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UNITED STATES ATOMIC ENERGY COMMISSION

# APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

## SUPPLEMENT A—PRECEPTOR STATEMENT

This page is to be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. Page 2 may be used for comments and additional information.

10. NAME AND ADDRESS OF APPLICANT PHYSICIAN (Include ZIP Code.)

Yashbir Mehta, M.D., Radiation Therapy
Louis A. Weiss Memorial Hospital, Chicago, Illinois 60640

11. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 10 ABOVE

| (A) ISOTOPE | (B) CONDITIONS DIAGNOSED OR TREATED | (C) No. Cases Observed (See 1 in key below) | (D) No. Cases Involving Personal Participation (See 2 in key below) |
|---|---|---|---|
| I-131 or I-125 | Diagnosis of thyroid function | | 20 |
| | Determination of blood and blood plasma volume | | 25 |
| | Liver function studies | | 20 |
| | Fat absorption studies | | 20 |
| | Kidney function studies | | 20 |
| | In vitro studies | | 20 |
| Cr-51 | Gastrointestinal protein loss studies | | 20 |
| | Determination of red blood cell volume and studies of red blood cell survival | | 30 |
| Fe-59 | Iron turn over studies | | |
| Co-58or Co-60 | Intestinal absorption studies | | |
| K-42 | Potassium space determinations | | |
| I-131 | Thyroid imaging | | 50 |
| | Brain tumor localization and cardiac imaging | | 40 |
| | Cisternography | | |
| | Lung imaging | | 25 |
| | Liver imaging | | 40 |
| | Kidney imaging | | 40 |
| | Placenta localization | | 40 |
| Cr-51 | Placenta localization | | |
| | Spleen imaging | | 10 |
| Au-198 | Liver imaging | | |
| Hg-197 | Brain imaging | | |
| | Kidney imaging | | |
| Hg-203 | Brain imaging | | |
| Sr-85 | Bone imaging | | |
| Tc-99m | Brain imaging | | 40 |
| | Thyroid imaging | | 40 |
| | Salivary gland imaging | | 40 |
| | Blood pool imaging | | |



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# APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

## SUPPLEMENT A—HUMAN USE

| (A) ISOTOPE | (B) CONDITIONS DIAGNOSED OR TREATED | (C) No. Cases Observed (See 1 in key below) | (D) No. Cases Involving Personal Participation (See 2 in key below) |
|---|---|---|---|
| Tc-99m | Placenta localization | | |
| | Liver and spleen imaging | | |
| | Lung imaging | | |
| | Bone imaging | | |
| Xe-133 | Blood flow studies and pulmonary function studies | | |
| Se-75 | Pancreas imaging | | |
| P-32 | Treatment of polycythemia, leukemia, and Bone metastases | | 10 |
| | Intracavitary treatment | | 10 |
| I-131 | Treatment of thyroid carcinoma | | 15 |
| | Treatment of hyperthyroidism and cardiac condition | | 5 |
| Au-198 | Intracavitary treatment | | |
| Co-60 or CO-137 | Interstitial treatment | | 100 |
| | Intracavitary treatment | | 300 |
| Ir-192 | Interstitial treatment | | 100 |
| Co-60 CO-137 | Teletherapy treatment | | 5000 |
| Sr-90 | Treatment of eye disease | | 100 |

Key to Column (C) and (D) above

1. Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.

2. Personal participation should consist of (a) supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed; (b) collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data; and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

12. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING 1968-1971; more than 1000 hrs.

13. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF

F. Hendrickson, M.D., Presbyterian-St.Luke's Hospital, Chicago, IL 60612
Byun, M.D., Edgewater Hospital Chicago, Illinois
R. Phillips, M.D., Lutera[illegible] General Hospital, Park Ridge, Illinois

Presbyterian-St.Luke's Hosp.
AT Chicago, IL 60612
(Institution) Name and Address

12-00929-01
12-00929-13
(Byproduct Material License Number)

R Hendrickson M.D.
F. Hendrickson, M.D.
(Signature of Preceptor)

# Brachytherapy Accessories

3M's brachytherapy accessories are designed to provide the radiation therapist, physicist and technician with a well-shielded storage and work area.

