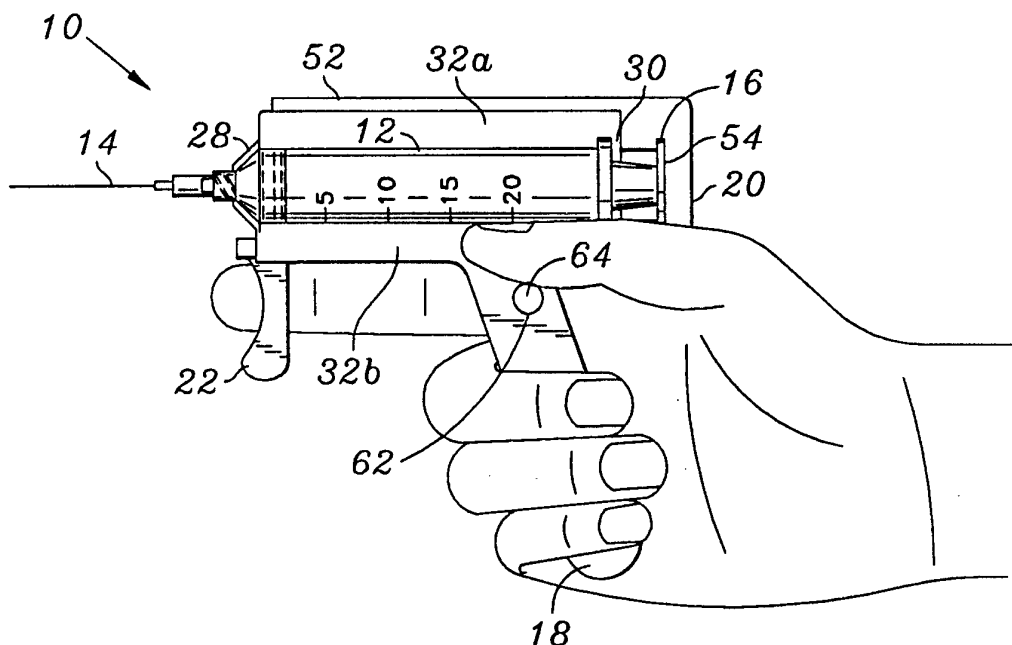




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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## (54) Title: NEEDLE ASPIRATION TISSUE EXTRACTION DEVICE



## (57) Abstract

The tissue extraction device is configured as a fine needle cytology device (10) for extracting tissue samples for cytologic examination. The device has a handle (18) and a generally U shaped slide member (20) with a trigger (22) attachable thereto.

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NEEDLE ASPIRATION TISSUE EXTRACTION DEVICEIncorporation by Reference

This patent application incorporates by reference the entire contents of U.S. Serial Number 08/225,594, filed April 11, 1994 and U. S. Serial Number 08/331,283, filed October 27, 1994.

Field of the Invention

The present invention relates generally to tissue extraction devices, and more particularly to hand-held devices for extracting tissue samples by needle aspiration.

Background of the Invention

Biopsy devices utilizing needle aspiration to extract tissue samples are well known to those skilled in the art. Such devices are extremely useful to obtain samples of tissue suspected of being cancerous so that such tissue may be examined in order to confirm such suspected diagnosis. Such devices are frequently used when sampling suspected cancerous tissue in the lungs, breasts, and prostate, as well as other body organs. Numerous other applications, e.g., gynecologic, head and neck, lymph nodes, various soft tissue biopsies, have also been found for these devices.

Generally, such biopsy instruments extract a sample of tissue from a tissue mass by either drawing a tissue sample into a hollow needle via an external vacuum force (fine needle aspiration cytology) or by severing and containing a tissue sample within a notch or reservoir formed on a stylet.

Typical of such devices utilizing a vacuum force are those disclosed in United States Letters Patent No. 5,246,011 issued to Cailouette and United States Letters Patent No. 5,183,052 issued to Terwilliger. Such fine needle aspiration cytology devices contemplate the process of advancing a hollow needle into a tissue mass and then applying a vacuum force to draw a sample into the needle and hold the same therein while the tissue is

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extracted. Such devices, however, fail to adequately sever and contain such tissue samples as the vacuum force may not be sufficiently strong to sever and hold the sample within the biopsy needle.

5 Generally, such biopsy instruments extract samples of tissue through a small needle usually in the range of 25-20 gauge. A vacuum force is usually applied by a standard syringe attached to the needle, while the needle is passed several times in the tissue. A column of cells  
10 is then accumulated in the hollow channel of the needle as the needle is passed multiple times into the tumor mass. This procedure can be performed with a syringe alone or in a syringe holding device.

Such syringe holding devices have been in use for at  
15 least two decades. A typical device used to perform this technique is disclosed in United States Patent No. 3,819,091, issued to Anders K.Y. Hollander of Boras, Sweden the teachings of which are incorporated herein by reference. Another such device incorporating a syringe  
20 holder is disclosed in Patent No. 2,472,116, issued to Hyla F. Maynes, the teachings of which are likewise incorporated herein by reference. A still further device which deals with an adjustable aspirating syringe is disclosed in United States No. 2,863,452, issued to  
25 Leighten Ogle, and incorporated herein by reference. These devices were primarily issued as syringe holders and were generally not used for fine needle aspiration cytology except for the device designed by Hollander which was specifically designed for aspiration cytology.  
30 The device designed by Hollander has a capability of being usable with one hand and further has a capability of utilizing disposable syringes and needle.

The advantages provided by the Hollander device are that it is economical, can be used with one hand, and can  
35 provide excellent cytology specimen when used correctly. However, disadvantages also exist with the Hollander device in that the user's hand must be placed behind the

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piston of the syringe, thereby requiring a distance of approximately 7½ inches to 8½ inches from the user's hand to the tissue to be biopsied. This distance is substantial and makes for difficult needle placement, which can thus lead to an inaccuracy in diagnosis. Additionally, the Hollander device makes no provision for locking the device in a specific position so that a constant amount of suction may be applied. Furthermore, such device produces tension in the hand operating the device which can lead to inaccuracy in obtaining fine needle aspiration specimens.

Accordingly, there exists a substantial need in the art to provide an improved fine needle aspiration cytology device that will place the user's hand closer to the patient (i.e., the tissue to be sampled), and also to provide an aspiration cytology device having means for locking the device in a position to provide a fixed amount of suction. Additionally, there is needed an aspiration device wherein the hand is placed in a natural position of function as well as a device having a stable platform for retaining the syringe. These improvements would be particularly desirable when sampling in confined spaces with compact anatomy, such as tumors of the head and neck, where a misplaced needle might lead to a complication.

Alternatively, other biopsy instruments utilize a biopsy needle with a tissue sample recovery notch or reservoir formed thereon to extract a specimen, such as that described in U.S. Patent No. 3,477,423 issued to Griffith, often referred to as the TRU-CUT needle and that disclosed in United States Letters Patent No. 4,776,346 issued to Beraha et al. Such devices, however, suffer from the drawback of not effectively drawing a tissue sample of sufficient size into the biopsy notch on the cannula. Accordingly, such samples extracted by such biopsy needles may not provide sufficient tissue to perform an examination and thus require additional

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biopsies to be taken. Additionally, such needles suffer from the disadvantage of having to be advanced into the desired tissue site such that the needle may possibly extend beyond the tissue site, thus resulting in the recovery of an inaccurate or non-usable tissue sample or injury to adjacent organs or structures by overpenetration.

Further attempts in the art involved using specially designed cannulas to enhance the cutting and recovery of tissue samples as well as combining the application of a vacuum force to draw in a tissue sample into a biopsy cavity and then cutting the tissue contained therein. United States Patent No. 4,708,147 issued to Haaga discloses a cannula for a biopsy needle designed to cut a sample of tissue and then applying a vacuum to the cannula such that the tissue is drawn into the cannula and thus retained therein for recovery.

Additionally, United States Letters Patent No. 3,844,272 issued to Banko discloses a biopsy device wherein a suction force, created by a vacuum, draws a sample of tissue into a receiving compartment whereby two coaxial members are rotated relative to each other so that the members essentially coact to cut off the specimen and place it into a compartment (needle core biopsy). Such combination devices, however, fail to either sufficiently isolate a sample or fail to draw in a sample of sufficient size into a biopsy compartment. Additionally, such instruments typically are difficult to maneuver and manipulate and are not necessarily accurate or effective enough to achieve their desired purpose.

Accordingly, there exists a substantial need in the art to provide a tissue sample extractor capable of effectively and efficiently drawing in a suitable sample of tissue and isolating the tissue sample within the biopsy instrument. Additionally, there is a need for a biopsy device that is easy to use and can effectively be manipulated by one hand in light of the fact that it is

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advantageous to perform such biopsy procedures wherein the physician user is allowed to have an additional free hand. Furthermore, there is need in the art to provide a tissue sample extractor that not only provides tissue samples of sufficient size, but allows the user to take multiple tissue samples without having to repeatedly puncture and penetrate the tissue mass. Further, it would be of even greater advantage to provide a tissue sample extractor having the above-mentioned features and also utilizing a disposable cannula assembly.

#### Summary of the Invention

The present invention specifically addresses and alleviates the above-mentioned deficiencies associated with the art. In a first embodiment, the present invention comprises an aspiration cytology device comprising a handle and a generally U-shaped slide with trigger in operative combination. The handle is slotted to accommodate a standard syringe and to retain the same in a snug manner during use. The handle is further slotted and channeled to slidably receive the slide, and also includes a channel formed therein for housing a manually operable locking detent mechanism that selectively positions the slide relative the handle. Essentially, the detent locking detent mechanism housed within the handle selectively engages a respective one of a plurality of locking holes formed on the slide. The channel formed in the handle to house the detent locking mechanism is further preferably slotted on both sides for ambidextrous accommodation. In an alternative embodiment, the locking detent mechanism may be removed if that provision is not desired. The slide component comprises a generally U-shaped member defining first and second arms. The arms are designed and configured to slidably engage with the handle such that a respective one of the arms, having the plurality of apertures formed thereon, is oriented toward the locking detent mechanism. The slide also preferably has a trigger attachable

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thereto. The trigger may be added to the slide mechanism after the slide is passed through and received upon the handle. Once the trigger is so attached, the device is assembled and cannot become separated into its components without removal of the trigger. The slide is further slotted at its rear-most position within the closed end of the generally U-shape for accepting the end of the plunger on the syringe. When the syringe is placed in the appropriate retaining slots formed on the handle and the plunger is retained within the slide, the trigger is maintained at a first, forward-most position and may be easily reached with the index finger of the hand. When the trigger is pulled, it moves the slide to a second, rearward position thereby withdrawing the plunger in the syringe and generating suction through the needle. This pulling action is easily controlled because the hand is advantageously maintained in a natural position of function as the handle on the device is angled.

The first embodiment of the present invention is used by first placing a syringe in the slot formed on the handle and positioning the plunger in the slot formed on the slide. An appropriately sized needle is used, usually in the range of 25-20 gauge, and is placed on the end of the syringe. The plunger of the syringe is initially maintained in the first, forward-most position. The needle is then inserted into the tissue to be sampled. The trigger is then pulled causing the U-shaped slide to retract the plunger such that suction force is created within the barrel of the syringe (i.e., by virtue of the plunger's movement to a rearward position relative to the syringe). The locking detent formed within the handle will automatically be forced into a respective one of a series of holes formed on the bottom of the slide unless the user manually adjusts the detent mechanism, preferably by motioning his thumb to depress a detent knob attachable to the detent and receivable through the handle, to counteract the same. When the desired amount



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of suction is achieved, the detent knob is released and thus allows the locking detent to lockingly engage a respective hole, thereby allowing the user's index finger and hand to be relaxed. Following this simple to-and-fro motion, the device will accumulate cells in the barrel of the needle. When a sufficient number of passes of the device into the tissue have been made, the locking detent is again deactivated, preferably by depressing the detent knob with the thumb. The plunger of the syringe is therefore allowed to retract further to its closed position which automatically occurs by virtue of the vacuum created in the syringe barrel. The needle is then withdrawn from the tissue. The syringe is removed from the device. The collected cells are then forced onto a slide for cytologic evaluation.

The device is specifically designed to allow the physician user to accurately place a needle into a target area with little or no error by allowing the physician user to place his hand closer to the needle tip as well as place his hand in a position of natural function. The locking detent mechanism of the device is ergonomically designed to be easily manipulated with the thumb of the hand, thus enabling the physician user to keep one hand free at all times. The device is further designed to accommodate a standard syringe and will allow for cost effective and highly efficient tissue sampling.

It is therefore an object of the first embodiment of the present invention to provide a fine needle aspiration device that will effectively and efficiently remove cells for cytologic examination.

Another object of the first embodiment of the present invention is to provide a fine needle aspiration device that places the hand in a natural position of function so that the manipulation of the device will be precise and simply achieved.

Another object of the first embodiment of the present invention is to provide a fine needle aspiration

device having means for locking a syringe at a set position such that an amount of suction applied to the tissue is fixed and to further allow the user to relax his hand so that more accurate and precise manipulation  
5 can be achieved.

Another object of the first embodiment of the present invention is to provide for economic production of the device using heat stable materials such as metal or plastics.

10 Another object of the first embodiment of the present invention is to provide a fine needle aspiration device having a unique design whereby the barrel of the syringe is positioned above the hand, such that the user may place his hand closer to the tip of the needle, and  
15 therefore the tissue to be sampled, than current devices.

Another object of the first embodiment of the present invention is to provide a fine needle aspiration cytology device which may easily be adapted to CT guided, laparoscopic, stereotactic core guided, or ultrasound  
20 guided cytology techniques.

Yet another object of the first embodiment of the present invention is to provide a fine needle aspiration cytology device that can be easily held and manipulated with one hand, allowing the user to have one hand free.

25 In a second embodiment of the present invention comprises a tissue sample needle core biopsy needle specifically designed to allow the physician user to extract a sample of tissue in an effective and efficient manner while only requiring the user to use one hand to  
30 operate the device. The device comprises a first cannula having a specifically configured, sharpened, and beveled cutting tip and biopsy reservoir formed at its distal end wherein the biopsy reservoir is formed proximal to the cutting tip. The first cannula is attachable to a  
35 conventional syringe such that the biopsy reservoir is in fluid communication with the barrel piston of the syringe. Axially mounted about the first cannula is a

second cutting cannula, preferably having a sharpened cutting edge formed about its distal end and a shoulder attached to its proximal end. The second cannula is designed and configured to axially telescope relative the  
5 first cannula such that the second cannula selectively covers and uncovers the distal end of the first cannula. Disposed between the proximal ends of the first cannula and second cannula is a biasing member, preferably a spring, which urges the second cutting cannula to advance  
10 axially toward the distal end of the first cannula.

The syringe, the coaxially positioned first and second cannulas, and biasing member are preferably mountable within a hand-held introducer. Preferably, the introducer is comprised of two parts, namely a handle and  
15 syringe retainer as well as a plunger retractor member. The handle, syringe retainer, and plunger retractor member preferably cooperate to form a gun-like structure that is easy to grasp and manipulate with one hand. The handle and syringe retainer portion includes a grippable  
20 handle and means for retaining the syringe on the syringe retainer. The plunger retractor member includes a C-shaped member designed and configured to engage the plunger of the syringe. Additionally, the plunger retractor member includes a trigger-shaped member  
25 depending therefrom to enhance the grippability and function of the extractor. Furthermore, the plunger retractor member includes a cam bar that is pivotally attached to a tip portion of the C-shaped member. The cam bar is preferably provided with a first cam slot and  
30 a second cam abutment surface sized and configured to selectively control the axial position of the second cannula about the first cannula. The second cannula is preferably attached to a shoulder at its proximal end that is specifically designed and configured to engage  
35 the first cam slot and second cam abutment surface. When the shoulder is engaged with the first cam slot, the distal end of the second cannula is maintained in a

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distal axial position wherein the second cannula covers the biopsy reservoir formed on the first cannula but leaves the cutting tip of the first cannula exposed. When the shoulder is allowed to advance to the second cam abutment surface, the second cannula is maintained in a distal axial position wherein the distal end of the second cannula extends just beyond the biopsy channel of the first cannula. Additionally, the shoulder may be released altogether from the cam bar whereby the first cannula may be withdrawn from the second cannula while maintaining the second cannula resident in the patient. Such selective withdrawal of the first cannula enables multiple biopsies to be effectuated without multiple punctures of the patient's tissue mass to enhance the ability to remove multiple samples with one puncture. The cannula assembly may be rotated to position the biopsy channel a full range of 360 degrees without the need to rotate the handle.

In order to facilitate the selective axial positioning of the second cannula relative the first cannula, the introducer is preferably provided with a spring-activated detent or locking member and a plurality of locking apertures. Preferably, the locking member is disposed upon the handle and syringe retainer while the locking apertures are formed upon the plunger retractor member. Accordingly, the interconnection between the locking member and a respective aperture advantageously maintains the desired axial positions of the second cannula relative the first cannula whereby the second cannula is controllably axially telescoped about the first cannula. Importantly, this interconnection detachably maintains the second cannula in a distal and a proximal axial position wherein the second cannula is axially retracted about the biopsy reservoir of the first cannula. Such exposure of the biopsy reservoir via reciprocation of the second cannula from a distal position covering the biopsy channel to a proximal

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position and back to distal position coupled with vacuum ultimately enables a sample to be extracted by the extractor of the present invention.

