SCIMED® RADIUS™ STENT with DELIVERY SYSTEM

CAUTION: ***Federal Law restricts this device to sale by or on the order of a physician.***

INSTRUCTIONS FOR USE

TABLE OF CONTENTS

SCIMED® RADIUS™ STENT with DELIVERY SYSTEM

1. DEVICE DESCRIPTION

The SCIMED RADIUS™ Coronary Stent with Delivery System (**Figure 1**) includes:

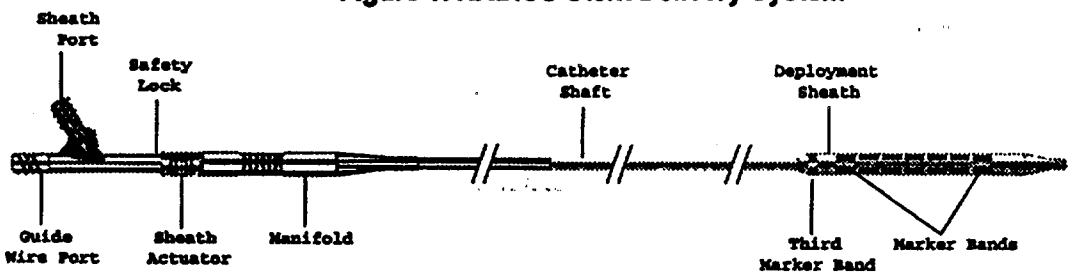
- a self-expanding nitinol multi-segmented stent premounted on an over-the-wire delivery catheter;
- a retractable deployment sheath that completely covers the stent on the delivery catheter;
- a safety lock located on the catheter manifold which is removed prior to stent deployment;
- a sheath actuator located on the catheter manifold which is retracted when stent deployment is desired;
- two radiopaque markers which aid in the accurate placement of the stent and a third radiopaque marker which allows monitoring of sheath retraction.

Table 1. Stent Specifications

STENT ORDER NUMBER	LABELED STENT DIAMETER (mm)	MAXIMUM STENT DIAMETER (mm)	STENT LENGTH AT LABELED DIAMETER (mm)	MINIMUM GUIDE CATHETER I.D. (inches)
RAD 14/3.0	3.0	3.75	14	.066
RAD 14/3.5	3.5	4.25	14	.066
RAD 14/4.0	4.0	4.75	14	.066
RAD 20/3.0	3.0	3.75	20	.066
RAD 20/3.5	3.5	4.25	20	.066
RAD 20/4.0	4.0	4.75	20	.066

The RADIUS over-the-wire Delivery System has a stent deployment sheath covering the stent which is retracted when stent deployment is desired. The stent is deployed by retracting the sliding sheath actuator located on the catheter manifold; the stent self-expands. A safety lock, located behind the sheath actuator, prevents accidental deployment. Two radiopaque markers are located under the sheath to aid in stent placement. A third marker, located under the proximal end of the sheath allows physicians to monitor sheath retraction.

Figure 1. RADIUS Stent Delivery System



2. INDICATIONS AND USAGE

The SCIMED® RADIUS™ Coronary Stent with Delivery System is indicated for use in patients with symptomatic ischemic heart disease due to discrete *de novo* native coronary artery lesions (length < 30mm) with a reference vessel diameter ranging from 2.75 to 4.25 mm and is intended to improve coronary luminal diameter (see Individualization of Treatment). Long-term outcome (beyond 6 months) for this permanent implant is unknown.

3. CONTRAINDICATIONS

The SCIMED RADIUS Stent is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulant therapy is contraindicated.
- Patients judged to have a lesion which prevents complete inflation of an angioplasty balloon.

4. WARNINGS and PRECAUTIONS

(see also Individualization of Treatment)

Warning

- Since the use of this device carries the associated risk of subacute thrombosis, vascular complications, and/or bleeding events, careful selection of patients is necessary.
- Persons allergic to nitinol may suffer an allergic reaction to this implant.
- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized SCIMED RADIUS Stents is unknown.
- When multiple stents are required, stent materials should be of similar composition.

4.1 Stent Handling - Precautions

- **For single use only. Do not resterilize or reuse. Note product "use before" date.**
- Do not remove the stent from the delivery system. The stent cannot be crimped on a balloon catheter for deployment or reloaded on the SCIMED® RADIUS™ Delivery System.
- Special care must be taken not to handle or in any way disrupt the stent on the delivery catheter.
- **Do not remove the yellow safety lock on the manifold until the stent has been properly positioned at the target lesion site.**
- **Do not use the stent system if the package has been exposed to high storage temperature.** The temperature indicator is a light gray or white dot inside a small red circle on the device packaging which turns black following exposure to a temperature above 55°C or 131°F.

4.2 Stent Placement - Precautions

- Do not use the RADIUS™ Stent in the treatment of restenotic lesions as the safety and effectiveness have not been established.
- **Do not oversize the stent as it may lead to vessel wall damage. Select the stent diameter according to Stent Sizing Guidelines (see section 9.1 Selection of Stent Size)**
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (i.e., CABG, further dilatation, placement of additional stents, etc).
- Use of a guide catheter with an inner diameter less than 0.066" may compromise arterial visualization and device performance.
- Do not use a guide wire having a diameter greater than 0.014".
- When the delivery catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Do not remove the safety lock or attempt to deploy the stent until the stent has been properly positioned for deployment and the hemostatic valve has been secured.
- If unusual resistance is felt when first attempting to retract the sheath actuator, the entire stent system should be removed.
- Do not attempt to reposition a partially deployed stent. Attempted repositioning of a partially deployed stent may result in severe vessel damage.
- Do not attempt to close the sheath over a partially deployed stent. This may damage the stent, push the stent distally, or result in vessel damage.
- Placing a stent across a side branch may compromise side branch patency.
- When treating multiple lesions in the same vessel, the distal lesion should be stented first, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent in the placement of the distal stent and reduces the risk of dislodging the proximal stent.

4.3 Post-Stent Placement - Precautions

- Great care must be exercised when crossing a newly deployed stent with a coronary guide wire or balloon catheter to avoid disrupting the stent geometry.
- Magnetic Resonance Imaging (MRI) scan on patients post-stent implantation may result in stent migration if the stent has not completely endothelialized. Animal studies of the RADIUS Stent have shown that endothelialization is complete within 28 days of implantation.

5.0 ADVERSE EVENTS

A non-randomized feasibility study was conducted to assess the RADIUS Stent with Delivery System in four sites in Europe. A multi-center, randomized Stent COmparative REStenosis (SCORES) trial was conducted to demonstrate equivalence of the RADIUS Stent to a commercially available (Palmaz-Schatz Balloon-Expandable Stent) coronary stent. These studies involved a total of 1372 patients, 821 patients treated with the RADIUS Stent, and 551 treated with the PALMAZ-SCHATZ™ Stent (study control).

Table 2: Summary of Clinical Trial Patient Enrollment
Patients Included in the Feasibility and SCORES Study (N=1372

	RADIUS	Palmaz-Schatz®	Total
Feasibility Study	103	-	103
SCORES Roll-in Phase	173	-	173
SCORES Randomized Trial	545	551	1096
Total	821	551	1372
De novo subgroup	497	491	988

5.1 Observed Adverse Events

The reporting of adverse event rates is based on the 1096 patients enrolled in the SCORES randomized clinical trial.