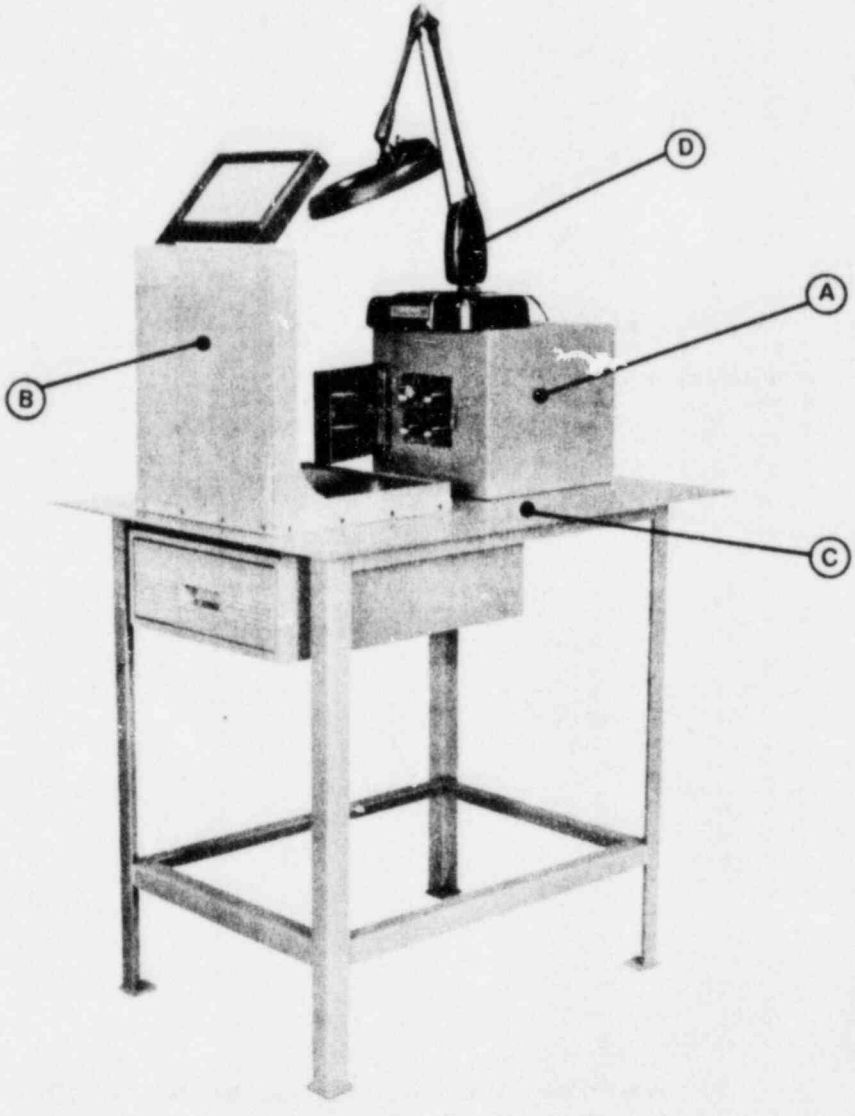
**A. Four-drawer storage safe**
No. 6624
This locking safe has four solid lead drawers which are custom-drilled to accommodate the users source inventories.

The safe's lead walls are 4 inches thick. Each solid lead drawer measures 1.5 x 2.0 x 9.0 inches. Overall safe dimensions are 11 x 11 x 12.5 inches. Weight of safe is 565 pounds.

**B. L Block** No. 6621
This protective handling and loading block minimizes radiation exposure to the user. It measures 14 x 14 x 16.5 inches high, is 1.75 inches thick, and has a high-density lead glass viewing window. Weight of L Block is 260 pounds.

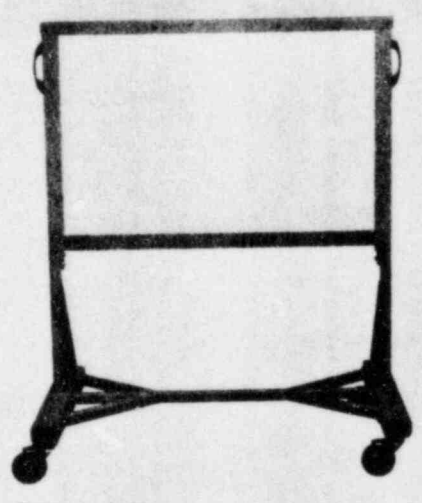
**C. Heavy-duty table** No. 6622
Designed to support 3M's four-drawer safe and L Block, this stationary table is 28 x 36 x 34 inches high, and weighs 130 pounds.

