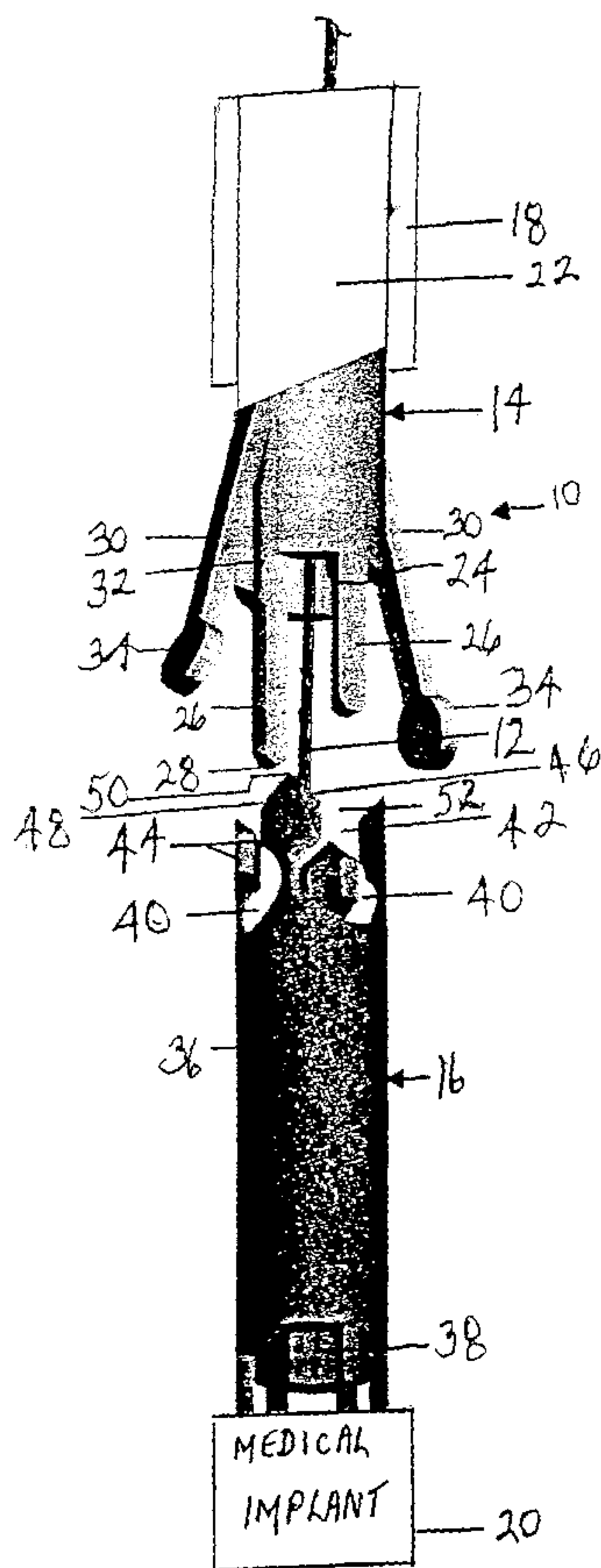




(86) Date de dépôt PCT/PCT Filing Date: 2001/10/17
 (87) Date publication PCT/PCT Publication Date: 2002/04/25
 (85) Entrée phase nationale/National Entry: 2003/03/28
 (86) N° demande PCT/PCT Application No.: US 2001/032184
 (87) N° publication PCT/PCT Publication No.: 2002/032496
 (30) Priorités/Priorities: 2000/10/18 (60/241,005) US;
 2001/10/17 (09/977,971) US

(51) Cl.Int.⁷/Int.Cl.⁷ A61M 29/00, A61F 2/24, A61F 2/06
 (71) Demandeur/Applicant:
 NMT MEDICAL, INC., US
 (72) Inventeurs/Inventors:
 FORDE, SEAN T., US;
 OPOLSKI, STEVEN W., US
 (74) Agent: BROUILLETTE KOSIE PRINCE

(54) Titre : MECANISME A FIXATION ET DETACHEMENT POUR JONCTION SUR FIL
 (54) Title: OVER-THE-WIRE INTERLOCK ATTACHMENT/DETACHMENT MECHANISM



(57) Abrégé/Abstract:

The over-the-wire interlock attachment/detachment mechanism includes a cylindrical lock receiving section (16) of a small attached to an implantable medical device (20) such as a blood clot filter, a stent, or a septal occluder. This cylindrical lock

(57) **Abrégé(suite)/Abstract(continued):**

receiving section (16) has a plurality of spaced, curved cutouts (40) to receive both the guide fingers (26) and contoured locking fingers (34) formed on a cylindrical locking section (14). The locking fingers (34) are angled outwardly from the cylindrical body (22) of the cylindrical locking section (14), and are moved inwardly into engagement with the curved cutouts (40) of the cylindrical lock receiving section (16) by a sheath (18) which slides over the cylindrical locking section (14) or other suitable operator.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
25 April 2002 (25.04.2002)

