**SULZER** *MEDICA*

**Sulzer IntraTherapeutics**

# IntraCoil® Self-expanding Peripheral Stent

**Femoropopliteal Arteries**

**Caution: Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).**

## INSTRUCTIONS FOR USE

### TABLE OF CONTENTS



## 1 DEVICE DESCRIPTION

The IntraCoil® Self-expanding Peripheral Stent consists of

- a 40 mm long nitinol coil stent with evenly placed coils in the open configuration, and
- an over-the-wire delivery catheter with radiopaque proximal and distal marker bands that aid in placement of the stent.

The stent is wound onto the distal end of the delivery catheter and secured at both ends to release wires. Retraction of white and black knobs located on the handle of the delivery catheter releases the respective proximal and distal ends of the stent. The IntraCoil® Self-expanding Peripheral Stent is available in the following diameters: 4, 5, 6, 7 and 8 mm. See Table 1 for specifications and stent/vessel sizing.

**Table 1. IntraCoil® Self-expanding Peripheral Stent Specifications**

| Model | Working Length | Model | Working Length | Stent Length | Stent Diameter | Vessel Diameter |
|---|---|---|---|---|---|---|
| VT440 | 63 cm | VT440135 | 135 cm | 40 mm | 4 mm | 3-4 mm |
| VT540 | 63 cm | VT540135 | 135 cm | 40 mm | 5 mm | 4-5 mm |
| VT640 | 63 cm | VT640135 | 135 cm | 40 mm | 6 mm | 5-6 mm |
| VT740 | 63 cm | VT740135 | 135 cm | 40 mm | 7 mm | 6-6.8 mm |
| VT840 | 63 cm | VT840135 | 135 cm | 40 mm | 8 mm | 6.9-7.8 mm |

## 2 INDICATIONS AND USAGE

The IntraCoil® Self-expanding Peripheral Stent is indicated for improving peripheral luminal diameter in patients with symptomatic atherosclerotic disease due to stenotic lesions (length ≤ 15 cm) or occlusive lesions (length ≤ 12 cm) in femoropopliteal arteries, to the bifurcation of the tibial artery, with a reference vessel diameter of 3.0 to 7.8 mm.

## 3 CONTRAINDICATIONS

The IntraCoil® Self-expanding Peripheral Stent is contraindicated for use in patients who have a lesion that cannot be crossed with a wire and/or balloon catheter.

# 4 GENERAL WARNINGS/ PRECAUTIONS

## 4.1 Warnings

- The stent is intended for use by physicians who have received appropriate training in interventional techniques and placement of intravascular stents.
- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated should be treated with caution due to possible early stent thrombosis.
- Appropriate sizing of the vessel is required to reduce the possibility of stent migration.

## 4.2 Precautions

Stent Handling Precautions

- The system is provided STERILE for one use only and should be used by the "Use Before Date" printed on the package. Do Not Resterilize.
- Carefully inspect the sterile package and device prior to use to verify that neither has been damaged during shipment.

Stent Placement Precautions

- If resistance is encountered at any time during the insertion procedure, do not force passage, which may cause damage to the stent or vessel. Remove device and assess reason for resistance. Use care to avoid kinking of the delivery catheter.
- The IntraCoil stent delivery system is not intended for repositioning or recapturing of the stent.
- If multiple stents are used, deliver the most distal stent first to minimize risk of stent dislodgement.

Post Stent Placement Precautions

- Caution should be used when crossing the deployed stent with any adjunctive devices.
- The stent is MRI safe with minimal artifacts (Teitelbaum, et.al., 1988).

# 5 ADVERSE EVENTS

## 5.1 Observed Adverse Events

A total of 357 patients were enrolled in a multi-center U.S. clinical trial as summarized in Table 2. Randomized patients from the U.S. Trial form the basis of the observed adverse events in Table 3 at nine months.

