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(54) Titre : ENSEMBLE D'AIGUILLE CREUSE
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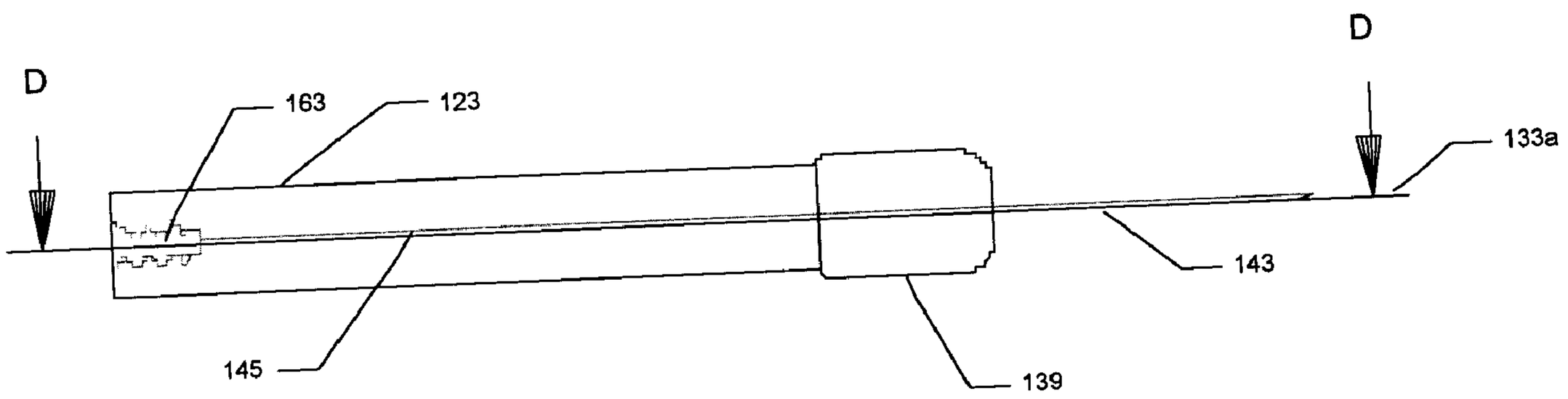


(57) Abrégé/Abstract:
Some embodiments of the invention provide a needle with a sharp open end and a blunt open end, housed in a barrel with an open anterior end and an open posterior end. The barrel can travel along the hub of the needle, for extending the needle for insertion into a blood vessel, and for retracting the needle into the barrel to avoid injury. The blunt open end can be fluidly connected to the inlet of a measurement apparatus, so that the blood can flow directly into the measurement apparatus, eliminating the traditional step of transferring the blood from a syringe to the measurement apparatus. The hollow needle assembly can remain attached to the measurement apparatus because of its small size, and the engagement of an optional safety cap to the open anterior end of the barrel, minimizes the risk of injury and blood contamination. Because a small blood sample is required, a very small needle shaft can be used, minimizing the discomfort experienced by the patient.

ABSTRACT OF THE DISCLOSURE

Some embodiments of the invention provide a needle with a sharp open end and a blunt open end, housed in a barrel with an open anterior end and an open posterior end. The barrel can travel along the hub of the needle, for extending the needle for insertion into a blood vessel, and for retracting the needle into the barrel to avoid injury. The blunt open end can be fluidly connected to the inlet of a measurement apparatus, so that the blood can flow directly into the measurement apparatus, eliminating the traditional step of transferring the blood from a syringe to the measurement apparatus. The hollow needle assembly can remain attached to the measurement apparatus because of its small size, and the engagement of an optional safety cap to the open anterior end of the barrel, minimizes the risk of injury and blood contamination. Because a small blood sample is required, a very small needle shaft can be used, minimizing the discomfort experienced by the patient.

Title: HOLLOW NEEDLE ASSEMBLY

Field Of The Invention

[0001] The invention relates to a hollow needle assembly for transferring fluid from one site to another. In particular, the invention relates to the hub of the needle, and a barrel that could sheathe the shaft of the needle.

Background Of The Invention

[0002] There are many medical diagnostic tests that require a blood sample. In general, conventional methods of collecting and analyzing blood leads to inevitable delays, unnecessary handling of the blood and the introduction of contaminants, which are all known sources of analysis error. More specifically, as per convention, a blood sample is typically withdrawn using one instrument/vessel and then transferred into another vessel for analysis. For example, a syringe is used to obtain a relatively large blood sample that is later injected into measuring instruments or cartridges of measuring instruments. Syringe extraction of blood is beneficial in circumstances where several milliliters of blood are needed, and also in circumstances that require protection of the blood from atmospheric contamination. Alternatively, much smaller blood samples (e.g. in the range of *micro-liters*) can be obtained using a pinprick and then a capillary tube that is inserted into a drop of blood that oozes onto the skin surface. Blood from the drop flows into the capillary tube as a result of capillary action. Irrespective of the amount, collected blood is transferred into another vessel to be analyzed. The eventual transfer of blood between vessels delays the actual analysis of the blood sample and also exposes the blood sample to contaminants. Moreover, the red blood cells are alive and continue to consume oxygen during any delay period, which in turn changes chemical composition of the

blood sample in between the time the blood sample is obtained and the time the blood sample is finally analyzed.

[0003] One example of a blood analysis technique that is affected by the aforementioned sources of error is co-oximetry. Co-oximetry is a spectroscopic technique that can be used to measure the different Hemoglobin (Hb) species present in a blood sample. The results of co-oximetry can be further evaluated to provide Hb Oxygen Saturation (Hb O_2 saturation) measurements. If the blood sample is exposed to air the Hb sO_2 saturation measurements are falsely elevated, as oxygen from the air is absorbed into the blood sample.

[0004] Another example of a blood analysis technique that is affected by the aforementioned sources of error is blood gases. Traditionally, blood gas measurement includes the partial pressure of oxygen, the partial pressure of carbon dioxide, and pH. From these measurements, other parameters can be calculated, for example, Hb O_2 saturation. Blood gas and electrolyte measurements usually employ biosensors. Bench-top analyzers are available, which (1) measure blood gases, (2) perform co-oximetry, or (3) measure blood gases and perform co-oximetry in combination. Some combinations of diagnostic measurement instruments also include electrolytes, making such instrument assemblies even larger. Because these instruments are large and expensive, they are usually located in central laboratories. Biosensor technology is also limited by the blood parameters it can measure. For example, biosensors are not currently available for measuring the Hb species measured by the available co-oximeters. Preferably, blood gases and co-oximetry are measured in arterial blood collected in a syringe, since arterial blood provides an indication of how well venous blood is oxygenated in the lungs. There are many benefits in providing these blood tests near or at the point of care of patients, but these are usually limited by the size and cost of the diagnostic measurement instruments. Those skilled in the art will appreciate that, as a non-limiting example,

assessment of the acid-base status of a patient requires both the measurement of hemoglobin (Hb) species in the blood and the blood pH.

[0005] Arterial blood must be collected by a doctor or a specially-trained technician, using a syringe, because of a number of inherent difficulties associated with the complicated collection procedure. Notably, the collection of arterial blood is far more painful, difficult and dangerous for a patient, especially an infant, than the collection of venous blood. If a small sample of arterial blood (for example a fraction of a milliliter) is required, a larger gauge needle (smaller diameter) could be used. The smaller the needle, the lower the level of trauma to the patient

Summary Of The Invention

[0006] According to an aspect of an embodiment of the invention there is provided a hollow needle assembly comprising: (a) a needle constructed of one or more than one part, the needle comprising a shaft having a first length dimension, and a central axis along the first length dimension, the shaft having a sharp open end, and a second end, and a lumen along the central axis from the sharp open end to the second end, and a hub with a passage, the hub having a front end and a back end and the passage having a front side located at the front end and a blunt open end located at the back end, wherein the second end of the shaft is mounted in the front side of the passage, and wherein the passage is fluidly connected to the lumen, and a first flow path is defined along the lumen and the passage, from the sharp open end to the blunt open end; and (b) a barrel constructed of one or more than one part, having an open anterior end and an open posterior end, the barrel comprising an internal chamber for housing the hub, wherein the hub can travel relative to the barrel, along the central axis, for extending the sharp open end outside the barrel, and for concealing the sharp open end within the internal chamber, the barrel also having a second length dimension, wherein the second length dimension is greater than the first length dimension.

[0007] Some embodiments of the invention provide a needle with a sharp open end and a blunt open end, housed in a barrel with an open anterior end and an open posterior end. The barrel can travel along the hub of the needle, for extending the needle for insertion into a blood vessel, and for retracting the needle into the barrel to avoid injury. The blunt open end can be fluidly connected to the inlet of a measurement apparatus, so that the blood can flow directly into the measurement apparatus, eliminating the traditional step of transferring the blood from a syringe to the measurement apparatus. The hollow needle assembly can remain attached to the measurement apparatus because of its small size, and the engagement of an optional safety cap to the open anterior end of the barrel, minimizes the risk of injury and blood contamination. Because a small blood sample is required, a very small

needle shaft can be used, minimizing the discomfort experienced by the patient.

[0008] Other aspects and features of the present invention will become apparent, to those ordinarily skilled in the art, upon review of the following description of the specific embodiments of the invention.

Brief Description Of The Drawings

[0009] For a better understanding of the present invention, and to show more clearly how it may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, which illustrate aspects of embodiments of the present invention and in which:

[0010] Figure 1A is a schematic drawing showing a top view of a needle for a hollow needle assembly according to a first embodiment of the invention;

[0011] Figure 1B is a left side-view of the apparatus shown in Figure 1A;

[0012] Figure 1C is a right side-view of the apparatus shown in Figure 1A;

[0013] Figure 1D is a cross-sectional view through the apparatus shown in Figure 1A along line D-D;

[0014] Figure 1E is a perspective view of the apparatus shown in Figure 1A;

[0015] Figure 1F is detailed view of the detail F shown in Figure 1E;

[0016] Figure 2A is a schematic drawing showing a top view of a barrel for a hollow needle assembly according to a first embodiment of the invention;

[0017] Figure 2B is a left side-view of the apparatus shown in Figure 2A;

[0018] Figure 2C is a cross-sectional view through the apparatus shown in Figure 2A along line C-C;

[0019] Figure 2D is a right side-view of the apparatus shown in Figure 2A;

[0020] Figure 2E is a cross-sectional view through the apparatus shown in Figure 2A along line E-E;

[0021] Figure 2F is a perspective view of the apparatus shown in Figure 2A;

[0022] Figure 3A is a schematic drawing showing a top view of a needle for a hollow needle assembly according to a second embodiment of the invention;

[0023] Figure 3B is a left side-view of the apparatus shown in Figure 3A;

[0024] Figure 3C is a right side-view of the apparatus shown in Figure 3A;

[0025] Figure 3D is a cross-sectional view through the apparatus shown in Figure 3A along line D-D;

[0026] Figure 3E is a perspective view of the apparatus shown in Figure 3A;

[0027] Figure 3F is an alternative perspective view of the apparatus shown in Figure 3A;

[0028] Figure 4A is a schematic drawing showing a top view of a barrel for a hollow needle assembly according to a second embodiment of the invention;

[0029] Figure 4B is a left side-view of the apparatus shown in Figure 4A;

[0030] Figure 4C is a cross-sectional view through the apparatus shown in Figure 4A along line C-C;

[0031] Figure 4D is a right side-view of the apparatus shown in Figure 4A;

[0032] Figure 4E is an alternative cross-sectional view through the apparatus shown in Figure 4A along line E-E;

[0033] Figure 4F is a perspective view of the apparatus shown in Figure 4A;

[0034] Figure 5A is a schematic drawing showing a top view of a needle and barrel assembled together with the needle concealed within the barrel, for a hollow needle assembly according to the second embodiment of the invention;

[0035] Figure 5B is a left side-view of the apparatus shown in Figure 5A;

[0036] Figure 5C is a right side-view of the apparatus shown in Figure 5A;

[0037] Figure 5D is a cross-sectional view through the apparatus shown in Figure 5A along line D-D;

[0038] Figure 5E is a perspective view of the apparatus shown in Figure 5A;

[0039] Figure 5F is an alternative perspective view of the apparatus shown in Figure 5A;

[0040] Figure 6A is a schematic drawing showing a top view of the needle and barrel assembled together, with the needle extended outside the barrel, for a hollow needle assembly according to a third embodiment of the invention;

[0041] Figure 6B is a cross-sectional view through the apparatus shown in Figure 6A along line B-B;

[0042] Figure 6C is an alternative cross-sectional view through the apparatus shown in Figure 6A along line C-C;

[0043] Figure 6D is a perspective view of the apparatus shown in Figure 6A;

[0044] Figure 7A is a schematic drawing showing a top view of a needle and barrel assembled together with the needle extended outside the barrel, for a hollow needle assembly according to a fourth embodiment of the invention;

[0045] Figure 7B is a left side-view of the apparatus shown in Figure 7A;

[0046] Figure 7C is a right side-view of the apparatus shown in Figure 7A;

[0047] Figure 7D is a cross-sectional view through the apparatus shown in Figure 7A along line D-D;

[0048] Figure 7E is detailed view of the detail E shown in Figure 7D;

[0049] Figure 8A is a schematic drawing showing a top view of the needle and barrel assembly shown in Figures 7A-E, with the needle concealed inside the barrel, and with an optional safety cap on for a hollow needle assembly according to the fourth embodiment of the invention;

[0050] Figure 8B is a left side-view of the apparatus shown in Figure 8A;

[0051] Figure 8C is a right side-view of the apparatus shown in Figure 8A;

[0052] Figure 8D is a cross-sectional view through the apparatus shown in Figure 8A along line D-D;

[0053] Figure 9A is a schematic drawing showing a top view of a needle and barrel assembled together, with the needle concealed inside the barrel, with a measurement apparatus 600a attached, and an optional safety cap on for a hollow needle assembly according to the fourth embodiment of the invention;

[0054] Figure 9B is a cross-sectional view through the apparatus shown in Figure 9A along line B-B;

[0055] Figure 9C is a perspective view of the apparatus shown in Figure 9A;

[0056] Figure 10A is a schematic drawing showing a top view of a needle also comprising a measurement apparatus like 600a shown in Figures 9A-C, for a hollow needle assembly according to a fifth embodiment of the invention;

[0057] Figure 10B is a cross-sectional view through the apparatus shown in Figure 10A along line B-B;

[0058] Figure 10C is a perspective view of the apparatus shown in Figure 10A;

[0059] Figures 11A - 11G are schematic drawings showing details of the measurement apparatus 600a shown in Figures 9A-C;

[0060] Figure 12A is a schematic drawing showing a top view of a needle also comprising a measurement apparatus 600b, for a hollow needle assembly according to a sixth embodiment of the invention;

[0061] Figure 12B is a cross-sectional view through the apparatus shown in Figure 12A along line B-B;

[0062] Figure 12C is a perspective view of the apparatus shown in Figure 12A;

[0063] Figures 13A-E are schematic drawings showing details of the measurement apparatus 600b shown in Figures 12A-C;

[0064] Figures 14A-G are schematic drawings showing details of the hollow fiber bundle 660 shown in Figures 13A-E;

[0065] Figures 15A-C are schematic drawings showing details of a measurement apparatus 600c that can be used with the needle of the first embodiment of the invention, as shown in Figures 1A-F;

[0066] Figure 16A is a schematic drawing showing a top view of the needle and barrel assembled together, with the needle extended outside the

barrel, for a hollow needle assembly according to a seventh embodiment of the invention;

[0067] Figure 16B is a cross-sectional view through the apparatus shown in Figure 16A along line B-B;

[0068] Figure 16C is a perspective view of the apparatus shown in Figure 16A; and

[0069] Figure 16D is a detailed view of the detail D shown in Figure 16B.

Detailed Description Of Preferred Aspects Of The Invention

[0070] Some embodiments of the invention provide one hollow needle assembly that is suitable for collection of a blood sample directly from a patient into the measurement apparatus; some embodiments of the invention provide one apparatus that is suitable for both the collection and measurement of a blood sample; and some embodiment of the invention provide one apparatus that is suitable for the collection of a blood sample, the extraction of plasma from the blood (sometimes referred to as whole blood, to distinguish blood from serum and plasma), and the measurement of both the whole blood and the plasma extracted from the whole blood. Currently a needle and syringe is required to collect the blood, and subsequently the blood is injected into the measurement apparatus after removing the needle from the syringe. The transfer of blood from a syringe to a measurement apparatus causes delays in testing, and an anticoagulant is required when blood is not tested within the first few minutes of collection. Moreover, handling the needle increases the risk of infection due to injury by the needle and subsequent infection by blood-borne pathogens, and in general, handling the blood in open vessels increases the risk of contamination by blood-borne pathogens. A further complication caused by the transfer of blood from a syringe to a measurement apparatus is contamination with air. Although blood is the fluid used to illustrate the function of the apparatus, those skilled in the art will appreciate that the present invention can also be used, for example without limitation, to transfer fluid from a plastic or rubber bag to a

measurement apparatus. Once a blood sample is drawn into a measurement apparatus, the blood sample can be analyzed without delay, and without having to transfer any portion of the blood sample into another vessel.

[0071] Current medical practice strongly advises against recapping needles in syringes, due to the risk of injury by the needle contaminated with blood, which may contain hazardous pathogens. In accordance with an embodiment of the invention, recapping or removing the needle is not required, and examples of specific embodiments are shown, where the needle can be retracted into a barrel, and then as an option, the end of the barrel is capped, as a further safeguard against accidental injury.

[0072] As a result of the rapidity of blood sample collection and measurement, the addition of an anticoagulant is not required to prevent clotting. However, it should be understood that the use of one or more reagents is considered to be within the scope of the present invention. The main parts of the present invention are a needle and a barrel, with an optional safety cap, which engages onto the open anterior end, an optional locking cap for locking the needle in position, and an optional spring for automatic needle retraction after the locking cap is loosened. The invention particularly relates to the hub of the needle, and the various functions of different parts of the hub, for example without limitation, extraction of plasma from whole blood.

[0073] Several embodiments of the invention are described in details, in order to describe the present invention. The common features in the different embodiments, are a needle with a flow path that begins at a sharp open end in the shaft of the needle, and terminates at a blunt open end in the hub of the needle, and a mobile barrel that extends the shaft of the needle for piercing a blood vessel, and then retracting the needle into the barrel for safe handling of the apparatus.

[0074] Referring to Figure 1A, shown is a schematic drawing illustrating a top view of a needle 100 for a hollow needle assembly according to a first embodiment of the invention; Figure 1B illustrates a left side-view of the apparatus shown in Figure 1A; Figure 1C illustrates a right side-view of the

apparatus shown in Figure 1A; Figure 1D illustrates a cross-sectional view through the apparatus shown in Figure 1A along line D-D; Figure 1E illustrates a perspective view of the apparatus shown in Figure 1A; and Figure 1F illustrates a detailed view of the detail F shown in Figure 1E.

[0075] Still referring to Figure 1, the needle 100 comprises a shaft 143 and a hub with a front end 139 and a back end 123. The shaft 143 has a sharp open end 147 and a second end, which is mounted in the passage 145 of the hub. A detailed view of the sharp open end 147 (detail F in Figure 1E) is shown in Figure 1F. The sharp open end 147 is usually the beveled end of the shaft, which is usually a hollow metal tube. The hollow portion is also referred to as the lumen 129. The bevel provides a point 121 for piercing the blood vessel. Also shown in Figure 1F is the central axis 133a, which runs through the center of the shaft 143, along its length. The length of the shaft 143 outside the hub is shown to have a length l_1. The section of the shaft 143 mounted inside the hub is not shown. The front end of the hub is shown as 139, and the back end of the hub is shown as 123. It should be understood that the front end refers to a general area of the hub, and does not specifically identify any point or local area. Similarly, it should be understood that the back end refers to a general area of the hub, and does not specifically identify any point or local area. The passage 145 of the hub is fluidly connected to the lumen 129 of the shaft, and a first flow path is defined by the sharp open end 147, which leads into the lumen 129, which leads into the passage 145 of the hub, and terminates at a blunt open end 137. The blunt open end 137 is located at the back end of the hub. The hub could comprise other features, which will be described later.