**D. Magnifying viewing lamp**
No. 6620
Designed for placement on top of 3M's four-drawer storage safe, this lamp uses shadow-free fluorescent illumination and a magnifying lens to aid the user in quick source identification and loading.




**Rolling Radiation Shield**
No. 6623

This movable shield provides radiation protection at bedside or in the operating room. Its 1 inch thick lead reduces the dose from a Cs-137 source by more than 90%. Dimensions of the shielded portion are 20 x 30 inches; the top of the shield is 41 inches off the ground. Weight is 300 pounds.



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# 3M Cesium-137 Tube Sources

All of 3M's afterloading applicators for treating uterine/cervical cancer use 3M Cesium-137 tube sources.

All 3M tube sources are constructed of two stainless steel capsules — an inner core and an outer casing. This double encapsulation maintains the integrity of the source and helps ensure user safety. Each source is loaded with thousands of ceramic microspheres labeled with Cs-137 which are tightly packed along the source's active length resulting in a consistently uniform dose distribution pattern.

3M Cesium-137 tube sources are available in standard or miniaturized size.

Each tube source is nickel plated and engraved with a nominal activity and serial number. In addition, each source is color coded on the eyelet end for quick, safe identification of source strength, resulting in minimal exposure during handling.

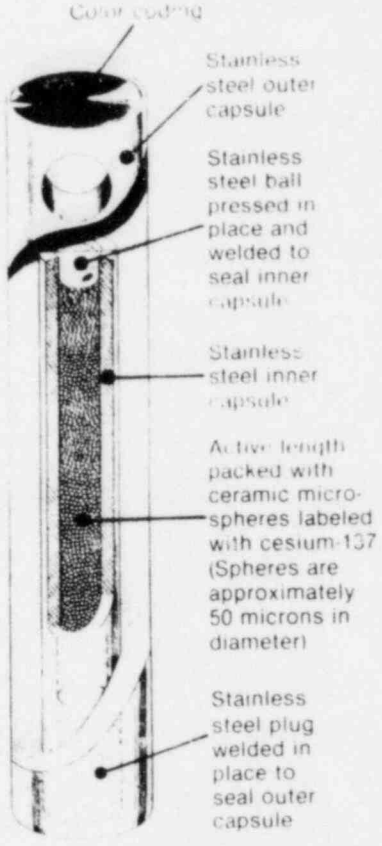
| | |
|---|---|
| 5 mg Ra equivalent | Blue |
| 10 mg Ra equivalent | Green |
| 15 mg Ra equivalent | Yellow |
| 20 mg Ra equivalent | Orange |
| 25 mg Ra equivalent | Red |
| 30 mg Ra equivalent | Violet |
| 35 mg Ra equivalent | White |
| 40 mg Ra equivalent | Black |

The U.S. Nuclear Regulatory Commission (NRC) has granted a three-year leak test interval on 3M standard Cs-137 tube sources (models 6500-6507). The NRC has specified the normal six month leak test interval for the miniaturized tube sources (models 6510-6513).

3M Cesium-137 sources are calibrated in units of millicuries cesium-137. Output from each source is compared directly with that from a National Bureau of Standards (NBS) calibrated cesium-137 source in a 4π ionization chamber. Calibration accuracy is within ±5%.

Milligram radium equivalent values for the Cs-137 sources are calculated by multiplying the cesium-137 millicurie value by 0.398. This factor is a ratio of exposure rate constants for cesium-137 (3.28 R•cm²/hr•mCi) and radium-226 (8.25 R•cm²/hr•mCi) as found in National Council on Radiation Protection and Measurement (NCRP) Report No. 41.

A certification sheet accompanies each order and lists the nominal and actual activities for each serialized source at the date of calibration. The certification also guarantees that bubble leak, immersion soak, and wipe tests have met 3M's stringent quality control standards.




Actual source activity at time of shipment is 0 to 10% above the nominal activity. Tube source activities in an order are grouped within ± 5% of the mean activity of those sources.

There is no additional charge for calibration and certification.

