

THE ICE3 CLINICAL TRIAL

Cryoablation of Early-Stage, Low-Risk Breast Cancer

The ICE3 Clinical Trial is the largest multi-center clinical trial ever completed for liquid-nitrogen (LN2) – based cryoablation for patients with low-risk, early-stage breast cancer without surgically removing the breast tumor.

Promising 5-Year Clinical Results

3.1%

Rate of local recurrence for patients treated with cryoablation and endocrine therapy

99.1%

Patients very satisfied or satisfied with cosmetic outcome

97%

Physicians very satisfied or satisfied with cosmetic outcome

For the full details of the ICE3 data, visit our website at icecure-medical.com/resources/ice3-trial



WHAT PATIENTS ARE SAYING ABOUT PROSENSE®...

"Having the cryoablation you don't need any type of cosmetic follow up, you don't have a scar, you don't have the feeling of having lost part of your breast because it's all still there...I would highly recommend this procedure for other women because it is so painless."

Pam D., ICE3 Patient

"Surgery is frightening and I have been there before, so I asked if there were any other options... I would definitely recommend that if you have a choice between surgery and cryoablation that you should certainly think about doing the cryoablation because first of all it's so much less expensive, it's not at all painful, you do not have to be put to sleep and you can go to the office, have it done, get up and leave, and go home, and it's all over."

Jean R., ICE3 Patient

*Disclaimer: Patient testimonials reflect individual experiences. Results vary and are not guaranteed. Always consult a qualified healthcare professional for medical advice.

ABOUT ICECURE MEDICAL

IceCure offers the choice of a minimally invasive cryoablation treatment option for some select benign and malignant breast tumors. The FDA-cleared and CE-marked ProSense® System uses liquid-nitrogen to generate ultra cold temperatures to destroy tumors by freezing them, offering a minimally invasive alternative to traditional surgery. The ProSense® system is also indicated for the treatment of fibroadenomas and for use in the fields of general surgery, oncology, gynecology, and proctology.

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ProSense® is cleared for the treatment of breast cancer in select markets; please refer to your local guidelines.



It's My Choice



CRYOABLATION FOR THE LOCAL TREATMENT OF LOW-RISK BREAST CANCER WITH ENDOCRINE THERAPY

A safe, effective, and less invasive treatment choice with satisfaction from cosmetic results

icecure-medical.com

I'VE BEEN DIAGNOSED WITH BREAST CANCER - WHAT ARE MY CHOICES?

After breast imaging and confirmation of cancer type by biopsy, surgical removal of the breast cancer tumor (e.g., "lumpectomy") is the conventional treatment, often followed by adjuvant therapies. However, for a select group of patients, surgery may not be the only option.

Cryoablation for early-stage, low risk breast cancer when combined with endocrine therapy offers the choice of a minimally invasive treatment. Cryoablation can be performed in your doctor's office under local anesthesia with minimal scarring.

Cryoablation is possible for the treatment of breast cancer in patients ≥ 70 years of age with biologically low-risk* tumors ≤ 1.5 cm in size and treated with adjuvant endocrine therapy, including patients not suitable for surgery of breast cancer treatment. Using extreme cold to destroy the tumor by freezing, cryoablation has been used for decades in clinical practice for the safe and effective ablation of benign and cancerous tumors.

* Biologically low-risk breast cancer is defined as unifocal tumor, size ≤ 1.5 cm, ER+, PR+, HER2-, Ki-67 $<15\%$ and/or genomic testing indicative of low-risk breast cancer, infiltrating ductal carcinoma (excluding lobular carcinoma, extensive intraductal component, or evidence of lymphovascular invasion), and clinically negative lymph node (N0).

WHAT ARE THE BENEFITS OF CRYOABLATION?

Maintain breast shape: No tissue is removed and there is minimal scarring. Most patients and physicians reported satisfaction or high satisfaction with cosmetic results*. No breast reconstruction needed.

Short, office-based procedure: Average cryoablation procedure time is approximately 30-45 minutes with no hospital waiting or overnight stay.

Recovery within 24 hours: Recovery to normal activity within median 1 day recovery time (range 0-8 days)**.

Minimal pain and discomfort: Cold numbs the area.

Local anesthesia: numbing agents are injected only into the area being treated. The ice formed during treatment can also have a numbing effect on the treatment area.

*99.1 % of patients and 97% of physicians responding to a survey stated they were 'satisfied' or 'very satisfied' with the breast cosmetic outcomes at 5 years follow up.

**Based on ICE3 study results.

WHAT HAPPENS AFTER MY CRYOABLATION PROCEDURE?

Patients who have undergone cryoablation for breast tumors have reported mild-to-moderate pain, edema (swelling), and bruising. Other adverse events can include the risk of incomplete ablation (not fully treating the tumor area) and skin burns to nearby tissue which can be mitigated by injected saline.

You will have a palpable mass (area that can be felt) while your body naturally reabsorbs the destroyed cells. The size of the mass typically reduces over time, depending on the initial size of the mass and other factors.

The mass may not completely resolve. Be sure to share with your breast imaging specialists that you have had cryoablation when you have follow up imaging (e.g., mammography, ultrasound, MRI).

Endocrine therapy (also known as hormonal therapy) will be included in your treatment plan with ProSense cryoablation. Discuss with your doctor why endocrine therapy is a necessary part of your treatment and how it should be taken.

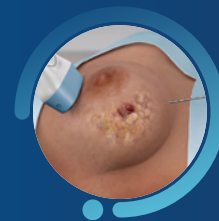
For a full discussion of what to expect post-cryoablation, read our patient leaflet found on icecure-medical.com or scan the QR code below.

PROSENSE™ CRYOABLATION: STEP-BY-STEP

During the minimally invasive ProSense™ cryoablation procedure, your doctor will inject local anesthesia and use ultrasound (sonographic) imaging to guide a small cryoprobe (thin hollow needle) into the breast tumor.

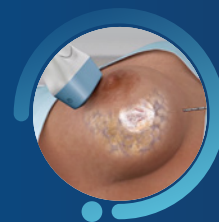
Once the cryoprobe is placed, it undergoes a freeze-thaw-freeze cycle, where extremely cold temperatures (lower than -170°C) destroy the breast tumor by creating an ice ball around the targeted tissue. The tissue destroyed by the ice ball is naturally reabsorbed by the body over time and adjacent tissue is left unharmed.

The procedure is monitored in real-time by ultrasound to ensure the ice ball is growing sufficiently around the tumor, including a margin (area of tissue surrounding the tumor, similar to surgery), and to avoid damage to the skin or muscle.



1

The cryoprobe is inserted into the tumor at a small incision site.



2

The tumor is enveloped by an ice ball. The extreme cold kills the tumor tissue.



3

The cryoprobe is removed and a Steri-Strip is applied, requiring no stitches.



For a full list of benefits and risks associated with cryoablation, read our patient leaflet at icecure-medical.com/prosense-cryoablation-breast-cancer-patient-information-fda-indication/