



## ST. JOHN MACOMB - OAKLAND HOSPITAL

August 8, 2012

U.S. Nuclear Regulatory Commission  
Aaron T. McCraw, Senior Health Physicist  
Region III, Division of Nuclear Materials Safety  
2443 Warrenville Rd., Suite 210  
Lisle, IL 60532-4352

Re: Event #48085      NRC License: #21-01190-05 St. John Macomb – Oakland Hospital

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Please accept the following detailed Plan of Correction as a follow up to the USNRC Survey conducted July 19-20, 2012 as a result of event #48085 for further consideration.

The following policy, procedure, and actions will be in place to correct the identified deficiency by September 30, 2012.

St. John Providence Health System's Policy, Radiation Oncology Time Out Procedures #1637.24 was originally reviewed and approved by the Chief of Radiation Oncology in April 2012. Following the event, the policy was immediately revised by the Radiation Safety Officer to include a qualified secondary staff member to perform the "time out" in conjunction with the physicist. Upon further review of the policy post survey by the Chief of Radiation Oncology, Chief Physicist, Radiation Safety Officer, and Director, the policy has thus been reviewed, verified, and determined to include all necessary components of a comprehensive, accurate "time out" procedure to ensure the safety of each patient.

An Instruction Manual regarding proper use of applicators and transfer tubes has been developed for the HDR staff. This manual will serve as a guide to train secondary staff who will be present during the HDR treatment and participating in the HDR "time out" procedure. In-service training and education will be provided by the physicists to the secondary staff utilizing this manual. Training and education will be completed by September 30, 2012.

Due to the exceptionality of endobronchial treatments not requiring a transfer tube, the radiation safety officer will file a report with the FDA, via Med Sun, to suggest examination of the equipment/software by the manufacturer in preventing this incident from reoccurring elsewhere. This report will be filed by September 15, 2012. The HDR staff will continue to label containers that store the transfer tubes for proper identification for treatment usage.

St. John Macomb – Oakland Hospital has concluded this event is unique and can state with high confidence this type of event has not occurred previously. This single event was self-identified without patient harm as our dosimetry calculations confirm. Safety methods that are practiced, such as utilizing towels/blankets to act as a barrier assured this patient was not harmed with a source skin burn. The patient has been able to successfully complete treatment in a follow up procedure as noted by the written directive.

Thank you for your time and consideration.

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## **Radiation Oncology Time out Procedures**

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### **PURPOSE:**

The purpose is to outline a time out process to be completed prior to any radiation oncology procedure to ensure each patient is treated appropriately.

### **POLICY**

Prior to any radiation therapy patient simulation, daily external beam treatment or Brachytherapy/HDR procedure a time out will be completed by all associates initiating the patient procedure. All time outs will include verification of correct patient using two identifiers initially identifier should be patient name and DOB, correct patient site, correct set up and correct procedure.

### **PROCEDURE**

"Time outs" will be completed prior to any patient procedure. Patient procedures include Ct simulation, Treatment Verification Simulation or initial treatment, Daily External Beam treatment, and brachytherapy treatments. "Time outs" are to be recorded in MOSAIQ under quality checklist (QCL) item "time out" or by means of assessment.

1. Ct simulation "time out" procedure:
  - A. Prior to any patient being brought into the simulation room the simulation tech will append a QCL or QCL item in impac/MOSAIQ for one treatment "time out" for appropriate departmental site for all patients scheduled for that day.
  - B. Prior to patient being brought into the simulation room the simulation tech should check for simulation orders and/or with the radiation oncologist the proper set up information, simulation site, and completion of consent.
  - C. Upon bringing patient into the simulation room the simulation tech will stop prior to initiating simulation and perform "time out" with the simulation patient. The "time out" will include patient identifying themselves and verifying date of birth. The patient will also confirm site & correct side that is to be simulated. After the "time out" occurs the QCL item therapist "time out" for that date and procedure can be completed.
  - D. If a patient is unable to assist in "time out", the "time out" should be performed with a secondary staff member that is familiar with the patient, the physician or patient representative.
  - E. If there is any question of patient site or identity the procedure should be stopped until verification is complete.
  - F. If oral, bladder or IV contrast is being used, patient ID and allergies are to be checked prior to administering any contrast. (See specific contrast policies)

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## Radiation Oncology Time out Procedures

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### 2. Initial treatment day or treatment Verification Simulation time out procedure:

- A. At the time of treatment planning dosimetrist will append QCL items for appropriate number of therapist "time outs" including treatment machine verification day and daily treatments. Therapist treating the patient should update the "time out" ensuring that there is appropriate count completed for number of patient treatments.
- B. Prior to patients first treatment, boost or change in treatment plan a therapist "time out" will be completed that includes verification of patient identification, correct site, correct set up position, review of physician orders, review prescription and plan, and verification that physics quality assurance is complete. After these items have been confirmed the appropriate therapist "time out" QCL will be completed for that patient and date in MOSAIQ.
  - i. Verification of set up includes patient positioning, tattoo verification and appropriate positioning, films or CT are approved by physicians. For emergency cases films should be approved prior to second treatment.
  - ii. Review of prescription and plan includes verification that the prescription matches what is being treated and that physician have approved prescription and plan.
  - iii. Work list for QCL items and Patient QCL items should be reviewed daily for each patient scheduled. If a "time out" was not performed on a patient a skip should be recorded in MOSAIQ with a note in captured skip stating the reason why the QCL "time out" was not complete. Examples may be: patient canceled their treatment or patient is on break. If a patient is on an extended break record one skip and update "time outs" to begin when patient returns from break.
  - iv. Additionally at the beginning of every patient course of treatment as a double check a QCL item energy check will be completed when verifying prescription, energy, daily treatment schedule and that treatment billing coordinates with what is being treated.

### 3. Daily external beam

- A. At the time of treatment planning dosimetrist will append QCL items for appropriate number of therapist "time outs" including treatment machine verification day and daily treatments. Therapist treating the patient should update the "time out" ensuring that there is appropriate count completed for number of patient treatments.
- B. Daily, prior to treating all patients, a "time out" will be completed by the therapist. The "time out" will include verification of correct patient, correct site, and correct procedure. The QCL item should be completed for appropriate date and patient.
  - i. Work list and Patient QCL items should be reviewed daily for each patient. If a "time out" was not performed on a patient a skip should be

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## Radiation Oncology Time out Procedures

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recorded in MOSAIQ with a note stating the reason why the QCL "time out" was not complete. Examples may be: patient canceled treatment, patient is on break. If a patient is on an extended break, record one skip and update "time outs" to begin when patient returns from break.

4. Brachytherapy /HDR "time out" and patient assessment procedure:

Prior to performing a brachytherapy/HDR procedure a "time out" procedure and patient assessment will be completed.

- A. The "time out" includes patient identification, correct site, correct route, correct procedure, correct applicator, correct connections and prescription verification.
- B. The "time out" will be initiated by a staff member before the HDR procedure begins, using active communication and calling for a "time out". The physicist and a qualified secondary staff member will formally check and confirm the correct HDR connection(s). The procedure will not begin until any questions or concerns are resolved. If questions or concerns are not resolved, the physicist and qualified secondary staff member should reference the Instruction Manual on applicators and transfer tubes for HDR procedures.
- C. Completion of the HDR patient assessment includes:
  - i. "time out" performed
  - ii. completed daily HDR Quality Assurance
  - iii. verification of number of catheter(s) used
  - iv. verification of treatment plan
  - v. verification of applicator
  - vi. presence of physicist and doctor
  - vii. treatment delivery as planned
  - viii. verification of dose recorded in chart
  - ix. post treatment radiation survey meter performed and documented

### **RESPONSIBLE PERSONS:**

All staff members involved in patient procedures including but not limited to Nurses, Physicians, Sim Techs, Therapists, Physicists, and Dosimetrist

### **EQUIPMENT:**

Ct Simulation units, HDR units, & all Linacs used for patient procedures.



## Radiation Oncology Time out Procedures

VERIFICATION AND REVIEW	
Reviewed: Lorrie Lipa, Paul Chuba, Jeff Colvin, Laura Smith	Dates of Review
	4/12, 7/12, 8/12

### APPROVAL / SIGNATURES

#### For Macomb Radiation Oncology Policy and Procedure Manual

<hr/>	<hr/>
Paul J. Chuba, M.D. Chief of Radiation Oncology	Date
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Jeff Colvin, MS Chief Physicist	Date
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Lorrie Lipa, MA, BSRT(T) Director	Date
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Laura T. Smith, MS, DABR RSO	Date