Optionally, the shoulder moves along a guide which  
5 restricts lateral movement thereof so as to ensure that the shoulder, and consequently the second cannula, move only longitudinally, i.e., directly toward the patient, during actuation of the device. The guide thus prevents bending of the cannula assembly, particularly in an  
10 upward direction, as has been found to be common during use of such devices.

The guide preferably comprises an elongate member having a channel formed therein such that the shoulder slides along the channel in a manner which prevents  
15 undesirable bending of the cannula assembly. Thus, the guide effectively prevents side-to-side and upward bending of the first biopsy cannula and the second cutting cannula.

According to the second embodiment of the present  
20 invention the shoulder is preferably configured as a disk, but may be of various other configurations, and the guide comprises a complimentary channel along which the shoulder moves as the shoulder urges the second cutting  
25 cannula to distally advance about the first biopsy cannula.

The beveled cutting tip of the first biopsy cannula preferably comprises a solid plug having a scalloped portion defining the sharpened bevel thereof. The scalloped portion is preferably, but not necessarily,  
30 formed via electron discharge machining, e.g., either standard or wire electron discharge.

The diameter of the solid plug of the beveled cutting tip of the first cannula is preferably either approximately equal to the outer diameter of the first  
35 biopsy cannula or it is approximately equal to the inner diameter of the second cutting cannula. Thus, the

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beveled cutting tip is configured to facilitate easy insertion of the cannula assembly into tissue.

The solid plug is preferably attached to the first biopsy cannula prior to forming the scalloped portion therein so as to provide a convenient means for handling the solid plug. Alternatively, the solid plug may be formed at the end of an elongate solid bar member and subsequently cut therefrom prior to insertion into the first biopsy cannula.

10 The beveled cutting tip is preferably attached to the first biopsy cannula via at least one of press fitting and crimping. Those skilled in the art will appreciate that various other different means for attaching the beveled cutting tip to the first biopsy  
15 cannula are likewise suitable. For example, thermal or electrical welding, adhesive bonding, or the use of various different mechanical fasteners may be utilized.

The biopsy reservoir preferably comprises an obstructing member for preventing the vacuum from pulling  
20 a tissue sample from the biopsy reservoir. The obstructing member preferably comprises an inwardly bent tab formed from the first biopsy cannula at a proximal portion of the periphery of the biopsy reservoir.

The obstructor is preferably formed in the biopsy  
25 reservoir by forming an undercut tab at a proximal end of the biopsy reservoir and then bending the undercut tab inwardly so as to prevent tissue samples from being pulled proximally through the lumen of the first biopsy cannula by the vacuum of the syringe, but still allows  
30 vacuum to be applied to the biopsy channel.

An optional seal is configured to mitigate vacuum leakage intermediate the first biopsy cannula and the second biopsy cannula. The seal preferably comprises an annular member formed of a resilient material disposed  
35 about the first biopsy cannula. The annular member is preferably biased in position via the biasing member or spring.

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Optionally, the sharpened cutting edge of the second cutting cannula comprises a beveled or slanted surface so as to afford more efficient cutting of the biopsy tissue sample.

5           The cannula assembly, comprised of the first biopsy cannula and the second biopsy cannula, and preferably further comprised of the biasing means and shoulder, preferably define an assembly which is removable from the introducer and which is disposable. Thus, after each  
10 procedure, the entire cannula assembly is easily removed from the introducer and is disposed of. A new cannula assembly is attached to the introducer prior to a subsequent use thereof.

In use, the introducer is initially maintained in an  
15 operable orientation wherein the second cannula is disposed in its distal axial position covering the biopsy reservoir but leaving the cutting tip of the first cannula exposed. In this position, the physician user grips the introducer and forces the coaxially positioned  
20 cannulas into the tissue mass. As the coaxially positioned cannulas advance into the tissue, the cutting tip of the first cannula selectively cuts and positions the tissue over and about the biopsy reservoir covered by the second cannula. Once positioned within the target  
25 mass, the plunger retractor member of the introducer is manually withdrawn rearwardly with respect to the handle and syringe retainer portion such that the second cannula is axially retracted to its proximal axial position wherein the biopsy reservoir of the first cannula becomes  
30 exposed to the tissue mass. Simultaneously, by such retracting or withdrawing of the plunger retractor member, the plunger of the syringe is retracted, thus creating a vacuum within the syringe that is communicated via the axial lumen of the first cannula into the biopsy  
35 reservoir. Due to the created vacuum, the cut tissue is drawn into the biopsy reservoir. Having contained the tissue therein, the cam bar of the introducer may be

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released from the shoulder attached to the second cannula whereupon, due to the action of the biasing member, the second cannula rapidly axially advances from the first cam slot to contact the second cam abutment surfaces of the cam bar, thus causing the second cannula to axially advance to its distal axial position. During this rapid axial advancement to the distal axial position, the cutting edge of the second cannula severs the tissue sample adjacent the biopsy reservoir and captures the same within the biopsy reservoir of the first cannula. Having thus captured the tissue sample, the introducer may then be removed and the tissue sample may be examined. Alternatively, the cam bar may be completely released from the shoulder of the second cannula thereby allowing the second cannula to remain resident within the tissue mass while withdrawing the first cannula therefrom. In such arrangement, the second cannula may subsequently be used as a passageway through which other multiple tissue samples may be extracted without the need for further puncture of the patient.

It is therefore an object of the second embodiment of the present invention to provide a tissue sample extractor that will effectively and efficiently remove a portion of tissue from a tissue mass.

Another object of the second embodiment of the present invention is to provide a tissue sample extractor that extracts a sample of tissue by simultaneously drawing a sample of tissue into a biopsy reservoir, via a vacuum, and severing and containing the sample within the biopsy reservoir.

Another object of the second embodiment of the present invention is to biopsy tissue without the need for axial advancement of a stylet into the tissue but rather, to biopsy tissue by exact placement of the covered biopsy reservoir within the tissue and eliminating any further axial movement of the same.



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Another object of the second embodiment of the present invention is to provide a tissue sample extractor that may be easily held and manipulated by one hand.

Another object of the second embodiment of the present invention is to provide a tissue sample extractor that allows a user to take repeated tissue samples from a tissue mass without having to repeatedly puncture the tissue mass.

Another object of the second embodiment of the present invention is to provide a tissue sample extractor which may be easily adapted for ultrasound, laparoscopic, C.T. guided and/or stereotactic biopsy techniques.

Yet another object of the second embodiment of the present invention is to provide a tissue sample extractor that is of simple construction, inexpensive to manufacture, and easy to use.

#### Brief Description of the Drawings

Figure 1 is a side view of a prior art aspiration device, as disclosed in United States Patent No. 3,819,019, with a syringe and needle inserted therein, said device being maintained in a first, closed position;

Figure 2 is a perspective view of a prior art aspiration device;

Figure 3 is a side view of the prior art aspiration device disclosed in United States Patent No. 3,819,019 wherein a hand of a user, to manipulate the device, is placed behind the syringe upon the proximal end of the device;

Figure 4 is a side view of the aspiration device depicted in Figure 1 being maintained in the first, closed position;

Figure 5 is a side view of the prior art device depicted in Figure 4 showing the position of a user's hand and fingers in relation to the device, syringe, and needle tip;

Figure 6 is a side view of a fine needle aspiration cytology device according to the first embodiment of the

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present invention. The figure further depicts a conventional needle and syringe interconnected thereto;

Figure 7 is a side view of the fine needle aspiration cytology device being held by the right hand  
5 of a user;

Figure 8 is a side view of the fine needle aspiration cytology device being maintained in a first position;

Figure 9 is a side view of the fine needle aspiration cytology device being maintained in a first  
10 position while being held in the right hand of a user;

Figure 10 is a side view of the prior art device depicted in Figure 1 being held in the right hand of a user;

Figure 11 is a side view of the fine needle aspiration cytology device being held by the right hand  
15 of a user;

Figure 12 is a side exploded view of the slide and trigger assembly of the fine needle aspiration cytology  
20 device;

Figure 13 is a cross-sectional side view of the fine needle aspiration cytology device showing the relative  
position of the slide with detent holes formed on the bottom arm thereof with respect to a locking detent  
25 mechanism disposed within the handle of the device;

Figure 14 is cross-sectional side view of the fine needle aspiration cytology device showing the slide in a  
rearward position relative the handle wherein the locking detent mechanism disposed within the handle is engaged  
30 with a respective one of the detent holes formed on the slide;

Figure 15 is a cross-sectional side view of the handle of the fine needle aspiration cytology device;

Figure 16 is a rear view of the handle of the  
35 device;

Figure 17 is a perspective view of the handle of the device;

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Figure 18 is an exploded perspective view of the handle and locking detent mechanism of the device;

Figure 19 is an exploded perspective view of the slide and trigger assembly of the device;

5 Figure 20 is an exploded perspective view of the handle assembly, slide, and trigger of the device;

Figure 21 is a perspective view of the device, as assembled, being maintained in a first forward-most position;

10 Figure 22 is a perspective view of the assembled device being maintained in a second, retracted position;

Figure 23 is a perspective view of a tissue sample extractor according to the second embodiment of the present invention;

15 Figure 24 is a perspective view of the tissue sample extractor as shown in use;

Figure 25 is a perspective view of the distal end of the first biopsy cannula of the tissue sample extractor

20 Figure 26 is a cross-sectional view taken along line 26-26 of Figure 25;

Figure 27 is a cross-sectional view taken along line 27-27 of Figure 25;

25 Figure 28 is a perspective view of the distal end of the second cutting cannula of the tissue sample extractor;

Figure 29 is a perspective view of the distal ends of the first biopsy cannula and the second cutting cannula wherein the first biopsy cannula is telescoped within the second cutting cannula;

30 Figure 30 is a perspective view of the first and second cannulas wherein the second cannula selectively covers a portion of the distal end of the first cannula;

35 Figure 31 is a perspective view of the distal ends of the first cannula and second cannula wherein the second cannula substantially covers the distal end of the first cannula;

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Figure 32 is an exploded view of the tissue sample extractor;

Figure 33 is a side view of the tissue sample extractor wherein the extractor is maintained in a configuration suitable for insertion into a tissue mass;

Figure 33a is a cross-sectional view of the first and second cannulas corresponding to the position of the extractor as depicted in Figure 33;

Figure 34 is a side view of the extractor while positioned to obtain a sample from a tissue mass;

Figure 34a is a cross-sectional view depicting the first and second cannulas corresponding to the position of the extractor as depicted in Figure 34 wherein the first cannula is advanced into a tissue mass;

Figure 35 is a side view of the extractor being maintained in a position suitable for recovery of the tissue sample;

Figure 35a is a cross-sectional view of the first and second cannulas corresponding to the configuration maintained by the extractor in Figure 35;

Figure 36 is a side view of the extractor wherein the introducer has been disengaged from the second cannula and the first cannula and introducer may be removed therefrom;

Figure 36a is a cross-sectional view of the first and second cannulas corresponding to the configuration of the extractor as depicted in Figure 36 wherein the second cannula is maintained stationary in the patient and the first cannula may be withdrawn therefrom;

Figure 37 is an end view of the disk guide assembly showing the second shoulder and cam bar in phantom;

Figure 38 is a perspective view of the disk guide assembly mounted to the tissue sample extractor of the present invention;

Figure 39 is a side view of the disk guide assembly of Figures 37 and 38;

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Figure 40 is an enlarged side view of a seal disposed about the first biopsy cannula and urged into abutment with the second shoulder via the spring so as to prevent vacuum leakage intermediate the first biopsy  
5 cannula and the second cutting cannula;

Figure 41 is an enlarged prospective view of the distal end of the first biopsy cannula and second cutting cannula showing the solid plug having a scooped out portion so as to define a sharp point, and also showing  
10 the biopsy reservoir formed in the first biopsy cannula so as to prevent biopsy tissue samples from being pulled into the lumen of the first biopsy cannula by the vacuum formed by the syringe, and also showing the slanted or beveled tip of the second cutting cannula; and

15 Figure 42, is a side view, partially in cross-section, of the first biopsy cannula and solid plug of Figure 41.

#### Detailed Description of the Preferred Embodiment

The detailed description set forth below in  
20 connection with the appended drawings is intended as a description of the presently preferred embodiment of the invention, and is not intended to represent the only forms in which the present invention may be constructed or utilized. The description sets forth the functions  
25 and the sequence of steps for constructing and operating the invention in connection with the illustrated embodiments. It is to be understood, however, that the same or equivalent functions and sequences may be accomplished by different embodiments that are also  
30 intended to be encompassed within the spirit and scope of the invention.

The needle aspiration tissue extraction device of the present invention is illustrated in Figures 6 through 42 which depict the presently preferred embodiments of  
35 the invention. Figures 1-5 illustrate prior art devices and the use thereof.

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Referring now to Figures 6-9 and 11-22, there is shown a first embodiment of the present invention, i.e., a fine needle aspiration cytology device 10. The device 10 is specifically designed and adapted to allow the user of the device 10, typically a physician, to obtain cytologic specimens for examination in a much more accurate and efficient manner than prior art devices, as well as obtain such samples in a manner that minimizes fatigue of the hands and fingers of the user which continues to be a problem with prior art devices.

Figure 1 depicts an aspiration device 100 typical of the prior art. The specific device 100 depicted is disclosed in United States Patent No. 3,819,091, issued to Anders K.Y. Hollander, the teachings of which are expressly incorporated herein. The device 100 comprises a hand-held unit capable of releasably engaging a conventional syringe 12 and needle 14. To facilitate handling of the device 100, there is provided a block 102 which orients the fingers of the operating hand toward the piston 16 of the conventional syringe 12, such that the piston 16 may be retracted by pulling upon the block 102. The block 102 is slidably received within a handle 104, the latter having a generally square-like orientation which disadvantageously places the hand in awkward position when the device 100 is utilized to extract tissue.

Figure 3 illustrates how such prior art device 100 is manually grasped while in use. As shown, the orientation of the device 100, due to its generally-squared shape, is recognized in the art as being quite awkward to manipulate. Additionally, Figure 3 depicts the relative distance between the fingers 106 of the user and the tip of the needle 14a. As those skilled in the art will recognize, this distance, which on the average is approximately  $7\frac{1}{2}$  to 8 inches, is considerable and greatly affects the ability of the user to accurately target the area from which biopsies are to be taken.

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Such prior art device 100 is further depicted in Figure 4, standing alone, and again in Figure 5 where there is depicted the approximate distance between the fingers of the user and the tip of the needle 14a.

5 In contrast to the prior art devices depicted in Figures 1-5, there is shown in Figure 6 a first embodiment of the present invention, i.e., an improved fine needle aspiration cytology device 10. The device 10 is specifically designed and configured to be used in  
10 combination with a conventional syringe 12 and needle 14 to obtain cytology specimens, solid tumors, or aspirating cystic lesions. As illustrated, the device 10 is designed to releasably engage and interconnect with the syringe 12 and needle 14 and orient the same in such a  
15 manner that biopsies may be collected therein in a much more efficient and accurate manner than prior art devices.

The first embodiment of the present invention 10 is comprised of a handle 18, generally U-shaped slide member  
20 20, and trigger 22 in operative combination, each component being shown alone or in combination in Figures 12-22.

With respect to Figures 15-18, and more particularly to Figure 18, there is shown the handle assembly 18 of  
25 the first embodiment of the present invention 10. As shown, the handle 18 comprises a front collar 28 formed at the distal end thereof for engaging the front barrel portion of the syringe. The handle further includes a rear collar 30 to accommodate and interconnect with the  
30 rear portion of a syringe. There is additionally provided a slot 24 formed within the rear collar to engage with a lip or flange typically formed on syringes so that such conventional syringes may be further secured thereto. Moreover, to provide means for interconnecting  
35 with the slide 20, there is formed upon the handle 18 upper and lower grooves or slots 32a, 32b which

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accommodate the slide assembly 20 so that such assembly 20 may be slidably received thereonto.

5 Additionally, the handle component 18 of the first embodiment of the present invention is provided with a locking detent mechanism 38 disposed within the interior thereof, such locking detent mechanism 38 being more clearly depicted in Figures 13-18. The detent locking mechanism 38 is housed within channel 60. As will be recognized, the locking detent 44 of the locking detent mechanism 38 extends upwardly through the handle 18 so that the detent 44 may engage a respective one of a plurality of apertures 40 formed on the slide. Such locking detent mechanism 38 advantageously allows the device 10 to be maintained in multiple locking positions, thus alleviating the need for the user to manually maintain the device 10 in fixed positions which, contrary to devices in the prior art, can cause significant fatigue.

15 The locking detent mechanism 38 disposed within the channel 60, in addition to detent 44, preferably further comprises a spring 42, and detent plug 48. Figure 18 further illustrates how these components of the locking detent mechanism 38 are received within the channel 60. As shown, the locking detent 44 is axially received within the channel, followed by the spring 42, and then the detent plug 48 which, when screwed within the channel 60, remains resident. Due to the biasing force of the spring 42, the locking detent 44 is axially forced upwardly so as to engage the respective apertures 40 formed on the slide 20. However, to allow for sliding movement of the slide 20, there is provided on the locking detent 44 an aperture 44a into which a knob 64 may be threadably received. Advantageously, knob 64 allows the detent 44 to be forced downwardly against the biasing force of the spring 42, thus permitting the slider 20 to move to and fro upon the handle 18.



