that upon rotation of the member about the longitudinal axis 25 of the catheter in the direction of arrow 218 (Fig. 15) a toroidal vortex fluid flow path is induced distally of the working head. This vortex flow is denoted by the arrows 220 and is in the direction towards the working head. This flow serves to draw the stone or venous valves to be acted upon by the catheter 200 into contact with the blades 204A and 204B. This in-drawing feature is of significant importance in applications wherein the stone or tissue to be destroyed is loose and not restrained by some body tissue, in order to ensure that the working does engage the stone or tissue to effect its destruction.

As can be seen in Fig. 12, the slots 214 are located between the bushing 208 and the inner surface of the shroud 212 and serve as passageways enabling the fluid (liquid) flowing through the interior of the catheter (and serving to cool and lubricate the moving components thereof as described with

reference to the embodiments of Fig. 1) to flow through the shroud's windows 216 out of the working head in the direction of arrows 222. The induced fluid flow distally of the head caused by the rotating blades also flows into the head and through the windows 216 (as shown by the arrows 220). These combined flows serve to push the duct walls or body tissue surrounding the stone away from the shroud 212, thereby aiding the shroud in protecting the patient from injury caused by the rotating blades.

As can be seen in Fig. 13 each blade tip is slightly rounded at 224 and projects a short distance, e.g., .005 to .010 inches, beyond the distal end 226 of the shroud 212. The rounded surfaces 224 serve as impact hammers to pulverize the stone upon contact therewith. In order to maximize the impact force the member 204 is relieved centrally at 228 so that the impaction surfaces 224 are located a substantial radial distance from the central axis 25 about which the member 204 rotates.

Operation of the catheter 200 to disintegrate a stone, such as a bile duct stone (not shown) is as follows. The catheter is introduced into an appropriate portion, e.g., the cystic duct, and then guided into the bile duct in which the stone is located and then until its working head is just proximately of the position of the stone. When the drive means is operated it causes the head 204 to rotate at a high rate of speed, e.g., 10,000 RPM or greater, thereby creating the vortex flow 220 which draws the stone into contact with the advancing head. The rapid rotation of the head 204 causes the impaction surfaces 224 to rapidly hammer away at the stone. This action pulverizes the stone, thereby resulting in its disintegration into particles of sufficiently small size as to be flushed from the duct by bodily fluids. The catheter is then withdrawn.

Operation of the catheter 200 to effect the in-situ destruction of valves in a section of vein (not shown) is accomplished in a similar manner. Thus the advancement of the catheter distally, coupled with the vortex flow at the distal end thereof, draws the fragile valve elements of the vein into contact with the rotating blades 204A and 204B, whereupon the

valve elements are destroyed or otherwise rendered inoperative. It should be noted that if the clearance between the blades and windows 216 is kept sufficiently small a shearing force results therebetween to aid in destroying the fragile valve elements.

It must be pointed out at this juncture that the other catheters, such as the heretofore described catheter 20, can be used to effect stone disintegration or in situ valvulectomy in lieu of the catheter 200. Thus, for some applications the working heads may be constructed like heads 24 and 100, with no shroud necessary.

As should now be appreciated the subject invention provides a catheter for use in a wide variety of non (or minimum) invasive surgical procedures. Those procedures specifically mentioned and discussed herein are by no means the only such procedures. Thus, other surgical procedures requiring access to an operative point or situs from a remote location may also be accomplished using the catheters of the subject invention, with such access being achieved either intraoperatively, percutaneously, or via a natural orifice.

Without further elaboration, the foregoing will so fully illustrate our invention that others may, by applying current or future knowledge, readily adopt the same for use under various conditions of service.

CLAIMS

1. A catheter for introduction into a lumen in a living being to open a restriction formed of an undesirable material in a portion of said lumen, said catheter comprising an elongated flexible member having a longitudinal axis, a working head located adjacent the distal end thereof, and drive means therefor, said catheter being characterized in that said working head comprises at least one, non-sharp, impacting surface, said drive means for effecting the high speed movement of said working head to impact said undesirable material to thereby open said restriction.

2. The catheter of Claim 1 wherein said restriction is opened by the dilation of said lumen portion adjacent said restriction resulting from said working head movement and/or the removal of some of said undesirable material resulting from said impacting surface impacting said undesirable material to break off particles therefrom, said particles being sufficiently small that they are enabled to flow distally without significant deleterious effects to distally located tissue.

3. The catheter of Claim 2 wherein said catheter includes means for producing a fluid flow adjacent said working head to carry said particles into repeated engagement with said impacting surface to successively reduce the size of said particles.

4. The catheter of Claim 3 wherein said working head is arranged for high speed rotation about said longitudinal axis.

5. The catheter of Claim 4 wherein said fluid flow is a vortex flow produced by the rotation of said working head.

6. The catheter of Claim 1 wherein said working head is arranged for high speed rotation about said longitudinal axis and wherein said non-sharp, impacting surface has a leading edge having a radius of curvature at least as large as any tissue wave produced by the movement of said surface thereacross.

7. The catheter of Claim 6 wherein said radius is in the range of .001 inch to .005 inches.

8. The catheter of Claim 1 wherein said working head is arranged for high speed rotation about said longitudinal axis and wherein said non-sharp, impacting surface is formed by an arcuate surface adjacent at least one cam surface.

9. The catheter of Claim 8 wherein said working head additionally comprises at least one relieved surface and said catheter additionally comprises means for ejecting a fluid at said working head, whereupon said relieved surface causes at least a portion of said fluid to be thrown in a direction having a component oriented outward radially with respect to said longitudinal axis.

