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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
5 June 2008 (05.06.2008)

PCT

(10) International Publication Number
WO 2008/066543 A1

(51) International Patent Classification:
A61B 1/32 (2006.01)

(21) International Application Number:
PCT/US2006/061246

(22) International Filing Date:
27 November 2006 (27.11.2006)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant *(for all designated States except US)*: **VYCOR MEDICAL LLC** [US/US]; 40 CHARDONNAY DRIVE, Coram, NY 11727 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **MANGIARDI, John R.** [US/US]; 54 DOUBLING ROAD, Greenwich, CT 06830 (US).

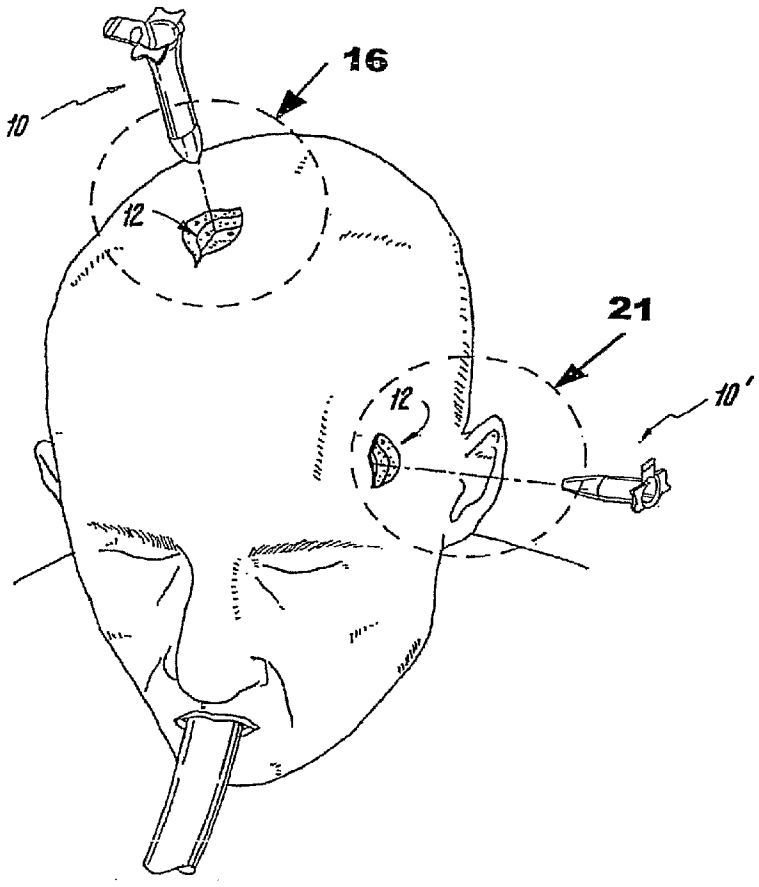
(74) Agent: **RZUCIDLO, Eugene C.**; Hunton & Williams LLP, 1900 K Street, N.W., Washington, DC 20006-1109 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: SURGICAL ACCESS INSTRUMENTS FOR USE WITH DELICATE TISSUES



(57) Abstract: One or more surgical instruments provide access to delicate tissue, such as brain tissue or breast tissue, through a transcutaneous incision, for a variety of reasons, such as to access a surgical site for providing a working channel for accessing delicate tissue by surgical instruments, to provide access to insert an inflatable prosthesis, or for providing an external buttress channel for supporting tissue thereon. The surgical instrument assembly includes an interleaved combination of an open sleeve hollow retractor and a tapered tipped wedge introducer. The wedge introducer is introduced into an area adjacent to the hollow sleeve. The distal tip of the wedge introducer extends beyond a distal end of the hollow retractor, forward of a distal end of the hollow retractor, so that the wedge introdticer traverses delicate tissue ahead of the distal end of the hollow retractor, guiding the hollow retractor into place to the delicate tissue.

WO 2008/066543 A1

Published:
— *with international search report*

SURGICAL ACCESS INSTRUMENTS FOR USE WITH DELICATE TISSUES

Field of Invention

This disclosure relates to surgical access instruments for use with delicate tissues and methods of use.

Background

Traditional surgical brain retractors are thin, firm bands of steel or other metal alloys, with abrupt or well-defined edges and have limited surface areas. The common structural form is a simple strip of sheet metal consisting of a metal strip which can be bent by hand and the surface of which typically is clearly outlined on the brain after a few minutes. Particularly noticeable are the pressure marks of the lateral spatula edges which indicate a high local compression stress. These traditional retractors can be introduced into the tissue of the brain or along brain surfaces, and then pulled with force to either separate or elevate the brain tissue during surgery. This method allows the target area to be illuminated and visualized in order to perform the surgical procedure. However, brain tissue is quite soft and delicate, particularly after trauma, loss of blood supply, or in the presence of brain edema. The brain tissue is a gel-like substance that can be easily damaged, and a complication known as "retraction injury" can occur, sometimes resulting in compromised brain function. The brain tissues can be torn by the relatively sharp edges of these retractors, and/or the retracted brain can loose blood supply when the local pressure beneath the retractor is greater than venous pressure. The result can be ischemic changes in the underlying brain and/or the more serious complication of venous brain infarction.

The combination factors including the softness of the brain tissue, and the effects of sharp, blunt edges and limited surface area of traditional metal band retractor also results in limited visualization of the surgical target area. The brain tends to extend beyond or "droop" around the edges of the retractor, limiting the area necessary for lighting and reducing overall visibility.

Furthermore, the amount of local pressure exerted by the retractor on the brain tissue must be limited to avoid injury, which may impede the surgeon's ability to safely gain enough visualization area. Oftentimes, the surgeon will resort to the

strategy of exposing far more of the brain tissue than is necessary or desirable to open the area around the brain widely enough so as to limit the amount of local retraction pressure. This method is undesirable, as compared to a less invasive approach, for both the patient and surgeon.

It would be advantageous to provide a surgical instrument assembly that safely addresses the short comings of the presently-known instruments.

Objects of the Invention

The objects and design principles of the surgical access instrument assemblies of this invention are as follows:

(1) to maximize surface area of the retractor, so as to distribute pressure evenly and minimize effective local retraction pressure;

(2) to enable integration with stereotactic neuro-navigation computer guidance system;

(3) to reduce the need to "pull" on a brain retractor, to obviate the possibility of accidental over-retraction and thereby avoid brain damage;

(4) to allow for binocular vision with the utilization of elliptical architecture;

(5) to allow for maximal lighting access clearance a target tissue visualization;

(6) to allow for minimization of brain disruption by limiting the corticotmy via use of a small elliptical window for the transcortical introducer;

(7) to allow for minimization of brain disruption with the utilization of tapered forward edges;

(8) to enable stable retraction fixation to avoid accidental retractor displacement;

(9) to provide retractors which are of lightweight materials to allow for ease of manipulation; and/or,

(10) to provide transparent retractors to allow for direct visualization of underlying brain tissue.

Other objects which become apparent from the following description of the present invention.

Summary of the Invention

In keeping with these objects and others which may become apparent, the present invention is directed toward an access assembly for surgical instruments. The access assembly for surgical instruments includes two principal components. One component is an internal instrument access assembly and the other is an external instrument access assembly. The internal instrument access assembly is designed to enter the brain to gain access to deeper internal brain structures. The external instrument access assembly is designed to elevate the surfaces of the brain to gain access to external structures along, around or beneath the brain. Both will be produced in varying sizes according to the needs of individual operations. The materials for these retractors will be composed of transparent biocompatible lightweight plastic. Each of the instrument assemblies include two separate parts, a retractor that also functions as a working channel, and a compatible introducer.

The internal instrument assembly is a wedge retractor introducer, which preferably includes a hollow wedge formed by all or part of a closed curve in cross section, such as an elliptical rounded wedge or an arch shaped wedge. It includes a hollow brain access working channel that can be fixed in space to a standard neurosurgical fixation cable device. First, a protruding introducer element, having a length greater than the length of the hollow working channel, is introduced into the working channel. Its distal smooth and relatively soft tapered end works to spread apart the brain hemispheres or other portions of delicate brain tissue. When the working channel is introduced, the introducer is removed, leaving the hollow working channel for the surgeon to access to the target tissues. Variations will include length (Z axis), and width and height (X and Y axes) of the elliptical working channel and introducer.

A fixation portion is designed to be attached to a standard neurosurgical armature fixation device.

The external surgical access instrument assembly is characterized by an arched hemi-elliptical architecture, wider along the base (X axis) than tall (Y axis). It is smooth, tapered at the leading edge, has a handle fixation portion that is o the same design as that of the internal instrument assembly, and is designed to be attached to a standard neurosurgical armature fixation device. Variations will be in length (Z axis) as well in X and Y axes.

Therefore, the present invention encompasses one or more surgical instrument assemblies to provide access to delicate tissue, such as brain tissue or breast tissue,

through a transcutaneous incision, for a variety of reasons, such as to access a surgical site; to provide access to insert an inflatable prosthesis; or to provide access for providing an external buttress channel for supporting tissue thereon. The surgical instrument assembly includes an interleaved combination of an open sleeve hollow retractor and a tapered tipped wedge introducer. The wedge introducer is introduced into an area adjacent to the hollow sleeve. The distal tip of the wedge introducer extends beyond a distal end of the hollow retractor, forward of a distal end of said hollow retractor, so that the wedge introducer traverses the delicate tissue ahead of the distal end of the hollow retractor, guiding the hollow retractor into place in the delicate tissue.

When used in conjunction with working surgical instruments, the distal end of the introducer has a small opening, preferably elliptically oval, to allow for removal of small portions of tissue from a surgical site.

The hollow retractor may have a diameter which is a closed curve, such as an elliptical oval. In such case, a tapered tipped wedge introducer is inserted into the inside of the closed curved hollow retractor. In an alternate embodiment, the tapered tipped wedge introducer may have a diameter which is an arc, wherein the arc is a portion of a closed curve, and further wherein the tapered tipped wedge is an arch insertable into the closed curved hollow retractor.

When used as an external working channel, the distal end of the working channel is bell shaped, to allow for increase for increased surface area exposure.

The hollow retractor may alternatively also be an arc of a portion of a closed curve, also forming an arch shape. In such case, the tapered curved tipped wedge introducer may also be an arc of a portion of a closed curve, also forming an arch shape.

In the case where the hollow retractor and/or the tapered tipped wedge introducer has a diameter of at least one arc of a curve, they preferably can have a decreasing curved cross sectional diameter.

Moreover, in such case where the hollow retractor is arch shaped, as opposed to being a closed curved shape, such as being an elliptical oval in cross section, the wedge introducer is placed adjacent to the concave inner portion of the hollow retractor.

If the hollow retractor is a closed curve, that is, having an elliptical oval cross section, preferably of decreasing diameter towards it distal, tissue contact edge, then

the combination of the hollow retractor and wedge introducer are used to either spread apart adjacent delicate tissues, such as the left and right hemispheres of the brain, or to traverse the delicate tissue, such as brain tissue, to provide internal access to a surgical site within the delicate tissue.