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To allow the knob 64 to engage with the detent 44 to thus permit the locking detent mechanism 38 to be selectively activated, there is provided a second channel 62 that traverses the channel 60 within which the locking mechanism is received. The second channel 62, which is preferably formed at right angles to the primary channel 60, is formed to have a generally elongate shape to allow the knob 64 to be depressible such that the locking detent 44 may be withdrawn to a point which will not interfere with the sliding movement of the slide 20. In a more preferred embodiment, the second channel 62 traverses the entire width of the handle 18 such that the depressible knob 64 may be connected to the locking detent 44 on either side of the handle 18 to thus allow the device 10 to be used ambidextrously.

Advantageously, such locking detent mechanism 38, by virtue of knob 64 attached thereto, is configured to allow the thumb on the hand of the user operating the device 10 to selectively position the slide 20 relative to the handle 18. As will be appreciated, by depressing the knob 64 of the locking detent mechanism 38, the slide 20 may freely move in forward and rearward directions. Such movement allows the user to draw a vacuum into the syringe 12 connected to the device 10 such that a biopsy sample is drawn into the needle 14. Furthermore, due to the plurality of apertures 40 formed on the bottom side of the slide 20, the device 10 of the present invention advantageously allows the user to selectively position the slide 20 with respect to the handle 18 such that a desired vacuum force can be selectively controlled and further, allows the device 10 to penetrate tissue at various depths while maintained in a locked position.

Referring now to Figures 12 and 14, there is illustrated an exploded side view of the slide assembly 20 of the first embodiment of the present invention. As illustrated, the slide assembly 20 comprises a generally U-shaped slide member 20 defining first and second arms

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50, 52 and further includes a syringe piston slot 54 formed at the closed end thereof. Additionally, the generally U-shaped slide member 20 includes a plurality of apertures 40 formed upon the bottom surface of the first arm 50 thereof for engaging the upwardly extendable locking detent 44, more clearly depicted in Figure 14. The slide assembly 20 further includes a trigger member 22 attachable to the generally U-shaped slide member 20 preferably by means of screw 56 receivable within a trigger screw hole 56a formed on the distal end of the first arm 50 of the generally U-shaped slide member 20. As those skilled in the art will appreciate, the slide assembly 20 of the present invention, as well as all other parts, are preferably fabricated from durable, sterilizable materials such as metal and/or plastics, such as polycarbonate. Alternatively, the device 10 of the present invention may be fabricated from materials that would enable the device to be disposed of after a single use.

Referring now to Figure 20, there is shown an exploded view of the components comprising the device 10. The exploded perspective view illustrates how the various components cooperate to form the device 10. Initially, the generally U-shaped slide member 20 is slidably connected to the handle 18 by virtue of arms 50, 52 which are received within grooves 32a, 32b respectively. Once having been slidably engaged thereto, the slide 20 may then have the trigger member 22 screwed thereonto by means of a screw 56, which may be received through the trigger member 22 and into the first or lower arm 50 of the generally U-shaped slide member 20. The knob 64 of the locking detent mechanism 38 may then be depressed and selectively released in the aforementioned manner such that the locking detent 44 may engage a respective one of the plurality of apertures 40 formed on the first or lower arm 50 of the generally U-shaped slide member 20.

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Once having been completely assembled, a generally gun-like structure, as depicted in Figure 21 is formed. The device 10 may then be interconnected with a conventional syringe, as depicted in Figure 13. Of particular importance is the fact that the syringe barrel is located above the handle 18 when connected thereto, which thus allows the device 10 to be manipulated such that the hand of the user is maintained in the forward position. Figure 7 depicts how the hand is maintained in such position when the device 10 is so grasped. Additionally, Figure 7 depicts the position of the index finger at the trigger 22 which advantageously allows the index finger to be placed at a position far closer to the needle 14, and thus the tissue, than current biopsy devices. In fact, the configuration of the slide 20 in relation to the handle 18 is such that the extended index finger of the operating hand, when holding the device 10, comes to within 1 1/2-2 inches from the position of needle entry. Such closer distance greatly enhances the user's ability to more accurately extract samples from a given tissue mass.

Figure 21 portrays the device 10 wherein the slide 20 is maintained in a forward-most position. This position would place the piston 16 of the syringe 12 in a forward-most position. Additionally, this position would be suitable for insertion of the needle 14 into the tissue prior to generating any suction within the syringe 12.

Figure 22, in contrast to Figure 21, depicts the device 10 being maintained in a second position wherein the slide 20 is withdrawn to a rearward position, which would, when syringe 12 is placed therein, create a vacuum to be drawn within the syringe 12. Such position would be maintained while a specimen was being extracted from a tissue mass.

Such first and second positions of the device 10, as depicted with the conventional syringe 12 connected

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therewith, are likewise depicted in Figures 13 and 14. Figure 13 depicts the conventional syringe 12 interconnected with the device 10 such that the plunger 16 of the syringe 12 is received within the notch 54 formed on the base of the generally U-shaped slide member 20. Additionally, the slide 20 is maintained in a forward-most position such that a vacuum force is not generated within the syringe 12 (i.e., the plunger 16 of the syringe 12 is maintained in a forward-most position). Figure 14, in contrast, depicts the plunger 16 of the conventional syringe 12 being retracted by virtue of the rearward movement of the slide 20 relative the handle 18. Such rearward movement causes a vacuum to be generated within the syringe 12 that facilitates the collection of samples from a tissue mass. In order to maintain the position of the slide 20 relative the handle 18, the locking detent mechanism 38 may be activated by manipulating knob 64 in the aforementioned manner. By locking the positioning of the slide 20 relative the handle 18, the user may be able to extract a tissue sample in a manner that is much less fatiguing than conventional prior art devices.

Further, to illustrate the contrast between the device 10 of the first embodiment of the present invention with the prior art device 100 depicted in Figures 1-4, there is shown in Figures 10 and 11 the relative positioning of the user's hand, with respect to each device 10, 100, when such devices 10, 100 are utilized. As shown in Figure 10, the prior art device 100 requires the user's hand to be positioned a significant distance away from the needle 14 to be inserted into the patient whereas the device 10 of the present invention, as illustrated in Figure 11, illustrates how the hand is placed much more closely to the needle 14. Such closer proximity of the user's hand relative the needle 14, which is approximately 1.5 inches to 2 inches, allows the device 10 of the present

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invention to be more accurate when inserting the needle into the target tissue mass. Additionally, the device 10, due to its ergonomic, generally gun-like structure, allows the user to place his or her hand in a position of natural function as opposed to the rather awkward handle arrangement of the prior art device 100.

There has thus been provided an aspiration cytology device 10 capable of effectively and efficiently obtaining fine needle aspiration specimens. The device 10, by its unique configuration, provides a significant advance in the design of a cytology device. The device 10 specifically obviates the need for the rods and slide block of the previous devices. It facilitates the use of an angled handle and allows forward position of the hand in a heretofore undescribed manner, also not described on previous aspirating devices, is the provision of simplified and easily operated locking detent with variable or staged position. It should be understood that various modifications within the scope of this invention can be made by one of ordinary skill in the art without departing from the spirit thereof. I therefore wish my invention to be defined by the scope of the appended claims as broadly as the art will permit, and in view of the specification if need be.

Figure 23, there is shown a second embodiment of the present invention, i.e., needle core biopsy instrument or tissue sample extractor 210 embodying the principles of the present invention. The instrument/extractor 210 comprises a first biopsy cannula 212 that is shaped and configured to be coaxially mounted within second cutting cannula 214. Both first biopsy cannula 212 and second cutting cannula 214 have proximal and distal ends, wherein the proximal end of the first biopsy cannula 212 and second cutting cannula 214 have proximal and distal ends, wherein the proximal end of the first biopsy cannula 212 is attached to the first shoulder 216 and the

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proximal end of the second cutting cannula 214 is attached to second shoulder 218.

The distal ends of first cannula 212 and second cannula 14 are more clearly depicted in Figures 25 and 28, respectively. The distal end of first cannula 212 includes a sharpened, beveled cutting tip 244 preferably having a gradual, upwardly extending slope that forms a shovel-type scooped shape. Such scoop-like shape advantageously allows for more efficient and less traumatic tissue penetration than other cannula cutting tips currently in use. Additionally, first cannula 212 has a hollowed-out biopsy reservoir 246, also shown in Figure 27, formed proximal the beveled cutting tip 244. The biopsy reservoir 246 preferably is formed having a semi-circular shape that advantageously allows for relatively large, generally cylindrically-shaped tissue samples to be extracted from the tissue mass. As will be discussed in more detail infra, the distal ends of the first and second cannulas 212, 214 cooperate via relative axial movement to cut and contain a tissue sample within the biopsy reservoir 246.

At the rear portion of biopsy reservoir 246 is a lumen or channel 213 which runs the length of first cannula 212 and allows the biopsy reservoir 246 to establish fluid communication with a conventional syringe 222 via connector 276, as shown in Figure 23. Such fluid communication between biopsy reservoir 246 and syringe 222 enhances the ability of the extractor 210 to draw in and isolate a tissue sample due to the generation of a vacuum force by the syringe 222, which shall be discussed below. The distal end of second cannula 214 is preferably formed having a hollow, frusto-conical shape that is designed and configured to allow first cannula 212 to axially pass therethrough. The distal rim 248a of the frusto-conical portion 248 is sharpened so that distal rim 248a may cut and contain a tissue sample disposed within biopsy reservoir 246 when the rim 248a is

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axially passed across the biopsy reservoir 246 of the first cannula 212.

As shown in Figure 29, the distal end of first cannula 212 of the second embodiment of the present invention freely passes, via axial movement, through the distal end 248 of second cannula 214. Second cannula 214 also preferably includes a barrel section 250 that serves as a sleeve to protect and contain a biopsy sample contained within a biopsy reservoir 246 when such sample is extracted from a tissue mass. The first and second cannulas may be formed in differing lengths and diameters to be utilized for a wide variety of tissue sampling applications such as breast, prostate, deep body, lung and other soft tissue biopsies.

In addition to being coaxially positioned relative to one another, first cannula 212 and second cannula 214 are maintained in an arrangement whereby the second cannula is constantly urged forward by biasing member 220, more clearly depicted in Figure 23. Preferably, biasing member 220 comprises a spring that is interposed between the first shoulder 216 formed on the first cannula 212 and second shoulder 218 formed on the second cannula 214. The distally urging biasing force exerted by spring 220 forces the second shoulder 218, and hence second cannula 214, to axially advance upon the first cannula 212.

In order to selectively control the position of the second cannula 214 relative to first cannula 212, the extractor 210 of the present invention advantageously incorporates the use of introducer 226. In the preferred embodiment, the introducer 226 is fabricated from polymer and/or metal materials that may be sterilized or disposed of, such materials being well known to those skilled in the art. Preferably, the introducer 226 is comprised of two parts, namely a handle and syringe retainer 228 and a plunger retractor member 230, more clearly depicted in Figure 32. The handle and syringe retainer 228 comprises

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a handle portion as well as structure sized and configured for detachably interconnecting with the conventional syringe 222. More specifically, the syringe retainer 228 preferably includes first and second syringe support members 258, 260 and syringe support collar 262 which engage the syringe 222 and firmly hold the syringe 222 in position. Additionally, there is provided slot 256 that is designed and configured to detachably engage with rim 222a on syringe 222 so as to further provide secure attachment with syringe retainer 228.

The plunger retractor member 230 of introducer 226 comprises a generally C-shaped member having a trigger member 232 depending therefrom. The rear portion of the plunger retractor member 230 has a slot 252 to receive plunger 224 on syringe 222. As will be discussed, slot 252 provides means for retracting the plunger 224 such that a vacuum is created in syringe 222 and ultimately in biopsy reservoir 246 via lumen 213 shown in Figure 25.

Mounted adjacent the top portion of the retractor member 230 is a cam bar 234, which is preferably pivotally mounted 236 thereon. As more clearly illustrated in Figure 32, the cam bar 234 includes a first cam slot 238 and a second cam abutment shoulder or surface 240. Additionally, cam bar 234 has a groove 242 which allows the coaxially positioned first cannula 212 and second cannula 214 to pass therethrough. As will be discussed, the first cam slot 238 and second cam abutment surface 240 provide means for adjusting the relative axial position of second cannula 214 with respect to first cannula 212.

The handle and syringe retainer 228 and plunger retractor member 230 are preferably connected to one another via a sliding-type engagement. More specifically, the plunger retractor member 230 is removably mounted onto the rear portion of syringe retainer 228 such that surface 230a is received upon upper guideway 264 and flanked by elongate guide members



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266 and 268. Additionally, surface 230b is received within lower guideway slot 270 such that trigger member 232 protrudes from the handle and syringe retainer 228 to form a gun-type configuration. In addition, the handle and syringe retainer 228 further include a spring-activated detent or locking member 272 to engage apertures formed on surface 230c of the plunger retractor member 230, said apertures being more clearly depicted as 274a,b in Figures 33, 34, 35, and 36. Such spring-activated locking member 272, when aligned with locking apertures 274a,b, provide means for positioning the handle and syringe retainer 228 with respect to the plunger retractor member 230 such that desired depths and axial positioning of the cannulas 212, 214 may be more easily attained when using the extractor 210. Importantly, spring-activated locking member 272, when aligned with locking aperture 274b, sets the position of cam abutment surface 240 for engagement of and stop of second shoulder 218 and second cannula 214, as depicted in Figures 35 and 35a.

Having thus described the structure of the biopsy instrument/extractor 210 of the second embodiment of the present invention, the operation of the same shall now be described with specific reference to Figures 33 through 36. Preparatory for use, the first and second cannulas 212 and 214 are coaxially positioned with biasing member 220 interposed between the shoulders 216 and 218. The proximal end 276 of the first cannula 212 may then be attached to the distal end of the syringe 222. As shown in Figure 33, the syringe 222 is mounted within handle and syringe retainer 228 with plunger 224 being received in slot 252 of the plunger retractor member 230. Additionally, cam bar 234 is positioned such that second shoulder 218 is received within first cam slot 238. Additionally, the spring-activated locking member 272 is received within locking aperture 274a in such a manner that relative orientation or position of the handle 228

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and plunger retractor member 230 is maintained unless otherwise manually adjusted. Figure 33a depicts the corresponding axial position (i.e., the distal axial position) between first cannula 212 and second cannula 214 while the introducer 226 is maintained in the initial orientation depicted in Figure 33. As illustrated, the second cannula 214 is selectively covers biopsy reservoir 246 while beveled cutting tip 244 axially protrudes or extend therebeyond.

10 While the introducer 226 and first and second cannulas 212, 214 are maintained in the orientation and relative axial position depicted in Figure 33 and Figure 33a, the introducer 226 is then gripped, as shown in Figure 24, and the first and second cannulas are manually  
15 pressed or inserted into a tissue mass from which a sample is to be extracted. As mentioned above, the introducer 226, namely the combination of handle and syringe retainer 228 and plunger retractor member 230, is formed to have a gun-like shape that allows the user to  
20 manually insert the coaxially positioned cannulas 212, 214 while maintained in this distal axial position and ultimately extract a sample of tissue using only one hand. Such design advantageously allows the physician user to utilize their other hand so as to manipulate the  
25 tissue or perform some other function as may be required.

During insertion of the first and second cannulas 212, 214 through the tissue, the user forces both interconnected portions 228, 230 of the introducer 226 into the tissue in a direction indicated by the arrows  
30 "A" in Figure 33. As should be noted, locking member 272 is engaged within aperture 274a during such insertion to prevent any relative axial movement between the handle 228 and plunger retractor member 230. Additionally, during such insertion the introducer 226 forces the  
35 cannulas 212, 214 into the tissue whereby the sharpened beveled cutting tip 244 is forced directly into the tissue, and the cutting tip 244 of the first cannula

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simultaneously cuts the tissue and positions the cut tissue adjacent its periphery so as to overlie the second cannula 214 adjacent the biopsy reservoir 246.

Once embedded within the tissue and having cut the tissue sample, the introducer 226 is manipulated such that the handle and syringe retainer 228 of the introducer 226 and first cannula 212 remains stationary while the plunger retractor member 230 is rearwardly retracted in the direction indicated by "B". The plunger retractor member 230 is retracted, via manipulation of trigger member 232, as the spring-activated locking member 272 is released by thumb pressure (i.e., overcome) from locking aperture 274a and subsequently engage with locking aperture 274b as shown in Figure 35. Due to the engagement of the second shoulder 218 with the cam slot 230 of the cam bar 234, during such rearward movement, the second cannula 214 axially retracts relative the first cannula 212 and is disposed in its proximal axial position wherein the biopsy reservoir 246 is exposed to the tissue mass 282, as depicted in Figure 34a. Accordingly, the axial retraction of the frusto-conical end portion 248 of second cannula 214 allows such cut tissue mass 282 to be received within the biopsy reservoir 246. Advantageously, during such retraction of the plunger retractor member 230 relative to handle and syringe retainer 223, a vacuum is generated in syringe 222 such that the previously cut tissue mass 282 is drawn downwardly into the biopsy reservoir 246 as depicted in Figure 34a.

