Medical-Surgical Division

3M Center
St. Paul, Minnesota 55144-1000
612/733 1110

3M

August 15, 1988

Bruce S. Mallet, Ph.D.
Chief, Materials Licensing
U.S. Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Re: Materials License 22-00057-59MD

A no fee

Dear Dr. Mallet:

This is in response to a letter from V.L. Miller dated September 24, 1987, requiring license amendments to authorize labeling changes for sources continuing by product material. These revisions became necessary subsequent to NRC's recodification of 10 CFR Part 35. Therefore, this letter constitutes a license amendment application to provide revised labeling for sources distributed under Materials License 22-00057-59MD.

Enclosed with this letter please find samples of revised labeling for I-125 Seeds and 3M Cesium - 137 sources. These items include vial labels, pig labels, and package inserts for source model numbers 6702, 6711, 6500, 6520, 6510, 6570. 6550, 6530, and 6540.

If you have any questions regarding this application, please feel free to contact me (612/733-6421).

Sincerely yours,

Jacquelyn D. Bush

Jacquelyn D. Bush
Sr. Regulatory Affairs Specialist
3M Medical-Surgical Division
3M Center, Building 270-4A-05
St. Paul, MN 55144-1000

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Enclosure

LABELING

for

I-125 SEEDS

License Amendment Application
Materials License 22-00057-59MD
August 15, 1988

CONTROL NO 86026

3M

Cesium-137 Brachytherapy Sources

Made in U.S.A. for
3M Medical-Surgical Division
St. Paul, MN 55144-1000

Description: Cesium-137 Sources consist of two stainless steel capsules, an outer casing and an inner core containing Cs-137-labeled ceramic microspheres.

Product No. _____ _____

Total activity this container _____ mCi Cs-137

Number of Sources _____

Assay date _____

Store source in shielded container provided, or in an equivalent container with a shielding value equal to one inch of lead.

See package insert for instructions on handling and storage of Cesium-137 Sources.

Caution
Radioactive
Material

WARNING: The U.S. Nuclear Regulatory Commission has approved this sealed source for distribution to persons licensed to use byproduct material identified in §35.400 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

CAUTION: Federal law restricts this device to sale by or on the order of a physician. Maintain proper radiation safety precautions at all times.

34-7025-5041-8 A 3/88

CONTROL NO. 86026

I-125 Seeds

3M

Therapeutic For Interstitial Brachytherapy 6702

Made in U.S.A. by
3M Medical Surgical Division

DESCRIPTION: I-125 Seeds consist of a welded titanium capsule containing iodine-125 adsorbed on anion-exchange resin spheres.

Apparent activity range: _____ mCi

Total apparent activity this vial: _____ mCi

Number of seeds _____ Assay Date _____

Lot no. _____

See package insert for instructions on handling and storage of I-125 Seeds.

Caution
Radioactive
Material

WARNING: The U.S. Nuclear Regulatory Commission has approved this sealed source for distribution to persons licensed to use byproduct material identified in §35.400 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and outside the United States, to persons authorized by the appropriate authority. **CAUTION:** Federal law restricts this device to sale by or on the order of a physician. Maintain proper radiation safety precautions at all times. 3/88

I-125 Seeds

3M

Therapeutic For Interstitial Brachytherapy 6711

Made in U.S.A. by
3M Medical-Surgical Division
St. Paul, MN 55144-1000

DESCRIPTION: I-125 Seeds consist of a welded titanium capsule containing iodine-125 adsorbed onto silver rod.

Apparent activity range: _____ mCi

Total apparent activity this vial: _____ mCi

Number of seeds _____ Assay Date _____

Lot no. _____

See package insert for instructions on handling and storage of I-125 Seeds.

Caution
Radioactive
Material

WARNING: The U.S. Nuclear Regulatory Commission has approved this sealed source for distribution to persons licensed to use byproduct material identified in §35.400 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and outside the United States, to persons authorized by the appropriate authority. **CAUTION:** Federal law restricts this device to sale by or on the order of a physician. Maintain proper radiation safety precautions at all times. 3/88

I-125 Seeds®

3M

In Carrier Therapeutic For Interstitial Brachytherapy

6720

Description: I-125 Seeds in Carrier consists of a group of I-125 Seeds housed at the fixed spacing indicated (center to center) within a braided absorbable carrier. The I-125 Seeds consist of a welded titanium capsule containing iodine-125 absorbed onto a silver rod. The carrier material is Ethicon no. 1 Vicryl® synthetic absorbable suture (Polyglactin 910).

Apparent activity range: _____ mCi

Total apparent activity _____ mCi

Number of seeds _____ Assay Date _____

Lot no. _____ Spacing _____

See package insert for instructions on handling and storage of I-125 Seeds in carrier.

Made in U.S.A. by
3M Medical-Surgical Division
St. Paul, MN 55144-1000

Caution
Radioactive
Material

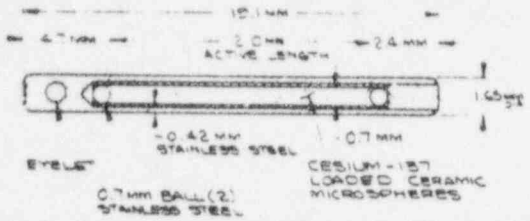
WARNING: The U.S. Nuclear Regulatory Commission has approved this sealed source for distribution to persons licensed to use byproduct material identified in §35.400 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority. **CAUTION:** Federal law restricts this device to sale by or on the order of a physician. Maintain proper radiation safety precautions at all times. **3/88**

3M Cesium-137

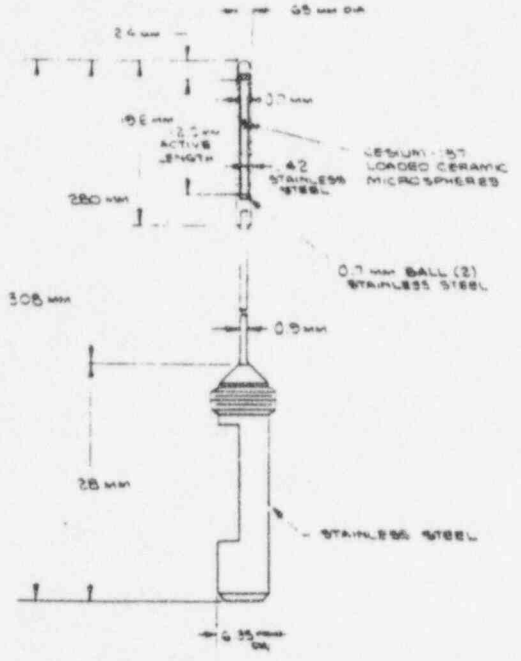
Miniaturized Tube Sources Series 6510, 6570
Heyman Afterloading Sources Series 6550

Description

3M Cesium-137 miniaturized tube sources consist of two stainless steel capsules - an outer casing and an inner core containing cesium-labeled ceramic microspheres packed along the active length. Each miniaturized tube source is nickel-plated, and engraved with the nominal activity and serial number.



3M Cesium-137 Heyman afterloading sources consist of a 3M Cesium-137 miniaturized tube source brazed to a 0.9 mm stainless steel wire. The distal end of the unit consists of a beveled handle with a screw-lock mechanism. The handle is engraved with the source nominal activity and serial number.



Physical Characteristics

Cesium-137 has a half-life of 30.0 years and decays with the emission of a monoenergetic gamma ray of 622 keV.

To correct for the physical decay of cesium-137, the decay factors at selected years after the assay date are shown in the table following.

Decay Chart for Cesium-137, Half-Life 30.0 Years

Years	Decay factor	Years	Decay factor	Years	Decay factor
0.0	1.00	3.5	.92	7.0	.85
0.5	.99	4.0	.91	7.5	.84
1.0	.98	4.5	.90	8.0	.83
1.5	.97	5.0	.89	8.5	.82
2.0	.95	5.5	.88	9.0	.81
2.5	.94	6.0	.87	9.5	.80
3.0	.93	6.5	.86	10.0	.79

Radiation Protection

The half-value layer in lead for cesium-137 is 6 mm.

Actions

3M Cesium-137 miniaturized tube sources and Heyman afterloading sources emit a gamma ray of 662 keV. The clinical efficacy of the sources is a result of interaction of this ionizing radiation with the tissue being treated.

Indications

3M Cesium-137 miniaturized tube sources are used primarily for the treatment of gynecological cancers, in addition to cancers located in or about other body cavities.[1] 3M Cesium-137 Heyman afterloading sources are used for treatment of endometrial cancer.[2]

3M Cesium-137 miniaturized tube sources and Heyman afterloading sources may be used in conjunction with other treatment modalities.

The use of 3M Cesium-137 sources for any indication should be prescribed by a qualified practitioner.

Precautions

Preparation for Use

3M Cesium-137 miniaturized tube sources and Heyman afterloading sources are radioactive and appropriate precautions must be taken when handling these sources. All steps of the use procedure should be planned in advance to minimize radiation exposure to personnel consistent with published exposure limits.[3]

Personnel monitoring is required for individuals working with cesium-137 sources. A film badge or TLD dosimeter worn on the body and, for handling, a ring dosimeter will provide adequate detection.

3M Cesium-137 miniaturized tube sources and Heyman afterloading sources must be stored in a protective lead safe or vault of such thickness as is necessary to reduce exposure rates to permissible levels.[4] When transporting sources within the hospital premises, an appropriate carrier with adequate shielding should be used.

All manipulations involving 3M Cesium-137 miniaturized tube sources and Heyman afterloading sources should be carried out behind shielding of such size and thickness as will adequately shield the operator. DIRECT CONTACT WITH THE SOURCES SHOULD BE AVOIDED. The preparation of applicators incorporating tube sources should be carried out behind a protective L-block, constructed of lead. In addition, 3M Cesium-137 sources should be handled only with forceps, with as much distance as practical between sources and the operator. 3M CESIUM-137 MINIATURIZED TUBE SOURCES AND HEYMAN AFTERLOADING SOURCES SHOULD NEVER BE TOUCHED WITH THE HANDS.

Radiation detection equipment should be available whenever 3M Cesium-137 miniaturized tube sources and Heyman afterloading sources are being handled.

Application to Patient

3M Cesium-137 miniaturized tube sources and Heyman afterloading sources should be used only by individuals who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

All practical physical protection should be provided during the application procedure. When the use of protective barriers is not practical, operators must rely on distance and speed to minimize radiation exposure.[4] Persons should not remain closer than necessary to the radioactive material, either before or after its introduction into the patient.

The correct fitting of an unloaded applicator to the anatomy of the patient should be verified prior to the insertion of cesium-137 miniaturized tube sources and Heyman afterloading sources to assure that the prescribed radiation dose is delivered to the patient. In addition, careful planning of the geometrical arrangement of the sources will reduce radiation exposure to personnel during the loading procedure by avoiding hesitation and changes.

Treatment of Patients

All patients should be informed of the nature of treatment with 3M Cesium-137 miniaturized tube sources and Heyman afterloading sources and the expected period of time during which radiation precautions will be necessary. Patients, their close associates, and associated medical personnel should be instructed in the necessary radiation safety procedures required for someone who is being treated with cesium-137. Guidelines for necessary precautions have been established by the National Council on Radiation Protection and Measurements and are detailed in NCRP Reports.[3, 4, 5, 6, 7]

The bed, cubicle, or room of the hospital patient should be marked with a sign or tag indicating the presence of brachytherapy sources. In addition, the patient's chart should indicate the number and nature of the sources, the total amount of activity, and time and date of application and anticipated removal.

The extent to which a patient with 3M Cesium-137 miniaturized tube sources and Heyman afterloading sources must be segregated depends upon the total activity used, its location in the patient, how long it is to be there, and to what exposure other persons near him are subject. Consideration must be given to the proximity of patients in adjoining rooms, since normal wall construction may have little value in shielding gamma radiation.

A patient being treated with 3M Cesium-137 miniaturized tube sources and Heyman afterloading sources should be restricted to his room. The patient must not be allowed to leave the hospital until the sources have been removed. During the course of treatment, the patient should carry a wristband or suitable identification which provides information regarding the radioactive nature of the treatment.

During the course of treatment with 3M Cesium-137 miniaturized tube sources and Heyman afterloading sources, surgical bandages and dressings should be changed only by individuals trained in radiation safety techniques. Dressings must not be discarded until they have been checked for the presence of sources and found to contain none. Bed baths should be omitted while the sources are in place. Nursing care necessary for the patient's well-being should be preplanned and delivered quickly to minimize time spent at the bedside.

If a source become loose or falls out, it should be picked up with forceps and placed in a shielded container in the patient's room. The physician and radiation protection supervisor should be notified of such an event as soon as possible after its occurrence.

Removal/Accountability

When 3M Cesium-137 miniaturized tube sources and Heyman afterloading sources are removed from a patient, the same radiation safety procedures used for insertion should be observed. All linens, dressings, clothing, and equipment should be kept within the cubicle or room where the removal takes place until all sources are accounted for. Appropriate detectors and a shielded carrier should be available in the room where source removal takes place.

After the removal procedure, it should be determined that all 3M cesium-137 sources have been removed. This may be accomplished by surveying the patient with an appropriate radiation detector.

Following their removal from a patient, 3M Cesium-137 miniaturized tube sources and Heyman afterloading sources must be returned to an individual designated as the source custodian for cleaning, inventory, and storage in a controlled area.

Cleaning/Sterilization/Storage

3M Cesium-137 miniaturized tube sources and Heyman afterloading sources should be cleaned following their removal from the patient and before being returned to a storage safe. While cleaning or sterilizing sources, adequate precaution should be taken to avoid radiation exposure to the staff, damage to sources, and loss of sources.

Cleaning of 3M Cesium-137 miniaturized tube sources and Heyman afterloading sources may be accomplished by rinsing or soaking the sources in water or, if dried fluids are present, in a hydrogen peroxide: water (1:1) solution. An ultrasonic bath may also be used. Following cleaning, 3M Cesium-137 sources should be air-dried or rinsed in alcohol.

Abrasive substances (e.g. metal cleaners, polishes) must not be used to clean 3M Cesium-137 miniaturized tube sources and Heyman afterloading sources. In addition, sources should not be allowed to contact mercury or mercury-containing solutions, or any other toxic or biologically hazardous materials.

3M Cesium-137 miniaturized tube sources and Heyman afterloading sources may be sterilized with steam (autoclave), dry heat, or ethylene oxide (EO). Regardless of the method selected, the sources should be placed in an adequately shielded container prior to placement in the sterilization chamber. Manipulation of the sources prior to or following sterilization should be carried out behind shielding of such size and thickness as will adequately shield the operator. In addition, the sources should be handled only with forceps. Autoclaves should be equipped with traps or other means to prevent source loss through the drain hole. 3M Cesium-137 miniaturized tube sources and Heyman afterloading sources withstand normal sterilization conditions of temperature and pressure. The sources retain their integrity at temperatures of 800° C for 60 minutes.

Leak Testing

3M Cesium-137 miniaturized tube sources and Heyman afterloading sources are leak tested prior to shipment and the results provided on shipping certification papers that accompany each shipment.

3M Cesium-137 miniaturized tube sources and Heyman afterloading sources must be leak tested periodically by the user according to requirements described in 10 CFR 35.59. The U.S. Nuclear Regulatory Commission has specified a six-month leak test interval for these sources, series 6510, 6570, and 6550 (formerly 6B6G).

Adverse Reactions

No adverse reactions involving 3M Cesium-137 miniaturized tube sources and Heyman afterloading sources have been reported.

Dosage and Administration

The total activity of 3M Cesium-137 miniaturized tube sources and Heyman afterloading sources required for any given treatment depends upon several factors, among which are tumor type and size, anatomical geometry, and previous radiation history of the tumor site. The treatment plan for a particular patient, including the number and strength of sources and the length of treatment time, should be prescribed by a qualified physician. Cesium-137 sources decay at a rate of approximately 2% per year, and, as a result, treatment times should be adjusted periodically.

