ICEfx™

Cryoablation System

CRYOABLATION

Predictable, reliable performance with seamless therapy delivery

Compact and powerful, with exceptional ease of technical operation

PI-806906-AA Printed in Germany by medicalvision.

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DINONC3697EA

Introducing the ICEfx™ Cryoablation System
powerful intuitive Cryoablation for your practice

The new ICEfx™ Cryoablation System offers predictable, reliable performance with seamless therapy delivery and exceptional ease of technical operation.

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.

Compact and Powerful

Easily mobilised

- Placement next to the scanner bed allows easy access to both the patient and the needles during a procedure
- Optional cart available

Powerful freezing performance

- Streamlined design offers the freezing performance you would expect from larger systems

Simple to Use

- Set-up and end-case wizards make it easy to prepare and complete a procedure
- Automatic needle recognition enables advanced funtionality and optimises needle performance
- Large timers allow freezing and thawing time to easily be seen from the control room
- Sequence programming streamlines operation for commonly used protocols

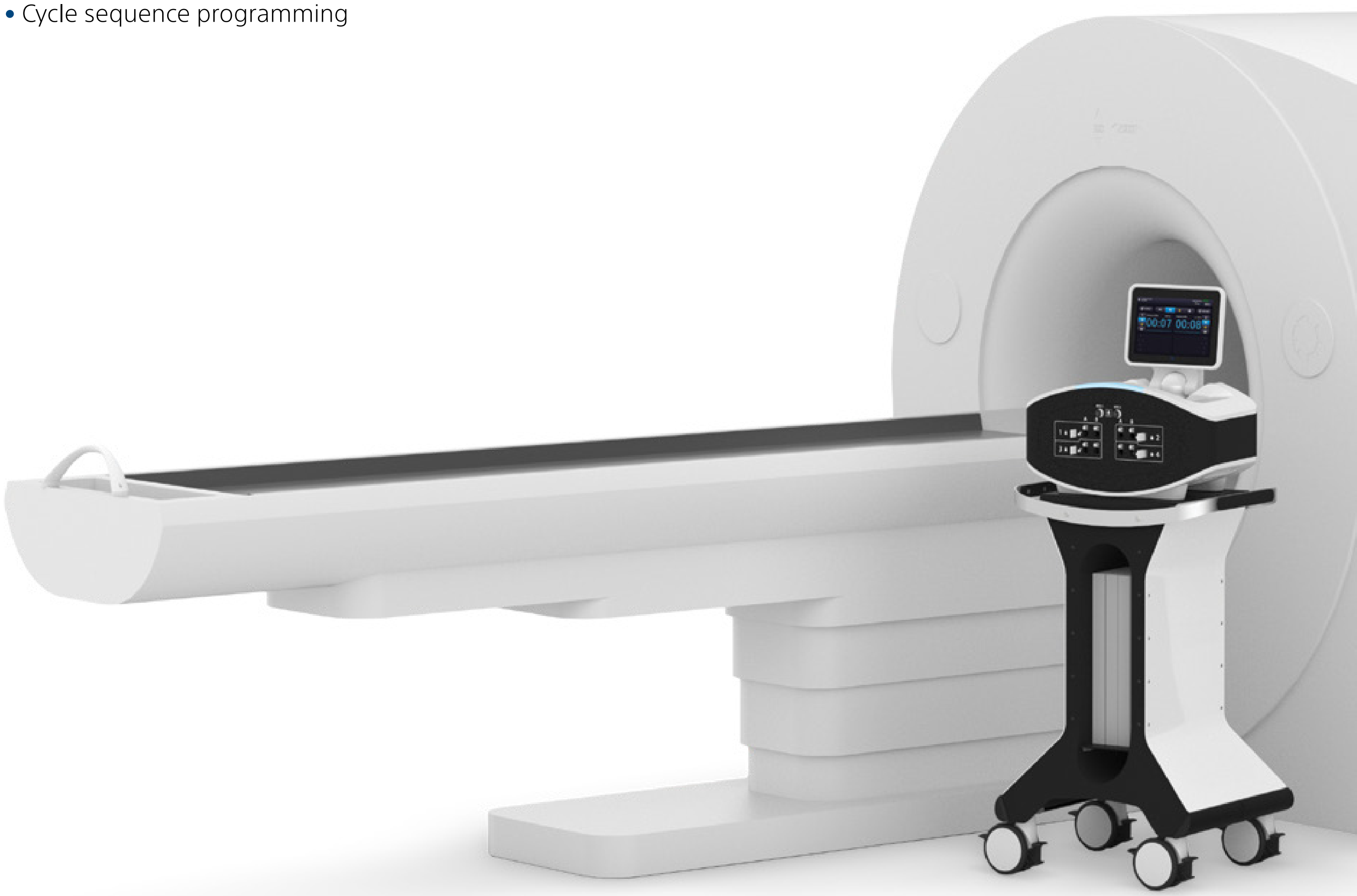
Advanced Needle Platform

- Helium-free thaw capability offers options to accelerate thaw-time and reduces logistic demands and procedure costs
- Proprietary cautery function ablates the needle track

Cryoablation redifined for your practice

ICEfx™ Cryoablation System

- Manoeuvrable cart and console
- Accommodates up to 8 needles on 4 channels
- CX needle technology
- Helium-free active thawing
- Intuitive user interface
- Cycle sequence programming

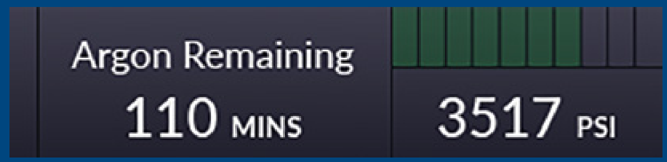


ICEfx™ Cryoablation System offers controlled and predictable ablation zones

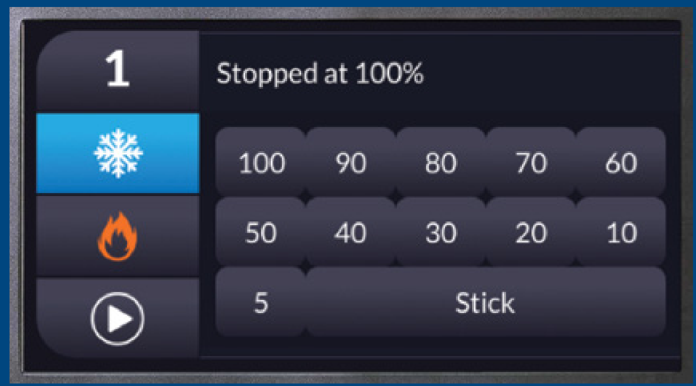
System Features Control Iceball Shape and Growth

- Adjustable freeze intensity regulates ice growth
  - Provides control near critical structures
  - Stick mode secures a needle during placement of additional needles
- Four separate system channels allow independent control per two-needle channel
- Activation of multiple needles provides opportunities to treat large tumours and to conduct multiple simultaneous treatments
- Different needle types can be combined to create optimal iceball shapes and sizes

