

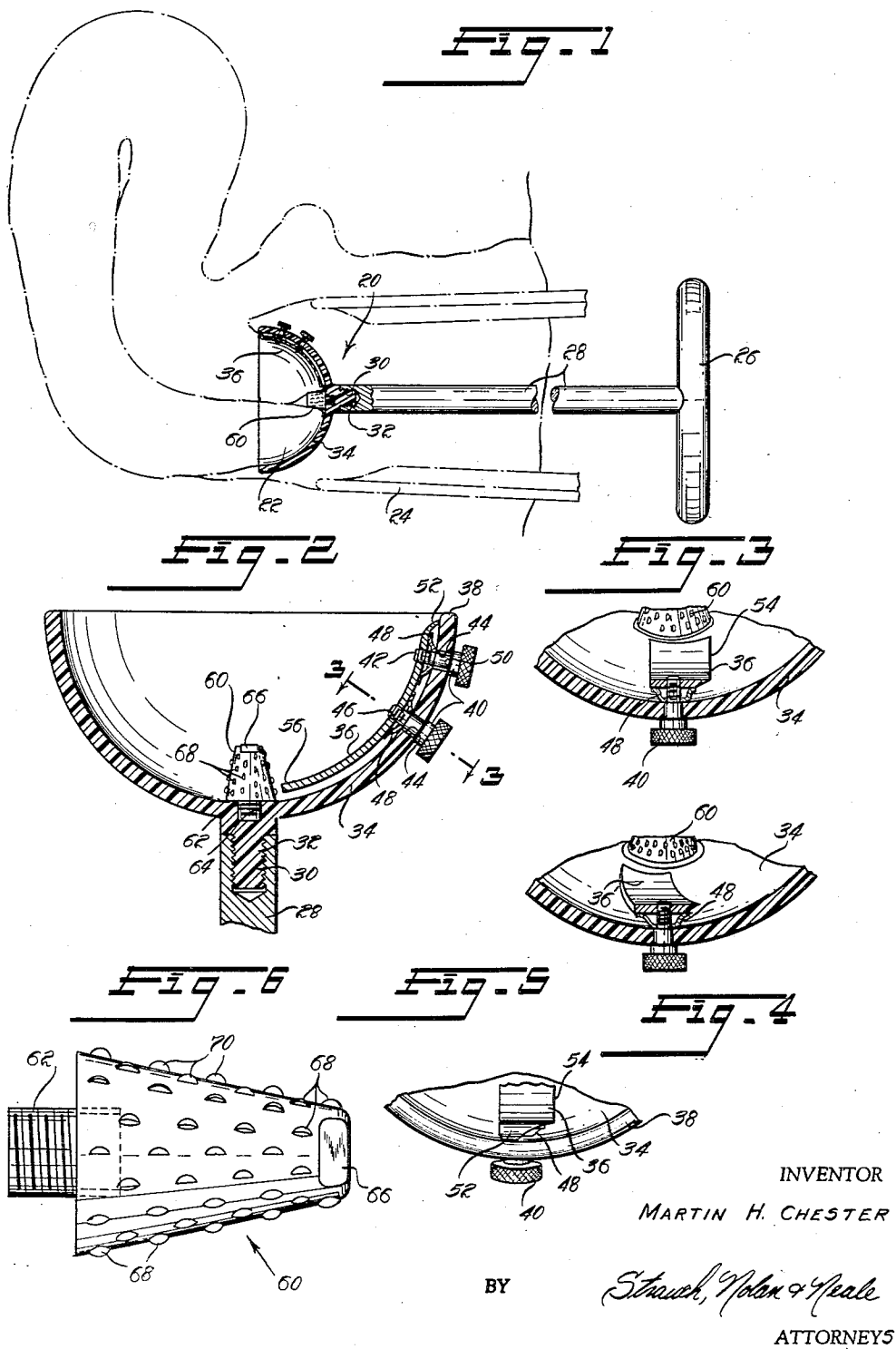
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CERVICOTOME

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CERVICOTOME

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This invention relates to a device for obtaining tissue from an organism and more particularly is primarily related to a surgical device incorporating cutting means for obtaining a tissue biopsy from substantially the entire circular surface of the uterine cervix. The device is termed a cervicotome and is used specifically for diagnosis of cancer of cervix.