10. The catheter of Claim 9 wherein said restriction is opened by the dilation of said lumen portion adjacent said restriction resulting from said working head rotating and/or the removal of some of said undesirable material resulting from said impacting surface impacting said undesirable material to break off particles therefrom, said particles being sufficiently small that they are able to flow distally without significant deleterious effects to distally located tissue.

11. The catheter of Claim 10 whereupon the rotation of said working head produces a fluid flow adjacent said working head to carry said particles into repeated engagement with said impacting surface to successively reduce the size of said particles.

12. A method for opening a restriction formed of an undesirable material in a portion of a lumen in a living being comprising the steps of introducing a catheter having an elongated flexible portion having a longitudinal axis and a working head located adjacent the distal end thereof into said lumen, said catheter being characterized in that said working head comprises at least one, non-sharp, impacting surface and is coupled to said drive means, locating said working head in said lumen to the situs of said undesirable material and thereafter operating said drive means to cause said working head to move at a high speed to impact said undesirable material to thereby open said restriction.

13. The method of Claim 12 additionally comprising the steps of introducing a fluid into said lumen adjacent said working head and causing at least the portion of said fluid to flow outward, with some directional components of said flow being substantially outward radially, whereupon said restriction is

opened by the dilation of said lumen portion adjacent said restriction resulting from said working head movement and/or the removal of some of said undesirable material resulting from said impacting surface impacting said undesirable material to break off particles therefrom, said particles being sufficiently small that they are enabled to flow distally without significant deleterious effects to distally located tissue.

14. The method of Claim 13 wherein said fluid flow adjacent said working head carries said particles into a repeated engagement with said impacting surface to successively reduce the size of said particles.

15. A method of dilating a portion of a lumen in a living being utilizing an elongated, small diameter, flexible catheter having a longitudinal axis and a distal end at which a working head is located, said working head being arranged for high speed movement with respect to said axis by associated drive means, said drive means being arranged to freely effect the movement of said working head even if said catheter is bent through an arc up to a minimum radius of curvature and without resulting in excessive vibration which could interfere with the lumen-dilating process, said method comprising inserting said catheter into said lumen from a remote location, causing said drive means to move said working head said high rate of speed and advancing said catheter into said lumen along said axis to said portion of said lumen as said working head is moving, whereupon the action of said working head causes said portion of said lumen to be enlarged.

16. The method of Claim 15 wherein a liquid is inserted into said lumen adjacent said working head and whereupon the movement of said working head in cooperation with said liquid effects the dilation of said lumen.

17. A method of dilating a portion of lumen in a living being utilizing an elongated, small diameter, flexible catheter having a longidutinal axis and a distal end at which a working head is located, said working head being arranged for high speed movement with respect to said axis by associated drive means, said

lumen portion including undesirable material located therein which may be loosened by the dilation action of said working head, said drive means being arranged to freely effect the movement of said working head even if said catheter is bent through an arc up to a minimum radius of curvature, said method comprising inserting said catheter into said lumen from a remote location, causing said drive means to move said working head with respect to said axis at a high rate of speed and advancing said catheter into said lumen along said axis to said portion of said lumen as said working head is moving, whereupon the action of said working head causes said portion of said lumen to be enlarged and wherein said working head causes any loosened materials to be of such sufficiently small size that they are permitted to pass distally of said lumen portion without causing significant deleterious effect to bodily tissue.

18. The method of Claim 17 additionally comprising the steps of providing a fluid to said lumen portion by said catheter, whereupon the movement of said working head imparts momentum in at least a radial direction to said fluid in the furtherance of said dilation action.

19. The method of disintegrating a stone within the body of a living being by utilizing an elongated, small diameter, flexible catheter having a longitudinal axis and a distal end at which a working head is located, siad working head being arranged for high speed movement with respect to said axis by associated drive means, said drive means arranged to freely effect the movement of said working head even if said catheter is bent through any arc up to a minimum radius of curvature, said method comprising inserting said catheter into said body from a remote location, causing said drive means to move said working head at a high rate of speed and advancing said catheter into contact with said stone along said axis as said working head is moving, whereupon the action of said moving working head causes the disintegration of said stone.

20. The method of Claim 19 wherein said method additionally comprises the step of creating a path of fluid flow distally of said working head to pull said stone toward said head.

21. The method of Claim 20 wherein said path of fluid flow is a vortex path.

22. An in-situ method of rendering valves in a section of vein inoperative by utilizing an elongated, small diameter, flexible catheter having a longitudinal axis and a distal end at which a working head is located, said working head being arranged for high speed movement with respect to said axis by associated drive means, said drive means being arranged to freely effect the movement of said working head even if said catheter is bent through any arc up to a minimum radius of curvature, said method comprising inserting said catheter into said vein from a remote location, causing said drive means to move said working head at said high rate of speed and advancing said catheter into said vein along said access axis said working head is moving, whereupon the action of said moving working head renders said valves inoperative.

23. The method of Claim 22 wherein said method additionally comprises the step of creating a path of fluid flow distally of said working head to pull said valves toward said head.

24. The method of Claim 23 wherein said path of fluid flow is a vortex path.

25. Apparatus for disintegrating a stone within the body of a living being, or for performing an in-situ valvulectomy in the vein of a living being, said apparatus being characterized in that it comprises an elongated, small diameter, flexible catheter having a longitudinal axis and a distal end at which a working head is located, said working head being arranged for high speed movement with respect to said axis by drive means located within said catheter, said drive means being arranged to freely effect the movement of said working means even if said catheter is bent through any arc up to a minimum radius of curvature, said working head comprising portions adapted to engage said stone or said valves at a high rate of speed to effect the destruction thereof.