Seven patients (7/545 or 1.3%) who received the SCIMED RADIUS™ Stent died during the clinical study. Two patients died during hospitalization and 5 died after hospital discharge and before 6 months. Three of the roll-in patients (3/173 or 1.7%) died during the clinical study. One patient died during hospitalization, and 2 died after hospital discharge and before 6 months.

The incidence of thrombosis in patients stented with the SCIMED RADIUS™ Stent during the SCORES trial was 0.2%, (1/545). The incidence of vascular complications after stent placement in the randomized comparative clinical trial with the RADIUS was 1.3%, (7/545). The rate of bleeding complications requiring transfusion was 0.2% (1/545).

The most severe MACE experienced by patients is recorded in Table 4 by time period. Some patients experienced both In-Hospital and Out-of-Hospital MACE. Patients are reported only once in the combined section of the table. The In-Hospital and Out-of-Hospital sections of the table are non-additive.

5.2 Stent Delivery Failure

Delivery failure of the RADIUS Stent occurred in 2.2%, (12/545) of the patients. Operator inability to deliver the first stent was 0.4%, (2/545), operator crossover from RADIUS to another device was 1.1%, (6/545), failure to implant the stent was 0.4% (2/545), and inaccurate stent deployment was 0.4% (2/545).

Table 3: Observed Adverse Events at 6 Months
Total Patients (N = 1096)

Complication		RADIUS™	PALMAZ-SCHATZ®	Difference [CI]
Any Complication x/n (%)		128/545 (23.5)	125/551 (22.7)	0.8% [-4.2%, 5.8%]
Death				
Combined In and Out of Hospital	x/n (%)	7/545 (1.3)	5/551 (0.9)	0.4% [-0.9%, 1.6%]
In Hospital		2/545 (0.4)	2/551 (0.4)	0.0% [-0.7%, 0.7%]
Out-of-Hospital		5/545 (0.9)	3/551 (0.5)	0.4% [-0.6%, 1.4%]
Q-wave MI				
Combined In and Out of Hospital	x/n (%)	4/545 (0.7)	5/551 (0.9)	-0.2% [-1.2%, 0.9%]
In Hospital		1/545 (0.2)	1/551 (0.2)	0.0% [-0.5%, 0.5%]
Out-of-Hospital		3/545 (0.6)	4/551 (0.7)	-0.2% [-1.1%, 0.8%]
Non-Q-wave MI				
Combined In and Out of Hospital	x/n (%)	7/545 (1.3)	10/551 (1.8)	-0.5 [-2.0%, 0.9%]
In Hospital		6/545 (1.1)	4/551 (0.7)	0.4% [-0.8%, 1.5%]
Out-of-Hospital		1/545 (0.2)	6/551 (1.1)	-0.9% [-1.8%, 0.0%]
Emergent CABG				
Combined In and Out of Hospital	x/n (%)	9/545 (1.7)	3/551 (0.5)	1.1% [-0.1%, 2.3%]
In Hospital		4/545 (0.7)	2/551 (0.4)	0.4% [-0.5%, 1.2%]
Out-of-Hospital		5/545 (0.9)	1/551 (0.2)	0.7% [-0.1%, 1.6%]
Non-Emergent CABG				
Combined In and Out of Hospital	x/n (%)	16/545 (2.9)	20/551 (3.6)	-0.7% [-2.8%, 1.4%]
In Hospital		0/545 (0.0)	1/551 (0.2)	-0.2% [-0.5%, 0.2%]
Out-of-Hospital		16/545 (2.9)	19/551 (3.5)	-0.5% [-2.6%, 1.6%]
Repeat Intervention				
Combined In and Out of Hospital	x/n (%)	50/545 (9.2)	54/551 (9.8)	-0.6% [-4.1%, 2.9%]
In Hospital		1/545 (0.2)	2/551 (0.4)	-0.2% [-0.8%, 0.4%]
Out-of-Hospital		49/545 (9.0)	52/551 (9.4)	-0.4% [-3.8%, 3.0%]
Stent Thrombosis	x/n (%)	1/545 (0.2)	2/551 (0.4)	-0.2% [-0.8%, 0.4%]
Bleeding Complications		80/545 (14.7)	75/551 (13.6)	1.1% [-3.0%, 5.2%]
Vascular Complications		7/545 (1.3)	6/551 (1.1)	0.2% [-1.1%, 1.5%]
Stroke/Cerebral Vascular Accident		5/545 (0.9)	1/551 (0.2)	0.7% [-0.2%, 1.6%]
Stent Delivery Failure	x/n (%)	12/545 (2.2)	21/551 (3.8)	-1.6% [-3.6%, 0.4%]

Early (in-hospital) refers to events during the hospitalization for the initial stent placement.
ANY Adverse event includes death, Q wave MI, non-Q wave MI, emergent CABG, target lesion revascularization, stent thrombosis, bleeding complications, vascular complications, and CVA
Bleeding Complications include hematoma, hemorrhage, significant access site bleeding, groin bleed

5.3 Potential Adverse Events

Adverse events (in alphabetical order) which may be associated with the use of a coronary stent in native coronary arteries (including those listed in Tables 3 and 4):

- Acute myocardial infarction
- Arrythmias, including VF and VT
- Death
- Dissection
- Drug reactions to antiplatelet agents/contrast medium
- Distal emboli, (air, tissue, or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and pain at insertion site
- Myocardial ischemia
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm

- Stent embolization
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident
- Total occlusion of coronary artery

6.0 CLINICAL STUDIES

As summarized in Table 2, a total of 1372 patients participated in two clinical studies, a non-randomized feasibility study conducted in Europe and a randomized clinical trial was conducted at 50 US centers. The Stent COmparative REStenosis (SCORES) randomized clinical trial was designed to demonstrate equivalence of the RADIUS Stent to a commercially available (Palmaz-Schatz Balloon-Expandable Stent) coronary stent. The SCORES study included 173 patients treated before the randomization began (roll-in phase) and 1096 randomized patients. Of these, 1096 patients with de novo or restenotic native coronary artery lesions, most (988) were treated for de novo lesions

The primary endpoint of six month clinical target vessel failure was defined as the composite of death, myocardial infarction (Q-wave and non-Q-wave), coronary artery bypass surgery (CABG), and percutaneous transluminal coronary angioplasty (PTCA), attributed to the target vessel. All major endpoints were adjudicated by an independent clinical events committee blinded to treatment assignment. The randomized trial was preceded by a non-randomized roll-in phase consisting of 173 patients. Note, one patient signed consent form for the SCORES trial, but withdrew prior to randomization and treatment. This patient is not included in Table 2.

Eligible patients, with angina or positive functional study, were identified for elective stenting of a *de novo* or restenotic native coronary artery lesion visually estimated to be between 2.75 mm and 4.25 mm in diameter and <30 mm in length.

The anticoagulation regimen administered was aspirin 325 mg/day for at least one year and Ticlopidine™ 250 mg twice daily for at least 30 days. Follow-up intervals were 2, 4 weeks and 6, 9 months. The study randomization was successful as both treatment groups were demographically equivalent. All randomized patients were included in the intent-to-treat efficacy analysis.

