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[54] **UTERINE ASPIRATION COLLECTION BAG**

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

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[58] **Field of Search** ..... 220/63, 65, 63 R; 128/275, 276

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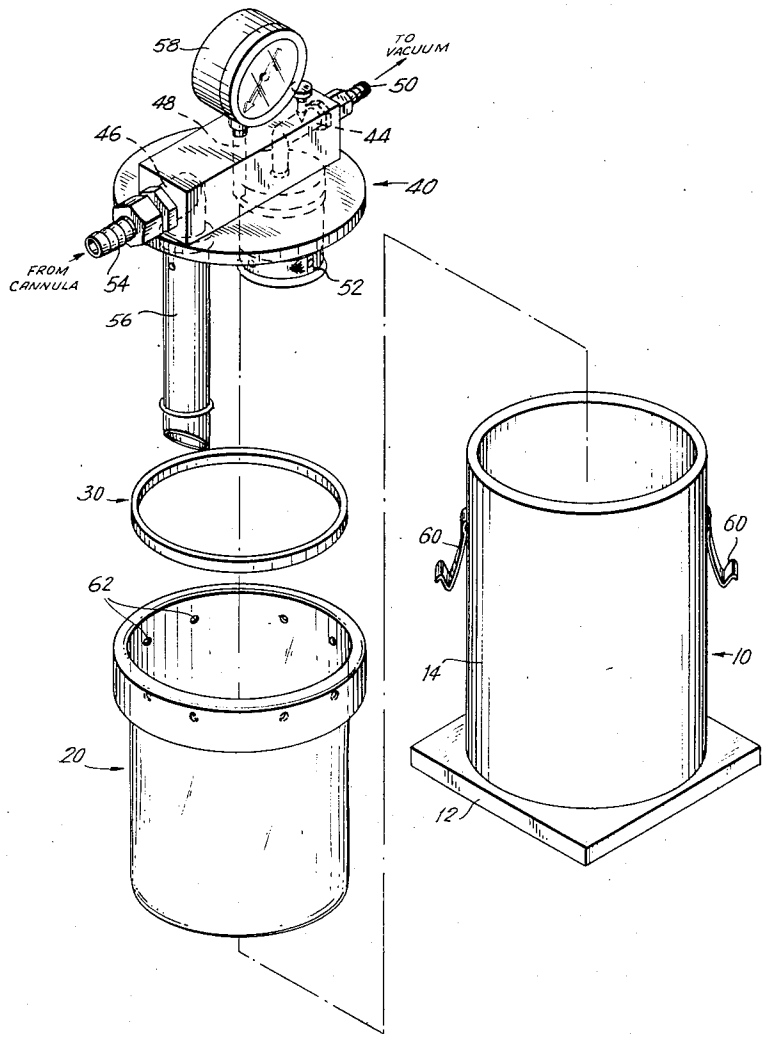
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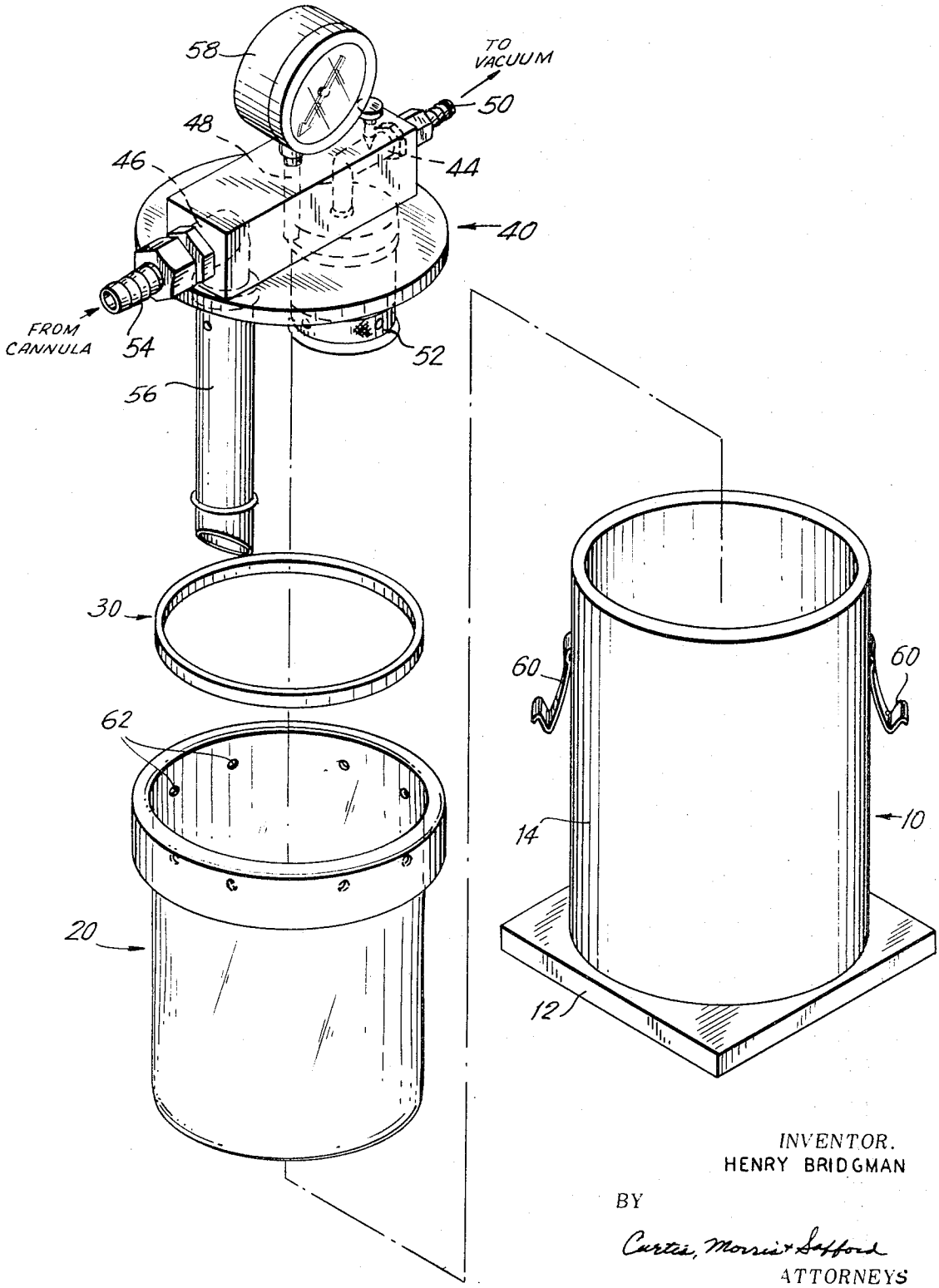
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[57] **ABSTRACT**

