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(54) **MINIMALLY INVASIVE RECTAL BALLOON APPARATUS**

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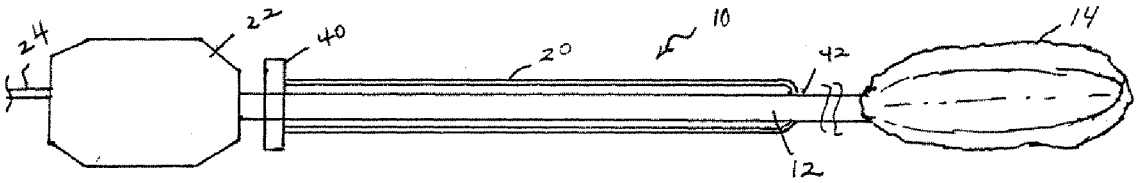
(57) **ABSTRACT**

A rectal balloon apparatus has a shaft with a fluid passageway extending therethrough, a balloon affixed over an end of the shaft such that the fluid passageway communicates with an interior of the balloon, and a sleeve slidably affixed over the shaft. This sleeve is movable between a first position overlying the balloon and a second position away from the balloon. The sleeve has an aperture at an end thereof such that the balloon extends outwardly of this aperture.



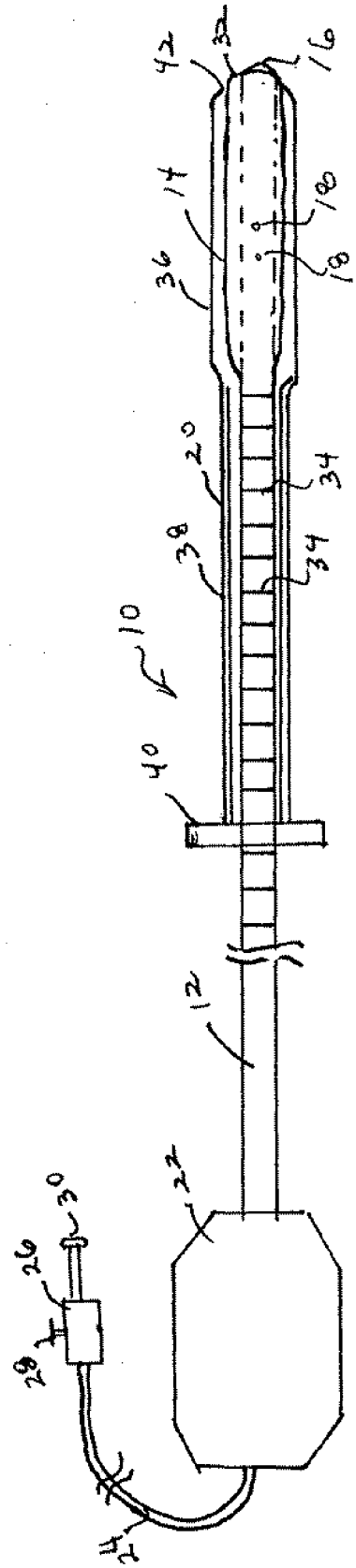

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FIG. 1

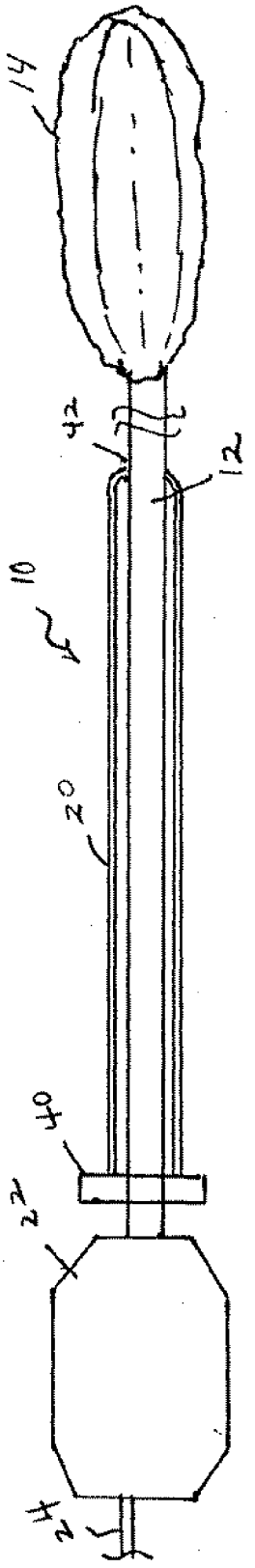
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FIG. 2

