

Initial Clinical Evaluation of QLRAD's Inframammary Fold Breast Wedge™ Device

Presented by:

Ramtin Zakikhani, MS DABR

Genesis Care

Sarasota, FL

Commercial Affiliations and Potential Conflicts of Interest

I am a co-designer of the IMF Breast Wedge that is sold by QLRAD.

Consultant for QLRAD.

Outline

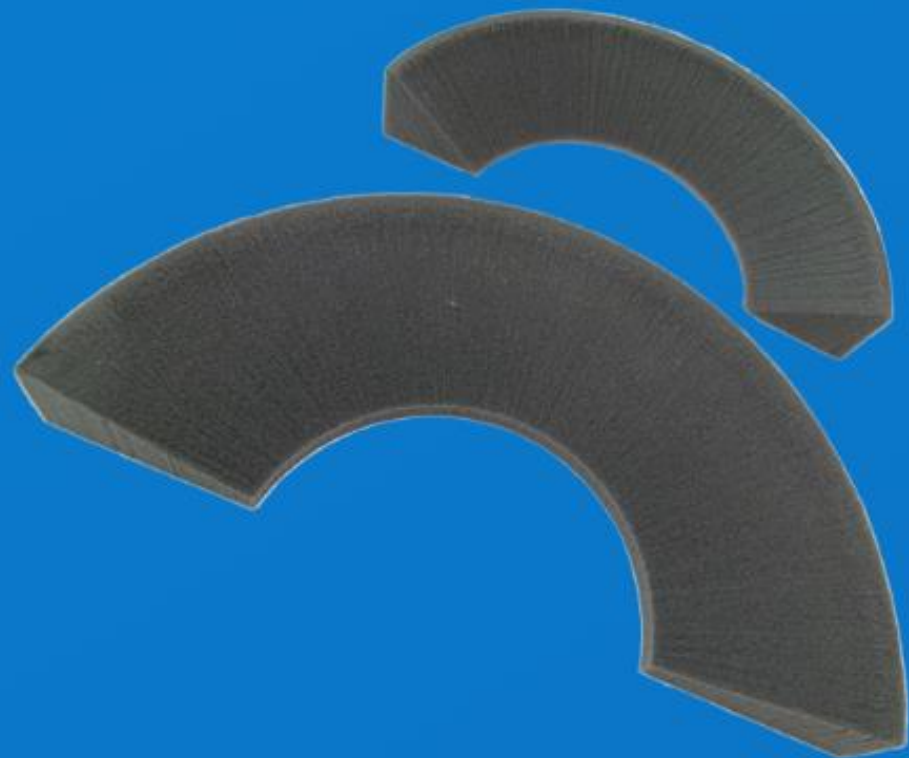
What is the
Inframammary Fold
Breast Wedge?

Why was it designed?

What clinical cases was it
designed for?

Other devices and
benefits?

How was it
dosimetrically evaluated
for clinical usage?



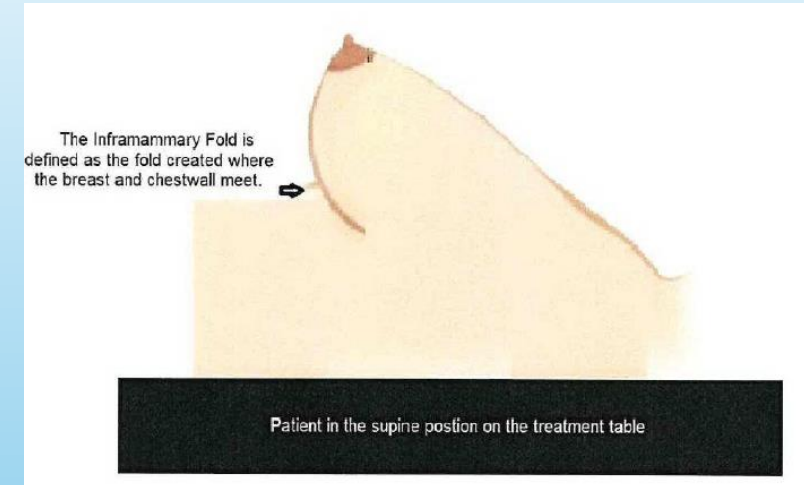
IMF BREAST WEDGE™



<https://qlrad.com/imf-breast-wedge/>

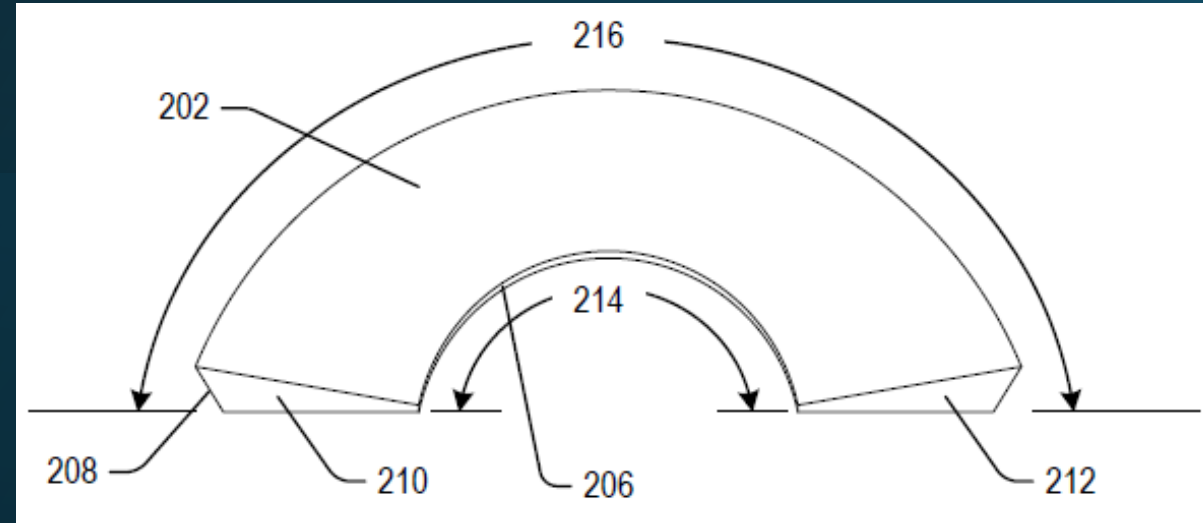
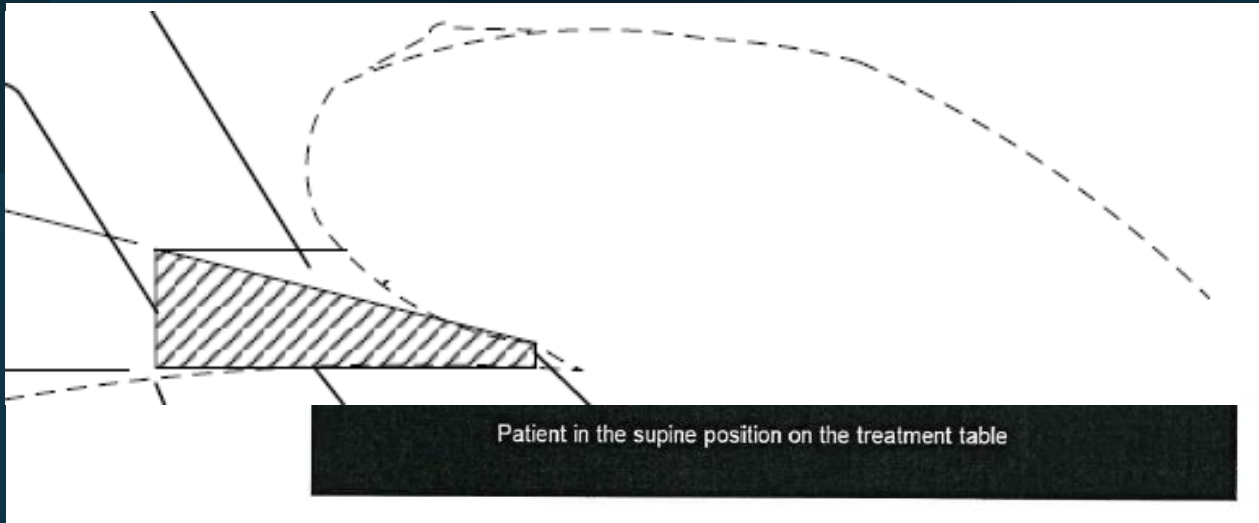
*Patent Pending

Design and Purpose



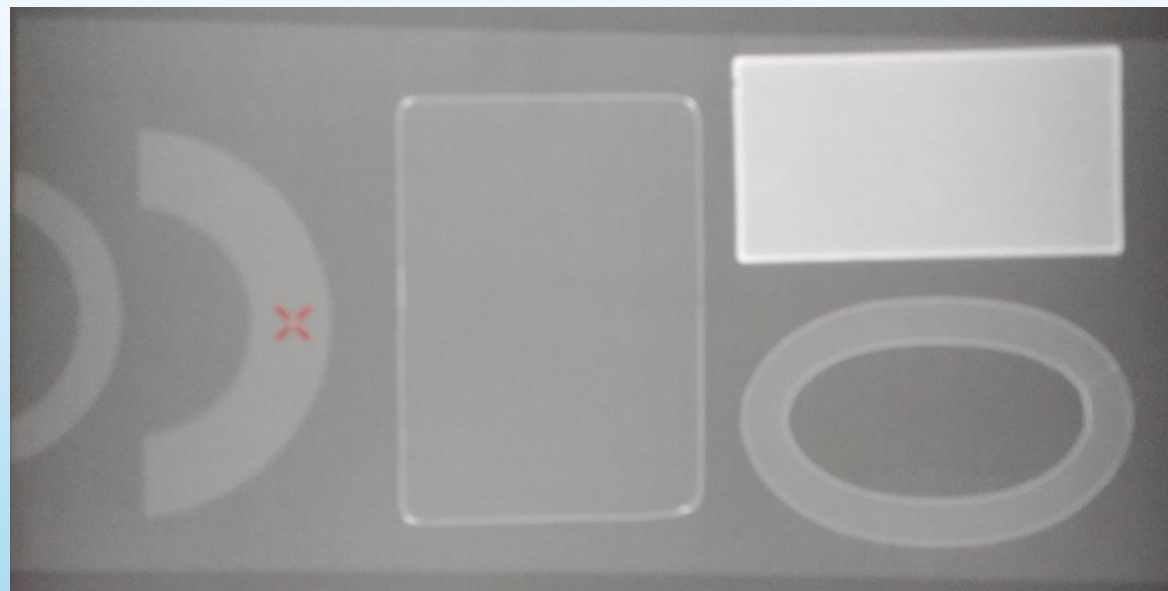
The IMF Breast Wedge was designed with an air equivalent material to create an “air” gap between the breast and chest

Design and Purpose

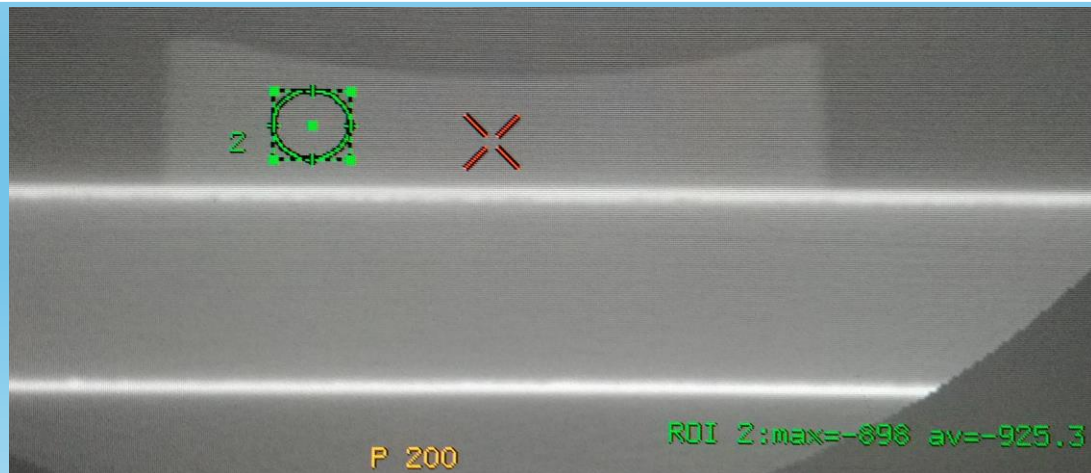


Its wedge shape allows the breast to be raised gradually from the point of contact of the breast at the chest such that the breast lays naturally on the device and holds it in place without any additional need for a fixation element.

