

[54] **THERAPEUTIC DILATOR, DISPOSABLE OR REUSABLE**

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[58] Field of Search 128/344, 325, 341, 361, 128/38, 40, 242, 246

[56]

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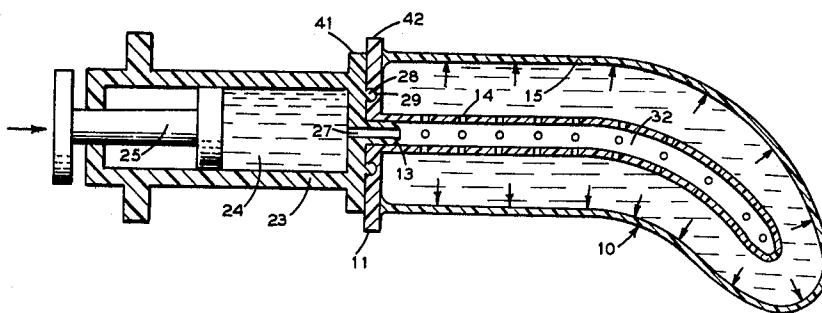
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[57]

ABSTRACT

An insertible and expandable dilator for use on a singular therapeutic basis to dilate a body channel, duct or tubular organ such as the urethra.

11 Claims, 6 Drawing Figures



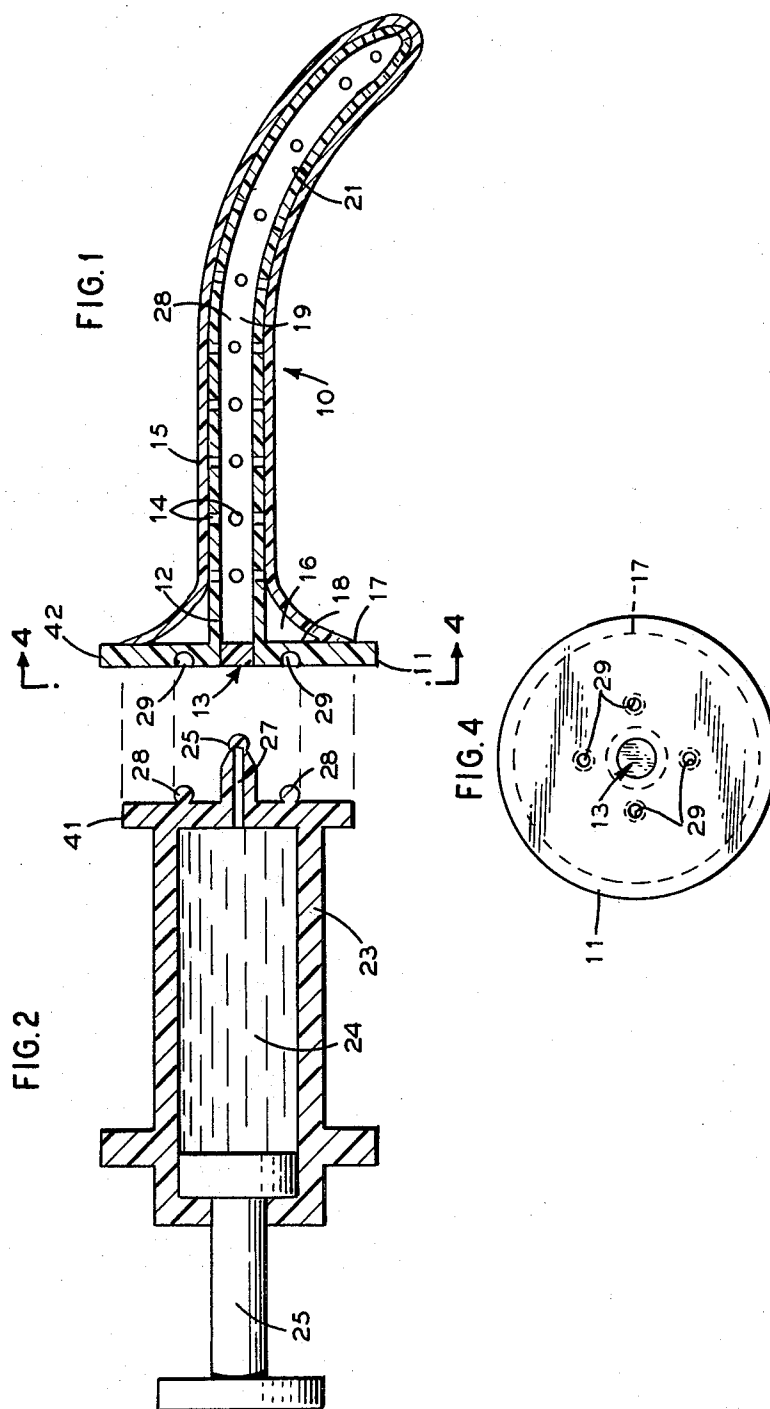


FIG. 3

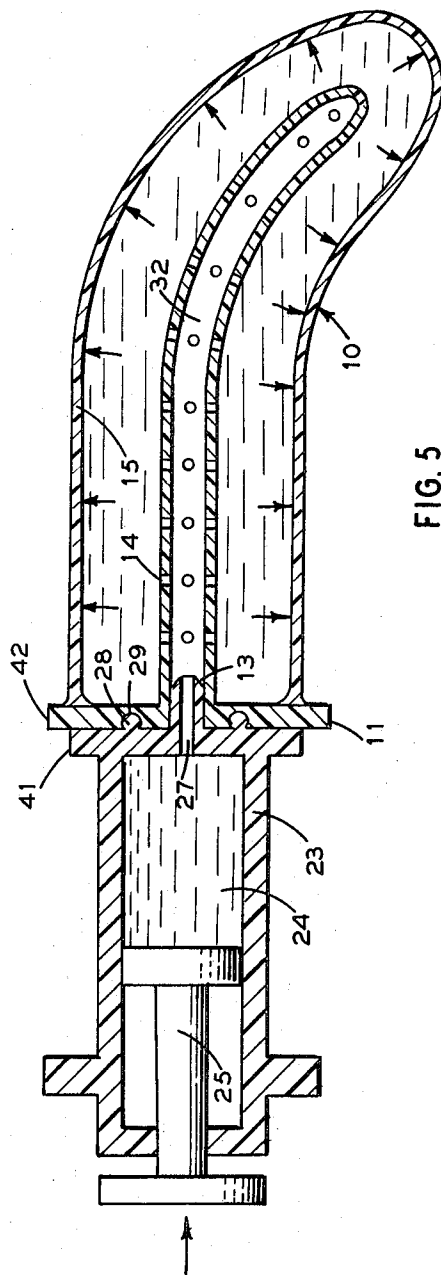


FIG. 5

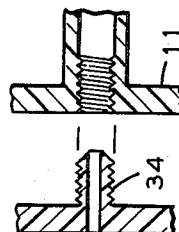
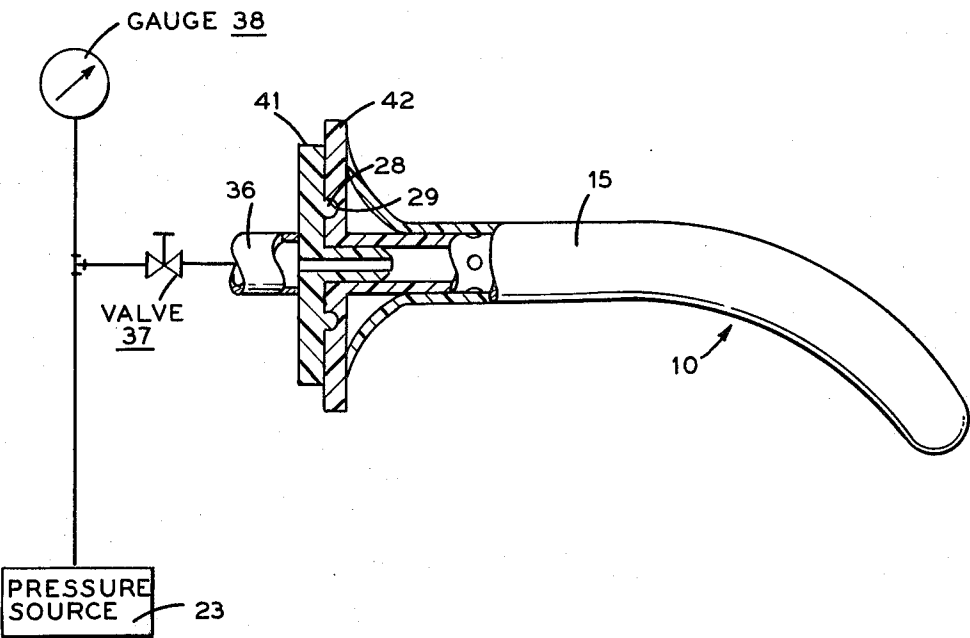


FIG. 6



THERAPEUTIC DILATOR, DISPOSABLE OR REUSABLE

This invention relates to therapeutic dilators (also known as sounds) for use in the treatment of strictures, narrowings or stenoses of parts of the human body.

