**U.S. Hospital Experiences with the Beta-Cath™ System for the Treatment of In-Stent Restenosis**

**William Beaumont Hospital**
Royal Oak, MI

*Data Presented By: Dr. William O’Neill*
- 155 patients treated since 12/00 have 180 - 360 day follow up
  - Of the 155 pts, 8 (5.2%) patients returned with TLR:
    - 5 due to geographic miss
    - 3 true treatment failures

**The Lindner Center, The Christ Hospital**
Cincinnati, OH

*John Young, MD, FACP, FACC, FCCP; Dr. Dean Kereiakes*
- 265 patients treated from 1/01 - 6/30/2002
  - 46 symptomatic, returned for re-angio
    - 23 had re-PCI;
      - 2 TSR (target stent restenosis)
      - 12 non-TSR (non-target stent restenosis)
      - 9 non-TVR
    - 11 had CABG;
      - 4 TSR
      - 7 non-TSR

**Forsyth Medical Center**
Winston-Salem, NC

*Data Presented By: Dr. Greg Braden*
- 288 patients treated from 12/00 - 4/02
- 206 patients with > 6 months follow-up
- 49 returned for re-angio
  - 10 (3.5%) TLR
    - 2 Total Occulsions
    - 9 re-PCI, 1 CABG

*Data presented during HMP “In-Stent Restenosis Treatment Controversies” webcast on May 14, 2002. For additional information, please contact Dr. O’Neill, Dr. Kereiakes, or Dr. Braden.
Beta-Cath™ 5F System and Beta-Cath™ 3.5F System

Beta-Cath™ 5F System Intended Uses

The Beta-Cath™ 5F System is intended to deliver beta radiation to the site of successful Percutaneous Coronary Intervention (PCI) for the treatment of in-stent Restenosis in native coronary arteries with discrete lesions (treatable with a 30 mm balloon) for the 30 mm and 40 mm systems and injury areas up to 40 mm for the 60 mm system in a reference vessel diameter ranging from 2.7 mm to 4.0 mm.

Beta-Cath™ 3.5F System Intended Uses

The Beta-Cath™ 3.5F System is intended to deliver beta radiation to the site of successful Percutaneous Coronary Intervention (PCI) for the treatment of in-stent Restenosis in native coronary arteries with discrete lesions (treatable with a 20 mm balloon) in a reference vessel diameter ranging from 2.7 mm to 4.0 mm.

Contraindications

- Unprotected left main disease (>50% narrowing).
- Patients in whom antithrombotic and/or anticoagulant therapy are contraindicated.

Warnings

- Every attempt should be made to avoid restenting of the target lesion to minimize the risk of thrombosis.

Delivery Catheter & Source Train Placement

- Use of an Internal Mammary (IM) Artery Guide Catheter may impede the path of the ACTIVE Source Train and cause unintentional exposure of radiation and/or unintended results (Only for Beta-Cath™ 3.5F System).
- Vessel trauma may result from the improper use of the Delivery Catheter. Follow the enclosed directions carefully. When the Delivery Catheter is in the body, it should be manipulated only under fluoroscopy. Never advance or withdraw the Delivery Catheter against resistance without first determining the reason for the resistance under fluoroscopy.
- Failure to correctly position the Source Train at the site in injury may underserve the targeted treatment area and expose tissue not targeted for treatment to unintentional radiation. Exceeding the prescribed radiation treatment time will result in a higher than intended dose. Migration or improper location of the Source Train may cause unintentional radiation exposure to occur. The effect of unintentional radiation exposures higher than intended doses are unknown.
- Do not overtighten the hemostatic valve as this may damage the Delivery Catheter and impede the path of the Source Train and may cause unintentional exposure of radiation and/or unintended results. Always check that the Source Train is fully retracted into the Delivery Catheter. On retraction, the Source Train in the Delivery Catheter must be retracted to the Delivery Catheter and into the Delivery Catheter and Procedure Accessory Pack before the expiration date noted on the package. Verify that the sterility of the device has not been compromised by assuring the package integrity has been maintained. The Delivery Catheter and Procedure Accessory Pack items are intended for single use. Do not re-sterilize and/or reuse these items.
- Do not use the Delivery Catheter if there is evidence of damage. If the Delivery Catheter Integrity Test detects a breach of catheter integrity, or restricted movement of the Source Train, perform an observation and return the Source Train to the Transfer Device. Return the Delivery Catheter to Novoste. Prepare another Delivery Catheter for use.
- Handle the Transfer Device carefully and do not use it dropped. Do not use the Transfer Device if the Transducers and indicators are not functioning correctly or the LED light test is not observed. Do not begin a procedure if the Light Bally light is blinking. If the Light Ballyy indicator starts blinking during a procedure, there will be enough battery power to complete the procedure.
- Do not use saline as a hydraulic fluid in the Transfer Device; corrosion may occur.

