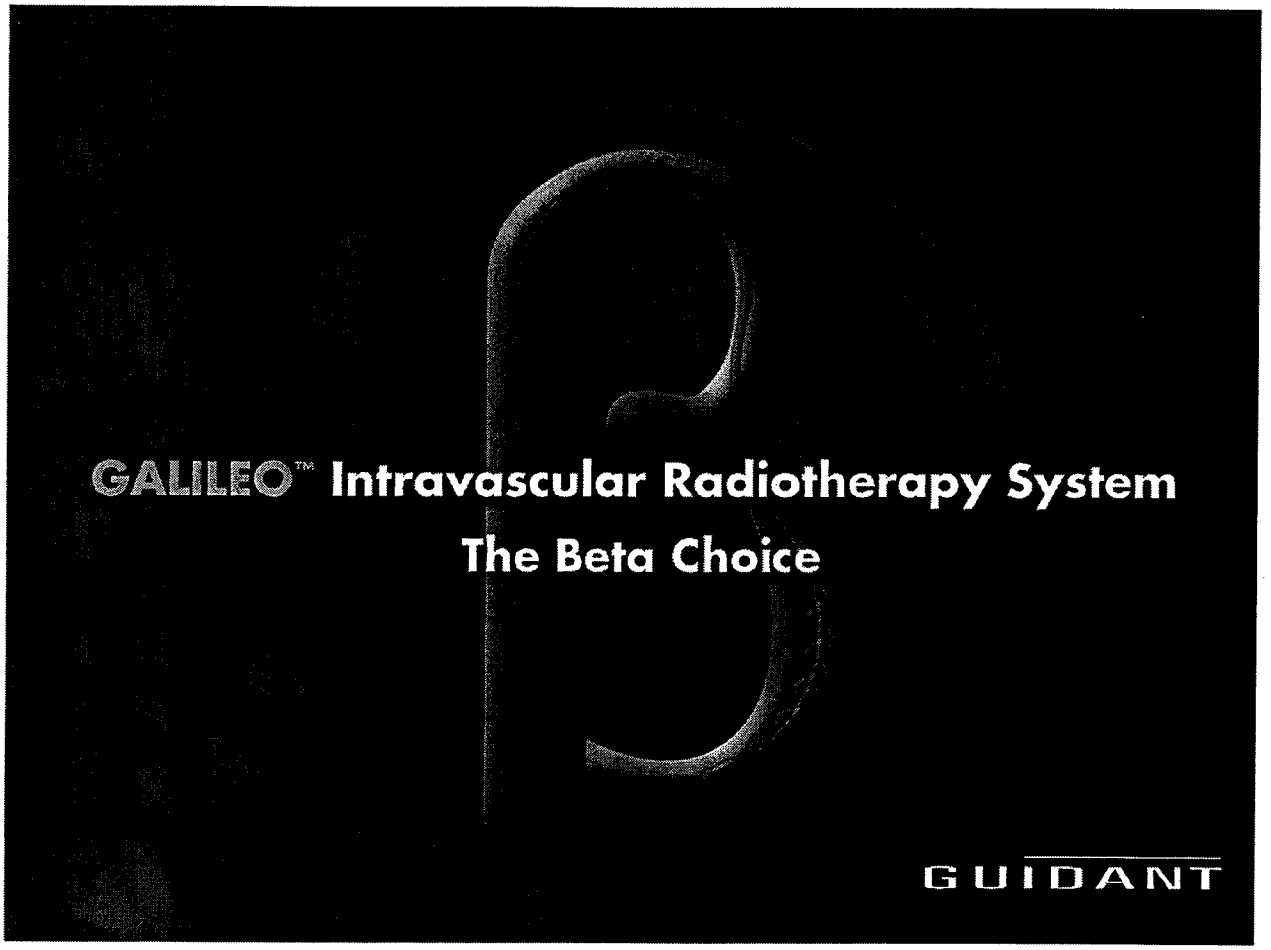
GALILEO™ Intravascular Radiotherapy System
The Beta Choice
GUIDANT

Why Intravascular Radiotherapy for Restenosis?