If the hollow retractor is arch-shaped, that is, having a diameter which is an arc, namely, a portion of a closed curve, then the combination of the hollow retractor and the wedge introducer are used to provide access to a delicate tissue, where the delicate tissue is supported upon the convex outer surface of the hollow retractor, forming a support buttress, after removal of the arch-shaped wedge introducer.

Additionally, if the hollow retractor is also arch-shaped, that is, having a diameter which is an arc, namely, a portion of a closed curve, then additionally the combination of the hollow retractor and the wedge introducer is used to provide access to a delicate tissue, where an inflatable member, such as a breast prosthesis, is inserted into the delicate breast tissue and inflated, after removal of the arch-shaped wedge introducer from the hollow arched retractor.

The tipped wedge introducer has an exterior surface corresponding to an interior surface of the hollow sleeve and the closed end tipped wedge introducer may have a diameter with an arc of a decreasing curved cross section approximating the arc of the curved cross section of the open sleeve of the retractor.

Preferably, the hollow retractor includes a handle attachable to a clamp.

Optionally, the hollow retractor and the tapered tipped wedge introducer include a lock temporarily locking said tapered tipped wedge introducer adjacent to the hollow retractor.

When the hollow retractor is elliptically oval in cross section, the closed plane curve is generated by a point moving in such a way that the sums of its distances from two fixed points is a constant, or the closed plane curve is a plane section of a circular cone that is a not perpendicular to an axis of the cone, thereby forming a planar elliptical oval slice through the cone.

Moreover, the hollow retractor may be flared at a proximal end. Additionally, where a base of a handle is attached, the handle may merge in a cascading shape, interrupting the continuous curve of the proximal end of the hollow retractor. Such a cascading dip in structure allows for easier finger access into the working channel of the hollow retractor.

Additionally, the hollow retractor may have a changing cross section, where the cross sectional diameter of the elliptical oval is wider or narrower at selected regions of the working channel of the hollow retractor.

Description of the Drawings

The present invention can best be understood in connection with the accompanying drawings. It is noted that the invention is not limited to the precise embodiments shown in drawings, in which:

Figure 1 is a view of a patient with a retractor assembly and a buttress channel positioned adjacent to a top of the head and lower skull.

Figure 2 is a perspective of retractor assembly of Figure 1.

Figure 3 shows exploded components of Figure 2.

Figure 4 is a top plan view of an introducer.

Figure 5 is a proximal end view of an introducer.

Figure 6 is a side sectional elevational view thereof.

Figure 7 is a top plan sectional view thereof.

Figure 8 is a sectional detail of a locking tab, taken from Fig. 7.

Figure 9 is a top plan view thereof.

Figure 10 is a proximal end view of the retractor.

Figure 11 is a side sectional elevation thereof.

Figure 12 is a top plan sectional view thereof.

Fig. 13 is a sectional detail view of the groove, taken from Fig. 12.

Fig. 14 is a sectional detail of locking tab and groove, taken at 14-14 of Fig. 2.

Fig. 15 is a proximal end view of the assembly, taken at arrow 15 in Fig. 2.

Fig. 16 is a view of the instrument assembly being inserted into the top of a skull.

Fig. 17 is a view of the instrument assembly spreading the brain lobes apart.

Fig. 18 is a view of the instrument assembly installed, taken at arrows 18-18 of Fig. 17, with an ear of introducer flexed.

Fig. 19 is a view of the instrument assembly with the introducer removed.

Fig. 20 is a view of surgical instruments within the retractor channel.

Fig. 21 is a diagrammatic sectional view of an embodiment which is installed transversely into tissue.

Fig. 22 is a view of the external instrument assembly system adjacent to the lower skull.

Fig. 23 is a view of the instrument assembly components of Fig. 22 exploded.

Fig. 24 is a perspective view of the instrument assembly system installed in the lower skull.

Fig. 25 is a diagrammatic side section of installed instrument assembly, with the introducer removed.

Fig. 26 is a diagrammatic view of the instruments working on an external tumor.

Fig. 27 is a diagrammatic view of an alternative embodiment, installed through forehead.

Fig. 28 is a diagrammatic view of the instrument assembly installed into breast tissue.

Fig. 29 is a perspective exploded view of a surgical kit.

Detailed Description

This disclosure relates to a surgical instrument assembly and system for use with delicate tissues and methods of using the instrument assembly. The instruments are designed for use during surgery on delicate tissues, such as brain and breast tissues, although they may be used in any medical context. The instrument assembly includes several portions, such as, an introducer portion, a tissue access channel retractor portion ("channel portion") having at least one handle portion, and a stylette portion. These instrument portions are formed to maximize the surface area of the retractor, which distributes pressure approximately equally though out the surrounding tissues and minimize effective localized retraction pressure on the tissues in contact or immediately surrounding the Instrument.

In one embodiment, the surgical instrument assembly can be a retractor in the form of an arch or arc shape, into which an arch or arc shaped wedge introducer may be inserted for surgical access to the external portions or surfaces of the brain.

In another embodiment, the surgical instrument assembly can be a retractor in the form of a wedge with a tapered elliptical cross sectional shape, into which a tapered elliptical cross sectional introducer may be inserted for surgical access to the external portions or surfaces of the brain.

Alternatively, the external retractor and wedge introducer may be used to insert medical/ cosmetic devices into or under delicate tissues.

The surgical instrument assembly system may also employ the external retractor as an external brain support buttress channel portion to lift the brain mass upward with respect to the cranium to provide stability and prevent the gelatinous brain materials from shifting during surgery. In the capacity of a brain support buttress channel portion ("buttress portion") also provides improved visualization and improved access to the surgical area by lifting the brain matter upward in the cranium.

The formation of the instrument assembly also eliminates the need to "pull" on a retractor portion to clearly visualize the surgical area by initially providing a sufficient work area via the channel retractor. The use of the tissue access channel retractor portion of the instrument assembly eliminates or greatly lowers the possibility of accidental over-retraction. By avoiding excess retraction, damage to the surrounding tissues is also avoided, including possible brain damage.

While other closed curve configurations may be used, the preferably elliptical or arch shaped architecture formation of the instrument assembly portions is such that medical staff is afforded binocular vision, rather than the monocular vision typically found in similar devices. This elliptical architecture also provides far greater clearance for lighting access to illuminate the target surgical area and allow full visualization of that area. The forward edge of the channel retractor is preferably tapered to gently separate tissue to obtain a surgical area and minimizes disruption of the tissue.

The surgical instrument assembly system may also be useful as an inserter instrument for breast implants.

The dimensions of the surgical Instrument assembly may vary and be modified according to an intended use. Generally, the surgical work space formed by the introducer portion 40 can have diameters of in the range of approximately 10 millimeters ("mm") to approximately 100 mm, and more typically in the range of approximately 25 mm to approximately 75 mm in its closed configuration. The open configuration of the introducer portion 40 may extend the diameter of the distal end 42 of the introducer portion 40 several millimeters, and may generally be determined by amount of extension desired by the surgical team during use as it is introduced into the lumen 22 of the retractor 20, and may include a flexible band portion 14 to enhance its flexibility. The open configuration may also be determined by the overall

desired circumference and diameter of the Surgical Instrument assembly for a particular use and may be manufactured in a variety of useful sizes to be available as is practical. The Surgical Instrument assembly may be formed of any biocompatible material which will provide sufficient stability and strength necessary to provide a surgical work area. The biocompatible material may be disposable or sterilize-able for repeated use. In one embodiment, the Surgical Instrument assembly may be formed of a lightweight plastic material for ease of manipulation and/or the material may be transparent to allow direct visualization of underlying brain tissue thorough the Instrument assembly portions.

The surgical instrument assembly system also enables integration with stereotactic neuro-navigation computer guidance systems to enhance visualization of the surgical area of the brain.

Figure 1 illustrates in diagrammatic fashion the surgical instrument assembly system 10 adjacent a surgical aperture in the cranium of an intubated patient. An external retractor system 100 is also spaced from the lower skull, and will be described later in the specification.

Figure 2 is an enlarged perspective view of the surgical instrument assembly system 10 as shown in Figure 1. The instrument assembly system 10 is comprised of two components, a retractor 20, and an introducer 40.

Figure 3 illustrates the relationship of introducer 40 to retractor 20, prior to assembly. It is desirable that the introducer is easily fixed to and removable from the retractor both prior to and during the surgical procedure.

As also shown in Figure 3, the surgical instrument assembly system may be formed by any method, including injection molding, as a single piece, or may be formed of two or more pieces which are permanently fixedly attached to each other. The distal end 42 of the introducer portion 40 is preferably a solid, rounded cone shape which may or may not include an opening 52 to the surrounding tissues as opposed to a cannula structure which always provides a distal opening. The distal end 42 preferably includes a gently increasing circumference 54, which increases and expands towards the proximal end 56 of the introducer portion 42. The introducer portion 40 has a main body 50, and may be divided into two approximate handle halves 46, having V-shaped cutouts 48 between the handle halves. The halves of the proximal end 56 are an integral unit, the term "halves" is used as a descriptor only and does not describe separable parts, as opposed to two disassemblable halves. The

proximal end 56 may include at least one handle portion 46 which extends outwardly at an angle of approximately 90 degrees. A handle portion 46 may be useful to allow a medical team member to physically insert, manipulate or hold the handle portion 46, or a conventional surgical fixation cable may be attached to the handle portion 12. At least one of the handle portions 46 include at least one indentation or groove 44 to accept or snap into an additional portion of the surgical instrument assembly 10.

Figures 4-8 show a variety of views of the retractor portion 20 of this disclosure, including retractor 20 having a hollow working channel 22 and handle 28. The retractor 20 is generally formed to dimensions and shapes to coincide with the introducer portion 40 that may be slidably inserted into the brain access work channel 22 of the retractor portion 20. The retractor portion 20 is generally shorter in length than the introducer portion 40 to allow the distal end 42 of the introducer portion 40 to interact with the surrounding housing 21 tissues. As best seen in Figures 6 and 7, the retractor portion 20 is formed as a hollow elliptical rounded wedge having a tapered distal leading edge 24. The proximal edge of the retractor 20 includes a slightly rounded lip 26 and a handle portion 28. At least one tab 30 is formed in wedge 21, just distal of lip 26. Tab 30 will positively align with groove 44 of introducer 40 to prevent or inhibit unnecessary movement or slipping of the instrument assembly components best seen in sectional view Figure 15. The handle portion 28 allows the retractor portion 20 to be fixed in space with the use of a standard or conventional neurosurgical fixation cable device.

