



PROCEDURE SCREEN



GAS INDICATOR DISPLAY



ADJUSTABLE FREEZE INTENSITIES

INTUITIVE USER INTERFACE PROVIDES EASY OPERATION

LARGE HD TOUCH-SCREEN CONTROLS SYSTEM OPERATION AND DISPLAYS PROCEDURE STATUS

- Buttons provide easy cryoablation control
- Color-coded bars visually display ongoing procedural summary of freeze, thaw and idle segments
- Enlarged, positionable timers allow monitoring of the procedure status from a distance
- Enlarged timers display elapsed cycle time and, when freezing, freeze intensity
- Optional cycle programming offers automation of frequently used freeze-thaw protocols

SYSTEM FEATURES CONTROL ICEBALL SHAPE AND GROWTH

- Adjustable freeze intensity regulates ice growth
 - Provides control near critical structures
 - Stick mode secures a needle during placement of additional needles
- Eight separate system channels allow independent control per channel
- Activation of multiple needles provides opportunities to treat large tumors and to conduct multiple simultaneous treatments
- Different needle types can be combined to create optimal iceball shapes and sizes

SYSTEM SOFTWARE STREAMLINES OPERATION

- Gas Indicators display real-time estimates of remaining gas time to minimize procedure interruption
- Online predictive diagnostics allow advance planning for maintenance
- Remote connectivity provides online software updates and downloads

ORDERING INFORMATION

PART NUMBER	VISUAL ICE™ MRI SYSTEM & ACCESSORIES	DESCRIPTION
H7493961070000	Visual ICE™ MRI Cryoablation System	A cryoablation system with built-in gas pressure regulators; two flexible gas supply lines (one argon, one helium) with pressure gauges; a system cover
H7493970071000	Visual ICE™ MRI Mobile Connection Panel	A Visual ICE™ MRI remote Mobile Connection Panel to support MRI needle connections in magnet room; a Mobile Connection Panel cover
H7493969970500	Visual ICE™ MRI Junction Box Assembly	Two Visual ICE™ MRI Junction Box Assemblies containing gas, electrical and fiber optic connectors; One Penetration Panel
ASM7005	Visual ICE™ MRI Junction Box Harness (5 m)	One Visual-ICE™ MRI Junction Box Harness (5 m) containing gas, electrical and fiber optic lines and connectors, packed in a protective case
ASM7010	Visual ICE™ MRI Junction Box Harness (10 m)	One Visual ICE™ MRI Junction Box Harness (10 m) containing gas, electrical and fiber optic lines and connectors, packed in a protective case
ASM7015	Visual ICE™ MRI Junction Box Harness (15 m)	One Visual ICE™ MRI Junction Box Harness (15 m) containing gas, electrical and fiber optic lines and connectors, packed in a protective case

PART NUMBER	MRI CRYOABLATION KITS	CONFIGURATION	NEEDLE SHAFT LENGTH	ACTIVE THAW
FPRPR3192	IceSeed™ 1.5 MRI Cryoablation Needle	Straight	17.5 cm	Helium
FPRPR3194	IceSeed™ 1.5 MRI 90° Cryoablation Needle	90°	17.5 cm	Helium
FPRPR3193	IceRod™ 1.5 MRI Cryoablation Needle	Straight	17.5 cm	Helium
FPRPR3195	IceRod™ 1.5 MRI 90° Cryoablation Needle	90°	17.5 cm	Helium

SYSTEM SPECIFICATIONS

OPERATING CONDITIONS

- Relative Humidity (operating conditions): 30% to 75%
- Temperature: -15 °C to + 50 °C
- Relative Humidity (storage): 10% to 90%

TRANSPORTATION CONDITIONS

- When shipping a system, use the original shipping containers to prevent damage during transport
- If the original shipping containers are not available, the customer takes responsibility to ensure proper transport conditions are satisfied or contacts Gall Customer Service to obtain the appropriate shipping container

MECHANICAL SPECIFICATIONS: CONSOLE

- Weight: 170 lbs
- Height: 42 in, monitor down
62 in, monitor up
- Footprint: 22 x 26 in
- Storage Compartment Weight Capacity: 50 lbs
- Monitor Storage Basin Weight Capacity: 20 lbs
- Closed Monitor Weight Capacity: 20 lbs

