BeStent™ 2 [illegible]
OVER-THE-WIRE CORONARY STENT DELIVERY SYSTEM

INSTRUCTIONS FOR USE

Caution: Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician. Refer to accompanying instructions For Use.

Contents

I.P.(atm)
Inflation Pressure

LOT
Lot Number

Maximum Guidewire Diameter

MSID
Max Stent Inner Diameter

MGCID
Minimum Guiding Catheter I.D.

NBP
Nominal Balloon Pressure

STENT ∅
Nominal Stent Diameter

STENT
Nominal Stent Length

Post-Deployment Stent I.D.

RBP
Rated Burst Pressure

REF
Reference Number

Single Use

STERILE R
Sterilization using Irradiation

Use By Date

STERILE UNLESS PACKAGE IS OPEN OR DAMAGED

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Medtronic AVE

Rev 003/xxxx/PKG5014009

Medtronic AVE BeStent™ 2 with Discrete Technology™
OVER-THE-WIRE CORONARY STENT DELIVERY SYSTEM

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I. DEVICE DESCRIPTION

The Medtronic AVE BeStent™ 2 with Discrete Technology™ Over-the-Wire Coronary Stent Delivery System (BeStent™ 2) includes:

- A pre-mounted 316L stainless steel stent with gold markers embedded in each end. The markers facilitate stent visibility under fluoroscopy.
- A sheathless, extended pressure over-the-wire coronary stent system providing symmetrical stent deployment utilizing an extended pressure balloon.
- Delivery system with discrete balloon technology with a larger proximal pillow.
- Two radiopaque (gold) markers embedded in the inner shaft beneath the balloon, proximal and distal to the stent. The markers are visible under fluoroscopy.
- Third and fourth shaft markers are located approximately at 90 cm and 100 cm, respectively, from the distal tip.

The BeStent™ 2 can be re-inflated to the rated burst pressure (RBP), without moving the placement of the balloon within the stent, to optimize stent apposition.

Figure 1.
Medtronic AVE BeStent™ 2 Over-The-Wire Stent Delivery System Graphic

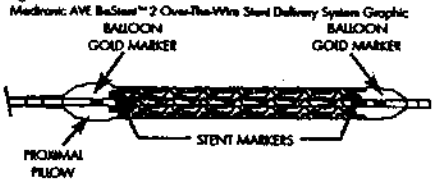


Table 1. Device Specifications

Stent Diameter	Stent Length	Minimum Guiding Catheter I.D.*	Stent Deployment Pressure	Rated Burst Pressure (RBP)	Max. Allowable Stent I.D.
3.5 mm	9 mm	0.064 inch	8 atm	16 atm	4.5mm
3.0 mm	12 mm	0.064 inch	8 atm	16 atm	3.5mm
4.0 mm	12 mm	0.064 inch	8 atm	15 atm	4.5mm
3.5 mm	15 mm	0.064 inch	8 atm	16 atm	4.5mm
3.0 mm	18 mm	0.064 inch	8 atm	16 atm	3.5mm
4.0 mm	18 mm	0.064 inch	8 atm	15 atm	4.5mm
3.5 mm	24 mm	0.064 inch	8 atm	16 atm	4.5mm
3.0 mm	30 mm	0.064 inch	8 atm	16 atm	3.5mm
4.0 mm	30 mm	0.064 inch	8 atm	15 atm	4.5mm

2. INDICATIONS

The BeStent™ 2 is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de novo lesions (length ≤ 30 mm) in native coronary arteries with reference vessel diameters ranging from 3.0 mm to 4.0 mm.

3. CONTRAINDICATIONS

The BeStent™ 2 is contraindicated for use in:

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

4. WARNINGS AND PRECAUTIONS

(see also Individualization of Treatment)

- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events.
- Patients allergic to 316L stainless steel may suffer an allergic reaction to this implant.
- Only physicians who have received appropriate training should perform implantation of the stent.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized coronary stents is unknown at present.
- When multiple stents are required, it is recommended that stent materials should be of similar composition.
- Long-term outcome for this permanent implant is unknown at present.

4.1 Stent Handling - Precautions

- For single use only. Do not resterilize or reuse. Note product "Use By" date.
- Do not remove stent from its Delivery System as removal may damage the stent and/or lead to stent embolization. The BeStent™ 2 stent is intended to perform as a system and is not designed to be crimped onto another delivery device.
- Stent Delivery System should not be used in conjunction with any other stents.
- Special care must be taken not to handle or in any way disrupt the stent position on the delivery device. This is most important during catheter removal from packaging, placement over guidewire, and advancement through rotating hemostatic valve adapter and guiding catheter hub.
- Excessive manipulation, e.g., rolling the mounted stent, may cause dislodgment of 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 it may cause uneven expansion and difficulty in deployment of the stent.

4.2 Stent Placement - Precautions

- Do not prepare or pre-inflate the Stent Delivery System prior to stent deployment, other than as directed. Use balloon purging technique described in section 9.3.2 Delivery System Preparation.
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g., CABG, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent when placing the distal stent and reduces the chances for dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel (see Stent/System Removal - Precautions).
- Placement of the stent has the potential to compromise side branch patency.
- Do not exceed Rated Burst Pressure as indicated on product label. Balloon pressures should be monitored during inflation (see Compliance Chart - Table 7). Use of pressures higher than those specified on product label may result in a ruptured balloon and potential intimal damage and dissection.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications can include bleeding, hematoma or pseudoaneurysm.

4.3 Stent / System Removal - Precautions

If balloon was not expanded, carefully withdraw stent delivery system into guiding catheter, using fluoroscopic guidance to guard against stent movement on the balloon. If any stent movement is detected, or resistance is felt, cease retraction at once and proceed to 4.3.1.

4.3.1 Removing the Stent Delivery System As a Single unit

If it is not possible to retract the stent delivery system safely into the guiding catheter it should be removed as a single unit. This must be done under direct visualization with fluoroscopy.

- Maintain guidewire placement across the lesion and carefully pull back the stent delivery system until the proximal balloon marker of the stent delivery system is aligned with the distal tip of the guiding catheter.
- The guiding catheter and the stent delivery system should be carefully removed from the coronary artery as a single unit.
- The system should be pulled back into the descending aorta toward the arterial sheath. As the distal end of the guiding catheter enters into the arterial sheath, the catheter will straighten, allowing safe withdrawal of the stent delivery system into the guiding catheter and the subsequent removal of the stent delivery system and the guiding catheter from the arterial sheath.
- Failure to follow these steps and/or applying excessive force to the stent delivery system can potentially result in loss or damage to the stent and/or stent delivery system components such as the balloon.

4.4 Post-implant Precautions

- Care must be exercised when crossing a newly deployed stent with an intravascular ultrasound (IVUS) catheter, a coronary guidewire, or a balloon catheter to avoid disrupting the stent geometry.
- Do not perform Magnetic Resonance Imaging (MRI) scans on patients post-stent implantation until the stent has

been completely endothelialized (eight weeks post stent implant) to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.

5. OBSERVED ADVERSE EVENTS

The BeStent™ 2 was designed to retain very similar fundamental material and design characteristics as the original BeStent, while enhancing user preferred properties such as trackability, flexibility, conformability and vessel wall coverage. Due to the similarities in design, the BeStent™ 2's long-term performance will be supported by the six-month clinical success of the BeStent as clinically evaluated in the BEST Trial.

A total of 652 patients were enrolled in a randomized, thirty-two (32) multi- center Clinical Trial to show equivalence in long-term clinical outcomes between the BeStent™ Coronary Stent and the Palmaz-Schatz® Stent (PS®) in de novo and restenotic native coronary lesions. Of these, 325 received the BeStent™ Coronary Stent and 327 patients received the Palmaz-Schatz® Stent (PS®). A total of 227 patients were enrolled in a separate registry with the BeStent™ 2 Coronary Stent. These patients form the basis of the observed events reported (see section 6, Clinical Studies).

5.1 BEST (BeStent ™ Trial) Randomized Clinical Trial

A total of 325 patients were enrolled in the BeStent™ arm of the BEST Trial to show equivalence in late-term clinical outcomes between the BeStent™ Coronary Stent and the Palmaz-Schatz® Stent (PS®) in de novo and restenotic native coronary lesions. Fifty seven of 325 (17%) who received the BeStent™ experienced

Summary of Clinical Trial Patient Enrollment

	Medtronic AVE BeStent™ or BeStent™ 2 Coronary Stent System	Palmaz-Schatz® Coronary Stent- Control	Patient Totals
BEST Trial (BeStent™)	325	327	652
BeStent™ 2 Registry	227	0	227
Patient Totals	552	327	879

Table 2. Adverse Events During the First 6 Months
% [±95 % Confidence Interval] Number/Denominator (n= 652 Patients)
All Randomized Patients in Best Trial:

	BEST TRIAL	
Complication	BeStent™ (n=325)	Palmaz-Schatz® (n=327)
Any Adverse Events	10.8% [7.6%,14.7%] [35/325]	10.1% [7.0%,13.9%] [33/327]
Early (in-hospital)	9.5% [6.6%,13.3%] [31/325]	7.3% [4.8%,10.7%] [24/327]
Out-of -hospital	1.5% [0.5%,3.6%] [5/325]	3.1% [1.5%,5.6%] [10/327]
Death Total	0.6% [0.1%,2.2%] [2/325]	0.9% [0.2%,2.7%] [3/327]
Early (in-hospital)	0.0% [0.0%,1.1%] [0/325]	0.0% [0.0%,1.1%] [0/327]
Out-of -hospital	0.6% [0.1%,2.2%] [2/325]	0.9% [0.2%,2.7%] [3/327]
Q-wave MI Total	1.5% [0.5%,3.6%] [5/325]	1.5% [0.5%,3.5%] [5/327]
Early (in-hospital)	1.2% [0.3%,3.1%] [4/325]	0.6% [0.1%,2.2%] [2/327]
Out-of -hospital	0.3% [0.0%,1.7%] [1/325]	0.9% [0.2%,2.7%] [3/327]
Non-Q-wave Total	2.5% [1.1%,4.8%] [8/325]	2.1% [0.9%,4.4%] [7/327]
Early (in-hospital)	2.5% [1.1%,4.8%] [8/325]	1.8% [0.7%,4.0%] [6/327]
Out-of -hospital	0.0% [0.0%,1.1%] [0/325]	0.3% [0.0%,1.7%] [1/327]
Emergent CABG Total	0.9% [0.2%,2.7%] [3/325]	0.6% [0.1%,2.2%] [2/327]
Early (in-hospital)	0.9% [0.2%,2.7%] [3/325]	0.6% [0.1%,2.2%] [2/327]
Out-of -hospital	0.0% [0.0%,1.1%] [0/325]	0.0% [0.0%,1.1%] [0/327]
Stent Thrombosis Total	0.9% [0.2%,2.7%] [3/325]	1.5% [0.5%,3.5%] [5/327]
Early (in-hospital)	0.6% [0.1%,2.2%] [2/325]	0.6% [0.1%,2.2%] [2/327]
Out-of -hospital	0.3% [0.0%,1.7%] [1/325]	0.9% [0.2%,2.7%] [3/327]
Bleeding Complications Requiring Procedural	1.8% [0.7%,4.0%] [6/325]	0.6% [0.1%,2.2%] [2/327]
Vascular Complications	6.2% [3.8%,9.3%] [20/325]	4.9% [2.8%,7.8%] [16/327]
Cerebrovascular Accidents	0.9% [0.2%,2.7%] [3/325]	0.9% [0.2%,2.7%] [3/327]
Stent Delivery Failure**	2.2% [0.9%,4.4%] [7/325]	1.2% [0.3%, 3.1%] [4/327]

*Any Adverse Event = Death, Q wave MI, non-Q wave MI, CABG, stent thrombosis, bleeding complications, vascular complications and CVA

NOTE: In cases where a patient experienced both an in-hospital event and an out-of-hospital event they are counted once in each group. They are counted only once in the event total. Hence, the sum of the in-hospital event rate and the out-of-hospital event rate may not equal the total event rate.