# Fax Cover Sheet

To: Aaron McCraw - 630-515-1259

From: Barbara Boudreau - SJMOH

586-573-5443-office

586-582-7921-fax

total pages

including cover: 26

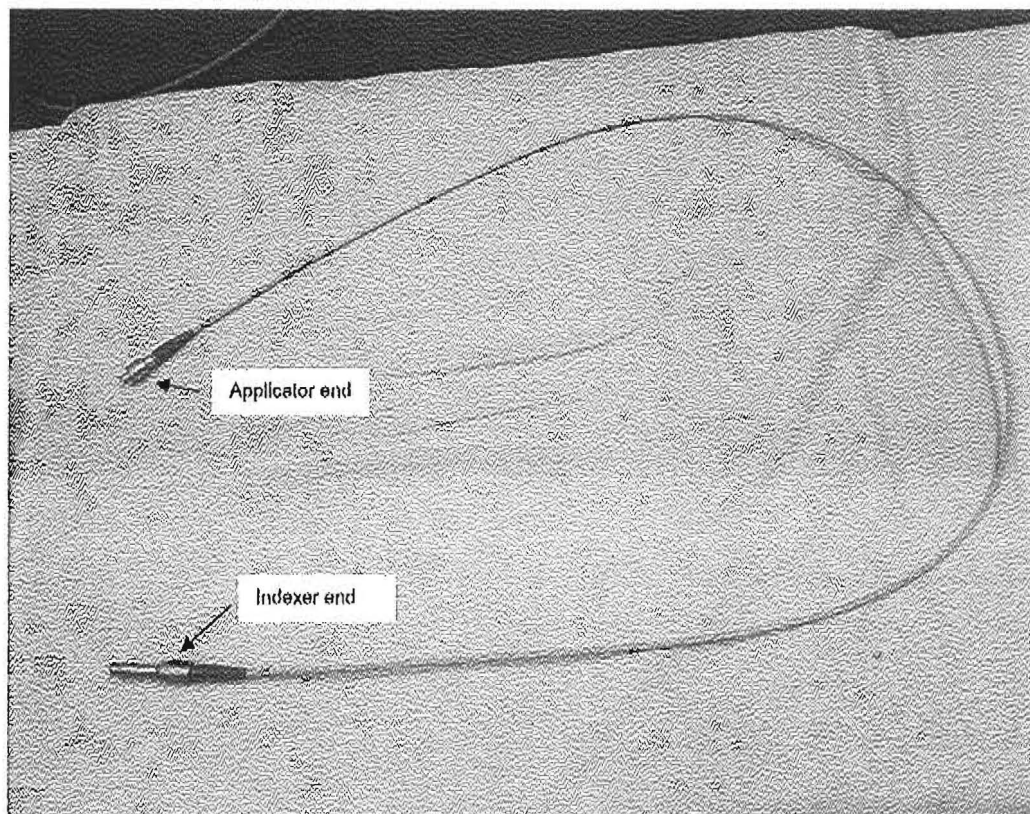


### **Instructions for HDR Staff on Applicators and Transfer Tubes**

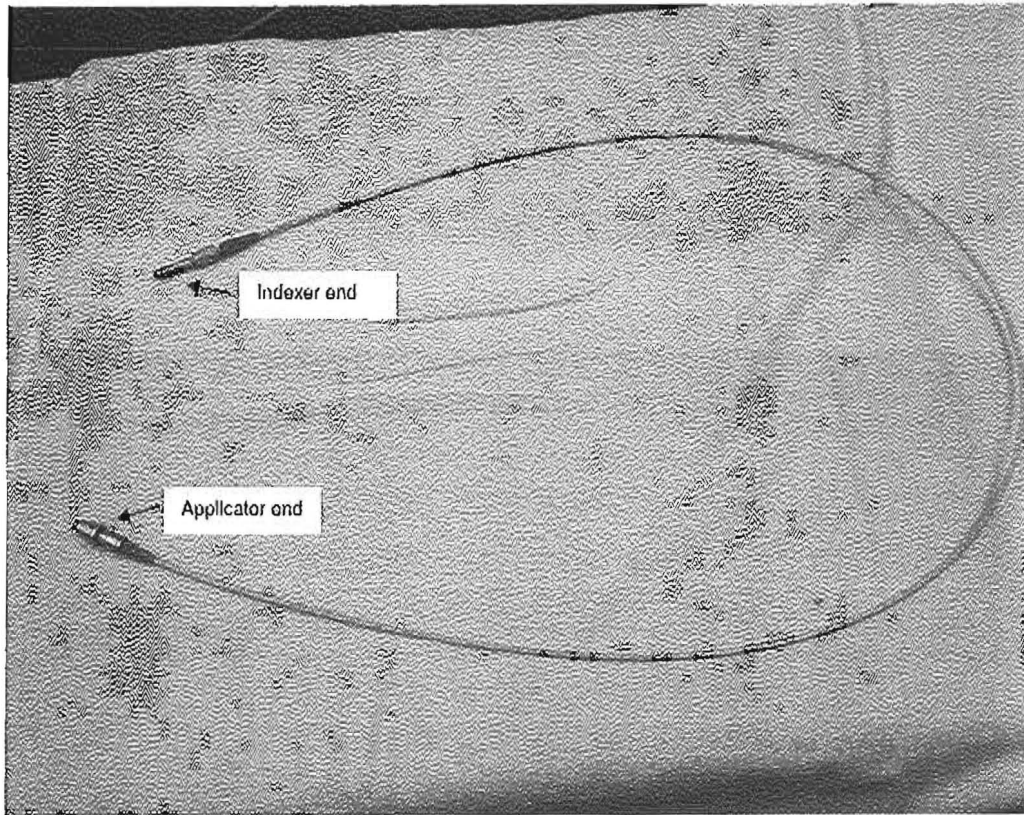
The following are instructions on the applicators, transfer tubes and connectors for the Nucletron HDR unit.

#### Description of the parts of the HDR unit, applicators and transfer tubes

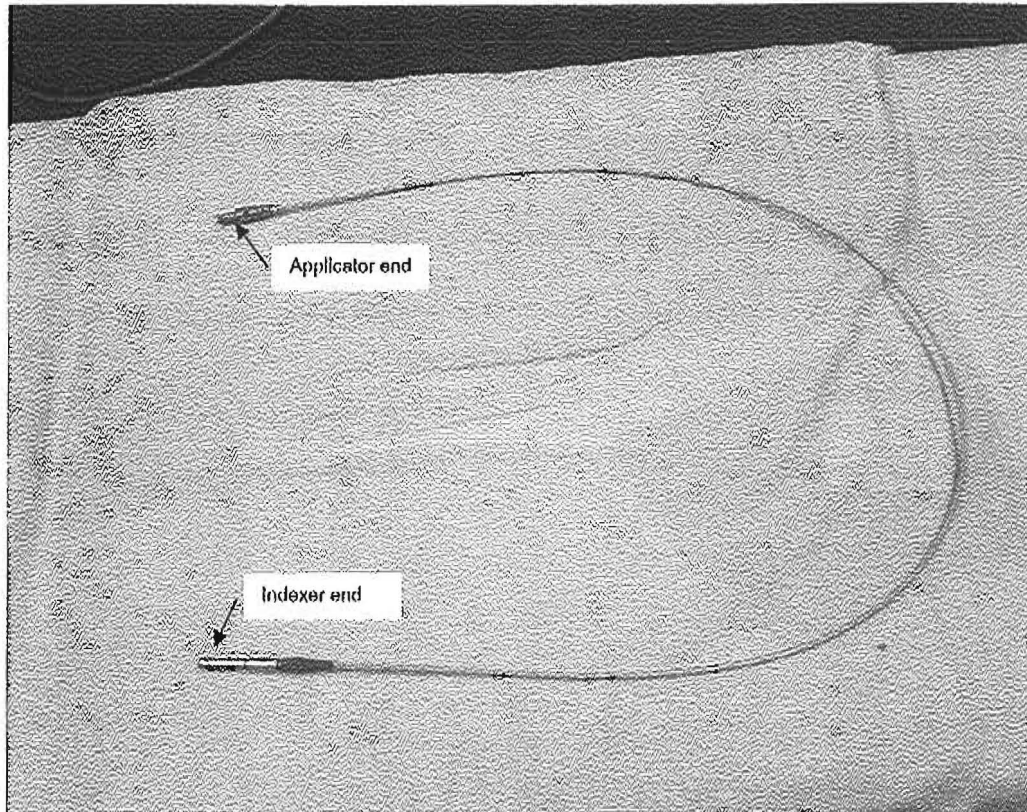
#### **Silver Metal Tandem, Ring and Cylinder Transfer Tubes**



