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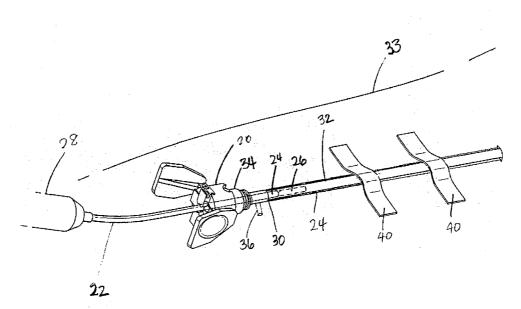
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(54) Title: CATHETER GRIP



(57) Abstract: A catheter grip adapted to couple with an introducer or sheath holds a catheter in position while in use in a patient's body. The grip has a hub defining a channel through which the catheter extends. The hub has a pair of grip members that work with each other to hold the catheter body between them, a pair of separators to release the catheter body, and a pair of tabs for the doctor to actuate the separators. Each pair of the grip members and the separators is situated on a different diameter of a surface that extends across the channel. Each grip member and separator is diametrically opposed to its mate and movement between the grip members are separators are coordinated in that as the grip members move toward each, the separators move away from each other, and vice

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CATHETER GRIP

FIELD OF INVENTION

This invention relates to catheters and catheter accessories, particularly, a device that holds a catheter in position while in use in a patient's body.

BACKGROUND OF THE INVENTION

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Electrode catheters have been in common use in medical practice for many years. They are used to stimulate and map electrical activity in the heart and to ablate sites of aberrant electrical activity. In use, an electrode catheter is inserted into a major vein or artery, e.g., femoral artery, and then guided into the chamber of the heart which is of concern. The catheter should preferably be deflectable to permit proper positioning of the electrodes on its distal end within the heart.

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Deflectable tip electrode catheters are well known. Such a catheter generally has a control handle at its proximal end for controlling deflection of the tip in one or more directions. For example, a particularly useful deflectable tip catheter is disclosed in U.S. Pat. No. Re. 34,502 to Webster, the disclosure of which is hereby incorporated by reference. This catheter comprises a puller wire that extends on-axis through an elongated reinforced catheter body and then off-axis in a deflectable tip portion. In this arrangement, longitudinal movement of the puller wire relative to the catheter body results in deflection of the catheter tip portion. Other examples of steerable catheters can be found in U.S. Pat. No. 5,431,168 to Webster entitled "Steerable Open-Lumen Catheter" and U.S. patent application Ser. No. 08/924,611 to Webster entitled "Omni-Directional Steerable Catheter," the reference. disclosures of which hereby incorporated by are

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One drawback to catheters and perhaps especially deflectable catheters is the difficulty of maintaining a catheter in position while in the patient's body. That is, once a suitable tissue site has been located for treatment or evaluation, such as mapping, ablation or the like, the physician is often caught in a predicament with maintaining at least one hand on the catheter while attempting to record or otherwise mark the location of the tissue site. The problem may be greater with deflectable catheters which can store torsional energy and therefore unwind and shift when released from the doctor's grasp. With the heart chamber being a dynamic environment surrounded by moving tissue and blood flow, the target site, which may be relatively small to begin with, can be readily lost with the slightest movement in the catheter.

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Because a catheter is typically used with an introducer or a sheath which facilitates the catheter's entry into the patient's body, it would be desirable to provide a catheter grip that attaches to the introducer. Often with one hand already working the introducer, an attending doctor could then

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readily use that same hand to operate the catheter grip. Moreover, it would be desirable to bias the grip toward a closed or gripping configuration so that actuation of the grip involves minimal action on behalf of the doctor.

SUMMARY OF THE INVENTION

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The present invention is directed to a catheter grip adapted to couple with an introducer or sheath and hold a catheter in position while in use in a patient's body. In one embodiment, the grip, which frees the hands of the attending doctor once he has located and placed the catheter in position, includes a hub defining a channel through which the catheter extends. The grip includes components for gripping the catheter, and components to release the catheter.

