



Texas Department of Health

Charles E. Bell, M.D.
Executive Deputy Commissioner

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Radiation Control
(512) 834-6688

January 10, 2002

U.S. Nuclear Regulatory Commission
Attn: Ms. Tracy Kime
Source Containment and Devices Branch
Office of Nuclear Material Safety
and Safeguards
Document Control Desk
P1-37
Washington, D.C. 20555

Re: Correct Pages Registry Sheet TX-1152-S-101-S

Dear Ms. Kime,

Enclosed is the corrected labeling for drawings associated with the new sheet mailed as month for TX-1152-S-101-S (previously TX-1068-S-101-S) for Iso-Star Texas, Inc., (formally International Isotopes Inc.). This sealed source sheet has been issued to allow a change in ownership of an existing licensee to up the maximum activity per seed and control by a new company. We would appreciate you distributing the correct drawing with the sheet to the other State Programs and NRC Regions, as appropriate.

Thank you for your cooperation and efforts.

Sincerely,

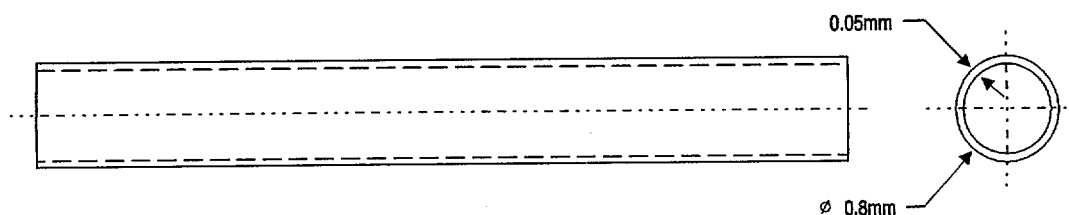
David M. Wood
Medical and Academic Licensing
Division of Licensing, Registration
and Standards
Bureau of Radiation Control

Enclosure: a/s

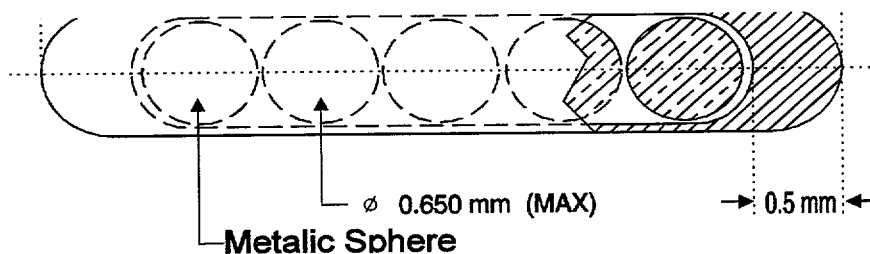
WMS12

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
No.: TX-1152-S-101-S
(Previously TX-1068-S-101-S)
ATTACHMENT 1

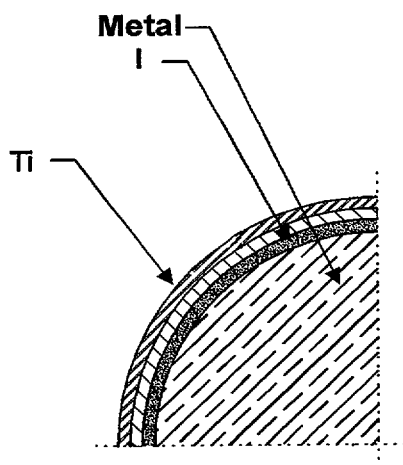
TITANIUM TUBE BEFORE WELD



TITANIUM TUBE AFTER WELD



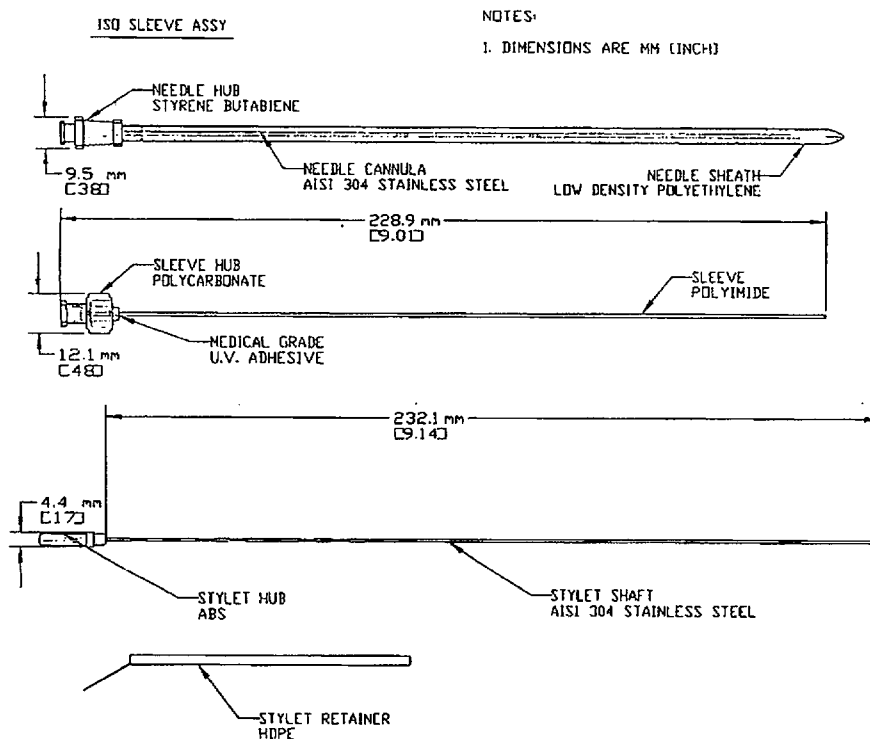
SINGLE SPHERE CUT-AWAY



Details of a Sphere

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
No.: TX-1152-S-101-S
(Previously TX-1068-S-101-S)
ATTACHMENT 2

ISO-SLEEVE ASSEMBLY



NOTES:
1. DIMENSIONS ARE MM (INCH)

LABEL FOR ISO-SLEEVE ASSEMBLY

isoleeveTM System
Iodine-125 Permanent Interstitial Seed System
Component # ISS-12501-Preloaded Assembly

imagyn



Contents: XX preloaded isoleeve needle assemblies

Sterile: For single use only

Corrected 1999 NIST WAFAC Total Number of Seeds: 00

Seed Activity (Avg): 0.000 mCi 0.000 U Calibration Date: 00/00/00

Total Seed Activity: 0.000 mCi 0.000 U Control # 3CO-01000000

Patient Name: JOHN DOE

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

Warning: The Bureau of Radiological Control, Texas Department of Health, has approved this sealed source for distribution to persons licensed pursuant to 25 TAC 289.252 or under equivalent licenses of the USNRC of and Agreement State, and outside the United States, to persons authorized by the appropriate authority

Imagyn Medical Technologies, Inc., Denton, Texas 76207

Made in USA

O 71805 Rev 0

U.S. Patent 5,928,130 and Patent Pending