

[54] SPECIMEN-TAKING DEVICE

[76] Inventor: **Kazimierz Zalucki**, 7 Holyoke St.,
Easthampton, Mass. 01027

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[56]

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Primary Examiner—Kyle L. Howell

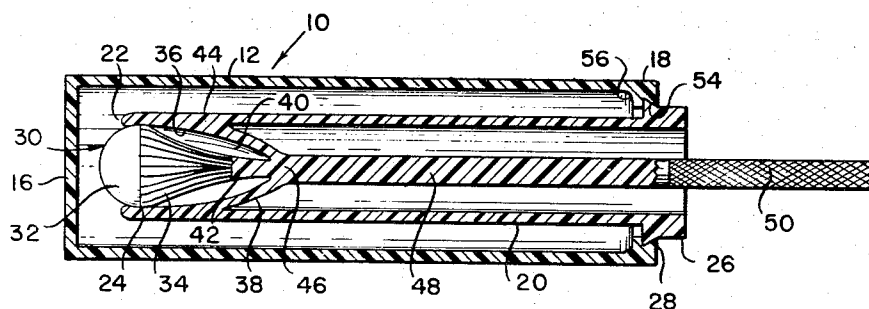
Attorney, Agent, or Firm—Shlesinger, Arkwright, Garvey & Dinsmore

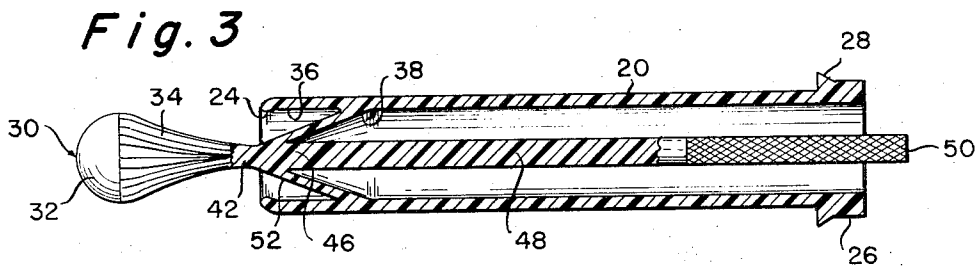
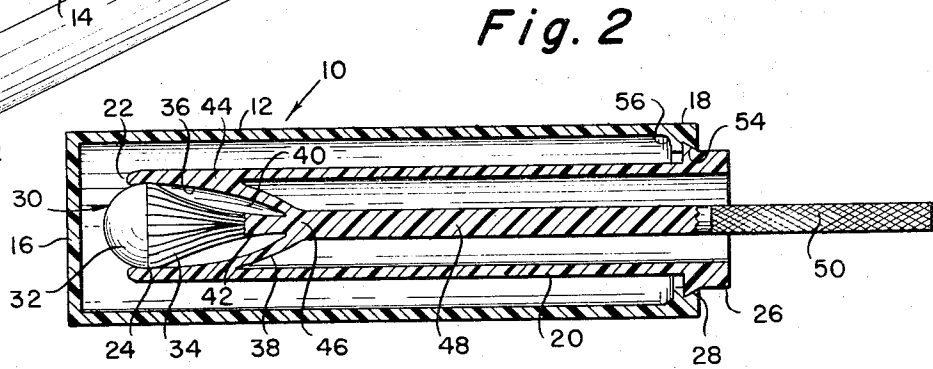
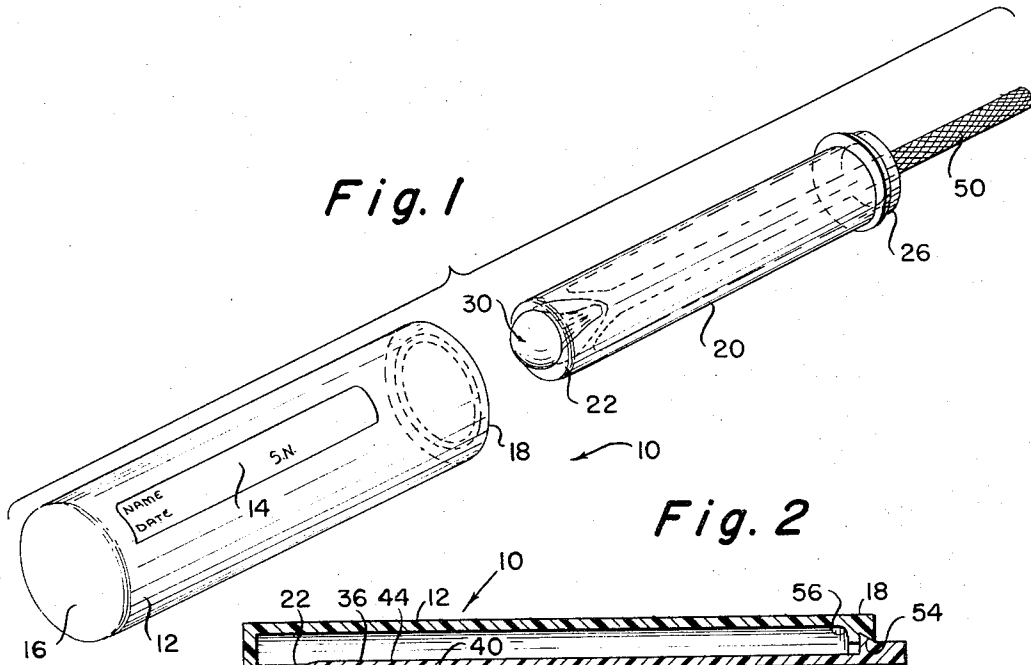
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ABSTRACT

