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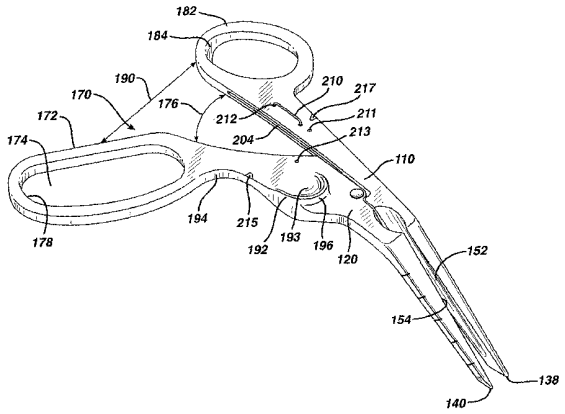
(54) Title: PERCUTANEOUS ENTRY SYSTEM AND METHOD



(57) Abstract: Apparatus (100) to achieve percutaneous entry to a blood vessel includes several coacting combinations of coacting instruments, some capable of independent action, as well as enabling clear visualisation of the operative area, precise location of the operative site, capture and immobilization of the vessel, and guidance in the positioning and insertion of the puncturing needle. Additionally, apparatus (100) is provided for the placement of a sponge (700) directly on the entry wound in the vessel to reduce bleeding. the present invention also sets forth a method for vascular puncture and more particularly for the arterial puncture procedure. The line of maximal pulsation is ascertained, and a small incision in the skin is made. A dissecting-retracting tool (100) is then employed to create a skin-to-vessel channel. The vessel is inspected through the spread fingers (146, 148). A tubular access conduit (300A), mounted on an obturator/carrier (400), is inserted until it rest upon the vessel. The dissector-retractor (100) is removed and the obturator (400) is withdrawn from the conduit (300A) leaving the conduit (300A) in place. A needle guide (500) is then passed down inside the conduit (300A) to contact the vessel. A needle is advanced to the anterior wall of the artery to enter the lumen. A sponge (700) can be positioned with the conduit (300A) pressed against the puncture site to reduce bleeding.

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PERCUTANEOUS ENTRY SYSTEM AND METHOD

SPECIFICATION

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

The present invention relates to medical procedures and instruments, and more particularly to apparatus and methods for dissection of tissue from skin to an underlying artery, and the methods of accomplishing such dissections and arterial punctures.

DESCRIPTION OF THE PRIOR ART

Present surgical practice for percutaneous puncture of the femoral artery with entry into the arterial lumen is a blind approach. The same is true for other arteries and veins accessible via the skin. These procedures have become evermore common and are frequent during procedures relating to invasive cardiology, invasive radiology, and cardiac surgery.

Currently, puncture of a femoral artery is accomplished by first feeling the pulse through the skin and underlying tissue; a trajectory or path for the needle is thereby estimated by the practitioner to properly engage the artery. The needle is then advanced toward the artery through the skin, and it is hoped that the needle will puncture the artery in its mid-line, which is optimal. However, often the needle

will puncture the artery in an off-center position, or the artery may be missed entirely, and multiple attempts executed before success. Further, if the artery is punctured off-center this is not evident. Thus, in general, the quality of the puncture is not known.

An off-center puncture makes insertion of the catheter more difficult and increases the likelihood of arterial trauma and tearing of the wall, resulting in more difficult hemostasis at the end of the procedure. Many factors interfere with a successful mid-line puncture, leading to an off-center puncture or missing the artery entirely. Subcutaneous tissue, particularly if fibrous, may deflect the needle from its intended path. Thicker subcutaneous tissue, as found in obese persons, increases the difficulty of accurately assuming the trajectory of the needle and resulting puncture of the artery, as well as depriving the operator of feeling that the puncture is actually occurring. Additionally, it must be estimated as to when the needle has actually entered the artery. Hence, many operators may push the needle through the rear wall without realizing that this has occurred.

Because of the uncertainty as to the location of the intersection of the needle with the artery and entry of the needle tip into the true lumen of the artery, many operators will intentionally push the needle to a greater depth so that the rear wall is also punctured (double-wall puncture), and then withdraw the needle slowly while awaiting the pulse of blood through the needle's open channel to indicate that the tip of the needle now lies inside the arterial lumen.

The difficulties enumerated above with respect to percutaneous vascular puncture are exacerbated when attempting a venous puncture, since pronounced pulsations to define the

vessel are absent, and venous walls are thinner, hence more easily damaged. Also, venous entry (e.g. jugular, subclavian) relies heavily on superficial anatomic landmarks, which are less precise.

Percutaneous entry of a blood vessel is facilitated by instruments or apparatus that dissect a channel or path from skin to vessel, thereby eliminating resistance to guidewires, catheters, or other implements. The geometry of contemporary instruments is such that the handles of the instrument, as held by the operator,
and the joint of the instrument obstruct and prevent a clear view of the tips and the pathway they are creating.

It is important that a dissecting instrument provide a clear, unobstructed view of the dissecting tips and the channel created therefrom. For a dissecting instrument to provide such visualization of the subcutaneous channel and the underlying blood vessel, the gripping handles must be offset from the dissecting blades or fingers in such a way as to provide a direct and clear line of sight down to the tips of the instrument and hence an unobstructed view of the surgical site. Additionally, the channel created by the fingers must be broad enough for visualization to occur.

Another problem associated with percutaneous entry into a blood vessel is the bleeding that results. After the needle is removed and/or any other invasive removed from the blood vessel, it is necessary to close the general area of the entry on the vessel. This however is not a completely successful method of preventing the bleeding. Since the pressure is applied externally on a relatively large area, there is always seepage resulting in bruising or even the buildup of adhesions from the internal blood.

Numerous surgical implements have been developed which would be useful in connection with the procedures to be accomplished by the present invention. However, none of these tools show or disclose configurations which meet the requirements for the procedures as set forth in the present invention. Some of the prior patents dealing with this subject matter are as follows.

U.S. Patent No. 5,797,939 to Yoon discloses a endoscopic scissor. Note that the finger loops of the handle are at an angle to the main shaft, and that they are spread when the cutting blades are open, and also spread when the cutting blades are closed. (See figure 3). Additionally, the cylindrical tubular section of the device allows for passage of accessories to the end of the blades.

U.S. Patent No. 5,356,408 to Rydell discloses a bipolar electrosurgical scissor instrument in which the handles are offset at 90° and remain in an apparently open position when the blade itself is closed. Additionally, the blades are bent at an angle to the linear axis of the device to provide for an unobstructed view of the cutting area. This actually is the closest reference to two of the features of the present invention namely the angle of the fingers and the position of the finger loops.

U.S. Patent No. 5,153,997 to Chiavaras et al. discloses ergonomics scissors in which the finger grips are at right angles to the blade.

U.S. Patent No. 4,889,112 to Schachner et al discloses a tracheostomy enlarging tool, which has offset probing fingers 107 and 108. These fingers have passage means in them to surround a wire which has been inserted into the trachea to

guide the fingers into the trachea so that the passage into the trachea can be enlarged to widen the opening.

U.S. Patent No. 4,819,636 to Gerich et al discloses a device for cutting and squeezing tubing, in which the finger mounts and the handles are offset from the cutting blades or working arms of the instrument.

U.S. Patent No. 4,140,124 to Curutchet discloses a surgical instrument having an offset handle with special means for holding the thumb and the fingers in a ergonomic position. This patent does not have the same orientation of the handles as does the present invention.

U.S. Patent No. 4,049,002 to Kletschka et al. discloses various scissors or clamps having fluid passages in the handles to allow fluid to be directed towards the tip of the implement. However, note that the passages are internal and are not used to coact with each other to form a cylindrical pathway between the blades.

U.S. Patent No. 3,987,542 to Visco discloses scissors with off-set handles. Additionally, although not for the same purpose, the blades of the scissors have tubular sections. These are more for strength than for any functional purpose.

U.S. Patent No. 1,214,562 to McGrath discloses lawn power sheers, which has off-set blades to the body portions 14 of the levers.

U.S. Patent No. 331,179 DES to Omichi discloses hair-cutting scissors with a curved blade.

U.S. Patent No. 310,714 DES to Dolwick discloses a surgical or dental scissors having the finger loops bent at an

angle from the main shaft of the device and having the blade portions bent similarly to form another angle so as to make the device a double curved instrument with the handles somewhat parallel to the blades and the main shaft at an angle to both.

U.S. Patent No. 258,714 DES to Backstrom discloses nail scissors having curved cutting blades.

U.S. Patent No. 239,910 to Megna discloses scissors having bent finger loops.

U.S. Patent No. 231,034 DES to Moore discloses a surgical clamp with bent fingers.

U.S. Patent No. 2,191 to Pitney discloses a speculum having fingers AA which coact with the handle BB for spreading. Figure 2 shows a levator, which is used to examine the anus once the fingers AA of the speculum are inserted.

OBJECTS AND SUMMARY OF THE INVENTION

Accordingly, to achieve the desired visualization of the operative site and the proper positioning of the needle to achieve the most effective puncture of a vessel, the present invention sets forth several coacting combinations of coacting instruments, some capable of independent action, as well as enabling clear visualization of the operative area, precise location of the operative site, capture and immobilization of the vessel, and guidance in the positioning and insertion of the puncturing needle.

Visualization of the operative area is accomplished by means of a dissecting-retracting tool with the hand-gripping and controlling members of the tool offset in two dimensions from angled blunt dissecting fingers to create a subcutaneous

path from skin to vessel, providing a clear line of sight through the dissecting fingers to their very tips. Once visualized dissection has occurred, conduit and obturator/carrier assemblies are matingly positioned within the blunt dissecting fingers to register with the ends of the dissecting fingers at the site of the blood vessel. The terminal ends of the conduit and obturator are angled and concavely shaped to conform to the vessel, and center the assembly on top of the vessel to be punctured. The dissector-retractor is removed and the obturator is then removed leaving the conduit in place and thus providing an open channel from skin to vessel surface. The conduit bears along its lower, inner surface a fine longitudinal groove capable of guiding a needle tip to the center of the blood vessel or, alternatively, guiding a light probe to illuminate the puncture site. This light probe along its upper surface carries a fine longitudinal groove that is also capable of guiding the needle to the center of the blood vessel. The light probe is centered within the conduit by mating a raised ridge along the longitudinal axis on the underside of the probe with the longitudinal groove located on the surface of the conduit. Centering of the illumination probe on the vessel is facilitated by a forked tip which captures the blood vessel equally on either side of the midline of the probe, and in the case of an artery, transmits arterial pulsations in a manner that enables the operator to feel that the illumination probe has captured and is centered on such artery.

Additionally, apparatus is provided for the placement of a sponge directly on the entry wound in the vessel. A sponge is positioned within the conduit and a sponge pusher pushes the sponge to the site of the entry where pressure is applied by the pusher directly on the site of entry to reduce the bleeding upon removal of the invasive items from the vessel.

These features facilitate a preferred single-wall puncture of the vessel and discourage the more harmful double-wall puncture.

The present invention also sets forth a method for vascular puncture and more particularly for the arterial puncture procedure. The operator begins by palpating an artery, such as the femoral artery. The line of maximal pulsation is ascertained, and a small incision in the skin is made. A dissecting-retracting tool is then employed to create a skin-to-vessel channel until the vessel to be punctured is reached. The tips of the dissecting-retracting tool then rest upon the vessel to be punctured, the blood vessel is palpated, and the fingers are spread into an open position by squeezing the handles toward one another. The vessel is inspected through the spread fingers. A tubular access conduit, mounted on an obturator/carrier, is inserted and advanced until it is positioned by the contoured ends of the conduit and obturator resting upon the artery with the concavity matching the radial curvature of the vessel. The dissector-retractor is removed over the obturator leaving the obturator and conduit in place. The obturator is then withdrawn from the conduit leaving the conduit in place. A flexible collar is wrapped around the protruding end of the conduit and adhesively affixed to the skin to stabilize the conduit and maintain its position. A light-probe is then passed down inside the conduit to contact the vessel. The forked tip of the light probe engages the surface of the vessel to transmit pulsations from said vessel in a manner that will permit the operator to feel that the probe is properly centered on the vessel. A longitudinal groove running the entire length of the upper surface of the probe to its tip allows a needle to be advanced to the anterior wall of the artery to enter the lumen. With the needle properly positioned within the arterial lumen, a guidewire is inserted via the needle into the lumen, after

which the needle and probe are removed leaving the guidewire in place. The conduit can remain in place for the entire procedure to maintain a tissue-free channel, or can be removed over the guidewire.

Accordingly, it is an object of the present invention to provide a group of coacting tools, some capable of independent action, which facilitate percutaneous vascular entry by efficiently enabling accurate percutaneous puncture of blood vessels.

It is another object of the present invention to eliminate double-wall punctures of vessels, to more accurately locate and position the needle for puncturing a vessel, to enable visualization of a vessel prior to puncturing the vessel in order to reduce the number of attempts necessary to successfully puncture a vessel.

It is another object of the present invention to minimize trauma and tearing of the blood vessel during puncture.

It is another object of the present invention to avoid mis-positioned punctures in the side of a vessel.

It is another object of the present invention to provide a dissecting-retracting tool having handles which are both angled and offset for increased comfort during squeezing action, due to the designed range of motion from opened to closed position.

It is another object of the present invention to provide a dissector-retractor for vascular puncture having laterally offset handles positioned to the side of the device, out of the direct line of sight, in order to provide unobstructed viewing of dissection.

It is another object of the present invention to provide a dissecting-retracting tool that spreads tissue as handles are squeezed and are moved to closed position.

