



PROCEDURE SCREEN



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 Gallil 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



VISUAL ICE™ MRI Cryoablation System

INTUITIVE USER INTERFACE

ENHANCED MR VISUALIZATION

CONTROLLED ABLATION ZONE



Visual ICE™ MRI Cryoablation System Indications, Safety, and Warnings

<https://www.bostonscientific.com/visualicemri-indications>



Cryoablation Needle IceRod™, IceSeed™, IceSphere™ Indications, Safety, and Warnings

<https://www.bostonscientific.com/cryoneedles-indications>



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VISUAL ICE™ MRI Cryoablation System

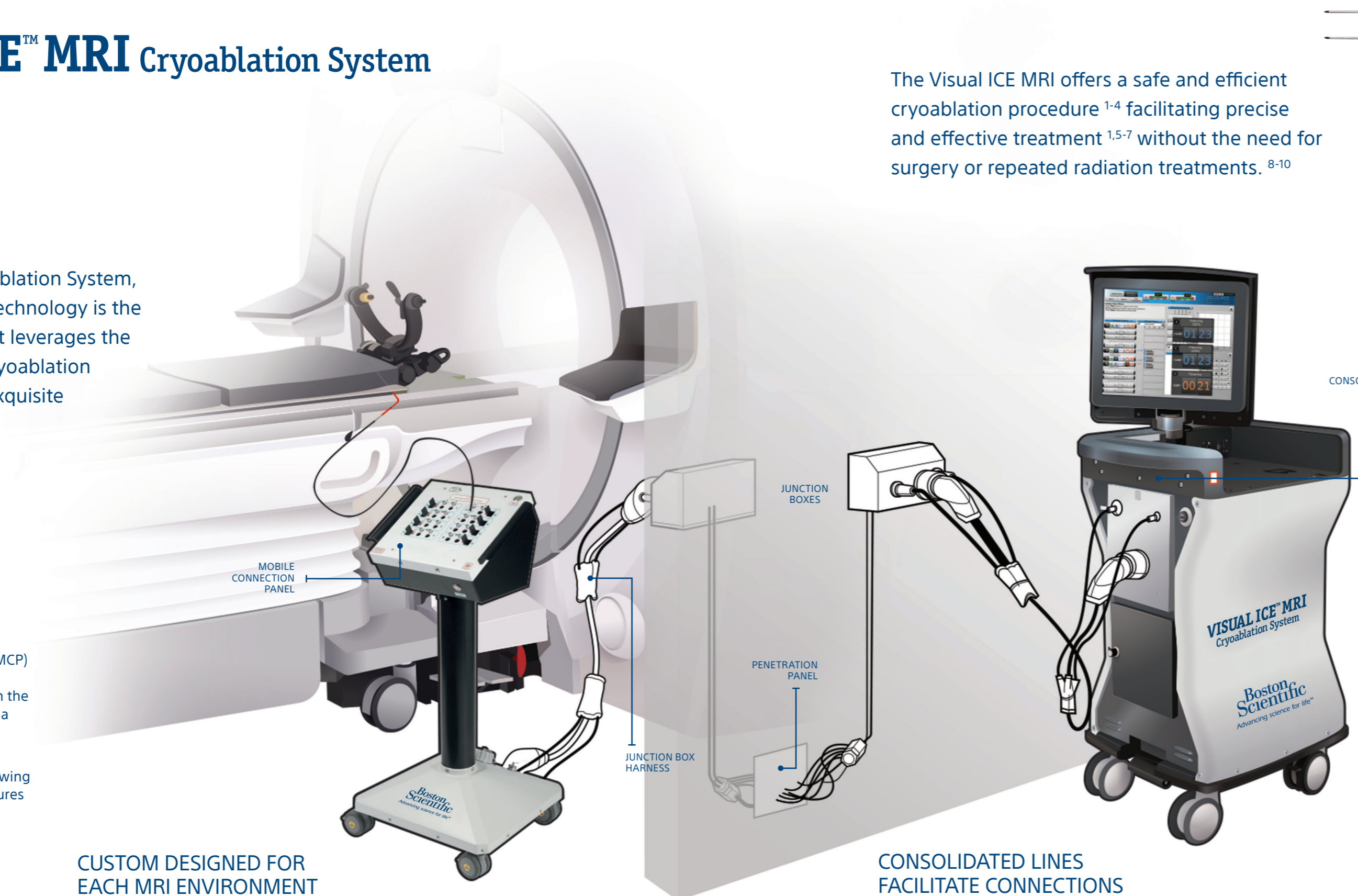
The Visual ICE MRI Cryoablation System, developed with Galil™ Technology is the only ablation system that leverages the unique advantages of cryoablation zone visibility with the exquisite image resolution of MR.

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

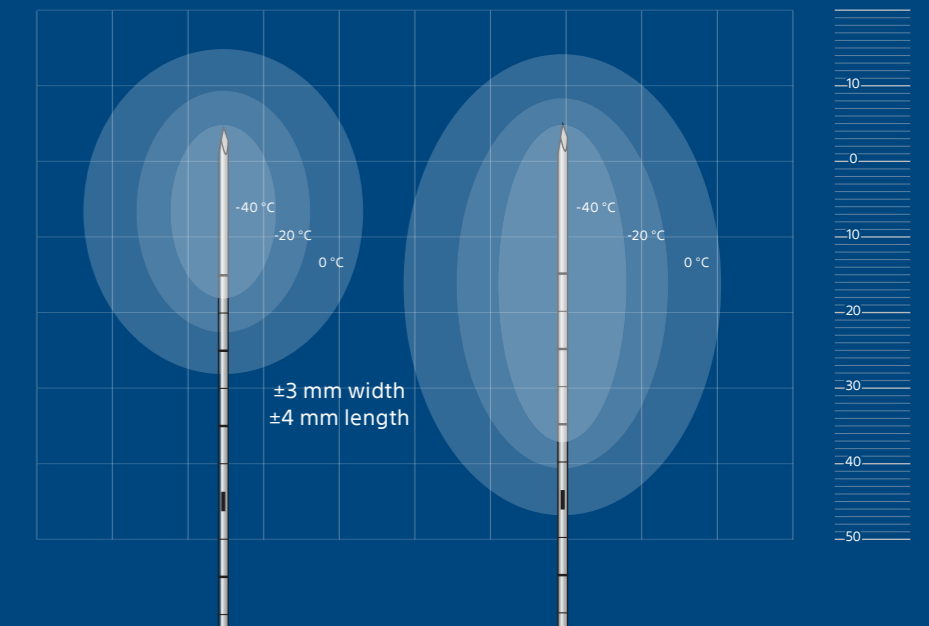
- Each system design accommodates customer and site requirements
- Integrated into MR rooms with minimal installation and minimal downtime



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

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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