DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

P960010

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 1997

Mr. Timothy J. Johnson
Regulatory Affairs Manager
Medtronic Interventional Vascular, Inc.
9410 Carroll Park Drive
San Diego, California 92121-2256

Re: P960010
Medtronic Wiktor® Prime Coronary Stent Delivery System
Filed: May 1, 1996
Amended: August 9, October 15, November 26 and 27, 1996, February 3, April 14, May 9, and 27, and June 9, 1997

Dear Mr. Johnson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Medtronic Wiktor® Prime Coronary Stent Delivery System. This device is indicated for the treatment of abrupt or threatened closure in patients with failed interventional therapy in native coronary arteries and bypass graft vessels with reference diameters in the range of 3.0 to 4.5 mm. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Expiration dating for this device has been established and approved at two years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

In addition under section 522(a) of the act manufacturers of certain types of devices identified by the act or designated by FDA are required to conduct postmarket surveillance studies. FDA has identified under section 522(a)(1)(A) the above noted device as requiring postmarket surveillance.

Upon approval and within thirty (30) days of first introduction or delivery for introduction of this device into interstate commerce you will be required to submit to FDA certification of the date of introduction into interstate commerce, a detailed protocol which describes the postmarket surveillance study, and a detailed profile of the study's principal investigator that clearly establishes the qualifications and experience of the individual to conduct the proposed study. For your information, general guidance on preparing a protocol for a postmarket surveillance study is enclosed.

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At that time you should submit five (5) copies to:

Postmarket Studies Document Center
1350 Piccard Drive (HFZ-544)
Rockville, Maryland 20850

Within sixty (60) days of receipt of your protocol, FDA will either approve or disapprove it and notify you of the Agency's action in writing. Do not undertake a postmarket surveillance study without an FDA approved protocol.

Failure to certify accurately the date of initial introduction of your device into interstate commerce, to submit timely an acceptable protocol, or to undertake and complete an FDA approved postmarket surveillance study consistent with the protocol, will be considered violations of section 522.

In accordance with the Medical Device Amendments of 1992, failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the act(21 U.S.C. 331(q)(1)(C)). Further, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties or other FDA enforcement actions including (but not limited to) withdrawal of your PMA.

If you have any questions concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch, at (301) 594-0639.

Under section 519(e) of the act (as amended by the Safe Medical Devices Act in 1990), manufacturers of certain devices must track their products to the final user or patient so that devices can be located quickly if serious problems are occurring with the products. The tracking requirements apply to (1) permanent implants the failure of which would be reasonably likely to have serious adverse health consequences; (2) life sustaining or life supporting devices that are used outside of device user facilities the failure of which would be reasonably likely to have serious adverse health consequences; and (3) other devices that FDA has designated as requiring tracking. FDA believes that your device is a device that is subject to tracking because it is a permanent implant whose failure would be reasonably likely to have serious adverse consequences.

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FDA's tracking regulations, published in the FEDERAL REGISTER on August 16, 1993, appear at 21 CFR Part 821. These regulations set out what you must do to track a device. In addition, the regulations list example permanent implant and life sustaining or life supporting devices that FDA believes must be tracked at 21 CFR § 821.20(b) and the devices that FDA has designated for tracking at 21 CFR § 821.20(c). FDA's rationale for identifying these devices is set out in the FEDERAL REGISTER (57 FR 10705-10709 (March 27, 1991), 57 FR 22973-22975 (May 29, 1992), and 58 FR 43451-43455 (August 16, 1993)). Pursuant to 21 CFR § 821.20(d), FDA will be adding coronary stents to these lists by publishing a notice in the FEDERAL REGISTER announcing that FDA believes that this device is subject to tracking under section 519(e)(1). This notice will also solicit public comments on FDA's determination.

If you have questions concerning this approval order, please contact Judy Danielson at (301) 443-8243.

Sincerely yours,

Susan Alpert

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Issued: 5-2-95

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 240
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Medtronic Wiktor® Prime Coronary Stent Delivery System

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SUMMARY of SAFETY and EFFECTIVENESS DATA

1. GENERAL INFORMATION

Device Generic Name:	Intravascular Stent
Device Trade Name:	Medtronic Wiktor® Prime Coronary Stent Delivery System
Applicant's Name:	Medtronic Interventional Vascular, Inc. 9410 Carroll Park Drive San Diego, CA 92121
PMA Number:	P960010
Date of Notice of Approval to the Applicant:	June 27, 1997

2. INDICATIONS FOR USE

The Medtronic Wiktor® Prime Coronary Stent Delivery System (hereinafter called the Wiktor® Coronary Stent System) is indicated for the treatment of abrupt or threatened closure in patients with failed interventional therapy in native coronary arteries and bypass graft vessels with reference diameters in the range of 3.0 to 4.5 mm. Long term outcome (beyond one year) for this permanent implant is unknown at present.

3. CONTRAINDICATIONS

Wiktor® Coronary Stents are 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

4.1 Warnings

Since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events, judicious selection of patients is necessary.

4.2 Precautions

Implantation of the stent should be performed only by physicians who have received appropriate training. Appropriate training consists of attendance at a stent training workshop, or specific training in coronary stenting techniques and procedures under the supervision of an interventional cardiologist experienced in coronary stent implantation.

Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.

Subsequent restenosis may require redilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized Wiktor® Coronary Stents is unknown at present.

4.2.1 Stent Handling - Precautions

For single use only. Do not resterilize or reuse. Note product "Use Before" date.

Do not remove stent from its delivery balloon as removal may damage the stent and/or lead to stent embolization.

Special care must be taken not to handle or in any way disrupt the helical wave form of the stent loops on the balloon. This is most important during catheter removal from packaging, placement over guide wire and advancement through hemostasis valve adapter and guiding catheter hub.

Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.

Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

4.2.2 Stent Placement - Precautions

Do not prepare or pre-inflate balloon prior to stent deployment. Use balloon purging technique described in the Instructions for Use.

Balloon pressures should be monitored during inflation. Do not exceed rated burst pressure as indicated on product label. Use of pressures higher than specified on product label may result in a ruptured balloon with possible intimal damage and dissection.

Do not expand the stent if it is not properly positioned in the vessel.

Do not attempt to pull an unexpanded stent back through the guiding catheter, dislodgment of the stent from the balloon may occur.

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 (further dilatation, placement of additional stents or coronary artery bypass surgery).

Do not place a stent in the aorta-ostial location because of a high risk of damage and/or dislodgment by a coronary guiding catheter.

Placement of a stent has the potential to compromise side branch patency.

Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

4.2.3 Post Stent Placement - Precautions

Use of mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser angioplasty catheters is not recommended in vessel segments already stented.

Avoid use of short monorail length intravascular ultrasound (IVUS) catheters because they may damage the stent.

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.

5. *DEVICE DESCRIPTION*

The Wiktor® Coronary Stent System is comprised of two components: the Wiktor® Coronary Stent and the balloon delivery catheter. The stent is a radiopaque wire formed into a sinusoidal wave pattern and wound into a helical configuration. It is made of biologically inert tantalum 0.005 inch diameter wire and is intended as a permanent implant in a coronary artery or bypass graft vessel. Tantalum has a low magnetic susceptibility. It is not affected by magnetic fields produced by magnetic resonance imaging (MRI) equipment, and does not cause significant artifacts in MRI scans.

The Wiktor® Coronary Stent is supplied premounted on 4.3F diameter balloon delivery catheter with a working length of 135 cm. The balloon catheter design is consistent with other commercially available percutaneous transluminal coronary angioplasty (PTCA) catheters. The balloon at the distal end is 25 mm in length. A centrally located, radiopaque marker band is within the balloon for visualization under fluoroscopy. The inner lumen of the catheter will accommodate a 0.018 inch guide wire. To ensure adequate visualization of the coronary vasculature with contrast media, the Wiktor® Coronary Stent System should be used with guiding catheters that have a minimum inner diameter of 0.083 inches or 2.1 mm.

6. *ALTERNATIVE PRACTICES OR PROCEDURES*

Alternative practices specific to the treatment of abrupt or threatened closure of a coronary artery or bypass graft vessel are repeat PTCA (either conventional or with an autoperfusion balloon), medication (e.g., thrombolysis), atherectomy, and emergency coronary bypass graft surgery.

7. *MARKETING HISTORY*

The Wiktor® Coronary Stent System has not been previously marketed in the United States, but is available for commercial sale in the following countries: Australia, Canada, Europe, Hong Kong, India, Latin America, Mexico, Singapore, South Africa and Japan.

The Wiktor® Coronary Stent System has not been withdrawn from marketing for any reason relating to the safety and effectiveness of the device.

8. *ADVERSE EFFECTS OF THE DEVICE ON HEALTH*

Three hundred seventy-three (373) patients were enrolled in an open multicenter clinical trial to evaluate the use of the Wiktor® Coronary Stent for treatment of abrupt or threatened closure in native coronary or bypass graft vessels. These patients form the basis for the observed events reported.

Fifteen patients in the clinical study died within 30 days of receiving the stent implant. Another patient died in the hospital 43 days following the stent implant procedure. Death in these 16 patients was due to: pulmonary embolism following coronary artery bypass (CABG) surgery (n=1), multisystem failure (n=7), exsanguination after retroperitoneal bleed with refusal of blood products (n=1), cardiac or cardiopulmonary arrest (n=2), cardiac arrest following CABG (n=1), vessel occlusion (n=1), vessel occlusion following CABG (n=1), MI with hemodynamic instability (n=1) and intracranial hemorrhage (n=1).

8.1 Observed Adverse Events

Table 1. Observed Adverse Events
Number (percent) of patients with the event at 30 days and 1 year

Adverse Event (in order of severity)	<30 days (n=373)	< 1 year (n=369) cumulative (includes <30 days)
Death	15 (4%)*	36 (9%)
Coronary artery bypass graft surgery (CABG)	32 (9%)**	75 (20%)
Myocardial infarction (MI)	57 (15%)	66 (18%)
Cerebrovascular Accidents	4 (1.1%)	5 (1.3%)
Thrombosis / Stent Occlusion ***	28 (8%)	-
Bleeding Complications - Access Site		
Hematoma - Requiring Surgery	20 (5%)	-
- Requiring Transfusion	25 (7%)	-
Pseudoaneurysm - Requiring Surgery	14 (4%)	-
- Requiring Transfusion	8 (2%)	-

*One additional patient died in hospital at 43 days
**Emergent CABG only
***Thrombosis / Stent Occlusion < 24 hours = 20 (5%)

Thrombosis/occlusion occurred in about 8% of patients, most commonly within one week after implantation. Subacute thrombosis is rare after routine PTCA. Thrombosis following stent implantation was associated with baseline angiographic and procedural factors including: vessel diameter <3 mm, intraprocedural thrombus, and dissection remaining following stent implantation.

8.2 Potential Adverse Events

Adverse events associated with the use of a coronary stent in native coronary or bypass grafts but not seen in this study may include (in order of severity):

- Death
- Coronary artery bypass graft surgery
- Myocardial infarction
- Stent thrombosis or occlusion
- Myocardial ischemia
- Arrhythmias (ventricular fibrillation, ventricular
- tachycardia, other)
- Stroke/Cerebrovascular Accidents
- Perforation of a coronary artery
- Emboli (air, tissue or thrombotic emboli)
- Stent embolization
- Hemorrhage requiring transfusion
- Hypotension
- Pseudoaneurysm or hematoma at the vascular access site
- Infection and pain at the vascular access site
- Spasm of a coronary artery

9. *SUMMARY OF STUDIES*

9.1 In Vitro (Laboratory) Studies

9.1.1..Biocompatibility

Wiktor® Coronary Stents are made from tantalum. The biocompatibility of the stent and the delivery catheter were shown to be acceptable. The following tests were performed in accordance with the Tripartite Guidance for Medical Devices and Good Laboratory Practice Regulations.

Cytotoxicity	Sensitization
Hemolysis	Irritation
Ames Mutagenicity	Acute Systemic Toxicity
Muscle Implantation	Chromosomal Aberration
Pyrogen	Sister Chromatid Exchange

9.1.2. Stent Percent Metal/Free Area Testing

Testing was conducted on five stent samples per diameter to assess the percentage in free or open area and the percentage metal surface area of stents at their labeled expanded diameters.

The percent free area values ranged from 90.4% for the 3.0 mm diameter stents, 91.8% for the 3.5 mm diameter stent, to 92.8% for the 4.0 mm and 92.9% for the 4.5 mm diameter stent.