# Silver Plastic Tandem, Ring and Cylinder Transfer Tubes

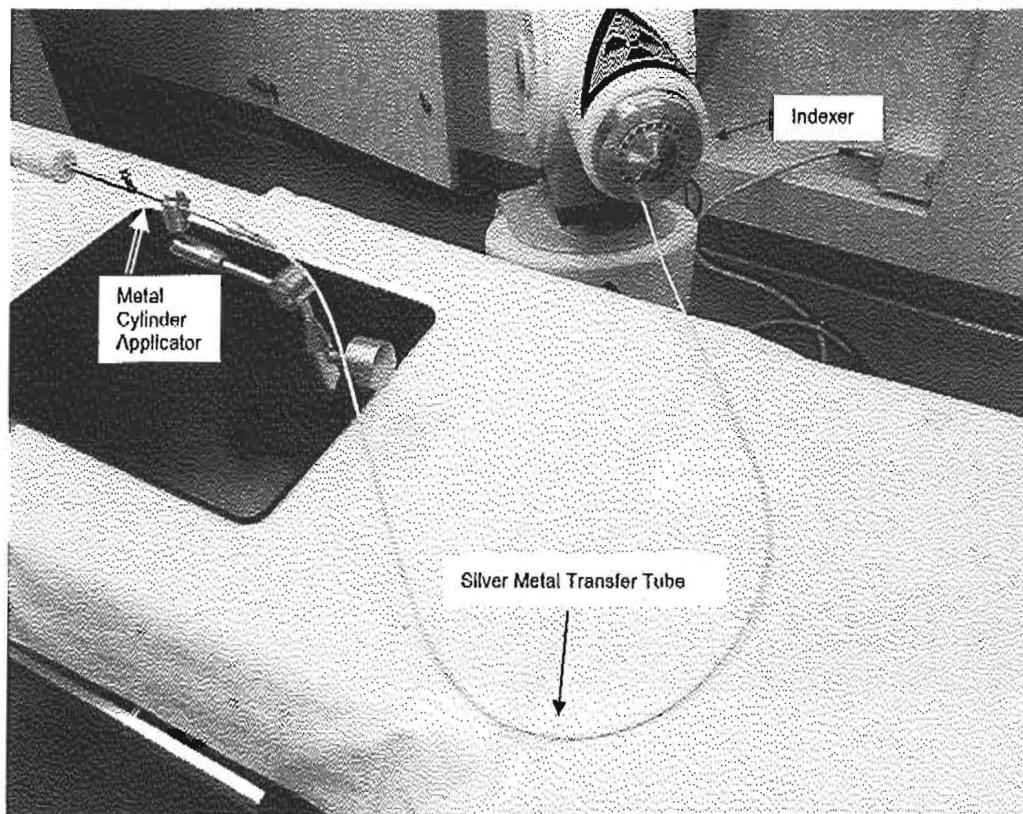


# Gold 6 French Transfer Tubes

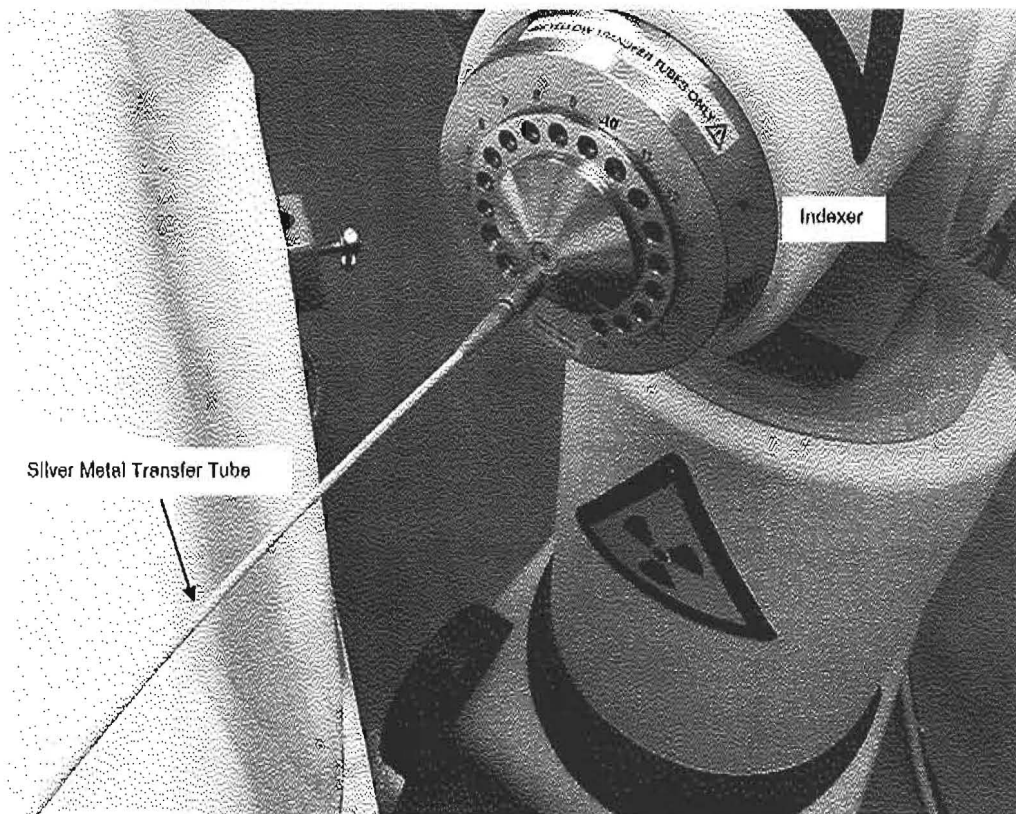
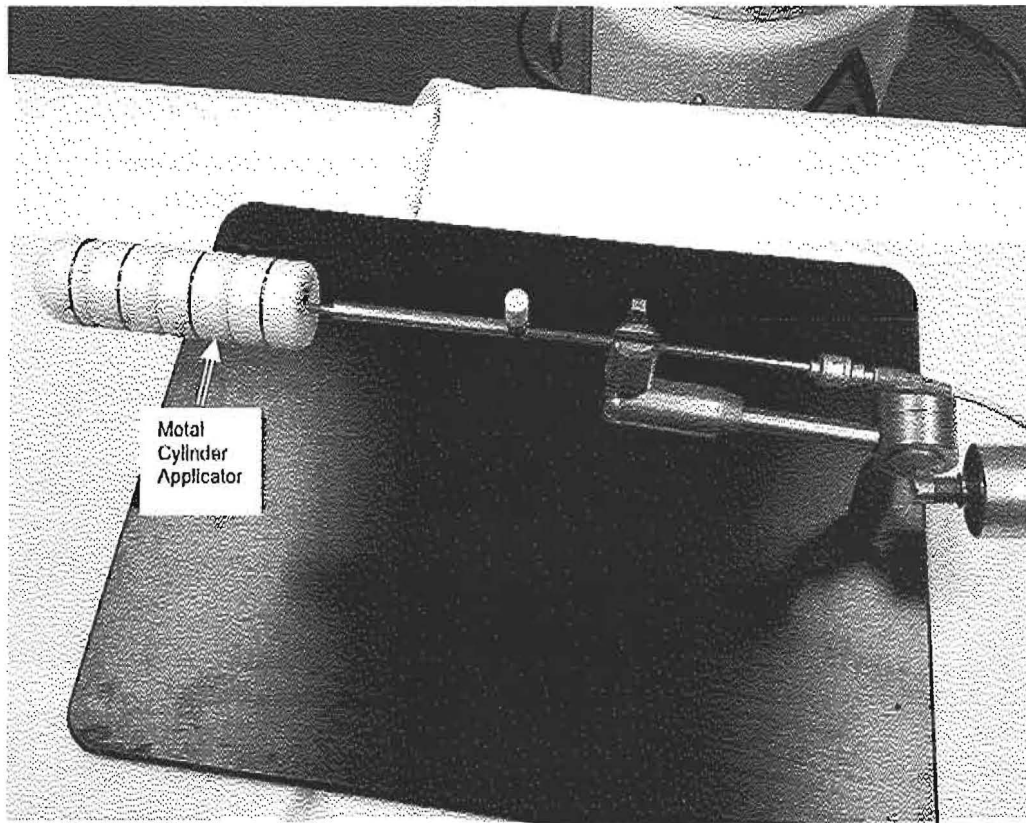


### Cylinders

Metal - Attach Transfer Tube 1 for metal applicators to the applicator and the other end to position 1 on the Indexer.



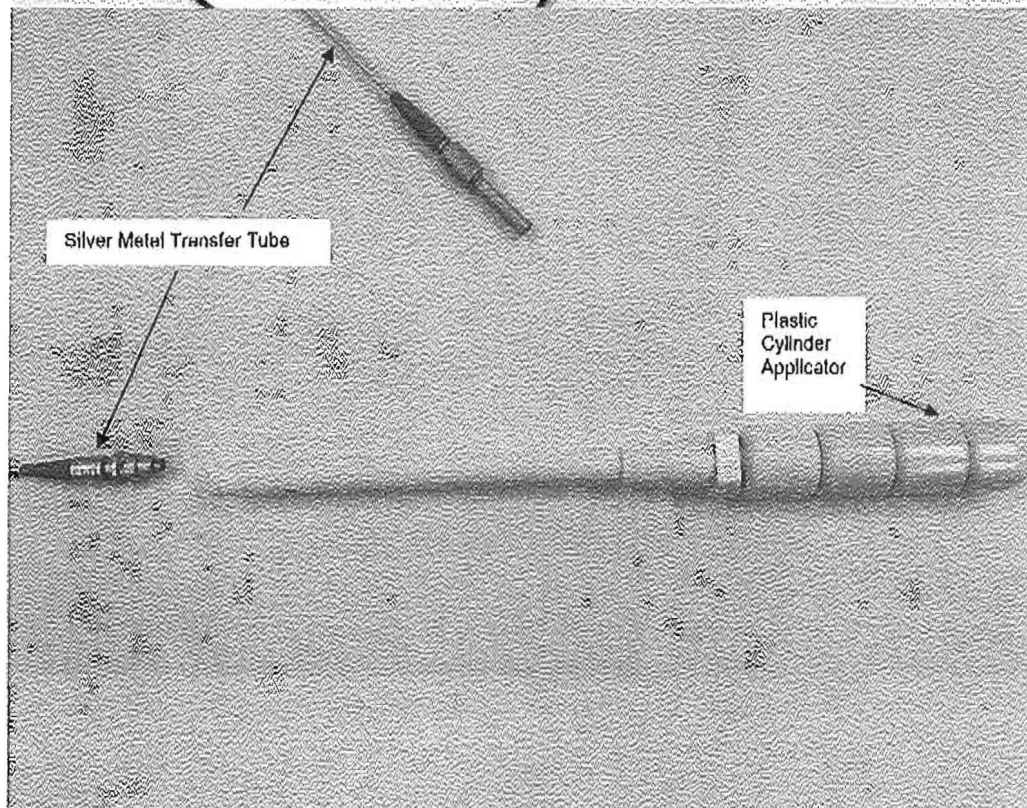
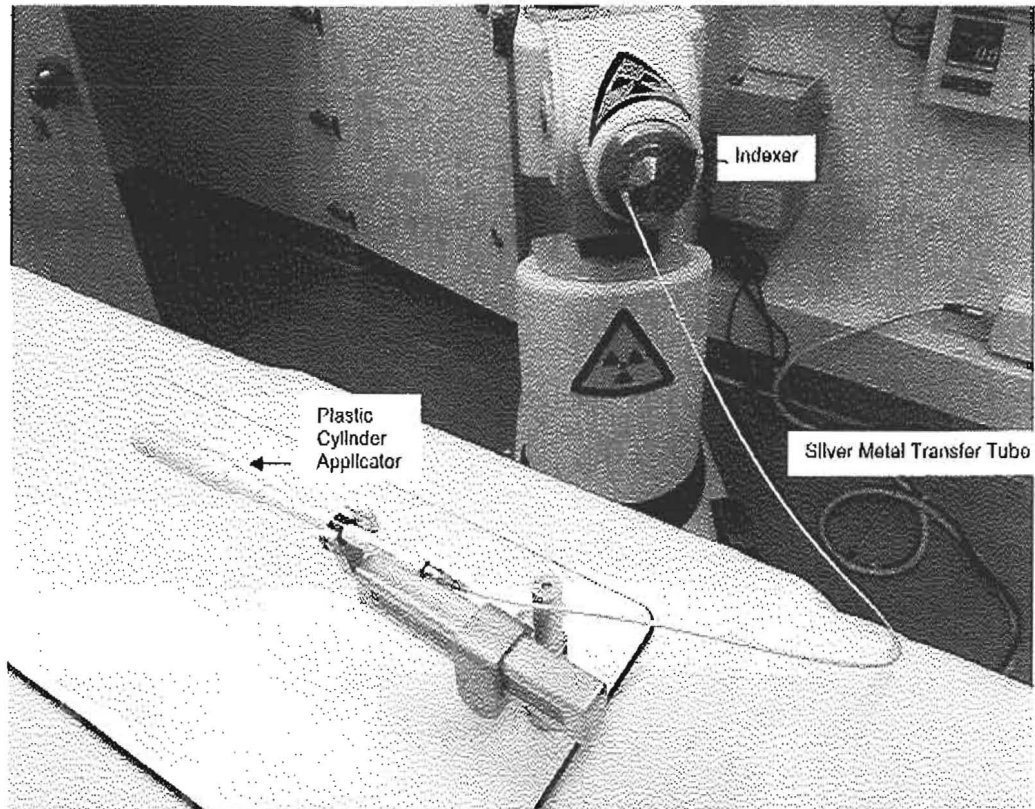






