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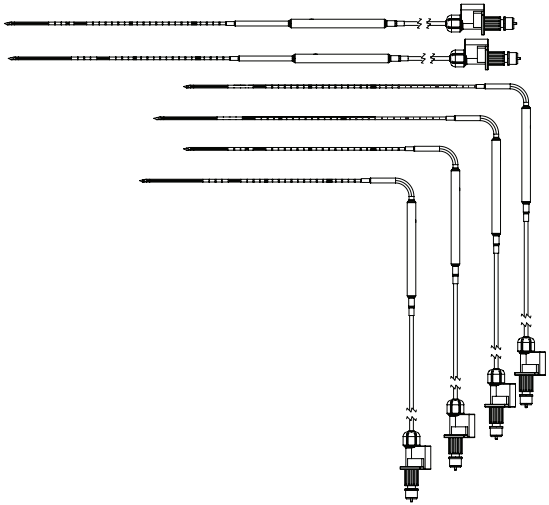
2.1 CX CRYOABLATION NEEDLES



EN INSTRUCTIONS FOR USE

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This document provides instructions for use and recommended guidelines exclusively for the Galil Medical 2.1 CX Cryoablation Needles.

This document is provided as an addendum to the *User Manual* supplied with each Galil Medical Visual-ICE™ Cryoablation System. The Visual-ICE System *User Manual* should be relied on for detailed information regarding the operation of the Galil Medical Visual-ICE™ Cryoablation System and 2.1 CX Cryoablation Needles.

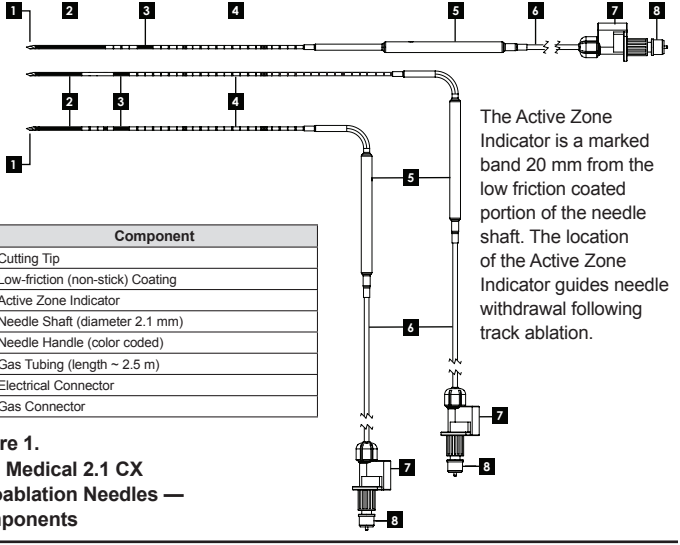
1 Product Description

1.1 Intended Use

The Medical patented 2.1 CX Cryoablation Needles are components used in conjunction with the Galil Medical Visual-ICE™ Cryoablation System when performing cryoablative tissue destruction through application of extremely cold temperatures. The needles are intended to convert high-pressure gas to either a very cold *Freezing* application or to a warm *Thawing* application.

1.2 Technical Description

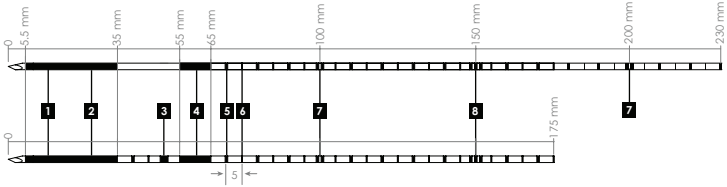
Disposable 2.1 mm Galil Medical 2.1 CX Cryoablation Needles (straight or angled 90°) have a sharp cutting tip, a shaft with distal coating, a color-coded handle, gas tubing, and a connector. All components are illustrated in Fig 1; needle marks and coating are shown in Fig 2.