26. The apparatus of Claim 25 wherein said working head comprises a member adapted for rotation about said axis and including portions arranged to impact said stone or said valves at radially displaced positions from said axis.

27. The apparatus of Claim 26 comprising shroud means mounted at the distal end of said catheter and covering said rotating member while allowing said impacting portions to extend therebeyond for engagement with said stone or said valves.

28. The apparatus of Claim 25 additionally comprising means for creating a path of fluid flow distally of said working head to pull said stone or said valves towards said head.

29. The method of stopping spasm in a lumen in a living being utilizing an elongated, small diameter, flexible catheter having a longitudinal axis and a distal end at which a working head is located, said working head being arranged for high speed movement with respect to said axis by associated drive means, said drive means being arranged to freely effect the movement of said working head even if said catheter is bent through any arc up to a minimum radius of curvature, said method comprising inserting said catheter into said lumen from a remote location causing said drive means to move said working head at said high rate of speed and advancing said catheter into said lumen along said axis as said working head is moving, whereupon the action of said working head causes said lumen to stop being in spasm and to remain out of spasm after said catheter is removed.

30. A catheter for introduction into a lumen in a living being to effect a procedure therein, said catheter being an elongated tubular flexible member having a distal end at which a working head is located, said catheter having an inner surface defining a passageway extending down said catheter, said working head being arranged for movement with respect to a central axis extending through said passageway, elongated drive means for said working head located within said passageway and extending down said catheter form a point adjacent said working head to a first remote proximal location, and elongated bearing means for said drive means, said bearing means also located within said passageway and extending down said catheter from a point adjacent said working head to a second remote proximal location, one of said two last mentiond means being formed of at least a first wire and the other of said last two mentioned means being formed of a spiral of at least a second wire wrapped about said first wire, said second wire forming a helical space between its convolutions, whereupon said catheter can be readily bent through any arc up to a minimum radius of curvature while said drive means is rotated freely with respect to said bearing means and to said catheter at a high rotational speed to effect the movement of said working head with respect to said axis, said bearing means and said drive means cooperating with each other to maintain said drive means at a substantially neutral position within said catheter when said catheter is bent through said arc and said drive means rotated at said high rotational speed without resulting in undue vibration which could interfere with said procedure.

31. The catheter of Claim 30 wherein said helical space is in communication with said inner surface and through which a cooling fluid may flow to contact said inner surface of said catheter and said first and second wires to expedite the rotation of said drive means with respect to said bearing means.

32. The catheter of Claim 30 wherein said bearing means is formed as said spiral.

33. The catheter of Claim 30 wherein said drive means is formed as said spiral.

34. The catheter of Claim 32 wherein said spiral bearing means includes a central passageway extending therethrough and wherein said drive means comprises a flexible shaft extending through said central passageway, said flexible shaft being arranged to rotate freely within said passageway.

35. The catheter of Claim 34 wherein said flexible drive means comprises at least one wire.

36. The catheter of Claim 34 wherein said flexible drive means comprises a cable of plural wires.

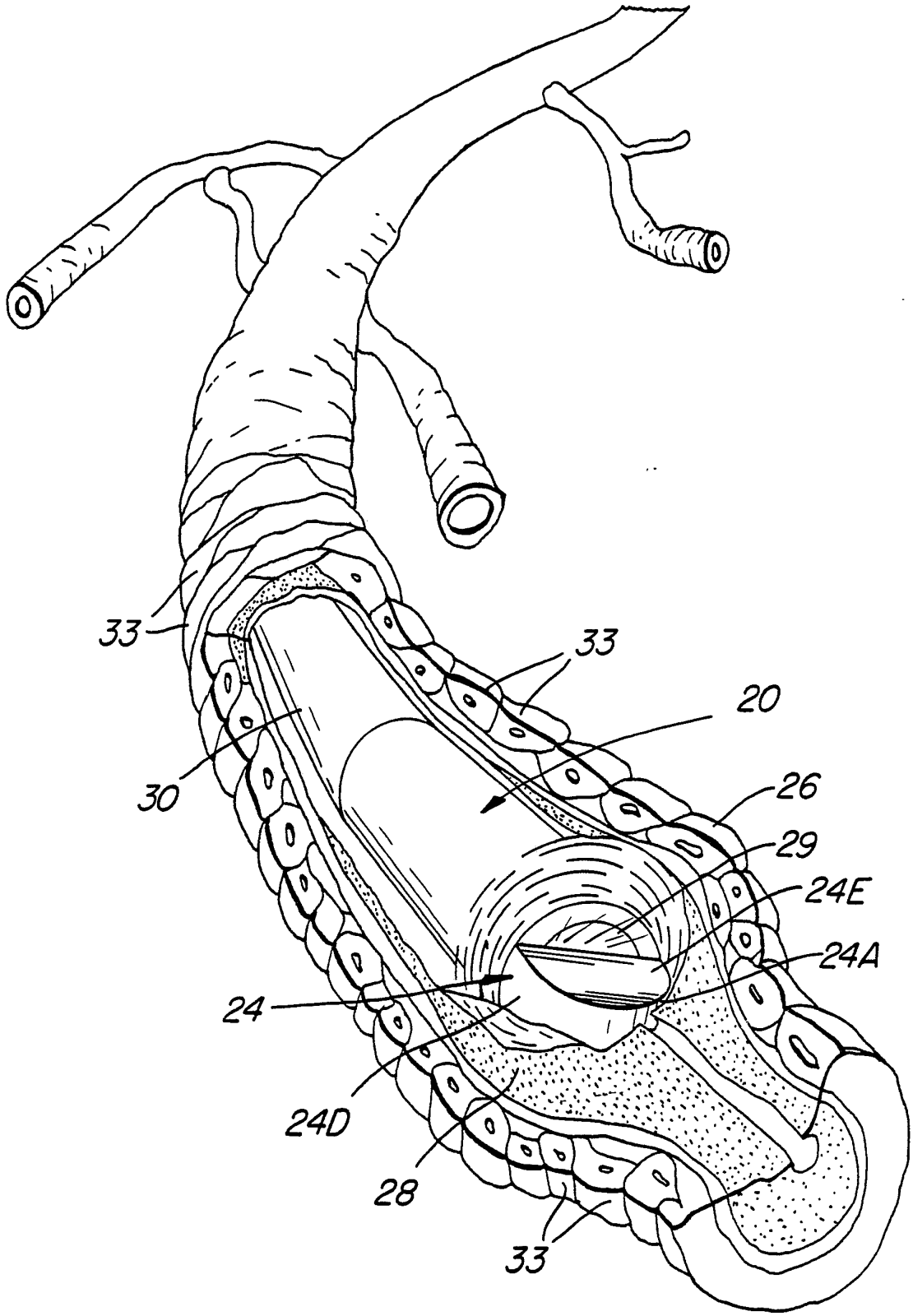
37. The catheter of Claim 36 wherein said cable is swaged or hammered to increase the surface area thereof.

