

[54] **MANUAL SUCTION CURETTAGE INSTRUMENTS**

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128/304; 27/24 R, 24 A

[57] **ABSTRACT**

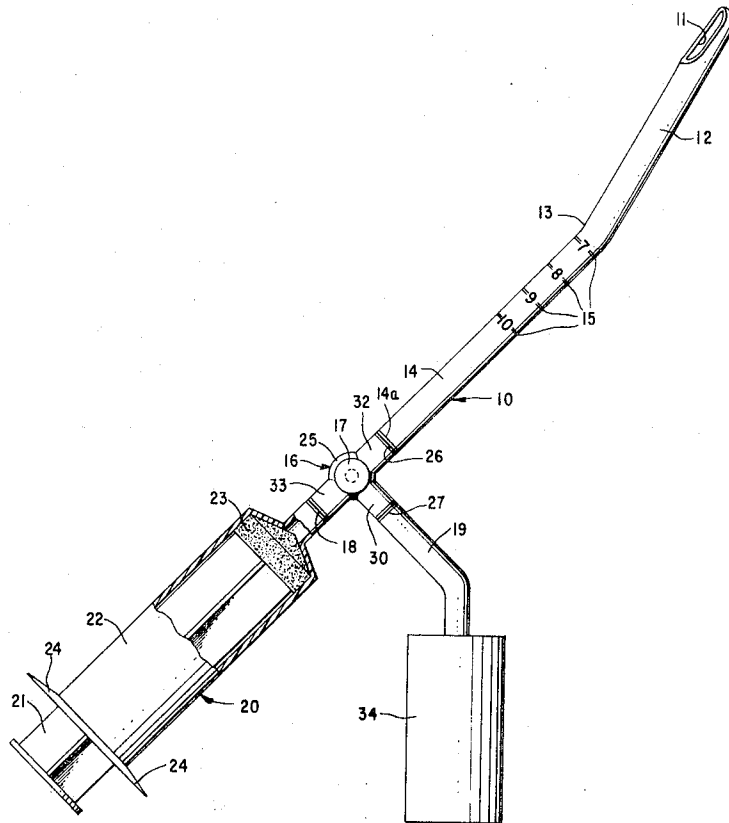
A disposable aspiration system for the manual performance of abortion during early uterine gestations includes a scoop-like curette tube adapted to be inserted in the vaginal uterine tract and an aspirator connected to the curette tube. In one form of the invention, a stopcock assembly is included between tube and aspirator to permit discharge of the aspirator during intermediate steps of the tissue removal process.