It is another object of the present invention to provide a dissector-retractor having a spread power grip which provides maximum squeezing force by allowing the handles to remain in a slightly open position (i.e., full dissection) when the instrument fingers are in the fully open position and thus, the range of separation of the tips is within the range of maximum strength for the gripping/squeezing action of the hand.

It is another object of the present invention to provide a dissector-retractor having angled fingers for unobstructed viewing of dissection. The instrument fingers are at a 20° to 70° angle to the plane of the dissector handles, moving them out of the plane of the handles and the hand of the operator, and can be located on a plane above or below the level of the handles.

It is another object of this invention to provide a dissector-retractor having dissecting fingers capable of spreading underlying tissue to create a broad, clear channel down to the blood vessel.

It is another object of the present invention to provide a dissector-retractor having tapered fingers with tapered cylindrical passages formed in the fingers to create a cylindrical channel down to the blood vessel when the fingers are in the fully open position.

It is still another object of the present invention to provide a dissector-retractor whose dissecting fingers at the tips taper to a point to allow for easier dissection in both

the downward and forward direction. Further, the bottom-to-top angle of the ends of the fingers match the angle of entry, and the side-to-center angle on the lateral surfaces of the fingers facilitates blunt dissection used in the fingers.

It is still another object of the present invention to provide a dissector-retractor having three-point stabilization of the apparatus when articulating the fingers by means of the index finger in an advanced foremost position, the thumb in a rear position, and the remaining fingers in another rearward position. This allows the index finger to apply downward pressure on the tips during dissection, and accurately control the direction of entry, thereby gaining greater control in manipulating the instrument.

It is another object of the present invention to provide a dissector-retractor having a contoured finger cup thereby allowing the index finger to apply forward and downward pressure on the tips during dissection, as well as overall stabilization of the instrument.

It is another object of the present invention to provide a dissector-retractor having a contoured finger rest for the index finger when not located in the actuating position.

It is another object of the present invention to provide a dissector-retractor having depth markings on the dissecting fingers which indicate the depth of the dissection, and hence the selection of lengths and types of coacting apparatus in accordance with the depth shown on the markings.

It is another object of the present invention to provide a dissector retractor having a locking mechanism that holds the dissecting tips open to a specific position.

It is another object of the present invention to provide a dissector-retractor which allows for a clear path of sight through the spread dissecting fingers to the very tips of the dissecting fingers.

It is another object of the present invention to provide a dissector retractor having spread instrument handles which allows for operation over the strongest range of thumb-to-finger and/or hand position, thus allowing the greatest force with the least exertion.

It is another object of the present invention to provide an access-conduit for use with a dissector-retractor, which creates an open channel from the skin surface down to the blood vessel and coacts with a channel formed by the blunt dissecting fingers.

It is another object of the present invention to provide an access-conduit having a central longitudinal groove to guide an illuminated light probe or needle down the center of the tube to the center of a blood vessel. Further, this groove is also used to orient the access-conduit when coacting with the obturator.

It is another object of the present invention to provide an access-conduit having an angled and curved distal tip, a top-to-bottom angle to match the angle of entry and a side-to-side curve to match the curve of the blood vessel, to capture a blood vessel and center the tube over the blood vessel.

It is another object of the present invention to provide an access-conduit adapted for use with a dissector-retractor which can be made in several lengths to match the appropriate skin-to-vessel distance necessary to contact the blood vessel involved.

It is still another object of the present invention to provide an access-conduit made from material which is light-transmitting to convey light through the walls of the tube to the vessel and/or to be made from an opaque material with an opaque surface to reflect light directed down the access-conduit towards the blood vessel.

It is still another object of the present invention to provide an illumination probe to illuminate the channel down to the blood vessel as well as to be used for locating the vessel by feeling for the pulse with the tip of the probe or to explore the vessel to determine if the vessel is unsound.

It is still another object of the present invention to provide an illumination probe having an angled/curved distal tip to fit over the blood vessel and feel the pulsations of the vessel, the distal tip having a top to bottom angle to match the angle of entry of the probe and having a side to side curve to match the curve of the blood vessel.

It is still another object of the present invention to provide a needle guide probe having a longitudinal channel that acts as a guide for a needle down the centerline of the probe to the center of a blood vessel to allow for a central puncture.

It is still another object of the present invention to provide a needle guide probe having a grooved channel which acts as a guide for a needle down the center of the guide to the center of the blood vessel to allow for a central puncture.

It is still another object of the present invention to enable coaction of positioning between the access-conduit and

the needle guide probe, and the needle guide probe with the access-conduit.

It is still another object of the present invention to provide for an illumination probe made of a material which can be illuminated, and which transmits light through the body of the illuminating probe to its distal end to illuminate the operative site.

It is still another object of the present invention to provide for an illumination probe which can be made from opaque material with an opaque surface to reflect light directed down the conduit towards the vessel to be punctured.

It is still another object of the present invention to provide an obturator which can hold one or two conduits, with each conduit on an opposite end with the conduits being of dissimilar size and/or shape.

It is still another object of the present invention to provide an obturator which is constructed to properly insert a conduit in an appropriate orientation with respect to the vessel to be punctured.

It is another object of the invention to provide an obturator with opposite ends rotated 180° in relation to each other so that the angle at the distal tip at one end is parallel to the angle at the distal tip of the other end, thus providing an end surface that is parallel to the skin to assist in proper visual orientation of the conduit/obturator assembly.

It is still another object of the present invention to provide an obturator having a mid-section configured to allow

for removal of the dissector-retractor from a coacting conduit/obturator assembly.

It is still another object of the present invention to provide an obturator that includes a retention mechanism to hold the conduit in position during manipulation of the conduit/obturator assembly.

It is still another object of the present invention to provide an obturator which is constructed to facilitate action by the operator to easily and accurately push the conduit and release same from the obturator.

It is still another object of the present invention to provide an obturator which is constructed with a partial shoulder to act as a stop for the access-conduit as it is being placed and held on the obturator, and to allow for access to the end of the conduit.

It is another object of the present invention to provide an obturator having an angled and curved distal tip to capture the blood vessel, and hold the obturator in place. The distal tip is angled from top to bottom to match the angle of entry and is curved from side to side to match the curve of the blood vessel.

It is still another object of the present invention to provide an obturator which is constructed having a depression to allow for access to the end of the conduit.

It is another object of the present invention to provide a method for puncturing a blood vessel which provides for coaction between a dissecting retracting tool, a conduit mounted on an obturator and a needle guide path in appropriate sequence to enable clear visualization of the channel from the

skin incision to the blood vessel to be punctured and/or accurate positioning of the puncture in the vessel.

It is another object of the present invention to provide a method which allows for capture of the blood vessel by the distal end of the conduit and obturator.

It is another object of the present invention to provide a method which allows for capture of the blood vessel by the needle- guide probe.

It is another object of the present invention to provide a method which allows palpation of the blood vessel by transmission of the pulse along a needle-guide probe from the blood vessel to the operator.

It is another object of the present invention to provide a method which allows palpation of the blood vessel by transmission of the pulse along an obturator from the blood vessel to the operator.

It is another object of the present invention to provide a method which allows palpation of the blood vessel by transmission of the pulse along the dissector-retractor from the blood vessel to the operator.

It is another object of the present invention to provide apparatus to enable application of specific localized pressure to the site of a percutaneous entry of a blood vessel.

It is another object of the present invention to provide apparatus for reducing the bleeding at the entry site of a vessel by direct application of a sponge to the site of the vessel opening.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention, reference may be had to the following description of exemplary embodiments of the present invention considered in connection with the accompanying drawings, in which:

FIG. 1 is a perspective view showing the blunt dissecting tool of the present invention in the closed position;

FIG. 2 is a view of the blunt dissecting tool shown in FIG. 1 with the dissecting fingers in the open position;

FIG. 3 is a view of the arm having the finger grips of the blunt dissecting tool shown in FIG. 1;

FIG. 4 is a view of the blunt dissecting tool of FIG. 1 together with coacting conduit and obturator;

FIG. 5 is an enlarged view of FIG. 4;

FIB. 6 is an enlarged view of the tips of the fingers of the blunt dissecting tool shown in Fig. 1;

FIG. 7 is a view similar to FIG. 4 with the blunt dissecting tool removed up along the obturator in a position for separation from the obturator and conduit assembly;

FIG. 8 shows an enlarged view of the end of the conduit shown in Fig. 11 from the front;

FIG. 9 is an enlarged view of the end of the needle guide shown in Fig. 13;

FIG. 10 is a view showing the needle guide within the conduit;

FIG. 11 is an enlarged view of the conduit;

FIG. 12 is an enlarged view of the obturator; and

FIG. 13 is an enlarged view of the needle guide.

FIG. 14 is a view showing the elements used for reducing the bleeding from a percutaneous entry to a vessel.

FIG. 15 shows the elements of FIG. 14 in the working relationship.

FIG. 16 shows the bottom of the conduit shown in FIG. 14.

FIG. 17 shows the bottom of the conduit from the front elevation.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIG. 1, a dissector/retractor tool is generally indicated at 100 and has 2 arms generally indicated at 110 and 120. The arms end in fingers 130 and 132 which are bent from the plane of the arms at an angle 131 of anywhere from 20° to 80° but preferably from 30° to 45°. The ends of the fingers 134 and 136, respectively on fingers 130 and 132 have points 138 and 140 which are pointed but not sharp and not rounded. The points are chamfered at the bottoms 142 and 144, respectively. The chamfer provides an angle which is complementary to the angle of the fingers to provide a flat plane with the horizontal. Chines on the flat plane at the outside lower leading surface of the fingertips 146 and 148, respectively provide for a sharp bottom when the dissecting fingers are acting together.

As shown in **FIG 2**, moving the arms of the dissector-retractor together will spread the fingers. The fingers of

the dissector-retractor, as shown in **FIGS. 2** and **3**, have tapered cylindrical passages formed on the facing surfaces so that when the fingers are spread to the maximum position, a cylindrical path is formed from the top of the arms to the tips of the fingers. The tapered cylindrical passages are indicated at 152 and 154 on the inner surfaces of thumb and finger arm 110 and 120, respectively. This cylindrical passage will allow a clear line of sight from the base of the fingers down to the tips 138,140.

As seen in FIG. 1, depth marking indicia 160, herein enumerated in mm., are formed on the top surface of the fingers and are oriented for viewing from the finger-grip portion. These indicia are an indication of the depth of tissue that has been penetrated by the fingers of the dissector-retractor. This provides an indication to the operator as to the length of conduit that will be necessary for the next step in the procedure.

The handle portion of the dissector-retractor, generally indicated at 170, contains a finger grip 172 possessing an oblong opening for two, three or four fingers. The finger grip is at an angle 176 to the thumb grip to provide the most comfortable position of the partially closed hand while holding the device.

Additionally, the offset of the finger grip provides for clear unobstructed view over arms, especially dissecting fingers of the dissector-retractor. There is a chamfer 178 on the inner surface of the finger grip to provide a smooth radius for comfort of the hand. The thumb grip 182 has a chamfer 184 on the inside of the grip. There is a space 190 between the finger grip and the thumb grip when the dissecting fingers of the arms are in the maximum open position. This space or distance provides a position in which the fingers and

the thumb are separated for the maximum strength of grip for the human hand.

The chamfered slopes on the sides of the hand grips, 178 for the fingers and 184 for the thumb, provide for maximum comfort. There is a also a forefinger stabilizing function generally indicated at 192.

The forefinger-stabilizer includes a resting position 194 for the forefinger when this finger is not being used for any special purpose, and a forefinger well or cup 193 which has a forward wall 196. The purpose of the forefinger well is to allow a position where the forefinger can be placed to exert force without slipping in controlling the dissector-retractor without slipping. The front wall 196 allows the forefinger to press downward and forward on the dissector-retractor. Together, the forefinger-well 193, the thumb 182, and the finger grip 172, establish a three-point stabilized position for holding and controlling the dissector-retractor during use.

Note that the forefinger-well 193 is displaced to the side of the dissecting fingers to maintain a clear line of sight to the cylindrical passage formed in the dissecting fingers when they are spread.

As shown in FIGS. 2 and 3, a spring mechanism generally indicated at 200, as shown on FIG. 2 or 3, having a spring with recessed channels 204,206 for the spring is provided to cause the fingers of the dissector retractor to rest normally in the closed position with the hand grips in the most widely spread position.

A locking bar 210 is mounted in a storage position on the thumb arm, there being two detents 212 or bore holes to hold

the ends of the locking bar 210 in a passive non-utilized position. When it is desired to maintain the dissecting fingers in a spread position, the locking bar 210 can be placed in bore holes 211 and 213 on the arms 110 and 120, respectively, to hold the arms apart in the spread position against the action of the spring. Alternatively, a locking bar can be used to engage cut-outs 215,217 on the sides of the arms to hold the position with dissecting fingers.

As shown in FIG. 4, two conduits 300A,B are mounted on an obturator generally indicated at 400. The conduits on the obturator fit within the cylindrical passage formed in the spread fingers of the dissector-retractor. Note that conduit 300A is longer than conduit 300B, as was previously discussed in connection with the markings 160 on the top face of the dissecting fingers.
The diameters of the obturator ends and associated conduits can also vary.

FIG. 5 is an enlarged view showing the lower conduit on the obturator within the cylindrical passage.

As shown in FIGS. 8 and 11, once the conduit is moved or advanced down to the bottom of the dissecting fingers, and is positioned over the blood vessel to be punctured, the matching curvatures at the bottom of the obturator and the bottom of the conduit respectively, will help the conduit find or position itself on top of the vessel. See FIGS. 8 and 11 for enlarged views of the conduit and FIG. 12 for an enlarged view of the obturator.