**Stent Delivery Failure: Failure to deliver the first assigned stent only

one or more adverse events during the first six months of the follow-up compared to 47 of the 327 (14%) Palmaz-Schatz® control patients. Adverse events reported during the first six months are shown in Table 2.

5.2 BeStent™ 2 Registry

A total of 227 patients were enrolled in a multi-center registry to evaluate the safety and efficacy of the BeStent™ 2 for treatment of symptomatic coronary artery disease. Adverse events reported during the first 30 days are shown in Table 3. A total of 11 of 227 patients (4.8%) who received the BeStent™ 2 stent experienced one or more adverse events during the first 30 days of follow-up.

5.3 Potential Adverse Events

Adverse events (in alphabetical order) may be associated with the use of a coronary stent in native coronary arteries (including those listed in Table 2 and 3).

- Acute myocardial infarction
- Arrhythmias, including VF and VT
- Death
- Dissection
- Drug reactions to antiplatelet agents/contrast medium
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and pain at insertion site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent thrombosis/occlusion
- Stroke/Cerebrovascular Accidents
- Total occlusion of coronary artery

Table 3. Adverse Events During the First 30 Days†
BeStent ™ 2 and Palmaz-Schatz® (from BEST) Patients
% [95 % confidence interval] (Number)

Complication	BeStent™ 2 (N=227)	Palmaz-Schatz® (N=327)
Any Adverse Events	4.8% [2.4%, 8.5%] (11/227)	9.2% [6.3%, 12.8%] (30/327)
Early (In-Hospital)	3.5% [1.5%, 6.8%] (8/227)	7.3% [4.8%, 10.7%] [24/327]
Out-of-hospital	1.3% [0.3%, 3.8%] [3/227]	2.1% [0.9%, 4.4%] [7/327]
Death Total	0.9% [0.1%, 3.1%] (2/227]	0.9% [0.2%, 2.7%] [3/327]
Early (In-Hospital)	0.0% [0.0%, 1.6%] (0/227]	0.0% [0.0%, 1.1%] [0/327]
Out-of-hospital	0.9% [0.1%, 3.1%] (2/227]	0.9% [0.2%, 2.7%] [3/327]
Q Wave MI Total	0.4% [0.0%, 2.4%] (1/227]	0.9% [0.2%, 2.7%] [3/327]
Early (In-Hospital)	0.4% [0.0%, 2.4%] (1/227]	0.6% [0.1%, 2.2%] [2/327]
Out-of-hospital	0.0% [0.0%, 1.6%] (0/227]	0.3% [0.2%, 1.7%] [1/327]
Non-Q Wave MI Total	0.9% [0.1%, 3.1%] (2/227]	1.8% [0.7%, 4.0%] [6/327]
Early (In-Hospital)	0.9% [0.1%, 3.1%] (2/227]	1.8% [0.7%, 4.0%] [6/327]
Out-of-hospital	0.0% [0.0%, 1.6%] (0/227]	0.0% [0.0%, 1.1%] [0/327]
Emergent CABG Total	0.4% [0.0%, 2.4%] (1/227]	0.6% [0.1%, 2.2%] [2/327]
Early (In-Hospital)	0.4% [0.0%, 2.4%] (1/227]	0.6% [0.1%, 2.2%] [2/327]
Out-of-hospital	0.0% [0.0%, 1.6%] (0/227]	0.0% [0.0%, 1.1%] [0/327]
Stent Thrombosis Total	0.9% [0.1%, 3.1%] (2/227]	1.5% [0.5%, 3.5%] [5/327]
Early (In-Hospital)	0.0% [0.0%, 1.6%] (0/227]	0.6% [0.1%, 2.2%] [2/327]
Out-of-hospital	0.9% [0.1%, 3.1%] (2/227]	0.9% [0.2%, 2.7%] [3/327]
Bleeding Complications Requiring Transfusion	1.8% [0.5%, 4.5%] (4/227]	0.6% [0.1%, 2.2%] [2/327]
Vascular Complications	0.4% [0.0%, 2.4%] (1/227]	4.9% [2.8%, 7.8%] [16/327]
Cerebrovascular Accidents	0.0% [0.0%, 1.6%] (0/227]	0.9% [0.2%, 2.7%] [3/327]
Stent Delivery Failure**	0.4% [0.0%, 2.4%] (1/227]	1.2% [0.3%, 3.1%] (4/327]

*Any Adverse Event – Death, Q wave MI, non-Q wave MI, CABG, stent thrombosis, bleeding complications, vascular complications and CVA

NOTE: In cases where a patient experienced both an in-hospital event and an out-of-hospital event they are counted once in each group. They are counted only once in the event total. Hence, the sum of the in-hospital event rate and the out-of-hospital event rate may not equal the total event rate.

**Stent Delivery Failure: Failure to deliver the first assigned stent only

†The BeStent™ and Palmaz-Schatz® Trials were non-concurrent, and statistical comparison is not appropriate

6. CLINICAL STUDIES

6.1 BEST Randomized Clinical Trial

A total of 652 patients were enrolled in a randomized, thirty-two (32) multi-center clinical trial to show equivalence in late-term clinical outcomes between the Medtronic BeStent™ Coronary Stent and the Palmaz-Schatz® Stent (PSD) in de novo and restenotic native coronary lesions. Of these, 325 received the BeStent™ Coronary Stent and 327 patients received the Palmaz-Schatz® Stent (PSD). The primary endpoint was defined as Major Adverse Clinical Events (MACE) at six months. MACE was defined as the occurrence of any of the following: death, Q wave or non Q wave MI, emergent CABG, or target lesion revascularization (TLR). A clinical events committee blinded to the treatment arm adjudicated all major clinical events and clinically driven TLR. Of the 652 patients studied, 325 subjects were randomized to the BeStent™ arm. Sixty-seven percent (218/325) were males ranging in age from 34 to 90 years with an average of 60 ± 11 years (means ± SD). In the 327 patients randomized to Palmaz-Schatz®, 69% (225/327) were males ranging in age from 24 to 91 with an average of 61 ± 11 years. Eligibility was determined by the presence of angina or positive functional study (Exercise Treadmill Test). Patients were identified for elective stenting of de novo or restenotic lesions in native coronary arteries having vessel diameter between 3.0 mm and 4.0 mm with a lesion length of ≤25 mm, which could be covered by an appropriate length Medtronic BeStent™ (BeStent™ 1). These patients underwent balloon angioplasty (1:1 balloon to artery ratio) after which a Stent Delivery System of the appropriate size was selected and deployed in the native coronary artery. Post deployment dilatation was performed utilizing a high-pressure balloon having a 1:1 balloon to artery ratio to obtain optimal stent apposition.

The anticoagulation regimen administered to 96% of patients was 325 mg/day of uncoated, water-soluble aspirin for at least 6 months and ticlopidine 250 mg twice a day for at least 30 days to 47% of the patients. At the discretion of the investigator, alternative therapy was allowed for non-optimal results, which were defined as >30 mm stents implanted, >10% residual stenosis, any residual dissection, TIMI flow grade 0-1, or the presence of thrombus.

Clinical follow-up intervals for all treated patients were 30 days, 6 months and 12 months. A subset of patients (first 150 patients in each arm of the randomized study) underwent angiographic follow-up at six months. All treated patients were included in the intent-to-treat efficacy analysis. The Principal Effectiveness and Safety results for the BEST Randomized Trial (BeStent™) compared to Palmaz-Schatz® are presented in Table 4. The relation of baseline and procedural variables to TLR was examined. The statistical predictors of TLR were post-procedure MLD, total length of stents implanted and pre-procedure diameter stenosis.

6.2 BeStent™ 2 Registry

The BeStent™ 2 Registry was a prospective, multi-center non-randomized trial conducted at eighteen (18) sites within the United States and three Middle East sites. This registry included 227 patients with de novo and restenotic native coronary artery lesions. An independent Clinical Events Committee adjudicated all of the major clinical endpoints and clinically driven TLR.

6.2.1 Primary Endpoints

The primary endpoint in the BeStent™ 2 Registry was defined as Major Adverse Clinical Events (MACE) rate, the composite of death, Q wave or non-Q wave myocardial infarction, emergent coronary artery bypass surgery, or target lesion revascularization (TLR) at 30 days.

6.2.2 Patients Studied

Of the 227 patients studied, 68.3% were male ranging in age from 36 to 83 years with an average of 62.4 years ± 10.6 (mean ± SD). All patients presented with angina or a positive functional study and were undergoing elective single de novo or restenotic lesion treatment in a native coronary artery. Eligible patients had visually estimated stenosis ≤ 28mm in length in a major coronary artery or major side branch ≥ 3.0mm and ≤ 4.0mm in diameter.

6.2.3 Methods

Patients in the BeStent™ 2 Registry underwent balloon angioplasty (1:1 balloon to artery ratio) after which a Stent Delivery System of the appropriate size was selected and deployed in the native coronary artery. Post deployment dilatation was performed utilizing a high-pressure balloon having a 1:1 balloon to artery ratio to obtain optimal stent apposition, post-procedure for all patients. Baseline quantitative coronary angiography was performed pre-procedure, following device deployment, and after final treatment.

Clinical follow-up was completed at 30 days. The anticoagulation regimen administered to 92.1% of the patients was 325mg/day of aspirin for at least 30 days. Clopidogrel, 75mg once a day, was administered to 80.2% of the patients for at least 14 days.