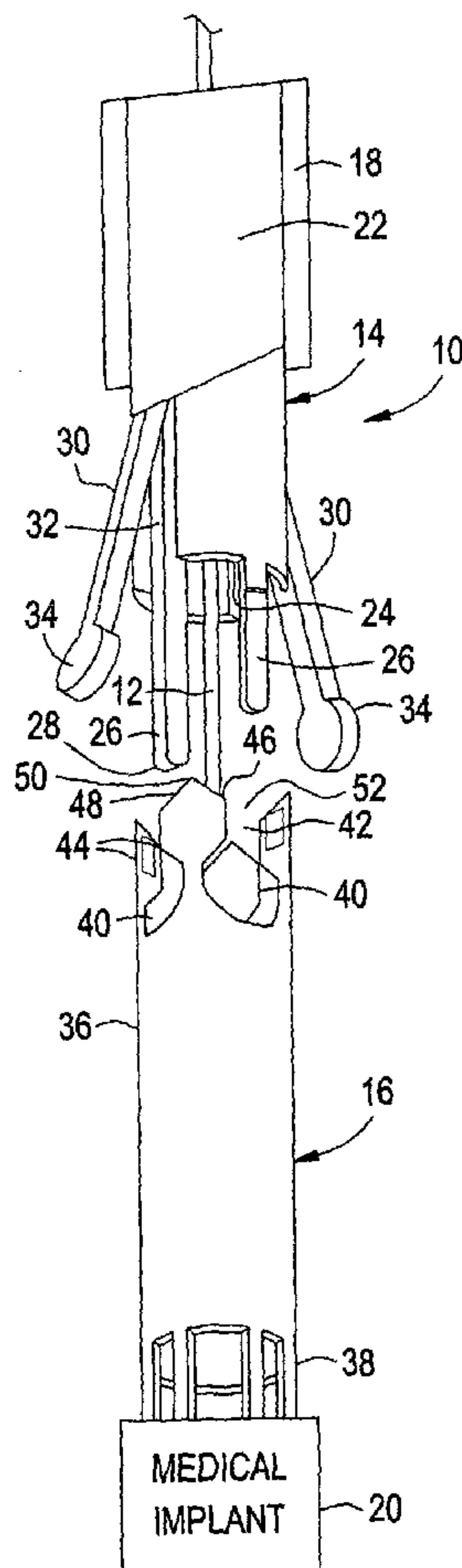
PCT

(10) International Publication Number
WO 02/032496 A1

- (51) International Patent Classification⁷: A61M 29/00, A61F 2/06, 2/24
- (21) International Application Number: PCT/US01/32184
- (22) International Filing Date: 17 October 2001 (17.10.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/241,005 18 October 2000 (18.10.2000) US
09/977,971 17 October 2001 (17.10.2001) US
- (71) Applicant: NMT MEDICAL, INC. [US/US]; 27 Wormwood Street, Boston, MA 02210 (US).
- (72) Inventors: FORDE, Sean, T.; 16 Frank Street, Watertown, MA 02472 (US). OPOLSKI, Steven, W.; 399 Concord Street, Carlisle, MA 01741 (US).
- (74) Agent: MOORE, Ronda, P.; Testa, Hurwitz & Thibault, LLP, High Street Tower, 125 High Street, Boston, MA 02110 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

[Continued on next page]

(54) Title: OVER-THE-WIRE INTERLOCK ATTACHMENT/DETACHMENT MECHANISM



(57) Abstract: The over-the-wire interlock attachment/detachment mechanism includes a cylindrical lock receiving section (16) of a small attached to an implantable medical device (20) such as a blood clot filter, a stent, or a septal occluder. This cylindrical lock receiving section (16) has a plurality of spaced, curved cutouts (40) to receive both the guide fingers (26) and contoured locking fingers (34) formed on a cylindrical locking section (14). The locking fingers (34) are angled outwardly from the cylindrical body (22) of the cylindrical locking section (14), and are moved inwardly into engagement with the curved cutouts (40) of the cylindrical lock receiving section (16) by a sheath (18) which slides over the cylindrical locking section (14) or other suitable operator.

WO 02/032496 A1

WO 02/032496 A1

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

(48) Date of publication of this corrected version:

6 September 2002

(15) Information about Correction:

see PCT Gazette No. 36/2002 of 6 September 2002, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

OVER-THE-WIRE INTERLOCK ATTACHMENT/DETACHMENT MECHANISM

This application claims the benefit of provisional patent application Serial No. 60/241,005 filed October 18, 2000.

Background of the Invention

[0001] In recent years, a number of medical devices have been designed which are adapted for compression into a small size to facilitate introduction into the heart or a vascular passageway and which are subsequently expandable. These devices, among others, include septal occluders, stents and free standing filters which expand and are held in position by engagement with the wall of an organ or vessel. It has been found to be advantageous to form such devices of a shape memory material having a first, relatively pliable low temperature condition and a second, relatively rigid high-temperature condition. By forming such devices of temperature responsive material, the device in a flexible and reduced stress state may be compressed to fit within the bore of a delivery catheter when exposed to a temperature below a predetermined transition temperature, but at temperatures at or above the transition temperature, the device expands and becomes relatively rigid.

[0002] Originally, these implantable medical devices were intended to permanently remain in place, but recently it has become advantageous to retrieve the previously implanted device.

[0003] The development of removable implantable medical devices such as septal occluders, stents and filters which expand and are held in position by engagement with the wall of an organ or vessel has led to the development of intra vascular snares to retrieve these foreign bodies, usually from the peripheral vessels of the cardiovascular system. Single loop snares, such as those shown by U.S. Patent Nos. 3,828,790 to Curtiss et al. and 5,171,233 to Amplatz et al. are commonly used snares. The Amplatz snare consists of a super-elastic nitinol cable with a single-formed loop. Because of the snare's super elastic construction, the loop can be introduced through small lumen catheters without risk of deformation. The loop is formed at approximately 90° to a cable, and this allows for the user to advance the loop over a foreign body and ensnare it by closing the loop with a small catheter. The foreign

body is removed from the vasculature by withdrawing the device into a guiding catheter or vascular sheath.