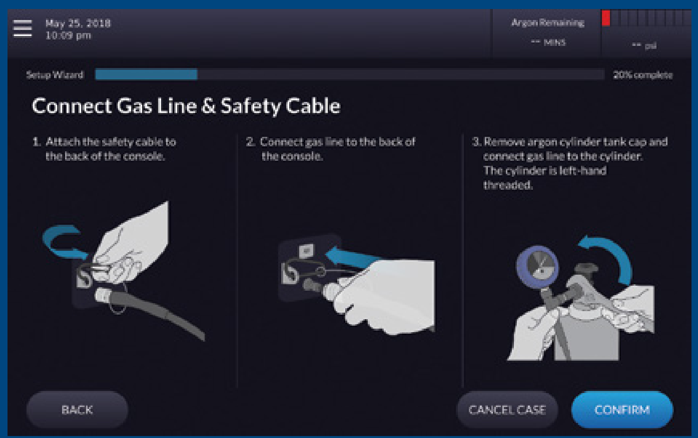
Gas indicators display



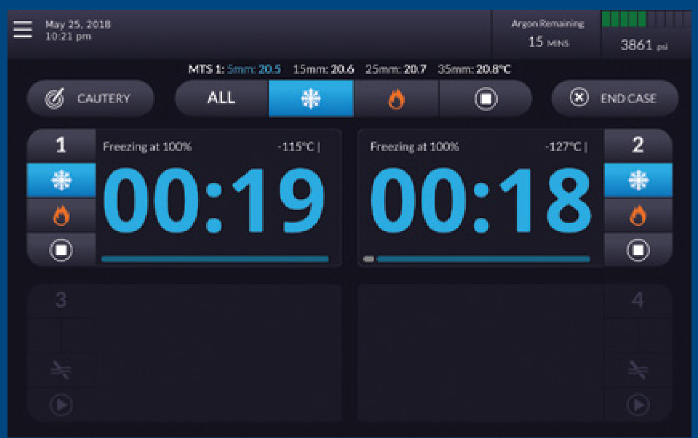
Adjustable freeze intensifies



Setup screen



Procedure screen



Intuitive User Interface Provides Ease of Operation

Touch-Screen Controls System Operation and Displays Procedure Status

- Responsive touch-screen interface provides accurate touch response enabling users to work quickly and accurately
- Set-up and end-case wizards guide users through gas and system setup steps, needles testing and, when the case is complete, dismantle instructions
- Colour-coded bars visually display ongoing procedural summary of freeze, thaw and idle segments
- Large timers allow monitoring of the procedure status from a distance
- Large timers display elapsed cycle time and, when freezing, freeze intensity
- Optional cycle programming offers automation of frequently used freeze-thaw protocols

Progressive cryoablation platform

system software streamlines operation

- Automatic needle detection assigns needle type to channel optimising gas delivery for enhanced needle performance
- Gas indicator displays cyliner pressure and real-time estimates of remaining gas time to minimise procedure interruption
- Online predictive diagnostics allow advance planning for maintenance
- Remote connectivity provides online software updates and downloads

