IceCure

ProSense™ Liquid Nitrogen (LN2) Cryoablation System

Generate ultra-cold temperatures quickly to create large lethal zones for maximum efficacy in tumor destruction.

Bringing the choice of advanced minimally invasive cryoablation treatment options for tumors to women's health and interventional oncology.

Cryoablation is Your Choice

Choose maximum tumor destruction with the ProSense Cryoablation System

The ProSense™ Cryoablation System is optimized to provide reliable cryotherapy in a variety of treatment settings. The moveable, liquid-nitrogen-based ProSense Cryoablation System can be used in office-based settings, radiology departments and the operating room.

Effective freeze
Rapid temperature drop with stable freezing at a low temperature

Low temperatures -160^{0}±10^{0C}
Creates large lethal zones

Large ice ball
Allows for target tissue engulfment with adequate margins

Easy to operate
Single cryoprobe, multiple freezing cycles, relocation options

Choose the power of Liquid Nitrogen cryoablation

Liquid Nitrogen (LN2) provides a superior cooling rate* for optimal tumor destruction.
The ProSense™ system achieves a sharp temperature decrease at the start of the freeze step to below -160°C and provides consistently low stable freezing temperatures throughout the procedure.

Quick cooling rate

Large lethal zone

Lower and more stable freezing temperatures

Environmentally friendly, no special storage conditions

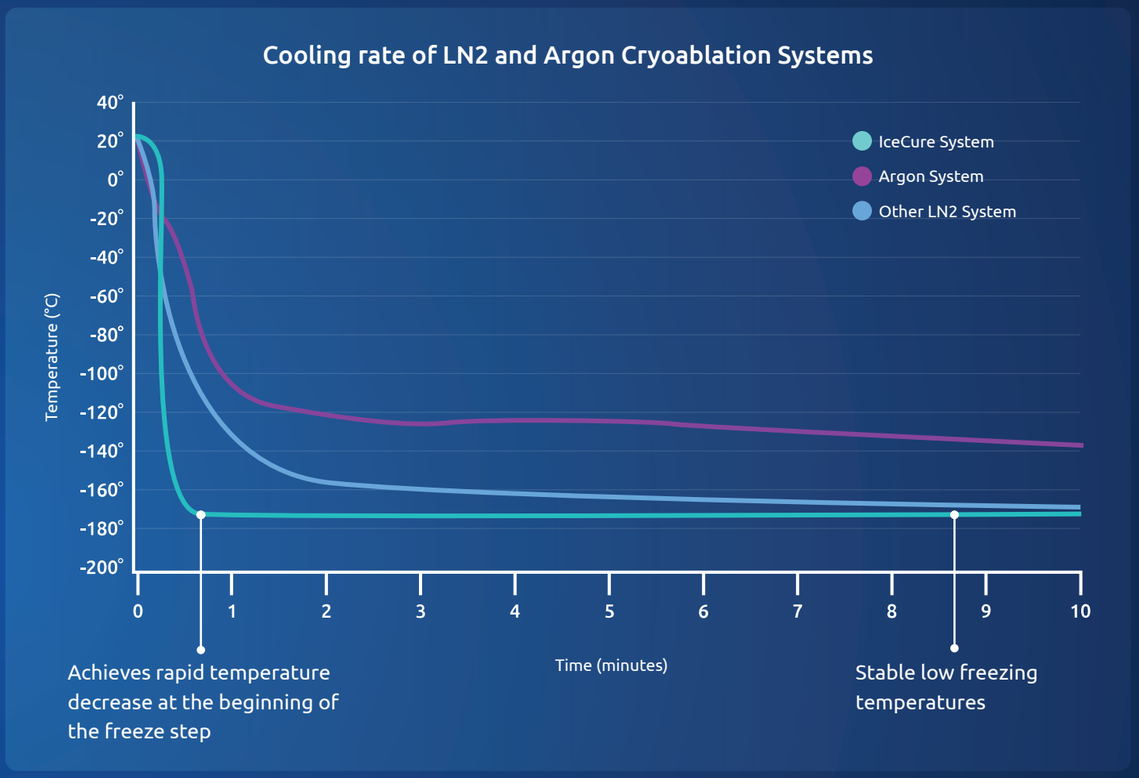
* Table 2.2 Temperature of some commonly used cryogens. Ed. Pasquali (2015). Cryosurgery: A Practical Manual. Springer

Choose, Ease of Use and Efficiency

Fits a variety of settings
- **Small footprint:** In the office or operating room
- **Refillable Liquid Nitrogen Dewar:** No gas lines, no on-site technicians, no specific safety rooms for storing large and hazardous high-press cylinder tanks required with argon-based cryoablation devices.

