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(19) **United States**(12) **Patent Application Publication** (10) **Pub. No.: US 2005/0251190 A1**
McFarlane (43) **Pub. Date: Nov. 10, 2005**(54) **PENETRATING TIP FOR TROCAR ASSEMBLY**(52) **U.S. Cl. 606/185**(76) **Inventor: Richard H. McFarlane, Singer Island, FL (US)**(57) **ABSTRACT**

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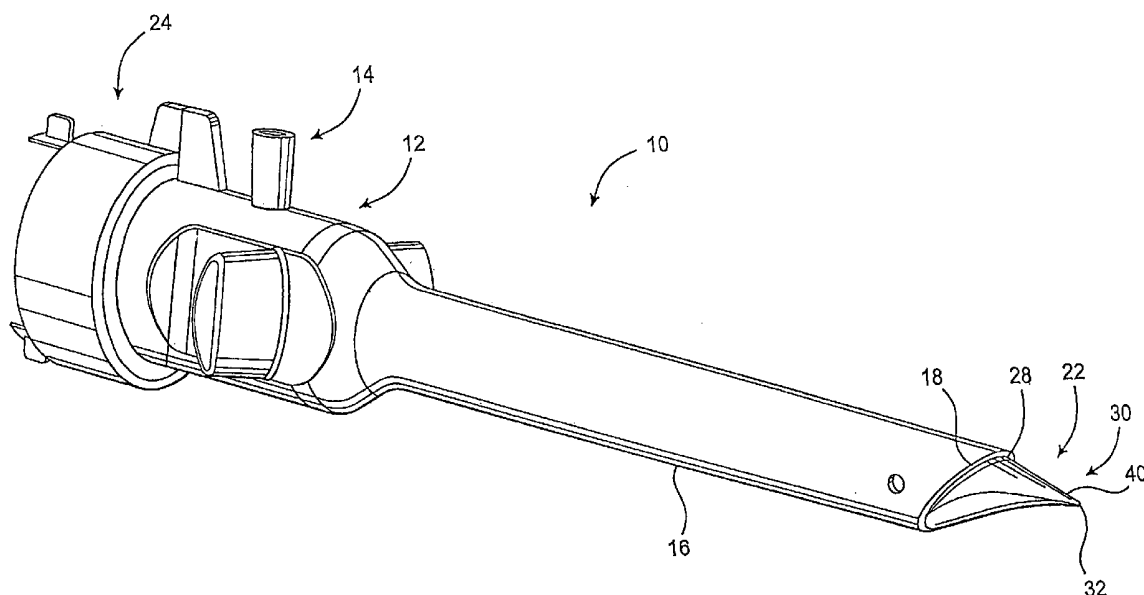
(21) **Appl. No.: 11/115,094**(22) **Filed: Apr. 26, 2005****Related U.S. Application Data**

(63) Continuation-in-part of application No. 10/120,895, filed on Apr. 11, 2002, now Pat. No. 6,884,253, which is a continuation-in-part of application No. 09/859,009, filed on May 16, 2001, now Pat. No. 6,478,806.

(60) Provisional application No. 60/204,396, filed on May 16, 2000.

Publication Classification(51) **Int. Cl.⁷ A61B 17/34**

A tissue penetrating instrument of the type used in the medical field and which may or may not be embodied in the form of an obturator associated with a trocar assembly, wherein the instrument includes an elongated shaft having a penetrating tip mounted on one end thereof. The penetrating tip includes a base secured to the one end of the shaft and a distal extremity spaced longitudinally outward from the base and formed into an apex which may be defined by a point or other configuration specifically structured to facilitate penetration or puncturing of bodily tissue. The apex may be substantially aligned with a linear extension of the central longitudinal axis of the shaft or alternatively, may be spaced laterally outward or off-set from the central longitudinal axis of the shaft. The penetrating tip further includes an exterior surface extending continuously between the apex and the base and configured to facilitate puncturing of the tissue and an enlargement of an access opening formed in the tissue, in a manner which facilitates separation of the tissue and minimizes cutting, severing or otherwise damaging the contiguous bodily tissue surrounding the access opening.



