

ORDERING INFORMATION

Cryoablation Systems

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

CX Cryoablation Needles

CRYOABLATION NEEDLES	PART NUMBER	CONFIGURATION	SHAFT DIAMETER (MM/GAUGE)	HANDLE COLOR	TRACK ABLATION RADIAL WIDTH/LENGTH
IcePearl™ 2.1 CX Cryoablation Needle	FPRPR3603	Straight	175 mm/14 G	White	2.1/13 mm
IcePearl™ 2.1 CX Cryoablation Needle	FPRPR3601	Angled 90°	175 mm/14 G	White	2.1/13 mm
IcePearl™ 2.1 CX L Cryoablation Needle	FPRPR3617	Angled 90°	230 mm/14 G	White	2.1/13 mm
IceFORCE™ 2.1 CX Cryoablation Needle	FPRPR3604	Straight	175 mm/14 G	Gray	2.5/29 mm
IceFORCE™ 2.1 CX Cryoablation Needle	FPRPR3602	Angled 90°	175 mm/14 G	Gray	2.5/29 mm
IceFORCE™ 2.1 CX L Cryoablation Needle	FPRPR3618	Angled 90°	230 mm/14 G	Gray	2.5/29 mm
IceRod™ 1.5 CX Cryoablation Needle	FPRPR3533	Angled 90°	175 mm/17 G	Red	2.3/30 mm
IceSphere™ 1.5 CX Cryoablation Needle	FPRPR3573	Angled 90°	175 mm/17 G	Yellow	1.7/14 mm

The CX Cryoablation Needles are designed for use with the Visual ICE™ and ICEfx™ Cryoablation Systems.



REFERENCE

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

CRYOABLATION NEEDLES (IceSeed 1.5, IceSphere 1.5, IceSphere 1.5 CX, IceRod 1.5, IceRod 1.5 PLUS, IceRod 1.5i-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.
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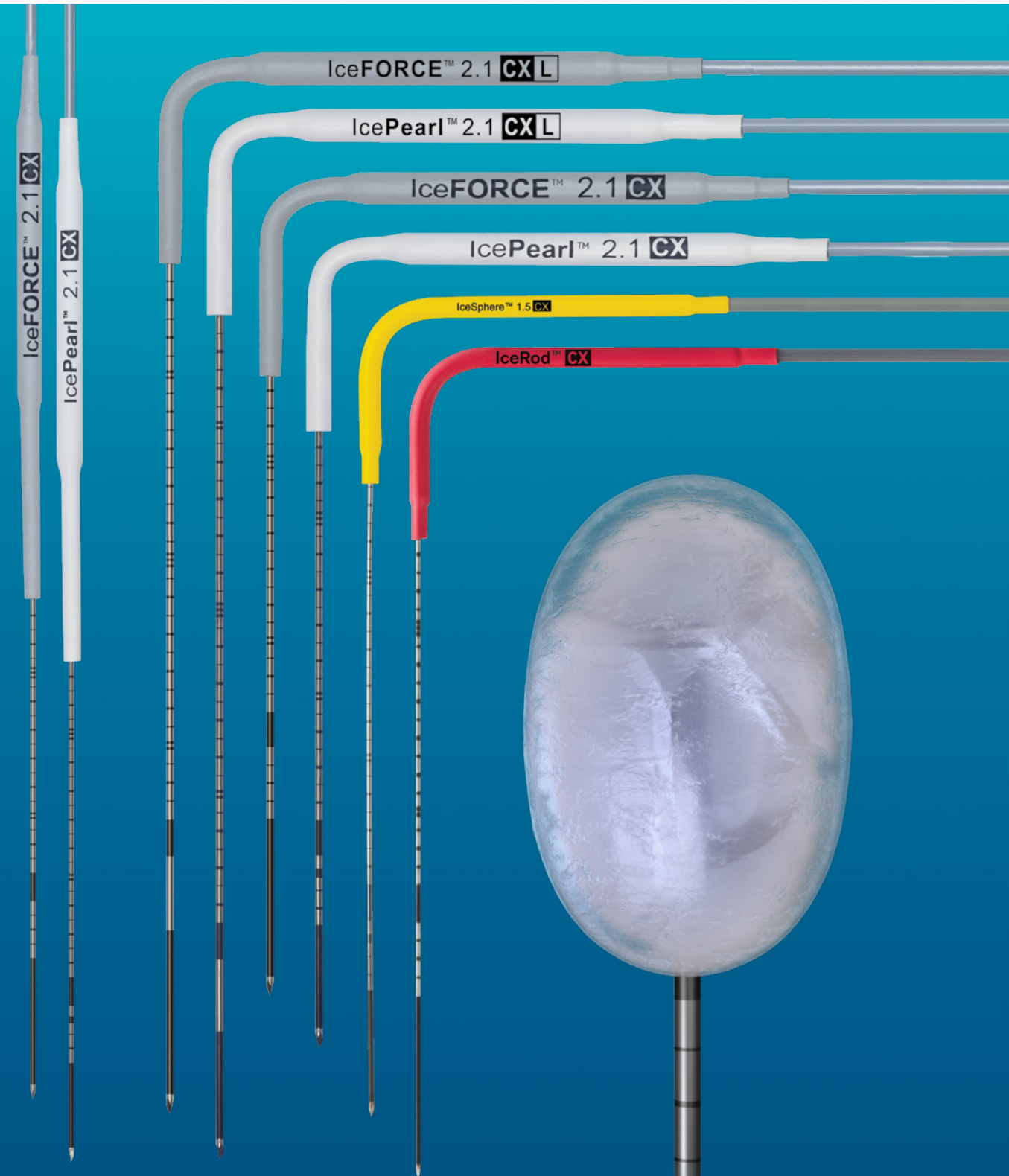
To order product or for more information contact customer service at 1.888.272.1001.

