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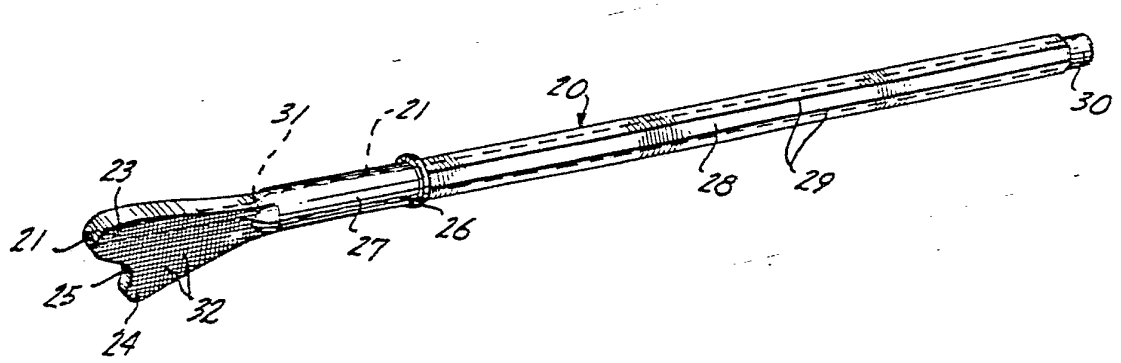
(54) **Title:** PAP SMEAR T-ZONE SAMPLER



(57) **Abstract**

An elongated aspirator tube (20) has a proximate end portion (29) adapted for quick connection to a suction-generating device (33 or 35) for collection of cell-containing mucus from the uterine endocervical canal (9), an a flattened distal end portion (22) forming a spatulate scraper for collecting cells exfoliated from the tranformation zone (5) of the uterine cervix. The scraper includes a frontal lobe (23) through which the bore (21) of the aspirator tube (20) opens, an adjacent lateral lobe (24) abuttable against the ring (11) of the cervix projecting into the vagina for positioning the blunt apertured distal end of the frontal lobe (23) at approximately the external os (6) and a concave transition portion (25) forming a scraping edge joining and faired into the adjacent edges of the two lobes (23 and 24). Mucus from the endocervical canal (9) is aspirated into the tube (20) and the entire transformation zone (5) scraped by rotation of the tube (20) for collection of freshly exfoliated cells to be deposited on a slide (36).

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Description

Pap Smear T-Zone Sampler

Technical Field

My invention relates to a cytological sampling instrument for collecting cells exfoliated from the uterine cervix.

Brief Description of the Background Art Drawings

The background art is described below with reference to the accompanying Figures 1, 2, 3 and 4 which are corresponding, somewhat diagrammatic, generally axial sections through a vaginal cavity showing in elevation the most popular prior art cytological sampling instruments currently in use.

Background Art

In each of the known cervical cytological sampling methods the object is to collect a large number of cells that originated at the uterine cervix and, to a lesser degree, at the uterus, to be deposited on a slide and "fixed" by application of fixative for preservation of the cells. After suitable processing, subsequent microscopic examination in a medical laboratory reveals whether or not abnormal cells are present which are indicative of cancer or lesions accepted as being precursors of cancer.

As illustrated in Figure 1, in one method the vagina 1 is distended by a speculum 2 enabling the portio vaginalis (vaginal portion) 11 of the cervix to be viewed, and a paddle-like scraper 3 is used to collect exfoliated cells from the posterior fornix 4 of the vagina, that is, from the "vaginal pool". This is the area selected for sampling by Papanicolaou because cells exfoliated from virtually all areas of the cervix and from the uterus gather in the vaginal pool, though

Papanicolaou proposed sampling this region by aspiration. Unfortunately, however, cells begin deteriorating immediately upon exfoliation to the point where at least a large proportion of the cells obtained in a vaginal pool smear have little or no diagnostic value. In addition, while large numbers of cells usually are obtained, the origins of the cells present in the vaginal pool at any given moment are not known so that there is no assurance that cells from areas prone to cancer will be obtained. It is now recognized that a false negative rate of about 50% can be expected for vaginal pool smears, that is, even after examination about one-half of the cases of invasive cervical cancer and cervical intraepithelial neoplasia ("CIN") remain undetected. Nevertheless, since vaginal pool smears are quickly, easily and inexpensively taken, they still are used to a large extent, particularly when funds for screening a large population are limited.

As early as 1947, the year in which the application resulting in Ayre United States patent No. 2,471,088 was filed, it was recognized that the vast majority of lesions resulting in invasive cervical cancer originate at the undulating circumferential border 5 between the squamous cells of the ectocervical epithelium 17 and the columnar cells of endocervical epithelium 18, which border is referred to as the squamo-columnar junction, the transformation zone or the "T-zone". Though the T-zone is variously located in different women, usually it is at or closely adjacent to the external os 6. It is extremely important that cells from this area be present in a sample.

Ayre invented the specially designed scraper 7 shown in Figure 2 to be used for scraping the entire circumferential extent of the T-zone for early detection of cell abnormalities. In general, the Ayre scraper has two lobes including a frontal lobe 8 insertable slightly into the endocervical canal 9 and an adjacent lateral lobe 10 abuttable against the vaginal portion

or ring 11 of the cervix. In this position the concave portion 12 of the scraper edge joining the two lobes is in engagement with the T-zone. The frontal lobe 8 acts as a pivot as the scraper is rotated for scraping of the entire circumferential extent of the T-zone.

Ayre, himself, recognized that a more reliable diagnosis could be obtained if the scraping sample was not the only sample obtained from a patient. He proposed that at least two separate sampling operations be performed --one using his scraper and another using a separate instrument for obtaining an additional sample directly from the endocervical canal. In fact, research has shown that relying solely on a sample obtained by use of an Ayre scraper can result in a false negative rate of as high as about 30%.

Methods for obtaining samples directly from the endocervical canal are shown in Figures 3 and 4. In the method of Figure 3, the narrow forward end of a pipette 13 is inserted into the endocervical canal. Preferably the tip of the pipette is positioned at about the external os, but it is difficult to position the pipette precisely so that sometimes the tip of the pipette is inserted almost up to the internal os 14 as shown in Figure 3. Suction is applied drawing mucus containing exfoliated cells into the lumen of the pipette. Published research suggests that carefully performed external os aspiration gives more reliable results than any other known single method. A problem, however, is that the endocervical epithelium, unlike squamous epithelium, is friable and prone to bleeding. Not only is bleeding worrisome to the physician and patient, but a sample containing any appreciable amount of blood cannot be evaluated by the cytologist with confidence. Another problem is that the method of Figure 3 more often should be performed by a physician, whereas the methods of Figures 1 and 2 can be performed by skilled paramedic technicians.