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To reach a target site within the patient's body, an elongated body of a catheter is passed through the channel and through the coupled introducer into the patient's vein. The hub has a pair of grip members that work with each other to hold the catheter body between them, a pair of separators to release the catheter body, and a pair of tabs for the doctor to actuate the separators. Each pair of the grip members and the separators is situated on a different diameter of a surface that extends across the channel, such that the pairs of grip members and separators are offset from each other by a predetermined angle and each grip member and separator is diametrically opposed to its mate.

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In one embodiment, the grip members and the separators are movable on tracks configured on the surface in alignment with the two diameters. The tracks have a female fitting portion which receives a male fitting portion configured on each grip member and separator and enables each grip member and each separator to move toward and away from its mate across the channel. The predetermined angle offset between the tracks optimizes the wedge action of the separators on the grip members in separating the grip members to release the catheter body.

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In another embodiment, the grip members are biased by an elastic member to move toward each other to clamp the catheter body. Interfacing ends of the grip members are notched and have a friction-inducing surface for a more secure hold on the catheter body. Moreover, Interfacing ends of the grip members and the separators may be angled to facilitate the leverage action of the separators on the grip members.

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BRIEF DESCRIPTION OF THE DRAWINGS

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Fig. 1 is a perspective view of an embodiment of a catheter grip of the present invention for use with an introducer (or sheath) and a catheter.

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- Fig. 2 is an exploded view of the grip of FIG. 1
- Fig. 3 is rear view of the grip of FIG. 1, the grip being shown in the closed position.

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Fig. 4 is a top view the grip of FIG. 1, the grip being shown in the closed position.

Fig. 5 is a side view of the grip of FIG. 1, with parts broken away for clarify, the grip being shown in the closed position.

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- Fig. 6 is a perspective frontal view of the grip of FIG. 1, with parts broken away for clarity, the grip being shown in the closed position.
- Fig. 7 is a perspective frontal view of the grip of FIG. 6, the grip being shown in the open or release position.

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DETAILED DESCRIPTION OF THE INVENTION

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FIG. 1 illustrates a catheter grip 20 in accordance with an embodiment of the present invention. The grip 20 is adapted to releasably grip and hold a catheter 22 in use in a patient's body for treatment or evaluation, such as mapping, ablation and the like. Once it is clamped on the catheter, the grip 20 effectively minimizes, if not prevents, the catheter from moving or shifting within the patient's body. As such, the grip 20 frees the hands of the attending doctor once he has closed the grip on the catheter. For purposes of the discussion herein, the catheter 22, as with most conventional catheters, has the elongated catheter body 24 that extends between a catheter tip section 26 and a control handle 28. The catheter body 22 and the catheter tip 26 are portions that generally enter the patient's body, whereas the control handle 28 remains outside the body.

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The catheter grip 20 is adapted for use with an introducer or sheath 30 having a tubular needle 32 that is inserted into a patient's vein or artery, typically in a leg 33. Introducers, sheaths are generally known and can take on many different configurations. Most have a valve 34 that is provided at the proximal end of the needle. The valve may or may not have a side port 36 for the introduction of

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a fluid to the entry site of the tubular needle **32**. Accordingly, the introducer or sheath (used interchangeably herein) is generally used to facilitate the entry of the catheter tip **26** (not shown) and body **24** into the vein by providing a prepared portal into the patient's body through the valve **34** and the needle **32**.

such as medical tape and bandages 39. The valve 34 and the hub 38 are releasably coupled to the extent that inadvertent detachment is avoided but intentional decoupling is facilitated. In that regard, the valve and the hub can be snap-fitted, threaded, latched together and/or detachably coupled by other similar methods. In the illustrated embodiment, the valve and hub are frictionally engaged by means of a female fitting formed in the proximal end of the valve and a closely-conforming male fitting

formed in the distal end of the hub. It is understood by one of ordinary skill in the art that the configuration, shape and/or size of the hub and the valve can vary. The grip **20** is preferably

Referring FIGS. 1 and 2, the grip 20 is configured as a cylinder or barrel which functions in part as a coupling hub 38 that attaches to the proximal end of the valve 34 before or, more preferably, after the introducer 30 has already been inserted and secured to the patient by conventional methods,

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in the patient's body.

