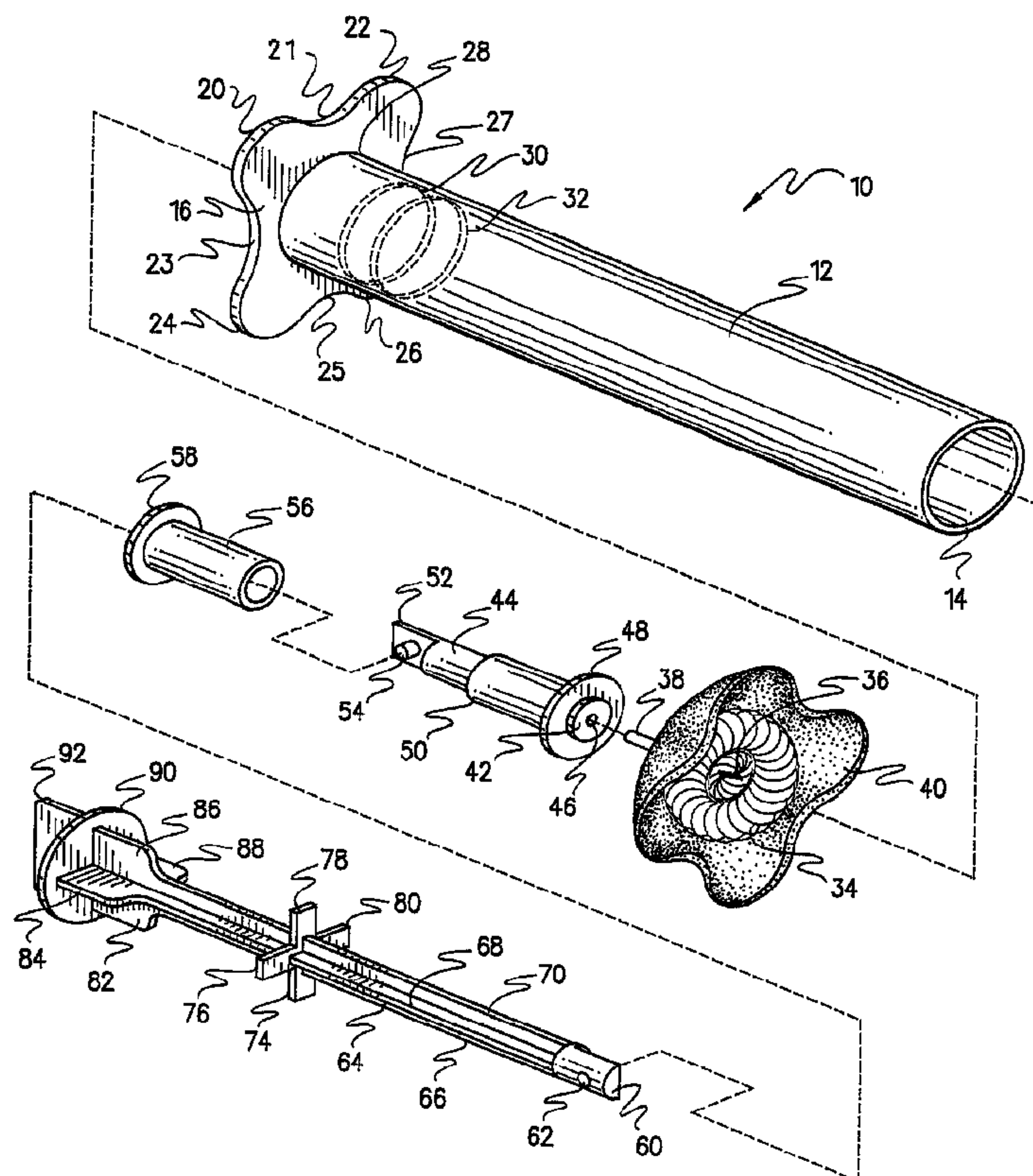




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(72) Inventeurs/Inventors:
WORTHEN, W. G., US;
WORTHEN, HOWARD V., US;
DUNN, W.J., US
(73) Propriétaire/Owner:
GYNETECH INC., US
(74) Agent: MARKS & CLERK

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(57) Abrégé/Abstract:

A cervical tissue sampling device (10) to allow women to collect tissue samples at home for transmission to a laboratory by mail or other means includes a cylindrical barrel (12) having an open circular front end (14) and an open circular rear end terminating in a radially extending irregularly shaped finger grip flange (16). A plunger assembly (33) slidably received within the barrel (12) includes a circular brush (34) and surrounding circular sponge (40) for collecting cervical tissue and mucus. The brush (34) and sponge (40) collection assembly is detachably secured to the plunger (33) shaft by a quick release connection (52, 54, 56, 58, 60, 62). In



(57) Abrégé(suite)/Abstract(continued):

use, the barrel (12) is inserted by a female into her vagina (v) with the sponge (40) and brush (34) disposed in a retracted condition within the barrel (12). After insertion, the plunger (33) is moved to an extended condition and rotated to collect tissue and mucus samples on the brush (34) and sponge (40). After the samples have been collected, the sponge (40) and brush (34) are detached from the plunger shaft (33) and mailed in a sealed container to a laboratory for analysis.

