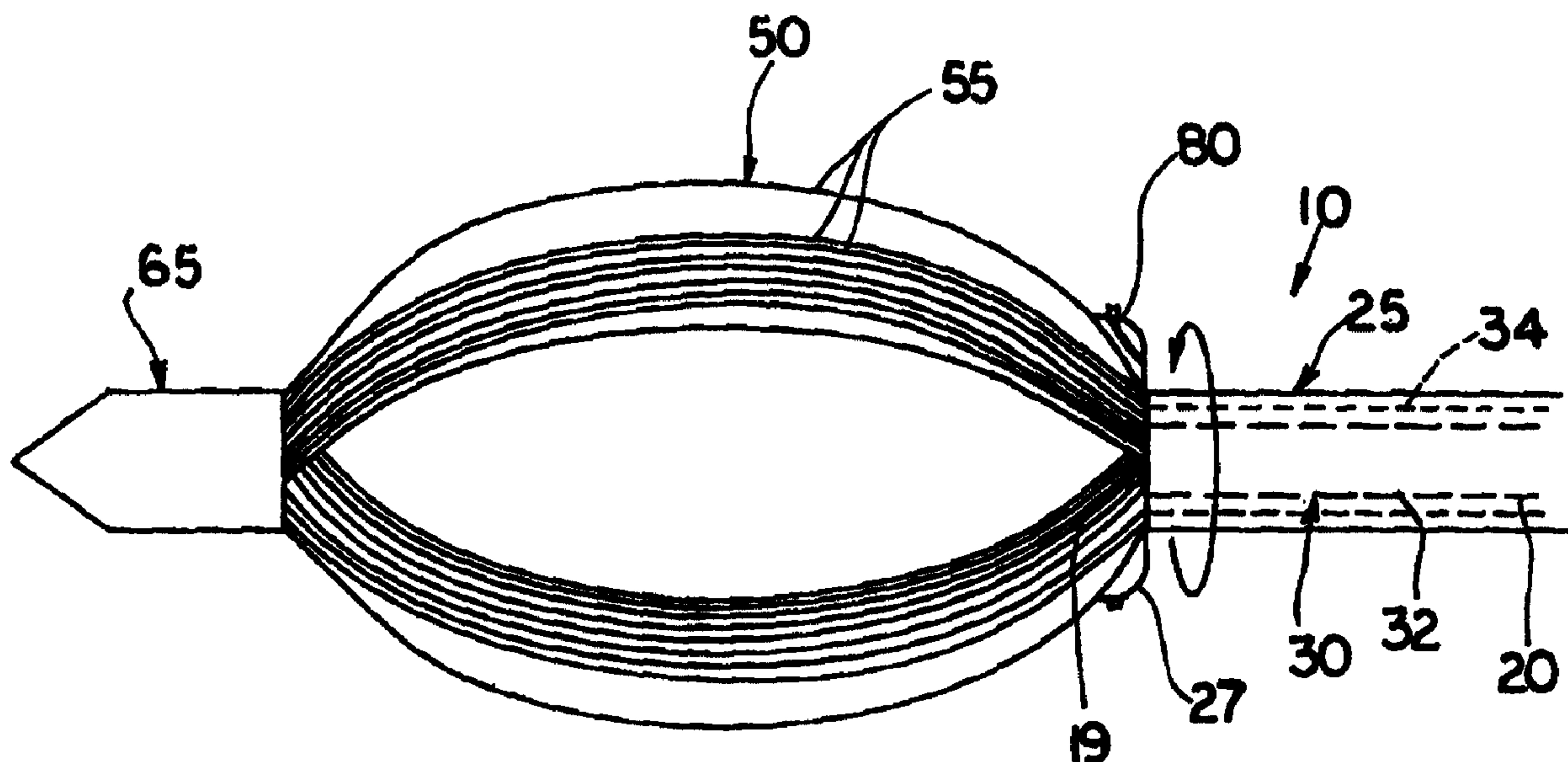




(86) Date de dépôt PCT/PCT Filing Date: 1998/07/23  
(87) Date publication PCT/PCT Publication Date: 1999/02/04  
(45) Date de délivrance/Issue Date: 2008/12/09  
(85) Entrée phase nationale/National Entry: 2000/01/20  
(86) N° demande PCT/PCT Application No.: US 1998/015160  
(87) N° publication PCT/PCT Publication No.: 1999/004704  
(30) Priorité/Priority: 1997/07/24 (US60/053,664)

(51) Cl.Int./Int.Cl. *A61B 17/3205* (2006.01),  
*A61B 18/04* (2006.01), *A61B 18/12* (2006.01),  
*A61B 17/00* (2006.01), *A61B 18/08* (2006.01),  
*A61B 18/20* (2006.01)  
(72) Inventeur/Inventor:  
MCGUCKIN, JAMES F., JR., US  
(73) Propriétaire/Owner:  
REX MEDICAL, INC., US  
(74) Agent: MCFADDEN, FINCHAM

(54) Titre : PROCEDE ET APPAREIL DE CHIRURGIE MAMMAIRE  
(54) Title: BREAST SURGERY METHOD AND APPARATUS



(57) Abrégé/Abstract:

The method and apparatus for subcutaneous target tissue mass through a cutaneous incision smaller than maximum transverse dimension of the tissue mass excised includes an axially elongated housing, tissue piercing means slidably resident within the housing and means connected to the elongated housing and resiliently radially expandable relative thereto for cutting said tissue mass to be excised.



**PCT**WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

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

<b>(51) International Patent Classification <sup>6</sup> :</b>  <b>A61B 17/32</b>	<b>A2</b>	<b>(11) International Publication Number:</b> <b>WO 99/04704</b>  <b>(43) International Publication Date:</b> 4 February 1999 (04.02.99)
<b>(21) International Application Number:</b> PCT/US98/15160  <b>(22) International Filing Date:</b> 23 July 1998 (23.07.98)  <b>(30) Priority Data:</b> 60/053,664                      24 July 1997 (24.07.97)                      US  <b>(71)(72) Applicant and Inventor:</b> McGUCKIN, James, F., Jr. [US/US]; 585 County Lane, Radnor, PA 19087 (US).  <b>(74) Agent:</b> QUINN, Charles, N.; Dann, Dorfman, Herrell & Skillman, Suite 720, 1601 Market Street, Philadelphia, PA 19103-2307 (US).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, 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), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>Without international search report and to be republished upon receipt of that report.</i>
<b>(54) Title:</b> BREAST SURGERY METHOD AND APPARATUS  <div data-bbox="315 1602 1722 2285" data-label="Image"> </div> <b>(57) Abstract</b>  <p>The method and apparatus for subcutaneous target tissue mass through a cutaneous incision smaller than maximum transverse dimension of the tissue mass excised includes an axially elongated housing, tissue piercing means slidably resident within the housing and means connected to the elongated housing and resiliently radially expandable relative thereto for cutting said tissue mass to be excised.</p>		



WO 99/04704

PCT/US98/15160

**BREAST SURGERY METHOD AND APPARATUS****Field of the Invention**

This invention relates to surgical apparatus and methods for obtaining a subcutaneous target mass having varied shape and dimension.

**Background of the Invention  
and Description of the Prior Art**

Modern medical diagnostics increasingly rely on complex imaging technologies to identify abnormal conditions and/or masses within the human body. Such technologies as magnetic resonance imaging (MRI), ultrasonics, computerized axial tomography (CAT scan), and mammogram x-rays, aid medical personnel in the initial identification of areas within the body exhibiting potentially dangerous, abnormal biological activity. The beneficial aspect of these technologies is their ability to image biological structures interior to the human body, providing a non-invasive tool useful in facilitating preliminary diagnosis and treatment of detected anomalies.

Detected subcutaneous biological growths, masses, etc. once identified generally require complete surgical excision or at the very least an open biopsy procedure.

Small masses such as calcifications encountered in breast tissue are generally removed in their entirety. The process of excising the mass is an invasive process, performed either during exploratory surgery or utilizing specifically designed surgical apparatus. The retrieved specimen is subsequently pathologically analyzed to determine its

WO 99/04704

PCT/US98/15160

biological properties, i.e. benign or malignant.

Several types of apparatus are known for use in removing portions of subcutaneous masses in breast tissue targeted by these imaging techniques. However, these apparatus generally either obtain only small tissue specimens from the main mass or cause significant surface scarring due to the size of the incision necessary to remove the mass with a safe resection margin.

One type of specimen retrieval is performed with needle aspiration devices. These devices have a needle with an end hole. The needle is advanced to a desired location where a sample specimen is obtained via suction. Size and quality of specimens obtained by these devices are often poor, requiring multiple sampling of each desired target mass. Moreover, tissue encountered along the path to the desired location is unavoidably removed. A hollow channel is created upon withdrawal of the device from the patient, thereby allowing "seeding" of the hollow channel removal tract with abnormal cells. Some needle systems utilize an enlarged needle end hole, creating a boring probe which obtains a greater portion of tissue. This lessens the likelihood that the specimen will be too small but increases the amount of surface scarring due to the larger size incision required.

The percutaneous incisions needed when multiple needle channels or large needle bore channels are used often result in significant scarring, dimpling and disfigurement of surface tissue.



WO 99/04704

PCT/US98/15160

Needle side cutting devices have a blade extending around the circumference of a hollow needle shaft. The shaft and blade are axially rotated around the skin entry site, allowing a larger overall specimen to be excised. Target tissue is sliced and a non-contiguous specimen is obtained due to the spiral blade path. While these needle side cutting devices facilitate capture of larger sample specimens, they require resection of a relatively large core of tissue between the incision and the specimen desired to be resected. Additionally, needle side cut devices result in irregularly shaped specimens and subcutaneous cavities having irregular and/or bleeding margins.

Hence, the known devices are particularly ill suited in retrieving tissue masses from the female breast, due to the interest in preserving cosmetic integrity of the surface tissue as well as the inability of the known devices to remove most masses/calcifications during a single application.

#### **Summary of the Invention**

This invention provides surgical apparatus and methods where size and shape of subcutaneous tissue identified for excision is minimally dependent on dimensions of the percutaneous incision. The apparatus and methods have specific utility in breast surgery.

In one of its aspects this invention provides apparatus for excision of the subcutaneous target tissue mass through a cutaneous incision smaller than maximum transverse dimension of the tissue mass excised where the apparatus includes an

WO 99/04704

PCT/US98/15160

axially elongated member including cutaneous tissue piercing means at one end and means connected to the elongated member and being radially expandable relative thereto for cutting a circumferential swath of radius greater than maximum transverse dimension of the elongated member and greater than maximum transverse cross-sectional dimension of the target tissue mass in order to separate the target tissue mass from surrounding tissue for excision thereof through the incision. The apparatus may further include an expandable aseptic shield concentric with the elongated member and axially slidably advanceable over the cutting means when in the radially expanded configuration, to collectibly bag the target tissue mass detached from the patient by the cut circumferential swath, for aseptic removal in an axial direction together with the elongated member through the incision resulting from entry of the cutaneous tissue piercing means.

The apparatus may yet further include a sheath which is axially slidably concentric with the elongated member and connected to first ends of the cutting means for expanding the cutting means from generally linear and axial orientation to a curved basket-like orientation by axial movement relative to the elongated member.

In yet another of its aspects the invention provides apparatus for excision of a sub-cutaneous target tissue mass through a cutaneous incision smaller than maximum transverse dimension of the tissue mass excised where the apparatus includes an axially elongated member through which cutaneous tissue piercing means may be extended to emerge at one end



WO 99/04704

PCT/US98/15160

thereof. The apparatus further includes means insertable through the elongated member which is radially expandable relative to the elongated member for cutting a conical swath having base radius greater than maximum transverse dimension of the elongated member and greater than maximum transverse cross-sectional dimension of the target tissue mass, for separating the target tissue mass from surrounding tissue for removal thereof through the incision. In this embodiment of the invention the apparatus further preferably includes expandable aseptic shield means insertable through the elongated member and advanceable over the path of the cutting means to radially expand and collectibly bag the tissue mass detached from a patient by the conical swath cutting for aseptic removal in an axial direction through the elongated member and the incision resulting from entry of the cutaneous tissue piercing means.

In one of its aspects this invention preferably provides such apparatus having a piercing segment for penetrating a percutaneous entrance incision. The forward edge of the piercing segment preferably separates breast tissue in the path of the target tissue to be excised. The piercing segment preferably passes through the specimen to be excised, delivering an associated preferably circular array of preferably highly flexible cutting blades to the interior identified subcutaneous breast growth.

The circular array of preferably flexible cutting blades is preferably radially expanded by action of an attached actuating shaft. The blades radially expand to preferably cut

by electro-cauterizing the breast tissue as they rotate around a defined periphery. The blades preferably outwardly expand to envelope the target tissue specimen and axially rotate to separate the target tissue growth from surrounding breast tissue. The target tissue growth is excised from surrounding breast tissue outside the periphery of the circular blade path and is preferably secured by a snaring membrane placed riding over the circular array of flexible cutting blades.

The membrane is preferably secured over the blade array through an integral drawstring assembly contracting the mouth of the snaring membrane. The membrane-encased blade array is preferably drawn into a recovery sheath and compressed for  
10 aseptic removal from the excision site.

In preferred embodiments of the invention, the tissue piercing means is slidably resident within the housing or containment sheath. The tissue piercing means being insertable through the containment sheath to a position to make the cutaneous incision.

In accordance with another embodiment of the present invention there is provided apparatus including an axially elongated housing for excision of a subcutaneous target tissue through a cutaneous incision smaller than maximum transverse dimension of the tissue excises, characterized by means resident within and slidably emergable from a housing and being radially expandable relative thereto upon axial emerging movement from the housing into position about the target tissue for circumferentially cutting around  
20 the target tissue with cutting radius greater than maximum transverse dimension of the incision and greater than maximum transverse dimension of the target tissue, to separate the target tissue from surrounding tissue for excision thereof through the incision, and by



tissue envelopment means residing within the housing and being axially slidably advanceable out of the housing and radially expandable through a cut path around the target tissue resulting from action of the cutting means for collectably enveloping the target tissue for removal in an axial direction through the incision.

Yet another embodiment of the present invention provides a surgical apparatus for cutting a tissue mass comprising: an elongated housing; first and second support members positioned within the elongated housing and movable from within the housing to a radially diverged position outside the housing, a distance between a tip of the first support member and a tip of the second support member being greater than a diameter of the housing in the radially diverged position; and an electrocautery wire for cutting the tissue, the electrocautery wire positioned within the elongated housing and advanceable from the housing along the support members to a position to cut the tissue mass.

A further embodiment of the present invention provides a surgical apparatus comprising an elongated housing; first and second support members positioned within the elongated housing and movable from within the housing to a radially diverged position outside the housing, a tip of the first and second support members extending past the target tissue mass; and a tissue containment bag positioned within the elongated housing and advanceable from the elongated housing along an outer periphery of the support members to remove cut tissue, the tissue containment bag enlarged as it is advanced along the support members.

In accordance with a further embodiment of the present invention, there is provided a surgical apparatus for cutting a tissue mass comprising: an elongated housing

having a distal portion; a rotatable shaft positioned in the elongated housing; and a plurality of flexible electrocautery cutting blades extending from the housing, the plurality of cutting blades being radially expandable from a first position defining a first diameter to a second position defining a second larger diameter, the plurality of cutting blades being rotatable and transmitting electrical energy to the tissue mass to cut the tissue mass.

A still further embodiment of the present invention provided a surgical apparatus for cutting a tissue mass comprising: an elongated housing having a distal portion; a rotatable shaft positioned in the elongated housing; a plurality of cutting blades extending  
10 from the housing, the plurality of cutting blades being radially expandable from a first position defining a first diameter to a second position defining a second larger diameter to cut the tissue mass; and a membrane advanceable with respect to the cutting blades to remove the cut tissue.

In accordance with another embodiment of the present invention provides a surgical apparatus for cutting a tissue mass comprising: an elongated housing having a distal portion and a tissue penetrating member at the distal portion for penetrating tissue to access the tissue mass; an actuation member positioned in the elongated housing; a plurality of cutting blades extending from the housing, the plurality of cutting blades connected to a distal portion of the housing and being radially expandable from a first  
20 position defining a first diameter to a second position defining a second larger diameter to cut the tissue mass, the plurality of cutting blades being radially expandable in response to actuation of the actuation member.



Yet another embodiment of the present invention provides a surgical apparatus for cutting a tissue mass via application of electrical energy to tissue comprising an elongated housing, the elongated housing having a distal portion and a first transverse dimension, and a cutting member radially extendable with respect to the housing, the cutting member being rotatable to separate the target tissue mass from surrounding tissue thereby cutting a swath of tissue having a transverse dimension greater than the first transverse dimension of the elongated housing, the cutting member being connectable to an electrical power source to transmit electrical energy to the tissue to cut the tissue mass.