#	Component
1	Cutting Tip
2	Low-friction (non-stick) Coating
3	Active Zone Indicator
4	Needle Shaft (diameter 2.1 mm)
5	Needle Handle (color coded)
6	Gas Tubing (length ~ 2.5 m)
7	Electrical Connector
8	Gas Connector

Figure 1.
Galil Medical 2.1 CX Cryoablation Needles — Components

IcePearl 2.1 CX and IcePearl 2.1 CX L Needle Shafts



IceFORCE 2.1 CX and IceFORCE 2.1 CX L Needle Shafts

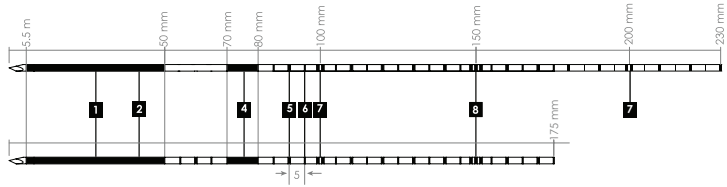


Figure 2. Galil Medical 2.1 CX Cryoablation Needles — Needle Shaft Features

#	Features	Description
1	Heating Portion	Located within the distal needle shaft below the coated area
2	Low-friction Coating	Starts 5.5 mm from tip; ends 35 mm from IcePearl 2.1 CX tip
		Starts 5.5 mm from tip; ends 50 mm from IceFORCE 2.1 CX tip
3	Single-thick Mark	Located 50 mm from tip (IcePearl 2.1 CX only)
4	Active Zone Indicator	Starts 55 mm from IcePearl 2.1 CX tip; 10 mm band
		Starts 70 mm from IceFORCE 2.1 CX tip; 10 mm band
5	Thick Marks	Starts 40 mm from IcePearl 2.1 CX tip, in 10 mm intervals Starts 70 mm from IcePearl 2.1 CX L tip, in 10 mm intervals
		Starts 60 mm from IceFORCE 2.1 CX tip, in 10 mm intervals Starts 90 mm from IceFORCE 2.1 CX L tip, in 10 mm intervals
6	Thin Marks	Starts 45 mm from IcePearl 2.1 CX tip, in 10 mm intervals Starts 75 mm from IcePearl 2.1 CX L tip, in 10 mm intervals
		Start 55 mm from IceFORCE 2.1 CX tip, in 10 mm intervals Start 85 mm from IceFORCE 2.1 CX L tip, in 10 mm intervals
7	Double-thick Mark	Located 100 mm from tip for all 2.1 CX needles and Located 200 mm from tip for IcePearl 2.1 CX L and IceFORCE 2.1 CX L
8	Triple-thick Mark	Located 150 mm from tip

1.3 Galil Medical 2.1 CX Cryoablation Needles

Table 1. Needle Configurations

Needle Brand Name	Configuration	Needle Shaft Length	REF	Handle Color
IcePearl™ 2.1 CX	Straight	175 mm	FPRPR3603	White
IcePearl™ 2.1 CX	Angled 90°	175 mm	FPRPR3601	White
IcePearl™ 2.1 CX L	Angled 90°	230 mm	FPRPR3617	White
IceFORCE™ 2.1 CX	Straight	175 mm	FPRPR3604	Gray
IceFORCE™ 2.1 CX	Angled 90°	175 mm	FPRPR3602	Gray
IceFORCE™ 2.1 CX L	Angled 90°	230 mm	FPRPR3618	Gray

1.4 Needle Performance - Cryoablation

In vivo iceball dimensions and resulting ablation zone are determined by the selected cryoablation needle, number of needles placed, tissue and tumor characteristics, thermal heat sink from surrounding vasculature, and treatment duration. Monitoring iceball formation provides direct control throughout the procedure and is key to cryoablation success.

NOTE: Using ultrasound or CT visualization, monitor iceball formation throughout the cryoablation procedure.

1.4.1 Laboratory Testing

Iceball shapes and dimensions are specific to the needle brand. The following laboratory models of iceball dimensions are provided to assist users in selecting the cryoablation needle(s) and needle placement to appropriately ablate the target area. Typically, in vivo dimensions are smaller than the dimensions generated in the laboratory.

Laboratory testing was performed in room temperature gel; measurements were made after two 10-minute Freeze cycles separated by a 5-minute passive *Thaw* cycle. Accuracy is ± 3 mm width, ± 4 mm length.

