

June 8, 2005
Inova Fairfax Hospital
3300 Gallows Road
Falls Church, Virginia 22042-3300

U. S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

RECEIVED
REGION I
2005 JUN 10 AM 10: 21

Reference: NRC license # 45-17128-01 03012235

Inova Fairfax Hospital requests our Materials License be amended as follows:

- (1) Add Samir Kanani, M.D., Radiation Oncology, as an authorized user. Attached is the preceptor statement outlining Dr. Kanani's training at the University of Maryland, Baltimore, Maryland. Dr. Kanani is licensed to practice medicine in the Commonwealth of Virginia. We wish Dr. Kanani be approved for the procedures outlined in 10 CFR 35.300 and 10 CFR 35.400. Additionally Dr. Kanani should be approved for Iodine-125 for GliaSite brachytherapy and Iridium-192 for use in a High Dose Remote Afterloader Unit.
- (2) To change the use status of one of our sealed sources:

Beta Therapy Source NB-1 Manufactured by New England Nuclear Model 67-851 Serial number - 0240 Original activity - 100 mCi Original assay date - August 4, 1977
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We request that this source status be changed from clinical to site storage status.

137190
NMSS/RGNI MATERIALS-002

- (3) Request that three (3) additional sealed source assemblies be deleted from our NRC license (listed as items 6J, 7J, 8J and 9J on the license):

Novoste Beta-Cath System Radioactive Transfer Device Jacked radiation source train Active length – 30 mm 12 sources per assembly Last source returned to vendor: Radioisotope: Sr-90 Transfer Device SN: 01078N Radiation Source Train SN: ZA823 Total activity: 1.33 GBq Assay date: Jan 6, 2003	Novoste Beta-Cath System Radioactive Transfer Device Jacked radiation source train Active length – 40 mm 16 sources per assembly Last source returned to vendor: Radioisotope: Sr-90 Transfer Device SN: 01052N Radiation Source Train SN: ZB615 Total activity: 1.91 GBq Assay date: Sep 15, 2003	Novoste Beta-Cath System Radioactive Transfer Device Jacked radiation source train Active length – 60 mm 24 sources per assembly Last source returned to vendor: Radioisotope: Sr-90 Transfer Device SN: 92948 Radiation Source Train SN: ZA779 Total activity: 3.14 GBq Assay date: Sep 17, 2002
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These source trains were shipped to Novoste on May 20, 2005. Attached are copies of the shipping documents. The Point-of-Contact at Novoste is Pamela Crane (877-753-8535).

- (4) Delete Paragraphs 6F, 7F, 8F and 9F from the license. The Guidant Galileo Radiotherapy System was never in the possession of Inova Fairfax Hospital. This license addition was made in preparation of receiving this new technology at Inova Fairfax Hospital. Before receipt of the Guidant system, the clinical decision was made not to use this system.

If you have any questions concerning this request, please contact Gary F. Talkington, Radiation Safety Officer, at (703) ~~698~~-3394 or Gary.Talkington@inova.com.

776

Thank you for your time and attention in this matter.



Colleen Cohen
Senior Director, Outpatient and Ambulatory Services
Inova Fairfax Hospital/Inova Fairfax Hospital for Women and Children

cc:

Gary F. Talkington
Radiation Safety Officer

Michael Taylor
Director, Medical Physics

Keith Turner
Director, Radiation Oncology Department

Glenn L. Tonnesen, M.D.
Medical Director, Radiation Oncology
Chairman, Radiation Safety Committee

July 12, 2004

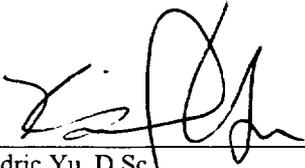
Samir Kanani MD
Radiation Oncology
3300 Gallows Road
Falls Church, VA 22042-3300

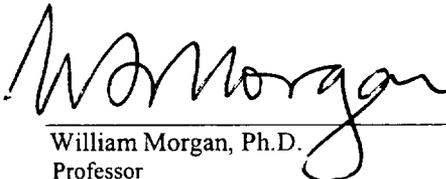
Dear Dr. Kanani:

The following information is enclosed for your records. It outlines the classroom and laboratory training received in basic radioisotope handling techniques during residency from 7/1/2000-6/30/2004.

Field of Training	Location and dates	Lecture/Lab Courses (hours)	Supervised Lab Experience (hours)
Radiation Physics and instrumentation	University of Maryland 22 S. Greene Street Baltimore, MD 21201 7/1/2000-6/30/2004	250	
Radiation Protection	SAA	20	
Mathematics pertaining to use and measurement of radioactivity	SAA	27	
Radiation biology	SAA	200	320

The training and experience indicated above was obtained under the supervision of:


Cedric Yu, D.Sc.
Director of Medical Physics and Professor


William Morgan, Ph.D.
Professor

SUPPLEMENT C. 2002-2003 RADIATION ONCOLOGY RESIDENT EXPERIENCE LOG

The completed form should be given to the Program Director by July 1, 2003. To be completed by the Program Director:

TO BE COMPLETED BY THE PROGRAM DIRECTOR AT PRIMARY INSTITUTION.