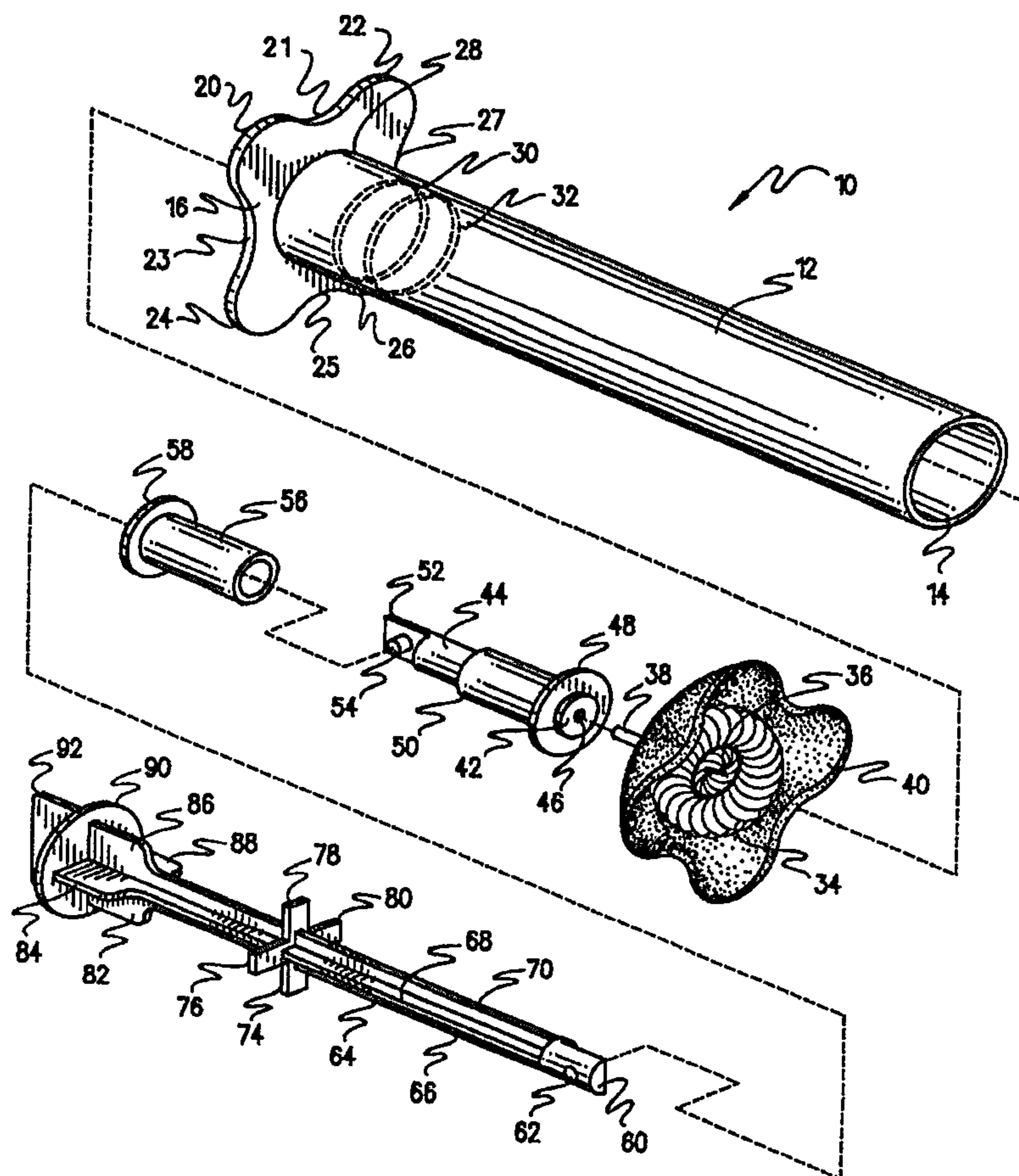
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(21) International Application Number: PCT/US95/00610 (22) International Filing Date: 17 January 1995 (17.01.95) (71) Applicant: GYNETECH, INC. [US/US]; P.O. Box 101, Springdale, AR 72765 (US). (72) Inventors: WORTHEN, W., G.; 3301 Shook Drive, Springdale, AR 72764 (US). WORTHEN, Howard, V.; 7507 South Ross Avenue, Oklahoma City, OK 73159 (US). DUNN, W., J.; 2659 Ferguson Avenue, Fayetteville, AR 72703 (US). (74) Agent: COX, Boyd, David; One McIlroy Plaza, Suite 506, P.O. Box 573, Fayetteville, AR 72701 (US).		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, UZ, VN, ARIPO patent (KE, MW, SD, SZ), European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: CERVICAL TISSUE SAMPLING DEVICE**(57) Abstract**

A cervical tissue sampling device (10) to allow women to collect tissue samples at home for transmission to a laboratory by mail or other means includes a cylindrical barrel (12) having an open circular front end (14) and an open circular rear end terminating in a radially extending irregularly shaped finger grip flange (16). A plunger assembly (33) slidably received within the barrel (12) includes a circular brush (34) and surrounding circular sponge (40) for collecting cervical tissue and mucus. The brush (34) and sponge (40) collection assembly is detachably secured to the plunger (33) shaft by a quick release connection (52, 54, 56, 58, 60, 62). In use, the barrel (12) is inserted by a female into her vagina (v) with the sponge (40) and brush (34) disposed in a retracted condition within the barrel (12). After insertion, the plunger (33) is moved to an extended condition and rotated to collect tissue and mucus samples on the brush (34) and sponge (40). After the samples have been collected, the sponge (40) and brush (34) are detached from the plunger shaft (33) and mailed in a sealed container to a laboratory for analysis.



