# Iodine-125 Radioactive Seed Localization (RSL) of Non-palpable Breast Lesions

Radiation Safety Training for Surgeons

Authored by Florida Hospital Radiation Safety Office
Revision Date 1/11/17

# Training Audience and Purpose

- This training will be provided to all individuals involved in I-125 Radioactive Seed Localizations (RSL) for non-palpable breast lesions at on-boarding to the process and annually thereafter

- This training is required by the Florida Hospital Broad Scope Radioactive Materials License #2897-1 and Florida Administrative Code 64E-5

# Training Outline

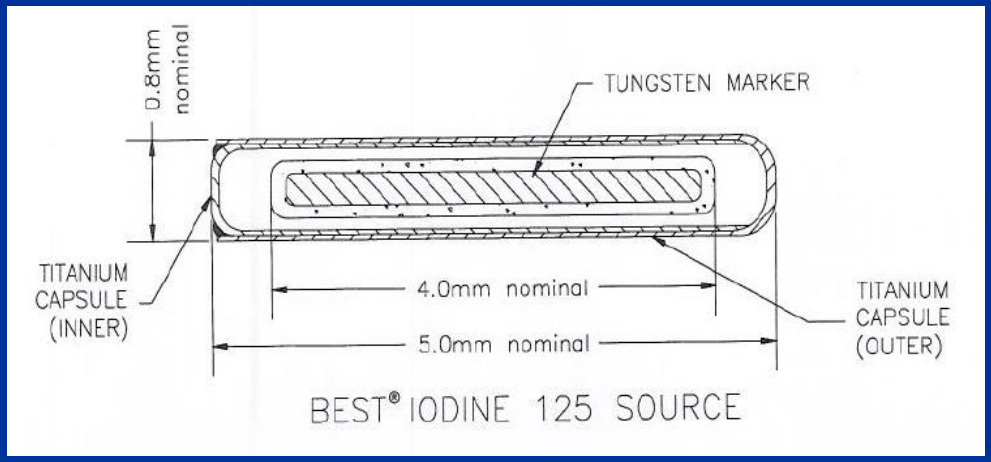
- Introduction to Iodine-125 Seeds
- Size and appearance of I-125 Seeds
- Safe handling and shielding instructions
- Caution Radioactive Materials Signage
- Routine monitoring of areas where I-125 seeds are used
- Emergency procedures
- Radiation Safety Office contact information
- Overview of procedure and process

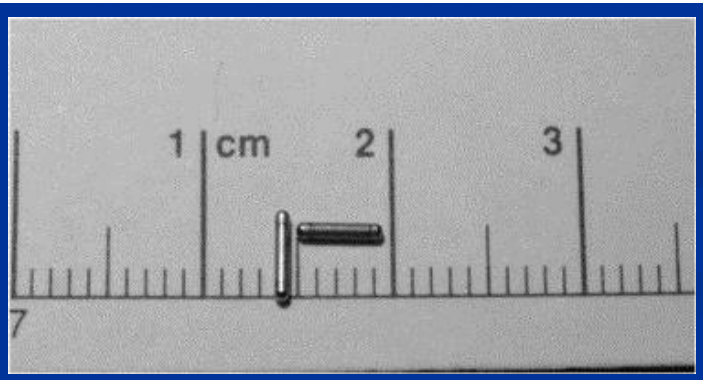
# Introduction to Iodine-125 Seeds

- Iodine-125 is a radioactive material that gives off low energy x-rays as it undergoes natural radioactive decay
  - The x-rays are about the same energy as those used in mammography
  - I-125 has a 60 day half-life, which means that in 60 days it will be half as strong as it was initially, after 120 days it will be 25% as strong as it was initially, etc
- The RSL process uses a sealed source called a "Seed"
  - Unless a Seed is ruptured (e.g. cut in half), there is no possibility for Radioactive Material Contamination of areas where the seed has been placed
- The amount of radioactive material in each seed is very low
  - When the seed is in the tissue or specimen, there is minimal radiation safety concerns, since the low energy x-rays are mostly absorbed by the tissue
  - The patient can be safely released after implant without restrictions, except to interrupt breast feeding if applicable

