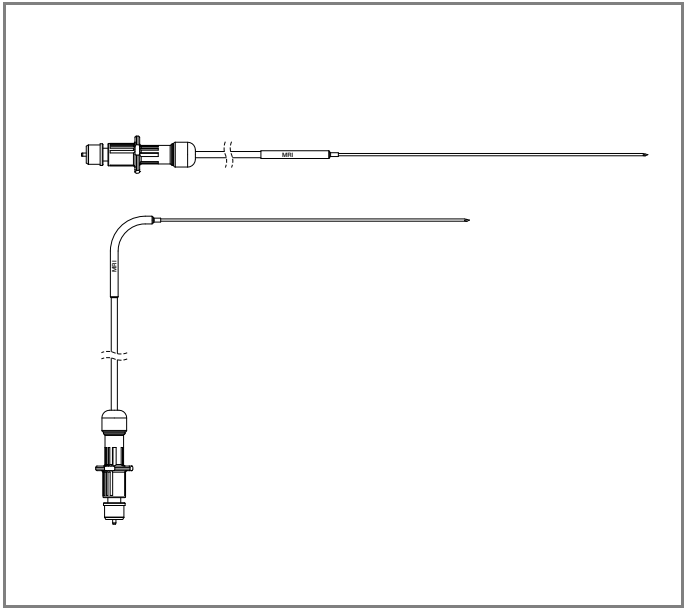
GALILMEDICAL

17G MRI CRYOABLATION NEEDLES

INSTRUCTIONS FOR USE



CE 0473

Rx only CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.	
CE Mark of Conformity	Do not reuse
Use by	LOT Batch code
Date of manufacture	STERILE EO Sterilization using ethylene oxide
REF Catalog number	Consult instructions for use
Manufacturer	EC REP Authorized representative in the European Community
Do not use if package is damaged	MR MR conditional
QTY Quantity	

This document provides instructions for use and recommended guidelines exclusively for the Galil Medical 17G MRI Cryoablation Needles.

This document is provided as an addendum to the *User Manual* supplied with each Galil Medical *Cryoablation System.* The system *User Manual* should be relied on for detailed information regarding the operation of Galil Medical's Cryoablation Systems and Cryoablation Needles.

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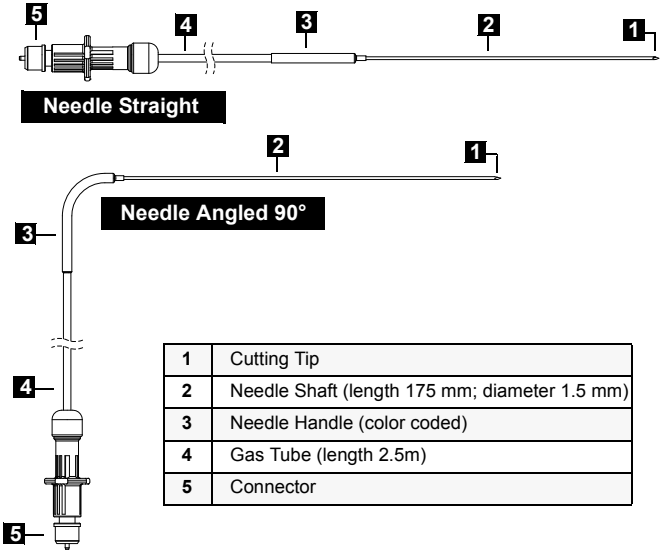
1 Product Description

1.1 Intended Use

The Galil Medical patented 17G MRI Cryoablation Needles are components used in conjunction with a Galil Medical Cryoablation System when performing cryogenic destruction of tissue and are intended to convert high-pressure gas to either a very cold *Freezing* application or to a warm *Thawing* application.

1.2 Technical Description

Each 17-gauge disposable MRI cryoablation needle (straight or angled 90°) has a sharp cutting tip, a shaft, a color-coded handle, a gas tube, and a connector. All components are illustrated in Fig 1; needle markings are shown in Fig 2.