In FIG. 11 , the conduit generally indicated at 300 has an end contour or profile adapted to coact with the surface of the blood vessel. The diameter of the conduit generally indicated at 302 extends for a length 304, which coincides

with the length of the wide end of the obturator to maintain the conduit fully on the obturator while it is being inserted through the cylindrical passage of the dissecting fingers. The conduit creates an open access channel from the skin surface down to the blood vessel. The tip is scooped out at 308 so as to have a left to right curvature that will conform to the surface of the blood vessel and continue to engage the vessel even if the conduit is raised to a greater angle than its intended angle of entry.

Additionally, a guide channel 312 in the conduit acts to align itself and receive a guide rib 420 on the obturator to align the conduit with the obturator, as will be discussed further below.

The angle at the bottom of the conduit is the same angle as the bottom of the dissecting fingers and will be the same as the bottom of the obturator which is complementary to the angle of the dissecting finger so as to provide a generally horizontal flat surface to lie fully in contact with the vessel to be punctured.

As shown in FIG. 12, the obturator generally indicated at 400 has a long end 402 and a shorter end 404. We will describe only the longer end for purposes of brevity. The longer end has an end 406 possessing a profile similar to that of the conduit in that it has a chamfer angle complementary to the angle of the dissecting fingers and equal to that of the conduit, and is also curved from side to side to facilitate contact with the rounded surface of the vessel to be punctured. The opposite end 407 has a profile similar to end 406 but rotated 180° to provide an end surface parallel to the opposite end surface. The parallel opposing end surfaces aid in visual orientation of the obturator/conduit assembly in the dissector-retractor tool.

The obturator has a guide rib 420 running the length of the larger diameter section 402 and which is adapted to coact with a guide groove 312 in the conduit to position the conduit and prevent rotation of the conduit. A tab 430 formed in the larger section of the obturator provides a spring friction contact with the conduit to prevent movement of the conduit with respect to the obturator.

A stopping shoulder 440 is provided at the end of the wide section of the obturator to prevent the conduit from backing up onto the obturator. Additionally, an arrow pointer shown as 450 on the smaller end of the obturator but which also appears on the other end, provides a tactile contact to give the operator an indication of the orientation of the obturator and conduit assembly. A depression 460 in he obturator allows the finger access to the end of the conduit when pushing conduit off obturator.

As shown in FIG. 5, the conduit/obturator assembly is placed within the tubular channel created by the spread fingers of the dissector-retractor. Subsequently, the dissector-retractor is withdrawn by sliding the dissector-retractor up the conduit as shown in FIG. 7 until it reaches the narrow central section of the obturator 410, at which point the obturator will fit loosely in the cylindrical channel created by coaction of the cylindrical channel formed in the dissecting fingers, and this will facilitate removal of the obturator from the dissector-retractor. The obturator is then removed from the conduit leaving the conduit in place.

As shown in FIGS. 9,10 and 13, a needle guide-illuminator is provided which is adapted to fit within the conduit once the obturator has been removed.

As shown in FIG. 13, the needle guide-illuminator is generally indicated at 500 and has two panels 510,520 which form a trough or groove 530 to guide a needle from the handle portion 550 down to the end of the guide 540. The end of the guide 540 has two tips 542 and 544 which are formed by the end of the guide and which have a scooped out portion so that the ends of the guide 542,544 will overlie and capture between them an underlying blood vessel.

Additionally, the panels 510,520 form a concavity upward. When fitted within the conduit as shown in FIG. 10, the needle- guide illuminator has a stop member 560, which will position the needle guide so that the end 540 is in registration with the end of the conduit 306, and a rib guide 580 on its underside to align it properly within the conduit. There is an attaching point 570 on the handle of the needle guide illuminator for attachment of a fiberoptic bundle. Also there is a roughened or beaded finger grip 552, offset from the guide path 530 on the handle 550, for manipulation of the light guide.

Because of the longitudinal play between the needle guide and the conduit, the needle guide will be capable of movement with a pulsating vessel, such as the femoral artery, and this will be transmitted to the operator who is gripping the handle. He will then be able to manipulate the needle guide to position it on the blood vessel to be punctured and will be able to see down to the point of the puncture through the conduit.

The conduit and the needle guide can be made of optically clear material so that a fiberoptic bundle when attached to the end of the needle guide will provide a stream of light within the conduit that will illuminate the operative site of the puncture.

Additionally, the conduit and the needle guide can have an inner reflective surface that will help reflect light within the conduit to further enhance the illumination of the puncture cite.

The method of use can now be discussed. The operator begins by palpating the femoral artery. The line of maximal pulsation is ascertained, a skin-to-artery trajectory is pictured, and a small incision in the skin is made with a blade. The dissector-retractor is now employed to create a skin-to-vessel channel. The point of the tips of the dissecting fingers are inserted through the skin incision at a desired angle (usually between 30° and 45°) and advanced by forward pressure directed by forefinger, alternating with squeezing of the handles to open the dissecting fingers, thereby performing a blunt dissection until the femoral artery is reached.

The under-surface of the tips is configured to be parallel to the artery so that upon reaching this vessel, the closed tips can rest upon and contact the artery and transmit arterial pulsations. At this point the dissecting fingers are opened, the channel can be illuminated and the artery inspected visually, if desired.

Having ascertained by palpation and/or visualization that the subcutaneous channel has reached the femoral artery, the tubular access conduit is inserted (with the use of the obturator) between the dissectors fingers down to the arterial surface. The configuration of the conduit's distal end, angled to parallel the artery and concave left-to-right to match the radial curvature of the vessel, permits the coacting distal ends of the conduit and obturator to engage the arterial surface and capture it in precise alignment. Slight downward pressure permits appreciation of the arterial

pulsation and verification that the conduit is centered in the artery. The dissector/retractor is now removed over the obturator leaving the obturator with the conduit in place.

The obturator is then withdrawn from the conduit and the obturator is set aside. A flexible collar is wrapped around the protruding proximal end of the conduit and the adhesive-bearing wings pressed against the skin, thereby stabilizing the position of the conduit. The channel provided by the conduit is ample for irrigation and suction, if and when needed, to enhance visualization of the vessel and its pulsations. Additional light may be introduced into the conduit by an external focused lamp, such as those designed to be worn on the forehead, or the illumination may be provided by attaching a fiberoptic source to its proximal end.

The illumination probe is then passed down the conduit along its bottom surface where it is guided by a thin channel in the conduit. When the contoured tip of the illumination probe-needle guide engages the arterial surface, the transmitted pulsations can be firmly felt, particularly if the probe is pressed slightly against the artery. If the probe is illuminated, the artery and its pulsations can be visualized, and proper left to right centering of the probe over the artery can be verified.

When the vessel is illuminated and visually inspected, disease of the arterial wall may be recognized, in which case the operator may choose to move up or down the artery to a more suitable point of entry, thus avoiding any arteriosclerotic plaque.

The upper surface of the probe bears a fine groove running its entire length and over the distal contoured tip. This groove can be visualized and is centered on the artery.

The needle tip is placed in the groove and slid down the entire length of the probe and then centrally punctures only the anterior wall of the artery to enter the lumen directly, and a double wall puncture is avoided.

When blood pulsation through the needle verifies proper entry into the vascular lumen, the guide wire is inserted. Then the probe and needle are removed. The operator must decide at this juncture whether to leave the conduit in place for the entire procedure. If not, then the conduit must be removed over the guide wire following the needle. The role of the PERCUTANEOUS ENTRY SYSTEM in the arterial puncture is now completed, and the access procedure can now be continued according to standard practice with dilating catheter and sheath passing over the guide-wire into the vessel.

From the above discussion one can appreciate the value of vascular puncture under direct palpation and/or observation, where the artery is clearly visualized, its pulsation is clearly seen and topical. Also the artery is distinguishable from the adjacent femoral vein and nerve, which can be damaged by offline passage of the needle. The PERCUTANEOUS ENTRY SYSTEM of the present invention provides a new and superior method for the percutaneous introduction of catheters and other medical instruments into the vascular system under direct palpation and/or vision. The unique features of the system enable a truly central puncture of the blood vessel at the desired angle of entry, thereby minimizing trauma to the vascular wall and adjacent structures.

FIGS. 14,15,16,17 show apparatus for a closure pressure sponge assembly to be used with the blunt dissecting apparatus for percuteaneous entry through blood systems.

Since percutaneous entry into a blood vessel requires a puncture of the blood vessel, it may result in an ireeglar puncture. The puncture must eventually be closed for hemostatis. The traditional method has been to apply gross pressure to the area of the puncture. The process is not localized because force is applied to a broad area of skin. Complications, particularly hemotoma of various sizes, are common.

To reduce this problem the present invention provides an add-on kit for the percutaneous dissecting and access system which includes a tubular conduit generally indicated at 600 which provides a clear cylindrical path from the skin of the patient to the vessel to be entered. Thus direct pressure that is specific and localized to the entry site is possible. An obturator or sponge pusher generaly indicated at 800 is also included. The sponge pusher or obturator is intended to exert pressure directly and exclusively at the site of the entry into the vessel to maintain pressure for a length of time needed for clotting and hemostatis of the vessel.

Lastly, a "sponge" generally indicate at 700 which may be of a non-woven structure, or a woven gauze-like mesh design, and may also be of a bioresorbable material, is intended to be inserted into the conduit. The sponge pusher would follow behind the sponge to deliver the sponge to the site of the entry and exert a resilient force at the desired site. The sponge pusher would maintain light pressure on the sponge and hence on the vessel that has been entered until natural hemostatis occurs.

Upon accomplishing hemostatis, the bioresorbable sponge may be removed or could be left in place. To facilitate removal of the sponge it may be necessary to stitch the sponge with a long suture generally indicated at 710 prior to its

insertion into the conduit. In this way, the operator can remove the sponge simply by tugging on the suture.

It should be noted that bottom of the conduit is similar to the bottom of the conduit previously described. The distal end 610 is cut at an angle which would enable the distal end to lie flat at the angle of percutaneous entry.

Additionally, the cut of the angle through the cylindrical conduit produces an oval shape having a long axis intended to lie parallel to the vessel being entered and the bottom also has a curved surface perpendicular to the long axis 620 of the oval formed at the bottom. The curve 630 enables the conduit to lie relatively flat on the vessel to be entered or which has been entered.

The very tip of the conduit 640 is also opened up to enable the conduit to lie and find the vessel that it is coact with.

The pusher could be similar to the obturator previously discussed. The necessary elements of the pusher are a distal end 810 having a bottom surface 820 similar to the bottom surface of the obturator previously described and adapted to form the same angle as the distal end of the conduit and have a shape complementary to that of the distal end of the conduit to form a continuous surface with the end of the conduit so that a uniform pressure can be applied to the sponge so as to have the sponge seek around or curve with the surface of the vessel that has been entered.

Therefore, the bottom of the pusher will be oval in shape similar to that shown in FIG. 16 having a long axis and a short axis with a curved portion perpendicular to the long axis to allow it to rest with a greater surface area on the

vessel to be entered. This shape will then push the sponge into greater conformity with the surface of the vessel. The length of the pusher must be sufficient so that an end of the pusher will extend from the end of the conduit when the sponge has been pushed down to the bottom of the conduit and is resting on the vessel.

The advantage of direct visualization may be even more valuable for venous entry, since pronounced pulsations to define the vessel are absent and venous walls are thinner, hence more easily damaged. Also venous entry (for example into the jugular or subclavian) relies heavily on superficial anatomic landmarks which are less reliable than direct visualization .

Some advantages of the present invention over prior art are that the dissection tool has angled dissecting fingers to allow for unobstructed view of the surgical site, that the handles are offset from the central axis of the tool thereby allowing for additional unobstructed view of the surgical site, that the range of motion of the handles are designed in such a manner so that maximum squeezing forces apply during dissection while opening the dissecting fingers, that the dissecting fingers of the instrument are concave in design through which surgical instruments can be passed to the vascular puncture site, that the fingers are broad to create a broad, clear channel, and that the access conduit contains a rounded distal end which hugs the blood vessel and orients the conduit into an optimal access position, that the access conduit contains a grooved bottom edge to guide the puncturing instrument into an optimal central position on the vascular wall and can be illuminated to provide better illumination, that the illumination probe has a forked tip to engage the artery and hold it during puncture, and that the illumination

probe contains a groove channel to guide the needle to a centrally located point on the vascular wall.

While the invention has been described in its preferred embodiment, it is to be understood that the words which have been used are words or description rather than limitation and that changes may be made within the purvey of the appended claim without departing from the true scope and spirit of the invention in its broader aspects.

It will be understood that the embodiments described herein are merely exemplary and that a person skilled in the art may make many variations and modifications without departing from the spirit and scope of the invention. All such modification and variations are intended to be included within the scope of the invention as disclosed herein.

CLAIMS

I claim:

1. Apparatus for performing percutaneous entry to a blood vessel comprising:

dissector comprising:

two arms disposed in a first plane

a finger grip and a thumb grip at the end of the arms a pair of dissecting fingers extending from the other ends of the arms disposed in a second plane at an angle to the first plane,

pivot means connecting the arms to enable spreading of the dissecting fingers upon movement of the finger grip and thumb grip towards each other

tapered passages formed on adjacent surfaces of the dissecting fingers,

the tapered passages on the dissecting fingers coacting to form a cylindrical passage upon spreading of the dissecting fingers,

a conduit comprising:

a cylindrical tube having a distal and a proximal end,

a longitudinal groove formed in the inner surface of the cylinder wall to act as a needle guide,

the diameter of the outer wall of the conduit adapted to coact with the cylindrical passage formed by the tapered passages of the dissecting fingers to allow sliding movement of the conduit in the cylindrical passage formed by the dissecting fingers,

the distal end of the conduit formed at an angle complimentary to the angle of the second plane in which the dissecting fingers lie so as to be substantially parallel to the first plane in which the arms of the dissector are disposed.

an obturator comprising:

an elongated mid-section,

an end section formed on at least one of the ends of the mid-section,

the obturator end section adapted to fit within the conduit in frictional sliding relation to the inner wall of the conduit,

an end surface formed at the end of each obturator end section,

each end surface having an elliptical form shaped and disposed at an angle to register with the distal end,

the elongated mid-section constructed to allow passage of the mid-section through the cylindrical passage formed by the coacting tapered passages of the dissecting fingers.

a needle guide comprising:

two wings joined at a central section having a distal and proximal end,

the length of the wings greater than the length of the conduit and adapted for coaction of the needle guide within the conduit,

ends of the wings at the distal end of the guide shaped to form separated points adapted to lie on and capture a blood vessel,

a handle at the proximal end of the guide connected to one of the wings and extending away from the longitudinal axis of the guide,

a groove running the length of the central section to act as a needle guide.