# Size and Appearance of I-125 Seeds

- The Seeds used are Best Medical International I-125 Model 2301
  - The Seed is 5 mm in length and 0.8 mm in diameter
  - The Seed has a metallic appearance since it has a solid Titanium casing
  - Inside the Titanium casing is a Tungsten Marker (metal that shows up on X-ray images) on which the I-125 is attached



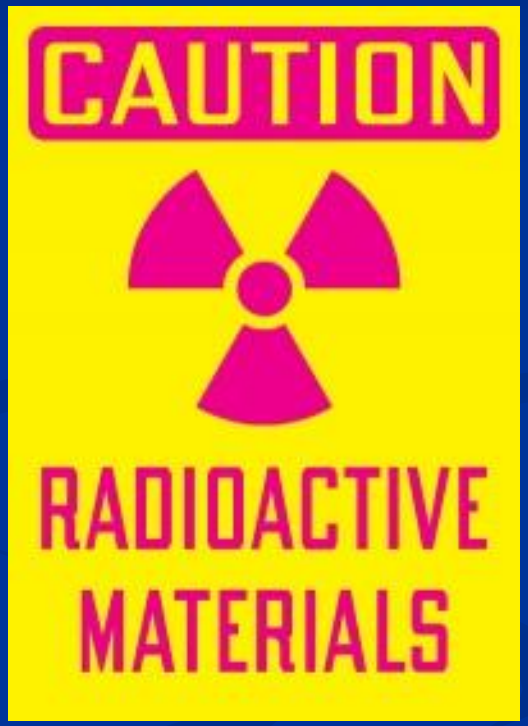



# Radiation Safety – Safe Handling and Shielding Instructions

- Time: The less time around the I-125 Seed, the less radiation exposure you will receive
- Distance: The greater the distance between you and the I-125 seed, the less radiation exposure you will receive
  - Never handle seed with fingers; instead use tweezers or pick-ups
- Shielding: When possible (for example, prior to insertion and after removal from specimen), the I-125 Seed should be shielded in a lead container

# Posting with Caution Radioactive Materials (CRAM) Signage

- Radioactive Materials are required to be secured and/or supervised at all times.
- A CRAM sign must be posted and entry to the following areas must be secured during the situations listed in the following slide.



# Posting with CRAM Signage

- Imaging
  - When seeds are stored and not in use
    - i.e. in a locked cabinet or a hot lab
  - When seeds are stored in implantation room and staff/physician are not present
- Surgery
  - When specimens containing seeds are unsupervised
- Pathology
  - When specimens containing seeds are unsupervised
  - When removed seeds are stored for retrieval
    - i.e. in lead container

# Routine Monitoring of I-125 Seeds All Departments

- I-125 Seed must be accounted for at all times

- If an I-125 Seed cannot be accounted for using visual means, using a radiation detection device, or through review of documentation, the following is required:

**HARD STOP IN PROCESS UNTIL I-125 SEED CAN BE ACCOUNTED FOR**

Note that patient care to ensure no harm comes to the patient may proceed

# Routine Monitoring of I-125 Seeds All Departments

- A radiation detection device (survey meter or Neoprobe) should be present at all times to monitor and/or locate I-125 seeds

  Note: excludes transportation

- Areas where I-125 seeds are, or were, present should be monitored with a radiation detection device to ensure rapid identification of and remediation of a broken or leaking source

# Emergency Procedure – Surgery Response to a Source Rupture

- **If seed becomes ruptured (*e.g.* cut in half):**
  - Use the Neoprobe to locate and remove seed in its entirety
  - Check surrounding tissue with Neoprobe on I-125 (Seed) setting for contamination
  - If contamination found, administer Potassium Iodide (KI) to patient following physician orders
    - FDA Guidance states 130 mg of KI for adults
  - Using tweezers or pick-ups, place entire seed on top of excised specimen and close specimen bag/cup/board
  - Make note of compromised seed in Pathology order documentation and on the specimen bag/cup/board
  - Contact Mark Seddon, RSO at 407-834-2210

# Emergency Procedure – Pathology Response to Leaking/Cut Source

- Routinely monitor specimens and workstation with survey meter before, during, and after all of the seed cases to ensure rapid identification and remediation of a broken or leaking source

