

ORDERING INFORMATION

| CATALOG NUMBER | ICEFX™ CRYOABLATION SYSTEM AND ACCESSORIES |
|----------------|--|
| FPRCH8000-02 | ICEfx System, Console only |
| FPRCH8010-02 | ICEfx Cart |
| FPRCH4000-02 | Dual Tank Cylinder Gas Adapter, 5M PSI |

| PART NUMBER | CX CRYOABLATION NEEDLES | CONFIGURATION | SHAFT LENGTH/ GAUGE | TRACK ABLATION RADIAL WIDTH/LENGTH |
|-------------|---------------------------------------|---------------|---------------------|------------------------------------|
| FPRPR3603 | IcePearl™ 2.1 CX Cryoablation Needle | Straight | 175 cm/14 G | 2.1/13 mm |
| FPRPR3601 | IcePearl 2.1 CX Cryoablation Needle | Angled 90° | 175 cm/14 G | 2.1/13 mm |
| FPRPR3617 | IcePearl 2.1 CX L Cryoablation Needle | Angled 90° | 230 cm/14 G | 2.1/13 mm |
| FPRPR3604 | IceForce™ 2.1 CX Cryoablation Needle | Straight | 175 cm/14 G | 2.5/29 mm |
| FPRPR3602 | IceForce 2.1 CX Cryoablation Needle | Angled 90° | 175 cm/14 G | 2.5/29 mm |
| FPRPR3618 | IceForce 2.1 CX L Cryoablation Needle | Angled 90° | 230 cm/14 G | 2.5/29 mm |
| FPRPR3533 | IceRod™ 1.5 CX Cryoablation Needle | Angled 90° | 175 cm/17 G | 2.3/30 mm |
| FPRPR3573 | IceSphere™ 1.5 CX Cryoablation Needle | Angled 90° | 175 cm/17 G | 1.7/14 mm |

SYSTEM SPECIFICATIONS

OPERATING CONDITIONS

- Temperature: 10 °C to 40 °C
- Relative Humidity: 30% to 75%

STORAGE CONDITIONS

- Temperature: -15 °C to + 50 °C
- Relative Humidity: 10% to 90%

MECHANICAL SPECIFICATIONS: ICEfx CONSOLE

- Weight: 44 lbs
- Height: 11 in, monitor down
19 in, monitor up
- Foot Print: 14 x 21 in

MECHANICAL SPECIFICATIONS: ICEfx CART

- Weight: 50 lbs
- Height: 36 in
- Foot Print: 18 x 21 in

GAS SUPPLY SPECIFICATIONS

ARGON GAS SUPPLY

- Purity Level: 99.998% or higher
- Solid particle size: < 5 µm

GAS CYLINDER SPECIFICATIONS

- Maximum Pressure: 41.4 MPa 6000 psi
- Recommended Volume of Gas Cylinder: 42 – 50 L
- Connector Valve: CGA677

CX CRYOABLATION NEEDLES ARE ENGINEERED FOR OPTIMAL CLINICAL PERFORMANCE

Featuring a proprietary needle design providing precise placement, size and control.

Excellent freezing performance with a portfolio of CX cryoablation needles in a range of ellipsoidal and spherical-shaped ablation zone sizes, delivering the coldest and largest ice on the market on the smallest diameter needle shaft.

CX needles eliminate the need for helium to conduct active thawing, resulting in up to 65% total gas cost savings.¹

The track ablation feature with the CX needle allows for thermal ablation to induce tissue necrosis along the needle track thereby creating an environment not conducive to tumor cell proliferation.²



ICEFX™ Cryoablation System



PRECISE ICEBALL FORMATION

INTUITIVE USER INTERFACE

COMPACT SYSTEM DESIGN

Boston Scientific
Advancing science for life™

Peripheral Interventions
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

To order product or for more information contact customer service at 1.888.272.1001.

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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. **PI-719210-AA**

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¹ BSC Internal Test Reports. Data on file.
² Akhavan, A, et al. Tumour seeding: a rare complication of ablative therapy for clinically localised renal cell carcinoma. BMJ Case Reports 2012; doi:10.1136/bcr-2012-006948

ICEFX™ Cryoablation System

ICEfx Cryoablation System, offers predictable, reliable cryoablation performance and seamless therapy delivery with the exceptional ease of technical operation.

PRECISE CONTROL

- Four independent channels supporting up to eight of the most advanced cryoablation needles.
- Two multi-point thermal sensors for detecting location and temperature for procedural performance.
- CX needles allow for helium-free thawing and track ablation options.

COMPACT DESIGN

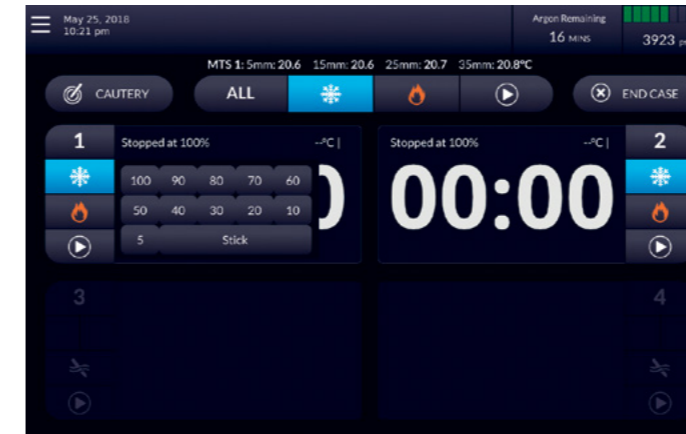
- Smaller footprint and weight allows for mobilization of the console.
- Mobile cart offers a center storage area for accessory bag or four needle boxes.