- Restenosis - significant clinical challenge
  - Average incidence 20-30%
    - Simple lesions <15%
    - Complex lesions >40%
- In-stent restenosis >50% incidence of restenosis
- No effective treatment for in-stent restenosis

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INHIBIT - Purpose

Assess the safety and effectiveness of intracoronary beta radiation using a Phosphorus-32 (^{32}P) source delivered into a centering balloon via an automatic afterloader (SDU) following successful coronary intervention in patients with in-stent restenosis

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INHIBIT - Study Design

- Prospective, multicenter, blinded, randomized trial
- Enrolled 332 patients with in-stent restenosis
  - 166 patients received Placebo
  - 166 patients received ^{32}P

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INHIBIT - Major Inclusion Criteria

Patients over 18 years with angina who had previously been stented

In-stent restenosis > 50% (by visual estimate)

Target lesion in native coronary vessel with reference diameter between 2.4 and 3.7 mm

Length of PTCA/stented lesion ≤ 47 mm

Multivessel coronary intervention with one vessel receiving randomized treatment

Single lesion, single vessel

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INHIBIT - Study Endpoints

Safety Endpoint

9 month MACE (death, MI, target lesion revascularization)

Efficacy Endpoint

9 month angiographic binary restenosis (greater than or equal to 50% diameter stenosis at follow-up angiography)

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INHIBIT - Clinical Trial Summary

Trial Initiated	August 14, 1998
Enrollment Completion	December 7, 1999
Site Participation Europe, Asia, Australia)	24 worldwide (U.S.,
Principle Investigator	Ron Waksman, MD
Results Presented	November 15, 2000

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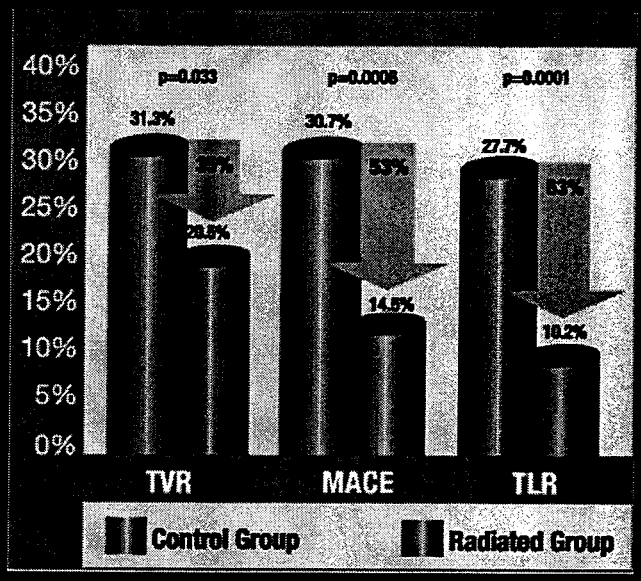
INHIBIT
Demonstrated Safety



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INHIBIT - Demonstrated Safety

	Single Position	Tandem Position
Binary Restenosis Rates Analysis Segment	49%	46%
MACE with TLR	48%	54%
MACE with TVR	20%	38%

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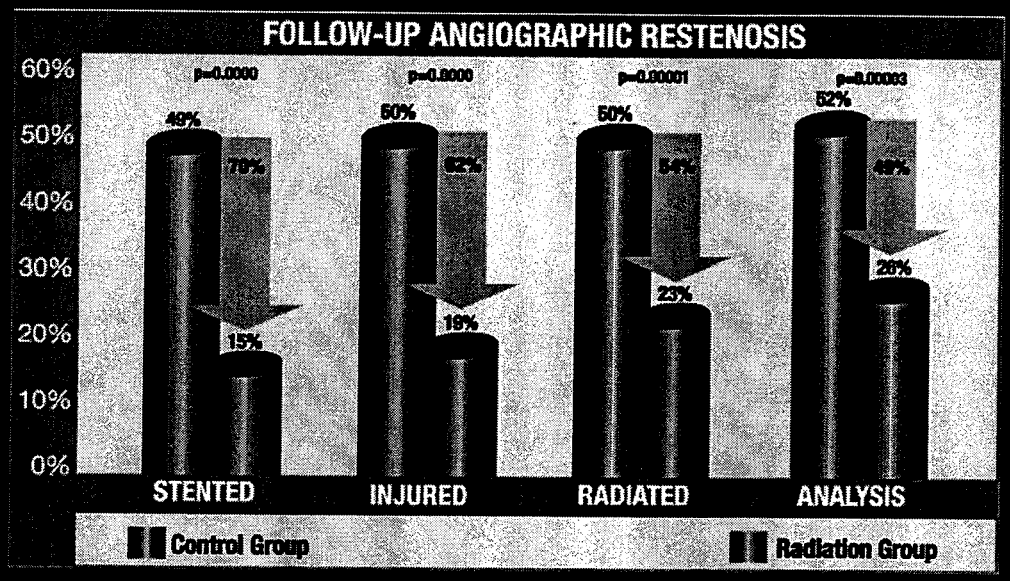
INHIBIT - Demonstrated Efficacy



