This document provides instructions for use and recommended guidelines exclusively for the disposable Galil Medical Urethral Warming Set.

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

1 Product Description ................................................................. 1
   1.1 Intended Use ................................................................. 1
1.2 Technical Description ............................................................. 1
   1.2.1 Flexible Warmer Cassette ............................................. 1
   1.2.2 Urethral Warming Catheter with Warmer Tubing #1 and #2 ..... 2
   1.2.3 Warmer Tubing #3 .......................................................... 3
   1.3 Product Specifications ....................................................... 4

2 How Supplied ................................................................................. 5

3 Indications for Use ....................................................................... 5

4 Contraindications ........................................................................ 5

5 Warnings ...................................................................................... 5

6 Precautions ................................................................................... 6
   6.1 General .................................................................................. 6
   6.2 Handling and Sterilization ..................................................... 6
   6.3 During Use ............................................................................. 7
   6.4 After Use ............................................................................... 7

7 Potential Adverse Events ............................................................. 8

8 Directions for Use ......................................................................... 8
   8.1 Removal from Package ........................................................ 8
   8.2 Setting Up the Urethral Warmer System ............................... 8
   8.3 Performing the Urethral Warmer System
       Integrity and Functionality Test ........................................ 19

9 Removal of Urethral Warming Set Components After Use ........... 20

10 DISCLAIMER OF WARRANTY .................................................. 20
1 Product Description

1.1 Intended Use

The Galil Medical Urethral Warming Set, a disposable component used in conjunction with a Galil Medical Urethral Warmer System, is intended to warm urethral tissue when performing cryogenic destruction of prostatic tissue with a Galil Medical Cryoablation System. The Urethral Warmer System is designed to circulate a warm solution through a warming catheter to maintain urethral tissue near body temperatures while the surrounding prostate tissue is being frozen. The disposable Urethral Warming Set is not intended for use when performing minimally-invasive cryoablation procedures on organs other than the prostate.

1.2 Technical Description

The disposable Urethral Warming Set is a closed-circuit catheter and tubing system through which sterile saline - warmed by flow through a warmer cassette - is circulated. The disposable set comprises three separate sterile packs:

- **Flexible Warmer Cassette** (Fig 1)
- **Urethral Warming Catheter** with **Warmer Tubing #1 and #2** (Fig 2)
- **Warmer Tubing #3** (Fig 3)

Clamps, luer-lock connectors and a flow indicator accompany tubing components.

When the warmer cassette has been inserted into the fluid warming device, the tubing components assembled, the tubing inserted into a peristaltic pump system, and the Urethral Warmer System activated, warm saline can be circulated through the closed-loop system.

**NOTE:** For detailed information regarding the Urethral Warmer System, refer to the Instructions for Use supplied with the system.

1.2.1 Flexible Warmer Cassette (Fig 1)

**NOTE:** The numbers in square brackets correspond to the components labelled in Fig 1.

The Flexible Warmer Cassette [1] is a soft, rectangular-shaped plastic cassette encased within a rigid plastic framework. Two lengths of plastic tubing [2] are integrated into the cassette at one end, each of which has a plastic tubing clamp [3] at the other end. The blue alignment marker [4] and rigid guide rail [5] facilitate correct insertion of the Flexible Warmer Cassette into the fluid warming device (illustrated in Fig 5). The drip chamber [6] connected to the upper tubing is to be discarded; it is not used with the Urethral Warming Set.
NOTE: The drip chamber is not required for use with the Urethral Warmer System and is discarded (as shown in Fig 4).

### 1.2.2 Urethral Warming Catheter with Warmer Tubing #1 and #2 (Fig 2)

**NOTE:** The numbers in square brackets correspond to the components labelled in Fig 2. The Catheter/Tubing pack contains the Urethral Warming Catheter [1], Warmer Tubing #1 [2] and Warmer Tubing #2 [3]. In addition, an integrated flow indicator [4], and a clamp [5] surrounding a tubing segment, are included.

The Urethral Warming Catheter is designed to be inserted into the urethra prior to initiation of prostatic tissue freezing and to remain *in situ* throughout the procedure.
The Urethral Warming Catheter, which forms part of the closed-circuit warming system, transfers warmth from the circulating saline to the urethral tissue.

The catheter has a protective double sheath. When unfilled, the catheter gauge is 16 French (Fr); when filled with saline, the catheter expands to approximately 22Fr.

### 1.2.3 Warmer Tubing #3 (Fig 3)

**NOTE:** The numbers in square brackets correspond to the components labelled in Fig 3.

The Warmer Tubing #3 is used to connect the Flexible Warmer Cassette (inserted in the fluid warming device) and the IV bag of saline.