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With the introducer **30** secured to the patient's body and the grip **20** coupled to the introducer at its proximal end, the catheter tip **26** and body **24** can be inserted through the grip and the coupled introducer for entry into the patient's body further through the needle **32**. As best shown in FIGS. 2-3, the hub **38** is also configured with a channel **40** that extends between a distal end **42** and a proximal end **44**, the latter of which has an aperture **46** formed in an end wall **48** that extends across the channel. The aperture **46** and the hub **38** are generally concentric about an axis **50** through the channel **40** and each is configured to permit the passing and generally free movement of the catheter tip section **26** and body **24** distally and proximally through the channel **40**.

constructed of a suitably rigid material (including plastic, steel, synthetic or natural rubber, and the like, or combinations thereof) to accomplish its function of holding and maintaining the catheter in position

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In the illustrated embodiment, the grip 20 includes a pair of grip members 52 situated on a proximal surface 54 of the wall 48. The grip members 52 are aligned along a diameter 56 of the proximal surface 54 and face each other from across the aperture 46. In accordance with the present invention, the grip members 52 can move radially inward toward each other to clamp onto the catheter body 24 extending through the aperture 46 and the channel 40. To facilitate this movement, the grip members 52 travel on a first track 58 formed in the proximal surface 54 along the diameter 56, which

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is illustrated with a generally vertical orientation. The grip members **52** and the track **58** are engaged with each other by means of corresponding male and female fitting portions. Referring also to FIG. 4, the disclosed embodiment of the track **58** has a slot **60** with a T-shaped cross-section **62** which receives a ridge **64** with a T-shaped cross-section **66** formed in a distal surface **68** of each grip member **52**. Guided by the track **58**, the grip members **52** are slidable inwardly and outwardly along the diameter **56**.

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It is understood that the aperture **46** itself need not be (and is not) physically affected by movement of the grip members **52**. It is therefore also understood that the aperture may be configured at any location along the length of the channel **40** and that the grip members **52** need not be in close proximity to nor proximal of the aperture **46**. However, because the aperture **46** can guide the travel path of the catheter body **24** in the channel, it may be preferable in most instances that the grip members **52** and the aperture **46** be configured at least adjacent to each other along the channel **40**. In the illustrated embodiment, the grip members and the aperture are in close proximity of each other and the grip members are immediately proximal of the aperture.

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Referring to FIGS. 2 and 6, an inner end 70 of each grip member 52 is configured with a notch 72 so that the pair can have a more secure hold on the catheter body 24 between them. In particular, the notch 72 provides better conformity between the interfacing inner ends 70 and the circumference of the catheter body 24. Depending on the size, flexibility and/or elasticity of the catheter body, the inner ends (notched or otherwise) may or may not be in contact with each other when the grip members 52 are clamped on the catheter body 24. In any case, the grip members 52, having a greater frictional contact with the catheter body as provided by the notches, minimize if not prevent translational or rotational movement in the catheter body once released from the hands of the doctor. To that end, surface 74 of the notches 72 may be textured and/or covered with a friction-inducing material 76 (not shown). Once closed, the grip 20 is "hands-free" in minimizing the need for the doctor to hold the catheter body 24 in position for fear that the catheter may shift or move out of position.

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In accordance with the present invention, the grip members **52** "rest" in a closed (or grip) position, as shown in FIGS. 3 and 6, under the bias of an elastic member or band **78** shown in FIG. 2. The elastic member sits in a groove **80** configured in an outer section **82** of each grip member **52**. The elastic member **78** exerts around its circumference a force directed radially inward such that the grip members **52** are under a predetermined bias to move toward (if not to make contact with) each other and/or remain in the closed position until actively opened by the user.

