Image based Brachytherapy-HDR applications in Partial Breast Irradiation

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Acknowledgements

- Hani Gaballa, PhD
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- May Lim, MD

Main Modalities in Breast RT

- **External Beam Radiation Therapy**
  - Classical 2-D planning
  - 3D-Conformal RT (3D-CRT)
  - IMRT – Forward planning
- **Localized boost**
  - LDR Brachytherapy

NSABP PROTOCOL B-39
RTOG PROTOCOL 0413

Randomized Phase 3 Study of Conventional Whole Breast Radiation Versus Partial Breast Radiation for Women With Stage 0, 1, or 2 Breast Cancer

LIJ-NSUH Co-Principal Investigators

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Lora Weiselberg,M.D.

GOAL

EVALUATE EFFECTIVENESS OF PARTIAL BREAST IRRADIATION (PBI) COMPARED TO WHOLE BREAST (WBI) RADIATION IN PROVIDING LOCAL TUMOR CONTROL IN THE BREAST FOLLOWING LUMPECTOMY

RATIONALE FOR NSABP-39 PROTOCOL

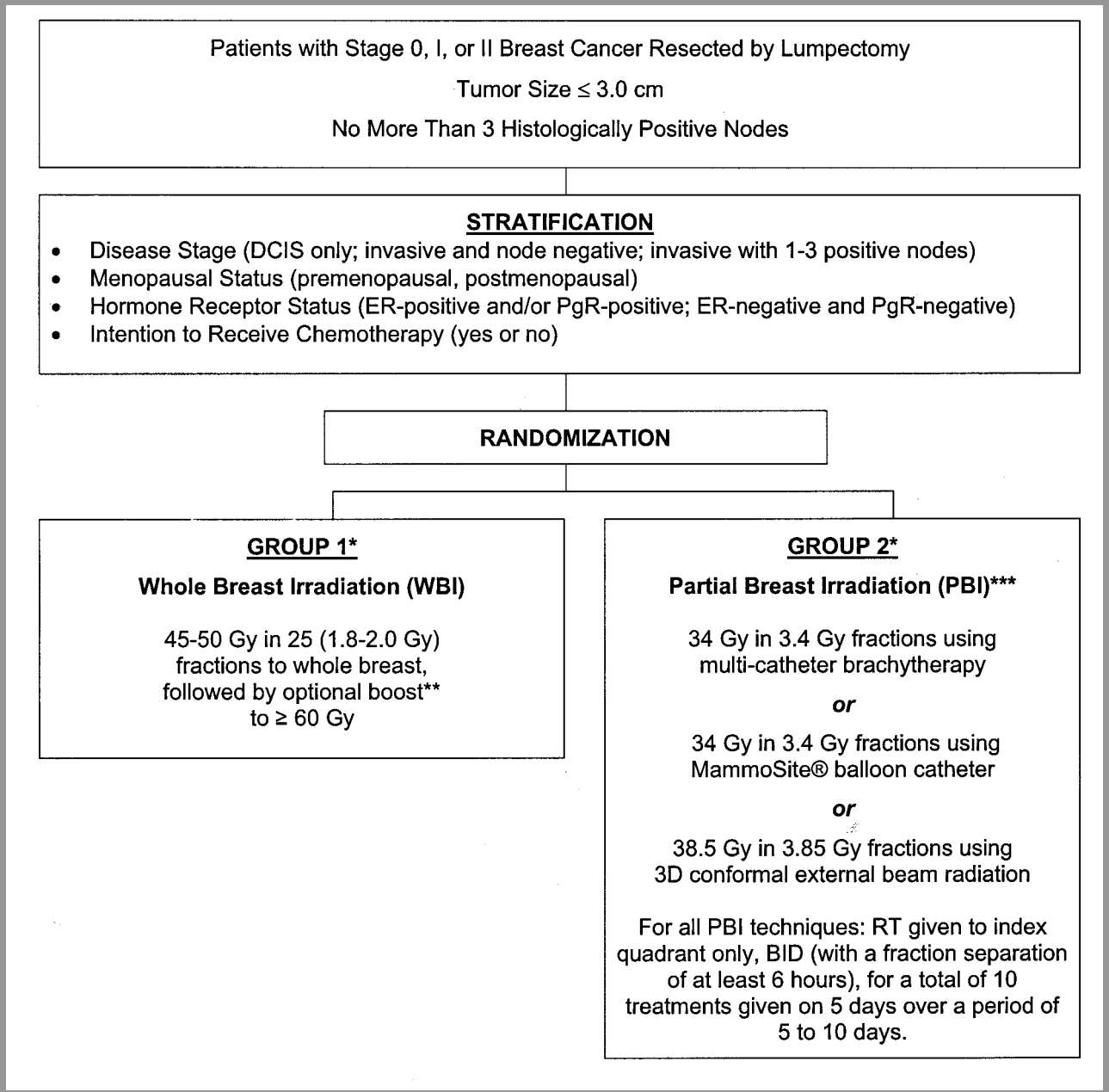
- LOCAL CONTROL IN AREA OF LUMPECTOMY SAME, WHETHER PATIENT TREATED WITH WBI OR PBI (3-4% LOCAL RECURRENCE)
- INCIDENCE OF "ELSEWHERE FAILURES" IN IPSILATERAL BREAST SAME AS THE UNTREATED CONTRALATERAL BREAST

- Am J Surg. 2000:180:299-304; Int J Radiat Oncol Biol Phys 55(2):289-293,2003; Int J Radiat Oncol Biol Phys 57(5):1247-1253,2003

PATIENT ELIGIBILITY

- FEMALE WHO IS 18 YEARS OR OLDER
- STAGE 0,1,or 2 BREAST CANCER; TUMOR SIZE MUST BE 3 CM OR LESS
- DCIS OR INVASIVE ADENOCARCINOMA
- GROSS DISEASE MUST BE UNIFOCAL WITH NEGATIVE MARGINS
- PATIENTS WITH INVASIVE BREAST CANCER MUST HAVE AXILLARY STAGING (SENTINEL NODE OR AXILLARY DISSECTION, IF POSITIVE SENTINEL NODE MUST HAVE AXILLARY DISSECTION WITH MINIMUM 6 NODES)
- MUST BE RANDOMIZED WITHIN 42 DAYS OF LAST SURGERY
- HORMONAL RECEPTORS MUST BE DONE PRIOR TO RANDOMIZATION
- TARGET/LUMPECTOMY CAVITY MUST BE CLEARLY DELINEATED & MUST BE LESS THAN OR EQUAL TO 30% WHOLE BREAST VOLUME ON PRE-RANDOMIZATION CT SCAN
- INVOLVED BREAST MUST FIT CRITERIA FOR PBI TECHNIQUE FOR WHICH RADIATION ONCOLOGY FACILITY HAS BEEN ACCREDITED

NSABP B39/RTOG 0413 FLOW DIAGRAM



CT based pre-Planning for PBI

- **CT acquired with the patient in the treatment position. For patients on Protocol this means:**
- **Acquisition parameters:**
  - Table index = 3 mm
  - Slice thickness = 3 mm
- **Two setup points for central axis entrance/exit position – as if the patient is treated with external beam with the appropriate gantry angle - are needed to assist in planning and treatment if the patient is randomized to external beam**

WBI TECHNIQUES/DOSES

- WBI 50 Gy in 2 Gy daily fractions or 50.4 Gy in 1.8 daily fractions, 5 days/week
- Photon or electron boosts are permitted but are not required and may deliver 10-14 Gy in 5-7 fractions to prescription volume

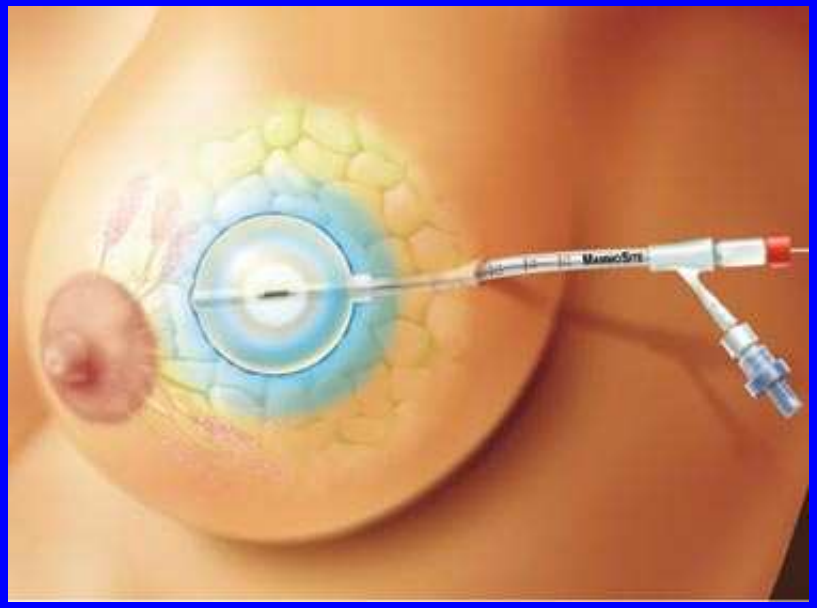
PBI BY MAMMOSITE BALLOON

- Mammosite catheter will be placed by closed catheter technique only and as soon as possible after randomization has taken place
- 10 mm of breast tissue surrounding the lumpectomy cavity, as delineated by the CT scan, will be treated for 34 Gy in 10 fractions, 2 fractions per day in 5 days, over 5-10 days period
- Minimum balloon surface to skin distance of 5 mm, although ideally should be 7 mm or more
- To assure continued integrity of balloon throughout treatment, ultrasound or x-ray verification must be done prior to each treatment to evaluate for any change in balloon diameter

PBI BY MULTI-CATHETER BRACHYTHERAPY

- Interstitial catheters must be placed by closed cavity technique immediately after randomization
- A 15 mm width of tissue around the lumpectomy cavity, as outlined from the CT scan, will be treated with a dose of 34 Gy, delivered in 10 fractions in 5 days, over a period of 5-10 days, with minimum of 6 hours between fractions
- Only HDR (High Dose Rate) radiation allowed
- Dose to overlying skin cannot exceed

Brachytherapy Simulation and Treatment with the MammoSite Applicator



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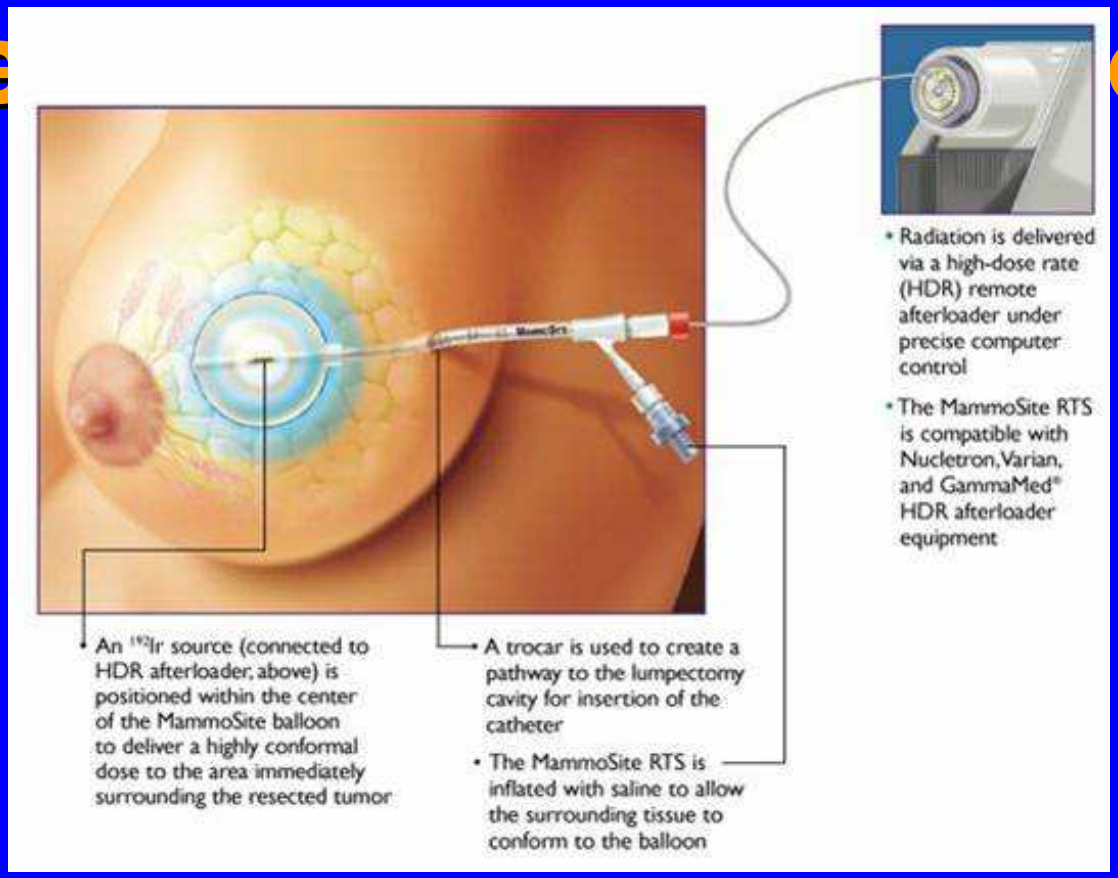
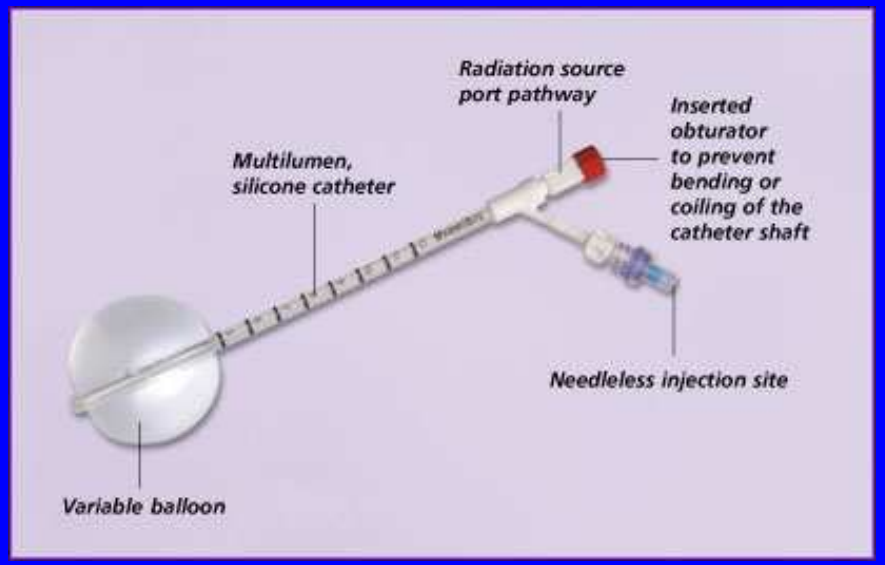

• Radiation is delivered via a high-dose rate (HDR) remote afterloader under precise computer control
• The MammoSite RTS is compatible with Nucletron, Varian, and GammaMed® HDR afterloader equipment
• An ^{192}Ir source (connected to HDR afterloader, above) is positioned within the center of the MammoSite balloon to deliver a highly conformal dose to the area immediately surrounding the resected tumor
• A trocar is used to create a pathway to the lumpectomy cavity for insertion of the catheter
• The MammoSite RTS is inflated with saline to allow the surrounding tissue to conform to the balloon

MammoSite Treatment Prescription

- Dose is prescribed to a distance of 1.0 cm. from the surface of the Balloon
- Prescription dose is 34 Gy in 10 Fractions, b.i.d.



Balloon Configurations

A variety of MammoSite balloon designs allow accommodation of various cavity shapes and sizes

Balloon Configuration
4 – 5 cm Sphere
5 – 6 cm Sphere
4 x 6 cm Ellipsoidal

CT based Patient Evaluation for PBI with MammoSite balloon

- **Assess the lumpectomy cavity size, shape and location for MammoSite eligibility**
- **Minimum balloon size is 35 cc**
  - The cavity will stretch with the balloon in place, however, cavities less than 15 cc are too small
- **Cavity proximity to the chest wall should not deform the balloon geometry.**
  - Asymmetry along the balloon transverse diameters should not exceed 2 mm
- **Distance to skin should be less than 6 mm**
- **The cavity shape must meet the conformance criteria.**
  - Conformance factor should be within 90%.