Figure 9 illustrates a side view of a retractor 20, having a proximal end 26 of the surgical instrument assembly and optionally having a handle portion 28 perpendicular to the proximal end 26; and an elliptical length of the retractor 21 extends to the rounded distal end 24. Fig. 10 is a frontal view of the retractor 20, showing the lumen 30 and the handle portion 28. Fig. 11 is a cross-sectional view of the retractor 20 of the rounded shape of the retractor 20 to avoid damage to delicate tissues. Fig. 12 is a top plan view of the retractor 20, emphasizing the groove like cut-out hole 30 which can allow the introducer 40 to integrally fit and temporarily lock/snap into hole 30, thereby causing both the retractor 20 and introducer 50 to function as one, while desired by the medical team. Fig. 13 is an enlarged view of the grooved hole 30. Fig. 14 is a cross-sectional view of the tab 44 of the introducer 20 while it is engaged within the grooved hole 30 of the retractor 20.

Shown in Figure 15 is a proximal end view of assembled instrument where the handle portions 46 overlying lip 26 of retractor 20, and V-shaped cutouts 48 residing in lumen 22. Handle 28 of retractor 20 is molded integral with lip 26, providing both rigidity and strength. Figure 15 also shows that where a base of handle 28 is attached to retractor 20, handle 28 may optionally merge in a cascading shaped dip 28a, interrupting the continuous curve of the proximal end of hollow retractor 20. Such a cascading dip 28a allows for easier finger access into the working channel of hollow retractor 20.

Figures 16-20 illustrate diagrammatically the method if installing surgical instrument assembly 10 into the aperture 12 in cranium 14. As seen in Figure 16, instrument assembly 10 is inserted into aperture 12. Distal end 42 of introducer 40 is abutting brain tissue 60. As instrument assembly 10 is introduced, distal end 42 of introducer 40 begins to spread lobes 62 and 64 of brain 60, as shown in Figure 17. Figure 18 is an elevational view of the installed surgical instrument assembly 10, taken along arrows 18-18 of Figure 17. Upon installation, handles 46 of introducer 40 may be flexed inward, thereby releasing the tab 30 of retractor 20 from the groove 44 of introducer 40. Figure 19 illustrates introducer 40 during removal from lumen 22 of retractor 20. Figure 20 shows surgical instruments 70 within lumen 22 of retractor 20, examining brain tissue 60.

Figure 21 is a diagrammatic perspective view of an embodiment of the surgical instrument assembly 10, adjacent an aperture 12 located at the temple region of a patient's cranium 14. In this embodiment, the overall length of surgical instrument assembly 10 is sufficient to transversely penetrate the cranium and brain tissue 60. Surgical instrument assembly 10 is shown installed in Figure 22.

Figure 23 is a perspective view of the external retracting buttress channel 100. External buttress channel instrument assembly 100 is comprised of buttress channel component 200, and wedge introducer component 400. External buttress channel component 200 has a generally arched, hemi-elliptical architecture, where it is wider along the base than it is tall or high. The buttress channel component 200 includes a smooth, tapered leading edge 202. A handle fixation member 204 is approximately perpendicular to the rounded lip 206 of the proximal end 208. The handle member 204 may be employed as an attachment point to a standard neurosurgical armature fixation device. The external buttress channel component 200 may be used to lift,

support or manipulate the brain within the skull cavity to provide additional or improved vision of the surgical area, as seen in Figure 24.

Also seen in Figure 23 is the external wedge introducer portion 400 for the external buttress channel component 200. Buttress channel 200 is designed to gain access to external structures along, around or beneath the brain by elevating the surfaces of the brain to allow access to surgical locations on or near the surface of the brain tissues. In operation, prior to insertion, introducer portion 400 is attached to buttress channel 200 such that sloping distal end 402 protrudes from the distal open end 210 of buttress channel 200. This pushes away brain tissue at the outer brain surface 66 gently during insertion. After insertion, introducer portion 400 is withdrawn to leave a working channel of decreasing hemi-oval cross section from proximal end 208 to distal end 210. Radial surface of buttress channel 200 supports the outer surface 66 of the brain tissue 60, best seen in Figure 24. Note that surface of wedge introducer 400 conforms to the inside of buttress channel surface; proximal end 208 and handle member 204 conform to proximal end 406 and fixation member 408 of introducer 400 respectively. Fixation member 204 of buttress channel 200 is designed to be attached to a standard neurosurgical armature fixation device.

Figures 25 and 26 are diagrammatic view of the instruments working on an external tumor, where the further surgical instruments 70 are inserting in t0 the operating space formed by the instrument assembly system to allow the surgical team to work on the tissues as necessary.

Figure 27 is a diagrammatic view of an embodiment, which may be installed through the forehead as necessary for surgical procedures. Figure 28 is a diagrammatic view of the instrument assembly installed into breast tissue 68, where it may be used for insertion of implants 72 and the like.

Figure 28 shows use of an arched buttress channel 200 and wedge introducer component 400 which may be used, for example, for access to brain tissue or for inserting an inflatable prosthesis into breast tissue.

Fig. 29 is a perspective exploded view of a surgical kit. The Kit 600 includes an injection-molded or vacuum-formed housing 602, providing cavities 604 to receive components of the surgical instrument assembly system 10 and the external retracting buttress channel system 100. A stylette 80 may also be included. Upon placement of all desired components within the housing 602, the sterile kit will be sealed with a

Tyvek sheet 606. Upon removal of sheet 606 by the surgeon, the sterile components of kit 600 can be utilized and employed as required in a surgical operation.

In the foregoing description, certain terms and visual depictions are used to illustrate the preferred embodiment. However, no unnecessary limitations are to be construed by the terms used or illustrations depicted, beyond what is shown in the prior art, since the terms and illustrations are exemplary only, and are not meant to limit the scope of the present invention.

It is further known that other modifications may be made to the present invention, without departing the scope of the invention, as noted in the appended Claims.

Claims:

1. An apparatus providing access to delicate tissue through a transcutaneous incision comprising:

an interleaved combination of an open sleeve hollow retractor and a tapered tipped wedge introducer;

said wedge introducer being introduced into an area adjacent to said hollow sleeve;

a distal tip of said wedge introducer extending beyond a distal end of said hollow retractor, at a location region forward of a distal end of said hollow retractor, so that said wedge introducer traverses the delicate tissue ahead of said distal end of the hollow retractor, guiding said hollow retractor into place to the delicate tissue; and,

said tapered tipped wedge introducer being removable from said open sleeve of said hollow retractor adjacent the delicate tissue, leaving the delicate tissue exposed to a said open sleeve of said hollow retractor.

2. The apparatus providing access into delicate tissue as in Claim 1 further comprising:

said hollow retractor having an open sleeve having a diameter of at least one arc of a curve having a decreasing curved cross sectional diameter;

said tapered tipped wedge introducer having a diameter of at least one arc of a curve having a decreasing curved cross sectional diameter;

said tapered tipped wedge introducer retractor having a length exceeding a predetermined length of said hollow retractor, providing an advancing member extending forward of a distal end of said hollow retractor;

said tapered tipped wedge introducer having an exterior surface corresponding to an interior surface of said hollow sleeve;

said tapered tipped wedge introducer having a diameter with an arc of a decreasing curved cross section approximating said arc of said curved cross section of said open sleeve;

said hollow retractor and said tapered tipped wedge introducer being insertable adjacent to the delicate tissue; and,

said hollow retractor and said tapered tipped wedge introducer being advanced together to the delicate tissue.

3. The apparatus as in Claim 1 wherein said hollow retractor provides access for at least one surgical instrument to a surgical site within the delicate tissue.

4. The apparatus for providing access to delicate tissue as in Claim 1 wherein the hollow retractor and the interleaved tapered tipped wedge introducer spread a portion of delicate tissue apart from another portion of delicate tissue toward the surgical site.

5 The apparatus for providing access to delicate tissue as in Claim 1 wherein the hollow retractor and the interleaved tapered tipped wedge introducer intersect transversally into a portion of delicate tissue at the surgical site.

6. The apparatus as in Claim 1 wherein said hollow retractor supports the delicate tissue thereupon.

7. The apparatus as in Claim 1 wherein said apparatus provides access for at least one inflatable prosthetic member into the delicate tissue and inflating the inflatable member.

8. The apparatus as in Claim 1 wherein said hollow retractor includes a handle attachable to a clamp.

9. The apparatus as in Claim 1 wherein said hollow retractor and said tapered tipped wedge introducer include a lock temporarily locking said tapered tipped wedge introducer adjacent to said hollow retractor.

10. The apparatus for providing access to delicate tissue as in Claim 2 wherein said at least one arc of said curve of said diameter of said hollow retractor is a closed plane curve.

11. The apparatus for providing access to delicate tissue as in Claim 2 wherein said at least one arc of said curve of said diameter of said hollow retractor is an arc of a portion of a closed plane curve.

12. The apparatus as in Claim 1 wherein a distal end of said tapered introducer has a small opening at a distal end thereof, allowing for removal of small portions of tissue from a surgical site.

13. The apparatus for providing access to delicate tissue as in Claim 2 wherein said at least one arc of said curve of said diameter of said hollow retractor is an arc of a portion of a closed plane curve wherein the closed plane curve is generated by a point moving in such a way that the sums of its distances from two fixed points is a constant.

14. The apparatus for providing access to delicate tissue as in Claim 2 wherein said at least one arc of said curve of said diameter of said hollow retractor is an arc of a portion of a closed plane curve wherein the closed plane curve is an elliptical oval-shaped plane section of a circular cone that is a not perpendicular to an axis of the cone.

15. The apparatus for providing access to delicate tissue as in Claim 14 wherein said at least one arc of said curve of said diameter of said hollow retractor is an arc of a portion of a closed plane curve wherein the closed plane curve is an elliptical oval.

16. The apparatus for providing access to delicate tissue as in Claim 2 wherein said arc of said hollow retractor is a portion of a continuous arc.

17. The apparatus for providing access to delicate tissue as in Claim 2 wherein said arc of said hollow retractor is a continuous arc.

18. The apparatus for providing access to delicate tissue as in Claim 2 wherein said arc of said tapered tipped wedge introducer is a portion of a continuous arc.

19. The apparatus for providing access to delicate tissue as in Claim 2 wherein said arc of said tapered tipped wedge introducer is a continuous arc.

20. The apparatus for providing access to delicate tissue as in Claim 2 wherein said closed plane curve is flared outward at a proximal end.

21. A method of providing access into delicate tissue for at least one surgical instrument assembly comprising the steps:

making an incision into delicate tissue;

providing a hollow retractor having an open sleeve having a diameter of at least one arc of a curve having a decreasing curved cross sectional diameter;

providing a tapered tipped wedge introducer having a diameter of at least one arc of a curve having a decreasing curved cross sectional diameter

introducing said tapered tipped wedge introducer into an area adjacent to said hollow sleeve having said at least one arc of a curve having a decreasing curved cross sectional diameter;

said closed end tipped wedge introducer having an exterior surface corresponding to an interior surface of said hollow sleeve;

said closed end tipped wedge introducer having a diameter with an arc of a decreasing curved cross section approximating said arc of said curved cross section of said open sleeve;

placing said hollow retractor and said tapered tipped wedge introducer into the delicate tissue;

advancing said hollow retractor and said tapered tipped wedge introducer through said delicate tissue to a surgical site therein;

retracting said tapered tipped wedge introducer from said open sleeve of said hollow retractor adjacent the tissue; and,

accessing at least one surgical instrument to the surgical site within the delicate tissue.