[0004] In an attempt to provide a snare with improved cross sectional vessel coverage, multi-loop snares such as those shown by U.S. Patent Nos. 5,098,440 to Hillstead and 6,099,534 to Bates have been developed. These snares include loops which are joined only at their proximal ends to a shaft, and otherwise are not joined at any point between the shaft and the distal ends of the loops. This provides the advantage over single loop snares of enhanced cross sectional vessel coverage, and the free distal ends of the loops can be brought together to engage multiple surfaces of an intravascular medical device to be removed.

[0005] The problem with known snare recovery devices is that they are difficult to advance over a medical implant device and require skilled manipulation to retrieve an implanted device. Once the medical implant device is engaged by a recovery snare, there is no assurance that the device will not slip out of the snare during the recovery process.

[0006] It is particularly difficult to remove medical implants from the heart, such as septal occluders, with known snare recovery devices. Such snare recovery devices normally require appropriate sizing to the vasculature in order to facilitate successful ensnarement, and the geometry of multi loop snares is difficult to maintain during delivery. The relative position of the loops can change, both within a catheter or delivery tube and within a vessel, and the loops can actually become displaced or entangled during delivery.

Summary of the Invention

[0007] A primary object of the present invention is to provide a novel and improved over-the-wire interlock attachment/detachment mechanism adapted to engage and positively lock on to an implanted medical device.

[0008] Another object of the present invention is to provide a novel and improved over-the-wire interlock attachment/detachment mechanism which automatically aligns to form an interlock attachment with an implanted medical device.

[0009] A further object to the present invention is to provide a novel and improved over-the-wire interlock attachment/detachment mechanism well adapted for use with over-the-wire implanted medical devices.

[0010] Yet another object of the present invention is to provide a novel and improved over-the-wire interlock attachment/detachment mechanism which includes a cylindrical locking section for engagement with a cylindrical lock receiving section connected to the medical implant.

[0011] A further object of the present invention is to provide a novel and improved over-the-wire interlock attachment/detachment mechanism which includes no overlapping components and which maintains a low profile configuration during passage through a vessel and/or catheter.

[0012] These and other objects of the present invention are achieved by providing a cylindrical lock receiving section of a small diameter attached to an implantable medical device such as a blood clot filter, a stent, or a septal occluder. This cylindrical lock receiving section has a plurality of spaced, curved cutouts to receive both the guide fingers and contoured locking fingers formed on a cylindrical locking section. The locking fingers are angled outwardly from the cylindrical body of the cylindrical locking section, and are moved inwardly into engagement with the curved cutouts of the cylindrical lock receiving section by a sheath which slides over the cylindrical locking section, or by another suitable operator which can be activated to move the fingers inwardly.

Brief Description of the Drawings

[0013] Figure 1 is a perspective view of the over-the-wire interlock attachment/detachment mechanism of the present invention with the control sheath shown in section;

[0014] Figure 2 is a perspective view of an over-the-wire free standing filter with the cylindrical lock receiving section for the over-the-wire interlock attachment/detachment mechanism of Figure 1;

[0015] Figure 3 is a perspective view of the partially engaged locking and lock receiving sections for the over-the-wire interlock attachment/detachment mechanism of Figure 1;

[0016] Figure 4 is a perspective view of the engaged locking and lock receiving sections for the over-the-wire interlock attachment/detachment mechanism of Figure 1;

[0017] Figure 5 is a second embodiment of a locking section for the over-the-wire interlock attachment/detachment mechanism of the present invention; and

[0018] Figure 6 is a third embodiment of a locking section for the over-the-wire interlock attachment/detachment mechanism of the present invention.

Description of the Preferred Embodiments

[0019] Referring to Figure 1, the over-the-wire interlock attachment/detachment mechanism of the present invention indicated generally at 10 is adapted for movement along a conventional guidewire 12 such as a .014" guidewire. The over-the-wire interlock attachment/detachment mechanism includes a male locking section 14, a female lock receiving section 16, and a tubular sheath 18 dimensioned to slide over the male and female sections. Preferably, the female section 16 is secured to an implantable medical device 20 such as a septal occluder, a filter or stent to be released in the heart or a blood vessel or other vessel of the human body or to be retrieved or repositioned within the heart or vessel.

[0020] The male locking section 14 includes a tubular body 22 which defines an open ended central chamber 24 through which the guidewire 12 passes. Projecting outwardly from the forward end of the tubular body 22 are one or more elongate guide fingers 26. These guide fingers are straight, elongate pins with arcuately shaped ends 28, and two such guide fingers are shown in Figure 1 although more than two can be provided. The outer surface of each guide finger is preferably coextensive with the outer surface of the tubular body 22.

[0021] Also projecting outwardly from the forward end of the tubular body 22 are one or more flexible, elongate locking arms 30 which are substantially equal in width to the width of the guide fingers 26. Underlying each of the locking arms is a slot 32 formed in the tubular body to receive the locking arm. When unconfined, each locking arm is formed to angle outwardly beyond the outer surface of the tubular body 22.

[0022] A shaped locking member 34 is formed at the end of each locking arm. Preferably, this locking member, which extends laterally from at least one side of the locking arm, is circular in shape, but other shapes which extend laterally from the locking arm including but not limited to an ellipse, a "T", a rectangle, a square, a hook, a triangle or an "L" can be used. A circular locking member facilitates engagement with the lock receiving

section 16. The guide fingers and locking arms are equally spaced around the tubular body 22. They are preferably equal in number, and although two of each are shown, more can be used.

[0023] The female lock receiving section 16 includes a tubular body 36 which defines an open ended central chamber 38 for receiving the guidewire 12. The tubular body 36 is substantially equal in diameter to the tubular body 22 so that the two are coextensive when the male locking section is engaged with the female lock receiving section.