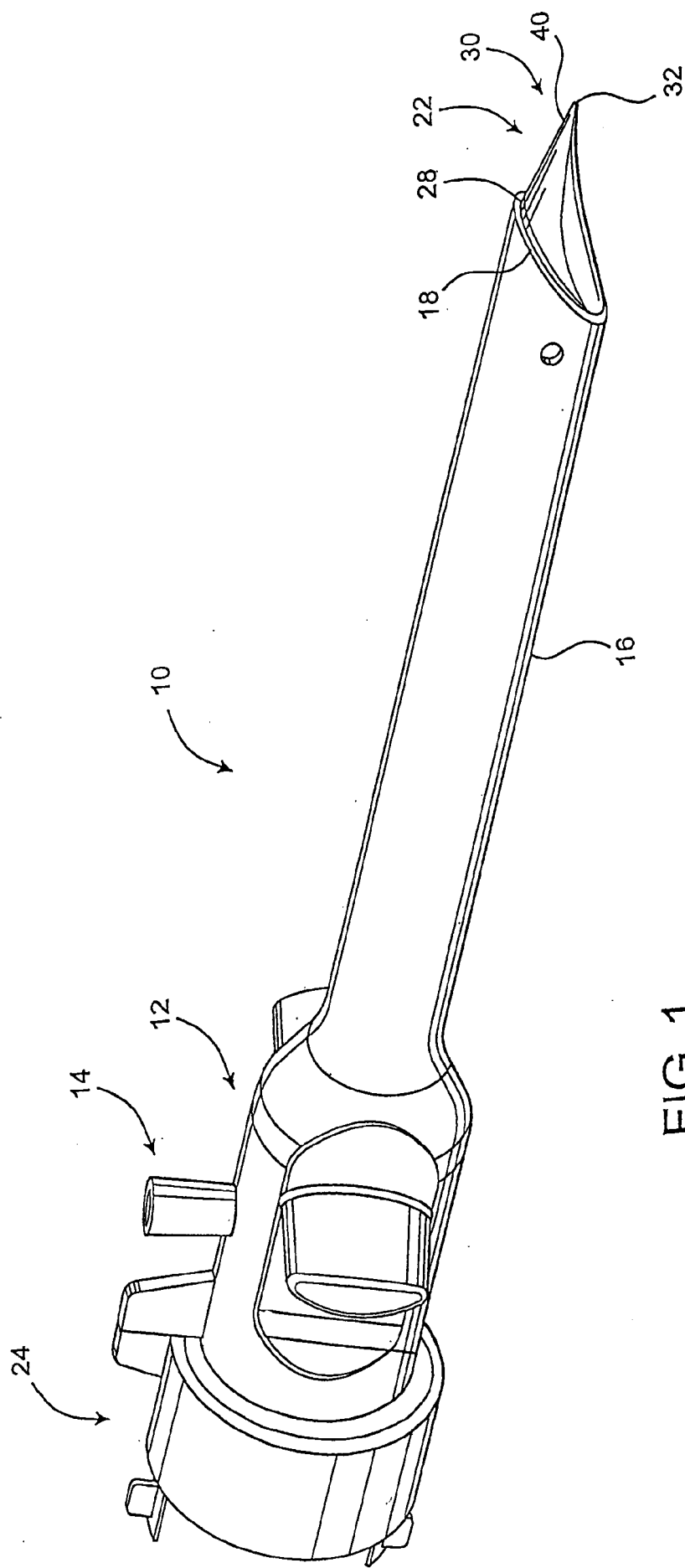


FIG. 1

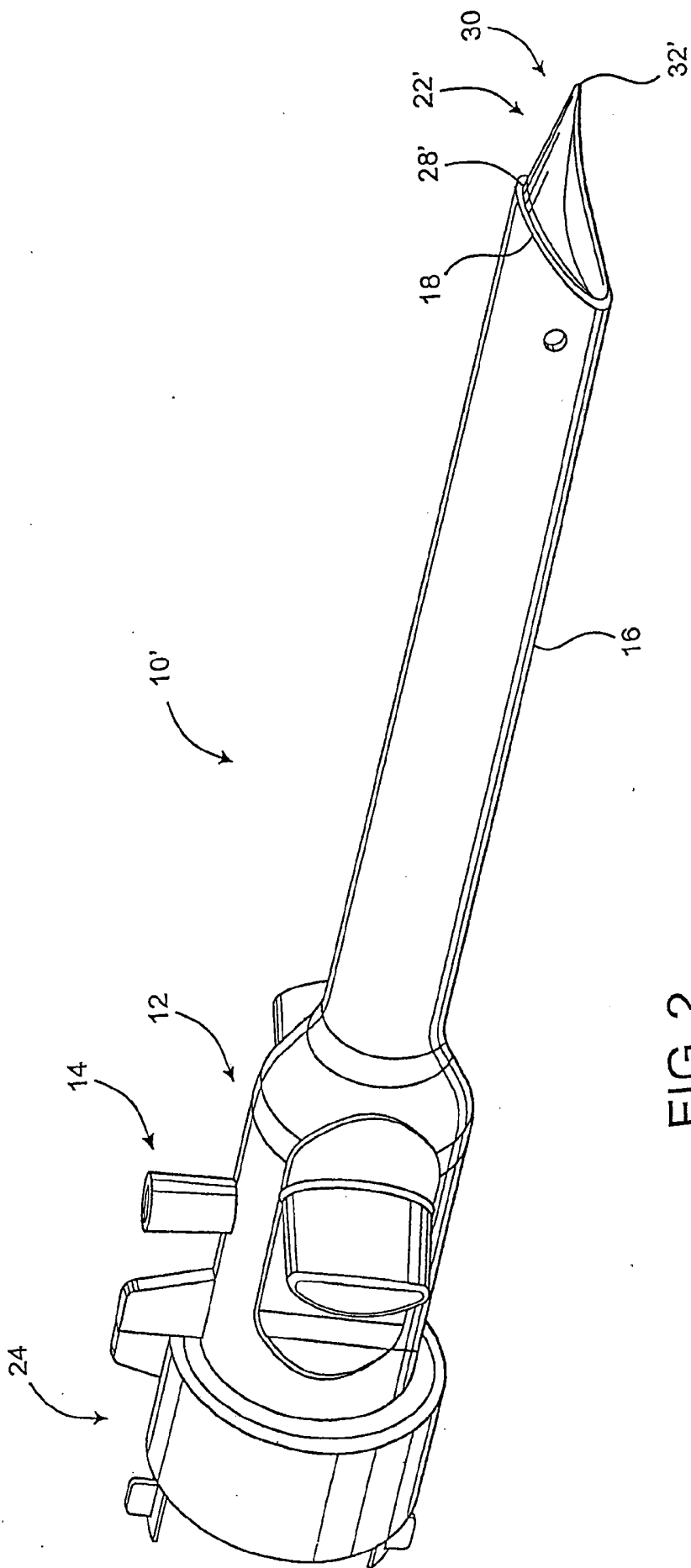
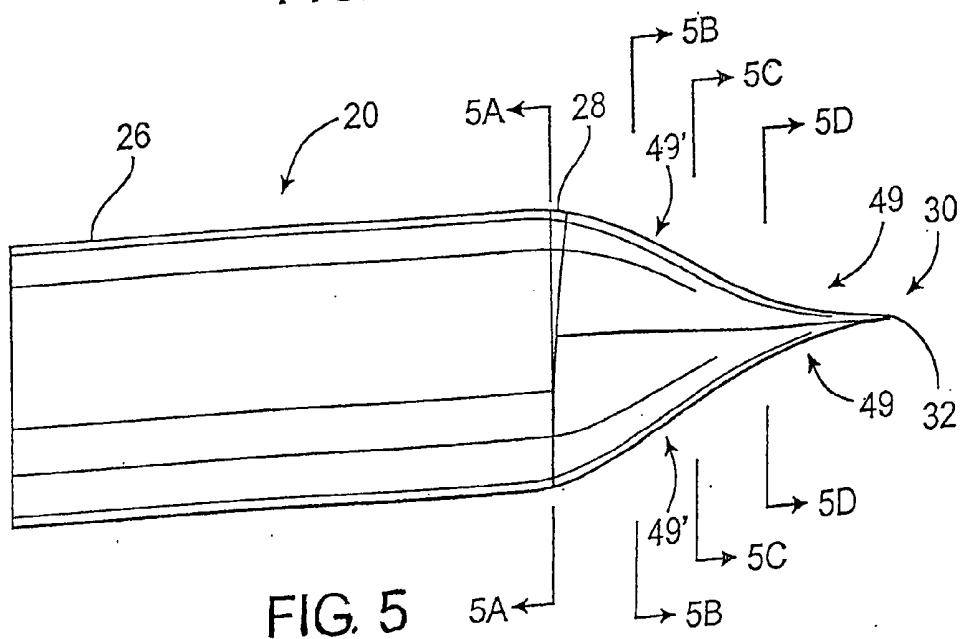
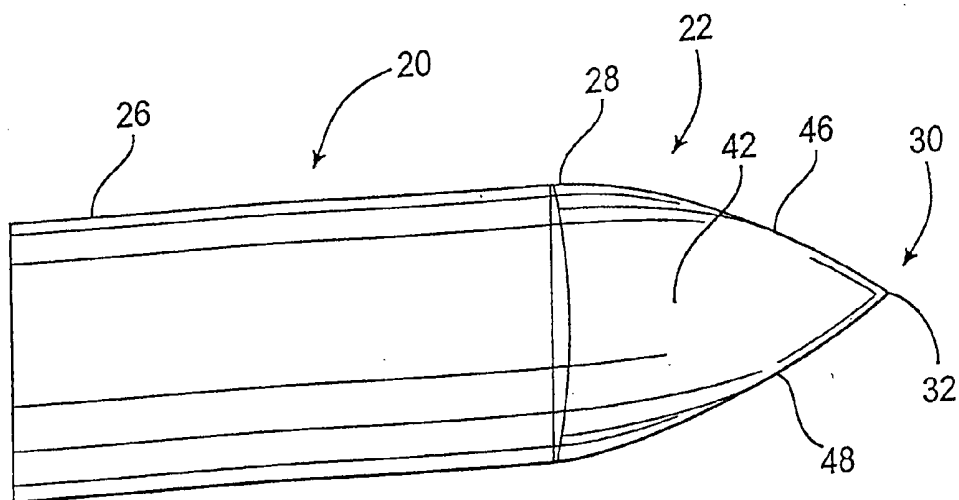
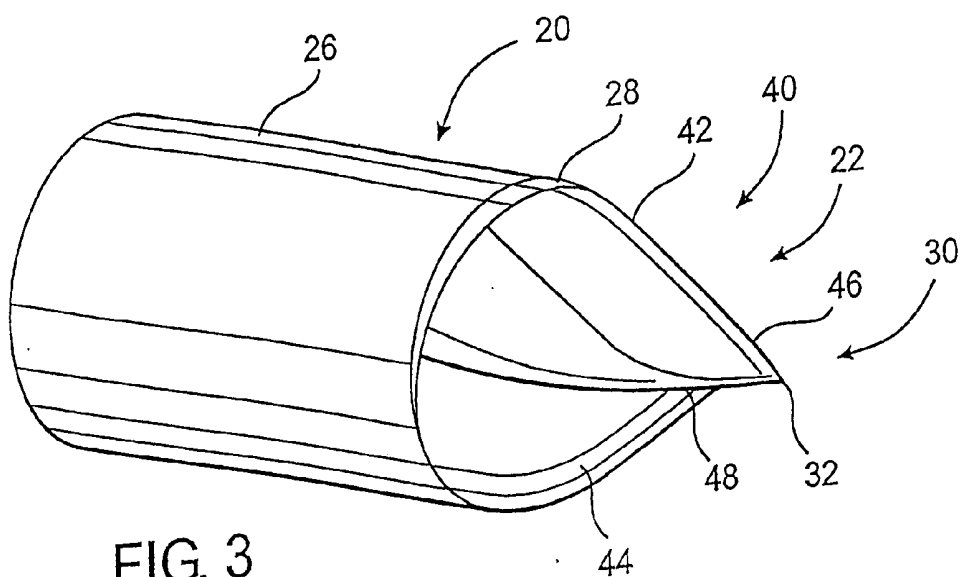