Having effectively drawn the mass of tissue 282 to be extracted into the biopsy reservoir 246, the cam bar 234 is manually raised in the direction indicated by the letter "D" in Figure 35 such that the second shoulder 218 is released from first cam slot 238. Spring member 220 preferably provides sufficient force such that upon release from first cam slot 238 the second cannula 214 rapidly axially advances with sufficient force to cause

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the sharpened distal end 248a of the second cannula 214 to sever and retain the tissue sample 282a to be extracted within biopsy reservoir 246. Such forward axial movement of the second cannula 212 continues until  
5 the second shoulder 218 abuts the second cam abutment surface 240. The cross-sectional view depicting this distal axial position of the second cannula 214 depicted in Figure 35a, which corresponds with the abutment between second shoulder 218 and second cam abutment  
10 surface 240, as shown in Figure 35. As shown, in this distal axial position, the second cannula 214 securely captures the cut tissue mass 282a within the biopsy reservoir.

Having thus isolated the tissue sample 282a from  
15 tissue mass 282, the extractor 210, and hence first and second cannulas 212, 214, may both be removed from the tissue mass by withdrawal of the extractor 210 where the tissue sample 282a may be recovered from the biopsy reservoir 246 and subsequently examined. Alternatively,  
20 as illustrated in Figure 36, the present invention provides that cam bar 234 may be raised even further about pivot 236 to allow second shoulder 218, and thus second cannula 214, to remain in place while introducer 226, syringe 222, and first cannula 212 may be manually  
25 withdrawn in the direction indicated by the arrow "E". Advantageously, by allowing the second cannula 214 to remain stationary within tissue mass 282, the user, if desired, may make further tissue sample extractions through second cannula 214 in the manner described above.  
30 Advantageously, by using the extractor 210 of the present invention, the user will not have to make repeated punctures into the tissue which will thus facilitate the extraction of multiple samples while subjecting the subject to a less traumatic experience as compared to  
35 other devices known in the art.

Referring now to Figures 37-39, a disk guide assembly 298 comprises first 300 and second 302 disk

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guides having a circular channel 303 formed therein so as to slidably receive the second shoulder 218. Second shoulder 218 is thus prevented from moving side-to-side and upward by the disk guide assembly 298, particularly during the insertion process. This disk guide assembly allows rotation of the cannula assembly through 360 degrees.

As those skilled in the art will appreciate, it is common to exert pressure upon the tissue sample extractor of the present invention during the insertion process which tends to bend the first biopsy cannula 212 and the second cutting cannula 214 upward with respect to the device. Such bending of the first biopsy cannula 212 and second cutting cannula 214 is undesirable because it interferes with proper operation of the device. Thus, the optional disk guide assembly 298 assures reliable operation of the present invention.

The disk guide assembly 298 may either be formed as an integral part of the device or, optionally, may comprise an add-on assembly. Those skilled in the art will appreciate that various different configurations of the disk guide assembly 298 are likewise suitable for limiting movement of the second shoulder 218 in a longitudinal direction with respect to the first biopsy cannula 212 and second cutting cannula 214.

Referring now to Figure 40, an optional seal 310 is disposed about the first biopsy cannula 212 and urged into abutment with the second shoulder 218 such that it prevents vacuum leakage intermediate the first biopsy cannula 212 and the second cutting cannula 214. The seal 310 preferably has shoulder 312 formed thereon so as to receive the distal end of the spring 320. Those skilled in the art will appreciate that various other configurations of the optional seal 310 are likewise suitable.

Referring now to Figures 41 and 42, the second cutting cannula 214 is preferably formed to have a

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slanted or beveled cutting tip 335 formed thereon so as to facilitate reliable cutting of the biopsy tissue samples.

5 The biopsy reservoir 246 is preferably formed to have an obstructor 328 disposed at the proximal end thereof so as to prevent vacuum from pulling the cut tissue sample into the lumen 213 of the first biopsy cannula 212. The obstructor 328 is preferably formed by forming an undercut 326 at the proximal end of the biopsy  
10 reservoir 246 and then bending the proximal protruding portion or tab 328 formed thereby in the wall of the first biopsy cannula 212 inward so as to partially obscure the lumen 213 of the first biopsy cannula 212. The tab 328 is bent sufficiently to assure that the  
15 biopsy tissue sample remains within the biopsy reservoir, yet still allows the vacuum to draw the tissue sample into the biopsy reservoir. Optionally, similar but shallower undercut 322 may be formed at the distal end of the biopsy reservoir 246 to define distal tab 324.

20 The tip 320 of the first biopsy cannula 212 is preferably formed by machining a solid plug 332, preferably via electron discharge machining, i.e., either standard or wire electron discharge machining, so as to form a scooped out portion 334 which defines a sharp  
25 point 336.

The solid plug 332 may either first be attached to the first biopsy cannula 212, so as to facilitate handling thereof during the machining process, or alternatively, may be formed at the end of an elongate  
30 bar and then cut therefrom prior to insertion into the first biopsy cannula 212.

The solid plug 332 is preferably attached to the first biopsy cannula 212 via forming at least one crimp 323 in the first biopsy cannula 212, which is pressed  
35 into a corresponding cut-out or dimple formed in the solid plug 332 or by being press fit into the first biopsy cannula 212. Alternatively, those skilled in the

art will appreciate that various other different means, as discussed above, may be utilized to attached the solid plug 332 to the first biopsy cannula 212. Further, various different combinations of such means may be  
5 utilized.

The cross-sectional area or profile defined by the scooped out portion 334 of the solid plug 332 facilitates easy insertion into tissue, while maintaining sufficient strength to prevent premature dulling or deformation of  
10 the sharp point 336.

The diameter of the solid plug 332 may either be approximately equal to the outer diameter of the first biopsy cannula 212, so as to provide a substantially flush fit therewith, or alternatively may similarly be  
15 approximately equal to the inner diameter of the second cutting cannula 214.

According to the second embodiment of the present invention, the cannula assembly, comprised of the first biopsy cannula 212, the second cutting cannula 214, and preferably the spring 220, seal 310, and second shoulder  
20 218 as well, are preferably formed so as to be disposable. Thus, these items are preferably formed of comparatively inexpensive materials, which is made possible due to their limited expected life. By making  
25 the cannula assembly disposable, a high degree of convenience is achieved. Thus, the cannulas do not need to be sterilized between uses, rather a new cannula assembly is installed for each use.

The major structural components of the first and  
30 second embodiments of the present invention are preferably fabricated from stainless steel, polycarbonate, aluminum, or titanium, so as to be durable. Those skilled in the art will appreciate that various other materials are likewise suitable.  
35 Alternatively, the structural components may be formed of other, less durable, materials, so as to facilitate the fabrication of a low cost, disposable device.

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There has thus been disclosed a tissue sample extractor, with various preferred embodiments thereof, having been described in detail with the various advantages being set forth. It is understood, however, 5 that equivalents are possible and that variations in structure may be made that fall within the underlying principles of the present invention.



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## WHAT IS CLAIMED IS:

1. A manually operated aspirating device used in combination with a conventional needle and syringe with plunger comprising:

5 a) a handle releasably attachable to said syringe, said handle having at least one collar formed atop thereof for attaching said syringe to said handle; and

10 b) a slide slidably attachable to said handle, said slide having a slot formed thereon for releasably engaging with the end of said plunger, said slide being so attachable to said handle that when said syringe is attached to said handle, said slide may selectively position said plunger relative  
15 said syringe.

2. The device of Claim 1 wherein:

20 a) said slide comprises a generally U-shaped member having a pair of outwardly extending arms, said slot for releasably engaging said plunger being formed at the closed end of said generally U-shape; and

b) said handle includes first and second channels formed atop thereof for slidably engaging a respective one of said pair of arms.

25 3. The device of Claim 2 wherein said slide further comprises a trigger member attachable to a respective one of said pair of outwardly extending arms of said generally U-shaped member, said trigger member being so attachable to said generally U-shaped member  
30 that when said generally U-shaped member is slidably attached to said handle, a generally gun-like structure is formed, said trigger providing means for allowing a user to actuate said slide relative said handle.

35 4. The device of Claim 3 wherein said device is configured such that the hand of the user is placed in a forward position wherein the index finger of a user's hand is oriented toward the target tissue and is

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positioned from 1 inch to 4 inches proximal the tip of said needle.

5. The device of Claim 2 wherein:

5 a) a respective one of said pair of arms includes a plurality of apertures formed thereon, said apertures being spaced about the length of said one of said pair of arms; and

10 b) said handle includes a detent locking mechanism disposed therein, said detent locking mechanism having an upwardly biased locking detent oriented and configured to selectively engage a respective one of said plurality of apertures, said engagement between said locking detent and said  
15 respective one of said plurality of apertures maintaining said slide and said handle in releasably rigid attachment.

6. The device of Claim 5 wherein said detent locking mechanism further includes a knob protruding outwardly from said handle, said knob allowing the user  
20 to selectively engage said locking detent with a respective one of said plurality of apertures, said knob extending outwardly from said handle such that said knob may be manually accessed by the hand of the user.

7. The device of Claim 6 wherein said knob of said  
25 locking detent mechanism is designed and oriented to be accessed by the thumb of said user.

8. The device of Claim 5 wherein when said slide is retracted, a vacuum is generated within said syringe and said needle, said retraction of said slide being  
30 selectively controllable by said detent locking mechanism.

9. The device of Claim 6 wherein said knob is releasably attachable to said locking detent mechanism on either side of said handle, said attachment to either  
35 side of said handle providing means for allowing said device to be used by either the left or right hand of a user.

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10. The device of Claim 2 wherein said device is fabricated from sterilizable materials.

11. The device of Claim 10 wherein said device is fabricated from at least one of the group of materials  
5 consisting of stainless steel, polycarbonate, aluminum, and titanium.

12. The device of Claim 1 wherein said handle includes first and second collars formed atop thereof for attaching said syringe to said handle.

10 13. A tissue sample extractor comprising:

a) a first biopsy cannula having proximal and distal ends, said distal end having a sharpened beveled cutting tip and a biopsy reservoir formed thereon, said biopsy reservoir being formed proximal  
15 said cutting tip;

b) a second cutting cannula having proximal and distal ends, said second cutting cannula being axially mounted about said first biopsy cannula such that said first biopsy cannula is partially  
20 telescoped within said second cutting cannula, said distal end of said second cutting cannula having a sharpened cutting edge formed thereon;

c) an introducer, said introducer being designed and configured to simultaneously and detachably engage with said first biopsy cannula and  
25 said second cutting cannula; and

d) wherein said introducer controllably moves said second cutting cannula about said first biopsy cannula such that said distal end of said second  
30 cutting cannula selectively covers and uncovers said distal end of said first biopsy cannula.

14. The tissue sample extractor of Claim 13 wherein said introducer urges said second cutting cannula to selectively cover said biopsy reservoir and leave said  
35 sharpened beveled tip uncovered in a first distal position and allows said second cutting cannula to

uncover the biopsy reservoir in a second proximal position.

15       15. The tissue sample extractor of Claim 14 wherein said introducer further urges said second cutting cannula to extend beyond said biopsy channel of said first biopsy cannula in the distal position.

10       16. The tissue sample extractor of Claim 15 wherein said extractor further comprises a device for creating a vacuum, said device being attached to and in fluid communication with said proximal end of said first biopsy cannula, said device being designed and configured to cause a vacuum to be generated within said first biopsy cannula when said second cutting cannula is withdrawn over the biopsy reservoir of said first cannula, said vacuum being sufficiently strong to cause a portion of  
15       said tissue to be drawn into said biopsy reservoir.

20       17. The tissue sample extractor of Claim 16 wherein said device for creating a vacuum is interconnected with said introducer such that said introducer simultaneously causes said device for creating a vacuum to generate said vacuum said second cutting cannula is urged into said second proximal position.

25       18. The tissue sample extractor of Claim 15 wherein said introducer further includes an apparatus for detachably maintaining said second cutting cannula in said proximal and distal positions.

30       19. The tissue sample extractor of Claim 18 wherein when said first biopsy cannula is advanced into said tissue and said second cutting cannula is withdrawn to said second proximal position, said second cutting cannula may then be advanced into said distal position such that said second cutting cannula cuts and isolates a tissue sample within said biopsy reservoir.

35       20. A tissue sample extractor comprising:  
a) a first biopsy cannula having proximal and distal ends, said proximal end having a first shoulder attached thereto, said distal end having a

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sharpened beveled cutting tip and a biopsy reservoir formed thereon, said biopsy reservoir being formed proximal said cutting tip;

5           b) a device for creating a vacuum, said device being attached to said first shoulder and in fluid communication with said biopsy reservoir of said first biopsy cannula.

10           c) a second cutting cannula having proximal and distal ends, said proximal end having a second shoulder attached thereto, said distal end having a sharpened cutting edge formed thereon, said second cutting cannula being axially mounted about said first biopsy cannula such that said first biopsy cannula is partially telescoped within said second cutting cannula;

15           d) a biasing member disposed between said first shoulder and said second shoulder such that said second shoulder urges said second cutting cannula to distally advance about said first biopsy cannula; and

20           e) an introducer, said introducer being detachably engaged with said device for creating a vacuum and said second shoulder of said second cutting cannula, said introducer being so attached to said second cutting cannula and said device for creating a vacuum that said introducer controllably adjusts the relative positions of said first and second cannulas such that said distal end of said second cutting cannula is selectively movable about said first biopsy cannula.

30           21. The tissue sample extractor of Claim 20 wherein:

          a) said device for creating a vacuum comprises a conventional syringe and plunger;

35           b) said biasing member disposed between said first shoulder and said second shoulder comprises a spring member; and

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5 c) said introducer comprises a handle and syringe retainer in combination with a plunger retractor member, said handle and syringe retainer and said plunger retractor member being so combined that said retainer and said retractor member cooperate to form a gun-like member.

10 22. The tissue sample extractor of Claim 21 wherein said plunger retractor member comprises a generally C-shaped member having a trigger-shaped member depending therefrom and a slot formed thereon to engage said plunger, said generally C-shaped member having a cam bar pivotally attached along a top portion thereof, said cam bar having a first cam slot and a second cam abutment surface, said first cam slot and said second cam abutment  
15 surface being designed and configured to detachably engage with said second shoulder of said second cutting cannula, said first cam slot and said second cam abutment surface being spaced such that said second cutting  
20 cannula is urged forward about said first biopsy cannula such that said distal end of said first biopsy cannula is selectively covered by said second cutting cannula.

23. The tissue sample extractor of Claim 22 wherein:

25 a) said first cam slot detachably engages said second shoulder such that said second cutting cannula selectively covers said biopsy reservoir and leaves said sharpened beveled cutting tip uncovered; and

30 b) said second cam abutment surface detachably engages said second shoulder such that said second cutting cannula covers said biopsy reservoir.

24. The tissue sample extractor of Claim 23 wherein said introducer may be used by a single hand.

35 25. The tissue sample extractor of Claim 24 wherein said cannula assembly and said introducer cooperate to allow said first biopsy cannula and said second cutting

cannula to be oriented such that said biopsy reservoir is covered and sharpened beveled cutting tip is exposed when said first biopsy cannula and said second cutting cannula are inserted into a tissue mass.

5           26. The tissue sample extractor of Claim 25 wherein said cam bar may be manually adjusted such that said second shoulder is urged from said first cam slot to said second cam abutment surface, said cam bar being further manually adjustable such that said second shoulder is  
10           releasable from said second cam abutment surface such that said cutting cannula may be axially removed from said second cutting cannula.

          27. The tissue sample extractor of Claim 26 wherein when said first biopsy cannula and said second cutting  
15           cannula are embedded within a tissue mass and said biopsy reservoir is exposed by withdrawal of second cutting cannula, said cam bar may be manually adjusted such that said biasing member forces said second cutting cannula to  
20           distally advance over said biopsy reservoir of said first biopsy cannula wherein said distal advancement forces said second cutting cannula to sever a portion of said tissue and contain said portion within said biopsy reservoir.

          28. The tissue sample extractor of Claim 27 wherein  
25           said cam bar may be further manually adjusted such that said second cutting cannula may be left embedded within said tissue mass, said second cutting cannula being so embedded that second cannula acts as a conduit, whereby at least one additional sample of tissue may be extracted  
30           through said second cutting cannula.

          29. A method of extracting a sample of tissue from a tissue mass comprising:

          a) inserting a first and second cannula  
          within said tissue mass, said first cannula being  
35           partially telescoped within said second cannula, said first cannula having a sharpened beveled cutting tip and biopsy reservoir formed at a distal

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end thereof, said second cannula having a sharpened cutting edge formed about a distal end thereof, said first cannula being so telescoped within said second cannula such that said sharpened beveled cutting tip protrudes from said second cannula while said biopsy reservoir remains covered by said second cannula;

b) withdrawal of said second cutting cannula to expose biopsy reservoir in first cannula and by manipulating the trigger on the C-shaped piece;

c) simultaneously applies a vacuum force to the interior of said first cannula such that a sample of tissue is drawn into said biopsy reservoir, the cam then releases the disc on the second cutting cannula thereby allowing the biasing member to;

d) axially advance said second cannula about said first cannula such that said second cutting cannula severs said tissue collected about said biopsy reservoir and encases said sample within said biopsy reservoir; and

e) removing said sample encased within said biopsy reservoir.