Program Number / Program Name	4302321040 University of Maryland Program	City/State	Baltimore, MD
Program Director Name	Jeanette Linder, MD	Signature	<i>JLinder</i>

TO BE COMPLETED BY THE RESIDENT (RESIDENTS ARE ALSO ENCOURAGED TO MAINTAIN A LIST OF SPECIFIC CASES).

Resident Name	Samir Kanani, M.D.	Signature	<i>Samir Kanani</i>
Time Period to be Covered by Log	From:7/2000	To:6/30/2004	

List Institutions used for outside rotations:	Dates: From - To
1.St. Jude Children's Hospital	6/3/02-6/28/02
2.Indiana University	6/9/03-7/1/03
3.	

1. **Adult External Beam Simulated: Primary Site (Non-Metastatic Disease):**

Type	# Cases
Breast: Intact	50
Breast: Post-Mastectomy	21
Bone/Soft Tissue Sarcoma	2
Central Nervous System	39
Head/Neck: Intact	58
Head/Neck: Post-Operative	29
Gastrointestinal: Esophagus	22
Gastrointestinal: Stomach	
Gastrointestinal: Pancreas	4
Gastrointestinal: Hepatobiliary	
Gastrointestinal: Colon	
Gastrointestinal: Rectum	13
Gastrointestinal: Anus	
Gastrointestinal: Other	32
Genitourinary: Prostate	113
Genitourinary: Bladder	4
Genitourinary: Testes	1
Genitourinary: Other	
Gynecologic: Cervix Intact	10
Gynecologic: Cervix Post-Hysterectomy	2
Gynecologic: Uterus	8
Gynecologic: Other	3
Hodgkin's Lymphoma	10

Type	# Cases
Non-Hodgkin's Lymphoma	13
Leukemia / Myeloma	1
Other Hematologic Malignancies	9
Skin	8
Thorax: Small Cell Lung Cancer	7
Thorax: Non-small Cell Lung Cancer	63
Thorax: Other	2
Benign: Heterotopic Bone	20
Benign: Eye	
Benign: Other (does not fit in other categories)	16
All Others (Give Examples)	7 Endocrine

Total Primary Site Adult External Beam	574
Total Secondary (Metastatic) Adult External Beam Simulated (Not Covered Above Under Primary Site)	138
Total Adult External Beam Simulated Cases (Primary Plus Secondary [c equals total cases a plus b])	712

2. Pediatric External Beam Simulated:

Pediatric Cases:	Primary Institution # Simulated	Outside Institution(s) # Simulated
Leukemia	0	2
Medulloblastoma	1	2
CNS (Non-Medulloblastoma)	0	2
Hodgkins's Lymphoma	0	2
Non-Hodgkins's Lymphoma	0	0
Rhabdomyosarcoma / STS	0	0
Ewing's Sarcoma / Bone Tumor	1	0
Neuroblastoma	0	0
Retinoblastoma	0	0
Wilms' Tumor	0	0
Other: Describe case(s) for Primary or other institution	1 Nasopharynx	1 Peripheral Nerve Sheath

3. Brachytherapy

	Primary Institution			Outside Institution		
	# Cases Performed	# Cases Observed	# LDR/HDR	# Cases Performed	# Cases Observed	# LDR/HDR
INTRACAVITARY						
Number of Patients	20	13		5	1	
Number of Insertions	34	15		6	1	
Cervix / Uterus	35	15	17/33	6	1	6/1
Endobronchial						
Esophagus / Bile Duct						
Other						
INTERSTITIAL (including seeds)						
Number of Patients	44	6				
Number of Implants	44	6				
Breast						
Soft Tissue Sarcoma						
Head & Neck						
Prostate	44	6	50/0			
GYN / Pelvis						
Other						
Surface Applications (moulds, plaque, Sr-90)	2	1				
Unsealed Sources (e.g. I-131 oral, P-32 colloid, Sr- 89, Sm-153, other)	3	8				
Endovascular Insertions						

4. Specific Radiotherapy Techniques: Cases As Primary Resident In Treatment Planning

Type	# Simulated
Mantle	5
Craniospinal	8
Total Body Irradiation	2
Total Skin Irradiation	0
Stereotactic Radiosurgery: Brain	24
Stereotactic Radiosurgery: Other	1

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper: Gary Talkington, RSO / 703-698-3394 Fairfax Inova Hospital Radiation Oncology 3300 Gallows Road Falls Church, VA 22042-3300 USA	Air Waybill No. <u>8473 7207 0346</u> Page 1 of 1 Pages Shippers Reference Number (optional)
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Consignee:
 Patricia Blute (770)-717-0904 ext. 5480
 Novoste Corporation - Rad Material Receiving
 4350 International Blvd
 Norcross, GA 30093 USA



Two completed and signed copies of this Declaration must be handed to the operator.

