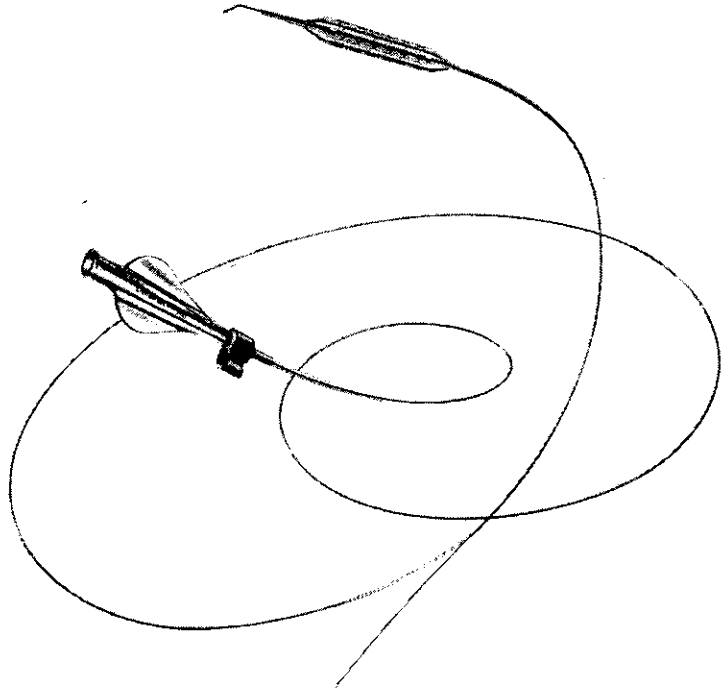
Rithron

Pre-mounted Coronary Stent on a
Fast Exchange Delivery Catheter



Instructions for Use

BIOTRONIK

CAUTION

Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician.

Contents

1. Device Description **1**
2. Indications for Use **2**
3. Contraindications **3**
4. Warnings and Precautions **4**
4.1 Warnings 4
4.2 Precautions 4
4.2.1 General Precautions 4
4.2.2 Stent Handling 5
4.2.3 Stent Placement 5
4.2.4 Stent System Removal 6
4.2.5 Post Implantation 6
4.2.6 Magnetic Resonance Imaging (MRI) 6
5. Adverse Events **7**
5.1 Observed Adverse Events 7
5.2 Potential Adverse Events 9
6. Clinical Study **10**
6.1 Purpose 10
6.2 Conclusions 10
6.3 Study Design 10
6.3.1 Primary Endpoint 12
6.3.2 Secondary Safety Endpoints 12
6.3.3 Secondary Efficacy Endpoints 12
6.4 Patient Demographics 13
6.5 Clinical Study Results 13
6.5.1 Statistical Adjustments for Baseline and Demographic Characteristics 13
6.5.2 Primary Endpoint Analyses 14
7. Directions for Use **19**
7.1 Stent Delivery System Preparation 19
7.2 Pre-Flush Guide Wire Lumen 19
7.3 Insertion Technique 20
7.4 Stent Deployment 22
7.5 Balloon Deflation and Catheter Removal 23
8. Warranty / Liability **24**
9. Technical Specifications **25**

1. Device Description

The Rithron-XR Coronary Stent System is a coronary stent delivery system, consisting of a coronary stent, the Tenax-XR stent, pre-mounted on a fast exchange PTCA carrier and delivery catheter. The Tenax-XR stent is a tubular slotted, balloon expandable coronary stent sculpted by laser from a single tube of 316L stainless steel and completely coated with amorphous silicon carbide (a-SiC:H).

The carrier and delivery catheter is based on a fast-exchange PTCA catheter. The expansion of the stent is accomplished by a balloon situated at the catheter distal tip. Two radiopaque markers are located at both ends of the balloon; the stent is centered on the expansion balloon between the markers to facilitate fluoroscopic visualization and positioning. The inner distal lumen of the catheter permits the use of guide wires of 0.014" or smaller to facilitate advancement of the catheter to and through the lesion(s) to be treated. The guide wire lumen starts at the catheter tip and ends at the guide wire exit port (28 cm from the distal end). The coronary stent delivery system is compatible with guiding catheters with an inner diameter of ≥ 0.055".