30. The method of Claim 29 wherein an introducer is utilized to simultaneously withdraw said second cannula relative to said first cannula and cause said vacuum to be generated within said first cannula.

31. The method of Claim 30 wherein said introducer utilizes a conventional syringe to generate a vacuum within said first cannula.

32. The method of Claim 30 wherein said introducer is designed and configured to be used by one hand of the user.

33. A tissue sample extractor comprising:

a) a first biopsy cannula having proximal and distal ends, said proximal end having a first shoulder attached thereto, said distal end having a sharpened beveled cutting tip and a biopsy reservoir



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formed thereon, said biopsy reservoir being formed proximal to said cutting tip;

5 b) a device for creating a vacuum, said device being attached to said first shoulder and in fluid communication with said biopsy reservoir of said first biopsy cannula;

10 c) a second cutting cannula having proximal and distal ends, said proximal end having a second shoulder attached thereto, said distal end having a sharpened cutting edge formed thereon, said second cutting cannula being axially mounted about said first biopsy cannula such that said first biopsy cannula is partially telescoped within said second cutting cannula;

15 d) a biasing member disposed between said first shoulder and said second shoulder such that said second shoulder urges said second cutting cannula to distally advance about said first biopsy cannula;

20 e) a guide along which said second shoulder moves as said second shoulder urges said second cutting cannula to distally advance about said first biopsy cannula; and

25 f) an introducer, said introducer being detachably engaged with said device for creating a vacuum and said second shoulder of said second cutting cannula, said introducer being so attached to said second cutting cannula and said device for creating a vacuum that said introducer controllably  
30 adjusts the relative positions of said first and second cannulas such that said distal end of said second cutting cannula is selectively movable about said first biopsy cannula.

35 34. The tissue sample extractor of Claim 33 wherein:

a) said device for creating a vacuum comprises a conventional syringe and plunger;

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b) said biasing member disposed between said first shoulder and said second shoulder comprises a spring member; and

5 c) said introducer comprises a handle and syringe retainer in combination with a plunger retractor member, said handle and syringe retainer and said plunger retractor member being so combined that said retainer and said retractor member cooperate to form a gun-like member.

10 35. The tissue sample extractor of Claim 34 wherein said plunger retractor member comprises a generally C-shaped member having an attachable trigger-shaped member depending therefrom and a slot formed thereon to engage said plunger, said generally C-shaped member having a cam  
15 bar pivotally attached along a top portion thereof, said cam bar having a first cam slot and a second cam abutment surface, said first cam slot and said second cam abutment surface being designed and configured to detachably engage with said second shoulder of said second cutting  
20 cannula, said first cam slot and said second cam abutment surface being spaced such that said second cutting cannula is urged forward about said first biopsy cannula such that said distal end of said first biopsy cannula is selectively covered by said second cutting cannula.

25 36. The tissue sample extractor of Claim 35 wherein:

a) said first cam slot detachably engages said second shoulder such that said second cutting cannula selectively covers said biopsy reservoir and  
30 leaves said sharpened beveled cutting tip uncovered; and

b) said second cam abutment surface detachably engages said second shoulder such that said second cutting cannula covers said biopsy  
35 reservoir.

37. The tissue sample extractor of Claim 36 wherein said introducer may be used by a single hand.

38. The tissue sample extractor of Claim 37 wherein the cannula assembly and said introducer cooperate to allow said first biopsy cannula and said second cutting cannula to be oriented such that said biopsy reservoir is covered and said sharpened beveled cutting tip is exposed when said first biopsy cannula and said second cutting cannula are inserted into a tissue mass.

39. The tissue sample extractor of Claim 38 wherein said cam bar may be manually adjusted such that said second shoulder is urged from said first cam slot to said second cam abutment surface, said cam bar being further manually adjustable such that said second shoulder is releasable from said second cam abutment surface such that said cutting cannula may be axially removed from said second cutting cannula.

40. The tissue sample extractor of Claim 39 wherein when said first biopsy cannula and said second cutting cannula are embedded in a tissue mass and said biopsy reservoir is exposed by withdrawal of second cutting cannula, said cam bar may be manually adjusted such that said biasing member forces said second cutting cannula to distally advance over said biopsy reservoir of said first biopsy cannula wherein said distal advancement forces said second cutting cannula to sever a portion of said tissue and contain said portion within said biopsy reservoir.

41. The tissue sample extractor of Claim 40 wherein said cam bar may be further manually adjusted such that said second cutting cannula may be left embedded within said tissue mass, said second cutting cannula being so embedded that second cannula acts as a conduit, whereby at least one additional sample of tissue may be extracted through said second cutting cannula.

42. The tissue sample extractor of Claim 33 wherein said guide is configured to prevent side-to-side and upward bending of said first biopsy cannula.

43. The tissue sample extractor of Claim 33 wherein said second shoulder is configured as a disk and said guide comprises a complimentary channel along which said second shoulder moves as said second shoulder urges said  
5 second cutting cannula to distally advance about said first biopsy cannula.

44. The tissue sample extractor of Claim 33 wherein said beveled cutting tip of said first biopsy cannula comprises a solid plug having a scalloped portion  
10 defining the sharpened bevel thereof.

45. The tissue sample extractor of Claim 44 wherein the scalloped portion of said beveled cutting tip may be formed via electron discharge machining.

46. The tissue sample extractor of Claim 44 wherein  
15 said beveled cutting tip is attached to said first biopsy cannula by at least one of press fitting and crimping.

47. The tissue sample extractor of Claim 33 wherein said biopsy reservoir comprises an obstructing member for preventing the vacuum from pulling a tissue sample from  
20 said biopsy reservoir.

48. The tissue sample extractor as recited in Claim 47 wherein said obstructing member comprises an inwardly bent tab formed from said first biopsy cannula at a periphery of said biopsy reservoir.

49. The tissue sample extractor as recited in Claim  
25 33 further comprising a seal configured to mitigate vacuum leakage intermediate said first biopsy cannula and said second cutting cannula.

50. The tissue sample extractor as recited in Claim  
30 49 wherein said seal comprises an annular member formed of a resilient material disposed about said first biopsy cannula, said annular member being biased in position via said biasing member.

51. The tissue sample extractor of Claim 33 wherein  
35 the sharpened cutting edge of said second cutting cannula comprises a bevel.

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52. The tissue sample extractor of Claim 44 wherein the diameter of said solid plug is approximately equal to the outer diameter of said first biopsy cannula.

53. The tissue sample extractor of Claim 44 wherein  
5 the diameter of said solid plug is approximately equal to the inner diameter of said second cutting cannula.

54. The tissue sample extractor of Claim 33 wherein said first biopsy cannula and said second cutting cannula are configured to be removable from said introducer and  
10 may be disposable.

55. A tissue sample extractor comprising:

a) a first biopsy cannula having proximal and distal ends, said proximal end having a first shoulder attached thereto, said distal end having a  
15 sharpened beveled cutting tip and a biopsy reservoir formed thereon, said biopsy reservoir being formed proximal to said cutting tip;

b) a device for creating a vacuum, said device being attached to said first shoulder and in  
20 fluid communication with said biopsy reservoir of said first biopsy cannula;

c) an obstructing member for preventing the vacuum from pulling a tissue sample from said biopsy reservoir.

d) a second cutting cannula having proximal and distal ends, said proximal end having a second shoulder attached thereto, said distal end having a  
25 sharpened cutting edge formed thereon, said second cutting cannula being axially mounted about said first biopsy cannula such that said first biopsy  
30 cannula is partially telescoped within said second cannula;

e) a biasing member disposed between said first shoulder and said second shoulder such that  
35 said second shoulder urges said second cutting cannula to distally advance about said first biopsy cannula; and

f) an introducer, said introducer being detachably engaged with said device for creating a vacuum and said second shoulder of said second cutting cannula, said introducer being so attached to said second cutting cannula and said device for creating a vacuum that said introducer controllably adjusts the relative positions of said first and second cannulas such that said distal end of said second cutting cannula is selectively movable about said first biopsy cannula.

56. The tissue sample extractor of Claim 55 wherein said obstructing member comprises an inwardly bent tab formed at a periphery of said biopsy reservoir.

57. A method for forming a tissue sample extractor biopsy cannula, said method comprising the steps of:

a) forming a scalloped portion in a solid plug via electron discharge machining such that a sharp point is defined; and

b) attaching the solid plug to a cannula having a lumen by inserting a portion of the solid plug into the lumen of the cannula.

58. The method of Claim 57 wherein the step of forming a scalloped portion in a solid plug comprises forming a scalloped portion in a solid plug having a diameter approximately equal to that of the cannula.

59. The method of Claim 57 wherein the step of forming a scalloped portion in a solid plug comprises forming a scalloped portion in a solid plug having a diameter greater than that of the cannula, but less than inner diameter of cutting cannula.

60. The method of Claim 57 wherein the step of attaching the solid plug to the cannula is performed prior to the step of forming a scalloped portion in the solid plug.

61. The method as recited in Claim 57 wherein the step of attaching the solid plug to the cannula comprises at least one of press fitting and crimping.

62. The method as recited in Claim 57 further comprising the step of forming a biopsy reservoir in the cannula.

5 63. The method as recited in Claim 62 further comprising the step of forming an undercut tab at a proximal end of said reservoir and the step of bending the undercut tab inwardly so as to form an obstructor for preventing tissue samples from being pulled by vacuum from the biopsy reservoir into the cannula.

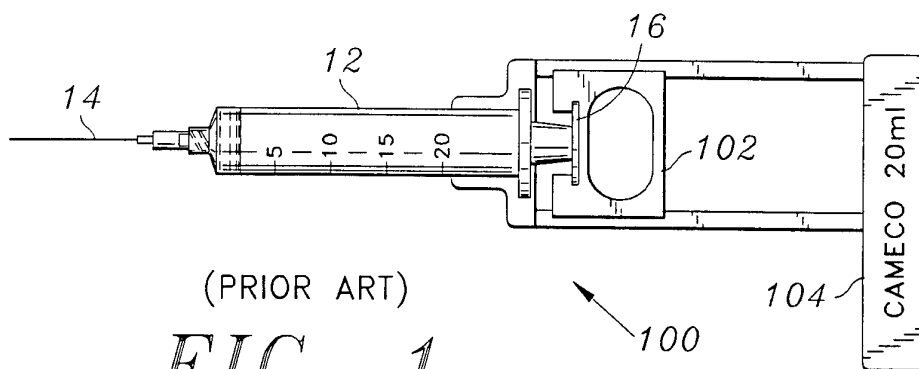
10 64. A disposable cannula assembly for a tissue sample extractor, said cannula assembly comprising:

a) a first biopsy cannula having proximal and distal ends, said distal end having a sharpened beveled cutting tip and a biopsy reservoir formed thereon, said biopsy reservoir being formed proximal  
15 said cutting tip;

b) a second cutting cannula having proximal and distal ends, said second cutting cannula being axially mounted about said first biopsy cannula such  
20 that said first biopsy cannula is partially telescoped within said second cutting cannula, said second cutting cannula having a sharpened cutting edge formed thereon; and

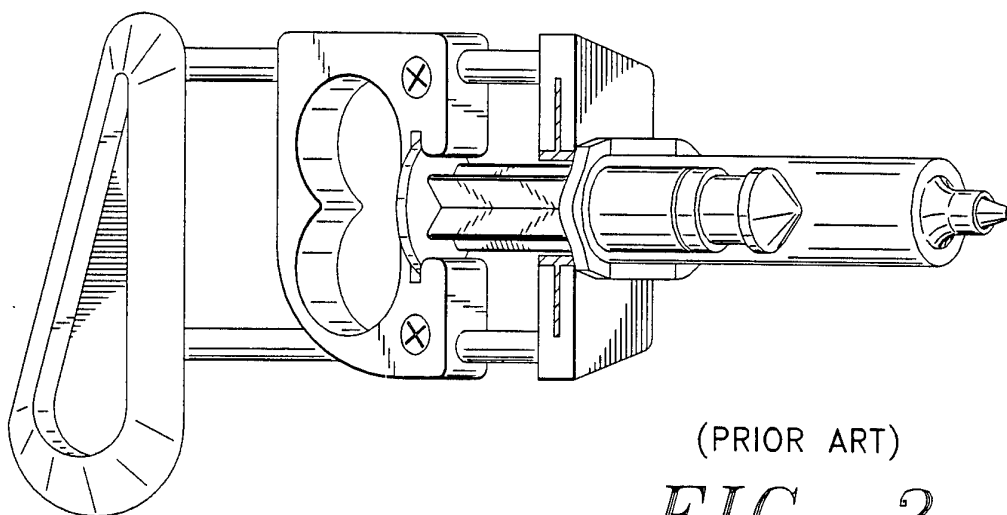
c) said first biopsy cannula and said second  
25 cutting cannula being configured for removable attachment to an introducer.

65. The cannula assembly of Claim 63 further comprising a spring disposed about said first biopsy  
30 cannula for biasing said second cutting cannula distally relative to said first biopsy cannula.



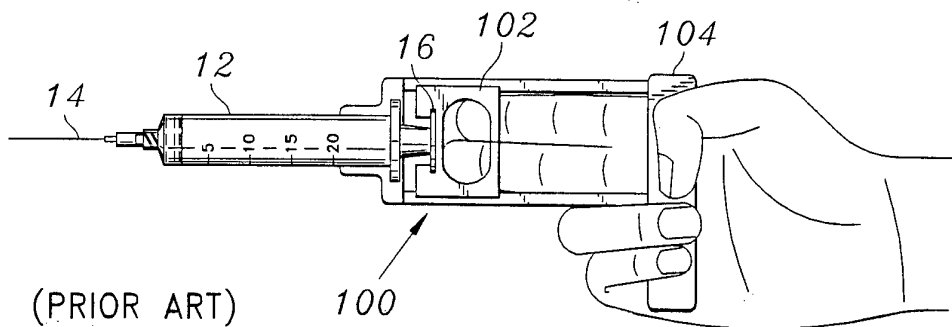
(PRIOR ART)

FIG. 1



(PRIOR ART)

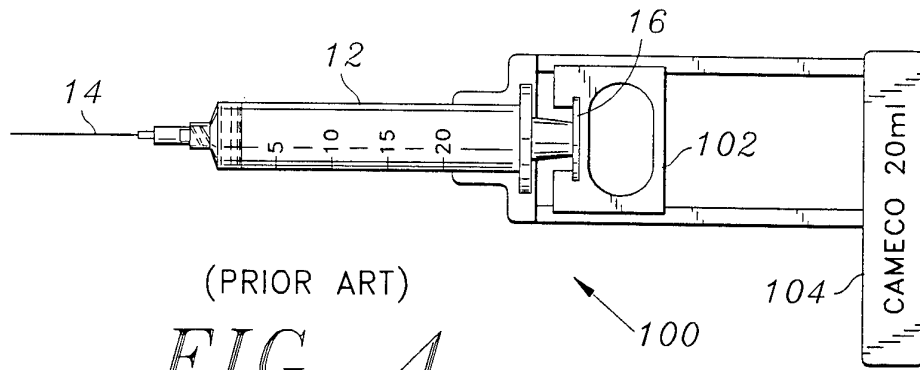
FIG. 2



(PRIOR ART)

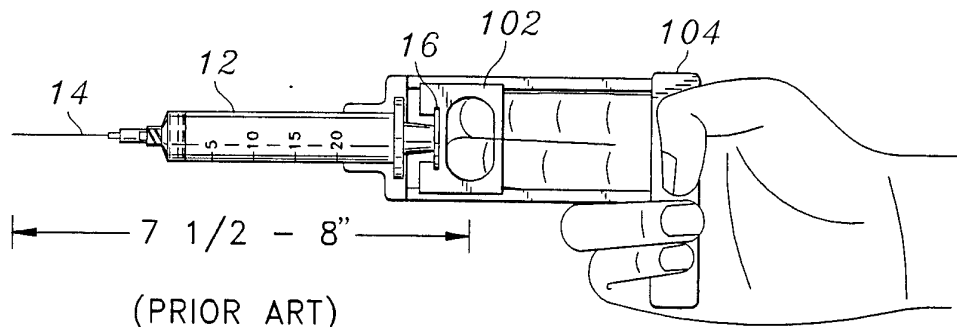
FIG. 3





(PRIOR ART)

FIG. 4



(PRIOR ART)

