Treatment of In-Stent Restenosis via a Gastroepiploic Artery Coronary Bypass Graft with Brachytherapy using the Novoste™ Beta-Cath™ 3.5F System

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Background:
A 55-year-old male presented with premature coronary artery disease and past medical history positive for 5 previous CABG’s, multiple PCI’s, Type 1 DM, hyperlipidemia, PVD, bilateral iliac stenting, and renal artery stenting. He was treated for In-Stent Restenosis (ISR) at the University of Alabama on August 7, 2002. The patient’s first CABG was at age 36, most recent CABG was in 1999 involving a Gastroepiploic artery bypass graft using the Right Gastroepiploic Artery (RGEA) to the RCA. Subsequent interventions to the RGEA to the RCA occurred in April 2001, May 2002, and angiography in August 2002, revealing 80% ISR distal to the anastomosis of the RGEA to the native RCA. The patient was scheduled for PCI of the native RCA and Vascular Brachytherapy using the Novoste™ Beta-Cath™ 3.5F System.

Procedure:
The left axillary artery was accessed with a micropuncture set, a 7Fr sheath and a 7Fr Multi-purpose guide (ACS) utilized to cannulate the celiac artery. A 0.035” glide wire with a 5F 125 cm vertebral glide catheter was advanced through the multi-purpose guide to the right Gastroepiploic Artery. A 0.014” Luge wire was advanced across the lesion at the RGEA-RCA anastomosis. Gastroepiploic PCI of the In-Stent Restenosis was performed with a 2.25 x 9 mm NC Rail balloon followed by 2.5 x 15mm balloon to <20% residual stenosis. A Novoste™ β-Rail™ 3.5F Delivery Catheter was positioned across the lesion and the 30mm length Sr90 jacketed radiation source train was advanced by the Radiation Oncologist for 3 minutes 5 seconds to deliver a calculated dose of 18.4 Gy.

Conclusion:
Percutaneous intervention involving the RGEA Graft can pose many challenges to the Cardiologist. To intervene on a distal RGEA to the native RCA anastomosis lesion, the guide catheter has to engage into the celiac trunk advancing through the hepatic artery downward into the gastroduodenal artery and upward into the RGEA anastomosis and native RCA lesion. The Novoste™ Beta-Cath™ 3.5F System’s soft, small diameter β-Rail™ 3.5F Delivery Catheter provides excellent support and trackability in treating one of the Interventional Cardiologist’s biggest challenges.
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 20 mm balloon) in a reference vessel diameter ranging from 2.7 mm to 4.0 mm. Noovoste 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 restorability.

Avoid vessel or lesion morphologies that would preclude revascularization 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):

• Arrhythmia • Arterial Damage, Dissection or Perforation • Vascular Access Site Hematoma • Contrast-Induced Nephrotoxicity • Neurologic Complications • Allergic Reactions • Infection • Stroke • Thrombosis • Occlusion • Renal Insufficiency • Coronary Artery Bypass Graft Surgery • Slow Flow-Phenomenon • AV Fistula
• Pseudoaneurysm • Left Ventricular Dysfunction • Systemic Atherosclerosis • Endocarditis • Distal Emboliizations • Vasospasm • Arterial Perforation • Retroperitoneal Hematoma

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

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

Beta-Cath™ System Preparation

• Prior to any procedure, the equipment should be thoroughly examined to verify the proper function and integrity of the system.
• Utilize a manual Blood Pressure Cuff to monitor patient status. Safety personnel, implement contamination control procedures and call your Novoste Representative.
• 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 Guide Control Switch is completely closed, as incomplete closure may render the Gate incapable. 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 cpm/100 cm² (or the level determined by local regulation or institutional policy) or the leak test results exceed 11,000 dpm (or the level determined by local regulation or institutional policy) for any sample the contaminated objects 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 60 mm System and the Beta-Cath™ 3.5F System requires scheduled maintenance by

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• Failure to comply with the specific use of 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.
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