[0076] Still referring to Figure 1, the back end of the hub also provides a female receptor 163 with internal threads, for receiving a measurement apparatus, for example, the measurement apparatus 600c shown in Figures 15A-C. Mating external threads are shown in tubing 672 of Figures 15A-B, for securing the hollow needle assembly with the measurement apparatus 600c.

[0077] Referring to Figure 2A, shown is a schematic drawing illustrating a top view of a barrel 200 for a hollow needle assembly according to a first embodiment of the invention; Figure 2B illustrates a left side-view of the apparatus shown in Figure 2A; Figure 2C illustrates a cross-sectional view through the apparatus shown in Figure 2A along line C-C; Figure 2D illustrates a right side-view of the apparatus shown in Figure 2A; Figure 2E illustrates an alternative cross-sectional view through the apparatus shown in Figure 2A along line E-E; and Figure 2F illustrates a perspective view of the apparatus shown in Figure 2A. The barrel 200 shown in Figure 2 should be combined with the needle 100 shown in Figure 1, to provide the first embodiment of a hollow needle assembly. Other embodiments of hollow needle assemblies are shown later. Also illustrates in Figures 2A, B & D-F is an opening 167 for the needle shaft 143 (Figure 1) in the open anterior end 159, an opening 165 for the back end of the hub 123 (Figure 1) in the open posterior end 161, and an axis 133b which runs through the center of the barrel, along the length of the barrel shown as l_2. In order for the barrel to conceal the sharp end of the shaft, 147 (Figure 1), l_2 must be greater than l_1. The barrel 200 comprises an internal chamber 153 for housing the front end 139 of the hub, . In the specific embodiments shown later, the central axis 133a of the needle and axis 133b of the barrel are shown to be coaxial, but the axes could also be parallel without being coaxial, for example, depending on the outer design of the barrel, which does not have to be cylindrical.

[0078] Referring to Figure 3A, shown is a schematic drawing illustrating a top view of a needle for a hollow needle assembly according to a second embodiment of the invention; Figure 3B illustrates a left side-view of the apparatus shown in Figure 3A; Figure 3C illustrates a right side-view of the apparatus shown in Figure 3A; Figure 3D illustrates a cross-sectional view through the apparatus shown in Figure 3A along line D-D; Figure 3E illustrates a perspective view of the apparatus shown in Figure 3A; and Figure 3F illustrates an alternative perspective view of the apparatus shown in Figure 3A. The apparatus 100 illustrated in Figure 3 is similar to the apparatus 100 illustrated in Figure 1, and accordingly, elements common to both share

common reference numerals. The primary differences, illustrated in Figure 3, are that the back end of the hub 139 contains external threads 173 for mating with internal threads 175 in a complementary barrel 200 shown in Figure 4, and the blunt open end 137 is housed in a tapered projection 171, wherein the tapered projection resembles the male end of a syringe. Those skilled in the art will appreciate that other suitable mating ends can be used, for example without limitations, internal and external threads, and Leuer lock mechanisms, and are considered to be within the scope of the present invention.

[0079] Referring to Figure 4A, shown is a schematic drawing illustrating a top view of a barrel 200 for a hollow needle assembly according to a second embodiment of the invention; Figure 4B illustrates a left side-view of the apparatus shown in Figure 4A; Figure 4C illustrates a cross-sectional view through the apparatus shown in Figure 4A along line C-C; Figure 4D illustrates a right side-view of the apparatus shown in Figure 4A; Figure 4E illustrates an alternative cross-sectional view through the apparatus shown in Figure 4A along line E-E; and Figure 4F illustrates a perspective view of the apparatus shown in Figure 4A. The apparatus 200 illustrated in Figure 4 is similar to the apparatus 200 illustrated in Figure 2, and accordingly, elements common to both share common reference numerals. The primary difference, illustrated in Figure 4, is the internal threads 175. The threads 175 as shown in Figure 4, do not run continuously throughout the length of the barrel, and prevents the hub from moving beyond the threaded area in the barrel 200, even if the opening 167 was larger than the opening 165.

[0080] Referring to Figure 5A, shown is a schematic drawing illustrating a top view of a needle and barrel assembly 300 with the needle shaft 143 concealed within the barrel according to the second embodiment of the invention; Figure 5B illustrates a left side-view of the apparatus shown in Figure 5A; Figure 5C illustrates a right side-view of the apparatus shown in Figure 5A; Figure 5D illustrates a cross-sectional view through the apparatus shown in Figure 5A along line D-D; Figure 5E illustrates a perspective view of

the apparatus shown in Figure 5A; and Figure 5F illustrates an alternative perspective view of the apparatus shown in Figure 5A. The apparatus 300 illustrated in Figure 5 is an assembly of the needle 100 illustrated in Figure 3, and the barrel 200 illustrated in Figure 4, and accordingly, elements common to these share common reference numerals.

[0081] Referring to Figure 6A, shown is a schematic drawing illustrating a top view of the needle and barrel assembly 400, with the needle extended outside the barrel, for a hollow needle assembly according to a third embodiment of the invention; Figure 6B illustrates a cross-sectional view through the apparatus shown in Figure 6A along line B-B; Figure 6C illustrates an alternative cross-sectional view through the apparatus shown in Figure 6A along line C-C; and Figure 6D illustrates a perspective view of the apparatus shown in Figure 6A. The apparatus 400 illustrated in Figure 6 is an assembly of a modified needle 100 illustrated in Figure 1, and modified barrel 200 illustrated in Figure 2, and accordingly, elements common to these share common reference numerals. The primary differences illustrated in Figure 6 are: in the needle 100, the external diameter of the hub is uniform throughout most of the hub, the blunt open end 137 is housed in a tapered projection 171, which resembles the male end of a syringe, and a stud 115 projects from the hub, at a location around the front end 139 of the hub; in barrel 200, the internal diameter of the internal chamber (shown in Figure 2 as 153) is uniform throughout the length l_2, a slot 113 is cut through the wall of the barrel for a length l_3 and having a width w, wherein l_3 is at least slightly longer than the length of the shaft shown as l_1. The internal diameter of the internal chamber 153 is approximately equal to the external diameter of the hub, in order that the needle 100 would slide smoothly inside the barrel, for extending and retracting the sharp open end of the shaft. The stud 115 fits into the slot 113, with the stud slightly extended beyond the barrel, in order that the smooth sliding motion of the needle inside the barrel, would be accomplished using a finger pressed against the stud 115. The width of the slot w is slightly larger than the diameter of the stud, in order for the slot 113 to act as a track for the stud 115, without unnecessary friction. The stud 115 can only move

along the length l_3 of the slot 113, and helps to keep the needle inside the barrel. A locking cap as described later, is not essential because the user could lock the needle in a position during use, by pressing a finger against the stud 115.

[0082] Referring to Figure 7A, shown is a schematic drawing illustrating a top view of a needle and barrel assembly 500 with the needle extended outside the barrel, according to a fourth embodiment of the invention; Figure 7B illustrates a left side-view of the apparatus shown in Figure 7A; Figure 7C illustrates a right side-view of the apparatus shown in Figure 7A; Figure 7D illustrates a cross-sectional view through the apparatus shown in Figure 7A along line D-D; and Figure 7E illustrates a detailed view of the detail E shown in Figure 7D. The needle of apparatus 500 illustrated in Figure 7 is similar to the needle 100 illustrated in Figure 1, and the hub of apparatus 500 illustrated in Figure 7 is similar to the hub 200 illustrated in Figure 2, and accordingly, elements common to them share common reference numerals. The primary differences, illustrated in Figure 7, are a locking cap 181, external threads at the open posterior end 161 of the barrel, and a spring 187. The locking cap 181 is fitted with a flexible member 185 at the juncture of the locking cap 181 and the open posterior end 161 of the barrel. The locking cap has internal threads that mate with the external threads at the open posterior end 161. The spring 187 is located within the internal chamber 153, between the open anterior end 159 of the barrel, and the front end 139 of the hub. The flexible member 185 is a hollow O-ring preferably made from plastic or rubber, and expands towards the axes 133a and 133b, when the locking cap is tightened, causing the flexible member 185 to press against the hub. As the flexible member 185 presses against the hub, the needle becomes locked in the current position. Although threads are a preferred means of operating the locking cap 181, those skilled in the art will appreciate that a locking cap could also operate by frictional engagement of a locking cap similar to that of the apparatus 500 illustrated in Figure 7, but without threads, to the open posterior end 161 of the barrel without threads. A second embodiment of a flexible member 185 (an O-ring with a C-shaped

cross-sectional area) is shown in Figure 16, and it should be understood that these are just non-limiting examples of means used to lock the needle in position. Those skilled in the art will appreciate that other means of locking the needle in position exist, and are considered to be within the scope of the present invention.

[0083] Referring to Figure 8A, shown is a schematic drawing illustrating a top view of the needle and barrel assembly 700, as shown in Figure 7, with the needle concealed inside the barrel, and with an optional safety cap 189 engaged, according to the fourth embodiment of the invention; Figure 8B illustrates a left side-view of the apparatus shown in Figure 8A; Figure 8C illustrates a right side-view of the apparatus shown in Figure 8A; and Figure 8D illustrates a cross-sectional view through the apparatus shown in Figure 8A along line D-D. The apparatus 700 illustrated in Figure 8 is similar to the apparatus 500 illustrated in Figure 7, and accordingly, elements common to both share common reference numerals. The primary differences, illustrated in Figure 8, are that the needle shaft 143 is withdrawn inside the barrel 200, and a safety cap 189 is fitted over the open anterior end 159 of the barrel, to further protect the user from accidental injury.

[0084] Referring to Figure 9A, shown is a schematic drawing of an apparatus 800, illustrating a top view of a needle and barrel assembly 700 shown in Figure 8, with a measurement apparatus 600a attached, according to the fourth embodiment of the invention; Figure 9B illustrates a cross-sectional view through the apparatus shown in Figure 9A along line B-B; and Figure 9C illustrates a perspective view of the apparatus shown in Figure 9A. Details of the measurement apparatus 600a are illustrated in Figures 11A-G. The blunt open end of the hollow needle assembly 700 is shown as 137a. When apparatus 600a and apparatus 700 are fluidly connected, the new blunt open end of the extended fluid path is shown as the vent 137b of the measurement apparatus 600a.

[0085] Referring to Figure 10A, shown is a schematic drawing of an apparatus 900, illustrating a top view of a needle 100 permanently joined to a

measurement apparatus like 600a, as illustrated in Figures 11A-G, according to a fifth embodiment of the invention; Figure 10B illustrates a cross-sectional view through the apparatus shown in Figure 10A along line B-B; Figure 10C illustrates a perspective view of the apparatus shown in Figure 10A. The only outlet is the vent of the measurement apparatus 600a, shown as the blunt open end 137. Moreover, a single flow path is defined from the sharp open end 147, to the blunt open end 137. The needle 100 and measurement apparatus 600a together form a needle with a larger hub, and with the flow path of the measurement apparatus 600a integrated in the flow path of the hollow needle assembly.

[0086] Referring to Figures 11A-G, shown are schematic drawings providing details of the measurement apparatus 600a illustrated in Figures 9A-C and Figures 10A-C. The measurement technology includes spectroscopy with the optional use of one or more than one reagent. Referring to Figure 11A, shown is schematic drawing of a front view of the measurement apparatus 600a illustrated in Figures 9A-C and Figures 10A-C, showing the sample inlet 612 and the vent 137. Referring to Figure 11B, shown is a perspective view of the measurement apparatus 600a. Referring to Figure 11C, shown is a schematic drawing of a top view of the apparatus shown in Figure 11A, with a wall-portion 624a of the optical chamber 616, and two guide lines for filling the apparatus with blood. Referring to Figure 11D, shown is a cross-sectional view of the apparatus illustrated in Figure 11C along line D-D. Referring to Figure 11D, shown is a schematic drawing of the inlet 612, the inlet chamber 670, which can accept the outlet 171 of a needle (for example, one shown in Figure 3), the inlet transition chamber 614, the optical chamber 616, the overflow chamber 618, the optical chamber wall-portions 624a and 624b. Referring to Figure 11E, shown is a cross-sectional view through the apparatus 600a illustrated in Figure 11C along line E-E, showing the outflow 620, the capillary break 622, and the vent 137. Referring to Figure 11F, shown is a left side-view of the apparatus 600a illustrated in Figure 11C. Referring to Figure 11G, shown is an alternative cross-sectional view through the apparatus 600a illustrated in Figure 11F along line G-G,

showing the complete flow path, beginning at the sample inlet 612, and terminating at the vent 137, with the inlet chamber 670, the inlet transition chamber 614, the optical chamber 616, the overflow chamber 618, the outflow chamber 620, the capillary break 622 fluidly connected in series.

[0087] Referring to Figure 12A, shown is a schematic drawing illustrating a top view of a needle 1000, the hub of the needle also comprising a measurement apparatus 600b, for a hollow needle assembly according to a sixth embodiment of the invention; Figure 12B illustrates a cross-sectional view through the apparatus shown in Figure 12A along line B-B; Figure 12C is a perspective view of the apparatus shown in Figure 12A. Details of the measurement apparatus 600b are illustrated in Figure 13.

[0088] Referring to Figures 13A-E, shown are schematic drawings illustrating details of the measurement apparatus 600b shown in Figures 12A-C. The apparatus 600b is also a plasma extraction apparatus, and the measurement technology includes spectroscopy with the optional use of one or more than one reagent, and biosensor technology. Referring to Figure 13A is a top view of the apparatus 600b showing the sample inlet 612, the inlet chamber 670, a whole blood optical chamber wall-portion 624a, a plasma optical chamber wall-portion 626a, and three vents 137a, 137b, and 137c. The apparatus 600b contain two independent flow paths and one dependant flow path. The flow paths are illustrated in Figure 13E.

[0089] Referring to Figure 13E, shown is the sample inlet 612, the inlet chamber 670. The sharp open end of a needle of the present invention is inserted into a blood vessel, allowing the blood to flow into the apparatus 600b, arriving at first at the manifold 640; from the manifold 640, the blood is distributed into the two main flow paths: the first flow path includes in series, the whole blood biosensor inlet transition chamber 642, the whole blood biosensor chamber 674, the whole blood biosensor outflow chamber 620b, the whole blood biosensor capillary break 622b, and terminating at the whole blood biosensor vent 137b; the second flow path includes in series, the whole blood spectroscopic inlet transition chamber 614a, the whole blood optical

chamber 616a, the filtration chamber 634 (for extracting plasma from the whole blood using the hollow fiber bundle 660 with closed flange 682; shown in details in Figure 14), the filtration chamber outflow 620a, the filtration chamber capillary break 622a, and terminating at the filtration chamber vent 137a. A third flow path is defined as a plasma flow path, but is still in fluid connection with the sample inlet 612. The third flow path continues from the filtration chamber 634 at the plasma collection chamber 636, and includes in series the plasma biosensor chamber 672, the plasma spectroscopic inlet transition chamber 614b, the plasma optical chamber 616b, the plasma capillary break 622c, and terminating at the plasma vent 137c. One plasma biosensor is shown as 652c, which is which is electrically connected through a medium 676c to the electrical output contact 654c. Two whole blood biosensors are shown as 652a and 652b, which are connected to their respective electrical output contacts 654a and 654b, through respective media 676a and 676b.

[0090] Referring to Figure 13B, shown is a cross-sectional view through apparatus 600b illustrated in Figure 13A along line B-B, showing parts already identified for Figure 13E.

[0091] Referring to Figure 13C, shown is a cross-sectional view through apparatus 600b illustrated in Figure 13A along line C-C, showing parts already identified for Figure 13E.

[0092] Referring to Figure 13D, shown is a rear view of apparatus 600b illustrated in Figure 13A, showing the three electrical contacts 654a, 654b, and 654c for the three respective biosensors 652a, 652b, and 652c.

[0093] Referring to Figures 14A-G, shown are schematic drawings illustrating details of the hollow fiber bundle 660 shown inside the plasma extraction chamber 634 illustrated in Figure 13. The hollow fiber bundle 660 comprises several hollow fibers 696, held together by two flanges 682 and 684. Referring to Figure 14A, shown is a top view of the hollow fiber bundle 660, illustrating the closed flange 682, and the perforated flanged 684, and a hollow fiber 696. Referring to Figure 14B, shown is a left side-view of the

hollow fiber bundle 660, illustrating the closed flange 682. Referring to Figure 14C, shown is a right side-view of the hollow fiber bundle 660, illustrating the perforated flange 684, and the open end 690 of a hollow fiber. Referring to Figure 14D, shown is a cross-sectional view through the bundle 660 shown in Figure 14A along line D-D. Referring to Figure 14E, shown is a perspective view of the hollow fiber bundle 660, showing the closed flange 682. Referring to Figure 14G, shown is a perspective view of the hollow fiber bundle 660, showing the perforated flange 684, and the open end 690 of a hollow fiber. The hollow fibers are inserted inside perforations in the flange 684 and sealed at the juncture of the hollow fiber and the flange. Referring to Figure 14F, shown is a detailed view of the cross-section of a hollow fiber, according to detail F identified in Figure 14D, showing the lumen of the fiber 692, and the wall of the fiber (also referred to as membrane) 694. In some embodiments, the walls of the fiber contain pores with an approximate distribution of diameters ranging from about 0.1 micrometer to about 10 micrometers. In some embodiments, the internal diameter of the hollow fiber (also referred to as hollow fiber filter) ranges approximately from about 0.1 mm to about 1 mm. Those skilled in the art will appreciate that blood flow decreases the viscosity of the blood and therefore enhances separation (or filtration, or extraction) of plasma from blood; separation of plasma from blood also increases with increasing pore size, decreasing thickness of the membrane 694, and increasing membrane surface area. The surface area increases in proportion to the number of hollow fibers used.

[0094] Referring to Figures 15A-C, shown are schematic drawings of a measurement apparatus 600c suitable for attachment to a needle illustrated in Figures 1A-F, via the internal threads in female receptor 163, and the matching threads in the inlet tubing 672 shown in Figure 15. Referring to Figure 15A, shown is a side view of the apparatus 600c. Referring to Figure 15B, shown is a cross-sectional view through the apparatus 600c shown in Figure 15A along line B-B. Referring to Figure 15C, shown is a perspective view of the apparatus 600c. The apparatus 600c illustrated in Figures 15A-C is similar to the apparatus 600a illustrated in Figures 13A-E, and accordingly,

elements common to them share common reference numerals. The primary difference is that apparatus 600c does not have a filtration chamber for extracting plasma from whole blood.

[0095] Referring to Figures 16A-D, shown are schematic drawings showing a needle and barrel assembly, with the needle extended outside the barrel, for a hollow needle assembly according to a seventh embodiment of the invention; Figure 16B illustrates a cross-sectional view through the apparatus shown in Figure 16A along line B-B; Figure 6D illustrates a perspective view of the apparatus shown in Figure 16A; and Figure 16C illustrates a detailed view of the detail D shown in Figure 16D, illustrating the second embodiment of a flexible member 185. The apparatus 1100 illustrated in Figure 8 is similar to the apparatus 500 illustrated in Figure 7, and accordingly, elements common to both share common reference numerals. The primary differences, illustrated in Figures 16A-D, are the absence of a spring, and the axis 133c of the back end of the hub running through the blunt open end 137, is different from axes 133a and 133b. In this specific embodiment of the apparatus, the axis 133c is orthogonal to axes 133a and 133b.