[0024] The female lock receiving section includes a plurality of shaped locking cutouts 40 which are shaped to conform to and receive the shaped locking members 34. The number of shaped locking cutouts 40 is equal to the number of guide fingers 26 and locking arms 30. Extending into each of the shaped locking cutouts 40 is a straight, open ended, cutout entry section 42 which is formed to receive either a guide finger 26 or a locking arm 30.

[0025] The shaped locking cutouts 40 and open ended entry cutout sections 42 are equally spaced around the tubular body 36 to conform to the spacing of the guide fingers 26 and locking arms 30. Outwardly projecting spacer sections 44 extend outwardly between adjacent shaped cutouts and open ended entry cutout sections and each terminate in inclined outer end surfaces 46 and 48 which form an apex 50. Each inclined outer surface angles downwardly toward an open ended entry cutout section 42 and the inclined outer end surface 46 of a spacer section 44 forms with the inclined outer end surface 48 of an adjacent spacer section an enlarged outwardly tapered opening 52 for each open ended cutout section.

[0026] The female lock receiving section 16 is secured to one end of a medical implant 20, which can be an over the wire device such as a septal occluder. For purpose of illustration, the female lock receiving section is shown with the over-the-wire free standing filter 54. The free standing filter 54 has a filter body with an elongate guidewire receiving member 56 extending centrally therethrough to define an open ended channel configured to receive a plurality of different sized guidewires. An expandable and contractible frame 58 surrounds the elongate guidewire receiving member and is connected at a proximal end to the elongate guidewire receiving member. A porous embolic capturing unit 60 has an open end 62 connected to the frame and a closed end 64 connected to the elongate guidewire receiving member which extends through the porous embolic capturing unit.

[0027] Figures 1, 3 and 4 disclose the manner in which the over-the-wire interlock attachment/detachment mechanism 10 is operable to positively engage and remove a medical implant 20 from a body organ or vessel. The male locking section 14 is enclosed within the sheath 18 so that the locking arms 30 are forced into the slots 32 and do not project outwardly beyond the periphery of the male locking section. In this configuration, the male locking section is passed along the wire 12 until it is positioned in close proximity to the female lock receiving section 16. At this point, the sheath 18 is drawn back to permit the locking arms 30 to angle outwardly from the male locking section 14. The male locking section is then moved toward the female lock receiving section 16 until the guide fingers 26 engage the outer end surface 46 or 48 of a spacer section 44. As the male locking section continues to move toward the female lock receiving section, each guide finger will be guided by an inclined outer end surface 46 or 48 into an open ended cutout entry section 42 which then guides the guide finger into the associated shaped cutout 40. The over-the-wire interlock attachment/detachment mechanism is now in the configuration illustrated in Figure 3. It will be noted that when the guide fingers move into the open ended cutout entry sections 42, they position the locking arms 30 and the locking members 34 above and in alignment with open ended cutout sections 42 and their associated shaped cutouts 40. Now, shown in Figure 4, the tubular sheath 18 is moved forwardly over the tubular bodies 22 and 36 to force the locking members 34 into the shaped cutouts 40 and positively engage the male locking section 14 with the female lock receiving section 16.

[0028] Once a positive engagement has been established between the male locking section and female lock receiving section, the over-the-wire interlock attachment/detachment mechanism can be drawn back over the wire 12 to remove the medical implant 20. Because of the positive locking engagement, forces present on the medical implant as it is withdrawn will not result in detachment from the over-the-wire interlock attachment/detachment mechanism. This is very important for medical implants such as the removable filter 54 where hooks 58 must be withdrawn from the wall of the vessel.

[0029] It is often difficult to accurately position a medical implant within a vessel without disconnecting or misaligning the implant relative to the positioning device. This problem is rectified by the over-the-wire interlock attachment/detachment mechanism 10. The medical implant 20 with an attached female lock receiving section 16 is positively locked to the male locking section 14 in the manner shown by Figure 4 before it is moved over the wire 12 into

position within a body vessel. The positive locking action between the male locking section and female lock receiving section facilitates accurate positioning of the medical implant within a vessel without misorientation or the likelihood of a disconnect. Once the implant device is positioned, the sheath 18 can be moved back as shown in Figure 3 allowing the locking arms 30 to spring outwardly to disengage the locking members 34 from the shaped cutouts 40. Now the male locking section 14 can be drawn back over the wire 12 away from the female lock receiving section 16.

[0030] The sheath 18 may be replaced by other operating mechanisms capable of moving the locking arms 30 into the slots 32. For example, elongate tethers attached to the ends of the locking arms which extend back through the central chamber 24 might perform this function.

[0031] The male locking section 14 can be modified as shown in Figures 5 and 6 to provide a flexible end section 68 adjacent to the elongate guide fingers 26 and elongate locking arms 30. By providing a flexible section 68 in the body 22 proximal to the guide fingers and locking arms, it becomes easier to align the guide fingers, locking arms and locking members 34 with the cutouts in the female lock receiving section 16. The flexible section 68 can be formed in a variety of ways. For example, a spring section can be welded or bonded to the body 22 between the main portion of the body and the guide fingers and locking arms to form the flexible section 68. Ideally, as shown in Figure 5, the body 22 is formed with a unitary spring section 68 by cutting the body in a spiral to create a helical spring 70. This can be done with a laser which can also be used to shape the guide fingers, locking arms and locking members in the tubular body 22.

[0032] Alternatively, as shown in Figure 6, a flexible, tubular polymer section 72 can be formed between the main portion of the body 22 and the guide fingers and locking arms to provide the flexible section 68.