Efficient
- **Easy installation:** Minimal procedure set-up time.
- **Single cryoprobe system:** can create large lethal zones with a single point of entry similar to 3 smaller cryoprobes in a multiprobe system.

User-friendly
- **Touch-screen system:** Intuitive user interface, with step-by-step instructions and pre-set freeze-thaw-freeze protocols.
- **Multiple languages**
- **Various cryoprobe types**: to optimize treatment to the size and location of the lesion



High Cooling Rate = Fast Freezing Lethal Area < -19°C

Tatsutani K, Rubinsky B., Effect of thermal variables on frozen human primary prostatic adenocarcinoma cells. Urology (1996) 48:441-447

High freeze rate cryoablation results in an immune response stimulation with a significant increase in tumor-specific T cells in the tumor-draining lymph node, a reduction of metastases and an improved survival.

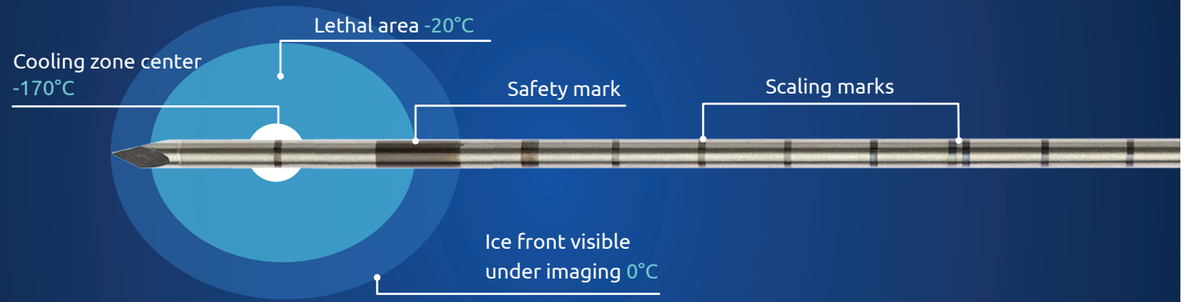
Sabel et al., Rate of Freeze Alters the Immunologic Response After Cryoablation of Breast Cancer. Ann Surg Oncol (2010) 17:1187–1193

Choose ProSense™ advanced cryoprobe technology

Best practices enable a large, and well-defined lethal zone surrounding the tumor

0°C Ice front

-40°C/-20°C
Internal temperature



Adaptable
Cryoprobes come in several diameters, lengths and create either spherical or elliptical ice ball shapes

Environmentally friendly
Small disposable cryoprobes are environmentally friendly and compliant with environmental guidelines

Safe
Safety mark allows you to know where on the cryoprobe the ice ball will form in order to avoid skin injury

Efficient
Cryoprobes can be relocated up to three times per patient during a single procedure

Maximum cooling
The cooling zone center creates temperatures as low as -170°C

Simple
Single cryoprobe system simplifies set-up time

Choose various cryoprobe types for optimal adjustment to the size and location of the target tissue*

2.4mm/13G | Cryoprobe | 124 mm | FAP7600000

	2 min	3 min	5 min	8 min	10 min	15 min
Ice front 0°C	20x24	23x27	28x31	33x36	35x38	39x42
Lethal area -20°C	16x20	18x22	22x25	24x27	26x29	29x31
Lethal area -40°C	12x17	14x18	16x19	17x20	17x21	19x21

2.4mm/13G | Cryoprobe | 134 mm | FAP7800000

	2 min	3 min	5 min	8 min	10 min	15 min
Ice front 0°C	19x34	24x36	30x41	35X46	38X47	46X51
Lethal area -20°C	16x30	20x32	24x35	28x38	30x39	34x39
Lethal area -40°C	13x27	16x29	18x30	21x32	22x33	24x33

3.4mm/10G | Cryoprobe | 127 mm | FAP7100000

	2 min	3 min	5 min	8 min	10 min	15 min
Ice front 0°C	23X30	25X32	31X36	36X40	38X43	44X48
Lethal area -20°C	19X25	22X27	25X29	29X32	30X33	33X36
Lethal area -40°C	15X21	17X22	19X24	21X26	22X27	24X28

