

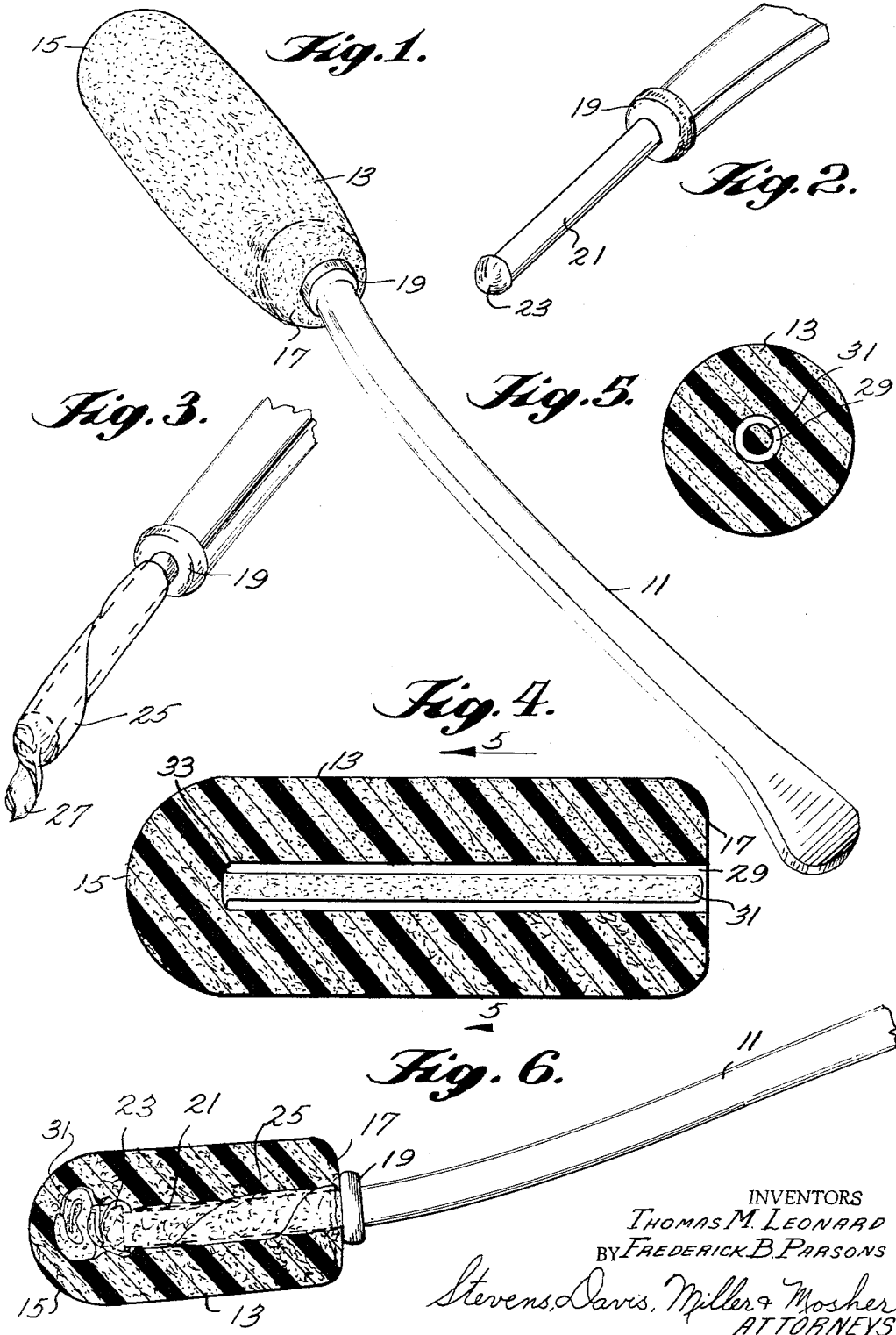
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VAGINAL CLEANSER

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VAGINAL CLEANSER

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This invention relates to surgical instruments and more particularly to a vaginal cleansing instrument.

