ABSTRACT: An intrauterine washing device including an inlet and an outlet tube in adjacent relationship with their forward end portions adapted to be inserted into the uterus. The tubes are open at their rear ends and have a plurality of openings in their forward end portions. Adjustable sealing means is positioned on the tubes so that when the forward end portions of the tubes are inserted into the uterus, the sealing means may be positioned so as to seal the entrance to the uterus. A connector is mounted on the rear end of at least one of the tubes and is associated with the rear end of the other tube. Means are positioned on the connector for mounting a source of washing fluid thereon in communication with the rear end of the inlet tube. Additionally, means are positioned on the connector for mounting a source of suction thereon in communication with the rear end of the outlet tube. In this manner, when suction is applied to the device sealed in position with respect to the uterus a negative pressure will be provided in the uterus and washing fluid will flow from a connected source of washing fluid through said inlet tube and into the uterus through the openings in the forward end portion of the inlet tube. Cells and other matter will be accumulated from the uterus and will enter the outlet tube with the washing fluid through the openings in the forward end portion of the outlet tube and will continue to pass through the length of the tube for collection at the rear end thereof.
INTRAUTERINE WASHING APPARATUS

BACKGROUND OF THE INVENTION

Previous to the advent of the negative pressure jet washer, in the field of diagnosing various types of intrauterine cancer as endometrial carcinoma in its early stages, the known methods for obtaining cells for diagnosis were not entirely satisfactory. There was a considerable need for an improved diagnostic device which would greatly improve the results. The jet washer of the type employed as a part of the combination of this invention has satisfactorily satisfied the deficiency in the medical field.

Routine vaginal and cervical smears are unsatisfactory for use in detecting endometrial carcinoma due to the fact that the endometrium does not exfoliate as readily as the cervix uteri or vagina. Accordingly, the number of cells reaching the vaginal pool is relatively small and the cells themselves frequently degenerate whereby the whole sample is heavily diluted by material from the cervix and vagina.

Various devices other than the negative pressure jet washer have been proposed to increase the efficiency of the test for endometrial carcinoma, such as the introduction of the sterile saline solution under pressure. This procedure has been found to be unsatisfactory due principally to the fact that diseased cells are often forced into other cavities, such as the Fallopian tubes thereby spreading disease to other parts of the body. Additionally, rotary brush units have been employed, however, such units are unsatisfactory since they are difficult to sterilize and a possibility also exists that bristles will break off during the sampling process thereby cause irritation and inflammation to the interior parts of the patient.

From the above, it is apparent that there was a need in the art for the provision of an intrauterine sampling device which will produce a sufficient and desirable amount of cell tissue for effective diagnosis. The solution to this need is the jet washer of the type disclosed in the combination of this invention. The jet washer avoids the problem of possible irritation of the inner parts of the patient and in particular the problems coexistent with many painful procedures of examination. In this manner, the necessity of an anesthetic is eliminated thereby allowing the doctor to simply obtain a sample in his office quickly and efficiently. Naturally, as discussed above, it also satisfies the need of providing a sample of washing device which would alleviate the danger of cells being washed to other parts of the body such as out the Fallopian tubes.

Another existent problem which is alleviated by the jet washer occurs when devices are utilized and inserted into the uterus and that there is a danger of the device being inserted too far so that it will pierce the uterus wall causing serious internal damage to the patient. With the jet washer it is possible to have an adjustable device whereby the distance it extends into the uterus can be regulated for a particular different size or shape uterus.

It should also be kept in mind that although the washer has use in intrauterine diagnosis, particularly for the use of diagnosing endometrial carcinoma as described herein for exemplary purposes, it is possible to adapt the device for many other uses such as in the lungs. In a similar manner, a sampling of tissue may be removed from the lungs for testing purposes. Furthermore, the washer may be used for radiation therapy in which radiopaque dye may be irrigated through the uterus. Also, this device as well may be used as a means for introducing therapeutic medicament in that the application of the fluid is localized.

As is known in the art, the negative pressure washing device employs adjacent inlet and outlet tubes open at both ends and insertable into the uterus. Sealing means is provided on the tubes to seal the entrance to the uterus. The rear end of one of the tubes is connected to a source of washing fluid and the rear end of the other of the tubes is connected to a source of suction, the uterus will be provided with a negative pressure and washing fluid will pass from the fluid source through the inlet tube, circulate through the uterus collecting cells and other matter therefrom and pass through the outlet tube for collection.

With this type of washing apparatus for irrigating the uterus under negative pressure within the uterus, a highly desirable amount of cell tissue can be collected therefrom for analysis while minimizing the danger of malignant material entering the other body passages. Furthermore, the apparatus may be easily and painlessly used in the doctor's office without the necessity of administering anesthetic to the patient while still obtaining an improved sample of tissue for further diagnostic processes. Furthermore, the washer is adjustable so as to properly fit the uterus into which it is inserted to avoid the danger of damage to the patient. The apparatus is economic to produce, efficient to use and is disposable after a single use. It should also be noted that the outer surface of the end portions of the tubes inserted into the uterine wall is roughened so that, if desired, additional matter may be collected by a slight scraping action as the device is inserted or removed from the uterus.

