

**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 Galil Medical Cryoablation System User Manuals.

**Contraindications** There are no known contraindications.

**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**

**GALIL MEDICAL'S CRYOABLATION TECHNOLOGY HAS NOT BEEN CLEARED BY THE  
FDA FOR FOCAL TREATMENT OF PROSTATE CANCER WITH FOCAL THERAPY**

## **Clinical Guidelines, Expert Opinions**

1. National Institute for Health and Clinical Excellence (NICE). Focal Therapy Using Cryoablation For Localised Prostate Cancer. April 2012.
2. Heidenreich A, Bastian PJ and Zattoni F et. al. Guidelines on Prostate Cancer. European Associations of Urology 2013.
3. van den Bos W, Muller BG and Scardino PT et. al. Focal Therapy in Prostate Cancer: International Multidisciplinary Consensus on Trial Design. *Eur Urol* 2014; 65(6):1078-83.
4. Jarow JP, Thompson IM and Morton Jr. RA et. al. Drug and Device Development for Localized Prostate Cancer: 2014 Report of a Food and Drug Administration (FDA) / American Urological Association (AUA) Public Workshop. *Urology* 2014.

## **Epidemiology**

1. Colin SM, Martin RM and Metcafe C et. al. Prostate-cancer mortality in the USA and UK in 1975-2004: an ecological study. *Lancet Oncol* 2008; 9(5) 445-452.
2. Karavitakis M, Ahmed HU and Winkler MH et. al. Trends in Pathologic Outcomes After Introduction of Active Surveillance in the UK: Implication for Focal Therapy. *The Prostate* 2012; 72:1464-1468.

## **Clinical Overview (Paper Reviews)**

1. Bozzini G, Colin P and Betrouni N et. al. Focal therapy of prostate cancer: energies and procedures. *Urologic Oncology: Seminars and Original Investigations* 31 (2013) 155–167.
2. Ganzer R, Fritsche HM and Blana A et. al. Fourteen-year oncological and functional outcomes of high-intensity focused ultrasound in localized prostate cancer. *2013 BJU International*.
3. Resnick MJ, Koyama T and Penson DF et. al. Long-Term Functional Outcomes after Treatment for Localized Prostate Cancer. *N Engl J Med*. 2013 January 31; 368(5): 436–445.

## **Diagnosis and Disease Identification**

1. Johnstone PAS, Rossi PJ and Master V et. al. ‘Insignificant’ prostate cancer on biopsy: pathologic results from subsequent radical prostatectomy. *Prostate Cancer and Prostatic Diseases* (2007) 10, 237–241.
2. Isariyawongse BK, Leon S and Moul JS et al. Significant Discrepancies Between Diagnostic and Pathologic Gleason Sums in Prostate Cancer: The Predictive Role of Age and Prostate-Specific Antigen. *Urology* 2008 (72): 882–886.
3. Taira AV, Merrick GS and Wallner KE et al. Performance of transperineal template-guided mapping biopsy in detecting prostate cancer in the initial and repeat biopsy setting. *Prostate Cancer Prostatic Dis* (13) 2009.

## **Patient Selection**

1. Ward JF and Pisters LL. Considerations for Patient Selection for Focal Therapy. *Ther Adv Urol* 2013; 5(6) 330-337.
2. Passoni NM and Polascik TJ. How to Select the Right Patients for Focal Therapy of Prostate Cancer? *Curr Opin Urol* 2014 (24): 203-208.

## Clinical Studies

1. Guazzoni G. Focal therapy for organ confined prostate cancer: an investigative prospective pilot study [ClinicalTrials.gov identifier NCT00928603]. ClinicalTrials.gov Web site. <http://clinicaltrials.gov/ct2/show/NCT00928603?term=NCT00928603&rank=1>.
2. Ward JF. Regional cryoablation for localized adenocarcinoma of the prostate [ClinicalTrials.gov identifier NCT00877682]. ClinicalTrials.gov Web site. <http://clinicaltrials.gov/ct2/show/NCT00877682?term=NCT00877682&rank=1>.
3. Eastham J. A phase II study of focal cryoablation in low-risk prostate cancer [ClinicalTrials.gov identifier NCT00774436]. ClinicalTrials.gov Web site. <http://clinicaltrials.gov/ct2/show/NCT00774436?term=NCT00774436&rank=1>.

## Clinical Studies Outcomes

1. Bahn DK, Silverman P and Rewcastle JC et. al. Focal prostate cryoablation: initial results show cancer control and potency preservation. *J Endourol* 2006; 20(9) 688-692.
2. Lambert EH, Bolte K and Katz AE. Focal cryosurgery: encouraging health outcomes for unifocal prostate cancer. *Urology* 2007; 69(6): 1117-1120.
3. Ellis DS, Manny Jr TB and Rewcastle JC. Cryoablation as primary treatment for localized prostate cancer followed by penile treatment rehabilitation. *Urology* 2007; 69(2):306-310.
4. Onik G, Vaughan D and Brady J et. al. "Male lumpectomy": focal therapy for prostate cancer using cryoablation. *Urology* 2007; 70(Suppl): 16-21.
5. Onik G, Vaughan D, Lotenfoe R, et al. The "male lumpectomy": Focal therapy for prostate cancer using cryoablation results in 48 patients with at least 2-year follow-up. *Urol Oncol* 2008;26:500 –5.
6. Truesdale MD, Cheetham PJ and Katz AE et. al. An Evaluation of Patient Selection Criteria on Predicting Progression-Free Survival After Primary Focal Unilateral Nerve-Sparing Cryoablation for Prostate Cancer Recommendations for Follow Up. *The Cancer Journal* 2010, 16: 544-549.
7. Bahn D., De Castro Abreu A.L., Gill I.S. et al. Focal cryosurgery for clinically unilateral, low-intermediate risk prostate cancer in 73 men with a median follow-up of 3,7 years. *Eur Urol* 2012 ; 62 : 55-63.
8. Ward JF and Jones JS. Focal cryotherapy for localized prostate cancer: a report from the national Cryo On-Line Database (COLD) Registry. *BJU Int* 2012; 109: 1648-54.
9. Hale Z., Miyake M. and Rosser CJ et. al. Focal cryosurgical ablation of the prostate: a single institute's perspective. *BMC Urology* 2013, 13:2.