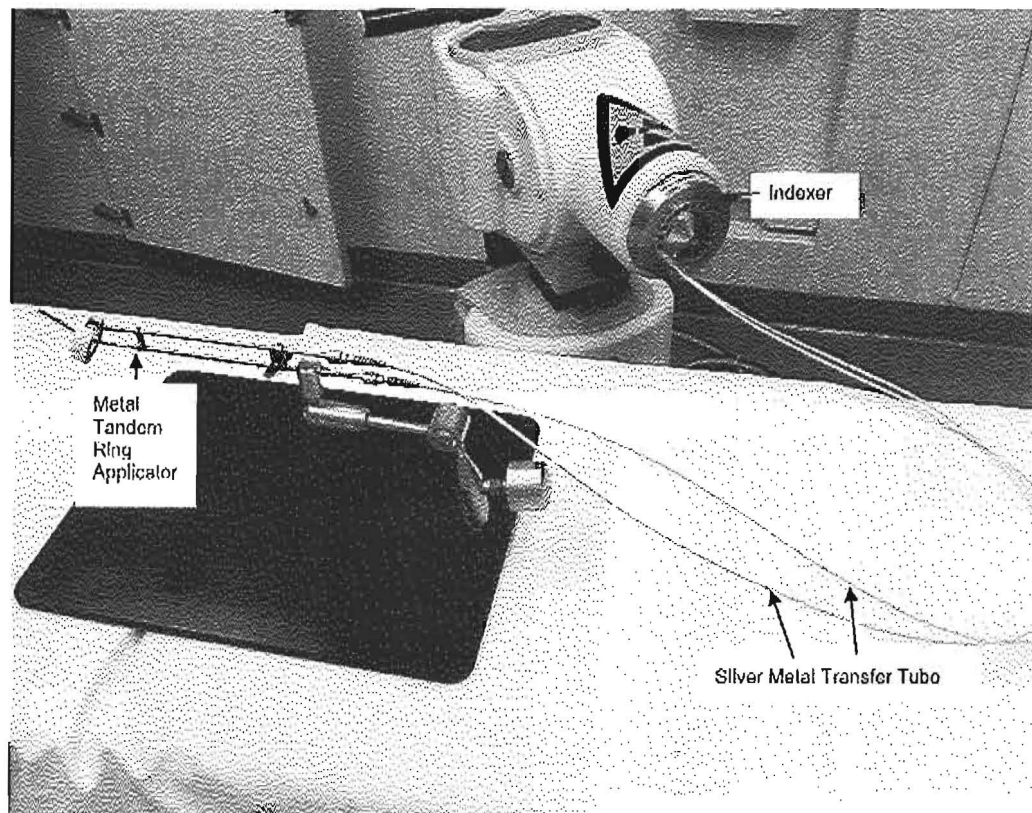
### Cylinders

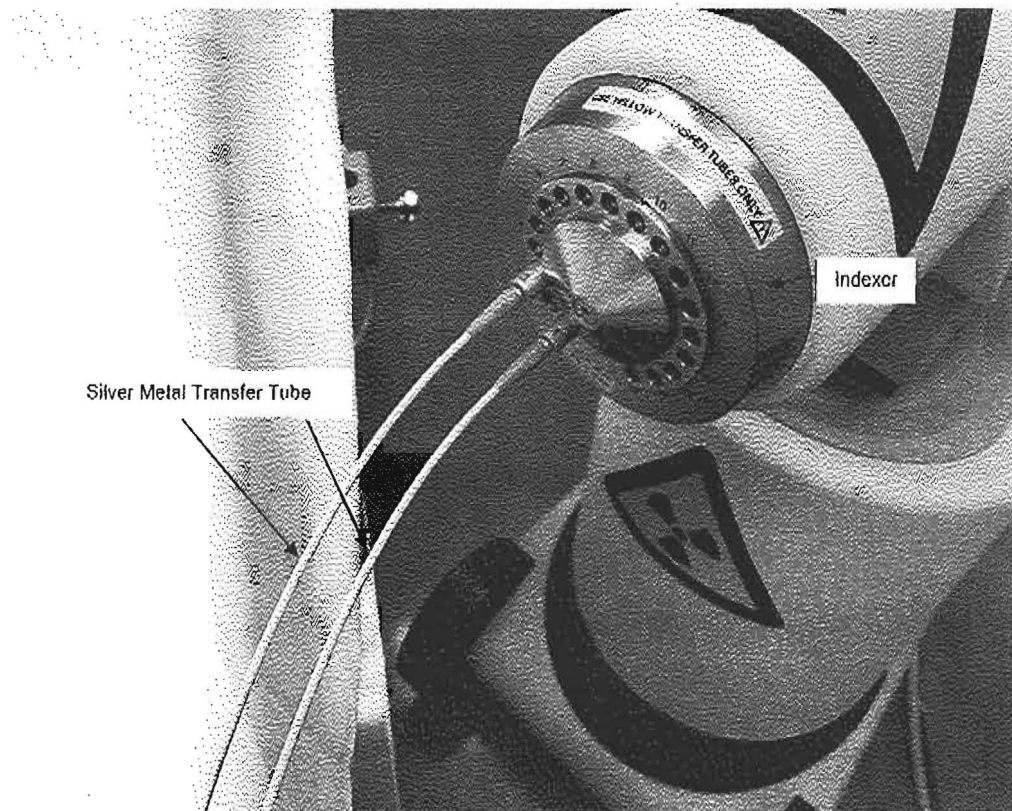
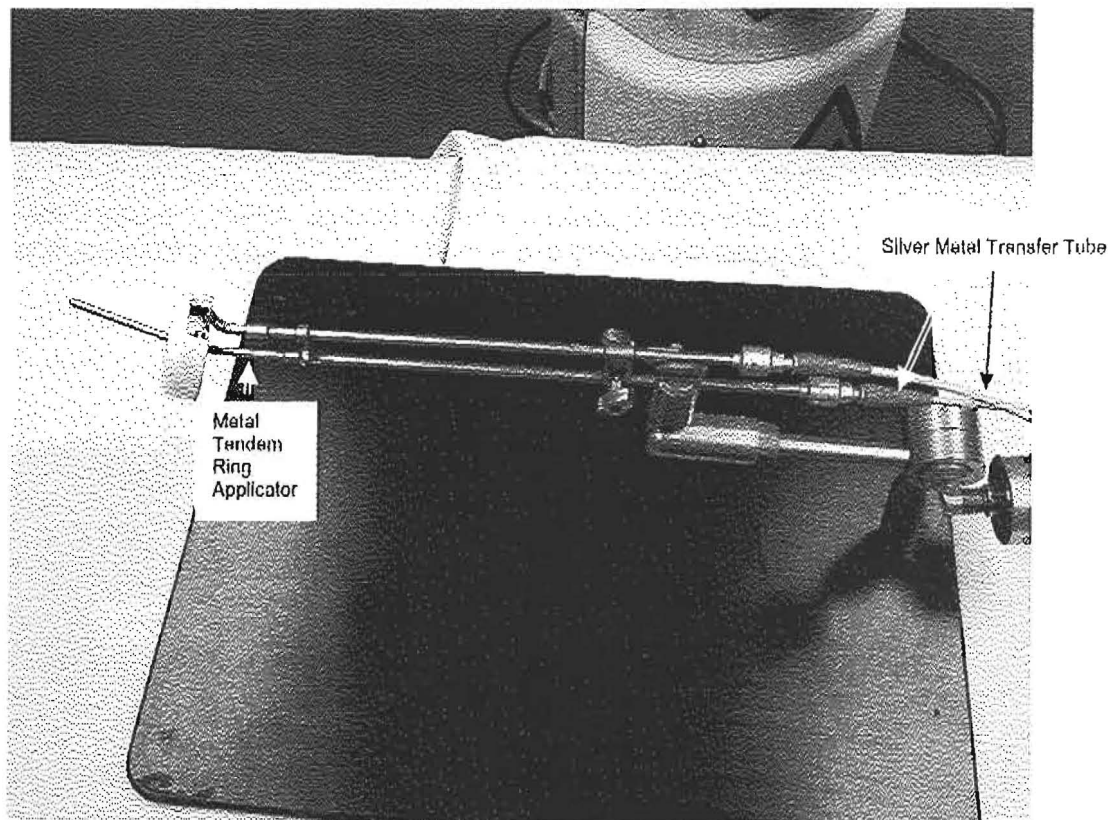
Plastic - Attach Transfer Tube 1 for plastic applicators to the applicator and the other end to position 1 on the Indexer.



### Tandem Ring

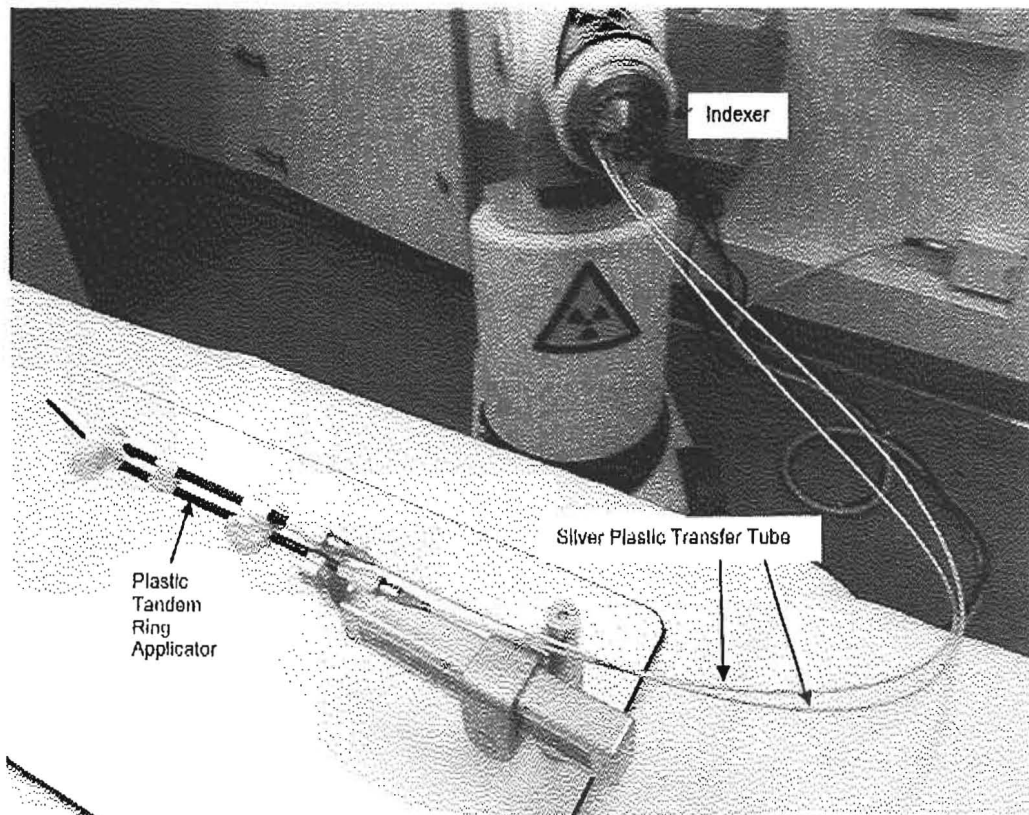
Metal - Attach Transfer Tube 1 for metal applicators to the ring and the other end to position 1 on the Indexer. Attach Transfer Tube 3 for metal applicators to the tandem and the other end to position 3 on the Indexer.



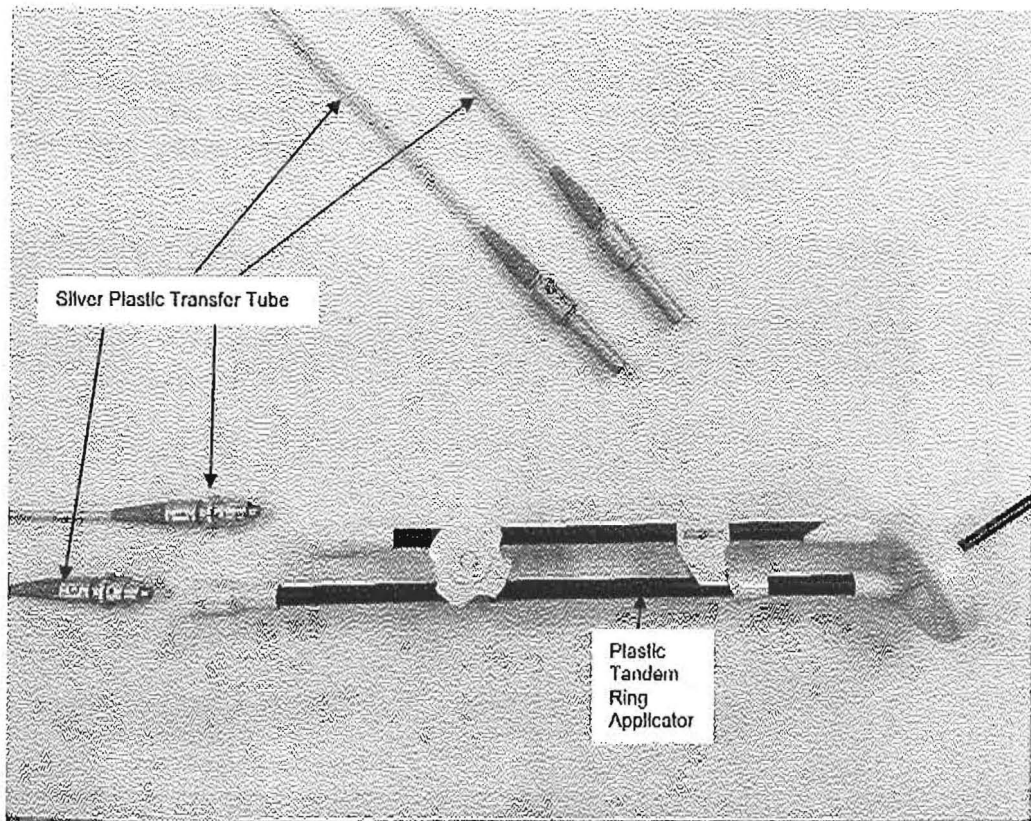


### Tandem Ring

Plastic - Attach Transfer Tube 1 for plastic applicators to the ring and the other end to position 1 on the Indexer. Attach Transfer Tube 3 for plastic applicators to the tandem and the other end to position 3 on the Indexer.