Design and Purpose

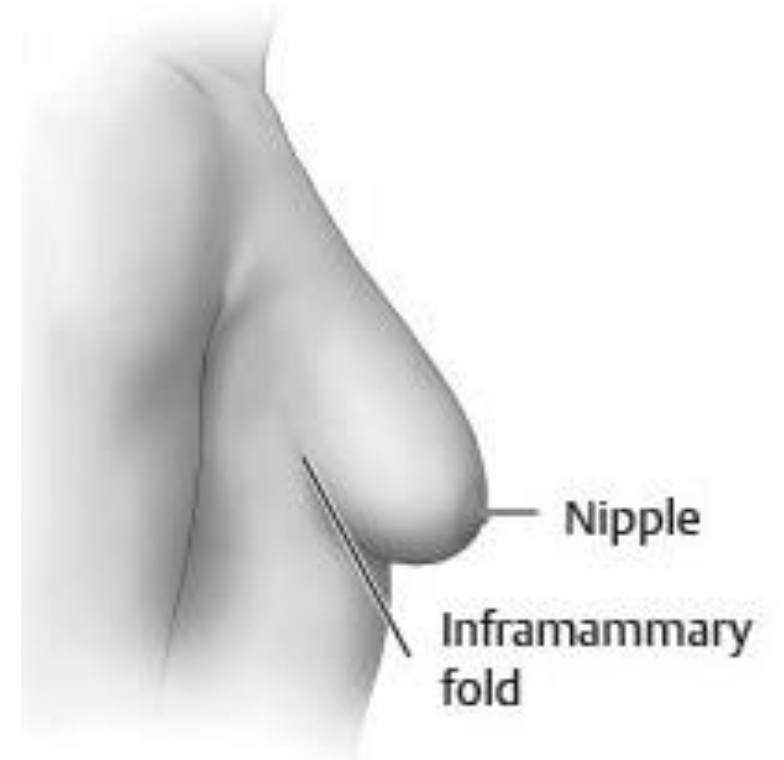


A clinical CT of the IMF Breast Wedge shows that it is air equivalent similarly to a rectangular support sponge or hand held patient ring. CT# ~ -925 HU



Breast Radiotherapy

- The **inframammary fold (IMF)** is the natural crease beneath the breast where skin-on-skin contact occurs.

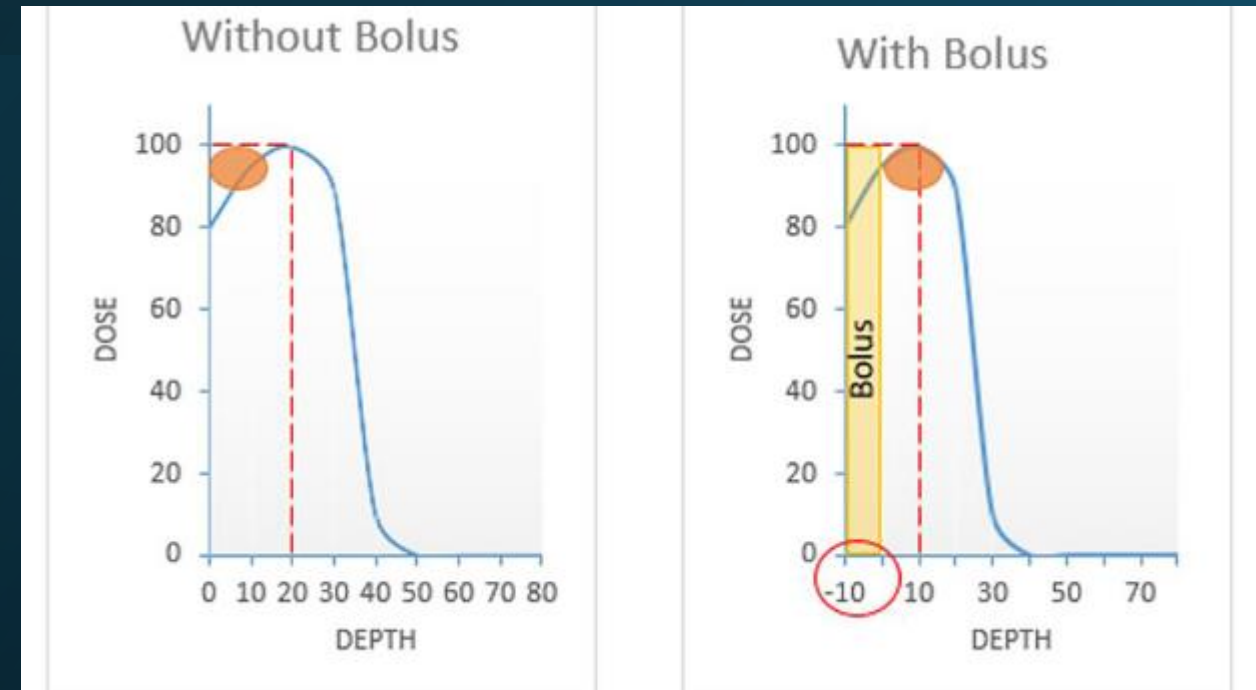


Breast Radiotherapy - Side Effects

When a patient has an IMF, during breast radiotherapy the scatter radiation from tissue surrounding the IMF and the radiation at the IMF **can lead to skin damage** as this skin is not located at the surface of the patient or at beam entry but at depth in the patient where dose buildup is allowed to occur and the “**skin sparing effect**” of photons **do not apply**. That protection is lost, and full dose may reach the skin.



This is also known as a **bolus effect** since the skin in the IMF is compressed or in close contact with the lower breast which acts to increase the dose to the skin that is adjacent to it.



Toxicity

Because of the bolus effect patients may experience:

- **Dry desquamation** (peeling, flaking skin).



Toxicity

Because of the bolus effect patients may experience:

- **Moist desquamation** (oozing, ulceration).



Toxicity

Because of the bolus effect patients may experience:



- Pain, erythema, and delayed healing.
- These complications can affect treatment adherence, patient quality of life and tumor response
- More visits/follow ups can lead to an increased cost of care

Current Solutions

As we saw earlier, the bolus effect at the IMF can cause increased skin reactions.

Thus taking measures to eliminate the bolus effect will reduce or eliminate this risk.

Skin care regimens: Moisturizers, and low-dose corticosteroids.

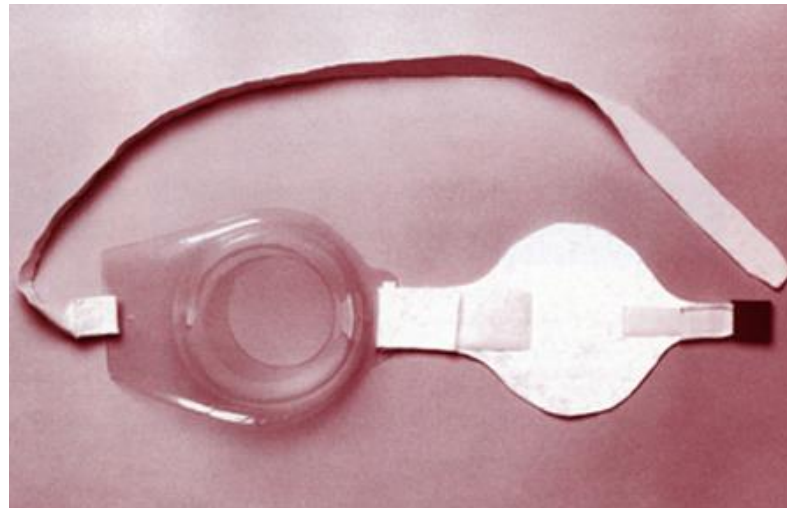
Current Solutions

Bubble Wrap



Current Solutions

The Treatment Brassiere



New Breast Configuration with Brassiere

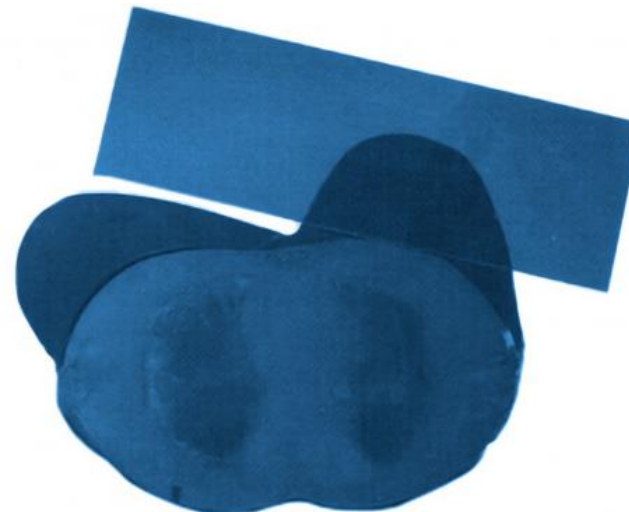
<https://www.supertechx-ray.com/BreastImagingandMammography/PatientCare/RSD-BR-100.php>

