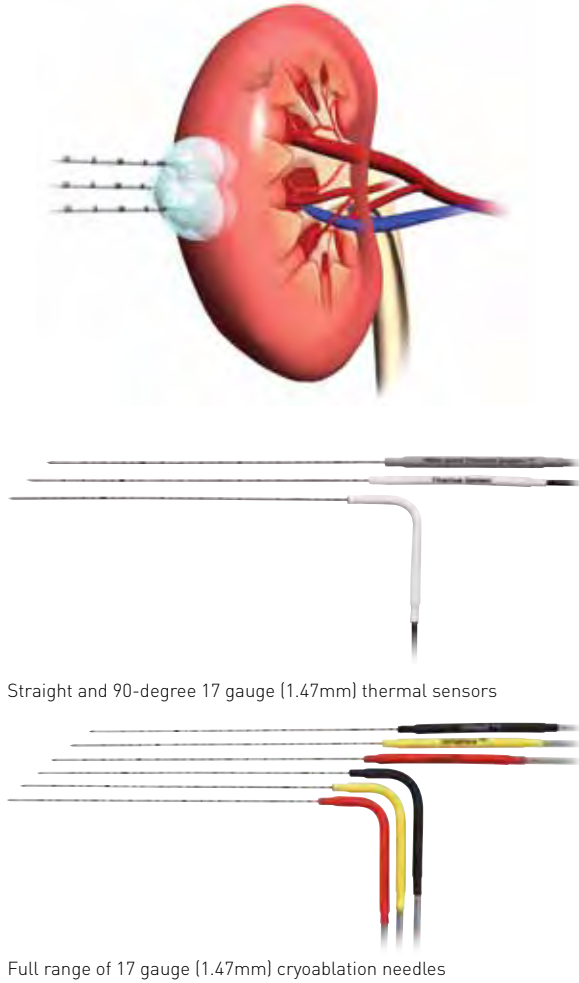


Image-Guided Percutaneous Renal Cryoablation

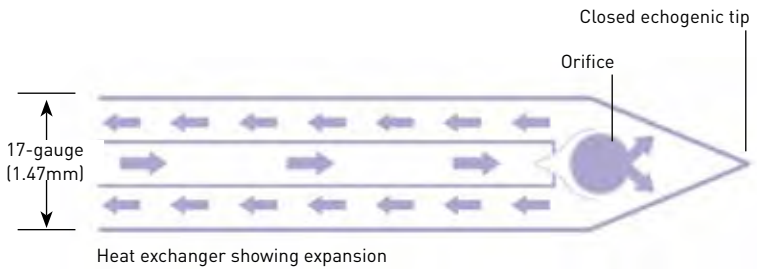
Image-Guided Percutaneous Renal Cryoablation. CT or MRI-guided freezing of solid renal tumors by inserting cryoablation needles through the skin and directly into the tumor without a surgical incision.

Cryoablation is a well-established technology for the treatment of various benign and malignant conditions. Combining Galil Medical's patented freezing technology and ultra-thin cryoablation needles to your CT or MRI imaging capabilities will truly bring you *A New Vision of Precision*.



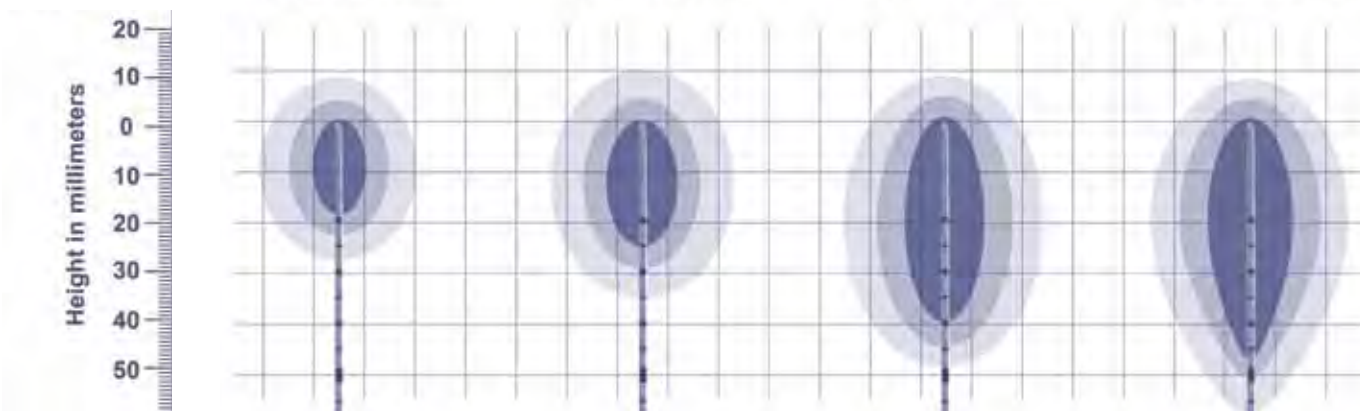
Percutaneous ablation using 17-gauge cryoablation needles and CT or MRI guidance takes minimally-invasive tumor destruction to a whole new level.