10        A further embodiments of the present invention provides a surgical apparatus for cutting a tissue mass comprising an elongated housing configured to penetrate tissue, and means for cutting a circumferential swath of tissue to separate the tissue mass from surrounding tissue, the cutting means connected to an electrical power source and radially extendable from a first position to a second position further spaced from the housing, the cutting means applying electrical energy to tissue and being rotatable to cut the circumferential swath of tissue internal of the cutting means.

20        A still further embodiment of the present invention provides a surgical apparatus for cutting a tissue mass via application of electrical energy to tissue comprising an elongated housing, the elongated housing having a distal portion and a first transverse dimension, and a cutting member radially extendable with respect to the housing, the cutting member being rotatable to separate the target tissue mass from surrounding tissue thereby cutting a swath of tissue having a transverse dimension greater than the first

transverse dimension of the elongated housing, the cutting member being connectable to an electrical power source to transmit electrical energy to the tissue to cut the tissue mass, and an expandable collection member advanceable distally to remove the cut swath of tissue.

In a method aspect which is disclosed subcutaneous breast growths are removed. A percutaneous surface incision is prepared for reception of surgical apparatus. Through use of suitable medical imaging technologies, the cutting apparatus device is guided to the area of the target subcutaneous breast growth while preferably maintaining a fixed subcutaneous reference point. A circular array of blades is then preferably radially  
10 expanded, preferably forming a cutting basket having dimensions larger than the target subcutaneous breast growth. Radial expansion and rotation of the electro-cauterizing blades separates the targeted growth from surrounding tissue. A snaring membrane advances over the blade array and is secured by an integral drawstring assembly. A recovery sheath compresses the membrane, encasing the target growth as it is withdrawn from the subcutaneous breast cavity. As a result, a growth which is large relative to the entrance incision is excised.



In another of its method aspects there is disclosed a procedure for excision of a sub-cutaneous target tissue mass through a cutaneous incision which is smaller than maximum transverse dimension of the target tissue mass to be excised where the procedure includes an advancing tissue piercing means towards a patient to create an incision in the patient's skin, slidably advancing cutting means through the incision and into sub-cutaneous tissue until in position to radially expand and cut a circumferential swath around the target tissue mass larger than the incision, cutting a circumferential swath around the target tissue mass thereby separating the target mass from the surrounding tissue, slidably advancing flexible aseptic containment means over the  
10 separated target tissue mass to a position of closure about the target tissue mass and withdrawing the flexible aseptic containment means, with the target tissue mass aseptically contained therewithin, through the incision. The method may further include collapsing the cutting means after cutting the swath.

Also disclosed is a procedure for excision of sub-cutaneous target tissue mass through a cutaneous incision smaller than maximum transverse dimension of the target tissue mass to be excised where the procedure includes advancing tissue piercing means towards the patient to create an incision in the patient's skin, slidably advancing cutting means through the incision and into sub-cutaneous tissue until in position to gradually radially expand and cut a conical swath about the target tissue mass larger than the  
20 incision thereby separating the target tissue mass from the surrounding tissue, slidably advancing flexible aseptic containment means over the separated target tissue mass to a position of closure around the target tissue mass and withdrawing the flexible aseptic

containment means with the target tissue mass aseptically contained therewithin through the incision. This method preferably further includes radially inwardly collapsing the cutting means, which is preferably wire, after cutting the conical swath and may yet further include radially inwardly cutting tissue along the base of said cone by a passage of the cutting wire therethrough and thereafter closing flexible aseptic containment means over about the periphery of the cone and the target tissue mass contained therewithin.

#### Brief Description of the Drawings

10            Figure 1 is a side view of one embodiment of apparatus manifesting aspects of the invention with the cutting blades in radially expanded condition.

             Figure 2 is a side view of the surgical apparatus illustrated in Figure 1 of the cutting blades in their non-expanded condition.

             Figure 3 is a front view of a modified version of the apparatus illustrated in Figures 1 and 2 with the cutting blades in a non-expanded condition as illustrated in Figure 2.

20



WO 99/04704

PCT/US98/15160

Figure 4 is a front view of a modified version of the apparatus illustrated in Figures 1 through 3 with the cutting blades in their radially expanded condition as illustrated generally in Figure 1.

Figure 5 is a broken schematic partially sectioned view of female breast tissue with the apparatus illustrated in Figures 1 through 4 in position within the breast in the process of removing a target tissue mass from the breast with the target tissue mass encased within an aseptic shield portion of the apparatus.

Figure 6 is a side view of a portion of apparatus according one preferred embodiment of the invention shown in the course of practicing a preferred method aspect of the invention.

Figure 7 is a side view of a part of the apparatus illustrated in Figure 6 showing additional parts of one preferred apparatus embodiment of the invention in the course of practicing the inventive method.

Figure 8 is a side view of the apparatus illustrated in Figure 7 showing the support struts deployed.

Figure 9 is a side view of the preferred embodiment of the apparatus showing the struts deploying about a percutaneous growth.

Figure 10 is a side view of the preferred embodiment of the apparatus showing advancement of the cutting wire along a strut margin.

Figure 11 is a side view of the apparatus shown in Figure 10 with the cutting wire fully deployed.

WO 99/04704

PCT/US98/15160

Figure 12 is a side view of the preferred embodiment of the apparatus depicting a new cutting wire retraction.

Figure 13 is a side view of the preferred embodiment of the apparatus showing advancement of the bagging structure.

Figure 14 is a side view of the preferred embodiment with tissue containment bagging completed.

Figure 15 is a side view of the preferred embodiment of the apparatus showing the containment sheath deploying.

Figure 16 is a side view of the preferred embodiment of the apparatus showing the containment sheath normally deployed.

Figure 17 is an isometric view of the apparatus shown in Figure 16.

Figure 18 is a broken view of the tissue containment bag showing the drawstring tissue.

Figure 19 is a side view similar to Figure 16 but showing the containment sheath fully deployed.

Figure 20 is a side view similar to Figure 19 but showing the containment sheath being withdrawn.

Figure 21 is a side view similar to Figure 19 showing optional use of a medicament bag and a radiological marker

Figure 22 is a side view similar to Figure 19 showing optional use of liquid medication supported in part by the containment sheath.

Figure 23 is an elevation of a support member.

Figure 24 depicts the female breast and illustrated the incision resulting from practice of the method.



WO 99/04704

PCT/US98/15160

Figure 25 is partial end elevation taken looking from the right in Figure 8.

Figure 26 is partial end elevation taken looking from the right in Figure 10.

Figure 27 is partial end elevation taken looking from the right in Figure 16.

#### **Detailed Description of the Preferred Embodiments**

This invention provides surgical apparatus and methods for excision of percutaneous breast tissue. The apparatus has the capability to pass through an incision substantially smaller than the maximum percutaneous target specimen dimension occupying an excision site.

In one embodiment the surgical apparatus preferably cuts the target tissue with an electro-cauterizing, circular array of flexible cutting blades, preferably collecting the specimen

within the periphery of an expandable blade path; thus the complete growth is preferably obtained in a single procedure. The tissue is preferably returned as a complete specimen or, alternatively, in segments within a snaring membrane. A recovery sheath is preferably positioned to further encase and compress the blade array upon contraction.

Referring to Figures 1 and 5, the illustrated embodiment of surgical apparatus 10 includes an inner rotatable shaft 20, a tubular recovery sheath 25, a snaring membrane 30, a circular array of radially flexible and expandable cutting blades generally designated 50, a membrane drawstring 80, a membrane mouth section 27 of recovery sheath 25, a power source (not shown) and a tissue piercing member 65.

10        Membrane 30 preferably has an inner surface 32 coaxially parallel with shaft 20, and an outer surface 34. Inner surface 32 of membrane 30 preferably slidably facingly contacts the outside surface of shaft 20. Membrane 30 is adjustably positioned in either the distal or proximate direction through the proximate end of shaft 20.

Tubular recovery sheath 25 preferably includes a distal pleated mouth section 27, an outer surface, and an inner surface facingly coaxially contacting membrane 30. The inner surface slidably engages outer surface 34 of membrane 30. Shaft 20 defines a rotational axis 12.

Shaft 20 rotates as denoted by arrow 12. Rotatable shaft 20 of surgical apparatus 10 is preferably rotated manually, through mechanical hand control. However, shaft 20  
20        may be operably linked with an electrical motor, not shown, which may



WO 99/04704

PCT/US98/15160

be driven by power source 15.

Circular cutting blade 50 includes individual flexible blades 55 which are preferably anchored between piercing member 65 and proximate end of shaft 20. Blades 55 are preferably electro-cauterizing, heated by electrical power source 15.

The materials utilized to construct surgical apparatus 10 are preferably radiopaque to be visible using modern medical imaging systems.

Referring to Figure 2, surgical apparatus 10 is shown with individual flexible blades 55 in their non-expandable, tissue insertion orientation. In this insertion orientation the blades are parallel with and of slightly smaller diameter than tubular recovery sheath 25. Tubular recovery sheath 25 includes a snaring membrane 30 having a mouth section 27 and a drawstring 80, for drawing membrane 30 closed once it has been opened. Drawstring 80 is positioned along the distal margin of mouth section 27.

Mouth section 27 of membrane 30 expands outwardly in response to pulling of a polyvinyl tab or ripcord upon reaching the excision site. The polyvinyl tab or ripcord is preferably at the end of shaft 20 to the right, which is not shown in the drawing. The polyvinyl tab or ripcord is not visible in the drawing.

Recovery sheath 25 is preferably advanced over circular array of cutting blades 50 and preferably secured in place around the cutting blades and the excised specimen by pulling the drawstring towards the proximate end of shaft 20.

Referring now to Figure 3, piercing segment 65 is formed to separate subcutaneous tissue in the path between the surface incision and the growth.

Figure 3 and Figure 4 show a modification of the embodiment of surgical apparatus 10 illustrated in Figures 1 and 2. In the modification illustrated in Figures 3 and 4, shaft 20 includes an interior channel extending forwardly through the center of the cutting blade circular array 50 and connecting with piercing membrane 65. A shaft stem section which is not shown connects to a dye port 70 in piercing member 65 for optional delivery of marking fluid to subcutaneous areas. Dye port 70 enables operators of apparatus 10 to deliver marking substances to the subcutaneous excision site.

10 Alternatively, a titanium clip can be ejected from a clip fastening surface 75 for marking excision sites for future medical imaging analysis.

As shown in Figure 4, the circular array 50 of cutting blades 55 expands radially upon relative moment of shaft 20 in the direction of piercing member 65, defining a cutting orientation. Flexible cutting blades 55 are preferably electro-cauterizing, cutting as they outwardly expand and as they rotate after radially outward expansion. Upon rotation of flexible cutting blades 55 in the direction indicated by arrow A in Figure 4, the target tissue growth is separated from the surrounding subcutaneous breast tissue and remains within the periphery of the circular blade path.

As variations, the circular array of flexible cutting blades 50 may employ radially  
20 expandable ultrasonic cutting means, referred to as “harmonic scalpels”, or laser cutting means.



The method of excising subcutaneous breast target tissue growths is shown in Figure 5. In Figure 5 the edges of a surgical site where a growth has been removed is indicated as 100; removal of the growth has created subcutaneous cavity 105. As shown, subcutaneous cavity 105 is separated from a surface incision by an excision distance 95.

In preparation for removing the subcutaneous breast tissue growth, percutaneous tissue is cut to produce an incision. A piercing member 65 of surgical apparatus 10 is placed at the incision. An excision path is created by forcing piercing member 65 through the subcutaneous breast tissue between the percutaneous incision and the identified target tissue growth. The target tissue growth is the desired excision site which is visualized via a medical imaging system such as ultrasound or mammography. The tip of surgical apparatus 10 is advanced until the piercing segment passes through the growth to be excised.

Once apparatus 10 is properly positioned relative to the target tissue mass as indicated by the medical imaging system, the proximate end of shaft 20 is urged towards piercing member 65. Flexible cutting blades 55 radially expand to define subcutaneous margin 100. The array of flexible cutting blades 50 is then rotated about the shaft axis as indicated by arrow 12, separating the target tissue growth along margin 100.

Membrane 30 is then advanced over the circular array of cutting blades 50 and secured by pulling integral drawstring 80 to the right in Figure 5 towards the end of shaft 20. Drawstring 80 secures the distal margin of membrane 30. The mouth 27 of sheath 25 is expanded by the polyvinyl pull tab when drawn towards the end of shaft 20.

Circular array of cutting blades 55, now encased by membrane 30, is drawn into

the mouth of snaring sheath 25 and removed from subcutaneous cavity 105.

In the preferred embodiment shown in Figures 5-8, a plurality of guide struts or support members generally designated 206 are advanced through a skin surface incision 126 and past a target tissue mass 228 via a tubular housing defining an extrication channel. As shown in Figures 7 and 8, guide struts (support members) 206 are inserted through surface incision 126 and moved to a position to define a conically shaped desired excision margin respecting the target tissue mass 228, shown in Figure 11. As shown in Figures 8 through 10, the extension and configuration of struts 206 from surface incision 126 past target mass 228 creates a gradually expanding subcutaneous retrieval path referred to as a conical penumbra 208.

As shown in Figures 10 through 13, an electro-cauterizing cutting snare in the form of wire loops is advanced along guide struts 206, creating a conically shaped excision margin.

Referring to Figures 10-17, the cutting snare is advanced beyond the length of the guide struts 206 to where the cutting snare is drawn closed by pulling a integral drawstring towards the exterior of the skin. As shown in Figures 15 through 17, mouth 27 of sheath 25 is advanced along the defined extrication channel and expanded by pulling the polyvinyl pull tab which is not shown. As shown in Figures 18 through 24, guide struts 206 are enveloped by snaring sheath 25 and may be removed from subcutaneous cavity through an extrication channel.

In one preferred practice of the invention as depicted in Figures 6 through 27 and using the apparatus shown therein, the apparatus includes a support conduit designated



generally 202 and axially elongating skin cutting means 204 having a cutting blade 205 which is insertable through support conduit 202 as illustrated generally in Figure 6. Skin cutting means 204 and particularly cutting blade 205 to make a suitable incision in the skin, preferably in the human breast designated generally 246 in Figure 24 where the skin is designated 224 in the drawing figures including Figure 6 and Figure 24. The incision is made to provide access to a target tissue mass designated generally 228 in the drawings which has been previously identified preferably using x-ray mammographic techniques as being dangerous and hence to be removed.

Once a skin incision has been made by skin cutting means 204 and appropriate  
10 use of cutting blade 205 thereof, skin cutting means 204 is preferably withdrawn axially through support conduit 202, moving to the left in Figure 6, and support means designated generally 207 and having a plurality of support members designated generally 206 is inserted axially through support conduit 202 and into the subcutaneous tissue 226 of the breast as indicated generally in Figure 7, with the direction of travel of support means 207 indicated generally

WO 99/04704

PCT/US98/15160

by arrow A in Figure 7.

As support members 206 of support means 207 are inserted into the sub-cutaneous tissue 226, support members expand 206 radially due to influence of resilient spring means 210, illustrated in dotted lines in Figure 8 and forming a portion of support means 207 to a position where support members 206 define a conical penumbra enveloping target tissue mass 228. The conical penumbra 208 defines planes of incision for removal of target tissue mass 228 and a medically advisable amount of surrounding sub-cutaneous healthy tissue 226.

As support members 206 radially diverge one from another due to the influence of resilient spring means 210, remote tips 209 of support members 206 define a circle which in turn defines the base of conical penumbra 208. Remaining, proximate ends of support members 206 are pivotally connected to a supporting shaft, not numbered in the drawings, for pivoting rotation thereabout in response to spring 210.

Once support members 206 have been deployed, into the position illustrated in Figure 8, the target tissue mass is well within the conical penumbra defined by support members 206.

A pair of tissue cutting wire loops 214 are positioned about the bases of support members 206, as illustrated generally in Figure 9, and are supported by and emerge from respective support catheters 212, also illustrated in Figure 9. Support catheters 212 are sufficiently rigid that when force is applied in the axial direction to support catheters 212 is indicated by arrows B and B' in Figure 9, support

WO 99/04704

PCT/US98/15160

catheters 212 move to the right in Figure 9 advancing tissue cutting wire loops 214 along the outer periphery of support members 204 as depicted generally in Figure 10.

As support catheters 212 are moved to the right in Figures 9 and 10, additional lengths of tissue cutting wires 214 is supplied through support catheters 212 so that tissue cutting wires 214, which are in the form of loops about the exterior surfaces of support members 206 as illustrated in Figure 10, can enlarge as the circumference of the conical penumbra, measured about the slant surface of the conical penumbra defined by support members 206 as illustrated in Figure 10, increases.

Support catheters 212 are urged to the right in Figure 10 until tissue cutting wire loops 214 pass the remote tips 209 of support members 206 and define a pair of essentially coincident and in any event concentric circles forming the base of conical penumbra 208.

