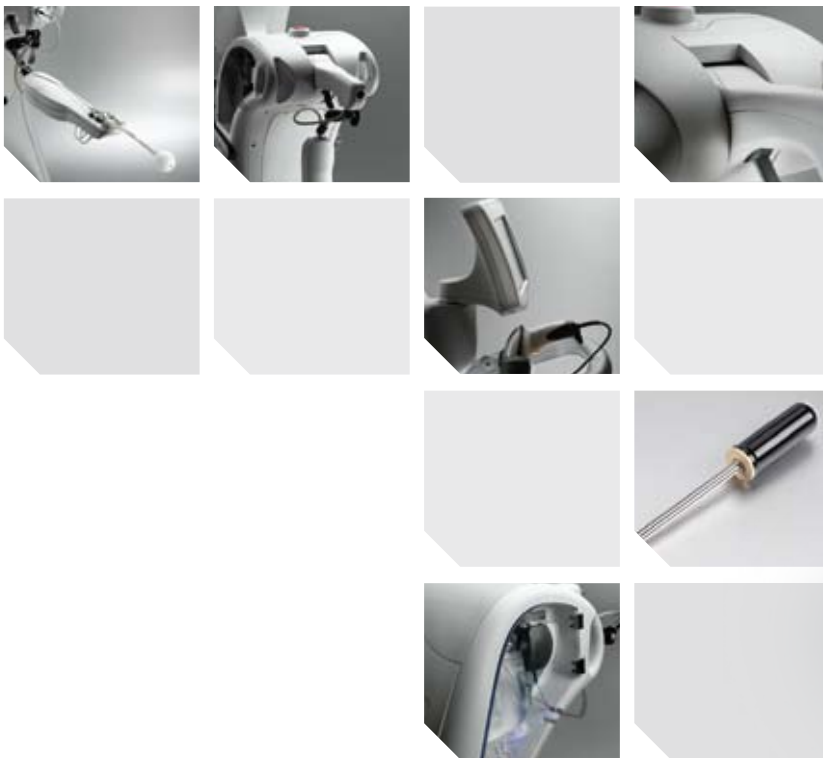


## > **Axxess with Axxent**

Innovative technology for the practice of radiation oncology



# Axxent

Electronic Brachytherapy System®

## Platform Technology

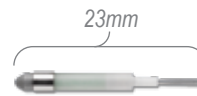
The Axxent Electronic Brachytherapy System is a leading-edge technology that utilizes a proprietary miniaturized X-ray source to apply radiation directly to a tumor bed within the body. The Axxent System may be used for accelerated partial breast irradiation in the treatment of early-stage breast cancer and for irradiation in endometrial cancer treatment.

The Axxent X-ray Source mimics certain characteristics of the most common HDR brachytherapy isotope  $^{192}\text{Ir}$ . The unique combination of high dose rate and low energy radiation offered by the Axxent HDR X-ray Source enables the procedure to be done under the supervision of a radiation oncologist in a minimally shielded setting. This allows providers and patients increased access to brachytherapy treatment.

The Axxent Electronic Brachytherapy System will allow for easy incorporation of additional applications.



Axxent Controller



Miniaturized X-ray source, shown actual size



## Product Overview



Axxent HDR X-ray Source



Axxent Balloon Applicator

## Advanced Technology

An estimated 250,230<sup>1</sup> women in the U.S. alone will be diagnosed with breast cancer in 2008. Because most of these women have their breast cancer detected at an early localized stage, they can be offered the choice of Breast Conserving Therapy over mastectomy. Recent data<sup>2,3</sup> has shown promising results with new radiation techniques that make it easier for patients to comply with their radiation therapy requirements after lumpectomy surgery.

Additionally, an estimated 38,897<sup>1</sup> women in the U.S. will be diagnosed with endometrial cancer in 2008.

The Axxent System by Xofig, Inc., offers an advanced radiation treatment option that is easier, faster, and more accessible to patients and providers than many other currently available choices:

- No radioactive isotopes
- Potentially minimizes exposure to healthy tissue
- Minimal room shielding requirements
- Low barrier to entry
- On/off capability for enhanced radiation safety

## Clinical Evidence

The Axxent System provides a therapeutic dose to radiation directly to the region at risk. The relatively lower energy radiation minimizes exposure to surrounding healthy tissue beyond the prescription point<sup>4</sup>.

## Comparative Treatment Volume Doses to Breast Tissue

| Treatment Volume Dose                       |  |                            |                           |
|---|--|----------------------------|---------------------------|
|   | Dickler et al <sup>1</sup>                             | Dickler et al <sup>1</sup> | Smitt, Kirby <sup>2</sup> |
|   | Balloon Applicator with <sup>192</sup> Ir Seed Stepped | Axxent 50kV X-ray Stepped  | Axxent 50kV X-ray Stepped |
| PTV (cc)                                    |  |                            | 98-123                    |
| PTV Coverage (% V100)                       | 96.5%  | 96.5%                      | 90.0%                     |
| V100 (cc)                                   | 83.6   | 83.6                       | 89-112                    |
| V150 (cc)                                   | 36.2   | 51.4                       | 45-51                     |
| V200 (cc)                                   | 9.8  | 27.7                       | 19-22                     |
| Ipsilateral Breast V50 (17 Gy) <sup>1</sup> | 19.8%  | 13.0%                      | P<0.05                    |
| Ipsilateral Lung V30 (10.2 Gy) <sup>1</sup> | 3.7%   | 1.1%                       |                           |
| Heart V5 (0.17 Gy) <sup>1</sup>             | 59.2%  | 9.4%                       |                           |

<sup>1</sup> Dickler et al, A Dosimetric Comparison of MammoSite HDR Brachytherapy and Axxent Electronic Brachytherapy, Brachytherapy 6 (2007) 164-168.  
<sup>2</sup> Smitt & Kirby, Dose-volume characteristics of a 50kV source for intracavitary accelerated partial breast irradiation. Brachytherapy 6 (2007) 207-211.



