

NSABP B-39/RTOG 0413

Surgical Issues

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B-39 Protocol Officer

Questions for the Audience

- How many of you like football?
- How many of you like Boston as a city?
- How many of you are Boston Patriot fans?
- Why?



Patient Characteristics

- Selection criteria
 - Stages 0, I and II breast cancer
 - EIC, young age, lobular histology allowed
 - Negative nodes
 - Positive nodes (1-3)
 - IBC/DCIS \leq 3 cm.
 - No multicentric disease

Patient Characteristics

- Lumpectomy margins: microscopically negative
- Nodes status: 0-3 positive nodes
- Sentinel nodes permitted
 - If negative, no further axillary dissection
 - If positive, axillary dissection required (min. 6 nodes)

Patient Characteristics

- Patients randomized after lumpectomy
- Brachytherapy catheters placed after randomization
- Mammosite® placed after randomization

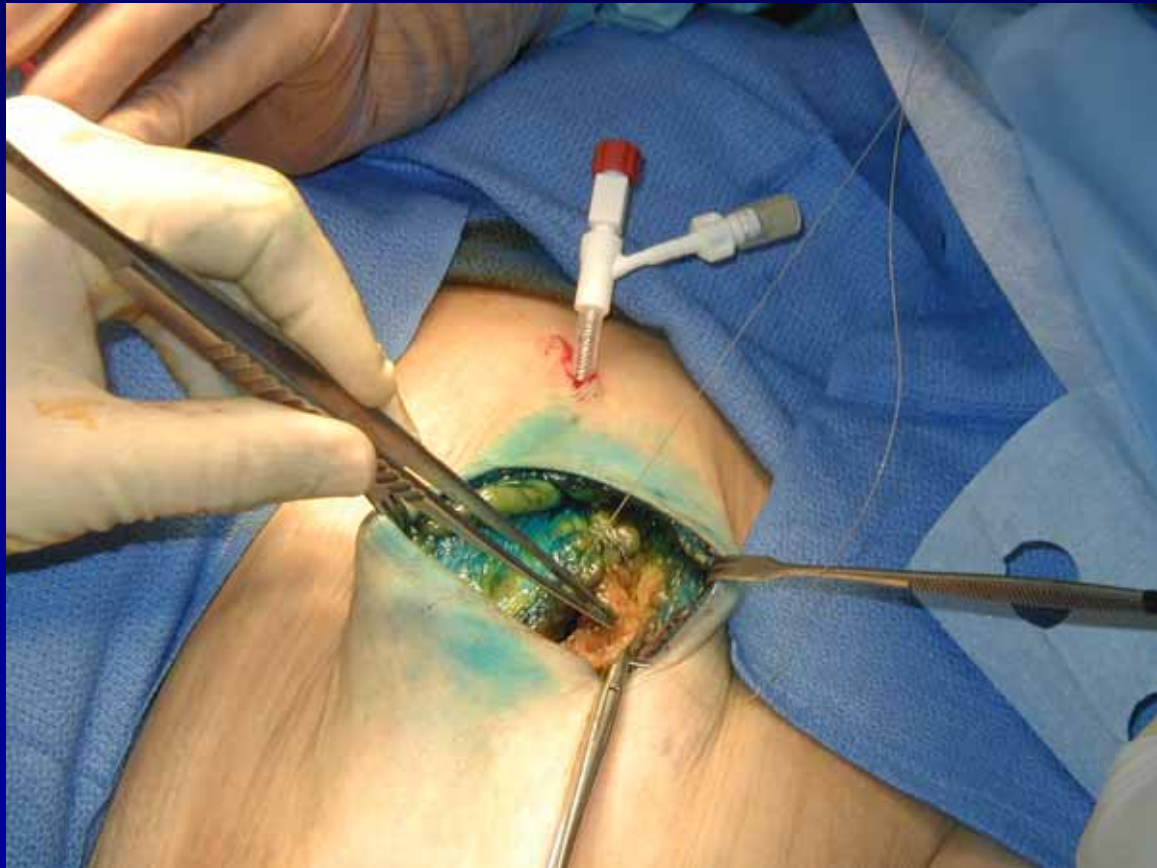
Implantation of Catheter

- Post Lumpectomy
 - Ultrasound assisted in imaging suite
 - Operating room +/- ultrasound
- Methods of Implantation
 - Scar Entry Technique (SET)
 - Lateral
 - Inframammary fold