9.1.3. Stent Length/Stent Diameter

Testing was conducted to quantitatively determine the decrease in the length of the stent as a function of stent diameter as the stent goes from the unexpanded to the expanded state. A minimum of 20 stent samples were measured per diameter.

The 3.0 mm system showed the least change (-0.4 mm) in length as the stent went from the unexpanded to expanded state. The 4.5 mm system showed the greatest change (-3.1 mm) in length as the stent was expanded. These results are consistent with the larger stent resulting in the greatest change in length as the stent is expanded.

9.1.4. Stent Uniformity

The uniformity of the expanded stent was tested by measuring 25 inflated stents at three points along the length of the stent. Five stents of each labeled diameter were tested. The stents exhibited less than 0.1 mm deviation from the average stent diameter. It was concluded that the stent expands uniformly.

9.1.5. Stent Radial (Hoop) Strength

Testing was performed to determine the radial force required to initiate elastic deformation (pressure at which deformation is no longer completely reversible) of intact stents which had been expanded to their labeled diameter. Testing was conducted on 40 intact coronary stents (10 of each labeled diameter). The stents were expanded to their labeled diameters, subjected to radial force testing, and the radial or circumferential force required to initiate permanent stent deformation was recorded.

The results indicate that the stent provides an adequate safety factor. The pressure required to deform the diameter of the stent (minimum mean pressure of 224 mm Hg) is two to three times the pressure exerted by estimated arterial spasm pressures.

When extreme pressure was applied to induce permanent stent deformation, the amount of

initial irreversible stent deflection was approximately 0.3 mm. The pressures required to permanently deform the stent were far in excess of what the stent would be exposed to in the vascular system.

9.1.6. Stent Fatigue: Finite Element Analysis

Computer aided finite element analysis was used to predict the stress fatigue life of an expanded stent to the maximum recommended expanded diameter and to a worse case expansion (maximum delivery balloon diameter plus tolerance). The finite element analysis results predicted an infinite fatigue life for all sizes of the stent. Both of these analyses indicated a satisfactory safety factor.

9.1.7. Stent Fatigue: Accelerated

Accelerated fatigue testing was conducted on 25 stents to 390,000,000 cycles. This test period corresponds to the equivalent of 10.3 years. A scanning electron microscope (SEM) at 500X magnification found that the test samples did not exhibit cracking (macro or micro), flaking, peeling or wire degradation when compared to control samples.

9.1.8. Residual Stress Analysis Using X-Ray Diffraction

Testing was conducted to identify the degree of residual stress presented in the tantalum wire as a result of being fabricated into a helical sinusoidal wave. Micro X-ray diffraction of two samples of the fabricated stent and four samples of unformed stent material were performed for analysis of residual stress. The X-ray diffraction for the formed and expanded stents demonstrated measurable but low values for residual stress.

9.1.9. Stent Recoil

Testing was conducted to determine the amount of recoil that may occur in the stent after balloon deflation. Samples of five stents were expanded on each of the four diameter catheter balloons. The balloons were deflated and the stents were removed for measurement of the outside diameter. The average recoil of the stent expanded on the 3.0 mm balloon was 0.3 mm. The average recoil of the stent expanded on the 3.5 mm, 4.0 mm and 4.5 mm balloons was 0.1 mm. The amount of recoil for the stent does not affect the reliability of the device.

9.1.10. Stent Magnetic Resonance Imaging

A review of the literature indicated that tantalum has a low magnetic susceptibility. It is not affected by magnetic fields produced by magnetic resonance imaging (MRI) equipment, and does not cause significant artifacts in MRI scans.

9.1.11 Stent Expansion

Unexpanded stents were examined by SEM at 500X magnification. After stent expansion to the rated burst pressure (RBP), additional SEM analysis of the wire surface and cross-sections was conducted. None of the unexpended or expanded stents exhibited cracking, or other deformation of the wire.

9.1.12. Stent Dimensional Verification

Dimensional analysis of the stent sinusoidal wave showed that the measurements of the wire diameter, wave amplitude, wave radius and wavelength were consistent and met their respective specifications.

9.1.13. Maximum Pressure (Balloon Burst Strength)

The Wiktor® Coronary Stent System balloon burst strength was determined by cyclic inflation and deflation of balloons at increasingly higher pressures until balloon burst. A minimum sample of 47 catheters per balloon diameter was used. Following are the results of this testing:

Balloon Diameter	Mean Burst Pressure (Atm)	Rated Burst Pressure
3.0 mm	13.3	8
3.5 mm	12.0	8
4.0 mm	10.8	7
4.5 mm	10.1	6

9.1.14. Stent Diameter vs Balloon Inflation Pressure (Balloon Compliance)

Testing was conducted to determine the balloon/stent diameter under various inflation pressures. A minimum sample of 47 catheters per balloon diameter was used for this testing. The pressure (atmospheres) necessary to inflate the 3.0, 3.5, 4.0 and 4.5 mm diameter balloons was consistent with the labeled inflation pressure of those balloons.

9.1.15. Bond Strength

The tensile strength of the proximal balloon bond and all adhesive bonds of the stent delivery catheter met their respective in-house specifications (minimum 1.5 pounds). Testing occurred on a minimum sample of 28 catheters per balloon diameter. For all diameters of the delivery catheter, the average tensile strength of the proximal balloon bonds ranged from 3.9 to 7.3 pounds, and the average tensile strength of the adhesive bonds ranged from 5.6 to 9.7 pounds.

9.1.16. Diameter and Profile

Measurements of the shaft outer diameter at three points along the length of the stent delivery catheter shaft were taken to determine the profile. Ten sample catheters were used for the testing. Measurements showed that the catheter shaft diameter was consistent with the labeled diameter of 4.3F nominal (1.42 mm). The diameter range was from 4.22F (1.40 mm) to 4.38F (1.46 mm).

9.1.17. Balloon Inflation and Deflation Times

To determine the inflation and deflation times of the balloon, a minimum of 20 test samples per balloon diameter were inflated and deflated and the time recorded with a digital timer. Results showed that the mean time required for balloon inflation (1.0 to 1.6 seconds) and deflation (4 to 8 seconds) was within specification.

9.1.18. Balloon Deflatability

To determine that the balloon can be completely deflated after delivery of the stent, three balloons of each size were inflated inside a simulated blood vessel of silicone tubing submerged in 37°C water. Each stent was deployed, the balloon deflated, and the catheter withdrawn from the simulated vessel. All test devices were completely deflated and successfully withdrawn without disturbing the deployed stents.

9.1.19. Tip Pulling and Torquing

Testing was conducted on 12 samples to determine the tensile strength of the delivery

catheter distal tip and the ability of the distal tip to withstand torque. The results demonstrated acceptable tensile strength of the distal tip. A minimum of 99 rotations of the device was achieved without tip breakage demonstrating acceptable torque strength.

9.1.20. Crossing Profile

The crossing profile for the stent/balloon was measured on a minimum of 20 samples per balloon size. The measured profiles were in compliance with specifications.

9.1.21. Sterility

The Wiktor® Coronary Stent System is sterilized by a validated 100 percent ethylene oxide (EtO) sterilization process. The validation protocol was based on the EN/IOS/AAMI requirements for both the sterilization equipment and process. Validation results demonstrated that the sterilization process achieved a sterility assurance level of 10^{-6} for the device.

9.1.22 Product/Package Stability Studies

Testing was performed to evaluate the functional stability of the Wiktor® Coronary Stent System and the ability of the package to maintain sterility over a period of two years. Functional stability testing was conducted on 30 samples and included dimensional verification of the stent, balloon deflatability and burst strength, and bond strength of the balloon delivery catheter. Packaging stability was evaluated through tensile testing and a microbial challenge of 30 packages aged over a two year period. Test results indicated that the package components are stable and sterility is maintained for two years. Based upon these results, an expiration date of 24 months has been established.

9.2. In-Vivo (Animal) Studies

9.2.1. Stent Visualization Studies

Visibility verification studies were conducted using standard catheterization laboratory fluoroscopic and x-ray equipment to demonstrate stent visibility both within and outside of living animals. The studies demonstrated that the stent is visible using standard catheterization laboratory visualization equipment.

9.2.2. Stent Placement Studies

In-vivo animal studies were conducted to determine the functionality and placement of the intracoronary stent in numerous canines, swine and sheep. The studies confirmed the percutaneous stent deployment technique, uniform stent expansion, and conformation to artery curvature. The delivery system demonstrated pushability and trackability with no complications including no vessel perforation, no stent migration from the intended implant site, no collapse after implant, and no thrombosis. An additional in-vivo placement study was conducted; five canine animal models were implanted with the 4.5 mm diameter stent. The study confirmed that the correct guide catheter size is instrumental in the placement procedure.

9.2.3. Stent Chronic Studies

In-vivo testing was conducted to examine the angiographic patency, evidence of thrombus, and histologic evidence of re-endothelialization and healing in vessels in the canine model. Twenty-two stents were placed into the left anterior descending or left circumflex coronary arteries of 21 dogs. All stents were placed at the desired site without embolization or migration. Two canines expired post-procedure from causes unrelated to the implanted stent. Two other canines expired at one and two days post-procedure from cardiac related causes. Angiography was performed and the remaining animals were sacrificed at 2 weeks, 6 weeks, 3 months and 6 months and subjected to gross pathological and microscopic histological analysis. One specimen had intimal proliferation at two weeks with 80% stenosis due to

probable overexpansion of the stent. The remaining stent specimens were patent, and there was no evidence of myocardial infarction, spasm, rupture, or aneurysm formation during the 2 week to 6 months follow-up intervals. The stents were covered with neointimal cells which reached maximal thickness by six weeks then gradually thinned. The implanted stents did not cause loss of side branch arteries.

Additional in-vivo testing of the stent was conducted in 28 swine. Nineteen stents were implanted in atherosclerotic left anterior descending or left circumflex arteries of 18 swine. Animals were sacrificed at 2 weeks, 4 weeks, 6 weeks, 6 months, and 8 months after placement of overexpanded (by 15%) stents. Post-procedure angiography demonstrated 100% patency. No evidence of spasm, stenosis, thrombosis or stent migration was reported.

Twenty stents were implanted two each into the coronary arteries of 10 swine. There were no complications or technical difficulties during introduction and placement of the stent. All angiographic assessments, post-placement and at 1 and 4 weeks follow-up, exhibited fully patent stented segments with no signs of intraluminal defects or stent occlusion. Scanning electron microscopy (SEM) demonstrated stent wires to be covered with endothelium by the first postoperative week. These results were consistent with the previous animal studies.

In-vivo testing was also conducted in 18 dogs. Each dog was implanted with more than one stent in tandem in one vessel in 18 tandem stent procedures (total 36 stents). Follow-up intervals were at 2 weeks, 1 month, 3 months and 6 months. Explanted stent cross sections were harvested for pathological and histological analysis. Two canines died at day two due to cardiac causes, one of which may have been due to stent perforation/thrombosis. All remaining follow-up angiographic exams indicated a patent tandem stent segment with histologically minimal neointimal proliferation. One six month specimen showed an increased neointimal thickness (>1200 Fm) which was determined patent by angiography. Tandem stent placements compared favorably with single stent implants in the same animal model.

A long term implant study was conducted to assess biocompatibility and patency rates using four canines. Animals were followed for 6.2, 5, 5, and 4.6 years after stent implantation. Results indicated normal healing response with sufficient endothelialization and no evidence of stent migration, closure, thrombosis, medial hyperplasia, inflammation, or foreign body reaction. Luminal narrowing, luminal stent protrusion, intimal hyperplasia, medial thinning and fibrosis were either not present or minimal for all stents. Stents remained patent as verified by scanning electron microscopy (SEM). The long term effects of stent implantation in animals was consistent with normal vessel healing.

The animal implant studies demonstrated that the stent has an acceptable patency rate and acceptable histopathology. Additionally, functionality testing evaluating the catheter delivery system showed the system performs according to its intended use.

9.3. Clinical Studies

A prospective, multicenter, non-randomized clinical study was conducted to determine the safety and effectiveness of the Wiktor® Coronary Stent System. Primary objectives of the study were to determine: 1) the rate of acute procedural success; 2) the rates of major complications (myocardial infarction, death, CABG or percutaneous target lesion revascularization (PTLR); and, 3) the causes of unsuccessful stent placement in the setting of suboptimal PTCA results in native coronary vessels and saphenous vein grafts.