Various techniques and instruments for obtaining tissue cells and scrapings from the cervix are known in the prior art and many instruments are presently commercially available. Such instruments are in the form of curettes, scrapers or punches. Several curette devices have been proposed for obtaining biopsy tissues but these devices attempt to confine the tissue to the squamo-columnar junction of the cervix proximate the entrance or os of the cervical canal. One type of prior art curette consists of two conical cups having their large ends open and opposed. One cone is inserted, small end first, into the cervical canal and the other cone then axially shifted into engagement with the inserted cone, thereby securing scrapings of tissue from the squamo-columnar junction, in essence, a scraping technique. A second type of curette is a spiral wedge shape blunt nose blade that is inserted into the cervical canal and rotated, also essentially a scraping instrument. Others of the devices known to prior art are pure scraping instruments, as exempted by Patents Nos. 2,471,088 and 2,514,665, and are used to obtain cell or tissue scraping from and adjacent the squamo-columnar junction.

In all of the aforementioned instruments, the basic process is one of scraping although the opposed cone curette may secure a tissue cone. A further prior art type of device is a cervical punch biopsy instrument so constructed to permit the operator to take and remove "bites" of cervical tissue for biopsy studies. This instrument is operated in a manner similar to a hand punch but uses a "snake-jaw" head, resulting in bites, rather than true punches, of tissue. A disadvantage of this device is that it lacks positive control over the depth of the bite permitting the strong possibility of causing considerable bleeding and trauma to the cervix. The "bite" area is relatively small, making it necessary to take multiple specimens in quadrants around the cervical os, and even then a complete coverage of the epithelial surface of a large or lacerated cervix cannot be properly obtained.

The cervicotome of this invention is materially distinct from any known prior art cervical biopsy device in that it is primarily a bladed instrument capable of obtaining controlled microscopic slices of the epithelial layer, with a fraction of a millimeter of subepithelial layer, from substantially the entire circular surface of the cervix with minimum resultant trauma. The instrument is basically a hemispherical cup attached at its base to an elongate handle. The cup includes an internal curved knife disposed between its edge and a location proximate the base. The cup and knife are placed over the cervix and rotated to remove a microscopically thin surface layer from

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substantially the entire cervical surface. The blades are adjustable for varying the depth of cut and the cups and blades are furnished in several sizes to fit different size cervixes. At the same time, at the discretion of the operator, a small coaxial attachment with multiple serrated cutting edges is provided and may be utilized on the inside of the cup to partly penetrate the os and obtain cervical canal tissue.

When prior art instruments are employed and tissue scrapings of the epithelial cells from the squamo-columnar junction are obtained, the scrapings are usually stained by the Papanicolaou method and a cytologic diagnosis obtained. The present invention is utilized in obtaining tissue structure suitable for a histologic diagnosis.

As compared with a histologic diagnosis, the cytologic diagnosis of carcinoma is much more difficult and is subject to a greater percentage of false positive diagnoses. Tests have shown that a significant percentage of healthy females, subjected to a cytological examination, show abnormal or atypical cells due solely to the response of such cells to irritants, and not to carcinoma. The cytologic technique does not permit an evaluation of the presence of invasion. Nor does it, in the absence of invasion (carcinoma-in-situ) permit interpretation of the orderliness of maturation of the epithelium; an important factor in differentiating an atypical hyperplasia from carcinoma.

Authorities in the fields of gynecology and cancer are of the firm opinion that cervical smears and cervical scrapings cannot replace the adequate cervical biopsy. The final "court," so to speak, for cytologic cancer diagnosis is confirmation by histologic diagnosis.

