



Advancing Science. Transforming Care.

**INTRA-OPERATIVE RADIATION THERAPY  
FOR EARLY STAGE BREAST CANCER  
IN  
DENVER, COLORADO, USA**

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**LEADING HOSPITALS.  
TRUSTED CARE.**

# VIEW FROM MY OFFICE – DENVER, COLORADO



# SEQUENCE OF EVENTS

<b>May 25, 2011</b>	<b>Cancer Committee Presentation</b>
<b>July 15, 2011</b>	<b>AXXENT system purchase</b>
<b>October 31, 2011</b>	<b>IRB approval</b>
<b>November 2, 2011</b>	<b>First IORT case</b>
<b>January 10, 2013</b>	<b>Completed accrual with 51 patients</b>

# XOFT AXSENT SYSTEM OVERVIEW

**Axxent System  
Controller**



**Balloon  
Applicators**



**X-RAY source**



# INCLUSION CRITERIA

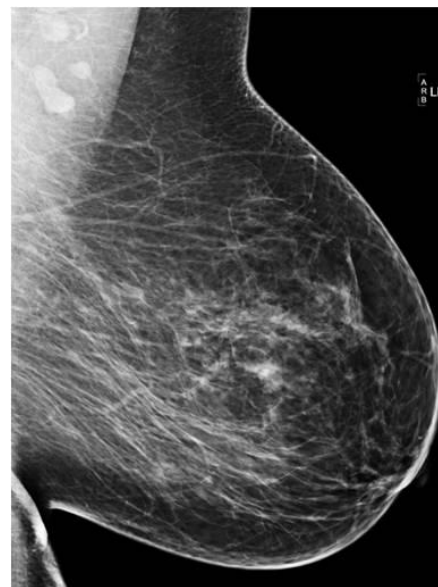
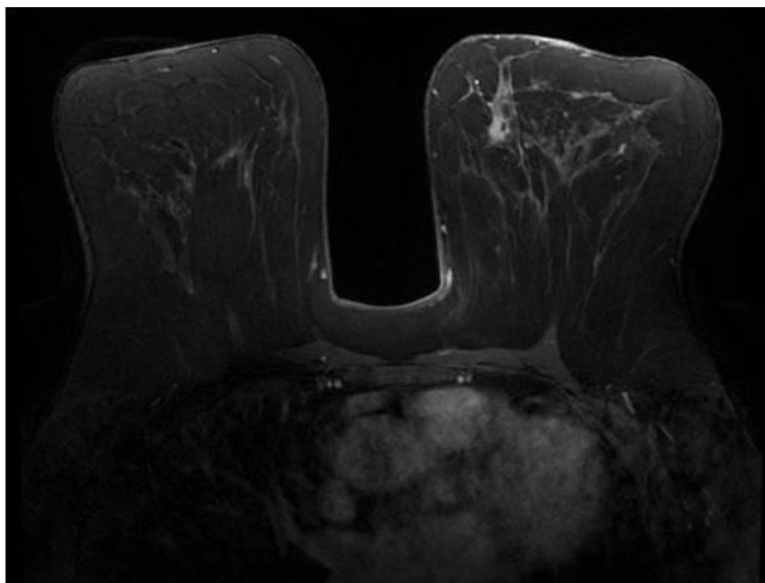
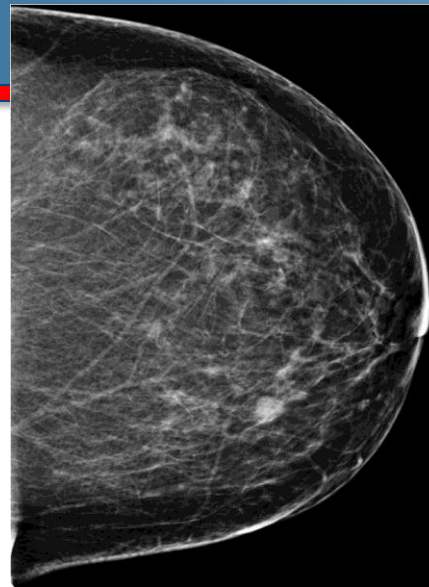
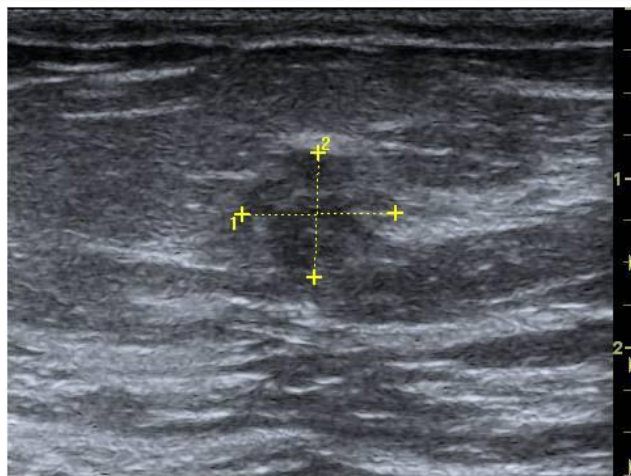
- 1. Women  $\geq$  40 years old**
- 2. Single lesion**
- 3. Infiltrating ductal carcinoma**
- 4. Cancer  $\leq$  2.5 cm on preoperative radiographic imaging**