A patient cohort, enrolled in an independent, multicenter, coronary interventional registry for a commercially available stent served as the control group. Comparable clinical data obtained from this control group were used to address two additional objectives:

- To compare the Wiktor® Coronary Stents and control stents with respect to thirty day clinical success defined as freedom from death, myocardial infarction (MI), emergency

CABG and PTLR within thirty days of the initial stent procedure (the primary clinical outcome).

- To compare the Wiktor® Coronary Stent and control stents with respect to long-term clinical success, defined as freedom from death, MI and target lesion revascularization (TLR) including any CABG and any PTLR within one year of the initial stent procedure (the secondary clinical outcome).

9.3.1. Study Inclusion and Exclusion Criteria

9.3.1.1 Inclusion Criteria

Patients with a confirmed history of symptoms and diagnosis of coronary artery disease who are acceptable candidates for CABG surgery may be selected for inclusion in the study.

1) The patient must be an adult.
2) The patient must be able to consent to the procedure.
3) The patient must have a coronary vasculature considered suitable for stenting with one of the following indications in a native vessel or bypass graft.

   a) Abrupt Closure defined as abrupt cessation of flow within a dilated vessel, either sustained or transient, which causes a TIMI 0 or 1 flow or a severe flow limiting dissection leading to total occlusion, without distal antegrade flow.

   b) Threatened Closure defined as a failed interventional result characterized by any one of the following:
      i) reduced or delayed TIMI 2 antegrade flow
      ii) angiographic evidence of a dissection with persistent filling defects indicating myocardial ischemia
      iii) residual stenosis of $\geq$ 50% without reduced antegrade flow or angiographic evidence of dissection without apparent myocardial ischemia
      iv) angiographic deterioration with evidence of progressive dissection, flap, haziness, recoil or worsening residual stenosis.

   These criteria will be determined by the Angiographic Core Laboratory. In case of missing angiographic sequences at the exact time of threatened closure (i.e., threatened closure event was not filmed), physician determined percent diameter stenosis may be used.

4) Patients must agree to undergo long term clinical follow-up examinations at one month, three months, six months and every six months thereafter until study termination.

9.3.1.2. Exclusion Criteria

1) Patients with severe left main disease.
2) Patients who are contraindicated for anticoagulation, thrombolytic or antiplatelet therapy.
3) Patients with interventions performed shortly after myocardial infarction with angiographic evidence of thrombus and/or poor distal flow in the culprit vessel.
4) Diffuse disease distal to treatment site enough to impair distal runoff.
5) Patients with combined medical conditions that could adversely affect the long-range follow-up of the stented vessel.
6) Patients who cannot understand the study, are mentally incompetent, or unwilling to participate for the duration of the study.
7) Graft lesions located at the distal anastomotic site where extreme differences (greater than 1.5 mm) between the graft diameter and the diameter of the native vessel exist.
8) Unresolved thrombus at the lesion site.
9) Cardiogenic shock (Patients with systolic blood pressure of less than 80 mm Hg,

requiring inotropic support, IABP and/or fluid challenge at the time of the procedure).

10) Vessels in which the limits of the dissection are unable to be determined.

9.3.2. Study Population

Between November 21, 1990 and April 29, 1994, a total of 373 patients were enrolled at 18 centers participating in the clinical study of the Wiktor® Coronary Stent System. During approximately the same period (August 24, 1990 and March 31, 1994), the control study cohort of 428 patients were enrolled in a coronary interventional registry to evaluate the control stent.

The coronary interventional registry collected data on unplanned use of the control stent. The unplanned uses included all of the following modes: treatment of suboptimal results from a prior device, treatment after failure of a prior device, treatment to manage abrupt closure, or correction of a device-related complication in another segment. In order to assure comparability between the Wiktor® Coronary Stent and control stent groups, standardized definitions were used for both cohorts.

The registry coordinating center received Wiktor® Coronary Stent procedural data and follow-up data through one year in an identical format that was used for the control stent cases. Quantitative and qualitative analysis of the cineangiograms were performed, using the same methods, at the same core laboratory.

The coordinating center subjected the Wiktor® Coronary Stent data to routine editing and verification procedures before creating analysis data sets. The Wiktor® Coronary Stent analysis data sets, together with data sets created from the control stent cases in the registry, were used by the coordinating center to perform the statistical analyses.

Comparable Wiktor® Coronary Stent and control stent data were available for demographics, clinical presentation, procedural parameters, core lab procedural angiography, in-hospital patient course and follow-up through one year. The registry database did not include post-procedure stent thrombosis, post-discharge bleeding complications, angiographic follow-up at six months, post-procedure or clinical follow-up beyond one year. No attempt was made by the registry to retrieve these items that were not in common with the Wiktor® Stent study group

9.3.3. Demographics and Baseline Clinical Characteristics

Wiktor® Coronary Stent and control stent demographic and baseline clinical characteristics are listed in Table 2. Prior PTCA, inoperable/high risk, multiple vessel disease and left main ≥ 50% residual stenosis demonstrated an association with the primary or secondary outcome of the study. These four factors were regarded as potential confounding variables and were included in the pool of candidate predictor variables in the statistical models used to test the primary and secondary hypotheses.

Table 2. Baseline Demographics and Clinical Characteristics

	Device Used		
	Wiktor Coronary Stent (WCS)	Control	p-value
Total Patients	373	428	
Age (Years)	62.6 ± 10.7	61.9 ± 10.7	
% 65 Years or Older	43.2 (161/373)	43.7 (187/428)	
% Male	74.3 (277/373)	60.7 (260/428)	< .001
Time Since 1st Chest Pain	58.0 ± 75.2 (287)	36.2 ± 54.9 (340)	< .001
% with Prior PTCA	48.5 (177/365)	36.7 (157/428)	< .001
Time Since Last PTCA (months)	12.0 ± 23.9 (163)	18.1 ± 28.9 (156)	.041
% with Prior CABG	47.8 (178/372)	19.6 (84/428)	< .001
% with Severe Concomitant Disease	19.5 (64/328)	10.1 (42/417)	< .001
% Inoperable High Risk	19.0 (49/258)	11.9 (48/405)	.011
% History of MI	56.1 (197/351)	49.5 (212/428)	.067
% History of CHF	13.4 (39/290)	8.2 (33/402)	.026
% History of Diabetes	25.3 (94/371)	16.4 (70/426)	.002
% History of Hypertension	60.7 (224/369)	52.6 (224/426)	.021
% History of CAD	48.2 (93/193)	41.1 (156/380)	
% Current Smoker	21.5 (80/372)	15.7 (67/428)	.033
Angina Status			
No Angina	3.8 (14/368)	3.7 (16/428)	
Stable Angina	17.4 (64/368)	20.8 (89/428)	
Unstable Angina	75.0 (276/368)	69.6 (298/428)	
Pain Only with MI	3.8 (14/368)	5.8 (25/428)	
Reason for Revascularization			.048
Angina	88.5 (330/373)	86.0 (368/428)	
Silent Ischemia	0.3 (1/373)	1.2 (5/428)	
Acute MI	5.9 (22/373)	9.6 (41/428)	
Other	5.4 (20/373)	3.3 (14/428)	
MI Within 6 Weeks	23.6 (88/373)	28.7 (123/428)	.099
Multi-Vessel Disease	69.6 (247/355)	57.5 (245/426)	.001
Ejection Fraction (mean %LV-EF)	55.0 ± 15.5 (146)	57.8 ± 12.2 (243)	.067
Left Main ≥ 50% Residual Stenosis	9.9 (29/294)	5.6 (24/425)	.033

Wiktor® Coronary Stent and control stent baseline lesion characteristics are listed in Table 3.

Table 3. Baseline Lesion Characteristics

	Device Used		
	WCS	Control	p-value
Total Lesions	437	481	
Vessel			< .001
LAD (%)	18.7 76/406	32.2 138/429	
LM (%)	0.5 2/406	2.3 10/429	
RCA (%)	25.9 105/406	43.4 186/429	
LCX (%)	14.3 58/406	17.5 75/429	
CABG (%)	40.6 165/406	4.7 20/429	
Location in Segment			.042
Proximal (%)	33.8 134/396	35.0 145/414	
Mid (%)	37.9 150/396	45.4 188/414	
Distal (%)	14.1 56/396	10.4 43/414	
Ostial (%)	11.1 44/396	7.7 32/414	
Anastomosis (%)	3.0 12/396	1.4 6/414	
ACC/AHA Classification			.001
A (%)	13.9 55/395	7.0 29/414	
B1 (%)	25.8 102/395	21.0 87/414	
B2 (%)	35.4 140/395	41.5 172/414	
C (%)	24.8 98/395	30.4 126/414	
Restenotic Lesion (%)	27.2 113/415	24.7 110/446	
Sawtooth (%)	0.0 0/411	0.5 2/410	
Intimal Flap (%)	3.6 15/411	3.2 13/410	
Angulation ≥ 45 Degrees (%)	12.9 51/396	25.0 103/412	< .001
Bifurcation Type			< .001
A: Prebranch (%)	5.1 20/396	10.6 44/416	
B: Postbranch (%)	5.8 23/396	10.6 44/416	
C: Parent Vessel Only (%)	3.3 13/396	8.7 36/416	
D: Bifurcation (%)	3.5 14/396	5.8 24/416	
E: Ostial (%)	0.8 3/396	2.4 10/416	
F: Prebranch and Ostial (%)	1.5 6/396	0.5 2/416	
Tortuosity			.046
Severe (%)	0.5 (2/397)	1.4 (6/417)	
Moderate (%)	2.5 (10/397)	5.3 (22/417)	
None (%)	97.0 (385/397)	93.3 (389/417)	

	Device Used		
	WCS	Control	p-value
Thrombus	14.1 (56/397)	7.9 (33/417)	.005
Eccentricity	32.7 (130/397)	39.3 (164/417)	.051
Receives Collaterals	3.5 14/397	12.5 52/417	. 001
Supplies Collaterals	5.0 20/397	4.8 20/417	
Calcium	12.9 51/396	25.2 105/416	< .001
Ulcerated	12.4 51/411	11.9 52/438	
Total Occlusion	8.1 32/397	16.8 70/416	< .001
Mean Lesion Length (mm)	11.4 ± 6.6 386	12.7 ± 9.2 368	.027
Mean Vessel Diameter (mm)	3.19 ± 0.50 396	3.05 ± 0.51 415	< .001
Pre-Stent Lesion Characteristic			
Lumen Irregularity	7.7 30/389	4.4 17/390	.049
Intimal Flap	2.8 11/389	1.5 6/390	
Ectasia	0.0 0/364	0.3 1/365	
Perforation	1.1 (4/364)	0.3 (1/365)	
Dissection Grade			.007
A	5.2 20/386	2.9 11/376	
B	17.9 69/386	13.6 51/376	
C	16.1 62/386	23.4 88/376	
D	22.5 87/386	25.0 94/376	
E	3.6 14/386	5.3 20/376	
F	4.9 19/386	7.4 28/376	
TIMI Flow			.013
Grade 0	2.6 (10/381)	5.1 (19/376)	
Grade 1	3.4 13/381	7.7 29/376	
Grade 2	6.8 26/381	7.7 29/376	
Grade 3	87.1 332/381	79.5 299/376	
Minimum Luminal Diameter (mm)	1.70 ± 0.76 368	1.50 ± 0.81 294	.001
% Diameter Stenosis	46.6 ± 21.7 368	50.3 ± 25.7 294	.052

The following eight factors demonstrated an association with the primary or secondary outcome of the study: target lesions located in saphenous vein grafts (SVG), ACC/AHA lesion classification, tortuosity, calcified lesions, mean vessel diameter, dissection grade, TIMI flow, and minimum luminal diameter (MLD). Two additional factors: restenotic lesions and percent diameter stenosis demonstrated an association with the primary outcome but were not different between the Wiktor® Coronary Stent and control stent groups. These factors were regarded as potential confounding variables and were included in the pool of candidate predictor variables in the statistical models used to test the primary and secondary hypotheses.

9.3.4. Evaluation of Gender Bias

To determine whether gender bias had occurred during the clinical study, the ratio of women to men treated in the Wiktor® Coronary Stent study was compared to that of the control study. The percent male was 74.3% in the Wiktor® Coronary Stent study and 60.7% in the control study. The difference was statistically significant ($p<.001$). However, statistical analysis of the Wiktor® Coronary Stent clinical data did not show an association between gender and the primary or secondary clinical outcomes.