2. Apparatus for performing percutaneous entry to a blood vessel comprising:

a dissector comprising:

two arms,

a pair of dissecting fingers,

pivot means connecting the arms to enable spreading of the dissecting fingers,

the tapered passages on the dissecting fingers coacting to form a cylindrical passage upon spreading of the dissecting fingers.

a conduit comprising:

a cylindrical tube having a distal and a proximal end,

the diameter of the outer wall of the conduit adapted to coact with the cylindrical passage formed by the tapered passages of the dissecting fingers to allow sliding movement of the conduit in the cylindrical passage formed by the dissecting fingers,

an obturator comprising;

an elongated mid-section,

an end section formed on at least one of the ends of the mid-section,

the obturator end section adapted to fit within the conduit in frictional sliding relation to the inner wall of the conduit,

an end surface formed at the end of each obturator end section.

a needle guide comprising,

two wings joined at a central section having a distal and proximal end,

the length of the wings greater than the length of the conduit and adapted for coaction of the needle guide within the conduit,

a groove running the length of the central section to act as a needle guide.

3. The apparatus claimed in claim 2, further comprising;

the dissector has two arms disposed in a first plane,

a finger grip and a thumb grip at the end of the arms,

the pair of dissecting fingers extending from the other ends of the arms disposed in a second plane at an angle to the first plane,

the pivot means connecting the arms to enable spreading of the dissecting fingers actuate upon movement of the finger grip and thumb grip towards each other.

4. The apparatus claimed in claim 2, further comprising:

the dissector has two arms disposed in a first plane,

a finger grip and a thumb grip at the end of the arms,

a pair of dissecting fingers extending from the other ends of the arms disposed in a second plane at an angle to the first plane.

the conduit has a cylindrical tube with:

a longitudinal groove formed in the inner surface of the cylinder wall, and

the distal end of the conduit formed at an angle complementary to the angle of the second plane in which the dissecting fingers lie so as to be substantially parallel to the first plane in which the arms of the dissector are disposed.

5. The apparatus claimed in claim 2, further comprising the obturator having;

an end surface formed at least one end of the obturator,

each end surface having an elliptical form shaped and disposed at an angle to register with the distal end of the conduit,

the elongated mid-section constructed to allow passage of the mid-section through the cylindrical passage formed by the coacting tapered passages of the dissecting fingers.

6. The apparatus claimed in claim 2 further comprising the needle guide having:

the ends of the wings at the distal end of the needle guide shaped to form separated points adapted to lie n and capture a blood vessel,

a handle at the proximal end of the guide connected to one of the wings and extending away from the longitudinal axis of the guide.

7. A dissector comprising:

two arms disposed in a first plane,

a finger grip and thumb grip at one end of the arms,

a finger receptacle comprising a well for the end of the index finger,

a pair of dissecting fingers extending from the other ends of the arms disposed in a second plane at an angle to the first plane,

pivot means connecting the arms to enable spreading of the dissecting fingers upon movement of he finger grip and thumb grip towards each other,

a tapered passage formed on adjacent surfaces of the dissecting fingers,

the tapered passages on the dissecting fingers coacting to form a cylindrical passage upon spreading of the dissecting fingers,

the cylindrical passage formed to enable viewing of the end of the dissecting fingers through the passage,

each of the ends of the dissecting fingers ending in a linear edge having a top and a bottom,

the linear edge formed at a bow angle complimentary to the angle of the second plane to allow the ends of the fingers to lie flat,

the dissecting fingers tapering towards the ends of the fingers and the linear edge tapering from the top to the bottom,

the top of the dissecting fingers having indicia thereon for indicating the tips of the dissecting fingers penetration into tissue.

the finger grip, the thumb grip and the finger receptacle for the third finger displaced from the line of sight to

enable unobstructed view of the tips of the dissecting fingers during the deployment of the dissecting fingers,

the finger grip and the thumb grip in spaced relation when the dissecting fingers are closed to enhance ergonomic comfort of the hand during use of the dissector and to position the fingers and thumb at optimum distance for maximum gripping strength of the hand.

8. A dissector comprising:

two arms disposed in a first plane,

a finger grip and thumb grip at one end of the arms,

a pair of dissecting fingers extending from the other ends of the arms disposed in a second plane at an angle to the first plane,

a finger receptacle for a third finger disposed on one of the arms to enable coaction between the thumb and two spaced fingers to enable application of downward and forward force on the ends of the dissecting fingers, and to stabilize the dissector during use,

pivot means connecting the arms to enable spreading of the dissecting fingers upon movement of the finger grip and thumb grip towards each other,

9. The apparatus claimed in claim 8 further comprising:

the finger receptacle for the third finger comprising:

a well for the end of the index finger.

10. The apparatus claimed in claim 8 further comprising:

the dissecting fingers having a tapered passage formed on adjacent surfaces of the dissecting fingers,

the tapered passages on the dissecting fingers coacting to form a cylindrical passage upon spreading of the dissecting fingers,

the cylindrical passage formed to enable viewing of the end of the dissecting fingers through the passage.

11. The apparatus claimed in claim 8, further comprising:

each of the ends of the dissecting fingers ending in a linear edge having a top and a bottom,

the linear edge formed at a bow angle complimentary to the angle of the second plane to allow the ends of the dissecting fingers to lie flat.

12. The apparatus claimed in claim 8, further comprising;

each of the ends of the dissecting fingers ending in a linear edge having a top and a bottom,

the dissecting fingers tapering towards the ends of the fingers and the linear edge tapering from the top to the bottom.

13. The apparatus claimed in claim 11, further comprising:

each of the ends of the dissecting fingers ending in a linear edge having a top and a bottom,

the top of the dissecting fingers having indicia thereon for indicating the tips of the dissecting fingers penetration into tissue.

14. The apparatus claimed in claim 10, further comprising;

each of the ends of the dissecting fingers ending in linear edge having a top and a bottom,

each linear edge formed at a bow angle complimentary to the angle of the second plane to allow the ends of the fingers to lie flat.

15. The apparatus claimed in claim 14, further comprising:

each of the dissecting fingers tapering towards the end of the fingers and the linear end tapering from the top to the bottom.

16. The apparatus claimed in claim 10, further comprising:

the top of the dissecting fingers having indicia thereon for indicating the tips of the dissecting fingers penetration into tissue.

17. The apparatus claimed in claim 10, further comprising:

the finger grip, the thumb grip and the finger receptacle for the third finger displaced from the line of sight to enable unobstructed view of the tips of the dissecting fingers during deployment of the dissecting fingers.

18. The apparatus claimed in claim 8 further comprising:

the finger grip and the thumb grip are disposed in spaced relation when the dissecting fingers are in the closed position to enhance ergonomic comfort of the hand during use of the dissector and to position the fingers and thumb at optimum distance for maximum gripping strength of the hand.

19. A conduit for use in percutaneous entry to a blood vessel, comprising:

a cylindrical tube having a distal and a proximal end,

a needle guide groove formed in the inner surface of the cylinder wall,

the needle guide groove adapted to coact with a needle guide with a corresponding rib, to position the needle guide within the conduit.

A rib formed on the other side of the needle guide groove adapted to position the conduit in a cylinder having an axial opening,

the diameter of the outer wall of the conduit adapted to allow sliding movement of the conduit in a cylindrical passage formed by a dissecting tool,

the distal end of the conduit formed at an angle to enable the end of the conduit to lie relatively horizontal while the conduit is at the angle of the percutaneous entry,

the distal end of the conduit including a cut-out at the tip of conduit for seeking the surface of a blood vessel

and positioning the end of the conduit over the blood vessel,

indicia disposed on the proximal end of the conduit for visual and tactile determination of orientation of the conduit

20. The apparatus claimed in claim 19, further comprising:

a needle guide groove formed in the inner surface of the cylinder wall,

the needle guide groove adapted to coact with a needle guide having a corresponding rib to position the needle guide within the conduit,

21. The apparatus claimed in claim 19, further comprising:

a rib formed on the other side of the needle guide groove adapted to position the conduit in a cylinder having an axial opening.

22. The apparatus claimed in claim 20, further comprising:

indicia disposed on the proximal end of the conduit for visual and tactile determination of orientation of the conduit when disposed within a percutaneous entry.

23. The apparatus claimed in claim 22 further comprising:

a cut-out portion on the distal edge of the conduit adapted to facilitate the positioning of the conduit over a blood vessel.

24. An obturator for use with a conduit in percutaneous entry to a blood vessel comprising:

an elongated mid-section,

an end section formed on each of the ends of the mid-section,

the two end sections being of different length,

the two end sections being of different diameter adapted to fit different surrounding conduits and or sheaths,

each obturator end section adapted to fit within the conduit in frictional sliding relation to the inner wall of the conduit,

at least one of the end sections of the obturator is cylindrical in shape,

an end surface formed at the end of each obturator end section,

at least one of the end surfaces having an elliptical form shape and is disposed at an angle complementary to the angle of percutaneous entry,

at least one of the end surfaces formed with a curve along the long axis of the elliptical form shape to facilitate resting of the curved end surface of the obturator on the curved surface of vessel,

at least one of the end sections having a positioning rib adapted to align the obturator with a coacting conduit or sheath,

at least one end section of the obturator having a resilient member resiliently protruding from the end section adapted to coact with a surrounding conduit or sheath to enhance friction between the obturator surrounding conduit or sheath,

a partial shoulder on at least one end section of the obturator to facilitate removal of the obturator from a conduit or sheath,

a flattened section on at least one end of the mid-section displaced from the partial shoulder adapted to allow access to an axial end of a conduit for assistance in removal of a conduit.

25. An obturator for use with a conduit in percutaneous entry to a blood vessel comprising:

an elongated mid-section,

an end section formed on at least one of the ends of the mid-section,

at least one of the end sections of the obturator is cylindrical in shape,

an end surface formed at least one of the end of each obturator end section,

at least one of the end surfaces having an elliptical form shape and is disposed at an angle complementary to the angle of percutaneous entry,

at least one of the end surfaces formed with a curve along the long axis of the elliptical form shape adapted

to facilitate resting of the curved end surface of the obturator on the curved surface of the vessel.

26. The apparatus claimed in claim 25 further comprising:

an end section formed on each of the ends of the mid section,

the two end sections being of different diameter adapted to fit different surrounding conduits and or sheaths,

each obturator end section adapted to fit within the conduit in frictional sliding relation to the inner wall of the conduit or sheath.

27. The apparatus claimed in claim 25, further comprising:

at least one of the end sections having a positioning rib adapted to align the obturator with a coacting conduit or sheath.

28. The apparatus claimed in claim 25, further comprising:

at least one end section of the obturator having a resilient member resiliently protruding from the end section adapted to coact with a surrounding conduit or sheath to enhance friction between the obturator surrounding conduit or sheath.

29. The apparatus claimed in claim 25, further comprising:

a partial shoulder on at least one end section of the obturator to facilitate removal of the obturator from a conduit or sheath.

30. The apparatus claimed in claim 25, further comprising:

a flattened section on at least one end of mid-section displaced from the partial shoulder adapted to allow access to an axial end of a conduit for assistance in removal of a conduit.

31. A needle guide adapted for use in percutaneous entry to a blood vessel, comprising:

two wings joined at a central section, the joined wings having a distal and proximal end,

the length of the wings adapted to be greater than the length of a conduit and adapted for coaction of the needle guide within a conduit,

the ends of the wings at the distal end of the guide shaped to form separated points adapted to lie on and capture a blood vessel,

a handle at the proximal end of the needle guide connected to one of the wings and extending away from the longitudinal axis of the guide,

the handle has a beaded surface to facilitate gripping by the user,

a groove running the length of the central section to act as a needle guide,

a rib on the opposite side of the groove intended for positioning the needle in a groove formed in a conduit to position the needle guide with a conduit,

a stop formed on the needle guide to position the needle guide with relation to a coacting sheath or conduit,

the material forming the needle guide is translucent,

light source connector on the handle of the needle guide to bring light to the needle guide to illuminate the needle guide and the area at the end of the needle guide,

the distal end of the wings lying at an angle approximate complementary to the angle of the percutaneous entry.

32. A needle guide adapted for use in percutaneous entry to a blood vessel, comprising:

two wings joined at a central section, the joined wings having a distal and proximal end,

the length of the wings adapted to be greater than the length of a conduit and adapted for coaction of the needle guide within a conduit,

the ends of the wings at the distal end of the guide shaped to form separated points adapted to lie on and capture a blood vessel,

a groove running the length of the central section to act as a needle guide,

the distal end of the wings lying at an angle approximately complementary to the angle of the percutaneous entry.

33. The apparatus claimed in claim 32, further comprising:

the length of the wings adapted to be greater than the length of a conduit and adapted for coaction of the needle guide within a conduit.

34. The apparatus claimed in claim 32, further comprising:

a handle at the proximal end of the needle guide connected to one of the wings and extending away from the longitudinal axis of the guide.

