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.

TREATMENT PLANNING

2D Treatment Planning
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
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.

PRINCIPAL INVESTIGATOR
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SPONSOR
Xoft, Inc.
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:

<table>
<thead>
<tr>
<th>Treatment Options for Brachytherapy Alone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Fractions</td>
</tr>
<tr>
<td>----------------------</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Treatment Options for Brachytherapy Combined with EBRT</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBRT @ 1.8 Gy Per Fraction</td>
</tr>
<tr>
<td>----------------------------</td>
</tr>
<tr>
<td>45</td>
</tr>
<tr>
<td>45</td>
</tr>
</tbody>
</table>

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

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