

# Treating with eBx



## Data Collection Study for the Treatment of Endometrial Cancer Using FDA-Cleared Xoft Axxent® Electronic Brachytherapy System®

### STUDY DESIGN

Multicenter, non-randomized, data collection study to evaluate the acute safety and performance of the FDA-cleared Axxent® Electronic Brachytherapy System® and vaginal applicator for intracavitary vaginal cuff treatment.

### SAMPLE SIZE

Up to approximately fifteen (15) patients.

### SITES

Up to ten (10) U.S. sites.

### PRIMARY ENDPOINTS

#### Device Performance

- Assess number of patients who were able to complete treatment delivery using the Xoft Axxent Electronic Brachytherapy System.

#### Safety

- Adverse events that occur during the administration of vaginal brachytherapy treatment and immediately following brachytherapy prior to discharge from the treatment facility, and at one month and three months after completion of the brachytherapy treatment.

### TREATMENT DEVICE

The device to be used is the Axxent Electronic Brachytherapy System for the treatment of endometrial cancer. The system includes the X-ray source, controller and the vaginal applicator. The device manufacturer is Xoft, Incorporated. All Xoft technology cleared by the FDA for the treatment of endometrial cancer can be used in this data collection study.

### PRINCIPAL INVESTIGATOR

Adam T. Dickler, M.D.  
Little Company of Mary Hospital  
Evergreen Park, IL

### SPONSOR

Xoft, Inc.

### Treatment Planning

#### 2D Treatment Planning Requirements for Brachytherapy

2D treatment planning may be performed according to the standards of the treating institution. All dosimetric data will be acquired from reproducing the 2D plan used to treat the patient for the first fraction onto the CT scan. 2D planning will be completed for each fraction.

#### 3D Treatment Planning Requirements for Brachytherapy

In addition, for all sites, including those who perform 2D treatment planning as their standard for study purposes, CT-based 3D treatment planning data is required for all patients.



## Brachytherapy Treatment

### BRACHYTHERAPY ALONE WITHOUT EXTERNAL BEAM RADIATION THERAPY TREATMENT

If vaginal brachytherapy is administered as the sole treatment for early-stage endometrial cancer, the following treatment options apply:

Treatment Options for Brachytherapy Alone		
Number of Fractions	Dose Per Fraction (Gy)	Prescription Point
3	7.0	0.5 cm depth
4	5.5	0.5 cm depth

*Approximately the upper half, fifty percent of the proximal length of the vagina (or approximately 5 cm of the length of the vagina depending on the patient's anatomy) will be treated.*

### BRACHYTHERAPY & EXTERNAL BEAM RADIATION THERAPY (EBRT) TREATMENT

If vaginal brachytherapy is administered in combination with external beam radiation therapy for early stage endometrial cancer, they will be treated with 45 Gy of external beam radiation and the vaginal brachytherapy prescription when combined with EBRT will be prescribed to the vaginal surface using one of the two treatment options below:

Treatment Options for Brachytherapy Combined with EBRT			
EBRT @ 1.8 Gy Per Fraction	Number of Brachytherapy Fractions	Brachytherapy Dose Per Fraction (Gy)	Prescription Point
45	2	8.0	Vaginal Surface
45	3	6.0	Vaginal Surface

*Approximately the upper half, fifty percent of the proximal length of the vagina (or approximately 5 cm of the length of the vagina depending on the patient's anatomy) will be treated.*

## PATIENT SELECTION

Patients that are candidates for vaginal cuff brachytherapy alone, based upon the treating physician's medical judgment, are eligible to participate in this study. This includes patients with certain Stage I and Stage II endometrial cancers and may include patients who require EBRT and/or chemotherapy. Specific inclusion criteria and exclusion criteria are listed below.

### INCLUSION/EXCLUSION CRITERIA

#### Inclusion Criteria

- Any type of endometrial (uterine) cancer Stage I and Stage II
- Post-hysterectomy

#### Exclusion Criteria

- Endometrial (uterine) cancer Stage IA Grade 1
- Scleroderma
- Collagen vascular disease
- Active lupus

For more information, visit [www.xoftinc.com](http://www.xoftinc.com)

345 Potrero Ave. Sunnyvale, CA 94085 USA • 408.419.2300 • 877.963.8327 • Fax 408.419.2301

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Xoft, Inc. is actively seeking qualified sites to participate in this landmark study. If you are interested, please contact:

**Kelly W. Elliott, RN, MS**  
Vice President, Clinical Affairs

Xoft, Inc., 345 Potrero Ave.,  
Sunnyvale, CA 94085

Cell: 719-640-4197

[Kelliott@xoftinc.com](mailto:Kelliott@xoftinc.com)

