

[54] MEDICAL INSTRUMENTS

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[73] Assignee: Medical Concepts, Inc., El Segundo, Calif.

[22] Filed: June 28, 1971

[21] Appl. No.: 157,196

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 65,816, Aug. 21, 1970, abandoned.

[52] U.S. Cl. 128/304, 128/276, 128/348, 128/17

[51] Int. Cl. A61b 17/22, A61m 1/00, A61m 25/00

[58] Field of Search 128/2 R, 2 B, 304, 128/348, 350 R, 351

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Primary Examiner—Channing L. Pace

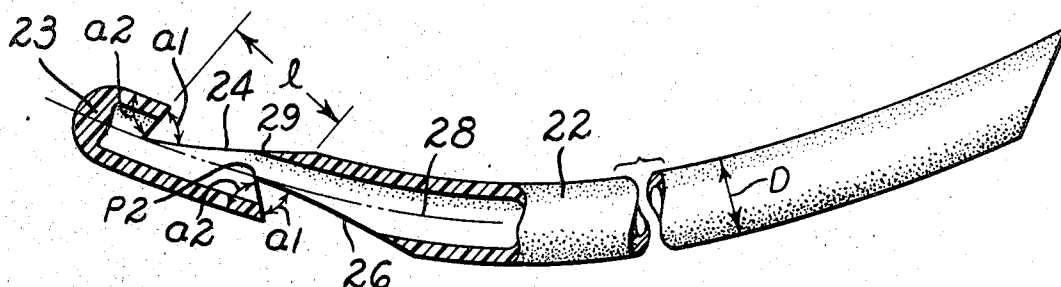
Attorney—Harris, Kern, Wallen & Tinsley

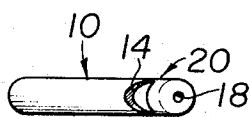
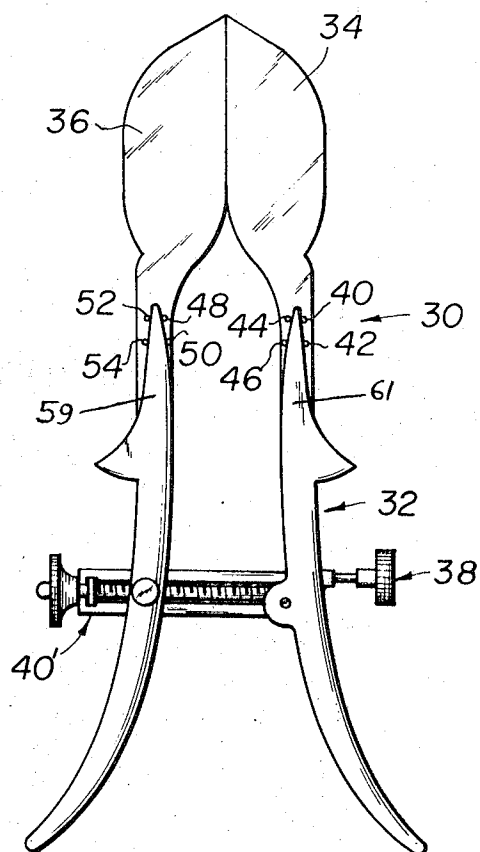
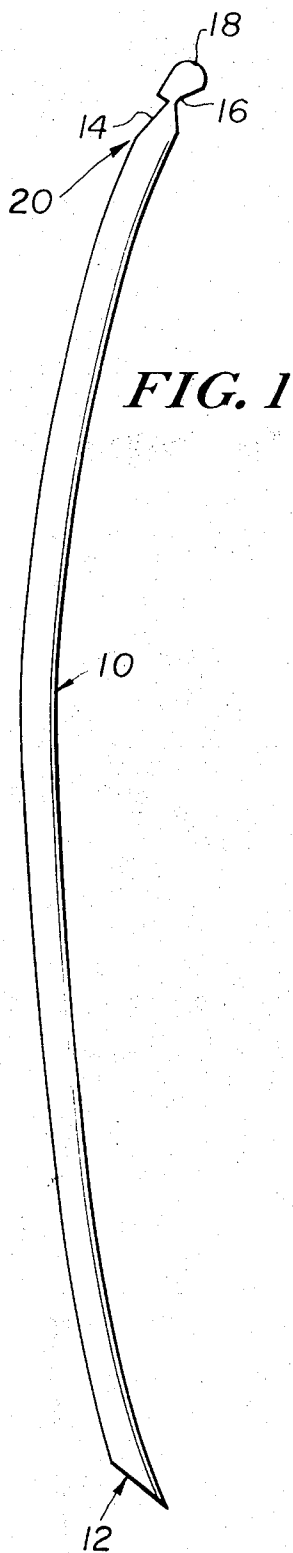
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ABSTRACT

