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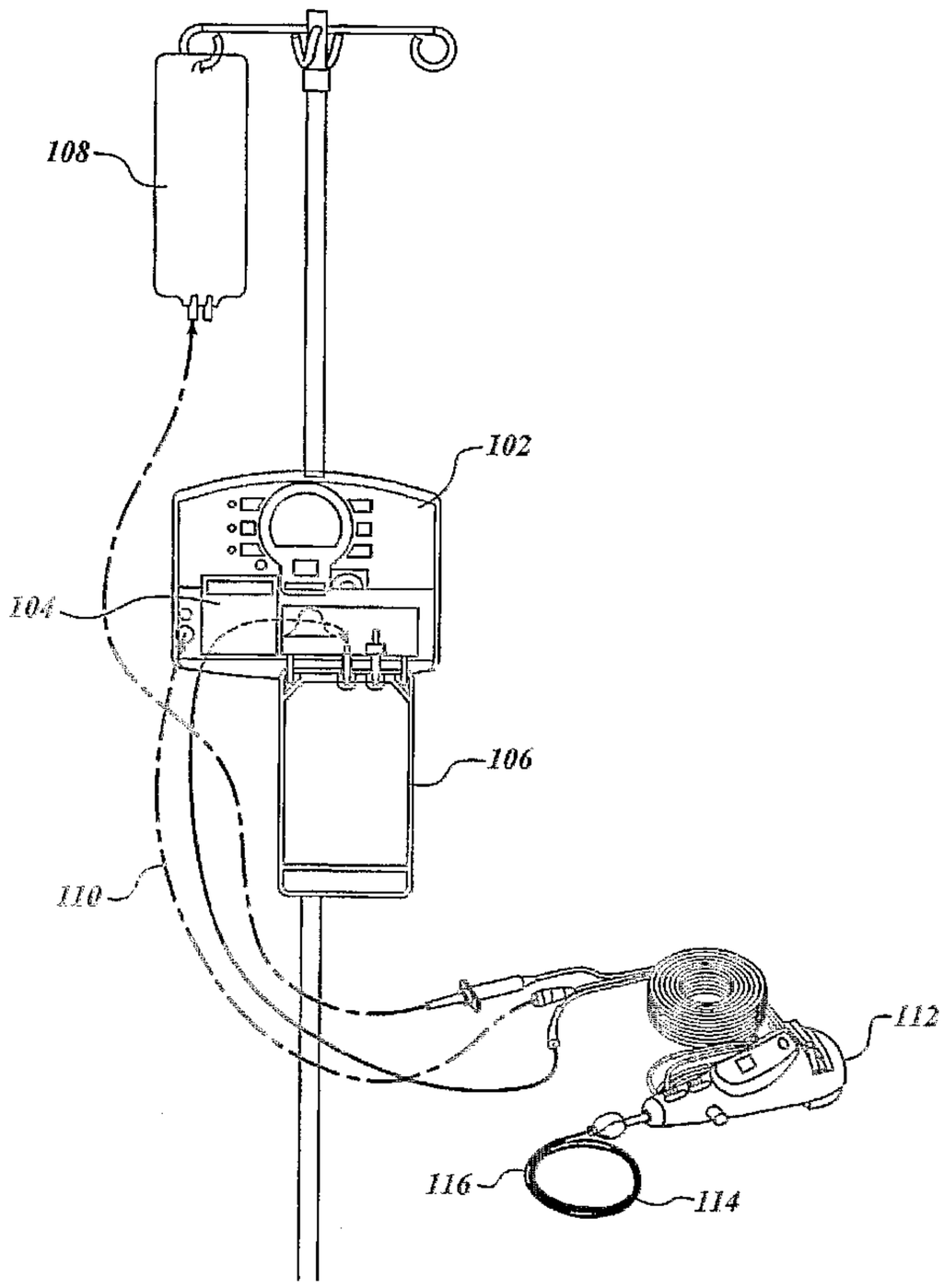
(54) Titre : CATHETERS CHIRURGICAUX POSSEDANT DES SURFACES DE COUPES DIFFERENTIELLES
(54) Title: INTERVENTIONAL CATHETERS HAVING DIFFERENTIAL CUTTING SURFACES



(57) Abrégé/Abstract:
An interventional catheter incorporates an advanceable, rotatable operating head or cutter assembly (50, 72, 80, 120, 140) having one or more distally located differential cutting surfaces (52, 74, 82, 124, 145, 154, 164) having a cant angle of less than 90°, the cant angle being an angle of intersection of the cutting surface and a line tangent to the circumference of the cutter assembly. A fixed blade cutter assembly (50, 72, 80, 120, 140) has a plurality of differential cutting surfaces (52, 74, 82, 124, 145, 147, 154,

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(57) Abrégé(suite)/Abstract(continued):
164) with large ports (68, 125, 143) provided between neighboring differential cutting blades providing access to a sealed lumen and aspiration system. A dual cutter assembly having a fixed blade cutter assembly (200) and an adjustable blade cutter assembly (210) is also provided. A drive shaft provides rotation and torque from a drive system to the cutter assembly and may be coupled to the cutter assembly by means of an articulating bearing assembly (250).

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(54) Title: INTERVENTIONAL CATHETERS HAVING DIFFERENTIAL CUTTING SURFACES

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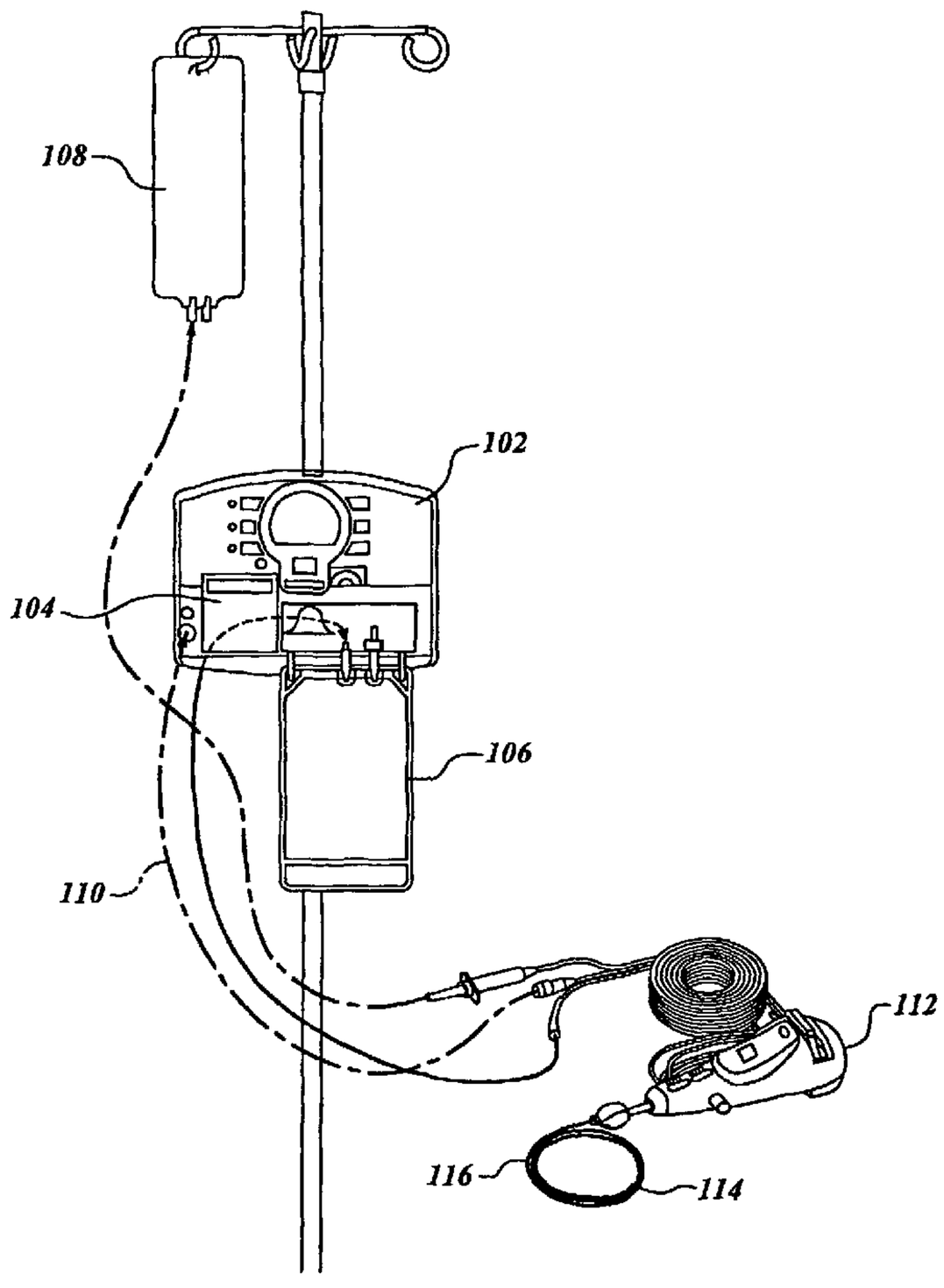

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INTERVENTIONAL CATHETERS HAVING DIFFERENTIAL CUTTING SURFACES

Cross-Reference to Related Applications

This application claims priority to U.S. Patent Application No. 60/453,846 filed March 10, 2003, U.S. Patent Application No. 10/442,888 filed May 20, 2003, and U.S. Patent Application No. 10/760,759 filed January 20, 2004.

Field of the Invention

The present invention relates to systems for removing material, such as obstructions and partial obstructions, from an internal lumen or cavity of a mammalian subject, such as a blood vessel, a portion of the gastrointestinal tract, dural spaces associated with the spinal cord, and the like. More particularly, the present invention relates to interventional catheters having advanceable, rotatable operating heads incorporating differential cutting surfaces.

Background of the Invention

Removal of disease such as atherosclerotic plaque, thrombus, and other types of obstructions and partial obstructions from internal body lumens or cavities is a well-established interventional technique. Numerous interventional catheters have been conceived and developed. Most of these systems require placement of a guiding catheter and guide wire prior to introduction of the interventional catheter and placement of the interventional catheter at the target operating site. Advanceable, rotating operating heads have been used to cut and/or ablate obstructions. Many of these prior art systems incorporate aspiration systems to remove the ablated material from the site.

Despite the many and varied approaches to the material removal systems, many challenges remain in providing systems for removing material from a lumen, such as a blood vessel, safely and reliably and without causing complications. The safety and reliability of the system is manifestly critical. Recovery of debris generated during a material removal operation, or maceration of the debris to a particle size that will not produce blood vessel damage or embolic events is essential. The flexibility and size of an interventional catheter is also an important feature. The system must be small enough and flexible enough to navigate through sometimes tortuous internal structures and passageways, such as blood vessels, for placement at the target interventional site. The interventional catheter must also have

sufficient stiffness and integrity to operate reliably at high rotational rates while allowing for aspiration and/or infusion of fluids to the site.

In interventional catheters that employ a "cutting head," any cutter structures must be benign during navigation of the operating head to and from the interventional target site, yet effectively remove material during the operation. In addition, cutter structures must effectively remove disease or undesired material without damaging delicate neighboring tissue, such as blood vessel walls or other healthy tissue, which often surrounds and may be attached to the undesired material. Thus, it is important for cutter structures of interventional catheters to accurately and reliably differentiate between the disease or undesired material and healthy tissue.

Cutter assemblies operating according to the principles of differential cutting have been developed. Differential cutting blades exert high shear forces against relatively hard substrates to cut or ablate relatively hard, inelastic material. Softer, elastic structures, such as healthy tissue, blood vessel walls, and the like are deformed rather than cut by differential cutting blades, which reduces the shear forces and protects elastic structures from damage. Less elastic material does not deform when contacted by a differential cutting blade, and shear stresses are consequently exerted on less elastic material to cut or scrape and ablate the material without damaging elastic tissue in proximity. In this manner, fragments of diseased, undesirable material are removed by differential cutting blades, while the more elastic, healthy tissue remains undamaged.

U.S. Patent 4,445,509 describes differential cutting in the context of an atherectomy device. This patent describes a cutter assembly having a plurality of cutting flutes, each cutting flute having a blade surface operating according to the principle of differential cutting. The flute density and blade cant angle are disclosed as being key to providing effective differential cutting. Specifically, the cant angle, or angle of intersection of the cutting face and the circumference at the point of contact with the tissue is at least 90° and preferably about 110°. The face of the cutting flute also has a slight concave curvature.

Some interventional catheters use diamond grit on a cutting surface in an effort to provide highly divided, small particle size debris. Diamond grit particles, however, don't operate as differential cutters because, depending on their orientation on the cutting surface, their exposed surfaces form random cant angles, or angles of attack, to produce different cutting characteristics at different points of contact with tissue. Because not all of the diamond grit surfaces operate as differential cutting mechanisms, the diamond grit is more likely to damage elastic, healthy tissue such as blood vessel walls.

The extent and consistency of the disease or undesired material forming an obstruction are frequently not well characterized prior to intervention. Thus, although interventional catheters and cutter assemblies having different sizes and material removal properties may be provided, and may even be interchangeable on a material removal system, it is difficult to ascertain which combination of features will be most effective in any particular intervention prior to insertion of the device. Various quick-connect systems have been developed to permit removal and installation of multiple operating catheters during a single surgical intervention. This is not ideal, since interchange, withdrawal and insertion of multiple interventional catheters is time consuming, may result in increased blood loss during the intervention, and increases the risk of the operation. Having access to multiple cutter assemblies having different sizes and different material removal properties on a single interventional operating catheter is highly desirable.

In particular, it is desirable to use an interventional catheter having a small diameter during the catheter insertion and removal routine and having a cutter assembly that expands to provide a larger diameter cutter during operation when located at the target site. Numerous expandable cutter assemblies for interventional catheters have been developed. The following U.S. Patents disclose various approaches to expandable cutter assemblies: 6,565,588B1; 5,540,707; 5,192,291; 5,224,945; 5,766,192; 5,158,564; 4,895,560; 5,308,354; 5,030,201; 5,217,474; 5,100,425; and 4,966,604.

Summary of Invention

Interventional catheters of the present invention incorporate a material removal component, referred to herein as a "cutter" or "cutter assembly" or "operating head" at their distal ends. The cutter assembly is operably connected to a rotatable and axially translatable drive shaft and catheter system, drive system, and control systems. The "cutter assembly" comprises one or more distally located cutting or abrading surface(s), or blades, that operates according to the principles of differential cutting. The cutting surfaces or blades are preferably substantially rigid and multiple blades or cutting surfaces are preferably radially symmetrical. The differential cutting surfaces or blade(s) have one or more beveled edges having a cant angle, or angle of attack, of less than 90° to provide effective differential cutting.

As used herein in the description of various components, "proximal" refers to a direction toward the system controls and the operator along the path of the drive shaft and catheter system, and "distal" refers to the direction away from the system controls and the

operator along the path of the drive shaft and catheter system toward or beyond a terminal end of the cutter assembly. In general, interventional catheters of the present invention comprise a cutter assembly comprising at least one differential cutting surface positioned at or near the distal end of the interventional catheter system.

