Medical Products Division/3M

3M Center
St. Paul, Minnesota 55101
612/733 1110

2552

RECEIVED

DEC 5 AM 7 24

3M

November 26, 1980

U... REG.
HH... ION

Joseph Del Medico
U.S. Nuclear Regulatory Commission
Division of Fuel Cycle and Material Safety
Washington, D.C. 20555

Re: Control No. 02783

Dear Mr. Del Medico:

This is in response to your letter of July 25, 1980, regarding package inserts for I-125 Seeds. Specifically, this submission provides copies of the package inserts for models 6701, 6702, and 6711, which we have revised and reprinted, as agreed to in my letters dated June 3 and 16, 1980, and our telephone conversation of July 9, 1980.

The package inserts for I-125 Seeds contain the following three changes from those texts previously submitted.

1. In the PRECAUTIONS section, addition of the following text as paragraph 7 under 'Preparation for Use/ Sterilization'.

   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.

2. In the first paragraph in the LICENSING section, addition of the symbol, R, following 'I-125 Seeds, to indicate that the phrase is a registered trademark and, hence, the product distributed only by 3M.

FOIA-84-801
APPENDIX / Item 10

COPIES SENT TO OFF. OF
INSPECTION

3. In the first paragraph in the LICENSING section, revision of the phrase 'Group IV of 10 CFR Part 35' (incorrectly printed in the original inserts) to 'Group VI of 10 CFR Part 35'.

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

Sincerely yours,

Jacquelyn D. Bush

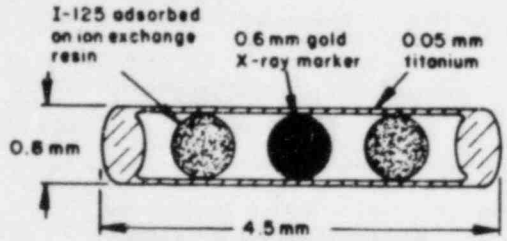
Jacquelyn D. Bush
Sr. Regulatory Compliance Coordinator
Medical Products Division/3M
3M Center, Bldg. 230-3-02
St. Paul, Minnesota 55144

JDB:tmf

I-125 Seeds
No. 6701

Description

I-125 Seeds 6701 consist of a welded titanium capsule containing Iodine-125 adsorbed on two anion exchange resin spheres. A spherical gold x-ray marker is included, which serves as a means of visualization on radiographs.



Physical Characteristics

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

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 x-rays of 27.4 and 35.5 keV. 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, slow growth rate, and low to moderate radiosensitivity.

I-125 Seeds may be used to treat superficial, intraabdominal or intrathoracic tumors. Tumors of the head, neck, lung, pancreas, and prostate (early stages) are commonly treated.

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 I-125 Seeds.[1]

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.[2]

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 commerically-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.

Application to P nt

I-125 Seeds 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 governmental agency authorized to license the use 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.[2]

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 by National Council on Radiation Protection and Measurements and are detailed in NCRP Reports.[2, 3, 4, 5, 6]

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 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 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

NRC regulations (10 CFR 35.14) describe requirements for leak testing radioactive sources.

I-125 Seeds that retain clinical utility for periods of more than six months must be tested at intervals of six months or less as defined in NRC regulations. I-125 Seeds are leak tested prior to shipment and the results are shown on the shipment identification papers that accompany each shipment. I-125 Seeds having a nominal activity of 0.55 mCi comp. will decay in 180 days and will not require leak testing by the user.

Adverse Reactions

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

Dosage and A ministration

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[9] 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.[8] This anisotropy should be considered in dose distribution calculations.

Iodine-125 has a 60.2 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

I-125 Seeds will pass through a No. 17 gauge needle. Most implants have been performed with afterloading techniques using an inserter attached to hollow needles. Several devices are available for this purpose. Individual seeds may be implanted using the Scott, Mick and Henschke applicators designed for this purpose. The Royal Marsden Gold Grain gun will not accept I-125 Seeds.

How Supplied

I-125 Seeds are available with an activity per seed of 0.10 to 1.00 mCi comp (norninal 0.55 mCi comp.). The product is supplied as a group of seeds with an assay within a stated range on the assay date. I-125 Seeds with an activity to 40 mCi comp. are available upon special request for use as calibration check sources.

I-125 Seeds are packaged in a screw-cap, 1-dram glass vial, which is labeled to indicate the isotope, amount of activity, activity range and the assay date. Any discrepancy between the number of seeds listed on the certification sheet accompanying the order and the number contained in the vial(s) should be reported to 3M within 24 hours of receipt of the shipment. The vial is contained in a lead pig which is labeled to provide the same information, as well as the number of seeds therein and precautionary regulatory statements pertaining to licensing of the product.

I-125 Seeds are NOT sterile when shipped.