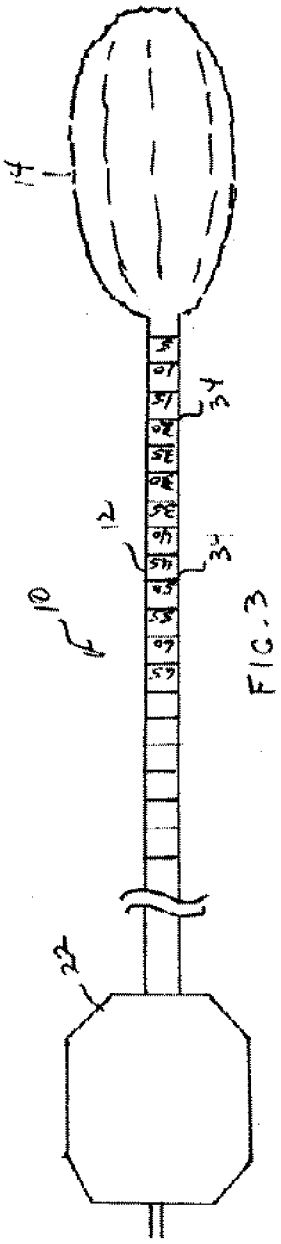

FIG. 3

FIG. 4

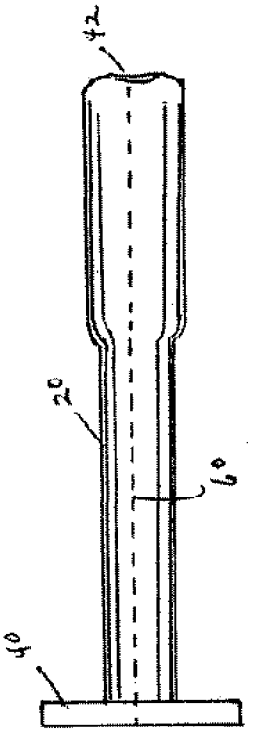

FIG. 5

MINIMALLY INVASIVE RECTAL BALLOON APPARATUS

CROSS-REFERENCE TO RELATED U.S. APPLICATIONS

[0001] Not applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not applicable.

NAMES OF PARTIES TO A JOINT RESEARCH AGREEMENT

[0003] Not applicable.

REFERENCE TO AN APPENDIX SUBMITTED ON COMPACT DISC

[0004] Not applicable.

BACKGROUND OF THE INVENTION

[0005] 1. Field of the Invention

[0006] The present invention relates to an apparatus for facilitating performance of diagnostic and therapeutic treatment of disease. Particularly, the present invention relates to rectal balloons that are used for immobilizing the region surrounding the prostate during pre-treatment simulation and target localization, as well as during the delivery of radiation therapy to treat prostate cancer. More particularly, the present invention relates to minimally invasive rectal probes.

[0007] 2. Description of Related Art Including Information Disclosed Under 37 CFR 1.97 and 37 CFR 1.98.

[0008] Treatment of prostate cancer using radiation therapy is difficult due to the prostate's position near radiation-sensitive tissues, and is further complicated by prostate motion. Adenocarcinoma of the prostate commonly occurs in the posterior portion of the prostate gland which is in very close proximity to the rectal wall. To plan external beam radiation treatment, urethrograms, CT scans and magnetic resonance imaging (MRI) have all been used to visually localize the prostate, as well as the normal critical structures in the surrounding area.

[0009] U.S. Pat. No. 5,476,095 issued on Dec. 19, 1995, to Schnall et al., describes an insertable pickup probe for use in providing diagnostic MRI images. The pickup probe in its preferred embodiment is for use in imaging the male prostate and comprises an elongated shaft supporting an inflatable patient interface balloon at its distal end. The interface balloon comprises an inner balloon and an outer balloon, between which a receiving coil is positioned. A lumen for air supply is provided in the shaft for expanding the inner balloon against the outer balloon to place the receiving coil in close proximity to the area of interest in order to provide MRI images.