How Supplied

3M Cesium-137 miniaturized tube sources are available, in series 6510 (with eyelet), 19 mm long × 1.65 mm diameter, with an active length of 12 mm. The sources contain cesium-137 in amounts listed below, by product number.

Series 6510

Model	mg Ra equivalent
6510	5
6511	10
6512	15
6513	20
6514	25

Sources of the same dimensions, constructed without an eyelet, are available upon special request, as series 6570.

3M Cesium-137 Heyman afterloading sources, series 6550, are available as miniaturized tube sources brazed to a 0.9 mm stainless steel wire; the distal end consists of a beveled handle with a screw-lock mechanism for sealing into Heyman afterloading capsules. The sources, Model 6551, contain 10 mg Ra equivalents of activity. Other 6550 series Heyman sources containing 5, 15, and 20 mg Ra equivalent are available upon special request.

Each 3M Cesium-137 miniaturized tube source is nickel-plated and engraved with the nominal activity (in milligram radium equivalents) and serial number. This same information is engraved on the handle of each 3M Heyman afterloading source.

3M Cesium-137 miniaturized tube sources and Heyman afterloading sources are packaged in a lead pig which is labeled to indicate the isotope, amount of activity, and calibration date, as well as precautionary regulatory statements pertaining to licensing of the product.

Licensing

The U.S. Nuclear Regulatory Commission has approved this sealed source for distribution to persons licensed to use byproduct material identified in §35.400 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

Federal law restricts this device to sale by or on the order of a physician.

References

1. Fletcher, GH, M.D., ed., *Textbook of Radiotherapy*, Lea & Febiger, Philadelphia, Pa., 1973.
2. Simon, N and Silverstone, SM Intercavitary Radiotherapy of Endometrial Cancer by Afterloading. J. Gynecologic Oncology, 1:1 (1972), 13-16.
3. NCRP Report No. 37, NCRP Publications, P.O. Box 30175, Washington DC 20014
4. NCRP Report No. 40, NCRP Publications, P.O. Box 30175, Washington DC 20014
5. NCRP Report No. 41, NCRP Publications, P.O. Box 30175, Washington DC 20014
6. NCRP Report No. 48, NCRP Publications, P.O. Box 30175, Washington DC 20014
7. NCRP Report No. 49, NCRP Publications, P.O. Box 30175, Washington DC 20014

34-7025-2726-7

Radiation Therapy Products
3M Health Care Group

Bldg. 225-5S-01, 3M Center
St. Paul, MN 55144-1000

3M

LABELING

for

I-125 SEEDS

License Amendment Application
Materials License 22-00057-59MD
August 15, 1988

I-125 Seeds

3M

Therapeutic For Interstitial Brachytherapy 6702

Made in U.S.A. by
3M Medical-Surgical Division

DESCRIPTION: I-125 Seeds consist of a welded titanium capsule containing iodine-125 adsorbed on silver ion exchange resin spheres.

Apparent activity range: _____ mCi

Total apparent activity this vial: _____ mCi

Number of seeds: _____ Assay Date: _____

Lot no: _____

See package insert for instructions on handling and storage of I-125 Seeds.

Caution
Radioactive
Material

WARNING: The U.S. Nuclear Regulatory Commission has approved this sealed source for distribution to persons licensed to use byproduct material identified in §35.400 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and outside the United States, to persons authorized by the appropriate authority.
CAUTION: Federal law restricts this device to sale by or on the order of a physician. Maintain proper radiation safety precautions at all times. 3/88

I-125 Seeds

3M

Therapeutic For Interstitial Brachytherapy 6711

Made in U.S.A. by
3M Medical-Surgical Division
St. Paul, MN 55144-1000

DESCRIPTION: I-125 Seeds consist of a welded titanium capsule containing iodine-125 adsorbed onto silver rod.

Apparent activity range: _____ mCi

Total apparent activity this vial: _____ mCi

Number of seeds: _____ Assay Date: _____

Lot no: _____

See package insert for instructions on handling and storage of I-125 Seeds.

Caution
Radioactive
Material

WARNING: The U.S. Nuclear Regulatory Commission has approved this sealed source for distribution to persons licensed to use byproduct material identified in §35.400 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and outside the United States, to persons authorized by the appropriate authority.
CAUTION: Federal law restricts this device to sale by or on the order of a physician. Maintain proper radiation safety precautions at all times. 3/88

I-125 Seeds®

3M

In Carrier Therapeutic For Interstitial Brachytherapy 6720

Description: I-125 Seeds in Carrier consists of a group of I-125 Seeds housed at the fixed spacing indicated (center to center) within a braided absorbable carrier. The I-125 Seeds consist of a welded titanium capsule containing iodine-125 absorbed onto a silver rod. The carrier material is Ethicon no. 1 Vicryl® synthetic absorbable suture (Polyglactin 910).

Apparent activity range: _____ mCi

Total apparent activity _ _____ mCi

Number of seeds _____ Assay Date _____

Lot no. _____ Spacing _____

See package insert for instructions on handling and storage of I-125 Seeds in carrier.

Made in U.S.A. by
3M Medical-Surgical Division
St. Paul, MN 55144-1000

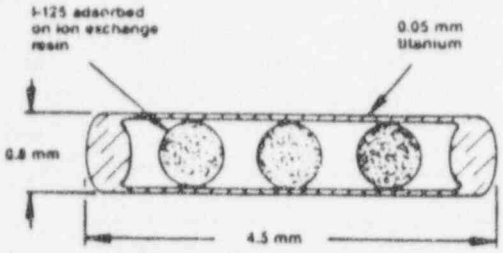
Caution
Radioactive
Material

WARNING: The U.S. Nuclear Regulatory Commission has approved this sealed source for distribution to persons licensed to use byproduct material identified in §35.400 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.
CAUTION: Federal law restricts this device to sale by or on the order of a physician. Maintain proper radiation safety precautions at all times. **3/88**

I-125 Seeds
No. 6702

Description

I-125 Seeds 6702 consist of a welded titanium capsule containing iodine-125 adsorbed on anion exchange resin spheres.



Physical Characteristics

Iodine-125 has a half-life of 59.6 days[1] and decays by electron capture with the emission of characteristic photons and Auger electrons. The electrons are absorbed by the titanium wall of the I-125 Seed. The principal photon emissions are 27.4 and 31.4 keV x-rays and a 35.5 keV gamma.[2]

To correct for the physical decay of Iodine-125, the decay factors at selected days after the assay date are shown in the table below.

Iodine-125 Decay Chart
(59.6 day Half-Life[1])

Days	Decay Factor	Days	Decay Factor
0	1.000	36	0.658
2	0.977	38	0.643
4	0.955	40	0.628
6	0.933	42	0.614
8	0.911	44	0.599
10	0.890	46	0.586
12	0.870	48	0.572
14	0.850	50	0.559
16	0.830	52	0.546
18	0.811	54	0.534
20	0.792	56	0.521
22	0.774	58	0.509
24	0.756	60	0.498
26	0.739	62	0.486
28	0.722	64	0.475
30	0.705	66	0.464
32	0.689	68	0.453
34	0.673	70	0.443

Radiation Protection

The half value thickness of lead for Iodine-125 is 0.025 mm. Thus, a 0.25 mm lead sheet will provide > 99% reduction in exposure.

Actions

The clinical efficacy of I-125 Seeds derives solely from the interaction of the emitted ionizing radiation with the tissue being treated.

Dose distribution around each individual seed is not isotropic.[2,3,4] This anisotropy should be included in dose distribution calculations.

Titanium encapsulation assures good tissue compatibility and results in a total self-absorption of approximately 16%.

Indications

I-125 Seeds with apparent activities from 5 to 40 mCi are indicated for interstitial treatment of tumors which have the following characteristics: unresectable, localized, and moderate radiosensitivity.

I-125 Seeds may be used for selected radiation applications as temporary implants.

I-125 Seeds are indicated to treat residual tumors following completion of a course of external radiation therapy. In addition, recurrent tumors may be implanted with I-125 Seeds.[5,6]

Contraindications

As with other brachytherapy sources, treatment of tumors in generally poor condition (eg, ulcerated) is not recommended with I-125 Seeds.

Warnings

1) Seeds Intended For Temporary Implant And Reuse
When loading or removing I-25 Seeds from plastic or rubber afterloading catheters, use a vented chemical hood which has adequate air flow up the stack and a filtered exhaust. If a chemical hood is not available a plastic glove box specifically designed for work with radioactive iodine may be substituted, provided it is properly vented.

If a razor blade, scalpel, or other sharp tool is used to remove I-125 Seeds from the afterloading catheters, use extra care to avoid contacting or cutting a Seed. A Seed which has been damaged (nick, cut, slice, or other type of damage) will release I-125 into the environment.

To assure that Seeds have not been damaged following removal from the afterloading catheters, a contamination survey should be conducted using a radiation monitor capable of detecting 30keV photons. This survey should include wipe (or leak) tests of Seeds and an overall area survey. For Seed leak test details, contact 3M Customer Service at 1-800-328-1671. Residents of Minnesota or Canada call 612-733-9181.

2) Seed Corrosion
The titanium shell of the I-125 Seed has excellent corrosion resistance under normal use. However, do not expose a Seed to acid or alkaline solutions exceeding 1 molar. Seeds are not affected by common solvents such as acetone and alcohol or by mild detergents.

Precautions

1) Personnel Monitoring
I-125 Seeds are radioactive, and appropriate precautions must be taken when handling the sources. All steps of the implantation procedure should be planned in advance to minimize radiation exposure to personnel consistent with published exposure limits.[7]

Personnel monitoring is required. A film badge or TLD dosimeter worn on the body and a ring badge (during Seed handling) is adequate.

2) I-125 Seed Shipping Container
I-125 Seeds are shipped in a shrink-wrapped glass vial which is inside a shrink-wrapped lead container. The lead effectively shields > 99.9% of the photons from I-125.

The glass vial with its black plastic cap is encased in a clear plastic shrink-wrap film having a line of red "3M" logos visible along one section of the film.

The shrink-wrap film can be removed by using a razor blade to slit the film along the length of the vial. This should be carefully done so that the vial does not slip from hand or gripping tool. As an alternative, the film can be cut just beneath and around the entire cap. After doing so, the cap will unscrew and the film will remain on both the cap and the glass vial. The film becomes cloudy and distorted if the vial is autoclaved, but printing on the vial label is readable. Hand dose can be minimized with shielding, distance and short handling time.

3) Seed Handling
Handling of I-125 Seeds should be done behind shielding of adequate thickness. Forceps, either reverse or normal action, should be used to maintain operator to Seed distance. If normal action forceps are used, gentle pressure should be applied so that Seeds are not damaged. I-125 SEEDS SHOULD NOT BE PICKED UP WITH THE FINGERS.

4) Seed Sterilization
I-125 Seeds are NOT sterile when shipped. Before implantation, they must be sterilized using steam or ethylene oxide (EO). DO NOT USE DRY HEAT OR CHEMICAL STERILIZATION.

Steam Sterilization (autoclave): Use the normal cycle (121 degrees C at 15 psi for 15 to 30 minutes) or the flash cycle (133 degrees C at 30 psi for about 3 minutes). DO NOT EXPOSE SEEDS TO TEMPERATURES AND PRESSURES IN EXCESS OF 138 DEGREES C and 35 PSI.

Ethylene Oxide (EO) Sterilization: Use cycle and aeration times recommended by the sterilizer's manufacturer or use those determined by the hospital.

Whether steam or ethylene oxide is used, I-125 Seeds should be sterilized in an adequately shielded container.

Lead Shipping Container: If Seeds are sterilized in the lead shipping container, the lead cover on the container and plastic cap on the glass vial therein should be removed to allow steam or ethylene oxide to access the Seeds.

Other Containers: I-125 Seeds can be loaded into stainless steel cartridges designed to be used with the Mick Applicator, or into the nylon and teflon tubes used with Henschke or Scott applicators. USE ETHYLENE OXIDE TO STERILIZE SEEDS LOADED TO THE PLASTIC TUBES; STEAM HEAT WILL WARP THE TUBES AND PREVENT SEED RECOVERY.

When in doubt about compatibility of steam heat with various Seed containers, load them with non-radioactive Seeds to determine the effect of steam on the container material and on Seed recovery.

5) Accidental I-125 Seed Damage
Although I-125 Seeds have a high structural integrity, it is possible through rough handling, exposure to excessive temperature or crushing, to rupture a Seed causing it to release "free" I-125. If this happens the area of the accident should be closed off; the Seeds should be sealed in a container; personnel movement should be controlled to avoid spread of any radioactive contamination; and the area and personnel should be decontaminated according to established procedures. Personnel working in or near the accident should also undergo a thyroid scan to determine if I-125 has accumulated in this organ through contact, ingestion, or inhalation of the radionuclide.

Application to Patient

I-125 Seeds should be used only by individuals who are qualified by training and experience in the safe use and handling of radionuclides.

Radiation detection equipment, capable of detecting 30 keV photons, should be available whenever I-125 Seeds are being handled. The seeds are quite small and it may be difficult to locate a dropped seed visually.

All practical physical protection should be provided during the implantation procedure. Frequently, however, protective barriers are not practical in the surgery. In this circumstance, operators must rely upon distance and speed to minimize radiation exposure.[4,9,10,11]

Treatment of Patient

All patients should be informed of the nature of I-125 Seed implants and the expected period of time during which radiation precautions will be necessary. Patients, their close associates and associated medical personnel should be instructed in the necessary radiation safety procedures required for someone who has received an I-125 Seed implant. Guidelines for necessary precautions have been established.[7]

All patients should be advised of the possibility that, during a course of treatment, one or more I-125 Seeds might slough off and become detached as a tumor regresses and becomes smaller. Under these circumstances, any bandages or linens which come into contact with the site of the implant should be scrutinized for small metallic seeds (¼ of an inch long). Patients should be advised that whenever seeds are found, they should be picked up with a spoon and placed in a jar or other container, and placed in an inaccessible area in the home. The radiation center should be notified of such an event as soon as possible after its occurence.

Accountability / Disposal

Iodine-125 is an accountable radioactive material. I-125 Seeds should, therefore, be strictly controlled and stored in a locked safe. If any significant material cannot be accounted for, the loss must be reported to the appropriate federal or state licensing agency.

When disposal is indicated, I-125 Seeds should be transferred to an authorized radioactive waste disposal agency. I-125 Seeds should never be disposed of in normal waste.

An I-125 Seed disposal service is provided by 3M Radiation Therapy Products. Customers wishing to dispose of I-125 Seeds in this manner must contact the 3M Company for approval and specific shipping container and forms.

Material approved for return must comply with Department of Transportation regulations (49 CFR, Parts 171-177) regarding packaging and labeling. Shipments are to be directed to: 3M / Radiation Therapy Products, TCAAP Building 590, New Brighton, Minnesota, 55112.

Leak Testing

I-125 Seeds are leak tested prior to shipment and have passed a leak test showing < 0.005 uCi of removable I-125 as required by NRC regulation 10 CFR 35.59. This leak test value is printed on the Certification form that accompanies each shipment.

I-125 Seeds that retain clinical utility for more than six months must be leak tested "...at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State...(except for) sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within six months before the date of use or transfer..." as prescribed in 10 CFR 35.59

Model No. 6702 I-125 Seeds intended for temporary implants (5 to 40 mCi) might fall into the above category and, if so, would need to be leak tested. Additionally, since the higher activity Seeds are often reused, leak testing at more frequent intervals is recommended. For leak test details, contact 3M Customer Service at 1-800-328-1671. Residents of Minnesota or Canada can call 612-733-9181.

Adverse Reactions

No adverse reactions involving I-125 Seeds have been reported.

