

[54] **DISTALLY VALVED CATHETER DEVICE**

[75] Inventor: **Thomas E. Tate**, New Hyde Park, N.Y.

[73] Assignee: **Medical Evaluation Devices & Instruments Corp.**, Gloversville, N.Y.

[22] Filed: **Oct. 15, 1973**

[21] Appl. No.: **406,605**

[52] U.S. Cl. **128/2 M, 128/2.50 R, 128/348, 128/DIG. 9**

[51] Int. Cl. **A61m 25/00**

[58] Field of Search **128/2 R, 2 M, 2.05 R, 348, 128/349 R, 350 R, 351, DIG. 9; 251/DIG. 3**

[56] **References Cited**

UNITED STATES PATENTS

342,275	5/1886	Walters.....	137/505.22
396,754	1/1899	Mayfield	128/349 R
399,540	3/1889	Lee	128/349 R

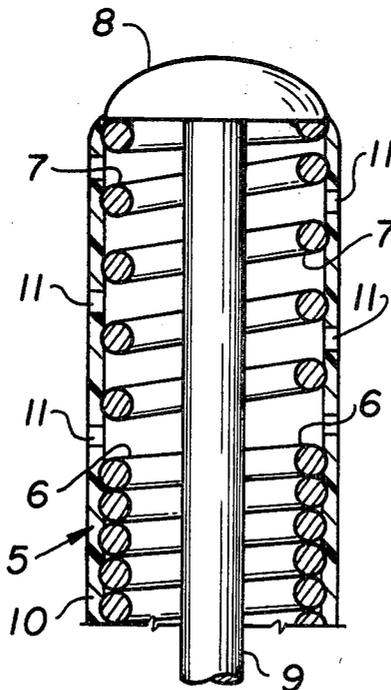
623,022	4/1899	Johnson	128/349 R X
812,020	2/1906	Crippen	27/24 A
2,189,129	2/1940	Bridwell.....	251/DIG. 3
3,757,768	9/1973	Kline.....	128/2 M

