United States Patent

[11] 3,633,565

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[54] **CLINICAL SPECIMEN-COLLECTING AUSTRUMENT**
5 Claims, 6 Drawing Figs.

[52] **U.S. Cl.** ..... **128/2 R,** 128/221, 128/253, 128/304, 145/116
[51] **Int. Cl.** **A61b 10/00,** A61b 17/22, B27c 05/00
[50] **Field of Search** ..... 128/2, 2 B, 253, 302, 303, 304, 305; 145/117, 116, 123, 126; 77/67, 70

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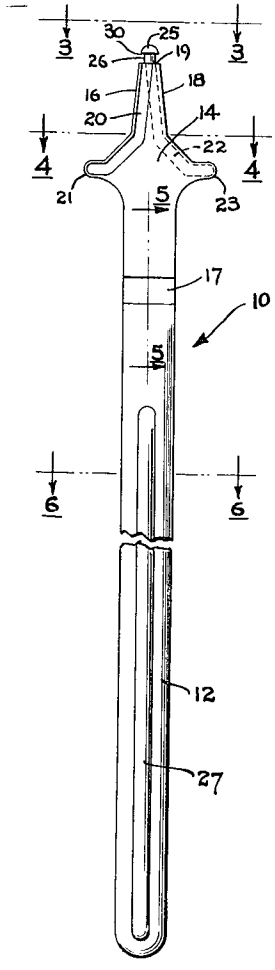
ABSTRACT: An elongate clinical instrument comprises a blade and handle for collecting cells and tissues from body cavities, particularly for the detection of squamous carcinoma of the cervix. Two slanted spaced-apart edges on the blade tip describe a conical path during manual rotation in situ and gather specimens in troughs adjoining the edges. The blade tip is manually separable from the handle for forwarding to a pathology laboratory.