**Table 2. Patient Enrollment in Clinical Studies**

| | IntraCoil® Stent | PTA | Patient Totals |
|---|---|---|---|
| U.S. Trial | | | |
| Roll-in patients | 91 | -- | 91 |
| Randomized patients | 135 | 131 | 266 |
| **PATIENT TOTALS** | **226** | **131** | **357** |

A total of eighteen deaths occurred in the U.S. randomized trial (five stent patients, thirteen percutaneous tranluminal angioplasty (PTA) patients). The five stent patients died after discharge, the first at 52 days from multiple system failure, the second at 693 days from colon cancer, the third at 738 days from unknown cause, the fourth at 757 days from lung cancer and the fifth at 789 days from cardiac death. Of the thirteen PTA deaths, one occurred in-hospital (due to renal failure and pulmonary edema), and twelve after discharge (at 34, 37, 252, 390, 505, 652, 690, 699, 762, 839, 840 and 962 days post-procedure). Causes of death for the late cases were, respectively, renal failure, septicemia, cardiac arrest, cardiogenic shock with severe CAD, lung cancer, respiratory failure, cardiac death, cardiac death, unknown, complications from extraction bile duct stone, stroke and cardiac death.

There were nine deaths in the Roll-in group; at 49, 84, 324, 581, 607, 645, 875, 883 and 1026 days post-procedure. Causes of death were, respectively, congestive heart failure, hepatic failure, multi-system failure, colon cancer, unknown, stroke, complications from MS, ischemic cardiomyopathy and respiratory failure.

**Table 3. Adverse Events during the First 9 Months**
**%[± 95% Exact Confidence Intervals] (Number) All randomized U.S. patients (n=266)**

| Adverse Event | IntraCoil® Stent (n=135) | PTA (n=131) | Difference [95% CI] |
|---|---|---|---|
| **ANY MACE Event** | 16.3% [10.8%, 23.4%] (22) | 16.0% [10.2%, 23.1%] (21) | 0.3% [-8.0%, 9.3%] |
| **Early (in-hospital)** | 0.7% [0%, 3.7%] (1) | 2.3% [0.6%, 6.3%] (3) | -1.6% [-6.0%, 2.1%] |
| **Out-of-hospital** | 15.6% [10.0%, 22.8%] (21) | 13.7% [8.4%, 20.7%] (18) | 1.8% [-7.0%, 10.5%] |
| **Death Total** | 0.7% [0%, 3.7%] (1) | 3.1% [1.1%, 7.2%] (4) | -2.3% [-7.0%, 1.4%] |
| **Early (in-hospital)** | 0% [0%, 2.6%] (0) | 0.8% [0%, 3.8%] (1) | -0.8% [-4.6%, 2.1%] |
| **Out-of-hospital** | 0.7% [0%, 3.7%] (1) | 2.3% [0.6%, 6.3%] (3) | -1.6% [-6.0%, 2.1%] |
| **Q-wave MI Total** | 0% [0%, 2.6%] (0) | 0% [0%, 2.7%] (0) | 0.0% [-3.1%, 3.0%] |
| **Early (in-hospital)** | 0% [0%, 2.6%] (0) | 0% [0%, 2.7%] (0) | 0.0% [-3.1%, 3.0%] |
| **Out-of-hospital** | 0% [0%, 2.6%] (0) | 0% [0%, 2.7%] (0) | 0.0% [-3.1%, 3.0%] |
| **Non-Q-wave MI Total** | 2.2% [0.6%, 6.2%] (3) | 0% [0%, 2.7%] (0) | 2.2% [-0.7%, 6.7%] |
| **Early (in-hospital)** | 0% [0%, 2.6%] (0) | 0% [0%, 2.7%] (0) | 0.0% [-3.1%, 3.0%] |
| **Out-of-hospital** | 2.2% [0.6%, 6.2%] (3) | 0% [0%, 2.7%] (0) | 2.2% [-0.7%, 6.7%] |
| **Amputation Total** | 0% [0%, 2.6%] (0) | 0.8% [0%, 3.8%] (1) | -0.8% [-4.6%, 2.1%] |
| **Early (in-hospital)** | 0% [0%, 2.6%] (0) | 0.8% [0%, 3.8%] (1) | -0.8% [-4.6%, 2.1%] |
| **Out-of-hospital** | 0% [0%, 2.6%] (0) | 0% [0%, 2.7%] (0) | 0.0% [-3.1%, 3.0%] |
| **Abrupt Closure Total** | 0% [0%, 2.6%] (0) | 2.3% [0.6%, 6.3%] (3) | -2.3% [-6.9%, 0.6%] |
| **Early (in-hospital)** | 0% [0%, 2.6%] (0) | 2.3% [0.6%, 6.3%] (3) | -2.3% [-6.9%, 0.6%] |
| **Out-of-hospital** | 0% [0%, 2.6%] (0) | 0% [0%, 2.7%] (0) | 0.0% [-3.1%, 3.0%] |
| **Subacute Closure Total** | 0.7% [0%, 3.7%] (1) | 2.3% [0.6%, 6.3%] (3) | -1.6% [-6.0%, 2.1%] |
| **Early (in-hospital)** | 0.7% [0%, 3.7%] (1) | 1.5% [0.3%, 5.4%] (2) | -0.8% [-4.8%, 3.0%] |
| **Out-of-hospital** | 0% [0%, 2.6%] (0) | 0.8% [0%, 3.8%] (1) | -0.8% [-4.6%, 2.1%] |
| **Distal Embolization Total** | 0% [0%, 2.6%] (0) | 0.8% [0%, 3.8%] (1) | -0.8% [-4.6%, 2.1%] |
| **Major Bleeding Complications** | 0.7% [0%, 3.7%] (1) | 0.8% [0%, 3.8%] (1) | -0.02% [-3.9%, 3.6%] |
| **Major Vascular Complications** | 3.7% [1.5%, 8.1%] (5) | 4.6% [2.0%, 9.6%] (6) | -0.9% [-6.7%, 4.6%] |
| **Renal Failure** | 0% [0%, 2.6%] (0) | 2.3% [0.6%, 6.3%] (3) | -2.3% [-6.9%, 0.6%] |