Exit markers are located 92 cm (brachial technique) and 102 cm (femoral technique) from the distal end of the catheter. The coronary stent is delivered to the intended implantation location by means of the fast exchange delivery catheter and then expanded to its final diameter by dilating the balloon. The stent remains in the vessel as a permanent implant. To facilitate the catheter handling, a "click-in" hypotube fastener has been applied to the catheter hub. This should be used when the system is stored on the preparation table.

NOTE:

This fastener is intended to hold only the hypotube section of the catheter. The distal shaft should not be held by the "click-in" fastener.

2. Indications for Use

The Rithron-XR Coronary Stent System is indicated for use in patients eligible for balloon angioplasty with symptomatic ischemic heart disease characterized by discrete de novo coronary artery lesions with reference vessel diameter from ≥ 3.0 mm to ≤ 4.0 mm, the target lesion length is ≤ 20.0 mm.

3. Contraindications

The use of the Rithron-XR premounted Coronary Stent System, and stent implantations in general, is contraindicated for use in:

- patients in whom antithrombogenic and anticoagulant therapy is contraindicated;
- patients who exhibit stenoses that inhibit the complete inflation of an angioplasty balloon;
- patients who are allergic to stainless steel, gold, or silicon carbide, or exhibit incompatibility with the coating material (amorphic silicon carbide).

4. Warnings and Precautions

4.1 Warnings

- Do not attempt to remove or readjust the stent on the delivery system. The stent cannot be removed and placed on another balloon catheter.
- The appropriate anticoagulation and/or antiplatelet therapy should be used due to the risk of subacute thrombosis, vascular complications, and/or bleeding events.
- When multiple stents are required, stent materials should be of similar composition.
- Subsequent restenosis may require repeat dilation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of coronary stents is presently unknown.

4.2 Precautions

4.2.1 General Precautions

- Only physicians thoroughly trained and educated in the performance of percutaneous transluminal coronary angioplasty (PTCA) and stent implantation should use this device.
- PTCA and stent implantation are recommended only at hospitals where emergency coronary artery by-pass can be immediately performed in the event of a potential injury or life-threatening complication. A cardiac surgery team should be on standby when an interventional procedure is being performed.
- Do not use the stent system if the outer or the inner package is damaged or opened.
- Use only guide wires with a maximum 0.014" diameter. Use within guiding catheters with an inner diameter of ≥ 0.055".

4.2.2 Stent Handling

- Use prior to the "use before" date.
- Store in a dark, cool and dry place.
- Exercise care during handling to reduce the possibility of disrupting the delicate placement of the stent on the balloon, accidental breakage, bending or kinking of the catheter shaft.
- This device is designed and intended for single use only. Do NOT resterilize and/or reuse.
- Prior to procedure, the system should be visually examined to verify function and ensure that its size is suitable for the specific procedure for which it is to be used.
- Do not expose the stent system to organic solvents, e.g. alcohol.

4.2.3 Stent Placement

- Do not prepare or pre-inflate balloon prior to stent deployment other than as directed.
- Do not expand the stent if it is not properly positioned in the vessel.
- The inflated diameter of the balloon should never exceed the original diameter of the vessel proximal and distal to the lesion.
- Balloon pressure should not exceed the Rated Burst Pressure. Use of a pressure-monitoring device is mandatory to prevent over-pressurization.
- Use only an appropriate balloon inflation medium (e.g. 50:50 mixture by volume of contrast medium and saline). Never use air or any gaseous medium to inflate the balloon.
- When the catheter is in the body, it should be manipulated while under sufficient and/or high quality fluoroscopy.

4.2.4 Stent System Removal

If strong resistance is met during manipulation, stop the procedure and determine the cause of resistance before proceeding. If the stent cannot be deployed, the entire system and the guiding catheter should be removed as one unit; do not attempt to retrieve the stent back through the guiding catheter; dislodgment of the stent may result.