FIG. 5

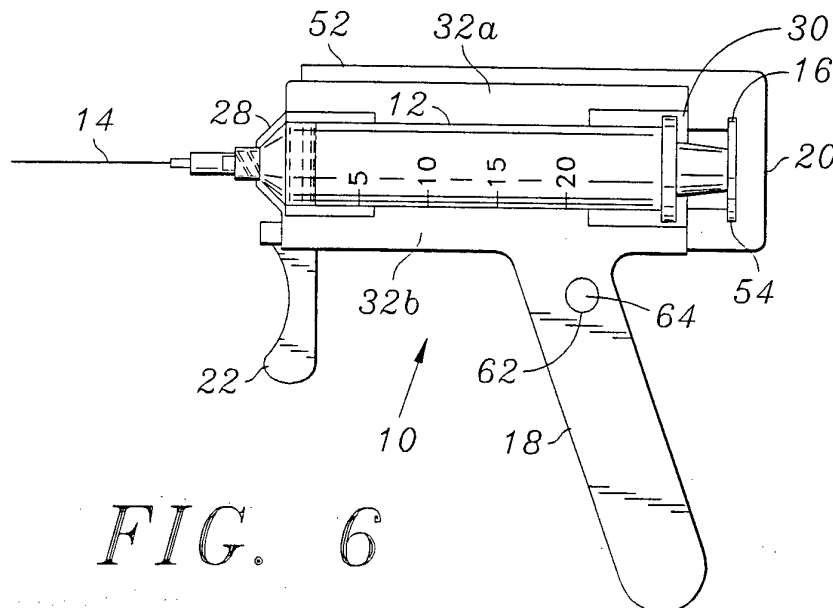


FIG. 6

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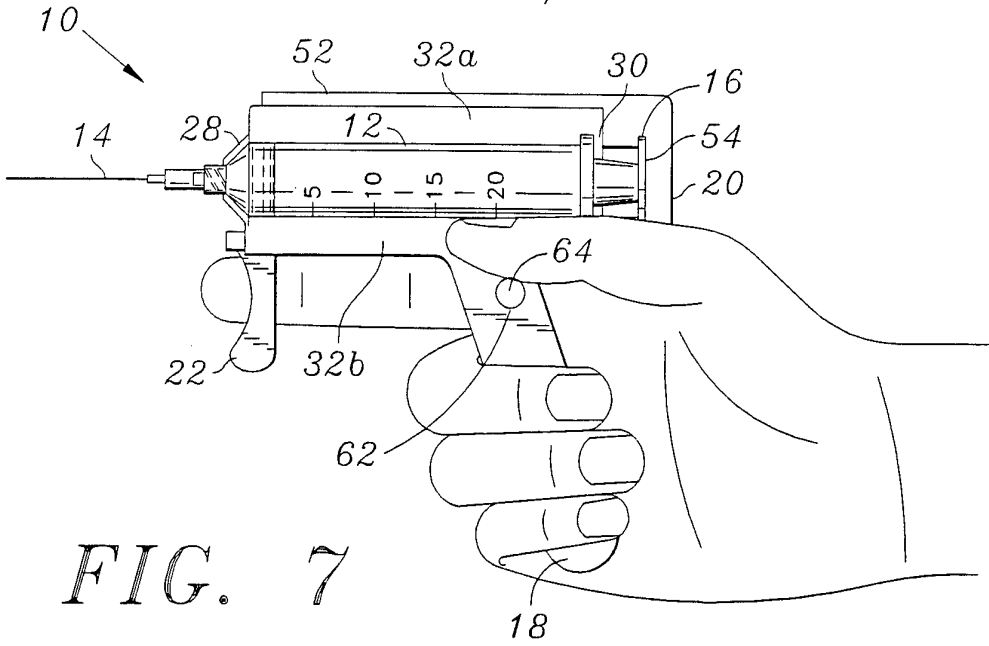


FIG. 8

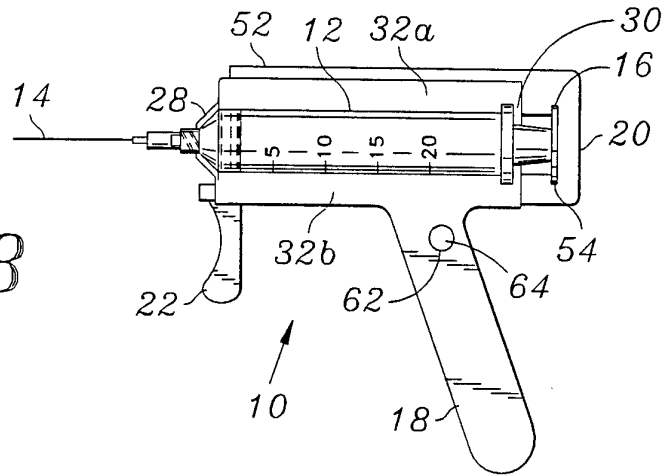
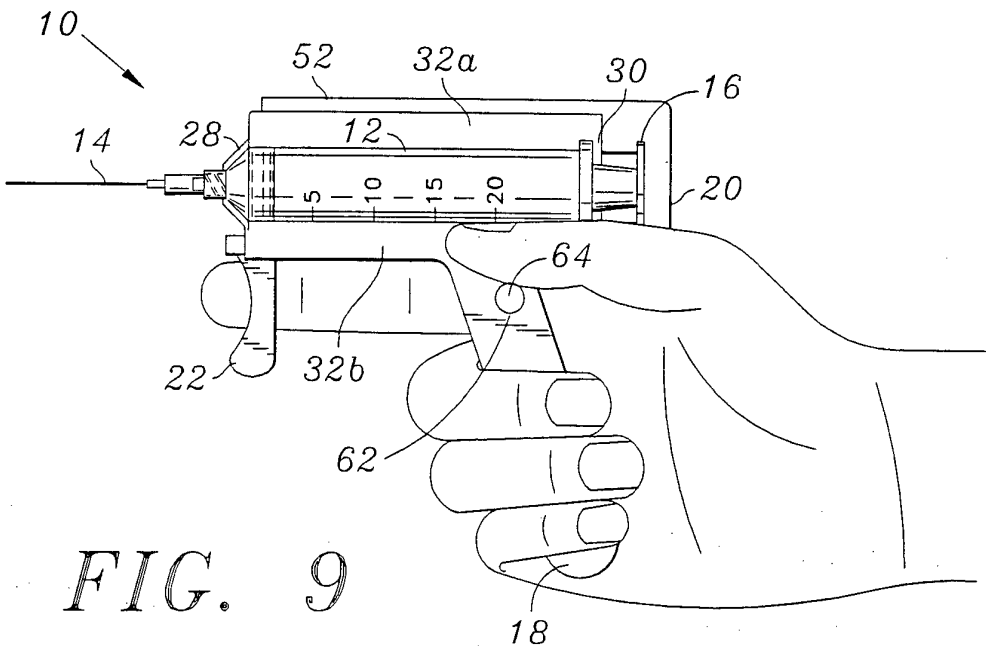
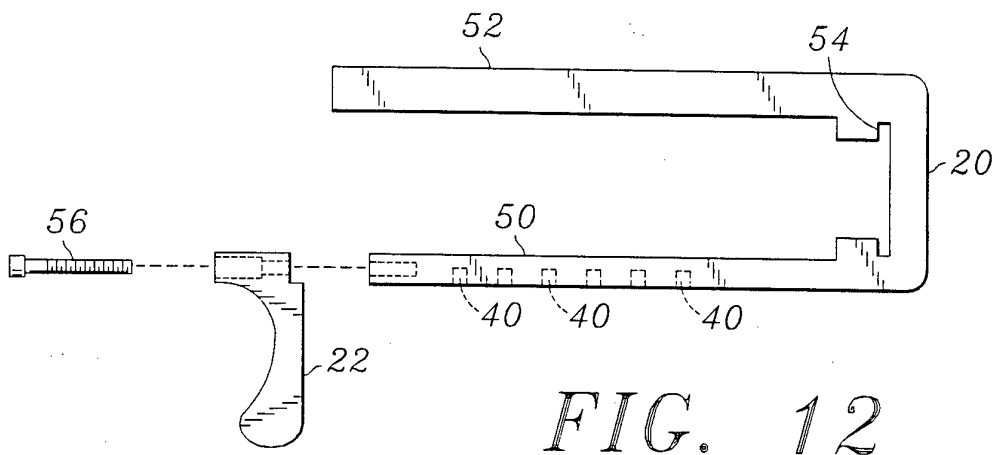
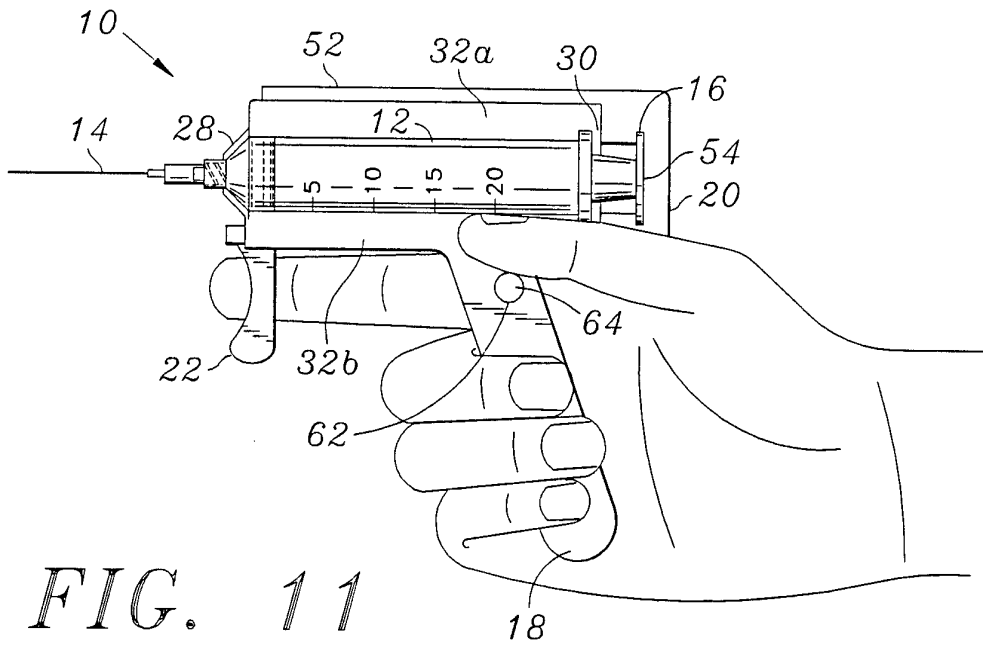
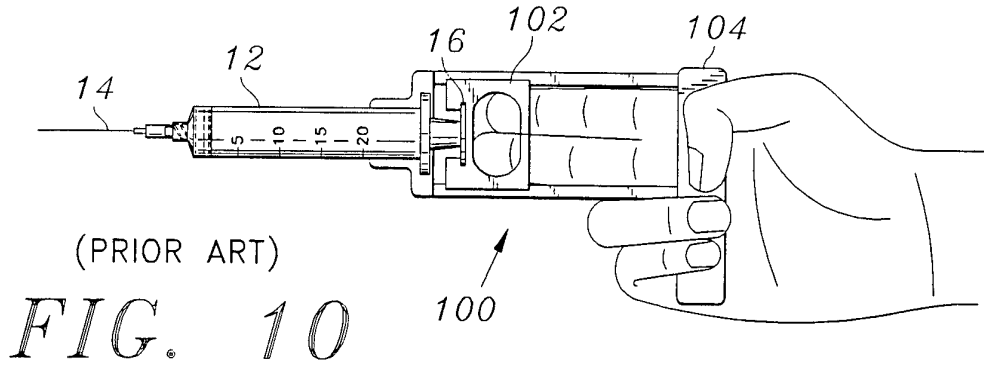