As stated above, this type of jet washing type of apparatus has proven to be at least as successful as any other known method for obtaining the most uniform type of cell sampling from the interior of the uterus. Continuous use of the negative pressure jet washer has produced the development in order to use the washer effectively and efficiently, the assistance of a second person is required to hold the inlet tube submerged in a container of liquid at its rear end while the physician taking the sample connects the source of suction generally a syringe to the rear end of the outlet tube and applies the suction force to perform the lavage. It would certainly be an additional improvement to the art to provide an effective means for coupling the washing device to the source of fluid and to the suction source so that a single physician may independently conduct the entire sample taking procedure. Furthermore, it would be an additional advantage if he independently, may then use the same group of elements to transfer the collected sample to the ultimate container which will be used to transfer the sample to the area utilized for testing purposes. With the development of a structure of this type, the need of the second person or the assistant is eliminated and the washing device and combined structure can be utilized as efficiently and effectively as the presently known negative pressure washing device is utilized by two persons acting in cooperation.

SUMMARY OF THE INVENTION

Along the primary objectives of the invention is to provide a jet washing device which employs the advantages of the well known intrauterine washing device as well as providing means for incorporating the washing structure, the source of fluid, and the source of suction into one interconnected assembly so as to enable the one person to perform the lavage and collect a sample without the necessity of assistance from another person. Additionally, the structure of this invention provides means for facilitating the transfer of the collected sample into the retention container for shipment to the area where it will be subjected to a variety of tests. Additionally, this invention provides a more aseptic means for handling the washing fluid and the collected sample during the entire washing operation than the technique previously known in the art.

In summary, an intrauterine washing apparatus is provided which includes an inlet tube and an outlet tube in adjacent relationship with the forward end portions of the tubes being adapted to be inserted into the uterus. The tubes are open at the rear end and have a plurality of openings in their forward end portions. Adjustable sealing means are positioned on the tube so that when the forward end portions are inserted into the uterus the fluid is supplied in such a manner as to seal the entrance to the uterus. A connector is mounted on the rear end of at least one of the tubes and is associated with the rear end of the other tube. Means are positioned on the connector for mounting a source of washing fluid thereon in communication with the rear end of the inlet tube. Means are also posi-
tioned on the connector for mounting a source of suction thereon in communication with the rear end of the outlet tube. In this manner, when suction is applied to the device in sealed position with respect to the uterus, a negative pressure will be provided in the uterus and washing fluid will flow from a connected source of washing fluid through the inlet tube and into the uterus. It will pass through the openings in the forward end portion of the inlet tube, accumulate cells and matter from the uterus and enter the outlet tube through the openings in the forward end portion of that tube. It will then pass through the outlet tube for collection at the rear end thereof.

Other objects and advantages will become apparent from the following detailed description which is to be taken in conjunction with the accompanying drawing illustrating several preferred embodiments of this invention.

BRIEF DESCRIPTION OF THE INVENTION

With the foregoing in mind, reference is made to the accompanying drawing in which:

FIG. 1 is a perspective view of a commercial type kit incorporating the invention along with the elements which may be utilized with the invention to carry out a complete sampling procedure;

FIG. 2 is a perspective view of the apparatus of the kit of FIG. 1 in assembled position with the forward portion of the washing apparatus inserted within the uterus in sample taking position with arrows showing the direction of flow;

FIG. 3 is a perspective view of elements of the commercial kit of FIG. 1 in interconnected relationship for the process of transferring a collected sample to a container for shipment;

FIG. 4 is a top plan view of the connector portion of the device of the invention with the remainder of the device broken away and removed;

FIG. 4A is a side elevation view of a capped collection container.

FIG. 5 is a bottom view thereof.

FIG. 6 is a sectional elevation view thereof taken along the plane of line 6—6 of FIG. 4.

FIG. 7 is a sectional elevational view thereof taken along the plane of line 7—7 of FIG. 4.

FIG. 8 is a sectional elevation view thereof taken along the plane of line 8—8 of FIG. 4.