Dosage and Administration

The total activity of I-125 Seeds required for any given treatment depends upon the tumor volume and the previous radiation history of the tumor site. Established practice[12,13] should be followed for the calculation of the total activity to be implanted, the proper placement of the sources within the tissue, and the evaluation of the radiation dose distribution achieved.

Dose distribution around each individual seed is not isotropic.[2,3,4] This anisotropy should be considered in dose distribution calculations.

Iodine-125 has a 59.6 day half-life. Decay corrections must be made in order to properly calculate the activity of the seeds on the day they are implanted.

Directions for Use

1) Seeds Intended For Permanent Implant
I-125 Seeds pass through a 17 gauge needle and are implanted using a Seed "applicator" attached to a 17 gauge or larger needle. Common Seed applicators are the Mick, Henschke and Scott. The Royal Marsden Gold Grain gun can be used to implant Seeds provided a special modification is requested of the manufacturer.

2) Seeds Intended For Temporary Implant
I-125 Seeds are usually loaded into plastic tubing or other devices (e.g. gold eye plaques) to facilitate afterloading procedures and Seed recovery.

How Supplied

Model No. 6702 I-125 Seeds are available with apparent activities from 5.0 to 40 mCi per Seed.

The Seeds are packaged in a shrink-wrapped screw-cap glass vial, which is labeled with: activity range in mCi; total activity in mCi; assay date, number of Seeds and Seed Lot number. The glass vial is contained in a shrink-wrapped lead "pig" similarly labeled. The pig label has, in addition, precautionary regulatory statements pertaining to licensing of the Seeds.

I-125 Seeds are NOT sterile when shipped.

Licensing

The U.S. Nuclear Regulatory Commission has approved this sealed source for distribution to persons licensed to use byproduct material identified in §35.400 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and outside the United States, to persons authorized by the appropriate authority.

Federal law restricts this device to sale by or on the order of a physician.

References

1. A Handbook of Radioactivity Measurements Procedures Second Edition. *NCRP Report* No. 58, Washington, D.C. (1985)

2. Ling, C.C., Yorke, E.D., Spiro, I.J., Kubiatowicz, D.O., and Bennett, D., Physical Dosimetry of I-125 Seeds of a New Design For Interstitial Implant. *Int. J. Radiation Oncology Biol. Phys.* 9: 1747-1752 (1983)

3. Ling, C.C., Schell, M.C., and Yorke, E.D., Two-dimensional Dose Distribution of I-125 Seeds. *Medical Physics* 12, no. 5: 652-655 (1985)

4. Ling, C.C., Anderson, L.L. and Shipley, W.U., Dose Inhomogeneity in Interstitial Implants Using I-125 Seeds. *Int. J. Radiation Oncology Biol. Phys.* 5: 419-425 (1979)

5. Hilaris, B.S., (ed.) *Handbook of Interstitial Brachytherapy.* Publishing Sciences Group Inc., Acton, Massachusetts (1975)

6. Marchese, M.J., Hall, E.J., Hilaris, B.S., Clinical, Physical and Radiobiological Aspects of Encapsulated Iodine-125 in Radiation Oncology. *Endocurietherapy / Hyperthermia Oncology* 1: 67-82 (1985)

7. Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides. *NCRP Report* No. 37, Washington, D.C. (1970)

8. Protection Against Radiation From Brachytherapy Sources. *NCRP Report* No. 40, Washington, D.C. (1972)

9. Specification of Gamma-Ray Brachytherapy Sources. *NCRP Report* No 41, Washington, D.C. (1974)

10. Radiation Protection for Medical and Allied Health Personnel. *NCRP Report* No. 48, Washington, D.C. (1976)

11. Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV. *NCRP Report* No. 49, Washington, D.C. (1976)

12. Hilaris, B.S., "Brachytherapy Treatment Planning" in *Brachytherapy Oncology Update 1984*, (Hilaris, B.S. and Nori, D., ed.) Memorial Sloan-Kettering Cancer Center, 1275 York Avenue, New York, NY, pp 5-10.

13. Anderson, L.L., Kuan, H.M., and Ding, I.Y., "Clinical Dosimetry With I-125", In *Modern Interstitial and Intracavitary Radiation Cancer Management*, (F.W. George III ed.) *MASSON* Publishing USA, Inc., New York (1981), pp 9-15.

Note: The NCRP (National Council on Radiation Protection and Measurements) documents are available from: NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

34-7024-2998-5

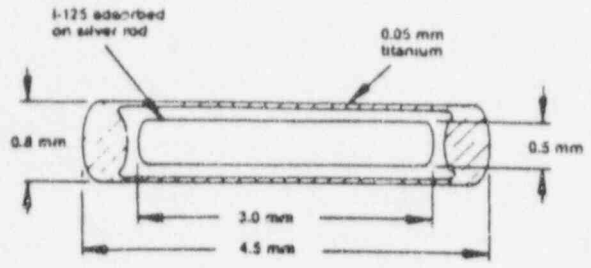
~~3M Medical-Surgical Division~~ Radiation Therapy Products
St. Paul, MN 55144-1000 3M Health Care Group
Bldg. 225-5S-01, 3M Center

3M

I-125 Seeds®
No. 6711

Description

I-125 Seeds 6711 consist of a welded titanium capsule containing Iodine-125 adsorbed onto a silver rod.



Physical Characteristics

Iodine-125 has a half-life of 59.6 days[1] and decays by electron capture with the emission of characteristic photons and Auger electrons. The electrons are absorbed by the titanium wall of the I-125 Seed. The principal photon emissions are 27.4 and 31.4 keV x-rays and a 35.5 keV gamma. Also emitted are 22.1 and 25.2 keV fluorescent x-rays from the silver rod.[2]

To correct for the physical decay of Iodine-125, the decay factors at selected days after the assay date are shown in the table below.

Iodine-125 Decay Chart (59.6 day Half-Life[1])

Days	Decay Factor	Days	Decay Factor
0	1.000	36	0.658
2	0.977	38	0.643
4	0.955	40	0.628
6	0.933	42	0.614
8	0.911	44	0.599
10	0.890	46	0.586
12	0.870	48	0.572
14	0.850	50	0.559
16	0.830	52	0.546
18	0.811	54	0.534
20	0.792	56	0.521
22	0.774	58	0.509
24	0.756	60	0.498
26	0.739	62	0.486
28	0.722	64	0.475
30	0.705	66	0.464
32	0.689	68	0.453
34	0.673	70	0.443

Radiation Protection

The half value thickness of lead for Iodine-125 is 0.025 mm. Thus, a 0.25 mm lead sheet will provide > 99% reduction in exposure.

Actions

The clinical efficacy of I-125 Seeds derives solely from the interaction of the emitted ionizing radiation with the tissue being treated.

Dose distribution around each individual seed is not isotropic.[2, 3, 4] This anisotropy should be included in dose distribution calculations.

Titanium encapsulation assures good tissue compatibility, and together with the silver rod, results in a total self-absorption of approximately 35%.

Indications

I-125 Seeds with apparent activities from 0.1 to 1.0 mCi are indicated for permanent interstitial treatment of tumors which have the following characteristics: unresectable, localized, slow growth rate, and low to moderate radiosensitivity. Seeds in this apparent activity range may be used to treat superficial, intraabdominal, and intrathoracic tumors. Tumors of the head, neck, lung, pancreas, and prostate (early stages) are commonly treated.

I-125 Seeds with total apparent activities greater than 1.0 mCi are indicated for interstitial treatment of tumors which have the following characteristics: unresectable, localized, and moderate radiosensitivity. These seeds may be used for selected radiation applications as temporary implants.

I-125 Seeds are indicated to treat residual tumors following completion of a course of external radiation therapy. In addition, recurrent tumors may be implanted with I-125 Seeds.[5, 6]

Contraindications

As with other brachytherapy sources, treatment of tumors in generally poor condition (e.g. ulcerated) is not recommended with I-125 Seeds.

Warnings

1) Seeds Intended For Permanent Implant

Do not force an I-125 Seed into (or from) any implant tube, needle, or cartridge; doing so may damage the wall or end welds of the Seed, potentially causing release of I-125 into the environment and into body fluids should the Seed be implanted. If a Seed has been visibly damaged in any way, discard it immediately to radioactive waste and check the area for contamination. UNDER NO CIRCUMSTANCES SHOULD VISIBLY DAMAGED SEEDS BE IMPLANTED.

2) Seeds Intended For Temporary Implant And Reuse

When loading or removing I-125 Seeds from plastic or rubber afterloading catheters, use a vented chemical hood which has adequate air flow up the stack and a filtered exhaust. If a chemical hood is not available, a plastic glove box specifically designed for work with radioactive iodine may be substituted, provided it is properly vented.

If a razor blade, scalpel, or other sharp tool is used to remove I-125 Seeds from the afterloading catheters, use extra care to avoid contacting or cutting a Seed. A Seed which has been damaged (nick, cut, slice, or other type of damage) will release I-125 into the environment.

To assure that Seeds have not been damaged following removal from the afterloading catheters, a contamination survey should be conducted using a radiation monitor capable of detecting 30 keV photons. This survey should include wipe (or leak) tests of Seeds and an overall area survey. For Seed leak test details, contact 3M Customer Service at 1-800-328-1671. Residents of Minnesota or Canada call 612-733-9181.

3) Seed Corrosion

The titanium shell of the I-125 Seed has excellent corrosion resistance under normal use. However, do not expose a Seed to acid or alkaline solutions exceeding 1 molar. Seeds are not affected by common solvents such as acetone and alcohol or by mild detergents.

Precautions

1) **Personnel Monitoring**

I-125 Seeds are radioactive, and appropriate precautions must be taken when handling the sources. All steps of the implantation procedure should be planned in advance to minimize radiation exposure to personnel consistent with published exposure limits.[7]

Personnel monitoring is required. A film badge or TLD dosimeter worn on the body and a ring badge (during Seed handling) is adequate.

2) **I-125 Seed Shipping Container**

I-125 Seeds are shipped in a shrink-wrapped glass vial which is inside a shrink-wrapped lead container. The lead effectively shields > 99.9% of the photons from I-125.

The glass vial with its black plastic cap is encased in a clear plastic shrink-wrap film having a line of red "3M" logos visible along one section of the film.

The shrink-wrap film can be removed by using a razor blade to slit the film along the length of the vial. This should be carefully done so that the vial does not slip from hand or gripping tool. As an alternative, the film can be cut just beneath and around the entire cap. After doing so, the cap will unscrew and the film will remain on both the cap and the glass vial. The film becomes cloudy and distorted if the vial is autoclaved, but printing on the vial label is readable. Hand dose can be minimized with shielding, distance and short handling time.

3) **Seed Handling**

Handling of I-125 Seeds should be done behind shielding of adequate thickness. Forceps, either reverse or normal action, should be used to maintain operator to Seed distance. If normal action forceps are used, gentle pressure should be applied so that Seeds are not damaged. I-125 SEEDS SHOULD NOT BE PICKED UP WITH THE FINGERS.

4) **Seed Sterilization**

I-125 Seeds are NOT sterile when shipped. Before implantation, they must be sterilized using steam or ethylene oxide (EO). DO NOT USE DRY HEAT OR CHEMICAL STERILIZATION.

Steam Sterilization (autoclave): Use the normal cycle (121 degrees C at 15 psi for 15 to 30 minutes) or the flash cycle (133 degrees C at 30 psi for about 3 minutes). DO NOT EXPOSE SEEDS TO TEMPERATURES AND PRESSURES IN EXCESS OF 138 DEGREES C and 35 PSI.

Ethylene Oxide (EO) Sterilization: Use cycle and aeration times recommended by the sterilizer's manufacturer or use those determined at the hospital.

Whether steam or ethylene oxide is used, I-125 Seeds should be sterilized in an adequately shielded container.

Lead Shipping Container: If Seeds are sterilized in the lead shipping container, the lead cover on the container and plastic cap on the glass vial therein should be removed to allow steam or ethylene oxide to access the Seeds.

Other Containers: I-125 Seeds can be loaded into stainless steel cartridges designed to be used with the Mick Applicator, or into the nylon and teflon tubes used with Henschke and Scott applicators. USE ETHYLENE OXIDE TO STERILIZE SEEDS LOADED INTO THE PLASTIC TUBES; STEAM HEAT WILL WARP THE TUBES AND PREVENT SEED RECOVERY.

When in doubt about compatibility of steam heat with various Seed containers, load them with non-radioactive Seeds to determine the effect of steam on the container material and on Seed recovery.

5) **Accidental I-125 Seed Damage**

Although I-125 Seeds have a high structural integrity, it is possible through rough handling, exposure to excessive temperature, or crushing to rupture a Seed causing it to release "free" I-125. If this happens the area of the accident should be closed off, the Seeds should be sealed in a container; personnel movement should be controlled to avoid spread of any radioactive contamination; and the area and personnel should be decontaminated according to established procedures. Personnel working in or near the accident should also undergo a thyroid scan to determine if I-125 has accumulated in this organ through contact, ingestion, or inhalation of the radionuclide.

Application to Pe[illegible]t

I-125 Seeds should be used only by individuals [illegible] are [illegible]lied by training and experience in the safe use and handling of radionuclides.

Radiation detection equipment capable of detecting 30 keV x-rays, should be available whenever I-125 Seeds are being handled. The seeds are quite small and it may be difficult to locate a dropped seed visually.

All practical physical protection should be provided during the implantation procedure. Frequently, however, protective barriers are not practical in the surgery. In this circumstance, operators must rely upon distance and speed to minimize radiation exposure.[8, 9, 10, 11]

Treatment of Patient

All patients should be informed of the nature of I-125 Seed implants and the expected period of time during which radiation precautions will be necessary. Patients, their close associates and associated medical personnel should be instructed in the necessary radiation safety procedures required for someone who has received an I-125 Seed implant. Guidelines for necessary precautions have been established.[7]

All patients should be advised of the possibility that, during a course of treatment, one or more I-125 Seeds might slough off and become detached as a tumor regresses and becomes smaller. Under these circumstances, any bandages or linens which come into contact with the site of the implant should be scrutinized for small metallic seeds (¼ of an inch long). Patients should be advised that whenever seeds are found, they should be picked up with a spoon and placed in a jar or other container, and placed in an inaccessible area in the home. The radiation center should be notified of such an event as sooon as possible after its occurrence.

Accountability / Disposal

Iodine-125 is an accountable radioactive material. I-125 Seeds should, therefore, be strictly controlled and stored in a locked safe. If any significant material cannot be accounted for, the loss must be reported to the federal or state licensing agency.

When disposal is indicated, I-125 Seeds should be transferred to an authorized radioactive waste disposal agency. I-125 Seeds should never be disposed of in normal waste.

An I-125 Seed disposal service is provided by 3M Radiation Therapy Products. Customers wishing to dispose of I-125 Seeds in this manner must contact the 3M Company for approval and specific shipping container and forms.

Material approved for return must comply with Department of Transportation regulations (49 CFR Parts 171-177) regarding packaging and labeling. Shipments are to be directed to: 3M / Radiation Therapy Products, TCAAP Building 590, New Brighton, Minnesota, 55112.

Leak Testing

I-125 Seeds are leak tested prior to shipment and have passed a leak test showing < 0.005 μCi of removable I-125 as required by NRC regulation 10 CFR 35.59. This leak test value is printed on the Certification form that accompanies each shipment.

I-125 Seeds that retain clinical utility for more than six months must be leak tested "...at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State...(except for) sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within six months before the date of use or transfer..." as prescribed in 10 CFR 35.59.

I-125 Seeds intended for temporary implants (1 to 40 mCi) might fall into the above category and, if so, would need to be leak tested. Additionally, since the higher activity Seeds are often reused, leak testing at more frequent intervals is recommended. For leak test details, contact 3M Customer Service at 1-800-328-1671. Residents of Minnesota or Canada can call 612-733-9181.