35. The apparatus claimed in claim 32, further comprising:

a rib on the opposite side of the groove intended for positioning the needle in a groove formed in a conduit to position the needle guide with a conduit.

36. The apparatus claimed in claim 32, further comprising:

a stop formed on the needle guide to position the needle guide with relation to a coacting sheath or conduit.

37. The apparatus claimed in claim 32, further comprising:

the material forming the needle guide is translucent,

light source connector on the handle of the needle guide to bring light to the needle guide to illuminate the needle guide and the area at the end of the needle guide.

38. A method for performing percutaneous entry to a blood system comprising:

making an incision in the skin,

inserting a dissecting tool in the skin incision,

dissecting tissue by spreading of the dissecting fingers of the dissecting tool until ascertaining the presence of the vessel to be punctured,

inserting a conduit and obturator to lie on top of the vessel and capture said vessel through a cylindrical passage formed between the fingers,

separating the obturator from the conduit,

sliding the obturator out of the conduit,

inserting a needle into the conduit to contact the vessel,

puncturing the vessel with the needle.

39. The method claimed in claim 38 further comprising:

the step of placing a needle guide into the conduit to guide needle.

40. The method claimed in claim 39 further comprising;

the step of adding a light source to the needle guide to illuminate the end of the needle guide.

41. The method claimed in claim 40 further comprising:

the step of inserting a guide wire into the punctured vessel; and

removing the needle.

42. A method for performing percutaneous entry to a blood system comprising:

making an incision in the skin,

inserting a dissecting tool in the skin incision,

viewing the tissue to be dissected through a cylindrical passageway formed by coaction of the dissecting fingers of the dissecting tool,

dissecting tissue by spreading of the dissecting fingers until visualization of the vessel to be punctured.

43. The method claimed in claim 42 wherein the step of dissecting tissue by spreading of the dissecting fingers until visualization of the vessel to be punctured in achieved is done by direct visualization.

44. The method claimed in claim 43 wherein dissecting the tissue by spreading of the dissecting fingers until visualization of the vessel to be punctured occurs is done by indirect visualization, namely palpation.

45. The method claimed in claim 44 further comprising the step of puncturing the vessel with the needle.

46. A method for performing percutaneous entry to a blood system comprising:

making an incision in the skin,

inserting a dissecting tool in the skin incision,

viewing the tissue to be dissected through a cylindrical passageway formed by coaction of the dissecting fingers of the dissecting tool,

dissecting tissue by spreading of the dissecting fingers until visualization of the vessel to be punctured,

inserting conduit mounted on obturator into cylindrical passageway,

capturing the blood vessel with the conduit and obturator by laying the end of the conduit and obturator upon the vessel,

securing the conduit to the skin,

separating the dissecting tool from the conduit,

sliding the dissecting tool up and over the conduit, sliding the obturator out of the conduit and spreading the finger of the dissecting tool to remove it from the obturator,

inserting a probe in the conduit to confirm location of the blood vessel,

illuminating the vessel,

moving a needle through the cylindrical passage to the center point of the vessel,

moving the needle along a guide path,

guide path in needle guide, and

puncturing the vessel with the needle.

47. The method claimed in claim 46 wherein the step of illuminating the vessel includes the step of shining light down the sight path formed by spreading the fingers of the dissecting fingers.

48. The method claimed in claim 46 wherein the step of illuminating the vessel includes the step of attaching a light source to the conduit.

49. The method claimed in claim 46 wherein the step of illuminating the vessel includes the step of attaching a light source to a needle guide.

50. The method claimed in claim 46 wherein the step of moving the needle along a guide path includes the step of moving the needle along a guide path formed in the conduit.

51. The method claimed in claim 46 wherein the step of moving the needle along a guide path includes the step of placing a needle guide in the conduit and then moving the needle along the guide path in the needle guide.

52. The method claimed in claim 46 further comprising the steps of

inserting a guide wire into the punctured vessel; and

removing the needle from the punctured vessel.

53. A method for performing percutaneous entry into a visible element within a body comprising:

making an incision in the skin;

inserting a dissecting tool in the skin incision;

dissecting tissue by spreading the dissecting fingers of the dissecting tool until ascertaining the presence of the element to be reached within the body;

inserting a conduit through the dissecting fingers of the dissecting tool;

withdrawing the dissecting tool from the incision leaving the conduit in place.

54. A method for performing percutaneous entry to a visible element within a body comprising:

making an incision in the skin,

inserting a dissecting tool into the skin incision,

viewing the tissue to be dissected through a cylindrical passageway formed by coaction of the dissecting fingers of the dissecting tool;

dissecting tissue by spreading of the dissection fingers until visualization of the body element is achieved;

inserting a conduit through the viewing passageway of the dissecting tool into the area to be received.

55. A hand implement comprising:

two arms disposed in a first plane,

each of the two arms having a near end and a far end,

a thumb grip at the near end of one end of the arms,

a grip for at least one finger at the near end of the other of said arms,

pivot means connecting the arms to enable spreading of the far ends of the two arms upon movement of the grip for at least one finger and the thumb grip towards each other,

a finger receptacle for another finger disposed on one of the arms to enable coaction between the thumb, the other finger, and the fingers in the grip for at least one finger to stabilize the implement during use of the implement including movement of the arms.

56. The apparatus claimed in claim 55 further comprising:

the finger receptacle for another finger comprising a well for the end of the index finger.

57. The apparatus claimed in claim 56 wherein the well for the index finger is disposed in the arms between the near end of the arm and the pivot means.

58. The apparatus claimed in claim 57 wherein the thumb grip and the grip for at least one finger are displaced from the finger receptacle when the far ends of the arms are disposed in the closed position.

59. The apparatus claimed in claim 58 wherein the finger grip and the thumb grip are in spaced relation when the far ends of the arms are closed to enhance ergonomic comfort of the hand during use of the hand implement.

60. The apparatus claimed in claim 56 further comprising the thumb grip at the near end of the arms and the grip for at least one finger at the near end of the other set of arms being positioned to allow so that at least one of said two arms is bent to enable a clear view of the pivot means from the line bisecting the angle formed by the near end of the arms.

61. Apparatus for performing percutaneous entry to a blood vessel comprising:

a dissector comprising;

two arms,

a pair of dissecting fingers,

pivot means connecting the arms to enable spreading of the dissecting fingers,

the tapered passages on the dissecting fingers coacting to form a cylindrical passage upon spreading of the dissecting fingers,

a conduit comprising:

a cylindrical tube having a distal and a proximal end,

the diameter of the outer wall of the conduit adapted to coact with the cylindrical passage formed by the tapered passages of the dissecting fingers to allow sliding movement of the conduit in the cylindrical passage formed by the dissecting fingers,

an obturator comprising;

an elongated mid-section,

an end section formed on at least one of the ends of the mid-section,

the obturator end section adapted to fit within the conduit in frictional sliding relation to the inner wall of the conduit,

an end surface formed at the end of each obturator end section;

a sponge adapted to fit within the conduit, and

a sponge pusher, the sponge pusher extending longer than the length of the conduit and sized to fit within the conduit.

62. The apparatus claimed in claim 61 further comprising:

the sponge having a round or elliptical shape.

63. The apparatus claimed in claim 61 further comprising:

the sponge formed from a bioresorbable material.

64. The apparatus claimed in claim 61 further comprising:

the sponge being formed from a non-woven material.

65. The apparatus claimed in claim 61 further comprising:

the sponge having retrieval means for remotely removing the sponge from the site of application.

66. The apparatus claimed in claim 61 further comprising the retrieval means comprising a suture connected to the sponge and extending beyond the length of the conduit.

67. A method for performing percutaneous entry to a blood system comprising:

making an incision in the skin,

inserting a dissecting tool in the skin incision,

dissecting tissue by spreading of the dissecting fingers of the dissecting tool until ascertaining the presence of the vessel to be punctured,

inserting a conduit and obturator to lie n top of the vessel and capture said vessel through a cylindrical passage formed between the fingers,

separating the obturator from the conduit,

inserting a needle into the conduit to contact the vessel,

puncturing the vessel with the needle,

removing the needle from the punctured vessel,

placing a sponge in the conduit, and

applying pressure on the sponge through the conduit to restrict bleeding until hemostasis is achieved.

68. The method claimed in claim 67 further comprising the steps of:

moving the sponge to the site of the puncture by means of a sponge pusher.

69. The method claimed in claim 67 further comprising the steps of:

retrieving the sponge from the puncture site by means of sponge retrieval means extending through the conduit.

70. The method claimed in claim 67 wherein the step of moving the sponge to the site of the puncture and applying pressure to the sponge is performed by the obturator.

71. Apparatus for limiting bleeding from a percutaneous puncture of a blood vessel comprising:

a conduit comprising;

a cylindrical tube having a distal and a proximal end,

the distal end of the conduit formed at an angle to enable the end of the conduit to lie relatively horizontal while the conduit is at angle of the percutaneous entry;

a sponge, the sponge adapted to fit within the conduit;

a sponge pusher, the sponge pusher sized to fit within the walls of the cylindrical tube and having a length sized to extend from the conduit to enable the sponge pusher to push the sponge to the distal end of the

conduit against the site of a percutaneous entry in the vessel;

the sponge pusher being strong enough to apply pressure to the sponge to restrict bleeding from percuteneous puncture.

72. The apparatus claimed in claim 71 further comprising the distal end of the conduit having an eliptical form at the long axis of the elipse to lie parallel to a vessel to be punctured; and

the distal end formed with a curve perpendicular to the long axis of the lipse, to facilitate resting on a curve surface of a vessel.

73. The apparatus claimed in claim 71 further comprising:

the distal end of the conduit including a cut-out at the tip of the conduit for seeking the surface of a blood vessel and positioning the end of the conduit over the blood vessel.

74. The apparatus claimed in claim 71 further comprising:

indicia disposed on the proximal end of the conduit for visual and tactile determination of orientation of the conduit.

75. The apparatus claimed in claim 71 further comprising:

retrieval means connected to the sponge to remove the sponge through the conduit.

76. The apparatus claimed in claim 75 wherein the retrieval means connected to the sponge comprise a suture extending the length of the conduit and extending from the conduit.

77. The apparatus claimed in claim 75 wherein the sponge is made of a bioresorbable material.

78. The apparatus claimed in 77 wherein the sponge comprises:

a non-woven material.

79. The apparatus claimed in claim 75 wherein the sponge pusher comprises an obturator.

80. A method for limiting bleeding from a percutaneous puncture of a blood vessel comprising the steps of:

placing a conduit in the skin incision for the percuteaneous puncture;

positioning the distal end of the conduit over the site of the puncture in the blood vessel;

contacting the surface of the vessel around the site with the distal end of the conduit;

positioning a sponge inside the conduit at the distal end in contact with the vessel at the site of the puncture;

pressing the sponge against the site of the puncture to stop bleeding from the puncture site, and

maintaining pressure on the sponge within the conduit until hemostasis is accomplished.

81. The method claimed in claim 80 further comprising the steps of removing the spnge from the site of the puncture.

82. The method claimed in claim 81 wherein the step of removing the sponge comprises the step of removing the conduit containing the sponge from the site of the puncture.

83. The method claimed in claim 81 wherein the step of removing the sponge comprises the step of pulling a strand attached to the sponge and extending from the proximal end of the conduit.

84. The method claimed in claim 80 wherein the step of positioning the sponge inside the conduit at the distal end comprises the steps of pushing the sponge with a sponge pusher down to the distal end of the conduit.

85. The method clamed in claim 80 wherein the step of pressing the sponge against the site of the puncture comprises the step of pressing the sponge pusher against the sponge within the conduit and in contact with the site of the puncture on the blood vessels.

