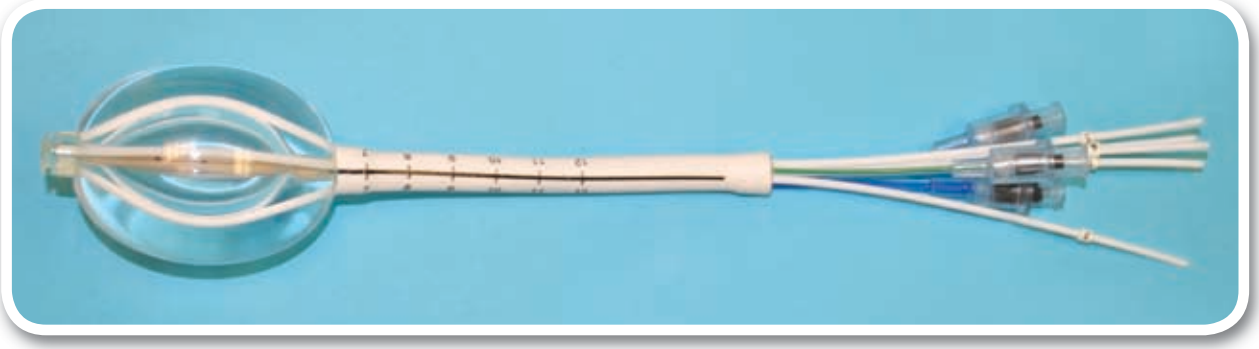
Best® medical international

Best Double-Balloon Breast Brachytherapy Applicator

The Best Double-Balloon Breast Brachytherapy Applicator utilizes an outer balloon to expand within and shape the resection cavity, and an inner balloon which expands independently of the outer balloon. This allows physicians to position 4 treatment catheters within the outer balloon, optimizing both dose conformality and homogeneity.

- Improved dose distribution and conformality
- Less dose to critical organs such as skin, lung, heart, chest wall, etc.
- Convenient to use
- US FDA 510(k) registered



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NOVEL BRACHYTHERAPY BREAST BALLOON APPLICATOR WITH SUPERIOR DOSIMETRY FOR RADIATION DELIVERY

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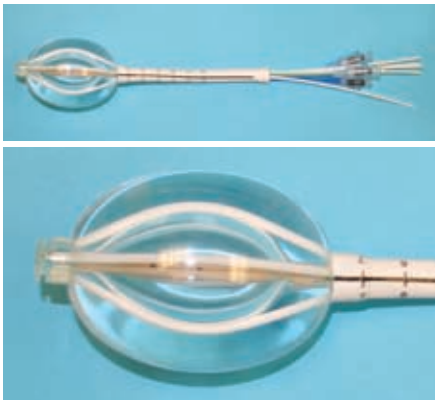
Abstract

Today, in addition to interstitial brachytherapy, two devices are commercially available for Accelerated Partial Breast Irradiation (APBI). The first one is a balloon design that offers multiple treatment catheters at fixed distance from the central catheter which limits the ability of dose avoidance from critical structures like skin and lung. The second design utilizes the treatment catheters as a scaffolding device which expands and shapes the resection cavity. Since the catheters are in direct contact with tissue, radiation doses on contact are extremely high and therefore not optimal. Here, we describe an Avoidance Double Balloon Breast Brachytherapy Device that optimizes radiation dose delivery by shaping the resection cavity with an outer balloon and allowing an inner balloon to position the treatment catheters significantly away from the central axis of the balloon.