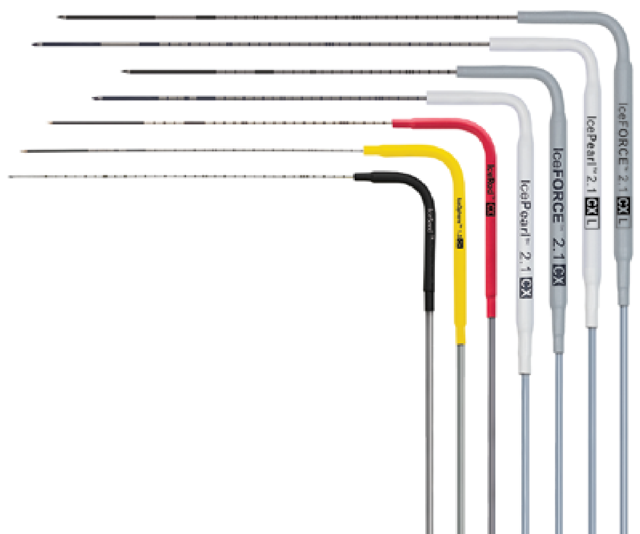
Cryoablation visualisation

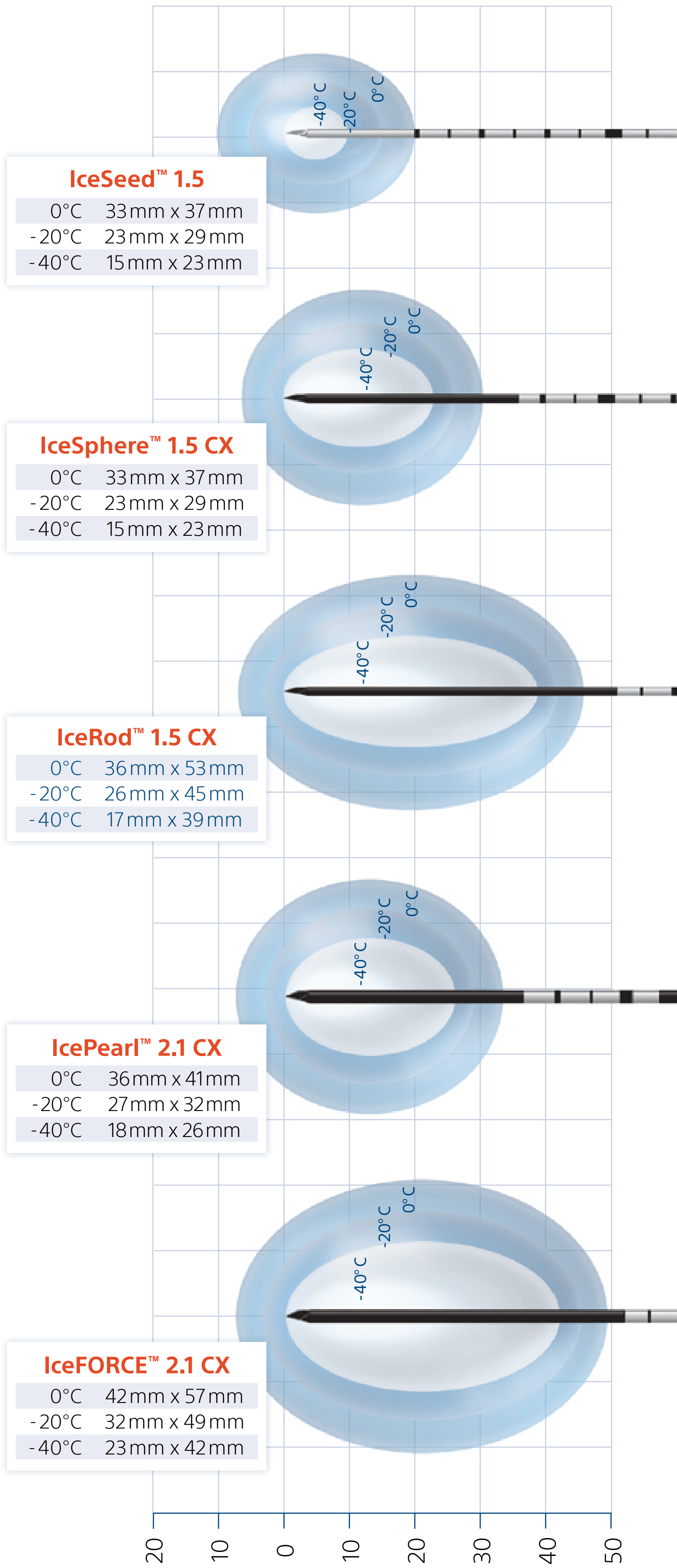
allows monitoring of iceball information

- Data was collected in 37°C gel; in-vivo dimensions may be smaller than the dimensions generated in laboratory conditions

NEEDLES for ICEfx™ Cryoablation Procedures

- IceSeed™ 1.5 Cryoablation Needles
- IceSphere™ 1.5 CX Cryoablation Needles
- IceRod™ 1.5 CX Cryoablation Needles
- IcePearl™ 2.1 CX Cryoablation Needles
- IceFORCE™ 2.1 CX Cryoablation Needles