22. A method of providing access into delicate tissue for at least one surgical instrument comprising the steps:

making an incision into delicate tissue;

providing a hollow retractor having an open sleeve having a diameter of at least one arc of a curve having a decreasing curved cross sectional diameter;

providing a tapered tipped wedge introducer having a diameter of at least one arc of a curve having a decreasing curved cross sectional diameter

introducing said tapered tipped wedge introducer into an area adjacent to said hollow sleeve having said at least one arc of a curve having a decreasing curved cross sectional diameter;

said closed end tipped wedge introducer having an exterior surface corresponding to an interior surface of said hollow sleeve;

said closed end tipped wedge introducer having a diameter with an arc of a decreasing curved cross section approximating said arc of said curved cross section of said open sleeve;

placing said hollow retractor and said tapered tipped wedge introducer into the delicate tissue;

advancing said hollow retractor and said tapered tipped wedge introducer through said delicate tissue to a surgical site therein;

retracting said tapered tipped wedge introducer from said open sleeve of said hollow retractor adjacent the tissue; and,

supporting the delicate tissue thereupon.

23. A method of providing access into delicate tissue for at least one surgical instrument comprising the steps:

making an incision into delicate tissue;

providing a hollow retractor having an open sleeve having a diameter of at least one arc of a curve having a decreasing curved cross sectional diameter;

providing a tapered tipped wedge introducer having a diameter of at least one arc of a curve having a decreasing curved cross sectional diameter

introducing said tapered tipped wedge introducer into an area adjacent to said hollow sleeve having said at least one arc of a curve having a decreasing curved cross sectional diameter;

said closed end tipped wedge introducer having an exterior surface corresponding to an interior surface of said hollow sleeve;

said closed end tipped wedge introducer having a diameter with an arc of a decreasing curved cross section approximating said arc of said curved cross section of said open sleeve;

placing said hollow retractor and said tapered tipped wedge introducer into the delicate tissue;

advancing said hollow retractor and said tapered tipped wedge introducer through said delicate tissue to a surgical site therein;

retracting said tapered tipped wedge introducer from said open sleeve of said hollow retractor adjacent the tissue; and,

accessing at least one inflatable prosthetic member into the delicate tissue and inflating the inflatable member.

24. An apparatus providing access to delicate tissue through a transcutaneous incision comprising:

an interleaved combination of an open sleeve hollow retractor and a tapered tipped wedge introducer;

said open sleeve hollow retractor being tapered;

said open sleeve hollow retractor having a decreasing elliptical cross section;

said wedge introducer being tapered;

said wedge introducer having a decreasing elliptical cross section;

said wedge introducer being introduced into an area adjacent to said hollow sleeve;

a distal tip of said wedge introducer extending beyond a distal end of said hollow retractor, at a location region forward of a distal end of said hollow retractor, so that said wedge introducer traverses the delicate tissue ahead of said distal end of the hollow retractor, guiding said hollow retractor into place to the delicate tissue;

said tapered tipped wedge introducer being removable from said open sleeve of said hollow retractor adjacent the delicate tissue, leaving the delicate tissue exposed to a said open sleeve of said hollow retractor;

said tapered tipped wedge introducer having an exterior surface corresponding to an interior surface of said hollow sleeve;

said hollow retractor and said tapered tipped wedge introducer being insertable adjacent to the delicate tissue;

said hollow retractor and said tapered tipped wedge introducer being advanced together to the delicate tissue;

said hollow retractor providing access for at least one surgical instrument to a surgical site within the delicate tissue;

said hollow retractor including a handle attachable to a clamp;

said handle having a base where said handle is attached to said hollow retractor, said handle merging with said base in a cascading shape, interrupting the continuous curve of the proximal end of the hollow retractor, said cascading dip providing easier finger access into a working channel of said hollow retractor; and,

said hollow retractor and said tapered tipped wedge introducer including a lock temporarily locking said tapered tipped wedge introducer adjacent to said hollow retractor.

25. An apparatus providing access to delicate tissue through a transcutaneous incision comprising:

an interleaved combination of an open sleeve hollow retractor and a tapered tipped wedge introducer;

said open sleeve hollow retractor being tapered;

said open sleeve hollow retractor being arch shaped, having a decreasing arched cross section;

said wedge introducer being tapered;

said wedge introducer being arch shaped, having a decreasing arch shaped cross section;

said wedge introducer being introduced into an area adjacent to said hollow sleeve;

a distal tip of said wedge introducer extending beyond a distal end of said hollow retractor, at a location region forward of a distal end of said hollow retractor, so that said wedge introducer traverses the delicate tissue ahead of said distal end of the hollow retractor, guiding said hollow retractor into place to the delicate tissue;

said tapered tipped wedge introducer being removable from said open sleeve of said hollow retractor adjacent the delicate tissue, leaving the delicate tissue exposed to a said open sleeve of said hollow retractor;

said tapered tipped wedge introducer having an exterior surface corresponding to an interior surface of said hollow sleeve;

said hollow retractor and said tapered tipped wedge introducer being insertable adjacent to the delicate tissue;

said hollow retractor and said tapered tipped wedge introducer being advanced together to the delicate tissue;

said hollow retractor providing access for at least one surgical instrument to a surgical site within the delicate tissue;

said hollow retractor including a handle attachable to a clamp;

said handle having a base where said handle is attached to said hollow retractor, said handle merging with said base in a cascading shape, interrupting the

continuous curve of the proximal end of the hollow retractor, said cascading dip providing easier finger access into a working channel of said hollow retractor; and,

said hollow retractor and said tapered tipped wedge introducer including a lock temporarily locking said tapered tipped wedge introducer adjacent to said hollow retractor.