Of the 545 patients receiving the RADIUS™ stent in the SCORES trail, 497 patients were treated for *de novo* lesions and 48 patients for restenotic lesions. The target vessel failure-free rate at 6 months was 88.6% for patients with *de novo* lesions and 64.2% for patients with restenotic lesions with an associated difference of 24.4% and 95% confidence interval of [9.0%, 39.8%]. Likewise, the Out-of-hospital MACE rate was 10.5% for patients with *de novo* lesions and 35.4% for patients with restenotic lesions with a difference of -24% [-38.7%, -11.2%].

Table 4 shows the results for the 988 patients treated for *de novo* lesions.

Table 4: Principal Effectiveness and Safety Results for the SCORES Trial
Patients with *de novo* Lesions (N=988)

EFFECTIVENESS MEASURES			
	RADIUS n=497	PS n=491	Difference [CI]
Technical Success by QCA x/n (%)	485/494 (98.2)	450/474 (94.9)	3.2%[0.9%, 5.5%]*
Procedure Success by QCA x/n (%)	478/494 (96.8)	442/476 (92.9)	3.9%[1.1%, 6.7%]**
In-Stent % Diameter Stenosis Post-procedure	12.0±9.7 493 (-29.1, 41.3)	12.1±9.4 457 (-21.5, 40.0)	-0.1%[-1.1%, 0.9%]
In-Stent % Diameter Stenosis at 6 Months Post-procedure	36.8±19.9 112 (-18.1, 77.9)	37.0±18.3 111 (2.0, 100.0)	-0.2%[-4.4%, 4.0%]
In-Stent Restenosis at 6 Months x/n (%)	28/112 (25.0)	21/111 (18.9)	6.1%[-4.8%, 16.9%]
TLR-free at 6 Months	93.3%[91.5%, 95.1%]	92.4%[90.5%, 94.4%]	0.9%[-2.6%, 4.4%]
TVR-free at 6 Months	90.6%[88.5%, 92.7%]	90.0%[87.8%, 92.3%]	0.6%[-3.4%, 4.6%]
TVF-free at 6 Months[1]	88.6%[86.4%, 90.9%]	87.4%[85.0%, 89.8%]	1.2%[-3.1%, 5.5%]
SAFETY MEASURES			
	RADIUS n=497	PS n=491	Difference [CI]
MACE — In Hospital x/n (%)	12/497 (2.4)	12/491 (2.4)	0.0%[-1.9%, 1.9%]
MACE — Out of Hospital x/n (%)	52/497 (10.5)	59/491 (12.0)	-1.6%[-5.5%, 2.4%]
MACE rate at 6 months x/n (%)	63/497 (12.7)	71/491 (14.5)	-1.8%[-6.1%, 2.5%]
Stent Thrombosis x/n (%)	1/497 (0.2)	2/491 (0.4)	-0.2%[-0.9%, 0.5%]
Vascular Complications[2] x/n (%)	8/497 (1.6)	4/491 (0.8)	0.8% [-0.5%, 2.2%]
Bleeding Complications[3] x/n (%)	79/497 (15.9)	70/491 (14.3)	1.6%[-2.8%, 6.1%]
Stroke/CVA x/n (%)	4/497 (0.8)	1/491 (0.2)	0.6%[-0.3%, 1.5%]

* *Difference statistically significant*

Technical success: Attainment of the final result of <50% residual stenosis of the target vessel using the assigned treatment device alone (i.e. without the use of other types of stents or new balloon devices).

Procedure success: Achievement of the final diameter stenosis of <50% of the target vessel using the assigned treatment device and any adjunctive device without occurrence of a MACE during the hospital stay.

QCA: Quantitative Coronary Angiography

% Diameter Stenosis (DS): Diameter Stenosis by QCA

Instent Restenosis: >50% DS

Target Lesion Revascularization (TLR) Free: No repeat PTCA or CABG performed on the coronary lesion originally treated in the trial. (K-M = actuarial freedom from TLR by Kaplan-Meier survival analysis).

Target Vessel Revascularization (TVR) Free: No Repeat PTCA or CABG performed on the coronary vessel originally treated in the trial. (K-M = actuarial freedom from TVR by Kaplan-Meier survival analysis).

Target Vessel Failure (TVF) Free: No death, Q-wave MI or non-Q-wave, CABG to the target vessel, and/or repeat intervention to the target vessel. (K-M = actuarial freedom from TVF by Kaplan Meier survival analysis).

Repeat Intervention: The return of a patient to the catheterization laboratory for re-insertion of a guiding catheter followed by a new angioplasty at the same site.

MACE: Major Adverse Cardiac Event (includes death, MI, emergent CABG and target lesion revascularization).

In-hospital clinical event: Any MACE occuring prior to hospital discharge, as determined by the Independent Clinical Events Committee.

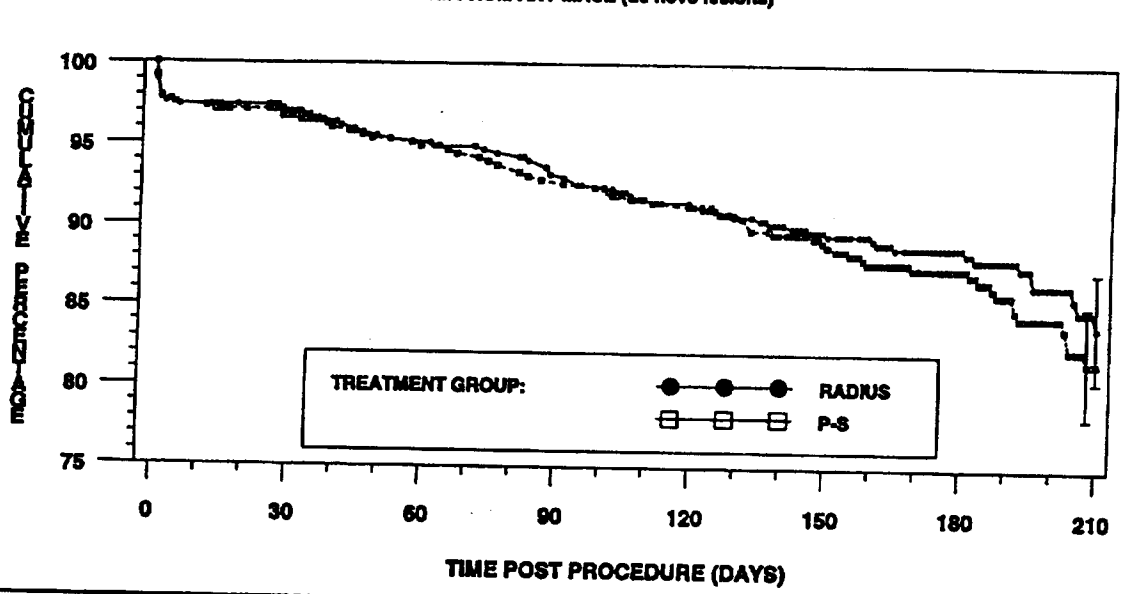
Out-of-hospital clinical event: Any MACE occurring from hospital discharge up to six months of clinical follow-up, as determined by the Independent Clinical Events committee.

Stent Thrombosis: Any cardiac death, subacute closure requiring revascularization of the target site or total closure indicated by QCA within 30 days of the index intervention.

Vascular Complications: Any hematoma > 5 cm, arteriovenous fistula, pseudoaneurysm, retroperitoneal bleed, peripheral nerve disorder, and surgical repair.

Bleeding Complication: Hematoma, Hemorrhage, Significant access site bleeding, and Groin bleed.