[56] **References Cited**

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5 Claims, 3 Drawing Figures



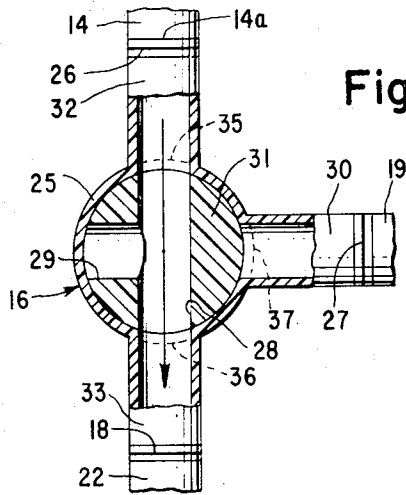


Fig. 2

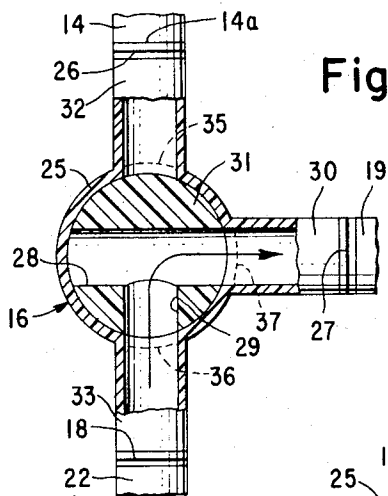


Fig. 3

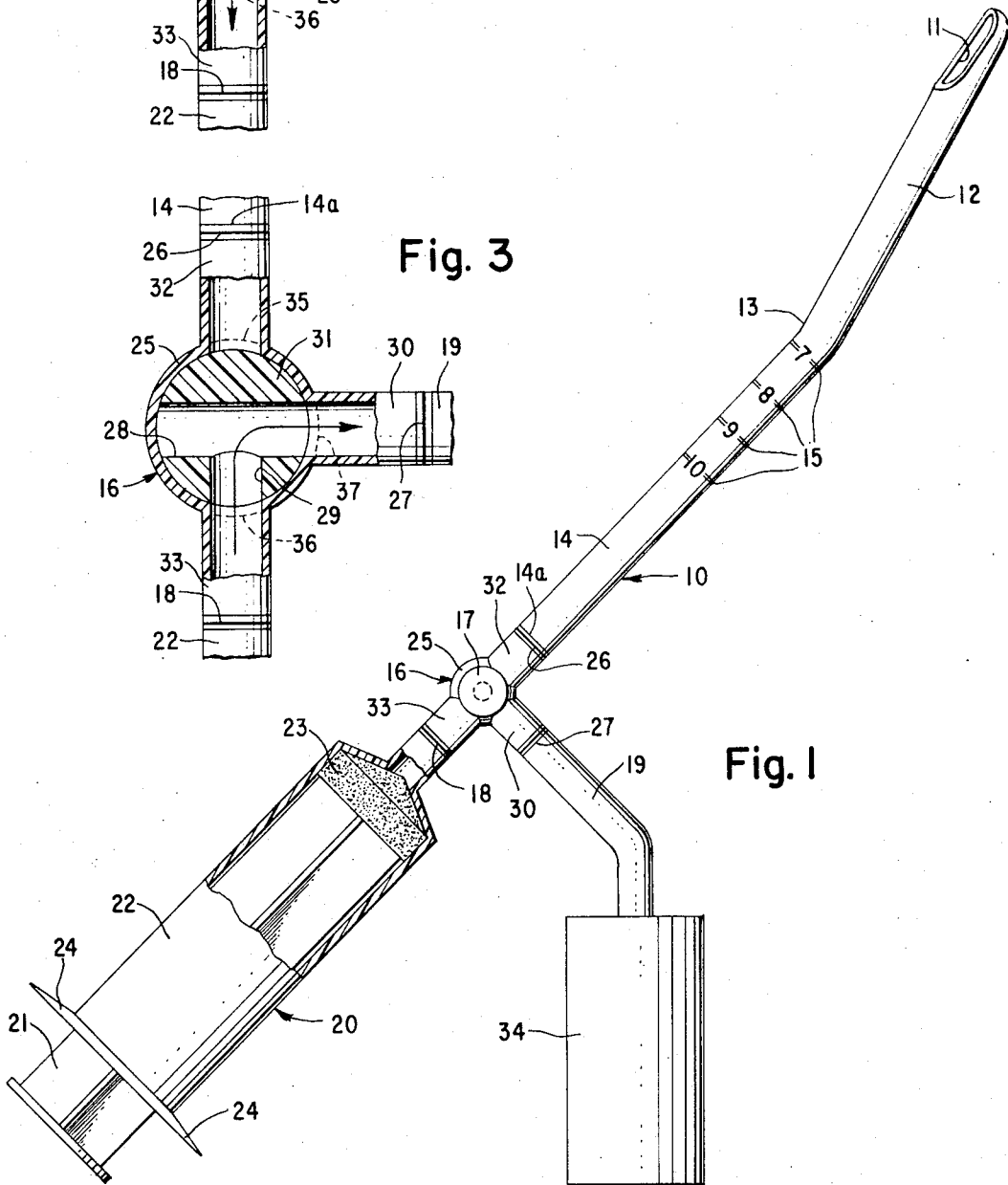


Fig. 1

MANUAL SUCTION CURETTAGE INSTRUMENTS

BACKGROUND OF THE INVENTION

This invention relates to manually operated suction curettage instruments for performing abortions during an early stage of pregnancy.

The substantial increase in the number of abortions of pregnancies currently being demanded and performed as a result of the recent relaxation of abortion laws in a number of states has created several distinct problems relative thereto. First, the mere increase in the number of applicants has frequently resulted in a substantial waiting period in order for the patient to enter a hospital. This can, in itself, result in difficulty since the longer an abortion is delayed, the greater is the risk of complication.

Second, the instruments used in hospitals are relatively expensive, and non-portable, such as a Berk vacuum machine using a Vacurette aspirating tube which may cost up to \$1,000 and which has substantially more vacuum pressure than necessary for use in abortions of early stage uterine gestations. The maximum aspiration pressure of such machines is typically 100 mm of Hg. and the complete pressure range can be traversed quite rapidly. On occasion, since satisfactory aspiration pressure is dependent upon the physical characteristics of the individual person, the use of a machine with such pressure capability may prove unsafe.