In the method of Figure 4 the soft tip 15 of

a saline-moistened cotton-tipped applicator 16 is inserted into the endocervical canal and rotated and moved in and out. While less traumatic than the method of Figure 3, there still is a substantial chance of endocervical mucosal injury and bleeding. Also, cells valuable for diagnostic purposes adhere in the interstices of the cotton fiber. Further, it is difficult to transfer the sample to a slide, and vigorously rubbing the cotton-tipped applicator on the slide distorts the cells making them difficult to evaluate.

Adherence of and damage to cells also is a problem with the methods of Figures 1 and 2 because most scrapers presently used are manufactured from thin strips of wood and cells become trapped in the pores and cracks in the wood. There also is a possibility of abrading the cervix with the irregular edge of a wood scraper.

Often two or more of the above conventional methods are performed in sequence on each patient. Prior research has demonstrated that the combination of prior art methods resulting in the lowest false negative rate, a rate as low as 2%, is the combination of the methods of Figures 2 and 3, that is, the combination of T-zone scraping and external os aspiration. In spite of experts' recommendations that this combination of methods be used, physicians continue to use suboptimal methods, possibly because of the difficulty of performing an external os aspiration. For example, in a recent survey, only 3.1% of pathologists representing 675 cytology laboratories stated that a combined external os aspiration and T-zone scraping sample was a "type of routine gynecologic smear" received by their laboratories.

A major problem in obtaining Pap smears is that any cells that are allowed to dry before being fixed become distorted and impossible to evaluate. Under ideal circumstances a sample is fixed almost immediately, within seconds after being obtained. This

problem is magnified when a combination of prior art methods is used because usually all of the separate samples are obtained and placed on a slide before any sample is fixed, with the result that at least some air drying occurs.

Slides received at a laboratory show significant variation, illustrating a wide range of sampling techniques and methods of transfering collected cell-containing material to a slide. Individual slides may have a single large blop, multiple streaks, globs or a small spot of material such that it is difficult to examine individual cells, making examination time consuming and sometimes inaccurate.

In addition, a substantial proportion of slides received by a laboratory must be classified as "unsatisfactory" because no diagnosis can be given due to an inadequate amount of cell-containing material and/or significant air drying artifact. The proportion of "unsatisfactory" slides varies widely; for example, in one research study involving ten clinics using the same method, T-zone scraping, only one-half of 1% of the slides from one clinic had to be labeled unsatisfactory, whereas 25.6% of the slides from another clinic had to be labeled unsatisfactory because of an inadequate quantity of well defined cells. In this case, the patient must be scheduled for an additional smear sample to be taken which, in effect, doubles the inconvenience to the patient, the work of the doctor or paramedic and the consequent expense. Also, the patient may be distressed from having been asked to return for an additional smear, regardless of the reassurances that she receives from the physician that an abnormality is unlikely.

Different instruments and methods have been proposed to solve one or more of the problems discussed above. For example, to reduce expense it has been proposed that a sample be obtained by the patient herself, such as by use of a specially designed tampon

or a "vaginal irrigation" kit, and mailed directly to the medical laboratory. High false negative rates have been demonstrated for self-obtained samples and, accordingly, use of these methods has been discouraged.

One study, in an attempt to explain the high false negative rate when screening for cervical intraepithelial neoplasia, verified that high numbers of cells are trapped in cotton-tipped applicators and wooden scrapers, whereas relatively few cells are trapped in plastic instruments; yet use of plastic instruments has been discouraged because such instruments have been manufactured with sharp edges that can lacerate the cervix.

Kohl in his U.S. patent Re. 27,915 disclosed a scraping instrument having a narrow aspiration pipette projecting forward from the scraping edge of the instrument for insertion into the endocervical canal. As the narrow projecting end of the pipette is inserted into the canal, the scraper and pipette pivot about a flexible shock-absorbing joint to align the axis of the pipette with the length of the endocervical canal. Possible disadvantages of the Kohl construction include:

the Kohl instrument is intended to be gripped at an annular flange projecting from the proximate end portion of the instrument, which may make the Kohl instrument difficult to manipulate;

as with other known aspiration pipettes, it may be difficult to position the pipette precisely and, during insertion, the sharp narrow forward end may lacerate or puncture the friable endocervical epithelium, causing bleeding;

once the instrument is inserted, substantial dexterity would be required to hold the forward end portion of the instrument substantially stationary while the plunger is retracted to draw mucus into the lumen of the instrument; if the forward end portion of the instrument is not maintained stationary, in-and-out movement of the sharp tip of the pipette may cause

bleeding;

the small plunger may not be able to generate sufficient suction to draw viscous cell-containing mucus into the lumen of the tube;

diagnostically valuable cells may be trapped in the corrugations of the flexible joint;

the concave scraping edge of the Kohl instrument is designed for engagement with the vaginal ring of the cervix rather than with the transformation zone; if the T-zone is located even slightly inward of the external os, few, if any, cells from the transformation zone would be collected on the smooth cylindrical periphery of the aspiration pipette; and

scraper lobes project oppositely from the pipette so that as the instrument is rotated cells gather on both lateral sides of the scraper portion of the instrument.

Shute in his United States patent No. 3,088,454 disclosed another type of cervical sampling instrument having a scraper and an aspirator tube. Unlike applicant's instrument, the Shute device is designed to obtain the aspiration sample from the internal os, and as the Shute device is rotated, substantially the entire lengthwise extent of the endocervical canal is scraped by a serrated edge which may cause bleeding.

Robinson in his United States patent No. 4,043,322, disclosed an aspiration instrument having a forward projecting, sharp-edged blade for obtaining tissue samples from the walls of a uterus.

Crane et al. in their United States patent No. 4,078,656 disclosed a return mailer type package for an Ayre scraper, a cotton-tipped applicator, a slide and an ampule of fixative.

Disclosure of the Invention

In accordance with the present invention I provide an aspirator tube having a flattened distal end

portion forming a spatulate scraper including a frontal lobe through which the bore of the tube opens and an adjacent lateral lobe abuttable against the vaginal ring of the cervix for positioning the apertured tip of the frontal lobe approximately at the external os. A concave transition section of the scraping edge of the spatulate scraper between the two lobes is shaped substantially complementally to the inner margin of the vaginal ring of the cervix for engagement with the transformation zone. In use, suction is applied to the proximate end portion of the tube for drawing cell-containing mucus into the tube, followed by rotation of the tube for scraping the entire circumferential extent of the T-zone. The aspiration sample is pooled onto a slide and the scraping sample deposited in the pool, whereupon the combined sample is spread thinly and evenly as a monolayer of cells on the slide surface.