IceSeed™ 1.5

0°C	33mm x 37mm
-20°C	23mm x 29mm
-40°C	15mm x 23mm

IceSphere™ 1.5 CX

0°C	33mm x 37mm
-20°C	23mm x 29mm
-40°C	15mm x 23mm

IceRod™ 1.5 CX

0°C	36mm x 53mm
-20°C	26mm x 45mm
-40°C	17mm x 39mm

IcePearl™ 2.1 CX

0°C	36mm x 41mm
-20°C	27mm x 32mm
-40°C	18mm x 26mm

IceFORCE™ 2.1 CX

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

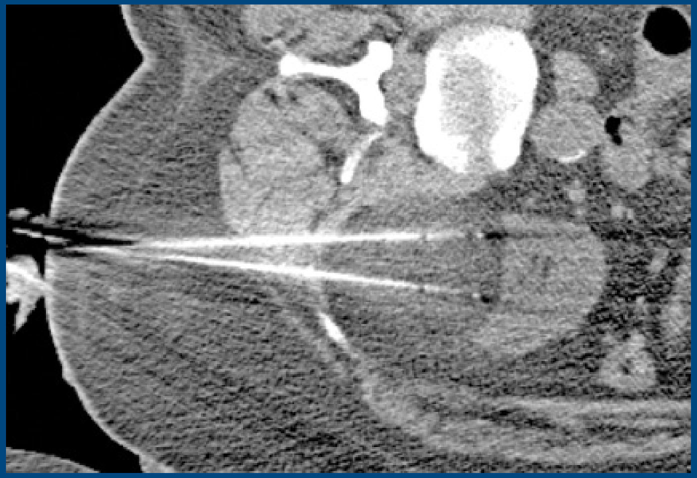
Height in millimetres

This data was collected at 21°C (room ±3mm width ±4mm length temperature)

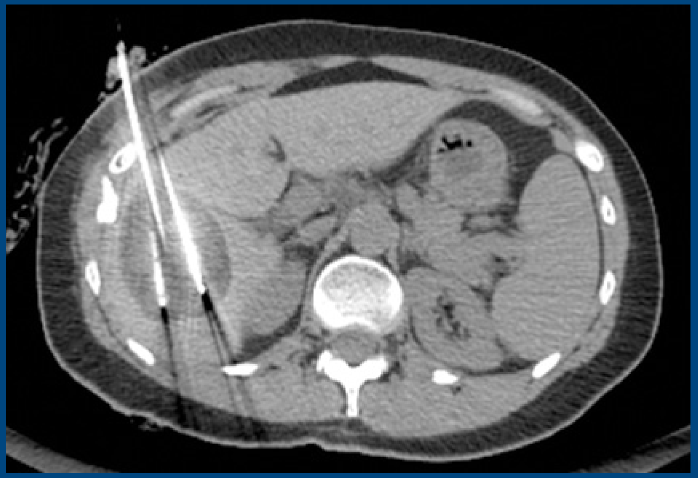
Cryoablation Couples unique treatment zone visualisation with effective ablation

- Excellent safety and efficacy profiles[1-5]
- Exceptional local tumour control following single treatment[2,6,7,8]
- Durable with low incidence of tumour recurrence and low risk of metastatic progression[2,6]
- Short hospital stay, low morbidity and rapid recovery[6,9,10]
- Less blood loss versus surgery[10-12]
- Option for conscious sedation with local anaesthesia[13-15]
- Repeatable[2]