WARNING
 Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to penalties.

Transport Details

This shipment is within the limitations prescribed for: (delete non-applicable)	Airport of Departure:
PASSENGER AND CARGO AIRCRAFT	[Redacted]

Airport of Destination: **ATL**

Shipment type: (delete non applicable)
 Radioactive

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification				Quantity and type of packing	Packing Inst.	Authorization
UN or ID Number	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group			
UN 2915	Radioactive Material Type A Package	7		Sr-90, Metal, Solid 1 Type A Package <u>1.38</u> GBq	II Yellow TI= <u>0.2</u> 30.5 cm dia. 34.5 cm height	

Additional Handling Information : This shipment contains radioactive material in a medical device intended for use in or incident to research or diagnosis, or treatment. This shipment prepared in accordance with ICAO/IATA. This material is owned by, and is being returned to the consignee.

24 hr Emergency Response: Chemtrec 1-800-424-9300

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.

Name/Title of Signatory GARY F TALKINGTON
Radiation Safety Officer
 Place and Date Falls Church VA
MAY 20, 2008
 Signature [Signature]
 (see warning above)

FedEx US Airbill
Express

FedEx
Tracking
Number

8473 7207 0346



1 From Please print and press hard
 Date May 20, 2005 Sender's FedEx Account Number ~~02000-0212~~ 3
 Sender's Name GARY R TALKINGTON Phone 703, 776-3394
 Company Inova Fairfax Hospital Radiation Oncology
 Address 3300 Gallows Road Dept./Floor/Suite/Room
 City Falls Church State VA ZIP 22042-3300

2 Your Internal Billing Reference
 First 24 characters will appear on invoice

3 To
 Recipient's Name _____ Phone (770) 717-6086
 Company NOVOSTE CORP/ RADIATION FAC
 Recipient's Address 4350 INTERNATIONAL BLVD Dept./Floor/Suite/Room
 We cannot deliver to P.O. boxes or P.O. ZIP codes.
 Address _____
 To request a package be held at a specific FedEx location, print FedEx address here
 City NORCROSS State GA ZIP 30093-3017

4a Express Package Service Packages up to 150 lbs.
 FedEx Priority Overnight Next business morning* FedEx Standard Overnight Next business afternoon* FedEx First Overnight Earliest next business morning delivery to select locations**
 FedEx 2Day Second business day* FedEx Express Saver Third business day*
FedEx Envelope rate not available. Minimum charge: One-pound rate

4b Express Freight Service Packages over 150 lbs.
 FedEx 1Day Freight* Next business day** FedEx 2Day Freight Second business day** FedEx 3Day Freight Third business day**
 * Call for Confirmation

5 Packaging * Declared value limit \$500
 FedEx Envelope* FedEx Pak* Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak FedEx Box FedEx Tube Other

6 Special Handling Includes FedEx address label only
 SATURDAY Delivery Available only for FedEx Priority Overnight, FedEx 2Day, FedEx 1Day Freight, and FedEx 2Day Freight to select ZIP codes HOLD Weekday at FedEx Location Not available for FedEx First Overnight HOLD Saturday at FedEx Location Available only for FedEx Priority Overnight and FedEx 2Day to select locations
 Does this shipment contain dangerous goods?
 No Yes As per attached Shipper's Declaration Yes Shipper's Declaration not required Dry Ice Dry Ice, 9, UN 1845 x _____ kg
 Cargo Aircraft Only
 Dangerous goods (including Dry Ice) cannot be shipped in FedEx packaging.

7 Payment Enter FedEx Acct. No. or Credit Card No. below.
 Sender Acct. No. in Section 1 will be billed Recipient Third Party Credit Card Cash/Check
 FedEx Acct. No. 2255-8805-8 Exp. Date _____
 Credit Card No. _____
 Total Packages 1 Total Weight 25 Total Declared Value† \$ 0.00
 †Our liability is limited to \$100 unless you declare a higher value. See back for details. FedEx Use Only

8 Sign to Authorize Delivery Without a Signature

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

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 or call 1.800.GoFedEx 1.800.463.3339.

0288759124

SIF • Rev. Date 11/03 • Part #158279 • ©1994-2003 FedEx • PRINTED IN U.S.A.

PULL AND RETAIN THIS COPY BEFORE AFFIXING TO THE PACKAGE.