Appropriateness Criteria for Treatment

- Balloon Volume: 35cc-70cc
- Balloon Surface Dose: <200% of the Prescribed Dose
- Skin Dose: <150% of the Prescribed Dose
- Balloon Conformity To the

Table 1: Physical Characteristics for the Variably Inflated 4-5 cm MammoSite

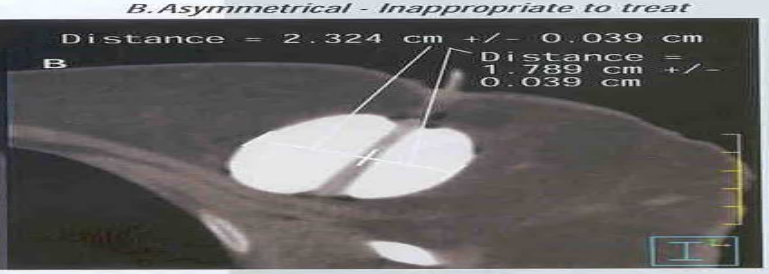
MammoSite Nominal Fill Volume (cc)	Width (cm)	Length (cm)	Dose Rate (cGy/min/Ci)* @ 1 cm
34	4.00	4.00	8.43
36	4.05	4.05	8.20
38	4.15	4.10	7.98
40	4.20	4.10	7.79
42	4.30	4.15	7.58
44	4.35	4.20	7.44
46	4.45	4.25	7.27
48	4.50	4.30	7.10
50	4.55	4.30	6.97
52	4.65	4.35	6.83
54	4.70	4.35	6.70
56	4.75	4.40	6.58
58	4.85	4.40	6.44
60	4.90	4.45	6.35
62	4.95	4.50	6.26
64	5.00	4.55	6.15
66	5.05	4.60	6.05
68	5.10	4.60	5.97
70	5.15	4.65	5.89

* Dose Rate calculation is at 1 cm off the balloon surface

Figure 4: Assessment of Balloon Symmetry

A. Symmetrical - Appropriate to treat

B. Asymmetrical - Inappropriate to treat



Radiation Oncologist

- **CT Simulation:**
  - Palpate and mark the skin point closest to the balloon
  - Place an aluminum wire over the mark in a Sup-Inf direction
  - Approve/ Reject Appropriateness of the MammoSite for Treatment.
- **Daily Simulation: Approves Balloon Volume and Position (variation <10%)**
- **Balloon Re-inflation and/or replacement (e.g.: if the balloon ruptures during the treatment).**
- **Administer the Daily Treatments.**
- **Deflate and remove the Balloon in case of Emergency during the Radiation Treatment.**
- **Deflate and remove the Balloon at the end of Treatment**

Radiation Therapist

- **CT Simulation:**
  - Position patient
  - Place an aluminum wire over the skin mark in a Sup-Inf direction
  - Acquire CT study and transfer to VoxelQ.
- **Reference Simulation**
  - Obtain pair of simulation films for reference and for verification of DRR's
- **Daily:**
  - Acquire single view film at Oldelft Simulator before each fraction.
  - Lead Patient to HDR Room and set for treatment

Medical Physicist

- **CT Simulation:**
  - Perform virtual simulation and analysis to obtain parameters for the appropriateness evaluation
  - Derive parameters for Glancing BEV and generate DRR's
  - Determine the optimum position for the radiation source
  - Generate Brachytherapy Isodose plan and DVH's
  - Determine treatment time according to source activity
- **Reference Simulation**
  - Analyze reference Appositional Film and Glancing BEV film.
  - Verify agreement with CT Sim DRR's.
  - Obtain approval from Radiation Oncologist
- **Daily Simulation:**
  - Analyze reference film for Volume and Position
  - Assist RO with Balloon Re-inflation and/or replacement if needed

Medical Physicist - II

- **Daily Treatments**
  - Prepare HDR unit and perform daily QA.
  - Document test results for each fraction
  - Program and check HDR treatment parameters for each fraction. Adjust and verify treatment times.
  - Monitor treatment at the control, as per regulations
  - Survey Patient and Room after each treatment fraction
  - Perform continuing QA, capture charges and maintain HDR equipment and source Records
  - Assist RO in Deflating and removing the Balloon in case of Emergency during the Radiation Treatment.
  - Review chart at completion of treatment

Nurse

- Monitor patient status throughout treatment period.
- Assist RO in Deflating and removing the Balloon at end of Treatment.
- Review chart at completion of treatment

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Radiation Oncology Department

MammoSite-CT Virtual Simulation

Date:

Patient Information:
Patient Name: Medical Record Number:
Radiation Oncologist : Medical Physicist:

Surgery Information:
1. Balloon Placement Date:
2. Fill Volume (cc):

CT Scan Protocol Parameters:
-Protocol Name: Table Top Brain -Image Size: 360:
-Couch Index: 1 mm -Slice Thickness 1mm
-Scanning Length: Estimated Balloon Diameter +5 cm

Virtual Simulation Appositional Plane Film Setup Parameters:

-Gantry Angle: -Couch Angle:

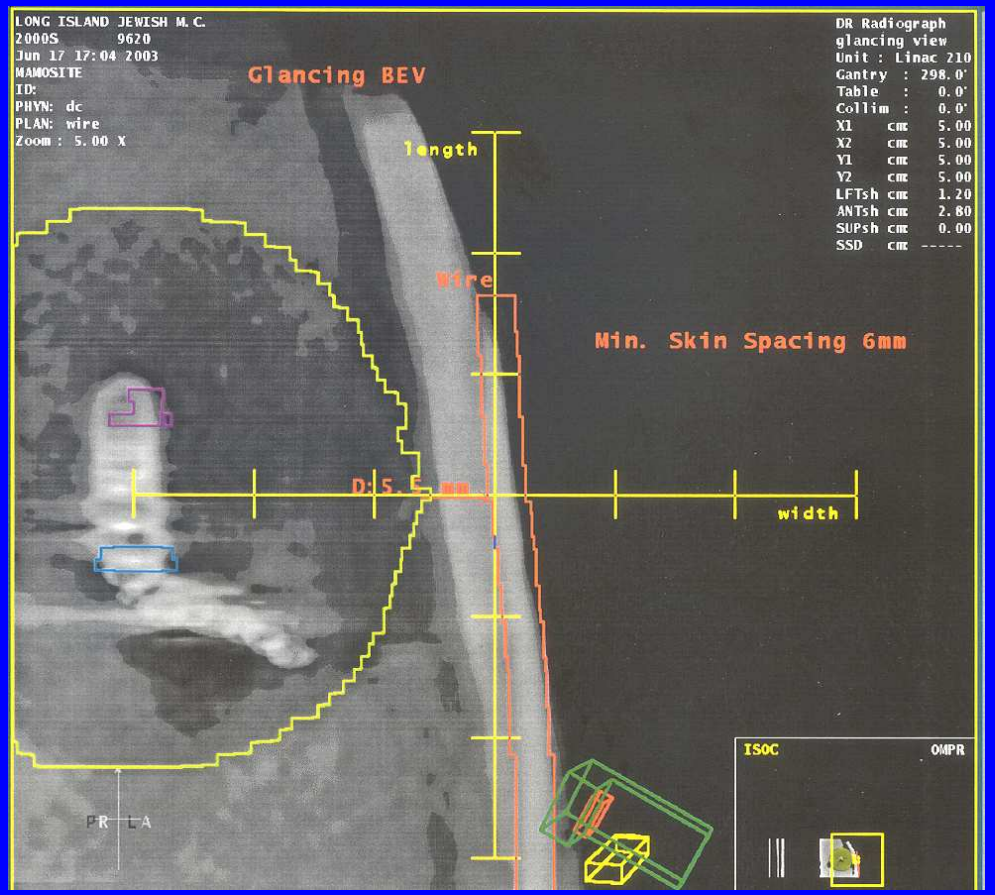
Evaluation of Balloon Parameters From Virtual Simulation:
1. Measured Balloon Length (mm):
2. Measured Balloon Maximum Transverse Width (mm)
3. Corresponding Balloon Volume from Table (cc):
4. Balloon Lateral Shift (mm):
5. HDR Final Indexer Position (mm):
6. Balloon Asymmetry (mm):
7. Conformance of Lumpectomy Cavity to Balloon Volume:

Virtual Simulation Min. Skin Spacing BEV Setup Parameters:
-Couch Lateral Shift from Balloon Center:
-Couch Vertical Shift from Balloon Center:
-Gantry Angle: -Couch Angle:
Estimated Min. Skin Spacing (mm):

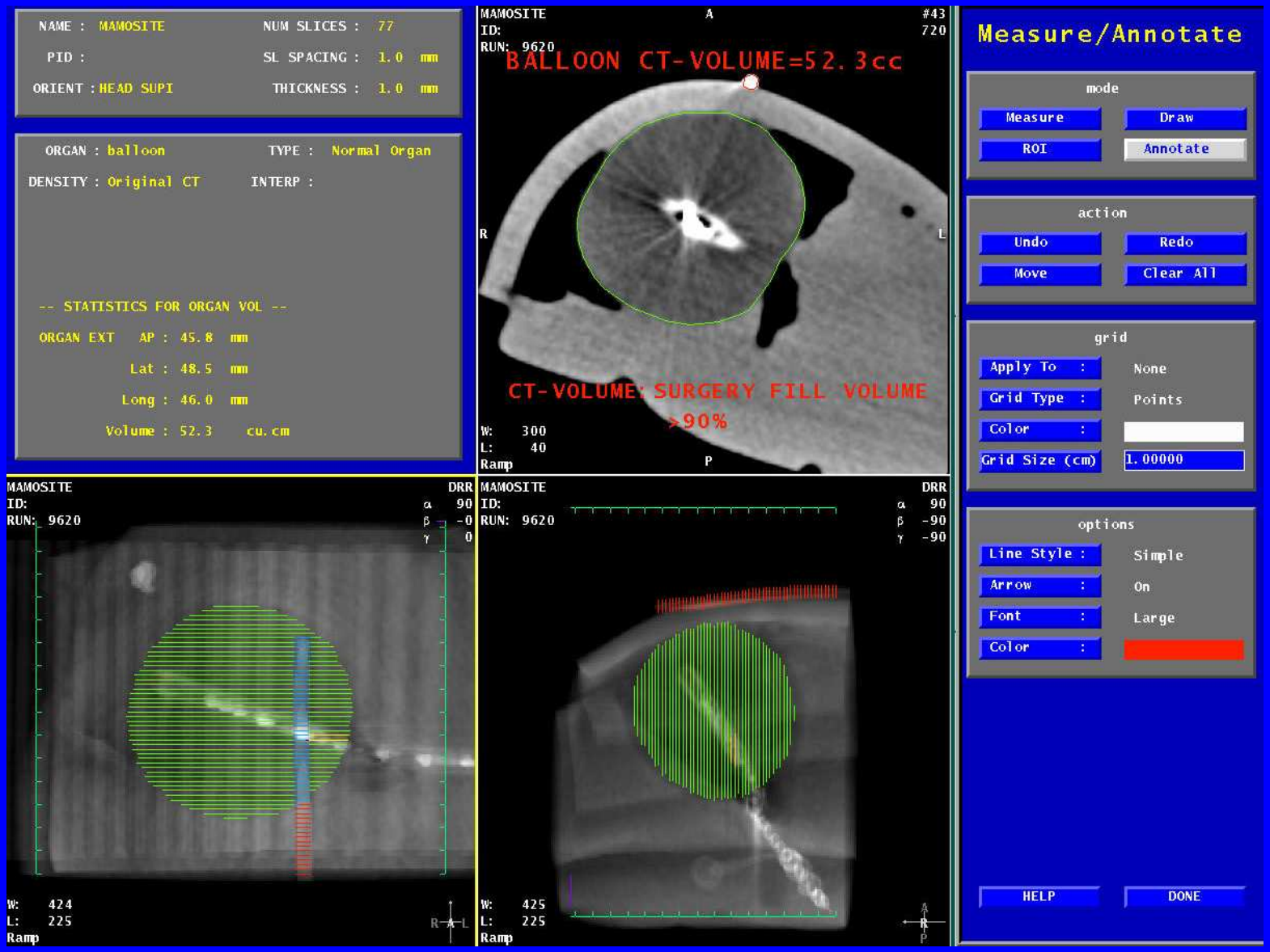
Appropriateness of Radiation Therapy Treatment:
1. Assessment of Balloon Asymmetry (Tolerance <2.0 mm)
   Acceptable : Yes/No
2. Assessment of Balloon Conformance (Tolerance > 90%)
   Good Conformance Yes/No
3. Assessment of Minimum Skin Spacing (Tolerance > 7.0 mm)
   Acceptable: Yes/No

CT Simulation

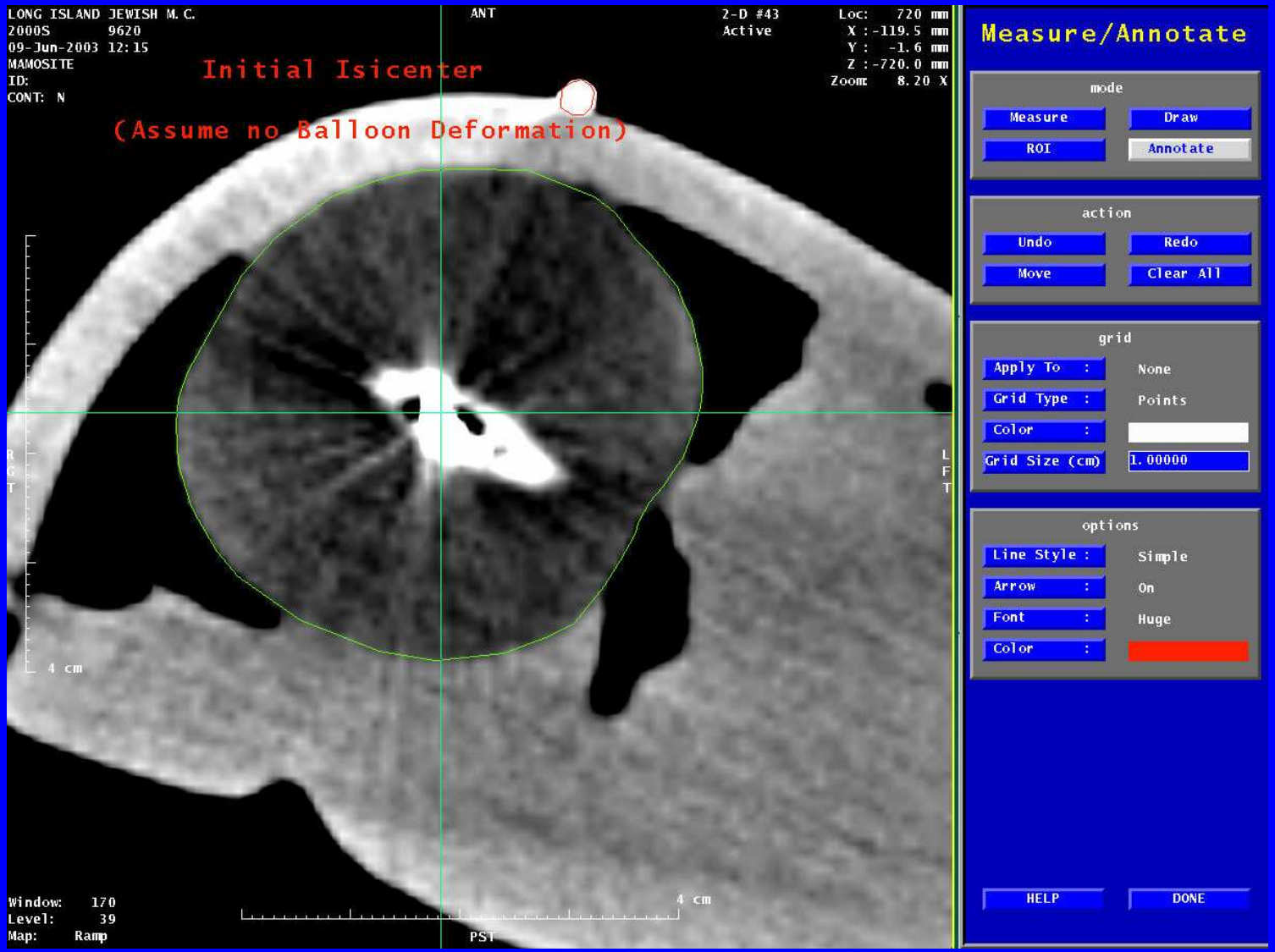
- **Appositional Plane BEV:**
  (Balloon Length Balloon Width, Balloon Asymmetry, Balloon Asymmetry, Balloon Displacement)