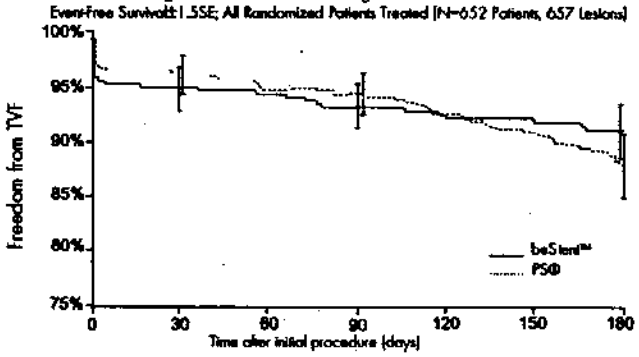
The principal effectiveness and safety results for the BeStent™ 2 Registry are compared to the results of the Palmaz-Schatz® control group in the BEST Randomized Trial and are presented in Table 5. These two studies were non-concurrent, and statistical comparison is not appropriate. The relation of baseline and procedural variables to Target lesion Revascularization (TLR) was examined. The statistical predictors of TLR were post-procedure MLD and total length of stents implanted.

Table 4 Principal Effectiveness and Safety Results (BEST Trial)
All Randomized Patients Treated (N=652 Patients)
Percent (95% Confidence Interval) (Number)

Efficacy Measures	BeStent™ (N=325 Patients)	Palmaz-Schatz® (N=327 Patients)	Difference 95% C.I.
Device Success	93.2% (89.9%,95.7%) (303/325)	93.9 (90.7%,96.2%) (307/327)	-0.7% (-4.4%, 3.1%)
Acute Procedure Success	95.4% 92.5%, 97.4% (310/325)	96.3 93.7% 98.1% (315/327)	-0.9% (-4.0%, 2.1%)
Post-Procedure In-Stent MLD (in mm)			
Mean ±SD (N)	2.82+0.40 (319)	2.80+0.41 (321)	0.02% (-0.05%, 0.08%)
(95% CI)	(2.76, 2.86)	(2.76, 2.85)	
Range (min, max) (95% CI)	(1.92, 4.49)	(1.61,4.49)	
6 Months Follow-up In-Stent % DS			
Mean ± SD (N)	32.9%+22.9% (103)	38.1%+21.5% (102)	-1.0% (-2.6%, 0.5%)
(95% CI)	(28.5%, 37.4%)	(33.9%, 42.3%)	
Range (min, max) (95%CI)	(-12.9%, 100.0%)	(-7.1%, 100.0%)	
6 Months Follow-up In-Stent Binary	16.5% (9.9%,25.1%)	26.5% (18.2%,36.1%) (27/102)	-10.0% (-21.1%, 1.2%)
Restenosis rate	(17/103)		
Post-Procedure hospital length of stay (days)			
Mean ± SD (N) (95%CI)	1.4+1.6 (325) (1.3, 1.6)	1.3+0.9 (327) (1.2, 1.4)	0.2 (0.0, 0.4)
Range (min, max)	(0,14)	(0,8)	
TLR-free at 180 days	95.9% (93.4%, 98.3%)	90.8% (87.2%, 94.3%)	5.1% (0.8%, 9.4%)
TVR-free at 180 days	94.5% (91.7%, 97.4%)	89.4% (85.7%, 93.2%)	5.1% (0.4%, 9.8%)
TVF-free at 180 days	90.5% (86.9%, 94.2%)	87.1% (82.9%, 91.1%)	3.5% (-2.0%, 9.1%)
Safety Measures & Other Clinical Events to 6 months			
In-Hospital MACE (Death, QMI, TLR, Emergent CABG)	4.3% (2.4%, 7.1%) (14/325)	2.8% (1.3%,5.2%) (9/327)	1.6% (-1.3%, 4.4%)
Out-of-Hospital MACE (Death, QMI, TLR, Emergent CABG)	4.9% (2.8%, 8.2%) (16/325)	10.1% (7.0%, 13.9%) (33/327)	-5.2% (-8.9%, -1.5%)
Bleeding Complications	1.8% (0.7%, 4.0%) (6/325)	0.6% (0.1%, 2.2%) (2/327)	1.2% (-0.5%, 2.9%)
CVA to 180 days	0.9% (0.2%, 2.7%) (3/325)	0.9% (0.2%, 2.7%) (3/327)	0.0% (-1.5%, 1.5%)
Vascular Complications	6.2% (3.8%, 9.3%) (20/325)	4.9% (2.8%, 7.8%) (16/327)	1.3% (-2.2%, 4.8%)
Stent Thrombosis to 30 days	0.9% (0.2%, 2.7%) (2/325)	1.5% (0.5%, 3.5%) (5/327)	-0.6% (-2.3%, 1.1%)

MACE = Major Adverse Cardiac Event: Death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization.
TLR-Free = Freedom from target lesion revascularization.
TVR-Free = Freedom from target vessel revascularization.
TVF-Free = Freedom from death, MI, and target vessel revascularization
Device Success = Achievement of a final residual diameter stenosis <50% (by QCA) without use of a device outside of the assigned treatment strategy. If no in-stent measurements were available, in-lesion measurements were used. If no QCA was available, visual estimates were used.
Acute Procedure Success = Achievement of a final residual diameter stenosis of <50% using any percutaneous method and no in-hospital MACE (death, Q wave MI, emergent CABG, and TLR). If no QCA was available, visual estimates were used, and if no in-stent measurements were available, in-lesion measurements were used.
In-Hospital MACE = Death, Q wave MI or non-Q wave, emergent CABG, or target lesion revascularization prior to hospital discharge.
Out-of-Hospital MACE = Death, Q wave MI or non-Q wave, emergent CABG, or target lesion revascularization after hospital discharge and through 180 days.
Bleeding Complications = Transfusions of blood products due to blood loss from the percutaneous revascularization procedure.
CVA = Acute neurological deficits recorded by the clinical sites that persisted >24 hours.
Vascular Complications = Hematoma at access site >4 cm, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure related transfusion or vascular surgical repair.
Stent Thrombosis = Angiographic thrombus or subacute closure within the stented vessel, or any death not attributed to a non-cardiac cause in the absence of documented angiographic stent patency within the first 30 days.

Figure 2. Survival Free from Target Vessel Failure
Event-Free Survival±1.5SE; All Randomized Patients Treated (N=652 Patients, 657 Lesions)



	Time after initial procedure (days)								
	0	7	14	30	60	90	120	150	180
beStent™									
#Entered	325	322	308	307	304	299	294	289	278
#Lost to Follow-up	0	2	1	2	3	1	2	10	52
#Incomplete	0	0	0	0	0	0	0	0	0
# At Risk	325.0	321.0	307.5	306.0	302.5	298.5	293.0	284.0	252.0
# Events	3	12	0	1	2	4	3	1	4
# Events/Month		51.4	0.0	1.9	2.0	4.0	3.0	1.0	4.0
% Survival	99.1%	95.4%	95.4%	95.1%	94.4%	93.2%	92.2%	91.9%	90.5%
SE	0.5%	1.2%	1.2%	1.2%	1.3%	1.4%	1.5%	1.6%	1.9%
PS®									
# Entered	327	324	315	314	312	307	303	294	282
# Lost to Follow-up	0	1	0	1	2	1	3	5	48
# Incomplete	0	0	0	0	0	0	0	0	0
# At Risk	327.0	323.5	315.0	313.5	311.0	306.5	301.5	291.5	258.0
# Events	3	8	1	1	3	3	6	7	9
# Events/Month		34.3	4.3	1.9	3.0	3.0	6.0	7.0	9.0
% Survival	99.1%	96.6%	96.3%	96.0%	95.1%	94.2%	92.3%	90.1%	87.0%
SE	0.5%	1.0%	1.0%	1.1%	1.2%	1.3%	1.5%	1.7%	2.1%

Tests Between Groups

Test	ChiSquare	Deg Fdm	Pvalue
log-Rank	2.48	1	0.115
Wilcoxon	2.22	1	0.136

Table 5 Principal Effectiveness and Safety Results to 30 days for
BeStent™ 2 Registry (N=227 Patients)
Percent [95% Confidence Interval] (Number)

Efficacy measures	BeStent™ 2 (N=227 Patients)	Palmaz-Shatz® (N=327 Patients)
Device Success	95.2% [91.5%, 97.6%] (216/227)	93.9% [90.7%, 96.2%] (307/327)
Acute Procedure Success	97.8% [94.9%, 99.3%] (222/227)	96.3% [93.7%, 98.1%] (315/327)
Post-Procedure In-Stent MLD (in mm)		
Mean ± SD (N)	2.81±0.46 (224)	2.80±0.41 (321)
[95% CI]	[2.75, 2.87]	[2.76, 2.85]
Range (min, max) [95% CI]	(1.69, 4.15)	(1.61, 4.31)
Post-Procedure In-Stent % DS		
Mean ± SD (N)	3.8%±9.6% (224)	8.0% ± 10.5% (321)
[95% CI]	[2.5%, 5.1%]	[6.8%, 9.1%]
Range (min, max) [95% CI]	(-25.7%, 27.0%)	(-29.3%, 38.8%)
Post-Procedure hospital length of stay (days)		
mean ± SD (N) [95% CI]	1.4±1.1 (218) [1.2, 1.5]	1.3 ± 0.9% (327) [1.2, 1.4]
Range (min, max)	[0.0, 8.0]	[0.0,8.0]
TLR-free at 30 days	99.6% [98.4%, 100.0%]	98.5% [97.2%, 99.8%]
TVR-free at 30 days	98.7% [96.7%, 100.0%]	98.5% [97.2%, 99.8%]
TVF-free at 30 days	96.4% [93.2%, 99.6%]	96.0% [93.9%, 98.1%]
Safety measures & Other Clinical Events to 30 days		
In-Hospital MACE (Death, QMI, TVR, Emergent CABG)	2.2% [0.7%, 5.1%] (5/227)	2.8% [1.3%, 5.2%] (9/327)
Out-of-Hospital MACE (Death, QMI, TVR, Emergent CABG) to 30 days	1.3% [0.3%, 3.8%] (3/227)	1.2% [0.3%, 3.1%] (4/327)
Bleeding Complications	1.8% [0.5%, 4.5%] (4/227)	0.6% [0.1%, 2.2%] (2/327)
CVA to 30 days	0.0% [0.0%, 1.6%] (0/227)	0.9% [0.2%, 2.7%] (3/327)
Vascular Complications	0.4% [0.0%, 2.4%] (1/227)	4.9% [2.8%, 7.8%] (16/327)
Stent Thrombosis to 30 days	0.9% [0.1%, 3.1%] (2/227)	1.5% [0.5%, 3.5%] (5/327)