Figure 2. Freedom From Any MACE: (Target Vessel Failure: TVF)
Death, MI (Q-Wave and Non Q-Wave), CABG, Repeat Intervention
Event-Free Survival to 6 Months ± 1.5 SEM, Patients with *de novo* Lesions (N=988)



	Time After Procedure (days)									
	0	7	14	30	60	90	120	150	180	210
	RADIUS (n=497)									
Number at Risk	497	490	482	479	463	448	435	422	380	257
Number of Events	5	13	13	15	23	33	41	50	53	61
% Survival	99.0	97.4	97.4	97.0	95.3	93.1	91.4	89.4	88.6	83.8
% SEM	0.5	0.7	0.7	0.8	1.0	1.2	1.3	1.4	1.5	2.2
	Palmaz-Schatz (n=491)									
Number at Risk	491	474	466	462	436	414	403	387	353	238
Number of Events	4	12	14	16	24	33	40	50	55	66
% Survival	99.2	97.5	97.5	96.7	94.9	92.8	91.2	88.7	87.4	81.6
% SEM	0.4	0.7	0.8	0.8	1.0	1.2	1.3	1.5	1.6	2.3

Difference not statistically significant by product-limit estimates (Kaplan-Meier) Log Rank or Wilcoxon Chi-Square

7. PATIENT SELECTION AND TREATMENT

7.1 Individualization of Treatment

The risks and benefits of using the SCIMED® RADIUS™ Stent should be carefully considered for each patient before use. Patient selection factors to be assessed should include the risk of prolonged antiplatelet therapy. Stenting is generally avoided in those patients at heightened risk of bleeding (e.g., patients with recently active gastritis or peptic ulcer disease).

Premorbid conditions that increase the risk of a poor initial result or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure, and severe obesity) should be reviewed. The relationship of baseline and procedural variables to TVF was examined. The statistically significant predictors of TVF were thrombus prior to

the procedure and longer lesions. Predictors of a lower probability of TVF were male patients, lesions of the RCA, and larger acute gain.

7.2 Use In Special Populations

The safety and effectiveness of the RADIUS™ Stent have not been established in:

- Patients with native coronary artery **reference vessel diameters of less than 2.75 mm or greater than 4.25mm.**
- Patients **with unresolved vessel thrombus at the lesion site.**
- Patients with lesions located in the left main coronary artery, ostial lesions, or lesions located at a bifurcation.
- Patients with diffuse disease or **poor outflow distal** to the identified lesion.
- Patients with **a recent acute myocardial infarction** where there is evidence of thrombus or poor flow.
- Patients with **more than two overlapping stents** due to risk of thrombosis and restenosis.
- Patients for longer than 6 months.

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser angioplasty catheters to treat in-stent stenosis has not been established.

8. HOW SUPPLIED

CONTENTS

One (1) SCIMED RADIUS Stent System

One (1) Directions for Use Manual

One (1) patient tracking and information packet

One (1) 5 cc syringe

HANDLING

- STERILE. This device is sterilized with ethlyene oxide gas. Non-pyrogenic. If the integrity of the packaging has been compromised, do not use or attempt to resterilize the RADIUS Stent and contact your local SCIMED Sales Representative.
- Do not use the product after its expiration date.

STORAGE

- Do not use the stent system if the package has been exposed to high storage temperature. The temperature indicator is a light gray or white dot inside a small red circle on the device packaging which turns black following exposure to a temperature above 55°C or 131°F.

9. OPERATOR'S INSTRUCTIONS

9.1 Selection of Stent Size

Careful stent sizing is important to successful stenting. In general, the **stent size should be chosen to match the normal (reference) vessel diameter adjacent to the lesion.** The RADIUS Stent is capable of expansion to a maximum stent diameter 0.75 mm greater than the labeled diameter. Stent sizing guidelines for each stent labeled diameter and corresponding maximum stent diameter are given in Table 5.

NOTE: If the reference vessel diameter is the maximum of the recommended range, the next larger size stent should be used.

Table 5: Stent Sizing Guidelines

Labeled Stent Diameter (mm)	Recommended Vessel Diameter (mm)		Maximum Stent Diameter* (mm)
	Minimum	Maximum	
3.0	2.75	3.25	3.75
3.5	3.25	3.75	4.25
4.0	3.75	4.25	4.75

**Stent will not expand beyond this diameter.*

CAUTION: **Do not oversize** The effect of oversizing of the stent is unknown. Select the stent diameter according to Table 5: Stent Sizing Guidelines..

9.2 Inspection Prior To Use

Step	Action
1	Examine the temperature indicator located on the package and verify that the stent system has not been exposed to an excessive storage temperature. The temperature indicator is a dot inside a small red circle on the device packaging. The dot is normally light gray or white when stored at proper temperatures. It will turn black when exposed to excessive temperatures.
2	Carefully remove the system from the package and inspect for bends, kinks, and other damage. Do not use if any defects are noted.

9.3 Materials Required

Quantity	Material
	Appropriate guiding catheter(s) (0.66" minimum ID)
1000 U/500 cc	Heparinized Normal Saline (HepNS)
1	0.014 inch guide wire
1	Rotating hemostatic valve
	60% contrast diluted 1:1 with normal saline
1	Torque device (wire)

9.4 Preparation

CAUTION: **Leave the yellow safety lock in place during catheter preparation**

Step	Action
1	Flush guide wire port on manifold with HepNS until fluid exits from distal end of lumen.
2	With the distal portion of the manifold pointing up, flush the sheath port on the manifold with HepNS until air has been purged from the system.

9.5 Delivery Procedure

CAUTION: **Leave the yellow safety lock in place while advancing the delivery system to the target lesion site.**

Step	Action
1	Prepare the vascular access site according to standard practice.

2	Predilate the lesion with a PTCA catheter.
3	Before inserting the delivery system into the guiding catheter, be sure that a hemostatic valve is on the guiding catheter.
4	Wipe the exposed guide wire with HepNS to remove residual blood or contrast.
5	Backload delivery system onto proximal portion of guide wire while maintaining guide wire position across target lesion.
6	Loosen the hemostatic valve and advance the delivery system over the guide wire until the stent is slightly distal (1-2 mm) to the target lesion site (using the two distal radiopaque markers to indicate stent position). Then pull back on the delivery system until the stent is directly aligned with the target lesion site. This will remove any slack in the delivery system just prior to deployment.
7	Tighten rotating hemostatic valve. Stent is now ready to be deployed.

9.6 Deployment Procedure

Step	Action
1	Remove the yellow safety lock from the catheter manifold by pulling the tab straight out from the actuator rail slot. Do not twist or bend the tab.
2	Slowly retract the sheath actuator 2-3mm. If any distal movement of the stent is observed (using the two distal radiopaque markers on the catheter as an indication of stent positioning), pull back the entire delivery system to realign the stent with the target lesion site.
3	Continue to slowly retract the sheath actuator until it has traveled the full length of the manifold rail. While retracting the actuator, the proximal radiopaque marker (third marker from the distal end) will be moving in a one to one relationship with the deployment sheath.
4	Once the stent is deployed, loosen the hemostatic valve and slowly withdraw the delivery catheter while maintaining guide wire position. Observe the withdrawal of the delivery catheter under fluoroscopy to ensure that the tip of the catheter does not catch on the edge of the stent. If resistance is encountered, carefully move the delivery system distally, rotate it, and gently withdraw. Caution: Do not try to close the sheath by readvancing the sheath actuator. Remove the system with the actuator in the retracted position.
5	Confirm stent position and deployment using standard angiographic techniques. For optimal results, the entire stenosed segment should be covered by the stent, the stent should be in full-contact with the vessel wall, and the final stent diameter should match the size of the reference vessel diameter. If necessary, subsequent balloon dilatation may be performed to optimize stent deployment. Caution: Unlike balloon expandable stents, the RADIUS™ stent material does not recoil. Therefore, any oversizing of the post deployment balloon may result in an oversizing of the stent to the reference vessel diameter.