Current Solutions

The Treatment Brassiere



Cross Section of Phantom with Unconfined Breast Shape



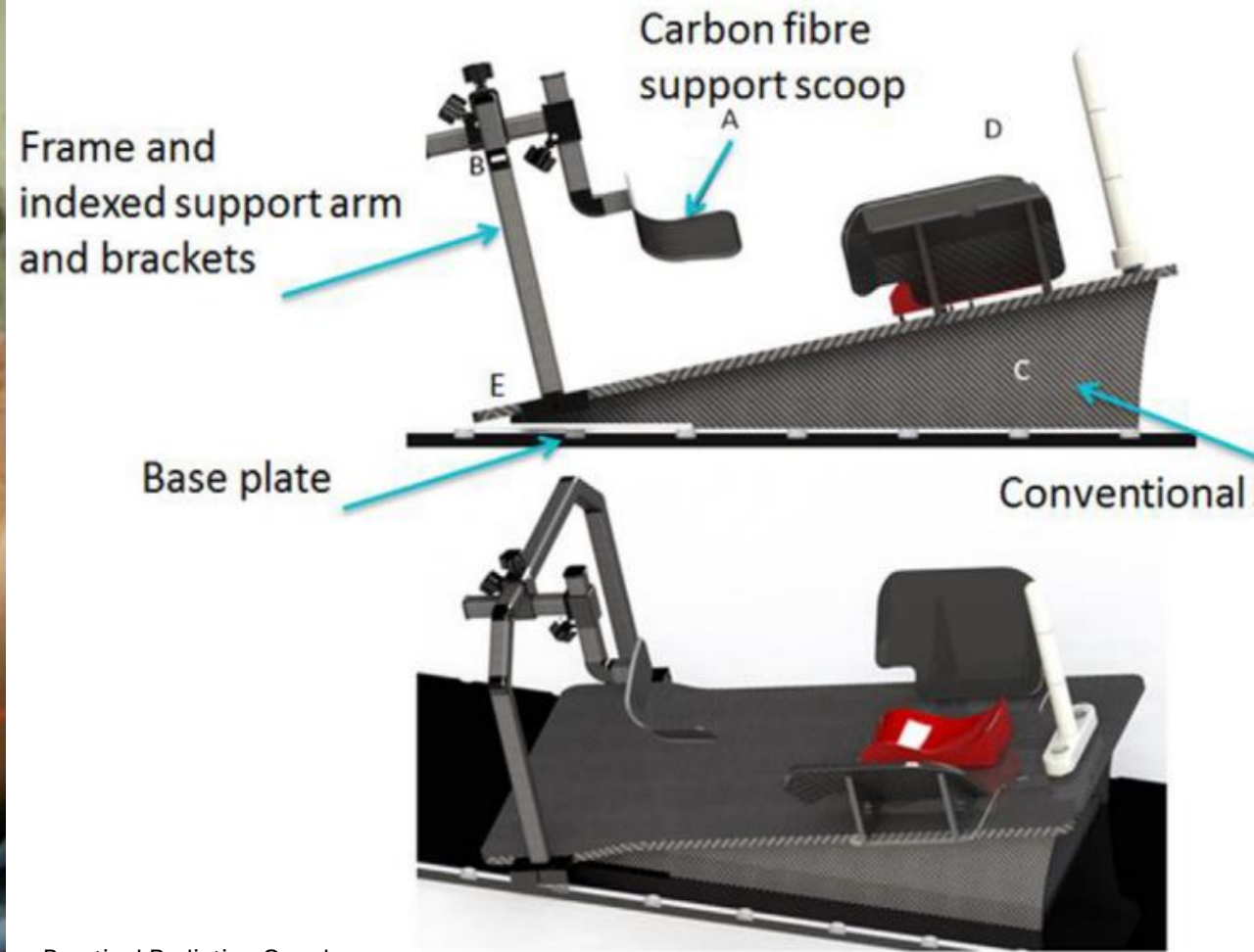
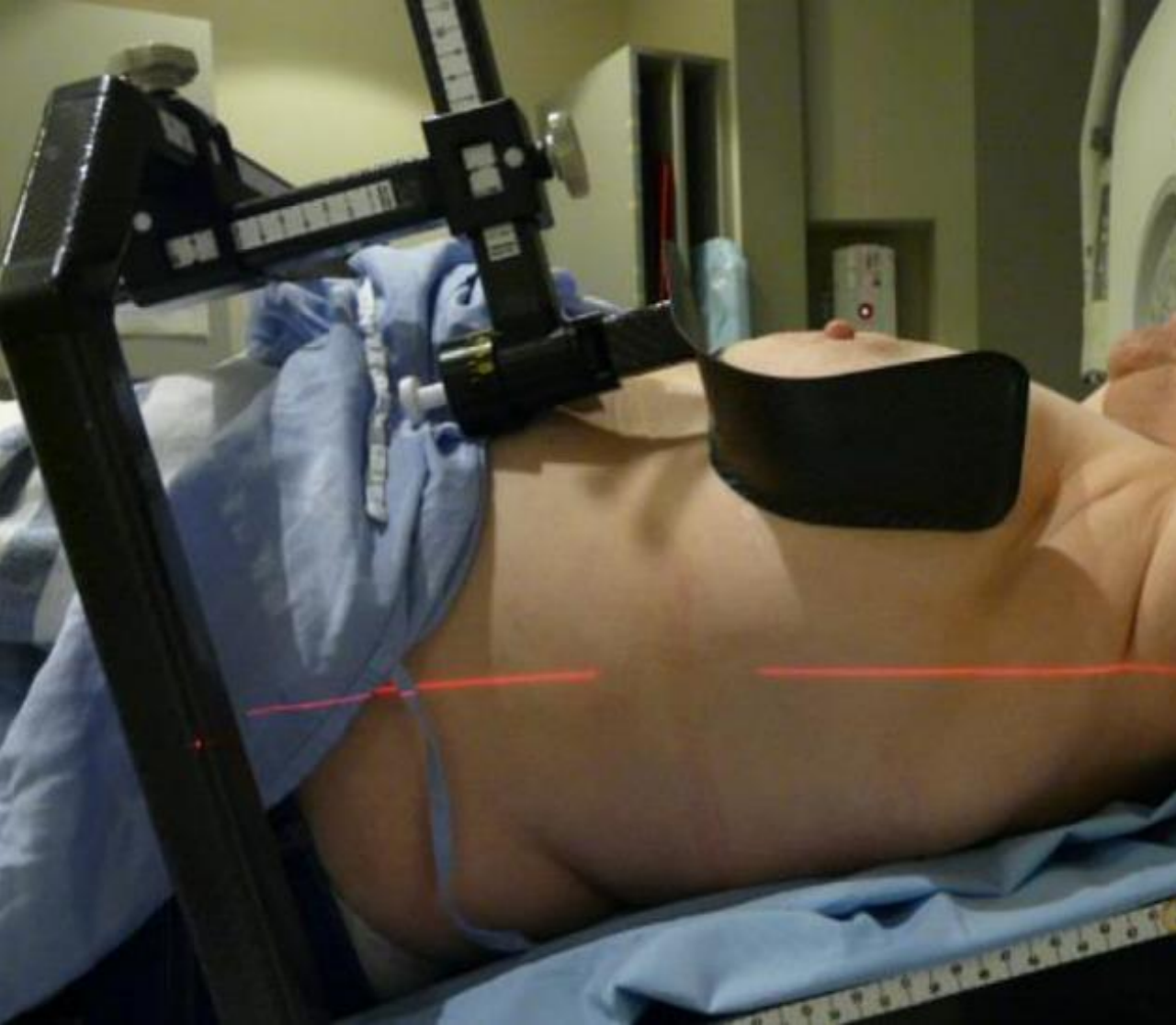
Cross Section of Phantom with Breasts Reshaped by Treatment Brassiere



Current Solutions



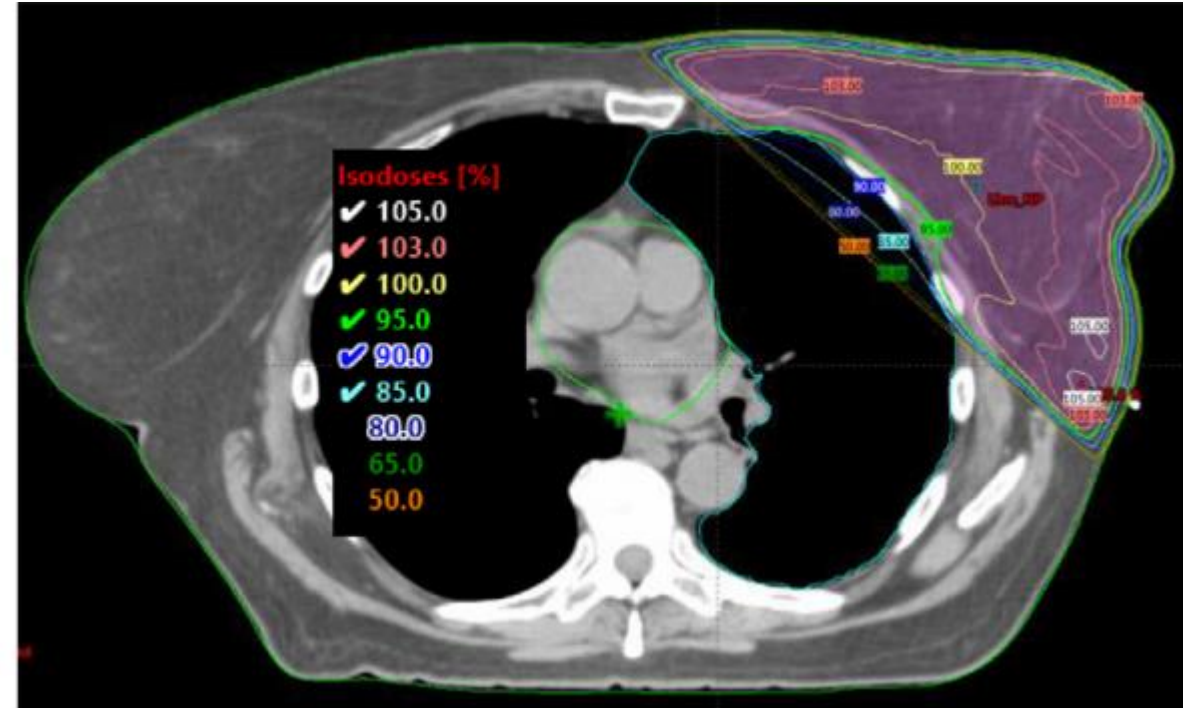
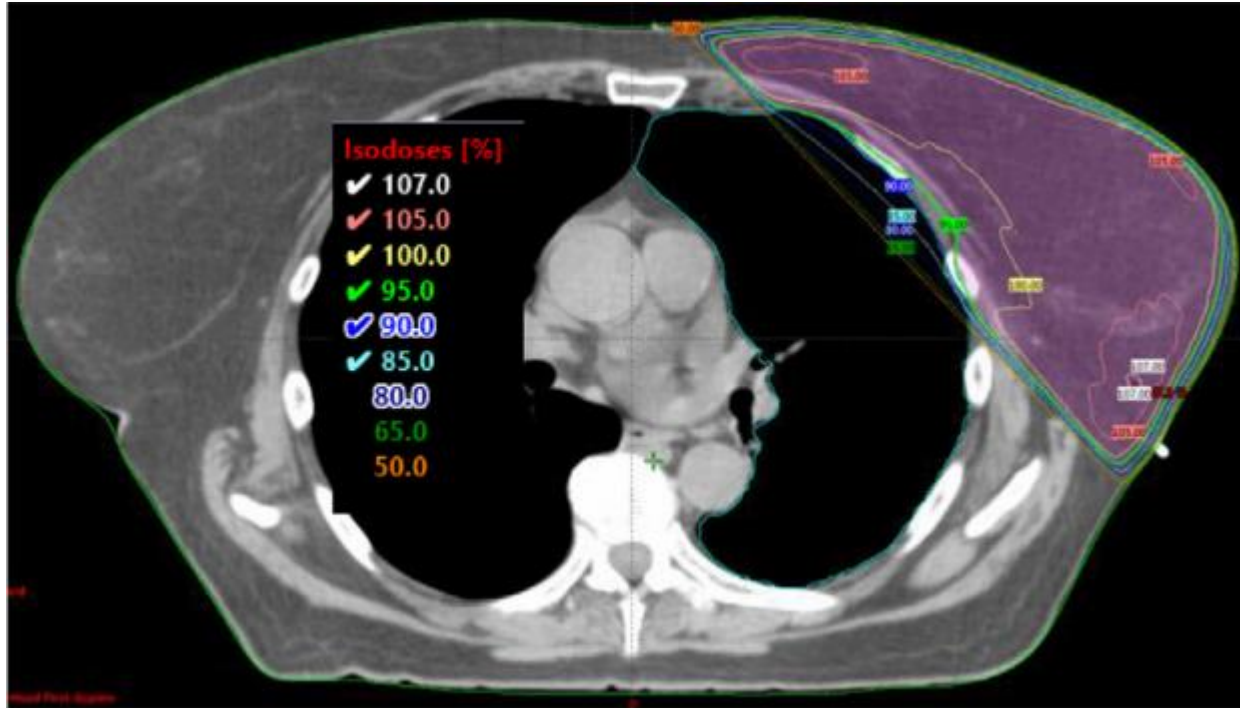
Prone breast board