Unused I-125 Seeds intended for permanent implants (nominal strength of 0.55 mCi) will not require additional leak testing providing they are disposed of within six months of the date shown on the Seed Certification form.

Adverse Reactions

No adverse reactions involving I-125 Seeds have been reported.

Dosage and Administration

The total activity of I-125 Seeds required for any given treatment depends upon the tumor volume and the previous radiation history of the tumor site. Established practice[8, 13] should be followed for the calculation of the total activity to be implanted, the proper placement of the sources within the tissue, and the evaluation of the radiation dose distribution achieved.

Dose distribution aro[illegible]d eac[illegible]ividual seed is not isotropic.[2, 3, 4] This anisotropy should be included [illegible] dose distribution calculations.

Iodine-125 has a 59.6 day half-life.[1] Decay corrections must be made in order to properly calculate the activity of the seeds on the day they are implanted.

Directions for Use

1) Seeds Intended For Permanent Implant

I-125 Seeds pass through a 17 gauge needle and are implanted using a Seed "applicator" attached to a 17 gauge or larger needle. Common Seed applicators are the Mick, Henschke and Scott. The Royal Marsden Gold Grain gun can be used to implant Seeds provided a special modification is requested of the manufacturer.

2) Seeds Intended For Temporary Implant

I-125 Seeds are usually loaded into plastic tubing or other devices (e.g. gold eye plaques) to facilitate afterloading procedures and Seed recovery.

How Supplied

Model No. 6711 I-125 Seeds are available with apparent activities from 0.10 to 5.0 mCi per Seed and, by special request, from 5.1 to 40 mCi per Seed.

The Seeds are packaged in a shrink-wrapped screw-cap glass vial, which is labeled with: activity range in mCi, total activity in mCi, assay date, number of Seeds and Seed Lot number. The glass vial is contained in a shrink-wrapped lead pig similarly labeled. The pig label has, in addition, precautionary regulatory statements pertaining to licensing of the Seeds.

I-125 Seeds are NOT sterile when shipped.

Licensing

The U.S. Nuclear Regulatory Commission has approved this sealed source for distribution to persons licensed to use byproduct material identified in §35.400 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

Federal law restricts this device to sale by or on the order of a physician.

References

1. A Handbook of Radioactivity Measurements Procedures Second Edition. *NCRP Report* No. 58, Washington, D.C. (1985)

2. Ling, C.C., Yorke, E.D., Spiro, I.J., Kubiatowicz, D.O., and Bennett, D., Physical Dosimetry of I-125 Seeds of a New Design For Interstitial Implant. *Int. J. Radiat. Oncology Biol. Phys.* 9: 1747-1752 (1983)

3. Ling, C.C., Schell, M.C., and Yorke, E.D., Two-dimensional Dose Distribution of I-125 Seeds. *Medical Physics* 12, no. 5: 652-655 (1985)

4. Ling, C.C., Anderson, L.L. and Shipley, W.U., Dose Inhomogeneity in Interstitial Implants Using I-125 Seeds. *Int. J. Radiation Oncology Biol. Phys.* 5: 419-425 (1979)

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7. Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides. *NCRP Report* No. 37, Washington, D.C. (1970)

8. Protection Against Radiation From Brachytherapy Sources. *NCRP Report* No. 40, Washington, D.C. (1972)

9. Specification of Gamma-Ray Brachytherapy Sources. *NCRP Report* No. 41, Washington, D.C. (1974)

10. Radiation Protection for Medical and Allied Health Personnel. *NCRP Report* No. 48, Washington, D.C. (1976)

11. Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV. *NCRP Report* No. 49, Washington, D.C. (1976)

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13. Anderson, L.L., Kuan, H.M., and Ding, I.Y., "Clinical Dosimetry With I-125", in *Modern Interstitial and Intracavitary Radiation Cancer Management*, (F.W. George III ed.) Masson Publishing USA, Inc., New York (1981), pp 9-15.

Note: The NCRP (National Council on Radiation Protection and Measurements) documents are available from: NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

34-7024-3003-3

~~3M Medical-Surgical Division~~ Radiation Therapy Products
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Bldg. 225-5S-01, 3m Center

3M

I-125 Seeds in Carrier
No. 6720

Description

I-125 Seeds in Carrier consists of Model No. 6711 I-125 Seeds (welded titanium capsule containing I-125 adsorbed onto a silver rod) spaced at a fixed distance within #1 Vicryl® (polyglactin 910) absorbable suture. The Seeds are located at the distal 2 to 30 cm of suture and a surgical needle (½ circle taper point) is attached to the other end. The portion of the suture containing the I-125 Seeds is housed in a stainless steel ring which attenuates > 99.9% of the I-125 photons. I-125 Seeds in Carrier is sterile when shipped.

Physical Characteristics

Iodine-125 has a half-life of 59.6 days[1] and decays by electron capture with the emission of characteristic photons and Auger electrons. The electrons are absorbed by the titanium wall of the I-125 Seed. The principal photon emissions are 27.4 and 31.4 keV x-rays and a 35.5 keV gamma. Also emitted are 22.1 and 25.2 keV fluorescent x-rays from the silver rod.[2]

To correct for the physical decay of Iodine-125, the decay factors at selected days after the assay date are shown in table below.

Iodine-125 Decay Chart
(59.6 day Half-Life[1])

Days	Decay Factor	Days	Decay Factor
0	1.000	36	0.658
2	0.977	38	0.643
4	0.955	40	0.628
6	0.933	42	0.614
8	0.911	44	0.599
10	0.890	46	0.586
12	0.870	48	0.572
14	0.850	50	0.559
16	0.830	52	0.546
18	0.811	54	0.534
20	0.792	56	0.521
22	0.774	58	0.509
24	0.756	60	0.498
26	0.739	62	0.486
28	0.722	64	0.475
30	0.705	66	0.464
32	0.689	68	0.453
34	0.673	70	0.443

Radiation Protection

The half value thickness of lead for Iodine-125 is 0.025 mm. Thus, a 0.25 mm lead sheet will provide > 99% reduction in exposure.

Actions

The clinical efficacy of I-125 Seeds derives solely from the interaction of the emitted ionizing radiation with the tissue being treated.

Dose distribution around each individual seed is not isotropic.[2, 3, 4] This anisotropy should be included in dose distribution calculations.

Intramuscular implantation studied in rats show that the absorption of the carrier in I-125 Seeds in Carrier is minimal until about the 40th postoperative day. Absorption is essentially complete between the 60th and 90th day.[5]

Indications

I-125 Seeds in Carrier is indicated for permanent interstitial implantation of selected tumors which are localized, either unresectable or residual after excision of the primary lesion, and of low to moderate radiosensitivity.

I-125 Seeds in Carrier may be indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy.[6, 7, 8]

Contraindications

As with other brachytherapy sources, treatment of tumors in generally poor condition (e.g. ulcerated) is not recommended with I-125 Seeds in Carrier.

Warnings

I-125 Seeds in Carrier is shipped sterile and must not be resterilized.

Precautions

1) Personnel Monitoring

I-125 Seeds in Carrier is radioactive, and appropriate precautions must be taken during handling. All steps of the implantation procedure should be planned in advance to minimize radiation exposure to personnel consistent with published exposure limits.[9]

Personnel monitoring is required. A film badge or TLD dosimeter worn on the body and a ring badge (during Seed handling) is adequate.

2) I-125 Seeds in Carrier Shipping Container

I-125 Seeds in Carrier is shipped sterile in a stainless steel ring which attenuates > 99.9% of the photons from I-125. If possible, the implant procedure should be planned so that the Seeds can reside within the ring in a sterile field until moments before they are sewn into the tissue.

3) Handling

Any manipulation of I-125 Seeds in Carrier should be carried out in a sterile environment behind shielding of adequate thickness. The I-125 Seeds in Carrier should be handled with forceps only and with as much distance as practical between Seeds and the operator.

Seed spacing in the Vicryl suture can be changed using forceps to manipulate the Seeds. CARE MUST BE TAKEN TO AVOID CRUSHING SEEDS.

The implant procedure may require that Seeds in Carrier be cut into sections. CARE MUST BE TAKEN TO AVOID CUTTING SEEDS.

4) Seed Sterilization

I-125 Seeds in Carrier is sterile when shipped and SHOULD NOT BE RESTERILIZED.

5) Accidental I-125 Seed Damage

Although I-125 Seeds have a high structural integrity, it is possible through rough handling, exposure to excessive temperature, crushing or cutting to rupture a Seed causing it to release "free" I-125. If this happens the area of the accident should be closed off; the Seeds should be sealed in a container; personnel movement should be controlled to avoid spread of any radioactive contamination; and the area and personnel should be decontaminated according to established procedures. Personnel working in or near the accident should also undergo a thyroid scan to determine if I-125 has accumulated in this organ through contact, ingestion, or inhalation of the radionuclide.

Application to Patient

I-125 Seeds in Carrier should be used only by individuals who are qualified by training and experience in the safe use and handling of radionuclides.

Radiation detection equipment capable of detecting 20 keV photons should be available whenever I-125 Seeds in Carrier are being handled.

All practical physical protection should be provided during the implantation procedure. Frequently, however, protective barriers are not practical in the surgery. In this circumstance, operators must rely upon distance and speed to minimize radiation exposure.[10, 11, 12, 13]

Treatment of Patient

All patients should be informed of the nature of I-125 Seed implants and the expected period of time during which radiation precautions will be necessary. Patients, their close associates and associated medical personnel should be instructed in the necessary radiation safety procedures required for someone who has received an I-125 Seed implant. Guidelines for necessary precautions have been established.[9]

Accountability / Disposal

Iodine-125 is an accountable radioactive material. I-125 Seeds in Carrier should, therefore, be strictly controlled and stored in a locked safe. If any significant material cannot be accounted for, the loss must be reported to the federal or state licensing agency.

When disposal is indicated, I-125 Seeds in Carrier should be transferred to an authorized radioactive waste disposal agency. I-125 Seeds should never be disposed of in normal waste.

An I-125 Seed disposal service is provided by 3M Radiation Therapy Products. Customers wishing to dispose of I-125 Seeds in Carrier in this manner must contact the 3M Company for approval and specific shipping container and forms.

Material approved for return must comply with Department of Transportation regulations (49 CFR Parts 171-177) regarding packaging and labeling. Shipments are to be directed to: 3M / Radiation Therapy Products, TCAAP Building 590, New Brighton, Minnesota, 55112.

Leak Testing

Prior to fabrication of I-125 Seeds in Carrier, all I-125 Seeds have passed a leak test showing < 0.005 uCi of removable I-125 as required by NRC regulation 10 CFR 35.59. This leak test value is printed on the Certification form that accompanies each shipment.

Adverse Reactions

No adverse reactions involving I-125 Seeds in Carrier have been reported.

Dosage and Administration

The total activity of I-125 Seeds in Carrier required for any given treatment depends upon the tumor volume and the previous radiation history of the tumor site. Established practice[14, 15] should be followed for the calculation of the total activity to be implanted, the proper placement of the sources within the tissue, and the evaluation of the radiation dose distribution achieved.

Dose distribution around each individual seed is not isotropic.[2, 3, 4] This anisotropy should be accounted for in dose distribution calculations.

Iodine-125 has a 59.6 day half-life. Decay corrections must be made in order to calculate properly the activity of the seeds on the day they are implanted. Seeds are movable within the carrier to enable the practitioner to establish the correct seed-to-seed spacing based on the isotopic decay curve.

Directions for Use

I-125 Seeds in Carrier is supplied with an attached surgical needle. With the patient appropriately anesthetized, a qualified practitioner may place the seeds in carrier throughout the tumor volume according to a preplanned geometric arrangement. The implantation of I-125 Seeds in Carrier does not require use of conventional I-125 Seed applicators.

How Supplied

I-125 Seeds in Carrier is STERILE having ten I-125 Seeds spaced 1 cm center to center in a braided #1 Vicryl (polyglactin 910) suture. The usual activity ranges for the ten Seeds is 0.40 to 0.42 mCi. Other activity ranges may be available. These vary from 0.2 to 1.0 mCi, each having a 6% activity spread. Other configurations of I-125 Seeds in carrier (up to 20 Seeds with Seed spacing ranging from 0.5 to 1.5 cm center to center) may be available at special request.

A ½ circle taper point needle is attached to one end of the suture. The distal end of the suture containing the Seeds is housed within a stainless steel ring.

The stainless steel ring is sealed in a moisture-resistant foil bag which is enclosed in a Steri-Lok® gas sterilization bag.

Affixed to the Steri-Lok bag are two labels showing the following information: 1) Activity range in mCi; Total activity; Number of Seeds; Assay date; Seed Lot number and Seed spacing and 2) "Sterility guarantee unless package is damaged or open".

The Steri-Lok bag is enclosed within a clear plastic bag which must remain intact in order for the I-125 Seeds in Carrier to be returned for partial credit.

I-125 Seeds in Carrier is sterile when shipped.

Licensing

The U.S. Nuclear Regulatory Commission has approved this sealed source for distribution to persons licensed to use byproduct material identified in §35.400 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

Federal law restricts this device to sale by or on the order of a physician.

References

1. A Handbook of Radioactivity Measurements Procedures Second Edition. *NCRP Report* No. 58, Washington, D.C. (1985)

2. Ling, C.C., Yorke, E.D., Spiro, I.J., Kubiatowicz, D.O., and Bennett, D., Physical Dosimetry of I-125 Seeds of a New Design For Interstitial Implant. *Int. J. Radiation Oncology Biol. Phys.* 9: 1747-1752 (1983)

3. Ling, C.C., Schell, M.C., and Yorke, E.D., Two-dimensional Dose Distribution of I-125 Seeds. *Medical Physics* 12, no. 5: 652-655 (1985)

4. Ling, C.C., Anderson, L.L. and Shipley, W.U., Dose Inhomogeneity in Interstitial Implants Using I-125 Seeds. *Int. J. Radiation Oncology Biol. Phys.* 5: 419-425 (1979)

5. Data on file within 3M

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8. Marchese, M.J., Hall, E.J., Hilaris, B.S., Clinical, Physical and Radiobiological Aspects of Encapsulated Iodine-125 in Radiation Oncology *Endocurietherapy / Hyperthermia Oncology* 1: 67-82 (1985)

9. Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides. *NCRP Report* No. 37, Washington, D.C. (1970)

10. Protection Against Radiation From Brachytherapy Sources. *NCRP Report* No. 40, Washington, D.C. (1972)

11. Specification of Gamma-Ray Brachytherapy Sources. *NCRP Report* No. 41, Washington, D.C. (1974)

12. Radiation Protection for Medical and Allied Health Personnel. *NCRP Report* No. 48, Washington, D.C. (1976)

13. Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV. *NCRP Report* No. 49, Washington, D.C. (1976)

14. Hilaris, B.S., "Brachytherapy Treatment Planning" in *Brachytherapy Oncology Update* '84, (Hilaris, B.S. and Nori, D., ed.) Memorial Sloan-Kettering Cancer Center, 1275 York Avenue, New York, NY, pp 5-10.

15. Anderson, L.L., Kuan, H.M., and Ding, I.Y., "Clinical Dosimetry With I-125", in *Modern Interstitial and Intracavitary Radiation Cancer Management.* (F.W. George III ed.) *MASSON* Publishing USA, Inc., New York (1981), pp 9-15.