- Emergency procedures to be followed in the event contamination is identified
  - Remove gloves and set on workstation
  - Survey hands to ensure no contamination present
  - Contact Radiation Safety Office (407-834-2210)
  - Radiation Safety or Nuclear Medicine personnel will come decontaminate area

# Emergency Procedure – All Departments
# Response to Unaccounted for or Ruptured Source

To minimize the risk of inadvertent exposure to seeds:

- If a seed cannot be located visually or with radiation detection device, post a CRAM sign, secure the area, and contact the Radiation Safety Office immediately

- If a seed is ruptured (e.g. cut in half), follow department specific emergency procedures

# Emergency Procedure – All Departments Patient Follow-up for Explantation

- If the patient does not have the seed explanted within 5 days of implant, the facility commits to make multiple attempts to contact the patient to ensure removal as soon as possible, and will contact the Radiation Safety Office

- The Radiation Safety Office will perform a dose assessment, and provide further guidance to the facility

# Emergency Procedure – All Departments
# Radiation Safety Office Contact Information

- Radiation Safety Office Phone Number:

  407-834-2210

  Mark Seddon, Radiation Safety Officer

- Authorized User information is available from the Radiation Safety Office

- Notify the Radiation Safety Office if the patient has a medical emergency or dies

# The Process

- Seed is inserted in Radiology
- Patient returns within 5 days for surgical removal
- Proper documentation of specimen containing radioactive I-125 seed is required
- Specimen is sent to pathology

# The Neoprobe

- A **Neoprobe** is a handheld radiation detection device used to locate radioactive sources during intraoperative procedures


# Operating the Neoprobe

- Make sure that the correct wireless probe (Bluetooth II) or a corded probe is be used

- Make sure the correct radionuclide is selected on Neoprobe
  - Press gray "Radionuclide" button on back of the Neoprobe base unit and make sure correct green light on front is lit
  - This enables the Neoprobe to distinguish between Tc-99m in lymph nodes injection and I-125 in seeds

# Count rate to determine margins

- Charts are specific to each Neoprobe and are attached to each unit
- Surgery Staff will be responsible for assuring the correct chart is available to the surgeon
- The surgeon will know the process to use this chart to determine count rates and margins
    - To find count rate at specified distances, the surgeon will find the closest seed activity in the left column and read across
- The chart shown here is an excerpt from one specific Neprobe and does not cover all seed activities

**Florida Hospital Celebration Health**

**Iodine-125 Radioactive Seeds for Breast Localization**

**NEOPROBE GDS (SN 82465050)**

**Bluetooth II Probe (SN 1100-01295)**

**Neoprobe Counts Versus Distance for a Range of Seed Activities**

| | Distance (cm) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Activity (µCi)** | **0.5** | **1** | **1.5** | **2** | **2.5** | **3** | **3.5** | **4** | **4.5** | **5** |
| **310** | 44030 | 49330 | 32979 | 25536 | 16906 | 12610 | 9123 | 6452 | 4742 | 3647 |
| **300** | 46792 | 48646 | 32255 | 24905 | 16440 | 12247 | 8850 | 6255 | 4595 | 3532 |
| **290** | 49055 | 47922 | 31515 | 24264 | 15970 | 11880 | 8577 | 6057 | 4447 | 3418 |
| **280** | 50865 | 47158 | 30756 | 23612 | 15494 | 11511 | 8302 | 5858 | 4299 | 3303 |
| **270** | 52267 | 46354 | 29979 | 22948 | 15014 | 11139 | 8025 | 5659 | 4151 | 3188 |
| **260** | 53303 | 45507 | 29183 | 22273 | 14529 | 10765 | 7747 | 5458 | 4002 | 3073 |
| **250** | 54008 | 44617 | 28368 | 21587 | 14039 | 10388 | 7468 | 5258 | 3853 | 2958 |
| **240** | 54418 | 43683 | 27534 | 20889 | 13544 | 10008 | 7187 | 5056 | 3704 | 2842 |
| **230** | 54561 | 42702 | 26678 | 20179 | 13043 | 9625 | 6905 | 4854 | 3554 | 2727 |
| **220** | 54464 | 41673 | 25802 | 19456 | 12538 | 9239 | 6621 | 4651 | 3404 | 2611 |
| **210** | 54150 | 40594 | 24905 | 18721 | 12027 | 8850 | 6336 | 4447 | 3253 | 2494 |
| **200** | 53639 | 39462 | 23986 | 17974 | 11511 | 8459 | 6050 | 4243 | 3102 | 2378 |
| **190** | 52945 | 38274 | 23044 | 17214 | 10990 | 8065 | 5762 | 4038 | 2951 | 2261 |
| **180** | 52082 | 37028 | 22078 | 16440 | 10463 | 7668 | 5472 | 3832 | 2799 | 2144 |
| **170** | 51058 | 35720 | 21089 | 15653 | 9931 | 7268 | 5181 | 3625 | 2647 | 2027 |
| **160** | 49878 | 34348 | 20076 | 14853 | 9394 | 6865 | 4889 | 3418 | 2494 | 1910 |
| **150** | 48543 | 32907 | 19038 | 14039 | 8850 | 6459 | 4595 | 3210 | 2341 | 1792 |
| **140** | 47051 | 31394 | 17974 | 13211 | 8302 | 6050 | 4299 | 3001 | 2188 | 1674 |

