

Dear Editor/Producer:

Imagine. A nick of the skin, a flash of cold, and 25 minutes on an exam table. For thousands of women, this may soon be a cure for cancer.

**NAME in LOCATION** is one of the first facilities to use this new ultra-fast, effective, non-surgical procedure to treat certain types of breast cancer as part of a major national clinical trial. Termed cryoablation, the technique involves exposing a tumor to extreme cold to freeze it from the inside out, causing diseased cells to die off. They are then absorbed by the immune system over time.

The benefits of cryoablation over traditional cancer surgery are significant, including faster recovery, improved cosmetic results, greater patient comfort, less procedural risk and lower cost. As one of the first participating hospitals in the trial, HOSPITAL is playing a key role in potentially making the treatment a new non-surgical paradigm in the treatment of women with certain types of breast cancer.

Cryoablation is well-established for the treatment of liver, lung and other tumors. Numerous smaller studies have already evaluated its effectiveness in the treatment of breast malignancies. It also has a long history of success with benign breast fibroadenomas. Now thanks to major technological advances in cryoablation delivery technology, the technique has become precise and practical enough to administer in a large scale clinical trial, expected to involve at least 150 patients at 20 hospitals nationwide.

**Dr. NAME is spearheading participation of FACILITY** in this trial and is an expert on the subject.

We'd like to suggest a segment with the doctor on cryoablation's quality-of-life and clinical benefits to women and future in the treatment of breast cancer. The segment can be filmed in the physician's office where the procedure would typically take place, with a patient available for an interview. A demonstration of the cryoablation probe itself would make a dramatic visual focal point for the story as a ball of ice grows rapidly on the thin probe tip just as it would inside the patient's breast.

The attached press release provides additional details about cryoablation and the clinical trials. We'll call you shortly to follow up on your interest.

Cordially,

HOSPITAL REPRESENTATIVE

## **FACILITY** Helps Launch National Trial of Groundbreaking Non-Surgical Breast Cancer Treatment

With its first successful procedure this week, **FACILITY (CITY, STATE)** is helping to launch a groundbreaking multi-center clinical trial of cryoablation (exposure to extreme cold temperatures) to treat breast cancer without the trauma of surgery. Utilizing the innovative IceSense3™ System to treat certain early stage tumors without, tissue removal and minimal scarring, the ICE<sup>3</sup> trial will significantly expand data on the technique. Potentially, it will usher in a new paradigm in the treatment of the disease.

According to **NAME, MD**, who performed the procedure, it involves placing a small IceSense3™ nitrogen-cooled probe into the center of a tumor to freeze it from the inside out. The rapid temperature drop freezes diseased cells causing them to crack open and die; the dead cells are then absorbed by the immune system over time.

The benefits of cryoablation over traditional surgical tumor removal are significant, including fast recovery, improved cosmetic results, greater patient comfort, no need for general anesthesia or hospital operating room (O.R.), and lower cost. Cryoablation essentially involves a nick in the skin and the destruction of a tumor in place with minimal discomfort. The procedure is typically performed in a physician's office under ultrasound guidance in less than 30 minutes.

Cryoablation is well-established for the treatment of liver, kidney, prostate and other cancers. Numerous more limited studies have suggested the treatment for certain small breast malignancies, including a recent ACOSOG trial and extensive long-term ongoing, unpublished studies in Japan. The IceSense3 Cryoablation System™, developed by IceCure Medical (Caesarea, Israel/Memphis, TN) specifically for breast applications, has a long history of successful treatment of benign breast fibroadenomas and is being studied in various other malignant diseases including lung and kidney.

"We are extremely pleased to give selected women an opportunity to take advantage of the clinical and quality-of-life benefits of this treatment and to see its full promise move rapidly towards fruition," says Dr. NAME. He points out physicians at HOSPITAL have a long history in the use of cryoablation in various applications as well as in active research of innovative techniques in the diagnosis and treatment of breast disease.

The ongoing refinement of cryoablation technology itself makes treatment more effective. The IceSense3™ device delivers a stable cycle of extremely cold temperatures and relies on a maneuverable, disposable probe and compact high tech console. For the first time, these advances make precise targeting of tumors extremely reliable.

The ICE<sup>3</sup> trial is recruiting and following women aged 65 years and older diagnosed with certain tumor sub-types and measuring less than 1.5 centimeters in diameter. Crafted by a diverse and esteemed scientific advisory board, the trial is underway at 20 carefully selected sites throughout the United States. As a market leader in cryoablation treatment of breast disease, IceCure will utilize its resources to provide clinical and technological support to sites in the cancer trial.