A combination of disposable medical instruments is provided which can be used when performing an abortion including a speculum comprising metal jaw members and disposable plastic tip members. The plastic tip members are fitted on the jaw members in snap-fit relationship and are shaped so that they adequately expose the cervix and tend to bring it forward toward the vaginal opening. A disposable curette or cannula for a suction aspirator is also provided and comprises a tube of plastic material which is sufficiently flexible to permit relatively easy bending of the tube during use and yet sufficiently rigid to maintain the desired tubular configuration during such bending. The tube is provided at its operative end with a pair of holes on opposite sides thereof, each of a size sufficient to pass the embryonic tissue therethrough.

3 Claims, 17 Drawing Figures





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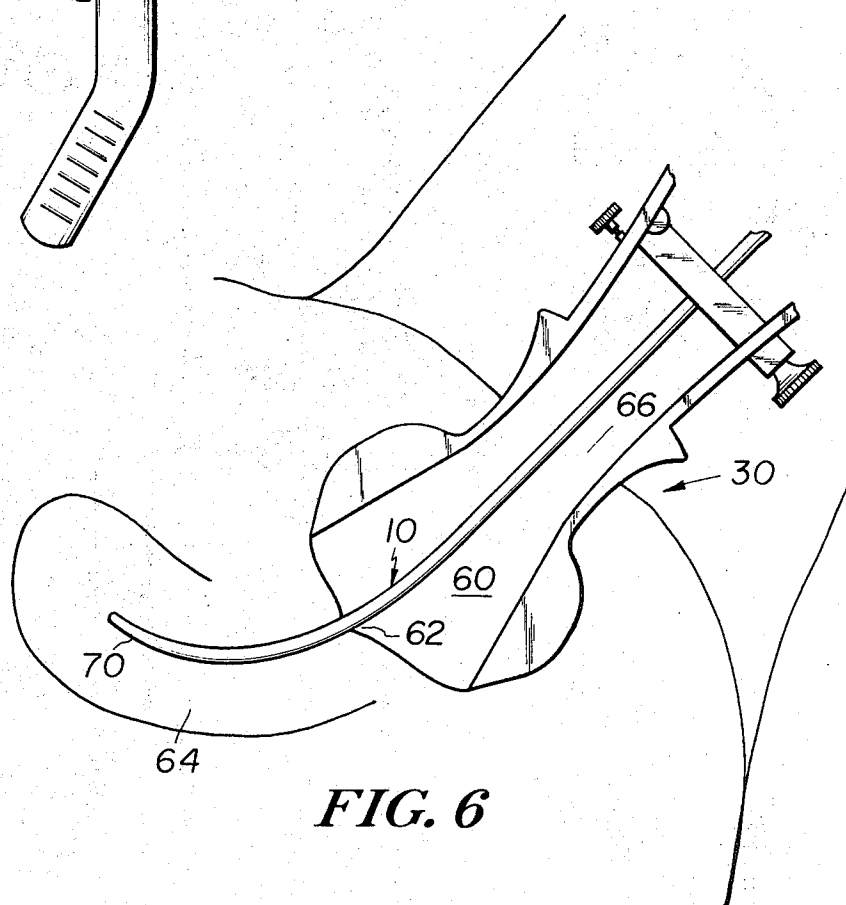
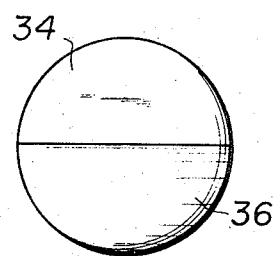
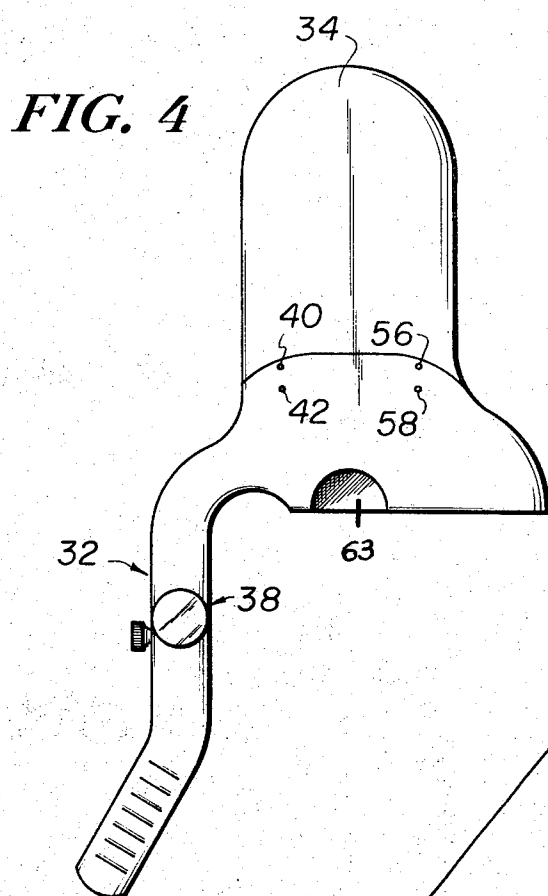