We claim:

1. An over-the-wire interlock attachment/detachment mechanism for a medical implant comprising:
 - a male locking body member having a forward end,
 - a flexible locking support having a locking member formed thereon which extends from the forward end of said male locking body member, said flexible locking support, when unrestrained, extending laterally and angularly outward from said male locking body member, and
 - a female lock receiving body member for receiving said locking member, said female lock receiving body member having a first body end and being formed with an indented portion adjacent to said first body end to receive and engage said locking member.
2. The over-the-wire interlock attachment/detachment mechanism of claim 1, wherein said female lock receiving body member is secured to said medical implant.
3. The over-the-wire interlock attachment/detachment mechanism of claim 1 wherein a lock operating sheath is mounted to slide on said male locking body member, said lock operating sheath operating to engage said flexible locking support to move said locking support inwardly toward said male locking body member.
4. The over-the-wire interlock attachment/detachment mechanism of claim 1 wherein said male locking body member and female lock receiving body member are cylindrical members of substantially equal diameter.
5. The over-the-wire interlock attachment/detachment mechanism of claim 4 wherein a lock operating sheath is mounted to slide on said male locking body member, said

lock operating sheath operating to engage said flexible locking support to move said locking support inwardly toward said male locking body member.

6. The over-the-wire interlock attachment/detachment mechanism of claim 5, wherein said female lock receiving body member is secured to said medical implant.

7. The over-the-wire interlock attachment/detachment mechanism of claim 1 wherein a plurality of spaced flexible locking supports extend from the forward end of said male locking body member, each of said spaced flexible locking supports being formed by an elongate, flexible locking arm having a first arm end connected to said male locking body member, said elongate flexible locking arm extending angularly outward from said first arm end when said elongate flexible locking arm is unrestrained.

8. The over-the-wire interlock attachment/detachment mechanism of claim 7 wherein a locking member is formed on each elongate, flexible locking arm and is spaced from the first arm end thereof and outwardly from the forward end of said male locking body member,

said female lock receiving body member being formed with indented portions adjacent to said first body end to receive and engage said locking members.

9. The over-the-wire interlock attachment/detachment mechanism of claim 8 wherein each elongate, flexible locking arm has a free end spaced from the first arm end thereof, said locking member being formed by a shaped, enlarged section at the free end of said elongate flexible locking arm.

10. The over-the-wire interlock attachment/detachment mechanism of claim 9 wherein said male locking body member and female lock receiving body member are cylindrical members of substantially equal diameter.

11. The over-the-wire interlock attachment/detachment mechanism of claim 10 wherein a lock operating sheath is mounted to slide on said male locking body member, said lock operating sheath operating to engage said elongate flexible locking arms to move said elongate flexible locking arms and locking members inwardly toward said male locking body member.

12. The over-the-wire interlock attachment/detachment mechanism of claim 11 wherein said female lock receiving body is cut away to provide spaced openings forming said indented portions, each said spaced opening being formed to receive a flexible locking arm and the locking member formed thereon.

13. The over-the-wire interlock attachment/detachment mechanism of claim 12 wherein each such spaced opening includes an elongate, open ended entry section shaped to receive an elongate flexible locking arm and an enlarged locking cutout connected to said elongate open ended entry section, said enlarged locking cutout being shaped to receive and conform in shape to said locking member.

14. The over-the-wire interlock attachment/detachment mechanism of claim 1 wherein said flexible locking support includes at least one elongate flexible locking arm having a first end connected to said male locking body member, said elongate flexible locking arm extending angularly outward from said first arm end when said elongate flexible locking arm is unrestrained, said locking member being formed on said elongate flexible locking arm, and

wherein at least one elongate guide finger extends from the forward end of said male locking body member,

said female lock receiving body being cut away to provide a plurality of spaced openings each formed to receive an elongate flexible locking arm and locking member or a guide finger.

15. The over-the-wire interlock attachment/detachment mechanism of claim 14, wherein said female lock receiving body member is secured to said medical implant.

16. The over-the-wire interlock attachment/detachment mechanism of claim 14 wherein a lock operating sheath is mounted to slide on said male locking body member, said lock operating sheath operating to engage said at least one elongate flexible locking arm to move said elongate flexible locking arm and locking member inwardly toward said male locking body member.

17. The over-the-wire interlock attachment/detachment mechanism of claim 16 wherein each such spaced opening includes an elongate, open ended entry section shaped to receive an elongate flexible locking arm or guide finger and an enlarged locking cutout connected to said elongate open ended entry section, said enlarged locking cutout being shaped to receive and conform in shape to said locking member.

18. The over-the-wire interlock attachment/detachment mechanism of claim 17 which includes a plurality of spaced elongate flexible locking arms and a plurality of spaced elongate guide fingers, said female lock receiving body including a plurality of spaced openings at least equal in number to the number of elongate flexible locking arms and elongate guide fingers.

19. The over-the-wire interlock attachment/detachment mechanism of claim 18 wherein said male locking body member and female lock receiving body member are cylindrical members of substantially equal diameter.

20. The over-the-wire interlock attachment/detachment mechanism of claim 2 wherein said medical implant is a free standing over-the-wire filter.