FIG. 9





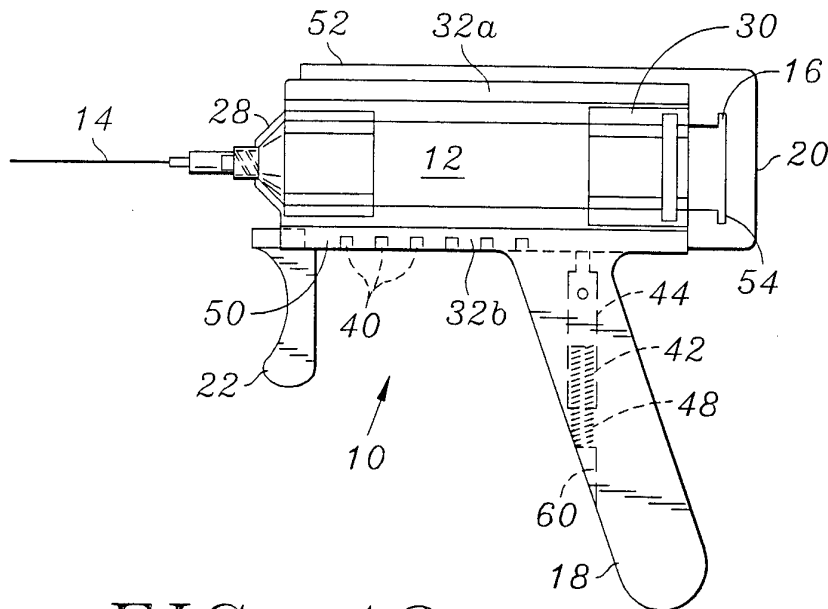


FIG. 13

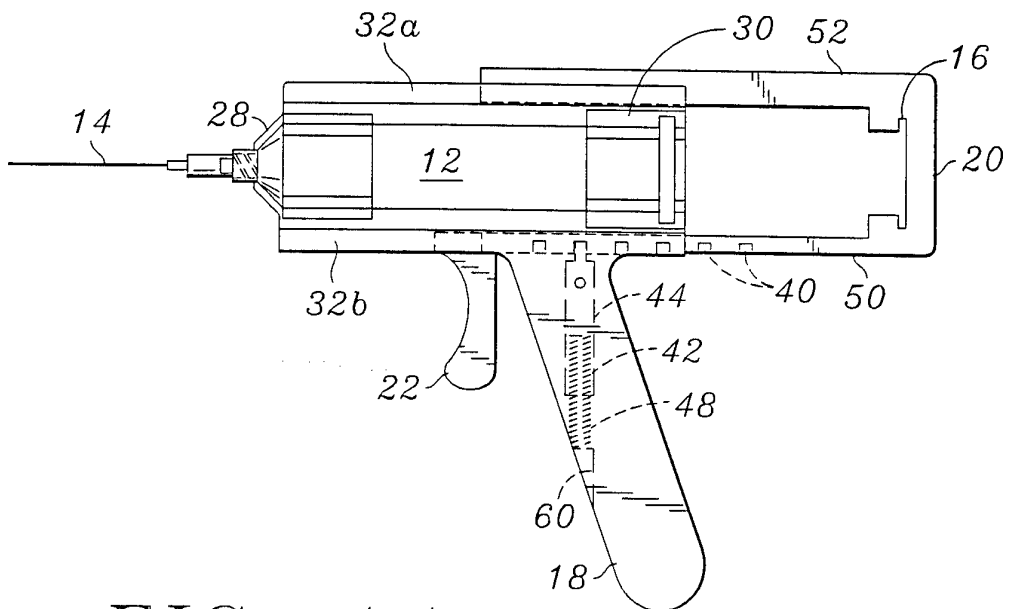


FIG. 14

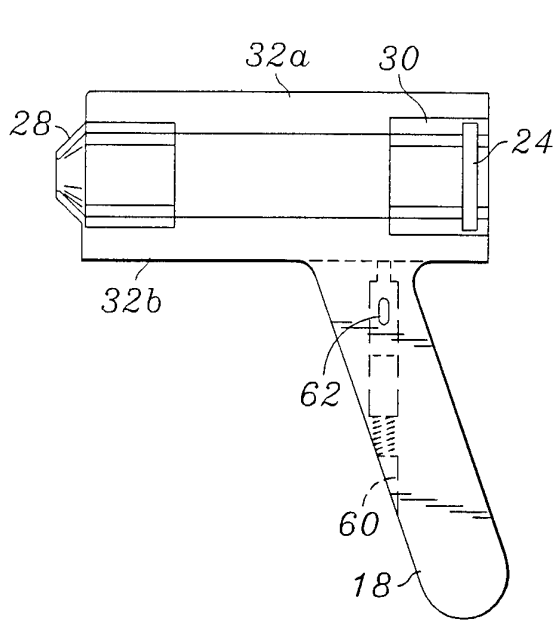


FIG. 15

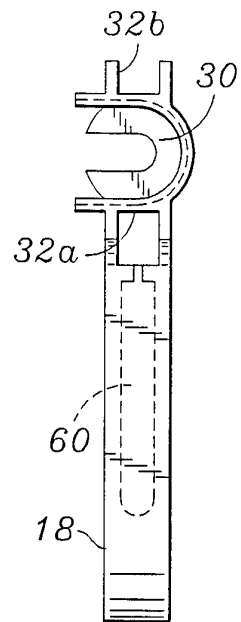


FIG. 16

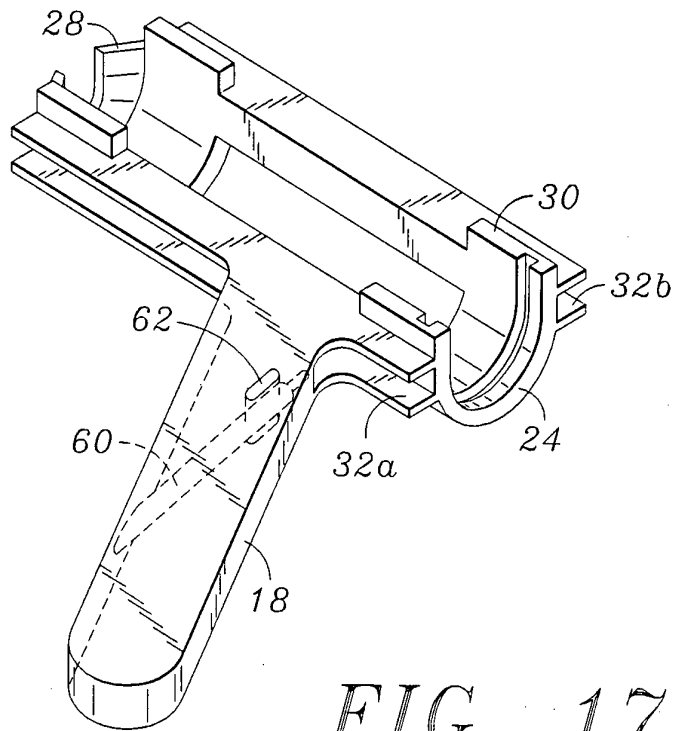


FIG. 17

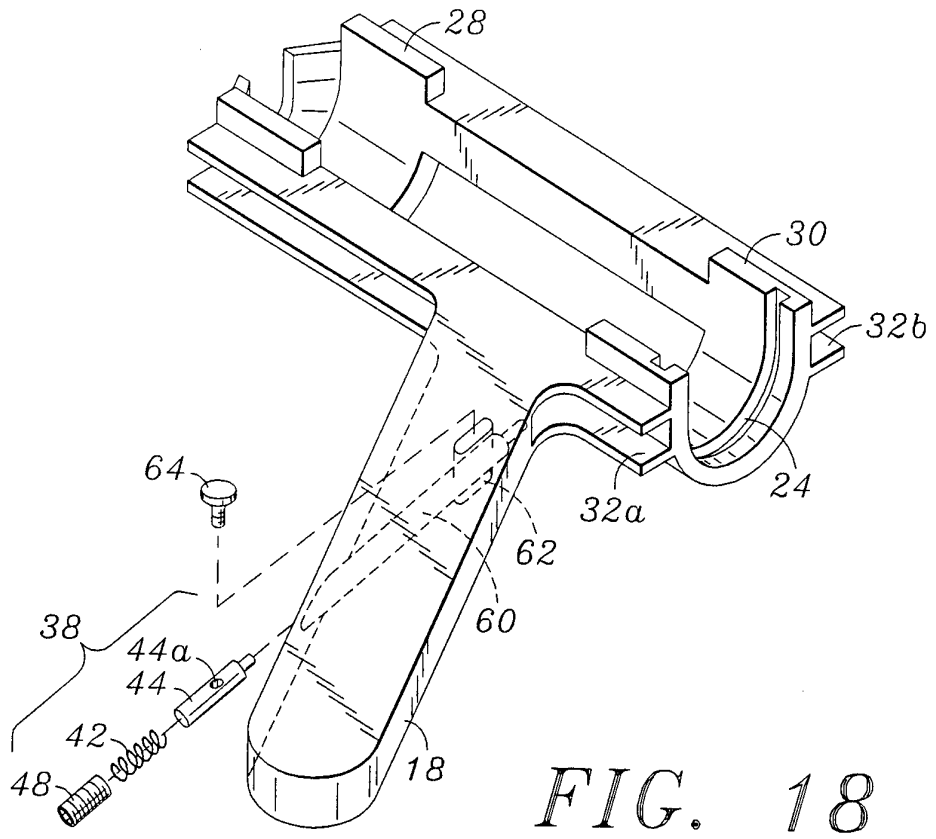


FIG. 18

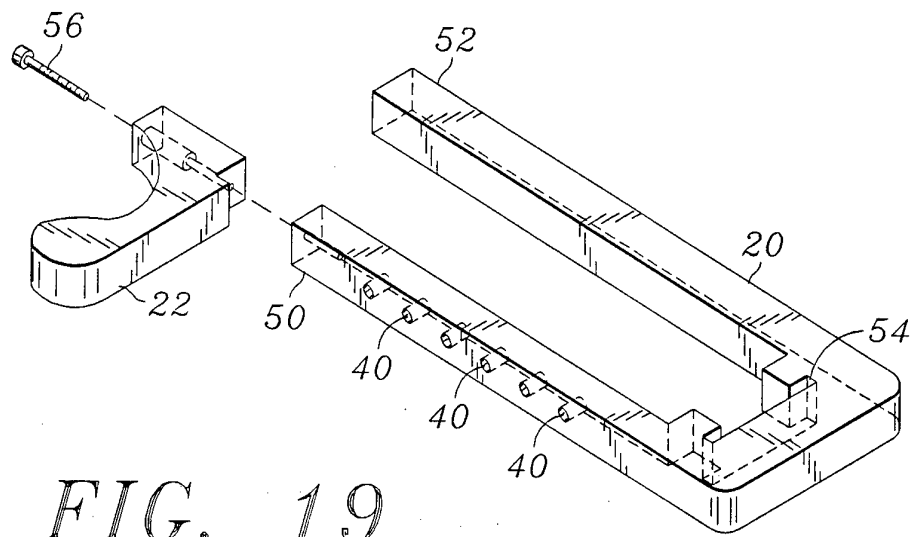


FIG. 19

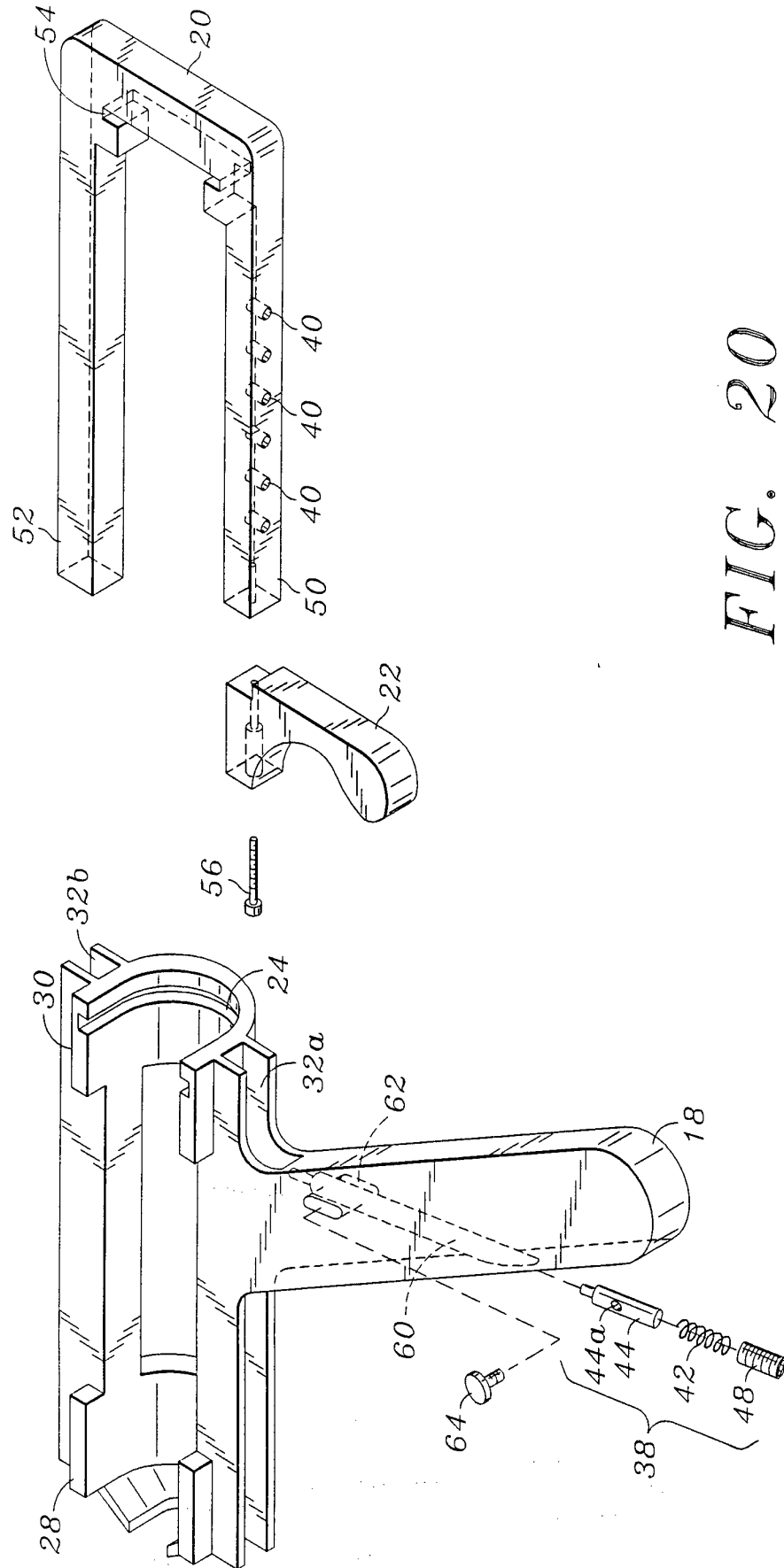


FIG. 20

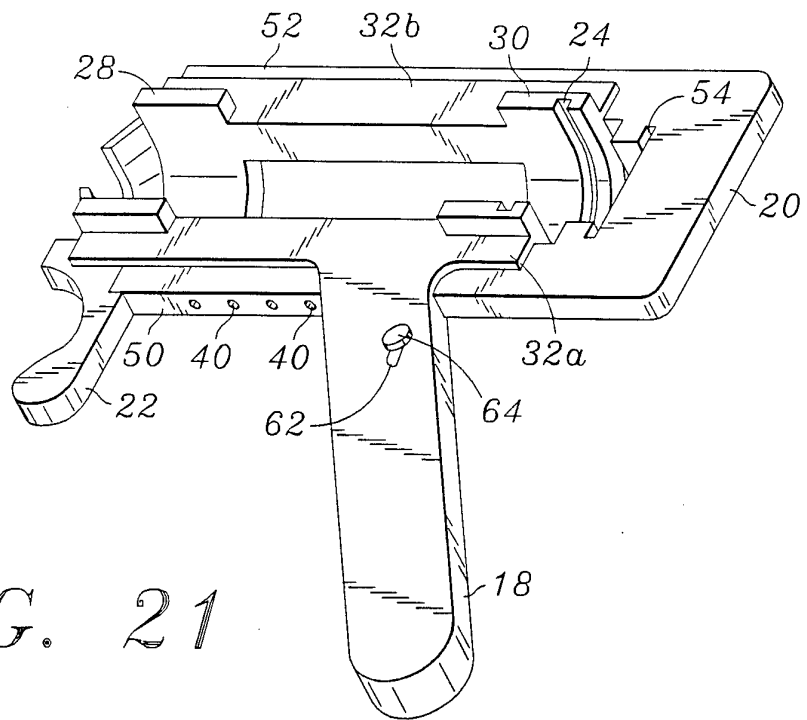


FIG. 21

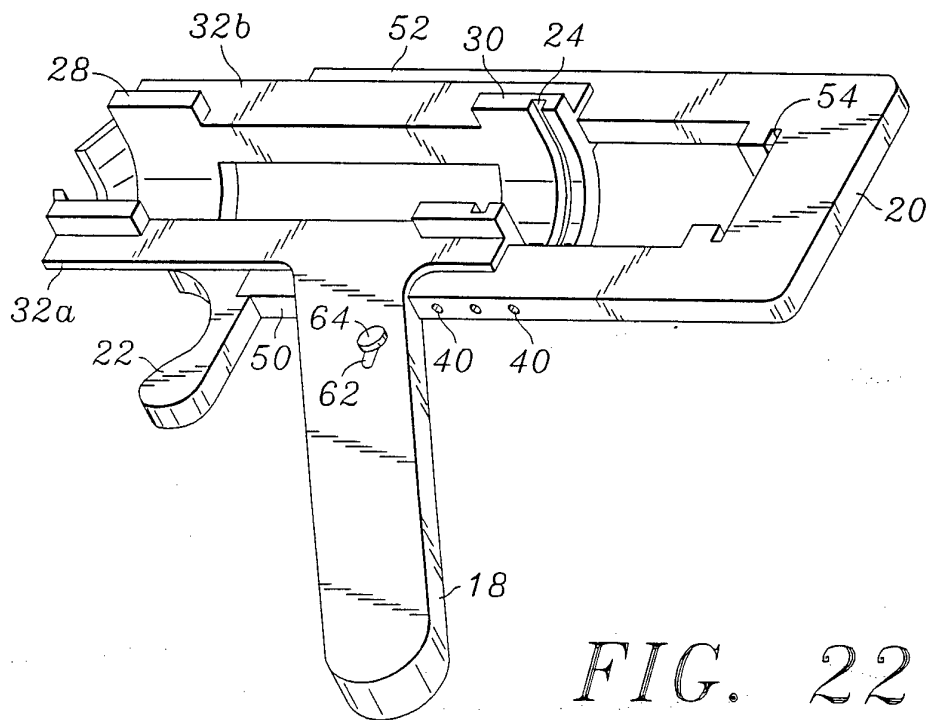


FIG. 22



FIG. 24

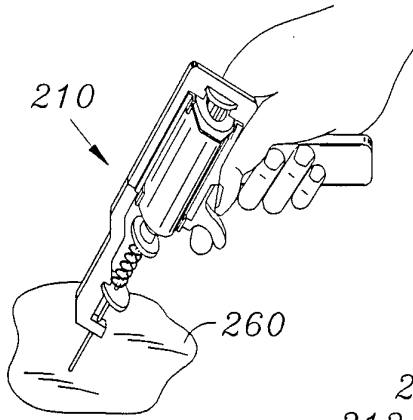


FIG. 23

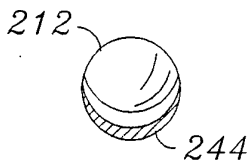
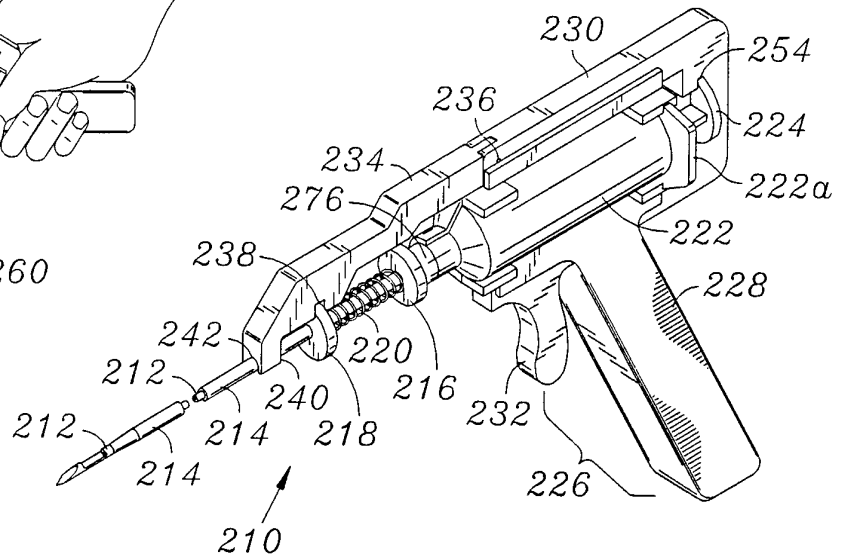


