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3M Health Care**

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**Important Safety Information About 3M Heyman Applicators**

TO: OWNERS OF ALL 3M CESIUM-137 HEYMAN AFTERLOADING APPLICATORS

FROM: DAVID O. KUBIATOWICZ AND H. LEE MARKS  
3M PROFESSIONAL SERVICES

SUBJECT: CS-137 SOURCE AND/OR HANDLE SEPARATION FROM STAINLESS STEEL SHAFT.

DATE: OCTOBER 1989

Our records show that 3M Afterloading Applicators have been shipped to your hospital. By way of this letter 3M is alerting you to possible separation of the Cs-137 source and/or handle from the stainless steel shaft of the Applicator.

The enclosed Package Insert shows the points of detachment circled in red. At these points, the Cs-137 source and handle are attached to the stainless steel shaft using a silver braze.

TO MINIMIZE CONSEQUENCES OF A DETACHED SOURCE, PLEASE CHECK VISUALLY AND/OR WITH A RADIATION MONITOR EACH TIME THE HEYMAN APPLICATORS ARE INSERTED AND REMOVED FROM A PATIENT TO CONFIRM THAT THE CS-137 SOURCE HAS NOT DETACHED FROM THE HEYMAN SHAFT.

If a Cs-137 source or handle detaches from the stainless steel shaft on your Heyman Applicators, please contact 3M Customer Service at 800-328-1671 for repair instructions.

Whereas frequency of Cs-137 source and/or handle detachment is less than 1% of all 3M Heyman Applicators sold, two recent source separations at different hospitals has resulted in the mailing of this letter.

We are studying possible causes of braze joint failure on the Heyman Applicators, and will notify you of relevant findings.

If you want additional technical information please call David Kubiadowicz at 612-733-9127 or Lee Marks at 612-733-8996.

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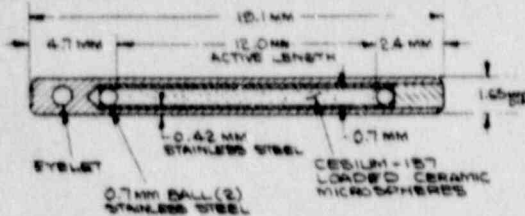
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# 3M Cesium-137

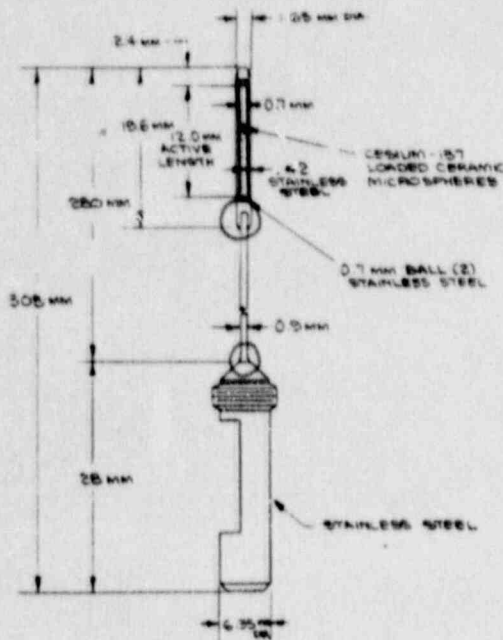
## Miniaturized Tube Sources Series 6510, 6570 Heyman Afterloading Sources Series 6550

### 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.<sup>1</sup> 3M Cesium-137 Heyman afterloading sources are used for treatment of endometrial cancer.<sup>2</sup>

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.<sup>3</sup>

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.<sup>4</sup> 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.<sup>4</sup> 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 Patient

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 x 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, G.H., M.D., ed., *Textbook of Radiotherapy*, Lea & Febiger, Philadelphia, Pa., 1973.
2. Simon, N and Silverstone, S.M. *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