FIG. 7.

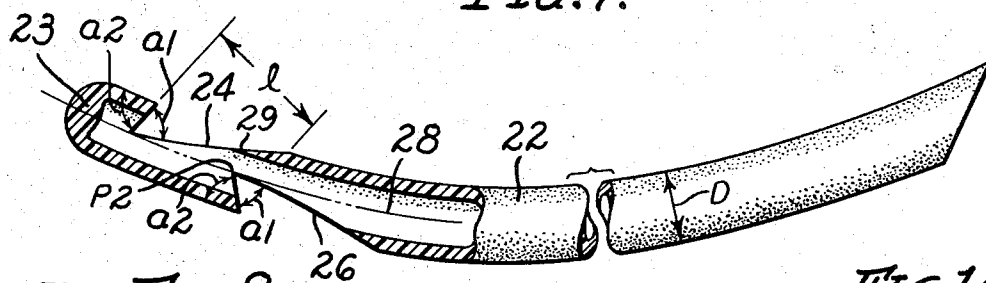


FIG. 8.

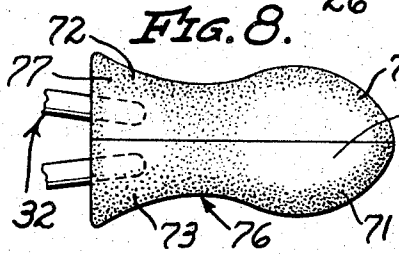
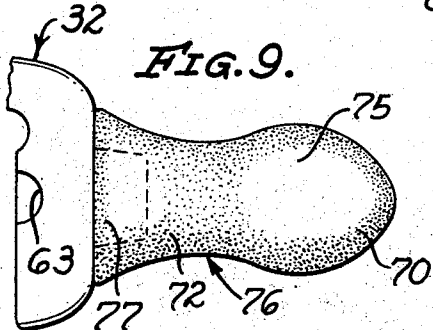


FIG. 9.



MEDICAL INSTRUMENTS

This application is a continuation-in-part of my co-pending application Ser. No. 65,816, filed Aug. 21, 1970, entitled Medical Instruments now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to a combination speculum and curette (also known as a cannula) for a suction aspirator, and to the speculum and curette individually.

Present day techniques for performing an abortion include the dilatation and curetage technique and the suction aspirator technique. It has generally been found that the suction aspirator technique is preferred, since less damage is done and the operation is less painful.