Licensing

I-125 Seeds are licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to §§ 35.14 and 35.100 Group VI of 10 CFR Part 35 or under equivalent licenses of Agreement States.

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

References

1. Hilaris, BS, ed. *Handbook of Interstitial Brachytherapy*. Publishing Sciences Group, Inc., Action, MA, 1975.
2. NCRP Report No. 37. NCRP Publication, P.O. Box 30175, Washington, DC 20014
3. NCRP Report No. 40. NCRP Publication, P.O. Box 30175, Washington, DC 20014
4. NCRP Report No. 41. NCRP Publication, P.O. Box 30175, Washington, DC 20014
5. NCRP Report No. 48. NCRP Publication, P.O. Box 30175, Washington, DC 20014
6. NCRP Report No. 49. NCRP Publication, P.O. Box 30175, Washington, DC 20014
7. Scallon, et al. Permanent interstitial therapy using low energy and long half-life radiation sources. *American Journal of Roentgenology*. 105:1 (1969), 157-164
8. Ling, C. *Proceedings of Fourth International Conference on Medical Physics*. Ottawa, Canada, July, 1976
9. Anderson, LL Dosimetry with I-125. To be published. Presented at International Endocurietherapy Meeting. LAC/USC, Los Angeles. June 30 - July 2, 1978

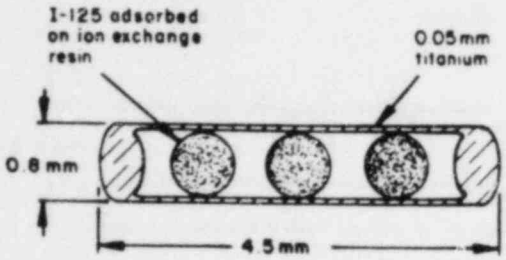
Medical Products Division/3M
225-5S 3M Center
St. Paul, MN 55144

3M

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 x-rays and Auger electrons. The electrons are absorbed in the titanium wall of the of the I-125 Seed. The principal radiation emissions are x-rays of 27.4 keV and 35.5 keV.

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 x-rays of 27.4 and 35.5 keV. 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 I-125 Seeds.[1]

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.[2]

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 commerically-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.

Application to Pat

I-125 Seeds 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 governmental agency authorized to license the use 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.[7]

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 by National Council on Radiation Protection and Measurements and are detailed in NCRP Reports.[2, 3, 4, 5, 6]

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 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 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

NRC regulations (10 CFR 35.14) describe requirements for leak testing radioactive sources.

I-125 Seeds that retain clinical utility for periods of more than six months must be tested at intervals of six months or less as defined in NRC regulations. I-125 Seeds are leak tested prior to shipment and the results are shown on the shipment identification papers that accompany each shipment.

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] 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.[8] This anisotropy should be considered in dose distribution calculations.

Iodine-125 has a 60.2 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

I-125 Seeds will pass through a No. 17 gauge needle. Most implants have been performed with afterloading techniques using an inserter attached to hollow needles.

How Supplied

I-125 Seeds are available with an activity per seed of 0.10 to 40 mCi comp. The product is supplied as a group of seeds with an assay within a stated range on the assay date.

I-125 Seeds are packaged in a screw-cap, 1-dram glass vial, which is labeled to indicate the isotope, amount of activity, activity range and the assay date. Any discrepancy between the number of seeds listed on the certification sheet accompanying the order and the number contained in the vial(s) should be reported to 3M within 24 hours of receipt of the shipment. The vial is contained in a lead pig which is labeled to provide the same information, as well as the number of seeds therein and precautionary regulatory statements pertaining to licensing of the product.

I-125 Seeds are NOT sterile when shipped.

Licensing

I-125 Seeds[9] are licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to §§ 35.14 and 35.100 Group VI of 10 CFR Part 35 or under equivalent licenses of Agreement States.

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

References

1. Hilaris, BS, ed. *Handbook of Interstitial Brachytherapy*. Publishing Sciences Group, Inc., Action, MA, 1975

2. NCRP Report No. 37. NCRP Publication, P.O. Box 30175, Washington, DC 20014

3. NCRP Report No. 40. NCRP Publication, P.O. Box 30175, Washington, DC 20014

4. NCRP Report No. 41. NCRP Publication, P.O. Box 30175, Washington, DC 20014

5. NCRP Report No. 48. NCRP Publication, P.O. Box 30175, Washington, DC 20014

6. NCRP Report No. 49. NCRP Publication, P.O. Box 30175, Washington, DC 20014

7. Scallon, et al. Permanent interstitial therapy using low energy and long half-life radiation sources. *American Journal of Roentgenology*. 105:1 (1969), 157-164

8. Ling, C *Proceedings of Fourth International Conference on Medical Physics*. Ottawa, Canada, July, 1976

9. Anderson, LL Dosimetry with I-125. To be published. Presented at international Endocurietherapy Meeting. LAC/USC, Los Angeles, June 30 - July 2, 1978