Note: The NCRP (National Council on Radiation Protection and Measurements) documents are available from: NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

34-7024-3001-7

~~3M Medical-Surgical Division~~ Radiation Therapy Products
St. Paul, MN 55144-1000 3M Health Care Group
Bldg. 225-5501, 3M Center

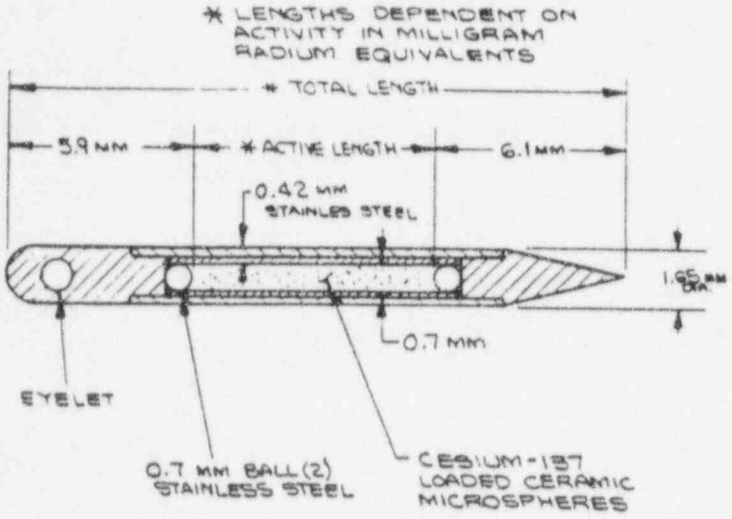
3M

3M Cesium-137 Needle Sources

Series 6530, 6540

Description

3M Cesium-137 needle sources consist of two stainless steel capsules - an outer casing and an inner core containing cesium-labeled ceramic microspheres packed along the active length. Each full strength needle source is nickel-plated; half strength needles are identified by gold plating.



Physical Characteristics

Cesium-137 has a half-life of 30.0 years and decays with the emission of a monoenergetic gamma ray of 622 keV.

To correct for the physical decay of cesium-137, the decay factors at selected years after the assay date are shown in the table below.

Decay Chart for Cesium-137, Half-Life 30.0 Years

Years	Decay factor	Years	Decay factor
0.0	1.00	5.5	.88
0.5	.99	6.0	.87
1.0	.98	6.5	.86
1.5	.97	7.0	.85
2.0	.95	7.5	.84
2.5	.94	8.0	.83
3.0	.93	8.5	.82
3.5	.92	9.0	.81
4.0	.91	9.5	.80
4.5	.90	10.0	.79
5.0	.89		

Radiation Protection

The half-value layer in lead for cesium-137 is 6 mm.

Actions

3M Cesium-137 needle sources emit a gamma ray of 662 keV. The clinical efficacy of the sources is a result of interaction of this ionizing radiation with the tissues being treated.

Indications

3M Cesium-137 needle sources are indicated for interstitial treatment of cancers, and may be used in conjunction with other treatment modalities.

The use of 3M Cesium-137 sources for any indication should be prescribed by a qualified practitioner.

Precautions

Preparation for Use

3M Cesium-137 needle sources are radioactive and appropriate precautions must be taken when handling these sources. All steps of the use procedure should be planned in advance to minimize radiation exposure to personnel consistent with published exposure limits.[1]

Personnel monitoring is required for individuals working with cesium-137 sources. A film badge or TLD dosimeter worn on the body and, for handling, a ring dosimeter will provide adequate detection.

3M Cesium-137 needle sources must be stored in a protective lead safe or vault of such thickness as is necessary to reduce exposure rates to permissible levels[2]. When transporting sources within the hospital premises, an appropriate carrier with adequate shielding should be used.

All manipulations involving 3M Cesium-137 needle sources should be carried out behind shielding of such size and thickness as will adequately shield the operator. DIRECT CONTACT WITH THE SOURCES SHOULD BE AVOIDED. The preparation of needle sources for patient application should be carried out behind a protective L-block, constructed of lead. In addition, 3M Cesium-137 needle sources should be handled only with forceps, with as much distance as practical between sources and the operator. 3M CESIUM-137 NEEDLE SOURCES SHOULD NEVER BE TOUCHED WITH THE HANDS.

Radiation detection equipment should be available whenever 3M Cesium-137 needle sources are being handled.

Application to Patient

3M Cesium-137 needle sources should be used only by individuals who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

All practical physical protection should be provided during the application procedure. When the use of protective barriers is not practical, operators must rely on distance and speed to minimize radiation exposure.[2] Persons should not remain closer than necessary to the radioactive material, either before or after its introduction into the patient.

The radiation dosimetry should be calculated prior to the insertion of cesium-137 needle sources, to assure that the prescribed dose is delivered to the patient. In addition, careful planning of the geometrical arrangement of the sources will reduce radiation exposure to personnel during the insertion procedure by avoiding hesitation and changes.

Treatment of Patient

All patients should be informed of the nature of treatment with 3M Cesium-137 needle sources and the expected period of time during which radiation precautions will be necessary. Patients, their close associates, and associated medical personnel should be instructed in the necessary radiation safety procedures required for someone who is being treated with cesium-137. Guidelines for necessary precautions have been established by the National Council on Radiation Protection and Measurements and are detailed in NCRP Reports.[1, 2, 3, 4, 5]

The bed, cubicle, or room of the hospital patient should be marked with a sign or tag indicating the presence of brachytherapy sources. In addition, the patient's chart should indicate the number and nature of the sources, the total amount of activity, and time and date of application and anticipated removal.

The extent to which a patient with 3M Cesium-137 needle sources must be segregated depends upon the total activity used, its location in the patient, how long it is to be there, and to what exposure other persons near him are subject. Consideration must be given to the proximity of patients in adjoining rooms, since normal wall construction may have little value in shielding gamma radiation.

A patient being treated with 3M Cesium-137 needle sources should be restricted to his room. The patient must not be allowed to leave the hospital until the sources have been removed. During the course of treatment, the patient should carry a wristband or suitable identification which provides information regarding the radioactive nature of the treatment.

During the course of treatment with 3M Cesium-137 needle sources, surgical bandages and dressings should be changed only by individuals trained in radiation safety techniques. Dressings must not be discarded until they have been checked for the presence of sources and found to contain none. Bed baths should be omitted while the sources are in place. Nursing care necessary for the patient's well-being should be preplanned and delivered quickly to minimize time spent at the bedside.

If a source becomes loose or falls out, it should be picked up with forceps and placed in a shielded container in the patient's room. The physician and radiation protection supervisor should be notified of such an event as soon as possible after its occurrence.

Removal/Accountability

When 3M Cesium-137 needle sources are removed from a patient, the same radiation safety procedures used for insertion should be observed. All linens, dressings, clothing, and equipment should be kept within the cubicle or room where the removal takes place until all sources are accounted for. Appropriate detectors and a shielded carrier should be available in the room where source removal takes place.

After the removal procedure, it should be determined that all 3M Cesium-137 needle sources have been removed. This may be accomplished by surveying the patient with an appropriate radiation detector.

Following their removal from a patient, 3M Cesium-137 needle sources must be returned to an individual designated as the source custodian for cleaning, inventory, and storage in a controlled area.

Cleaning/Sterilization/Storage

3M Cesium-137 needle sources should be cleaned following their removal from the patient and before being returned to a storage safe. While cleaning or sterilizing sources, adequate precaution should be taken to avoid radiation exposure to the staff, damage to sources, and loss of sources.

Cleaning of 3M Cesium-137 needle sources may be accomplished by rinsing or soaking the sources in water or, if dried fluids are present, in a hydrogen peroxide: water (1:1) solution. An ultrasonic bath may also be used. Following cleaning, 3M Cesium-137 needle sources should be air-dried or rinsed in alcohol.

Abrasive substances (e.g. metal cleaners, polishes) must not be used to clean 3M Cesium-137 needle sources. In addition, sources should not be allowed to contact mercury or mercury-containing solutions, or any other toxic or biologically hazardous materials.

3M Cesium-137 needle sources are NOT sterile when shipped and as such must be sterilized with steam (autoclave), dry heat, or ethylene oxide (EO) prior to patient application. Regardless of the method selected, the sources should be placed in an adequately shielded container prior to placement in the sterilization chamber. Manipulation of the sources prior to or following sterilization should be carried out behind shielding of such size and thickness as will adequately shield the operator. In addition, 3M Cesium-137 needle sources should be handled only with forceps. Autoclaves should be equipped with traps or other means to prevent source loss through the drain hole.

3M Cesium-137 needle sources withstand normal sterilization conditions of temperature and pressure. 3M Cesium-137 needle sources retain their integrity at temperatures of 800° C for 60 minutes.

Leak Testing

3M Cesium-137 needle sources are leak tested prior to shipment and the results provided on shipping certification papers that accompany each shipment.

3M Cesium-137 needle sources must be leak tested periodically by the user according to requirements described in 10 CFR 35.59. The U.S. Nuclear Regulatory Commission has specified a six-month leak test interval for 3M Cesium-137 needle sources, series 6530 and 6540 (formerly model 6B6G).

Adverse Reactions

No adverse reactions involving 3M Cesium-137 needle sources have been reported.

Dosage and Administration

The total activity of 3M Cesium-137 needle sources required for any given treatment depends upon several factors, among which are tumor type and size, anatomical geometry, and previous radiation history of the tumor site. The treatment plan for a particular patient, including the number and strength of sources and the length of treatment time, should be prescribed by a qualified physician. 3M Cesium-137 needle sources decay at a rate of approximately 2% per year, and, as a result, treatment times should be adjusted periodically.

How Supplied

3M Cesium-137 needle sources are available as full-strength (models 6530 through 6533), half-strength (models 6534 through 6537) sources, or a high intensity (10mg Ra equivalent) needle (series 6540). Characteristics of each source are listed below, by product number.

Model Number	mg Ra equivalent	Dimensions (mm)	Active length (mm)
6530	1.0	27.0 x 1.65	15.0
6531	1.5	34.5 x 1.65	22.5
6532	2.0	42.0 x 1.65	30.0
6533	3.0	57.0 x 1.65	45.0
6534	0.5	27.0 x 1.65	15.0
6535	0.75	34.5 x 1.65	22.5
6536	1.0	42.0 x 1.65	30.0
6537	1.5	57.0 x 1.65	45.0
6540	10.0	22.0 x 1.65	10.0

Each full strength cesium-137 needle source is nickel-plated. Half-strength sources are gold-plated.

3M Cesium-137 needle sources are packaged in a lead pig which is labeled to indicate the isotope, amount of activity, and calibration date, as well as precautionary regulatory statements pertaining to licensing of the product.

Licensing

The U.S. Nuclear Regulatory Commission has approved this sealed source for distribution to persons licensed to use byproduct material identified in §35.400 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

Federal law restricts this device to sale by or on the order of a physician.

References

1. NCRP Report No. 37. NCRP Publications. P.O. Box 30175. Washington DC 20014
2. NCRP Report No. 40. NCRP Publications. P.O. Box 30175. Washington DC 20014
3. NCRP Report No. 41. NCRP Publications. P.O. Box 30175. Washington DC 20014
4. NCRP Report No. 48. NCRP Publications. P.O. Box 30175. Washington DC 20014
5. NCRP Report No. 49. NCRP Publications. P.O. Box 30175. Washington DC 20014

34-7025-2727-5

Radiation Therapy Products
3M Health Care Group

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3M

APR 30 1987

MEMORANDUM FOR: Vandy L. Miller, Chief, Medical, Academic and Commercial Use Safety Branch, NMSS

FROM: W. L. Axelson, Chief, Nuclear Materials Safety and Safeguards Branch, Region III

SUBJECT: 3M - UPDATE ON CUSTOMER INSTRUCTIONS FOR REUSABLE I-125 BRACHYTHERAPY SEEDS

The purpose of this memorandum is to provide you with a progress report on 3M providing specific instructions recommended by the Office for Analysis and Evaluation of Operational Data (AEOD) to customers reusing high intensity iodine-125 brachytherapy seeds. At the time of our last memorandum to you, dated January 30, 1987, we were awaiting a response to a request for 3M to adopt AEOD's recommendations. Since that time, we discussed the recommendations with 3M's management during a February 12, 1987 site visit. In a letter dated March 16, 1987, 3M responded to our request and committed to revising the product labeling and instructions for these seeds as requested. A copy of the letter is attached. We have discussed the March 16 response with 3M management and asked them to submit actual samples of the labels and instructions when they are complete. Upon receipt, we will amend 3M's license (No. 22-00057-59MD) to incorporate the commitments in the March 16 letter and the actual instructions and labels.

As of this date, 3M has the following in place:

1. An internal procedure to identify and review precautions with each new customer for the reusable iodine-125 seeds. Attached is a copy of a January 30, 1987 letter from 3M which lists customers using the iodine-125 seeds as of that date. This list could be used to send an NRC notice to all users regarding precautions.

2. A warning notice that is included with each shipment of reusable seeds. The notice has been utilized since August 12, 1985 and is described in the attached August 12, 1985 3M letter.

3. Instructions to customers which discuss precautions for ruptured seeds. The instructions currently include recommendations for decontamination surveys and bioassays for individuals handling the seeds. We have attached a January 17, 1985 letter which includes the instructions.

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As you recall during our meeting with the Commissioners' technical assistants on this subject, Margaret Federline, Commissioner Carr's technical assistant, requested that we follow up with her on this matter. Accordingly, you may wish to inform her and the other assistants regarding 3M's actions.

This should close out our response to your December 12, 1986 technical assistance request. If you have any questions, please contact Bruce Mallett at FTS 388-5742.

W. L. Axelson, Chief
Nuclear Materials Safety
and Safeguards Branch

Attachments: As stated

cc w/o attachments:
K. Black, AEOD

RIII 9/29/87
Mallett/jl
04/29/87

RIII
Axelson
4/30/87

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

August 12, 1986

AEOD/C601

MEMORANDUM FOR: John G. Davis, Director
Office of Nuclear Material Safety and Safeguards

James M. Taylor, Director
Office of Inspection and Enforcement

FROM: C. J. Heltemes, Jr., Director
Office for Analysis and Evaluation
of Operational Data

SUBJECT: AEOD CASE STUDY REPORT ON THE RUPTURE OF AN IODINE-125 BRACHYTHERAPY SOURCE AT THE UNIVERSITY OF CINCINNATI MEDICAL CENTER

Attached for your information and action is the AEOD Case Study Report on the Rupture of an Iodine-125 Brachytherapy Source at the University of Cincinnati Medical Center. This report was issued December 27, 1985 for peer review and has been revised based on the comments received during the peer review.

Our study, together with peer review comments, have led us to make the following recommendations:

1. The Office of Inspection and Enforcement (IE) should send an Information Notice to the affected licensees describing the event at the University of Cincinnati and describing the action taken by the licensee and the source manufacturer (3M Company) to prevent the recurrence of similar events.

2. The Office of Nuclear Material Safety and Safeguards (NMSS) in conjunction with the appropriate regional office should insure that the 3M Company's license and the license(s) of any other NRC licensees who supply high intensity iodine seeds be amended to require that, in addition to instructions and safety precautions regarding use of the seeds that are normally communicated to purchasers or other users of the seeds, specific instructions and safety precautions for reusing the seeds be communicated. These procedures should include, as a minimum, the recommendation that the removal of the seeds from catheters be done under a fume hood and recommended safety precautions for insuring the prompt detection of a leaking seed, for example, performing comprehensive wipe surveys of tools and the area used for the removal and reloading of the seeds or leak testing the seeds following the removal/reloading operation.

3. The Office of Nuclear Material Safety and Safeguards (NMSS) should explore the option of addressing the reuse of the high activity iodine-125 seeds during the license issue, renewal, or amendment process and consider requiring licensees who will be using the seeds to submit procedures for handling the seeds to NRC for review.

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We request that prompt consideration be given to implementing the recommendations.

If we can be of further assistance in this regard or if you have questions on other matters regarding the report, please contact Samuel L. Pettijohn of this office on X24496.