ORDER # (REF) : TDA-2030

Jacketed Radiation Source Train (JRST)
 Description: SICW.2.H 30 : series of 12 radiopaque marker welded to each end.
 Radionuclide: Sr-90

Active Length: 30 mm
 Model SICW.2 sealed sources jacketed in a stainless steel coil (0.47 mm OD) with non-radioactive
 Total Activity: 1.33 GBq Assay Date: 6Jan03

Recommended Radiation Treatment

Transfer Device Serial #: 01078N

Radiation Source Train Serial #: ZA823

	Effective Date From: 27Aug04		To: 25Feb05	
	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	<input type="text" value="220"/> <input type="text" value="3,40"/>
	≥ 3.5 to ≤ 4.0	> 3.35 to ≤ 4.0	23.0	<input type="text" value="275"/> <input type="text" value="4,35"/>

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

	Effective Date From: 26Feb05		To: 27Aug05	
	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	<input type="text" value="222"/> <input type="text" value="3,42"/>
	≥ 3.5 to ≤ 4.0	> 3.35 to ≤ 4.0	23.0	<input type="text" value="278"/> <input type="text" value="4,38"/>

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: 0.0876 Gy·s⁻¹ ±20% in H₂O at 2mm from the center line of the Radiation Source Train. Date: 6Jan03

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: 0.111 GBq/Source

The contained activity per source is the product of the measured source train absorbed dose rate in Gy/sec, at 2 mm from the source center line in water and the conversion factor 34.2 mCi/seed (1.27 GBq/seed) 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: 2.5 mm Diameter: 0.38 mm ISO 2919 classification: C53X_{1,2,3}11

¹ 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: 14Jun02

Novoste Leak Test:

H₂O passed over the Radiation Source Train and then analyzed for radioactive content
 Result: <185 Bq Date: 27Aug04

Wood 8/27/04

***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
 3890 Steve Reynolds Blvd.
 Norcross, Georgia
 USA 30093
 Tel: +1 800 NOVOSTE

Certified by Novoste Corporation:
Phillip B. Butte 8/27/04
 Manufacturing Date
Phillip B. Butte 8/27/04
 Quality Assurance Date





Novoste Corporation

Product Return Instructions

4350 International Boulevard
Norcross, Georgia 30093

Return Products To: **Novoste Corporation**
Radioactive Handling Facility
3890 Steve Reynold Blvd
Norcross, GA 30093

Customer Account Services Phone: 1-800-668-6783
1-770-717-0904
Customer Account Service Fax: 1-877-753-8537
1-770-717-5193

Attention: Bryce Drake or Ron Davis

Customer Number	End User Number	Order	Call	Purchase Order	Print Date
20000433	20000434		CA9499	Closed Account	5/10/2005

SOLD TO
 Inova Fairfax Hospital
 Inova Health Systems
 Accounts Payable
 P.O. Box 695
 Merrifield, VA 22116-0695

EMERGENCY
 Fairfax Inova Hospital
 Radiation Oncology
 3300 Gallows Road
 Falls Church, VA 22042-3300

Return Shipment Details For Active Items:

- Use FedEx account number 225588058 for return shipments. (1-800-GO-FEDEX)
- Bill Novoste Corporation for all charges.
- You may track your FedEx shipment via the internet at <http://www.fedex.com/us/tracking>
- A copy of the Notification document should accompany your shipment.
- Please return transfer devices to the following address:
 Novoste Corporation
 Radioactive Material Handling Facility
 4350 C International Blvd.
 Norcross, GA 30093
 Attn: Ron Davis
- For any questions, contact Customer Account Services at 1-800-NOVOSTE (668-6783) then press 2.

Account Manager	Entered By	
Leith, L	0-NOAGRE	



Novoste Corporation

4350 International Boulevard
Norcross, Georgia 30093

Customer Notification of Shipment/Return

Customer Account Services Phone: 1-800-668-6783

1-770-717-0904

Customer Account Services Fax: 1-877-753-8537

1-770-717-5193

Customer Number	End User Number	Order	Call	Purchase Order	Print Date
20000433	20000434		CA9499	Closed Account	5/10/2005

SOLD TO

Inova Fairfax Hospital
Inova Health Systems
Accounts Payable
P.O. Box 695
Merrifield, VA 22116-0695

END USER

Fairfax Inova Hospital
Radiation Oncology
3300 Gallows Road
Falls Church, VA 22042-3300

Gary Talkington (RSO)
703-698-3394

Product(s) To Be Shipped To

Item / Description	Due Date	Quantity	Unit Price	Net Price

Product(s) To Be Returned To Novoste Corporation

Item / Description	Lot/Serial	Due Date	Quantity	Unit Price	Net Price
P02751 / TDA-2030-021 3.5F 30MM ACTIVE DEVICE	01078n	05/24/05	1	\$0.00	\$0.00

See attachments for return instructions.

Account Manager	Entered By	Total
Leith, L	0-NOAGRE	\$0.00

SHIPPERS DECLARATION FOR DANGEROUS GOODS

Shipper:
 Gary Talkington, RSO / 703-698-3394
 Fairfax Inova Hospital
 Radiation Oncology
 3300 Gallows Road
 Falls Church, VA 22042-3300
 USA

Air Waybill No. 8473 7221 - 3665
 Page 1 of 1 Pages
 Shippers Reference Number
 (optional)

Consignee:
 Patricia Blute (770)-717-0904 ext. 5480
 Novoste Corporation - Rad Material Receiving
 4350 International Blvd
 Norcross, GA 30093 USA



Two completed and signed copies of this Declaration must be handed to the operator.