Prior to this invention, the technique of obtaining an adequate circular cervical biopsy was rather complex and time consuming, and little control was had over the depth of cut, often resulting in severe trauma. This invention enables an accurate and adequate microscopic circular cervical biopsy to be obtained very rapidly yet safely under usual office examination conditions. A substantially complete, or desired area, cervix surface biopsy is obtained and the depth of cut is controlled. This technique will be of great value in diagnosis of carcinoma-in-situ or pre-invasive intra epithelial circumscribed form of cervical cancer. Under present techniques it is almost impossible to detect the invasiveness of a cancer of the cervix by cytologic studies.

Because there are many cases of carcinoma of the cervix arising from the intra-epithelial area of the cervix to subsequently become invasive into the cervical canal, the additional concentric attachment with multiple serrated cutting edges is of great value in obtaining cell and tissue specimens more adequate than scrapings from the cervical canal. This type of cancer can be easily missed by the biopsy punch or by the cytologic techniques used with smears and scrapings. The serrated extension of one form of the invention will collect bits of tissue from the cervical canal which can be brushed off on a slide for cytological diagnosis or they could be placed in a fixative and centrifuged into a "button," which can be sectioned and studied as a tissue biopsy. It is conceivable that exfoliated cells from carcinoma of the uterine fundus could be picked up by this attachment thereby increasing its value as a diagnostic instrument.

Accordingly a primary object of this invention resides in providing a novel device for obtaining tissue from the cervix.

Another object resides in the provision of a novel cutting device for obtaining a tissue biopsy from the cervix, with high degree of control as to the specimen obtained, and minimum trauma.

Still another object resides in the provision of a novel

cervical instrument incorporating means for simultaneously obtaining a substantially complete circular biopsy from the cervical surface and a complete sampling of the tissue at the entrance of the cervical canal. It is a related object to provide in a novel efficient instrument a novel arrangement including a cup with an internal curved blade and a centrally disposed multiple edge cutter.

A further object resides in providing a cup-shaped bladed instrument, adapted to confine the cervix, and remove a circular cervical biopsy, having a handle attachment providing proper access to the cervix, the cup and blade being removable from the handle for replacement with various sized cups and blades.

A still further object resides in the provision of a removable and adjustable blade held within the cervix confining cup.

Another object resides in providing blades of single and double curvature within the cervix confining cup.

An additional object resides in the provision, in a cup-shaped cervical biopsy instrument, of a removable coaxial plug having multiple cutting edges for obtaining bits of tissue from the cervical canal.

Further novel features and objects of this invention will become apparent from the following detailed description and the appended claims taken in conjunction with the accompanying drawings showing a preferred embodiment thereof, in which:

Figure 1 illustrates in phantom lines a section view looking at the side of a uterus with the cervicotomy of this invention shown in partial section and disposed with its cup in confining relation over the cervix;

Figure 2 is an enlarged view of the cutting cup and the coaxial serrated attachment according to a preferred form of the present invention;

Figure 3 is a section view taken on line 3—3 of Figure 2 illustrating a single curvature blade in cross section;

Figure 4 is a section view similar to Figure 3 illustrating a modified double curvature blade;

Figure 5 is an enlarged detail view of the cup edge illustrating the outer end of the blade; and

Figure 6 is a greatly enlarged side view of the coaxial cutting plug used in one combination form of the present invention illustrating a preferred type of multiple cutting blades.

With reference now to the drawing, Figure 1 illustrates the surgical instrument 20, a cervicotomy, positioned through the vaginal tract and over the cervix 22 which has been exposed to visual examination by a vaginal or bivalve speculum 24.

The cervicotomy 20 has a handle 26 with an integral shaft 28 long enough to reach an exposed cervix with the handle proper remaining exterior. The shaft end has a blind coaxial bore 30 tapped to receive a threaded projection 32 integrally provided on the central exterior bottom of a cervix cup 34. Cup 34 is preferably hemispherical and is also preferably made of clear plastic such as Lucite to permit visual monitoring of the cervical surface prior to and during removal of tissue. If desired the cup may be of other suitable materials such as stainless steel, although the Lucite or clear plastic cups can be inexpensively molded and hence can be disposable after use.