It is an object of the present invention to provide an improved speculum, and particularly a speculum having disposable portions which portions are the only portions which enter a patient. A further object is to provide a speculum with a new and improved tip configuration and with tips which may be flexible to conform to the vaginal walls.

It is a further object of this invention to provide an improved cannula for a suction aspirator, and particularly a disposable cannula for a suction aspirator. A further object is to provide a cannula having a new and improved tip opening configuration providing several advantages in a single structure.

It is a still further object of the present invention to provide disposable medical instruments which can be used to perform an abortion in an efficient, painless, safe and sterile manner and one which is substantially nontraumatic.

SUMMARY OF THE INVENTION

According to the present invention, there is provided in combination, a speculum comprising a pair of jaw members, handle means for moving said jaw members between closed and open positions, stop means for holding the jaw members in an open position, said jaw members being made of rigid material, and a pair of speculum tip members one being releasably secured to the other end of each of said jaw members, and a cannula for a suction aspirator comprising a tube of material which tube is sufficiently flexible to permit it to be relatively easily bent and is sufficiently rigid to maintain a tubular configuration during such bending, said tube being open at one end thereof for attachment to the outlet of a suction aspirator or the like, and said tube having an opening adjacent its other end of a size and shape adapted to pass embryonic tissue therethrough upon the application of sufficient suction to its said one end.

According to the present invention, there is further provided a speculum comprising a pair of jaw members, handle means for moving the jaw members between closed and open positions, stop means for holding the jaw members in an open position, said jaw members being made of rigid material, and a pair of speculum tip members one being releasably secured to the other end of each of said jaw members.

According to the present invention, there is still further provided a suction for a suction aspirator comprising a tube of material which tube is sufficiently flexible to permit it to be relatively easily bent and is sufficiently rigid to maintain a tubular configuration during such bending, said tube being open at one end thereof

for attachment to the inlet of a suction aspirator or the like, and said tube having an opening adjacent its other end of a size and shape adapted to pass embryonic tissue therethrough upon the application of sufficient suction to its said one end.

The preferred cannula is made of a plastic material, such as polyethylene or polyvinyl chloride. It is relatively inexpensive and, due to its flexibility and tip design, it can be inserted into the uterus via the cervix without initially determining the depth of the cervix by "sounding" with the conventional soft metal sound, because it serves as both sound and curette. Unlike conventional sounds and curettes it will not puncture the wall of the uterus. Further, again because it is flexible, it tends to conform to the shape of the uterus and therefore to be less painful to the patient.

The speculum tips may be disposable and can be provided in a variety of sizes and shapes and degrees of stiffness. Important considerations are the flexibility of the material and the configuration of the tips which aid in "vaulting" the vaginal walls. The vaulting exposes the cervix by moving it forward toward the vaginal opening. It is the shape and length of the speculum tips and the cooperation thereof with the vaginal walls which causes the desired vaulting and stabilization of the vaginal muscles.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a cannula in accordance with the present invention;

FIG. 2 is a plan view of the operative end of the cannula of FIG. 1;

FIG. 3 is a side view of a speculum in accordance with the present invention;

FIG. 4 is a top view of the speculum of FIG. 3;

FIG. 5 is a front elevational view of the speculum of FIG. 3;

FIG. 6 is a schematic view of the speculum and cannula in use;

FIG. 7 is a view similar to that of FIG. 1 showing an alternative form of cannula incorporating a presently preferred embodiment of the invention;

FIGS. 8 and 9 are views similar to those of FIGS. 3 and 4 showing an alternative form of speculum tip incorporating a presently preferred embodiment of the invention;

FIGS. 10 and 11 are views similar to that of FIG. 6 showing the speculum of FIGS. 8 and 9 in use;

FIGS. 12 and 13 are views similar to those of FIGS. 8 and 9 showing another alternative embodiment of the speculum tips;

FIG. 14 is a view similar to those of FIGS. 8 and 12 showing another alternative embodiment of the speculum tips;

FIG. 15 is a view similar to those of FIGS. 8, 12 and 14 showing another alternative embodiment of the speculum tips;

FIG. 16 is an end view of the tips of FIG. 15; and

FIG. 17 is a view illustrating the tips of FIG. 15 in use.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. 1 and 2, there is shown one embodiment of a cannula 10 in accordance with the present invention. The cannula 10 is for use with a suction aspirator which is a wellknown device that need not be described for the purposes of the present invention.

