

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

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[*] Notice: The portion of the term of this patent subsequent to Sept. 28, 1988, has been disclaimed.

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 801,613, Feb. 24, 1969, Pat. No. 3,608,540.

[52] U.S. Cl. **128/2 F, 128/282, 128/300**

[51] Int. Cl. **A61b 10/00**

[58] Field of Search **128/2 F, 2 R, 2 B, 273, 280, 128/281, 282, 299-302, 304**

[56] **References Cited**

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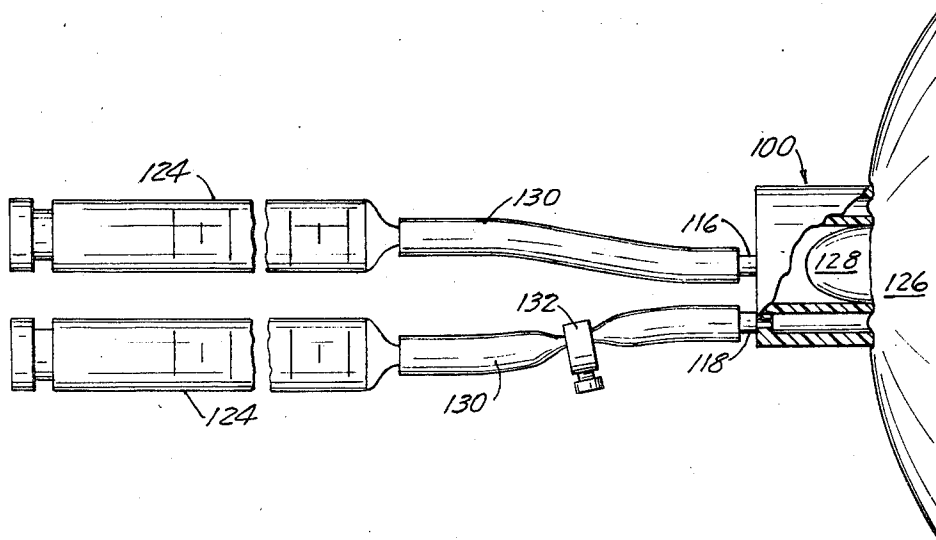
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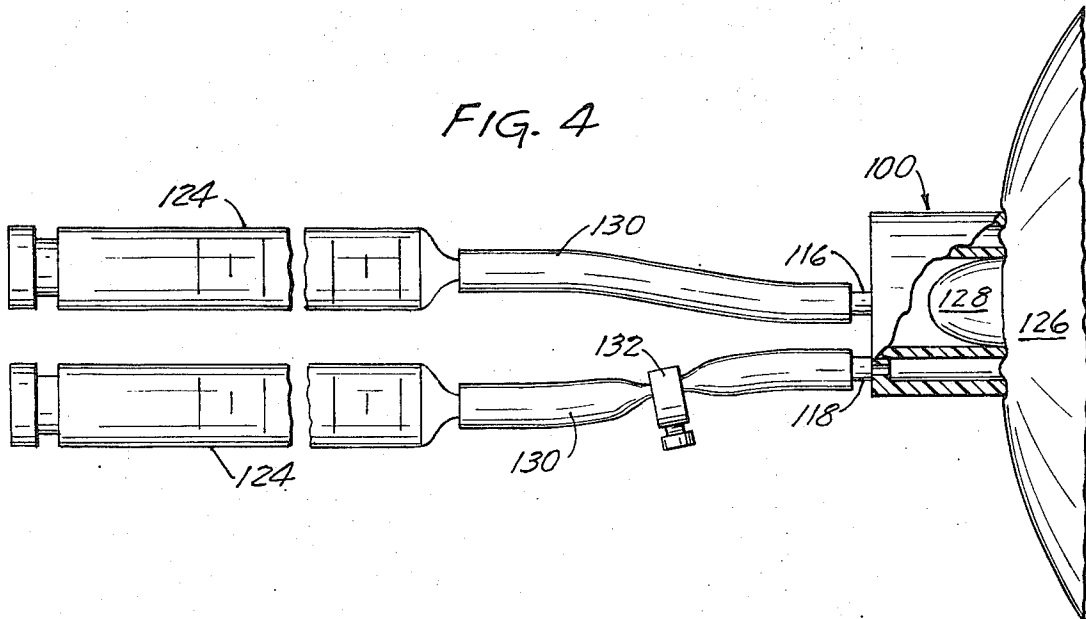
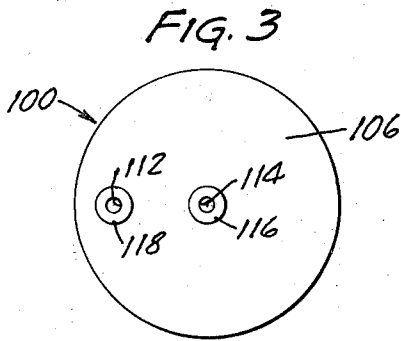
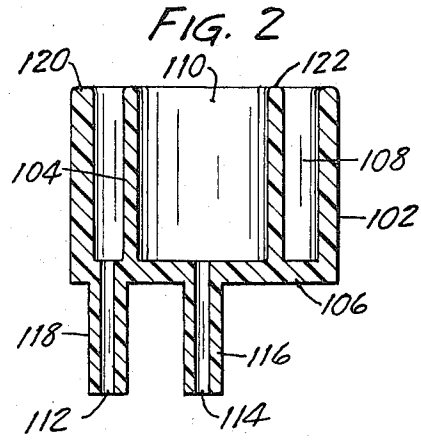
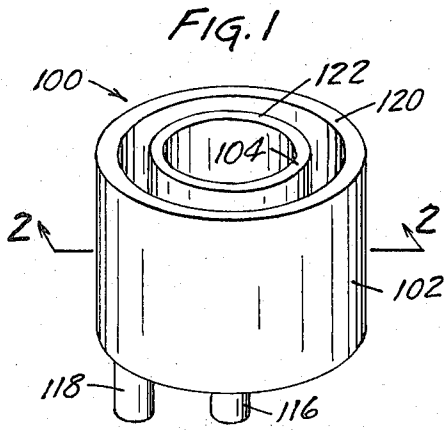
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[57] **ABSTRACT**