4.2.5 Post Implantation

The use of mechanical atherectomy devices or laser catheter is not recommended in the stented area.

4.2.6 Magnetic Resonance Imaging (MRI)

Nonclinical testing at field strengths of 1.5 T or less, and a maximum spatial gradient of 2.3 gauss/cm, showed that the Rithron-XR stent should not migrate in this MR environment. This device has not been evaluated for heating in the MR environment. MR imaging quality may be compromised if the area of interest is in exact same area or relatively close to the position of the stent. This stent has not been evaluated to determine if it is safe in MRI systems with field strength greater than 1.5 Tesla.

5. Adverse Events

5.1 Observed Adverse Events

A total of 250 patients were enrolled in the Rithron-XR Stent System US Registry, a prospective, multi-center, consecutive, non-randomized registry study. The control group from the European TRUST Randomized Trial served as the control group.

Table 1: Reported Adverse Events

MACE	#	% (N)
TVR Free at 180 days	237	94.6% (251)
TVF Free at 180 days	232	92.6% (251)
In-Hospital Complications		
MACE (Death, MI, Emergent CABG, TLR)	4	1.6% (250)
Death	0	0.0% (250)
Q-wave MI	0	0.0% (250)
Non-Q-wave MI	4	1.6% (250)
Emergent CABG	0	0.0% (250)
Target Lesion Revascularization (TLR)	0	0.0% (250)
Target Vessel Revascularization, non TLR	0	0.0% (250)
Bleeding Complication	0	0.0% (250)
Cerebrovascular Accident (CVA)	0	0.0% (250)
Vascular Complication	3	1.2% (250)

Out-of-Hospital Complications (up to 180 days)		
MACE (Death, MI, Emergent CABG, TLR)	14	5.8% (241)
Death	3	1.2% (241)
Q-wave MI	0	0.0% (241)
Non-Q-wave MI	0	0.0% (241)
Emergent CABG	0	0.0% (241)
Target Lesion Revascularization (TLR)	1	0.4% (241)
Target Vessel Revascularization, non TLR	3	1.3% (240)
Bleeding Complication	0	0.0% (240)
Cerebrovascular Accident (CVA)	0	0.0% (240)
Vascular Complication	1	0.4% (240)
Out-of-Hospital Complications (up to 360 days)		
MACE (Death, MI, Emergent CABG, TLR)	29	12.7% (229)
Death	4	1.7% (229)
Q-wave MI	0	0.0% (229)
Non-Q-wave MI	0	0.0% (229)
Emergent CABG	0	0.0% (229)
Target Lesion Revascularization (TLR)	3	1.3% (229)
Target Vessel Revascularization, non TLR	6	2.7% (226)
Bleeding Complication	0	0.0% (226)
Cerebrovascular Accident (CVA)	0	0.0% (226)
Vascular Complication	1	0.4% (226)

MACE – Death, MI, emergent CABG, or target lesion revascularization.

Cerebrovascular Accident (CVA) – Sudden onset of vertigo, numbness, aphasia, or dysarthria due to vascular lesions of the brain such as hemorrhage, embolism, thrombosis, or rupturing aneurysm, that persisted >24 hours.

5.2 Potential Adverse Events

Possible complications include, but are not limited to:

- Death
- Acute myocardial infarction
- Cardiac dysrhythmia (ventricular fibrillation)
- Injury to the coronary artery wall, Intimal tear
- Arteriovenous fistula
- Pseudoaneurysm formation
- Hypo/hypertension
- Angina
- Dissection
- Stroke / CVA
- Myocardial ischemia
- Incomplete stent apposition
- Coronary artery spasm
- Restenosis of the dilated artery
- Total occlusion of the coronary artery
- Emergency CABG
- Infection
- Hemorrhage or hematoma
- Embolism
- Thrombosis
- Allergic reactions
- Cardiac tamponade
- Stent embolization
- Fever
- Stent migration

6. Clinical Study

6.1 Purpose

The Rithron-XR Stent System US Registry (#G000119) was a prospective, multi-center, consecutive, non-randomized registry study designed to assess the safety and effectiveness of the Rithron-XR Coronary Stent System in the treatment of single *de novo* lesions in native coronary arteries.