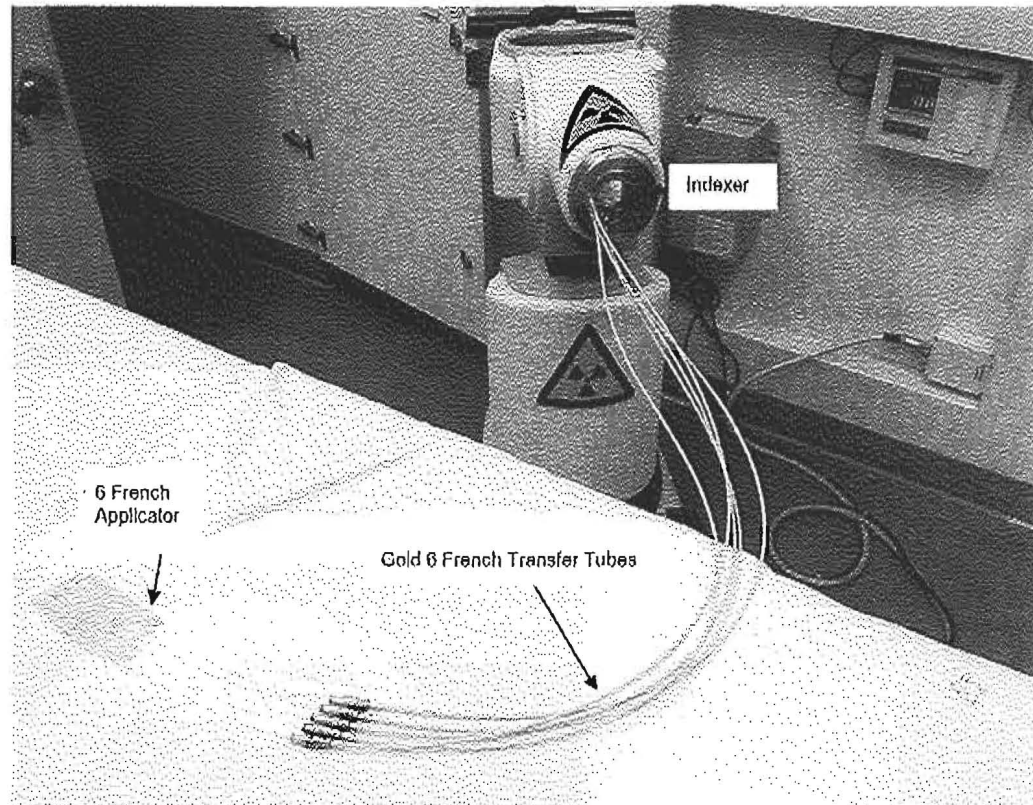


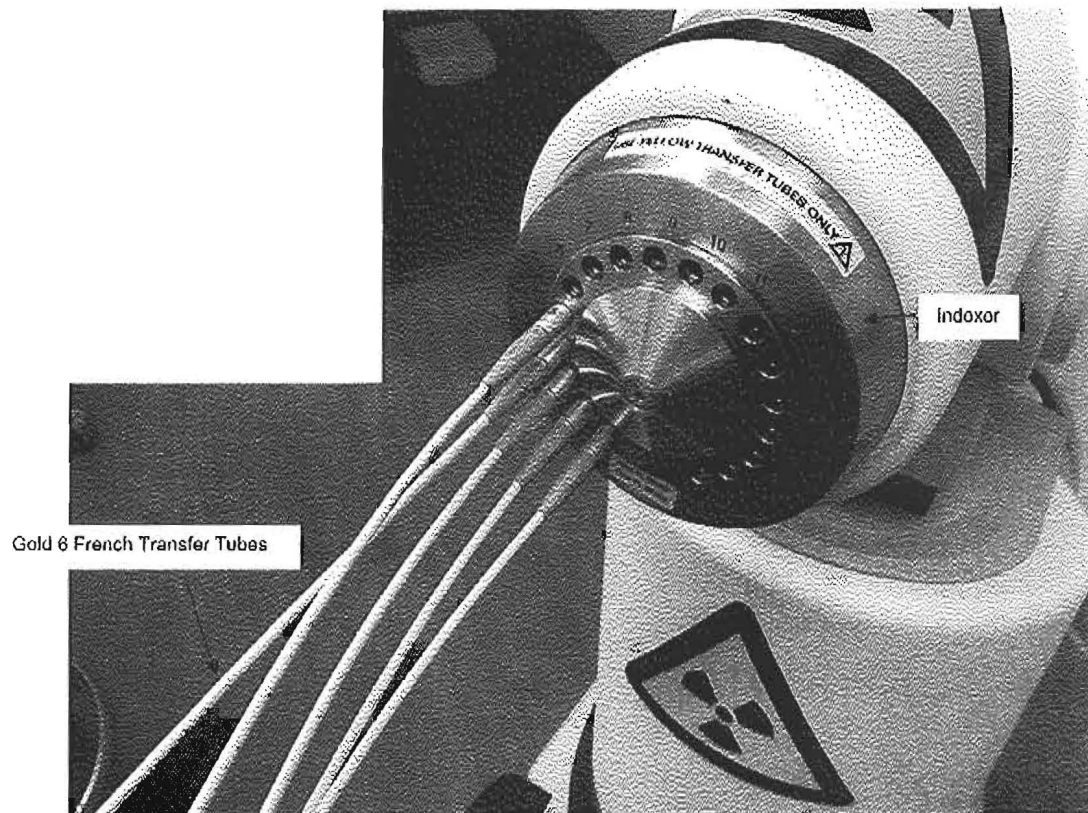
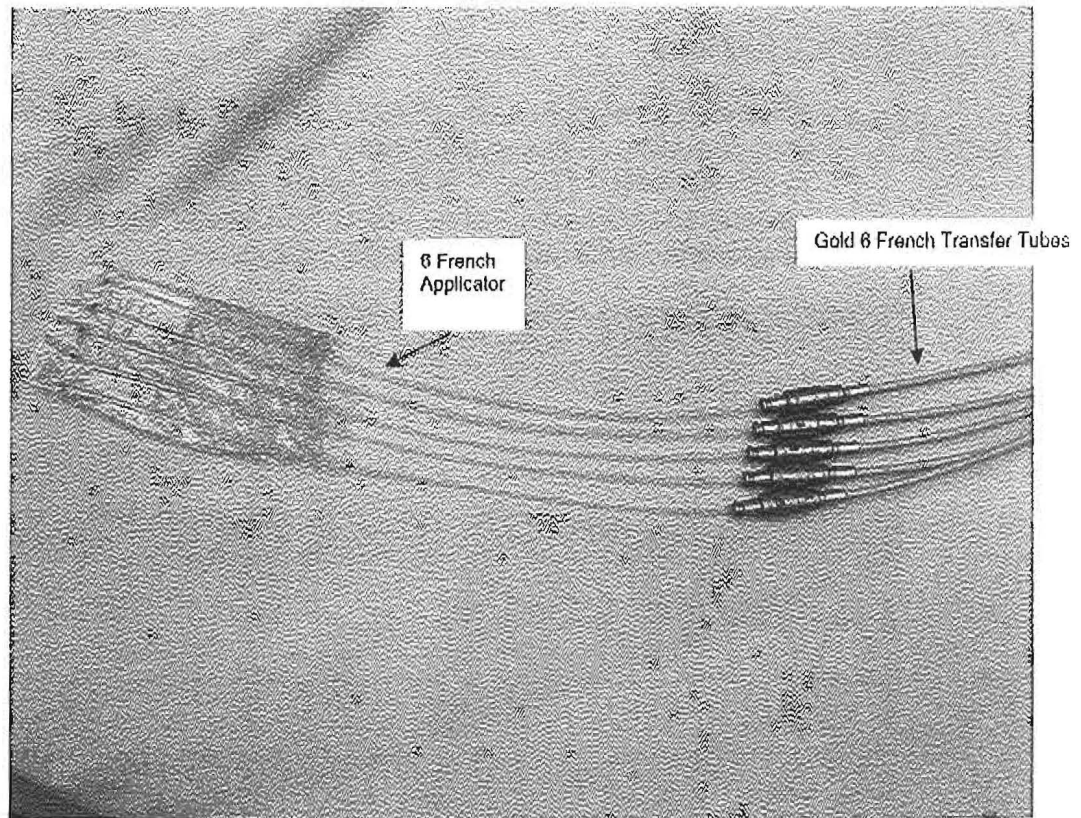




