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[54] METHOD AND APPARATUS FOR AIDING IN THE DETECTION OF BREAST CANCER

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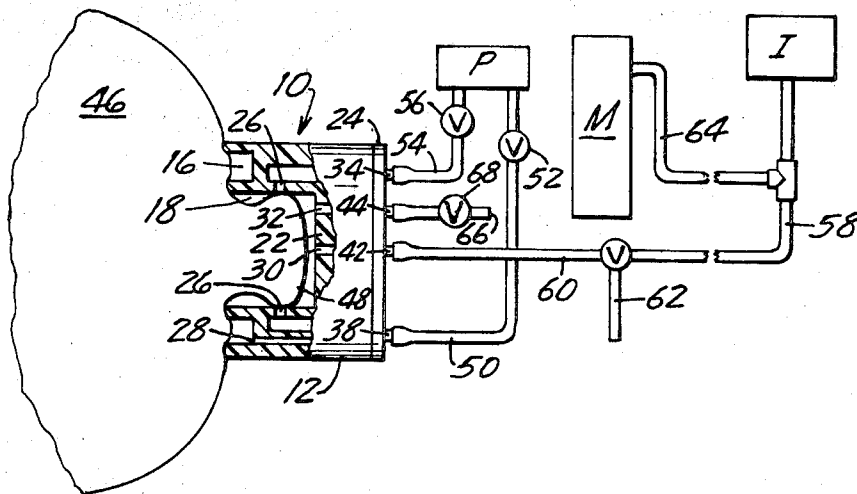
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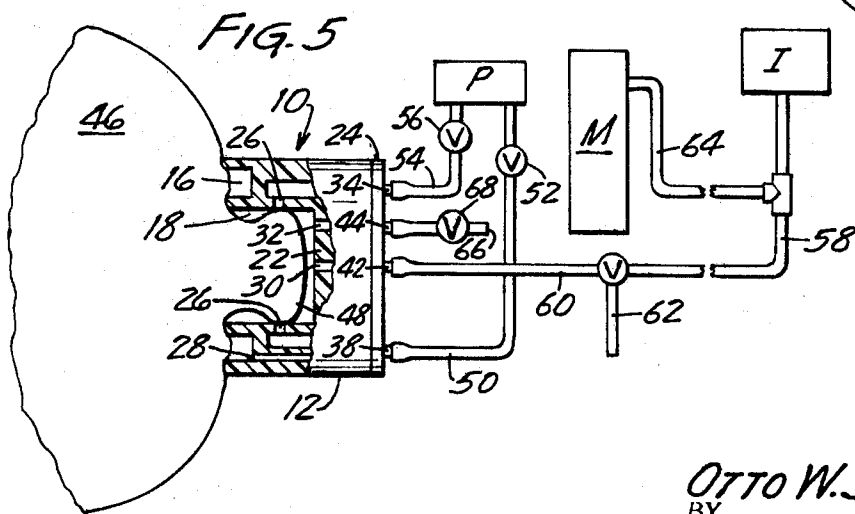
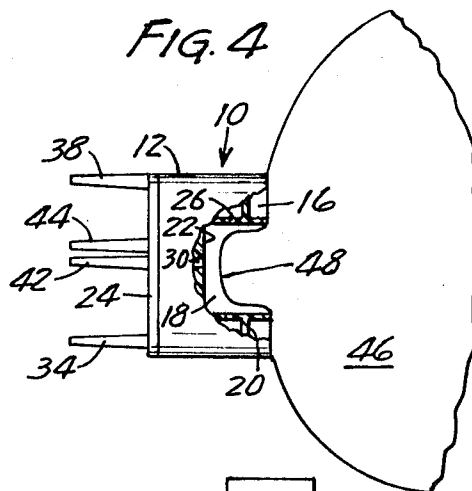
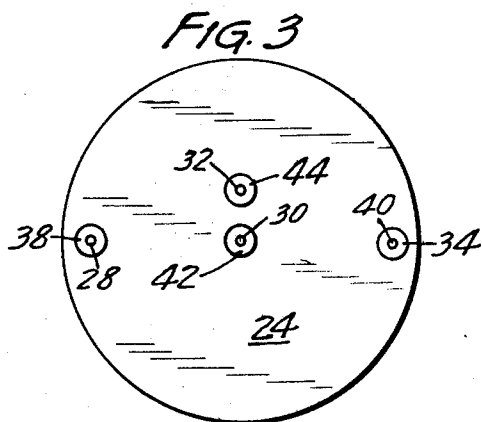
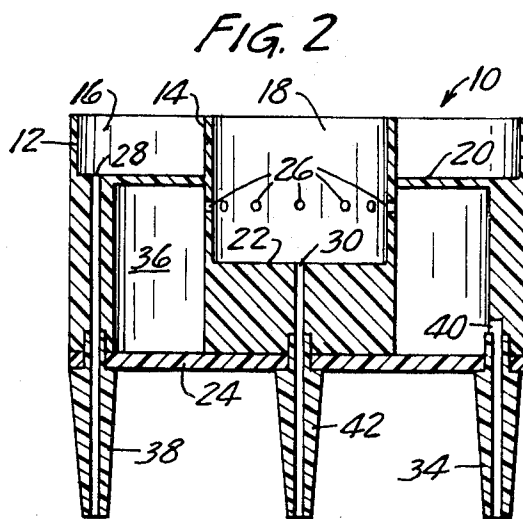
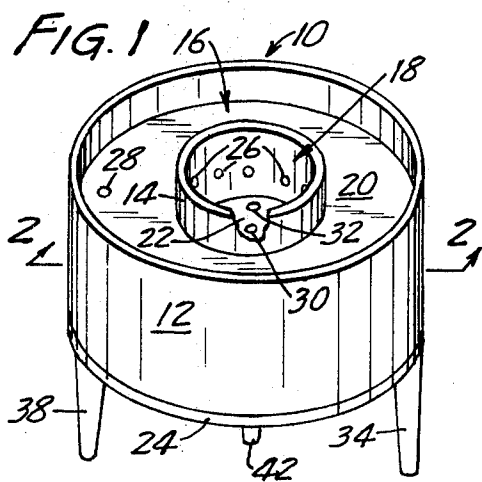
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ABSTRACT: An apparatus is provided for infusing saline solution through the ductal system of the human breast, the apparatus comprising a cup having outer and inner sidewalls defining a peripheral and a central recess opening into the mouth of the cup with openings in the cup for drawing a vacuum in each of the recesses to sealingly attach the apparatus to the breast over the nipple and and enable infusion of solution into the breast ductal system. A method for detection of cancer of the breast is provided by drawing a vacuum around the breast nipple, then irrigating the breast ducts with saline solution infused through the nipple and thereafter examining epithelial cells in the saline solution following irrigation for abnormalities.