**ANY MACE Event** includes death, peri-procedure Q Wave MI, target lesion revascularization (TLR)
**Early (in-hospital)** refers to events during the hospitalization for the initial trial treatment. In cases where a patient experienced both an in-hospital event and an out-of-hospital event, they are counted once in each group, but only once in the event total. Hence, the sum of the in-hospitand the out-of-hospital event rate may not equal the total event rate.
**Amputation:** any requirement for amputation transmetatarsal or higher that was unanticipated before the procedure.
**Abrupt Closure:** slow or reduced flow due to mechanical dissection (of grade E or higher), thrombus, or severe microvascular spasm that resulted in additional unplanned stent use or surgery.
**Subacute Closure:** target lesion site occlusion within 30 days of the procedure.
**Distal Embolization:** migration of a filling defect or thrombus to a distal vessel.
**Renal Failure:** decrement in renal function related to the index procedure requiring temporary or chronic dialysis; or repeat hospitalization for worsening renal function attributable to the index procedure.

## 5.2 Potential Adverse Events

Adverse events (in alphabetical order) that may be associated with the use of vascular stents in peripheral vessels (in addition to those listed in Table 3) include:

- AV Fistula Formation
- Dissection
- Drug reactions to antiplatelet agents/ contrast medium
- Hematoma
- Hypotension/hypertension
- Infection and/or pain at the access site
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stroke/cerebrovascular accident
- Vessel perforation or rupture

## 5.3 Observed Device Malfunctions

Five stent delivery failures were attributed to release wire breakage (2) and failure of stent to deploy (3). In the two wire breakage cases the release wire was successfully manipulated to deploy the stent. In the three non-deployment cases, two devices were removed unused. In the third case the physician released the distal stent end, after which the proximal end fully deployed.

## 6 CLINICAL STUDIES

A total of 357 patients were treated at 23 U.S. investigational sites (Table 2). The purpose of the study was to compare the IntraCoil stent to balloon angioplasty in the superficial femoral and popliteal arteries. Physicians unfamiliar with coil stents were allowed to complete learning cases before starting in the randomized trial. These ninety-one learning cases are referred to as the Roll-in group. A total of 266 patients were enrolled in the U.S. Randomized Trial which is summarized below.

**Study Endpoints:** The primary endpoint was the determination of MACE at nine months. MACE was defined as a composite of death within 30 days, peri-procedural Q Wave MI, and clinically driven target lesion revascularization (TLR) within nine months. Secondary endpoints included acute angiographic success, major complication rate at 30 days and change in ankle/brachial index. An independent clinical events committee adjudicated all of the major clinical endpoints.

