

ProSense™

Liquid Nitrogen (LN2) Cryoablation System

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

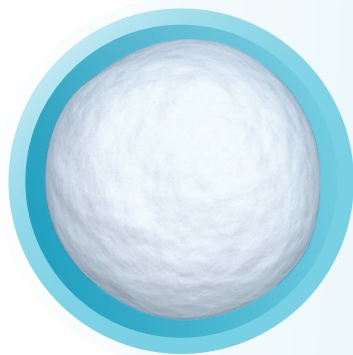


 **IceCure**
Innovating Cryotherapy Solutions

Setting new standards in minimally-invasive tumor therapy for women's health and interventional oncology



The ProSense™ System is setting the new gold standard in cryoablation



Effective freeze
Rapid temperature drop with stable freezing



Low temperatures -160^o+/-10^oC
Creates large lethal zones



Large ice ball
Passive thaw between freezing steps



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

The ProSense™ Cryoablation System is optimized to provide reliable cryotherapy in a variety of treatment settings. The easily maneuverable system can be used in the operating room, radiology department, or office-based setting.

Powerful, compact, efficient & user-friendly

Powerful

- LN2's powerful freezing performance enables temperatures to quickly drop to below -160°C and stay consistently low during the freeze steps

Compact

- Small footprint in the operating room or office
- The LN2 system removes the need to connect to gas lines (required with argon-based ablation systems)

Efficient

- Easy installation with minimal procedure set-up time
- Single cryoprobe system can be quickly and safely relocated up to three times



LN2 Dewar

User-friendly

- Touch-screen system monitor provides an intuitive user interface, with step-by-step instructions and pre-set freeze-thaw-freeze programs based on tumor size in multiple languages
- Options for straight cryoprobe handle and 90-degree cryoprobe handle depending on the procedure being performed

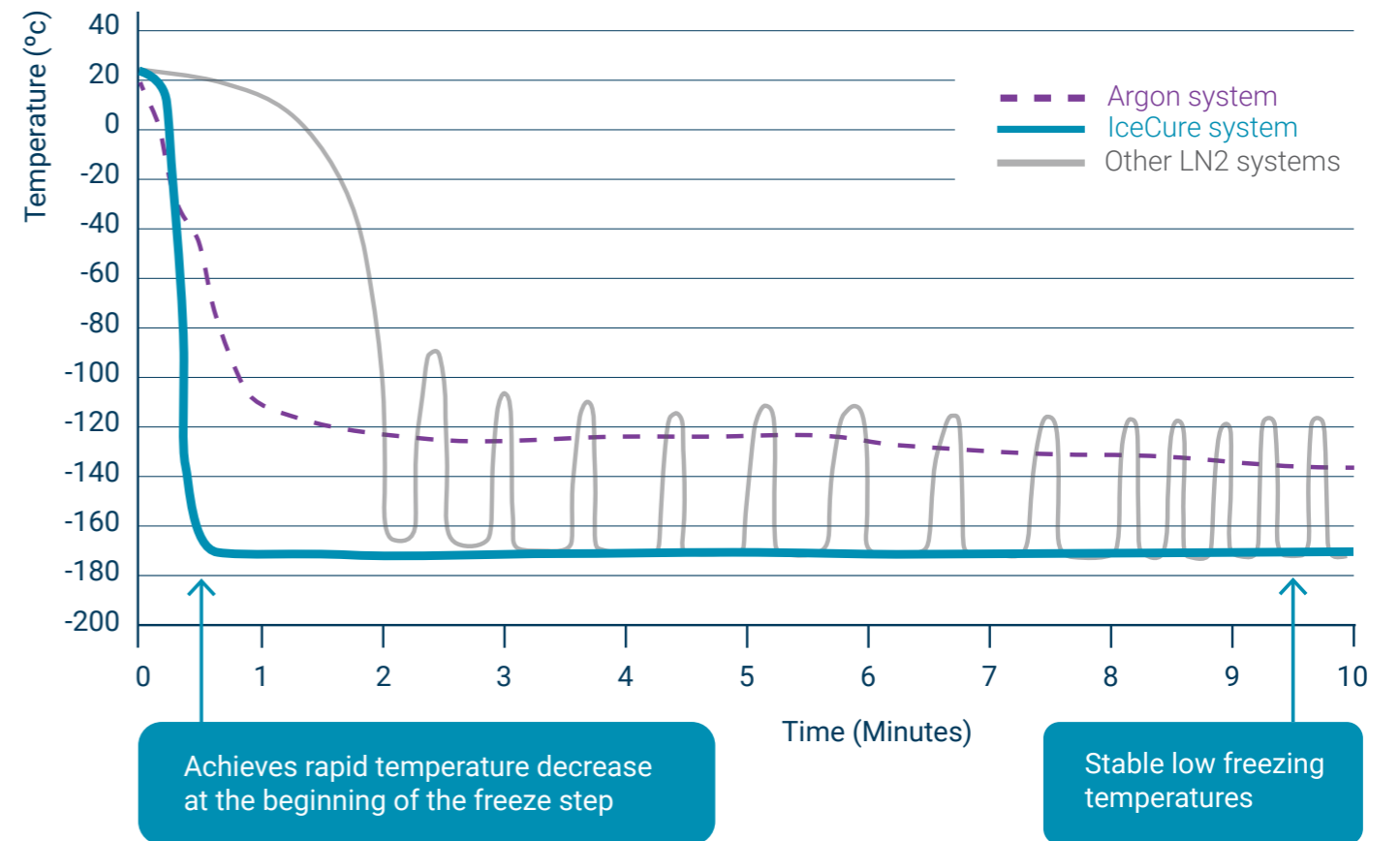
Elevate your practice with the power and ease of Liquid Nitrogen