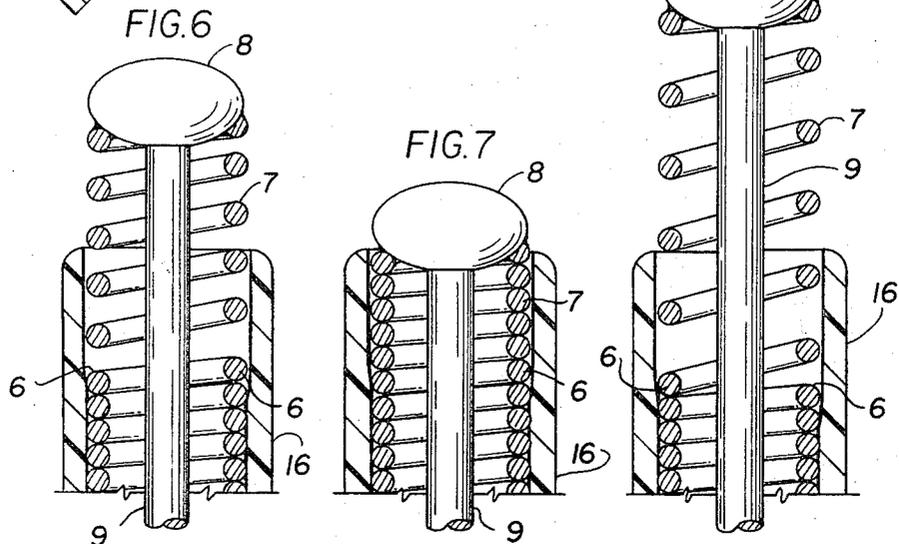
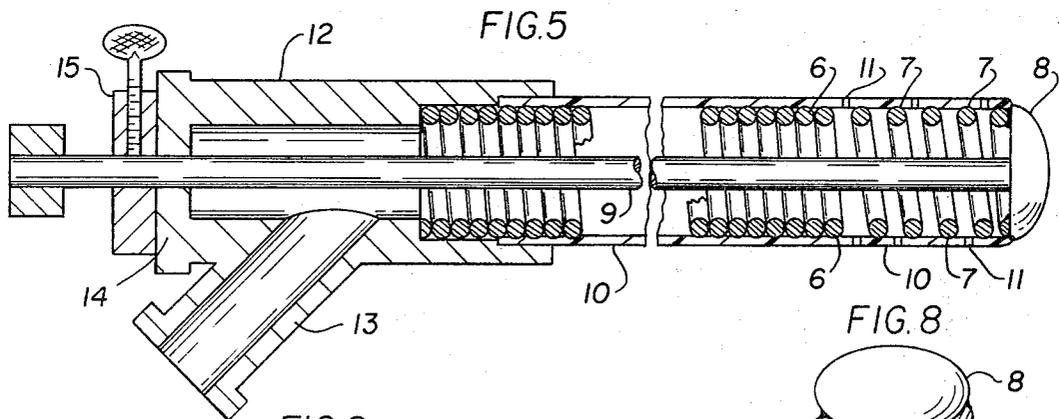
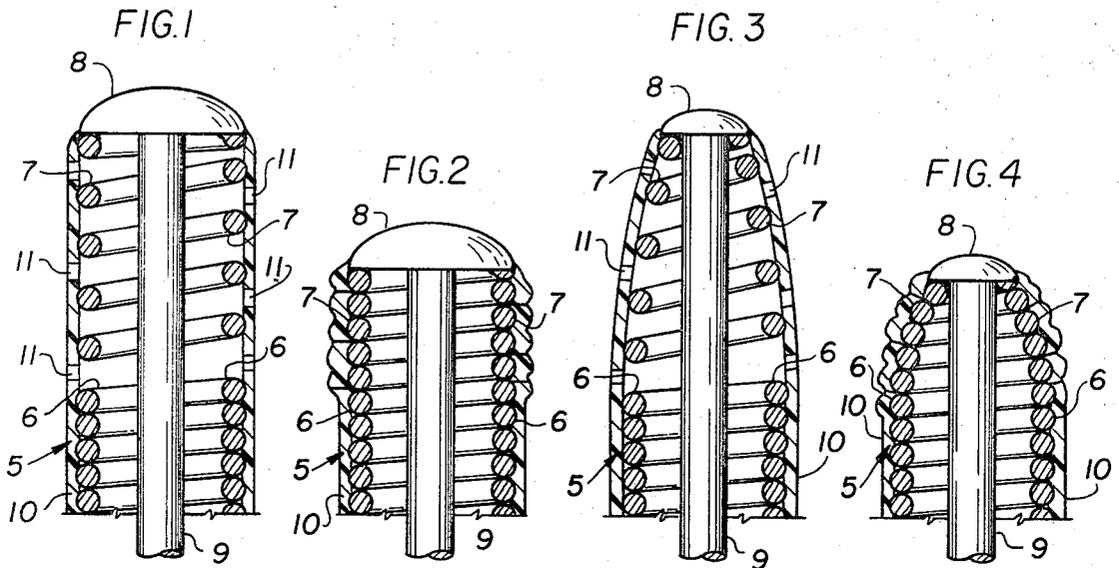
Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—Thomas E. Tate