# EXCLUSION CRITERIA

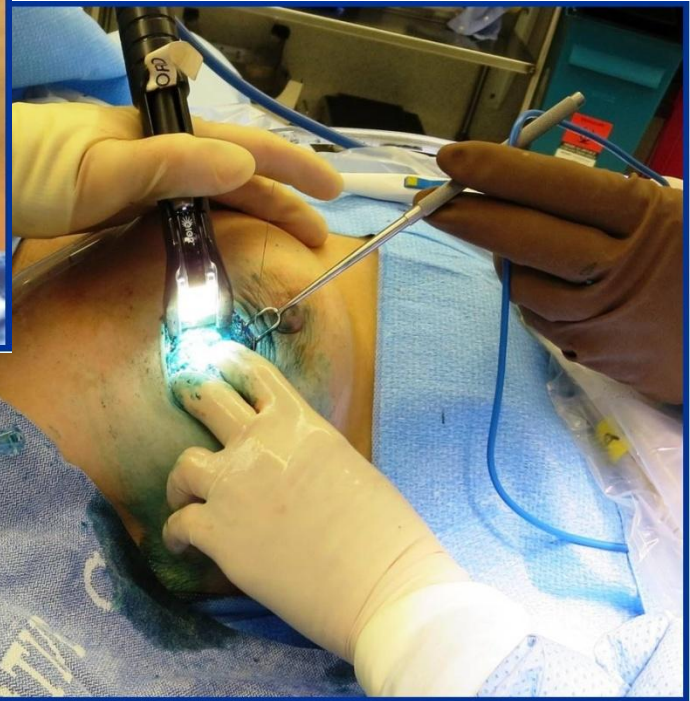
- 1. Multifocal cancer**
- 2. Lymphovascular invasion**
- 3. Extensive intraductal component**
- 4. History of breast cancer and/or radiation**
- 5. Neo-adjuvant therapy**
- 6. Pregnancy or lactation**
- 7. Scleroderma, active lupus, ipsilateral pacemaker**



