ORDERING INFORMATION

Cryoablation Systems

PART NUMBER	CRYOABLATION SYSTEMS AND ACCESSORIES
FPRCH6000-02	Visual ICE™ System
FPRCH8000-02	ICEfx™ System, Console only
FPRCH8010-02	ICEfx Cart

CX Cryoablation Needles

CRYOABLATION NEEDLES	PART NUMBER	CONFIGURATION	SHAFT DIAMETER (MM / GAUGE)	SHAFT LENGTH (CM)	HANDLE COLOR	TRACK ABLATION RADIAL WIDTH / LENGTH
IcePearl™ 2.1 CX	**FPRPR3603**	Straight	2.1 mm / 14 G	17.5 cm	White	2.1 / 13 mm
IcePearl™ 2.1 CX	**FPRPR3601**	Angled 90°	2.1 mm / 14 G	17.5 cm	White	2.1 / 13 mm
IcePearl™ 2.1 CX L	**FPRPR3617**	Angled 90°	2.1 mm / 14 G	23 cm	White	2.1 / 13 mm
IceForce™ 2.1 CX	**FPRPR3604**	Straight	2.1 mm / 14 G	17.5 cm	Gray	2.5 / 29 mm
IceForce™ 2.1 CX	**FPRPR3602**	Angled 90°	2.1 mm / 14 G	17.5 cm	Gray	2.5 / 29 mm
IceForce™ 2.1 CX L	**FPRPR3618**	Angled 90°	2.1 mm / 14 G	23 cm	Gray	2.5 / 29 mm
IceRod™ 1.5 CX	**FPRPR3533**	Angled 90°	1.5 mm / 17 G	17.5 cm	Red	2.3 / 30 mm
IceSphere™ 1.5 CX	**FPRPR3573**	Angled 90°	1.5 mm / 17 G	17.5 cm	Yellow	1.7 / 14 mm
IceSeed™ 1.5 CX	**H7493967433170**	Angled 90°	1.5 mm /17 G	17.5 cm	Black	1.6 / 14 mm
IceSeed™ 1.5 CX S	**H7493967233100**	Angled 90°	1.5 mm /17 G	10 cm	Black	1.6 / 14 mm