Suction aspirators are provided with suction inlet to which the cannula 10 is adapted to be releasably attached by means of an open end 12. Cannula 10 comprises a pair of substantially oppositely disposed holes 14 and 16 each of a size and shape such that they will pass embryonic tissue therethrough to the suction outlet of a suction aspirator.

It has been found that the use of two holes provides improved performance. In particular, it has been found that when one hole is clogged by tissue, the passage of fluid, or air, through the other hole tends to aid in drawing the tissue through the clogged hole. In fact, tissue of a size four times that of a hole has been found to pass therethrough. The use of the oppositely disposed pair of holes also prevents an undue suction build-up when one hole is clogged. It will be appreciated that an undue suction build-up can damage the tissue lining the wall of the uterus. Of course, suction aspirators are designed to normally provide a suction which would not be harmful, such as 25 inches of mercury. It has been found that with the present invention a suction of approximately nineteen inches of mercury is required to remove the embryonic tissue when effecting the termination of an early pregnancy.

The cannula 10 may be provided with a hole 18 in its operative end 20 which may be used for cleaning of the cannula 10. However, it is generally not desired that cannula 10 be cleaned or sterilized since it is made of a relatively inexpensive material and is readily disposable. Thus, cannula in accordance with this invention are expected to be sterile wrapped and merchandised as units to be disposed after one use. In fact, it has been found that if cannulas of polyvinyl chloride or other plastics are sterilized too often, they tend to lose the desired flexibility.

An alternative and presently preferred embodiment of the cannula is illustrated in FIG. 7 and comprises a cannula 22 having the same general configuration as the cannula 10 of FIG. 1 and formed of a length of plastic tubing with a closed end 23, which may be formed by heating and inwardly compressing the end of the tubing. A small hole may be provided in the end 23 corresponding to the hole 18 of FIG. 1, but the hole 18 is not necessary in either of the embodiments illustrated.

Holes 24 and 26 are provided in the tubing adjacent the end 23 and substantially opposite to each other, with the holes slightly spaced from each other along the center line 28 of the tubing. In the preferred embodiment, each of the holes 24, 26 is a V-shaped notch with the apex substantially at the center line 28, and with the apex P_2 of hole 26 substantially opposite the downstream end 29 of the hole 24. In the preferred form, the length (1) of the opening along the surface of the tubing, is approximately twice the outside diameter (D) of the tubing. Also in the preferred embodiment, the angle α_1 of the notch which forms the opening, and the angle α_2 between the upstream edge of the notch and the outer wall of the tubing are each less than 90° . The provision of α_2 less than 90° provides a slight scraping edge at the wall of the tubing.

Another advantage achieved with the construction illustrated in FIG. 7 is the high flexibility of the tip while at the same time having a cannula which is not subject to collapse and which will be sufficiently stiff to maintain a given shape. The tubing has a relatively thick wall which prevents any collapsing of the tubing under the suction operation. Typically a 6 mm O.D.

tubing will have a 1 mm thick wall. In the area between the apex of the notch of the hole 26 and the downstream end of the hole 24, the amount of wall is substantially reduced and the cannula is quite flexible in this area, substantially reducing the likelihood of perforation of the uterus by the end 23.

The cannula is made of a material having the characteristic of being sufficiently flexible to permit bending of the cannula to conform it to the vaginal opening and the opening of the uterus. The material is, however, sufficiently rigid to maintain the tubular configuration of the cannula during such bending which is necessary to proper use thereof. The ability of the cannula to bend has been found to greatly facilitate abortions and make the patients less uncomfortable. In addition, it has been found that "sounding" is not required when utilizing the present cannula. Previously, "sounding" techniques were required to determine the depth of the uterus so that when relatively rigid cannula were used, they were not inserted too far causing damage to the wall of the uterus and possible subsequent hemorrhaging.

