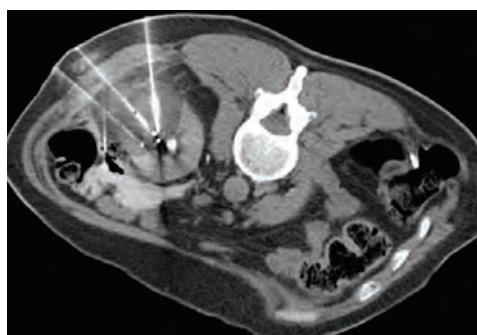




Why Choose Cryoablation

Cryoablation has unique radiographic conspicuity of the ablation zone¹

- Distinct iceball visibility²
- Image guidance (ultrasound, CT or MRI) provides direct control of the location and size of the iceball
- Real time monitoring of the ablation zone² optimizes adequate tissue coverage and avoids damage to adjacent structures



Images courtesy of David J. Breen, MD, Clinical Radiology Department, Southampton University Hospital, Southampton, UK

The ablation zone is controllable and predictable with cryoablation

- Multiple needle placement to fully cover the tumor³
- Simultaneous needle activation³

Cryoablation has excellent patient outcomes

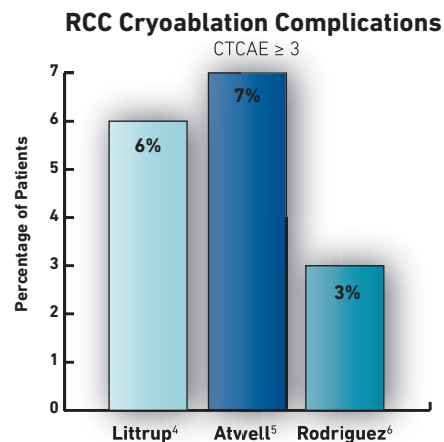
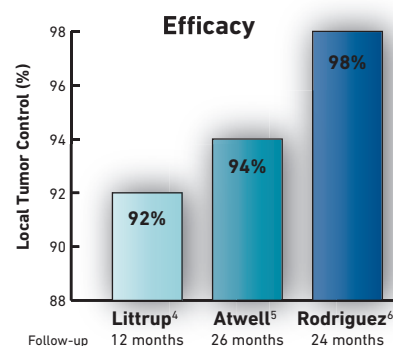
- Local tumor control after a single treatment^{4, 5, 6}
- Durability with low incidence of tumor recurrence⁵
- Demonstrated 95% effectiveness in targeted tumors⁶
- Excellent safety and efficacy profiles^{3, 7, 8}
- Nephron-sparing treatment^{9, 10} with no impact on post ablative renal function¹¹
- Low risk of metastatic progression^{12, 13}

Cryoablation can be used to treat a range of tumor sizes and difficult locations^{3, 14}

- Cryoablation zone is well demarcated³
- Iceball visibility for intraprocedural control and monitoring^{1, 2, 3}
- Multiple tumors can be treated in one session¹⁵

Cryoablation has low complication rates

- Rate of clinically important complications (CTCAE \geq 3) following RCC cryoablation is low^{4, 5, 6}

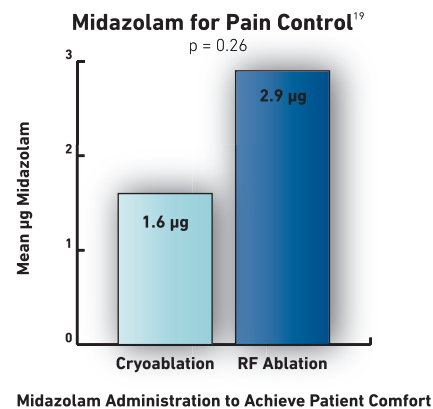
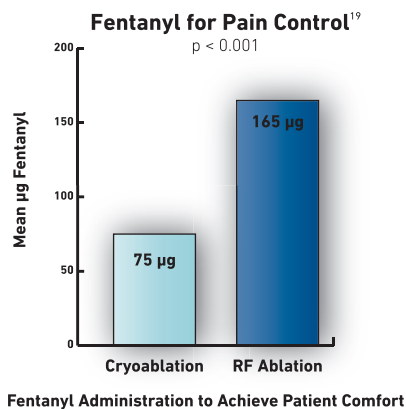


Cryoablation is a minimally invasive procedure, with multiple benefits:

- Less blood loss versus surgery^{10, 11, 16}
- Short hospital stay^{10, 11, 17}
- Short recovery time¹⁰
- Low morbidity for rapid return to everyday life¹⁰
- May be suitable for patients who cannot tolerate general anesthesia^{18, 19}

There is minimal intra-procedural pain with cryoablation

- Lower dose of analgesics needed with cryoablation than when performing RF ablation¹⁹
- Increased potential for procedure completion as patients can tolerate the procedure¹⁹
- Can be performed under conscious sedation⁴ versus general anesthesia