REFERENCE

1. BTG: Internal Test Reports. Data on file.

ICESEED™ CRYOABLATION NEEDLE

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE:** The Boston Scientific disposable IceRod Cryoablation Needle, IceSphere Cryoablation Needle, IceSeed Cryoablation Needle, IcePearl Cryoablation Needle, and IceForce Cryoablation Needle (CX Needles) are meant to be connected to a Boston Scientific ICEfx Cryoablation System or Visual-ICE Cryoablation System when performing cryoablative tissue destruction through application of extremely cold temperatures. The needles are intended to convert high-pressure gas to either a very cold Freezing application or to a warm Thawing application. The Boston Scientific disposable IceRod Cryoablation Needle, IceSphere Cryoablation Needle, IceSeed Cryoablation Needle, IcePearl Cryoablation Needle, and IceForce Cryoablation Needle (CX Needles), when used with a Boston Scientific ICEfx Cryoablation System or Visual-ICE Cryoablation System, are designed to destroy tissue by the application of extremely cold temperatures.A full list of the cryoablation system specific indications can be found in the respective Boston Scientific cryoablation system user manual. **CONTRAINDICATIONS:** There are no known contraindications specific to use of CX Needles. **WARNINGS:** • A thorough understanding of the technical principles, clinical applications, and risk associated with cryoablation is necessary before using this product. Refer to the ICEfx Cryoablation System or Visual-ICE Cryoablation System User Manuals for optional education. • Do not use this device for any purpose other than the stated intended use. • Observe the expiration date of this product. Do not use past the listed expiration date. • Select CX Needles appropriate for the application and tumor size. The iceball shape and size for CX Needles are described in the Device Description Section. • Do not use CX Needles within a Magnetic Resonance Imaging (MRI) suite or environment. • Use special care to ensure that a cryoablation needle does not come into contact with an implanted device. • Cryoablation needles have sharp tips. Use care to ensure safe handling of a cryoablation needle to eliminate the risk of injury or possible exposure to blood-borne pathogens. • The sterile field and sterility of the cryoablation needle should be maintained at all times. Do not contaminate the distal end of the sterile cryoablation needle. • CX Needles are designed and indicated for Freezing and Thawing applications. These needles are not designed, indicated or tested for thermal protection. Serious injury to patient tissue may result if used for thermal protection. • Inspect the packaging for damage. Do not use the needle if packaging appears opened or damaged; in the event of such occurrence, contact Boston Scientific Technical Assistance Center to arrange return of the complete package with the product. • Do not use the needle if it is bent or damaged while attempting to unpack or use it. Never use a defective needle for a cryoablation procedure. A defective cryoablation needle that has a gas leak can cause a gas embolism or pneumatosis in the patient. • Avoid bending the needle shaft. Do not grasp needles with auxiliary instruments as this may cause damage to the needle shaft. • During use, avoid damage to the needle from other surgical instruments. • Do not kink, pinch, cut or pull excessively on the needle tubing. Damage to needle handle or tubing may cause the needle to become unusable. • Ensure appropriate stability of tubing to avoid inadvertent movement of tubing or needle shifting during a procedure. • Each needle must be locked into a needle channel before initiating a cryoablation procedure to avoid the risk of forceful ejection of the needles while under gas pressure. • Prior to starting a cryoablation procedure, set up the cryoablation system (reference the SYSTEM SETUP Section within the cryoablation system User Manual) and then perform the Needle Integrity and Functionality Test. This test must be successfully completed in order to begin the procedure. • Do not use the needle if there is no ice formation during the Freeze phase while performing the Needle Integrity and Functionality Test. Refer to cryoablation system user manual for troubleshooting. If the issue does not resolve, obtain a new needle and repeat the testing procedure. • Do not use the needle if bubbles are seen escaping from the needle during Needle Integrity and Functionality Test. • Ensure adequate measures are taken to protect organs and structures adjacent to the targeted tissue. • Continuously monitor needle insertion, needle positioning, iceball formation and removal using image guidance (such as direct visualization, ultrasound, or Computed Tomography (CT)) to ensure adequate tissue coverage and to avoid damage to adjacent structures. • Use Boston Scientific's Multi-Point 1.5 Thermal Sensor Device (MTS) to monitor the freeze / thaw temperatures for the intended treatment protocol or to monitor tissue temperature near critical structures. • In the rare event that a needle breaks while inserted in the tissue, act immediately to remove needle parts from the patient's body and report such event to Boston Scientific. • If a needle unintentionally strikes bone, do not start or continue the