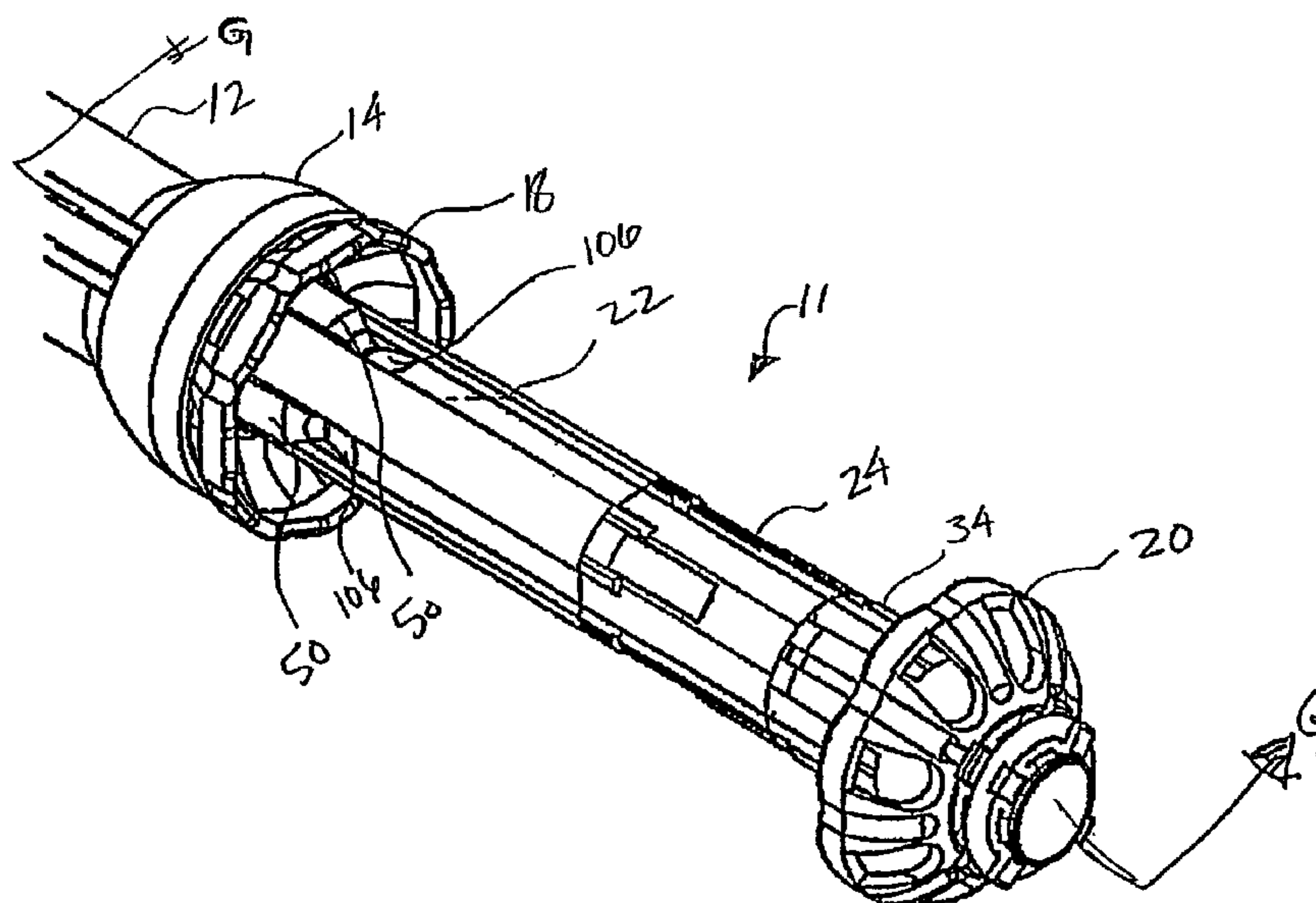




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(72) Inventeurs/Inventors:
PHILLIPS, PAUL JOSEPH, US;
CORBETT, ROBERT KELLY, US;
CONNERS, JOHN A., US
(73) Propriétaire/Owner:
SHERWOOD SERVICES AG, CH
(74) Agent: SMART & BIGGAR

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OPEN POSITION

(57) **Abrégé/Abstract:**

The invention relates to a device for transanally inserting through the lower bowel one of two unitary members of a Biofragmentable Anastomosis Ring (BAR). The device comprises a curved shaft with a handle and an actuating knob at the proximal end, a nest formed at the distal end of the shaft adapted to mount a BAR carrier assembly, and a second passageway formed through the shaft that terminates at a distal open end formed through the nest. The BAR carrier assembly includes unitary male and female members that collectively comprise the BAR, male and female carriers for mounting the respective unitary member, and a collet for locking in and releasing the BAR from the BAR carrier assembly once both unitary members are secured to respective open ends of the upper and lower bowel section. The BAR Carrier Assembly is actuatable in one of three positions: open, closed, and released.



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ABSTRACT

The invention relates to a device for transanally inserting through the lower bowel one of two unitary members of a Biofragmentable Anastomosis Ring (BAR). The device
5 comprises a curved shaft with a handle and an actuating knob at the proximal end, a nest formed at the distal end of the shaft adapted to mount a BAR carrier assembly, and a second passageway formed through the shaft that terminates at a distal open end formed through the nest. The BAR carrier
10 assembly includes unitary male and female members that collectively comprise the BAR, male and female carriers for mounting the respective unitary member, and a collet for locking in and releasing the BAR from the BAR carrier assembly once both unitary members are secured to respective
15 open ends of the upper and lower bowel section. The BAR Carrier Assembly is actuatable in one of three positions: open, closed, and released.

TRANSANAL ANASTOMOSIS RING INSERTION DEVICE

BACKGROUND OF THE INVENTION

1. Field of the Invention

5 The present invention generally relates to a surgical device, and more particularly to an anastomosis ring insertion device for use in anastomosing tubular body organs in connection with, for example, intestinal surgery.

2. Prior Art

10 After a surgical procedure, such as cutting and removing a diseased or cancerous portion of the bowel, the severed ends of the bowel must be anastomosed or rejoined. Several procedures are available for anastomosing two sections of hollow tubular body organs, such as the
15 intestines. Known procedures for anastomosing two sections of hollow tubular body organs together include suturing, stapling or clamping the severed ends together. For example, U.S. Patent Nos. 4,576,167, No. 4,603,693 and No. 4,646,745 are directed to anastomosis procedures utilizing
20 circular surgical staplers for anastomosing two hollow body organs.

 Another procedure uses anastomosis buttons and clamps to join two sections of hollow body organs together. U.S. Patent Nos. 3,771,526, No. 4,055,186 and No. 4,154,241 are
25 exemplary of such anastomosis devices. The devices disclosed in these patents utilize inserter rods which are forced upwardly into the rectum through the anus in order to position one half of a clamp device in the lower colon and engage the other half of the clamp device positioned in the
30 upper colon, so as to draw and join the two hollow body organ halves together.

 Still another procedure involves use of an anastomotic device that is the subject of U.S. Patent Nos. 4,467,804, No. 4,467,804 and No. 4,766,898, which are assigned to the

assignee of the present invention, and marketed and sold under the VALTRAC® trademark. The anastomotic device disclosed under these patents receives the open ends of intestines to be purse stringed and anastomosed over and
5 between a pair of ring members that comprise the VALTRAC®. The ring members have mechanical connecting means which mate with each other in order produce secure serosa-to-serosa apposition of the ends of the intestines and maintains a satisfactory patency until healing occurs and the ring
10 members degrade into small harmless fragments which are eliminated from the body. The ring members, also referred to collectively as a Biofragmentable Anastomosis Ring (BAR), are formed of a bio-absorbable material that permits disintegration of the BAR in a relatively short period of
15 time after healing of the intestines begins, thereby eliminating the need for metal staples and clamps which do not disintegrate and pass through the patient's system. Acceptable materials for manufacturing the BAR are disclosed in U.S. Patent No. 3,297,033 and include, but are not
20 limited to, poly-hydroxy acetic ester and lactate copolymers which are herein incorporated by reference. However, use of this type of anastomotic device requires that the surgeon work solely through an abdominal opening made in the patient, which is disadvantageous when performing
25 anastomosis to the lower bowel due to the limited space available in the pelvic area for performing such a procedure.

U.S. Patent No. 5,464,415 discloses a sutureless anastomosis gun for a BAR for use in sutureless anastomosis
30 of the intestine near the anus. The anastomosis device disclosed in this patent drives an inner sleeve and a ring seat by means of nut and screw rod arrangement such that the end of the rectum is pushed precisely to enter the gap of the BAR and then the BAR is exactly closed about the portion
35 of the intestines to be anastomosed. Thereafter, the ring seat and the BAR are disengaged and the anastomosis gun

removed from the rectum. However, the anastomosis gun of this type does not transanally insert one member of the BAR so that an exact closing about the portion of the intestines to be anastomosed is not required.

5 U.S. Patent Nos. 4,667,673 and 5,282,810, also assigned to the assignee of the present invention, disclose an anastomosis applicator device for mounting the BAR and a method for inserting the applicator and BAR transanally. The device includes a mounting extension for mounting the two
10 halves of the BAR and an inserter which is curved and adapted for transanal insertion. The inserter portion of the applicator passes through the interior of the rectum and out through the exterior of the anus so that the placement of the BAR can be done without the difficulty present in having
15 to access the lower bowel area solely through the pelvic area.

However, it is desirable that further improvements to the transanal applicator be made related to better mounting and application of the device during an anastomosis
20 procedure.

OBJECTS AND SUMMARY OF THE INVENTION

A principle object of the present invention is to provide an applicator insertion device for surgically inserting a BAR.

25 It is a further object of the present invention to provide an insertion device for surgically inserting a unitary member of a BAR in an open end of the lower bowel through the anal orifice.

It is another object of the present invention to
30 provide an insertion device for surgically inserting a unitary member of a BAR in an open end of the upper bowel through an abdominal insertion.

It is still a further object of the present invention to provide an insertion device that swiftly and easily

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mounts, closes, and releases both unitary members of the BAR in order to clamp the open ends of the bowel in a contiguous manner.

These and other objects of the present invention are realized in a presently preferred embodiment thereof, described by way of example and necessarily by way of limitation, which provides for an insertion device for transanally inserting one of two unitary members of a BAR through the rectum and securing it to the open end of the lower bowel, while inserting the other unitary member through an abdominal opening and securing it to the open end of the upper bowel. The insertion device of the present invention comprises a curved shaft with a handle and knob at the proximal end, a nest formed at the distal end thereof adapted to mount a BAR carrier assembly, and communicating first and second passageways formed through the shaft which terminate at a distal end opening formed through the nest.

The BAR carrier assembly includes unitary male and female members that collectively comprise the BAR, male and female carriers for temporarily mounting both unitary members of the BAR onto the insertion device, a protective cover for safe and comfortable transanal insertion of the insertion device, and a collet/drawbar arrangement for locking in and releasing the BAR from the BAR Carrier Assembly once both unitary members are secured to respective open ends of the upper and lower bowel and then mated together prior to release. In the preferred embodiment, both unitary male and female members include a plurality of openings interposed between scallops in juxtaposition relationship which are formed through the dome of each unitary member. The openings promote the fragmentation of the BAR after a period of time by allowing the BAR to break down into smaller pieces when it begins to disintegrate, thereby allowing the fragments to more easily pass out the body through the stool. The scallops which form the outer edge of each unitary member form a continuous bumpy pattern

thereabout that serves to better clamp the open ends of the bowel between the two unitary members of the BAR when mated together, thereby promoting vascularity of healthy bowel tissue during anastomosis.

5 The knob positioned at the proximal end of the shaft communicates with a threaded body that includes a threaded channel adapted to engage a rod member connected to a flexible shaft member. Formed or attached thereto at the distal end of the shaft member is a drawbar adapted to
10 engage the connectors of the collet. The collet has a body having a distal end that includes an elongated stem with a wedge formed at the free end thereof while a plurality of connectors at the opposite end of the collet body extend generally axially therefrom.

15 Both male and female carriers have hollow generally tubular bodies with opposed proximal and distal openings, respectively. The proximal opening of the male carrier includes a concentric pattern of connectors adapted for attachment to the distal opening of the female carrier while
20 the distal opening of the male carrier forms a plurality of generally axially extending legs with retaining jaws formed at the free end thereof.

During manufacturing, the female carrier and female member are pre-loaded to the distal end of the insertion
25 device by engaging the female carrier to the shaft and inserting the female carrier through the aperture formed through the dome of the female member. Mating prongs formed on the female member then engage slots formed on the female carrier, thereby seating the female carrier securely in the
30 nest of the insertion device. Further, the collet is pre-loaded to the male carrier by inserting the collet through the male carrier so that the wedge of the collet is placed between the plurality of legs, thereby biasing apart the legs. Prior to inserting the collet through the male
35 carrier, the male member is pre-loaded to the distal end of the male carrier so that the retaining jaw formed at the

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free end of each leg of the carrier is advanced through the aperture formed in the dome of male member. Once the legs are advanced through the aperture of the male member so that the retaining jaws engage the peripheral area around the aperture, the wedge of the collet is then inserted through the male carrier until the bump formed opposite of each retaining jaw engages a retaining ridge formed around the circumference of the wedge and biases apart the plurality of legs. A biasing means, for example a garter spring, is received around the inside of each retaining jaw so as to provide a counter force that locks the wedge of the collet between the legs of the male carrier, thereby locking the male member to the distal end of the male carrier.

In operation, a surgeon makes an abdominal opening through an incision made in the patient in order to access the bowel area. The surgeon then severs the bowel into an upper bowel section and a lower bowel section and then cleans the edges of each respective bowel section of any cancerous or diseased portion in order to ensure healthy tissue is present for anastomosis. The pre-loaded male member with the male carrier attached thereto is then inserted through the abdominal opening by the surgeon and the edge of the upper bowel section is secured around the outer edge of the male member in a contiguous manner thereto by employing, for example a purse string stitch pattern, using a absorbable suture material to secure the edge of the upper bowel section. After the upper bowel section is secured, the surgeon inserts the distal end of the shaft, with the pre-loaded female member attached thereto, through the rectum of the patient and into the bowel until the shaft appears through the lumen of the lower bowel section.

Once the shaft has been inserted through the lower bowel, the edge of the lower bowel section is secured around the outer edge of the female member in a manner similar to the securement of the upper bowel section to the male member. Upon securing both upper and lower bowel sections,

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the surgeon attaches the male carrier with its connected male member to the distal end of the female carrier, so as to place the BAR Carrier Assembly in the open position with the female member spaced apart from the male member along the axis of the Carrier Assembly. Further, when the male carrier is attached to the female carrier, the collet engages the drawbar so that the collet can release the male member at the appropriate time when the device is actuated.

Once the BAR Carrier Assembly is in the open position, the surgeon actuates the device in order to place the Carrier Assembly in the closed position and mate the male member to the female member. In order to actuate the device and place the BAR Carrier Assembly in the closed position, the surgeon rotates the knob of the device between the thumb and forefinger in a clockwise direction, which causes the male and female carriers to be pulled into the second passageway of the shaft due to the drawbar's engagement with the collet. As both carriers are pulled into the second passageway by the drawbar, the male member is brought to mating engagement with the female member seated in the nest of the shaft, thereby placing the BAR Carrier Assembly in the closed position.

During the mating sequence between the male member and the female member, the mating prongs of the female member engage respective slots formed in the tubular member of the male member in such a manner as to maintain contiguous contact between the opposing portions of the upper and lower bowel sections secured to the outer edge of each respective unitary member. Once the two unitary members are mated and both sections of the bowel secured, the surgeon places the BAR Carrier Assembly in the release position by rotating the knob in a counter-clockwise direction. This counter-clockwise rotation causes the drawbar to move in an axial direction away from the knob, thereby causing the collet to move forward relative to the male carrier. The relative forward movement of the collet also removes the wedge from

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between the plurality of legs of the male carrier and releases the mated unitary members of the BAR from the BAR Carrier Assembly. Once release of the BAR has been effected, the surgeon withdraws the shaft of the device from
5 the lower bowel section of the patient and the procedure is completed.

In an alternative embodiment, the proximal end of the collet has a cross bar-like configuration similar to the one formed at the distal end of the drawbar in the preferred
10 embodiment, while the alternative drawbar has a plurality of connectors similar to those formed at the proximal end of the collet body in the preferred embodiment. The alternative embodiment, with the exception of the collet and drawbar, is structurally and operatively the same as the
15 preferred embodiment.

In one broad aspect, there is provided a medical device for use in joining of free ends of two tubular members comprising: first and second ring members, said first and second ring members being securable to a
20 respective free end of each tubular member to be anastomosed, an insertion device having a distal end and a proximal end, said insertion device adapted for transanally inserting the first of said ring members so that said first ring member extends through one of the free ends of the
25 tubular members, a carrier assembly attachable to said distal end of said insertion device, said carrier assembly including first and second carriers for attachment and release of said first and second ring members, said first carrier being attachable to said distal end of said
30 insertion device and a distal end of said second carrier

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including a plurality of axially extending legs, and said first and second ring members being positionable at first and second predetermined distances from each other; wherein: said second carrier being attachable to said first carrier;
5 and the distal ends of the legs being biased radially inward toward one another by application of a radial force to said distal ends thereof, said radial force being applied by a biasing means.

BRIEF DESCRIPTION OF THE DRAWINGS

10 FIG. 1 is a perspective view of the anastomotic device according to the present invention;

FIG. 2 is a partial cross-section view of the shaft and handle of the anastomotic device shown in FIG. 1 according to the present invention;

15 FIG. 3 is an exploded view of the distal end of the anastomotic device illustrating the various components of the BAR Carrier Assembly according to the present invention;

FIG. 4 is a side view of the male member according
20 to the present invention;

FIG. 5 is a cross-section view of the male member shown in FIG. 4 along lines **A-A** according to the present invention;

FIG. 6 is a perspective view of the male member
25 shown in FIG. 4 according to the present invention;

FIG. 7 is a top view of the male member shown in FIG. 4 according to the present invention;

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FIG. 8 is a side view of the female member
according to

the present invention;

FIG. 9 is a cross-section view of the female member shown in FIG. 8 along lines B-B according to the present invention;

5 FIG. 10 is a top view of female member shown in FIG. 8 according to the present invention;

FIG. 11 is a perspective view of the female member shown in FIG. 8 according to the present invention;

10 FIG. 12 is a side view of the male carrier according to the present invention;

FIG. 13 is a cross-section view of the male carrier shown in FIG. 12 along lines C-C according to the present invention;

15 FIG. 14 is a perspective view of the male carrier shown in FIG. 12 according to the present invention;

FIG. 15 is an end view of the male carrier shown in FIG. 12 according to the present invention;

FIG. 16 is a side view of the collet according to the present invention;

20 FIG. 17 is a cross-section view of the collet shown in FIG. 16 along lines D-D according to the present invention;

FIG. 18 is a perspective view of the collet shown in FIG. 16 according to the present invention;

25 FIG. 19 is a side view of the female carrier according to the present invention;

FIG. 20 is a cross-section view of the female carrier shown in FIG. 19 along lines E-E according to the present invention;

30 FIG. 21 is a perspective view of the female carrier shown in FIG. 19 according to the present invention;

FIG. 22 is an end view of the female carrier shown in FIG. 19 according to the present invention;

FIG. 23 is a side view of the distal end of the shaft according to the present invention;

35 FIG. 24 is a cross-section view of the distal end of

the shaft shown in FIG. 23 along lines F-F showing the nest and second passageway according to the present invention;

FIG. 25 is an end view of the distal end of the shaft shown in FIG. 23 according to the present invention;

5 FIG. 26 is a perspective view of the drawbar according to the present invention;

FIG. 27 is an end view of the drawbar shown in FIG. 26 according to the present invention;

10 FIG. 28 is a perspective view of the distal end of the shaft illustrating the BAR Carrier Assembly in the open position;

FIG. 29 is a cross-section view of the distal end of the shaft and BAR Carrier Assembly shown in FIG. 28 along lines G-G according to the present invention;

15 FIG. 30 is a perspective view of the distal end of the shaft illustrating the BAR Carrier Assembly in the closed position;

FIG. 31 is a cross-section view of the distal end of the shaft and BAR Carrier Assembly shown in FIG. 30 along 20 lines I-I according to the present invention;

FIGS. 31A-31C illustrate the mating sequence between the male member and the female member when the BAR Carrier Assembly is being placed in the closed position shown in FIG. 31 according to the present invention;

25 FIG. 32 is a perspective view of the distal end of the shaft illustrating the BAR Carrier Assembly in the released position according to the present invention;

FIG. 33 is a cross-section view of the distal end of the shaft and BAR Carrier Assembly shown in FIG. 32 along 30 lines J-J according to the present invention;

FIG. 34 is a perspective view of the protective showing the preferred embodiment according to the present invention;

FIG. 35 is a perspective view showing an alternative embodiment of the protective cover according to the present 35 invention.