FIG. 2



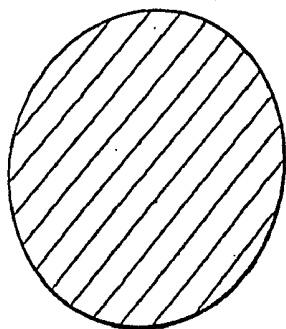


FIG. 5A

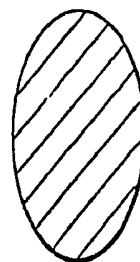


FIG. 8A

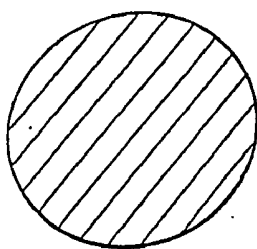


FIG. 5B

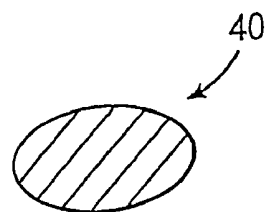


FIG. 8B

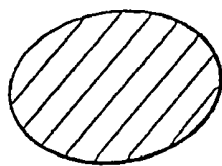


FIG. 5C

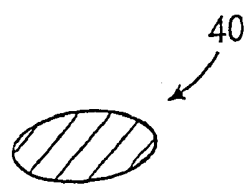


FIG. 8C



FIG. 5D

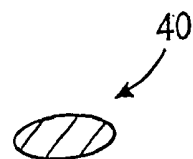


FIG. 8D

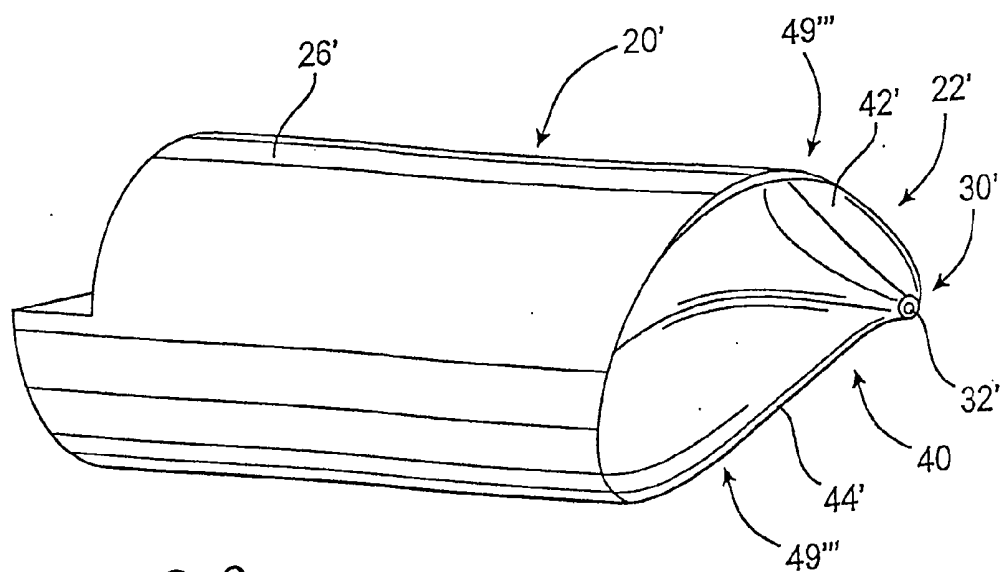


FIG. 6

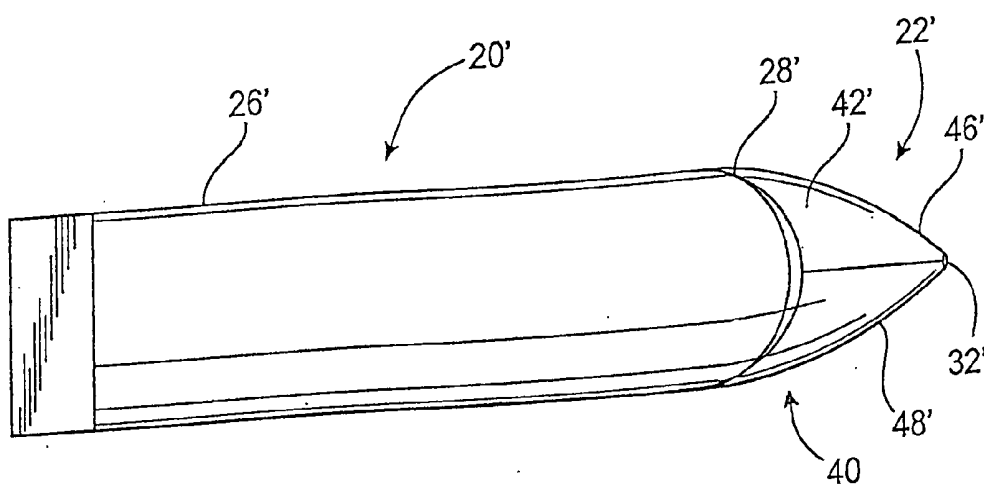


FIG. 7

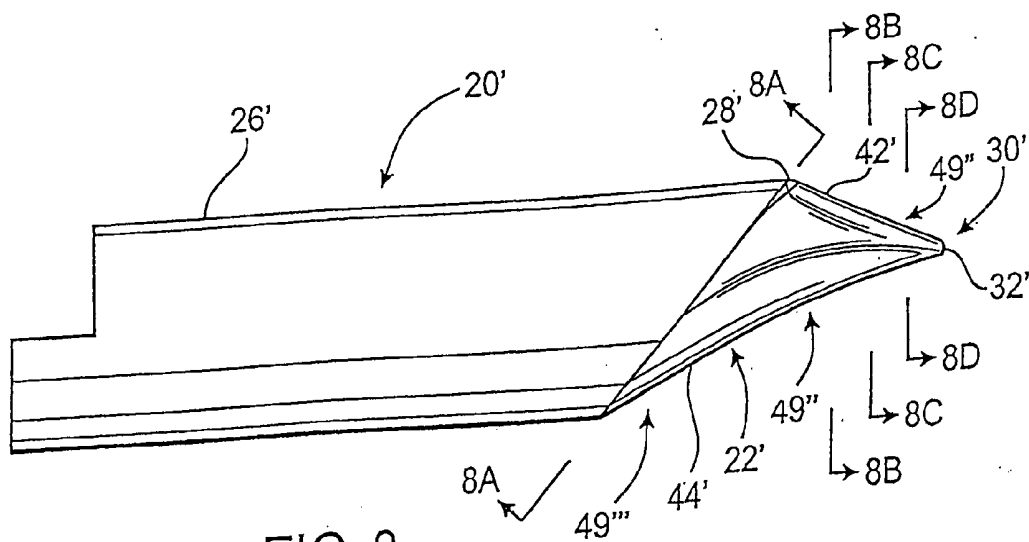
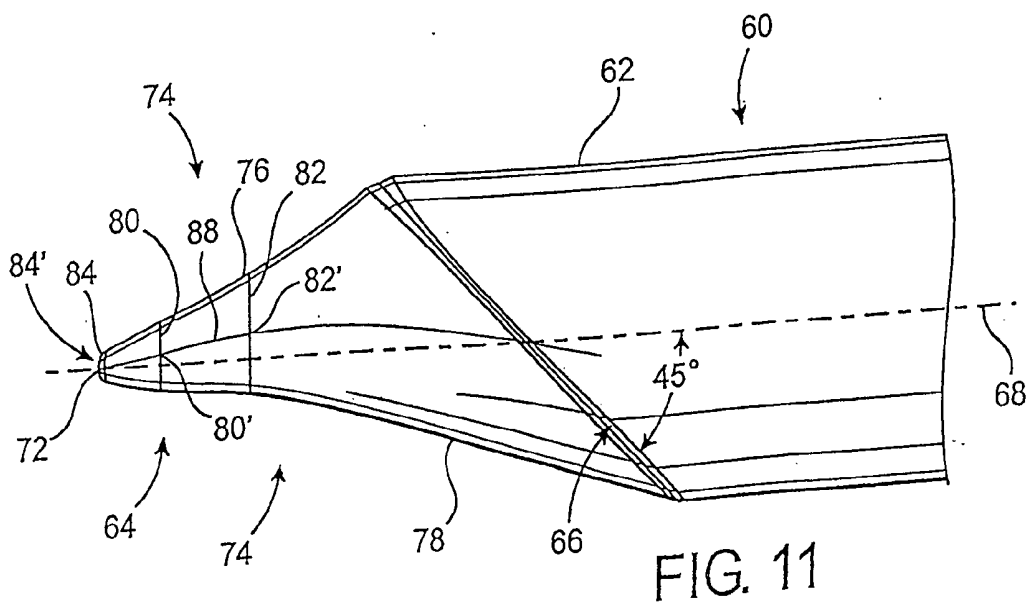
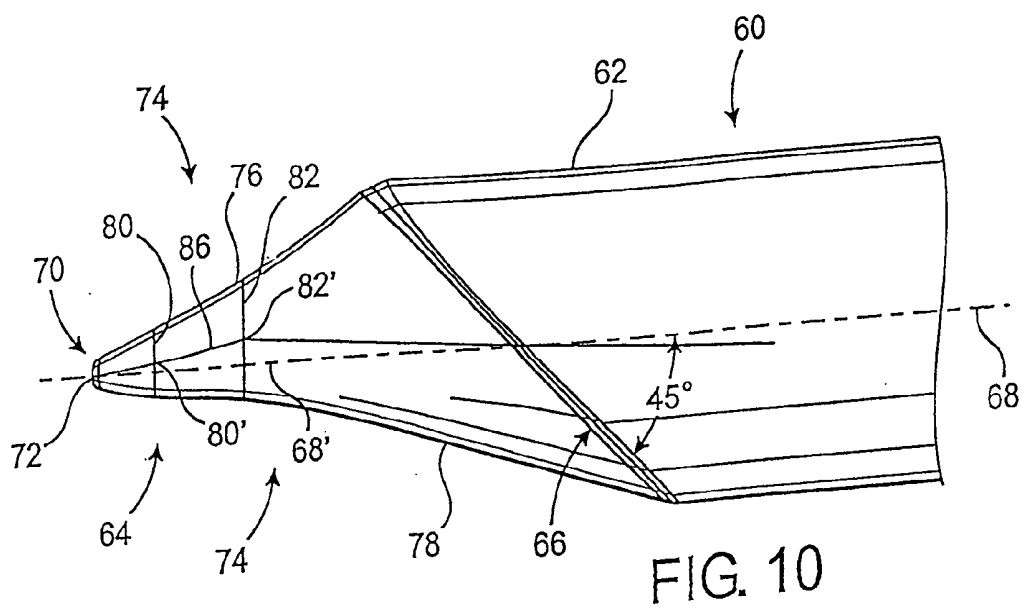
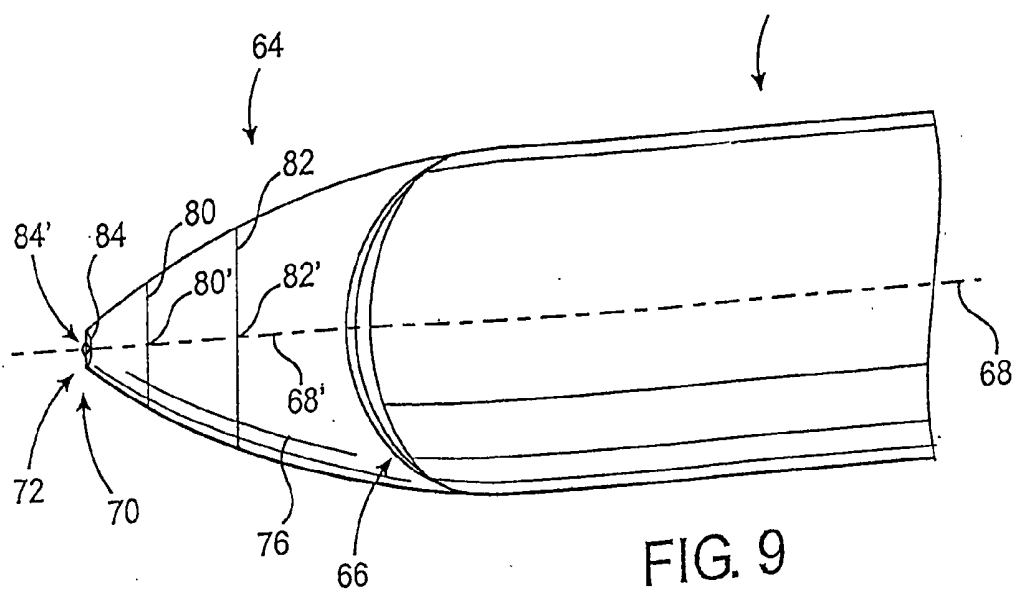


