



January 21, 2008

NMSS

United States
Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

03009293

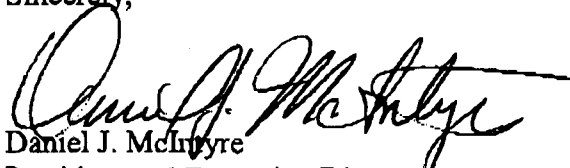
SUBJECT: The Charlotte Hungerford Hospital License #06-08349-04 Amendment

Dear Sir/Madam:

We would like to add an additional sealed source to our Nuclear Regulatory License #06-08349-04, page one part 7D. This particular sealed source is manufactured by Mills Biopharmaceuticals, LLC and distributed by CORE ONCOLOGY under the trade name of PROSTA SEED, model 125SL. We believe that this is a better sealed source and will enhance our LDR operation.

We attached some additional information from the distributor for your information. Please add the above sealed source to our current list in the Nuclear Regulatory License. Our current list of sealed sources in the Nuclear Regulatory License should remain as is.

Sincerely,



Daniel J. McIntyre
President and Executive Director

DJM:ksm

cc: Gerald Randall
Lee Anne Zarger

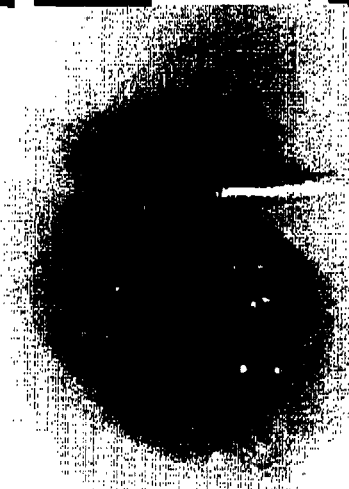
attachments



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- Excellent dose distribution
- Full length X-ray marker
- Guaranteed source availability
- Superior Customer Service
- Favorable Terms and Policies
- Low and high activity levels available
- Manufactured and Calibrated to NIST and AAPM standards



Specifications at a Glance

Model	125SL
Dimensions	4.5 mm long, 0.8 mm outside diameter, 0.05 mm wall (dimensions are Nominal)
Encapsulation	Titanium
Carrier for I-125	Silver spheres
X-ray Marker	Five (5) Silver spheres
Photon Energies	27.4 & 31.4 keV X-rays, 35.5 keV gamma photon, 22.1 & 25.5 keV fluorescent X-rays from Silver spheres.
Assay Method	Calibration to NIST traceable source of the same model using a well re-entrant chamber
Source Strengths	Model 125SL 0.229-1.266 U

Core Oncology Clinician Services

Prostate Brachytherapy Seeds

Isoloader® Workstation
 The Isoloader Physics Workstation, and view the **Specifications**.

Prescription Loading Services
 Prescription loaded for your patients, and ready to use.

C20™ Pre-loaded Applicator Cartridges
 Shielded, disposable cartridge for the MICK® applicator.

Fiducial Markers
 Visicoll's flexible helical design allows for accurate placement and reduced artifact.

Core™ Brachytherapy Needles
 Superior sharpness in every needle. Available in preloaded or MICK® styles.

Mills Biopharmaceuticals, LLC
 Manufacturing & design information.

Programs

Clinical Training Programs

Resources

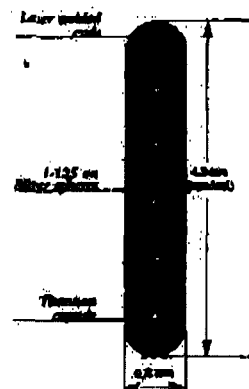
Links & Resources

Physical Characteristics

ProstaSeed® I-125 brachytherapy sources (Model 125SL) consist of a welded titanium capsule containing Iodine I-125 adsorbed onto five (5) Silver spheres which also serve as radiographic markers, to identify source location and orientation. ProstaSeed sources are supplied in the following configurations:

- Loose, non-sterile
- Non-sterile loaded in C20™, 20-seed shielded disposable cartridges for the Mick® applicator
- Non-sterile loaded in Mick® disposable cartridges
- Prescription loaded and sterilized, stranded or loose
- Sterile loaded in IsoCartridge® with synthetic spacers

Non-sterile seeds must be sterilized prior to use. Please refer to the Instructions for Use (IFU) for sterilization information.



