

CRYOABLATION NEEDLES ENGINEERED FOR EFFICIENCY AND PERFORMANCE

Innovative needle portfolio consists of classic and helium-free CX cryoablation needles to accommodate a variety of procedural applications.

Proprietary CX technology combines freezing with advanced thawing and track ablation.

Helium-free iThaw™ and FastThaw™ capabilities eliminate the need for helium while providing similar or accelerated thaw performance.¹

Cautery for track ablation function creates a zone of coagulative cellular necrosis around the needle track that may reduce the risk of track seeding.

ORDERING INFORMATION

CRYOABLATION SYSTEM	PART NUMBER
Visual ICE™ Cryoablation System	FPRCH6000-02

CRYOABLATION PORTFOLIO OF NEEDLES

The following chart lists 90° and straight needles. Please contact your Boston Scientific representative for MRI compatible needles, needle kits and cryoablation systems.

CRYOABLATION NEEDLES	PART NUMBER	SHAFT LENGTH / GAUGE	TRACK ABLATION RADIAL WIDTH/LENGTH
IceSeed™ 1.5 90°	FPRPR3202	17.5 cm / 17 G	
IceSeed 1.5 Straight	FPRPR3201	17.5 cm / 17 G	
IceSphere 1.5 S 90°	FPRPR3561	10 cm / 17 G	
IceSphere 1.5 CX 90°	FPRPR3573	17.5 cm / 17 G	1.7 mm / 14 mm
IceRod 1.5 CX 90°	FPRPR3533	17.5 cm / 17 G	2.3 mm / 30 mm
IceRod 1.5 i-Thaw® Straight	FPRPR4009	17.5 cm / 17 G	
IcePearl™ 2.1 CX 90°	FPRPR3601	17.5 cm / 14 G	2.1 mm / 13 mm
IcePearl 2.1 CX L 90°	FPRPR3617	23 cm / 14 G	2.1 mm / 13 mm
IcePearl 2.1 CX Straight	FPRPR3603	17.5 cm / 14 G	2.1 mm / 13 mm
IceForce™ 2.1 CX 90°	FPRPR3602	17.5 cm / 14 G	2.5 mm / 29 mm
IceForce™ 2.1 CX L 90°	FPRPR3618	23 cm / 14 G	2.5 mm / 29 mm
IceForce 2.1 CX Straight	FPRPR3604	17.5 cm / 14 G	2.5 mm / 29 mm

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 Gallil Medical Cryoablation Needles and Systems are intended for cryoablative destruction of tissue during surgical procedures. The Cryoablation Needles, used with a Gallil 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. Gallil 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 Gallil Medical Cryoablation System User Manuals. **CONTRAINDICATIONS:** There are no known contraindications specific to use of a Gallil 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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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:

- Weight: 220 lbs
- Height: 42 in, monitor down
62 in, monitor up
- Foot Print: 22 x 26 in
- Storage Compartment Weight Capacity: 50 lbs
- Monitor Storage Basin Weight Capacity: 20 lbs
- Closed Monitor Weight Capacity: 20 lbs

GAS SUPPLY SPECIFICATIONS

ARGON CYLINDER:

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

HELIUM CYLINDER:

- Purity Level: 99.995% or higher
- Solid particle size: < 5 µm

GAS CYLINDER SPECIFICATIONS

- Maximum Pressure: 6000 psi
- Recommended Volume of Gas Cylinders: 42-50 L
- Connector Valve: CGA677



VISUAL ICE™ Cryoablation System



PROGRESSIVE
CRYOABLATION
PLATFORM

INTUITIVE USER
INTERFACE

OPTIMAL
ABLATION
ZONE CREATION

Boston Scientific
Advancing science for life™

Peripheral Interventions

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

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PI-755102-AB

VISUAL ICE™ Cryoablation System

CONTINUOUS AND UNRIVALED INNOVATION

Visual ICE Cryoablation System delivers the next generation of therapy delivery and superior iceball performance.