Lumpectomy



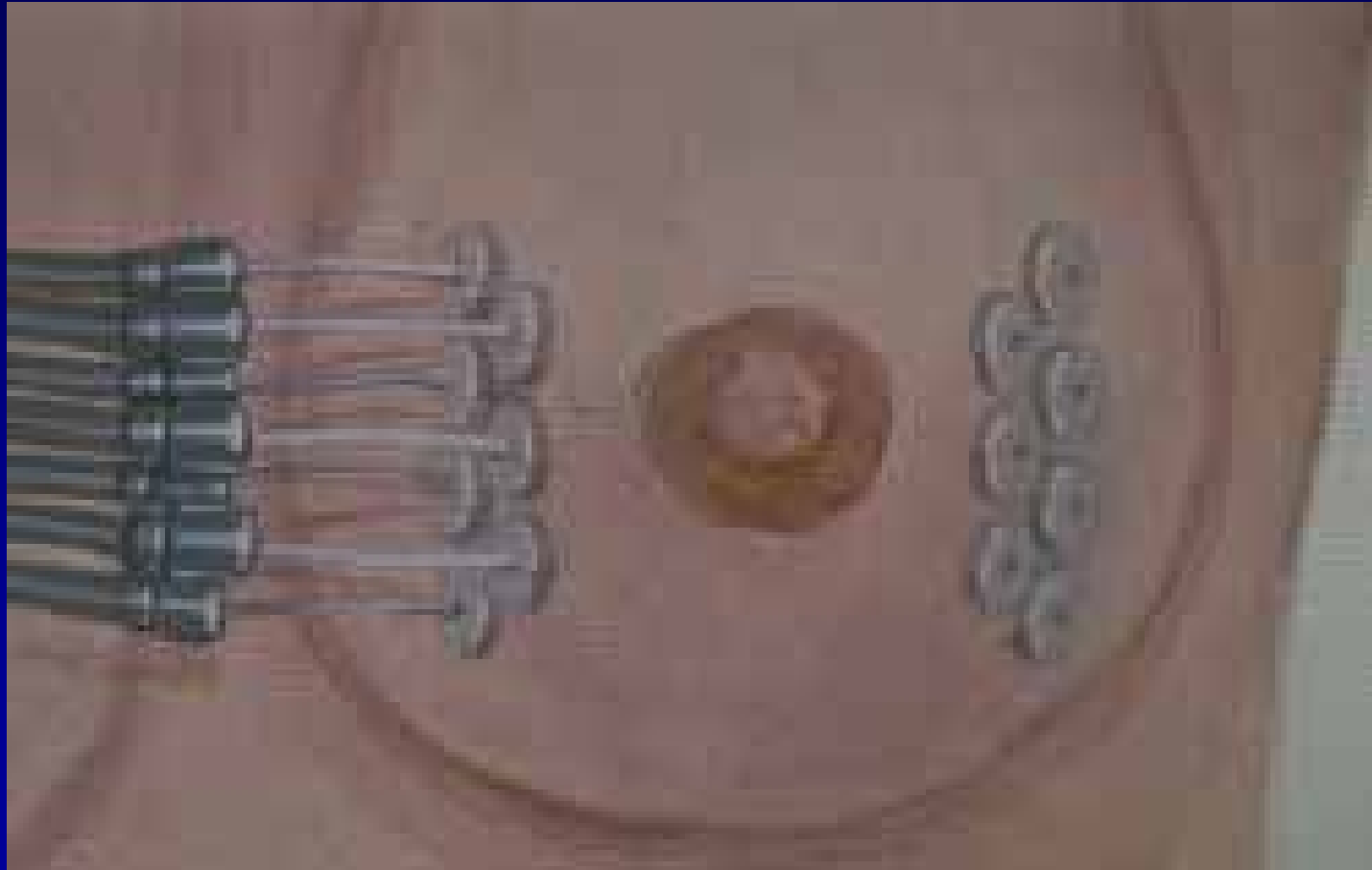
Subcutaneous Closure



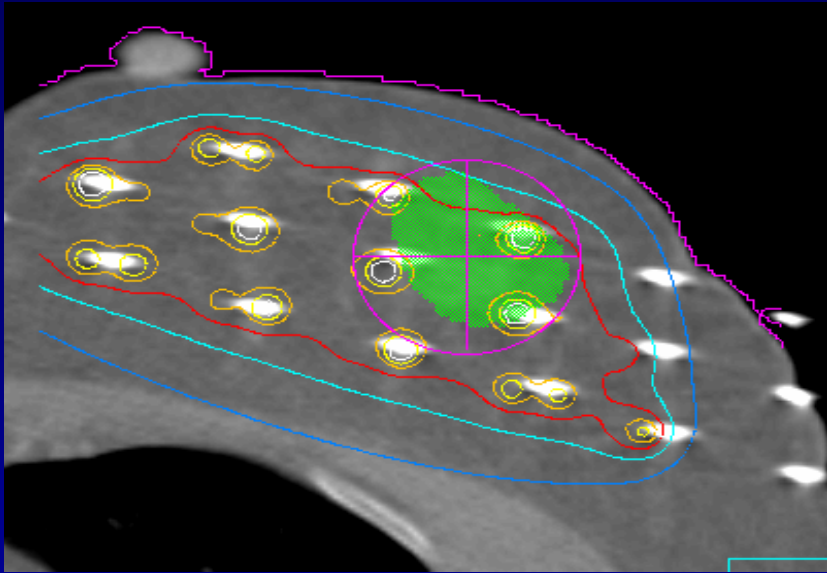
Technical Concerns

- Excise an ellipse of skin routinely or when lesion is more superficial to have a better balloon to skin distance
- Skin distance issues
 - Scar entry technique
 - Collagen injections
 - Different balloon designs

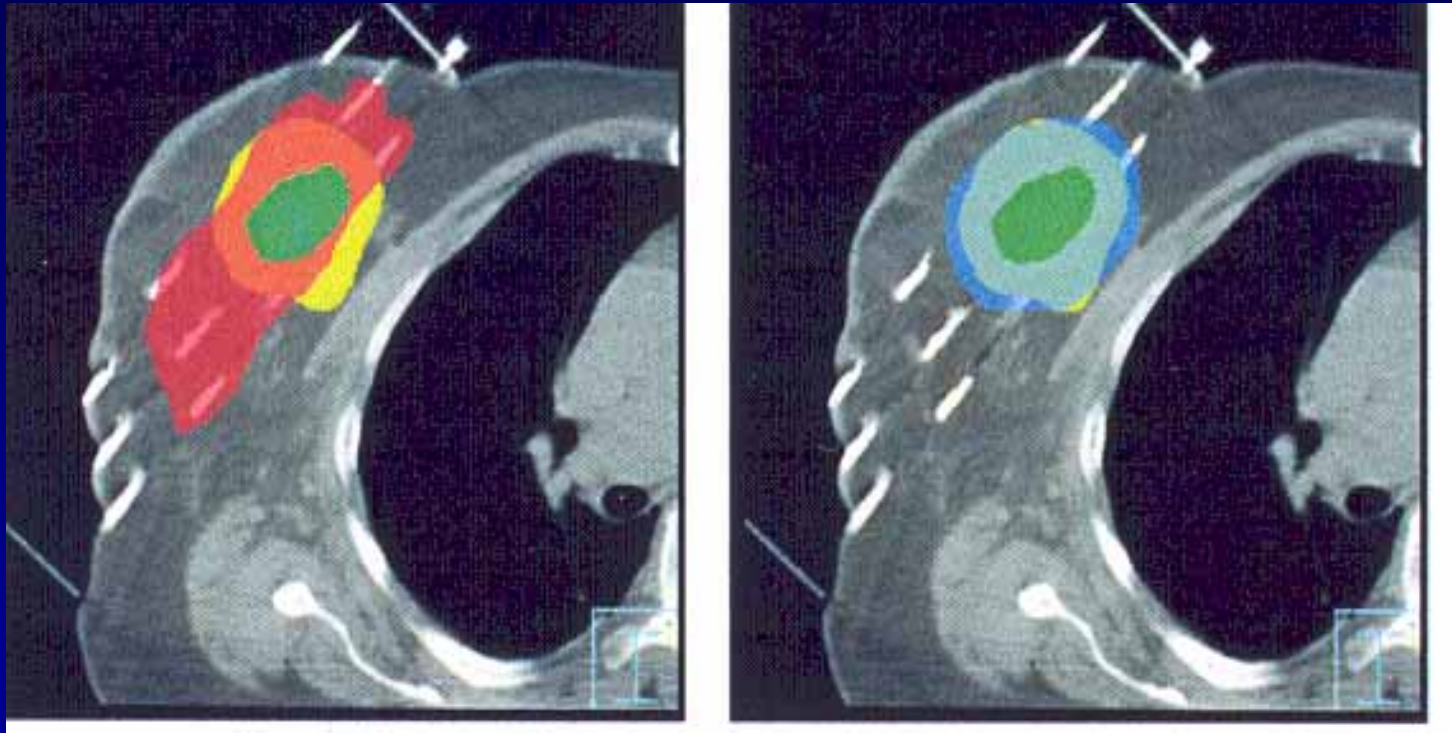
Brachytherapy with Interstitial Catheters