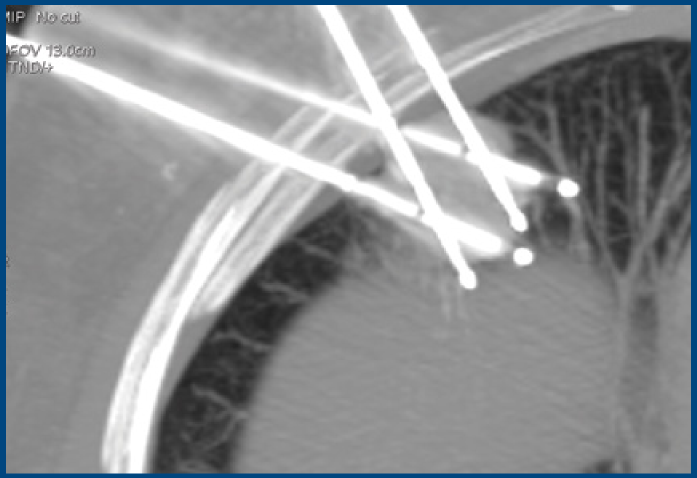
Axial Renal CT



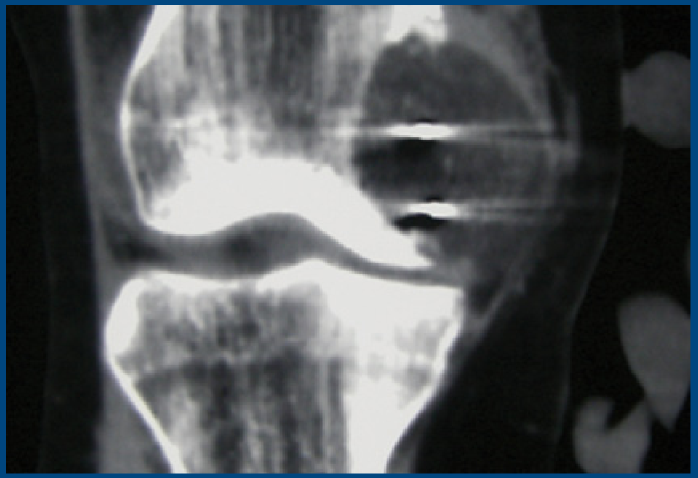
Axial Liver CT



Axial Lung CT



Axial Bone CT



Images Courtesy of:
Stuart G. Silverman, MD, Department of Radiology, Brigham and Women's Hospital Boston, MA, USA.
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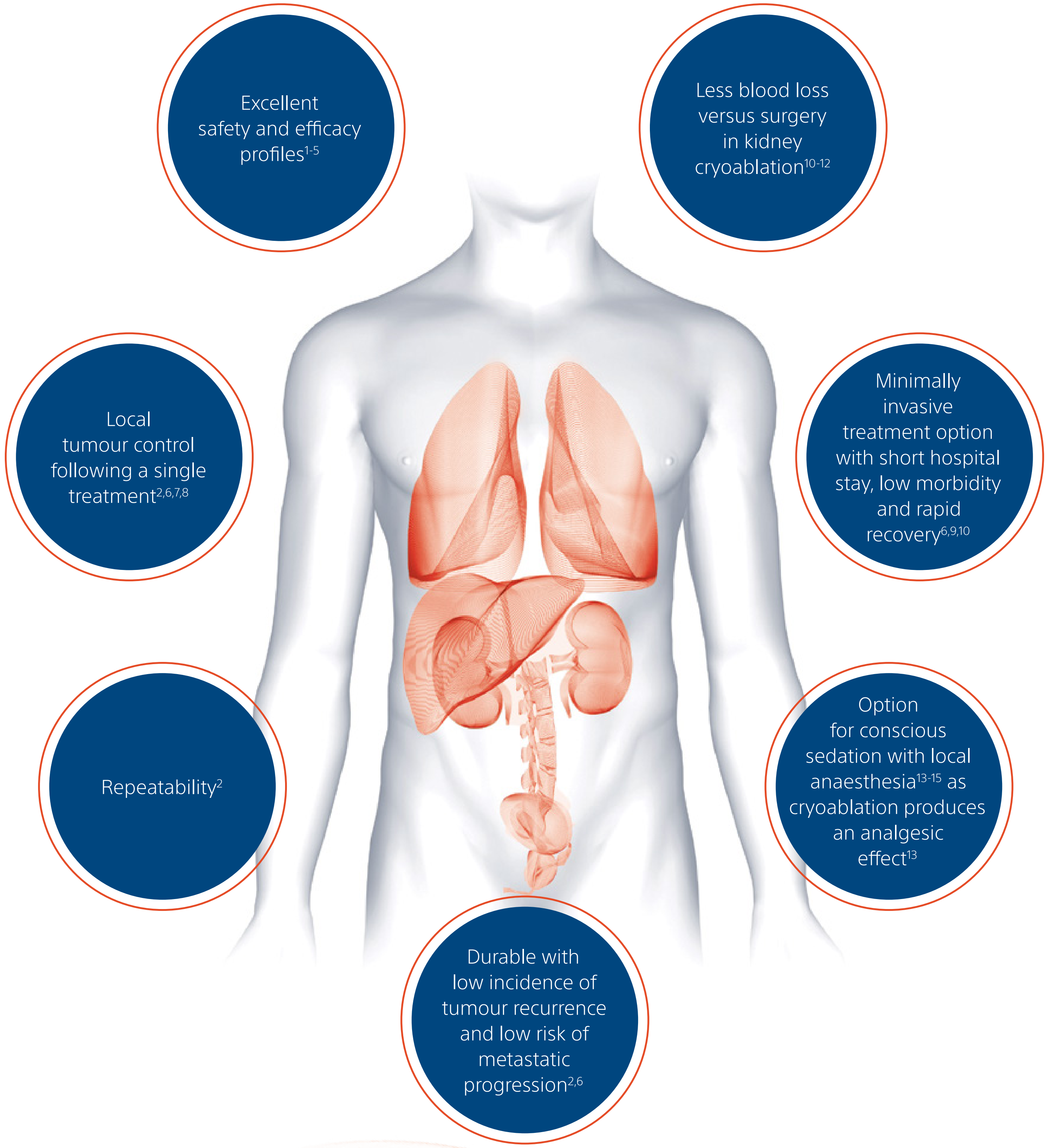
Cryoablation provides excellent patient benefit outcomes