MECHANICAL SPECIFICATIONS: MOBILE CONNECTION PANEL

- Weight: 45 lbs
- Height: 39 in
- Footprint: 20 x 18 in

MECHANICAL SPECIFICATIONS - JUNCTION BOX

- Wall footprint: 10 in x 5 in, protruding 4" out of the wall
- Note: about 24" of clearance is needed from the front of the Junction Box to allow easy connections

MECHANICAL SPECIFICATIONS - PENETRATION PANEL

- Footprint: 8 in x 6 in minimum
- Note: about 12" of clearance is needed from the front of the Penetration Panel to allow space for gas, electrical and fiber optics connections

EXTERNAL GAS SUPPLY

- 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
- Connector Valve: CGA677

ACCURACY OF DISPLAYED VALUES

- Supplied Gas Pressure Accuracy: ±50 psi, over range of 1000 psi to 6000 psi
- Built-in Regulator Gas Pressure: ±50 psi, over range of 1000 psi to 4000 psi
- Time Intervals: ±5 seconds over any 10 minute interval

ELECTRICAL SPECIFICATIONS

- Input Voltage: 100 to 240 VAC, single phase
- Input Frequency: 50-60 Hz
- VA Rating: 450 VA
- IP Rating: IP10
- Fuse Rating: T 5.0A
- Electrical Protection: Class I, Type BF protection against shock
- Signal Input/Output Ports:
 - one (1) Ethernet port
 - one (1) USB 2.0 full-speed port
 - one (1) Auxiliary Display port

MRI CONDITIONAL SAFETY

- The Visual-ICE™ MRI Cryoablation System has been tested to be safe for use with 1.5 and 3 Tesla scanners

RECOMMENDED SCAN SEQUENCES TO MINIMIZE NEEDLE HEATING

- Normal Operating Mode
- SAR of ≤ 1.5 watts per kilogram
- Scan duration less than one minute per scan

CRYOABLATION NEEDLES (ICESEED 1.5, ICESPHERE 1.5, ICESPHERE 1.5 CX, ICEROD 1.5, ICEROD 1.5 PLUS, ICEROD 1.5 THAW, ICEROD 1.5 CX, ICEPEARL 2.1 CX AND ICEFORCE 2.1 CX) AND ICEPIX AND VISUAL ICE CRYOABLATION SYSTEMS

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

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VISUAL ICE™ MRI Cryoablation System