## Cs-137 Sources

| New Cat. No. | Old Cat.No. | mg Ra equiv. | Active Length (mm) | Purchase Price Each | Yearly Lease Price Each |
|---|---|---|---|---|---|
| **Standard Tube Sources (20.0 mm x 3.1 mm)** | | | | | |
| 6500 | 6D6C-CA | 5 | 14 | $265 | $61.69 |
| 6501 | 6D6C-CA | 10 | 14 | $280 | $65.18 |
| 6502 | 6D6C-CA | 15 | 14 | $295 | $68.68 |
| 6503 | 6D6C-CA | 20 | 14 | $310 | $72.17 |
| 6504 | 6D6C-CA | 25 | 14 | $325 | $75.66 |
| 6505 | 6D6C-CA | 30 | 14 | $340 | $79.15 |
| 6506 | 6D6C-CA | 35 | 14 | $355 | $82.64 |
| 6507 | 6D6C-CA | 40 | 14 | $370 | $86.14 |
| 6509 | | dummy source | — | $20 | — |

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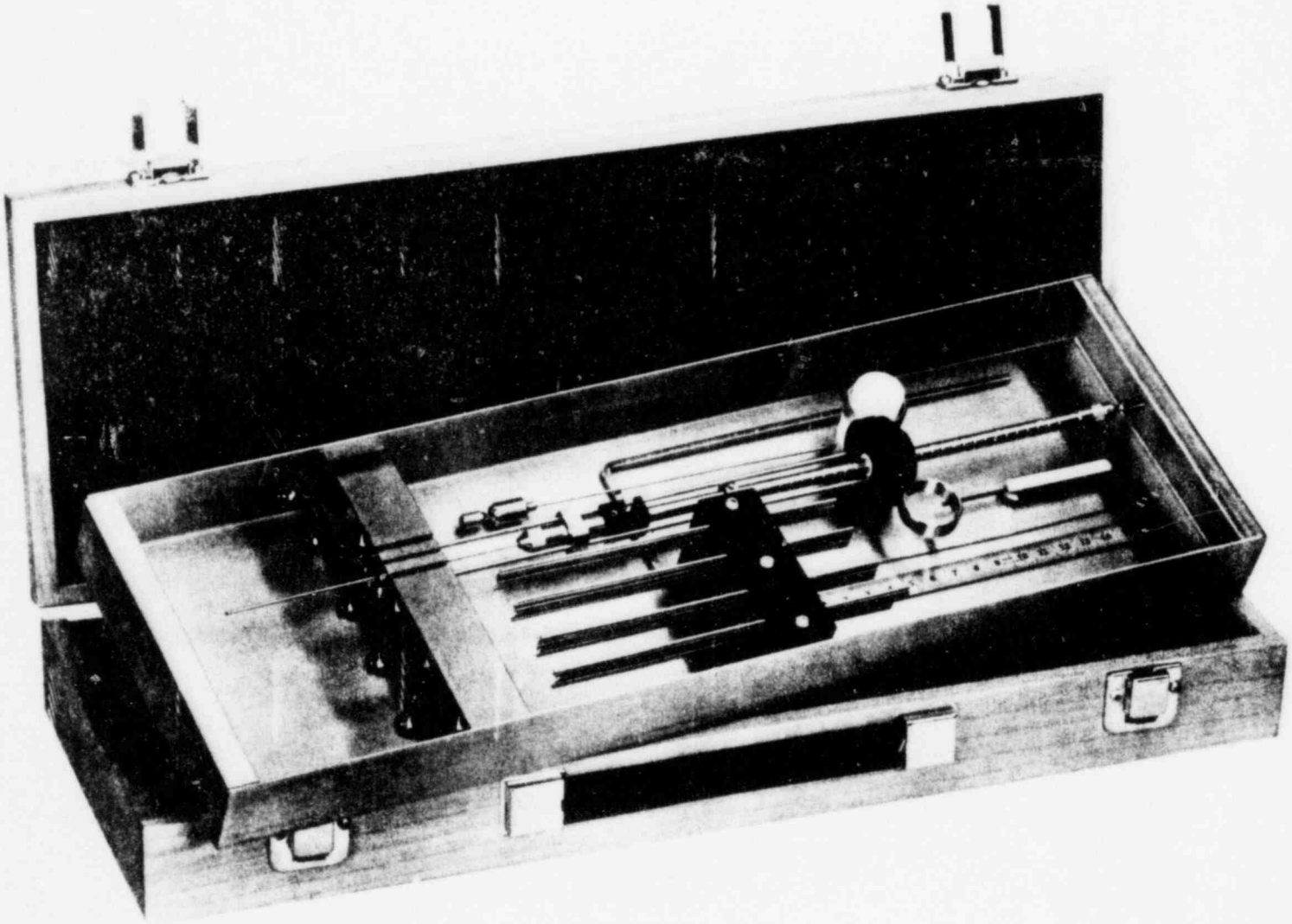
L.A. WEISS MEMORIAL HOSPITAL
NRC LICENSE #12-02[illegible]01

