

Jan. 6, 1970

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3,487,834

PARACERVICAL AND PUDENDAL APPLIANCE

Filed Aug. 16, 1967

2 Sheets-Sheet 1

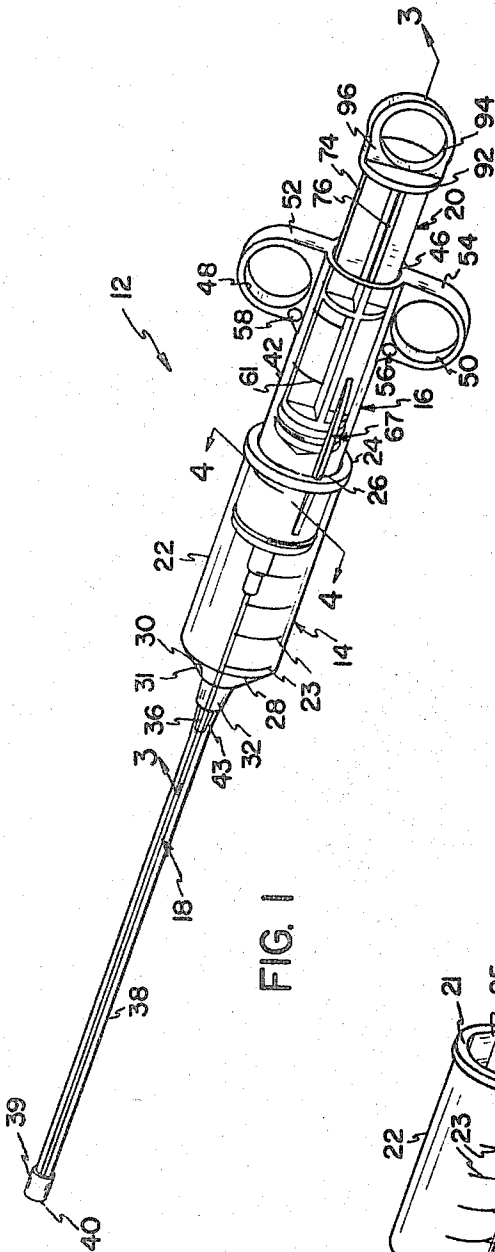


FIG. 1

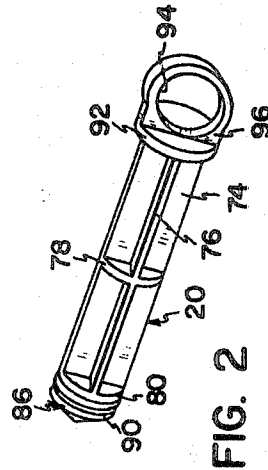


FIG. 2

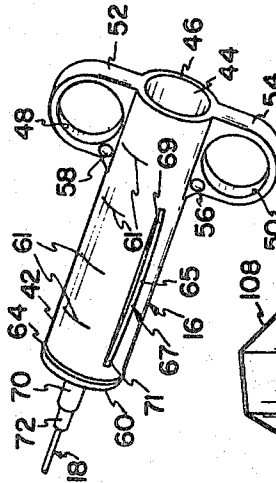


FIG. 3

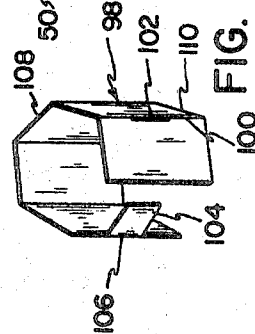
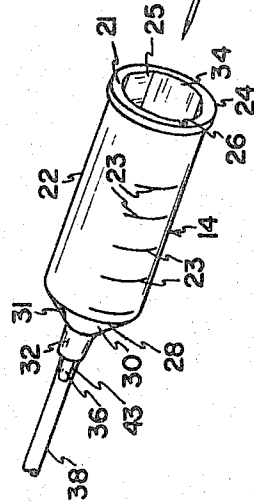