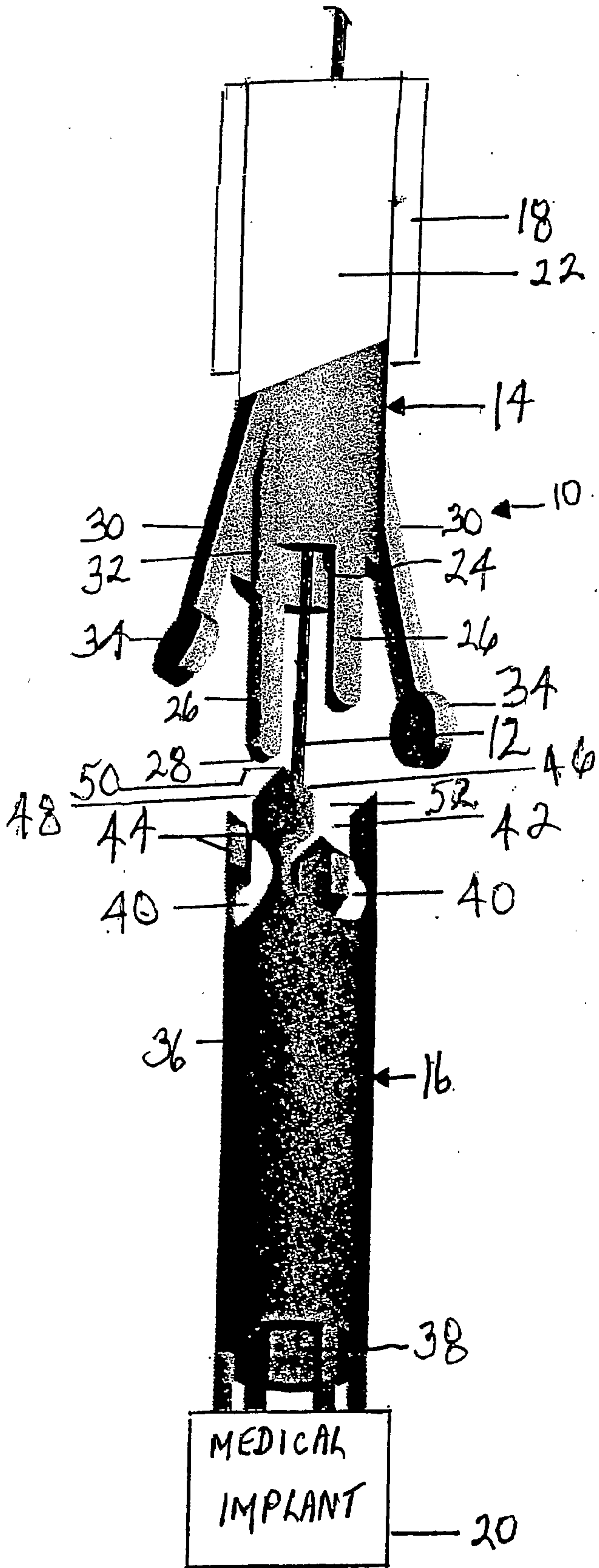


FIG. 1

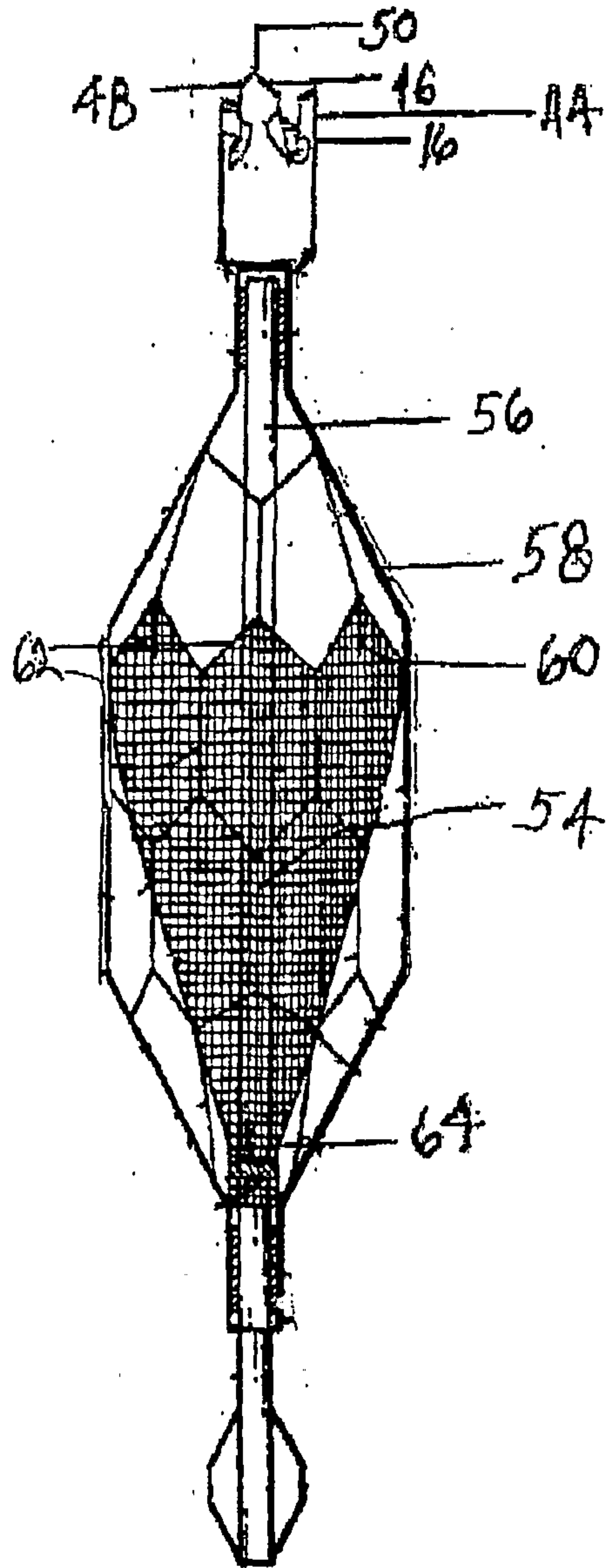


FIG. 2

