3M Corporate Product Responsibility

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

3M

April 5, 1991

Patricia J.Pelke
Materials Licensing Section
U. S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Re: NRC Control No. 91041
Materials License No. 22-00057-59MD

Dear Ms. Pelke:

This letter is to submit additional information to NRC Control No. 91041, as we discussed during our recent telephone conversation. The license amendment application which is the subject of this control number was originally submitted by 3M on February 15, 1991.

Specifically, this submission includes labeling for I-125 Seeds, which we have revised since our February application to incorporate editorial changes requested by Medi+Physics, Inc. Among the revisions are a change in the telephone number for the Medi+Physics Canadian office, incorporation of a unique 11-digit packaging stock number to each item, and correction of typographical errors. There are no changes of substance to these labeling items.

In response to your request, I am enclosing copies of correspondence from 3M and Medi+Physics, Inc., notifying the user community of this change in ownership of I-125 Seeds. The 3M letter has been sent to approximately 3,100 individuals, to include 3M's customer list and all members of AAPM, the American Association of Physicists in Medicine. The letter from Medi+Physics was sent to radiation oncologists and medical physicists, totally approximately 1,200. The Medi+Physics letter, in particular, advises the customer that shipping and product return activities will continue to be conducted from the New Brighton plant.

I appreciate your timely review of our license amendment application. If you have additional questions, please feel free to contact me (612/733-6421).

Sincerely yours,

Jacquelyn D. Bush
Sr. Regulatory Affairs Specialist
3M Corporate Product Responsibility
3M Center, 225-3N-02
St. Paul, MN 55144-1000

LABELING

for

I-125 SEEDS 6702, 6711

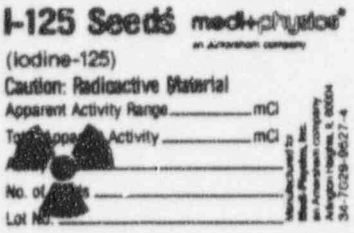
Control No. 91041

Materials License No. 22-00057-59MD/

VIAL LABEL for I-125 SEEDS

PIG LABELS FOR I-125 SEEDS 6702, 6711, 6720

VIAL LABEL for I-125 SEEDS



PIG LABELS for I-125 SEEDS 6702, 6711, 6720

I-125 Seeds®

medi+physics®
an Amersham company

Therapeutic For Interstitial Brachytherapy 6702

Manufactured for
Medi-Physics, Inc.
an Amersham company
Arlington Heights, IL 60004

DESCRIPTION: I-125 Seeds consist of a welded titanium capsule containing iodine-125 absorbed 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. 34-7029-9530-6

Caution
Radioactive
Material

WARNING: The U.S. Nuclear Regulatory Commission has approved the 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.

I-125 Seeds®

medi+physics®
an Amersham company

Therapeutic For Interstitial Brachytherapy 6711

Manufactured for
Medi-Physics, Inc.
an Amersham Company
Arlington Heights, IL 60004

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. 34-7029-9531-6

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.

I-125 Seeds®

medi+physics®
an Amersham company

In Carrier
Therapeutic For Interstitial Brachytherapy
6720

Manufactured for
Medi-Physics, Inc.
an Amersham company
Arlington Heights, IL 60004

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 adsorbed 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.

34-7029-9532-4

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.

PACKAGE INSERTS for I-125 SEEDS 6702, 6711
and I-125 SEED-IN-CARRIER 6720

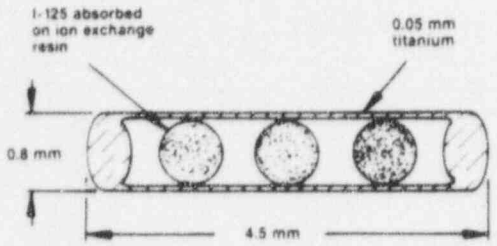
CERTIFICATION SHEET FOR SEALED SOURCES

ENCLOSURE WARNING CARD

I-125 Seeds
No. 6702

Description

I-125 Seeds 6702 consist of a welded titanium capsule containing Iodine-125 absorbed 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-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 Medi-Physics, Inc. Customer Service at 1-800-228-0126. Residents of Canada call 1-416-847-1166.

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 implantations procedure should be planned in advance to minimize radiation exposure to personnel.