FIG. 26

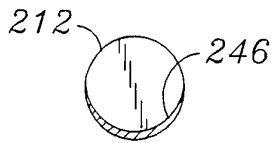


FIG. 27

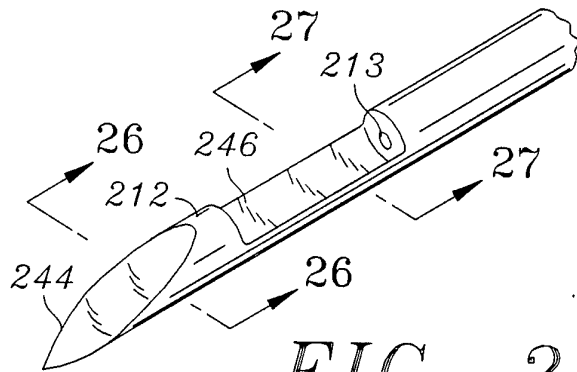


FIG. 25

FIG. 28

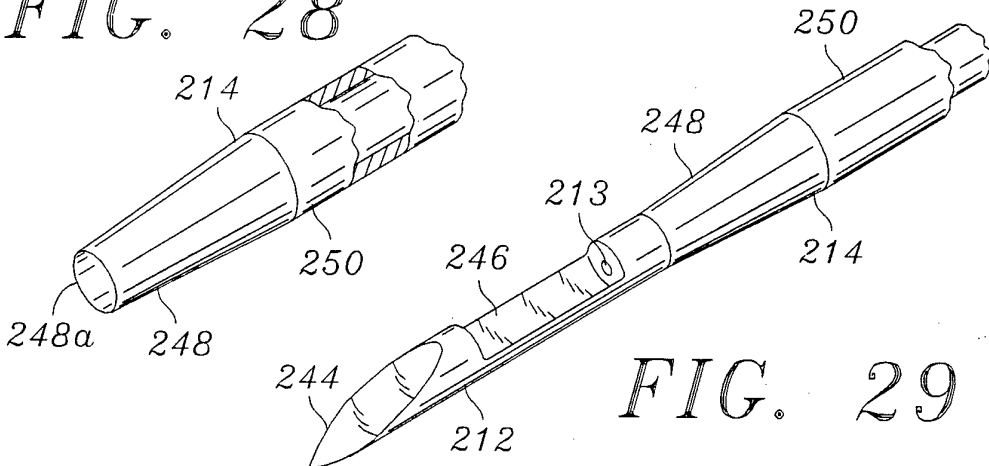


FIG. 29

FIG. 30

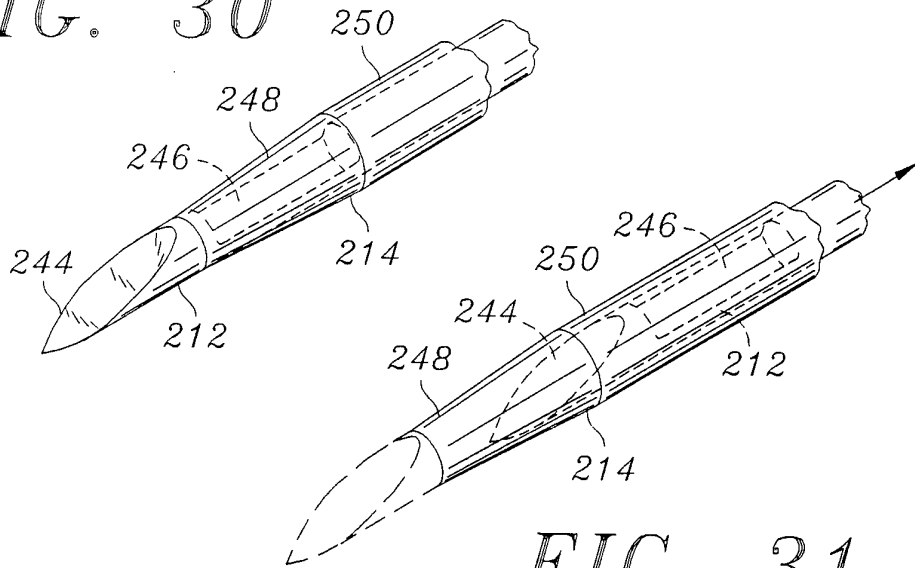


FIG. 31

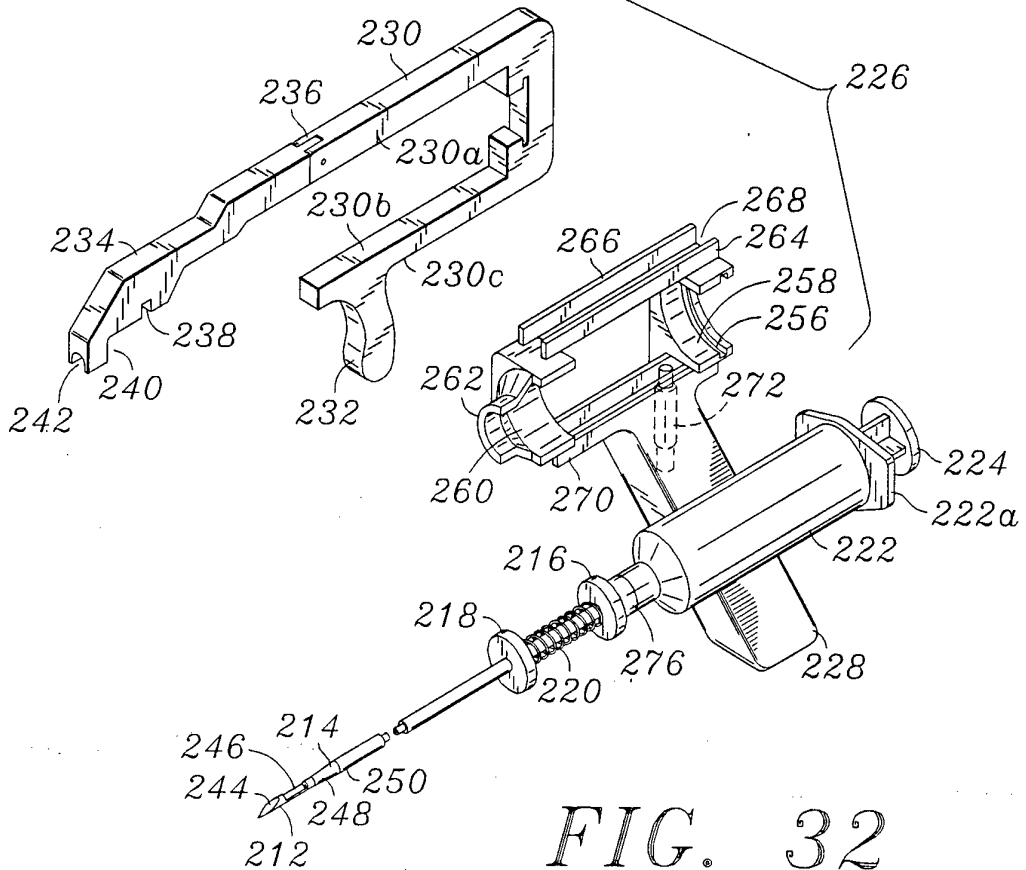


FIG. 32

FIG. 33

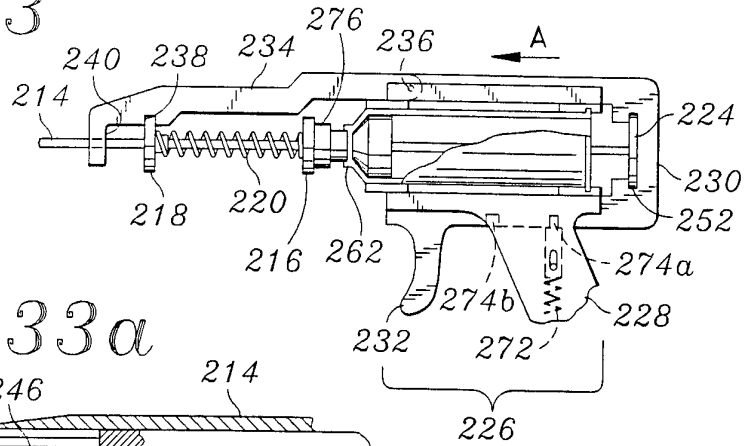


FIG. 33a

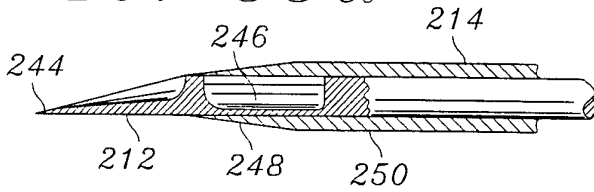


FIG. 34

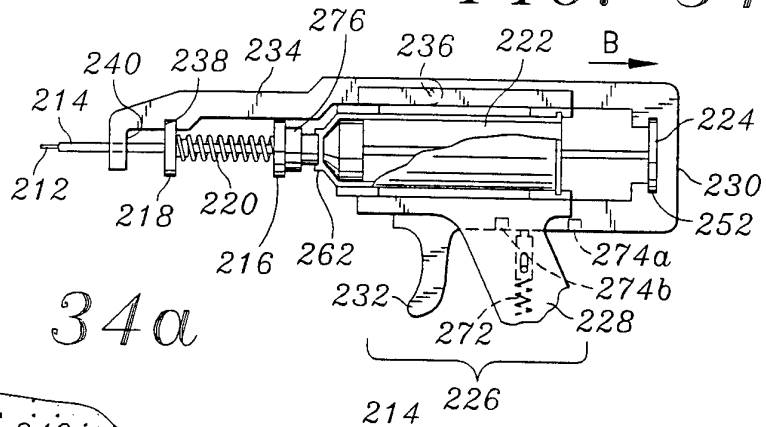


FIG. 34a

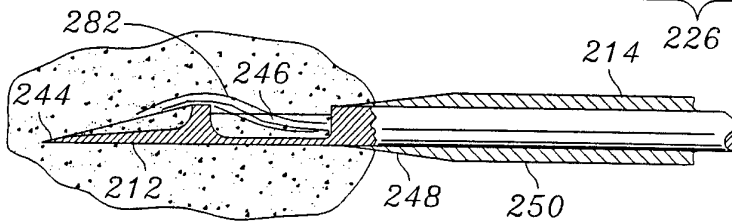


FIG. 35

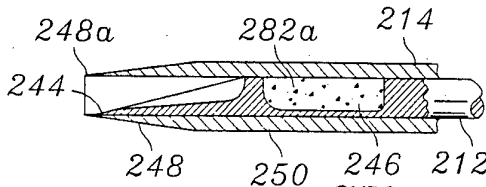
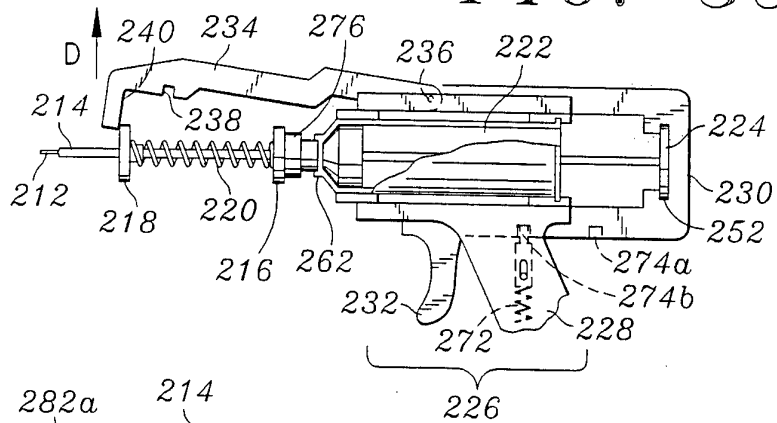


FIG. 35a

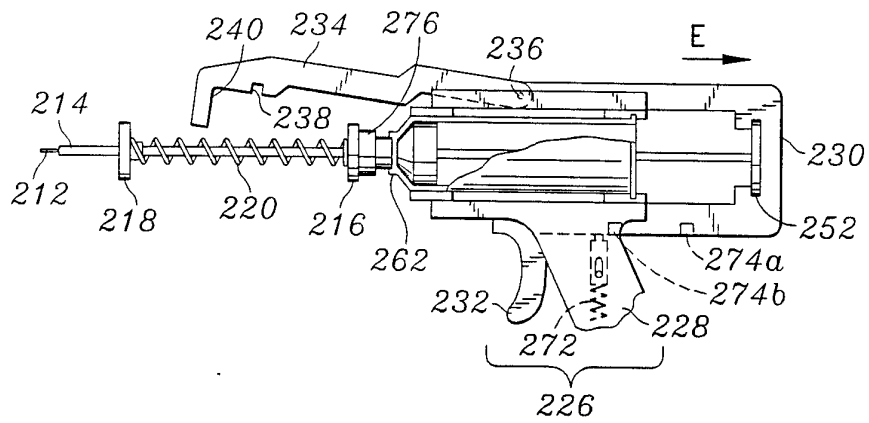


FIG. 36

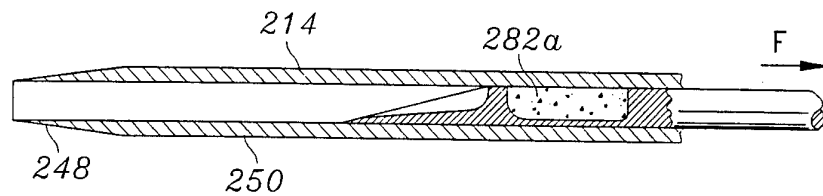


FIG. 36a

FIG. 37

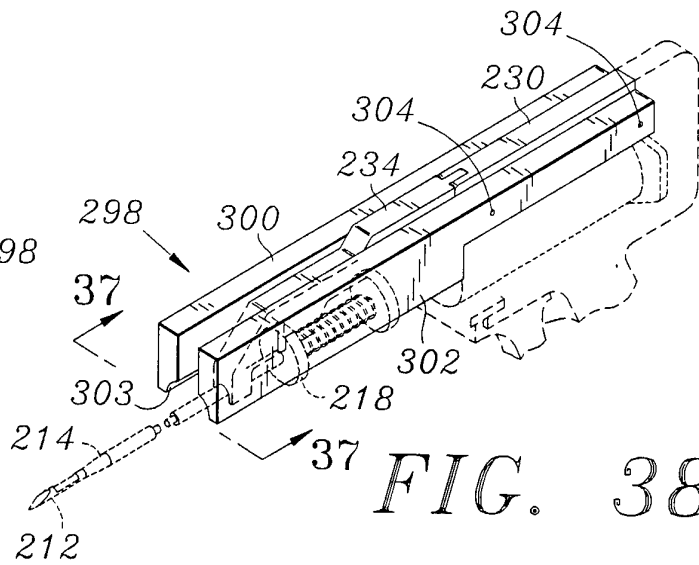
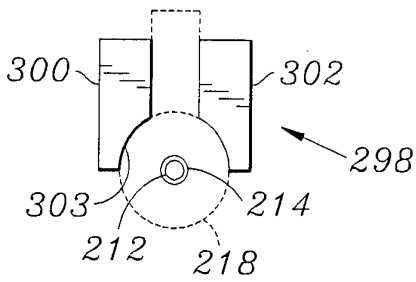


FIG. 38

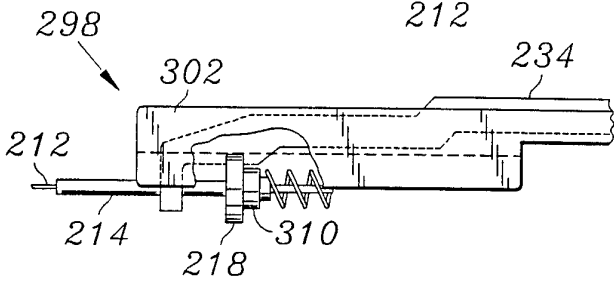


FIG. 39

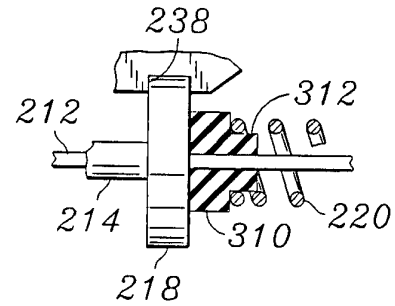


FIG. 40

FIG. 41

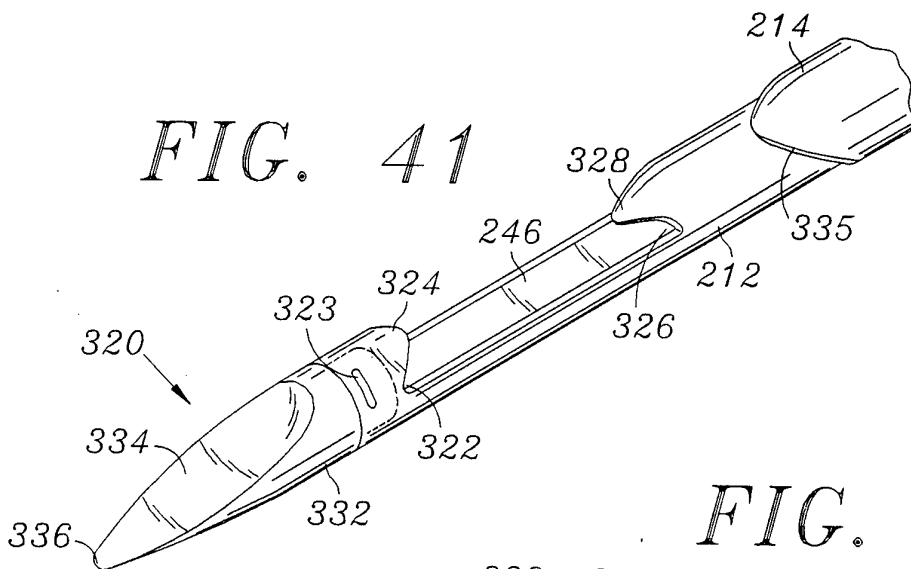
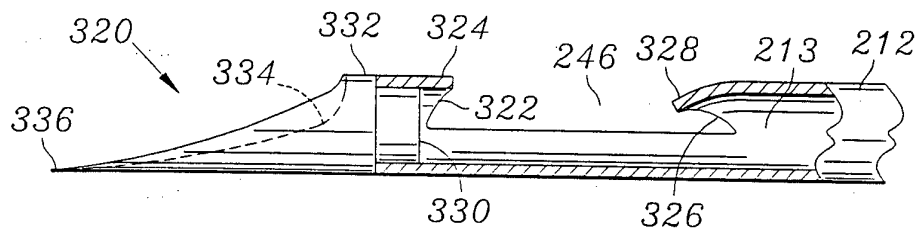


FIG. 42



INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US95/04161

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 10/00  
US CL :128/749-754, 756

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/749-754, 756

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
. NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 5,213,110 (KEDEM ET AL.) 25 May 1993, see entire reference.	1-8, 15-19

Further documents are listed in the continuation of Box C.  See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 11 JULY 1995	Date of mailing of the international search report 25 JUL 1995
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