Anatomically, the vagina is a tube, lined with mucous membrane. To all practical purposes, it is a cul-de-sac, open only at the external end because the cervical os is closed except during labor and is only slightly open during the menstrual flow and a few weeks postpartum. In the nonpregnant woman the cervix will admit only an instrument of very small caliber, about the diameter of an 18-gauge needle. Even with this slim instrument a certain amount of pressure is required to introduce it.

With these facts in mind, it is not illogical to consider the vagina as part of the external part of the body rather than as an internal organ. It can be compared to the umbilicus, the nose, the ear, or simply an indentation in the body, lined with specialized epithelial cells. Normally, the vaginal walls are approximated, though capable of enough distention to pass a fetal head without laceration.

The epithelial cells forming the lining of the vagina are not delicate. Histologic sections show the vaginal epithelium to be thicker than the membrane lining the stomach. The entire lining (except the hymenal ring) is sparsely supplied with sensory nerves, so there is very little sensitivity in the vaginal canal and practically none at the surface of the cervix. The cervix can be grasped by a tenaculum or cauterized without local or general anesthesia.

The normal vaginal secretions arise from Bartholin's glands, Skene's glands, and the cervical glands. In the healthy, normal vagina these secretions are clean, mucoid, and tenacious, and have high lubricating properties. Erotic emotions, whether physically or mentally aroused, tend to increase the flow of these secretions. In addition to the natural moistness of the vagina, there is always present some debris, consisting of desquamating epithelial cells. In many women blood left from menstrual flow and the deposition of seminal fluid also add to the debris found in the normal vagina. Since the vaginal walls are normally approximated, most of this vaginal debris cannot be eliminated even by gravity.

Due to constant body temperature, the largely protein nature of vaginal debris, and the presence of carbohydrate (as glycogen), the vagina makes an excellent incubator for a long list of pathogenic and nonpathogenic bacteria, as well as protozoa and fungi.

It is fortunate that the normal acidity of the vagina exerts an inhibiting effect on the propagation of most pathogens. This acidity does not kill the pathogens but merely restrains their multiplication. These pathogens are always present, ready to form the nucleus of an extensive growth at the first favorable change.

Accordingly the vagina should be kept clean and its cleansing should be a regular part of personal hygiene.

Most gynecologists recommend douches of some kind when vaginal discharge causes the patient to complain of discomfort or embarrassment due to odor, itching, irritation, or other symptoms. Over years of observation it has been amply demonstrated that douches are inadequate as a means of cleansing because there is no scrubbing action. Patients instructed to douche before coming for a vaginal examination often present copious mucoid extraneous material in the folds of the vagina

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and on the cervix. All gynecologists know the necessity of the familiar green-soap cleansing of the vagina before specific treatment. Many times this is necessary before a thorough visual examination can be made.

Normal vaginal hygiene is always desirable, but it is imperative in abnormal vaginal invasion by Monilia, Trichomonas and nonspecific bacterial vaginitis. Here, again ordinary douching is inadequate, regardless of the type of detergent or medication used.

Accordingly, an object of the present invention is to provide an improved instrument for vaginal cleansing.

A further object of the present invention is to provide an instrument for thoroughly cleansing the vagina.

A further object of the present invention is to make possible thorough vaginal cleansing.

These objects are accomplished by the vaginal cleansing instrument of the present invention. The instrument according to the present invention comprises a soft cylindrical sponge made of a polyurethane foam. The sponge, approximately two and one-quarter inches long and seven-eighths of an inch in diameter, is firmly mounted on a curved plastic handle about nine inches long. The instrument can be sterilized by boiling without damage to either the handle or the sponge. It is important that the sponge be mounted on the handle so that there is no danger from the sponge coming loose from the handle even after the instrument has been sterilized by boiling. The sponge is mounted on the handle by wrapping the end of the handle on which the sponge is to be mounted with surgical tape and then applying two coats of glue on the surgical tape. The sponge is provided with an axially extending aperture and the handle is inserted into this aperture after the two coats of glue have been applied. The first coat of glue prevents the second coat of glue from being wiped away from the surface as the handle is inserted in the sponge. The surgical tape provides an ideal surface to which the glue can make a tenacious bond.