More particularly, this invention relates to a sound which may be used for a single treatment and then disposed of; the use is the expansion on a singular basis of the urethral channel.

In general, a stricture of the urethra is an abnormal narrowing or loss of distensibility of that channel, either congenital or acquired. Such strictions produce adverse effects in the human body due to the interference with urinary flow, with eventual bladder damage and incomplete elimination of urine. The urethra is not evenly calibrated along its longitudinal axis; it varies in size also in different individuals. Therefore, one cannot always hold fast to a specific classification. However, in medical parlance, one may classify an abnormal narrowing of the adult urethra as one which will impede the passage of a No. 26F sound (i.e., a sound having a cross-sectional circumference of millimeters).

Urethral strictures may occur at any point along, or involve any segment of, the urethra, from and including the bladder outlet (bladder neck or internal urethral orifice) to and including the external urethral meatus (opening or orifice). Strictures, if not properly treated, may result in damage to the bladder and kidneys, such as kidney failure, urinary tract infections, bladder diverticula, calculi, abscesses and fistulae. However, careful attention and persistence in treatment will restore a urethra to normal caliber.

In a majority of cases, the interior circumference of the stricture is not longitudinally consistent, and the stricture usually appears as a ring or annulus of fibrous tissue along the channel. More than one stricture may be present in a urethra. A stricture usually presents as an area of scar tissue on the inner surface of the urethra; it usually causes obstruction to the passage of an examining instrument of the same caliber as the normal urethra.

Strictures of the urethra are usually treated by conservative therapy, that is, instrumental dilatation; it is seldom necessary to resort to surgical correction. Urethral dilatation with a semi-rigid instrument or sound entails less risk of trauma to the urethra and of the creation of false passages or ruptures of the urethra than does treatment with a metal sound.

Some tortuous strictures will not allow the passage of a conventional sound; similarly the presence of false passages in the urethra may prevent progressive insertion of a sound. These cases may be best treated by the insertion into the urethra of a fine filiform (of only a few mm circumference) of semi-rigid material. Sometimes several filiforms may be inserted simultaneously, side by side, and one will eventually be able to be threaded through the stricture and into the bladder. A larger caliber dilator (bougie or sound) is then attached to the distal end of the filiform, and this in turn is passed through the strictured area. If the resistance of the stricture to dilatation is marked, a hollow bougie may be left in the urethra for several days before further dilatation is attempted.

After dilatation of a urethral stricture to normal caliber, the urethra must be re-examined and calibrated at intervals to ascertain that re-narrowing has not oc-

curred. Several dilatations at intervals are sometimes necessary to ensure complete elimination of the obstruction. Some patients may continue to require interval dilatations on a permanent basis.

In the treatment of dilatation, the initial sound passed is of small circumference. Then sequentially increasing sizes of sounds are passed; usually each successive sound is 2 millimeters greater in circumference than its precursor. This progression is continued until the resistance of the stricture prevents the passage of a sound, or until the normal caliber of the urethra is attained. Dilatation past the normal caliber causes damage to the urethra, with the possible consequence of further scarring and stricture formation. If normal urethral caliber cannot be reached due to resistance of the structure, repetition of the process at a later time may be successful. Gradual dilatation over a number of sessions is sometimes necessary.

The difficulty with the art of instrumentation of the urethra is that trauma may result, producing hemorrhage and tissue damage, progressing to fibrous scar tissue formation and thus re-stricturing. The larger the number of sounds passed, and the greater the force required to pass the sounds, the greater the likelihood of urethral damage.

The urethra is extremely prone to infection, so only sterile instruments can be inserted. Sterilization and re-sterilization of metal or semi-rigid instruments requires much time, whatever the method used. The three common methods are (1) auto-claving — exposure to steam under high pressure; (2) gas sterilization — exposure to formaldehyde; (3) soaking in antiseptic solutions. Whenever a large number of patients have to be treated, the delay caused by the necessity for re-sterilization of the instruments before each use is considerable. Auto-claving requires a further period to allowing cooling of the instruments to body temperature; gas sterilization requires the washing or bathing of the instruments in sterile water or saline to remove any traces of the cytotoxic agent; as does soaking with the bactericidal solutions.

What is needed in the art is a single pre-sterilized instrument to accomplish rapid dilatation of the urethral stricture or strictures, without producing trauma, hemorrhage, rupture, false passages or subsequent re-scarring; without introducing infection; without delay between treatment of subsequent patients.