6.2 Conclusions

The data received and analyzed from the Rithron-XR Stent System US Registry study demonstrate the safety and effectiveness of the Rithron-XR Coronary Stent System when analyzed individually and when compared to the control arm of the TRUST randomized study. The clinical data, therefore, provides assurance that the Rithron-XR Coronary Stent System is safe and effective in the treatment of single *de novo* lesions in native coronary arteries as specified in the Indications for Use.

6.3 Study Design

The Rithron-XR Stent System US Registry was a prospective, multi-center, consecutive, nonrandomized registry. The study enrolled 250 patients from 17 clinical sites in the US and Canada. Enrollment in the Rithron-XR Stent System US Registry was completed in March 2002.

Patients enrolled in the study met the following criteria:

- Planned single lesion/single stent treatment in a de novo native coronary artery, with the target vessel reference site between 3.0 mm and 4.0 mm in diameter and a target lesion length ≤20 mm by visual estimates
- Target lesion in a native coronary artery with greater than or equal to 50% and less than 100% stenosis
- The patient or guardian provided written informed consent using a form that was reviewed and approved by the Human Investigational Review Board of the respective clinical site.

Patients were excluded if any of the following criteria were met:

- The patient was not an acceptable candidate for emergent coronary artery bypass surgery
- The patient had a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine, clopidogrel, stainless steel or a sensitivity to contrast media, which could not be adequately pre medicated
- The patient had left ventricular ejection fraction of <30%
- The patient had a myocardial infarction within the last 48 hours, or in the investigators' opinion, the patient was currently experiencing a myocardial infarction
- The patient suffered a stroke or transient ischemic neurological attack (TIA) within the past 12 months
- The patient suffered an episode of ventricular tachycardia resulting in syncope within the last 6 months.

The control arm from the European TRUST Randomized Trial acts as the control group for the US IDE registry. The TRUST Randomized Trial was designed as a randomized, prospective, multi-center study to evaluate the safety and efficacy of the Tenax-XR silicon carbide coated stent (the same stent used in the Rithron-XR Coronary Stent System) in comparison with commercially available "bare metal stents". The study enrolled 485 patients (238 study devices and 247 control devices) at 38 study sites in Europe and Canada. Data from the control arm of the TRUST Randomized Trial was compared and adjudicated to the endpoints, hypothesis, definitions, and procedures of the Rithron-XR Stent System US Registry. Statistical comparisons of the endpoints were made once the differences between the Rithron XR Stent System US Registry and the TRUST Randomized Trial were adjusted.

The TRUST control arm represents contemporary stenting outcomes and is statistically more flexible than a historical control (referred to as an OPC, Objective Performance Criterion). This flexibility is derived from using the entire dataset of the TRUST control arm for case-mix adjustment of unique patient characteristics of the Rithron-XR Stent System US Registry that may affect the estimates of safety and efficacy endpoints. Moreover, all stents used in the TRUST trial control arm are balloon expandable stainless steel stents that were legally marketed in the U.S., Canada, or European Union.

6.3.1 Primary Endpoint

The primary endpoint for which this trial was powered was Target Vessel Failure (defined as the combined clinical endpoint of cardiac death, recurrent myocardial infraction or clinical driven repeat revascularization of the target vessel) at 6 months after the index procedure as compared to the control group from the European TRUST Randomized Trial.

6.3.2 Secondary Safety Endpoints

The secondary safety endpoints investigated in this trial included:

Major Adverse Cardiac Events (MACE), defined as a combined clinical endpoint which includes death, Q wave or non Q wave MI, emergent bypass surgery, or repeat target lesion revascularization, 30 days and 6 months after stent placement, and in the incidence of vascular and bleeding complications

6.3.3 Secondary Efficacy Endpoints

The secondary efficacy endpoints that were investigated in this trial included rates of device success, lesion success, procedure success. Additionally, the minimal lumen diameter (in stent and in lesion) post-procedure and 180 days after the index procedure, and angiographic binary restenosis (≥ 50% diameter stenosis) 180 days after the index procedure were also included.