MACE = Major Adverse Cardiac Event: Death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization.
TLR-Free = Freedom from target lesion revascularization.
TVR-Free = Freedom from target vessel revascularization.
TVF-Free = Freedom from death, MI, and target vessel revascularization
Device Success = Achievement of a final residual diameter stenosis <50% (by QCA) without use of a device outside of the assigned treatment strategy. If no in-stent measurements were available, in-lesion measurements were used. If no QCA was available, visual estimates were used.
Acute Procedure Success = Achievement of a final residual diameter stenosis of <50% using any percutaneous method and no in-hospital MACE (death, Q wave MI, emergent CABG, and TVR). If no QCA was available, visual estimates were used, and if no in-stent measurements were available, in-lesion measurements were used.
In-Hospital MACE = Death, Q wave MI or non-Q wave, emergent CABG, or target lesion revascularization prior to hospital discharge.
Out-of-Hospital MACE = Death, Q wave MI or non-Q wave, emergent CABG, or target lesion revascularization after hospital discharge and through 180 days.
Bleeding Complications = Transfusions of blood products due to blood loss from the percutaneous revascularization procedure.
CVA = Acute neurological deficits recorded by the clinical sites that persisted >24 hours.
Vascular Complications = Hematoma (>5 cm for BeStent 2 patients and >4cm for PS patients), false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure related transfusion or vascular surgical repair.
*Due to the difference in definition for hematoma between the BEST and BeStent 2 trials, it was confirmed that none of the vascular complications in either trial involved a hematoma.
Stent Thrombosis = Angiographic thrombus or subacute closure within the stented vessel, or any death not attributed to a non-cardiac cause in the absence of documented angiographic stent patency within the first 30 days.

Table 6. Survival Free from Target Vessel Failure
Event-free Survival ± 1.5SE
All Patients Treated (N=554 Patients, 557 Lesions)

	Time after initial procedure (days)				
	0	7	14	21	30
BeStent™ 2					#Entered
227	222	209	208	207	#Lost to
Follow-up	3	7	1	1	81
#Incomplete	0	0	0	0	0
# At Risk	225.5	218.5	208.5	207.5	166.5
# Events	2	6	0	0	0
# Events/Month		25.7	0.0	0.0	0.0
% Survived	99.1%	96.4%	96.4%	96.4%	96.4%
SE	0.6%	1.3%	1.3%	1.3%	1.6%
PSD					
# Entered	327	324	315	314	313
# Lost to Follow-up	0	1	0	1	0
# Incomplete	0	0	0	0	0
# At Risk	327.0	323.5	315.0	313.5	313.0
# Events	3	8	1	0	1
# Events/Month		34.3	4.3	0.0	3.3
% Survived	99.1%	96.6%	96.3%	96.3%	96.0%
SE	0.5%	1.0%	1.0%	1.0%	1.1%

Tests Between Groups

Test	Chi-Square	Deg Fdm	P-value
Log-Rank	0.03	1	0.865
Wilcoxon	0.03	1	0.860

7 PATIENT SELECTION AND TREATMENT

7.1 Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of BeStent™ 2. Patient selection factors to be assessed should include a judgement regarding risk of prolonged anticoagulation. Stenting should be generally avoided in those patients at heightened risk of bleeding (e.g., those patients with recently active gastritis or peptic ulcer disease) (see Contraindications).

Premorbid conditions that increase the risk of poor initial results or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure, and sever obesity) should be reviewed.

Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3.0 mm, intra-procedural thrombosis, poor distal flow, and/or dissection following stent implantation. In patients that have undergone coronary stenting, the persistence of a thrombus or dissection is considered a marker for subsequent thrombotic occlusion. These patients should be monitored very carefully during the first month after stent implantation.

7.2 Use in Special Populations

The safety and effectiveness of the BeStent™ 2 have not been established in:

- Patients with unresolved vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameters < 3.0 mm.
- Patients with lesions located in the unprotected 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 recent acute myocardial infarction where there is evidence of thrombus or poor flow.
- Patients with restenotic lesions.

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

8. HOW SUPPLIED

STERILE: This device is sterilized with e-beam radiation. It is intended for single use only. Non-pyrogenic. Do not use if package is opened or damaged.

CONTENTS: One (1) Medtronic AVE BeStent™ 2 with Discrete Technology™ Over-the-wire Coronary Stent Delivery System.

STORAGE: Store in a cool, dry, dark place.

9. CLINICIAN USE INFORMATION

9.1 Inspection Prior to Use

Carefully inspect the sterile package before opening. It is not recommended that the product be used after the "Use By" date. If the integrity of the sterile package has been compromised prior to the product "Use By" date (e.g., damage of the package) contact your local Medtronic AVE, Inc. Representative for return information. If the sterile package appears intact, carefully remove the system from the package and inspect for bends, kinks and other damage. Verify that the stent is located between the radiopaque markers. Do not use if any defects are noted.

9.2 Materials Required

9.3 Preparation

Quantity	Material
	Appropriate guiding catheter. (see Table 1- Device Specifications)
1	20 cc syringe.
	Heparinized Normal Saline.
1	0.014 inch x 300 cm guidewire.
1	Rotating hemostatic valve.
	Contrast medium diluted 1:1 with heparinized normal saline.
1	Inflation device.
1	Torque device.
Optional	Three-way stopcock.

9.3.1 Guidewire Lumen Flush

Step	Action
1.	Flush Stent Delivery System guidewire lumen with heparinized normal saline until fluid exits the distal tip.
2.	Remove protective sheath covering from the stent/balloon. Care should be taken not to disrupt the stent.
3.	Verify that the stent is positioned between the proximal and distal balloon markers.

9.3.2 Delivery System Preparation

Step	Action
1.	Fill a 20 cc syringe with 5 cc of contrast/heparinized normal saline mixture (1:1)
2.	Attach to delivery system and apply negative pressure for 20-30 seconds.
3.	Slowly release pressure to allow negative pressure to draw mixture into balloon lumen.
4.	Detach syringe and leave a meniscus of mixture on the hub of the balloon lumen.
5.	Prepare inflation device in standard manner and purge to remove all air from syringe and tubing.
6.	Attach inflation device to catheter directly ensuring no bubbles remain at connection.
7.	Leave on catheter pressure (neutral position). Note: Do not pull negative pressure on inflation device after balloon preparation and prior to delivering the stent.
8.	Moisten the stent with heparinized normal saline by submerging the stent into a sterile bowl containing the solution. Note: Do not use gauze sponges to wipe down the stent as fibers may disrupt the stent.
9.	Visually inspect the stent to ensure the stent is placed within the area of the proximal and distal balloon markers.

9.4 Delivery Procedure

Step	Action
1	Prepare vascular access site according to standard PTCA practice.
2	Pre-dilate the lesion/vessel with appropriate diameter balloon having a ratio of 1:1 with the diameter of the vessel.
3	Maintain neutral pressure on inflation device. Open rotating hemostatic valve to allow for easy passage of the stent. Note: If resistance is encountered, do not force passage. Resistance may indicate a problem and may result in damage to the stent if it is forced. Remove the system and examine.
4	Ensure guiding catheter stability before advancing the stent delivery system into the coronary artery. Carefully advance the stent delivery system into the hub of the guiding catheter.
5	Note: If the physician encounters resistance to the stent delivery system prior to exiting the guiding catheter, do not force passage. Resistance may indicate a problem and may result in damage to the stent if it is forced. Maintain guidewire placement across the lesion and remove the stent delivery system as a single unit. (see - Stent/System Removal - Precautions)
6	Advance delivery system over the guidewire to the target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque markers on the balloon as a reference point. If the position of the stent is not optimal, it should be carefully repositioned or removed (see Stent/System Removal - Precautions). Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion segment of the vessel. (Stent markers should be located between balloon markers, refer to Figure 1)
7	Optimal stent placement requires the distal end of the stent to be placed approximately 1 mm beyond the distal end of the lesion.
8	Sufficiently tighten the rotating hemostatic valve. Stent is now ready to be deployed.

9.5 Deployment Procedure

Step	Action
1	Deploy stent by inflating balloon to nominal pressure to expand the stent. Note: Refer to product labeling and Table 6 for the proper stent inflation pressure. The BeStent™ 2 may be inflated beyond nominal, without repositioning, up to rated burst, to assure complete apposition of the stent to the artery wall. Do not exceed Rated Burst Pressure. Do not expand the stent beyond the maximum allowable stent I.D. (see Table 1)
2	Maintain inflation pressure for 15-30 seconds for full expansion of the stent.
3	Note: Under-expansion of the stent may result in stent movement. Care must be taken to properly size the stent to ensure the stent is in full contact with the arterial wall upon deflation of the balloon.

9.6 Removal Procedure

Step	Action
1	Deflate the balloon by pulling negative pressure on the inflation device. Allow adequate time, at least 15 seconds, for full balloon deflation. Longer stents may require more time for deflation.
2	Open the hemostatic valve to allow removal of the delivery system.
3	Maintain position of guiding catheter and guidewire to prevent it from being drawn into the vessel. Very slowly withdraw the balloon from the stent maintaining negative suction, allowing movement of the myocardium to gently dislodge the balloon from the stent.
4	After removal of the delivery system, tighten the hemostatic valve.
5	Repeat angiography and visually assess the vessel and the stent for proper expansion.
6	A second balloon inflation may be required to ensure optimal stent expansion. In such instances, a non-compliant, higher-pressure balloon of adequate size (the same size as the stent delivery system balloon or larger) and length may be used to accomplish this. Note: In smaller or diffusely diseased vessels, the use of high balloon inflation pressures may over-expand the vessel distal to the stent and could result in vessel dissection. Do not expand the BeStent™ 2 stent beyond the maximum allowable stent I.D. (see Table 1).
7	The final internal stent diameter should be equal to or slightly larger than the proximal and distal reference vessel diameters.
8	Repeat angiography to evaluate and determine procedure status or termination. Note: Should the need arise for placement of a second stent to adequately cover the lesion length, placement of the stent most distal in the artery should be done prior to placement of the proximal stent, if possible.
9	Note: Observation of the patient and angiographic evaluation of the stent site should be performed periodically within the first 30 minutes after stent placement. If stent placement is associated with the onset of thrombus or suspected thrombus in the region of the stented segment, intracoronary infusions of a thrombolytic agent is recommended.

9.7 in vitro Information.