CERVICAL TISSUE SAMPLING DEVICE**Technical Field**

Microscopic screening of slides of sampled cervical tissue and mucous has proven to be a highly effective method of reducing the mortality rate of women from cervical cancer. The American Cancer Society recommends that women obtain the so-called Pap-Smear test not less than annually. Unfortunately, many women do not participate in annual screening for a variety of reasons, including the personally invasive nature of the procedure, the high cost of an office visit to a gynecologist, distrust of the accuracy of the test, and time lost from work or other activities to visit a physician's office to be tested. Studies indicate that effective annual screening should reduce the incidence and mortality of invasive cervical cancer by ninety percent.

Disclosure Of Invention

In order to address these concerns, the present invention provides a cervical tissue sampling device which allows females to obtain in the privacy of the individual's home a viable specimen including endocervical, cervical, and vaginal cavity cells for laboratory testing. The inventive cervical tissue sampling device allows women to collect tissue samples at home for transmission to a laboratory by mail or other means and includes a cylindrical barrel having an open circular front end and an open circular rear end

terminating in a radially extending irregularly shaped
finger grip flange. A plunger assembly slidably
received within the barrel includes a circular brush and
surrounding circular sponge for collecting cervical
5 tissue and mucous. The brush and sponge collection
assembly is detachably secured to the plunger shaft by
a quick release connection. In use, the barrel is
inserted by a female into her vagina with the sponge and
brush disposed in a retracted condition within the
10 barrel 12. After insertion, the plunger is moved to an
extended condition and rotated to collect tissue and
mucous samples on the brush and sponge. After the
samples have been collected, the sponge and brush are
detached from the plunger shaft and mailed in a sealed
15 container to a laboratory for analysis.

These and various other advantages and features
of novelty which characterize the invention are pointed
out with particularity in the claims annexed hereto and
forming a part hereof. However, for a better
20 understanding of the invention, its advantages, and the
objects obtained by its use, reference should be made to
the drawings which form a further part hereof, and to
the accompanying descriptive matter, in which there is
illustrated and described a preferred embodiment of the
25 invention.

Brief Description Of The Drawings

Figure 1 is a front perspective view illustrating the cervical tissue sampling device of the present invention in an assembled, retracted condition.

5 Figure 2 is a rear perspective view illustrating the cervical tissue sampling device of the present invention in an assembled, retracted condition.

Figure 3 is a rear perspective view illustrating the plunger assembly of the cervical tissue sampling device of the present invention.

10 Figure 4 is a front end elevational view illustrating the cervical tissue sampling device of the present invention in a retracted condition.

Figure 5 is a rear end elevational view illustrating the cervical tissue sampling device of the present invention.

15 Figure 6 is a side elevational view illustrating the cervical tissue sampling device of the present invention in a retracted condition.

Figure 7 is a top plan view illustrating the cervical tissue sampling device of the present invention in a retracted condition.

Figure 8 is an exploded perspective view illustrating the component parts of the cervical tissue sampling device of the present invention.

25 Figure 9 is a rear perspective view illustrating the cervical tissue sampling device of the present invention in an extended condition.

Figure 10 is a diagrammatic view illustrating the manner of use of the cervical tissue sampling device of the present invention.

Best Mode For Carrying Out The Invention

5 Referring now to the drawings, wherein like reference numerals designate corresponding structure throughout the views, and referring in particular to Figures 1, 2, and 8, the cervical tissue sampling device
10 10 according to a first preferred embodiment of the invention includes an elongated substantially rigid, substantially cylindrical barrel 12 possessing a circular open front end 14 and terminating at a rear open circular end 28 within a circular recess 29 in an irregularly shaped radially extending finger grip flange
15 16. The barrel 12 and flange 16 are preferably formed from #PE2067 low-density polyethylene, available from Branchcomb Industries, Sapulpa, Oklahoma. As shown in Figures 4, 5, and 8, the finger grip flange 16 possesses convex arcuately curved corner projecting portions 20,
20 22, 24, and 26 spaced around the periphery of the flange 16. These corner projections are separated by respective concave arcuate recesses 21, 23, 25, and 27. As may be appreciated with reference to Figure 2, the barrel 12 may be integrally molded with the flange 16,
25 or alternatively may be assembled from separate components by press fitting the rear circular open end 28 of the barrel 12 into a conforming aperture formed centrally in the flange 16. Suitable adhesives may also

be employed to effect securement of the flange 16 to the barrel 12. The barrel 12, as depicted in Figure 8, possesses internal axially spaced annular ridges 30 and 32 formed internally within the barrel 12 adjacent flange 16 for the purpose of retaining a plunger assembly therein, in a manner to be described subsequently in greater detail.

With reference to Figures 3 and 8, the cervical tissue sampling device 10 according to the present invention includes a plunger assembly 33 terminating at a distal end in a circular brush 34 preferably formed by twisting nylon bristles between strands of stainless steel wire 36. A suitable brush is made from type 304 stainless steel wire, 0.02 inches in diameter, mil spec MS209956, and type 612 natural level nylon, 0.005 inches in diameter, FDA# 21CFR177-1500, and is available from Gordon Brush Company, Los Angeles, California. The initially straight brush is subsequently deformed into the generally circular illustrated configuration, with a stem portion 38 of the stainless steel wire 36 extending rearwardly through a central aperture of a circular sponge 40. A suitable sponge is a 2 inch diameter circle of 0.0625 inch thick open-cell cellulose sponge, # 1935, with a 0.25 inch central hole, available from Lundell Manufacturing Corporation, Minneapolis, Minnesota. The circular brush 34 has a diameter of about 3.5 centimeters, while the surrounding sponge 40 has a diameter of about 5.0 centimeters. A typical

