Kidney Cryoablation
Information for patients and their families

A clinically proven treatment for kidney cancer that avoids open surgery and protects your quality of life
I had a 2cm tumor and my urologist immediately suggested cryoablation. He explained that it would save my kidney without the need for any surgical incisions. The procedure went very well.

I wanted it all out of the way as quickly as possible so that I could get back to work! I chose cryoablation because it was minimally invasive and there was a good chance that my renal [kidney] function could be preserved.

I felt well immediately after the treatment. After 24 hours, I had no pain at all.

Compared to other treatments, cryoablation is less traumatic and it preserves more renal function. For a partial nephrectomy you need a very good surgeon and there is the risk of bleeding.

It was an excellent treatment; I recovered quickly and had no pain. It was truly minimally invasive with less risks than the more traditional surgery.

I was lucky that my tumor was discovered in the early stages. It was 2cm and the doctor immediately mentioned cryoablation as an option. I liked the idea – it saved my kidney and there was no need to cut me open. They did it and it was successful.
Introduction

Being diagnosed with kidney (renal) cancer can be incredibly stressful for you and your loved ones, but medical advances mean that today, the chances of you beating the disease are better than ever before.

Your doctor will discuss with you the different treatments available for the cancer in your kidney. Historically, the only option was surgery to remove either the whole kidney (nephrectomy) or the part of the kidney where the tumor was located (partial nephrectomy). Now, there are treatments available which require only small incisions or none at all. This booklet is designed to provide you with more information on one of these treatments – cryoablation.

Cryoablation (also called cryotherapy) is a minimally invasive procedure which uses extremely cold temperatures to kill cancer cells, while preserving surrounding tissues. Doctors all over the world have been using cryoablation to treat different types of cancer for many years, and studies demonstrate that it is extremely effective at destroying kidney tumors, while protecting healthy tissue. Because the procedure is minimally invasive, patients experience a short hospital stay and rapid return to normal activity, offering considerable quality-of-life benefits over open surgery and other treatment options, and a lower risk of side effects.

1. Guazzoni et al, J Urology, 2010
What is cryoablation?

Cryoablation uses extremely cold temperatures to kill cancer cells. Doctors started using it to treat small kidney cancer tumors as early as 1999, and the results have been extremely impressive.

To treat a patient with cryoablation, doctors create ice using specially designed probes, through which compressed gas is circulated. The ice is very precisely shaped and positioned by the doctor to freeze the tumor and destroy all of the cancerous tissue within the kidney, while healthy tissue and surrounding organs are protected.

What are the benefits of cryoablation?

Cryoablation offers many advantages over other treatment options, including:

- **A minimally invasive** (small or no incisions) treatment option
- A treatment that has demonstrated **95% effectiveness** in targeted tumors
- **Nephron-sparing treatment** (healthy, functioning kidney remains)
- **8-year clinical data** support safety and effectiveness
- **Decreased blood loss** versus surgery (including laparoscopic surgery)
- **Multiple tumors** can be treated in one session
- **Single treatment**, performed on outpatient basis or requiring just one overnight stay
- **Shorter recovery time than partial nephrectomy** permits rapid return to everyday life
- **Can be used when other treatments**, such as prior surgery, **have failed**
- May be suitable for **patients who cannot tolerate general anesthesia**
- **Less painful** than radiofrequency ablation
- **Lower morbidity (side effects) than partial nephrectomy** (including laparoscopic) or radiofrequency ablation
- **Can be repeated**, should the cancer ever come back

---

1. Shingleton et al, J Urology, 2001
3. Guazzoni et al, J Urology, 2010
4. Lucas & Cadeddu, J Endourology, 2010
5. Aron et al, J Urology, 2010
7. DeCastro et al, Urology, 2010
10. Gupta et al, J Urology, 2006
11. Allaf et al, Radiology, 2005
12. Weld & Landman, BJU International, 2005
How is cryoablation performed?