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CX CRYOABLATION NEEDLES

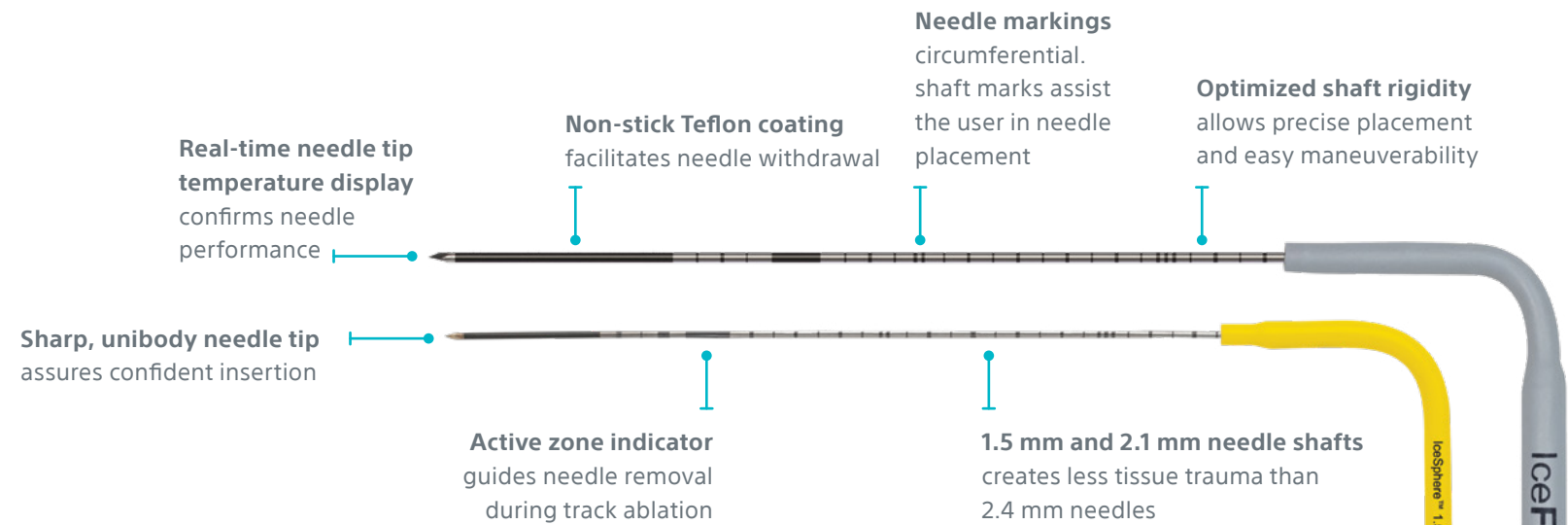
Engineered For Optimal Clinical Performance



