

Two New Publications from the Independent THERMAC Trial Featuring IceCure's ProSense® in Breast Cancer Finds 95% of Patients Satisfied with Thermal Ablation; ProSense® Cryoablation Achieves Highest Complete Ablation Rate

Article published in European Journal of Surgical Oncology focused on cosmetic outcomes and patient satisfaction reports 95% of patients were very satisfied or satisfied with thermal ablation

Article published in Radiology demonstrated that cryoablation with ProSense® achieved the highest complete ablation rate compared to alternatives with no adverse events

CAESAREA, Israel, Sept. 8, 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 two publications reporting positive results for the ProSense® cryoablation system in breast cancer stemming from the THERMAC Trial, an independent study taking place in the Netherlands which compares different methods of thermal ablation used for early-stage breast cancer. ProSense® has regulatory approval for breast cancer in the European Union.



"These peer-reviewed publications further advance ProSense®'s clinical validation," stated IceCure's Chief Executive Officer, Eyal Shamir. "In the THERMAC Trial, ProSense® cryoablation outperformed alternative thermal ablation techniques and delivered cosmetic

outcomes superior to surgery, showcasing its safety and efficacy in early-stage breast cancer. We are grateful to Dr. Sophie Wooldrik and her team in the Netherlands for their rigorous research and interest in evaluating minimally invasive modalities."

Both published papers, based on the THERMAC Trial, were led by Dr. Sophie Wooldrik, Department of Surgery, Franciscus Gasthuis & Vlietland, in Rotterdam, the Netherlands. Some data from these publications were previously presented at medical conferences including the European Conference on Interventional Oncology 2025, the Society of Interventional Oncology (SIO) 2025 Annual Meeting, and the 2024 European Society of Breast Imaging where the study won the Young Physician Scientist Competition.

THERMAC Trial was a phase II study which compared radiofrequency ablation (RFA), microwave ablation (MWA), and cryoablation with ProSense® for early-stage breast cancer. Forty-one (41) patients were included in the study. Based on the phase II results, the study's investigators concluded that cryoablation is the preferred technique for comparison with surgery in a future phase III trial.

The article published in *European Journal of Surgical Oncology*(EJSO) titled "Cosmetic outcome and patient satisfaction following percutaneous thermal ablation of early-stage breast cancer; results of an open label randomized phase 2 trial" assessed patient-reported cosmetic outcome and satisfaction following percutaneous thermal ablation with ProSense® and breast-conserving surgery.

The findings included the following:

- Overall median cosmetic outcome was good after thermal ablation, and intermediate after surgery (1.6 vs 1.8; P = 0.07)
- Most domains of BREAST-Q (a widely used patient-reported outcome instrument measuring health-related quality-of-life and patient satisfaction in breast surgery) were scored higher after thermal ablation as compared to breast conserving surgery
 - 95% of patients were very satisfied or satisfied with thermal ablation
 - 91% would prefer thermal ablation over surgery
- On BCCT core (a method for the objective evaluation of breast cancer conservative treatment) 94% of cases were rated as good or excellent after thermal ablation, compared to 80% after surgery

An article related to the same study was published in <u>Radiology</u>, titled "Percutaneous Thermal Ablation for Early-Stage Breast Cancer: An Open-Label, Randomized, Phase II Trial to Select the Preferred Technique for Evaluating Thermal Ablation as a Surgical Alternative."

The findings included the following:

- Cryoablation with ProSense® achieved the highest complete ablation rate with no complications, supporting its selection for a phase 3 trial
- Cryoablation with ProSense® was associated with zero cases requiring oncoplastic surgery, compared to 2 (40%) in the RFA group, and 2 (11%) in the MWA group
- RFA was halted early due to protocol-defined issues
- MWA delivered moderate efficacy

About ProSense®

The ProSense® Cryoablation System provides a minimally invasive treatment 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 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 that 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 alternative to hospital 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 Statements

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 that cryoablation is the preferred technique for comparison with surgery in a future phase III trial. 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.

IR Contact:

Email: <u>investors@icecure-medical.com</u>

Michael Polyviou Phone: 732-232-6914

Logo: https://mma.prnewswire.com/media/2319310/IceCure Medical Logo.jpg

C View original content: https://www.prnewswire.com/news-releases/two-new-publications-from-the-independent-thermac-trial-featuring-icecures-prosense-in-breast-cancer-finds-95-of-patients-satisfied-with-thermal-ablation-prosense-cryoablation-achieves-highest-complete-ablation-rate-302548874.html

SOURCE IceCure Medical