[0010] Typically, the planning of radiation therapy for the treatment of prostate cancer involves the patient undergoing a CT-based simulation scan of the pelvis to determine the location of the prostate gland. In the simulation phase, the patient is placed on CT equipment that is preferably similar to the radiation treatment equipment (except that it does not generate the high energy radiation beam). The simulation equipment is positioned to simulate the delivery of the sequence of treatment beams prescribed by the treating oncologist. Normally, during the simulation procedure, CT images are acquired. These CT images allow the oncologist to locate the position of the tumor and help to facilitate the composition of a radiation treatment plan. This treatment plan delineates the positions of the radiation equipment components for delivery the treatment beams.

[0011] During the actual treatment phase, the patient is placed in the same position on the treatment equipment as in the simulation scans. Radiation-emitting devices are generally known and used for radiation therapy in the treatment of patients. Typically, a radiation therapy device includes a gantry, which can be swiveled around a horizontal axis of rotation in the course of a therapeutic treatment. A linear accelerator is located in the gantry for generating a high-energy radiation beam for therapy. During treatment, the radiation beam is provided by this equipment and is delivered to the patient at the precise location as delineated by the physician during simulation. A further feature of radiation therapy involves portal images, which are commonly used in radiation therapy to verify and record the patient tumor location. Portal images include manual (film) and electronic images (EPI) taken before and/or after the treatment.

[0012] During external beam radiation therapy, radiation is directed to the target prostate which is near the rectal wall. A misdirected radiation beam may perforate the rectal wall causing radiation proctitus (rectal bleeding). This toxicity is related to the total radiation dose prescribed and the volume of the anterior rectal wall receiving a high radiation dose. A major factor limiting radiation oncologists' attempts to reduce the volume of the anterior rectal wall receiving a high radiation dose is the position of the prostate gland as well as the intrinsic motion up to 5 mm in the anterior to posterior direction caused by rectal peristalsis. Accordingly, oncologists generally will add a margin to the radiation field in order to ensure that the entire prostate gland receives the prescription dose. This margin is typically on the order of 5 to 15 mm. As a consequence, lower doses of radiation may need to be used so as not to overexpose radiation sensitive structures. However, this may lead to inadequate radiation treatment and a higher probability of local cancer recurrence.

[0013] U.S. patent Publication No. 2003/0028097, published on Feb. 6, 2003 to D'Amico et al., describes an immobilizer probe system and method. This system has an insertable probe for immobilizing a region of interest during staging and radiation therapy thereof. In particular, this device uses a balloon having a rectangular cross section connected to a shaft. The shaft extends to an end of the balloon so as to allow fluid flow through an interior of the shaft and into the balloon so as to selectively inflate the balloon once the balloon is installed into the rectal cavity. The balloon, shaft and handle are bonded together so that they move radially as a single unit when torque is applied. A syringe is provided which connects the shaft and serves as an air pump to deliver a volume-limited amount of air to the air lumen of the shaft to the balloon. A stop cock is provided to maintain the air within the balloon.

[0014] One of the problems with the subject of U.S. patent Publication No. 2003/0028-97 is the discomfort associated installing the rectal balloon within the rectal cavity. In particular, a relatively sturdy and wide diameter shaft is connected to a relatively large thick-walled balloon. Because the balloon is not supported by anything other than by the shaft, the balloon is formed of a relatively rugged and thick material. Because of the relatively large size of the shaft and the

thick material of the rectangular-cross section balloon, the installation of the rectal balloon creates a large amount of discomfort for a patient. Additionally, it is often difficult for the medical personnel to know exactly how far within the rectum the balloon has been installed. It is difficult to achieve a standardized and fixed position of the balloon during each and every use. The medical personnel must generally approximate the desired position of the balloon within the rectal cavity. As such, a need has developed whereby the rectal balloon can be formed of a minimal diameter shaft and of a balloon of relatively thin material.

[0015] It is a object of the present invention to provide a rectal balloon apparatus which is easy to use and easy to install.

