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**DUCTAL LAVAGE FINDS CELLULAR INDICATORS OF  
INCREASED BREAST CANCER RISK, ACCORDING TO NEW STUDY**

**St. Luke's Medical Center Among the First to Offer Procedure to  
High-Risk Women**

**MILWAUKEE, Wis., Nov. 6, 2001**— A study published today in the *Journal of the National Cancer Institute* shows that ductal lavage, an innovative procedure offered at St. Luke's Medical Center, found abnormal breast cells in 24 percent of study participants at high risk for breast cancer. The findings are significant because previous research has shown that abnormal or “atypical” milk duct cells signal a markedly increased risk of breast cancer.

Physicians at the newly established High Risk Clinic, part of the St. Luke's Comprehensive Breast Health Center, were among the first in the country to be trained in ductal lavage. Wendy Mikkelson and Judy Tjoe, breast surgeons, are currently using the technique to help high-risk women make decisions about whether to pursue active risk-reduction measures such as drug therapy, closer surveillance and surgical interventions.

“For the first time, ductal lavage is allowing us to evaluate the breast from the inside-out instead of the outside-in,” said Wendy Mikkelson, MD. “By looking at the cells, we can get a very individual picture of someone’s risk, which we can use to help tailor our approach to risk reduction.”

The concept behind ductal lavage is based on the fact that most breast cancers begin in the milk ducts. The procedure involves inserting a tiny catheter into these milk ducts, and washing the

## **Ductal Lavage/Add One**

ducts with saline to collect cells. The sample is sent to a laboratory for analysis to search for atypical, risk-increasing cells.

“One of the exciting aspects of ductal lavage is the ability to repeatedly access the same milk duct. That way, we can follow the cells over time and keep track of what’s happening,” said the High Risk Clinic's Judy Tjoe, MD.

The multi-center study involved 507 high-risk women and 19 centers in the U.S. and Europe. Participants were classified as high risk for breast cancer if they previously had breast cancer; were positive for BRCA1/BRCA2 mutations; or had a 5-year Gail risk of at least 1.7%. (The Gail Index uses risk factors such as age, family history, age at first menstrual period and the number of breast biopsies to calculate a woman’s chance of developing breast cancer.)

The study compared ductal lavage to nipple aspiration, an older method of collecting milk duct fluid from the surface of the nipple. The data showed that ductal lavage found atypical cells 3.2 times more often than nipple aspiration. In addition, ductal lavage collected more cells – a median of 13,500 cells per duct versus 120 cells per breast with nipple aspiration. Only 27% of the nipple aspiration samples were sufficient for analysis. In contrast, 78% of the ductal lavage samples were adequate for analysis.

The study examined procedure comfort as well. Using a scale of 1 to 100, participants were asked to rate their experience. A score of 1 represented a painless experience and 100 represented an extremely painful experience. The median response was 24, indicating that most subjects did not find ductal lavage uncomfortable.

“This study is important because it shows that ductal lavage can collect atypical cells in a minimally invasive fashion. It offers a new way to think about assessing breast cancer risk.” said Dr. Mikkelsen.

High-risk women interested in learning more about ductal lavage can call the High Risk Clinic at the St. Luke's Comprehensive Breast Health Center at 414-385-2301.

## **Facts about Breast Cancer**

According to a report from the National Cancer Institute (NCI), about one in eight women in the United States will develop breast cancer during her lifetime.<sup>i</sup> This year, an estimated 192,200 women will learn they have invasive breast cancer and 40,200 women will die from the disease.<sup>ii</sup>

## **Ductal Lavage/Add Two**

Breast cancer is the second leading cause of cancer death for women (after lung cancer) and the leading overall cause of death in women between the ages of 40 and 55.

St. Luke's Medical Center, the Comprehensive Breast Health Center, and the High Risk Clinic are all part of Aurora Health Care, a community-owned Wisconsin Health Care provider and a nationally recognized leader in efforts to improve the quality of health care. Aurora has care sites in 65 communities in eastern Wisconsin.

### **Additional Information**

The clinical study was sponsored by Pro•Duct Health, a medical device company, which recently entered into a merger agreement with Cytoc Corporation (NASDAQ:CYTC). The devices used in ductal lavage have been cleared for marketing in the U.S. More information on ductal lavage can be found at [www.ductallavage.com](http://www.ductallavage.com).

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<sup>i</sup> Surveillance, Epidemiology, and End Results Program (SEER) publication, SEER Cancer Statistics Review 1973-1996, National Cancer Institute.

<sup>ii</sup> American Cancer Society; *Cancer Facts & Figures 2001*; Special Section: Breast Cancer.