The cannula is preferably made of a plastic material, such as polyvinyl chloride or polyethylene. It has been found that a cannula made of such plastic having an outside diameter of 4 millimeters can be used successfully to remove embryonic tissue during the first eight weeks of pregnancy. It has been further found that such a cannula having an outside diameter of 6 millimeters can be safely used to remove embryonic tissue up to the tenth week of pregnancy. It has also been found that such a cannula can be safely used up to the fourteenth week to terminate pregnancies.

In 75 percent of the abortions performed using the present cannula, less than thirty cubic centimeters of blood was passed. In fact, it is believed that the total amount of blood loss is due to the removal of the embryonic tissue. There is only gentle scraping but the tip design prevents application of force which would damage walls and the patient can generally leave immediately after the operation has been performed. In fact, the total time for performing the operation is a matter of minutes and the removal of the embryonic tissue may take as little as 30 seconds. The operation, contrary to prior art, is performed without dilation of the cervix.

One embodiment of a speculum 30 in accordance with the present invention is shown in FIGS. 3, 4 and 5. The speculum comprises a rigid member 32 and semi-rigid tip members 34 and 36. The member 32 may be conventional in design and is preferably made of metal. The member 32 is provided with well-known stop means 38 for holding the tip members 34 and 36 in any desired open position of a plurality of possible open positions. The member 32 is further provided with well-known adjustable pivot means 40' for varying the sizes of the available open positions.

Member 32 is provided with abutments, of which abutments 40, 42, 44, 46, 48, 50, 52, 54, 56, and 58 can be seen in FIGS. 3 and 4. The abutments cooperate with suitable depressions (not shown) in the tip members 34 and 36 to permit the tip members 34 and 36 to be snapped on to the jaws 59 and 61 of member 32 and fixedly held in position during use. The tip members may be pulled off after use and other tip members snapped on.

One form of tip members 34 and 36 is shown in the drawings which members cooperate to provide an outer periphery which is substantially cylindrical and terminates in a spherical head portion which outer periphery closely conforms to the configuration of the vagina. The tip members 34 and 36 are preferably made of a plastic material, such as polyvinyl chloride, and are of a thickness such that they yield slightly during use and are less uncomfortable to the patient. The member 32 may also be provided with an opening 63 to accommodate the clitoris during an operation as is well known.

An alternative and presently preferred embodiment of the speculum is shown in FIGS. 8 and 9, with tips 70, 71 carried on the conventional speculum member 32. Various conventional speculums are shown in U.S. Pats. Nos. 2,672,859; 2,954,025; 3,110,305; 3,246,646; and 3,332,414. The tips 70, 71 preferably are disposable and may be installed by being a press fit onto projections 72, 73 carried on the member 32. Interengaging detents or other retaining devices (not shown) may be incorporated in the tips and projections if desired.

The preferred configuration for the tips 70, 71 is shown in FIGS. 8 and 9, with the tips circular in cross-section and having a projectile shaped end 75 with a zone 76 of reduced diameter intermediate the end 75 and the base 77.

While it is preferred that the tips of the speculum be removable and disposable, they could be permanently affixed to the main body member 32 if desired. The speculum tips preferably are made of a semi-rigid or flexible material such as polyethylene or silicone rubber or the like which permits flexing or bending of the ends of the tips.

In FIG. 6 the cannula 10 and speculum 30 are shown in their operative positions, the human body being shown schematically. It will be noted that speculum tips 34 and 36 being made of semi-rigid material flex and conform somewhat to the vaginal wall as it opens the vagina, referenced 60, to expose the cervix 62 of the uterus 64. The speculum 30 stabilizes the vaginal muscles while drawing the cervix forward toward the vaginal opening 66. The use of the speculum with the tips of FIGS. 8 and 9 is shown in FIGS. 10 and 11, with the tips in the closed position in FIG. 10 and with the tips expanded to an open position in FIG. 11, with the tip ends 75 being bent inward by engagement with the vaginal muscles. The forward movement of the cervix is readily seen in a comparison of FIGS. 10 and 11.

The movement forward is a most important advantage and is due to the flexibility of the tip members and their shape. Previous speculums tended to go in deeper than the present speculum and to have relatively straight rigid jaw members which tended to open the vagina in such a manner that the cervix was forced back. The present speculum causes a vaulting of the vaginal wall, exposing the cervix 62 and tending to bring it forward.