A cylindrical tube has a retractable specimen gathering piece at one end thereof connected to a reciprocable activating member which extends out of the other end of the tube, the tube having a cylindrical cover into which the specimen gathering end thereof is inserted, the cover containing information identifying the person from whom the specimen is taken.

9 Claims, 3 Drawing Figures





SPECIMEN-TAKING DEVICE

BACKGROUND OF INVENTION

This invention relates to specimen gathering devices for obtaining samples from inaccessible parts of body cavities.

It is the usual practice to employ trained medical personnel to obtain specimens and cultures for analysis from body cavities, such as the vagina, rectum, nose, ears, mouth or throat. The care that must be taken to obtain a specimen from the desired area of interest, precluding of contamination of the specimen taken, and minimizing of the chance of injury to delicate cavity areas, has required the use of trained personnel.

Consequently, it has been necessary for individuals to make appointments and to appear at doctors offices or hospitals to have tests made. This requirement entailed loss of time and considerable expense to the individual, contributing toward a negligent and procrastinating attitude regarding many tests that should be taken at regular time intervals.

The present invention seeks to correct this situation while making it possible for the individual to conveniently, safely, and correctly obtain their own specimen or culture which can then be forwarded directly to the laboratory for analysis.

SUMMARY OF INVENTION

Accordingly, this invention contemplates providing a specimen gathering device which can be safely used by untrained individuals to obtain their own specimens which can then be sealed and forwarded to a laboratory for testing and evaluation.

The specimen taking device is designed so that it is self-contained, and can be self-administered. The samples are sealed automatically to prevent contamination, and the device inserted within a container having identification data thereon. The entire assembly can then be mailed to the laboratory.

The specimen taking device permits an individual to safely obtain specimens from remote internal areas of body cavities for laboratory analysis as effectively as though such specimens were taken by medically trained personnel. As a result, more frequent and regular checks of vital body areas are likely to be made by the public in general, contributing significantly to the health and well-being of the public at large.

These and other features and advantages of the invention will become more apparent from the following description and drawings.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the two main parts of the invention.

FIG. 2 is a sectional view of the assembled unit.

FIG. 3 is a partial section of the insertion tube with the probe in extended specimen gathering position.

DESCRIPTION OF THE INVENTION

FIGS. 1 through 3 show the preferred embodiment of the instant invention. FIG. 1 shows the specimen-taking device generally indicated 10, in perspective, with the tubular container or cover 12 removed. The container 12 has an identification label 14, which provides space for the name and the date to be placed thereon, as well as an identification or serial number. It is possible that

such a label could be used to provide complete data, including the return address of the individual submitting the specimen. This would permit the laboratory to remove the label after the tests were completed and to affix it to a return envelope in which the results of the tests on the specimens by the laboratory were to be mailed back to the individual submitting the specimen.

The container 12 is of hollow construction and has an enclosed end 16 and an open end 18 which fits over and around the cylindrical insertion tube assembly 20.