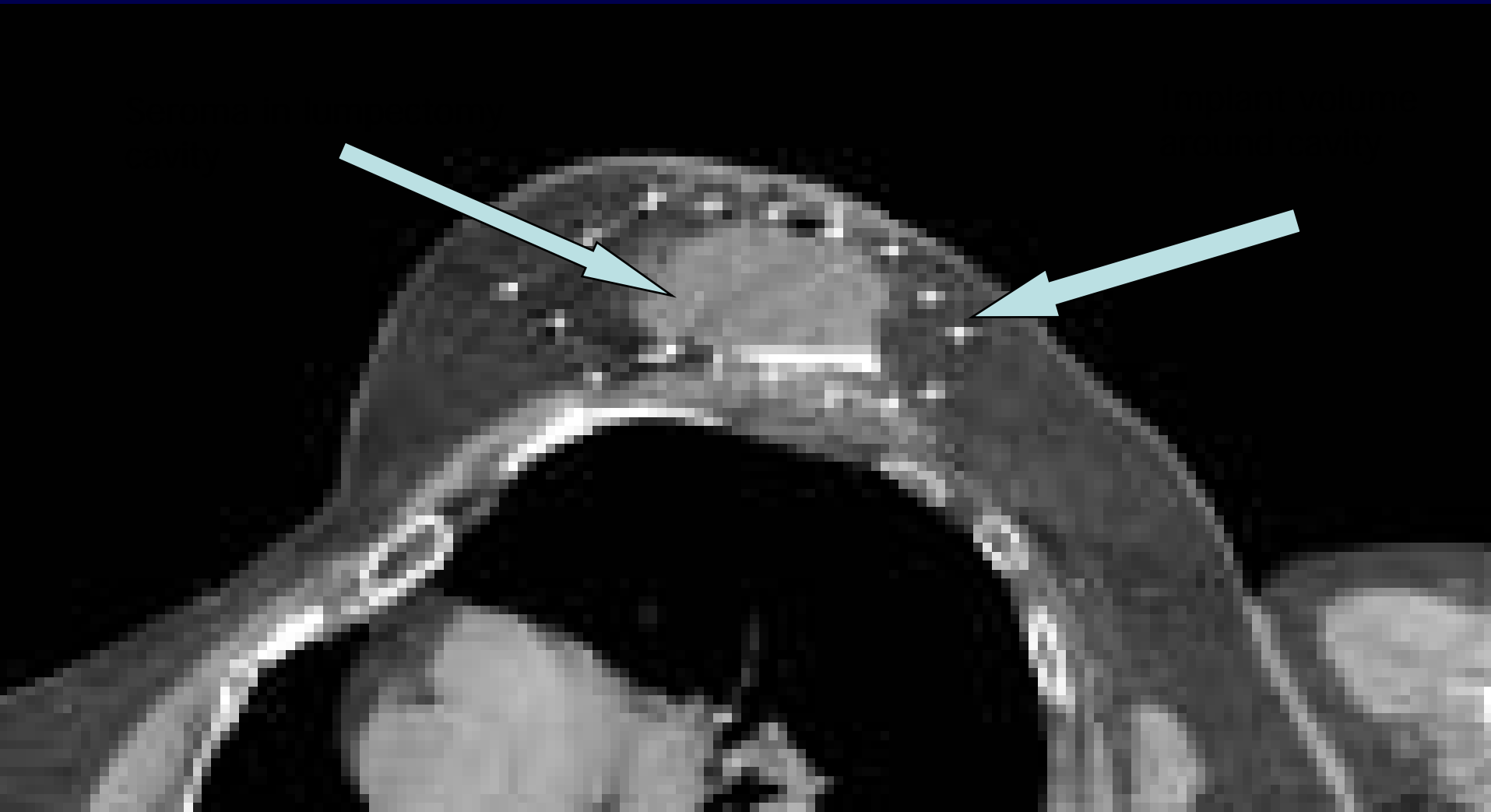


Breast Brachytherapy: Multi-plane catheter-based Radiotherapy



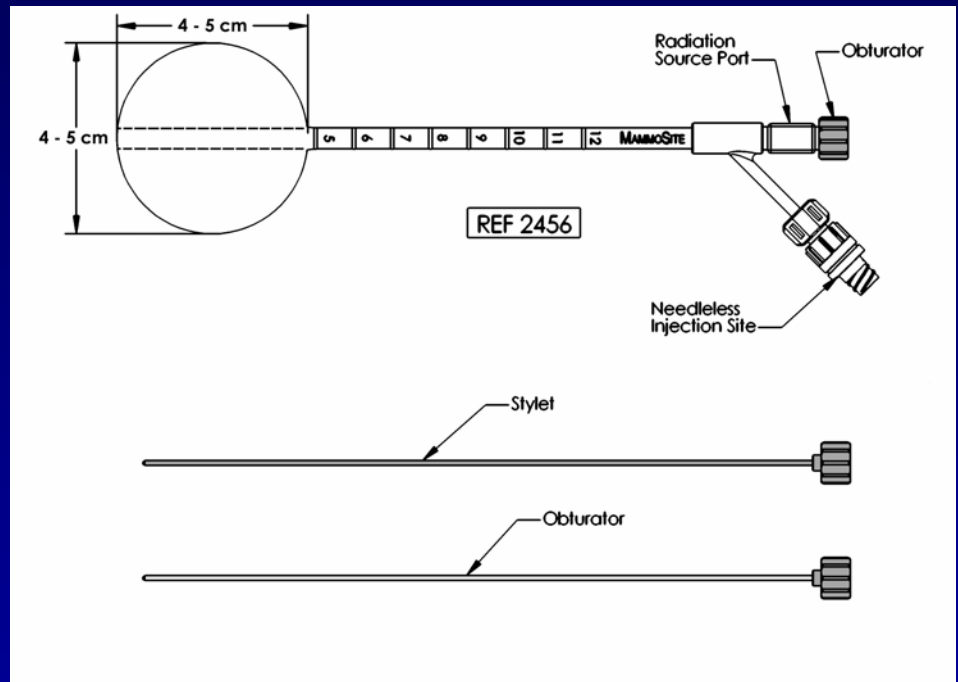
Multi-plane Catheter-based Implants





MammoSite® Insertion Techniques

MammoSite[®] Balloon Applicator



Elliptical Balloons



Ultrasound Guided Placement



Ultrasound Verification

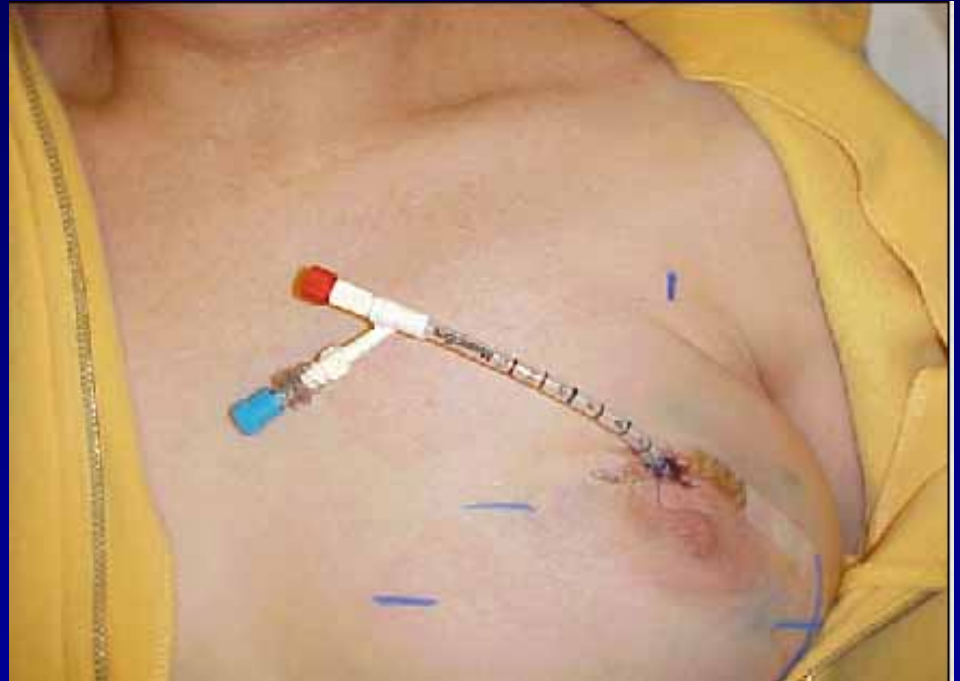