ICEfx™ Cryoablation effectively treats a range of applications

Kidney

Cryoablation is a well-established and accepted therapy for T1a renal masses and is included as a treatment option in multiple guidelines[17-20]

- Cryoablation preserves renal function[20,21]
- Collecting system injury is rare, even when the iceball overlaps the renal sinus[20,23]
- Anterior and central renal masses can be successfully ablated[6,23-25] and tumours near the ureter or bowel can be safely managed and treated[26,27]
- Control of iceball size and growth can avoid damage to adjacent non-targeted tissue[1]

Lung

Cryoablation of lung metastases may be a first-line therapeutic alternative[28]

- Central lesions abutting bronchi and lesions within the chest wall or involving pleura can be safely and effectively treated with cryoablation[29-32]
- Percutaneous cryoablation for metastatic lung tumours provides local control[33,34] and low rates of severe complications[30]

Prostate

Cryoablation is a minimally invasive, efficacious treatment option with curative intent for prostate cancer[37-40]

- Primary and salvage cryoablation provide excellent local control,[40,41] low risk of metastases[41] and long-term prostate cancer specific survival[37,40,41]

Liver Metastases

For appropriate patients, cryoablation is an option for hepatic metastases[42-45]

- Visibility of the ablation zone is a key advantage, allowing intraprocedural monitoring to avoid involvement of nearby critical structures and to optimise tumour coverage[42,43]
- Hepatic tumours ≤4 cm can be successfully ablated with low local recurrence rates and low rates of complications[43,45]

Bone Metastases

- Monitoring the ablation margin optimises tumour coverage[45] and reduces the risk of injury to adjacent critical structures[46-51,53]
- Studies show clinically significant54 durable pain reduction for the majority of metastatic bone tumour patients treated with cryoablation[47,55-57]
- Cryoablation delivers faster pain relief[56] than radiotherapy[58]

Ordering information

Part Number	Cryoablation Needle Kits	Description
FPRCH8000	ICEfx™ Cryoablation System	A cryoablation system with built-in gas pressure regulators; one flexible argon gas supply line with pressure gauge; a console cover
FPRCH8010	ICEfx™ Cryoablation System Cart	An ICEfx™ System cart with a tool-free console locking system and storage for up to four needle boxes.