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METHOD AND APPARATUS FOR AIDING IN THE DETECTION OF BREAST CANCER

The present invention relates to a method and apparatus for aiding in the detection of breast cancer in females. More particularly, this invention provides a method for obtaining epithelial cells from the lining of the breast ducts and a device for practicing this method.

Breast cancer ranks as the number one malignancy in the human female and accounts for approximately one-fourth of all cancers in women. Studies have shown a definite correlation between the size of the original cancer or lesion at the time of diagnosis and the mortality rates for cancers of the breast. The smaller the size of the lesion, the more likely the recovery of the patient.

At the present time, early diagnosis of possible breast cancer is usually conducted by touch, and/or mammograms (breast X-rays) to determine the presence of suspicious breast lesions. Upon detection of lesions the differential diagnosis between benign lesions and malignant lesions in the female breast is generally confirmed by biopsy done under general anesthesia in a hospital. Only about one in four lesions is found to be malignant and the prognosis for cancer of the breast has improved very little over the last several decades. The diagnostic procedure, being cumbersome, costly and time consuming, is done only when circumstances, such as discovery of an unusual lump in the breast, arouse sufficient suspicion on the part of the physician to warrant the pain and inconvenience of a biopsy to the patient.

The present invention is believed to provide a detection method for breast cancer which can be used in routine physical examinations and involves little discomfort to the patient. This invention provides a detection method for breast cancer as valuable as the routine "Pap" smear now used for the early diagnosis of uterine cancer.

Natural secretions from the breast are an uncommon symptom of breast cancer, and even if present may or may not contain cancer cells. Thus, even though it has been known that breast cancer begins in the lumina of the ductal system of the breast, no way has heretofore been presented for obtaining cells from the lining of the ducts themselves.