Refill to Original Volume

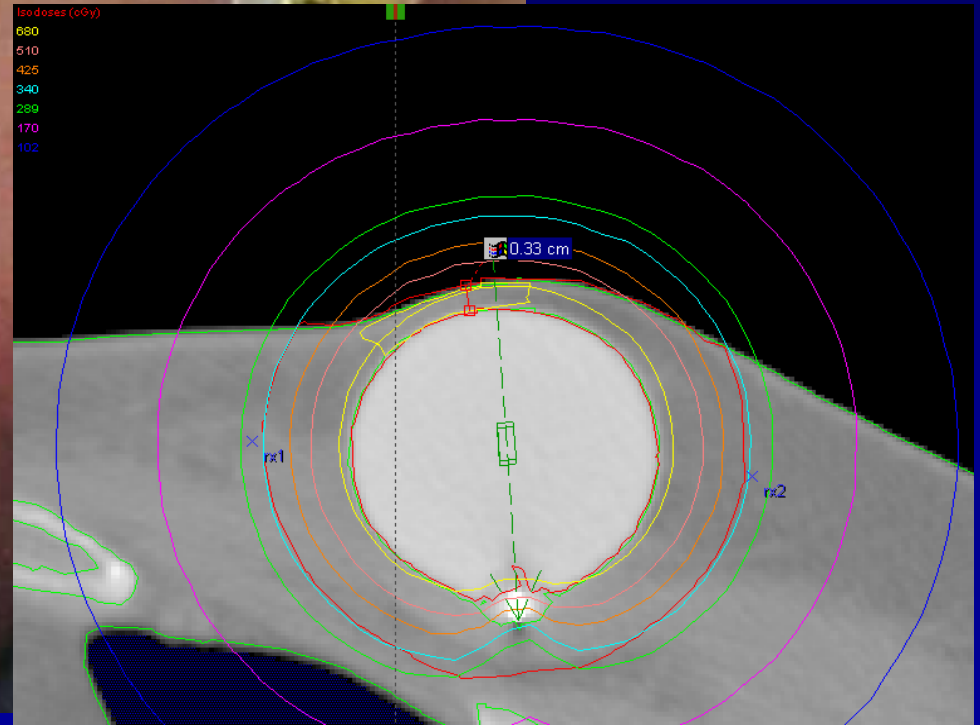
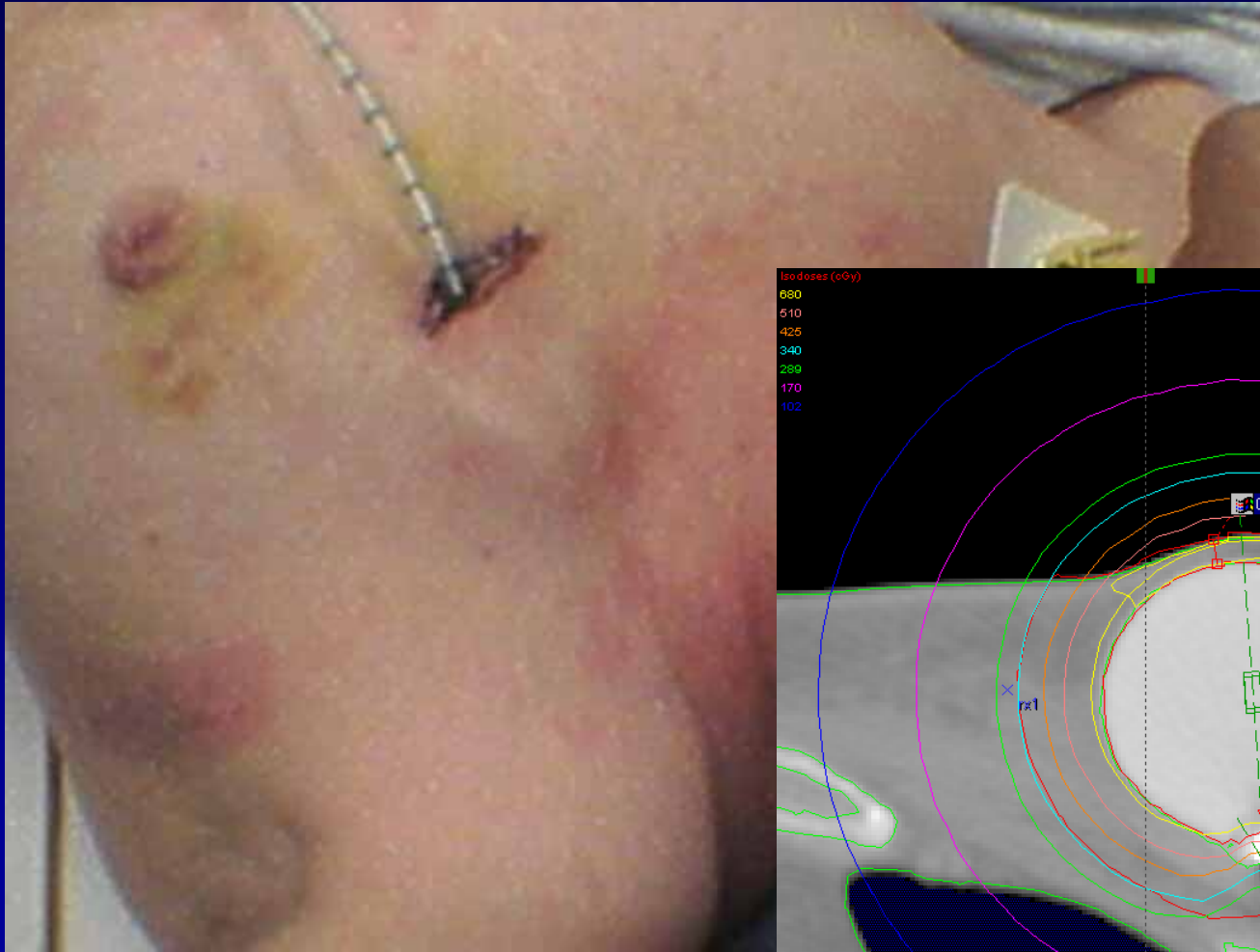


Implant Procedure - SET

- In procedure room under local anesthesia
- Confirm cavity size via ultrasound
- Open narrow section of lumpectomy scar - expand opening and track as needed
- Drain fluid from cavity
- Insert MammoSite® catheter

