

What is Intraoperative Radiation Therapy (IORT) for Breast Cancer?

Breast IORT is radiation treatment delivered as a single radiation dose at the time of breast conserving surgery (lumpectomy). IORT is a form of brachytherapy, where radiation is delivered within the surgical cavity. Brachytherapy using the Xoft Axxent Electronic Brachytherapy System minimizes radiation exposure to surrounding healthy tissue. During IORT, a balloon and miniature x-ray source are temporarily placed inside the surgical cavity to deliver radiation in order to eliminate potential remaining cancer cells.

Clinical Support for Intraoperative Radiation Therapy (IORT) A study with over 2,000 patients

*TARGIT-A Trial-Single IORT Fraction versus EBRT traditional radiation treatment*²

Clinical Study Conclusion: "TARGIT concurrent with lumpectomy within a risk-adapted approach should be considered as an option for eligible patients with breast cancer carefully selected as per the TARGIT-A trial protocol, as an alternative to postoperative external beam breast radiotherapy."^{2,3}

References.

1. Dickler, et al. "A Dosimetric comparison of MammoSite high dose rate brachytherapy and Xoft Axxent electronic brachytherapy." Brachytherapy (6) 2007, 164-168.
2. Risk-adapted targeted intraoperative radiotherapy versus whole-breast radiotherapy for breast cancer: 5-year results for local control and overall survival from the TARGIT-A randomised trial. Lancet Volume 383, No. 9917, p603-613, 15 February 2014.
3. TARGIT-A Trial performed with Carl Zeiss Meditec AG IntraBeam System.

Important Patient Information:

This brochure is not intended to provide any medical advice. Only your doctor can advise you as to which treatment options are appropriate, depending on the type and stage of your condition. Your doctor must exercise his or her individual medical judgment in making treatment decisions as each patient has a unique clinical presentation and treatment needs.

The Xoft Axxent Electronic Brachytherapy System (eBx) is indicated for use to deliver intracavitary or intraoperative brachytherapy wherever the physician chooses to deliver brachytherapy. The safety and effectiveness of the Axxent Electronic Brachytherapy System as a replacement for whole breast irradiation in the treatment of breast cancer has not been established. Your doctor will advise you as to which treatment options are appropriate, depending on the type and stage of your condition.

Be sure to speak with your physician regarding the warnings, precautions, and potential complications/adverse events associated with the use of this device. Common side effects include minor local tissue events such as a feeling of heaviness, redness, bruising, and breast pain/tenderness. All of these are common side effects of breast surgery and/or radiation therapy. They are usually temporary and of short duration. There are other important warnings, precautions, and potential complications/adverse events. You should discuss these with your doctor.

Watch an IORT procedure
www.xoftinc.com/treating_iort.html



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MC421 Rev C

Breast cancer treatment in as little as 1 day



Intraoperative Radiation Therapy (IORT)

"I came in with cancer, went to sleep, and when I woke up, I was completely done with my breast cancer treatment"

-Marianne (IORT Patient)

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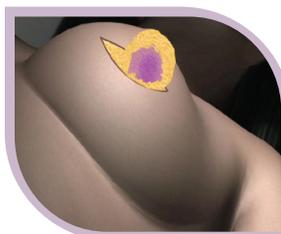
"The fact that my treatment was done before I even woke up is beyond words" says Marianne. Three days after her IORT treatment, Marianne was dancing at a wedding to the song 'I Will Survive'. "You've got to dance that dance. Since my IORT, I'm doing great and I feel fine. I want more women to know about this. I just can't believe how lucky I was to have this type of procedure available to me in my community," she added. - Marianne

Radiation Therapy at the Time of Breast Cancer Surgery

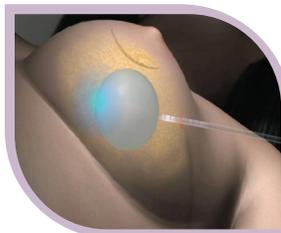
Some patients with early stage cancer may now have the option of receiving both cancer surgery and radiation treatment at the same time— eliminating the need for weeks of travel, disruption to their daily lives, and anxiety. This treatment is called Intraoperative Radiation Therapy (IORT). For patients meeting certain criteria, IORT can deliver a complete dose of radiation in one treatment during the surgical procedure.

Your surgeon will remove the cancer while preserving the remaining breast tissue. Immediately after the cancer is removed, a small inflatable balloon is placed into the surgical cavity. Radiation therapy utilizing the Xofig System is then delivered and can take as little as 8 minutes to complete. Once radiation therapy is delivered, your surgeon will remove the balloon and complete your operation.

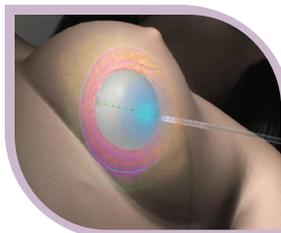
IORT Procedure



Tumor is removed



Balloon applicator is placed into the cavity



Radiation treatment is delivered in as little as 8 minutes



Balloon is removed and the cavity is closed

Is IORT Right for Me?

A discussion with your surgeon about Breast IORT, as well as other treatment options, is necessary to determine if you are a candidate. Advantages of IORT for early stage breast cancer include:

- » Intraoperative Radiation Therapy at the time of surgery avoids the need for 6 to 7 weeks of post-operative External Beam Radiation Therapy (EBRT). For you, this means less travel, fewer days off work, fewer appointments, and less emotional stress.
- » Radiotherapy is delivered directly to the tumor bed, the part of the breast at highest risk of recurrence.
- » If reconstruction is a consideration it can be completed during your surgery.
- » Less radiation is delivered to surrounding healthy organs and tissue.¹