6.4 Patient Demographics

The Rithron-XR Stent System US Registry involved 250 patients, of which 188 were male (75.2%) and 62 were female (24.8%) with a mean age of 62.1 years (range: 37 – 84 years). The majority of patients presented with a history of hypertension requiring medication (64.5%) and with a single major native coronary > 50% stenosed (68.2%).

6.5 Clinical Study Results

6.5.1 Statistical Adjustments for Baseline and Demographic Characteristics

Prior to comparing the results of the Rithron-XR Stent System US Registry to the TRUST Control group on the incidence of MACE and TVF, baseline and demographic characteristics were compared between the two groups to assess comparability. The prevalence of smokers was significantly lower in Rithron-XR than in TRUST Control (19.0% vs. 30.0%; p=0.006). Other than this risk factor, the Rithron-XR patients generally had significantly more co-morbidities than did the TRUST Control patients. Specifically, the Rithron-XR patients were older, though not significantly, by an average of 1.2 years (p=0.201). Rithron-XR patients had a significantly higher prevalence of history of diabetes, history of hypertension requiring medication, history of dyslipidemia requiring medication, (p<0.001 for all), and history of CABG (p=0.025). In addition, Rithron-XR patients had significantly more major native coronaries >50% stenosed (p=0.011) and a significantly lower ejection fraction (p<0.001) than did the TRUST Control patients.

With regard to baseline lesion characteristics, the Rithron-XR patients had significantly lower mean percent diameter stenosis (67.70% versus 74.85%; p<0.001) and significantly larger mean minimal lumen diameter (0.92 mm vs. 0.74 mm; p<0.001) than did TRUST Control patients. Rithron-XR patients had significantly less prevalence of LAD as the target lesion vessel than did the TRUST Control group (38.2% vs. 49.4%; p=0.014).

All baseline demographic and lesion characteristics that were found to be significantly different between the two groups were included as covariates in the analysis comparing the groups using multivariate regression techniques.

6.5.2 Primary Endpoint Analyses

Safety and effectiveness was measured as the combined clinical endpoint of target vessel failure (TVF, defined as the combined clinical endpoint of cardiac death, recurrent myocardial infarction or clinically driven repeat revascularization of the target vessel) 6 months after the index procedure. The observed TVF rate in this registry was compared to the control arm of the TRUST Randomized Trial.

The primary analysis was based on a case-mix analysis as discussed in the protocol, which yielded similar results as the direct comparison of Rithron-XR and TRUST. The focus of the case-mix analysis was to compare Rithron-XR Stent System US Registry vs. TRUST (all patients) on 180-day TVF by first determining an objective performance criterion (OPC), or an expected 180-day TVF rate for Rithron-XR patients, using TRUST data. As stated in the protocol, this was to be performed by first relating TRUST baseline demographic and lesion characteristics to 180-day TVF in TRUST by a multivariate regression model (Cox Proportional Hazards regression was used in order to account for censoring) and then plugging in baseline characteristics of Rithron-XR patients into this TRUST-based model to determine the OPC. Once an OPC was determined, a non-inferiority analysis of the true Rithron-XR 180-day TVF rate was to be statistically compared to this OPC. The resulting model led to an OPC of 7.5% at 180 days. A delta of 4% was applied for the analysis of non-inferiority.

From the Rithron-XR Stent System US Registry report, the observed 180-day TVR rate was 7.4% with a two-sided 95% CI of 4.1% to 10.7%. Since the upper bound of this two-sided 95% confidence interval is less than 11.5% (the non-inferiority limit), non-inferiority to the OPC is met.

The Kaplan-Meier estimates of freedom from TVF and freedom from MACE at 180 days were 92.5% and 93.1%, respectively for the Rithron-XR Stent System US Registry patients. The device success rate in these patients was 97.2% (244/251). The lesion success rate was 100% (251/251). The overall procedure success rate was 98.4% (246/250).