FIG. 4



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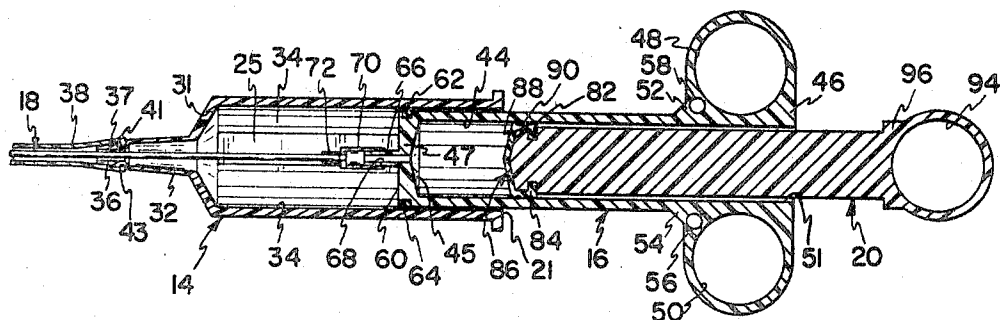


FIG. 3

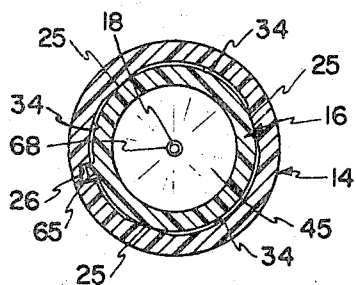


FIG. 4

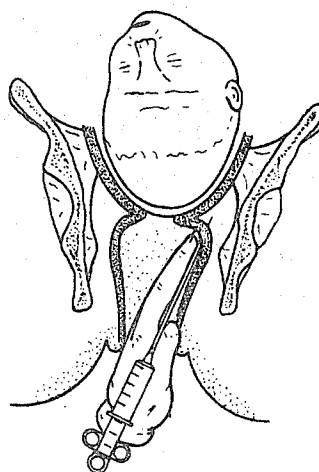


FIG. 7

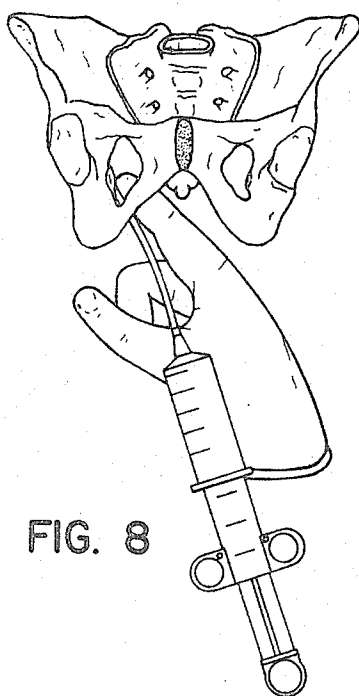


FIG. 8

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 Filed Aug. 16, 1967, Ser. No. 661,027
 Int. Cl. A61m 5/18

U.S. Cl. 128—218

8 Claims

ABSTRACT OF THE DISCLOSURE

A system comprising an apparatus particularly adapted for use in administration of paracervical and pudendal anesthesia, and the conducting of paracentesis and similar surgical procedures in relatively inaccessible locations, said apparatus comprising a hypodermic syringe assembly including a small diameter flexible elongated needle sheath completely enclosing the sharpened needle tip until just before penetration and connected at one end to a comparatively transparent outer barrel, which slidably receives the cylinder of a syringe, both the syringe cylinder and the outer barrel having visible graduations to respectively indicate the volume of the fluid in the syringe cylinder at any given time and the length of needle ejected through an elastomeric sheath closure beyond the leading end of the sheath by advancement of the syringe cylinder within the outer barrel. A keyway combination interposed between the outer barrel and the syringe cylinder accommodates uninhibited axial movement therebetween and simultaneously obviates relative rotational movement to insure that the respective graduations on the barrel and the cylinder remain readably juxtaposed at all times.

This invention generally relates to new and useful improvements in the hypodermic syringe art and, more particularly, to apparatus adapted for use in relatively inaccessible locations such as in administering paracervical or pudendal anesthesia, and in conducting paracentesis, or similar surgical procedures.

The conventional type of hypodermic syringe used in the above-identified procedures usually includes a barrel, a plunger, and a hypodermic needle. Inasmuch as each region of interest is relatively inaccessible, special techniques have been used in order that the physician using such a hypodermic syringe can satisfactorily accomplish the desired purpose.