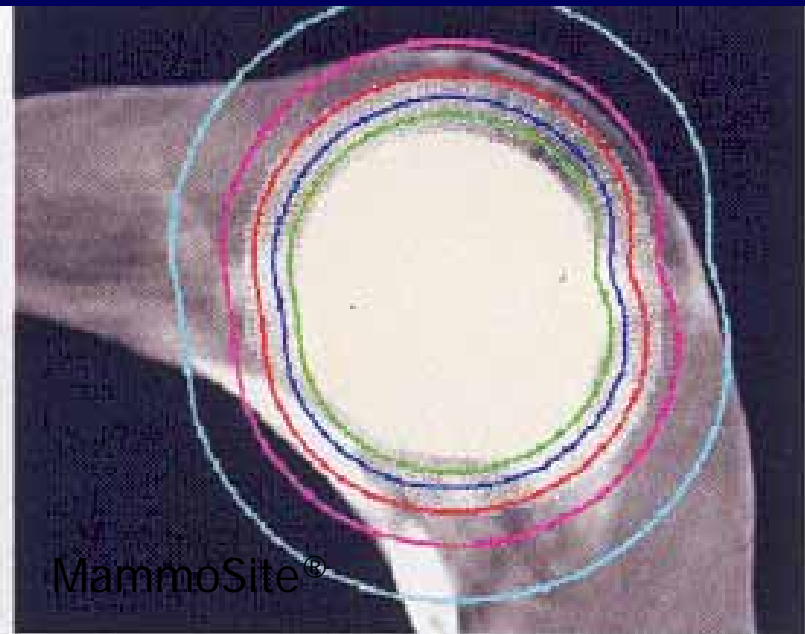
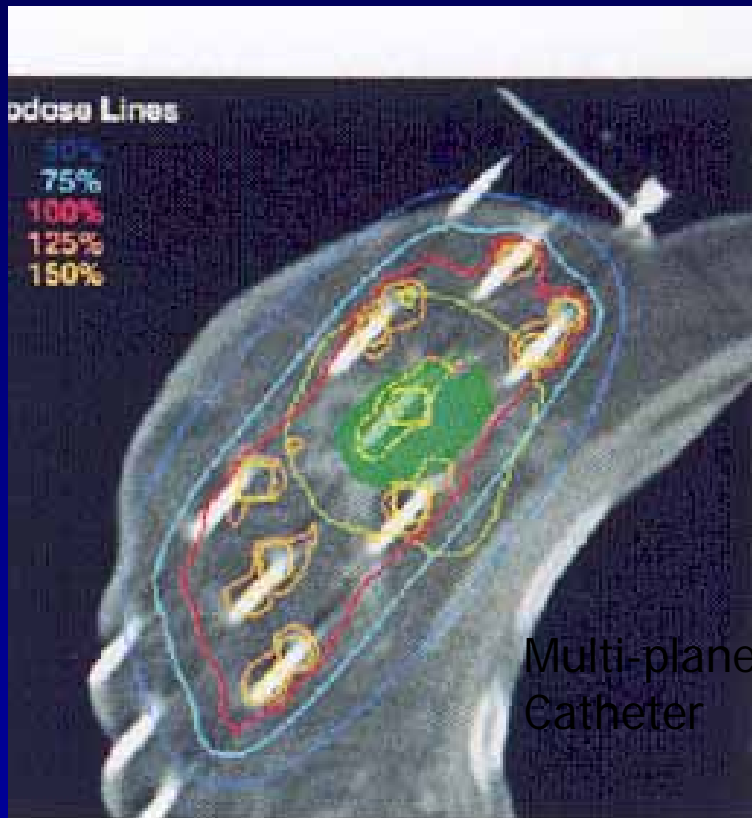


SET (Scar Entry Technique)



Comparison of Techniques

MP Catheter vs. MammoSite®



Appropriateness for Treatment: Skin Distance

- Balloon — skin distance > 5 mm
- Preferred: > 7 mm



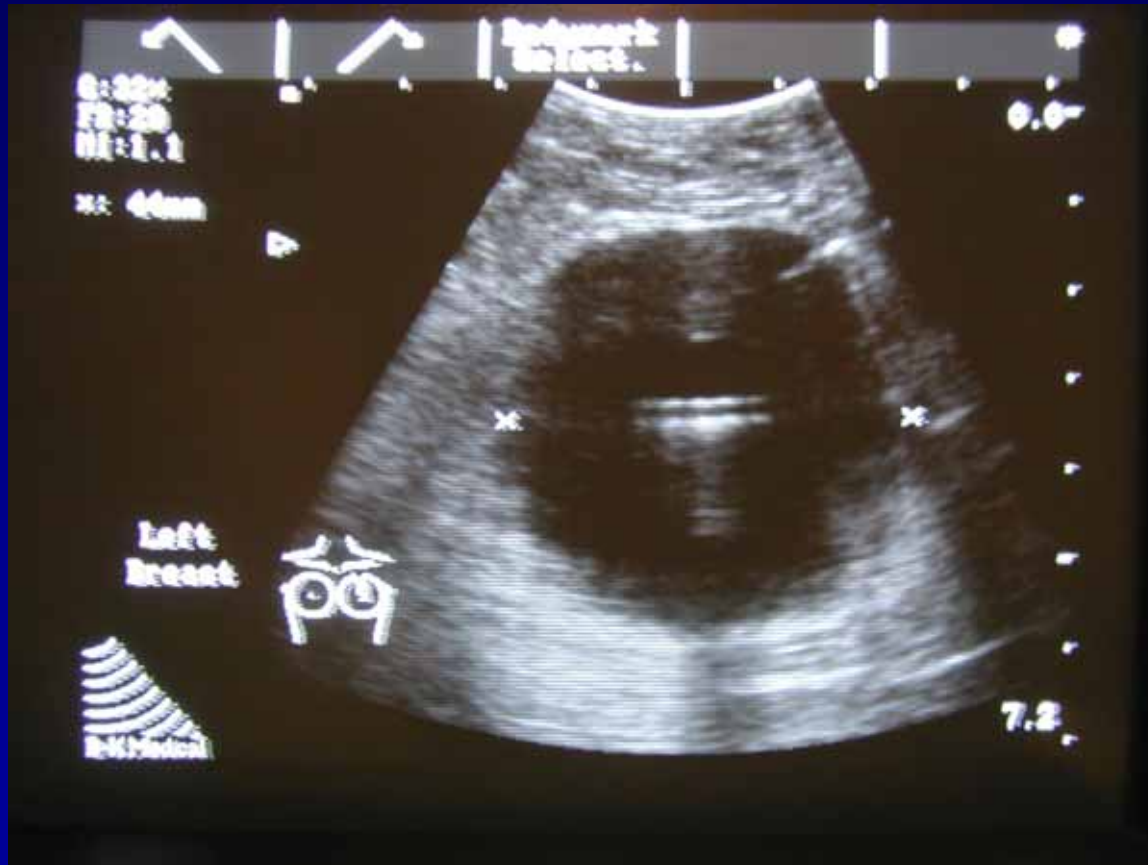
Placement of Catheter

- Check balloon prior to placement for shape and to ensure no leak of fluid
- The catheter is filled with a mixture of 5% non-ionic contrast and 95% injectable saline
- Fill volumes must be at least 35cc = 4cm diameter of balloon, and no more than 70 cc = 5cm as maximum diameter of balloon

