Available for the treatment of early-stage breast cancer
The Xoft System is FDA cleared, CE marked and licensed in Canada for the treatment of early-stage breast cancer. The procedure, called intraoperative radiation therapy, or IORT, allows radiation oncologists and breast cancer surgeons to work together to deliver a full course of radiation treatment in one day, at the time of lumpectomy, to select early-stage breast cancer patients, while the patient is under anesthesia. More than 50 leading healthcare facilities around the globe have adopted Xoft IORT and have successfully treated more than 2,000 patients. The Cleveland Clinic also included IORT in its list of “Top 10 Medical Innovations for 2015.”

Facts about breast cancer
- Breast cancer is the second most common cancer among American women, after skin cancer.¹
- 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.¹
- 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.³
- Early detection can lead to treatment that saves the lives of thousands of women each year.⁴

An alternative to traditional external beam radiation therapy (EBRT)
IORT with the Xoft System uses a proprietary, miniature x-ray source to precisely deliver a targeted dose of radiation directly to the lumpectomy cavity. The Xoft System offers a number of benefits to patients and clinicians, including:
- Reduces the number of radiation treatments to one, which is delivered at the time of lumpectomy. This compares to EBRT, which can require daily treatments for up to eight weeks.
- IORT offers many patient benefits including convenience, lower costs, fewer side effects, and shorter treatment times, which can allow patients to resume normal activities within days rather than weeks, as compared to traditional treatment.
- Reduces risk to nearby healthy tissue and organs such as the heart, lung, and ribs due to the fast dose fall-off rate.
- Short radiation delivery times lasting between 8-12 minutes on average, which results in significant time and cost savings for the patient and the healthcare system, while also reducing the amount of time that the patient is under anesthesia
- Isotope-free, requires minimal shielding, enabling medical professionals to remain in the room during treatment.
- Uses a low energy, 50 kV x-ray source.

About the Procedure
IORT involves one dose of concentrated radiation treatment, precisely delivered at the time of lumpectomy, from directly inside the lumpectomy cavity.
- After a breast surgeon performs a lumpectomy and receives the initial pathology report, a flexible balloon applicator is temporarily placed inside the tumor cavity.
- A radiation oncologist places the miniature x-ray source inside a balloon shaped catheter, which is then placed inside the breast and used to deliver the single dose of radiation directly to the tumor bed. Medical personnel may remain behind a rolling shield during treatment.
- The high dose rate radiation treatment can be completed in as little as eight minutes. Once complete, the surgeon withdraws the catheter, removes the balloon applicator, and closes the incision.

Study compares IORT utilizing the Xoft® System to EBRT
A growing body of favorable clinical data supports the use of IORT in patients meeting specific selection criteria. iCAD is currently conducting the largest, multi-center study to assess long-term safety and efficacy, cosmetic
outcomes and quality of life for patients undergoing IORT with the Xoft System across the U.S. and Europe. This study, named ExBRT (“A Safety and Efficacy Study of Intra-Operative Radiation Therapy (IORT) Using the Xoft Axxent eBx System at the Time of Breast Conservation Surgery for Early-Stage Breast Cancer”), compares the Xoft System to traditional external beam radiation therapy (EBRT). Nearly 700 patients have enrolled in the ExBRT study to-date at 24 active sites.¹

Candidates for treatment with the Xoft System should meet specific selection criteria and be treated under IRB-approved protocols to ensure they are treated in accordance with all federal, institutional and ethical guidelines.

⁵Clinicaltrials.gov