Part Number	Cryoablation Needle Kits	Configuration	Needle Shaft Length	Thaw
FPRPR3201	IceSeed™ 1.5 Cryoablation Needle	Straight	175 cm	–
FPRPR3202	IceSeed™ 1.5 Cryoablation Needle	90°	175 cm	–
FPRPR3573	IceSphere™ 1.5 CX 90° Cryoablation Needle	90°	175 cm	i-Thaw/FastThaw
FPRPR4009	IceRod™ 1.5 i-Thaw Cryoablation Needle	Straight	175 cm	i-Thaw
FPRPR3533	IceRod™ 1.5 CX 90° Cryoablation Needle	90°	175 cm	i-Thaw/FastThaw
FPRPR3601	IcePearl™ 2.1 CX 90° Cryoablation Needle	90°	175 cm	i-Thaw/FastThaw
FPRPR3603	IcePearl™ 2.1 CX Cryoablation Needle	Straight	175 cm	i-Thaw/FastThaw
FPRPR3617	IcePearl™ 2.1 CX L 90° Cryoablation Needle	90°	203 cm	i-Thaw/FastThaw
FPRPR3602	IceFORCE™ 2.1 CX 90° Cryoablation Needle	90°	175 cm	i-Thaw/FastThaw
FPRPR3604	IceFORCE™ 2.1 CX Cryoablation Needle	Straight	175 cm	i-Thaw/FastThaw
FPRPR3618	IceFORCE™ 2.1 CX L 90° Cryoablation Needle	90°	203 cm	i-Thaw/FastThaw

System Specifications

Operation Conditions
- Relative Humidity (operating conditions): 30% to 75%, Temperature: 10°C to + 40°C
- Relative Humidity (storage): 10% to 90%, Temperature: -15°C to +50°C

Transportation Conditions
- When shipping the ICEfx™ system, use the original shipping containers to prevent damage during transport
- If the original shipping containers are not available, the customer takes responsbility to ensure proper transport conditions are satisfied or contacts BTG Customer Service to obtain the appropriate shipping container

Mechanical Specifications – Console
- Weight: 20kg
- Foot print: 36x53cm
- Height: 28cm, monitor down, 48cm, monitor up

Mechanical Specifications – ICEfx™ Cart
- Weight: 20kg
- Foot print: 36x53cm
- Height: 28cm, monitor down, 48cm, monitor up

External Gas Supply
- Argon Cylinder: Purity Level 99.998% or higher
- Solid Particle size: <5μm

Gas cylinder specifications
- Maximum pressure: 31 MPa (4500 psi, 310 bar)
- Recommended volume of gas cylinder: 42-50L

Accuracy of displayed values
- Temperature Accuracy: ±3°C over r ange of -60°C +40°C
- Supplied Gas Pressure Accuracy:
  ± 50 psi, over range of 1000 psi to 6000 psi
  ± 3.4 bar over range of 69 bar to 414 bar
  ± 0.314 MPa over range of 6.9 MPa to 41.4 MPa
- Built-in Regulator Gas Pressure:
  ± 50 psi, over range of 1000 psi to 4000 psi
  ± 3.4 bar over range of 69 bar to 276 bar
  ± 0.314 MPa over range of 6.9 MPa to 27.6 MPa
- Time intervals: ±5 seconds over any 10 minute interval

Electrical specifications
- Input Voltage: 100 to 240 VAC, single phase
- Input Frequency: 50-60Hz • VA Rating: 250 VA
- IP Rating: IP10 • Fuse Rating: T 2A
- Electrical Protection: Class I, Type BF protection against shock
- Signal Input/Output Ports: one (1) Ethernet port, one (1) USB 2.0 full-speed port

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