There are two approaches used to treat kidney tumors with cryoablation; the type chosen will depend on your physician’s judgment, and the location and size of the tumor(s) to be treated.

**Laparoscopic kidney cryoablation**

A laparoscopic, or keyhole, procedure is performed through three or four small incisions. A tiny camera is inserted into the abdominal cavity through one of these small incisions and sends images to a screen. The camera allows the doctor to have excellent visibility to position the probes and to accurately control the size, shape and location of the ice. The position and size of the ice will also be checked by a special ultrasound scan to help make sure all of the tumor is treated.

**Percutaneous kidney cryoablation**

An image-guided procedure uses CT (computerized tomography), MR (magnetic resonance) or, occasionally, ultrasound imaging technology to give the doctor a clear view on a screen of the area to be treated. This means the tiny laparoscopic camera is not required. The imaging technology allows the doctor to accurately insert the cryoablation probes through the skin into the kidney tumor, carefully position them and control the creation of the ice to help make sure all of the tumor is treated.

---

“I was in the hospital for a short time, I had no pain and the experience was fantastic. I have already recommended cryoablation as a treatment to a friend of my sister and, as a family doctor, I would recommend kidney cryoablation to any suitable patient that I may see in my own practice.”

Kidney cryoablation patient
What happens to the tumor once it has been frozen?

The cryoablation freezing process destroys the cells in the tumor, and so there is no need to remove this dead tissue. The body’s own immune system recognizes the cells are dead and sends white blood cells to clear them away. Once this process is complete, only scar tissue remains inside the body where the tumor was previously located.

Will cryoablation cure my cancer?

If your doctor considers you to be suitable for kidney cryoablation, it is likely that the procedure will effectively treat your cancer.

Kidney cryoablation is a local treatment, meaning it targets the tumor(s) identified in your kidney at the time of the procedure.

The graph opposite shows results from a number of studies looking at the effectiveness of cryoablation in treating kidney cancer. It shows that cryoablation successfully destroyed the cancer in the targeted tumors in between 80 and 100% of patients.

“I am very grateful to my doctor and to cryoablation – this should be the new gold standard treatment.”
Kidney cryoablation patient

“I am delighted with my experience of cryoablation; I had my treatment over four years ago.”
Kidney cryoablation patient
Effectiveness of Cryoablation for Kidney Cancer
(% Successful Local Tumor Control)

Local tumor control is a measure of how well the cancer has been destroyed or limited in the target tissue. A high number means more effective control at time of follow up.

Percutaneous Kidney Cryoablation:
Study 1: Littrup et al, JVIR, 2007
Study 2: Rodriguez et al, Cardiovasc Intervent Radiology, 2011
Study 3: Atwell et al, J Urology, 2010

Laparoscopic Kidney Cryoablation:
Study 4: Aron et al, J Urology, 2010
Study 5: Guazzoni et al, J Urology, 2010
How does kidney cryoablation compare to radiofrequency ablation (RFA)?

RFA is another treatment for kidney cancer. RFA uses high temperatures to destroy the tumor(s) while cryoablation uses extremely cold temperatures to destroy the cancer. Like cryotherapy, RFA is a minimally invasive therapy, because there are no major surgical incisions and there is no need to remove the dead tissue from the body. *Studies indicate that cryoablation is more effective than RFA in the treatment of kidney tumors.* This may be due to better visualization – doctors report that it is easier for them to see the target area clearly during cryoablation procedures than RFA procedures, which helps them ensure all the diseased tissue is effectively treated.

- Cryoablation may be a more effective treatment than RFA\(^1\)
- Generally, there are fewer side effects with cryotherapy than with RFA\(^1\)
- Cryoablation is less painful than RFA\(^2\)
- RFA may require a general anesthetic more often than cryoablation

*Image-guided cryoablation – as opposed to the limitations of some other ablation modalities [treatments] – allows us to clearly visualize and control the ablation during the study, so as to ensure the targeted tumor is completely and effectively treated.*

Dr David Breen,
Consultant Abdominal Radiologist, Southampton, UK

1. Weld & Landman, BJU International, 2005
2. Gupta et al, J Urology, 2006
Effectiveness of Cryoablation Compared to Radiofrequency Ablation (RFA) for Kidney Cancer (% Successful Local Tumor Control)

Local tumor control is a measure of how well the cancer has been destroyed or limited in the target tissue. A high number means more effective control at time of follow up.