Table 7: Medtronic AVE BeStent™ 2 Stent Inner Diameter (mm) vs. Inflation Pressure (ATM)

Stent Diameter (mm)	MEDTRONIC AVE BeSTENT™ 2 STENT INNER DIAMETER (MM) Deployed stent inner diameter following balloon deflation												
	6 ATM	7 ATM	8* ATM	9 ATM	10 ATM	11 ATM	12 ATM	13 ATM	14 ATM	15** ATM	16*** ATM	17 ATM	18 ATM
3.0	2.80	2.90	3.00	3.05	3.10	3.15	3.20	3.25	3.30	3.35		3.45	3.50
3.5	3.30	3.40	3.50	3.55	3.60	3.65	3.70	3.75	3.80	3.85		3.95	4.00
4.0	3.80	3.90	4.00	4.05	4.10	4.15	4.20	4.25	4.30		4.40	4.45	

* Nominal Deployment Pressure (8 ATM)

** Rated Burst Pressure for 4.0 mm diameter devices (15 ATM). DO NOT EXCEED.

*** Rated Burst Pressure for 3.0 mm and 3.5 mm diameter devices (16 ATM). DO NOT EXCEED.

Note: 95 percent of all data points will fall within ± 10 percent of table values at nominal deployment pressure. The nominal in vitro device specification does not take into account lesion resistance. Stent sizing should be confirmed angiographically.

Note: Do not expand the stent beyond the maximum allowable stent I.D. (see Table 1)

Note: Balloon pressures should be monitored during inflation. Do not exceed Rated Burst Pressure as specified on product label as this may result in a ruptured balloon with possible intimal damage and dissection.

10. PATIENT INFORMATION

In addition to the Instructions for Use, the BeStent™ 2 is packaged with additional specific information which include:

- A Patient Guide which includes information on Medtronic AVE, Inc., the implant procedure and Medtronic AVE, Inc. coronary stents.
- A Coronary Stent Implant Card that includes both patient information and stent implant information. All patients will be instructed to keep this card in their possession at all times for procedure/stent identification. (Note: The Coronary Stent Implant Card is located in the back of the Patient Guide.)

DISCLAIMER OF WARRANTY

NOTE: ALTHOUGH THE CORONARY STENT DELIVERY SYSTEM, HEREAFTER REFERRED TO AS "PRODUCT," HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC AVE, INC. HAS NO CONTROL OVER CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC AVE, INC., THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC AVE, INC. 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 AVE, INC. 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.

REFERENCES

The physician should consult recent literature on current medical practice on stent deployment, such as published by the American College of Cardiology / American Heart Association.

The revision number, month and year of these instructions is included for the user's information on the first page of these instructions. In the event 2 years have elapsed between this date and product use, the user should contact AVE Ireland Ltd., to see if additional information is available.

PATENTS

Product(s) and/or methods of manufacture under one or more of the following patents: U.S. Patent Nos. RE 32,983; RE 33,561; 5,836,965; 5,776,161; 6,090,127. Foreign Patents granted. Other U.S. and Foreign Patents pending.

BeStent 2

INSTRUCTIONS FOR USE

Caution: Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician. Refer to accompanying Instructions For Use.

Contents

IP(atm)
Inflation Pressure

LOT
Lot Number

Maximum Guidewire Diameter

MSID
Maximum Stent D.

MGCID
Minimum Guiding Catheter I.D.

NBP
Nominal Balloon Pressure

STENT ∅
Nominal Stent Diameter

STENT
Nominal Stent Length

Post-Deployment Stent I.D.

RBP
Rated Burst Pressure

REF
Reference Number

Single Use

Sterilization using Irradiation
STERILE R

Use By Date

STERILE UNLESS PACKAGE IS OPEN OR DAMAGED

Manufacturer:
Medtronic, Inc.
Minneapolis, MN55432
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Medtronic AVE

Rev D.xxxx/IS28728-01

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Medtronic AVE BeStent™ 2 with Discrete Technology™

RAPID EXCHANGE CORONARY STENT DELIVERY SYSTEM

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

Table of Contents

1. DEVICE DESCRIPTION

The Medtronic AVE BeStent™ 2 with Discrete Technology™ Rapid Exchange Coronary Stent Delivery System (Bestent™ 2) includes:

- A pre-mounted 316L stainless steel stent with gold markers embedded in each end. The markers facilitate stent visibility under fluoroscopy.
- A sheathless, rapid exchange coronary stent delivery system with perfusion capability providing symmetrical stent deployment utilizing an extended pressure balloon.
- Delivery system with discrete balloon technology with a larger proximal pillow.
- Two radiopaque markers embedded on the inner shaft (at each end of the balloon), proximal and distal to the stent. A third radiopaque marker is located proximal to the perfusion sideholes. The markers are visible under fluoroscopy.
- Fourth and fifth shaft markers are located approximately at 95 cm and 105 cm, respectively, from the distal tip.

The BeStent™ 2 with Discrete Technology™ Rapid Exchange Coronary Stent Delivery System is a two-lumen catheter with four sideholes proximal to the balloon. One lumen is used for inflation of the balloon. The other lumen permits:

1. The perfusion of blood to the distal vessel during balloon inflation (average rate of 2cc/min. at nominal pressure).
2. The use of a guidewire to facilitate the advancement of the catheter to and through the stenoses to be dilated.

The BeStent™ 2 can be reinflated to the rated burst pressure (RBP), without moving the placement of the balloon within the stent, to optimize stent apposition.

Figure 1
Medtronic AVE BeStent™2 Rapid Exchange Coronary Stent Delivery System Graphic

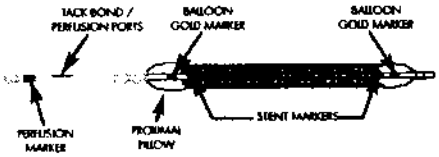


Table 1. Device Specifications

Stent Diameter	Stent Length	Minimum Guiding Catheter I.D.	Stent Deployment Pressure	Rated Burst Pressure (RBP)	Max. Allowable Stent I.D.
3.5 mm	9 mm	0.064 inch	8 atm	16 atm	4.5mm
3.0 mm	12 mm	0.064 inch	8 atm	16 atm	3.5mm
4.0 mm	12 mm	0.064 inch	8 atm	15 atm	4.5mm
3.5 mm	15 mm	0.064 inch	8 atm	16 atm	4.5mm
3.0 mm	18 mm	0.064 inch	8 atm	16 atm	3.5mm
4.0 mm	18 mm	0.064 inch	8 atm	15 atm	4.5mm
3.5 mm	24 mm	0.064 inch	8 atm	16 atm	4.5mm
3.0 mm	30 mm	0.064 inch	8 atm	16 atm	3.5mm
4.0 mm	30 mm	0.064 inch	8 atm	15 atm	4.5mm

2. INDICATIONS

The BeStent™ 2 is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de novo lesions (length ≤ 30 mm) in native coronary arteries with reference vessel diameters ranging from 3.0 mm to 4.0 mm.

3. CONTRAINDICATIONS

The BeStent™ 2 is contraindicated for use in:

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

4. WARNINGS AND PRECAUTIONS

(see also Individualization of Treatment)

- The rapid exchange delivery system will allow for perfusion at an average rate of 2cc/min at nominal pressure during the 15-30 second stent deployment procedure only. The Rapid Exchange Stent Delivery System is not intended for use as a stand alone PTCA perfusion catheter.
- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events.
- Patients allergic to 316L stainless steel may suffer an allergic reaction to this implant.
- Only physicians who have received appropriate training should perform implantation of the stent.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term out come following repeat dilatation of endothelialized coronary stents is unknown at present.
- When multiple stents are required, it is recommended that stent materials should be of similar composition.
- Long-term outcome for this permanent implant is unknown at present.

4.1 Stent Handling - Precautions

- For single use only. Do not resterilize or reuse. Note product "Use By" date.
- Do not remove stent from its delivery system as removal may damage the stent and/or lead to stent embolization. The BeStent™ 2 Stent is intended to perform as a system and is not designed to be crimped onto another delivery device.
- Stent Delivery System should not be used in conjunction with any other stents.
- Special care must be taken not to handle or in any way disrupt the stent position on the delivery device. This is most important during catheter removal from packaging, placement over guidewire, and advancement through rotating hemostatic valve adapter and guiding cathe ter hub.
- Excessive manipulation, e.g., rolling the mounted stent, may cause dislodgment of the s tent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as it may cause uneven expansion and difficulty in deployment of the stent.

4.2 Stent Placement - Precautions

- Do not prepare or pre-inflate the stent delivery system prior to stent deployment, other than as directed. Use balloon purging technique described in section 9.3.2 Delivery System Preparation.
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g., CABG, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent when placing the distal stent and reduces the chances for dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel (see Stent/System Removal - Precautions).
- Placement of the stent has the potential to compromise side branch patency.
- Do not exceed Rated Burst Pressure as indicated on product label. Balloon pressures should be monitored during inflation (see Compliance Chart - Table 7). Use of pressures higher than those specified on product label may result in a ruptured balloon and potential intimal damage and dissection.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications can include bleeding, hematoma or pseudoaneurysm.
- During perfusion, the use of pressures greater than nominal (8 ATM) for stent deployment may compromise the perfusion capability and guidewire movement during inflation of the stent delivery system

4.3 Stent / System Removal - Precautions

If balloon was not expanded, carefully withdraw stent delivery system into guiding catheter, using fluoroscopic guidance to guard against stent movement on the balloon. If any stent movement is detected, or resistance is felt, cease retraction at once and proceed to 4.3.1.

4.3.1 Removing the Stent Delivery System As a Single unit

If it is not possible to retract the stent delivery system safely into the guiding catheter it should be removed as a single unit. This must be done under direct visualization with fluoroscopy.

- Maintain guidewire placement across the lesion and carefully pull back the stent delivery system until the proximal balloon marker of the stent delivery system is aligned with the distal tip of the guiding catheter.
- The guiding catheter and the stent delivery system should be carefully removed from the coronary artery as a single unit.
- The system should be pulled back into the descending aorta toward the arterial sheath. As the distal end of the guiding catheter enters into the arterial sheath, the catheter will straighten, allowing safe withdrawal of the stent delivery system into the guiding catheter and the subsequent removal of the stent delivery system and the guiding catheter from the arterial sheath.
- Failure to follow these steps and/or applying excessive force to the stent delivery system can potentially result in

loss or damage to the stent and/or stent delivery system components such as the balloon.

4.4 Post-Implant Precautions

* Care must be exercised when crossing a newly deployed stent with an intravascular ultrasound (IVUS) catheter, a coronary guidewire, or a balloon catheter to avoid disrupting the stent geometry.
* Do not perform Magnetic Resonance Imaging (MRI) scans on patients post-stent implantation until the stent has been completely endothelialized (eight weeks post stent implant) to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.

5. OBSERVED ADVERSE EVENTS

The BeStent™ 2 was designed to retain very similar fundamental material and design characteristics as the original BeStent™, while enhancing user preferred properties such as trackability, flexibility, conformability and vessel wall coverage. Due to the similarities in design, the BeStent™ 2's long-term performance will be supported by the six-month clinical success of the BeStent™ as clinically evaluated in the BEST Trial. Additionally, acute device performance (deliverability) of the BeStent™ 2 RX catheter is based on the clinical evaluation of an additional Medtronic AVE stent mounted on the identical catheter.