A method for detection of cancer of the breast is provided which comprises drawing a partial vacuum around the area of the breast immediately peripherally surrounding the breast nipple to restrain sphincter contraction of the duct openings in the nipple area, then, while maintaining this first mentioned partial vacuum, intermittently applying a zone of reduced pressure to the nipple itself for the extraction of secretion therefrom in sufficient quantity for the cytological examination of epithelial cells found therein for abnormalities. An apparatus is also provided for practicing the method.

2 Claims, 4 Drawing Figures





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METHOD AND APPARATUS FOR AIDING IN THE DETECTION OF BREAST CANCER

This application is a continuation-in-part of application Ser. No. 801,613 filed Feb. 24, 1969, now U.S. Pat. No. 3,608,540.

INTRODUCTION

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 unique application of suction for obtaining epithelial cells from the lining of the breast ducts and an apparatus for practicing this method.

BACKGROUND OF THE INVENTION

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.

Natural secretions from the breast are an uncommon symptom of breast cancer, and even if cancer is 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 effective way has heretofore been presented for obtaining satisfactory cell material from the lining of the ducts themselves for proper study.

THE INVENTION

This invention represents a substantial improvement over that described in my previous application in that the present invention provides a greatly simplified method for obtaining cells from the breast ducts for examination and a correspondingly less complex apparatus for its practice. This improved method in its simplicity closely resembles the routine "Pap" smear test procedure for the early detection of vaginal cancer.

