

FDA CLEARS XOFT'S AXXENT™ ELECTRONIC BRACHYTHERAPY SYSTEM FOR TREATMENT OF BREAST CANCER

New Technology Delivers Non-Radioactive, Localized Radiation Therapy Direct to Cancer Sites in Minimally Shielded Clinical Setting

FREMONT, Calif., Jan. 4, 2006 – Signaling another advance in the fight against breast cancer, Xoft, Inc., today announced that it has received clearance from the U.S. Food & Drug Administration (FDA) for the Axxent™ Electronic Brachytherapy System for the treatment of breast cancer. Electronic Brachytherapy is a proprietary technology platform designed to deliver localized, non-radioactive, isotope-free radiation treatment in a minimally-shielded clinical setting under the supervision of a radiation oncologist.

“We look forward to being able to offer this exciting new way to deliver non-radioactive radiation therapy for the treatment of breast cancer,” said Vivek Mehta, MD, director for the Center of Advanced Targeted Radiation Therapy at the Swedish Cancer Institute in Seattle. “Unlike brachytherapy sources containing radioactive isotopes, the non-radioactive Electronic Brachytherapy X-ray source can be turned on and off at will, enabling it to be delivered in virtually any clinical setting rather than in heavily-shielded environments. The result is on-demand X-ray treatments that we expect will improve access to critical radiation therapy.”

Used to treat cancer for more than 100 years, radiation therapy is administered after breast-sparing surgery to kill any stray cancer cells that might remain in the breast and is proven to reduce the rate of local recurrences and improve long-term survival. Ample data from several randomized controlled clinical studies has demonstrated that radiation therapy is an essential component of treatment for breast cancer when the patient wishes to conserve her breast with lumpectomy surgery as opposed to undergoing a full mastectomy. However, more recent studies have shown that many patients opt out of receiving breast sparing surgery with radiation therapy due to time, distance, or difficulty accessing radiation therapy centers.

“As electronic brachytherapy now moves into clinical practice, all indications are that this technology represents a leap forward in cancer treatment,” said Kambiz Dowlatabadi, MD, professor of surgery and senior attending, Rush University Medical Center in Chicago. “However, as important as the clinical benefits are, the true breakthrough may relate to easy and convenient access to non-radioactive brachytherapy for women who today opt for mastectomy or lumpectomy without radiation therapy.”

The Axxent Electronic Brachytherapy System uses disposable micro-miniature X-ray radiation sources to deliver ionizing radiation treatment directly to tumor beds. In its first indication for use, the

Axxent System can be used to deliver a course of radiation therapy for early stage breast cancer. It gives radiation oncologists the flexibility to deliver radiation at multiple energy levels, while at the same time eliminating the need for heavily shielded environments so that it can be used in a broader range of clinical settings. This may accelerate patient choice of breast sparing lumpectomy surgery with adjuvant radiation therapy over the alternative of a full mastectomy.

As a platform technology, the Axxent Electronic Brachytherapy System is designed to address a variety of oncological and non-oncological indications. Xoft is actively working on expanding its product offering to include several complementary oncology indications.

In a survey conducted at the recent American Society for Therapeutic Radiology and Oncology (ASTRO) Meeting, 90 percent of radiation oncologists believe that Electronic Brachytherapy is an exciting new radiation therapy technology for the treatment of cancer. And, a solid majority said that once Electronic Brachytherapy received clearance from the FDA they would likely incorporate the technology into their practice.

"Xoft's proprietary Electronic Brachytherapy was designed to leverage the clinical benefits of both traditional brachytherapy and external beam radiation while reducing the time required to deliver the therapy," said Michael Klein, Xoft CEO and president. "In the same way that linear accelerators made cobalt radiation therapy obsolete more than a generation ago, Electronic Brachytherapy has significant potential to make many isotope based modalities obsolete. The result is a powerful new tool that will help breast surgeons and radiation oncologists work together to provide the best possible therapy with the greatest clinical outcomes for breast cancer patients."

About Xoft, Inc.

Xoft is developing leading-edge new technologies for the practice of radiation oncology through Electronic Brachytherapy, which utilizes proprietary miniaturized X-ray tube technology. The Axxent Electronic Brachytherapy System, Xoft's first treatment system, is designed for use in Accelerated Partial Breast Irradiation for the treatment of early stage breast cancer. This solution provides a therapeutic dose of intracavitary radiation directly to the region at risk without the complex handling and resource logistics necessary when performing brachytherapy using radioactive isotopes.

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