

# Treating with eBx



## Xoft Electronic Brachytherapy Clinical Protocol for the Primary Treatment of Non-Melanoma Skin Cancer

### STUDY NAME

Skin Protocol: CTPR-0002 Rev C – July 2, 2009: Data collection from patients treated with Xoft Electronic Brachytherapy for the treatment of non-melanoma skin cancer (NMSC).

### PRINCIPAL INVESTIGATOR

Ajay Bhatnagar, M.D., MBA - Radiation Oncologist

### STUDY DESIGN

Multi-center, non-randomized, prospective study for the treatment of non-melanoma skin cancer (basal cell carcinoma and squamous cell carcinoma) using Xoft Electronic Brachytherapy as the primary treatment for NMSC.

### SITES

Up to five (5) U.S. sites may participate.

### SAMPLE SIZE

Up to fifty (50) patients may be enrolled.

### PRIMARY ENDPOINTS

1. Local recurrence at six (6) months, one (1) year, two (2) years, three (3) years, four (4) years, and five (5) years.
2. Serious adverse events related to the radiation treatment or treatment device through five (5) year follow-up.

### SECONDARY ENDPOINTS

1. Cosmesis at one (1) month, three (3) months, and six (6) months, and at one (1) year, two (2) years, three (3) years, four (4) years, and five (5) years.
2. Occurrence of radiation therapy-related skin toxicities at one (1) month, three (3) months, six (6) months, and at one (1) year, two (2) years, three (3) years, four (4) years, and five (5) years.

### TREATMENT DEVICE

The device to be used is the Xoft Axxent Electronic Brachytherapy system FDA cleared to deliver high dose rate X-ray radiation for brachytherapy. The FDA-cleared Xoft Axxent surface applicator will be used in conjunction with the Axxent System. Any FDA-cleared shielding may be used if shielding is needed between the applicator and the skin.

### SPONSOR

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### MONITORING

Xoft, Inc.

### STATISTICAL ANALYSES

Warner Statistical Services

### Treatment Options

Prescription Dose	Fractionation Schedule
30 Gy to 64 Gy	2 Gy to 10 Gy per fraction (Administer no more than one fraction per day)

*Note: If the investigator is considering administering more than 3 Gy per fraction, the investigator should consider fraction administration at a minimum of 48 hours apart. The minimum number of fractions will be 8 fractions for all prescription doses for the treatment of NMSC.*



## STUDY CONTACTS

### Principal Investigator

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### Study Sponsor

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

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