- Small diameter cryoablation needles can be used in groups to create a more uniform and predictable freeze zone.¹
- A variety of needle types and customizable software control enable sculpting of an iceball that matches the size and shape of the tumor.
- Ultra-thin thermal sensors allow real-time temperature monitoring ensuring that lethal temperatures are obtained throughout the targeted tissue.
- Small diameter cryoablation needles may reduce the risk of bleeding complications.



Isotherm Data (below) showing size and temperatures of freeze zones after two cycles of 10-minute freezing separated by a 5-minute thaw in gel at room temperature.

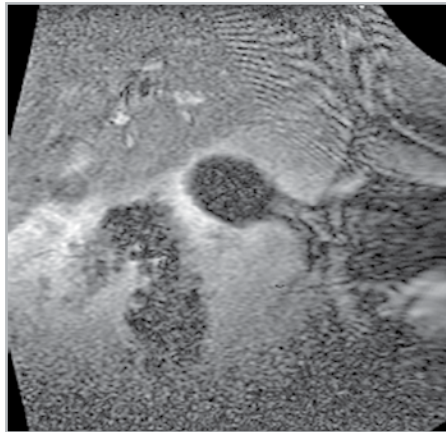
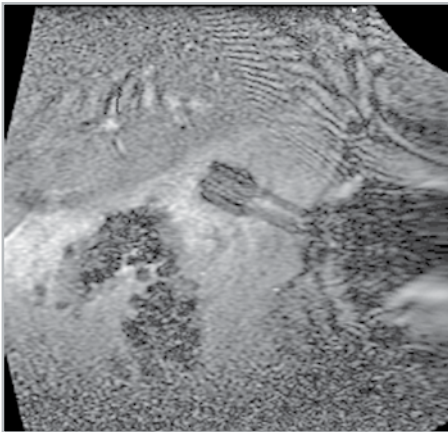
| ISOTHERM DATA | IceSeed® 1.47 mm 17-gauge | IceSphere® 1.47 mm 17-gauge | IceRod® 1.47 mm 17-gauge | IceBulb® 1.47 mm 17-gauge |
|---------------|------------------------------|--------------------------------|-----------------------------|------------------------------|
| 0° C | 31mm x 36mm | 37mm x 45mm | 40mm x 58mm | 40mm x 67mm |
| -20° C | 19mm x 26.5mm | 24mm x 34mm | 27mm x 50mm | 28mm x 55.5mm |
| -40° C | 10.5mm x 19mm | 15mm x 25mm | 16mm x 41mm | 17mm x 48mm |



Width ±2mm,
Length ±3mm.



Coronal MRI images during a renal cryoablation procedure show 3 cryoablation needles (in cross-section) in the renal cell tumor before freezing (left). After 15 minutes of freezing (right), the iceball is clearly visible as a round hypo-intense region.



Sagittal MRI scans from the same procedure show the cryoablation needles along their lengths before treatment (left) and at 15 minutes of freezing (right); again, with clear visualization of the iceball. As in the coronal image above, at 15 minutes of freezing, imaging confirms that the iceball covers the tumor but does not touch the nearby colon.

Intraprocedural Image-Guidance.

CT or MRI imaging throughout the procedure allows you to **TARGET**, **MONITOR**, and **CONTROL** the cryoablation process to ensure complete coverage of the tumor and the desired tissue margin while ensuring adjacent structures are not impacted.

Target.

Utilize CT or MRI imaging for precise placement of cryoablation needles and thermal sensors.

Monitor.

Intraprocedural images allow you to determine how well the target area is being covered by the freeze zone.