Practical Radiation Oncology,
Volume 11, Issue 6,
2021,
Pages 470-479,

Current Solutions

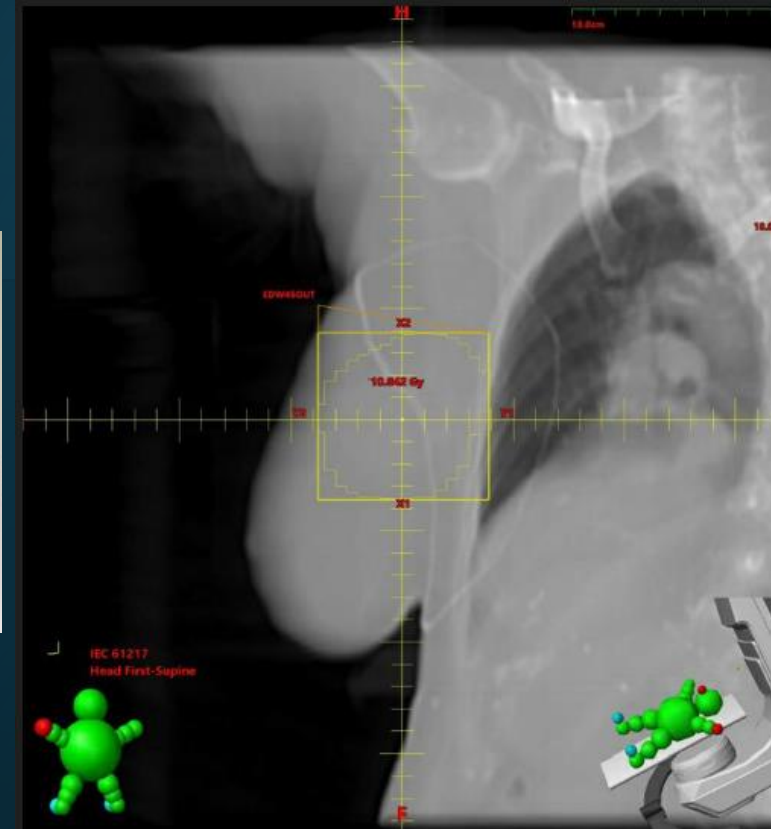
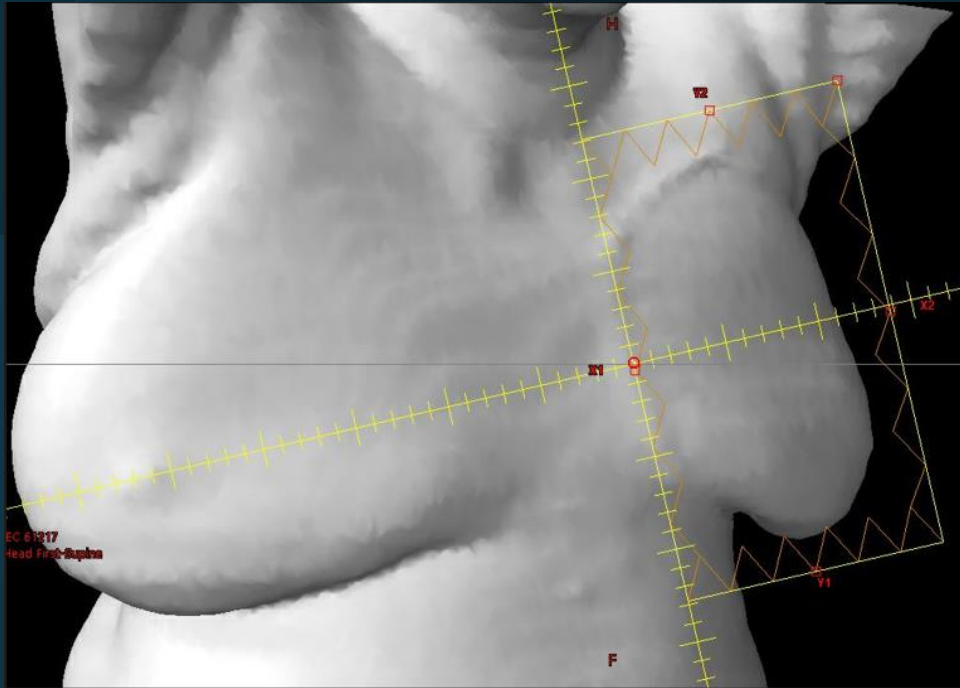
CARA
(Carbon-fiber
Adjustable Reusable
Accessory)



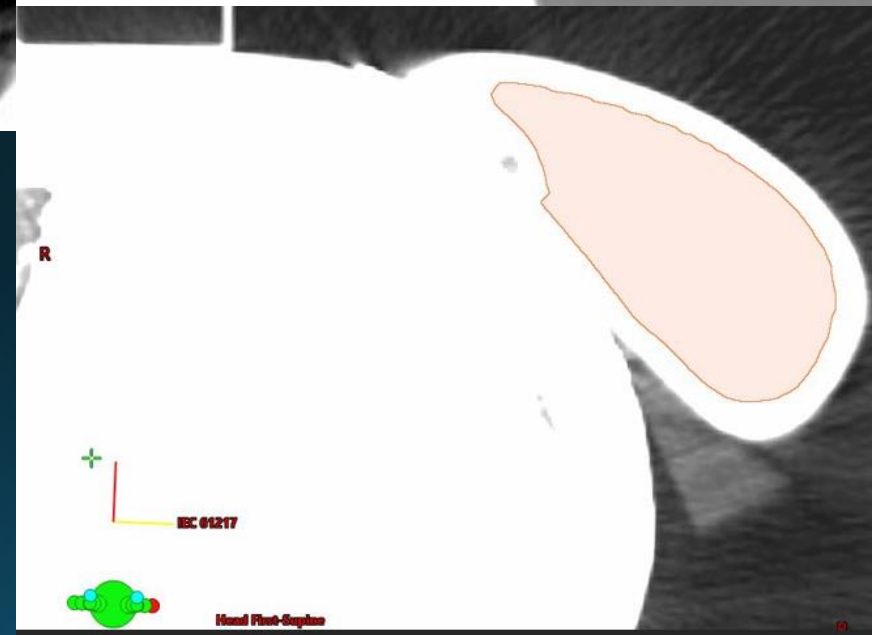
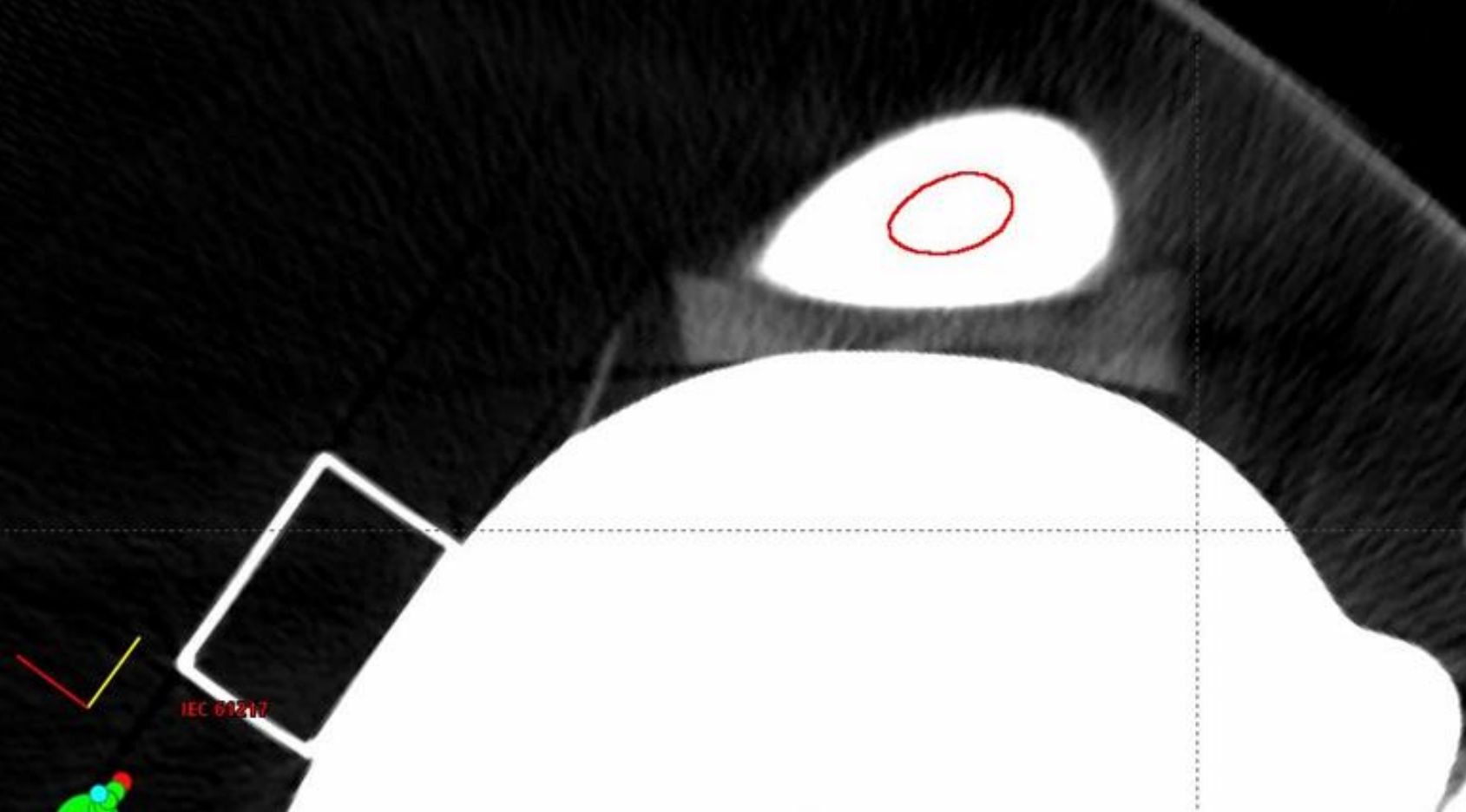
Current Solutions

CARA
(Carbon-fiber
Adjustable Reusable
Accessory)

Current Solutions



IMF Breast Wedge



Current Solutions

IMF Breast Wedge

Current Solutions

This device is also used during Radiotherapy to sites near **any skin fold**:

- **Pelvis/Thigh RT:** Separating the groin from the thigh
- **HN RT:** Neck fold separation for larger patients
- **Upper Arm RT:** Increasing the skin separation at the underarm



Dosimetric Evaluation of the IMF Breast Wedge

Evaluating how the dose under the breast and at the chest surface is influenced by the use of the IMF Breast Wedge was necessary to validate its proposed benefits