FIG. 9 is a partially sectional elevation view of an alternate embodiment of the device of the invention shown in combination with a source of suction, a source of washing fluid, and a collection container;

FIG. 10 is a side elevation view of a capped collection container which may be utilized with the device of this invention;

FIG. 11 is a partially sectional side elevation view of a second alternate embodiment of the device of this invention shown in combination with source of suction, a source of washing fluid, and a collection container;

FIG. 12 is a fragmentary sectional elevation view of a portion of the connector part of the second alternate embodiment;

FIG. 13 is a side elevation view of a capped collection container with a sample contained therein for shipment for testing and with a central portion of the container having been broken away and removed;

FIG. 14 is a partially sectional elevation view of a third alternate embodiment of the invention shown in combination with a source of suction, a source of washing fluid, and a collection container;

FIG. 15 is a fragmentary sectional view of the connector portion of the embodiment of FIG. 14; and

FIG. 16 is an elevational view of a capped collection container containing a sample ready for shipment for testing purposes with a central portion of the container having been broken away and removed.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 is illustrative of a typical commercial package 20 of elements which may be utilized to carry out a washing procedure either by a physician in his office or in a hospital with all of the elements being disposable after collection and ultimate testing of the collected sample. As shown in FIG. 1, the elements may be all mounted to a mounting board 21 by means of a formed flexible plastic transparent cover 22 which may be bound to the board in any common manner such as adhesive bonding. A package such as package 20 is commonly formed by a vacuum-forming process whereby the flexible plastic cover 22 is drawn into sealing contact with the backing board 21 and in surrounding relationship with each of the elements being packaged so as to retain these elements in sealed position within the finished package 20.

Packaged within kit or package 20 is an intraterine washing device 23, a common type of plastic disposable syringe 24 which may function as a suction source and a temporary collection container, and a common type of plastic disposable sample container which may be used for ultimate shipment of the collecting sample as well as being adaptable for various ultimate testing procedures such as centrifugation. The collection container 25 has a cap 26 positioned thereon in sealed relationship when it is contained within the package 20. Cap 26 is naturally removable to permit access to the interior of tube 25 so that a sample may be positioned therein.

Consequently, package 20 represents all of the elements which a physician would need to carry out a washing procedure with the exception of the washing fluid itself. When it is desirable to take an actual washing, the package 20 is opened and the various elements are removed for assembly. As shown in FIGS. 1 and 2, device 23 includes an inlet tube 27, and outlet tube 28, a sealing means 29, and a connector 30.

As previously discussed, collection container 25 contains a removable cap 26 which is interengaged with tube 25 by means of threads on the exterior surface of the upper portion of tube 25. After cap 26 has been removed from container 25, the threads on the upper portion of container 25 interengage with a mating surface on the interior portion of connector 25 so that connector 30 is then in threaded interengagement with container 25.

Syringe 24 includes a barrel portion 31 and a plunger and stopper assembly 32 slidably mounted within the barrel. Syringe 24 is a common type of plastic disposable syringe.

The forward reduced portion 33 of barrel 31 has a threaded inner surface which interengages with projection 34 on the rear rim of cylindrical tube portion 35 of connector 30. Projections 34 are tapered so as to engage with the threaded inner surface of reduced ed portion 33 in an interlocking fashion to positively retain syringe 24 in connection relationship with connector 30 and consequently washing device 23. The engagement between syringe 24 and tube portion 35 is additionally assisted by the female luer taper on portion 35 and the corresponding male luer taper on syringe 24. Cylindrical portion 35 is hollow and therefore permits communication with the interior of barrel 31 through the forward opening in syringe 24.

Connector 30 consists primarily of a disc-shaped top surface or base 36 with a depending sidewall or skirt 37 so as to approximate the basic shape of a cap. A tubular shaped projection or dome 38 extends from the upper surface or base 36 across the entire diameter of connector 30 and is also integrally connected with the rear tubular projection 35. The major portion of projection 38 is open on its undersurface. The remaining small portion 39 is closed on its entire circumference and is integral and in communication with rear cylindrical portion 35.

Between cylindrical portions 39 and 35 which form the tube retention cylinder or sleeve, there is a small ring 39 mounted therein to separate portion 39 from portion 35 and to provide a smaller diameter opening then present in either of the two
portions. Ring 35° provides a seat for the rear surface of tube 28.

Tube 28 is cemented into cylindrical retention sleeve or member 39. Other types of common interengagement means between tubular concentric cylinders will naturally adequately suffice here also. As previously discussed, ring 35° acts as a seat or stop to prevent tube 28 from projecting into sleeve or cylindrical projection 35. As discussed above, projection 35 has a female luer taper and along with the projection 34 assures a positive retention when reduced portion 33 of syringe 24 is attached.

The inner surface of depending side wall 37 has threads 40 thereon, the purpose of which will be discussed in detail below. Additionally, on the exterior surface of skirt 37 of connector 30, there are ribs 48 to facilitate gaining a more secure grip on connector 30 when assembling and disassembling the apparatus. Skirt 37 is interrupted at diametrically opposed points on the circumference to form a pair of vertical openings 41 and 42 which form projection 38.

Connector 30 also includes a vertical tubular prong 42' which has a passage therethrough for communication with the undersurface of the connector 30.

Connector 30 is mounted on washer 23 with the rear end portion of tube 28 extending into the sleeve formed by the combination of cylindrical portion 39 and rear cylindrical portion of tube 28. Tube 28 is held in position by a frictional or cemented interengagement between the inner surface of the sleeve portion of connector 30 and the outer surface of tube 28 or any other common bonding means.