cervix has a diameter of 5.0 to 5.5 centimeters. The stem portion 38 of the stainless steel wire 36 is press fit within a central bore 46 formed in a radially enlarged circular end flange 42 of a stem 44. The stem 44 is inserted through a sleeve 50 terminating in a second radially enlarged circular end flange 48. Accordingly, the end flange 42 forms an abutment surface for the rear face of the sponge 40 and serves to press the sponge 40 against the rear face of the circular brush 34. The flange 42 also serves as a stop restricting forward axial movement of sleeve 50 due to flange 42 having a greater outer diameter than the inner diameters of flange 48 and sleeve 50. The stem 44 terminates at an axially inward end in a semi-cylindrical connector tab end portion 52. A pin 54 extends transversely to the axis of the stem 44 from a central location on the flat interior surface of connector tab portion 52. A second sleeve 56 which includes a radially enlarged terminal circular flange 58 is dimensioned for a relatively tight fitting, sliding, frictional engagement over the stem 44 and also over a plunger shaft 64. As shown in Figure 8, the plunger shaft 64 terminates in a second semi-cylindrical connector tab end portion 60 provided with a transversely extending aperture 62 dimensioned for frictional engagement with the pin 54 of tab end portion 52 of stem 44. Accordingly, it may now be understood that a selectively detachable connection is formed by

stem 44 and plunger shaft 64, such that the stem 44 and attached brush 34 and sponge 40 may be removed as desired by sliding sleeve 56 rearwardly along shaft portion 64 until engaged tab end portions 52 and 60 are exposed. The pin 54 may then be manually disengaged from aperture 62, to complete detachment of stem 44 from shaft 64.

The plunger shaft 64 is formed by four axially extending ribs 66, 68, 70, and 72 disposed at ninety degree circumferential increments. A supporting cross formed by intersecting strut members 74, 76, 78, and 80, which form radially outwardly extending projections at a medial position of shaft 64, serves to maintain the plunger shaft 64 approximately centered within the barrel 12 in an assembled condition. The supporting cross cooperates, in the manner of a detent, with internal ridges 30 and 32 within barrel 12 (Figure 8) to prevent inadvertent extension or retraction of the plunger assembly 33. A rear end portion of the plunger shaft 64 terminates in radially enlarged portions 82, 84, 86 and 88 integrally molded with a cylindrical end plug 90. An axially projecting gripping flange 92 extends transversely from an outer end face of plug 90 to provide a manual grasping surface to enable a user to extend, retract, and rotate the plunger assembly 33 relative to the barrel 12. The various components of the plunger assembly 33 are preferably formed from

#PP14B12A co-polymer polypropylene, available from Branchcomb Industries, Sapulpa, Oklahoma.

5 In the manner of use of the cervical tissue sampling device according to the present invention, a female lies in a generally reclined position as illustrated in Figure 10 and inserts the barrel 12 into the vagina V. It should be noted that the barrel 12 of the cervical tissue sampling device 10 is shown in a partially inserted position in Figure 10. In practice, 10 the barrel 12 is further inserted such that the circular open front end 14 of barrel 12 contacts the face of the cervix C, thereby allowing slight pressure to be applied to the face of the cervix C. In so doing, the os (or opening) of the cervix C is substantially axially 15 aligned with the barrel 12 and when the plunger assembly 33 is extended, as described below, the bristles of the brush 34 are allowed to enter the os in order to obtain endocervical cells for analysis.

20 With the plunger assembly 33 disposed in the retracted condition depicted in Figures 1 and 2, the supporting cross formed by struts 74, 76, 78, and 80 is disposed between ribs 30 and 32 (Figure 8). In this condition, the circular sponge 40 is in a folded orientation within barrel 12, as shown in Figures 1, 2, 25 4, 6, and 7. The retracted condition of the sponge 40 is such that the sponge 40 is substantially located within the radial boundary of barrel 12 to facilitate insertion. After insertion of the barrel 12, the female

extends the plunger assembly 33 with the aid of finger gripping flange 16, plug 90, and integral gripping flange 92. The extension of the plunger assembly 33 causes the supporting cross to snap past rib 32 (Figure 8) due to the resilient nature of the plastic material forming struts 74, 76, 78, and 80. The plug 90 then is received in recess 29 (Figure 2) in flange 16, limiting further extension of the plunger assembly 33. The recess 29 forms a journal bearing surface for rotationally mounting the plug 90 and attached plunger shaft 64 in an axially central orientation to facilitate sample collection. The sponge 40 then, due to its natural resiliency, springs to the open orientation shown in Figure 9, exposing the circular brush 34 illustrated in Figure 8. The exposed brush 34 and sponge 40 then collect endocervical, cervical cap, and vaginal wall tissue and mucous samples from the vagina V and cervix C, facilitated by manual rotation of the plunger assembly 33 by the user via gripping flange 92.

After sampling is complete, the female retracts the plunger assembly 33 to its starting position, aided by the tactile indication of retraction provided by the snapping of the support cross past rib 32, protecting the collected specimen on the brush 34 and sponge 40 within the barrel 12. The female then withdraws the device 10 by grasping flange 16, removes the plunger assembly 33 from the barrel 12, and detaches the axially outer end portion of the plunger assembly 33 including

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brush 34 and sponge 40, utilizing the detachable connection formed by connector tabs 52 and 60 shown in Figure 8.