Although the "cutting" surfaces or blades of interventional catheters of the present invention may be sharp and may actually "cut" material at the target site, the term "cut" or "cutting," as used herein, refers to cutting, scraping, ablating, macerating and otherwise breaking down undesired material into removable particles or smaller, removable units of material. "Cutters," "cutter assemblies," "cutting surfaces" and "blades" likewise refer to structures for cutting, scraping, ablating, macerating and otherwise breaking down material into smaller pieces.

Cutter assemblies of the present invention may comprise at least one differential cutting surface, and generally comprise a plurality of differential cutting blades. A cutter assembly may have fixed and/or adjustable blades. In one embodiment, a fixed blade cutter assembly comprises a plurality of differential cutting blades and a plurality of generally large aspiration ports formed between neighboring differential cutting blades. Although the differential cutting surfaces on the fixed blade cutter assembly are not adjustable, the fixed blade cutter assembly may provide a range of cutting diameters as a consequence of the generally ovoid or conical external profile of the cutter assembly. In another embodiment, a plurality of pivotable differential cutting blades are incorporated in an expandable cutter assembly that is navigable to the intervention site in a smaller diameter condition, then adjusted to a larger diameter condition at the target site during operation, and finally withdrawn from the intervention site in a smaller diameter condition. In another embodiment, cutter assemblies of the present invention incorporate both fixed differential cutting blades and pivotable differential cutting blades in a dual or composite cutter assembly.

The drive shaft that conveys rotation and torque from a drive system to the cutter assembly must be small enough and flexible enough to be navigated through small and tortuous passageways during navigation of the cutter assembly to the target removal site, and must have sufficient mechanical integrity to transfer high rotational and torque loads and operate in a high vacuum, aspirate withdrawal environment. Multi-filar helical coils are used as drive shafts in many types of interventional catheters having a rotatable operating head. Several preferred drive shaft embodiments are described below.

Interventional catheters of the present invention preferably include an aspiration system for removal of debris from the intervention site, generally via aspiration through one or more material removal ports provided in the cutter assembly or another component in proximity to the cutter assembly. Debris generated during a material removal operation is entrained in fluids (e.g. blood), and the aspirate fluid containing debris is removed by aspiration through the material removal ports and withdrawn through a sealed lumen of the interventional catheter. The sealed lumen is connectable to a vacuum source and aspirate collection system. The material removal ports may be disposed between blade surfaces of the cutter assembly and preferably have a large surface area.

Liquid infusion may be provided in proximity to the cutter assembly in addition to or alternatively to aspiration. Infusion of liquids may be used to provide additional liquid volume for removal of debris, or to deliver lubricating fluids, treatment agents, contrast agents, and the like. Infusion of fluids in proximity to the area of a material removal operation may be desirable because it tends to reduce the viscosity of the materials being removed, thus facilitating removal through relatively small diameter lumens. Infusion of liquids also desirably tends to reduce the volume of blood removed during a material removal operation. According to one embodiment, a sealed lumen formed between the cutter assembly drive shaft and a catheter may alternatively and selectively be used as aspirate removal system and an infusion system. The sealed lumen may thus be selectively connectable to a vacuum source and aspirate collection system for aspiration, and an infusion source for infusion of liquids. Ports in or in proximity to the cutter assembly may be thus be employed, selectively, as aspiration and infusion ports.

Interventional catheters of the present invention may also incorporate an articulating bearing that improves the flexibility of the system and facilitates navigation of the cutter assembly through tortuous passageways during guidance to and from the intervention site. The bearing system couples cutter assemblies and operating heads of the present invention to the drive shaft so that torque and rotation are conveyed from the drive shaft to the cutter assembly. The bearing system also couples the cutter assembly or operating head to a static catheter system, or sheath, that provides a sealed lumen and generally does not rotate during operation of the interventional catheter. The bearing system provides enhanced flexibility at the connection that joins the operating head, drive shaft and catheter, and also provides a channel for aspiration and/or infusion of fluids.

Brief Description of the Drawings

Figure 1 shows exemplary components of an interventional catheter assembly of the present invention having an operating head comprising differential cutting surfaces and an articulating bearing.

Fig. 2 shows a prior art differential cutter assembly described in U.S. Patent 4,445,509, wherein the differential cutter blades have cant angles of greater than 90°.

Figure 3A shows an enlarged side view of an exemplary fixed blade cutter assembly of the present invention having a plurality of differential cutting surfaces and aspiration ports.

Figure 3B shows an enlarged perspective view of the fixed blade differential cutter assembly of Figure 3A.

Figure 3C shows an enlarged cross-sectional view of the fixed blade differential cutter assembly of Figures 3A and 3B illustrating differential cutting surfaces having cant angles of less than 90°.

Figures 4A and 4B show schematic diagrams illustrating the effect on a relatively elastic surface of a differential cutting surface having a 90° cant angle (Fig. 4A) as used in prior art devices and a differential cutting surface having a 60° cant angle (Fig. 4B) as used in cutter assemblies of the present invention.

Figures 5A and 5B illustrate schematic cross-sectional views of differential cutter assemblies of the present invention having three differential cutting surfaces (Fig. 5A) and six differential cutting surfaces (Fig. 5B).

Figures 6A and 6B illustrate another embodiment of a fixed diameter cutter assembly having a plurality of differential cutting surfaces. Fig. 6A shows a schematic isometric view of the cutter assembly and Fig. 6B shows a schematic distal end view of the cutter assembly.

Figures 7A and 7B illustrate schematic distal and proximal end views, respectively, of another embodiment of a fixed blade cutter assembly of the present invention having a plurality of differential cutting surfaces.

Figures 8A and 8B illustrate additional types of cutter blades of the present invention incorporating differential cutting surfaces.

Figures 9A and 9B show enlarged schematic diagrams of a composite cutter assembly of the present invention comprising two types of differential cutter surfaces in a dual cutter, with the proximal end of the cutter assembly mounted to an articulating bearing. Figure 9A shows the differential cutter and bearing assembly in an assembled condition, while Figure 9B shows the differential cutter and bearing assembly in an exploded, unassembled condition.

Figures 10A and 10B are fluoroscopic x-ray images of a coronary artery having a removal site, wherein Figure 10A depicts the nearly totally and diffusely occluded artery before the operation of the removal system and Figure 10B depicts a cleared artery after use of the interventional catheter assembly of the present invention.

Figures 11A-11C show the results of operation of cutter assemblies having various characteristics in a laboratory stained bovine aorta model as described in Example 2. Figure 11A shows damage done to the bovine aorta after operation of a cutter assembly having a plurality of cutting surfaces having a cant angle of 90°. Figure 11B shows damage done to the bovine aorta after operation of a cutter assembly having randomly oriented diamond grit particles on an outer, operating surface. Figure 11C shows the results of operation of a cutter assembly having a plurality of differential cutting surfaces having a cant angle of 60° and demonstrates that the bovine aorta was not damaged with this cutter assembly.

Figures 12A-12F show the results of operation of cutter assemblies having various characteristics in porcine blood vessels as described in Example 3.

Detailed Description of Preferred Embodiments

Exemplary interventional catheters and material removal systems, components and subassemblies suitable for use in connection with components of the present invention are disclosed and described in the publications incorporated herein by reference, including U.S. Patent 6,565,588B1 and PCT Patent Publication WO 01/76680. The cutter assemblies and bearing assemblies described herein may be used with interventional catheters having a variety of drive, control and other systems. The cutter assembly is provided at or near a distal end of the interventional catheter and is guided to and from a desired material removal site through internal passages, such as blood vessels, as is well known in the art. At the target removal site, the cutter assembly is actuated to cut, grind or ablate, or otherwise separate and break down undesired occlusive material. In many embodiments, the occlusive material is removed the site by means of an aspiration system or another debris removal system.

Figure 1 illustrates an exemplary interventional catheter and operating system of the present invention. In the interventional catheter and control system shown in Fig. 1, console unit 102 is provided for housing certain power, control and display functions. Console 102 may have adjustable controls that permit the operator to adjust operating parameters of the interventional catheter. Control features may include a system on/off actuator, selectable torque buttons to adjust cutter assembly rotational torque, selectable rotation features providing fixed and/or variable rotational speeds during actuation of the cutter assembly, a

display of the real-time rotational speed of the cutter assembly during actuation, a timer control and/or actuation time counter to display the length of time of actual cutter operation, a motor only control to activate or shut off a rotational drive system without affecting aspiration and/or infusion, an aspiration and/or infusion only control to activate or shut off an aspiration and/or infusion function without affecting the rotational drive, and the like.

In the embodiment of Fig. 1, aspiration or vacuum motor 104 is mounted on or in console 102, as is a liquid/debris collection receptacle 106 and a liquid supply 108. Power connector 110 provides power to other interventional catheter components. Suitable electrical and liquid flow conduits are provided for operable communication between console 102 and catheter control module 112. Control module 112, in this embodiment, houses the motor drive for rotating a cutter assembly of the interventional catheter and also incorporates certain connectors and systems for communicating torque and rotation to a drive shaft having an operating head, such as a rotatable cutter assembly, mounted at or near its distal end, and for facilitating liquid infusion to and/or liquid and debris removal from the operating head. Control module 112 also incorporates systems facilitating axial translation of the interventional catheter, indicated generally at 114, and an operating head 116, such as a rotatable, advanceable cutter assembly having at least one differential cutting surface, to and from an internal target material removal site. An articulating bearing, described herein, may be incorporated in proximity to the operating head to provide greater flexibility at the distal portion of the interventional catheter.

In the interventional catheter system illustrated in Fig. 1, certain power, control and display functions are provided separately in console 102 and catheter control module 112. It will be recognized that these power, control and display functions may be provided in a single unit, or may be separated in a plurality of control units. Likewise, it will be recognized that the cutter assemblies and differential cutting surfaces of the present invention may be incorporated in interventional catheters having different types of power, display and control systems, and providing different functions. Differential cutting surfaces of the present invention may be incorporated in any type of interventional catheter that may be employed for removal of undesired material located within a human or animal body.

The operating head of the interventional catheter of the present invention may comprise any of a variety of cutting devices or assemblies having one or more stiff and/or sharp cutting surface(s) for cutting, fragmentizing, pulverizing, ablating, scraping, grinding or otherwise reducing the size of and/or separating undesired material from healthy tissue, such as the walls of a blood vessel, in proximity to the target removal site. For example, the

cutting surfaces may include one or a combination of blade(s), spring(s), metallic or ceramic or composite surfaces having at least one surface that operates according to the principle of differential cutting.

Some exemplary materials of construction for the cutting surface(s) of the cutter assembly include metals, metal alloys, ceramics and cermet materials, such as but not limited to, various types of stainless steels, such as series 300 and/or 400, vanadium steel, nickel-titanium, titanium, titanium-containing metals and oxide ceramics. Metallic materials such as stainless steels may be hardened using well-known techniques. In general, cutter surfaces are constructed from hard materials and may be treated to impart even greater hardness to the cutter surfaces. Cutter surfaces constructed from a material that is harder than the materials used to construct stents are generally provided. The cutter assembly, or sub-components thereof, such as the cutting surfaces, may be coated with a radio-opaque material such as gold, platinum, inks and the like, to render the expandable cutter assembly radioscopically visible and to assist a medical professional in guiding and positioning the cutter assembly relative to an occlusion.

Fig. 2 illustrates an enlarged cross-sectional view of prior art differential cutter surfaces according to U.S. Patent 4,445,509 (hereinafter referred to as " '509 patent"). A plurality of cutting flutes 14 are provided with corresponding cutting faces 18. Fluid ports 15 are provided as passageways having a rearward or longitudinal component and are intended for withdrawal of fluids and debris from the intervention site to cavity 40. The cutter assembly, as illustrated, rotates in a clockwise direction during a material removal operation. The cant angle, which is illustrated as angle α, is the angle of intersection of cutting face 18 and the circumference C, or a line tangent to circumference C of the cutter assembly. According to the '509 patent, cant angles of about 110°, and cant angles deviating from 110° by about 20° provide acceptable differential cutting properties.

Figs. 3A-3C illustrate fixed blade cutter assemblies having a plurality of differential cutting surfaces according to the present invention. Cutter assembly 50 comprises a plurality of cutter blades 52 arranged in a radially symmetrical arrangement with respect to a central longitudinal axis of the cutter assembly. Each of the cutter blades 52 is joined at a distal end to form a distal bore 54 which serves as a rotating bearing for a guidewire when a guidewire is used in a material removal operation. Cutter blades 52 may alternatively terminate at their distal ends in a blunt or pointed structure without forming a distal bore in cutter assemblies that are employed without guidance over a guidewire. Cutter blades 52 terminate at their proximal ends in a proximal ring-like collar 55 that is mounted to a drive shaft, a catheter

system, or an intermediate bearing structure providing operable connections between the cutter assembly, the drive shaft, and the catheter system.

The overall outer configuration of cutter assembly 50 is generally round from an axial view and oblong or frusto-conical from a profile view. The outer edges of cutter blades 52 taper along a curved line between a smaller diameter distal bore 54 and a larger diameter proximal collar 55. This configuration allows the smaller diameter distal end of the cutter assembly to penetrate an obstruction or partial obstruction and, as the cutter assembly is advanced through the obstruction, a progressively larger bore is provided as the diameter of the cutter assembly increases toward its distal end. The inside curved profile of the blade contour generally corresponds to the outer curved contour of the blade. In many embodiments, cutter blades 52 have a generally constant chord between proximal collar 55 and distal bore 54, providing a strong, yet thin blade.

Ports 68 formed by the boundaries of neighboring pairs of cutter blades 52 and the distal and proximal rings are large and generally triangular in configuration, having curved sides. Ports 68 provide access to an internal space and aspiration lumen for removal of fluids and debris during a material removal operation. Because cutter blades incorporating differential cutting surfaces of the present invention can be provided as thin blades, the port size can be maximized. The total cross-sectional area of the ports, compared to the total cross-sectional of the inside surfaces of the cutter blades in cutter assemblies of the present invention is generally at least 1.5:1, preferably at least 2:1, more preferably at least 2.5:1; and more preferably yet at least 3:1.

Each of the cutter blades 52 has a differential cutter surface 56 that contacts material to be removed when cutter assembly 50 is rotated during a material removal operation. In the cutter assembly embodiment shown in Figs. 3A-3C, cutter assembly 50 is configured to rotate in a counterclockwise direction. Differential cutter surfaces of the present invention have a cant angle α, which is the angle of intersection of cutter surface 56 and a line tangent to the circumference of the cutter assembly, of less than 90°. In some embodiments of cutter surfaces of the present invention, the cant angle is less than 80°; in other embodiments of cutter surfaces of the present invention, the cant angle is less than 70°; in yet other embodiments of cutter surfaces of the present invention, the cant angle is less than 60°; in alternative embodiments of cutter surfaces of the present invention, the cant angle is less than 50°; in still other embodiments of cutter surfaces of the present invention, the cant angle is less than 40°. The cant angle is generally greater than 15°, may be greater than 25°, and is often greater than 30° or 40°.