9.3.5. Results

A total of 383 procedures were performed in 373 patients enrolled in the Wiktor® Coronary Stent study. Of 635 Wiktor® Coronary Stent attempts, 599 (94%) stents were successfully deployed. The distribution of stent sizes is provided in Table 4.

Table 4. Wiktor® Coronary Stent Balloon Diameters Attempted

3.0 mm	22.8% (145/635)
3.5 mm	35.1% (223/635)
4.0 mm	24.1% (153/635)
4.5 mm	18.0% (114/635)

Failure to place 36 Wiktor® Coronary Stents in 31 patients was associated with the following causes:

- Stent deformed or dislodged during deployment (n=10)
- Inability to cross the lesion with a stent (n=8)
- Stent deformed or snagged after successful deployment (n=7)
- Inability to access the treatment site (n=6)
- Mechanical deployment problems (n=4)
- Inability to place multiple stents (n=1)

Stent deformation (stretching or compressing the coils) resulted from catching the stent on the end of the guide wire, balloon catheter, or a guiding catheter. Following failed implantation, stents were retrieved by withdrawing the delivery system if they remained on the balloon, or by the use of a snare device, if the stent had embolized. Some patients (n=4) received emergent coronary artery bypass graft surgery following a failed attempt at stent implantation.

Table 5 summarizes the effectiveness data. Acute procedural success was defined as reduction in stenosis severity to $\leq$50 percent residual stenosis by the angiographic core laboratory and the absence of major complications (death, myocardial infarction, bypass surgery or redilitation) during the hospital stay. In the Wiktor® Coronary Stent

study, the overall acute procedural success rate was 73.5% (274/373). When stratified by indication, the Wiktor® Coronary Stent acute procedural success rates ranged from 62.5% (20/32) for abrupt closures to 85.8% (121/141) in SVG target lesions. After adjusting for indication, there was no significant difference between the Wiktor® Coronary Stent and control stent with respect to acute procedural success; however, the differences across indications were significantly different.

Table 5. Effectiveness Measures

	WCS	Control Stent	p-value
Procedure Success			
Number of Patients	n = 373	n = 428	
Native Vessel Target Lesions	65.9% (153/232)	73.8% (298/404)	.037
Abrupt Closure	62.5% (20/32)	57.6% (38/66)	-
Threatened Closure	66.5% (133/200)	76.9% (260/338)	.008
SVG Target Lesions	85.8% (121/141)	75.0% (18/24)	-
All Target Lesions Combined	73.5% (274/373)	73.8% (316/428)	-
Initial Angiographic Assessment			
Number of lesions	n = 393	n = 361	
Percent Diameter Stenosis after Device (%)	15% ± 21%	23% ± 17%	<.001
Minimum Luminal Diameter (mm)	2.8 ± 0.8	2.4 ± 0.6	<.001
Six Month Angiographic Assessment			
Number of lesions	n = 58	n/a	n/a
Percent Diameter Stenosis (%)	39% ± 28%	n/a	n/a
Minimum Luminal Diameter (mm)	2.0 ± 1.0	n/a	n/a
Angiographic Restenosis (> 50%)	29%	n/a	n/a

Based on the angiographic core laboratory results, acute angiographic success was comparable between lesions treated with the Wiktor® Coronary Stent and the lesions treated with the control stent. Angiographic success was met in 92% (350/379) percent of the lesions treated with the Wiktor® Coronary Stent and 91.5% (353/386) of the lesions treated with the control stent. Angiographic assessment six months following placement of the Wiktor® Coronary Stent was obtained in 58 patients. Restenosis defined as >50% stenosis was observed in 29% (17/58) of the patients. The control cohort did not include a six month angiographic follow-up.

Principle clinical utility and safety results are summarized in Table 6.

Table 6. Safety Measures

	In-Hospital		30 Days		1 Year	
Patient Characteristic	Control Stent (n=428)	WCS (n=373)	Control Stent (n=428)	WCS (n=373)	Control Stent (n=425)	WCS (n=369)
Death	2.6 (11/428)	4.3** (16/373)	2.6 (11/427)	4.0 (15/373)	4.7*** (20/425)	8.9*** (33/369)
Any MI	15.0 (64/428)	13.9 (52/373)	15.9 (68/427)	15.3 (57/373)	19.1 (81/425)	17.9 (66/369)
Revascularization						
Any CABG	10.0 (43/428)	11.5 (43/373)	10.5 (45/427)	12.3 (46/373)	19.5 (83/425)	20.3 (75/369)
E-CABG	7.2 (31/428)	8.3 (31/373)	7.5 (32/427)	8.6 (32/373)	8.2 (35/425)	8.7 (32/369)
PTLR	5.6 (24/428)	3.2 (12/373)	6.3 (27/427)	4.3 (16/373)	21.6 (92/425)	17.9 (66/369)
Clinical Events						
Death/MI/E-CABG/ PTLR	22.9 (98/428)	22.3 (83/373)	24.1 (103/427)	23.1 (86/373)	40.9 (174/425)	40.1 (148/369)
Death/MI/TLR	24.8 (106/428)	25.2 (94/373)	26.2 (112/427)	26.3 (98/373)	47.5 (202/425)	48.2 (178/369)
Hemorrhage Requiring Transfusion	10.7 (46/428)	13.1 (49/373)	n/a	n/a	n/a	n/a
Vascular Event Requiring Surgery	8.2 (35/428)	8.8 (33/373)	n/a	n/a	n/a	n/a
Cerebrovascular Accident	0.2 (1/428)	0.5 (2/373)	n/a	n/a	n/a	n/a
Thrombosis During Procedure	1.4 (6/428)	2.7 (10/373)	n/a	n/a	n/a	n/a

* All values are percentages of the groups.
** One patient died in hospital 43 days after the implant procedure.
*** Significantly different (p=.017)

The primary clinical outcomes evaluated freedom from death, myocardial infarction (MI), emergency CABG (E-CABG), and percutaneous target lesion revascularization (PTLR) within thirty days of the initial stent procedure. The secondary clinical outcome evaluated freedom from death, MI, and target lesion revascularization (TLR) within one year of the initial stent procedure. To estimate the relative risks of these outcome measures, the results were analyzed using a multivariate analysis.

The estimated relative risk was further adjusted to account for known differences with respect to various patient demographics and lesion characteristics between the two study cohorts. Table 7 presents the relative risk of the primary and secondary clinical outcomes after adjusting for vessel type (native/graft), indications for use (abrupt/threatened closure), potential confounders (class B2 or C lesions and restenotic lesions) and early learning experience.

The early learning experience refers to the difference between the Wiktor® Coronary Stent study and the control study as to when the investigational sites initiated enrollment in the study cohort. The Wiktor® Coronary Stent database began with the initial stent implant by each participating investigator, whereas the control stent database began after a minimum of five successful stent implants were performed by each participating investigator.

Table 7. Relative Risk

	Relative Risk	95% C.I.	p-value
Primary Clinical Outcome	1.162	0.806 - 1.677	0.4
Secondary Clinical Outcome	1.060	0.810 - 1.387	0.6

As indicated in Table 7, the relative risk of a primary endpoint (i.e., 30 day death, MI, E-CABG or PTLR) was 1.162 times (p=.4) that of the control stent. The relative risk of a secondary endpoint (i.e., one year death, MI, or TLR) was 1.060 times (p=.7) that of the control stent. However, the statistical modeling for the secondary endpoint did not result in a good fit of the data to the model. Only minor differences in parameter estimates were observed when stratification was performed.

10. CONCLUSIONS DRAWN FROM STUDIES

Multicenter clinical study data show that the Wiktor® Coronary Stent is comparable to a U.S. commercially available coronary stent (control stent) in the setting of unacceptable PTCA results in native vessels and in lesions arising in saphenous vein grafts.

The nonclinical and clinical studies provided reasonable assurance that the Wiktor® Coronary Stent is safe and effective for chronic placement in a coronary artery or saphenous vein graft to obtain vessel patency in the treatment of unacceptable PTCA results, when used according to the Labeling and Instructions for Use.

11. PANEL RECOMMENDATIONS

In accordance with the provisions of section 515(c)(2) of the Federal Food, Drug, and Cosmetic Act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

12. FDA DECISION

The FDA issued an approval order on June 27, 1997. The applicant's manufacturing facility was inspected and was found to be in compliance with the device Good Manufacturing Practice regulations.

13. APPROVAL SPECIFICATIONS

Directions for use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Post-approval Requirements and Restrictions: See approval order.

The Approval Order, Summary of Safety and Effectiveness Data, and labeling can be found on the Internet at http: //www.fda.gov/cdrh/pmapage.html.

14. REFERENCES

Matsumoto, AH, Teitelbaum, GP, Lindison, DJ, Savin, M, Strecker, EP, Barth, KH, In Vivo MR Imaging Evaluation of Tantalum Vascular Stents in Dog Arteries, Radiology 169: 387, 1988.

Shellock, FG, MR Imaging of Metallic Implants and Materials: A Compilation of the Literature,

Am. J. Radiol. 151: 811-814, 1988.

Matsumoto, AH, Teitelbaum, GP, Barth, KH, Carvlin, MJ, Savin, MA, Strecker, EP, Tantalum Vascular Stents: In Vivo Evaluation with MR Imaging, Radiology 170: 753-755, 1989.

Scott, NA, Pettigrew, RI, Absence of Movement of Coronary Stents after Placement in a Magnetic Resonance Imaging Field, Amer. J. Card. 73: 900-901, 1988.

Shellock, FG, Morisoli, S, Kanal, E, MR Procedures and Biomedical Implants, Materials and Devices: 1993 Update, Radiology 189: 587-599, 1993.

Tietelbaum, GP, Bradley, WG, Klein, BD, MR Imaging Artifacts, Ferromagnetism, and Magnetic Torque of Intravascular Filters, Stents and Coils, Radiology 166: 657-664, 1988.

General Program Memorandum # G91-1: Device Labeling Guidance

Medtronic

Coronary Stent Delivery System

ENVELOPE CONTAINS:

- *Physician Instructions for Use*
- *Patient Manual*
- *Temporary Patient ID Card*
- *Device Registration Form*
- *Business Reply Envelope*

IMPORTANT: **Completing the enclosed device re**
our implanted medical devices and
identification card. This will also i
Tracking Requirements.

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gistration form will allow Medtronic to track
provide your patient with a permanent
ısure compliance with U.S. Medical Device

U43569001 Rev.01 187994-001

Medtronic

WIKTOR PRIME

CORONARY STENT DELIVERY SYSTEM

Instructions for Use Manual

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MEDTRONIC WIKTOR® PRIME CORONARY STENT DELIVERY SYSTEM

Instructions for Use Manual

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MEDTRONIC WIKTOR®
CORONARY STENT

DEVICE DESCRIPTION

The Medtronic Wiktor® Prime Coronary Stent Delivery System is comprised of two components: the Medtronic Wiktor® Coronary Stent and the balloon delivery catheter. The Medtronic Wiktor® Coronary stent is a radiopaque tantalum wire formed into a sinusoidal wave pattern and wound into a helical configuration. It is supplied premounted on the balloon catheter delivery system. A radiopaque marker band is located at the balloon center on the delivery catheter. The device is supplied in a sterile pouch, for single use.

INDICATIONS

The Medtronic Wiktor® Prime Coronary Stent Delivery System is indicated for the treatment of abrupt or threatened closure in patients with failed interventional therapy in native coronary arteries and bypass graft vessels with reference diameters in the range of 3.0 to 4.5 mm (see Individualization of Treatment). Long-term outcome (beyond one year) for this permanent implant is unknown at present.

CONTRAINDICATIONS

Medtronic Wiktor® Coronary Stents are 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.

WARNINGS

Since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events, judicious selection of patients is necessary.

PRECAUTIONS
(see also INDIVIDUALIZATION OF TREATMENT)

- Implantation of the stent should be performed only by physicians who have received appropriate training. **Appropriate training** consists of attendance at a stent training workshop, or specific training in coronary stenting techniques and procedures under the supervision of an interventional cardiologist experienced in coronary stent implantation.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require redilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized Medtronic Wiktor® Coronary Stents is unknown at present.