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To open the grip members 52, the grip has a pair of separator or wedgers 84 that are also situated on the proximal face 54 but along a diameter 86 that is offset between about 60-120 degrees, and more preferably about 90 degrees, from the diameter 56 of the grip members 52. Like the grip members, the wedgers 84 face each other from across the aperture 46 and can move toward and away from each other. In accordance with the present invention, the catheter body 24 is released by the grip 20 when the grip members 52 are separated or driven away from each other, that is, radially outward, by the wedgers 84, as shown in FIG. 7. To facilitate this action, the wedgers 84 travel along a track 88 also formed in the proximal surface 54 along the diameter 86, best seen in FIG. 5, with a generally horizontal orientation. The wedgers 84 and the track 88 are engaged with each other by similar means of a male and female fitting portion. In the illustrated embodiment, the track 88 has a slot 90 with a T-shaped cross-section 92 which receives a ridge 94 with a T-shaped cross-section 96 formed in a distal surface of each wedger 84. Guided by the track 88, the wedgers 84 can slide inwardly and outwardly along the diameter 86 of the surface 54. And, because the wedgers 84 and the grip members 52 interact and are interdependent, as described below in further detail, they have portions that affect and/or contact each other and are therefore in close proximity of each other within the grip.

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The wedgers 84, as the name implies, serve to wedge between and drive apart the grip members 52 in releasing the latter's hold on the catheter body 24. Inner ends 98 and 100 of the grip members 52 and the wedgers 84, respectively, are angled or chamfered at their corners 99 and 101, for example, at an angle ranging between about 30 and 60 degrees, and preferably at about 45 degrees, to facilitate this action. The convergence at the inner ends 100 of the wedgers 84 however is not to a point so the inner ends 100 will not protrude toward the catheter body 24 to the extent they contact or cause interfere with the catheter body 24.

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For optimum leverage between the grip members 52 and the wedgers 84, the inner ends 98 and 100 can be angled at a complementary angle, for example, where the total of the angles of the inner ends equals about 90 degrees). However, it is understood by one of ordinary skill in the art that the slant or degree of angle of the inner ends may be varied for different efficiencies of operation. For example, a more obtuse angle may offer a different feel or tension in the operation of the grip 20, than would a more acute angle. Moreover, the angle (which may or may not be identical between the wedge members 84 and the grip members 52) may also depend on or relate to the offset angle between the tracks 56 and 86.

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In any case, the grip members **52** are moved toward each other for a closed or grip position (FIG. 6), and away from each other for a release position (FIG. 7). Correspondingly, the wedge members **84** are moved toward each other for a wedge position (FIG. 7), and away from each other for a separated position (FIG. 6). In view of the foregoing description, it is clear that the movements of the pairs of grip members **52** and wedge members **84** are coordinated and interdependent in a manner whereby one pair moves toward each other as the other pair moves away from each other.

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Movement of the wedge members 84 toward each other to release the catheter body 24 is actuated primarily by means of a pair of tabs 102 that the user actuates. The tabs are pivotably attached to hinges 104 provided on the hub 38 and situated generally on the diameter 86 in alignment with the wedgers 84. The hub may be indexed to facilitate this alignment. In the illustrated embodiment, the hinges 104 are distal of the surface 54 and the tabs 102 extend slightly proximally from the hub 38 with their free ends 106 separated by a maximum distance which decreases to a minimum distance when the tabs are squeezed together by the user. When squeezed, the tabs act on the wedgers 84 through an angled ridge or cam 108 provided on an inner surface 110 of each tab. As can be seen in FIG. 7, as the free ends 106 approach each other, each cam 108 engages an adjacent wedger 84 to drive it inwardly toward its mate.

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In accordance with the present invention, the tabs **102** are biased away from each other by leaf springs **112** (best seen in FIGS. 6 and 7) such that the tabs spring apart when the user stops squeezing. The bias of the elastic member **78** around the grip members **52** also tends to urge the wedgers **84** to move away from each other. The wedge members **80** therefore "rest" apart from each other (at their maximum separation) until they are moved toward each other by the tabs. It is understood that the tabs may be biased to spring apart by other means. To that end, the leaf springs **112** may be connected or be integrated a single piece extending across the channel **40** to leverage the tabs **102** against each other so they move in a coordinated manner, that is, similarly and coincidentally.

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Advantageously, a doctor can use the very hand working the introducer **30** to actuate the tabs **102**, and do so without changing hand position. The grip **20** therefore provides improved ergonomics for the doctor, if not a more versatile working environment in which he has more mobility, or at least more freedom with his hands once the grip **20** is closed on the catheter body **24**.