# RADIOGRAPHIC WORKUP



# SLN BIOPSY FOLLOWED BY LUMPECTOMY





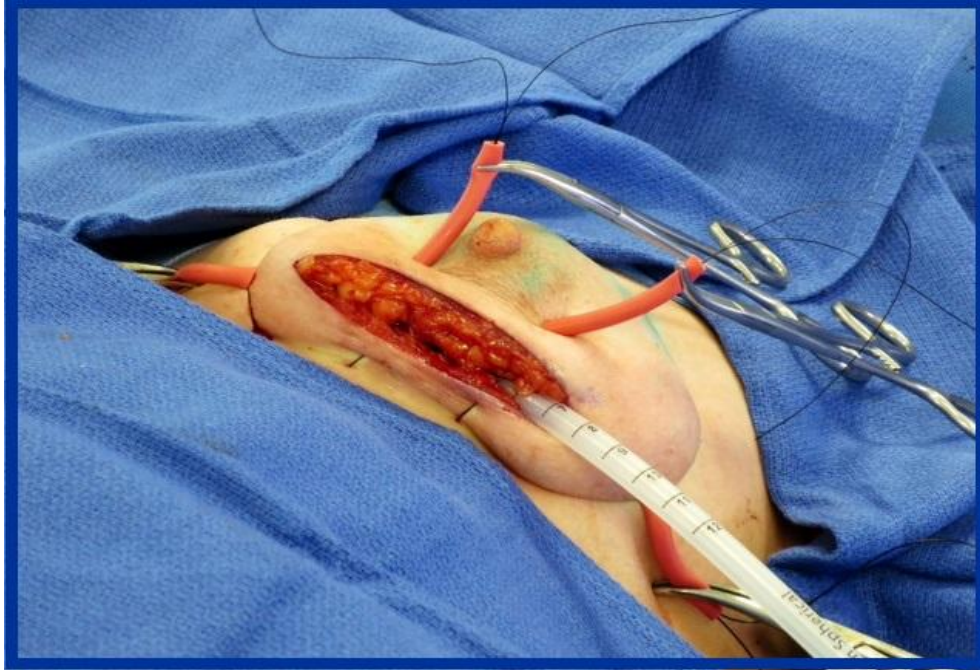
# SHIELD PLACEMENT



# BALLOON PLACEMENT



# BALLOON PLACEMENT

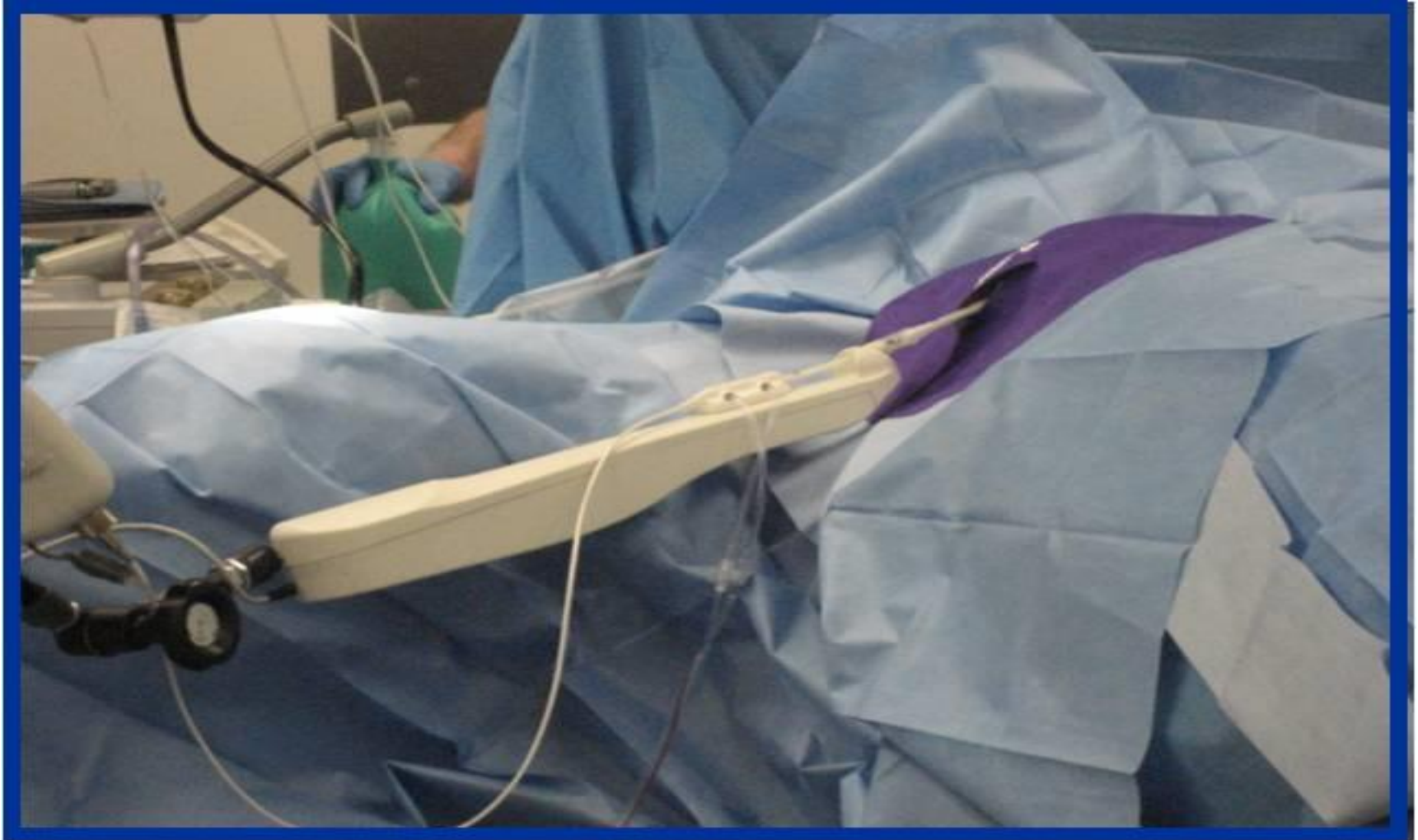




# BALLOON DOCKING



# DELIVERY OF ELECTRONIC BRACHYTHETRAPY





# PROCEDURE RESULTS

- **51 patients - to OR for IORT**
  - **1 patient - technical difficulties**
  - **5 patients - positive intra-operative SLNs**
  - **3 patients - IORT but positive SLNs on final pathology**
  - **2 patients - Positive margins**
- 
- **40 (78%) patients completed IORT per protocol**
  - **Average age - 63.8 years**
  - **Average tumor size - 1.04 cm**

# PROCEDURE CHARACTERISTICS

<b>Average total procedure time</b>	<b>1 hour 47 minutes</b>
<b>Average radiation delivery time</b>	<b>512.4 seconds (8.5 mins)</b>
<b>Average balloon size</b>	
<b>3 to 4 cm balloon</b>	<b>37 patients</b>
<b>4 to 5 cm balloon</b>	<b>3 patients</b>
<b>Average balloon fill</b>	<b>31.75 ml</b>