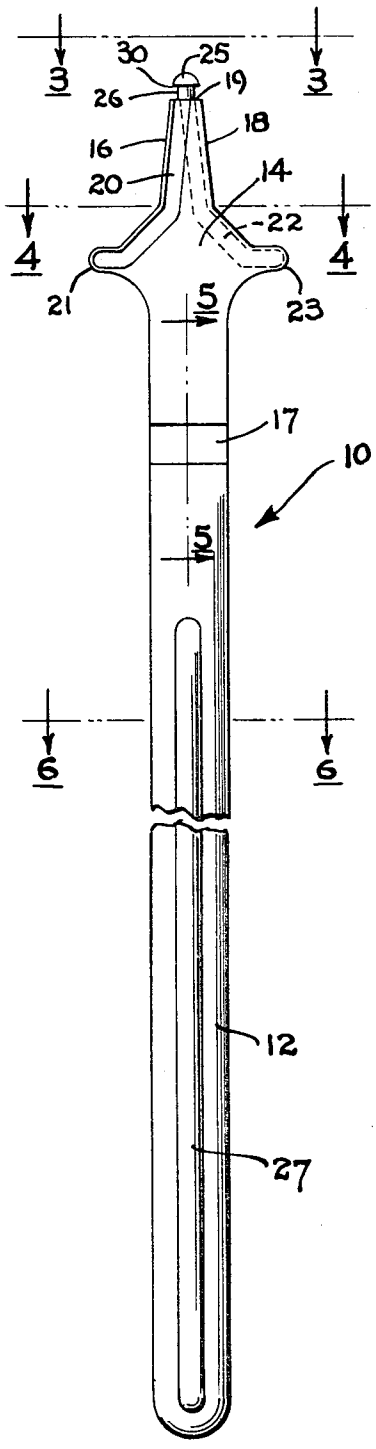


FIG. 1

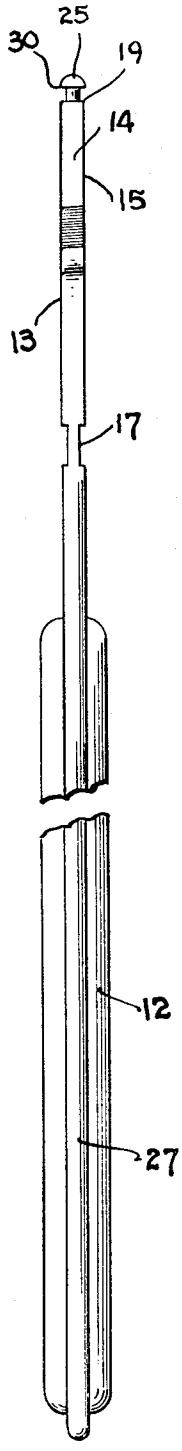


FIG. 2

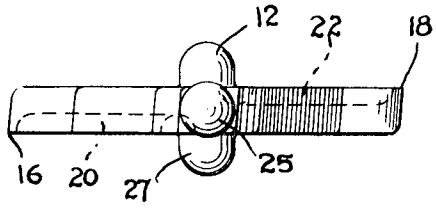


FIG. 3

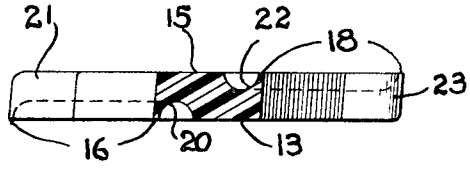


FIG. 4

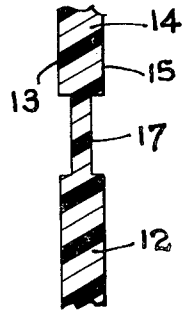


FIG. 5

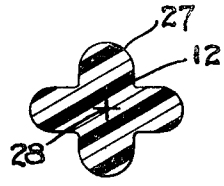


FIG. 6

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CLINICAL SPECIMEN-COLLECTING INSTRUMENT

BACKGROUND OF THE INVENTION

Devices commonly used for collection of samples as required for detection of interuterine cancer or the like typically include simple swabs, small wood sticks, brushes, or else relatively elaborate and costly aspirators. Since the cancer cells are fragile and break or fall away easily from any surface supporting them, and since surrounding tissues usually obscure the test area, it is often difficult to know whether such cells which might have been initially resting on a swab or stick were jarred or rubbed off and lost in the attempt to remove the same from the test situs.

The problems associated with specimen collecting in the foregoing context are notably difficult in the case of squamous carcinoma which most commonly originates at the squamo columnar junction. An accurate determination of cancer requires a complete survey of the entire test area, which would involve multiple biopsies, and even these would represent localized portions rather than a comprehensive sampling of the total area. Ideally, fragments of tissue must be recovered representing the total test situs to permit preparation of histological slides which retain tissue architecture as opposed to cytology slides which present a collection of isolated cells. Surfaces which merely contact a tissue of a swab or stick collect only loose particles and not tissue fragments. Moreover, many doctors lack the time and patience to transfer every collected cell and particle from a stick onto a microscopic slide, whereby valuable diagnostic material may be lost, resulting in a risk or erroneous conclusion in respect of the patient's condition.

Due to the foregoing limitations, many Pap Smears cannot be accurately diagnosed or else render only an ambiguous result. Where this is the case, a surgical procedure called "cold conization" is typically resorted to. However, this is a relatively major operation requiring hospitalization and general anesthesia. The invention device disclosed herein is designated to bridge this diagnostic gap between the office "Pap Smear" and the hospital "cold cone" thereby preserving many women from the risk of nondetection on one hand or the discomfort, danger, and expense inherent in a major operation.

SUMMARY OF THE INVENTION

The invention in this case consists of an elongate tool or implement **10** for clinical or office use by physicians, and comprising a handle portion **12** and a blade portion **14**. Blade portion **14** is essentially flat or planar and has a pair of oppositely facing and spaced-apart edges **16** and **18** adapted to scrape the entire circumference of the squamo columnar junction area with a deep-ploughing action. A storing groove or trough **20** and **22** adjoins each of the edges **16** and **18**, respectively, and receives the samplings progressively obtained by the stated edges during rotation of the instrument. Rotation is accomplished by force manually applied to handle portion **12**. Following removal of implement **10** from the cervical canal, force is manually applied to portions **12** and **14** as required to break the implement at the location of thinned neck portion **17** therebetween, after which blade **14** with the collected matter in grooves **20** and **22** may be dropped into a biopsy bottle and sent to a laboratory for pathological analysis.

BRIEF DESCRIPTION OF THE DRAWING

FIG. **1** shows a partly fragmented elevational view of the structure disclosed herein,

FIG. **2** shows a view corresponding with FIG. **1** but with the structure rotated 90° relative thereto,

FIG. **3** shows a tip view looking downward onto the structure shown in FIGS. **1** and **2**,

FIG. **4** shows a cross-sectional view taken along line **4—4** of FIG. **1**,

FIG. **5** shows a cross-sectional view taken along line **5—5** of FIG. **1**, and

FIG. **6** shows a cross-sectional view taken along line **6—6** of FIG. **1**.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. **1**, implement **10** may be seen to comprise handle portion **12** and flat blade portion **14** integrally formed therewith of substantially rigid material such as plastic. Blade portion **14** has oppositely facing substantially parallel surfaces **13** and **15** seen particularly from FIG. **2**, and a structurally weakened neck portion **17** defined by a transverse groove across both surfaces **13** and **15** resulting in a reduced cross-sectional thickness as shown more clearly in FIG. **5**.