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As mentioned, the grip 20 rests in the closed position, with the grip members 52 being in contact with each other under the bias of the elastic member 78 and the wedgers 84 separated and generally free from compression by the tabs 102 (FIG. 3). By squeezing the tabs 102, the doctor opens the grip 20 so that he can pass the catheter tip and body through the aperture 46 and into the introducer 30. As long as the tabs 102 are squeezed, the cams 108 press on the wedgers 84 inwardly keeping the grip members 52 wedged apart. The catheter body 24 can then be advanced by rotation or translation to the grip 20 as needed to reach the target site inside the patient's body (FIG. 7).

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After the target site has been reached and the catheter body 24 is in position, the doctor releases the tabs 102 which separate under the force of the leaf spring 112. Without any compressive force pushing the wedgers 84, they are forced outwardly by the inwardly-moving grip members 52 acting under the force of the elastic member 78 which clamps the grip members 52 on the catheter body 24 (FIG. 6). The notches 72 close around the circumference of the catheter body and the friction-inducing surface 74 securely holds the catheter body 24 to resist sliding or twisting caused by any torsional or coiled energy stored in the catheter body. To adjust or reposition the catheter body 24, the doctor re-squeezes the tabs 102 to re-separate the grip members 52. Indeed, release of the grip 20 to separate the grip members 52 at any time can be momentary or of a longer duration as desired by the doctor.

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It is understood by one of ordinary skill in the art that configuration of the grip and its components can be varied. For example, the grip can be biased toward the open position, such that a band acts to close the wedge members with a leaf spring and/or the tabs separating the grip members. Furthermore, the tabs may be take on a different shape or extend from the hinge at a different angle.

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The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention.

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Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.

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WHAT IS CLAIMED IS:

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1. A grip for use with a catheter having an elongated catheter body, comprising:

a hub with a channel through which the catheter body can extend, the hub having a surface extending across the channel;

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a first track configured along a first diameter of the surface, a second track configured along a second diameter of the surface, said first and second diameters being angularly offset from each other;

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a pair of grip members adapted to move toward each other along said first track and hold between them the catheter body;

a pair of separators adapted to move toward each other along said second track and separate the grip members to release the catheter body; and

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a pair of actuators configured to drive the separators toward the grip members in response to manipulation by a user.

2. A catheter grip of claim 1, wherein the actuators are biased against driving the separators toward the grip members.

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3. A catheter grip of claim 1, wherein the grip members move toward each other as the separators move away from each other.

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4. A catheter grip of claim 1, wherein the separators move toward each other as the grip members move away from each other.

5. A catheter grip of claim 1, further comprising a bias member biasing the grip members toward each other.

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6. A catheter grip of claim 1, wherein said tracks are angularly offset at a predetermined angle of about 90 degrees.

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7. A catheter grip of claim 1, wherein said surface is formed on a wall extending across the channel, the wall having an aperture through which the catheter body extends.

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8. A catheter grip of claim 1, wherein the hub is adapted to be coupled with an introducer or sheath.

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9. A catheter grip of claim 1, wherein one of the first track and the grip members has a male engagement portion that is received in a corresponding female engagement portion in the other of the first track and the grip members.

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10. A catheter grip of claim 1, wherein one of the second track and the separators has a corresponding male engagement portion that is received in a corresponding female engagement portion in the other of the first track and the separators.

11. A catheter grip of claim 1, wherein inner ends of the separators and the grip members are angled.

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12. A catheter grip of claim 1, wherein inner ends of the grip members have a notch.

13. A grip for use with a catheter having an elongated catheter body, comprising:

a hub with a channel through which the catheter body can extend, the hub adapted to be coupled with an introducer or a sheath;

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first opposing means to grip the catheter body within the channel;

actuating means responsive to a user to actuate said second means.

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second opposing means adapted to release the catheter body from the first means; and

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14. A grip of claim 13, wherein said first opposing means comprises a pair of grip members that are adapted to hold between them the catheter body.

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15. A grip of claim 13, wherein said second opposing means comprises a pair of wedge members that are adapted to separate the first opposing means.

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16. A grip of claim 13, wherein the third means are adapted to drive said second means between said first means to release the catheter body from the grip.