Placement of Catheter

- The catheter should come out either laterally or thru incision
- The introducer trocar should be brought into the lumpectomy site thru a lateral incision in the breast

Ultrasound Image of MammoSite



CT Image of MammoSite[®]



3-Dimensional rendering of applicator surface

Determine Appropriateness for Treatment

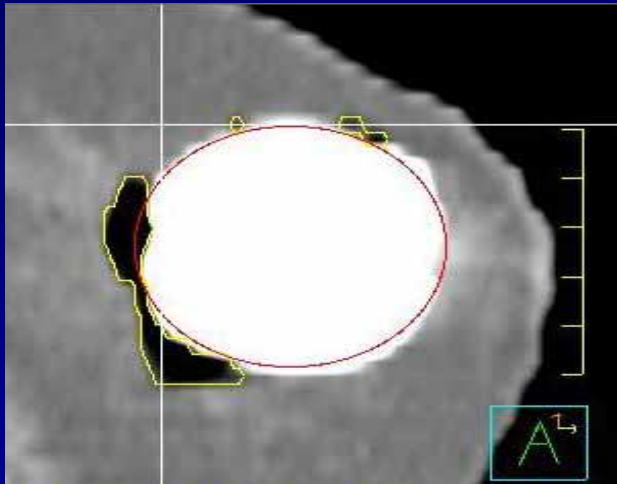
- Balloon diameter
- Tissue conformance
- Skin separation
- Balloon symmetry

Appropriateness for Treatment: Diameter

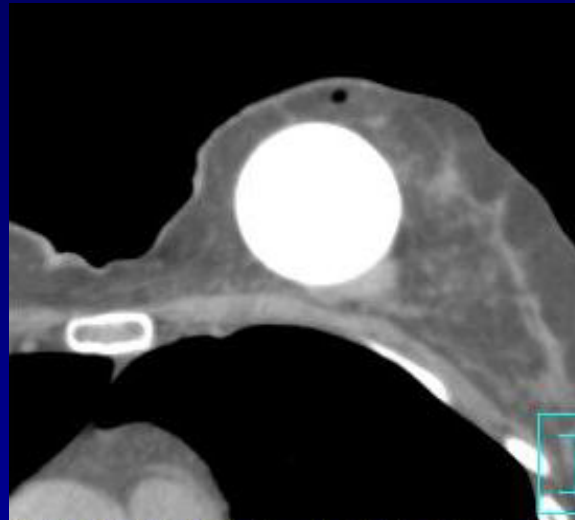


- Balloon diameter:
4.0 - 5.0 cm
5.0 – 6.0 cm
- Predicted by inflation volume (QA)

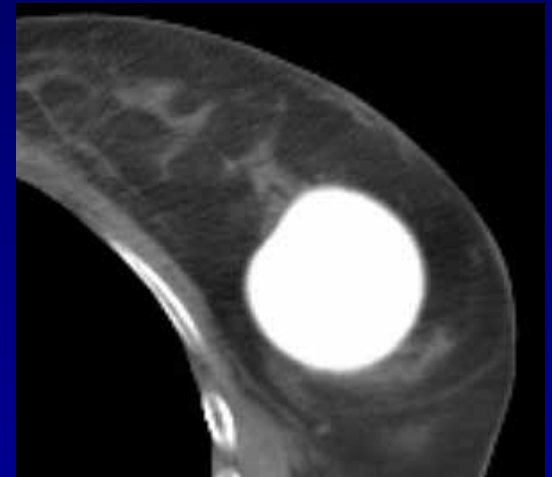
Breast Tissue Conformity: *The Good, the Bad & the Ugly*



