

IceCure's ProSense® Cryoablation Featured in 4 Independent Breast Cancer Studies Presented at Radiological Society of America 2025 Annual Meeting

Abstracts presented include 3 studies involving 263 patients, adding to a growing body of evidence across diverse patient populations supporting broader adoption of ProSense®

CAESAREA, Israel, Dec. 10, 2025 /PRNewswire/ -- IceCure Medical Ltd. (NASDAQ: ICCM) ("IceCure", "IceCure Medical" or the "Company"), developer of minimally-invasive cryoablation technology that destroys tumors by freezing as an option to surgical tumor removal, today announced that four abstracts featuring data from independent studies conducted by ProSense® users were accepted and presented at the Radiological Society of North America's ("RSNA") Annual Meeting, which took place from November 30 to December 4, 2025 in Chicago, Illinois.



The RSNA's Annual Meeting, the world's largest radiology conference with around 50,000 attendees from 160 countries, is a prestigious global platform for presenting clinical data. The acceptance of four abstracts this year, each showcasing results achieved with IceCure's technology, represents another significant international recognition of the effectiveness and growing adoption of ProSense® by the medical community for the treatment of breast cancer.

"The broad range of independent studies conducted, peer reviewed, published and presented by ProSense® users supports the widescale adoption of our cryoablation system and is highly encouraging for women who seek a non-surgical option," said Eyal Shamir, IceCure's Chief Executive Officer. "At RSNA 2025, radiologists from across the U.S. and the globe gathered to learn about the latest technologies that can lead to better patient outcomes, and we are proud that ProSense® was presented to these doctors. We continue

to see growing interest in ProSense® following the U.S. Food and Drug Administration's ("FDA") recent marketing approval in low-risk breast cancer."

Independent studies presenting data on ProSense® included the following:

1. **Abstract Title:** <u>Ultrasound-guided Cryoablation for Breast Cancer in Non-Surgical</u> Patients

Key Finding: PCA was successful in 100% of luminal cancers up to 2.5 cm

Researchers (Spain): Laura Abelairas Lopez, MD, Lucia Grana Lopez, MD, Laura Lopez, MD, Ignacio Fernandez Sobrado

Purpose: To present a single-center experience on the use of percutaneous cryoablation ("PCA") for the local control of breast cancer ("BC") in patients who elect not to undergo a surgery or were considered inoperable

Results: 73 women who were considered inoperable were treated under local anesthesia with PCA. 69 of them (median age 87 years, range 48-98 years) had at least one imaging examination performed 6 months after the procedure. Median tumor size was 23 mm, range 6-46 mm. The mean follow-up was 19.8 months (range 6-45 months). 60 patients were luminal BC, 3 were Her2 (+) and 8 were triple negative tumors. All luminal cancers received endocrine therapy. Complete tumoral necrosis was achieved in 56 tumors (81.2%). There was axillary progression in two triple negative BC. Recurrence in a different location was diagnosed in two patients. PCA was successful in 100% of luminal cancers up to 2.5 cm. No major complications were seen and the procedure was well tolerated.

Conclusions: Percutaneous cryoablation is a minimally invasive procedure, without significant complications. It could be a safe alternative to surgery for the management of early-stage breast cancer.

2. **Abstract:** Non-Surgical Treatment of Breast Cancer: A Comparison of Outcomes

Between Cryoablation with Hormonal Therapy Versus Cryoablation Alone and Hormonal
Therapy Alone in Patients Not Eligible for Surgery

Key Finding: Statistically significant difference between the Cryoablation-with-HT and the HT-only groups, expressing the added value of Cryoablation

Researchers (Italy): Federica Di Naro, MD, Sofia Elisabetta Baldi Giorgi, Francesca Pugliese, MD, Sofia Vidali, Tommaso Amadori, MD, Diego De Benedetto, Jacopo Nori Cucchiari

Purpose: To evaluate the most effective non-surgical treatment for breast cancer in surgery-ineligible patients, comparing ultrasound-guided Cryoablation combined with hormonal therapy (HT) versus Cryoablation alone and hormonal therapy alone

Results: 111 patients (mean age 81.2 years, ±11.3) not-suitable for surgery due to comorbidities and/or advanced age were enrolled, with a total of 125 biopsy-confirmed malignant breast lesions. Tumor size reduction was significantly different between the groups (P=0.0005), with greatest reduction in the Cryoablation-with-HT group (83.3%, mean reduction of 13.6 mm), followed by Cryoablation-only (61.7%, mean reduction of 8.2 mm),

and HT-only (42.1%, mean reduction of 7.4 mm). Tumors with complete remission (CR, RECIST 1.1) were similar between the Cryoablation-with-HT and Cryoablation-only groups (74.4% and 78.3%, respectively), followed by the HT-only (36.1%). Pairwise comparisons revealed a significant difference between the Cryoablation-with-HT and the HT-only groups for Contrast-Enhanced Mammography ("CEM")-enhancement, size reduction (%), and CR, expressing the added value of Cryoablation (P=0.0041, P<0.0001 and P<0.0001, respectively).

