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Marco

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[54] **UTERINE EVACUATION ASSEMBLY**

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[52] **U.S. Cl.**..... **128/304,** 128/276, 220/63 R

[51] **Int. Cl.**.. **A61b 17/22,** A61m 1/00, B65d 25/18

[58] **Field of Search**..... 128/275, 276, 302, 128/304

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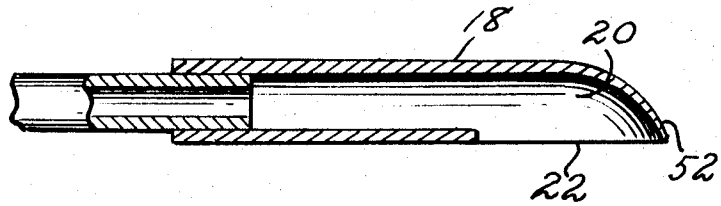
[57] **ABSTRACT**

A disposable uterine evacuation assembly for applying aspiration curettage to the uterine cavity wall. A hollow transparent plastic cannula is connected by a flexible plastic tube to a receptacle which is in turn connected to a vacuum source for applying vacuum pressure to an inlet slot in the tip portion of the cannula. The receptacle consists of a pair of nested transparent plastic bags, the inner bag being perforated to trap solids therein while permitting liquids to flow into the outer bag. The cannula has a rigid handle section and a flexible intermediate section which permits bending to conform to the curves of the cervical canal, and the slot in the cannula tip is arranged parallel to the longitudinal axis of the cannula and has flattened edges to provide flush engagement against the uterine cavity wall.

7 Claims, 7 Drawing Figures



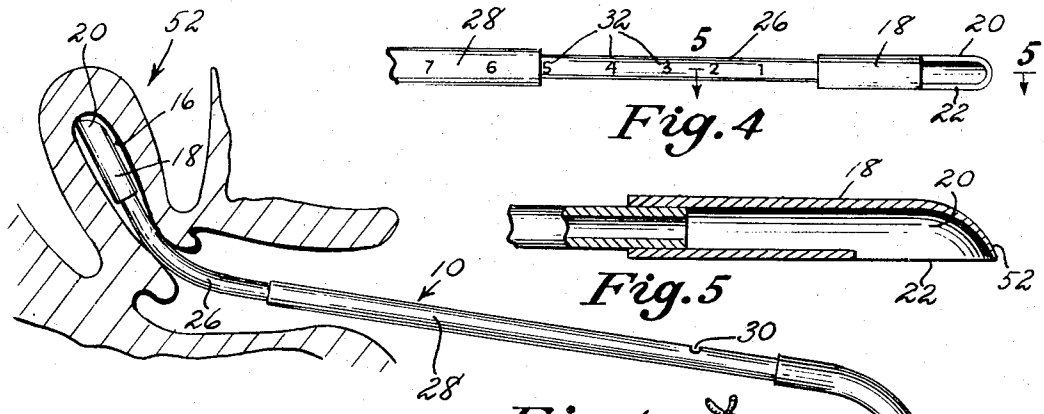


Fig. 1

Fig. 4

Fig. 5

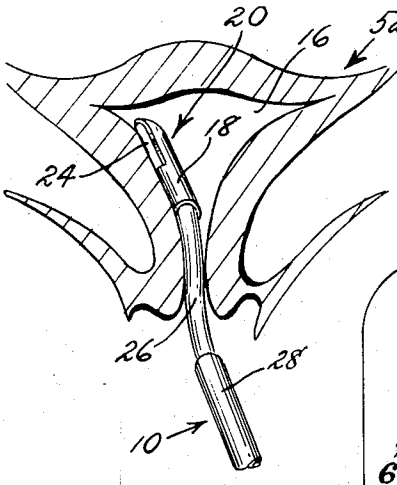
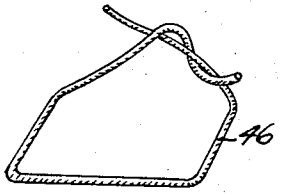
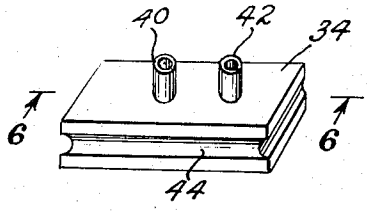
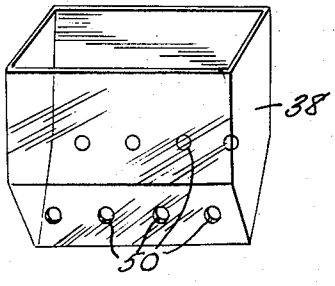