SYSTEM FEATURES

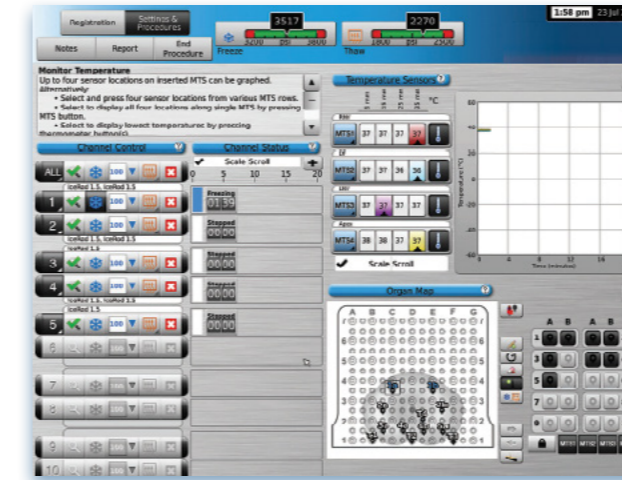
- Large touch-screen monitor
- Ten separate system channels allow independent control per channel
- Twenty needle ports provide opportunity to treat large tumors and to conduct multiple simultaneous treatments
- Enlarged, positionable timers allow procedural status monitoring from a distance
- Operates with Argon and/or Helium depending on cryoablation needles used



INTUITIVE USER INTERFACE PROVIDES AN EASE OF OPERATION

ENHANCED SYSTEM FUNCTIONALITY

- Consistent gas flow rates are maintained to active needles, producing the strongest possible ice
- Software controls optimize performance for simultaneous activation of multiple needles
- Software functions can be customized based on procedure and need for advanced functions
- Secondary internal gas dryers produce consistent iceballs and boost freezing performance



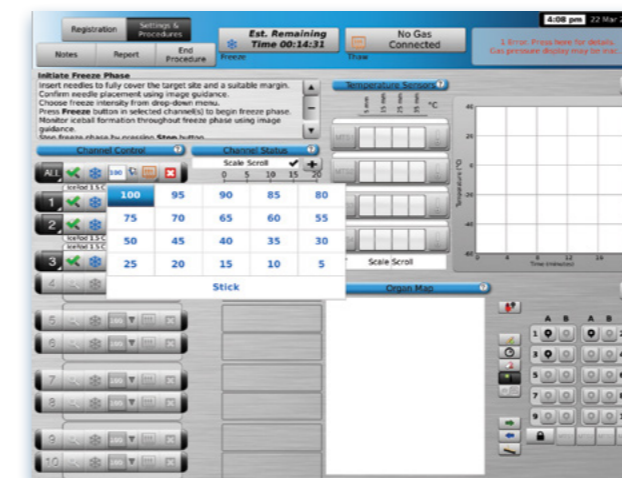
Procedure Screen

PRECISE CONTROLS PRODUCE OPTIMAL ABLATION ZONES

- Visual Ice Cryoablation System offers dual-stage gas dryers for superior iceball performance
- Different needle types can be combined to create optimal iceball shapes and sizes
- Real-time needle tip temperature displays

CONFIGURABLE DISPLAY

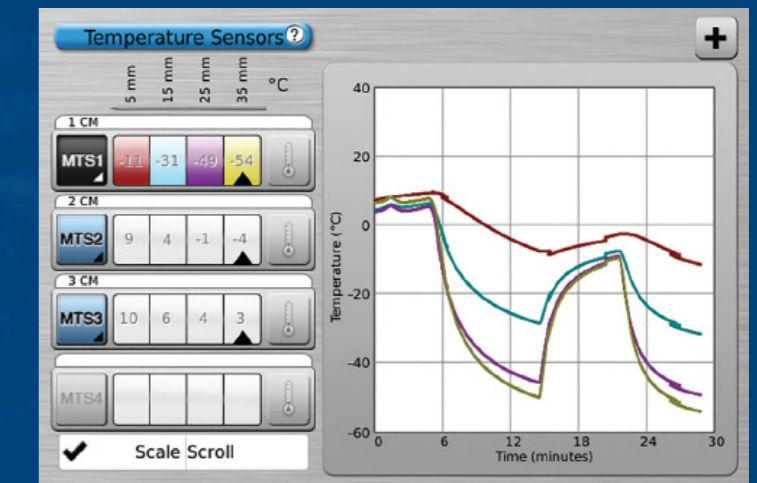
- Large HD touch screen controls operation and displays procedure status
- Enlarged, positionable timers allow procedure status monitoring from a distance
- Selections to maximize, minimize, scale or scroll customize the displayed data
- Color coded bars display ongoing procedural summary



THERMAL SENSORS MONITOR SURROUNDING TISSUE

Patented Multi-Point Thermal Sensors™ measure temperature in four points along a 3 cm distance to continuously monitor temperature in surrounding tissue

Real-time numeric and graphical displays from inserted MTS needles provide visual feedback on temperatures near critical structures and/or ablation sites



Temperature Sensor Section