### 6 French Catheters

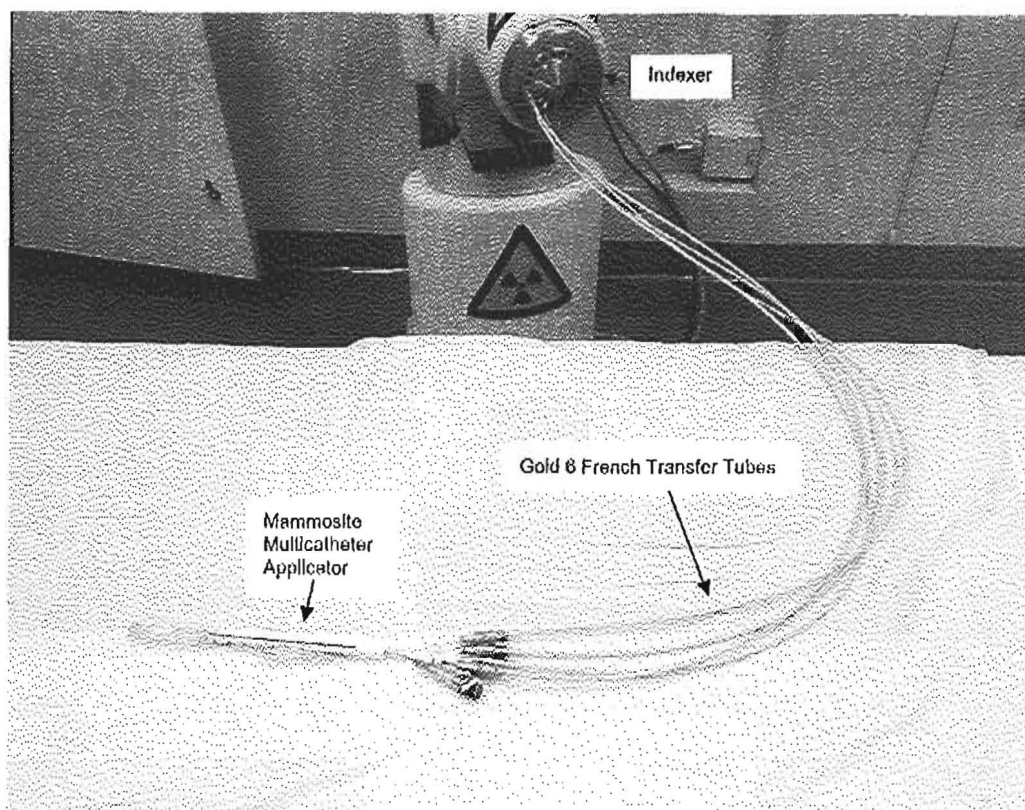
6 French Catheters include prostate, Mammosite MultiCatheter, Savi, interstitial and Syed applicators. Attach the appropriate numbered Gold 6 French Transfer Tube to the same number catheter and connect the other end of the Transfer Tubes the appropriate numbered location in the Indexer.



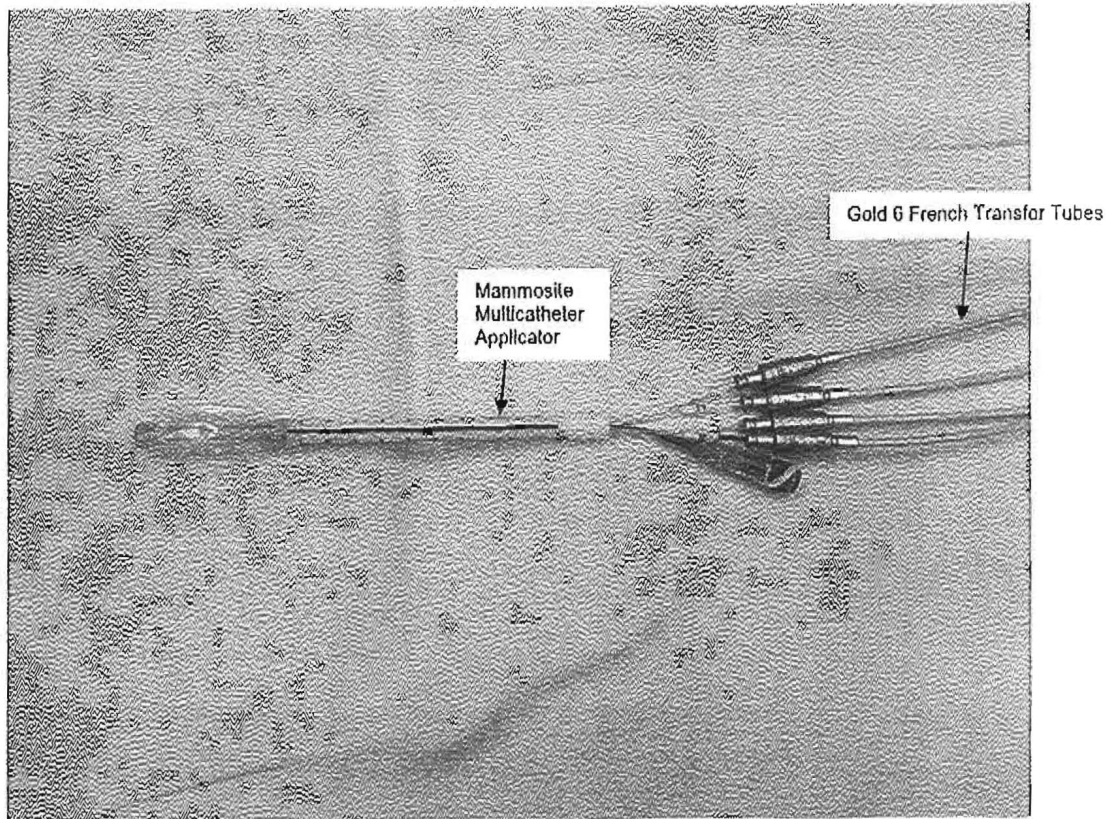


### Mammosite Multi Catheter Applicator

Attach Transfer Tubes 1 to 4 to the appropriately numbered catheter and connect the other end of the Gold 6 French Transfer Tubes to the appropriately numbered location in the Indexer.

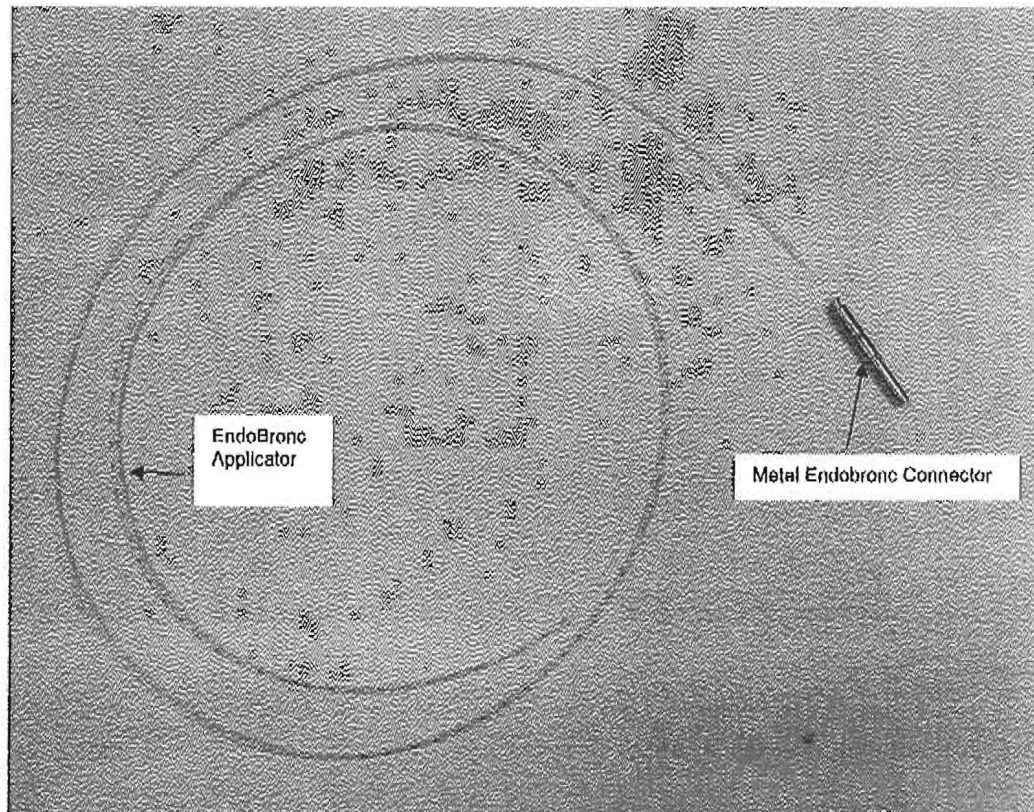


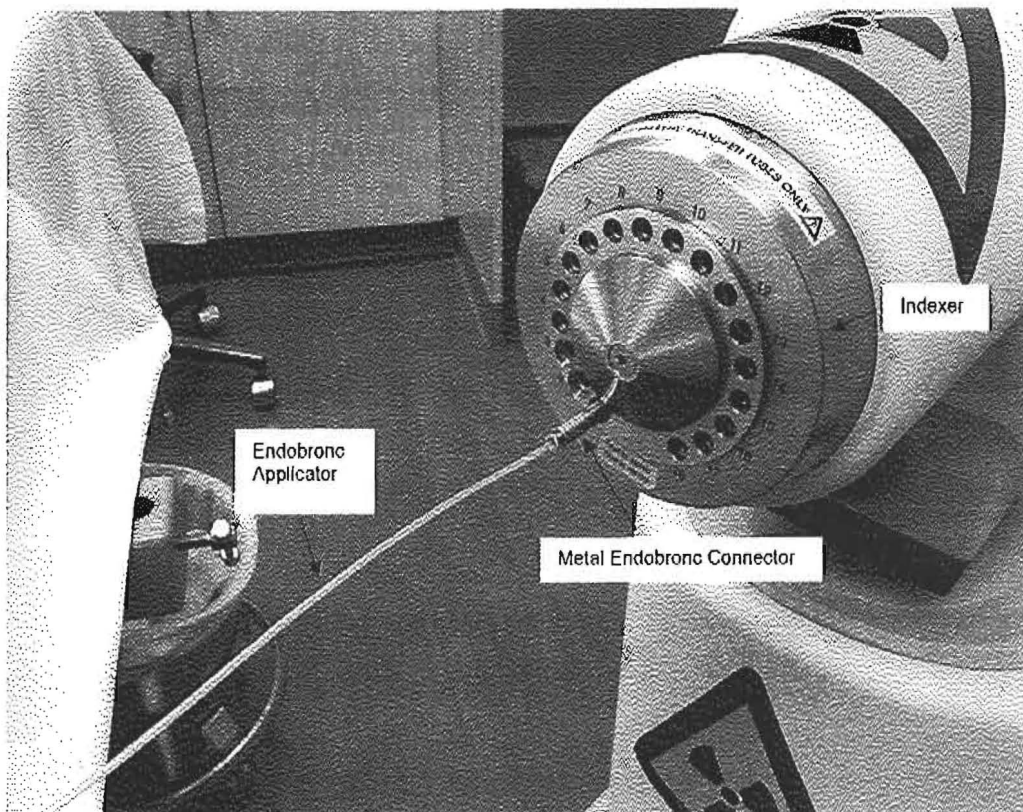
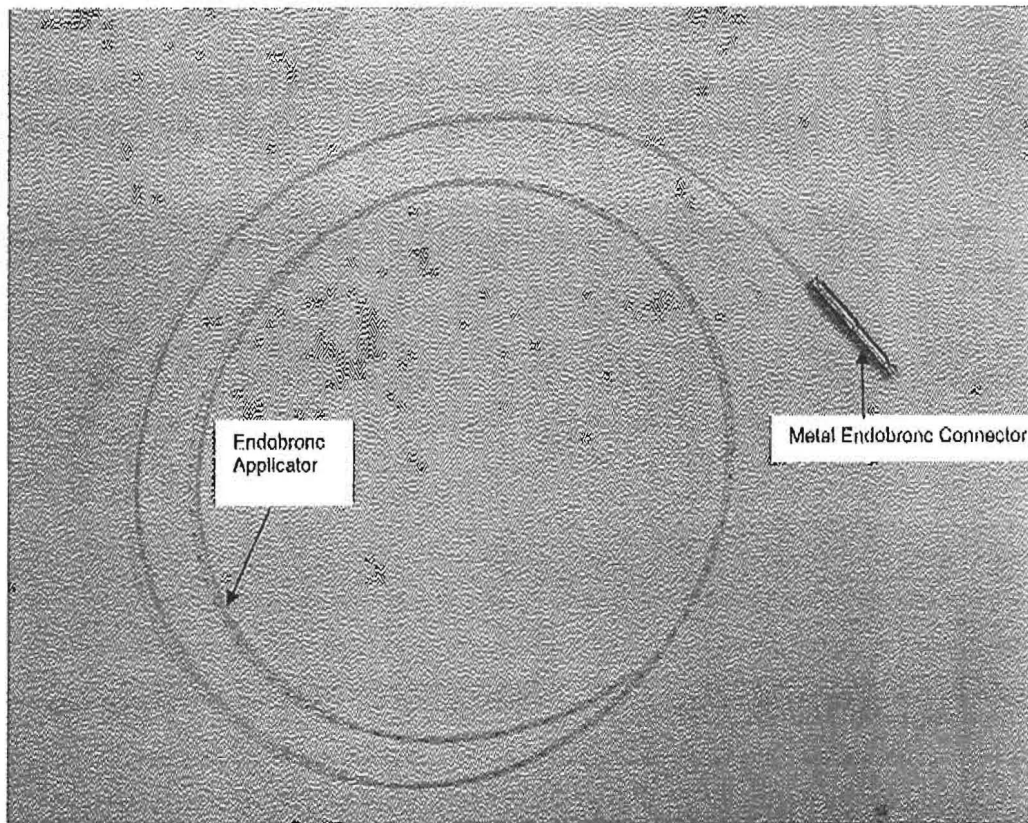