[0096] While the above description provides example embodiments, it will be appreciated that the present invention is susceptible to modification and change without departing from the fair meaning and scope of the accompanying claims. Accordingly, what has been described is merely illustrative of the application of aspects of embodiments of the invention. Numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

CLAIMS:

1. A hollow needle assembly comprising:

a needle constructed of one or more than one part, the needle comprising a shaft having a first length dimension, and a central axis along the first length dimension, the shaft having a sharp open end, and a second end, and a lumen along the central axis from the sharp open end to the second end, and a hub with a passage, the hub having a front end and a back end and the passage having a front side located at the front end and a blunt open end located at the back end, wherein the second end of the shaft is mounted in the front side of the passage, and wherein the passage is fluidly connected to the lumen, and a first flow path is defined along the lumen and the passage, from the sharp open end to the blunt open end; and

a barrel constructed of one or more than one part, having an open anterior end and an open posterior end, the barrel comprising an internal chamber for housing the hub, wherein the hub can travel relative to the barrel, along the central axis, for extending the sharp open end outside the barrel, and for concealing the sharp open end within the internal chamber, the barrel also having a second length dimension, wherein the second length dimension is greater than the first length dimension.

2. A hollow needle assembly according to claim 1, wherein the barrel has a slot through its wall, and the hub has a stud projecting from a location around the front end, and wherein the stud fits into the slot, and the stud travels along the slot, as the shaft is extended and retracted.

3. A hollow needle assembly according to claim 1, wherein a safety cap is engaged over the open anterior end when the shaft is inside the barrel, to avoid accidental injury by the needle.

4. A hollow needle assembly according to claim 1, wherein the open anterior end is a first annular stop, and the open posterior end is a

second annular stop, for restricting movement of the front end of the hub within the internal chamber.

5. A hollow needle assembly according to claim 1, wherein the front end of the hub is cylindrical having an outside diameter, and the internal chamber of the barrel is cylindrical having an inside diameter, wherein the inside diameter is approximately equal to the outside diameter.

6. A hollow needle assembly according to claim 1, wherein the front end of the hub is cylindrical with external threads, and the internal chamber of the barrel is cylindrical with internal threads, wherein the external threads mate with the internal threads, the external threads and internal threads enabling rotation of the barrel around the shaft to become transformed into movement of the needle along the central axis, and wherein the movement is restricted to the portion of the barrel with threads.

7. A hollow needle assembly according to claim 1, wherein the back end of the hub protrudes through the open posterior end of the barrel and also through a locking cap, the locking cap is frictionally engaged to the open posterior end, and a flexible member is fitted inside the locking cap at the juncture of the locking cap and the open posterior end, permitting compression of the flexible member when the locking cap is pushed towards the sharp open end along the central axis, resulting in movement of the flexible member towards the central axis, thereby locking the needle in a position along the central axis.

8. A hollow needle assembly according to claim 1, wherein the back end of the hub protrudes through the open posterior end and also through a locking cap, the locking cap contains internal threads and the posterior end contains external threads, whereby the internal threads mate with the external threads, and the compression of the flexible member is accomplished by tightening the locking cap around the posterior end, thereby locking the needle in a position along the central axis..

9. A hollow needle assembly according to claim 8, wherein the flexible member is made of rubber or plastic.

10. A hollow needle assembly according to claim 8, wherein the flexible member is configured as a hollow O-ring or an O-ring with a C-shaped cross-section.

11. A hollow needle assembly according to claim 1, wherein the hub and the barrel are made out of plastic.

12. A hollow needle assembly according to claim 8, wherein a spring is fitted in the internal chamber of the barrel, around the shaft and between the front end of the hub and the open anterior end of the barrel, for retraction of the needle within the barrel, after the flexible member is relaxed by loosening the locking cap.

13. A hollow needle assembly according to claim 1, wherein the locking cap is also the second annular stop.

14. A hollow needle assembly according to claim 1, wherein the mechanism of mating the blunt open end with an inlet of a measurement apparatus, includes a locking mechanism for keeping the hollow needle assembly attached to the measurement apparatus, for safe use.

15. A hollow needle assembly according to claim 1, wherein the fully extended shaft, outside the barrel, has a length that is in the approximate range of about 5 mm to about 30 mm.

16. A hollow needle assembly according to claim 1, wherein the blunt open end is located along a second axis, the second axis fixed by the blunt open end and a length portion of the passage adjacent to the blunt open end, and wherein the second axis is different from the central axis.

17. A hollow needle assembly according to claim 1, wherein the central axis is parallel to a length portion of the barrel.

18. A method of filling a measurement apparatus with blood by engaging the blunt open end of the hollow needle assembly according to claim 1, to an inlet of a measurement apparatus, and piercing a blood vessel with the sharp open end of the hollow needle assembly according to claim 1.

19. A method of filling a measurement apparatus with blood according to claim 17, wherein the blood vessel is an artery or a vein.

20. A hollow needle assembly according to claim 1, wherein the first flow path at the back end of the hub also comprises a measuring apparatus with a second flow path, wherein the second flow path is integrated with the first flow path, and wherein the blunt open end coincides with a vent of the measurement apparatus.

21. A hollow needle assembly according to claim 20, wherein the measurement apparatus comprises one or more that one flow path, and the wherein the flow path is defined from a sample inlet of the measurement apparatus, to a vent of the measurement apparatus.

22. A hollow needle assembly according to claim 20, wherein the measurement apparatus comprises one or more than one vent.

23. A hollow needle assembly according to claim 20, wherein the measurement apparatus comprises one or more than one optical chamber along the flow path, for spectroscopic measurement.

24. A hollow needle assembly according to claim 20, wherein the measurement apparatus comprises one or more than one biosensor along the flow path, for analyte measurement.

25. A hollow needle assembly according to claim 20, wherein the measurement apparatus comprises one or more than one reagent, along the flow path.

26. A hollow needle assembly according to claim 20, wherein the measurement apparatus comprises a filtration chamber along the flow path, for extracting plasma from whole blood.