Fig. 2







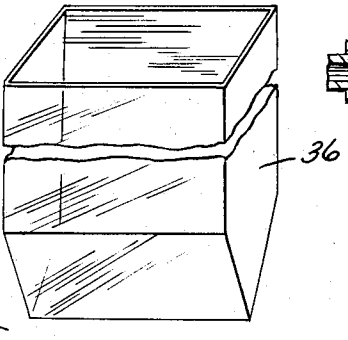


Fig. 3

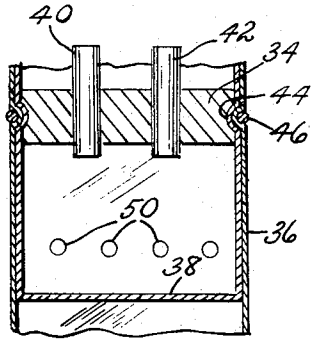
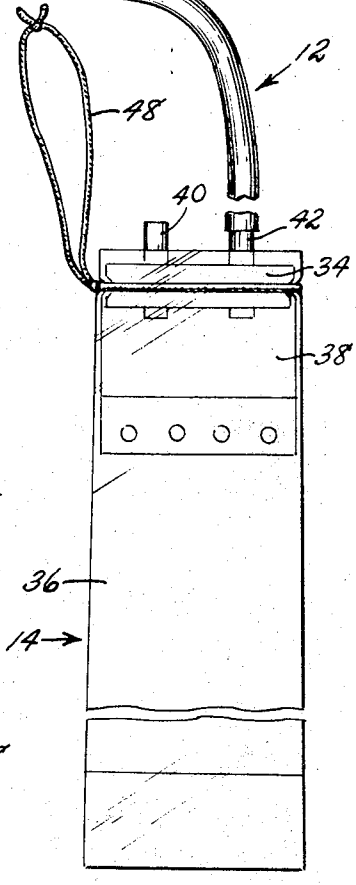


Fig. 6



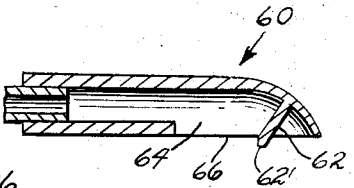


Fig. 7

UTERINE EVACUATION ASSEMBLY

The present invention relates to a novel and improved uterine evacuation assembly, and in particular to a disposable assembly for use in vacuum curettage procedures.

Recent surgical developments have favored the performance of surgical abortion operations in relatively early stages of pregnancy so that the application of vacuum curettage to the walls of the uterus has largely replaced the earlier scraping methods. The vacuum method has proved safer, less painful and often more effective than the scraping technique, but its practical application has incurred difficulties and presented problems.

In previously devised devices for the vacuum aspiration of the uterus, the cannulas employed have been so designed that the tip does not remain flush with the uterus wall, thereby permitting the loss of vacuum and necessitating the use of excessively high vacuum pressures which often result in injury to the tissues. The use of pre-curved cannulas has been attempted to facilitate insertion, but when such cannulas are rotated, they tend to press into the tissue of the uterus wall. A straight cannula, on the other hand, is difficult to introduce, so that it becomes necessary to dilate the canal to a greater degree than would be desirable.

Because of the conventional cannula design which makes necessary the use of excessively high vacuum pressures, heavy-duty and expensive assembly components are required, so that it has hitherto been impossible to produce a simple inexpensive and effective assembly which can be discarded after use so as to eliminate the time-consuming cleansing and sterilizing operations.

It is an object of the present invention to provide a disposable uterine evacuation assembly which is of simple construction and is economically made in a unitary form from plastic material, the assembly being provided as a self-contained, preassembled and presterilized unit which may be discarded after use.

Another object of the invention is the provision of a uterine evacuation assembly of the character described in which the cannula is so designed as to provide effective aspiration action with relatively low vacuum pressures, thereby enabling the unit to be ready for instant use with any type of aspirator equipment which may be available.

Still another object of the invention is the provision of a uterine evacuation assembly of the character described which includes a disposable tissue trap which is external of and remote from the aspirator apparatus and which may be hung in sight of the physician performing the operation. In conventional evacuation systems, the tissue is usually separated and trapped in collection bottles mounted in the aspirator apparatus and out of sight of the physician. In addition, after the tissue is collected, the machine cannot be re-used until it is cleaned and sterilized, such immobilization creating a problem in clinics in which successive operations are performed.