Medical Products Division/3M
225-5S 3M Center
St. Paul, MN 55144

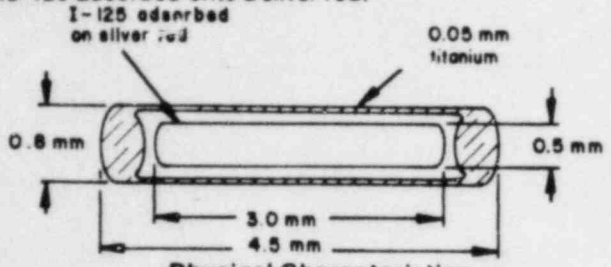
3M

I-125 Seeds®
No. 6711

2552

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 60.2 days and decays by electron capture with the emission of characteristic x-rays and Auger electrons. The electrons are absorbed by the titanium wall of the I-125 Seed. The principal radiation emissions are x-rays of 27.4 keV and 35.5 keV.

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 x-rays of 27.4 and 35.5 keV. 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 together with the silver rod, results in a total self-absorption of approximately 35%.

Indications

I-125 Seeds with activities from 0.1 to 1.0 mCi comp. are indicated for interstitial treatment of tumors which have the following characteristics: unresectable, localized, slow growth rate, and low to moderate radiosensitivity. Seeds in this 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 activities greater than 1.0 mCi comp. 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 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 (e.g. ulcerated) is not recommended with I-125 Seeds.[1]

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.[2]

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 monitoring.

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 commerically-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.

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 and whose experience and training have been approved by the appropriate governmental agency authorized to license the use 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.[2]

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 by National Council on Radiation Protection and Measurements and are detailed in NCRP.[2, 3, 4, 5, 6]

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 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

NRC regulations (10 CFR 35.14) describe requirements for leak testing radioactive sources.

I-125 Seeds that retain clinical utility for periods of more than six months must be leak tested at intervals of six months or less as defined in NRC regulations.

I-125 Seeds are leak tested prior to shipment and the results are shown on the shipment identification papers that accompany each shipment. I-125 Seeds having a nominal activity of 0.55 mCi comp. will decay to 0.07 mCi in 180 days and will not require leak testing by the user.

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[9] 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.[8] This anisotropy should be included in dose distribution calculations.

Iodine-125 has a 60.2 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

I-125 Seeds will pass through a No. 17 gauge needle. Most implants have been performed with afterloading techniques using an inserter attached to hollow needles. Several devices are manufactured for this purpose. Individual seeds may be implanted using the Scott, Mick, and Henschke applicators designed for this purpose. The Royal Marsden Gold Grain gun will not accept I-125 Seeds.

How Supplied

I-125 Seeds, model 6711, are available with an activity per seed of 0.10 to 40 mCi comp. The product is supplied as a group of seeds with an assay within a stated range on the assay date.

I-125 Seeds are packaged in a screw-cap, 1-dram glass vial, which is labeled to indicate the isotope, amount of activity, activity range, and the assay date. Any discrepancy between the number of seeds listed on the certification sheet accompanying the order and the number contained in the vial(s) should be reported to 3M within 24 hours of receipt of the shipment. The vial is contained in a lead pig which is labeled to provide the same information, as well as the number of seeds therein and precautionary regulatory statements pertaining to licensing of the product.

I-125 Seeds are NOT sterile when shipped.

Licensing

I-125 Seeds are licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to §§ 35.14 and 35.100 Group VI of 10 CFR Part 35 or under equivalent licenses of Agreement States.

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

References

1. Hilaris, Basis, M.D., ed. *Handbook of Interstitial Brachytherapy*. Publishing Sciences Group, Inc., Action, MA, 1975.
2. NCRP Report No. 37. NCRP Publications, P.O. Box 30175, Washington, D.C., 20014.
3. NCRP Report No. 40. NCRP Publications, P.O. Box 30175, Washington, D.C., 20014.
4. NCRP Report No. 41. NCRP Publications, P.O. Box 30175, Washington, D.C., 20014.
5. NCRP Report No. 48. NCRP Publications, P.O. Box 30175, Washington, D.C., 20014.
6. NCRP Report No. 49. NCRP Publications, P.O. Box 30175, Washington, D.C., 20014.
7. Scallon, et al. *American Journal of Roentgenology*. Vol. 105, No. 1 (1969), pp. 157-164.
8. Ling, Cliff. *Proceedings of Fourth International Conference on Medical Physics*. Ottawa, Canada, July, 1976.
9. Anderson, L.L. To be published. Presented at International Endocurietherapy Meeting, LAC/USC, Los Angeles, 6/30/78-7/2/78.

Medical Products Division/3M
225-5S 3M Center
St. Paul, MN 55144

3M