Stented artery with area of in-stent restenosis.

Balloon angioplasty catheter inside stented artery.

Radiation Source Train placed at treatment site for < 5 minutes.

Artery post balloon angioplasty and Vascular Brachytherapy treatment.

Intravascular radiation within a stent is intended to lessen the chance for renarrowing of a previously treated artery.

The Transfer Device hydraulically delivers the Radiation Source Train to the attached Delivery Catheter.
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 Rstenosis in native coronary arteries with discrete lesions (measurable with a 20 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 Rstenosis in native coronary arteries with discrete lesions (measurable with a 20 mm balloon for 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 may 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 vessel, use fluoroscopy under direct visualization. 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 of intended radiation treatment may cause unintentional radiation exposure to the patient or personnel.
• Upon removal of the radiation source train, ensure that the system is no longer radioactive after all treatments and instrument adjustments have been made.
• Should a change in the source train or instrument be required, it is important to ensure the integrity of the delivery system before beginning a new treatment.

Intravascular Radiation Procedure
• If the fluid in the capped Fluid Collection Bag after the procedure is found to be contaminated after scanning, then follow the Transfer Device manufacturer’s instructions for cleaning and disinfection.

Potential adverse Events
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.

Beta-Cath™ System Preparation
• Prior to any treatment, the equipment should be thoroughly examined to verify the proper function and integrity of the system.
• Use the Delivery Catheter and Procedure Accessory Pack before the expiration date noted on the package. Verify that the sterility of the devices has not been compromised by assuring the package integrity and ensuring that the package has not been damaged in transit.
• Do not re-sterilize or reuse these items.
• Do not sterilize 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, note the 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 if dropped. Do not use the Transfer Device if the controls and indicators are not functioning correctly or the LED light test is not observed. Do not begin a procedure if the Low Battery light is blinking. If the Low Battery light is 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 Tyvek Port Hole 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 the Source Train is placed in the Delivery Catheter.
• Use care when attaching components to the Transfer Device to ensure that the Sterile Bag does not get pinched in the process.

Intravascular Radiation Procedure
• Radiation Induced Malignancy • Aneurysm • Excessive Embolization • Artery Bypass Graft Surgery • Slow Flow-Phenomenon • AV Fistula • Pseudaneurysm • Left Ventricular Dysfunction • Systemic Atherolembolization • Endocarditis • Distal Embolizations • Vasospasm • Arterial Perforation • Retroperitoneal Hematoma
• Beta-Cath™ 3.5F System
• Beta-Cath™ 5F System

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