<b>Average radiation dose</b>	<b>20 Gy</b>
<b>Average skin-to-balloon distance</b>	<b>1.21 cm</b>

# FOLLOW UP

- **40 patients have completed IORT protocol**
- **Average follow up - 29 months**
- **One patient has been diagnosed with a brain metastases at two years**
- **2 patients have died of unrelated causes**
- **No evidence of any local recurrences**

# IORT - ONE YEAR FOLLOW UP

## NORMAL BREAST

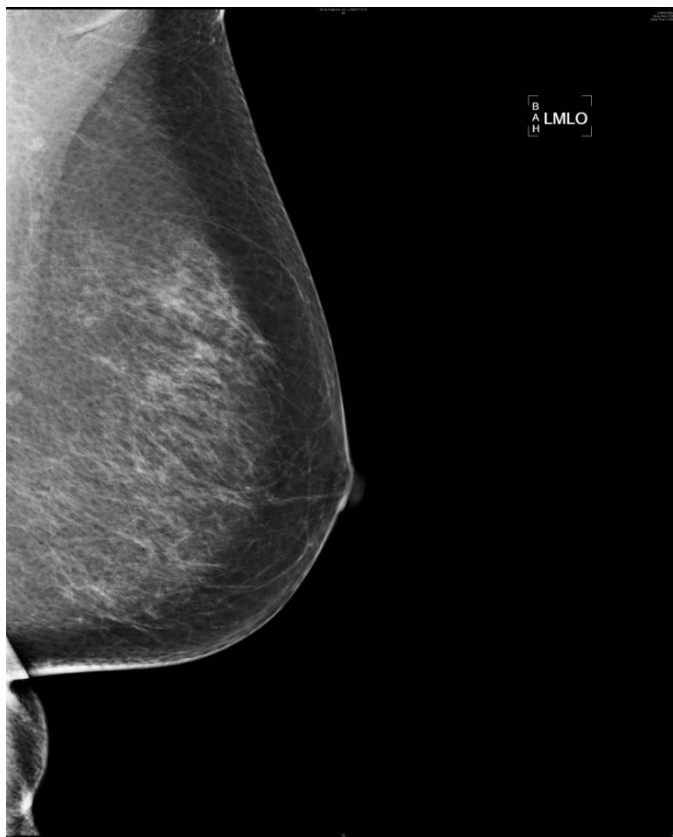


## 1 YEAR POST IORT



# IORT – ONE YEAR MAMMOGRAPHIC FOLLOW UP

## SCREENING MAMMOGRAM



## ONE YEAR POST-OP





# CONCLUSION

**Early results of intra-operative radiation therapy using the Axxent Electronic Brachytherapy System in the United States support the use of IORT for treatment of early stage breast cancer.**

**A Safety and Efficacy Study  
of Intra-Operative Radiation  
Therapy (IORT) Using the Xoft®  
Axxent® eBx™ System at the  
Time of Breast Conservation  
Surgery for Early Stage Breast  
Cancer**

“**ExBRT**”