FIG. 8



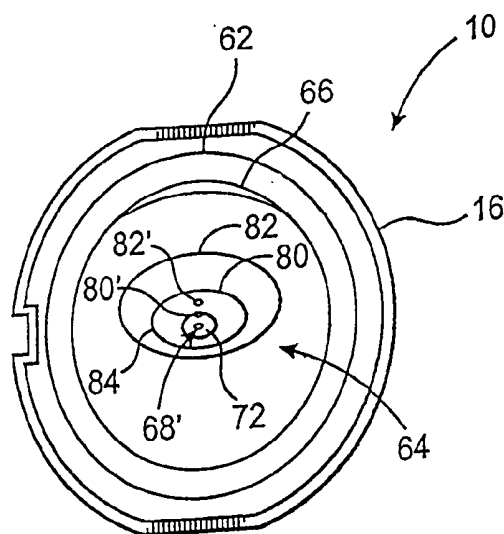


FIG. 12

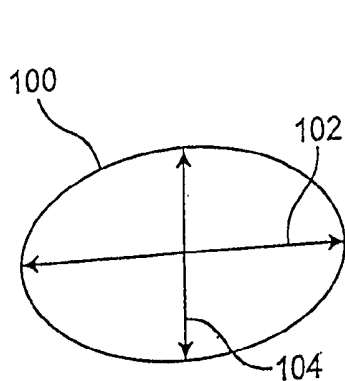


FIG. 13

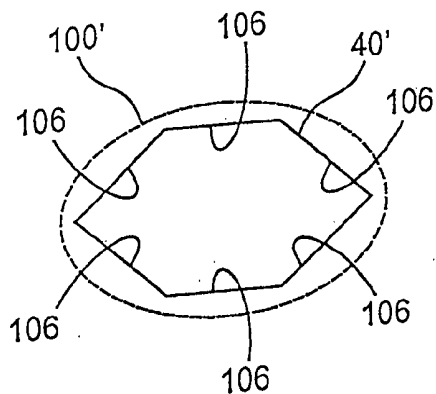


FIG. 13A

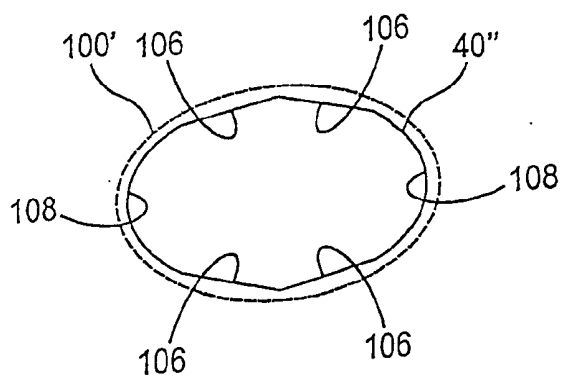


FIG. 13B

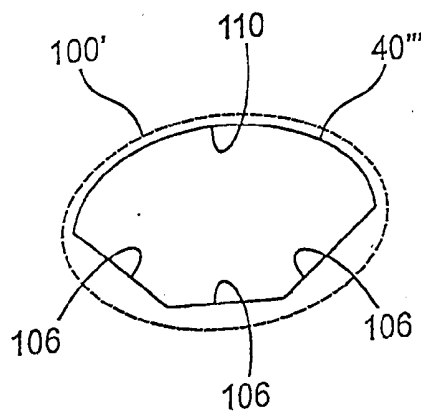


FIG. 13C

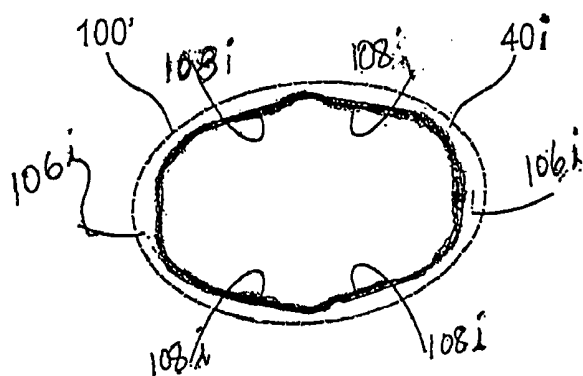


FIG. 13D

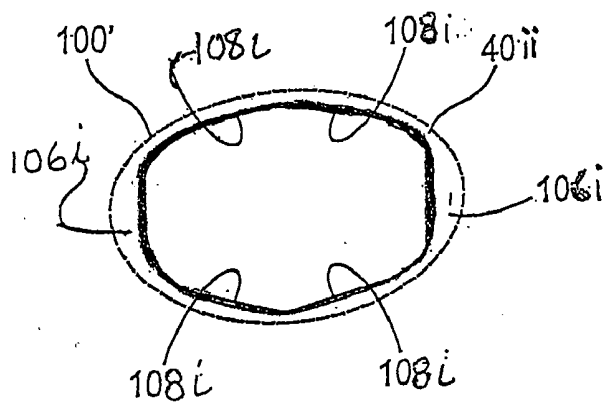


FIG. 13E

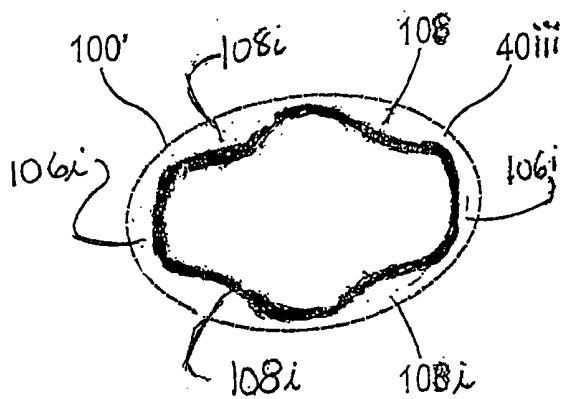


FIG. 13F

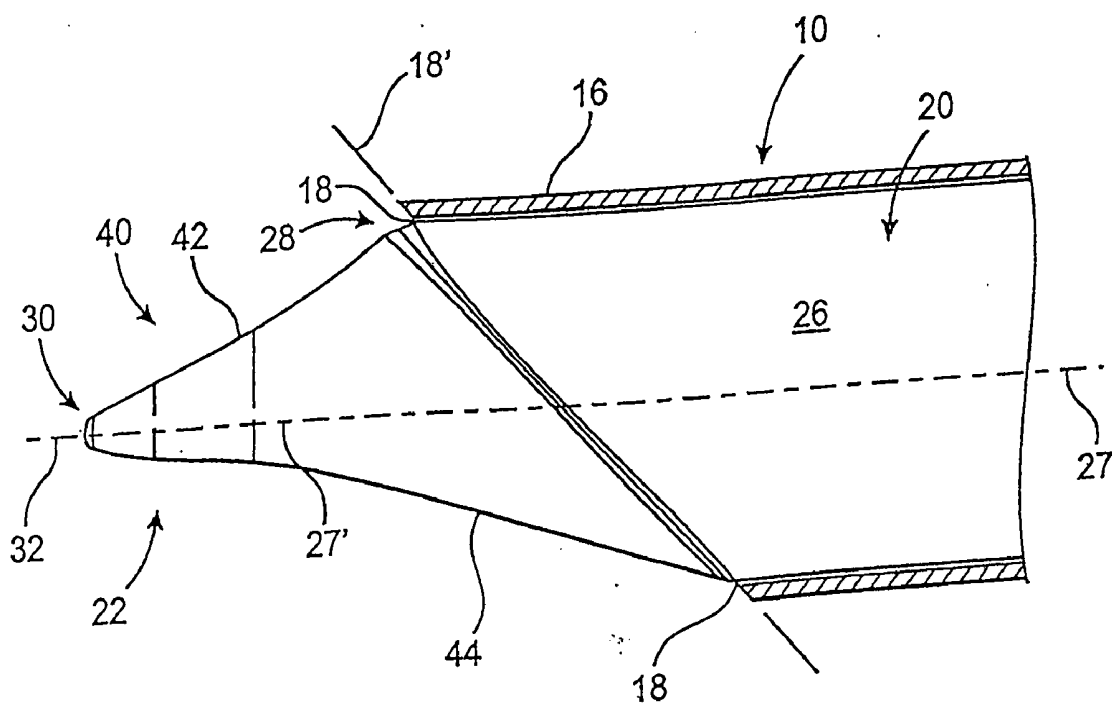


FIG. 14

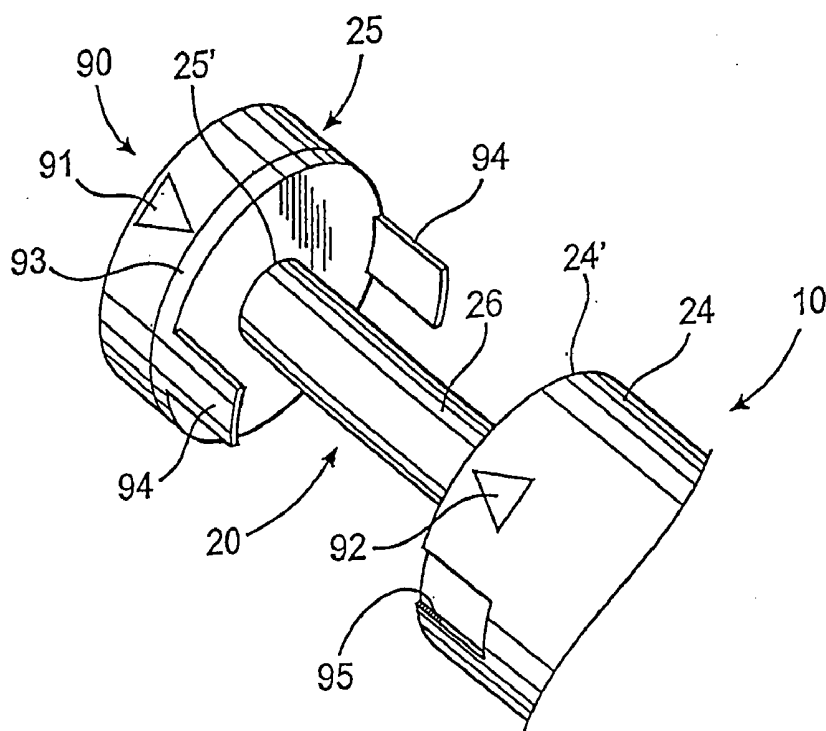


FIG. 15

PENETRATING TIP FOR TROCAR ASSEMBLY**CLAIM OF PRIORITY**

[0001] The present application is a Continuation-In-Part application of previously filed, now pending application having Ser. No. 10/120,895, which was filed on Apr. 11, 2002 and which is set to issue as U.S. Pat. No. 6,884,253 on Apr. 26, 2005, which itself was filed as a Continuation-In-Part application of a previously filed, then pending application, namely, Ser. No. 09/859,009 filed on May 16, 2001, which matured into U.S. Pat. No. 6,478,806, and which in turn, was based on and a claim to priority made under 35 U.S.C. Section 119(e) to an earlier filed, U.S. provisional patent application having Ser. No. 60/204,396 and a filing date of May 16, 2000, all of which are incorporated herein in their entirety by reference.