3.4mm/10G | Cryoprobe | 140 mm | FAP7200000

	2 min	3 min	5 min	8 min	10 min	15 min
Ice front 0°C	22X37	26X40	32X42	37X46	41X48	46X52
Lethal area -20°C	18X32	23X34	27X36	31X37	33X38	36X41
Lethal area -40°C	15X28	18X30	21X30	23X32	25X33	26X35

3.4mm/10G | Cryoprobe | 185 mm | FAP7410000

	2 min	3 min	5 min	8 min	10 min	15 min
Ice front 0°C	22X37	26X40	32X42	37X46	41X48	46X52
Lethal area -20°C	18X32	23X34	27X36	31X37	33X38	36X41
Lethal area -40°C	15X28	18X30	21X30	23X32	25X33	26X35

*All ice ball measurements performed in room temperature gel. Width x length measurements are in mm. Measurements are ±3 mm. Cryoprobe figures are for illustration only.

Choose optimal tumor coverage and easy ice ball visualization

1. Cryoprobe selection

Choose the appropriately sized cryoprobe based on:

- Desired length for target tissue from skin per penetration point.
- Size of the ice ball desired for target tissue size, margins and the lesion shape (active freeze zone).

2. Navigation

Ensure the cryoprobe cooling zone center is placed centrally in the lesion for optimal treatment with CT or ultrasound image guidance.

3. Treatment

Select the appropriate freeze-thaw-freeze treatment cycle times

- Passive thawing of the frozen tissue is an important factor in tissue destruction
- Thaw and second freeze steps should be approximately the same length of time as the first freeze step.

4. Monitoring

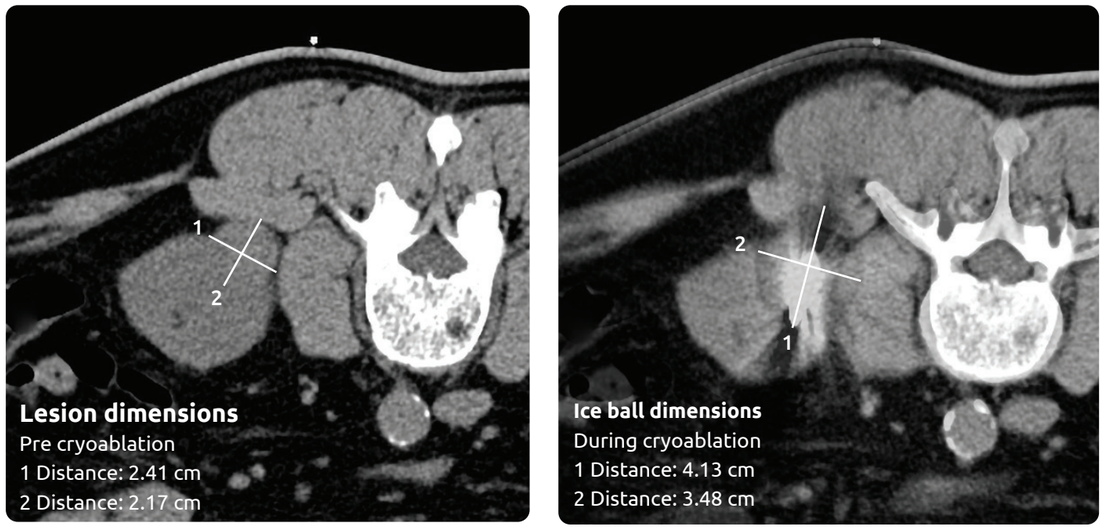
Easily visualize the ice ball growth in real time until it reaches the desired size.

Choose excellent patient outcomes from cryoablation

"Cryoablation is a procedure that we know is safe, efficacious, cost effective and cosmetically superior to surgical removal… My patients have been very happy with the short, painless procedure, and the ability to return to normal activity immediately."

Andrew Kenler, MD, FACS, Breast Surgeon, Connecticut, United States

Real-time CT imaging during a renal tumor cryoablation procedure



Clear view of ice ball boundary using single cryoprobe to treat large renal tumor

Choose a minimally-invasive alternative to standard surgical procedures

Advantages

Safe
Repeatable procedure with exceptional safety profile

Effective
Well established with excellent efficacy and low tumor recurrence rate

Faster recovery
Patients return immediately to daily activities

Local anesthesia
Great option for patients who want to avoid risks from general anesthesia

Minimal pain
Ice ball has an analgesic effect to reduce pain

Convenient
Can be done on an outpatient basis or with a shortened hospital stay

The ProSense™ System effectively treats a range of applications

Cryoablation has been clinically proven as a safe and effective method to treat a wide variety of tumors, including breast, kidney, lung, liver, and bone. Approved clinical indications for use may vary based upon your region's regulatory body.