Freezing process as needle integrity may be compromised. Replace the needle prior to continuing the procedure. • Needle handles and the needle shaft may frost during freezing. Avoid prolonged contact with frosted portions of the needle handle to avoid unintended thermal tissue damage to the patient or clinician. The patient's skin surface should be protected by warm saline irrigation or other means as determined by the physician. • Needle tubing may become extremely cold when conducting freeze cycles during a cryoablation procedure. It is important that a patient's skin is protected from direct contact with needle tubing to avoid the potential for thermal injury to the patient. Ensure an appropriate insulating barrier is placed as needed (such as towels) or other method is employed to prevent needle tubing from touching a patient's skin. • Ensure the Active Zone Indicator is not positioned outside the patient's skin when track ablation (Cautery function) is activated. • The needle handle may become warm during active thawing. Prolonged contact with warm portions of the needle handle could cause unintended thermal tissue damage/burn to the patient or clinician. • Active thawing produces heat along the distal needle shaft. Use care to avoid thermal injury/burn to nontargeted tissues. • Ensure adequate thawing or cooling before attempting to remove needles from the patient. • Discontinue all needle operation prior to needle removal to minimize risk of thermal injury and/or tissue injury. • When conducting FastThaw Function or track ablation (Cautery function), be alert for the Active Zone Indicator as when track ablation is activated and when the needle is withdrawn to prevent unintended tissue damage from the hot needle. • Remove needles from the patient prior to disconnecting needles from the Boston Scientific cryoablation system. • Dispose of needle(s) in accordance with the Disposal Section. • No data regarding cryoablation in combination with other therapies is available from Boston Scientific. **PRECAUTIONS:** General • Boston Scientific CX Needles operate only with a Boston Scientific ICEfx Cryoablation System or Visual-ICE Cryoablation System. • Boston Scientific recommends that only needles of the same type be placed together in a single channel. Using needles of differing types in a channel may affect the accuracy of the Gas Indicator. • Confirm availability of sufficient gas to conduct the planned procedure: the number of needles, needle operations activated, gas cylinder size, pressure and gas flow affect the required gas volume. Handling • Use of multiple needles is recommended to fully cover a target site and provide a suitable margin. • Multiple needles placed in an adjacent configuration will typically create a large, coalesced iceball. Iceball formation must be monitored using image guidance to optimize a successful ablation procedure. • Availability of a back-up needle is recommended should a replacement or additional needle be required during a procedure. • If the Boston Scientific cryoablation system contains pressurized helium, track ablation (Cautery function), i- Thaw Function and FastThaw Function cannot be activated. Procedural • In a safe and controlled fashion, twist the protective sleeve in a rotational motion while simultaneously pulling it away from the device handle. Take extra care when removing the protective sleeve from the device to avoid contact with the distal end of the needle. **ADVERSE EVENTS:** The potential adverse events associated with the device and/or cryoablation procedure include, but are not limited to: • Allergic reaction (contrast, device, other) • Angina • Arrhythmia • Atelectasis • Bladder spasms • Bleeding/hemorrhage • Burn/frostbite • Cerebrovascular accident (CVA)/stroke • Cryoshock phenomenon (e.g. multi organ failure, severe coagulopathy, disseminated intravascular coagulation (DIC)) • Death • Distension • Edema/swelling • Ejaculatory dysfunction • Embolism (air, device, thrombus) • Erectile dysfunction • Fever • Fistula • Fracture • Gastrointestinal symptoms (e.g. nausea, vomiting, diarrhea, constipation) • Healing, impaired • Hematoma • Hematuria • Hemothorax • Hepatic dysfunction/failure • Hernia • Hypertension • Hypotension • Hypothermia • Ileus • Impotence • Infection/abscess/sepsis • Inflammation • Muscle spasm • Myocardial infarction • Necrosis • Need for additional intervention or surgery • Nerve injury • Neuropathy • Obstruction • Pain/discomfort • Perforation (including organ and adjacent structures) • Pericardial effusion • Perirenal fluid collection • Pleural effusion • Pneumatosis (air or gas in an abnormal quantity and/or place in the body) • Pneumothorax • Post ablation syndrome (e.g. fever, pain, nausea, vomiting, malaise, myalgia) • Renal insufficiency/failure • Renal parenchymal or capsule fracture • Respiratory distress/insufficiency/failure • Scrotal edema • Stenosis/stricture • Subcutaneous emphysema • Thrombosis/thrombus • Tissue damage • Transient ischemic attack (TIA) • Tumor cell seeding • Urethral sloughing • Urinary frequency/urgency • Urinary incontinence • Urinary retention • Urinary tract infection • Vasovagal response • Vessel trauma (e.g. dissection, injury, perforation, pseudoaneurysm, rupture, or other) • Wound infection **97188508 A.1**