Personnel monitoring is required. Typically 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 black "Medi-Physics, Inc." 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 (EtO). 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 (EtO) Sterilization. Use cycle and aeration times recommended by the sterilizer's manufacturer or 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 and Scott applicators. USE ETHYLENE OXIDE TO STERILIZE SEEDS LOADED INTO THE PLASTIC TUBES; STEAM HEAT WILL WARP THE TUBES AND PREVENT SEED RECOVERY.

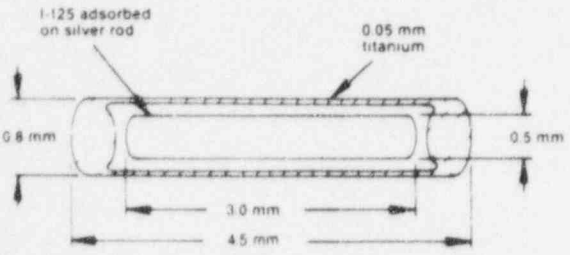
When in doubt about compatibility of steam heat with various Seed containers, load them with non-radioactive Seeds to determine the effect of steam on the container material and on Seed recovery.

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.

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, scapel, 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 Medi-Physics, Inc. Customer Service at 1-800-228-0126. Residents of Canada call 1-416-847-1166.

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 implantations procedure should be planned in advance to minimize radiation exposure to personnel.

Personnel monitoring is required. Typically 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 black "Medi-Physics, Inc." logos visable 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 (EtO). 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 (EtO) 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.

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.

Personnel monitoring is required. Typically 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.

Manufactured for
Medi-Physics, Inc., an Amersham company
Arlington Heights, IL 60004

medi+physics®
an Amersham company

Certification	**85-3.006**
Iodine-125 Sealed Sources For Medical Uses	**March 1991**

Consignee: _____

Address: _____

The following radioactive sources are certified by Medi-Physics, Inc., an Amersham company, to have been subjected to the tests described below and to have been given the results listed.

Model Number					
Lot Number					
Quantity					
Activity Range (mCi)*					
Total Activity (mCi)*					
Assay Date					

All seeds have passed a leak test showing $< 0.005\ \mu Ci$ 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 above 1.2 or 1.6 respectively multiplied by the stated apparent activity in millicuries. "Model 6720 I-125 Seeds® In Carrier contains Model 6711 Seeds."

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

_____ _____

Quality Control **Date**

Certification

Iodine-125 Sealed Sources For Medical Uses

Form 29466 - C - PWO

Amersham
Amersham International plc
Amersham U.K.

Consignee
Address

The following specified radioactive sources manufactured for Medi-Physics, Inc., an Amersham company, have been subjected to the tests described below and to have been given the results listed.

Model Number								
Lot Number								
Quantity								
Air kerma rate* at 1 metre in μGy/h	**Range**	**Maximum**						
		Midpoint						
		Minimum						
Total air kerma rate at 1 metre in μGy/h**								
Equivalent activity* in mCi	**Range**	**Maximum**						
		Midpoint						
		Minimum						
Total equivalent activity in mCi**								
Measurement Date								

All seeds have passed a leakage and contamination test showing less than 0.185 kBq, 0.005 μCi of removable iodine-125 activity. No other certification is to be implied.

*"Air kerma rate", "Total air kerma rate", "Equivalent activity" and "Total equivalent activity" are descriptive of the radiation **Output** and not the content activity.

**"Total" is defined as the sum of the individual values for each seed in the lot.

For accounting and regulatory purposes calculate the content activity of Model 6702 and Model 6711 seeds by multiplying the stated equivalent activity in millicuries by 1.2 and 1.6 respectively. Multiply the content activity in millicuries by 37 to obtain the SI value in megabecquerels (MBq).

Read the reverse side of this form for information about Seed construction, method of calibration and definitions of "air kerma rate" and "equivalent activity".

Quality Control	Date

ENCLOSURE WARNING CARD

Warning:

I-125 SEEDS INTENDED FOR PERMANENT IMPLANT

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

I-125 SEEDS INTENDED FOR TEMPORARY IMPLANT AND REUSE

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

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

To assure that Seeds have not been damaged following removal from th afterloading catheters, conduct a contamination survey with a radiatic capable of detecting 30 keV photons. This survey should include wip of Seeds and an overall area survey. For Seed leak test details, conta Inc. Customer Service at 1-800-228-0126. Residents of Canada cal

INSTRUCTIONS PROVIDED TO CUSTOMERS
REGARDING
RETURN OF I-125 SEEDS TO NEW BRIGHTON PLANT

medi+physics®

an Amersham company

Dear Customer:

You have received a shipment of I-125 Seeds®. The terms of your purchase included the privilege of returning unused packs to Medi-Physics, Inc. for reimbursement (minus restocking charge).