### **About IceCure Medical**

IceCure Medical is a medical device company that develops and markets minimally invasive, office-based cryoablation treatment solutions for women's health. Its support of patients and physicians through its Breast Health Options advocacy program embodies its firm commitment to affordable care. The proprietary IceSense3™ Cryoablation System offers a comfortable, ultrasound-guided procedure to treat breast tumors. The company was founded in 2006 with main offices in Caesarea, Israel and U.S. headquarters in Memphis, TN. For more information, visit [www.icecure-medical.com](http://www.icecure-medical.com), [www.breasthealthoptions.com](http://www.breasthealthoptions.com), and @CoverCryo on Twitter.

### **About FACILITY**

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# FACT SHEET

## Cryoablation: The First Non-Surgical Treatment for Breast Cancer in Clinical Trial

*Representing a major clinical breakthrough, cryoablation is a comfortable, simple and fast non-surgical treatment for certain early-stage breast cancers. The procedure exposes diseased tissue to extreme cold (cryo) to destroy (ablate) it. Cryoablation can be accomplished in as little as 30 minutes in a physician's office under ultrasound guidance for precise tumor localization.*

### The Procedure

The IceCure IceSense3 probe is inserted into the breast through a small 3 mm incision made under a local anesthetic. The IceSense3 system circulates liquid nitrogen through the probe causing a rapid temperature drop that freezes the breast tumor from the inside out.

Treatment time varies with the tumor size and can be as little as 25 minutes for a small malignant tumor. After treatment, the probe is warmed and removed from the breast.

The IceSense3's extreme cold disrupts cellular function, destroying the targeted tissue. Over time, the ablated tumor is reabsorbed by the body and replaced with breast tissue. Unlike a conventional lumpectomy or mastectomy, the treatment preserves breast volume and minimizes risk of hematoma or infection by eliminating any cavity at the tumor site. Patients typically recover almost immediately, experiencing minimal discomfort and excellent cosmetic results with no scarring. Patients can return to normal activity quickly without post-procedure prescription pain medicine.

Compared to invasive surgeries, cryoablation offers significant cost savings by eliminating hospitalization and anesthesiology fees, while minimizing personal and professional downtime. Currently, the IceSense3™ is widely available for treatment of benign breast tumors called fibroadenomas and is being studied for the treatment of some types of malignant tumors.

### The IceSense3™ Solution

The IceSense3™ cryoablation solution consists of a compact touch-screen console and set of small hollow, disposable probes in a variety of sizes. Together, the two components optimize treatment effectiveness, comfort, safety and speed for patients based on tumor size and location.

The IceSense3™ system takes advantage of nitrogen's low freezing temperature to rapidly yield the coldest and most stable and effective temperatures for cryoablation available today. A special heat exchange mechanism at the probe tip confines the freezing of tissue to the targeted areas. The resulting ice ball should engulf the tumor and at least 1 cm of healthy tissue as it freezes from the inside out.

While cryoablation has been employed for some time to treat other tumor types—including prostate and renal cancers, IceCure is working to bring the advantages of tumor ablation to women. Physicians control the probe from the console touch screen, along with push buttons, handle, or foot pedal.

### **The ICE3 Trial**

IceCure Medical is committed to the advancing research into the use of IceSense3™ cryoablation for breast cancer treatment. This year, the company launched the [landmark, multi-center ICE<sup>3</sup> trial](#) of in office cryoablation for certain breast cancers as an alternative to surgery, with a five-year follow up to determine disease-free survival. The trial involves women age 65 and older who have been diagnosed with a low risk form of cancer with tumors measuring less than 1.5 centimeters in diameter. These patients may also receive adjunctive therapy, such as radiation or drug treatment, based on local standards of care. Devised by a highly regarded, diverse scientific advisory panel, the Ice3 trial is being conducted at 20 sites throughout the U.S. It involves physicians well versed in IceSense3™ technology through prior use for the treatment of non-cancerous breast fibroadenomas.

IceSense3™ technology achieved FDA 510k clearance in 2010 The ICE3 trial is being conducted to substantiate the value of the technology in breast cancer treatment and is not required for FDA approval.

### **Additional Studies**

Additional relevant breast cancer cryoablation research includes:

- Simmons, R. Abstract Title: A Phase II Trial Exploring the Success of Cryoablation Therapy in the Treatment of Invasive Breast Carcinoma: Results from ACOSOG (Alliance) Z1072.
- Sabel MS, Su G, Griffith KA et al. Rate of Freeze Alters the Immunologic Response After Cryoablation of Breast Cancer. *Annals of Surgical Oncology*; Vol.17 Issue 4, Apr. 2009.