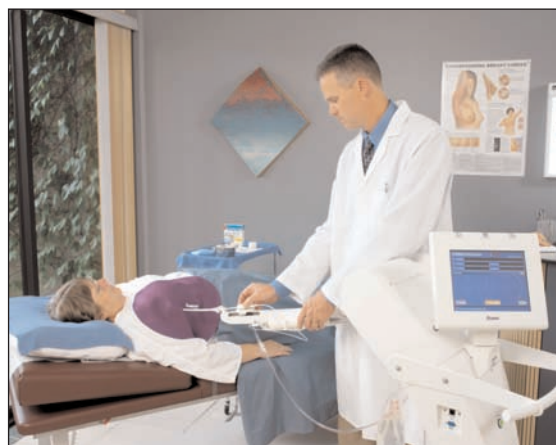


## **AXXENT® ELECTRONIC BRACHYTHERAPY SYSTEM REVOLUTIONARY NEW TECHNOLOGY WILL CHANGE THE WAY BREAST RADIATION THERAPY IS DELIVERED**

**E**lectronic Brachytherapy represents a dramatically new way to deliver radiation therapy. It is a concept that combines the benefits of radiation delivered from within the body with the concept of linear accelerators. Xoft, Inc. (Fremont, CA), has received clearance from the FDA for its **Axxent® Electronic Brachytherapy System** which is currently indicated for use in Accelerated Partial Breast Irradiation (APBI) following lumpectomy for treatment in early stage breast cancer. Other indications are currently under development. It utilizes a proprietary miniaturized x-ray source designed to deliver a therapeutic, non-radioactive, isotope-free radiation dose directly to a tumor bed within the body. Because it is non-radioactive, the Axxent System does not require the complex handling or heavy environmental shielding logistics that are associated with conventional high dose rate (HDR) brachytherapy or powerful linear accelerators.

The Axxent System is designed to give radiation oncologists the flexibility to deliver radiation at multiple energy levels. Vivek Mehta, MD, Director of the Center of Advanced Targeted Radiation Therapy at the Swedish Cancer Institute (Seattle, WA), finds that “Xoft has created a system that allows delivery of very low energy x-rays in an on/off manner—that is not radioactive. This makes it a particularly appealing device.” Dr. Huan B. Giap, MD, PhD, Radiation Oncologist, Scripps Clinic (San Diego, CA) agrees with Dr. Mehta: “This is a brand new concept that will basically enhance the way that we give radiation treatment. The Axxent System has a man-made radiation source that gives us more control. We can create the radiation when we want it and we can create how much we want.”



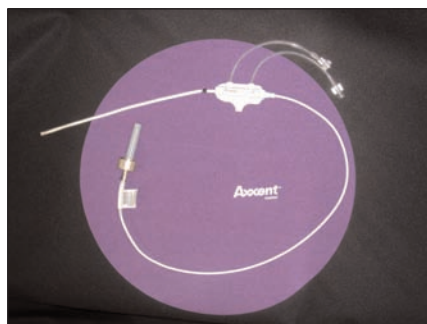
In the region targeted for therapy, the radiation from the Axxent System source is designed to mimic <sup>192</sup>Ir, generally considered to be the gold standard for HDR brachytherapy. Unlike Iridium, radiation is greatly attenuated beyond the area under a flexible shielding drape, the Axxent FlexiShield, which will make it safe for radiation treatment staff to be present with minimal additional shielding. Dr. Mehta notes that the Axxent System “looks to be very similar to what Iridium would do if you were to take a small pellet of it and drop it in the same spot. The difference is with radioactive Iridium, you have to store it in-between treatments and you would need special shielding around the room because it is constantly giving off decay, whether or not you are treating.” The Xoft electronic brachytherapy procedure, on the other hand, can take place in any ordinary outpatient treatment room with no concern about active isotope decay, handling, or disposal. Dr. Giap notes: “The way the system was designed makes it not only safer for the patient, but also “friendlier” than traditional brachytherapy. The personnel who operate the system can be in the room with the patient, and this could have a positive psychological effect on the patient.” Additionally, when you no

longer have shielding requirements, the Axxent System also becomes portable, which will allow it to be used in a broader range of clinical settings. According to Dr. Giap, “the mobility of the system can potentially give radiation oncologists and surgeons an additional tool to perform intra-operative radiation therapy during the surgery to enhance the local control.” The faster dose fall-off beyond the therapeutic prescription point should also have the added effect of minimizing radiation exposure of healthy tissue and nearby organs.

Laboratory analysis and benchtop measurements have shown that the Axxent System is very effective in terms of safety and administration of the radiation dose, and Mark McLaughlin, MD, Radiation Oncologist, Wellstar Kennestone Hospital (Marietta, GA), says that now we have to see if it will work well in human patients. “We think it's going to be a potential breakthrough. It's the same type of radiation that's done with HDR brachytherapy, but the radiation is generated differently. In the animal and phantom models, the radiation dose to the actual tumor bed is exactly the same as what we get with HDR brachytherapy, so we feel that we are going to see a very similar outcome as we would see with other radiation equipment.”

Radiation therapy, used to treat cancer for more than a century, is administered after breast-sparing surgery to kill stray cancer cells

that might remain in the breast. Radiation has been proven to reduce the rate of local recurrences and improve long-term survival. Data from several randomized controlled clinical studies has demonstrated that radiation used after Breast Conservation Surgery is a necessary component of treating breast cancer when the patient wishes to conserve her breast with lumpectomy surgery as opposed to undergoing a full mastectomy, with a survival rate equivalent to mastectomy (1). With the minimally invasive APBI procedure, studies have shown that with a




treatment time reduced from seven weeks to five days (as compared with whole-breast, external-beam radiation) and with proper patient selection and quality assurance, the five-year recurrence rate for APBI is less than 5 percent (2). Recent studies have also shown, however, that many patients chose not to receive radiation therapy because of problems accessing radiation therapy centers. Dr. McLaughlin believes that the Axxent System will make radiation a convenient option for those patients. “In the past, patients had to drive many miles to have this technology and now they won't have to. The Axxent System is going

to be significantly less expensive to start up because clinics won't have to worry about the high cost associated with shielding, special housing or regulatory requirements. That will be a huge advantage to clinics in smaller towns or communities.”

As a platform technology, the Axxent Electronic Brachytherapy System can potentially be adjusted to mimic the penetration and dose rate characteristics of a variety of isotopes and will ultimately be able to treat a variety of anatomies with highly targeted radiation.

### About Xoft

Xoft, Inc. is a privately-held medical device company developing and commercializing revolutionary miniaturized electronic brachytherapy technology. The Company is dedicated to improving patients' lives by providing high quality, innovative, safe and effective medical products for use in radiation oncology applications. 

For more information about The Axxent Electronic Brachytherapy System, please call 1-877-963-8327; contact a company representative at ASTRO, booth #951; or visit the company's Web site at [www.xoftinc.com](http://www.xoftinc.com).

### References:

1. Fisher B, *et al.* Twenty-year follow-up of a randomized trial comparing total mastectomy, lumpectomy, and lumpectomy plus irradiation for the treatment of invasive breast cancer. *N Engl J Med.* 2002;347(16):1233-1241.
2. Arthur DW, *et al.* Accelerated partial breast irradiation: an updated report from the American Brachytherapy Society. *Brachytherapy.* 2002;1(4):184-190.