Conventional syringes having application in the aforementioned procedures are frequently difficult and sometimes dangerous to use. Most conventional syringes have a long uncovered needle which must be manipulated with glove-covered fingers of the physician. Frequently during manipulation of the syringe the sharpened needle tip penetrates the gloves and thereby contaminates the needle. Moreover, in administering paracervical anesthesia, it is relatively easy for the unprotected needle to undesirably and inadvertently penetrate the vaginal wall or even the fetal tissue as the physician is attempting to approach the site of the intended injection. Finally, in the administration of paracervical and pudendal anesthesia, it has been extremely difficult to conveniently detect both the exact depth the needle has penetrated the site and the amount of anesthesia which has been injected at the site. A somewhat similar problem is encountered in paracentesis, which procedure involves a surgical puncture of an anatomical cavity. In such procedures, it has been extremely difficult for physicians to conveniently discern the depth to which the needle has entered into the cavity.

Recent efforts to cover the needle with a cannula and the like have not solved persisting problems which include

(a) inability to facilitate provide for precise measurement of the needle penetration, (b) troublesome difficulties in manipulation of the instrument continually risking needle injury to the patient as well as infection due to sepsis and (c) lack of capability to always and easily jointly inform the physician of the depth of needle penetration, if any, and the volume of fluid in the syringe cylinder.

It is, therefore, a basic object of this invention to provide a novel system, including method and syringe apparatus, for overcoming problems of the type mentioned above.

Another primary object of the present invention is to provide a novel hypodermic syringe assembly having a long needle which is completely aseptically enclosed within a small diameter needle sheath attached at one end to an outer barrel until the actual moment of penetration at which time the syringe cylinder is manually advanced within and relative to the outer barrel a precisely measurable distance to essentially aseptically eject the needle tip from the sheath a precise known depth into the patient.

It is a further important object of the present invention to provide a hypodermic syringe assembly having graduation markings to accommodate precise measurement of the depth of penetration of the needle into the patient and accurate determination of the volume contained within or ejected from the syringe, at any instant in time during use.

It is another primary object of the present invention to accommodate continuous unobstructed visual observation of separate graduation markings on a syringe assembly during use of the assembly.

One still further object of the present invention is to provide a novel needle sheath and/or a novel outer barrel-to-syringe cylinder relationship which accommodates sterile, facile, accurate and safe manipulation of an elongated syringe needle.

These and other objects and features of the present invention will become more fully apparent from the following description and appended claims taken in conjunction with the accompanying drawings wherein:

FIGURE 1 is a perspective of the presently preferred syringe assembly embodiment of the present invention, shown in assembled relation;

FIGURE 2 is an exploded perspective of the syringe assembly embodiment of FIGURE 1, with parts broken away for ease of illustration;

FIGURE 3 is a longitudinal cross-section taken along line 3—3 of FIGURE 1, revealing the internal configuration of the components in assembled relation;

FIGURE 4 is a transverse cross-section taken along line 4—4 FIGURE 1;

FIGURE 5 is a fragmentary perspective of the syringe of FIGURE 1 equipped with a stop collar;

FIGURE 6 is a perspective of the stop collar of FIGURE 5, with the collar in its open position and removed from the syringe assembly; and

FIGURES 7 and 8 schematically illustrate ways in which the syringe assembly of FIGURE 1 may be used.

Reference is now made to FIGURES 1—6 of the drawings, which illustrate the presently preferred embodiment of the invention. A hypodermic syringe assembly, generally designated 12, comprises five major components, namely, a graduated outer barrel 14, a sheath 38, a syringe cylinder 16, an elongated needle 18, and a plunger 20.

Preferably the outer barrel 14, the cylinder 16, and the plunger 20 are each unitarily molded into separate, one-piece components from a synthetic resin, such as, for example, a polypropylene, a polystyrene, a polyvinyl, or methyl methacrylate resin. The one-piece construction of each component accomplishes formation of finger loops

and other structural elements without requiring time consuming and expensive welding or like joining of parts. Moreover, unitary construction of the components generally provides for more smooth cooperation between components due to maintenance of more satisfactory tolerances.