Calibration and Quality Assurance

Calibration

Each ProstaSeed I-125 brachytherapy source has been calibrated using the 05/Jul/2001 NIST Wide Angle Free Air Chamber standard for this seed model. Source measurements are made using a pressurized ionization chamber that has been calibrated with a source of direct traceability to the National Institute of Standards and Technology (NIST) and is routinely verified with sources of direct traceability to an AAPM Accredited Dosimetry Calibration Laboratory. The resulting calibration certification provided with each shipment is reported in Air-Kerma strength traceable to the

Apparent Activity (mCi) Converted from Sk, 99 std	Air Kerma Strength (U or µGy m ² /h) Sk, 99std
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05/Jul/2001 NIST Wide Angle Free Air Chamber calibration standard. ProstaSeed I-125 brachytherapy sources comply with the AAPM TG-43U1, Update of Task Group No. 43 Report: A revised AAPM protocol for brachytherapy dose calculations. Guidance to users was provided by AAPM and recommendation is detailed in references 1 and 2. Apparent Activity (mCi) value is also provided for user convenience. Air-Kerma strength has been converted to Apparent Activity using an equivalence of 1 mCi (app) = 1.27 U.

Quality Assurance

Each ProstaSeed is 100% visually inspected, gauged for proper length and diameter, cleaned for surface contaminants, and leak tested prior to shipment. Please refer to Product Insert Data Sheet for leak testing methodology.

Technical Data

The following technical data sets are available for ProstaSeed I-125 sources upon request:

- Consensus Data Set
- TG-43 Data Set
- Monte Carlo Data Set
- Nomogram

1 Williamson, J.F., Coursey, B.M., Deward, L.A., Hanson, W.F., Nath, R., and Ibbott, G., Guidance to users of Nycomed Amersham and North American Scientific, Inc. I-125 Interstitial Sources: Dosimetry and calibration changes; Recommendations of the American Association of Physicists in Medicine Radiation Therapy Committee Ad Hoc Subcommittee on Low-Energy Seed Dosimetry, Med. Phys., 26, 570-573 (1999).

2 Rivard, M.J., Coursey, B.M., DeWerd, L.A., Hanson, W.F., Huq, M.S., Ibbott, G.S., Mitch, M.G., Nath, R., and Williamson, J.F., Update of AAPM Task Group No. 43 Report: A revised AAPM protocol for brachytherapy dose calculations, Med. Phys., 31, 633-674 (2004).

0.191 - 0.196	0.229 - 0.248
0.197 - 0.212	0.250 - 0.269
0.213 - 0.230	0.270 - 0.292
0.231 - 0.249	0.293 - 0.316
0.250 - 0.270	0.317 - 0.342
0.271 - 0.293	0.344 - 0.372
0.294 - 0.318	0.373 - 0.403
0.319 - 0.345	0.405 - 0.438
0.346 - 0.375	0.439 - 0.476
0.376 - 0.407	0.477 - 0.516
0.408 - 0.441	0.518 - 0.560
0.442 - 0.479	0.561 - 0.608
0.480 - 0.520	0.609 - 0.660
0.521 - 0.564	0.661 - 0.716
0.565 - 0.612	0.717 - 0.777
0.613 - 0.664	0.778 - 0.843
0.665 - 0.720	0.844 - 0.914
0.721 - 0.781	0.915 - 0.991
0.782 - 0.847	0.993 - 1.075
0.848 - 0.919	1.076 - 1.167
0.920 - 0.997	1.168 - 1.266