Conclusions: Cryoablation with hormonal-therapy significantly reduces tumor size and residual disease more effectively than therapy alone, making it a promising option for patients not-eligible for surgery.

3. **Abstract Title**: Correlation of Lesion Conspicuity in Contrast-Enhanced Mammography (CEM) with Tru-Cut Scar Biopsy Results in the Assessment of Ultrasound-Guided Cryoablation Outcome

Key Finding: Significant association between biopsy and lesion conspicuity on CEM

Researchers (Spain): Federica Di Naro, MD, Francesca Pugliese, MD, Sofia Elisabetta Baldi Giorgi, Giuliano Migliaro, MD, Giulia Bicchierai, Chiara Bellini, MD, Jacopo Nori Cucchiari

Purpose: To evaluate the role of lesion conspicuity at 12-month CEM follow-up as a predictor of cryoablation outcome

Results: 79 patients (mean age 85.7 years old, ±6.0) with biopsy-proven malignant breast lesions ≤35 mm, underwent ultrasound-guided cryoablation. Among the 79 patients, 48 (60.8%) underwent both CEM and Biopsy at 12 months. Among them, 35 (61.4%) lesions showed no enhancement. Among the 22 (38.6%) lesions showing enhancement, 6 had low LC, 11 moderate LC, and 5 high LC. A significant fair agreement (Cohen's Kappa coefficient = 0.32 [95% CI: 0.11-0.52]) between CEM and biopsy was shown. Fisher's exact test P-value was 0.0003 reflecting a significant association between biopsy and conspicuity. Lesions with absent or low LC correlated with negative histology (B2), while lesions with residual malignant histology (B5) were associated with moderate-high LC. In assessing cryoablation efficacy, CEM demonstrated negative predictive value (NPV) of 100%, Sensitivity of 100%, Specificity of 68.6% and positive predictive value (PPV) of 27.3%.

Conclusions: Lower lesion conspicuity on CEM indicates higher cryoablation success, useful for follow-up.

4. **Abstract Title**: Imaging Findings After Cryoablation of Breast Cancer: Tips and Tricks to Know That the Procedure was Successful Without Biopsy

Researchers (Spain): Laura Abelairas Lopez, MD, Lucia Grana Lopez, MD, Laura Lopez, MD, Ignacio Fernandez Sobrado

Teaching Points: Described the findings on mammography, ultrasound, and CEM after PCA of breast BC, as well as the signs of residual tumor or recurrence.

About ProSense®

The ProSense® Cryoablation System is the first and only medical device to receive FDA marketing authorization for the local treatment of low-risk breast cancer with adjuvant endocrine therapy for women aged 70 and above, including patients who are not suitable for surgical alternatives for breast cancer treatment. A full list of benefits and risks can be found on the Company's website.

ProSense® is a minimally invasive cryosurgical tool that provides the option to destroy tumors by freezing them. The system uniquely harnesses the power of liquid nitrogen to create large lethal zones for maximum efficacy in tumor destruction in benign and cancerous lesions, including in the breast, kidney, lung, and liver.

ProSense® enhances patient and provider value by accelerating recovery, reducing pain, surgical risks, and complications. With its easy, transportable design and liquid nitrogen utilization, ProSense® opens the door to fast and convenient office-based procedures for breast tumors.

About IceCure Medical

IceCure Medical (NASDAQ: ICCM) develops and markets advanced liquid-nitrogen-based cryoablation therapy systems for the destruction of tumors (benign and cancerous) by freezing, with the primary focus areas being breast, kidney, bone and lung cancer. Its minimally invasive technology is a safe and effective option to surgical tumor removal that is easily performed in a relatively short procedure. The Company's flagship ProSense® system is marketed and sold worldwide for the indications cleared and approved to date including in the U.S., Europe, and Asia.

Forward Looking Statement

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements. For example, IceCure is using forward looking statements in this press release when it discusses: the potential for clinical data presented at RSNA 2025 to further support or accelerate broader adoption of ProSense; statements regarding the potential clinical benefits of cryoablation, including ProSense as a non-surgical option for breast cancer patients; expectations relating to continued interest in ProSense following the FDA's recent marketing approval for use in low-risk breast cancer; and the Company's belief that ProSense may lead to improved patient outcomes or expanded clinical use. Historical results of scientific research and clinical and preclinical trials do not guarantee that the conclusions of future research or trials will suggest identical or even similar conclusions. Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among others: the Company's planned level of revenues and capital expenditures; the Company's available cash and its ability to obtain additional funding; the Company's ability to market and sell its products; legal and regulatory developments in the United States and other countries; the Company's ability to maintain its relationships with suppliers, distributors and other partners; the Company's ability to maintain or protect the validity of its patents and other intellectual property; the Company's ability to expose and educate medical professionals about its products; political, economic and military instability

in the Middle East, specifically in Israel; as well as those factors set forth in the Risk Factors section of the Company's Annual Report on Form 20-F for the year ended December 31, 2024 filed with the SEC on March 27, 2025, and other documents filed with or furnished to the SEC which are available on the SEC's website, www.sec.gov. The Company undertakes no obligation to update these statements for revisions or changes after the date of this release, except as required by law.

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