The preferred speculum tip configuration is the projectile shape which makes for ease in inserting the instrument. The pronounced hump in the tip configuration and the flexible nature of the tips enables the instrument when in the open position, to conform to the generally spherical shape of the opened vagina without producing localized pressure and injury at the vaginal

wall, and to produce the vaginal vaulting and cervical forward movement.

Some additional alternative embodiments for the speculum tips which are flexible in nature and produce the desired ball or spherical shape when opened are shown in FIGS. 12-16. The tips 70, 71 are shown as solid members in FIGS. 8 and 9, but could be hollow and could be shells (as in a clamshell shovel). The tips 80, 81 have the ball or projectile form of the tips 70, 71 when viewed from the side as in FIG. 12; however the sides 82, 83 are flat. The tips 80, 81 may be solid or hollow or could be shells, the latter being shown in FIGS. 12 and 13. The tips 80, 81 may be semirigid or flexible throughout as the tips 70, 71 or alternatively, may be made of a rigid material, such as styrene, and designed with a thinner section in the reduced zone 84 so that flexing will occur at the zone 84 when the tips are in use. The expression "semi-rigid speculum tips" is intended to cover both the overall semirigid tips and the tips which are semi-rigid at the zone adjacent the jaws.

Another embodiment similar to that of FIGS. 12 and 13, but with open sides, is shown in FIG. 14 with tips 86, 87. In the embodiment of FIGS. 15-17, tips 88, 89 are generally flat when in the closed position of FIGS. 15 and 16 and may have an arcuate cross-section as seen in FIG. 16. The tips 88, 89 are semi-rigid along their length and will assume the ball or spherical shape when opened after insertion, as shown in FIG. 17. Linear polyethylene is a suitable material for the tips 88, 89, which may have thicker or wider walls adjacent the jaws for increased strength and/or stiffness.

While the removable and disposable form is preferred for the tips, they could be made integral with the handle and jaw in the same manner as in some prior speculums.

In use, the cannula 10 is inserted through the cervix 62 into the uterus 64 and rotated until it is seen through the tubing of the suction aspirator, which is semi-transparent, that the embryonic tissue 70 is being removed. It is important to note that the present combination of instruments provides completely disposable members, insuring the utmost sterility and safety, and conform as much as possible to the human body in a yieldable manner permitting the entire operation to be as painless as possible and to be performed as quickly and safely as possible.

While the principles of the invention have been described with reference to specific embodiments thereof, it is to be clearly understood that the description has been made only by way of example and is not intended as a limitation to the scope of the invention as set forth in the accompanying claims.

What is claimed is:

1. A cannula for a suction aspirator comprising a unitary plastic tube, which tube is sufficiently flexible to permit it to be relatively easily bent and is sufficiently rigid to maintain a tubular configuration during such bending, said tube being open at one end thereof for attachment to the inlet of a suction aspirator or the like, and said tube having first and second openings in the tube wall adjacent the other end of the tube, said openings being generally V-shaped notches with a short upstream edge and a long downstream edge and with the length of the downstream edge of each of the openings in the order of twice the outside diameter of the tube, said openings being spaced axially along the tube

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from each other and on opposite sides of the tube, with each of said openings extending substantially to the center line of the tube, and with the apex of said second opening substantially opposite the downstream end of said first opening whereby said other end may be bent over at said second opening apex more than 90 degrees.

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2. A cannula as defined in claim 1 wherein said openings are generally V-shaped notches with the angles between the tube wall and the upstream edge of each of the notches less than 90°.

3. A cannula as described in claim 1 wherein said other end of said tube is closed.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,769,980 Dated November 6, 1973

Inventor(s) Harvey Karman

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 1, line 64, "suction" (first occurrence) should be
--cannula--

Column 2, line 1, "sucntion" should be --suction--

Column 8, line 5, (Claim 3), "described" should be --defined--

Signed and sealed this 2nd day of April 1974.

(SEAL)
Attest:

EDWARD M. FLETCHER, JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents