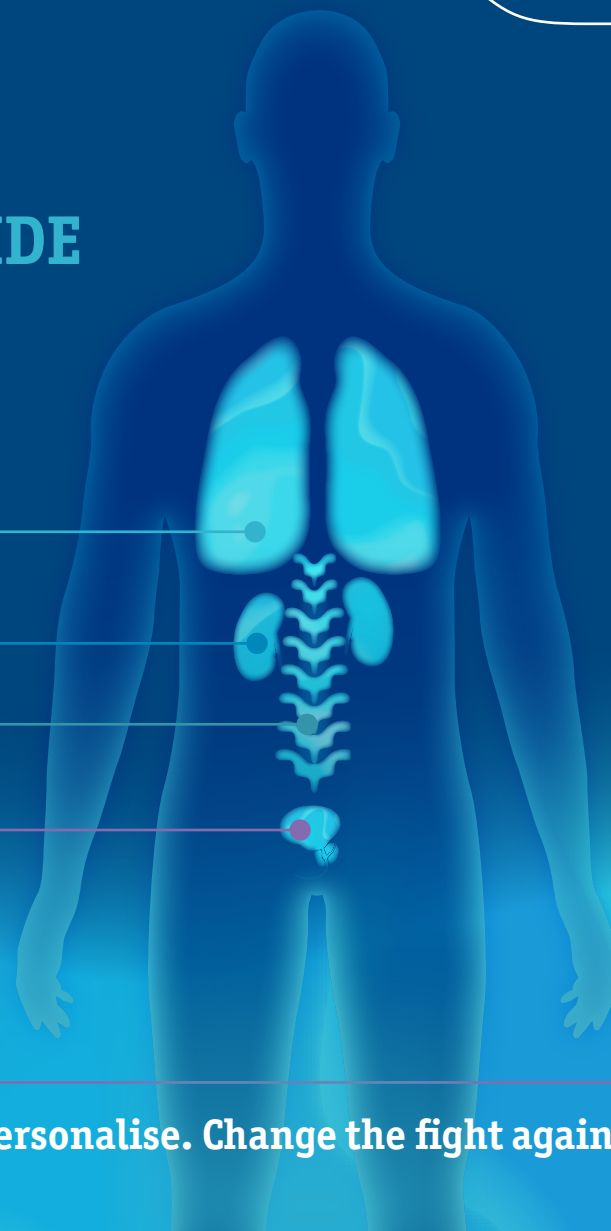


CRYOABLATION TREATMENT GUIDE



- The confidence to choose. The power to personalise. Change the fight against cancer.

WHY CRYOABLATION?

Cryoablation offers clinicians a number of unique advantages:

- Treatment zone visibility and control
- Reduced pain due to analgesic effect of ice
- Ability to treat multiple tumours in one session
- Ability to use ice in proximity to critical structures/vasculature
- Ability to use multiple probes to “sculpt” the shape of iceball and ablate larger tumours

Boston Scientific’s comprehensive cryoablation portfolio includes the narrowest gauge needles available today, allowing precise iceball shaping while minimising bleeding.

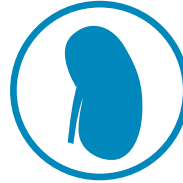
This guide has been developed to help you select the correct type and number of needles for each case.

MENU

INDICATIONS



ICE
CREATION



RENAL
CRYOABLATION



MSK*
CRYOABLATION
*Musculoskeletal

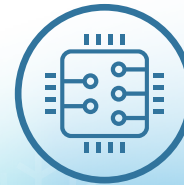


LUNG
CRYOABLATION



PROSTATE
CRYOTHERAPY

PRODUCT PORTFOLIO



CRYOABLATION
SYSTEMS



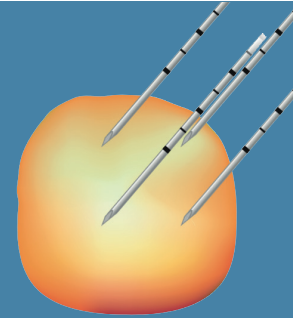
CRYOABLATION
NEEDLES

The confidence to choose. The power to personalise. Change the fight against cancer

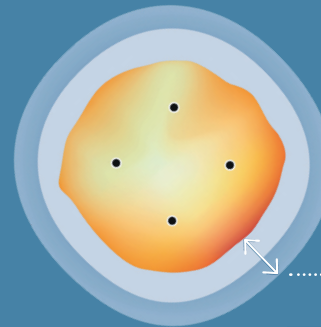


Iceball dimensions presented in this guide are provided to assist clinicians in selecting the cryoablation needle(s) and placing the needles to appropriately ablate the target area.

- In clinical use, patient anatomy, tissue and tumour properties affect needle placement.
- The following aspects of the individual case affect iceball size:
 - Tissue and tumour characteristics
 - Surrounding vasculature
 - Treatment duration
- Intraoperative imaging is important to monitor iceball formation throughout the procedure and is key to a successful cryoablation.
- Isotherms represented in this guide were conducted in a laboratory setting in 37°C temperature-controlled gel. Isotherm measurements were made following two 10-minute freeze cycles separated by a 5-minute passive thaw on each needle type and size.

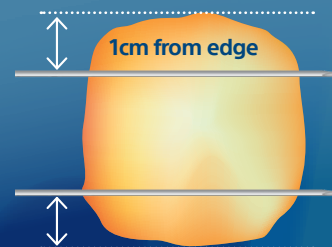


To optimise tumour coverage and provide appropriate margins, the use of multiple needles is recommended. Multiple needles placed in an adjacent configuration will typically create a large, coalesced iceball.



To optimise appropriate margins, needles should be placed to create lethal ice beyond the perimeter of the target tissue (5-10mm, depending on tissue type).

Extend ice 5-10mm beyond tumour edge



Needle tips extend 5-10mm beyond tumour edge

Place needles no further than 1cm from the tumour's edge



CRYOABLATION OF RENAL TUMOURS



“Oncologic outcomes of image-guided renal cryoablation for RCC are competitive with those of partial nephrectomy and are associated with a low complication rate.”
Breen DJ et al. 2018¹

“The median hospital stay of 1 day (range 0-8 days) was also notable... This compares favourably with a median PN stay of 4 days.”
Breen DJ et al. 2018¹

RATIONALE AND ADVANTAGES

- Comparable outcomes to resection/LPN with lower complication rate and shorter hospital stay¹
- Over 15 years of published data²
- EuRECA Registry comprising over 800 patients (on-going)³
- Improved outcomes versus RFA^{2,4,5}
- Suitable for use in traditionally ‘unablatable’ tumour locations:
 - Into the collecting system^{6,7}
 - Near critical structures¹
 - Effective in T1a and T1b tumours^{*1,8}

TYPICAL PATIENT PRESENTATION



Stage 1 T1a tumours¹⁰⁻¹²
T1b tumours (by advanced users)¹³



Single lesion



- Useful where nephron preservation is imperative
 - e.g. solitary kidney, poor renal function, or genetic predisposition to multiple renal tumours)^{14,15}
- Useful for central tumours
 - due to cryoablation’s collagen-preserving properties (limiting pelvicalyceal damage) and ability to retract tumours peripherally prior to ablation^{16,17}



- Patients less suitable for surgery, elderly or comorbid patients¹⁰⁻¹²
- Patients with a single kidney (offers advantages in this scenario over other techniques)¹⁴



TECHNICAL CONSIDERATIONS





CRYOABLATION OF RENAL TUMOURS



TECHNICAL CONSIDERATIONS



FREEZE-THAW PROTOCOL



Typical freeze-thaw protocol for renal cryoablation as used by David Breen, Alex King et al, Southampton University Hospital, UK



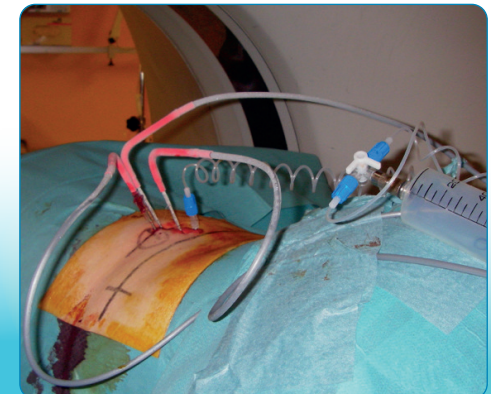
PROCEDURAL CONSIDERATIONS

- Renal cryoablation may be performed using general anaesthesia or conscious sedation¹⁴
- 90° needle handles are typically used
- Adjacent structures can be protected to avoid impact of freezing with:
 - Use of Multi-point Thermal Sensors (MTS)
 - Organ displacement:
 - Hydrodissection using saline and contrast
 - Dissection using CO₂
 - Balloons/gels, etc

CO₂ dissection to displace adjacent organs prior to renal ablation



90° needle placement



NEEDLE SELECTION



RESOURCES





CRYOABLATION OF RENAL TUMOURS



NEEDLE SELECTION

TUMOUR SIZE



<2cm



2-3cm



3-4cm



>4cm

NEEDLE TYPE & QUANTITY

ICESPHERE™ 1.5 CX

x2 NEEDLES



ICEROD™ 1.5 CX

x3 NEEDLES



ICEROD™ 1.5 CX

x4 NEEDLES



ICEFORCE™ 2.1 CX

x3 NEEDLES





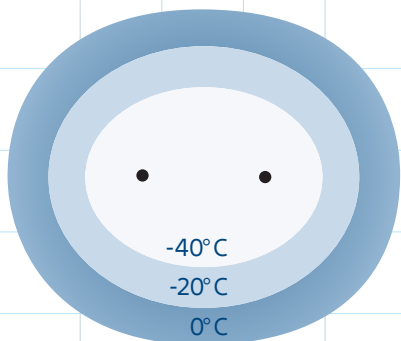
CRYOABLATION OF RENAL TUMOURS



ICESPHERE™ 1.5 CX

x2 NEEDLES

Actual Size $\pm 5\text{mm}$

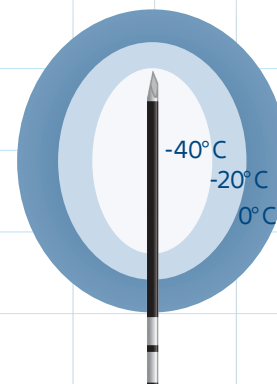


0°C	46mm x 39mm
-20°C	36mm x 29mm
-40°C	26mm x 19mm

ICESPHERE™ 1.5 CX

Shaft Length: 17.5cm
Shaft Diameter: 1.5mm/17G

$\pm 3\text{mm}$ width $\pm 4\text{mm}$ length



0°C	31mm x 36mm
-20°C	22mm x 28mm
-40°C	13mm x 23mm



CRYOABLATION OF RENAL TUMOURS



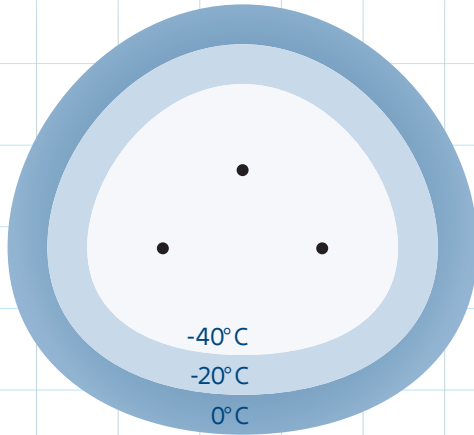
Millimeters

20
10
0
10
20
30
40
50
60

ICEROD™ 1.5 CX

x3 NEEDLES

Actual Size $\pm 5\text{mm}$



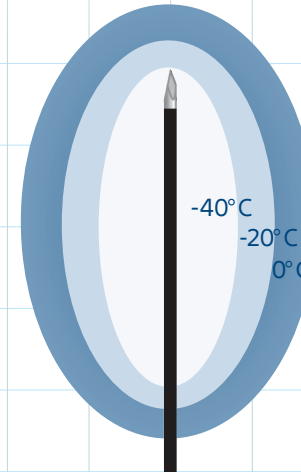
0°C	59mm x 53mm
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-40°C	39mm x 33mm

ICEROD™ 1.5 CX

Shaft Length: 17.5cm

Shaft Diameter: 1.5mm/17G

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0°C	36mm x 53mm
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-40°C	16mm x 39mm

Millimeters

20
10
0
10
20
30
40
50
60



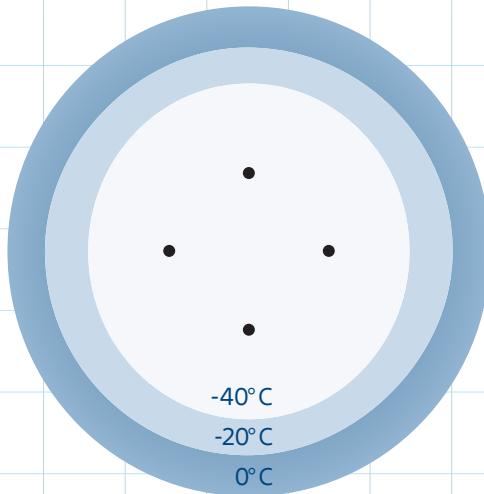
CRYOABLATION OF RENAL TUMOURS



ICEROD™ 1.5 CX

x4 NEEDLES

Actual Size $\pm 5\text{mm}$

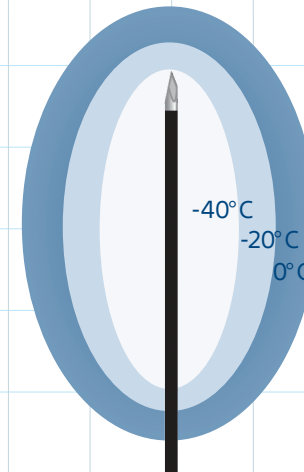


0°C	60mm x 61mm
-20°C	51mm x 51mm
-40°C	40mm x 42mm

ICEROD™ 1.5 CX

Shaft Length: 17.5cm
Shaft Diameter: 1.5mm/17G

$\pm 3\text{mm}$ width $\pm 4\text{mm}$ length



0°C	36mm x 53mm
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-40°C	16mm x 39mm



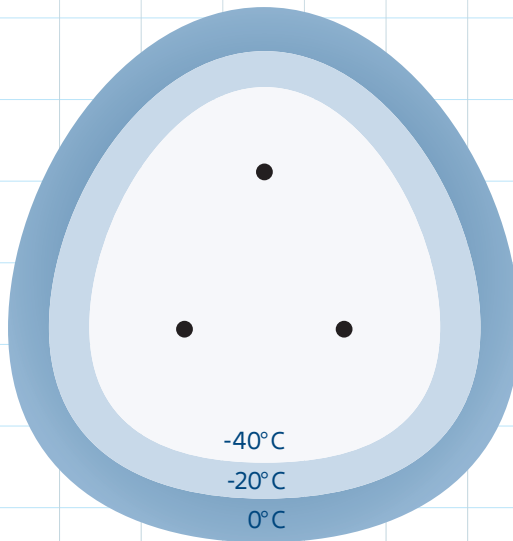
CRYOABLATION OF RENAL TUMOURS



ICEFORCE™ 2.1 CX

x3 NEEDLES

Actual Size $\pm 5\text{mm}$

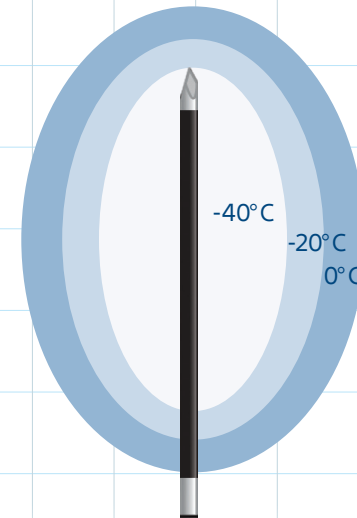


0°C	64mm x 67mm
-20°C	54mm x 56mm
-40°C	44mm x 47mm

ICEFORCE™ 2.1 CX

Shaft Length: 17.5cm
Shaft Diameter: 2.1mm/14G

$\pm 3\text{mm}$ width $\pm 4\text{mm}$ length



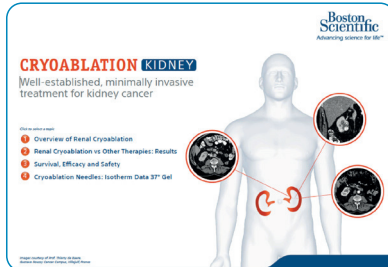
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-40°C	23mm x 42mm



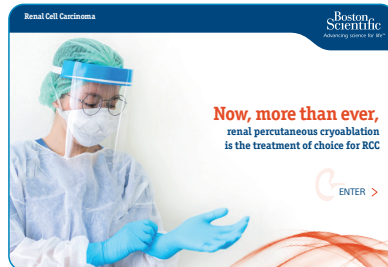
CRYOABLATION OF RENAL TUMOURS: RESOURCES



GENERAL INFORMATION



Overview of renal cryoablation, including key clinical data



Explore the benefits of renal cryoablation from the perspective of different stake-holders

CASE STUDIES



PROF ALEX KING
UNIVERSITY HOSPITAL SOUTHAMPTON,
SOUTHAMPTON, UK

Cryoablation of Exophytic Right Renal Tumour

Cryoablation of 7cm Renal Tumour after Previous Contralateral Nephrectomy

Cryoablation of Bilateral Renal Tumours



PROF THIERRY DE BAERE
GUSTAVE ROUSSY CANCER INSTITUTE,
VILLEJUIF, FRANCE

Cryoablation of 2.3cm RCC Following Previous Contralateral Partial Nephrectomy

KEY PUBLICATION SUMMARIES

ROSENBERG ET AL, 2011

PUBLICATION SUMMARY — RENAL

Percutaneous Cryoablation of Renal Lesions with Radiographic Ice Ball Involvement of the Renal Sinus: Analysis of Hemorrhagic and Collecting System Complications

AJR Am J Roentgenol 2011; 196(4):935-9
Rosenberg MDL, Kim CYL, Tishian MZ, Suberlak MWL, Sopko DR1, Polascik TJ2 and Nelson RC1
1. Department of Radiology and 2. Department of Surgery-Urology, Duke Medical Center, NC

THOMPSON ET AL, 2015

PUBLICATION SUMMARY — RENAL

Comparison of Partial Nephrectomy and Percutaneous Ablation for cT1 Renal Masses

Eur Urol 2015; 67(2):252-259
Thompson RH1, Atweil TJ2, Schmit G2, Lohse CM3, Kurup AN2, Weisbrod AJ2, Pucka SP1, Stewart SB1, Callstrom MR2, Chevillier JC4, Boorjian SA1, Leibovich BC1
1. Department of Urology, 2. Department of Radiology, 3. Department of Health Science Research, 4. Department of Pathology, Mayo Clinic and Mayo Medical School, Rochester, Minnesota.

BREEN ET AL, 2018

PUBLICATION SUMMARY — RENAL

Image-guided Cryoablation for Sporadic Renal Cell Carcinoma: Three- and 5-year Outcomes in 220 Patients with Biopsy-proven Renal Cell Carcinoma

Radio 2018; doi.org/10.1148/radiol.2018180249
Breen DJ1, King AJ1, Patel N1, Lockyer RJ2, Hayes M2
1. Department of Radiology and 2. Department of Urology, University Hospital Southampton NHS Trust, England. Department of Radiology, Karmanos Cancer Institute, Detroit, Michigan.

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“ Bone tumour cryoablation is a safe procedure with a very low rate of major complications. ”
Auloge P et al. 2019. University Hospital of Strasbourg, France^{18*}

RATIONALE AND ADVANTAGES

Studies show that cryoablation of bone and soft tissue tumours:

- Improves quality of life and functional status¹⁹⁻²¹
- Offers lower morbidity and faster recovery than surgery²⁰
- Reduces the use of pain medication, including opioids, and associated side effects^{20,21}
- Is a repeatable therapy that can be combined with stabilisation, fixation and reconstruction techniques²⁰
- Allows monitoring and modifications during procedure based on motor-evoked neural response²²
- In bone metastases, offers a palliative impact that is faster than radiation^{18,20}

TYPICAL PATIENT PRESENTATION



Metastatic bone tumours: <8cm²³
Soft tissue tumours: No upper limit²⁴



Single or multiple lesions



- No oven-effect. Ice propagates better in the bone
- Can be used under local anaesthesia
 - Ability to control response of nerves by interacting with the patient
- Safety and efficacy of the treatment can be improved by combining treatment with motor-evoked potentials
- Can be combined with cementoplasty



- Patients with non-operable lesions, or mutilating surgery (bones, vertebrae, soft-tissues)
- Patients who do not tolerate general anaesthesia





TECHNICAL CONSIDERATIONS



FREEZE THAW PROTOCOL



Typical freeze-thaw protocol for metastatic bone tumours as used by Doctor Julien Garnon, University Hospital of Strasbourg, Strasbourg, France



PROCEDURAL CONSIDERATIONS

- Cryoablation needles are compatible with use of any trocar
- Navigation during insertion of needles can be facilitated with the use of more rigid, 14G needles
- The number of needles is not limited, allowing for treatment of large lesions
- Cryoablation does not interfere with metallic prostheses
- Cryoablation of MSK tumours is compatible with cementoplasty
- For neurological safety, motor-evoked potentials can be monitored during cryoablation



NEEDLE SELECTION



RESOURCES





NEEDLE SELECTION

TUMOUR SIZE

<2cm

2-3cm

3-4cm

>4cm

NEEDLE TYPE & QUANTITY

ICESPHERE™ 1.5CX

x2 NEEDLES



ICEROD™ 1.5 CX

x3 NEEDLES



ICEFORCE™ 2.1 CX

x3 NEEDLES



ICEFORCE™ 2.1 CX

x3 NEEDLES

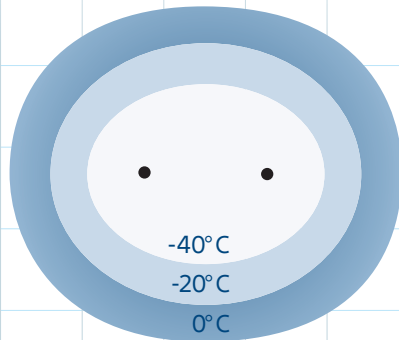




ICESPHERE™ 1.5 CX

x2 NEEDLES

Actual Size $\pm 5\text{mm}$

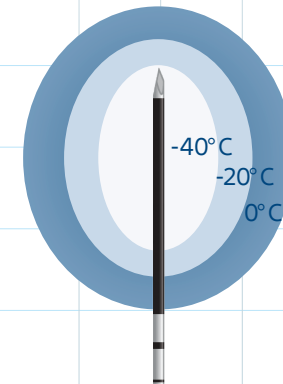


0°C	46mm x 39mm
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-40°C	26mm x 19mm