Breast

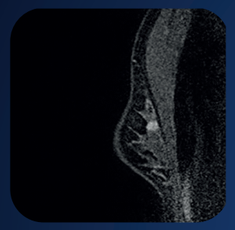
Cryoablation for breast tumors provides a minimally invasive treatment option to destroy breast tumors without removing them (lumpectomy), allowing women to maintain the shape of their breast. ProSense uniquely enables a fast and convenient office-based procedure with minimal pain, rapid recovery and fewer complications compared to surgical alternatives.

The ProSense System has been used to treat fibroadenomas successfully since 2012.

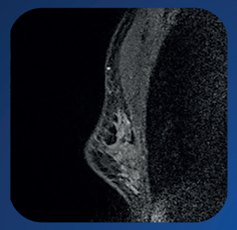
Since 2014, the ProSense System is being used in the ICE3 clinical trial: Which is the largest controlled multi-location clinical trial ever performed for cryoablation of small, low-risk breast cancer* with promising interim results.

Case Study:

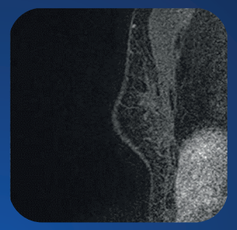
Breast Cryoablation - Maintaining Cosmetic Appearances
A female patient with stage 1 cancer in the right breast was treated with the ProSense™ Cryoablation System under ultrasound guidance in June 2012. The patient exhibited no recurrence of breast cancer four years after the cryoablation procedure. There were no complications or adverse events and the patient had good cosmetic results.
Courtesy of Professor Eisuke Fukuma, MD, PhD



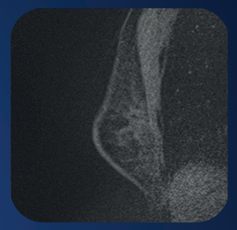
MRI
Pre-cryoablation



MRI 1 Month
Post-cryoablation



MRI 16 Months
Post-cryoablation



MRI 38 Months
Post-cryoablation

"Cryoablation offers an exciting, minimally invasive option to open surgery in the treatment of small, early-stage breast cancer tumors. The innovative Liquid Nitrogen (LN2) based ProSense™ System provides more efficient, targeted treatment to completely destroy the tumor in a quick, office-based procedure"

Professor Eisuke Fukuma, MD, PhD, Chairman of Breast Center, Kameda Medical Center, Japan

Kidney

Cryoablation for kidney tumors is a well-established and proven treatment option that preserves renal function. It has comparable oncological outcomes to surgery, with fewer complications and a shorter hospital stay.*

"Cryoablation for renal tumors is feasible, safe, efficient, cost-effective with a low complication rate and can easily be repeated. It is a noticeably quick procedure compared to surgery; patients we treat in the morning are heading to lunch by noon."

Professor Ofer Nativ, MD, Urological Surgeon, Elisha Hospital, Haifa, Israel

Bone

As a palliative therapy, cryoablation in metastatic bone tumors improves quality of life, significantly reduces pain with a lower morbidity and a quick recovery.*

"An advantage of the ProSense™ System compared to other ablation devices is that the patient does not feel any pain during the treatment or afterwards. Because we can easily check the ablation area and see the ice ball forming easily with CT or ultrasound, we can be very safe in covering the tumor area needed without harming any sensitive structures close to the target."

Professor Franco Orsi, MD, Director of Interventional Oncology, European Institute of Oncology, Milan, Italy

Lung

Cryoablation in the treatment of lung cancer offers a safe option for patients with stage I lung cancer with good overall long-term survival. It can also be used as a palliative treatment to achieve tumor debulking and symptom relief in advanced stage lung cancer.*

"In 101 patients with T1N0M0 non-small cell lung cancer, we found that utilizing the Liquid Nitrogen (LN2) based ProSense™ System to be a promising treatment for tumors <1.8cm in size. Furthermore, LN2 systems have higher power and lower cost when compared to argon gas cryoablation systems."

Dr. Hiroaki Nomori, Kameda Medical Center, Japan

*For details about specific claims mentioned within this document, please refer to icecure-medical.com for detailed explanation and sources.