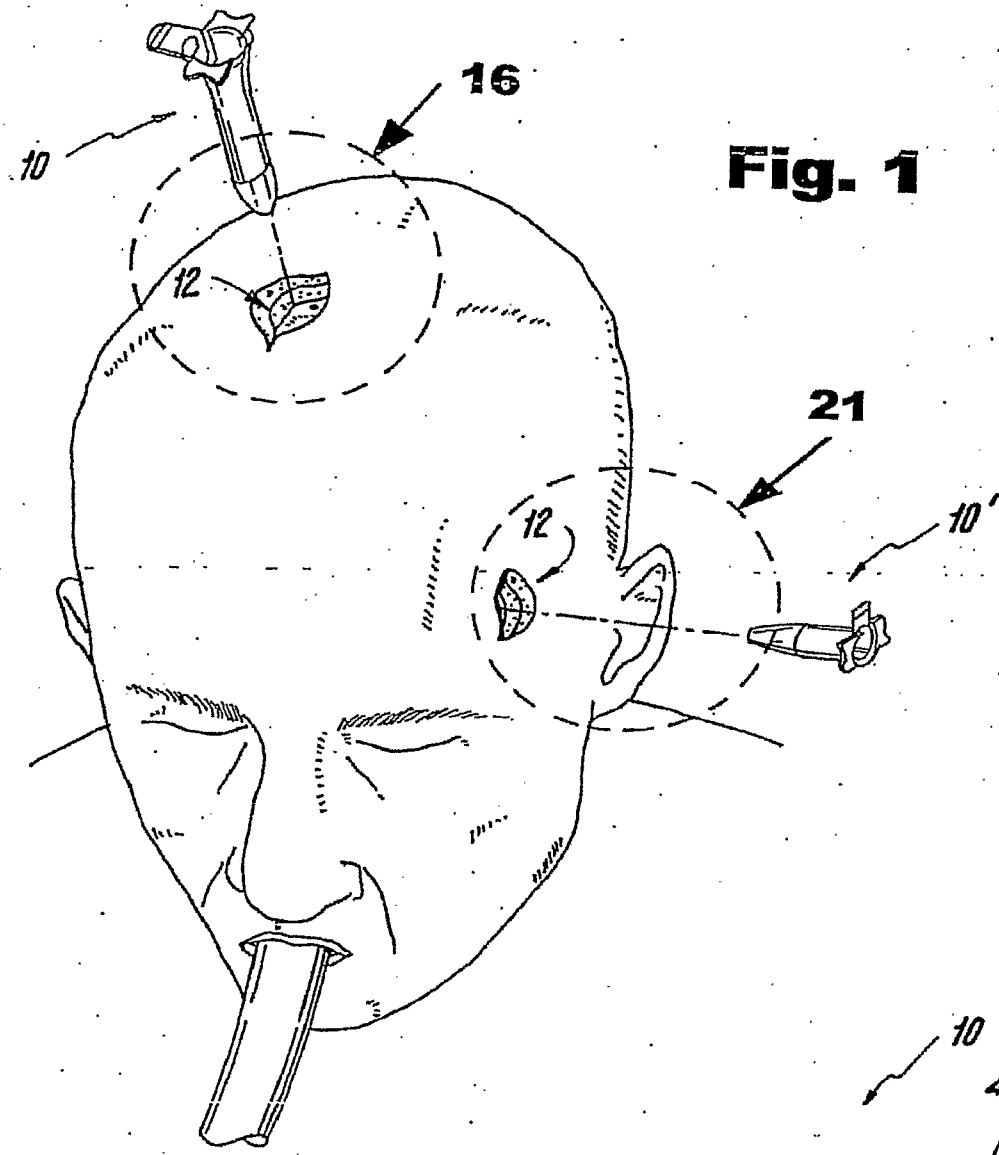


Fig. 1

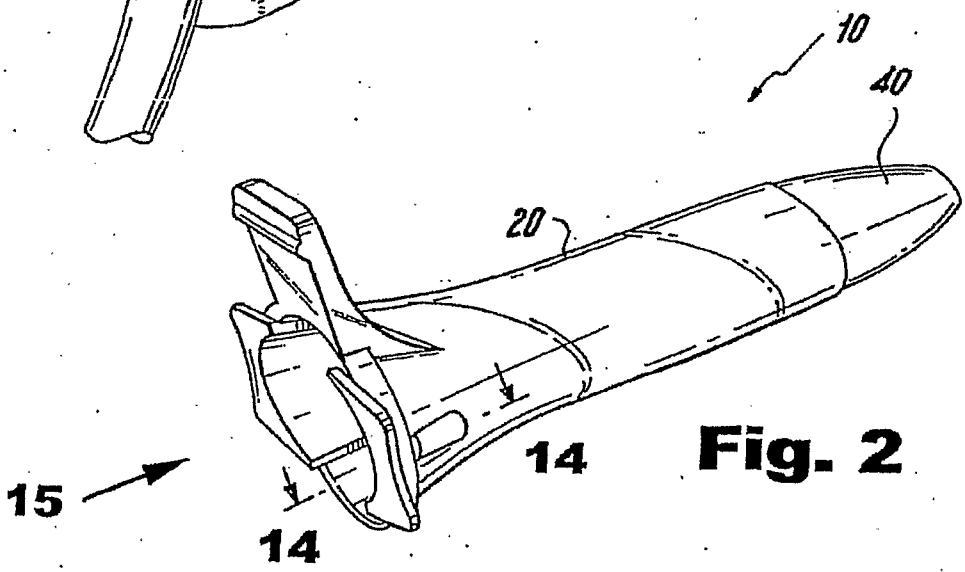


Fig. 2

Fig. 3

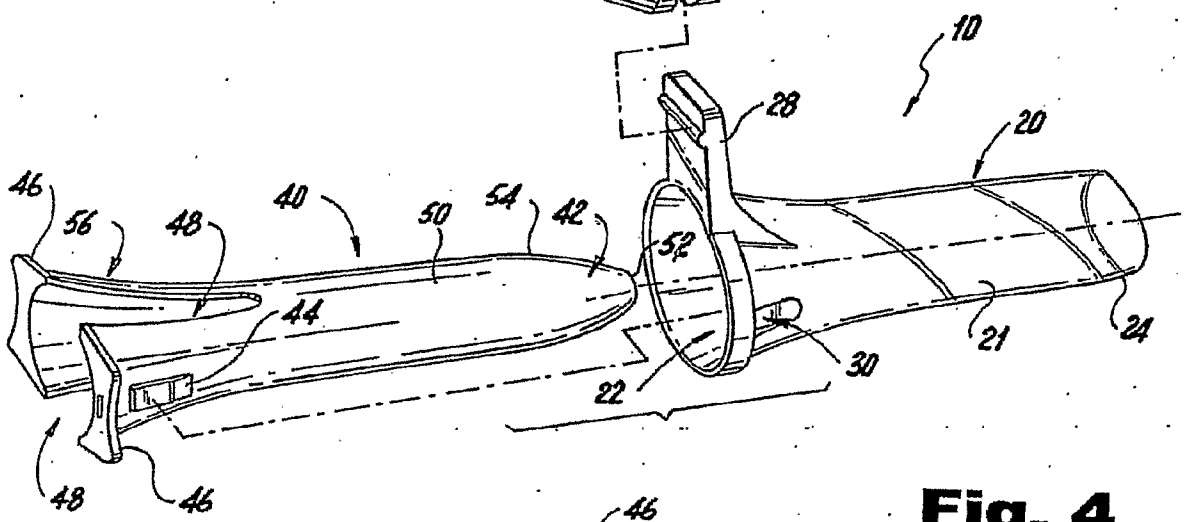


Fig. 4

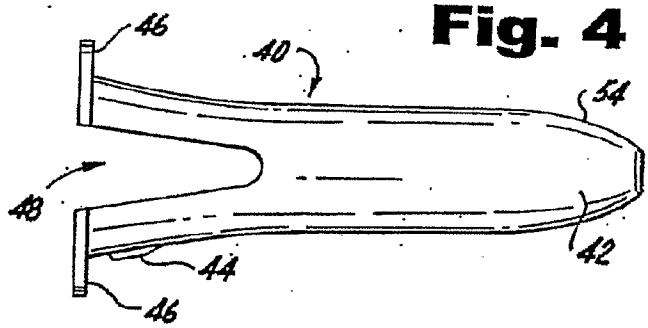


Fig. 5

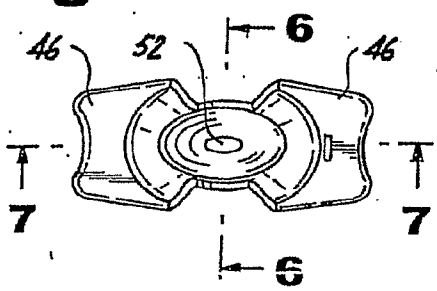
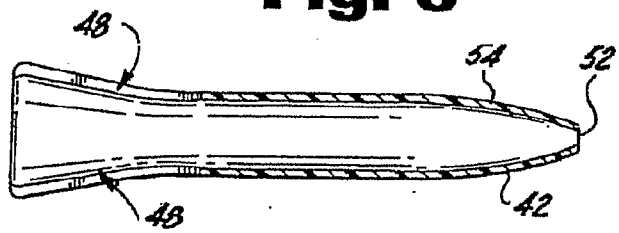