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FIG. 36 is a perspective view showing an alternative embodiment of the collet according to the present invention;

FIG. 37 is a side view of the collet shown in FIG. 36 according to the present invention;

5 FIG. 38 is a perspective view showing an alternative embodiment of the drawbar according to the present invention;

FIG. 39 is an end view of the drawbar shown in FIG. 38 according to the present invention;

10 FIG. 40 is a cross-section view of the drawbar shown in FIG. 38 along lines K-K according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings, the preferred embodiment of
15 the anastomosis device of the present invention is illustrated and generally indicated as 10 in FIG. 1. As shown in FIG. 1, the anastomosis device 10 comprises a curved elongated shaft 12 integrally attached to or formed with a handle 13 at its proximal end, while a BAR carrier
20 assembly 11 is attachable to distal end of shaft 12.

Referring to FIG. 2 a partial cross-section showing the interior of the anastomosis device 10 is illustrated. Handle 13 forms a hollow tubular configuration having connected first and second passageways 43 and 45, respectively, that
25 extend axially therethrough from a first opening formed at the proximal end of anastomosis device 10 through the shaft 12 where the second passageway 45 terminates at a second opening formed at the distal end thereof. The first passageway 43 extends axially from the first opening
30 through the handle 13 where it communicates with the smaller diameter second passageway 45 where the handle 13 meets the shaft 12.

Preferably, shaft 12 comprises a two-part assembly that includes first and second identical halves 65 and 67 (FIG.

25) that are attached together by pins (not shown) inserted and secured through holes 41 formed through the body of shaft 12. Although the preferred embodiment discloses a pin and hole arrangement for securing first and second halves 65 and 67 together, it is within the scope of the present invention that halves 65 and 67 can be attached by other securing means to include, but not limited to, adhesive bonding, tongue and groove arrangement, riveting or other suitable means of attachment. Preferably, shaft 12 and handle 13 are made from a hard plastic material or any kind of material suitable for injection molding. However, in the alternative, metal may also be used to manufacture the shaft 12 and handle 13.

A window 17 (FIG. 1) is formed through handle 13 for providing a visual indication to the surgeon as to the state of closure of the BAR Carrier Assembly. A color mark or other visual indicator (not shown), such as a notch, is provided on a rod member 23 that is seen through window 17 when anastomosis device 10 is actuated and the BAR Carrier Assembly 11 is being placed in the closed position. The state of closure is determined by how much mark 10 fills window 17, with full closure having mark 10 filling the entire window 17.

A knob 15 having a gripping surface adapted for secure gripping between a user's thumb and forefinger is provided for actuating anastomosis device 10 from an open to a closed position, and finally to a release position. Knob 15 further includes an annular-shaped threaded body 21 with an undercut 39 interposed therebetween. The threaded body 21 is disposed in the first passageway 43 and forms an internal axial threaded channel 29 therethrough that includes a series of threads (not shown) adapted for engagement to rod member 23. The distal end of first passageway 43 has a lip 37 adapted for engagement to undercut 39, so that threaded body 21 is retained inside passageway 43 while permitting

body 21 to freely rotate therein. Rod member 23 also has a series of threads formed around the outer surface thereof that mate and engage the threads of threaded body 21 when the proximal end of rod member 23 is inserted into the threaded channel 29 during assembly of the anastomosis device 10. Rotation of knob 15 in a clockwise direction rotates threaded body 21 so that rod member 23 is pulled axially toward knob 15 while rotation of knob 15 in a counter-clockwise direction extends the rod member 23 away from knob 15. Although the preferred embodiment of the present invention discloses a clockwise rotation of knob 15 for axially pulling in rod member 23 and a counter-clockwise rotation for axially extending away member 23, it is within the scope of the present invention that rotation of knob 15 can be in either direction for pulling in or extending out member 23.

Integrally attached to or formed with the distal end of rod member 25 is a flexible shaft member 25 that extends through the portion of the second passageway 45 that is formed through shaft 12. A plurality of channeling members 27 are strategically located at points along the top and bottom portions of second passageway 45 for guiding the shaft member 25 along passageway 45 during its back-and-forth motion as the anastomosis device 10 is actuated, as shall be explained in greater detail later. The shaft member 25 is preferably a flat strip integrally attached to or formed with a cross-shaped drawbar 16 at the free end thereof. Drawbar 16 is adapted for engagement to the BAR carrier assembly 11 that is attachable to the distal end of anastomosis device 10.

Referring to FIG. 3, an exploded view of the distal end of the anastomosis device 10 and its attachable BAR carrier assembly 11 is shown. The BAR carrier assembly 11 comprises a BAR 19 that includes a female member 18 and a male member

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20 that mate together to form a unitary biofragmentable anastomosis ring. As shall be discussed in greater detail later, female member 18 engages a female carrier 22 by inserting the carrier 22 through an aperture 54 formed through the female member 18. Female carrier 22 has a hollow generally tubular shape with open ends and is adapted for engagement with shaft 12 when the proximal end of the carrier 22 is inserted into the second passageway 45. A male carrier 24, also forming a hollow generally tubular body with open ends and a plurality of legs 60 formed at the distal end thereof, is attachable to the female carrier 22 when the BAR Carrier Assembly 11 is placed in the open position. During manufacturing, a collet 28 is pre-loaded to the male carrier 24 and male member 20 and is provided for locking and subsequently releasing the wedge 84 of collet 28 from between the plurality of legs 60 of carrier 24 when collet 28 is inserted into the hollow generally tubular body of the male carrier 24 and through the plurality of legs 60. Prior to locking wedge 84 between the plurality of legs 60, legs 60 are inserted through the aperture 32 of male member 20 and engaged to the peripheral area around aperture 32, so that when wedge 84 is inserted through legs 60 and biases apart legs 60, the male member 20 is effectively locked to the male member 20. A biasing means 26, for example an O-ring or garter spring, is provided around the free end of the plurality of legs 60 for applying a counter-biasing force that locks against wedge 84 between the plurality of legs 60 and pre-loads the male member 20 to the male carrier 24, as shall be explained in greater detail later.

Besides both male and female members 18 and 20, BAR carrier assembly 11 further comprises respective female and male carriers 22 and 24 and collet 28 and is attachable to the distal end of shaft 12. The distal end of shaft 12 forms an annular nest 14 where the second opening

communicates with the second passageway 45 formed inside shaft 12. Nest 14 has a dome-like shape that forms a receptacle adapted for seating the dome-side of the female member 18. Extending axially from the second opening 33 is drawbar 16. As shall be explained in greater detail below, drawbar 16 is inserted through an aperture 54 formed in the center of the female member 18 that is seated in nest 14, and is designed to engage and retain the BAR Carrier Assembly 11 to the shaft 12.

10 Referring to FIGS. 4-7, the male member 20 is illustrated in greater detail. Male member 20 includes a dome 30 with an aperture 32 formed in center thereof, while a concentric pattern of openings 53 are in juxtaposition between scallops 55 formed around the exterior surface of dome 30. Each opening 53 forms a bullet shaped aperture through dome 30 while each scallop 55 cuts a small arc along the outer edge 49 between each opening 53. Dome 30 further includes an interior cavity 40 having an outer edge 49 which surrounds a tubular member 34 that extends axially from the aperture 54 through cavity 40. A portion of the exterior surface of tubular member 34 forms a plurality of axially extending ring raceways 36 which are equally spaced around the circumference of member 34. These ring raceways 36 are shallow channels extending axially along the exterior surface of tubular member 34 from the free end thereof to a point approximately halfway up member 34 where each raceway 36 terminates forming a slot 38 that communicates with the interior area of member 34. The interior area of tubular member 34 forms a ring channel 46 that includes a series of axially extending grooves 42 spaced equally around the circumference of the interior surface thereof and formed between the protruding shallow channels of the ring raceways 36.

Referring to FIGS. 8-11, the female member 18 is shown

in greater detail. Female member 18 includes a concentric-shaped dome 48 similar configuration to dome 30 of male member 20 and has an interior cavity 56 having an outer edge 58 and an inner edge 57 that forms an axial aperture 54 in the center of dome 48. Dome 48 further includes the same pattern of openings 53 and scallops 55 found on male member 20, which form a similar concentric pattern as disclosed above. Extending axially from the inner edge 57 of aperture 54 and into the interior of cavity 56 are a plurality of mating prongs 50 with a pawl 52 formed at the free end of each prong 50. Each pawl 52 forms a protruding portion adapted for engagement with a respective slot 36 of the male member 20 when the female member 18 is mated thereto. The leading edge of each pawl 52 is angled in order to provide a tunneling action that tunnels under and clears any obstruction, for example a severed bowel section, that might obstruct any one of the raceways 36 during mating of the male member 20 to the female member 18.

Referring to FIGS. 12-15, the male carrier 24 is shown in greater detail. Male carrier 24 comprises a carrier body 70 having a hollow generally tubular shape that forms a carrier channel 76 with opposing distal and proximal open ends 59 and 61. The distal open end 59 forms the plurality of generally axially extending legs 60 that are spaced equally around the circumference of open end 59 and set at a slight inward angle thereto. The free end of each leg 60 forms retaining jaws 64 having upper and lower jaws 66 and 68, respectively. The upper and lower jaws 66 and 68 form a pocket adapted to receive a biasing means 26, for example a resilient O-ring or garter spring, for biasing the plurality of legs 60 together, however any type of resilient biasing means is felt to fall within the scope of the present invention. Opposite each upper jaw 66 is a bump 63 adapted to engage and retain wedge 84 of collet 28, as shall be

explained in greater detail later. The carrier body 70 further includes a plurality of axially extending slots 62 spaced equally around the circumference of the proximal open end 61 in juxtaposition relation between each first carrier raceway 72. Each first carrier raceway 72 forms an exterior shallow channel adapted for engaging and guiding the prongs 50 toward mating engagement with the male member 20 when the BAR Carrier Assembly is placed in the closed position. Provided at the proximal end of male carrier 24 are a plurality of connecting members 74 spaced equally around the circumference of the male carrier channel 76 at the entrance thereof and in axial alignment with the slots 62. Connecting members 74 are adapted for engagement with connection slots 104 of female carrier 22 when male carrier 24 is connected thereto.

Referring to FIGS. 16-18, collet 28 is shown in greater detail. Collet 28 serves as part of the release mechanism when the BAR 19 is being released from the BAR carrier assembly 11 and comprises first and second generally identical halves 94 and 96, respectively, as illustrated in FIG. 18. Preferably, the two halves 94 and 96 are attached to one another by tongue and groove arrangement strengthened by adhesive bonding, although any other suitable means of attachment, such as, but not limited to ultrasonic welding, riveting or a combination of any of the above, is felt to fall within the scope of the present invention. Each halve 94 and 96 includes opposing tongue 81 and 83 and groove 85 and 87 arrangements, respectively, for properly orienting and connecting the two halves 94 and 96 together by inserting the tongue 81 of halve 94 into the groove 85 formed in halve 96. Conversely, the tongue 83 of halve 96 is inserted into the groove 87 formed in halve 94 when the two halves 94 and 96 are attached prior to bonding the two halves 94 and 96 together in a unitary structure using a suitable adhesive.

The proximal end of the collet body **80** includes a plurality of prongs **86** with a connector **88** formed at the free end of each respective prong **86**. The connectors **88** are adapted for engagement with the drawbar **16** while the distal
5 end of the collet body **80** forms an elongated stem **82** having a wedge **84** at the free end thereof. The wedge **84** has a truncated conic section and a retaining ridge **100** formed around the upper section of wedge **84** adapted for retaining bump **63** of legs **60**. As shall be explained in greater detail
10 later, the wedge **84** forms a part of the release mechanism that locks in as well as releases the BAR **19** during use of the anastomosis device **10**.

Referring to FIGS. **19-22**, the female carrier **22** is shown in greater detail. Female carrier **22** includes a
15 carrier body **108** that has a generally hollow tubular shape with opposing proximal and distal open ends **105** and **107**. Formed through the carrier body **108** are opposing retaining windows **102** adapted for engagement with the shaft **12** when the female carrier **22** is inserted thereto. A means for
20 guiding the female member **18** axially along the exterior surface of female carrier **22** is provided in the form of a pair of opposing second carrier raceways **112**. Second carrier raceways **112** comprise exterior shallow channels adapted for engaging and guiding the four mating prongs **50** of the female
25 member **18** along the female carrier **22** until the prongs **50** engage retaining slots **106** formed at the mid point of each respective raceway **112**.

Distal open end **107** forms an annular opening that includes a plurality of connection slots **104** spaced equally
30 around the circumference thereof, which are adapted for connection to a respective connecting member **74** of male carrier **24**. The connection slots **104** have beveled surfaces that facilitate engagement with the connection members **74** in a loose attachment fit thereto. Distal open end **107** forms

one end of female carrier channel 110 that communicates through the hollow tubular configuration of female carrier 22 to the proximal opening 105.

Referring to FIGS. 23-25, the distal end of shaft 12 is shown in greater detail. Shaft 12 comprises two identical halves 65 and 67 that are preferably injection molded and attached to one another by adhesive bonding or other suitable means of attachment. As noted above, the nest 14 includes a flared cup-shaped receptacle 128 having the distal opening 89 formed in the center therethrough which communicates with second passageway 45. Spaced apart from distal opening 89 of shaft 12 along the surface thereof are opposed shaft windows 120 that each form respective opposing retaining fingers 118. Each retaining finger 118 includes a tang 122 at the free end thereof. Each tang 122 has a protruding portion 123 adapted to engage a respective retaining window 102 when the proximal open end 105 of female carrier 22 is inserted into the second passageway 45 through nest 14. As illustrated in FIGS. 24 and 25, second passageway 45 forms an axial channel with a plurality of guides 130 equally spaced around the circumference thereof for guiding the proximal open end 105 of the female carrier 22 into the passageway 45. The guides 130 are adapted to engage the respective second carrier raceway 112 of female carrier 22 so that the carrier 22 slides into the second passageway 45 until the tangs 122 of the retention fingers 118 engage the retaining window 102 of female carrier 22, thereby retaining the proximal open end 105 of the female carrier 22 inside shaft 12 while the distal open end 107 thereof extends out from passageway 45.

As the female carrier 22 is inserted into second passageway 45, the drawbar 16 disposed therein is concurrently inserted through the female carrier channel 110 of female carrier 22. Drawbar 16 forms a cross-bar

configuration having first, second, third and fourth axial channels 148, 150, 152 and 154 that extend the length of drawbar 16. In order to engage the connectors 88 of collet 28, the free end of drawbar 16 includes a cross bar 132
5 having four wings 134 with beveled edges adapted to engage the connectors 88 and prevent disengagement therefrom when drawbar 16 is pulled into second passageway 45, as shall be discussed in greater detail below. Spaced apart from cross bar 132 along drawbar 16 and positioned in each channel
10 148, 150, 152 and 154 is a stop 124 provided for preventing the connectors 88 of collet 28 from being inserted too far down the drawbar 16 when the collet 28 is engaged thereto.

During manufacturing, collet 38 is pre-loaded to the male carrier 24 by inserting collet 28 through male carrier
15 24 so that the wedge 84 of collet 28 is placed between the plurality of legs 60 of carrier 24, thereby biasing apart the legs 60. Prior to inserting collet 28 through male carrier 24, male member 20 is attached to the distal end of the male carrier 24, so that each retaining jaw 64 formed at
20 the free end of each leg 60 is advanced through aperture 32 formed in dome 30 of male member 20. Once plurality of legs 60 are advanced through aperture 32 so that the retaining jaws 64 engage the peripheral area around the aperture 32, the wedge 84 of collet 28 is then inserted through the
25 carrier channel 76 of male carrier 24 until the retaining ridge 100 formed around the circumference of wedge 84 engages bump 63 formed opposite of each retaining jaw 64, thereby biasing apart legs 60. A biasing means 26, for example a garter spring, is received inside each retaining
30 jaw 64 so as to provide a counter force that locks the wedge 84 between the legs 60, thereby locking the male member 20 to the distal open end 59 of male carrier 24.

Referring to FIGS. 28-35, the method for using the anastomosis device 10 will be discussed. During a surgical

procedure for joining two severed halves of hollow body organs, such as intestines, the proximal open end 105 of female carrier 22 is inserted into the second passageway 45 of shaft 12 until the retaining fingers 118 engage the retaining windows 102 of shaft 12, thereby pre-loading the carrier 22 to shaft 12. Once the female carrier 22 is pre-loaded to the shaft 12, carrier 22 is inserted through the aperture 54 of female member 18 until the dome 48 thereof is seated in nest 14. Once the female member 18 is seated a protective cover 138 is inserted over the distal open end 107 of female carrier 22 in order to protect the patient during insertion of the anastomosis device 10 through the rectum.

FIG. 34 shows the preferred embodiment of the protective cover 138. Cover 138 comprises a cover body 140 having a bullet-shaped configuration that forms an interior cavity 140 with an opening 144 adapted to receive and retaining the distal open end 107 of female carrier 22. A plurality of axially extending retaining guides 146 are formed on the interior surface of cavity 140 for guiding the distal end of female carrier 22 and retaining carrier 22 therein. FIG. 35 shows an alternative embodiment of the protective cover 138, designated 238, is similar to the preferred embodiment discussed above except the cover 238 includes a cover body 254 that has a plurality of scallops 256 formed on the exterior surface thereof to assist the user in gripping the cover 238.

In a surgical procedure to anastomosis two hollow body organs together, the surgeon first makes an abdominal opening by making an incision in the abdominal area of a patient in order to access the bowel region. The surgeon then severs the diseased portion of the bowel into a lower and an upper bowel sections (not shown), respectively, and cleans the respective edges of the severed bowel of any remaining diseased portions in order to ensure that only

healthy tissue is to be anastomosed. Once the free ends of each bowel section have been cleaned, the surgeon inserts the pre-loaded male carrier 24 through the abdominal opening and secures the free end of the upper bowel section around the outer edge 49 of male member 20 in a contiguous manner using a purse string stitch that utilizes suitable absorbable sutures known in the art such as, but not limited to coated or uncoated polyglycolic acid suture. Once the upper bowel section has been secured, the surgeon inserts the distal end of shaft 12 of anastomosis device 10 into the rectum and through the bowel region until the distal end of shaft 12 appears through the lumen of the lower bowel section. The surgeon then secures the free end of the lower bowel section around the outer edge 55 of female member 18 using the same purse string stitch as described above.

After the lower bowel section is properly secured to the female member 18, the surgeon attaches the male carrier 24 to the female carrier 22 already attached to the drawbar 16 of shaft 12. The attachment of the two carriers 22 and 24 is accomplished by engaging the connecting members 74 of the male carrier 24 to the connecting slots 104 of female carrier 22 in secure engagement thereto, thereby placing the BAR carrier assembly 11 in the open position, as illustrated in FIGS. 28 and 29. Further, when male carrier 24 is attached to the female carrier 22, the connectors 88 of collet 28 have already been attached to cross bar 132 of drawbar 16, so that the collet 28 can release the male member 20 at the appropriate time when the device 10 is actuated and drawbar 16 is extended axially away from shaft 12 in order to release the female member 18 and male member 20 from the BAR Carrier Assembly 11, as shall be discussed in greater detail below.

Referring to FIGS. 30 and 31, the closed position of the BAR carrier assembly is shown. After the male member 20 is locked to the BAR carrier assembly 11 by collet 28 and is

placed in the open position, the surgeon then actuates anastomosis device 10 so as to place the assembly 11 in the closed position and mate the male member 20 to the female member 18. In order to place the BAR carrier assembly 11 in the closed position, the surgeon rotates the knob 15 in a clockwise direction, thereby rotating the rod member 23 in an axial direction toward knob 15. This axial movement of the rod member 23 toward knob 15, releases the female carrier 22 from engagement with retaining fingers 118 of shaft 12, so that the carrier 22 and male carrier 24 are pulled into the second passageway 45 of the anastomosis device. This movement of the carriers 22 and 24 into the second passageway 45 concurrently causes the male member 20, which is attached to the male carrier 24, to move towards, and eventually mate with, the female member 18.