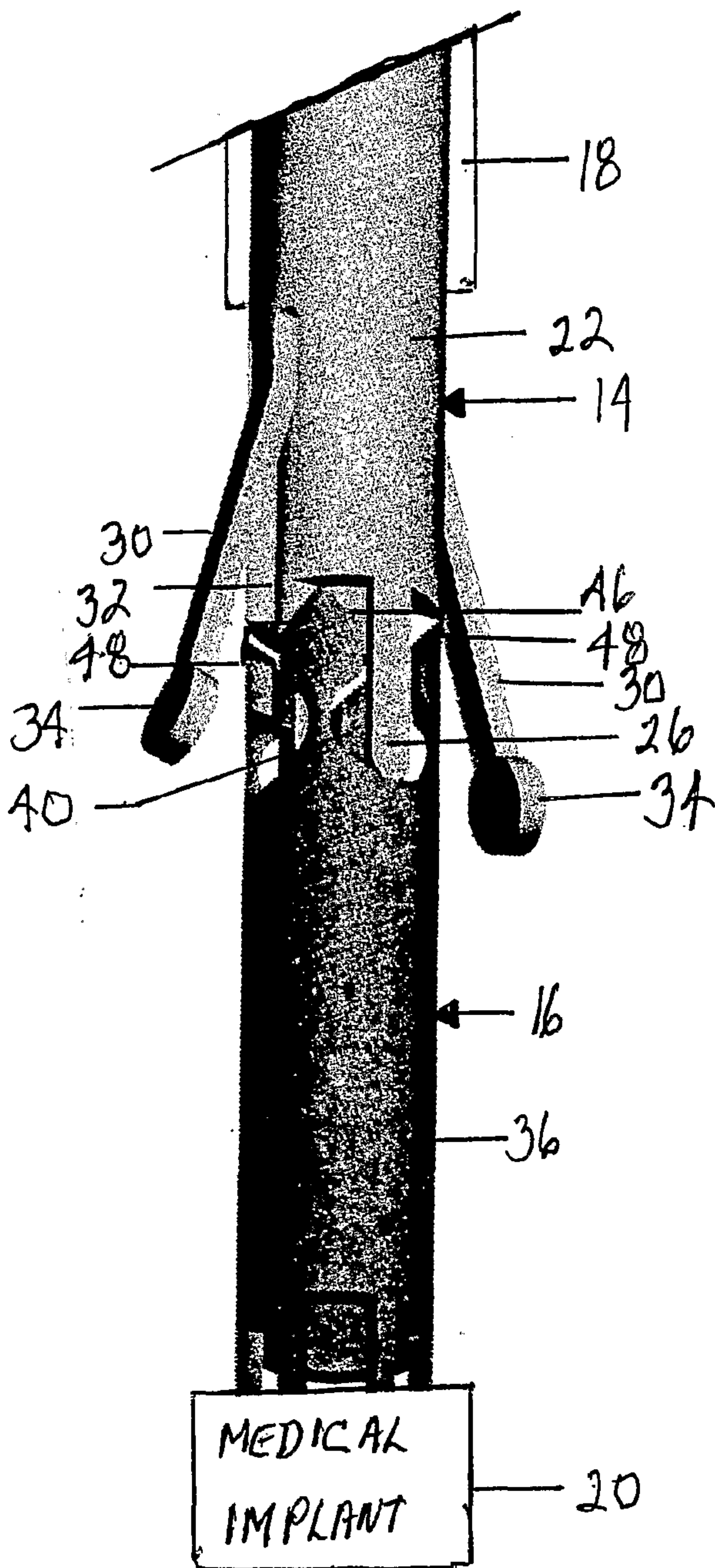


FIG. 3

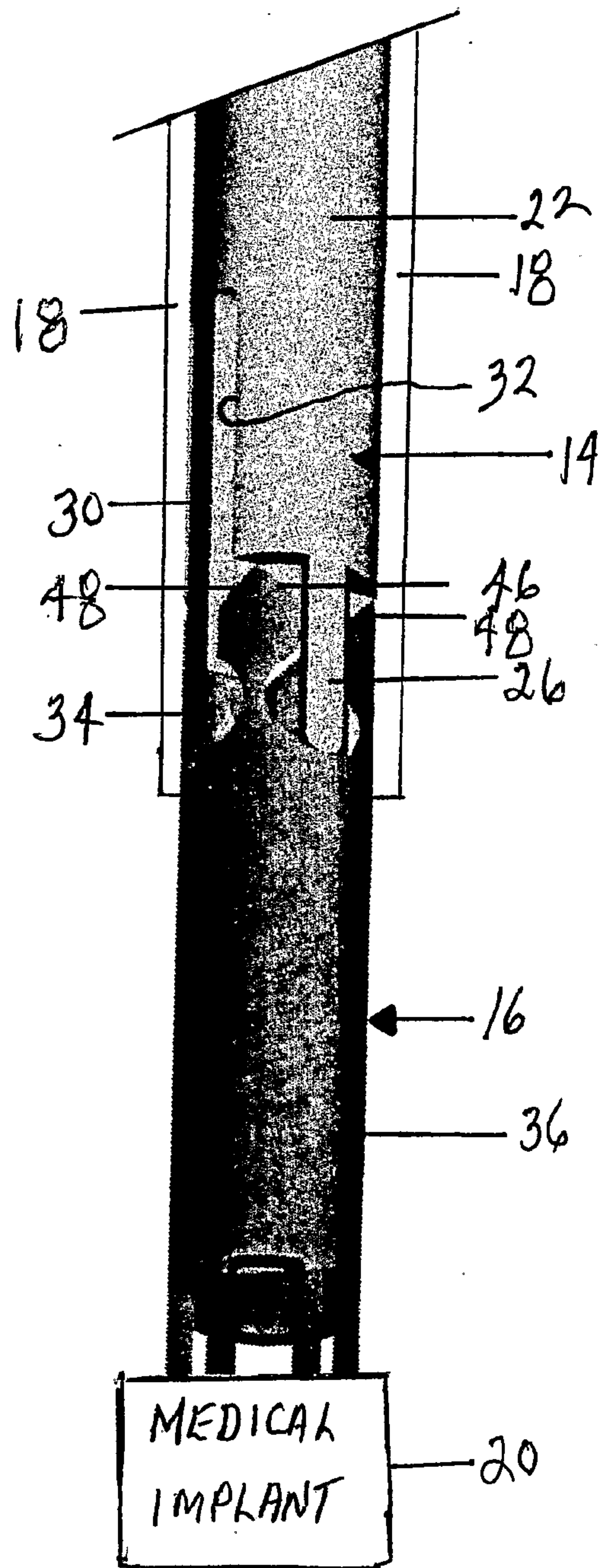


FIG. 4