17. A grip of claim 13, further comprises means for biasing the first means toward hold the catheter body.

18. A grip of claim 13, further comprises means for biasing the actuation means against actuation of the second means.

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19. A grip for use with a catheter having an elongated catheter body, comprising:

a hub with a channel through which the catheter body can extend, the hub having a surface extending across the channel, the hub adapted to couple with an introducer or a sheath;

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a first track configured along a first diameter of the surface, a second track configured along a second diameter of the surface, said first and second diameters being generally perpendicular to each other;

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a pair of grip members adapted to move toward each other along said first track and hold between them the catheter body;

a pair of separators adapted to move toward each other along said second track to separate the grip members and release the catheter body; and

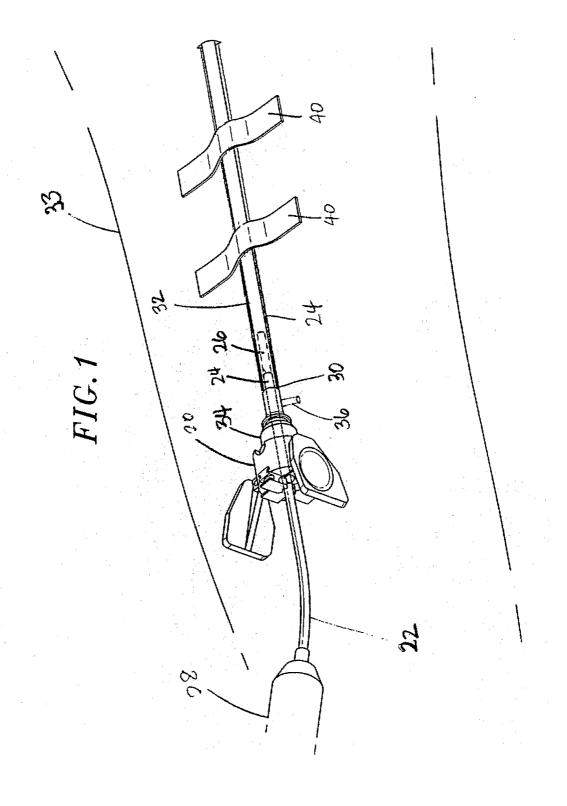
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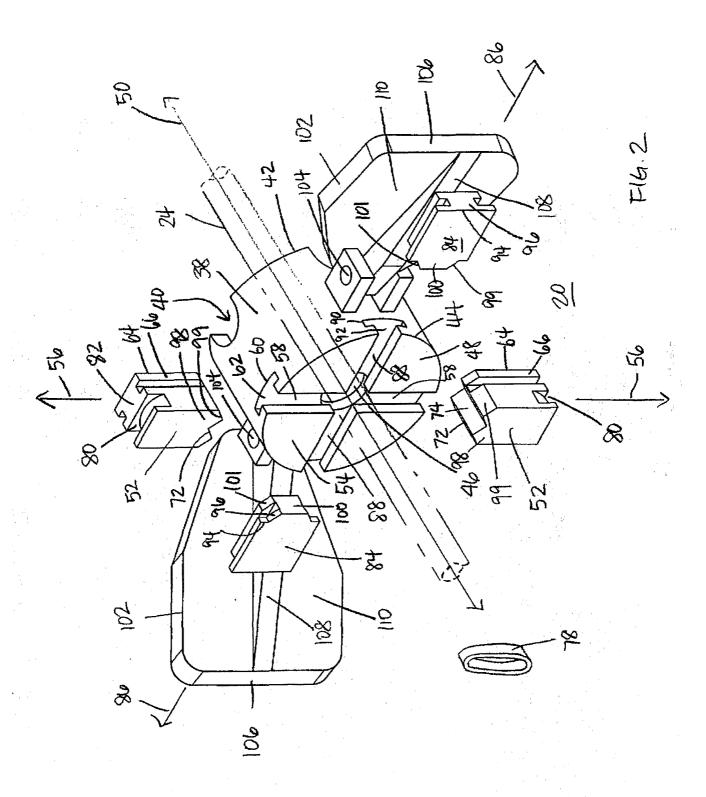
a pair of actuators responsive to manipulation by a user to drive the separator toward the grip members, each actuator having a cam surface acting on an outer end of a different separator;