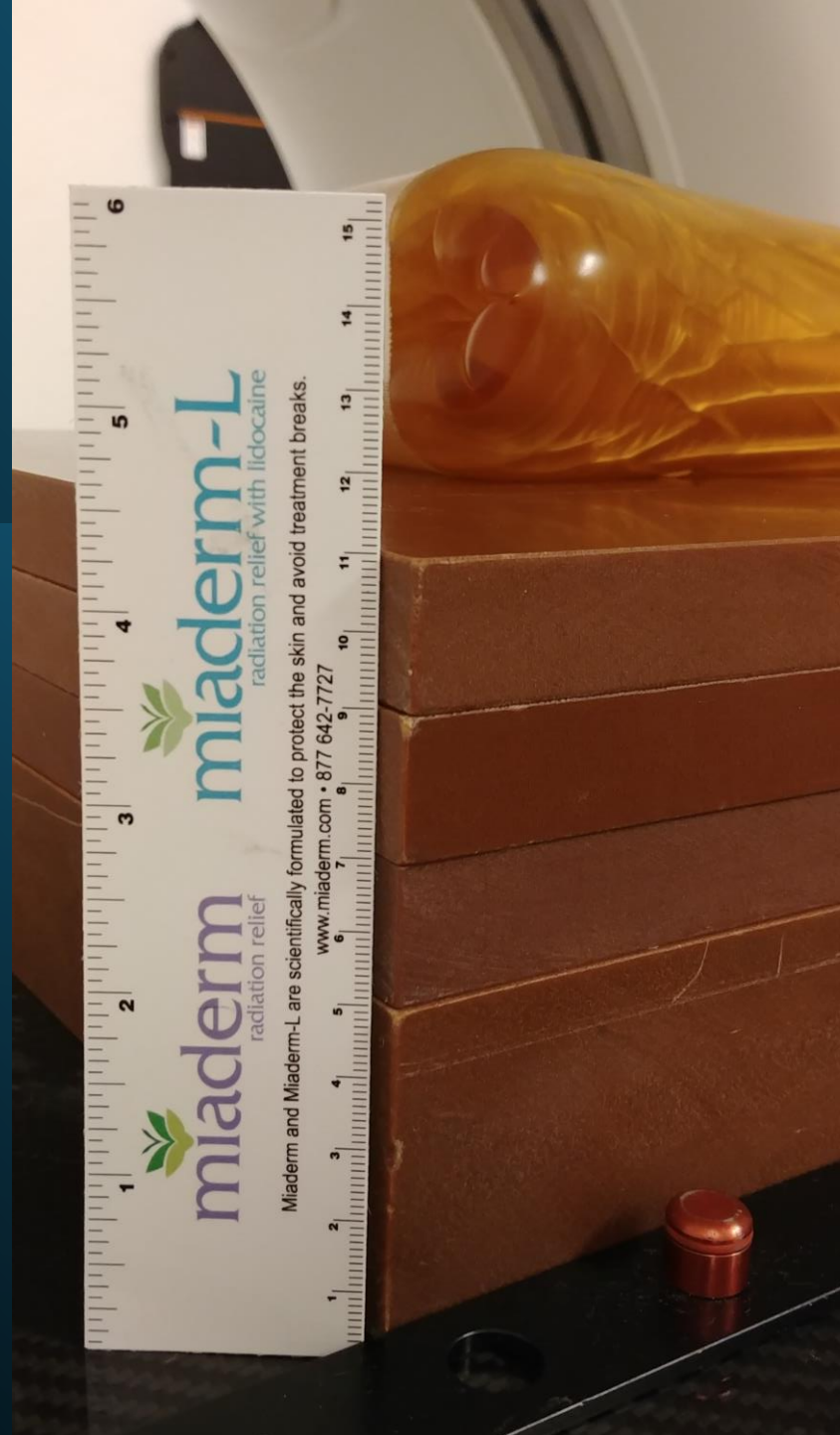
A patient phantom was created with folded bolus to simulate a breast that was placed on Solid Water plates which simulated the chest wall.

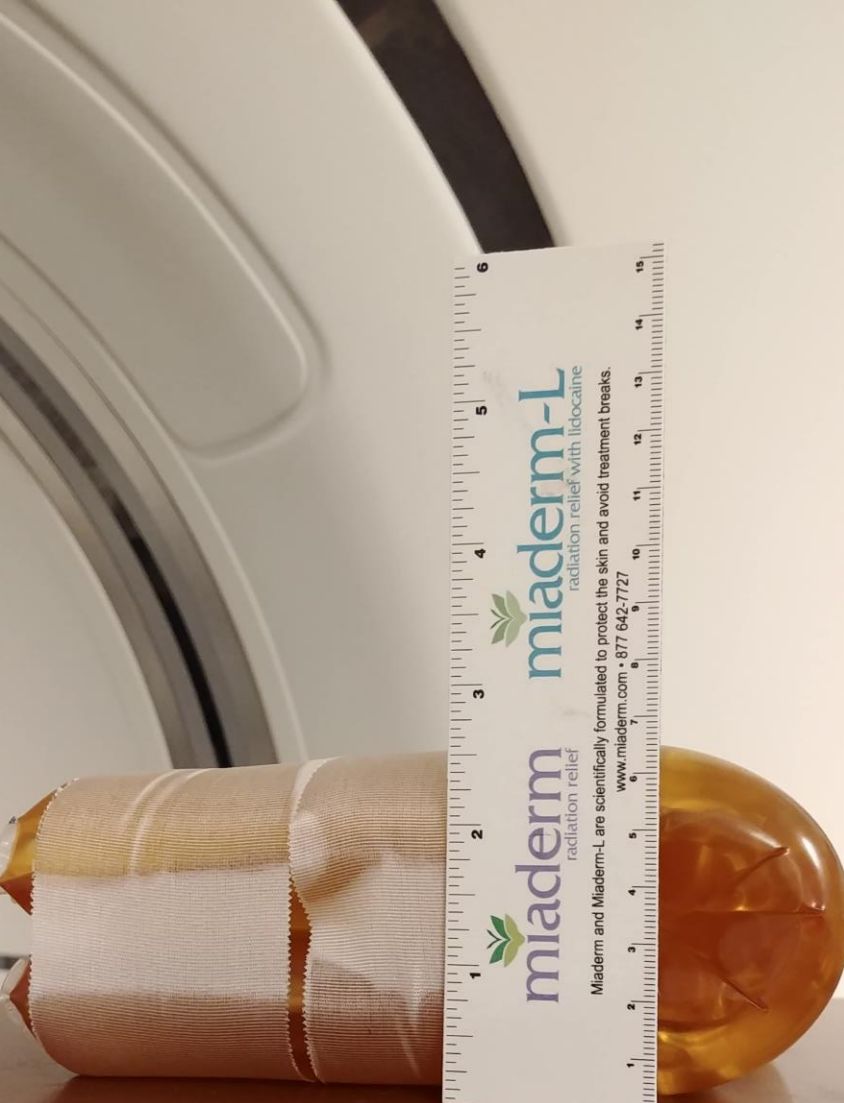
Dosimetric Evaluation

Phantom Dimensions

“Chest” – Solid Water

30 cm x 30 cm x 11 cm high





Dosimetric Evaluation

Phantom Dimensions

“Breast” - Folded Bolus

6 cm high (Ant/Post) x 14 cm wide laterally (Lt/Rt)
x 15 cm long (Sup/Inf)

Dosimetric Evaluation

Phantom Setup, Marking and Scanning

CT Scan #1

IMF Breast Wedge
in position

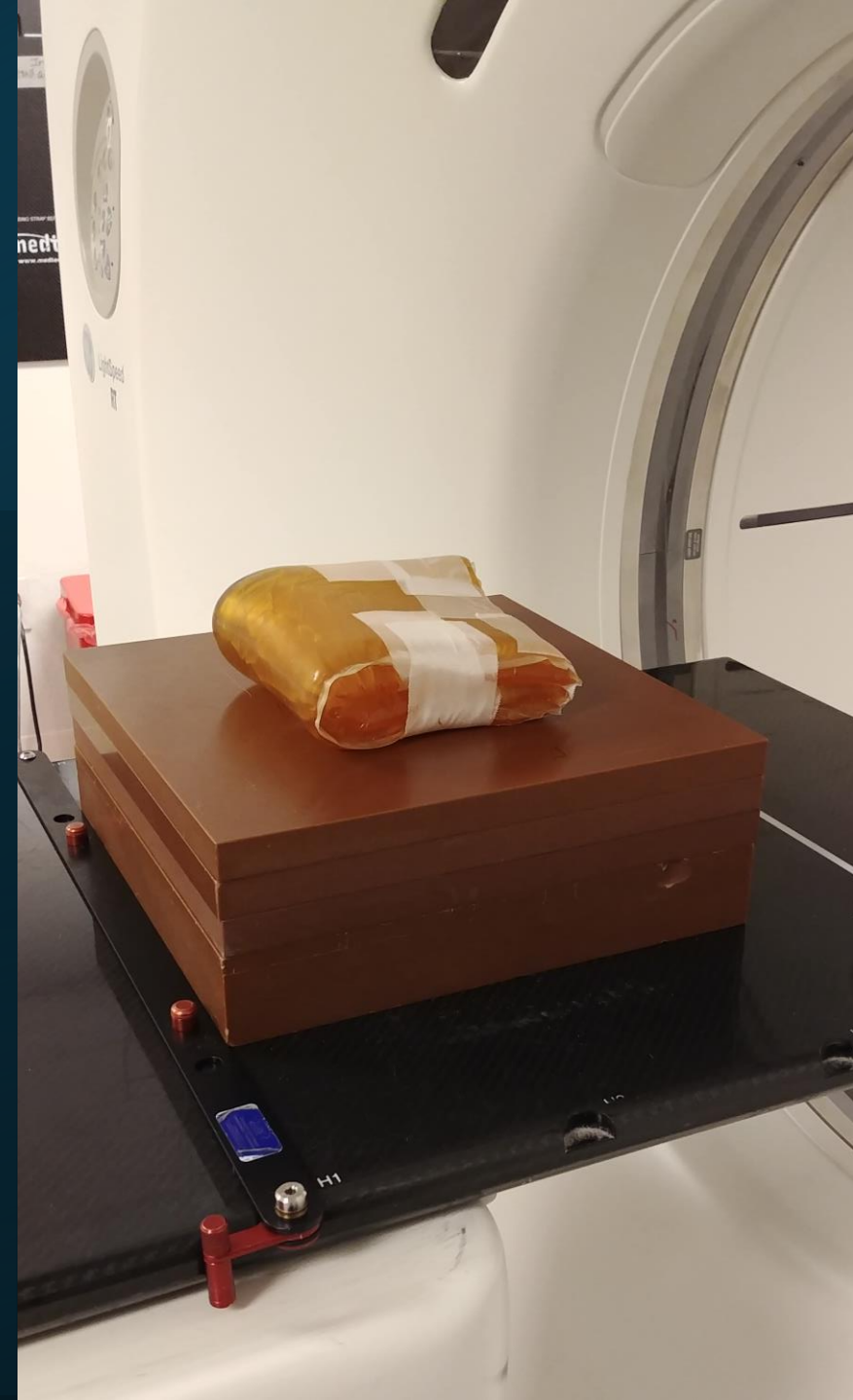


Dosimetric Evaluation

Phantom setup, Marking and Scanning

CT Scan #2

“Breast” in natural position on
the “Chest”



Dosimetric Evaluation

Phantom Setup,
Marking and
Scanning

BB placement
under “Breast”

