Experiencia con la mesa prona Affirm Tomobiopsia y Brevera

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Fundación Tejerina

Centro de Patología de la Mama

DISCLOSURE

- No potential conflicts of interest to disclose.

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OBJECTIVES

- Describe how the addition of 3D mammography to current practice can introduce new challenges that can be solved with Tomosynthesis biopsy.

- Explain the main clinical benefits of 3D image-guided biopsy with Tomosynthesis.

- Analize the implementation of Brevera® breast biopsy system with real-time imaging verification (CorLumina®) in our center. Initial results.

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- Introduction.
- 3D Biopsy. Justification.
- 3D Biopsy. Upright and Prone.
- 3D Prone Biopsy. Clinical Advantages.
- Brevera® Breast Biopsy System with CorLumina® Imaging Technology.
- Brevera®. Our results.
- Conclusion.

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Image guided Incisional Breast Biopsy

Procedure to obtain a representative histological sample of a suspicious lesion

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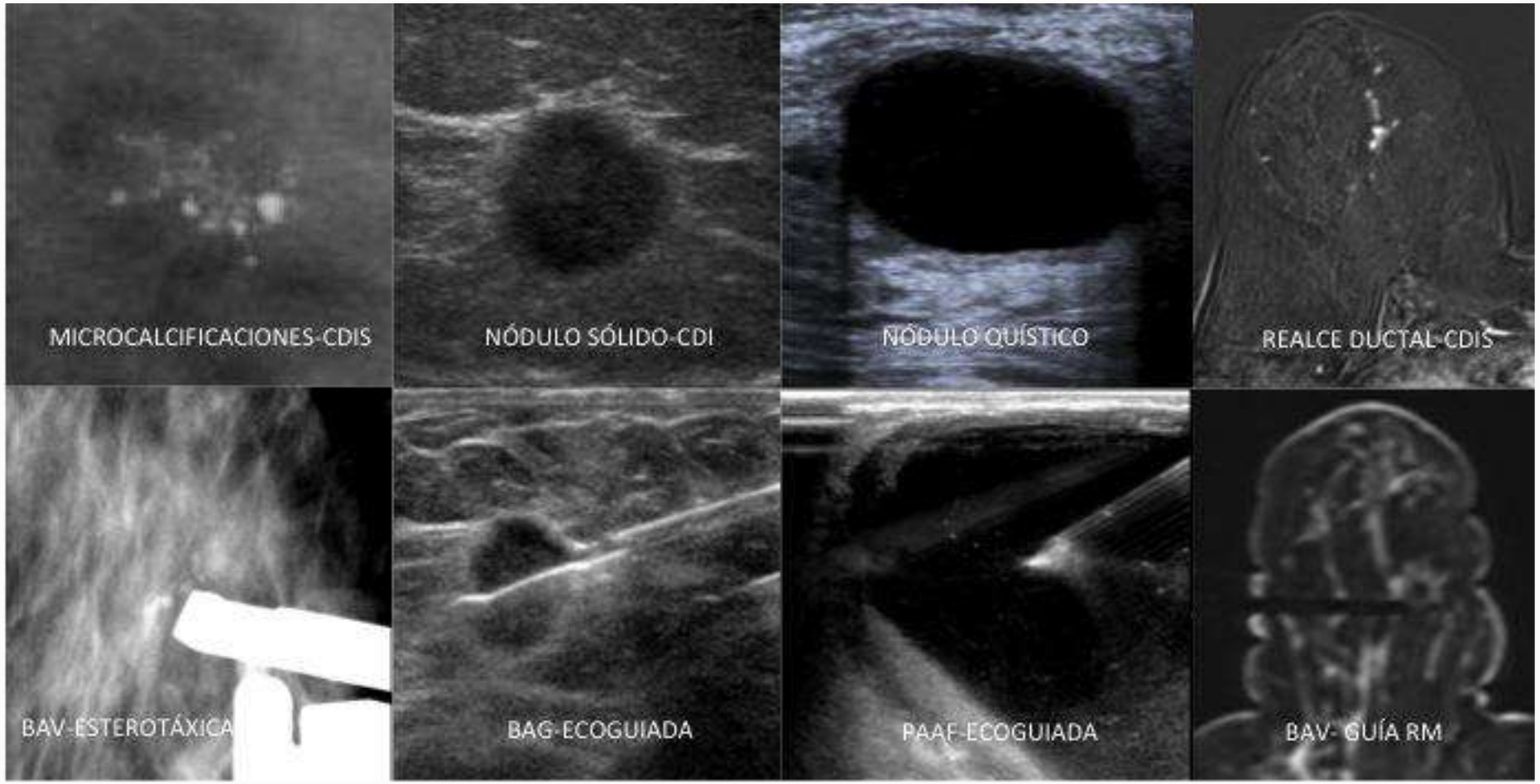
The image finding will determine the type of biopsy



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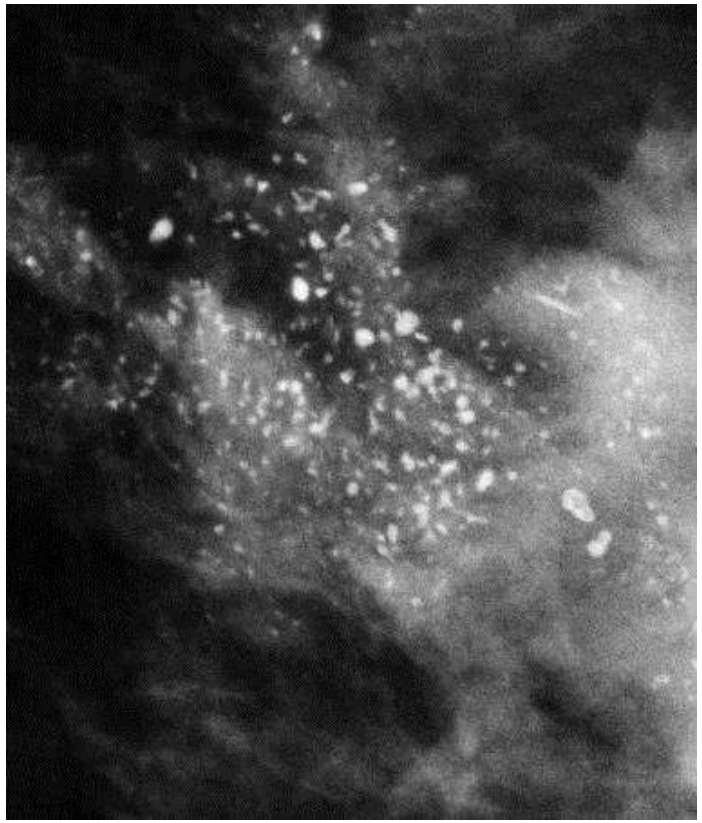
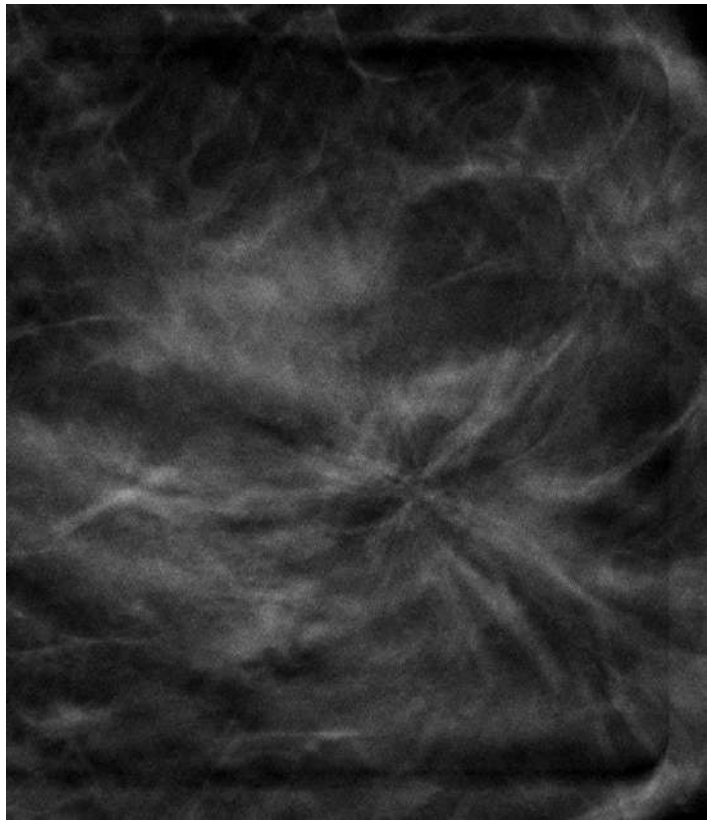
Stereotactic Breast Biopsy





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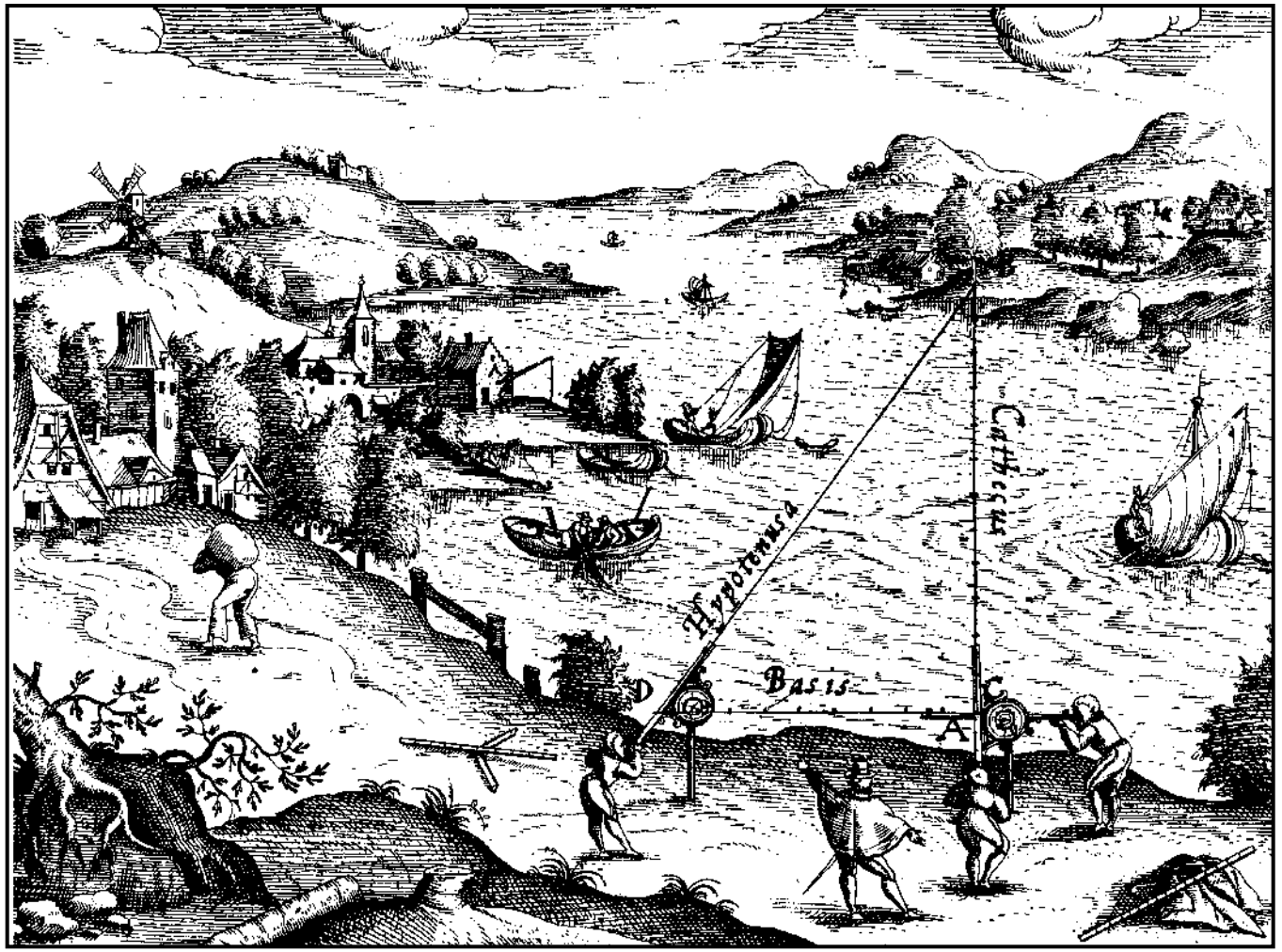
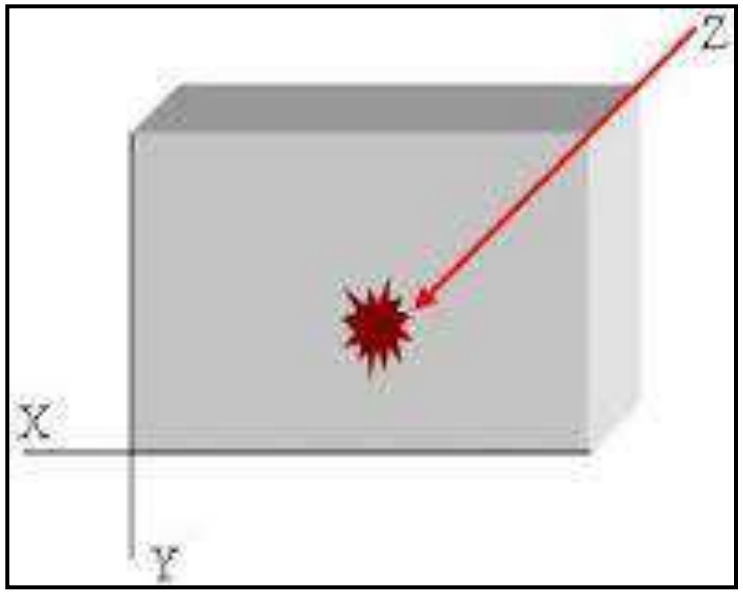
Stereotactic Fundamentals





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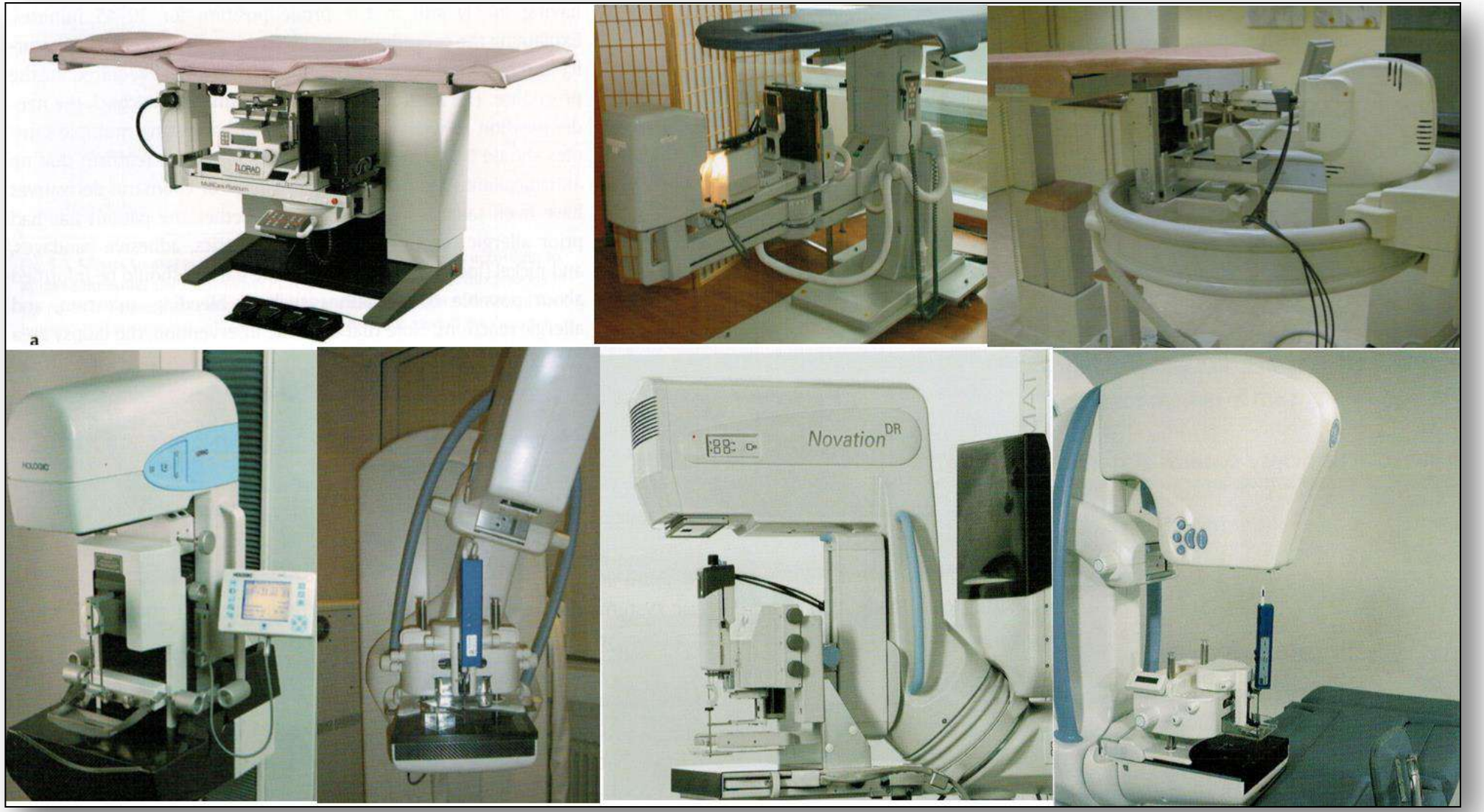

What we had untill now…

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3D MAMMOGRAPHY

- ACTUAL MAMMOGRAPHY.
- Reduce false positive screening recalls.
- Increase in Cancer detection rate: invasive and DCIS.

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Abstract ▾ Send to: ▾

Radiology. 2013 Apr;267(1):47-56. doi: 10.1148/radiol.12121373. Epub 2013 Jan 7.

Comparison of digital mammography alone and digital mammography plus tomosynthesis in a population-based screening program.

Skaane P[1], Bandos AI, Gullien R, Eben EB, Ekseth U, Haakenaasen U, Izadi M, Jebsen IN, Jahr G, Krager M, Niklason LT, Hofvind S, Gur D.

Radiology. 2013 Jan 7

For complete findings, please click here http://radiology.rsna.org/content/early/2013/01/01/radiol.12121373.full

OBJECTIVE

This study was performed to assess cancer detection rates and false-positive rates before arbitration, positive predictive values for women recalled after arbitration, and the type of cancers detected with use of digital mammography alone and digital mammography combined with tomosynthesis in a large prospective screening trial

MATERIALS AND METHODS

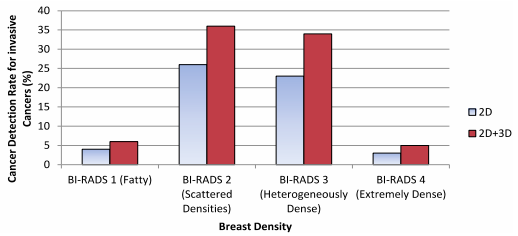
12631 women who gave written consent from November 22, 2010 to December 31, 2011 participated in this prospective screening study. An interim analysis of results from these examinations was performed and the results were independently read and interpreted by four different radiologists. These examinations were interpreted by using digital mammography alone and digital mammography plus tomosynthesis

FINDINGS

	Digital Mammography alone: number/1000 women screened	**Digital Mammography plus Tomosynthesis:** number/1000 women screened	**Relative Change:** adjusted for reader
False-positive rate before arbitration	61.1	53.1	↓15%
Cancer Detection Rate (invasive and in-situ cancers)	6.1	8.0	↑27%
Cancer Detection Rate (invasive cancers)	4.4 (56 detected)	6.4 (81 detected)	↑40% (25 additional)

CONCLUSION

The authors concluded that the addition of tomosynthesis to digital mammography in the screening population resulted in a significant increase in cancer detection rate, particularly for invasive cancers, and a simultaneous significant decrease in false-positive rate. The increase was observed across all breast densities.



Relative Change: adjusted for reader
↓15%
↑27%
↑40% (25 additional)

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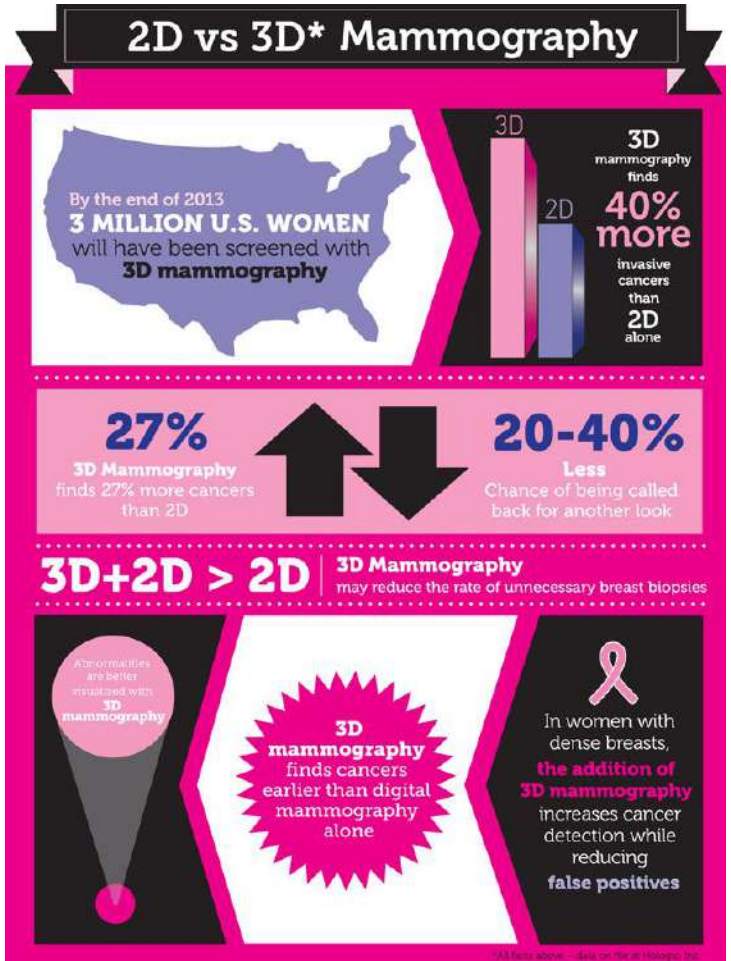
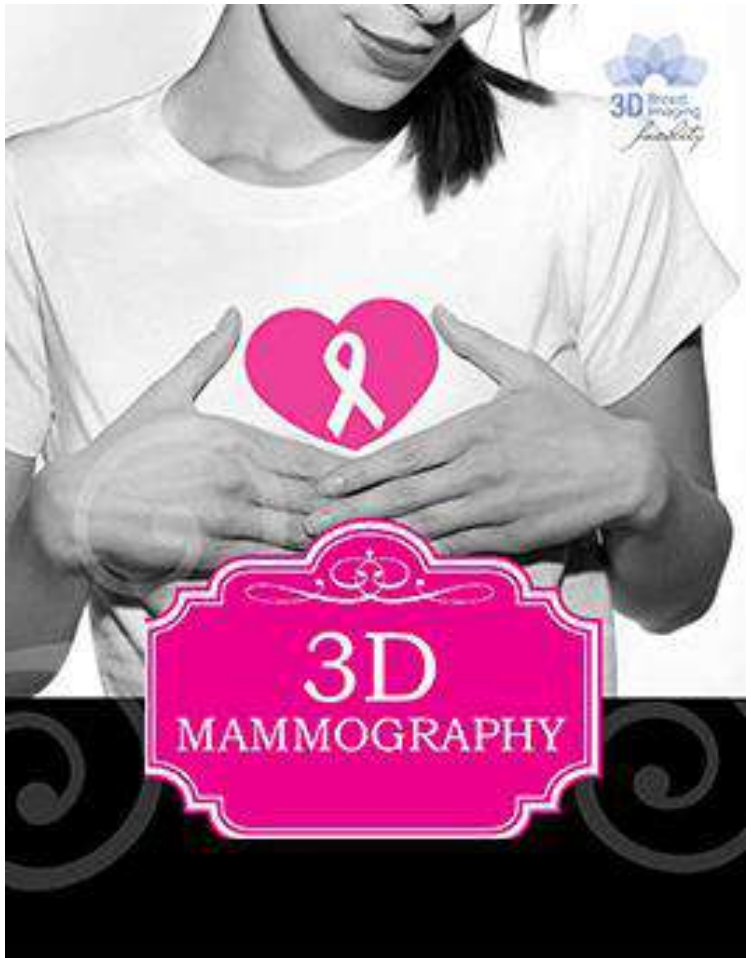
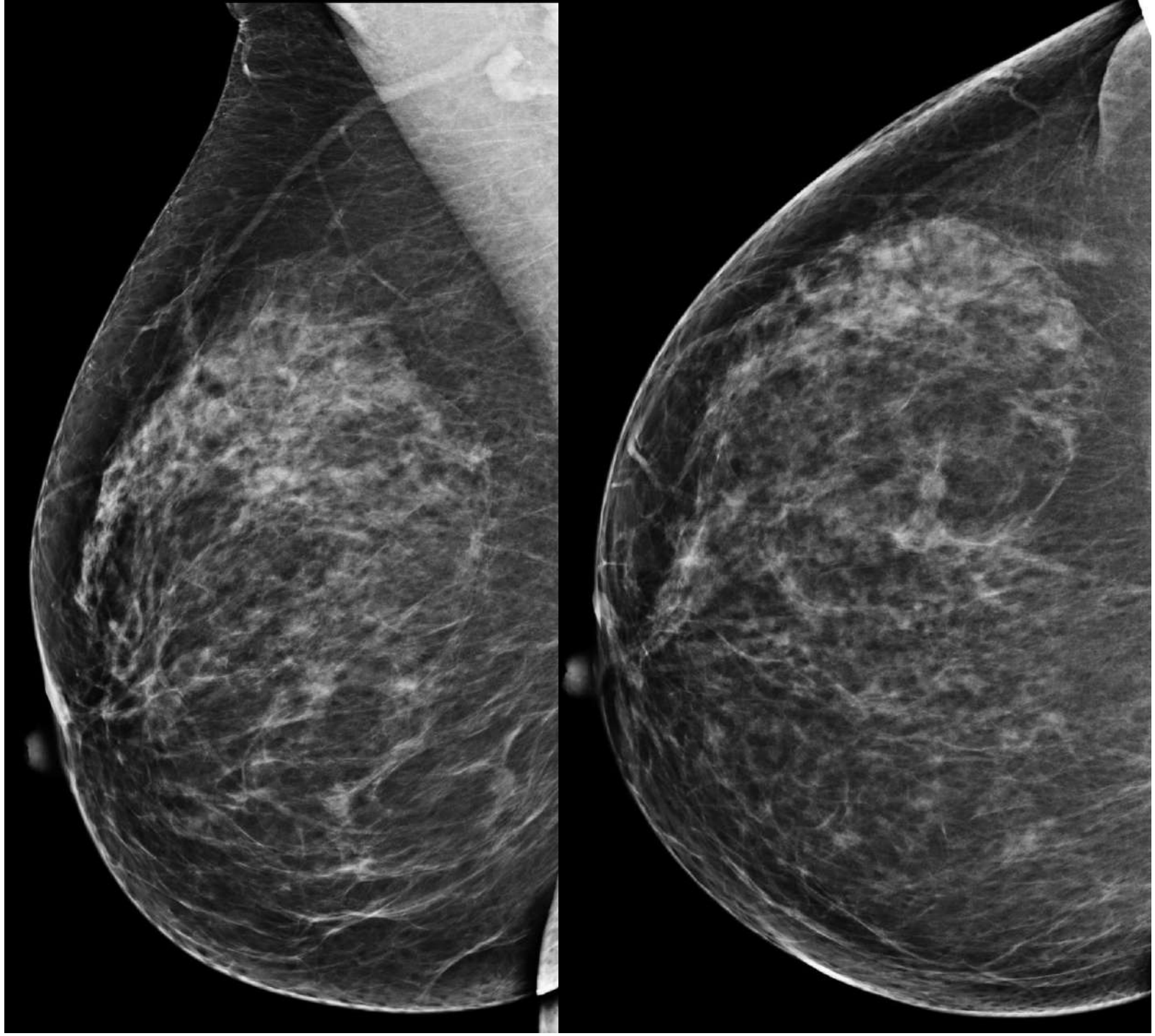
3D
MAMMOGRAPHY
IS HERE.
Everything is sharper and clearer in 3D.


