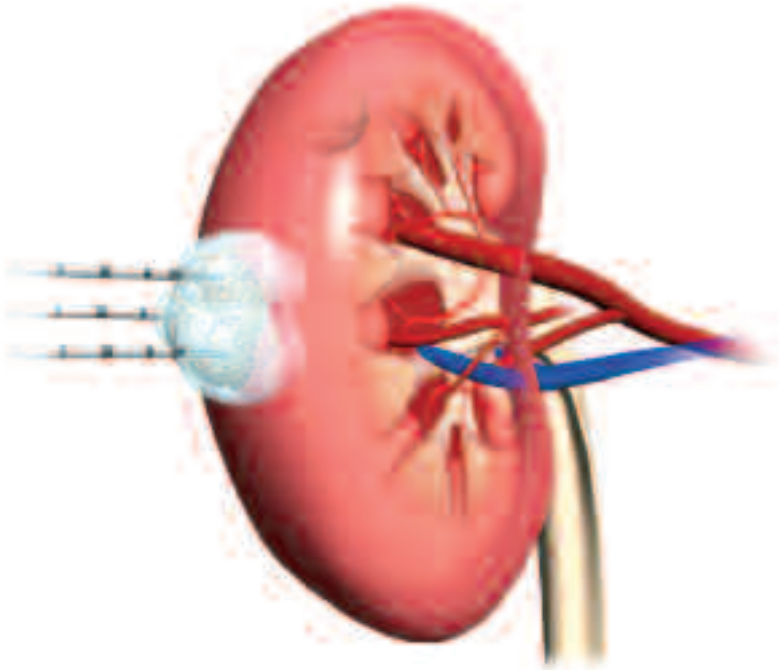
Urology

Cryoablation of Small Renal Tumors

GALILMEDICAL

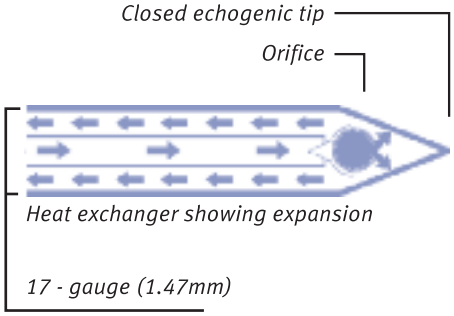
Cryotherapy. Minimally invasive treatment for small RCC

Cryotherapy is a well-established, technology for the treatment of various benign and malignant conditions. Renal cryoablation provides a minimally invasive, nephron-sparing treatment for patients diagnosed with small RCC.



Targeted and accurate ablation using 17-gauge cryoablation needle technology

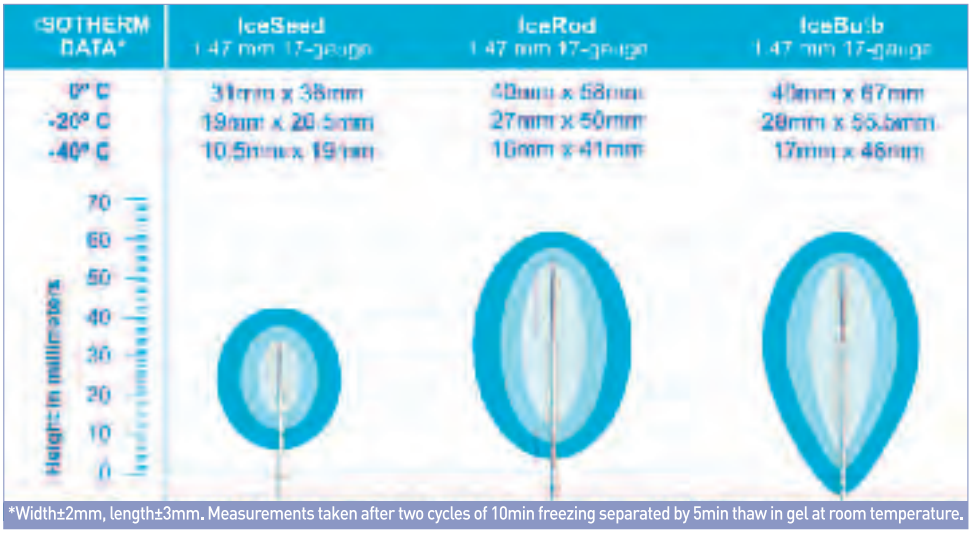
Galil Medical's patented freezing technology is based on the Joule-Thomson effect to produce extremely low temperatures. As compressed Argon gas passes through the cryoablation needle, the tip of the needle is cooled, forming an iceball, which engulfs the tumor and destroys the tissue. A variety of cryoablation needle types, standard configurations and software control enables sculpting of a precise freeze zone to match the size and shape of the tumor.



Ultra-thin cryoablation needles provide accuracy and control

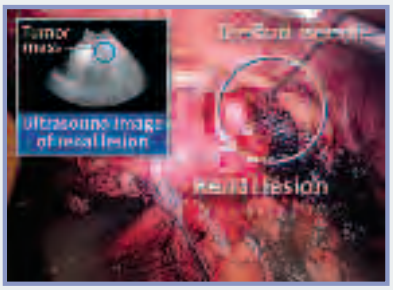
Innovative 17-gauge cryoablation needles offer ease of use and a high level of precision. When cryoablation needles are inserted percutaneously, there is no need for sheaths, guidewires, or dilators. Features include:

- Targeted ablation with minimal trauma
- Echogenic cryoablation needle tip clearly visible under all imaging modalities
- Cryoablation needles may be repositioned during procedure

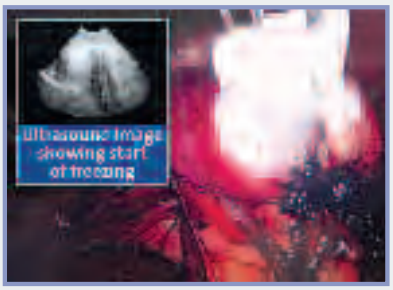


*Width±2mm, length±3mm. Measurements taken after two cycles of 10min freezing separated by 5min thaw in gel at room temperature.