A total of 652 patients were enrolled in a randomized, thirty-two (32) multi-center Clinical Trial to show equivalence in late-term clinical outcomes between the Medtronic BeStent™ Coronary Stent and the Palmaz-Schatz® Stent (PS®) in de novo and restenotic native coronary lesions. Of these, 325 received the BeStent™ Coronary Stent and 327 patients received the Palmaz-Schatz® Stent (PS®). A total of 227 patients were enrolled in a separate registry with the BeStent™ 2. These patients form the basis of the observed events reported (see section 6, Clinical Studies).

Summary of Clinical Trial Patient Enrollment

	Medtronic AVE BeStent™ or BeStent™ 2 Coronary Stent System	Palmaz-Schatz® Coronary	Stent Control Patient Totals
	BEST Trial (BeStent™)	325	327
652	BeStent™ 2 Registry	227	0
Patient Totals	552	327	879

Table 2. Adverse Events During the First 6 Months
% [±95 % Confidence Interval] Number/Denominator (n= 652 Patients)
All Randomized Patients in Best Trial:

	BEST TRIAL	
Complication	BeStent™ (n=325)	Palmaz-Schatz® (n=327)
Any Adverse Events	10.8% [7.6%,14.7%] [35/325]	10.1%[7.0%,13.9%] [33/327]
Early (in-hospital)	9.5% [6.6%,13.3%] [31/325]	7.3% [4.8%,10.7%] [24/327]
Out-of-hospital	1.5% [0.5%,3.6%] [5/325]	3.1% [1.5%,5.6%] [10/327]
Death Total	0.6% [0.1%,2.2%] [2/325]	0.9% [0.2%,2.7%] [3/327]
Early (in-hospital)	0.0% [0.0%,1.1%] [0/325]	0.0% [0.0%,1.1%] [0/327]
Out-of-hospital	0.6% [0.1%,2.2%] [2/325]	0.9% [0.2%,2.7%] [3/327]
Q-wave MI Total	1.5% [0.5%,3.6%] [5/325]	1.5% [0.5%,3.5%] [5/327]
Early (in-hospital)	1.2% [0.3%,3.1%] [4/325]	0.6% [0.1%,2.2%] [2/327]
Out-of-hospital	0.3% [0.0%,1.7%] [1/325]	0.9% [0.2%,2.7%] [3/327]
Non-Q-wave Total	2.5% [1.1%,4.8%] [8/325]	2.1% [0.9%,4.4%] [7/327]
Early (in-hospital)	2.5% [1.1%,4.8%] [8/325]	1.8% [0.7%,4.0%] [6/327]
Out-of-hospital	0.0% [0.0%,1.1%] [0/325]	0.3% [0.0%,1.7%] [1/327]
Emergent CABG Total	0.9% [0.2%,2.7%] [3/325]	0.6% [0.1%,2.2%] [2/327]
Early (in-hospital)	0.9% [0.2%,2.7%] [3/325]	0.6% [0.1%,2.2%] [2/327]
Out-of-hospital	0.0% [0.0%,1.1%] [0/325]	0.0% [0.0%,1.1%] [0/327]
Stent Thrombosis Total	0.9% [0.2%,2.7%] [3/325]	1.5% [0.5%,3.5%] [5/327]
Early (in-hospital)	0.6% [0.1%,2.2%] [2/325]	0.6% [0.1%,2.2%] [2/327]
Out-of-hospital	0.3% [0.0%,1.7%] [1/325]	0.9% [0.2%,2.7%] [3/327]
Bleeding Complications Requiring Transfusion	1.8% [0.7%,4.0%] [6/325]	0.6% [0.1%,2.2%] [2/327]
Vascular Complications	6.2% [3.8%,9.3%] [20/325]	4.9% [2.8%,7.8%] [16/327]
Cerebrovascular Accidents	0.9% [0.2%,2.7%] [3/325]	0.9% [0.2%,2.7%] [3/327]
Stent Delivery Failure**	2.2%[0.9%,4.4%] [7/325]	1.2% [0.3%, 3.1%] [4/327]

*Any Adverse Event = Death, Q wave MI, non-Q wave MI, CABG, stent thrombosis, bleeding complications, vascular complications and CVA

NOTE: In cases where a patient experienced both an in-hospital event and an out-of-hospital event they are counted once in each group. They are counted only once in the event total. Hence, the sum of the in-hospital event rate and the out-of-hospital event rate may not equal the total event rate.

**Stent Delivery Failure: Failure to deliver the first assigned stent only

5.1 BEST (BeStent ™ Trial) Randomized Clinical Trial
A total of 325 patients were enrolled in the BeStent™ arm of the BEST Trial to show equivalence in late-term clinical outcomes between the Medtronic BeStent™ Coronary Stent and the Palmaz-Schatz® Stent (PS®) in de novo and restenotic native coronary lesions. Fifty seven of 325 (17%) who received the BeStent™ experienced one or more adverse events during the first six months of the follow-up compared to 47 of the 327 (14%) Palmaz-Schatz® control patients. Adverse events reported during the first six months are shown in Table 2.

5.2 BeStent™ 2 Registry
A total of 227 patients were enrolled in a multi-center registry to evaluate the safety and efficacy of the BeStent™ 2 for treatment of symptomatic coronary artery disease. Adverse events reported during the first 30 days are shown in Table 3. A total of 11 of 227 patients (4.8%) who received the BeStent™ 2 experienced one or more adverse events during the first 30 days of follow-up.

5.3 Potential Adverse Events
Adverse events (in alphabetical order) may be associated with the use of a coronary stent in native coronary arteries (including those listed in Table 2 and 3).

- Acute myocardial infarction
- Arrhythmias, including VF and VT
- Death
- Dissection
- Drug reactions to antiplatelet agents/contrast medium
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and pain at insertion site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent thrombosis/occlusion
- Stroke/Cerebrovascular Accidents
- Total occlusion of coronary artery

Table 3. Adverse Events During the First 30 Days†
BeStent ™ 2 and Palmaz-Schatz® (from BEST) Patients
% [95 % confidence interval] (Number)

Complication	BeStent™ 2 (N=227)	Palmaz-Schatz® (N=327)
Any Adverse Events	4.8% [2.4%, 8.5%] (11/227)	9.2% [6.3%, 12.8%] (30/327)
Early (In-Hospital)	3.5% [1.5%, 6.8%] (8/227)	7.3% [4.8%, 10.7%] [24/327]
Out-of-hospital	1.3% [0.3%, 3.8%] (3/227]	2.1% [0.9%, 4.4%] [7/327]
Death Total	0.9% [0.1%, 3.1%] [2/227]	0.9% [0.2%, 2.7%] [3/327]
Early (In-Hospital)	0.0% [0.0%, 1.6%] [0/227]	0.0% [0.0%, 1.1%] [0/327]
Out-of-hospital	0.9% [0.1%, 3.1%] [2/227]	0.9% [0.2%, 2.7%] [3/327]
Q Wave MI Total	0.4% [0.0%, 2.4%] [1/227]	0.9% [0.2%, 2.7%] [3/327]
Early (In-Hospital)	0.4% [0.0%, 2.4%] [1/227]	0.6% [0.1%, 2.2%] [2/327]
Out-of-hospital	0.0% [0.0%, 1.6%] [0/227]	0.3% [0.2%, 1.7%] [1/327]
Non-Q Wave MI Total	0.9% [0.1%, 3.1%] [2/227]	1.8% [0.7%, 4.0%] [6/327]
Early (In-Hospital)	0.9% [0.1%, 3.1%] [2/227]	1.8% [0.7%, 4.0%] [6/327]
Out-of-hospital	0.0% [0.0%, 1.6%] [0/227]	0.0% [0.0%, 1.1%] [0/327]
Emergent CABG Total	0.4% [0.0%, 2.4%] [1/227]	0.6% [0.1%, 2.2%] [2/327]
Early (In-Hospital)	0.4% [0.0%, 2.4%] [1/227]	0.6% [0.1%, 2.2%] [2/327]
Out-of-hospital	0.0% [0.0%, 1.6%] [0/227]	0.0% [0.0%, 1.1%] [0/327]
Stent Thrombosis Total	0.9% [0.1%, 3.1%] [2/227]	1.5% [0.5%, 3.5%] [5/327]
Early (In-Hospital)	0.0% [0.0%, 1.6%] [0/227]	0.6% [0.1%, 2.2%] [2/327]
Out-of-hospital	0.9% [0.1%, 3.1%] [2/227]	0.9% [0.2%, 2.7%] [3/327]
Bleeding Complications Requiring Transfusion	1.8% [0.5%, 4.5%] [4/227]	0.6% [0.1%, 2.2%] [2/327]
Vascular Complications	0.4% [0.0%, 2.4%] [1/227]	4.9% [2.8%, 7.8%] [16/327]
Cerebrovascular Accidents	0.0% [0.0%, 1.6%] [0/227]	0.9% [0.2%, 2.7%] [3/327]
Stent Delivery Failure**	0.4% [0.0%, 2.4%] [1/227]	1.2% [0.3%, 3.1%] [4/327]

*Any Adverse Event = Death, Q wave MI, non-Q wave MI, CABG, stent thrombosis, bleeding complications, vascular complications and CVA
NOTE: In cases where a patient experienced both an in-hospital event and an out-of-hospital event they are counted once in each group. They are counted only once in the event total. Hence, the sum of the in-hospital event rate and the out-of-hospital event rate may not equal the total event rate.

**Stent Delivery Failure: Failure to deliver the first assigned stent only
†The BeStent™ and Palmaz-Schatz® Trials were non-concurrent, and statistical comparison is not appropriate

6. CLINICAL STUDIES

6.1 BEST Randomized Clinical Trial

A total of 652 patients were enrolled in a randomized, thirty-two (32) multi-center clinical trial to show equivalence in late-term clinical outcomes between the Medtronic BeStent™ Coronary Stent and the Palmaz-Schatz® Stent (PS®) in de novo and restenotic native coronary lesions. Of these, 325 received the BeStent™ Coronary Stent and 327 patients received the Palmaz-Schatz® Stent (PS®). The primary endpoint was defined as Major Adverse Clinical Events (MACE) at six-months. MACE was defined as the occurrence of any of the following: death, Q wave or non Q wave MI, emergent CABG, or target lesion revascularization (TLR). A clinical events committee blinded to the treatment arm adjudicated all major clinical events and clinically driven TLR.