The subject invention answers the needs of the art as heretofore set forth, with special emphasis on an insertible and expandible dilator or sound, for use on a singular therapeutic basis to achieve dilatation of the urethra of an individual patient.

Therefore, the object of this invention is to provide a disposable sound for singular use in the dilatation of the urethra of a patient.

Another object of this invention is to provide for the dilation of the urethra by hydraulic pressure through the use of the aforesaid instrument.

A further object of this invention is to provide a sound for the aforesaid purpose having integral therewith a reservoir of liquid which may be placed under pressure.

A still further object is to provide a modular unit for expanding such urethra being separably engaged to a reservoir adapted with pressure means.

Other objects and many of the attendant advantages of this invention will readily become evident to one

skilled in the art after a review of the specification and accompanying drawings wherein:

FIG. 1 is a cross-section of the expandable sound.

FIG. 2 is a cross-section of a typical reservoir adapted for engagement to the expandable sound of FIG. 1.

FIG. 3 is a cross-sectional view of the devices of the instrumental units of FIG. 1 and 2 separably engaged to each other.

FIG. 4 is a view of FIG. 1 taken on line 4—4 of FIG. 3.

FIG. 5 is a view of the device of FIG. 1 engaged to a conventional hydraulic pressure and having a gauge and valve for the measurement and control of pressure with the expandable unit.

FIG. 6 and thereon show typical engagement means for use in securing the modular units of FIG. 1 and 2.

Similar numerals refer to similar parts throughout the several views.

Referring to FIG. 1, the expansible sound 10 of this invention is provided with a base 11 to which is secured a long, flexible, hollow, curved plastic rod or tube 12 similar to a sausage or long balloon having at least one end adapted with a relatively large opening 13 communicating with the exterior of the base as shown. The flexible rod or tube 12 is provided with a plurality of either perforations, openings or orifices 14. The length of the rod or tube 12 is covered in a snug-like fashion with a thin, flexible and expansible covering such as a thin plastic sheet similar to the finger 15 of a glove, the open end 16 of which is secured 17 circumferentially to the inner surface 18 of the base 11 as indicated. As shown in FIG. 1, the curved end-portion of the tube terminates in a rounded end and the aforesaid finger-like covering fits snugly over the body and such rounded end of said tube. The interior 19 of the flexible rod or tube 14 communicates with the interior or inner surface 21 of the thin balloon 15 along the length of the curved rod or tube 12 by means of the aforesaid openings or perforations 14 in such rod 12.

As shown in FIG. 2, the reservoir 23 containing sterilized fluid such as distilled water 24 or normal saline is provided with a seal 25 such as a removable cap which may be easily removed by a cutting instrument or punctured by a hollow needle. The reservoir 23 is provided with means such as a plunger or piston 25 for the application of pressure to body of distilled water 24 or fluid contained in such reservoir 23. The volume of sterilized fluid 24 in such reservoir 23 should always be equal to or slightly exceeding that of the fully expanded volume of the balloon 10. It is preferred to have both the reservoir and plunger made of rigid plastic. However, glass may be used, or any other material that functions as described. The reservoir may also be marked with indicia correlated to the volume of fluid in the reservoir.

Further, when said seal 25 is broken, the orifice 27 of reservoir 23 is inserted into the opening 13 in the base 11 which communicates with the interior 28 of the hollow rod or tube 14. As indicated in FIG. 3, the reservoir 23 is separably engaged to flexible or expandable sound 10 by means of the engagement of a male 28 and female 29 snap. When pressure is applied to the plunger 25, it is transmitted to the interior of the reservoir 23 or syringe. This action hydraulically forces the water 24 into the perforated rod or tube 12 and through the openings 14 therein to the inner surface of the flexible covering 21. In this manner, the balloon 15

will be ultimately expanded in a uniform manner around the flexible rod or tube 12 as shown.

FIG. 3 also shows the manner of engaging the individual units together. However, the base 11 of the expandable unit 10 is larger than the base 31 of the reservoir 23, so that, the expandable sound 10 can simply be snapped away from the reservoir 23 and then disposed of. FIG. 4 shows the base with its female engagement slots and, in one preferred embodiment, the central opening 13 which communicates with the interior 32 of the expandable sound 10.

There are many mechanical means for uniting the units shown in FIG. 1 and 2. For example, FIG. 5 shows a screw 34 type arrangement, however, the snap arrangement heretofore described is preferred.

In FIG. 6, an alternative embodiment is shown wherein the hydraulic pressure line 36 is adapted with a valve 37 and gauge 38 for the measurement and control of the pressure within the disposable sound 10. There are many conventional reservoirs which may be utilized, however, we prefer the syringe 23 type reservoir.