Brief Description of Drawings of the Preferred Embodiment

The details of my invention will be described in connection with the accompanying drawings of my preferred embodiment in which,

Figure 5 is a top perspective of a Pap smear T-zone sampler in accordance with the present invention,

Figure 6 is a top perspective of a kit including the sampler of Figure 5, a cotton-tipped applicator, a glass slide, a protective slide case and a package for those components, as well as alternative suction-generating devices for use with the sampler,

Figure 7 is a fragmentary side elevation of the distal end portion of the sampler of Figure 5,

Figure 8 is an end elevation of the sampler of Figure 5,

Figures 9 and 10 are corresponding, somewhat diagrammatic, generally axial sections of a vaginal cavity illustrating a sampler in accordance with the present invention being used for collecting a sample of

cell-containing material, with parts broken away, and Figures 11, 12, 13 and 14 are corresponding, fragmentary, somewhat diagrammatic, top perspectives illustrating the sample being deposited on a glass slide and fixed, and

Figure 15 is a somewhat diagrammatic, generally axial section through a vaginal cavity illustrating an alternative manner of collecting a sample by use of the Pap smear T-zone sampler of Figure 5, with parts broken away.

Definition

As used herein, "lobe" means a blunt nosed projection that is at least somewhat flattened in that it has at least one substantially flat side face.

Best Mode for Carrying Out the Invention

As shown in Figure 5, the Pap smear T-zone sampler of the present invention is an elongated aspirator tube 20 having a substantially linear axial through bore 21. The distal end portion 22 of the tube is flattened forming a spatulate scraper. In profile, such scraper is shaped substantially the same as an Ayre scraper in having a forward projecting or frontal lobe 23 and an adjacent generally radially projecting or lateral lobe 24. A concave transition section 25 of the scraping edge of the scraper is faired into the adjacent edges of the two lobes. All corners forming junctions between the sides and edges of the scraper are rounded.

A circumferential rib 26 divides the long barrel of the tube into a cylindrical stem 27 carrying the spatulate scraper and a long straight handle portion 28. Such handle portion is of hexagonal cross section, forming longitudinally extending grip-promoting ridges 29. The relatively short proximate end portion 30 of the tube is cylindrical.

The bore 21 of the tube opens at about the center of the blunt rounded tip of the scraper frontal lobe 23. Throughout the length of the scraper portion 22, such bore is of uniform, but small, diameter. Proceeding toward the proximate end of the tube, the diameter of the bore increases abruptly forming an annular step 31. Throughout the length of the barrel of the tube, the diameter of the bore is uniform, but large in comparison to the diameter of the distal portion of the bore extending through the spatulate scraper.

It is preferred that the aspirator tube be injection molded from plastic material. Also it is preferred that both sides of the flattened spatulate scraper be planar. However, injection molded plastic material has a tendency to shrink in the center of a large thick area forming a characteristic depression or "dish". By tapering the spatulate scraper from top to bottom, that is, by gradually and uniformly decreasing the thickness of the scraper outward toward the tip of the lateral lobe, as shown in Figure 8, shrinking of the plastic material at the center of the lateral lobe is less of a problem and both sides of the scraper will be substantially planar rather than having substantial central depressions.

Preferably the planar side faces of the scraper are slightly hydrophilic, which can be achieved by adding a hydrophilic substance to the plastic material from which the scraper is formed or, as shown in the drawings, by texturing such sides by molding short criss-crossed ribs 32 integrally in the sides of the scraper as best seen in Figure 5.

As shown in Figures 9 and 10, in a simple "one-step" operation involving only a single insertion of the Pap smear T-zone sampler of the present invention into the vagina, both an external os endocervical aspiration sample and a T-zone scraping sample can be obtained. The sampler is inserted lengthwise into the

vagina 1 distended by a conventional speculum 2 and the broad rounded tip of the frontal lobe 23 is substantially self-centering in the endocervical canal 9 without fear of lacerating or puncturing the cervix. The leading edge of the scraper lateral lobe 24 is located for engagement with the vaginal ring 11 of the cervix to position the apertured tip of the frontal lobe slightly inward of the external os 6. The scraping edge of the scraper, formed by the concave transition section 25 and the adjacent edges of the two lobes, is in engagement with the T-zone 5.

Suction is applied to the tube at its proximate end portion, such as by use of a rubber squeeze bulb 33 having its apertured tip 34 snugly fitted over the cylindrical proximate end portion 29 of the tube in sealing engagement. Alternatively, the flared, distal, lumen-forming end portion of a conventional syringe, such as the syringe 35 shown in Figure 7, can be fitted inside the bore of the cylindrical proximate end portion of the tube so that the syringe can be used as a suction-generating device. In either case, the suction is concentrated in the endocervical canal because the distal end portion of the tube bore is of small diameter. Even viscous cell-containing mucus will be drawn into the tube.

While the aspirator tube itself is disposable after use, preferably the suction-generating device is reusable and, accordingly, it is preferred that no mucus be drawn into the suction-generating device, which could contaminate future samples. Since, in the barrel of the tube, the tube bore is of large diameter, a substantial amount of mucus can be drawn into the tube without entering the suction-generating device. In addition, the abrupt step 31 of the bore causes a turbulent flow tending to retain the mucus in the distal end portion of the tube bore, as opposed to a laminar flow which could result in mucus flowing horizontally into the suction-generating device.

After the aspiration sample has been drawn into the tube, the tube is rotated at least one full turn as the scraping edge of the spatulate scraper is held gently against the vaginal ring of the cervix. The entire circumferential extent of the T-zone is scraped for collecting freshly exfoliated cells. The scraping sample adheres to the leading side of the scraper because the sides of the scraper are textured or slightly hydrophilic.

An alternative to the two sequential sample-collecting steps described above is to obtain the aspiration sample as the scraper is being rotated, in which case cell-containing material accumulating at the rotating leading side of the scraper may be drawn into the tube bore with mucus from the endocervical canal. Another alternative is to rotate the tube for obtaining the scraping sample first, followed by withdrawing the tube slightly and then applying suction for obtaining the aspiration sample so that exfoliated cells from the T-zone that did not adhere to the leading side of the scraper will be drawn into the tube bore.

Regardless of the sample-collecting method that is used, in rapid sequence the aspirated sample and the scraped sample are deposited on a glass slide 36 and fixed, as shown in Figures 11 through 14. As indicated in Figure 11, first the aspiration sample is pooled onto the slide immediately adjacent to its frosted end 37. Next the scraped sample is transferred to the slide by gently rubbing the leading side of the scraper in the pool as illustrated in Figure 12. The combined sample is spread substantially uniformly and thinly on the upper surface slide, as illustrated in Figure 13, by butting the circumferential rib 26 of the tube against a longitudinal edge of the slide with the cylindrical sample-spreading stem 27 resting flatly on the upper surface of the slide and moving the tube lengthwise of the slide away from its frosted end. Immediately following spreading of the sample, the

sample is fixed, such as by use of a conventional spray-type fixative as illustrated in Figure 14.

The entire sample transferring and fixing operation can be performed in a matter of a few seconds so that there will be no appreciable air drying of either sample. Each slide should have a thin monolayer of well preserved cells, making microscopic examination and diagnosis quick and reliable.

