

[54] INTRA-UTERINE BIOPSY APPARATUS

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West, Olympia, Wash. 98501[22] Filed: **Aug. 17, 1973**[21] Appl. No.: **389,361****Related U.S. Application Data**

[63] Continuation-in-part of Ser. No. 260,370, June 7, 1972, abandoned.

[52] U.S. Cl. **128/2 B; 128/2 W; 128/269**[51] Int. Cl. **A61b 10/00**[58] Field of Search **128/2 B, 2 W, 2 R, 269, 128/296, 260**[56] **References Cited****UNITED STATES PATENTS**

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[57]

ABSTRACT

Biopsy apparatus for collecting specimen cell matter from the endometrium of the uterus comprises an introducer tube and a biopsy sponge on the forward end of a long flexible shank. The introducer tube has a lead portion sized to comfortably enter and occupy the endocervical passage and includes an enlarged outwardly located chamber to occupy the vagina. The chamber facilitates manipulation of the biopsy sponge during specimen collecting within the uterine cavity. Shoulder means associated with the introducer tube operate upon coming against the cervix to limit the depth of insertion of the lead portion of the introducer tube.

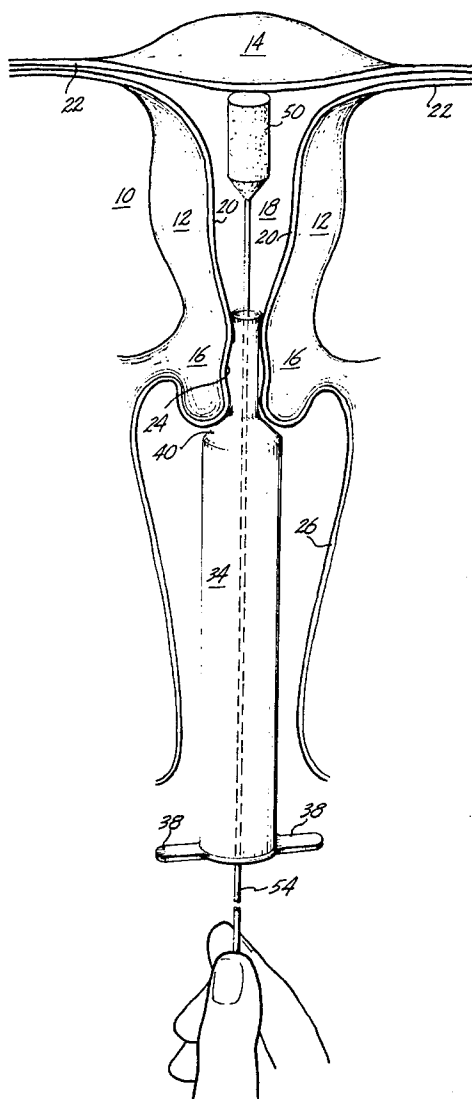
7 Claims, 4 Drawing Figures

Fig. 1.