Differential cutter surfaces may be optimized for use in different types of cutting environments, for different types of materials being removed, and for different applications, by providing different cant angles, providing that the cant angle for differential cutting is less than 90°. Because differential cutter surfaces having cant angles of less than 90° provide more effective differential cutting, fewer cutter surfaces may be required for material removal operations. In general, in cutter assemblies having fewer blades, the blades have a thin cross-sectional dimension, allowing for larger aspiration ports and greater aspiration efficiency. Cutter assemblies of the present invention are benign to healthy, elastic tissue while providing effective removal of less elastic, disease tissue and providing high aspiration rates for removal of debris.

Cutter surfaces 56 may be provided on a leading blade surface 58 that is a planar surface. Trailing blade surfaces 60 may comprise a compound surface composed of two or more adjoining surfaces 62 and 64 provided at angles to one another. In the embodiment shown in Figs. 3A-3C, leading blade surfaces 58 are longer than trailing blade surfaces 60, and leading blade surfaces 58 intersect trailing blade surfaces 60 at an inner region at a substantially right angle. The outer terminal edges 66 of blades 52 formed at the intersection of cutter surfaces 56 and trailing blade surfaces 60 preferably form an acute angle to one another and are preferably sharpened. In many embodiments of cutter assemblies of the present invention, neither the leading nor the trailing blade surfaces are aligned radially with respect to the longitudinal axis of the cutter assembly.

Figure 4 illustrates, schematically, the cutting action of a blade 70 having a 90° cant angle rotating in a counterclockwise direction (Fig. 4A) and the cutting action of a blade 71 having a 60° cant angle rotating in a counterclockwise direction (Fig. 4B). Differential cutting blade 71 having a 60° cant angle, as shown in Fig. 4B, is gentle and benign when it contacts a resilient surface, yet it effectively cuts and abrades less resilient materials to provide effective removal of disease material such as plaque, calcified material and thrombus. Cutting blade 70 having a 90° cant angle, as shown in Fig. 4A, can be quite damaging to resilient surfaces. The laboratory tests described in Example 2, below, provide data confirming the improved properties of cutting blades having a 60° cant angle compared to cutting blades having a 90° cant angle.

Figures 5A and 5B illustrate cutter assemblies having different numbers and arrangements of differential cutting surfaces. Any number of cutter blades may be employed in cutter assemblies and interventional catheters of the present invention. Cutter assemblies

having three, five, six and seven cutter blades that are radially symmetrical are especially preferred for many applications.

Fig. 5A shows a cutter assembly 72 having three radially symmetrical cutter blades 74 that provide differential cutting when cutter assembly 72 is rotated in a clockwise direction. Cutter blades 74 terminate at a distal end in distal bore 75 and terminate at a proximal end in proximal collar. Cutter surfaces 77 have a cant angle α of less the 90°. Cutter surfaces 77 are provided on a leading blade surface 78 that is a planar surface. Trailing blade surfaces 79 have a tapered configuration. In the embodiment shown in Fig. 5A, leading blade surfaces 78 are longer than trailing blade surfaces 79, and leading blade surfaces 78 intersect trailing blade surfaces 79 at an inner region at an obtuse angle.

Fig. 5B shows an embodiment of cutter assembly 80 having six radially symmetrical cutter blades 82 that provide differential cutting when cutter assembly 80 is rotated in a clockwise direction. Cutter blades 82 terminate at a distal end in distal bore 83 and terminate at a proximal end in proximal collar. Cutter surfaces 85 have a cant angle α of less the 90°. Cutter surfaces 85 are provided on a leading blade surface 86 that is a planar surface. Trailing blade surfaces 87 have a tapered or compound configuration. In the embodiment shown in Fig. 5B, leading blade surfaces 86 intersect trailing blade surfaces 87 at an inner region at an acute angle.

Figures 6A and 6B illustrate yet another cutter assembly 120 having a plurality of cutting blades 122, each cutting blade being provided with a differential cutting surface 124. Cutter assembly 120 has seven cutter blades provided in a radially symmetrical arrangement with ports 125 provided between each neighboring pair of cutter blades. Ports 125 are large and have a generally ovoid configuration with curved walls. Cutter assembly 120 is rotatable in a clockwise direction to provide differential cutting.

Cutter blades 122 terminate at a distal end in distal bore 126 and terminate at a proximal end in proximal collar 128. Cutter surfaces 124 have a cant angle α of less the 90°. Cutter surfaces 124 are provided on a leading blade surface 131 that is a planar surface. Trailing blade surfaces 130 have a tapered or compound configuration. In the embodiment shown in Figs. 6A and 6B, edges 129 of cutter surfaces 124 at their largest diameter point extend beyond the diameter of proximal collar 128. Edges 129 have a curved profile along their length between distal bore 126 and proximal collar 128 that extends to a larger diameter than proximal collar 128 and then tapers to join proximal collar 128. This cutter blade profile permits effective removal of material to form a passageway through obstructions that is larger in diameter than the proximal collar of the cutter assembly and promotes side cutting. This

cutter blade profile may be particularly advantageous for use in interventional catheter systems in which the cutter assembly is guided by remote steering technologies rather than being advanced on a guidewire.

Figures 7A and 7B illustrate yet another cutter assembly 140 having a plurality of differential cutting blades 142 and aspiration ports 143. In this embodiment, both leading blade surfaces 144 and trailing surfaces 146 are compound surfaces and differential cutting surfaces are provided on both leading and trailing blade surfaces. Leading blade surfaces 144 form differential cutting surfaces 145, while trailing blade surfaces 146 form differential cutting surfaces 147. Differential cutting surfaces 145 and 147 all have cant angles of less than 90° to provide effective and safe differential cutting properties.

Differential cutting surfaces 145 and 147 operate when cutter assembly 140 is rotated in clockwise and counterclockwise directions, respectively. Providing differential cutting surfaces on both the leading and trailing surfaces of cutting blades dramatically increases the versatility of the cutter assembly when it is used in conjunction with a bi-directional motor drive. In preferred embodiments, differential cutting surfaces 145 and 147 have different cant angles to provide different differential cutting properties. Differential cutting surfaces 145 may have a cant angle of less than 90° and more than about 70°, while differential cutting surfaces 147 may have a cant angle of less than 70° and more than 30°. The operator may select the direction of drive shaft and cutter assembly rotation to employ the differential cutter blades having the differential cutting properties most suitable for removal of particular material during a material removal process. Various combinations of differential cutter blades and differential cutting surfaces having various cant angles may be used in differential cutting blades having dual differential cutting surfaces.

The fixed blade cutter assemblies described above have multiple cutter blades and multiple differential cutter surfaces. The cutter assemblies and cutter blades may be provided in various configurations, presenting various external profiles, and having various port surface area to internal blade surface area ratios. In general, the plurality of differential cutting surfaces provided in a cutter assembly having a single differential cutting surface on each blade each have the same cant angle. In alternative embodiments, different cant angles may be provided on single differential cutting surfaces on individual cutting blades forming a cutter assembly. Thus, for example, a fixed blade cutter assembly having six radially symmetrical cutter blades may be provided having three cutter blades with differential cutting surfaces having a first cant angle less than 90° and three cutter blades with differential cutting surfaces having a second cant angle less than 90° and different from the first cant angle. The

cutter blades having differential cutting surfaces with different cant angles are preferably provided in an alternating arrangement.

Figures 8A and 8B illustrate yet additional types of differential cutting blades 150 and 160 that may be used, for example, as pivoting differential cutting blades in an expandable type of cutting assembly, which is described in more detail below. Differential cutting blade 150 comprises a generally planar surface 152 having a differential cutting surface 154 at a peripheral edge. Planar surface 152 may be mounted on or integral with mounting tabs or rods 156 for mounting blades 150 to a cutter assembly structure. Differential cutting blade 160 comprises a generally planar surface 162 having a differential cutting surface 164 at a peripheral edge and a mounting rod 166 for mounting blades 160 to a cutter assembly structure. Differential cutting surfaces 154 and 164 have cant angles, as defined above, of less than 90°.

The profile of differential cutting surfaces may be symmetrical, as exemplified by differential cutting surface 154 in Fig. 8A or asymmetrical, as exemplified by differential cutting surface 164 in Fig. 8B. Asymmetrical cutting surfaces are generally provided having a larger diameter profile near the distal face 168 of the cutter blade when it is assembled in a cutter assembly, although various asymmetrical surface configurations may be used. The differential cutting surfaces are preferably provided substantially along the peripheral edge of cutting blades 150 and 160 and may extend over a distal face 168 of cutter blade 162, for example. Cutter blades 152 and 162 may have a substantially constant thickness throughout their bodies, with diminishing thickness at the differential cutting surfaces 154 and 164, respectively, forming sharp edges at the cutting surface peripheral edges. Alternatively, cutter blades 152 and 162 may have a variable thickness throughout their bodies and may continuously or variably taper toward differential cutting surfaces 154 and 164.

The surfaces opposing planar surfaces 152 and 162 (not shown) may be planar over their entire surfaces and terminate without tapering in peripheral surfaces 154 and 164. Alternatively, the opposing surfaces may have differential cutting surfaces in proximity to their peripheral edges to provide cutter blades 150 and 160 having dual differential cutter surfaces. In a dual differential cutter configuration, cutter blades may operate as differential cutting surfaces in either direction of rotation of a drive motor. As described above, in a dual differential cutter configuration, opposite cutter surfaces may have different cant angles, both less than 90°, to provide enhanced cutter assembly versatility. Although cutter blades 150 and 160 are illustrated having solid surfaces, and this embodiment is preferred for many

applications, alternative embodiments may be provided in which cutter blades 150 and 160 have cut-out portions or cavities on their planar surfaces.

Figures 9A and 9B illustrate dual differential cutter assemblies having a fixed differential cutter assembly 200, an adjustable differential cutter assembly 210 shown in an expanded diameter condition in which the blades are in a radial configuration, and a bearing 250 communicating between the cutter assemblies, the drive shaft, and the catheter assembly. Fixed cutter assembly 200 is preferably provided at a distal end of the assembly, with adjustable cutter assembly 210 mounted proximally to the fixed cutter assembly. Suitable fixed cutter assemblies have been described above. In the embodiment shown in Figs 9A and 9B, differential cutting blades provided on the fixed cutter assembly and on the differential cutter assembly have approximately the same length. In alternative embodiments, differential cutting blades on either the fixed or adjustable blade cutter may have different lengths.

Adjustable diameter differential cutter assembly 210 comprises a plurality of generally planar cutter blades 212, each having at least one differential cutting surface 214 extending substantially along a peripheral edge. Differential cutting surfaces 214 have cant angles of less than 90°, as described in detail above. In general, from three to seven or more pivotable differential cutting blades may be provided on adjustable cutter assembly 210. The cant angles of differential cutting surfaces 214 may be the same as or different from cant angles of differential cutting surfaces provided on fixed differential cutter assembly 200. In a preferred embodiment, the cant angles of differential cutting surfaces 214 are less than the cant angles of differential cutting surfaces provided on fixed differential cutter assembly 200.

Mounting rods 216 of cutter blades 212 are pivotably mounted in mating slots 218 of adjustable cutter support 220 having a central passageway 222 communicating with a central bore of the distal cutter and a central bore of bearing assembly 250. Central passageway 222 generally forms part of an aspiration and/or infusion lumen. Cutter support 220 is configured to support cutter blades 212 in a tangential position, in which they lie flat against a support face to present a smaller diameter profile and in a radial position, in which they extend radially to present a larger diameter, differential cutting profile. The cutter blades may be adjusted between the tangential and radial orientations by changing the direction of rotation of the drive system, or using alternative mechanisms. Aspiration and/or infusion ports may be provided in cutter support 220. Additional details concerning the structure and function of this type of adjustable cutter assemblies are described in U.S. Patent 6,565,588 B1 and PCT International Patent Publication WO 01/76680 A1.

Bearing assembly 250 provides operable coupling of an operating head, such as dual cutter assemblies 200 and 210, directly or indirectly to a drive shaft that transfers torque and rotation to the operating head. The bearing assembly is also operably coupled, directly or indirectly, to a static (non-rotating) catheter system providing a sealed lumen for aspiration and/or infusion of liquids. Bearing system 250 articulates to improve the overall flexibility and guidability of the operating head as it is navigated to and from the material removal site and provides an internal channel for aspiration and/or infusion of liquids through the bearing system.

Bearing system 250 comprises an internal shaft 260 coupled, directly or indirectly, to the drive shaft at a proximal end 262 and coupled, directly or indirectly, to the operating head at a distal end 264. Bearing system 250 additionally comprises a cylindrical static member 280 provided as an outer sleeve that is fixedly coupled at or near a proximal end to a distal end of the catheter system to provide a sealed internal lumen and catheter system. Internal shaft 260 and static member 280 are operably coupled by one or more connecting structures, such as rods 282 retained in slots 284 formed in static member 280.

Static member 280 is mounted on a peripheral surface of internal shaft 260 so that rods 282 are retained in slots 284 and ride in a curved annular seat 266 formed on internal shaft 260. Curved annular seat 266 has a variable diameter, with a central smaller diameter section flaring in both distal and proximal directions to larger diameter distal and proximal boundaries 268 and 270, respectively. Rods 282 ride in the curved annular seat to provide limited pivoting of internal shaft 260 and the operating head with respect to static member 280 and the catheter assembly. The profile and depth of the curved annular seat may be adjusted and configured to provide a desired degree of articulation. This bearing system thus provides limited articulation of the operating head with respect to the catheter assembly and facilitates both navigation of the operating head to and from the target material removal site, and operation of the operating head at the target material site to ablate occlusive material.

Drive shafts for use in interventional catheters of the present invention generally comprise helical coil or braided shafts may comprise composite drive shafts having variable flexibility and/or torque carrying capability at different sections along their length. In one embodiment, a helical coil drive shaft is provided having a less flexibility and higher torque carrying capability at a proximal portion and greater flexibility and less torque carrying capability at a distal portion. The proximal portion of the drive shaft may comprise a helical coil shaft having more files than the helical coil shaft forming the distal portion of the drive shaft. In one embodiment, a proximal drive shaft section comprises a tri- or quad-filar helical

coil, while a distal drive shaft section comprises a bi- or tri-filar helical coil, respectively. In a drive shaft having a braided construction, a proximal drive shaft section comprises more strands than a distal drive shaft section.

In another embodiment, a proximal drive shaft section comprises a multi-filar helical coil in which the adjacent files are closely spaced, while a distal drive shaft section comprises a single or multi-filar helical coil in which the adjacent files are spaced from one another by a space corresponding to at least the diameter of a file. The spaces may be greater, depending on the flexibility and torque-carrying requirements of the distal drive shaft section. A preferred drive shaft may comprise a distal section having a helical coil with spaced apart files over which a sealing member is installed. The sealing member is preferably no thicker than the diameter of a drive shaft file and is constructed from durable, flexible plastic materials such as polyfluorotetraethylene (PFTE). A heat shrinkable PFTE tube may be installed and shrunk to conform generally to the configuration of the distal drive shaft spaced apart files to provide a sealed distal drive shaft lumen, and to improve the lubricity of the distal drive shaft section as it is navigated to and from the target material removal site. The outer sealed layer may extend a distance of from about 2 cm to about 40 cm from the distal end of the drive shaft, more preferably from about 5 cm to about 15 cm from the distal end of the drive shaft.

