

# Leading global centers select the Xoft System for treatment of early-stage breast cancer

Multiple factors including clinically-proven efficacy, shorter treatment time, greater flexibility, easy portability and lower cost drive adoption

## IORT Benefits

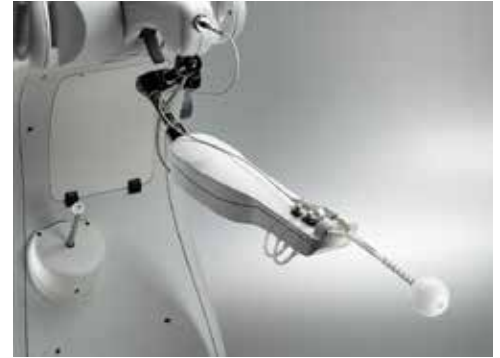
- Targeted treatment
- Fewer side effects compared to traditional treatment<sup>3</sup>
- Reduced costs
- Increased convenience
- Improved quality of life

## Results with the Xoft System

- Eliminates the need for 6-8 weeks of EBRT
- Accelerated 8-10 minute treatment time increases operational efficiency and patient satisfaction
- Highly mobile platform system offers superior flexibility and versatility
- Miniaturized x-ray source delivers precise therapy, minimizing dose to surrounding healthy tissue
- Multiple sizes of flexible, disposable balloon applicators optimize targeted treatment and reduce risk of infection

## Driving excellence in patient-centric, value-based care

Advances in technology continually inspire healthcare leaders to identify and evaluate alternative technologies that expand and improve the treatment options they offer patients. One innovative technology on the market today is intraoperative radiation therapy (IORT), a radiation treatment that delivers a full course of targeted radiation inside the body, directly within the tumor cavity at the time of lumpectomy.



Four renowned experts in the treatment of early-stage breast cancer recently adopted the Xoft® Axxent® Electronic Brachytherapy (eBx®) System® at their hospitals. Their decision to utilize the Xoft System highlights the many valuable advantages of this revolutionary technology for breast cancer treatment centers dedicated to providing the highest quality care for their patients. To date, more than 50 cancer treatment centers around the world have adopted Xoft IORT, including many that transitioned to the Xoft System after using alternative IORT options.

## Challenges

### Patient compliance issues with external beam radiation therapy (EBRT)

- Multiple doses of radiation administered over several weeks with EBRT
- To avoid challenges and stressors of EBRT, patients may elect a mastectomy rather than breast-conserving surgery, or fail to comply with follow-up treatment.<sup>1,2</sup>
- Longer treatment times, less flexibility and mobility with alternative IORT options
- Leading breast cancer treatment centers seeking to provide their patients with the widest range of proven-effective options for their care

## Solution

The Xoft System delivers the advantages of IORT with proven efficacy, superior flexibility, mobility, and lower cost.

The Xoft System is FDA cleared, CE marked and licensed in a growing number of countries for the treatment of cancer anywhere in the body, including treatment of early-stage breast cancer, gynecological cancers and non-melanoma skin cancer.





## Martin Health System, Stuart, FL

### Dr. Craig Wengler

*"During my fellowship at Cleveland Clinic, my team used a competing IORT technology, however when I came to Martin Health System, we initiated the switch to use the Xoft System because of the reduced treatment time, cost and flexibility."*

*"Due to the efficiency of the disposable applicator and the precision of IORT, I am able to perform multiple cases back-to-back."*

*"The Xoft System's portability allows me to treat more patients within a given day."*

Craig Wengler, MD  
Breast Surgeon

Martin Health System is a not-for-profit, community-based health care organization with 13 locations throughout Martin and St. Lucie Counties in South Florida. Dr. Wengler, as a breast surgical oncologist with the Robert and Carol Weissman Cancer Center at Martin Health, regularly treats patients with early-stage breast cancer. In search of an innovative, cost-effective solution to enhance the hospital's portfolio of breast cancer treatment offerings, Dr. Wengler adopted the Xoft System in 2015.



Martin Health System, Stuart, FL

*"During my fellowship at Cleveland Clinic, my team used a competing IORT technology, however when I came to Martin Health System, we initiated the switch to use the Xoft System because of the reduced treatment time, cost and flexibility," said Dr. Wengler. "Due to the efficiency of the disposable applicator and the precision of IORT, I am able to perform multiple cases back-to-back."*

The Xoft System's balloon-shaped applicators are individually wrapped for sterility and the range of applicators may be filled with varying volumes of saline to best fit the contour of the surgical cavity and allow delivery of a more conformal radiation dose. Eliminating the need for sterilization often reduces time between cases. The Xoft IORT Atlas provides surgeons with 33 pre-calculated (TG-43) plans, compared to alternative technologies that offer limited size options.

In comparing technologies, Dr. Wengler found that treatment with some IORT options can take up to 35 minutes, while the course of treatment with Xoft is usually completed in only 8-10 minutes. The Xoft technology also features a proprietary, miniaturized x-ray source that is extremely flexible, durable and stable. The compact size of the Xoft System means that it can be easily transferred to multiple locations within the hospital system. Dr. Wengler noted, "The Xoft System's portability allows me to treat more patients within a given day." Other IORT technologies feature a larger x-ray source and heavier equipment that is fragile and cannot be easily relocated.