INTUITIVE USER INTERFACE

ENHANCED MR VISUALIZATION

CONTROLLED ABLATION ZONE



VISUAL ICE™ MRI Cryoablation System

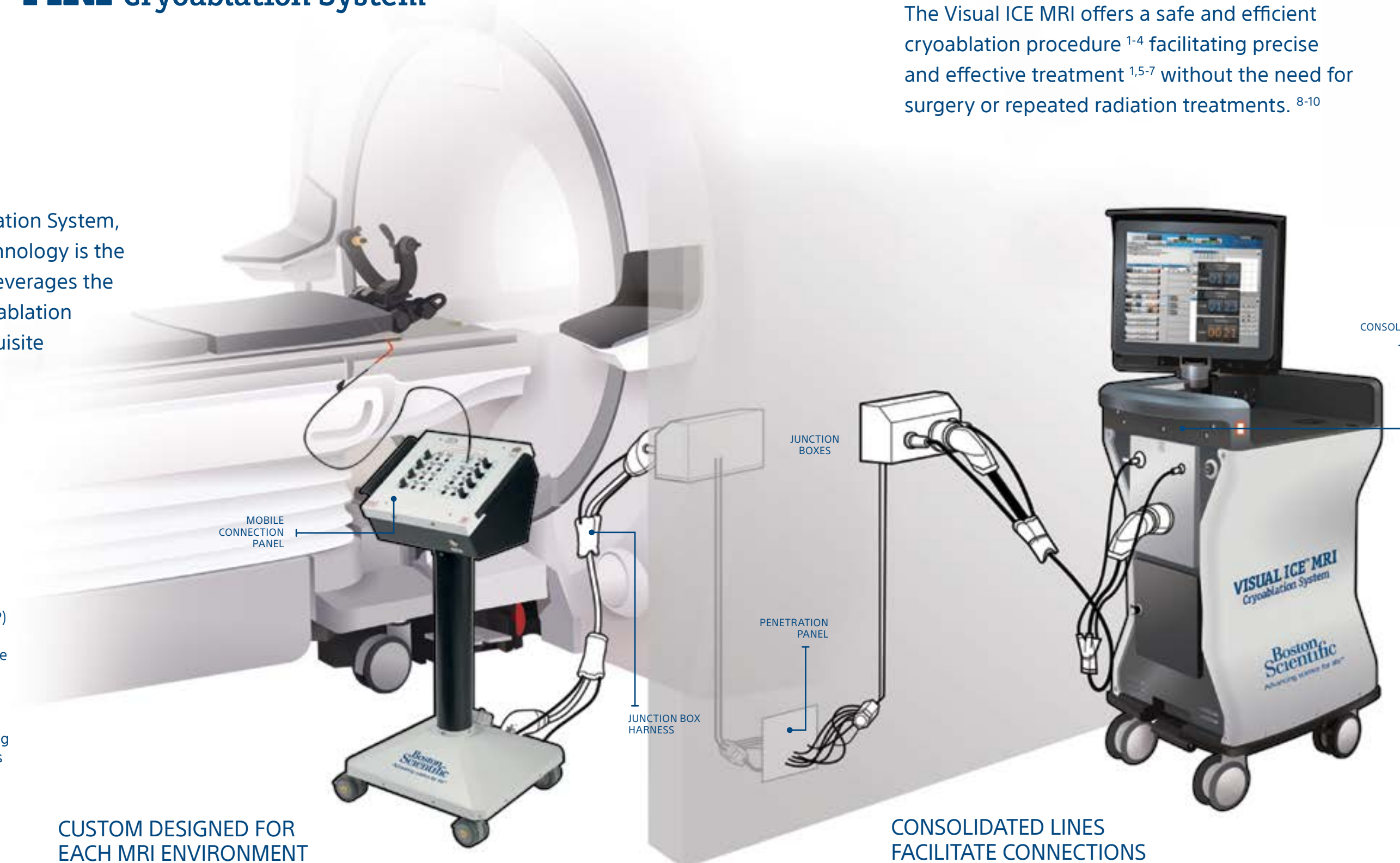
The Visual ICE MRI Cryoablation System, developed with Galil™ Technology is the only ablation system that leverages the unique advantages of cryoablation zone visibility with the exquisite image resolution of MR.

SPECIALIZED FOR THE MAGNET ROOM

- The Mobile Connection Panel (MCP) is placed within the MR room, allowing for easy access to both the patient and the needles during a procedure.
- Sixteen needles may be simultaneously connected, allowing a range of cryoablation procedures

CUSTOM DESIGNED FOR EACH MRI ENVIRONMENT

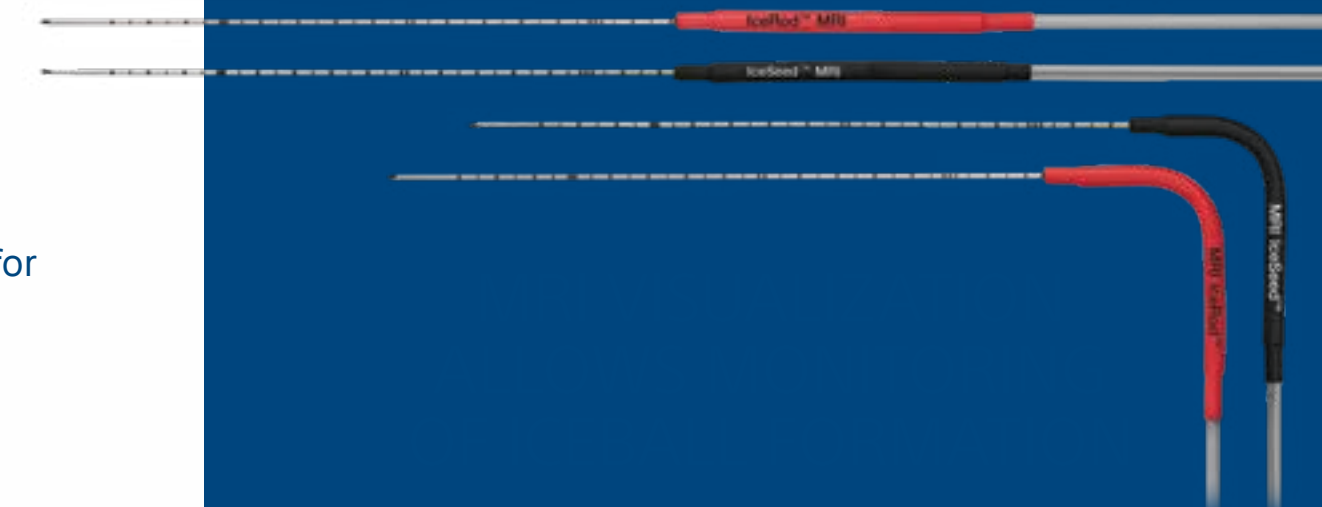
- Each system design accommodates customer and site requirements
- Integrated into MR rooms with minimal installation and minimal downtime