While the combination of external os aspiration and T-zone scraping is the most reliable sampling method for detecting the presence of abnormal cells, in some women there simply is not enough mucus at the external os that an aspiration sample can be obtained. The so-called "dry cervix" is particularly prevalent in peri- or post-menopausal women. Nevertheless, as illustrated in Figure 15, the Pap smear T-zone sampler of the present invention still can be used in a simple one-step operation for obtaining samples of exfoliated cells both from the endocervical canal and the T-zone, even from a woman having "dry cervix".

As shown in Figure 15, the shaft 38 of a cotton-tipped applicator 16 can be inserted into the narrow distal end portion of the bore 21 of the tube 20 up to the soft tip 15 of the applicator. Preferably the diameter of the tube bore is only slightly greater than the diameter of the shaft so that the cotton-tipped applicator is received in the tube bore in snug engagement for firmly connecting the applicator to the aspirator tube.

In use, the aspirator tube still is substantially self-centering as it is inserted lengthwise into the vagina 1 for inserting the tip of the cotton-tipped applicator into the endocervical canal 9. When fully inserted, the scraping edge of the flattened spatulate scraper portion 22 of the tube is in engagement with the T-zone 5. As the tube is rotated for obtaining a T-zone scraping sample, simultaneously exfoliated cells in the endocervical canal are collected

on the tip of the cotton-tipped applicator. After at least one full revolution, the tube is withdrawn and, quickly, the cotton-tipped applicator and the leading side of the scraper are rubbed gently against a glass slide for transferring cellular material to the slide. The combined samples are fixed immediately.

The present invention also can be used for obtaining a sample for hormonal evaluation, which sample preferably is obtained from the proximal third of the lateral vaginal wall. For example, following the sample obtaining, transferring and fixing operation described with reference to Figures 9 through 14 or Figure 15, the top edge of the scraper opposite its lateral lobe can be rubbed gently against the lateral vaginal wall between the blades of the speculum. This sample from the lateral vaginal wall can be deposited on a separate slide or at one end portion of the slide containing the cervical scrape sample.

As illustrated in Figure 6, preferably the present invention is provided in a kit including: the Pap smear T-zone sampler 20 of the present invention, which usually will be used to obtain an external os aspiration sample and T-zone scraping sample as shown in Figures 9 and 10; a long shafted cotton-tipped applicator 16, which can be used for wiping away excess mucus from the vaginal portion of the cervix or which can have its shaft shortened for insertion into the bore of the sampler as illustrated in Figure 15; a slide 36 for receiving a sample taken by use of the sampler of the present invention; a rigid slide case 39 for protecting the slide in transit to a medical laboratory; and a folding cardboard package 40 which may be of the return mailer type. Also required for use of the present invention is a suction-generating device; either a 30 cc rubber squeeze bulb 33 or a 10 cc plastic syringe 35 can be provided separately. Similarly, spray fixative is preferred and also can be provided separately.

With respect to the preferred dimensions for the invention, to assure adequate suction by use of a 30 cc rubber squeeze bulb or a 10 cc syringe, the diameter of the narrow distal end portion of the tube bore should be no greater than about 1/8 inch (.32 cm). As discussed above, preferably the diameter of the narrow portion of the bore is substantially the same as the diameter of the shaft of a cotton-tipped applicator which, for applicators currently available, is about 3/32 inch (.24 cm). The diameter of the larger proximate end portion of the bore should be at least about 1-1/2 times, preferably about 2 times, the diameter of the narrow distal end portion of the bore for creating the abrupt step between the two bore portions and for storing a substantial quantity of mucus.

The transverse thickness of the spatulate scraper should be small, preferably no greater than about twice the diameter of the narrow portion of the tube bore, because there is less chance of a "dish" resulting in a thin section of injection molded plastic material than in a thicker section. Nevertheless, the scraper must be thick enough that the lateral walls of the tube bore will not break or bend appreciably during use of the instrument. In the preferred embodiment, the scraper is tapered uniformly from its thickest top portion, which is about 3/16 inch (.48 cm) thick, to its thinnest bottom portion, which is about 3/32 inch (.24 cm) thick, as shown in Figure 8.

The frontal lobe should be broad in comparison to the diameter of the narrow portion of the tube bore to eliminate the possibility of perforating the cervix. Preferably the breadth of such lobe, that is, the upright dimension as shown in Figure 7, is at least twice the diameter of the narrow portion of the tube bore, in the preferred embodiment about 1/4 inch (.64 cm) which is between 2 and 3 times the preferred bore diameter. In addition, the tip of the frontal lobe should be blunt and rounded, having a radius of

curvature at least equal to about the diameter of the narrow portion of the tube bore. In the preferred embodiment, the tip of the frontal lobe is substantially semicircular, the radius of curvature being about 1/8 inch (.32 cm).

The leading edge of the lateral lobe must project outward a distance sufficient for engagement with the vaginal ring of the cervix and in the preferred embodiment such lobe projects outward about 7/16 inch (1.1 cm) from the axis of the tube bore. In addition, such leading edge must be located rearward from the apertured tip of the frontal lobe a distance such that the apertured tip of the frontal lobe is in close proximity to the external os when the leading edge of the lateral lobe is in engagement with the vaginal ring of the cervix. In the preferred embodiment, the leading edge of the lateral lobe is located about 1/4 inch (.64 cm) rearward of the tip of the frontal lobe.

The corners forming junctions between the scraper lateral side faces and the T-zone scraping edge, which includes the adjacent edges of the frontal and lateral lobes and the concave transition section between the lobes, must be rounded sufficiently as to prevent abrading the cervix yet should not be so rounded as to prevent a good scraping effect for collecting exfoliated cells. Preferably the radius of curvature of each of such corners is about .01 inch (.25 mm), and should be no greater than about .03 inch (.76 mm). The top edge of the scraper, which may be used to obtain a sample from the lateral vaginal wall, can have somewhat sharper longitudinally extending corners because the vaginal wall is less friable and prone to bleeding than the cervix. Preferably the radius of curvature of each upper longitudinally extending corner is about .001 inch (.025 mm) or less.

With respect to the cylindrical proximate end portion of the tube, the outside diameter and the length of such end portion must be sufficient for firm

sealing engagement in the aperture of a conventional 30 cc rubber squeeze bulb. In the preferred embodiment, the outside diameter of the proximate end portion is about 1/4 inch (.64 cm) and such end portion is about 11/32 inch (.87 cm) long. Similarly, the inside diameter of the proximate end portion must be such as to fit over the distal, lumen-forming tip of a conventional 10 cc syringe in snug sealing engagement. A diameter of about 5/32 or 3/16 inch (.40 or .48 cm) for the distal end portion of the tube bore meets this requirement.

Finally the length and diameter of the long straight handle portion of the tube should be sufficient that the tube can be manipulated easily. In the preferred embodiment, the barrel of the tube is about 6 inches (15 cm) long and the distance between opposite flat sides of the handle portion is slightly greater than 1/4 inch (.64 cm) such that the handle portion is about the same size and is the same shape as a pencil, assuring easy handling of the instrument.

The sampler can be injection molded from clear polypropylene plastics material, in which case the sampler is sufficiently inexpensive that it can be thrown away after use.