Fig. 6



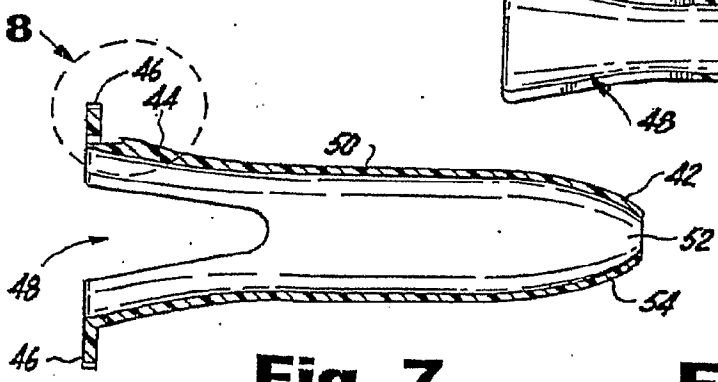


Fig. 7

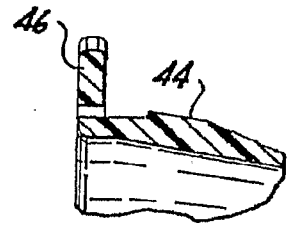


Fig. 8

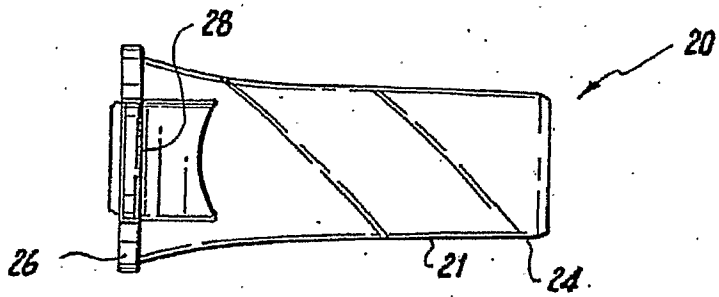


Fig. 9

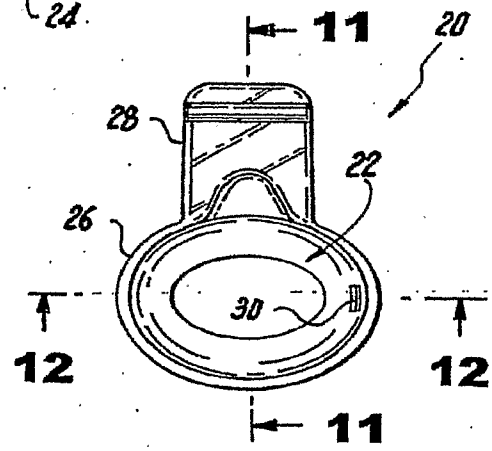


Fig. 10

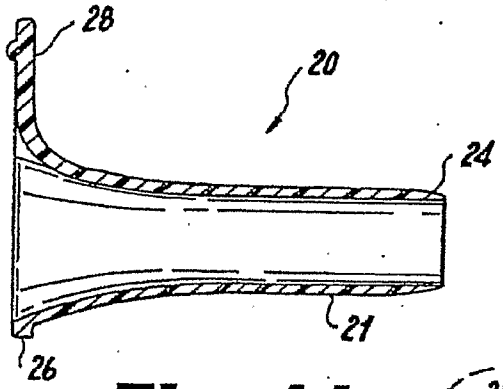


Fig. 11

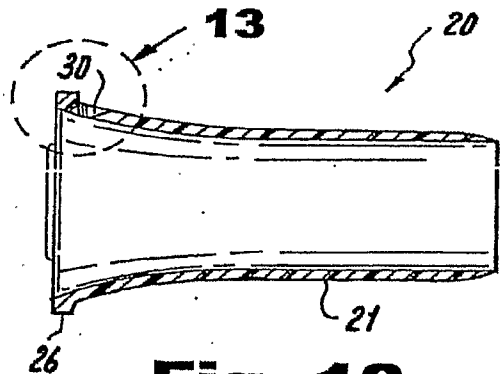


Fig. 12

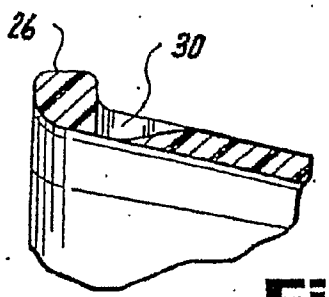


Fig. 13

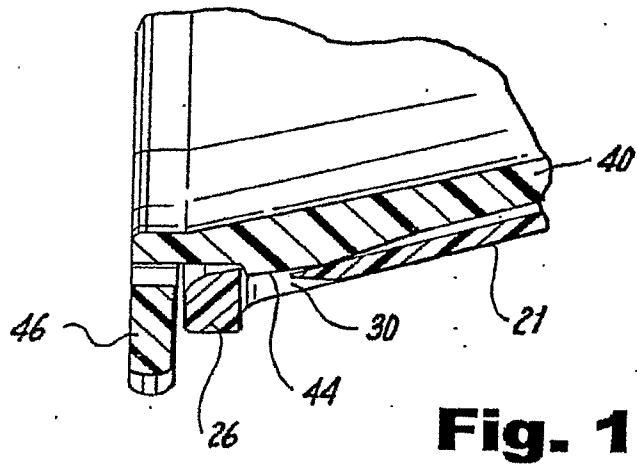


Fig. 14

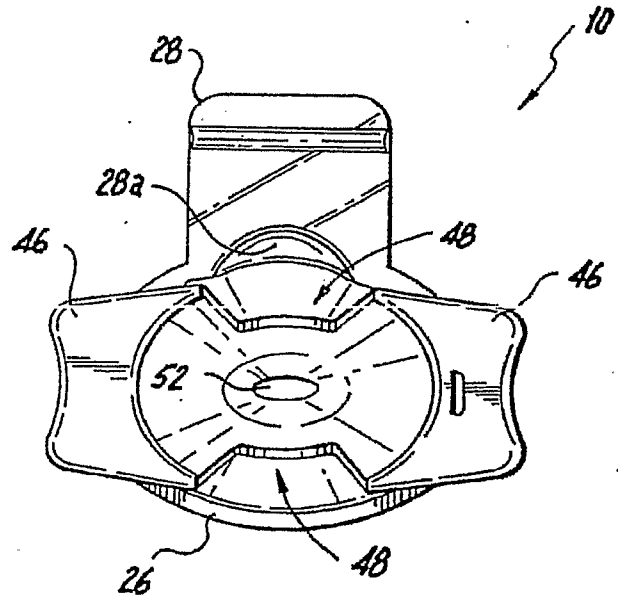


Fig. 15

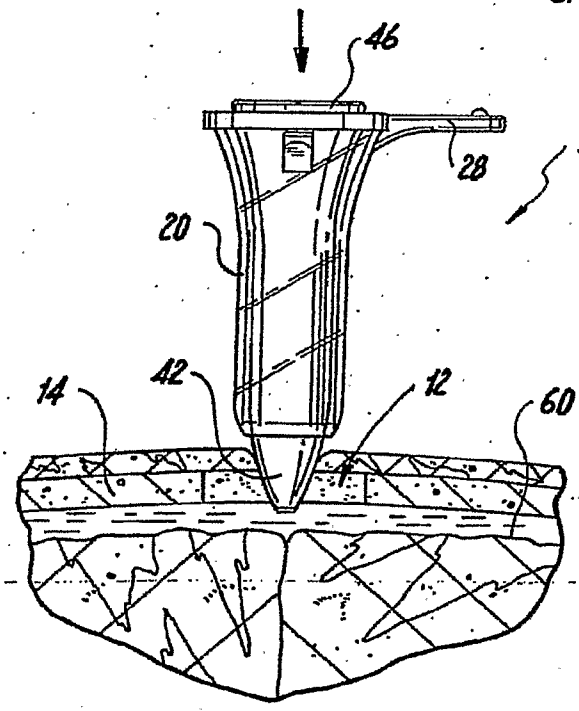