CRYOABLATION NEEDLES (IceSeed 1.5, IceSphere 1.5, IceSphere 1.5 CX, IceRod 1.5, IceRod 1.5 PLUS, IceRod 1.5 i-Thaw, IceRod 1.5 CX, IcePearl 2.1 CX and IceForce 2.1 CX) and ICEFX and VISUAL ICE CRYOABLATION SYSTEMS

INDICATIONS: The Galil Medical Cryoablation Needles and Systems are intended for cryoablative destruction of tissue during surgical procedures. The Cryoablation Needles, used with a Galil Medical Cryoablation System, are indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology, and urology. Galil Medical Cryoablation Systems are designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors and skin lesions) by the application of extremely cold temperatures. A full list of specific indications can be found in the respective Galil Medical Cryoablation System User Manuals. **CONTRAINDICATIONS:** There are no known contraindications specific to use of a Galil Medical Cryoablation Needle. **POTENTIAL ADVERSE EVENTS:** There are no known adverse events related to the specific use of the Cryoablation Needles. There are, however, potential adverse events associated with any surgical procedure. Potential adverse events which may be associated with the use of cryoablation may be organ specific or general and may include, but are not limited to abscess, adjacent organ injury, allergic/anaphylactoid reaction, angina/coronary ischemia, arrhythmia, atelectasis, bladder neck contracture, bladder spasms, bleeding/hemorrhage, creation of false urethral passage, creatinine elevation, cystitis, diarrhea, death, delayed/non healing, disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT), ecchymosis, edema/swelling, ejaculatory dysfunction, erectile dysfunction (organic impotence), fever, fistula, genitourinary perforation, glomerular filtration rate elevation, hematoma, hematuria, hypertension, hypotension, hypothermia, idiosyncratic reaction, ileus, impotence, infection, injection site reaction, myocardial infarction, nausea, neuropathy, obstruction, organ failure, pain, pelvic pain, pelvic vein thrombosis, penile tingling/numbness, perirenal fluid collection, pleural effusion, pneumothorax, probe site paresthesia, prolonged chest tube drainage, prolonged intubation, pulmonary embolism, pulmonary insufficiency/failure, rectal pain, renal artery/renal vein injury, renal capsule fracture, renal failure, renal hemorrhage, renal infarct, renal obstruction, renal vein thrombosis, rectourethral fistula, scrotal edema, sepsis, skin burn/frostbite, stricture of the collection system or ureters, stroke, thrombosis/thrombus/embolism, transient ischemic attack, tumor seeding, UPJ obstruction/injury, urethral sloughing, urethral stricture, urinary fistula, urinary frequency/urgency, urinary incontinence, urinary leak, urinary renal leakage, urinary retention/oliguria, urinary tract infection, vagal reaction, voiding complication including irritative voiding symptoms, vomiting, wound complication, and wound infection. **PI-719210-AA**