**Patients Studied:** Eligible patients were candidates for percutaneous transluminal angioplasty (PTA), with symptomatic leg ischemia, requiring treatment of the superficial femoral/popliteal vessel with an occluded lesion length ≤ 12 cm or stenotic lesion length ≤ 15 cm and located proximal to the bifurcation of the tibial artery.

**Methods:** Patients were prospectively randomized to treatment with the IntraCoil® stent or PTA. Patients in the PTA arm were allowed to crossover to the IntraCoil® stent arm only if 1) acute results indicated abrupt closure or impending closure due to severe recoil or extensive dissection, not correctable despite repeated balloon inflations to high pressure, longer inflation, or larger balloon size (if appropriate) or 2) during follow-up there was angiographically defined restenosis or dissection that was limb threatening.

Clinical follow-up visits were conducted at six months, nine months and one year, with continuing annual follow-up for safety. To assess patency, nine-month angiographic follow-up was requested from the first 250 patients. Patients were to receive aspirin (325 mg daily) and ticlopidine HCL (250 mg/twice daily) at least one day before the procedure. They were to continue the aspirin therapy indefinitely and the ticlopidine for one month post-procedure. Anticoagulation therapy was at the discretion of the physician.

**Results:** The study was stopped early due to slow patient enrollment. The slow enrollment was attributed to physician's reluctance to include all eligible lesions in a randomized study with balloon angioplasty. Baseline characteristics were similar for the two treatment groups in the randomized trial (Table 4).

**Table 4. Baseline Characteristics**
**All randomized U.S. patients (n=266 patients, 352 lesions)**

| Characteristics | IntraCoil® Stent (n=135 patients, 177 lesions) | PTA (n=131 patients, 175 lesions) | Difference [95% CI] |
|---|---|---|---|
| Age (yrs), mean±SD (N) | 66.8±10.6 (129) | 68.1±10.2 (131) | -1.3[-3.8, 1.3] |
| Number of men | 67.4% (87/129) | 63.4% (83/131) | 4.1% [-7.5%, 15.6%] |
| History of smoking | 81.9% (104/127) | 80.0% (104/130) | 1.9% [-7.7%, 11.5%] |
| History of diabetes mellitus | 38.0% (49/129) | 37.4% (49/131) | 0.6% [-11.2%, 12.4%] |
| History of myocardial infarction | 37.2% (48/129) | 29.1% (37/127) | 8.1% [-3.4%, 19.6%] |
| Reference vessel diameter (mm), mean±SD (N) | 4.20±0.96 (150) | 4.16±1.05 (150) | 0.04 [-0.19, 0.27] |
| Lesion length (cm), mean±SD (N) | 3.56±3.00 (147) | 3.26±2.96 (144) | 0.29 [-0.39, 0.98] |
| Occlusion | 22.7% (40/176) | 16.8% (31/184) | 5.9% [-2.3%, 14.1%] |

All patients were included in the intent-to-treat efficacy analysis. No statistical difference was found for nine month MACE between the IntraCoil® stent and PTA groups. Table 5 shows the principal effectiveness and safety results for this comparison.

Additional analyses were conducted to determine if the equivalent results continued through long-term follow-up. Figures 1 and 2 show the primary endpoint, actuarial freedom from MACE, and freedom from TLR, through three years. The TLR rate based on the length of the lesion treated is shown in Figure 3. Lesion length is grouped in 3 cm categories: 0-3 cm, 3-6 cm, 6-9 cm, 9-12 cm and 12-15 cm.