1.3 Product Specifications

<table>
<thead>
<tr>
<th>Materials</th>
<th>Flexible Warmer Cassette</th>
<th>Polyurethane and PVC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urethral Warming Catheter</td>
<td>Silicone and PVC</td>
<td></td>
</tr>
<tr>
<td>Warmer Tubing #1</td>
<td>Tygon® tubing</td>
<td></td>
</tr>
<tr>
<td>Warmer Tubing #2</td>
<td>PVC</td>
<td></td>
</tr>
<tr>
<td>Warmer Tubing #3</td>
<td>PVC</td>
<td></td>
</tr>
<tr>
<td>Flow indicator</td>
<td>Styrene butadiene copolymer</td>
<td></td>
</tr>
<tr>
<td>Tubing clamps</td>
<td>PVC</td>
<td></td>
</tr>
<tr>
<td>Connectors</td>
<td>Acrylic resin</td>
<td></td>
</tr>
</tbody>
</table>

Sterilization Method

Flexible Warmer Cassette: Gamma (R) radiation
All other components: Ethylene Oxide (EO)
2 How Supplied

The disposable Urethral Warming Set is supplied in three separate sterile packs, each pack containing one of the following:

- Flexible Warmer Cassette (illustrated in Fig 1)
- Urethral Warming Catheter with Warmer Tubing #1 and #2 (illustrated in Fig 2)
- Warmer Tubing #3 (illustrated in Fig 3)

**NOTE:** In addition to the Urethral Warming Set components, a 1-liter or 3-liter bag (hospital’s preference) of sterile saline (*Saline for Irrigation* is recommended) – with two connecting ports – is required. An ampule of sterile indigo carmine (or methylene blue) is recommended.

**• Storage**

Store components in original containers in a cool, dry place.

**NOTE:** The Galil Medical Urethral Warmer System (Fluid Warming device and Peristaltic Pump device) is supplied separately.

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3 Indications for Use

The Galil Medical Urethral Warming Set is a set of components intended for use only with a Galil Medical Cryoablation System. These Cryoablation Systems, designed to destroy tissue by the application of extremely cold temperatures, are indicated for use in numerous surgical fields, including *urology*. In the field of urology, the Galil Medical Cryoablation Systems are specifically indicated for ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia (BPH).

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4 Contraindications

There are no known contraindications for using the Galil Medical Urethral Warming Set.

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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.
• **BEFORE THE PATIENT IS ANESTHETIZED**, Integrity and Functionality Tests on the Cryoablation Needles, Thermal Sensors and Urethral Warming Set must be completed successfully.

• Excessive warming of the urethra could result in damage to the urethral and peri-urethral tissues. Always monitor the system temperature display to ensure temperatures do not exceed 43°C.

• The Galil Medical Urethral Warming Set 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 or saline leakage, creating an increased risk of urethral complications.

• Whenever operating Galil Medical Cryoablation Systems to perform cryoablation procedures on the prostate, the use of Galil Medical's Urethral Warmer System and Disposable Urethral Warming Set is strongly recommended. By transferring warmth to the urethral tissue during the procedure, the system serves to protect the urethra from tissue damage.

• The Fluid Warming device should be connected directly to the electrical wall outlet. The pre-set operating temperature of 43°C should not be changed.

• Insertion of a warming catheter into the urethra should be performed while the peristaltic pump of the Urethral Warming System is turned to 0.

• If there is a significant delay in the case, turn OFF power to the Fluid Warming device to prevent overheating.

### 6 Precautions

#### 6.1 General

• The disposable Urethral Warming Set is not intended for use when performing minimally-invasive cryoablation procedures on organs other than the prostate.

#### 6.2 Handling and Sterilization

• Observe the expiration date of this product. Do not use past the listed expiration date.

• Urethral Warming Set components are provided for one-time use only. The components have not been tested for multiple use. Do not resterilize the components by any means.

• Before opening a pack, check the sterilization indicator in the external packaging.
• Inspect the packaging for damage. Do not use a Urethral Warming Set component 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.

• Before use, always inspect the Urethral Warming Set components for damage, bending or kinking. A bent or damaged component must never be used.

• Care should always be taken to ensure safe handling and disposal of Urethral Warming Set components to eliminate the risk of injury or possible exposure to blood-borne pathogens.

• When using the Urethral Warmer System and Urethral Warming Set components, take care not to pinch, kink, or inadvertently cut any tubing.