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 and provides consistently stable freezing temperatures throughout the procedure.

- ✓ Quick cooling rate
- ✓ Lower and more stable freezing temperatures
- ✓ Large lethal zone
- ✓ Environmentally friendly, no restrictions on storage

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



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

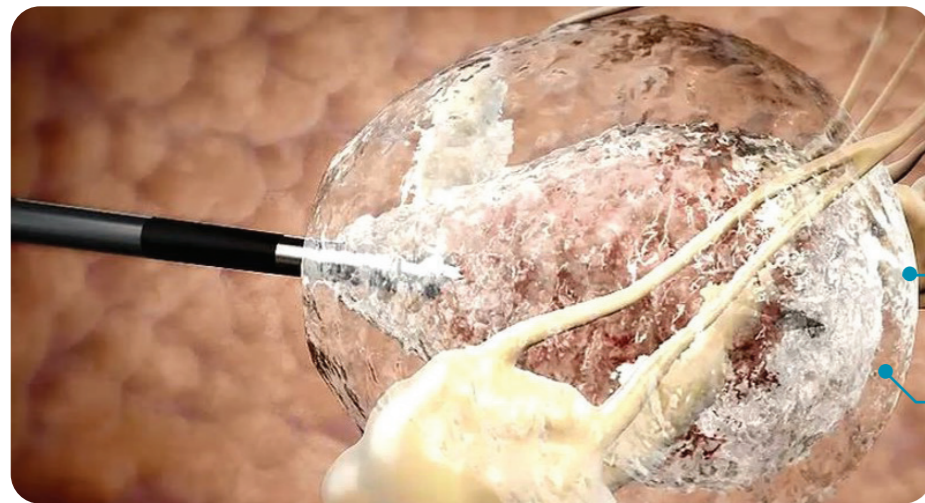
Tatsutani K, Rubinsky B., Effect of thermal variables on frozen human primary prostatic adenocarcinoma cells. Urology (1996) 48:441-447

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



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

Cooling zone center -170°C

Lethal area -20°C

Safety mark

Ice front visible under imaging -3°C



Simple

Single cryoprobe system simplifies set-up time

Adaptable

Cryoprobes come in several diameters, lengths and create both round and elliptical shapes

Environmentally friendly

Small disposable cryoprobes are environmentally friendly and compliant with environmental guidelines

Versatile

Cryoprobes can be relocated up to three times

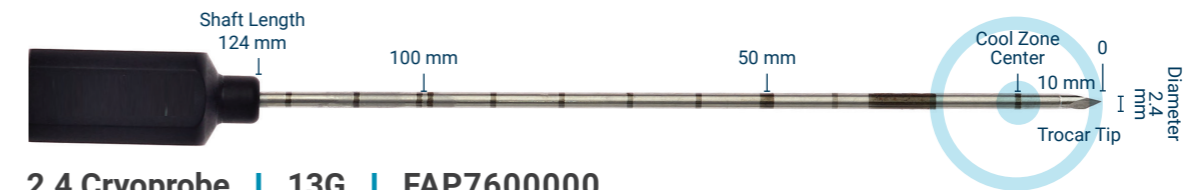
Maximum cooling

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

Safe

Safety mark allows you to know where the cryoprobe is safe to touch

Various cryoprobe sizes enable ice ball targeted to size of the ablation zone*



2.4 Cryoprobe | 13G | FAP7600000

	2 min	3 min	5 min	8 min	10 min	15 min
Ice front -3°C	20X24	23X27	28X31	33X36	35X38	39X42
Lethal area <-19°C	16X20	18X22	22X25	24X27	26X29	29X31