38. The catheter of Claim 34 wherein said spiral bearing is of generally rectangular cross sectional area.

39. The catheter of Claim 38 wherein said spiral bearing means is formed of a tough, yet flexible and relatively low frictional material.

40. The catheter of Claim 39 wherein said material is beryllium-copper.

FIG. 1



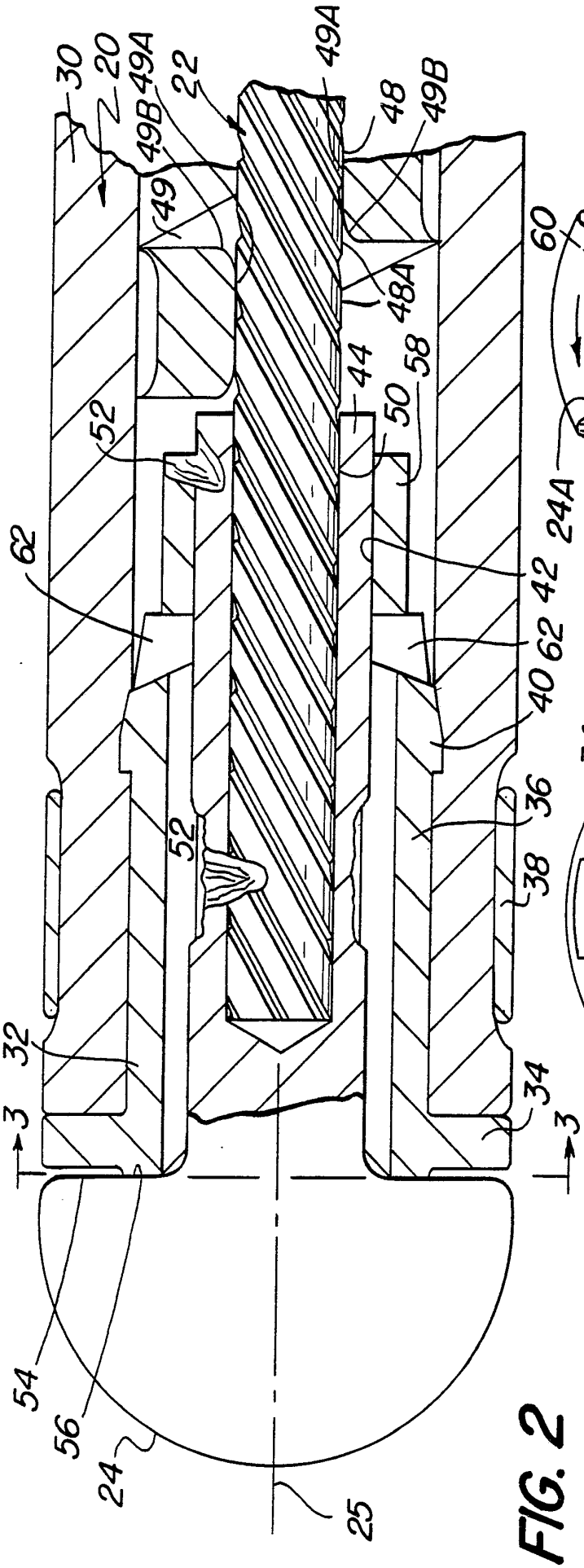


FIG. 2

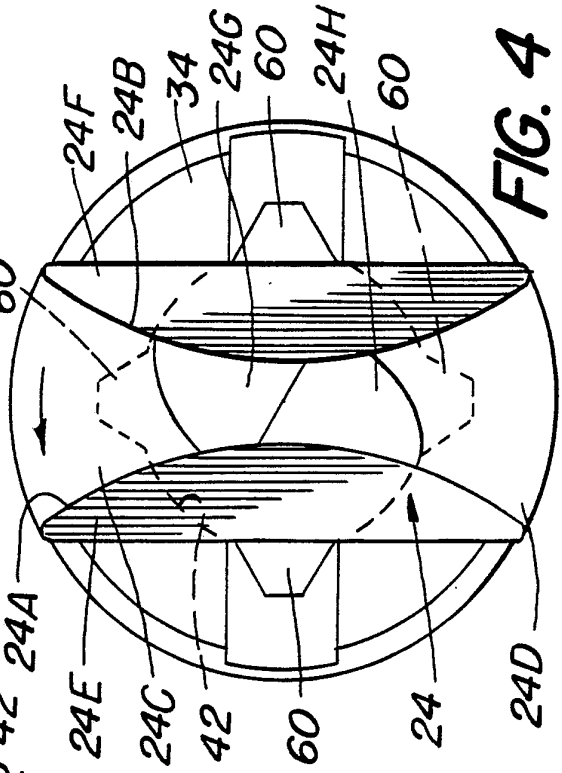


FIG. 4

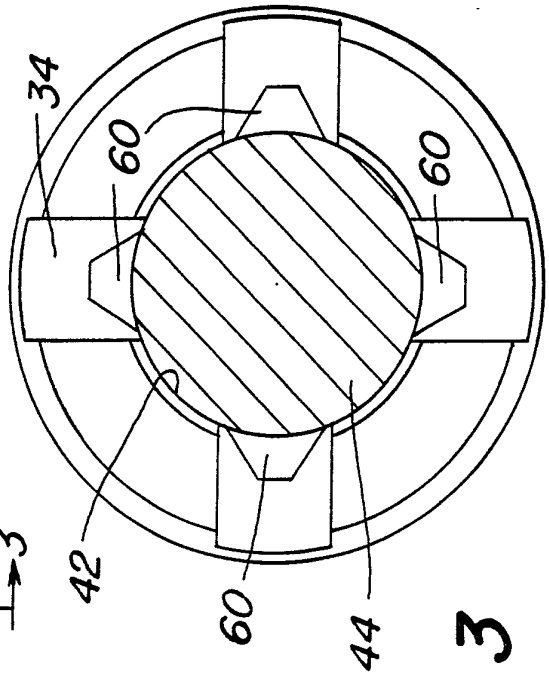


FIG. 3