Once tissue cutting wire loops 214 have reached this position due to movement of support catheters 212, the wire forming tissue cutting wire loops 214 are drawn to the left, through respective support catheters 212. This causes the respective tissue cutting wire loops 214 each to cinch together as the wires are withdrawn as indicated generally by arrows C, C' in Figure 11. As the tissue cutting wires are drawn to the left in Figure 11 through respective support catheters 212, the wire loops each cinch together thereby cutting circular incisions through the sub-cutaneous tissue; this action is illustrated generally in Figure 11 where the



WO 99/04704

PCT/US98/15160

respective tissue cutting wire loops are shown partially, but not completely, cinched. Two wire loops are preferable, for symmetrical application of force.

Once tissue cutting wire loops 214 have been completely cinched and the wires withdrawn to the position illustrated in Figure 12 by continually drawing the respective tissue cutting wires 214 in the directions indicated by arrows D, D' in Figure 12, the conical penumbra 208 defines planes of incision created by action of tissue cutting wire loops 214 where those planes of incision are shown in dotted lines in Figure 12. Note that two dotted lines are shown at the extreme right of Figure 12 to indicate that two circular planar incisions created by action of respective tissue cutting wire loops 214. Desirably, these two circular planar incisions are essentially congruent one with another.

Once tissue cutting wire loops 214 have been completely withdrawn into the position illustrated in Figure 12, a suitable tissue containment bag structure 216 is advanced outwardly of support conduit 202, around the outer periphery of support means 207 and particularly support members 206. Tissue containment bag 216 preferably has a pair of drawstrings 218, which may be metal, suture material, suitable plastic monofilaments and the like, which are sewn or threaded into tissue containment bag 216 proximate the vertical right-hand margin thereof appearing in Figure 13. Drawstrings 218 have extremity portions 219 illustrated in Figure 13.

Once tissue containment bag 216 has been advanced so that its margin 217 has traveled inwardly with respect to the

WO 99/04704

PCT/US98/15160

breast past the remote tips 209 of members 206, to the position generally corresponding to the base of conical penumbra 208, drawstring extremities 219 are pulled to the right in Figures 13 and 14, thereby causing looped drawstrings 218, 218' to close margin 217 of bag 216, causing margin 217 to circularly gather as shown in Figure 14.

Once margin 217 of bag 216 has been circularly gathered thereby effectively closing bag 216 about the target tissue mass 228 of interest, an expandable sheath 230 is advanced through the interior of support conduit 202 about tissue containment bag 216 with expandable sheath 230 moving in the direction indicated by arrow F in Figure 15. Expandable sheath 230 has a pleated expandable portion 231, which is resilient and seeks to expand radially outwardly to relieve internal stresses such that upon expandable portion 231 reaching terminus 203 of support conduit 202 which is within sub-cutaneous tissue 226, expandable portion 231 expands radially into the configuration illustrated generally in Figure 16. Expandable portion 231 of sheath 230 is preferably pleated, as depicted in Figure 17.

Expandable sheath 230 and particularly expandable portion 231 thereof provides support in the form of radially inwardly directed force on tissue containment bag 216 as bag 216 with target tissue mass 228 enveloped therein is pulled to the left in Figures 16, 19 and 20 as indicated generally by arrows G in Figure 19 and arrow H in Figure 20. The radially inward force provided on tissue containment bag 216 and target tissue mass 228 contained therein by expandable sheath 230, as tissue



containment bag 216 is pulled to the left in Figure 19, compresses tissue mass 228 into a smaller volume and essentially squashes tissue mass 228 into a longitudinally elongated form for passage through support conduit 202. Application of the radial force to tissue mass 228 reduces the transverse cross-sectional dimension of tissue mass 228 to at least the diameter of support conduit 202 as tissue containment bag 216 is drawn through the funnel-shaped expandable portion 231 of sheath 230 and into the interior of support conduit 202.

Once bag 216 and tissue mass 228 contained therein have been removed from the sub-cutaneous tissue, expandable sheath 230 may be removed by pulling it in the direction indicated by arrow H in Figure 20.

Optionally, while expandable sheath 230 is in position and perhaps only part way removed from the resected area of interest, a medicament bag 232 may be inserted into the resected area through the interior of support conduit 202 and through expandable sheath 230, as indicated in Figure 21. This may provide means for supplying radioactive gas to provide radiation therapy to the resected area. Additionally, a radiographic marker depicted as 236 may be implanted into the resected area of interest, using the balloon or otherwise while expandable sheath 230 remains in the area of the resection. As an additional option while expandable sheath remains in position thereby maintaining a void in the resected area of the sub-cutaneous tissue, liquid medication indicated schematically as 234 in Figure 22 may be supplied to the



resected area. In such case expandable sheath maintaining the resected tissue in a spaced-apart condition facilitates application of the liquid medication to all parts of the resected volume.

Utilizing the method and apparatus as described hereinabove results in a small, tunnel like incision approaching the skin of the breast with a larger, resected mass being removed therefrom; the resulting internal incision is depicted 244 in Figure 24.

Support members 206 preferably have metallic tips to provide radiopaque characteristics as indicated by 238 in Figure 23 and may also have metallic or other radiopaque marker bands indicated as 240 in Figure 23. Central portions 242 of support  
10 members 206 are preferably radiolucant as indicated by the stippling in Figure 23.

CLAIMS:

1. Apparatus including an axially elongated housing for excision of subcutaneous target tissue through a cutaneous incision smaller than maximum transverse dimension of the tissue excised, characterised by tissue piercing means slidably resident within the housing; and means residing within the housing and being slidably emergable from the housing and resiliently radially expandable relative to the housing for cutting a conical swath having radius greater than maximum transverse dimension of the elongated housing and greater than maximum transverse cross-sectional dimension of the target tissue to separate the target tissue from surrounding tissue for excision thereof through the incision.

2. Apparatus for excising subcutaneous target tissue through a cutaneous incision smaller than maximum transverse dimension of the tissue excised, characterized by an axially elongated member including cutaneous tissue piercing means at one end and means connected to the elongated member and being radially expandable relative thereto for cutting a circumferential swath of radius greater than maximum transverse dimension of the elongated member and greater than maximum transverse cross-sectional dimension of the target tissue to separate the target tissue from surrounding tissue for excision thereof through the incision.

3. The apparatus according to claim 1 or 2, wherein the cutting means transmits electrical energy to electro-cauterize the tissue.

4. The apparatus according to claim 1, 2 or 3, further comprising containment means within the housing for containment of the excised target tissue, said containment means being axially slidably advanceable out of the housing and expandable around the target tissue to envelope the target tissue for removal.

5. Apparatus including an axially elongated housing for excision of a subcutaneous target tissue through a cutaneous incision smaller than maximum transverse dimension of the tissue excised, characterized by means resident within and slidably emergable from the housing and being radially expandable relative thereto upon axial emerging movement from the housing into position about the target tissue for circumferentially cutting around the target tissue with cutting radius greater than

maximum transverse dimension of the incision and greater than maximum transverse dimension of the target tissue, to separate the target tissue from surrounding tissue for excision thereof through the incision, and by tissue envelopment means residing within the housing and being axially slidably advanceable out of the housing and radially expandable through a cut path around the target tissue resulting from action of the cutting means for collectably enveloping the target tissue for removal in an axial direction through the incision.

6. The apparatus of claim 5, further comprising means for closing the tissue envelopment means about any target contained therewithin by moving a periphery of the tissue envelopment means radially inward.

7. The apparatus of claim 6, further comprising a tissue piercing means slidably resident within the housing.

8. The apparatus of claim 7, wherein at least the tissue piercing means is detectable ultrasonically.

9. The apparatus of claim 7, wherein at least the tissue piercing means is detectable using mammographic x-ray.

10 The apparatus of claim 6, further comprising means for electrically heating the tissue cutting means for cauterizing cutting to detach the target tissue from surrounding tissue.

11. The apparatus of claim 6, further comprising means for electrically energizing the tissue cutting means for coagulating tissue around the target tissue during cutting.

12. The apparatus of any one of claims 1 to 9, wherein the tissue cutting means is further characterized by a laser.

13. The apparatus of any one of claims 1 to 9, wherein the tissue cutting means is further characterized by wire.

14. The apparatus of any one of claims 1 to 6, wherein at least the tissue cutting means is detectable ultrasonically.

15. The apparatus of any one of claim 1 to 6, wherein at least the tissue cutting means is detectable using mammographic x-ray.

16. The apparatus of any one of claim 1 to 6, wherein the tissue cutting means



includes a blade.

17. The apparatus of any one of claims 5 to 16, wherein the tissue envelopment means is a flexible membrane.

18. The apparatus of claim 5, further comprising drawstring means for closing the tissue envelopment means about the tissue cutting means and any target tissue contained therewithin.

19. The apparatus of claim 18, further comprising means for electrically heating the tissue cutting means for cauterizingly cutting to detach the target tissue from surrounding tissue.

20. The apparatus of claim 18, further comprising means for electrically energizing the cutting means for coagulating tissue around the target tissue during cutting.

21. The apparatus of any one of claims 5 to 20, further comprising means for rotating the tissue cutting means.

22. The apparatus of claim 7, wherein the incision making tissue piercing means is slidably resident within a containment sheath.

23. The apparatus of claim 22, wherein the incision making tissue piercing means is insertable through the containment sheath to a position to make a cutaneous incision.

24. The apparatus of claim 22, further comprising a catheter resident within the containment sheath and axially slidably movable with respect thereto into the subcutaneous tissue for delivery of marking fluid to the subcutaneous tissue.

25. The apparatus of claim 22, further comprising means slidably resident within the containment sheath and axially movable therethrough for delivery of a medical imaging clip into the subcutaneous tissue.

26. The apparatus of any one of claims 5 to 11, in which the tissue cutting means is further characterized by at least two coaxial wire loops.

27. The apparatus of any one of claims 5 to 26, wherein the cutting means is further characterized by being resiliently radially expandable for cutting a conical swath having radius greater than maximum transverse dimension of the housing and greater than maximum transverse cross-sectional dimension of the target tissue to separate the

target tissue from surrounding tissue for excision thereof through the incision.

28. The apparatus of claim 27, wherein the tissue envelopment means is further characterized by being axially slidably advanceable and radially expandable through the conical swath to collectably bag the target tissue for aseptic removal in an axial direction through the housing and the incision.

29. The apparatus of claim 28 being further characterized by a sheath axially slidably resident within and concentric with the elongated housing for applying radially inward force on the target tissue bagging means and any target tissue contained therewithin prior to removal thereof from the subcutaneous tissue via the housing.

30. The apparatus of claim 29 being further characterized by a drawstring for closing the bag about any target tissue contained therewithin by radially inward movement of a circular periphery of the bag.

31. A surgical apparatus for cutting a tissue mass comprising:

an elongated housing;

first and second support members positioned within the elongated housing and movable from within the housing to a radially diverged position outside the housing, a distance between a tip of the first support member and a tip of the second support member being greater than a diameter of the housing in the radially diverged position; and

an electrocautery wire for cutting the tissue, the electrocautery wire positioned within the elongated housing and advancable from the housing along the support members to a position to cut the tissue mass.

32. The apparatus of claim 31, further comprising a tissue containment bag positioned within the elongated housing and advancable from the elongated housing along the support members to contain and remove the cut tissue.

33. The apparatus of claim 31, wherein the support members radially diverge from the elongated housing to form a conical penumbra.

34. The apparatus of claim 33, wherein the electrocautery wire is advanced over an outer periphery of the support members and a loop formed by the wire is enlarged as the wire advances over the support members, the wire advancing to a position at a base of



the conical penumbra.

35. A surgical apparatus comprising:

an elongated housing;

first and second support members positioned within the elongated housing and movable from within the housing to a radially diverged position outside the housing, a tip of the first and second support members extending past the target tissue mass; and

a tissue containment bag positioned within the elongated housing and advancable from the elongated housing along an outer periphery of the support members to remove cut tissue, the tissue containment bag enlarged as it is advanced along the support members.

36. The apparatus of claim 35, further comprising an electrocautery wire advancable along the support members prior to advancement of the containment bag.

37. A surgical apparatus for cutting a tissue mass comprising:

an elongated housing having a distal portion;

a rotatable shaft positioned in the elongated housing; and

a plurality of flexible electrocautery cutting blades extending from the housing, the plurality of cutting blades being radially expandable from a first position defining a first diameter to a second position defining a second larger diameter, the plurality of cutting blades being rotatable and transmitting electrical energy to the tissue mass to cut the tissue mass.

38. The apparatus of claim 37, wherein the shaft is manually rotated.

39. The apparatus of claim 37, wherein the shaft is rotated by a power source.

40. The apparatus of claim 37, further comprising a membrane advanceable with respect to the cutting blade to collect the cut tissue mass.

41. The apparatus of claim 40, further comprising a drawstring operatively associated with the membrane to close the membrane about the cut tissue.

42. The apparatus of claim 37, wherein the movement of the shaft moves the cutting blades to the radially expanded position.

43. The apparatus of claim 42, wherein movement of the shaft in a distal



direction moves the cutting blades to the radially expanded position.

44. The apparatus of claim 37, wherein the flexible blades form a circular array in the second position.

45. The apparatus of claim 44, wherein the flexible blades are parallel in the first position.

46. A surgical apparatus for cutting a tissue mass comprising: an elongated housing having a distal portion; a rotatable shaft positioned in the elongated housing; a plurality of cutting blades extending from the housing, the plurality of cutting blades being radially expandable from a first position defining a first diameter to a second position defining a second larger diameter to cut the tissue mass; and a membrane advanceable with respect to the cutting blades to remove the cut tissue.

47. The apparatus of claim 46, further comprising a drawstring operatively associated with the membrane to close the membrane about the cut tissue.

48. A surgical apparatus for cutting a tissue mass comprising: an elongated housing having a distal portion and a tissue penetrating member at the distal portion for penetrating tissue to access the tissue mass; an actuation member positioned in the elongated housing; a plurality of cutting blades extending from the housing, the plurality of cutting blades connected to a distal portion of the housing and being radially expandable from a first position defining a first diameter to a second position defining a second larger diameter to cut the tissue mass, the plurality of cutting blades being radially expandable in response to actuation of the actuation member.

49. The apparatus of claim 48, wherein the cutting blades are electrocautery blades to electrocauterize tissue.

50. The apparatus of claim 49, further comprising a shaft rotatably mounted within the elongated housing to rotate the cutting blades in their second position to cut tissue.

51. The apparatus of claim 50, wherein the plurality of cutting blades form a circular array in the second position.

52. The surgical apparatus of claim 50, wherein the tissue is cut internal of the cutting blades.

53. A surgical apparatus for cutting a tissue mass via application of electrical energy to tissue comprising an elongated housing, the elongated housing having a distal portion and a first transverse dimension, and a cutting member radially extendable with respect to the housing, the cutting member being rotatable to separate the target tissue mass from surrounding tissue thereby cutting a swath of tissue having a transverse dimension greater than the first transverse dimension of the elongated housing, the cutting member being connectable to an electrical power source to transmit electrical energy to the tissue to cut the tissue mass.

54. The apparatus of claim 53, further comprising a rotatable shaft positioned in the elongated housing, wherein the cutting member is rotated by rotation of the shaft.

55. The apparatus of claim 54, wherein the shaft is manually rotated.

56. The apparatus of claim 54, wherein the shaft is rotated by a power source.

57. The apparatus of claim 53, wherein the distal portion of the elongated housing is configured to pierce tissue.

58. The apparatus of claim 53, further comprising a membrane advanceable with respect to the cutting member to collect the cut tissue mass.

59. The apparatus of claim 53, further comprising a plurality of cutting members rotatable to cut the swath of tissue.

60. The apparatus of claim 53, further comprising a slidable member positioned in the elongated housing wherein movement of the slidable member moves the cutting member to the radially extended position.

61. The apparatus of claim 53, wherein the cutting member is parallel to the longitudinal axis of the housing in a retracted position.

62. The surgical apparatus of claim 53, wherein the transmission of electrical energy via the cutting member cuts the tissue mass internal of the cutting member.

63. A surgical apparatus for cutting a tissue mass comprising an elongated housing configured to penetrate tissue, and means for cutting a circumferential swath of tissue to separate the tissue mass from surrounding tissue, the cutting means connected to an electrical power source and radially extendable from a first position to a second



position further spaced from the housing, the cutting means applying electrical energy to tissue and being rotatable to cut the circumferential swath of tissue internal of the cutting means.

64. The surgical apparatus of claim 63, further comprising means to rotate the cutting means.

65. The surgical apparatus of claim 63, further comprising a membrane advanceable with respect to the cutting means to remove the tissue.

66. The surgical apparatus of claim 63, further comprising a slidable member positioned in the elongated housing wherein axial movement of the slidable member radially extends the cutting means.

67. The apparatus of claim 63, wherein the cutting means comprises a plurality of cutting blades forming a circular array in the second position.

68. The apparatus of claim 63, further comprising an expandable member advanceable distally with respect to the housing to remove the cut swath of tissue.