2.4 Cryoprobe | 13G | FAP7800000

	2 min	3 min	5 min	8 min	10 min	15 min
Ice front -3°C	19X34	24X36	30X41	35X46	38X47	46X51
Lethal area <-19°C	16X30	20X32	24X35	28X38	30X39	34X39



3.4 Cryoprobe | 10G | FAP7100000

	2 min	3 min	5 min	8 min	10 min	15 min
Ice front -3°C	23X30	25X32	31X36	36X40	38X43	44X48
Lethal area <-19°C	19X25	22X27	25X29	29X32	30X33	33X36



3.4 Cryoprobe | 10G | FAP7200000 185 mm | FAP7410000

	2 min	3 min	5 min	8 min	10 min	15 min
Ice front -3°C	22X37	26X40	32X42	37X46	41X48	46X52
Lethal area <-19°C	18X32	23X34	27X36	31X37	33X38	36X41

*All ice ball measurements performed in room temperature gel.



Enabling optimal tumor coverage and easy ice ball visualization

1. Cryoprobe selection

Choose the appropriately sized cryoprobe based on:

- Desired length for target tissue location and position
- 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

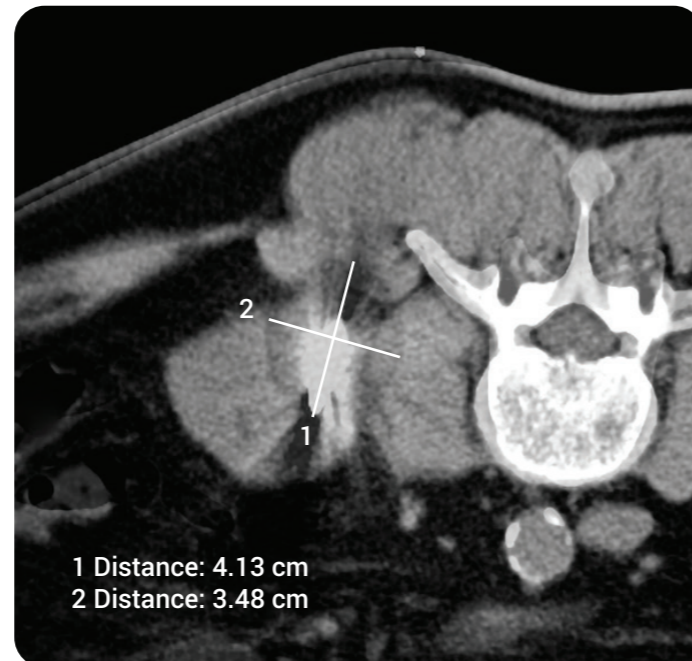
Select the appropriate freeze-thaw-freeze treatment cycle times

- Passive thawing of the frozen tissue is a prime destructive factor
- 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

Real-time CT imaging during a renal tumor cryoablation procedure



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

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

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

Reduces risks associated with 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 in breast tumors provides cosmetically superior results when compared to lumpectomy. The procedures generally take under an hour and patients can resume normal activity quickly.

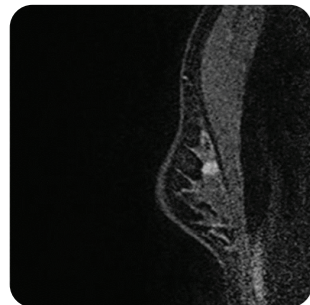
- The ProSense™ System has been used to treat fibroadenomas successfully since 2012.
- Since 2014, the ProSense™ System is being investigated in the ICE3 clinical trial: The largest controlled multilocation clinical trial ever performed for nitrogen-based cryoablation of small, low-risk, early-stage malignant breast tumors without subsequently removing them.

Case Study:

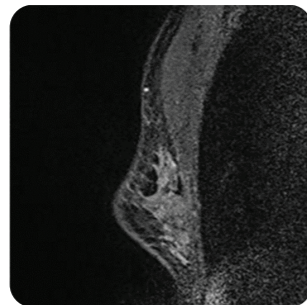
Breast Cryoablation - Maintaining Cosmetic Appearances

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.