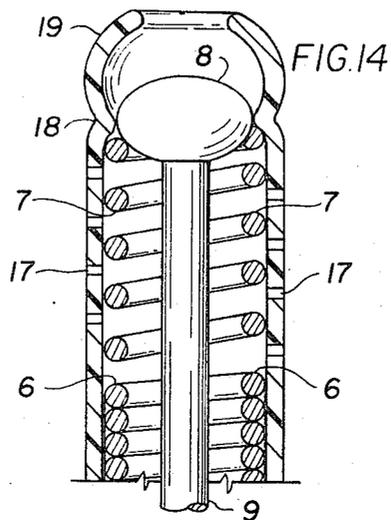
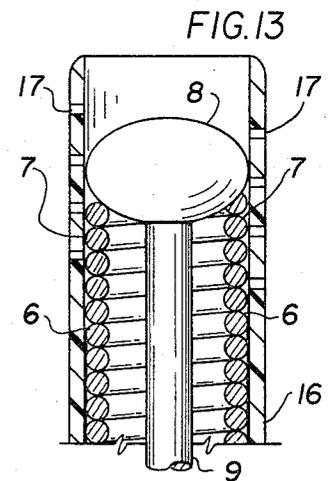
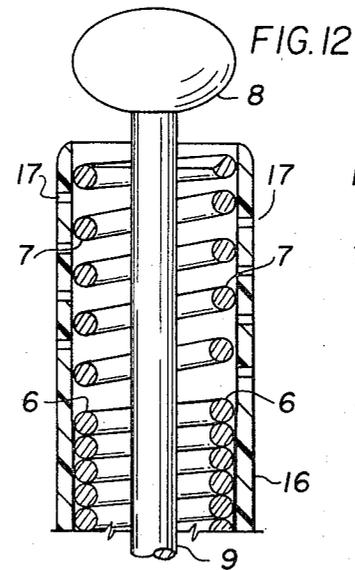
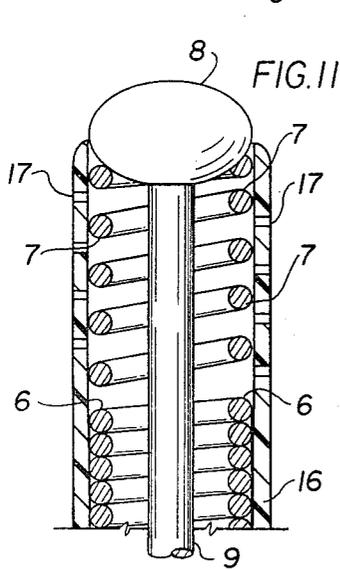
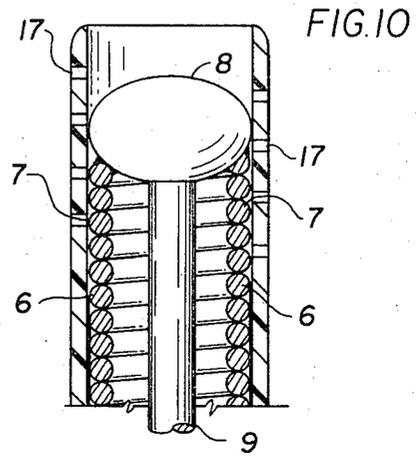
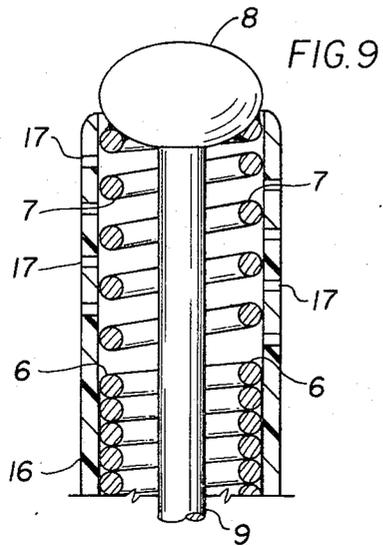
[57] **ABSTRACT**

The disclosure is that of an invention directed to spring guides, catheters, combined guide-catheters or intra-venous feeding tubes in which the distal end is provided with a normally-open proximally-controlled flow shut off valve. The valve is formed as a helically wound spring distal extension with the coils normally separated to define passages for fluid flow therebetween and a proximally operated wire stylette is used to axially contract the spring extension so that the coils thereof are brought into mutual contact, thus closing the passages therebetween.

8 Claims, 14 Drawing Figures







DISTALLY VALVED CATHETER DEVICE

THE INVENTION

This invention relates generally to new and useful improvements in spring guides, catheters, combined guide-catheters or intravenous feeding tubes of the types frequently used for relatively long time retention within a vein or other vessel of an animate being and particularly seeks to provide a novel such device in which the distal end thereof includes a normally-open proximally-controlled flow shut off valve.

Heretofore, in many types of diagnostic tests or subsequent chemo-therapy treatments or intra-venous feedings it has been, and still is, customary to employ percutaneous techniques for the insertion of spring guides, catheters, combined guide-catheters or intravenous feeding tubes and to withdraw same from the vessel involved after each test or treatment stage has been completed, because none of such devices have been provided with valves for preventing back flow of fluids whenever the use thereof is to be temporarily suspended or for permitting the internal cleaning of such devices between test or treatment stages, even though through the use of external inert coatings, such as those provided by the group of polyfluoroethylene compounds, they could otherwise be permitted to remain in place during the interim periods without damaging effects to the vessels involved.

However, in accordance with this invention such devices may be provided with distal end shut off valves so constructed that the initial insertion, retention and ultimate retraction of such devices is not adversely affected, while still permitting the valves to be operated at any desired time.