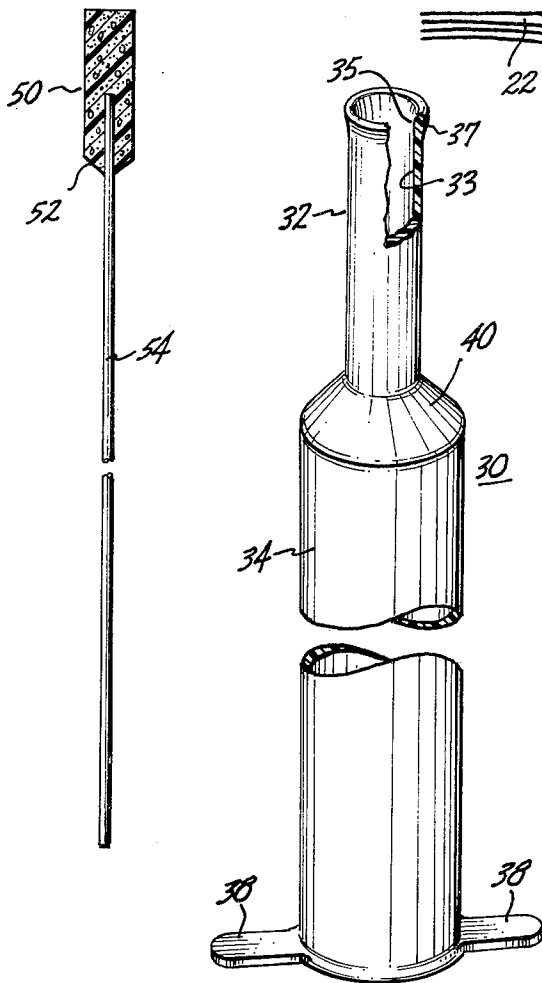


Fig. 2.

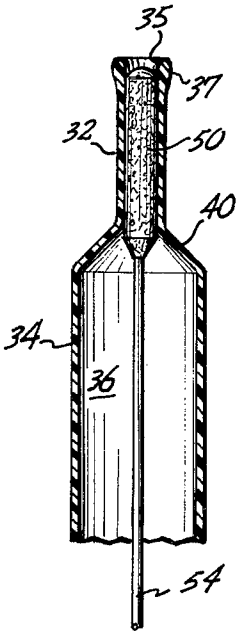


Fig. 4.

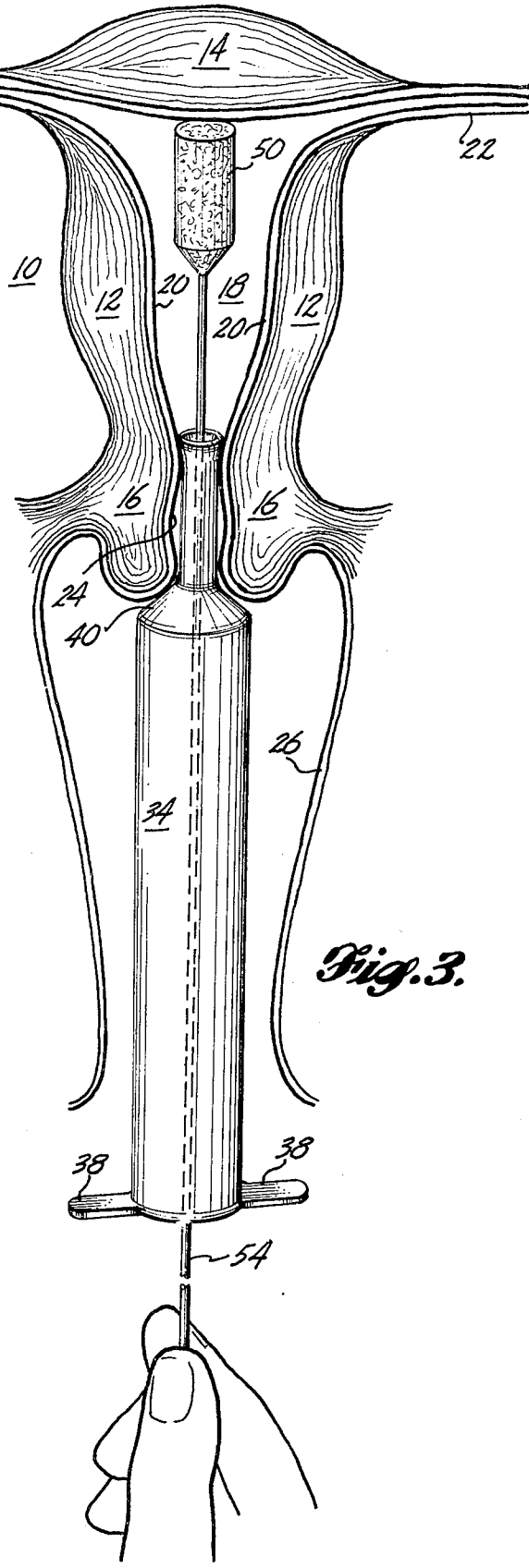


Fig. 3.

