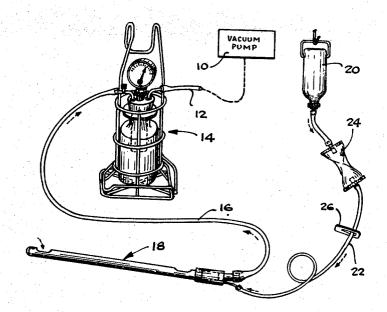
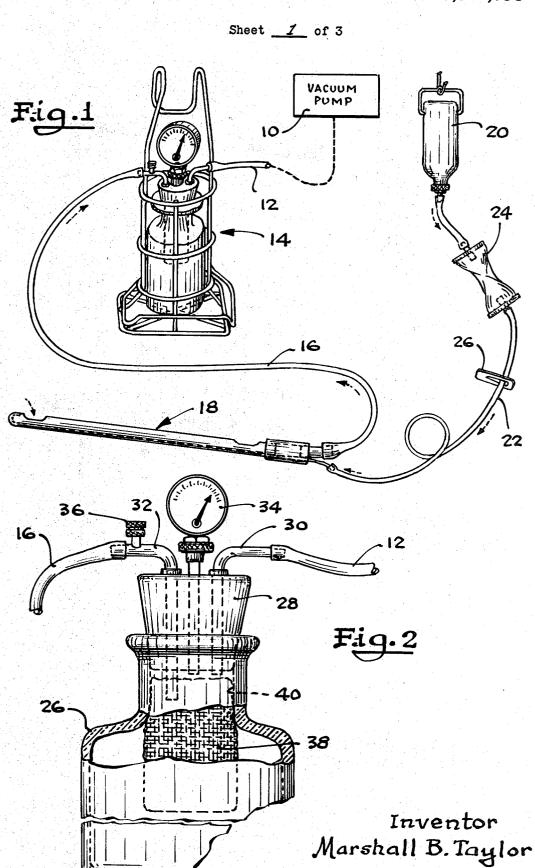
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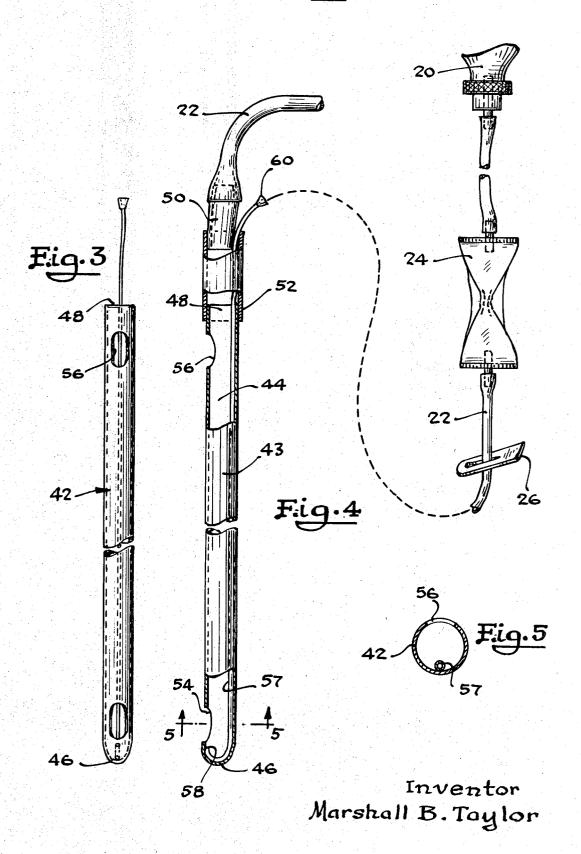
Primary Examiner—Charles F. Rosenbaum Attorney—Dominik, Knechtel & Godula

ABSTRACT: A vacuum curette and curettage assembly for vacuum evacuation of the uterus. An elongated tube having a length sufficient to sound the depth of a uterus, and a rounded contact forward end with an aspiration inlet. The rearward end of the elongated tube has an opening which is connected to vacuum tubing leading to a vacuum trap and to a source for creating a vacuum. Saline flush tubing extends along the length of the elongated tube and is mounted to the wall thereof. The flush tubing is connected to the saline tubing and to a saline source so that a saline drip is introduced through a discharge opening of the flush tubing in the area of the aspiration inlet, to thereby counteract clogging of tissue passing through the elongated tube. An aperture at the rear of the tube allows finger control of the negative pressure within the tube during the evacuation procedure.