WARNING
 Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to penalties.

Transport Details
 This shipment is within the limitations prescribed for:
 (delete non-applicable)
 AIRPORT OF DEPARTURE:
 PASSENGER AND CARGO AIRCRAFT

Airport of Destination
 ATL

Shipment type: (delete non applicable)
 Radioactive

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification				Quantity and type of packing	Packing Inst.	Authorization
UN or ID Number	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group			
UN 2915	Radioactive Material Type A Package	7		Sr-90, Metal, Solid 1 Type A Package <u>3.14</u> GBq	II Yellow TI= <u>0.3</u> 30.5 cm dia. 34.5 cm height	

Additional Handling Information : This shipment contains radioactive material in a medical device intended for use in or incident to research or diagnosis, or treatment. This shipment prepared in accordance with ICAO/IATA. This material is owned by, and is being returned to the consignee.

24 hr Emergency Response: Chemtrec 1-800-424-9300

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.

Name/Title of Signatory GARY F. TALKINGTON
Radioactive Safety Officer
 Place and Date Falls Church VA
MAY 20, 2005
 Signature [Signature]
 (see warning above)

FedEx US Airbill
Express

FedEx
Tracking
Number

8473 7221 3665

Sender's Copy

1 From Please print and press hard.
Date May 20, 2005 Sender's FedEx Account Number
Sender's Name Gary F. Talkington Phone 703, 776-3394
Company INVA FAIRFAX HOSPITAL
Radiation Oncology
Address 3300 Ballous Road
City Falls Church State VA ZIP 22042-3300

2 Your Internal Billing Reference
First 24 characters will appear on invoice.
3 To
Recipient's Name _____ Phone (770) 717-6086

Company NOVOSTE CORP / RADIATION FAC
Recipient's Address 4350 INTERNATIONAL BLVD
We cannot deliver to P.O. boxes or P.O. ZIP codes.
Address _____
To request a package be held at a specific FedEx location, print FedEx address here.
City NORCROSS State GA ZIP 30093-3017

4a Express Package Service Packages up to 150 lbs.
 FedEx Priority Overnight Next business morning*
 FedEx Standard Overnight Next business afternoon*
 FedEx First Overnight Earliest next business morning delivery to select locations**
 FedEx 2Day Second business day*
 FedEx Express Saver Third business day*
*FedEx Envelope rate not available. Minimum charge: One-pound rate.

4b Express Freight Service Packages over 150 lbs.
 FedEx 1Day Freight* Next business day**
 FedEx 2Day Freight Second business day**
 FedEx 3Day Freight Third business day**
*Call for Confirmation.

5 Packaging *Declared value limit \$500
 FedEx Envelope*
 FedEx Pak* Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak.
 FedEx Box
 FedEx Tube
 Other

6 Special Handling (include FedEx address in Section 3)
 SATURDAY Delivery Available ONLY for FedEx Priority Overnight, FedEx 2Day, FedEx 1Day Freight, and FedEx 2Day Freight to select ZIP codes.
 HOLD Weekday at FedEx Location (Not Available for FedEx First Overnight)
 HOLD Saturday at FedEx Location Available ONLY for FedEx Priority Overnight and FedEx 2Day to select locations.
Does this shipment contain dangerous goods?
 No Yes (see per attached Shipper's Declaration) Yes Shipper's Declaration not required
Dry Ice Dry Ice, 9, UN 1845 _____ kg
Cargo Aircraft Only
Dangerous goods (including Dry Ice) cannot be shipped in FedEx packaging.

7 Payment Bill to: Enter FedEx Acct. No. or Credit Card No. below.
 Sender Acct. No. in Section 1 will be billed. Recipient Third Party Credit Card Cash/Check
FedEx Acct. No. / Credit Card No. 2255-8805-8 Exp. Date _____
Total Packages 1 Total Weight 25 Total Declared Value* \$ _____ .00
FedEx Use Only

8 Sign to Authorize Delivery Without a Signature

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

466

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By using this Airbill you agree to the service conditions on the back of this Airbill and in our current Service Guide, including terms that limit our liability.
Questions? Visit our Web site at fedex.com
or call 1.800.GoFedEx 1.800.463.3339.

0288759124

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PULL AND RETAIN THIS COPY BEFORE AFFIXING TO THE PACKAGE.