The instrument is used by first immersing it in a cleansing germicidal solution which lubricates the sponge. The sponge is then inserted into the vagina and the entire vagina is then cleansed by a gentle rotating motion which is imparted to the sponge by means of the handle. After approximately ten or 15 seconds of this vaginal scrubbing the instrument is withdrawn and the vagina is rinsed with a plain warm water douche. The whole procedure does not add more than one or two minutes to the time devoted to bathing.

It is important that the sponge be so constructed that there is no danger that the handle will poke through the sponge when it is being inserted into the vagina. For this reason the sponge is constructed to have a compressed mass over the end of the handle. This compressed mass adds strength to the sponge and eliminates any danger of the handle poking through the sponge.

Many other advantages and objects of the present invention will become readily apparent as the following detailed description of the invention unfolds and when taken in conjunction with the drawings, wherein:

FIG. 1 is a perspective view of the instrument of the invention;

FIG. 2 is a perspective view of the end of the handle to which the sponge is attached with the sponge removed;

FIG. 3 shows the end of the handle shown in FIG. 2 with the surgical tape wrapped thereon;

FIG. 4 is a sectional view of the sponge before it is mounted on the handle;

FIG. 5 is a cross-sectional view of a sponge shown in FIG. 4 taken along the lines 5-5 in FIG. 4; and

FIG. 6 is a view in partial section illustrating the sponge mounted on the handle in detail.

As shown in FIG. 1, the vaginal cleansing instrument

comprises an elongated plastic handle 11 on which a cylindrical sponge 13 is firmly mounted. The outer end 15 of the sponge is rounded, as is the inner end 17. The sponge 13 abuts against a collar 19 formed on the handle 11 and more clearly shown in FIG. 2. The material of the sponge 13 is polyurethane foam and preferably is a polyester-urethane foam. The material is sufficiently flexible and springy that it can be easily compressed to less than $\frac{1}{2}$ of its volume and it springs quickly back to its original shape. Yet the material has sufficient tensile rigidity that it can be machined at high speeds into the desired shape. This combination of high flexibility and machinability is achieved because the material is partially open celled and partially closed celled. In addition to these advantages the polyurethane foam material has the advantages that it can be repeatedly sterilized by boiling without being damaged, it is not affected by molds or yeasts, and it is strong and will not easily tear.

Extending from the collar 19 is a cylindrical stem 21 and the sponge 13 surrounds the stem 21 and is fixed thereto. The end of the stem 21 is formed into a knob 23. The handle 11 extends away from the sponge 13 initially along the axis of the sponge 13 and then curves gently away from this axis. This shape facilitates the insertion of the instrument to the inner end of the vagina. Prior to mounting the sponge 13 on the stem 21, the stem 21 is wrapped with the surgical tape 25 as illustrated in FIG. 3. A portion of the surgical tape 25 extends over the knob 23 and beyond and is formed into a loose mass 27. After the tape 25 has been applied to the stem 21, a first coating of glue is applied to the tape 25 and allowed to dry. Then a second coating of glue is applied to the first coating of glue, and while the second coating of glue is still wet the sponge 13 is mounted on the stem 21. The sponge 13 is provided with an aperture extending axially from the end 17 of the sponge and the stem 21 with the tape 25 and the two coats of glue is inserted into this aperture so that the sponge 13 seats against the collar 19. The first coat of glue prevents the second coat of glue from being wiped away by the sponge 13 as the stem 21 is inserted into the sponge so that the glue will be distributed over the entire surface of the tape 25. The sponge 13 is then compressed around the stem 21 so that the glue bonds the sponge 13 to the taped stem 21 to securely fix it thereto.