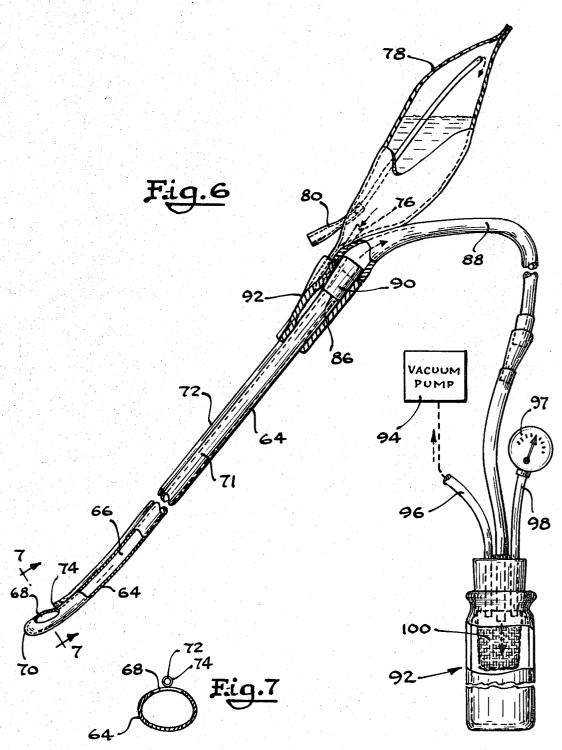




Sheet 2 of 3



Sheet <u>3</u> of 3



Inventor Marshall B. Taylor

VACUUM CURETTE

This invention relates to a vacuum curette and assembly for evacuating the uterus of tissue. In particular, the invention relates to a vacuum curette and assembly for evacuating the uterus of gestational tissue to effect therapeutic abortion, or for evacuating the uterus following incomplete and missed abortion, as well as evacuating the uterus in delayed postpartum hemorrhage or the like.

Vacuum curettage has received recent and extensive attention in the art as an improved means for evacuating the uterus in medically indicated therapeutic abortion and for treating incomplete or missed abortion, as well as other conditions. The vacuum procedure promises advantages over the conventional sharp curettage procedure in that more effective evacuation is obtained in shorter time and with a lesser loss of blood. The art has come to recognize there is a lesser likelihood of residual material remaining in the uterus after vacuum curettage than with sharp curettage. The art has also come to believe that vacuum curettage causes the gestational tissue to be sheared from the uterine surface in an atraumatic manner to thereby cause less endometrial or myometrial damage, and less blood loss.

In vacuum curettage, an elongated tube is used in which an aspiration inlet is provided at the front or proximal end, and to which a connecting vacuum line is joined to the rear or distal end. The normal procedure provides for dilating the cervix of the uterus to a size greater than the tube or curette so that the curette may be introduced into the uterus to the full depth of the endometrial cavity. The practitioner moves the front end of the curette continuously over the surface of the uterus and suction induces the fetal or gestational tissue through the aspiration inlet. This tissue is usually passed out of the curette into a communicating vacuum trap or container. The inside diameter of the curette or tube is limited because of the feasible cervical dilations, and such limited diameter often leads to clogging of the fetal tissue within the passageway of the curette.

It is important to control the suction or negative pressure within the curette because of the possible threat of damage of the uterine wall. Higher pressures have been required also to move tissue through the curette. Conventional valve means are generally provided at the vacuum source or vacuum trap to control the negative pressure, but it is desirable to provide means to reduce the negative pressure requirements and the threat of damage to the uterine wall. A more sensitive and responsive control of the suction level is also desirable so that the medical practitioner may quickly alter such levels in accordance with the manner in which an evacuation is proceeding.

It is accordingly one object of the present invention to provide an improved vacuum curette and curettage assembly which permits efficient uterine evacuation to be effected within a relatively short time and with reduced levels of blood loss.

Another important object of the invention is a vacuum curette and curettage assembly in which an evacuation procedure is effective within relatively short periods of time and under reduced pressure requirements to minimize the possibility of damage to the uterine wall.

Another important object of the invention is a vacuum curette and curettage assembly in which undesired levels of clogging are prevented by providing a physiological saline flush proximate to the aspiration inlet of the vacuum curette.

