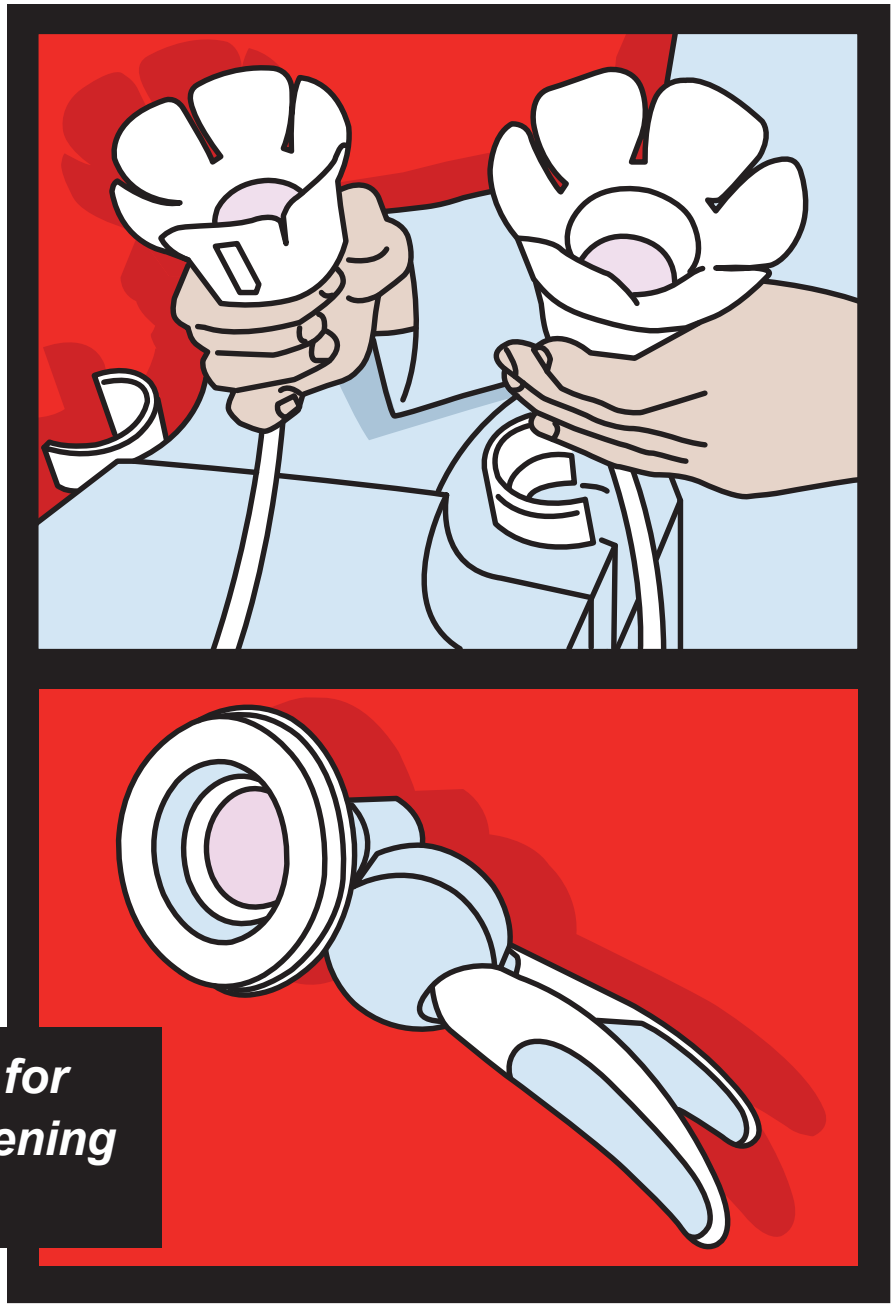
Nipple Aspirate Test is No Substitute for Mammogram

Many women admit that getting a mammogram is no fun, and may wish there was an easier, more comfortable way to screen for breast cancer in its earliest and most treatable stages.