A further object of the invention is the provision of a uterine evacuation assembly of the character described in which the cannula portion is so designed as to be able to pass easily and safely along the varying curved canals of the uterus, and as to minimize the possibility of perforation of the uterine wall. In addition

the cannula tip is designed to make flush engagement with the uterine wall at the area of aspiration, thereby avoiding air leakage and enabling the assembly to be operated at low vacuum pressures.

In accordance with the present invention, there is provided a disposable uterine evacuation assembly comprising a hollow cannula, a tissue trap receptacle, and a flexible tube connecting the cannula to the receptacle. The cannula comprises a forward tip section, a flexible intermediate section, and a rigid handle section joined together to form an integral unit. The tip section has a slot formed in the side wall thereof and arranged parallel to the longitudinal axis of the cannula for flush engagement with the wall of the uterine cavity through cooperation of the flexible intermediate section, whereby suction is applied through the slot to said wall when vacuum pressure is introduced within the cannula. The wall of the tip section is also made thin and flexible to prevent perforation of the uterine wall.

The tissue trap receptacle includes an elongated outer flexible bag, a smaller inner flexible bag nested within the upper end of the outer bag, and a head piece mounting the nested bag. A pair of tubes extend through the head piece and communicate with the interior of the inner bag which is provided with a plurality of apertures. One of the tubes is connected to the flexible tube carrying the cannula, and the other tube is connected to a vacuum source such as a motor driven aspirator. The vacuum source thus applies suction through the nested bags and the flexible tube to the cannula.

Additional objects and advantages of the invention will become apparent during the course of the following specification when taken in connection with the accompanying drawings, in which:

FIG. 1 is an elevational view of a uterine evacuation assembly made in accordance with the present invention, and showing the manner in which the cannula is inserted within the uterine cavity;

FIG. 2 is a diagrammatic view of the uterine cavity showing the manner in which the cannula tip is applied to the wall thereof;

FIG. 3 is an exploded perspective view of the tissue trap receptacle of the assembly of FIG. 1;

FIG. 4 is an enlarged elevational view of the cannula portion of the assembly of FIG. 1;

FIG. 5 is a section taken along line 5—5 of FIG. 4;

FIG. 6 is a section through the upper portion of the tissue trap receptacle, as taken along line 6—6 of FIG. 3; and

FIG. 7 is an enlarged section similar to FIG. 5, but showing a cannula tip of modified construction.

Referring in detail to the drawings, FIG. 1 shows a uterine assembly made in accordance with the present invention, and generally comprising a plastic cannula 10 connected by a length of flexible tubing 12 to a tissue trap receptacle 14. The receptacle 14 in turn communicates with a conventional motor-driven vacuum aspirator (not shown) in a manner to be presently described, so that suction is applied through the tip of the cannula 10 to the walls of a uterine cavity 16.

The cannula 10 is formed of three separate plastic sections welded together to form an integral unit. At the forward end of the cannula 10 is a tip section including a cylindrical tubular portion 18 made of a rigid transparent plastic material and a front terminal portion 20 molded with a wall which is appreciably thinner

than the wall of portion **18**, so that it is relatively soft and bendable. At one side of the terminal portion **20**, the wall is cut away in such a manner as to form flat edges **22** defining therebetween an inlet slot **24**. As shown in FIGS. **4** and **5**, the slot **24** is elongated and lies in a plane parallel to the longitudinal axis of the cannula **10**.

Secured to the cylindrical tip portion **18** is an intermediate section **26** which communicates with a handle section **28**. The intermediate section **26** comprises a length of tubing which is flexible and bendable. The handle section **28** comprises an elongated rigid plastic tube which is long enough to be grasped by the user, and serves as a handle for the cannula **10**. The handle section **28** is formed with an aperture **30** which is normally covered by the thumb of the user during operation of the assembly, and which may be uncovered to serve as an emergency release for the built up vacuum. In addition, the handle section **28** and intermediate section **26** may be calibrated with a centimeter scale **32** which visibly indicates to the physician the extent to which the cannula has penetrated, thereby minimizing the danger of perforating the uterus.

The tissue trap receptacle **14** comprises a head piece **34** mounting a pair of transparent plastic bags **36** and **38**. The head piece **34** has a body portion made of rigid plastic, and may be formed in the flat rectangular form shown. Extending through the body portion and projecting upwardly therefrom are a pair of spaced tubes **40** and **42**. Extending centrally around the periphery of the head piece **34** is a continuous groove **44** which serves as a means for attaching the bags **36** and **38** to the head piece **34**, as will be presently described.