Still another important object of the invention is a vacuum 65 curette and curettage assembly of an improved construction which counteracts slogging tendencies in the curette and higher pressure requirements when evacuating a uterus during therapeutic abortion, or in other procedures where tissue is to be evacuated from the uterus.

Yet still another important object of the invention is a vacuum curette and curettage assembly which leads to an improved evacuation of nonfetal particles under lower pressure levels while counteracting any tendencies of such particles to clog the vacuum curette.

A still further object of the invention is a vacuum curette and curettage assembly in which the negative pressure within the vacuum curette may be selectively controlled by more sensitive response means which are controlled by the practitioner during the evacuation procedure.

Yet another important object of the invention is to provide a vacuum curette and curettage assembly which allows the medical practitioner to use finger control of the same hand which manipulates the vacuum curette for selectively attaining desired negative pressure levels within the curette in accordance with demands which arise during the evacuation procedure.

Objects such as the foregoing are attained together with still other objects which will occur to practitioners from time to time by the invention of the following disclosure, including drawings wherein:

FIG. 1 is a perspective view of a curettage assembly of the invention, with parts removed and other parts indicated diagrammatically;

FIG. 2 is a portional side elevational view, on an enlarged scale, of the containers in the vacuum trap shown in FIG. 1;

FIG. 3 is a top plan view of the vacuum curette on an en-25 larged scale, which is shown in the assembly of FIG. 1;

FIG. 4 is a side elevational view of the vacuum curette of FIG. 3, and other components of the curettage assembly with parts removed;

FIG. 5 is a sectional view along line 5-5 of FIG. 3;

FIG. 6 is a perspective view, with parts removed and parts indicated diagrammatically, of an alternative embodiment of a curettage assembly; and

FIG. 7 is a sectional view along line 7-7 of FIG. 6.

The use of the same numerals in the various views of the 35 drawing will indicate a reference to the same structures, parts or elements, as the case may be.

Referring to the drawings, the assembly includes a vacuum source such as a pump indicated at 10, connecting vacuum tubing 12 between the pump and a vacuum trap indicated generally at 14, connecting vacuum tubing 16 joining the vacuum trap and a vacuum curette indicated generally at 18. A source of physiological saline 20 is joined by connecting saline tubing 22 go to the vacuum curette 18. The saline tubing 22 is shown with conventional drip 24 and constriction plate or valve 26 which can selectively reduce the diameter of tubing 22 to control the flow or drip of saline to the vacuum curette.

The vacuum trap is shown as including an open top container or bottle 26 which is stoppered by closure 28. The closure is provided with substantially rigid angle conduit 30 to which connecting vacuum tubing 12 is engaged, and with another substantially rigid angle conduit 32 to which connecting vacuum tubing 16 is engaged. Conduit 32 is shown with an escape valve or container pressure control 36. The closure is additionally provided with a pressure gauge 34. The angle conduits 30 and 32, and gauge 34 communicate with the interior of the bottle 26, and with a foraminous container or wire basket 38 which may be frictionally mounted or secured to the neck 40 of the container.

Referring now to FIGS. 3—5, the vacuum curette is shown as an elongated tube 42 having a continuous side wall 43 to define a substantially circular passageway 44. The front or proximal end of the tube 46 is rounded to provide a probing or contact surface within the uterus. The rear or distal end of the tube has an opening 48 which communicates with a tubular coupler 50, and is held to such tubular coupler by a fastening sleeve 52 which may be bonded to the distal end of the tube and to the tubular coupler 50.

70 The continuous tubing wall is preferably transparent throughout its entire area so that passage of the gestational or other uterine tissue may be observed by the user. Transparent plastic tubing serves such purpose well, although tubing having limited transparent areas or portions could also be used.
75 An aspiration inlet 54 is shown at the proximal end of the

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tube, and such inlet is shown as having a generally oval configuration which, of course, follows the curved tubing wall. The distal end of the tube is shown as having a finger control aperture 56 which opening may be selectively reduced or closed by the thumb or finger of the user to control the negative pressure within the tube. The aperture is also shown as having a generally oval configuration which follows the curved tubular wall. The user can selectively and variously balance the aperture 56 relative to the aspiration inlet 54 to control the levels of negative pressure within the elongated tube. This control is independent of other means to control the negative pressure, such as at the vacuum source or escape valve 36 at the vacuum trap.