It is important in the illustrated device that the material from which the outer barrel 14 and the syringe cylinder 16 are formed be transparent or translucent in order that the position of the leading end of the syringe cylinder 16 within the outer barrel 14 be readily visible to the physician through graduations on the outer barrel and that the position of the leading end of the plunger 20 within the cylinder 16 be readily visible to the physician through graduations on the syringe cylinder. For convenience, the term transparent, as used in this specification, is intended to mean any level of light transmission which accommodates visual observation of the position of one component within another component.

The outer barrel 14 integrally comprises a hollow tubular section 22 which is open at the rear end 21, said end 21 being provided with an external annular collar or flange 24. Internally, the bore of the tubular section 22 comprises three flat surfaces 25 (best shown in FIGURES 2 and 4), which are spaced approximately 120° apart. The three surfaces 25 are normal to a bisecting radial line and are respectively interposed between arcuate surfaces 34. Thus, surfaces 25 compress an O-ring at the leading end of the syringe cylinder 16 to accommodate selective manual axial displacement of the syringe cylinder 16 within the outer barrel 14 only when desired and frictionally resist inadvertent displacement of the cylinder within the barrel.

One of the arcuate surfaces 34 of the bore of the tubular section 22 is provided with an essentially rectangularly shaped keyway 26 opening into the interior of the outer barrel 14 and extending from the annular collar 24 along a substantial axial length of the barrel 14. Although the illustrated embodiment shows a keyway which is rectangular in cross section, the present invention contemplates the use of any number of axially extending grooves of essentially any suitable configuration including serrations.

The tubular section 22 is exteriorly provided with graduations 23 which have an important function that will be more fully discussed hereafter. The graduated indicia 23 preferably are colored marks identifying spaces of known distance, such as centimeters and one-half centimeters or other distances. In the illustrated embodiment, the marks 23 are bright red in color and the distance between any two adjacent marks is one centimeter. If desired, additional indicia may be added to indicate subdivisions of the known distance.

The leading end 28 of the tubular section 22 integrally comprises a frusto-conical end wall 30, which is integrally joined at its forward end to a slightly forwardly tapered coaxial extension 32 having a substantially reduced inside and outside diameter, the bore of which is in open, axial communication with the interior of the barrel 14. Optionally, the end wall 30 can be provided with an eccentric aperture 31 which provides an air passageway between the interior of the barrel 14 and the atmosphere such that air may pass therethrough when the cylinder 16 is reciprocally moved in the barrel 14.

The forward end of the tubular extension 32 terminates in an internally stepped, externally tapered tip 36 which extends forwardly and frictionally mates in force-fit overlapping relation with one end of the elongated flexible tubular sheath 38. By force-fitting the proximal end 43 of the sheath 38 over the tip 36 which has an outside diameter larger than the inside diameter of the sheath, the proximal end 43 will tend to contract to its original diametral size by reason of the memory of the material from which the tube is fabricated. This will cause a portion of the proximal end to recede and hold within an

external groove 41 in the tip 36 (FIGURE 3). The tip 36 is provided with an axial bore 37 and is of reduced inside diameter only slightly greater than the outside diameter of the needle 18. Thus, the tip 36 effectively guides the needle 18 as it is axially displaced central of the sheath 38.

The sheath 38 closely surrounds the needle 18 in spaced relation and is preferably formed of a transparent synthetic resin, such as polyvinyl chloride, which is resiliently flexible. The sheath 38 is somewhat shorter in length than the needle 18 to accommodate projection of the needle 18 a desired distance beyond the blunt leading end of the sheath 38.

The leading end of the sheath 38 is concealed or covered by an end cap or closure 39, preferably formed of highly elastic latex or suitable resilient synthetic material. The at rest diametral side of the cap 39 is smaller than the outside diameter of the sheath 38 such that, when installed, the cap 39 is maintained on the sheath by an elastic compression force which resists separation of the cap 39 from the sheath 38. Thus, the needle 18 is completely sealed within the sheath 38 and the closure 39 and is thereby aseptically protected from contamination following sterilization. When the needle is ejected from the sheath 38, the front or leading end 40 of the cap 39 is penetrated by the needle and when the needle is retracted again into the sheath, the cap 39 essentially aseptically reseals the needle within the sheath 38.

The syringe cylinder 16 comprises a hollow tubular member 42 and is internally provided with a cylindrical bore 44. The internal bore 44 terminates at the leading end of the cylinder in a converging conical surface 45 comprising part of the end wall 47. The end wall 47 and an integral forwardly extending exteriorly tapered cylinder tip 66 have an axial common bore 68 communicating between the hollow bore of the needle 18 and the bore 44. The bore 44 is open at 51 adjacent the rear portion 46.