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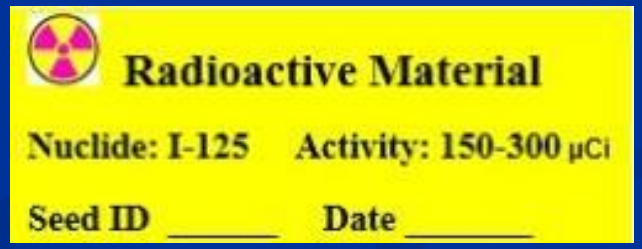
# Labeling Radioactive Material Stickers with Seed ID

- **EXTREMELY IMPORTANT PART OF THE PROCESS!!!!!!**

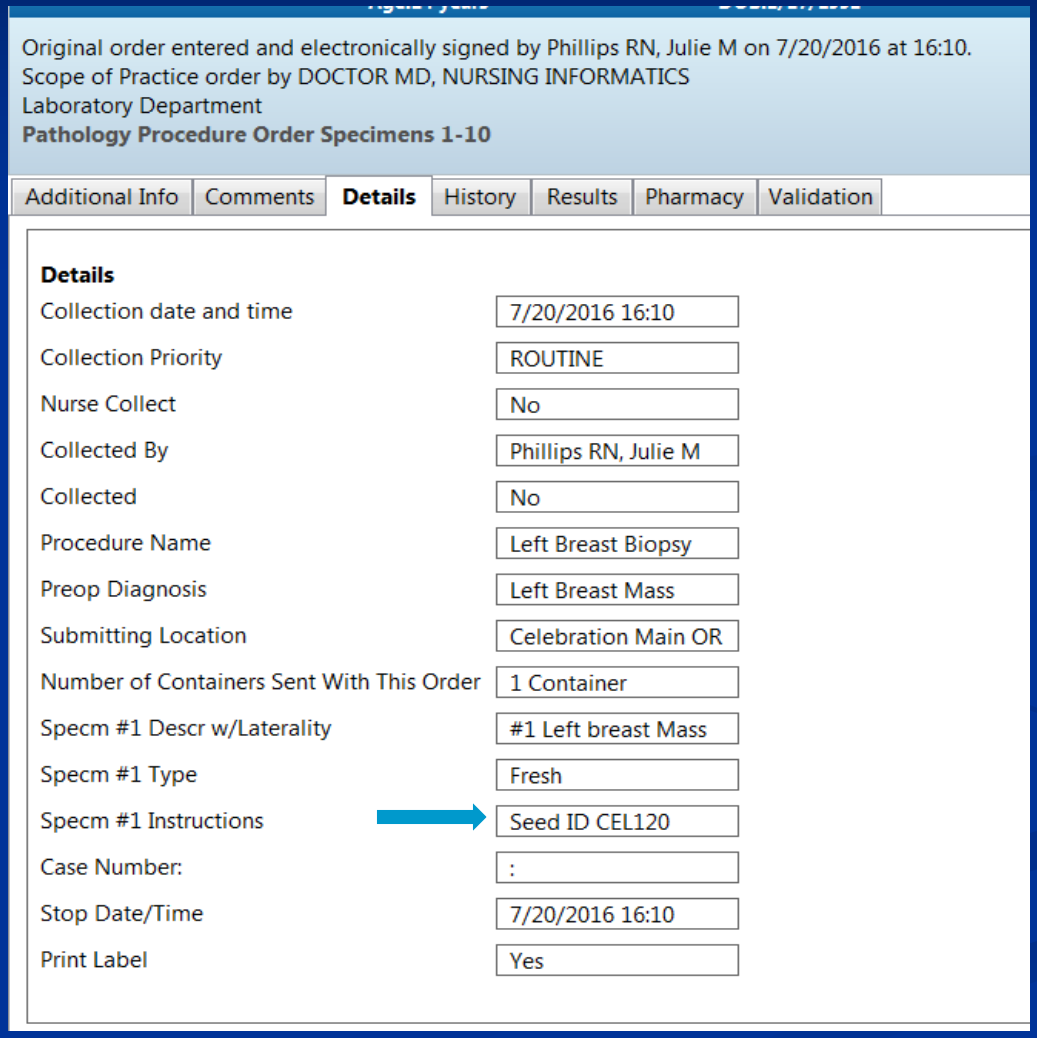
- Each seed is assigned unique identifiers upon arrival and are tracked through entire process to disposal
  - Seed ID and Date of surgery very important
- Write Seed ID and Date on each label
  - Seed ID can be found:
    - In patient record
    - On mammography films
  - Seed ID may contain a 3 letter location identifier (Example Seed ID CEL 1)
  - Do not confuse Seed ID with Seed Activity (a number followed by "uCi")
- Place Label Specimen Board/Cup/Bag