Cryoablation is the only ablative technology which allows the surgeon to actively control the tumour destruction in real time. This huge advantage is likely responsible for the wonderful results experienced by our cryoablation patients.

Dr. Jaime Landman, Professor of Urology and Radiology, Irvine, CA, USA
How does kidney cryoablation compare to laparoscopic partial nephrectomy (LPN)?

LPN is surgery to remove (by cutting out) the diseased part of the kidney. The healthy part of the kidney remains in the body. As with laparoscopic cryoablation, LPN is a keyhole procedure, carried out via three or four small incisions near the kidney. Specially designed laparoscopic surgical tools are passed through these incisions and manipulated directly by the surgeon or by a robotic machine to cut out the diseased tissue, which is removed from the body at the end of the procedure. During LPN, clamps are used to stop the blood supply to the kidney and minimize the risk of severe bleeding (hemorrhage) when the tumor is cut out. The blood supply can only be clamped for 20-30 minutes before the healthy parts of the kidney are damaged, meaning the surgeon has to work quickly.

Studies show that LPN and kidney cryoablation are both very effective at treating kidney cancer, but that the LPN procedure takes longer, involves a greater loss of blood and a higher risk of complications. 

- Cryoablation and LPN both have recurrence-free rates of over 95% (in other words, the cancer did not come back in over 95% of patients treated)\(^1\)
- Cryoablation generally does not require clamping of the renal vessels during the procedure
- Cryoablation is a less invasive procedure than LPN. This means there is less blood loss and fewer complications with cryoablation\(^{1,2}\)
- Because of the lower risk of complications, cryoablation patients generally have shorter recovery times and they are able to resume normal activities more quickly than LPN patients
- LPN requires a general anesthetic, whereas cryoablation may not

The graph on page 11 shows the results of studies which compared patients who had received cryoablation, RFA and LPN, in terms of the complications experienced.\(^1\)

“LPN, while remaining an important treatment option, should no longer be considered minimally invasive as it is a moderately invasive option. The safety and effectiveness of kidney cryoablation make this technique a truly minimally invasive treatment for kidney cancer.”

Dr Jaime Landman, Professor of Urology and Radiology, Irvine, CA, USA

---

1. Weld & Landman, BJU International, 2005
Average Complication [Morbidity] Rates (%) Experienced by Patients who were Treated with Laparoscopic Partial Nephrectomy (LPN), Cryoablation or Radiofrequency Ablation (RFA) for Kidney Cancer

A low number means fewer people experienced complications

Graph shows average complication [morbidity] rates across a variety of studies, which were reviewed and compared by two US doctors in 2005.

I reviewed the literature and the results. Cryoablation was better versus partial nephrectomy. Cryoablation is less shocking to the body. There is also less risk of bleeding and there is no drainage required after surgery – this was important to me.

Kidney cryoablation patient

1. Weld & Landman, BJU International, 2005
What about microwave therapy, irreversible electroporation (IRE) and high-intensity focused ultrasound (HIFU)?

Microwave therapy and IRE are new therapies for kidney cancer, which are still in the experimental stages. Because they are so new, they are so far unproven, and we need to wait for more studies to be completed to be able to compare the cancer-free survival and complication rates with those of other treatments.

Clinical studies which looked at HIFU as treatment for kidney cancer have found that it had poor results and was not an effective treatment. Because of this, many centers have now stopped offering HIFU as a treatment option for kidney cancer.  

What are the risks and side effects of cryoablation?

Your doctor will advise you that any medical procedure has risks associated with it. However, **cryoablation avoids many of the risks and complications of other therapies**, particularly surgery. As the graph on page 11 shows, it has minimal risk of complications due to bleeding or an extended hospital stay, and in some cases, a general anesthetic is not required.