Poor conformity

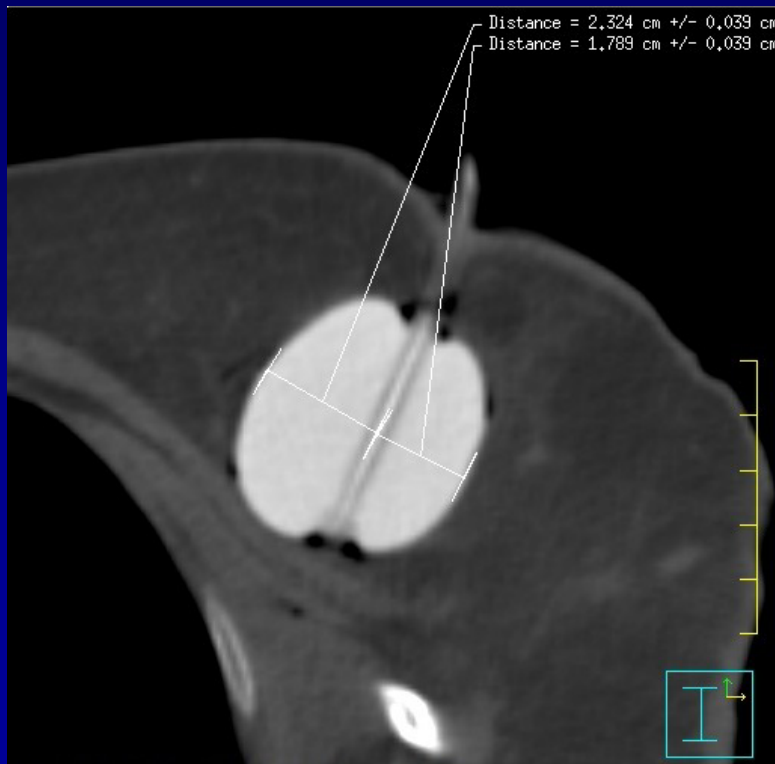


Questionable conformity

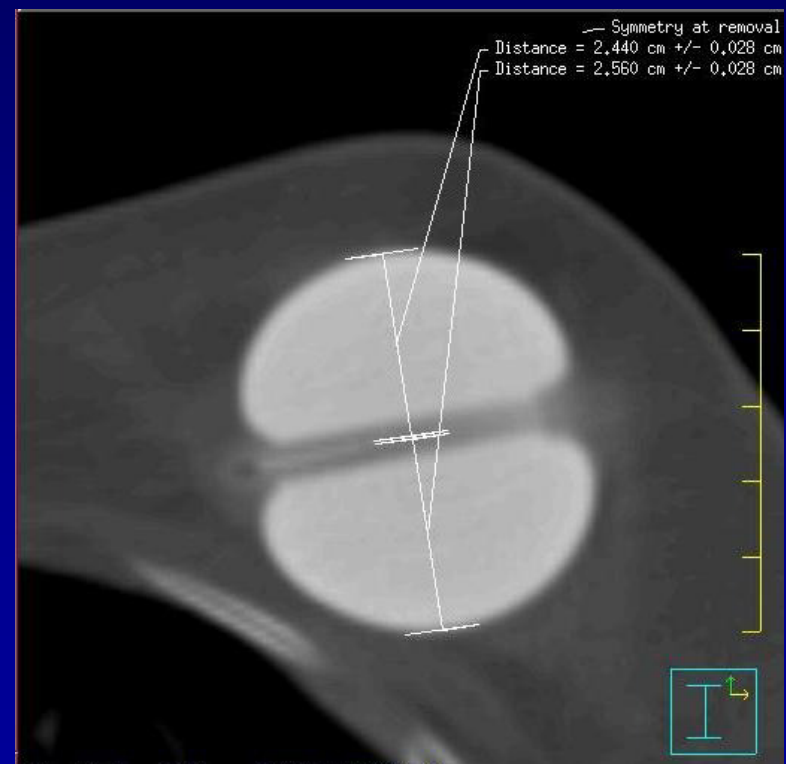


Good conformity

Appropriateness for Treatment: Symmetry

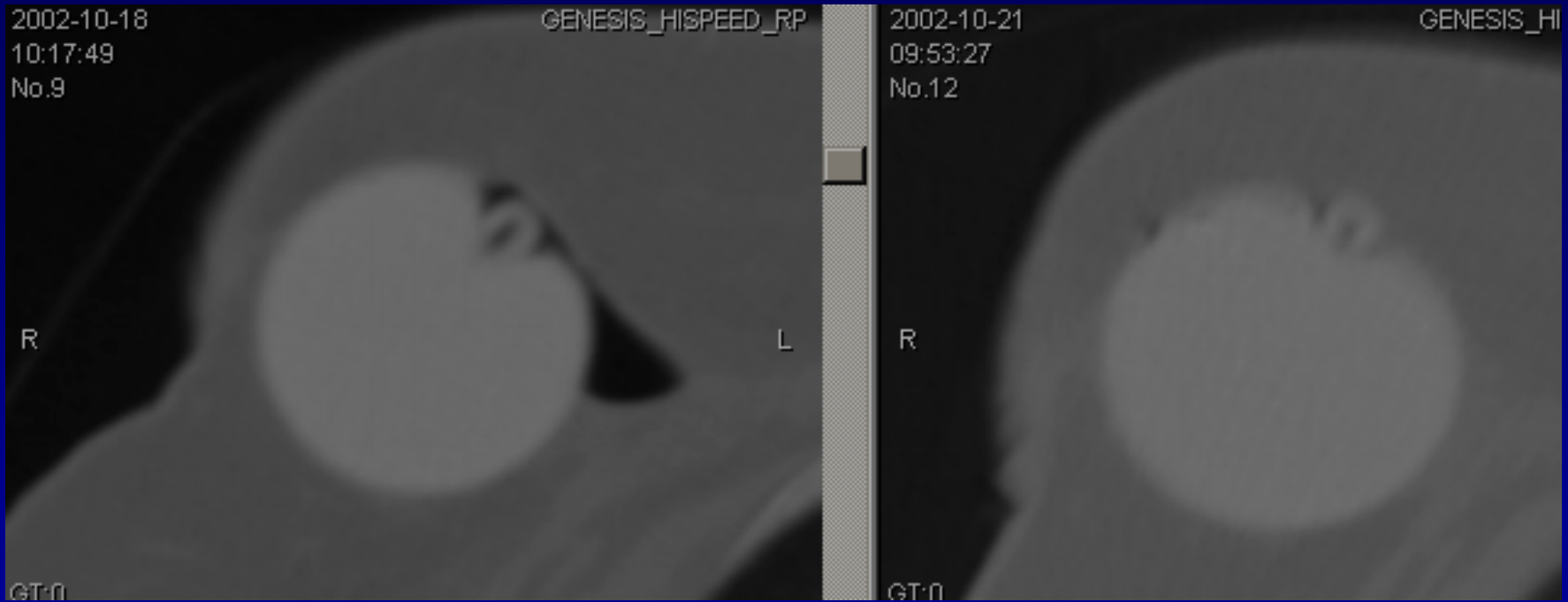


Asymmetrical

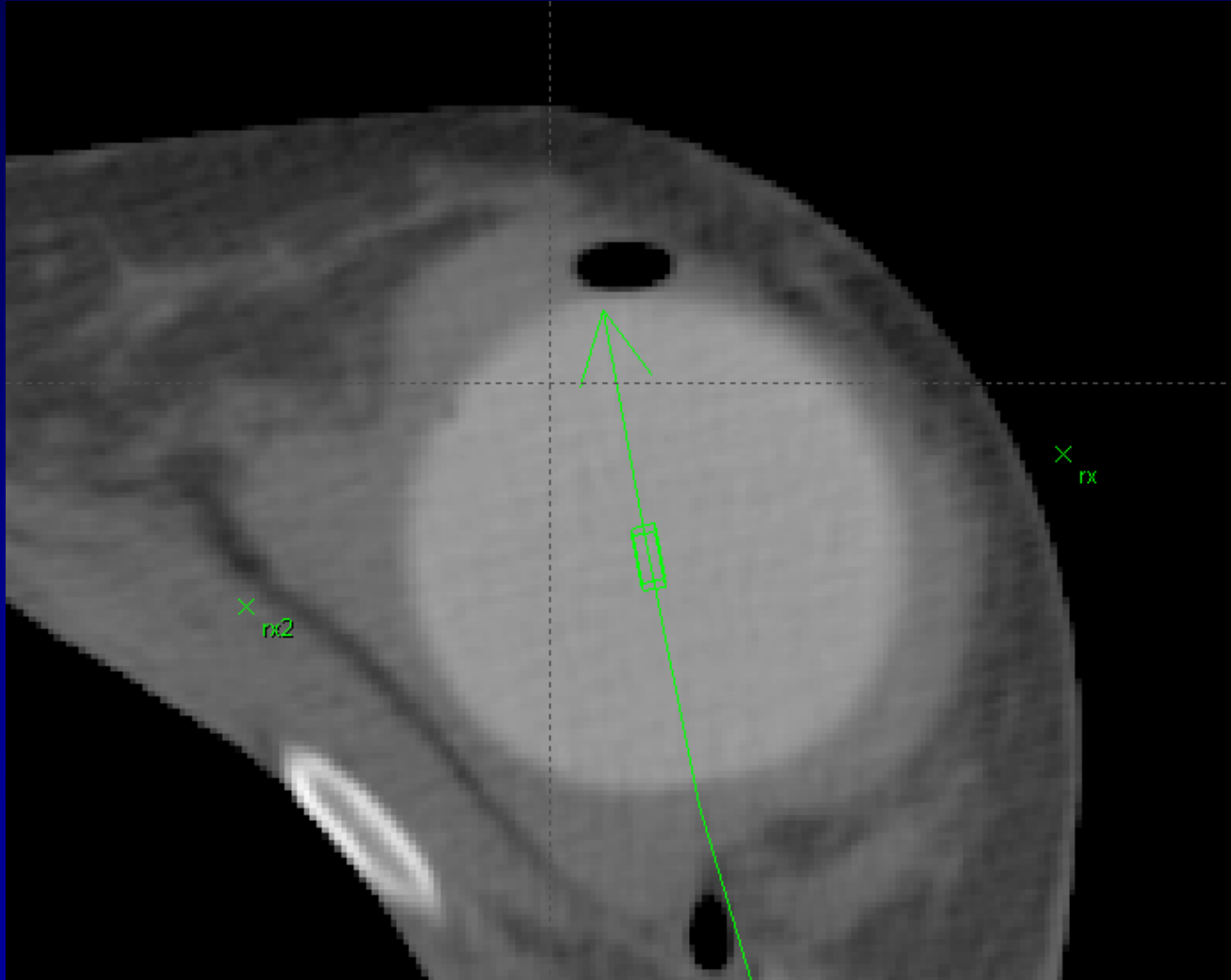


Symmetrical

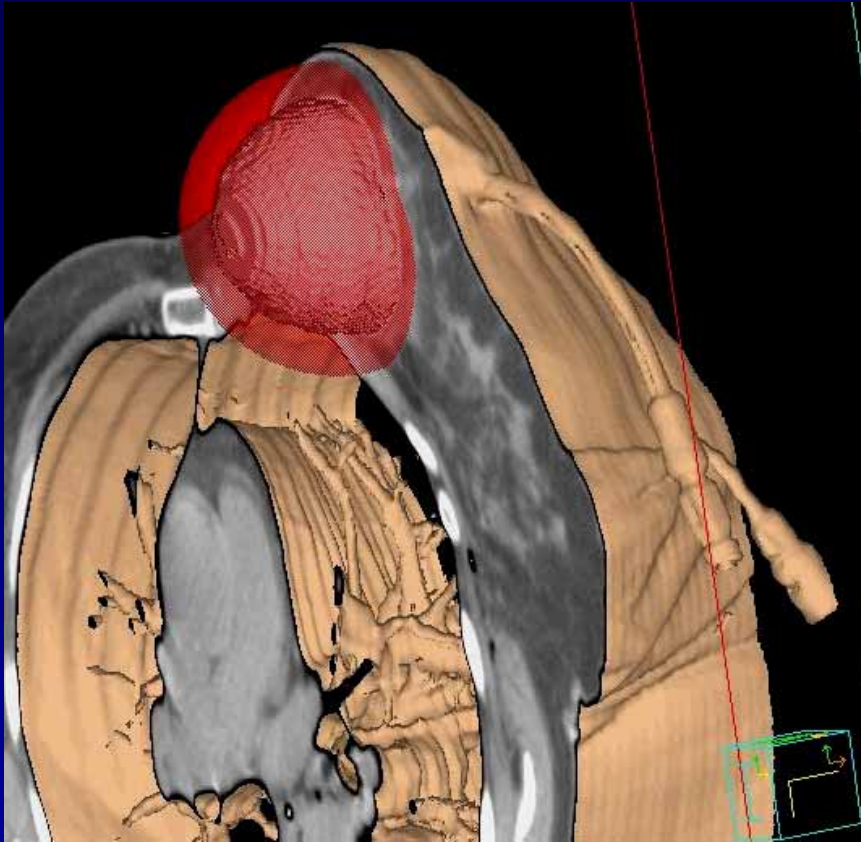
Resolution of Air Pocket (3 days)



Organized Hematoma



Prescription Dose



- 34 Gy
- 10 fractions over 5 -7days

3-Dimensional rendering of applicator surface and prescription dose cloud.

Two weeks from Treatment