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INHIBIT - Demonstrated Flexibility

	Single Position	Tandem Position
Dwell Time	4 min	8 min
Lesion Length	13.6mm	22.9mm
Injured Length	22.7mm	37.5mm
Radiated Length	27mm	54mm

Calculations represent averages

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INHIBIT - Conclusion

INHIBIT Trial results have supported the hypotheses for significant reduction in:

- **MACE at 290 days as defined by the composite of death, MI, and target lesion revascularization (TLR)**
- **Angiographic binary restenosis rate (>50% diameter stenosis) at follow-up angiography**

Tandem positioning to cover diffuse lesions >22 mm with ^{32}P was feasible, safe and effective.

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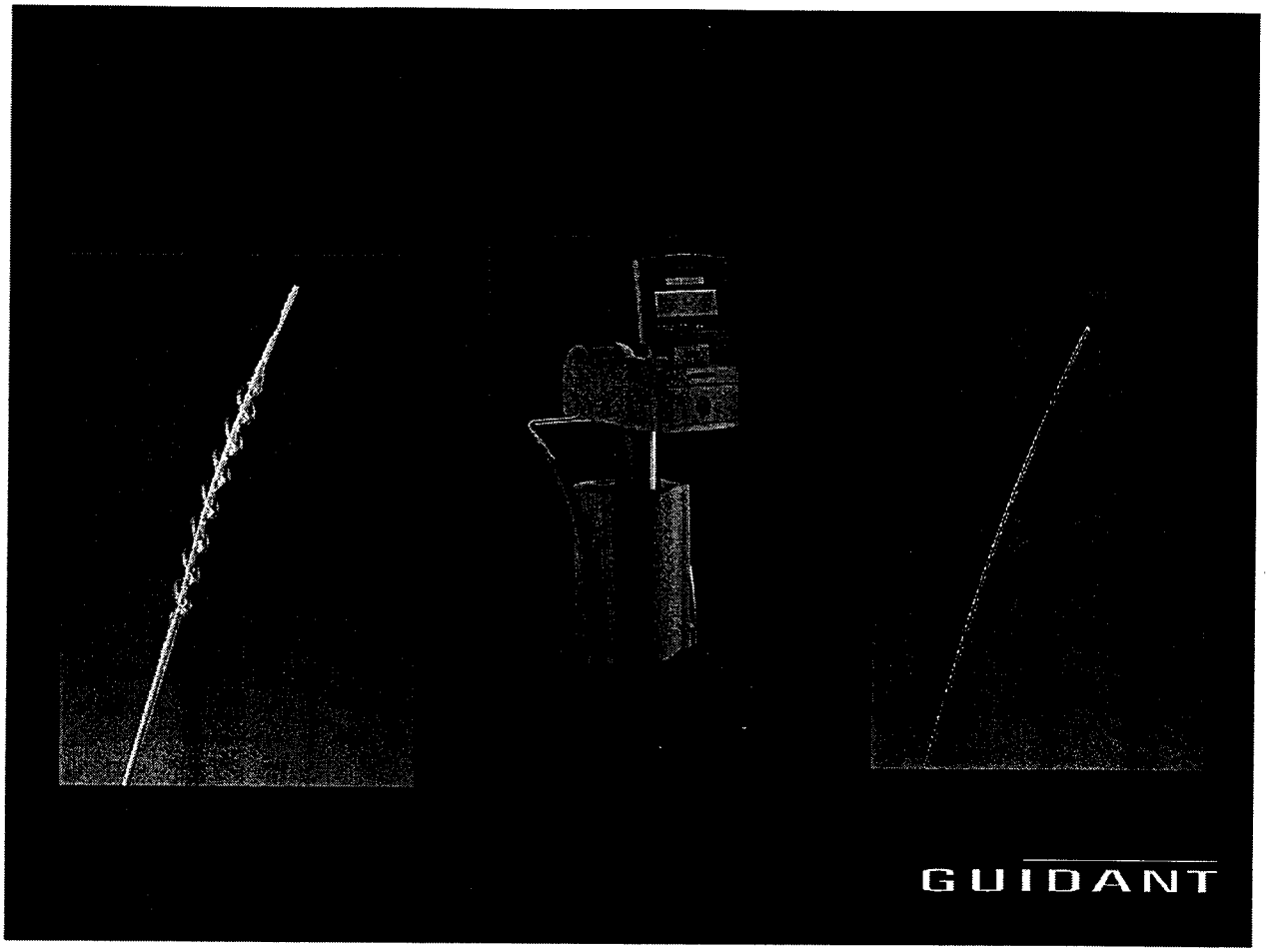
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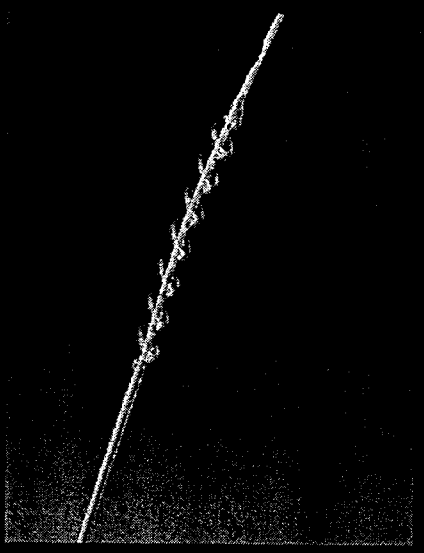
Centering Catheter Precision