# Specimen Documentation and Handoff

- Document the Seed ID in the electronic Pathology Procedure Order in the Specimen Instruction tab just below the specimen type
- Prior to sending the specimen to imaging and/or the lab, two procedural personnel will visually and audibly confirm the following information on the specimen container and label:
  - Identification of tissue
  - Laterality
  - Patient's name and date of birth
  - Seed ID
- Specimen is taken to imaging or imaged in the OR using a Trident Specimen Processor; image acquired and read by Radiologist to confirm appropriate tissue and seed was excised
- Specimen is then taken to pathology where seed is removed during grossing
- The seed is placed in decay-in-storage, and finally transferred back to main hospital

# Documenting the Seed ID in the Pathology Procedure Order



Original order entered and electronically signed by Phillips RN, Julie M on 7/20/2016 at 16:10.
Scope of Practice order by DOCTOR MD, NURSING INFORMATICS
Laboratory Department
**Pathology Procedure Order Specimens 1-10**

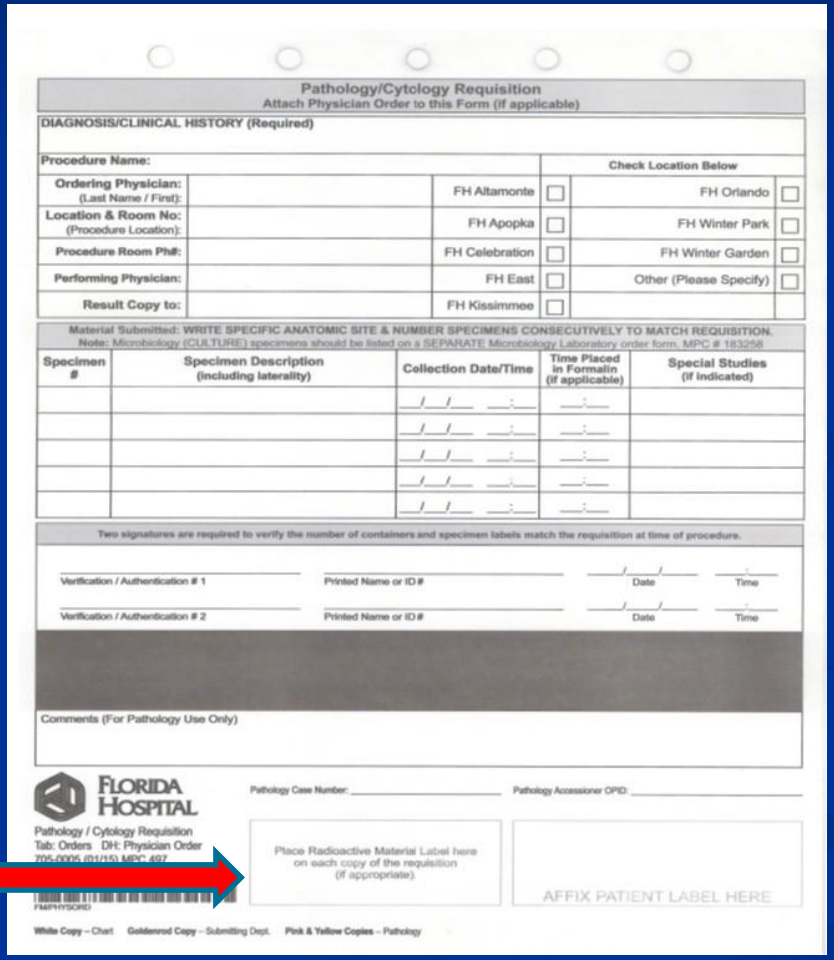
Additional Info | Comments | **Details** | History | Results | Pharmacy | Validation