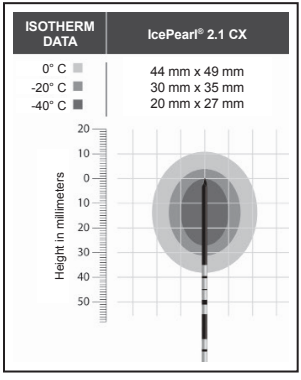


Figure 3.
IcePearl 2.1 CX Isotherm Data

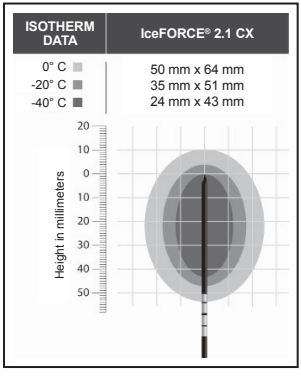


Figure 4.
IceFORCE 2.1 CX Isotherm Data

1.4.2 Porcine Testing

An in-vivo study was conducted in the porcine model to characterize the performance of the IcePearl 2.1 CX L and IceFORCE 2.1 CX L cryoablation needles in lung tissue. The ablation zones produced by these needles were demarcated by histopathology and the dimensions of the ablated tissue were measured. The measurements were taken at the largest point of the ablated volume. The largest diameter of the ablated zone of lung tissue was measured to be 28 mm for the IcePearl 2.1 CX L needle and 34 mm for the IceFORCE 2.1 CX L needle. These results are consistent with laboratory measurements in ice balls produced by these needles in gel.

The study concluded that the IcePearl 2.1 CX L and the IceFORCE 2.1 CX L needles are appropriate for use in cryoablation therapy in lung tissue.

1.5 Needle Performance - Active *Thaw*

The Galil Medical 2.1 CX Cryoablation Needles support active thawing using helium, or active thawing without helium using an i-Thaw™ internal heater. In addition, the i-Thaw heater can be activated to conduct the optional *FastThaw*. The *FastThaw* function generates a temperature that is higher than that required for i-Thaw, resulting in a faster thaw time.

1.5.1 Laboratory Testing

Laboratory testing was performed in 37°C gel to evaluate the thawing performance of Galil Medical 2.1 CX Needles and provide users with comparative thawing characteristics. A single 10-minute Freeze cycle was conducted to create an iceball on each test needle.

Activation of Galil Medical 2.1 CX Needles *FastThaw* for a five minute thaw results in iceball thawing approximately 18% faster than Galil Medical 2.1 CX Needles operated in i-Thaw mode for five minutes.

NOTE: *In vivo* thawing performance will be determined by numerous factors, including brand (type) and number of cryoablation needles used, needle location, tissue characteristics, and duration of *Thaw* activation.

1.6 Needle Performance - *Track Ablation*

When Galil Medical 2.1 CX Cryoablation Needles are connected to a Galil Medical Visual-ICE Cryoablation System, activation of *track ablation* is an option. During *track ablation*, the needle heats to an internal temperature of over 220°C, transferring heat along a 13 mm segment of the distal shaft of the IcePearl 2.1 CX needle and a 29 mm segment of the distal shaft of the IceFORCE 2.1 CX needle.

1.6.1 Porcine Testing

An *in vivo* study was conducted in porcine liver tissue to evaluate *track ablation* performance of the IcePearl 2.1 CX needle and the IceFORCE 2.1 CX needles and to measure the depth of tissue necrosis. *Track ablation* was performed in the porcine tissue. Histological assessment demonstrated a fairly uniform zone of tissue necrosis surrounding the path of *track ablation*. The average width of the zone of histologically-confirmed tissue damage, measured from the edge of the needle track to the normal tissue interface is described below.

Product Name	**Track Ablation** *(30 seconds)*	**Track Ablation** *(3 minutes)*
IcePearl 2.1 CX IcePearl 2.1 CX L	~2.1 mm ± 0.6 mm	~2.1 mm ± 0.6 mm
IceFORCE 2.1 CX IceFORCE 2.1 CX L	~2.5 mm ± 0.4 mm	~2.5 mm ± 0.4 mm

1.7 Product Specifications

Disposable 2.1 CX Cryoablation Needles are individually packaged in sealed film-Tyvek® pouch. Each pouch is labeled Sterile, for SINGLE USE only.

Materials	Needle Shaft	Stainless steel
	Low-friction Shaft Coating	Teflon® type fluoropolymer
	Needle Handle	Brass (coated with heat shrink tubing)
	Gas Tubing	Polyurethane
	Connector	Polyoxymethylene
Sterliization Method	Ethylene Oxide (EO)	

℞ only

CE CE Mark of Conformity	 1 Do not reuse
 1 Use by	LOT 1 Batch code
 1 Date of manufacture	STERILE EO 1 Sterilization using ethylene oxide
REF 1 Catalog number	 1 Consult instructions for use
 1 Do not use if package is damaged	EC REP 1
 1 Manufacturer	 2 MR unsafe
QTY Quantity	

Footnotes

1. EN ISO 15223-1:2012 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
2. ASTM F 2503 – 13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

2 How Supplied

Disposable Galil Medical 2.1 CX Cryoablation Needles are packaged in a sealed film Tyvek® pouch. Each pouch is labeled Sterile, for SINGLE USE only.