69. The apparatus of claim 68, wherein the expandable member is distally movable between a first position within the elongated housing and a second position extending from the elongated housing, the expandable member movable independently of movement of the cutting means between the first and second positions.

70. The apparatus of claim 69, further comprising tissue penetrating means extending distally from the elongated housing.

71. The apparatus of claim 63, wherein the elongated housing is configured with a pointed piercing member to penetrate tissue.

72. A surgical apparatus for cutting a tissue mass via application of electrical energy to tissue comprising an elongated housing, the elongated housing having a distal portion and a first transverse dimension, and a cutting member radially extendable with respect to the housing, the cutting member being rotatable to separate the target tissue mass from surrounding tissue thereby cutting a swath of tissue having a transverse dimension greater than the first transverse dimension of the elongated housing, the cutting member being connectable to an electrical power source to transmit electrical energy to the tissue to cut the tissue mass, and an expandable collection member



advanceable distally to remove the cut swath of tissue.

73. The apparatus of claim 72, wherein the expandable member is distally movable between a first position within the elongated housing and a second position extending from the elongated housing.

74. The apparatus of claim 73, further comprising a tissue piercing element extending distally from the elongated housing.

1/7

FIG. 1

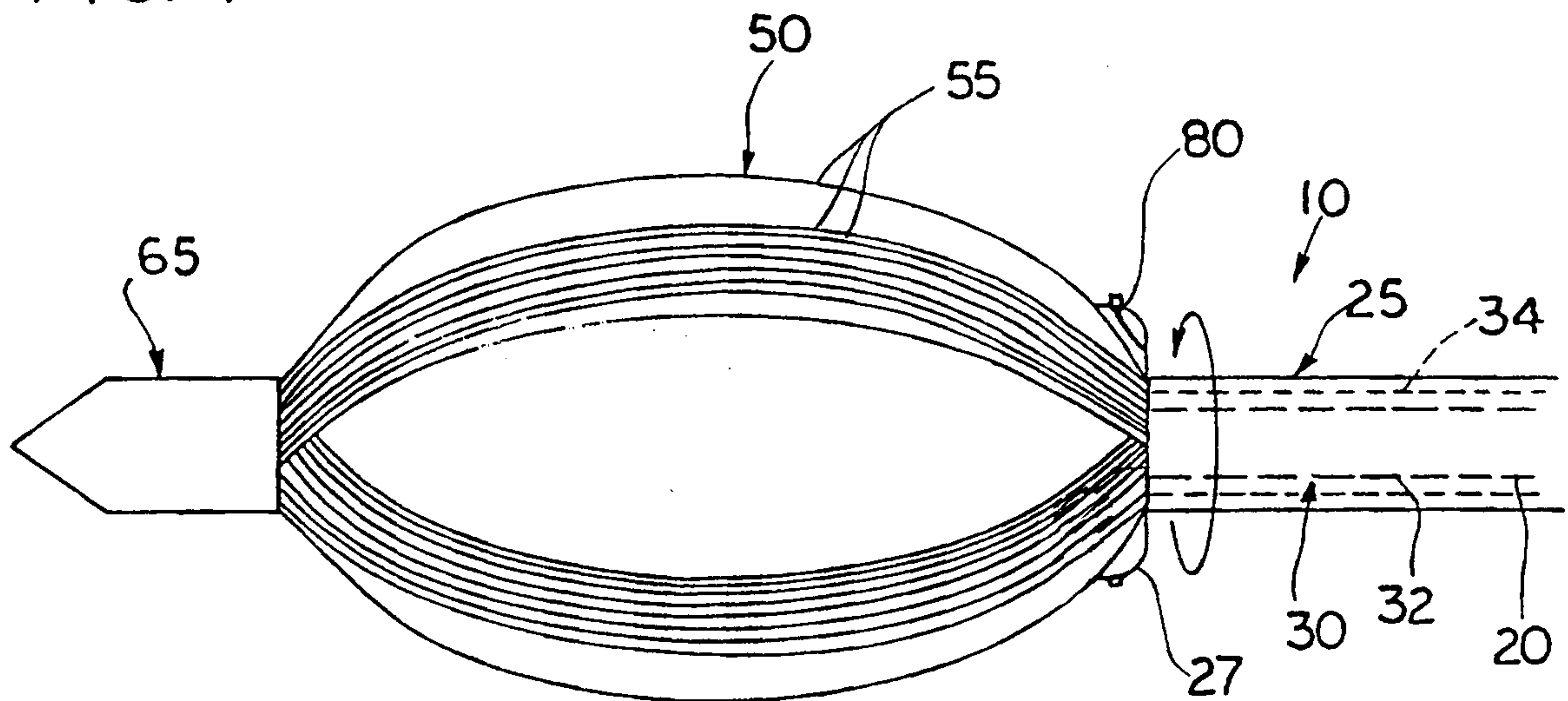


FIG. 2

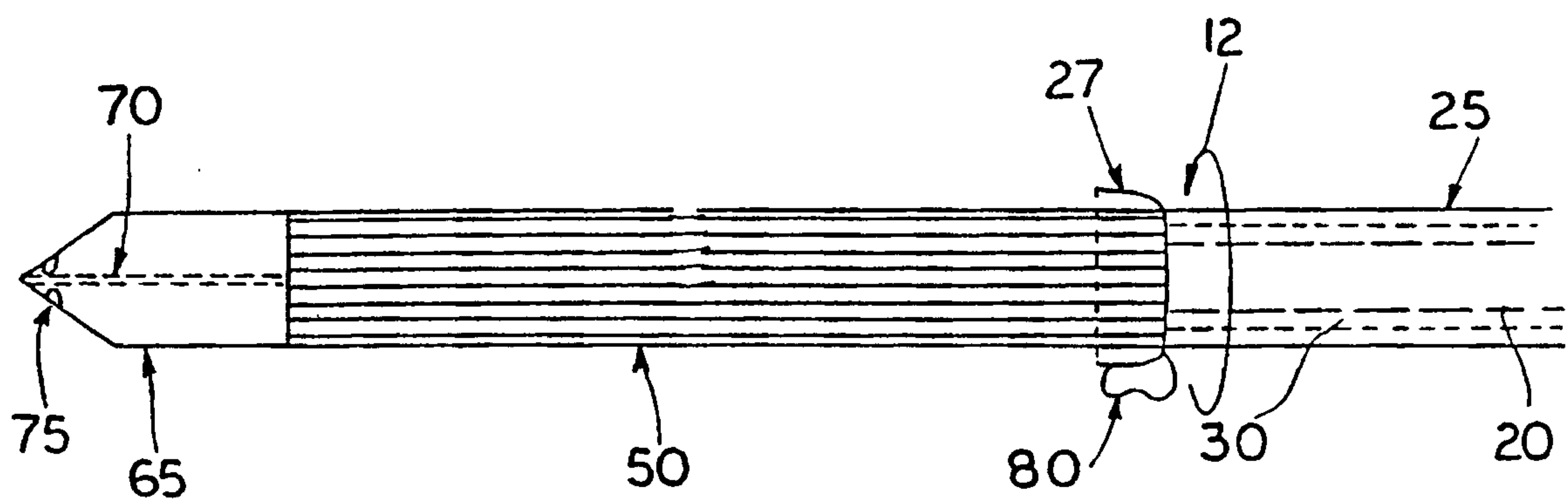
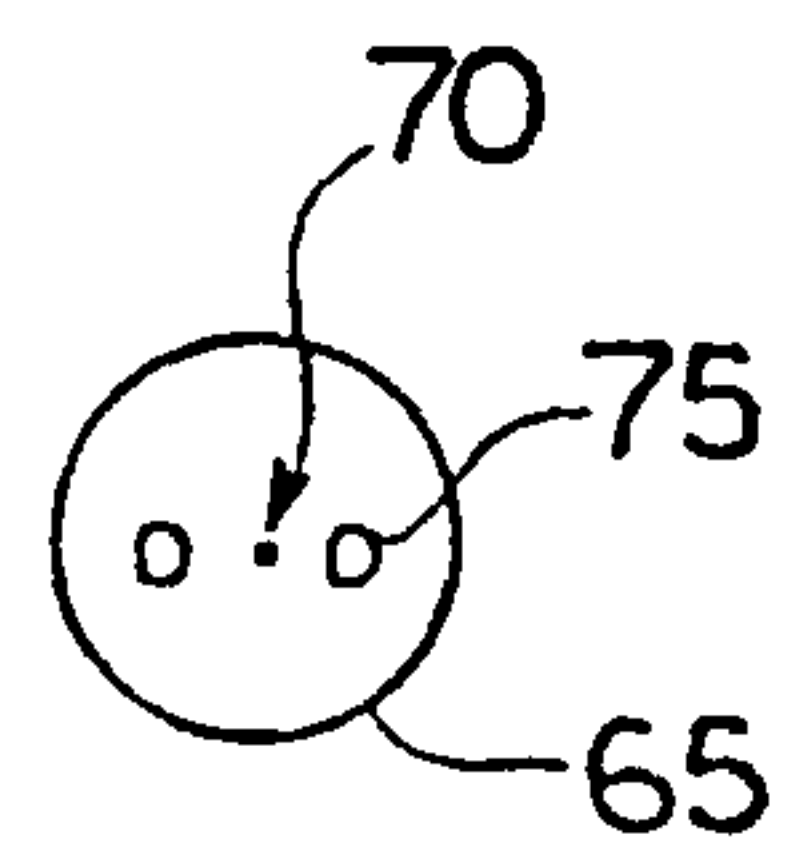