In a uterine aspiration apparatus, a plastic collection bag is used inside a single rigid collection bottle. The bag is of a design that it does not collapse when the aspiration vacuum is applied to the bottle. The bag collects the produces of the operation and thus (1) keeps the rigid bottle clean for the next operation, and (2) conveniently stores the aspirated material for future laboratory analysis or recording purposes.

6 Claims, 1 Drawing Figure





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UTERINE ASPIRATION COLLECTION BAG

This invention relates generally to medical equipment and particularly to equipment used in uterine aspiration. This application is a continuation-in-part of my copending application entitled Collection Bottle, Ser. No. 63,480, filed on Aug. 13, 1970, now U.S. Pat. No. 3,713,444.

Within the past 15 years, a technique called uterine aspiration, or vacuum curettage, has been developed for performing abortions during the early months of pregnancy. The earliest reference to this technique appeared in an article by Y. T. Wu and H. C. Wu, entitled "Suction in Artifical Abortion — 300 Cases" in the *Chinese Journal of Obstetrics and Gynecology*, Vol. 6, 1958, beginning at page 447. A recent survey of the subject appeared in an article by D. Kerslake and D. Casey entitled "Abortion Induced by Means of Uterine Aspirator" in *Obstetrics and Gynecology*, Vol. 30. July 1967, pages 35 – 45. Very briefly the technique is to aspirate the conceptus from the uterus using a tube which has a flexible connection to a source of suction. A typical apparatus includes a suction curet having an oval mount at its end, or on one side, and an air hole at the other end to control the suction. A rubber pressure tubing connects the curet to a transparent, e.g., glass, container which in turn is connected to a suction pump. Aspiration of the uterine contents usually takes less than 2 minutes and the debris can readily be seen as it appears in the glass container.