Referring to FIG 31, a cross-section view of the male member 20 fully mated to the female member 18 with the BAR carrier assembly 11 in the closed position is illustrated. As the male carrier 24 is pulled into the second passageway 45, the pawl 52 of each mating prong 50 of female member 18 eventually engages the respective slot 38 formed in the tubular member 34 of the male member 18, thereby mating the two members 18 and 20 in a unitary structure.

Referring to FIGS. 31A-31C, the mating sequence between the female and male members 18 and 20 is illustrated. In FIG. 31A the prongs 52 of female member 18 engage the ring raceway 36 of the tubular member 34 of male member 20 as the two members 18 and 20 begin to mate. FIG. 31B illustrates the prongs 52 beginning to engage the slots 38 of male member 20 while FIG. 31C shows the prongs 52 fully inserted into the slots 38 and the two unitary members 18 and 20 fully mated.

Referring to FIGS. 32 and 33, the BAR carrier assembly 11 is shown in the release position. Once the unitary

members 18 and 20 are mated, the surgeon rotates knob 15 in a counter-clockwise direction so that the drawbar 16 moves in an axial direction away from knob 15. As the drawbar 16, which is engaged to the prongs 86 of the collet 28, moves axially, the wedge 84 is concurrently removed from between the legs 60 of male carrier 24, thereby causing the legs 60 to collapse toward each other as the biasing means 26 forces the legs 60 inward and releases the BAR 19.

Referring to FIGS. 40 and 41, an alternative embodiment of collet 28 is shown and generally designated as 328. Collet 328 is of unitary manufacture and comprises a collet body 380 that includes a drawbar portion 392 formed at one end and a wedge 384 formed at the other end thereof. The drawbar portion 392 includes first, second, third and fourth axial channels 383, 385, 387 and 389 that extend axially along portion 392 and terminate at crossbar 397. Cross bar 397 has a generally cross-bar configuration that forms first, second, third and fourth wings 370, 371, 372, and 373, respectively, at the free end of drawbar 316. Each wing 370, 371, 372, and 373 in combination with an adjacent wing 370, 371, 372, or 373 forms an axially extending wing channel 399 that forms at the free end of drawbar portion 392 and tapers down to a respective channel 383, 385, 387 and 389.

The collet body 380 further comprises a middle portion 396 of generally tubular cross section that is interposed between drawbar portion 392 and a front portion 394. Front portion 394 has a conical member 395 that meets a stem 382 and terminates with a wedge 384 formed at the free end thereof. Wedge 384 is of similar construction as wedge 84 and is used in the similar lock and release arrangement described in the preferred embodiment.

Referring to FIGS. 38-40, an alternative embodiment of drawbar 16 is shown and generally designated as 316. Drawbar

316 comprises two identical halves 315 and 317 which are attached to each other by adhesive bonding or other suitable means of attachment. Each wing 370, 371, 372, and 373 of crossbar 397 is adapted for engagement with drawbar 316.

5 Drawbar 315 includes a proximal end 321 and a distal end 322. As seen in FIG. 43, proximal end 321 includes a pair of rounded ends 313 with a slot 319 formed therebetween and a channel 324 that extends through the proximal end 321 in traverse relation to the axis of drawbar 316. Slot 319

10 extends vertically between the pair of rounded edges 313 and is adapted to receive the free end of shaft member 25. Preferably, shaft member 25 also includes an opening (not shown) that aligns with opening 324 when member 25 is attached to the proximal end 321 of drawbar 316. A pin (not

15 shown) is then inserted through the entire channel 324 and engaged thereto by means well known in the art so that shaft member 25 is secured to the drawbar 316. Alternatively, other means of securing shaft member 25 to the proximal end 321 of drawbar 316 that fall within the scope of the present

20 invention include, but are not limited to, a snap fit attachment, riveting or tongue and groove engagement.

Distal end 322 of drawbar 316 forms a plurality of axially extending connectors 320 that extend away from the free end thereof. Connectors 320 are of similar

25 construction as the connectors 88 disclosed in the preferred embodiment of the collet 28 and are adapted for similar engagement with the drawbar portion 392 of collet 328 when the male carrier 24 is attached to the female carrier 22 by the surgeon when placing the BAR Carrier Assembly in the

30 open position. The construction and structure of the other portions of the insertion device 10 remain unchanged.

It should be understood from the foregoing that, while particular embodiments of the invention have been illustrated and described, various modifications can be made

35 thereto without departing from the spirit and scope of the

invention. Therefore, it is not intended that the invention be limited by the specification; instead, the scope of the present invention is intended to be limited only by the appended claims.

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CLAIMS:

1. A medical device for use in joining of free ends of two tubular members comprising:

first and second ring members, said first and
5 second ring members being securable to a respective free end of each tubular member to be anastomosed,

an insertion device having a distal end and a proximal end, said insertion device adapted for transanally inserting the first of said ring members so that said first
10 ring member extends through one of the free ends of the tubular members,

a carrier assembly attachable to said distal end of said insertion device, said carrier assembly including first and second carriers for attachment and release of said
15 first and second ring members, said first carrier being attachable to said distal end of said insertion device and a distal end of said second carrier including a plurality of axially extending legs, and

said first and second ring members being
20 positionable at first and second predetermined distances from each other;

wherein:

said second carrier being attachable to said first carrier; and

25 the distal ends of the legs being biased radially inward toward one another by application of a radial force to said distal ends thereof, said radial force being applied by a biasing means.

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2. The medical device according to claim 1, wherein said first and second ring members each comprise a dome, each of said domes further comprising an inner periphery that forms an aperture and an outer periphery that forms an outer edge.

3. The medical device according to claim 2, wherein each of said respective domes further forms an interior cavity.

4. The medical device according to claim 1, wherein said first and second ring members are positionable in opposed relation to one another.

5. The medical device according to claim 3, wherein said first and second ring members are positionable in opposed relation to one another so that said interior cavity of each of said respective dome faces the interior cavity of the other.

6. The medical device according to claim 1, wherein when said first and second ring members are positioned at said first predetermined distance, said carrier assembly is in an open position.

7. The medical device according to claim 1, wherein when said first and second ring members are positioned at said second predetermined distance, said carrier assembly is in a closed position.

8. The medical device according to claim 1, wherein when said first and second ring members are positioned at said second predetermined distance, the respective secured free end of each of the tubular members are in contiguous contact with the other tubular member in an anastomotic state.

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9. The medical device according to claim 7, wherein said second carrier comprises a hollow tubular body forming a channel therethrough having distal and proximal open ends thereof, wherein said second carrier further comprises a plurality of axially extending second raceways formed along an exterior of said second carrier, said second raceways adapted for guiding said first ring member toward said second ring member when said carrier assembly is placed in the closed position.

10 10. The medical device according to claim 9, wherein said first carrier comprises a hollow tubular body forming a channel therethrough having distal and proximal open ends thereof, said first carrier further comprises a plurality of axially extending first raceways formed along an exterior surface thereof, said first raceways adapted for guiding the said first ring member towards the second ring member when said carrier assembly is placed in the closed position.

11. The medical device according to claim 9, wherein each of said plurality of legs has a pair of jaws at the free end thereof.

12. The medical device according to claim 11, wherein each said pair of jaws is adapted to receive said biasing means.

13. The medical device according to claim 12, wherein said biasing means is a garter spring.

14. The medical device according to claim 12, wherein said biasing means is an O-ring.

15. The medical device according to claim 1, which further comprises a lock and release for locking said first ring member to said first carrier and subsequently releasing

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said first and second ring members from said carrier assembly after said first and second ring members have been placed in said second predetermined distance from one another.

5 16. The medical device according to claim 15, wherein said lock and release comprises a collet body having a proximal end and a distal end, said distal end of said collet body including an elongated stem with a wedge formed at the free end thereof.

10 17. The medical device according to claim 16, wherein said collet body is adapted for insertion through said proximal open end of said second carrier such that said wedge biases apart said plurality of legs.

18. The medical device according to claim 17, wherein
15 said second ring member is locked in place to said distal open end of said second carrier by placement of said plurality of legs through an aperture of said first ring member and placement of said wedge of said collet body between said plurality of legs, thereby forcing apart said
20 plurality of legs by the presence of said wedge while said biasing means simultaneously applies a counter force that locks said plurality of legs against said wedge.

19. The medical device according to claim 18, wherein
25 said proximal end of said insertion member includes an actuator, said actuator being capable of effecting the release of said second ring member from said second carrier by moving said wedge in an axial direction from between said plurality of legs such that said biasing means collapses said plurality of legs in the absence of said wedge and
30 releases said second ring member.

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20. The medical device according to claim 10, wherein when said first and second ring members are positioned at said first predetermined distance, said carrier assembly is placed in an open position.

5 21. The medical device according to claim 10, wherein when said first and second ring members are positioned at said second predetermined distance, said carrier assembly is placed in a closed position.

22. The medical device according to claim 21, wherein
10 when said carrier assembly is placed in said closed position, said first ring member is mated to said second ring member in such a manner as to collectively form a sphere-like shape with a slot formed along the equator, said slot adapted for receiving thereabout said secured free ends
15 of said tubular member in a contiguous manner.

23. The medical device according to claim 22, wherein said first ring member is mated to said second ring member by guiding said first ring member axially towards said second ring member along said first and second raceways.

20 24. The medical device according to claim 19, wherein said actuator includes a rotatable knob.

25. The medical device according to claim 2, wherein each of said domes, includes a plurality of openings therethrough.

25 26. The medical device according to claim 2, wherein said inner periphery of each of said first and second members forms a bumpy pattern adapted for gripping the secured free ends of the tubular member therebetween.

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27. The medical device according to claim 16, wherein said insertion device comprises an actuator, said actuator being operably connected to a shaft member, said shaft member including a drawbar for operably engaging said proximal end of said collet body in order to release the mated first and second ring members.

28. The medical device according to claim 26, wherein said insertion device further comprises a shaft at said distal end thereof and a handle formed at the proximal end thereof.

29. The medical device according to claim 28, wherein said handle forms a window, said window giving a visual indication of the state of the actuation of said carrier assembly.

30. The medical device according to claim 28, wherein said visual indication of the state of actuation is a color mark.

31. The medical device according to claim 28, wherein said visual indication of the state of actuation is a notch formed through said shaft member, said notch providing a visual indication of the state of actuation by the percentage of said notch that is visible through said window.

32. The medical device according to claim 10, wherein when said carrier assembly is placed in said closed position, said actuator operates to axially pull said first carrier into the distal end of said insertion device until said second carrier is received into said distal end, thereby mating said first and second ring members.

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33. The medical device according to claim 23, wherein said distal end of said insertion device forms a nest, said nest adapted to receive said first ring member.

34. The medical device according to claim 32, wherein
5 to mate said first and second ring members, said first ring member is disposed in said nest and said second ring member is driven axially towards said first ring member along said first and second carriers until said first ring member mates with said second ring member.