10 Patient Information

In addition to this Instructions for Use booklet, the SCIMED® RADIUS™ Coronary Stent with Delivery System is packaged with additional patient specific information which includes:

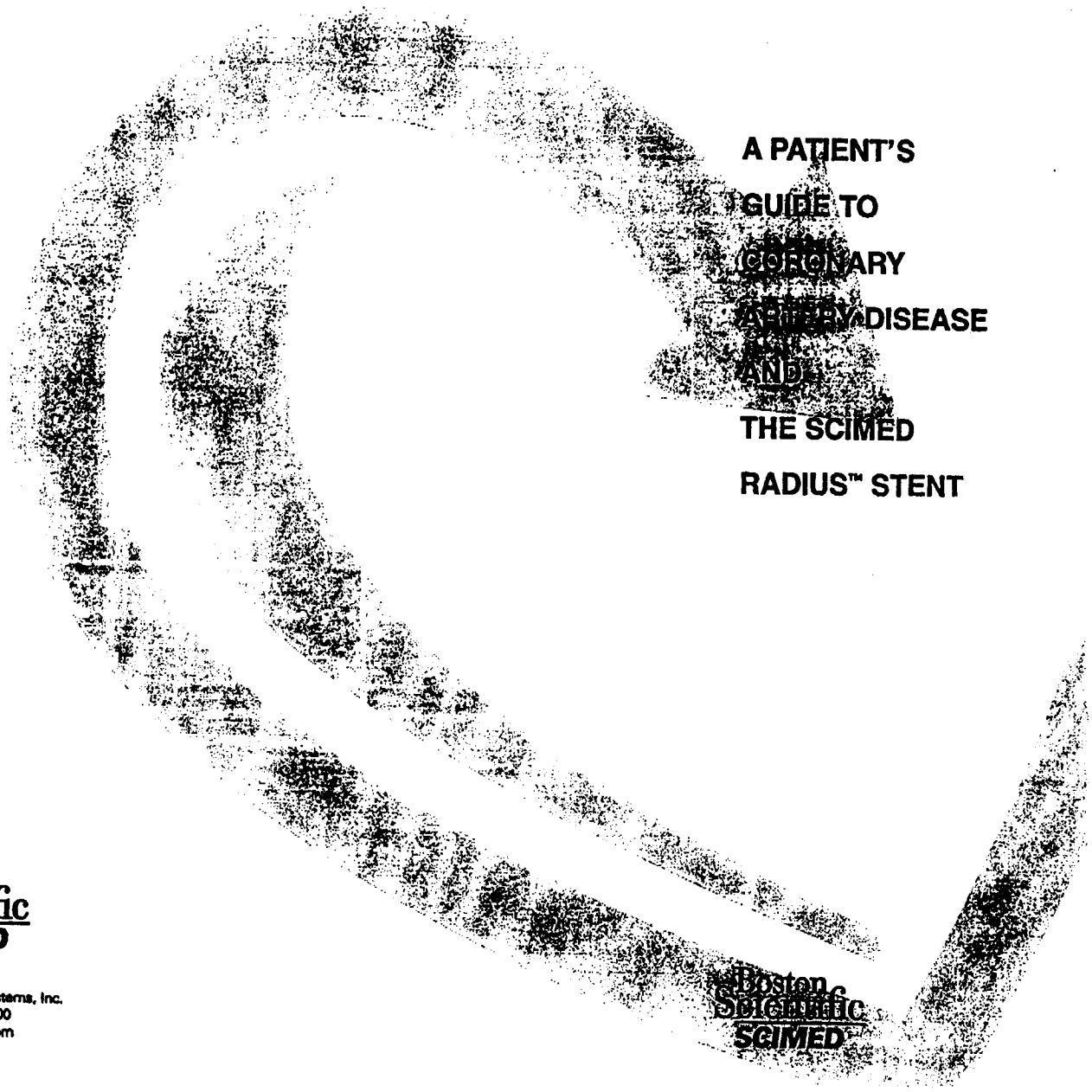
1. A patient Teaching Guide which includes information on Coronary Artery Disease, the implant procedure and the SCIMED RADIUS Stent.
2. A device tracking form which will be completed by the Hospital staff and forwarded to SCIMED. This information will be used to track all patients who receive a SCIMED RADIUS Stent, as required by Federal regulation.
3. A patient implant card that lists patient information. All patients are expected to keep this card in their possession at all times for procedure/stent identification.

Boston Scientific
SCIMED

SCIMED Life Systems, Inc.
6655 Wedgwood Road
Maple Grove, MN
55311-3646, U.S.A.
Telephone: 612-494-1700
Toll Free: 800-832-PTCA (7822)

Distributed in Europe by:
Boston Scientific International
91, Boulevard National
92257 La Garenne Colombes Cedex
France

19077-01
JUN 98
AWREV AB



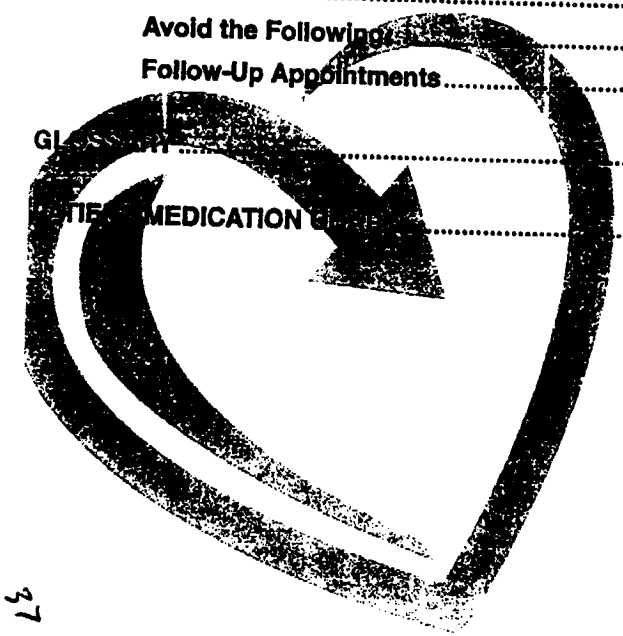
A PATIENT'S GUIDE TO CORONARY ARTERY DISEASE AND THE SCIMED RADIUS™ STENT

Boston Scientific SCIMED

Scimed Life Systems, Inc.
Tel 612.494.1700
www.scimed.com

Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.