Numerous tests have been conducted using interventional catheters having differential cutting surfaces as described herein. For example, the systems have been used to treat acute coronary syndrome and acute myocardial infraction in native coronary arteries. Furthermore, the systems have been used for preparing occluded saphenous vein grafts for accepting a stent. Example 1, described below, shows images of blood vessels before and after a material removal operation, and Example 2 describes laboratory tests demonstrating the aspiration efficiency of an interventional catheter assembly of the present invention.

Example 1

Figs. 10A and 10B are fluoroscopic x-ray images showing the results of using an interventional catheter assembly of the present invention. Fig. 10A shows a nearly totally and diffusely occluded artery having a coronary bypass graft. The patient was injected with an ionic contrast agent to visualize blood flow and blockages.

The interventional catheter system of the present invention is used to clear the obstruction, often followed by insertion of a stent. A guiding catheter is inserted into the patient and a guide wire was directed to the target site in the artery. The cutter is rotated at

35,000 to 40,000 rpm's while aspirating at the target site. The cutter is advanced with little applied force into the lesion for 3 seconds at a rate of at 1mm per second. The advancing movement is paused to allow cut particles to be aspirated into the cutter assembly and then the advancing movement is repeated. Contrast agent is applied to the area to visualize the intermediate results of the cutting and to decide on whether to use an expanded diameter of the adjustable cutter on further passes into the target site. A stent is inserted at the target site. Fig. 10B shows the same artery and coronary bypass graft of Fig. 10A, following removal of obstructions using the interventional catheter assembly described herein, followed by stenting.

Example 2

Figures 11A-11C show the results of operation of cutter assemblies having various characteristics in a laboratory stained bovine aorta model. Longitudinal slices of a bovine aorta are used as test specimens. The tissue surfaces are lubricated with water. The cutter assembly is oriented at a 45 degree angle relative to the tissue surfaces. The cutter is biased into the tissue surface and run back and forth 2 to 3 times. The tissue is stained with conventional green food coloring and viewed. In other tests, silver nitrate may be used as an staining agent.

Figure 11A shows damage done to the bovine aorta after operation of a cutter assembly having a plurality of cutting surfaces having a cant angle of 90°. Figure 11B shows damage done to the bovine aorta after operation of a cutter assembly having randomly oriented diamond grit particles on an outer, operating surface. Figure 11C shows the results of operation of a cutter assembly having a plurality of differential cutting surfaces having a cant angle of 60° and demonstrates that the bovine aorta was not damaged with this cutter assembly. All cutter assemblies had a fixed maximum diameter of 1.75 mm.

Example 3

Figures 12A-12F show the results of vessel wall damage by operation of cutter assemblies having various characteristics in porcine blood vessels that do not have lesions. A dual differential cutter assembly, according to the present invention, is used on the Right Coronary Arteries and the Left Circumflex Arteries of a five (5) pig animal subjects. The Left Anterior Descending Arteries of the subjects is used as controls.

The cutter assembly is turned on to rotate the cutter at the target site and aspiration is activated. The fixed cutter is first used as the primary cutter at 1.75 mm in diameter. The

cutter travels a 2.5 to 5.0 mm path and then retracted. Standard contrast agent is injected at the target site to check for spasm of the vessel. When vessel spasm is detected, the procedure is paused or nitroglycerin is injected to the site for the spasm to release. The adjustable cutter is used as the primary cutter for a next pass at 2.5 mm diameter.

The animals are survived for 28 days to allow for any vessel damage or restenosis to appear. The animals are sacrificed and a cross-sectional slice is made of the vessel. Imaging is by fluoroscopy. The pathology of the vessel showed very little vessel wall damage. All arteries completely healed and there appeared to be no inflammatory changes or evidence of thrombus.

The present invention has been described with reference to specific embodiments and figures. These specific embodiments should not be construed as limitations on the scope of the invention, but merely as illustrations of exemplary embodiments. It is further understood that many modifications, additions and substitutions may be made to the described interventional catheter and control system without departing from the broad scope of the present invention.

We Claim:

1. An interventional catheter assembly comprising:
   a. a rotatable drive shaft in operable communication with a drive system; and
   b. a cutter assembly having a generally circular profile from a radial view and comprising at least one differential cutting surface having a cant angle of less than 90°, the cant angle being an angle of intersection of the cutting surface and a line tangent to the circumference of the cutter assembly.
2. An interventional catheter assembly of claim 1, additionally comprising an aspiration system forming a sealed lumen connectible to a vacuum source.
3. An interventional catheter assembly of claim 2, additionally comprising a bearing system coupling the cutter assembly to the drive shaft and to the sealed lumen, the bearing system providing limited articulation of the cutter assembly with respect to the axis of the drive shaft.
4. An interventional catheter assembly of claim 1, wherein the cutter assembly comprises a fixed blade cutter assembly having at least two fixed differential cutting surfaces.
5. An interventional catheter assembly of claim 4, wherein the external profile of the fixed blade cutter assembly is generally ovoid or oblong from a profile view.
6. An interventional catheter assembly of claim 4, comprising from about three to about seven fixed differential cutting surfaces.
7. An interventional catheter assembly of claim 4, wherein the fixed differential cutting surfaces taper along a curved line between a smaller diameter distal end and a larger diameter proximal end of the cutter assembly.
8. An interventional catheter assembly of claim 7, wherein the fixed differential cutting surfaces have a generally constant chord between the distal and proximal ends of the cutter assembly.
9. An interventional catheter assembly of claim 4, additionally comprising an aspiration system forming a sealed lumen connectible to a vacuum source, and wherein the cutter assembly additionally comprises a port formed between each neighboring pair of cutter surfaces, the ports providing access to the sealed lumen.
10. An interventional catheter assembly of claim 9, wherein the ratio of a total cross-sectional area of ports compared to a total cross-sectional area of internal cutter blade surfaces is at least 1.5:1.

11. An interventional catheter assembly of claim 10, wherein the ratio of a total cross-sectional area of ports compared to a total cross-sectional area of internal cutter blade surfaces is at least 3:1,

12. An interventional catheter assembly of claim 4, wherein each differential cutting surface is provided on a generally planar leading blade surface.

13. An interventional catheter assembly of claim 4, wherein each differential cutting surface is provided at an outer terminal edge of a cutter blade, and the angle formed between the differential cutting surface and a trailing blade surface is an acute angle.

14. An interventional catheter assembly of claim 13, wherein the outer terminal edge of each cutter blade is sharpened.

15. An interventional catheter assembly of claim 4, wherein each differential cutting surface is provided on a cutter blade, each cutter blade terminates at a proximal end in a proximal collar, and each differential cutting surface has an external profile that, at its largest diameter, is larger than the diameter of the proximal collar.

16. An interventional catheter assembly of claim 4, comprising a plurality of radially arranged cutter blades, each cutter blade having a leading blade surface comprising a differential cutting surface and a trailing blade surface comprising a differential cutting surface.

17. An interventional catheter assembly of claim 16, wherein each of the leading blade and trailing blade surfaces is a compound surface.

18. An interventional catheter assembly of claim 16, wherein the differential cutting surfaces of the leading blade surfaces and trailing blade surfaces both have cant angles of less than 90°, and the cant angles of the differential cutting surfaces of the leading and trailing blade surfaces are different.

19. An interventional catheter assembly of claim 1, wherein the differential cutting surface is provided at a peripheral edge of a generally planar blade surface associated with one or more mounting tabs for mounting blade surfaces to a cutter assembly structure.

20. An interventional catheter assembly of claim 19, wherein the differential cutting surface is symmetrical along its length with respect to a central cutter assembly axis.

21. An interventional catheter assembly of claim 19, wherein the differential cutting surface is asymmetrical along its length with respect to a central cutter assembly axis.

22. An interventional catheter assembly of claim 21, wherein the differential cutting surface has a larger diameter near a distal face when the cutter surface is assembled in the cutter assembly.

23. An interventional catheter assembly of claim 1, wherein the cutter assembly is a dual differential cutter assembly having a fixed blade cutter assembly with at least two differential cutting surfaces and an adjustable blade cutter assembly having at least two differential cutting surfaces.

24. An interventional catheter assembly of claim 23, wherein the adjustable blade cutter assembly has a plurality of radially arranged cutter blades with at least one differential cutter surface on each blade, and the cutter blades are pivotably adjustable between a tangential orientation and a radial orientation.

25. An interventional catheter assembly of claim 23, wherein the cant angles of differential cutting surfaces on the fixed blade cutter assembly and differential cutting surfaces on the adjustable blade cutter assembly have different cant angles.

26. An interventional catheter assembly of claim 1, wherein the drive shaft comprises a helical coil having varying flexibility and/or torque-carrying capability along its length.

27. An interventional catheter assembly of claim 26, wherein the drive shaft is less flexible and has higher torque carrying capacity at a proximal portion and is more flexible and has lower torque carrying capacity at a distal portion.

28. An interventional catheter assembly of claim 27, wherein the drive shaft is a multi-filar helical coil and a proximal portion of the drive shaft comprises more files than a distal portion of the drive shaft.

29. An interventional catheter assembly of claim 27, wherein the drive shaft is a helical coil and, at a distal portion of the drive shaft, files comprising the helical coil are spaced apart from one another by a space corresponding to at least the diameter of a file.

30. An interventional catheter assembly of claim 29, additionally comprising a sealing member installed over the distal portion of the drive shaft composed of spaced apart files.

31. An interventional catheter assembly of claim 29, wherein the sealing member closely contacts but is not bonded to the distal portion of the drive shaft.

32. An interventional catheter assembly of claim 30, wherein the sealing member comprises PFTE.

33. An interventional catheter assembly of claim 1, additionally comprising a console unit in communication with the rotatable drive shaft housing power, control and display functions.

34. An interventional catheter assembly of claim 1, additionally comprising a control module housing a drive motor in operable communication with the rotatable drive shaft.

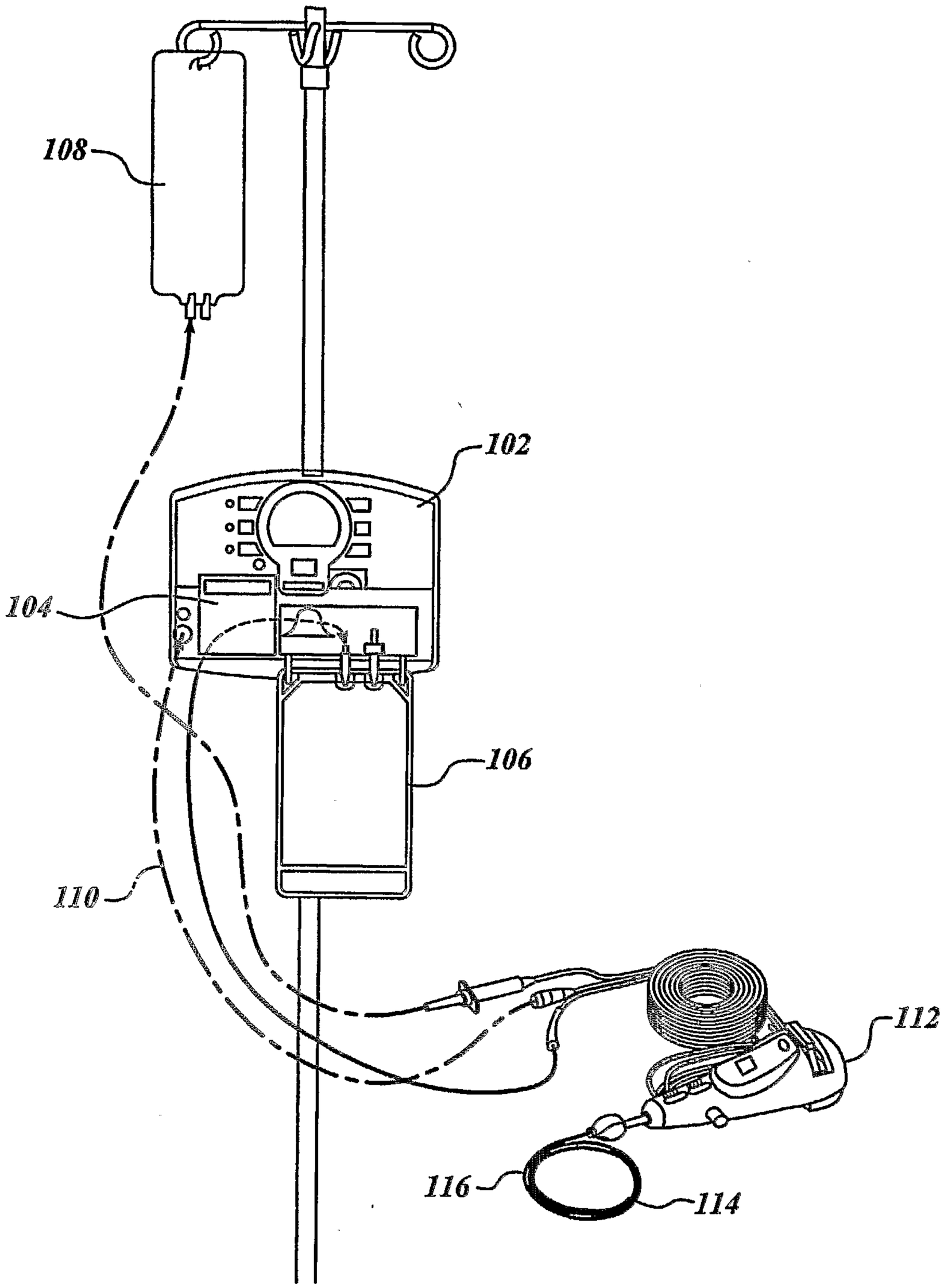


FIG.1

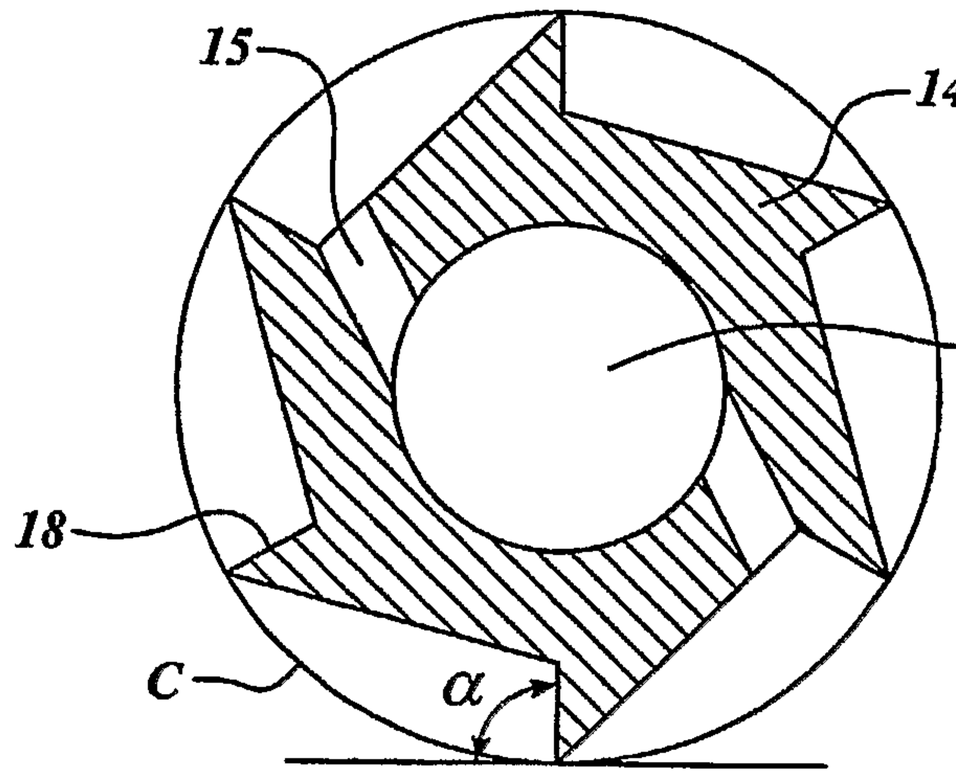


FIG.2
(PRIOR ART)