The present invention provides a method to infuse a liquid into the breast ducts to irrigate the ductal system and cause epithelial cells from the duct lining to be dispersed therein and withdrawn with the irrigating liquid from the breast. The invention also provides a unique disposable apparatus for practicing the method.

Briefly, the method of this invention for the detection of breast cancer in the human female, and other female mammals having similar breast structures, comprises (1) dilation of the nipple of the breast to distend the breast duct openings which open thereinto, (2) infusion of an aseptic physiologically inert free-flowing liquid into said breast ducts through the dilated nipple openings to irrigate the ducts and cause epithelial cells lining the ducts to slough off and disperse in the irrigating liquid and (3) withdrawal of the irrigating liquid from the dilated nipple openings for microscopic examination of epithelial cells dispersed therein to ascertain whether or not any are malignant.

The apparatus of the invention for practicing the method may comprise a cup having a continuous outer sidewall and a continuous inner sidewall spaced therefrom defining a continuous peripheral recess and a central recess, both opening into the mouth of the cup. The cup is adapted so that as it is pressed against the breast the peripheral recess surrounds the nipple area and the nipple is received within the central recess. The cup has openings therein for drawing a vacuum in each of said recesses to seal the cup against the breast and to dilate the nipple of the breast received within the central recess of the cup. The cup is provided with vacuum openings into the peripheral and central recesses to seal the cup to the breast. Liquid infusion and air vent openings also open into the central recess whereby liquid can be infused into and withdrawn from the breast ducts through the dilated nipple,

the vent opening permitting release of trapped air from the central recess as liquid is infused thereinto.

A presently preferred apparatus of the present invention for infusing the breast ducts with irrigating liquid and withdrawing the irrigating liquid therefrom comprises generally a circular cup having a continuous outer sidewall and a continuous inner sidewall concentric therewith defining a peripheral recess and a central recess opening into the mouth of the cup with the central recess being deeper than the peripheral recess, the cup having a bottom forming a hollow chamber surrounding the portion of the inner sidewall depending below the floor of the peripheral recess. The continuous inner sidewall has openings therearound above the floor of the central recess and below the floor of the peripheral recess at spaced intervals therearound communicating with the hollow chamber. The cup further has a liquid infusion passage and an air-venting passage, which may also serve as a liquid withdrawal passage, opening into the central recess and a vacuum drawing passage opening into the peripheral recess.

The practice of the method and the construction of the presently preferred form of apparatus for practicing the method are described in more detail with reference to the accompanying drawing wherein:

FIG. 1 is a perspective view of the liquid infusion apparatus of the present invention;

FIG. 2 is a cross-sectional view of the device of FIG. 1 on an (taken substantially along the plane of section line 2—2 of FIG. 1);

FIG. 3 is a bottom view of the device of FIG. 1;

FIG. 4 is a side view of the device illustrated in approximately actual size, with parts being broken away for clarity of detail, in position against a breast to begin practice of the method of the invention;

FIG. 5 is a view similar to FIG. 4 on an enlarged scale with the device in position and functioning in the practice of the method of the invention.

Referring first to FIG. 1 of the drawing, a presently preferred form of apparatus or device is illustrated for infusing the breast ducts of a human female with an irrigating liquid and withdrawing the irrigating liquid therefrom. The device is seen to comprise a cup 10 having a continuous outer sidewall 12 and a continuous inner sidewall 14, which define respectively a peripheral recess 16 and a central recess 18 opening into the mouth of the cup. The floor 20 of the peripheral recess 16 is above the floor 22 of the central recess 18 so that the peripheral recess 16 is considerably shallower than the central recess 18. Bottom 24 closes the bottom of the cup 10.

Because the cup 10 illustrated in the preferred embodiment is generally cylindrical, the outer sidewall 12 and the inner sidewall 14 have circular peripheries and form concentric tubes with the peripheral recess 16 being in the form of an annular channel and the central recess 18 being in the form of a cylindrical bore. Opening circumferentially around the inner sidewall 14 below the flat floor 20 of the peripheral recess 16 and above the flat floor 22 of the central recess 18 are a plurality of passages 26. Further, opening into the floor 20 of the peripheral recess 16 is a vacuum-drawing passage 28 and opening into the floor 22 of the central recess 18 are liquid infusion passage 30 and air-venting passage 32, respectively. Liquid can be withdrawn from either passage 30 or 32. There is one further vacuum drawing passage in the cup 10, which does not appear in FIG. 1 although the flexible tubing connecting means for the passage is visible as tapered rigid tubular shaft 34 depending from the bottom 24 of the cup 10.