TABLE OF CONTENTS



ABOUT THIS BOOKLET

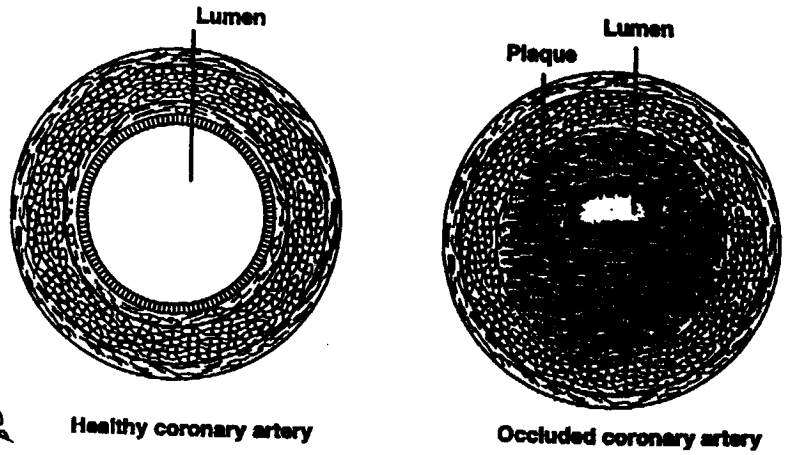
Your doctor has prescribed a Scimed RADIUS™ Stent to help manage your coronary artery disease (CAD). The RADIUS Stent will be implanted into your coronary artery following an angioplasty procedure. This stent is a small metallic implant that will act as miniature scaffolding to help your artery maintain its shape, strength and integrity. More and more doctors and their patients with CAD are relying on implantable coronary stents to hold the artery open to improve blood flow.

The information in this booklet will help to prepare you for your hospital stay, the implant procedure and your recovery. It describes the RADIUS Stent, how the RADIUS Stent is implanted and what you can do to speed your recovery. If you have questions about your stent or the procedure after you read this booklet, be sure to ask your doctor.

WHAT IS CORONARY ARTERY DISEASE (CAD)?

Coronary Artery Disease (CAD) affects the coronary arteries that surround the heart. These coronary arteries supply blood with oxygen to the heart muscle to make it function properly. The likelihood of having CAD is greater if you are male, are overweight, smoke cigarettes or have a close relative with CAD. Other risk factors include high blood pressure, the presence of diabetes or high blood cholesterol levels.

CAD occurs when the inner walls of the coronary arteries thicken due to a build-up of cholesterol and other fats, calcium and other elements carried in the blood. This build-up is called *plaque*. As the plaque develops, the artery narrows. Blood flow through the *lumen*, the center of the artery, is restricted so less oxygen and other nutrients reach the heart muscle. This condition, known as *atherosclerosis*, may lead to chest pain, (*angina pectoris)* or a heart attack (*myocardial infarction)*. Symptoms of angina include pressure, tightness, or pain in the chest, arm, back, neck, or jaws. Heartburn, nausea, vomiting, shortness of breath, and heavy sweating may also occur.



Healthy coronary artery

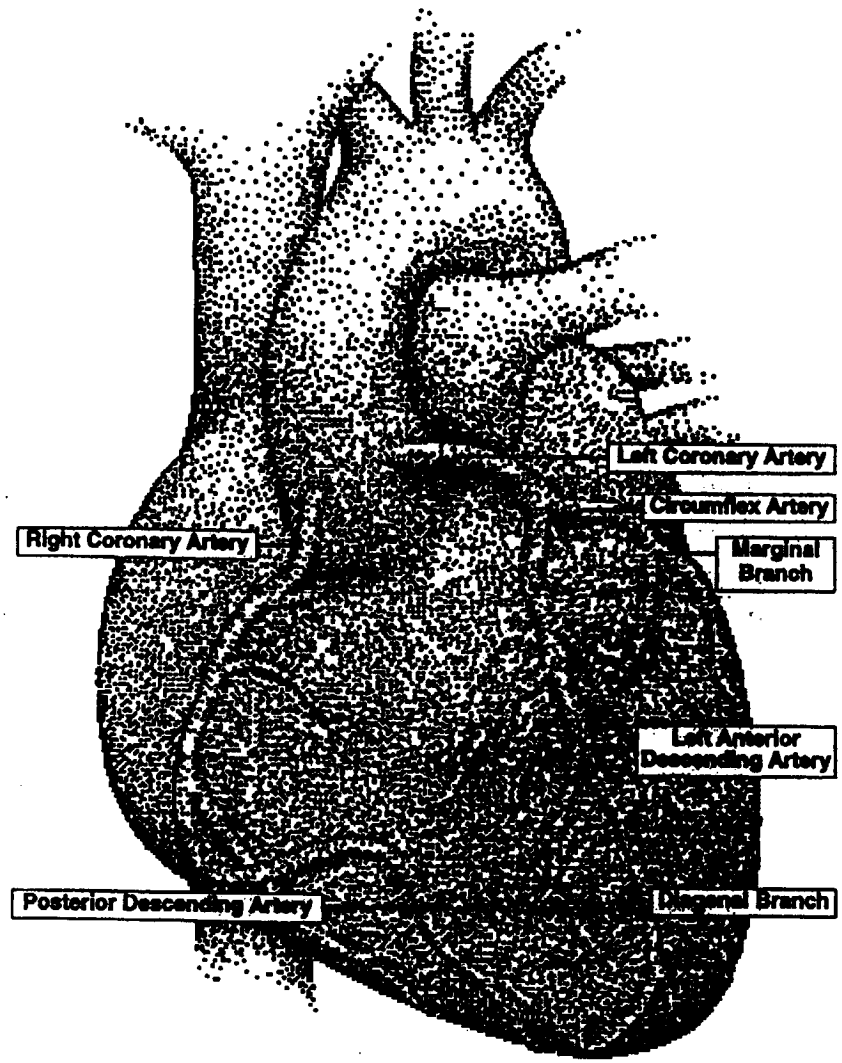
Occluded coronary artery

WHAT IS CORONARY ARTERY DISEASE? *(continued)*

Doctors may use various tests to diagnose CAD. An ECG (EKG), or *electrocardiogram*, measures your heart's electrical activity and may show whether parts of your heart muscle have been damaged by a heart attack resulting from CAD. A *stress test* records your heart's electrical activity while you are exercising and may tell your doctor whether part of your heart muscle is damaged. One important way to diagnose CAD is to perform a *coronary angiogram*, also called cardiac catheterization. This is done by injecting a contrast dye into the coronary arteries so they can be seen on an x-ray screen. The x-ray will show if artery narrowing has occurred.

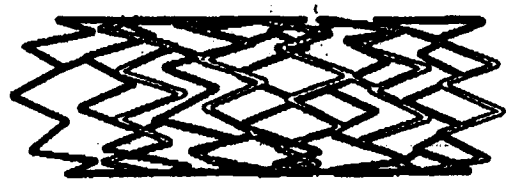
Coronary artery disease may be managed through a combination of changes in lifestyle and physical activity, diet and medical treatment. The therapy your doctor recommends will depend on the severity of the disease. Medical treatments may include medications, angioplasty, stent implantation or coronary artery bypass surgery.

Coronary arteries carry blood that supply nutrients and oxygen to the heart.



YOUR SCIMED RADIUS™ STENT

The Scimed RADIUS Stent is a small, metal mesh tube. The stent is mounted at the end of a long plastic tube, or catheter, and is held in place on the catheter by a sheath. The catheter is used to deliver the stent to the location where it is to be implanted. When the sheath is pulled back, the stent quickly self-expands until it has made contact with the artery wall, adapting to fit the shape, size and bends of the artery. Once in place, the stent will remain in your artery. Over time, the lining of the artery wall will grow around the stent as the stent continues to support the artery. Blood will then flow through the artery without contacting the stent.



