ABOUT THE XOFT AXXENT ELECTRONIC BRACHYTHERAPY SYSTEM FOR INTRAOPERATIVE RADIATION THERAPY

With the Xoft® Axxent® Electronic Brachytherapy System® from iCAD, patients with early stage breast cancer can receive a single course of radiation therapy during their lumpectomy in the form Intraoperative Radiation Therapy (IORT). IORT is administered in the operating room at the time of lumpectomy. After the tumor is removed, radiation is targeted directly into the cavity helping to kill remaining cancer cells. This technique allows doctors to administer high doses of radiation to the target area without exposing surrounding healthy tissue and organs. A single dose of IORT may have as much effect on the tumor site as 10–20 daily radiation treatments.¹

The Xoft System can also be used to administer radiation therapy in the form of accelerated partial breast irradiation (APBI), which is typically delivered twice daily for five days after surgery. Both IORT and APBI provide patients with radiation treatment options that are significantly shorter than the current standard course of traditional external beam radiation, which is delivered five days per week over six to seven weeks.

The Xoft System requires a minimally shielded environment, allowing the physician to remain in the treatment or standard operating room during treatment. It is also relatively small in size and can easily be transported for use either within a facility or between separate locations. Furthermore, faster dose fall-off of the low-energy, isotope-free miniaturized X-ray source minimizes exposure to healthy adjacent tissues.

About Electronic Brachytherapy

Electronic Brachytherapy is a type of radiotherapy that utilizes a miniaturized isotope-free high dose rate X-ray source to apply radiation directly to the cancer site. The goal is to target the radiation dose to the cancerous area, sparing healthy tissue and organs. Brachytherapy has proven to be a highly successful treatment for cancers of the endometrium, cervix, breast and skin.

The Xoft System is a proprietary electronic brachytherapy platform designed to deliver isotope-free radiation treatment in virtually any clinical setting under radiation oncology supervision, without the limitations of radionuclides. Dose rates from the Xoft System are set to an operating voltage of 50kV, which allows for minimal shielding allowing the treatment team to interact with the patient during therapy delivery.

How the Procedure Works
Treatment is administered under the direction of a radiation oncologist who prescribes the radiation treatment plan. After the breast surgeon performs the lumpectomy and receives the initial pathology report, a flexible balloon is placed inside the tumor cavity. It is then inflated with a sterile saline solution to fit snugly into the lumpectomy cavity. The radiation oncologist then connects the appropriate size balloon applicator to a source catheter.

The patient is prepped with a flexible X-ray shield that is draped over the breast. A miniature X-ray source located in the catheter provides the treatment within the inflated balloon inside the breast. The system then administers the radiation treatment, with no additional shielding necessary. The X-ray source remains in the balloon and delivers radiation for as little as 8 minutes. The positioning of the X-ray source and the dosage required to effectively treat the cancer have already been determined in the treatment plan. The X-ray source catheter is then turned off and withdrawn. Once treatment is complete, the surgeon closes the incision and the process is completed. Typically, the patient is able to return home the same or very next day after surgery with minimal recovery time.

IORT drastically reduces the multiple treatments required with traditional External Beam Radiation Therapy to just one dose. External Beam Radiation usually requires the patient to have daily treatments lasting up to seven weeks. This can be logistically difficult for women who live far away from the treatment center or hospital, as well as for women who work or who cannot afford to take time off. IORT also mitigates side effects associated with External Beam Radiation such as radiation burn and fatigue.

A post-market study to assess the safety and efficacy of the Xoft System is currently underway. “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,” is a prospective, multi-center, historical control trial. Researchers plan to enroll up to 1,000 patients at as many as 50 study sites across the U.S. and Europe. Study subjects will be followed for 10 years after treatment to determine the safety and efficacy of IORT with the Xoft System, and interim data will be collected on an annual basis. The studies will also assess cosmetic outcomes and quality of life for subjects treated with Xoft IORT. As of September 2013, the study has enrolled 19 hospitals and centers and treated 120 patients, making it the largest Xoft study to date.

The Xoft System uses a small, isotope-free flexible, electronic X-ray source to deliver radiation directly to an internal target.

The lightweight, mobile Xoft System requires minimal shielding, and can be moved easily between multiple operating/treatment rooms to deliver radiation therapy.

The Xoft System control arm.