3D
MAMMOGRAPHY
IS HERE.
Because she matters.


2D vs 3D* Mammography
By the end of 2013
3 MILLION U.S. WOMEN
will have been screened with
3D mammography
3D
2D
3D mammography finds 40% more invasive cancers than 2D alone
27%
3D Mammography finds 27% more cancers than 2D
20-40%
Less
Chance of being called back for another look
3D+2D > 2D
3D Mammography may reduce the rate of unnecessary breast biopsies
Abnormalities are better visualized with 3D mammography
3D mammography finds cancers earlier than digital mammography alone
In women with dense breasts, the addition of 3D mammography increases cancer detection while reducing false positives


3D MAMMOGRAPHY™
3D
STANDARD OF CARE


3D
MAMMOGRAPHY



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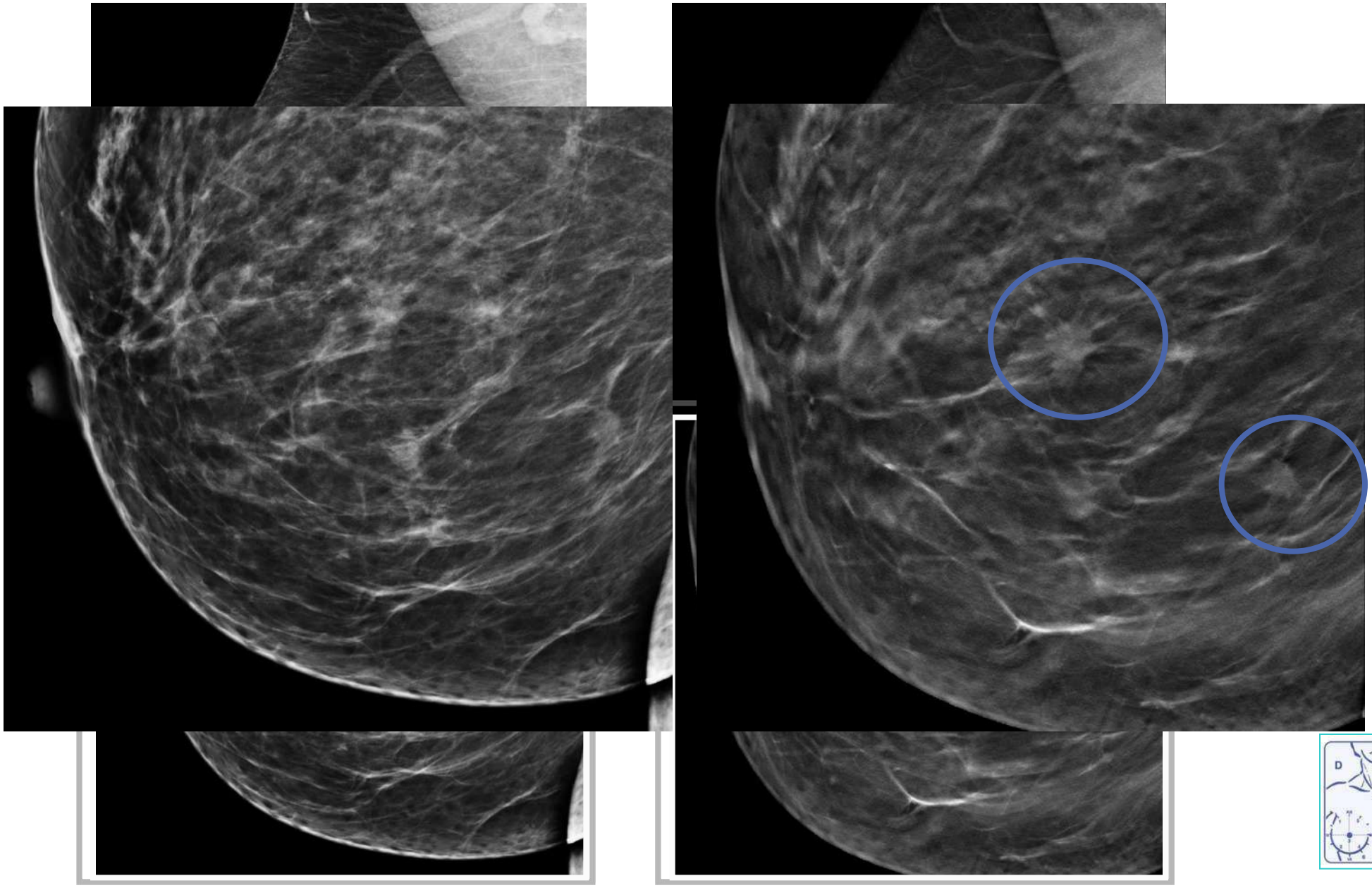

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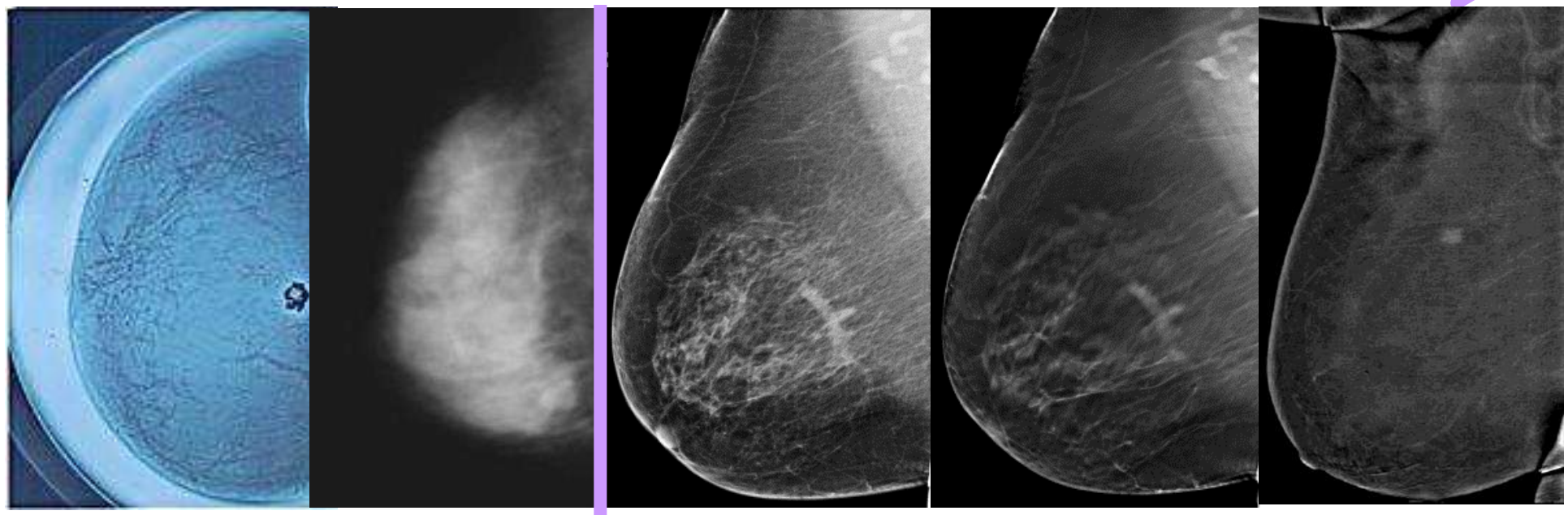
3D BIOPSY JUSTIFICATION



XEROMAMMOGRAPHY	ANALOGIC MAMMOGRAPHY	DIGITAL MAMMOGRAPHY	3D TOMOSYNTHESIS MAMMOGRAPHY	CONTRAST MAMMOGRAPHY TOMOSYNTHESIS I-VIEW
70	70 - 90	2000	2010	2014

CONVENTIONAL
STEREOTACTIC
PRONE
TABLE

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BREAST TOMOSYNTHESIS GUIDED BIOPSY

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2013
AFFIRM Vertical

2016
AFFIRM Prone

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AFFIRM 3D BIOPSY

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3D UPRIGHT

- Image quality
- Wider biopsy window
- **Access some posterior lesions**
- Tomo biopsy +++++
- **Cost**

3D PRONE

- **Dedicated room +++**
- **Better patient tolerance**
- Wider biopsy window
- Image quality
- Tomo biopsy +++++

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February 2016

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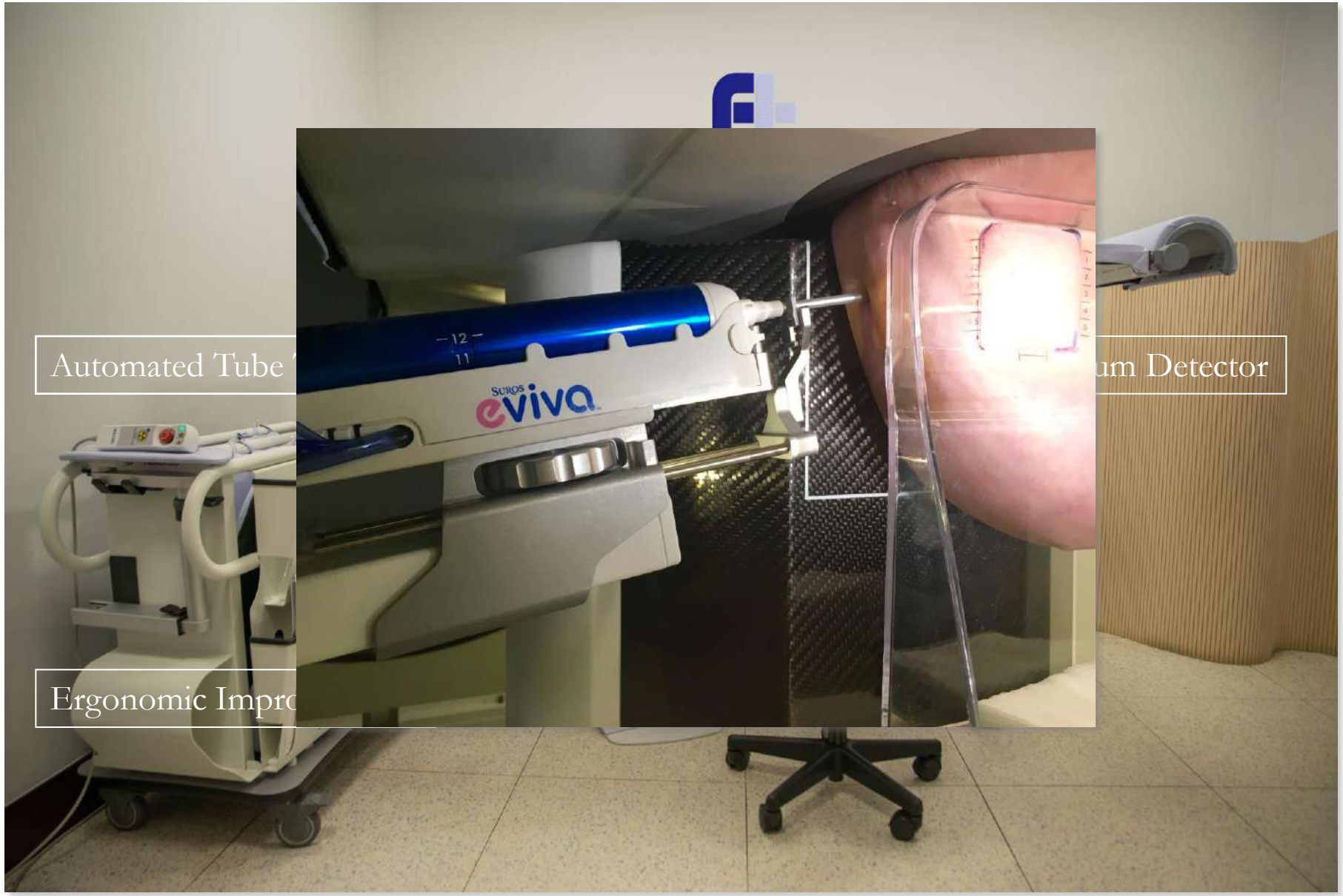
PRONE TABLE CENTRO DE PATOLOGÍA DE LA MAMA



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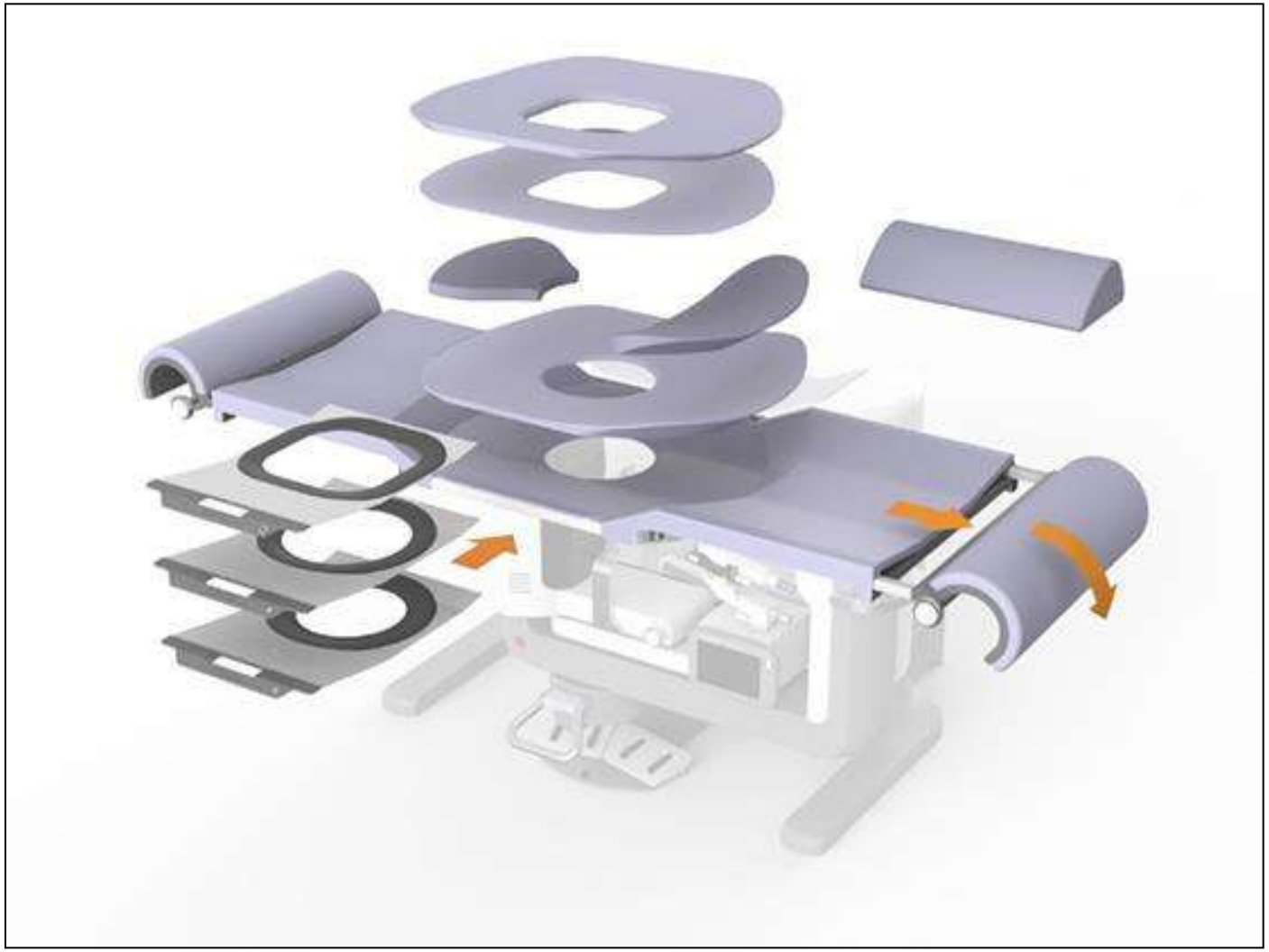

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Affirm™ PRONE

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CLINICAL ADVANTAGES

- Ergonomic improvements.
- Software improvements.
- Image capability: 3D and selenium detector.
- Problem solving in complex biopsies.
- Excellent patient experience.

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Complex biopsies

- Thin Breast Compression (Less than 2.5 cm).

C-Arm

- Subtle microcalcifications.
- Low-Contrast lesions: Distortions (3D).

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Lateral Access C-Arm

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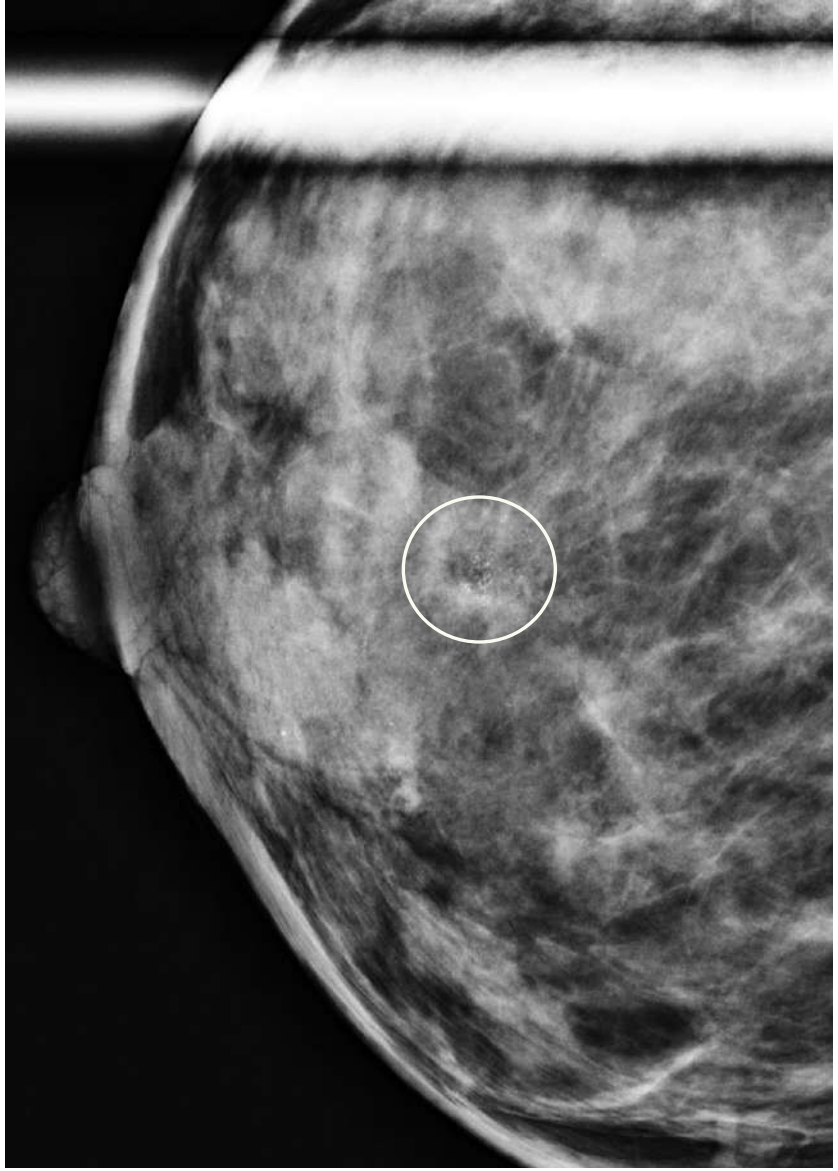

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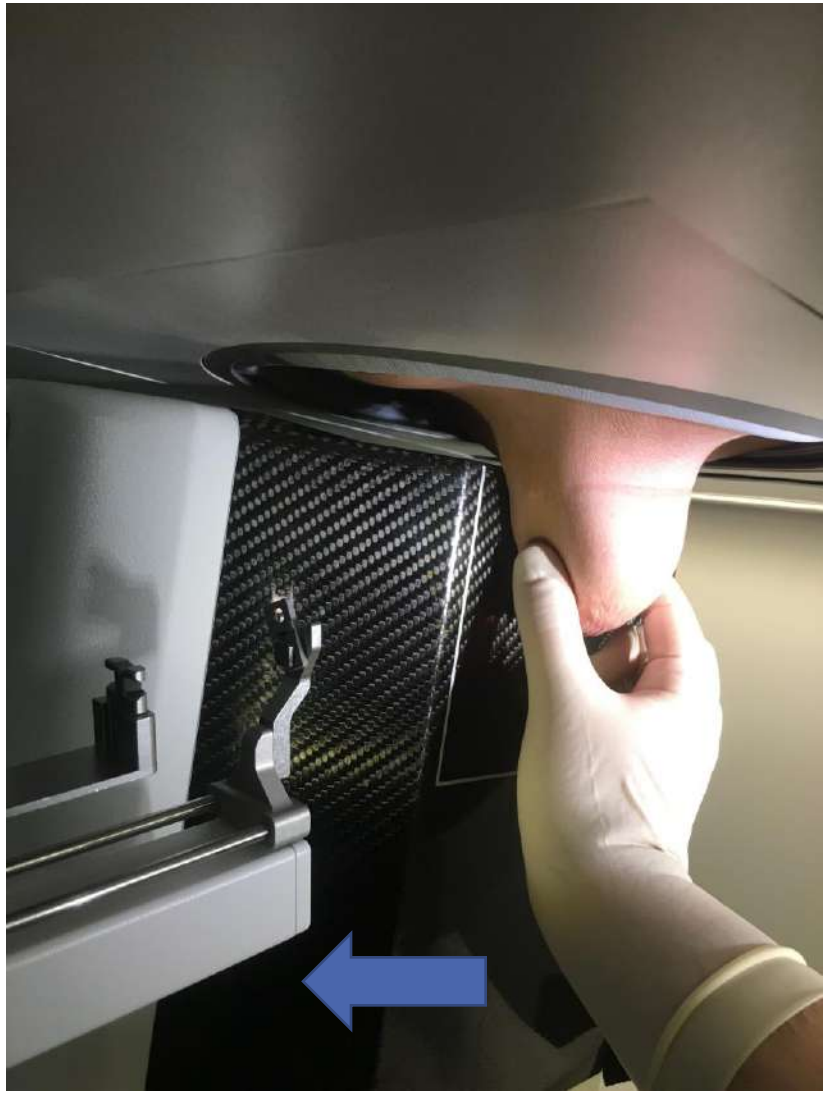