• Before turning the Urethral Warmer System power ON, check to make sure all four tubing clamps are completely OPEN and do not impede the flow of fluid.

6.3 During Use

• Ensure all connections between the Urethral Warming Set components are tight.

• Do not kink, pinch, cut or pull excessively on tubing.

• When adjusting the pump flow rate, do not exceed a rate of 550ml/min (Speed 8).

• Check saline flow by confirming the flow indicator is spinning.

• Verify that the displayed temperature of the fluid warmer device does not exceed 43°C during operation.

6.4 After Use

• Following completion of the final Freeze cycle, the Urethral Warming Catheter should be left in situ with the Urethral Warmer System operational for at least 20 minutes (or for a time period at the discretion of the physician). If it is difficult to remove the catheter after the Freezing process, allow further time to ensure sufficient thawing before again attempting to remove the catheter.

• Failure to drain the warmer cassette will cause difficulty in removing it from the fluid warming device. Forcing the cassette out may cause it to rupture.

• Care should always be taken to ensure safe handling and disposal of Urethral Warming Set components. To eliminate the risk of injury or possible exposure to blood-borne pathogens, used items 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 Galil Medical Urethral Warming Set. 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

The disposable Urethral Warming Set components should be removed from their sterile packs and placed in a sterile work area, in the sequence described in Setting Up the Urethral Warmer System, below.

8.2 Setting Up the Urethral Warmer System

1. Hang the sterile saline bag on the IV pole ram hook.
2. Inject one ampule of sterile indigo carmine (or methylene blue) into the sterile irrigation solution bag (per physician’s preference).
3. Open the pack containing the Flexible Warmer Cassette (Fig 1).
   Disconnect the drip chamber from the Flexible Warmer Cassette and discard (together with attached tubing) (Fig 4).
4. Stretch the warmer cassette slightly then insert it into the opening on the front of the fluid warming device, pushing it all the way in while aligning the blue alignment marker on the cassette guide rail with the blue alignment dot marked on the warming device casing (Fig 5).

**NOTE:** When fully inserted, the guide rail should protrude no more than 0.5cm from the front of the fluid warming device. *Failure to fully insert the cassette may result in damage to the cassette.*

**IMPORTANT:** During set up of the Urethral Warming Set, all tubing clamps, including the clamps on the cassette tubing, should be CLOSED.

5. Open the sterile outer pack containing the Urethral Warming Catheter with Warmer Tubing #1 and #2 (refer to Fig 2). At this stage, do not remove the catheter from its own pack.

**NOTE:** Place the sterile catheter on a sterile table and secure it in such a way to maintain catheter sterility.
6. Remove the white plastic luer-lock cap from the end of the warmer cassette’s outermost tubing (closest to the guide rail) by turning the cap counter-clockwise as shown in Fig 6.

![Fig 6. Removing the Plastic Luer-Lock Cap](image)

7. Attach the male luer-lock connector of Tubing #2 to the female luer-lock connector of the warmer cassette’s outermost tubing (closest to the guide rail). When pushing the connectors together, turn the connector on Tubing #2 in a clockwise direction (Fig 7); ensure the two connections are locked tightly.

![Fig 7. Connecting Warmer Tubing #2 to the Warmer Cassette Lower Tubing](image)

NOTE: Reference catheter-to-cassette connection (Fig 9).

8. Open the sterile pack containing Warmer Tubing #3 (see Fig 3).

9. Attach the female luer-lock connector of Tubing #3 to the male luer-lock connector of the warmer cassette’s innermost tubing (farthest from the guide rail - see Fig 8). When pushing the connectors together, turn the connector on Tubing #3 in a clockwise direction; ensure the two connections lock together tightly.

NOTE: Reference catheter-to-cassette connection (Fig 9).
Fig 8. Connecting Warmer Tubing #3 to the Warmer Cassette Upper Tubing
Fig 9. Catheter-to-Cassette Connection
10. Holding Tubing #1 in both hands, feed the portion located between the green labels into the peristaltic pump head (Fig 10).

**IMPORTANT:** Tubing #1 from the IV bag should enter the pump head from the right side - fluid flow direction is from right to left (as indicated by the arrows in Fig 10).

11. Carefully bend the tubing over the roller taking care to properly align it with the groove in each of the tubing retainers located on both the left and right side.

**Fig 10. Feeding Warmer Tubing #1 into the Peristaltic Pump Head**

**IMPORTANT:** Tubing #1 from the IV bag should enter the pump head from the right side - fluid flow direction is from right to left (as indicated by the arrows in Fig 10).