**Table 5. Principal Effectiveness and Safety Results**
**All randomized U.S. patients (n=266)**

| Efficacy Measures | IntraCoil® Stent (n=135 patients, 177 lesions) | PTA (n=131 patients, 175 lesions) | Difference [95% CI] |
|---|---|---|---|
| Acute angiographic success | 85.4% (152/178) | 82.2% (143/174) | 3.2%[-4.5%,10.9%] |
| Acute (30 day) procedure success | 80.6% (108/134) | 77.1% (101/131) | 3.5%[-6.3%,13.3%] |
| Device success | 91.8% (123/134) | 89.3% (117/131) | 2.5%[-4.6%,9.5%] |
| Change of ABI (from baseline to 9 mos.) | 0.19 ± 0.20 (83) | 0.08 ± 0.19 (64) | 0.1 [0.04,0.16] |
| Range (min, max) | (-0.43, 0.56) | (-0.25, 0.52) | |
| 9-mo follow-up in-lesion binary restenosis rate | 41.2% (40/97) | 33.7% (31/92) | 7.5%[-6.2%,21.3%] |
| TLR-free at 9 months (K-M) | 85.7% [79.9%, 91.5%] | 83.9% [78.0%, 89.7%] | 1.8%[-6.4%,10.2%] |
| TVR-free at 9 months (K-M) | 81.1% [73.9%, 88.4%] | 83.1% [76.1%, 90.2%] | -2.0%[-12.1%,8.1%] |
| MACE-free at 9 months (K-M) | 80.5% [73.2%, 87.8%] | 81.2% [73.9%, 88.4%] | -0.7%[-11.0%,9.6%] |
| **Safety Measures** | | | |
| In-Hospital MACE | 0.7% (1/135) | 2.3% (3/131) | -1.5%[-4.5%,1.4%] |
| Out-of-Hospital MACE to 9 months | 15.6% (21/135) | 13.7% (18/131) | 1.8%[-6.7%,10.3%] |
| Major Complications at 30 days | 1.5% (2/135) | 8.4% (11/131) | -6.9%[-12.1%,-1.7%] |
| Major bleeding complications | 0.7% (1/135) | 0.8% (1/131) | 0.0%[-2.1%,2.1%] |
| Major vascular complications | 3.7% (5/135) | 4.6% (6/131) | -0.9%[-5.7%,3.9%] |
| Amputation to 9 months | 0.0% (0/135) | 0.8% (1/131) | -0.8%[-2.3%,0.7%] |
| Abrupt closure | 0.0% (0/135) | 2.3% (3/131) | -2.3%[-4.9%,0.3%] |
| Subacute closure | 0.7% (1/135) | 2.3% (3/131) | -1.5%[-4.5%,1.4%] |
| Distal embolization | 0.0% (0/135) | 0.8% (1/131) | -0.8%[-2.3%,0.7%] |
| Renal Failure | 0.0% (0/135) | 2.3% (3/131) | -2.3%[-4.9%,0.3%] |

**Numbers are** % (counts/sample size) or mean ± standard deviation. **CI** is Confidence Interval.

**Acute Angiographic Success:** achievement of a final residual stenosis of <50% and ≥20% improvement in diameter stenosis by QA.

**Acute Procedural Success:** achievement of a final residual diameter stenosis of <50% and ≥20% improvement in diameter stenosis by QA without death, stroke, Q wave MI, bleeding requiring >2 units transfusion, or any other complication which was device- or procedure- related and which required an unanticipated interention or surgical procedure within the first 30 days after treatment. If no in-stent measurements were available, in-lesion measurements were used, and if no QA was available, visual estimates were used.

**Device Success:** achievement of a final residual diameter stenosis of <50% by QA with successful delivery of the assigned device at least once and freedom from stent embolization, from stent migration, and from use of a device outside the assigned treatment strategy. If no in-stent measurements were available, in-lesion measurements were used, and if no QA was available, visual estimates were used.

**K-M:** survival estimates by Kaplan-Meier method. Standard Error estimates by Greenwood formula.

**TLR:** target lesion revascularization. **TVR:** target vessel revascularization. **MACE:** death, peri-procedural Q wave MI, or target lesion revascularization. **In-Hospital:** prior to hospital discharge. **Out-of-Hospital:** after hospital discharge.

**Major complications at 30 days:** MACE plus amputation, major bleeding complication, renal failure and abrupt closure

**Amputation:** any requirement for amputation transmetatarsal or higher that was unanticipated before the procedure.

**Abrupt Closure:** slow or reduced flow due to mechanical dissection (of grade E or higher), thrombus, or severe microvascular spasm that resulted in additional unplanned stent use or surgery.

**Subacute Closure:** target lesion site occlusion within 30 days of the procedure.

**Distal Embolization:** migration of a filling defect or thrombus to a distal vessel.

**Renal Failure:** decrement in renal function related to the index procedure requiring temporary or chronic dialysis; or repeat hospitalization for worsening renal function attributable to the index procedure.