Two diametrically opposite finger loops 48 and 50 are integrally injection molded with the tubular member 42. Although the finger loops 48 and 50 are shown as round apertures in this particular embodiment, any suitable configuration could be used to accommodate adequate fore and aft control of the syringe assembly 12. The small apertures 56 and 58 in the fillets 52 and 54 result from the molding process and serve no special function subsequent to the formation of the syringe cylinder 16.

The forward surface 60 of the end wall 47 is substantially flat and the radial periphery of the end wall 47 is provided with an annular groove 62 which receives an O-ring 64 in a snug-fitting relation. The O-ring 64 is primarily compressed against the surfaces 25 of the barrel 14 to restrain any selected relative position of the cylinder 16 within the barrel 14 while accommodating relative manual displacement between the two as desired. The O-ring may be bright in color for easy visual observation within the barrel 14 relative to the graduations 23.

As best shown in FIGURES 1 and 4, the exterior of the tubular member 42 comprises an integrally molded outwardly projecting key 67 tapered along the outer edge in both directions toward ends 69 and 71 thereby providing a center section 65 of maximum cross sectional area. The key 67 is sized to slideably fit within and be guided by the keyway 26 of the outer barrel 14 so that the cylinder 16 may be axially reciprocated within the barrel 14 without relative rotation therebetween.

The syringe cylinder 16 is further exteriorly provided with graduated indicia 61 disposed in juxtaposed relation to the graduations 23, the relation being always maintained by the key 67, keyway 26 arrangement for simultaneous viewing of both graduations by the user. It is presently preferred that the indicia 61 be graduated in cubic centimeters (cc.) and half cubic centimeters, although any suitable units and sub-units could be used. Moreover, it is presently preferred that the indicia 61 be col-

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ored differently than the indicia 23 to additionally emphasize the separate scales. For example, the indicia 61 may be black to contrast with the mentioned red indicia 23.

It is to be appreciated, for example, that, if desired, the graduations 23 could be suitably placed in reverse order upon the exterior surface of the syringe cylinder 16 and correlated with the end 24 of the barrel for gauging the location of the tip of the needle relative to the end 40 of the closure 39.

The needle 18 is conventional and integrally comprises a steel hub 70 adapted to press-fit tightly upon the tapered exterior surface of the tip 66. At its forward end, the hub 70 is provided with a diametrically reduced coaxial tubular extension 72 which rigidly embraces the proximal end of the elongated steel needle 18. Moreover, the needle 18 is of such external diametral size that it will fit slideably and in guided relation through the bore 37, as shown in FIGURE 3. The forward end of the needle is beveled and sharpened to facilitate facile penetration of the flesh.

If it is desired, a suitably sized annular sleeve (not shown) may be loosely placed over the hub 70 to abut the front surface 60 of the end wall 47. The annular sleeve will act as a stop to inhibit the distance to which the cylinder 16 may be advanced in the barrel 14 and thereby limit the length of needle 18 which may be ejected through the cap 39. The length of the sleeve may be selected to limit the length of maximum needle extension to, for example, $1\frac{1}{2}$ centimeters, for administering paracervical anesthesia.

The plunger 20, molded as one piece as previously described, includes two flat, essentially identical structural ribs 74 and 76 disposed at right angles relative to each other. The ribs 74 and 76 are reinforced by a central transverse disc 78, a rigid front end portion 80 and a rigid back end portion 92.

The front end portion 80 is provided with a diametrically reduced annular peripheral groove 82, adjacent a shoulder 90; which groove 82 receives the anchor portion 84 of a snap-on piston-forming plug 86 (FIGURE 3), preferably formed of yieldable rubber. The forward conical end of the plug 86 is tapered to match both the end 88 of the portion 80 and the tapered surface 45 of the internal bore 44. The plug 86 functions as a sliding seal against the bore 44 of the cylinder 16 when the syringe assembly is ready for use.

The rearward end of the plunger 20, beyond the portion 92, comprises a rearwardly projecting integrally molded thumb-loop 94. The loop 94 is formed in a rearwardly projecting flange 96.