[0016] It is another object of the present invention to provide a rectal balloon whereby the position of the balloon can be easily ascertained by medical personnel.

[0017] It is a further object of the present invention to provide a rectal balloon apparatus which maximizes the comfort to the patient.

[0018] It is still a further object of the present invention to provide a rectal balloon apparatus which is easy to manufacture and relatively inexpensive.

[0019] These and other objects and advantages of the present invention will become apparent from a reading of the attached specification and appended claims.

BRIEF SUMMARY OF THE INVENTION

[0020] The present invention is a rectal balloon apparatus that comprises a shaft having a fluid passageway extending therethrough, a balloon affixed over an end of the shaft such that the fluid passageway communicates with an interior of the balloon, and a sleeve slidably affixed over the shaft. The sleeve is slidably movable between a first position overlying the balloon and a second position away from the balloon.

[0021] In the present invention, a handle is affixed to the shaft at an end opposite the balloon. The handle has a tube connecting thereto. This tube communicates with the fluid passageway of the shaft. The tube has a valve connected thereto for selectively allowing a fluid to pass through the tube and the shaft so as to inflate the balloon.

[0022] The shaft extends through the balloon so as to have an end of the shaft contacting an end of the balloon. This end of the shaft is curved. The balloon is formed of a silicone material.

[0023] In the present invention, the sleeve has a first portion overlying the balloon when in the first position. The sleeve has a second portion overlying the shaft when in this first position. A flange is formed at an end of the second portion opposite the first portion. The first portion has a diameter that is greater than a diameter of the second portion. The first portion resides in sliding contact with the shaft. The first portion has an aperture therein opposite the second portion. The balloon has an end extending outwardly of this aperture. The balloon is folded compactly over the shaft and interposed between an interior of the sleeve and the shaft.

[0024] The shaft has indicia formed on an exterior surface thereof relative to a position of the balloon. In particular, this indicia is indicative of the distance that the balloon is positioned within the rectum.

[0025] In an alternative form of the present invention, the sleeve has perforations formed longitudinally therealong such that the sleeve can be split apart when moved to the second position. As such, the sleeve can be detached from the shaft after the balloon has been installed into its desired position.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0026] FIG. **1** is a side elevational view, partially transparent, which shows the rectal balloon apparatus with the sleeve in a first position.

[0027] FIG. **2** is a side elevational view of the rectal balloon apparatus of the present invention with the sleeve in a second position.

[0028] FIG. **3** is a illustration of the rectal balloon apparatus of the present invention with the sleeve removed from the shaft.

[0029] FIG. **4** is an isolated view showing the compact folding of the balloon over the end of the shaft.

[0030] FIG. **5** is an isolated view of the sleeve as used in the rectal balloon apparatus of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0031] Referring to FIG. **1**, there is shown the rectal balloon apparatus **10** in accordance with the preferred embodiment of the present invention. The rectal balloon apparatus **10** includes a shaft **12** having a fluid passageway extending therethrough. A balloon **14** is affixed over the end **16** of the shaft **12**. The fluid passageway of the shaft **12** can communicate with the interior of the balloon **14** through holes **18** formed adjacent to the end **16** of shaft **12**. A sleeve **20** is slidably affixed over the shaft **12**. As illustrated in FIG. **1**, the sleeve **20** is in a first position which overlies the balloon **14**.

[0032] The shaft **12** is a generally longitudinal shaft which has the fluid passageway extending through the center thereof. A handle **22** is affixed to the shaft **12** opposite the balloon **14**. The handle **22** can have a variety of configurations. Ideally, FIG. **1** illustrates the handle **22** as having a rather square or octagonal configuration. However, various shapes can be utilized within the concept of the present invention. A tube **24** is connected the handle **22** and extends so as to communicate with the interior passageway of the shaft. Tube **24** is utilized so that air or saline fluids can be delivered into the interior passageway of the shaft **12** and, ultimately, into the interior of the balloon **14**. A stop cock **26** is connected to the tube **24** at an end thereof. A valve **28** facilitates the ability of the stop cock **26** to open and close so as to selectively allow the fluid to pass into the tube. A connector **30** allows the tube **24** to be connected to a supply of the fluid. When the stop cock **26** is opened by the rotation of the valve **28**, the fluid will flow through the tube **24**, through the interior passageway of the shaft **12**, and into the interior of the balloon **14**. The valve **28** can then be closed so as to maintain the inflated configuration of the balloon **14**. When the procedure is finished, and the fluid needs to be removed from the balloon **14**, the valve **28** of stop cock **26** can then be opened so as to allow for the release of fluid therethrough.