FIG. 2 which is a sectional view of the assembled specimen-taking device shows in more detail the structural configurations of the device. The cylindrical insertion tube 20 has a rounded annular scraping edge 22, and an annular sealing surface 24 on the interior of the insertion tube 20 immediately adjacent to the annular scraping edge 22. The other end of the cylindrical insertion tube 20 has a flanged annular seal construction 26 having an annular negative sloped sealing lip 28.

FIG. 2 shows the assembled specimen-taking device as it would be sold and as it would be shipped after use to the laboratory for testing. The specimen gathering piece generally indicated at 30 is shown in FIG. 2 in the retracted sealed position. It has an outer hemispherical probe section 32 and on the inner probe section is a reduced and tapered sample gathering section containing longitudinally extending ferrules 34 which contact and gather specimens. The smooth inwardly tapering section 36 of the insertion tube immediately behind the annular seal surface 24 is integral with a continuous tapered and conical shaped elastic diaphragm 38 which cooperates to form one of the walls of the annular chamber 40 between them and the ferrule section 34 of the specimen gathering member 30.

The narrow neck section 42 of the specimen gathering member 30 connects the ferrule section 34 of the probe to the central portion of the generally conically shaped diaphragm 38. The intermediate section 46 is an integral part of the central and outer side of the flexible diaphragm 38, as well as constituting the inner end of the operating stem 48 which has a knurled surface 50 to give good gripping action and prevent slipping when the user forces the stem 48 either inwardly or outwardly during the course of obtaining specimen material.

FIG. 3 shows the specimen gathering member in an extended position, with the ferrules 34 exposed for obtaining sample material. It will be noted that the stem 48 has been pressed into the insertion tube 20 so that the forward end section 46 presses against the flexible plastic diaphragm 38 inverting it and permitting movement of the sample gathering member 30 outwardly from the rounded scraping edge 22 of the insertion tube 20 to expose the ferrules 34. The outer portion of the diaphragm 52, as shown in FIG. 3 extends to a point approximately even with the annular sealing surface 24 at the end of insertion tube 20. After the area to be sampled is engaged and the cultures taken, the knurled section 50 is grasped and the stem 48 pulled outwardly at the end adjacent the seal container interlock 26, retracting the specimen gathering member 30 back into the tube and into the position shown in FIG. 2. The specimen is contained within the sample holding chamber 40 in an airtight sealed configuration by the en-

gement of the outer periphery of the hemispherical member 32 with the sealing surface 24 of the cylindrical insertion tube 20.

The container 12 is then placed over the insertion tube assembly 20 and its end seal groove 54 passed 5 over the negative sloping sealing lip 28 of the seal container interlock 26, with its shoulder 56 in tight sealing engagement therewith.

The reassembled unit is then ready to be mailed to the laboratory for testing of the sample contained and 10 sealed within the sample holding chamber 40.

OPERATION

The invention is designed for use in gathering cells from the vaginal and cervical areas for cytologic evaluation, and is used for diagnosing in a manner similar to the commonly used Papanicolaou Smear test.

However, the invention can be used to gather samples from other remote portions of body cavities, such as the nose, ear and rectum. In each of these cases special adaptive configuration and sizes are assumed, but 20 the basic principles are the same.

The preferred embodiment for construction of the spherical probe 30 is that of a low durometer reading rubber to permit insertion with the least discomfort. 25 However, it is also contemplated that for mass production techniques, it would be desirable to use a suitably moldable type of soft resilient plastic for the construction of these devices.

It should be noted that the outer end annular surface 30 22 of the insertion tube 20 has rounded edges to facilitate penetration and preclude any injury to internal organs. The ferrules 34 will give a scraping action with a slight rotary motion, so as to induce cells and specimen to accumulate thereon and possibly move back along the tapered surface to the narrow neck portion 42, 35 prior to retraction of the specimen gathering member 30 to its initial position within the tube.

The configuration of the diaphragm 38 is preferred, but it is understood that there may be some variation 40 in this configuration to permit the hinging and moving action desired when the stem 48 is reciprocated.

The device, being designed for self-use in gathering specimen samples permits the cover container 12 to be readily removed by pulling it free from the insertion tube 20. The insertion tube 20 has a smooth exterior 45 surface, and for use, surgical jelly is preferably applied thereto to provide lubrication when the insertion tube 20 is forced into the cavity and subsequently rotated.