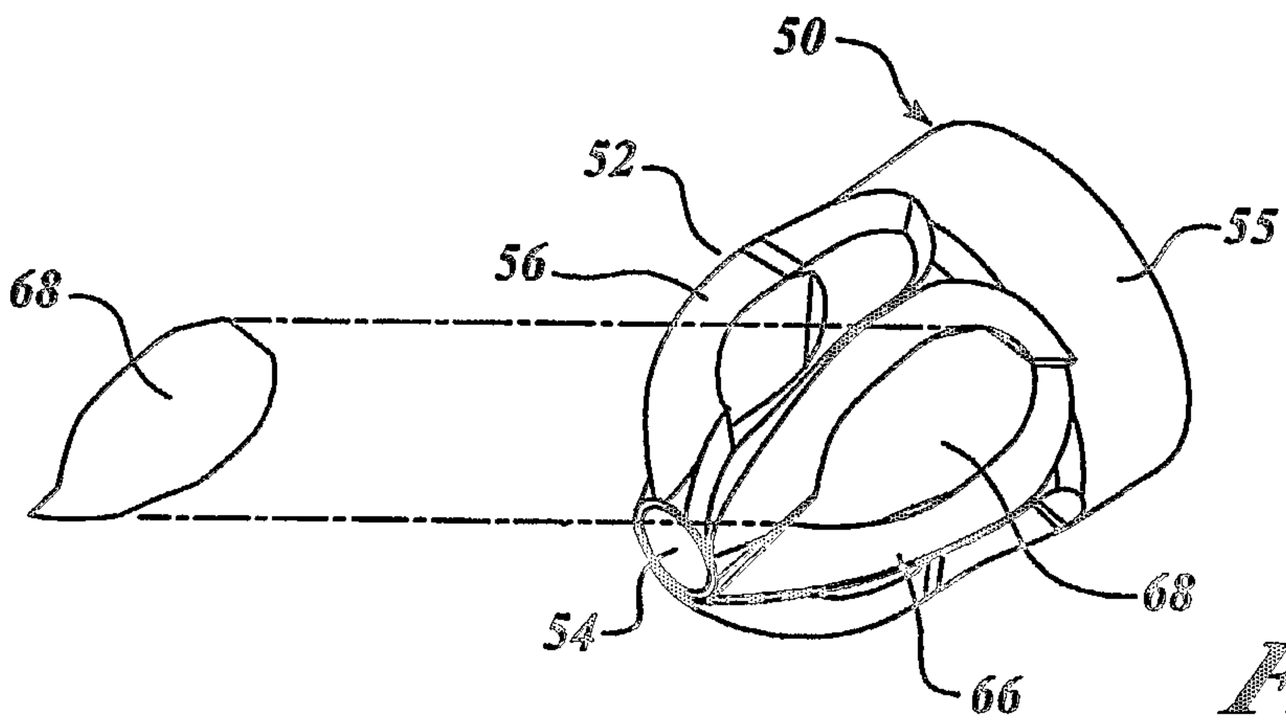


FIG.3A

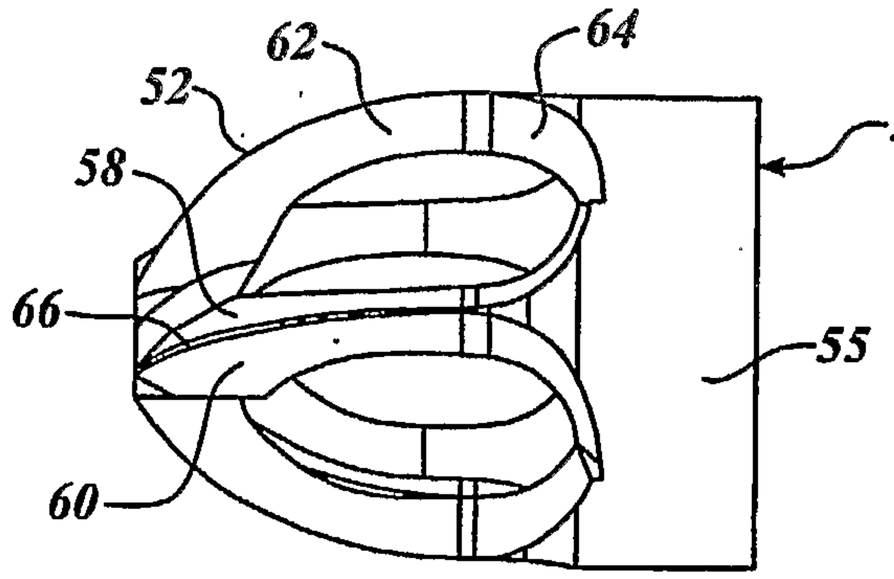


FIG.3B

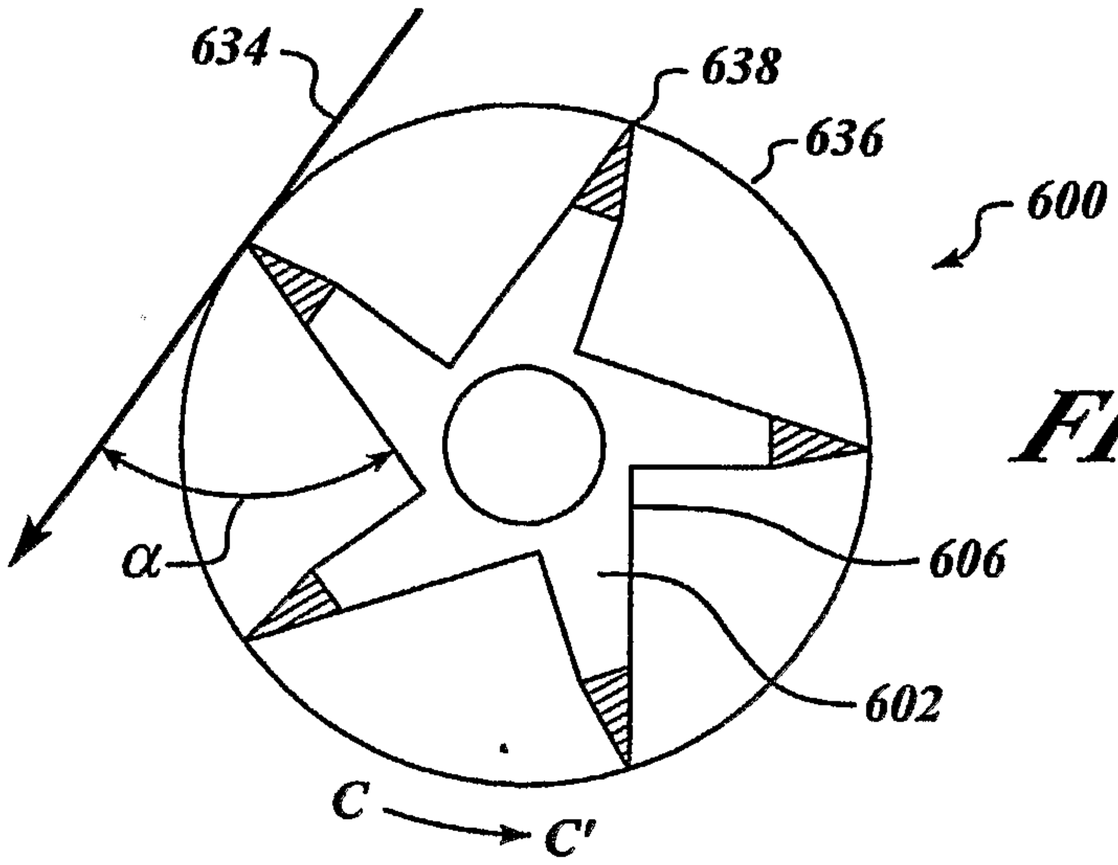
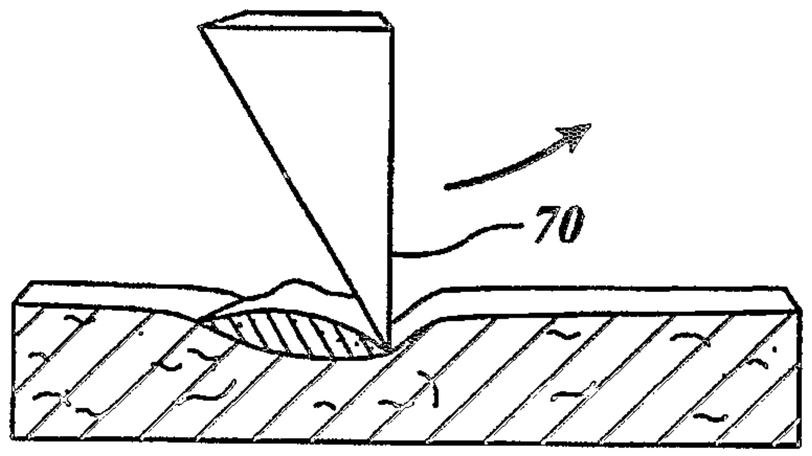


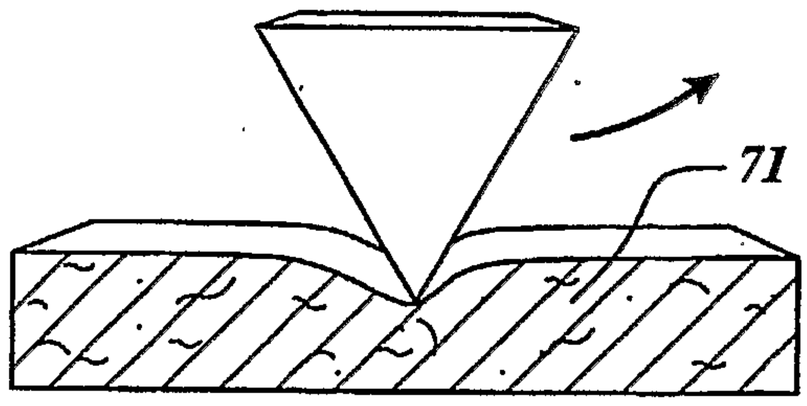
FIG.3C



90° ANGLE

FIG.4A

(PRIOR ART)