Surrogate for TLD
placement in TPS





Dosimetric Evaluation

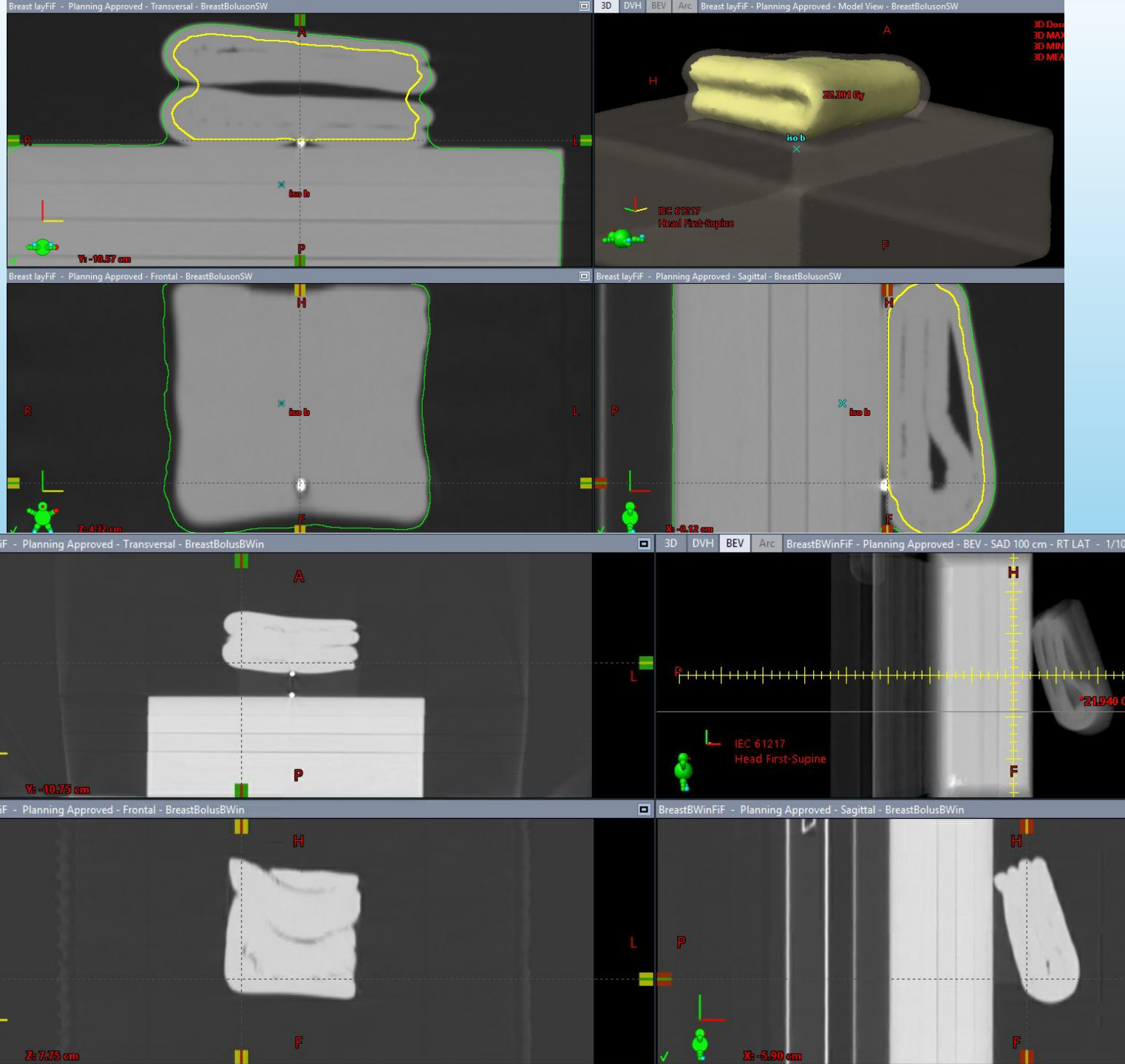
Phantom Setup, Marking and Scanning

BB placement under IMF Breast Wedge
Surrogate for TLD placement in TPS

Dosimetric Evaluation

Treatment Plan Creation

Dose Calc at BB
VS
TLD



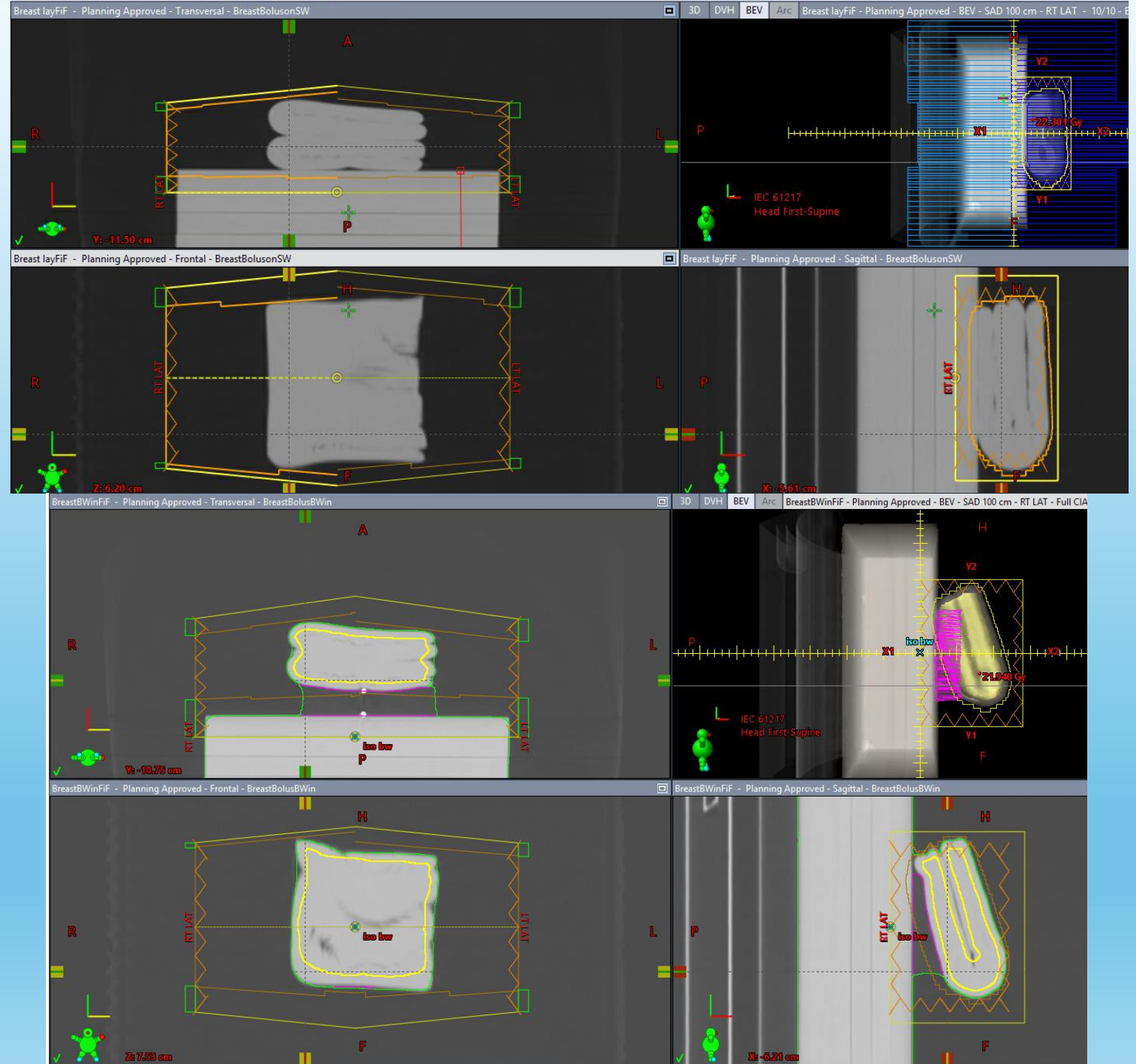
Dosimetric Evaluation

Treatment Plan Creation

Field-in-Field/ Step and Shoot

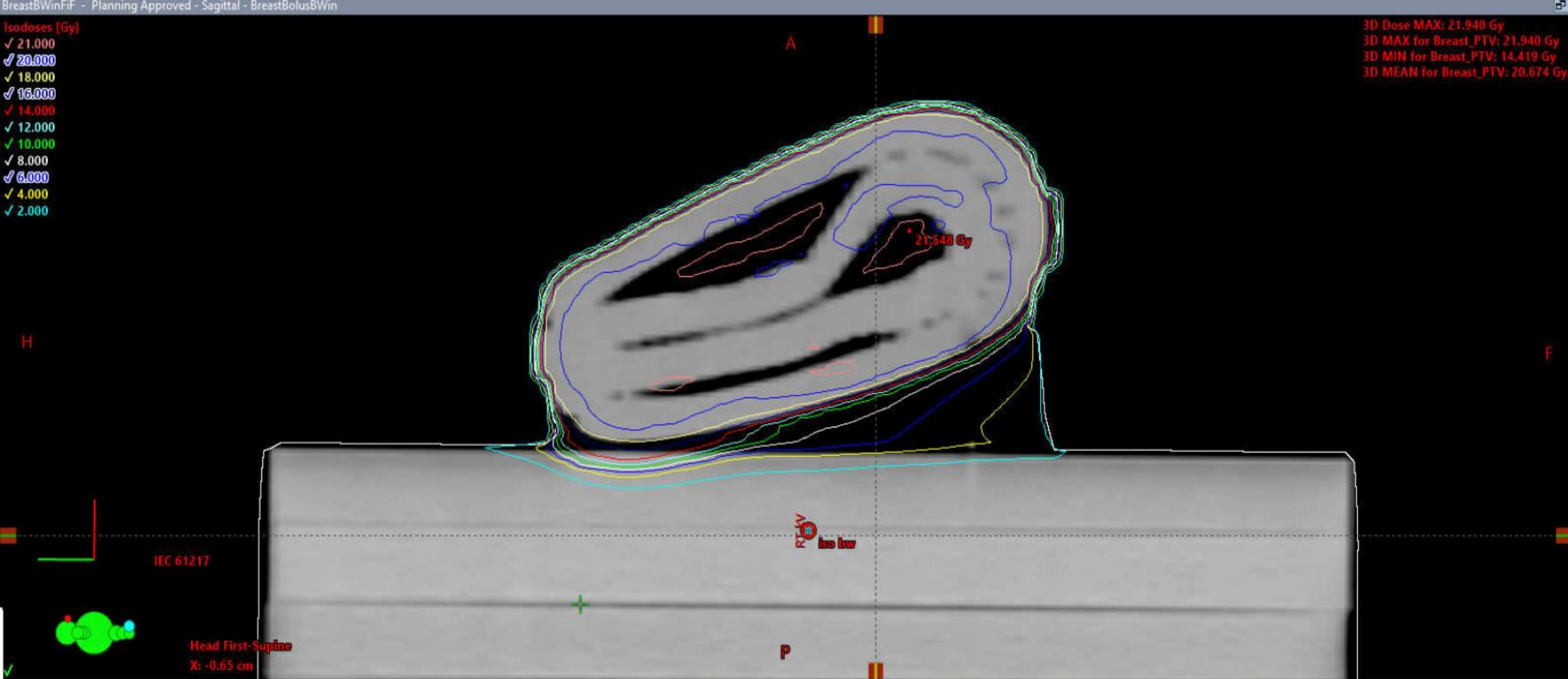
Two tangent beams

200 cGy/fx



- Isodoses [Gy]
- ✓ 21.000
- ✓ 20.000
- ✓ 18.000
- ✓ 16.000
- ✓ 14.000
- ✓ 12.000
- ✓ 10.000
- ✓ 8.000
- ✓ 6.000
- ✓ 4.000
- ✓ 2.000

3D Dose MAX: 21.940 Gy
 3D MAX for Breast_PTV: 21.940 Gy
 3D MIN for Breast_PTV: 14.419 Gy
 3D MEAN for Breast_PTV: 20.674 Gy