Some companies today are promoting a test in which a breast pump is used to collect fluid from a woman's nipple to screen for abnormal and potentially cancerous cells. This test—called a nipple aspirate—is being marketed as the latest and greatest tool in early breast cancer screening, one that is easier, more comfortable and less painful than the mammogram.

However, there is no clinical evidence to support these claims, says David L. Lerner, M.D., a medical officer at the Food and Drug Administration (FDA) and a specialist in breast imaging.

"FDA's concern is that the nipple aspirate test is being touted as a standalone tool to screen for and diagnose breast cancer as an alternative



Not FDA-cleared for breast cancer screening or diagnosis!

"The bottom line is that women should not rely solely on these nipple aspirate tests for the screening or diagnosis of breast cancer."

to mammography," Lerner explains. "Our fear is that women will forgo a mammogram and have this test instead." This could result in serious health consequences if breast cancer goes undetected, he notes.

FDA is unaware of any valid scientific data to show that nipple aspirate tests, when used on their own, are an effective screening tool for any medical condition, including the detection of breast cancer or other breast disease, Lerner says. Researchers are still studying whether these tests may one day be used, in conjunction with other medical devices, to screen for disease.

In February 2013 FDA issued a warning letter to Atossa Genetics, Inc. that, among other things, informed the company that their test was misbranded in that its labeling was false or misleading. The agency asked the firm to take prompt action to correct the violations addressed in the warning letter. In October 2013, Atossa initiated a voluntary recall to remove the ForeCYTE Breast Health Test from the market.

Unsubstantiated Claims

In addition to stating that the test can help women 18 years and older determine their risk level for breast cancer, Atossa claimed that its test was "literally a Pap smear for breast cancer." According to FDA medical officer Michael Cummings, M.D., who reviews obstetrical and gynecological devices for the agency, this claim is unsubstantiated.

"The cervical Pap smear has a known clinical benefit supported by extensive clinical studies over many years," Cummings says. "Its scientific ability to screen for cervical cancer is unquestioned." The nipple aspiration test has no such evidence supporting it, he attests.

In addition, Lerner explains that if a Pap smear shows abnormal cells of the cervix, there are follow-up procedures that can be done to try to identify the location of those cells, after which a biopsy of the area is possible. With a breast nipple aspirate, if there are abnormal cells, the test does not target where those cells are coming from, so a biopsy may not be possible. Moreover, while the risk of abnormal cervical cells progressing to cancer is known, the risk of abnormal breast cells progressing to cancer is not.

Lerner says the test may produce results that are falsely positive or falsely negative. "False positives are possible because cells can be damaged in the aspiration process and look abnormal," he notes. "We are even more concerned about false negatives," he adds. Companies acknowledge that over 90% of their fluid samples may contain either very scant cells or no cells at all. Yet the companies call such results "diagnostically useful" and even conclude that a patient is healthy based on a cell-free sample, he says. "The test may be missing cancers and giving women dangerous false assurance," Lerner says.

Mammography Still the Best

The mammogram can be uncomfortable for the woman being screened because it compresses the breast to flatten out the breast tissue and increase the clarity of the X-ray image. Still, FDA is not alone in believing that mammography is the most effective method for screening for breast cancer. Other organizations agree, including the American Cancer Society, the American College of Radiology (the professional society of physicians who specialize in medical imaging) and the National Cancer Institute, a division of the National Institutes of Health.

The National Cancer Institute states that screening mammography can help reduce the number of deaths from breast cancer among women ages 40 to 70. The National Comprehensive Cancer Network (NCCN) 2013 guidelines state that the clinical utility of nipple aspiration is still being evaluated and that it should not be used as a breast cancer screening technique.

FDA recommends that women who have received a nipple aspirate test as a form of breast cancer screening should also have a mammogram according to screening guidelines or as recommended by their doctor, and should talk to their health care professional about whether additional tests are needed.

"The bottom line is that women should not rely solely on these nipple aspirate tests for the screening or diagnosis of breast cancer," Lerner says. "Mammography is still the gold standard."

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