The method employed may be very briefly reviewed. The perineum, vagina and cervix are disinfected. The cervix is then drawn forward with a vulsella. The direction of the cervical canal and the depth of the uterine cavity are determined with a uterine sound. It is a common practice to dilate the cervix to allow easy insertion of the suction curet. However, dilation may be unnecessary in certain cases, and when not needed, an anesthesia generally is not used. When dilation is required, a local or general anesthesia is administered. The suction curet of appropriate diameter and design is inserted carefully into the cervix. The suction is then started. In a few seconds, the suction reaches a working level which typically is at a mean level of 18 inches of mercury (relative). THe suction curet is moved gently up and down over all aspects of the uterine cavity. The debris from the conceptus passes visibly into the glass container, either whole or piecemeal. The degree of suction can be controlled with some aspirators by putting a thumb over an airhole at the base of the curet as well as by using some device on the pump. During the aspiration process, the uterus reacts by contracting and decreasing in volume. Aspiration usually takes less than 2 minutes. It is thought to be complete when the uterine wall feels smooth and no further debris emerge.

A typical apparatus used for uterine aspiration consists of a curet connected by a hose to a collection bottle which in turn is connected by a second hose to a vacuum pump. The collection bottle, with the traditional glass collection jar, presents certain disadvantages, during both the operation and the normal post-operative procedures. These include: performing a fetal count; cleaning the collection jars; handling, storing, transporting and disposing of the aspirated matter; and avoiding contamination of the removed material when certain subsequent testing, etc., is indicated.

Immediately after the surgeon has completed the vacuum curettage, and before the patient is permitted to proceed to the recovery room, an examination is made of the fetal parts to assure their complete removal. With the traditional collection jar, it is difficult by direct observation through the glass to make this fetal part count aNd it is generally necessary to open the bottle and spread out its solid contents. This count is sometimes facilitated by the use of a porus gauze bag in the collection bottle which separates the solid and liquid material. The bottle is opened, the gauze bag removed, after which the fetal count is performed on a cloth. It is preferable to count the fetal parts in a liquid than in a semi-dry environment; yet when it is attempted to count the parts in the traditional collection jar, it becomes difficult to segregate the uncounted parts from those already counted. The count has to be done accurately and rapidly; because if parts are unaccounted for, the surgeon must continue the operation until all parts are removed. These difficulties associated with performing the fetal count are eliminated with the apparatus of the present invention.

In addition to the fetal count, the aspirated material is also subject to post-operative examinations (e.g., laboratory, pathology, etc.) which are normally done at locations remote from the operating theatre. For these analyses it is important that there be a minimum chance of contamination, or other interaction between the removed material and the environment. Since most of the removed material is blood, it reacts almost immediately with oxygen in the air, and is therefore desirable for laboratory testing purposes that the removed products of conception have minimum exposure to the environment before they are tested. Heretofore, the collection bottle was opened, the contents were poured into a container, which was then sealed, and sent out to the laboratory area for analysis. In certain instances, the laboratory was not scheduled to perform the necessary tests when the specimens arrived and it then became necessary for laboratory to store the material which was done typically by freezing. The placing of the material into a container for freezing often required a further undesirable transfer of the material into a new container.

The post-operative handling of the collected material, and cleaning of the collection bottle itself is a distasteful time consuming chore. The uterine contents, aspirated from a patient in the early stages of pregnancy, have a consistency resembling fish entrails accompanied by some blood and other fluids. Heretofore, the bottles had to be, almost always, emptied and cleaned manually. This was a very unpleasant task.

An additional consideration about the collected products of conception, centers on the fact that this material has a very high hormone content. It is often necessary to transfer and store this material because of its hormone content (e.g., to extract the hormone material for use in studies, or in the preparation of certain drugs having a hormone content.) Thus, for this further consideration, it becomes important that the aspirated material be collected with a minimum handling, and not be exposed to the environment more than absolutely necessary, and be held in a container that can be readily transported, stored, and in which is not fragile.

A solution to these and other requirements is provided by the present invention in which an hermetically tight collection bag is employed inside the collection

bottle. Aspirated uterine contents are deposited in the collection bag only, and do not come into contact with the inside of the collection jar itself. It has been found that because of the vacuum inside the collection bottle, extending between the vacuum source and the curet, a special bag is needed. This bag does not collapse under the influence of the vacuum. In particular, the pressures in the space between the collection bag and the collection jar must be equalized. If provision is not made to equalize pressure around the collection bag, the bag may become sucked into the vacuum source thereby preventing the entire vacuum curettage apparatus from functioning, and also possibly damaging the passageway leading from the vacuum source, or even the vacuum source itself.