SUPPLEMENT #4

# MICK APPLICATOR

FOR IMPLANTATION OF I-125 SEEDS AND AU-198 GRAINS



## Mick Radio-Nuclear Instruments, Inc.

1470 Outlook Avenue, Bronx, N.Y. 10465
(212) 597-3999

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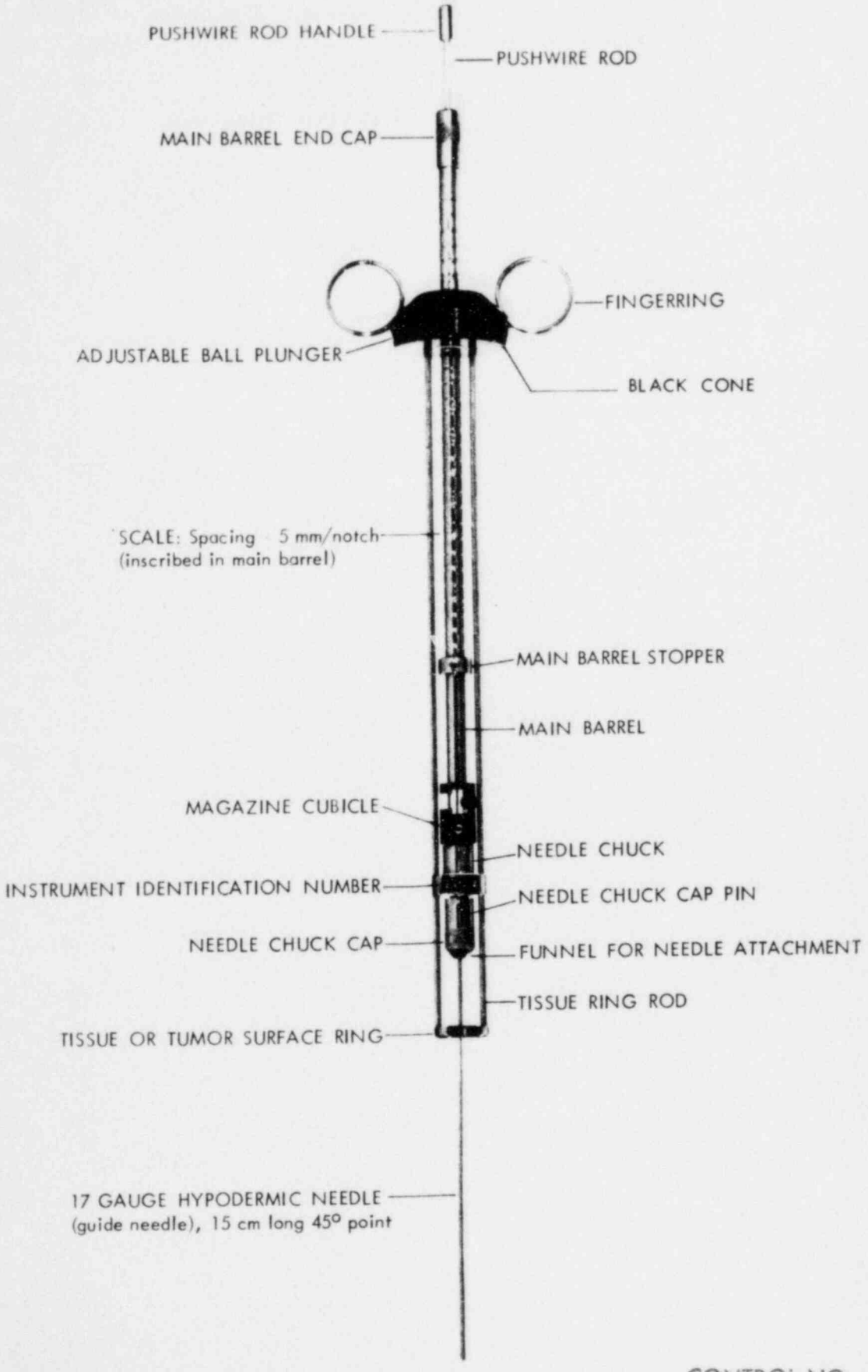
# DESCRIPTION

