

Treating with eBx



EXIBT™

Electronic Xoft® Inter-society Brachytherapy Trial

Breast surgeons and radiation oncologists across the country now have an opportunity to participate in a landmark, multi-center national Accelerated Partial Breast Irradiation (APBI) trial. The EXIBT study is the first of its kind to use an independent core lab to evaluate outcomes of patients treated with the Xoft Electronic Brachytherapy System® for:

- Mammographic changes
- Cosmesis

The purpose of the study is to better understand the long-term outcomes in women treated with this accessible, patient-friendly method of APBI. The Xoft Axxent System is FDA cleared for commercial use, so your participation in this study will help us collect data to better assess skin and subcutaneous cosmetic outcomes, and further prove the safety and efficacy of APBI using electronic brachytherapy.

The Oversight Committee, made up of key thought leaders from three societies, will monitor study conduct. The American Brachytherapy Society (ABS), the American Society of Breast Surgeons (ASBrS), and the American College of Radiation Oncology (ACRO), are all represented and will oversee the conduct of this registry.

THE OVERSIGHT COMMITTEE MEMBERS INCLUDE THE FOLLOWING

(IN ALPHABETICAL ORDER):

Douglas Arthur, M.D.	ABS
Peter Beitsch, M.D.	ASBrS (PI)
D. Jeffrey Demanes, M.D.	ACRO
Arve Gillette, M.D.	ACRO
Michael Kinney, M.D.	ASBrS
Henry Kuerer, M.D.	ASBrS
Helen Pass, M.D.	ASBrS
Rakesh Patel, M.D.	ABS (PI)
Frank Vicini, M.D.	ABS
David Wazer, M.D.	ABS & ACRO
James Welsh, M.D.	ACRO
Pat Whitworth, M.D.	ASBrS



STUDY DESIGN

- Prospective enrollment, non-randomized, observational study
- Up to 400 patients
- 50–100 sites
- Annual follow-up through 5 years

STUDY ENDPOINTS

Primary Endpoints

- Subcutaneous toxicities through 5 years
- Skin toxicities through 5 years
- Cosmesis
- QOL assessment

Secondary Endpoints

- Local-regional breast failure at 5 years
- Survival
- Device performance

PATIENT SELECTION: INCLUSION/EXCLUSION GUIDELINES

Inclusion Guidelines

- Patient 50 years of age or older
- Estrogen receptor positive
- Tumor size \leq 3 cm
- Tumor histology: invasive carcinoma or DCIS
- Patient is node negative
- Patient has negative surgical margins
- Life expectancy $>$ 5 years

Exclusion Guidelines

- Pregnancy or breast-feeding
- Collagen Vascular Disease
 - > Scleroderma
 - > Systemic sclerosis
 - > Active lupus
- Infiltrating lobular histology
- Previous ipsilateral radiation to the thorax or breast



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

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