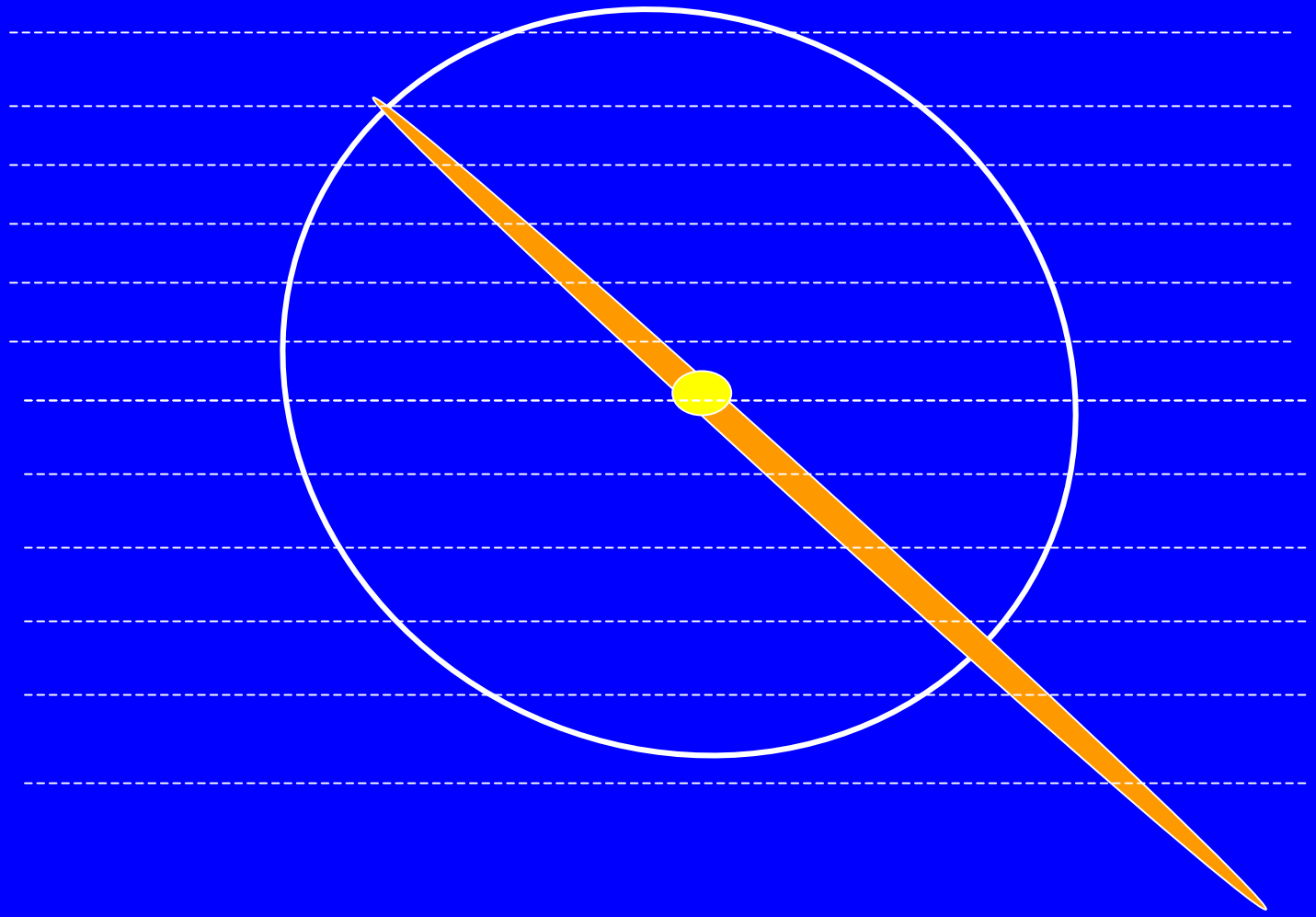
Determination of Balloon Volume



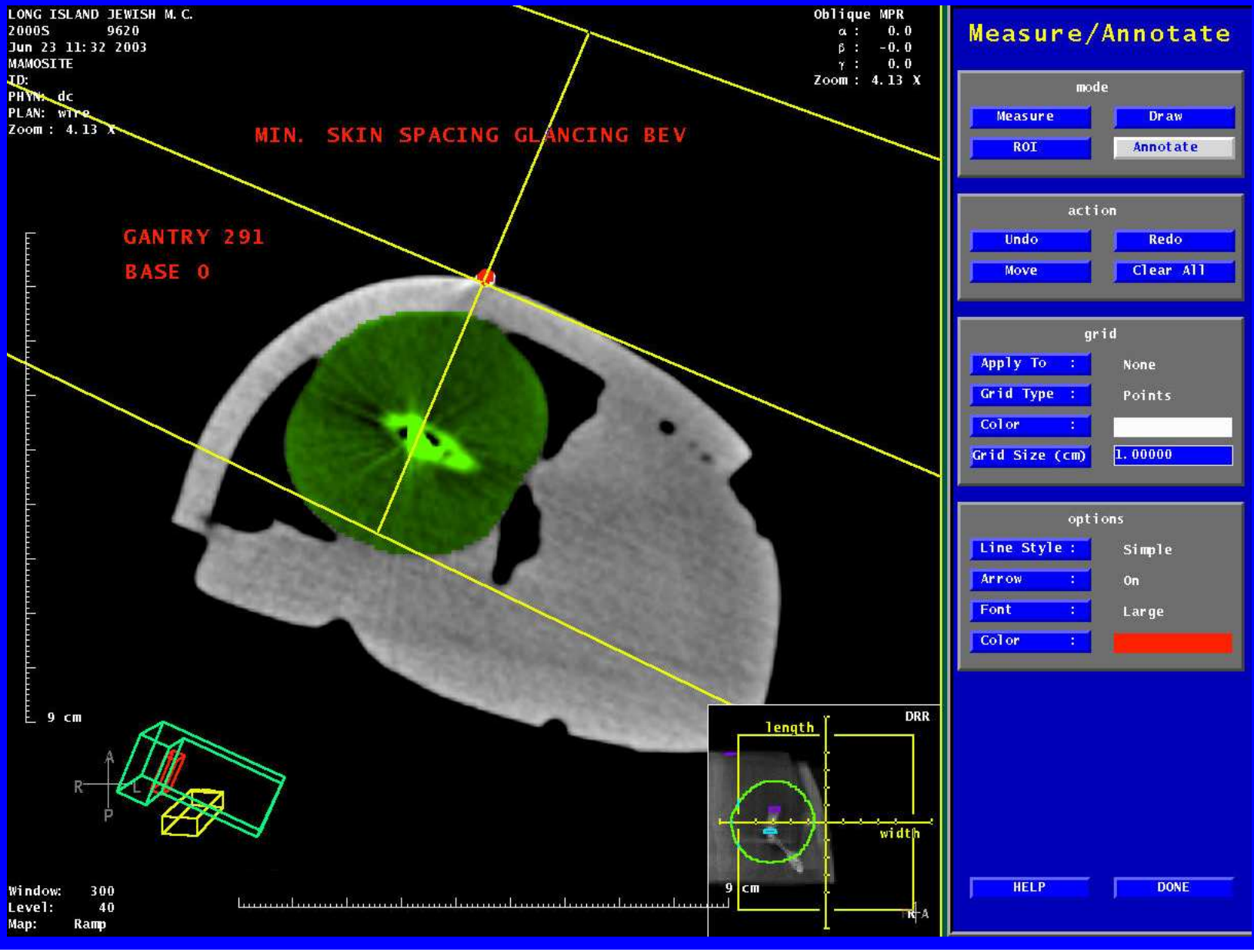
Localize the Center of the Balloon



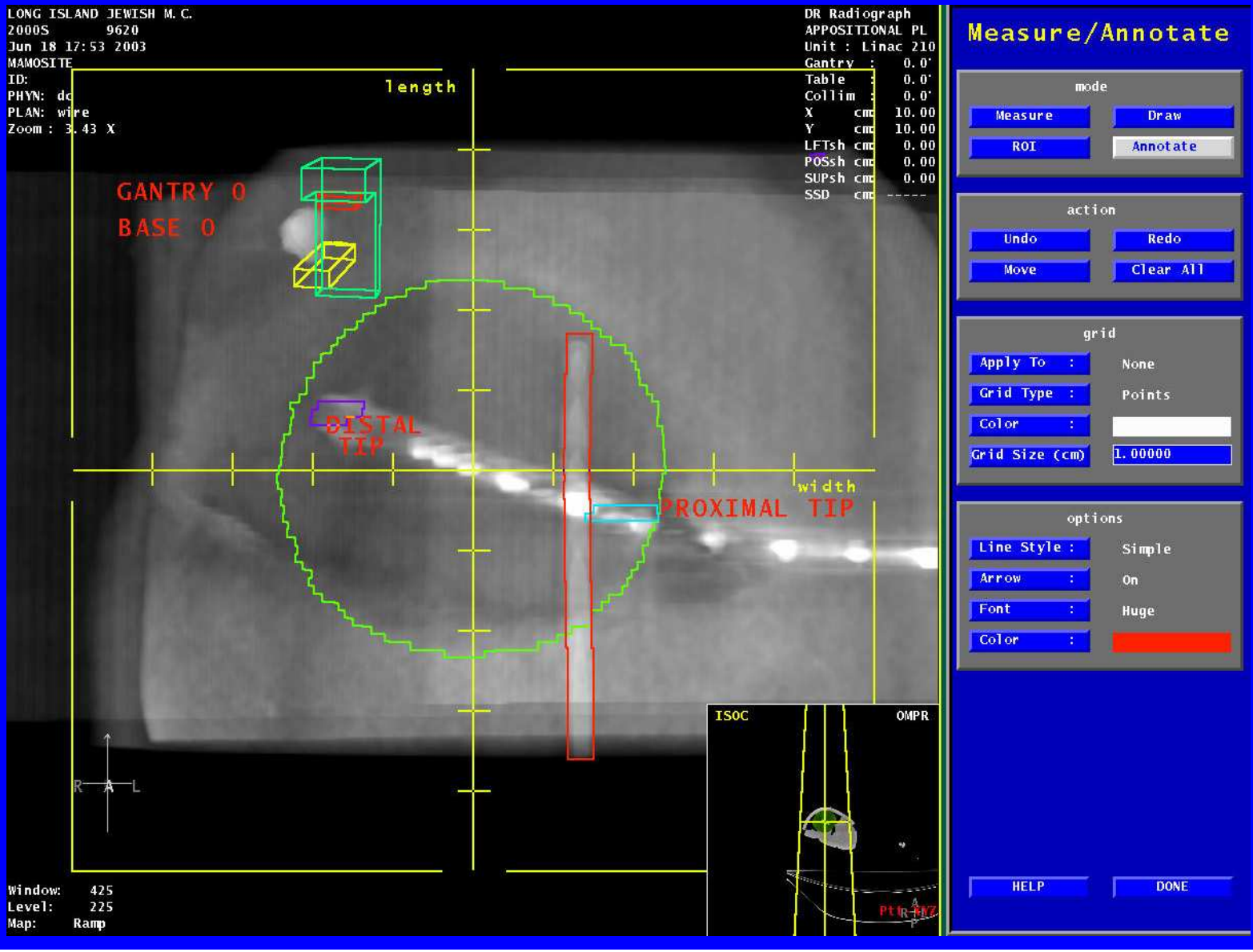
For an arbitrarily oriented balloon, only the central cut will show the catheter in the center of the balloon's cross section



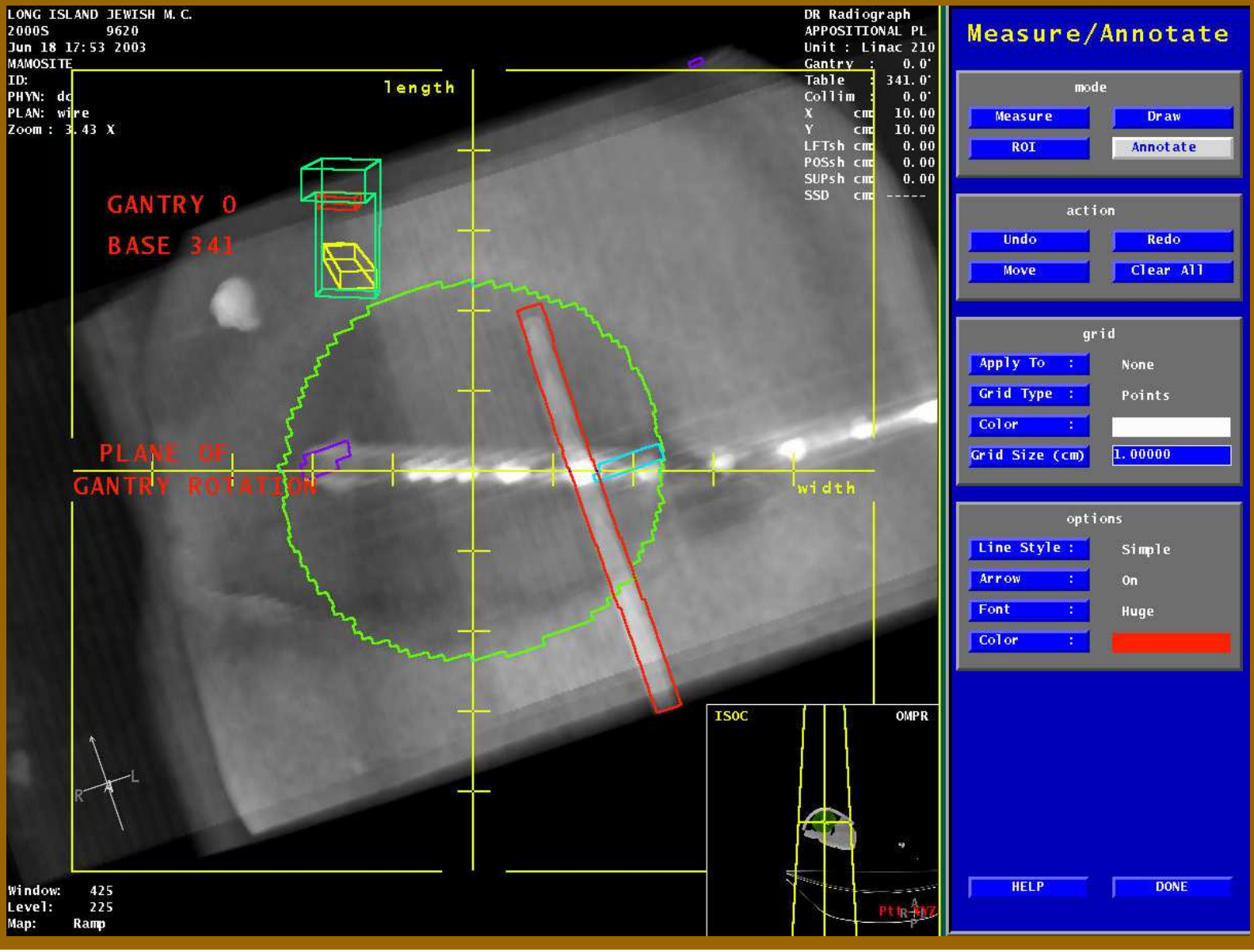
Measure the distance from the Balloon to the Skin



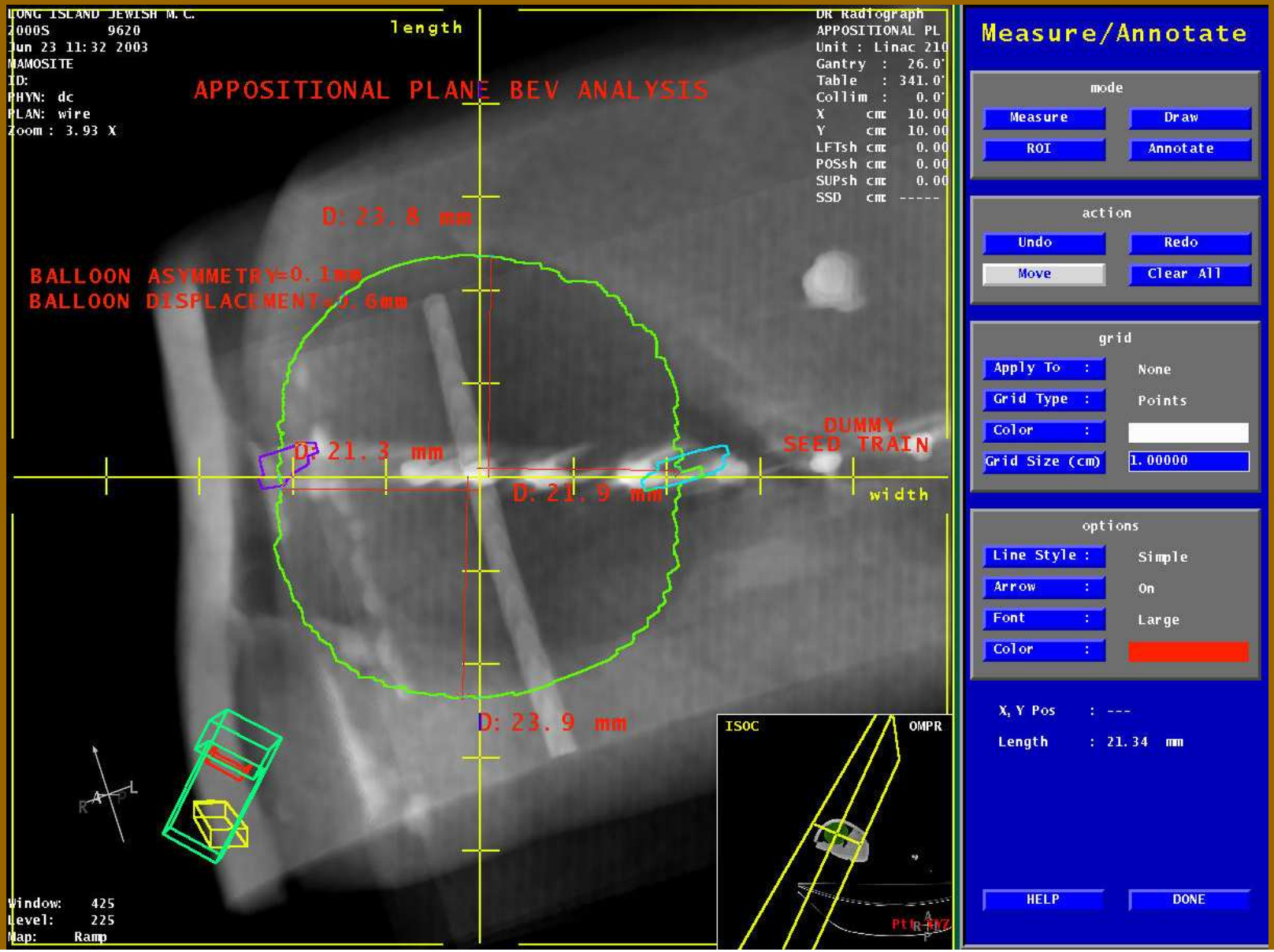
Step 1- Isocenter approximately at center of balloon



Step 2 – Couch is Rotated to bring the Catheter to the Plane of Gantry Rotation



Step 3 – Rotate the Gantry to Obtain the Maximum Catheter Span



Find the Glancing Angle View
Measure Distance to skin

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MammoSite-CT Standard Simulation Form

Date:

Patient Information:
Patient Name : Medical Record Number:
Radiation Oncologist : Physicist:

CT Virtual Simulation Appositional Plane Film Setup Parameters

Gantry Angle : Couch Angle:

Measured Balloon Parameters from Apposition Film:
-Balloon Length (mm):
-Balloon Max. Transverse Width (mm):
-HDR Final Indexer Position (mm):
-Balloon Asymmetry (mm):

CT Virtual Simulation Min. Skin Spacing Glancing Film Setup Parameters:
Couch Lateral Shift from Balloon Center (Lt +ve):
Couch Vertical Shift from Balloon Center:
Gantry Angle : Coach Angle:

Measured Min. Skin Spacing From Glancing Film (mm):

Radiograph Appositional Plane Film Setup Parameters:

Gantry Angle : Couch Angle:
KVP : MAS :

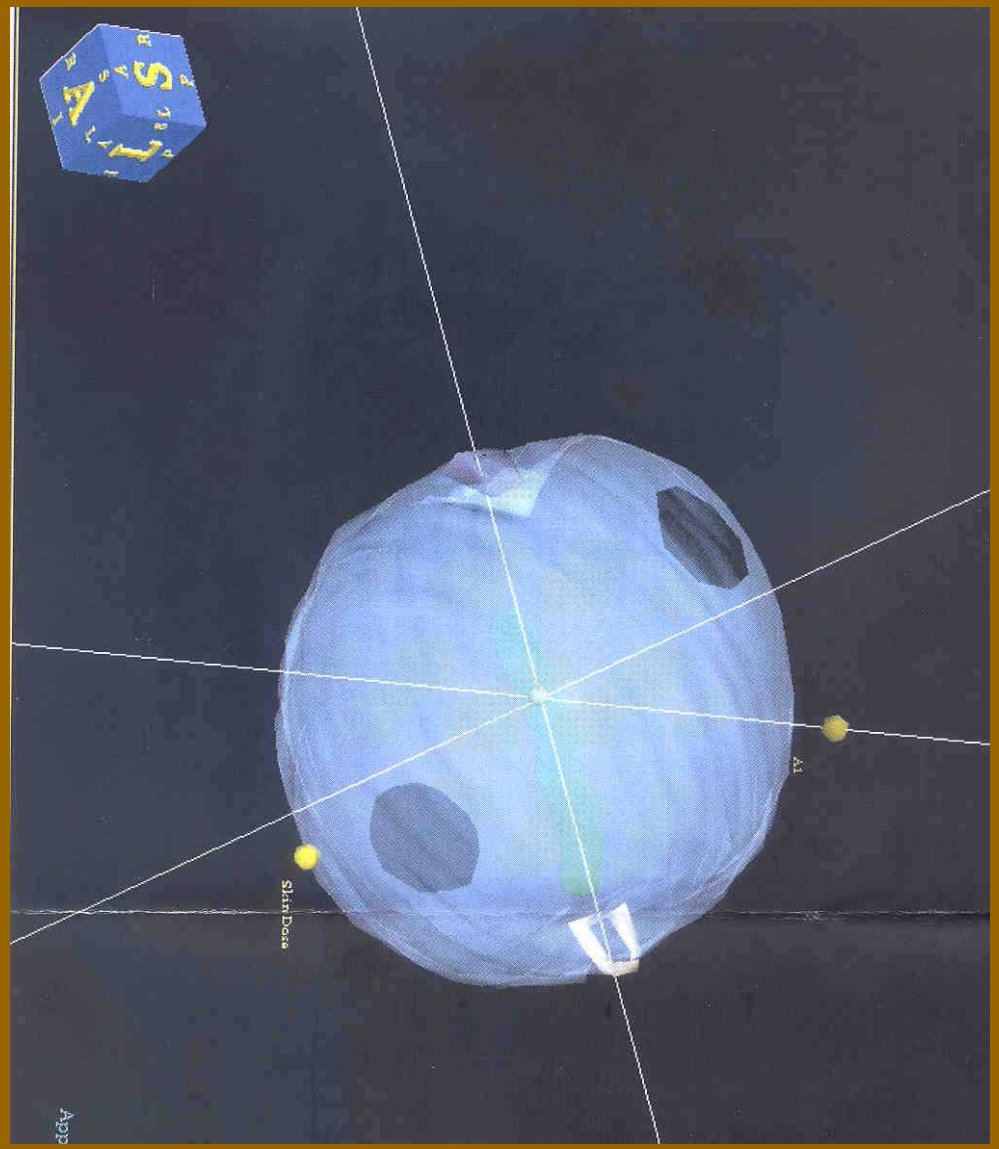
Measured Balloon Parameters From Radiograph:
-Balloon Length (mm):
-Balloon Max. Transverse Width (mm):
-HDR Final Indexer Position (mm):
-Balloon Asymmetry (mm):