C. J. Heltemes, Jr., Director
Office for Analysis and Evaluation
of Operational Data

Attachment:
As Stated

cc: D. Ross, RES
G. Wayne Kerr, SP
T. Murley, R-I
J. Nelson Grace, R-II
J. Keppler, R-III
R. Martin, R-IV
J. Martin, R-V
D. Humenansky, OCM
V. Stello, EDO
J. Roe, DEDO
T. Rehm, AO/EDO
J. Sniezek, DEDROGR

AEOD/C601

Case Study Report

on the

Rupture of an Iodine-125 Brachytherapy Source

at the University of Cincinnati Medical Center

by the

Office for Analysis and Evaluation of Operational Data
Nonreactor Assessment Staff

August 1986

Prepared by:
Samuel L. Pettijohn

This report documents the results of a study completed by the Office for Analysis and Evaluation of Operational Data (AEOD) with regard to particular operating events. The findings and recommendations do not necessarily represent the final position or requirements of the responsible program office nor the Nuclear Regulatory Commission.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The University of Cincinnati Medical Center reported to the Nuclear Regulatory Commission (NRC) Region III by telephone the rupture of an iodine-125 seed (nominal activity of 40 millicuries). The seed, which was one of eight seeds being used by the University of Cincinnati Medical Center for brachytherapy treatment of brain tumors, was ruptured during removal of the seed from Heyer-Schulte coaxial catheters. The seeds, containing iodine-125 adsorbed on anion exchange resin spheres within a .05 mm thick welded titanium capsule, are manufactured by the 3M Company. The 3M Company specification sheet for the seeds indicates that the seeds can be used as removable brachytherapy implants. Because of the initial high activity of the seeds, the seeds can be used to treat several patients. Furthermore, users of the seeds are motivated to reuse the seeds because of the relatively high cost of the seeds. The use of the seeds as removable implants is in contrast with the use of lower activity (0.1 to 1 millicurie) iodine-125 seeds also manufactured by the 3M Company, which are used as permanent implants (e.g., prostate cancer treatment).

The seeds are loaded into catheters for use in temporary brachytherapy implants.* Therefore, each reuse of the seeds involves removing them from old catheters and loading them into new ones. It was during this process of removing the seeds from old catheters using scissors, a razor blade, and a needle that one of the seeds was ruptured. The cause of the rupture was determined to be a cut by the scissors or one of the other sharp objects used to cut the catheters to free the seeds.

Licensee personnel were not immediately aware that one of the seeds had been ruptured.** Consequently, the seeds were loaded into new catheters and implanted in the scheduled patient. As a result, the patient received a thyroid burden and exposure of 557 microcuries and 2087 rads respectively.

The discovery by licensee personnel that a seed(s) had been ruptured followed the discovery of iodine-125 contamination on a source storage/transport bucket for iridium-192 that had been stored in the brachytherapy source room (BSR). The iodine-125 contamination on the source storage/transport bucket and the iodine-125 seed rupture were discovered on the day after the seeds were removed from an old catheter and loaded into the new catheter and implanted in the patient.

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*Seeds used in permanent implants may also be loaded into catheters; however, there is no requirement to remove the seeds from the catheters since the implants are permanent.

**During the period in which the seeds were possessed by the hospital, the seeds had been removed from old catheters and loaded into new catheters on two separate occasions.

The removal of the seeds from the old catheters and loading of the seeds into the new catheters were done in the BSR, an area not ventilated by a fume hood. As a result, the BSR, including the exhaust system, was contaminated (1000-11000 dpm/200 cm^2). Also, although the BSR exhaust system was on at least for a period of time after the seed rupture, the pressure in the BSR was apparently higher than that in the area outside of the BSR. This higher pressure apparently resulted from a blockage in the BSR exhaust system. This resulted in some iodine-125 being released into an area where a number of hospital personnel received uptakes of iodine-125. In total, at least 60 hospital personnel, including personnel involved in the control and clean-up of the contamination, and a friend of the patient received thyroid uptake doses of .04 to 209 nanocuries.

Following the seed removal operation, the work area (in the BSR) and the tools used in the removal and loading of the seeds were surveyed with a survey meter normally capable of detecting low levels of iodine-125. However, the BSR had high background radiation which apparently masked the positive indication of contamination. The licensee did not perform wipe surveys normally done to detect low levels of contamination. After the contamination was discovered, licensee personnel took action to control and decontaminate the area.

Because of the seed rupture event, the University of Cincinnati decided to terminate the use of high activity iodine-125 seeds until the safety and health physics aspects of the use of these seeds were studied.*

AEOD undertook a review of this incident to determine if there is a generic problem associated with the reuse of high activity iodine-125 seeds in brachytherapy implant protocols, and to assess any associated health and safety problems.

The incident at the University of Cincinnati is the only incident of its type known to us involving high activity (30-40 millicurie) iodine-125 seeds. There have been several similar incidents involving the use of low activity (0.1-1 millicurie) iodine-125 seeds. (See NRC Information Notices 80-35 and 80-35, Supplement 1.)

Based on our evaluation of this incident we found that:

1. The risk of an iodine-125 seed rupture is relatively high when the seeds are reused for several patients. The risk of a seed rupture is associated with:

   -- The susceptibility of the seeds to damage from typical tools used for removing the seeds (razor blade, scissors, etc.); and

   -- The discolored or stained condition of the catheters after use in therapy, making viewing of the seeds difficult.

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*As of the date of this report the University of Cincinnati has not resumed the practice of reusing the seeds to treat multiple patients.

2. The consequence of the seed rupture at the University of Cincinnati, involving patient and other personnel uptakes and facility contamination, could have been mitigated by adequate radiation surveys of the work area and the tools used to remove the seeds from the catheter, or by performing a leak test of the seeds. Additionally, personnel uptakes other than the patient and the facility contamination could have likely been prevented if the seed removal operation had been performed under a fume hood.

3. It appears that the consequence (personnel uptakes, and personnel and facility contamination) of a similar event could also be mitigated by employing radiation safety procedures designed to detect promptly if a seed is ruptured and to prevent personnel uptakes and personnel and facility contamination. Such procedures would include: performing the removal/reloading operation in a fume hood; performing wipe surveys of tools and the area used for the removal and reloading of the seeds; or leak testing the seeds following the removal/reloading operation.

In addition to the specific findings stated above, we believe that attention should be called to one other aspect of the incident:

-- The University of Cincinnati's licensed program represents a large isotope research and medical use program that typically employs a full-time health physics staff which is generally familiar with the use of a wide variety of radioisotopes. In this event, however, it appears that licensee personnel failed to appreciate or understand the potential for a seed to be ruptured by the seed removal operation or the consequence of such a rupture, in that the protocol describing procedures to be followed for temporary implants did not require (1) that the seed removal operation be conducted in a fume hood; or (2) that a wipes survey leak test* be performed to verify the integrity of the seeds before the sources were reused.

Based on our findings, we recommend that:

1. The Office of Inspection and Enforcement (IE) send an Information Notice to the affected licensees describing the event at the University of Cincinnati and describing the action taken by the licensee and the source manufacturer (3M Company) to prevent the recurrence of similar events.

2. The Office of Nuclear Material Safety and Safeguards (NMSS) in conjunction with the appropriate regional office should insure that the 3M Company's license and the license(s) of any other NRC licensees who supply high intensity iodine seeds be amended to require that, in addition to instructions and safety precautions regarding use of the seeds that are normally communicated to purchasers or other users of the seeds, specific instructions and safety precautions for reusing the seeds be communicated.

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*NRC regulations do not require such a leak test.

These procedures should include, as a minimum, the recommendation that the removal of the seeds from catheters be done under a fume hood and recommended safety precautions for insuring the prompt detection of a leaking seed, for example, performing comprehensive wipe surveys of tools and the area used for the removal and reloading of the seeds or leak testing the seeds following the removal/reloading operation.

3. The Office of Nuclear Material Safety and Safeguards (NMSS) should explore the option of addressing the reuse of the high activity iodine-125 seeds during the license issue, renewal, or amendment process and consider requiring licensees who will be using the seeds to submit procedures for handling the seeds to NRC for review.

1. INTRODUCTION

The University of Cincinnati reported to NRC Region III by telephone that an iodine-125 brachytherapy source was found to be leaking. The licensee later submitted a written report giving an account of the circumstances surrounding the source rupture (Ref. 1).

In the month following the event, inspection personnel from the NRC Region III office conducted a special inspection to review the facts surrounding the source rupture. The results of this inspection are documented in Region III Inspection Report No. 30-02764/84-02 (Ref. 2).

The University of Cincinnati's medical isotope program is licensed under 10 CFR Part 33 and Part 35, "Broad Scope Byproduct Material License." A "Broad Scope Byproduct Material License," among other things, authorizes licensees to employ a radiation safety committee to conduct safety evaluations of proposed uses (including human use) of byproduct material (e.g., review facilities and equipment, operating or handling procedures, training and experience of users, etc.) and approve such uses in lieu of requesting from NRC approval of proposed uses. The other type of byproduct material license for human use issued by NRC is a "Limited Scope Medical License" authorized under 10 CFR Part 35. This license, among other things, differs from the "Broad Scope Byproduct Material License" in that specific isotopes or groups of isotopes and their authorized uses are listed in the license and any changes in authorized use must be approved by NRC before the changes are implemented.

In regard to the use or reuse of high intensity iodine-125 seeds, the following observations are made relative to licensing:

-- Under the "Broad Scope Byproduct Material License," the use of the seeds is authorized through the mechanism of approval of uses of byproduct material by the radiation safety committee.

-- Under the "Limited Scope Medical License," the use of the seeds is authorized through 10 CFR Part 35.100(f)(8) which authorizes the use of "Iodine-125 as seeds for interstitial treatment of cancer."

-- The "Limited Scope Material License" requires the licensee to follow the radiation safety and handling instructions approved by the Nuclear Regulatory Commission or an Agreement State and furnished by the manufacturer in the leaflet or brochure that accompanies the source.

AEOD's review and analysis of the incident was undertaken to determine whether there is a generic problem with the reuse (treating several patients with the same set of seeds) of high activity iodine-125 seeds, and to assess any associated health and safety problems. This review is primarily based on information obtained from the licensee's report, the NRC Region III inspection report and a telephone conversation with University of Cincinnati personnel involved with the radiation therapy program. The incident at the University of Cincinnati is the only incident of its type known to us involving high activity (30-40 millicurie) iodine-125 seeds. There have been several similar incidents involving the use of low activity (0.1-1 millicurie) iodine-125 seeds. (See NRC Information Notices 80-35 and 80-35, Supplement 1.)

Section 2 is a description of the source rupture event; Section 3 is an analysis of the event; Section 4 discusses the licensee's and the source manufacturer's actions following the event; Section 5 gives the findings of the study; and Section 6 contains the conclusions and recommendations of the study. Appendix A is a copy of the licensee's protocol for the use of iodine-125 seeds in brachytherapy; Appendix B is the manufacturer's specification sheet for the iodine-125 seeds; Appendix C is the manufacturer's specification sheet for the Heyer-Schulte coaxial catheters; and Appendix D is the manufacturer's specification sheet for the MiniMonitor 125 radiation survey meter.

2. DESCRIPTION OF THE EVENT

2.1. General

The source rupture event at the University of Cincinnati involved the rupture of a high activity (40 millicurie) iodine-125 seed. The seed was one of eight seeds being used as a temporary implant in the brachytherapy treatment of brain tumors. The seeds were manufactured by the 3M Company. Because the seeds could be used as temporary brachytherapy implants and because of the high activity and relatively high cost of the seeds, the University of Cincinnati was using the same set of seeds to treat several patients. This reuse of the seeds involved removing the seeds from catheters and loading them into new catheters prior to each insertion. The use of high activity iodine-125 seeds as removable brachytherapy sources was a new procedure at the University of Cincinnati.* Previous uses of iodine-125 seeds involved the use of low activity iodine-125 seeds (0.1-1 millicurie) as permanent brachytherapy implants.

2.2 Chronology of Events

The following excerpt from the NRC Region III inspection report gives a chronology of licensee actions leading to the rupture of the iodine-125 seed. (For further details see Ref. 2.)

(1) On Friday (day 1), the Radiation Safety Office received 400 millicuries of iodine-125 brachytherapy seeds. A total of 10 seeds, 40 millicuries each, were inventoried.

(2) On Monday (day 4), eight of the ten seeds were prepared and implanted.

(3) On Friday (day 8), the seeds were removed from the first patient.

(4) On Monday (day 11), the eight seeds were removed from the original catheters. Five seeds were prepared for treatment of patient 2, however, this treatment was cancelled.

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*A protocol describing procedures to be followed for temporary brain implants received radiation safety committee approval prior to use of the seeds (Appendix A).

(5) On Monday (day 18), the five seeds were removed from the catheter and eight seeds were prepared and implanted into patient 3.

(6) On Tuesday (day 19), a wipe test of a shipping container revealed iodine-125 contamination. Source of contamination was traced to the brachytherapy source storage room [BSR].

(7) On Wednesday (day 20), a wipe test of the patient's head and bandage revealed no contamination.

(8) On Thursday (day 21), a thyroid count on the technician who prepared the seeds revealed a 209 nanocurie uptake.

(9) On Friday (day 22), air flow rates in the brachytherapy source storage room were determined. Urine bioassays of personnel working with the seeds revealed na ocurie amounts of iodine-125.

(10) On Saturday (day 23), the seeds were removed from patient 3. After explant, a survey of the patient's neck revealed a radiation level of 1.5 mR/hr at two inches from the thyroid. The patient was discharged.

(11) On Tuesday (day 26), a urine bioassay from the patient revealed 57.6 microcuries of iodine-125. The NRC in Region III was notified.

(12) On Wednesday (day 27), a thyroid bioassay on patient 3 revealed a burden of 557 microcuries.

(13) On Thursday (day 28), determination of area contamination continued.

(14) On Friday (day 29), the NRC Region III was informed of current conditions and actions taken. Decontamination of the storage room [BSR] continued.

(15) On Monday (day 32), the exhaust system in the storage room [BSR] was modified to increase flow rates.

(16) On Tuesday (day 33), evaluation of contaminated areas continued.

(17) On Wednesday (day 34), the condition of the patient was determined. The walls in the storage room [BSR] were painted to "fix" the contamination.

(18) On Thursday (day 35), air samples taken from the storage room [BSR] revealed no detectable activity.

3. ANALYSIS OF THE EVENT

3.1 Seed Rupture

A review of the manufacturer's specification sheet for the iodine-125 seeds shows that the seeds consist of a welded titanium capsule containing iodine-125 adsorbed on anior exchange resin spheres (Appendix B). The titanium capsule wall thickness is .05 mm. The capsule is a cylinder .8 mm in diameter and 4.5 mm long. The catheters used at the University of Cincinnati were Heyer-Schulte coaxial after-loading catheters made of a silicone elastomer. They consist of an inner and an outer catheter, 16.5 cm long and 15 cm long, respectively (Appendix C). The catheter manufacturer specifies that the catheters are recommended for "single use only"; therefore, reuse of the iodine-125 seeds contained in the catheters requires removing the seeds from the old catheter and loading them into a new catheter.

The technique used for removing the seeds from the catheters at the University of Cincinnati consisted of first cutting the ends off of the catheters using scissors and then using a razor blade to shear the plastic tubing longitudinally in such a manner as to expose the bare seed within the catheter enough so that forceps could grasp the seed. This same technique was reportedly used for removing the seeds on both day 11 and day 18. The protocol describing procedures to be followed for using the hign activity iodine-125 seeds for temporary implants did not address how to remove the seeds from the catheters. The technologist involved in the seed removal feels that the seed was likely ruptured by the scissors when the ends of the catheters were cut off.