Fig. 16

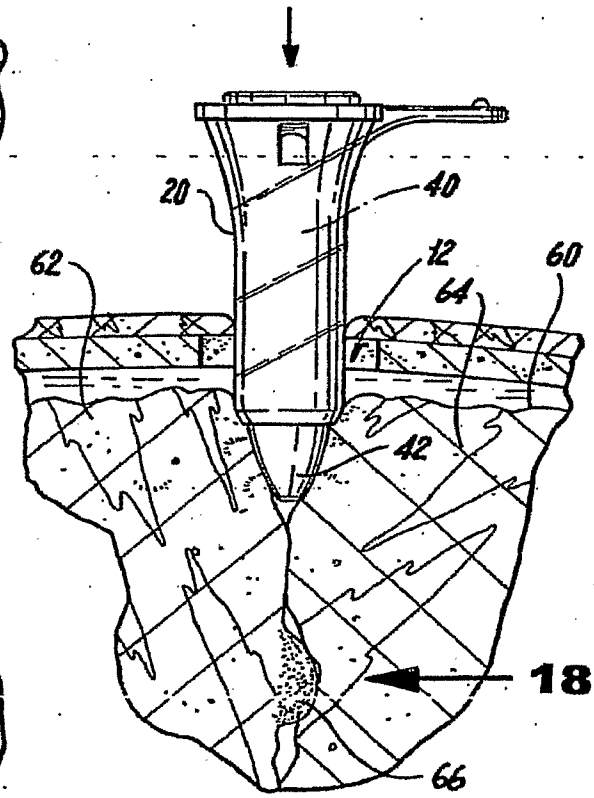


Fig. 17

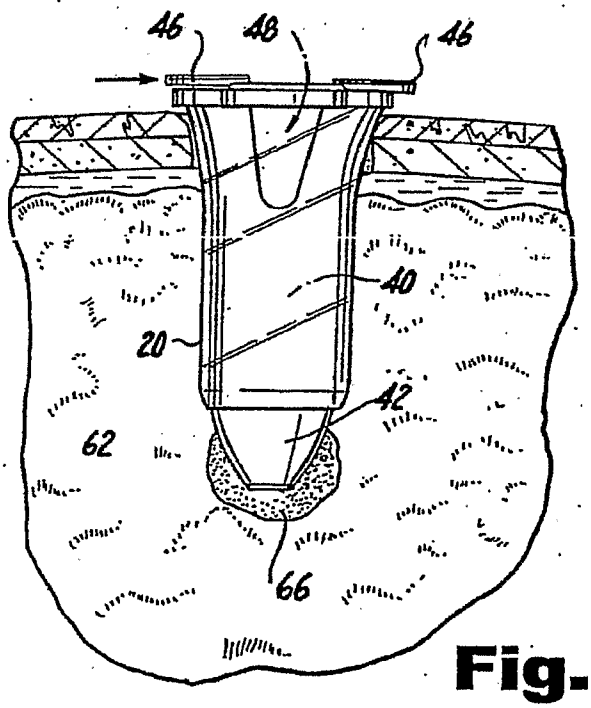


Fig. 18

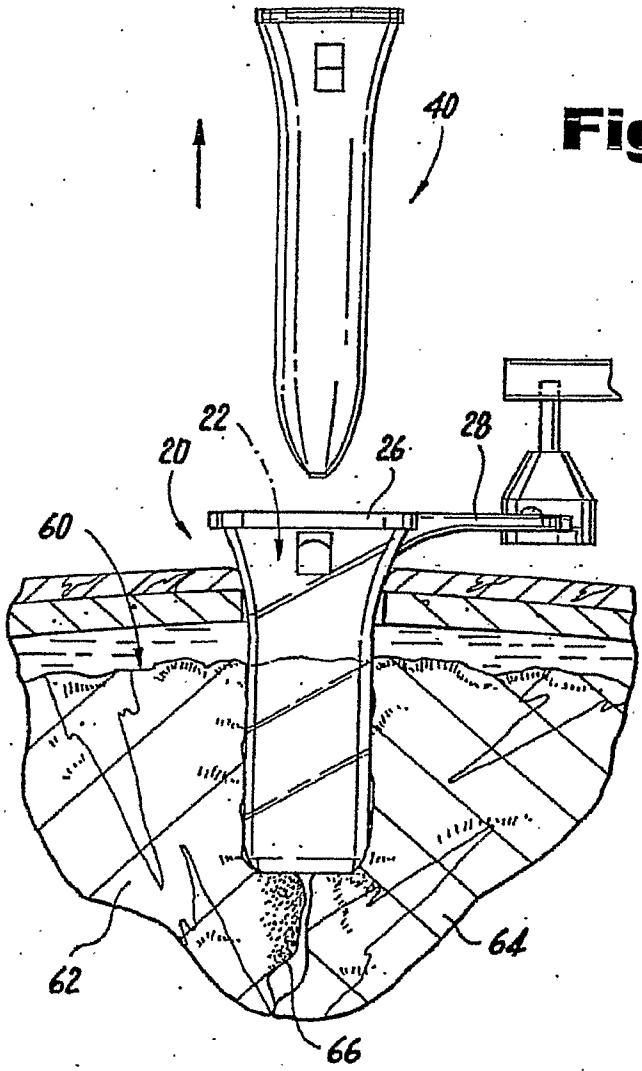


Fig. 19

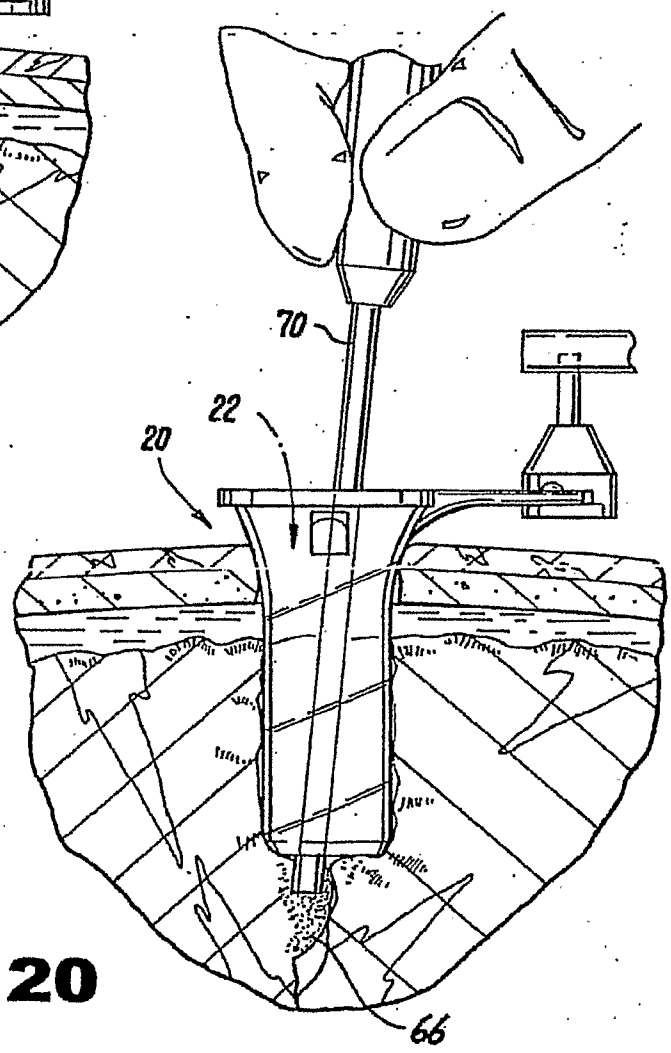


Fig. 20

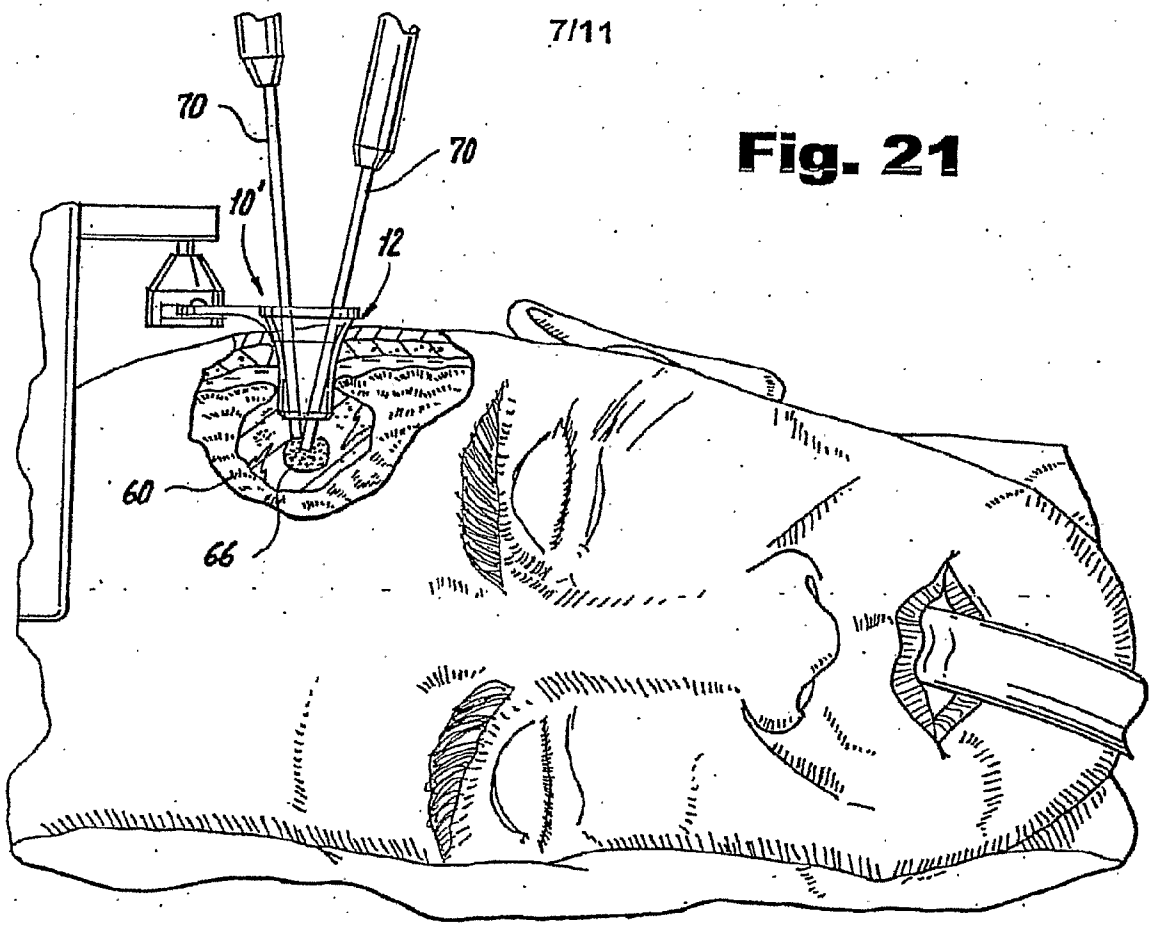


Fig. 21

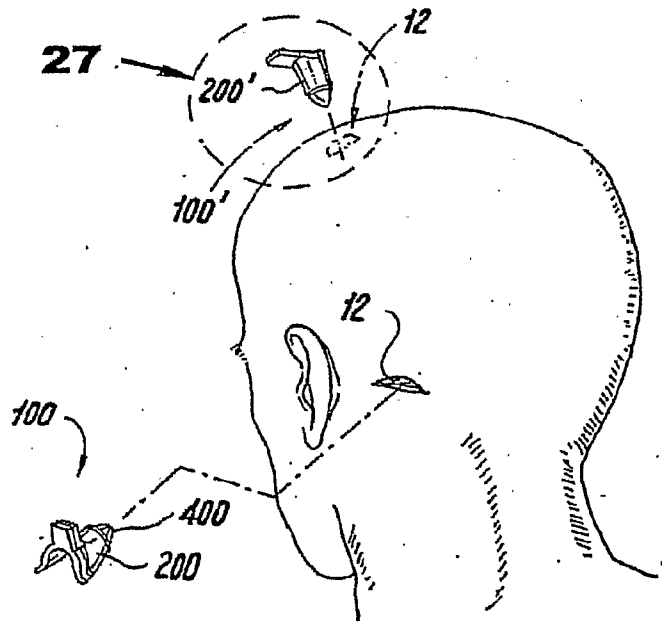


Fig. 22

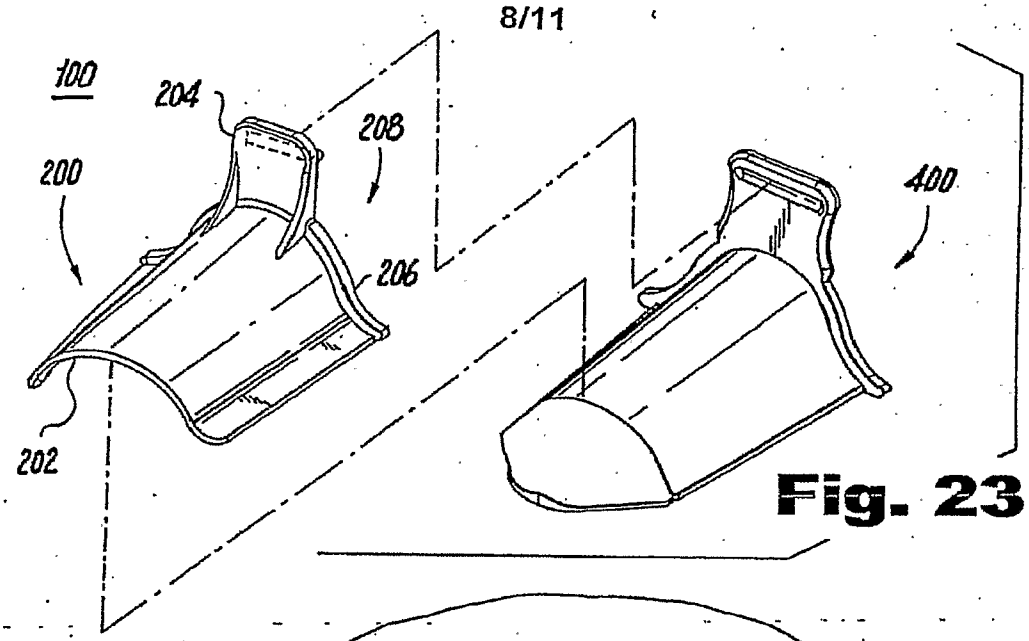


Fig. 23

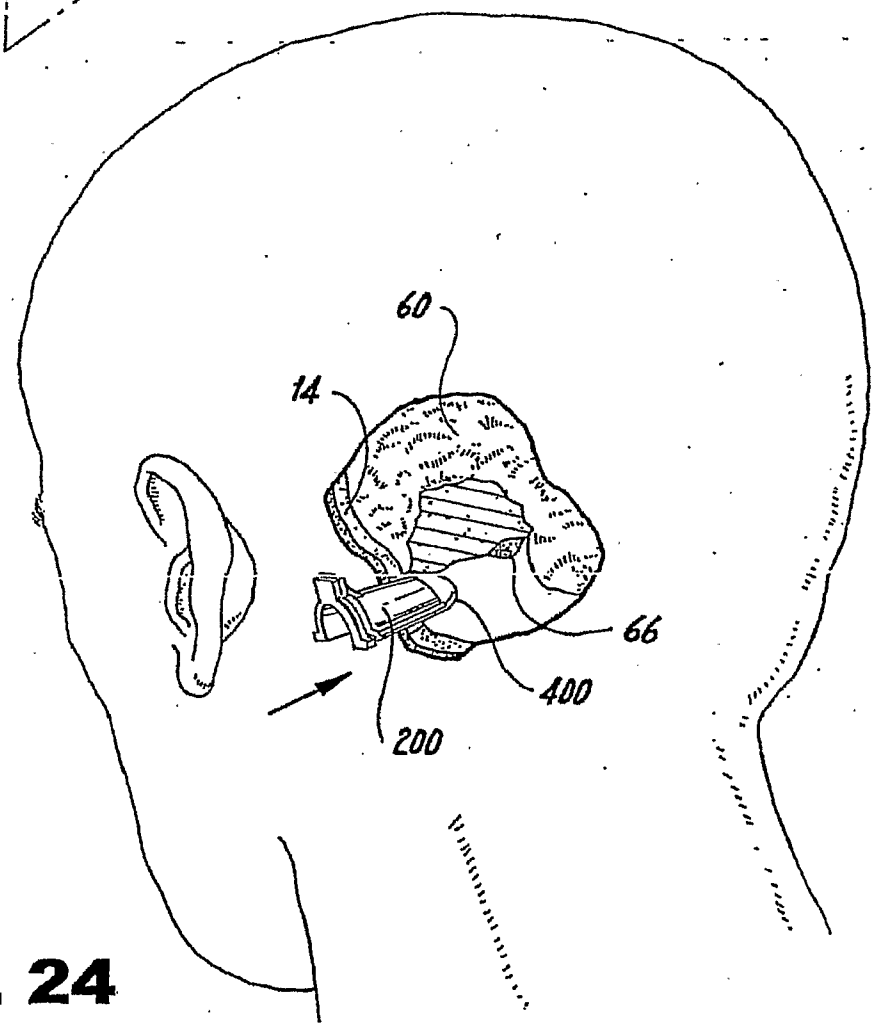


Fig. 24

Fig. 25

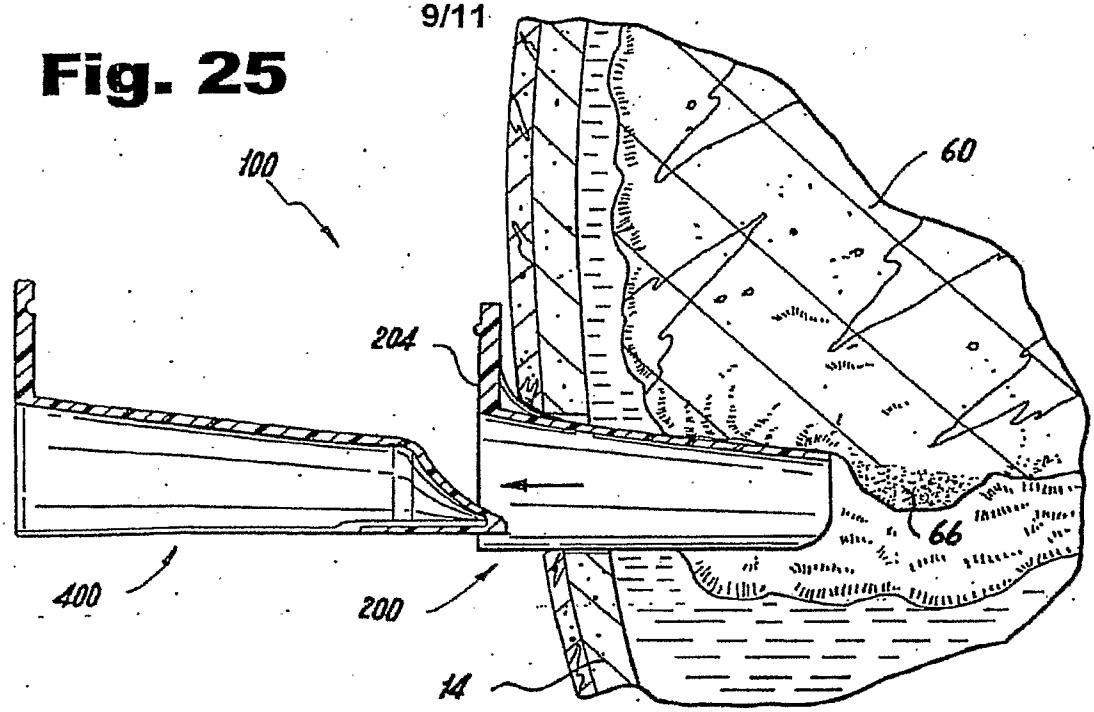
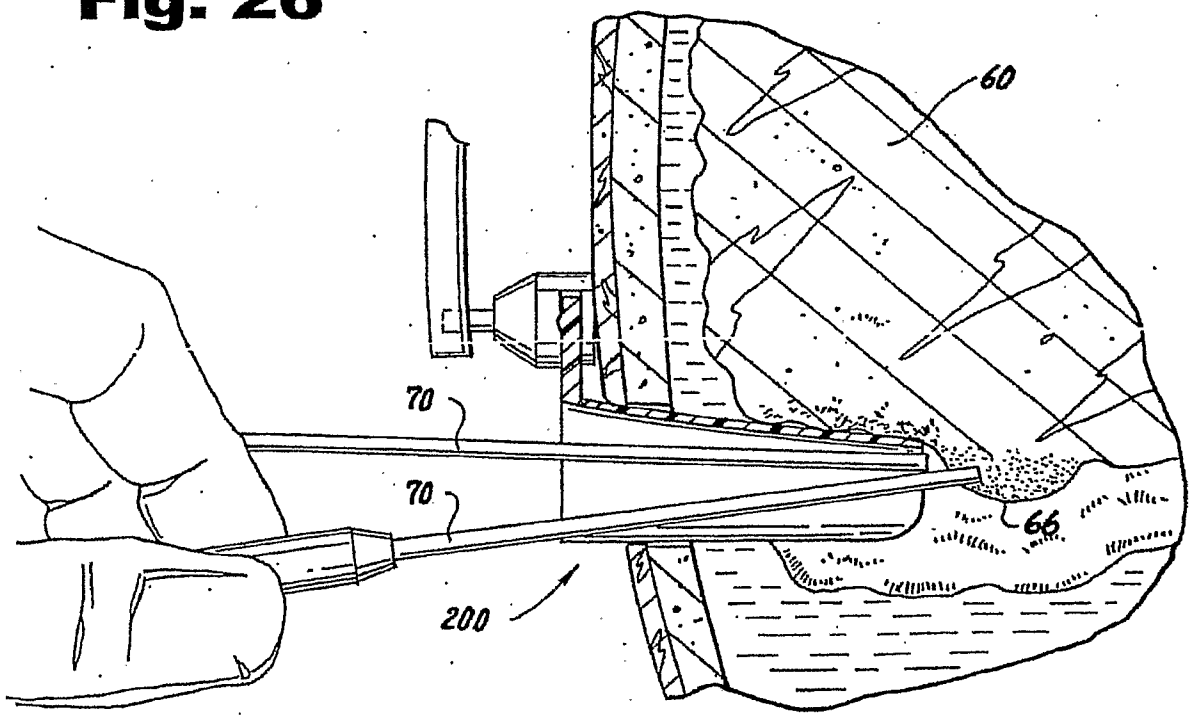