There is, therefore, a real need for an inexpensive, simple, safe, and portable system which may be readily used in the offices of a qualified physician. Such a system would enable the cost attendant with abortions to drop substantially and be within the economic reach of many persons currently unable to afford an abortion. Such a system would also enable abortions to be performed at their earliest possible stage without the significant delay encountered with hospital abortions. Finally, it would enable the abortion to be performed by a system designed for the earliest stages of pregnancy where a lower aspiration pressure may be incorporated, thus, avoiding any dangers in the use of excessive, unnecessary pressure; such lowered pressure also improving the sensitivity with which the instrument may be used.

SUMMARY OF THE INVENTION

It is, therefore, an object of the present invention to provide manually operated apparatus for the performance of abortions during an early stage of uterine pregnancies.

It is also an object of the present invention to provide manually operated aspirating apparatus for the performance of abortions during an early stage of uterine pregnancy which uses a lower maximum aspirating pressure than prior such apparatus.

It is another object of the present invention to provide manually operated aspirating apparatus for the performance of abortions during an early stage of uterine pregnancy which is relatively inexpensive to manufacture, is simple to operate, and is safe to use.

It is still another object of the present invention to provide manually operated apparatus for the performance of abortions during an early stage of uterine pregnancy which is portable and also completely disposable after use.

It is still a further object of the present invention to provide manually operated apparatus for the performance of abortions during an early stage of uterine pregnancy which has greater sensitivity and control than prior such apparatus.

In accordance with the present invention, apparatus for the manual removal of fetal tissue during early uterine gestations includes an elongated curette tube having distal portion and a proximate portion. The tube has a distal opening at the end of the distal portion and a proximate opening at the end of the proximate portion. The proximate end and distal end form an angle slightly less than 180°, which substantially corresponds to the angle of vaginal-uterine tract of a human female. The curette tube distal portion is adapted to be inserted in the vaginal uterine tract of pregnant female. Also included is a manually operated aspirator having a cylindrical portion and a plunger portion. The aspirator has an opening at one end communicating with the proximate opening of the curette tube. The plunger portion is disposed within the cylindrical portion and forms a hermetic seal therewith. The plunger portion is adapted for linear movement within the cylindrical portion and is capable of creating a suction at the distal opening of the curette tube in response to the linear movement of the plunger whereby material may be drawn through the distal opening into the cylindrical portion of the aspirator.

In one form of the invention, a manually operated stopcock, capable of being used in one of two operable positions is disposed between the curette tube and aspirator. The stopcock has an inlet portion, an outlet portion, and a discharge portion, the inlet portion being coupled to the proximate opening, the outlet portion coupled to the aspirator opening and the discharge portion adapted to being coupled to a collecting element. The stopcock is used for directing the flow of material from curette tube to aspirator in a first and normal position, the discharge portion being blocked in this position, and for directing the flow of removed material between aspirator and discharge portion in a second and discharge position.

For a better understanding of the present invention, together with other and future objects thereof, reference is made to the following description, the scope of the invention being set forth in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 illustrates a partially sectioned elevation view of the present invention.

FIG. 2 illustrates a cross sectional view of a two-way stopcock of the present invention in one position of its use.

FIG. 3 illustrates a cross sectional view of the two-stopcock of the present invention in another position of its use.

DESCRIPTION AND OPERATION OF THE APPARATUS

Referring first to FIG. 1, shown there is the over-all hand operated suction curettage instrument of the present invention. The instrument comprises in its basic form, two parts, the curette tube 10 and the hand-operated suction device or aspirator 20.

The curette tube 10 is a hollow, scoop-like tube substantially cylindrical in shape having a distal opening 11 at one end and adapted to be connected to the aspirator 20 at the opposite end. The distal opening 11 is angular and of relatively substantial size. More specifically, opening 11 essentially represents the intersection of an imaginary plane at a steep angle with the cylindrical tube. The end of the distal portion 12 of the tube 10 is intended to be inserted into the uterus of the patient with opening 11 juxtaposed to the fetus. The end of the distal portion 12 forms a slight angle elbow 13 with the end of a proximate portion 14, thereby more or less following the shape of the vaginal and uterine portions of the female body. Proximate portion 14 also has a proximate opening 14a at the end thereof remote from the distal portion 12.

Along the straight part of the proximate portion 14 of the tube 10 but close to the elbow 13 may be inscribed a series of calibration marks 15. As shown in FIG. 1, these calibration marks are indicated as 7 cm-10 cm which represents the measured length of the tube 10.