Two months from Treatment



Four months from Treatment



Two years from Treatment





Day 2 on treatment



MammoSite on treatment



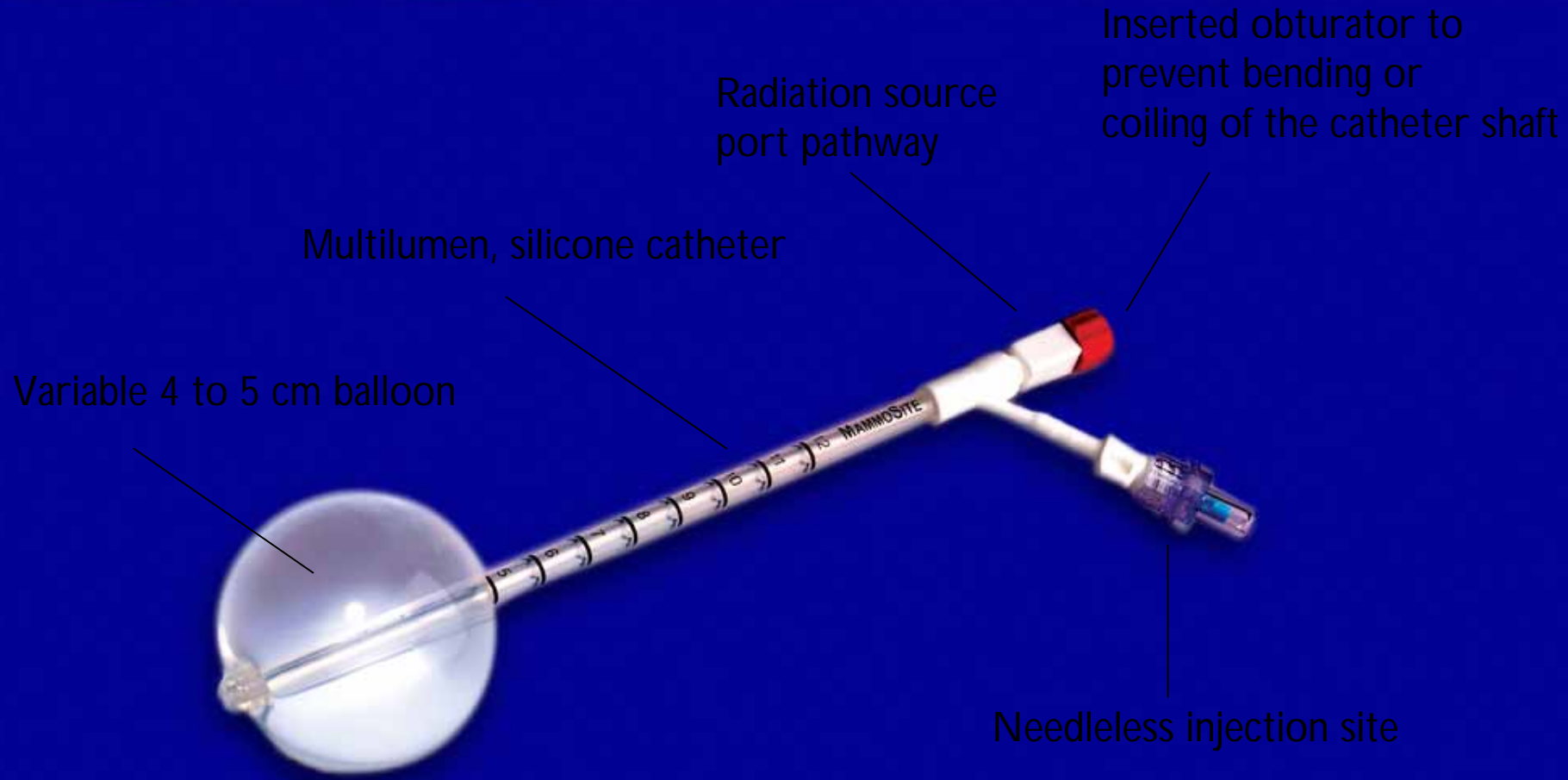
2 weeks post treatment



Post MammaSite

Summary

- Strict criteria is used for patient selection
- Careful lumpectomy and closure
- Careful balloon placement technique optimizes success for treatment



Radiation source
port pathway

Inserted obturator to
prevent bending or
coiling of the catheter shaft

Multilumen, silicone catheter

Variable 4 to 5 cm balloon

Needleless injection site