Of the 652 patients studied, 325 subjects were randomized to the BeStent™ arm. Sixty-seven percent (218/325) were males ranging in age from 34 to 90 years with an average of 60 ± 11 years (means ± SD). In the 327 patients randomized to Palmaz-Schatz®, 69% (225/327) were males ranging in age from 24 to 91 with an average of 61 ± 11 years. Eligibility was determined by the presence of angina or positive functional study (Exercise Treadmill Test). Patients were identified for elective stenting of de novo or restenotic lesions in native coronary arteries having vessel diameter between 3.0 mm and 4.0 mm with a lesion length of ≤25 mm, which could be covered by an appropriate length Medtronic BeStent™ (BeStent™). These patients underwent balloon angioplasty (1:1 balloon to artery ratio) after which a stent delivery system of the appropriate size was selected and deployed in the native coronary artery. Post deployment dilatation was performed utilizing a high-pressure balloon having a 1:1 balloon to artery ratio to obtain optimal stent apposition. The anticoagulation regimen administered to 96% of patients was 325 mg/day of uncoated, water-soluble aspirin for at least 6 months and ticlopidine 250 mg twice a day for at least 30 days to 4.7% of the patients. At the discretion of the investigator, alternative therapy was allowed for non-optimal results, which were defined as >30 mm stents implanted, >10% residual stenosis, any residual dissection, TIMI flow grade 0-1, or the presence of thrombus.

Clinical follow-up intervals for all treated patients were 30 days, 6 months and 12 months. A subset of patients (first 150 patients in each arm of the randomized study) underwent angiographic follow-up at six months. All treated patients were included in the intent-to-treat efficacy analysis. The Principal Effectiveness and Safety results for the BEST Randomized Trial (BeStent™) compared to Palmaz-Schatz® are presented in Table 4. The relation of baseline and procedural variables to TLR was examined. The statistical predictors of TLR were post-procedure MLD, total length of stents implanted and pre-procedure diameter stenosis.

6.2 BeStent™ 2 Registry

The BeStent™ 2 Registry was a prospective, multi-center non-randomized trial conducted at eighteen (18) sites within the United States and three Middle East sites. This registry included 227 patients with de novo and restenotic native coronary artery lesions. An independent Clinical Events Committee adjudicated all of the major clinical endpoints and clinically driven TLR.

6.2.1 Primary Endpoints

The primary endpoint in the BeStent™ 2 Registry was defined as Major Adverse Clinical Events (MACE) rate, the composite of death, Q wave or non-Q wave myocardial infarction, emergent coronary artery bypass surgery, or target lesion revascularization (TLR) at 30 days.

6.2.2 Patients Studied

Of the 227 patients studied, 68.3% were male ranging in age from 36 to 83 years with an average of 62.4 years ± 10.6 (mean ± SD). All patients presented with angina or a positive functional study and were undergoing elective single de novo or restenotic lesion treatment in a native coronary artery. Eligible patients had visually estimated stenosis ≤ 28mm in length in a major coronary artery or major side branch ≥ 3.0mm and ≤ 4.0mm in diameter.

6.2.3 Methods

Patients in the BeStent™ 2 Registry underwent balloon angioplasty (1:1 balloon to artery ratio) after which a stent delivery system of the appropriate size was selected and deployed in the native coronary artery. Post deployment dilatation was performed utilizing a high-pressure balloon having a 1:1 balloon to artery ratio to obtain optimal stent apposition, post-procedure for all patients. Baseline quantitative coronary angiography was performed pre-procedure, following device deployment, and after final treatment.

Clinical follow-up was completed at 30 days. The anticoagulation regimen administered to 92.1% of the patients was 325mg/day of aspirin for at least 30 days. Clopidogrel, 75mg once a day, was administered to 80.2% of the patients for at least 14 days.

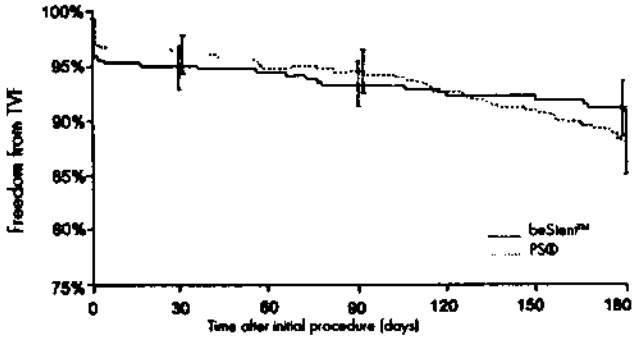
The principal effectiveness and safety results for the BeStent™ 2 Registry are compared to the results of the Palmaz-Schatz® control group in the BEST Randomized Trial and are presented in Table 5. These two studies were non-concurrent, and statistical comparison is not appropriate. The relation of baseline and procedural variables to Target lesion Revascularization (TLR) was examined. The statistical predictors of TLR were post-procedure MLD and total length of stents implanted.

Table 4 Principal Effectiveness and Safety Results (BEST Trial)
All Randomized Patients Treated (N=652 Patients)
Percent [95% Confidence Interval] (Number)

Efficacy Measures	BeStent™ (N=325 Patients)	Palmaz-Schatz® (N=327 Patients)	Difference 95% C.I.
Device Success	93.2% [89.9%,95.7%] (303/325)	93.9 [90.7%,96.2%] (307/327)	-0.7 [-4.4%, 3.1%]
Acute Procedure Success	95.4% [92.5%, 97.4%] (310/325)	96.3 [93.7%, 98.1%] (315/327)	-0.9% [-4.0%, 2.1%]
Post-Procedure In-Stent MLD (in mm)			
Mean ±SD (N)	2.82+0.40 (319)	2.80+0.41 (321)	0.02% (-0.05%, 0.08%)
[95% CI]	[2.76, 2.86]	[2.76, 2.85]	
Range (min, max) [95% CI]	(1.92, 4.49]	(1.61,4.49]	
6 Months Follow-up In-Stent % DS			
Mean ± SD (N)	32.9%+22.9% (103)	38.1%+21.5% (102)	-1.0% [-2.6%, 0.5%]
[95% CI]	[28.5%, 37.4%]	[33.9%, 42.3%]	
Range (min, max) [95%CI]	(-12.9%, 100.0%]	(-7.1%, 100.0%]	
6 Months Follow-up In-Stent Binary	16.5% [9.9%,25.1%]	26.5% [18.2%,36.1%] (27/102)	-10.0% [-21.1%, 1.2%]
Restenosis rate	(17/103)		
Post-Procedure hospital length of stay (days)			
Mean ± SD (N) [95%CI]	1.4+1.6 (325) [1.3, 1.6]	1.3+0.9 (327) [1.2, 1.4]	0.2 [0.0, 0.4]
Range (min, max)	(0,14)	(0,8)	
TLR-free at 30 days	95.9% [93.4%, 98.3%]	90.8% [87.2%, 94.3%]	5.1% [0.8%, 9.4%]
TVR-free at 30 days	94.5% [91.7%, 97.4%]	89.4% [85.7%, 93.2%]	5.1% [0.4%, 9.8%]
TVF-free at 30 days	90.5% [86.9%, 94.2%]	87.0% [82.9%, 91.1%]	3.5% [-2.0%, 9.1%]
Safety Measures & Other Clinical Events to 6 months			
In-Hospital MACE (Death, QMI, TLR, Emergent CABG)	4.3% [2.4%, 7.1%] (14/325)	2.8% [1.3%,5.2%] (9/327)	1.6% [-1.3%, 4.4%]
Out-of-Hospital MACE (Death, QMI, TLR, Emergent CABG)	4.9% [2.8%, 8.2%] (16/325)	10.1% [7.0%, 13.9%] (33/327)	-5.2% [-8.9%, -1.5%]
Bleeding Complications	1.8% [0.7%, 4.0%] (6/325)	0.6% [0.1%, 2.2%] (2/327)	1.2% [-0.5%, 2.9%]
CVA to 180 days	0.9% [0.2%, 2.7%] (3/325)	0.9% [0.2%, 2.7%] (3/327)	0.0% [-1.5%, 1.5%]
Vascular Complications	6.2% [3.8%, 9.3%] (20/325)	4.9% [2.8%, 7.8%] (16/327)	1.3% [-2.2%, 4.8%]
Stent Thrombosis to 30 days	0.9% [0.2%, 2.7%] (2/325)	1.5% [0.5%, 3.5%] (5/327)	-0.6% [-2.3%, 1.1%]

MACE = Major Adverse Cardiac Event: Death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization.
TLR-Free = Freedom from target lesion revascularization.
TVR-Free = Freedom from target vessel revascularization.
TVF-Free = Freedom from death, MI, and target vessel revascularization.
Device Success = Achievement of a final residual diameter stenosis <50% (by QCA) without use of a device outside of the assigned treatment strategy. If no in-stent measurements were available, in-lesion measurements were used. If no QCA was available, visual estimates were used.
Acute Procedure Success = Achievement of a final residual diameter stenosis of <50% using any percutaneous method and no in-hospital MACE (death, Q wave MI, emergent CABG, and TLR). If no QCA was available, visual estimates were used, and if no in-stent measurements were available, in-lesion measurements were used.
In-Hospital MACE = Death, Q wave MI or non-Q wave, emergent CABG, or target lesion revascularization prior to hospital discharge.
Out-of-Hospital MACE = Death, Q wave MI or non-Q wave, emergent CABG, or target lesion revascularization after hospital discharge and through 180 days.
Bleeding Complications = Transfusions of blood products due to blood loss from the percutaneous revascularization procedure.
CVA = Acute neurological deficits recorded by the clinical sites that persisted >24 hours.
Vascular Complications = Hematoma at access site >4 cm, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure related transfusion or vascular surgical repair.
Stent Thrombosis = Angiographic thrombus or subacute closure within the stented vessel, or any death not attributed to a non-cardiac cause in the absence of documented angiographic stent patency within the first 30 days.