Therefore, an object of this invention is to provide a novel lumen-containing catheter-like device for insertion into and retention within a blood or other vessel of an animate being and which is provided with a shut off valve at its distal end.

Another object of this invention is to provide a device of the character stated in which the distal end thereof includes a helically coiled spring of which the helices at the tip thereof are normally separated whereby to permit fluid to flow either into or out of the lumen thereof and in which proximally actuated means are provided for axially compacting the normally separated helical coils into contact with each other whereby to shut off fluid flow to or from the lumen.

Another object of this invention is to provide a device of the character stated in which the distal end of the spring is permanently closed and the closure thereof is affixed to the distal end of an internal wire stylette, the proximal end of which extends proximally beyond the proximal end of the entire device whereby to permit proximal movement of the stylette to close the normally open valve.

Another object of this invention is to provide a device of the character stated in which at least the distally valved end thereof is provided with a thin flexible inert sheathing surrounding and bonded to the separated helices of the spring and having a plurality of radial perforations or apertures aligned with the spaces between the normally separated helices to permit free flow of fluid into or out of the spring lumen and to be compactable when the spring tip is proximally retracted into its closed valve status.

Another object of this invention is to provide a device of the character stated in which the inert sheathing thereof is sufficiently thick as to be relatively non-axially compactable and in which the distal end portion of the sheathing is not bonded to the normally separated distal helices of the spring whereby to permit the separated distal helices of the spring to partake of axial movement relative to the sheath.

Another object of this invention is to provide a device of the character stated in which the closure for the distal end of the spring is axially movable relative thereto and is affixed to the distal end of the wire stylette whereby to permit the closure itself to serve as a valve supplementary to that provided by the normally separated distal helices of the spring.

A further object of this invention is to provide a device of the character stated in which the valve-forming helices of the distal tip may be of progressively reduced radii whereby to form a distally tapering tip.

A further object of this invention is to provide a device of the character stated that is simple in design, rugged in construction and sufficiently economical to manufacture as to be disposable after a single use, if desired.

With these and other objects, the nature of which will become apparent, the invention will be more fully understood by reference to the drawings, the accompanying detailed description and the appended claims.

In the drawings:

FIG. 1 is a somewhat schematic longitudinal section of the distal end of a valved device constructed in accordance with this invention and shows the valve thereof in its normally open position;

FIG. 2 is a view similar to FIG. 1 but showing the valve in its closed position;

FIG. 3 and 4 are similar to FIGS. 1 and 2 but showing a tapered distal tip;

FIG. 5 is a schematic longitudinal section of a typical completed device showing a fitting at the proximal end for control of the stylette and for connection with an external fluid supply or receiver.

FIGS. 6-8 show a modified construction that may be used when the inert sheath of the spring is relatively thick and imperforate;

FIGS. 9 and 10 are comparable to FIGS. 6-8 but show a further modification that may be used when the relatively thick inert sheath of the spring is radially perforated or apertured;

FIGS. 11-13 show a further modification in which the closure for the distal end of the spring is rigidly affixed to the distal end of the wire stylette while being unattached to the distal end of the spring; and

FIG. 14 is a further modification, based primarily upon FIGS. 11-13, and showing one manner of necking down the sheathing to limit the distal elongation of the spring and to provide a distal stop or abutment for the closure.

Referring to the drawings in detail the invention, as illustrated, may be embodied in any diagnostic, surgical or treating device that includes (see FIGS. 1 and 2) an elongated body generally indicated 5 preferably formed from a helically wound spring having its proximal coils 6 in contact with each other and having its distal coils 7 normally separated to function as a valve-forming compression spring distal extension of the body.

The distal tip of the separated coils 7 is sealed by a solid closure 8 welded or otherwise permanently affixed thereto and a flexible wire stylette 9 extends through the lumen of the spring body 5 and has its distal end affixed to the closure 8 and is sufficiently long that its proximal end projects proximally beyond the proximal end of the spring body 5 so that tension can be applied thereto when desired in order to axially compact the coils 7 into mutual contact, thus shutting off any fluid flow therebetween into or out of the body lumen. Obviously, release of tension on the stylette 9 will permit the coils 7 to again separate for resumption of fluid flow therebetween.