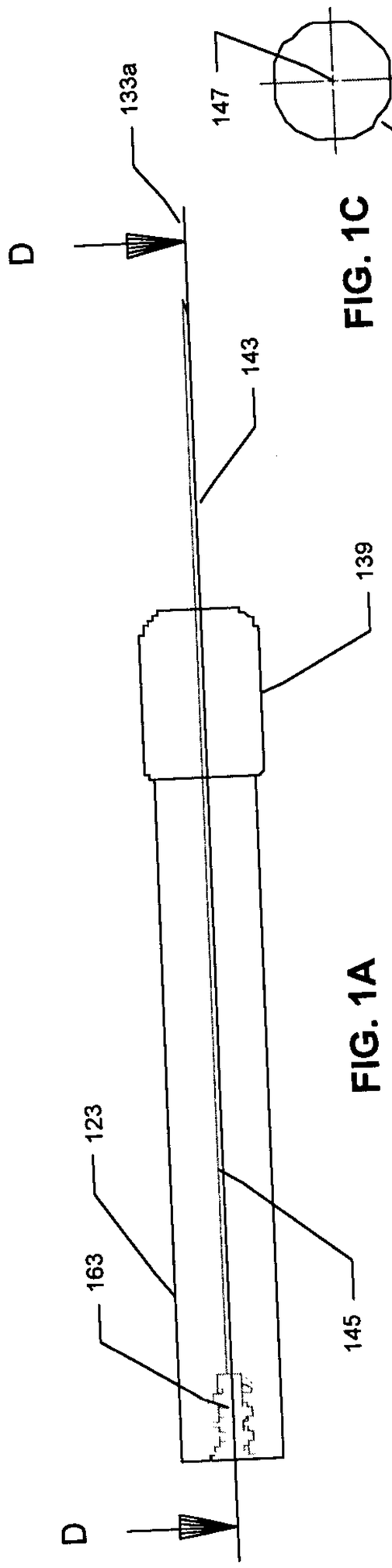


FIG. 1A

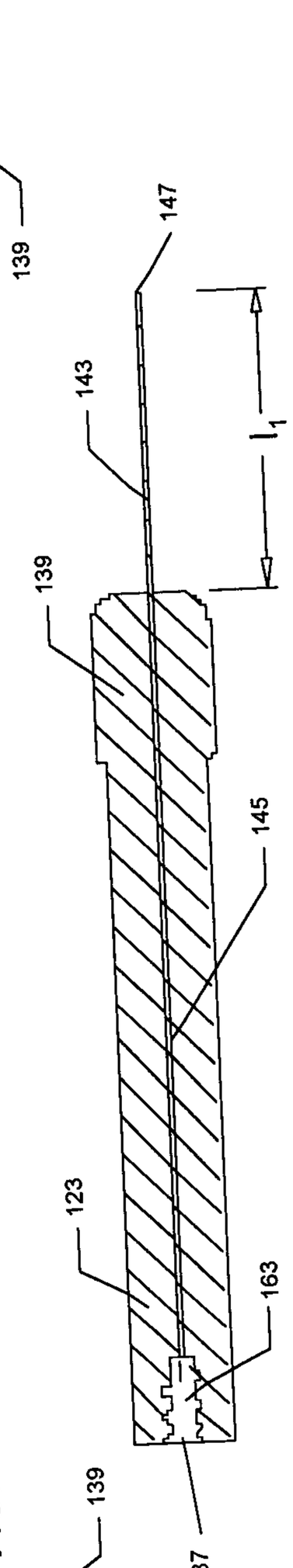


FIG. 1B

FIG. 1C

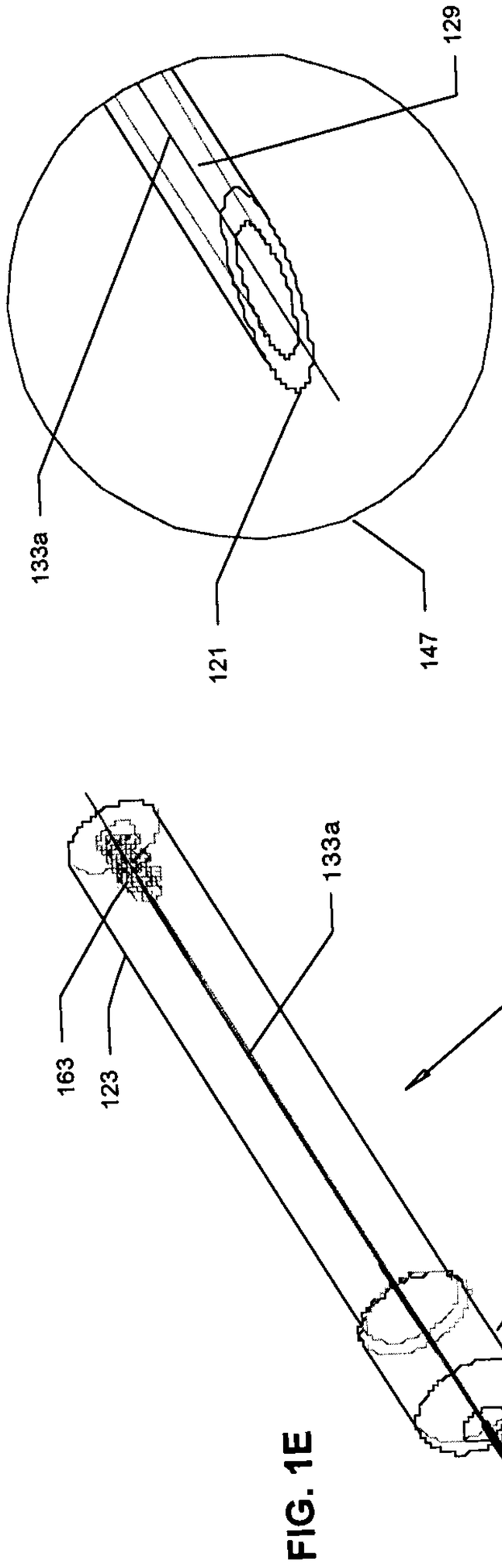


FIG. 1D

FIG. 1E

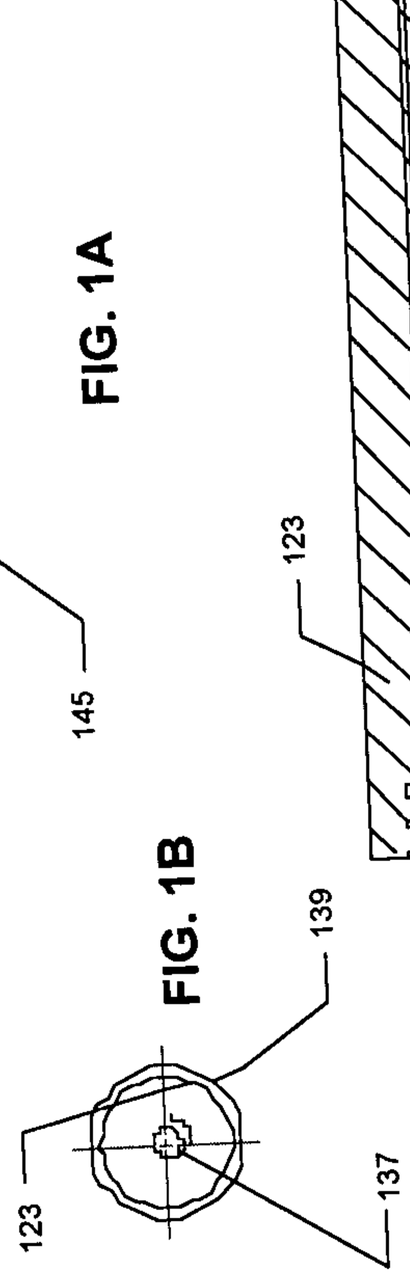


FIG. 1F

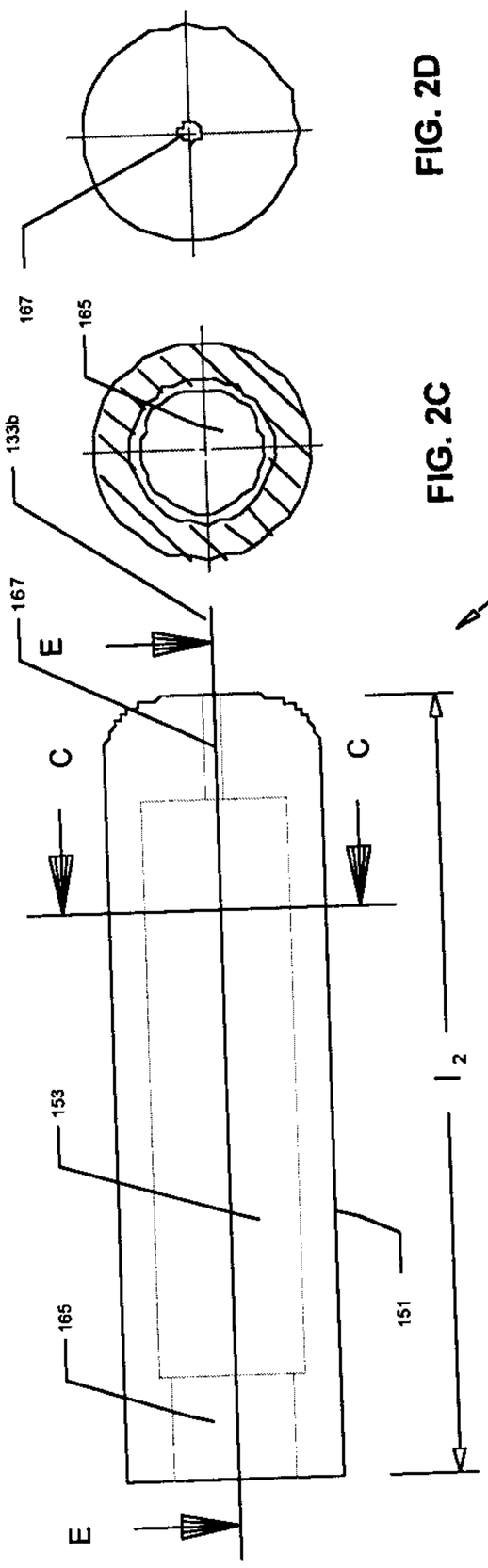


Fig. 2A

Fig. 2B

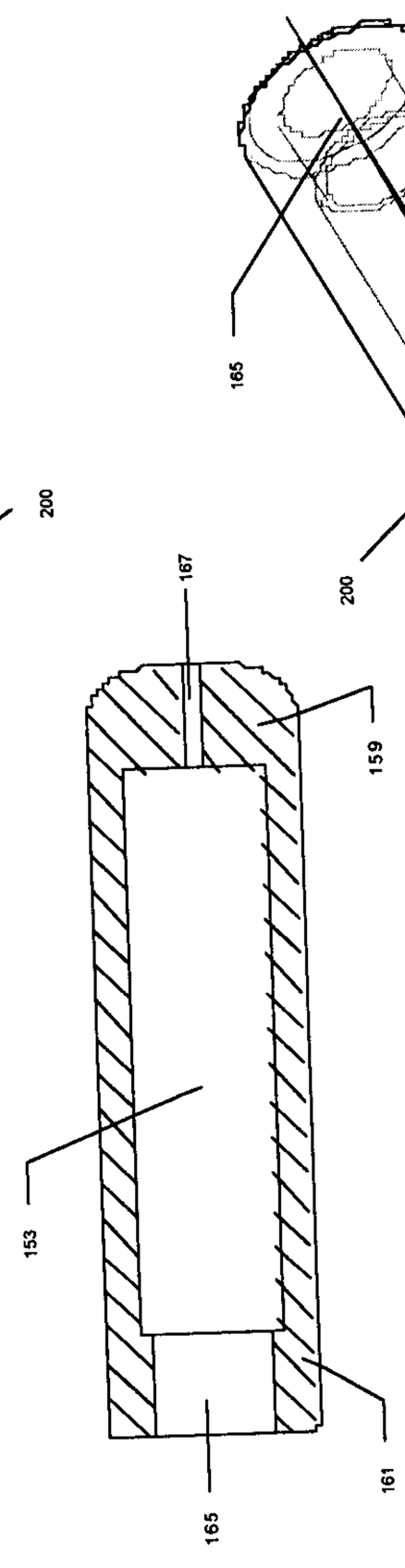


FIG. 2E

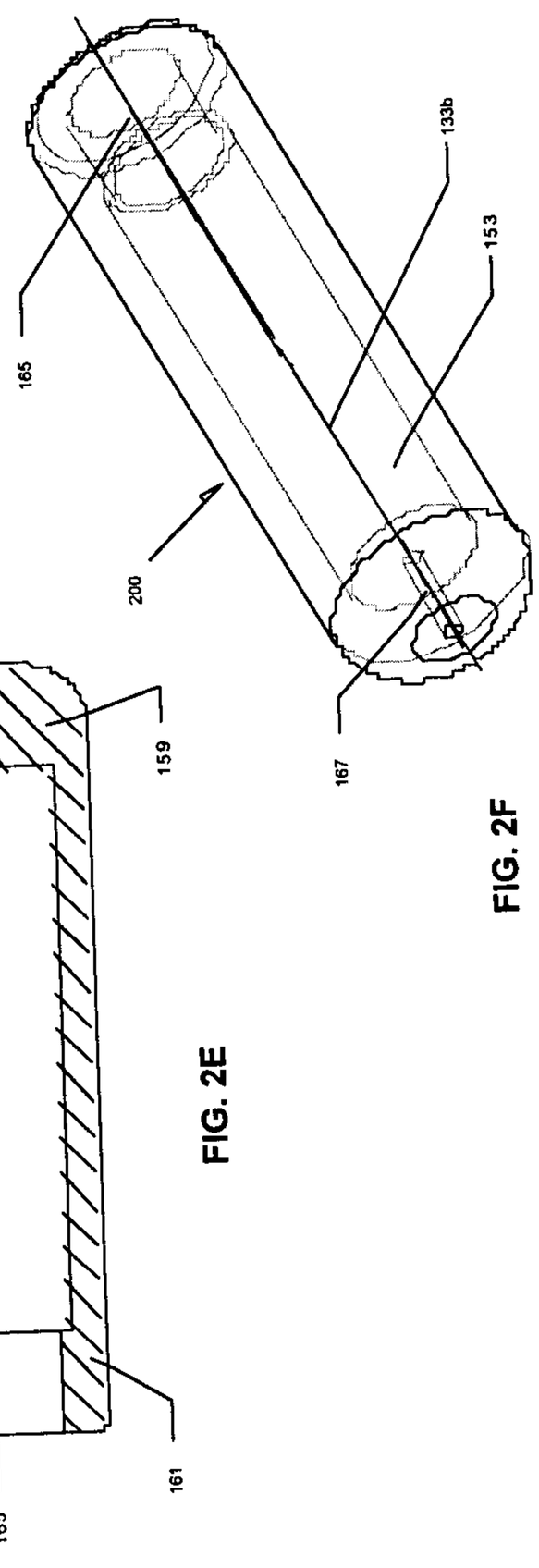


FIG. 2F

FIG. 2C

FIG. 2D

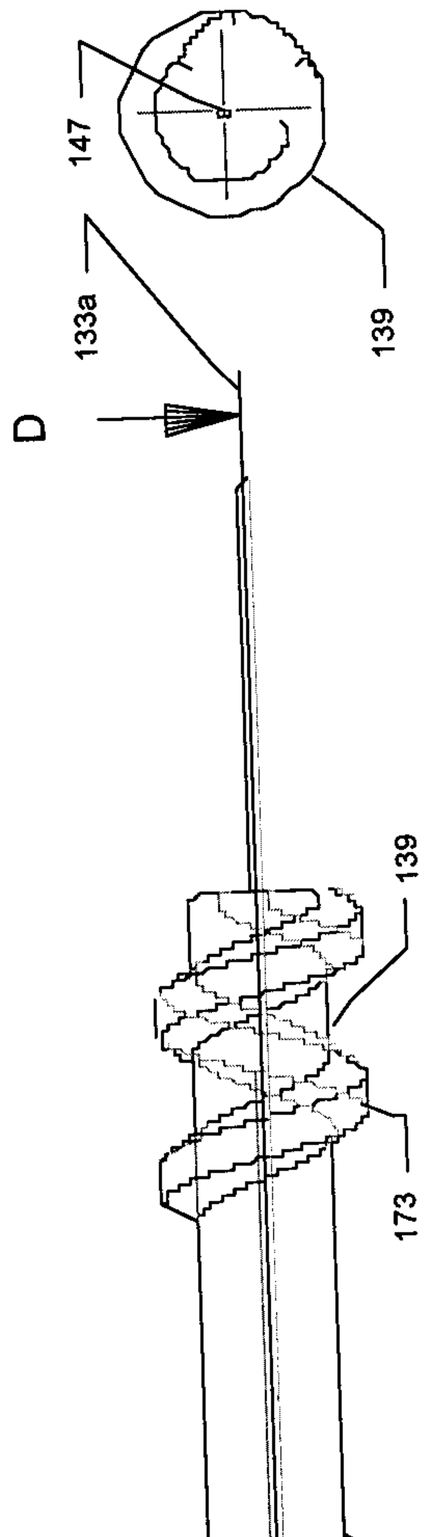


FIG. 3A

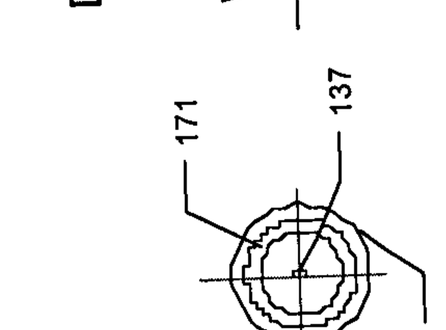


FIG. 3B

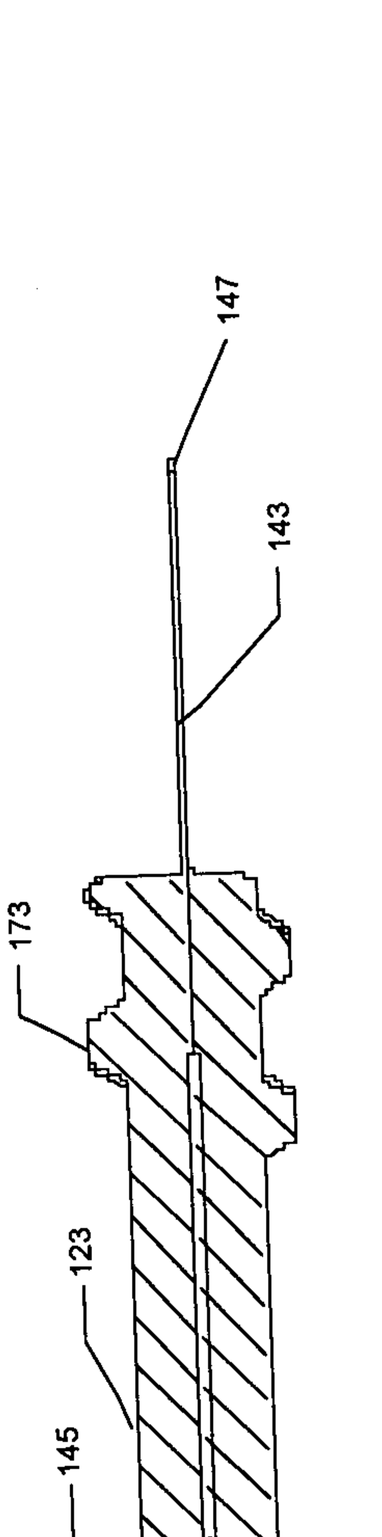


FIG. 3C

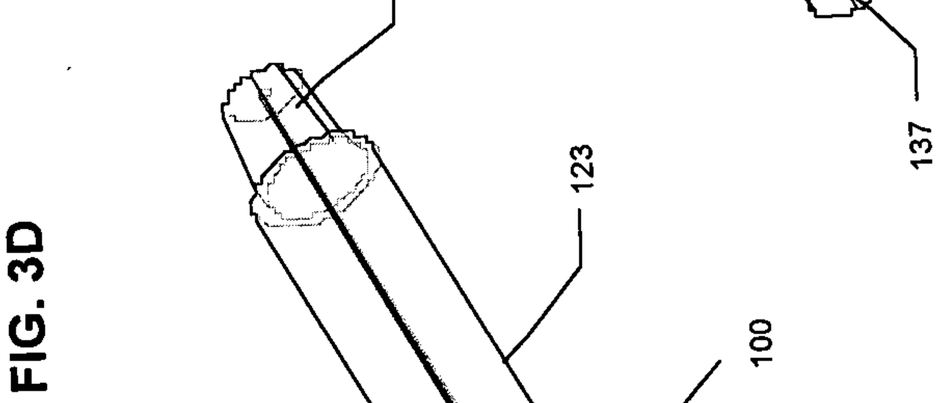


FIG. 3D

FIG. 3E

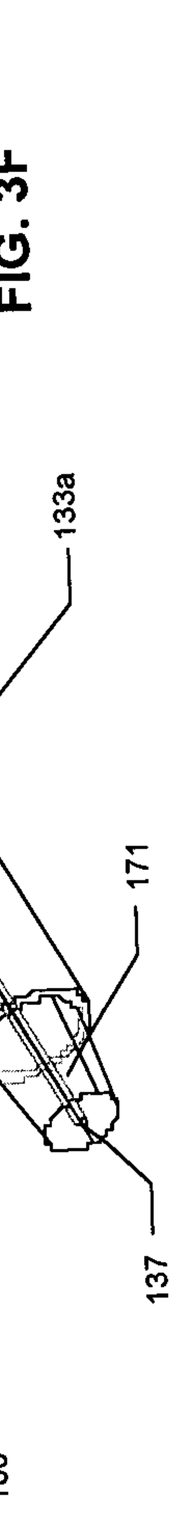


FIG. 3F

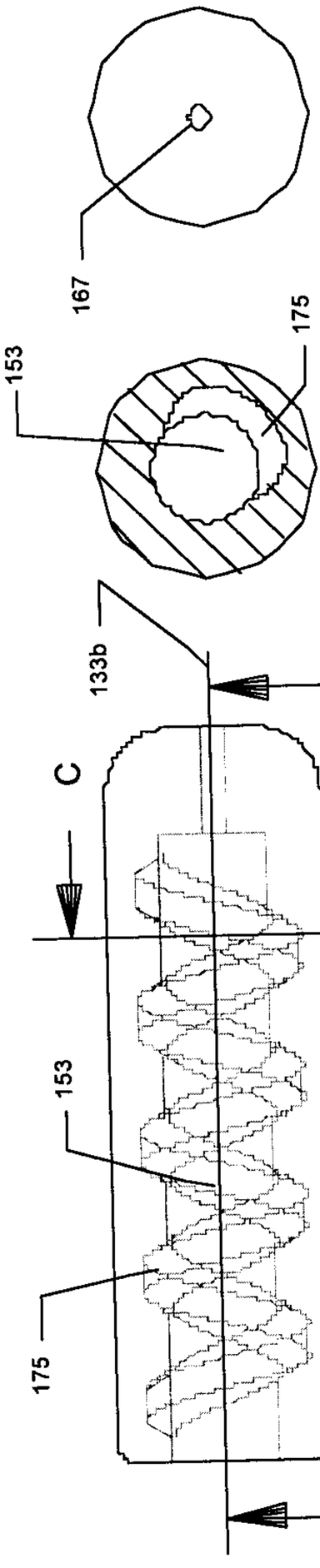