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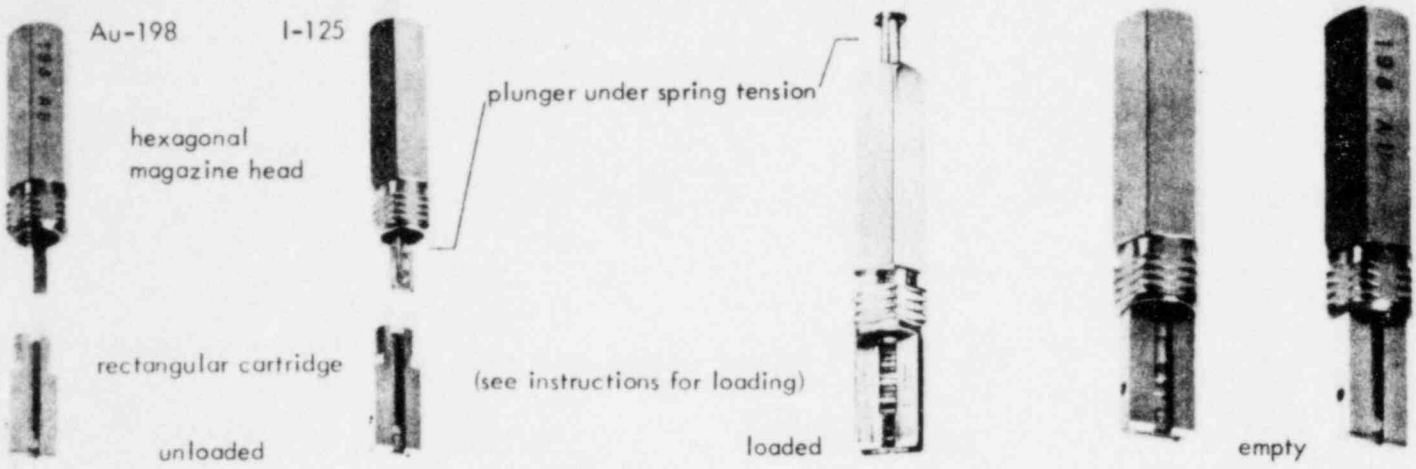
# MAGAZINE




# THE MICK APPLICATOR

is based on the same afterloading principle as the Henschke Implant Instrument and the I-125 Gun. These instruments are provided with a ratched mechanism assuring accurate placement of seeds at any desired depth up to 12 cm. Needles can be withdrawn at 5 mm steps and seeds are manually transferred by means of a stylet into the tumor.

# FEATURES

- lightweight
- easy handling due to simplicity of instrument
- quick exchange of needles without removal of magazine
- suitable for single seed or superficial implants
- ideal for implants of the prostate
- fast insertion of seeds
- accurate placement of seeds up to 12 cm
- minimum exposure due to high density material in magazine
- rugged construction
- all material stainless steel or surface treated
- easy cleaning

# SET INCLUDES:

7308 - Mick Applicator
7609 - magazines (5)
7308-3 - hypodermic stainless steel needles (15 cm long)(32)
7610 - stainless steel ruler (1)
7308-5 - needle holder (1)
7308-6 - magazine holder (1)
7701 - obturators (4)
7702 - loop wire (1)
7703 - needle funnel attachment (1)
7704 - stainless steel L-ruler (1)
7308-7 - stainless steel lift-out tray for sterilization (1)
7308-8 - wooden carrying case (1)

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# INSTRUCTIONS

**Modified by P. Veerling**

## INTRODUCTION

The preparation of the Mick applicator prior to surgery is most important. Many difficulties and inconveniences will be avoided by carefully following certain steps. As with any other new equipment, it is vital to get acquainted with its features and functions before using in surgery. Particular attention should be given to the details of attaching the guide needles to the applicator to insure proper seating and fit, and to the vertical spacing procedures during implantation of the seeds.

The Mick applicator is basically a very simple instrument and its construction is rugged enough so that damage during normal use is practically impossible. Naturally, good care must be taken after each use. All parts should be cleaned and stored in their designated locations. The needles should be placed in the needle holder, which contains four slots for eight needles each. The magazine holder is provided with five holes to store five magazines. The instrument can be cleaned by soaking in hydrogen peroxide immediately after use followed by gentle scrubbing with a soft brush and spraying with jets of water. The sterilization tray can be cleaned with a regular stainless steel cleaning spray. After all parts are correctly stored, it is immediately visible if the set is complete.