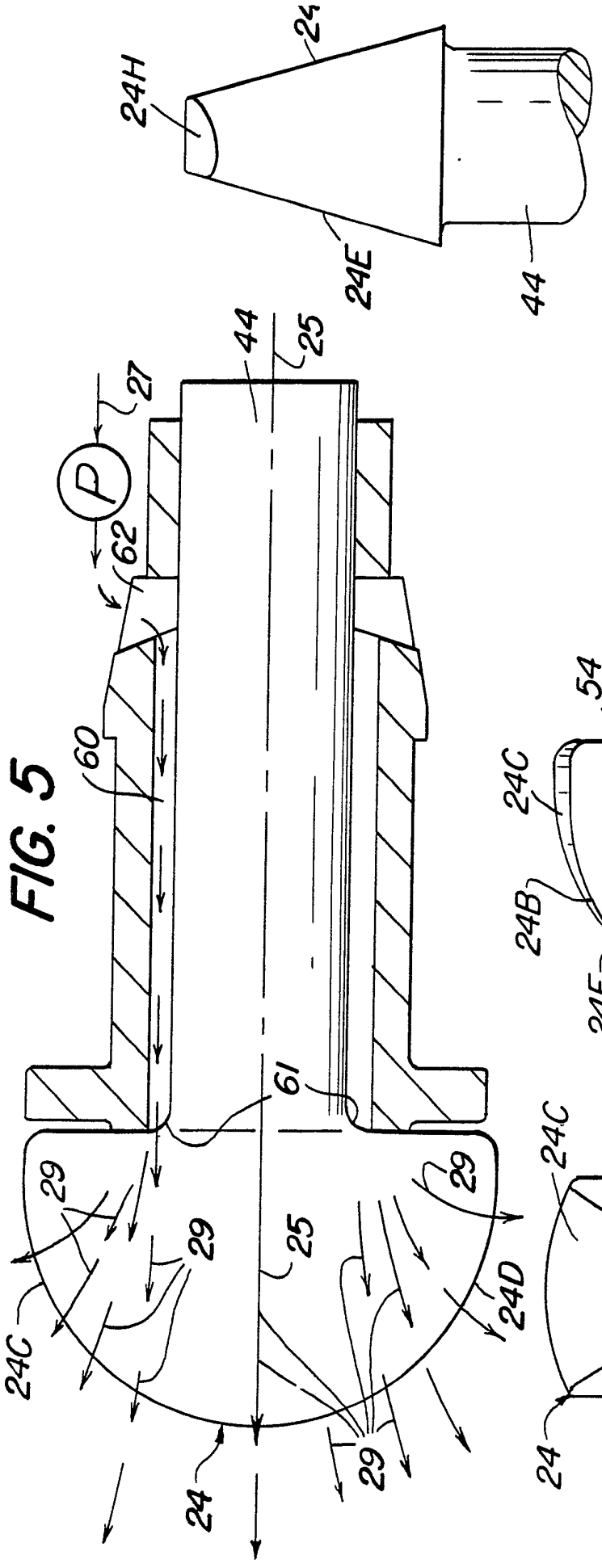


FIG. 5

FIG. 8

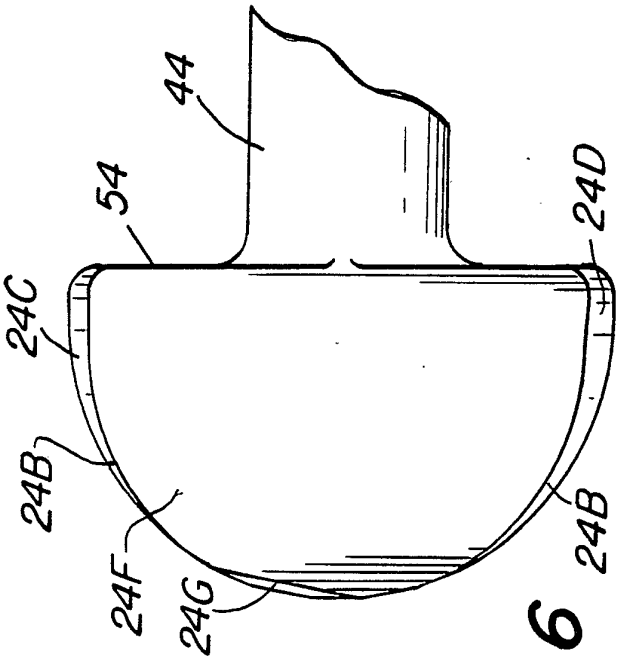


FIG. 7

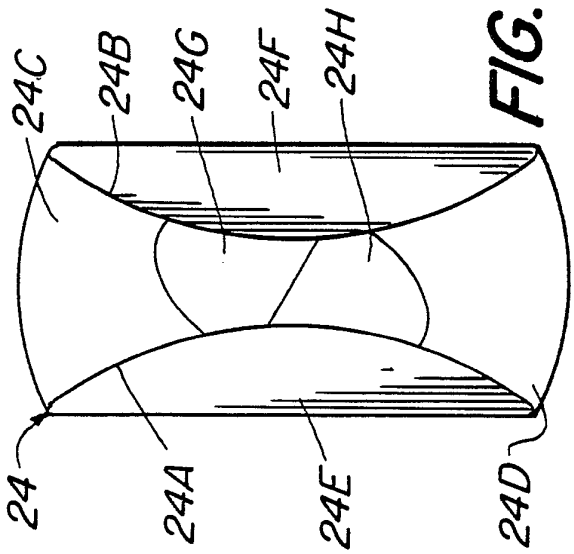


FIG. 6

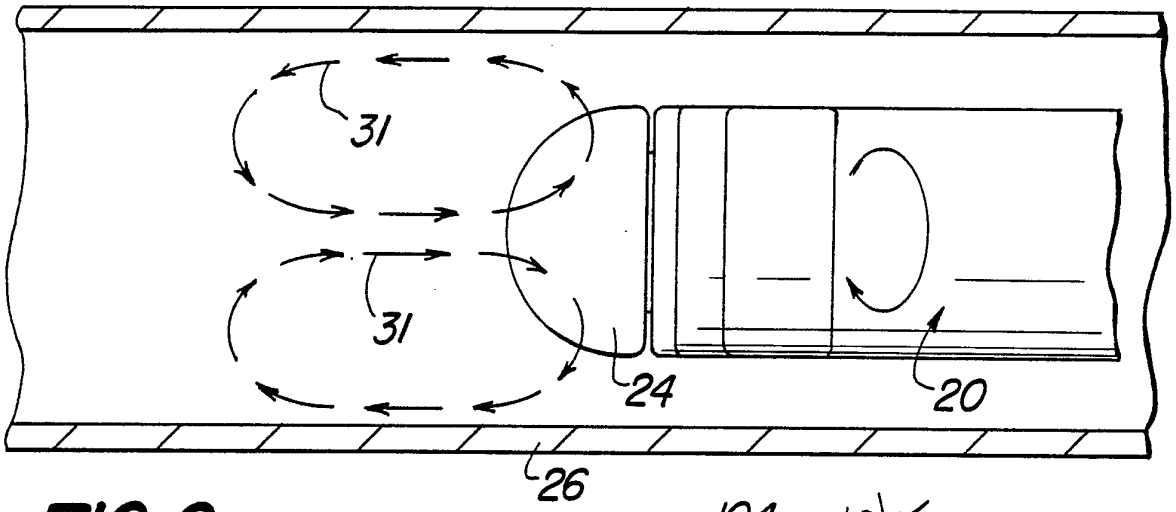
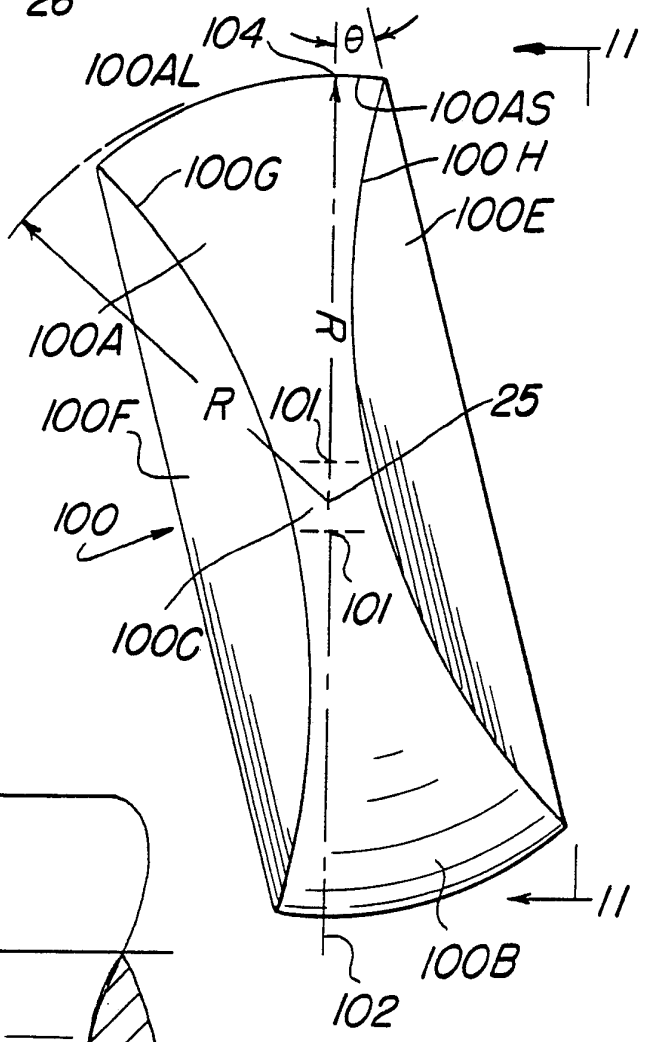