FIG. 4A

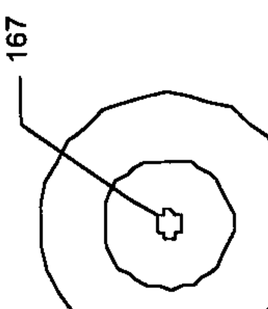


FIG. 4B

FIG. 4C

FIG. 4D

FIG. 4E

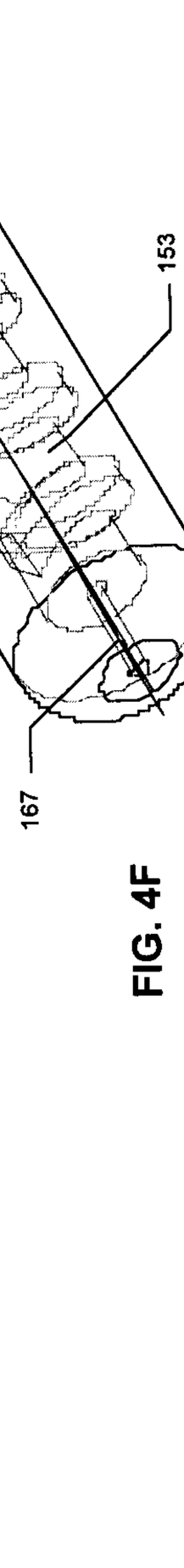


FIG. 4F

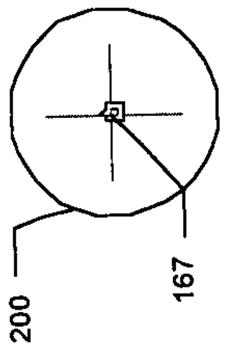


FIG. 5C

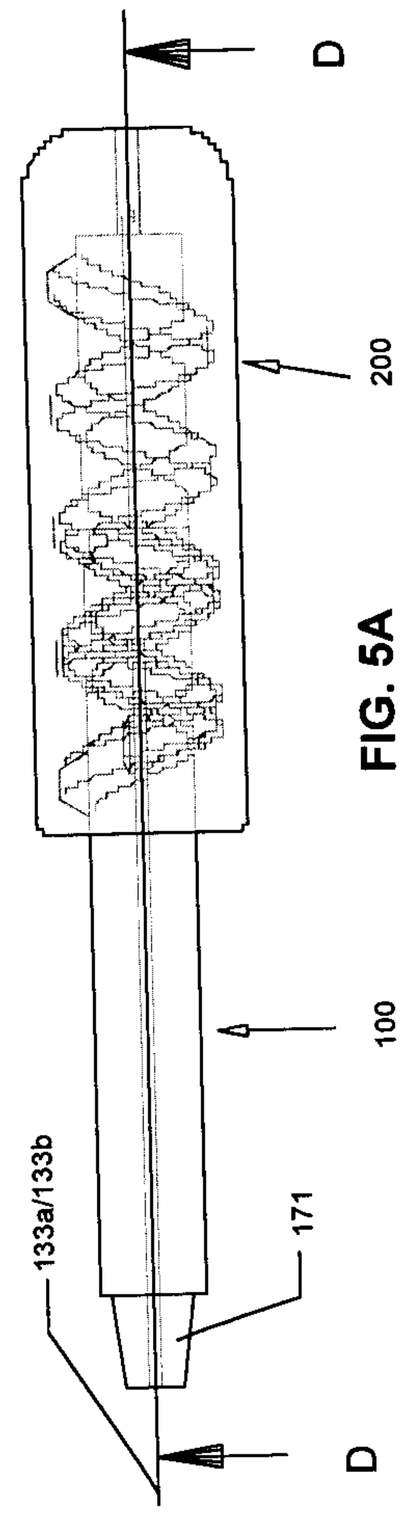


FIG. 5A

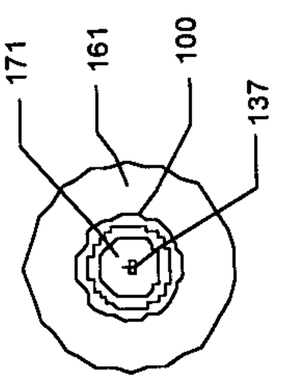


FIG 5B

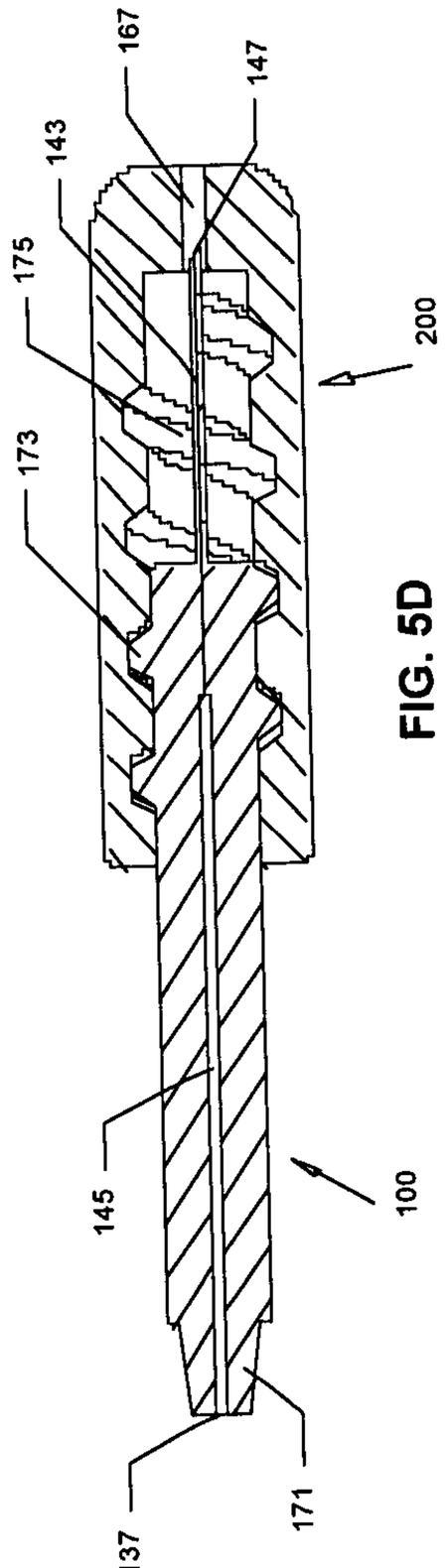


FIG. 5D

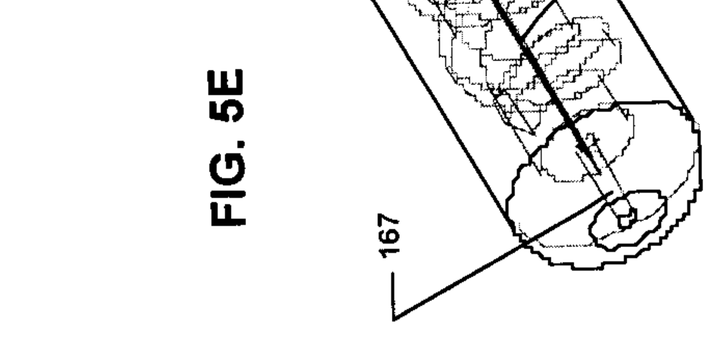


FIG. 5E

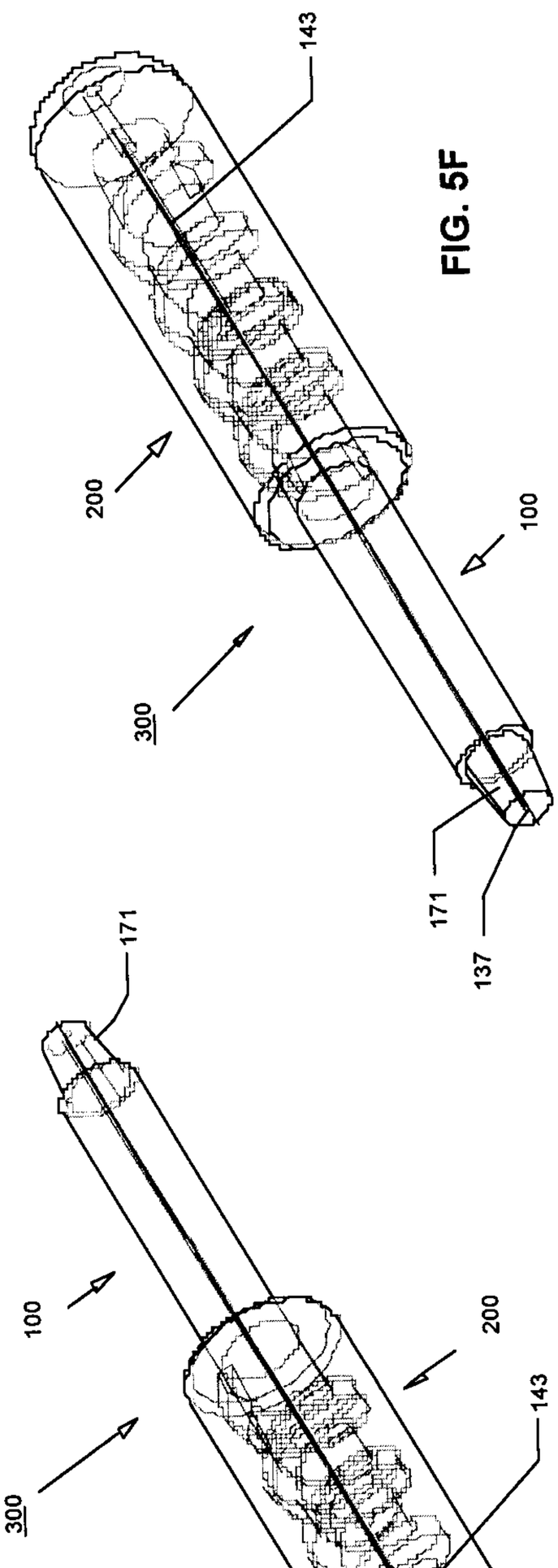


FIG. 5F

FIG. 6A

FIG. 6B

FIG. 6D

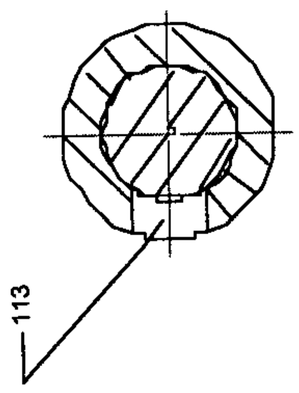


FIG. 6C

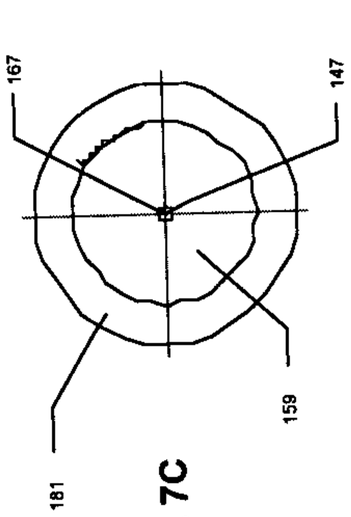


FIG. 7C

FIG. 7A

FIG. 7D

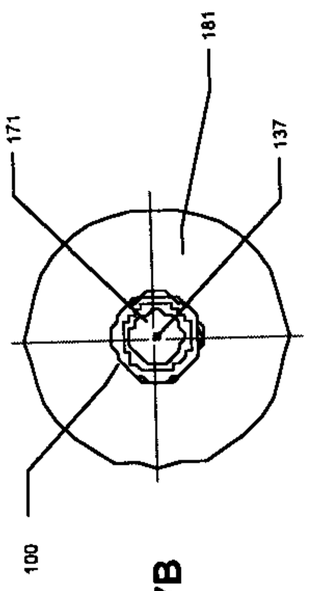


FIG. 7B

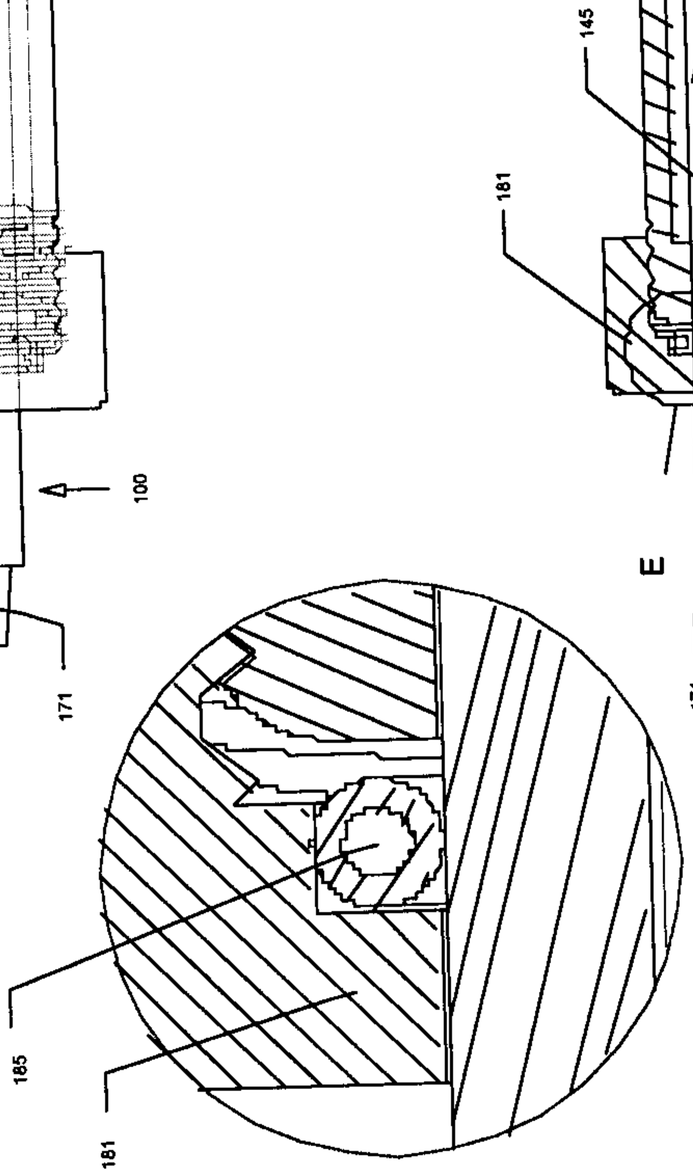