[0033] The opposite end **16** of the shaft **12** contacts the end **32** of the balloon **14**. The end **16** is suitably curved or dome-shaped so as to allow the shaft **12** to facilitate the introduction of the balloon **14** into the rectal cavity. The shaft has markings **34** formed therealong. Markings **34** are indicative of the distance that the balloon **14** has been inserted into the rectal

cavity. As such, the markings **34** provide a clear indication to the medical personnel of the desired location of the rectal balloon **14**.

[0034] The sleeve **20** is slidably affixed over the shaft **12** and is movable between the first position, as illustrated in FIG. **1**, overlying the balloon **14** and a second portion away from the balloon **14** (as illustrated FIG. **2**). The sleeve has a first portion **36** which overlies the balloon when the sleeve **20** is in the first position. The sleeve **20** also has a second portion **38** which overlies the shaft **12** when the sleeve **20** is in the first position. A flange **40** is formed at an end of the second portion **38** opposite the first portion **36**. Flange **40** facilitates the ability to move the sleeve **20** between the first and second positions. The sleeve **20** also has an aperture **42** at an end opposite the flange **40**. The end **32** of balloon **14** and the end **16** of shaft **12** extend outwardly of the aperture **42**. The first portion **36** has a greater diameter than that of the second portion **38**. The second portion **38** is closely juxtaposed against the outer surface of the shaft **12**. The balloon **14** is neatly folded compactly over the shaft **12** and between an interior of the second portion **36** of sleeve **20** and the exterior of shaft **12**.

[0035] In normal use, when it is desired to introduce the rectal balloon apparatus **10** of the present invention into the rectum of a patient, the sleeve **20** will be in the first position, as illustrated in FIG. **1**. The end **16** of the shaft **12**, along with the end **32** of the balloon **14** and the aperture **42** of the sleeve **20**, will allow the rectal balloon apparatus **10** to be easily inserted into the rectum of the patient. Because of the structure of the sleeve **20**, the shaft **12** can be of a minimal diameter, because the structural strength of the shaft **12** does not have to be very great. The shaft **12** can be flexible and of very small diameter. The structural integrity for insertion is facilitated by the rigid structure of the sleeve **20**. Similarly, the balloon **14** can be made of a relatively thin-walled material, such as silicone. Since the balloon **14** is neatly disposed within the interior of the sleeve **20**, it does not have to have the thick walls of the prior art in order to withstand the forces imparted during the insertion of the apparatus **10** within the rectum. The proper positioning is caused by the sliding of the sleeve **20** through the rectum. The desired location of the balloon **14** is established by noting the positioning through the use of the indicia **34**.

[0036] FIG. **2** illustrates the apparatus **10** after the apparatus has been installed within the rectum. Once the apparatus **10** has been installed, the sleeve **20** is pulled to its second position along the shaft **12** by imparting a force onto the flange **40** in the direction toward the handle **22**. As such, the aperture **42** at the end of the sleeve **20** will pass over the exterior surface of the balloon **14**. The fluid can be introduced through the tube **24** and through the interior passageway of the shaft **12** so as to inflate the balloon **14**. The balloon **14** can be designed so as to have a seating area so that the prostate can be properly positioned thereon. After the procedure has been completed, the balloon **14** can be deflated and easily pulled outwardly of the rectum in its deflated condition.

[0037] FIG. **3** shows an isolated view of the apparatus **10** of the present invention with the sleeve **20** removed. Under normal use, and as will be described hereinafter, the sleeve **20** can be suitably perforated so that it can be split apart and removed from the shaft **12**. In FIG. **3**, it can be seen that the indicia **34** has numerical reference associated therewith. These numerical references are indicative of the distance that the balloon **14** has been inserted into the rectum.

