



Breast Cancer Cryoablation Informed Consent

By signing below, I am verifying that Dr. Belinda Barclay-White and her staff have adequately explained the procedure to me, including the risks, benefits, and alternatives to this procedure.

Patient Name: _____ **I understand that:**

- This is a minimally invasive technique that uses extremely cold temperatures to destroy cancer cell in the breast without requiring tumor removal via surgery.
- The physician will insert a probe into the tumor using ultrasound guidance via a small skin nick in the breast after injecting the local anesthesia to numb the affected area.
- Then using a freeze-thaw-freeze algorithm based on the tumor size, an ice ball will engulf the lesion in the breast destroying the targeted cells inside the lesion and the blood vessels that supply it. The destroyed cells will be re-absorbed by the body over time. This may take up to 18 months.
- Alternatives to this procedure are observation or surgical removal.
- Cryoablation does replace lumpectomy, however it does not exclude the possible need for radiation.
- The benefits of this procedure include: no tissue deficits, use of local anesthesia only, and minimal recovery time, and stimulation of the immune system to fight the cancer.
- Possible adverse effects of this procedure are mild pain, risk of infection, and risk of frostbite to exposed skin, but these are extremely uncommon.
- Risk of cancer reoccurrence in the breast: The success of cryoablation depends on the ability of the cancer to be completely seen by ultrasound. If ultrasound underestimates the size and location of your cancer; then the cancer may not be completely killed by the cryoablation. If the cancer is not completely killed, the untreated part of the cancer will have a chance to grow and spread beyond the breast. To reduce the risk of the cancer spreading, the treated breast will be monitored regularly for signs of remaining or recurring cancer so that it can be biopsied and removed.
- Cryoablation is experimental for invasive lobular carcinoma and DCIS. These would be out of protocol for the established parameters in the United States.

Patient consent: The procedure was explained to the me in detail by Dr. Belinda Barclay-White and her staff prior to scheduling cryoablation and again today before the procedure. I understand that cryoablation therapy is FDA approved in the breast for fibroadenomas and other areas of the body. A phase 3 IceCure trial of 149 patients shows 98% of participants showed no evidence of recurrence of Invasive ductal cancer at 3 years. This trial is ongoing to look at 5 and 10 year reoccurrence I understand the phase 2 Z1072 trial that explores the effectiveness of cryotherapy in the treatment of breast cancer is on-going. It was successful in 100% of patients with tumors < 1cm, and 92% of patients with tumors 1.5 cm or less. After surgical consultation, Dr. Belinda Barclay-White is performing this procedure instead of surgical excision of the cancer at my request. The advantages and disadvantages of this cryoablation therapy for my cancer and surgical excision (lumpectomy) for my cancer were discussed in detail on several occasions.

Implant patients only:

I understand that there is a risk to the integrity of my implant with cryotherapy. The risk is a puncture to the implant during the introduction of the anesthetic or by the cryoablation probe. I am aware of this possibility and will ask questions prior to the exam regarding this if I feel the need to do so. **Please initial:** _____

The above information was explained to me and I authorize Dr. Belinda Barclay-White to perform the procedure:

Patient Signature: _____ Date: _____

I declare herewith that I supplied the patient with an explanation of the above-described treatment, and that I verified her comprehension of the information.

Physician Signature: _____ Date: _____

Witness Signature: _____ Date: _____

Legal Guardian Signature: (If patient is under 18 years old) _____