Stent Handling - Precautions

- **For single use only.** Do not resterilize or reuse. Note product "Use Before" date.
- **Do not remove stent from its delivery balloon** as removal may damage the stent and/or lead to stent embolization.
- Special care must be taken not to handle or in any way disrupt the helical wave form of the stent loops on the balloon. This is most important during catheter removal from packaging, placement over guide wire and advancement through hemostasis valve adapter and guiding catheter hub.
- Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent

Stent Placement - Precautions

- **Do not prepare or pre-inflate balloon prior to stent deployment.** Use balloon purging technique described in the Instructions for Use.

- Balloon pressures should be monitored during inflation. **Do not exceed rated burst pressure as indicated on product label.** (See Balloon Inflated Diameter dimensions in Table 5). Use of pressures higher than specified on product label may result in a ruptured balloon with possible intimal damage and dissection.
- Do not expand the stent if it is not properly positioned in the vessel. (See instructions for Removal of Unexpanded Stent.)
- **Do not attempt to pull an unexpanded stent back through the guiding catheter; dislodgement of the stent from the balloon may occur.**
- 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 (further dilatation, placement of additional stents or coronary artery bypass surgery).
- Do not place a stent in the aorta-ostial location because of a high risk of damage and/or dislodgement by a coronary guiding catheter.
- Placement of a stent has the potential to compromise side branch patency.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.

Post Stent Placement - Precautions

- Use of mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser angioplasty catheters is not recommended in vessel segments already stented.
- Avoid use of short monorail length intravascular ultrasound (IVUS) catheters because they may damage the stent.
- 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.

ADVERSE EVENTS

Three hundred seventy-three (373) patients were enrolled in an open multicenter clinical trial to evaluate the use of the Medtronic Wiktor® Coronary Stent for treatment of abrupt or threatened closure in native coronary or bypass graft vessels. These patients form the basis for the observed events reported (see Clinical Study).

Fifteen patients in the clinical study died within 30 days of receiving the stent implant. Another patient died in the hospital 43 days following the stent implant procedure. Death in these 16 patients was due to: pulmonary embolism following CABG (n=1), multisystem failure (n=7), exsanguination after retroperitioneal bleed with refusal of blood products (n=1), cardiac or cardiopulmonary arrest (n=2), cardiac arrest following CABG (n=1), vessel occlusion (n=1), vessel occlusion following CABG (n=1), MI with hemodynamic instability (n=1) and intracranial hemorrhage (n=1).

Observed Adverse Events

TABLE 1

Number (percent) of patients with the event at 30 days and 1 year

Observed Adverse Events		
Adverse Event (in order of severity)	**<30 days (n=373)**	**<1 year (n=369)** cumulative (includes <30 days)
Death	15 (4%)*	36 (9%)
Coronary artery bypass graft (CABG)	32 (9%)**	75 (20%)
Myocardial infarction (MI)	57 (15%)	66 (18%)
Cerebrovascular Accidents	4 (1.1%)	5 (1.3%)
Thrombosis/Stent Occlusion***	28 (8%)	–
Bleeding Complications		
- Access Site		
Hematoma		
- Requiring Surgery	20 (5%)	–
- Requiring Transfusion	25 (7%)	–
Pseudoanuerysm		
- Requiring Surgery	14 (4%)	–
- Requiring Transfusion	8 (2%)	–

* One additional patient died in hospital at 43 days
** Emergent CABG only
*** Thrombosis/Stent Occlusion < 24 hours = 21 (5%)

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Thrombosis/occlusion occurred in about 8% of patients, most commonly within one week after implantation. Subacute thrombosis is rare after routine balloon angioplasty. Thrombosis following stent implantation was associated with baseline angiographic and procedural factors including: vessel diameter <3 mm, intraprocedural thrombus and dissection remaining following stent implantation.

Potential Adverse Events

Adverse events associated with the use of a coronary stent in native coronary or bypass grafts but not seen in this study may include (in order of severity):

- Death
- Coronary artery bypass graft surgery
- Myocardial infarction
- Stent thrombosis or occlusion
- Myocardial ischemia
- Arrhythmias (ventricular fibrillation, ventricular tachycardia, other)
- Stroke/Cerebrovascular Accidents
- Perforation of a coronary artery
- Emboli (air, tissue or thrombotic emboli)
- Stent embolization
- Hemorrhage requiring transfusion
- Hypotension
- Pseudoaneurysm or hematoma at the vascular access site
- Infection and pain at the vascular access site
- Spasm of a coronary artery

CLINICAL STUDY

Three hundred seventy-three (373) patients were enrolled between 1990 and 1994 at eighteen centers in an open multicenter clinical trial to evaluate the use of the Medtronic Wiktor® Coronary Stent for treatment of abrupt (n=38) or threatened (n=335) closure in native coronary or bypass graft vessels. A total of 635 stent implants were attempted and adverse events reports are based on follow-up of 373 patients to 30 days and 369 patients to one year. Mean duration of follow-up was 24 months (range 1 day to 58 months).

Objectives: The primary objectives of the clinical study were to determine the rate of acute procedural success, the rates of major clinical event (myocardial infarction, death, CABG surgery or percutaneous target lesion revascularization (PTLR)), and the causes of unsuccessful stent placement in the setting of suboptimal PTCA results in native vessels and saphenous vein grafts.

Methods: Patients had an abrupt or threatened closure of a native coronary artery or saphenous vein graft. **Abrupt Closure** was defined as abrupt cessation of flow within a dilated vessel, either sustained or transient, which causes a TIMI 0 or 1 flow or a severe flow limiting dissection leading to total occlusion, without distal antegrade flow. **Threatened Closure** was defined as a failed interventional result characterized by any one of the following:
1) reduced or delayed TIMI 2 antegrade flow
2) angiographic evidence of a dissection with persistent filling defects indicating myocardial ischemia, 3) residual stenosis of ≥50% without reduced antegrade flow or angiographic evidence of dissection without apparent myocardial ischemia, or 4) angiographic deterioration with evidence of progressive dissection, flap, haziness, recoil or worsening residual stenosis. **Procedural success** was defined as reduction in stenosis severity to ≤50% residual stenosis by angiographic core laboratory and the absence of major complications (death, myocardial infarction, bypass surgery or redilatation) during the hospital stay.

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Follow-up assessment occurred at hospital discharge, one month and one year following stent implant, including anginal status and any major clinical event or other adverse event (thrombosis, stent occlusion, cerebrovascular accidents, and vascular complications) since the previous follow-up. A subset of patients (n=58) received repeat coronary angiograms at 6 ±1 months that were reviewed by independent core lab analysis. Patients received **anticoagulation** including: heparin prior to stent implant to maintain the ACT >300 seconds during the implant procedure, post-procedure coumadin to maintain prothrombin time with INR 2.5–3.5 for three months, and aspirin daily for six months.

Patients Studied: Implant of 635 Wiktor® Stents was attempted in 373 patients. A total of 599 stents (94%) were successfully deployed in 342 patients (92%).

A total of 66 patients (18%) receiving Wiktor® Coronary Stents exhibited angiographic restenosis at follow-up and had a subsequent redilatation of a stented lesion within 1 year.

Failure to place the Medtronic Wiktor® Coronary Stent was associated with:

- stent deformed or dislodged during deployment (n=10)
- inability to cross the lesion with a stent (n=8)
- stent deformed or snagged after successful deployment (n=7)
- inability to access the treatment site (n=6)
- mechanical deployment problems (n=4)
- inability to place multiple stents (n=1).

Stent deformation (stretching or compressing the coils) resulted from catching the stent on the end of a guide wire, balloon catheter or a guiding catheter. Following failed implantation, stents were retrieved by withdrawing the delivery system if they remained on the balloon, or by the use of a snare device, if the stent had embolized. Some patients (n=4) received emergent coronary artery bypass graft surgery following a failed attempt at stent implantation.

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TABLE 2

Principal Effectiveness and Safety Results All patients implanted with one or more Wiktor* stents (n=373) Number (percent) or mean ± SD and (range), [95% confidence interval]	
Effectiveness Measures	
Procedure Success	274/373 (73%) [69%, 78%]
Initial angiographic assessment (n=393 lesions)	
Percent Diameter Stenosis after Device (%)	15% ± 21% (-43% - 100%) [13%, 17%]
Minimal Lumen Diameter (mm)	2.8 ± 0.77 (0 - 4.7) [2.7, 2.9]
Six month angiographic assessment (n=58)	
Percent Diameter Stenosis after Device (%)	39% ± 28% (-17% - 100%) [31%, 46%]
Minimal Lumen Diameter (mm)	2.0 ±1.0 (0 - 4.0) [1.7, 2.3]
Angiographic Restenosis (>50%)	17/58 (29%) [18%, 43%]
Percutaneous Target Lesion Revascularization	
- at 30 days	16/373 (4%) [3%, 7%]
- at 1 year	66/369 (18%) [14%, 22%]
Safety Measures	
In-Hospital Clinical Events*	83/373 (22%) [18%, 27%]
Clinical Events* through 30 days	86/373 (23%) [19%, 28%]
Clinical Events** through 1 year	178/369 (48%) [43%, 53%]
Cerebrovascular Accidents in-hospital	2/373 (0.5%) [0.1%, 1.9%]
Bleeding Complications*** requiring Transfusion	49/373 (13%) [10%, 17%]
Vascular Complications*** requiring Surgery	33/373 (9%) [6%, 12%]
No Bleeding or Vascular Complications***	313/373 (84%) [80%, 88%]

* Clinical Events consists of Death, Myocardial Infarction, Emergent Coronary Artery Bypass Surgery or Repeat Angioplasty at the target lesion (primary endpoint).

** Clinical Events consists of Death, Myocardial Infarction, Any Coronary Artery Bypass Surgery or Repeat Angioplasty at the target lesion (secondary endpoint).

*** In-hospital

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INDIVIDUALIZATION OF TREATMENT

The risks and benefits of using the Medtronic Wiktor® Coronary Stent should be carefully considered for each patient before use. Patient selection factors to be assessed should include risk of prolonged anticoagulation. Stenting is generally avoided in those patients at heightened risk of bleeding (e.g., patients with recently active gastritis or peptic ulcer disease). Coronary artery bypass surgery should be considered in patients with an acutely closed, unprotected left main artery.

TABLE 3

Considerations for Using the Wiktor® Coronary Stent
The Wiktor® Coronary Stent should be considered in situations of: • Acute Closure TIMI 0-1 flow Severe flow limiting dissection • Threatened Closure TIMI 2 flow Dissection Ischemia Significant residual stenosis (≥50%) Angiographic deterioration or haziness **Avoid use in patients with:** • Contraindications to antiplatelet or anticoagulation therapy • Vessels < 3mm diameter • Poor distal flow or "no reflow" • Unresolved thrombus at lesion site • Dissections whose limits cannot be visualized

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Use in Special Populations

The safety and effectiveness of the Medtronic Wiktor® Coronary Stent has not been established for patients with any of the following characteristics:

- Patients with **unresolved vessel thrombus at the lesion site.**
- Patients with coronary artery or bypass graft **reference vessel diameter <3 mm.**
- 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 lesions.
- Patients with a recent **acute myocardial infarction** where there is evidence of thrombus or poor flow.
- Patients with significant **impairment of left ventricular function.**
- The risk of thrombosis may be increased when **multiple overlapping stents** are used. Full expansion of the stent and the use of appropriate anticoagulation or antiplatelet therapy may reduce this risk.

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INSTRUCTIONS FOR PLACEMENT OF THE MEDTRONIC WIKTOR® CORONARY STENT

CAUTION: Implantation of the stent should be performed only by physicians who have received appropriate training. **Appropriate training** consists of attendance at a stent training workshop, or specific training in coronary stenting techniques and procedures under the supervision of an interventional cardiologist experienced in coronary stent implantation.

General Use Information

Standard techniques for placement of a femoral sheath, guiding catheter, and coronary guide wire should be employed during use of the Medtronic Wiktor® Coronary Stent device. If the lesion has not been predilated to a diameter able to accommodate the stent delivery catheter, predilatation is required.

In general, dilatation with a balloon diameter with a ratio of 1:1 with the diameter of the vessel is required.

Predilatations of the vessel must take into account proximal atherosclerotic plaque which may inhibit advancement of the stent and atherosclerotic plaque distal to the lesion which may prevent advancement of the device across the primary lesion or otherwise restrict blood flow. In preparing the vessel, optimal coronary vasodilatation, anticoagulant, and antiplatelet therapy is essential.