SMART & BIGGAR
OTTAWA, CANADA

PATENT AGENTS

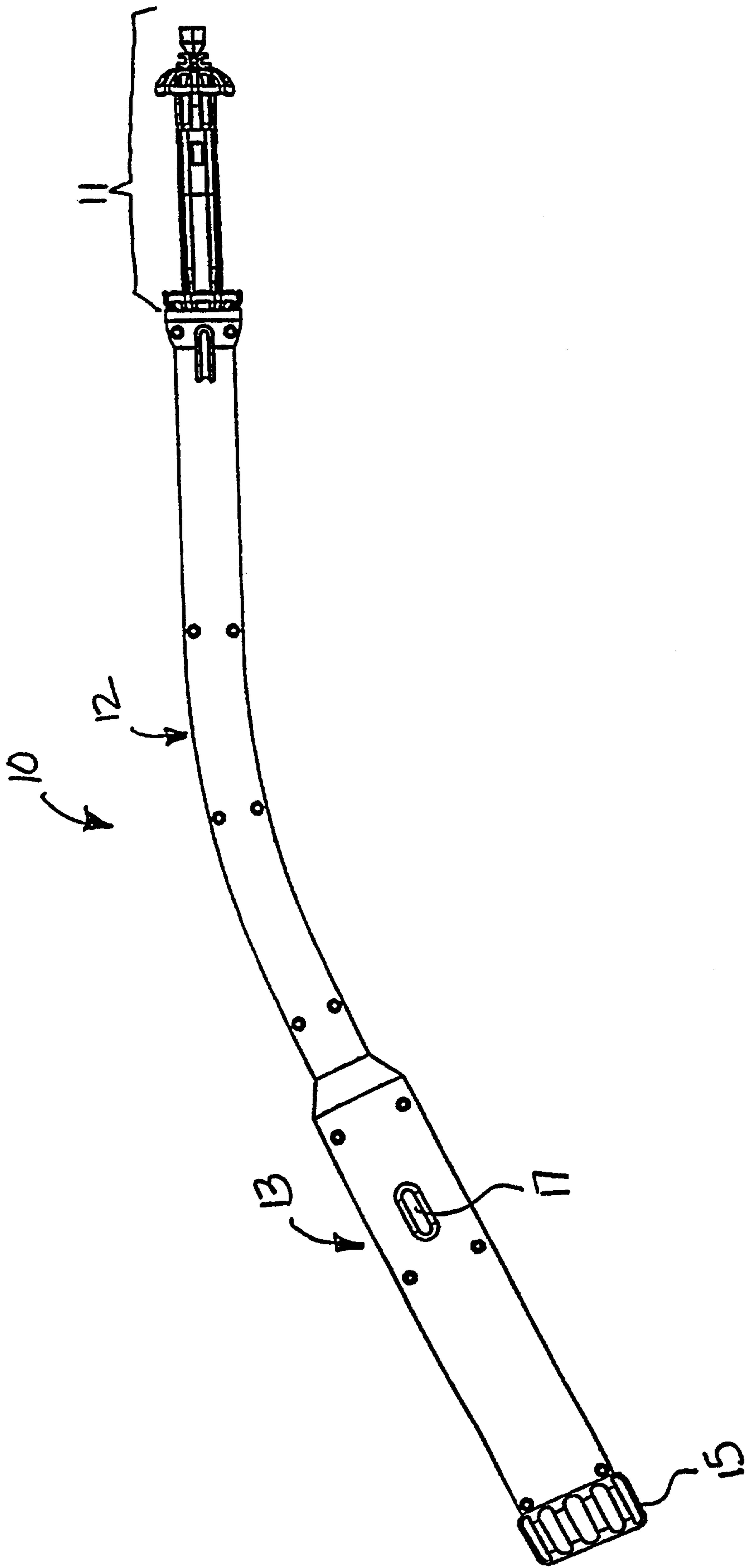


FIG. 1

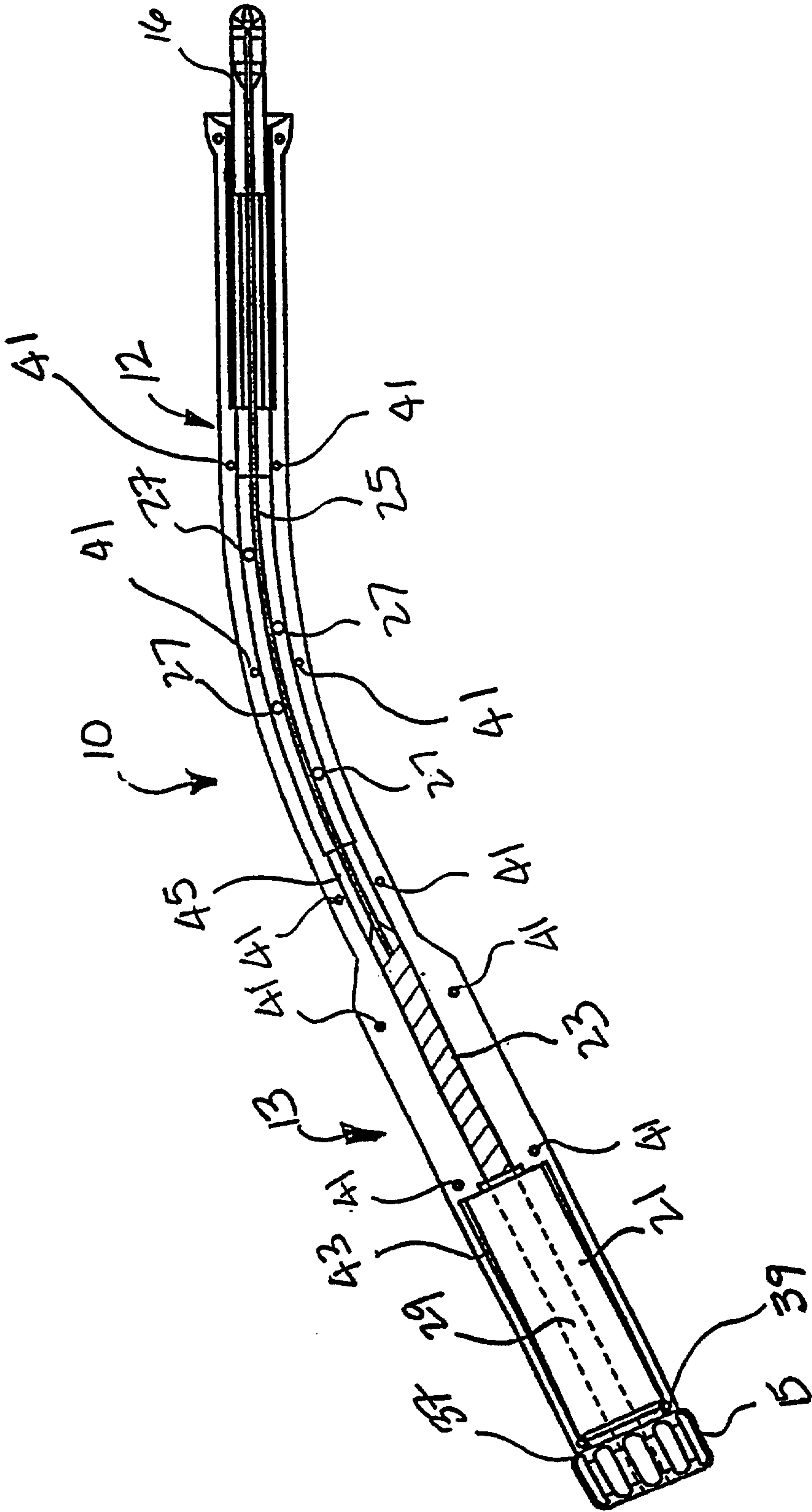


FIG. 2

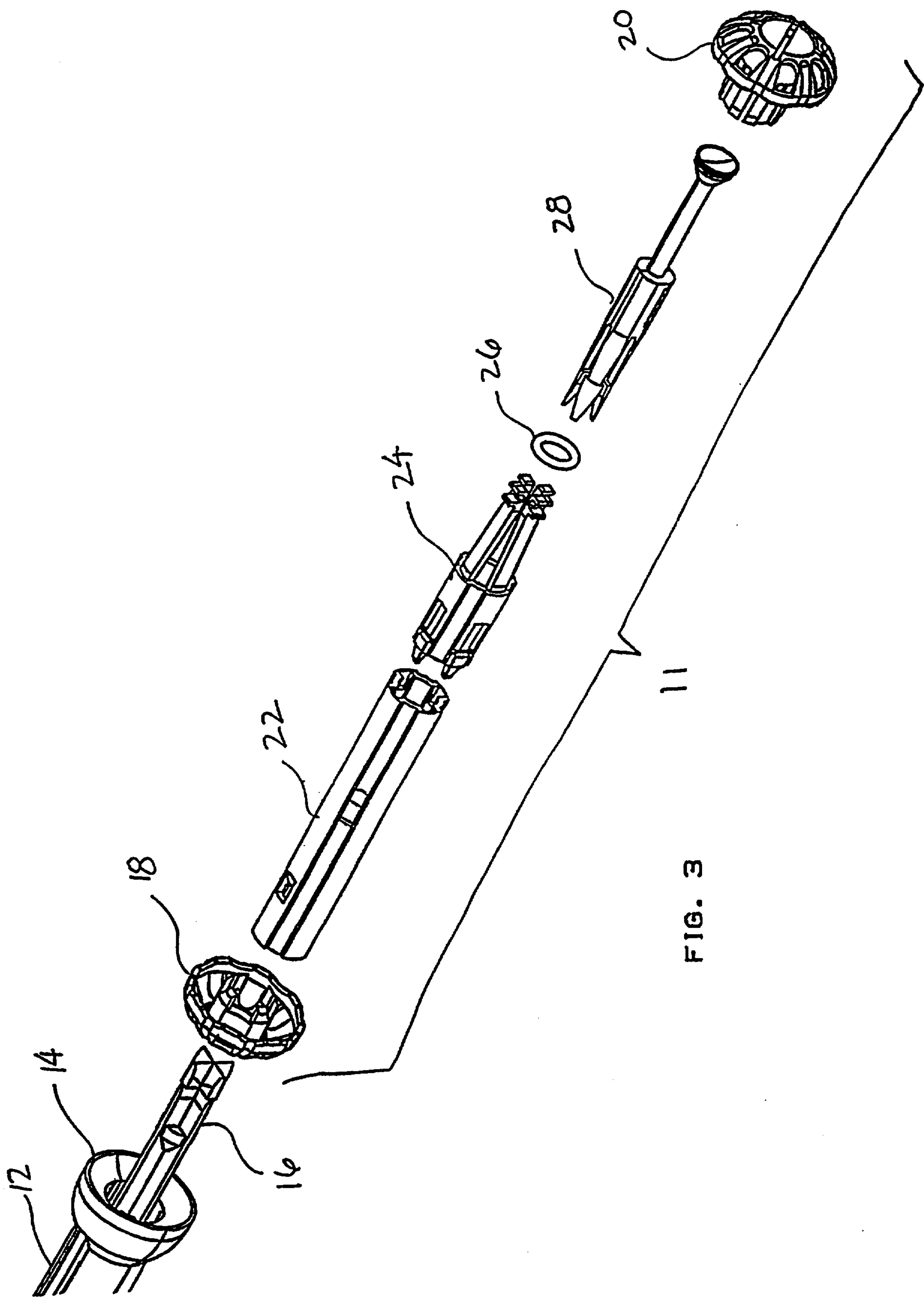
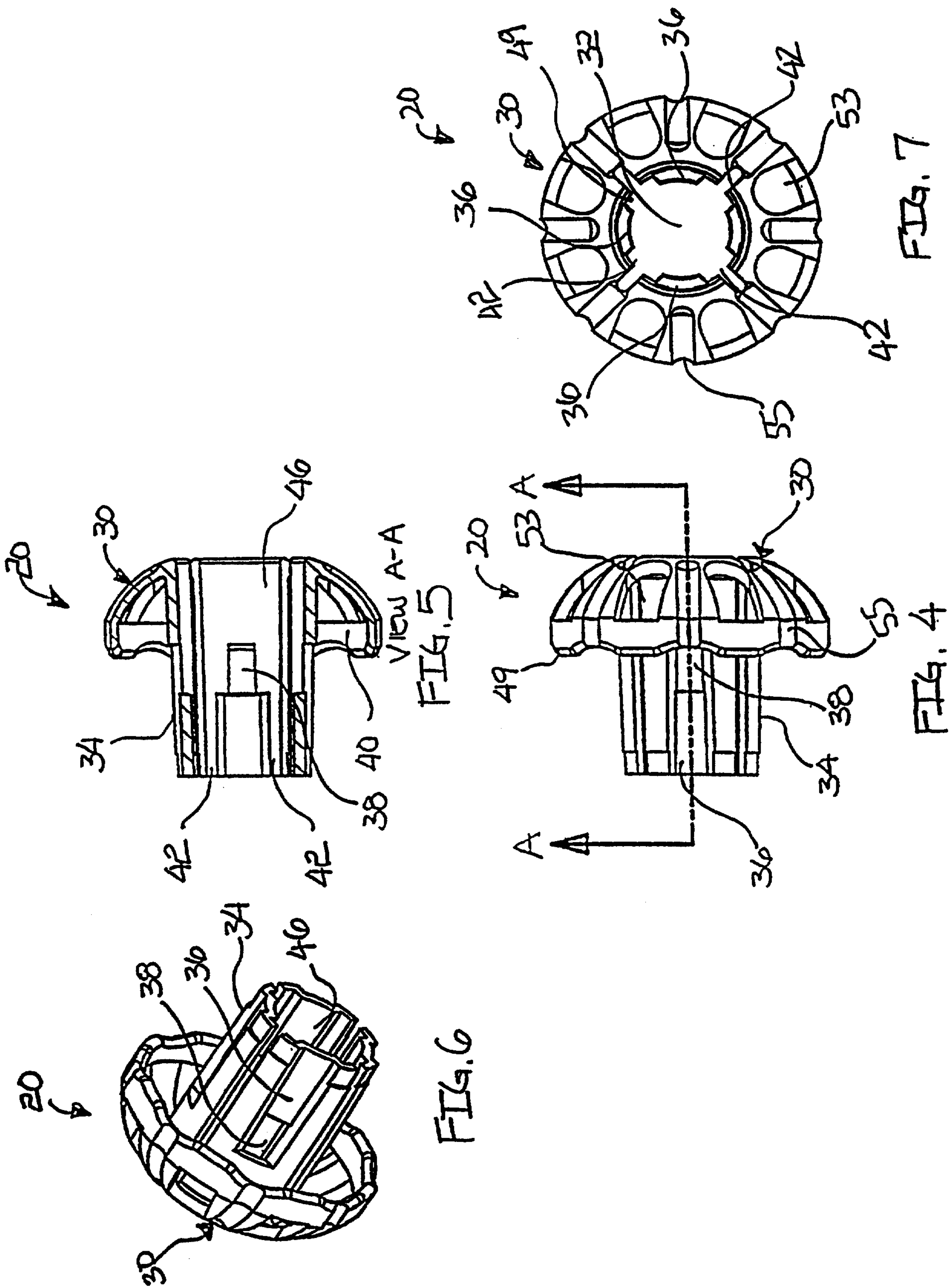
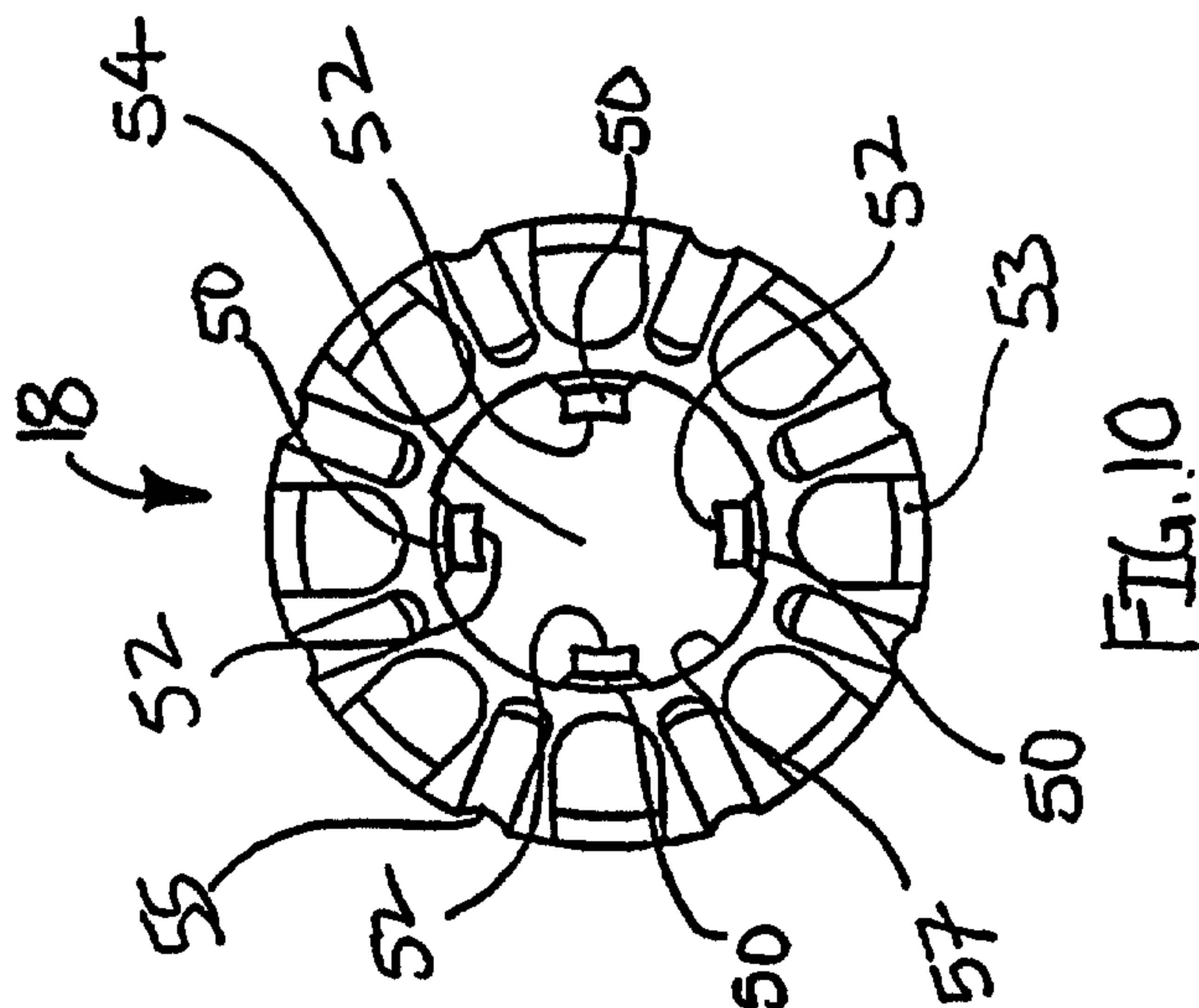
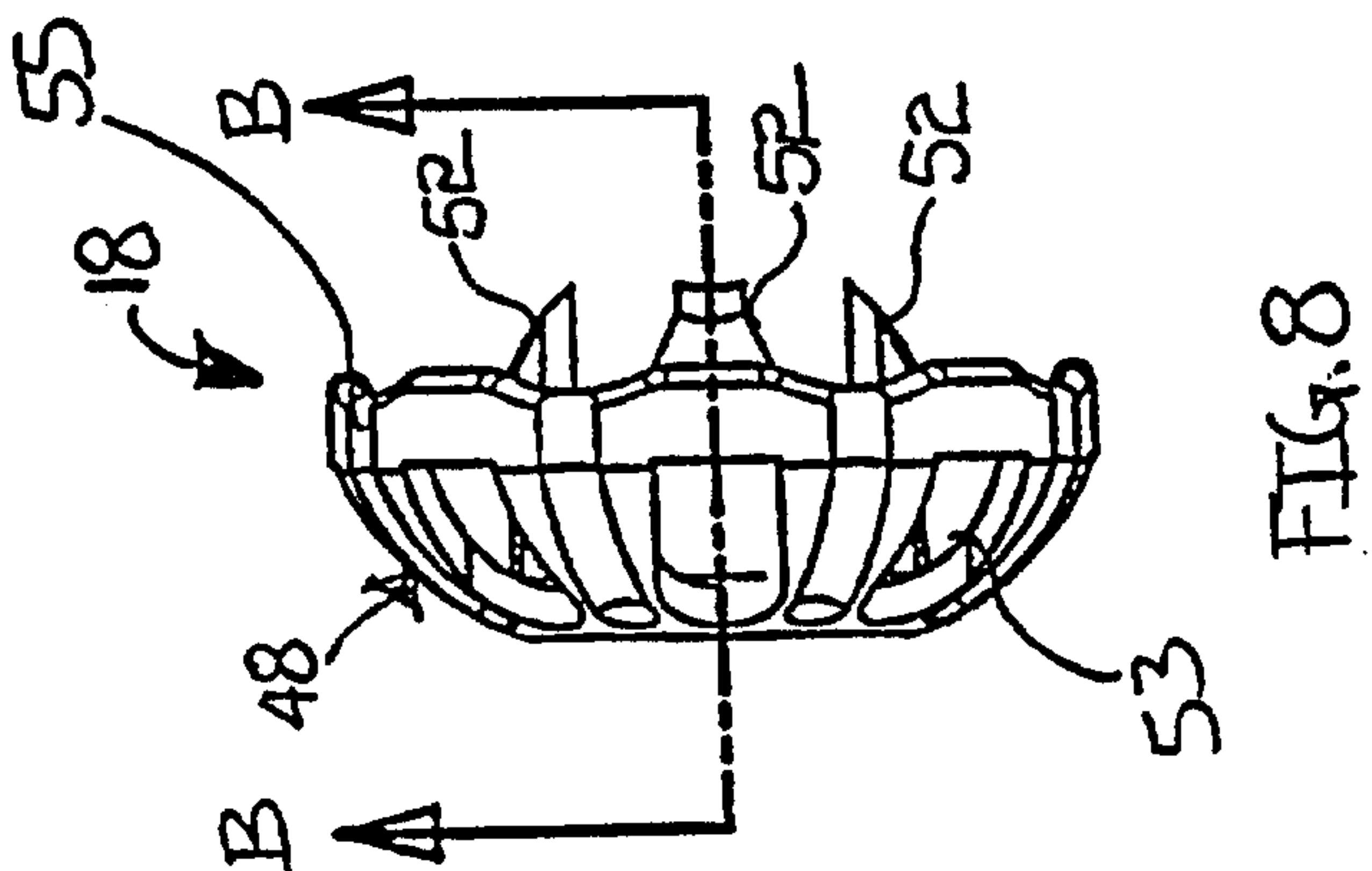
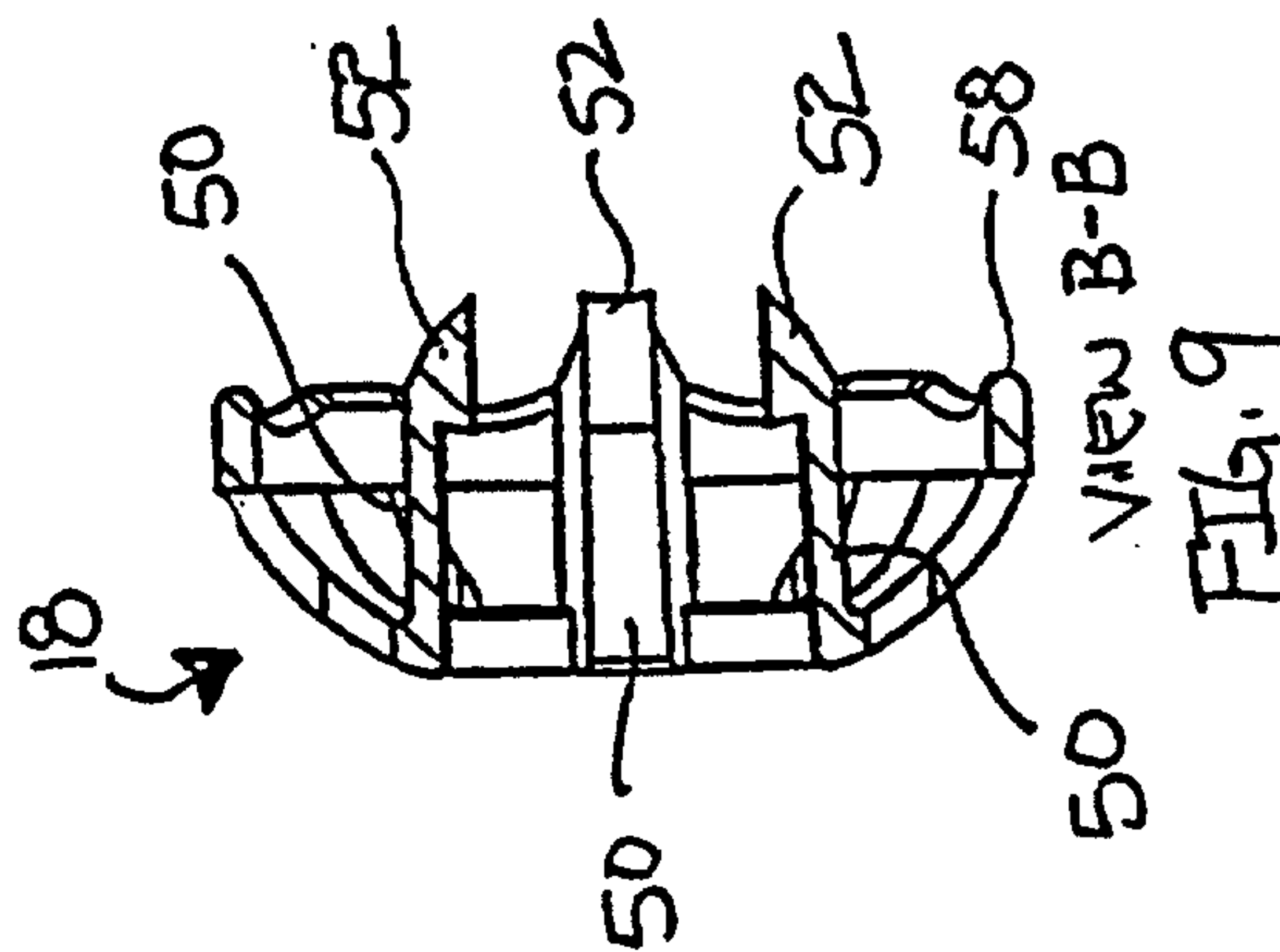
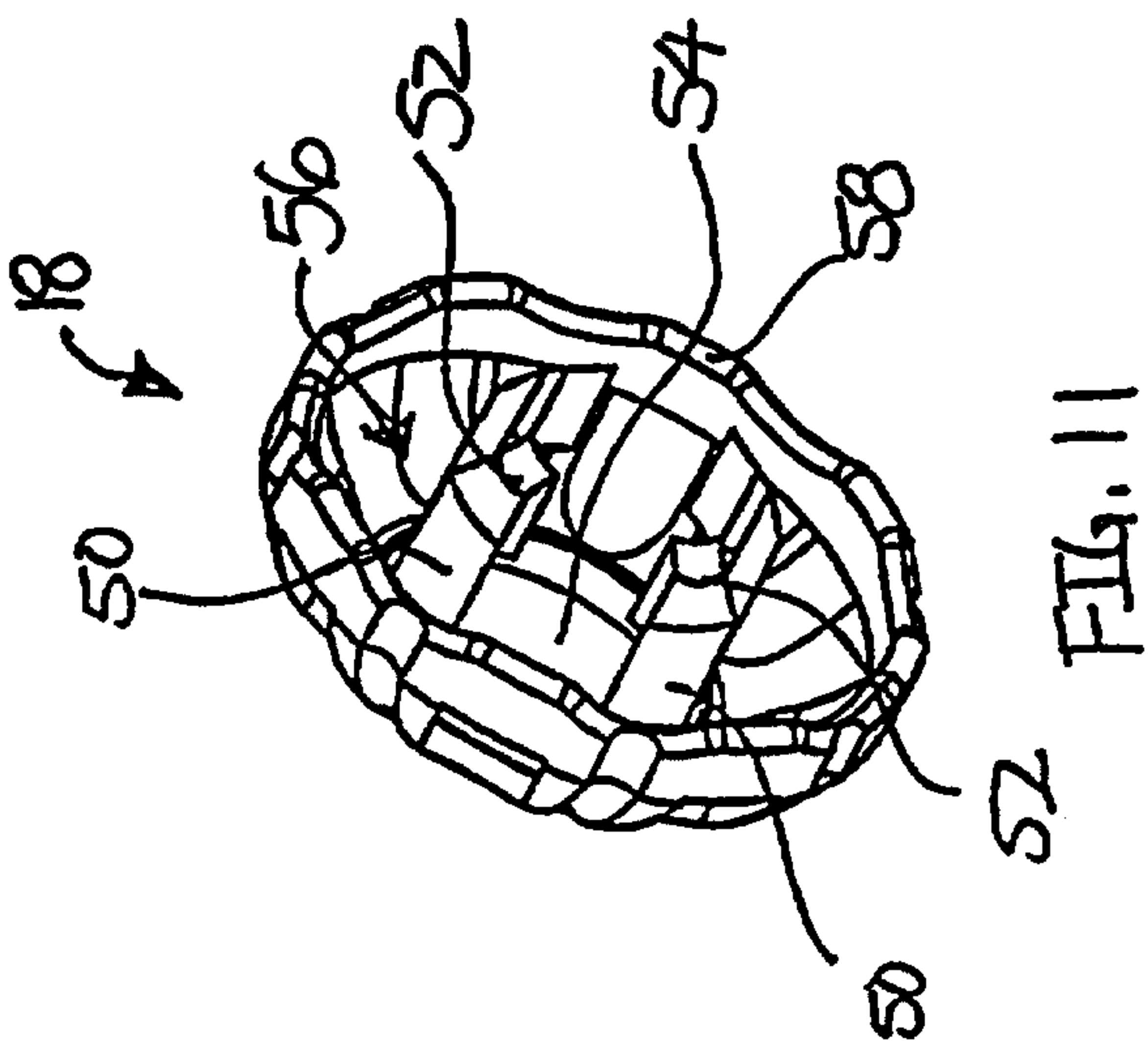
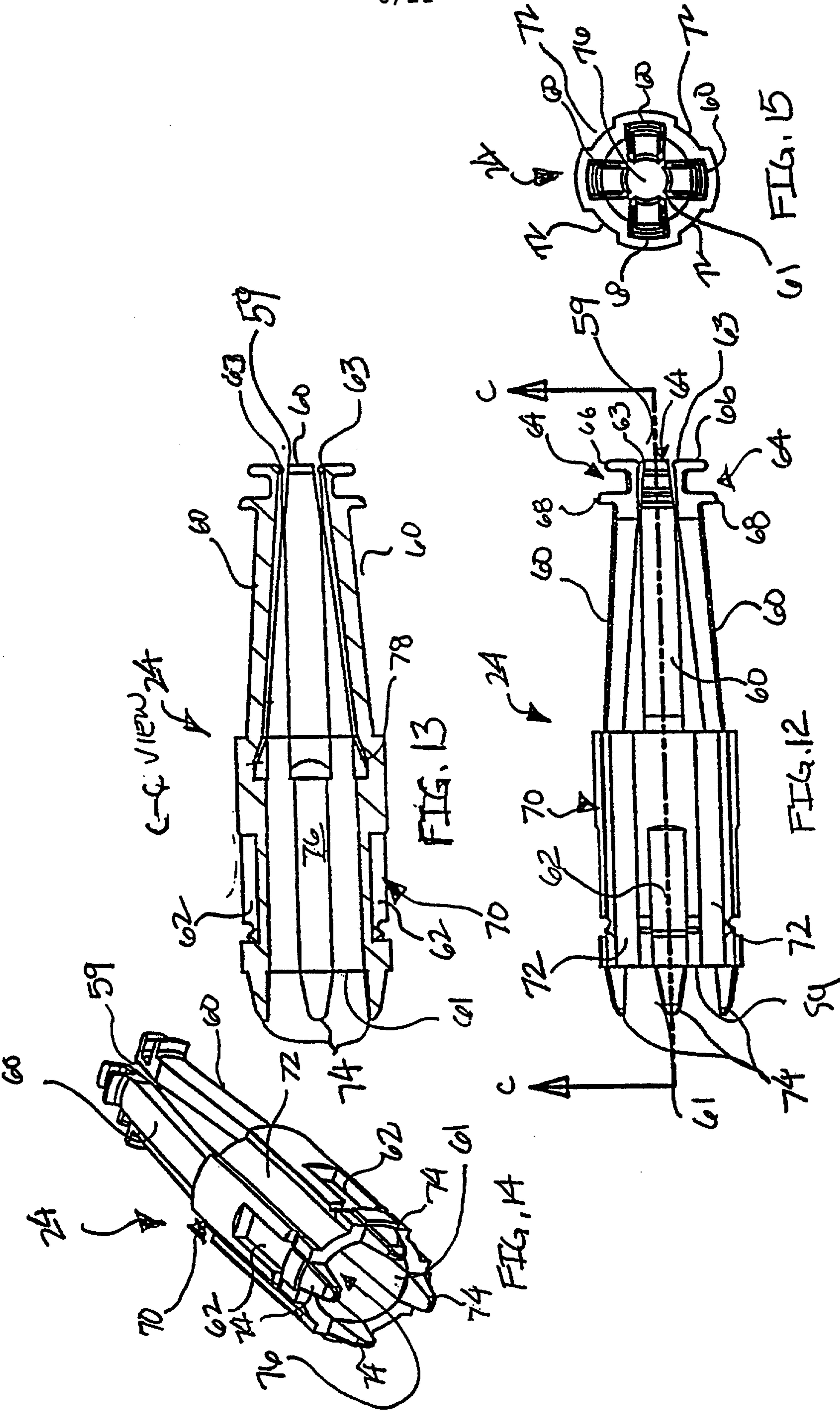