BACKGROUND OF THE INVENTION**[0002] 1. Field of the Invention**

[0003] The present invention is directed towards a medical instrument of the type structured for use in laparoscopic and/or endoscopic surgery such as, but not limited to, a trocar assembly which includes an elongated shaft having a penetrating tip formed on one end thereof. The penetrating tip includes an exterior surface configuration structured to facilitate the forming of an access opening in bodily tissue in a manner which requires a minimum application of an inwardly directed, linear pushing force on the instrument, but rather, which is more responsive to a back and forth or "reciprocal" twisting motion. The configuration of the penetrating tip is at least partially characterized by a perpendicular cross-section of the exterior surface having a substantially elliptical configuration along at least a majority of the tip.

[0004] 2. Description of the Related Art

[0005] In the medical field there are numerous instruments specifically designed to penetrate bodily tissue so as to provide access to internal body cavities or organs. More specifically, a preliminary procedure during the performance of surgery is the creation of an access opening into the body cavity at a predetermined surgical site. In the past, such access openings were formed by the creation of substantially large incisions through the body wall or outer tissue. The size of an incision would depend on the type of surgery, and accordingly, the surgical instruments involved. On completion of the surgical procedure, the large incision would be closed using conventional techniques. However, due to the traumatic nature of such open surgical procedures, the period of time required for the patient to completely heal was significant. In addition, the pain or discomfort during the recuperative period was a serious problem.

[0006] Because of the above noted disadvantages, attempts have been made, which were specifically directed towards new surgical procedures as well as instruments utilized in the support of such procedures. More recently, it has become quite common to employ an alternative type of surgery known as laparoscopic and/or endoscopic surgery, wherein one or more small openings, utilizing appropriate penetrating instruments, are formed in a patient's abdomen typically, to provide access into the intended body cavities wherein surgery on a targeted organ or organs may take

place. Unlike the large incision required during open surgery, the much smaller access openings facilitate healing following the surgery and as expected, result in significantly less discomfort to the patient.

[0007] Depending on the type of laparoscopic surgery being performed, the instrumentation used to form the one or more small access openings may vary. However, common to such medical penetrating instruments is the provision of a sharpened or otherwise configured penetrating tip. By way of example, instrumentation utilized in the performance of laparoscopic surgery are commonly referred to as trocar devices or trocar assemblies. In conventional fashion, a trocar assembly normally includes a trocar sleeve or cannula and an obturator to which the penetrating tip is attached. Utilizing such instrumentation, access is gained to a body cavity or organ by penetrating the bodily tissue defining the exterior wall of the cavity, in order that laparoscopic surgery may be performed.

[0008] The obturator, serving as the penetrating instrument, passes along or is positioned within the lumen of the cannula or trocar sleeve. The penetrating tip is formed on the distal end of the obturator and is forced through the skin until entry to the body cavity has been established. The trocar sleeve, is then forced through the perforation, formed by the obturator and the obturator is withdrawn, leaving the trocar sleeve or cannula as an access passage to the intended body cavity or organ. In related laparoscopic or endoscopic surgical techniques, the penetrating instrument may be used with the trocar sleeve or surgical access cannula or may be used as a "stand alone" device to puncture through the skin and underlying bodily tissue. A small access opening is thereby formed and a separate access cannula, catheter or other surgical instrument is inserted into communication with the now accessed body cavity or organ.

[0009] The aforementioned, substantially conventional, medical penetrating instruments normally include a penetrating tip having a sharpened point spaced distally from a base which is connected to one end of the obturator or penetrating instrument. Also, the conventional structure of such penetrating tips typically include either a conical or a multi-sided, substantially pyramidal configuration. The design and structuring of penetrating tips for the type of medical instruments described herein is/are important for the efficient formation of the small access opening, as set forth above. However, such penetrating tips should efficiently and cleanly create the access opening in a manner which serves to at least partially dilate or enlarge the opening, as the shaft of the obturator or other penetrating instrument passes through the bodily tissue. It is, of course, equally important that a minimal amount of damage, in terms of severing or cutting, be done to the contiguous body tissue surrounding the access opening during the initial penetration, as well as the enlargement of the access opening, as the penetrating instrument is positioned into direct communication with the intended body cavity or organ.

[0010] Accordingly, there is a need in the field of medical instrumentation for an instrument which may be used independently or which may be associated with a trocar assembly and associated components such as, but not limited to, a trocar sleeve, etc. Any such an improved instrument would preferably be designed to include an improved penetrating tip which is structured to facilitate the smooth and/or clean

formation of a small access opening through the puncturing of the body wall. The penetrating tip should preferably include an exterior surface, as well as a distal extremity or apex, and a base which are cooperatively structured and efficiently configured. The structuring of these components should be such as to effectively enlarge the access opening, as the penetrating instrument is advanced therethrough into communicating relation with a predetermined body cavity or organ. Further, the disposition, dimension, configuration and overall structure of any such inventive penetrating tip should be such as to form the access opening without causing any unnecessary or inadvertent cutting, severing or like damage to the outer tissue being penetrated or to the internal organs, once the penetrating tip enters the intended body cavity.

SUMMARY OF THE INVENTION

[0011] The present invention is intended to address these and other needs in the art and as such, is directed towards a penetrating instrument of the type used in laparoscopic, endoscopic or like, minimally invasive surgical procedures, and which is preferably, but not necessarily, embodied in a trocar assembly. In such embodiment, the trocar assembly includes a trocar housing and a trocar sleeve or cannula having an open distal end communicating with a centrally disposed lumen or passage within the trocar sleeve and within the housing. The trocar assembly further includes an obturator comprising an elongated shaft having a proximal end and an oppositely disposed distal end on which a penetrating tip is either formed or secured. Whether or not embodied in a trocar assembly, the elongated shaft and the penetrating tip of the obturator are specifically structured to create a small access opening in the body wall or outer tissue of a patient so as to establish communication with an internal body cavity or organ on which a surgical procedure is to be performed.

[0012] The penetrating instrument of this invention is designed and structured to effectively create the small access opening by penetrating through the skin and underlying body tissue of a patient in a manner which serves to separate and enlarge the created access opening, as the penetrating tip, shaft and/or trocar sleeve pass there-through and into the patient's abdominal body cavity. As explained in greater detail herein, the overall structure, configuration, dimension and disposition of the penetrating instrument is such as to accomplish an effective separation of the bodily tissue being penetrated with a minimal application of an inwardly directed linear force. In doing so, the structure of the penetrating instrument dilates the outer tissue in a manner which minimizes damage to the tissue. Also, the possibility of inadvertently injuring blood vessels, etc. is minimized, as is the possibility of injuring internal organs once the instrument's penetrating tip enters the intended body cavity. More specifically, the instrument of the present invention, whether associated with a trocar assembly or used independently thereof, comprises an obturator having an elongated shaft and a penetrating tip integrally formed on or otherwise secured to the distal end thereof. When in the preferred embodiment of a trocar assembly, the penetrating tip is cooperatively disposed, dimensioned and configured relative to and/or with the trocar sleeve, and in particular, with the open distal end thereof. The penetrating tip includes a base and a distal extremity configured to define an apex. It is pointed out, here, that the term "apex" is meant to include a variety of different configurations, which may vary from a

sharpened point to a tapered locale, as may be defined by the converging of the penetrating tip's exterior surface from a base thereof and extending continuously to the distal extremity or apex. In a preferred embodiment of the present invention, described in greater detail herein, the apex of the penetrating tip is disposed coincident to a central longitudinal axis of the elongated obturator shaft. Other embodiments of the present invention contemplate the apex of the penetrating tip being spaced laterally outward or in an off-set, somewhat eccentric position relative to the central longitudinal access of the elongated obturator shaft.

[0013] Although it may assume a variety of configurations as further described herein, the penetrating tip of this invention is preferably structured to facilitate the separation of the body tissue and penetration of the body cavity wall or lining in a manner which minimizes damage to the tissue and other risk of injury to the patient. More specifically, the penetrating tip includes an exterior surface, preferably extending between the base and the apex thereof, that comprises a cross section having a "substantially elliptical" configuration. The interior of the penetrating tip may include a variety of different structures, such as being solid, hollow or partially hollow. It is pointed out that the term "substantially elliptical" as used herein to describe the configuration of the cross section of the exterior surface of the penetrating tip is not meant to define a true or precise ellipse, alone. Rather, the term "substantially elliptical" as used herein is meant to include a variety of different configurations, all of which substantially conform to an ellipse. More specifically, the outer circumference or sectional configuration of the exterior surface of the penetrating tip, preferably taken along a plane perpendicular to the central longitudinal access of the shaft, may include one or more curvilinear segments, a combination of curvilinear segments and linear segments or a plurality of linear segments, wherein the various linear and/or curvilinear segments are collectively interconnected in a closed or continuous configuration.

[0014] Accordingly, the structure of the instrument of the present invention, whether or not embodied in a trocar assembly, includes an elongated shaft having a penetrating tip with an exterior surface configuration and/or other components thereof, which are cooperatively dimensioned, configured, and disposed to more safely facilitate the formation of an access opening and the dilation of the surrounding bodily tissue during the insertion of the penetrating instrument into the patient. More specifically, the preferred exterior surface configuration of the penetrating tip enters the designated bodily tissue in a manner which minimizes damage and/or cutting or severing of the tissue during the passage of the penetrating tip, as well as an adjacent portion of the shaft and/or trocar sleeve, through the created access opening.

[0015] The objects, features and advantages of the present invention noted above, as well as others, will become more clear when the drawings as well as the detailed description of the invention in various embodiments, below, are taken into consideration.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] For a fuller understanding of the nature of the present invention, reference should be had to the following detailed description taken in connection with the accompanying drawings in which:

[0017] FIG. 1 is a perspective view of a penetrating instrument according to the present invention embodied in a trocar assembly wherein the distal extremity or apex of the penetrating tip is disposed coincident to a central longitudinal axis of the instrument shaft.

