

Xoft® Axxent® Electronic Brachytherapy (eBx®) System® for Breast IORT Fact Sheet

Available to treat early stage breast cancer

The Xoft System is cleared by the FDA to use Intraoperative Radiation Therapy (IORT) to treat early stage breast cancer at the time of a lumpectomy.

- Breast cancer is the second most common cancer among American women, after skin cancer.ⁱ
- Breast cancer is the second leading cause of cancer death in women, exceeded only by lung cancer. It claims the lives of about 40,000 women in the US each year.ⁱⁱ
- Overall, 61% of breast cancers are diagnosed at the localized stage, an early stage in which the cancer has not spread to the lymph nodes or locations outside the breast.ⁱⁱⁱ
- Early detection can lead to treatment that saves the lives of thousands of women each year.^{iv}
- Treatments for breast cancers include surgery, radiation therapy, chemotherapy, hormone therapy, targeted therapy and bone-directed therapies.^v

An alternative to traditional external beam radiation therapy (EBRT)

IORT utilizing the Xoft System uses isotope-free radiation to deliver a therapeutic dose directly to a target site inside the body. It uses a miniaturized high-dose rate x-ray source that:

- Reduces the number of treatments to one at the time of lumpectomy, compared to EBRT which usually requires 30-35 daily treatments over a period of 5-7 weeks.
- Requires minimal shielding while also enabling medical personal to remain in the room during treatment.
- Reduces risk to nearby healthy tissue and organs such as the heart, lung, and rib due to the faster dose fall-off rate.
- Uses a low energy 50 kV x-ray source.

IORT for early stage breast cancer treatment

IORT is delivered immediately following lumpectomy during surgery to prevent the recurrence of early stage breast cancer. IORT requires one treatment.

- After a breast surgeon performs a lumpectomy and receives the initial pathology report, a flexible balloon applicator is placed inside the tumor cavity.
- A radiation oncologist directs treatment through a catheter placed within the inflated balloon applicator inside the breast. Medical personnel remain behind a rolling shield during treatment.
- The high dose rate radiation treatment may take as little as 8 minutes. Once complete, the surgeon withdraws the catheter, removes the balloon applicator, and closes the incision.

Study compares IORT utilizing the Xoft® Axxent® eBx™ System to EBRT

The largest IORT study to date using the Xoft System, this multicenter study aims to enroll 1,000 patients across US and Europe to assess long-term safety and efficacy, cosmetic outcomes and quality of life.

- The study has 23 active centers that have treated 440 patients with IORT, as of Sept. 1, 2014.
- Patients will be followed for 10 years post treatment with assessments every six months until year two. After the second year, patients will be assessed yearly.

ⁱ Breast Cancer Statistics, Centers for Disease Control and Prevention website, Accessed Sept. 8, 2014. Available at: <http://www.cdc.gov/cancer/breast/statistics/index.htm>

ⁱⁱ Breast Cancer Statistics, Centers for Disease Control and Prevention website, Accessed Sept. 8, 2014. Available at: <http://www.cdc.gov/cancer/breast/statistics/index.htm>

ⁱⁱⁱ Cancer Facts & Figures 2014, p.11. Accessed Sept. 8, 2014. Available at: <http://www.cancer.org/research/cancerfactsstatistics/index>

^{iv} Can breast cancer be found early? American Cancer Society website. Accessed Sept. 8, 2014. Available at: <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-key-statistics>

^v How is breast cancer treated? American Cancer Society website. Accessed Sept. 8, 2014. Available at: <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-treating-general-info>