INTRA-UTERINE BIOPSY APPARATUS

This application is a continuation in part of my prior U.S. application Ser. No. 260,370, filed June 7, 1972 now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention:

This invention relates to a medical biopsy apparatus for collecting cells from the female body for cytologic evaluation. More particularly, this invention relates to an apparatus including an introducer tube and a biopsy sponge on an elongated flexible shaft. The introducer tube establishes a smooth passage within the endocervix for the introduction of the biopsy sponge into the uterine cavity and includes a roomy chamber outward of the smooth passage permitting manual manipulation of the flexible shank of the biopsy sponge to facilitate the collection of specimen cell matter from the internally flaring endometrium of the uterus.

2. Description of the Prior Art.

An appreciation of past techniques and apparatuses employed in obtaining specimen cell matter from cervical, endocervical and intra-uterine surfaces and areas within the female body, practiced in aid of diagnosing for the presence of carcinoma, can be had from technical articles published for the edification of the medical profession.

It was stated in an article in February 1972 that intra-uterine sponge biopsy was then a new method to obtain samples of endometrium and endocervix cell matter suitable for histological evaluation. The analysis of specimens obtained by sponge biopsy were compared with material obtained by formal curettage and it was confirmed that the sponge biopsy technique had the ability to detect the presence of endometrium cancer in a very high proportion of the patients subjected to the technique. It was disclosed to employ an introducer tube of small diameter for placement in the endocervical area of the uterus. The tube contained, compacted therein in the forward end, a sponge comprising two folded halves juxtaposed to each other. Which, when extruded from the introducer tube assumed a vee-shape as the halves spread apart within the uterus affording contact with opposed portions of the endometrium. The sponge is then withdrawn from the uterus through the cervical canal and through the vagina for subsequent histologic examination of the specimen thus collected. It will be apparent that by reason of the flexibility of the strand and its inability to function in torque or rotation the collecting sponge may not be manipulated within the uterine cavity. Further, in this technique there can be no discrimination between cell matter collected from the endometrium and cell matter collected from the endocervix or, for that matter from the cervix itself. This, because the method did not teach the withdrawal of the sampling sponge into the introducer while the same is in the cervical canal so that it could be shielded as the instrument withdrawn from the body cavity.

Another specimen collector comprised a tubular introducer member having substantially uniform cross sections throughout its length and provided with an entrant or lead portion and a follower portion separated by an outstanding flange which limited the penetration of the entrant portion into the cervical canal. However, this specimen collector which was in the form of a piston within the entrant end of the tube was manipulated

forwardly and rearwardly by means of a shank having a substantially the same cross-section as the internal passage of the introducer tube. Thus lateral manipulation of the specimen collector vis-a-vis the axis of the introducer tube is precluded. Relative movement between the specimen collector and the introducer is substantially a linear function devoid of any lateral variations. It would appear that substantial angular manipulation of the introducer tube itself is required in order that the specimen collector may be directed in lateral paths to obtain and collect specimens of the inwardly flaring or spreading endometrium of the uterus. In order to accomplish this, substantial angular distortion of the cervical canal by means of the elongated introducer follower portion would be necessitated causing considerable discomfort to the patient under examination.