## PREPARATION FOR USE

The stainless steel tray containing the applicator and accessories should be examined for completeness. All parts should be visually examined and any moving parts should be quickly tested for smoothness of motion. The guide needles should be straight, not crimped, and the points should be sharp.

The first step in preparing the instrument for implantation of I-125 seeds is loading of the magazines. The magazines are stored in the magazine holder of the stainless steel tray and may be removed by unscrewing counter-clockwise (clockwise for storage). The magazine consists of two components: magazine head and cartridge. The magazine head is a hexagonal body containing a plunger under spring tension. The cartridge has a rectangular shape and contains a slot to hold the I-125 seeds. The front of the cartridge is open for loading. The cartridge is best loaded using our V-block (see our leaflet for loading accessories). Pick up the seeds with our special forceps and feed it into the slot from top to bottom. It is important that the seed is not dropped into the cavity, but placed carefully at the bottom of the cartridge. The next seed is picked up in the same manner and fed into the slot until it rests parallel on top of the previous one. This procedure is repeated until the cartridge is filled to capacity of ten (10) seeds. The seeds should slide smoothly and fit across the opening in the front of the cartridge. Seeds which are under or oversized should not be used since they could cause jamming of the magazine or applicator. When the cartridge is loaded to capacity, insert the magazine head plunger into the cartridge slot and turn clockwise with slight downward pressure until it stops. The magazine is now ready for implantation and can be put back into the stainless steel tray.

The entire stainless steel tray and its contents may be sterilized by autoclaving just prior to use. The wooden case is used for transportation and shelf storage only.

Magazines for Au-198 grains are available and work with the same principle, except that the receiving slot is smaller to accommodate the size of the grains. Au-198 magazines are easily identified because of their golden color.

## AFTERLOADING TECHNIQUE

The implantation of the I-125 seeds is done by means of an after-loading technique. This technique consists of five basic steps: 1) plan distribution of seeds; 2) insert guide needles; 3) attach applicator to needles; 4 insert magazine containing radioactive seeds and; 5) implant seeds through guide needles.

Using the tumor volume and shape, seed strength, and desired therapeutic dose, the spacing between guide needles and between seeds should be planned so as to achieve the desired therapeutic effect with a minimum of complications. The dosimetry of I-125 seed implants is discussed in *Handbook of Interstitial Brachytherapy*, edited by Basil S. Hilaris, M.D. of Memorial Sloan Kettering Cancer Center (published by Publishing Sciences Group, Inc., Acton, Mass. 1975).

Insertion of guide needles may be accomplished as follows. Insert hollow 17 gauge stainless steel needles, 15 cm long, and ground to a 45 degree point, around the periphery of the tumor mass. (For implants through the intact skin, needles with sharp points are preferrable, but for intrathoracic and intra-abdominal implants, it is better to use less sharp needles that do not penetrate and change their position so easily). For a spherical shaped tumor, 0.55 millicurie nominal seed strength and an aim of 16000 rads delivered through total decay, needles are usually spaced 1 cm apart for tumors up to 4 cm in diameter, 1.5 cm apart for tumors from 4 cm to 8 cm, and 2 cm apart for larger tumors. All needles should be inserted parallel to each other. The direction of the needles must be considered carefully before starting, so that their position may be palpated and the maximum number of seeds inserted through one needle. Each guide needle is 15 cm long which means that the length of guide needle implanted within a tumor bed may be calculated once the length of protruding needle is known. This will give a guide as to the number of seeds to be inserted in each needle, once the vertical spacing is also determined.

Attachment of the applicator to the guide needles may be accomplished as follows. After all needles have been inserted into the tumor to the required depth, remove applicator instrument from the stainless steel tray. With one hand, hold the instrument in vertical position by inserting thumb and index finger through the finger ring and with the other hand pull out stylet to its extreme end. In order to avoid deeper penetration of the guide needle, a hemostat may be clamped to the needle at the tissue surface prior to attaching the applicator to the needle. Next, lower the applicator instrument over the protruding part of the needle and when it has reached a definite stop, turn the needle chuck-cap clockwise as far as possible.

With the needle firmly attached to the instrument, a pin located in the needle chuck-cap will appear in the middle of the tissue ring cut-out. Check if needle is firmly attached to the instrument by slightly lifting the instrument upward while grasping the needle firmly. Care must be taken at this point not to displace the correctly inserted needle by pulling it out of the tissue.