With reference now to Figures 2, 3 and 5, a thin curved razor edge blade 36 is maintained within the cup 34 and extends from adjacent the cup rim 38 to a position terminating short of what would be the geometric pole of the hemispherical cup. The bowed curvature of blade 36 is permanent except for inherent blade resilience. Such curvature can be essentially meridional as illustrated in Figure 3, or it can be formed with a double curvature to provide a substantially spiral form, as illustrated by blade 36' in Figure 4, which will provide a slic-

ing cut rather than a pressing cut, when the instrument 20 is rotated.

The blade 36 is removably and adjustably fastened in a spaced relation adjacent the inner surface of cup 34 by thumb screws 40 which have threaded shanks 42, projecting through apertures 44 in the cup wall, threaded into tapped holes 46 in the blade 36. The length of threaded shanks 42 projecting past the blade 36 should be kept to a minimum and should be smoothly finished to prevent unnecessary localized contact against the cervix while the cervicotomy is rotated. Thin spring washers 48, disposed between the inner surface of cup 34 and the blade 36, bias the blade to a spaced position away from the inner surface of the cup. The spring biased blade maintains thumb screw shoulders 50, formed adjacent the thumb screw heads, against the exterior surface of the cup 34. Thus, manipulation of thumb screws 40 will cause the blade 36 to move toward or away from the inner surface of cup 34, and removal of thumb screws 40 from threaded engagement with the blade 36 will permit removal of the blade and spring washers for sterilization or replacement. The blade thickness and its spacing from the cup wall, particularly in Figure 1, are exaggerated in the drawings for clarity of elements.

The end 52 of blade 36, which is adjacent the cup rim 38, is reduced in width, and is bent toward and contacts the cup wall, as clearly illustrated in Figure 5; the inherent resilience of the thin blade permitting the main blade body to be adjustably spaced relative to the cup wall while the blade end portion 52 remains in contact with the cup wall. Cutting edge 54 of blade 36 extends the entire length of the blade including the end portion 52. Thus the blade end 52 will make a terminal cut of the sliced tissue at a location adjacent the cup rim 38. The polar end 56 may be similarly formed to centrally terminate the sliced tissue if desired. However, as will be described, a cutter attachment 60, when used, will be in close proximity to the polar end 56 of blade 36 and at that position will cause effective separation of the sliced tissue from the cervix.

The cups 34 are made in several sizes, e. g., small, medium and large, to accommodate the variations in cervixes, and matched blades are provided for each size. All cups can be adapted for attachment to one handle.

Operation

After the vaginal tract has been expanded by the speculum to expose the cervix to visual examination and the operator determines a proper size cervical cup 34 and matched blade 36 to be used on the cervicotomy, the blade spacing will be adjusted to obtain a microscopic slice that will remove the stratified squamous epithelium and a fraction of a millimeter of sub-epithelial layer. The instrument is then inserted through the vaginal tract and the cup end placed to contain essentially the entire cervix. If the cup is made of Lucite or other clear plastic, the operator can carefully monitor a specific surface area of the cervix from which a tissue biopsy is desired, placing the blade cutting edge adjacent that area and terminating the cutting action when the desired area has been covered. However, as the normal diagnosis will require a complete circular cervical biopsy, the operator, using an appropriate slight pressure against the cervix, will rotate the cervicotomy 360°, the transparent cup enabling close control of the slicing technique, thereby removing a substantially complete circular tissue specimen that will include tissue from the squamo-columnar junction.

The removed slice of tissue will tend to roll or fold under the leading portion of the knife in front of the thumb screws and will remain in the cup when the cervicotomy is withdrawn. This instrument and technique will result in biopsy tissue from a desired area or from the entire cervical surface without excessive trauma or bleeding and which will enable a histologic diagnosis to be accomplished.