[0038] FIG. **4** shows that the balloon **14** is neatly folded and compressed over the outer diameter of the shaft **12**. The shaft **12** will have a rounded end **16** abutting the end **32** of the balloon **14**. As such, a comfortable rounded profile is provided at this end **32**. The balloon **14** has an end **50** which is sealed over the outer diameter of the shaft **12**.

[0039] FIG. **5** is an isolated view of the shaft **20**. Importantly, in FIG. **5**, it can be seen that the sleeve **20** has perforations **60** extending longitudinally therealong. These perforations are arranged such that when the sleeve **20** is pulled toward the handle **22**, proper pulling forces can cause the sleeve **20** to split longitudinally therealong so that the sleeve **20** can be permanently removed from the shaft **12**. The sleeve **20** also has an aperture **42** formed at an end opposite to the flange **40**. The aperture **42** allows the end **32** of the balloon **14** to extend slightly outwardly therefrom. As such, the end **42** will create a smooth contour, in combination with the end **32**, so as to facilitate the ease of insertion of the apparatus **10**.

[0040] The foregoing disclosure and description of the invention is illustrative and explanatory thereof. Various changes in the details of the illustrated construction can be made within the scope of the present claims without departing from the true spirit of the invention. The present invention should only be limited by the following claims and their legal equivalents.

I claim:

1. A rectal balloon apparatus comprising:

a shaft having a fluid passageway extending therethrough;

a balloon affixed over an end of said shaft such that said fluid passageway communicates with an interior of said balloon; and

a sleeve slidably affixed over said shaft and movable between a first position overlying said balloon and a second position away from said balloon.

2. The apparatus of claim **1**, further comprising:

a handle affixed to said shaft at an end opposite said balloon.

3. The apparatus of claim **2**, said handle having a tube connecting thereto, said tube communicating with said fluid passageway of said shaft.

4. The apparatus of claim **3**, said tube having a valve means connected thereto, said valve means for selectively allowing a fluid to pass through said tube and said shaft to said balloon.

5. The apparatus of claim **1**, said shaft extending through said balloon so as to have an end of said shaft contacting an end of said balloon.

6. The apparatus of claim **5**, said end of said shaft being rounded.

7. The apparatus of claim **1**, said balloon being formed of a silicone material.

8. The apparatus of claim **1**, said sleeve having a first portion overlying said balloon in said first position, said sleeve having a second portion overlying said shaft in said first position.

9. The apparatus of claim **8**, said sleeve having a flange at an end of said second portion opposite said first portion.

10. The apparatus of claim **8**, said first portion having a diameter that is greater than a diameter of said second portion, said second portion residing in sliding contact with said shaft.

11. The apparatus of claim **8**, said first portion having an aperture at an end opposite said second portion, said balloon having an end extending outwardly of said aperture.

12. The apparatus of claim **1**, said balloon being folded compactly over said shaft and interposed between an interior of said sleeve and said shaft.

13. The apparatus of claim **1**, said shaft having indicia formed on an exterior surface thereof relative to a position of said balloon.

14. The apparatus of claim **1**, said sleeve having a perforation formed longitudinally therealong such that said sleeve can be split apart when moved to said second position.

15. A rectal balloon apparatus comprising:

a shaft having a fluid passageway extending therethrough;

a balloon affixed over an end of said shaft such that said fluid passageway communicates with an interior of said balloon; and

a sleeve positioned over said balloon, said sleeve having an aperture at an end thereof, said balloon having an end extending outwardly through said aperture, said balloon being interposed between said shaft and an inner surface of said sleeve.

16. The apparatus of claim **15**, said sleeve slidably affixed over said shaft and movable between a first position overlying said balloon and a second position away from said balloon.

17. The apparatus of claim **15**, said sleeve having a first portion overlying said balloon and a second portion overlying said shaft.

18. The apparatus of claim **17**, said sleeve having a flange at an end of said second portion opposite said first portion.

19. The apparatus of claim **15**, said shaft having indicia formed on an exterior surface thereof relative to a position of said balloon.

20. The apparatus of claim **15**, said sleeve having a perforation formed longitudinally therealong such that said sleeve can be split apart.

* * * * *