Dosimetric Evaluation

Treatment plan creation

Field-in-Field/Step and Shoot

Two tangent beams

200 cGy/fx x 10 fx's

Dosimetric Evaluation

Treatment Delivery

Post CBCT, the BB is
replaced with a TLD

Setup without IMF
Breast Wedge

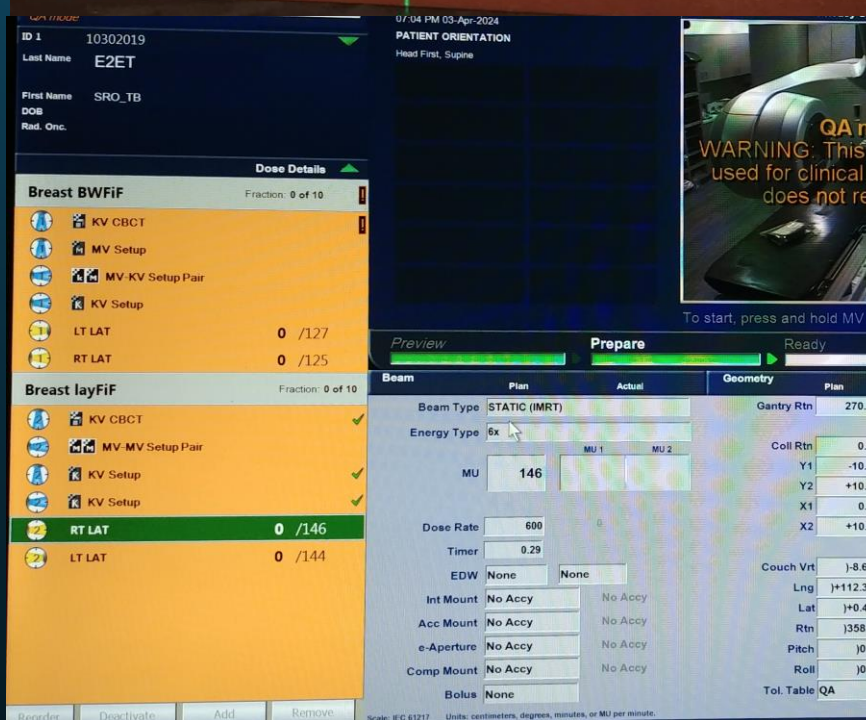
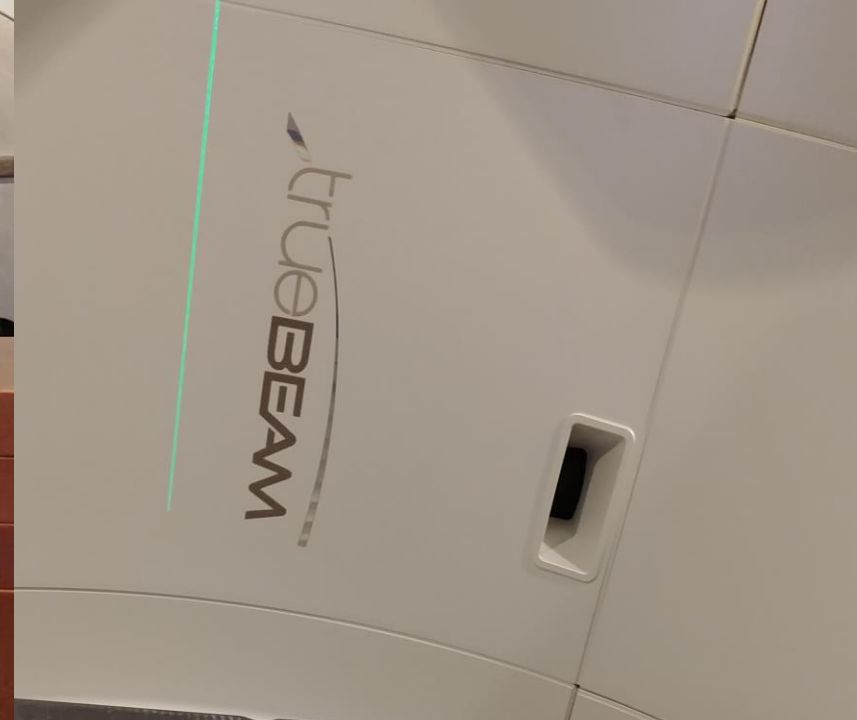
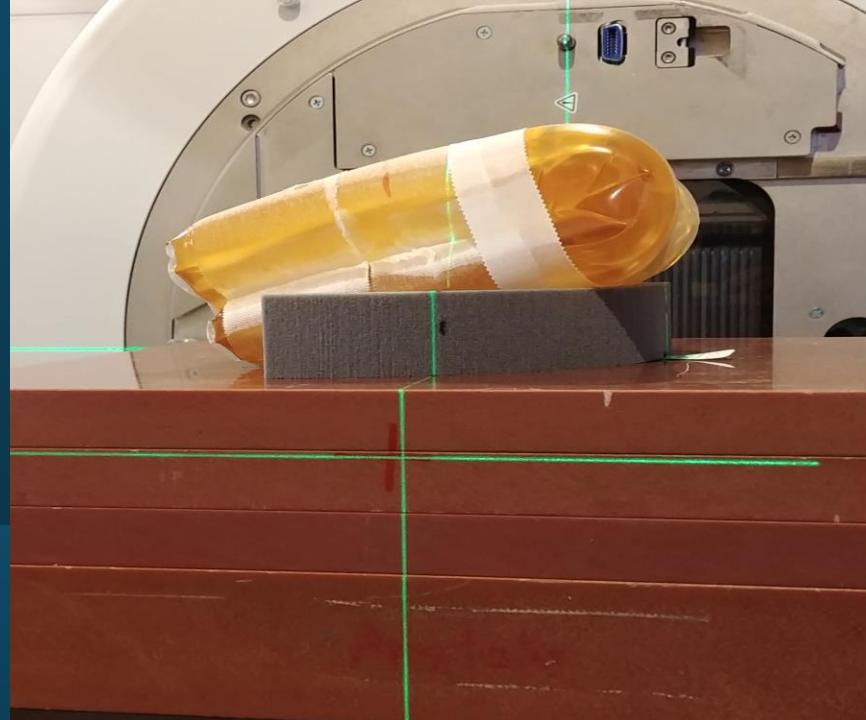


Dosimetric Evaluation

Treatment Delivery

Post CBCT, the BB is replaced with a TLD

Setup with IMF Breast Wedge



E2ET, SRO_TB (10302019) - External Beam Planning (Administrator)

QuickLinks E2ET, SRO_TB (10302019) Worklist

File Edit View Insert Planning Tools Window

Selection Contouring Image Registration External Beam Planning Brachytherapy Planning Brachytherapy 2D Entry Plan Evaluation

Course: IMF Breast Wedge

- Plan: Breast BW
- Plan: Breast BWFiF
- Plan: Breast BWin
- Plan: Breast IaEZ1
- Plan: Breast lay
- Plan: Breast layF
- Plan: Breast layFiF**

Plan: Breast layFiF

- Image: BreastBolusonSW
- Registered Images
- Structure Set: CT_1
 - Structure: BODY
 - Structure: Breast_L
 - Structure: NS_Fiducial
 - Structure: TLD

Breast layFiF - Planning Approved - Transversal - BreastBolusonSW

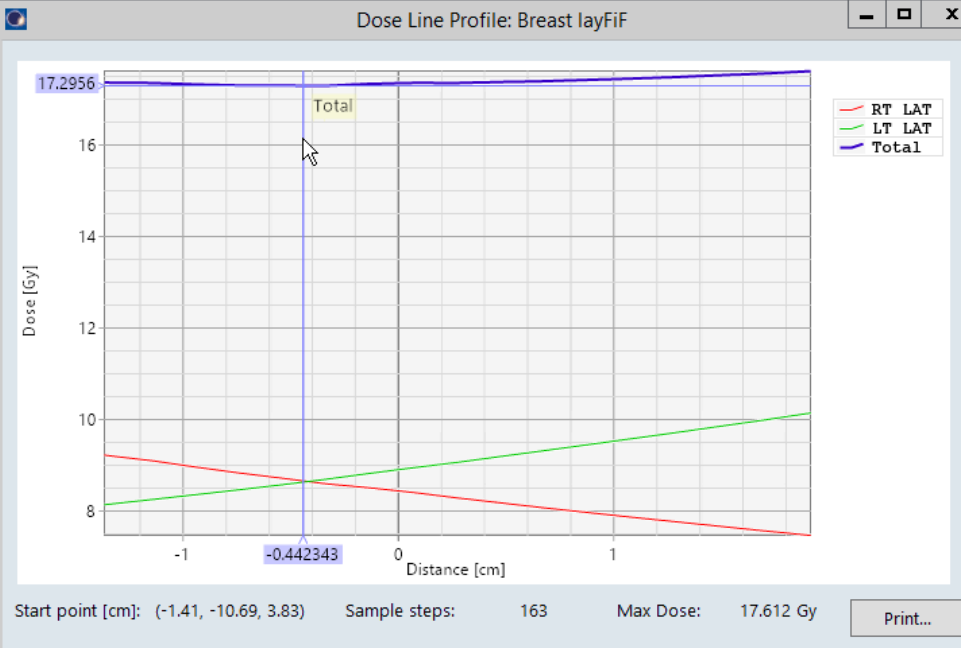
Isodoses [Gy]

- ✓ 22.000
- 21.000
- ✓ 20.000
- 19.000
- ✓ 18.000
- 17.000
- 16.000

Isodoses [Gy]

- ✓ 22.000
- ✓ 21.000
- ✓ 20.000
- ✓ 19.000
- ✓ 18.000
- ✓ 17.000
- ✓ 16.000

RT LAT Y: -10.69 cm

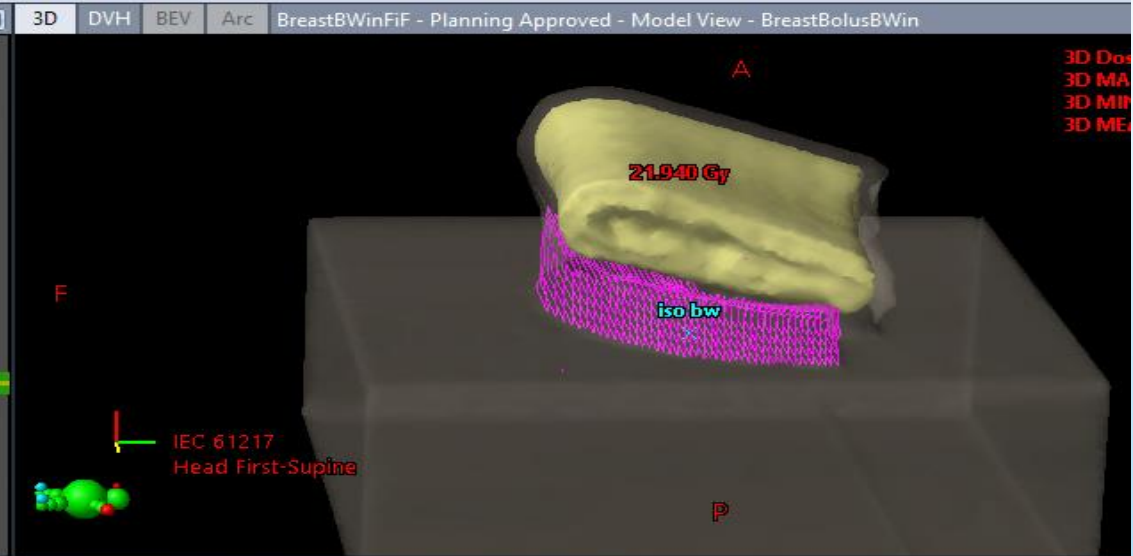
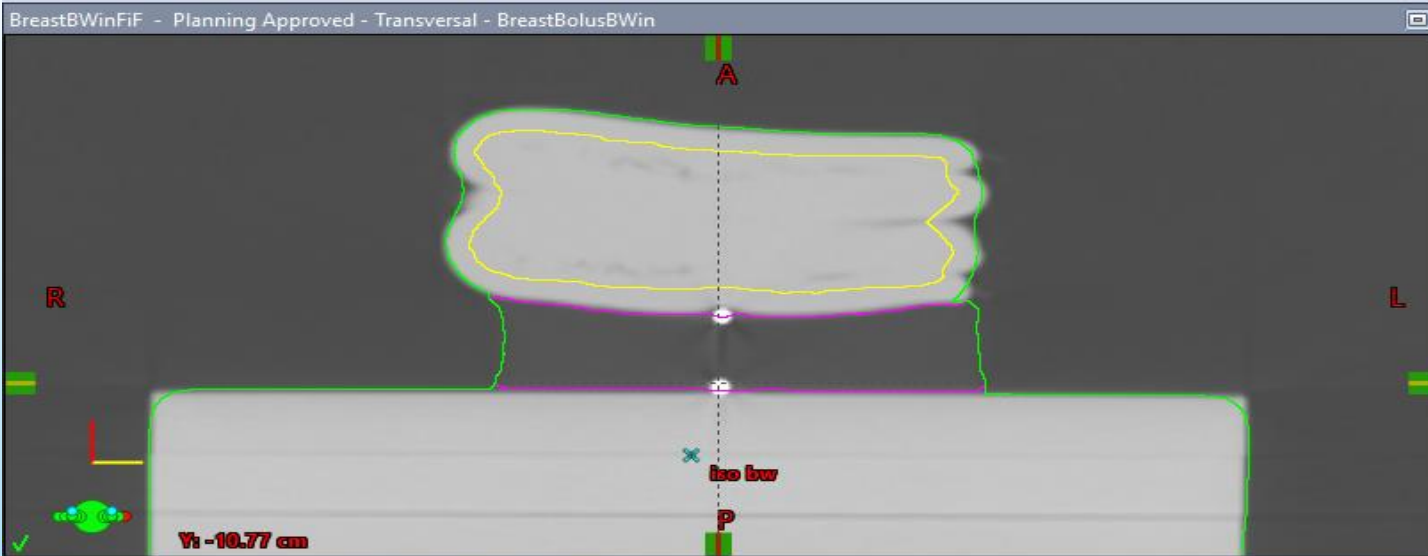