[0018] FIG. 2 is a perspective view of another penetrating instrument according to the present invention which is also embodied in a trocar assembly wherein the distal extremity or apex of the penetrating tip is disposed in off-set relation to the central longitudinal axis of the instrument shaft.

[0019] FIG. 3 is a perspective view of another embodiment of a penetrating instrument shown in partial cutaway to better illustrate a penetrating tip associated with the present invention.

[0020] FIG. 4 is a top view of the embodiment of FIG. 3.

[0021] FIG. 5 is a side view of the embodiment of FIGS. 3 and 4.

[0022] FIG. 5A, 5B, 5C and 5D are sectional views of the embodiment shown in FIG. 5 and taken along lines 5A-5A, 5B-5B, 5C-5C, and 5D-5D, respectively.

[0023] FIG. 6 is a perspective view of yet another embodiment of a penetrating instrument, similar to that of FIG. 2, but shown in partial cutaway to better illustrate the penetrating tip associated therewith.

[0024] FIG. 7 is a top view in partial cutaway of the embodiment of FIG. 6.

[0025] FIG. 8 is a side view in partial cutaway of the embodiment of FIGS. 6 and 7.

[0026] FIG. 8A, 8B, 8C, and 8D are sectional views of the embodiment shown in FIG. 8 and taken along lines 8A-8A, 8B-8B, 8C-8C, and 8D-8D, respectively.

[0027] FIG. 9 is a top view of another embodiment of a penetrating instrument according to the present invention including a penetrating tip and associated shaft, in partial cutaway.

[0028] FIG. 10 is a side view of the embodiment of FIG. 9.

[0029] FIG. 11 is a side view of a structural variation of the embodiment of FIG. 10.

[0030] FIG. 12 is a front end view of the embodiment of FIGS. 9 through 11.

[0031] FIG. 13 is a schematic representation of a substantially elliptical configuration representative of a transverse or perpendicular cross-section taken from the exterior surface of a preferred penetrating tip according to the present invention.

[0032] FIG. 13A is a schematic representation of another embodiment of a substantially elliptical configuration representative of a cross section taken from the exterior surface of another penetrating tip according to the present invention.

[0033] FIG. 13B is a schematic representation of yet another embodiment of a substantially elliptical configuration representative of a cross section taken from the exterior surface of another penetrating tip according to the present invention.

[0034] FIG. 13C is a schematic representation of yet another embodiment of a substantially elliptical configuration representative of a cross section taken from the exterior surface of another penetrating tip according to the present invention.

[0035] FIG. 13D is a schematic representation of yet another embodiment of a substantially elliptical configuration representative of a cross section taken from the exterior surface of another penetrating tip according to the present invention.

[0036] FIG. 13E is also a schematic representation of another potential embodiment of a substantially elliptical configuration representative of a cross section taken from the exterior surface of another penetrating tip according to the present invention.

[0037] FIG. 13F is also a schematic representation of yet another potential embodiment of a substantially elliptical configuration representative of a cross section taken from the exterior surface of another penetrating tip according to the present invention.

[0038] FIG. 14 is a longitudinal view in partial section and cutaway of yet another preferred embodiment of the present invention showing the penetrating tip in an operative position relative to a trocar sleeve.

[0039] FIG. 15 is a perspective view in partial cutaway of yet another preferred embodiment of the present invention directed to structural components associated with a trocar assembly embodying the instrument of the present invention.

[0040] Like reference numerals refer to like parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0041] As shown in the accompanying Figures, the present invention is directed towards a medical instrument of type structured for use in minimally invasive surgery, such as laparoscopic or endoscopic surgery. Moreover, the instrument of the present invention is preferably, but not necessarily, embodied in a trocar assembly, such as, but in no way limited to, the trocar assemblies shown in FIGS. 1, 2, 12, 14 and 15 and generally indicated as 10 and 10', which assemblies depict a distinctive shape developed by and proprietary to Taut, Inc. of Geneva, Ill.

[0042] A trocar assembly, whether that indicated by reference numeral 10, 10' or another, typically includes a trocar housing 12, which may include a connector structure 14 communicating with the interior of the housing 12 and structured to establish interconnection with a supply of fluid, such as carbon dioxide gas, used to inflate a body cavity as typically performed during laparoscopic or endoscopic surgery.

[0043] Trocar assembly 10, 10' also includes an elongated cannula or trocar sleeve 16 dimensioned and structured to removably receive an obturator 20, perhaps best shown in FIGS. 3-5, comprising an elongated shaft 26, along the interior, centrally disposed passage or lumen associated with the sleeve 16. The elongated shaft 26 has a penetrating tip, generally indicated as 22, secured to the distal end of shaft 26 and extending outwardly from a distal open end 18 of the trocar sleeve 16.

[0044] It is pointed out that the present invention can be utilized with trocar assemblies, such as **10** and **10'** as well as others. While the trocar assemblies shown in **FIGS. 1, 2** and **15** appear to be substantially equivalent structures, they differ from one another primarily in the structural configuration of the obturators **20** and **20'**, and mostly in the structure of the respective penetrating tips **22** and **22'**. Also, in each of the embodiments of **FIGS. 1, 2** and **15** it is preferred that a mounting hub **24** be connected or secured to a proximal end of the trocar sleeve **16**, adjacent or contiguous to the trocar housing **12**. As explained hereinafter with primary reference to **FIG. 15**, the mounting hub **24**, secured to a proximal end of the trocar sleeve **16**, is structured for mounting or interconnection with an end portion or gripping portion **25** secured to a proximal end **25'** of the elongated shaft **26** defining the obturator **20**.

[0045] As indicated above, the preferred embodiments of the present invention includes the elongated shaft **26**, at least partially defining the obturator **20**. The shaft **26** or **26'** has the distal end integrally formed with or otherwise fixedly connected or secured to the corresponding penetrating tip **22** or **22'**. The elongated shaft **26** also has a proximal end **25'** which is oppositely disposed to the penetrating tip **22** and which is preferably secured to the gripping portion **25**, as noted above and in **FIG. 15**. While the elongated shafts **26** and **26'** are primarily disclosed as including a solid material construction, it is emphasized that either may include a substantially hollow, elongated configuration terminating in the respective penetrating tip **22** or **22'**. Alternatively, the penetrating tips **22, 22'**, of the various embodiments may be formed to be substantially or at least partially hollow. It is to be understood that the penetrating tips **22, 22'** may have a variety of other interior structures, such as being solid or at least partially solid.

[0046] With primary reference to the embodiment of **FIG. 1, FIGS. 3 through 5**, and **FIG. 14**, the shaft **26** of the present invention comprises the penetrating tip **22** having a base **28** integrally or otherwise fixedly secured to the distal end of shaft **26**. The opposite end of the penetrating tip **22** terminates in a distal extremity generally indicated as **30**. Further, the penetrating tip **22** has an exterior surface extending continuously between the base **28** and the distal extremity **30**. The distal extremity **30** may be more specifically defined as an "apex" **32** which may be structured to have, but does not necessarily require, a slightly blunted configuration. However, the apex **32** may also assume a variety of other configurations, such as that shown in the embodiment of **FIG. 2** and indicated as **32'**. That is, while the term "point" may be used to describe an apex **32**, this is not necessarily meant to define a true, sharply pointed structure. On the contrary, in the most preferred embodiments, the apex **32** and/or **32'** is structured to be sufficiently blunt to eliminate or significantly reduce the danger of inadvertent puncturing of a patient's organ(s) once the penetrating tip has passed through exterior bodily tissue and entered into the patient's abdominal cavity or other internal cavity. In that the apex **32** and **32'** of the inventive penetrating tip may assume a variety of different structural configurations, all of which are intended to facilitate the clean, efficient passage through the outer body wall of a patient, the term apex, rather than point, is used to generically and more accurately describe each of the plurality of tip configurations. Further, the apex **32, 32'**, regardless of its specific shape, may be defined as a convergent locale of the exterior surface **40** of

each of the corresponding penetrating tips **22, 22'**, as the exterior surface **40** extends from the respective bases **28, 28'** to and including the distal extremity **30, 30'**.

[0047] Still referring to **FIGS. 1, 3** through **5**, and **14**, the more preferred embodiments of the invention comprise the apex **32** being disposed coincident with the central, longitudinal axis **27** of the elongated shaft **26**, or more precisely, a linear extension **27'** of the central longitudinal axis **27**. Further, at least one preferred embodiment comprises the exterior surface **40** including at least two surface segments **42** and **44**. As shown in **FIGS. 3 and 4**, the surface segments **42** and **44** are at least minimally segregated by two at least partially, oppositely disposed and curved edge portions **46** and **48**. The edge portions **46** and **48** may be specifically shaped or configured to define cutting and/or dilating edges and extend along at least a portion of the distance between the apex **32, 32'** and the base **28, 28'**.

[0048] For example, the longitudinal curvilinear configuration of the surface segments **42** and **44** are preferably at least partially defined by a complex curve. In turn, the complex curvilinear configuration of each of the surface segments **42** and **44**, as viewed longitudinally from the apex **32** to the base **28**, comprises at least one substantially concave segment **49** and either a linear or minimally convex curve portion or section **49'**. As a result, the overall configuration of the exterior surface of the penetrating tip **22** and its cooperative structuring with the apex **32** facilitates the forming and subsequent enlargement of an access opening in the body wall of a patient, without requiring a heavily applied, inwardly directed, linear pushing force. As such, the access is formed in a manner more of a dilating action, which minimizes cutting of and/or other damage to bodily tissue as the penetrating tip **22**, as well as a portion of the shaft **26** and/or sleeve **16** passes through the access opening into a patient's abdominal cavity or other anatomical structure.