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PI-886609-AC

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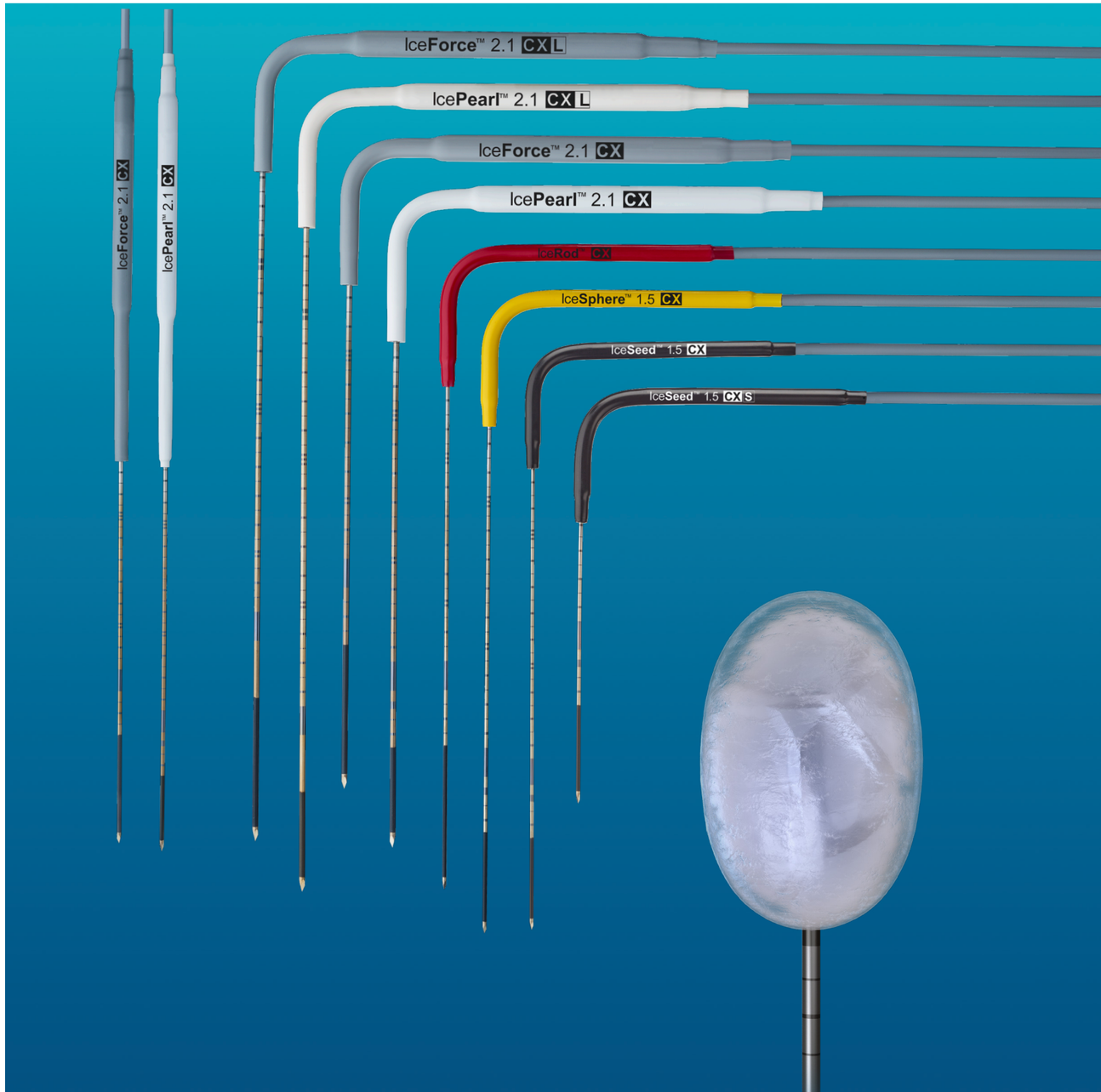
CX CRYOABLATION NEEDLES