FIG. 3





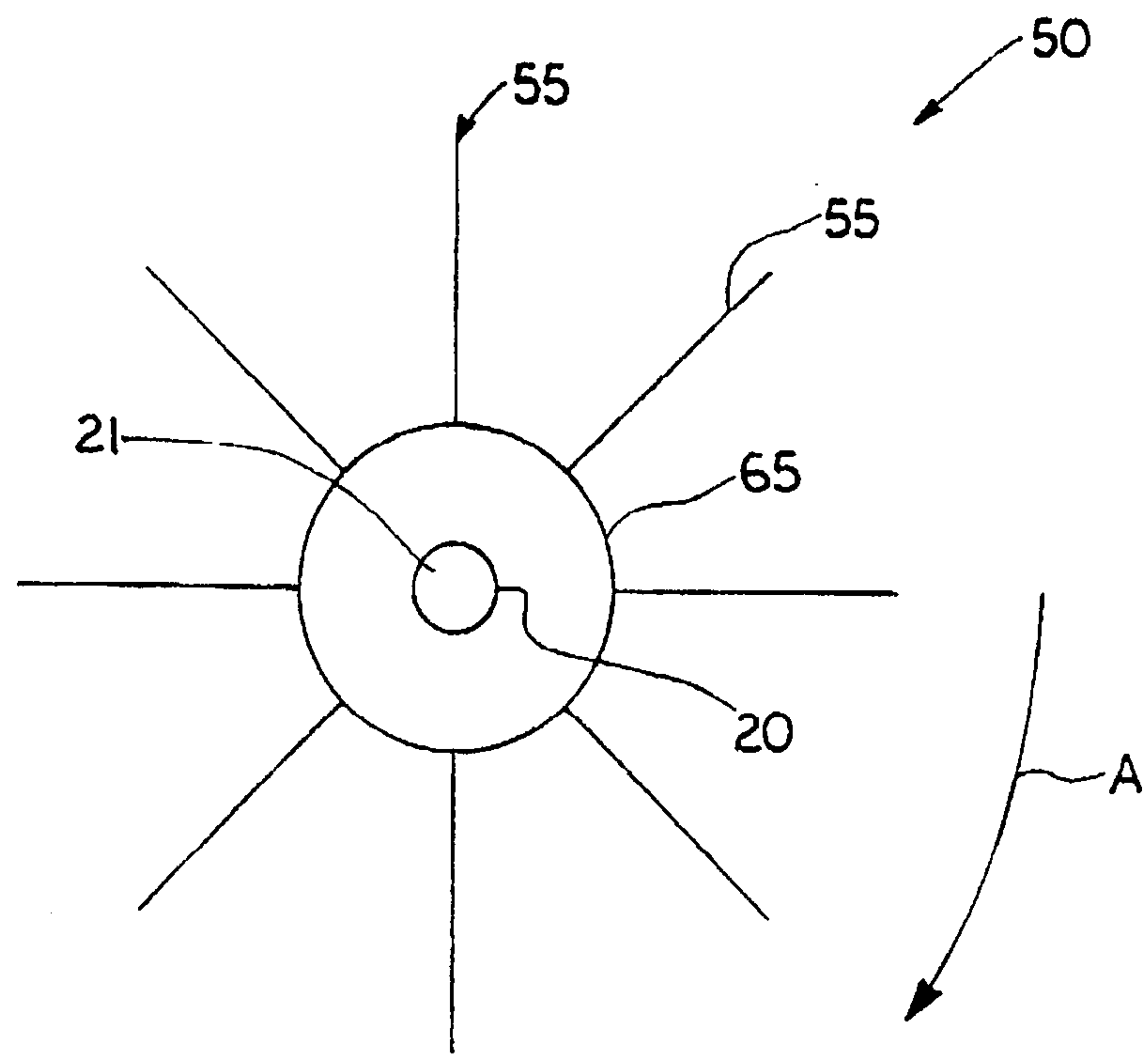


FIG. 4

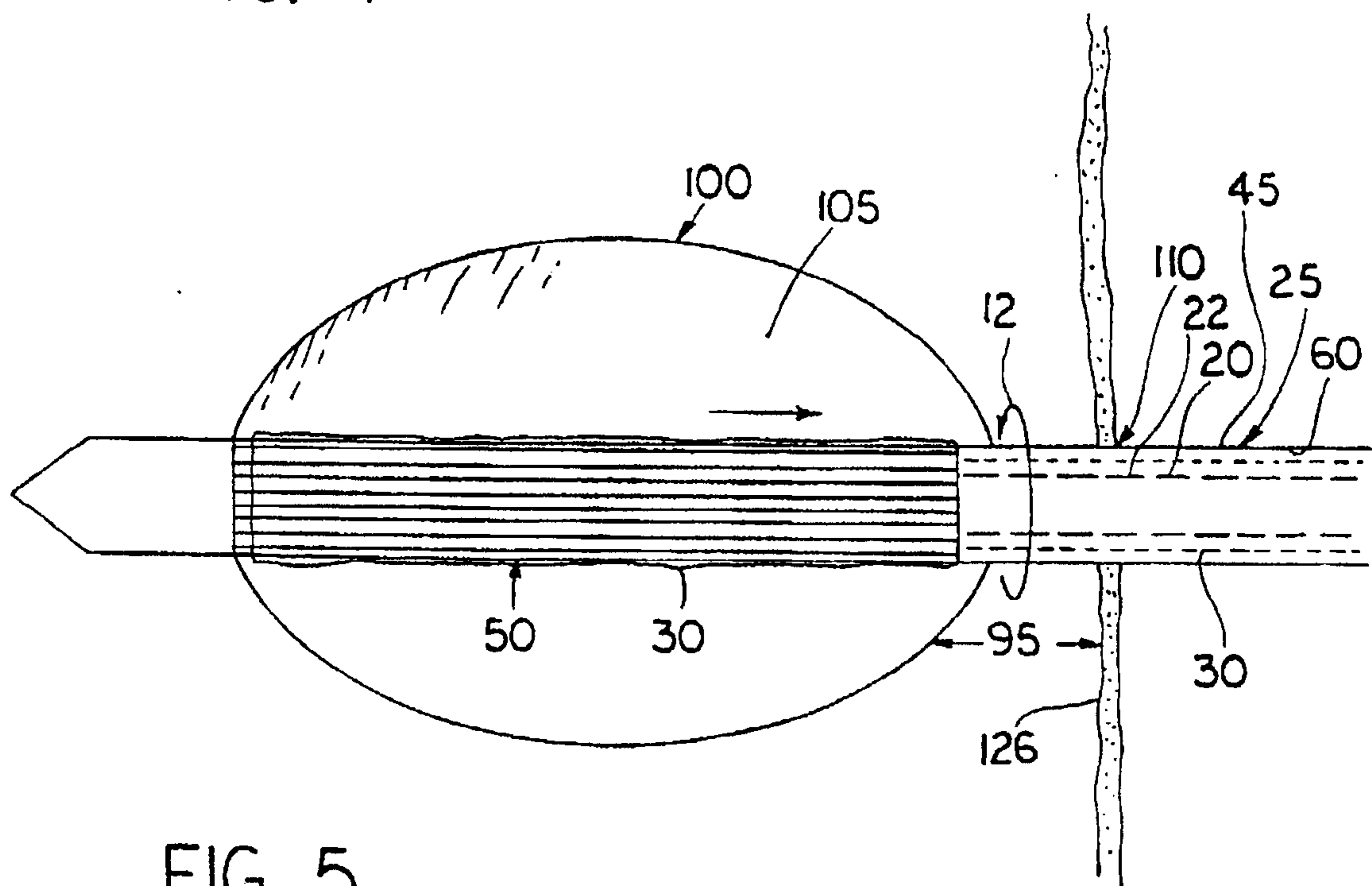


FIG. 5

3/7

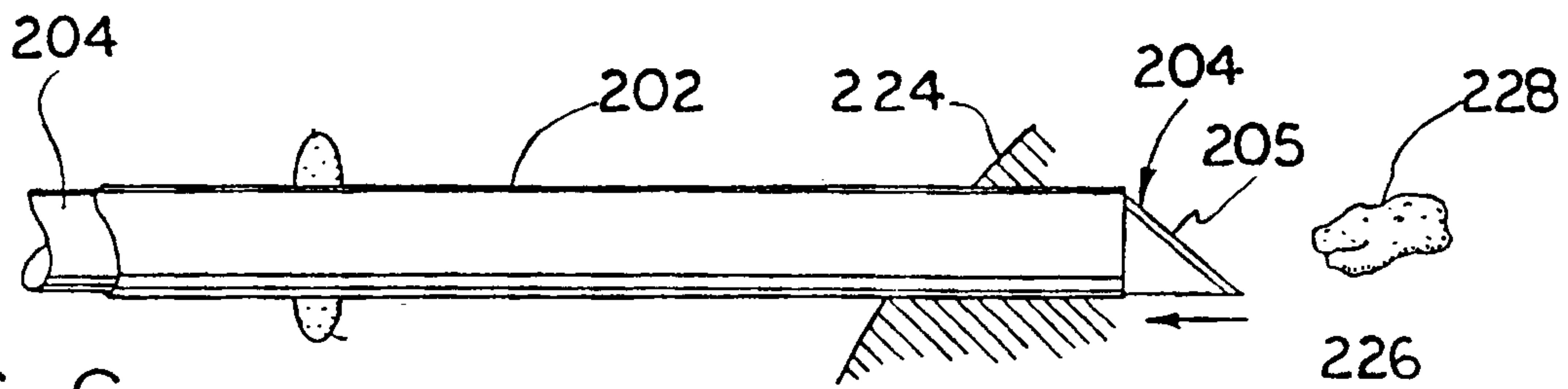


FIG. 6

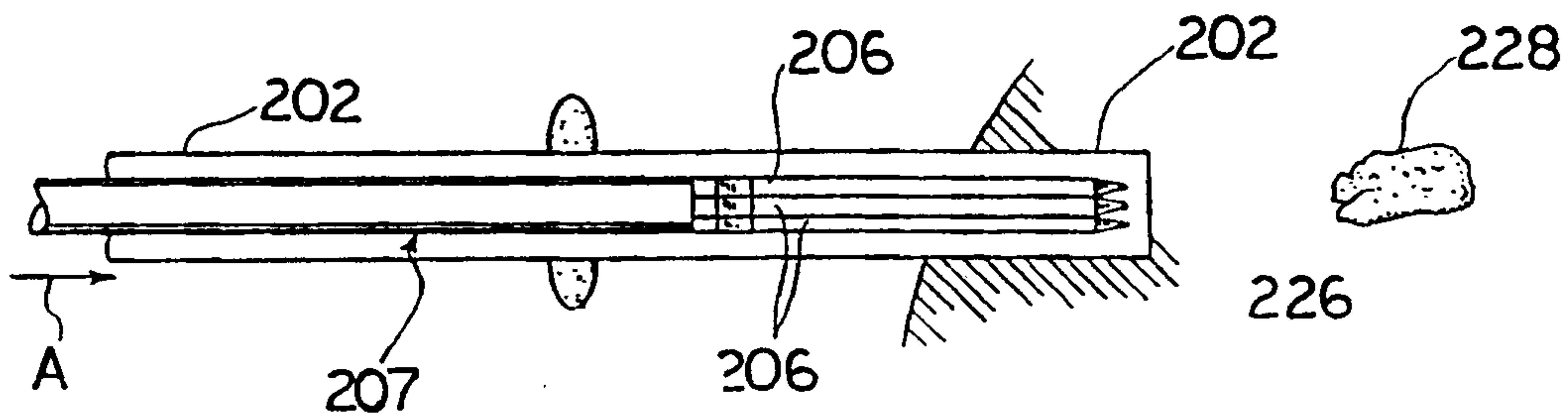


FIG. 7

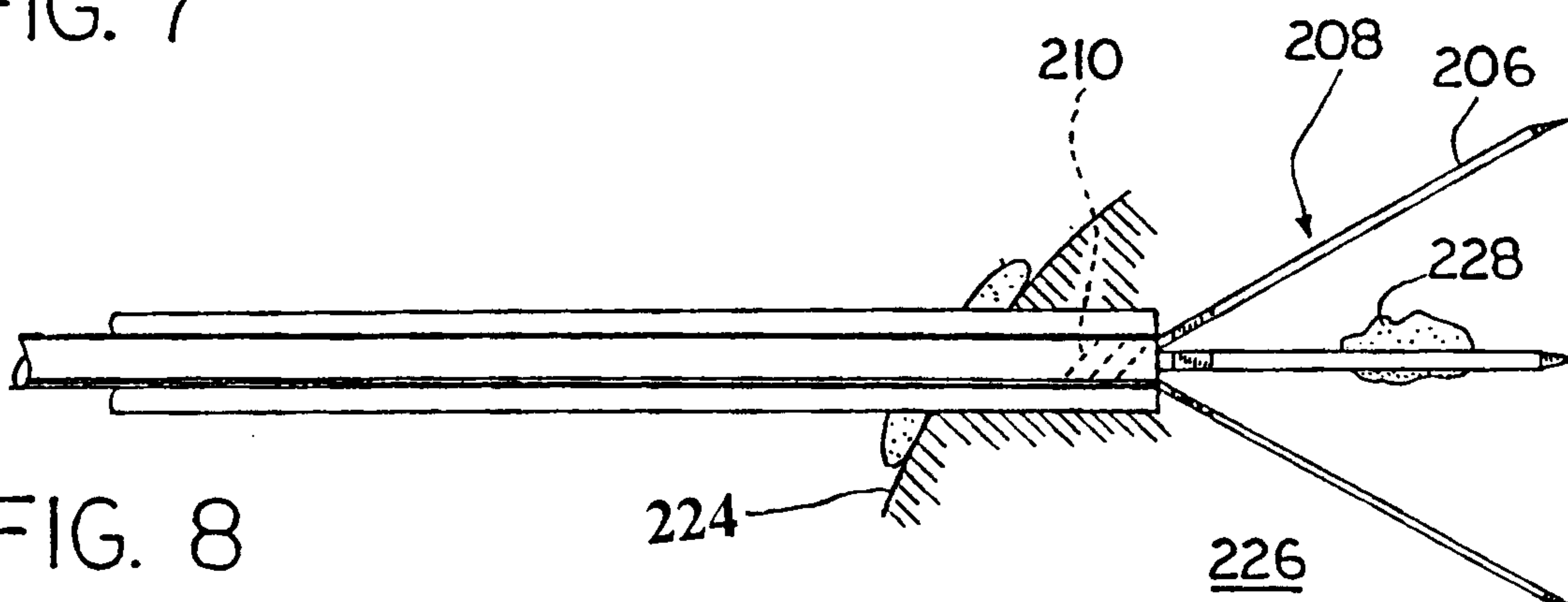


FIG. 8