In operation, the sound 10 as shown in FIG. 1 will be inserted in the urethra. The circumference of the outer portion of the deflated sound 10 should be between about 8 mm. and 40mm. Also, females usually require a sound having a circumference of between about 26 mm and 30 mm and males usually require a sound having a circumference of between about 22mm and 26mm. In some cases, however, a requirement could be made for a sound having an expanded circumference as high as about 40 mm and as low as 8 mm for operativeness in treatment. Also, the length of the sound for the male should be about 22.86 cms and the curve end should approximate the Van Buren arc. For use on a female, the length of the sound 10 should be about 15.24 cms and a Mc Crea type curve should be utilized.

A competent operator should have no difficulty in inserting the aforescribed sound in the urethra of either a male or female. After the sound 10 is inserted, the seal 25 is broken and the orifice 27 of the reservoir 23 is snapped into position on the sound 10 by inserting element 27 into opening 13 and pressing the flange 41 and 42 together with the fingers until the units 10 and 23 are joined as shown in FIG. 3.

The operator may then inflate the sound 10 by applying pressure to the reservoir or syringe 23 and with experience, the physician will be able to feel the maximum desirable pressure. Usually, the desirable inflated circumference for the male is 26 mm while that of the female is 28 mm.

After the sound has remained in the desired inflated form within the urethra for the desired period of time, the physician may withdraw the plunger outwardly to its fullest extent and withdraw the deflated sound from the urethra comfortably without the danger of seriously injuring the patient because the smooth surface of the sound will slide over the surface of the urethra.

At this point, pressure is applied to the flange 42 of the sound 10 separating it from the flange 41 of the reservoir 23. And, the sound 10 may be discarded.

As may be seen from the aforesaid description and drawings, a novel device is described with provision for further improvement. For example, there are many and varied materials in the plastic art that may be utilized for the construction of this device. They may range in physical properties from flexible to semi rigid or rigid.

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For example, there are many individual plastics which vary in physical properties depending on the method of processing of the plastic and the degree of polymerization of the item being produced.

What is claimed is:

1. A disposable therapeutic sound for use in the dilation of the urethra comprising:
a base having an opening and engagement means,
a hollow elongated tube attached to said base in communicating relationship with said latter opening,
said tube having a body provided with a curved end portion terminating in a rounded end,
said tube also provided with a plurality of openings communicating with said opening of said base through said hollow body of said tube,
an elastic and expandable finger-like covering having an opening and fitting snugly over said body and rounded end of said tube,
the periphery of said opening of said latter cover secured circumferentially to said base,
the circumference of said covering ranging from 8 mm to 40 mm,
a reservoir containing sterilized fluid having an end provided with an opening and engagement means,
said reservoir separably secured to said base by the engagement of both of the aforesaid engagement means,
said reservoir also in fluid communication with said tube,
means for applying pressure to said reservoir causing said fluid to flow through said opening of said reservoir into said hollow elongated tube and out through said orifices of said tube into said expandable covering expanding the same and said urethra.
2. The disposable device of claim 1 wherein said reservoir and pressure means is a syringe.
3. The disposable device of claim 2 wherein the syringe is made of rigid plastic provided with a marking

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- correlated to the volume of fluid in said sound.
4. The disposable device of claim 1 wherein said sterilized fluid is sterile water.
5. The disposable device of claim 1 wherein the circumference of said covered elongated tube when deflated is between about 14 and 16 mm.
6. The disposable device of claim 1 wherein said covering in the expanded state follows the profile of the elongated tube.
7. The disposable device of claim 1 wherein said elongated tube has a curved end portion corresponding to a Mc Crea curve.
8. The disposable device of claim 1 wherein said elongated tube has a curved end portion corresponding to a Van Buren curve.
9. The disposable device of claim 1 wherein said covering in the expanded state has a circumference between about 26 and 30 mm.
10. The disposable device of claim 1 wherein said covering in the expanded state has a circumference between about 22 mm and 26 mm.
11. A portable device for engagement to a reservoir in the fabrication of an expandable and disposable sound, said device consisting essentially of:
a base having an opening and engagement means,
a hollow elongated tube attached to said base in communicating relationship with said latter opening,
said tube having a body provided with a curved end portion terminating in a rounded end,
said tube also provided with a plurality of openings communicating with said opening of said base through said hollow body of said tube, and
an elastic and expandable finger-like covering having an opening and fitting snugly over said body and rounded end of said tube,
the periphery of said opening of said latter cover secured circumferentially to said base,
the circumference of said covering ranging from 8 mm to 40 mm.

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