FIG. 7E

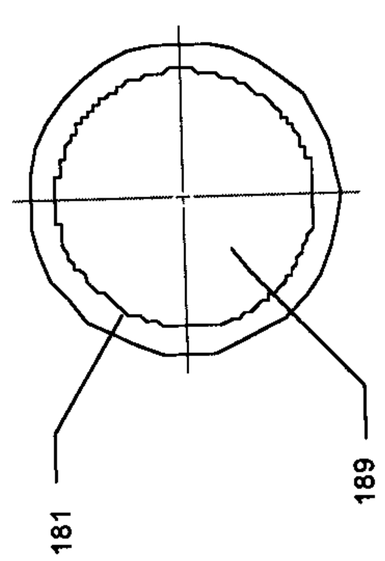


FIG. 8C

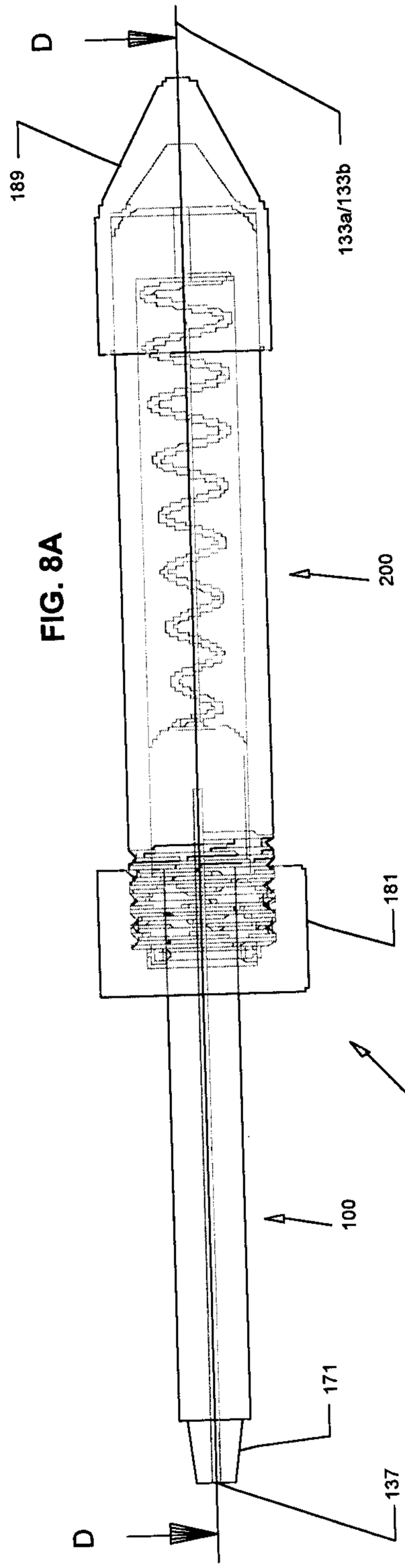


FIG. 8A

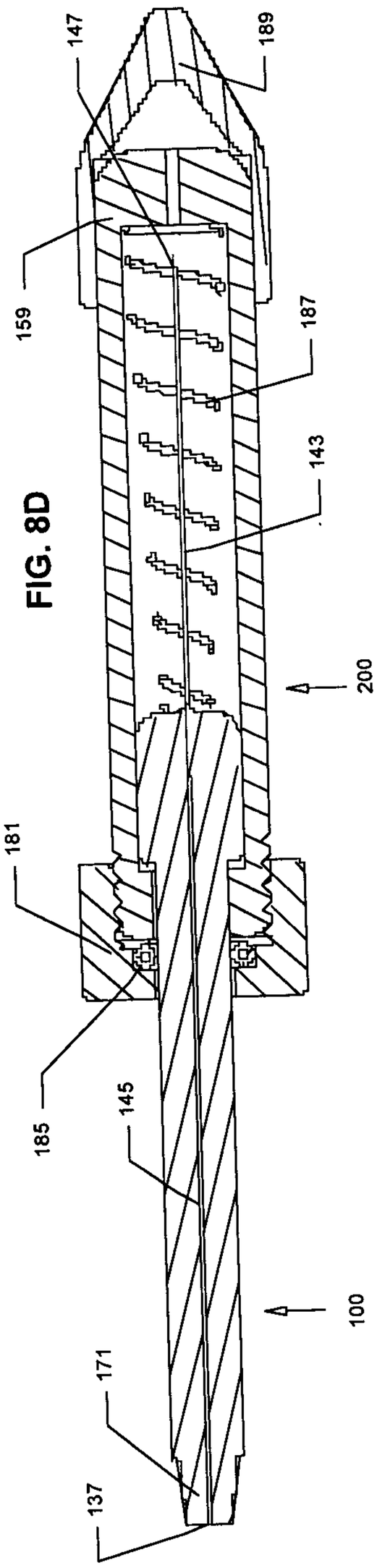


FIG. 8D

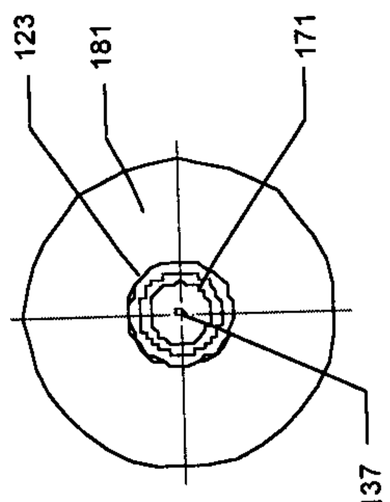


FIG. 8B

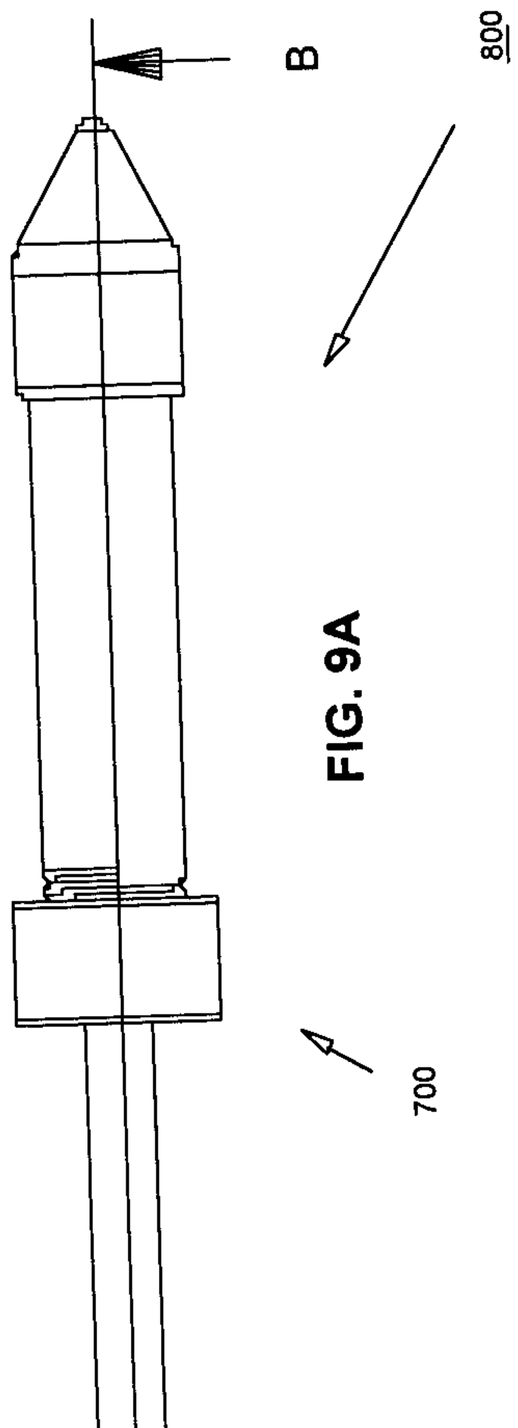


FIG. 9A

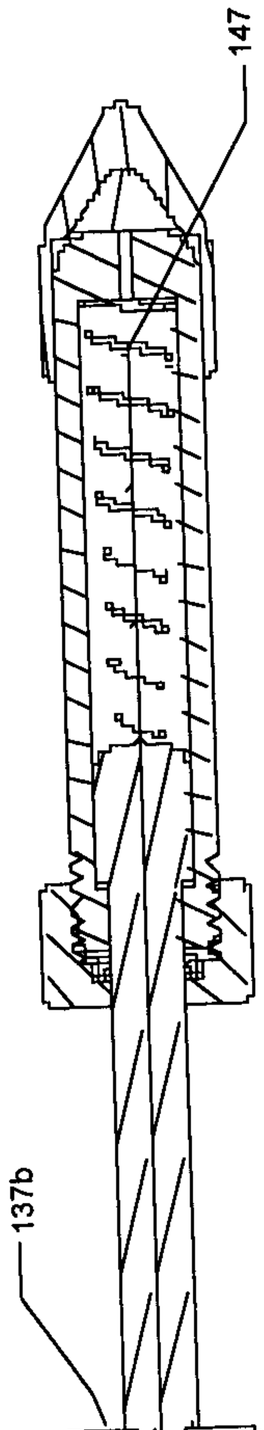


FIG. 9B

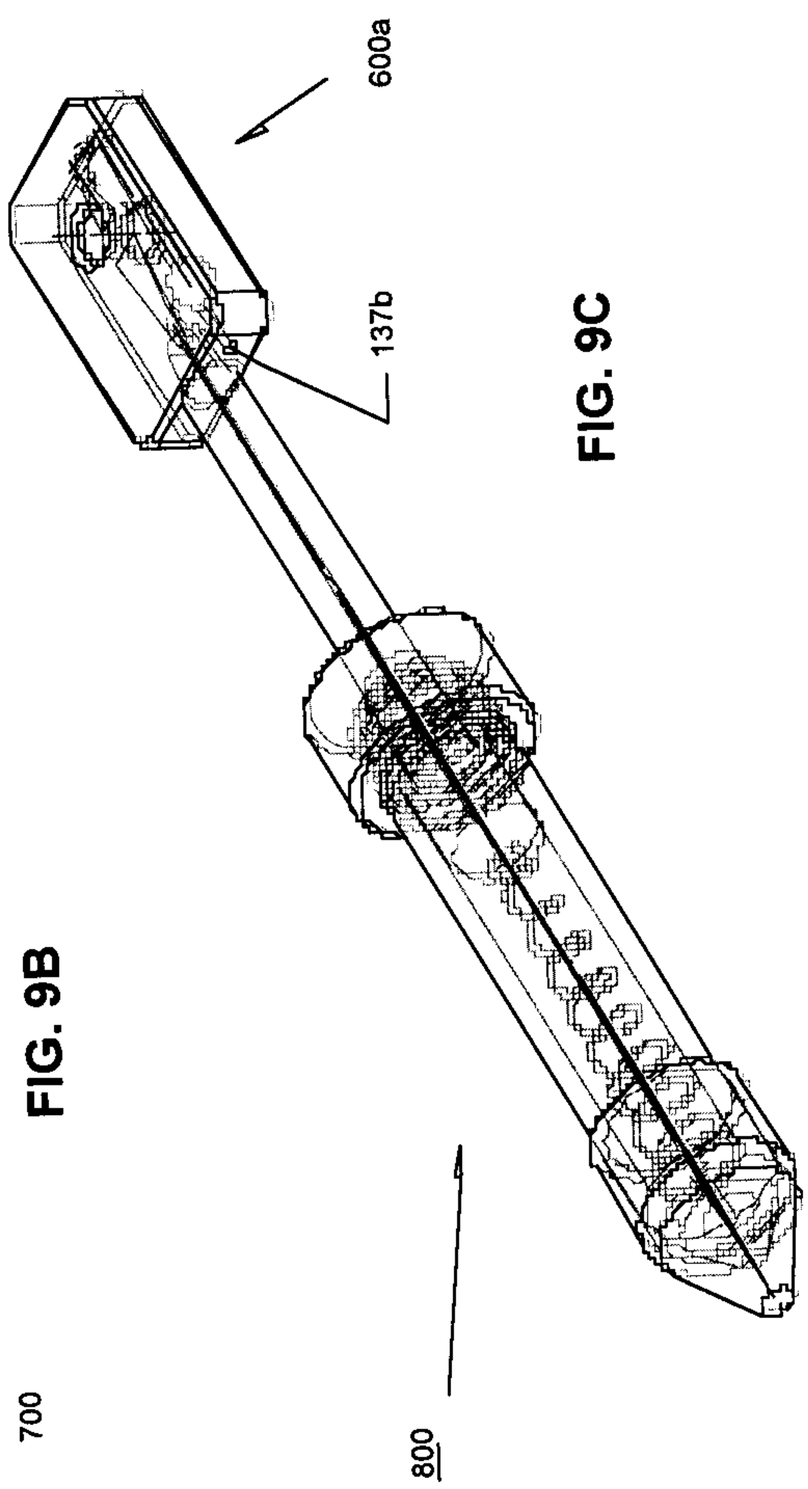


FIG. 9C

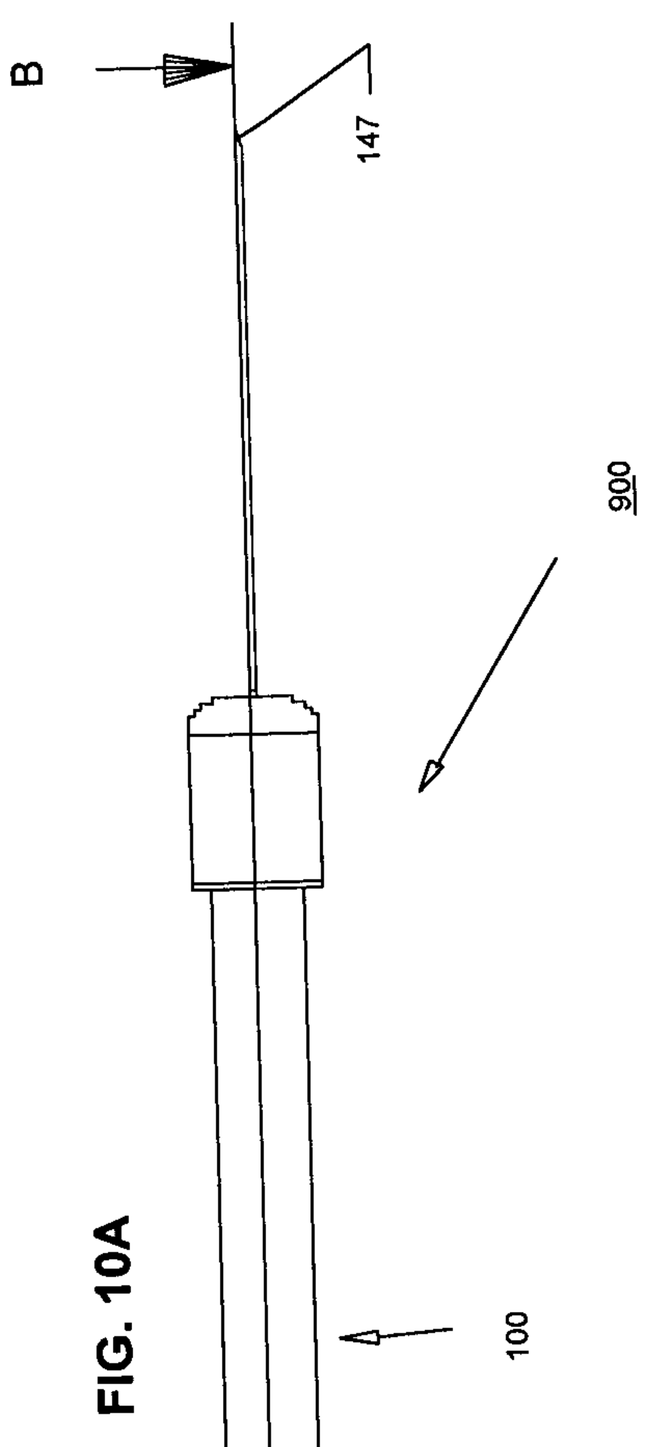


FIG. 10A

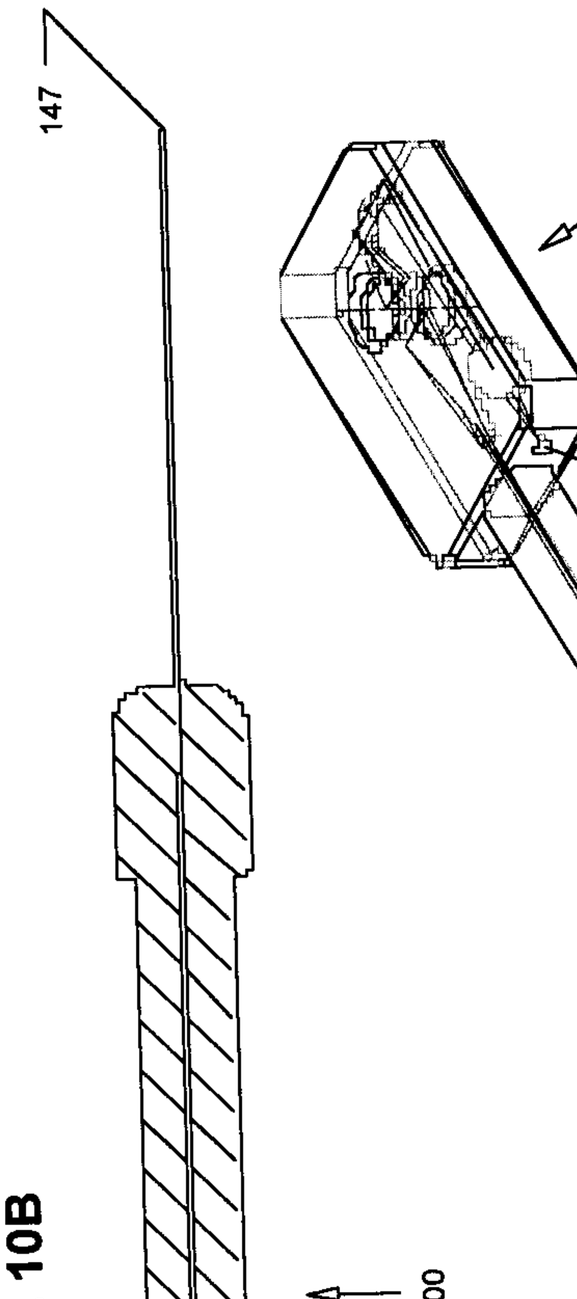


FIG. 10B

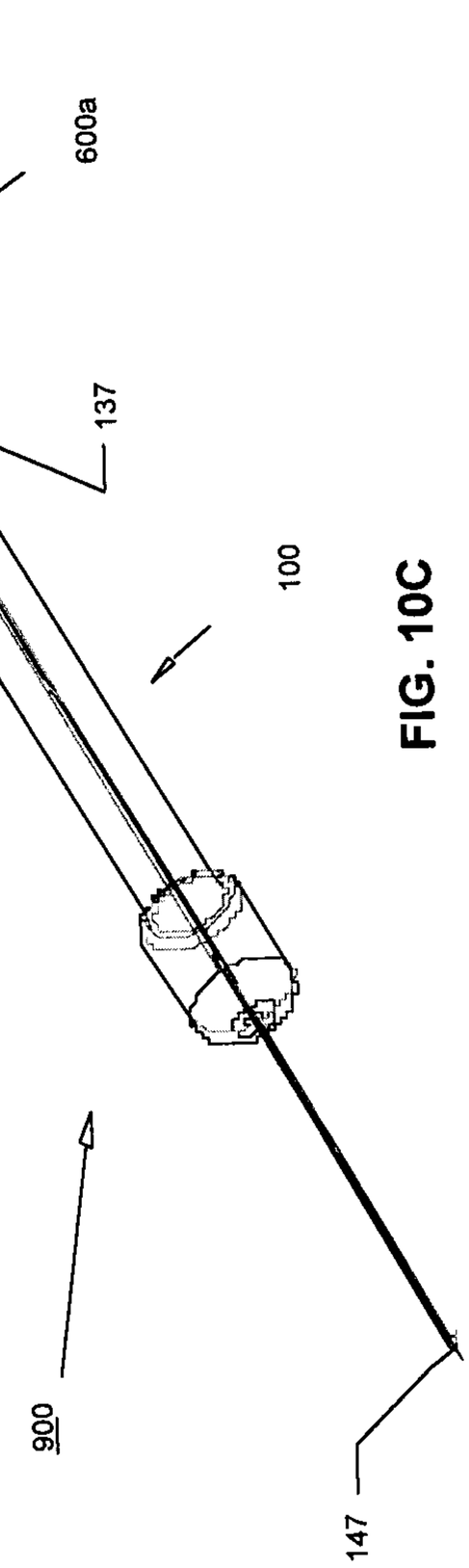


FIG. 10C

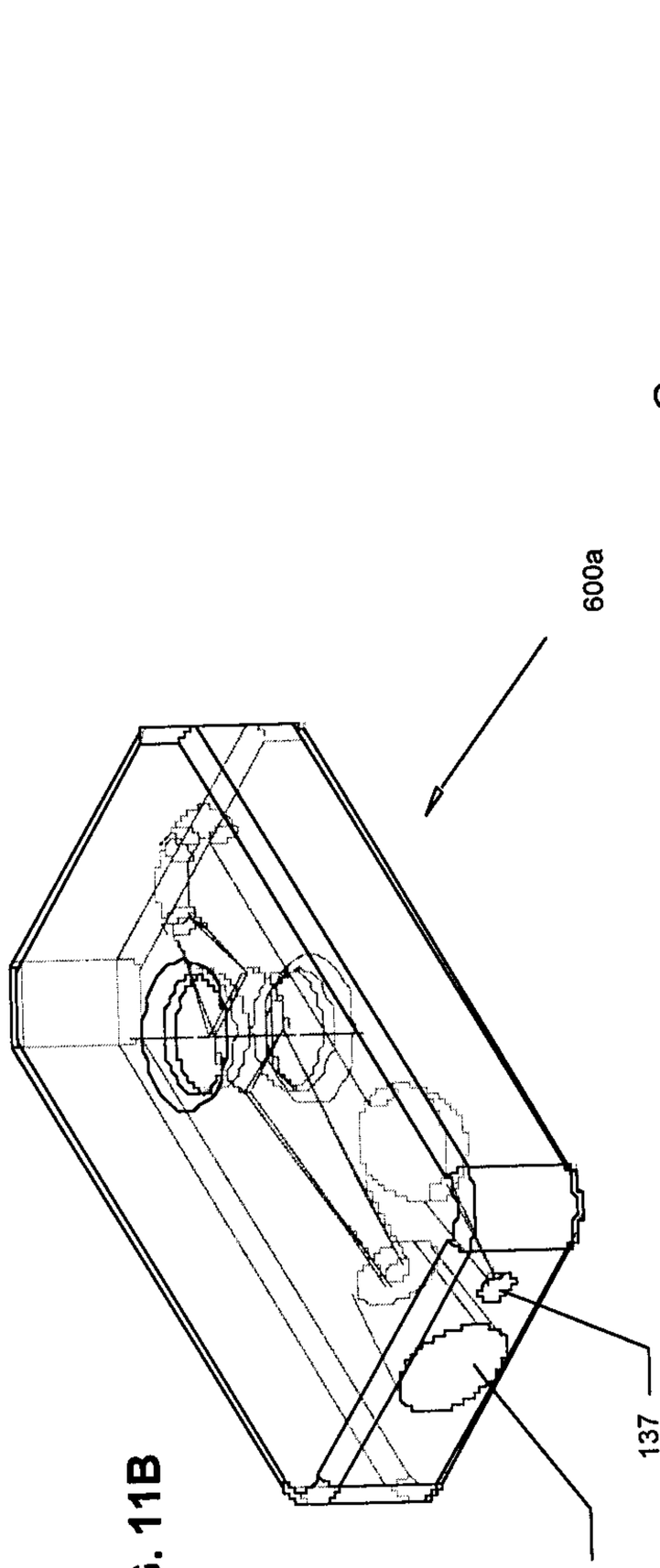


FIG. 11B

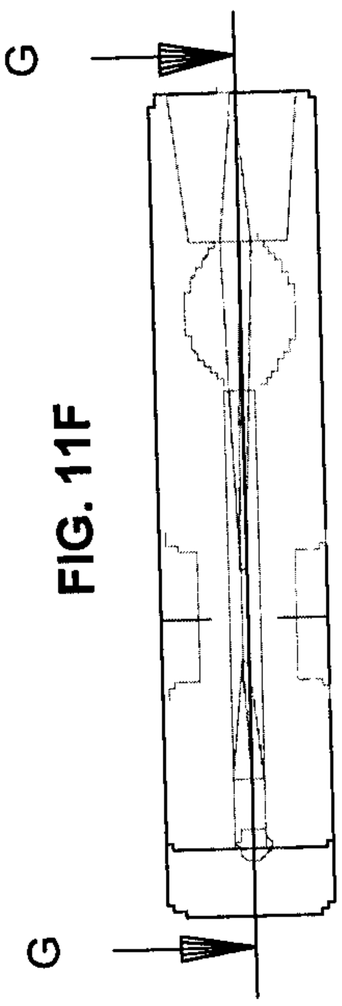


FIG. 11F

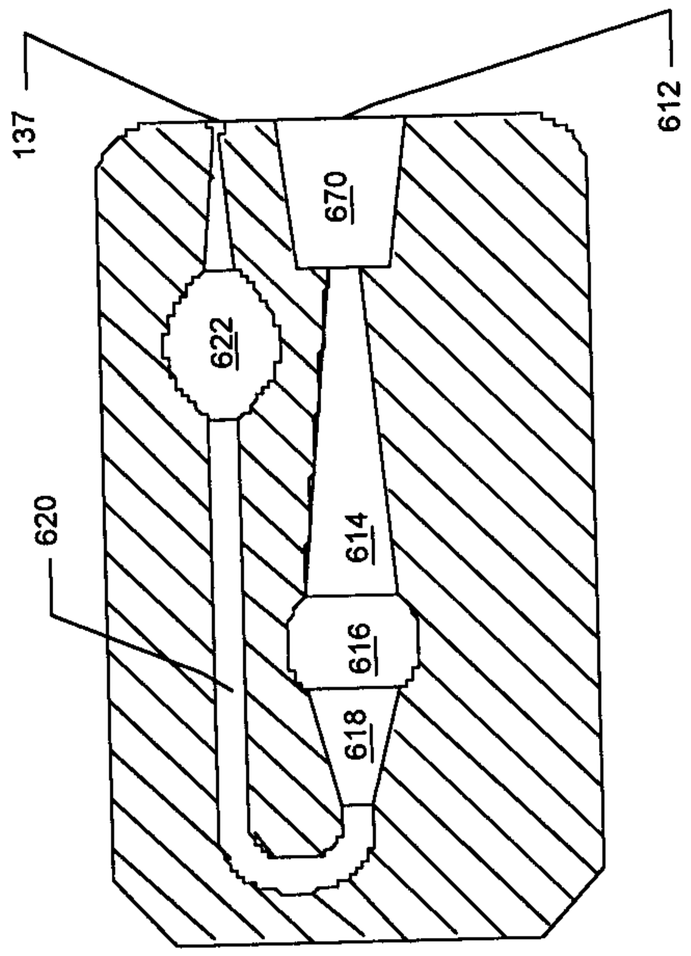


FIG. 11G