With one hand hold the main barrel end-cap and with the other hand push down the finger rings. This will bring the tissue ring down to the tissue surface encircling the neck of the hemostat. The hemostat may be removed at this point. The number appearing on top of the black cone on the main barrel indicates the depth of the needle where the first seed should be placed.

Insertion of the seed magazine is as follows. The loaded magazine is taken out of the storage position and inserted all the way into the magazine cubicle of the instrument. Note, that the stylet must be fully retracted out of position in order to allow the cartridge to be inserted. The magazine is firmly in place once a click is heard indicating that the small ball is caught in the indentation of the cubicle and the cartridge slot is facing in the same direction as the slot in the cubicle.

Implantation of the seeds is accomplished as follows. The first of the ten seeds in the cartridge is deposited into the needle by pushing the stylet all the way down. In order to penetrate hard tissue it may be necessary to apply extra pressure to push the wire rod handle as it reaches its end. If the stylet is not completely depressed, the seed will remain in the needle. Palpation of the under side of the tumor mass during this process can generally give assurance that the seed has in fact been deposited at the bottom of the needle.

To insert the next seed, first hold the main barrel of the applicator like a pencil, simultaneously resting the middle and ring fingers against the black cone, and raise the main barrel by two notches if a 1 cm spacing is desired (three notches for 1.5 cm). Pull the stylet out to its extreme end and observe the retraction of the extended plunger in the hexagonal magazine head. This movement indicates that the next seed has placed itself into the proper position in the cartridge for transfer into the guide needle. Repeat procedure. If the plunger does not move, a slight tapping or amount of pressure with the finger tip to the plunger will most likely place the seed into the proper position. If the stylet still does not go through, exchange the magazine and check for deformed seeds. Never force the stylet. After the plunger has dropped completely, the magazine is empty and the stylet can no longer be advanced. A new cartridge may be exchanged in readiness for subsequent seed implantation.

During the implant procedure, it is recommended that the instrument be rinsed frequently in normal saline or heparin solution in order to remove tissue or blood which will interfere with smooth movement of the moving parts of the applicator. A small syringe or asepto is helpful in forcing the solution through the chuck and magazine cubicle areas.

In addition to radiation exposure precautions, an accurate accountability of all sources must be maintained. For this reason, records of sources implanted and remaining sources must coincide with the number of seeds available. All instruments and surgical accessories including sponges and suction devices should be surveyed immediately after the implant procedure. Follow up of patients may be necessary in order to retrieve sources which are sloughed off post operatively.

Another danger in use of the applicator for I-125 seeds is the rupture of the outer metal encapsulation. This could occur through excessive use of force in the event of a sticking seed or seed in a cartridge. The tiny ceramic beads containing radioactive I-125 are barely visible once the capsule is ruptured. This can be avoided by proper use of the instrument and sizing of the seeds before use.

An individual familiar with radiation safety procedures and pertinent regulations should be consulted prior to undertaking an implant program in order to assure proper radiation safety of personnel, patient, patient's family, and the general public. A number of guidelines are available through the National Council on Radiation Protection and Measurements, 4201 Connecticut Avenue, NW, Washington, D.C. 20008 and the source suppliers.

## CLEANING

Immediately after the implant procedure and before start of the cleaning operations, all guide needles should be checked for possible remaining seeds. This can be accomplished by inserting the loop wire through each needle and observing for any seeds which are ejected from the bottom.

For best results remove tissue and blood from instrument immediately after use. Soaking in hydrogen peroxide or heparin solution should loosen all biological materials. The applicator and accessories should be gently scrubbed with a soft brush and loose materials washed away with a jet of water. A loop wire is included for removing stubborn debris from guide needles. Keeping the instruments clean and in good operating condition insures a precise and efficient implant procedure.

## RADIATION SAFETY

Using the Mick applicator and accessories entails handling solid radioactive sources, namely I-125 seeds, Au-198 grains and similar sources. As with any other sources, the principles of time, distance, and shielding should be utilized. Personnel monitoring devices, such as low energy pocket chambers, film badges and thermoluminescence dosimeter devices, should be utilized. Portable shielding devices for bodies and eyes are available as accessories through this company. Lead-rubber gloves are available for surgical manipulation and handling during the implant procedure. These are especially effective for I-125 seed implants because of the low energy of the radionuclide.