## Monash Cancer Centre, a partnership between Peter MacCallum Cancer Centre & Monash Health Victoria, Australia

Dr. Steven David and Dr. Jane Fox

*"We are thrilled to adopt a system that can be used for the treatment of cancer anywhere in the body and look forward to pursuing other IORT applications in the future."*

Dr. Steven David,  
Radiation Oncologist

*"We are encouraged by the research to date as the global community of treatment centers continues to provide appropriate patients with the unique option to complete a full dose of radiation therapy in a single treatment."*

Dr. Jane Fox, Director,  
Breast Services

Monash Cancer Centre at Moorabbin Hospital is a key provider within Monash Health – Victoria, Australia's largest health service. The Monash Cancer Centre provides more than 1.5 million residents of southern Melbourne with access to world leading cancer treatment, and integrates services from Peter MacCallum Cancer Centre and Monash Health in one convenient location. Seeking to strengthen their distinguished reputation as a front-runner in cancer treatment, Dr. Steven David, Radiation Oncologist, and Dr. Jane Fox, Director, Breast Services, made a collaborative decision to implement the Xoft System in early 2017, making them the first hospital to offer IORT with the Xoft System in Australia.



Having used another IORT option in the past, Dr. David, radiation oncologist, outlined the key differentiators that led to his decision to adopt the Xoft System. "The technology's minimal shielding requirements and small footprint allow it to be easily transported between multiple departments, enabling us to treat patients across a range of clinical indications," said Dr. David. "In our detailed review of the available radiation therapy solutions, the Xoft System's distinguished versatility across a variety of clinical applications, mobility, and unique patient benefits made it the preeminent solution for our practice. We are thrilled to adopt a system that can be used for the treatment of cancer anywhere in the body and look forward to pursuing other IORT applications in the future."

Dr. Fox, breast surgeon, explained how the Xoft System underscores the facility's commitment to providing optimal quality of care to their patients. "IORT offers women with early-stage breast cancer another therapeutic option, and, we believe, a better patient experience with less treatment morbidity, and a more rapid return to normal activity. We hope the breast service, and other Monash Cancer Centre tumor services, will be able to contribute to understanding the use of this technology in other disease types and stages," said Dr. Fox. "We are encouraged by the research to date as the global community of treatment centers continues to provide appropriate patients with the unique option to complete a full dose of radiation therapy in a single treatment."



## Lutheran Hospital, Fort Wayne, IN

### Dr. Rachael Hayes

*"Since IORT with the Xoft System delivers radiation directly into the tumor cavity in minutes, my patients spend less time under anesthesia and we are able to complete more cases in a day."*

*"I specifically appreciate the advantages of the balloon applicators. Compared to other IORT technology I have utilized in the past, these applicators offer superior flexibility in precisely fitting the cavity to ensure conformal radiation dose."*

Dr. Rachael Hayes,  
Breast Surgeon

Lutheran Hospital is a 365-bed tertiary care facility in Northern Indiana that has been in operation since 1904. Dr. Rachael Hayes, a breast oncology surgeon who joined Lutheran in August 2015, previously used an alternative IORT option with her patients. After a review to identify the best system for Lutheran, she also concluded that the Xoft System provided several superior advantages and adopted the technology in 2016.



IORT with the Xoft System offers patients a safe and effective solution with a number of unique benefits including added convenience, reduced costs and fewer side effects," said Dr. Hayes. "With more targeted and efficient treatment, patients are able to return to their normal lives more quickly."

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A growing body of favorable clinical data supports the use of IORT in patients meeting specific selection criteria.<sup>3,4</sup> Lutheran Hospital is one of 27 centers, including Martin Health System and Monash Cancer Centre, participating in the largest clinical trial to-date of IORT using the Xoft System. The study compares IORT with the Xoft System to traditional radiation therapy in 1,200 patients. Early results have demonstrated low rates of recurrences and high-grade adverse events with excellent to good cosmesis two year post-treatment.<sup>5</sup>

**References:** 1. William F. Athas, et al. New Mexico Tumor Registry, University of New Mexico Health Sciences Center, Albuquerque. Travel Distance to Radiation Therapy and Receipt of Radiotherapy Following Breast-Conserving Surgery. Journal of the National Cancer Institute, Vol. 92, No. 3, February 2, 2000. 2. Vaidya A, et al. PCN148 Cost Effectiveness Analysis of Targeted Intraoperative Radiotherapy Alone (TARGIT-A) in Early Breast Cancer Patients: Value In Health 17 (2014) A323–A686. TARGIT-A Trial performed with Carl Zeiss Meditec AG IntraBeam System. 3. Epstein M, et al. Acute and Chronic Complications in Breast Cancer Patients Treated with Intraoperative Radiation Therapy. Ann Surg Oncol. 2016 Oct;23(10):3304-9. 4. M Silverstein, et al. Intraoperative Radiation Using Low-Kilovoltage X-Rays for Early Breast Cancer: A Single Site Trial. The Annals of Surgical Oncology; August 2017 Online. 5. Syed N, et al. Electronic Brachytherapy at the Time of Breast Conservation Surgery for Early-Stage Breast Cancer: Early Follow-up Results of a Non-randomized, Multi-center Trial. Presented at ASTRO 2017