The stem 48 is pressed inwardly adjacent the end 26 50 of the insertion tube 20 to force the specimen gathering member 30 outward into position for gathering desired samples. At this point, the entire insertion tube can be twisted or rotated to assist the ferrules 34 in their scraping and gathering action. After this twisting action, the knurled portion 50 of the stem 48 is grabbed and pulled 55 to retract the specimen gathering member 30 into the sealed closed position shown in FIG. 2. The container 12 is passed over the end of the insertion tube and pressed down into sealing engagement with the sealing flange section 26 of the insertion tube as shown in FIG. 2 and described above. The label 14 is then filled out 60 and the entire assembly mailed to the laboratory for test and evaluation.

With regard to the identification system, it is also possible to provide a coded identification number for

purposes of identification, so that the name of the person submitting the sample would remain anonymous. In this instance the identification number would be permanently imprinted or stencilled on the container tube.

It can readily be seen that the subject invention makes possible the use of a self-administered device which is of simple and cheap manufacture, permits the taking of samples in the privacy of one's home, and eliminates the need for trained medical personnel to take an accurate sample which can be sealed.

The parts themselves could be produced for substantially less than a dollar, and the parts could be sterilized and sealed to preclude infection.

While this invention has been described, it will be understood that it is capable of further modification, and this application is intended to cover any variations, uses and/or adaptations of the invention following in general, the principle of the invention and including such 20 departures from the present disclosure as come within known or customary practice in the art to which the invention pertains, and as may be applied to the essential features hereinbefore set forth, as fall within the scope of the invention or the limits of the appended claims.

What is claimed is:

1. A device for obtaining specimens from internal areas of body cavities, comprising:

- a. an elongated tubular support member,
- b. a specimen gathering member disposed adjacent the forward end of the elongated tubular member and configured and disposed so that it can be retracted into the forward end of the tubular support member;
- c. hinge means connected to the rear of the specimen gathering member and to the inside of the tubular support member for permitting movement of the sampling member into and out of the forward end of the tubular support member,
- d. an activating rod connected to the specimen gathering member at its rearward end and extending through said tubular support member and out of the rear end of the tubular support member,
- e. sealing means defined by the forward end of the tube and a portion of the sampling means for sealing the specimen taken by the specimen-gathering member.

2. The device for obtaining specimens from internal 50 areas of body cavities as set forth in claim 1, wherein:

- a. a removable cylindrical cover member is disposed over the elongated tubular support member covering the forward end thereof and being in sealing engagement with the elongated tubular support member,
- b. label and identification means is contained on the outer surface of the cover member.

3. The device for obtaining specimens from internal areas of body cavities as set forth in claim 2, wherein:

- a. the label and identification means includes an area for a return address which is removable from the cover member.

4. The device for obtaining specimens from internal areas of body cavities as set forth in claim 1, wherein:

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- a. the seal means includes an annular sealing surface adjacent the forward end of the insertion tube which engages the periphery of the specimen gathering member.
- 5. The device for obtaining specimens from internal areas of body cavities as set forth in claim 1, wherein:
 - a. the specimen gathering member includes a forward hemispherical section, and a rearwardly tapering section which has specimen collecting means thereon.
- 6. The device for obtaining specimens from internal areas of body cavities as set forth in claim 5, wherein:
 - a. the specimen collecting means includes a plurality of longitudinally extending ridges.
- 7. The device for obtaining specimens from internal areas of body cavities as set forth in claim 1, wherein:
 - a. the seal means includes an annular sealing surface adjacent the forward end of the insertion tube which engages the periphery of the specimen gathering member.

- ering member,
- b. the specimen gathering member includes a forward hemispherical portion which engages the annular sealing surface of the insertion tube, and
- c. the specimen gathering member also includes a specimen gathering section at the rear of the hemispherical portion, and immediately adjacent the hinge means, on which specimen collecting means is disposed.
- 8. The device for obtaining specimens from internal areas of body cavities as set forth in claim 1, wherein:
 - a. the hinge means is a flexible member and is integrally connected to the juncture of the specimen gathering member and the activating rod.
- 9. The device for obtaining specimens from internal areas of body cavities as set forth in claim 1, wherein:
 - a. the elongated tubular support member, the specimen gathering member, the hinge member, and the activating rod are all one continuous unitary molded plastic piece.

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