1	Cutting Tip
2	Needle Shaft (length 175 mm; diameter 1.5 mm)
3	Needle Handle (color coded)
4	Gas Tube (length 2.5m)
5	Connector

Fig 1. 17G MRI Cryoablation Needle — Components

Needle markings begin 20 mm from the needle tip and include a thin mark every 5 mm, a thicker mark every 10 mm, a single heavy mark at 50 mm, a double-heavy mark at 100 mm, and a triple-heavy mark at 150 mm.

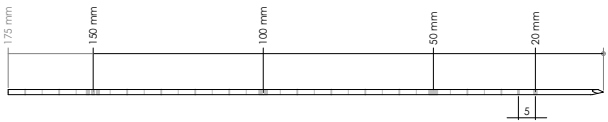


Fig 2. 17G MRI Cryoablation Needle Shaft Markings

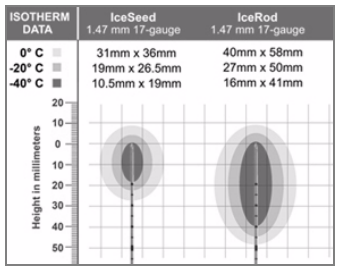
1.3 Galil Medical 17G MRI Cryoablation Needles

Cryoablation Needle Type		Handle Color
Straight	**Angled 90°**	
IceSeed ® MRI	IceSeed ® MRI	Black
IceRod ® MRI	IceRod ® MRI	Red

NOTE: Galil Medical's standard Cryoablation Needles are described in the Galil Medical 17G Cryoablation Needles *Instructions for Use*.

1.4 Needle Performance

The needle type determines the iceball dimensions. Iceball dimension measurements were made after two cycles of 10 min 100% *Freezing* separated by 5 min *Thawing* in gel at room temperature. Accuracy is ±2 mm width, ±3 mm length.



NOTE: For information regarding software-control of needle performance, refer to the appropriate cryoablation system *User Manual*.

1.5 Product Specifications

Materials	Needle Shaft	Stainless steel
	MRI Needle shaft	Nickel-Chromium superalloy
	Needle Handle	Brass (coated with heat shrink tubing)
	Gas Tube	Polyurethane
	Connector	Polyoxymethylene
Sterilization Method	Ethylene Oxide (EO)	

2 How Supplied

The 17G disposable MRI cryoablation needles are packaged in a sealed film-Tyvek® pouch. Each pouch is labeled Sterile, for SINGLE USE only.

NOTE: The Galil Medical Cryoablation System is supplied separately.

Needle connectors are protected by a rubber cap. This cap should be removed before connecting a needle to a cryoablation system.

- **Storage**

  Store in the original package in a cool, dry place.

- **Use By**

  Refer to expiration date marked on the external packaging.

3 Indications for Use

The Galil Medical Cryoablation Systems are intended for cryogenic destruction of tissue during surgical procedures; various Galil Medical ancillary products are required to perform these procedures. Galil Medical Cryoablation Systems are indicated for use as a cryosurgical tool in the fields of *general surgery*, *dermatology*, *neurology* (including cryoanalgesia), *thoracic surgery*, *ENT*, *gynecology*, *oncology*, *proctology* and *urology*. These Systems are designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors, skin lesions and warts) 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.

4 Contraindications

There are no known contraindications specific to use of the Galil Medical 17G MRI Cryoablation Needles.