Inlet tube 27 is of a smaller diameter than outlet tube 28 and is attached to the forward and intermediate portions of tube 28. The rear portion 43 of smaller diameter inlet tube 27 is free from movement with respect to tube 28 and extends a predetermined distance to the rear end of tube 28. Since both tubes are of a flexible material, the rear portion of tube 27 may be bent away from adjacent alignment with tube 28 and, in fact, may be bent to at least a 90° angle with respect to the axis of tube 28 as shown in FIG. 1. Since tube 27 extends rearwardly of the rear end of tube 28, it will pass through openings 41 and 42 and extend to the rear of the washing device 23. This makes packaging of the product much simpler as well as enabling tube 27 to be deformed so as to extend into container 25 in the manner described above. Naturally, in preferred use all components are packaged and sterilized and the package should allow aseptic removal of each component.

As shown in FIG. 2, when the various elements in kit 20 are assembled for operation, initially kit 20 is opened and cap 26 is removed from tube 25. A common type of washing fluid, such as a saline solution is then poured into container 25 to a desired level. Tube 25 may be externally marked with a volumetric scale. Tube 25 with saline solution therein is then brought into communication with the washing device 23 and the rear free end portion 43 of tube 27 is then bent to an approximate right angle position with respect to the axis of the remainder of tubes 27 and 28 and extended into tube 28 so that the open rear tip of tube 27 is positioned within the saline solution. Openings 41 and 42 permit freedom of movement for rear portion 43 of tube 27 so that it may be deformed as indicated.

Tube 25 is then engaged with connector 30 by means of the threaded outer surface of tube 25 and threads 40 on the skirt portion 37 of connector 30. This threaded interengagement positively positions tube 25 with respect to the washing device 23.

Syringe 24 is then interengaged with rear portion 35 on connector 30 by means of the interengagement between stud 34 and the threaded surface on the interior reduced portion 33 of syringe barrel 31 in a luerlike fashion. At this point, washing device 23 is in fixed connection with a source of washing fluid contained within tube 25 and a source of vacuum represented by syringe 24. The apparatus is therefore in condition for taking of a sample.

The normal procedure is then followed for taking an intrauterine washing sample with a jet washer of this type. Initially, the uterus of the particular patient is sounded to determine its size and shape of the uterus. Adjustable sealing member 29 is then positioned with respect to the tip portion of tubes 27 and 28 to assure that the tip portions extend the desired amount into the uterus and do not come in contact with or pierce any of the interuterine walls causing damage to the patient. As previously discussed, sealing member 29 is adjustable with respect to the tubes in that it is in a sliding frictional engagement with the outer surface of tubes 27 and 28 to facilitate its movement. Sealing member 29 is formed of a common resilient impervious material to facilitate its introduction and sealing engagement it is formed in an arrow-shaped configuration. A material such as rubber has been found to be adequate for use as sealing member 29.

Subsequent to the sounding operation, the tip portion of washer 23 is extended into the uterus until sealing member 29 seals the entrance of the uterus by coming into contact and sealing engagement with the walls of the cervix. As previously discussed, this operation is substantially painless to the patient and requires no anesthetic of any type. Furthermore, since both the source of suction and source of fluid are interconnected with the washer, there is no need for more than one doctor or person to be present to handle all of the necessary apparatus for the taking of a washing. It should be kept in mind that connection of the source of suction can be made subsequent to insertion of washer 23 within the uterus. The sequence of operations is a matter of preference.

With washer 23 properly inserted into the uterus and connected to a source of washing fluid in tube 25 to a source of suction in the form of syringe 24, a sample may now be taken. As shown in FIG. 2, the arrows represent the path of flow of the washing fluid and the movement of plunger 32 of syringe 24 to initiate movement of the washing fluid and collection of the sample. As plunger 32 is withdrawn as shown, air is withdrawn from tube 28, the interior of the uterus 44 and tube 27 thereby bringing the interior of the uterus to a condition of negative pressure.

As shown, the washing fluid is then drawn by the vacuum created from tube 25 into the rear opening of tube 27 and through tube 27 and out of the forward end portion thereof through small openings 45. The fluid then washes against the walls of the uterus and enters the larger and more plentiful openings 46 in the forward end portion of outlet tube 28 along with accumulated cell samples from the interior of the uterus and passes through tube 28 into syringe barrel 31 for initial collection. In this manner, the desired amount of washing fluid is transferred from tube 25 through the uterus and into barrel 31 with the accumulated cell and tissue matter from the interior of the uterus.

The device is held securely during taking of a sample either by holding container 25 or by the syringe barrel 31 with one hand while plunger 32 is pulled back with the other hand.