**Binary restenosis rate**: percentage of lesions with≥ 50% in-lesion minimal lumen diameter stenosis at follow-up angiogram.

**Figure 1. Survival Free From MACE (to 1080 days)**
**Event-Free Survival ± 1.5 SE; All Randomized Patients Treated With Survival Information**

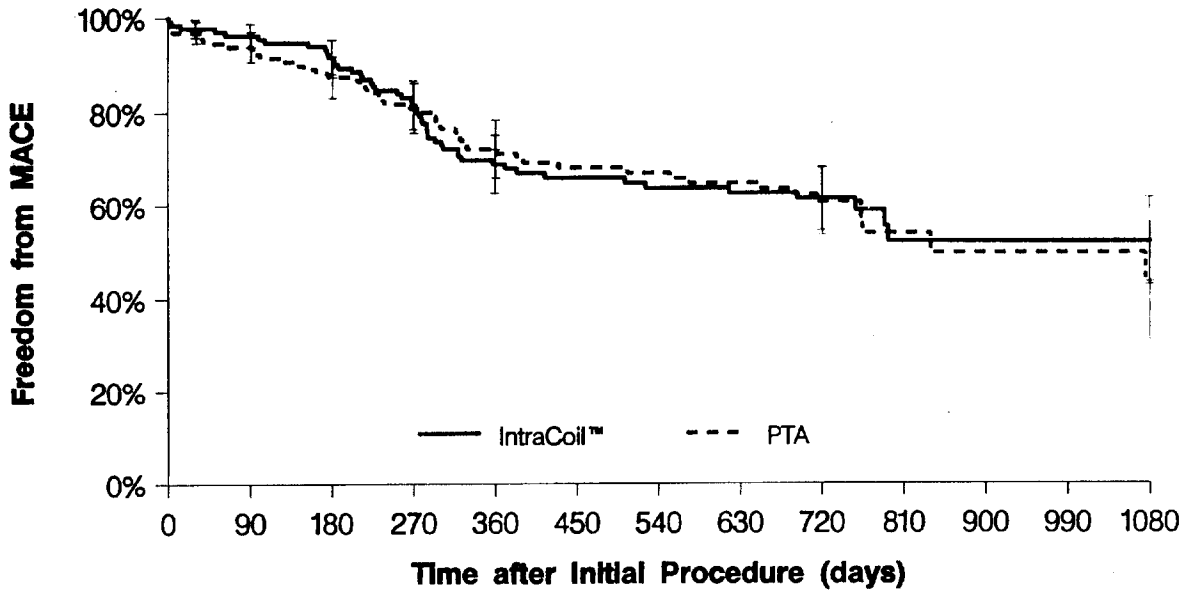



**Figure 2. Survival Free From Target Lesion Revascularization (to 1080 days)**
**Event-Free Survival ± 1.5 SE; All Randomized Lesions Treated With Survival Information**