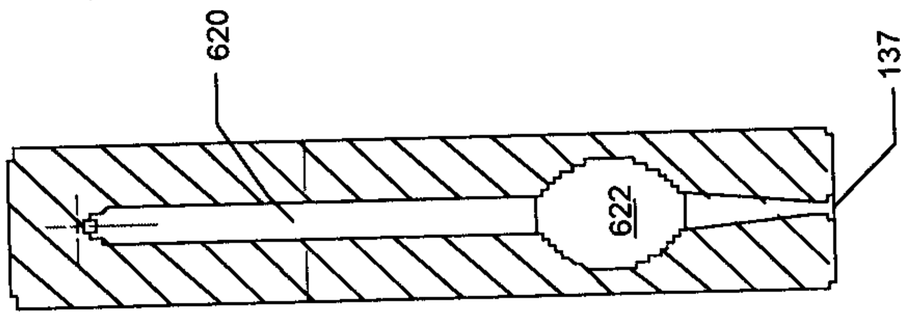


FIG. 11E

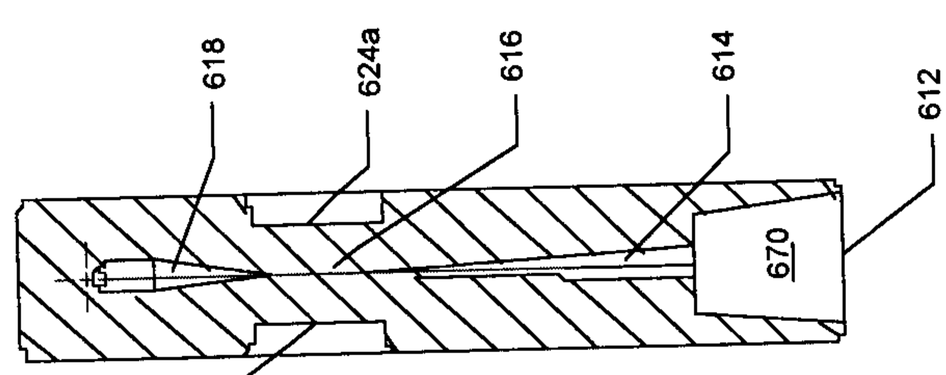


FIG. 11D

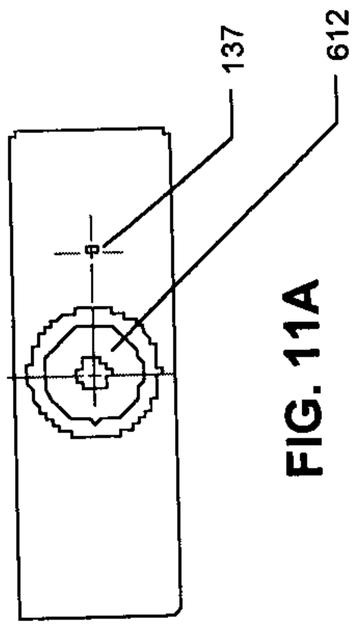


FIG. 11A

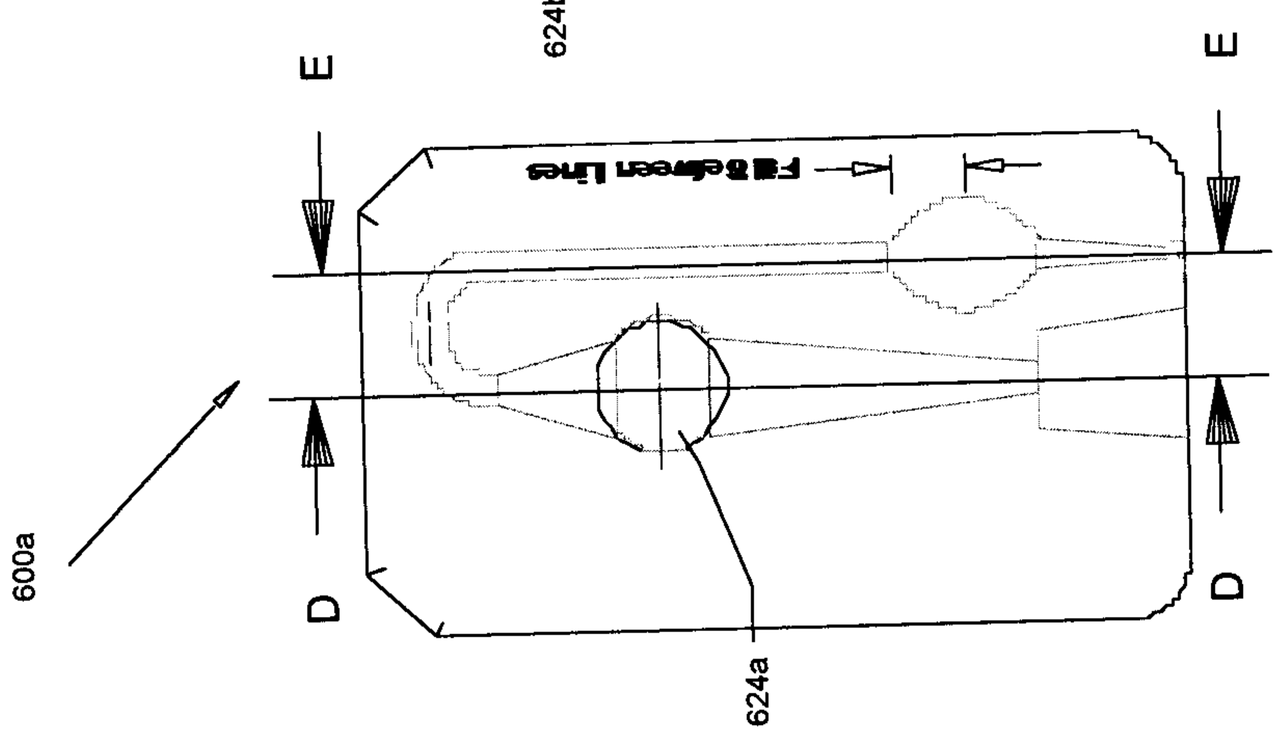


FIG. 11C

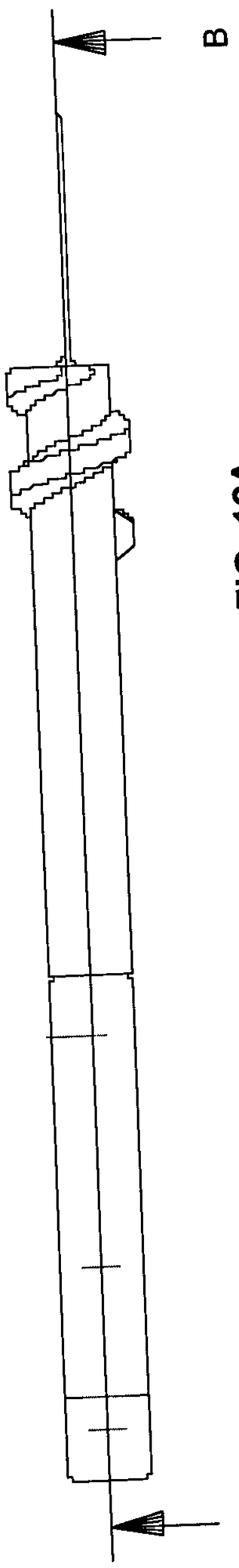


FIG. 12A

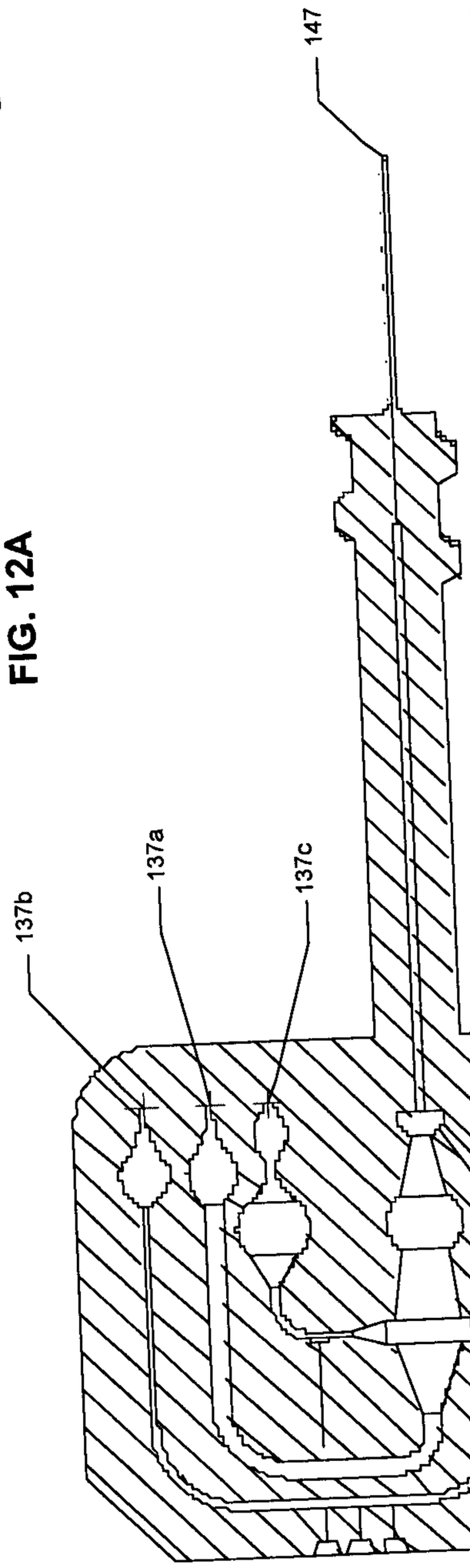


FIG. 12B

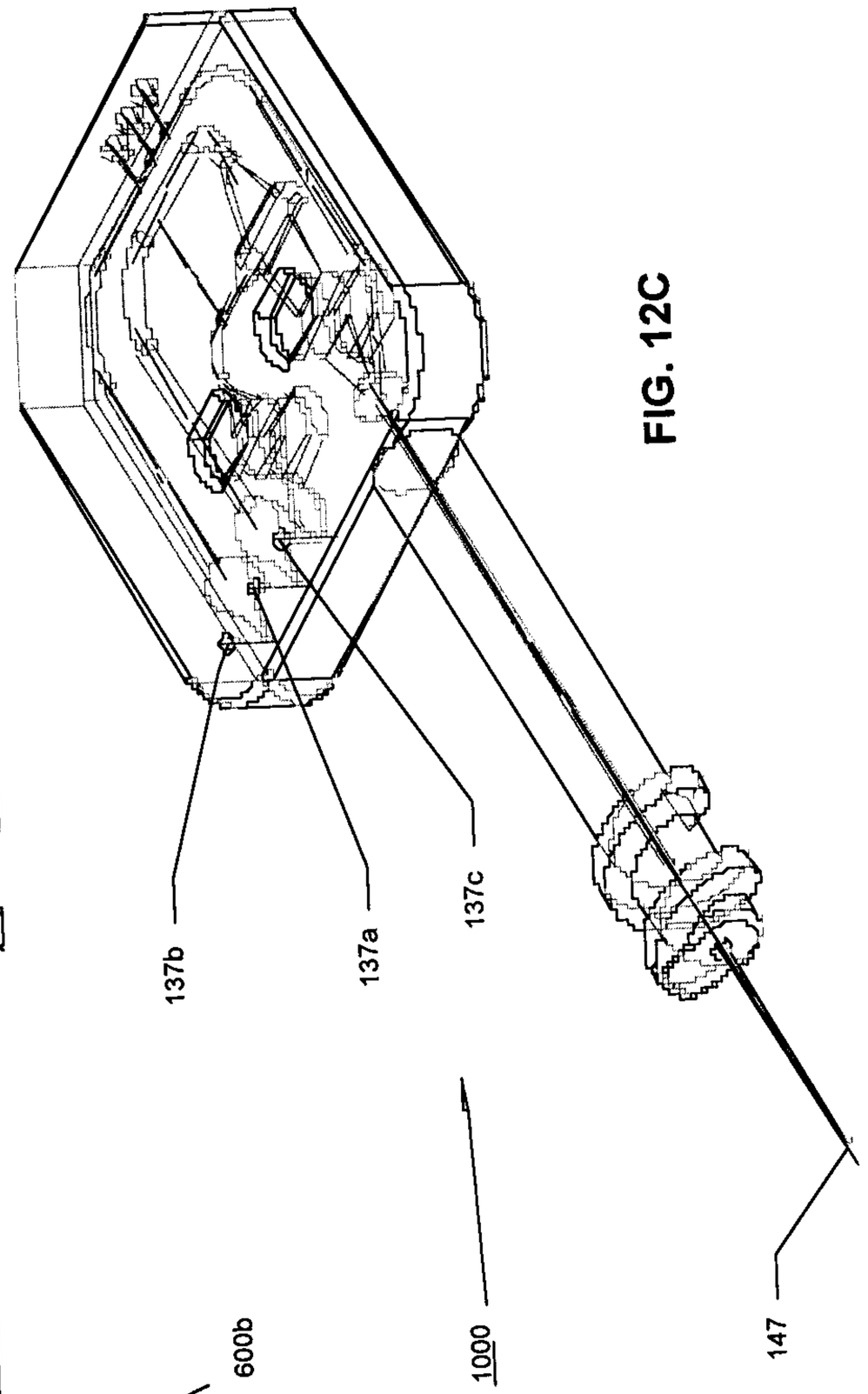


FIG. 12C

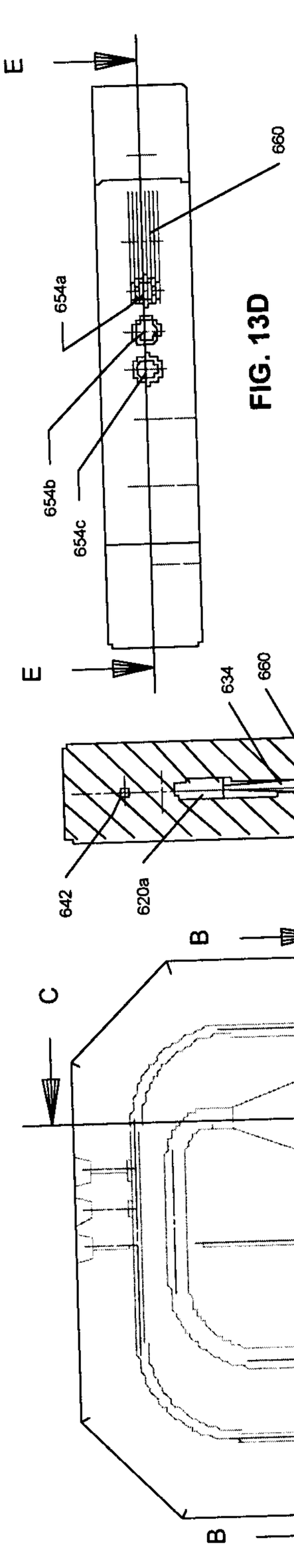


FIG. 13D

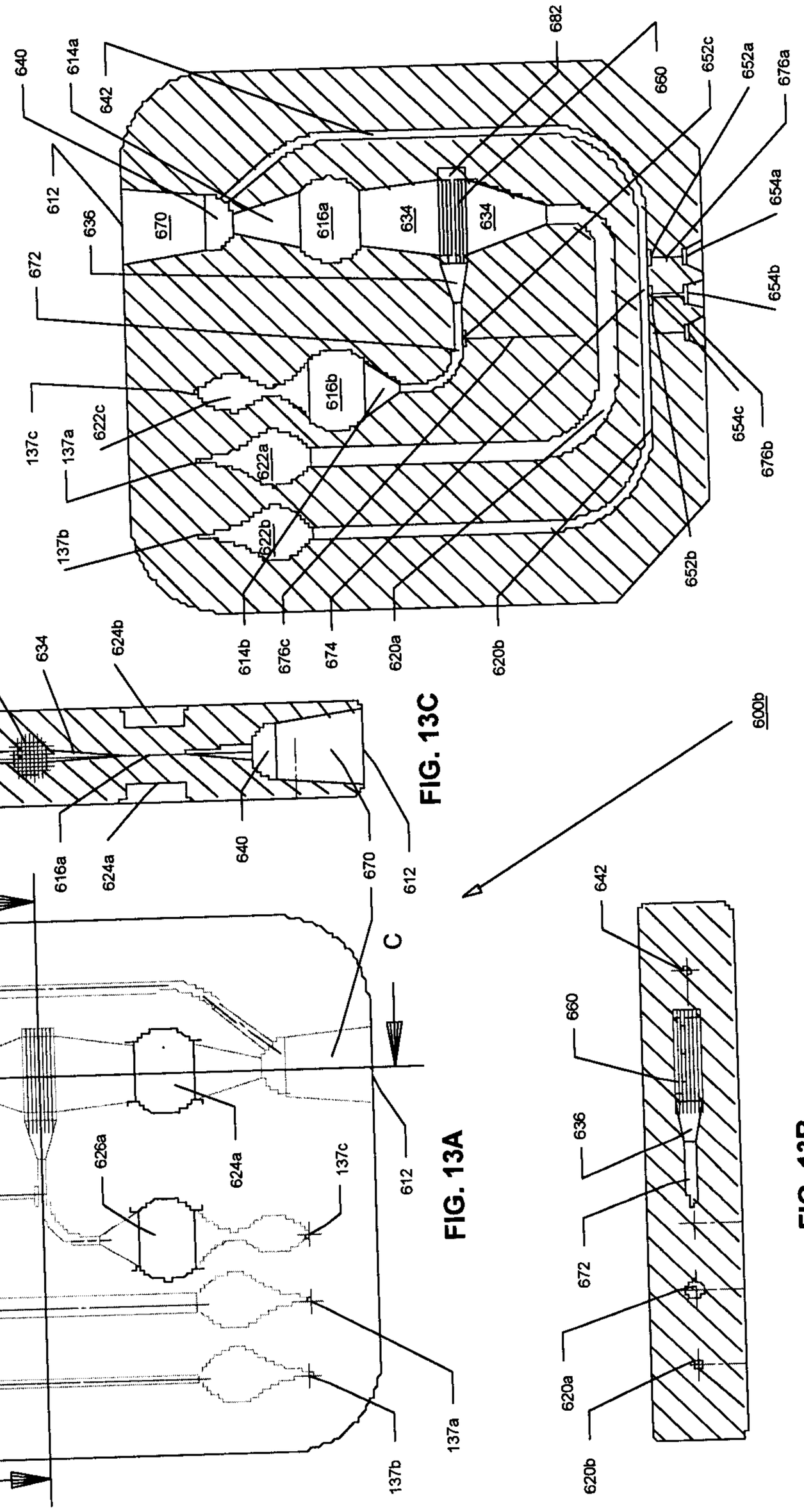


FIG. 13E

FIG. 13C

FIG. 13A

FIG. 13B

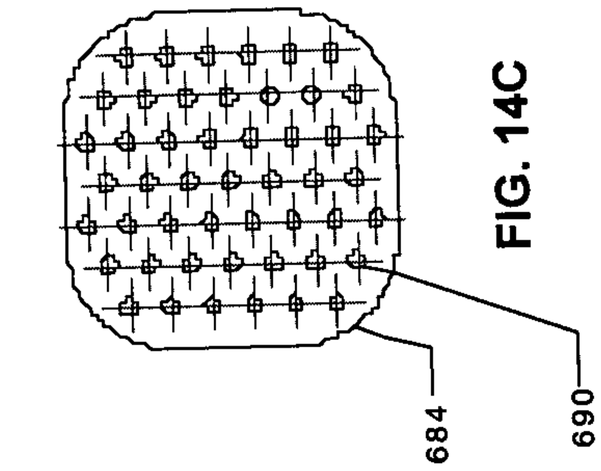


FIG. 14C

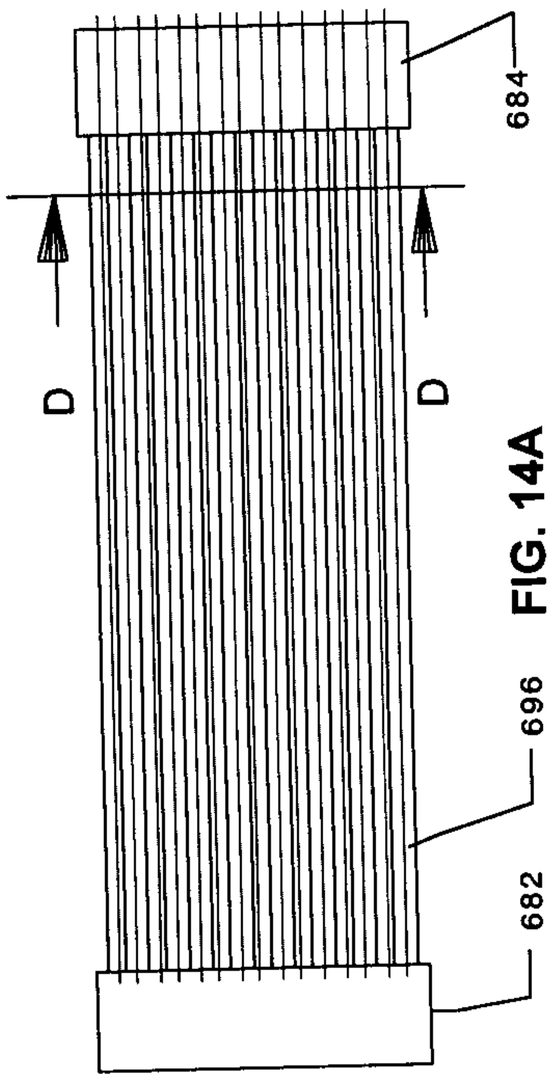


FIG. 14A

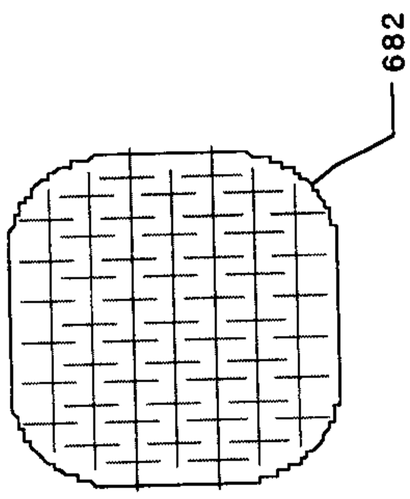


FIG. 14B

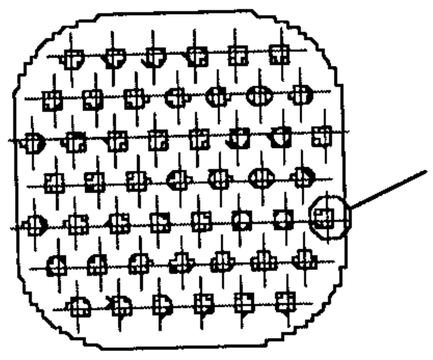