Tissue from cervical canal

Illustrated in the assembled cervicotome in Figures 1 and 2 and in detached, greatly enlarged detail in Figure 6, is a small frusto-conical cutter attachment 60 having a threaded insert 62 coaxially fixed, as by threads or welding to the large end of the attachment. Cutter 60 is removably fastened to the inside of a cup 34 by threaded engagement of insert 62 with a tapped bore 64 in the inside of cup 34 coaxial with the external shaft attachment projection 32. The small end of cutter 60 may, if desired, be provided with side flats 66 for engagement by a suitable tool (not shown) to aid its removal from the cup when specimens have been obtained. The cutter can be removed by hand if desired but tissue specimens might be lost due to surface contact. Cutter attachment 60 may be of any suitable shape such as a cylinder, a conoid, or an ellipsoid, however it should be sufficiently small to permit easy introduction into the cervical os when the cervicotome cup is placed over the cervix.

The exterior surface of cutter 60 is provided with a plurality of cutting edges, preferably a multiplicity of minute cutting teeth 68 arranged with front flat faces 70 facing the direction of instrument rotation. When the cutting attachment 60 is used, it will project into the cervical canal and upon rotation of the cervicotome the teeth 68 will remove a multiplicity of small bits of columnar tissue from the canal wall. The bits of tissue collect on the face 70 of each tooth 68 and after removal of the instrument, may be collected and used for cytologic study or, as discussed hereinbefore, they can be combined with a fixative and centrifuged to a button which can be sliced and studied as in a histologic diagnosis.

Cutter attachments 60 are made in different sizes for use in the combination instrument to adapt it to variations in size and shape of the cervix and conditions of the cervical os and canal, due to ridges, lacerations, etc.

With the foregoing discussion and description in mind it will be apparent that a new surgical device has been disclosed that will enable an operator to rapidly obtain a cervical tissue biopsy adequate for histologic diagnosis for essentially all conditions of cancer of the cervix. The instrument includes a cup enclosed curved blade for placement over an exposed cervix to obtain a microscopic circular cervical tissue biopsy of substantially the entire cervix. The blade is adjustable to vary the thickness of tissue obtained. To enable accurate visual control during operation the cervix cup is preferably made of a clear plastic such as Lucite. A small central cutting attachment is removably fastened to the inside bottom of the cup and obtains tissue from the cervical canal for diagnosis. Cup and blade combinations can be made of varying sizes for different size cervixes and the central cutter attachment can also be furnished in various sizes.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed and desired to be secured by United States Letters Patent is:

1. A device for obtaining a tissue biopsy comprising: a cup-shaped means, and a thin curved blade fastened on and in spaced relation to the inside surface of said cup-shaped means.

2. A device for obtaining a cervical tissue biopsy under visual monitoring by the operator, comprising: a transparent cup-shaped means, and a thin curved blade fastened on and in spaced relation to the inside surface of said cup-shaped means.

3. A surgical instrument for obtaining a tissue biopsy

comprising: a cup-shaped means having a bottom and an annular side wall; a handle having an elongate shaft; means connecting said shaft to the exterior of the bottom of said cup-shaped means; a thin blade shaped in substantial conformation to the inner surface of said cup-shaped means; and means connecting said blade to said cup-shaped means with the blade cutting edge extending from a position closely adjacent the terminal edge of said side wall to a position proximate the center of said bottom and spaced a slight distance from the inside surface of said side wall.

4. A surgical instrument as defined in claim 3, wherein said means connecting said blade to said cup-shaped means comprises: adjustable and removable means to enable variation of the spacing between the blade and said side wall and to permit removal of said blade from said cup-shaped means.

5. A surgical instrument as defined in claim 4, wherein said means connecting said blade to said cup-shaped member comprises: a thumb screw having a shouldered head, disposed on the exterior of said cup-shaped member, and a threaded shank projected through the side wall of said cup-shaped member; a tapped aperture in said blade engaged by said threaded shank; and a spring means disposed between said blade and the inside surface of said cup-shaped member adjacent said thumb screw to bias said blade away from the wall of the cup-shaped member and force the shouldered head into engagement with the exterior of the cup-shaped member.