It should be noted that outlet tube 28 is of considerably larger diameter than inlet tube 27 and that the holes 46 in the tip of outlet tube are larger than the openings 45 in the tip of inlet tube and additionally are more plentiful. This gives an effective suction or outlet area which is significantly greater than the effective inlet area as represented by the total of all of the openings in the outlet and inlet tubes. In this manner, the uterus is constantly under negative pressure which facilitates the prevention of fluid filling up the uterus and extending into other body passages such as the Fallopian tubes 47 which could cause spread of diseased tissue to other portions of the body.

The negative pressure within the uterus due to the increased suction area also facilitates the action of the washing fluid as it enters the uterus through openings 45. It has been found with the shown arrangement of holes that the fluid will exit from openings 46 at substantially right angles to the axis of inlet tube 27 so as to directly contact the adjacent walls of the
uterus in the form of a spray. This spray action serves to loosen tissue from the walls of the uterus and facilitates collection of an effective cross sectional sample from the interior of the uterus walls. The fluid coming out of openings 45 in the form of a spray then circulates through the uterus in contact with the walls thereof and is drawn into openings 46 of outlet tube 28 and passes into barrel 31 of syringe 24 with accumu-
lated cell tissue and other matter. In this manner, a particularly effective sampling of cell tissue from the interior of the uterus is obtained and collected within syringe 24 along with the washing fluid from tube 25.

The next step in the sequence of operations is to remove the apparatus including washer 23 from the uterus once again without pain or discomfort to the patient either during sampling or removal of the device from the uterus and then to disconnect syringe 24 from connector 30 with the sample still being contained within barrel 31 of syringe 24. The forward reduced portion 33 of syringe 24 is then positioned on cylin-
drical prong 42 so that the opening therein is in communication with the opening in syringe barrel 31 at the forward end thereof and then plunger 32 is depressed to transfer the collected sample from barrel 31 into tube 25. FIG. 3 of the drawing shows this step in the sequence of operations with the arrow showing the direction of travel of the plunger of syringe 24 and the direction of flow of the washing fluid and sample from barrel 31 into tube 25.

Tube 25 is then threadedly disengaged from connector 30 and cap 26 is threadedly interengaged therewith to seal container 26a with the collected sample. This tube is then shipped to whatever laboratory desired for ultimate testing of the sample. All of the components of the assembly including the source of suction and the source of fluid are disposable after use. Common plastic materials have been found to work satisfactorily for construction of the various components. It should also be kept in mind that connector 30 makes possible the entire sequence of operations from initial connection to the ultimate collection of the sample without the necessity of nonconnected elements so that one doctor or operator may carry out the entire sampling procedure quickly and efficiently without the necessity of an additional person being present to assist.

To assist in assuring that proper flow occurs within the uterus from initiation of the suction means until ultimate collection of the sample within syringe barrel 31, at least one primer hole is positioned between the interconnected forward portions of the tubes 27 and 28 to initiate flow between those tubes and the forward tips of tube 27 and 28 have openings therein to also direct additional flow into the uterus between tubes 27 and 28.

When connector 30 is removed from tube 25 after collection of the sample, naturally the rear portion 43 of tube 2 also is removed from tube 25 thereby permitting complete disassociation of tube 25 from washer 23 and to permit the ultimate capping of tube 25 for transmittal to a laboratory for testing.

An alternate embodiment is depicted in FIGS. 9 and 10. The flow characteristics in regard to the inlet and outlet tubes and through the uterus and the method of inserting the washer into the uterus and taking a sample is identical in this embodiment as described in regard to the initially discussed embodiment of this disclosure and applies equally as well to the additional two embodiments described below.

For operation of washer 23a with its connector means, the following elements are utilized and interconnected in order to carry out a sampling process. A wash solution container 25a and a specimen collection container 49a are utilized with each container having a threaded upper outer surface portion for interengagement with the connector portion 30a of the washer 23a. Both containers 25a and 49a are similar in construction to container 25 utilized in connection with the above discussed embodiment.

The washer includes an inlet tube 27a, an outlet tube 28a and the adjustable acorn-shaped rubber sealing means 29a. These elements are substantially identical to the correspond-

ing elements of the above discussed embodiment. However, the difference in structure of washer 23a from washer 23 lies in connector 30a. Connector 30a has a base portion and two threaded cylindrical recesses in its undersurface so that the threaded upper end portions of containers 25a and 49a respectively in threaded interengagement. Connector 30a has an opening in its upper surface to receive the rear end portion of inlet tube 27a in alignment with one of the recesses so that the rear end portion of inlet tube 27a can pass therethrough and come into communication with washed solution container 25a to receive the washing fluid. Similarly, connector 30a has a passage in its upper surface in communication with the other recess in its undersurface so that the rear end portion of outlet tube 28a can extend therethrough and into communication with the interior of collection container 49a. Tubes 27a and 28a are permanently affixed to connector 30a in that the tubes are cemented in position respectively within openings 50a and 51a in connector 30a. An attachment may be accomplished in a similar manner as utilized in regard to the tube and connector connection of the above discussed initial embodiment.