References

1. Breen DJ, Raiton NJ. Minimally Invasive Treatment of Small Renal Tumors: Trends in Renal Cancer Diagnosis and Management. *Cardiovasc Intervent Radiol* 2010; 33:896-908.
2. Cornelius F, Balageas P, Le Bras Y, et al. Radiologically-guided thermal ablation of renal tumours. *Diag Interv Imaging* 2012; 93: 246-261.
3. Tattli S, Acar M, Tuncali K, et al. Percutaneous cryoablation techniques and clinical applications. *Diag Interv Radiol* 2010; 16: 90-95.
4. Littrup PJ, Ahmed A, Aoun HD, et al. CT-guided Percutaneous Cryotherapy of Renal Masses. *J Vasc Interv* 2007; 18: 383-392.
5. Atwell TD, Callstrom MR, Farrell MA, et al. Percutaneous Renal Cryoablation: Local Control at Mean 26 Months of Follow-up. *J Urol* 2010; 184: 1291-1295.
6. Rodriguez R, Cizman Z, Hong K, et al. Prospective Analysis of the Safety and Efficacy of Percutaneous Cryoablation for pT1NxMx Biopsy-Proven Renal Cell Carcinoma. *Cardiovasc Intervent Radiol* 2011; 34: 573-578.
7. Guazzoni G, Cestari A, Buffi N, et al. Oncologic Results of Laparoscopic Renal Cryoablation for clinical T1a Tumors: 8 Years of Experience in a Single Institution. *Urol* 2010; 76(3): 624-629.
8. Aron M, Kamoi K, Remer E, et al. Laparoscopic Renal Cryoablation: 8-Year, Single Surgeon Outcomes. *J Urol* 2010; 183: 889-895.
9. Lucas SM, Cadeddu JA. The Importance of Nephron-Sparing Focal Therapy: Renal Function Preservation. *J Endourol* 2010; 24(5): 769-774.
10. Goyal J, Sidana A, Georgiades CS, et al. Renal Function and Oncologic Outcomes after Cryoablation or Partial Nephrectomy for Tumors in Solitary Kidneys. *Kor J Urol* 2011; 52: 384-389.
11. Mues AD, Landman J. Results of kidney tumor cryoablation: renal function preservation and oncologic efficacy. *World J Urol* 2010; 28(5): 567-570.
12. Schmit GD, Thompson RH, Kurup AN. Percutaneous cryoablation of solitary sporadic renal cell carcinomas. *BJU Intl* 2012; doi: 10.1111/j.1464-410X.2012.11230.x.
13. Kunkle DA, Uzzo RG. Cryoablation or Radiofrequency Ablation of the Small Renal Mass. A Meta-analysis. *Cancer* 2008; 113(10): 2671-2680.
14. Rosenberg MD, Kin CY, Tsivian M, et al. Percutaneous Cryoablation of Renal Lesions With Radiographic Ice Ball Involvement of the Renal Sinus: Analysis of Hemorrhagic and Collecting System Complications. *Am J Roentgenol* 2011; 196(4): 935-939.
15. DeCastro GJ, Gupta M, Badani K, et al. Synchronous Cryoablation of Multiple Renal Lesions: Short-term Follow-up of Patient Outcomes. *Urol* 2010; 75: 303-306.
16. Haramis G, Graversen JA, Mues AD, et al. Retrospective Comparison of Laparoscopic Partial Nephrectomy Versus Laparoscopic Renal Cryoablation for Small (<3.5 cm) Cortical Renal Masses. *J Lap Adv Surg Tech* 2012; Laparoendosc Adv Surg Tech 2012; 22(2): 152-157.
17. Haber GP, Lee MC, Crouzet S, et al. Tumor in Solitary Kidney: Laparoscopic Partial Nephrectomy vs Laparoscopic Cryoablation. *BJU Intl* 2012; 109(1): 118-124.
18. Gupta A, Allaf ME, Kavoussi LR, et al. Computerized Tomography Guided Percutaneous Renal Cryoablation with the Patient Under Conscious Sedation: Initial Clinical Experience. *J Urol* 2006; 175: 447-453.
19. Allaf ME, Varkarakis IM, Bhayani SB, et al. Pain Control Requirements for Percutaneous Ablation of Renal Tumors: Cryoablation versus Radiofrequency Ablation – Initial Observations. *Radiol* 2005; 237: 366-370.

Indications for Use:

The Galil Medical IceRod® CX Cryoablation Needle is intended for cryoablative destruction of tissue during surgical procedures. The IceRod CX Needle, used with the Visual-ICE® Cryoablation System, is 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 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.

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 Visual-ICE Cryoablation System.

A full list of the warnings, precautions, and adverse events can be found by referencing the IceRod CX Instructions for Use document or the Visual-ICE Cryoablation System User Manual.

Rx only

www.galilmedical.com

Galil Medical Inc.

4364 Round Lake Road
Arden Hills, MN 55112
USA
Tel: +1 877 639 2796

Galil Medical Ltd.

Tavor Building 1
Yokneam
Israel 20692
Tel: +972 (4) 9093200