- Facilitate centering and flow
- Stabilize position of Source Wire
- Protect Source Wire from blood contact
- Define treatment area using markers
- Short tip RX
- .014" guide wire use
- 7F guiding catheter use

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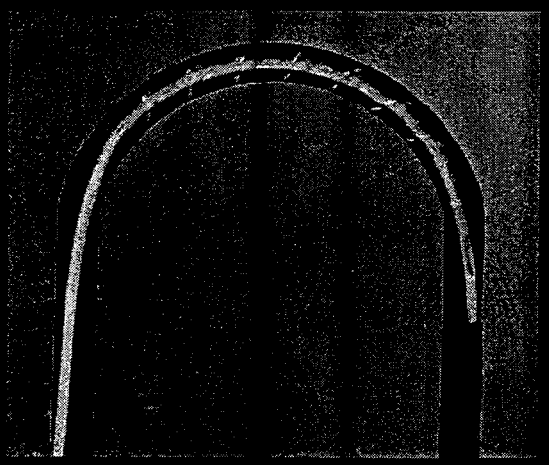
Centering Catheter Designed to Optimize Uniformity in Dose Delivery

Centered System



Centered System

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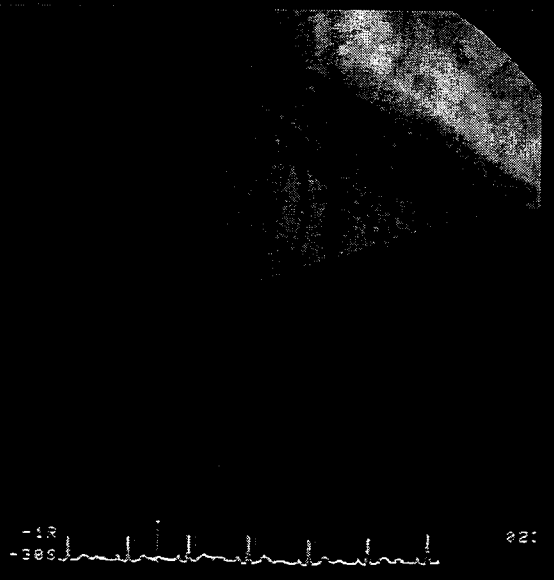
Centering Catheter - In Use