As shown in FIGS. 4 and 5, the aperture in the sponge 13 into which the stem 21 is inserted is designated by the reference number 29. This aperture 29 is formed so that a central axially positioned tongue 31 of polyurethane foam is left in the center of the aperture 29. Prior to the insertion of the stem 21, the polyurethane tongue 31 is compressed and bunched together up at the inner end 33 of the aperture 29, as illustrated in FIG. 6. Then when the stem 21 is inserted into the aperture 29, the mass 27 also operate to prevent the stem 21 from being compressed tongue 31, together with the soft mass 27 will provide a reinforced structure preventing the stem 21 from being pushed through the sponge 13 when it is being used. The compressed tongue 31 and the taped mass 27 also operate to prevent the stem 21 from being inadvertently pushed through the sponge 13 when the stem 21 is being inserted into the aperture 29 in the assembly of the sponge 13 on the handle 11. In the assembled instrument, as illustrated in FIG. 6, the sponge 13 is so securely bonded to the stem 21 that it is virtually impossible to pull the sponge 13 off of the stem 21; in fact the sponge 13 will rupture before the bond between the sponge 13 and the stem 21 will be broken. This tenacity with which the sponge 13 is mounted on the stem 21 is not diminished when the instrument is sterilized by boiling.

As shown in FIG. 6 the diameter of the taped stem 21 is about $\frac{1}{3}$ the diameter of the sponge 17. Because the polyurethane foam material 13 easily compresses to a

small part of its uncompressed volume, the sponge 13 can be easily compressed around the stem 21 to a little more than a third of its normal diameter.

The instrument is used by first immersing the sponge 13 in a cleansing solution which in its concentrated form consists of a 26% solution of alkylamine lauryl sulphate to which 2% by volume of hexachlorophene is added. The alkylamine lauryl sulphate is a detergent widely used in dentifrices and soap substitutes. The hexachlorophene is a well recognized germicide. The cleansing solution into which the sponge 13 is immersed is made from the concentrated solution by adding a few drops of the concentrated solution to a small quantity of warm water. The sponge 13 is then completely immersed into this diluted solution. The sponge 13 is then inserted into the vagina and the entire vagina is cleansed by a gentle rotating motion imparted to the sponge 13 by the handle 11. The polyurethane foam material becomes slippery when it has the cleansing solution applied thereto and this fact, together with the fact that the polyurethane sponge material is easily compressed to a much smaller volume, makes it very easy to insert the sponge into the vagina.

Polyurethane was selected for the sponge 13 because it is a good sponge in that it holds a lot of water, it compresses easily to a much smaller volume yet it returns immediately to its original shape after it is compressed, it is not effected by molds or yeast, it can be repeatedly boiled without being damaged, it is strong and will not easily tear yet it machines relatively easily so that the desired shape can be obtained without too much difficulty.

The instrument of the invention has been used experimentally on 200 patients to determine its effectiveness. Each patient was examined vaginally and the general appearance and history of discharge and discomfort noted. Only patients with a vaginal discharge sufficient to soil the clothing were included. Before beginning treatment, a hanging drop specimen from each patient was examined for *Trichomonas vaginalis*. A monilia culture was taken in 154 cases. Papanicolaou smears were made in 100 cases. Bacterial examination (Gram stains) were made in 20 cases.

All patients were examined at weekly intervals while they continued the daily vaginal cleansing at home.

RESULTS OF TESTS

Monilia cultures

Total number of patients	154
1st week, number positive	44
2nd week, number positive	16
3rd week, number positive	11

The 11 positive cases in the third week of treatment included six pregnant women and one diabetic.

*Trichomonas vaginitis**

Total number of patients	200
1st week, number positive	*16
2nd week, number positive	1
3rd week, number positive	0

*Vaginal swabbing was supplemented with a sulfa-base vaginal cream in three cases.

Gram smears

Before treatment all 20 patients showed a low count of Doderlein bacilli and an abnormally high count of other bacteria and pus cells. After treatment all showed an increase of Doderlein bacilli and a great decrease of other bacteria.

Papanicolaou smears

Papanicolaou smears showed very interesting changes after this cleansing method. The smears taken after a period of cleansing were easier to interpret because of the absence of pus and other extraneous material. In the 100 smears taken before cleansing, only one was re-

ported as Class I (no infection). After a minimal period of one week's cleansing 50 percent were reported as Class I (no infection). In this short series two Papanicolaou smears that had been reported as Class II were changed to Class III when the smears were repeated after a period of cleansing. The cytologist stated that the first smears contained so many pus cells that the abnormal epithelial cells could not be seen. This suggests that a period of routine cleansing is desirable before a smear is made.