The Seed vials must not be opened or damaged in any way.

The condition of the Seed units must be perfect as they will be resold to other users.

The Seeds must be returned and received by Medi-Physics, Inc., within seven days from the date shipped to your hospital in order to qualify for reimbursement. Reason for Return sheet must be completed and returned with seeds.

Shipment of radioactive materials is controlled by a number of government agencies, including the Department of Transportation and the Nuclear Regulatory Commission. These regulations require proper packaging for shipment, marking, labeling, and certification of the packages by the shipper. You, as a shipper, are responsible to see that these regulations are met.

The Seeds must be shipped back to our facilities via air freight, prepaid. Each unit of Seeds incorporates its own shielded container which should be adequate for the shipment of your Iodine to Medi-Physics, Inc. However, final determination of the adequacy of the shielding is your responsibility as the shipper. It is legally required that you monitor the package you ship for external contamination and external radiation dose rate prior to presenting it for shipment to Medi-Physics, Inc.

Please prepare the shipment in the following manner:

1) Place the securely taped units in the carton. Fill any void with packing.

2) Complete Reason for Return sheet and place in carton.

3) Tape the carton closed.

4) Affix the address label which we have provided.

5) Using a suitable survey meter, carefully measure the radiation dose on all six surfaces of the package. This reading must NOT exceed 0.5 milliroentgens per hour. If it does, please call the undersigned.

March 1991
34-7029-9646-2

One mCi Equivalent I-125 Seed

Half life: 59.6 days

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

medi+physics®

an Amersham company

If you return radioactive material to Medi-Physics, Inc. you become the shipper. To comply with the requirements of the International Civil Aviation Organization, you must have on file a copy of these test results for the package. This insert provides the required information.

Purpose

Under contract to Medi-Physics, Inc., 3M Electrical Specialties Division (a specific licensee) must meet "Code of Federal Regulations, Titles 10 and 49", "International Atomic Energy Agency, Safety Series #6", and "International Civil Aviation Organization" guidelines. Changes in these guidelines over the past twelve (12) years required re-evaluation of our packaging system. Compliance to these guidelines is demonstrated by performing "Packaging Integrity Tests" from Section 173.465 of Title 49; Section VII, Parts 701 through 714 of IAEA, and Sections 7.9 through 7.10 of IACO. This report documents our compliance with the above guidelines. Specific test records are on file in the Quality Control Department of 3M Electrical Specialties Division, Building 590 TCAAP, New Brighton, Minnesota.

Carton Specification Numbers

For discussion purposes and ease of identification, the carton tested is referred to by its Corrugated Fiberboard Specification Number. This number is subject to change, normally a result of updates or changes that alter the physical characteristics of a carton would result in retesting being performed. These occurrences will be addressed in the future with addendums to this report.

Medical Therapy Source Group

Container Description: RSC - Specification Number 34-7020-2349-9B (subject to change, see Carton Specification section above); common name, Nuclear Medical Shipper

Physical Description: Size - 8.5" x 8.5" x 5.0" - 0.2 cu ft
Weight - 6 lbs, 5.5 oz (9 medical therapy, vials, lead)
Isotope/Form - I-125 absorbed on resin or silverwire.

Primary Items Shipped: Medical Therapy Sources

Packaging Description: Each vial is placed into the foam or corrugated pad, covered with the top spacer, stapled shut and security tape is applied. See figures 29 through 31.

CORRESPONDENCE

from

3M and MEDI+PHYSICS,INC.

to

I-125 Seed User Community

Control No. 91041
Materials License No. 22-00057-59MD

Medical Device Division
3M Health Care

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

3M

February 19, 1991

Dear Customer:

This letter is to advise you of a major change in 3M's I-125 Seed business.

The 3M Medical Device Division has signed an agreement with Medi-Physics, Inc., an Amersham Company, Arlington Heights, Illinois, for the sale of 3M's I-125 Seed business. The transfer to Medi-Physics of all I-125 Seed business operations involving order-taking, customer service and technical service will take place on April 1, 1991.