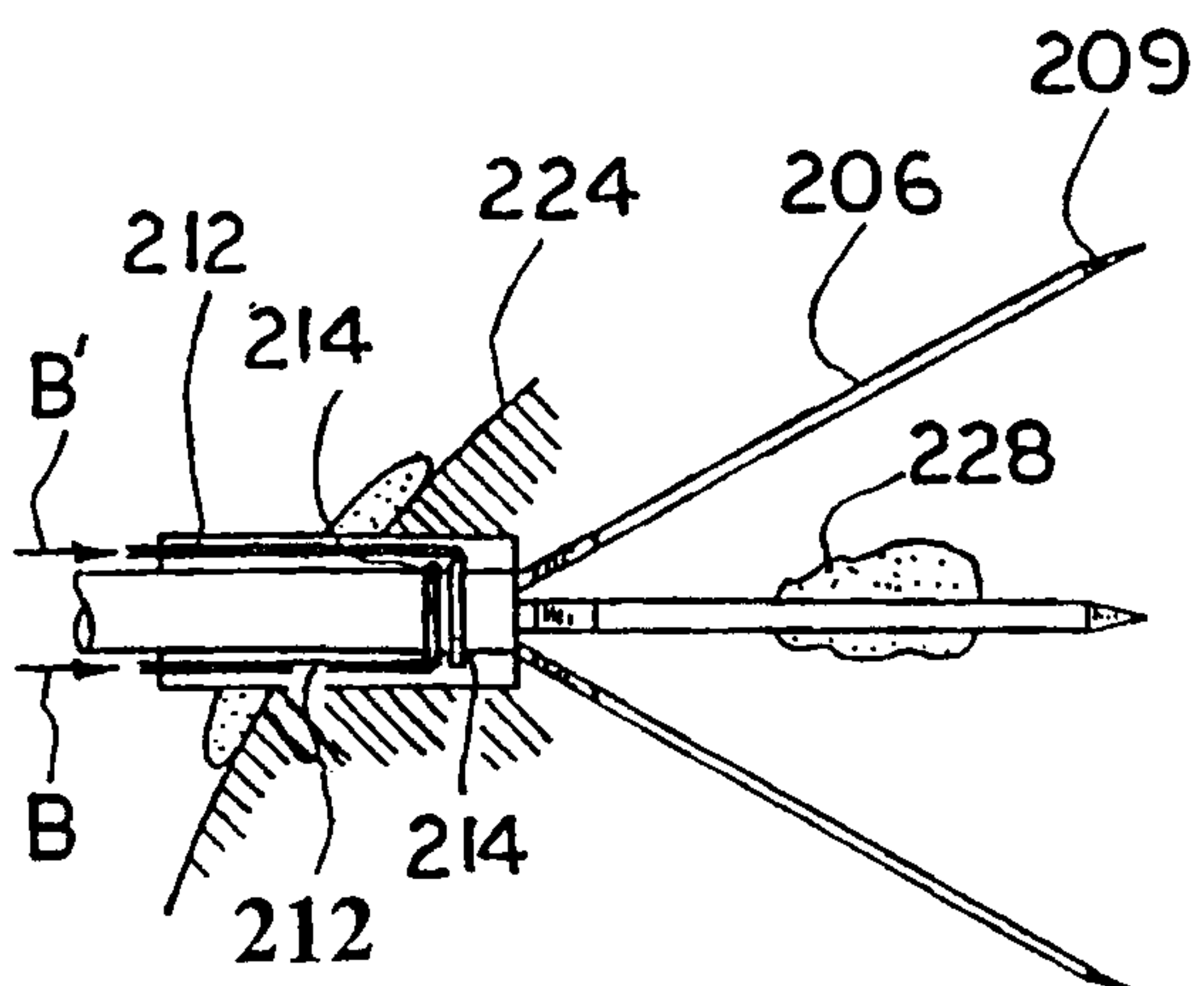


FIG. 9

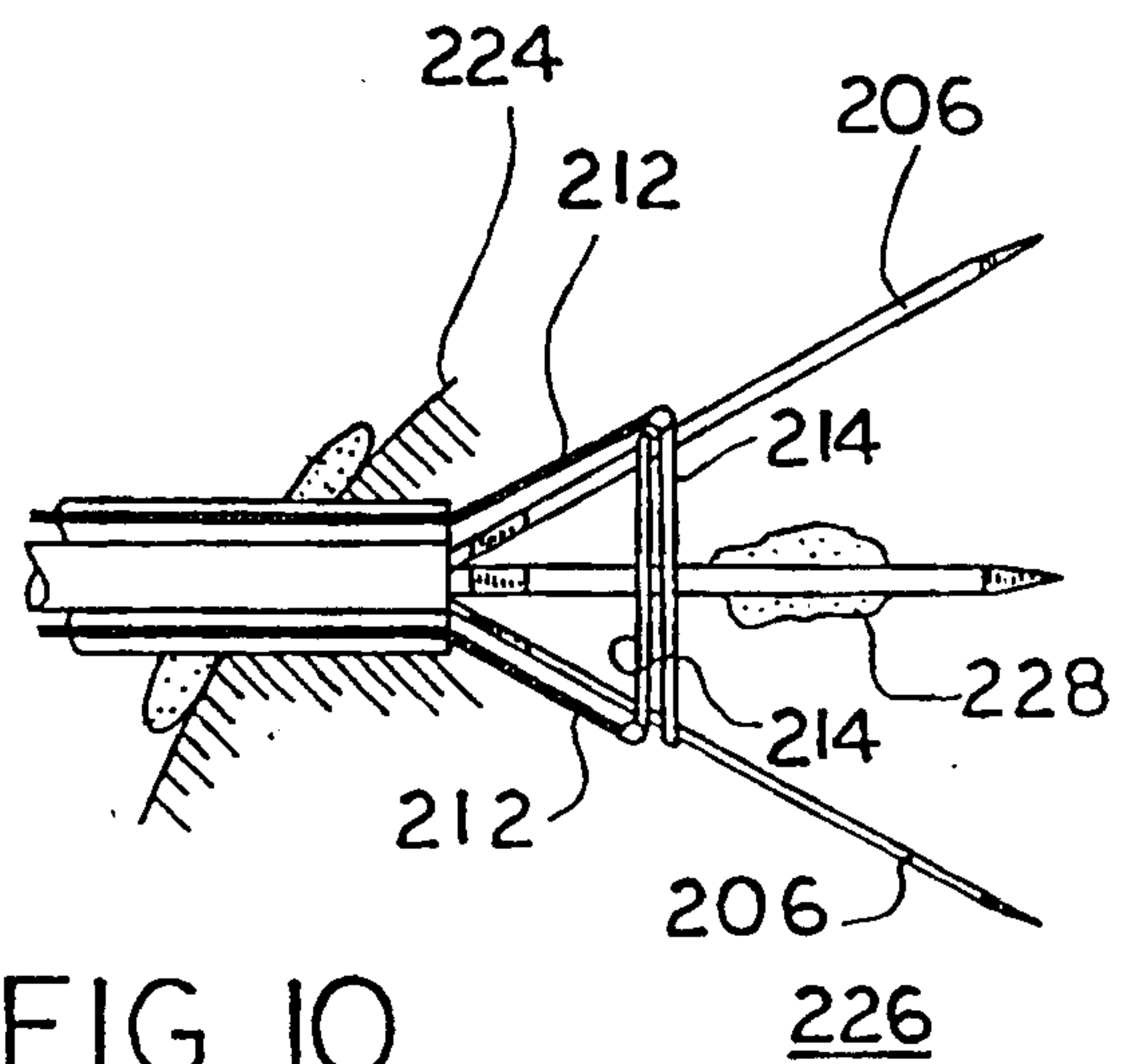


FIG. 10



4/7

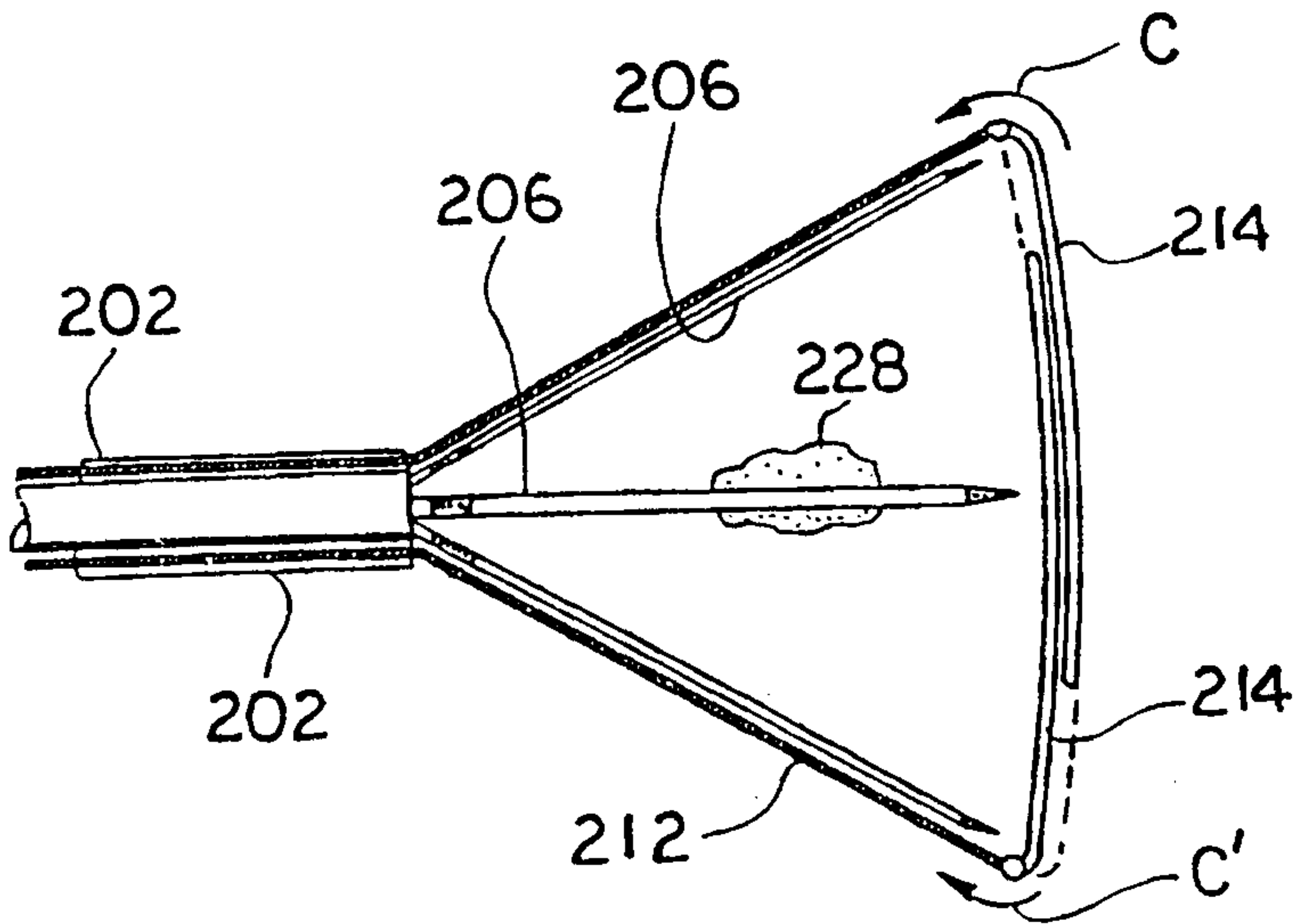


FIG. 11

FIG. 12

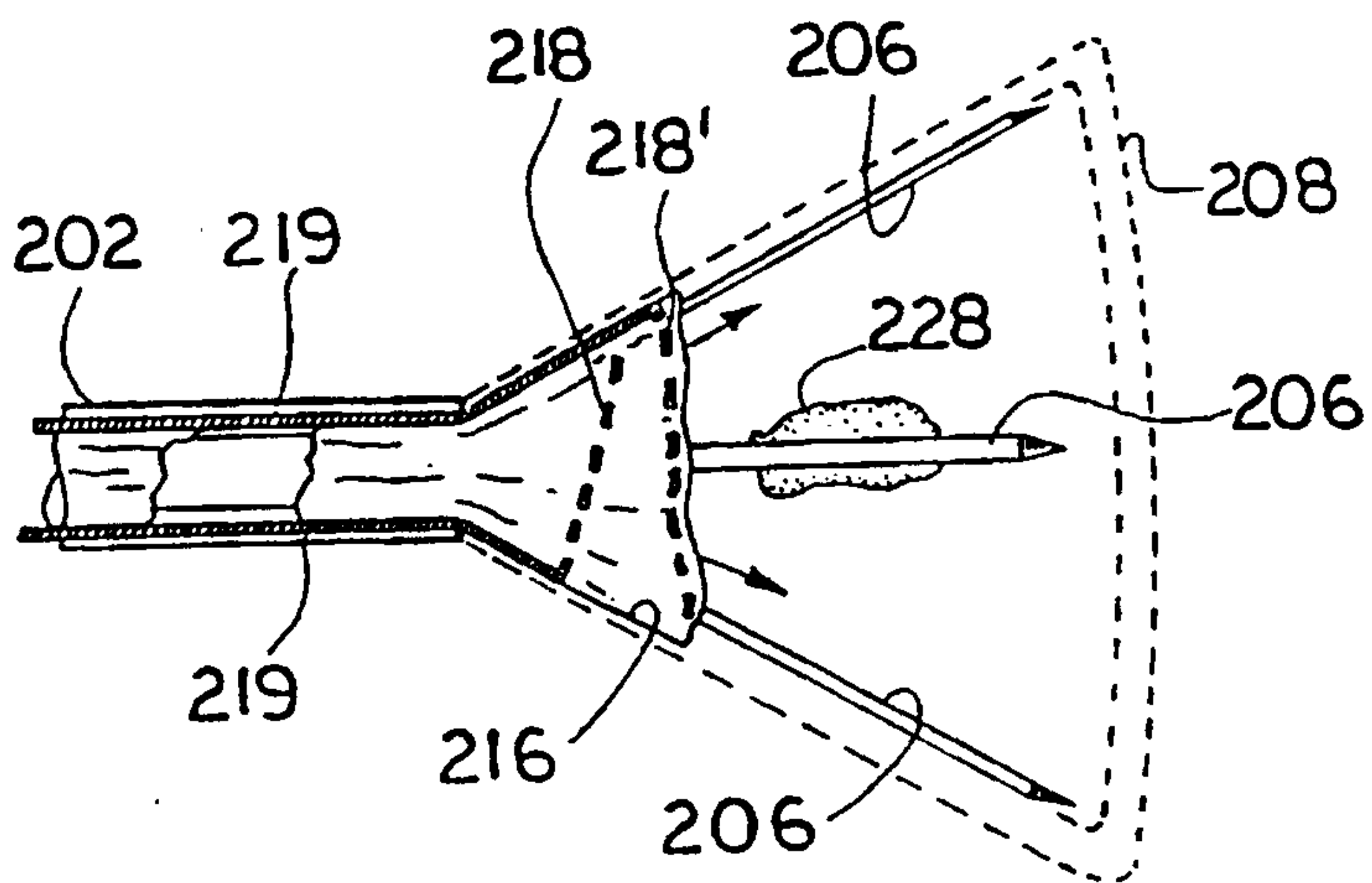
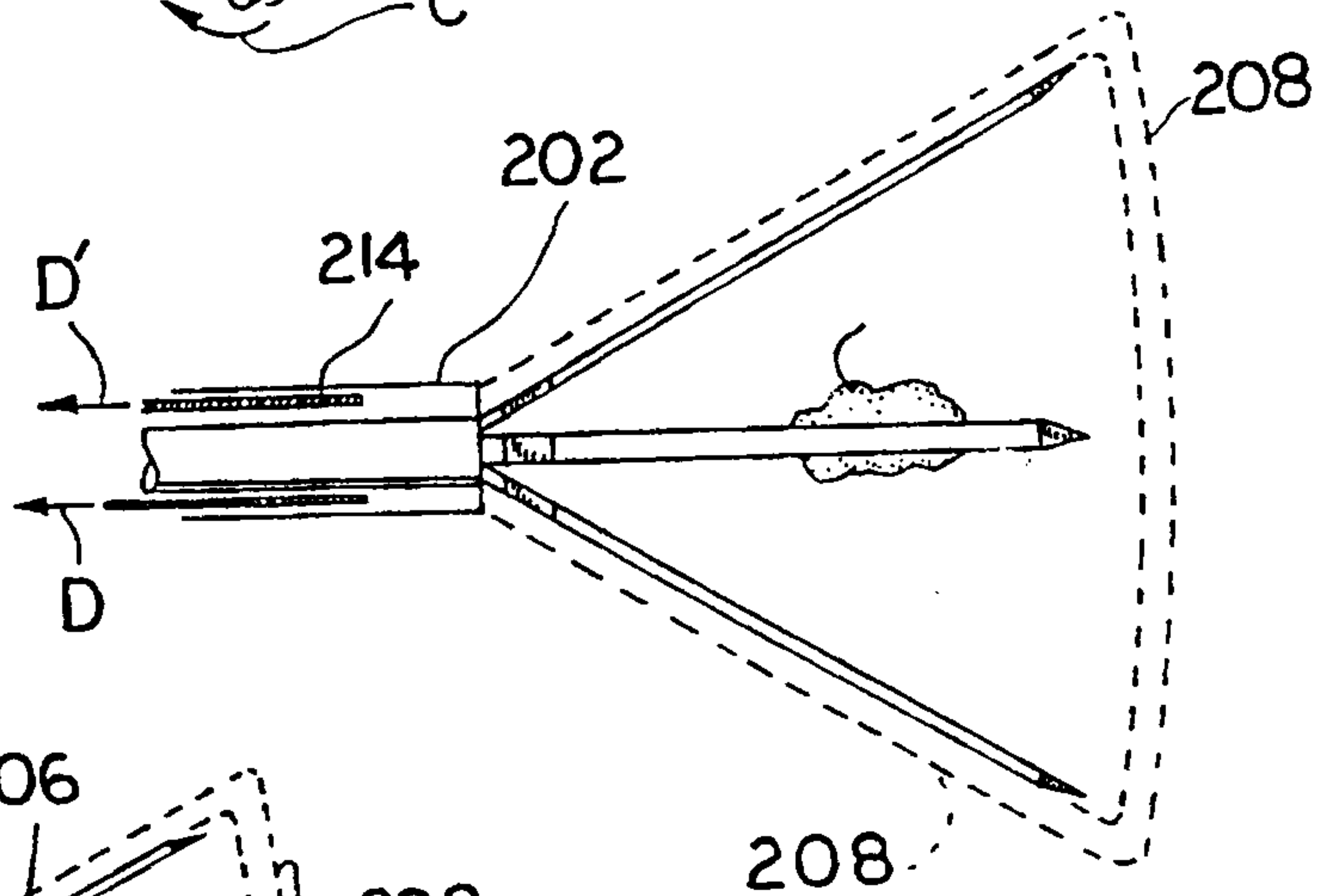
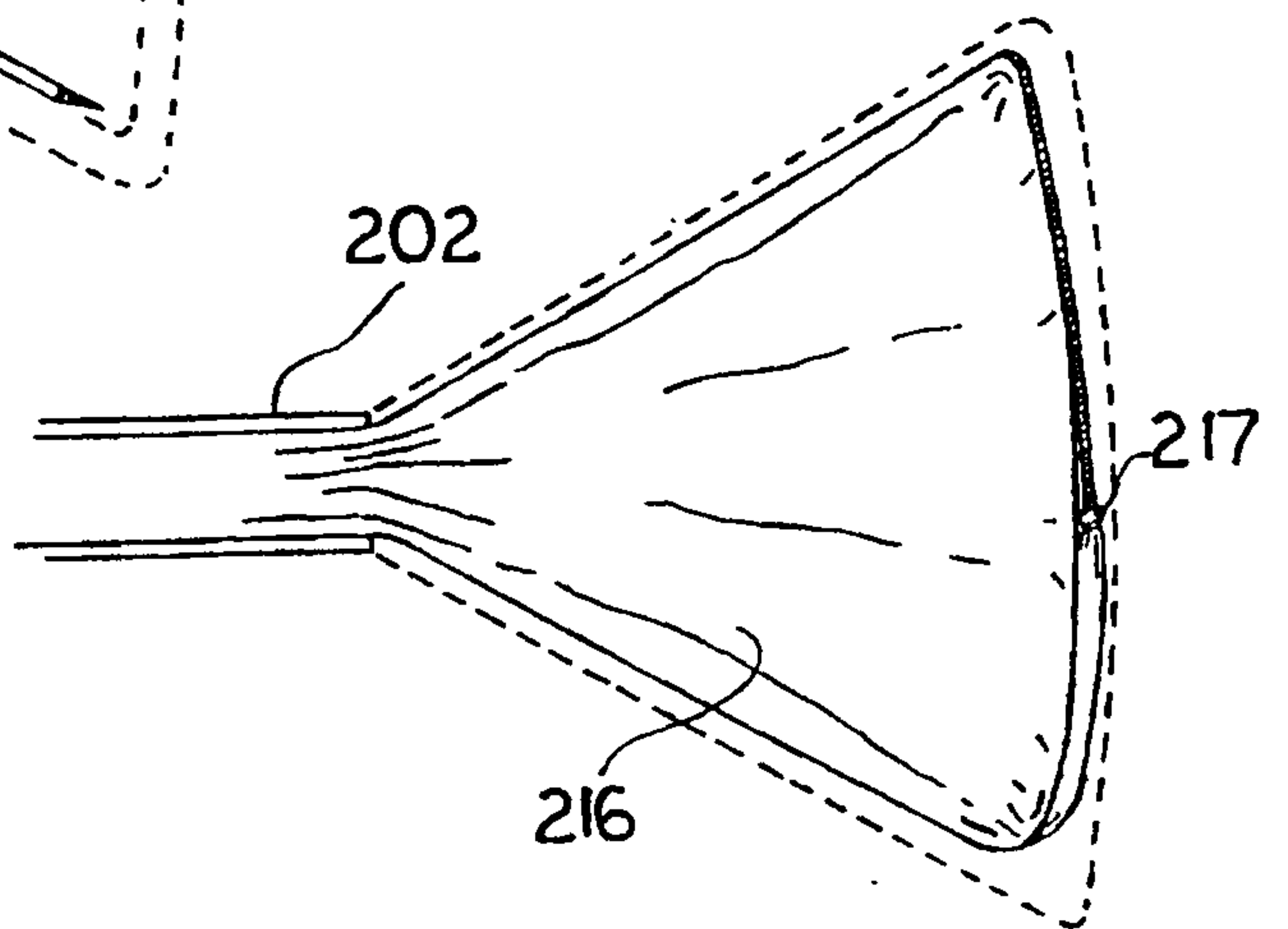