ICESPHERE™ 1.5 CX

Shaft Length: 17.5cm
Shaft Diameter: 1.5mm/17G

$\pm 3\text{mm}$ width $\pm 4\text{mm}$ length



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-40°C	13mm x 23mm



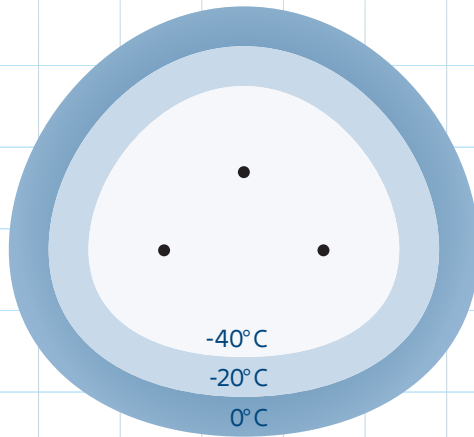
CRYOABLATION OF MSK TUMOURS



ICEROD™ 1.5 CX

x3 NEEDLES

Actual Size $\pm 5\text{mm}$

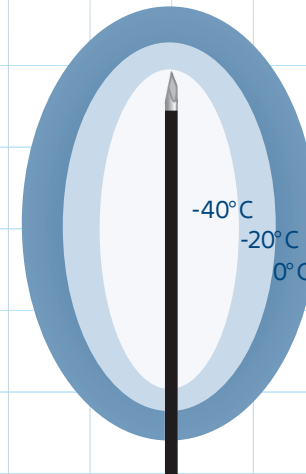


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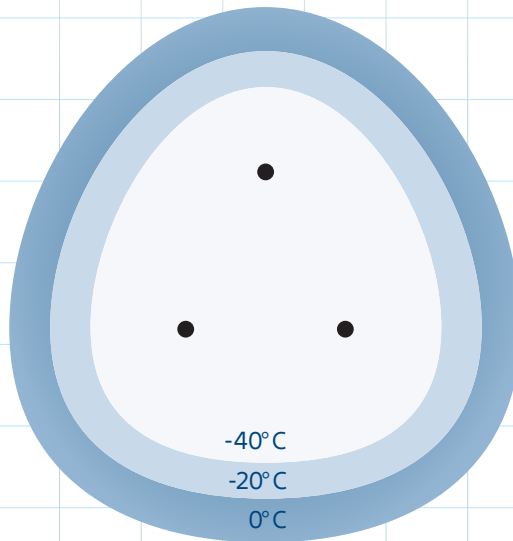
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ICEFORCE™ 2.1 CX

x3 NEEDLES

Actual Size $\pm 5\text{mm}$



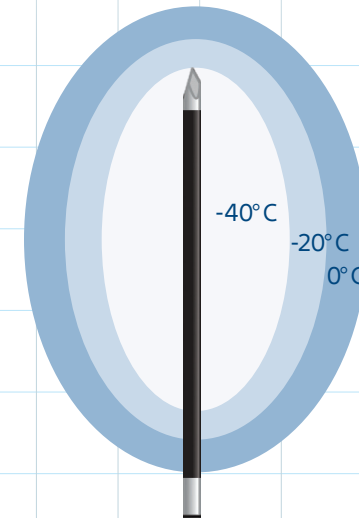
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ICEFORCE™ 2.1 CX

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Shaft Diameter: 2.1mm/14G

$\pm 3\text{mm}$ width $\pm 4\text{mm}$ length



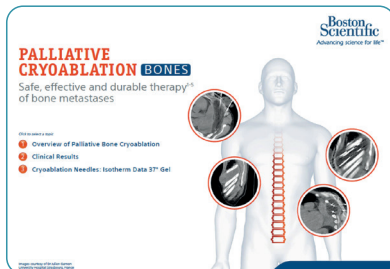
0°C	42mm x 57mm
-20°C	32mm x 49mm
-40°C	23mm x 42mm



CRYOABLATION OF MSK TUMOURS: RESOURCES



GENERAL INFORMATION



Overview of cryoablation for bone tumours, including key clinical data

CASE STUDIES



DR JULIEN GARNON
UNIVERSITY HOSPITAL OF STRASBOURG,
STRASBOURG, FRANCE

Cryoablation of Large Rib
Metastatic Bone Lesion



Cryoablation of Right Iliac Metastasis for
Pain Palliation & Local Tumour Control



Cryoablation of Large Rib Metastasis
Near the Brachial Plexus



DR XAVIER BUY
BERGONIE INSTITUTE OF ONCOLOGY,
BORDEAUX, FRANCE

Cryoanalgesia of Post-Amputation
Neuroma



Cryoanalgesia of 6.5cm
Desmoid Tumour



Cryoanalgesia of Scar Tissue Adhesion
to Spinal Sympathetic Chain Following
Radiation Therapy



DR CLAUDIO SALLEMI
POLIAMBULANZA HOSPITAL,
BRESCIA, ITALY

Percutaneous Cryoablation of Breast
Cancer Bone Metastasis



DR NICOS FOTIADIS
THE ROYAL MARSDEN HOSPITAL,
LONDON, UK

Cryoablation of Symptomatic Recurrent
Neck Desmoid Tumour



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CRYOABLATION OF LUNG TUMOURS



“Cryoablation uniquely offers visibility of the ablation margin with cross-sectional imaging... which defines the ablation zone and allows for complete tumour ablation while avoiding adjacent normal tissues, and can be used along the pleura without procedural pain.”

de Beare T et al. 2015²⁵

RATIONALE AND ADVANTAGES

Unique radiographic visibility of the ablation zone²⁵

- Provides real-time control over extent of ablation²⁶
- Facilitates intraprocedural adjustment to optimise treatment and to minimise damage near critical structures²⁷
- w Delivers correlative image-pathologic ablation zone²⁸

Minimal pain associated with the procedure

- Ice is a natural analgesic
- Can be performed under conscious sedation²⁵

Versatile treatment

- Preserves respiratory function^{29,30}
- Offers repeatability for recurrence or new malignancies²⁹
- Places minimal limitations on future therapies³¹

TYPICAL PATIENT PRESENTATION



2-4cm^{25,32}



Single or multiple lesions (avoid bilateral treatment in the same session)



- Preferred treatment for tumours abutting the pleura²⁵
- Suitable for tumours located near the mediastinum or the peripheries³³



- No extrapulmonary metastases³⁴
- Able to tolerate procedure^{32*}



TECHNICAL CONSIDERATIONS



A patient fit enough for a needle biopsy of the thorax is generally considered fit enough to undergo ablation





CRYOABLATION OF LUNG TUMOURS



TECHNICAL CONSIDERATIONS



FREEZE-THAW PROTOCOL

Studies suggest a triple freeze-thaw protocol of 3, 7, 10 minutes may be more efficient, more effective and reduce haemorrhage versus a double-freeze protocol.^{28,35} It is important to check the position of the needles before each freeze cycle as they may move during the thawing process³⁶