Claims

1. A medical sampling instrument comprising: an aspirator tube having a distal end portion forming a scraper, said scraper having a frontal lobe, the bore of said tube opening at the forward tip of said frontal lobe.

2. A medical instrument including an elongated aspirator tube having a generally axial through bore and a proximate end portion adapted for connection to a suction-generating device for producing suction in the tube to draw material into the tube bore through its distal end, characterized by the distal end portion of the tube having a frontal lobe and the distal end of the tube bore opening at generally the distal end of said frontal lobe, said frontal lobe forming a blunt apertured tip through which material can be drawn into the bore of the tube by suction produced by the suction-generating device.

3. A sampling instrument for collecting cells exfoliated from a uterine cervix, such instrument including an elongated aspirator tube having respective proximate and distal ends, characterized by the distal end portion of the tube including a scraper having a scraping edge engageable with the inner margin of the vaginal ring of the cervix and a frontal lobe insertable through the external os of the cervix for positioning said scraping edge in the area of the transformation zone, and further characterized by the tube having a through bore opening at the periphery of said frontal lobe.

4. The instrument of claim 3 wherein the tube bore opens substantially centrally of the frontal lobe.

5. The instrument of claim 3 wherein the height of the frontal lobe is greater than the transverse thickness of the frontal lobe, and the tip portion of the frontal lobe is substantially symmetrical about a transversely extending plane intersecting the bore axis.

6. The instrument of claim 3 wherein the periphery of the tip portion of the frontal lobe extends generally radially from the bore opening substantial distances in opposite directions for forming a blunt apertured tip.

7. The instrument of claim 3 wherein the periphery of the tip portion of the frontal lobe is arcuate in the area of the bore opening.

8. The instrument of claim 7 wherein the radius of curvature of the arcuate tip portion of the periphery of the frontal lobe in the area of the bore opening is at least as great as the diameter of the bore opening.

9. The instrument of claim 3 or 8 wherein the tip portion of the frontal lobe is substantially semicircular.

10. The instrument of claim 3 wherein the breadth of the frontal lobe is at least twice the diameter of the bore opening.

11. The instrument of claim 3 wherein the scraper includes a lateral lobe projecting transversely of the tube bore a distance sufficient for engagement of said lateral lobe with the vaginal ring of the cervix to limit insertion of the frontal lobe through the external os.

12. The instrument of claim 11 wherein the lateral lobe is located for positioning the frontal lobe bore opening in close proximity to the external os when the lateral lobe is in engagement with the vaginal ring of the cervix.

13. The instrument of claim 11 wherein the scraper is tapered outward in the direction of projection of the lateral lobe such that the scraper decreases in thickness from the tube bore toward the tip of the lateral lobe.

14. The instrument of claim 3 or 13 wherein the maximum transverse thickness of the frontal lobe is no greater than about twice the diameter of the bore opening.

15. The instrument of claim 3 or 13 wherein at least one lateral side of the scraper is substantially planar.

16. The instrument of claim 15 wherein the junction between the scraping edge of the scraper and the substantially planar lateral side of the scraper is rounded.

17. The instrument of claim 16 wherein the radius of curvature of the junction is at least about .01 inch (.25 mm).

18. The instrument of claim 16 wherein the radius of curvature of the junction is between about .01 inch (.25 mm) and about .03 inch (.76 mm).

19. The instrument of claim 15 wherein the scraper has a second longitudinally extending scraping edge located at generally the opposite side of the

scraper from the scraping edge engageable with the inner margin of the vaginal ring of the cervix.

20. The instrument of claim 19 wherein the junctions between the substantially planar lateral side of the scraper and the scraping edges are rounded.

21. The instrument of claim 20 wherein the junction between the substantially planar lateral side of the scraper and the second scraping edge is sharper than the junction between such lateral side and the other scraping edge.

22. The instrument of claim 19 wherein the radius of curvature of the junction between the substantially planar lateral side of the scraper and the second scraping edge is at least about .001 inch (.025 mm).

23. The instrument of claim 15 wherein the scraper is slightly hydrophilic.

24. The instrument of claim 23 wherein at least one side of the scraper is textured.

25. The instrument of claim 3 or 13 wherein opposite sides of the scraper are substantially planar.

26. The instrument of claim 3 wherein the tube is at least substantially rigid.

27. The instrument of claim 3 wherein the proximate end portion of the tube includes a barrel forming a handle.

28. The instrument of claim 27 wherein the handle has grip-promoting ridges.

29. The instrument of claim 27 wherein the barrel includes a cylindrical sample-spreading stem.

30. The instrument of claim 29 wherein the barrel has a circumferential guiding rib adjacent to the stem.

31. The instrument of claim 27 wherein at least a portion of the barrel is of hexagonal cross section.

32. The instrument of claim 3 wherein the diameter of the proximate end portion of the bore of the tube is substantially greater than the diameter of the distal end portion of the bore of the tube.

33. The instrument of claim 32 wherein the tube bore has a turbulence-generating step joining the proximate and distal portions of the tube bore.

34. The instrument of claim 3, including an applicator having an elongated shaft snugly received in the distal portion of the tube bore.

35. The instrument of claim 3 or 34 wherein at least a portion of the distal portion of the tube bore is of a diameter of about 3/32 inch (.24 cm).

36. A medical sampling kit comprising the instrument of claim 1, 2 or 3, and an applicator having an elongated shaft of cross-sectional size enabling said shaft to be inserted snugly into the distal portion of the tube bore for being held firmly in such tube bore portion.