FIG. 9



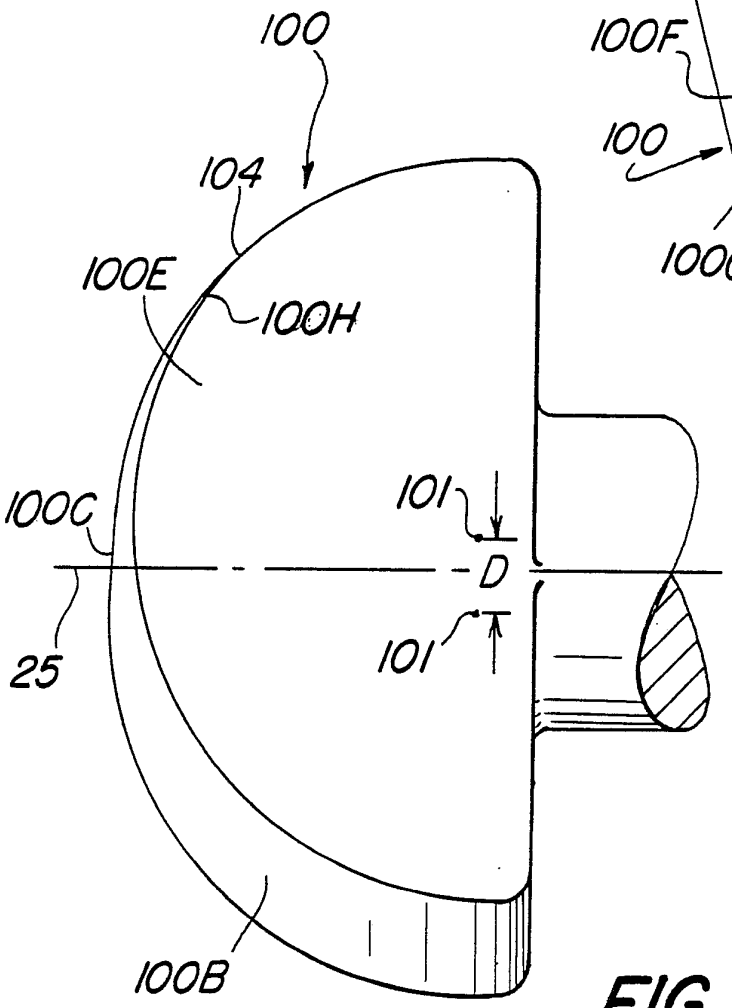


FIG. 10

FIG. 11

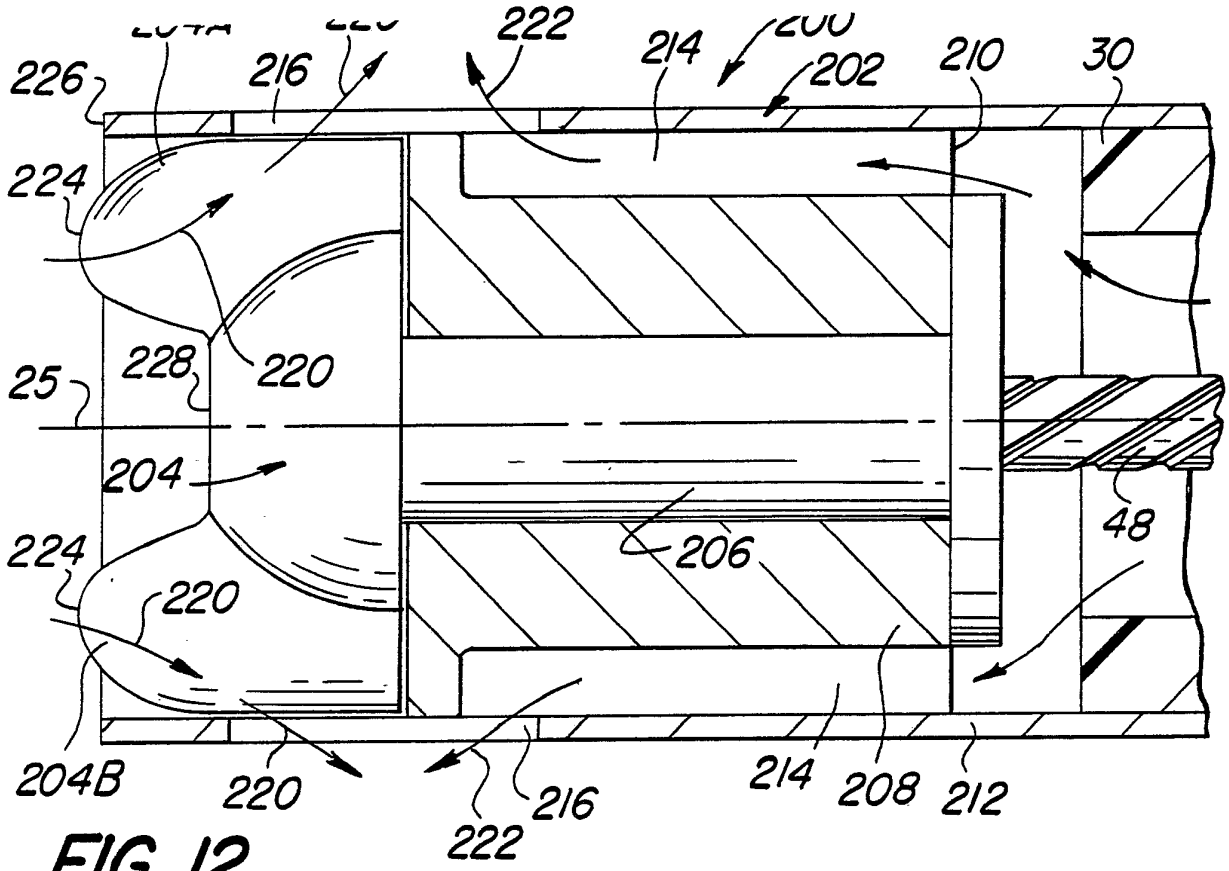


FIG. 12

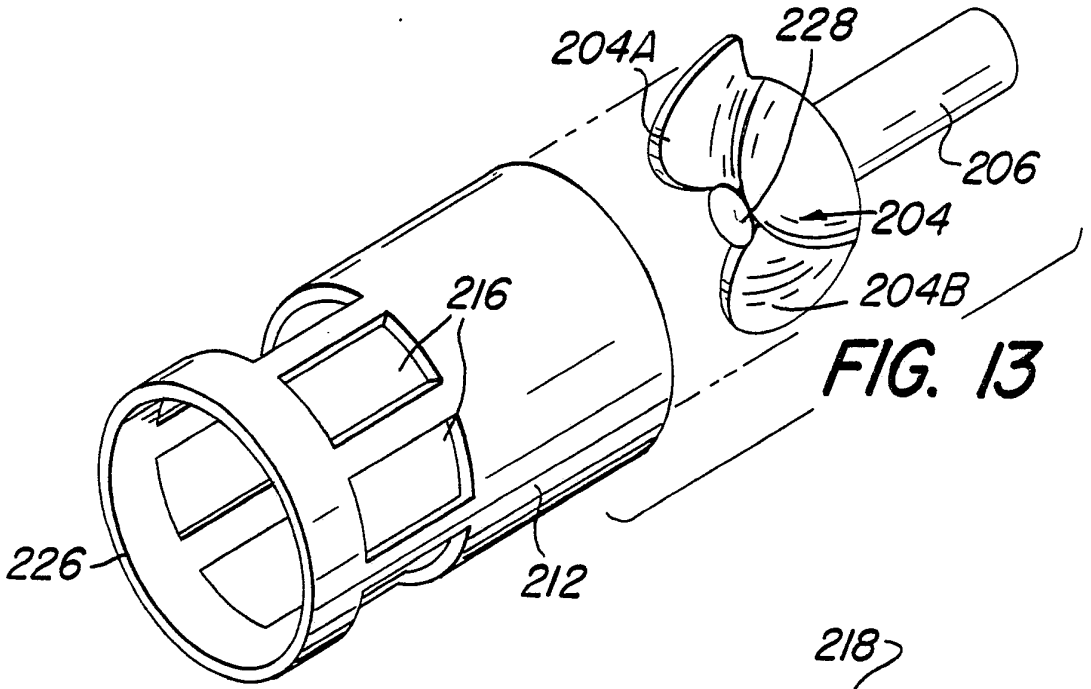


FIG. 13

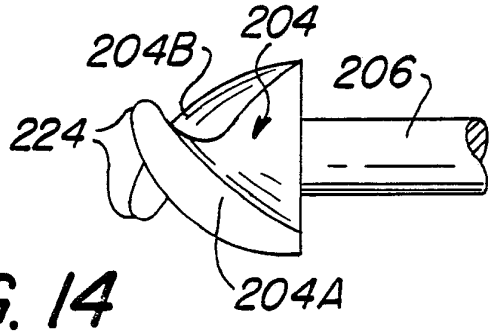


FIG. 14

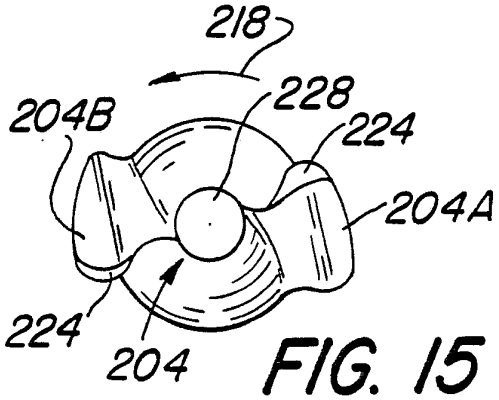


FIG. 15

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 86/02616

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 B 17/22; A 61 B 17/32

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	EP, A, 0191630 (INTRAVASCULAR SURGICAL INSTRUMENTS INC.) 20 August 1986, see claims 1,2,8-11; figures 1-3,8,12, 16; page 15, lines 2-9	25,30,32
A		1,31,34-36, 39,40

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* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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

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

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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
3rd June 1987	- 8 JUL 1987
International Searching Authority	Signature of Authorized Officer
EUROPEAN PATENT OFFICE	M. VAN MOL

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. [X] OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

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

1. [X] Claim numbers ..&&.., because they relate to subject matter not required to be searched by this Authority, namely:

&& Claims 12-24, 29
See PCT Rule 39.1(iv)
Method for treatment of the human or animal body by means of surgery or therapy, as well as diagnostic methods.

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

3. [ ] Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. [ ] OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

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

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

2. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. [ ] As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

[ ] The additional search fees were accompanied by applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/US 86/02616 (SA 15830)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 19/06/87

The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A- 0191630	20/08/86	None	