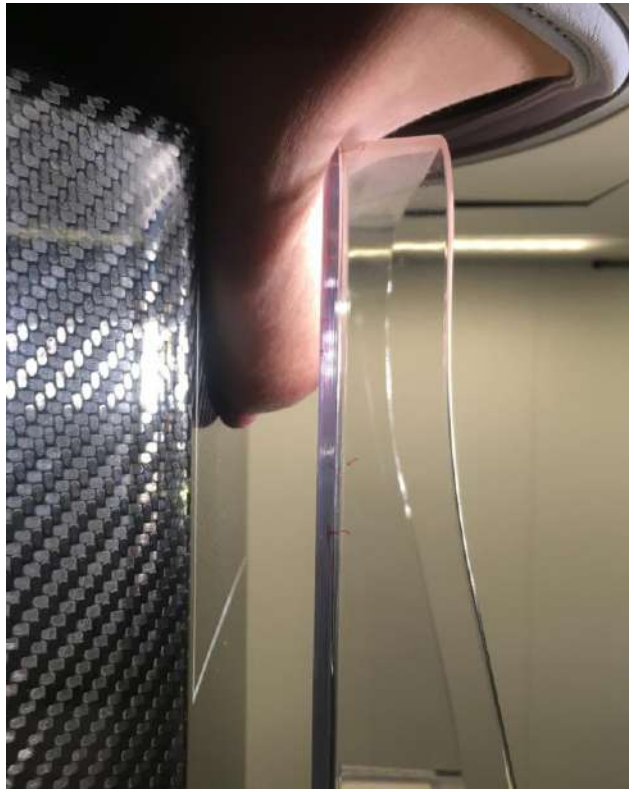

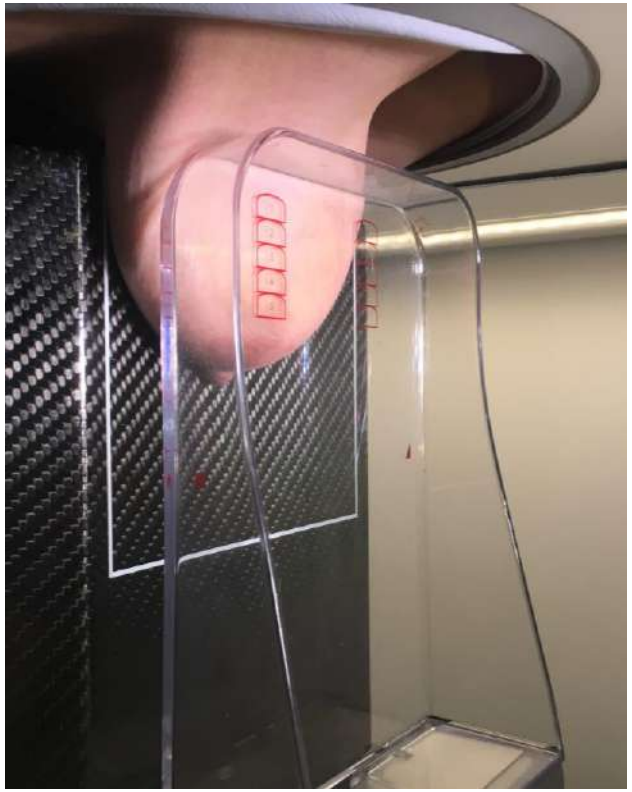

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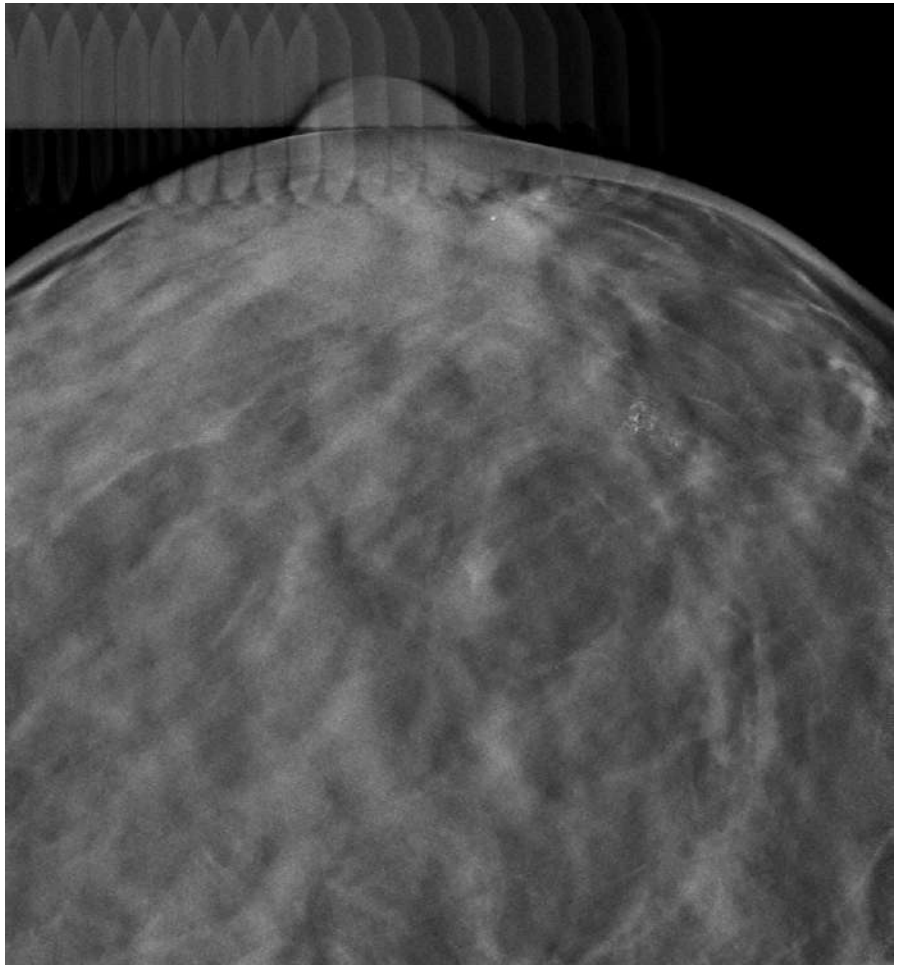

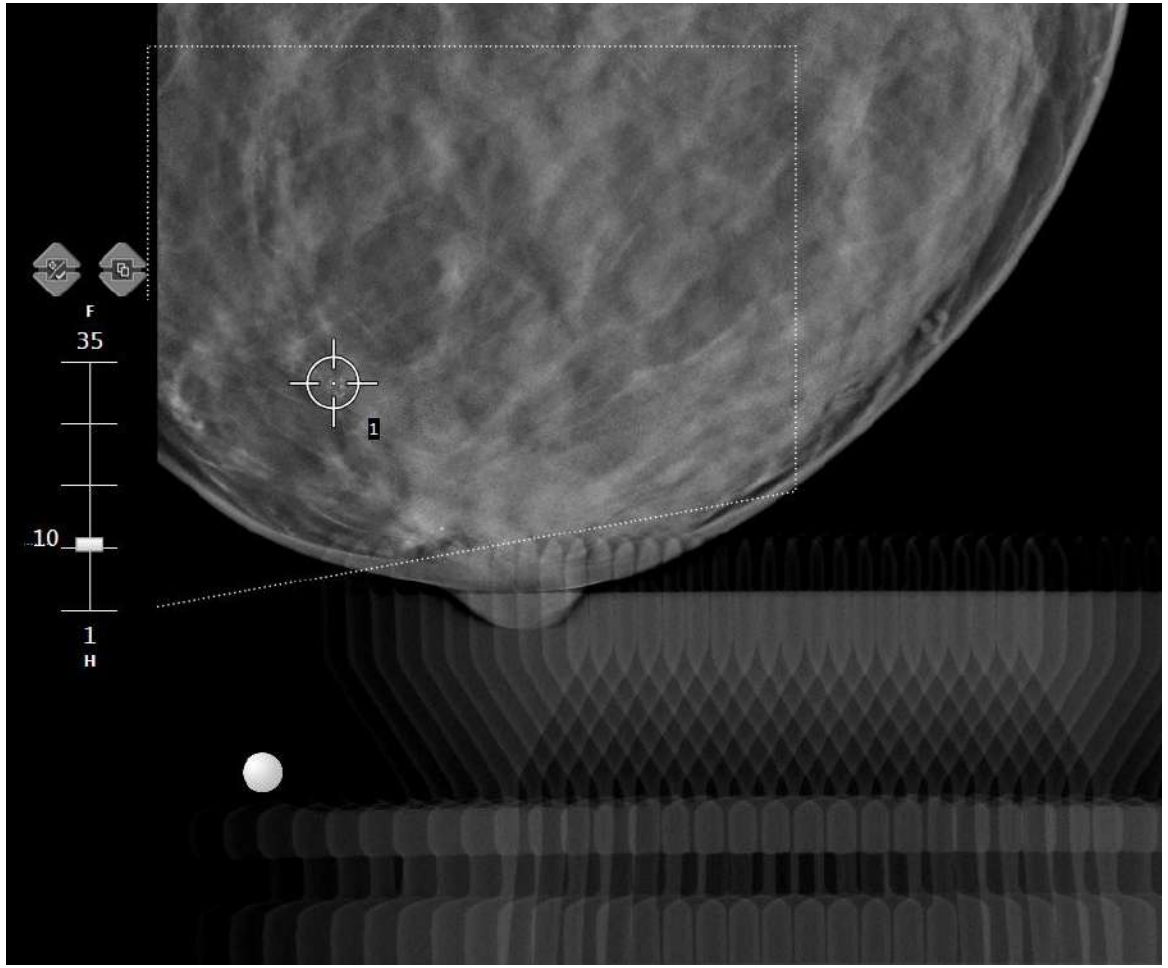

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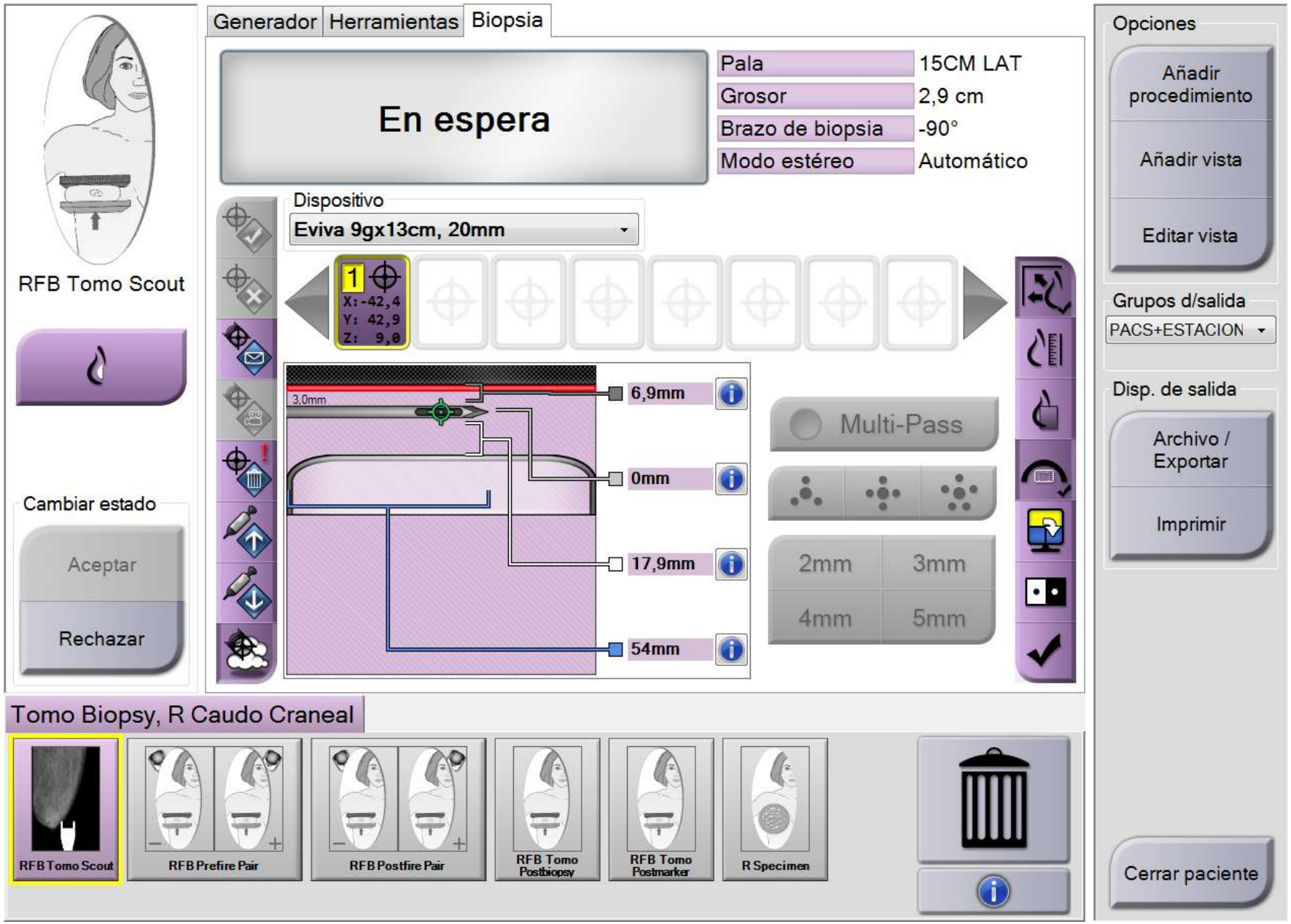

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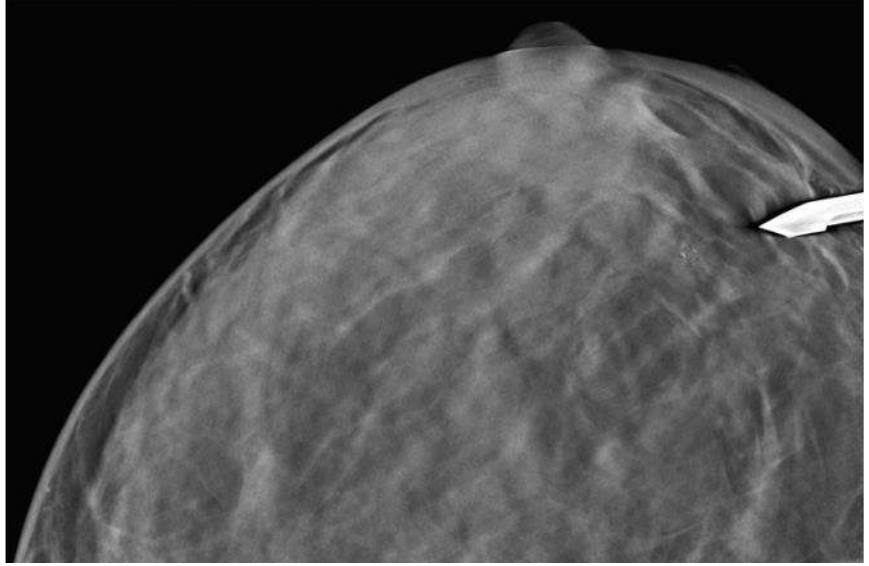

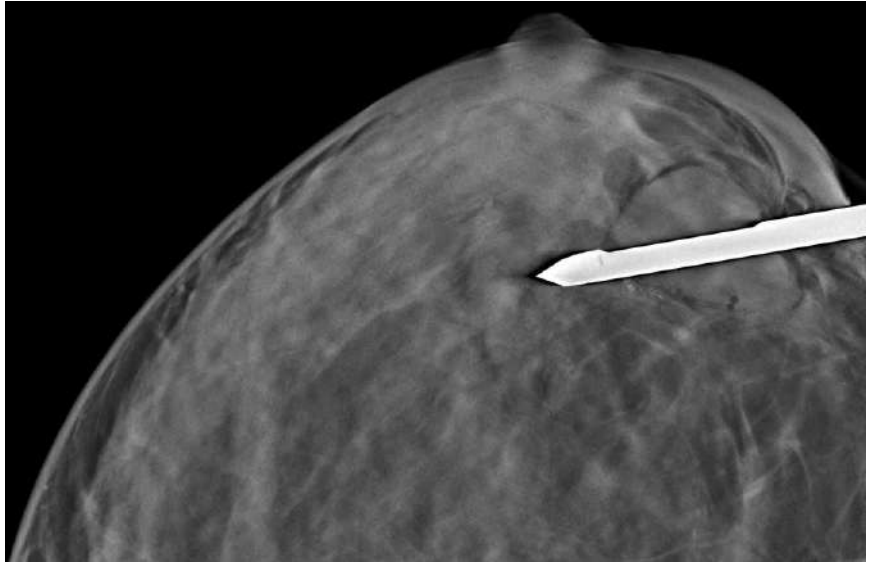

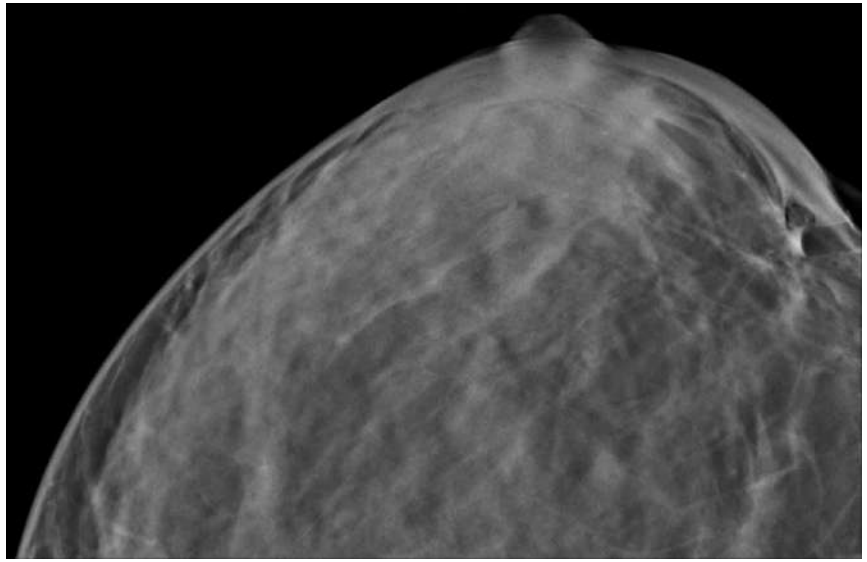

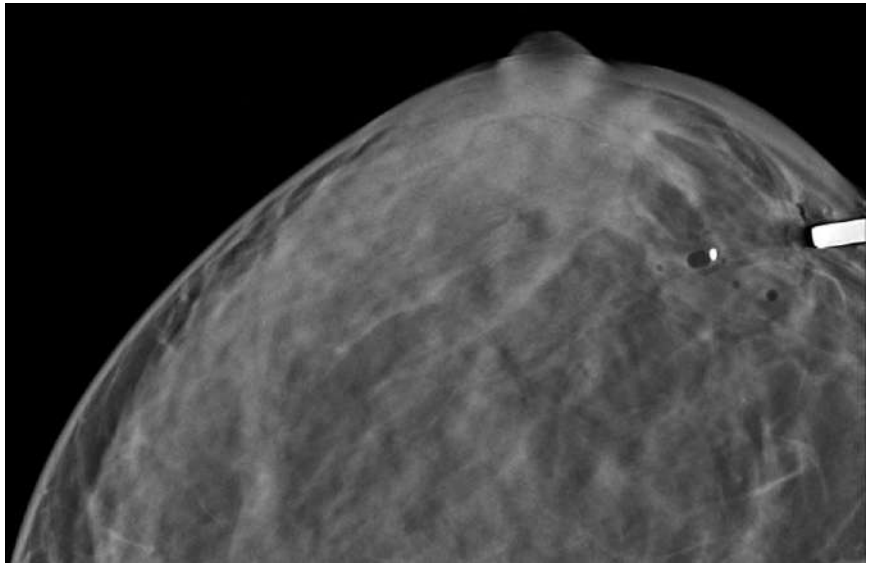

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DCIS

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Challenging lesions

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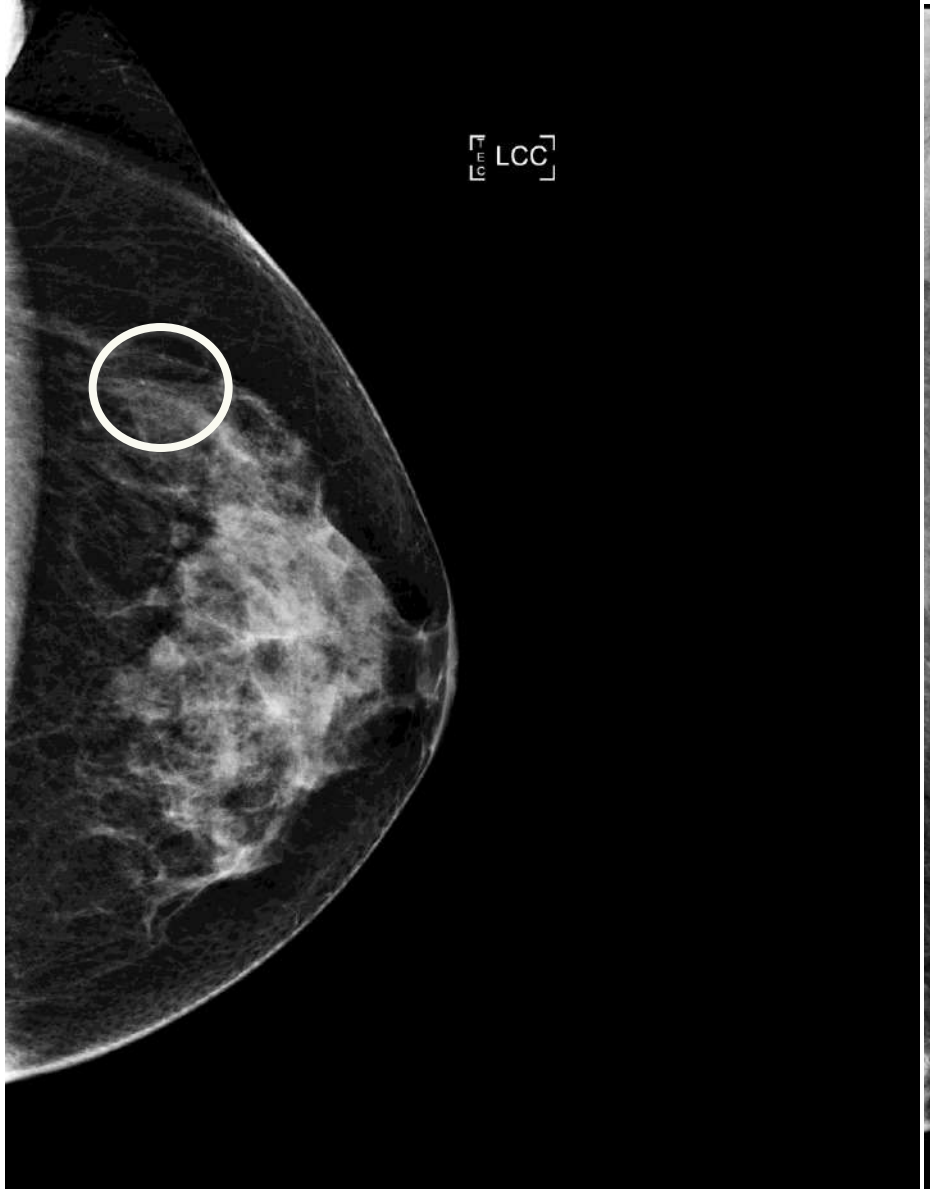

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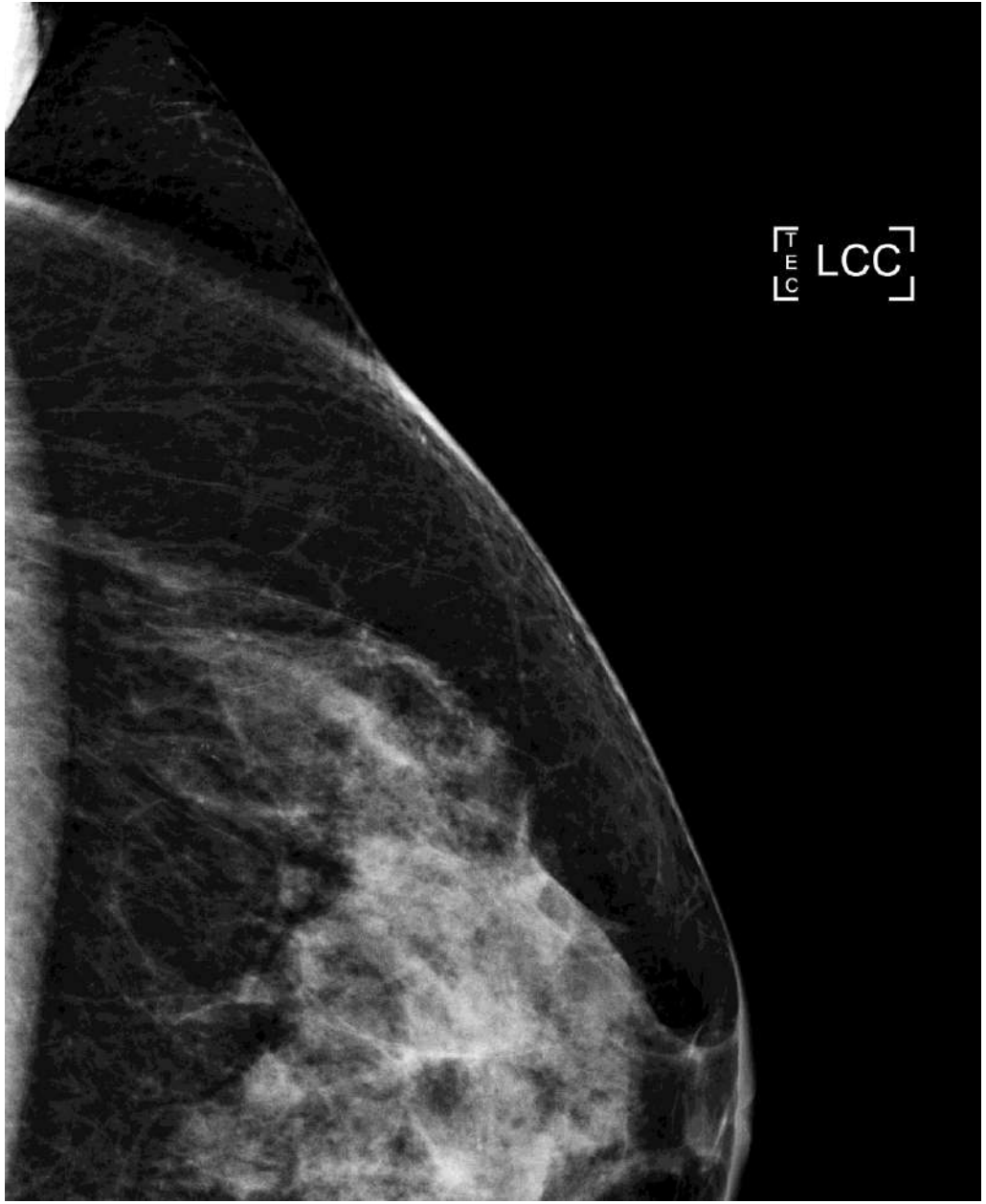

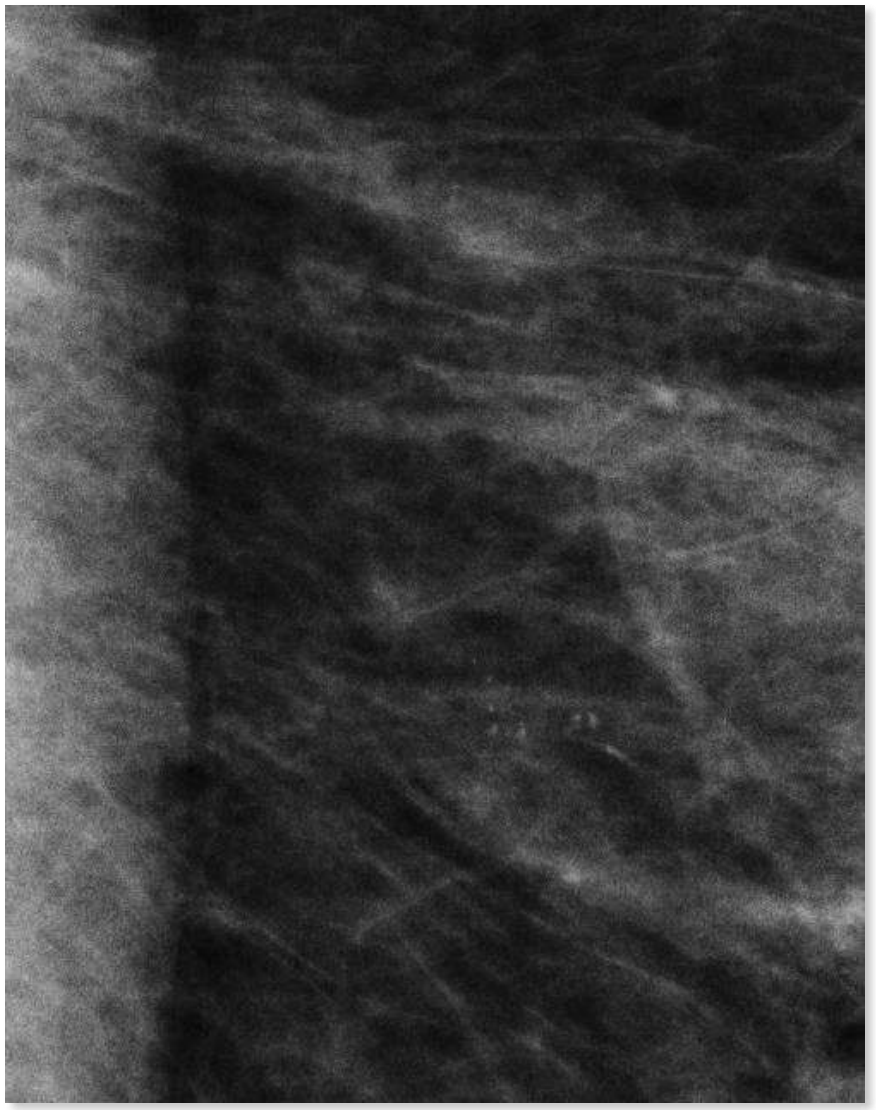

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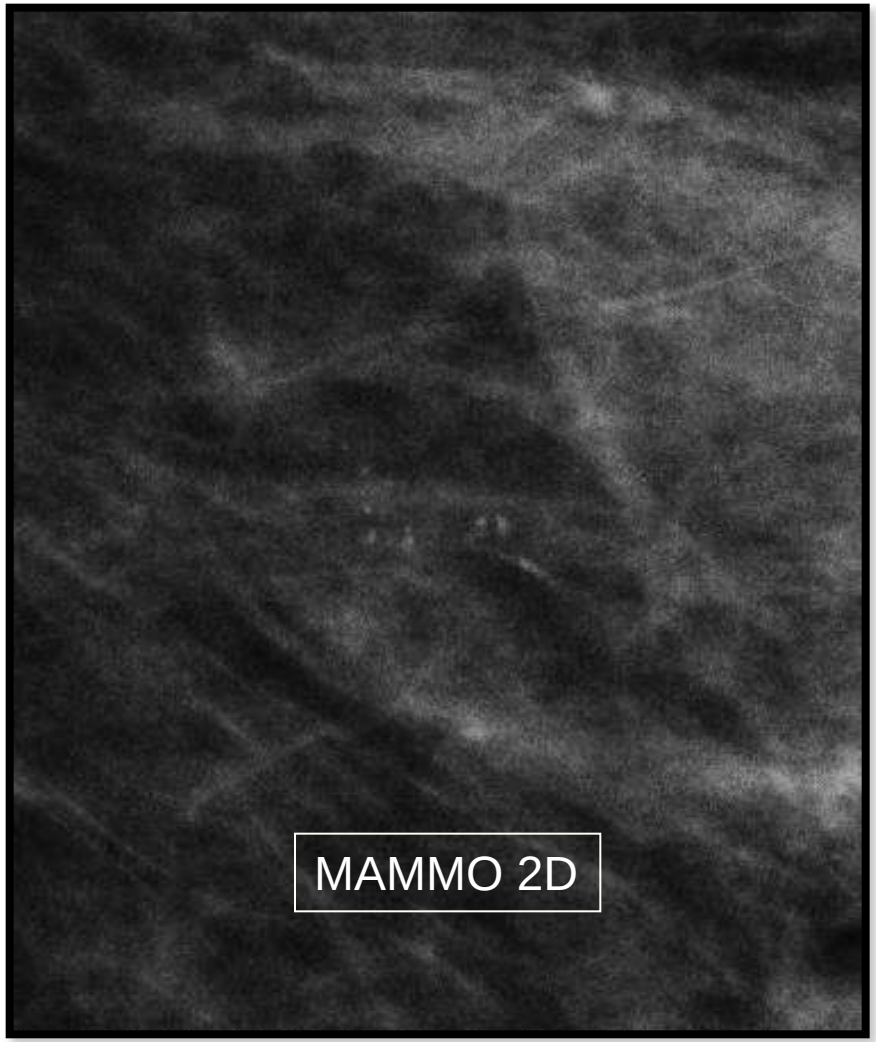

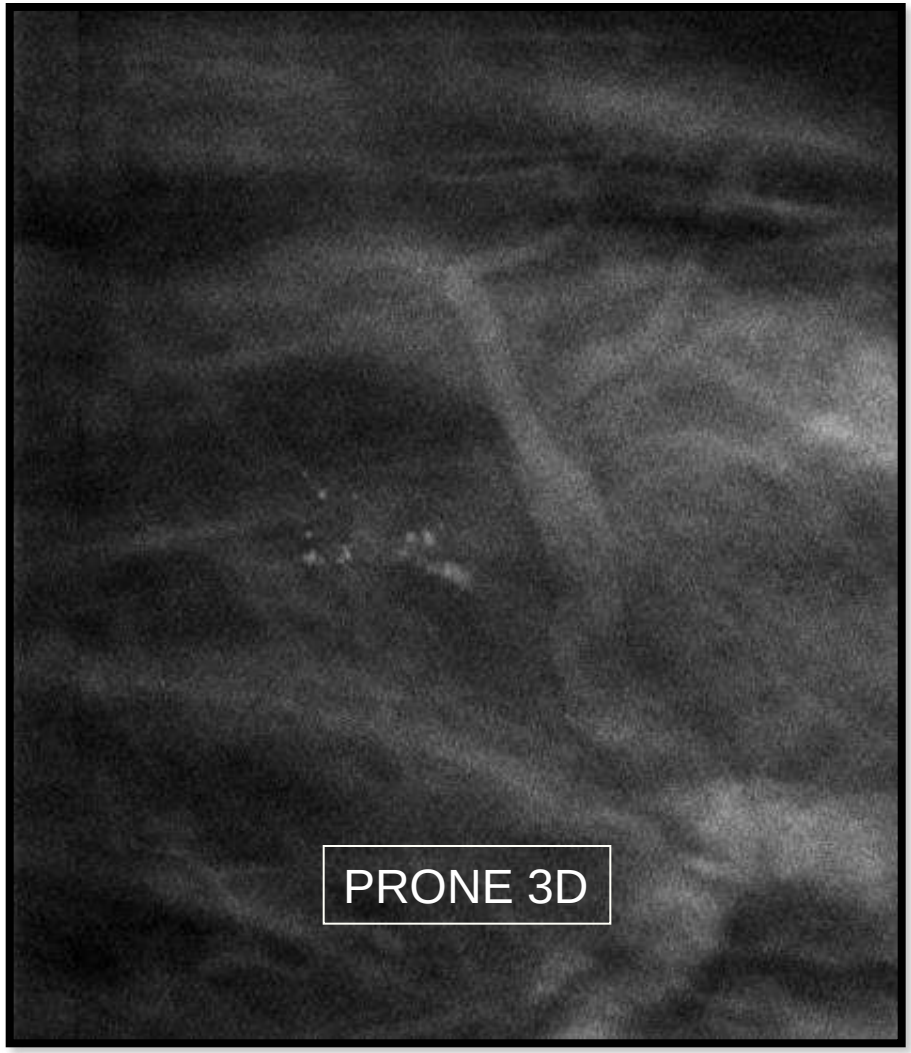

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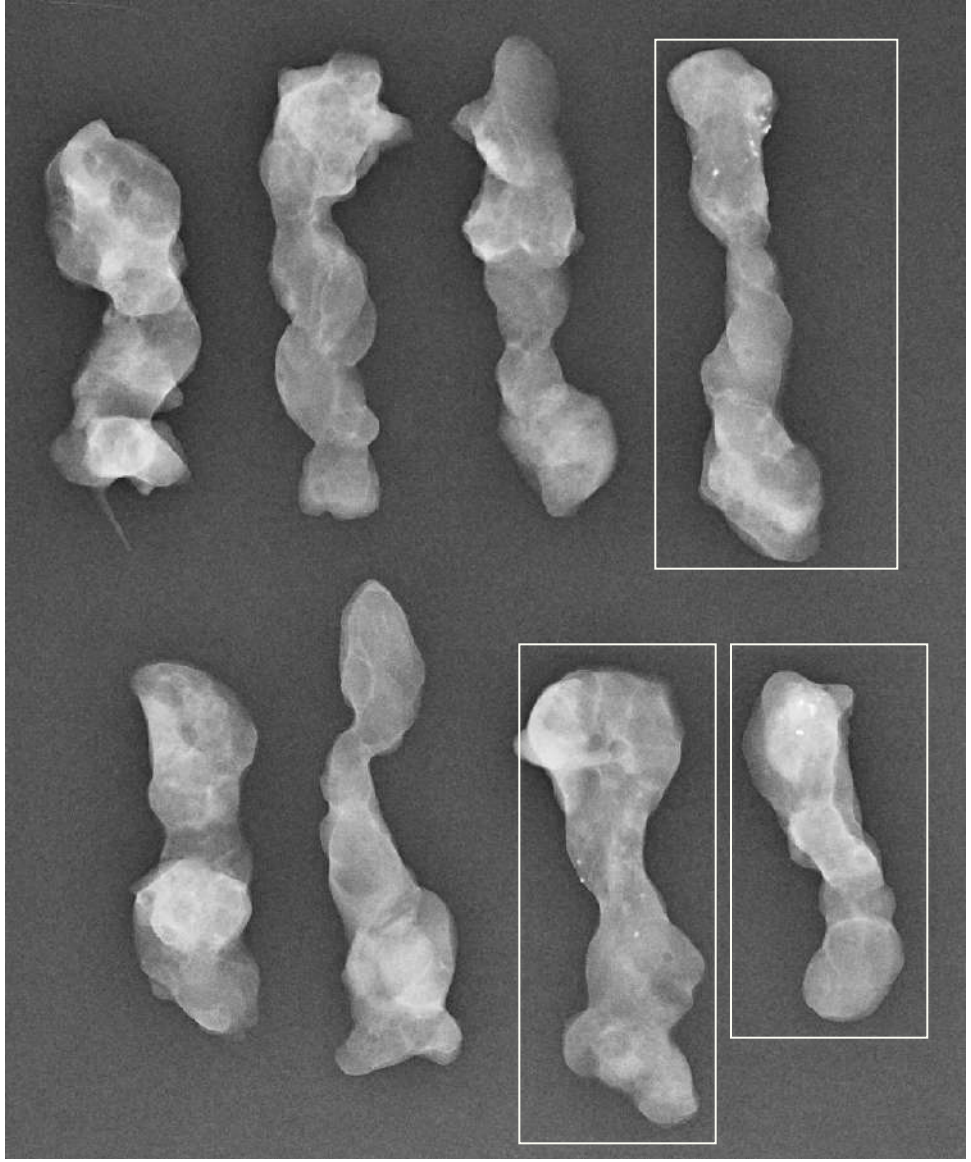

Low Grade DCIS

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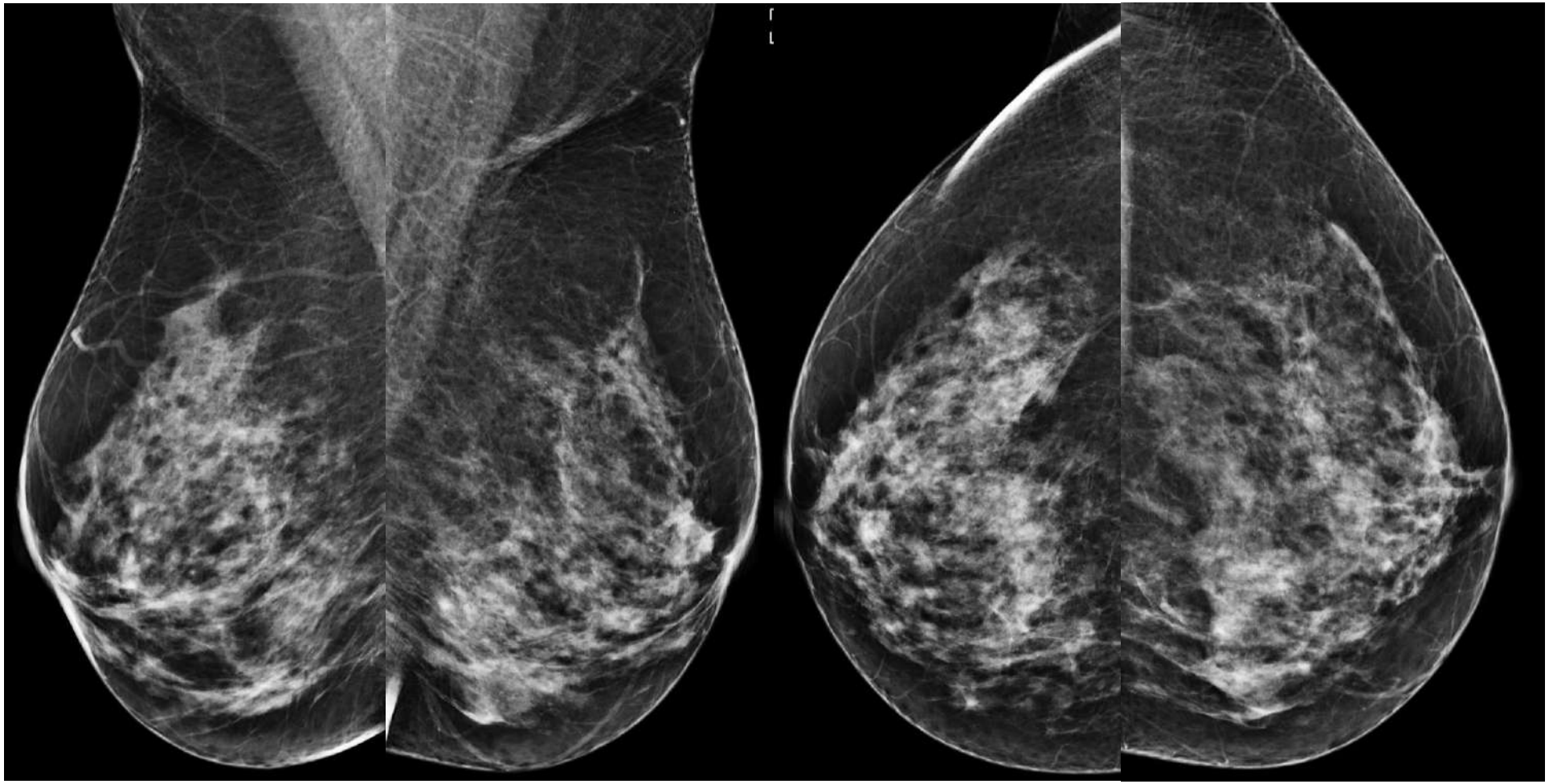

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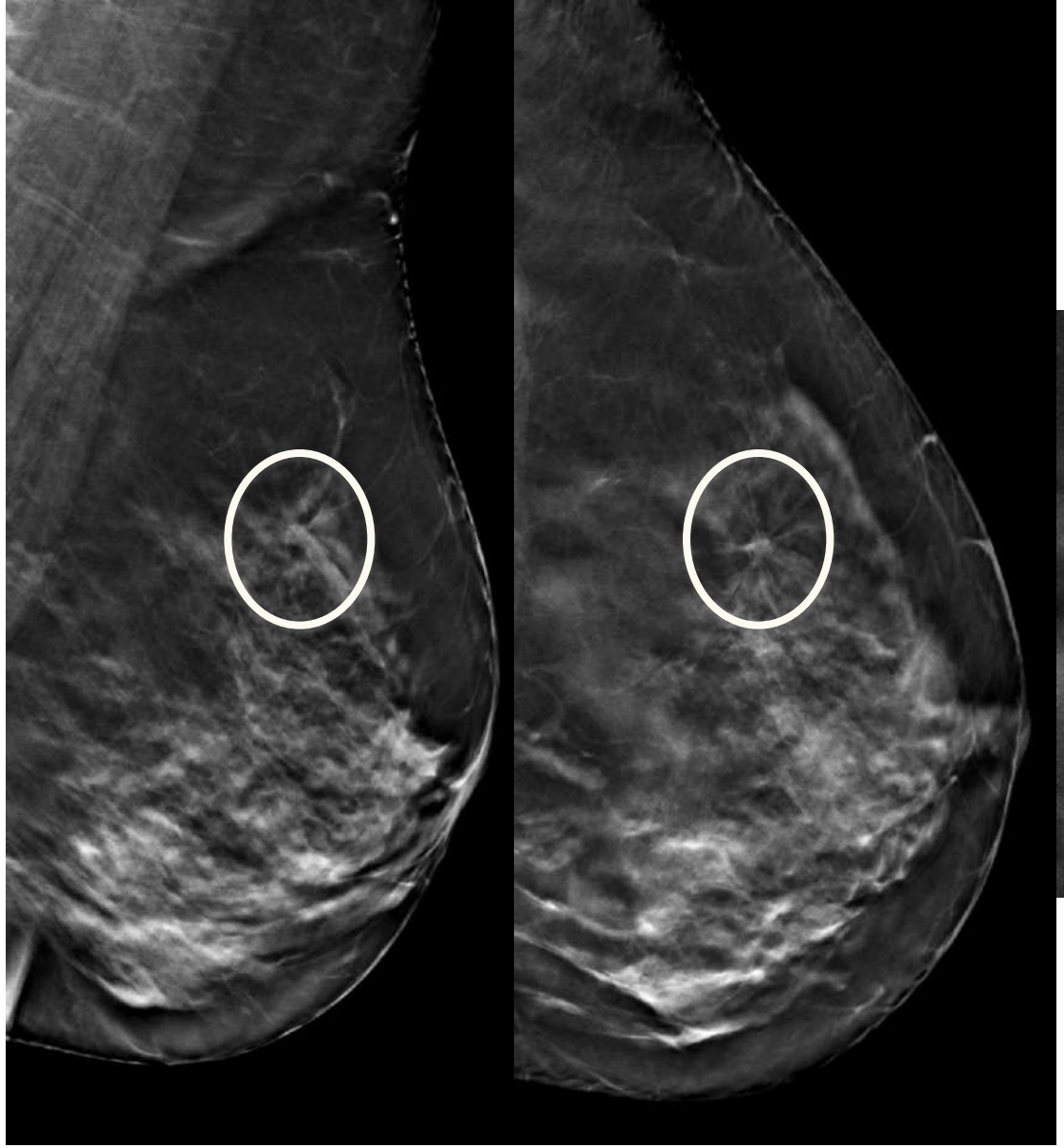

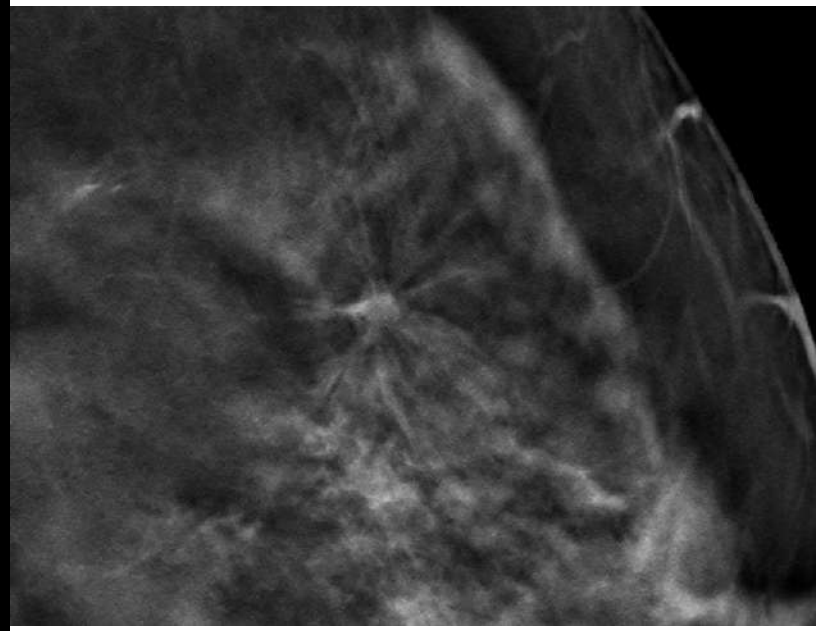

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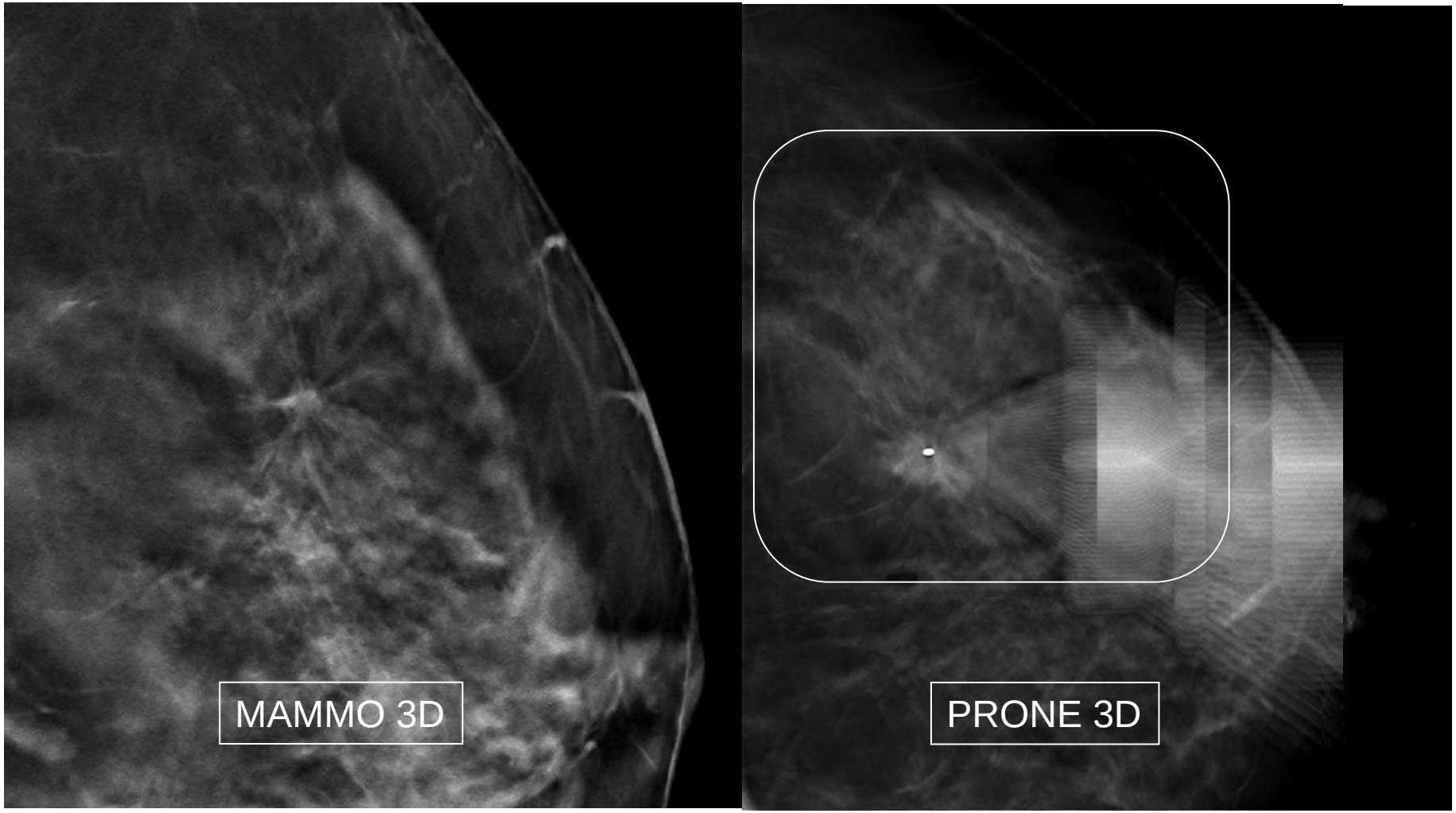