5 Warnings

- Do not use this device for any purpose other than the stated intended use.
- A thorough understanding of the technical principles, clinical applications, and risk associated with cryoablation procedures is necessary before using this product. Use of this device should be restricted to use by or under the supervision of physicians trained in cryoablation procedures with a Galil Medical Cryoablation System.
- The Galil Medical 17G MRI Cryoablation Needle is a disposable product and is designed as a single-use product. This device has not been validated for resterilization or reprocessing. Potential anticipated risks associated with reprocessing of this product include, but are not limited to, inadequate sterilization thereby creating an increased risk of patient infections and increased risk of blood-borne pathogen disease transmission; degradation of performance due to material fatigue and pressure/gas leakage, thereby creating an increased risk of patient embolism and risk of under or over patient treatment.
- **BEFORE THE PATIENT IS ANESTHETIZED**, Integrity and Functionality Tests on the Cryoablation Needles and Thermal Sensors must be completed successfully.
- A defective cryoablation needle with a gas leak can cause a gas embolism in the patient. Such needle must never be used and should be returned to Galil Medical for inspection and replacement.
- In the rare event that a needle breaks while inserted in the tissue, act immediately to remove needle parts from the patient's body and report such event to Galil Medical.
- If a needle inadvertently strikes bone, do not start or continue the *Freezing* process.

6 Precautions

6.1 General

- The physician is solely responsible for all clinical use of the cryoablation needle and for any results obtained by use of the system. All clinical decisions prior to and throughout the cryoablation procedure shall be made by the physician based upon his/her professional opinion.
- Training on appropriate use of a Galil Medical Cryoablation System is required prior to conducting cryoablation with a Galil Medical System.

- Continuously monitor the cryoablation procedure using imaging guidance such as *direct visualization*, *ultrasound*, *Computer Tomography (CT)* or *Magnetic Resonance Imaging (MRI)*.
- Use Galil Medical's 17G MRI Single-Point Thermal Sensors (TS) to monitor attainment of the freeze / thaw temperatures for the intended treatment protocol.
- Cryoablation causes freezing of tissue. To limit this effect to only the target ablation area, the physician should determine the means to protect adjacent organs and structures. As an example, the skin surface can be protected by warm saline irrigation or other means as determined by the physician.
- Always ensure selection of desired needle *type* at the physician's discretion. To identify needle type, refer to the color coding and printed text on the handle.
- When performing MRI-guided cryoablation procedures, ensure selection of Galil Medical's MRI-conditional needles (MRI text on the needle handle; packaging is labeled MR conditional).
- Do not use standard cryoablation needles (labeled MR unsafe) near magnetic resonance imaging (MRI) equipment.

6.2 Handling and Sterilization

- Observe the expiration date of this product. Do not use past the listed expiration date.
- Before opening a needle pack, check the sterilization indicator in the external packaging.
- Each cryoablation needle is provided for one-time use only. The needle has not been tested for multiple use. Do not resterilize a cryoablation needle.
- Inspect the packaging for damage. Do not use a cryoablation needle if packaging appears opened or damaged, or the device is damaged; in the event of such occurrence, contact a Galil Medical representative to arrange return of the complete package with the product.
- Open the outer pouch carefully; aseptically remove each inner pouch and transfer to the sterile area.
- Before use, always inspect needles for damage, bending or kinking. A bent or damaged cryoablation needle must never be used.
- Do not attempt to bend a straight cryoablation needle.
- Before use, always perform the Needle Integrity and Functionality Test. Do not use a cryoablation needle that has failed to pass the Needle Integrity and Functionality Test.
- Cryoablation needles have sharp tips. Care should always be taken to ensure safe handling of needles, to eliminate the risk of injury or possible exposure to blood-borne pathogens.

6.3 During Use

- Use imaging guidance to monitor needle insertion, positioning and removal.
- Always ensure use of needles in a strictly sterile environment.
- Ensure all connections between the cryoablation system and the cryoablation needle are tight.
- Do not kink, pinch, cut or pull excessively on needle tubing. Damage to needle handle or tubing may cause the needle to become inoperable.
- During use, avoid damage to the needle from other surgical instruments.
- Avoid bending the needle shaft. Do not grasp needles with auxiliary instruments as this may cause damage to the needle shaft.
- Do not expose a cryoablation needle to organic solvents such as alcohol, which may damage the needle.
- Do not immerse the proximal handle or cable connectors in fluids, which may affect performance.