FIG. 13

FIG. 14



5/7

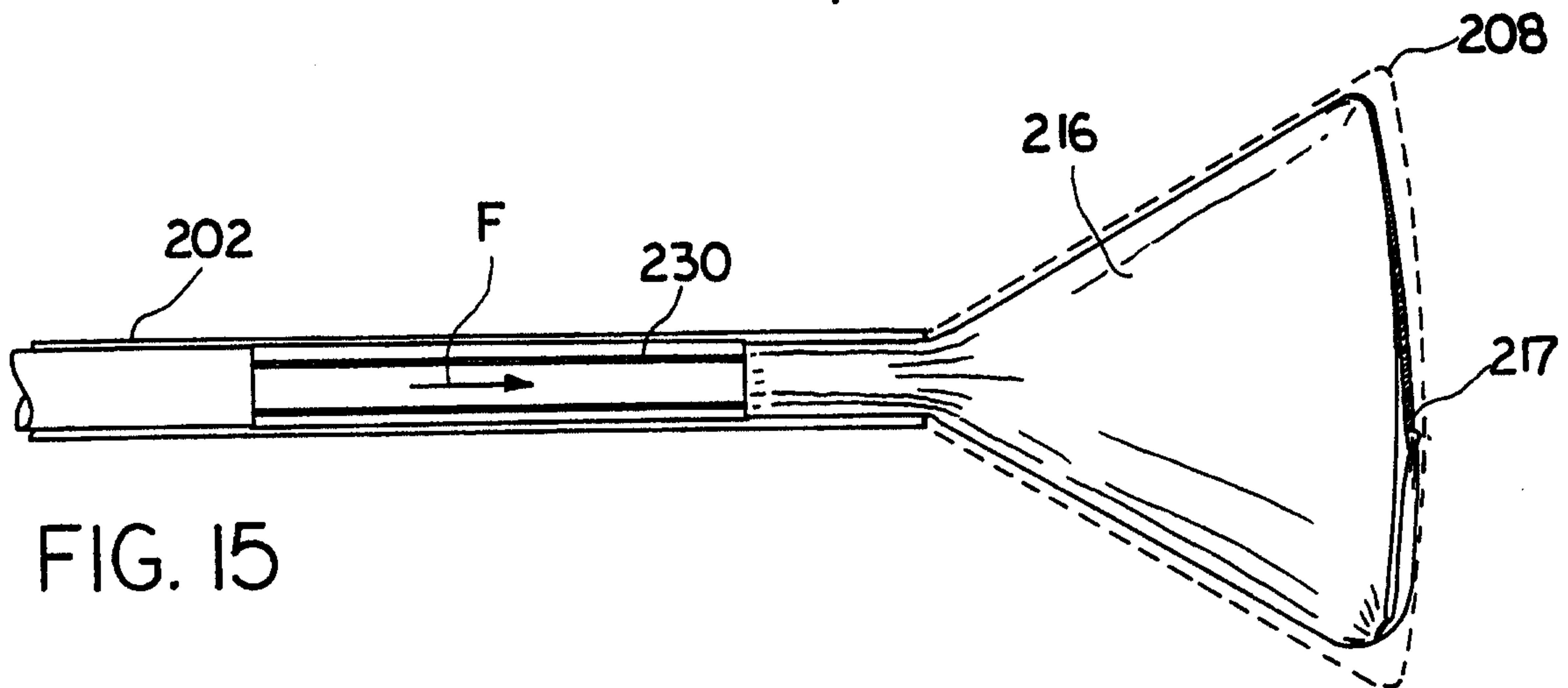


FIG. 15

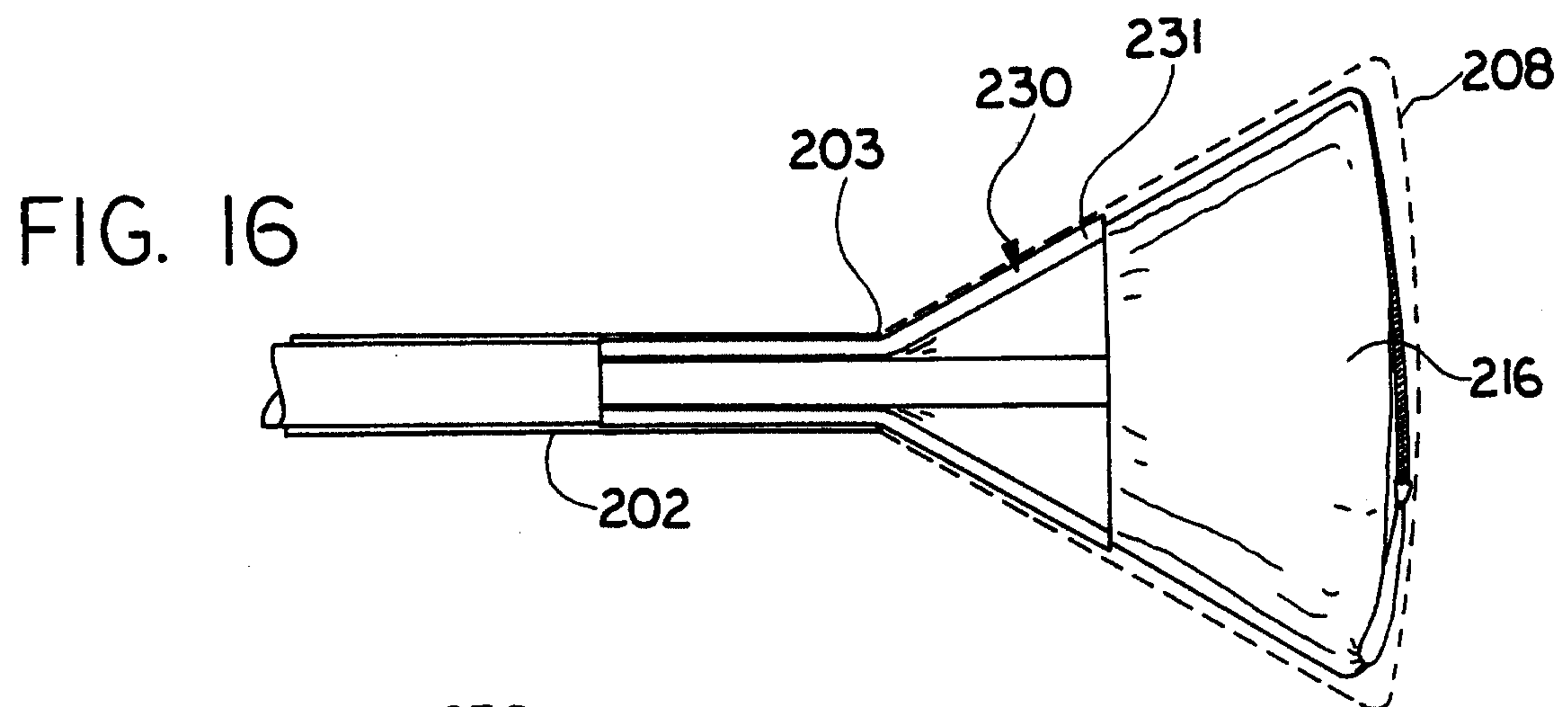


FIG. 16

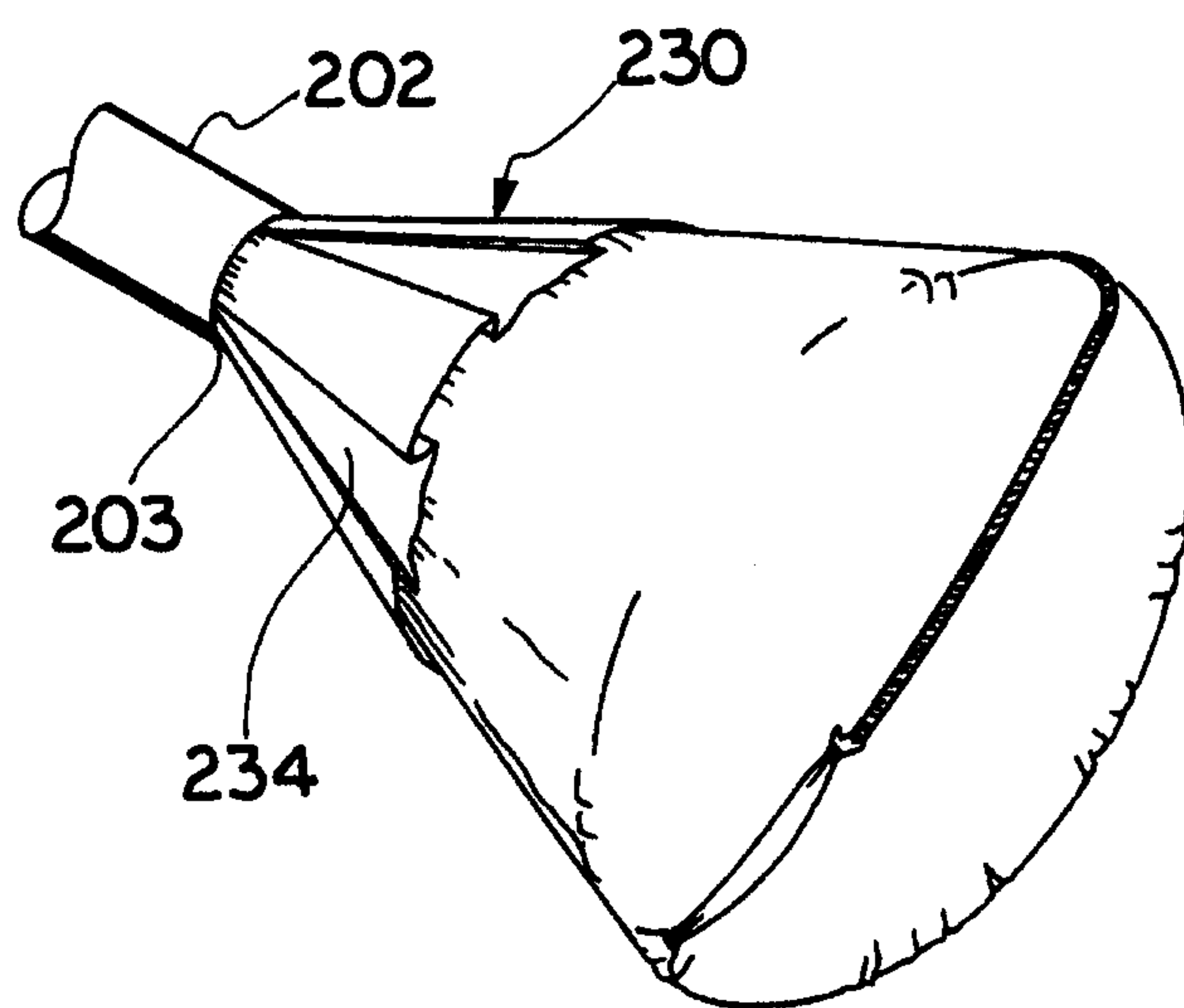


FIG. 17

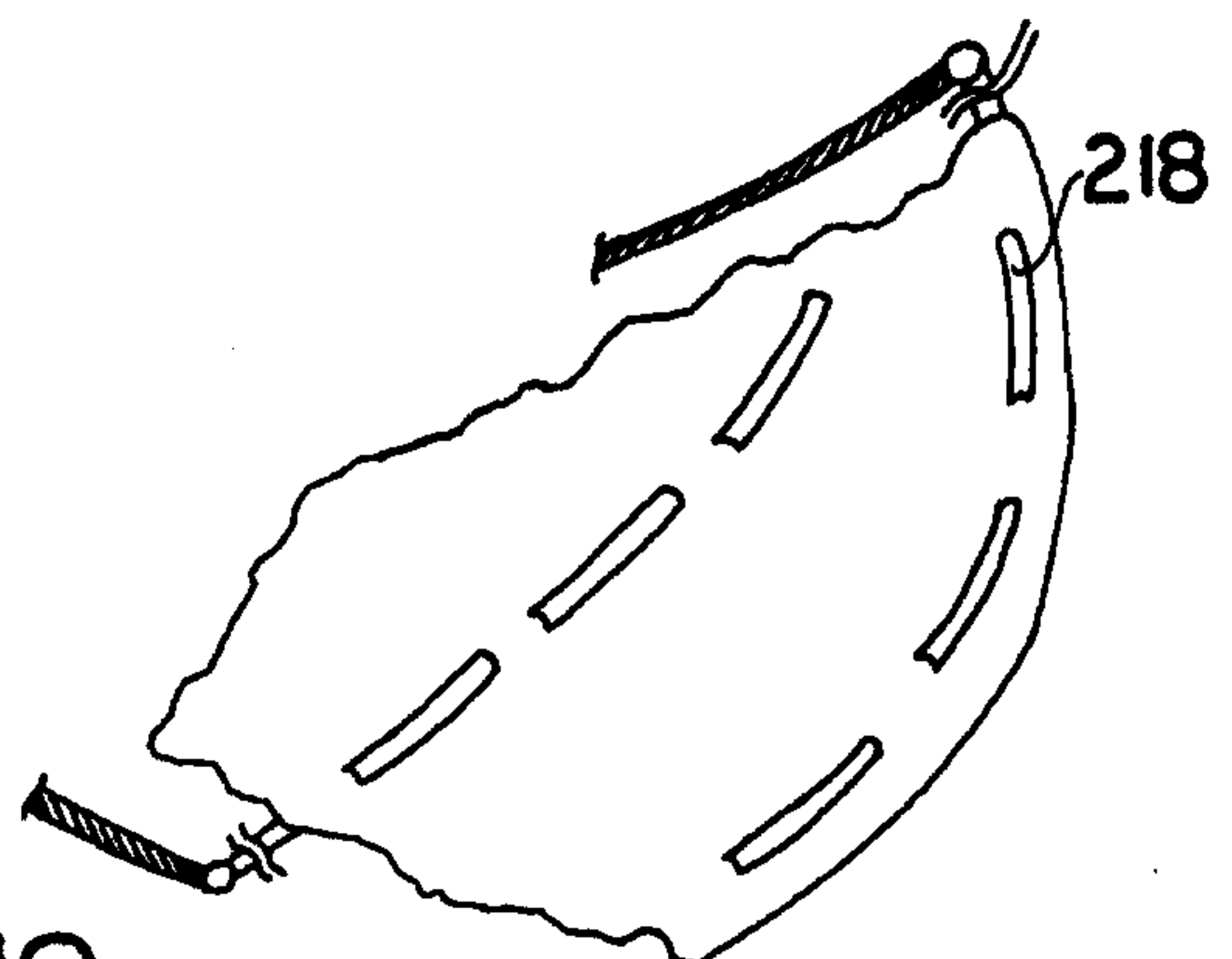
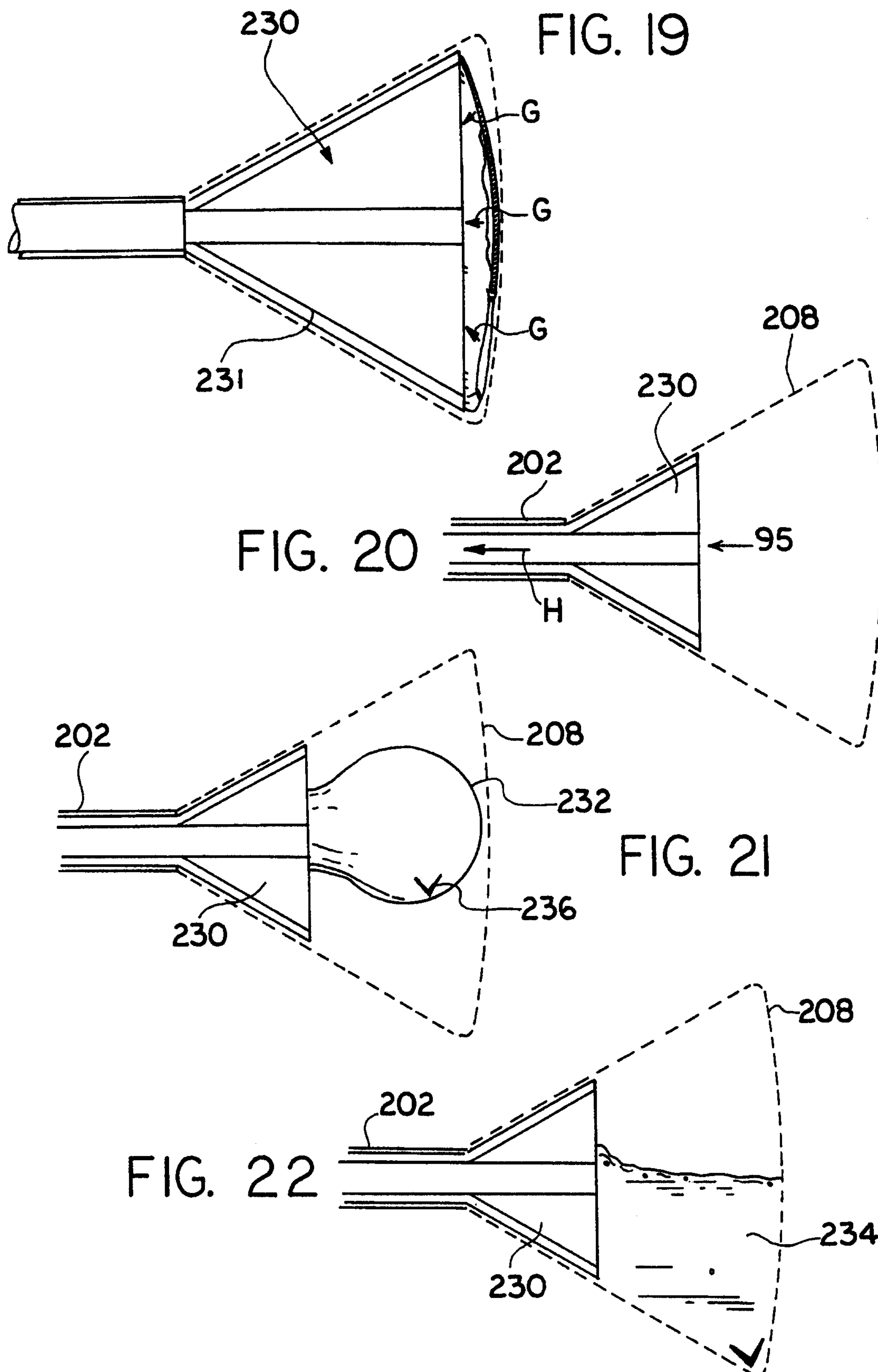