Dosimetric Evaluation

Dose calculation extraction without the IMF BW present

Breast layFiF - Planning Approved - Transversal - BreastBolusonSW

RT LAT Y: -10.75 cm

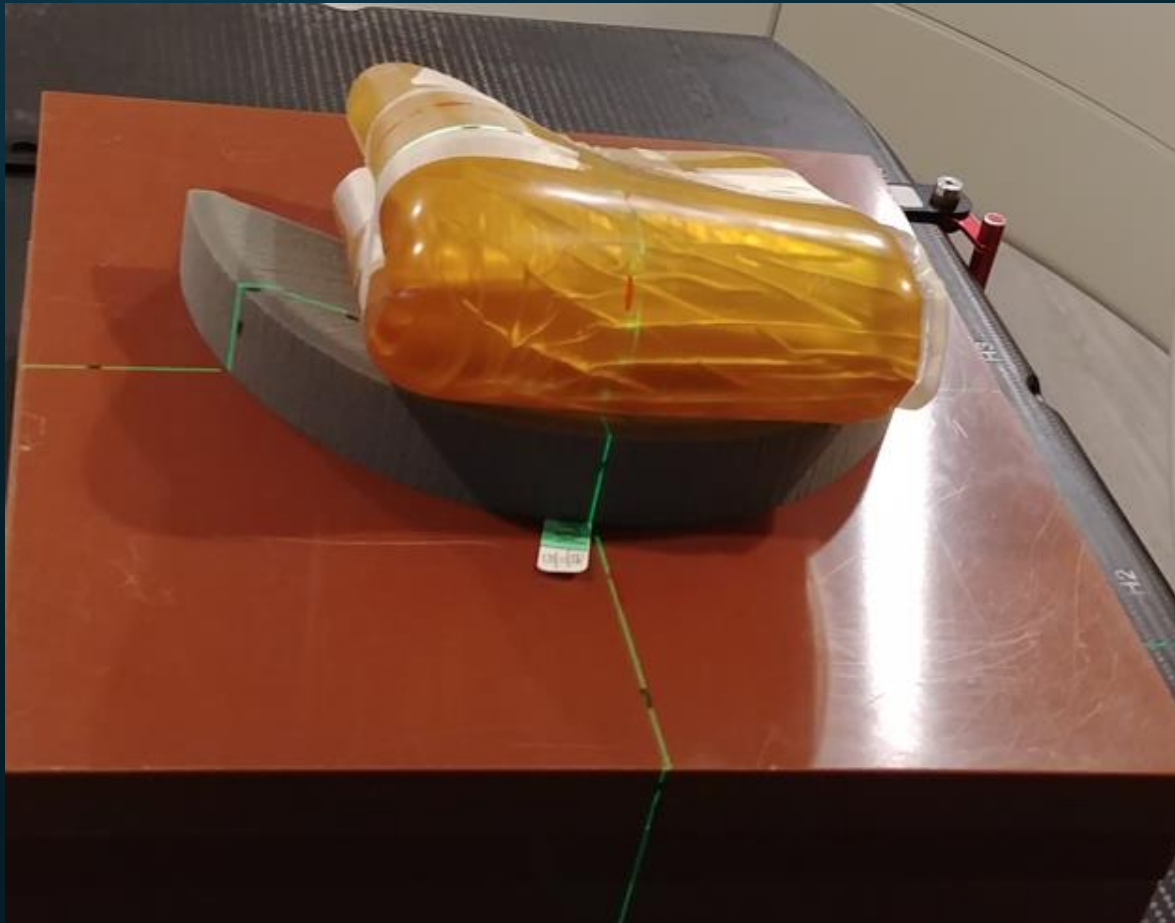


Dosimetric Evaluation

Dose calculation extraction
with the IMF BW present

Dosimetric Evaluation

Results



Dose located under the IMF BW over SW			
	Eclipse calculated dose (cGy)	TLD measured dose (cGy)	
	29.27	26.0	
	28.97		
	27.50		
	24.54	26.9	
	25.45		
	24.19		
	27.80		% diff
average	26.82	26.5	-1.4

Dosimetric Evaluation

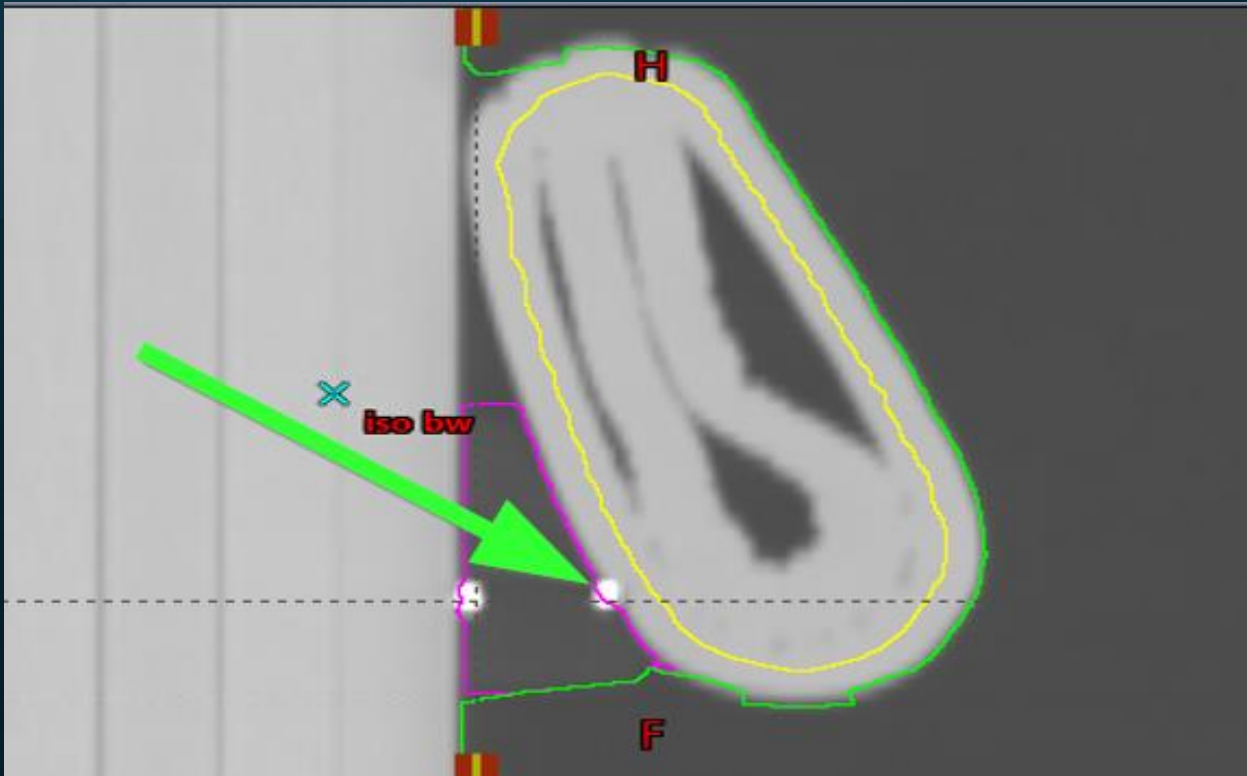
Results



Dose located under the Breast over SW		% diff	comment
Eclipse calculated dose (cGy)	TLD measured dose (cGy)		
172.08	159.1		
173.78			
173.75			
173.48	158.8		
172.97			
171.90			
average	172.99	-8.1	TLD Lab states uncertainty up to 10%

Dosimetric Evaluation

Results



Dose located under the breast while on the IMF BW			
Eclipse calculated dose (cGy)		TLD measured dose (cGy)	
177.50	187.7	189.3	% diff
179.05			
179.96			
183.15	190.9		
181.60			
183.54			
average	180.80	189.3	4.7

Dosimetric Evaluation

Results

	Eclipse calculated dose diff (%)	TLD measured dose diff (%)	Conclusion	Comments
% Difference in "Chest Surface" dose when using the Large IMF BW (Dose on SW)	-84.5	-83.4	(-) indicates that the Chest Wall is receiving less dose which validates the benefit of using the IMF Breast Wedge	Results are due to the air equivalent nature of the IMF BW.
% Difference in dose under the "Breast" when using the Large IMF BW (Dose under Bolus)	+4.5	+19.1	(+) indicates that there is an increase in dose to the breast which is beneficial as the goal is to treat the Breast	Rx = 200 cGy: 180.8 cGy = 90.4 % dose. For TLD 189.3 cGy = 94.7% dose which is higher than typical doses to the anterior surface of the breast.

Summary and Conclusions

- Initial evaluation of the Inframammary Breast Wedge in the clinic has shown that this device may help reduce or eliminate skin reactions during breast radiotherapy as the air gap that is created with the IMF Breast Wedge can reduce the scattered radiation dose to the inframammary skin fold since the IMF Breast Wedge is made of an air equivalent material.
- The IMF Breast Wedge is held in place by the breast. It is used during planning and every treatment fraction for the patient. Calculations with the Eclipse treatment planning system have shown that the IMF Breast Wedge will reduce the dose to the surface of the chest by up to 85% when using the large IMF Breast Wedge. Measurements have shown a similar dose reduction of 83% at the chest surface.
- Other solutions exist that can be more complex and less reproducible than the IMF Breast Wedge. QLRAD's IMF Breast Wedge has also been used in the clinic to help separate any skin fold throughout the body to reduce their resulting bolus effect.

Thank you
for your time
and
attention !

I would like to thank

Arjen Winkel and Tom Furno

Eric Dick and Genesis Care