Invasive Ductal Carcinoma

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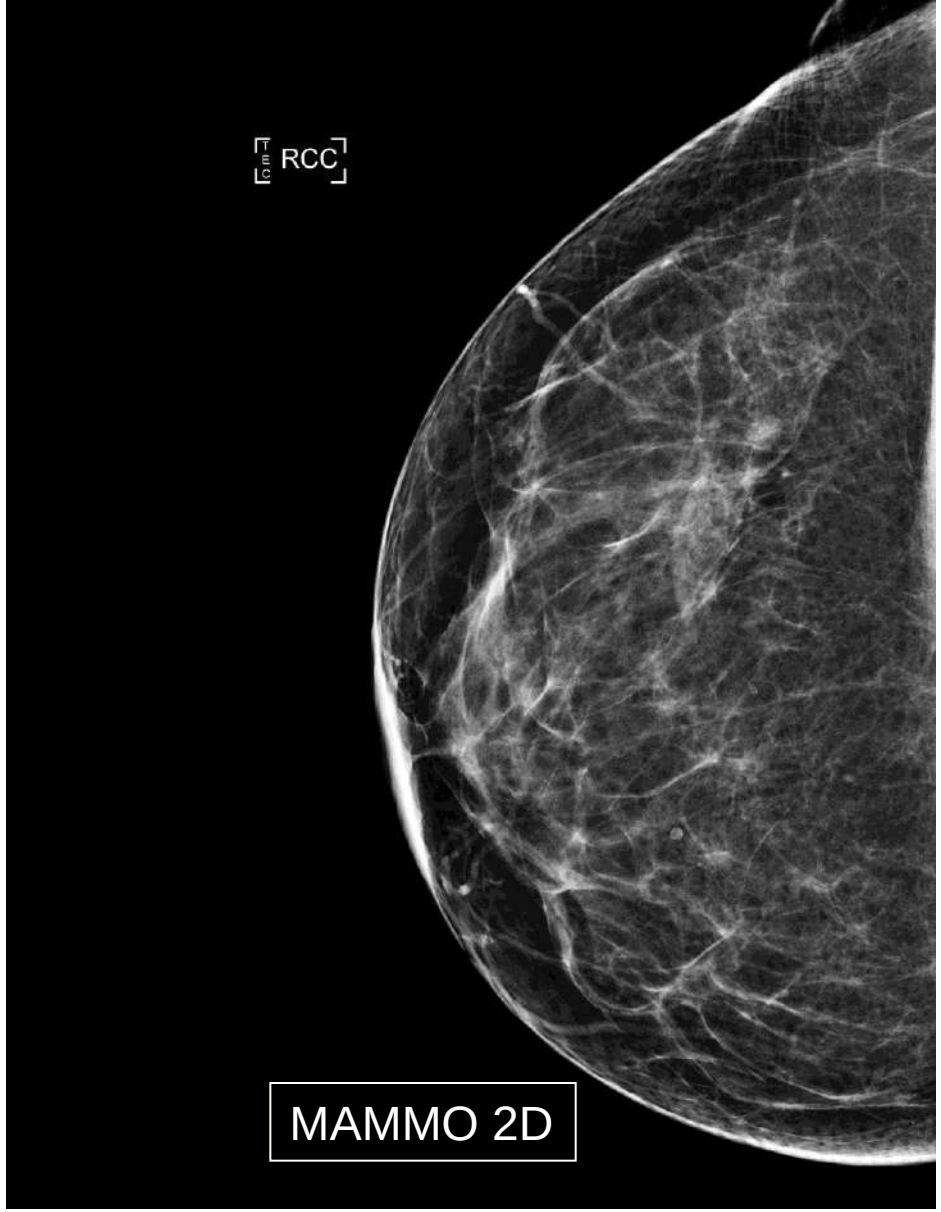

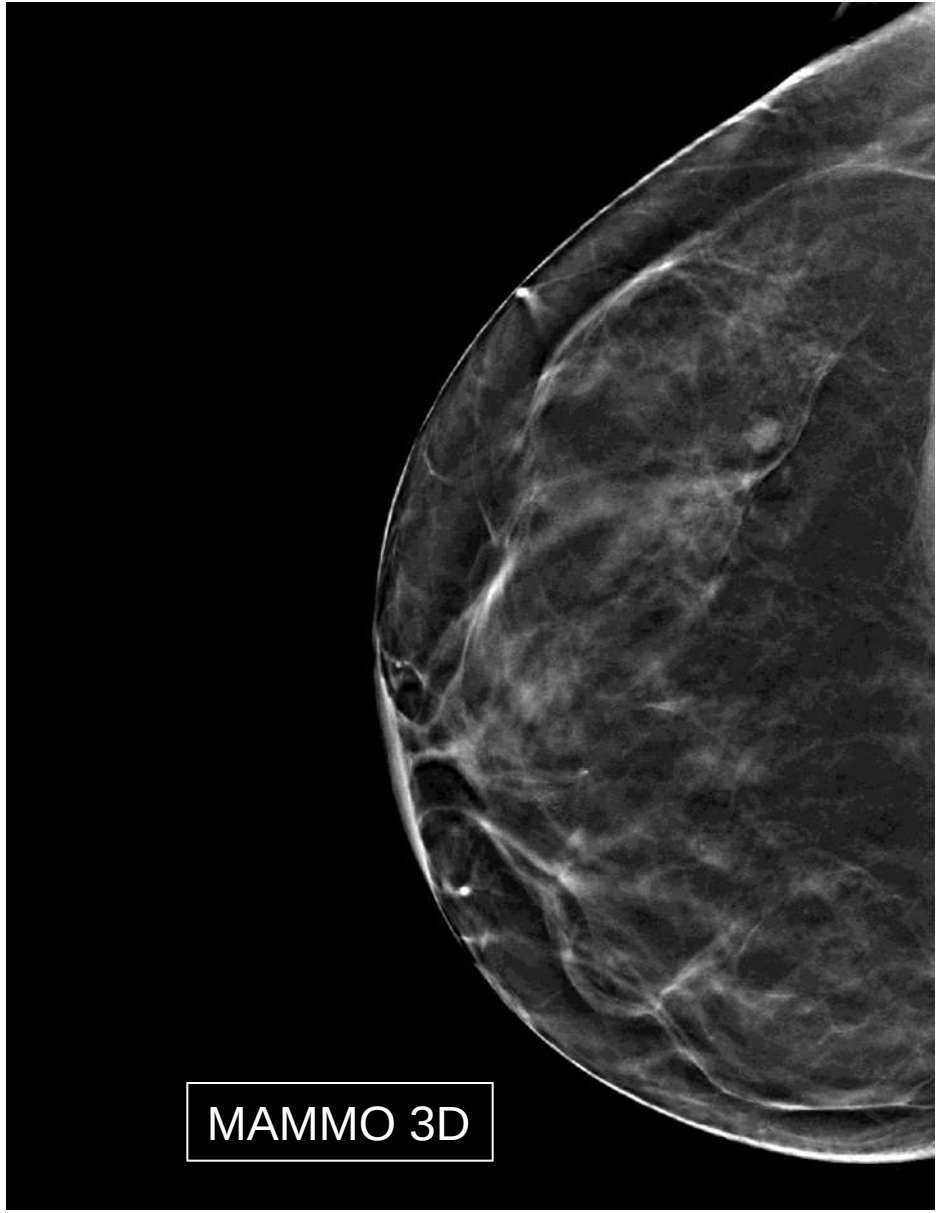

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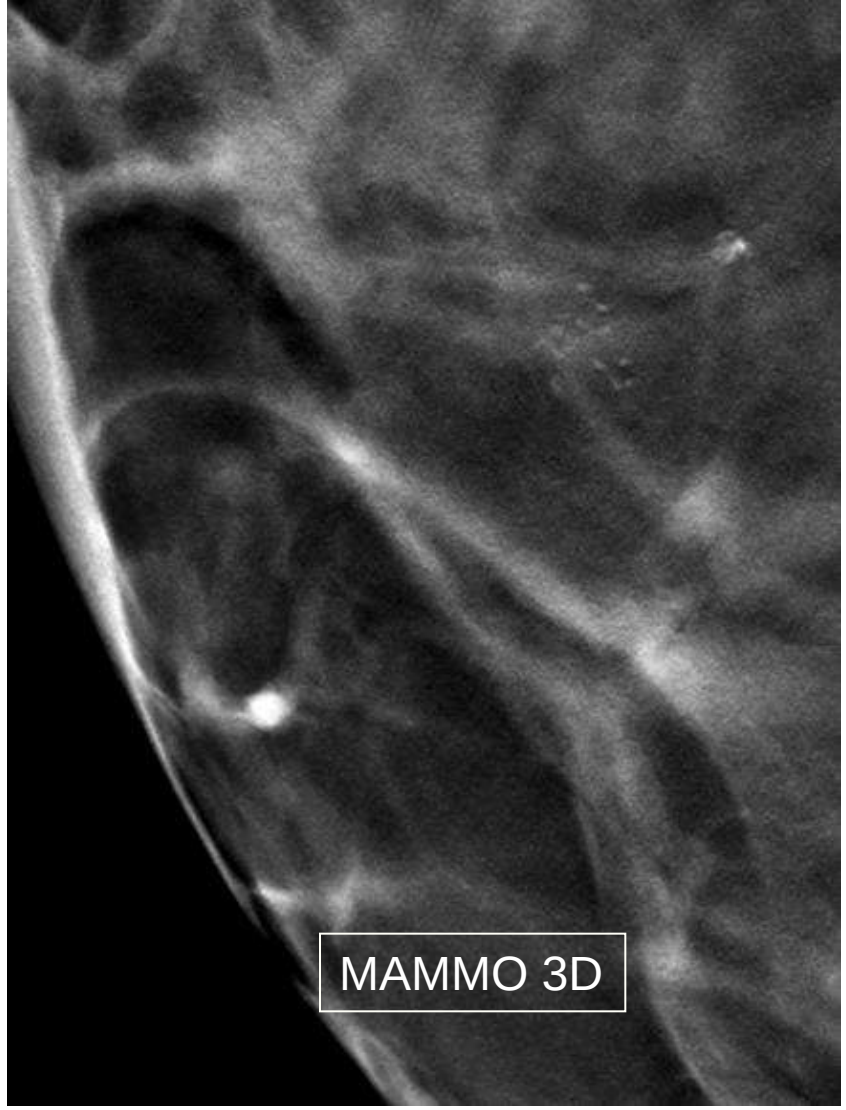

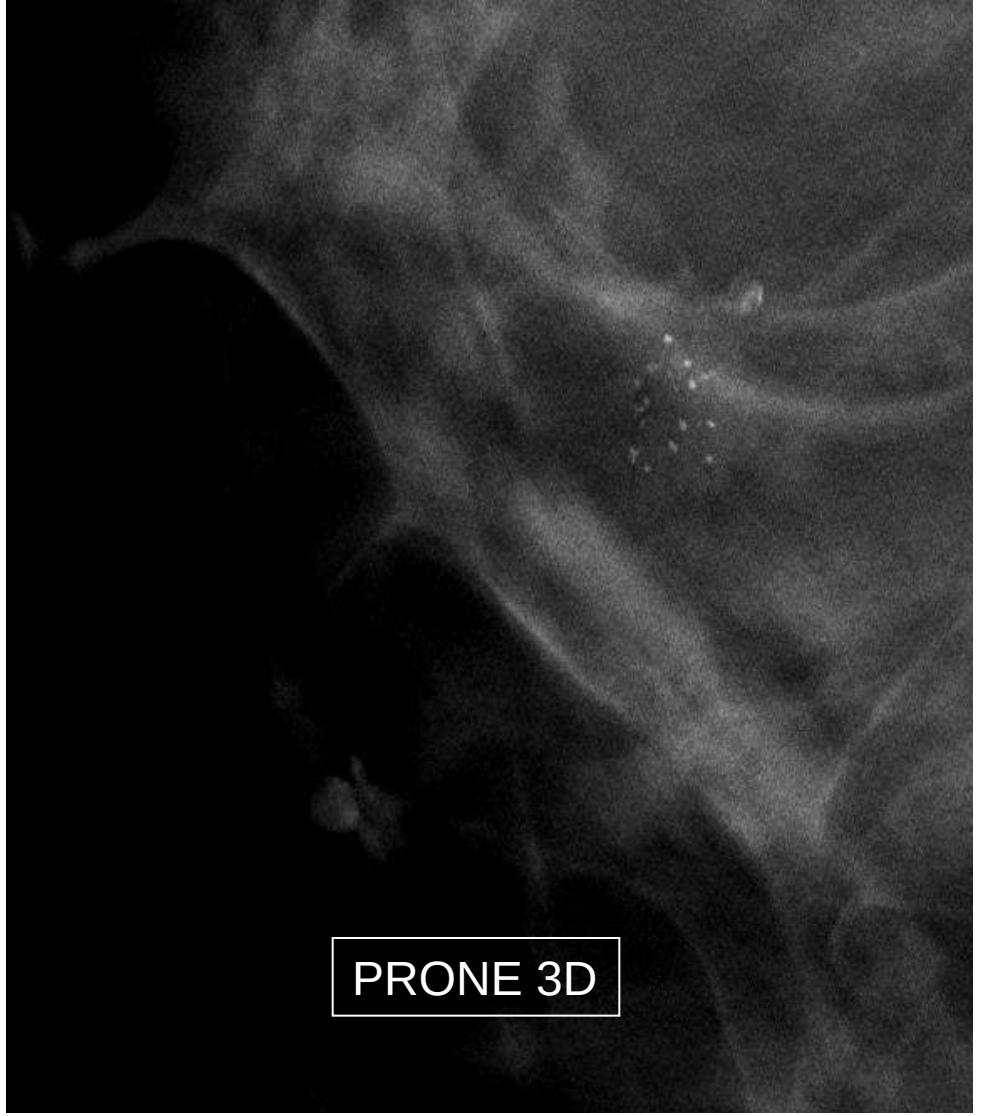

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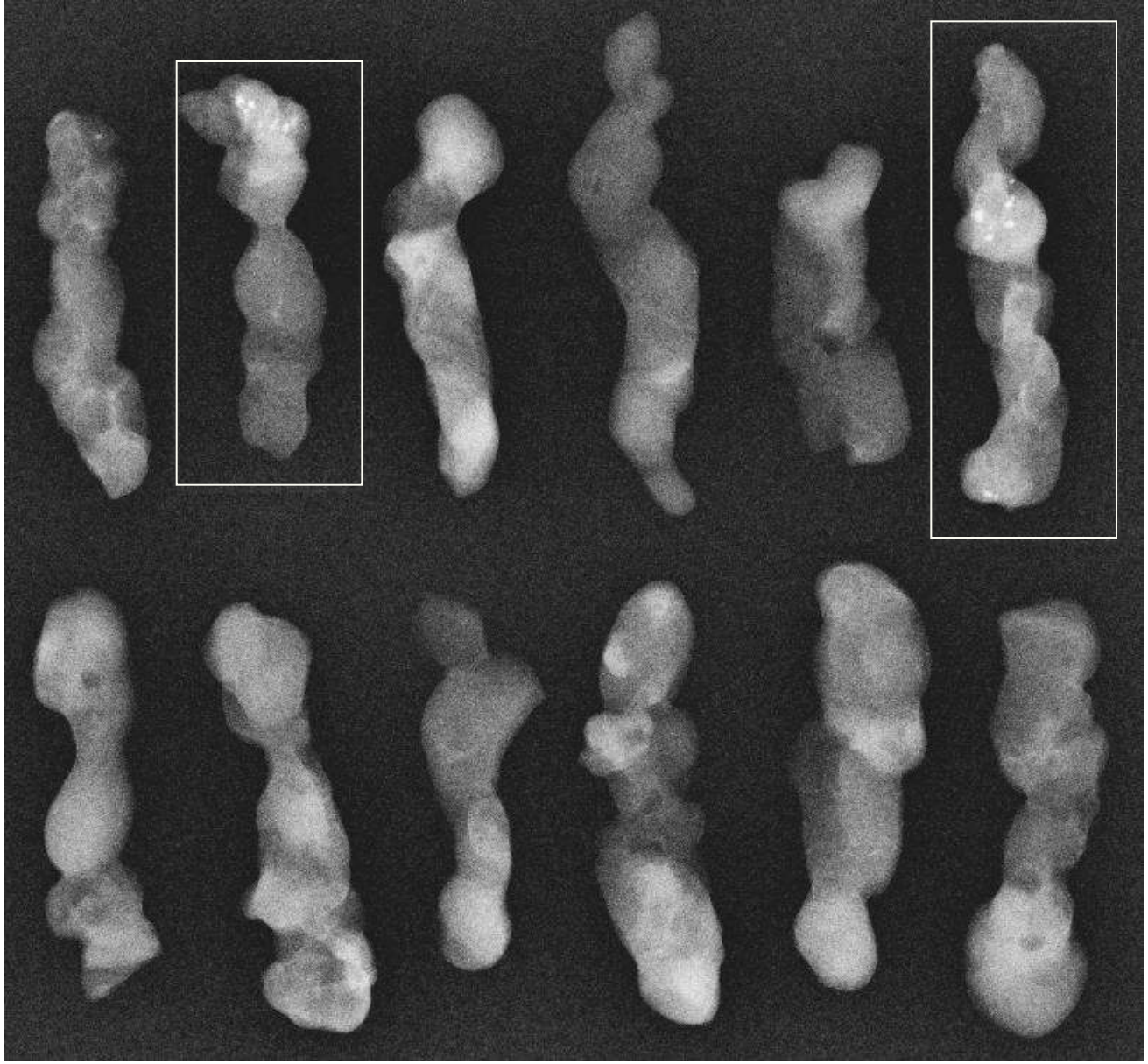

Atypical Ductal Hyperplasia

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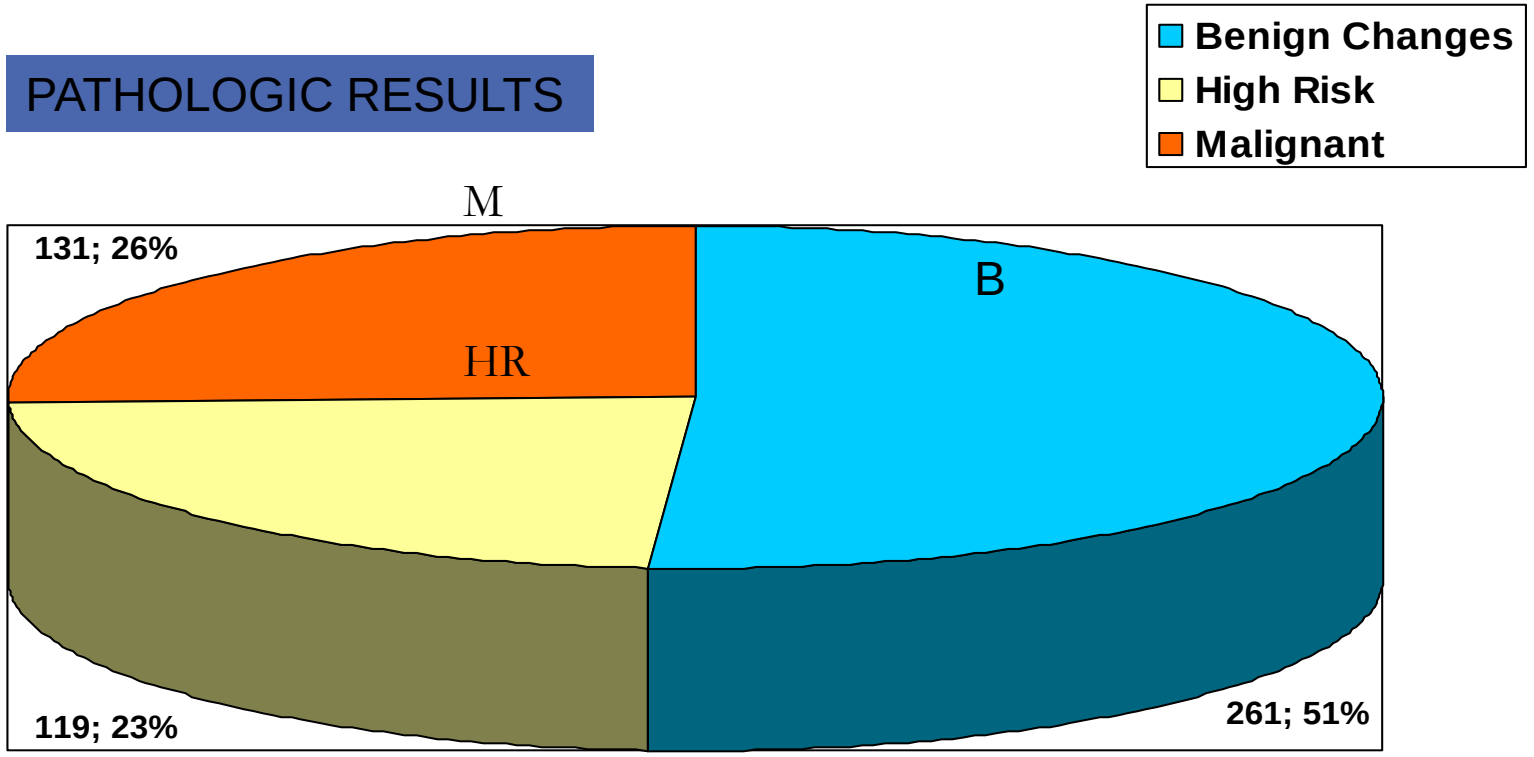
OUR EXPERIENCE

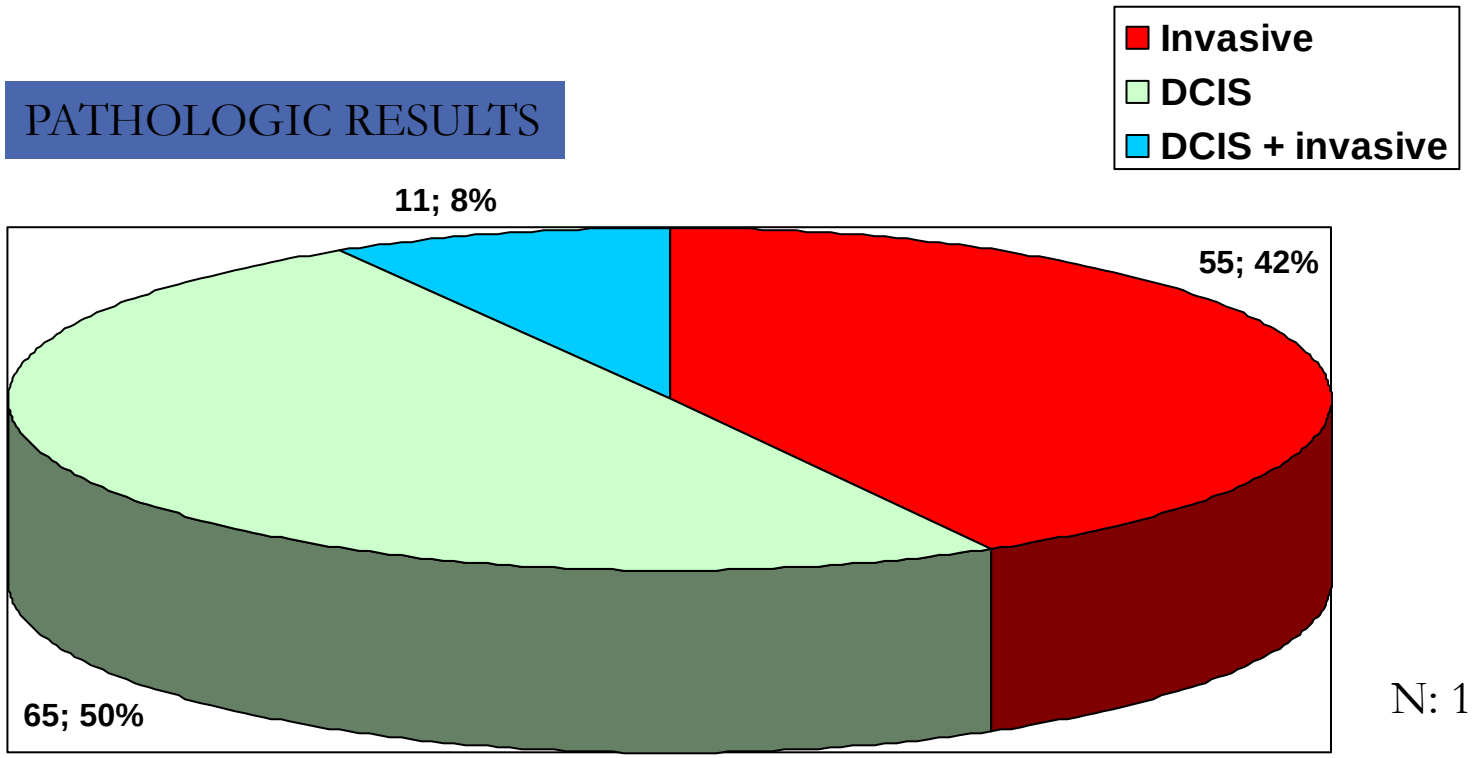
PATHOLOGIC RESULTS



N: 502

OUR EXPERIENCE

PATHOLOGIC RESULTS



N: 131

OUR EXPERIENCE

FINDING	Mean Size (mm)	% Malignancy	% High Risk	% Benign Changes
Calcifications High-Contrast	14,83	24,60 %	22,99 %	51,87 %
Mass Low-Contrast	11,44	39,53 %	13,93 %	46,51 %
Focal Asimmetry Low- contrast	10,14	17,24 %	13,79 %	68,97%
Distortion Low- Contrast	12,81	25,81 %	58,06 %	16,13%

OUR EXPERIENCE

		Affirm Prone (Tejerina Foundation) n = 100	Affirm vertical (Schrading) (1) n = 51	Conventional PS (Schrading) (1) n = 165
Total time	Mean	21.32 ± 6.57	12.9 3± .7	29.11± 0.1
	Median	20 (7-42)	13 (8-32)	28 (12-65)
Targeting time	Mean	1.65± 2.11	4.1± 1.8	15.0± 9.3
	Median	1 (1-14)	4 (2-12)	12 (2-34)
Sampling time	Mean	4.61 ± 3.40	8.3 ± 2.6	10.3 ± 4.5
	Median	4 (1-17)	8 (4-21)	9 (5-31)

(1)Schrading S, Distemaier M, Dirrichs T, et al. Digital Breast Tomosynthesis-guided Vaccum-assisted Breast Biopsy: Initial Experiences and Comparison with Prone Stereotactic Vaccum-assisted Biopsy. Radiology 2015 ;274 (3)

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OUR EXPERIENCE

		Affirm Prone (Tejerina Foundation) n = 100	Affirm vertical (Schrading) (1) n = 51	Conventional PS (Schrading) (1) n = 165
No. of images	Median	6 (3-14)	5 (4-8)	8 (5-13)

OUR EXPERIENCE

Overall Patient Experience	Affirm Prone (Tejerina Foundation) n = 100	% No.of patients
1	Excellent	84%
2	Very Good	12%
3	Good	3%
4	Fair	0%
5	Poor	0%

SUMMARY

- Introduction.
- 3D Biopsy. Justification.
- 3D Biopsy. Upright and Prone.
- 3D Prone Biopsy. Clinical Advantages.
- **Brevera® Breast Biopsy System with CorLumina® Imaging Technology.**
- Brevera®. Our results.
- Conclusions.

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Brevera® Breast Biopsy System with CorLumina® Imaging Technology

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Vaccum assisted breast biopsy system with real-time imaging (CorLumina®) for instant verification and automated post-biopsy specimen handling.