We will always look at alternative ablation options. However, with over a decade of experience and hundreds of patients successfully treated, cryoablation remains the ablative treatment of choice.

Dr Jaime Landman,  
Professor of Urology and Radiology, Irvine, CA, USA

---

1. Weld & Landman, BJU International, 2005  
Am I suitable for cryoablation?

You should discuss with your doctor whether cryoablation is a treatment option for you. Only a doctor experienced in cryoablation procedures can confirm if you are a suitable candidate for cryoablation. The size and location of your tumor(s) and your general health will all be factors in the decision. It is important to remember that patients who might not be suitable for other procedures are often candidates for cryoablation because of the low anesthetic requirement, the low risk of bleeding and other complications. Patients who have poor kidney function, Von Hippel Lindau syndrome, or a single kidney may also be good candidates for cryoablation.

How long does the procedure take?

Although each case is different, a laparoscopic kidney cryoablation procedure usually takes between two-and-a-half to three hours, while a case using the percutaneous approach lasts approximately one hour.

How will I feel after the procedure?

Many patients experience very little pain, but you may feel some discomfort. If this is the case, you will be given pain medicine to make you comfortable.

How long will I need to stay in the hospital?

Many doctors prefer their patients to stay in the hospital for at least one night after the procedure. This means the doctor can make sure patients are eating, drinking, walking and urinating satisfactorily before being discharged from the hospital. Of course, if there are any complications, patients may need to stay in the hospital longer, and local arrangements may vary.

“\nThe day after surgery, it didn’t feel like I had undergone any intervention.\nKidney cryoablation patient\n”

1. Lucas & Cadeddu, J Endourol, 2010
2. DeCastro et al, Urology, 2010
How long before I can return to work?
Your doctor will advise you when you can plan to return to work. This will depend on the extent of the disease treated, the approach used, your general health and also the type of work that you do. Most patients who do not have physically demanding jobs are able to return to work within two weeks, and often more quickly.

I was out of the hospital on Friday. I was back to work part-time three days later and full-time within ten days.
Kidney cryoablation patient

I heard cryoablation is an experimental therapy – is that true?
No. Galil Medical only markets products that have been cleared by the US Food and Drug Administration (FDA) for the ablation of cancerous or malignant and benign tumors or have received the CE Mark. CE Marking is a mandatory conformity mark for products placed on the market in the European Economic Area (EEA). With the CE Marking on a product, the manufacturer ensures that the product conforms with the essential requirements of the applicable EC (European Community) directives. In addition, the National Institute of Clinical Excellence (NICE) in the United Kingdom has ruled that there is sufficient evidence to support the safety and effectiveness of cryoablation as a treatment for kidney tumors.

The weeks before my treatment, I was extremely tired, and right after the procedure I felt rejuvenated and fit!
Kidney cryoablation patient
**The Kidneys**

The kidneys are bean-shaped organs, each about the size of an adult fist. Most people have two kidneys, and they are located in the lower back, one on either side of the spine. Healthy kidneys filter the blood to extract waste products, which are excreted from the body in the form of urine. They also regulate levels of other blood components, such as hormones, enzymes, electrolytes, salts and water. One important function of your kidneys is to keep your blood pressure stable.

Kidney cancer, also referred to as “renal cancer,” is more common in men than in women. The number of people being diagnosed with kidney cancer is increasing, but it has been suggested that this is due to more tumors being identified during routine scans and better testing, rather than more people actually getting kidney cancer. The most common type of kidney cancer is renal cell carcinoma (RCC) which starts in the nephron of the kidney.
**Glossary of Terms**

**Ablation**: The destruction of tissue by the application of extreme cold, heat or light (laser therapy which requires use of photo-sensitive drugs).

**Adrenal gland**: A small gland at the top of the kidney which releases hormones, including one which helps regulate the amount of water and salts in the blood.