### Endobronchial Applicator

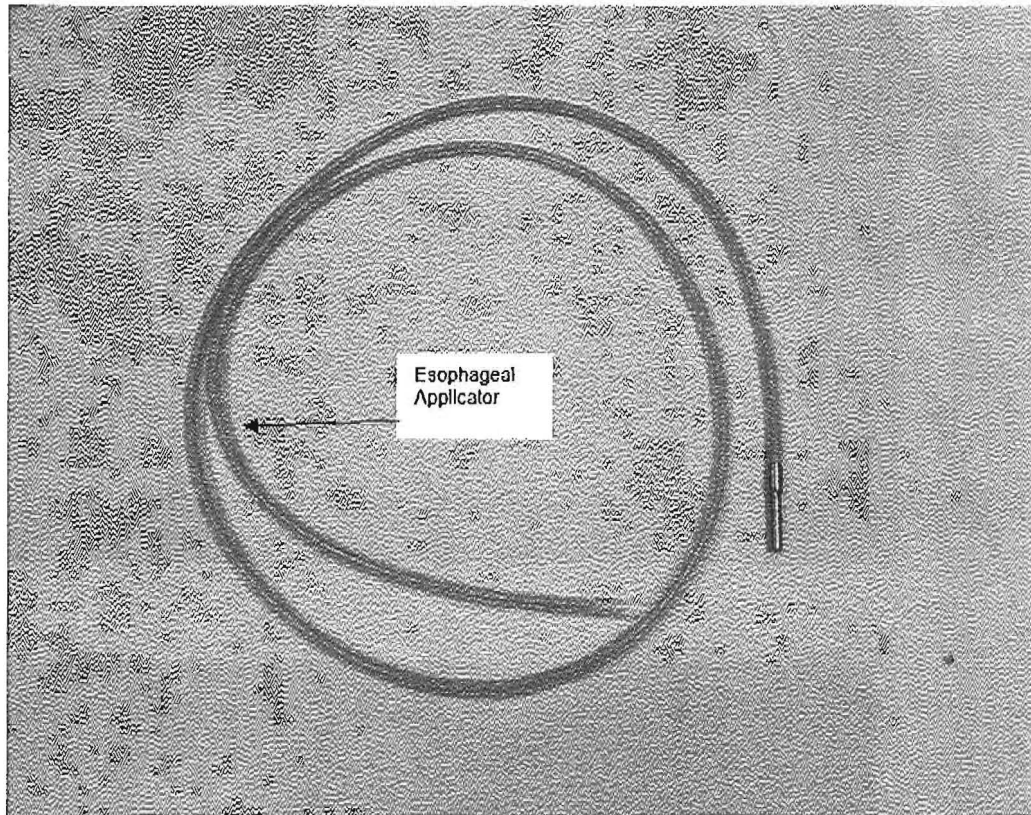
Attach the metal endobronc connector to the end of the endobronc catheter. Insert the connector into the correct numbered position in the Indexer.



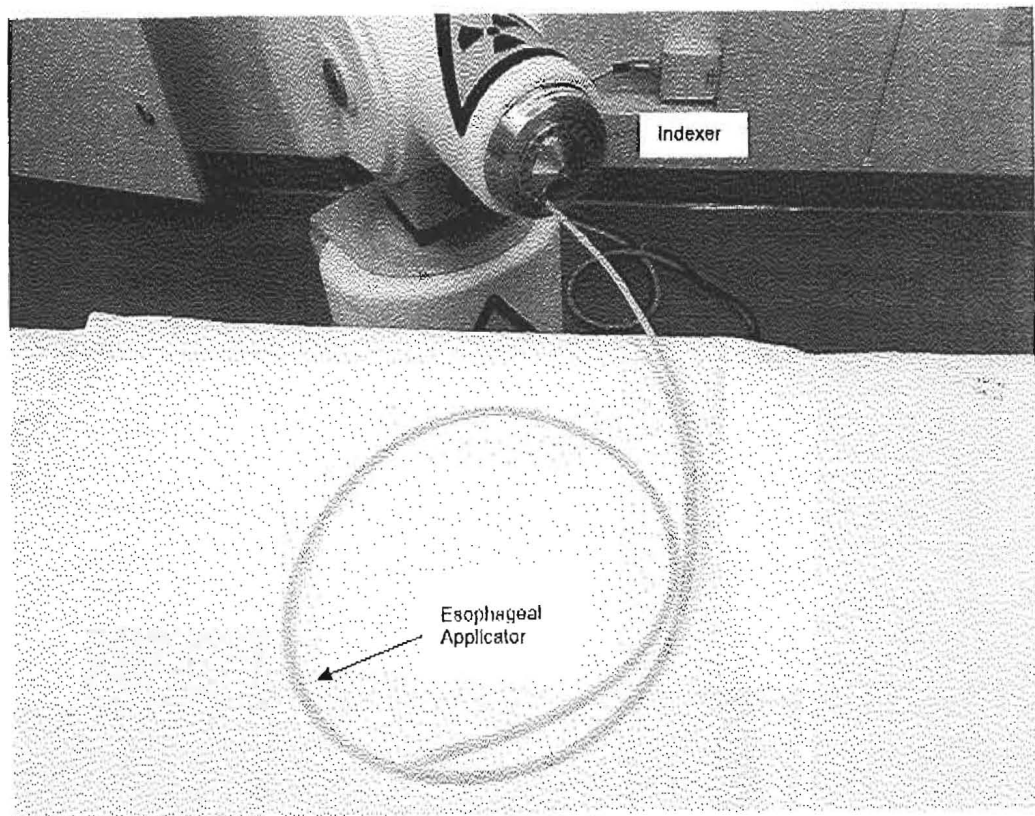
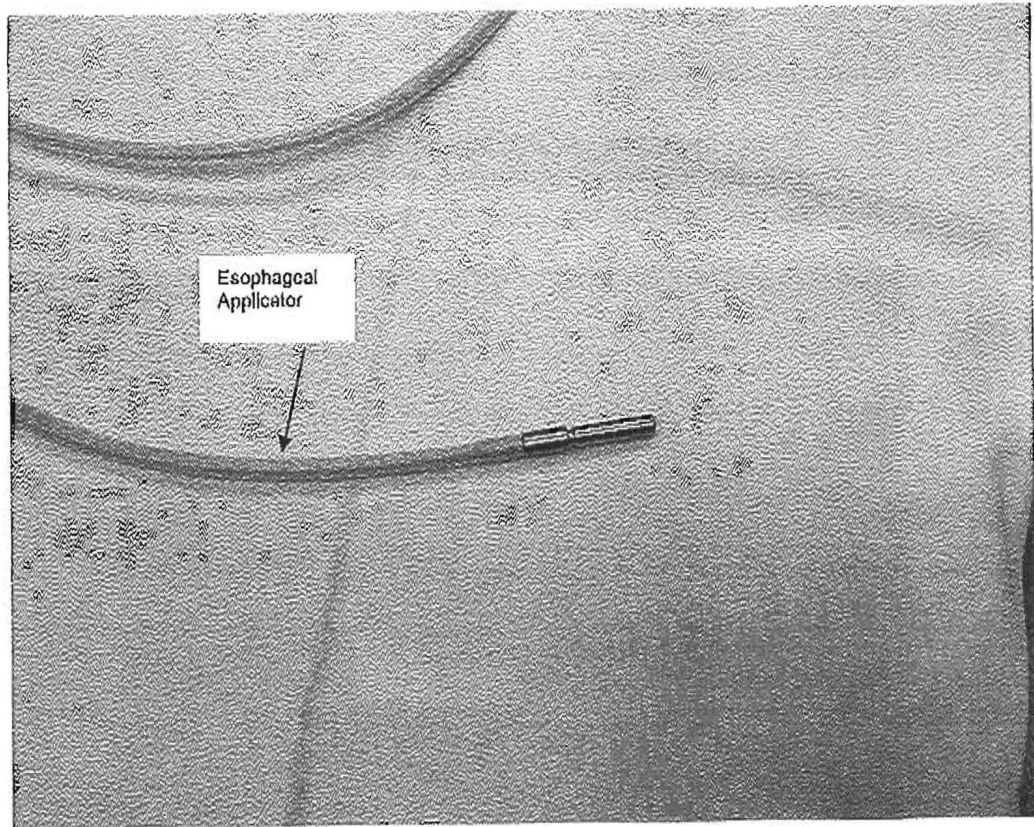