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Main Components

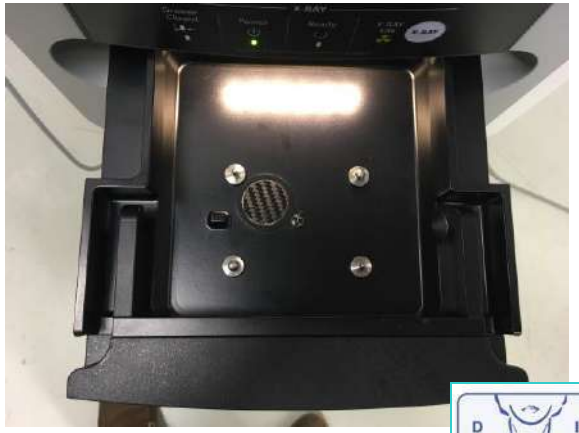
Technologist Display

Imaging Display

Driver-Biopsy Device

Vacuum line assembly and suction canister

Tissue filter drawer



Footswitch

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Steps for assembly

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Steps for assembly

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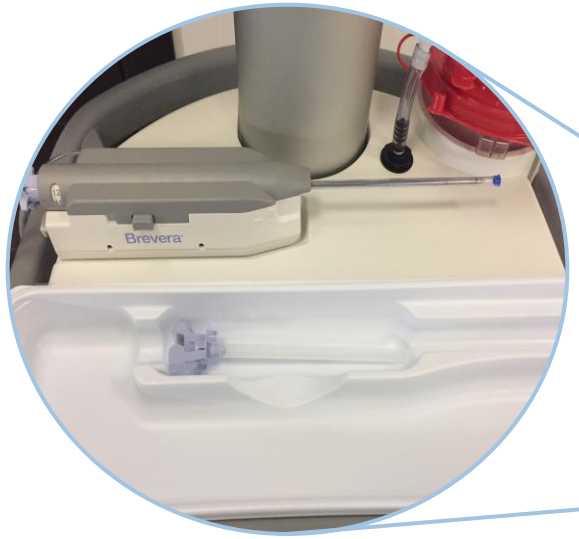

Steps for assembly

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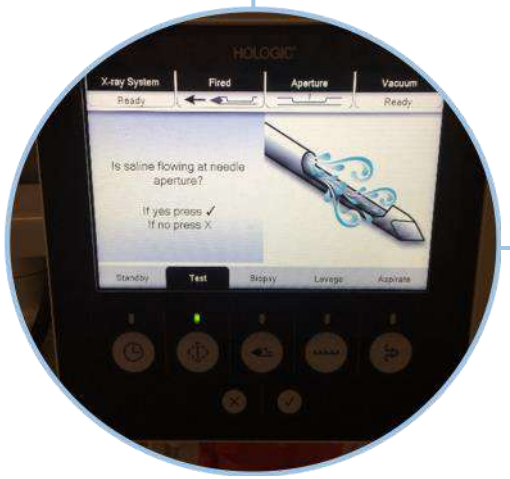
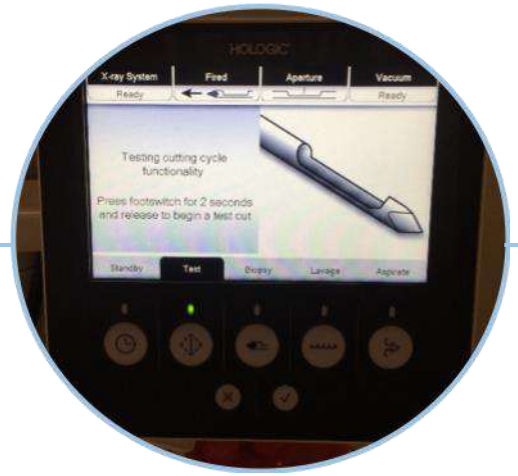
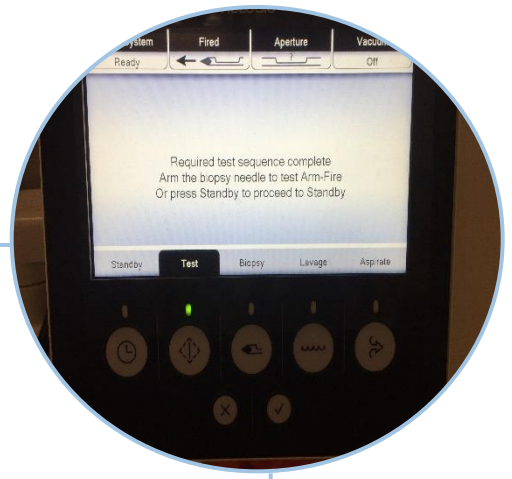
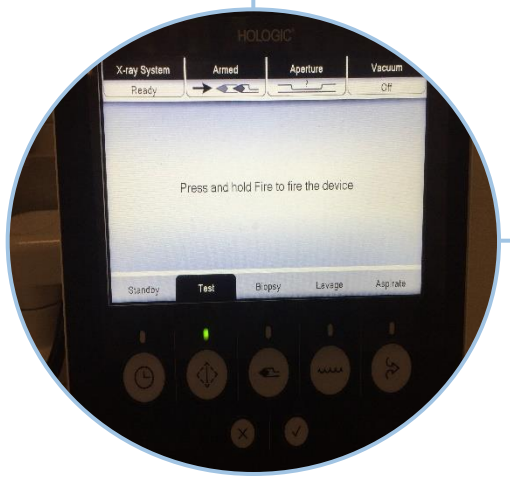
The Test Mode



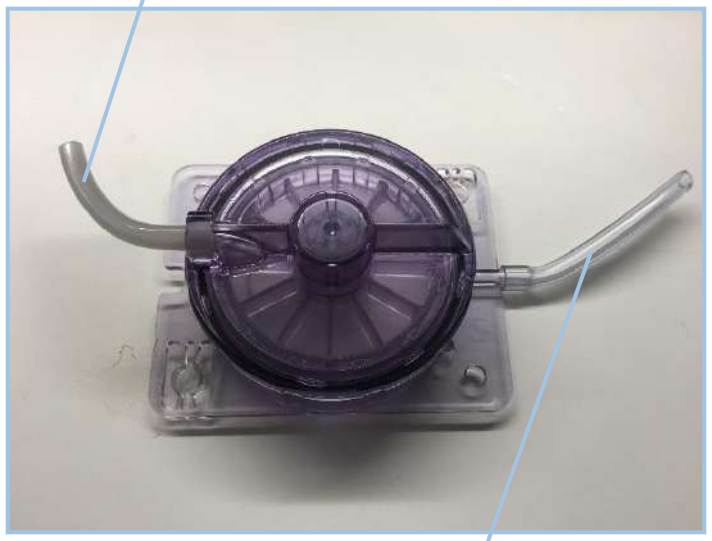




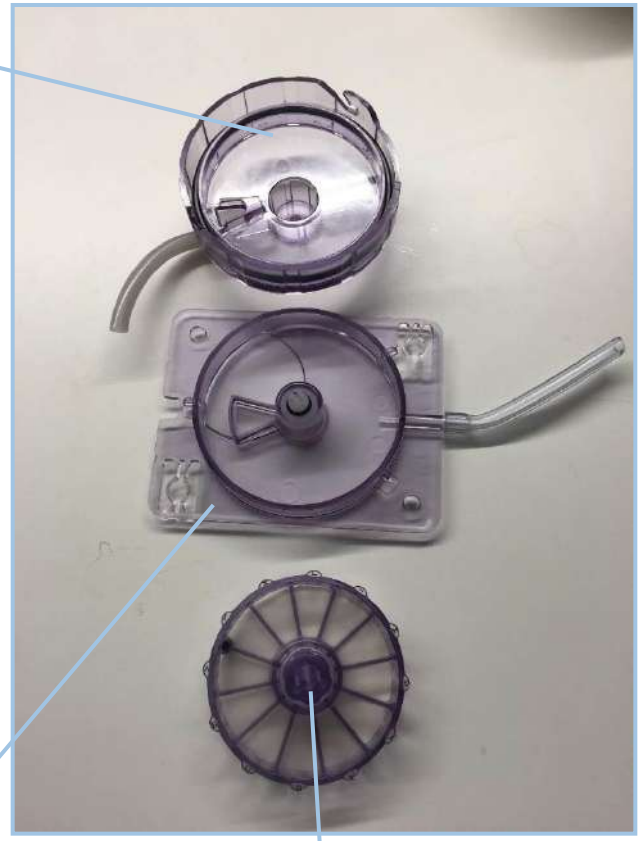


Tissue Filter Components

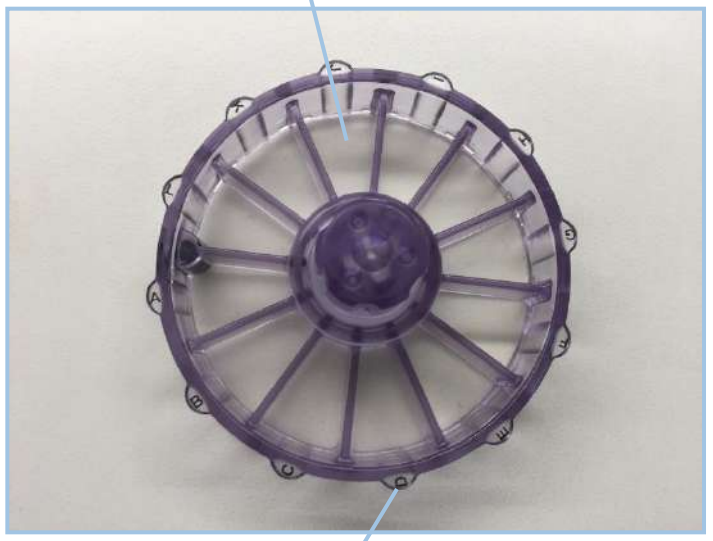
Tubing inlet from the biopsy needle



Tissue filter housing cover



Tissue filter chamber (12 chambers)



Tubing outlet to the tion canister (waste)

Tissue filter base

Tissue filter

Tissue filter chamber indicator (12 letter designation)

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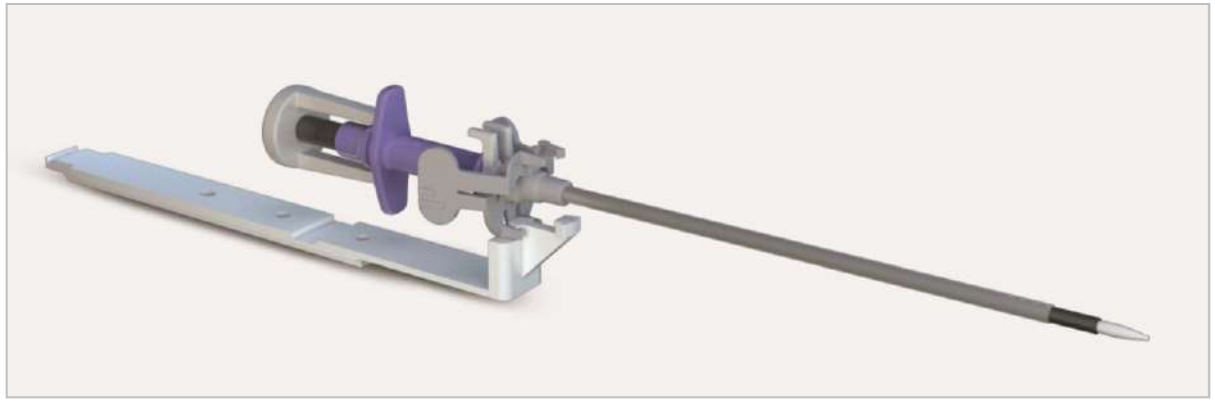

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How does it work?

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POTENTIAL CLINICAL ADVANTAGES

- Fast procedures
- Optimized technologist workflow
- Fewer steps
- Separates samples for pathology
- Improved sample identification
- Patient satisfaction

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BREVERA BREAST BIOSY SYSTEM

SAME PROCEDURE

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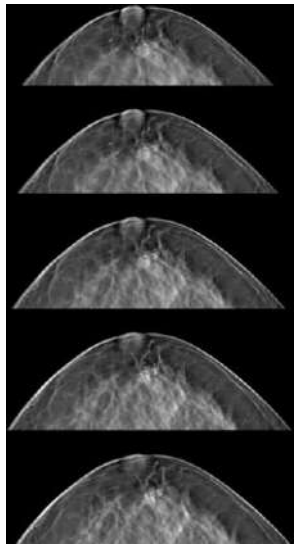
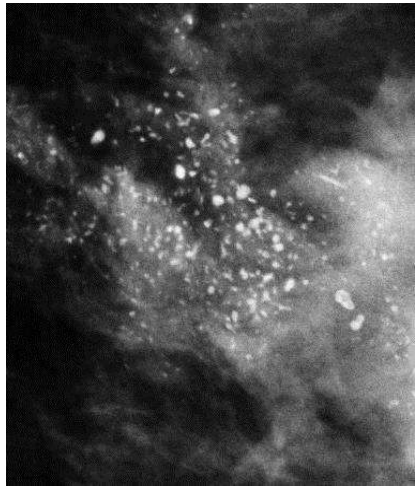
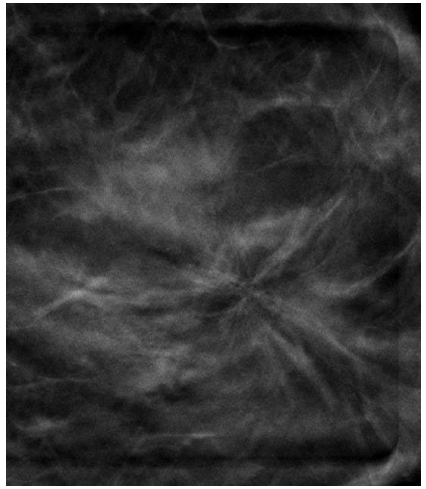
USUAL WORKFLOW







CALCIFIED

NON CALCIFIED

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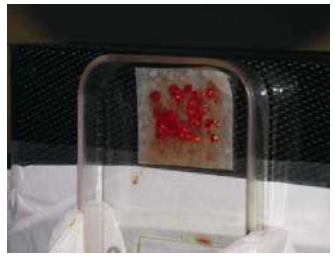
USUAL WORKFLOW



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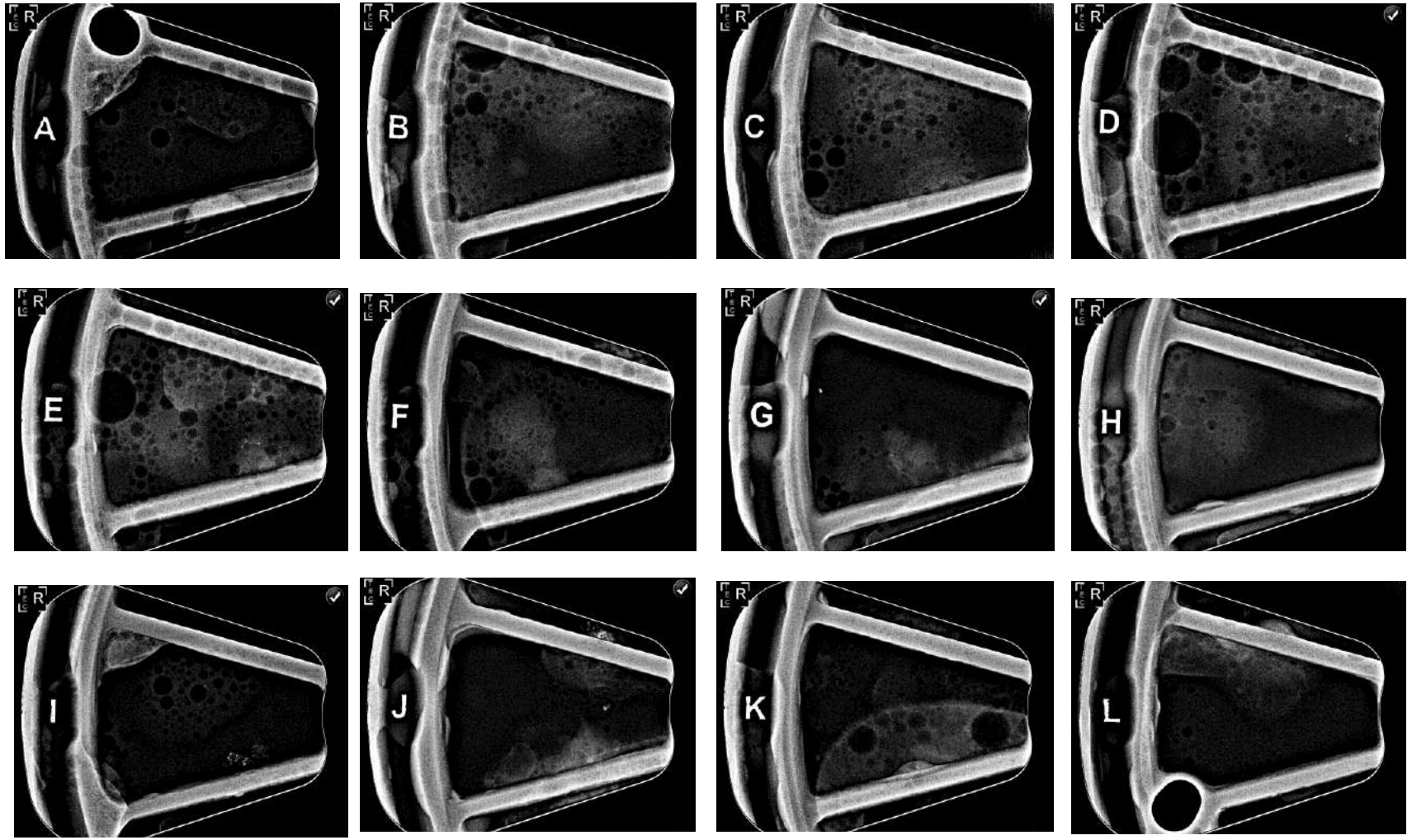
BREVERA WORKFLOW



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MULTICENTER STUDY

- CE MARKET
- July 2016. Animal Study. " GLP Acute Evaluation of the Brevera Vaccum-Assisted Breast Biopsy System in the Porcine Model".

- ***"A Retrospective/Prospective Study to Evaluate the Performance and operation of the Brevera Breast Biopsy System"***

- Retrospective/Prospective. Multicenter (Up to 10 sites). Controlled Data Collection Study.

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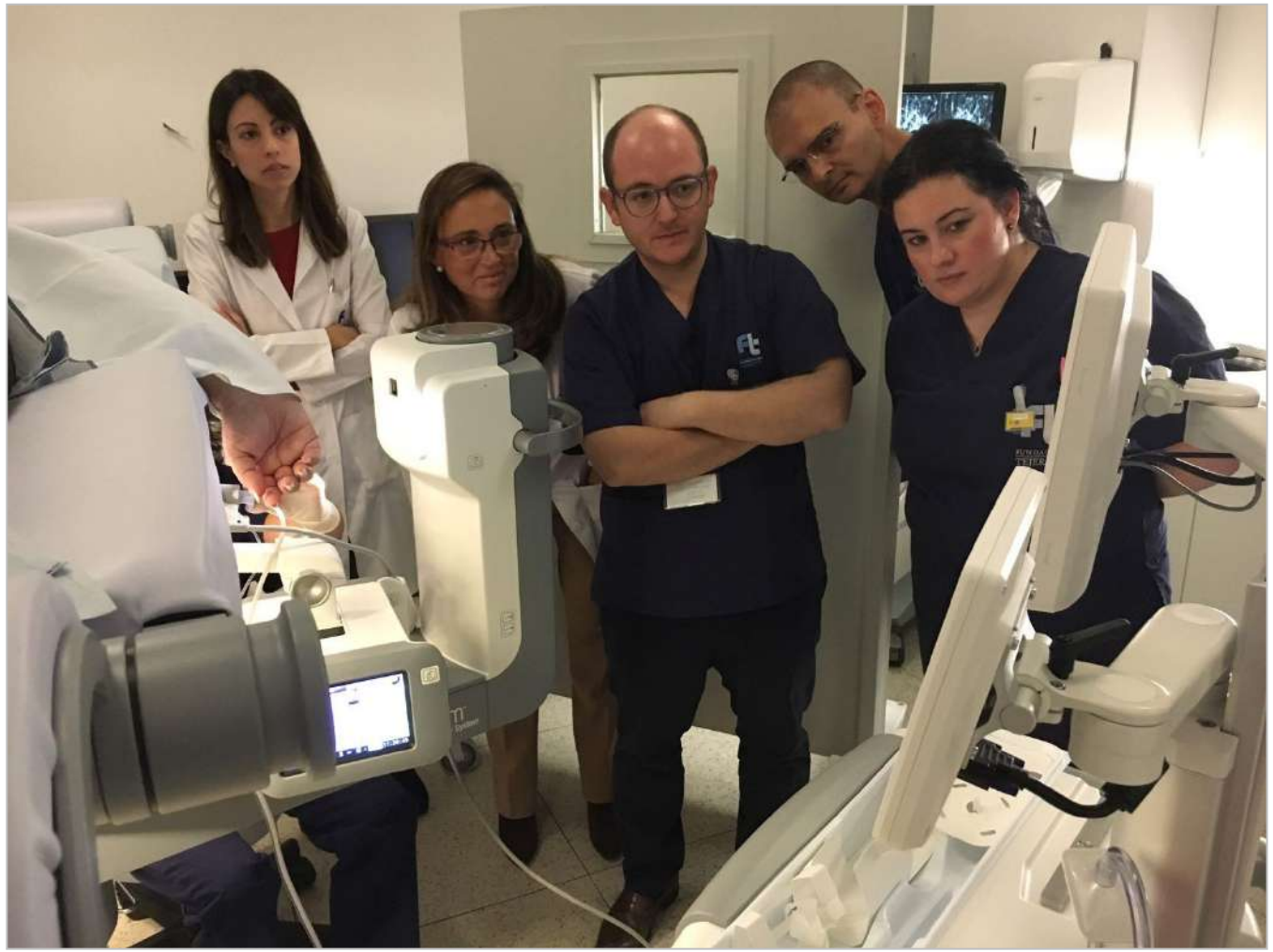
MULTICENTER STUDY



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CASE

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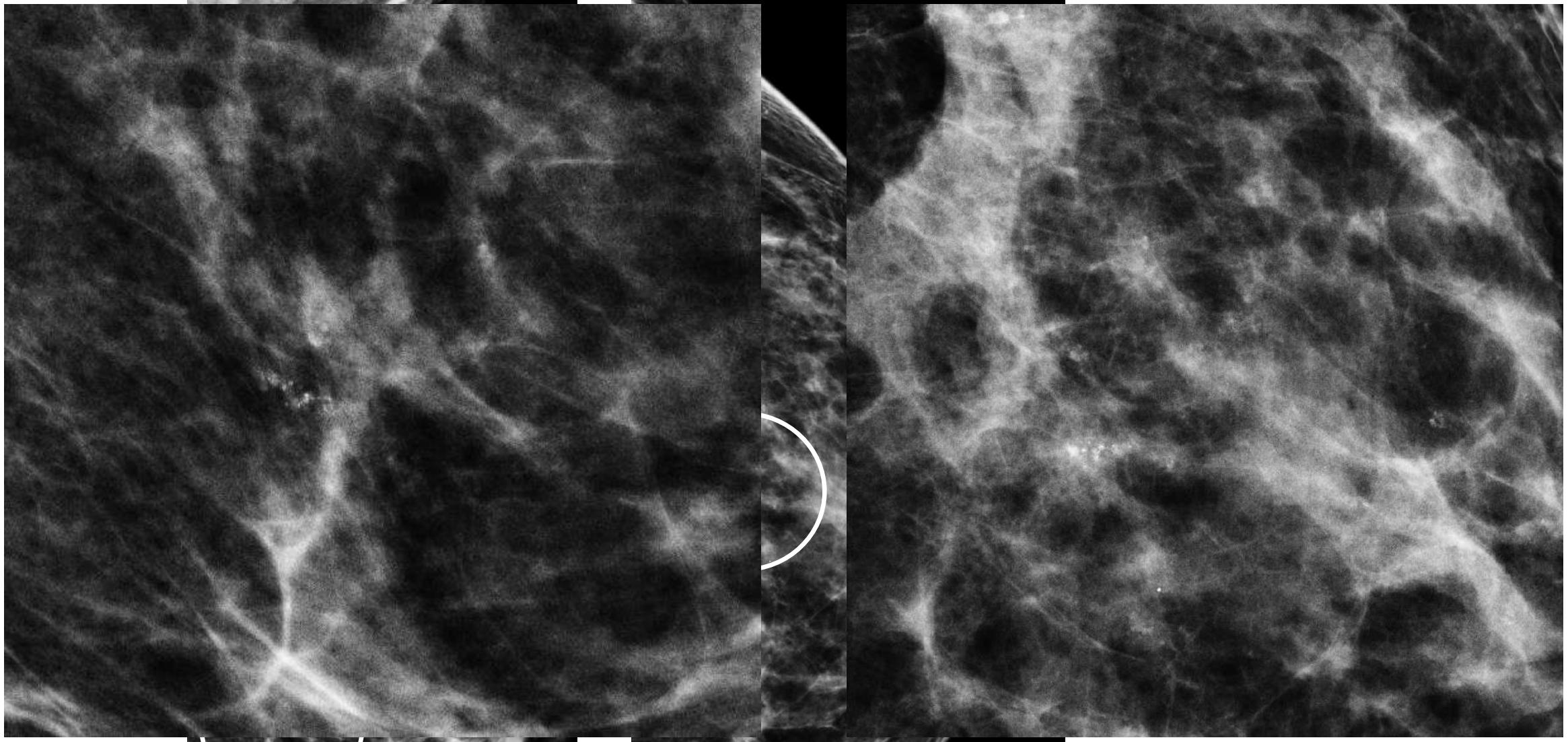