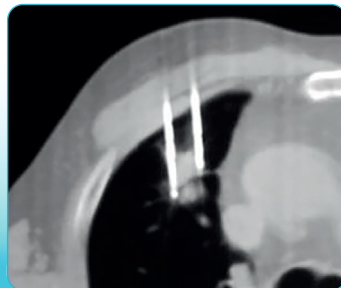
Typical freeze-thaw protocol as used by Prof Thierry de Baere, Gustave Roussy Cancer Institute, Villejuif, France



NEEDLE TECHNIQUES

CHOPSTICK/ BOOK-END

Two needles encase the tumour to stabilise it, avoiding the need to penetrate the tumour⁹



STICK-FREEZE

Stick-freeze (short initial freeze activation at reduced power) of a single needle inserted into the tumour 'sticks' the two together



IATROGENIC (INDUCED) PNEUMOTHORAX

Gas (room air or CO₂) is introduced into the pleural space to isolate the tumour from critical structures



NEEDLE SELECTION



RESOURCES





CRYOABLATION OF LUNG TUMOURS



NEEDLE SELECTION

TUMOUR SIZE



NEEDLE TYPE & QUANTITY

ICESPHERE™ 1.5 CX

x2 NEEDLES



ICEROD™ 1.5 CX

x3 NEEDLES



ICEROD™ 1.5 CX

x4 NEEDLES



ICEFORCE™ 2.1 CX

x3 NEEDLES





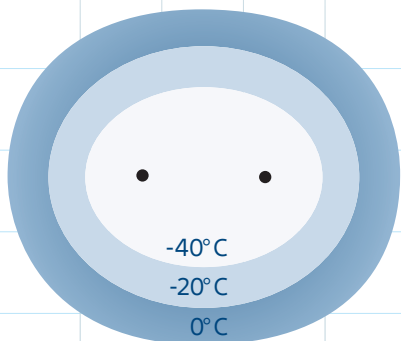
CRYOABLATION OF LUNG TUMOURS



ICESPHERE™ 1.5 CX

x2 NEEDLES

Actual Size $\pm 5\text{mm}$

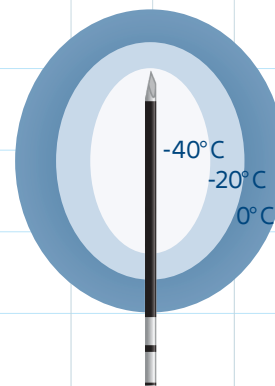


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-40°C	26mm x 19mm

ICESPHERE™ 1.5 CX

Shaft Length: 17.5cm
Shaft Diameter: 1.5mm/17G

$\pm 3\text{mm}$ width $\pm 4\text{mm}$ length



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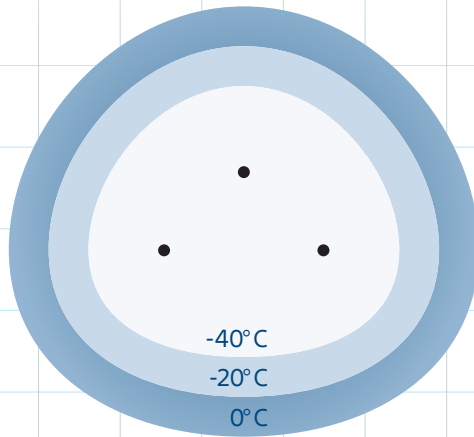
CRYOABLATION OF LUNG TUMOURS



ICEROD™ 1.5 CX

x3 NEEDLES

Actual Size $\pm 5\text{mm}$

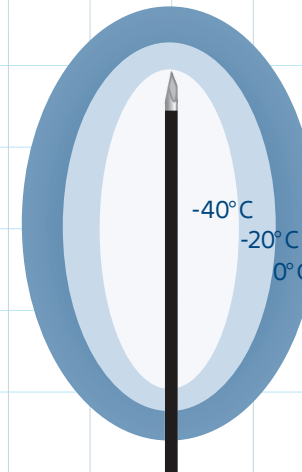


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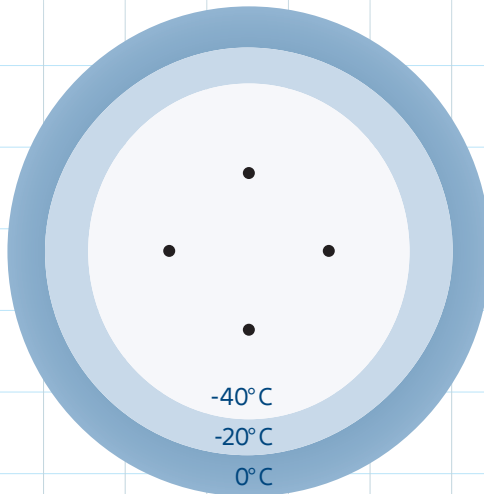
CRYOABLATION OF LUNG TUMOURS



ICEROD™ 1.5 CX

x4 NEEDLES

Actual Size $\pm 5\text{mm}$

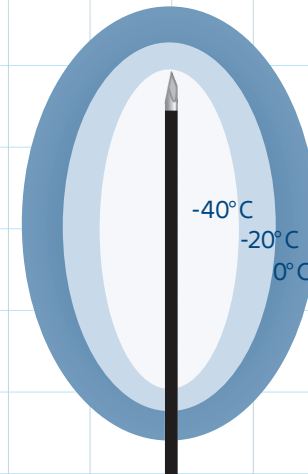


0°C	60mm x 61mm
-20°C	51mm x 51mm
-40°C	40mm x 42mm

ICEROD™ 1.5 CX

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Shaft Diameter: 1.5mm/17G

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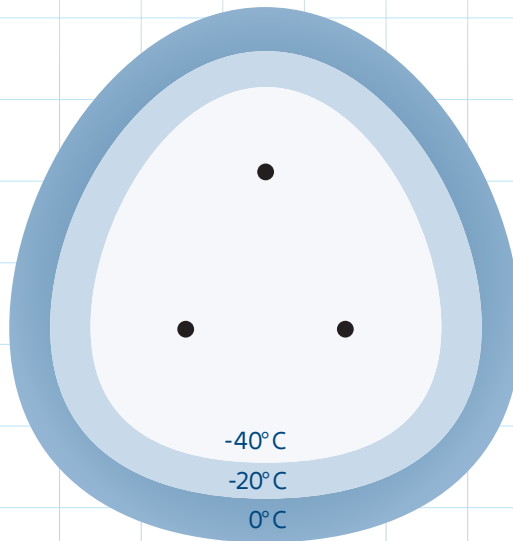
CRYOABLATION OF LUNG TUMOURS



ICEFORCE™ 2.1 CX

x3 NEEDLES

Actual Size $\pm 5\text{mm}$

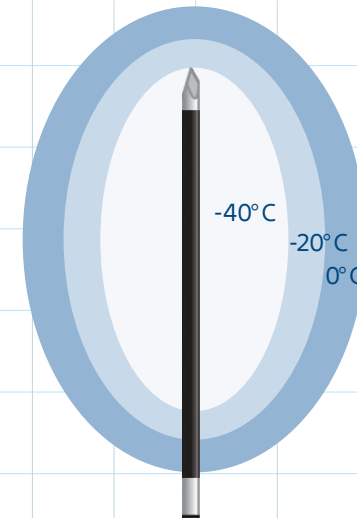


0°C	64mm x 67mm
-20°C	54mm x 56mm
-40°C	44mm x 47mm

ICEFORCE™ 2.1 CX

Shaft Length: 17.5cm
Shaft Diameter: 2.1mm/14G

$\pm 3\text{mm}$ width $\pm 4\text{mm}$ length



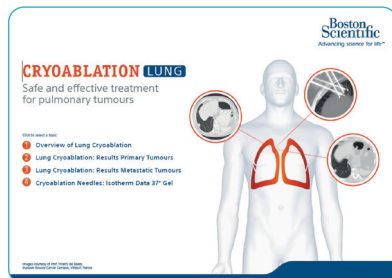
0°C	42mm x 57mm
-20°C	32mm x 49mm
-40°C	23mm x 42mm