60° ANGLE

FIG.4B

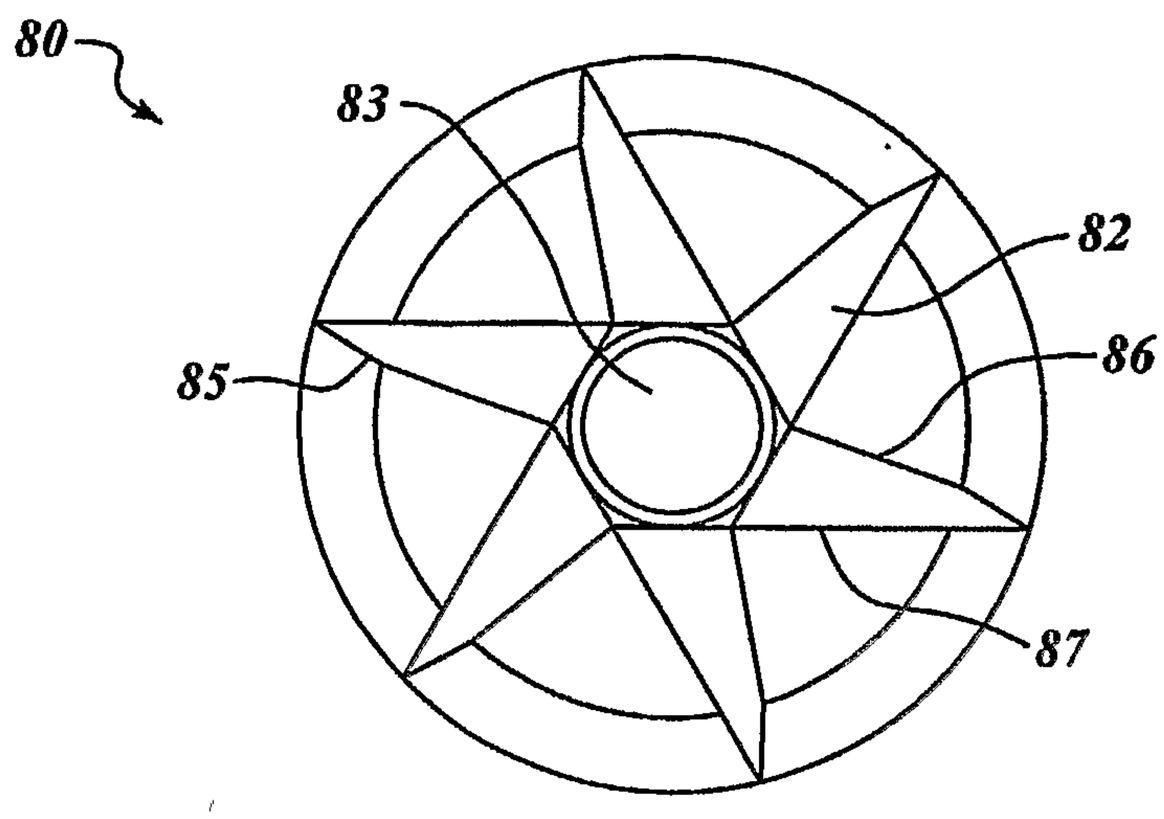


FIG. 5A

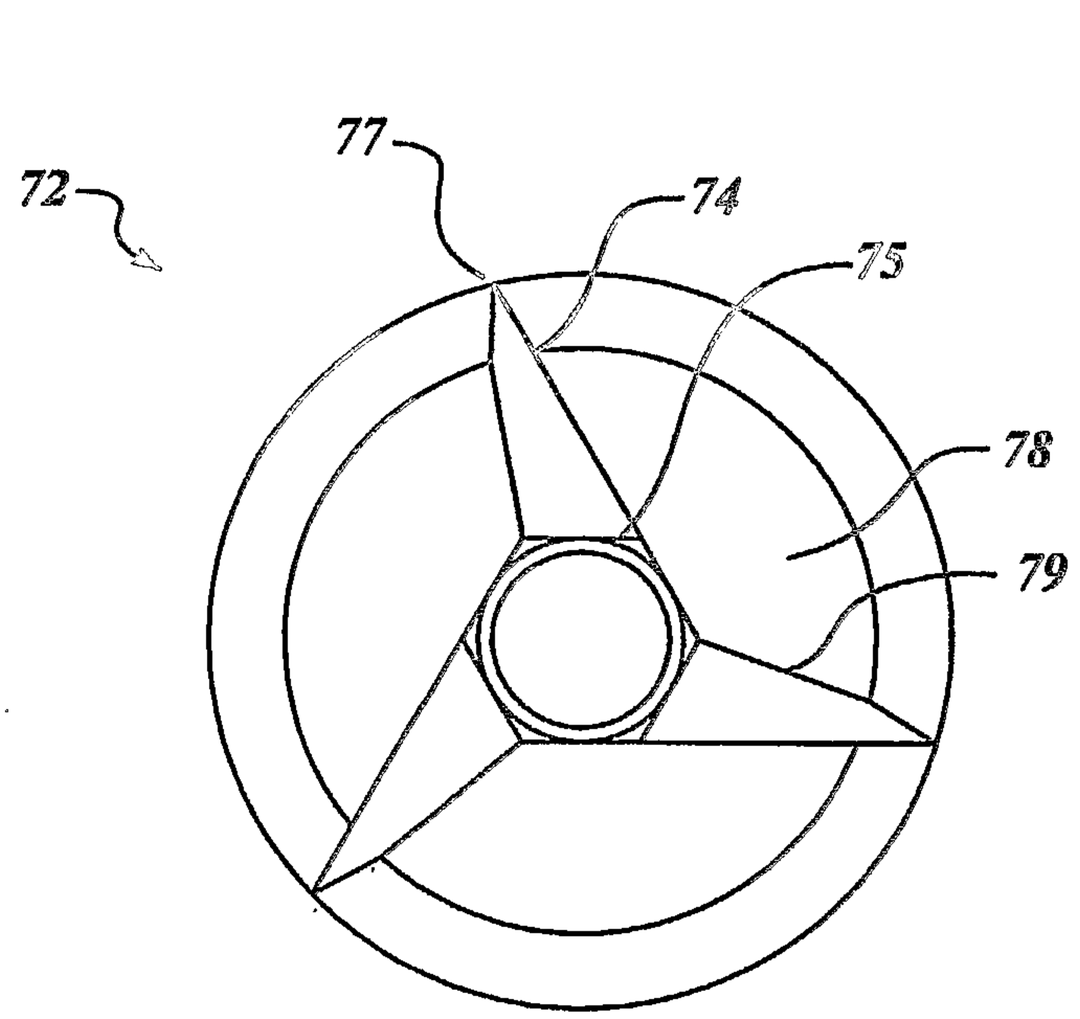


FIG. 5B

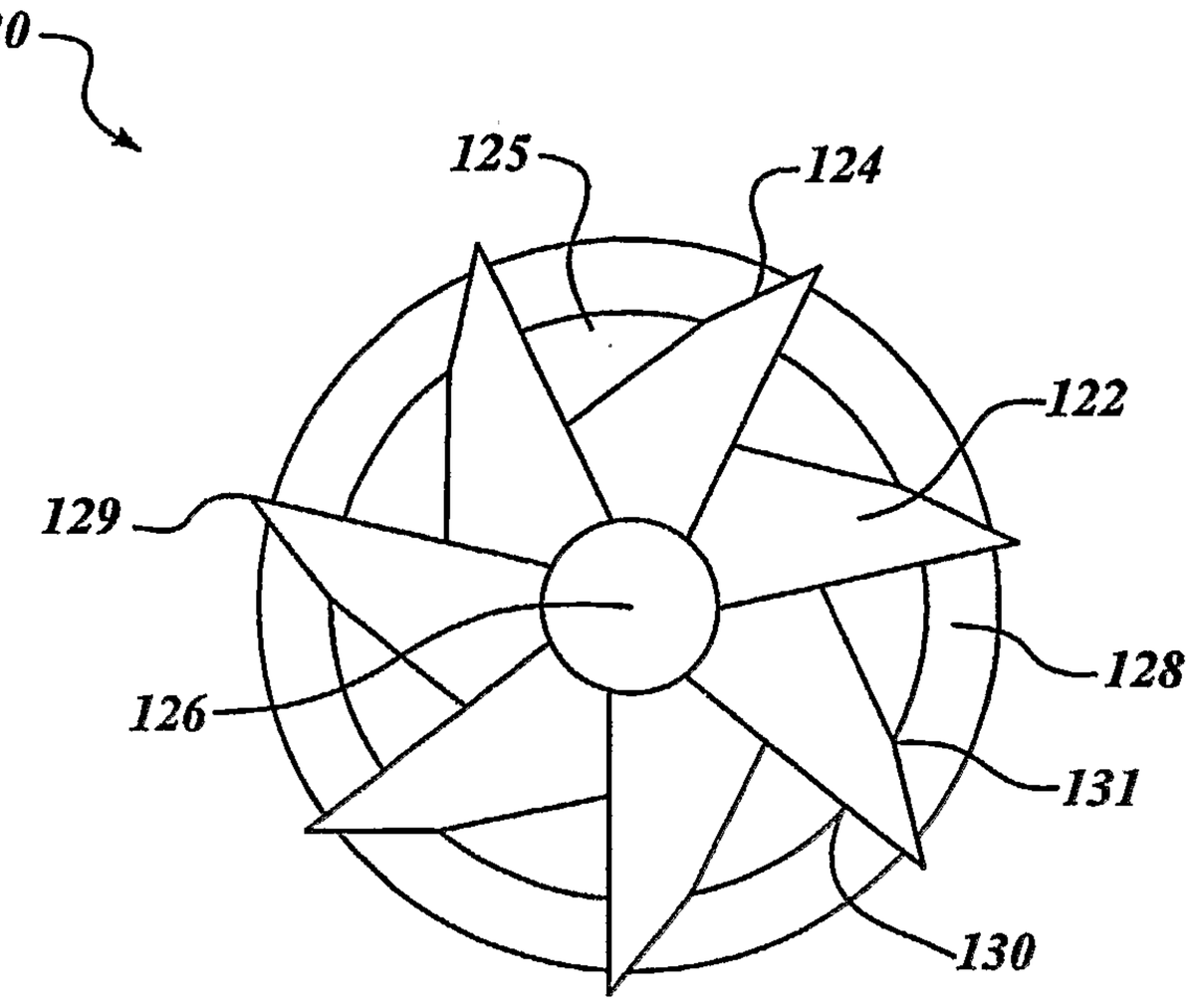
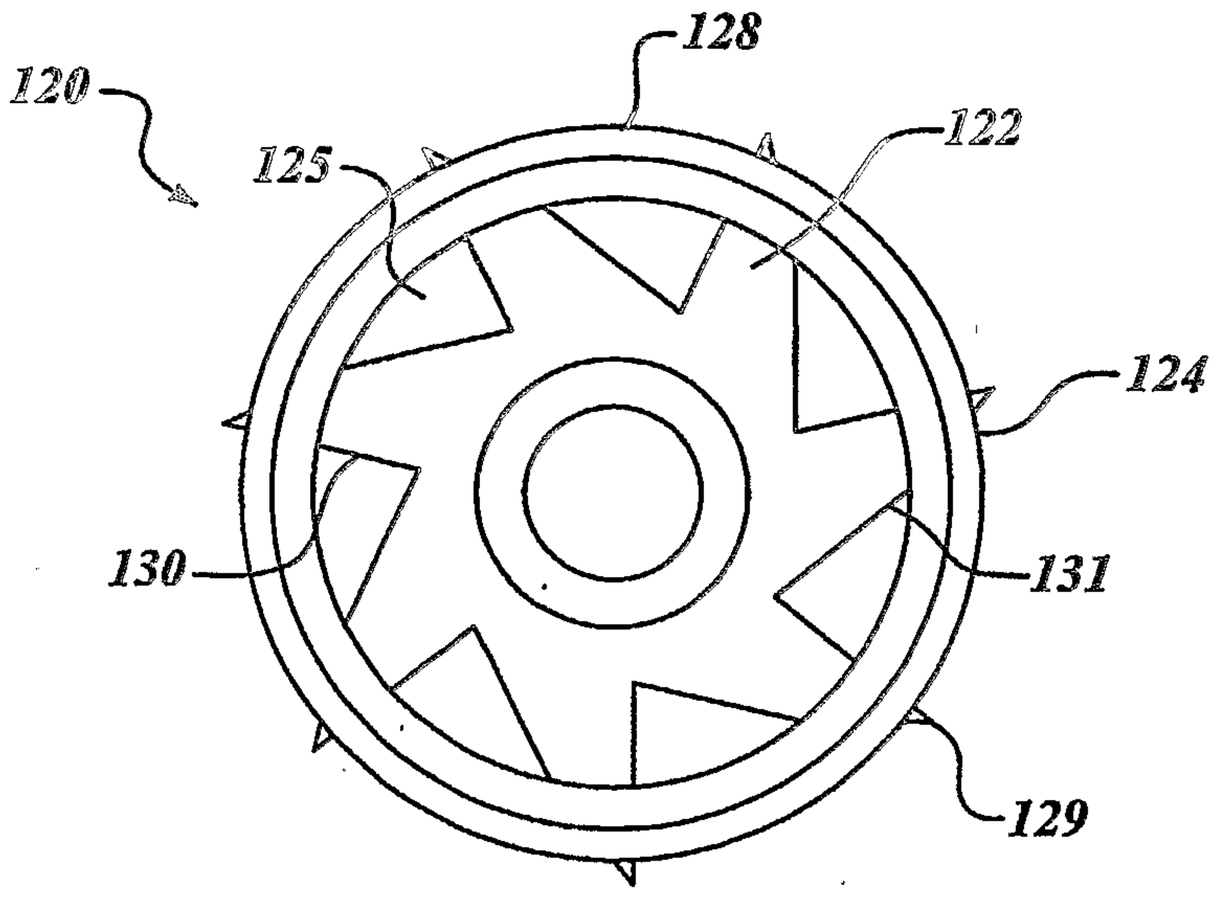