NOTE: A coronary artery segment containing a chronically implanted, endothelialized stent may be redilated using standard angioplasty techniques.

CAUTION: The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.

Guide Wire Use and Selection

Successful use of the stent usually requires support of an 0.014–0.018 inch coronary guide wire. A standard 0.018 inch guide wire with a soft, flexible tip is recommended to improve tracking and catheter support.

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If the case is started with a 0.014 inch guide wire compatible PTCA catheter for predilatation, standard guide wire exchange procedures should be followed if more guide wire support for stenting is indicated.

Guiding Catheter Selection

Correct guiding catheter selection and technique is critical for successful implantation of the stent. Assure that inside lumen of guiding catheter is of sufficient size to allow unobstructed passage of the stent/balloon catheter. The accessory peel-away stent introducer is used to carefully pass the stent delivery system through the hemostasis valve.

Minimum inside diameter requirements to the guiding catheter are shown in Table 4:

TABLE 4

Stent/Balloon Catheter Catalog Number	Balloon Inflated Diameter (mm)	Recommended Minimum I.D. for Guiding Catheter
6565	3.0 mm	0.083" or 2.1 mm
6570	3.5 mm	0.083" or 2.1 mm
6575	4.0 mm	0.083" or 2.1 mm
6545	4.5 mm	0.083" or 2.1 mm

Standard coronary catheter curves must provide excellent guiding catheter backup support to achieve successful stent placement.

NOTE: Standard Judkins catheter curves have proven to be most useful, but other catheter shapes may be employed. If poor guiding catheter backup support is observed during dilatation of the lesion, exchange guiding catheter for better backup support and/or alignment. In general, all large lumen 8 French guiding catheters will be suitable for placement of all stent sizes. **The Medtronic Wiktor® Prime Coronary Stent Delivery Systems will be accommodated in guiding catheters with a minimum inner diameter of 0.079" or 2.0 mm. However, Medtronic Interventional Vascular recommends a minimum inner diameter of 0.083" or 2.1 mm for guiding catheters to allow for adequate visualization of the coronary vasculature with contrast media.**

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NOTE: Using a guiding catheter with no sideholes may allow better visualization of the vessel and the target stent site. In particular, this may be more useful for distal lesion sites.

If additional guiding catheter support is required prior to stenting, catheter exchanges can be successfully made over a well-positioned guide wire.

Stent Size Selection

Careful stent sizing is important to successful stenting. In general, the stent size should be chosen to match the normal vessel diameter adjacent to the lesion. It is recommended to slightly oversize the stent by 10%–15% (or 0.5 mm) in relation to the reference vessel diameter.

> CAUTION: Excessive oversizing of the stent or use of higher than recommended inflation pressures may cause vessel dissection. The selected stent diameter should closely approximate the diameter of the vessel and only the recommended stent/balloon inflation pressures identified in Table 5 should be used for stent deployment.

Preparation of Stent Delivery Catheter

The Medtronic Wiktor® Coronary Stent is premounted on a stent delivery catheter.

1. Remove the stent delivery catheter system from the package and remove the L-mandril from the distal portion of the stent delivery catheter.
2. Inspect the stent to ensure that the stent is adequately centered on the balloon central marker band.

   CAUTION: **Do not remove stent from its delivery balloon** as removal may damage the stent and/or lead to stent embolization.

3. Inspect the stent wires to ensure that no loops are protruding away from the balloon. Use the thumb and forefinger to gently push any protruding loops down on the stent delivery catheter.

   CAUTION: Do not "roll" the mounted stent with your fingers as this action may loosen the stent from the delivery balloon.

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4. Carefully take the peel-away stent introducer out of the catheter package. Rinse introducer with heparinized saline solution.

5. Attach a hemostasis valve (minimum inner diameter of 0.110") to the guiding catheter and flush with heparinized saline in standard fashion to purge air.

   CAUTION: Do not prepare or pre-inflate balloon prior to stent deployment.

   CAUTION: Do not use gauze sponges to wipe down the stent delivery catheter as fibers may disrupt stent.

6. Remove existing pre-dilatation PTCA balloon catheter leaving guide wire in position. Exchange the PTCA catheter for the stent delivery catheter.

7. Insert the stent delivery system into the winged end of the introducer. Advance the introducer and stent delivery system as a single unit over the exchange guide wire up to the hemostasis valve.

8. Open the hemostasis valve to the fully open position, grasp the proximal portion of the introducer and the shaft of the stent delivery system as a unit and advance them through the hemostasis valve until the introducer is seated in the hub of the guiding catheter.

   CAUTION: If resistance is encountered, do not force passage. Resistance may indicate damage to stent.

9. Continue advancement of stent delivery system into the guiding catheter a minimum of 20 to 30 cm. Retract the introducer out of the hemostasis valve and peel it off the shaft of the catheter. Close the hemostasis valve just enough to control fluid leakage.

10. Continue to advance the stent delivery catheter through the guiding catheter.

11. Prior to the stent/balloon exiting the distal tip of guiding catheter, confirm under fluoroscopy the position of stent over balloon central marker band and that no stent loops protrude from the balloon. If the stent appears damaged, remove the unexpanded stent and catheter system and use a new one.

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Deployment of Stent

Stent Positioning

1. Ensure the guiding catheter is coaxially seated and stable before exiting the guiding catheter tip with the stent delivery balloon.

   CAUTION: If initial guiding catheter position is lost, with the stent distal to the tip of the guiding catheter, avoid pulling or pushing the guiding catheter over the stent. If this is done, the distal end of the guiding catheter may damage the stent loops or cause the stent to dislodge from the balloon stent delivery catheter. Remove the stent delivery system and guide catheter as a unit (refer to Removal of Unexpanded Stent) and re-evaluate guide catheter selection.

   CAUTION: If stent delivery catheter does not readily advance, do not force. Stent loops may accordion over balloon. If stent will not advance in spite of good guiding catheter support, consider dilating proximal obstructing plaque and/or using a smaller diameter stent. (Refer to Removal of Unexpanded Stent.)

   CAUTION: Do not place a stent in the aorta-ostial location because of the high risk of damage and/or dislodgement by a coronary guiding catheter.

2. Position the stent across the lesion. Optimal placement requires the distal end of the stent to be deployed a few millimeters distal to the beginning of the arterial segment to be stented. It is important that the entire target lesion is covered by the stent.

   CAUTION: Do not expand the stent if it is not properly positioned in the vessel. (See instructions for Removal of Unexpanded Stent.)

3. When the stent delivery balloon has been adequately positioned within the intended lesion site, prepare the balloon with standard contrast-saline mixture as follows:

   CAUTION: Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the stent.

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a. Prepare inflation device in standard manner and purge to remove all air from syringe and tubing.

b. Using a 20 cc syringe containing 5 cc of contrast-saline mixture, apply negative pressure for 10–15 seconds.

c. Release pressure, returning balloon to neutral and allowing negative pressure to draw contrast mixture into balloon lumen.

d. Detach syringe, leaving a meniscus of contrast mixture on the hub of the balloon lumen.

e. Attach inflation device to balloon lumen directly, ensuring no air bubbles remain at connection.

Balloon Expansion

Prior to stent expansion, utilize high resolution fluoroscopy to verify stent loops have not been damaged during positioning.

1. To expand the stent, inflate the delivery balloon to the nominal expansion pressure indicated in Table 5.

2. Increase inflation pressure to firmly embed stent loops into vessel intima. A 30–60 second inflation is recommended for full expansion. Do not exceed rated burst pressure of balloon as indicated in Table 5. Diameter of fully expanded stent should match or slightly exceed (10% to 15% or 0.5 mm) vessel diameter.

   CAUTION: Balloon pressures should be monitored during inflation. **Do not exceed rated burst pressure as indicated on product label.** (See Balloon Inflated Diameter dimensions in Table 5). Use of pressures higher than specified on product label may result in a ruptured balloon with possible intimal damage and dissection.

3. Deflate the balloon and verify angiographically that the stent is fully expanded. Reinflate the balloon as needed to achieve full stent expansion.

4. Check for full expansion of both the proximal and distal ends of the stent. If necessary, deflate the balloon, gently reposition the balloon proximally or distally, and reinflate the balloon to achieve full expansion of the ends of the stent

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Stent Delivery Balloon Compliance

The table below depicts the diameter of the stent delivery balloon at various inflation pressures. The balloon diameter is a close approximation of the inside luminal diameter of a deployed stent. **The stent wire diameter adds approximately 0.25 mm more to the balloon diameters listed in Table 5 below.**

TABLE 5

Medtronic Wiktor® Prime Coronary Stent Delivery System
Balloon Diameter (mm) at Listed Pressure (ATM)
Delivery Balloon Compliance

Rated Balloon Diameter (mm)	Atmospheres									
	1	2	3	4	5	Nominal 6	7	8	9	10
3.0	2.6	2.7	2.8	2.8	2.9	2.9	3.0	3.0*	3.1	3.2
3.5	3.0	3.1	3.2	3.3	3.4	3.5	3.6	3.7*	3.8	3.9
4.0	3.6	3.6	3.7	3.8	3.9	4.0	4.1*	4.1	4.2	
4.5	3.6	3.8	4.0	4.2	4.4	4.6*	4.7	4.9		

* Rated Burst Pressure

Balloon Deflation and Removal

Withdrawal of the stent delivery catheter should be done under fluoroscopic guidance to ensure free, unobstructed movement of the balloon out of the stented segment.

1. Deflate the balloon using the inflation device or a 20 ml syringe. Maintain negative deflation pressure for at least 30 seconds to be sure the balloon is completely deflated. (60 second deflation is recommended for 4.0 and 4.5 mm delivery systems.)
2. Initially advance the deflated balloon slightly forward then very slowly withdraw the balloon from the stent, maintaining negative pressure and allowing movement of myocardium to gently dislodge the balloon from the stent. **Maintain position of guiding catheter to prevent it from being drawn into vessel.**

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3. If the balloon does not easily disengage from stent and cannot be withdrawn, release vacuum on the inflation device to bring the delivery balloon to ambient pressure. Apply negative pressure to the balloon again for 30 seconds and then very slowly withdraw the balloon. This may facilitate disengagement of the balloon from the deployed stent.

   NOTE: If stent placement is associated with the onset of thrombus or suspected thrombus in the region of the stented segment, intracoronary infusion of a thrombolytic agent is recommended.

Post-Deployment Dilatation

Optimal stent placement and expansion appear to be key to successful stent patient outcomes. Subsequent balloon dilatation of the stent may be performed using an appropriately sized, low profile, balloon catheter. If the guide wire has been removed, the stented segment should be recrossed carefully with a very flexible coronary guide wire that has been prolapsed to avoid dislodging the fine stent loops. Balloon angioplasty is the ONLY interventional procedure that should be used post-stent implant. Subsequent balloon dilatation of a newly implanted stented lesion site may be performed *if necessary* to optimize results.

1. Select an appropriately sized balloon catheter and carefully position within the stent.
2. A 30–60 second inflation is recommended for full expansion.
3. Repeat inflations as needed to achieve full stent expansion.

   CAUTION: 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.

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Multiple Stent Placement Recommendations

If more than one stent placement is required, the following recommendations should be considered:

1. In relationship to the lesion site, the most distal area of narrowing should be stented first, followed by more proximal locations. Positioning a coronary stent distal to a stent already in place may displace or damage one or both stents.
2. Coronary stents placed in tandem should be placed with a slight overlap.

Removal of Unexpanded Stent

If there are doubts about the integrity of the stent loops or if stent cannot be deployed in the intended lesion site, do not attempt to expand the stent. To safely remove the stent catheter system:

1. Retract, under fluoroscopic guidance, the stented balloon to the tip of the guiding catheter.

   CAUTION: Do not attempt to pull an unexpanded stent/balloon back through the guiding catheter; dislodgement of the stent may occur.

2. Retract, as a single unit, the guiding catheter and the stented balloon catheter out of the ostium and into the ascending aorta. Always keep the coronary guide wire in position.
3. Inflate the stent balloon to one atmosphere.
4. While maintaining guide wire position, withdraw the guiding catheter and the stent delivery catheter system as one unit through the introducer sheath. If the entire system cannot be withdrawn into the introducer sheath, consideration should be given to removing the guiding catheter, stented balloon catheter, and the introducer sheath as a unit.
5. If the stent has dislodged from the balloon delivery catheter during withdrawal, maintain guide wire position to ensure the stent remains on the wire. A snare wire, such as the Microvena® nitinol gooseneck snare, can be inserted under fluoroscopy to grasp the stent to safely remove the system from the insertion site.