CRYOABLATION OF LUNG TUMOURS: RESOURCES



GENERAL INFORMATION



Overview of lung cryoablation, including key clinical data

CASE STUDIES



PROF THIERRY DE BAERE
GUSTAVE ROUSSY CANCER INSTITUTE,
VILLEJUIF, FRANCE

Cryoablation of mCRC in the Lung
Located Adjacent to the Aorta

Cryoablation of 32mm Soft Tissue
Sarcoma Lung Metastasis Abutting the Pleura

Cryoablation of Small Pulmonary
Metastasis



DR CLAUDIO PUSCEDDU
INTERVENTIONAL RADIOLOGY
ONCOLOGY DEPARTMENT,
AOBROTZU, ITALY

Cryoablation of 28mm NSCLC Abutting
the Pericardium and the Mediastinum
Anterior Space

Cryoablation of 20mm NSCLC Close
to the Pleura. Ground-Glass Opacity
Surrounding the Tumour

KEY PUBLICATION SUMMARIES

CALLSTROM ET AL, 2020

PUBLICATION SUMMARY – LUNG

**Multicenter Study of Metastatic Lung Tumors Targeted
by Interventional Cryoablation Evaluation (SOLSTICE)**

3 Thorax Oncol. 2020 May 1; Epub ahead of print.
Callstrom MP, Woodrum DM, Nichols FC, Pusccheddu C, Bay R, Sub R, Albin F, Pua M, Madoff DC, Bagla S, Papadimitrakou DC, Fernandez PC, Dargatz DA, Healey TT, Moore WH, Billinger TA, Naranjo-Arenas C, Kates R, Pua C, Haddad A, Taitel L, de Baere T, & Dargatz DA, et al. (2020) Solstice: A Multicenter Study of Metastatic Lung Tumors Targeted by Interventional Cryoablation Evaluation (SOLSTICE). J Clin Oncol. 38(12):1311-1318. doi:10.1200/JCO.2019.870000. Published online 2020 May 1. PMID: 32288888.

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CRYOABLATION OF PROSTATE TUMOURS



“ Prostate focal therapy offers men the opportunity to achieve oncological control while preserving sexual and urinary function. ”

Tay KJ et al. 2017³⁷

“ The ease of accessibility via transperineal needles and established oncologic efficacy make cryotherapy more desirable [than other focal therapies] for cancers in anterior locations. ”

Sivaraman A et al. 2016⁵⁵

RATIONALE AND ADVANTAGES

- High disease control rates³⁷⁻⁴⁰
- Low incontinence rates³⁸⁻⁴⁹
- Preservation of erectile function^{37-41, 46-52}
- Repeatable^{38,53,54}
- Fast recovery times⁴¹
- Low morbidity^{38,41,43}
- Excellent outcomes in anterior lesions
- Life expectancy of >10 years

TYPICAL PATIENT PRESENTATION



- Clinical stage T1c-T2a
- For focal treatments:
 - 50-60% of gland should be preserved



- Prostate-specific antigen <15ng/ml
- Gleason score ≤3 + 4
- Alternative to active surveillance



- Anterior lesions
- Selected lesions in the apex



- Low to intermediate-risk patients



TECHNICAL CONSIDERATIONS





CRYOABLATION OF PROSTATE TUMOURS



TECHNICAL CONSIDERATIONS



FREEZE-THAW PROTOCOL

Each 10-minute freeze cycle must include ≥ 3 minutes at $< -40^{\circ}\text{C}$ at the most lateral border of the tumour margin



Typical freeze-thaw protocol used by Taimur T Shah et al at Imperial College Hospital, London



PROCEDURAL CONSIDERATIONS

- Prostate cryotherapy is performed under ultrasound
- MRI/TRUS fusion-guided targeted biopsies should be performed
- Excellent option for anterior and selected apical tumours

FOCAL PROSTATE CRYOTHERAPY IN ANTERIOR LESIONS

- Excellent preservation of functional outcomes:^{41,58}
 - 100% continence preservation
 - >80% preservation of erectile function
 - 0% rectal injury
- Established oncologic efficacy

VS

LIMITATIONS OF HIFU FOR ANTERIOR LESIONS⁵⁹

- Ultrasound waves dissipate over longer focal distances
- Intervening prostatic tissue undergoes oedema, pushing target tissue further away
- No evidence that treatment of apical tumours is incontinence free



NEEDLE SELECTION



RESOURCES





CRYOABLATION OF

PROSTATE TUMOURS



NEEDLE SELECTION

PROSTATE LENGTH
(LONGITUDINAL PLANE)

<2.5cm

>2.5cm

NEEDLE TYPE

ICESPHERE™ 1.5 CX

ICEROD™ 1.5 CX

TUMOUR SIZE
(TRANSVERSAL PLANE)

<2cm

2-3cm

3-4cm

NEEDLE QUANTITY

X2

X3

X4

NEEDLE SELECTION

ICESPHERE™ 1.5 CX



ICESPHERE™ 1.5 CX



ICESPHERE™ 1.5 CX



ICEROD™ 1.5 CX



ICEROD™ 1.5 CX



ICEROD™ 1.5 CX





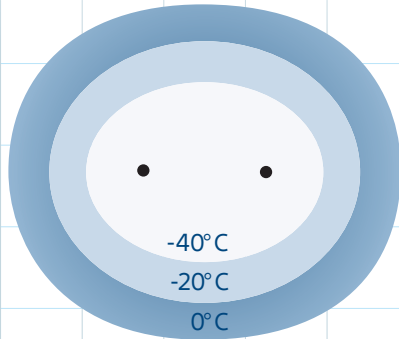
CRYOABLATION OF PROSTATE TUMOURS



ICESPHERE™ 1.5 CX

x2 NEEDLES

Actual Size $\pm 5\text{mm}$

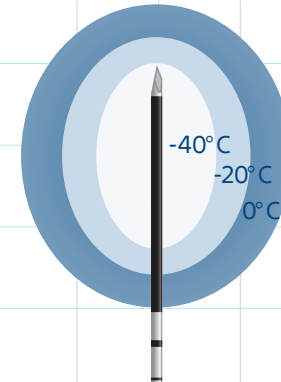


0°C	46mm x 39mm
-20°C	36mm x 29mm
-40°C	26mm x 19mm

ICESPHERE™ 1.5 CX

Shaft Length: 17.5cm
Shaft Diameter: 1.5mm/17G

$\pm 3\text{mm}$ width $\pm 4\text{mm}$ length



0°C	31mm x 36mm
-20°C	22mm x 28mm
-40°C	13mm x 23mm

Each 10-minute freeze cycle must include ≥ 3 minutes at $< -40^\circ\text{C}$ at the most lateral border of the tumour margin