Radiograph Min. Skin Spacing Glancing Film Setup Parameters:

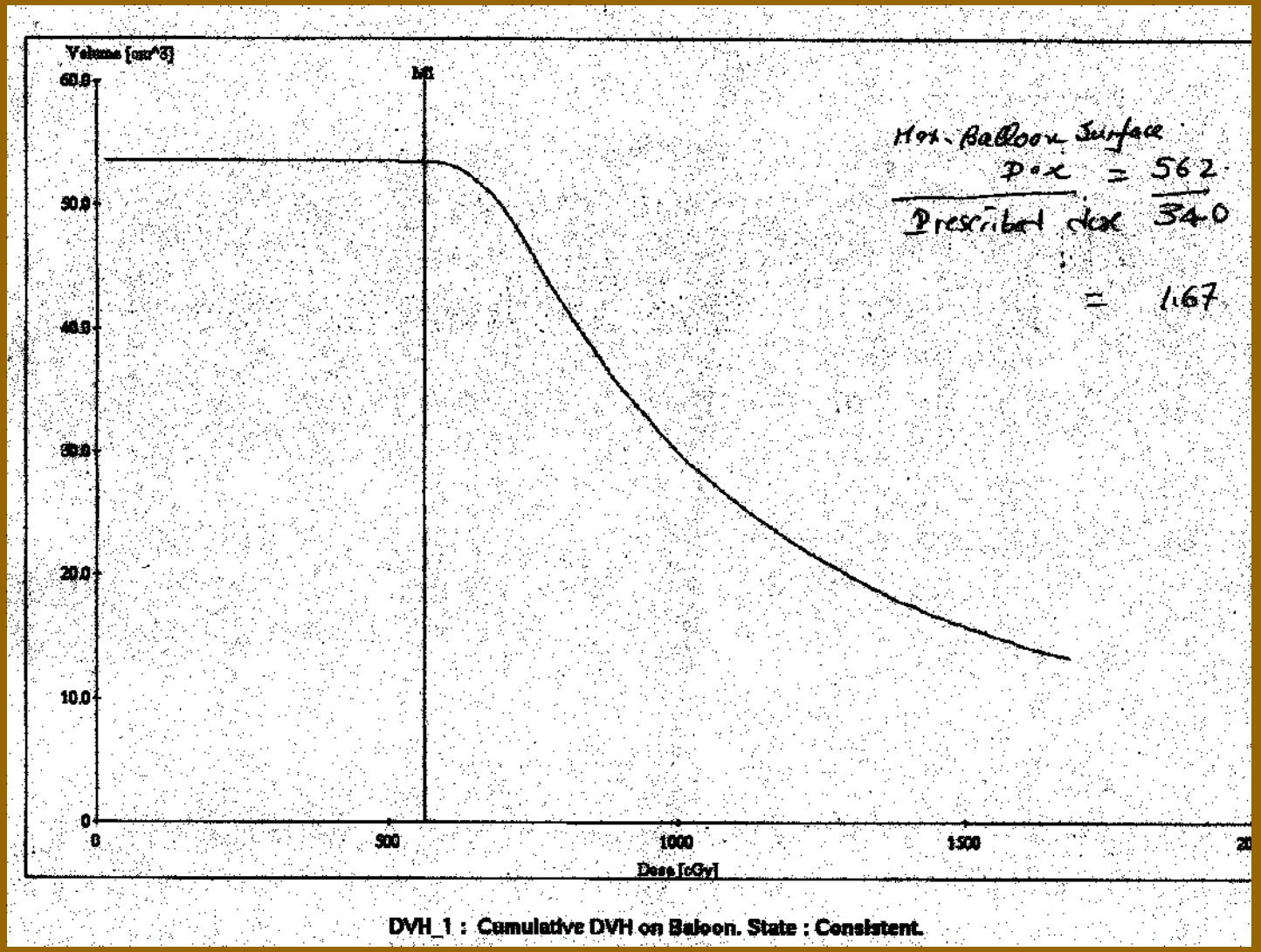
Gantry Angle: Couch Angle:
KVP: MAS:

Measured Min. Skin Spacing From Radiograph:

3D Dose surface around balloon- Plato system



DVH for the Balloon



DVH_1 : Cumulative DVH on Baloon. State : Consistent.

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MammoSite-Balloon Daily Simulation Volumetric Assessment

Patient Information

Patient Name: _____ Patient ID: _____
Physician: _____ Physicist: _____

Initial Simulation Setup Parameters + Balloon Geometry
Apposition Film:

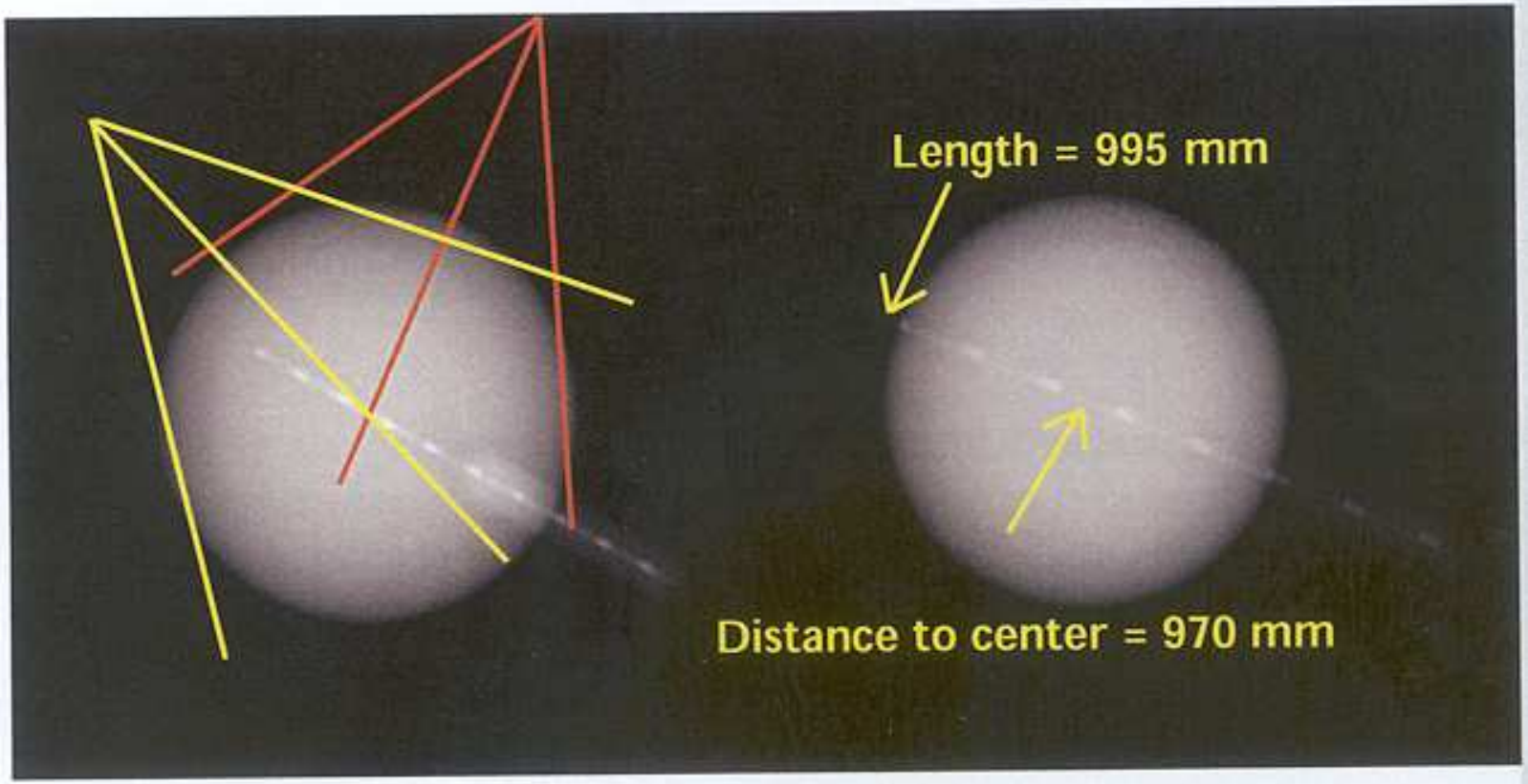
Gantry Angle: Couch Angle:
Radiograph (KVP/MAS):
Source-to-Balloon Distance (mm): Source to Film Distance (mm):
Reference Balloon Length (mm): Reference Balloon Max. Transverse Width (mm):
Calculated Balloon Volume From Table (cc):

DAILY SIMULATION

Fraction #	Date	Balloon Length/ max trvs. width (mm)	Estimated Balloon Volume (cc)	Balloon Variation (cc)	Volume Added (cc)	Physician	Physicist	Therapist

* Maximum Balloon Variation < 4.0 cc

Figure 7: Simulation Film of Dummy Seed Train Inside MammoSite Balloon



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MAMMOSITE-HDR EMERGENCY PROCEDURE

Radiation Oncologist has to be prepared to deflate and remove the applicator. Have a long forceps, a 60 cc syringe and sterile dressings available for immediate use.

1. If the source fails to retract to the safe depress **RED EMERCENCY Button** on master emergency stop switch. If the source retracts go to step 4.

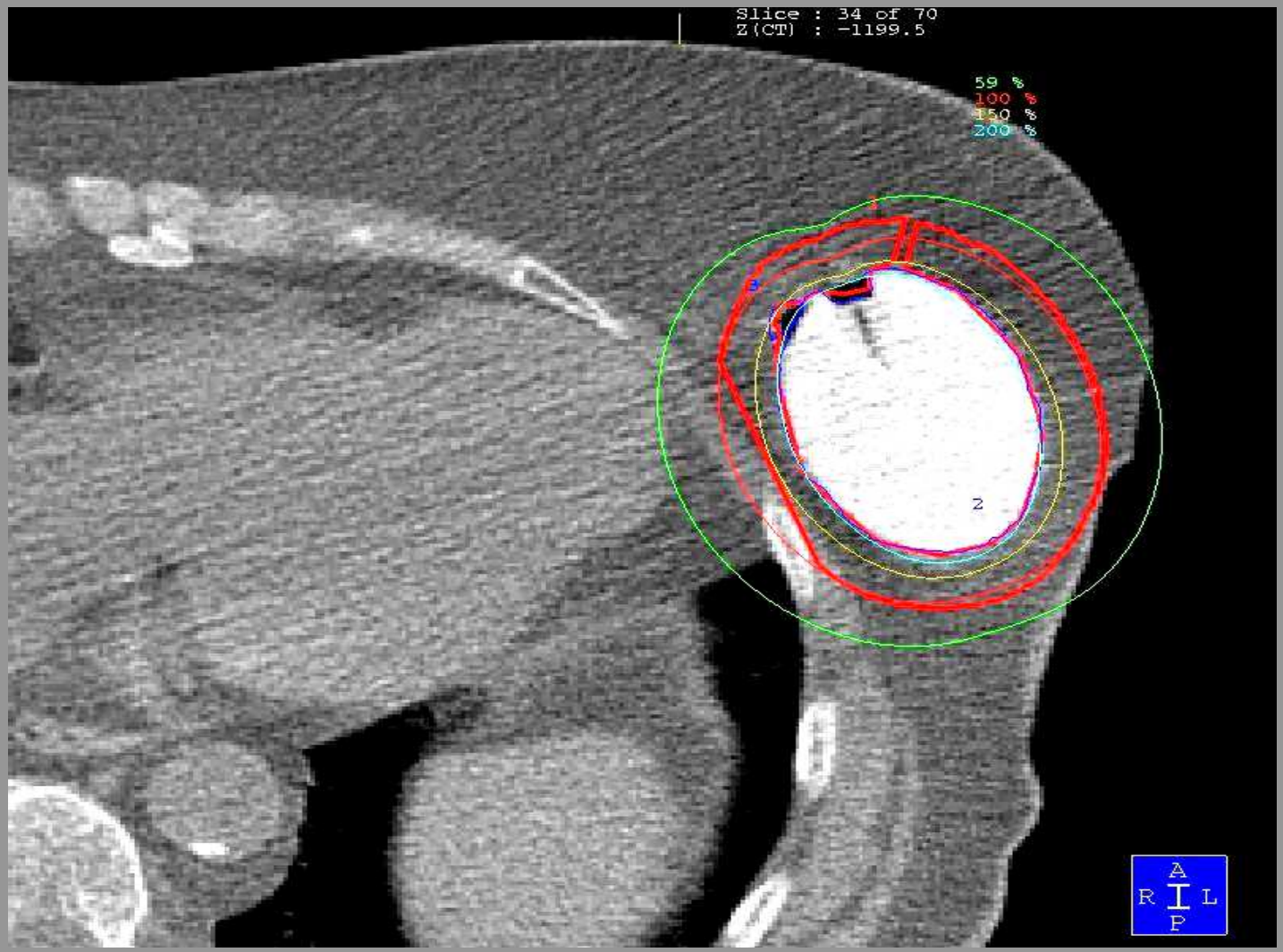
2. Immediately open the door to the treatment unit. Access the Gold hand crank on top of the HDR unit. Turn it in the direction of the arrows (on the hand crank). If the source retracts check the patient for radiation. If no radiation is detected Go to step 4.

3. If radiation is detected or if manual retraction fails the MammoSite applicator has to be removed immediately. **Do not attempt to cut the Catheter.** Radiation Oncologist has to deflate the balloon and remove the applicator. Using long forceps insert the applicator containing the source into the well. Guide the transfer tube through the recess at the container edge. **Immediately assist the patient from the room.** Leave the room and mark it **No Entry.**

4. Retain the treatment data printout and contact the following:
   -HDR/Nucletron Representative: Tel. (800) 336-2249
   -Radiation Safety Officer: (Beeper) Tel. (718) 448- 7548
   Do not attempt to use the unit until the problem is cleared.

5. The unintended radiation dose to which those present have been subjected should be estimated and recorded.

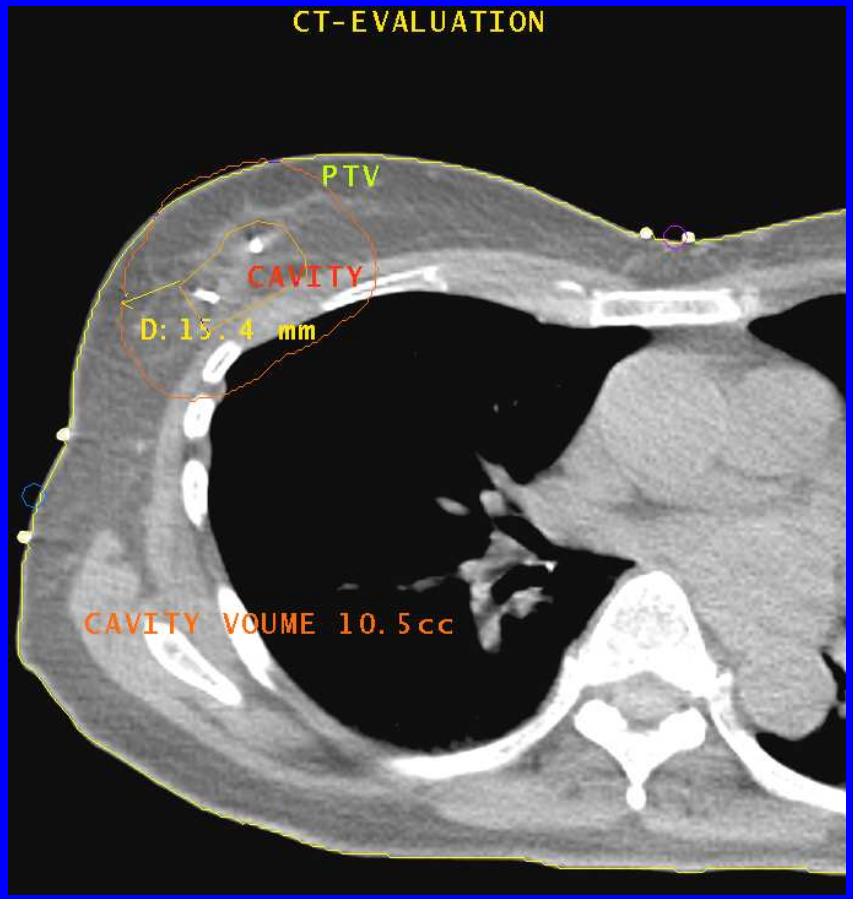
Elliptical Balloon Conforms the Dose Closely Around the Cavity, While Sparing Radiation to the Adjacent Lung and Heart