Comparisons of safety and effectiveness outcomes through 180 days between Rithron-XR Stent System US Registry patients and TRUST Control patients are presented in Table 2, Table 3, and Table 4.

Table 2: Safety and Effectiveness Results (up to 180 days)

	Rithron-XR (N=250 Pts N=251 Lesions)	TRUST (Control Group) (N=247 Patients N=247 Lesions)	Difference [95% CI]	P-value
Effectiveness Measures				
Lesion Success	100% (251/251)	100.0% (247/247)	0.0% [--, --]	N/A
Device Success	97.2% (244/251)	100.0% (247/247)	-2.8% [-4.8%, -0.8%]	0.015
Procedure Success	98.0% (245/250)	98.8% (244/247)	-0.4% [-2.5%, 1.7%]	1.000
TLR-Free at 180d	95.4%	93.8%	1.6% [-2.4%, 5.6%]	0.422
TVR-Free at 180d	94.6%	93.9%	0.8% [-3.4%, 4.9%]	0.694
TVF-Free at 180d	92.6%	93.5%	-0.8% [-5.4%, 3.7%]	0.744
MACE-Free at 180d	93.1%	93.5%	-0.4% [-4.9%, 4.1%]	0.879
Safety Measures and Other Clinical Events				
In-Hospital MACE	1.6% (4/250)	1.2% (3/247)	0.4% [-1.7%, 2.5%]	1.000
Out-of-Hospital MACE	5.8% (14/241)	5.3% (13/243)	0.5% [-3.6%, 4.5%]	0.846
MACE	7.1% (17/241)	6.6% (16/243)	0.5% [-4.0%, 5.0%]	0.859
Target Vessel Failure (TVF)	7.5% (18/241)	6.6% (16/243)	0.9% [-3.7%, 5.4%]	0.726
Bleeding Complication	0.0% (0/240)	0.0% (0/242)	0.0% [--, --]	N/A
Vascular Complication	1.7% (4/240)	0.0% (0/242)	1.7% [0.0%, 3.3%]	0.061
Cerebrovascular Accident (CVA)	0.0% (0/240)	0.0% (0/242)	0.0% [--, --]	N/A

Table 3 provides an analysis of Minimal Luminal Diameter (MLD) for both the in-stent and in-lesion target vessels. MLD is defined as the mean minimum lumen diameter derived from two orthogonal views by quantitative coronary angiography laboratory.

Table 3: Minimal Luminal Diameter Analysis

	RESULTS
Post-Procedure In-Stent Minimal Lumen Diameter (MLD, in mm)	
Mean ± SD (N)	2.80 ± 0.40 (248)
Range (min,max)	(1.71, 4.34)
Post-Procedure In-Lesion Minimal Lumen Diameter (MLD, in mm)	
Mean ± SD (N)	2.53 ± 0.47 (249)
Range (min,max)	(1.12, 4.35)
6-month Follow-up In-Stent Minimal Lumen Diameter (MLD, in mm)	
Mean ± SD (N)	2.02 ± 0.66 (198)
Range (min,max)	(0.00, 3.56)
6-month Follow-up In-Lesion Minimal Lumen Diameter (MLD, in mm)	
Mean ± SD (N)	1.90 ± 0.62 (198)
Range (min,max)	(0.00, 3.47)

Table 4 provides an analysis of in-stent binary restenosis (≥ 50% diameter stenosis) at 6 months after the index procedure for the Rithron-XR stent. If an in-stent measurement was not available, the in-lesion diameter was used in this analysis. The results of the binary restenosis are within the clinically acceptable ranges for stents.