By using the collection bag of this invention, it is possible to collect the aspirated products of conception completely in a liquid tight collection bag proportional in size to the collection bottle. At the end of an operation, the collection bottle is opened, and the collection bag having all the aspirated material is merely lifted out of the bottle. The bag is then tied or otherwise fastened to seal it with the aspirated material completely contained therein. The fetal count may be easily and rapidly performed when the material is in the collection bag, by appropriately squeezing the bag to move the solid material as needed. The bag, of course, is of a transparent material.

The further advantages of such a collection bag are numerous. The immediate one is in post operative clean-up routine. Since the liquid tight collection bag is inside the rigid collection jar, the jar has had no contact with the aspirated material, and is kept completely clean. This avoids an unpleasant and time consuming cleaning procedure. Furthermore, if a group of operations are to be performed in sequence, a single uterine aspiration apparatus may be used with a single bottle (and a stand by bottle or two) while merely changing the collection bag for each operation. Formerly it was necessary to have several collection bottles. This permits the uterine aspiration apparatus to be used almost continuously. Furthermore, when the aspirated material is to be transferred to a laboratory for further testing, or to another remote location, it may be easily transported in the collection bag itself. A collection jar, thus, is not needed to transfer the material. It will also be appreciated that when the material is to be sent to a laboratory, the rapid closing of the bag tends to inhibit contamination of the contents. Furthermore, the bag is preferably of such a material that the products of aspiration can be stored in the bag for a period of time, either at room temperature, or in a freezer. THe collection bag preferably is made of a material of sufficient toughness that, should it when full and sealed, be accidentially dropped, it will not burst, and spill its contents. Finally, when the contents of the bag are not required, the bag may serve as a convenient disposal container.

The above, and other objects, features and advantages of this invention, will become apparent in the following detailed description of an illustrative embodiment thereof, which is to be read in connection with the accompanying drawing wherein:

The FIGURE is an exploded three dimensional view of a collection bottle having a collection bag which is constructed in accordance with this invention.

Referring now to the FIGURE, there is shown a collection bottle having a collection jar **10** with a base **12** and side walls **14.** A collection bag **20** is to be placed in collection jar **10,** with the upper portion of the bag overlying, or folded over, the top of the jar walls. A gasket **30** is to be positioned over the upper rim of the side walls **14** of the collection jar, on top of the overlying portion of the collection bag. Above the gasket is a cap generally indicated **40.** A manifold **42** is mounted on the upper portion of the cap and has three apertures or ports, **44, 46,** and **48** extending through the manifold and the cap. The first port **44** provides a passage between a source of vacuum (not shown) and the inside of the collection bottle. A hose insert coupling **50** is at the outer end of the port, and a filter trap **52** at its inside end. The second port **46,** provides a passage between a hose (not shown) to be connected to the operating curet and the inside of the bottle. It includes on its outer end, a hose insert coupling **54** which is adapted to be connected to the hose (not shown), and at its inner end a dip tube **56** extending downward from the inside of the cap. The dip tube **56** directs the aspirated material during the course of the operation into the lower portion of the collection bag **20.** The third port **48** in the manifold and cap is connected to a vacuum gauge **58** that provides an indication of the vacuum inside the collection bottle when it is in operation. A more detailed description of the collection bottle and its parts is in my copending patent application cited above.

As indicated in FIG. **1,** the collection bottle is assembled by first placing the collection bag **20** inside the collection jar **10.** The gasket **30** is then placed on top of that portion of the collection bag **20** which overlies the upper rim of the collection jar **10.** The lid, which may have an inner flange (not shown) to properly center it on the gasket and collection jar is then placed on top of the gasket and two, (shown schematically) lock-down clips **60** on each side of the collection jar are used for securing the cap, gasket, and jar together. As the operation is to commence, a vacuum is drawn at port **44,** and as the operation progresses, the aspirated material enters through port **46** and accumulates in the bottom of the collection bag **20.**

The collection jar, collection bag, gasket and cap are all assembled and sealed prior to drawing the vacuum. When the vacuum is applied, it is important that the air pressure between the outside walls of the collection bag **20** and the bottom and side walls of the collection jar **10** are equal. If they are not equal, and the pressure on the outside of the bag (i.e., between the bag and the inside wall of the jar) is greater than the pressure on the inside of the bag, the bag will move away from the bottom and sides of the jar; and as the vacuum increases, the bag may be sucked into the vacuum port **44,** effectively clogging the vacuum source and cutting off the vacuum in the bottle. If only a small quantity of air is trapped between the collection jar and the collection bag, the bag is not sucked into port **44,** but the trapped air creates a bubble between the jar and bag. This reduces the collection capacity of the bottle, and increases the chance of collected material clogging the trap **52** or being carried over into the vacuum source if there is no trap. More important, however, volume of the trapped bubble fluctuates as the vacuum inside the collection bag varies (as it will during the normal course of an operation). This change in volume moves

the surface of the collection bag and as the operation progresses, and material is introduced into the collection bag, the bag will shift and move around. Thus, it is essential that the air pressure on both sides of that portion of the collection bag which is inside the collection bottle be substantially equal when the vacuum is initially turned on, and throughout the operation.