As shown in FIG. **1**, the outer bag **36** is elongated and is completely enclosed except for a top open end. The inner bag **38** is appreciably shorter than the outer bag **36** and is of lesser width so that it fits freely therein. Both bags **36** and **38** are made with a sufficient cross-sectional area to fit about the head piece **34**.

In the assembly of the tissue trap receptacle **14**, the bag **38** is inserted and nested within the top portion of bag **36**, and the head piece **34** is inserted within the mouth of the inner bag **38**. A cord or plastic strip **46** is bound around the mouth of the nested bags, the cord being received in the groove **44** of head piece **34**, as shown in FIGS. **1, 3** and **6**. After the cord **46** is tightly drawn and knotted, to secure the bags **36, 38** with an air-tight seal to the head piece **34**, the ends of the cord **46** may be tied together to form a loop **48** (FIG. **1**) by means of which the tissue trap receptacle **14** may be hung from the stirrup for observation of its contents by the physician during the operation.

Instead of binding with a cord, as previously described, the bags **36, 38** may be mounted on the head piece **34** by heat sealing or the like.

The inner bag **38** is provided with a plurality of small holes or apertures **50**, as shown in FIGS. **1, 3** and **6**, which allow for the separation and trapping of tissues drawn through the cannula **10**.

The tube **42** is connected by the flexible tubing **12** to the handle section **28** of the cannula **10**. The flexible tubing **12** is preferably of a length of approximately three feet to afford the physician a flexibility of movement in the use of the device. The tube **40** is connected by a length of plastic tubing (not shown) to a vacuum aspirator device of any standard construction, which is capable of drawing air out of the bags **36** and **38**, and thereby induce a vacuum condition at the front portion **20** of the cannula **10**.

In the operation of the assembly, the outer plastic bag **36** may initially be partially filled with water to provide weight and retain the bag in open condition, preventing its collapse when vacuum is introduced therein. When the vacuum aspirator is actuated, it draws the air out of the bags, **36, 38** creating a vacuum condition therein. Air is thus drawn through the tubes **40** and **12**, and through the hollow cannula **10**, causing aspiration at the slot **24** in the cannula tip section.

FIGS. **1** and **2** show the manner in which the cannula **10** is inserted into the uterus **52**. To perform an effective evacuation operation, the physician must move the slot **24** of the cannula **10** along the entire inner wall of the uterine cavity **16**, applying suction thereto. Consequently, the cannula **10** must be succesively rotated so that the slot **24** lies flush against said inner wall. The flexible intermediate section **26** of the cannula **10** is freely bendable to conform to the curve of the cervical canal of the patient, enabling an easier introduction of the cannula as well as movement during use. This reduces the necessity for dilation, which is painful, as well as the need for deep anaesthesia. In addition, the flexibility of the section **26** permits the cannula to be freely rotated without danger of puncturing the uterine wall, as might easily occur if the intermediate section **26** were made of rigid material. In FIG. **2**, for example, the cannula **10** is shown in a position in which the slot **24** is not in flush abutment with the wall of the uterine cavity **16**, and the cannula must be rotated to bring the flat edges **22** bordering the slot **24** into flush proximity with the endrometrium lining of the uterine wall.

The cannula **10**, the tubing **12** and the plastic bags **36, 38** are all made of transparent plastic material so that the physician may observe the flow therethrough of the aspirated matter drawn from the uterus, and thus determine by the flow when the slot **24** is in proper flush position against the uterine wall. It will be appreciated that since the cannula **10** is constructed to permit the flush engagement of slot **24** with the uterine wall, leakage of the vacuum at the cannula tip is minimized, thereby enabling lower vacuum pressures to be employed and thus reducing the possibility of tissue inversion by the sucking action. In conventional vacuum evacuation systems in use today, there is required approximately 28 inches of vacuum pressure. The construction of the tip section of the cannula **10** of the present invention, on the other hand, permits effective evacuation with the use of only approximately 17 inches of vacuum pressure. Since a standard vacuum aspirator will produce up to 22 inches of vacuum, it will be apparent that the assembly shown and described herein may be used with any such standard aspirator and does not require special suction equipment, as is the case with conventional uterine evacuation systems.