Control.

Use the obtained image-based information to make adjustments to the treatment, as needed. This may include repositioning the needles or adjusting other parameters of the freeze-thaw cycles in order to optimize treatment and minimize impact to healthy tissue.

Images courtesy of Stuart G. Silverman, MD, Department of Radiology, Brigham & Women's Hospital, Boston, MA, USA

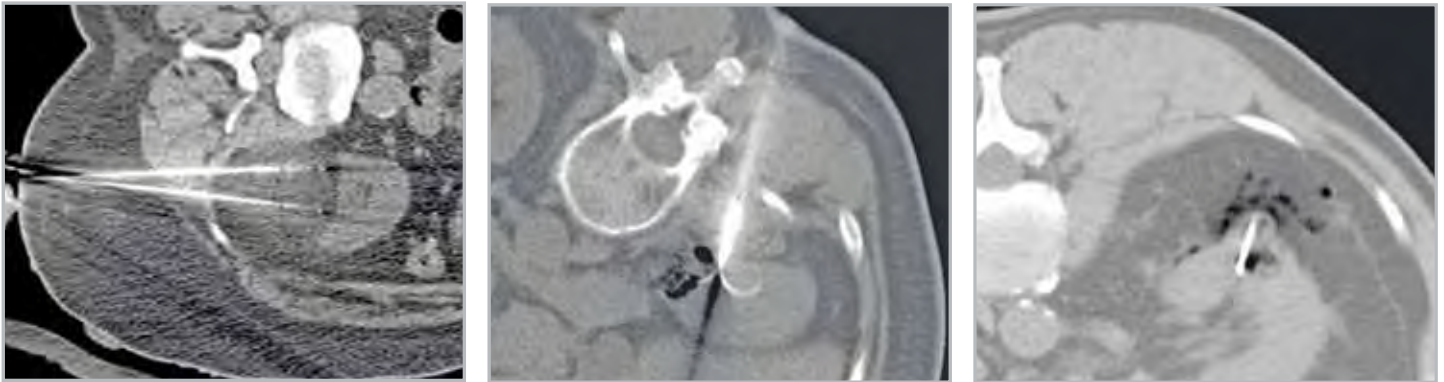
Benefits

Benefits of image-guided percutaneous cryoablation:

- Minimally invasive treatment
- Maximizes preservation of healthy tissue
- Allows treatment of multiple tumors during single session
- Real-time monitoring of treatment
- Percutaneous tumor ablation is associated with decreased length of hospital stay, decreased morbidity, and shorter patient recovery periods than operative therapy.²
- Treatment can be repeated to treat residual or recurring disease
- **Less procedure-associated pain in some applications than RFA³**
- **Improved visualization of the approximate treatment area over RFA (see images on back)**

Image-Guided Percutaneous Cryoablation: A New Vision of Precision

When choosing an ablation modality, clear visualization of the ablated area during the procedure is of primary importance to ensure optimal ablation of the target. As shown in the images below, the iceball is clearly visible during cryoablation (left) enabling procedure monitoring and control, while there is no clear demarcation of treated tissue surrounding the RF electrodes (center and right). All images are axial CT scans taken at the 12-minute mark of treatment.



CT images courtesy of The Division of Abdominal Imaging and Intervention at Brigham & Women's Hospital, Boston, MA, USA



Galil Medical offers the ONLY commercially available MRI compatible cryoablation system and needles.

Procedure at a glance:

- Regional or local anesthesia
- Position patient on CT or MRI gantry
- Perform pre-procedure scan
- Percutaneously insert 17-gauge cryoablation needle
- Scan to assess trajectory
- Advance needle into tumor and re-image
- Repeat for each needle and thermal sensor used
- Perform two freeze-thaw cycles, imaging at intervals to monitor iceball formation
- Remove needles and dress entry sites

References

1. Beland et al. Thermal Ablation in Interventional Oncology, Seminars in Roentgenology 2007;004.05: 175-190
2. Hinshaw et al. "Comparison of Percutaneous and Laparoscopic Renal Cryoablation." World Conference on Interventional Oncology. Washington, DC, May, 2007.
3. Allaf et al. Pain Control Requirements for Percutaneous Ablation of Renal Tumors: Cryoablation versus Radiofrequency Ablation – Initial Observations, Radiology 2005; 237:366-370



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