To achieve this end, of providing equal pressure on both sides of the collection bag, a series of apertures **62** are provided in the upper portion of the side walls of the collection bag **20.** These apertures permit the air on both sides of the bag to be maintained at a substantially constant pressure. If air is initially between the collection bag and the collection jar, as is usually the situation, it is removed when the vacuum is applied since the air can escape by passing through these apertures. As the collection bag starts to fill up, any remaining air caught inbetween the bag and the jar is squeezed upward and passes through these apertures **62.** Thus, by means of the apertures **62,** the collection bag stays in place during the course of the operation.

The location of the apertures **62** should be near the upper inside portion of the bottle. The apertures should be sufficiently high that the collected material will not rise above them, and spill through them onto the inside of the jar. The collection bottle is preferably of sufficient size to permit a bag of sufficient length, such that after the operation, the upper portion of the bag may be twisted around and knotted below the line of the apertures, to secure the bag and to confine its contents. It should be appreciated, however, that it is not essential that the bag be knotted on itself, and any suitable fastening means may be used, such as squeezing the upper portion of the bag together (of course this takes place below the line of apertures) and attaching a fastener, such as tape, or a non-cutting wire twist member to secure the bag shut.

In the bag, the vent holes **62** are located (1) high enough to prevent loss of the evacuated material, (2) yet low enough to clear the gasket and cap and also, (3) at a position to allow equalization of pressure. A typical size for the collection bag is about 2 liters volume below the vents.

Thus, there has been shown and described a collection bag for use in a collection bottle of a uterine aspiration apparatus. The bag, remains substantially in place lining the collection jar throughout the operation and collects the aspirated uterine material, and any flush liquids. When the operation is complete the bag may be lifted out; if necessary a fetal count may be performed by observing the contents through the walls of the bag without removing the material from the bag. The bag may then be tied off below the perferations, and thereby conveniently store the material for future transportation, laboratory analysis, recording, etc. It will be noted that the rigid collection jar itself has been kept completely clean.

A collection bag has been constructed in accordance with this invention and the following dimensions for that bag are set foth below. It should be understood however, that these dimensions are for purposes of example only, and variations may be made therefrom without departing from the spirit or scope of the invention:

bag length: 14 inches;
vent holes, measured from the bottom of the bag: 9½ inches;
bag width measured flat: 9 inches;
vent hole diameter: ¼ inch;
total number of vent holes per bag: eight;
distance between adjacent vent holes: 2¼ inches;
bag material, clear polyethylene;
bag wall thickness 1½ to 2 mils;
lower bottom portion of bag, heat sealed.

Although an illustrative embodiment of this invention has been described in detail herein with reference to the accompanying drawing, it is to be understood that the invention is not limited to that precise embodiment, and that various changes and modifications may be effected therein by one skilled in the art without departing from the scope or spirit of the invention.

What I claim is:

1. In a uterine aspiration system having a collection jar, cap means for sealing said jar, and vacuum means for producing a negative pressure in said sealed jar, the improvement comprising a collection bag having dimensions to fit inside said jar adjacent the inside jar walls, and to overlap at least the top of said jar along a seal between said jar and said cap means; said bag including appertures extending through its wall and positioned from its bottom so that the volume of said bag from its bottom to said appertures is sufficient to contain material aspirated by the system; said appertures permitting equalization of air pressure between the inside of said bag and the space between said bag and the walls of said jar during the production of negative pressure by said vacuum means, whereby no significant amount of air is entrapped between said bag and said walls of said jar which entrapped air would limit the capacity of said bag or might cause said bag to be sucked into said vacuum means.

2. In the system according to claim **1** wherein said bag volume exceeds 1 liter.

3. In the system according to claim **1** wherein said collection bag is transparent, whereby the aspirated material can be examined in the bag itself.

4. In a system according to claim **3,** wherein said collection bag is a clear polyethylene.

5. In a system according to claim **1,** wherein said appertures are one-quarter inch in diameter.

6. In a system according to claim **1,** wherein said bag wall has a thickness of 1½ to 2 mils.

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