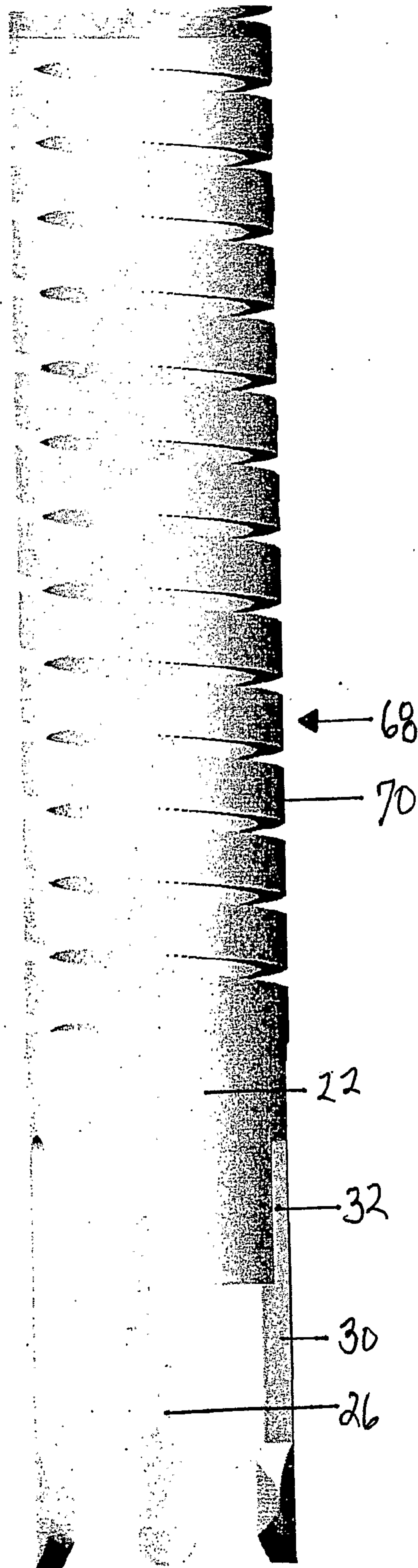


FIG. 5

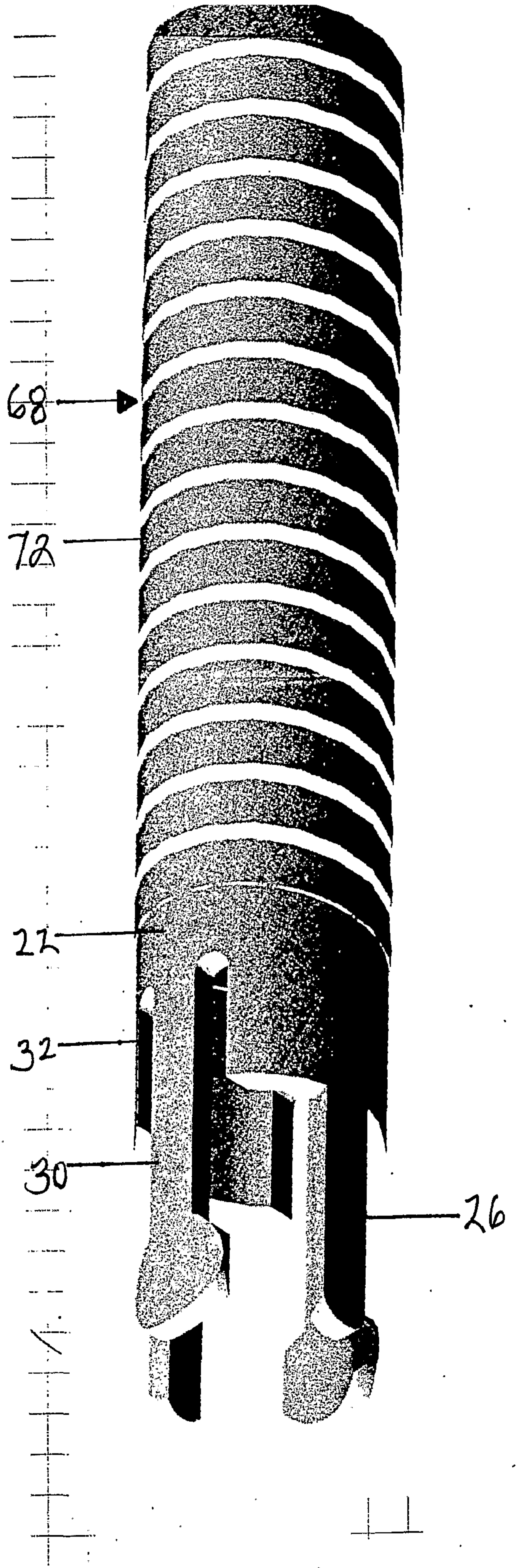


FIG. 6