120
125
124
122
129
128
126
131
130

FIG. 6A


128
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129

FIG. 6B

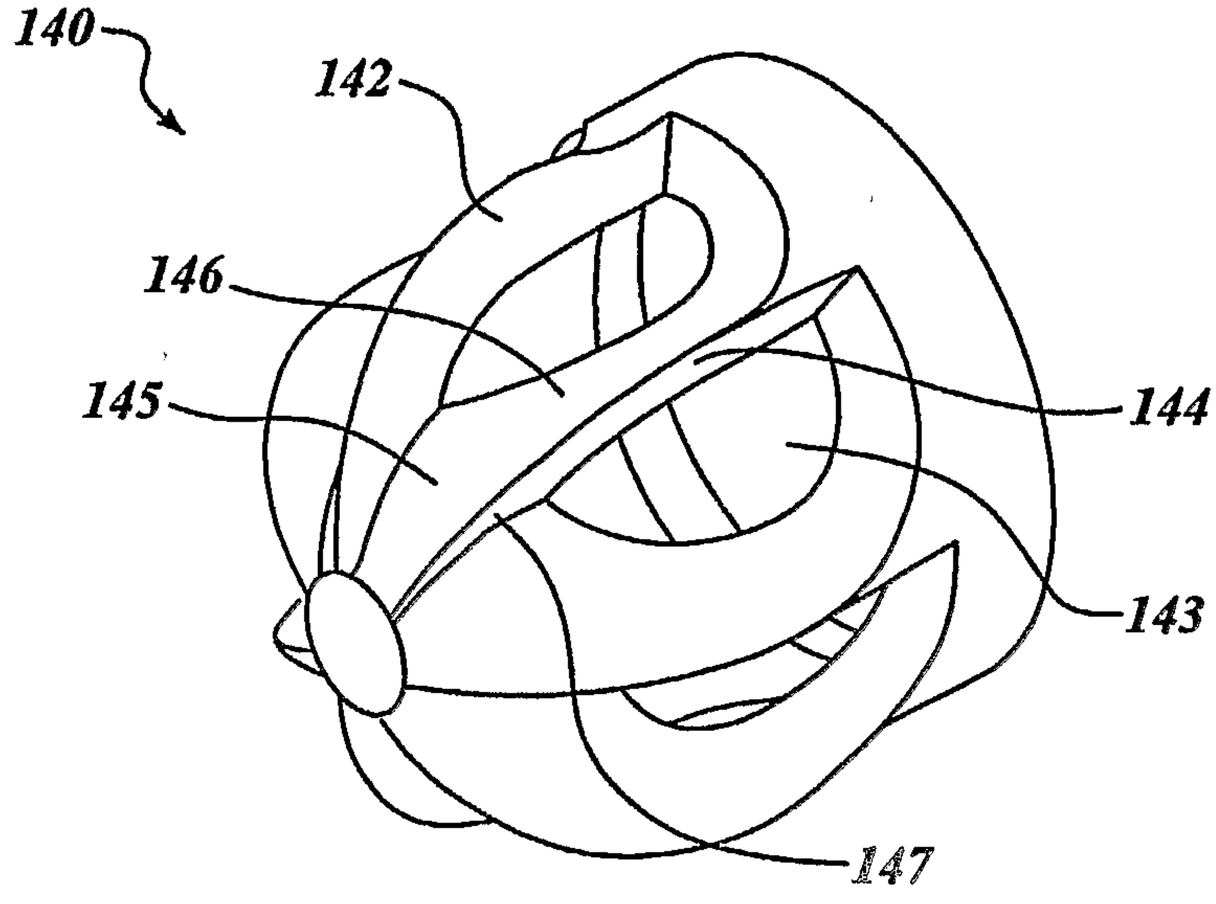


FIG. 7A

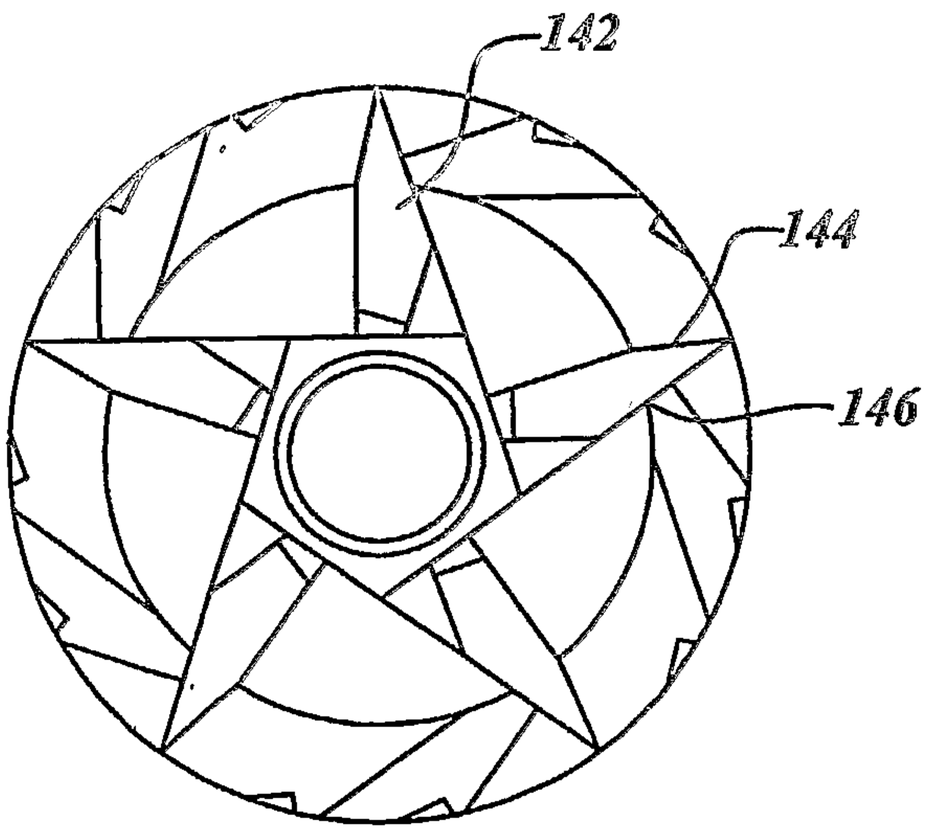


FIG. 7B

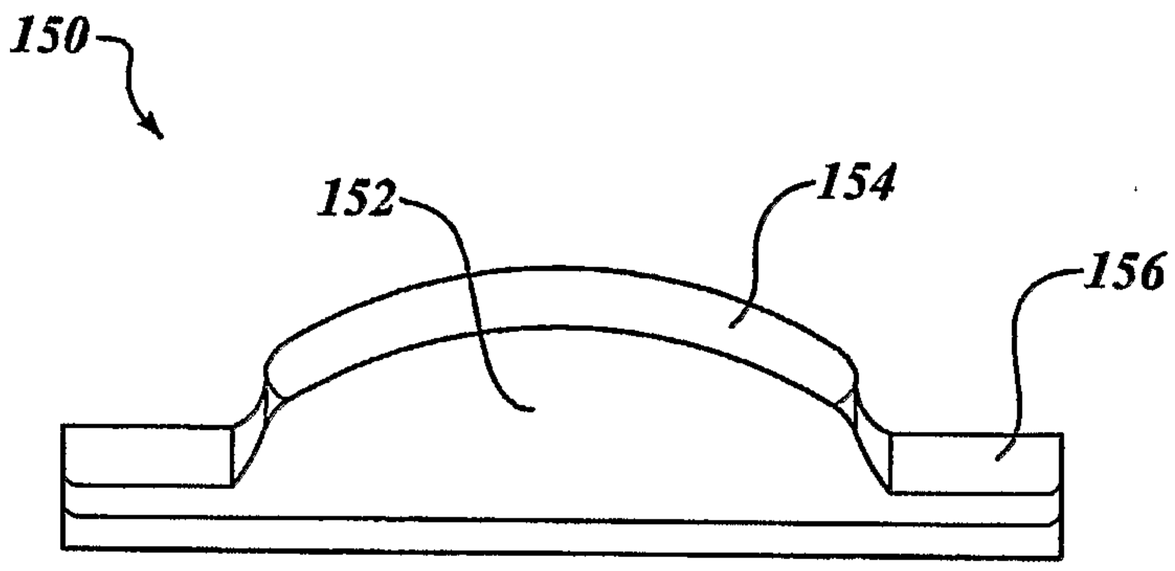


FIG. 8A

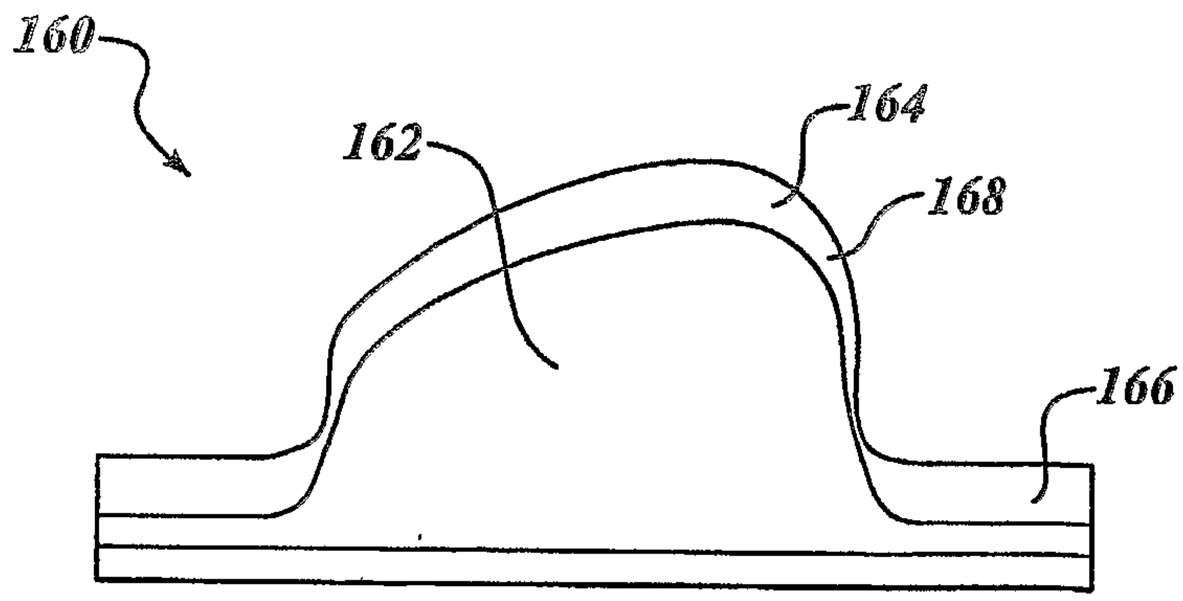
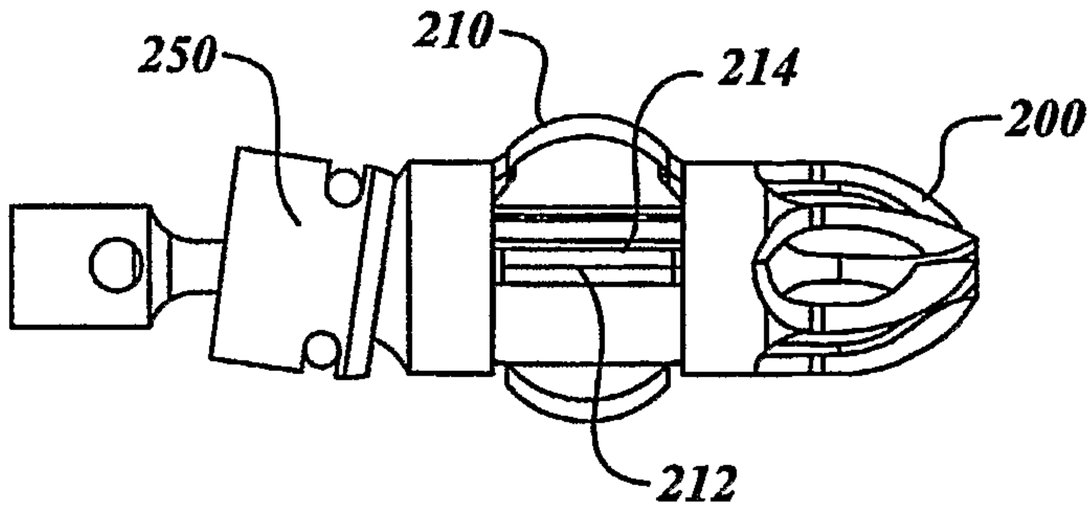


FIG. 8B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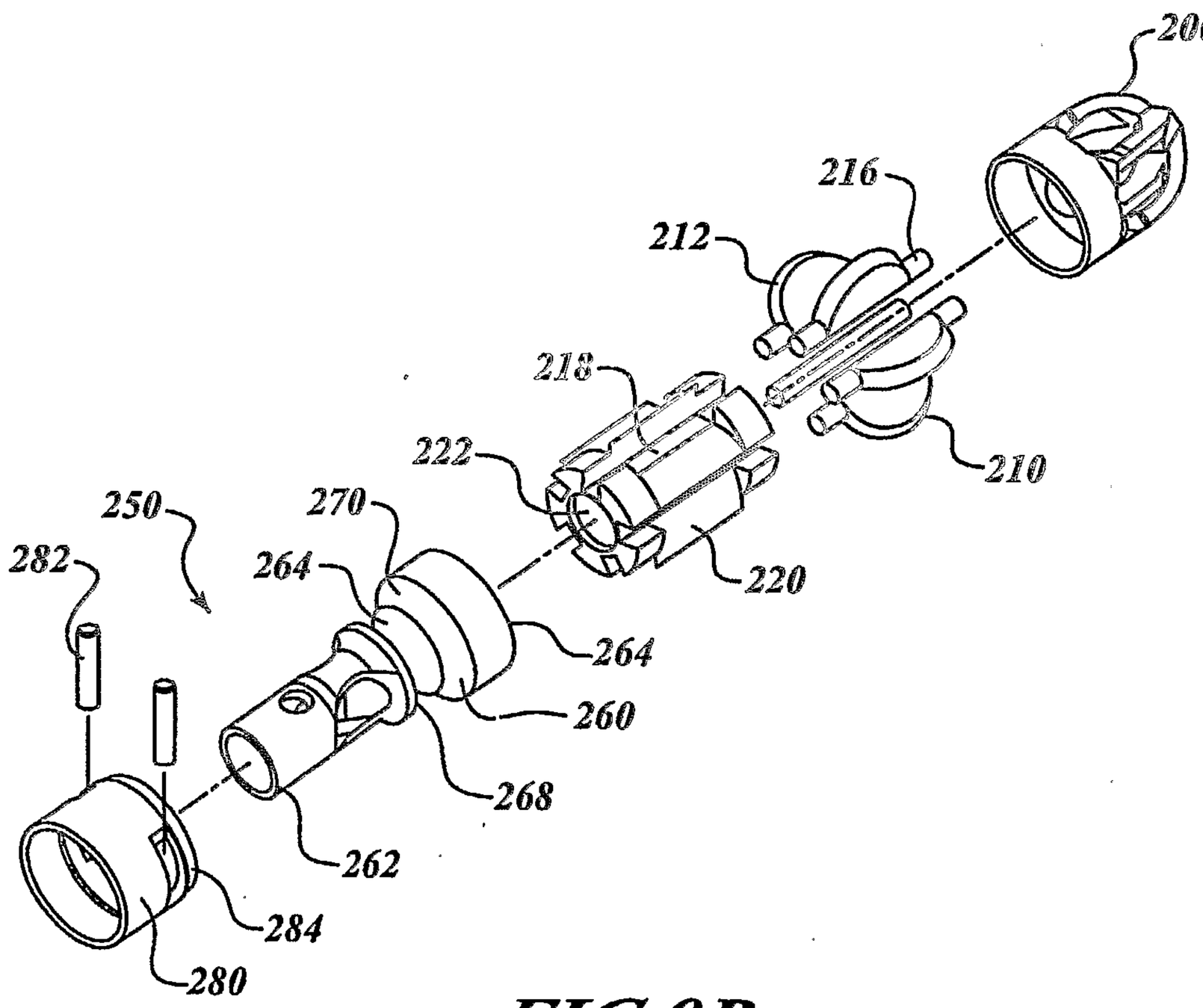
200
212

FIG.9A


200
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268
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284
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FIG.9B