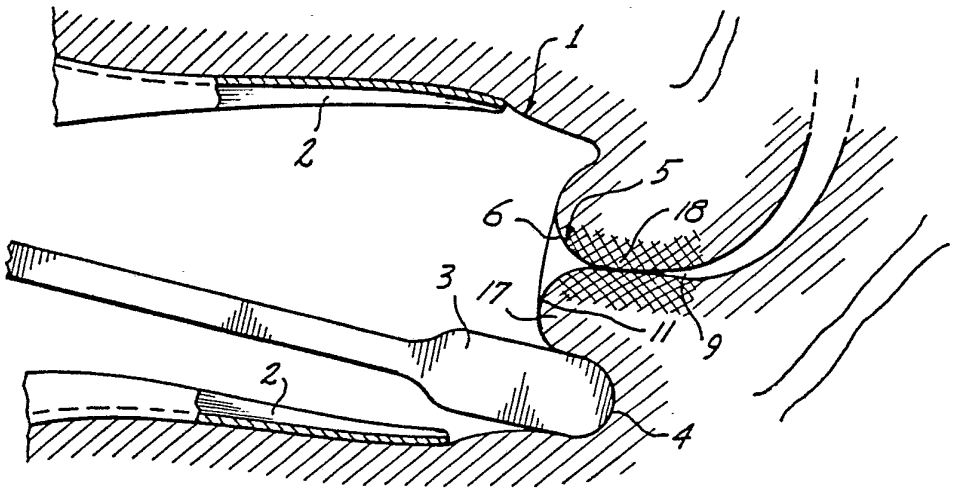


FIG. 1

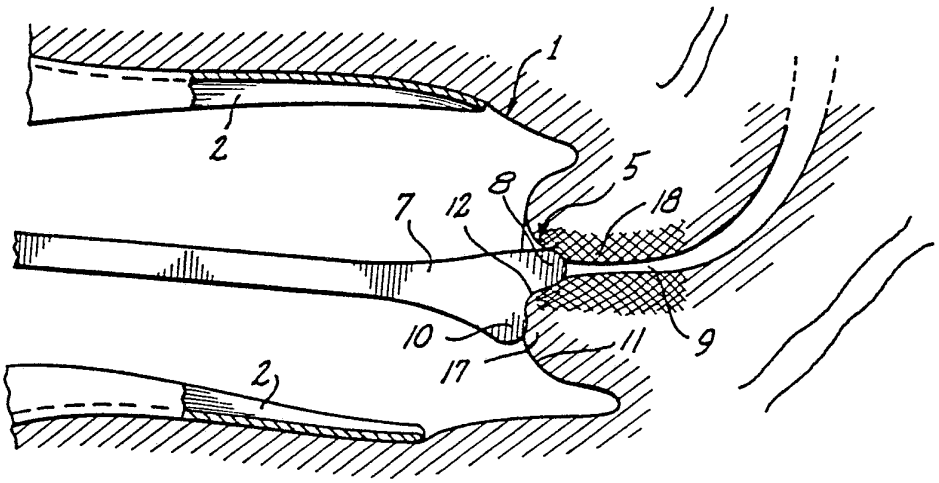


FIG. 2

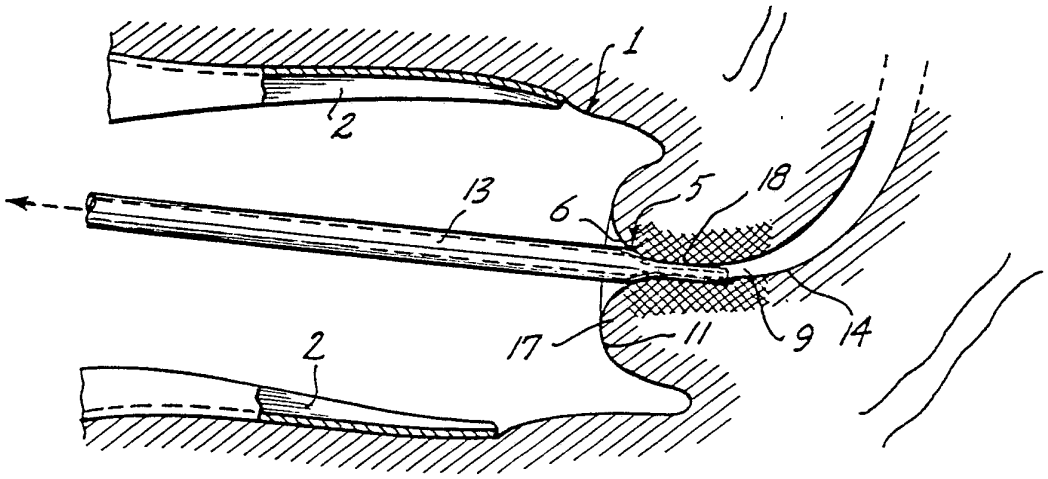


FIG. 3

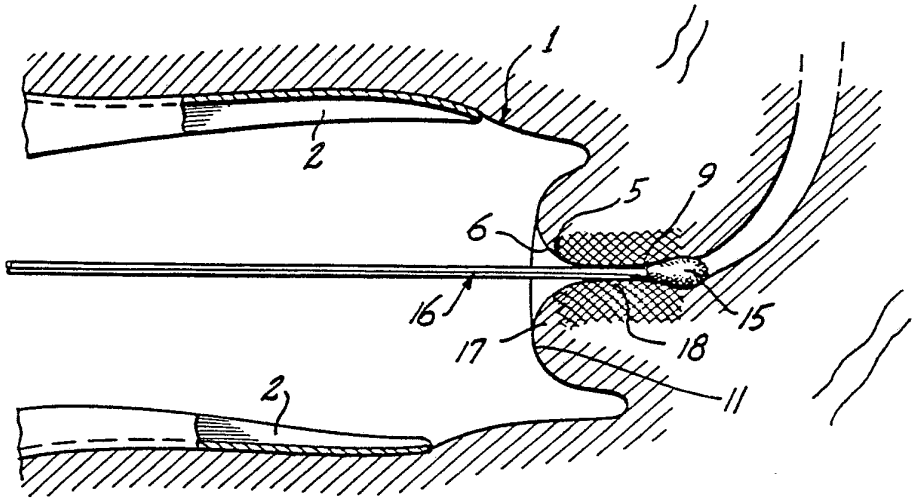
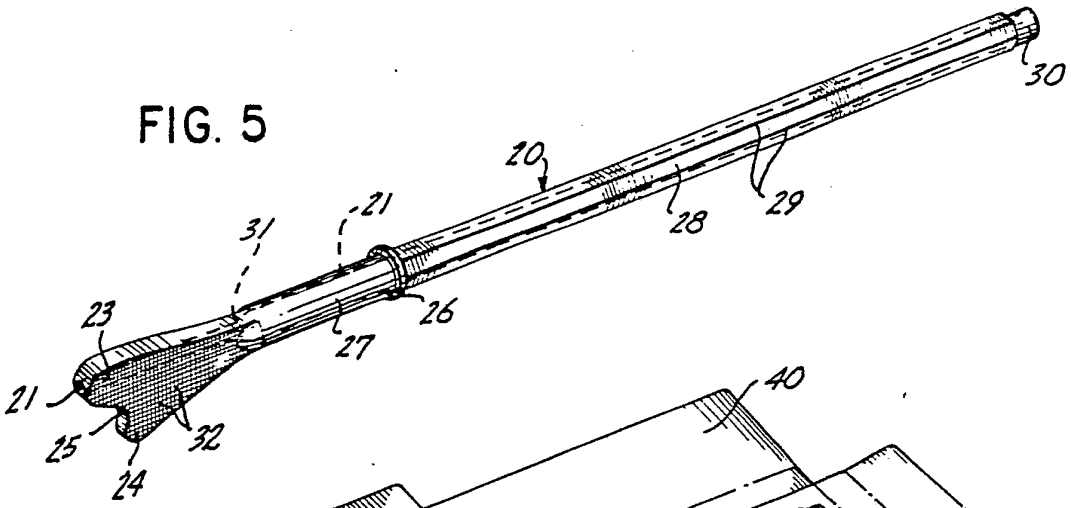