The cannula front terminal portion **20** has a curved top and front wall **52** which overlies the slot **24**, as shown in FIG. **4**. As previously indicated, this wall **52** is appreciably thinner than the wall of tubular portion **18** with which it is integral. The thickness of the wall **52** is so reduced that the wall is soft and pliable. Consequently, if the tip of the cannula **10** is pressed against the uterine wall, it will flatten out as it meets the resistance of the wall and thereby act as a buffer, preventing perforation of the wall tissue.

The entire assembly shown and described herein is so constructed that it may be provided as a disposable, throw-away unit which can be pre-sterilized and packaged in a plastic wrapper for immediate use with any type of available vacuum machine. The parts may be manufactured at such a low cost that the assembly may be discarded after use.

In operation, as blood fluids, tissue and solid particles are sucked into the cannula slot **24,** they are drawn through the hollow cannula **10** and tube **12** into the inner bag **38** of the tissue trap receptacle **14.** The small perforations **50** in the inner bag **38** permit the passage of the fluid portions of the aspirated material into the outer bag **36,** while the solid particles are retained in the inner bag **38.** After completion of the operation, the inner bag may be detached from the outer bag, and sent to a laboratory for analysis of its contents.

It will be appreciated that the perforated inner bag **38** serves as a filter which separates and retains solid particles while the fluids pass into and are retained by the outer bag **36.** If desired, instead of the perforated plastic inner bag **38,** other suitable filters may be employed. For example, a length or pad of gauze of appropriate thickness may be tied or otherwise secured about the head piece **34** so that it underlies the ends of tubes **40** and **42,** the gauze filtering the matter drawn through tube **42** and separating and retaining the solid materials for subsequent examination.

FIG. **7** illustrates a modified tip section **60** which may be employed in the cannula **10** for use with the assembly of the invention. The tip section **60** is similar to the tip section shown in FIGS. **4** and **5,** except that it is molded with a small plastic bridge in the form of a flat plate **62** extending between the side walls of the tip and across the elongated slot **64.** The bridge plate **62** is formed to project a slight distance below the plane of the flat edges **66** bordering slot **64,** a preferred projecting distance being approximately 1 millimeter.

In difficult cases, where it is found that vacuum suction alone is insufficient to effect complete evacuation, a cannula provided with the tip section **60** of FIG. **7** may be employed. As the cannula slot **66** is drawn along the surface of the uterine wall, the applied vacuum sucks the wall tissue upwardly toward slot **66** and into firm contact with the projecting portion **62'** of plate **62,** the latter serving to apply a light scraping action to the uterine wall surface which augments the suction action. The cannula tip **60** again has a curved front wall which is thinner than the wall of the remainder of the tip and is therefore sufficiently soft to prevent puncturing of the uterine wall.

While preferred embodiments of the invention have been shown and described herein, it will be obvious that numerous omissions, changes and additions may be made in such embodiments without departing from the spirit and scope of the invention.

What is claimed is:

1. For use in a uterine evacuation assembly for applying aspiration curettage to the wall of a uterine cavity from a vacuum source, a hollow cannula comprising a distal tip section, an intermediate flexible section and a rigid handle section joined together to form an integral unit, said handle section having means for attachment to said vacuum source, said tip section having a tubular body wall of circular cross section, a portion of said wall at the distal end thereof being cut away to form flat edges defining therebetween an elongated slot extending parallel to the longitudinal axis of said tip section for engagement with said uterine cavity wall and the application of suction thereto when vacuum is applied to the interior of said cannula, said distal tip section having a curved wall overlying said slot and extending across the distal end of said tip section, said curved wall having a thickness sufficiently small to enable said wall to flex and flatten out upon engagement with the wall of said uterine cavity.

2. A cannula according to claim **1** which said cannula sections are made of plastic material formed as an integral unit.

3. A cannula according to claim **1** in which said distal tip section includes a scraper wall extending transversely across said slot and spaced from said curved wall, said scraper wall having a free edge projecting outwardly of said slot.

4. A cannula according to claim **1** in which said cannula sections are made of transparent plastic material.

5. A cannula according to claim **1** in which the rigid handle section has a pressure relief aperture therein.

6. A cannula according to claim **1** in which said intermediate section comprises a length of flexible and bendable tubing.

7. A cannula according to claim **6** in which said intermediate section is of sufficient length for insertion of said distal section into the uterus with said intermediate section extending through the cervical canal, said intermediate section being sufficiently flexible to bend to conform to the curvature of the cervical canal while the inserted tip section is being manipulated by means of the handle section located outside the body.

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