Patients cooperated very well. Few complained of difficulty in performing the daily hygienic measure. After two or three experiences most women accepted vaginal cleansing as routinely as a daily bath. Discomfort or irritation occasionally reported was found to be the result of improper technique.

These observations lead to the belief that almost all women need to clean the vagina by some mechanical scrubbing action. Failure to observe vaginal hygiene is strongly suspected of promoting the propagation of the various invaders that cause vaginitis and chronic cervicitis.

The scrubbing method was also applied to patients who were being prepared for vaginal or abdominal surgery. The absence of postoperative vaginal infections and fever in these women suggests that cleansing the vagina before surgery will decrease postoperative morbidity. The possibility of decreasing recurring cystitis by mechanical vaginal cleansing is another avenue of promise for investigation.

The mechanical vaginal cleansing made possible by the present invention is a valuable aid in the treatment of vaginitis and cervicitis caused by *Trichomonas*, *Monilia* and nonspecific bacteria. When specific medication, such as sulfa creams, seems advisable, the medication can be applied on retiring and the vagina cleansed in the morning, avoiding the discomfort to the patient of wearing a pad during the day. The same routine with mycostatic preparations may also be followed.

Vaginal "scrubbing" shortens the time any medication is necessary. In some cases specific therapy is not needed.

When properly presented, mechanical cleansing is well accepted by patients, insuring good patient cooperation. "Scrubbing" is especially beneficial immediately following menstruation.

Mechanical cleansing as described here should be practiced during pregnancy because of the increased vaginal secretions at that time.

No harmful or undesirable effects were observed or reported in the experimented use.

The safe mechanical aid to vaginal cleansing provided by the present invention is a valuable addition to methods of treatment, the prevention of vaginal infections, and the elimination of physiologic leukorrhea. Objective observations strongly indicate that regular, proper use of this method will prove highly beneficial. Studies clearly indicate that *Trichomonas* and *Monilia* will not grow in a clean vagina.

The above description is of a preferred embodiment of the invention and many modifications may be made thereto without departing from the spirit and scope of the invention.

What is claimed is:

1. A vaginal cleansing instrument comprising an elongated handle formed into a stem at one end, a cylindrical sponge adapted to be inserted into and having a size and

shape to fit within the vagina surrounding said stem and fixed to said stem, the cylindrical surface of said sponge conforming to the surface traced by one side of a rectangle revolved about the parallel side as an axis an integral compressed mass of said sponge separate from the main body of said sponge being permanently formed internally within said sponge, attached to the main body of said sponge at one point, and positioned over the end of and adjacent to said stem, the portion of said sponge adjacent the external surface of said sponge being uncompressed.

2. A vaginal cleansing instrument comprising a plastic handle formed into a stem at one end, an adhesive tape wrapped around and secured to said stem, a sponge surrounding said stem and said tape and glued to said tape, said sponge being adapted to be inserted into and having a size and shape to fit within the vagina.

3. A vaginal cleansing instrument as recited in claim 2 wherein said tape extends over the end of said stem to comprise a soft mass bonded to said sponge by said glue.

4. A vaginal cleansing instrument as recited in claim 3 wherein said sponge has a compressed mass permanently formed internally within said sponge over said soft mass of tape and bonded to said mass of tape, the portion of said sponge adjacent the external surface of said sponge being uncompressed.

5. A vaginal cleansing instrument comprising a sponge having an elongated aperture defined therein with a tongue of the material of said sponge extending when in its uncompressed state axially along said aperture from the inner end of said aperture, said tongue being permanently compressed at the inner end of said aperture to define a compressed mass of said sponge at said inner end of said aperture, a handle inserted into said aperture and means bonding said sponge to said handle within said aperture, said sponge being adapted to be inserted into and having a size and shape to fit within the vagina.

6. A method of mounting a sponge on the handle of a surgical cleansing instrument comprising the steps of: forming an aperture in said sponge to fit around a stem of said handle, covering said stem with adhesive tape, then applying a first coat of glue over said tape and allowing said first coat of glue to dry, then after said first coat of glue is dry applying a second coat of glue over said first coat of glue, then while said second coat of glue is still wet inserting said stem into said aperture, and then compressing said sponge around said stem.

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