FIG. 1

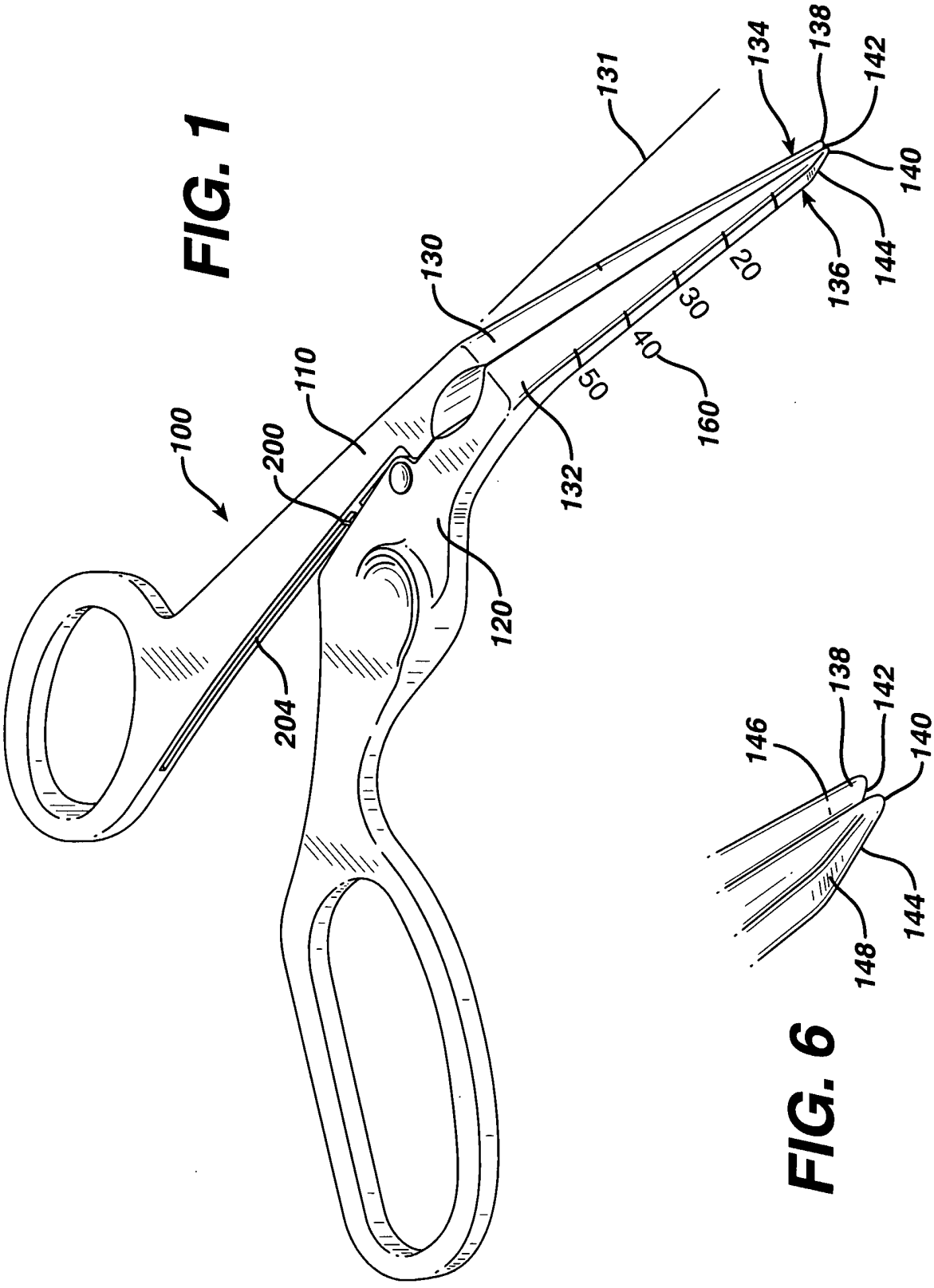
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FIG. 6

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FIG. 2

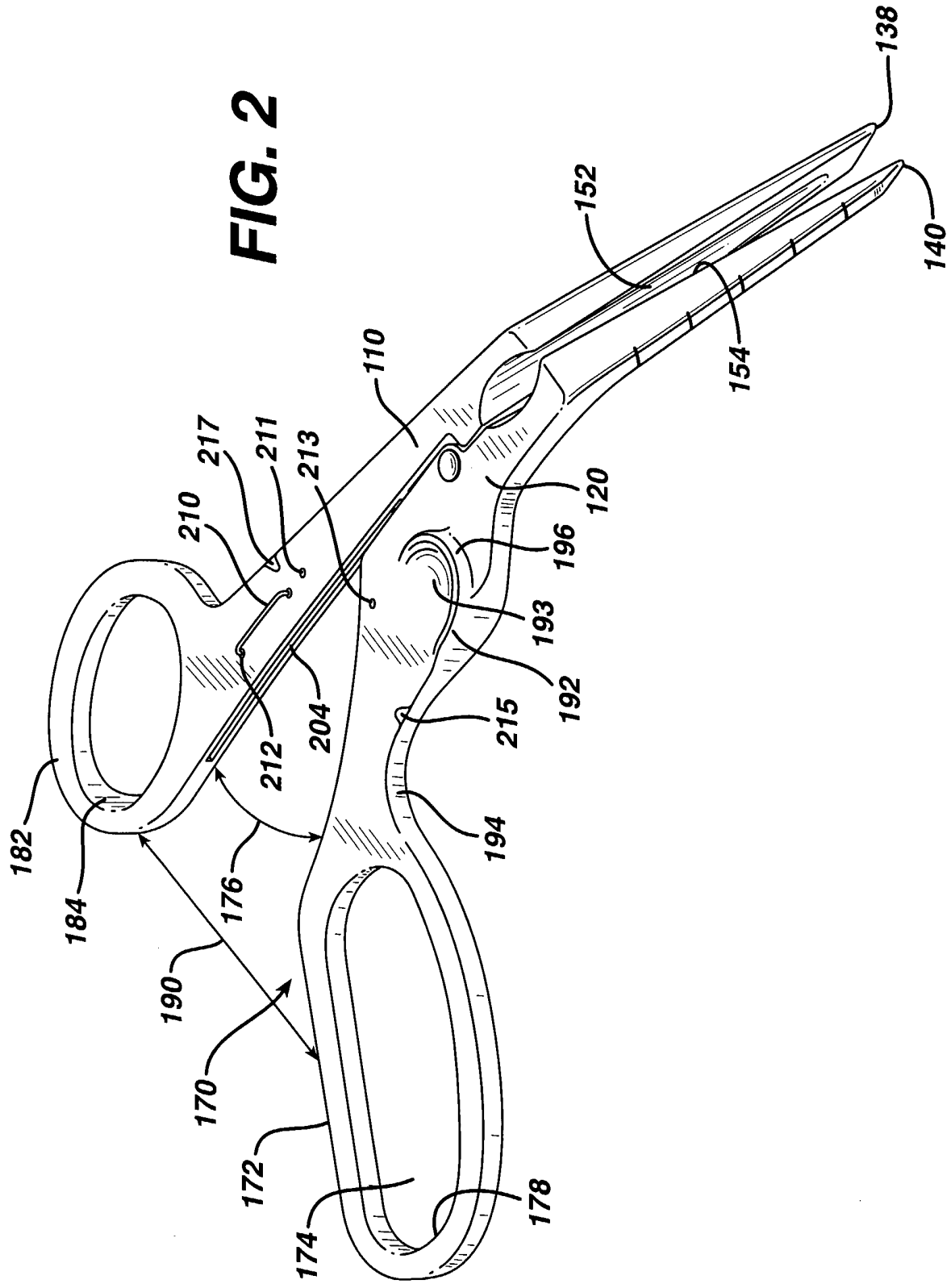
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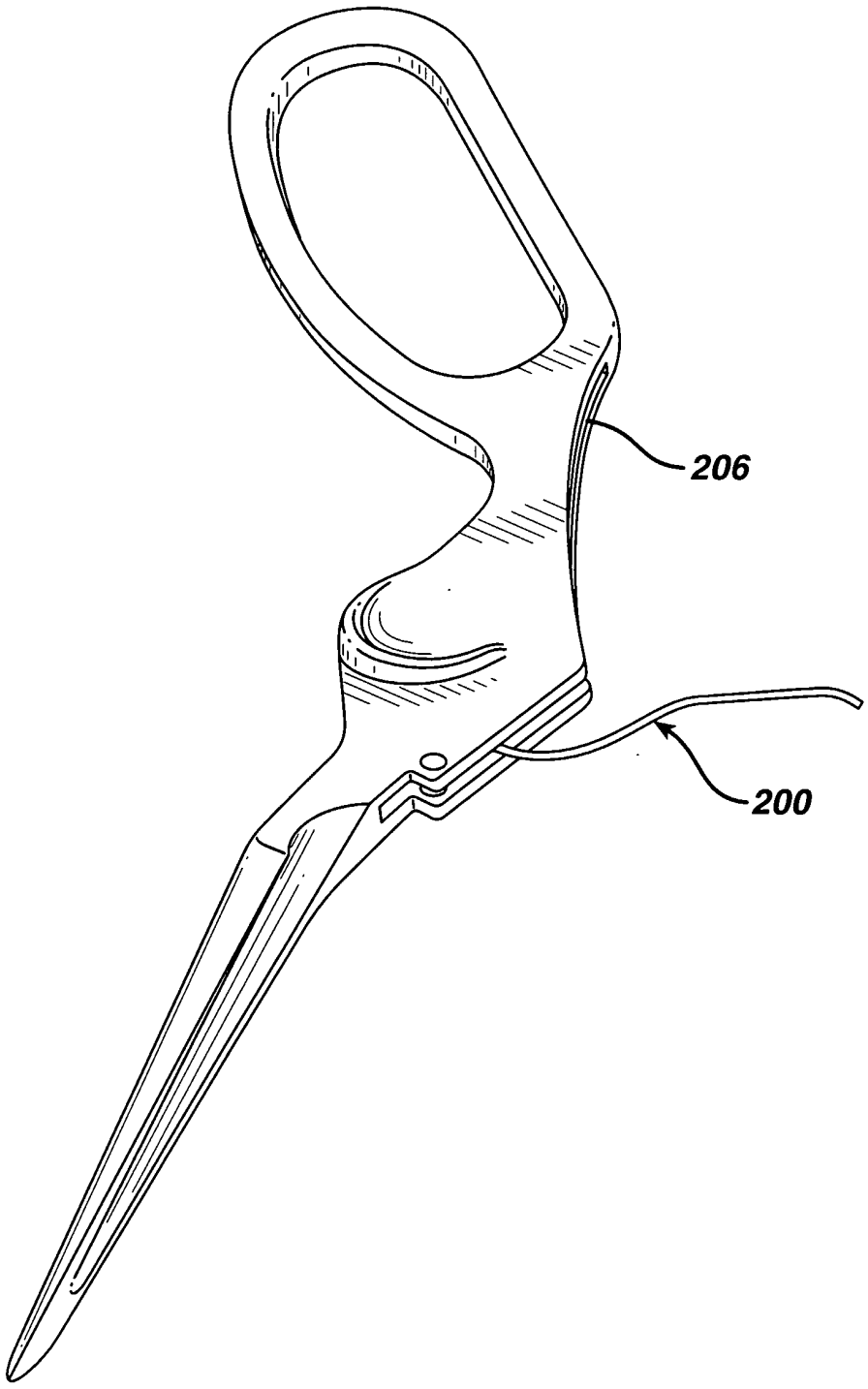
FIG. 3



