

November 29, 2005

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U.S.N.R.C. - Region I
Medical Licensing Section
Attn: Michelle Simmons
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406

RE: Control #137622

Dear Ms. Simmons,

I'm writing in reference to your request for additional information regarding a recent amendment to N.R.C. license (#37-09938-01). 03003119

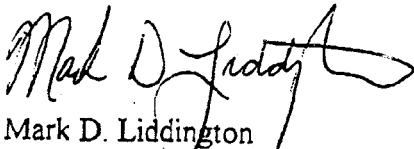
The information for the one source that we have on site is as follows:

Radionuclide:	Sr-90 (Jacketed Radiation Source Train)
Model:	SICW.2
Serial Number:	ZA905
Activity:	1.91 GBq
Calibration Date:	August 14, 2002

A copy of the source information is attached.

If you have any additional questions, please contact me at 717-291-9813.

Sincerely,



Mark D. Liddington
Consultant Medical Physicist for Easton Hospital

Enclosure/Attachement

138040

NMSS/RGNI MATERIALS-002



Active Transfer Device within White Lead-Lined Storage Container



ORDER # (REF):TDA-2040

Jacketed Radiation Source Train (JRST)

Active Length: 40mm

Description: SICW.2.H 40 : series of 16 Model SICW.2 sealed sources jacketed in a stainless steel coil (0.47 mm OD) with non-radioactive radiopaque marker welded to each end.

Radionuclide: Sr-90

Total Activity: 1.91 GBq

Assay Date: 14Aug02

Recommended Radiation Treatment

Transfer Device Serial #: 93110

Radiation Source Train Serial #: ZA905

Effective Date	From: 19Jan05	To: 19Jul05	2A 1/24/05	
Maximum Balloon Diameter (mm)	Reference Vessel Diameter (mm)	Dose @ 2mm (Gray)	Dwell Time (Secs) or (Mins, Secs)	
With Existing Stent	≥ 2.5 to < 3.5	≥ 2.7 to ≤ 3.35	18.4	208 3, 28
	≥ 3.5 to ≤ 4.0	> 3.35 to ≤ 4.0	23.0	260 4, 20

Use the following treatment chart ONLY after the required six month Leak Test is completed.

Effective Date	From: 20Jul05	To: 19Jan06	7/30/05	
Maximum Balloon Diameter (mm)	Reference Vessel Diameter (mm)	Dose @ 2mm (Gray)	Dwell Time (Secs) or (Mins, Secs)	
With Existing Stent	≥ 2.5 to < 3.5	≥ 2.7 to ≤ 3.35	18.4	211 3, 31
	≥ 3.5 to ≤ 4.0	> 3.35 to ≤ 4.0	23.0	263 4, 23

NOTE: If the ratio of the maximum balloon diameter to reference vessel diameter is between 1/1 and 1/1.2, dose can be prescribed according to balloon diameter. Dose can also be administered by visual assessment of reference vessel diameter.

Radiation Output: 0.0942 Gy·s⁻¹ ± 20% in H₂O at 2 mm from the center line of the Radiation Source Train. Date: 14Aug02

Result traceable to the National Institute of Standards and Technology.

Uniformity verified +/- 10% along the middle portion of the Radiation Source Train.

Sealed Radioactive Source:

AEA Technology, QSA GmbH, Model SICW.2

Radionuclide: Sr-90 Activity: 0.119 GBq/Source

The contained activity per source is the product of the measured source train absorbed dose rate in Gy/sec, at 2mm from the source center line in water and the conversion factor 34.2mCi/sec (1.27GBq/sec) per Gy/sec. The contained activity in the source train is equal to the contained activity per source times the number of sources in the train.

Description: Sr-90 wire in sealed single stainless steel capsule.

Length: 2.5mm

Diameter: 0.38mm

ISO 2919 classification: C53X1.2.3 11

Where X₁, X₂ and X₃ represent respective special "impact", "step" and "crush" tests simulated for circumstances that could reasonably be expected to exist outside the Beta-Cath™ 3.5F System during off-normal accident situations.

ISO Leak Test:

ISO 9978, Notes, immersion into ultrasonic cleaning water with detergent solution at 70°C for at least 30 mins.

Result: <185 Bq

Date: 17Jul02

Novoste Leak Test:

H₂O passed over the Radiation Source Train and then analyzed for radioactive content using liquid scintillation counting.

Result: <185 Bq

Date: 19Jan05

*Do not use or ship the device unless a leak test has been performed within the previous six months. Follow the radiation safety and handling instructions in the User's Manual. Test the device for leakage at intervals not to exceed 6 months. Use a leak test method capable of detecting 185 Bq (0.005 uCi) of Sr/Y-90. Immediately withdraw a leaking device from use and store it for disposal and/or return to Novoste. File a report of any leaking device with the authority and notify Novoste. Retain leak test records.

Sales and Service:
Novoste Corporation
4350 International Boulevard
Norcross, Georgia
USA 30093
Tel: +1 800 Novoste

Certified by Novoste Corporation:

Manufacturing Date: 1/9/05
Quality Assurance Date: 1/19/05

NON-STERILE



IPX1



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D04776 REV B 10/04

This is to acknowledge the receipt of your letter/application dated

11/29/2005, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 37-09938-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 138040.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.