SUMMARY OF THE INVENTION

In accordance with the instant invention biopsy apparatus for collecting cell matter from the endometrium of the uterus is provided which comprises a tubular thin-walled introducer member having a hollow lead portion and a hollow substantially larger follower portion. The introducer tube is passed through the vagina to a position where the lead portion is placed in the cervical canal. The larger follower portion provides a roomy chamber adjacently outward of the lead portion. Between the lead and the follower portions is an annular smoothly-faired shoulder which operates upon coming against the cervix to limit the depth of introduction of the lead or forward end of the introducer member. A biopsy sponge is carried into the body cavity, in place initially within the lead portion. The sponge has an elongated flexible shank extending rearwardly through the roomy chamber of the hollow follower portion and outward therefrom for manual manipulation. When it is desired to collect cell debris from the endometrium the obstetrician presses forwardly upon the flexible shank and ejects the biopsy sponge from within the lead portion and into the uterine cavity. By means of the extremely flexible shank and its relatively small cross-section vis-a-vis the passage of the lead portion, and of the chamber within the follower portion, upon the application of torque and by laterally cocking or distorting the shank the sponge can be caused to move in a somewhat conical path within the uterine cavity and thus collect specimens from practically the entire inner surface of the endometrium.

Among the important objects of this has been to provide a specimen collector adapted to withdraw fluids and cell matter from the endometrium of the uterus over a substantial portion thereof; to provide a new and improved introducer member for the biopsy sponge, comfortably acceptable to the patient so that the technique may be practiced in the office of an obstetrician; and to provide a specimen collector usable to obtain discriminate specimens from within the uterus and uncontaminated by cell matter that might be present in the endocervix at the cervix.

These and other and further objects and advantages of the present invention will become readily apparent from the following description and from the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view of a biopsy sponge and its elongated shank;

FIG. 2 is a perspective view of the introducer tube with portions broken away for convenience of illustration;

FIG. 3 is a schematic view showing the use of the biopsy apparatus in the performance of the technique of collecting cell matter from within the uterus; and

FIG. 4 is a view in cross-section showing details of the leading end of the introducer tube and showing the specimen collecting sponge in place as during introduction of the apparatus into a body cavity.

It will be apparent to those skilled in the art that this invention is susceptible to embodiment in other forms than as shown in the drawings. The disclosure herein is to be understood as an exemplification of a preferred form of the invention carrying out the principles of the invention and is not intended to delimit the invention to the specifically illustrated embodiment. The scope of the invention will be more clearly pointed out in the appended claims.

DESCRIPTION OF THE PREFERRED FORM OF THE INVENTION

In FIG. 3, wherein is depicted the situs of the human body in which this invention is particularly applicable, the uterus 10 is shown as a pear-shaped, thick-walled, hollow muscular organ comprising the myometrium 12, the fundus 14, the cervix 16. The uterine cavity 18 within the uterus includes the endometrium 20 comprising the surfaces from which it is desired to collect cell debris and cell matter for cytological evaluation. The Fallopian tubes are indicated at 22, 22. Within the cervix which is cylindrical, slightly swelled in its middle and about one inch in length, is the endocervical canal 24, the vagina 26 attaches to the cervix as shown. The mouth or entrance to the endocervical canal is spaced somewhat outward of the attachment of the walls of the vagina to the uterus. It is to be noted that the uterine cavity 18 is of a generally conical shape flaring upward from the cervical canal toward the paired, trumpet-shaped muscular canals comprising the Fallopian tubes 22, 22.

Referring to FIG. 2 the introducer member, designated as a whole by the numeral 30, comprises a lead portion 32 and a follower portion 34. The lead portion 32 is sized to be comfortably introduced through the cervix and into the endocervical passage, as shown in FIG. 3 until its inner end gains access to the uterine cavity 18. In a preferred form the lead portion 32, which is thin-walled, has internal passage 33 which flares slightly at 35 for a purpose later to be described. To accommodate the flare 35 the outer surface likewise curves outward slightly at 37. The whole tip of portion 32 is rounded and smoothed both to facilitate insertion into the endocervical canal and to insure expulsion and withdrawal of a biopsy sponge into passage 35 following the performance of the specimen collecting operation.

The follower portion 34 of the introducer tube 30 is of a very substantially increased cross-section relative to that of lead portion 32, whereby to provide a roomy chamber 36 immediately external of the outer end of passage 33. Follower portion 34 has arms or ears 38 out-standing at opposite side to facilitate gripping and

manipulation of the introducer tube by the gynecologist during insertion and its use within the body cavity.