Ordering information

Product name	Part number	Description	Shaft length	Tip shape	Cooling zone center from needle tip
Cryoprobes	FAP7100000	3.4 mm / 10G / Spheric	127 mm	Trocar	12 mm
	FAP7200000	3.4 mm / 10G / Elliptic	140 mm	Trocar	20 mm
	FAP7410000	3.4 mm / 10G / Elliptic	185 mm	Trocar	20 mm
	FAP7600000	2.4 mm / 13G / Spheric	124 mm	Trocar	10 mm
	FAP7800000	2.4 mm / 13G / Elliptic	134 mm	Trocar	14.5 mm

Product name	Part number	Description	Introducer active length	Tip shape
Introducers	FAC9000000	2.4 mm, Fit to cryoprobe diameter 13G (FAP7800000)	115mm	Trocar
	FAC9100000	3.4 mm, Fit to cryoprobe diameter 10G (FAP7200000)	122mm	Trocar
	FAC9200000	3.4 mm, Fit to cryoprobe diameter 10G (FAP7410000)	167mm	Trocar
ProSense™ cryoablation console (90° handle)	FAS3000000	100-127 VAC		
	FAS3100000	220-240 VAC		
ProSense™ cryoablation console (straight handle)	FAS3000000-2	100-127 VAC		
	FAS3100000-2	220-240 VAC		
Holder	FAG3000000	For use in interventional oncology cases / CT imaging		

Straight handle

90° handle

ProSense System Specifications

The ProSense™ Cryoablation System comes with two, 2 Liter liquid nitrogen dewars.
Other accessories include: Main chassis, adjustable touch screen, external accessories: introducers, holder (not available in some regions), foot pedal (not available in some regions), and cryoprobes*, **, ***

Operating Conditions

- Relative humidity: 30% to 85% not condensing at room temperature
- Temperature: 10° C; +40° C (50° F; 104° F)
- Atmospheric pressure: 700 hPa; 1060 hPa

Transportation and storage conditions

- Relative humidity: 30% to 85% not condensing
- Temperature: -20° C; +70° C (-4° F; 158° F)
- Atmospheric pressure: 500 hPa; 1060 hPa
- For ProSense™ System shipping, use the original shipping package to prevent damage during transportation
- If the original shipping packages are not available, the customer shall be fully responsible for any damage to the system elements during transportation

Mechanical specifications (excluding the screen)

- Height: 120 cm (47.24 inches)
- Depth: 70 cm (27.56 inches)
- Width: 50 cm (19.68 inches)
- Weight: 150kg
- Display: Panel PC, 15.6”, Single touch, Windows 7 OS
- Languages: English, Spanish, French, Italian, German, Russian

Gas supply ****

- Liquid nitrogen, Boiling point -196° C
- Internal LN2 canister / dewar
  - 2L capacity
  - Height: 36.8 cm (14.5 inches), Depth: 11.5 cm (4.5 inches), Width: 12.7 cm (5 inches)

Operating pressure

- Pressure range: 0-100 psi

Pressure sensor

- Power supply: 24 V
- Pressure range: 0.1 - 145 psi
- Accuracy: 1%
- Repeatability: ≤ ± 0.1

Type of internal cryometers:

Thermocouple type K

Temperature reading range of cryoprobe:

-196° C to +40° C

Electrical specifications

- Input voltage and frequency: 100-127 VAC, 12 A, 50/60 Hz, single phase or 220-240 VAC, 7 A, 50/60 Hz, single phase
- IP Rating: IP XO
- Electrical protection: Class I, Type BF protection
- Output ports: USB 2.0 full-speed port

*IceCure Medical systems, cryoprobes, introducers or accessories are available only in select markets.
**Cryoprobes, introducers, and temperature sensors are single-use items.
*** Cryoprobes are sold seperately
****LN2 is supplied, obtained, and refilled by local suppliers according to your regions regulations.

Choose Cryoablation with IceCure

IceCure is transforming healthcare by bringing the choice of advanced minimally invasive cryoablation treatment options for tumors to women's health and interventional oncology. The FDA cleared and CE marked ProSense System (TM Symbol) uses liquid-nitrogen to generate ultra cold temperatures to destroy tumors by freezing them. Supported by clinical experience across multiple areas of cancer care, IceCure is opening the door for quick, convenient office-based and CT room procedures.

IceCure Medical, LTD's cryoablation systems have worldwide distribution. Please check that the clinical indications discussed in this brochure have regulatory clearance for use in your country.

To learn more, visit: **www.icecure-medical.com**