The method described in my previous application enables the extraction of breast secretions having a sufficient quantity of epithelial cells therein for cytological examination from a high percentage of women. However, practice of the method requires a combination of suction and irrigation of the breast with an irrigating liquid. Thus, the epithelial cells of the breast secretion are carried in the irrigating liquid, causing a consequent high degree of preparation of the extracted secretion for cytological examination, and great care and

skill in the resulting examination of the extracted secretion; the method also requires the use of relatively elaborate apparatus in its practice.

The present invention provides a breast secretion extraction procedure involving the use of a novel combination of suction pressures to the breast to induce mammary secretions having sufficient cellular material for accurate diagnosis by cytological examination in a high percentage of women, e.g. 70 percent or more.

The method of this invention for the early diagnosis of breast cancer requires no irrigating liquid and thus minimizes the consequent possibility of contamination and misinterpretation of cytological findings inherent therein. This new method comprises (1) the application of a constant peripheral zone of reduced pressure, i.e., a suction pressure, to the area of the breast surrounding the nipple and in very close proximity thereto, and (2) the intermittent application of a zone of reduced pressure to the breast nipple itself to extract breast secretion from the nipple while maintaining the constant suction in the peripheral zone, (3) removal of beads of breast secretion from from the nipple, and (4) cytological examination of epithelial cells dispersed therein. Because of its innate simplicity, the absence of any foreign fluid mixed with the breast secretion, and the ease of examination of extracted secretion, this procedure is remarkably similar in its practice to the vaginal Pap smear test procedure.

The method of this invention enables a quick, simple and painless method for obtaining breast ductal secretions having a sufficiently representative quantity of ductal cells to enable reasonably accurate early diagnosis for the presence of breast cancer. The application of suction to the area of the breast immediately peripherally surrounding the nipple apparently inhibits, or restrains, any sphincter contraction otherwise present at the duct system openings into the nipple. The intermittent suction applied to the nipple area while maintaining the peripheral area under a constant reduced pressure causes beads of secretion to quickly form on the nipple, which beads may be readily removed for examination simply by wiping the nipple with albumen coated slides, followed by rapid fixation of the slides for cytological examination under suitable magnification. To cleanse the nipple and soften inspissated material which may be present at the mouths of the duct openings into the nipple before practicing the method, the application of a hot towel to the breast nipple and subsequent sterile cleansing of the nipple by the use of alcohol, Zephiran, 2% acetic acid or acetone is recommended.

The device or apparatus I have invented for practicing my new method comprises 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 and being otherwise sealingly separated from one another. The cup is adapted so that as it is pressed against the breast the peripheral recess closely surrounds the nipple area of the breast and the central recess receives the nipple therein. The cup has a pair of openings in the bottom thereof for creating suction in the recesses. One of the openings communicates with the peripheral recess to seal the cup against the breast and the other communicates with the central recess to withdraw breast secretion from the nipple of the breast received therewithin.

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 a form of apparatus for the practice of the invention;

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

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

FIG. 4 is a side view of the device of FIG. 1 in its functional position on the breast.

Referring first to FIG. 1, a form of device or apparatus for practicing the method of this invention is illustrated, being designated in its entirety by the numeral 100. This device comprises a cup having a continuous outer cylindrical sidewall 102 and a continuous inner cylindrical sidewall 104 concentrically spaced therefrom. The sidewalls rise from a flat, circular bottom wall 106 and divide the cup 100 into outer and inner recesses 108 and 110, respectively. The device can be of any suitable non-porous material but is preferably of a tough, rigid, transparent plastic inert to body fluids, such as polypropylene or polymethyl methacrylate, or other suitable tough synthetic plastic polymer. Ports 112 and 114 open through the bottom wall 106 of the cup respectively into outer and inner recesses 108 and 110. Tubular nipples 116 and 118, depending from the bottom 106 of the breast cup 100, provide means for the attachment of the mouth of a syringe thereto for evacuation of the recesses. As these devices are inexpensive enough to be discarded after use, any suitable port guide arrangement can be used, e.g., each port may simply be sealed with a rubbery sealing membrane which is puncturable by a hollow syringe needle.