A flush tube 57 is shown secured to the inside wall at the bottom of the elongated tube, and such flush tube may be bonded or otherwise secured to the tubing wall. Such tubing may be a flexible catheter such as Intracath tubing then may be made to conform the rounded proximal end 46 of the tube. A discharge opening 58 is provided at one end of the flush 20 tube in the area of the aspiration inlet 54. The other end of the flush tube 57 is provided with a entry opening 60 which is modified as a flared seat to which is mounted one end of saline tubing 22. To assure secure engagement, it is preferred that the end of the saline tubing 22 be bonded to the flared seat 60. 25 In operation, the physiological saline is continuously dripped into the flush tube and introduced into the passageway 44 of the elongated tube from the discharge opening 58. The drip rate is controlled by the conventional constriction plate 26 to desirably flush the inside of the elongated tube and thereby 30 counteract any tendency of clogging by gestational or other uterine tissue in the passageway 44 of the tube.

An alternative embodiment is shown in FIGS. 6 and 7 which is desirably used for uterine evacuation other than removing fetal or gestational tissue. Such a curettage assembly may be particularly used in instances of menopausal bleeding, or in other uterine evacuations which do not involve fetal tissue. The vacuum curette is shown as an elongated tube 64, which is substantially rigid and which defines an interior passageway 66 of generally circular cross section. An aspiration inlet 68 is end is rounded as at 70 to provide a desired contact point within the uterus.

As well as by providing intermittent suction through periodic lifting of the finger or thumb from the suction control aperture. Evacuation of the uterus can be completed within a few minutes as determined by the feel of the curette against the wall of the uterus.

Collected gestational or fetal tissue is retrieved from the mesh basket 38 in the vacuum trap, and the total aspirated fluid is measured in the vacuum bottle 26, as by precalibrated markings thereon. Any blood loss may then be determined by subtracting the volume of saline loss. In this way, confirmation within the uterus.

A circular flush tube 72 is shown bonded to the outside of the continuous wall 71 of tube 64, and such flush tube has a discharge opening 74 adjacent to the aspiration inlet 68. At the opposite end of the flush tube 72 is a drain inlet 76 which is disposed within a chamber defined by a plastic envelope 78. The saline source is connected to the envelope 78 through a coupler tubing 80 so that the physiological saline may be introduced and pooled within the chamber. Alternately, saline may be introduced at 76 by coupling tubing from an intravenous bottle. The opening 86 at the distal end of the elongated tube 64 communicates with connecting vacuum tubing 88 through tubular coupler 90 which is secured to the distal end of the tubing by an elastomeric coupling sleeve 92. The coupler, sleeve and connecting tubing are preferably bonded to one another.

The vacuum tubing 88 is joined to a vacuum trap 92 and is generally similar to the vacuum trap 14 of FIGS. 1 and 2. A vacuum source 94 is joined by connecting vacuum tubing 96 to the trap 92. A gauge 97 and tube 98 are shown mounted to the vacuum trap, which is also shown with a foraminous container or wire mesh basket 100 mounted in the interior 65 thereof.

The vacuum curette and the assembly of FIGS. 6 and 7 are not shown with pressure control means on the tube 64, although a finger control as previously described may be provided. This embodiment is useful in evacuating smaller tissue 70 particles from the uterus, such as smaller polyps and the smaller tissues which are to be a evacuated in menopause bleeding.

The dimensions of the vacuum curettes shown here may be varied, and it has been found that the length of the vacuum 75

curette may be selected from about 25 to about 30 30 cm, which length is generally adequate for sounding the depths of the average uterus which is to evacuated. The inside diameter of the vacuum curette may also vary, say, from about 7 to about 13 mm. It has been found that diameters in such range are adequate for conveying fetal tissue in therapeutic abortions, that is, up to about 12 weeks old. Vacuum curettes having dimensions within the foregoing range also have been successfully used for conveying gestational tissue following incomplete abortion or miscarriage. The aspiration inlet can also be varied in size, and it has been found that a diameter of about 1cm, is adequate for passing gestational tissue in therapeutic abortions and following missed or incomplete abortions. Fourteen gauge Intracath tubing, supplied by C. R. Bard Inc., Murray Hill, New Jersey, is successfully used as the flush tubing with vaccum curettes formed within the foregoing dimentional ranges.