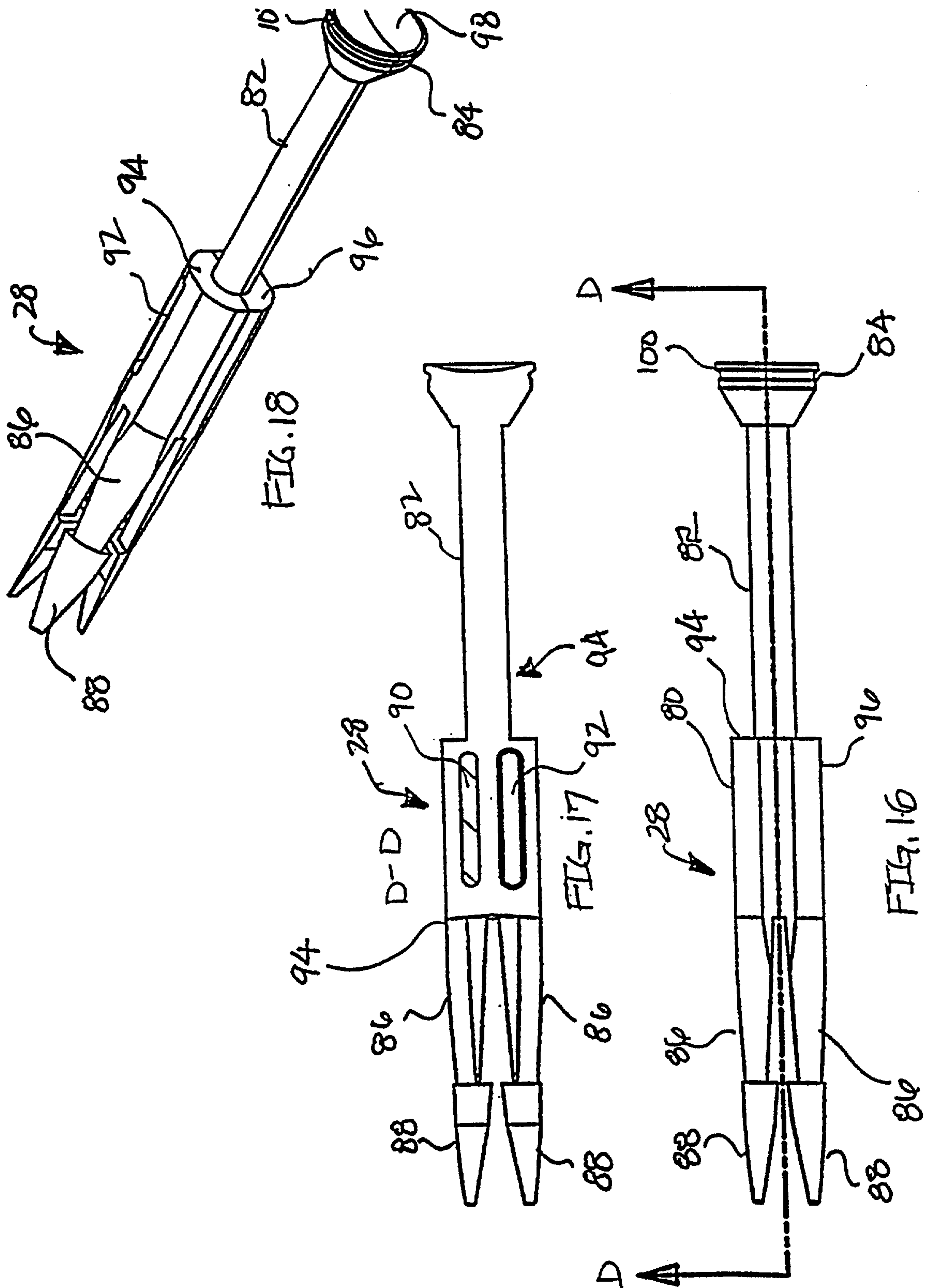
FIG. 3



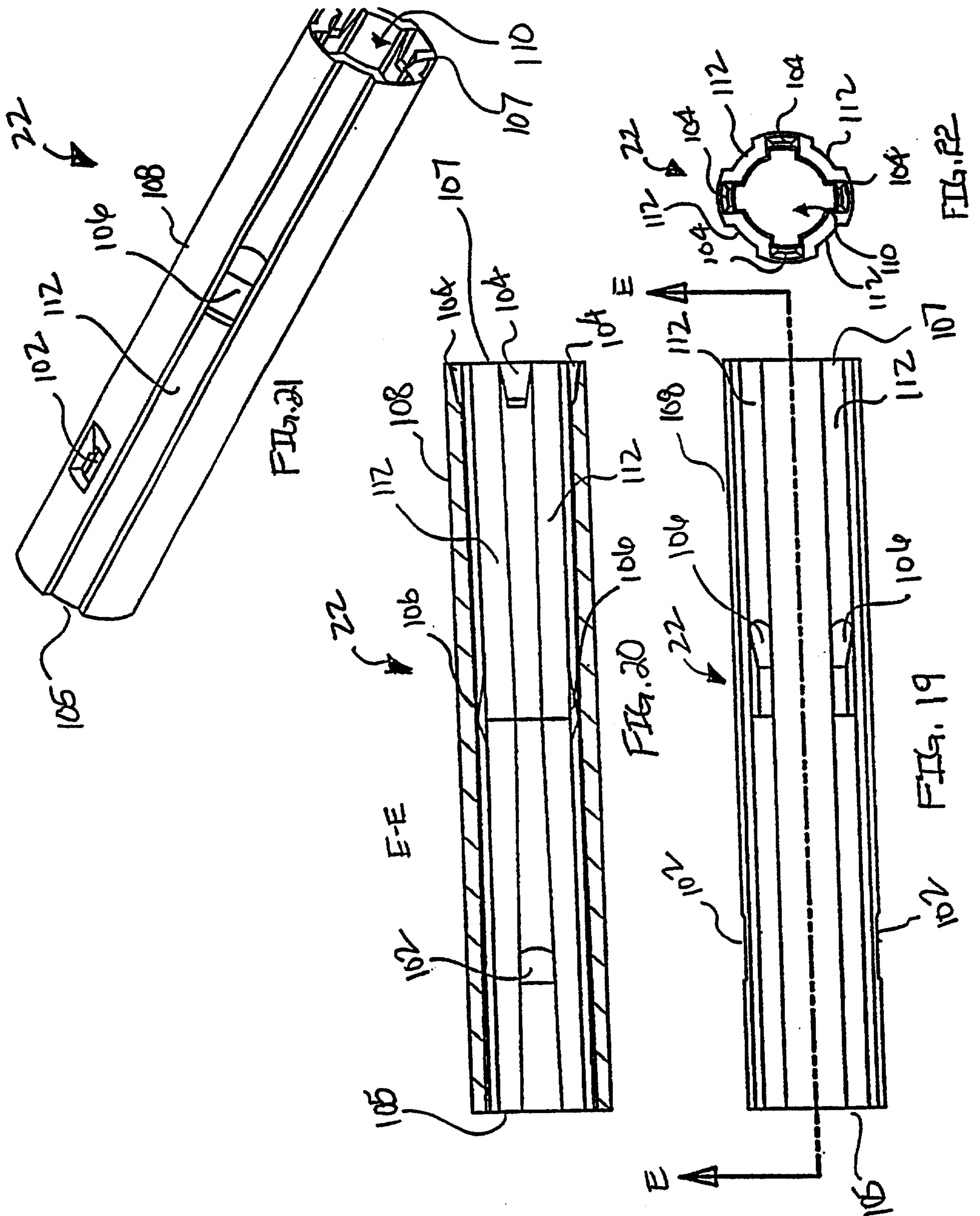


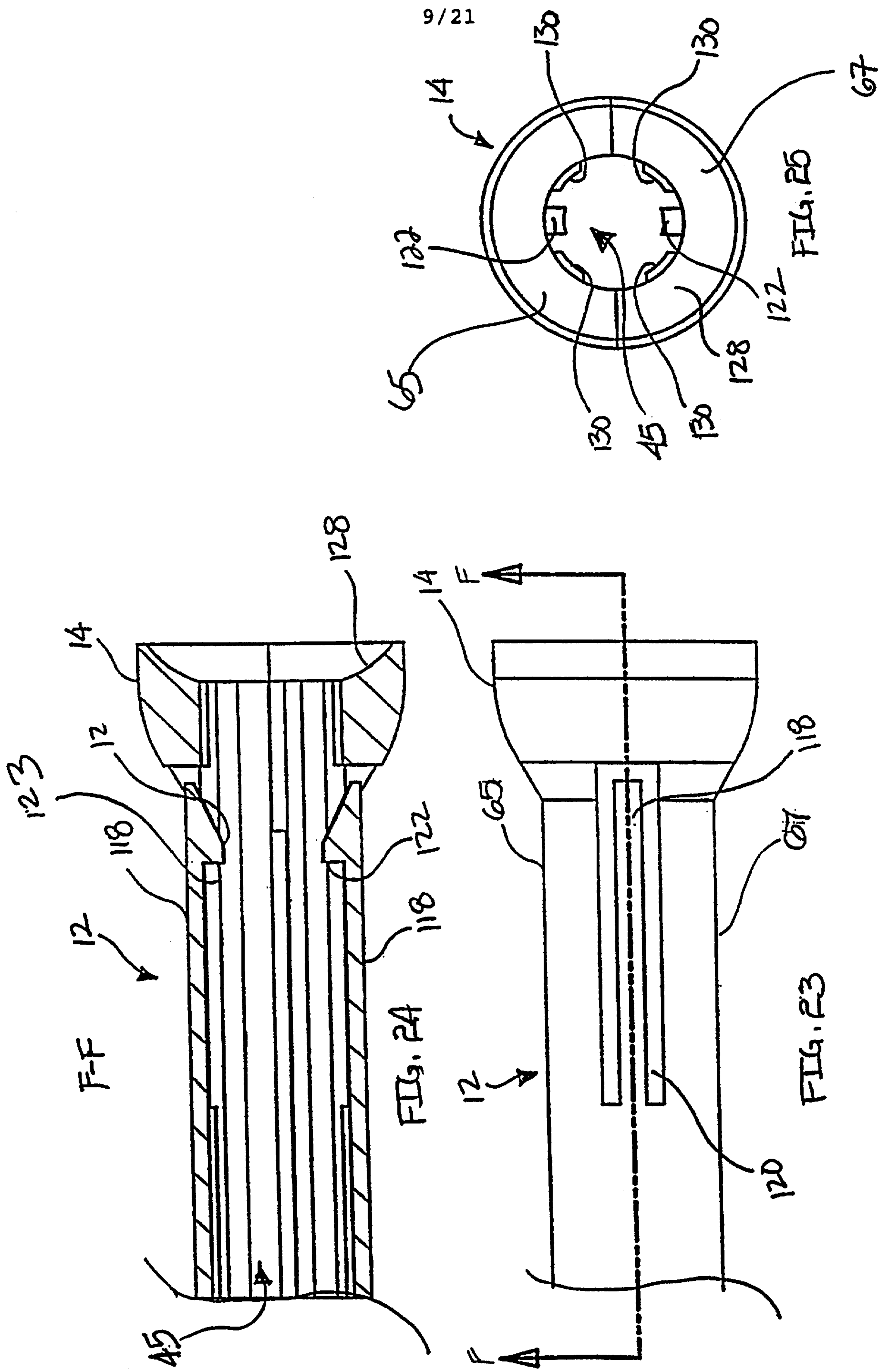


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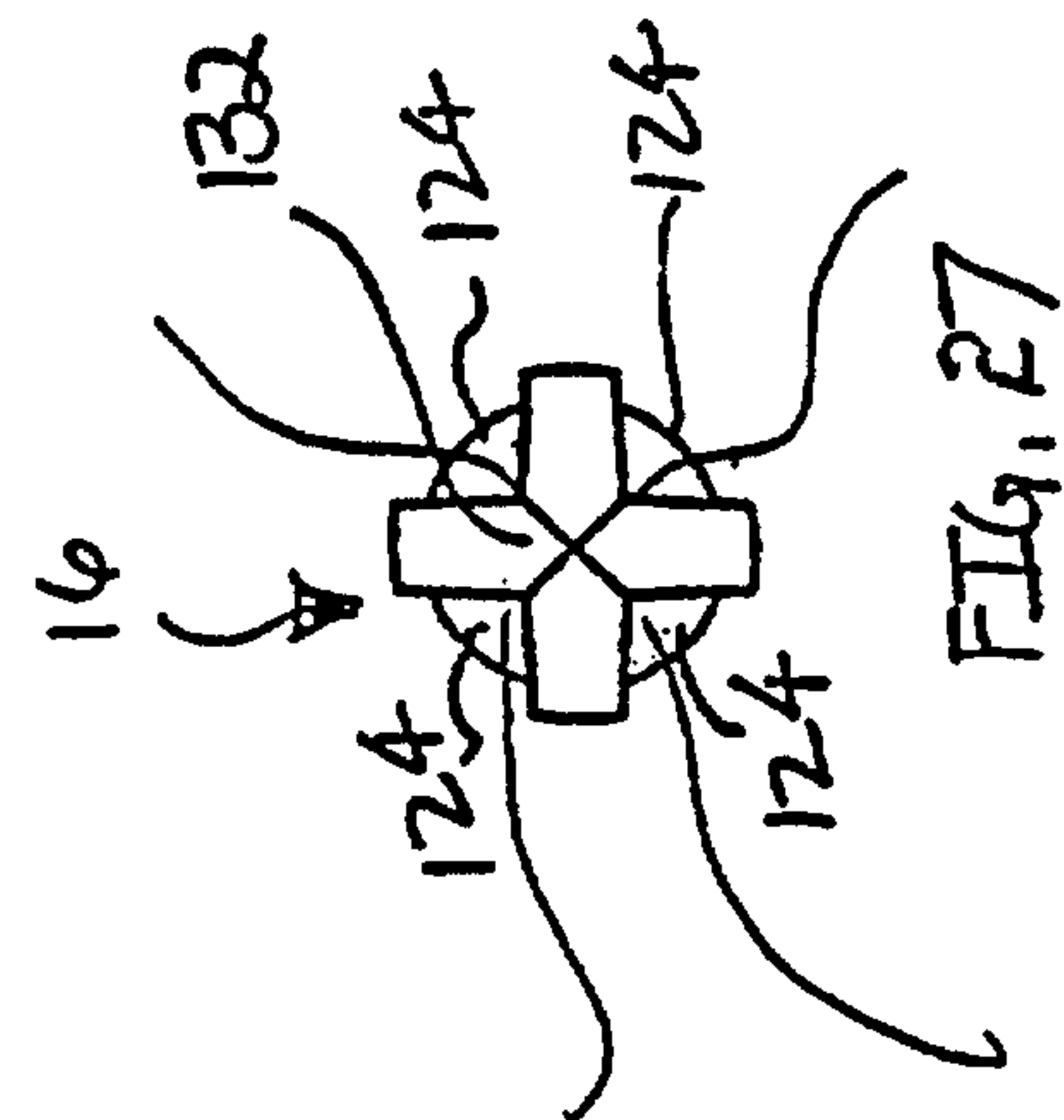
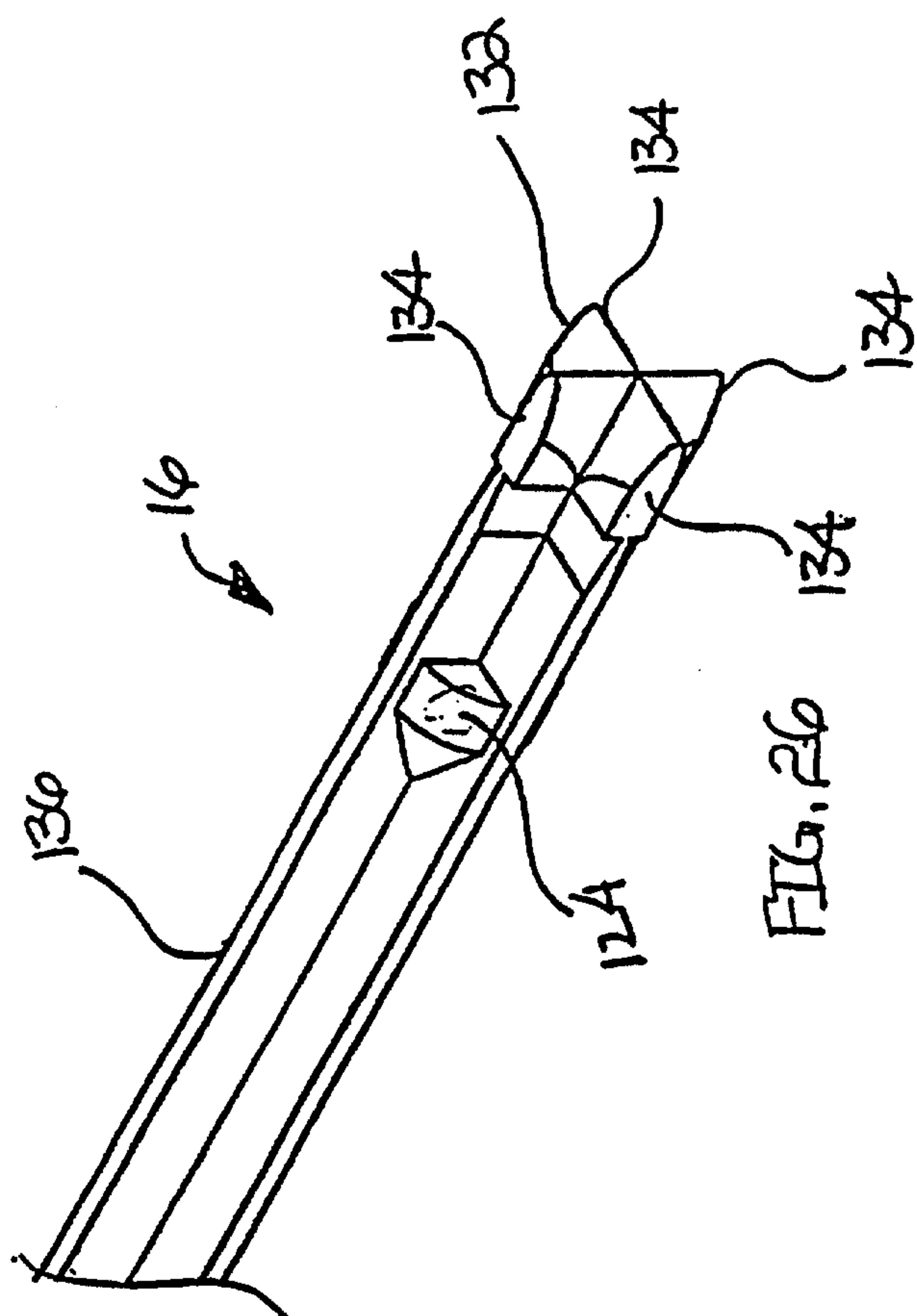