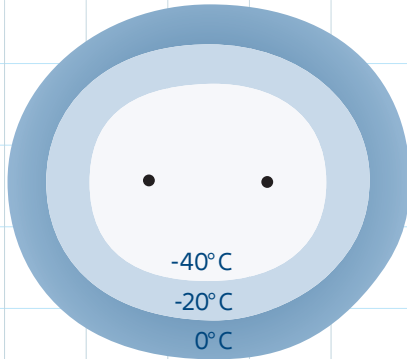
CRYOABLATION OF PROSTATE TUMOURS



ICEROD™ 1.5 CX

x2 NEEDLES

Actual Size $\pm 5\text{mm}$



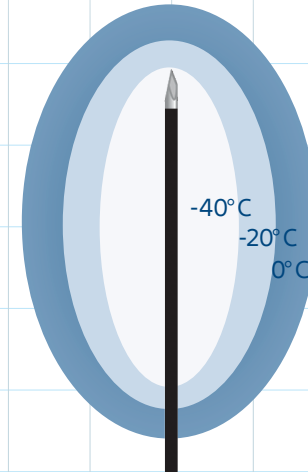
0°C	50mm x 44mm
-20°C	39mm x 34mm
-40°C	29mm x 24mm

ICEROD™ 1.5 CX

Shaft Length: 17.5cm

Shaft Diameter: 1.5mm/17G

$\pm 3\text{mm}$ width $\pm 4\text{mm}$ length



0°C	36mm x 53mm
-20°C	26mm x 45mm
-40°C	16mm x 39mm

Each 10-minute freeze cycle must include ≥ 3 minutes at $< -40^\circ\text{C}$ at the most lateral border of the tumour margin



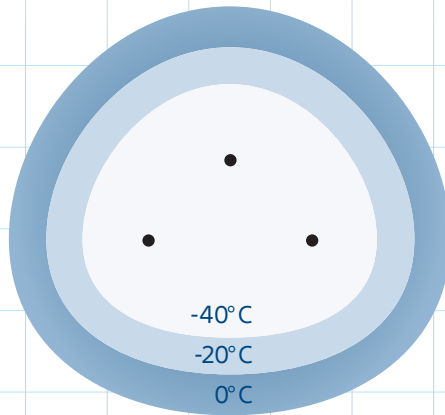
CRYOABLATION OF PROSTATE TUMOURS



ICESPHERE™ 1.5 CX

x3 NEEDLES

Actual Size $\pm 5\text{mm}$

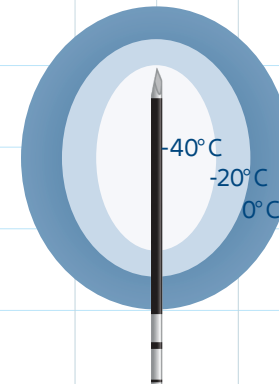


0°C	52mm x 48mm
-20°C	43mm x 37mm
-40°C	34mm x 28mm

ICESPHERE™ 1.5 CX

Shaft Length: 17.5cm
Shaft Diameter: 1.5mm/17G

$\pm 3\text{mm}$ width $\pm 4\text{mm}$ length



0°C	31mm x 36mm
-20°C	22mm x 28mm
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Each 10-minute freeze cycle must include ≥ 3 minutes at $< -40^\circ\text{C}$ at the most lateral border of the tumour margin



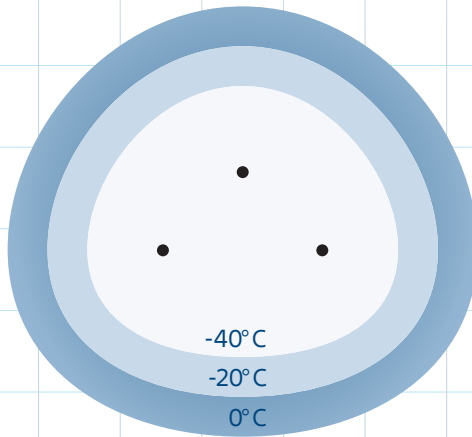
CRYOABLATION OF PROSTATE TUMOURS



ICEROD™ 1.5 CX

x3 NEEDLES

Actual Size $\pm 5\text{mm}$

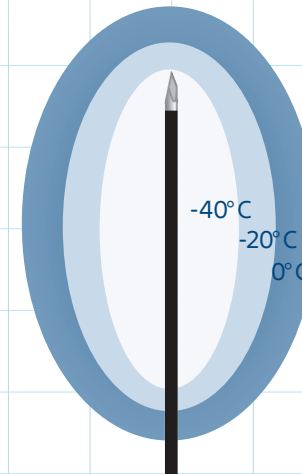


0°C	59mm x 53mm
-20°C	49mm x 43mm
-40°C	39mm x 33mm

ICEROD™ 1.5 CX

Shaft Length: 17.5cm
Shaft Diameter: 1.5mm/17G

$\pm 3\text{mm}$ width $\pm 4\text{mm}$ length



0°C	36mm x 53mm
-20°C	26mm x 45mm
-40°C	16mm x 39mm

Each 10-minute freeze cycle must include ≥ 3 minutes at $< -40^\circ\text{C}$ at the most lateral border of the tumour margin



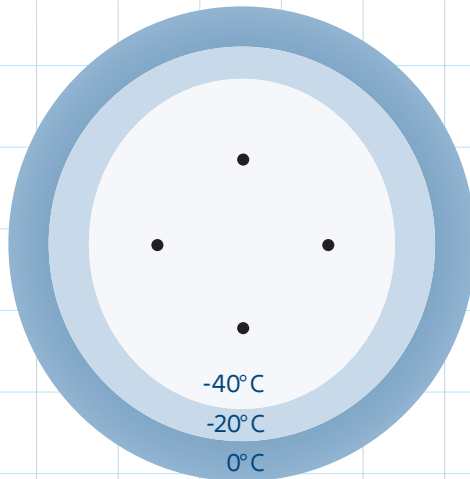
CRYOABLATION OF PROSTATE TUMOURS



ICESPHERE™ 1.5 CX

x4 NEEDLES

Actual Size $\pm 5\text{mm}$



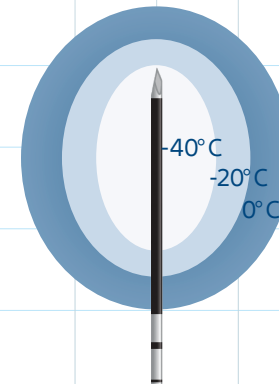
0°C	55mm x 58mm
-20°C	45mm x 47mm
-40°C	36mm x 39mm

ICESPHERE™ 1.5 CX

Shaft Length: 17.5cm

Shaft Diameter: 1.5mm/17G

$\pm 3\text{mm}$ width $\pm 4\text{mm}$ length



0°C	31mm x 36mm
-20°C	22mm x 28mm
-40°C	13mm x 23mm

Each 10-minute freeze cycle must include ≥ 3 minutes at $< -40^\circ\text{C}$ at the most lateral border of the tumour margin