Between lead portion 32 and follower portion 34 is the annular, smoothly-faired shoulder 40 which constitutes a limiting means in that, when the shoulder 40 comes against the mouth of the cervix as shown in FIG. 3, the depth of introduction of the lead or forward end 32 of the introducer member may not only be sensed by the obstetrician but in fact is physically controlled in that the tube 34 is of such size as it may not be forced into the endocervical canal.

The inner surface of the introducer member at the transition between passage 33 and the interior of chamber 36 is also smoothly faired as shown in FIG. 4.

In FIG. 1 is shown the biopsy sponge 50 which is cylindrical in shape having however, a tapered or somewhat pointed rear end 52. The flexible handle or shank 54 is securely embedded in the rear of sponge 50 in such a manner as to leave a substantial portion of the sponge ahead of the forward end of handle 54 to function as a cushion in the event that the sponge is pressed to a depth that it comes into contact with the inner surface of the fundus 14.

The sponge body 50 is formed of a flexible foam material derived from one of the synthetic plastic foams of which foamed polyethylene, foamed urethane or foamed vinyl chloride bases are typical examples. Suitable foams of the nature stated are classified in the plastics field as "open-cell". The inter-cellular material of such foams is substantially nonabsorbent. Such foam materials are usually non-wetting or normally incapable of taking in and holding substantial quantities of liquid as is the case with the more commonly known cellulose sponges. The density of useful synthetic foams falls in the range of two to three pounds per cubic foot. Too coarse a cell structure should be avoided. Ordinarily the cells at the surfaces of body 50 should be fairly visible to the human eye. They should be shear-cut or "topped" to form membrane-scraping collector cups. In other words, body 50 should be blanked or cut out of a larger piece of selected foam material by a shear-cutting operation that insures that some of the peripheries of the numerous cells is removed to convert the cells from substantially spherical voids to partial-spherical cups. It is desirable that the sponge body 50 have an abrasiveness suitable to scrape and abrade from the endometrium 20 or from the surface of fundus 14 cell debris and cell matter which, on the mucousal lining, is quite tenacious and not ordinarily to be collected by a light wiping action.

The handle or shank 54 of the biopsy sponge should be not only relatively and materially smaller in cross-section than the passage 33 of the lead portion 32, but quite obviously very, very much smaller than chamber 36. Handle 54 should also be relatively rigid or stiff longitudinally but be flexible enough to be bowed and manipulated quite easily by the gynecologist during the specimen collecting operation.

The technique of employing the disclosed biopsy apparatus involves the insertion or introduction of the introducer member through the vagina 26 with the lead portion 32 being inserted into the endocervical canal 24 as shown in FIG. 3. Normally at this stage in the operation the biopsy sponge 50 is placed in passage 33 as shown in FIG. 4, in which case it will be somewhat compressed due to its normally being slightly larger than passage 33. The relative size between sponge 50

and passage 33 should be such that it will easily pass through passage 33 when it is desired to extrude it therefrom into the operating or specimen-collecting position as in FIG. 3 within the uterine cavity 18. Sponge 50 may be projected into cavity 18 to the extent shown in FIG. 3 in which case it comes against the inner surface of the fundus 14. By being rotated there-against cell matter is collected from that surface. The gynecologist may also take specimens of cell matter from the flaring endometrium walls 20 of the uterus by rotating the handle 54. When shank 54 is canted in pas-10 sage 33, rotation will cause the sponge 50 to swing in a conical manner. This causes cell structure to be scrubbed or abraded from the endometrium surfaces of the uterine cavity 18. The roomy chamber 36 in the follower portion 34 permits the obstetrician to manipu-15 late the outward extending end of handle 54 and to bow it and flex it particularly within passage 33 whereby is obtained lateral displacement of the sponge 50 relative the axis of the introducer member 30. Also by manipu-20 lating the outer end of the introducer portion 34 with respect to the axis of the vagina 26 the linear direction of lead portion 32 can be changed thus swinging or canting the position of the sponge 50 into contact with the endometrium.