Scimed RADIUS Self-Expanding Stent
(Image is enlarged for the purpose of this manual)

BEFORE THE PROCEDURE

Your doctor will instruct you on how to prepare for the angioplasty prior to being admitted to the hospital. You may be asked to take aspirin and other prescribed medications for several days before the procedure (see page 14). It is important to tell your doctor if you cannot take aspirin or have a history of bleeding problems. Your doctor also needs to know if you are taking any other medications or have drug allergies.

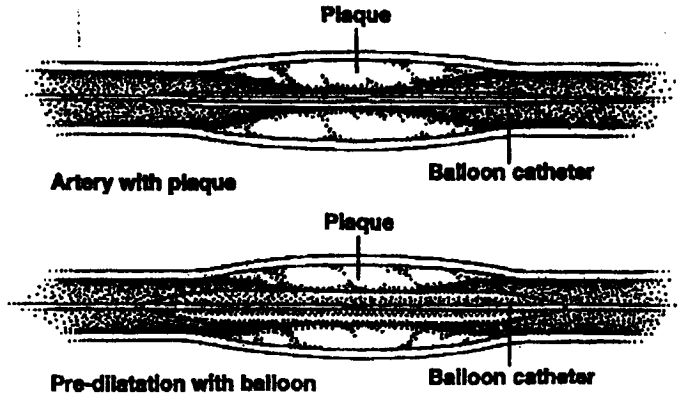
On the day of the procedure, you may be given a urinary catheter prior to the angioplasty. This may be done to minimize movement to and from a bedpan immediately after the procedure.

DURING THE PROCEDURE

Your angioplasty procedure will be performed in a specially equipped area of the hospital called the catheterization laboratory. After the stent is implanted, you will be moved to a cardiology ward for a short period where you can be monitored closely as you begin to recover. Altogether, your hospital stay could last one to three days before you are discharged to the care of your regular doctor.

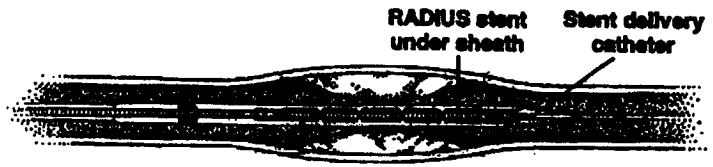
Angioplasty - Opening a Blocked Coronary Artery

First, your doctor will place an artery entry sheath in your groin. Then, your doctor will partially open the obstructed artery using a procedure called *percutaneous transluminal coronary angioplasty* (PTCA), *balloon angioplasty,* or *angioplasty*. Angioplasty opens the artery that is obstructed using a small, inflatable balloon on a catheter to move plaque away from the center of the artery, restoring blood flow. After this initial balloon inflation, your doctor will implant the RADIUS Stent to fully open the previously obstructed artery.

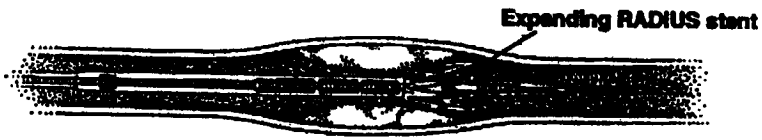


How the Stent is Implanted

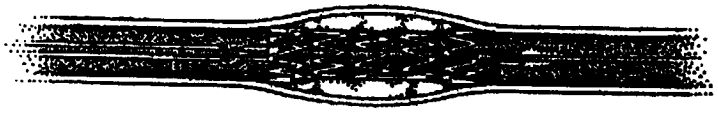
- First, your doctor will pass the stent, mounted on a delivery catheter, into the coronary artery.
- Then, your doctor will carefully position the stent at the place where the blockage was before angioplasty, known as the target site. By using a type of x-ray machine called a fluoroscope, your doctor will be able to see the RADIUS™ Stent inside the artery. This helps to position the stent at exactly the right location.
- Once the stent is in place, your doctor will remove the sheath from around the stent by slowly retracting a handle, or *actuator*, at the end of the delivery catheter.
- As the sheath is withdrawn, the RADIUS Stent expands until it fits the inner wall of the artery, shaping itself to the size and contours of your artery. With the stent in place, the delivery catheter is removed. The stent will remain in place and continue to keep the artery open.



Unexpanded RADIUS Stent in sheath



RADIUS Stent expands as sheath is withdrawn

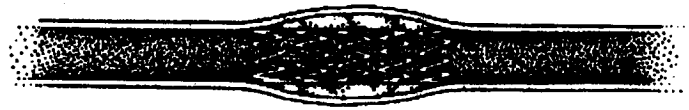


RADIUS Stent expanded, fits artery size and contour

How the Stent is Implanted *(continued)*

- Your doctor may choose to expand the stent further using an inflatable balloon similar to the one used to perform angioplasty. The balloon catheter is inserted inside the stent and is inflated to allow the stent to make better contact with the artery wall. This part of the procedure is called *post-dilatation*.
- Post-dilatation is done to assure full contact of the stent to the artery wall. Physicians call this proper *apposition*.

Post-dilatation



Final result

AFTER THE PROCEDURE

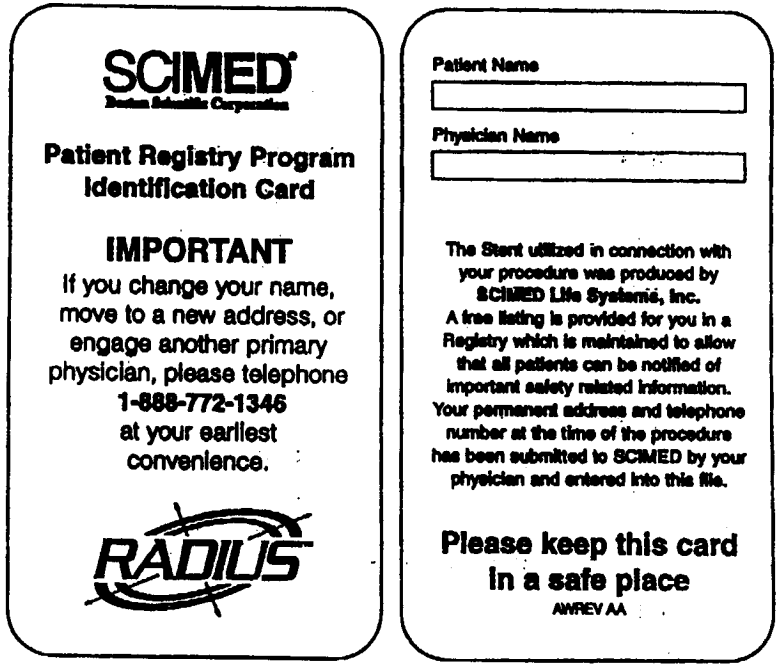
Recovery

After the procedure, you will go to a cardiology ward where medical staff will monitor your heart rate and blood pressure closely. Before returning to your room, the artery entry sheath may be removed from your leg and pressure applied to the puncture site until the bleeding has stopped. Your blood will be frequently tested to monitor and regulate medication levels for controlled blood consistency.

Once you return to your room from the recovery unit, family and friends may visit. You may drink and eat. Drinking plenty of fluids helps flush the contrast dye used during the procedure out of your system. For the first few days, your doctor will restrict your activities. Your doctor will advise you when to increase activities.