By way of example only and not for purposes of limiting the scope of this invention, one presently preferred embodiment of the invention that has experimentally proved very satisfactory for administering paracervical and pudendal anesthesia has an outer barrel 14 with a total length of $3\frac{1}{2}$ inches and an inside bore diameter of about $\frac{7}{8}$ inch. The internal keyway 26 is about $2\frac{1}{8}$ inches long and approximately $\frac{1}{16}$ inch deep. The barrel 14 carries a transparent flexible needle sheath 38 about $5\frac{3}{8}$ inches long with the latex end cap 39 extending about $\frac{5}{16}$ inch rearward of the distal end of the sheath. The barrel 14 has red marking graduated in one-half centimeter intervals and has a total marked distance of 4 centimeters. The syringe cylinder 16 is on the order of about $3\frac{13}{16}$ inches long and has an inside bore diameter of about $\frac{7}{8}$ inch. The exterior surface of the cylinder is provided with black graduations 61 calibrated in increments representing cubic centimeters of volume. A 20 gauge needle 7 inches long is attached to the leading end of the cylinder 16. Thus, when the cylinder 16 is inserted the maximum distance into the outer barrel 14 a maximum of 4 centimeters of needle will be exposed beyond the tip 40 of the sheath 38. The plunger 20 is approximately $4\frac{5}{8}$ inches long and the attached plug 86 has an outside diameter of about $1\frac{3}{16}$ inch which is slightly larger than the diameter of the plunger.

FIGURES 5 and 6 schematically illustrate a presently

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preferred disposable collar embodiment that may be used with the syringe assembly of FIGURE 1. The collar 98 is preferably formed of heavy paper or cardboard and folded into a polygonal configuration. One fold, preferably the first fold 100, of the collar 98 is provided with a central elongated slot 102 which is adapted to receive a projecting tab 104, projecting beyond the last fold 106. When the tab 104 is inserted in the slot 102 a closed polygon is formed.

Prior to sterilization of the syringe 12, the collar 98 is placed around the cylinder 16 such that one end edge 108 abuts the finger loops 48 and 50 and the second end edge 110 abuts the annular collar 24 on the barrel 14. The axial length of the collar 98 is selected such that, when the collar 98 is in assembled relation as shown in FIGURE 6, the needle 18 will be restrained within the sheath against penetration of the cap 39 by the needle tip. In this position the leading end of the cylinder at 60 will be disposed within the barrel 14 adjacent the rearmost or zero graduation 23. Therefore, the assembly 12 is set at zero ready for aseptic use by the physician. At that time, the collar 98, with one hand if desired, may be easily and rapidly removed by separating the tab 104 from the slot 102.

Reference is now made to FIGURES 7 and 8 which illustrate methods of using the improved syringe assembly 12. With specific reference to FIGURE 7, the preferred technique and procedure for a paracervical regional nerve block using the syringe assembly 12 is illustrated. Initially, the syringe cylinder 16 is filled with a desired anesthetic by either extending the needle 18 a sufficient distance through the cap 39 of the protective sheath 38 to accommodate aspiration of the anesthetic or by pre-filling the cylinder 16 before assembling the barrel 14. In the former procedure, the needle 18 is then withdrawn into the protective sheath 38. The needle sheath 38 is manipulated by the fingers within the body of a patient without danger of injury to the patient or puncture of surgical gloves from the needle until the tip 40 of the latex cap 39 is adjacent the injection site.

In this specific example, the areas for needle insertion are the posterolateral fornices of the vagina between 7 and 9, and 3 and 5 o'clock positions, respectively, and immediately outside the cervix. The needle should be directed at a tangent to the presenting part of the fetus. With the tip 40 at the desired injection site the needle 18 is extended through the cap 39 into the paracervical tissue at the base of the broad ligament to a depth of about 0.5 to 1.5 centimeters. The actual depth of needle penetration may be readily observed by correctly correlating the position of cylinder front surface 60 relative to the graduations 23. It is preferred that the syringe 12 be aspirated before injection to preclude inadvertent intravascular injection. Thereafter, five to ten cubic centimeters of anesthetic are slowly injected with periodic aspiration to avoid intravascular injection using the graduations 61 as a gauge. The needle is then withdrawn into the protective sheath 38 and the syringe 12 may be removed or repositioned at another injection site.

