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October 25, 2002

Handwritten notes:
Name: E.J.
Ref: 10277
Date Rec'd: 10-29-02
Amt Rec'd: 1200.00

Eric T. Jameson
Radioactive Materials Program
Environmental Protection Division
State of Georgia, Department of Natural Resources
4244 International Parkway, Suite 114
Atlanta, Georgia 30354

RE: Update to SSDR GA-1115-D-101-S

Mr. Jameson:

Novoste™ Corporation is requesting an update to SSDR certificate GA-1115-D-101-S to add a new design of the investigational Corona™ Delivery Catheter that is compatible with the *Model A1767 Transfer Device and AEAT SICW.2 sources.*

The following items are enclosed for your evaluation:

- Attachment A – Expanded Corona™ Delivery Catheter Description
- Attachments B, C – Corona™ Delivery Catheter Images
- Attachment D – Device, Source, Catheter, Guide Tube Compatibility Table

A check in the amount of \$1,200 is enclosed for this amendment. If you have questions about this application please contact me by email, creed@novoste.com, or in my absence, Bob Cooper, CHP, Regulatory Affairs at (770) 717-0904.

Kind regards,

Craig Reed, Director
Radiation Regulatory Affairs
Novoste™ Corporation

Attachment A

Corona™ System Delivery Catheter Description

Corona™ System Delivery Catheter designs exist for use with the Model A1730 Transfer Device and the Model A1767 Transfer Device.

The already registered Corona™ System Delivery Catheter for use with the A1730 Transfer Device has a 7F profile (7/3 mm diameter) to accommodate the large diameter Radiation Source Train used in that device.

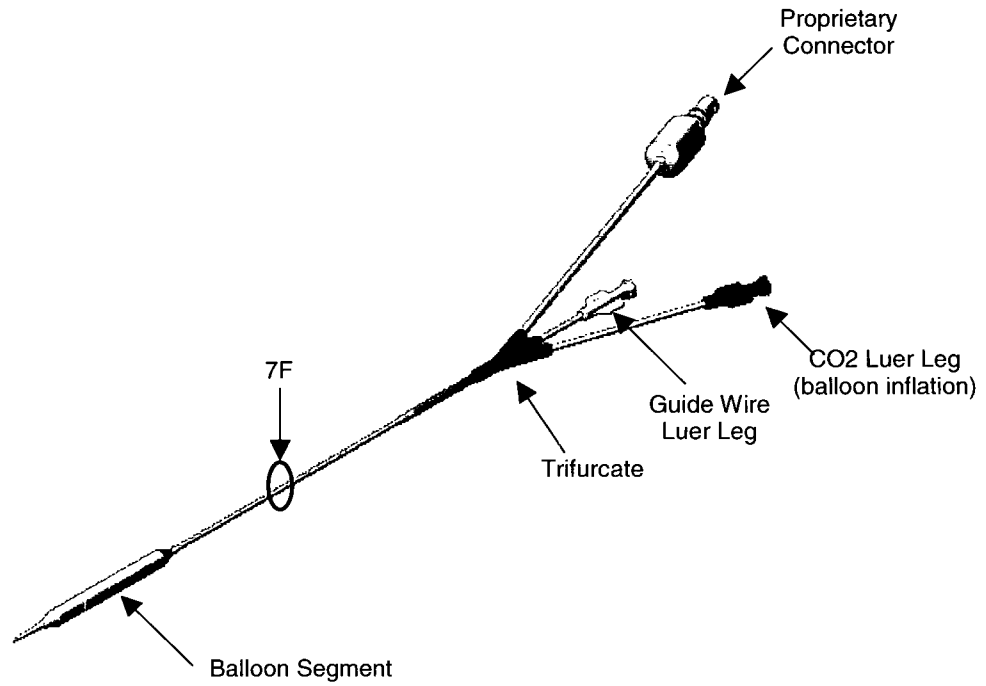
The new Corona™ System Delivery Catheter for use with the A1767 Transfer Device has a smaller 5F profile achievable with the small diameter Jacketed Radiation Source Train.

The overall length, outer diameter, source train lumen diameter and relative position of the Proprietary Connector leg, Guide Wire leg and CO₂ leg vary between the Corona™ Delivery Catheter designs, but the main shaft material (PEBAX), and four-lumen design are the same. Two images are provided on the following pages for comparison.

The Corona™ Systems are not yet approved for routine medical use. Routine medical use requires FDA approval (i.e., PMA) or clearance (i.e., 510k). Use for clinical research is subject to an FDA IDE.

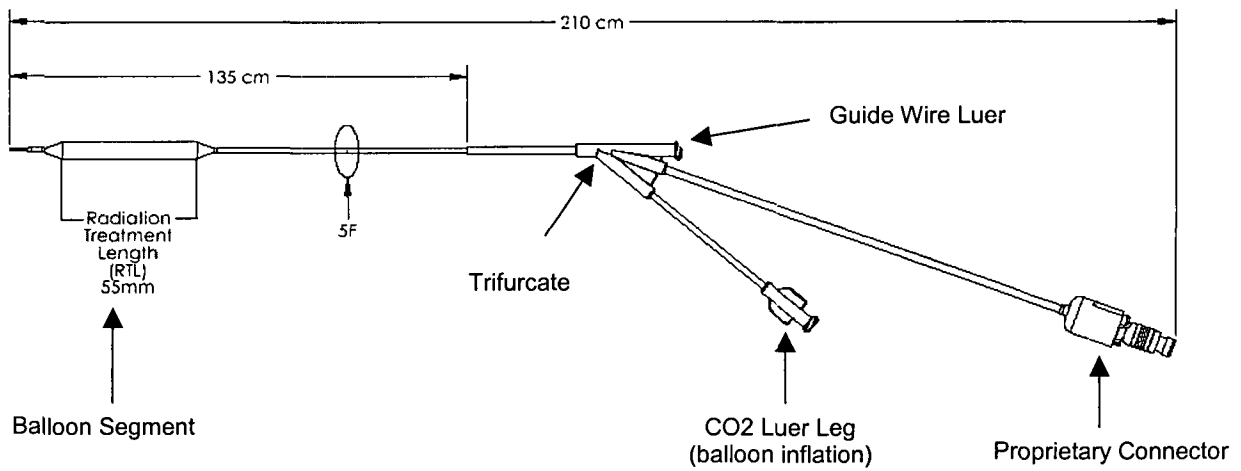
Attachment B

Image of Corona™ Delivery Catheter For Use with the A1730 Transfer Device



Attachment C

Image of Corona™ Delivery Catheter For Use with the A1767 Transfer Device



Attachment D

Device, Source, Catheter, Guide Tube Compatibility Table

A1000 Series Transfer Device	Source Model	Source Quantity	Maximum Total Sr-90 per Device (GBq)	Compatible Beta-Cath™ Delivery Catheter	Compatible Corona™ Delivery Catheter	Compatible Guide Tube
A1732	Bebig Sr0.S03 (or AEAT SICW.1)	12	2.22	5Fr	Not Available	GTA-0050
A1733	Bebig Sr0.S03 (or AEAT SICW.1)	16	2.96	5Fr	Not Available	
A1730	Bebig Sr0.S03 (or AEAT SICW.1)	24	4.44	5Fr	7Fr	
A1767	AEAT SICW.2	12	2.22	3.5Fr	Not Available	GTA-0035
		16	2.96		Not Available	
		24	4.44		5Fr	