**ABSTRACT**

**DEVICE DESCRIPTION**

Electronics (non-isotopic) high dose rate brachytherapy (EHRD) delivers HDR radiating loading to the tumor bed using an internally powered, disposable, flexible, micro-miniature x-ray source integrated into a cooled, flexible, disposable probe.

- A rate of 60-50 keV maximum energy are produced at the tip of the directable probe, which otherwise closely resembles current remote afterloading units.
- The Xoft microTube Flexible X-ray Probe can be inserted directly into tissue or into one or more lumens of an accessible body cavity or excised tumor bed such as with breast cancer or gynecologic cancers.
- The probe is driven by X-ray output from a sealed x-ray tube powered by a high voltage transformer and a current limiting resistor.
- The tip of the directs probe, which otherwise closely resembles current remote afterloading units.
- The balloon applicator: a sterile, disposable, single-use device is designed for the use of a cooled x-ray probe and functions as its guide.

**RESULTS: HISTOLOGY**

- In all early irradiated sections (1 hour – 5 days post-radiation), there was a small increase in apoptosis (ApopTag). This increase in apoptotic levels was no longer present in the later (13-14 day post-radiation) sections. This is a general observation that does not show a clear difference in the early and later sections.

- An increase in proliferation (PCNA) was observed at the later time points (13-14 days post-radiation) and was confined to the ductal epithelium. The wide spread nature of the PCNA stain indicates that the proliferation is part of a normal wound healing response to the radiation and the catheter insertion. See Fig. 6.

**RESULTS: SAFETY**

- Over all, there were no untoward effects directly related or linked to the balloon applicator, source, or radiation treatment in general.

**CONCLUSIONS**

- Two applicator balloons (test and control) were confirmed to the radiation catheter was expanded. Figure 6 shows the irradiation and potential damage irradiated in one animal. This damage was related to the balloon failure or migration.

**DOSIMETRY**

- X-ray chamber readings from each x-ray catheter for each fraction.

- The Xoft microTube balloon applicator with accompanying sources and equipment appears to be safe when implanted in a canine breast tissue model.

- The imaging demonstrated conformity and satisfactory infiltration performance of the device with no evident untoward effects in the surrounding area.

- The histopathology showed evidence for cell death in all cases that was limited to a small fraction of tissue directly surrounding the applicator. Perforation of tissue damage was within a safe range (below 900 microns). This damage is felt to result from the use of a caustic instrument during tissue resection.

**METHODS**

- **Objective**: In vivo clinical study was designed to evaluate the Xoft microTube Flexible X-ray Probe with regard to delivery of therapeutic does in therapeutic time.

- **GLP**: This study was conducted according to Good Laboratory Practice Procedures.

- **Subjects**: Five female New Zealand rabbits were used to provide 10 study fractions.

- **Treatments**: Animals received bilateral balloon implants to both udders. One udder received active radiation treatment and the opposite udder served as control.

- **Study Environment**: The animal was sedated using ketamine/xylazine in the headout position and anesthetized under the surgical light using the surgical light source.