NOTE: The Galil Medical Visual-ICE 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

Galil Medical 2.1 CX Cryoablation Needles are intended for cryoablative destruction of tissue during surgical procedures. The Galil Medical 2.1 CX Cryoablation Needles, used with the Visual-ICE 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.

The Visual-ICE 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. Contact Galil Medical for information on other specific indications for use.

4 Contraindications

There are no known contraindications specific to use of the Galil Medical 2.1 CX 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 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 with a Visual-ICE Cryoablation System.
- Galil Medical 2.1 CX Cryoablation Needles are disposable products and are designed for a single-use. These devices have not been validated for resterilization or reprocessing. Potential anticipated risks associated with reprocessing of 2.1 CX Needles 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 the shaft insulation with subsequent change in thermal properties; degradation of performance due to material fatigue resulting in pressure leakage, thereby creating a risk of under or over patient treatment; and degradation of performance due to gas leakage, thereby creating an increased risk of patient embolism.
- Each needle must be locked into a needle channel before initiating a cryoablation procedure.
- **BEFORE THE PATIENT IS ANESTHETIZED,** Needle Integrity and Functionality Tests on each cryoablation needle and thermal sensor 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 evaluation.
- Galil Medical 2.1 CX Needles are designed and indicated for *Freezing* and *Thawing* applications. These needles are not designed, indicated or tested for thermal protection. Serious injury to patient tissue may result if used for thermal protection.
- 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.
- When using a Galil Medical 2.1 CX Needle for *ActiveThaw*, *FastThaw* or *track ablation* the needle is extremely hot and requires careful use.
- Discontinue all needle operation prior to needle removal to minimize risk of tissue injury.
- Remove needles from the patient prior to disconnecting needles from the Visual-ICE Cryoablation System.

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 Visual-ICE Cryoablation System is required prior to conducting cryoablation with this system.
- Confirm availability of sufficient gas (argon/helium) to conduct the planned procedure: the number of needles, needle operations activated, gas cylinder size, pressure and gas flow affect the required gas volume. The following table is provided to assist in estimation of argon requirements for a procedure.

Cryoablation Procedure Example

Argon Cylinder Size	Gas Pressure	IceFORCE 2.1 CX Needles per Cylinder*	IcePearl 2.1 CX Needles per Cylinder*
42 L (US and Asia)	6000 psi	9	7
50 L (Europe)	4350 psi/300 bar	3	3

* Galil Medical 2.1 CX Needles operated for two 10-min Freeze cycles (100% intensity) and two 30-sec *track ablation* cycles

- Use of multiple needles is recommended to fully cover a target site and provide a suitable margin.

- Multiple needles placed in an adjacent configuration will typically create a large, coalesced iceball. Iceball formation must be monitored using image guidance to optimize a successful ablation procedure.
- Continuously monitor the cryoablation procedure using direct visualization or image guidance such as ultrasound or Computed Tomography (CT).
- Use Galil Medical's 1.5 mm Multi-Point Thermal Sensor™ (MTS) to monitor attainment of the freeze / thaw temperatures for the intended treatment protocol or to monitor tissue temperature near critical structures.
- 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.
- Needle tubing may become extremely cold when conducting freeze cycles during a cryoablation procedure. It is important that a patient's skin is protected from direct contact with needle tubing to avoid the potential for thermal injury to the patient. When preparing to conduct a cryoablation procedure, position the cryoablation system in a manner to avoid draping the tubing across the patient. Ensure an appropriate insulating barrier is placed as needed (such as towels) or other method is employed to prevent needle tubing from touching a patient's skin.
- If the Visual-ICE Cryoablation System contains pressurized helium, *track ablation* and *FastThaw* cannot be activated.
- Select Galil Medical Cryoablation eedles appropriate for the application and tumor size. The iceball shape and size for Galil Medical 2.1 CX Needles are described in Section 1.4.1 of this document, or in the respective needle Instructions for Use, Needle Performance section for other Galil Medical Cryoablation Needles.
- Galil Medical 2.1 CX Needles operate only with the Visual-ICE Cryoablation System.
- Availability of a back-up needle is recommended should a replacement or additional needle be required during a procedure.
- Do not use Galil Medical 2.1 CX Needles (labeled MR unsafe) near magnetic resonance imaging (MRI) equipment.
- Ensure appropriate stability of needle tubing to avoid inadvertent snagging of tubing and/or needle shifting during a procedure.