Unretouched image from PREVENT

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Source Wire Safety

Solid-form, beta isotope (Phosphorus-32) sealed within distal tip

.018 inch Nitinol hypotube

Travels through dedicated, dead-end catheter lumen

Re-usable

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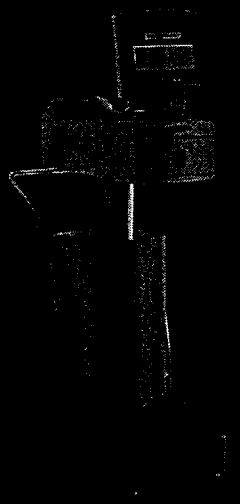
Automated Source Delivery Unit



- Touch-screen operation
- Software automates all dosimetry functions
- Automated Source Wire delivery and retraction
- Shields and stores the source wire
- Multiple safety features

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Rx ONLY

GALILEO™ Centering Catheter
GALILEO™ Source Delivery Unit

Indications

The GALILEO™ Intravascular Radiotherapy 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 ≤47 mm in a reference vessel diameter 2.4 mm to 3.7 mm.

Contraindications

- unprotected left main disease (>50% narrowing)
- patients in whom antiplatelet and/or anticoagulant therapy is contraindicated

Warnings

Physicians should pay special attention to these warnings about the GALILEO™ Intravascular Radiotherapy System:

- Every attempt should be made to avoid reStenting of the target lesion to minimize the risk of thrombosis.
- The GALILEO™ Intravascular Radiotherapy System, including the Centering Catheter, should be used by physicians trained in the practice of intravascular radiotherapy. A thorough understanding of the technical principles, clinical applications and risks associated with intravascular radiotherapy is necessary before performing the procedure.
- Misuse or malfunction of the GALILEO™ System can expose the patient, operator and others in the procedure room to unintended radiation exposure.
- Coronary intravascular radiotherapy should be performed only at hospitals where emergency coronary artery bypass surgery can be performed quickly in the event of a potentially injurious or life-threatening complication.
- To minimize the risk of thrombosis when new stents are implanted in conjunction with radiation therapy, a minimum of six months antiplatelet therapy is recommended. If a new stent is not implanted in conjunction with the radiation therapy, antiplatelet therapy should be administered at the physicians discretion. Refer to the *Centering Catheter Instructions for Use* for more information.
- Treatment should be interrupted and any extended wire must be retracted into the SDU if a patient requires defibrillation or cardioversion while either the InActive or Active wire is extended. The GALILEO™ System is not certified as defibrillation-proof.
- Coronary intravascular radiotherapy using the GALILEO™ System should be carried out only after achieving sufficiently successful intervention of stenotic atherosclerotic lesions in the native coronary arteries.
- Always perform patient, Centering Catheter, and SDU radiation surveys before and after every treatment. There is no guarantee that the SDU will detect a condition of the source not being in the storage safe under all fault conditions.
- Guide wire prolapse can occur as the Centering Catheter is withdrawn. Do not advance or retract the Centering Catheter over the floppy portion of the guide wire. Do not advance or retract the Centering Catheter unless the balloon is fully deflated and under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- The Centering Catheter is intended for single-procedure use only. Do not resterilize and/or reuse it, as this can compromise device performance and increase the risk of cross-contamination due to inappropriate reprocessing.
- The Centering Catheter should not be used for percutaneous transluminal coronary angioplasty (PTCA) and should not be used for vessel dilatation. The Centering Catheter is used solely for the centering of the radiation source.
- The balloon pressure of the Centering Catheter should not exceed the operating pressure of 4 atm. The operating pressure is based on results of *in vitro* testing. At least 90% of the balloons (with a 95% confidence) will hold pressure when inflated to the operating pressure (4 atm) for 15 minutes. Use of a pressure-monitoring device is recommended to prevent over-pressurization.
- Use the Centering Catheter prior to the "Use By" date specified on the package.