ORDER # (REF): TDA-2060

Jacketed Radiation Source Train (JRST) Active Length: 60mm
 Description: SICW.2.H 60 : series of 24 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: 3.14 GBq Assay Date: 17Sep02

Recommended Radiation Treatment

Transfer Device Serial #: 92948		Radiation Source Train Serial #: ZA779				
Effective Date	From: 25Oct04	To: 25Apr05				
	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	<table border="1"><tr><td>188</td><td>3, 08</td></tr></table>	188	3, 08
	188	3, 08				
≥ 3.5 to ≤ 4.0	> 3.35 to ≤ 4.0	23.0	<table border="1"><tr><td>235</td><td>3, 55</td></tr></table>	235	3, 55	
235	3, 55					

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

Effective Date	From: 26Apr05	To: 25Oct05				
	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	<table border="1"><tr><td>191</td><td>3, 11</td></tr></table>	191	3, 11
	191	3, 11				
≥ 3.5 to ≤ 4.0	> 3.35 to ≤ 4.0	23.0	<table border="1"><tr><td>238</td><td>3, 58</td></tr></table>	238	3, 58	
238	3, 58					

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: 0.1034 Gy-s⁻¹ ± 20% in H₂O at 2 mm from the center line of the Radiation Source Train. Date: 17Sep02

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: 0.131 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/seed (1.27GBq/seed) 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 classification¹: C53X1,2,3 11

¹ 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: 29May02

Novoste Leak Test:
 H₂O passed over the Radiation Source Train and then analyzed for radioactive content using liquid scintillation counting.
 Result: <185 Bq Date: 25Oct04

*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:
Johnnie K. White 10/22/04
 Manufacturing Date
Alfred C. [Signature] 10/23/04
 Quality Assurance Date

NON-STERILE


IPX1




Novoste Corporation Product Return Instructions

4350 International Boulevard
Norcross, Georgia 30093

Return Products To: **Novoste Corporation**
Radioactive Handling Facility
3890 Steve Reynold Blvd
Norcross, GA 30093

Customer Account Services Phone: **1-800-668-6783**
1-770-717-0904
Customer Account Service Fax: **1-877-753-8537**
1-770-717-5193

Attention: Bryce Drake or Ron Davis

Customer Number	End User Number	Order	Call	Purchase Order	Print Date
20000433	20000434		CA9740	Closed Account	5/10/2005

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Inova Fairfax Hospital
Inova Health Systems
Accounts Payable
P.O. Box 695
Merrifield, VA 22116-0695

**E
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Fairfax Inova Hospital
Radiation Oncology
3300 Gallows Road
Falls Church, VA 22042-3300

Return Shipment Details For Active Items:

- Use FedEx account number 225588058 for return shipments. (1-800-GO-FEDEX)
- Bill Novoste Corporation for all charges.
- You may track your FedEx shipment via the internet at <http://www.fedex.com/us/tracking>
- A copy of the Notification document should accompany your shipment.
- Please return transfer devices to the following address:
Novoste Corporation
Radioactive Material Handling Facility
4350 C International Blvd.
Norcross, GA 30093
Attn: Ron Davis
- For any questions, contact Customer Account Services at 1-800-NOVOSTE (668-6783) then press 2.

Account Manager	Entered By	
Leith, L	0-NOAGRE	



Novoste Corporation

4350 International Boulevard
Norcross, Georgia 30093

Customer Notification of Shipment/Return

Customer Account Services Phone: 1-800-668-6783
1-770-717-0904
Customer Account Services Fax: 1-877-753-8537
1-770-717-5193

Customer Number	End User Number	Order	Call	Purchase Order	Print Date
20000433	20000434		CA9740	Closed Account	5/10/2005

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Inova Fairfax Hospital
Inova Health Systems
Accounts Payable
P.O. Box 695
Merrifield, VA 22116-0695

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Fairfax Inova Hospital
Radiation Oncology
3300 Gallows Road
Falls Church, VA 22042-3300

Gary Talkington (RSO)
703-698-3394

Product(s) To Be Shipped To

Item / Description	Due Date	Quantity	Unit Price	Net Price

Product(s) To Be Returned To Novoste Corporation

Item / Description	Lot/Serial	Due Date	Quantity	Unit Price	Net Price
P02753 / TDA-2060-021 3.5F 60MM ACTIVE DEVICE	92948	05/24/05	1	\$0.00	\$0.00

See attachments for return instructions.

Account Manager	Entered By	Total
Leith, L	0-NOAGRE	\$0.00

SHIPPERS DECLARATION FOR DANGEROUS GOODS

Shipper: Gary Talkington, RSO / 703-698-3394 Fairfax Inova Hospital Radiation Oncology 3300 Gallows Road Falls Church, VA 22042-3300 USA	Air Waybill No. <u>5473 7221-3654</u> Page 1 of 1 Pages Shippers Reference Number (optional)
Consignee: Patricia Blute (770)-717-0904 ext. 5480 Novoste Corporation - Rad Material Receiving 4350 International Blvd Norcross, GA 30093 USA	
Two completed and signed copies of this Declaration must be handed to the operator.	
WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to penalties.	
Transport Details This shipment is within the limitations prescribed for: (delete non-applicable)	
Airport of Departure:	PASSENGER AND CARGO AIRCRAFT
Airport of Destination <p style="text-align: center;">ATL</p>	Shipment type: (delete non applicable) <p style="text-align: center;">Radioactive</p>

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification				Quantity and type of packing	Packing Inst.	Authorization
UN or ID Number	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group			
UN 2915	Radioactive Material Type A Package	7		Sr-90, Metal, Solid 1 Type A Package <u>1.51</u> GBq	II Yellow TI= <u>0.2</u> 30.5 cm dia. 34.5 cm height	

Additional Handling Information : This shipment contains radioactive material in a medical device intended for use in or incident to research or diagnosis, or treatment. This shipment prepared in accordance with ICAO/IATA. This material is owned by, and is being returned to the consignee.