**Details**

| | |
|---|---|
| Collection date and time | 7/20/2016 16:10 |
| Collection Priority | ROUTINE |
| Nurse Collect | No |
| Collected By | Phillips RN, Julie M |
| Collected | No |
| Procedure Name | Left Breast Biopsy |
| Preop Diagnosis | Left Breast Mass |
| Submitting Location | Celebration Main OR |
| Number of Containers Sent With This Order | 1 Container |
| Specm #1 Descr w/Laterality | #1 Left breast Mass |
| Specm #1 Type | Fresh |
| Specm #1 Instructions | Seed ID CEL120 |
| Case Number: | : |
| Stop Date/Time | 7/20/2016 16:10 |
| Print Label | Yes |

# During Periods of Computer Downtime

During periods of computer down time when the paper Pathology/ Cytology Requisition is used, a yellow radioactive material sticker is placed in the provided space near the bottom of the form on each copy of the requisition.



**Pathology/Cytology Requisition**
Attach Physician Order to this Form (if applicable)

DIAGNOSIS/CLINICAL HISTORY (Required)

Procedure Name:

| | | | | | |
|---|---|---|---|---|---|
| Ordering Physician: (Last Name / First): | | FH Altamonte | ☐ | FH Orlando | ☐ |
| Location & Room No: (Procedure Location): | | FH Apopka | ☐ | FH Winter Park | ☐ |
| Procedure Room Ph#: | | FH Celebration | ☐ | FH Winter Garden | ☐ |
| Performing Physician: | | FH East | ☐ | Other (Please Specify) | ☐ |
| Result Copy to: | | FH Kissimmee | ☐ | | |

Check Location Below

Material Submitted: WRITE SPECIFIC ANATOMIC SITE & NUMBER SPECIMENS CONSECUTIVELY TO MATCH REQUISITION.
Note: Microbiology (CULTURE) specimens should be listed on a SEPARATE Microbiology Laboratory order form, MPC # 183258

| Specimen # | Specimen Description (including laterality) | Collection Date/Time | Time Placed in Formalin (if applicable) | Special Studies (if indicated) |
|---|---|---|---|---|
| | | __/__/__ __:__ | __:__ | |
| | | __/__/__ __:__ | __:__ | |
| | | __/__/__ __:__ | __:__ | |
| | | __/__/__ __:__ | __:__ | |
| | | __/__/__ __:__ | __:__ | |

Two signatures are required to verify the number of containers and specimen labels match the requisition at time of procedure.

Verification / Authentication # 1 — Printed Name or ID # — Date — Time

Verification / Authentication # 2 — Printed Name or ID # — Date — Time

Comments (For Pathology Use Only)

FLORIDA HOSPITAL

Pathology Case Number: _____ Pathology Accessioner OPID: _____

Pathology / Cytology Requisition
Tab: Orders DH: Physician Order
705-0005 (01/15) MPC 497

Place Radioactive Material Label here on each copy of the requisition (if appropriate).

AFFIX PATIENT LABEL HERE

FMPHYSORD

White Copy – Chart Goldenrod Copy – Submitting Dept. Pink & Yellow Copies – Pathology

This concludes this module.