[0049] In the more preferred embodiments of the present invention, the exterior surface **40** of the penetrating tip **22** has a transverse or perpendicular cross section which is substantially elliptical. It is to be understood that the term "substantially elliptical," when referring to the cross sectional configuration of the exterior surface **40** or the transverse circumferential configuration thereof, is not meant to be limited to a true or precise elliptical configuration, only. To the contrary, the substantially elliptical configuration of the penetrating tip **22** or **22'** may assume differently shaped exterior surfaces and yet still be included or intended for inclusion within the phrase "substantially elliptical," as used herein.

[0050] To better illustrate this, reference will now be made to **FIGS. 13, 13A, 13B, 13C, 13D, 13E** and **13F**. As represented in **FIG. 13**, there is illustrated a schematic representation of a true or precise elliptical configuration, indicated as **100**. This elliptical configuration or ellipse **100** includes a primary longitudinal dimension **102** and a primary transverse dimension **104**. Upon reviewing the various embodiments of the penetrating tip disclosed herein (such as **22, 22', 64**, etc.) it will be noted that the size of the cross sectional configuration of the exterior surface **40** will change. In other words, the size of the cross section taken from any given penetrating tip **22, 22'**, etc. will be larger or smaller dependent upon whether the section is taken closer

to the apex 32 or closer to the base 28. This is due to the converging structure of the exterior surface 40 as it extends from the base 28 to the apex 32.

[0051] Therefore, with reference to FIG. 13, the term “substantially elliptical” configuration is meant to include variations in the shape of the sectional configuration of the exterior surface 40, due to the fact that either the primary longitudinal dimension 102 may be longer or shorter and/or the primary transverse dimension 104 may be longer or shorter. The result is a sectional configuration of the exterior surface 40, which while not precisely conforming to a precise elliptical configuration, schematically represented as 100, may still be considered a substantially elliptical configuration even though the overall shape is characterized by a flattened, elongated, oblong or other elliptical configuration having a variant shape.

[0052] In order to further clarify that the intended meaning of the phrase or term “substantially elliptical” when referring to the penetrating tip’s exterior surface 40 can apply to varied equivalent or substantially equivalent shapes, reference is now made to FIGS. 13-A, 13-B, 13-C, 13-D, 13-E and 13-F. It is emphasized that schematic representations illustrated in these Figures are intended to be representative only of a plurality of possible “substantially elliptical” configurations which the exterior surface 40 may assume. In these Figures, a true or precise elliptical configuration is indicated in phantom lines and is marked with reference numeral 100' and the exterior surface 40 is shown in a variety of different shapes as schematically represented as 40', 40'', 40''', respectively in FIGS. 13A, 13B, 13C, and 40i, 40ii and 40iii, respectively, in FIGS. 13D, 13E and 13F. These Figures illustrate that the specific shape(s) of the representative exterior surface configurations 40', 40'', 40''', 40i, etc. generally conform to the true elliptical configuration 100', and therefore, are clearly intended to be included within the generically descriptive term “substantially elliptical.” With specific reference to FIG. 13-A, the exterior surface 40' may include a plurality of linear segments 106 interconnected to one another to form a continuous, closed configuration. FIG. 13B is representative of an exterior surface 40'' including a plurality of plane curves or more specifically, curvilinear segments 108 connected to a plurality of linear segments 106. The embodiment of FIG. 13C discloses the exterior surface 40''' having at least one elongated plane curve or curvilinear segment 110 interconnected with at least one but preferably a plurality of linear segments 106 to collectively form a continuous, closed configuration. In addition, FIGS. 13D, 13E and 13F illustrate another possible exterior surface 40i, 40ii, 40iii, with a plurality of plane curves or curvilinear segments 108i interconnected with at least one but preferably a plurality of linear segments 106i to form a continuous, closed configuration which also can be said to be substantially elliptical or an equivalent thereto.

[0053] In the various preferred embodiments of the penetrating tip 20, 20', 64, etc., of the present invention, the cross sectional configuration of the exterior surface 40 is preferably oriented transverse or perpendicular to the linear extension 27' of the central longitudinal axis 27 of the shaft 26. Also, the cross section or an infinite number of such cross sections extend along at least a majority of the length of the penetrating tip 22, as demonstrated by the schematic and representative cross-sectional configurations in FIGS.

5B, 5C and 5D. Again, it is to be emphasized that the cross sectional configurations of FIGS. 5B through 5D are schematic representations and may be defined by other than a true or precise elliptical configuration such as that disclosed in, but not limited to, FIGS. 13A through 13F. Further by way of reference, the perpendicular cross-sectional configuration of the base 28, taken along the imaginary line 5A-5A, may be, but does not in all cases have to be, defined by a circumferential configuration in the form of a circle. In addition, the base 28 in at least one embodiment may comprise a transitional area or zone between the tip 22 and the distal end of the shaft 26.

[0054] It is pointed out that some variation in the substantially elliptical configuration of the cross section of the exterior surface of the penetrating tip may also be due to the existence of the aforementioned, segregating edge portions 46 and 48. As set forth above, the structure of the edge portions 46 and 48 may vary as they may or may not be structured to serve as cutting edges. Accordingly, the opposite ends of each of the representative elliptical configurations shown in FIGS. 5B, 5C, and 5D may also be varied to more accurately represent the inclusion of the edge portions 46 and 48. These edges may vary in cross-sectional configuration from a true cutting edge, as best demonstrated in FIG. 3, to a more rounded configuration, as indicated by the representative elliptical shapes of FIGS. 5B, 5C and 5D.

[0055] The various embodiments of the present invention, however, will preferably provide for efficient penetration of the outer bodily tissue and passage there-through in a manner which minimizes the danger of inadvertent puncturing of internal organs. More specifically, such initial penetration and passage of the either of the tips 22 and 22' as well as the respective shafts 26 and 26' and/or sleeve 16 will ideally be accomplished by the exertion of only a minimal amount of a linearly directed, “pushing” force on the instrument. Instead, penetration may be facilitated by applying a twisting motion, and preferably a back and forth or “reciprocal twisting” motion, to the device. In the more preferred embodiment incorporating a somewhat blunted point or apex 32 or 32', the chances are minimized of inadvertently puncturing and/or damaging an internal organ subsequent to the penetrating tip 22 or 22' passing through the exterior bodily tissue and into the body cavity in which the organ is located.

[0056] With primary reference now to the embodiment of FIGS. 2 and 6 through 8, one distinguishing structural feature is the location of the apex 32' in an eccentric or laterally spaced, off-set relation to an imaginary co-linear extension of the central longitudinal axis of the shaft 26'. Accordingly, the exterior surface 40 comprises two surface segments 42' and 44' which are non-symmetrical, in that surface segment 42' has a significantly smaller overall dimension than that of the surface segment 44'. As a result, the base 28' has a circumferential configuration preferably defined by an elongated ellipse, schematically represented in FIG. 8A and taken along lines 8A-8A of FIG. 8.

[0057] Similar to the embodiment of FIGS. 1 and 3 through 5, both of the exterior surface segments 42' and 44' have a longitudinal curvilinear configuration defined by a longitudinally oriented complex curve including at least a minimally concave portion 49'' and a linear portion 49'''. Similarly, the surface segments 42' and 44' are at least

minimally segregated from one another through the provision of the elongated curved edges **46'** and **48'**, extending from the apex **32'** towards the base **28'** and at least along a majority of the length of the penetrating tip **22'**. The edges **46'** and **48'** may have a more rounded or transversely curved configuration than that of the embodiment of **FIG. 3**, thereby providing a somewhat "blunted" edge configuration **46'** and **48'** which, differs from the edge portions **46** and **48** of the embodiment of **FIG. 3**.

[0058] However, the exterior surface **40** of the embodiment of **FIGS. 2 and 6** through **8** is structured to define an overall exterior surface configuration shaped to enlarge or at least partially dilate an access opening formed in the outer body wall by the penetrating tip **22'**, while minimizing any cutting, severing or damaging of the contiguous bodily tissue surrounding the formed access opening. Such a preferred structural configuration is further demonstrated in **FIGS. 8B, 8C and 8D** which represent a transverse circumferential configuration of the exterior surface **40** as also being substantially elliptical, within the intended meaning of this term, as has been described herein.

[0059] As with the embodiment of **FIGS. 1 and 3** through **5**, the opposite ends of the representative elliptical configurations of the perpendicular cross-sections of the penetrating tip **22'** shown in **FIGS. 8B, 8C, and 8D**, may be more precisely represented by narrowing the opposite ends to more accurately represent the edges **46'** and **48'**. Also, since the apex **32'** is laterally off-set from the central longitudinal axis of the shaft **26'**, the apex **32'** is not centered or centrally coincident with any of the elliptically configured cross-sections represented in **FIGS. 8A through 8D**. To the contrary, in the embodiment of **FIG. 5**, the apex **32** is coincident to the linear extension of the central longitudinal axis of the shaft **26** and would therefore be substantially centered relative to the circular cross-section of the base **28**, as shown in **FIG. 5A**, as well as the elliptically configured cross-sections of **FIGS. 5B through 5D**.

[0060] Another preferred embodiment of the penetrating instrument of the present invention is shown in **FIGS. 9 through 12** and comprises an obturator **60** including an elongated shaft **62** having a penetrating tip **64** integrally formed with or otherwise secured to the distal end of shaft **62**. Penetrating tip **64** includes a base **66**, which in the preferred embodiments of **FIGS. 9 through 12**, is extended along a predetermined angular orientation of generally about 45 degrees relative to a central longitudinal axis of the shaft **62**, schematically indicated as **68** in **FIG. 10**. The base **66** is integrally or otherwise attached to the distal end of the elongated shaft **62**, as shown. The opposite end of the penetrating tip **64** terminates in a distal extremity generally indicated as **70**, and more specifically, defined by an apex **72**. One feature of this embodiment is the disposition of the apex **72** coincident with the central longitudinal axis **68** of the shaft **62**, or more precisely, a linear extension **68'** of the central longitudinal axis **68**.

[0061] Additional structural features of this preferred embodiment include the exterior surface **74** including longitudinally extending, curved exterior surface segments **76** and **78**. Due at least in part to the angular orientation of the base **66**, the exterior surface segments **76** and **78** have different lengths, as best shown in **FIG. 10**, and are non-

symmetrical even though the apex **72** is disposed coincident with the central longitudinal axis **68** or the linear extension thereof **68'**.