A negative pressure application tube 52a passes through another opening 53a in the upper surface of connector 30a and is aligned so as to be in communication with the interior of collection tube 49a when it is connected to connector 30a. Tube 52a is mounted in opening 53a similar to the manner in which tubes 27a and 28a are mounted to the connector. At the opposite end of tube 52a is adapter 54a designed to receive and connect to the forward end of the syringe 24a so that there is communication between the interior of tube 52a and the interior of syringe 24a. Connector 30a also contains a vent in its upper surface which is positioned so as to permit com-
munication from the atmosphere to the interior of a washing solution container 25a mounted to connector 30a. This facilitates natural flow of the fluid through the system during operation and collection of the sample.

Operation may once again be accomplished by a single doctor or operator and is initiated by attachment of tubes 25a and 49a to connector 30a and additionally the connection of syringe 24a to adapter 54a. The washer is then properly positioned within the uterus and the plunger 32a is withdrawn so as to provide the negative pressure in the uterus and the system. Washed solution travels up through tube 27a into the uterus and then is drawn therefrom through outlet tube 28a with the collected cellular material into collection container 49a. After an adequate sample has been collected, the instrument is removed from the uterus and the collection container 49a is unscrewed from the connector 30a and a spare cap 26a is applied to it for transport to the laboratory. The remainder of the equipment would be normally discarded.

A second alternate embodiment is illustrated in FIGS. 11-13. Once again there is an inlet tube 27b, an outlet tube 28b, and adjustable sealing member 29b and a connector member 30b. Operation of members 27b, 28b and 29b including fluid flow through the tubes is identical to that described in respect to the above first two discussed embodiments. The difference in this embodiment lies in the connector member 30b which is of a molded plastic or similar material.

Connector 30b is adapted to receive a standard commercial type of diaphragm sealed prefilled wash solution vial of known volume 56b. Additionally, a standard type of transport centri
guge specimen collection container 49b is also receivable on connector 30b as well as syringe 24b. Connector 30b contains an inlet passage 57b passing therethrough which is open at two positions on the surface of connector 30b. The rear end of inlet tube 27b is mounted in one opening of passage 57b, the other end portion of passage 57b extends through spike 59b which is adapted to penetrate the diaphragm in vial 56b to per-
mit communication between the solution within the vial 56b and passage 57b and consequently inlet tube 27b.

A second passage 60b separated from passage 57b in con-
ector 30b extends through spike 59b into communication with the interior of vial 56b when the diaphragm on the for-
ward end thereof is punctured by spike 59b. The other end of
opening 60b communicates with the atmosphere. In this manner, passage 60b forms an atmospheric vest for vial or container 56b so that the solution therefrom may adequately serve as a washing solution for the system. A third passageway is illustrated as passageway 58b which is open at two positions on the surface of connector 30b. Outlet tube 28b is mounted in one end of passage 58b to provide communication between the interior of outlet tube 28b and passageway 58b. The other end of passage 58b is open to the interior of a collection container 49b frictionally mounted on connector 30b. A seal ring or gasket 61b is provided in recess on the exterior surface of connector 30b to form a seal with the interior surface of collection container 49b in frictional engagement with connector 30b.

The fourth passageway passing through connector 30b and open at two positions on the surface of connector is passageway 62b. This passageway is open on one end to the interior of a collection container 49b mounted to connector 30b and communicates at the other end with an adapter 63b extending from the adjacent side face of connector 30b. The adapter is adapted to receive syringe 24b so that the interior of the syringe barrel is in communication with passage 62b.

In operation, in performing a washing procedure, the diaphragm of a standard wash solution vial 56b which usually contains saline or sterile water is forced down over the diaphragm 32b, supporting spike 35b containing the solution delivery orifice or passageway 57b and vent orifice or passageway 60b and is firmly seated thereon. An empty specimen collection container 49b is force fitted onto connector 30b on the opposite face thereof. Adjustable rubber stopper 29b is then set at the most desirable distance from the forward tip of the washing apparatus.

A negative pressure source such as syringe 24b is then attached to adapter 63b. The doctor or operator would then introduce and seat the apparatus properly within the uterus until stopper 29b forms a seal in the cervical os. Syringe barrel 32b is then retracted to apply negative pressure and cause the washing solution to travel through passageway 57b and inlet tube 27b into the uterus. After the solution washes through the uterus it is drawn by the negative pressure into the openings in the forward end of outlet tube 28b and return through outlet tube 28b into passageway 58b and connector 30b and ultimately into collection container 49b. After an adequate sample has been collected the instrument is removed from the uterus and the specimen collection container is removed from the connector 30b and a cap 26b is applied to it to seal it for transport to the laboratory for ultimate testing purposes. The remainder of equipment is generally discarded.