6.4 After Use

- After disconnecting needles from the cryoablation system, use strong scissors to cut each needle at the point where the plastic tubing meets the handle.
- Cryoablation needles have sharp tips. Care should always be taken to ensure safe disposal of needles. To eliminate the risk of injury or possible exposure to blood-borne pathogens, used needles should be disposed of in a biohazard container, in accordance with hospital and safety regulations.

7 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 cryotherapy 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, DVT, ecchymosis, edema/swelling, ejaculatory dysfunction, erectile dysfunction (organic impotence), fever, fistula, glomerular filtration rate elevation, hematoma, hematuria, hypertension, hypotension, hypothermia, idiosyncratic reaction, ileus, impotence, infection, injection site reaction, myocardial infarction, nausea, neuropathy, obstruction, pain, pelvic pain, pelvic vein thrombosis, penile tingling/numbness, perforation GU, perirenal fluid collection, pleural effusion, pneumothorax, probe site paresthesia, prolonged chest tube drainage, prolonged intubation, pulmonary embolism, pulmonary 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.

8 Directions for Use

8.1 Removal from Package

1. Remove the cryoablation needle from the package and place in a sterile work area.
2. Place the needle in its appropriate position in the 17G Cryoablation Needle Holder, according to the planned needle configuration (refer to Needle Testing Device *Instructions for Use*). Remove the connector cap, then connect the needle to the corresponding port on the cryoablation system manifold (needle connection panel).

   The needle is now ready for the Integrity and Functionality Test.

NOTE: For detailed instructions on connecting needles to the system manifold, and performing the *Needle Integrity and Functionality Test*, refer to the appropriate *Cryoablation System User Manual*.

8.2 Needle Handling, Insertion and Removal

Correct insertion of cryoablation needles into the target tissue is the responsibility of the physician.

NOTE: Needles have a sharp tip - usually no additional incision is required.

Always use two hands and support the needle mid-shaft with two fingers to eliminate the risk of bending. Do not insert the needle into tissue while holding the handle with one hand only.

Insertion depth may be estimated using the needle marking on the shaft. Use imaging guidance as necessary to guide needle insertion and placement.

Use imaging guidance to verify that the cryoablation needle is placed at the desired location prior to activating the needle. Thaw as necessary before removing needle.

NOTE: Galil Medical's ultra-thin MRI needles are specially designed with a cone-shaped tip to minimize bleeding. However, some bleeding may occur. In the event of bleeding, apply treatment in accordance with good clinical practice and hospital's treatment protocol. For example, following removal of needle, hold compression until hemostasis is achieved and if necessary place appropriate dressing on needle insertion site.

9 DISCLAIMER OF WARRANTY

Although reasonable care has been used in the design and manufacture of this product, Galil Medical has no control over conditions under which this product is used. GALIL MEDICAL, THEREFORE, DISCLAIMS ALL WARRANTIES WHETHER EXPRESSED OR IMPLIED, WRITTEN OR ORAL, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY OF FITNESS FOR A PARTICULAR PURPOSE. GALIL MEDICAL SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE ARISING FROM OR RELATED TO THE USE OF THIS DEVICE.

For assistance, contact:

www.galilmedical.com

USA: **Galil Medical Inc.**, 4364 Round Lake Road, Arden Hills, MN 55112, USA.
Telephone: +1 877 639 2796, Fax: +1 877 510 7757

Europe: **Galil Medical UK Ltd**., The Office Building, Suite 21, Gatwick Road, Manor Royal, Crawley, West Sussex RH10 9RZ, United Kingdom.
Telephone: +44 (0) 1 293 459848, Fax: +44 (0) 1 293 459840

Galil Medical (Israel) Ltd., Industrial Park, Tavor Building 1, Yokneam 20692, Israel.
Telephone: +972 (4) 9093200, Fax: +972 (4) 9591077

EC REP **Obelis s.a.**, Boulevard Général Wahis 53, 1030 Brussels, Belgium.
Telephone: +32 2 732 59 54, Fax: +32 2 732 60 03, E-mail: mail@obelis.net

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