Reference is now made to FIGURE 8 which illustrates one satisfactory technique and procedure for a pudendal regional nerve block. More specifically, the syringe cylinder 16 is filled with anesthetic in the same manner as described above. The ischial spine is palpated through the vaginal wall with the middle finger and the needle sheath 38 is directed toward the ischial spine with the index finger. The needle 18 is then projected through the cap 39 into the adjacent flesh approximately 1 to 1.5 centimeters in the manner already described. The desired placement of the needle is near the sacrospinous ligament, inferior or caudal to the ischial spine. The actual depth of the penetration of the needle may be readily observed as earlier set forth. The syringe should be aspirated before injection of anesthetic agent and periodically during injection should preclude inadvertent intravascular

injection and five to ten cubic centimeters of anesthetic agent should be injected slowly. This procedure may then be repeated on the other side of the ischial spine.

It is therefore apparent from the foregoing specification that this invention uniquely provides an improved surgical instrument which accommodates a superior precision placement of the hypodermic needle without fear of injury to the patient or violation of asepsis. Moreover, in the illustrated embodiment of the invention the graduations are continually maintained in a convenient side by side relation and prevented from rotating out of view of the physician during use by the novel key-keyway combination.

The invention may be embodied in other specific forms without departing from the spirit of essential characteristics thereof. The present embodiment is, therefore, to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore to be embraced therein.

What is claimed and desired to be secured by United States Letters Patent is:

1. A hypodermic syringe assembly adapted for administering paracervical and pudendal anesthesia and performing paracentesis and similar surgical procedures, the syringe assembly comprising an outer barrel mounted upon a syringe cylinder in telescopic relation such that the distal end of the barrel carries a narrow gauge sheath substantially concentrically enclosing a needle carried at the distal end of the syringe cylinder, both the cylinder and the barrel having indicia over part of the respective arcuate surfaces thereof, positioned so as to be simultaneously viewable, the improvement comprising anti-rotation guide means interposed between the inside of the outer barrel and the outside of the syringe cylinder to accommodate relative axial displacement of the outer barrel and the syringe cylinder to selectively eject the tip of the needle beyond the distal end of the sheath while essentially prohibiting relative rotational movement of the outer barrel and the syringe cylinder.

2. A device as defined in claim 1 wherein said anti-rotation guide means comprises a key and a mating keyway, one of which comprises part of the outer barrel and the other of which comprises part of the syringe cylinder.

3. A device as defined in claim 1 wherein graduations are visibly disposed upon the syringe assembly for accurately measuring the relative positions of the needle tip and the distal end of the sheath particularly when the needle tip and distal end of the sheath are hidden from view whereby avoidance of said relative rotational movement obviates displacing the graduations out of view.

4. A device as defined in claim 1 wherein the distal end of the sheath is sealed by a closure which is easily punctured by the needle tip upon ejection of the needle tip beyond the sheath and which accommodates self-sealing of such a puncture when the needle tip is again retracted into the sheath.

5. In a hypodermic syringe, a reciprocable plunger telescopically received by a syringe cylinder carrying visible graduations extending part way around the curved surface thereof and an external barrel telescopically mounted upon the cylinder and carrying visible graduations disposed part way around the curved surface thereof in a generally juxtaposed relation to the cylinder graduations so that both graduations can be read from a single viewing position, said barrel and said cylinder being formed of transparent material to accommodate (a) visual observation of the position of the plunger within the cylinder in relation to the cylinder graduations and (b) visual observation of the position of the cylinder within the barrel in relation to the barrel graduations and means to accommodate selected relative axial displacement without rotational movement of the cylinder and the barrel such that the two sets of graduations are prevented from being relatively rotated out of the mentioned juxtaposed positions during use.

6. In a syringe as defined in claim 5 further comprising means for color coding the graduations to accommodate facile visual differentiation therebetween.

7. In a hypodermic syringe as defined in claim 5 wherein the syringe further comprises a removable, disposable collar interposed as a stop between the cylinder and the barrel to establish the cylinder at a predetermined position within the barrel and to prevent axial advancement of the cylinder relative to the barrel.

8. In a hypodermic syringe as defined in claim 5 wherein the outer barrel, cylinder and the plunger are essentially individually molded as one-piece units.

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