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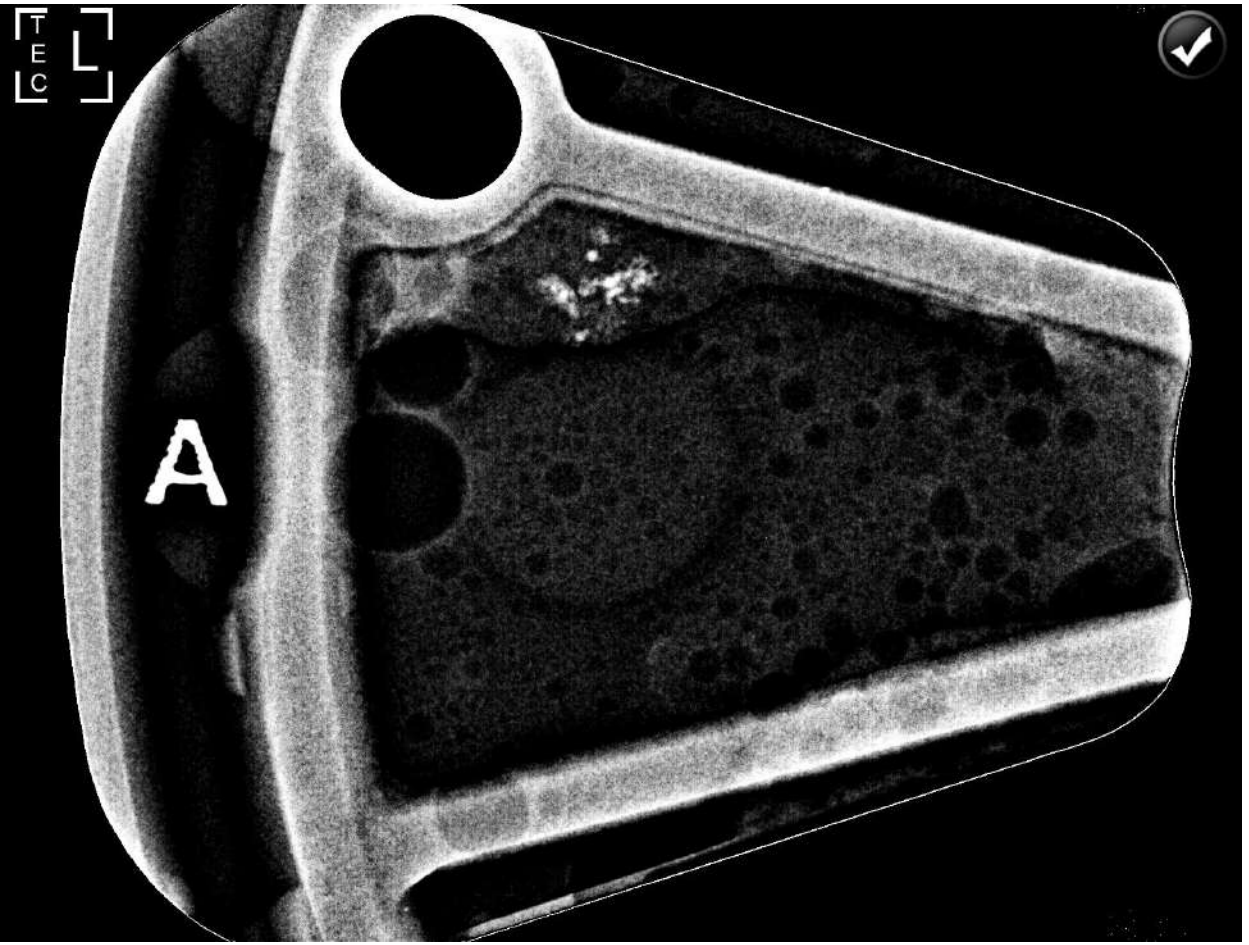

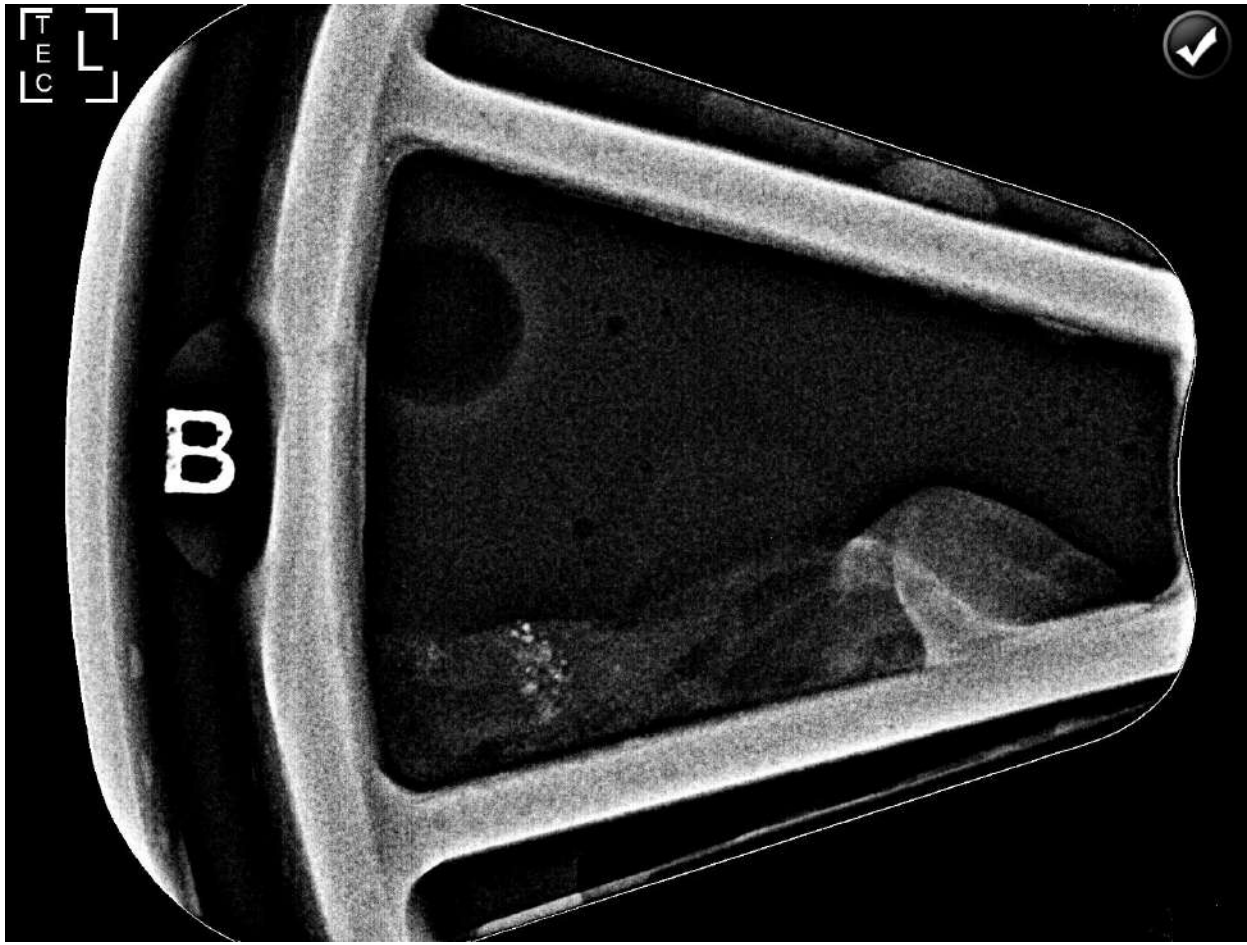

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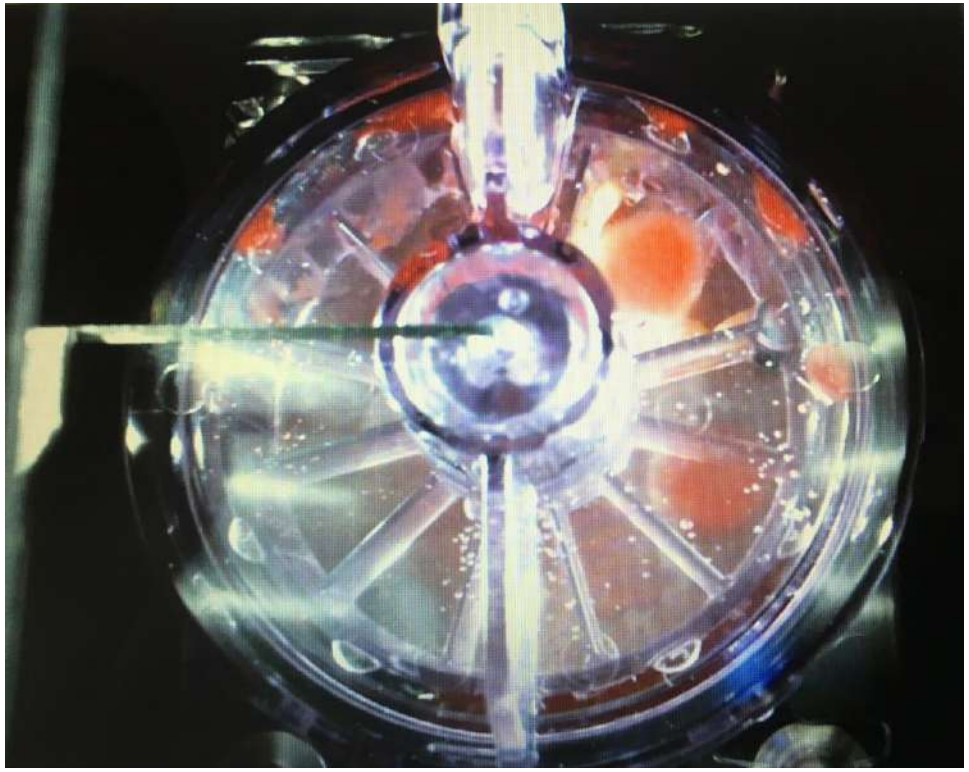

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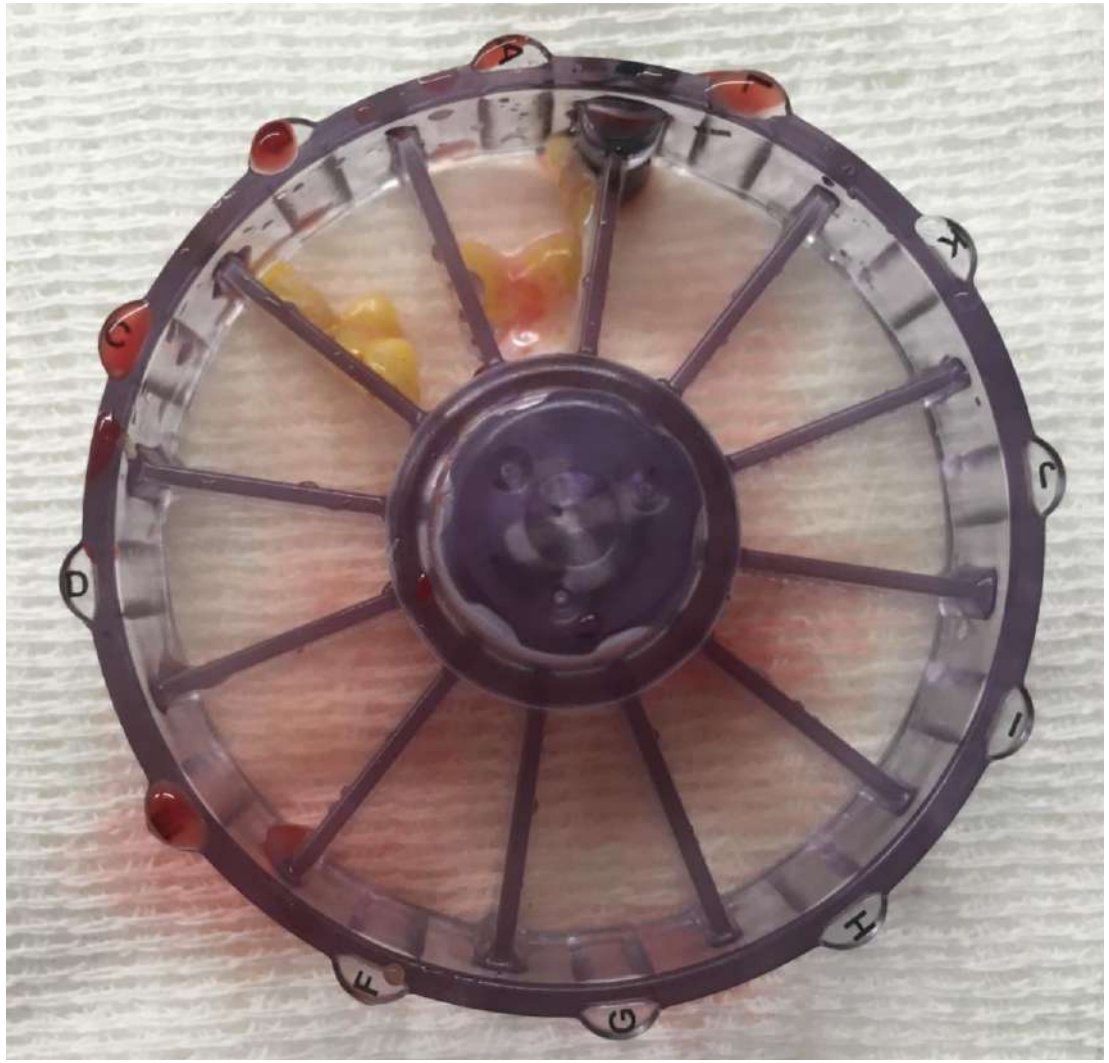

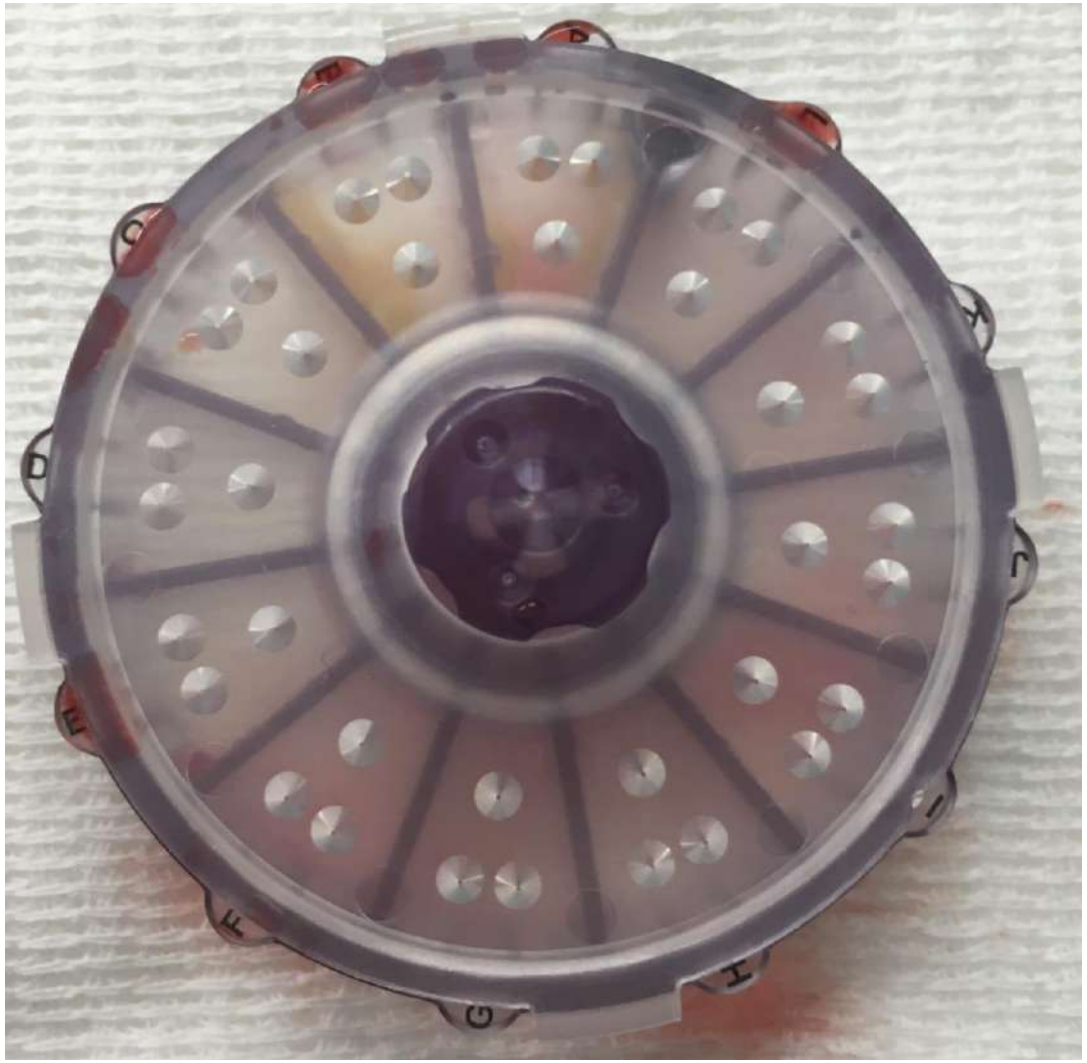

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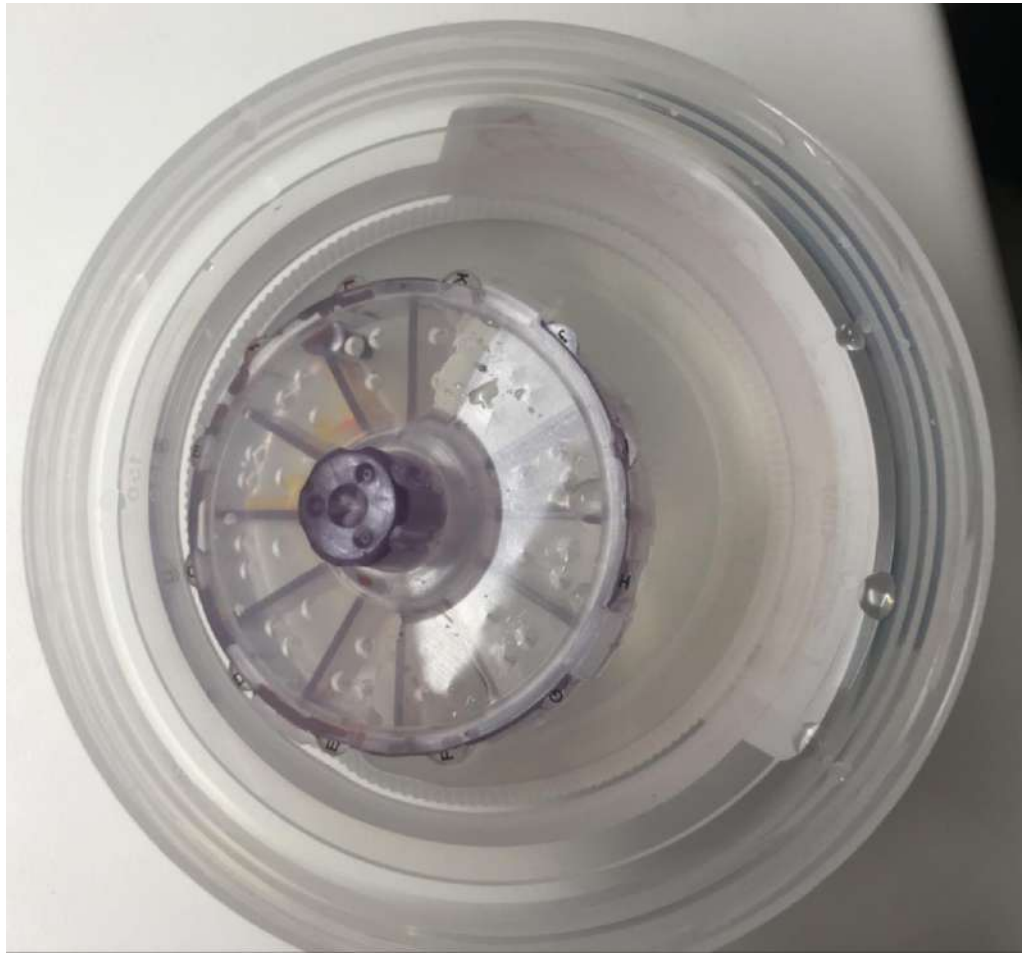

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CASE

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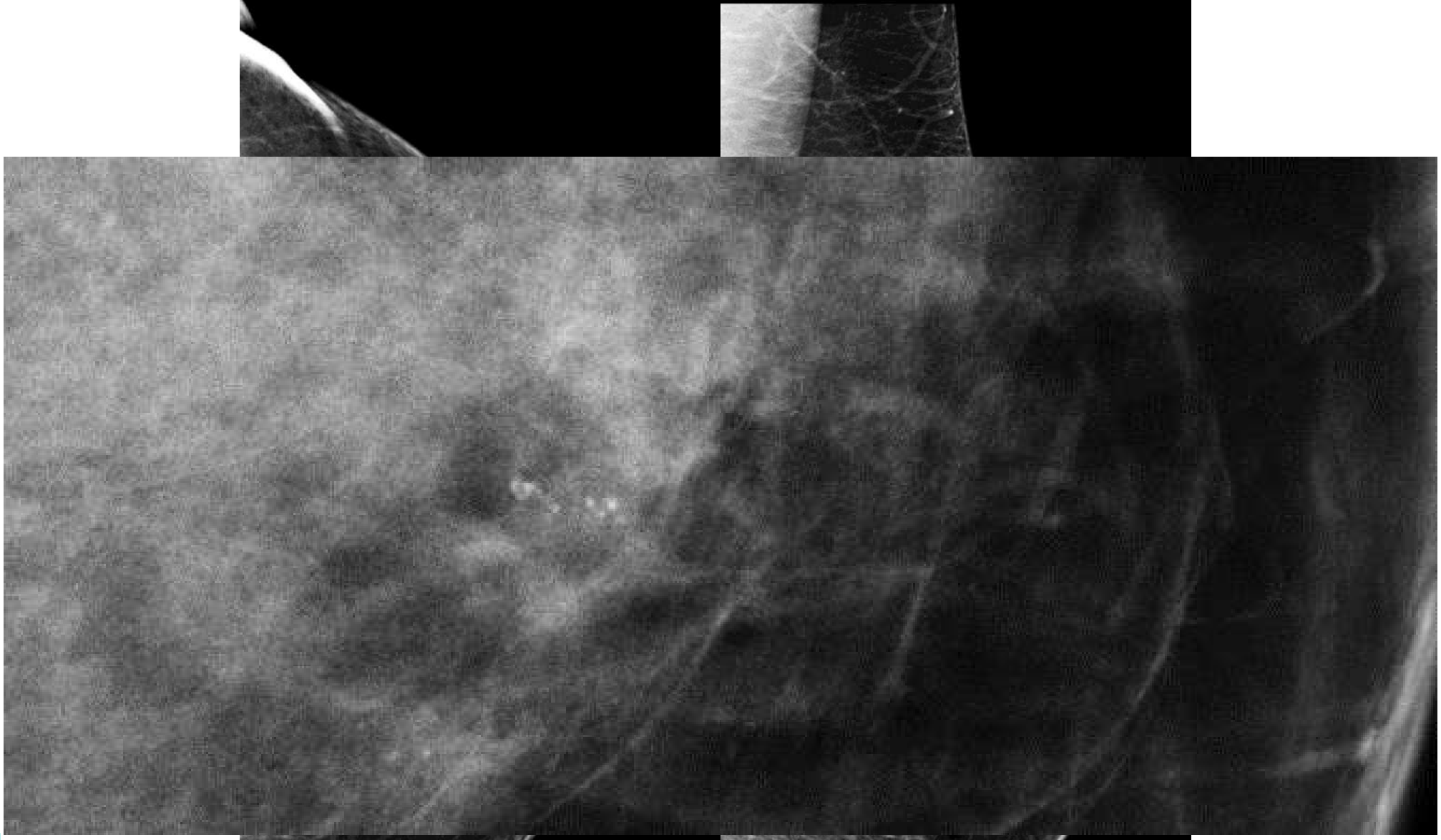

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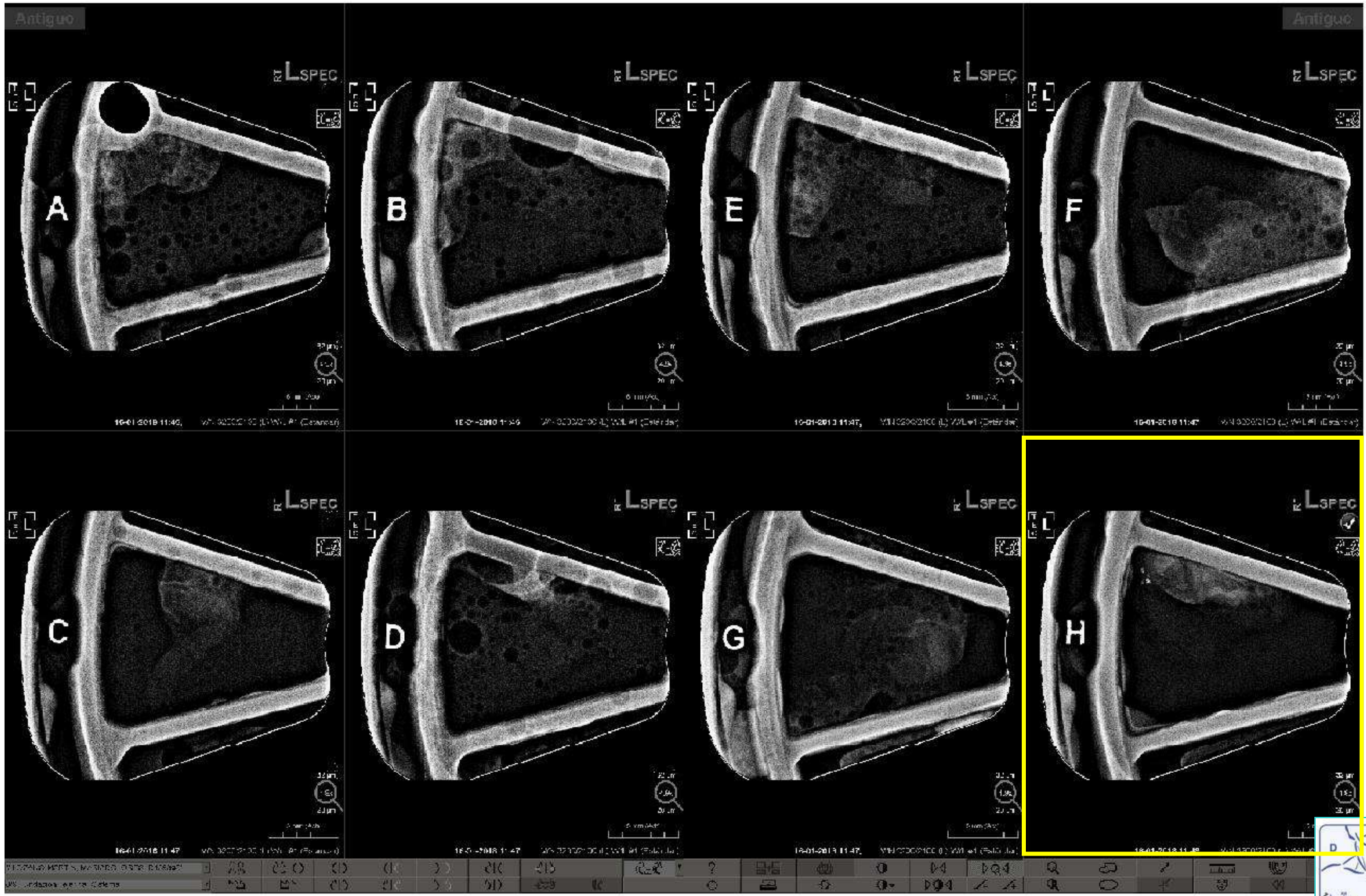