In a simplified form of the present invention, the curette tube 10 may be directly connected to the aspirator 20 without the use of a stopcock arrangement, which will be described in greater detail below. In this form, the proximate end of the tube 10 is coupled to the aspirator 20 by a hermetically sealed connector 18, such as a connector known commercially as a Luer-Lock. Such connection may be a threaded one, wherein the tube is screwed together with the aspirator at connection 18.

The aspirator 20 is a typical piston-type syringe having a plunger or piston portion 21 and a cylinder portion 22. At the head 23 of the plunger portion 21 is fastened a narrow cylindrical elastic element 23 typically made of rubber. Head 23 must intimately contact the internal walls of cylinder 22 to form a hermetical seal regardless of the position of the plunger portion 21. The cylinder portion 22 may include flanges 24 at the end of cylinder 22 to improve its ability to be held during use.

The aspirator 20 and curette tube 10 may be constructed of a disposable plastic, such as polyethylene or polypropylene.

In this form of the invention, the tube 10 may be also made integral with the aspirator 20 in a one-piece arrangement. This would represent a most economical and easily disposable form of the invention.

In the case of this form of the invention, the plunger 21 is first pushed forward and the distal end of the curette tube 10 is inserted into the uterus after anesthetizing the patient with other general or local anesthesia and the cervical opening is dilated. In the very early stages of pregnancy, a local anesthetic will likely suffice.

The aspiration system is used by first pushing the plunger 21 forward and inserting the curette tube 10 in the vaginal uterine tract.

The opening 11 of the tube 10 is juxtaposed to the fetal tissue to be removed. The plunger or piston 21 of the aspirator is then pulled back (no further than the cylinder end), creating a sufficient partial vacuum to fill up the cylinder 22 by suction. A 35cc or 50cc aspirator capacity will be sufficient in most cases. In the stages of pregnancy up to 9 weeks, there will generally

be, at most, two such tissue withdrawals required. In the very early weeks of pregnancy or if a larger (50cc) capacity aspirator is used, one fill up will remove all fetal tissue. After each fill up of the cylinder, the entire unit must be withdrawn from the patient and emptied.

Since a preferred technique is to leave the instrument in place, rather than remove it, to empty its contents, the second form of the invention has been devised. In this arrangement, a two-way stopcock 16 is inserted between the proximate end 14 of the curette tube 10 and the sealed connector 18. Stopcock 16 may be a separate device which may be incorporated between tube 10 and aspirator 20 by another sealed connector 26 and connector 18. Alternatively, the stopcock 16 may be constructed integral with the curette tube 10, thus forming a unitary element.

In either case, the stopcock 16 is incorporated between the curette tube 10 and aspirator 20 and includes a rotatable protusion 17 for moving the stopcock between positions. The stopcock 16 also includes an exit tube 30 that is coupled to collecting tube 19 by a hermetically sealed connector 27 for discharging the removed tissue into collecting bottle 34.

In FIGS. 2 and 3, the two positions of the stopcock are shown in cross section. Referring to FIG. 2, the stopcock includes a fixed collar 25 which retains and supports the movable central portion 31. Central portion 31 includes a through duct 28 which passes diametrically through the central portion 31. At right angles to the through duct 28, within the central portion 31 and communicating with duct 28, is a duct 29 of radial length. Collar 25 has openings 35, 36, 37 in line with the tube portions 32 and 33 and exit tube 30. In the normal connection of the stopcock 16 shown in FIG. 2, the removed tissue enters tube portion 32, passes through collar opening 35, through duct 28, out of collar opening 36, and into tube exit portion 33. Tube portion 33 leads to the aspirator 20. In this position, duct 29 leads to a blind exit and the opening 37 is blocked by the central portion 31 to prevent any material from entering there.

It is preferred that the stopcock ducts 28 and 29 be of similar diameter to that of the curette tube 10 in order that the capacity of the system be unimpaired and to prevent clogging of the stopcock 16.

On the discharge position shown in FIG. 3, the movable central portion 31 is rotated counterclockwise 90 degrees from the normal position. Collar opening 35 is now blocked and duct 28 faces collar opening 37 which feeds exit tube 30. Duct 29 faces collar opening 36 which feeds tube portion 33. In this position, the fluid which had been extracted and temporarily stored in the aspirator, is emptied so that the fluid enters tube portion 33, flows through duct 29 and through a portion of duct 28 into exit tube 30 and connection 19 to the collecting bottle. This direction of fluid is indicated by an arrow in FIG. 3.

The aspiration system, which includes the stopcock 16 is better adapted for later stage pregnancies (but generally less than 9 weeks), since the amount of material to be removed is greater. The use of the stopcock 16 obviates any need to remove the curette tube 10 once it has been inserted until all the fetal matter has been withdrawn. This significantly simplifies the operation.