FIG. 18



6/7



7/7

FIG. 23

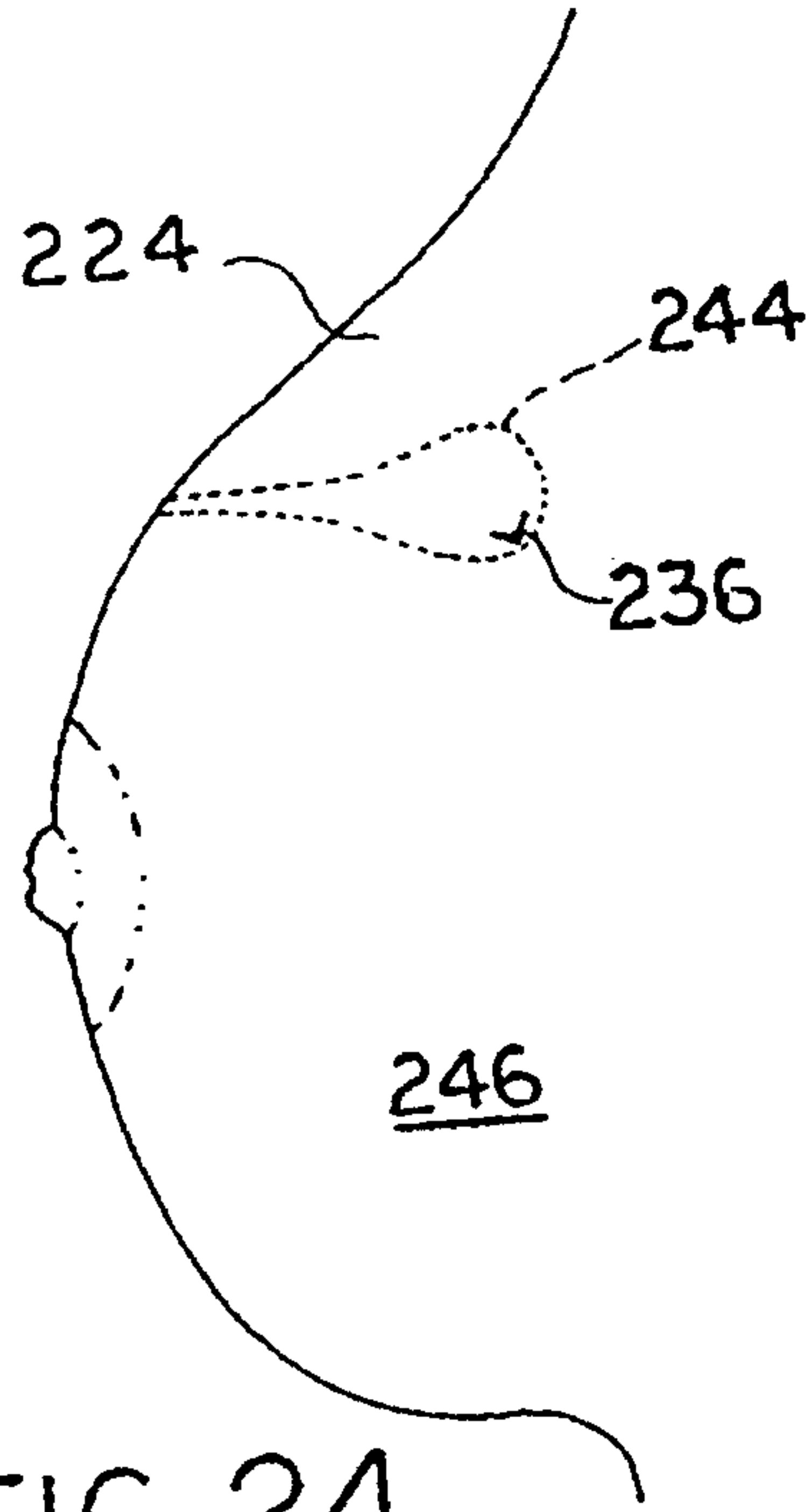
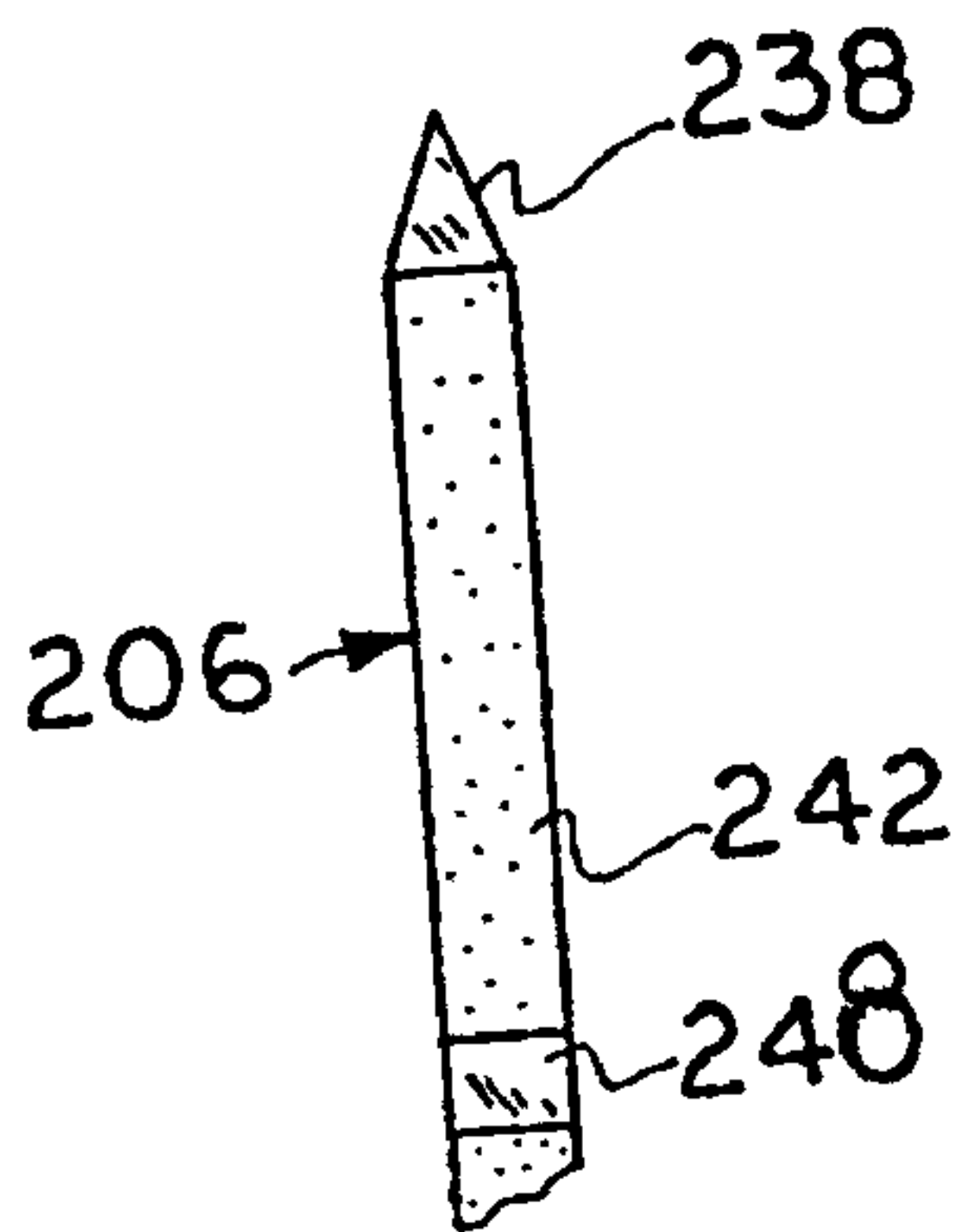


FIG. 24

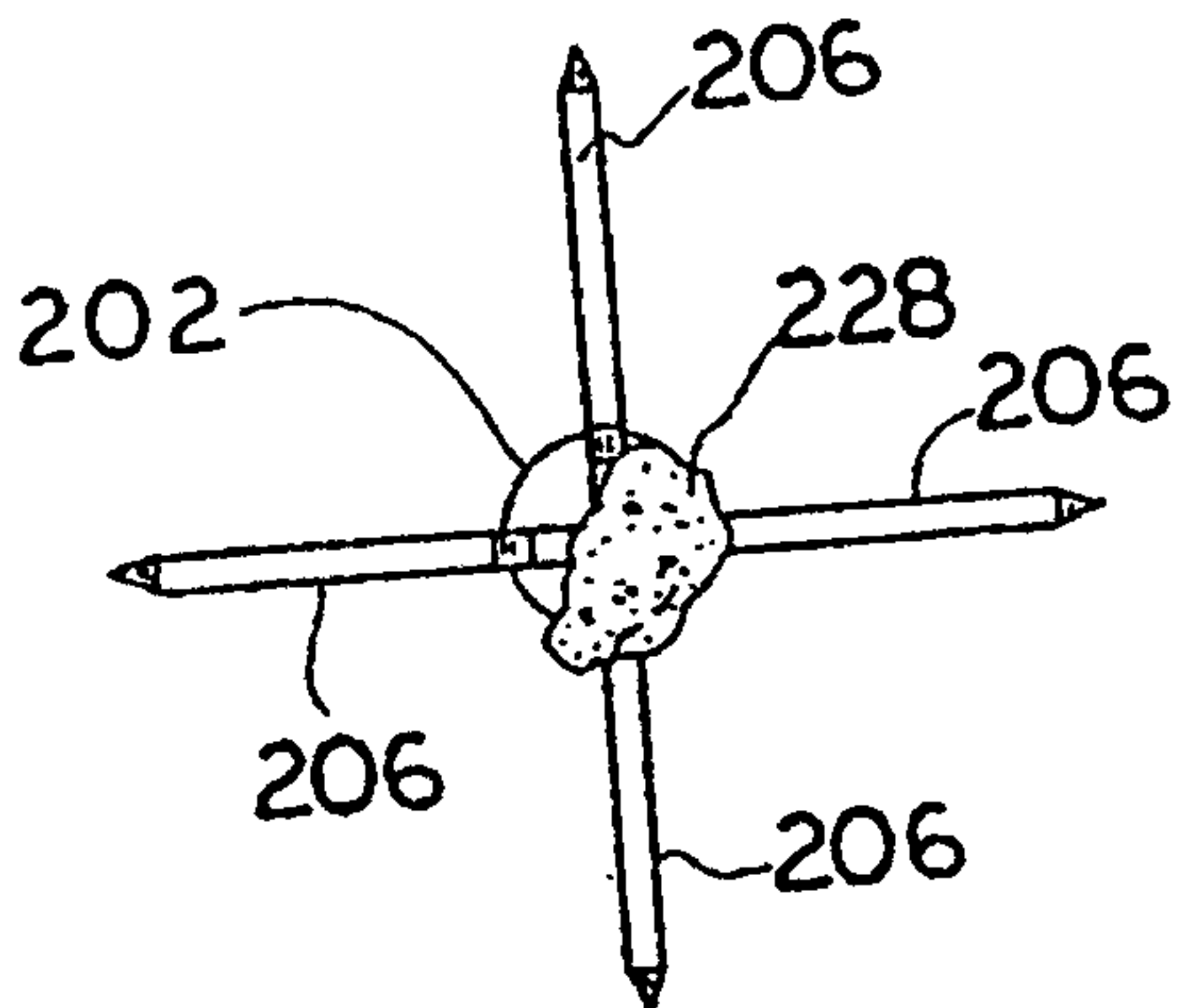


FIG. 25

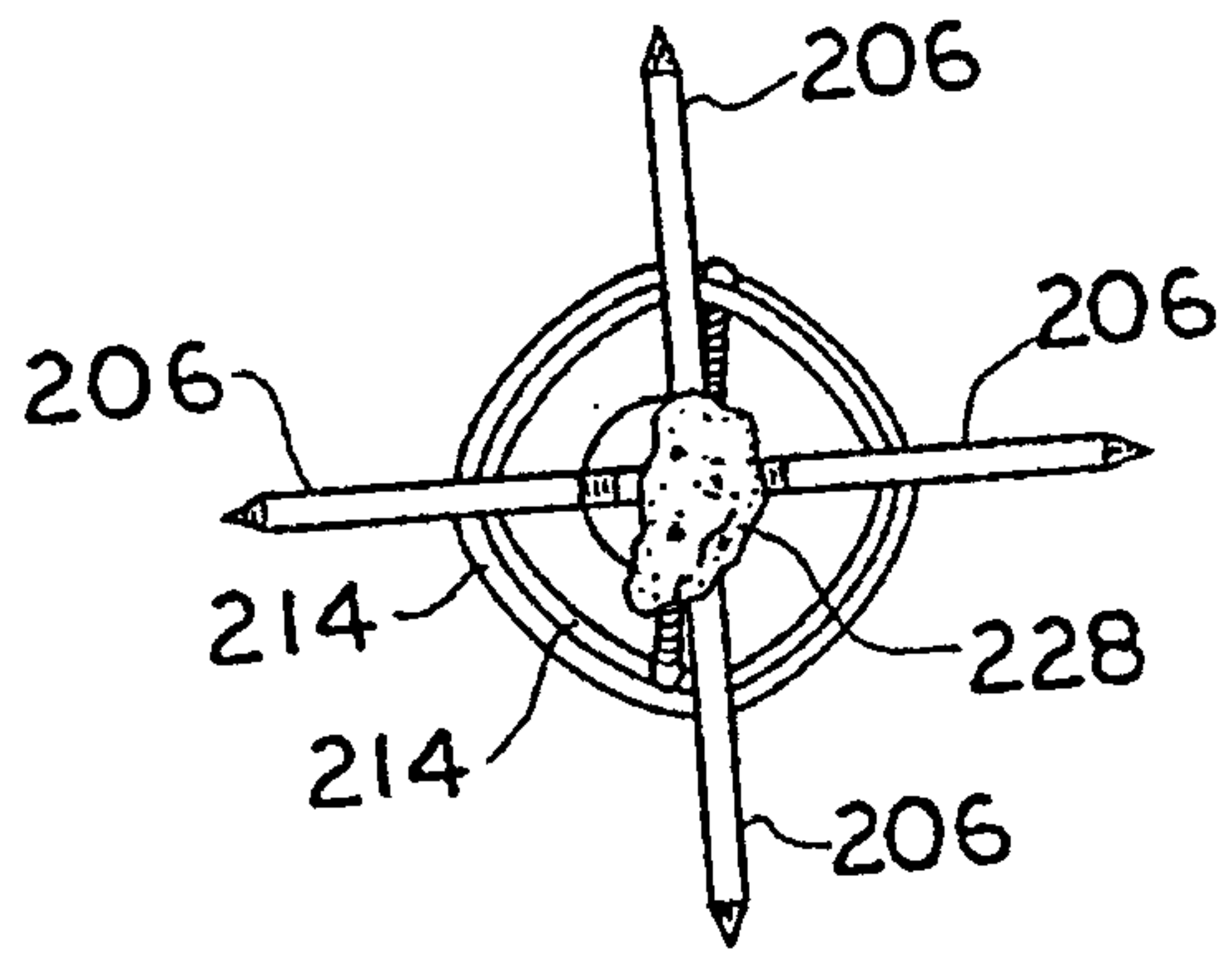


FIG. 26

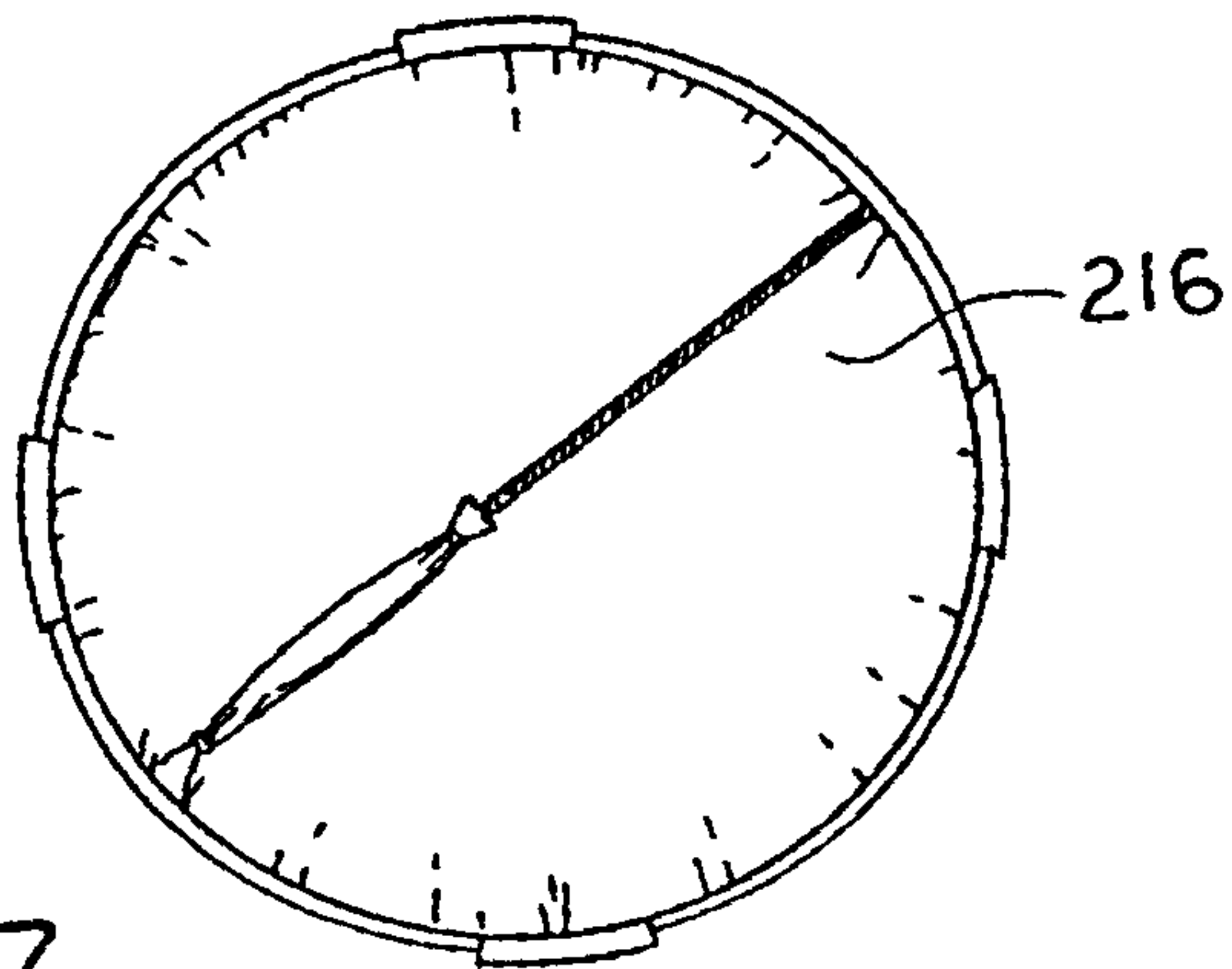


FIG. 27