- Use special care if placing a cryoablation needle near an implanted device.
- No data regarding cryoablation in combination with other therapies is available from Galil Medical.
- Use care in handling needle packages during transport and storage.
- Avoid extremes in temperature and humidity during transport and storage.

6.2 Handling and Sterilization

- Observe the expiration date of this product. Do not use past the listed expiration date.
- Before opening a needle pouch, check the sterilization indicator within the pouch.
- 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 the 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 bend a cryoablation needle.
- Following insertion of each needle into a needle connection panel port, lock each needle channel by engaging the locking bar.
- 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. Use care to ensure safe handling of needles to eliminate the risk of injury or possible exposure to blood-borne pathogens.

6.3 During Use

- Always ensure use of needles in a strictly sterile environment.
- Select and insert sufficient needles to ablate the target site.
- Ensure all connections between the cryoablation system and the cryoablation needle are tight.
- Use image guidance to monitor needle insertion, iceball formation, needle positioning and removal.
- Use image guidance to monitor adequate coverage of target tissue and to carefully monitor margins between ablation zone and critical adjacent structures.
- 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 or needle coating from handling or inappropriate contact with surgical instruments.
- The needle handle becomes cold during cryoablation. If the handle is in contact with skin, the skin surface should be protected by warm saline irrigation or other means as determined by the physician.
- Needle tubing becomes extremely cold when conducting cryoablation. Avoid allowing needle tubing to be in direct contact with a patient's skin. Place an appropriate insulating barrier (such as towels) or employ other methods to prevent needle tubing from touching a patient's skin.

  CAUTION: Avoid needle contact that could scrape the needle coating.
- Avoid bending the needle shaft. Do not grasp needles with auxiliary instruments as this may cause damage to the needle shaft.
- During a cryoablation procedure, do not immerse the proximal handle or gas tubing in fluids.
- Active *Thawing* produces heat along the distal needle shaft. Use care to avoid thermal injury to non-targeted tissues.
- Ensure adequate *Thawing* before attempting to remove needles.
- When conducting *track ablation*, be alert for the Active Zone Indicator as the needle is withdrawn to prevent unintended tissue damage from a hot needle.

• Do not expose a cryoablation needle to organic solvents such as alcohol which may damage the needle.

6.4 After Use

• After disconnecting needles from the cryoablation system, use strong scissors to cut each needle at the point where the gas tubing meets the handle.

• Cryoablation needles have sharp tips. Use care to ensure safe disposal of needles. To eliminate the risk of injury or possible exposure to blood-borne pathogens, dispose of used needles 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 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, leeding/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, 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

NOTE: Galil Medical 2.1 CX Cryoablation Needles are designed for use only with the Visual-ICE Cryoablation System. For information regarding software-control of needle performance, refer to the Visual-ICE Cryoablation System *User Manual*.

8.1 Needle Preparation

1. Using aseptic technique, carefully remove the cryoablation needle from the package and place in a sterile work area.
2. Prepare a large basin (at least 30 cm in diameter) containing sterile water or saline to conduct the needle testing.

CAUTION: Take care to maintain sterility of each needle during testing.

- Secure the needle tubing to the sterile table prior to beginning the needle testing process.
- Fill the basin halfway with sterile water or saline.
- Place the needles, individually or in groups, in the basin such that the full length of the needle is submerged in the sterile water or saline.

3. Remove the connector cap, then connect the needle to the selected port on the cryoablation system needle connection panel.

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

NOTE: For detailed instructions on connecting needles to the system's Needle Connection Panel and performing the Needle Integrity and Functionality Test, refer to the Visual-ICE Cryoablation System *User Manual*.**8.2 Needle Use**

8.2.1 Needle Handling and Insertion

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

NOTE: Although the needle has a sharp tip, a small skin incision may be made at the point of needle insertion.