Patient Registry Program

It is required that stent implant patients be tracked so that all patients can be notified about important safety-related information. You will be given a Patient Registry Program card after your procedure. Keep this card in a safe place and notify the manufacturer of any change of name, address, or change in your primary care physician. Notification of changes can be made by calling the toll free number listed on the card.



Front

Back

Taking Care of Yourself at Home

When you return home, you have an important role to play in your recovery. In a small fraction of patients, chest pain may return due to the build up of scar tissue in the treated artery. If this occurs, talk to your doctor to determine the cause of your pain and possible treatment recommendations. Carefully following your doctor's instructions regarding medications, exercise, diet and activities will speed your recovery and can help prevent future recurrence of artery narrowing. The medication chart at the end of this booklet lets you keep track of your treatment program, including medications, along with any questions you may have for your doctor at follow-up visits.

Here are some guidelines to follow:

- Return to normal activities gradually, pacing your return to activity as you feel better. Check with your doctor about strenuous activities.
- Contact your doctor or the hospital immediately if you experience pain, bleeding, discomfort or changes in angina symptoms—such as severity or frequency.
- Let your doctor know about any changes in lifestyle you make during your recovery period.
- Follow your doctor's instructions exactly regarding medications prescribed.
- Report side effects from medications immediately. These may include headaches, nausea, vomiting or rash.

- Do not stop taking your medications unless you are asked to stop by your doctor.
- Attend all follow-up appointments, including laboratory blood testing. Follow-up appointments are discussed on page 15.
- Tell your dentist or other medical personnel you are on blood thinners prior to any treatment. Postpone dental work until after your recovery.

Medications

Your doctor may prescribe a number of medications. Two commonly prescribed medications are aspirin and *Ticlopidine*. They thin the blood to prevent blood clots from forming and adhering to the surface of the stent. Patients who take these medications also are required to take blood tests frequently so their blood clotting time can be monitored. Your doctor will let you know when you can stop taking this medication. Until then, it is extremely important to follow your medication regimen. If you experience any unusual symptoms while taking Ticlopidine, notify your doctor immediately. Check with your doctor before taking antacids as they may decrease absorption of aspirin and other medications.

Avoid The Following

- Strenuous exercise, unless approved by your doctor.
- Dental work or any type of treatment that may result in bleeding while you are taking blood thinners.
- A Magnetic Resonance Imaging (MRI) medical scan within eight weeks of stent implant because it is not firmly anchored in the artery wall.

Follow-Up Appointments

You will need to see the doctor who implanted your stent for routine follow-up examinations. Schedule follow-up visits at two weeks, four weeks, and nine months after the procedure. During these visits, your doctor will monitor your progress and evaluate your medications, the clinical status of your CAD, and how the stent is working for you.

GLOSSARY

Actuator - The handle or mechanism on the end of the delivery catheter that the doctor pulls back to remove the sheath from the stent, allowing the stent to self-expand. See ***self-expanding stent***.

Angina Pectoris - Discomfort, pain, tightness or pressure in the chest, usually due to interference with blood flow to the heart muscle and precipitated by excitement or effort. May also cause profuse sweating, nausea, shortness of breath and associated pain in the neck, jaw, back, or arm.

Angioplasty - A procedure which proceeds and/or follows stent placement. A balloon catheter compresses the plaque against the artery wall, leaving a larger opening for the blood to pass through. Also known as percutaneous transluminal coronary angioplasty (PTCA).

Anticoagulant - Medicine that slows or prevents blood from clotting.

Antiplatelet - Medicine that acts against blood platelets in order to prevent clot formation.

Apposition - Refers to the position of the stent against the artery wall.

Atherosclerosis - A disease in which the flow of blood to the heart is restricted with plaque deposits (a build-up of cholesterol and other fats, calcium and certain other elements carried in the blood) and therefore, less oxygen and other nutrients reach the heart muscle. This may lead to chest pain (angina pectoris) or to a heart attack (myocardial infarction).

GLOSSARY *(continued)*

CAD - See ***Coronary Artery Disease***.

Catheter - A small thin plastic tube used to provide access to parts of the body, such as the coronary arteries of the heart.

Coronary - Related to arteries that supply blood to the heart.

Coronary Angiogram - A test that can determine if CAD is present. Contrast dye is injected into the coronary arteries and a fluoroscope allows the doctor to see the narrowed or blocked arteries, a stent, or catheter on an x-ray screen.

Coronary Arteries - The arteries that surround the heart and supply blood containing oxygen and nutrients to the heart muscle. Oxygen deprivation to the heart restricts heart function and may lead to chest pain (angina pectoris) or to a heart attack (myocardial infarction).

Coronary Artery Disease (CAD) - Disease affecting the coronary arteries that surround the heart and supply blood to the heart muscle. CAD occurs when the lumen of the coronary arteries become narrowed with plaque deposits (a build-up of cholesterol and other fats, calcium and other elements carried in the blood).

ECG - Electrocardiogram. See ***stress test***.

Exercise Electrocardiogram - See ***stress test***.

Ischemia - A condition that results from reduced blood flow to cells due to an obstruction. Ischemia is reversible if normal blood flow is restored.

Lumen - The inner channel of an artery or tube.

GLOSSARY *(continued)*

Myocardial Infarction - Permanent damage to the heart tissue and muscle due to the interruption of the blood supply to the area. Commonly referred to as a heart attack, which can occur when blood clots form on top of the atherosclerosis.

Percutaneous - Performed through the skin.

Percutaneous Transluminal Coronary Angioplasty - See ***Angioplasty***.

Plaque - An accumulation or build-up of calcium, cell debris, fatty deposits and collagen in a coronary artery that leads to narrowing of the lumen.

Post-Dilatation - After the stent has self-expanded, another balloon catheter may be inserted inside the stent and inflated to size the stent more precisely to the normal diameter of the artery.

PTCA - Percutaneous Transluminal Coronary Angioplasty.

Restenosis - Recurrent blockage or narrowing of an artery due to tissue formation after correction of the primary blockage with angioplasty or stent implantation.

Self-Expanding Stent - A stent that expands on its own up to the inner wall of the artery providing even, continuous contact with the inner wall of the artery to maintain blood flow. Other types of stents must be expanded to their final diameter by a balloon catheter from within the stent.

Sheath (artery entry sheath) - A short, thin plastic tube (catheter) used to provide access for the stenting procedure and sometimes left in place for a period of time after the procedure.

GLOSSARY *(continued)*

Stent - An expandable metal tube that supports the artery wall and maintains healthy blood flow through the opened artery.

Stress Test - A test used to measure electrical activity in the patient's heart (ECG) while the patient is doing a controlled exercise. The results determine if there has been damage to the heart or if blood flow has been restricted to areas of the heart.

Ticlopidine - A medicine that thins the blood and helps prevent clot formation.

Transluminal - Through the lumen which is the inner channel of an artery.

Vessel - A vein or artery.

MEDICATION CHART

This chart will be filled in by your nurse or physician to detail your medication schedule following implantation of a coronary stent.

Medication	Dose	When To Take It

Questions/Notes

Patient's Name: _____

Date of Stent Implantation: _____

Date	PT Results	INR Results	Date of Next Lab Test	Comments

Physician's Name: _____

Phone Number: _____

Suggested goals: Check to see what goals your physician has recommended for you.

PT Results: 16 - 18
INR Results: 2 - 3