5 It should be noted that the sponge 40 not only functions as a specimen collection agent, but also as a cloak of protection for the brush 34 and the specimen sample thereon. As the plunger assembly 33 is being retracted, the sponge 40 folds back to its position shown in Figures 1 and 2, thereby
10 encapsulating and protecting said brush and sample.

The sampling device 10 may be sold as a kit including a suitable lubricant gel to facilitate insertion, along with a small sealable container in which to mail or otherwise transmit detached outer end
15 portion of the plunger assembly 33 including the sponge 40 and brush 34 to a laboratory for analysis.

The device 10 is extremely inexpensive and simple to use. Thus, the device may be utilized by women in the privacy of their own homes to collect
20 tissue samples for analysis.

It is to be understood, however, that even though numerous characteristics and advantages of the present invention have been set forth in the foregoing description, together with details of the structure and
25 function of the invention, the disclosure is illustrative only, and changes may be made in detail, especially in matters of materials, shape, size and arrangement of parts, within the principles of the

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invention to the full extent indicated by the broad
general meaning of the terms in which the appended
claims are expressed.

The embodiments of the present invention in which an exclusive property or privilege is claimed are defined as follows:

1. A cervical tissue sampling device (10), comprising:

a barrel (12);

a plunger (33) disposed for reciprocal sliding movement in
5 said barrel (12); and;

collecting means (34, 40) for collecting tissue secured to
a distal end of said plunger (33); said collecting means (34,
40) including a brush (34) and a sponge (40) dimensioned and
disposed to at least partially surround said brush (34) when
10 said plunger (33) is retracted within said barrel (12).

2. The cervical tissue sampling device (10) of claim 1, wherein
said brush (34) is substantially circular.

3. The cervical tissue sampling device (10) of claim 2,
wherein said substantially circular brush (34) lies
15 substantially in a plane substantially transverse to a
longitudinal axis of said plunger (33).

4. The cervical tissue sampling device (10) of claim 2, wherein
said sponge (40) is substantially circular.

5. The cervical tissue sampling device (10) of claim 4,
20 wherein said substantially circular sponge (40), in an
extended condition, lies substantially in a plane
substantially transverse to a longitudinal axis of said
plunger (33).

6. The cervical tissue sampling device (10) of claim 1, wherein
said brush (34) is disposed adjacent to and axially outwardly
25 of said sponge (40).

7. The cervical tissue sampling device (10) of claim 1, further comprising connection means detachably securing said collecting means to said plunger (33).

8. The cervical tissue sampling device (10) of claim 7, wherein said connection means comprises selectively interlocking first (52) and second (60) tab portions.

9. The cervical tissue sampling device (10) of claim 8, wherein said first (52) and second (60) tab portions are each semi-cylindrical.

10. The cervical tissue sampling device (10) of claim 9, wherein said first tab portion (52) includes a transverse pin (54) and said second tab portion (60) includes a mating transverse aperture (62).

11. The cervical tissue sampling device (10) of claim 10, further comprising a sleeve dimensioned for selective frictional engagement over said first (52) and second (60) tab portions to selectively secure said collecting member to said plunger (33).

12. The cervical tissue sampling device (10) of claim 11, wherein said first (52) and second (60) tab portions include abutting flat interior surfaces.

13. The cervical tissue sampling device (10) of any one of claims 1 to 12, further comprising detent means (30, 32, 74, 76, 78, 80) to substantially prevent inadvertent extension or retraction of said plunger (33) relative to said barrel (12) and to provide a tactile indication to a user of plunger (33) retraction.

14. The cervical tissue sampling device (10) of claim 13, wherein said detent means (30, 32, 74, 76, 78, 80) comprises at least one axially spaced internal ridge (30, 32) in said barrel (12) dimensioned for engagement with at least one radially outwardly extending projection (74, 76, 78, 80) on said plunger (33).

15. The cervical tissue sampling device (10) of claim 1, further comprising bearing means (29, 90) for mounting said plunger (33) in an extended condition for substantially central rotation within said barrel (12).

16. The cervical tissue sampling device (10) of claim 15, wherein said bearing means (29, 90) comprises a plug (90) on said plunger (33) and a complementary recess (29) formed adjacent a proximal end of said barrel (12), said recess (29) dimensioned and disposed for at least partially receiving said plug (90) in said extended condition of said plunger (33).

17. The cervical tissue sampling device (10) of claim 16, wherein said recess (29) is disposed in a finger grip flange (16) formed adjacent said proximal end of said barrel (12).

18. A cervical tissue sampling device (10), comprising:

a barrel (12);