3M feels positive about this transaction because we believe that Medi-Physics, with a global commitment to the development and application of radioactive processes in medicine, will be in a better position to serve your needs in this important field.

Commencing on April 1, 1991, all present 3M I-125 Seed customers are asked to direct their orders, inquiries, etc., directly to Medi-Physics at the following numbers:

Orders, Customer Service Inquiries 1-800-228-0126

For questions regarding the transition of this business, please contact:

Joe Henderson 708-593-6300 ext. 265 Medi-Physics, An Amersham Company	or	John McNally 612-733-8912 3M

Sincerely,

T R Engels

Thomas R. Engels
Business Manager
Assessment & Therapy Products

TRE:wat

An Important Announcement Regarding

The I-125 Seed Business

On February 22 3M sent out a general announcment regarding the transfer of the Iodine-125 Seed business to Medi-Physics, an Amersham Company. We would like to offer some additional details on this transition.

- Medi-Physics will continue to offer the complete line of I-125 Seed products and accessories formerly carried by 3M
- Order shipping/receiving will continue from the 3M New Brighton, MN facility until the Medi-Physics plant is fully operational
- Authorized product returns should still be sent to the 3M site until further notice
- The 1991 Medi-Physics Price List for I-125 Products is attached
- Medi-Physics will honor all existing open purchase orders on 3M. Clients are requested to issue a new open p.o. to Medi-Physics. This p.o. should be directed to:

  Mrs. Alice Klimek
  Medi-Physics, Inc.
  2636 S. Clearbrook Drive
  Arlington Heights, IL 60005
- Requests for standing orders should be directed to the Medi-Physics client service representatives at 800-633-4123
- Current customers with a license on file at 3M will not be required to send a copy of their license to Medi-Physics at this time
- Medi-Physics will mail out a copy of the new product catalog as soon as it is available

We at Medi-Physics, along with our colleagues at 3M, will do everything in our power to assure a smooth orderly transition. If we can answer any other questions you may have regarding this transition, please call us.

Joe Henderson
Marketing Manager, Medi-Physics Radiation Therapy Products
(708) 593-6300, ext. 265

SOURCE AND DEVICE EVALUATION TECHNICAL ASSISTANCE REQUEST

TO: STEVEN BAGGETT, NMSS/IMNS, Mail Stop OWFN-6H3

FROM: 311 REGION: I II III IV V HQ (Circle One)

FTS PHONE NO. _____ DATE: _____

APPLICANT _____ LETTER/APPLICATION DATE 10/16/89

MAIL CONTROL NO.(S) _____ LICENSE NO.(S) _____

REQUEST ACTION (CHECK APPROPRIATE BOX)

( ) SOURCE REVIEW ( ) DEVICE REVIEW ( ) CUSTOM

( ) AMENDMENT OF REGISTTRATION SHEET NO. _____

( ) OTHER: _____

****

FOR NMSS/IMAB USE ONLY CONTROL NO. 89-691 MODELS: 6712

DATE RECEIVED 10/24 REVIEWER _____

TYPE OF ACTION (INDICATE NO. OF EACH ON THE LINES)

(X) SOURCE REVIEW 1 ( ) DEVICE REVIEW ____

(X) FORMAL ( ) AMENDMENT ( ) CUSTOM

( ) NO LICENSING ACTION REQUIRED

TOTAL REVIEWER HOURS SPENT ON EVALUATION ____ DATE COMPLETED _____

NOTES: _____ DEFICIENCY LETTER ___ DATE COMPLETED _____

DEFICIENCY PHONE CALL ____ DATE MADE _____

RESPONSE TO DEFICIENCY _____

TYPING DRAFT __ IN ___ OUT ___ FINAL ___ IN ___ OUT ___

****

FOR ARM/LFMB USE ONLY

FEES THAT HAVE BEEN PAID FOR : (INDICATE NO. OF EACH ACTION ON THE LINES)

(X) SOURCE REVIEW 1 ( ) DEVICE REVIEW ___ ( ) FORMAL X
( ) AMENDMENT ____ ( ) ARM/LFMB ___ ( ) CUSTOM ___

NOTES: _____

DATE TO ARM/LFMB: 11/10/89

DATE RETURNED: 12/22/89

SIGNED: Glenda Jackson

DATE: 12/22/89