[0062] Referring now to both **FIGS. 10 and 11**, the exterior surface **74** of the penetrating tip **64**, particularly including the exterior surface segments **76** and **78**, can define an at least partially concave, convex and/or complex, longitudinal extending curve(s). As a result, the perpendicular cross-sectional configuration of the penetrating tip **64**, such as along schematic cross-section lines **80** and **82**, comprises a substantially elliptical configuration. These elliptical configurations of sections **80** and **82** are also meant to be schematically representative of a variety of different shapes intended to be included within the meaning of the generic term "substantially elliptical," as has already been discussed in detail.

[0063] As noted, structural differences of the embodiment of **FIGS. 9 through 12** include the apex **72** being coincident with the longitudinal axis **68, 68'** of the shaft **62**, rather than being off-set therefrom. In addition, the complex curve of at least one of the exterior surface segments **76** or **78** would preferably include an elongated concave configuration extending from the apex **70** to towards the base **66** in order to facilitate the penetrating capabilities of the penetrating tip **64**. A concave configuration of one or both of the exterior surface segments **74** and **76** may be important, especially when the apex **72** assumes a more blunted shape as opposed to a sharpened point. It is further emphasized that the exterior surface **74**, including the exterior surface segments **76** and **78** may vary from that shown in **FIGS. 10 and 11**. Accordingly, dependent upon the configurations of the exterior surface **74**, any of an infinite number of perpendicular sections, such as those taken along schematic lines **80** and **82**, will have the aforementioned substantially elliptical configuration. Also, the centers as at **80'** and **82'** of the respective elliptical configurations as shown in **FIGS. 10 and 11** may be disposed along an imaginary straight line as at **86** and/or along an imaginary curved line as at **88**.

[0064] As set forth above, the apex **72** may be somewhat blunted rather than a true sharpened point, and thereby, as illustrated in **FIG. 11**, be at least partially defined by an end ellipse **84**. Again, the location of the centers **80'** and **82'** as well as the center **84'** of the end ellipse **84** may be disposed along a straight line **86** or a curved line **88** depending, at least in part, on the overall exterior surface configuration **74**, while the apex and/or the center point **84'** of the end ellipse **84** remains coincident with the longitudinal axis **68, 68'**. Naturally, as with the embodiments of **FIGS. 1 through 8**, the obturator **60** may be of the type to be used in combination with a trocar assembly generally indicated as **10** including the elongated trocar sleeve **16** as shown in both **FIGS. 1 and 12**.

[0065] Still referring to the embodiment(s) shown in **FIGS. 9 through 11**, it is noted that the base **66**, being angularly oriented at a preferred angle of 45 degrees relative to the longitudinal axis **68** and **68'**, defines an elliptical configuration somewhat similar to that shown in the embodiment of **FIG. 8A**. The precise shape of the preferred elliptical configuration will, of course, vary, dependent on the angular orientation of the base **66** relative to the longitudinal axis **68** being greater or less than the preferred 45 degree angle of incline, as indicated.

[0066] Another feature of at least one preferred embodiment of the present invention is shown in **FIG. 14**, wherein the laparoscopic instrument is embodied in a trocar assembly **10** having a trocar sleeve **16** with an open distal end **18**. As will also be explained with regard to the embodiment of **FIG. 15**, the elongated shaft **26** is positioned within the interior passage of the sleeve **16** and is longitudinally dimensioned to facilitate the positioning of the penetrating tip **22** in an operative position having a most preferred orientation. This operative position is at least partially defined by the penetrating tip **22** being disposed in a "closing" relation to the open distal end **18** so as to restrict or block the passage of any unwanted material, such as body tissue, from passing through the open distal end **18** into the interior of the sleeve **16**. The aforementioned operative position may be further defined by the penetrating tip **22**, and more specifically the base **28** thereof, having a common angular orientation relative to the open distal end **18**, or more specifically the plane defined by the open distal end **18**, as schematically represented by the plane or section line **18'**.

[0067] Accordingly, when the penetrating tip **22** is in the aforementioned operative position, the base **28** of the penetrating tip **22** is substantially aligned with the open end **18** and the plane **18'** defined thereby. The closing or blocking relation between the base **28** and the open end **18** is facilitated by the base having a somewhat common transverse dimension to the open end **18**, thereby effectively filling, blocking or closing the open end **18**, when the penetrating tip **22** is in the preferred, operative position, as shown in **FIG. 14**. Further, in this preferred embodiment the base **28** of the penetrating tip **22** is disposed at a predetermined angular orientation relative to the central axis **27** of the shaft **26**. This angular orientation corresponds to substantially the same angular orientation of the plane of the open distal end **18**, schematically demonstrated by the plane or section line **18'**. Therefore, the aforementioned operative position of the penetrating tip **22** may be further defined by the penetrating tip **22**, and more specifically, the base **28** being oriented at the same angle of inclination as the open end **18**.

[0068] As set forth above, the obturator **20** and in particular, the elongated shaft **26** is selectively positioned within the interior passage or lumen of the trocar sleeve **16**. The shaft **26** can be rotated within, as well as longitudinally positioned within the interior of the sleeve **16**. In order to properly position the shaft **26** relative to the sleeve **16** such that the operative position of the penetrating tip **22** is accomplished, the shaft **26** includes the aforementioned gripping portion **25** secured or otherwise connected to the proximal end **25'** thereof. To facilitate a precise positioning of the shaft **26**, in a manner which is convenient to a surgeon, the present invention includes an indexing assembly, generally indicated as **90**, which is preferably mounted at least partially on the gripping portion **25** and partially on the mounting hub **24**. As set forth above, the mounting hub **24** may be connected to the trocar housing and/or may at least partially define the proximal end of the trocar sleeve **16**. More specifically, the indexing assembly **90** includes a first indexing member **91** and a second indexing member **92** respectively formed on the gripping portion **25** and the mounting hub **24**. When the trocar assembly **10** is in use, the physician or other medical personnel places the elongated shaft **26** on the interior of the trocar sleeve **16** while exerting a pushing and/or rotating force on the gripping portion **25**. Proper

angular alignment between the penetrating tip **22** and the sleeve **16**, and more specifically, between the base **28** and the plane **18'** of the open distal end **18** is accomplished when the first and second indexing members **91** and **92** are brought into aligned registry with one another.

[0069] Further structural features of this preferred embodiment includes the provision of a stop structure. As set forth above, the longitudinal dimension of the shaft **26** is such as to dispose the penetrating tip **22** in the aforementioned operative position as demonstrated in **FIG. 14**. The operative position is at least partially obtained when the shaft **26** is fully extended through the mounting hub **24**, trocar housing **12** and remainder of the sleeve **16**. To facilitate proper positioning of the shaft **26** in this manner, a stop member as at **93** is mounted on the positioning member **25**. The stop member **93** is disposed to abut and come into "stopping" engagement with a portion of the mounting hub **24**, such as about the periphery thereof as at **24'**.

[0070] Accordingly, when indexing members **91** and **92** are aligned in the manner set forth above and when the stop member **93** engages the predetermined, interruptive portion of the proximal end of the sleeve **16**, such as the periphery **24'** of the mounting hub **24**, the medical personnel are sure that the instrument is operatively assembled and that the penetrating tip **22** is in the aforementioned operative position.

[0071] A connecting or locking assembly may also be included and may comprise one or more connecting or locking tabs **94**, which may be biased due to the structure or the material from which the tabs **94** are formed. The connecting tabs **94** are disposed and dimensioned to be removably received within connecting compartments or recesses **95** correspondingly disposed within the hub **24** or other portion of the proximal end of the trocar sleeve **16**, dependent on the type of the trocar assembly **10**, **10'** etc. being utilized.

[0072] Since many modifications, variations and changes in detail can be made to the described preferred embodiment of the invention, it is intended that all matters in the foregoing description and shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense. Thus, the scope of the invention should be determined by the appended claims and their legal equivalents.

[0073] Now that the invention has been described,

What is claimed is:

1. A laparoscopic instrument comprising:

- a) a trocar assembly including an elongated sleeve having an open distal end,
- b) an elongated shaft movably disposed within said sleeve and including a penetrating tip secured to one end thereof,
- c) said penetrating tip including an apex and a base and an exterior surface extending there between,
- d) said exterior surface having a cross section comprising a substantially elliptical configuration extending along at least a portion of said penetrating tip between said base and said apex, and

- e) said cross sectional configuration of said exterior surface being oriented generally perpendicular to a central longitudinal axis of said elongated shaft.
2. An instrument structured for use in laparoscopic surgery, said instrument comprising:
- a) a trocar assembly including an elongated sleeve having an open distal end and an elongated shaft disposable within said sleeve,
 - b) a penetrating tip secured to a distal end of said shaft and disposable in a predetermined operative position relative to said sleeve,
 - c) said penetrating tip comprising a base and a apex and an exterior surface extending therebetween,
 - d) said operative position comprising a portion of said penetrating tip disposed in substantially closing relation to said open distal end, and
 - e) said exterior surface having a cross section comprising a substantially elliptical configuration extending along at least a portion of said penetrating tip between said base and said apex.
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摘要(译)

一种用于医疗领域的组织穿透器械，其可以或可以不与套管针组件相关联的闭塞器的形式实施，其中该器械包括细长轴，该细长轴具有安装在其一端上的穿透尖端。穿刺尖端包括固定到轴的一端的基础部和远离基部纵向向外间隔开并形成成为顶点的远端，该顶点可以由特定构造的点或其他构造限定，以便于穿透或刺穿身体组织。顶点可以基本上与轴的中心纵向轴线的线性延伸部对齐，或者可选地，可以与轴的中心纵向轴线横向向外或偏离地间隔开。穿透尖端还包括在顶点和基部之间连续延伸的外表面，并且构造成便于组织的穿刺和组织中形成的进入开口的扩大，其方式有利于组织的分离并且最小化切割，切断或以其他方式损坏进入开口周围的邻接身体组织。

