

November 18, 2025



IceCure's ProSense® Cryoablation System Receives Regulatory Approval in Switzerland for Indications Including Breast, Lung, Liver, and Kidney Cancer

This latest approval further broadens global access to ProSense® and supports IceCure's commercial momentum following the U.S. Food and Drug Administration's ("FDA") recent marketing authorization of ProSense® in low-risk breast cancer

CAESAREA, Israel, Nov. 18, 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 the ProSense® system and cryoprobes for the treatment of malignant or benign tissue of the breast, lung, liver, kidney, and musculoskeletal (bone), including palliative interventions, has been officially registered and approved for distribution by Swissmedic, the Swiss Agency for Therapeutic Products. These indications are the same as those for which ProSense® is approved in the European Union.



"We believe approval in Switzerland adds to the strong regulatory and commercial momentum we've generated leading up to and following the FDA's recent marketing authorization for ProSense® in low-risk breast cancer," said Eyal Shamir, IceCure's Chief Executive Officer. "Gaining access to another important European market enhances our ability to scale adoption and brings us closer to making ProSense® a standard-of-care option to surgery for patients globally."

Switzerland is a leader in healthcare innovation and medical technology, providing high-quality healthcare to its citizens in a market-driven compulsory system. According to the KOF Swiss Economic Institute, the total healthcare market in Switzerland is projected to reach [\\$120 billion](#) in 2023, as the country spends [12%](#) of its GDP on healthcare, one of

highest in OECD countries.

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 expectation that approval in Switzerland will contribute to strong regulatory momentum and market adoption, and the future positioning of ProSense® as a standard-of-care treatment globally. 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: investors@icecure-medical.com

Michael Polyviou

Phone: 732-232-6914

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