24 hr Emergency Response: Chemtrec 1-800-424-9300

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.	Name/Title of Signatory <u>Gary F. Talkington</u> <u>Radiation Safety Officer</u> Place and Date <u>Falls Church VA</u> <u>May 20, 2005</u> Signature <u>[Signature]</u> (see warning above)
--	---

FedEx US Airbill
Express

FedEx
Tracking
Number

8473 7221 3654

1 From Please print and press hard.

Date May 20, 2005 Sender's FedEx Account Number

Sender's Name GARY F. TALKINGTON Phone 703, 776-3394

Company INOVA FAIRFAX HOSPITAL

Address RADIATION ONCOLOGY
3300 GALLONS ROAD Dept./Floor/Suite/Room

City Falls Church State VA ZIP 22042-3300

2 Your Internal Billing Reference
First 24 characters will appear on invoice.

3 To

Recipient's Name _____ Phone (770) 717-6086

Company NOVOSTE CORP/ RADIATION FAC

Recipient's Address 4350 INTERNATIONAL BLVD Dept./Floor/Suite/Room

We cannot deliver to P.O. boxes or P.O. ZIP codes.

Address _____
To request a package be held at a specific FedEx location, print FedEx address here.

City NORCROSS State GA ZIP 30093-3017

Try online shipping at fedex.com
By using this Airbill you agree to the service conditions on the back of this Airbill and in our current Service Guide, including terms that limit our liability.
Questions? Visit our Web site at fedex.com
or call 1.800.GoFedEx 1.800.463.3339

0288759124



4a Express Package Service Packages up to 150 lbs. (includes insurance)

FedEx Priority Overnight Next business morning* FedEx Standard Overnight Next business afternoon* FedEx First Overnight Earliest next business morning delivery to select locations*

FedEx 2Day Second business day* FedEx Express Saver Third business day*

FedEx Envelope rate not available. Minimum charge. One-pound rate.

4b Express Freight Service Packages over 150 lbs. (includes insurance)

FedEx 1Day Freight* Next business day** FedEx 2Day Freight Second business day** FedEx 3Day Freight Third business day**

* Call for Confirmation.

5 Packaging * Declared value limit \$500

FedEx Envelope* FedEx Pak* Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak FedEx Box FedEx Tube Other

6 Special Handling Includes FedEx address label (1000)

SATURDAY Delivery Available Daily for FedEx Priority Overnight, FedEx 2Day, FedEx 1Day Freight, and FedEx 2Day Freight to select ZIP codes HOLD Weekday at FedEx Location Not available for FedEx First Overnight HOLD Saturday at FedEx Location Available only for FedEx Priority Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods?
(If an answer must be checked)

No Yes See per attached Shipper's Declaration Yes Shipper's Declaration not required Dry Ice Dry Ice, 9, UN 1845 _____ x _____ kg Cargo Aircraft Only

Dangerous goods (including Dry Ice) cannot be shipped in FedEx packaging.

7 Payment Bill to: Enter FedEx Acct. No. or Credit Card No. below.

Sender Acct. No. in Section 1 will be billed. Recipient Third Party Credit Card Cash/Check

FedEx Acct. No. 2255-8805-8 Exp. Date _____
Credit Card No. _____

Total Packages	Total Weight	Total Declared Value†
<u>1</u>	<u>25</u>	\$ <u> </u> .00

†Our liability is limited to \$100 unless you declare a higher value. See back for details. FedEx Use Only

8 Sign to Authorize Delivery Without a Signature

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

466

PULL AND RETAIN THIS COPY BEFORE AFFIXING TO THE PACKAGE.