Following the discovery of iodine-125 contamination in the BSR and after the sources were removed from the patient, all sources were returned to the 3M Company for analysis. An excerpt from the 3M Company report of the analysis states: (Ref. 3)

> In conclusion, of the ten high-activity I-125 seeds returned to 3M for inspection following discovery of radioactive contamination at your institution, only one seed (seed #2) released I-125. In our estimation this release was caused by structural damage to the titanium shell of the seed in the form of a transverse cut near the weld end. The cut may have been caused by a scissors or wire cutter, etc., used to free seeds from the catheters prior to loading them into new catheters.

This result is consistent with the technologist's view of the cause of the seed rupture.

The technologist involved in the seed removal feels that this cut had likely occurred during removal of the seeds on day 11. The seeds removed at that time were contained in catheters that were stained from having been implanted in a tumor, thus making it difficult to see the seeds in the catheter. In addition, the technologist indicated that the inner catheter and outer catheter were stuck together and could not be separated, further hindering visibility of the seeds. By contrast, the seeds that were removed from the catheters on day 18 had not been used (i.e., the therapy use had been cancelled); therefore, the catheters were clear and allowed greater visibility of the seeds.

3.2 Contamination and Personnel Uptakes

The removal of the seeds on both day 11 and day 18 was done in the brachytherapy source room in an open area that was not ventilated by a fume hood. Also, the BSR apparently was under a slight positive pressure at the time because of a blockage in the room's exhaust system (a damper was partially closed) that reduced the exhaust flow rate to less than the exhaust flow rate for the area outside of the BSR.*

Licensee personnel stated that both times the seeds were removed, radiation surveys of the work area and the tools used in removing the seeds were made and that these surveys revealed no contamination. The surveys were made with a Nuclear Associate MiniMonitor 125 which, according to the manufacturer's specification sheet, has a minimum range of 0-500 counts per minute (cpm) (Appendix D). The Region II inspection report noted that the background radiation level in the BSR was normally high because of the proximity of other brachytherapy sources. This made it difficult to detect contamination using a survey meter. Wipe surveys, which involve wiping suspected contaminated areas with cotton swabs or similar material and later counting the wipes, were not done. Good health physics practices and NRC regulatory requirements indicate that, under the circumstances, wipe surveys should have been performed to look for contamination.** In addition, good health physics practices indicate that, since removal of the seeds from catheters involved non-routine handling of the seeds which increased the risk that seeds could be damaged, the seeds should have been leak-tested following removal of the seeds from the catheters. The protocol describing procedures to be followed for using the high activity iodine-125 seeds for temporary implants did not address wipe surveys or leak testing of the seeds.

On day 19, the day after the sources were implanted in a patient, the licensee discovered iodine-125 contamination on a source storage/transport bucket for iridium-192 that had been stored in the BSR. The iodine-125 contamination which was discovered during routine wipe surveys of the bucket (being prepared for shipment) averaged approximately 625 dpm/200 cm^2. The contamination was traced to the BSR. The BSR was sealed off and decontamination was begun. Wipe testing of the brachytherapy source room revealed contamination levels of 1000-11000 dpm/200 cm^2.

The day following the discovery of iodine-125 contamination in the BSR, licensee personnel wipe tested the patient's lead hat and bandage to check for contamination. No contamination was found. Later, after it was determined

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*Following the discovery of contamination in the BSR, it was closed off using plastic over the door. It was noted that the plastic was ballooned outward, indicating a positive differential pressure between the BSR and the area outside of the BSR.

**The licensee was cited by NRC/Region III for being in violation of 10 CFR 20.201(b), which requires licensees to make surveys as necessary and reasonable under the circumstances to evaluate the radiation hazards.

that the source of the iodine-125 contamination was the implanted seeds, a medical decision was made to leave the sources implanted for the prescribed period of the therapy (Ref. 4).*

The implanted seeds were removed from the patient on day 23. The catheters containing the seeds were placed in a lead-shielded container and taken to the radiation safety laboratory and placed in a fume hood. The catheters containing the seeds were later sent to the 3M Company for evaluation. A survey of the patient's room with a survey meter revealed no contamination. However, a survey of the patient revealed a radiation level of 1.5 millirem per hour 2 inches from the thyroid gland. The patient was released from the hospital on day 25. On day 27, the patient returned to the hospital for a bioassay and the results indicated a thyroid burden and exposure of 557 microcuries and 2087 rads, respectively.

The positive differential pressure between the BSR and the area outside it existed for several days following the discovery of iodine-125 contamination in the room. The positive differential pressure contributed to the airborne migration of the iodine-125 into adjacent areas. This resulted in numerous personnel who frequented these areas receiving uptakes of iodine-125. Other personnel involved in the control and cleanup of the contamination also received iodine-125 uptakes. Bioassay results for these personnel indicated that:

-- The technician who prepared the iodine-125 seeds had a thyroid uptake of 209 nanocuries; and

-- At least sixty hospital personnel and a friend of the patient had thyroid uptakes that ranged from .04 to 209 nanocuries.

The maximum permissible thyroid burden (MPBB) for iodine-125 is 500 nanocuries.

Although the contamination of the BSR was extensive, wipe surveys and air samples revealed that the contamination was essentially limited to the BSR. Wipe tests taken in the brachytherapy source room on day 29 showed contamination levels that ranged from 160-3900 dpm/200 cm^2 for the wall and floor to 1900 dpm/200 cm^2 on the lowered-ceiling tiles. A maximum total of 25 microcuries of iodine-125 was estimated to be in the paint on the walls. Air samples taken in the BSR on day 32 showed air concentrations of 125 dpm/20 ft^3 (less than the maximum permissible concentrations for restricted areas). Air samples taken outside of the BSR showed negligible iodine-125 concentrations. However, some contamination (low level) was found on the surface area of the BSR exhaust vent at the point of release.

The University of Cincinnati successfully decontaminated the BSR or fixed the contamination by repainting the walls.

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*Because a medical evaluation and decision was made to leave the implanted sources in place, the iodine-125 uptake by the patient was not deemed by NRC to be a medical misadministration as defined in 10 CFR 35.41.

4. LICENSEE AND SOURCE MANUFACTURER ACTIONS

4.1 Licensee Actions

As a result of the source rupture, the University of Cincinnati suspended the use of high intensity iodine-125 seeds pending the investigation of the event (Ref. 5).* The University of Cincinnati, in their response to the NRC Notice of Violation,** expressed concern that there was a likelihood of other occurrences of source ruptures involving the reuse of high intensity iodine-125 seeds.

An excerpt from the University of Cincinnati's response is as follows:

> The sealed source was opened by a radiation safety technologist under conditions of poor visibility. This accident could have happened at any installation in the country where the seeds would have been placed in plastic tubing which becomes discolored from use and an attempt made to retrieve the seeds and reutilize them because of their cost.

4.2 Source Manufacturer Actions

In a letter to NRC dated February 11, 1985, regarding the 3M Company's "peer review" of the AEOD preliminary case study report of the event, the Company stated that "subsequent to the Cincinnati incident, 3M upgraded its internal procedures aimed at providing additional control for institutions/uses involving high activity seeds."

The following description of the upgraded procedures was presented:

> 1. 3M Customer Service directs all phone inquires about the use of I-125 Seeds Model 6702 for brain implants to someone in Technical Service.
>
> 2. This Technical Service person summarizes 3M's REQUIREMENTS of an institution prior to selling the seeds for such use, which include submission to 3M of 1) a Brain Implant Protocol, 2) an Institutional Review Board (or equivalent) approval of that protocol, and 3) a copy of the Patient Informed Consent form. In the same phone conversation, risks and hazards associated with the handling of the 30-40 mCi seeds are summarized to include the consequences of cutting a seed while removing it from the afterloading catheters. (The Cincinnati incident is alluded to but the hospital is not identified.)

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*As of the date of this report the University of Cincinnati has not resumed the practice of reusing the seeds to treat multiple patients.

**The University of Cincinnati was in noncompliance with the License Condition 15, which states that sealed sources shall not be opened, and 10 CFR 20.210, failure to make adequate radiation surveys.

3. A follow-up Brain Implant Protocol letter is mailed to the customer.

Prior to the Cincinnati incident, a phone call was not always followed with a letter since it was believed that adequate verbal instructions were given to a knowledgeable customer.... Following the Cincinnati incident, a follow-up letter was always sent.... We believe that requiring a radiation safety section in the implant protocol provided adequate assurance that the seeds would not be mishandled if reused. The letters also directed the customer to knowledgeable people [in 3M] who could advise about the proper handling of seeds during reuse.

5. FINDINGS

1. The risk of an iodine-125 seed rupture is relatively high when the seeds are reused for several patients. The risk of a seed rupture is associated with:

   -- The susceptibility of the seeds to damage from typical tools used for removing the seeds (razor blade, scissors, etc.); and

   -- The discolored or stained condition of the catheters after use in therapy, making viewing of the seeds difficult.

2. The consequence of the seed rupture at the University of Cincinnati, involving patient and other personnel uptakes and the facility contamination, could have been mitigated by adequate radiation surveys of the work area and the tools used to remove the seeds from the catheter, or by performing a leak test of the seeds. Additionally, personnel uptakes other than the patient and the facility contamination could have likely been prevented if the seed removal operation had been performed under a fume hood.

3. It appears that the consequence (personnel uptakes, and personnel and facility contamination) of a similar event could also be mitigated by employing radiation safety procedures designed to detect promptly if a seed is ruptured and to prevent personnel uptakes and personnel and facility contamination. Such procedures would include: performing the removal/reloading operation in a fume hood; performing wipe surveys of tools and the area used for the removal and reloading of the seeds; or leak testing the seeds following the removal/reloading operation.

In addition to the specific findings stated above, we believe that attention should be called to one other aspect of the incident:

   -- The University of Cincinnati's licensed program represents a large isotope research and medical use program that typically employs a full-time health physics staff which is generally ... familiar with the use of a wide variety of radioisotopes. In this event, however, it appears that licensee personnel failed to appreciate or understand the potential for a seed to be ruptured by the seed removal operation or the consequence of

such a rupture. in that the protocol describing procedures to be followed for temporary implants did not require (1) that the seed removal operation be conducted in a fume hood; or (2) that a wipes survey leak test be performed to verify the integrity of the seeds before the sources were reused.

6. CONCLUSIONS AND RECOMMENDATIONS

Based on our findings, we recommend that:

1. The Office of Inspection and Enforcement (IE) send an Information Notice to the affected licensees describing the event at the University of Cincinnati and describing the action taken by the licensee and the source manufacturer (3M Company) to prevent the recurrence of similar events.

2. The Office of Nuclear Material Safety and Safeguards (NMSS) in conjunction with the appropriate regional office should insure that the 3M Company's license and the license(s) of any other NRC licensees who supply high intensity iodine seeds be amended to require that, in addition to instructions and safety precautions regarding use of the seeds that are normally communicated to purchasers or other users of the seeds, specific instructions and safety precautions for reusing the seeds be communicated. These procedures should include, as a minimum, the recommendation that the removal of the seeds from catheters be done under a fume hood and recommended safety precautions for insuring the prompt detection of a leaking seed, for example, performing comprehensive wipe surveys of tools and the area used for the removal and reloading of the seeds or leak testing the seeds following the removal/reloading operation.

3. The Office of Nuclear Material Safety and Safeguards (NMSS) should explore the option of addressing the reuse of the high activity iodine-125 seeds during the license issue, renewal, or amendment process and consider requiring licensees who will be using the seeds to submit procedures for handling the seeds to NRC for review.

7. REFERENCES

(1) Letter from Eugene L. Saenger, M.D., to NRC.

(2) Region III Inspection Report Number 30-02764/84-02 (DRSS).

(3) Letter from David Kubiatowicz, Medical Products Division, 3M Company to Peter Ho, M.D., Department of Radiation Therapy, University of Cincinnati Hospital General.

(4) Letter from Eugene L. Saenger, M.D., Chairman, Radiation Safety Committee, University of Cincinnati Medical Center, to William Axelson, NRC (Region III).

(5) Memorandum from Eugene L. Saenger, M.D., University of Cincinnati Medical Center to Bernard S. Arin, M.D. and Peter Y. C. Ho, M.D., University of Cincinnati Medical Center.

(6) Letter from Robert G. Wissink, Manager, Health Physics Services, 3M Company to Darrell Wiedeman, Chief, Materials Radiation Protection Section, NRC (Region III).

APPENDIX A

Protocol for the use of ^{125}I sealed sources for implant into patient's tumor:

1. Upon receiving ^{125}I shipment

   A. A wipe test is first made inside the source container bottle by Radiation Safety to detect possible leakage of the sealed source.

   B. Calibration of each shipment of sealed sources is done by Radiation Oncology with a dose calibrator using an NBS standard source (available late 1983).

2. Preparation for implants

   A. The ^{125}I seeds are loaded into shielded cartridges or afterloading devices by Radiation Oncology technologist/staff/residents with special tools designed for handling the seeds standing behind a lead shield or wearing a lead apron.

   B. Afterloading, the instruments used for handling the ^{125}I seeds will be checked with a thin window counter to check for leakage contamination due to possible mechanical damage to the seeds.

   C. The shielded cartridges or afterloading devices are gas sterilized for 24 hours or steam sterilized for 10 minutes.

3. During implant in patients and immediately post implant

   A. The instruments used in the implant should be monitored with a thin window counter after the implant to check for leakage contamination due to possible mechanical damage to the seeds.

   B. The suction apparatus, tubing and traps, including the Foley bag are checked for loose ^{125}I seeds and removed appropriately for disposal by Radiation Oncology or Radiation Safety.

4. Post implant monitoring - per Radiation Safety regarding exposure to personnel

5. If leakage is discovered

   A. Upon receiving shipment - container is to be sealed and disposed appropriately by Radiation Safety.

   B. During handling of seeds - all personnel or patients involved are to have their urine checked and undergo thyroid counting to monitor exposure.

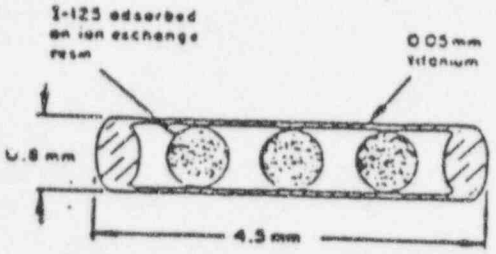
6. All unused ^{125}I seeds are to be returned to Radiation Safety for disposal except for reusable high activity ^{125}I seeds (40 mCi), which are to be stored in Radiation ONcology's shielded safe. These will be returned when the activity is below 10 mCi each.

7. All operators and technologists handling ^{125}I seeds will wear finger badges.

I-125 Seeds
No. 6702

Description

I-125 Seeds 6702 consist of a welded titanium capsule containing Iodine-125 adsorbed on anion exchange resin spheres.



Physical Characteristics

Iodine-125 has a half-life of 60.2 days and decays by electron capture with the emission of characteristic photons and Auger electrons. The electrons are absorbed by the titanium wall of the I-125 Seed. The principal photon emissions are 27.4 and 35.5 keV x-rays and a 35.5 keV gamma.

To correct for the physical decay of Iodine-125, the decay factors at selected days after the assay date are shown in the table below.

Decay Chart Iodine-125, Half Life 60.2 Days

Days	Decay Factor	Days	Decay Factor
0	1.000	36	0.661
2	0.977	38	0.646
4	0.955	40	0.631
6	0.933	42	0.617
8	0.912	44	0.603
10	0.891	46	0.589
12	0.871	48	0.575
14	0.851	50	0.562
16	0.832	52	0.550
18	0.813	54	0.537
20	0.794	56	0.525
22	0.776	58	0.513
24	0.759	60	0.501
26	0.741	62	0.490
28	0.724	64	0.479
30	0.708	66	0.468
32	0.692	68	0.457
34	0.676	70	0.447

Radiation Protection

The half value thickness of lead for Iodine-125 is 0.025 mm. Thus, a 0.25 mm lead sheet will provide > 99% reduction in exposure.