As an example of use, the vacuum curette and curettage assembly in FIGS. 1-5 is introduced into the uterus to the full depth of the endometrio cavity. The saline drip is open at a slow rate and the gauge of the vacuum extractor o bottle is set at 0.4 to 0.5 Kg/cm² of negative pressure, which is substantially below other pressure levels which have been used, say, about 0.9 to 1 Kg/cm². The suction control aperture 56 is closed by the thumb of the same hand which holds and gently sweeps the vacuum curette over the uterus in the way a vacuum cleaner goes over a rug. The tissue is aspirated into the curette from the uterine cavity and can be observed throughout the length of the tube because of the transparent walls. The tissue is kept moving through the curette by continuous movement of the curette over the surface of the uterus, as well as by providing intermittent suction through periodic lifting of the finger or thumb from the suction control aperture. Evacuation of the uterus can be completed within a few minutes as determined by the feel of the curette against the wall of the uterus.

Collected gestational or fetal tissue is retrieved from the mesh basket 38 in the vacuum trap, and the total aspirated fluid is measured in the vacuum bottle 26, as by precalibrated markings thereon. Any blood loss may then be determined by subtracting the volume of saline loss. In this way, confirmation of low blood loss is ascertained. The saline wash is introduced into the vacuum curette from the discharge opening 58 of the flush tube 57. This counters any tendencies of the fetal tissue to clog the passageway of the vacuum curette, and therefore permits the lower pressure levels which keeps down the blood loss. The practitioner may also manually free any fetal tissue which tends to collect or clog in connecting vacuum tubing 16

The present invention permits lower negative pressures to operate and to thus minimize the danger of uterine injury. Negative pressures of about 0.3 to 0.4 atmospheres (0.3 to 0.4 Kg/cm²) are generally sufficient to shear tissues from the uterine wall, and the curette assembly disclosed herein operates effectively within this general range, say between about 0.4 to 0.5 atmospheres. This allows the assembly to be readily used with hospital vacuum lines which generally operate between about 0.6 to 0.8 atmospheres, especially in conjunction with the finger control means for the operating pressure levels. This may be contrasted with previous higher negative pressure levels of up to one atmosphere and more which require heavy duty pumps not commonly available in many hospitals or medical treatment rooms.

The invention may now be practiced in the various ways which will occur to practitioners, and all such practice will comprise a part of the invention so long as it comes within the terms of the appended claims as given further meaning by the language of the preceding specification.

I claim:

- 1. A vacuum curettage assembly for evacuating tissue from the uterus, including:
- saline connecting tubing for a source of physiological saline,

- vacuum trap including a container, a reduced size foraminous container within said container, and vacuum connecting tubing, a part of said connecting tubing adapted to join a vacuum source;
- a vacuum curette including an elongated tube having a 5 proximal leading end for intrauterine insertion, an aspiration inlet toward the proximal end, a distal end, an opening at said distal end, coupling means at said distal end for engagement to another part of said connecting vacuum tubing, and flush tubing mounted to the wall of said elongated tube and extending substantially along the entire length of the elongated tube, said flush tubing having a discharge opening in the area of the aspiration inlet, and entry opening on a portion of said flush tubing projecting tube, and means for coupling said entry end to the source of physiological saline;

remote means to control negative pressure in the vacuum curettage assembly; and

means in said elongated tube for controlling negative pres- 20

sure levels independent of said remote means to control negative pressure in said vacuum curettage assembly.

- 2. A vacuum curettage assembly as in claim 1 wherein said vacuum trap includes a gauge to report negative pressure and valve means to control the negative pressure created by the vacuum source.
- 3. A vacuum curettage assembly as in claim 2 in which said vacuum curette further includes a finger control aperture in the wall of the elongated tube toward the distal end thereof, said aperture having a configuration which permits the user to selectively choose the size of the aperture and to close the aperture to thereby control the levels of negative pressure in the elongated tube.
- 4. A vacuum curettage assembly as in claim 1 wherein the beyond the opening at the distal end of said elongated 15 flush tubing extends along the length of the elongated tube and is bonded to the interior wall of said tube, said flush tubing having a discharge opening adjacent the aspiration inlet at the proximal end of the tube and an opposite entry opening extending out of the outlet opening at the distal end of the tube.

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