The Visual ICE MRI offers a safe and efficient cryoablation procedure¹⁻⁴ facilitating precise and effective treatment^{1,5-7} without the need for surgery or repeated radiation treatments.⁸⁻¹⁰

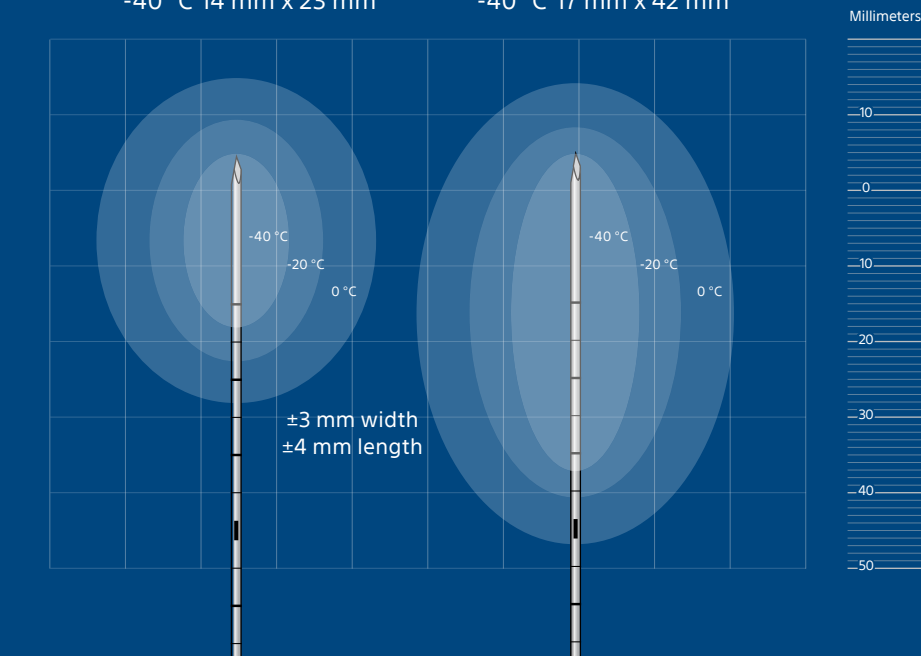
CONSOLIDATED LINES FACILITATE CONNECTIONS

- The Junction Box Harness organizes gas, fiber optic, and electrical lines into a single cable.
- Connectors are easily aligned and securely clicked into position



IceSeed™ 1.5 MRI
 0 °C 37 mm x 43 mm
 -20 °C 23 mm x 32 mm
 -40 °C 14 mm x 23 mm

IceRod™ 1.5 MRI
 0 °C 42 mm x 61 mm
 -20 °C 28 mm x 49 mm
 -40 °C 17 mm x 42 mm



- 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
- Data was collected in the 21° room temperature gel; in-vivo dimensions are typically smaller than the dimensions generated in room temperature laboratory conditions
- 0° ice (the visible edge of the iceball) is not lethal
- An iceball must extend 5-10 mm beyond the tumor margin for appropriate coverage
- Use multiple needles to fully cover a target site and to provide a suitable margin
- Space needles 0.5-1.0 cm; needles spaced too far apart risk areas of non-lethal ice

References:

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