Fig. 26



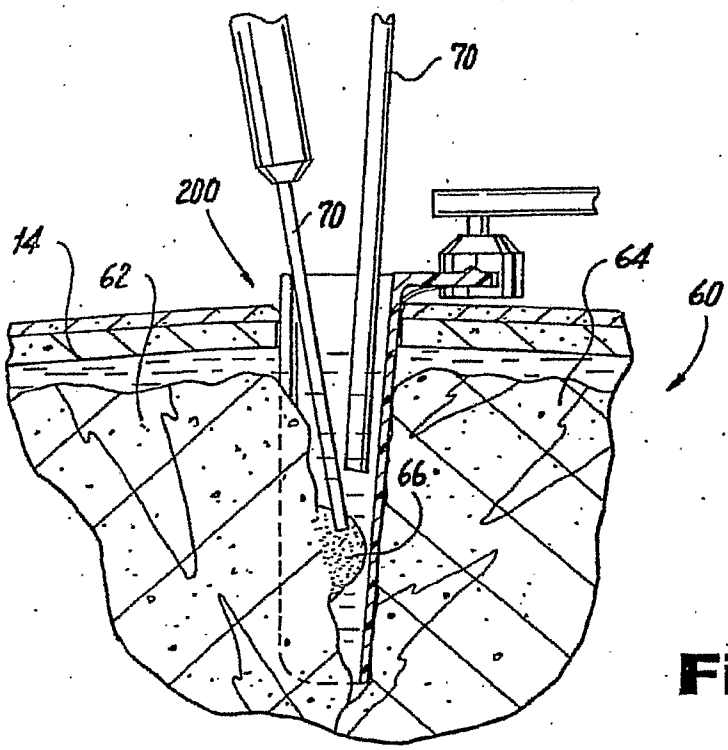


Fig. 27

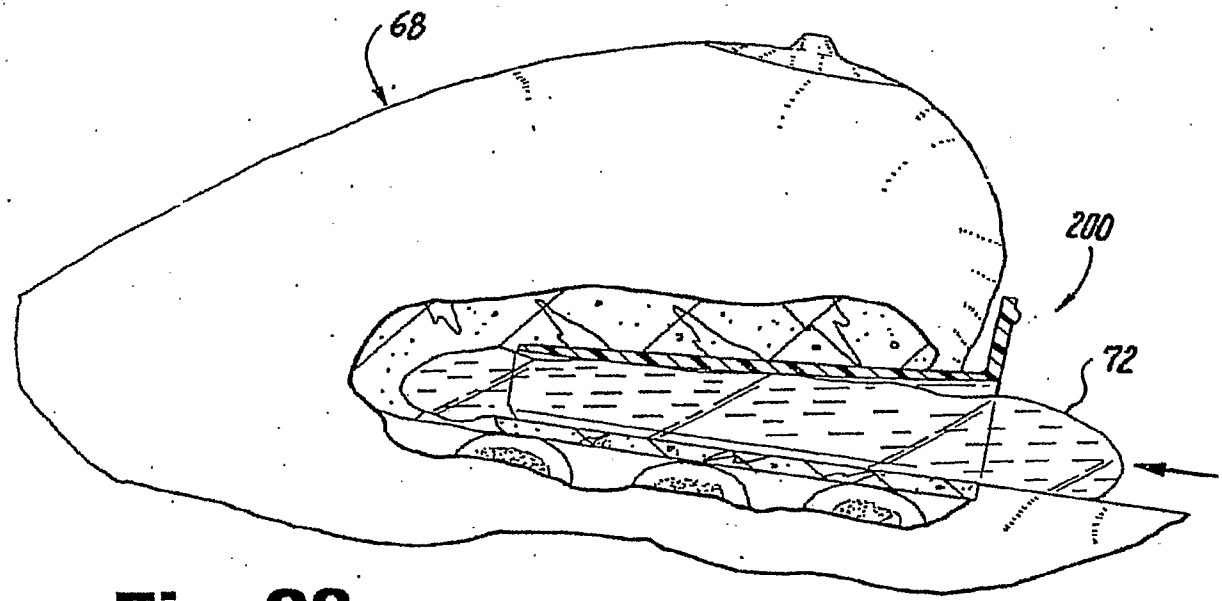
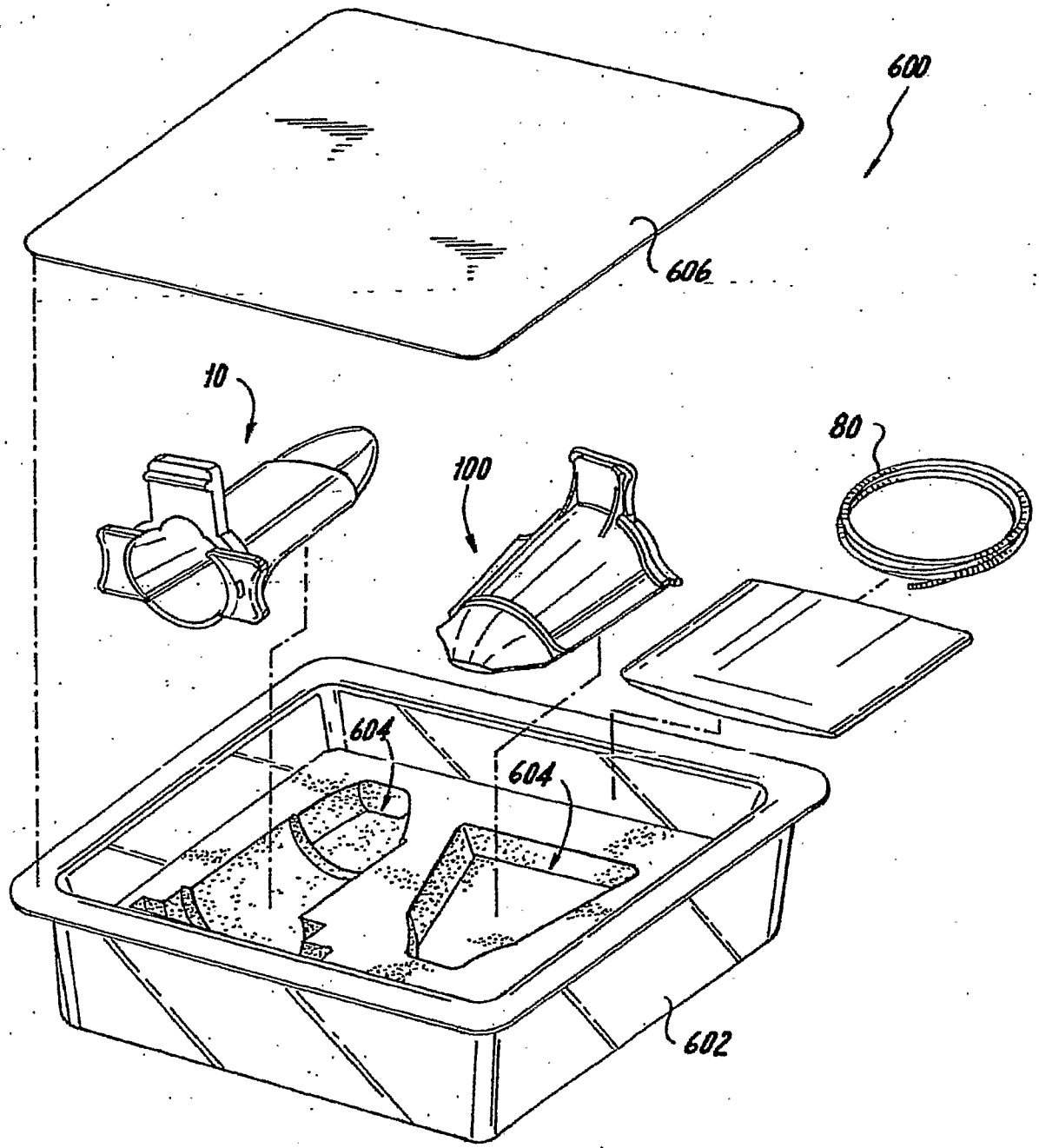


Fig. 28

Fig. 29



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/61246

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 1/32 (2007.01)
USPC - 600/210
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 1/32 (2007.01)
USPC - 600/210

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 20050273132 A1 (SHLUZAS et al) 08 December 2005 (08.12.2005) entire document	1-6, 8-22, 24
--		----------
Y		7, 23, 25
Y	US 7,081,089 B2 (BONADIO et al) 25 July 2006 (25.07.2006) entire document	7, 23
Y	US 20060122462 A1 (ROTH et al) 08 June 2006 (08.06.2006) entire document	25

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 July 2007	11 SEP 2007
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)