- The Transfer Device is not sterile. A sterile bag is provided to maintain a sterile field during the procedure. The inside portion of the tape covering the Y-Site Port and the Proprietary Connector Port Hole of the sterile bag is not sterile; remove from the sterile field.
- Use Caution when connecting the Proprietary Connector to the Transfer Device. The Proprietary Connector of the Delivery Catheter is no longer sterile once disconnected from the Transfer Device.
- Use care when attaching components to the Transfer Device to ensure that the Sterile Bag does not get pinched in the process. Ensure a sufficient number of sterile water-filled syringes are available before beginning treatment. Always reserve at least 10 ml of sterile water for the return of the Source Train to prevent unintentional radiation exposure.
- Ensure that the Gate Control Switch is completely closed, as incomplete closure may render the Gate inoperable. Intravascular Radiation Procedure
- Utilize a manual Blood Pressure Cuff to monitor patient status during the radiation treatment because arterial wave form pressure may be dampened while Delivery Catheter is in place.
- The Transfer Device contains radioactive material. Use of this device is restricted to persons licensed in the handling of radioactive materials. Personnel handling this device must follow the regulations, policies and procedures for their institution on the safety and hazards associated with radioactive materials.
- The individual performing the wipe and leak tests for radioactive material should use good contamination control techniques.
- If the transferable contamination exceeds 200 dpm/100 cm² (or the level determined by local regulation or institutional policy) or the leak test results exceed 11,100 dpm (or the level determined by local regulation or institutional policy), place the contaminated object(s) in a plastic bag and label "Caution Radioactive Material." Immediately inform institutional Radiation Safety personnel, implement containment control procedures and call your Novoste Representative. Should this occur, do not continue with this procedure.
- Illumination of the Red Pressure Indicator light during a procedure indicates excessive pressure is being used - reduce applied pressure to return to the Amber Pressure Indicator area to avoid excess use of fluid.
- Do not turn the Transfer Device power On or attempt to open the Gate Control Switch during the Drying Procedure.
- Failure to perform adequate visual and radiation surveys post-procedure to verify source accountability may subject patients and/or personnel to unintended radiation exposure.
- The Transfer Device for the Beta-Cath™ 3.5F 30 mm and 40 mm System requires scheduled maintenance by Novoste every 250 procedures or 6 months, whichever event occurs first. The Transfer Device for the Beta-Cath™ 5F 60 mm System and the Beta-Cath™ 3.5F System requires scheduled maintenance by

Additional potential Adverse Events associated with the radiation portion of vascular brachytherapy include, but are not limited to:

- Radiation Induced Malignancy
- Aneurysm
- Excessive radiation exposure to patient/staff
- Arterial Damage
- Coronary Artery By-pass Graft Surgery
- Thrombosis
- Restenosis
- Myocardial Infarction
- Death

Beta-Cath System

Best Vascular, Inc.
4530 International Blvd, Suite A • NEXCESS, GA 30091
Tel: +1 770.737.0904 • Fax: +1 770.737.1283

Novoste every 125 procedures or six months, whichever event occurs first.

- In the event a source becomes loose or needs to be transferred to a safe location, use the Source Recovery Tools with extreme care in source recovery. Improper use could damage sources and could potentially release unsealed radioactive material. Use of the Source Recovery Probe is the preferred method as it minimizes potential damage to a source restorers.
- Avoid vessel or lesion morphologies that would preclude recanulization or placement of the Delivery Catheter.

Potential adverse Events

The following adverse events were NOT observed during the clinical investigation, but are recognized as potential adverse events associated with the non-radioactive portion of vascular brachytherapy include (not limited to):

- Arhythmia
- Arterial Damage: Dissection or Perforation
- Vascular Access Site Hematoma
- Contrast-Induced Nephropathy
- Neurologic Complications
- Allergic Reactions
- Infection
- Stroke
- Thrombotic Occlusion
- Renal Insufficiency
- Coronary Artery Bypass Graft Surgery
- Slow Flow-Phenomenon
- AV Fistula
- Pseudoaneurysm
- Left Ventricular Dysfunction
- Systemic Atheroembolization
- Endocarditis
- Distal Embolizations
- Vasoospasm
- Arterial Perforation
- Retropertitoneal Hematoma