Turning now to FIG. 2, the construction of the cup 10 is illustrated in more detail. As is apparent from this figure an annular chamber 36 is formed within the cup 10, which annular chamber surrounds the lower portion of the recess 18. The circumferential openings 26 through the sidewall 14, separating the inner and outer recesses 16 and 18, open into this annular chamber 36. The connecting means 34 opens into a passage 40 which in turn opens into the hollow closed annular chamber 36 surrounding the lower portion of the inner recess

18 of the cup 10. As is also apparent in this figure, the vacuum-drawing passage 28 opening into the floor 20 of the peripheral recess 16 of the cup opens at its other end into the bottom of the cup where it connects to a tapered rigid shaft 38 depending from the bottom 24 of the cup, which shaft is a connecting means for connecting passage 28 with a piece of tubing as does each of the other connecting means 34, 42 and 44. Because of the way FIG. 2 is sectioned, the passage 32 does not appear as it is not in the cross-sectional detail.

As appears most clearly in FIG. 3, passages 30 and 32 opening into the floor 22 of the central recess 18 likewise open through the bottom 24 of cup 10 into the rigid tapered tubular shafts forming connecting means 42 and 44, respectively. Conveniently, the passages open through the bottom 24 of the cup in the manner illustrated; however, this is of course a matter of choice and they may open through the sidewall 12 or through some combination of the sidewall 12 and the bottom 24.

The cup 10 is preferably composed entirely of a clear, transparent plastic so that the physician can observe the procedure as it takes place; an acrylic resin such as polymethyl methacrylate has been found quite suitable. Polyamides, vinyls and olefins may also be used—as may thermosetting plastics.

Turning now to FIGS. 4 and 5, the practice of the method and the use of the device 10 in such practice are more particularly described. In FIG. 4 the device 10 is shown in approximately its actual size whereas in the other figures of the drawing the device is shown in various degrees of enlargement for ease of pictorial representation. Prior to placement of the device against the breast it is connected to the auxiliary equipment illustrated schematically in FIG. 5, which will be described in more detail hereafter.

First the breast 46 and the nipple 48 are cleansed with a 70 percent alcohol solution. Next, tincture of benzene or a nonallergenic skin adhesive is applied to the cleansed area around the nipple. Then, as illustrated in FIG. 4 the device 10 is placed against the breast 46 with the nipple 48 received in the central recess 18 of the device.

Next, a sufficient vacuum is drawn in the peripheral recess 16 of the device to seal it to the skin of the breast 46 around the nipple. This may be done by connecting flexible tubing 50 from the connection 38 to a vacuum pump P; a sufficient vacuum is indicated when the skin is observed to be drawn into the recess 16 as illustrated. Valve 52 may be used to maintain or release the vacuum.

Suction is then drawn in the central recess 18 by withdrawing air through the apertures 26 by means of tube 54 leading from the connection 34 to the vacuum pump P; sufficient suction is achieved when the nipple is sufficiently dilated circumferentially to seat firmly against the inner surface of the wall 14 of the recess 18 and seal off the apertures 26 as illustrated in FIG. 5. Valve 56 may be used to maintain or release the suction on the nipple.

Then, a 9/10 of 1 percent standard saline solution is infused into the breast through the dilated breast nipple 48 from a saline infusion vessel I by means of tube 58 leading therefrom to a valve V, and thence to the central recess 18 of the device 10 by means of tubing 60 leading to connection 42. The valve V may be closed or may selectively (a) connect the vessel I with recess 18, and (b) connect recess 18 with the saline withdrawal tube 62 from which saline from the breast 46 may be collected. Of course, when saline is being withdrawn from the breast, flow of saline into the breast from the vessel I is halted by the valve V. The vessel I is further connected to a 50 centimeter manometer M by means of tube 64.