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6. Biopsy forceps may also be used in grasping the proximal end of the Wiktor® Coronary Stent wire, thereby causing it to unravel and be removed.

   CAUTION: Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vascular access site. Complications could include bleeding, hematoma or pseudoaneurysm.

   CAUTION: **For single use only.** Do not resterilize or reuse. Note product "Use Before" date.

DETAILED DEVICE DESCRIPTION

The Medtronic Wiktor® Prime Coronary Stent Delivery System is comprised of two components: the Medtronic Wiktor® Coronary Stent and the balloon delivery catheter. The stent is a radiopaque wire with sinusoidal waves formed in a helical configuration. It is made of biologically inert tantalum 0.005 inch diameter wire and is intended as a permanent implant in a coronary artery or bypass graft vessel. Tantalum has a low magnetic susceptibility. It is not affected by magnetic fields produced by magnetic resonance imaging (MRI) equipment, and does not cause significant artifacts in MRI scans.

The Medtronic Wiktor® Coronary Stent is supplied premounted on 4.3F diameter balloon delivery catheter with a working length of 135 cm. The balloon catheter design is consistent with other commercially available PTCA catheters. The balloon at the distal end is 25 mm in length. A centrally located, radiopaque marker band is within the balloon for visualization under fluoroscopy. The inner lumen of the catheter will accommodate a 0.018 inch guide wire. To ensure adequate visualization of the coronary vasculature with contrast media, the Medtronic Wiktor® Prime Coronary Stent Delivery System should be used with guiding catheters that have a minimum inner diameter of 0.083 inches or 2.1 mm.

The assembly is supplied in a sterile package intended for single use. An accessory peel-away stent introducer tool is provided in the package to facilitate the introduction of the stent delivery system into the hemostasis valve.

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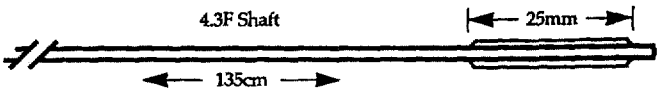
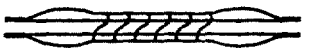
FIGURE 1. THE WIKTOR® PRIME
CORONARY STENT DELIVERY SYSTEM



Stent Delivery Catheter



Unexpanded Stent

Expanded Stent

Stent/Balloon Catheter Catalog Number	Balloon Inflated Diameter and Expanded Stent Inner Diameter	Nominal Stent Length
6565	3.0 mm	16 mm
6570	3.5 mm	16 mm
6575	4.0 mm	16 mm
6545	4.5 mm	16 mm

HANDLING AND STORAGE

Carefully inspect the sterile package before opening. It is not recommended that the product be used after its expiration date. If the integrity of the sterile package has been compromised prior to the product expiration date (e.g., damage of the package), contact your local Medtronic representative. Do not resterilize.

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DISCLAIMER OF WARRANTY

NOTE: ALTHOUGH THE STENT DELIVERY SYSTEM HEREAFTER REFERRED TO AS "PRODUCT" HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC, THEREFORE DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND MEDTRONIC TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

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SERVICE

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. In addition, Medtronic maintains a professional staff of consultants to provide technical and medical consultation to product users. For product availability and training information, contact your local Medtronic Representative or call or write to Medtronic.

FOR TECHNICAL INFORMATION

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Medtronic, Inc.
7000 Central Avenue NE
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USA
Telephone: 612-514-4000
FAX: 612-514-4879
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(24-hour consultation for physicians and medical professionals)

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Minneapolis, MN 55432-3576
USA
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1-888-549-7915
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FOR TECHNICAL INFORMATION

To Order:
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432-3576
USA
Telephone: 612-514-4000
FAX: 612-514-4879
Toll-free in the USA:
1-800-328-2518
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Technical Service:
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7000 Central Avenue NE
Minneapolis, MN 55432-3576
USA
Toll-free in the USA:
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Treating Coronary Artery Disease with Angioplasty and Coronary Stents

Patient Information

Medtronic

This booklet will help you gain a better understanding of coronary artery disease and two related interventional treatments: angioplasty and the implantation of coronary stents.

Contents

Coronary Artery Disease

Diagnostic Tests

The Consequences of Coronary Artery Disease

Treatment Options

The Angioplasty Procedure

Other Interventional Procedures

Stent Placement

Healthy Living

Your Physician's Role

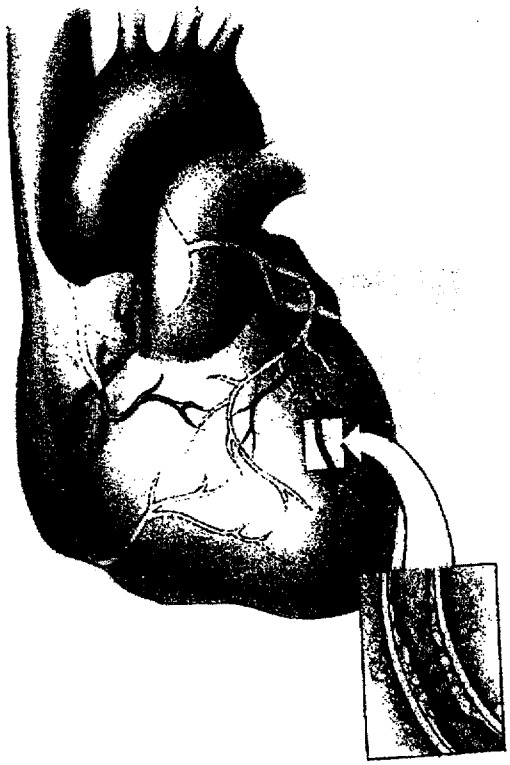
Conclusion

Coronary Artery Disease

The heart is a powerful muscle that must have a good supply of oxygen to function efficiently. Oxygen-rich blood is carried to the heart through three major coronary arteries that branch into a network of smaller vessels.

These coronary arteries can become blocked by a build-up of cholesterol (fatty deposits) called atherosclerotic plaque, or simply plaque. Any narrowing or blockage of the coronary arteries reduces the flow of blood and oxygen to the heart. This can cause chest pain (angina) and may lead to what is commonly known as a heart attack.

Treatment of coronary artery disease to increase the flow of blood through the coronary arteries may include drugs, coronary bypass surgery, or angioplasty — with or without a coronary stent. This booklet discusses the interventional treatments of angioplasty and the placement of coronary stents.



When coronary arteries are blocked by plaque, bloodflow and oxygen to the heart are reduced. Angina and heart attack may result.

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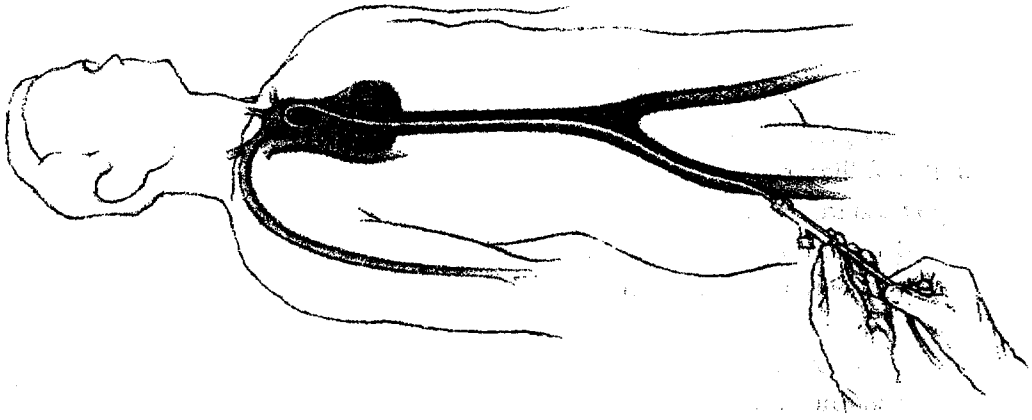
Diagnostic Testing

A stress test, or exercise electrocardiogram (ECG), is used in the diagnosis of coronary artery disease. If the results of a stress test indicate a need for further testing, a coronary angiogram (also called cardiac catheterization) will be performed.

An angiogram is an x-ray picture of a blood vessel which is obtained by injecting special dyes into the blood-stream. In a coronary angiogram, the blood vessels (coronary arteries) feeding the heart will be clearly defined, allowing the doctor to see exactly where the blockage or narrowing occurs.

The Coronary Angioplasty Procedure

Patients who have undergone a coronary angiogram will find that an angioplasty procedure is a very similar experience. Angioplasty (also known as Percutaneous Transluminal Coronary Angioplasty or PTCA) is a procedure to open narrowed or blocked coronary arteries by locating the blockage, pushing apart the obstruction and leaving a larger opening for blood to pass through. The angioplasty procedure is usually performed in a cardiac catheterization lab.



Angioplasty opens clogged arteries by pushing apart the obstruction. A PTCA Catheter is inserted into a blood vessel and advanced toward the blocked artery.

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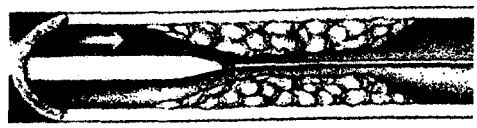
As during an angiogram, patients lie on an x-ray table with a camera moving over their chest area.

Patients usually receive medication before and during the angioplasty procedure to help them relax. However, they are generally awake and alert throughout the process so that they can respond to the physician's directions such as taking deep breaths, etc.

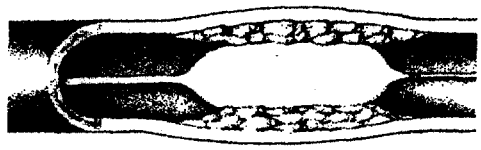
Angioplasty begins by inserting an introducer sheath into a blood vessel in the upper leg or groin area (or, alternatively, in the arm). The area around this blood vessel is first treated with a local anesthetic to numb it for the procedure.

A very small balloon catheter is passed through the sheath and into the blood vessel leading to the coronary arteries. With the help of x-ray dyes injected through the catheter, the physician can follow the path of the catheter on the fluoroscope as it is advanced toward the heart. Pictures may be taken just as during an angiogram.

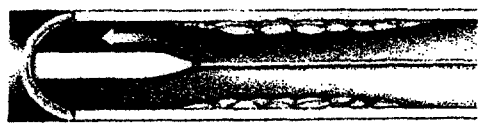


The balloon catheter nears the narrowed artery.

The balloon catheter enters the blockage and is positioned.



Once in place, the balloon is inflated to open the blockage, leaving a larger opening for blood to pass through.



After the vessel has been opened, the catheter is removed.

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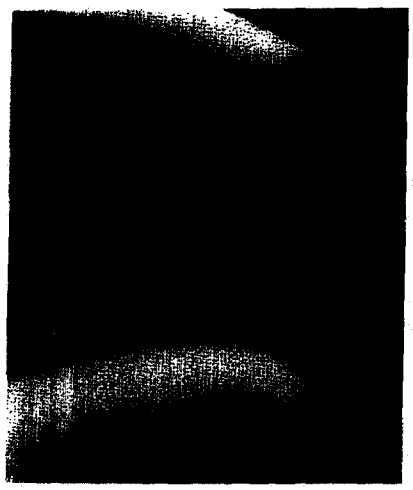
Once the catheter reaches the place in the artery that has narrowed, the balloon is centered and inflated to open the blockage, leaving a larger opening for blood to pass through.

While the balloon is inflated, some people feel chest pain similar to the angina they've experienced. This happens because the balloon is temporarily blocking the flow of blood and the oxygen that it carries to the heart. Patients should describe to the doctor any pain they feel. When the procedure is complete, the balloon catheter is withdrawn.

The Coronary Stent Procedure

In some cases, angioplasty alone may not be completely successful in treating the blocked artery. The artery may re-narrow (called restenosis) or re-close (called reocclusion) following the angioplasty procedure. To ensure that the artery remains open to allow for adequate blood flow, one or more coronary stents may be implanted in the artery. Coronary stents are generally made of metal strands or tubes, designed to provide scaffolding to support the artery. A stent can keep the artery open, restoring the flow of blood and oxygen to the heart.