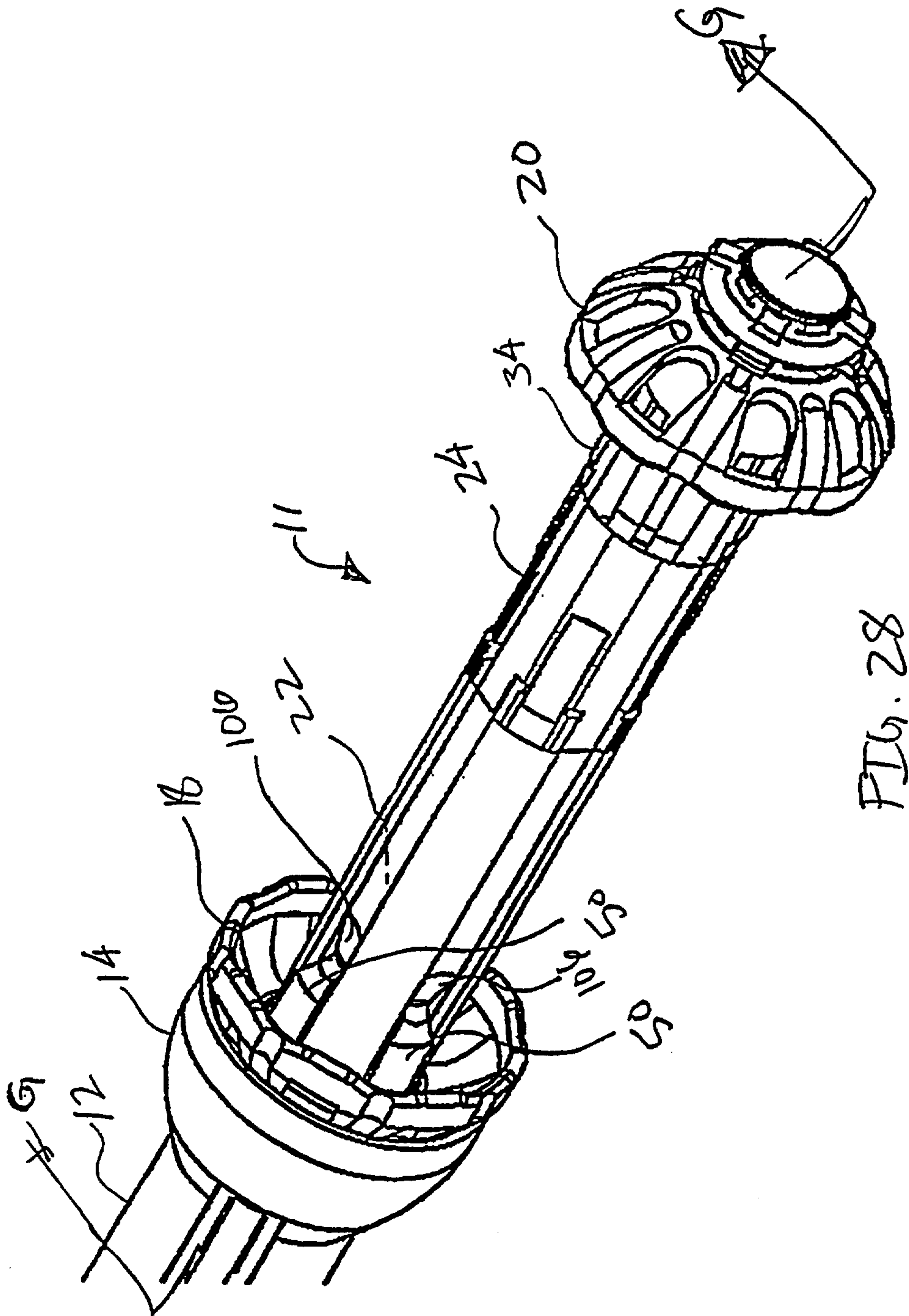
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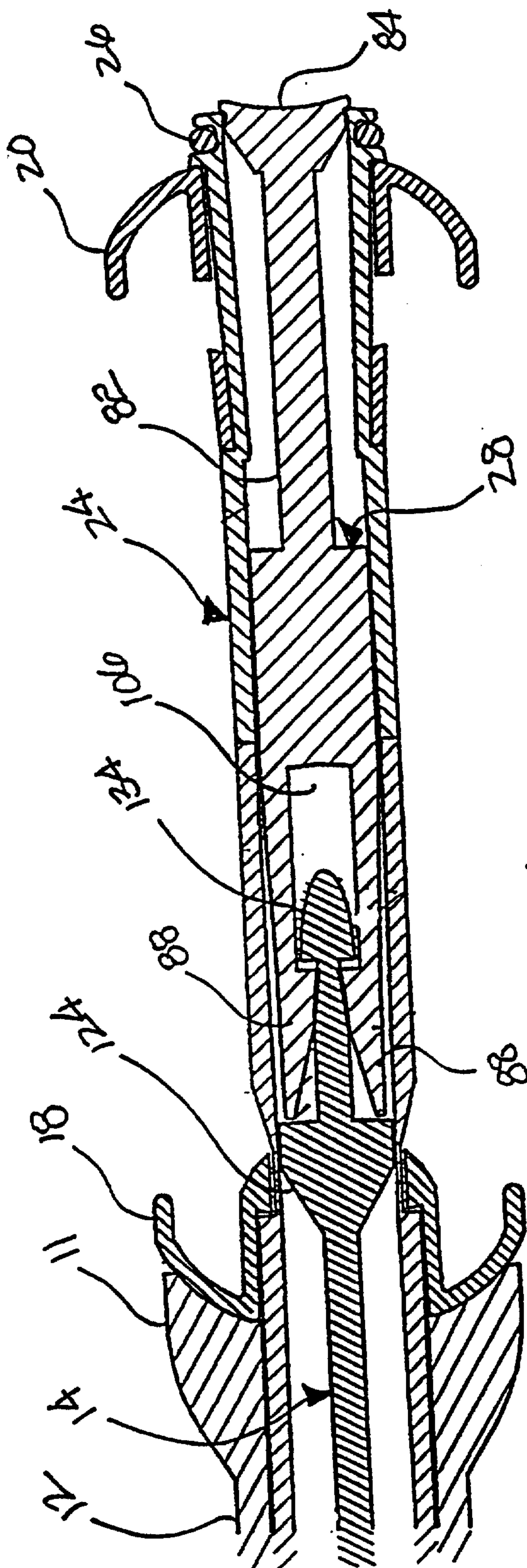
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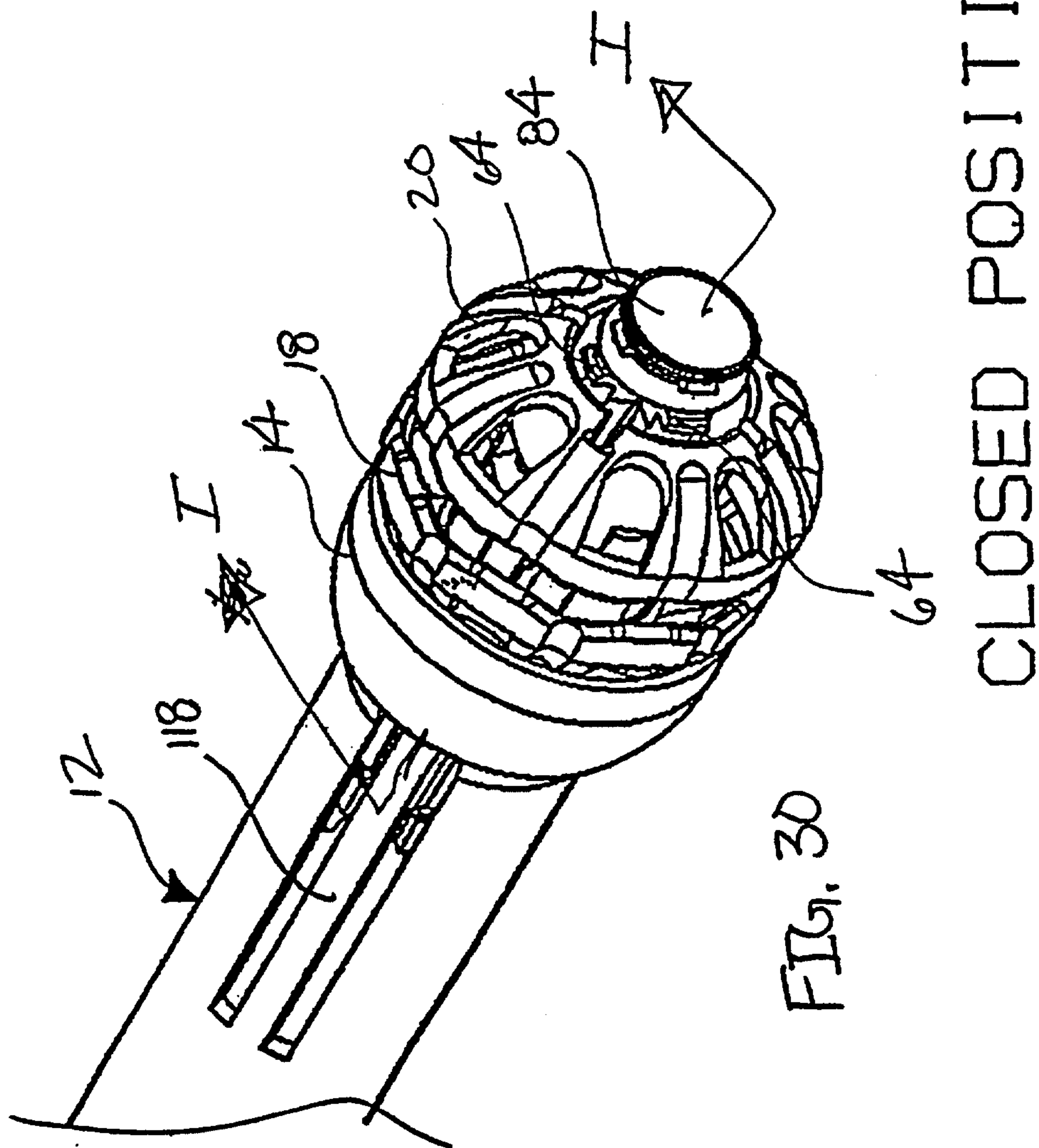
OPEN POSITION