Recognizing that such devices generally require the use of an inert smooth outer coating or sheathing such as that provided by a polyfluoroethylene compound, a thin flexible coating or sheathing 10 is applied to the full length of the device and is provided at its distal end with a plurality of radial slots or apertures 11 (see FIG. 1) aligned with the spaces between the normally separated coils 7. When tension is applied to the stylette 9 to close the valve tip, the coating 10 simply compacts into bellows-folds or pleats without preventing the spring coils 7 from being brought into mutual contact for valve closing purposes.

FIGS. 3 and 4 show a modification by which the principles of this invention may be applied to tapered distal tip if desired. Here, the normally separated coils 7 are of progressively decreasing radii in order to provide the desired taper and preferably the varying radii should be such as to permit the successive coils to become seated one upon another when the valve is in its closed position as indicated in FIG. 4.

However, if for any reason it should be desired to have the valve substantially flat in its closed position, the progressively decreasing radii of the coils 7 can be reduced further so that the coils can become nested in radial contact within a single plane, rather than becoming seated one upon another as in FIG. 4.

FIG. 5 shows a typical complete device in which the proximal end is provided with a fitting 12 having an angled fluid connector 13 and a proximal end 14 through which the proximal end of the stylette 9 passes for adjustable positioning as by a clamp 15.

Although it is believed that the nature of this invention will have become fully understood from the foregoing description, certain modifications thereof may be employed in the event that the sheathing or coating 10 should be too thick to permit its axial compaction by manipulation of the stylette 9.

For example, FIGS. 6-8 show a modification in which an imperforate relatively thick sheathing or coating 16 is bonded to the proximal coils 6 but is not bonded to the normally separated distal coils 7 so that the distal coils may partake of axial sliding movement within the distal end portion of the sheathing 16. FIG. 6 shows the normally open status of the distal end parts; FIG. 7 shows the distal end valve as it would be closed during insertion into a vessel; and FIG. 8 shows the distal end valve in a wider open position that may be achieved during retention in the vessel by pushing the stylette in a distal direction beyond the position normally achieved solely by the natural spring expansion of the distal coils 7. The distal end valve may of course be closed at any time to the condition shown in FIG. 7 by proximal manipulation of the stylette 9. In this modification fluid flows into or out of the lumen of the de-

vice through the passages between the distal coils 7 whenever those coils are in their separated condition and project beyond the distal end of the sheathing.

As a further example of such modifications, FIGS. 9 and 10 illustrate a different structure in which, as in the case of FIGS. 6-18, the sheathing or coating 16 is relatively thick but entirely surrounds the full length of the normally separated distal coils 7. Here, the sheathing 16 is provided with a plurality of radial slots or apertures 17 through which fluid flow into or out of the lumen of the device may occur, depending upon the open or closed condition of the distal end valve.

The normal condition of the distal end elements is shown in FIG. 9 in which the valve-forming portions thereof are open and the closure 8 forms a sliding seal at the distal end of the sheath 16. FIG. 10 illustrates the relative positions of the parts when the distal end valve is closed.

A further modification of that illustrated in FIGS. 9 and 10 is shown in FIGS. 11-13. Here, the closure element 8, while still being affixed to the distal end of the stylette 9, is free from attachment to the distal end of the coils 7 so that it may partake of relative motion with respect thereto and serve as a valve supplemental to that defined by the normally separated distal coils 7.

Thus, FIG. 11 shows the normal condition of the device with the normally separated valve-forming distal coils 7 retained within the distal end portion of the sheathing 16 and the closure 8 seated on the coils at the distal end of the sheathing. In this condition fluid flow may occur into or out of the lumen of the device through the sheath apertures 17 and the passages between the coils 7. Additional flow capacity may be provided, as shown in FIG. 12, by distally advancing the closure 8. FIG. 13 shows the valve of this modification in its closed position, which essentially is the same as in FIG. 10.

It also should be mentioned that the supplemental valve function of the closure 8 as shown in FIGS. 11-13 can readily be adapted to a sole direct or primary valve function simply by eliminating the valve-forming distal end spring coils 7 and having the closure seatable upon the distal end of the proximal coils 6. In such event the sheathing would be imperforate and the normal configuration would be somewhat similar to that shown in FIG. 7 and the open valve configuration would be somewhat similar to that shown in FIG. 12.