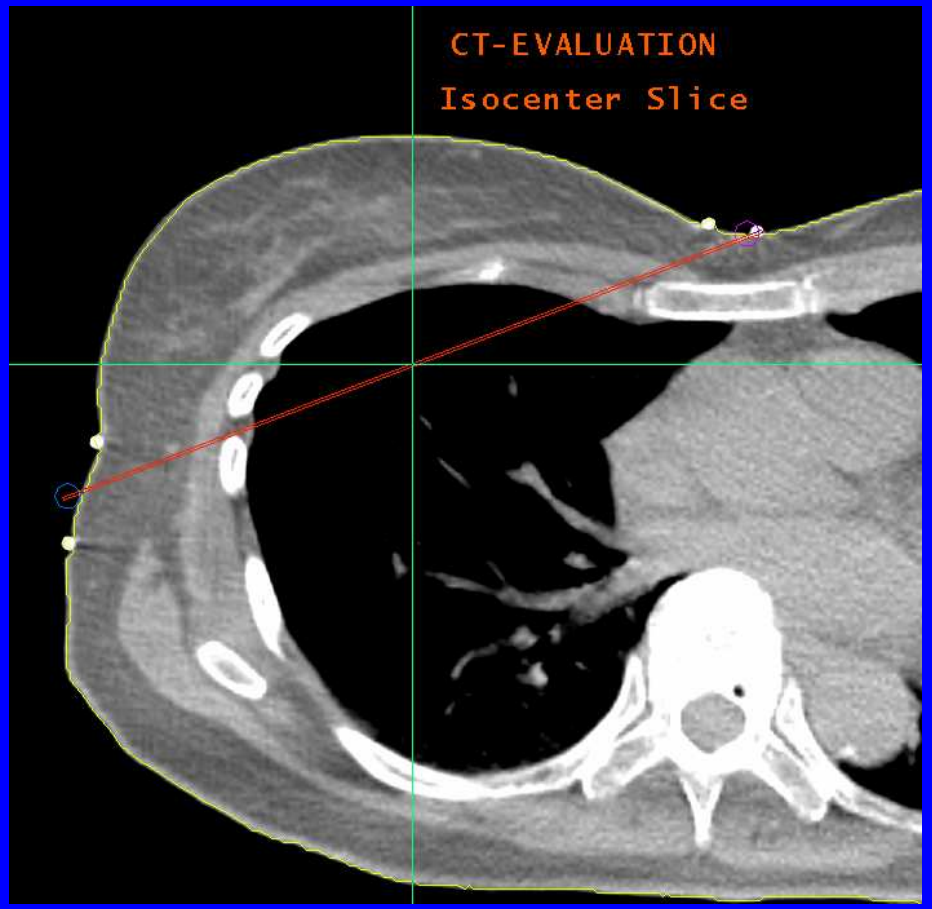


CT based Patient Evaluation for PBI with Multi-catheter volume implant

- **Form, volume and location are somewhat less restrictive with multi-catheter treatment than for MammoSite**
- **The cavity should be identifiable on CT.**
  - **Surgical clips, implanted during the lumpectomy at all margins, are ideal to facilitate this task**

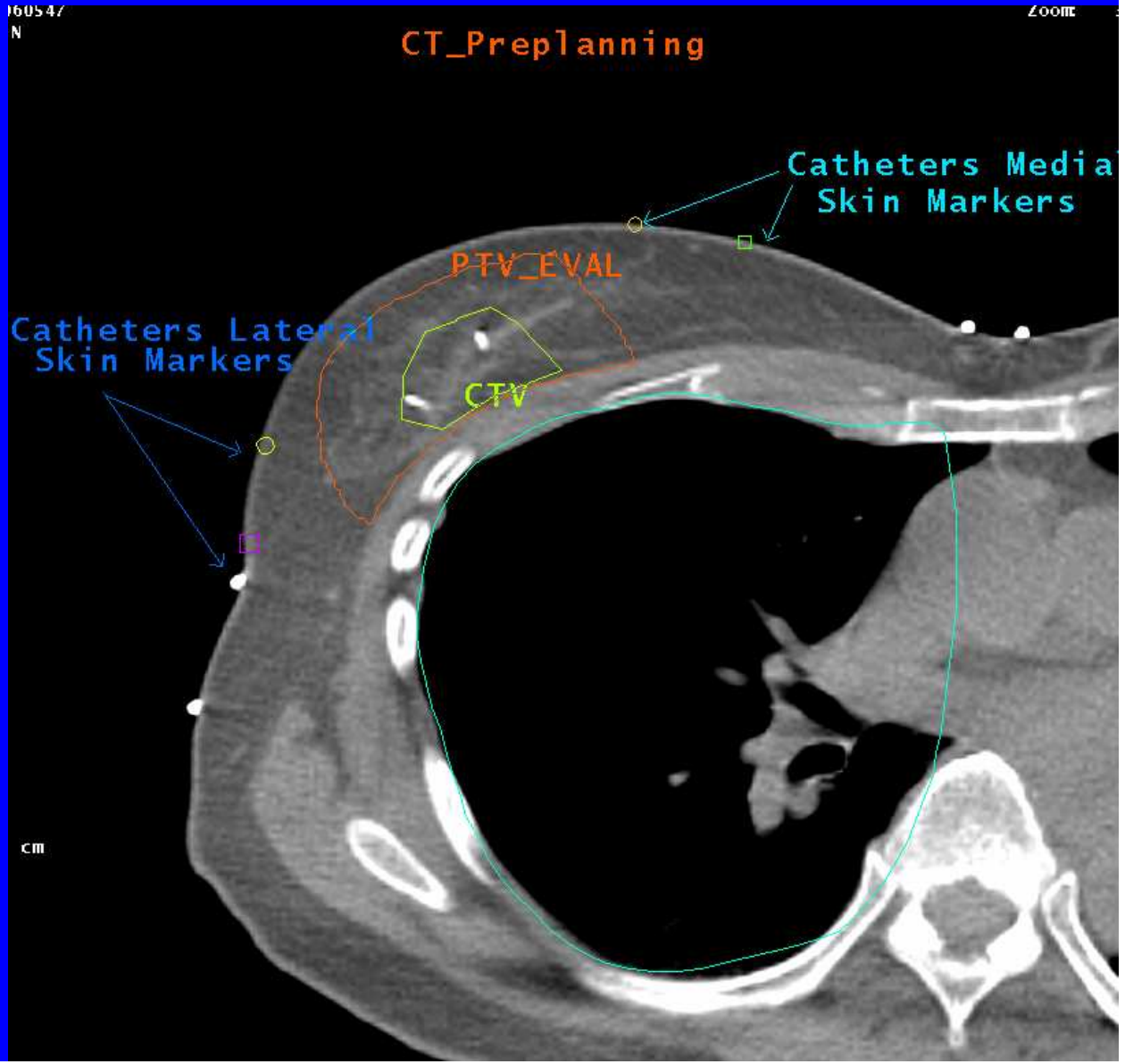
CT based pre-Planning for PBI





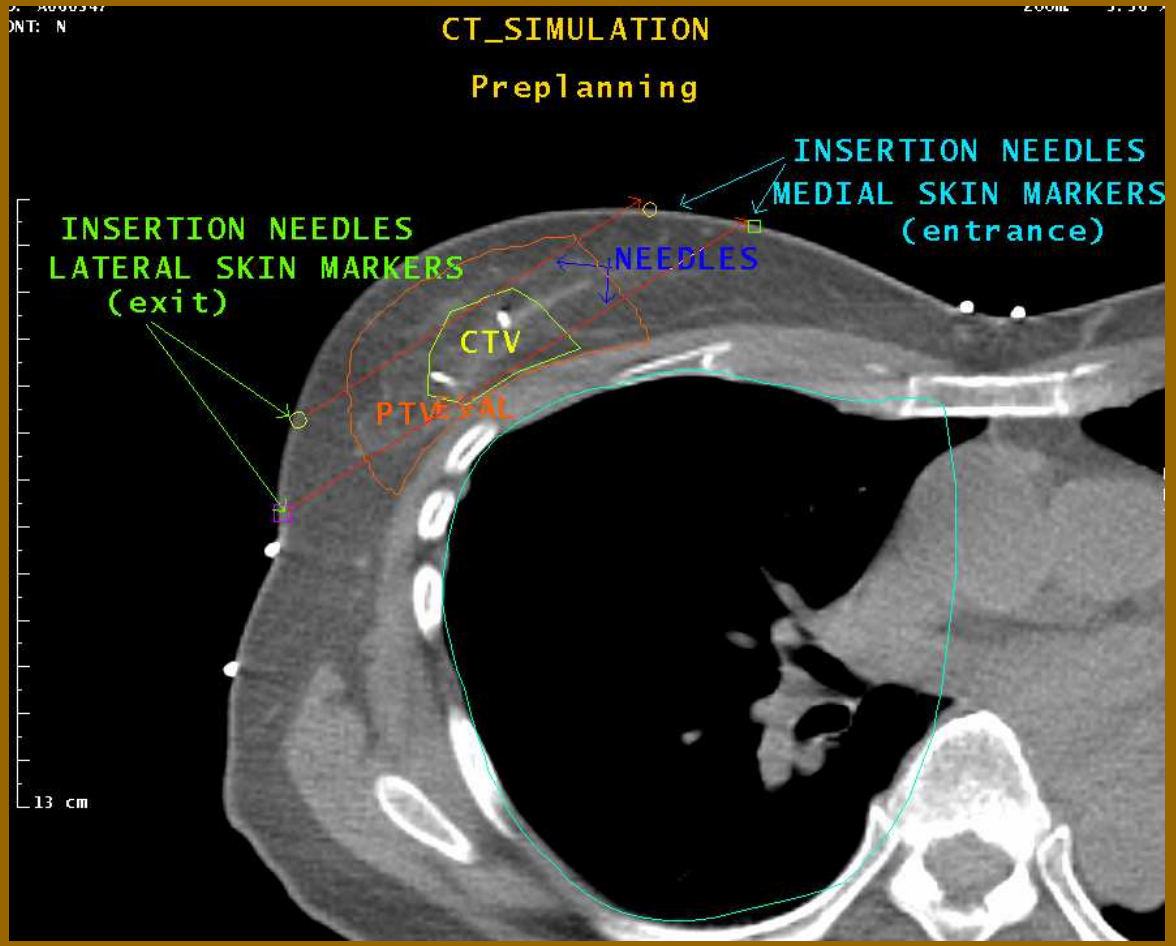
Delineation of volumes for PBI on CT

- The lumpectomy cavity is drawn by the MD on all CT slices.
- The PTV is generated by adding a 15 mm margin.
- The PTV is further modified to exclude the pectoralis muscle and the 5 mm layer below the skin to define a

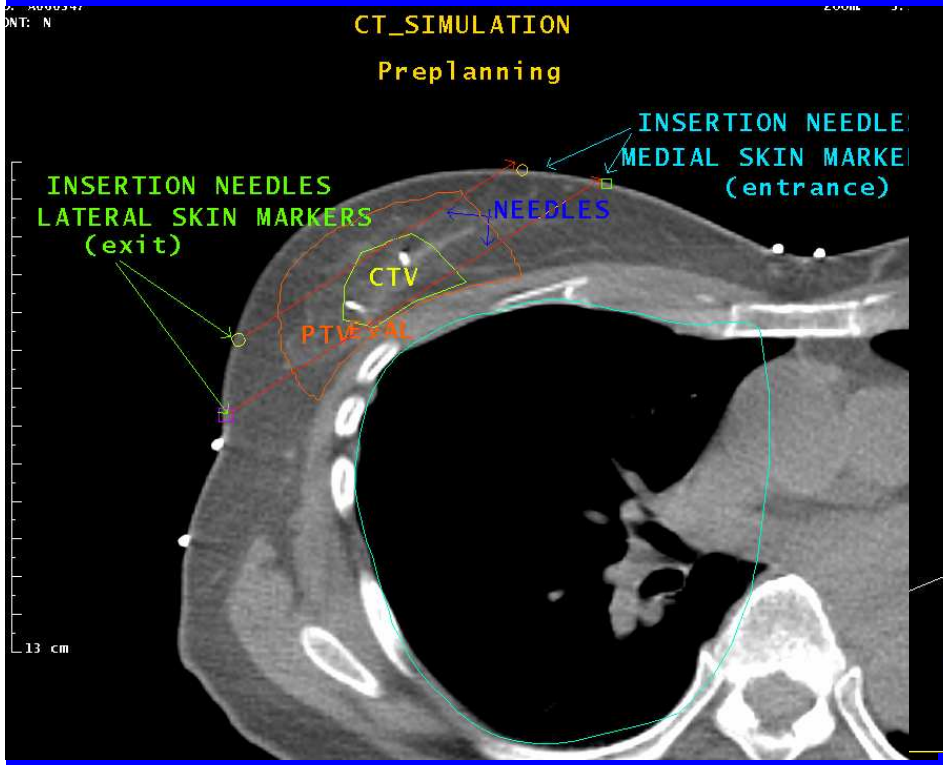


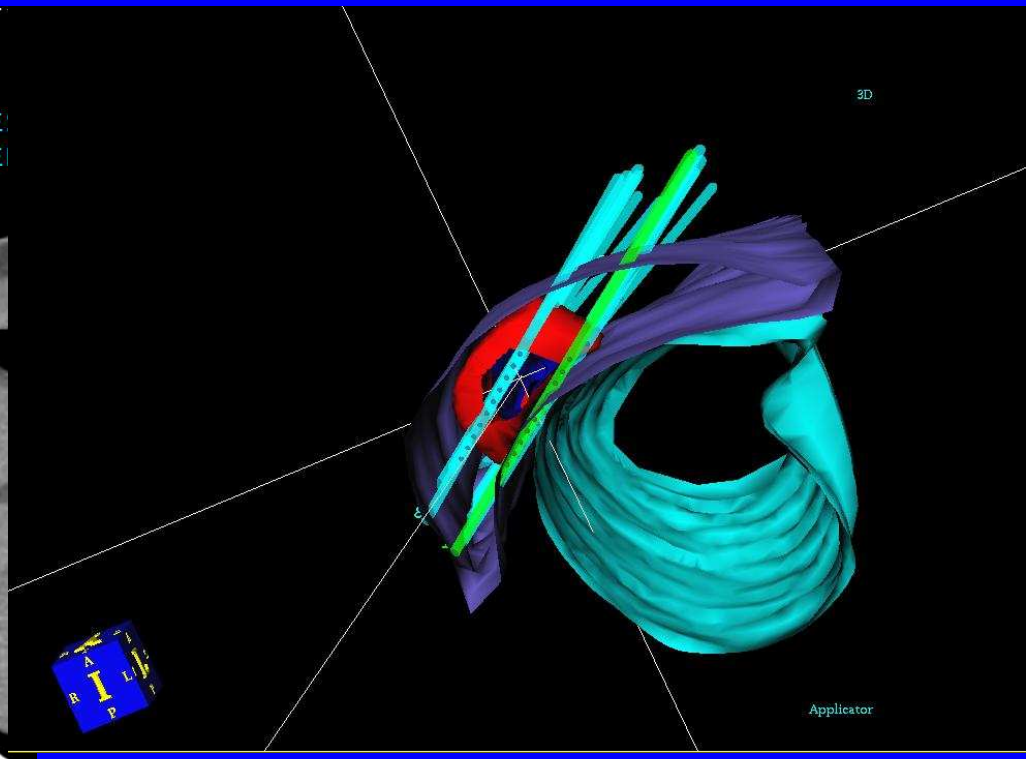
Design Goals of Catheter Layout

- A set of catheters in two planes parallel to the chest wall.
- Planes to sandwich the cavity, one above and one below.
- For larger volumes consider extra plane
- The needles should allow source positions 2 cm before and 2 cm beyond the delineated cavity.

