

GALILEO™ Intravascular Radiotherapy System
The Beta Choice

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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 \leq 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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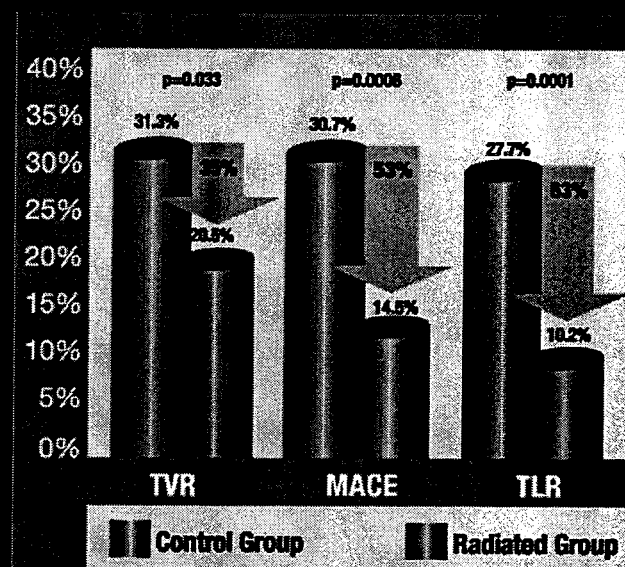
INHIBIT - Clinical Trial Summary

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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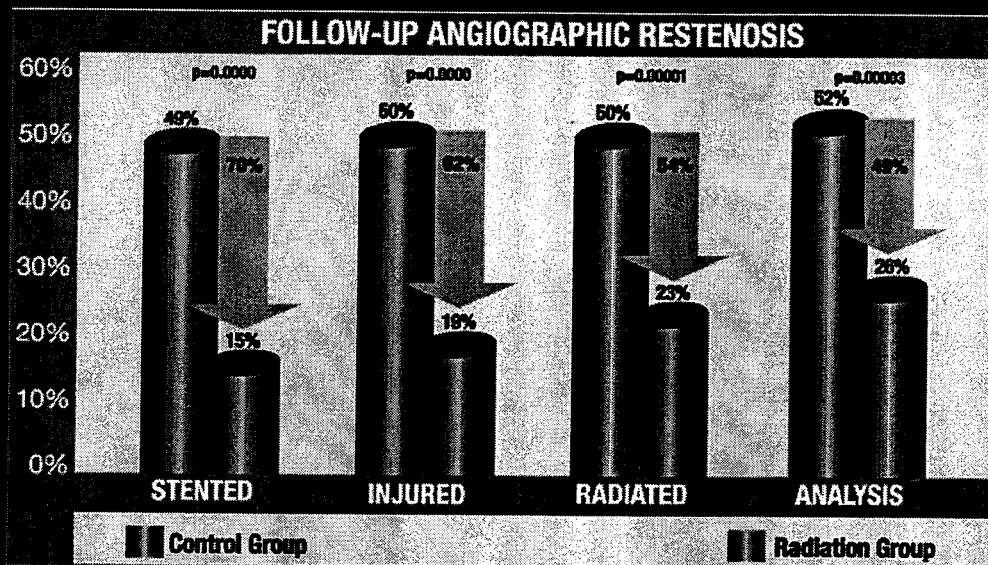
INHIBIT - Demonstrated Safety

Single Position Tandem Position

Binary Restenosis	49%	46%
Rates Analysis		
Segment		
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:

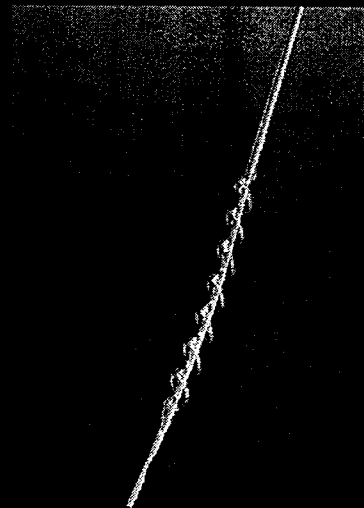
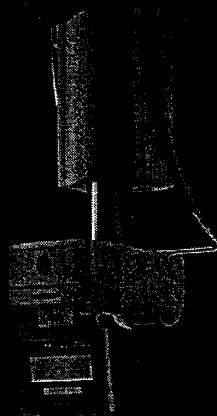
MACE at 290 days as defined by the composite of death, MI, and target lesion revascularization (TLR)

Angiographic binary restenosis rate (>50% diameter stenosis) at follow-up angiography

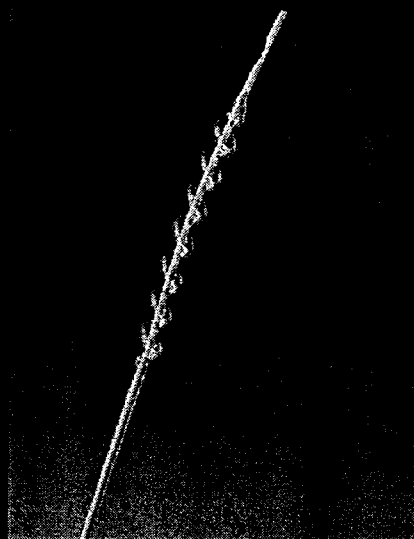
Tandem positioning to cover diffuse lesions >22 mm with ³²P was feasible, safe and effective.