Best Double Balloon Breast Applicator



Dosimetric Goals for Double Balloon

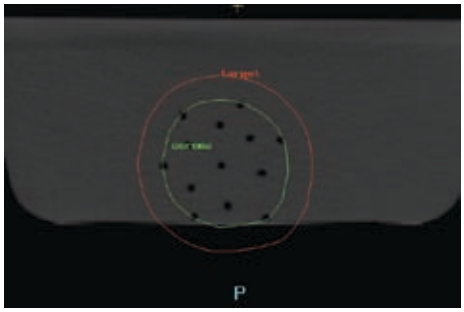
Develop a single entry, multi-catheter system which will be:

- Easy to implant (Contura, Savi)
- Easy to plan (Contura, Savi)
- Have the freedom to conform dose (multi-catheter interstitial)

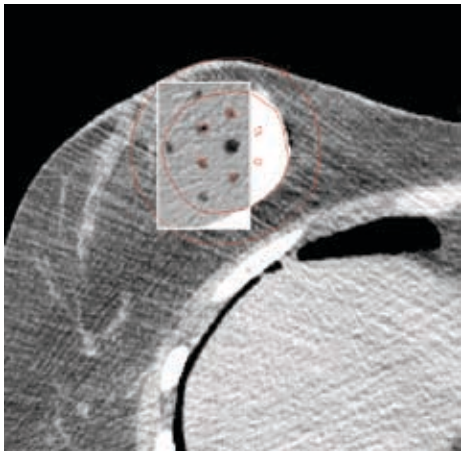
Material and Methods

- CT scan 2 sizes – Small and Large
- Fuse double balloon applicator scan with Contura and Savi patient with same seroma volume
- Compare dosimetric quantities

Defining Seroma and PTV

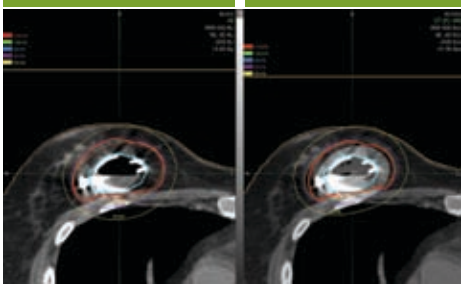


Fusion



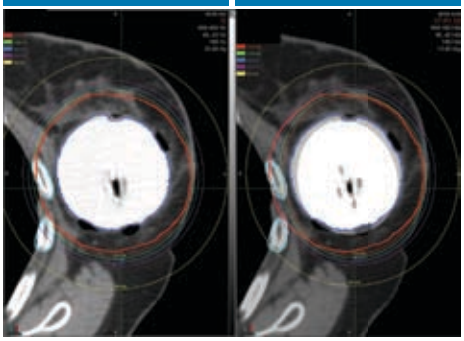
Small Volume Dosimetric Comparison

SAVI | Double Balloon



Large Volume Dosimetric Comparison

Contura | Double Balloon



Dosimetric Quantities used for Comparison

- Percentage target volume covered by prescription
- Dose to critical structures
- Dose Homogeneity Index (DHI) defined as:

$$DHI = \frac{V_{100} - V_{150}}{V_{100}}$$

Large Volume Dosimetric Comparison

Dosimetric Properties	Best Double Balloon Coverage	Contura
Seroma Cavity (cc)	104.6	104.6
PTV (cc)	157.8	157.8
% Seroma Coverage	100%	100%
% PTV Coverage by D90	100%	100%
V100 (cc)	133.5	200.3
V150 (cc)	42.2	66.6
V200 (cc)	11.1	12.5
DHI	0.68	0.67
Rib Dose (D2 cc)	109%	151%

Small Volume Dosimetric Comparison

Dosimetric Properties	Best Double Balloon Coverage	SAVI
Seroma Cavity (cc)	16.1	16.1
PTV (cc)	49.5	49.5
% Seroma Coverage	100%	100%
% PTV Coverage by D90	98%	92%
V100 (cc)	63.4	48.3
V150 (cc)	30.6	23.4
V200 (cc)	16.8	9.5
DHI	0.52	0.51
Rib Dose (D2 cc)	108%	126%

CONCLUSION

- With a multi-catheter system design, Double Balloon has the capability of conforming avoidance of dose to ROI
- Initial results in patients confirm the dosimetry conclusions