In use, the plunger 21 is pushed forward and the curette tube 10 is inserted into the vaginal uterine tract, with the opening 11 juxtaposed to the fetus. The stopcock 16 would ordinarily be in the normal position as in FIG. 2. As before, the patient usually has been given a general or local anesthetic. After insertion and alignment of the curette tube 10, the plunger 21 is pulled back and the tissue removed, so as to fill up the aspirator 20. In this form of the invention, adapted to later stage pregnancies, the 50cc aspirator capacity is preferred. Once filled, the curette tube 10 is left in place, the stopcock 16 rotated to the discharge position (FIG. 3), and the plunger pressed downward. The collected material passes from the aspirator 20 to the collecting bottle. The stopcock 16 is then returned to the normal position and the process repeated until all the fetal material is removed.

The curette tube 10 is to be constructed of predetermined, outside diameter which will vary depending on the stage of pregnancy. A range of diameters of 7 to 10mm will cover the range of pregnancies up to about 2 1/2 months. The following table indicates the suggested diameter tube according to the stage of pregnancy.

Diameter Size	Stage of Pregnancy
7-8mm	0-4 weeks
8-9mm	4-6 weeks
9-10mm	6-9 weeks

Although the above chart is a preferred range of tube diameters versus pregnancy stage, this chart is merely an example of typical ranges and specific cases may warrant a choice of diameter size outside of these specified values. A particular tube is chosen depending on the amount of fetal material to be removed and the dilation required.

As the table indicates, the earlier the pregnancy, the smaller the dilation and the smaller the size of the curette tube generally necessary to empty it.

As has been described above, the present invention provides a safe, portable and disposable apparatus for manually performing abortions of early uterine gestations. The apparatus and method is specifically adapted for use in a doctor's office as opposed to a hospital and, accordingly, offers a significant economy in such instruments and therefore in the ultimate cost of early abortions. (The instrument may, of course, be used in a hospital if desired, since it also offers additional advantages over presently available in-hospital systems in terms of increased sensitivity, flexibility, and control.)

While there have been described what are believed to be the preferred embodiments of the present invention, many variations and modifications will be obvious to those of ordinary skill in the art and it is intended to cover all such changes and modifications as fall within the true spirit and scope of the present invention.

I claim:

1. Apparatus for the manual removal of fetal tissue

during early uterine gestations comprising:

an elongated curette tube having a distal portion and a proximate portion, said tube having a distal opening at the end of said distal portion and a proximate opening at the end of said proximate portion, said proximate end and said distal end forming an angle slightly less than 180° substantially corresponding to the angle of the vaginal uterine tract of a human female, said curette tube distal portion adapted to be inserted in the vaginal uterine tract of a pregnant female;

a manually operated aspirator having a cylindrical portion and a plunger portion, said aspirator having an opening at one end, said plunger portion disposed within said cylindrical portion and forming a hermetic seal therewith, said plunger adapted for linear movement within said cylindrical portion;

and a manually operated stopcock capable of being used in one of two operable positions, said stopcock disposed between said curette tube and said aspirator, said stopcock having an inlet portion, an outlet portion and a discharge portion, said inlet portion being coupled to said proximate opening, said outlet portion coupled to said aspirator opening and said discharge portion adapted to be coupled to a collecting element, said stopcock for directing the flow of material from curette tube to aspirator in a first and normal position, the discharge portion being blocked in this position, and for directing the flow of removed material between aspirator and discharge portion in a second and discharge position, whereby said apparatus is adapted to create a suction at said distal opening of said curette tube by linear movement of said plunger in one direction to draw material through said distal opening into said aspirator when said stopcock is in said normal position and to discharge material collected in said aspirator by linear movement of said plunger in an opposite direction when said stopcock is in said discharge position.

2. Apparatus as described in claim 1 wherein said curette tube, stopcock, and aspirator are constructed primarily of plastic and the entire apparatus is disposable after use.

3. Apparatus as described in claim 1 wherein said curette tube is disconnectable from said stopcock and said stopcock is disconnectable from said aspirator.

4. Apparatus as described in claim 3, wherein said curette tube has a predetermined diameter size of 7 to 8 mm for pregnancies up to 4 weeks duration, of 8 to 9 mm for pregnancies from 4 to 6 weeks duration, and 9 to 10 mm for pregnancies from 6 to 12 weeks duration.

5. Apparatus as described in claim 4 wherein said distal opening is substantially oval in shape.

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