FIG. 14 shows a further modification, similar to that shown in FIGS. 11-13, in which the sheathing 16 may be necked down as at 18 to provide an abutment for preventing abnormal axial elongation of the distal coils 7 and in which the sheathing 16 may be extended beyond the distal end of the coils 7 to define a generally spherical retention cage 19 for the closure 8 which thus still can perform its supplemental valve function while still being restrained from axial movement beyond the distal tip of the sheathing extension.

A further modification (not shown) could be a variation of that shown in FIGS. 9 and 10. Here, the normally separated coils 7 would be interposed between the mutually contacting body coils 6 and a similarly coiled body distal tip, so that the similarly coiled distal tip, in effect, could serve as a sliding plug within the sheathing 16. Of course, in such a further modification the radial apertures 17 would be relatively relocated in order still to register with the spaces between the separated coils 7.

The principles of this invention are equally applicable to those currently used types of intravenous feeding tubes or catheters formed from plastic tubing, in which event it is only necessary to fit the distal end thereof with a normally open coiled spring valve as heretofore described and to include a proximally controlled stylette within the lumen.

It is of course to be understood that variations in arrangements and proportions of parts may be made within the scope of the appended claims.

I claim:

1. A flexible catheter-like device, including a flexible inner lumen-defining body having proximal and distal ends, a helically wound spring defining an open end distal extension of said inner body and having proximal and distal ends, said distal extension being formed with the coils thereof normally separated whereby to provide normally open passages therebetween for fluid flow into or out of the lumen of said inner body, said inner body being enclosed within an outer smooth flexible sheathing, firmly bonded thereto and formed from an inert plastic material, said sheathing extending distally beyond the distal end of said inner body to define a hollow tip for containing said spring-defined distal extension, means for closing the distal end of said distal extension, and a stylette passing through the lumen of said inner body and having its distal end affixed to said distal end closing means and having its proximal end extending proximally beyond the proximal end of said inner body for proximally contracting said distal extension to move the coils thereof into mutual contact, whereby to close the normally open passages therebetween.

2. The device of claim 1 in which said inner body is formed from a helically wound spring with the helices thereof in contact with each other and in which said distal end extension is formed as a continuation of said body spring.

3. The device of claim 1 in which the distally extending portion of said outer sheathing is coextensive in length with the said distal extension of said inner body and is firmly bonded to the separated coils thereof, said distally extending portion of said outer sheathing being provided with a plurality of radial apertures in register with corresponding passages between said normally separated coils.

4. The device of claim 1 in which the distally extending portion of said outer sheathing has a length sufficient to define a cavity for retaining said spring-defined

distal extension when said distal extension is proximally contracted to its mutual coil-contacting condition, said distally extending portion of said outer sheathing being unbonded to said spring-defined distal extension whereby to permit the coils of said distal extension to partake of axial movement relative thereto, said distal end closing means being sealed to the distal coil of said distal end extension.

5. The device of claim 1 in which the distally extending portion of said outer sheathing is coextensive in length with the said distal extension of said inner body but is unbonded thereto whereby to permit the coils of said distal extension to partake of axial movement relative thereto, said distally extending portion of said outer sheathing being provided with a plurality of radial apertures in register with corresponding passages between said normally separated coils, said distal end closing means being sealed to the distal coil of said distal end extension.

6. The device of claim 1 in which the distally extending portion of said outer sheathing is coextensive in length with the said distal extension of said inner body, but is unbonded thereto whereby to permit the coils of said distal extension to partake of axial movement relative thereto, said distally extending portion of said outer sheathing being provided with a plurality of radial apertures in register with corresponding passages between said normally separated coils, said distal end closing means being located distally of the distal end of said distal end extension and being axially movable relative thereto, whereby to serve as a valve supplementary to that defined by the coils of said distal end extension.

7. The device of claim 6 in which the distally extending portion of said outer sheathing additionally if provided with a distal extension having a proximal end and a distal end portion, the proximal end of said sheathing distal extension being necked down to restrain said distal end spring extension against abnormal axial elongation, said distal end portion of said sheathing extension being configured to define a generally spherical cage for freely retaining said distal end closing means therein.

8. The device of claim 1 additionally including means operably associated with the proximal end thereof for releasably retaining said stylette in a proximally retracted position such as to maintain said distal spring extension in its proximally contracted condition.

* * * * *

50

55

60

65