- 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 marks on the shaft. Use image guidance to guide needle insertion and placement.
- Use image guidance as necessary to verify that the cryoablation needle is placed at the desired location prior to activating the needle.

CAUTION:

After needle insertion, route the needle tubing in a manner that ensures it is not in contact with the patient's skin.

Place an appropriate insulating barrier (such as towels) or employ other methods to prevent needle tubing from touching a patient's skin.

- The needle handle becomes cold during cryoablation. If the handle is in contact with skin, the skin surface should be protected by warm saline irrigation or other means as determined by the physician.

8.2.2 Notes for Conducting *Freezing*

- Select Freeze intensity and initiate *Freezing*.
- Continue Freeze cycle for duration and intensity necessary to optimize cryoablation of the target site.

NOTE: See the Visual-ICE Cryoablation System *User Manual* for instructions on system controls available to manage each Freeze cycle.

CAUTION:

- Continuously monitor iceball formation using direct visualization or image guidance such as Ultrasound or Computed Tomography (CT) to ensure adequate tissue coverage and to avoid damage to adjacent structures.
- A portion of the handle will remain frost-free to facilitate intraprocedural handling.
- Pay attention to needle handle position. Prolonged contact with frosted portions of the needle handle could cause unintended thermal tissue damage to the patient or clinician.

• Avoid allowing needle tubing to be in direct contact with a patient's skin. Direct contact with needle tubing could cause unintended thermal damage to the patient's skin. Place an appropriate insulating barrier (such as towels) or employ other methods to prevent needle tubing from touching a patient's skin.

8.2.3 Notes for Conducting *Active Thawing*

• To enable i-Thaw or *FastThaw* operation, only argon gas must be connected to the Visual-ICE Cryoablation System. If helium is connected, i-Thaw and *FastThaw* operations are disabled; helium is then used for active *Thawing*.

NOTE: See the Visual-ICE Cryoablation System *User Manual* for instructions on system controls available for i-Thaw and *FastThaw* options.

CAUTION:

• The distal portion of the needle handle may become warm during thawing.

• Pay attention to needle handle position. Prolonged contact with warm portions of the needle handle could cause unintended thermal tissue damage to the patient or clinician.

• *Thaw* thoroughly and stop all needle operation prior to removing needles to minimize the risk of tissue injury.

• If needle sticking is experienced, use a slight, gentle twist of the needle followed by slow withdrawal.

8.2.4 Notes for Performing *Track Ablation*

• *Track ablation* can be activated at any time during a cryoablation procedure.

• Hold the needle in a stationary position during *track ablation*.

• *Track ablation* may be repeated as required. Prior to each reactivation, slowly withdraw per the table below, then activate *track ablation*.

Product Name	Withdrawal Distance
IcePearl 2.1 CX IcePearl 2.1 CX L	10 mm
IceFORCE 2.1 CX IceFORCE 2.1 CX L	25 mm

• For detailed instructions on using and controlling the *track ablation* option, refer to the Visual-ICE Cryoablation System *User Manual*.

CAUTION:

- Ensure the Active Zone Indicator is not positioned outside the patient's skin when *track ablation* is activated.
- Pay attention to needle position to avoid thermal injury to adjacent tissue/organs.
- The distal portion of the needle handle may become warm during *track ablation*.
- Pay attention to needle handle position. Prolonged contact with warm portions of the needle handle could cause unintended thermal tissue damage to the patient or clinician.

8.3 Needle Removal

If *track ablation* is performed:

- Do not remove the needle until needle cooling is complete.
- If needle sticking is experienced, use a slight, gentle twist of the needle followed by slow withdrawal.

If *track ablation* is not performed:

- *Thaw* thoroughly and stop all needle operation prior to removing needles to minimize the risk of tissue injury.

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

CAUTION:

Removing the needle while it is still hot presents a risk of injury to adjacent tissue and/or organs.

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 OR 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.

IcePearl® 2.1 CX Cryoablation Needle – REF FPRPR3603
IcePearl® 2.1 CX 90°Cryoablation Needle – REF FPRPR3601
IcePearl® 2.1 CX L 90°Cryoablation Needle – REF FPRPR3617
IceFORCE® 2.1 CX Cryoablation Needle – REF FPRPR3604
IceFORCE® 2.1 CX 90°Cryoablation Needle – REF FPRPR3602
IceFORCE® 2.1 CX L 90°Cryoablation Needle – REF FPRPR3618

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