**Fig 11. Aligning Tubing #1 with Groove in Tubing Retainer**

**NOTE:** The illustration below shows examples of correct and incorrect alignment. Fig 12 shows Tubing #1 correctly aligned with the tubing retainer.
12. Move the pump head lever in a *clockwise* direction to the fully-locked position (Fig 13 and Fig 14).

**IMPORTANT:** When performing **Step 12**, be careful not to damage the tubing with the tubing retainers while turning the pump head lever. Once completed, ensure the tubing is secured tightly (Fig 14) but not pinched or aligned incorrectly (as shown in the example in Fig 15).
IMPORTANT: Tubing retainers do not usually need readjustment when changing tubing so it is not necessary to attempt to move the tubing retainer adjusters up or down. These should remain positioned half-way from the top (Fig 14).

However, if tubing is seen to creep, open the pump head and move the tubing retainer adjusters down one notch. Then, close the pump head and turn ON the pump. If creeping persists, repeat this action.

Fig 14. Pump Head Lever in Fully-Locked Position

Fig 15. Example of Incorrect Tubing Position Causing Pinching
13. Adjust the pump flow rate speed selector to 8. **Do not exceed this speed.**

14. Close the plastic tubing clamp of Tubing #1 (Fig 16), then insert the spiked end of Tubing #1 into an insertion port on the IV bag (see Fig 17).

![Fig 16. Plastic Tubing Clamp on Tubing #1](image1)

15. Check that the plastic tubing clamp on the proximal end of Tubing #3 (the end farthest from the Fluid Warming device) is closed, then insert the spiked end of Tubing #3 into the remaining insertion port on the IV bag.

16. Carefully OPEN all plastic tubing clamps on Tubing #1 and Tubing #3, and the clamps on tubing segments near the Warmer Cassette. Refer to the illustration in Fig 18.

![Fig 17. Connecting Warmer Tubing to IV Bag](image2)
Fig 18. Urethral Warming Set - Tubing Connections
17. Connect each of the AC power cables from the fluid warming device and the peristaltic pump’s external isolation transformer, respectively, to the mains power wall outlet (110V or 220V, as applicable).

**NOTE:** Only the pump is connected to the transformer (Fig 19).

![Fig 19. Pump Connected to Transformer](image1)

18. Ensure the power switch on the transformer is in the ON position. Turn the power switch on the pump to ON (Fig 20) and make sure that the tubing lines fill with fluid.

![Fig 20. Pump Power ON](image2)
19. Turn the power switch on the warming device to ON (Fig 21).

Fig 21. Warming Device

20. Proceed to perform the *Urethral Warmer System Integrity and Functionality Test*, as described below.

### 8.3 Performing the Urethral Warmer System Integrity and Functionality Test

**IMPORTANT:** This test must be performed **before the patient is anesthetized**.

**NOTE:** In the event that impaired functionality is detected which results in a need to cancel or postpone the procedure, the patient will not have undergone anesthesia unnecessarily.

1. Verify that the flow indicator is spinning.
2. Wait until all lines are fully primed with fluid.
3. Mark the level of the saline in the IV bag for reference.
4. Allow the system to operate for 15 minutes, then check the level of the saline in the IV bag to verify that it has remained the same.

**IMPORTANT:** A decrease in the level of fluid below this line indicates a leak within the system. In this event, determine the source of the leak and take the appropriate corrective action. This may require simply tightening a loose connection or even replacing the catheter and/or tubing.

5. Inspect the entire environment for signs of leakage.

**NOTE:** In the event of product malfunction, replace the warming system disposables with a spare set and then repeat Step 1 through Step 5.

6. Turn the peristaltic pump speed to 0.

*The Urethral Warmer System is now ready for use.*
## 9 Removal of Urethral Warming Set Components After Use

**NOTE:** Before turning OFF the fluid warming device and pump, make sure the catheter has remained *in situ* for sufficient time after *Freezing* has stopped (at the physician’s discretion).

1. Turn OFF power to the fluid warming device and pump.
2. Remove the catheter from the urethra.
3. Close the tubing clamp on Warmer Tubing #3 (Fig 9).
4. Open the luer-lock connector between Warmer Tubing #3 and the warmer cassette upper tubing (refer to Fig 8) and carefully drain out all the saline from the warmer cassette into a bowl.
5. Gently pull the blue guide rail to remove the warmer cassette from the fluid warming device.
6. Lift the pump lever (see Fig 14) and remove the Warmer Tubing #1 from the pump.
7. Remove the IV bag from the pole.
8. Dispose of all used items in a biohazard container, in accordance with hospital and safety regulations.

## 10 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.