After inspissated material at the mouth of the nipple has been loosened, where necessary, and the nipple and nipple area have been cleaned as noted hereinbefore, the device is applied to the breast 126. Rims 120 and 122, respectively, of the outer and inner sidewalls of the cup 100 seat firmly against the flesh of the breast surrounding the nipple, the outer or peripheral recess 108 closely surrounding, but excluding, the nipple 128 of the breast and the inner or central recess 110 snugly received the nipple 128 therewithin. Following placement of the device, evacuation of the outer recess 108 is carried out. This may be accomplished by application of a conventional 10 c.c. syringe 124 to port extension 118 and withdrawal of the syringe plunger to the 5 or 6 c.c. mark whereupon clamp 132 may be tightened on the flexible tubing 130 interconnecting the syringe tip and the port extension to maintain a constant partial vacuum in the outer recess of the cup. Upon creation of reduced pressure by this means in the outer recess, the device is self-retained against the breast and sphincter contraction at the end of the duct system opening into the nipple is restrained. The extraction or withdrawal of breast secretion may begin.

To extract the breast secretion, the inner recess of the cup within which the nipple of the breast snugly rests is subjected to an intermittent partial suction, i.e. reduced pressure or partial vacuum, as through use of a 10 c.c. syringe applied to port extension 116 by means of another piece of flexible interconnecting tub-

ing 130 and the syringe plunger alternately withdrawn to the 5 or 6 c.c. mark and then pressed forward to first subject the nipple to suction pressure and then release the nipple from suction pressure and thus "milk" breast secretion from the nipple. The secretion thus obtained forms as beads on the nipple and may then be subjected to examination by known techniques for the pathological examination of cellular material contained therein, e.g. by serial smearing on albumen coated slides followed by fixation for microscopic examination, or other cytological examination procedure.

While the invention has been described with reference to human mammography and the early detection of cancer, the invention is applicable to the examination of any mammal and to the detection of other cellular disturbances in the breast ductal system.

That which is claimed is:

1. A method for withdrawing breast secretion for the detection of cellular abnormality within the breast of a mammalian female comprising (1) contacting the breast with a cup having a bottom and outer and inner continuous sidewalls spaced from one another dividing the cup into peripheral and central recesses opening into the mouth of the cup, the mouth of the cup being pressed against the breast with the nipple of the breast being received in the central recess and the portion of the breast immediately surrounding the nipple being contacted by the edges of said sidewalls and closing the mouth of the cup, (2) reducing the pressure in the peripheral recess of the cup to thereby firmly seat and hold the cup against the breast and, (3) while maintaining the reduced pressure in said peripheral recess intermittently reducing the pressure in the central recess to cause natural secretion from the breast to bead on said nipple, then (4) releasing the cup from the breast and removing said beads of natural secretion to enable examination of cells contained therewithin for detection of breast abnormalities.

2. A device adapted for self-retention on the breast of a mammalian female to facilitate the withdrawal of natural secretions therefrom, said device comprising a cup being generally circular in cross section and having a closed bottom with continuous concentrically spaced outer and inner sidewalls rising therefrom with the upper edges thereof terminated at and forming the mouth of the cup, said concentrically spaced sidewalls dividing said cup into a peripheral recess and a central recess opening into the mouth of the cup, said inner sidewall sealingly separating said central recess and said peripheral recess from one another, said central recess being of a size to snugly receive the nipple of a breast therewithin and said peripheral recess presenting a ring-shaped opening of a size to closely surround the portion of the breast immediately surrounding the nipple area, said cup having a pair of port means therein opening independently into each of said recesses, each of said port means including means for the attachment of suction means thereto so that when the device is placed in position against the breast with the nipple of the breast seated in said central recess the recesses of the cup may be individually depressurized.

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