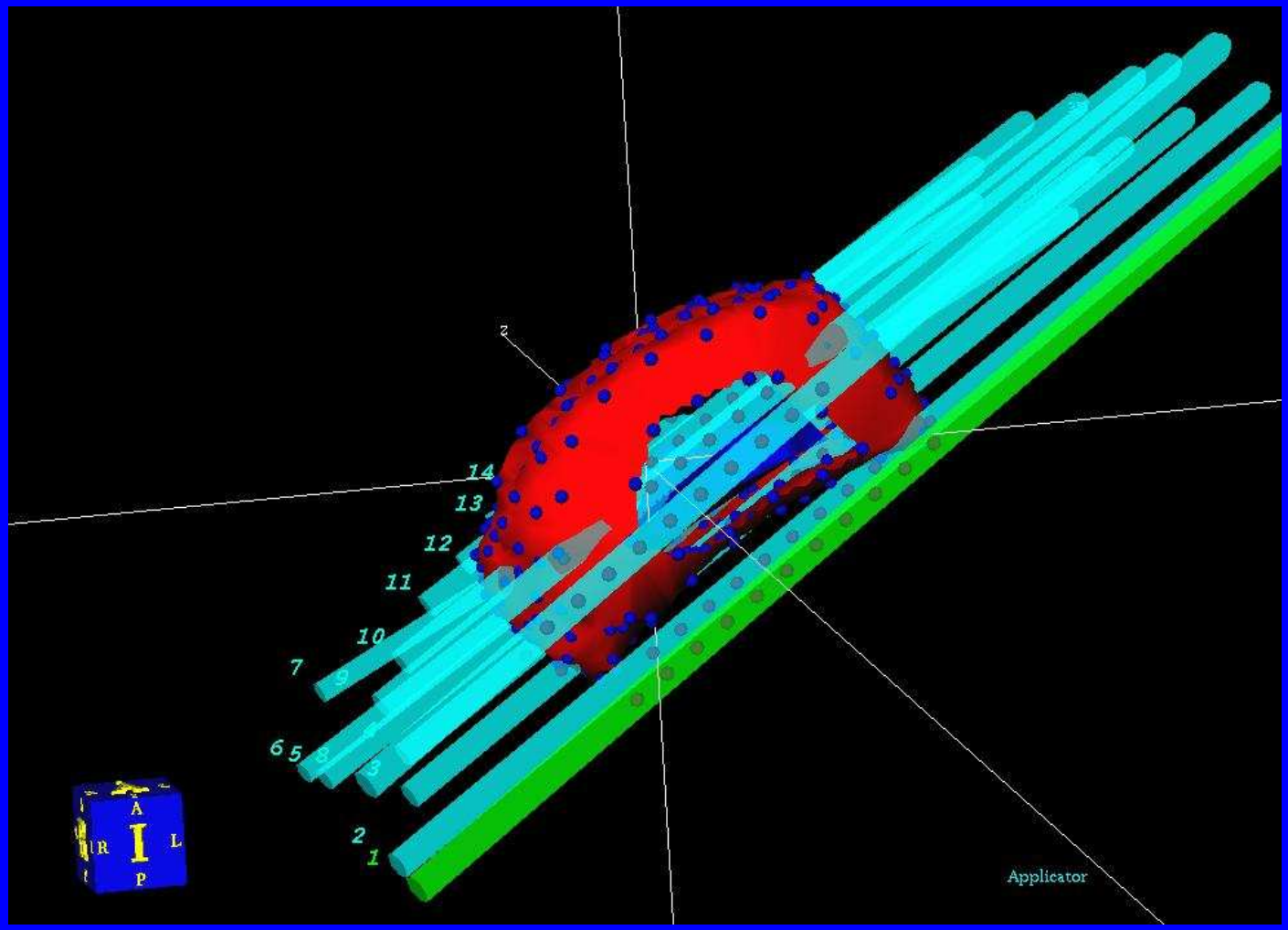


Use the simulated needle arrangement to reconstruct the catheters in PLATO

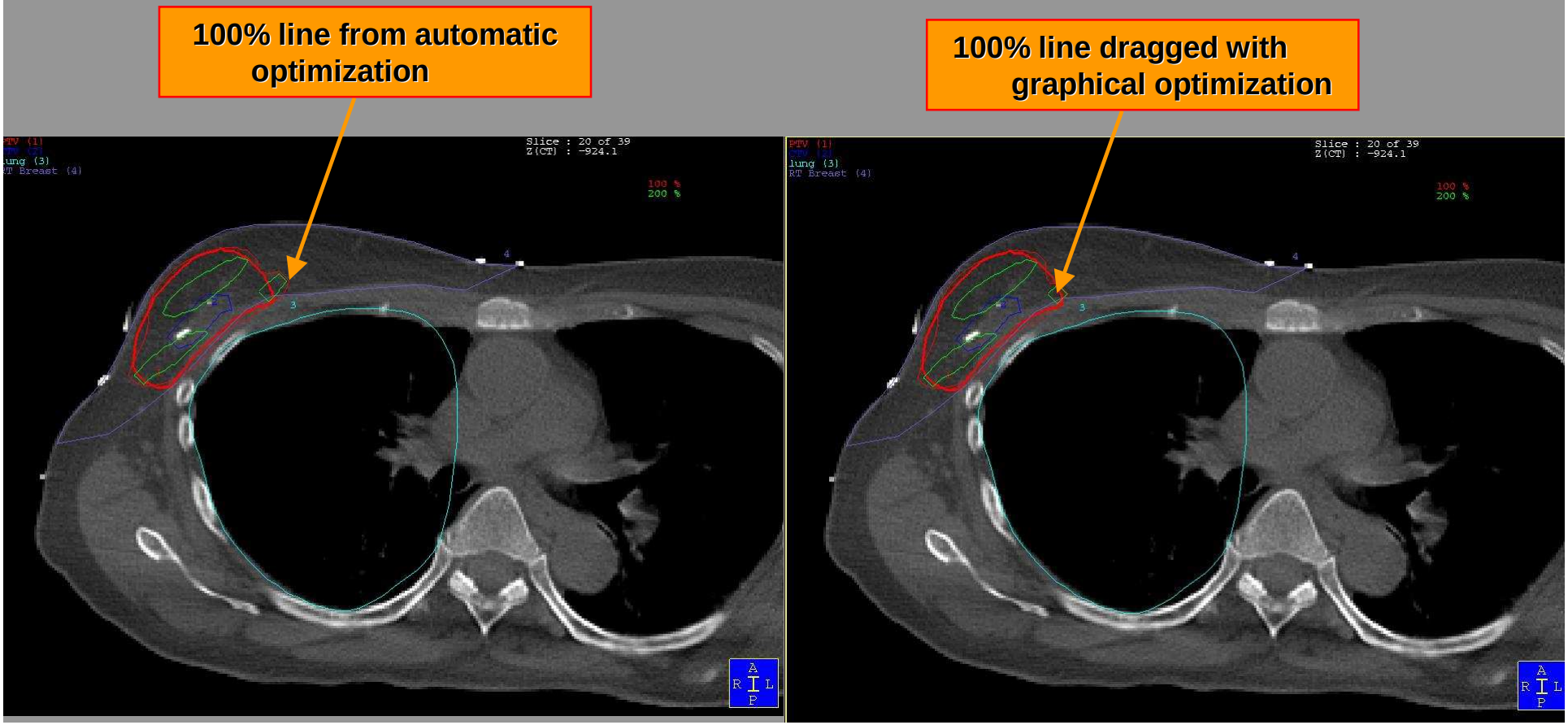




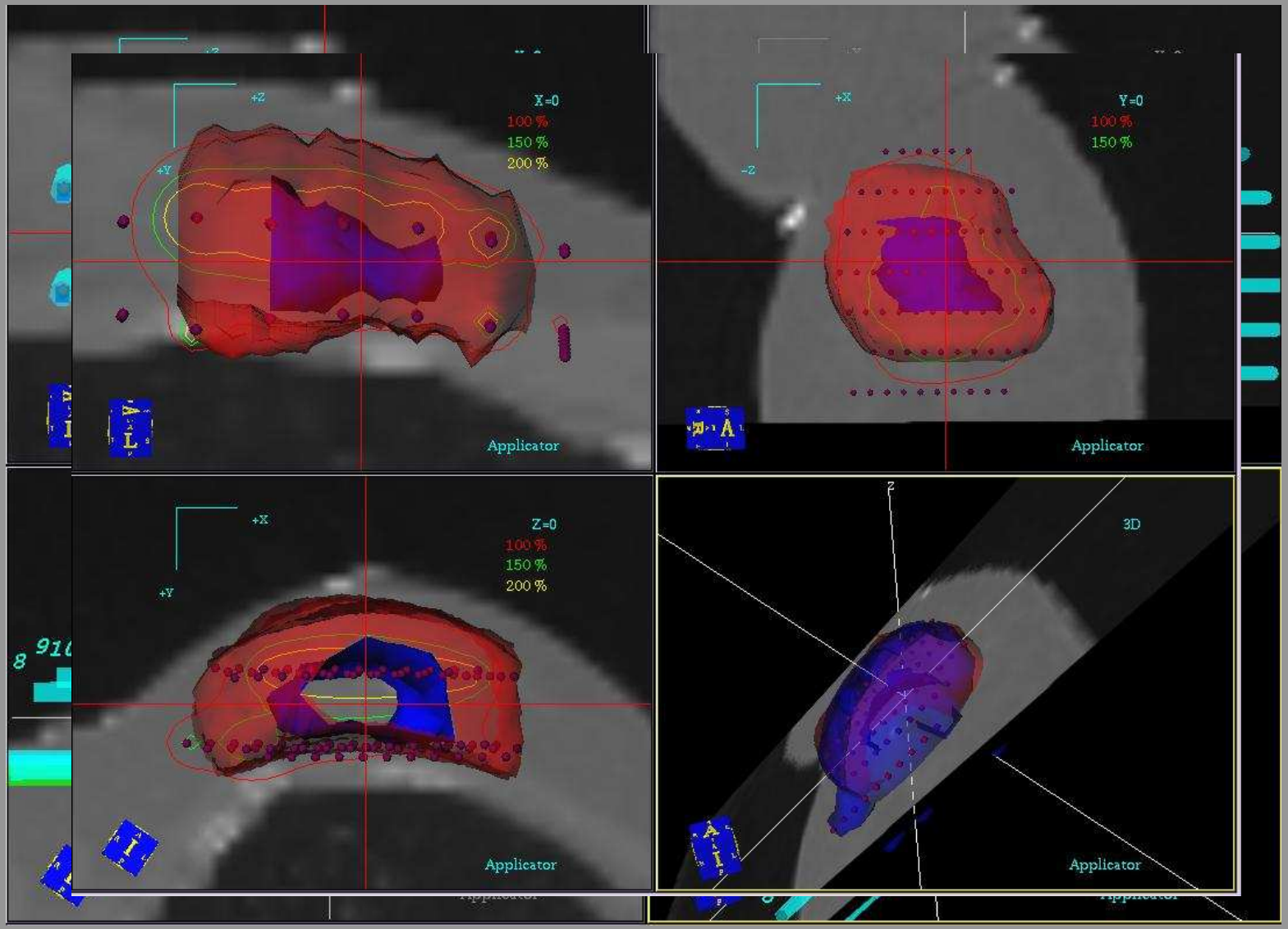
Define “Dose Points” encompassing the target to be used for volume optimization.



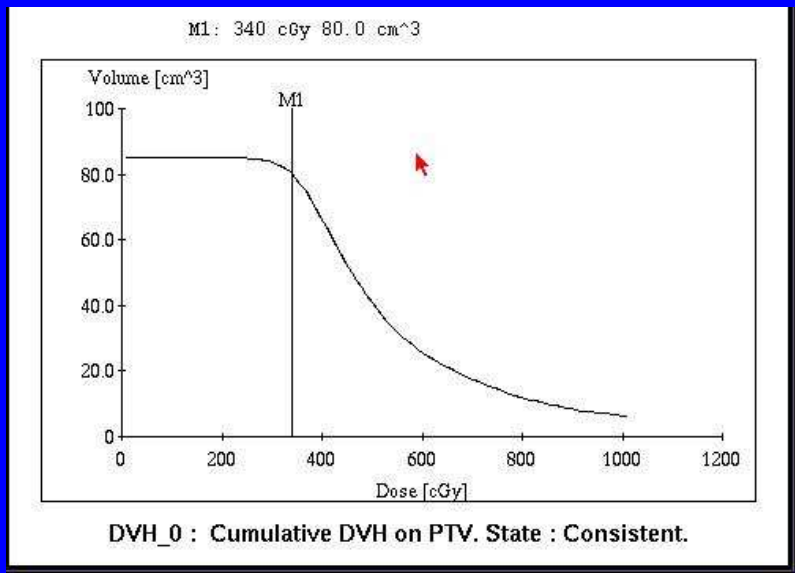
- **“Graphical Optimization” used interactively to drag isodose lines on axial slices and further modify the distribution obtained with the multipoint algorithm.**



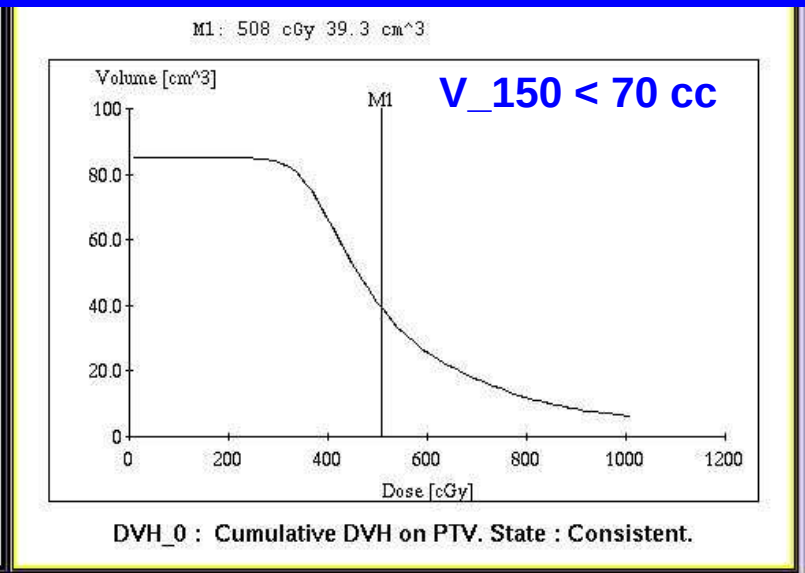
- **Preplan display with Isodose distribution**



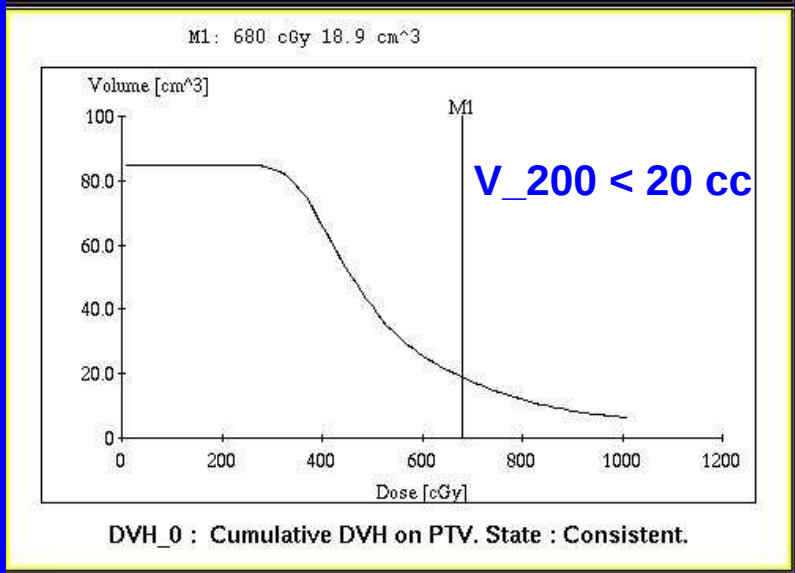
Preplan DVH for the PTV meets goals



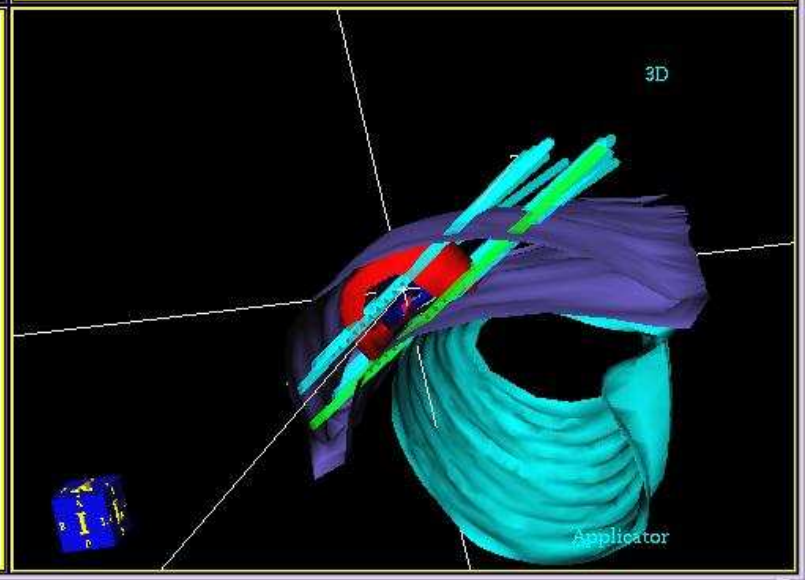
DVH_0 : Cumulative DVH on PTV. State : Consistent.



DVH_0 : Cumulative DVH on PTV. State : Consistent.

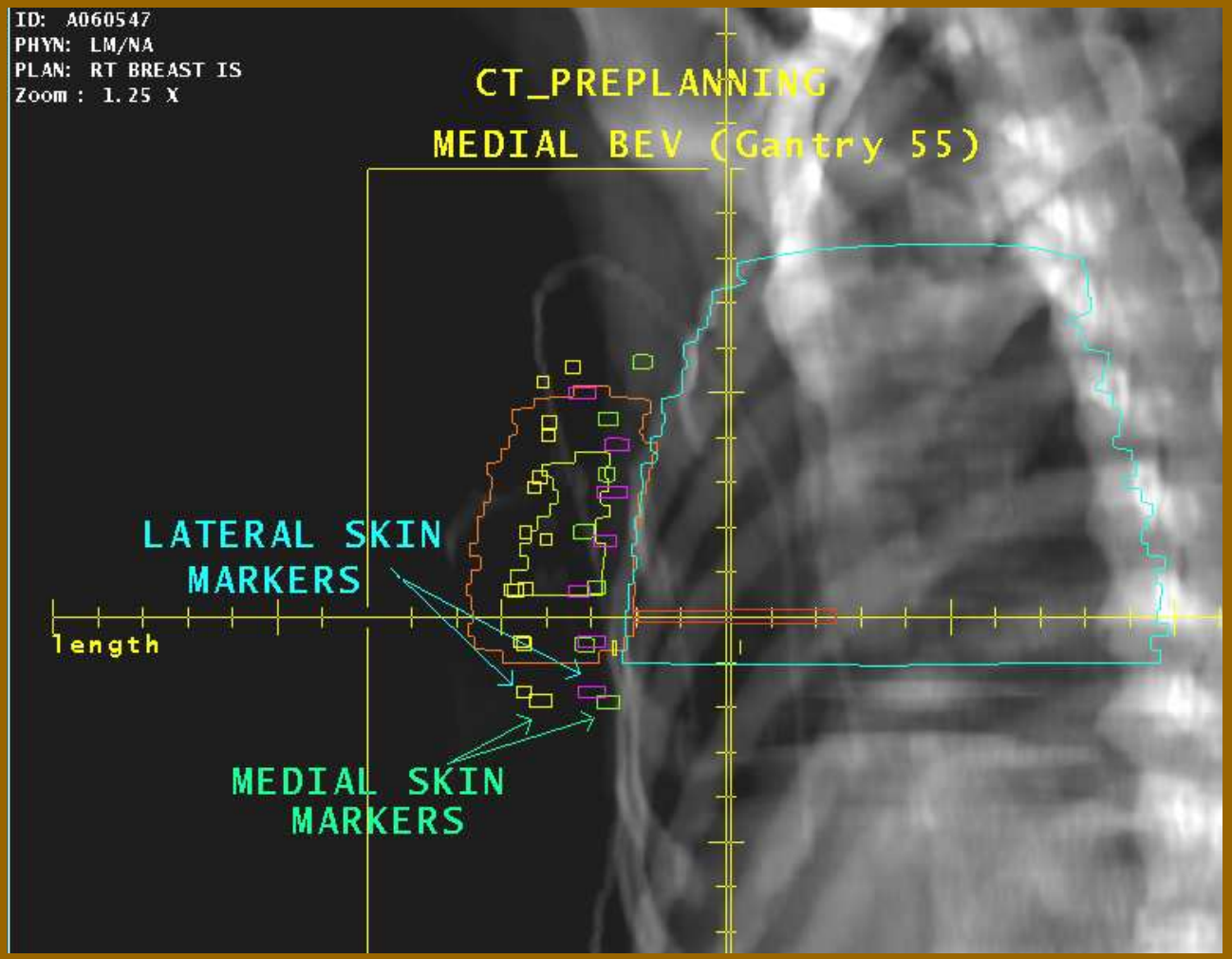


DVH_0 : Cumulative DVH on PTV. State : Consistent.