CX CRYOABLATION NEEDLES

FEATURES A PROPRIETARY NEEDLE DESIGN PROVIDING PRECISE PLACEMENT AND CONTROL

- Narrow, lightweight, 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 helium¹
- 2.1 CX needles consume 17%–29% less argon consumption than other 2.4 mm needles¹

Low-profile insulated handle allows close placement of multiple needles

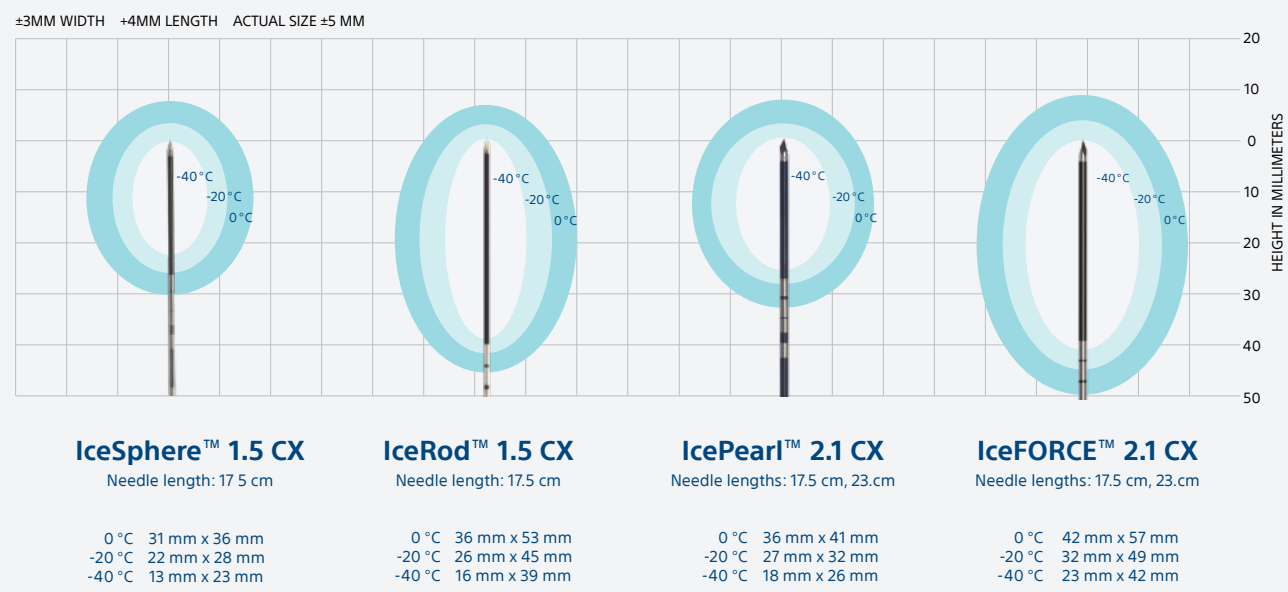
Small and flexible tubing minimizes needle migration and torque

Electrical connection delivers helium-free active thawing; Automates needle identification with the cryoablation system

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



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