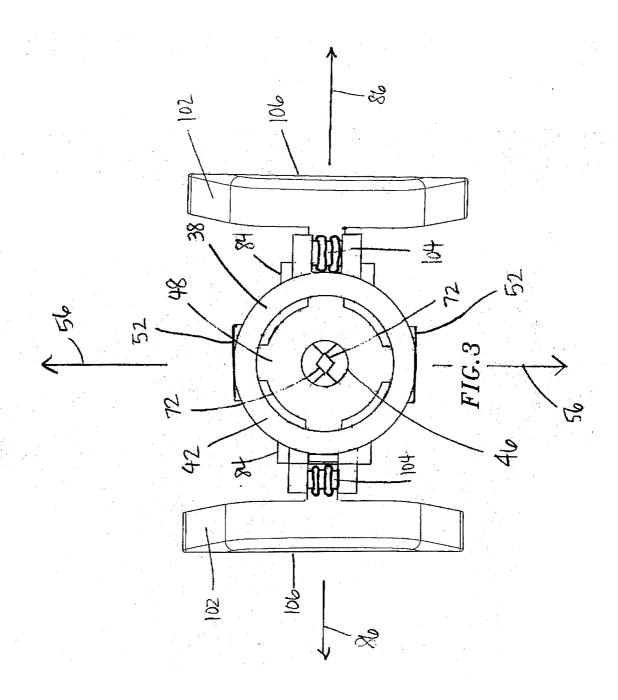
wherein the grip members are biased toward each other and the actuators are biased against driving the separators toward the grip members.

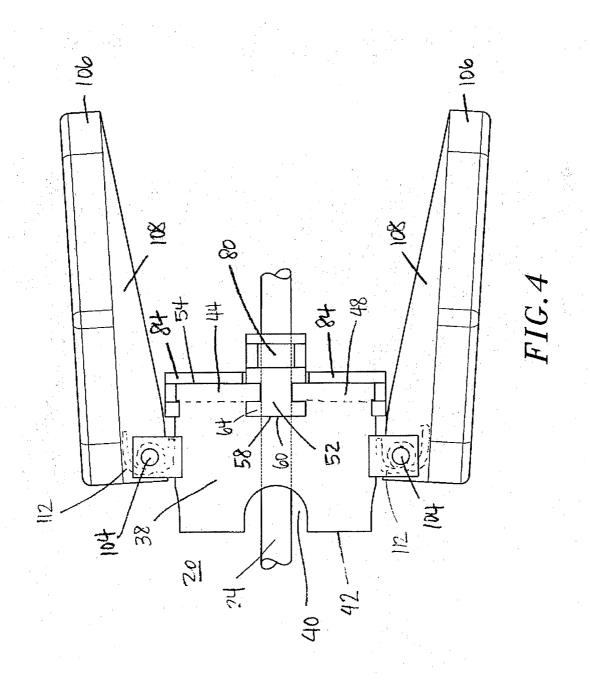
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	20. A grip of claim 19, wherein the grip is coupled to a proximal end of the introducer or sheath.
5	21. A grip of claim 19, wherein the actuators are adapted to be squeezed toward each other by the user.
10	22. A grip of claim 19, wherein the surface is configured on a wall extending across the channel, the wall having an aperture through which the catheter body extends.
	23. A grip of claim 22, wherein the wall is at a proximal end of the hub and the grip members and the separators are proximal of the aperture.
15	24. A grip of claim 21, wherein the actuators are hinged to the hub generally along the second diameter.
	25. A grip of claim 24, wherein the actuators are configured to be manipulated by one hand of the user.
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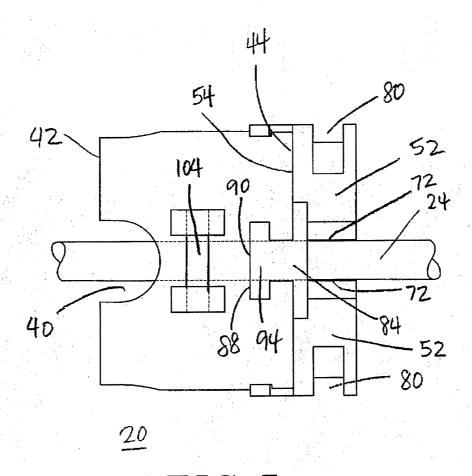
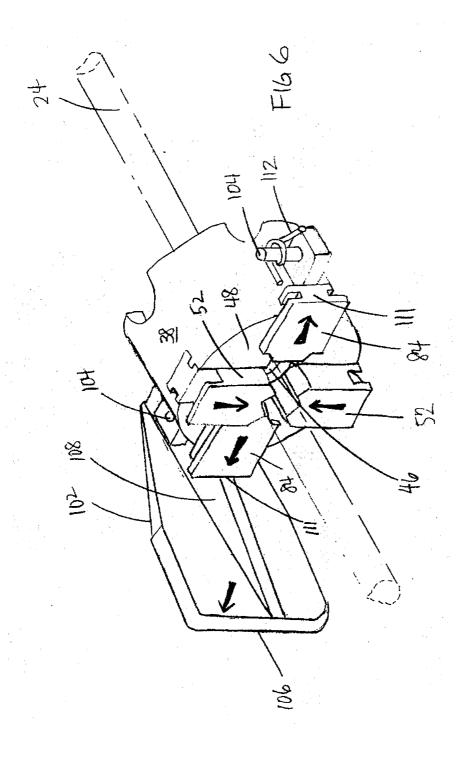
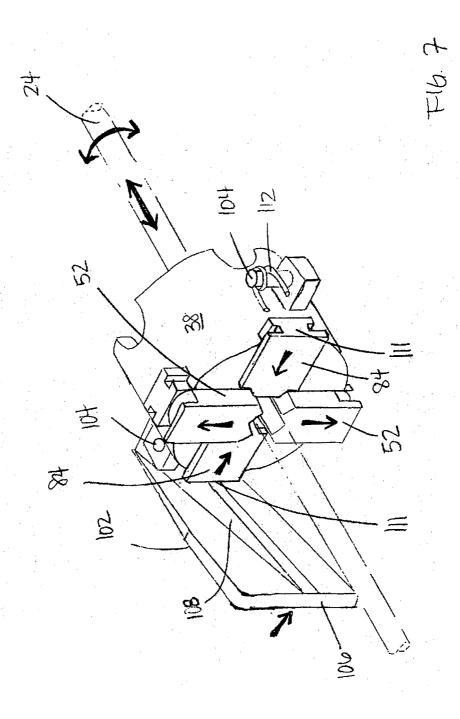