Axxent FlexiShield



Vaginal Applicator Set



Clamp and Base Plate

| Axxent Vaginal Applicator Set – Specifications   | Part Number |
|--|-------------|
| <b>Available Diameter/Length</b>   |             |
| Vaginal Applicator Set:<br>(Includes 4 applicators, source channels and carrying case) | AG3000      |
| Vaginal Applicator – diameter 20 mm, length 102 mm                                     | AG3020      |
| Vaginal Applicator – diameter 25 mm, length 103 mm                                     | AG3025      |
| Vaginal Applicator – diameter 30 mm, length 106 mm                                     | AG3030      |
| Vaginal Applicator – diameter 35 mm, length 107 mm                                     | AG3035      |
| Source Channel – length 15.9 cm  | E1000       |

| Axxent Balloon Applicator–BR Specifications   | Part Number |
|---|-------------|
| <b>Available Diameter/Volume</b>  |             |
| • 3-4 cm Spherical Balloon Applicator/30-45 cc  | AB2034      |
| • 4-5 cm Spherical Balloon Applicator/45-75 cc  | AB2045      |
| • 5-6 cm Spherical Balloon Applicator/65-130 cc   | AB2056      |
| • 5x7 cm Ellipsoidal Balloon Applicator/90-125 cc (Available at a later date)   | AB2057E     |
| • 6x7 cm Ellipsoidal Balloon Applicator/120-160 cc (Available at a later date)  | AB2067E     |
| <b>Multi-Lumens</b>   |             |
| <ul style="list-style-type: none"> <li>• Seroma Drainage Lumens</li> <li>• Balloon Inflation Lumen</li> <li>• 50 Kv X-ray Source Insertion</li> </ul> |             |
| <b>Markings</b>   |             |
| <ul style="list-style-type: none"> <li>• 1 cm intervals along shaft</li> </ul>  |             |

| Axxent Controller Specifications | Part Number                    |
|----------------------------------|--------------------------------|
| Axxent Controller                | XP1100                         |
| High Voltage Output              | 50 kV (selectable)             |
| Beam Current                     | 300 µA                         |
| <b>Dimensions</b>                |                                |
| Height                           | 52 in (133 cm)                 |
| Width                            | 21 in (53 cm)                  |
| Depth                            | 31 in (79 cm)                  |
| Weight                           | 202 lb (92 kg)                 |
| Maximum Inclination              | 10 degrees                     |
| <b>Power Specifications</b>      |                                |
| Line Power                       | 100-120V~, 220-240 V~, 150 VA  |
| Ion Calibration Chamber          |                                |
| Manufacturer/Model               | Standard Imaging/HDR 1000 Plus |
| Electrometer                     |                                |
| Manufacturer/Model               | Standard Imaging/Max 4000      |

| Axxent HDR X-ray Source 2.2 Specifications   | Part Number                |
|--|----------------------------|
| Axxent HDR X-ray Source  | S7500                      |
| X-ray Tube Diameter  | 2.25 mm                    |
| Assembly Length  | 250 mm                     |
| Assembly Diameter  | 5.4 mm                     |
| X-ray Source Power   | 15 watts                   |
| Typical Treatment Time   | 10 min                     |
| Maximum Number of Treatments per X-ray Source  | 10                         |
| <b>Source Includes</b>   |                            |
| <ul style="list-style-type: none"> <li>• Integral water cooling sheath</li> <li>• Low-force high-voltage connector</li> <li>• Flexible high-voltage cable</li> </ul> |                            |
| Nominal Dose Rate  | 0.6 Gy/min @ 3 cm in water |

### 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.

**To order by phone: 877-963-8327**

Xoft, Inc.

345 Potrero Avenue Sunnyvale, CA 94085

408.419.2300 • Fax 866.222.3404

[www.xoftinc.com](http://www.xoftinc.com)

<sup>1</sup> American Cancer Society, Cancer Facts & Figures 2008

<sup>2</sup> Benitez P, Keish, M, Vicini F, Stolier A, Scroggins T, Walker, A, White J, et al. "Five-year results: the initial clinical trial of Mammosite balloon brachytherapy for partial breast irradiation in early-stage breast cancer," American Journal of Surgery 194 (2007) 456-462

<sup>3</sup> Benitez P, Chen P, Vicini F, Wallace M, Kestin L, Edmundson G, et al. Partial breast irradiation in breast-conserving therapy by way of interstitial brachytherapy American Journal of Surgery 188 (2004) 355-364

<sup>4</sup> Dickler, A, Kirk, M, Seif, N, Griem, K, Dowlatshahi, K, Francescatti, D, Abrams, A, "A dosimetric comparison of MammoSite high-dose-rate brachytherapy and Xoft Axxent electronic brachytherapy." *Brachytherapy*, Volume 6, Issue 2, April-June 2007, 164-168