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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

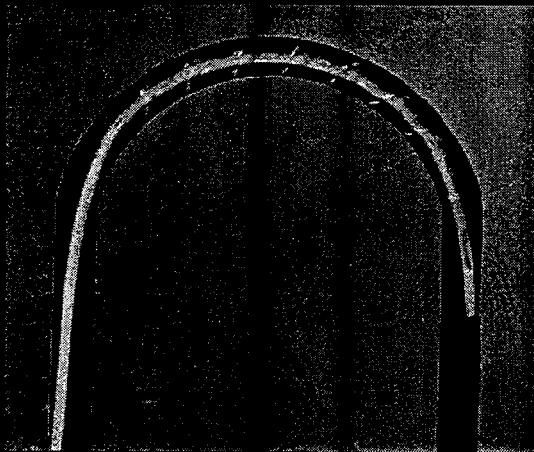
.014" guide wire use

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

-1R
-30S 22:

An ECG waveform is displayed on a black background. The waveform shows a regular rhythm with distinct P waves, QRS complexes, and T waves. The text "-1R" and "-30S" are positioned to the left of the waveform, and "22:" is to the right.

Unretouched image from PREVENT

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Source Wire Safety



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

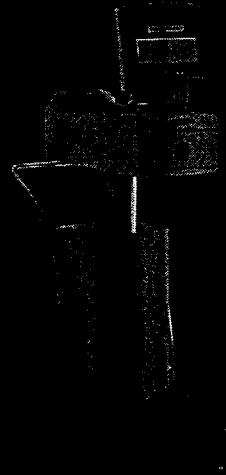
.018 inch Nitinol hypotube

**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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- Prepare and select the GAULEON[®] Centring Catheter as described in the Centring Catheter Instructions for Use.
- Prepare the GAULEON[®] SDU as described in the GAULEON[®] Source Delivery Unit Instructions for Use.

- patients with history of previous external radiotherapy to the heart or target

- coronary artery stents previously treated with radiotherapy

- **bulbar urethral lesions**
- **saphenous vein grafts or internal mammary bypass grafts**

- thoracic lesions
 - patients who experienced a myocardial infarction less than or equal to 72 hours prior to the procedure
 - unperforated left main stenosis >50%
 - acute-coronary lesions
 - patients with previously diagnosed valvular disease such as rheumatic mitral, aortic, or aortic regurgitation, Bicuspid Aortic Valve, etc.
 - facilitated drug administration other than intervention within intracoronary procedures
 - patients presenting with multiple vessel lesions
 - patients who have received a heart transplant
 - patients unable to tolerate the recommended dose per kilogram 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 the use of the investigational device in interventional catheterization and vascular hemodynamic procedures. The list is not limited to the following:
- endovascular fluids
 - coronary artery aneurysm
 - coronary artery spasm
 - coronary vessel dissection, perforation, rupture or injury
 - delayed angiographic visualization
 - drug reactions, allergic reaction to contrast media
 - embolism
 - endocarditis
 - hemorrhage or hematoma
 - hypohypertension
 - infection
 - loss of vaso-reactivity immediately following treatment
 - short-term hemodynamic decompensation

- Prepare and submit the GALELCO-Containing Calendar as described in the Containing Calendar instructions for Use.
 - Prepare the GALELCO-EDU as described in the GALELCO- Source Delivery Unit Instructions for Use.
- ### Special Considerations
- The GALELCO- Radiotherapy System has not been evaluated in the following patient or lesion sub-set:
- patients with history of previous adjuvant radiotherapy to the breast or target vessel area
 - coronary artery lines 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%
 - aortic-valve lesions
 - patients with previously depressed subintimate 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 radiotherapy 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
 - hemorrhages or hematomas
 - hypotension/hypoxemia
 - infection
 - loss of vessel-wall integrity immediately following treatment
 - short-term hemodynamic deterioration

- coronary artery aneurysm
- coronary artery spasm
- coronary artery thrombosis
- coronary vessel dissection, perforation, rupture or laceration
- delayed anastomosis
- drug reactions, allergic reaction to contrast media
- embolism
- endocarditis
- hemorrhage or hematomas
- hypotension
- infection
- loss of vessel-elasticity immediately following treatment
- short-term hemodynamic deterioration