A fourth embodiment is disclosed in FIGS. 14–16. In this embodiment, the washing device 23c includes substantially all of the same elements as in the previous embodiment including inlet tube 27c, outlet tube 28c and sealing means 29c. The difference in structure from the previous embodiment once again lies in connector 30c. The sequence of the washing operation from the point of passage of fluid through inlet tube 27c to the passage of fluid and collection sample out through outlet tube 28c is the same as that discussed in regard to the previously considered embodiment.

However, connector 30c is of a somewhat different structure and operates slightly differently in its adaptability to the source of washing fluid and the source of suction to be utilized in the washing operation.

Initially it should be pointed out that the rear end of inlet tube 27c is mounted in passage 63c in connector 30c. Passage 63c communicates with the exterior of connector 30c at two positions on its outer surface. Similarly, outlet tube 28c is mounted in one open end of passageway 64c which communicates with the exterior of connector 30c at two positions on its outer surface. The method of mounting tubes 27c and 28c within passages 63c and 64c are the same as that which may be employed to mount the inlet and outlet tubes in the connector of the previous embodiments. As discussed, this may be accomplished in a common manner such as by cementing the end portions of the tubes within the passageways. In any event, communication is provided between the respective passageways and the tubes mounted therein. A third passageway is also provided in connector 30c and communicates with the exterior of the connector 30c at separate positions. An adapter 66c having a passage therethrough is mounted by any common means within passage 65c at one open end thereof and the adapter 66c is designed to receive a source of suction such as syringe 24c so that the interior of syringe 24c communicates with the passage through adapter 66c and passageway 65c. The other end of passageway 65c is open on connector 30c adjacent to one end of passageways 63c and 64c.

A washing solution delivery tube 67c is mounted in the open end of passageway 63c which is remote from the end of passageway 63c having tube 27c mounted therein. Once again, delivery tube 67c is mounted within passageway 63c in any common well-known manner.

Connector 30c is adapted to receive a collection container 49c in frictional engagement with its exterior surface and in position so that the interior of collection container 49c communicates with passageways 65c and 64c on the surface at which position they are adjacent and open. A sealing ring or gasket 68c is provided in a recess on the surface of connector 30c to assure that an effective seal is provided between collection 49c and connector 30c. A wash solution container is mounted on connector 30c in a frictional or similar type of interengagement and is positioned so that the solution delivery tube 67c extends into wash solution container 69c so that the fluid therein may be drawn up through delivery tube 67c. A vent passageway 70c extends from the exterior of one opposing surface of connector 30c to the exterior of the other opposing surface to provide a passage through the connector and is positioned so that its one end communicates with the atmosphere and the opening at its other end communicates with the interior of wash solution container 69c. In this manner, passageway 70c forms an atmospheric vent to facilitate passage of the washing solution through the system.

As will be noted from the drawing, the exterior diameter of washing solution container 69c is considerably less than the interior diameter of collection container 49c as well as being of lesser length so that the entire washing solution container may be positioned within collection container 49c while still providing additional space therebetween for collection of the sample. As in the previous embodiments, the arrows depict the path of fluid flow during a sampling procedure.

To perform a washing procedure with this embodiment, the wash solution container 69c which could be manufactured prefilled or could be loaded at any time with a preferred amount of wash solution which is usually saline or sterile water is force fitted installed on the nipple or projection 71c on connector 30c. An empty specimen collection container 49c is placed over wash solution container 69c and force fitted onto connector 30c.

The rubber sealing means 29c would be preset a given distance from the end of tubes 27c and 28c for the particular uterus to be sampled as discussed above. A negative pressure source such as syringe 24c is then attached to adapter 66c.

The doctor or operator would then introduce the assembly into the uterus in the proper manner until rubber stopper sealing means 29c forms a seal in the cervical os. He then applies the negative pressure by means of withdrawing plunger 32c of syringe 24c to cause the wash solution to travel up through solution delivery tube 67c, through passageway 65c and connector 30c and through inlet tube 27c into the uterus. After the solution washes through the uterus it is withdrawn by the negative pressure through outlet tube 28c and passageway 64c into collection container 49c. After an adequate sample has been collected the instrument is removed from the uterus and the specimen collection container is discarded. A rubber stopper is applied to it to seal it for transport to the laboratory. Once again, the remainder of the equipment may be discarded if desirable.
Thus the aforementioned objects and advantages are most effectively attained. We claim:

1. An intrauterine washing device comprising: an inlet tube and an outlet tube in adjacent relationship side by side with the forward end portions thereof connected to one another and adapted to be inserted into the uterus; said tubes being open at the rear end and having a plurality of openings spaced longitudinally in the forward portions thereof at least one of the apertures in the forward end of each tube communicating with one another, the area of the apertures in the outlet tube being larger than that of the inlet tube; adjustable sealing means on said tubes so that when said forward end portions are inserted into the uterus said sealing means may be positioned so as to seal the entrance to the uterus; a connector mounted on the rear end of at least one of said tubes and associated with the rear end of the other tube; means on said connector for mounting a source of washing fluid thereon in communication with the rear end of said inlet tube; means on said connector for mounting a source of suction thereon in communication with the rear end of said outlet tube so that when suction is applied to said device sealed in position in the uterus a negative pressure will be provided in the uterus and washing fluid will flow from a connected source of washing fluid through said inlet tube and into the uterus through the openings in the forward end of said inlet tube, accumulate cells and matter from the uterus and enter the outlet tube through the openings in the forward end portion thereof and pass therethrough for collection.