Table 4: Binary Restenosis Analysis

	RESULTS
Post-Procedure In-Stent Percent Diameter Stenosis (% DS) Mean ± SD (N) Range (min,max)	 6.75 ± 7.63 (248) (-14.72, 35.78)
Post-Procedure In-Lesion Percent Diameter Stenosis (% DS) Mean ± SD (N) Range (min,max)	 16.07 ± 8.51 (249) (4.07, 53.72)
6-month Follow-up In-Stent Percent Diameter Stenosis (% DS) Mean ± SD (N) Range (min,max)	 26.79 ± 19.99 (198) (-16.89, 100.00)
6-month Follow-up In-Stent Binary Restenosis	14.6% (29 / 198)

7. Directions for Use

The stent should be deployed after the target lesion has been predilated using a PTCA catheter. Remove the initial PTCA catheter from the coronary system taking care to preserve the coronary guide wire position.

7.1 Stent Delivery System Preparation

1. Remove the stent delivery system and protection ring from the package and place it onto a sterile field.
2. Gently pull out the catheter from the protection ring.
3. Carefully remove the stylet and the balloon/stent protector by pulling on the very distal end of the stylet and protector.
4. Visually check the stent crimping, for uniformity, no protruding struts, and centering on the balloon.

7.2 Pre-Flush Guide Wire Lumen

5. Connect a syringe containing sterile saline to the attached "flushing needle". Apply the needle into the distal tip of the catheter and flush guide wire lumen.
6. Remove the syringe and the "flushing needle".
7. Avoid manipulation of the stent during removal from packaging and flushing of guide wire lumen.
8. Leave the prepared stent delivery system at ambient pressure.

CAUTION

Do not apply negative pressure to the catheter prior to placement of the stent across the lesion. This may cause premature dislodgment of the stent.

7.3 Insertion Technique

9. Attach a hemostatic valve to the Luer-port of the guiding catheter positioned within the vasculature.
10. Position the guide wire, under fluoroscopy, in accordance with PTCA techniques.
11. Back load the proximal end of the guide wire, into the distal tip of the catheter until it exits at the guide wire exit port 28 cm from the distal tip.
12. Carefully insert stent delivery system through the hemostatic valve and advance the system.

NOTE:

Make sure that the hemostatic valve is completely open before inserting the delivery system, since a partially opened valve might damage the stent or dislodge it from the centered location on the dilation balloon.

13. Advance the stent system through the guiding catheter using fluoroscopic guidance to determine when the catheter tip approaches the distal tip of the guiding catheter.

NOTE:

The shaft exit markers may be used to approximate when the catheter has reached the distal end of the guiding catheter.

14. Very carefully advance the stent delivery system into the coronary vasculature following the guide wire towards the lesion.
15. Position the stent within the lesion using the balloon radiopaque markers as reference points.

CAUTION

Do not attempt to pull an unexpanded stent back through the guiding catheter. It might be dislodged from the dilation balloon and cause distal embolization. If you feel any resistance when the catheter is pushed out of the end of the guiding catheter, be sure to determine the cause. If you cannot determine and eliminate the cause, then retract the entire system (guide wire, delivery system and guiding catheter) together, all at the same time as one unit.

7.4 Stent Deployment

16. Connect a syringe containing 3 ml of contrast medium to the connector at the proximal end of the catheter and apply negative pressure for about 15 seconds until no bubbles appear in the contrast medium solution. Return to neutral pressure allowing contrast media flow into the catheter lumen. Remove the syringe leaving a meniscus of contrast in the hub of the balloon lumen.
17. Prepare and remove air from inflating device according to manufacturer's recommendations and instructions.
18. Using a stopcock attach the inflation device to the stent delivery system. Avoid air entering the system.
19. Open stopcock on inflation device. Inflate the dilation balloon gradually to expand the stent to the calculated diameter in accordance with the compliance chart. Apply a constant pressure for at least 30 seconds.
20. Expanding the stent to a vessel diameter/stent diameter ratio of 1:1.15 is recommended.

CAUTION

Do not exceed Rated Burst Pressure (RBP).

NOTE:

Use multiple fluoroscopy views to ensure that the stent has been completely expanded.

21. Inflate the balloon once more in order to achieve optimum seating of the implanted stent.
22. If post dilatation seating is required, a non-compliant high-pressure balloon catheter can be used. The maximum size of the balloon should never exceed 4.0 mm.

