Choose Galil Medical
Prostate Cryoablation
Driving Cryoablation Technology Innovation in Urologic Oncology

- Proprietary 1.5 mm Ultra-Thin Cryoablation Needle Portfolio
- Patented Multi-Point Thermal Sensors™ (MTS)
- Advanced Visual-ICE® Cryoablation System Operating Exclusive i-Flow® Technology
- Proprietary i-Thaw® Technology

Proprietary 1.5 mm Ultra-Thin Cryoablation Needle Portfolio

Smallest Needles on the Market
- Minimally invasive
- Low morbidities\(^1\)\(^-5\)

Sharp Trocar Needle Tip
- Confident insertion
- Easy to steer and position

Patented Multi-Point Thermal Sensors™

- Four points of real-time temperature monitoring of ablation zones and adjacent anatomical structures
- High likelihood of preserving urinary continence with the use of Galil Medical’s MTS in salvage cryoablation treatment | 95 - 97.4% urinary continence\(^6\)
- Four independent temperature sensors, located at 5 mm, 15 mm, 25 mm, and 35 mm from the tip of the MTS, allows temperature monitoring along the entire length of the prostate (base to apex)
- Each thermal sensor can be individually monitored to a minimum temperature limit or a maximum rate of temperature drop
Precise Control to Shape and Manage Iceball Growth

Enhanced Procedure Control and Flexibility

- Independent control and operation of needles with 10 independent channels
- Potential to operate 20 needles (2 needles per channel)
- Adjustable freeze intensity to sculpt and customize ice formations

Advanced Visual-ICE® Cryoablation Technology

with Exclusive i-Flow® Technology and i-Thaw® Technology

Galil Medical’s innovative i-Flow® Technology is designed to:

- **Optimize**
  - Software algorithm optimizes all needle performance
- **Customize**
  - Each needle can be customized with a specific algorithm
- **Perform**
  - Consistently maintains specified flow rates of active needles for the strongest possible ice

Proprietary Needles with i-Thaw® Technology

- Active thawing without helium
- Reduced procedure cost and faster setup
- 20% faster thaw times than helium thaw
**Indications for Use**

The Galil Medical Cryoablation Systems are intended for cryoablative 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, and skin lesions) by the application of extremely cold temperatures. A full list of specific indications can be found in the Galil Medical Cryoablation System User Manuals.

**Contraindications**

There are no known contraindications.

**References**

4. Wenske S., Guernier S. and Katz A. Salvage Cryosurgery of the Prostate for Failure after Primary Radiotherapy or Cryosurgery: Long-term Clinical, Functional, and Oncological Outcomes in a Large Cohort at a Tertiary Referral Centre. EU Urology 2013 (64); 1-7.
7. Philippa Cheetham, and Aaron Katz, et. al. Long-Term Cancer-Specific and Overall Survival for Men Followed More Than 10 Years After Primary and Salvage Cryoablation of the Prostate. J. of Endourology 2010 ; 24,(7); 1123–1129.

**AUA Practice Guidelines on Primary Prostate Cancer Cryoablation**

- Clinically organ-confined prostate cancer of any grade with a negative metastatic evaluation
- Patients with PSA levels < 10 ng/mL

**Primary Cryotherapy is a Minimally Invasive Treatment Option for Prostate Cancer**

- 10-year prostate-cancer specific survival at 87%
- Encouraging biochemical and local control
- Improved quality of life outcomes

**AUA 2008 and NCCN 2011 Guidelines on Salvage Prostate Cancer Cryoablation**

- PSA < 10 ng/mL
- Life expectancy of > 10 year
- A long PSA doubling-time of ≥ 16 months
- Absence of seminal vesicle invasion
- A positive biopsy and a negative metastatic evaluation

**Salvage Cryotherapy is an Efficacious Treatment Option with a Curative Intent for Radio-recurrent Prostate Cancer**

- Excellent oncological outcome and high local control
- Fewer morbidities and low rate of complications
- Oncological outcomes comparable to surgery
- Encouraging biochemical and local control
- Less health care costs than salvage radical prostatectomy

**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 Galil Medical Cryoablation System.

A full list of the warnings, precautions, and adverse events can be found by referencing the respective device Instructions for Use document or Cryoablation System User Manual.

**Rx only**