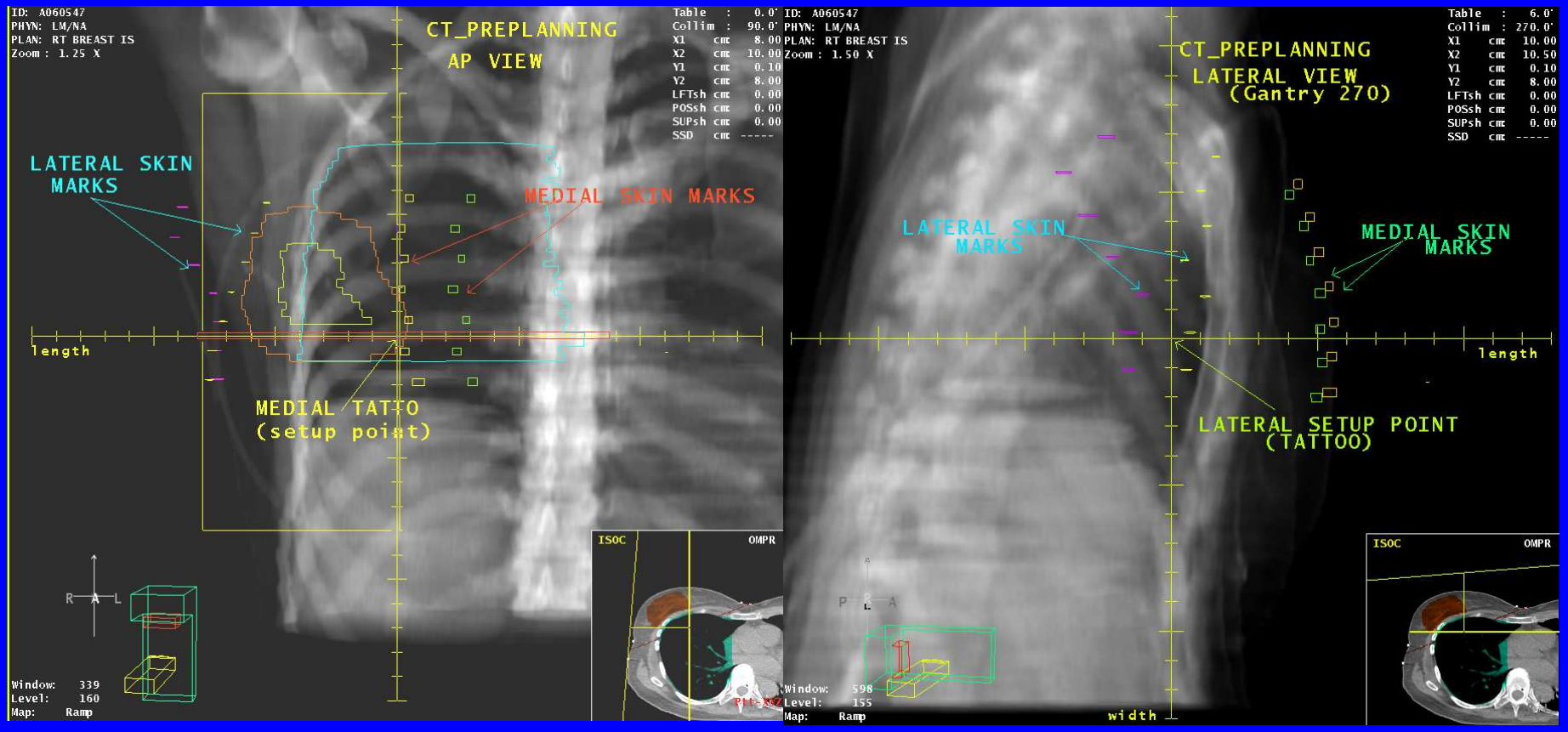
Pre-implant Marking of needle entrance and exit points - 1

- Confirm that entrance/exit positions of each individual catheter on the CT virtual fluoro matches the preplan in Plato.



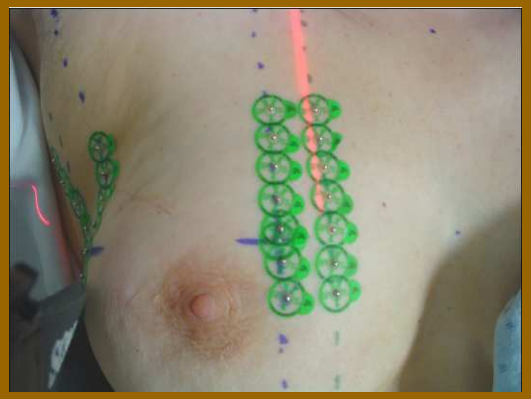
Pre-implant Marking of needle entrance and exit points - 2

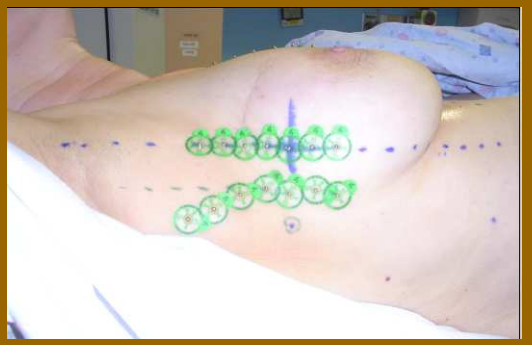
- Generate AP and LAT DRR's on the Virtual Sim, each centered on the corresponding setup marker.
- The therapist will use these two DRR's to mark the patient.

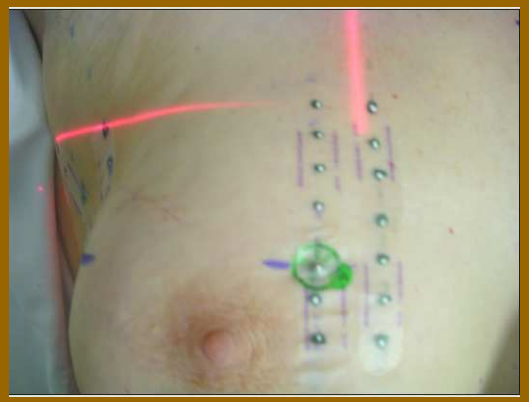


Pre-implant Marking

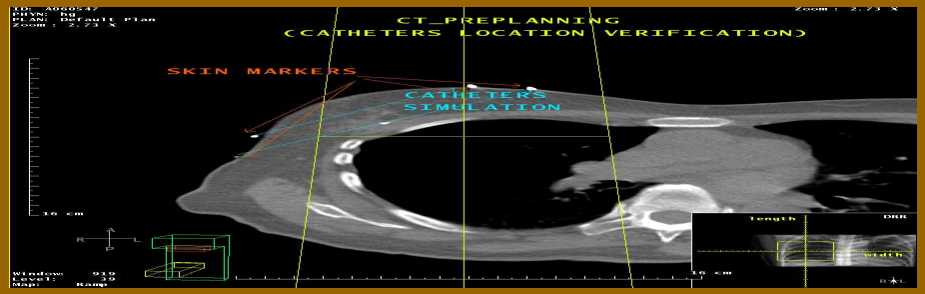
- The day before the procedure, the patient is setup in the Treatment/CT Position.
- Using both DRR's , the simulator therapist will mark the catheter position on the patient skin.
- The marks will be covered with a clear tape.







Verification of marking of needle entrance and exit points can be done with CT markers placed over the highlighted skin marks and comparing with the plan.

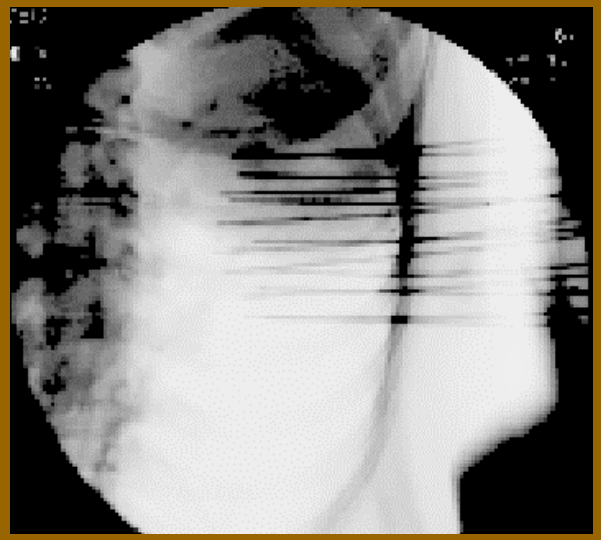


Needle Placement in OR

- A fluoroscopy unit is booked for the procedure (C-arm). The fluoro-unit will assist the physician to guide the insertion.
- Surgeon will scrub the patient. The clear tape will protect the simulation skin marks.
- The patient has to be positioned at the edge of the table before the anesthesia to avoid radiographic interference from metal at the side of the table.

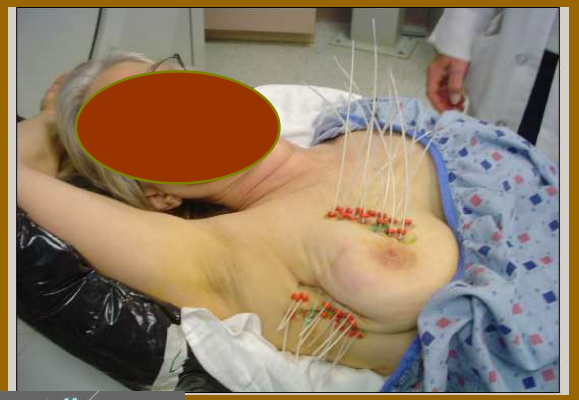
Guiding the needles according to plan

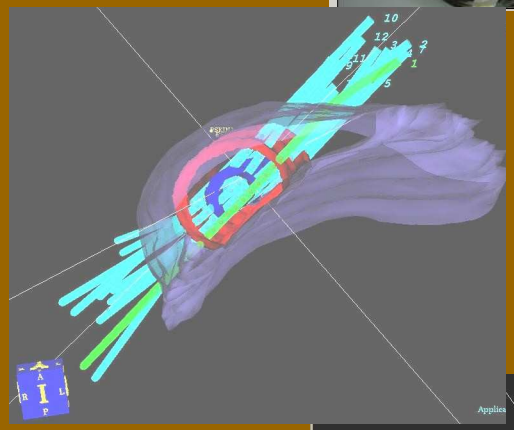
- The physician should be able to steer the needles from the insertion point if he/she can visualize the exit point while steering the needle.
- The radiation oncologist will point a long tweezers at the exit point mark, and rotate the c-arm fluoro unit until the entrance and exit points (medial and lateral) overlap while the surgeon is steering the needle under fluoro.
- It should take about 20 minutes to insert 12-15 needles
- Once all needles are placed, a film, orthogonal to the implant can be used to assess the needle alignment.

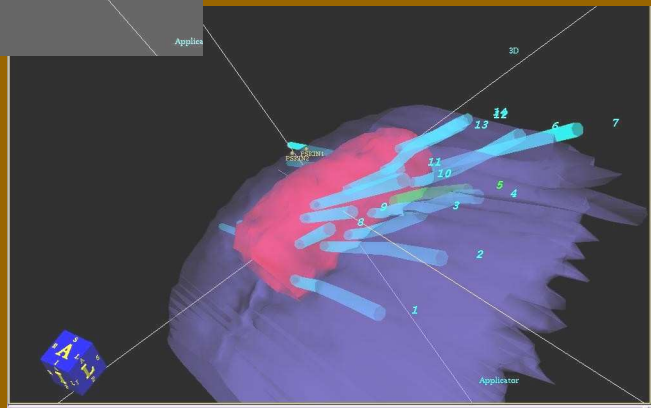


POST IMPLANT PLANNING

- The patient is scanned in the treatment position
- CT planning allows to reconstruct catheters and volumes simultaneously
- The implanted catheters sandwich the lumpectomy cavity , with almost even distance to PTV

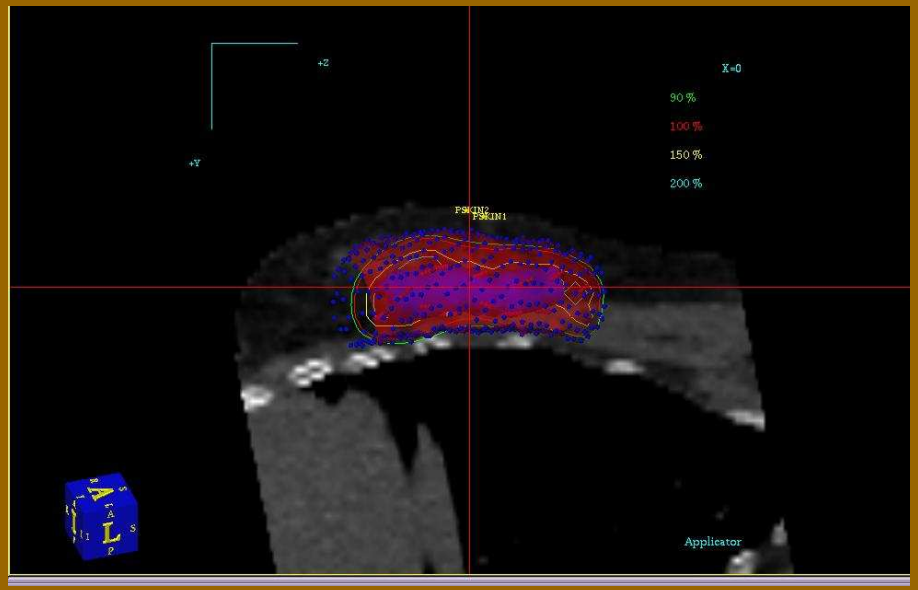




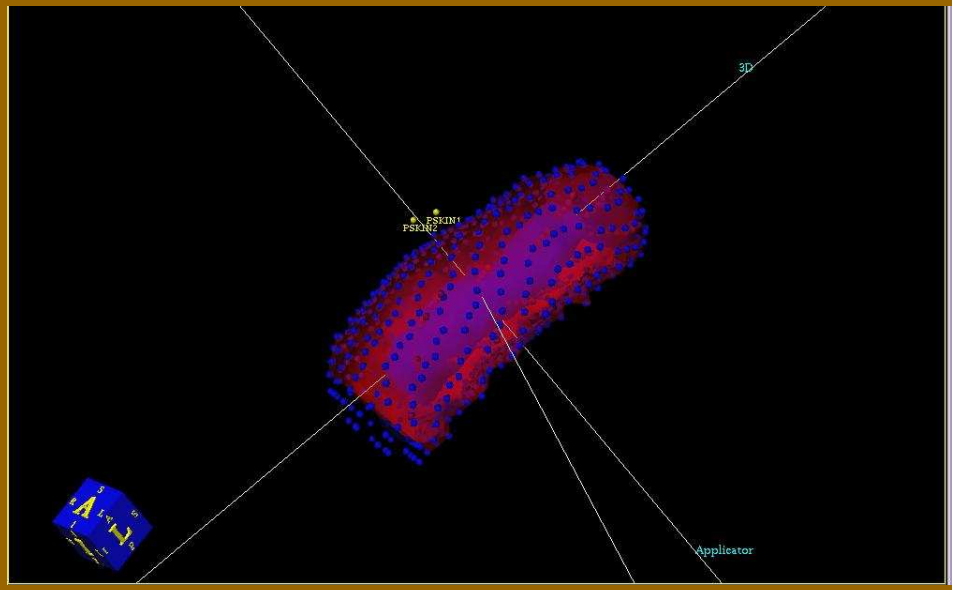


- **Dose volume optimization to dose points on the PTV surface, followed by graphical optimization to the PTV contour lines on axial slices**