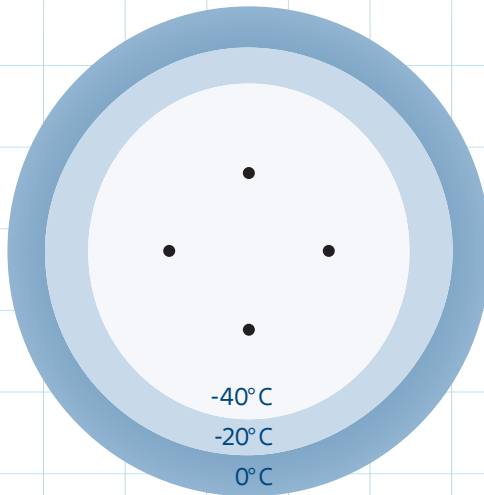
CRYOABLATION OF PROSTATE TUMOURS



ICEROD™ 1.5 CX

x4 NEEDLES

Actual Size $\pm 5\text{mm}$

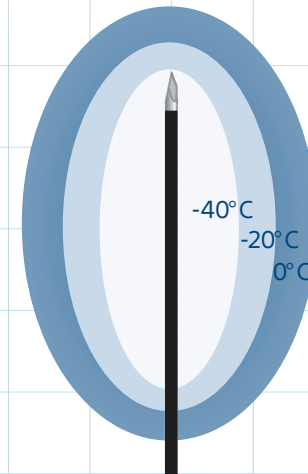


0°C	60mm x 61mm
-20°C	51mm x 51mm
-40°C	40mm x 42mm

ICEROD™ 1.5 CX

Shaft Length: 17.5cm
Shaft Diameter: 1.5mm/17G

$\pm 3\text{mm}$ width $\pm 4\text{mm}$ length



0°C	36mm x 53mm
-20°C	26mm x 45mm
-40°C	16mm x 39mm

Each 10-minute freeze cycle must include ≥ 3 minutes at $< -40^\circ\text{C}$ at the most lateral border of the tumour margin

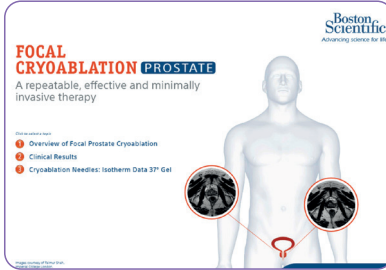


CRYOABLATION OF

PROSTATE TUMOURS: RESOURCES



GENERAL INFORMATION



Overview of cryoablation for prostate cancer, including key clinical data

CASE STUDIES



TAIMUR T SHAH

CHARING CROSS HOSPITAL,
IMPERIAL COLLEGE HEALTHCARE
NHS TRUST AND IMPERIAL COLLEGE
LONDON, UK

Focal Cryotherapy of a Localised
Intermediate-Risk Prostate Cancer
in a 61-Year-Old Man



Re-Treatment Focal Prostate Cryotherapy
of Anterior Lesion

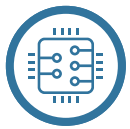


Salvage Focal Prostate Cryotherapy
of 1.2cc Anterior Lesion



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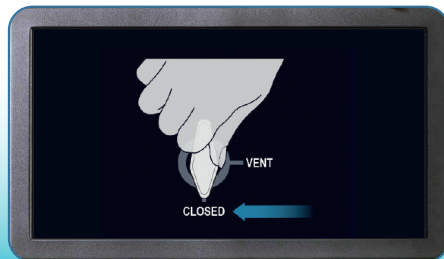


The ICEfx Cryoablation System is designed for interventional oncologists who want to offer their patients on-demand access to state-of-the-art ablation technology. ICEfx offers predictable, powerful performance with exceptional ease of technical operation.

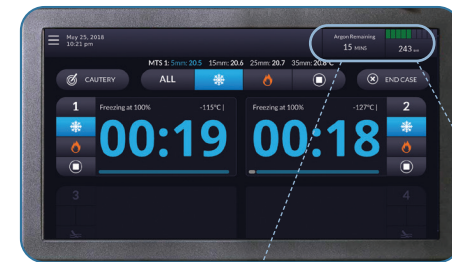
- Manoeuvrable cart and console
- Intuitive touch-screen interface and set-up wizard
- Accommodates up to:
 - 8 needles on 4 channels
 - 2 Multi-Point Sensors
- CX needle technology
- Helium-free active thawing
- Cycle sequence programming



Set-up wizard



Procedure screen



Gas indicator display



Adjustable freeze intensifies



MORE INFORMATION ON ICEfx



The Visual-ICE™ Cryoablation System provides powerful freezing performance and accommodates up to 20 needles for ultimate procedural flexibility.

- Intuitive interface with large touch-screen monitor, set-up wizard and icons to guide procedural actions.
- Accommodates up to:
 - 20 needles on 10 channels
 - 4 Multi-Point Sensors
- Enlarged, positionable timers allow procedural status monitoring from a distance
- Helium-enabled or helium-free thaw options available
- Software functions can be customised based on procedure and need for advanced functions



MORE INFORMATION ON VISUAL-ICE

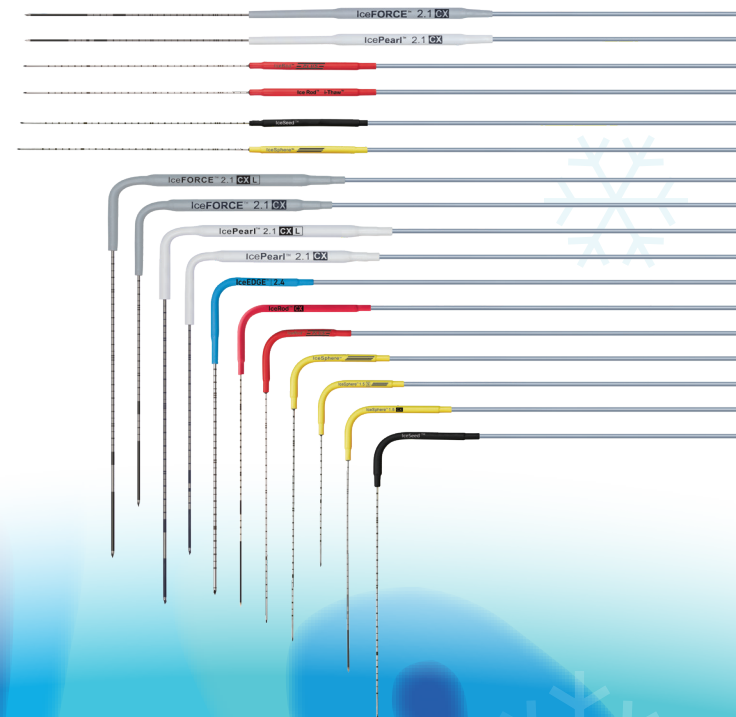


Boston Scientific offers a wide range of precisely engineered cryoablation needles that offer procedural versatility, maximum control and minimal bleeding. Our 1.5 needle range incorporates technology that allows impressive iceball volumes to be created on the finest gauge shaft available today.

- Straight or angled 90° configurations in a choice of lengths and diameters
- Three-facet sharp needle tip for easy percutaneous insertion and control
- Accurate shaft distance markers to optimise needle placement
- Lightweight handles to minimise torque on inserted needles, with colour-coding for ease of identification
- Unibody closed-tube design which minimises risk of gas leakage*

CX Cryoablation Needles feature:

- An integral heater to offer:
 - Cautery function for track ablation
 - Helium-free thaw options (i-Thaw™ and FastThaw™)
- Non-stick coating on distal shaft for ease of needle manoeuvre and removal



MORE INFORMATION ON NEEDLES

*vs welded tip designs





Needle Type	Needle Tip Angle		System Compatibility		
			Visual-ICE™	ICEfx™	Visual-ICE™ MRI
Image-Guided CX-1.5*	Straight	90°			
IceRod™ 1.5 CX		•	•	•	
IceSphere™ 1.5 CX		•	•	•	
Image-Guided CX-2.1*	Straight	90°			
IceFORCE™ 2.1 CX	•	•	•	•	
IceFORCE™ 2.1 CX 2.1 CX L		•	•	•	
IcePearl™ 2.1 CX	•	•	•	•	
IcePearl™ 2.1 CX L		•	•	•	
Image-Guided Classic 1.5	Straight	90°			
IceRod™ 1.5 MRI	•	•			•

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PI-1006301-AA