FIG. 14D

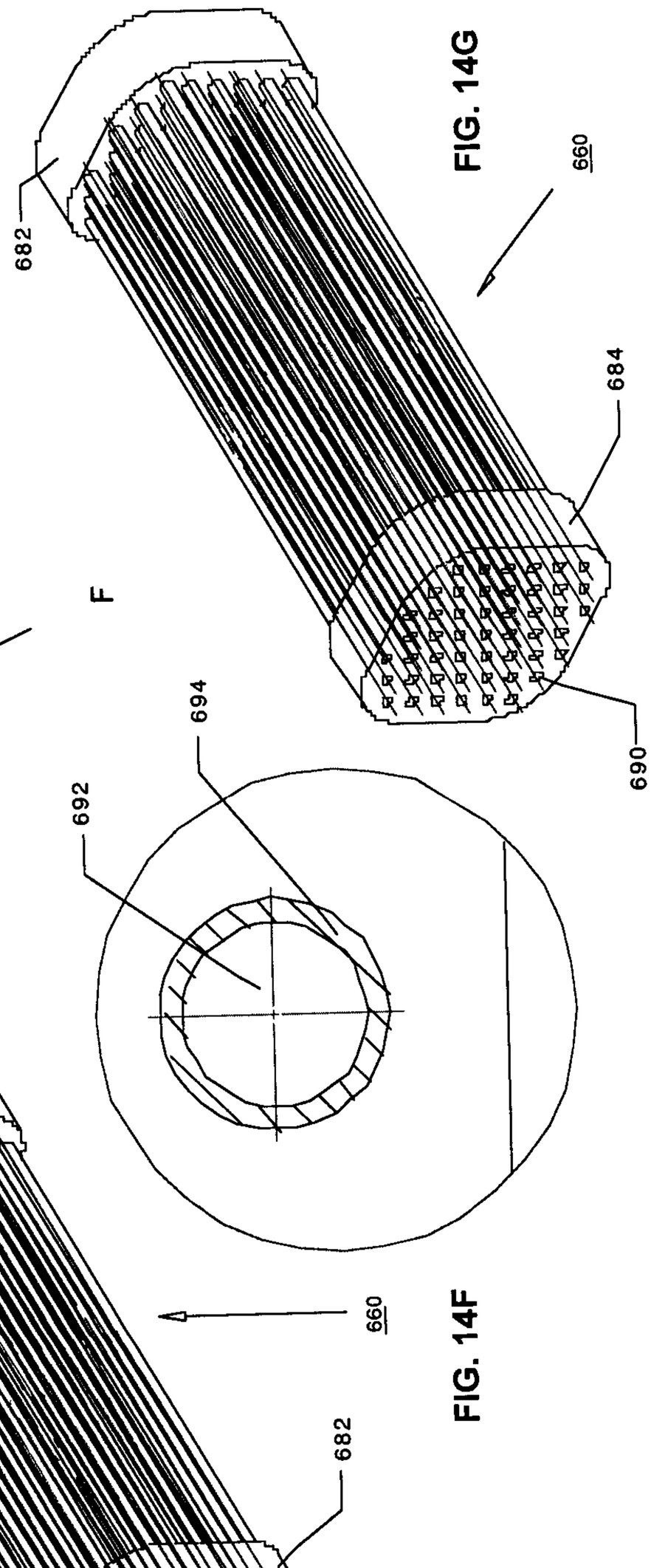


FIG. 14G

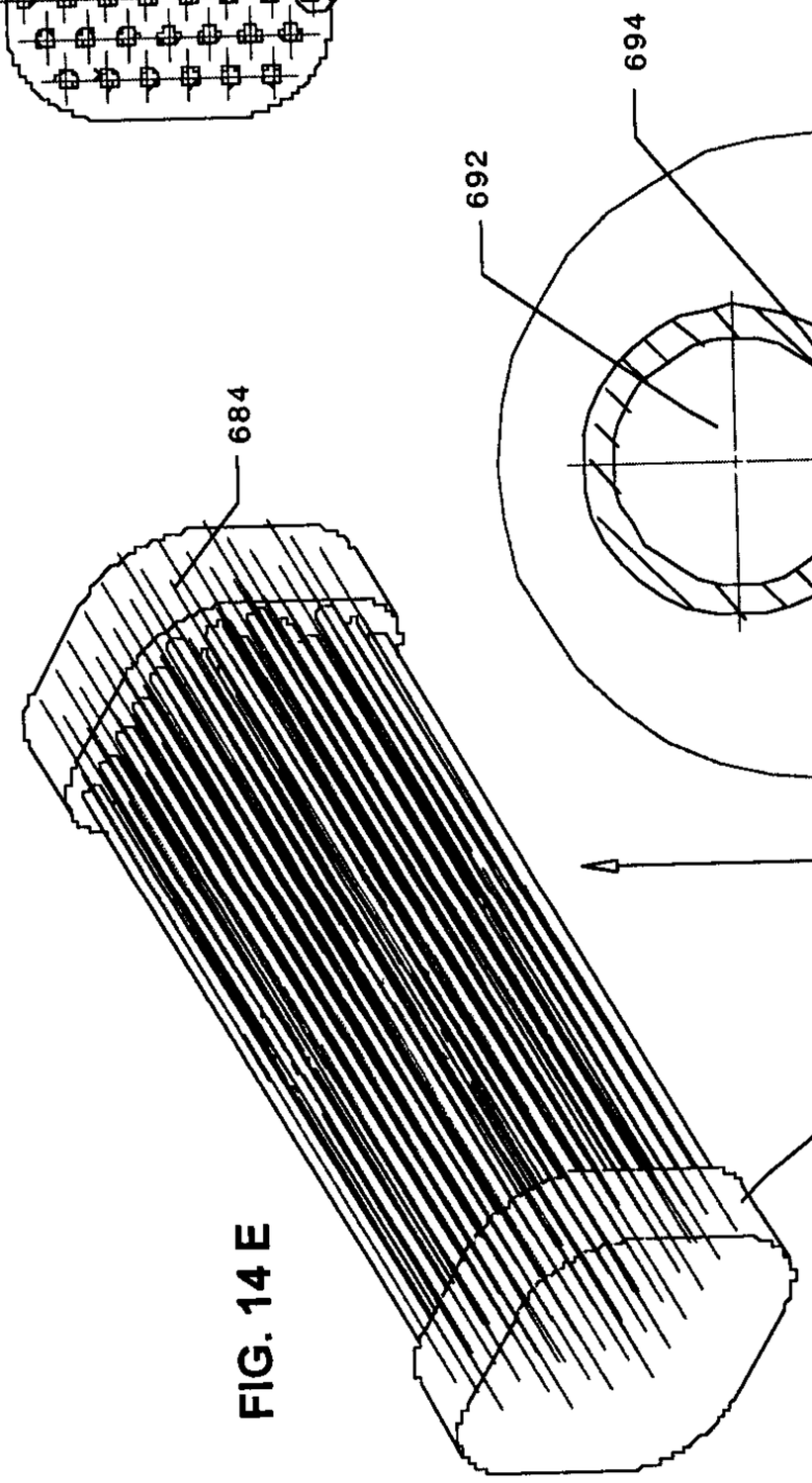


FIG. 14E

FIG. 14F

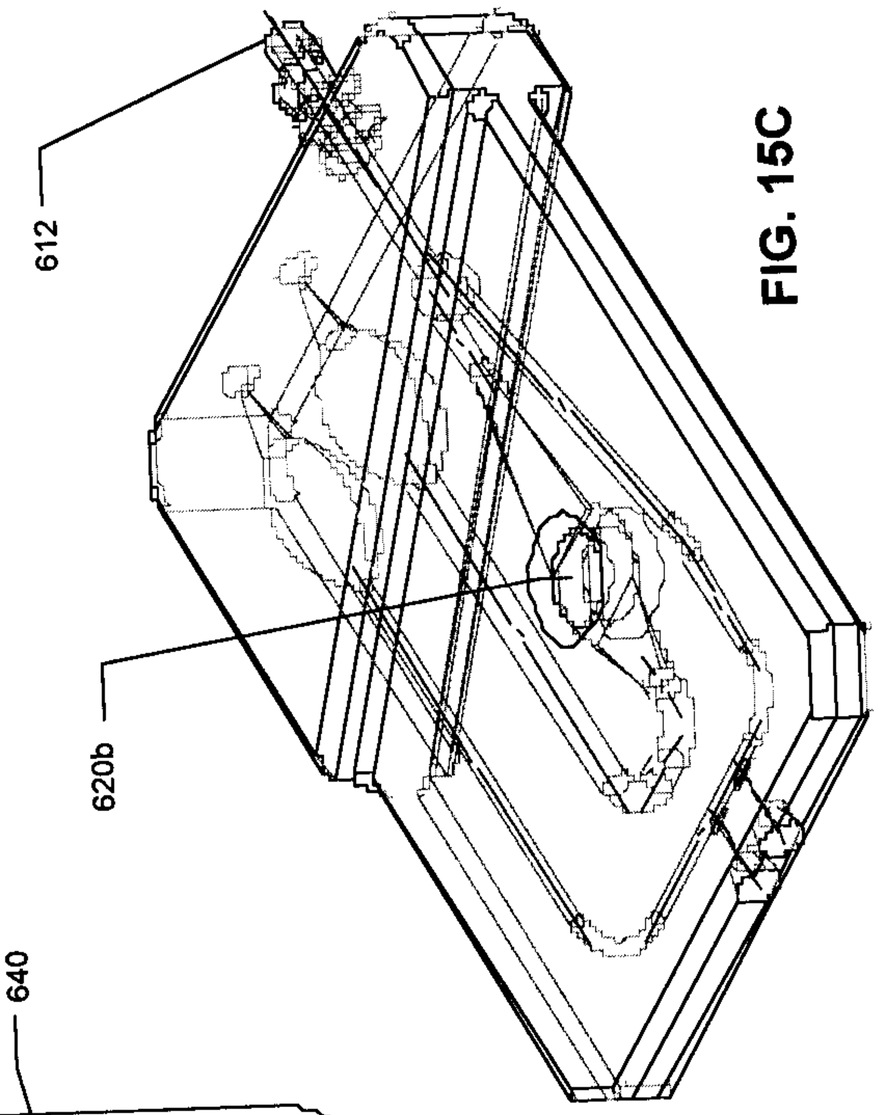


FIG. 15C

FIG. 15B

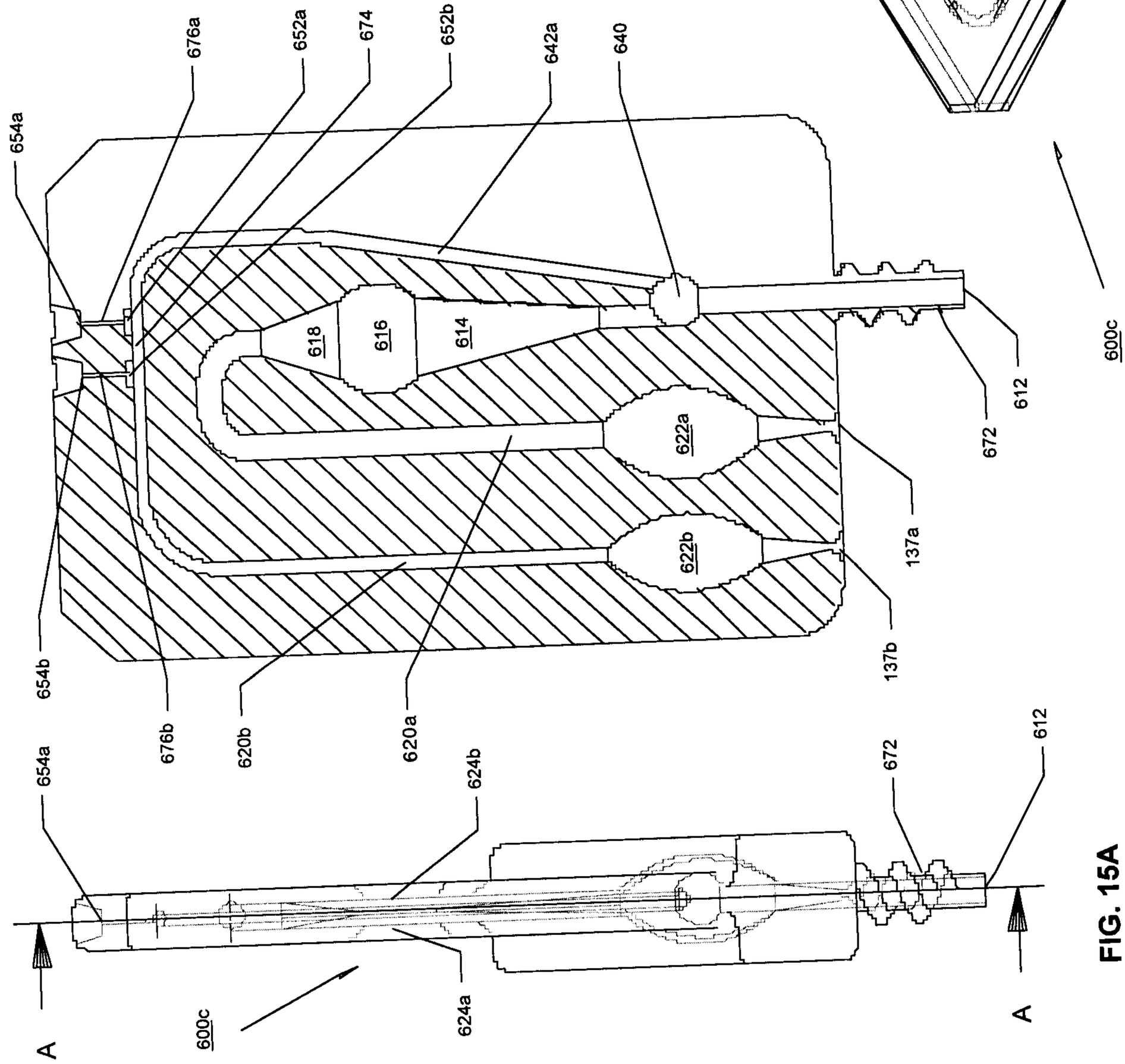


FIG. 15A

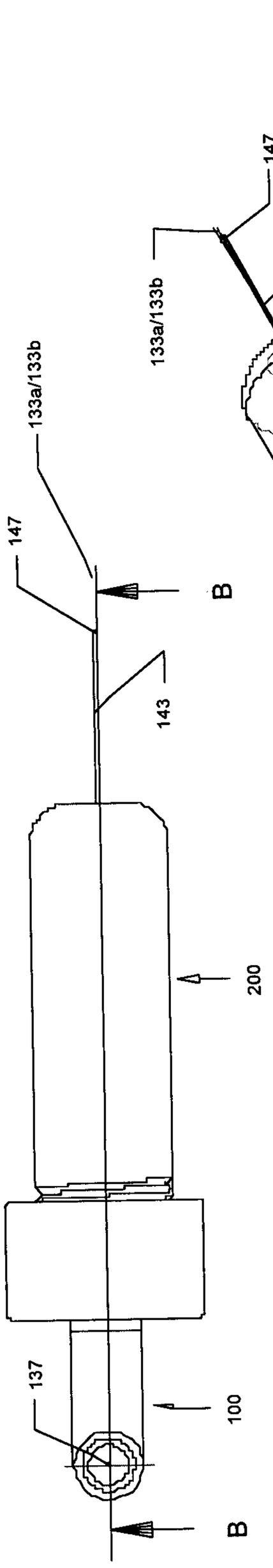


FIG. 16A

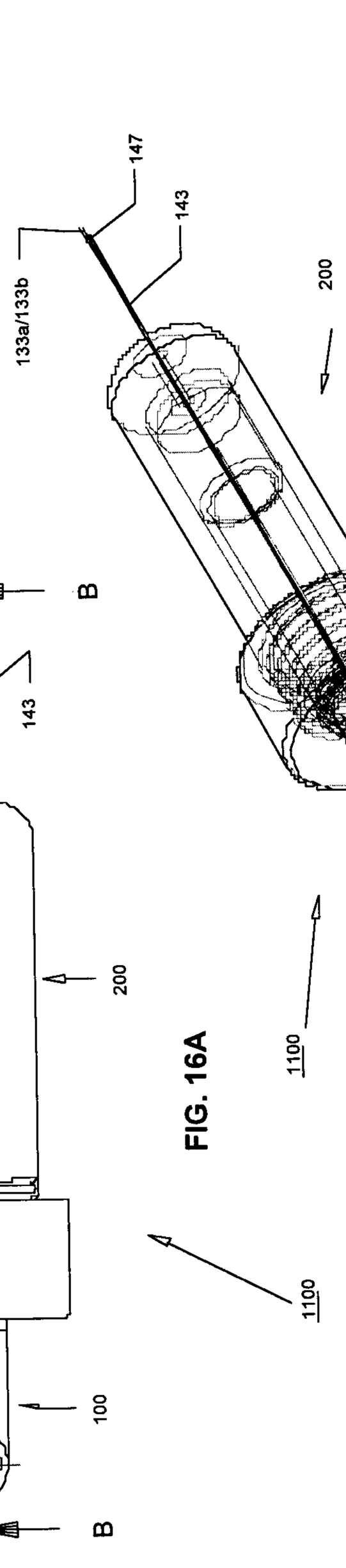


FIG. 16C

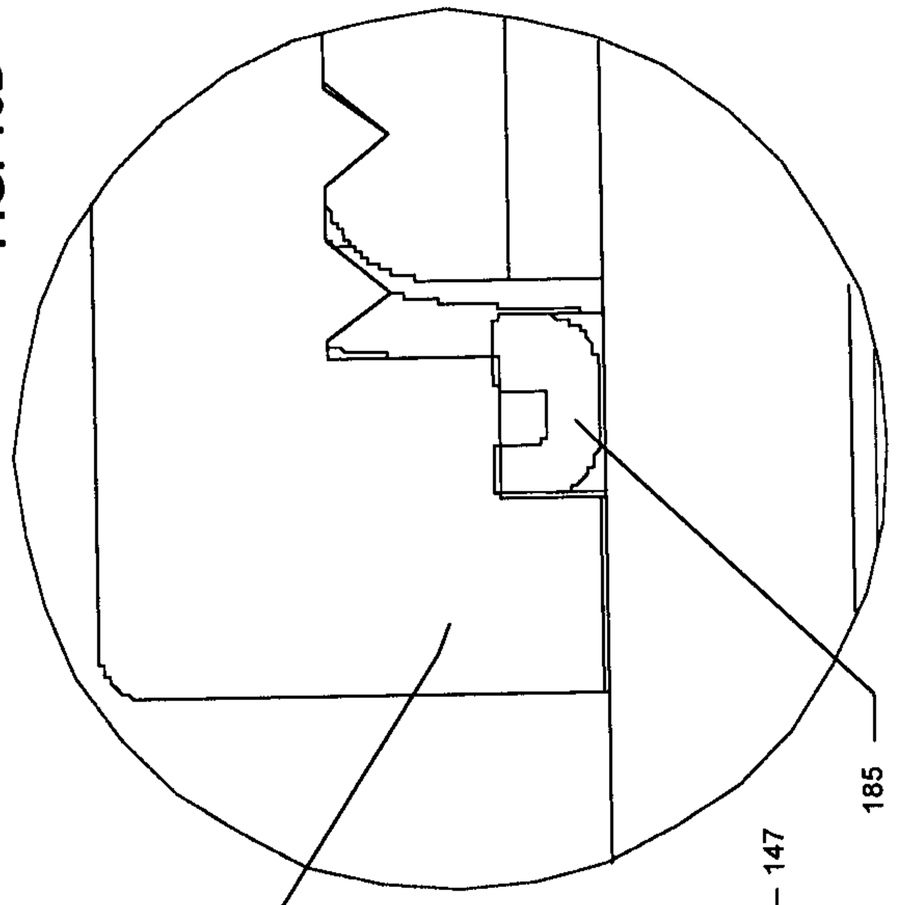


FIG. 16D

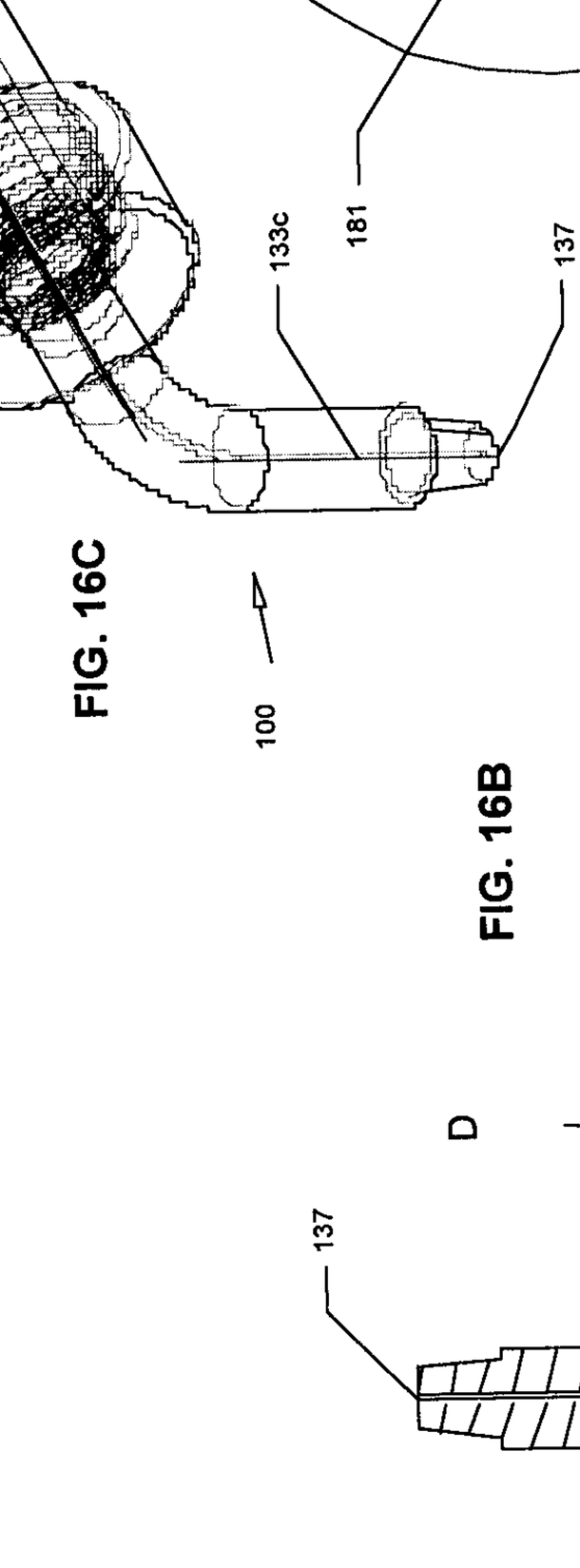
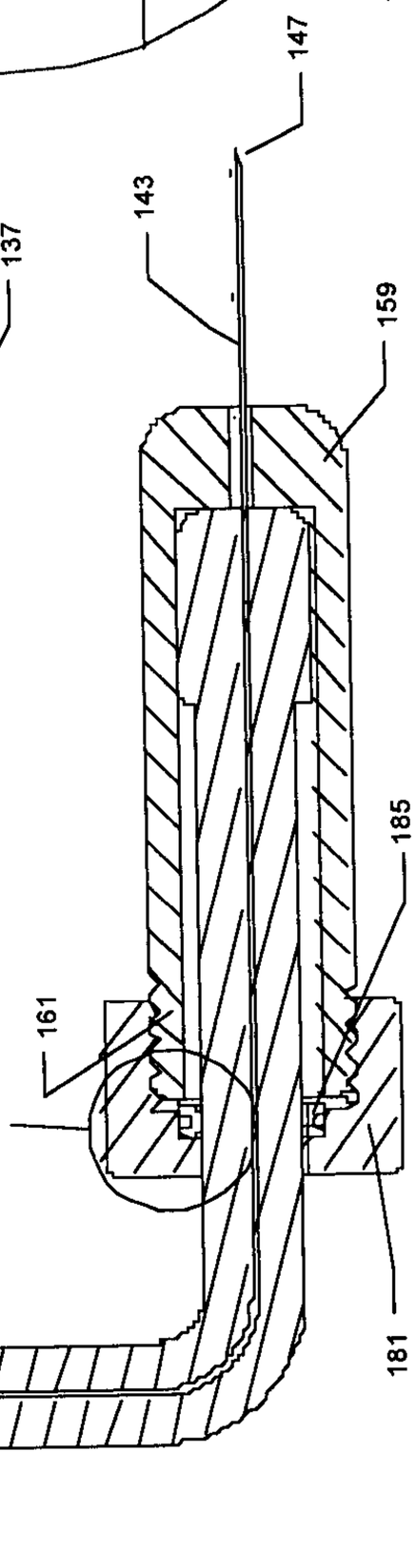
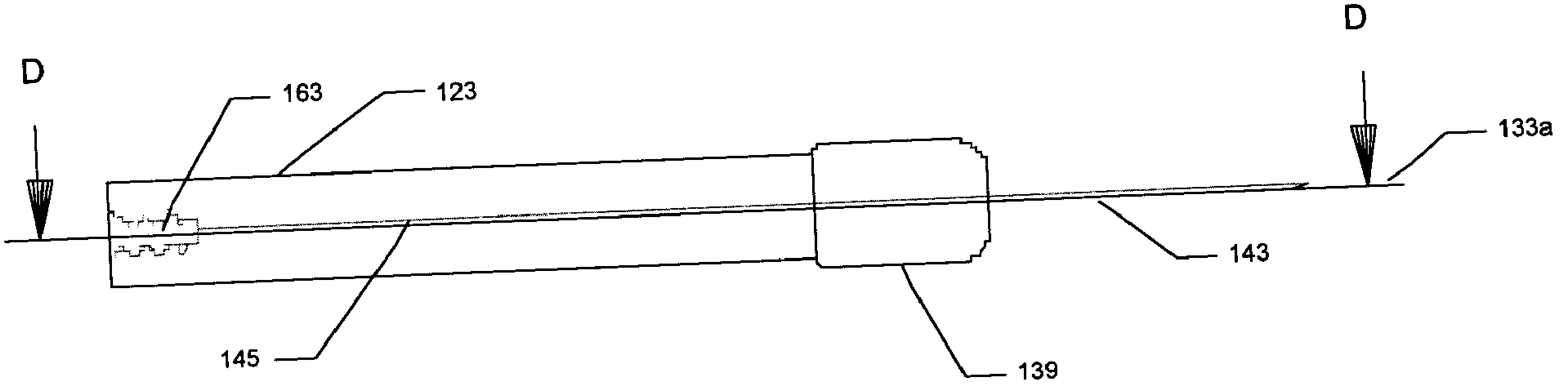


FIG. 16B

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163
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133a
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