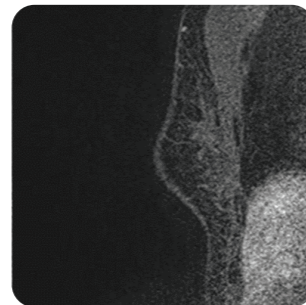
Courtesy of Professor Eisuke Fukuma, MD, PhD



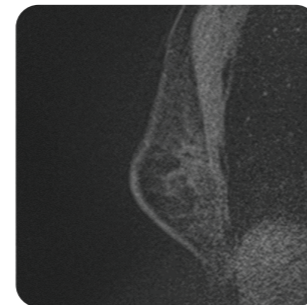
MRI
Pre-cryoablation



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



Cryotherapy for renal masses is a well-established and proven treatment option that preserves renal function, with low risk of injury to surrounding organs.

"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

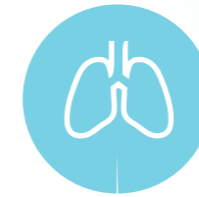


As a palliative therapy, cryoablation in metastatic bone tumors provide clinically significant pain reduction.

"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 relatively safe option for patients with stage I lung cancer and as a palliative treatment to achieve tumor debulking and symptoms 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."

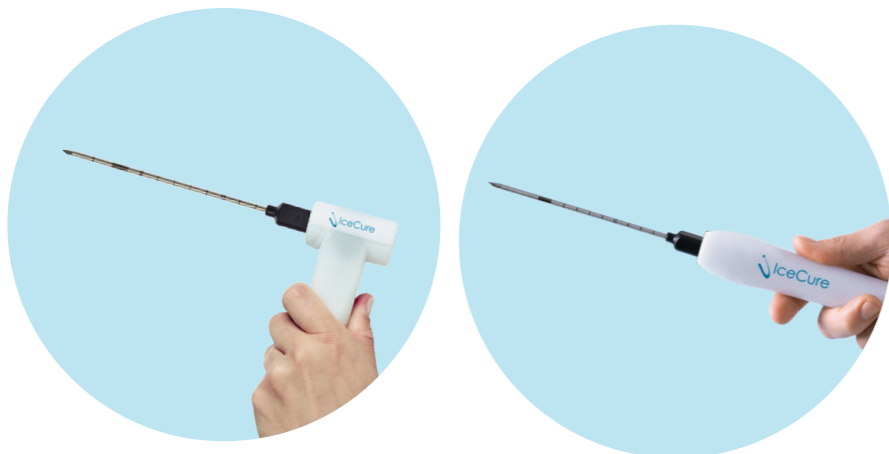
Dr. Hiroaki Nomori, Kameda Medical Center, Japan



Ordering information

Product name	Part number	Description	Shaft length	Tip shape	Cool zone center from needle tip
Cryoprobes	FAP7100000	3.4 mm / 10G / Spheric	127 mm	Trocar	12mm
	FAP7200000	3.4 mm / 10G / Elliptic	140mm	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 shaft length	Tip shape
Introducer	FAC9000000	2.5 mm, Fit to needle diameter 13G (FAP7800000)	115mm	Trocar
	FAC9100000	3.5 mm, Fit to needle diameter 10G (FAP7200000)	122mm	Trocar
	FAC9200000	3.5 mm, Fit to needle 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		



ProSense™ System specifications

The ProSense™ Cryoablation System includes: Main chassis, adjustable touch screen, external accessories: introducers, liquid nitrogen dewar, holder (not available in some regions), foot pedal (not available in some regions), and cryoprobes*.**

Operating conditions

- Relative humidity: 0% to 80% 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: $\leq \pm 0.1$

Type of cryometer: 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 against shock
- 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.

***LN2 is supplied, obtained, and refilled by local suppliers according to your regions regulations.





IceCure Medical, Ltd.

Founded in 2006, IceCure Medical has developed an advanced liquid nitrogen based cryoablation system that uses ultra-low freezing temperatures to destroy tumors (benign and cancerous) safely, quickly, and painlessly in a minimally-invasive procedure. After receiving FDA-clearance and CE-mark, the ProSense™ Cryoablation System is marketed and sold worldwide.

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



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* IceCure Medical systems are available in selected markets.
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