2. The invention in accordance with claim 1 wherein a source of suction is connected to said device.

3. The invention in accordance with claim 1 wherein a source of washing fluid is connected to said device.

4. The invention in accordance with claim 1 wherein said connector includes a disc-shaped base portion having a depending annular skirt extending downwardly therefrom, a pair of diametrically opposed slots vertically positioned on said connector means, a domelike projection extending upwardly from the base of said connector and being in communication with said slots and being open to the undersurface of the base portion of said connector and being open at both ends, a sleeve in alignment and connected to said domelike projection and having a passage therethrough, said outlet tube being mounted in one end of said sleeve and the other end of said sleeve being adapted to receive a source of suction, said slot facilitating positioning of said inlet and outlet tubes with respect to said connector.

5. The invention in accordance with claim 4 wherein the interior surface of said skirt is threaded to facilitate interengagement with the threaded upper portion of a container.

6. The invention in accordance with claim 4 wherein a tubular prong extends upwardly from the base portion of said connector with the passage therethrough facilitating transfer of fluid through the connector into a container attached thereto.

7. The invention in accordance with claim 4 wherein the sleeve extending from said connector has a female luer taper to facilitate connection to a source of suction, and a projection extends upwardly from the rim of said sleeve distal from the base of said connector to facilitate a fixed interengagement between the source of suction and said connector.

8. The invention in accordance with claim 1 wherein said connector includes a base portion having two adjacent cylindrical recesses formed on the undersurface thereof adapted to receive respectively a first container holding a source of washing fluid and a second container for collection of the sample from the uterus, said inlet tube mounted in an opening in said base portion and having its rear end positioned so as to extend into the washing fluid when a container holding washing fluid is mounted on said connector, said outlet tube mounted in an opening in said base portion and positioned so that the rear end thereof extends into the recess adapted to receive and interengage with a collection container, a negative pressure applicator tube mounted in an opening in the base of said connector so that one end portion thereof extends into the recess adapted to interengage with a collection container, the other end portion of said negative pressure applicator tube having an adapter mounted thereon for connection to a source of suction, a vent opening formed in the base portion of said connector for communication between the atmosphere and a container containing washing fluid mounted in the recess provided therefore in the connector.

9. The invention in accordance with claim 1 wherein said connector includes a base portion having a first passageway therethrough with two open ends, one open end of said first passageway in communication with the interior of said inlet tube with said inlet tube being mounted within a portion of said first passageway, the other end of said first passageway being adapted for communication with a source of washing fluid, a second passageway through said base portion having one open end in communication with said outlet tube and having the end portion of said outlet tube mounted in said second passageway, the other end of said second passageway adapted for communication with the interior of a collection container, said base portion having a third passageway therethrough, one open end of said third passageway having an adapter mounted thereon for connection to a source of suction and the other open end of said passageway in communication with a collection container mounted on said connector, a fourth passageway passing through the base portion of said connector and having one end thereof open to the atmosphere and the other end thereof in position for communication with a source of washing fluid mounted on said connector.

10. The invention in accordance with claim 9 wherein a spike having a penetrating end project from the base portion of said connector and is adapted to penetrate the diaphragm of a sealed washing solution container, said first and fourth passageways in the base of said connector extending through said spike and terminating at the penetrating end thereof so that when said spike enters said washing solution container air from the atmosphere may enter said container through said fourth passageway and washing fluid may enter said first passageway and thereafter said inlet tube.

11. The invention in accordance with claim 1 wherein said connector includes a base portion having a first passageway therethrough, one end of said first passageway adapted to communicate with said base portion of said inlet tube mounted therein the other end of said inlet tube mounted therein the other end of said second passageway in position to be in communication with a fluid collection container mounted on said connector, a third passageway in the base portion of said connector, an adapter mounted in one end of said third passageway and having a passage therethrough to permit communication between the interior of said outlet passage and having the rear end of said outlet tube mounted therein the other end of said second passageway in position to be in communication with a fluid collection container mounted on said connector, a fourth passageway in the base of said connector, one end of said fourth passageway open to the atmosphere and the other end of said fourth passageway positioned so as to be in communication with a source of washing fluid mounted on said connector, means on said connector to mount a collection container thereto, said means for mounting a source of washing fluid in position so that said delivery tube is in communication with said washing fluid and said fourth passageway is in direct communication with said washing fluid.