Precautions

The following precautions are important for the GALILEO™ Intravascular Radiotherapy System:

- Only Guidant-manufactured Cartridges, Source Wires, and Catheters should be used with the GALILEO™ Source Delivery Unit.
- The GALILEO™ System is designed to be used by a team of appropriately trained personnel. At a minimum, this team should include an interventional cardiologist, radiation oncologist and medical physicist.
- Prior to each use, ensure that all daily quality assurance checks have been performed.
- Before inserting the GALILEO™ Centering Catheter in the SDU, check the catheter shaft to ensure that there are no kinks or severe bends in order to avoid obstruction errors during treatment.
- In general, balloon diameter should be no more than 0.25 mm larger or smaller than the minimum lumen diameter (MLD) of the lumen in the area to be treated. Refer to the *Centering Catheter Instructions for Use* for specific sizing instructions.
- The total artery length that has undergone interventional treatment and injury (including post-stent dilatation) must not exceed 47 mm. Total injured arterial lengths exceeding 22 mm must be treated with tandem balloon positioning. Refer to the *Centering Catheter Instructions for Use*.
- During tandem balloon positioning procedures (that is, repositioning the balloon), ideal balloon positioning is achieved when there is no gap or overlap between the distal and proximal segments. At no time should an overlap exceeding 2 mm or a gap exceeding 1 mm be allowed. An overlap will increase the dose delivered to the overlap region, while a gap will decrease the dose delivered to the treated area. Refer to the *Centering Catheter Instructions for Use* for details.
- Do not use a Centering Catheter balloon size larger than the interventional device size used.
- Difficulty with advancement of the InActive or Active wires may be encountered if the catheter is used in patients with:
  - abnormal or severe vessel tortuosity
  - lesions located in extremely angulated vessel segments
- Saline should be used to inflate the balloon. Never use air or any other gaseous medium to inflate the balloon. Use of contrast medium to inflate the balloon will make it difficult to visualize Source Wire position and may attenuate radiation dose.
- Do not excessively tighten the hemostatic valve. This can prevent the proper advancement of the Source Wire.
- Do not hold the GALILEO™ Centering Catheter while the Source Wire is in transit.
- The SDU is non-sterile. When attaching the GALILEO™ Centering Catheter to the SDU, do not contaminate the sterile field or the sterile Centering Catheter. Avoid contact with the more distal portion of the catheter.
- The SDU will accept only the GALILEO™ Centering Catheter. Do not attempt to insert any other catheter.
- Prepare and select the GALILEO™ Centering Catheter as described in the *Centering Catheter Instructions for Use*.
- Prepare the GALILEO™ SDU as described in the GALILEO™ Source Delivery Unit Instructions for Use.

Special Considerations

The GALILEO™ Radiotherapy System has not been evaluated in the following patient or lesion subsets:

- patients with history of previous external radiotherapy to the heart or target vessel area
- coronary artery sites previously treated with radiotherapy
- bifurcation lesions
- saphenous vein grafts or internal mammary bypass grafts
- thrombotic lesions
- patients who experienced a myocardial infarction less than or equal to 72 hours prior to the procedure
- unprotected left main stenosis >50%
- aorto-ostial lesions
- patients with previously diagnosed autoimmune diseases such as rheumatoid arthritis, scleroderma, SLE
- fractionated dose administration other than interruption within index procedure
- patients presenting with multiple vessel lesions
- patients who have received a heart transplant
- patients unable to tolerate the recommended dwell time required by the system

Potential Adverse Events

The following adverse events were NOT observed during the clinical investigation, but are recognized as potential adverse events associated with interventional cardiology and vascular brachytherapy procedures. The list is not limited to the following:

- arteriovenous fistula
- coronary artery aneurysm
- coronary artery spasm
- coronary vessel dissection, perforation, rupture or injury
- delayed endothelialization
- drug reactions, allergic reaction to contrast media
- embolism
- endocarditis
- hemorrhage or hematoma
- hypo/hypertension
- infection
- loss of vaso-reactivity immediately following treatment
- short-term hemodynamic deterioration