7.5 Balloon Deflation and Catheter Removal

23. Deflate the balloon in accordance with standard PTCA procedures. Apply negative pressure to the balloon for at least 30 sec. before pulling carefully the catheter out of the vessel.
24. If the balloon cannot be withdrawn easily, rotate the catheter in a clockwise direction very carefully as you pull it out.
25. Observation of the patient and angiographic evaluation should be performed periodically in the 15 minutes after stent implantation.

8. Warranty / Liability

The product and each component of its system (hereinafter "the product") have been designed, manufactured, tested and packaged with all reasonable care. However, BIOTRONIK has no control over the conditions under which the product is used and a disturbance of the intended function of the product may occur for various reasons. In this respect, the warnings in this product publication/ instructions for use are expressly to be considered as an integral part of this Disclaimer and provide more detailed information. For this reason, BIOTRONIK disclaims all warranties, expressed or implied regarding the product, including but not limited to, any warranty of merchantability or fitness for a particular purpose of the product. Product descriptions or user guidelines in publications do not constitute any expressed representation or any expressed or implied warranty. BIOTRONIK is not liable for any direct, incidental or consequential damages or medical expenses caused by any use, defect, failure or malfunction of the product whether the claim is based on contract, warranty, tort or otherwise. This does not apply in the case of intention or in the case of gross negligence of legal representatives or executive staff of BIOTRONIK. In commercial transactions relating to merchants, the liability is limited to the compensation of typical damages; compensation for any untypical or incidental damage is excluded. These limitations of liability and warranty are not intended to contravene any mandatory provisions of law applicable in the respective country. If any clause of the Disclaimer is considered by a competent court to be invalid or to be in conflict with the applicable law, the remaining part of it shall not be affected and remain in full force and effect. The invalid clause shall be substituted by a valid clause which best reflects BIOTRONIK's legitimate interest in limiting its liability or warranty without infringing any mandatory provisions of applicable law. No person has any authority to bind BIOTRONIK to any warranty or liability regarding the product.

9. Technical Specifications

Shortening Table			
C-STENT ⌀/⌀ (mm)	3.0/3.16	3.5/3.66	4.0/4.16
⊢ ⊣ Before Dilatation	⊢ ⊣ After Dilatation		
10	9.6	9.6	9.6
15	14.6	14.6	14.5
20	19.6	19.6	19.5

Compliance Chart

P Atm	BALLOON ⌀ = C-STENT ⌀				C-STENT ⌀		
	3.0 mm	3.5 mm	4.0 mm		3.0 mm	3.5 mm	4.0 mm
1.97	2.74	3.18	3.68		2.90	3.34	3.84
2.96	2.82	3.27	3.79		2.98	3.43	3.95
3.95	2.90	3.36	3.88		3.06	3.52	4.04
4.93	2.95	3.44	3.94		3.11	3.60	4.10
5.92	3.00	3.50	4.00	NP	3.16	3.66	4.16
6.91	3.04	3.54	4.05		3.20	3.70	4.21
7.89	3.07	3.58	4.10		3.23	3.74	4.26
8.88	3.11	3.62	4.17		3.27	3.78	4.33
9.87	3.14	3.66	4.23		3.30	3.82	4.39
10.86	3.18	3.70	4.30		3.34	3.86	4.46
11.84	3.22	3.75	4.37	RBP	3.38	3.91	4.53
12.83	3.26	3.80	[illegible]		3.42	3.96	[illegible]
13.82	3.31	3.86	[illegible]		3.47	4.02	[illegible]
14.80	[illegible]	[illegible]	[illegible]		[illegible]	[illegible]	[illegible]
15.79	[illegible]	[illegible]			[illegible]	[illegible]	
16.78	[illegible]	[illegible]			[illegible]	[illegible]	

NP	In vitro testing has shown that the balloons will reach their nominal size at given Nominal Pressure.
RBP	In-vitro testing has shown that with 95 % confidence, 99.9 % of the balloons will not burst at or below Rated Burst Pressure.

Minimum Inner Diameter of Guiding Catheter = 0.055

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