It should be apparent that use of the apparatus dis- closed herein may be "in office" as distinguished from the prior techniques of curettage which usually were only practiced in a hospital or an elaborately equipped clinical facility. Thus this apparatus makes feasible 30 mass screening of females. Minimal discomfort, the re- quirement of only a very brief time, nominal expense, and avoidance of hospital and clinic charges are among apparent advantages.

While it is desirable that the technique be practiced 35 by trained personnel in the medical arts, it will be ob- served that the technique may also be carried out by trained paramedical people due to the simplicity of the technique and the inherent safeguards permitting the collection with accuracy and little or no discomfort of 40 intrauterine biopsy specimens.

In this course of the disclosure reference has been made to gynecologists and obstetricians. The use of those designations should not be considered as limita- 45 tive in respect of the use of the disclosed apparatus as it is intended for use by physicians and paramedical personnel and, on occasion, for self examination.

The apparatus disclosed is normally best produced of materials of a plastic origin not intended for reuse but economically priced for a single use and subsequent 50 disposal. The stem or shank 54 should not be brittle or easily frangible since it must be capable of accommo- dating longitudinal forces inward and outward and, as well, bowing and flexing for the manipulations de- scribed. I have found that a thin-walled extruded PVC 55 tube provides such desirable characteristics.

An appreciation of the invention can be derived from the following schedule setting forth preferred dimen- sions of various parts:

Sponge:

stem diameter, ca 2.5mm
stem length, ca 23 cm
sponge diameter, ca 7 mm
sponge length, ca 2.5/3 cm

Tube:

length neck 32, ca 2.5/3 cm
shoulder, ca 0.5 cm
body length ca 17 cm
5 body diameter, ca 2.2/5 cm.

One particular advantage arising from the use of the disclosed apparatus and the technique of the conical manipulation of the sponge in the uterine cavity is that specimens may be collected from the cornus or con-10 verging openings to the Fallopian tubes 22, 22. Experi- ence derived from curettage has shown that suspect tis- sue may be discovered in one cornu or in both. The ease with which the sponge herein may be manipulated increases the likelihood that very effective screening 15 will occur.

What is claimed is:

1. Biopsy apparatus for collecting cell matter from the endometrium of the uterus, comprising:

a tubular, thin-walled, introducer member having an opening at both ends;

said member comprising a hollow, lead portion adapted to be comfortably introduced through the cervix into the endocervical passage and to reach the uterine cavity;

25 said member also comprising an integral hollow elon- gated follower portion of substantially increased cross-section relative the cross-section of said lead portion and coaxially associated with the hollow of said lead portion whereby to provide a roomy chamber adjacently outward of said lead portion; said introducer member having externally between the rear of said lead portion and the front of said follower portion an integral, annular, smoothly- 30 faired shoulder defining means to limit the depth of penetration of the forward end of said lead portion into the uterine cavity;

a surface-abrading biopsy sponge of a size to pass through said hollow lead portion; and

an elongated flexible shank having its forward end securely embedded in the rear of said sponge, said shank being disposed within said introducer mem- 35 ber and being materially smaller in cross-section than the hollow of said lead portion and of a length to extend through said introducer member and out- ward of the chamber of said follower portion when the sponge is inserted into the uterine cavity.

2. The structure of claim 1 in which the forward end of the hollow lead portion is internally flared.

3. The structure of claim 1 in which the biopsy 40 sponge is slightly larger in cross-section than the hollow within the lead portion and is under compression dur- ing its passage therethrough.

4. The structure of claim 3 in which the rear of the biopsy sponge is conical.

5. The structure of claim 1 in which the introducer tube includes outstanding members at the rear of the follower portion to facilitate manual manipulation of said tube in the vagina.

6. The structure of claim 1 in which said shank is hol- 45 low.

7. The structure of claim 1 in which the annular shoulder of the introducer member is forwardly tapered.

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