Blade portion **14** is an elongate cutter shaped along the sides thereof to correspond generally with the natural contours of the cervix of a human uterus as required for maximum effectiveness in performing its intended function. Thus, the opposite side contours defined by thin lips or cutting edges **16** and **18** may be seen to diverge from relatively close proximity therebetween near distal end **19** to a maximum width at oppositely directed projections **21** and **23**. The edges **16** and **18** thus describe a conical path when implement **10** is rotated by manual force applied to handle **12**. If only one edge were made to function as a specimen collector, the lateral forces on such blade would be unbalanced during rotation of implement **10** and its longitudinal axis in the manner described below, whereby two oppositely directed edges are preferred in the symmetrical relationship suggested by edges **16** and **18**. A separate recessed groove adjoins each of the edges **16** and **18** as suggested by grooves **20** **22**, respectively, and extends coterminally therewith so as to describe the same conical path as edges **16** and **18** during rotation of implement **10** as discussed above. The number of edges **16**, **18** of adjoining grooves **20**, **22** could be more than two in number, but as a practical matter only two of each, as suggested by the structure shown in the accompanying drawing, have been found to provide all the advantages sought in this case. Also, while the angularity of the edges **16**, **18** and adjoining grooves **20**, **22** could be varied slightly, the preferred arrangement is for the included angle to be from about 10° to 30° between the edges in that portion between distal end **19** and line **4—4** in FIG. **1**, for example, increasing to about 45° to 60° included angle in the flared portion from line **4—4** to oppositely extending projections **21** and **23**. Of particular importance is the fact that edges **16**, **18** are directed in opposite directions as seen in FIGS. **3** and **4**.

Distal end **19** of implement **10** has a bulbous or mushroom-shaped protuberance extending therefrom and comprising button or dome **25** connected to end **19** by recessed shaft **26** of lesser diameter than portion **25**. Dome **25** has a peripheral scraping edge **30** thereon. Handle portion **12** may be cylindrical, but in the preferred embodiment has a plurality of longitudinal strengthening ribs **27** symmetrically arranged about the center axis **28** of the handle as seen particularly from FIG. **6**.

In operation, implement **10** is initially introduced onto the cervical canal with distal end **19** projecting therewithin and with oppositely directed projections **21** and **23** bearing against the outer surfaces of the squamo columnar junction. While thus positioned, implement **10** is rotated 360° about axis **28**, although such rotation could obviously be more than one complete turn. During the foregoing movement, edges **16** and **18** bear uniformly throughout their length with the surfaces which they contact and which have substantially the same contours as the path defined by the edges during the stated rotation. The relationship between edges **16**, **18** and grooves **20**, **22** as discussed above results in a plowing and scraping action whereby edges **16**, **18** detach cells, surface tissue and other diagnostic material from the test situs, such material being channeled into the mentioned grooves as it is progressively accumulated. During withdrawal of implement **10**, additional cells or the like are captured by the mild scraping action of the peripheral edge **30** of protuberance **25** and retained about recessed shaft portion **26** on distal end **19** of the imple-

ment. Thereafter, force is applied through portions **12** and **14** as required to fracture completely through groove **17** and separate the two stated portions. Blade portion **14**, with the collected matter in grooves **20**, **22** is then dropped into a biopsy bottle which is sealed and sent to a laboratory for pathological analysis.

From the foregoing, it may be seen that the structure and method in this case provide a rapid and effective means for collecting diagnostic matter and with a minimum of specialized skill. The plowing and scraping action of blade edges **16**, **18** assures complete collection of matter throughout the entire test area whereby a comprehensive sampling is achieved, and further assures that such matter will include surface tissue structure rather than loose cells only. The area thus sampled is wider and of greater yield potential than could be accomplished by multiple biopsies. The tissue sheared from the test surface is shallow, so that pain or postoperative bleeding are not encountered in using implement **10**. Moreover, the procedure can be carried out simply during the course of a pelvic examination in a medical office and requires no elaborate medical or hospital surgery equipment.

I claim:

1. An elongate substantially rigid implement for collecting diagnostic material in situs from body cavities, comprising:

handle means at one end of said implement for manually rotating said implement about a rotational axis through the longitudinal center of said elongate implement,

projection means extending radially from said handle means adjacent to and axially spaced from the distal end of said handle means,

blade means secured to said handle means,

said blade means including at least two spaced-apart slanted cutting edges, relative to said rotational axis, and which extend from said distal end of said implement and include the upper portions of said projection means and which describe a conical path during rotation of said implement, the lower portions of said projection means constituting a noncutting portion,

each of said blade means further including a recessed groove adjoining said cutting edge and extending along the length thereof for receiving said diagnostic material collected by said edge from said situs.

2. The structure set forth in claim **1** above, further including:

a structurally weakened neck portion between said handle means and said blade means for breaking the same apart by application of manual force thereto.

3. The structure set forth in claim **1** above, wherein:

said elongate implement further includes at said distal end a domelike protuberance having means to scrape over said situs when said implement is removed therefrom.

4. The structure set forth in claim **2** above wherein said elongate implement further includes a domelike protuberance and a reduced cylindrical portion fixed to said distal end, said protuberance having a peripheral edge thereon for scraping over said situs when said implement is removed therefrom.

5. The structure set forth in claim **2** above wherein said blade means comprises at least two oppositely facing substantially parallel surfaces.

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