Potential Benefits

Study participants may or may not have direct medical benefits. Possible benefits of the BCL System may include:

- Decreasing the chance of a positive margin
- Decreasing the need for, and expense and discomfort of, a second surgery
- Decreasing the amount of breast tissue removed during surgery, thereby better preserving the shape of your breast

Complete information on potential risks and benefits are outlined in the Informed Consent Form which you would review and sign should you choose to participate in the BCL Study.

To Learn More

Talk to your doctor or contact us below for more information about the study, risks, and requirements for participation. For more information, you can visit us at:

https://clinicaltrials.gov/ct2/show NCT04397185?term=cairnsurgical &draw=2&rank=2

or log onto:

https://www.cairnsurgical.com/ u-s-clinical-trial/

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The Breast Cancer Locator (BCL) Clinical Study

a clinical study for women who have recently been diagnosed with invasive breast cancer or ductal carcinoma in situ and are considering breast conserving surgery

The goals of breast conserving surgery are to remove the tumor without leaving any cancer behind and to minimize the amount of tissue removed, maintaining the breast's overall shape and appearance.

Breast conserving surgery is about 80% successful in removing the entire tumor. However, one in five women with breast cancer must have a second surgery because on final analysis there are some tumor cells at the edge of the tissue that was removed (a "positive margin").

A recent study showed that fewer than 20% of breast cancer tumors are round. When the tumor shape is irregular, it can be especially difficult for surgeons to identify its edges in order to remove it all.

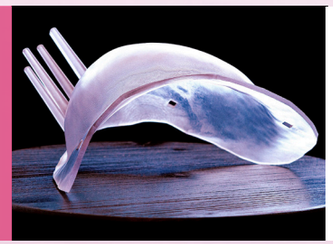
About the Breast Cancer Locator (BCL) Study

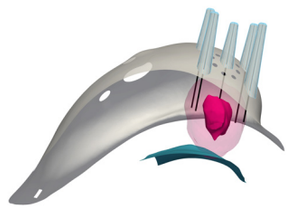
The Breast Cancer Locator (BCL) clinical study will determine whether an investigational tool for surgeons – the Breast Cancer Locator System – can improve a surgeon's ability to reduce positive margins during surgery.

The BCL System is being studied to determine if the guidance provided by the BCL allows the surgeon to more precisely perform breast conserving surgery.

It includes a bra-like plastic form (the Breast Cancer Locator) that is specially designed for each individual patient. This form is placed on the breast after the patient is asleep in the operating room and allows the surgeon to insert small wires in the breast to mark the tumor edges. The BCL system also includes an interactive three-dimensional picture of the tumor in the breast which shows the surgeon its shape and location.

The BCL device is specially designed for each patient's breast, and a 3D image guides the surgeon during surgery.





Is the BCL Study right for me?

You may be a candidate for the study if you can answer YES to the following questions:

- I am a female 18 years of age or older
- I have been diagnosed with invasive breast cancer or ductal carcinoma in situ
- My surgeon and I agree that breast conserving surgery is the best treatment for me

If you enroll in the BCL Study

Participants in this study will be randomized into either the "BCL" or "control" group. Randomization means you are put into a group by chance, like the flip of a coin. If you are placed in the "control group," the BCL device will not be utilized.

BCL Group

You will be scheduled for an MRI taken while you are lying on your back. A personalized BCL device will be created just for you using the images from the MRI. It takes about 10 days to create the BCL device; therefore, your surgery would be scheduled about 2 weeks from your agreement to participate in the study. This should not impact or significantly delay your surgery date. The BCL device and the 3D picture of the tumor in your breast will be used to guide your surgeon during surgery.

Control Group

You will not have the MRI taken while lying on your back. Your surgeon will not utilize the BCL device and will be guided by the standard technique: a wire will be placed in your breast to localize the tumor by a radiologist right before you go into the operating room for surgery.