Actions

I-125 Seeds emit 27.4 and 35.5 keV x-rays and a 35.5 keV gamma. The clinical efficacy of the sources derives solely from the interaction of these ionizing radiations with the tissue being treated.

Dose distribution around each individual seed is not isotropic. This anisotropy should be included in dose distribution calculations.

Titanium encapsulation assures good tissue compatibility and results in a total self-absorption of approximately 16%.

Indications

I-125 Seeds are indicated for interstitial treatment of tumors which have the following characteristics: unresectable, localized, and moderate radiosensitivity.

I-125 Seeds may be used for selected radiation applications as removable implants.

I-125 Seeds are indicated to treat residual tumors following completion of a course of external radiation therapy. In addition, recurrent tumors may be implanted with I-125 Seeds.

Contraindications

As with other brachytherapy sources, treatment of tumors in generally poor condition (eg, ulcerated) is not recommended with

Warnings

The I-125 Seed titanium capsule has excellent corrosion resistance, but it is attacked by concentrated hydrochloric acid. I-125 Seeds have been designed not to be used in a concentrated HCl environment.

Precautions

Preparation for Use/Sterilization

I-125 Seeds are radioactive and appropriate precautions must be taken when handling these sources. All steps of the implantation procedure should be planned in advance to minimize radiation exposure to personnel, consistent with published exposure limits.

Personnel monitoring is required for individuals working with I-125 Seeds. A film badge or TLD dosimeter worn on the body and, for handling, a ring badge will provide adequate detection.

I-125 Seeds are provided in a glass vial which should be maintained in a lead vial container for storage. When transporting seeds within the hospital premises, an appropriate carrier with adequate shielding should be used.

All manipulations involving I-125 Seeds should be carried out behind shielding of such size and thickness as will adequately shield the operator. DIRECT CONTACT WITH THE SOURCES SHOULD BE AVOIDED. In addition, I-125 Seeds should be handled only with forceps, with as much distance as practical between sources and the operator. I-125 SEEDS SHOULD NOT BE PICKED UP WITH THE HANDS.

I-125 Seeds are NOT sterile when shipped and as such must be sterilized with steam (autoclave) or ethylene oxide (EO) before implantation. Regardless of the method selected, I-125 Seeds should be placed in an adequately shielded container prior to placement in the sterilization chamber. Manipulation of the seeds prior to or following sterilization should be carried out behind shielding of such size and thickness as will adequately shield the operator. In addition, I-125 Seeds should be handled only with forceps, with as much distance as practical between sources and the operator. Autoclaves should be equipped with traps or other means to prevent seed loss through the drain hole.

I-125 Seeds have been designed to withstand normal autoclave temperature and pressure variations from 121° C at 15 psi to 138° C at 35 psi. I-125 SEEDS ARE NOT INTENDED TO BE STERILIZED USING DRY HEAT AND SHOULD NOT BE SUBJECTED TO TEMPERATURES AND PRESSURES IN EXCESS OF THESE LIMITS (138° C and 35 psi).

I-125 Seeds should be autoclaved in bulk or individually in appropriate containers of autoclave-compatible materials. These materials include stainless steel, glass, nylon, and teflon. I-125 Seeds may also be autoclaved in selected accessories to commercially-available implant tools. Among these accessories are the stainless steel cartridge of the Mick applicator and gun, and nylon and teflon tubing used as seed holders with Henschke and Scott applicators. When in doubt about the chemical nature of these seed holders, either sterilize the materials with ethylene oxide or autoclave a sample of the materials containing dummy seeds before attempting to load with radioactive seeds. DO NOT AUTOCLAVE I-125 SEEDS IN PLASTIC TUBING OR OTHER PLASTIC CONTAINERS.

Although I-125 Seeds have a high structural integrity, it is possible through rough handling, high temperatures or crushing, that a seed could leak or be ruptured. If such a rare occurrence does happen, the area should be closed off, the seeds packaged into a sealed container and the area decontaminated. Decontamination can be confirmed by taking "wipe" samples of the immediate area. Personnel movement should be controlled to avoid spread of any radioactive contamination. Whenever a source is damaged, personnel working in the area should undergo a thyroid scan to assure that they have not been contaminated by contact, ingestion or inhalation of Iodine-125.

Medical Products Division/3M

TCAAP
New Brighton, Minnesota 55112

3M

Certification	KM54963	70-4.9
Iodine-125 Sealed Sources For Medical Uses		1 Sep.1983

Consignee: UNIV CINCINNATI MED. CTR RADIOISOTOPE LAB

Address: 234 GOODMAN ST CINCINNATI, OH 45267

The following radioactive sources are certified by Minnesota Mining and Manufacturing Company (3M) to have been subjected to the tests described below and to have been given the results listed.

Model Number	6702					
Lot Number	IS-819					
Quantity	10					
Activity Range (mCi)*	38.0-40.0					
Total Activity (mCi)*	390.0					
Assay Date	8-13-84					

All seeds have passed a leak test showing <0.005 μCi of removable ^{125}Iodine activity. No other certification is to be implied.

* By "mCi" we mean "apparent activity in millicuries", which is descriptive of output activity only and not the total quantity of I-125 contained within the titanium capsule of the Seed.

For accounting purposes, the quantity of I-125 contained in Model 6702 or Model 6711 Seeds is about 1.2 or 1.6 respectively multiplied by the stated apparent activity in millicuries.

Read the reverse side of this form for information about Seed construction, method of calibration and definition of "apparent activity in millicuries".

Sharon J. Drew
Quality Control

9 August 1984
Date

Wilmes — Hug —

The following procedure is furnished by Phillip H. Gutin, M.D.,* for informational purposes:

The Coaxial Afterloading Catheter can be used for implantion of radioactive sources into brain tumors. The outer catheter is generally placed to a tumor target through a burr hole or twist drill hole using a stylet guided by computed-tomography directed stereotaxy. The catheter passes through the silicone base before entering the brain.

When the catheter is at the target, the silicone base is pushed down to the skin or to the skull. It can then be sutured in position, or, in the case of the skull, it can be glued to the bone with biological adhesive. Then, the outer catheter is glued to the base with biological adhesive. The stylet is removed and replaced with the inner catheter containing the radioactive sources. The inner catheter is secured to the outer catheter with a drop of biological adhesive.

HOW SUPPLIED

Each catheter is provided individually wrapped in a NONSTERILE condition, and consists of an external catheter with suturing flange and two telescoping internal catheters. All catheters must be cleaned and sterilized per the instructions below.

*Phillip H. Gutin, M.D.
University of California Hospitals
505 Parnassus
Department of Neurosurgery
Q83H423
San Francisco, 94143

Special order devices are supplied either sterile or nonsterile as indicated on the product label. Nonsterile products, if intended for implantation or an aseptic application, must be cleaned and sterilized prior to use. If your product is nonsterile, the cleaning and sterilization procedures given below have been found effective and are provided as a guide.

STERILIZATION

This product is recommended for single use only. It is recommended that each institution establish the efficacy of its sterilization procedure by a method which includes the sterilization of an intentionally contaminated product.

Do not sterilize in the packaging system supplied.

The following cleaning and sterilization techniques have been found effective and are provided as a guide:

Remove the Meyer-Schulte Coaxial Afterloading Catheter from its package in a clean environment using gloved hands. Lint, fingerprints, talc and other surface contaminants can cause foreign body reactions. Utmost caution should be taken to avoid contaminants.

Use an alcohol (ethyl or isopropyl) swab to remove oily surface contaminants.

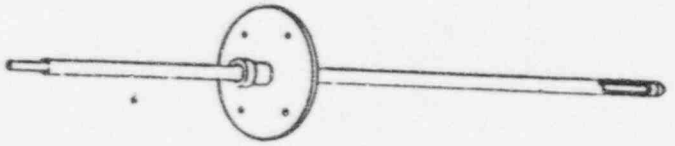
Hand wash soiled silicone devices for a maximum of 15 minutes in a solution of mild surgical soap or a one percent anionic detergent. If it is necessary to use a brush, only

SPECIFICATIONS (All Dimensions are Nominal)

Catalog Number	Description	Tip	Suture Collar Diameter	Catheter Length: Inner	Outer
GRB0035-01	Coaxial Afterloading Catheter	Clear	2 cm	16.5 cm	15 cm
-02		Radiopaque	2 cm	16.5 cm	15 cm
-03		Radiopaque	1 cm	23.5 cm	22 cm
-04		Radiopaque	2 cm	23.5 cm	22 cm

Special Order Devices are Manufactured & Distributed by:

AMERICAN MEYER-SCHULTE
Division of
American Hospital Supply Corporation
600 Pine Avenue
Goleta CA 93117
Telephone (805) 967-3451



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Functional failure of the catheter system due to separation of its component parts can result in serious complications. Catheters may migrate into other areas causing serious harm to the patient.

Infection is a common and serious complication of a catheter system and is most frequently caused by skin contaminants. Septicemia, which occurs most frequently in debilitated infants, can result from infections anywhere in the body and may develop with few or no symptoms. It may occur as a result of a wound infection. In the event of an infection, removal of the catheter system is indicated in addition to the appropriate chemotherapy.

RETURNED GOODS POLICY

U.S. Customers

Authorization must be received from American Hayer-Schulte, Division of American Hospital Supply Corporation, prior to the return of merchandise. Merchandise returned must have all manufacturer's seals intact and be received within 60 days of date of invoice to be eligible for credit or replacement. Returned products may be subject to restocking charges.

International Customers

Authorization for return of merchandise should be obtained from your respective dealer. Other conditions noted above also apply.

PRODUCT INFORMATION DISCLOSURE

American Hayer-Schulte has exercised reasonable care in the choice of materials and manufacture of this product. American Hayer-Schulte excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. American Hayer-Schulte shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this product. American Hayer-Schulte neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

PRODUCT ORDER INFORMATION

U.S. Customers - Catalog Products

To order directly in the U.S.A., please contact American V. Mueller, exclusive United States distributor for all American Hayer-Schulte products with distribution centers in Irvine and Hayward CA; Orlando FL; Norcross GA; McGaw Park IL; Bedford MA; Romulus MI; Minneapolis MN; Maryland Heights MO; Edison NJ; Columbus OH; Richardson and Woodland TX.

U.S. Customers - Special Products

For information on special order devices, please contact the Customer Service Department of American Hayer-Schulte, 600 Pine Avenue, Goleta CA 93117. Toll-free telephone (800) 235-5731.

International Customers - Catalog Products

For product information or to order directly, contact your local American Hayer-Schulte distributor or the American V. Mueller International Customer Service Department at 1500 Waukegan Road, McGaw Park IL 60085 USA. Telephone (312) 473-1500, Telex (TWX) 910 210-195.

In Canada, contact AHS/Medical Specialties, Division of McGaw Supply Ltd., 2390 Argentia Road, Mississauga, Ontario, Canada L5N 3P1. Telephone (416) 821-9891.

International Customers - Special Products

For information on special order devices, please contact the Customer Service Department at American Hayer-Schulte, 600 Pine Avenue, Goleta CA 93117 USA. Telephone (805) 967-3451, Telex (TWX) 910 334-1165.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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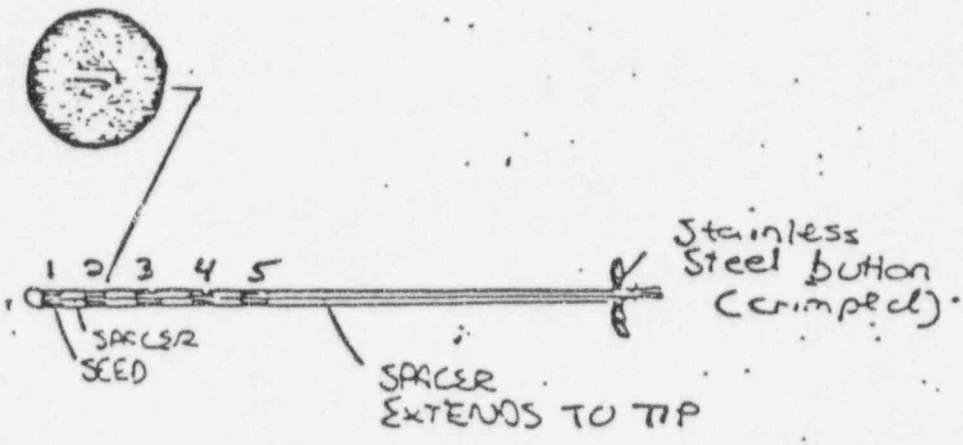
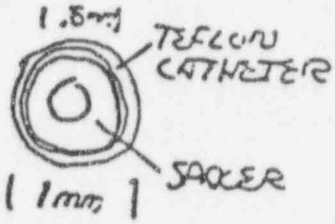


9 & 10 Loose pig



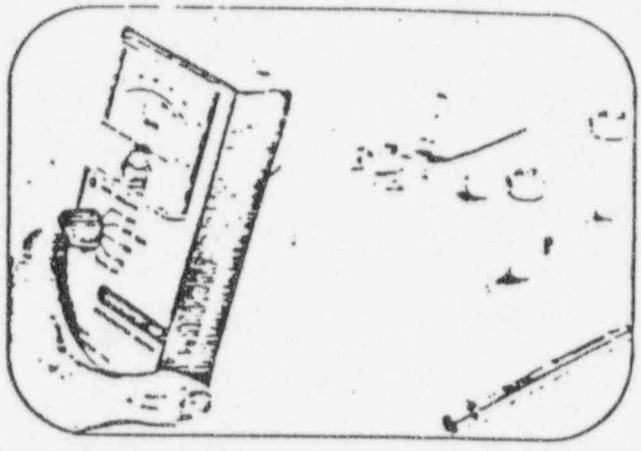
APPROXIMATELY ACTUAL SIZE

MiniMonitor 125

Contamination Monitor

Measures low-level ^{131}I surface contamination quickly and accurately

- High sensitivity (lower detection limit — 0.002 μCi).
- Three ranges (0-500, 5K and 50K cpm).
- Large-area, screened detector permits contact surface measurements.



For the first time, a compact, sensitive monitor is available for the detection of ^{125}I surface contamination levels as low as 0.002 μCi.

A large-area, thin-window GM detector, recessed in a conical housing on the back of the instrument, permits direct-contact measurements of surfaces. The maximum amount of removable contamination allowed* (0.005 μCi) is well within the detector limits of the unit. All surfaces as well as hands, clothing, shoes, etc., may be routinely monitored by using this hand-held instrument.

Lightweight (22 ounces) and portable, the monitor operates on 4 alkaline "AA" cells. All controls are conveniently located on the instrument's face. An LED indicator flashes with each incident radiation pulse. The LED also indicates that the unit is "on."

MiniMonitor 125 may be used as a convenient, general-response survey meter for radiation detection in the laboratory. The 3-range selector switch permits rapid changing of survey ranges. Radiation levels are read on a large 2½" meter. The monitor includes a plastic contamination shield for protecting the detector housing and a license-free radioactive source for checking the instrument's overall operation.

Detector: Halogen-quenched GM pancake tube, 1.2" diam.
Readout: 2½" analog meter, marked 0 to 500.
Ranges: 0-500, 0-5,000, 0-50,000 cpm.
Accuracy: ±10% of full scale.
Controls: Off, Battery Test, x100, x10, x1 ranges — all on one switch.
Time Constants: 10 secs (x1); 2 secs (x10); 0.3 secs (x100).
Batteries: Four "AA" alkaline cells (500-hour life).
Operating Temperature: −20°C to +55°C (−4°F to +130°F).
Temperature Dependence: ±15% over noted temperature range.
Construction: All solid state electronics. High-impact plastic case.
Accessories Supplied: Plastic contamination shield. License-free check source.
Size: 6" high x 3¼" wide x 2" thick. Weight: 22 ounces.

05-572 MiniMonitor 125 Contamination Monitor ___$325.00

*Per NRC or Agreement State regulations.