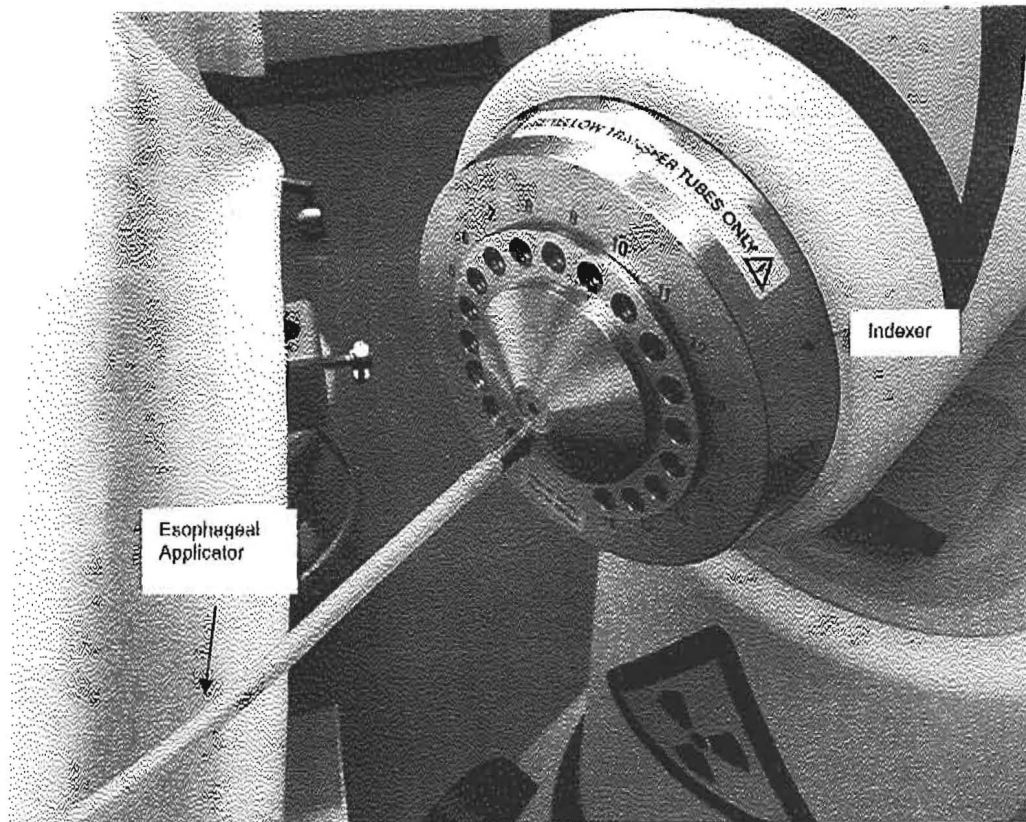
### Esophageal Applicator

Attach the metal endobronch connector to the end of the endobronch catheter. Insert the metal end of the Esophageal applicator into the correct numbered position in the Indexer.



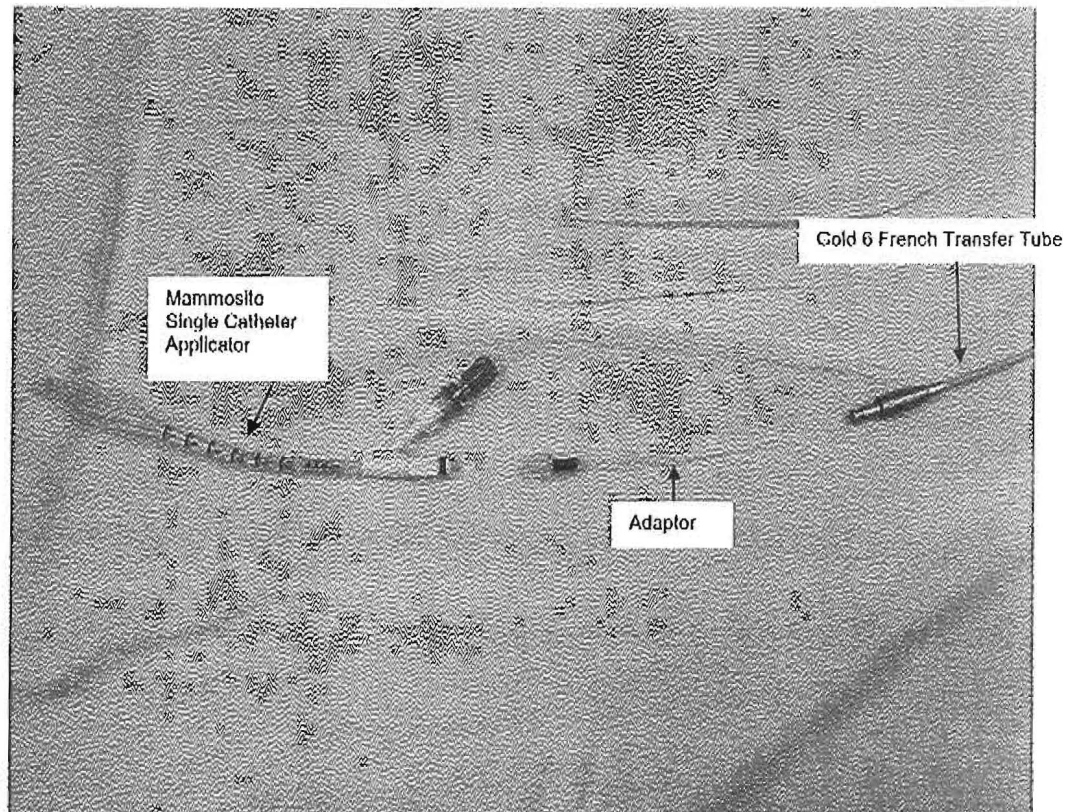


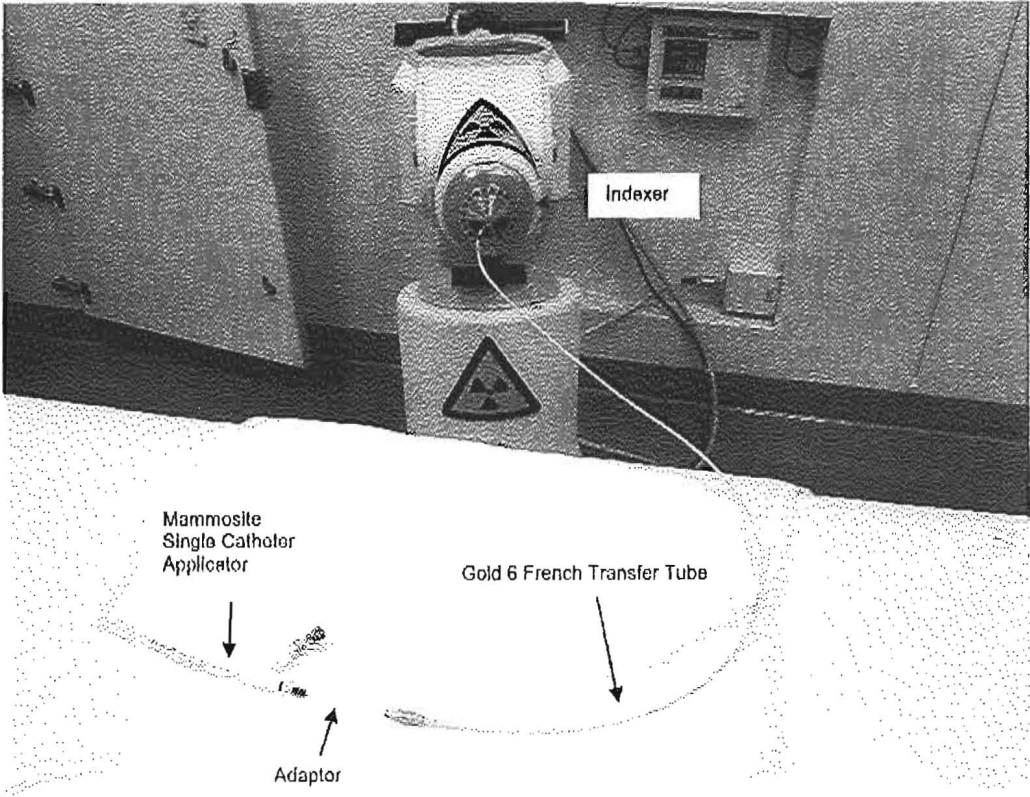
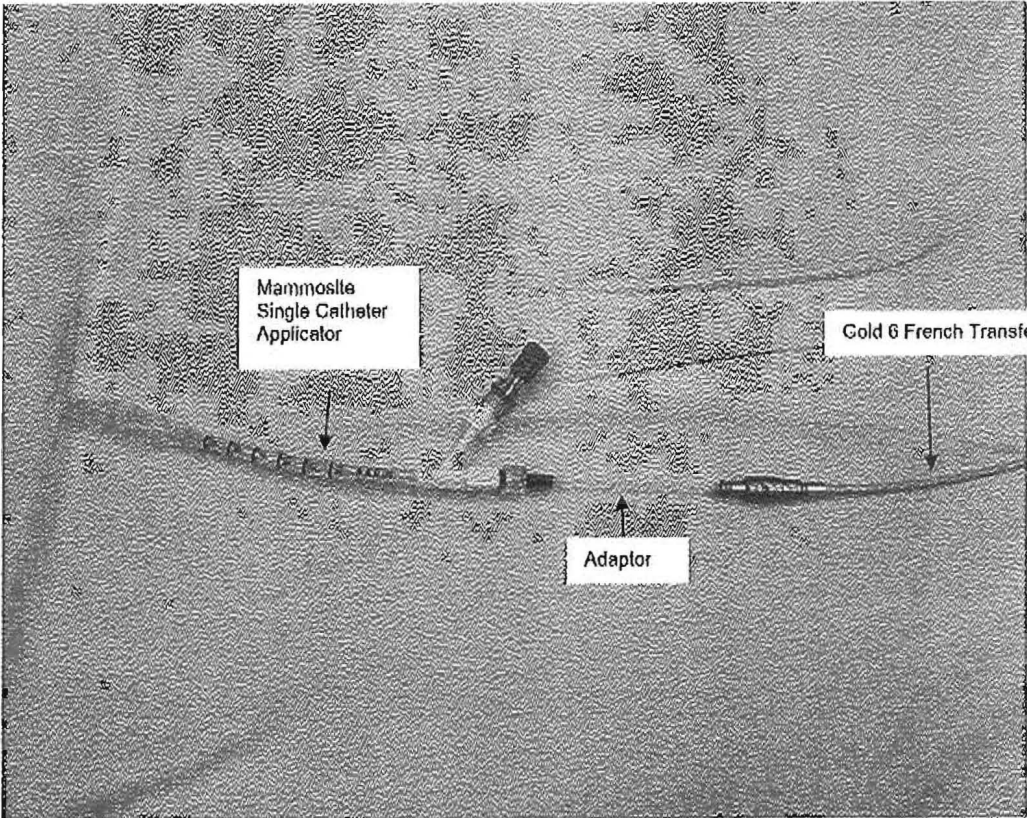




### Mammosite Single Catheter Applicator

Attach the Mammosite adapter on the Mammosite applicator.  
Attach Transfer Tube 1 to the adaptor and connect the other end of the Gold 6 French Transfer Tube to position number 1 in the Indexer.







### Savi Applicator

Slide the metal tube with knob over catheter 1 before connecting the Transfer Tubes. Attach Transfer Tube 1 to 6 for the small, 1 to 9 for the medium and 1 to 11 for the large Savi adaptor and connect the other end of the Gold 6 French Transfer Tubes to the appropriately number position in the Indexer.