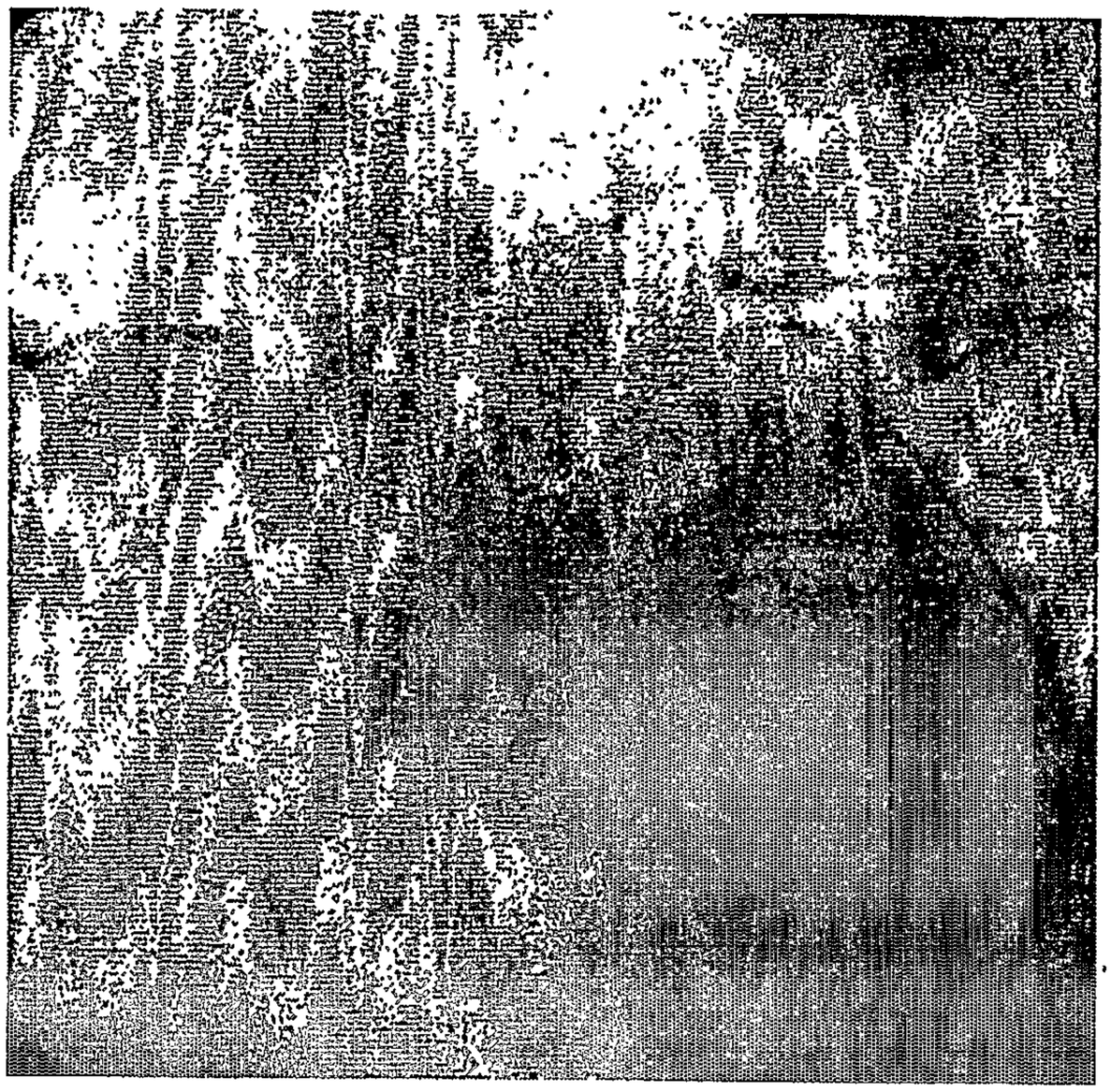


FIG.10A

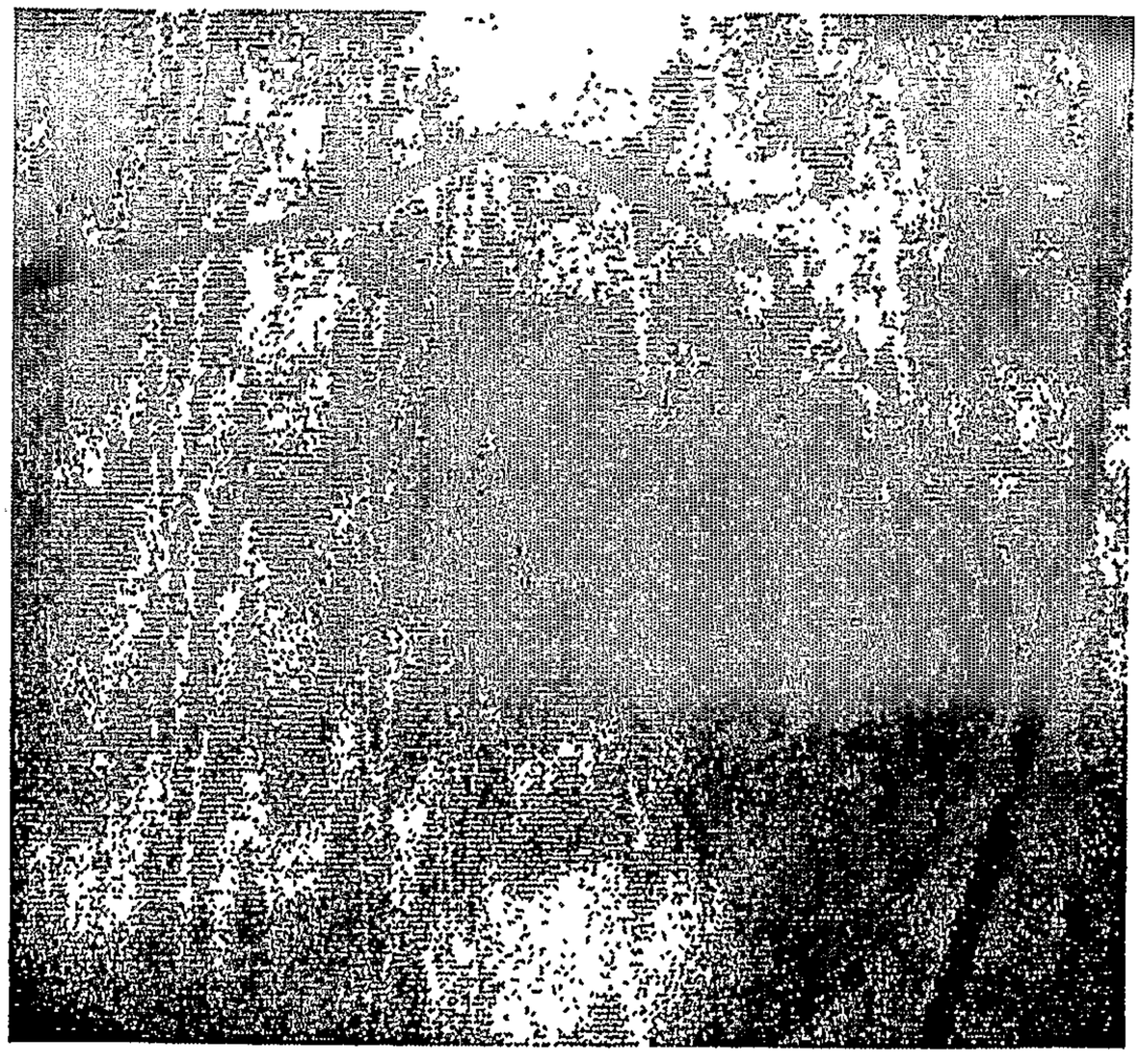


FIG.10B

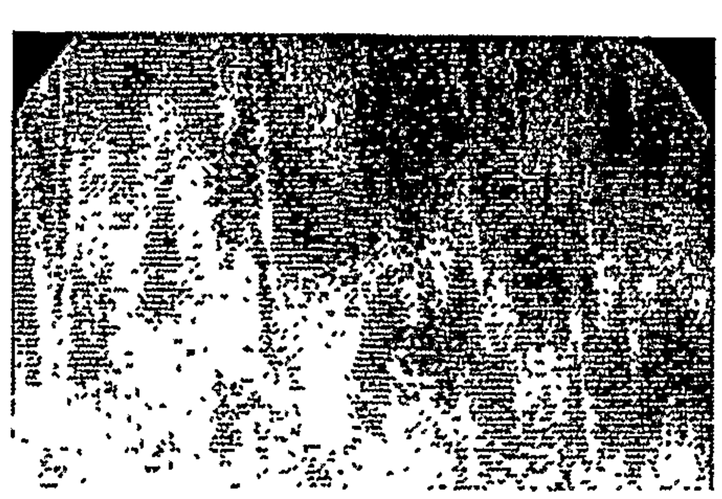


FIG.11A

FIG.11B

FIG.11C

FIG.12A

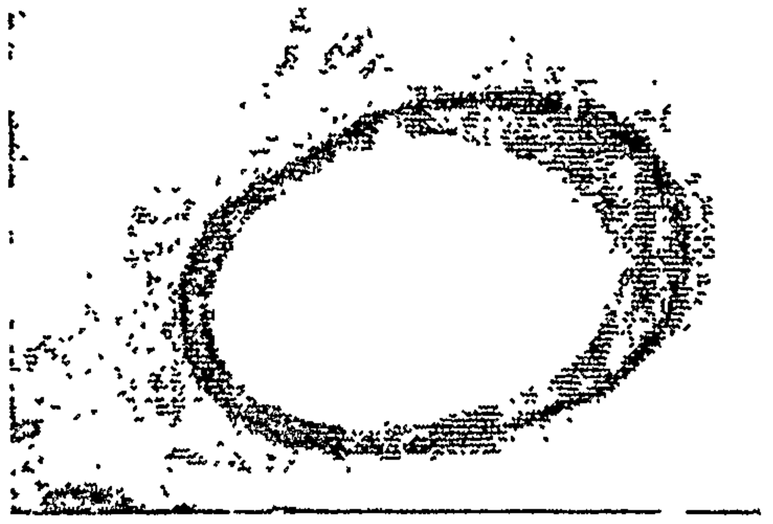


FIG.12B

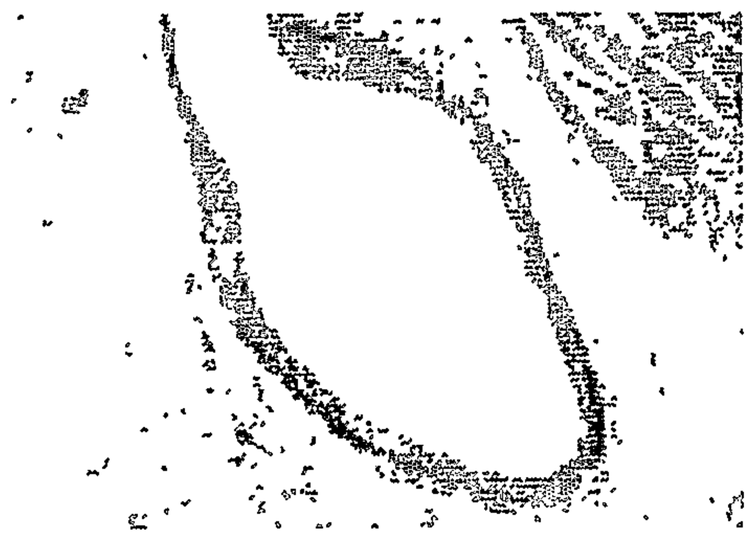


FIG.12C

FIG.12D

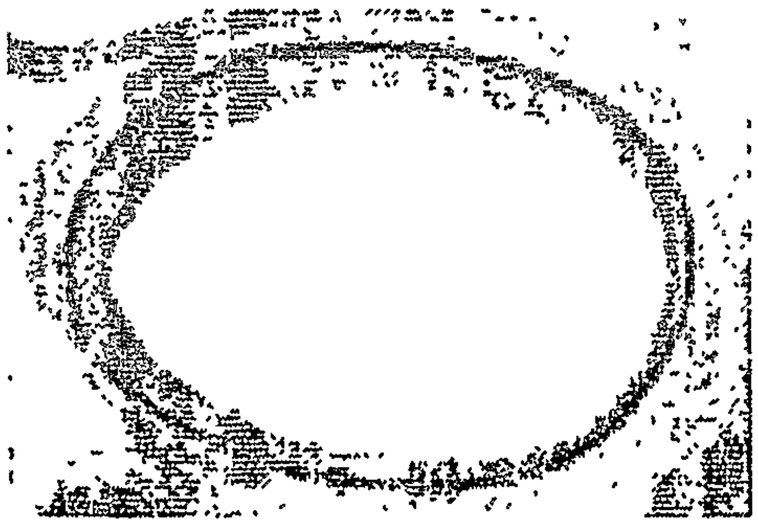


FIG.12E

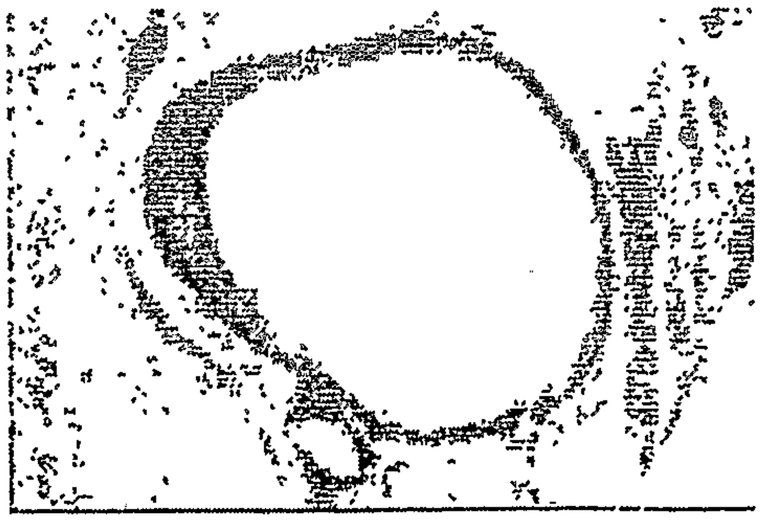
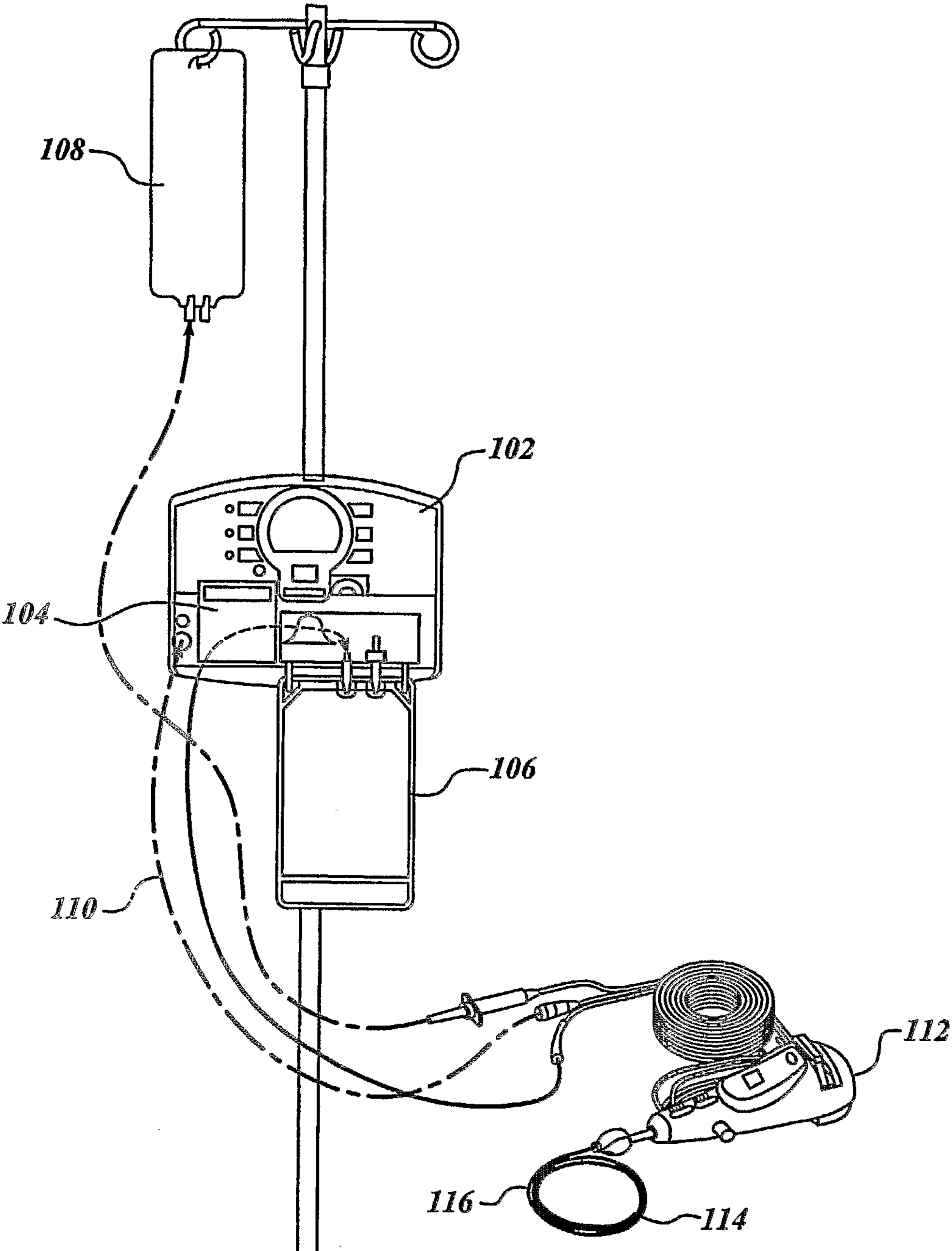


FIG.12F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