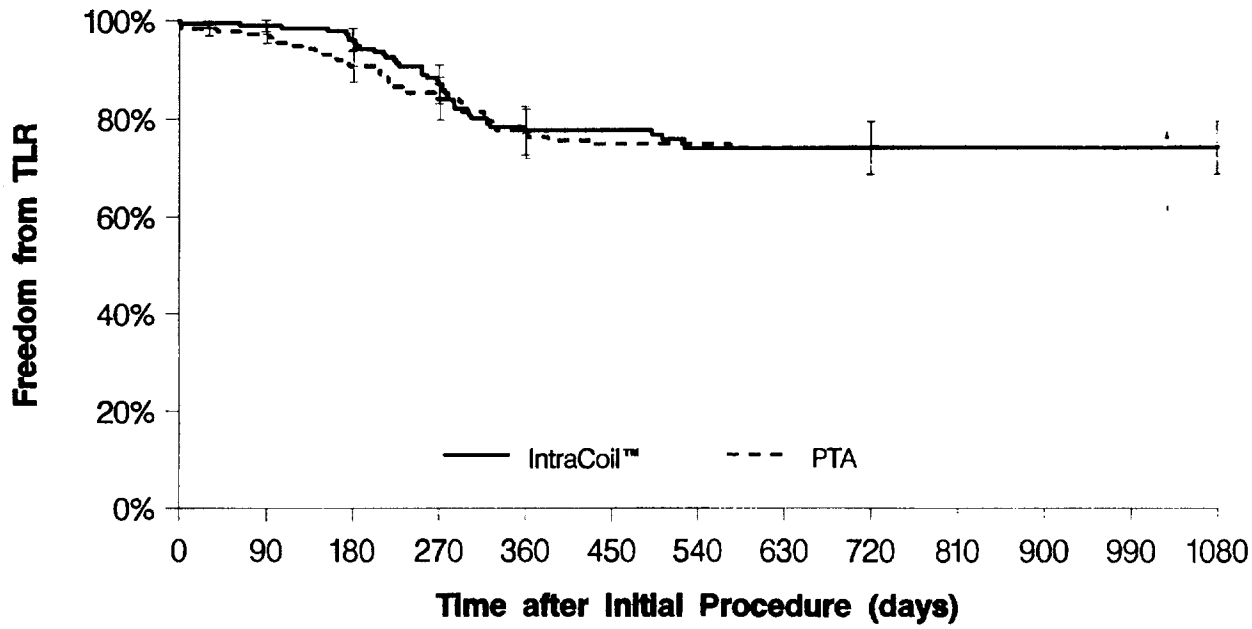
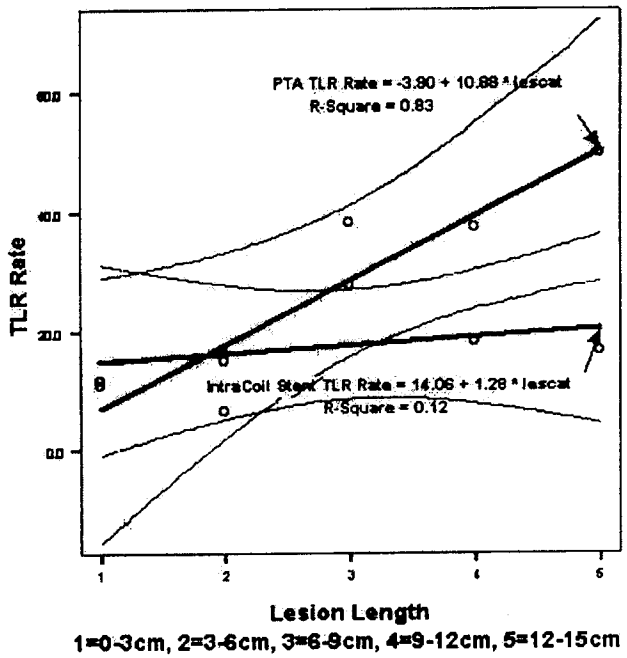


**Figure 3. 9 Month TLR Rate By Lesion Length**




| Lesion Length (cm) | IntraCoil Stent | PTA |
|---|---|---|
| 0-3 | 11.9% (7/59) | 11.0% (8/73) |
| 3-6 | 15.0% (6/40) | 6.7% (2/30) |
| 6-9 | 27.7% (8/30) | 38.5% (10/26) |
| 9-12 | 18.2% (2/11) | 37.5% (3/8) |
| 12-15 | 16.7% (1/6) | 50% (2/4) |

# 7 OPERATOR'S INSTRUCTIONS

## 7.1 Initial Preparation

1. After local anesthesia is administered, the femoral artery is entered with a puncture needle and a sheath is inserted: 7 Fr for 4 mm and 5 mm stents, 8 Fr for 6 mm and 7 mm stents, and 9 Fr for 8 mm stents.
2. A 0.035" (0.89 mm) diameter or smaller guidewire is introduced into the artery through the sheath and should be advanced across the stenosis, followed by a diagnostic catheter for contrast injection.
3. An injection of contrast media through the sheath should be done in order to confirm the lesion length and diameter.
4. A balloon dilatation catheter should be selected to correspond to the diameter of the artery proximal to the lesion to maximize the lumen area at the target lesion location.
5. . Choose the appropriate stent size for the vessel diameter using the specifications in Table 1.