The air vent 32 is connected through connection 44 to tube 66 which is interrupted 1 valve 68. In the infusion of the breast, sufficient saline solution is introduced into recess 18 while valve 68 is open to release trapped air therefrom and replace the air with saline solution. Valve 68 is then closed. After release of trapped air from the recess 18, the infusion vessel I is elevated to register about 40 centimeters pressure on the manometer scale and saline is infused into the breast

ducts. The valve V is then closed, and the saline infusion unit I lowered. Valve V is then opened to its (b) position and about 1 c.c. of fluid is allowed to escape from the duct system of the breast through the withdrawal tube 62. The valve V is then returned to its open position (a) after the vessel I is raised and the manometer reading registers 40 centimeters. Liquid is then again infused into the breast, the valve V closed, the vessel I lowered, and the valve V opened to position (b) to withdraw a second cubic centimeter of saline from the breast ducts. This procedure is again repeated, and the third centimeter of fluid removed from the breast duct system is prepared pathologically for cell examination. Throughout the procedure the nipple 48 is maintained in its dilated condition.

That which is claim is:

1. A method for the detection of breast cancer in female mammals comprising (1) dilating the nipple of the breast to distend the breast duct openings therethrough, (2) infusing an aseptic physiologically inert free-flowing liquid into said breast ducts through said dilated nipple openings to irrigate said ducts and cause epithelial cells lining said breast ducts to slough off and disperse in said liquid, and (3) withdrawing said irrigating liquid from said nipple openings for examination of the epithelial cells dispersed therein.

2. A method for the detection of breast cancer in the human female comprising (1) forming a seal around the nipple of the breast, (2) drawing a vacuum around said nipple within the sealed area to dilate said nipple and distend the breast duct openings therein, (3) infusing an aseptic physiologically inert free flowing liquid into said breast ducts through said distended nipple openings to irrigate said ducts and cause epithelial cells lining said ducts to slough off and become dispersed in said liquid, and (4) withdrawing said liquid from said nipple openings for examination of the epithelial cells dispersed therein.

3. The method of claim 2 wherein said nipple dilating vacuum is drawn around the circumferential periphery of said nipple.

4. The method of claim 2 wherein said liquid is an aqueous saline solution.

5. A device for use in an apparatus for infusing the breast ducts of a mammalian female with an irrigating liquid and then withdrawing the irrigating liquid therefrom, said device comprising a cup having a continuous outer sidewall and a continuous inner sidewall defining a peripheral recess and a central recess opening into the top of said cup, said central recess being deeper than said peripheral recess, said cup having a bottom forming a hollow chamber surrounding the portion of said inner wall extending below said peripheral recess, said continuous inner sidewall having openings at spaced intervals therearound communicating said central recess and said chamber, said cup having liquid infusion and liquid withdrawal passages opening into said central recess, and having vacuum passages opening into said chamber and said peripheral recess.

6. A device suitable for use in an apparatus for irrigating the breast ducts of the human female comprising a cup having outer and inner concentric continuous sidewalls forming an outer annular recess and a central recess, the floor of said central recess being below the floor of said peripheral recess, said cup having a bottom below the floors of said recesses and having a hollow chamber formed therein, said inner sidewall having a plurality of openings spaced circumferentially therearound communicating said central recess and said hollow chamber with one another, said cup having liquid infusion and liquid withdrawal passages opening into the floor of said central recess, and having vacuum drawing passages opening into said chamber and said annular recess.

7. The device of claim 6 wherein said cup has means thereon for facilitating the connection of tubing to said passages.

8. The device of claim 7 wherein said means are provided on the bottom of said cup.

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9. A device for use in an apparatus for the infusion of a liquid into the breast ducts of a human female and for withdrawing the liquid so infused, said device comprising a cup having a continuous outer sidewall and a continuous inner sidewall defining a peripheral recess and a central recess opening into the mouth thereof, said cup having openings therein for drawing a vacuum in each of said recesses when the mouth of said cup is pressed against the breast, said central recess being adapted to receive the nipple of the breast and to enable the same to dilate as a vacuum is drawn therewithin,

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said cup having a further opening therein into said central recess for infusing liquid thereinto, said cup having a further opening therein into said central recess to vent air therefrom as liquid is infused thereinto.

10. The apparatus of claim 9 wherein the openings for drawing a vacuum in said central recess are circumferentially spaced around the wall defining the recess and above the floor of the recess so as to draw the nipple into peripheral contact with such wall as suction is applied through said openings.

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