**Anesthesia**: The loss of sensation and usually of consciousness artificially produced by the administration of one or more agents that block the passage of pain impulses along nerve pathways to the brain.

**Artery**: Blood vessel that carries blood away from the heart.

**Biopsy**: The removal and examination of a sample of tissue for diagnostic purposes, for example to check if a tumor is cancerous or not.

**Cancer**: A malignant and invasive growth or tumor.

**Catheter**: A tube inserted into the bladder to temporarily drain urine into an external container.

**Cryoablation**: The destruction of tissue by the application of extremely cold temperatures.

**Cryotherapy**: See Cryoablation.

**CT**: Computerized tomography. Imaging technology which uses a computer to generate very clear 3-D images of the internal organs from a series of cross-sectional pictures, taken at very close intervals.

**Cystic mass**: Generally benign (non-cancerous) growths on the kidney, but some may contain pre-cancerous cells.

**Dialysis**: Artificial filtration of blood, used when natural kidney function fails.

**HIFU**: See High-intensity focused ultrasound.

**High-intensity focused ultrasound**: An experimental procedure which aggressively directs very strong sonic waves to a targeted area to destroy tissue.

**Incision**: A cut through the skin used in surgery. Conventional surgery requires large incisions to allow full access to the area to be treated, while laparoscopic or keyhole surgery requires just tiny incisions, through which specially designed instruments are passed.

**IRE**: See Irreversible electroporation.

**Irreversible electroporation**: An experimental procedure which uses very high voltage electrical pulses to destroy tissue, and which requires heart monitoring.

**Laparoscopic partial nephrectomy**: A minimally invasive procedure which involves the surgical removal (cutting out) of the diseased part of the kidney while the healthy part of the kidney remains in the body.

**Laparoscopy**: A minimally invasive surgical procedure which involves passing a tiny camera through a small incision in the abdomen to allow the surgeon to visualize the area to be treated. Laparoscopy avoids the need to open up the abdomen with a large incision, as required with conventional surgery.

**Local tumor control**: A measure of effectiveness for cancer treatments which looks at how well the cancer has been destroyed or limited in the target tissue

**LPN**: See Laparoscopic partial nephrectomy.

**Malignant**: Describes a condition which has a tendency to become progressively worse – frequently used to mean cancerous.

**Minimally invasive**: A procedure which avoids open surgery, requiring only very small surgical incisions or none at all, and which offers lower complication rates and faster recovery times than conventional surgery.

**MRI**: Magnetic resonance imaging technology – uses magnetic fields and radio waves to give very detailed pictures of the internal organs.

**Nephron**: Filtration unit within the kidney. Each kidney contains many nephrons and they are essential to the kidney being able to carry out its filtration and fluid-balancing function.

**Nephron-sparing**: Describes a procedure which removes diseased kidney while leaving nephrons which are unaffected by the disease in place, so the kidney can continue to function.

**Percutaneous**: Through the skin. In percutaneous kidney cryoablation, MRI, CT or ultrasound scanning allows the operator to clearly see the internal organs, and probes are passed directly through the skin into the kidney. Percutaneous procedures avoid the need to open up the abdomen with a large incision, as required with conventional surgery.

**Radiofrequency ablation**: Minimally invasive therapy which uses extremely high temperatures to kill cancer tumors.

**RCC**: See Renal cell carcinoma.

**Recurrence**: The return of cancer after treatment and after a period of time during which the cancer cannot be detected.

**Renal**: Related to the kidney(s).

**Renal cell carcinoma**: The most common form of kidney or renal cancer, accounting for approximately 85% of cases.

**Renal cell carcinoma staging**: Staging is used to describe the degree of progression and severity of kidney cancer.

- **T1a**: Confined to kidney and less than 4cm in size.
- **T1b**: Confined to kidney and between 4 and 7cm in size.
- **T2**: Confined to the kidney and greater than 7cm in size.
- **T3a**: Outside renal capsule invading the adrenal, renal sinus or perinephric fat.
- **T3b**: Tumor is invading the renal vein.
- **T3c**: Tumor is invading the vena cava.
- **T4**: Tumor is outside Gerota’s fascia and is invading adjacent organs.