INTUITIVE USER INTERFACE

- Simplified procedural interface offers equivalent iceball performance as larger cryoablation systems.¹
- Large timers allow visualization of case progression from a distance.
- Icons and system wizards guide procedural actions.

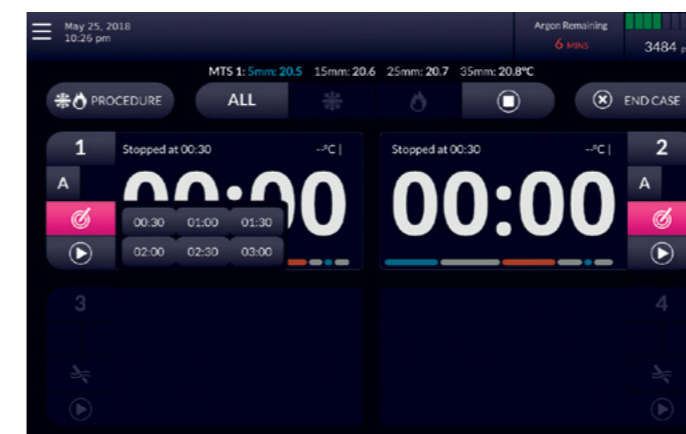
TOUCH SCREEN DISPLAY TO GUIDE PROCEDURAL EFFICIENCY



ICEfx allows for adjustable freeze cycles from 5% to 100%, providing precise control over iceball formation and location.

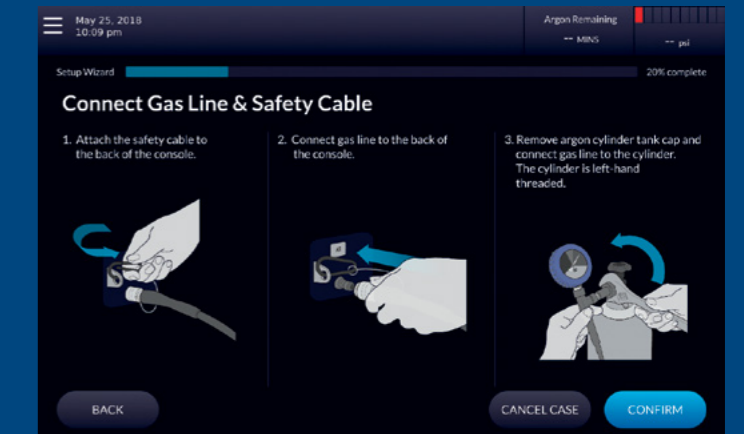


Customized cycle sequence programming allows frequently used freeze/thaw cycles to be programmed and saved. Pre-programming may shorten overall case duration.

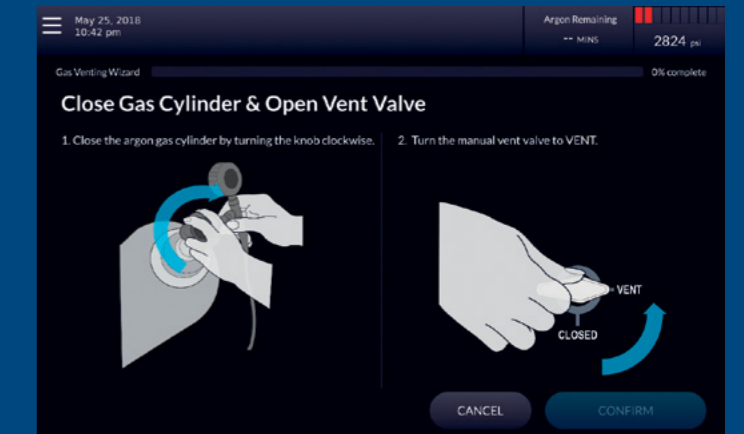


Cautery function allows track ablation to be performed creating a uniform zone of coagulative necrosis.²

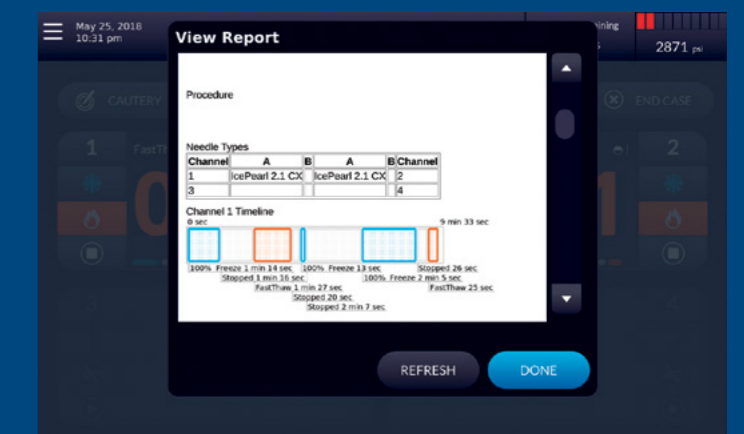
SYSTEM WIZARDS PROVIDE EXCEPTIONAL EASE OF USE



The on-screen set-up and shut-down wizards allow for step-by-step guidance of system operation.



CUSTOMIZED PROCEDURAL REPORTS



Provides case overview, needles, channels used, freeze times, and thawing durations, allows for viewing during the procedure.