Small diameter cryoablation needles reduce risk of bleeding complications[2]



Step 1:



Step 2:

Step 3:

Percutaneous cryoablation of small renal tumors is less painful than RF ablation[1]

Visualizing renal cryoablation

1. Intraoperative ultrasound exam is performed to identify and measure the target tumor prior to placement of the cryoablation needle. The insertion of the cryoablation needle and thermal sensors is performed under imaging guidance.
2. The iceball margins are visualized on ultrasound enabling real-time monitoring of the ice progression as well as the total size and depth of the ablated lesion. Thermal sensors are strategically positioned within the tumor and in the normal parenchyma to verify lethal freezing temperatures and protect healthy tissue.
3. Two freeze/thaw cycles are applied to achieve complete coverage of thetarget area.

Renal cryoablation: indications

- Peripheral or cortical lesions are ideal
- Solid lesions less than 4 cm
  - -Solitary kidneys
  - -Familial syndromes
  - -Renal insufficiency
  - -Prior renal surgery

Renal cryoablation: relative contra-indications

- Central/Hillar mass
  - close proximity to central vessels may hinder complete ablation
  - ablation is not advisable within the collecting system
- Tumors abutting renal pelvis
- Tumors greater than 4 cm due to greater probability of metastatic disease

Renal cryoablation: absolute contra-indications

- Metastatic disease (except for compassionate cases)

Benefits

Benefits:

- Minimally invasive treatment
- Nephron-sparing procedure
- Treat multiple tumors simultaneously
- Real-time temperature monitoring
- Low risk of bleeding
- Complete tumor ablation in single session[5]
- Can be repeated if residual tumor is found
- Shorter procedure with less complications[3]
- Rapid learning curve

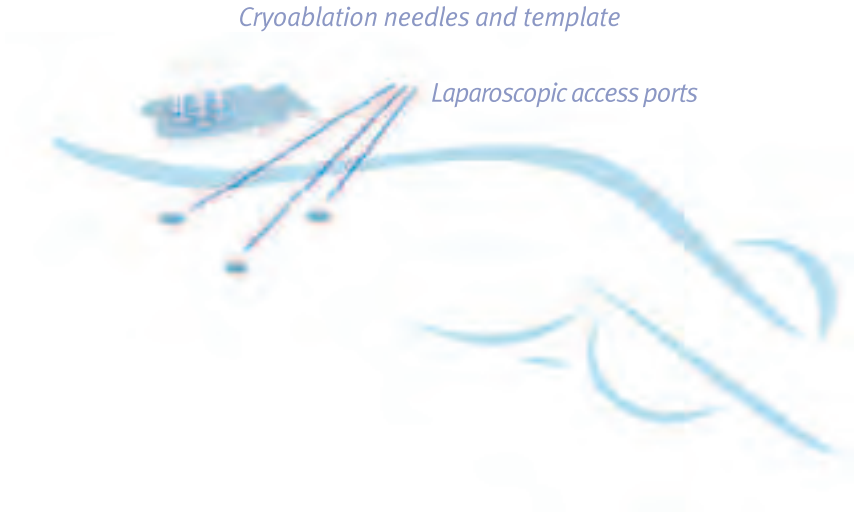
Access and imaging

Renal cryoablation can be performed using several flexible approaches. The integration of high resolution imaging with ultrasound, CT, or MRI enables a high level of control for needle placement and positioning, iceball formation in real-time and the freezing process.

- Open - Intraoperative ultrasound guidance is recommended
- Laparascopic - Intraoperative laparoscopic ultrasound guidance is recommended
- Percutaneous (best suited to lower pole lateral and/or posterior lesions) - Transabdominal US, CT or MRI as image guidance

Laparoscopic guidance

- General or regional anesthesia
- Prepare patient for laparoscopic procedure
- Transperitoneal or retroperitoneal approach
- Identify and measure the tumor
- Percutaneously insert 17-gauge cryoablation needles and thermal sensors into the tumor
- Perform two freeze/thaw cycles
- Monitor iceball formation using real-time ultrasound imaging
- Monitor temperatures with thermal sensors



US/CT/MRI guided

- Regional or local anesthesia
- Place patient in CT/MRI scanner
- Prone or decubitus position with posterolateral approach
- Percutaneously insert 17-gauge cryoablation needles and thermal sensors into the tumor
- Perform two freeze/thaw cycles
- Monitor iceball formation using transabdominal US, CT, or MRI
- Monitor temperatures with thermal sensors

References

1. Allaf et al. Pain Control Requirements for Percutaneous Ablation of Renal Tumors: Cryoablation versus Radiofrequency Ablation—Initial Observations. Radiology. 2005:237:366-370
2. Landman et al. Enhanced Renal Parenchymal Cryoablation with Novel 17-gauge Cryoprobes. Urology. 2004:64:173-175
3. Landman et al. Comparison of Laparoscopic partial nephrectomy and Laparscopic Cryoabltion for renal hilar tumors. Urology. 2005:67:50-54
4. Begun et al. Intermediate Results of Laparoscopic Cryoablation in 59 Patients at the Medical College of Wisconsin. The Journal of Urology 2006. 175, 1225-1229,
5. Silverman et al. Renal Tumors: MR Imaging–guided Percutaneous Cryotherapy. Radiology 2005:236:716-724

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