6. A surgical instrument as defined in claim 3, wherein said blade comprises: a razor edged knife of thin metal and relatively narrow width, said knife having a bowed curvature that will enable substantially conformation to the curvature of said cup from adjacent its rim to a position proximate the center of the cup bottom whereby the cutting edge is directed in substantial parallelism with the inner surface of the cup, and at least one end of said knife is bent in the opposite direction of said bowed curvature whereby that end will contact the inner surface of said cup.

7. A surgical cutting instrument for obtaining tissue from a cervix comprising: a substantially hemi-spherical cup; means attached to the external side of said cup for rotating said cup about its polar axis; a thin blade curved to substantially conform to the spherical inner surface of said cup and having one end adjacent the rim of said cup and the other end adjacent the polar axis of said cup; adjustable means fastening the blade on and in spaced relation to the inner surface of said cup to enable variations in blade spacing.

8. A device for obtaining a tissue biopsy comprising in combination: a cup-shaped means; a thin curved blade fastened on and in spaced relation to the inside surface of said cup-shaped means; and a plug device, fastened to the inside bottom of said cup-shaped means, having tissue collecting deformations on its surface.

9. A device as defined in claim 8 wherein said tissue collecting deformations on said plug device comprise a plurality of minute cutting blades extending from the plug surface.

10. A surgical instrument for obtaining tissue from a cervix comprising in combination: a substantially hemi-spherical cup; means attached to the external side of said cup for rotating said cup about its polar axis; a projecting plug-shaped device, fastened to the inside of said cup in alignment with said polar axis, having tissue collecting deformations on its surface; a thin blade curved to substantially conform to the spherical inner surface of said cup and having one end adjacent the rim of said cup and the other end adjacent said plug-shaped device at the polar axis of said cup; and adjustable means fastening the blade on and in spaced relation to the inner surface of said cup to enable variations in blade spacing.

11. A surgical instrument for obtaining a cervical tissue biopsy comprising in combination: a handle including an

elongate shaft; a clear transparent substantially hemispherical cup; detachable fastening means connecting said elongate shaft to the exterior of said cup with the axis of said shaft substantially aligned with the polar axis of said cup whereby rotation of said shaft will rotate said cup about its polar axis; a plug-shaped element having tissue collecting deformations on its surface; means detachably securing said element to the inside of said cup in alignment with the axis of said shaft; a thin blade shaped in substantial conformation to the inner surface of said cup; means projected through the wall of said cup for removably and adjustably fastening said blade on the inside of said cup in spaced relation to the inner wall surface of said cup and including means disposed exterior of said cup enabling removal and adjustment of said blade.

12. A cervicotome comprising: support structure, curved means for obtaining a substantially complete circular biopsy from the surface of a cervix, and including means adjustably securing said curved means on said support structure for controlling the thickness of said biopsy.

13. A cervicotome as defined in claim 12 including means on said support structure for simultaneously obtaining a substantially complete sampling of the tissue at the entrance portion of the cervical canal.

14. For use in a surgical cervical biopsy instrument: a thin knife blade of narrow width having a razor thin

cutting edge, said knife having a permanent bowed curvature enabling the knife to substantially conform to a spherical surface approximately the external shape of a cervix, said blade being apertured intermediate its ends to provide means for attachment to the instrument.

15. The knife as defined in claim 14 having one end bent in direction opposite to said bowed curvature.

16. For use in a surgical cervical biopsy instrument: a substantially hemi-spherical cup approximating the size of a cervix, means disposed approximate the geometric pole of said cup for fastening an external element and an internal element to said cup, and the wall of said cup being apertured to provide a means for fastening a cutting element to the inside of said cup.

17. The cup as defined in claim 16 comprising a clearly transparent material.

18. For use in a surgical cervical biopsy instrument; a plug-shaped device for obtaining columnar tissue from the cervical canal, having an attachment device fixed to one end for fastening to the instrument, and a plurality of minute cutters projecting from its surface.

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