INTUITIVE USER INTERFACE
ENHANCED MR VISUALIZATION
CONTROLLED ABLATION ZONE
The BTG 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 procedure facilitating precise and effective treatment without the need for surgery or repeated radiation treatments.

- The Junction Box Harness organizes gas, fiber optic, and electrical lines into a single cable.
- Connectors are easily aligned and securely clicked into position.
• 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 21º 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 5-10mm beyond the tumor margin for appropriate coverage
• Use multiple needles to fully cover a target site and to provide a suitable margin
• Space needles 0.5-1.0cm; needles spaced too far apart risk areas of non-lethal ice

References:
PROCEDURE SCREEN
ADJUSTABLE FREEZE INTENSITIES

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

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
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**MOBILE CONNECTION PANEL**

- **Closed Monitor Weight Capacity**: 20lbs
- **Monitor Storage Basin Weight Capacity**: 20lbs
- **Storage Compartment Weight Capacity**: 50lbs

**MECHANICAL SPECIFICATIONS - PENETRATION PANEL**

- Note: about 24" of clearance is needed from the front of the panel to allow space for gas, electrical and fiber optic lines and connectors, packed in a protective case
- **Footprint**: 10in x 5in, protruding 4in out of the wall

**MECHANICAL SPECIFICATIONS - JUNCTION BOX**

- **Footprint**: 20x18in
- **Height**: 39in
- **Weight**: 45lbs

**PART NUMBER | MRI CRYOABLATION KITS | CONFIGURATION | NEEDLE SHAFT LENGTH | ACTIVE THAW**

| FPRPR3192 | IceSeed™ 1.5 MRI Cryoablation Needle | Straight | 175mm | Helium |
| FPRPR3194 | IceSeed™ 1.5 MRI 90° Cryoablation Needle | 90° | 175mm | Helium |
| FPRPR3193 | IceRod™ 1.5 MRI Cryoablation Needle | Straight | 175mm | Helium |
| FPRPR3195 | IceRod™ 1.5 MRI 90° Cryoablation Needle | 90° | 175mm | Helium |

**ORDERING INFORMATION**

**PART NUMBER | VISUAL-ICE™ MRI SYSTEM & ACCESSORIES | DESCRIPTION**

| FPRCH7000 | Visual-ICE™ MRI Cryoablation Console | A cryoablation console with built-in gas pressure regulators; two flexible gas supply lines (one argon, one helium) with pressure gauges; a console cover and a cable management system for gas, electrical and fiber optic lines and connectors, packed in a protective case |
| FPRCH7100 | Visual-ICE™ MRI Mobile Connection Panel | A Visual-ICE™ MRI remote Mobile Connection Panel to support MRI needle connections in a magnet room; a Mobile Connection Panel cover |
| FPRCH7050 | 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 (5m) | One Visual-ICE™ MRI Junction Box Harness (5m) containing gas, electrical and fiber optic lines and connectors, packed in a protective case |
| ASM7010 | Visual-ICE™ MRI Junction Box Harness (10m) | One Visual-ICE™ MRI Junction Box Harness (10m) containing gas, electrical and fiber optic lines and connectors, packed in a protective case |
| ASM7015 | Visual-ICE™ MRI Junction Box Harness (15m) | One Visual-ICE™ MRI Junction Box Harness (15m) containing gas, electrical and fiber optic lines and connectors, packed in a protective case |

**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 insure proper transport conditions are satisfied or contacts Galil Customer Service to obtain the appropriate shipping container

**MECHANICAL SPECIFICATIONS: CONSOLE**

- **Weight**: 170lbs
- **Height**: 42in, monitor down
- **Footprint**: 22x26in
- **Storage Compartment Weight Capacity**: 50lbs
- **Monitor Storage Basin Weight Capacity**: 20lbs
- **Closed Monitor Weight Capacity**: 30lbs

**MECHANICAL SPECIFICATIONS: MOBILE CONNECTION PANEL**

- **Weight**: 60lbs
- **Height**: 60in, monitor up
- **Footprint**: 20x18in

**MECHANICAL SPECIFICATIONS - JUNCTION BOX**

- **Wall footprint**: 10in x 5in, protruding 4in 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**: 8in x 6in minimum
- **Note**: about 12" of clearance is needed from the front of the Penetration Panel to allow space for gas, electrical and fiber optic connections

**EXTERNAL GAS SUPPLY**

- Argon Cylinder:
  - Purity Level: 99.998% or higher
  - Solid particle size: <5μm
- Helium Cylinder:
  - Purity Level: 99.995% or higher
  - Solid particle size: <5μm

**GAS CYLINDER SPECIFICATIONS**

- **Maximum Pressure**: 2000psi
- **Connector Valve**: CGA677

**ACCURACY OF DISPLAYED VALUES**

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

**ELECTRICAL SPECIFICATIONS**

- **Input Voltage**: 100 to 240 VAC, single phase
- **Input Frequency**: 50-60Hz
- **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

**CONTACT**

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**INDICATIONS FOR USE**

The Visual-ICE™ MRI Cryoablation Systems are intended for cryoablative destruction of tissue during surgical procedures; various Galil Medical ancillary products are required to perform these procedures. Visual-ICE™ MRI Cryoablation Systems are indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryosurgical, thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology and urology. These 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 Visual-ICE™ MRI Cryoablation System User Manual.

**CONTRAINDICATIONS**

There are no known contraindications.

**WARNINGS/PRECAUTIONS/ADVERSE EVENTS**

A thorough understanding of the technical principles, clinical applications, and risks associated with cryoablation procedures is necessary before using Galil Medical products to conduct cryoablation. Use of such products should be restricted to use by or under the supervision of physicians trained in cryoablation procedures with a Visual-ICE™ MRI Cryoablation System.

A full list of the warnings, precautions, and adverse events can be found by referencing the respective device instructions for use or the Visual-ICE™ MRI Cryoablation System User Manual. Rx only.

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