

# VISUAL ICE™ Cryoablation System



**PROGRESSIVE  
CRYOABLATION  
PLATFORM**

**INTUITIVE USER  
INTERFACE**

**OPTIMAL ABLATION  
ZONE CREATION**

# VISUAL ICE™ Cryoablation System

## CONTINUOUS AND UNRIVALED INNOVATION

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



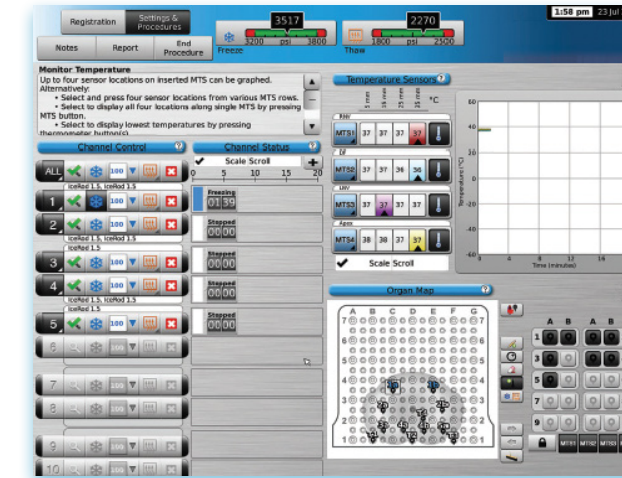
## SYSTEM FEATURES

- 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



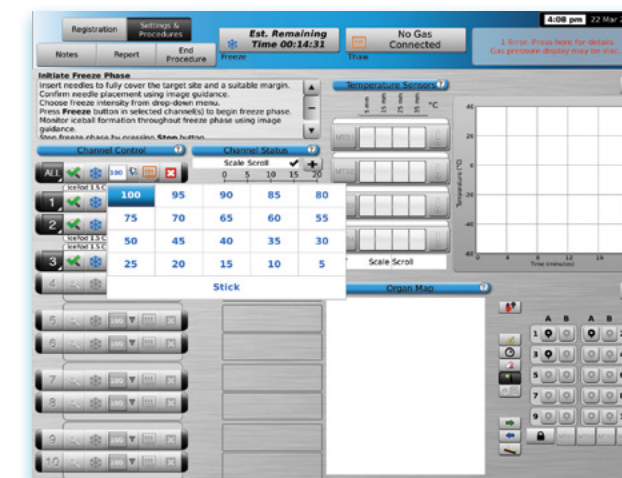
Procedure Screen

### 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

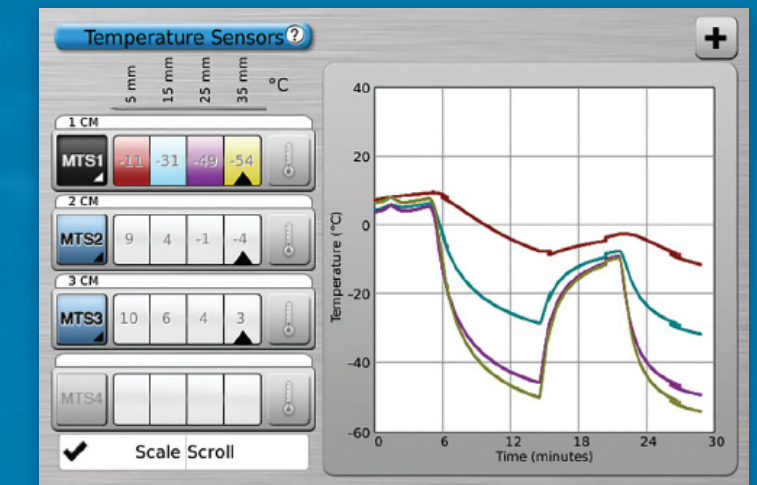
- Large HD touch screen controls operation and displays procedure status
- Enlarged, positionable timers allow procedure status monitoring from a distance
- Selections to maximize, minimize, scale or scroll customize the displayed data
- Color coded bars display ongoing procedural summary



## 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



# 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.<sup>1</sup>

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 90°	FPRPR3560	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
IceSphere 1.5 Straight	FPRPR3558	17.5 cm / 17 G	
IceRod™ 1.5 PLUS 90°	FPRPR3508	17.5 cm / 17 G	
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
IceEdge™ 2.4 90°	FPRPR3506	17.5 cm / 13 G	

## 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

### 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, UPI 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**

**Boston Scientific**

Advancing science for life™

### Peripheral Interventions

300 Boston Scientific Way  
Marlborough, MA 01752-1234  
[www.bostonscientific.com](http://www.bostonscientific.com)

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

© 2020 Boston Scientific Corporation or its affiliates. All rights reserved.

PI-755102-AA