**WARNING:** Appropriate sizing of the vessel is required to eliminate the possibility of stent migration.

6. If a long lesion is treated two or more successive IntraCoil stents may be implanted.

**CAUTION:** If multiple stents are used, deliver the most distal stent first to minimize risk of stent dislodgement.

## 7.2 Stent and Catheter System Preparation

**CAUTION:** Carefully inspect the sterile package and device prior to use to verify that neither has been damaged during shipment.

1. Remove the device from the package.
2. Remove the protective stylet from the guidewire lumen at the distal tip of the catheter.
3. Flush through the guidewire lumen using sterile saline.

## 7.3 Stent Implantation

1. Use an exchange 0.035" (0.89 mm) diameter guidewire or smaller to remove the balloon.
2. Under fluoroscopy, advance the delivery catheter over the guidewire to the site of the dilated lesion.

**CAUTIONS:**

- If resistance is encountered at any time during the insertion procedure, do not force passage, which may cause damage to the stent or vessel. Remove device and assess reason for resistance.
- Use care to avoid kinking the delivery catheter.

3. To position the stent correctly across the lesion, use the two (2) radiopaque rings that indicate the distal end and the proximal end of the deployed stent in an appropriately sized vessel. Position the distal marker slightly past the most distal point of the lesion (Figure 3).

**CAUTION:** The IntraCoil stent delivery system is not intended for repositioning or recapturing of the stent.

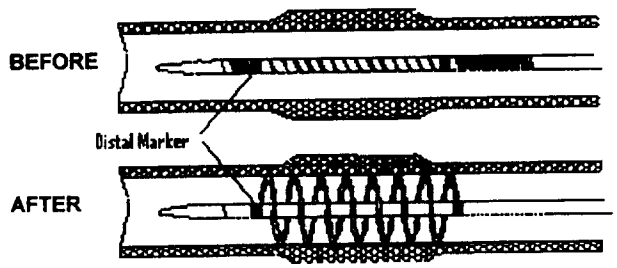



**Figure 3. Positioning and Releasing the Stent**

4. Remove the protective black safety sleeve from the handle.
5. To release the stent from the delivery catheter, first release the proximal end of the stent by slowly retracting the white knob until it reaches the stopper.
6. Then release the distal end of the stent from the delivery catheter by slowly retracting the black knob until it reaches the white knob.

**NOTE:** During deployment the stent shortens 30 to 40 percent from the proximal end towards the distal end to its nominal length (Figure 3).

7. Remove the delivery catheter cautiously and slowly under fluoroscopy, being careful not to catch the stent loops. Turn the catheter counterclockwise to facilitate removal.

**NOTE:** After placement of the stent, if expansion is not complete, a balloon (**not larger than the stent size**) can be cautiously placed inside the stent lumen for further expansion.

8. Verify stent patency and position

### 7.4 Tandem Stenting

1. If the lesion length requires using multiple stents always implant the most distal stent first by following the procedure described above.
2. When placing the subsequent stent, position the distal radiopaque marker 2-3 coils inside of the proximal end of the first stent.
3. Deploy the new stent and remove delivery catheter as described previously.

## 8 PATIENT SELECTION AND TREATMENT

### 8.1 Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of the IntraCoil® stent. In the U.S. Randomized Trial, the significant predictors of target lesion revascularization (TLR) were baseline ABI and pre-procedure reference vessel diameter (RVD). Larger RVD and higher baseline ABI were associated with lower occurrence of target lesion revascularization.

### 8.2 Specific Patient Populations

The safety and effectiveness of the IntraCoil® stent has not been established for patients with any of the following characteristics:

- Patients allergic to nickel.
- Patients with diffuse disease or poor outflow distal to the identified lesions(s).

- Patients with poor aortoiliac or common femoral "inflow."
- Patients with unresolved vessel thrombus at the lesion site.
- Patients with targeted lesions in vessels with a reference diameter ≤ 3mm.

## 9 HOW SUPPLIED

**STERILE:** This device is EtO sterilized. It is intended for single use only. Non-pyrogenic. Do not use if package is opened or damaged.

**CONTENTS:** IntraCoil® Self-expanding Peripheral Stent on delivery catheter
Instructions for Use Manual

## 10 REFERENCES

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### DISCLAIMER OF WARRANTY

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