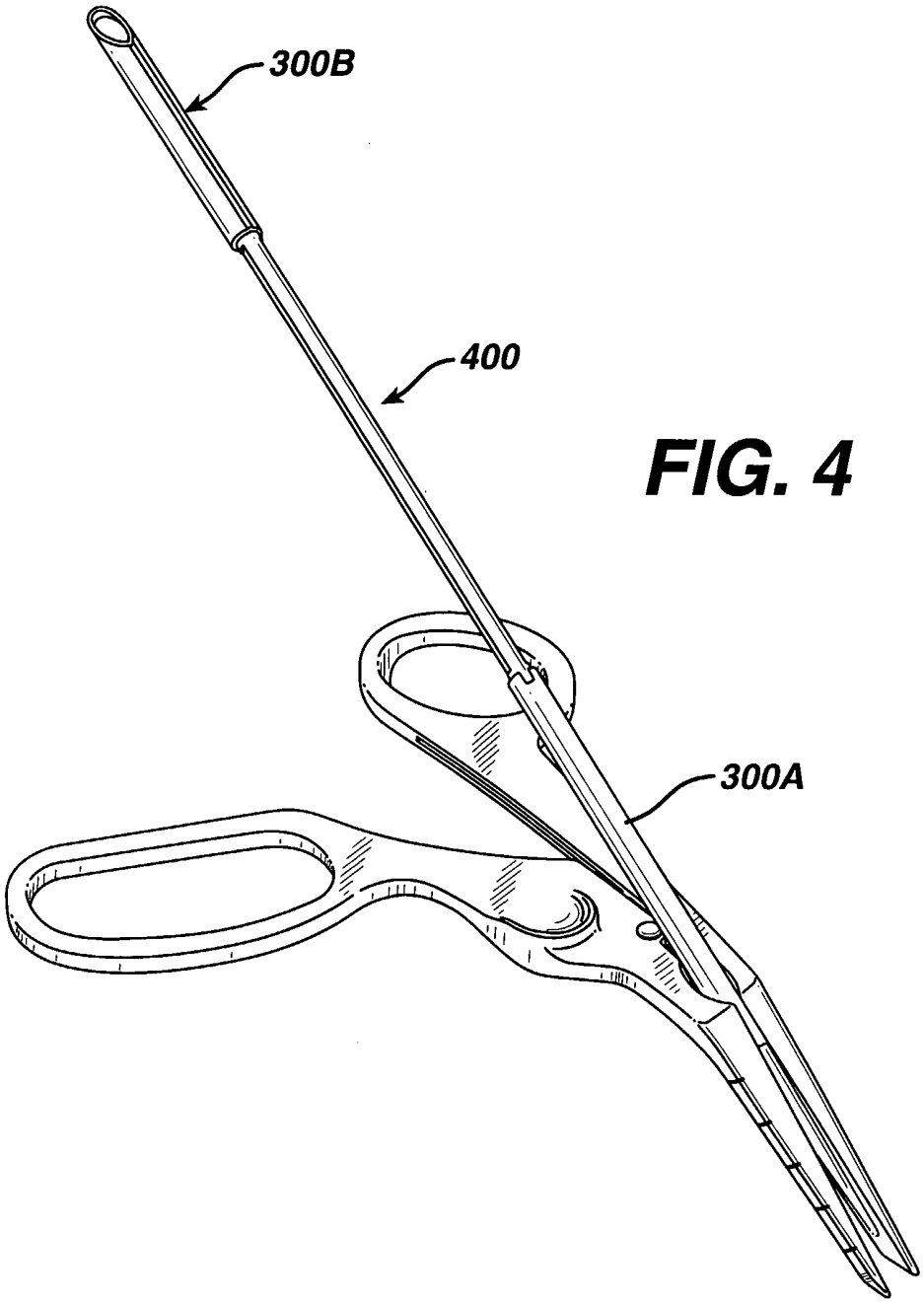


FIG. 4

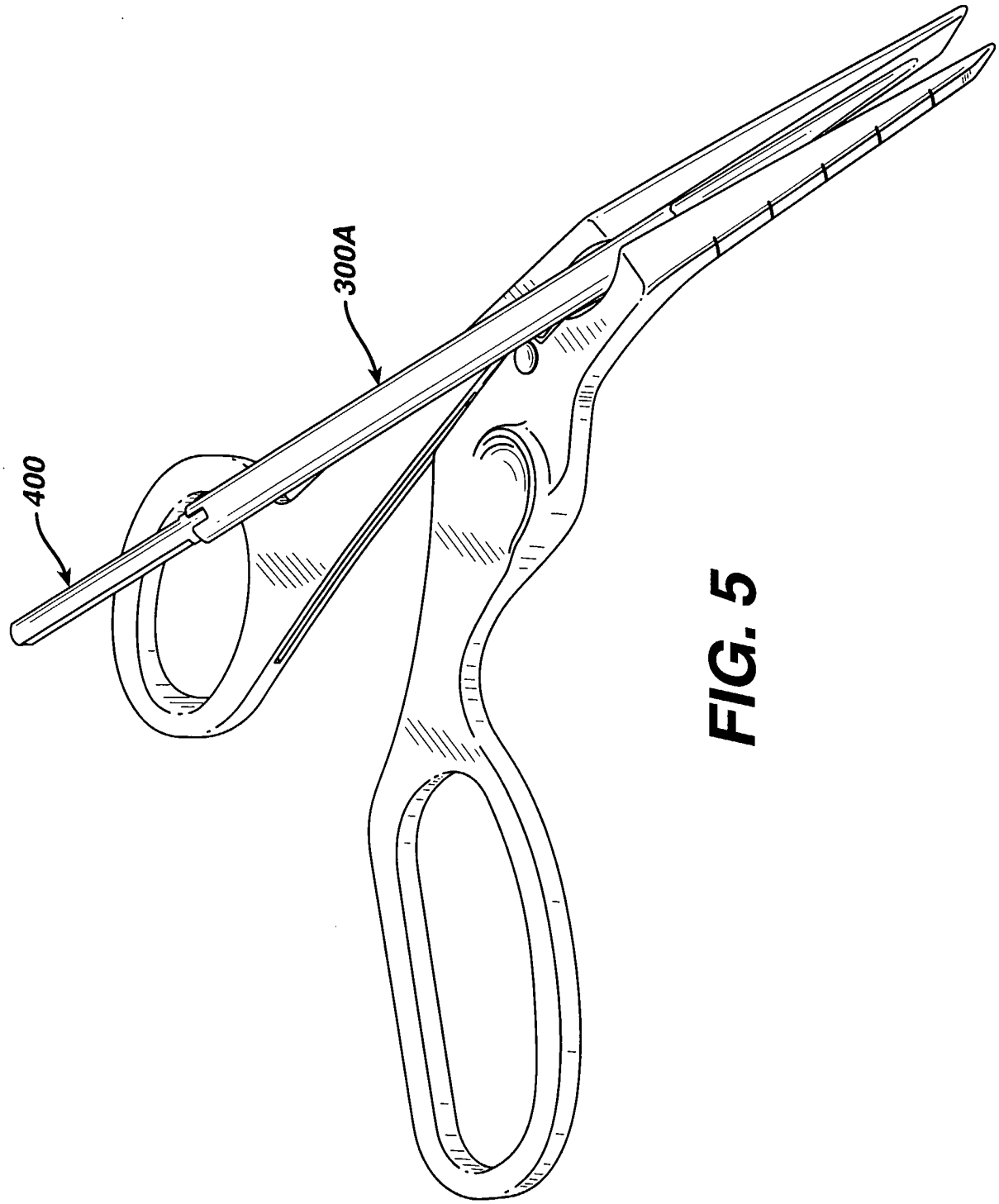


FIG. 5

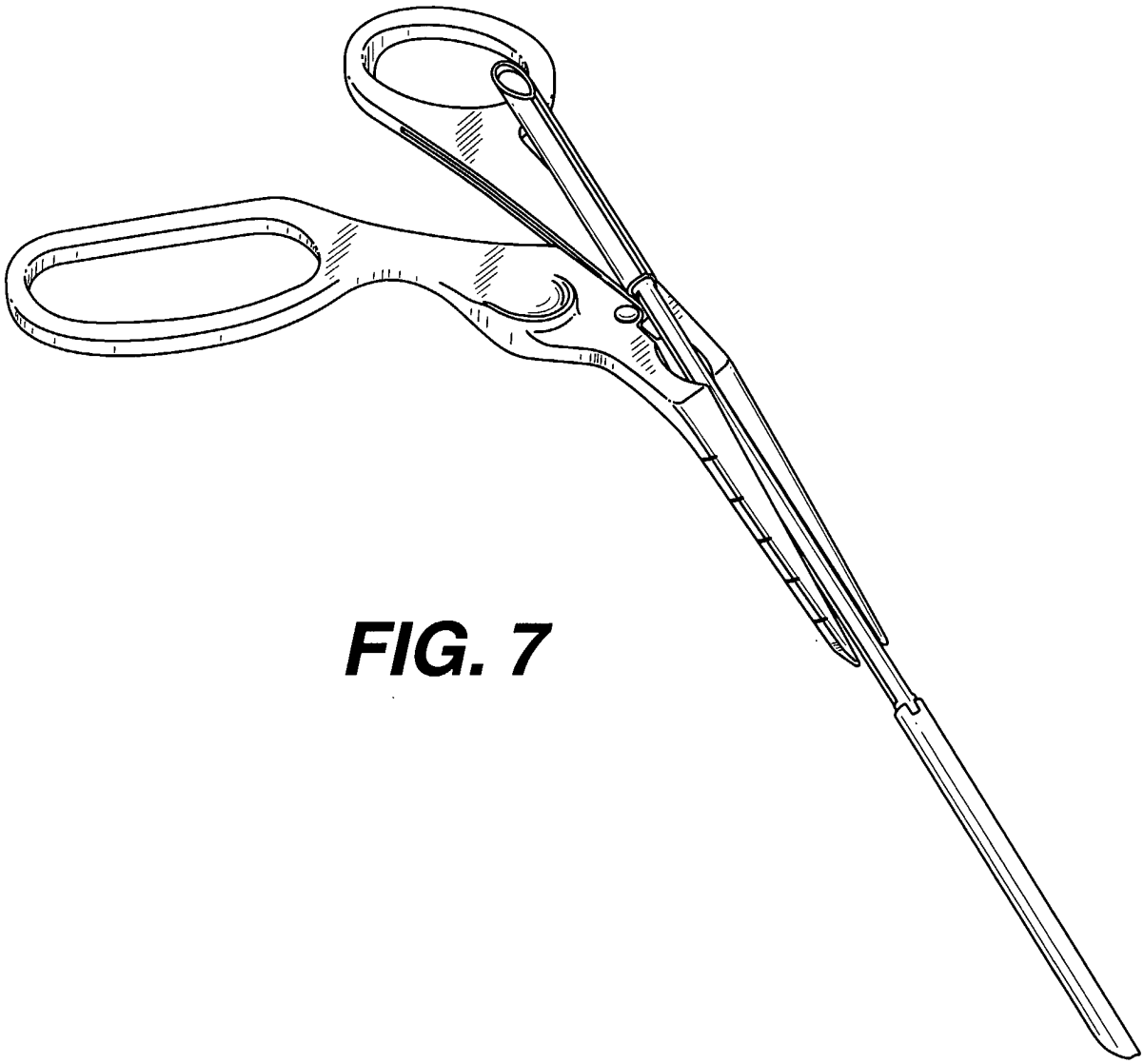


FIG. 7

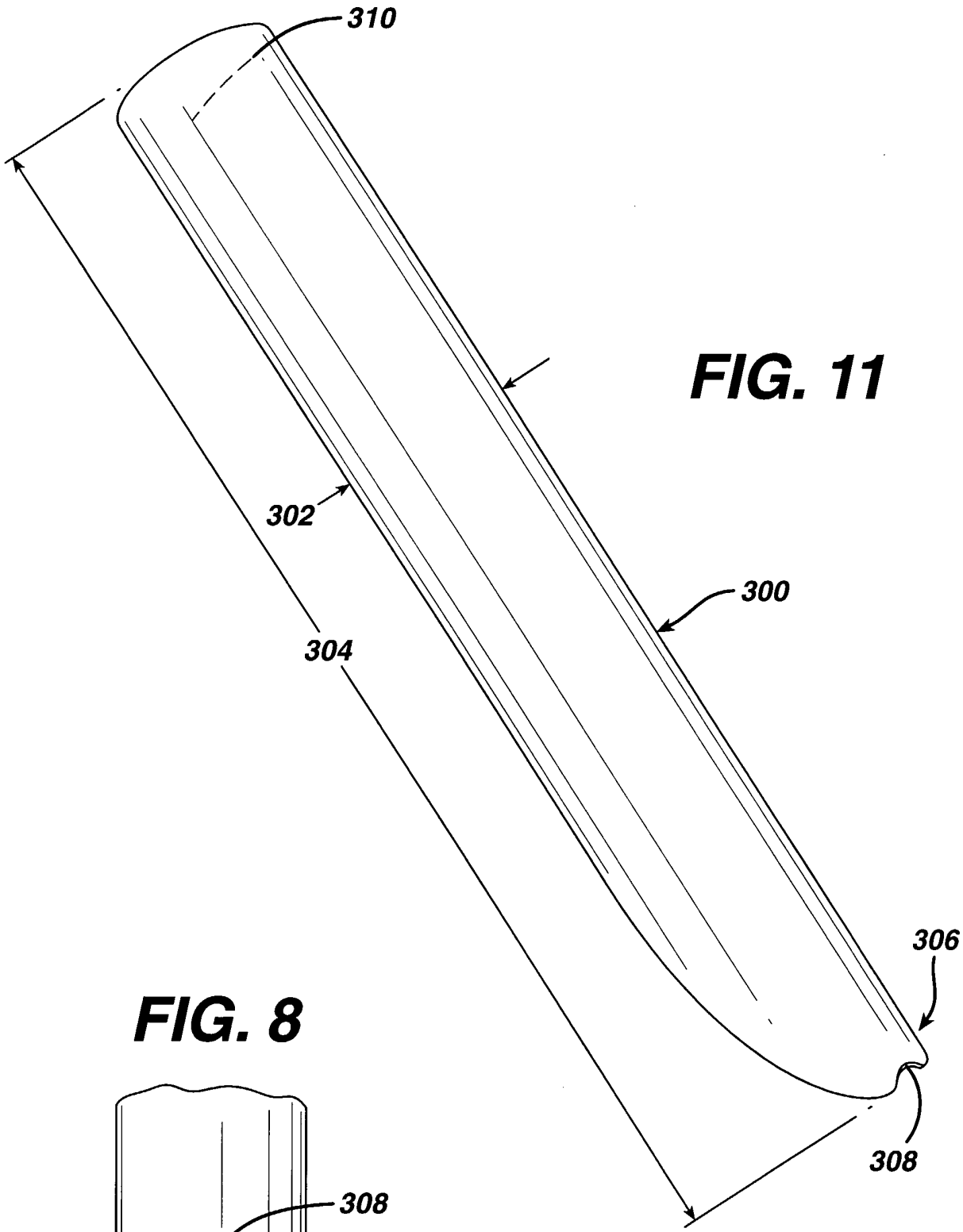


FIG. 11

FIG. 8

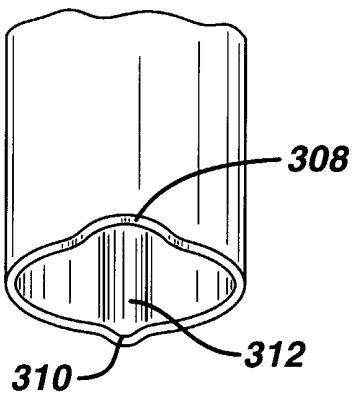


FIG. 13

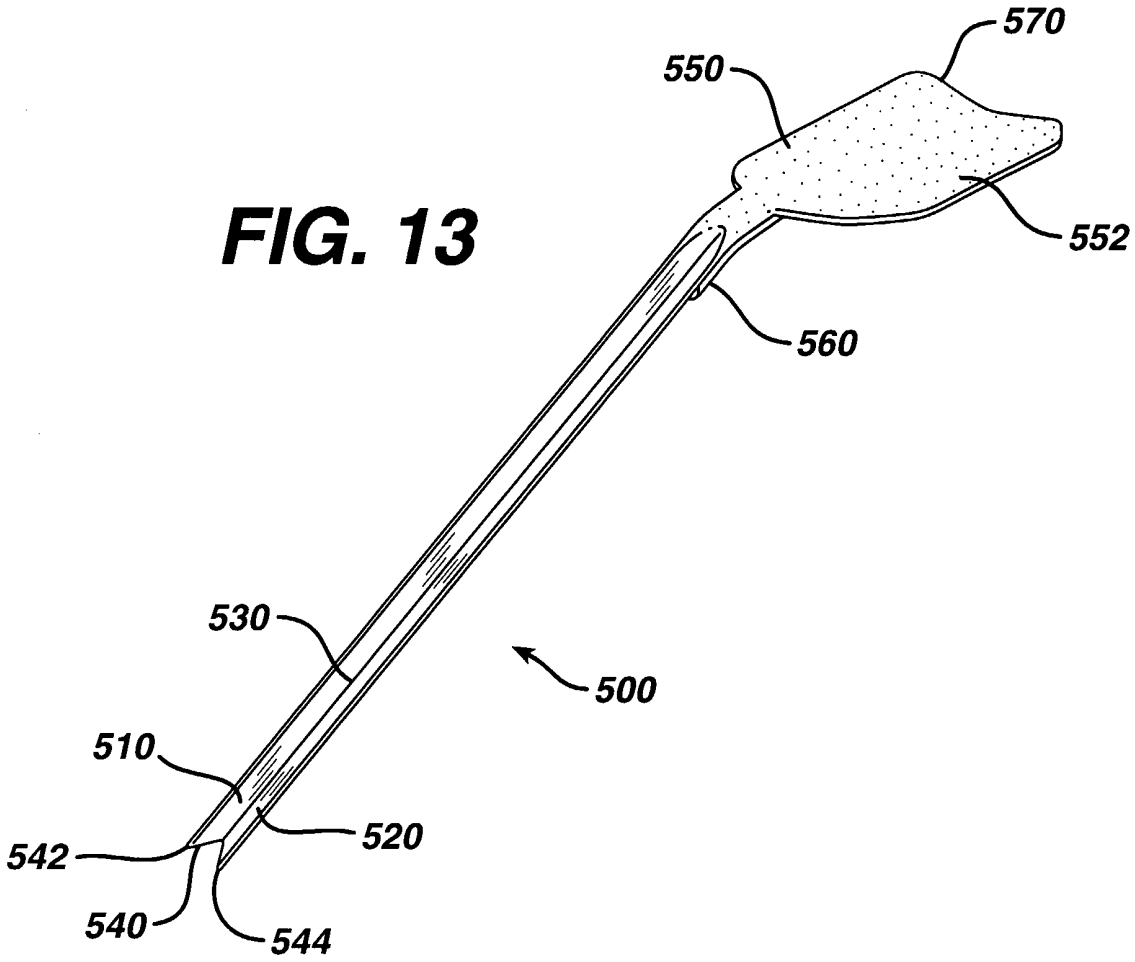
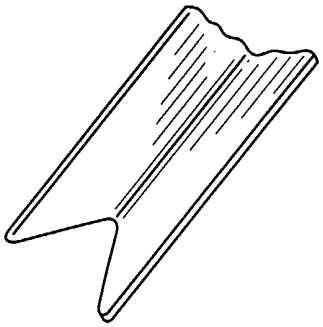