A coronary stent

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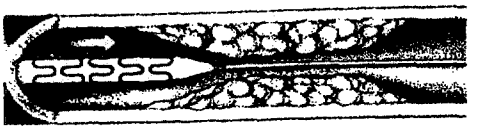
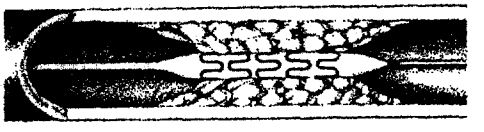
When a stent is to be implanted, a typical angioplasty procedure is performed in preparation for the stent implant.

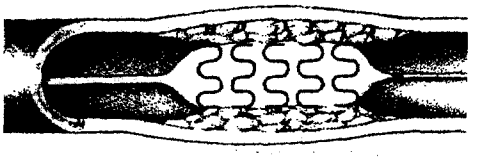
The stent is provided on the balloon portion of an angioplasty catheter for implant. The catheter carrying the stent is positioned at the area of narrowing or blockage in the artery. The balloon is then slowly inflated until the stent achieves full expansion and adapts to the shape and curve of your coronary artery. When the stent has been appropriately placed, the balloon catheter is deflated and withdrawn, leaving the expanded stent inside the artery. The stent is designed to remain in place to keep the vessel open so that blood can flow more easily. The lining of your artery will slowly grow over the stent, incorporating it into the artery wall. More than one stent may be used if the blockage is extensive.



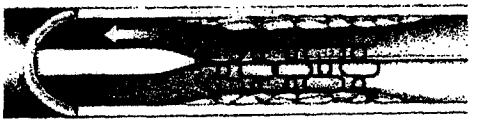
The balloon catheter, with the stent in place, is advanced toward the narrowed artery.



The catheter and stent are positioned at the blockage.



The balloon catheter is inflated to expand the stent.



The stent is embedded in the artery walls. The balloon is deflated and withdrawn, leaving the stent in place.

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The Importance of Your Medication Following Coronary Stent Placement

After your coronary stent has been placed, your physician will prescribe certain medications to thin your blood and prevent blood clots from adhering to the stent site. Anticoagulant medication, anti-platelet medication, and calcium channel blockers are often prescribed for a period of time following stent placement. Check with your doctor about using aspirin for purposes other than your prescribed therapy.

While you are taking this medication, do not have invasive surgical or dental procedures (e.g., appendectomy, tooth extraction, etc.) performed without first consulting your physician. **You will also need to inform any of your other physicians or dentists about the prescribed medication you are taking.**

Be sure to follow precisely the medication regimen and schedule given by your physician. Your physician may wish for you to chart your medication intake for review with you at follow-up appointments.

Your Follow-Up Schedule

It is important that you continue to see your physician for follow-up on a scheduled basis and that you take your medications in the manner prescribed. While you are taking anticoagulant medications, your physician will probably administer blood tests periodically to determine how fast your blood is clotting.

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Healthy Living

Angioplasty and the implantation of a coronary stent are not cures for coronary artery disease. Rather, they are an important treatment to reduce the effects of coronary artery disease. Another important element to recovery for many patients is making lifestyle changes to improve their health and minimize the impact of their heart disease.

Medical professionals recognize several factors that contribute to the build-up of plaque in the coronary arteries. The risk factors that can be controlled are:

- high blood pressure
- smoking
- high blood cholesterol
- body weight
- diabetes
- lack of proper exercise
- stress

With the help of your physician, you can evaluate your lifestyle and begin replacing high risk behaviors with more healthful habits.

Your physician may ask you to make some dietary changes that include reducing the fats and cholesterol in your diet and restricting foods that are high in vitamin K. Vitamin K contains a blood clotting factor which will reduce the effectiveness of the anticoagulant medication. Foods that have a high vitamin K content include: brussels sprouts, green tea, turnip greens, chick peas, cauliflower, kale, spinach, beef and pork liver, and broccoli. Foods with medium amounts of vitamin K include coffee, rolled oats, cabbage, iceberg lettuce, cheddar cheese, asparagus, and chicken liver.

Your Responsibilities

Medtronic maintains a patient registry to track your medical device, address, phone number, and the physicians involved in your heart care. A permanent coronary stent patient identification card will be sent to you shortly after your stent implant. **Please carry your identification card with you.** Please also inform Medtronic if you change doctors, move, or receive a new telephone number. Our address and toll-free telephone number are listed at the end of this brochure.

You should:

- Strictly adhere to your medication regimen and schedule.
- Keep all follow-up appointments with your physician.
- **Inform medical professionals, including dentists, that you have a coronary stent implanted and are taking medications for your blood.**
- Call your physician immediately if you experience:
  - recurrent chest pain
  - unusual bruising or bleeding
  - blood in your urine or stool
  - possible medication side effects including headache, nausea, vomiting, or rash.
- Begin replacing high-risk behaviors with more healthful ones.
- **Carry your coronary stent patient identification card at all times.**
- Inform Medtronic if you change doctors, move, or receive a new telephone number.

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GLOSSARY

Angina	Angina generally refers to chest pain, discomfort, pressure or tightness caused by decreased blood flow to the heart muscle. These symptoms may be accompanied by shortness of breath, nausea, and profuse sweating. Pain may also occur in the neck, jaw, back, or arm.
Angioplasty	A procedure using a dilatation, or balloon, catheter that is used to open a blockage in a blood vessel. Angioplasty may also be referred to as percutaneous transluminal coronary angioplasty (PTCA), or balloon angioplasty.
Anticoagulant	A medication that slows or inhibits clotting of blood.
Antiplatelet	A medication that decreases the clumping of platelets in the blood, helping to thin the blood and prevent clot formation.
Artery	A blood vessel that carries blood away from the heart.
Atherosclerosis	A disease process in which fatty substances (plaque) collect on the inner lining of the blood vessels leading to a narrowing or blockage of the arteries. The build-up is called atherosclerotic plaque or simply, plaque.
Catheter	A thin, flexible tube used to inject or withdraw fluid into the body or to provide a path for the introduction of treatment catheters. In angioplasty, guiding catheters provide access to the arteries of the heart and provide support for the passage of angioplasty balloon catheters which are used to reopen a blocked artery.
Contrast Medium	A dye solution injected into a blood vessel to make it visible by x-ray.
Coronary	Refers to the heart or coronary arteries.
Coronary Angiogram	A test used to diagnose coronary artery disease. Contrast medium (dye) is injected into the coronary arteries to make them visible by x-ray so that the precise area of blockage can be determined. This test is also known as cardiac catheterization.
Coronary Arteries	The blood vessels that carry oxygenated blood from the aorta to the heart muscle.
Coronary Artery Disease (CAD)	Disease of the heart in which the coronary arteries become narrowed or blocked by a gradual build-up of cholesterol within the artery wall. This build-up narrows the arteries and reduces the flow of blood to the heart. If the flow of blood is insufficient for the heart's function, severe symptoms such as chest pain (angina pectoris), heart attack (myocardial infarction), or rhythm disturbances (arrhythmias) may occur.
Electrocardiogram	A diagnostic test that shows the heart's electrical impulses. An

	electrocardiogram (ECG) may be done while resting or exercising.
Ischemia	Lack of blood supply to the heart due to an obstruction of an artery.
Lesion	An area of the blood vessel that has been narrowed by plaque, causing reduced blood flow.
Myocardial Infarction (MI)	An injury, which often causes permanent damage to the heart muscle, resulting from loss of blood supply from a coronary artery. Often referred to as a heart attack.
Plaque	A fatty deposit (cholesterol) that causes narrowing of a blood vessel.
PTCA	Percutaneous transluminal coronary angioplasty. (See angioplasty.)
Reocclusion	The re-closing of an artery that occurs at the same place where an angioplasty procedure was previously performed.
Restenosis	A narrowing of an artery that recurs at the same place where an angioplasty procedure was previously performed.
Stent	A metal support structure that expands and stays in place inside an artery to help keep it open. A stent is delivered to the site of a blockage by a dilatation, or balloon, catheter. When the balloon catheter is inflated, the stent is expanded to provide support for the artery. When the balloon catheter is deflated and withdrawn, the stent remains in place as a permanent implant.
Stress Test	A diagnostic test using an electrocardiogram (ECG) and a stationary bicycle or treadmill to look at areas of the heart that may have a decreased blood supply.

Medtronic Coronary Stents:

Intended Use
Intended for use in patients who experience abrupt or threatened closure of a coronary artery or bypass graft. One or more coronary stents may be used to keep the vessel(s) open.

Contraindications
Contraindicated for patients who have bleeding disorders or who are unable to take aspirin or blood thinning medications and patients whose coronary artery disease prevents expansion of the stent delivery balloon.

Warnings / Precautions
Subsequent reocclusion or restenosis of a stented vessel or a debranch artery may require further treatment including angioplasty, drug therapy or surgery.

Implanting a stent may lead to injury or closure of the vessel which may require further angioplasty and stent treatment.

Damage to the vascular access site may require surgical treatment.

Blood thinning medications, aspirin or other anti-platelet medications are essential to minimize the risk of clotting and for successful stent implantation and follow-up results.

Potential Adverse Effects
Potential side effects and complications associated with the use of coronary stents are similar to those experienced with standard percutaneous transluminal coronary angioplasty (PTCA) and include, but are not limited to, the adverse effects of progressive disease, drug therapy, use of the delivery system, and long-term implantation of the stent. Adverse effects may require repeat angioplasty, drug therapy or surgery.

Ask your doctor about any questions you may have regarding your therapy.

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United States of America
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432-3576
USA
Telephone: (612) 514-4000
FAX: (612) 514-6129
Toll-free: 1-800-551-5544
(8 a.m. to 5 p.m. CST)

Europe
Medtronic Europe S.A.
World Trade Center
2, Avenue Gratta Paille
C.P. 468
1000 Lausanne 30 Grey
Switzerland
Telephone: (41 21) 641 5200
FAX: (41 21) 641 5252

Canada
Medtronic of Canada Ltd.
6733 Kitimat Road
Mississauga, Ontario L5N 1W3
Canada
Telephone: (905) 826-6020
FAX: (905) 826-6620
Toll-free: 1-800-268-5346

Asia-Pacific
Medtronic Japan
Shuwa Kioi-cho Park Bldg., 5Fl.
3-6 Kioi-cho, Chiyoda-ku
Tokyo 102
Japan
Telephone: (81-3) 3230-2919
FAX: (81-3) 3230-2625

Latin America
Medtronic, Inc.
600 West Hillsboro Blvd.
Hillsboro Center, Suite 500
Deerfield Beach, FL 33441
USA
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CORONARY STENT IDENTIFICATION CARD

IN CASE OF A MEDICAL QUESTION OR EMERGENCY,
PLEASE CONTACT MY DOCTOR(S):

IMPLANTING DOCTOR_____

PHONE#_____

FOLLOW-UP DOCTOR_____

PHONE#_____

I AM TAKING A BLOOD THINNING DRUG ☐ YES ☐ NO

CATALOG NUMBER _____

LOT NUMBER_____

DATE OF IMPLANT_____

IMPLANT SITE(S): _____

_____

_____

_____

DOCTOR: PLEASE HIGHLIGHT THE SITE(S)
OF STENT IMPLANTS

[redacted]

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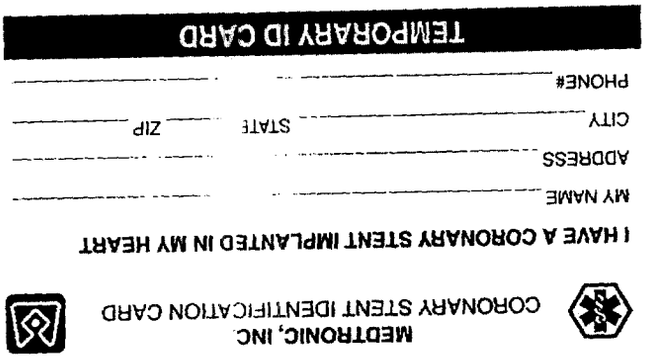

MEDTRONIC, INC.
CORONARY STENT IDENTIFICATION CARD

I HAVE A CORONARY STENT IMPLANTED IN MY HEART

MY NAME _____

ADDRESS _____

CITY _____ STATE _____ ZIP _____

PHONE# _____

TEMPORARY ID CARD

Dear Doctor or Nurse.

This is your patient's temporary coronary stent identification card. Please complete it and advise your patient to keep it where it may be readily located.

Medtronic will mail your patient a permanent, plastic identification card to replace this temporary card shortly.

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