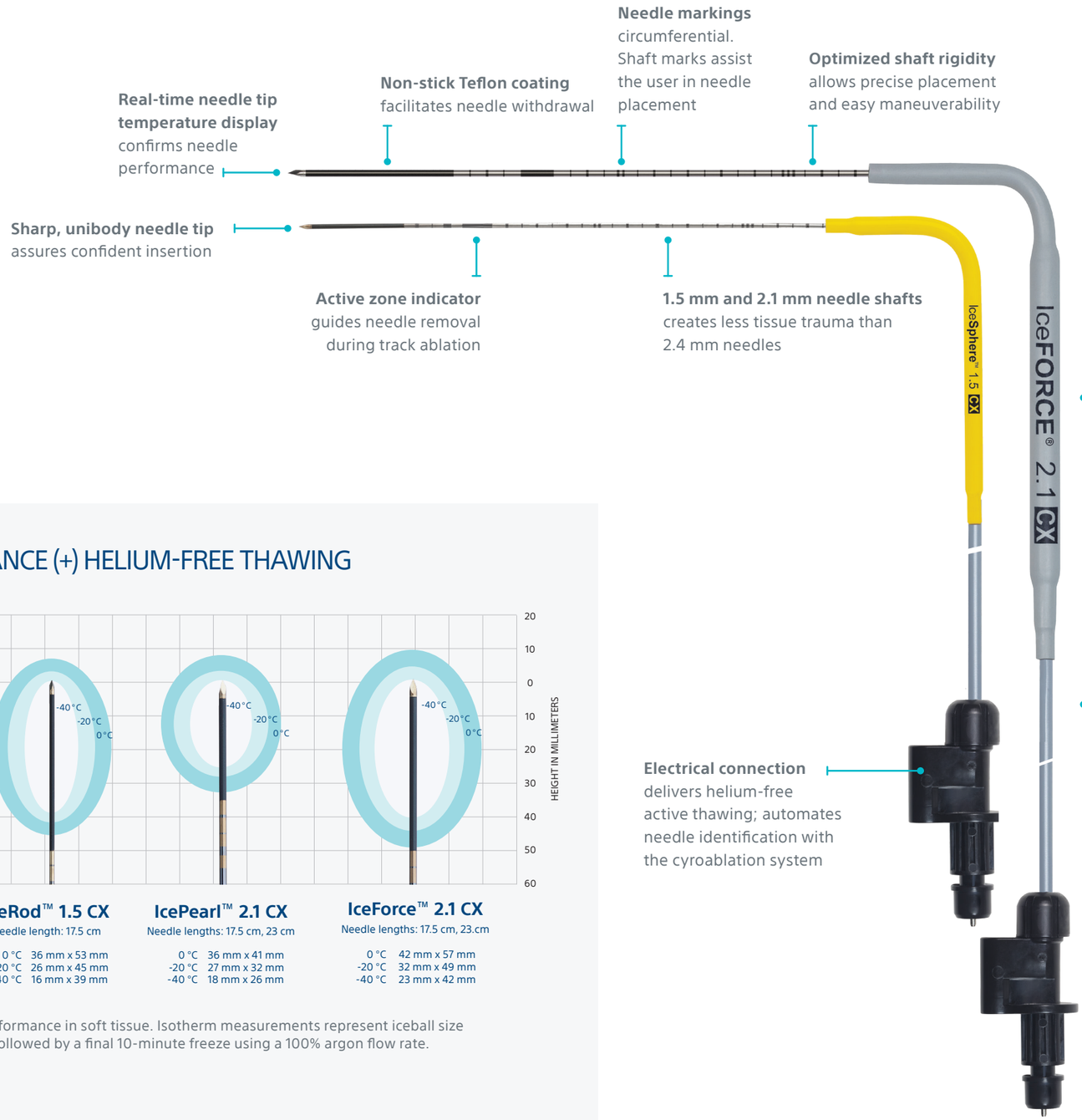
Engineered For Optimal Clinical Performance



CX CRYOABLATION NEEDLES

FEATURES A PROPRIETARY NEEDLE DESIGN PROVIDING PRECISE PLACEMENT AND CONTROL

- Narrow, lightweight, and low-profile design with 1.5 mm and 2.1 mm needles allows for placement of multiple needles in confined spaces
- Cryoablation visualization allows for optimal tumor coverage and improved CT artifact
- Sharp needle tip with a rigid, yet maneuverable needle shaft
- Built-in memory chip allows needles to be reconnected without the need to retest



HELIUM-FREE THAW OPTIONS VIA PROPRIETARY I-THAW™ FEATURE

- Eliminates set-up time, space, and overall gas costs while conserving an expensive, diminishing helium resource
- Exclusive FastThaw™ functionality reduces thaw time by up to 18% versus helium[1]
- 2.1 CX needles consume 17%–29% less argon consumption than other 2.4 mm needles[1]

CAUTERY FOR TRACK ABLATION

- Cautery function allows for track ablation to be performed, creating a uniform zone of coagulative necrosis

SUPERIOR FREEZING PERFORMANCE (+) HELIUM-FREE THAWING

IceSeed™ 1.5 CX
Needle length: 17.5 cm, 10 cm

0° C	29 mm x 34 mm
-20° C	20 mm x 26 mm
-40° C	13 mm x 20 mm

IceSphere™ 1.5 CX
Needle length: 17.5 cm

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

IceRod™ 1.5 CX
Needle length: 17.5 cm

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

IcePearl™ 2.1 CX
Needle lengths: 17.5 cm, 23 cm

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

IceForce™ 2.1 CX
Needle lengths: 17.5 cm, 23.cm

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

Data collected using 37° Celsius gel approximates conformance in soft tissue. Isotherm measurements represent iceball size after a 10-minute freeze and 5-minute passive thaw, followed by a final 10-minute freeze using a 100% argon flow rate.