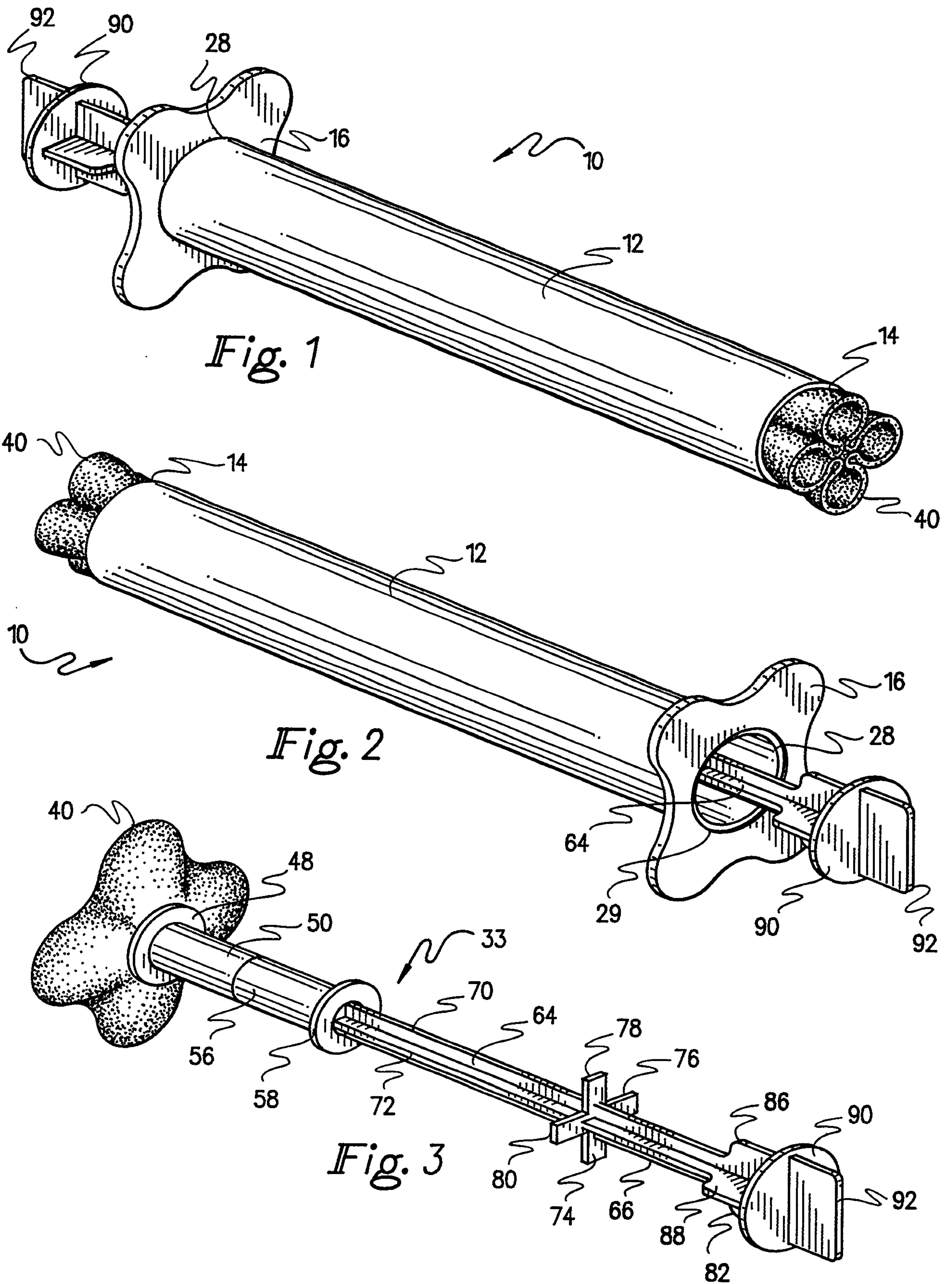
a plunger (33) disposed for reciprocal sliding movement in said barrel (12);