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6-6

FIG. 29



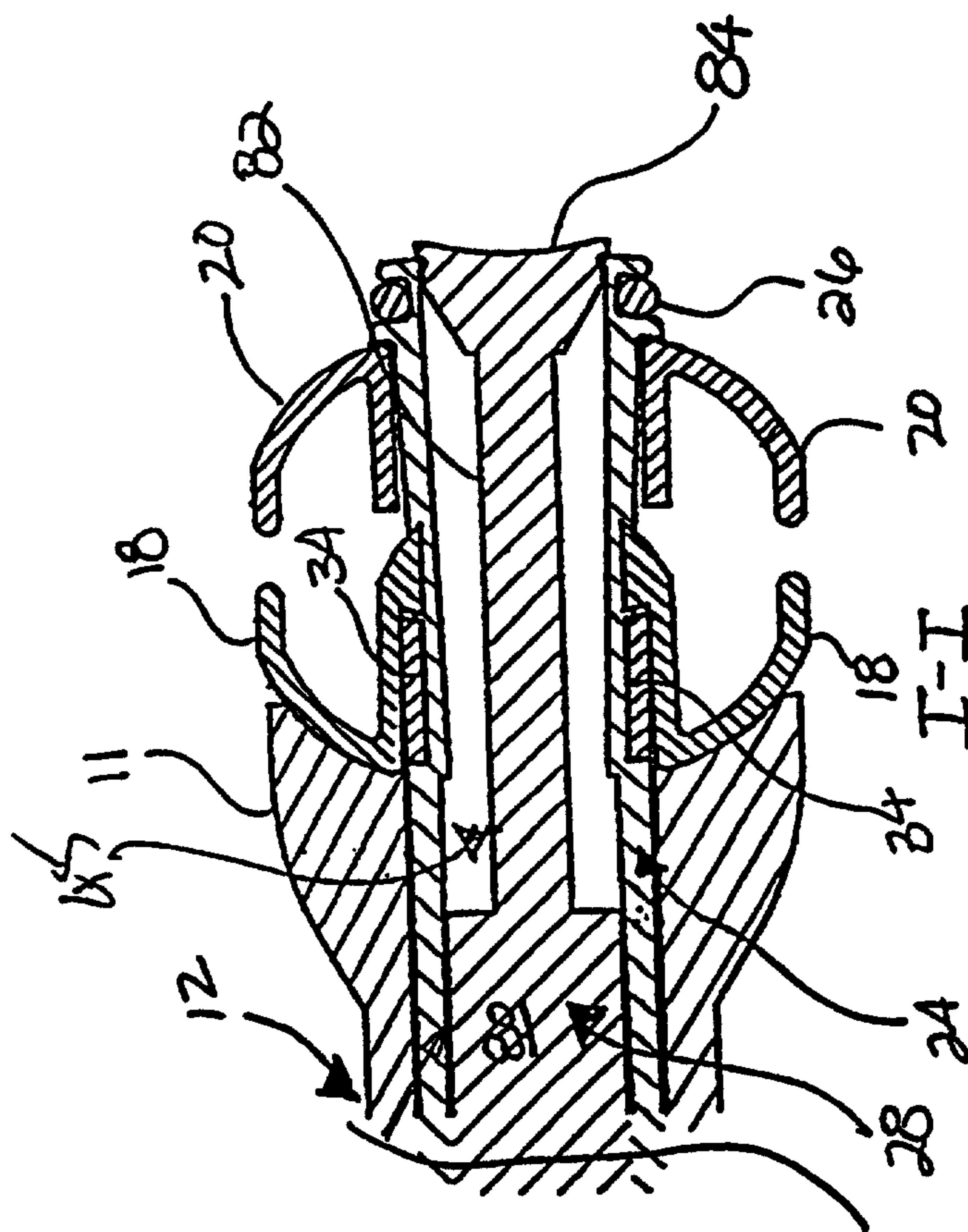
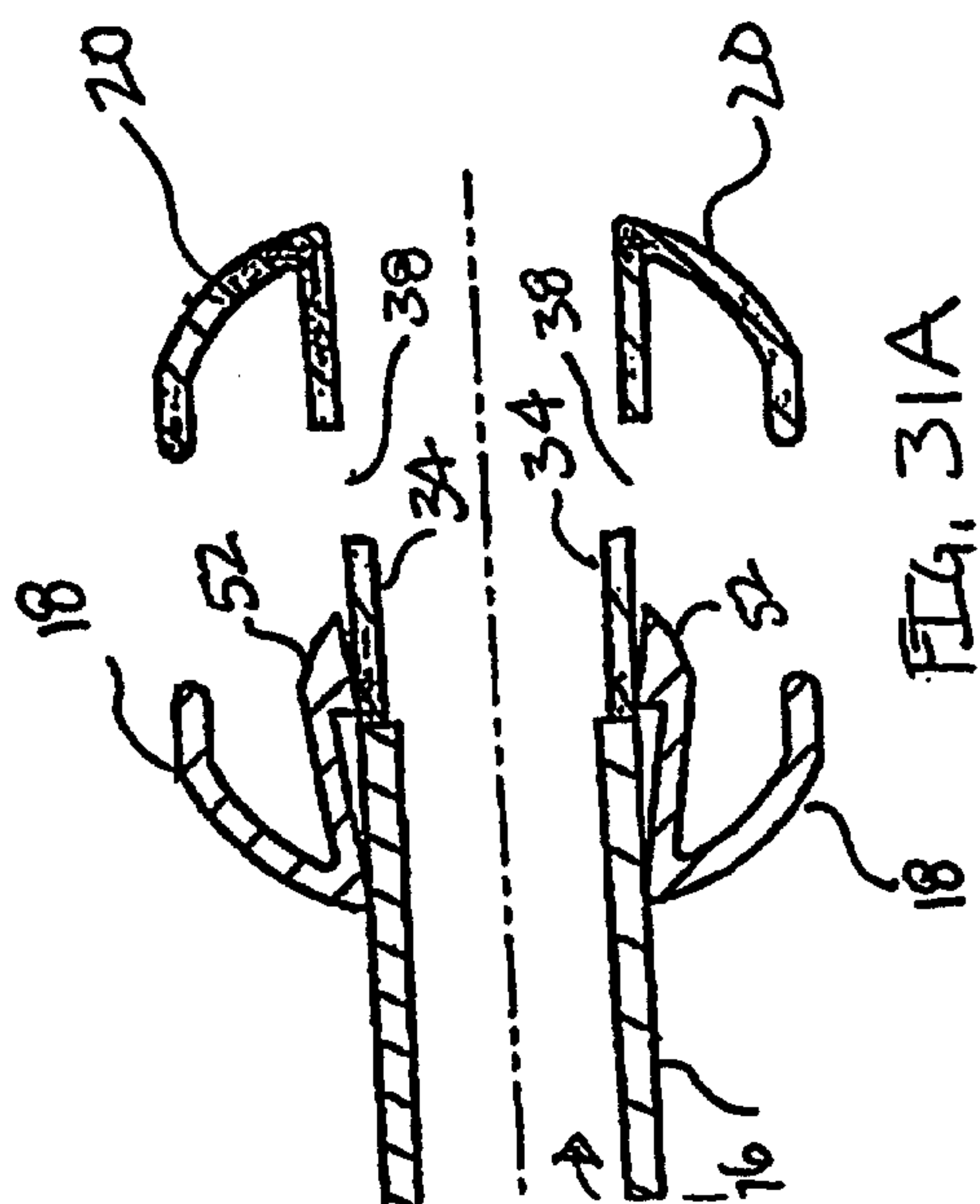
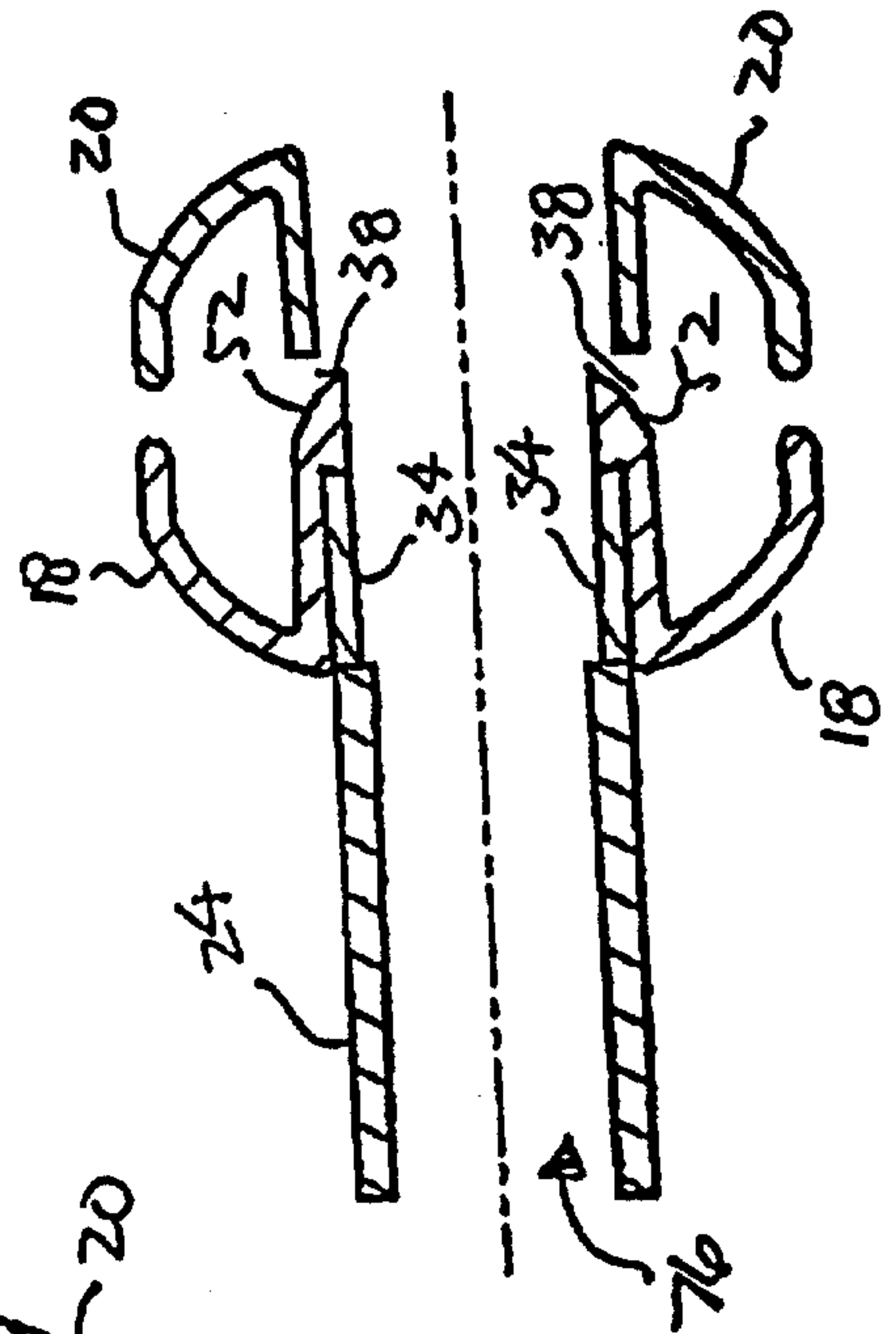
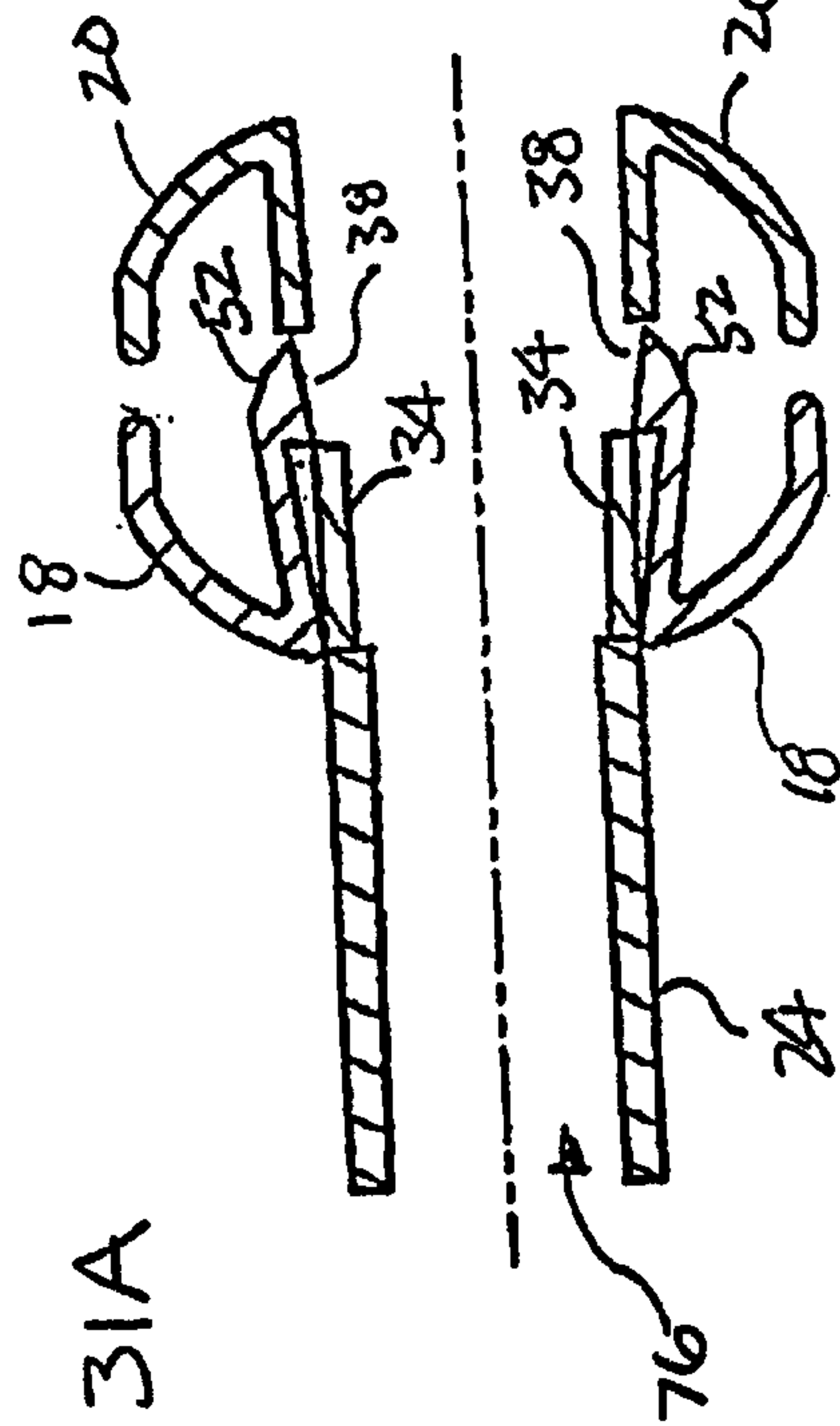


FIG. 31



MATING SEQUENCE



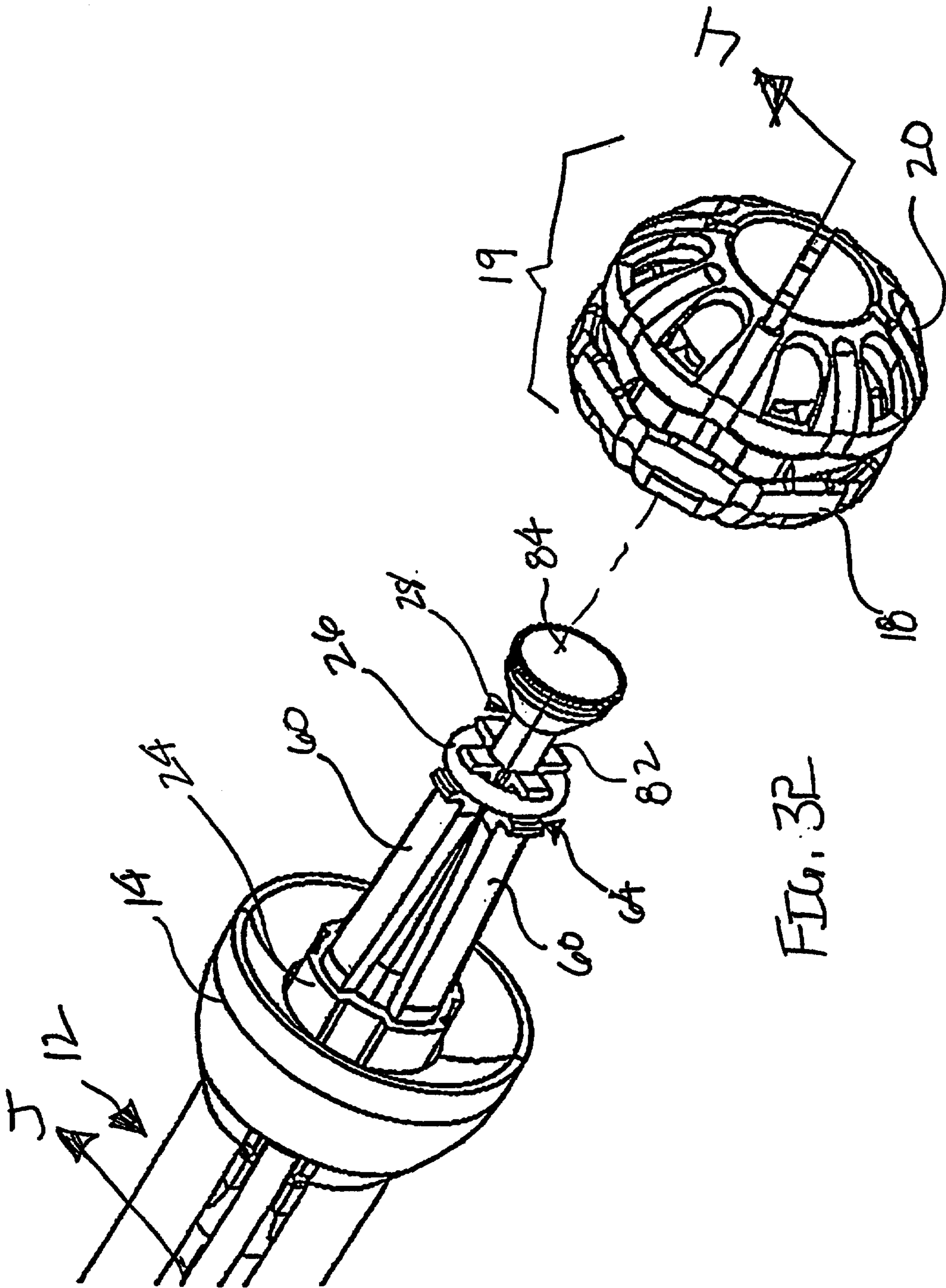
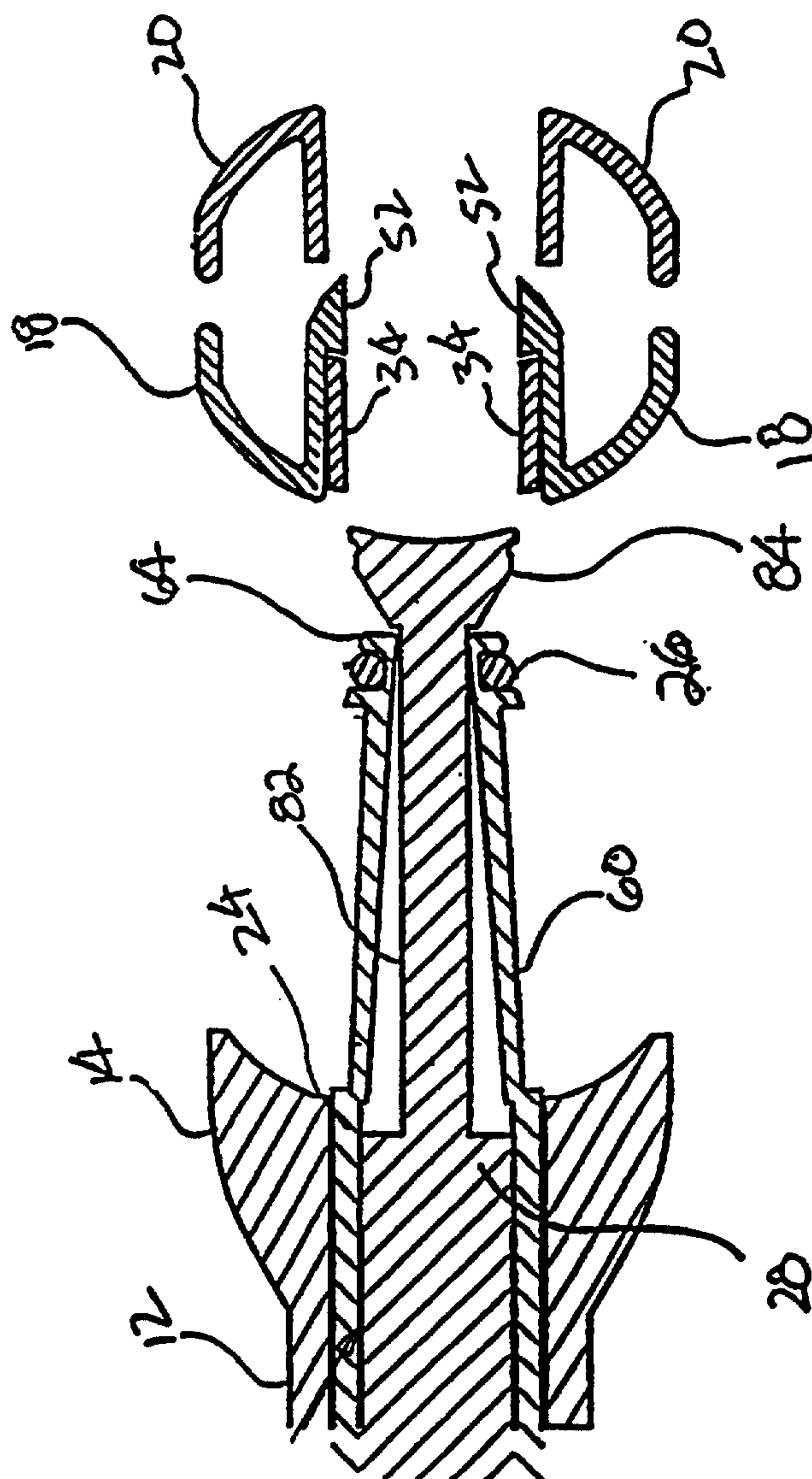