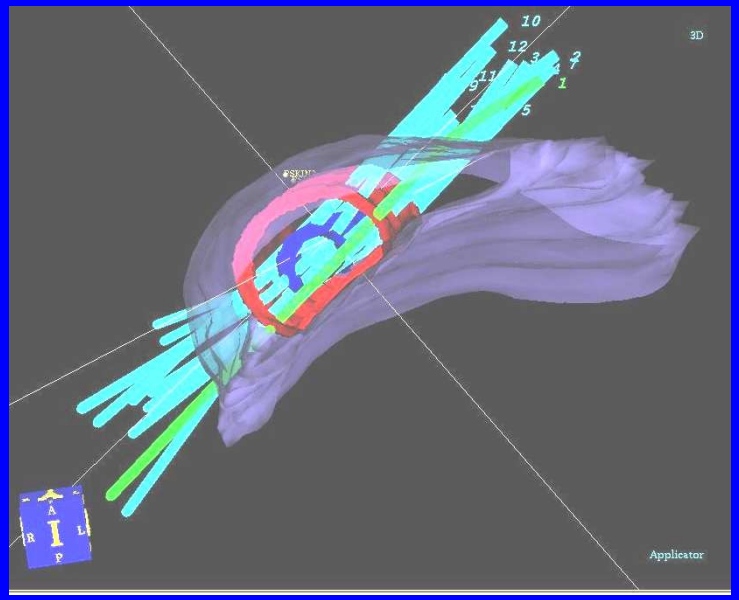
3D reconstruction across catheters

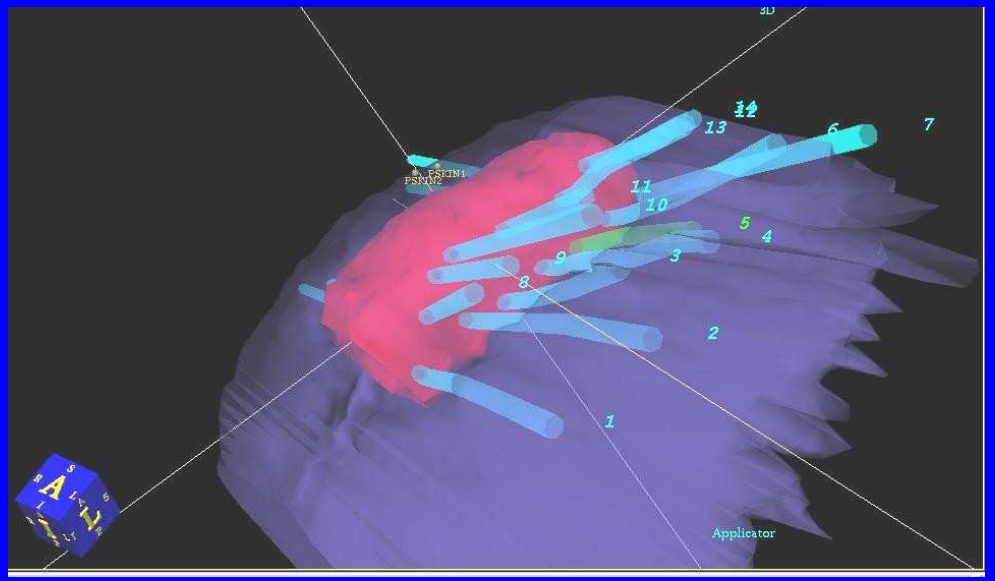


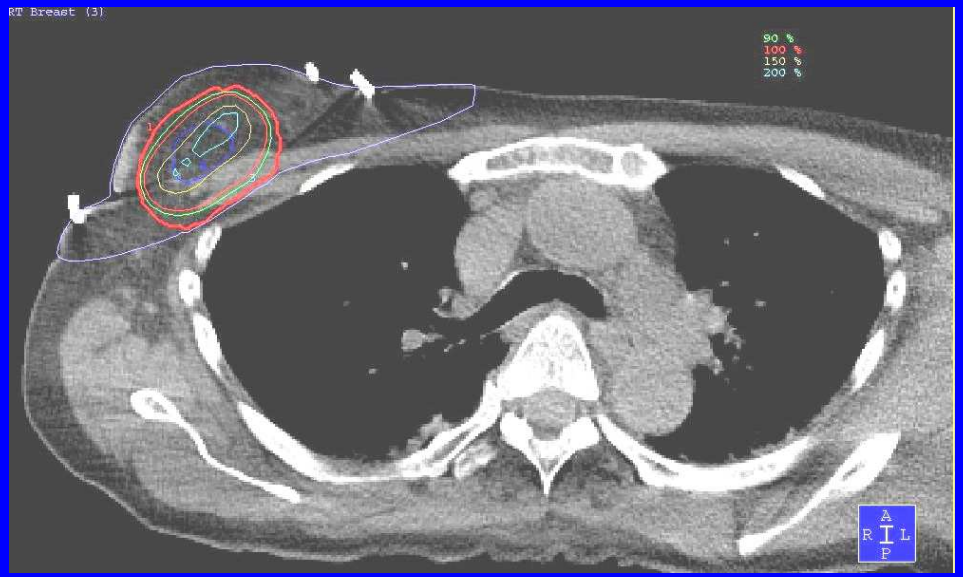
3D reconstruction along length of PTV



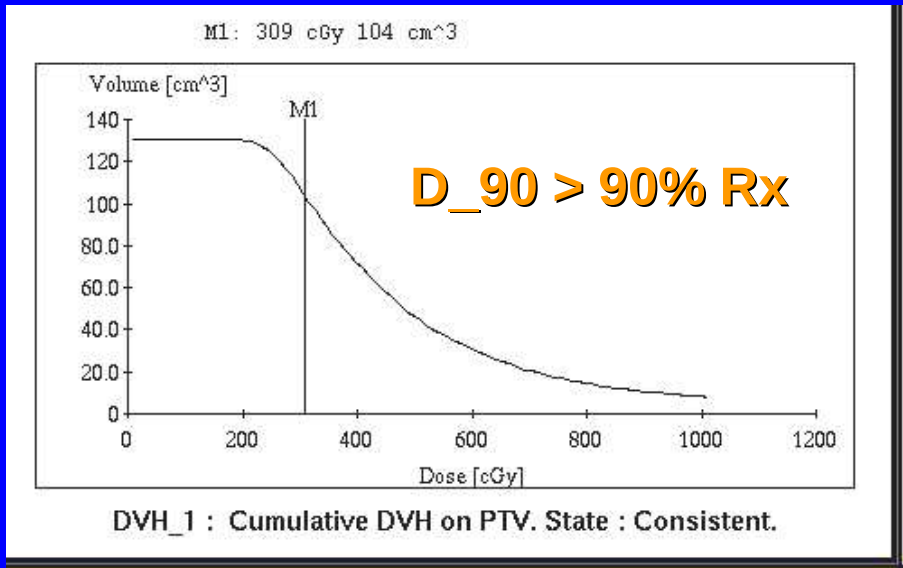
Dose Distribution

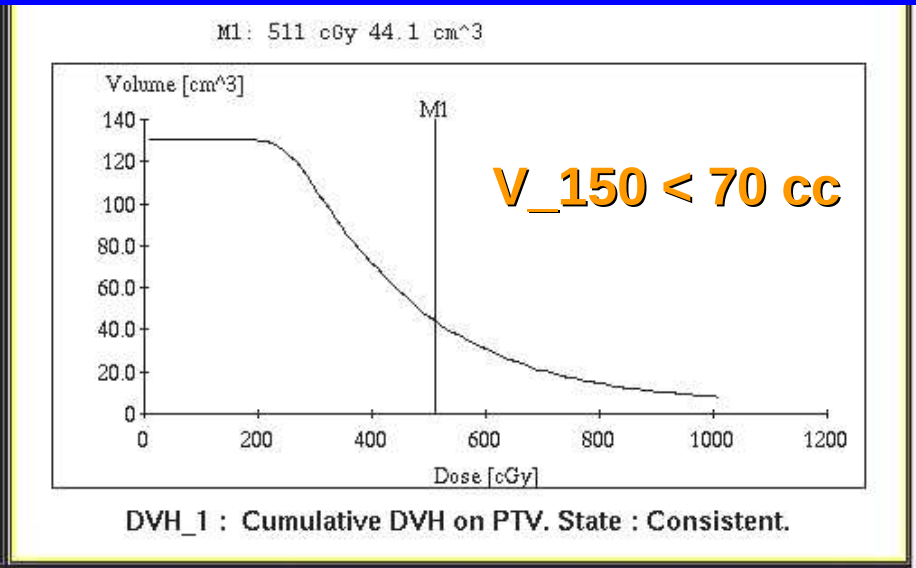


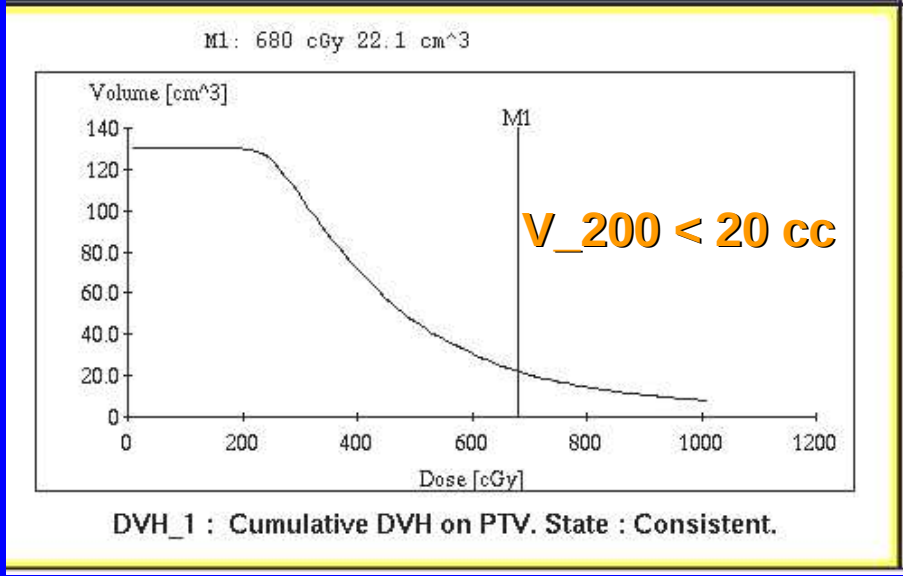


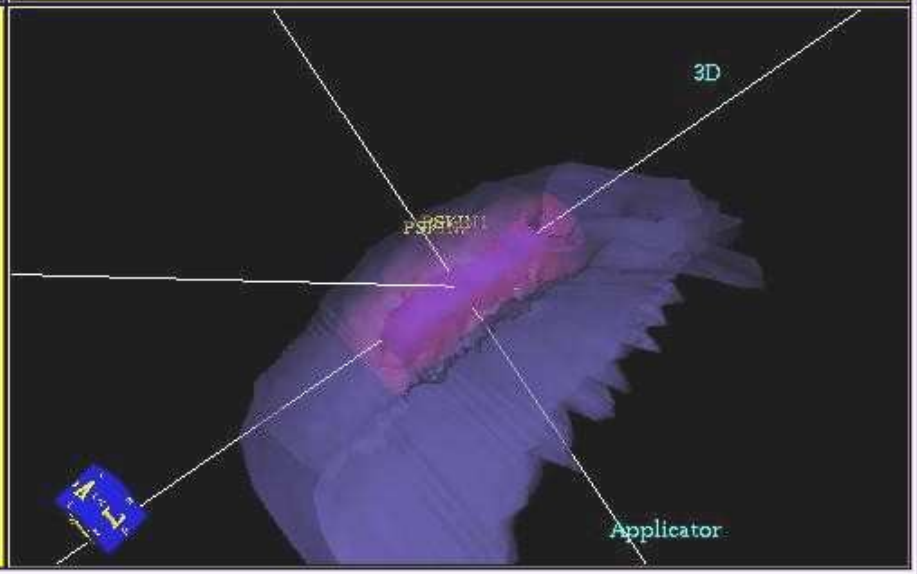


DVH based plan evaluation

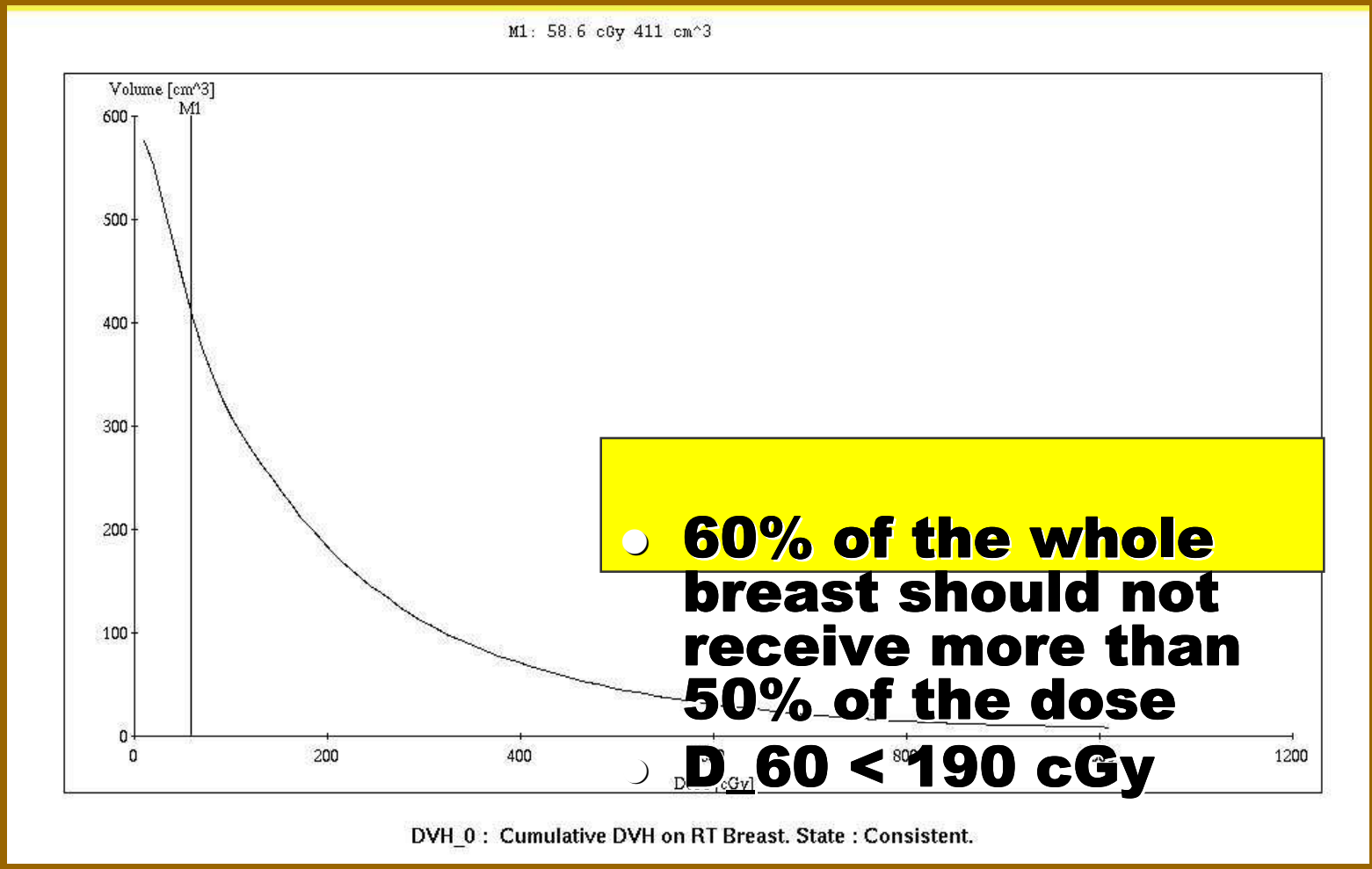








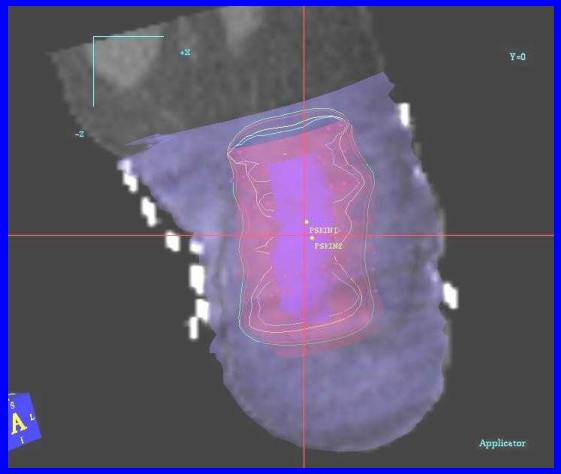
DVH based plan evaluation – Whole Breast



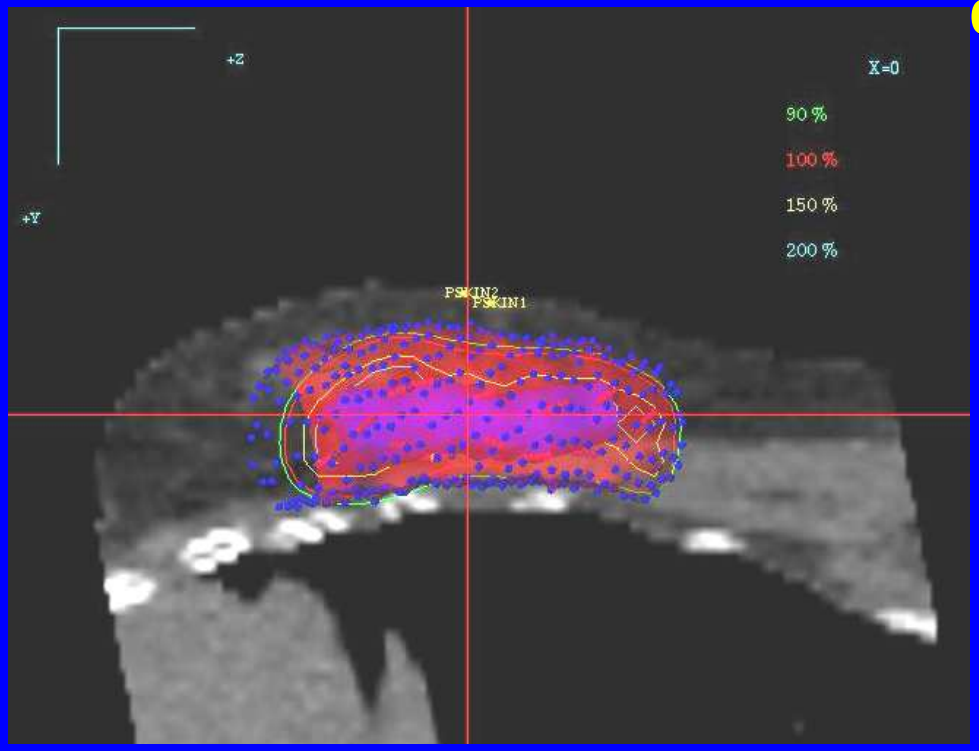
- **60% of the whole breast should not receive more than 50% of the dose**

D 60 < 190 cGy

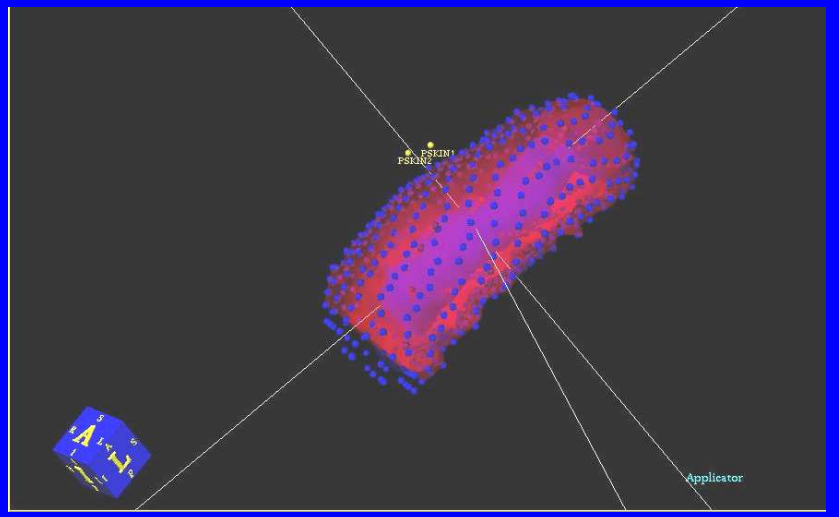
Dose Distribution



- Isodoses (90%, 100%, 150%,200% of Rx) in the catheters plane



- 3D optimized dose distribution. Dose points on the PTV surface 8mm apart



One month follow-up Evaluation

The medial skin marks are the entrance points for the insertion needles and the flexi-catheters.