ORDER # (REF) : TDA-2040

Jacketed Radiation Source Train (JRST)
 Description: SICW.2.H 40 : series of 16 radiopaque marker welded to each end.
 Radionuclide: Sr-90

Active Length: mm
 Model SICW.2 sealed sources jacketed in a stainless steel coil (0.47 mm OD) with non-radioactive
 Total Activity: 1.91 GBq Assay Date: 15Sep03

Recommended Radiation Treatment

Transfer Device Serial #: 01052N

Radiation Source Train Serial #: ZB615

Effective Date From: 7Jul04		To: 5Jan05		
	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	<input type="text" value="200"/> <input type="text" value="3,20"/>
	≥ 3.5 to ≤ 4.0	> 3.35 to ≤ 4.0	23.0	<input type="text" value="250"/> <input type="text" value="4,10"/>

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

Effective Date From: 6Jan05		To: 7Jul05		
	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	<input type="text" value="203"/> <input type="text" value="3,23"/>
	≥ 3.5 to ≤ 4.0	> 3.35 to ≤ 4.0	23.0	<input type="text" value="254"/> <input type="text" value="4,14"/>

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 2mm from the center line of the Radiation Source Train. Date: 15Sep03

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 2 mm from the source center line in water and the conversion factor 34.2 mCi/seed (1.27 GBq/seed) 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: 2.5 mm Diameter: 0.38 mm ISO 2919 classification: C53X_{1,2,3}11

¹ 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: 24Jul03

Novoste Leak Test:

H₂O passed over the Radiation Source Train and then analyzed for radioactive content using liquid scintillation counting.
 Result: <185 Bq Date: 28Jun04

***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
 3890 Steve Reynolds Blvd.
 Norcross, Georgia
 USA 30093
 Tel: +1 800 NOVOSTE

Certified by Novoste Corporation:
 E. Bawson 7-7-04
 Manufacturing Date
 J. Wood 7-7-04
 Quality Assurance Date

NON-STERILE



IPX1





Novoste Corporation

Product Return Instructions

4350 International Boulevard
Norcross, Georgia 30093

Return Products To: **Novoste Corporation**
Radioactive Handling Facility
3890 Steve Reynold Blvd
Norcross, GA 30093

Customer Account Services Phone: 1-800-668-6783
1-770-717-0904
Customer Account Service Fax: 1-877-753-8537
1-770-717-5193

Attention: Bryce Drake or Ron Davis

Customer Number	End User Number	Order	Call	Purchase Order	Print Date
20000433	20000434		CA9100	Closed Account	5/10/2005

SOLD TO
 Inova Fairfax Hospital
 Inova Health Systems
 Accounts Payable
 P.O. Box 695
 Merrifield, VA 22116-0695

UNDETERMINED
 Fairfax Inova Hospital
 Radiation Oncology
 3300 Gallows Road
 Falls Church, VA 22042-3300

Return Shipment Details For Active Items:

- Use FedEx account number 225588058 for return shipments. (1-800-GO-FEDEX)
- Bill Novoste Corporation for all charges.
- You may track your FedEx shipment via the internet at <http://www.fedex.com/us/tracking>
- A copy of the Notification document should accompany your shipment.
- Please return transfer devices to the following address:
 Novoste Corporation
 Radioactive Material Handling Facility
 4350 C International Blvd.
 Norcross, GA 30093
 Attn: Ron Davis
- For any questions, contact Customer Account Services at 1-800-NOVOSTE (668-6783) then press 2.

Account Manager Leith, L	Entered By 0-NOAGRE	
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Novoste Corporation

4350 International Boulevard
Norcross, Georgia 30093

Customer Notification of Shipment/Return

Customer Account Services Phone: 1-800-668-6783
1-770-717-0904

Customer Account Services Fax: 1-877-753-8537
1-770-717-5193

Customer Number	End User Number	Order	Call	Purchase Order	Print Date
20000433	20000434		CA9100	Closed Account	5/10/2005

SOLD TO

Inova Fairfax Hospital
Inova Health Systems
Accounts Payable
P.O. Box 695
Merrifield, VA 22116-0695

END USER

Fairfax Inova Hospital
Radiation Oncology
3300 Gallows Road
Falls Church, VA 22042-3300

Gary Talkington (RSO)
703-698-3394

Product(s) To Be Shipped To

Item / Description	Due Date	Quantity	Unit Price	Net Price

Product(s) To Be Returned To Novoste Corporation

Item / Description	Lot/Serial	Due Date	Quantity	Unit Price	Net Price
P02752 / TDA-2040-021 3.5F 40MM ACTIVE DEVICE	01052n	05/24/05	1	\$0.00	\$0.00

See attachments for return instructions.

Account Manager	Entered By	Total
Leith, L	0-NOAGRE	\$0.00

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

6/9/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 45-17128-01
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** 137190.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (R1)
(6-96)

Sincerely,
Licensing Assistance Team Leader

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

: Program Code: 02230
: Status Code: 0
: Fee Category: 7C 3E
: Exp. Date: 20130228
: Fee Comments: _____
: Decom Fin Assur Req'd: N

.....

LICENSE FEE TRANSMITTAL

A. REGION

I

1. APPLICATION ATTACHED

Applicant/Licensee: INOVA FAIRFAX HOSPITAL
Received Date: 20050610
Docket No: 3012235
Control No.: 137190
License No.: 45-17128-01
Action Type: Amendment

2. FEE ATTACHED

Amount: /
Check No.: _____

3. COMMENTS

Signed
Date

Mircea Lunel
6/17/2005

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /_/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____
Renewal _____
License _____

3. OTHER _____

Signed
Date