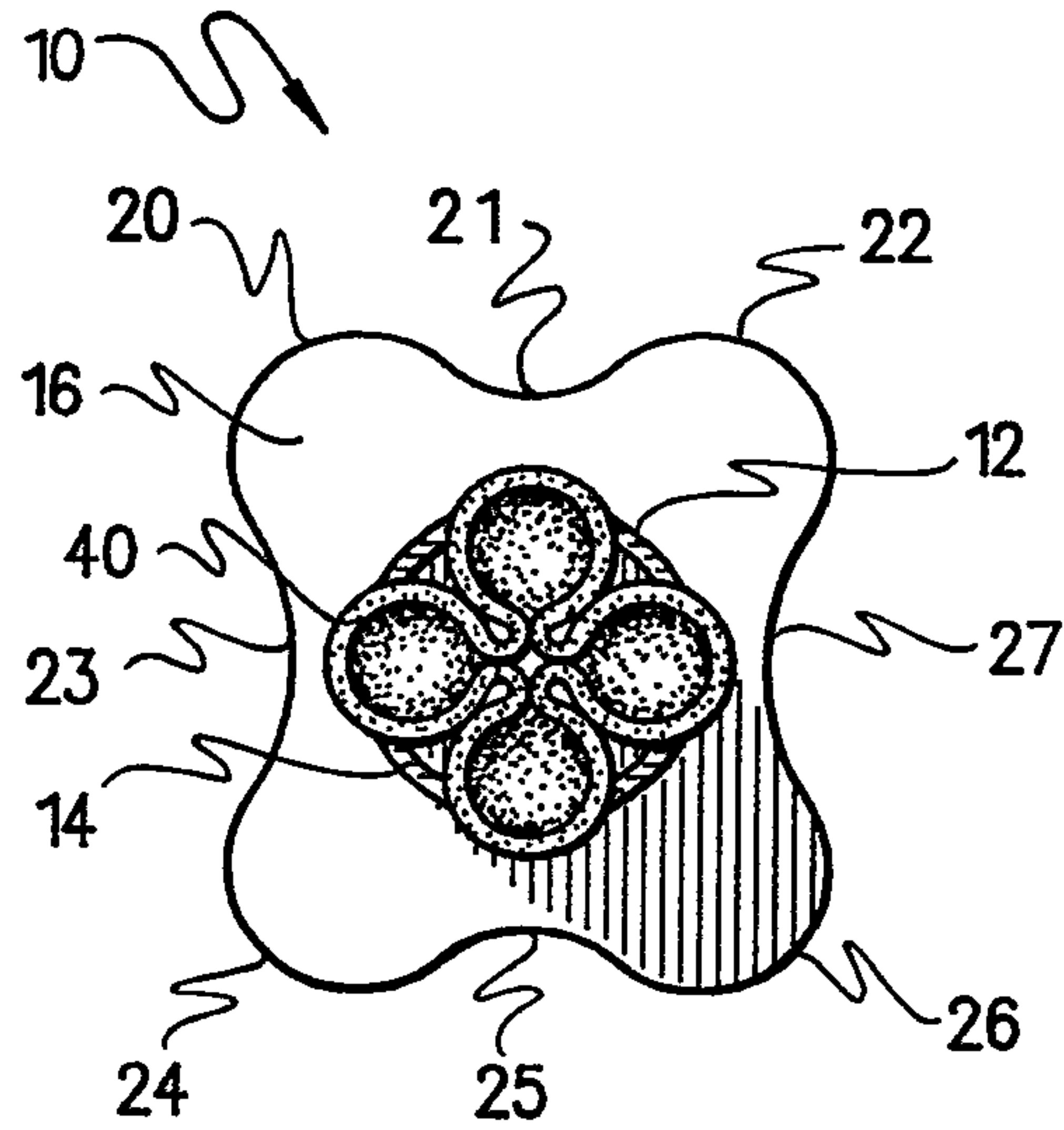
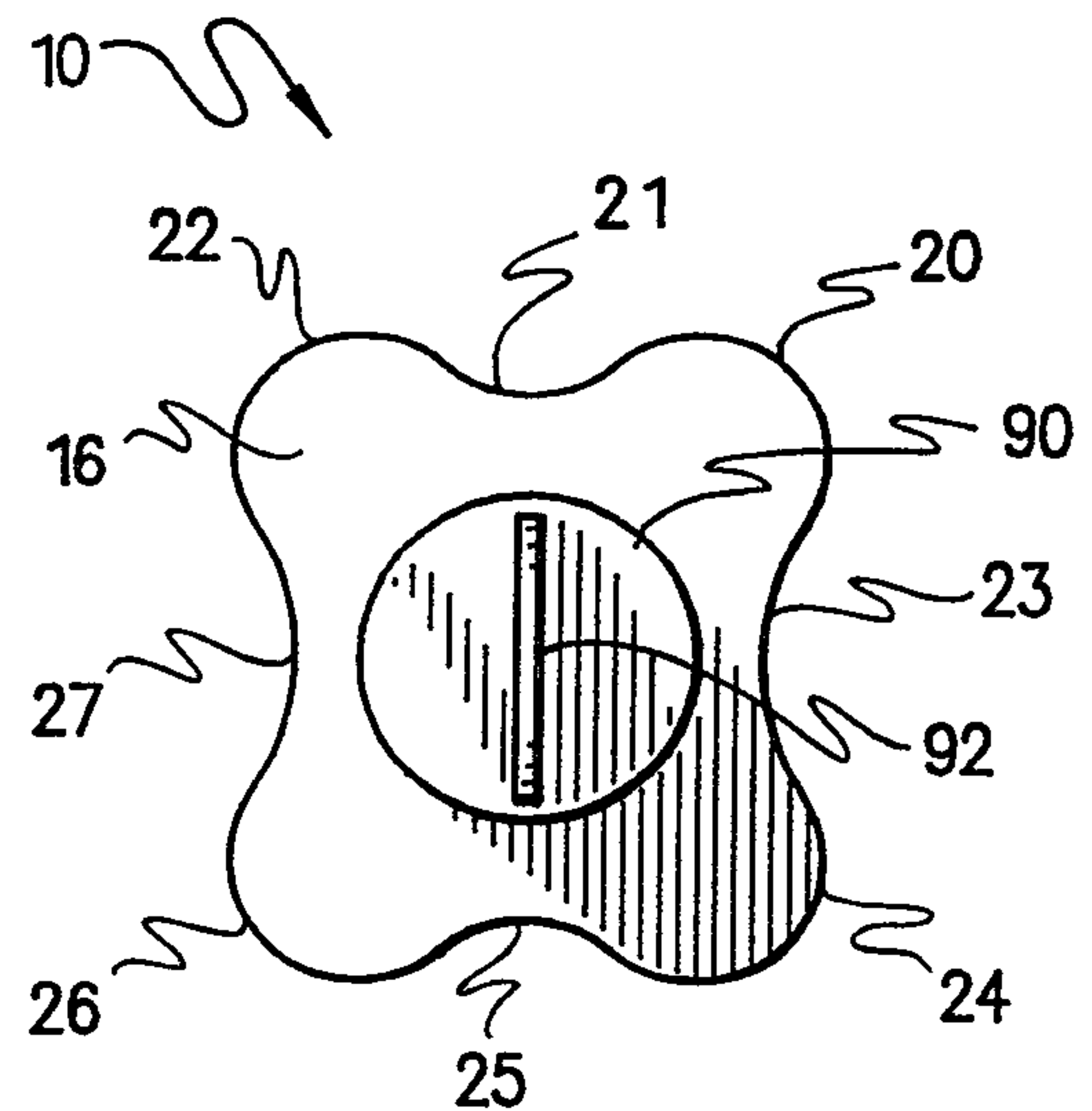
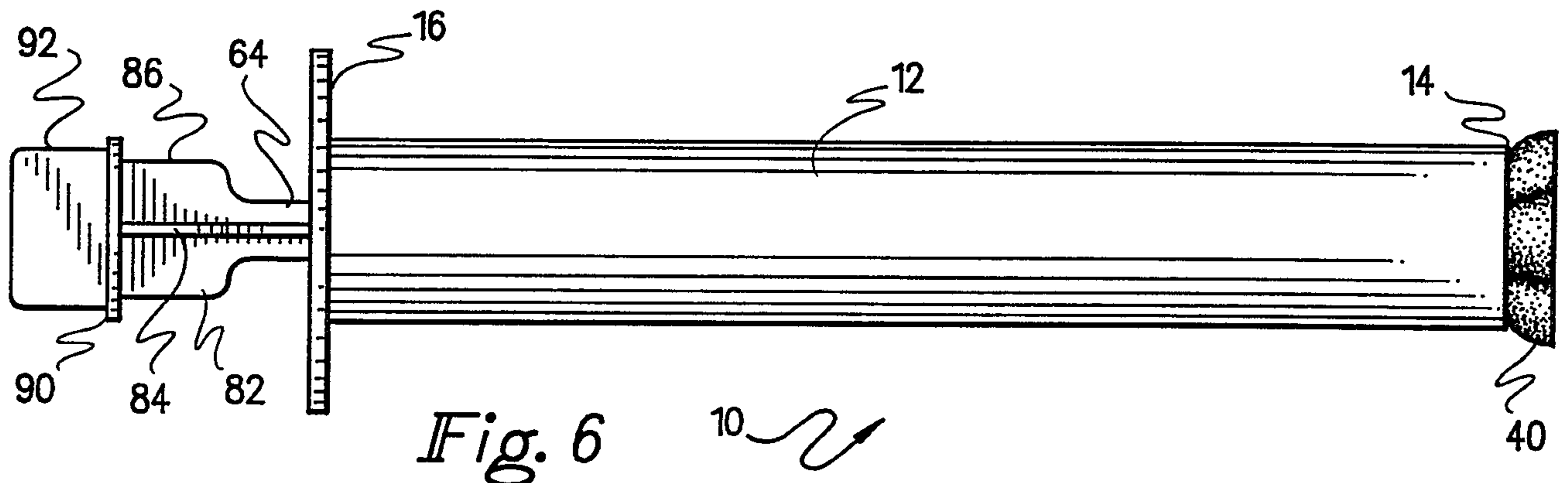
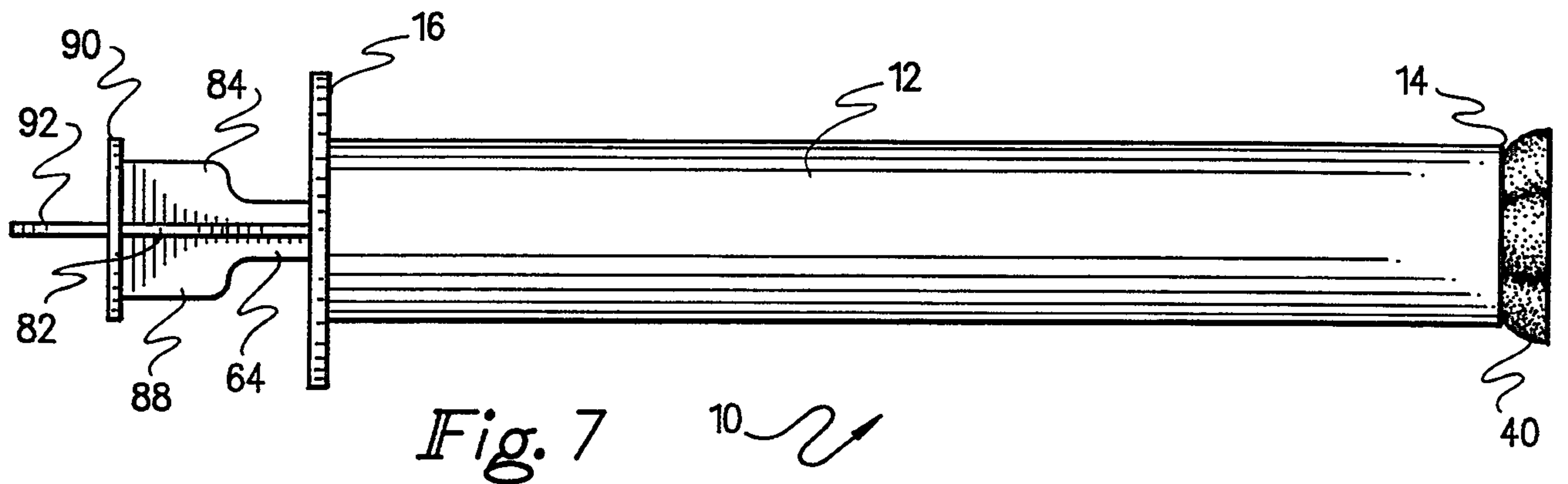
a thin, flexible, sponge (40) secured adjacent a distal end of said plunger (33), said sponge (40), in an extended condition of said plunger (33) substantially disposed in a plane substantially transverse to a longitudinal axis of said plunger (33);

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a brush (34) secured to said plunger (33) axially outwardly of said sponge (40); and

said sponge (40) dimensioned and disposed to at least partially surround said brush (34) when said plunger (33) is retracted within said barrel (12).



*Fig. 4**Fig. 5**Fig. 6**Fig. 7*