FIG. 9



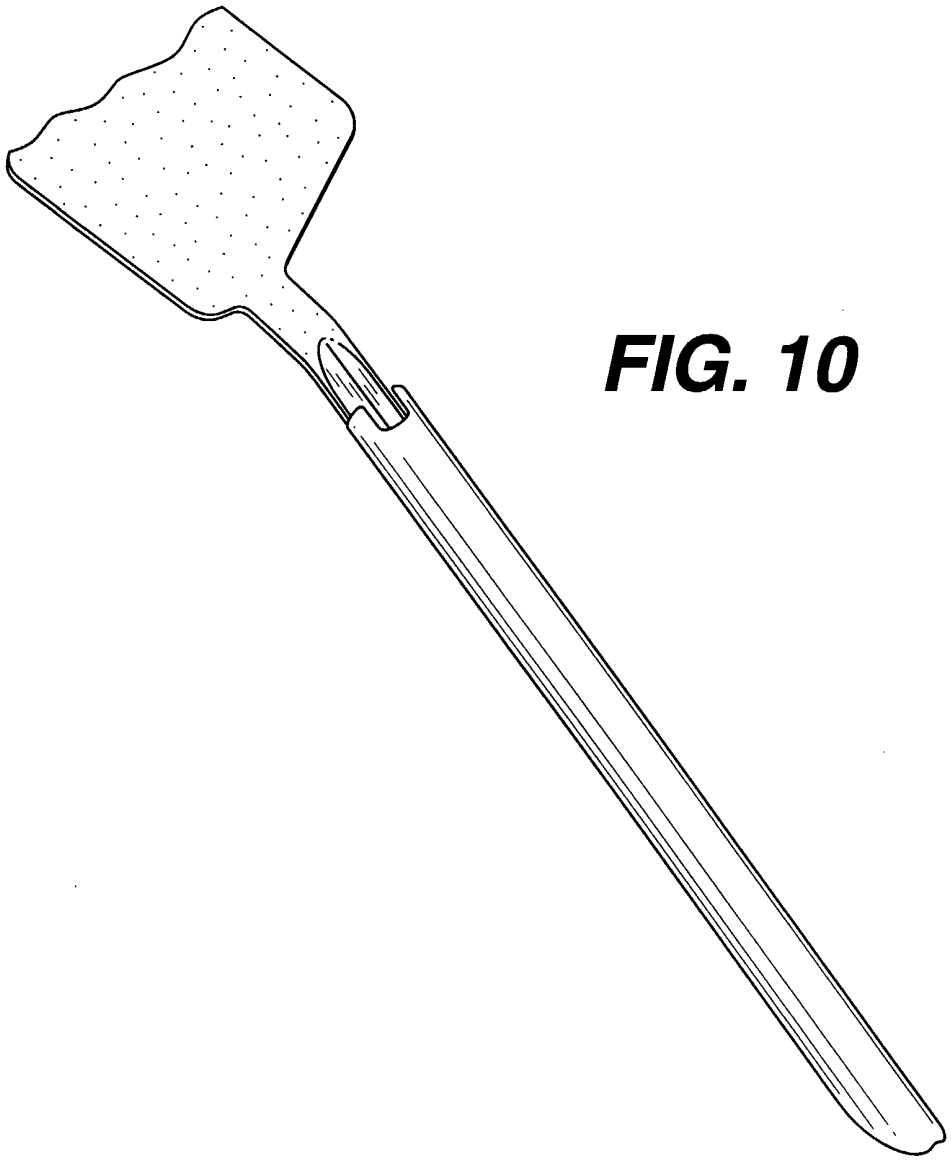


FIG. 10

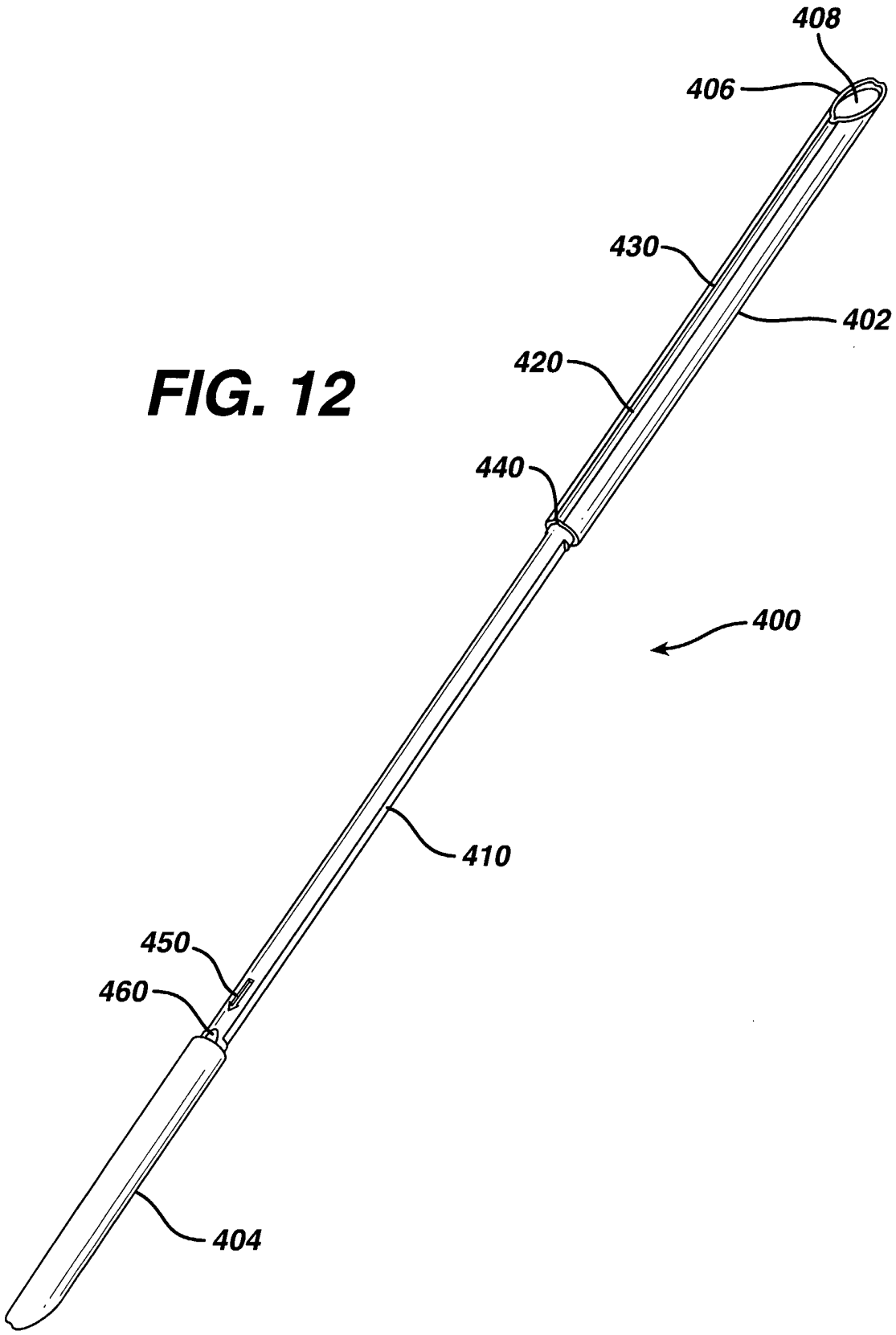


FIG. 12

FIG. 14

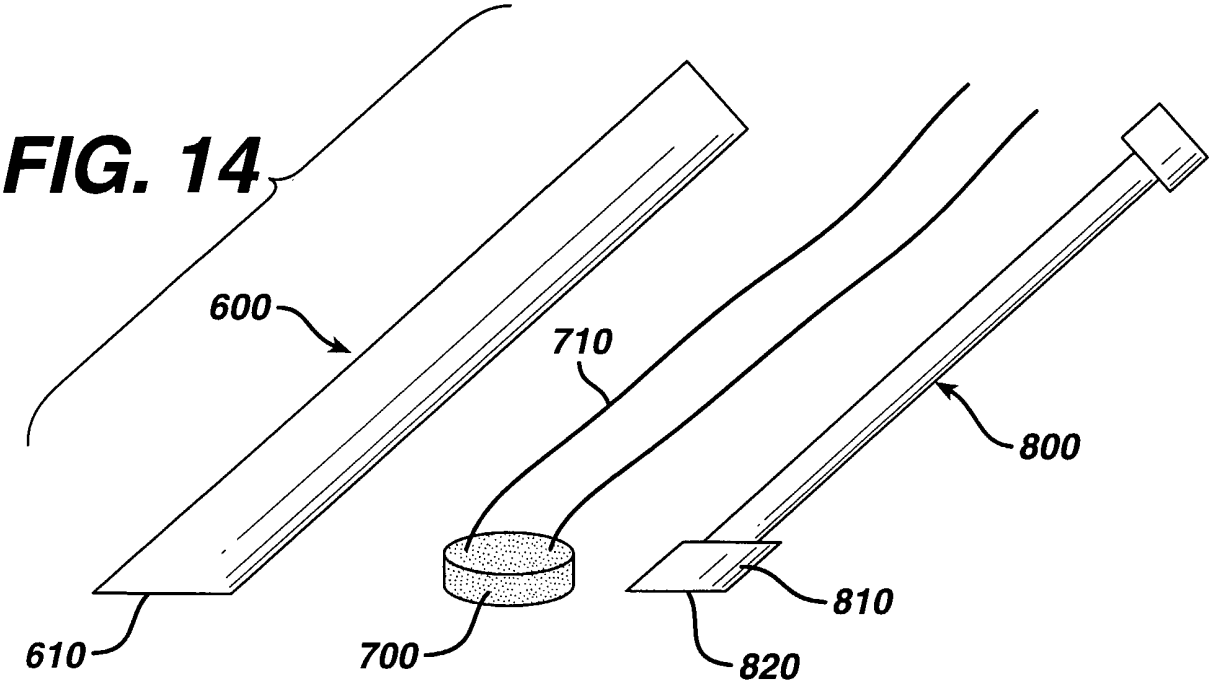


FIG. 15

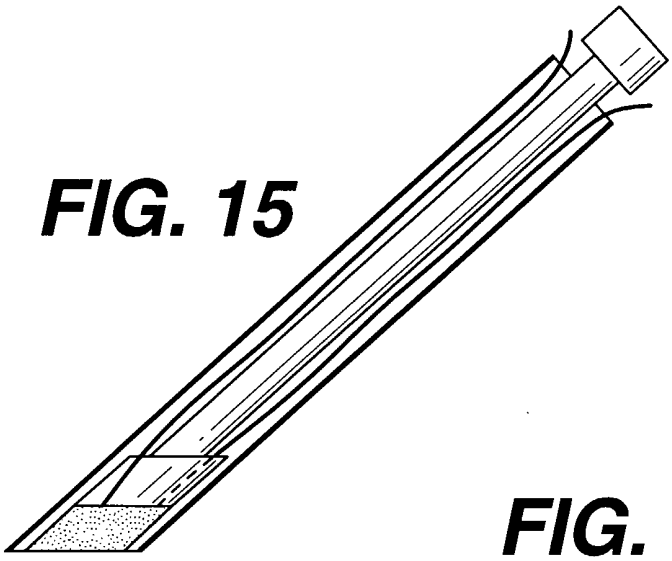


FIG. 17

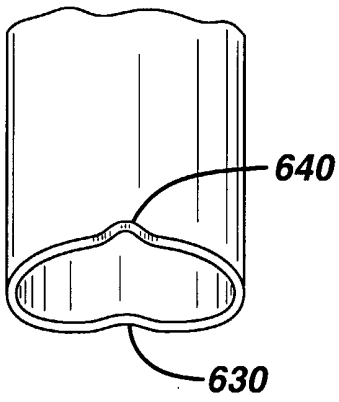


FIG. 16