FIG.5





INTERNATIONAL SEARCH REPORT

PCT/US2005/020927

a. classi IPC 7	FICATION OF SUBJECT MATTER A61M25/00						
According to	o International Patent Classification (IPC) or to both national classifica	ation and IPC	<u>.</u>				
B. FIELDS	SEARCHED						
Minimum do IPC 7	ocumentation searched (classification system followed by classification $A61\mbox{M}$	on symbols)					
Documenta	tion searched other than minimum documentation to the extent that s	such documents are included in the fields so	earched				
Electronic d	ata base consulted during the international search (name of data base	se and, where practical, search terms used	i)				
EPO-Internal, WPI Data, PAJ							
C. DOCUMI	ENTS CONSIDERED TO BE RELEVANT						
Category °	Citation of document, with indication, where appropriate, of the rel	evant passages	Relevant to claim No.				
А	US 2 234 686 A (WALTER CHARLES T) 11 March 1941 (1941-03-11) claim 1; figures 1-4)	1-25				
A	DE 198 26 746 C1 (SULZER OSYPKA 6 25 November 1999 (1999-11-25) abstract; figure 2	GMBH)	1-25				
А	EP 0 422 631 A (ABBOTT LABORATORI 17 April 1991 (1991-04-17) abstract; figure 18	IES)	1-25				
А	US 6 558 354 B1 (HOWELL GLADE H) 6 May 2003 (2003-05-06) abstract; figures 1-3		1–25				
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Furti	her documents are listed in the continuation of box C.	χ Patent family members are listed	in annex.				
,	itegories of cited documents:	"T" later document published after the inte or priority date and not in conflict with	the application but				
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