**Regional Lymph Nodes (N)**

- **N0**: No regional lymph node metastasis.
- **N1**: Metastasis in a single regional lymph node.
- **N2**: Metastasis in more than one regional lymph node.

**Distant Metastasis (M)**

- **M0**: No distant metastasis.
- **M1**: Distant metastasis.

**RFA**: See Radiofrequency ablation.

**Stage**: The extent of a cancer. See also Renal cancer staging.

**Tubule**: Tubes contained within the nephrons of the kidney.

**Ultrasound**: Imaging technology which uses sound waves to give images of the internal organs.

**Urea**: A waste product which accumulates in the blood and is extracted by the kidneys. Measuring urea levels in the blood gives an indication of how efficiently the kidneys are working.

**Ureters**: Tubes that carry urine from the kidneys to the bladder.

**Urethra**: Tube that carries urine from the bladder to the outside of the body.

**Urine**: Fluid produced by the kidneys made up of excess water and waste products. Urine is stored in the bladder before being excreted from the body via the urethra.

**Vein**: Blood vessel that carries blood from the body back to the heart.

**VHL**: See Von Hippel Lindau Syndrome.

**Von Hippel Lindau Syndrome**: A genetic condition that can result in multiple lesions on the kidney.
References


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 cynthiaesthesia), 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 respective Galil Medical Cryoablation System User Manuals.

Contraindications:

None known.

Warnings and Precautions

- A thorough understanding of the technical principles, clinical applications, and risk associated with cryoablation procedures is necessary before using this product. Use of this device should be restricted to use by or under the supervision of physicians trained in cryoablation procedures with a Galil Medical Cryoablation System.

- The physician is solely responsible for all clinical use of the cryoablation needle and for any results obtained by use of the system. All clinical decisions prior to and throughout the cryoablation procedure shall be made by the physician based upon his/her professional opinion.

- Training on appropriate use of a Galil Medical Cryoablation System is required prior to conducting cryoablation with a Galil Medical System.

- Additional product specific warnings and precautions may be found in the instructions for use provided with each product.

Potential Adverse Effects

Potential adverse effects that may be associated with the use of cryotherapy may be organ specific or general and may include, but are not limited to abscess, adjacent organ injury, allergic/anaphylactoid reaction, angina/coronary ischemia, arrhythmia, atelectasis, bleeding/hemorrhage, creatinine elevation, diarrhea, death, delayed/non healing, disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT), ecchymosis, edema/swelling, fever, fistula, glomerular filtration rate elevation, hematoma, hematuria, hypertension, hypotension, hypothermia, idiosyncratic reaction, ileus, infection, injection site reaction, myocardial infarction, nausea, neuropathy, obstruction, organ failure, pain, pelvic pain, pelvic vein thrombosis, perirenal fluid collection, pleural effusion, pneumothorax, pulmonary embolism, pulmonary failure, renal artery/renal vein injury, renal capsule fracture, renal failure, renal hemorrhage, renal infarct, renal obstruction, renal vein thrombosis, sepsis, skin burn/frostbite, stricture of the collection system or ureters, stroke, thrombosis/thrombus/embolism, transient ischemic attack, tumor seeding, UPJ obstruction/injury, urinary renal leakage, vaginal reaction, vomiting, wound complication, and wound infection.
<table>
<thead>
<tr>
<th>Notes</th>
<th>Patient number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Doctor’s name</td>
</tr>
<tr>
<td></td>
<td>Doctor’s contact number</td>
</tr>
<tr>
<td></td>
<td>Nurse’s name</td>
</tr>
<tr>
<td></td>
<td>Nurse’s contact number</td>
</tr>
<tr>
<td></td>
<td>Email</td>
</tr>
<tr>
<td></td>
<td>Appointment dates</td>
</tr>
</tbody>
</table>