FIG. 32

RELEASED POSITION



J-J

FIG. 33

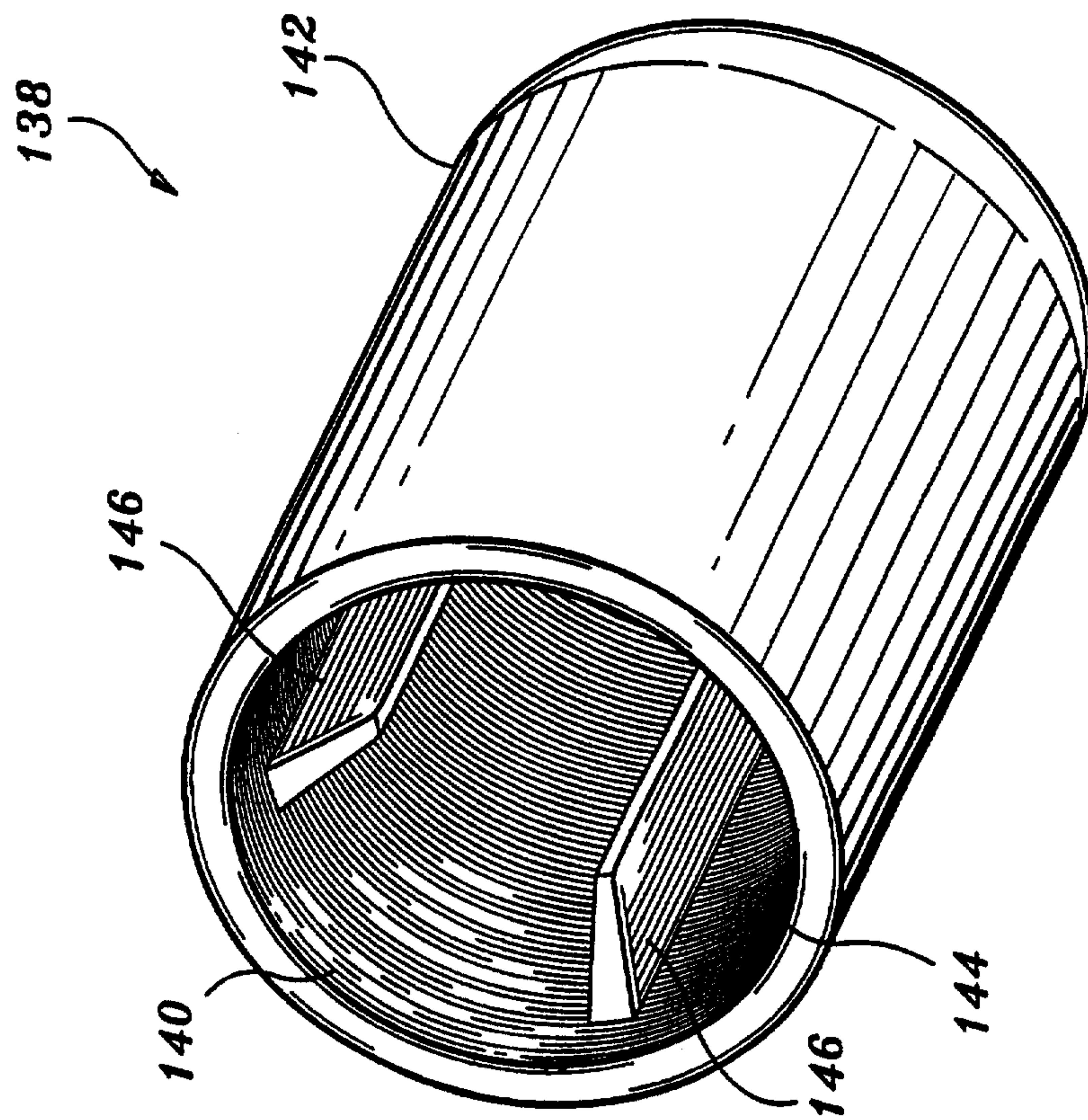


FIG. 34

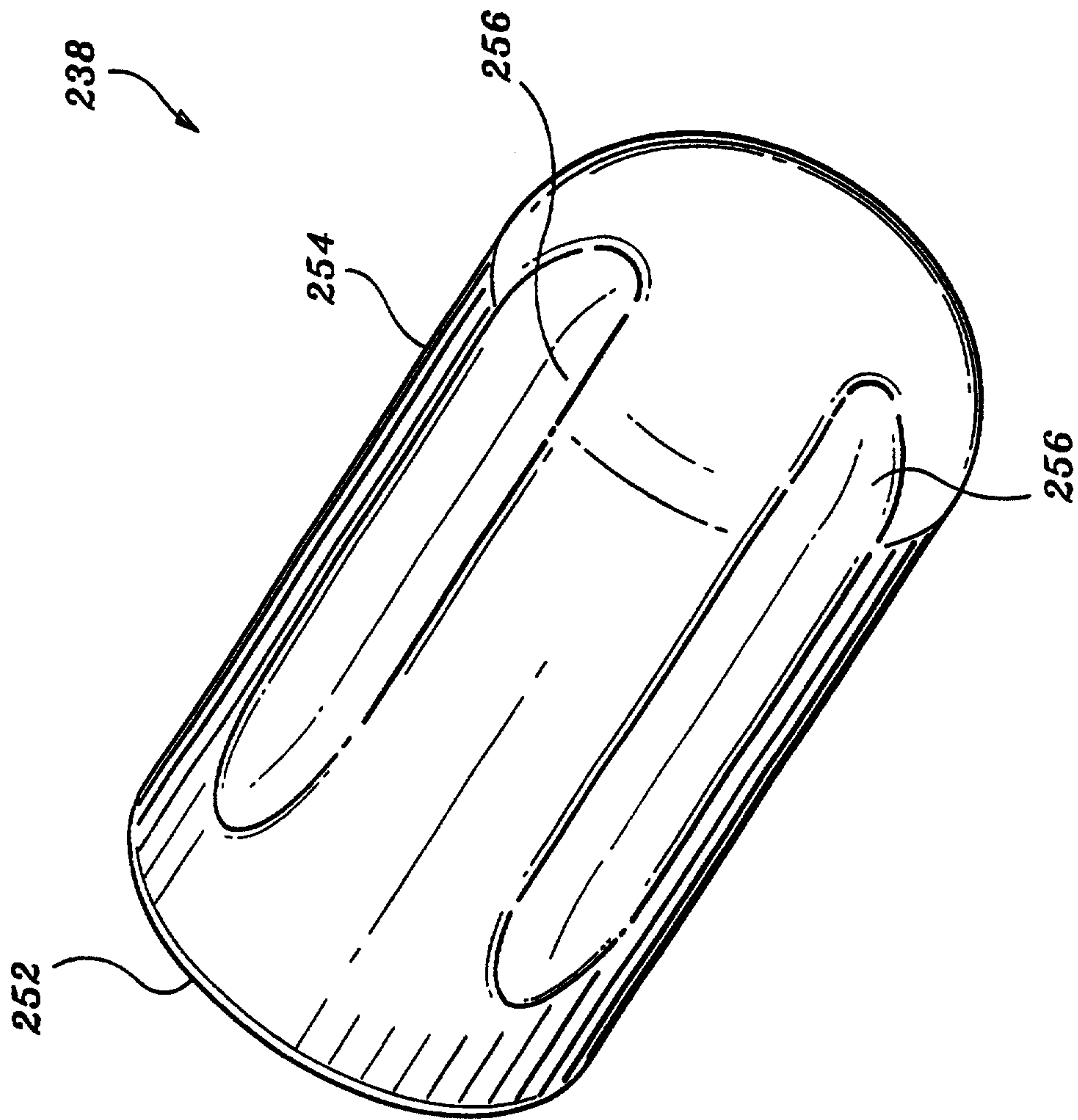
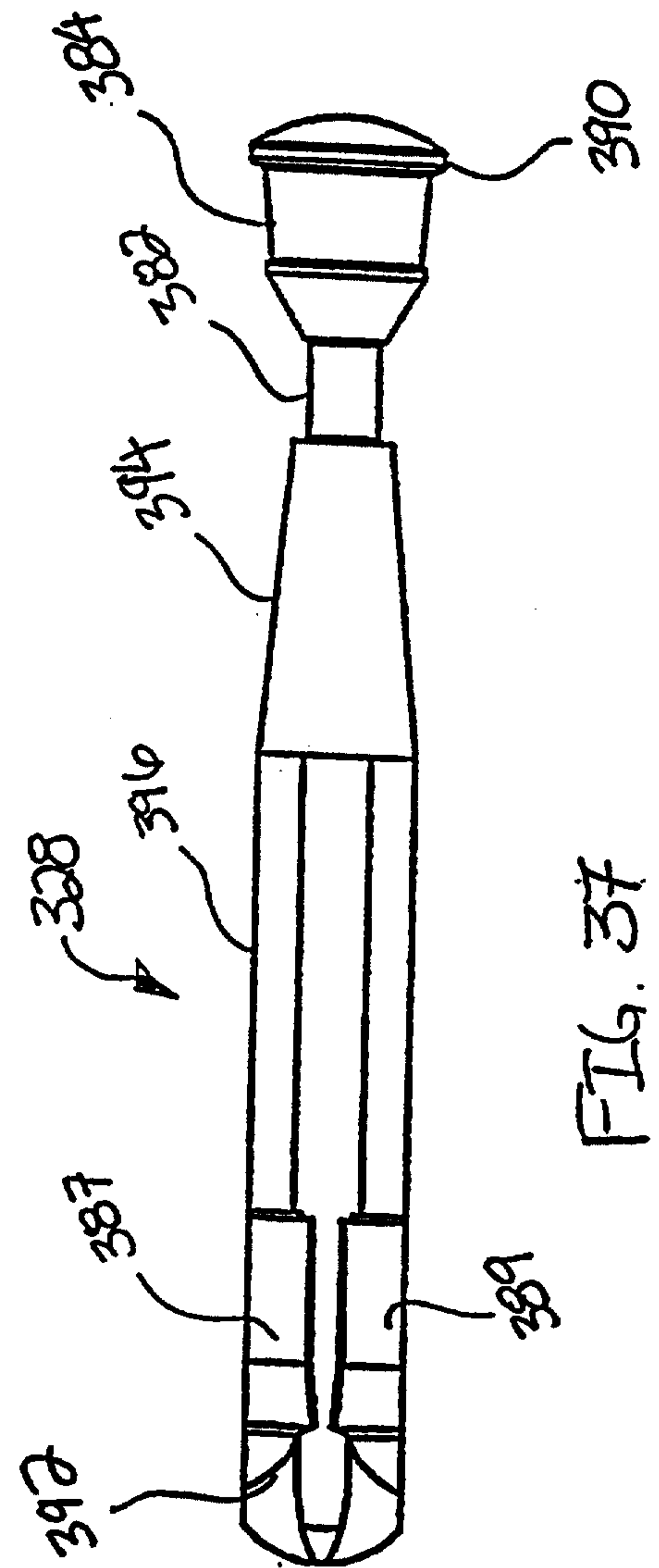
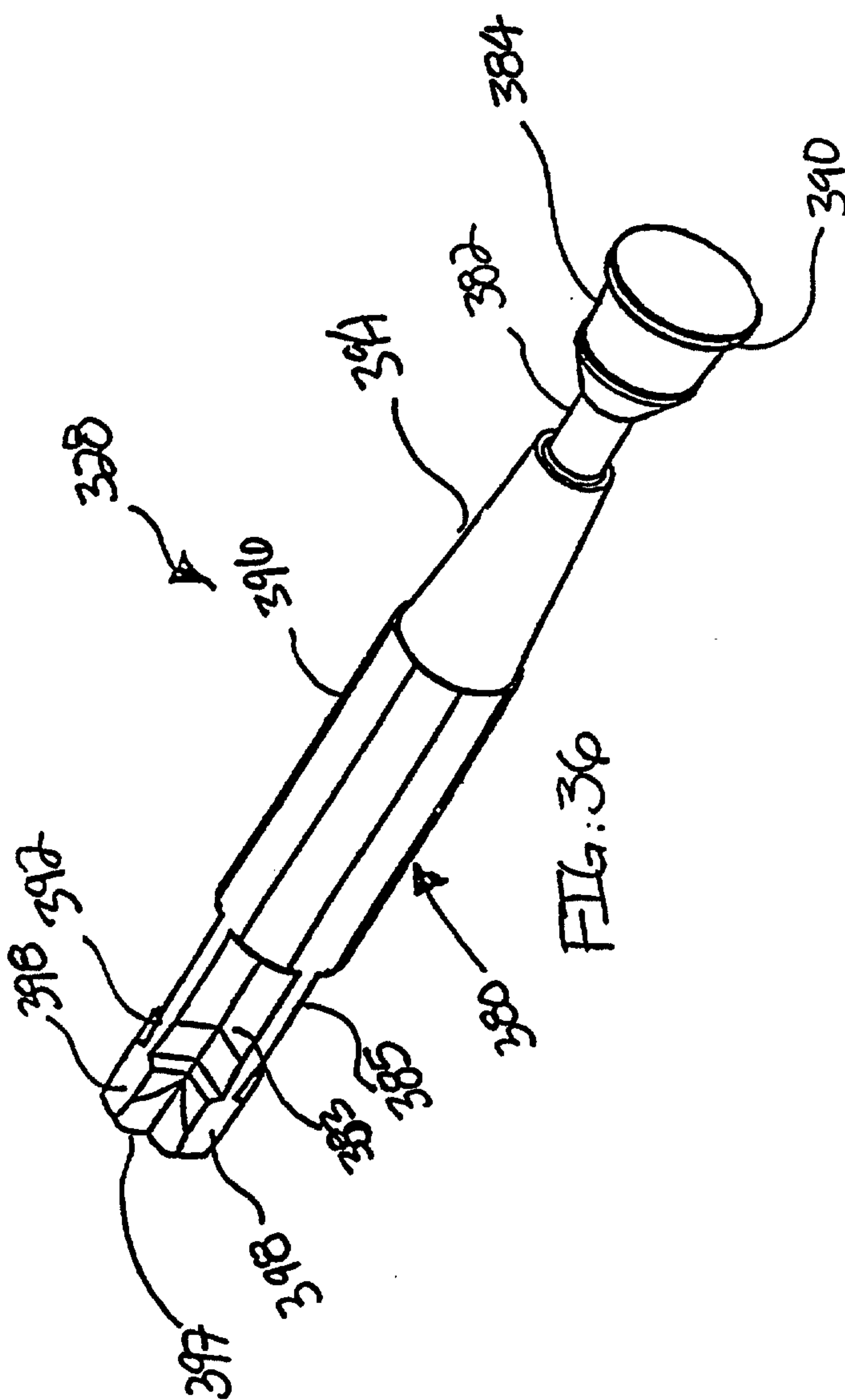
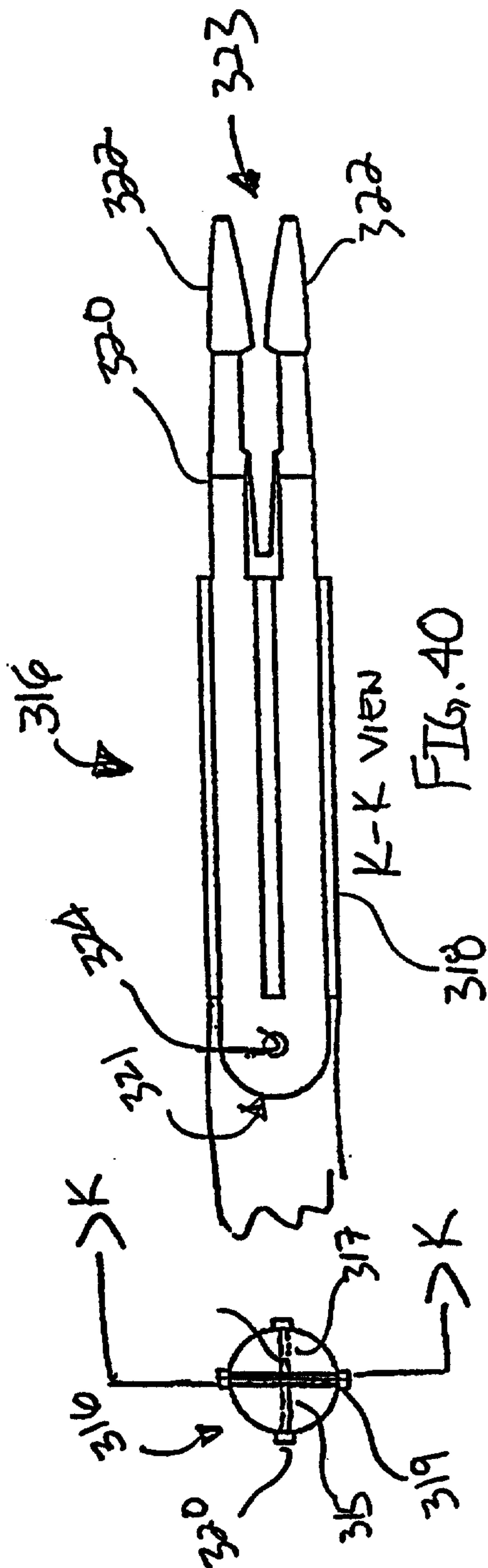
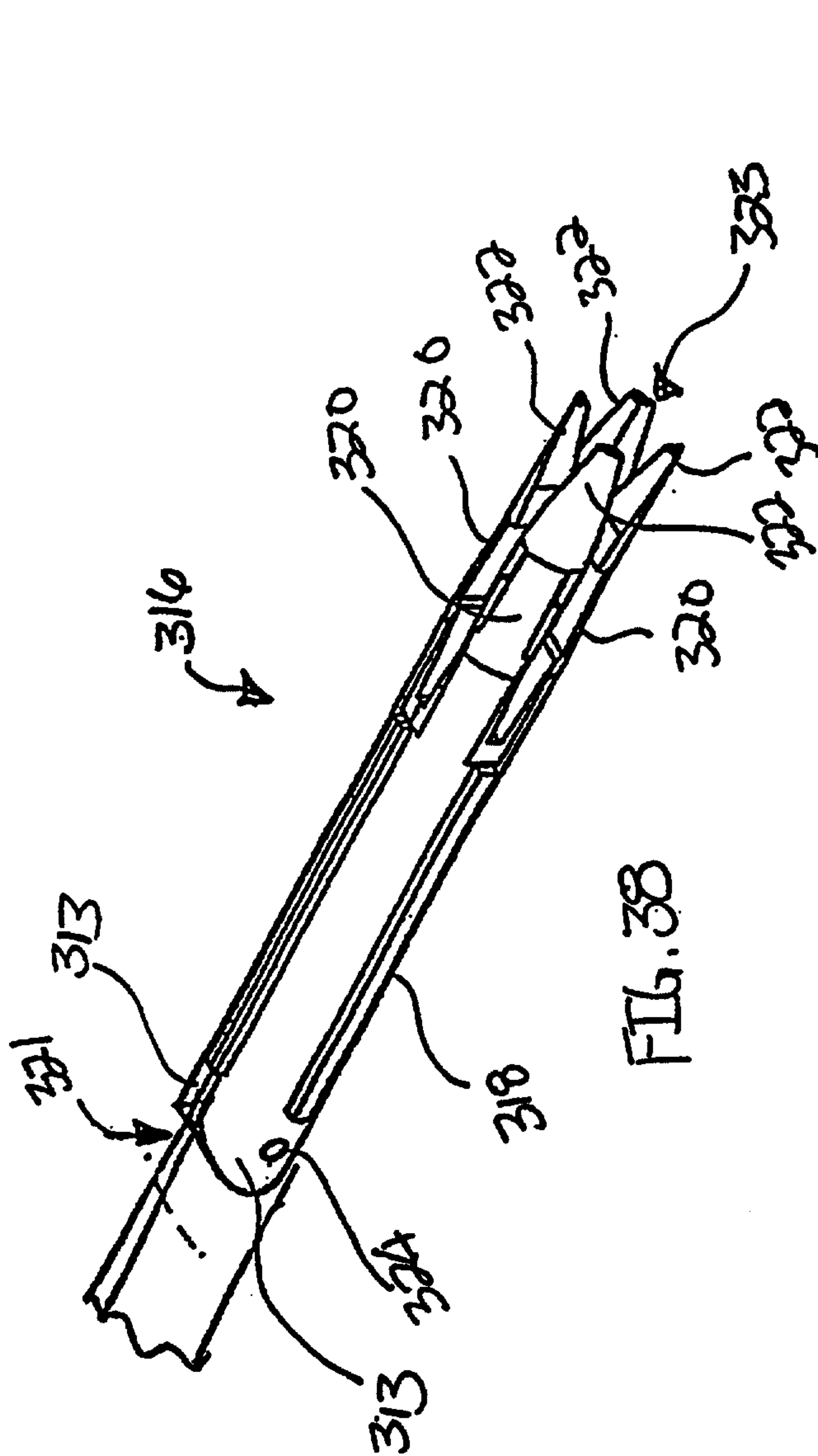
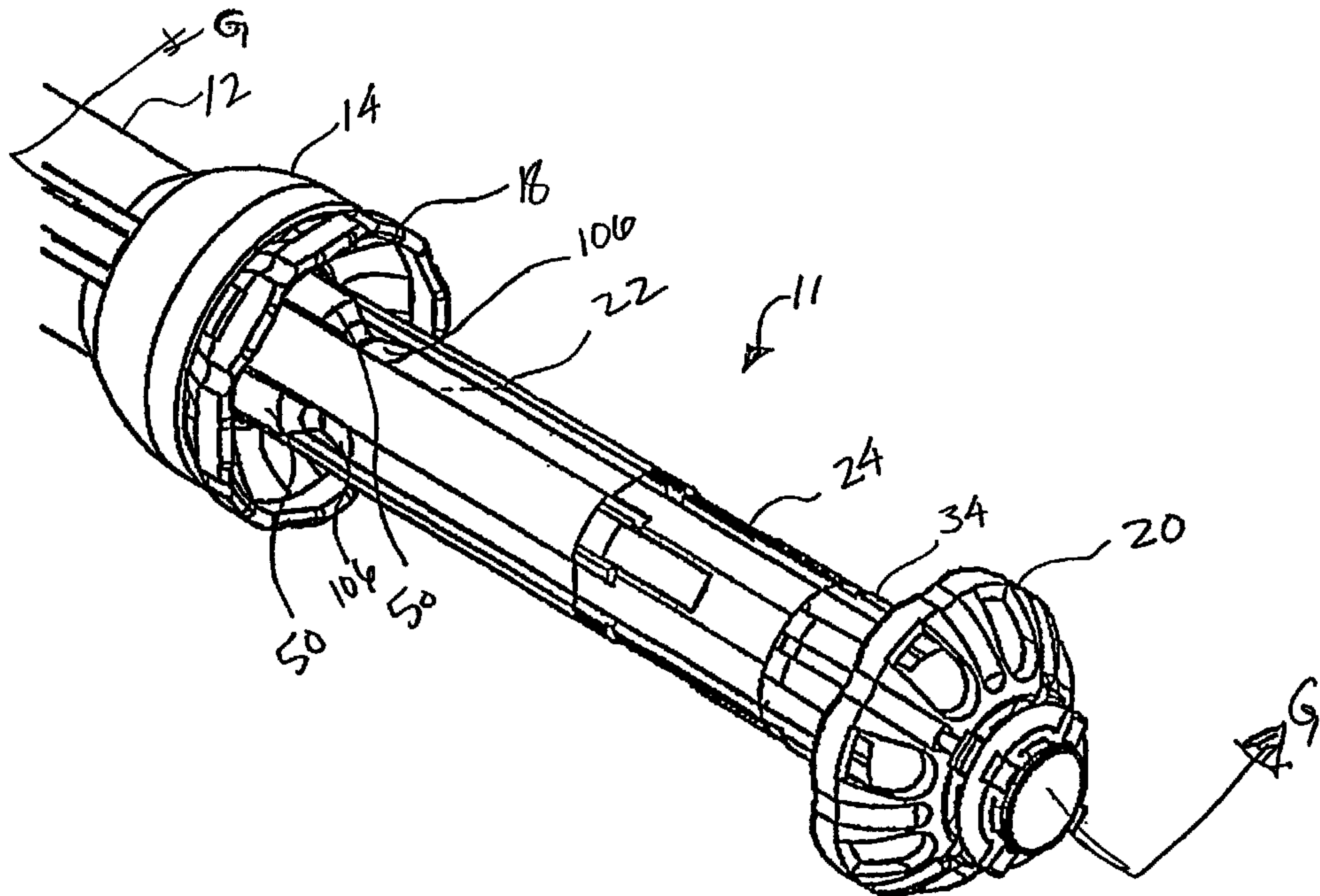


FIG. 35





K-K VUE
FIG. 40



OPEN POSITION