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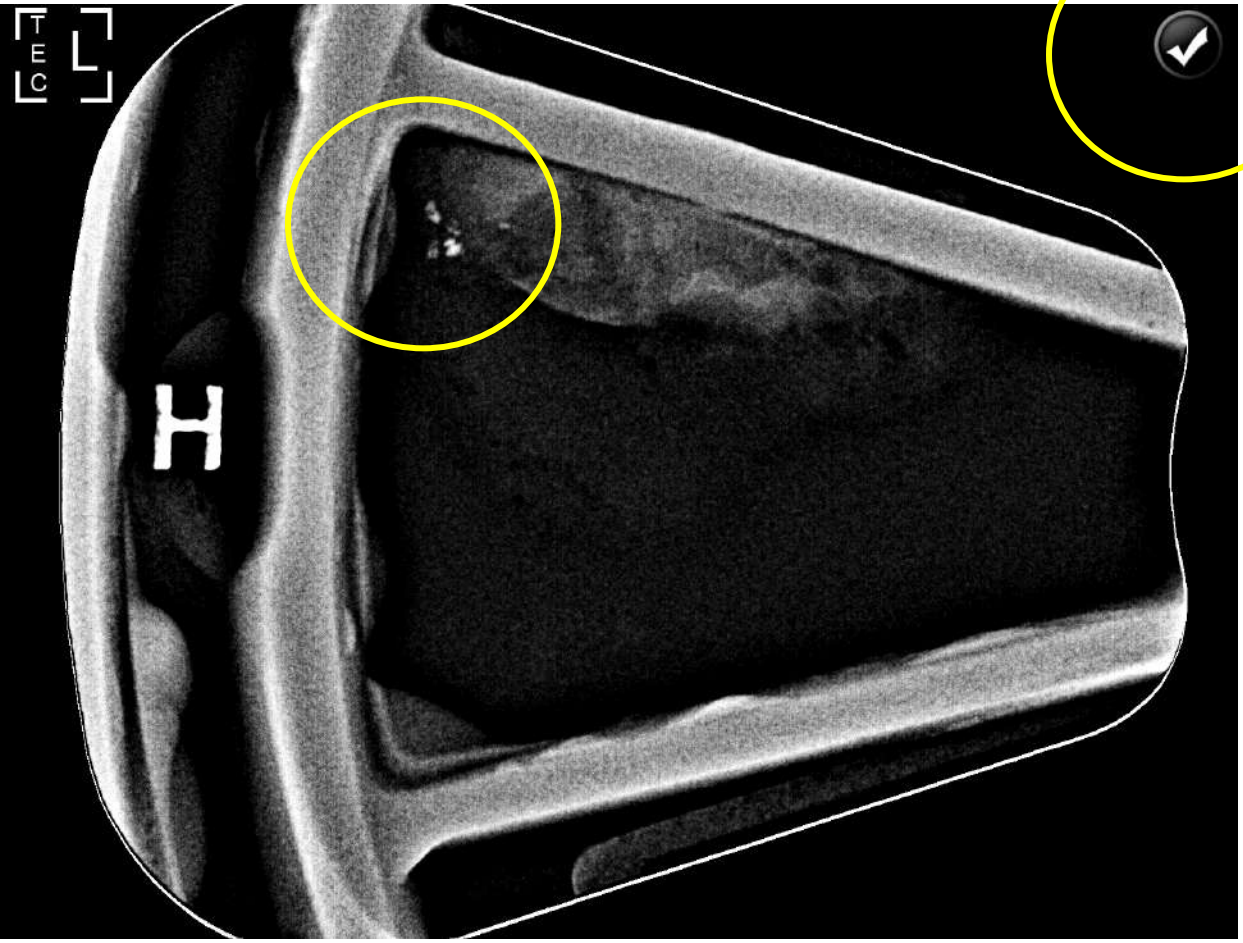

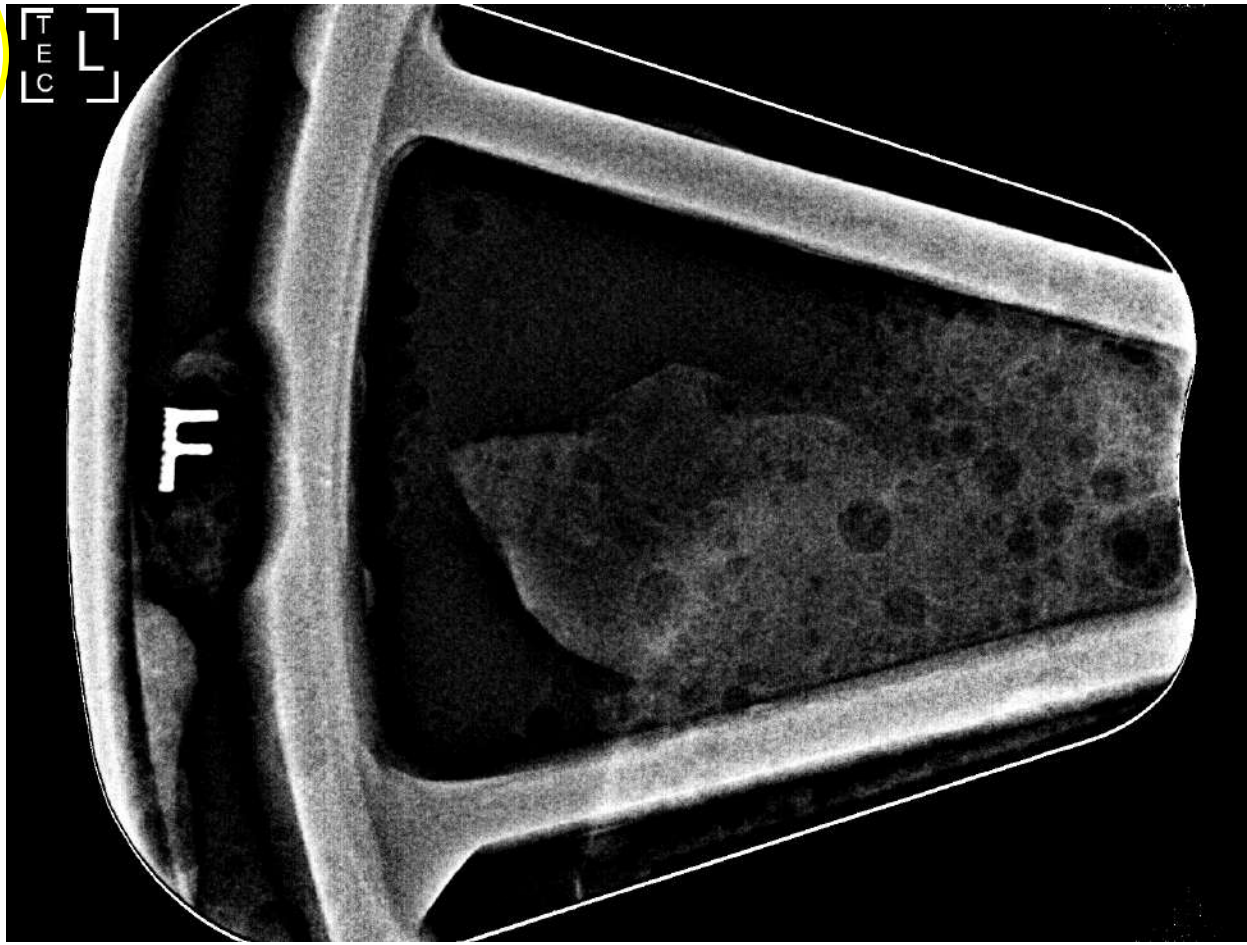

Sclerosin adenosis

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SUMMARY

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Brevera®. Our initial results

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MULTICENTER STUDY

- **First 60 cases.**
- 58 patients.
- 56 simple and 2 double biopsies.
- Mean age: 57 years.

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BREAST DENSITY	
ACR A	3,23%
ACR B	53,23%
ACR C	37,10%
ACR D	6,45%

IMAGE FINDING	
Microcalcifications	70,97 %
Distortion	29,03%
Mass	0%

MEAN SIZE	N 60
mm.	10.05

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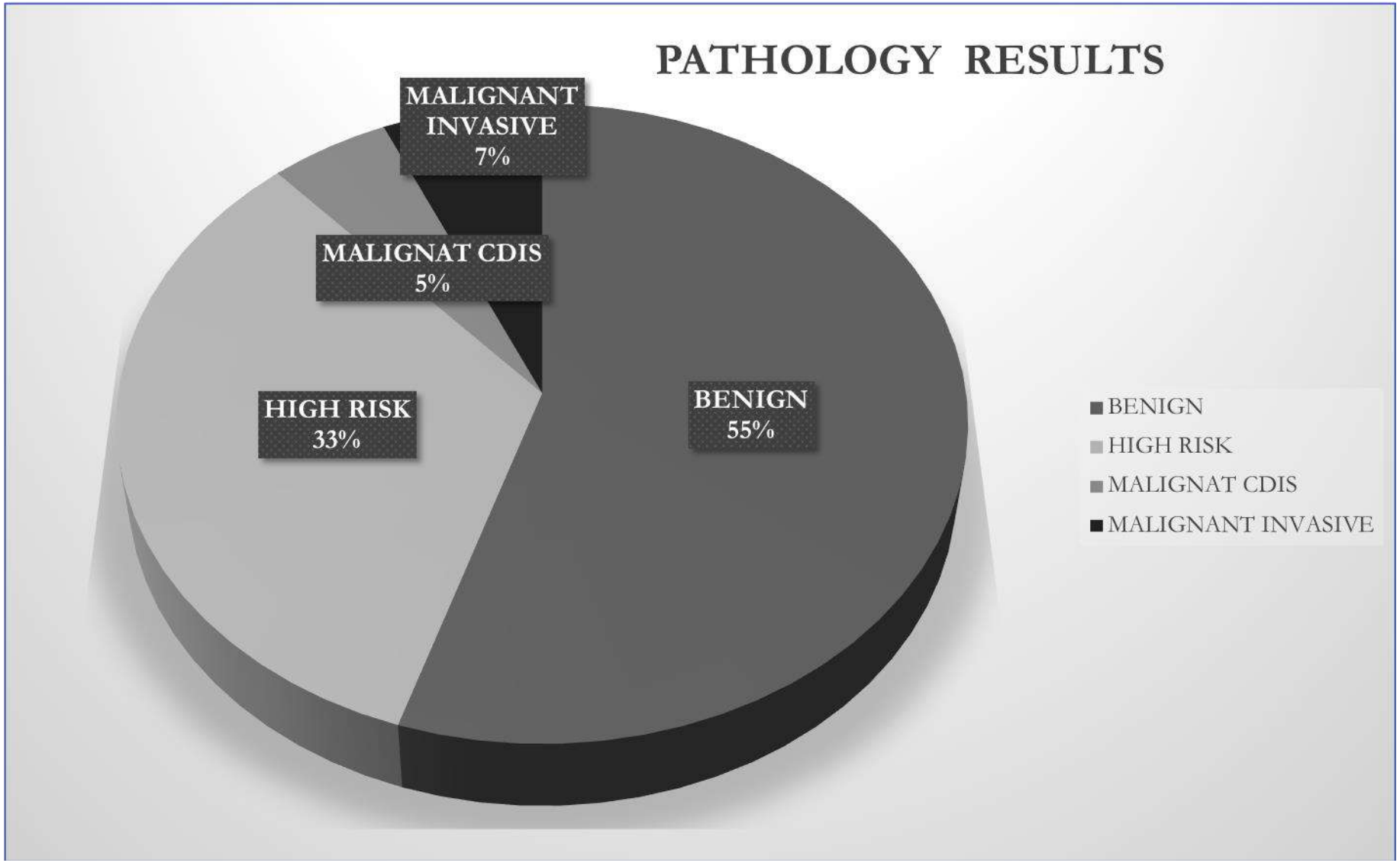

NO UNDERESTIMATION TO DATE

BIOPSY UNDERESTIMATION

- Number of cores
- Size (gauges)
- Correct targeting
- Calcifications in our sample
- Radiopathologic correlation
- Type of lesión
- Enviroment of the lesion

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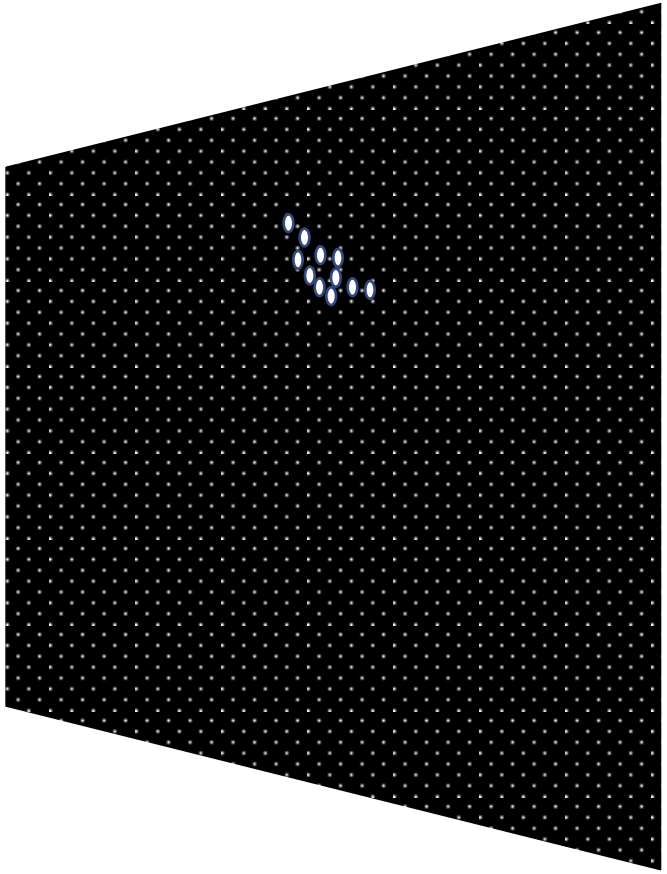
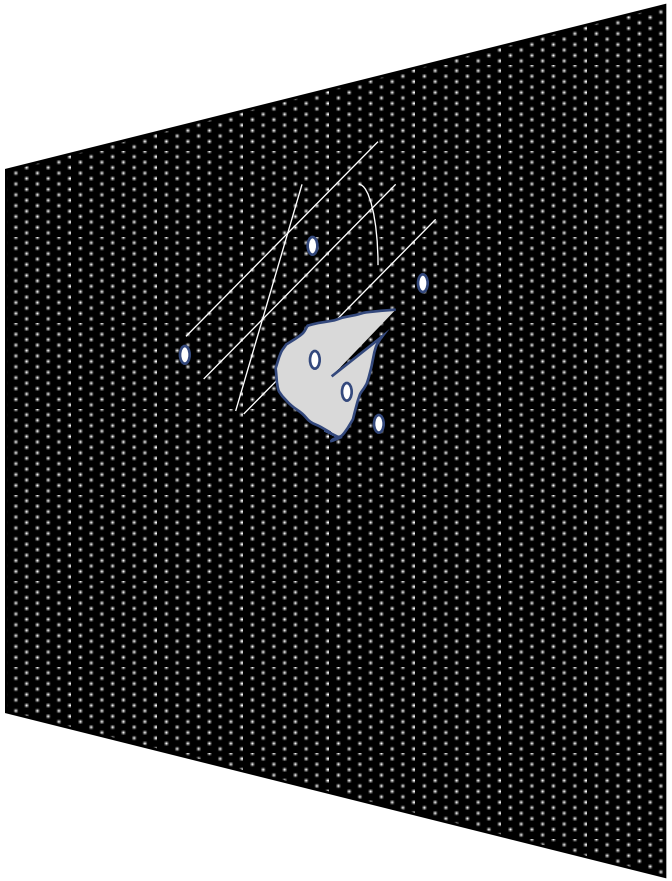
BIOPSY UNDERESTIMATION





BREVERA ADDING VALUE?

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NUMBER OF SAMPLES	N 60
Mean	9,23

	NUMBER OF SAMPLES WITH CALCIFICATIONS
Mean	4

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NEEDLE CAMERA	
Standard (20 mm)	90 % (54)
Petite (12 mm)	10% (6)

WEIGHT	
Average per lesion	2,30 g
Average per sample	0,24 g

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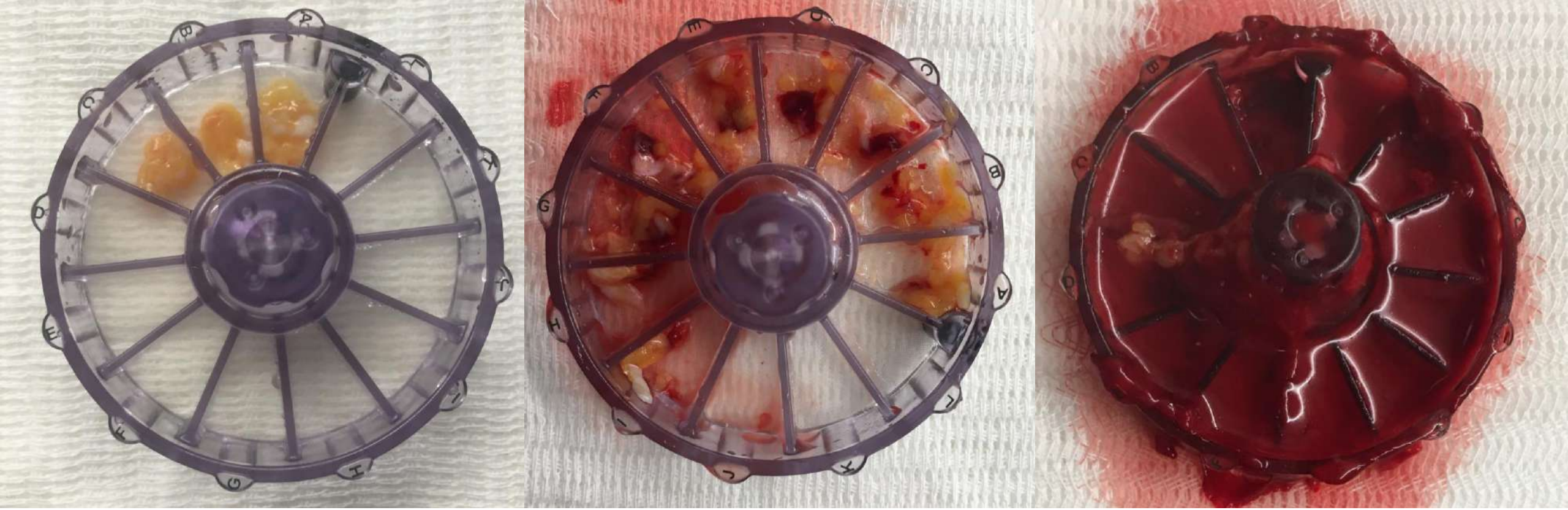

3 different cases and sample variability related to individual bleeding

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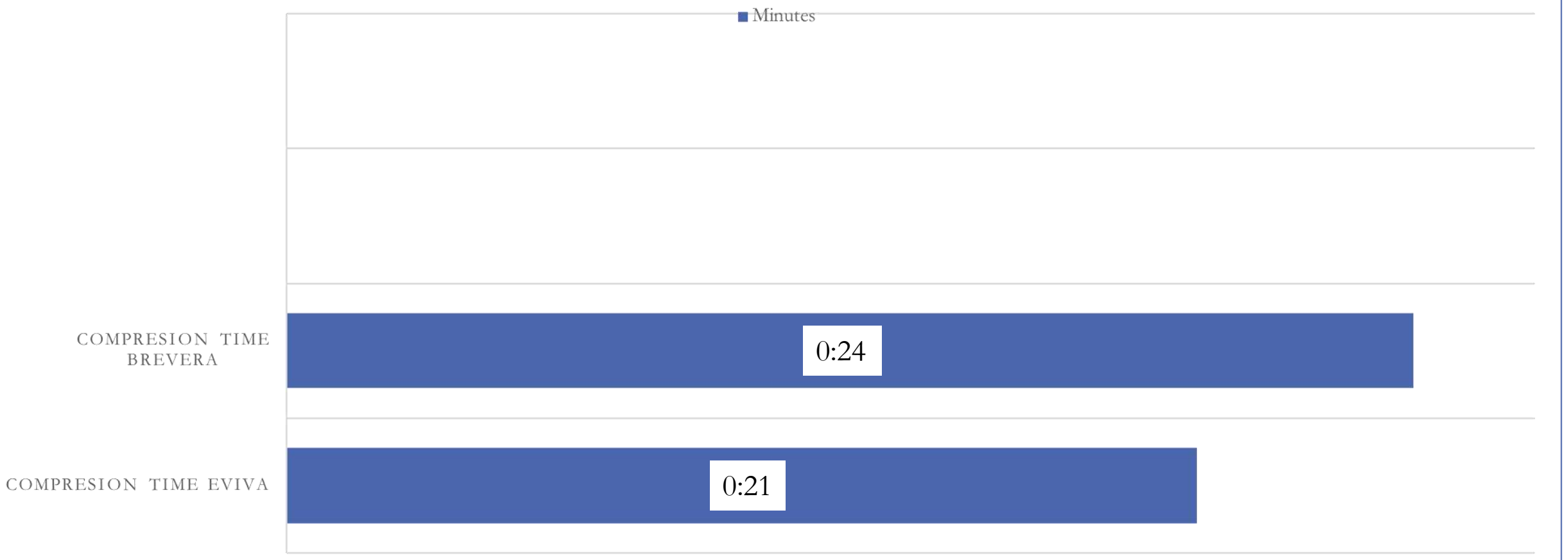
PROCEDURE TIME



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3 min.

1,42 min.

SETUP TIME

12 SAMPLES TIME

1 min.

52 seg.

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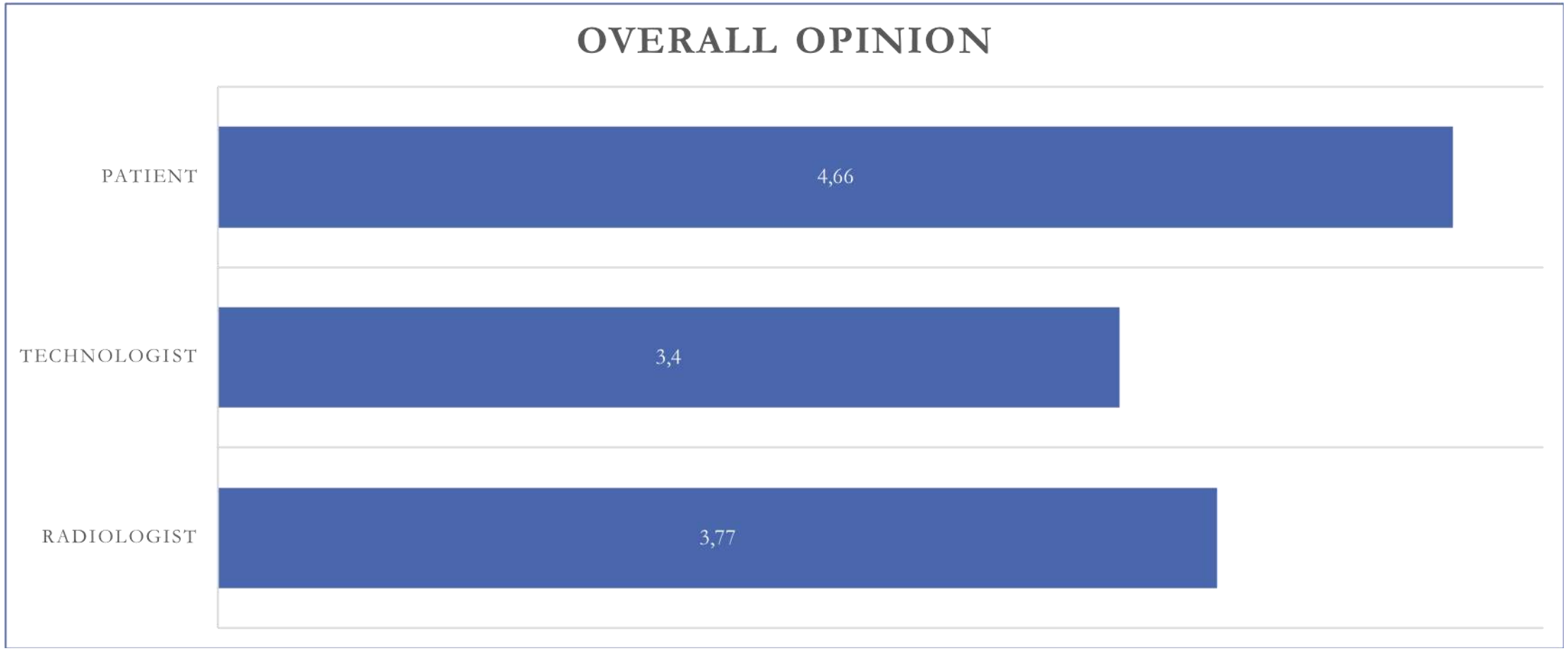

1. POOR
2. FAIR
3. GOOD
4. VERY GOOD
5. EXCELLENT

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SUMMARY

- Introduction.
- 3D Biopsy. Justification.
- 3D Biopsy. Upright and Prone.
- 3D Prone Biopsy. Clinical Advantages.
- Brevera® Breast Biopsy System with CorLumina® Imaging Technology.
- Brevera®. Our results.
- **Conclusions.**

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CONCLUSIONS

- 3D biopsy is a necessary solution in the day to day diagnostic work.
- Affirm prone dedicated table has shown significant improvements in image quality that facilitates complex biopsies.
- Brevera is a tool that offers confidence to physicians in breast biopsy procedures, specially in the cases of microcalcifications.
- More studies need to be done to demonstrate that biopsies with less amount of tissue can be done without risk of underestimation.
- The 3D biopsy combined with the implementation of a Brevera system make the biopsy procedure more accurate and safe.

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