This document provides instructions for use and recommended guidelines exclusively for the Galil Medical Prostate Procedure Template.

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 accessories.
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1 Product Description

1.1 Intended Use

The Galil Medical Prostate Procedure Template is a component intended for use when performing cryogenic destruction of prostatic tissue with a Galil Medical Cryoablation System. The Prostate Procedure Template is designed for use with Galil Medical’s 17G Cryoablation Needles and Single-Point Thermal Sensors™ and Multi-Point Thermal Sensors™. When planning and performing a prostate cryoablation procedure, the template aids the physician in precisely guiding the cryoablation needles and thermal sensors into the targeted tissue.

1.2 Technical Description

The reusable Prostate Procedure Template (Fig 1) is an aluminium device perforated with an array of 17-gauge holes, corresponding to the grid seen on transrectal ultrasound system screens. The holes are spaced 5 mm apart in both the vertical and horizontal directions. This arrangement is designed to help the physician visualize where the needles or thermal sensors will enter the prostate during insertion.

The Prostate Procedure Template has a different alpha-numeric grid scheme on each side. On one side (shown in Fig 1), vertical holes are marked from 0 to 12; horizontal from A to M. On the other (Fig 2), vertical holes are marked from 1 to 7; horizontal from A to G.

![Prostate Procedure Template - Holes Marked A-M and 0-12](Fig 1. Prostate Procedure Template - Holes Marked A-M and 0-12)
Prior to commencing a prostate cryoablation procedure, the sterilized template is mounted onto a stepper/stabilizer system in the OR and positioned near the patient’s perineum.

Galil Medical’s Prostate Procedure Templates are supplied with two mounting pins to facilitate attachment to most types of stepper/stabilizer systems. However, a brand-specific adapter may be required to mount the template to a specific stepper/stabilizer.

**NOTE:** For instructions on cleaning and sterilizing a Prostate Procedure Template, refer to Section 8.4.

### 1.3 Product Specifications

<table>
<thead>
<tr>
<th>Material</th>
<th>Prostate Procedure Template</th>
<th>Anodized aluminium</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Holes accommodate ≤17G items</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hole array: 13 columns x 13 rows</td>
</tr>
<tr>
<td>Mounting pins</td>
<td></td>
<td>Aluminium</td>
</tr>
<tr>
<td>Sterilization Method</td>
<td>Customer sterilized. See Section 8.4.</td>
<td></td>
</tr>
</tbody>
</table>
2 How Supplied
The Prostate Procedure Template is supplied non-sterile.

**NOTE:** The Galil Medical Cryoablation System and the stepper/stabilizer system are supplied separately.

- **Storage**
  Store in a manner that will not mar the Prostate Procedure Template surface or damage the precision holes.

3 Indications for Use
The Galil Medical Prostate Procedure Template is 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*. These Systems have numerous specific indications, including ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia (BPH).

4 Contraindications
There are no known contraindications for using the Galil Medical Prostate Procedure Template.

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 and Thermal Sensors must be completed successfully.

6 Precautions for Handling and Sterilization
- Do not use a Prostate Procedure Template if the packaging is damaged and the device appears damaged; in the event of such occurrence, contact a Galil Medical representative to arrange return of the complete package with the product.
- Always ensure use of the Prostate Procedure Template in a strictly sterile environment, using aseptic technique.
• Before dismantling the stepper, ensure all cryoablation needles and thermal sensors have been removed from the Prostate Procedure Template.

• The Prostate Procedure Template may be resterilized numerous times. Refer to Cleaning and Sterilization Protocol in Section 8.4.

• Follow hospital protocol for appropriate handling and storage of sterilized components.

• Before use, visually inspect the Prostate Procedure Template; use only if there is no apparent change in structural integrity or clarity of the alpha-numeric grid markings.

7 Potential Adverse Events

There are no known adverse events related to the specific use of the Galil Medical Prostate Procedure Template. 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, pneumoethorax, 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 Prepare the Prostate Procedure Template

1. The Prostate Procedure Template is a reusable component and must be sterilized in advance of each use. Sterilize the Prostate Procedure Template following the instructions in Cleaning and Sterilization Protocol, Section 8.4.
2. Using aseptic technique, place the sterilized Prostate Procedure Template in a sterile work area.

**NOTE:** Refer to the user manual accompanying the stepper for instructions on use and set up.

**NOTE:** For detailed instructions on using the Prostate Procedure Template, refer to the appropriate Cryoablation System *User Manual*.

### 8.2 Mount the Prostate Procedure Template into Position

1. Insert the Prostate Procedure Template pins into the holes in the bottom of the template and screw into position.
2. Mount the Prostate Procedure Template by fitting the template pins into the two holes on the stepper.
3. Tighten the screws to prevent template movement during needle insertion.
4. Adjust the stepper to align the template with the patient's perineum.

**NOTE:** The Prostate Procedure Template should be in position before inserting the ultrasound probe.

### 8.3 Dismount the Prostate Procedure Template After Use

1. Confirm that all needles and thermal sensors have been removed from the Prostate Procedure Template.
2. Loosen the screws on the stepper and remove the template.
3. Immediately remove major debris and fluids and rinse the Prostate Procedure Template to remove any blood or tissue from the surface or holes of the template, using appropriate cloth disposal in a biohazard container.
4. Use care, appropriate technique and respective hospital protocol to minimize blood-borne pathogen contamination.
5. Clean and sterilize the Prostate Procedure Template, following the instructions in *Section 8.4*.

### 8.4 Cleaning¹ and Sterilization Protocol²,³

1. After removing surface debris and fluids from the Prostate Procedure Template, soak the template and mounting pins in enzymatic detergent (for example 0.5% ANIOSYME DD1) for at least 5 minutes.
2. Using a cloth or sponge, wipe the template until it is visually clean.
3. Carefully remove debris from each hole with a small cleaning tool or needle; use of a high-pressure jet may be necessary to remove accumulated blood from the template holes.
4. Inspect the template to ensure no debris is detected.
5. Rinse the template under water for at least 1 minute.
6. Use a soft cloth to dry the template.
7. Perform steam sterilization in pre-vacuum mode, per the following parameters:
   • Three times pre-vacuum
   • Minimum sterilization temperature of 132°C
   • Full cycle time: 10 minutes
   • Drying time: 10 minutes

**NOTE:** Follow hospital protocol for appropriate storage and handling of the sterilized component.

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1 Cleaning guidelines are compatible with AAMI TIR 30:2003 and AAMI TIR 12:2004 standards.
2 Sterilization guidelines are compatible with appropriate medical device and EN sterilization standards.
3 Cleaning and sterilization validation was performed by Galil Medical Ltd. to ensure full compatibility with the Prostate Procedure Template.

**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.**