FIG. 4

FIG. 5



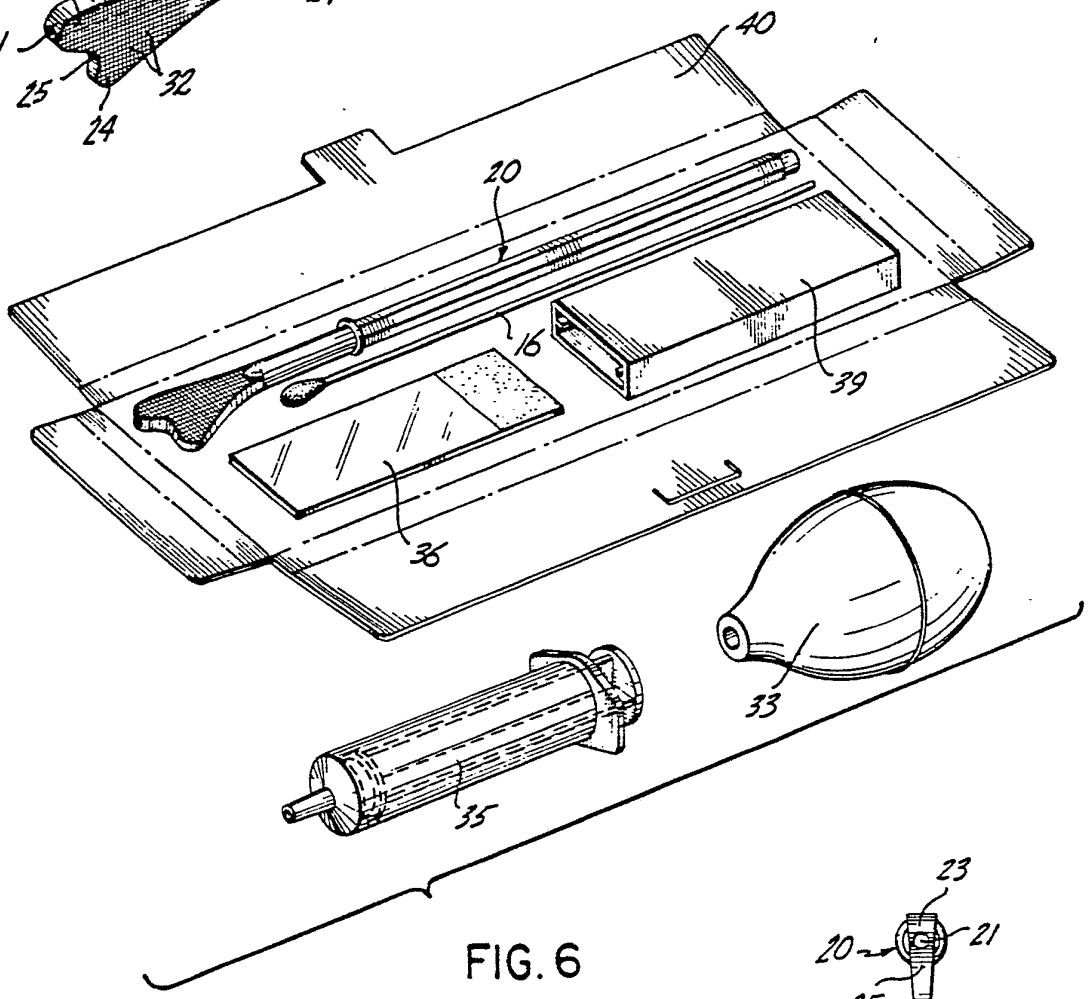


FIG. 6

FIG. 8

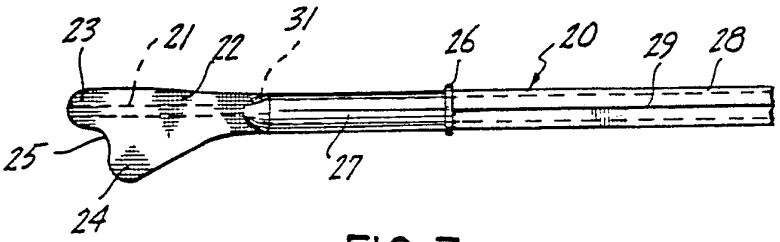


FIG. 7

FIG. 9

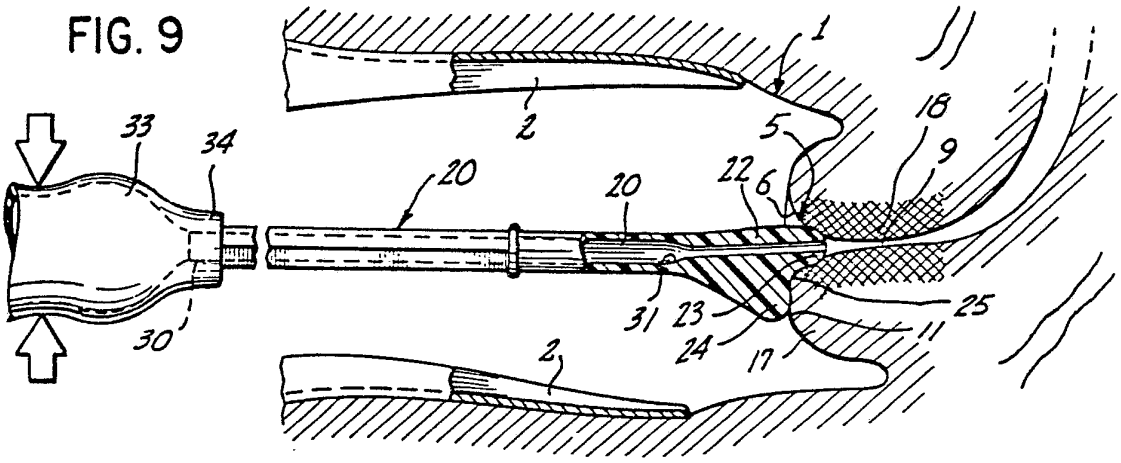


FIG. 10

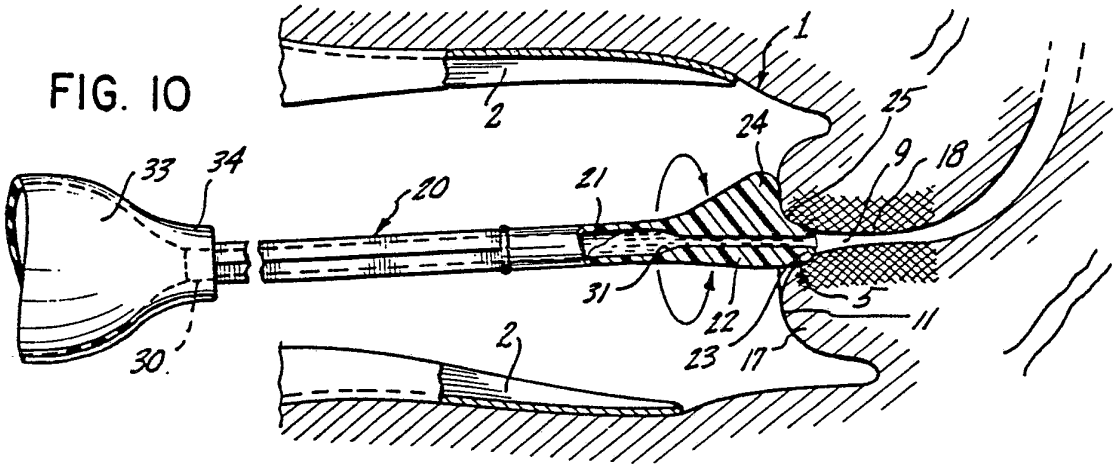


FIG. 11

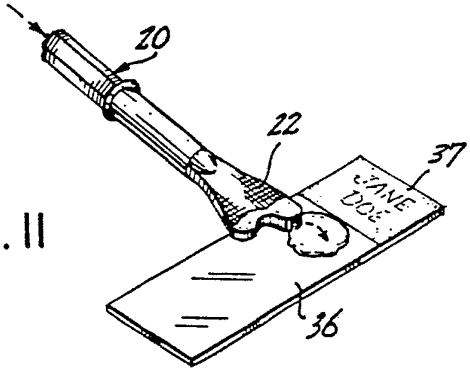


FIG. 12

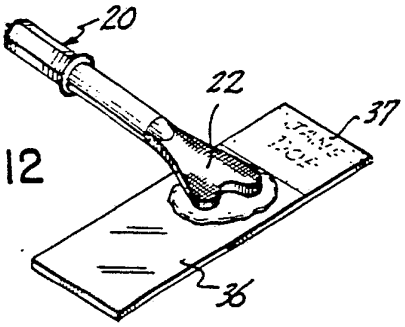


FIG. 13

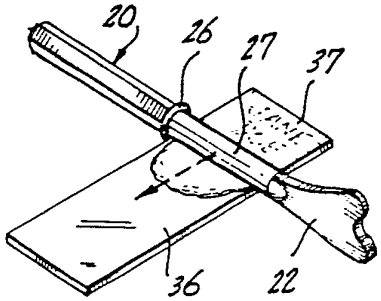
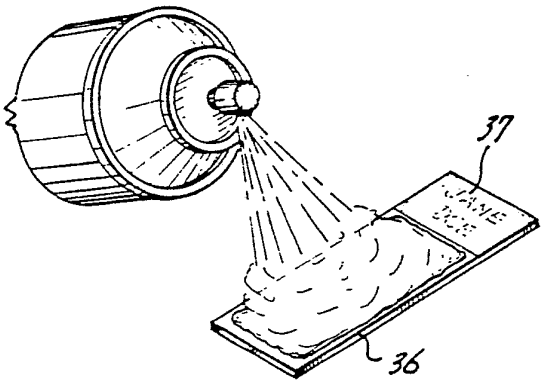


FIG. 14



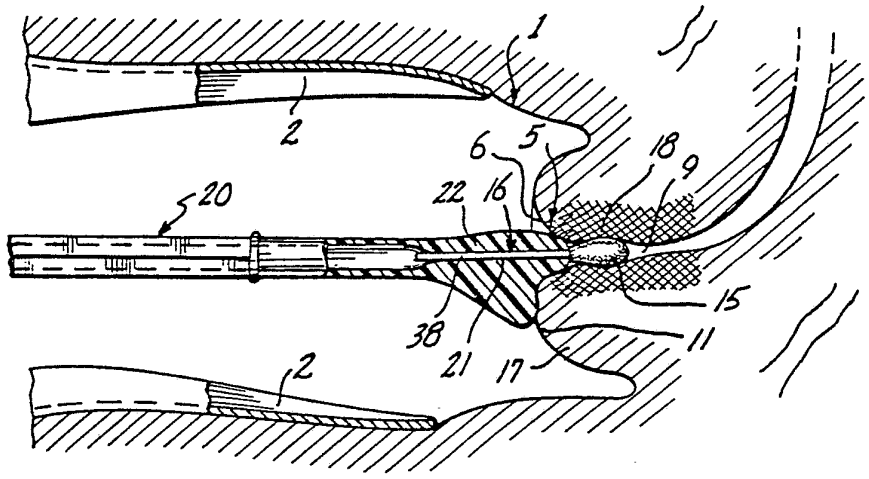


FIG. 15

INTERNATIONAL SEARCH REPORT

International Application No PCT/US81/00475

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[3] A61B 10/00
U.S. Cl. 128/758

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	128/757-759,276,278,304

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X	US,A, 3,088,454, Published 07 May 1963, SHUTE	1-36
X	US,A, 3,796,211, Published 12 March 1974, KOHL	1-12,14-20, 22-29,31-35
X	US,A, 3,485,236, Published 23 December 1969, FROST	1-12,14-20, 22-29,31-36
X	US,A, 3,640,268, Published 08 February 1972, DAVIS	30
X	US,A, 4,078,656, Published 14 March 1978, CRANE et al	36
A	US,E, RE 27,915, Published 05 February 1974, KOHL	1-36
A	US,A, 3,438,366, Published 15 April 1969, KARIHER et al	1-36
A	US,A, 4,016,865, Published 12 April 1977, FREDERICKS	1-36
A	US,A, 3,592,186, Published 13 July 1971, OSTER	1-36
A	US,A, 4,043,322, Published 23 August 1977, ROBINSON	1-36
A	US,A, 2,471,088, Published 24 May 1949, AYRE	1-36
X	N, GYNECOLOGICAL PATHOLOGY, CONF. BY AMER. COLL. OF OB. & GYN. AT SAN FRANCISCO, CALIFORNIA., JUNE 7-9, 1979, PP.1-11&28-45	1-12,14-20, 22-29,31-36

(Cont. On Suppl. Sheet 2)

* Special categories of cited documents: [15]

"A" document defining the general state of the art

"E" earlier document but published on or after the international filing date

"L" document cited for special reason other than those referred to in the other categories

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but on or after the priority date claimed

"T" later document published on or after the international filing date or priority date and not in conflict with the application, but cited to understand the principle or theory underlying the invention

"X" document of particular relevance

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
01 June 1981	10 JUL 1981
International Searching Authority [1]	Signature of Authorized Officer [20]
ISA/US	Kyle L. Howell

Form PCT/ISA/210 (second sheet) (October 1977)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

III		
X	N, SURG., GYN. & OB.,Vol. 87, No. 3,September 1948, P. 18	36
A	N, ACTA CYTOLO. 18(4): 291-296, July-August, 1974	1-36
A	N, OBSTET. & GYNECOL. 49(5): 576-580, May, 1977	1-36
A	N, KOSS, L.G., DIAG. CYTOL. AND ITS HISTORICAL BASIS, LIPPINCOTT, 1979, (76-81)	1-36
A	N, AM.J. CLIN. PATH.,73(2): 202-216, February 1980	1-36
A	N, CANCER,18(11): 1474-1478, November 1965	1-36

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers ....., because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers ....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.