Figure 2. Survival Free From Target Vessel Failure
Event-Free Survival±1.5SE; All Randomized Patients Treated (N=652 Patients, 657 Lesions)



	Time after initial procedure (days)								
	0	7	14	30	60	90	120	150	180
beStent™									
#Entered	325	322	308	307	304	299	291	289	278
#Lost to Follow-up	0	2	1	2	3	1	2	10	52
#Incomplete	0	0	0	0	0	0	0	0	0
# At Risk	325.0	321.0	307.5	306.0	302.5	298.5	293.0	284.0	252.0
# Events	3	12	0	1	2	4	3	1	4
# Events/Month		51.4	0.0	1.9	2.0	4.0	3.0	1.0	4.0
% Survived	99.1%	95.4%	95.4%	95.1%	94.4%	93.2%	92.2%	91.9%	90.5%
SE	0.5%	1.2%	1.2%	1.2%	1.3%	1.4%	1.5%	1.6%	1.9%
PSD									
# Entered	327	324	315	314	312	307	303	294	282
# Lost to Follow-up	0	1	0	1	2	1	3	5	48
# Incomplete	0	0	0	0	0	0	0	0	0
# At Risk	327.0	323.5	315.0	313.5	311.0	306.5	301.5	291.5	258.0
# Events	3	8	1	1	3	3	6	7	9
# Events/Month		34.3	4.3	1.9	3.0	3.0	6.0	7.0	9.0
% Survived	99.1%	96.6%	96.3%	96.0%	95.1%	94.2%	92.3%	90.1%	87.0%
SE	0.5%	1.0%	1.0%	1.1%	1.2%	1.3%	1.5%	1.7%	2.1%

Tests Between Groups

Test	Chi-Square	Deg Frdm	P-value
Log-Rank	2.48	1	0.115
Wilcoxon	2.22	1	0.136

Table 5 Principal Effectiveness and Safety Results to 30 Days for
BeStent™ 2 Registry (N=227 Patients)
Percent [95% Confidence Interval] (Number)

Efficacy measures	BeStent™ 2 (N=227 Patients)	Palmaz-Shatz® (N=327 Patients)
Device Success	95.2% [91.5%, 97.6%] [216/227]	93.9% [90.7%, 96.2%] [307/327]
Acute Procedure Success	97.8% [94.9%, 99.3%] [222/227]	96.3% [93.7%, 98.1%] [315/327]
Post-Procedure In-Stent MLD (in mm)		
Mean ± SD (N)	2.81±0.46 [224]	2.80±0.41 [321]
[95% CI]	[2.75, 2.87]	[2.76, 2.85]
Range (min, max) [95% CI]	[1.69, 4.15]	[1.61, 4.31]
Post-Procedure In-Stent % DS		
Mean ± SD (N)	3.8%±9.6% [224]	8.0% ± 10.5% [321]
[95% CI]	[2.5%, 5.1%]	[6.8%, 9.1%]
Range (min, max) [95% CI]	[-25.7%, 27.0%]	[-29.3%, 38.8%]
Post-Procedure hospital length of stay (days)		
mean ± SD (N) [95% CI]	1.4±1.1 [218] [1.2, 1.5]	1.3 ± 0.9% [327] [1.2, 1.4]
Range (min, max)	[0.0, 8.0]	[0.0,8.0]
TLR-free at 180 days	99.6% [98.4%, 100.0%]	98.5% [97.2%, 99.8%]
TVR-free at 180 days	98.7% [96.7%, 100.0%]	98.5% [97.2%, 99.8%]
TVF-free at 180 days	96.4% [93.2%, 99.6%]	96.0% [93.9%, 98.1%]
Safety measures & Other Clinical Events to 30 days		
In-Hospital MACE (Death, QMI, TVR, Emergent CABG)	2.2% [0.7%, 5.1%] (5/227)	2.8% [1.3%, 5.2%] (9/327)
Out-of-Hospital MACE (Death, QMI, TVR, Emergent CABG) to 30 days	1.3% [0.3%, 3.8%] [3/227]	1.2% [0.3%, 3.1%] (4/327]
Bleeding Complications	1.8% [0.5%, 4.5%] [4/227]	0.6% [0.1%, 2.2%] [2/327]
CVA to 30 days	0.0% [0.0%, 1.6%] [0/227]	0.9% [0.2%, 2.7%] [3/327]
Vascular Complications*	0.4% [0.0%, 2.4%] (1/227]	4.9% [2.8%, 7.8%] (16/327)
Stent Thrombosis to 30 days	0.9% [0.1%, 3.1%] [2/227]	1.5% [0.5%, 3.5%] [5/327]

MACE = Major Adverse Cardiac Event: Death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization.
TLR-Free = Freedom from target lesion revascularization.
TVR-Free = Freedom from target vessel revascularization.
TVF-Free = Freedom from death, MI, and target vessel revascularization
Device Success = Achievement of a final residual diameter stenosis <50% (by QCA) without use of a device outside of the assigned treatment strategy. If no in-stent measurements were available, in-lesion measurements were used. If no QCA was available, visual estimates were used. *
Acute Procedure Success = Achievement of a final residual diameter stenosis of <50% using any percutaneous method and no in-hospital MACE (death, Q wave MI, emergent CABG, and TVR). If no QCA was available, visual estimates were used, and if no in-stent measurements were available, in-lesion measurements were used.
In-Hospital MACE = Death, Q wave MI or non-Q wave, emergent CABG, or target lesion revascularization prior to hospital discharge.
Out-of-Hospital MACE = Death, Q wave MI or non-Q wave, emergent CABG, or target lesion revascularization after hospital discharge and through 180 days.
Bleeding Complications = Transfusions of blood products due to blood loss from the percutaneous revascularization procedure.
CVA = Acute neurological deficits recorded by the clinical sites that persisted >24 hours.
Vascular Complications = Hematoma (>5 cm for BeStent 2 patients and >4cm for PS patients), false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure related transfusion or vascular surgical repair.
*Due to the difference in definition for hematoma between the BEST and BeStent 2 trials, it was confirmed that none of the vascular complications in either trial involved a hematoma.
Stent Thrombosis = Angiographic thrombus or subacute closure within the stented vessel, or any death not attributed to a non-cardiac cause in the absence of documented angiographic stent patency within the first 30 days.

Table 6. Survival Free from Target Vessel Failure
Event-free Survival ± 1.5SE
All Patients Treated (N=554 Patients, 557 Lesions)

	Time after initial procedure (days)				
	0	7	14	21	30
BeStent™ 2					
#Entered	227	222	209	208	207
#Lost to Follow-up	3	7	1	1	81
#Incomplete	0	0	0	0	0
# At Risk	225.5	218.5	208.5	207.5	166.5
# Events	2	6	0	0	0
# Events/Month		25.7	0.0	0.0	0.0
% Survived	99.1%	96.4%	96.4%	96.4%	96.4%
SE	0.6%	1.3%	1.3%	1.3%	1.6%
PSD					
# Entered	327	324	315	314	313
# Lost to Follow-up	0	1	0	1	0
# Incomplete	0	0	0	0	0
# At Risk	327.0	323.5	315.0	313.5	313.0
# Events	3	8	1	0	1
# Events/Month		34.3	4.3	0.0	3.9
% Survived	99.1%	96.6%	96.3%	96.3%	96.0%
SE	0.5%	1.0%	1.0%	1.0%	1.1%

Tests Between Groups

Test	Chi-Square	Deg Free	P-value
Log-Rank	0.03	1	0.865
Wilcoxon	0.03	1	0.860

7 PATIENT SELECTION AND TREATMENT

7.1 Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of BeStent™ 2. Patient selection factors to be assessed should include a judgement regarding risk of prolonged anticoagulation. Stenting should be generally avoided in those patients at heightened risk of bleeding (e.g., those patients with recently active gastritis or peptic ulcer disease) (see Contraindications).

Premorbid conditions that increase the risk of poor initial results or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure, and severe obesity) should be reviewed.

Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3.0 mm, intra-procedural thrombosis, poor distal flow, and/or dissection following stent implantation. In patients that have undergone coronary stenting, the persistence of a thrombus or dissection is considered a marker for subsequent thrombotic occlusion. These patients should be monitored very carefully during the first month after stent implantation.

7.2 Use in Special Populations

The safety and effectiveness of the Medtronic BeStent™ 2 Coronary Stent Delivery System have not been established in:

- Patients with unresolved vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameters < 3.0 mm.
- Patients with lesions located in the unprotected 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 recent acute myocardial infarction where there is evidence of thrombus or poor flow.
- Patients with restenotic lesions.

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

8. HOW SUPPLIED

STERILE: This device is sterilized with e-beam radiation. It is intended for single use only. Non-pyrogenic. Do not use if package is opened or damaged.

CONTENTS: One (1) Medtronic AVE BeStent™ 2 with Discrete Technology™ Rapid Exchange Coronary Stent Delivery System.

STORAGE: Store in a cool, dry, dark place.

9. CLINICIAN USE INFORMATION

9.1 Inspection Prior to Use

Carefully inspect the sterile package before opening. It is not recommended that the product be used after the "Use By" date. If the integrity of the sterile package has been compromised prior to the product "Use By" date (e.g., damage of the package) contact your local Medtronic AVE, Inc. Representative for return information. If the sterile package appears intact, carefully remove the system from the package and inspect for bends, kinks and other damage. Verify that the stent is located between the radiopaque markers. Do not use if any defects are noted.

9.2 Materials Required

Quantity	Material
	Appropriate guiding catheter. (see Table 1- Device Specifications)
1	20 cc syringe.
	Heparinized Normal Saline.
1	0.014 inch x 300 cm guidewire.
1	Rotating hemostatic valve.
	Contrast medium diluted 1:1 with heparinized normal saline.
1	Inflation device.
1	Torque device.
Optional	Three-way stopcock.

9.3 Preparation

9.3.1 Guidewire Lumen Flush

Step	Action
1.	Attach the blue end of a syringe to the distal end of the catheter and flush the stent delivery system until fluid exits from the perfusion holes.
2.	Remove protective sheath covering from the stent/balloon. Care should be taken not to disrupt the stent.
3.	Verify that the stent is positioned between the proximal and distal balloon markers.

9.3.2 Delivery System Preparation

Step	Action
1.	Fill a 20 cc syringe with 5 cc of contrast/heparinized normal saline mixture (1:1)
2.	Attach to delivery system and apply negative pressure for 20-30 seconds.
3.	Slowly release pressure to allow negative pressure to draw mixture into balloon lumen.
4.	Detach syringe and leave a meniscus of mixture on the hub of the balloon lumen.
5.	Prepare inflation device in standard manner and purge to remove all air from syringe and tubing.
6.	Attach inflation device to catheter directly ensuring no bubbles remain at connection.
7.	Leave an ambient pressure (neutral position). Note: Do not pull negative pressure on inflation device after balloon preparation and prior to delivering the stent.
8	Moisten the stent with heparinized normal saline by submerging the stent into a sterile bowl containing the solution. Note: Do not use gauze sponges to wipe down the stent as fibers may disrupt the stent.
9.	Visually inspect the stent to assure the stent is placed within the area of the proximal and distal balloon markers.

9.4 Delivery Procedure

Step	Action
1	Prepare vascular access site according to standard PTCA practice.
2	Predilate the lesion/vessel with appropriate diameter balloon having a ratio of 1:1 with the diameter of the vessel.
3	Maintain neutral pressure on inflation device. Open rotating hemostatic valve to allow for easy passage of the stent. Note: If resistance is encountered, do not force passage. Resistance may indicate a problem and may result in damage to the stent if it is forced. Remove the system and examine.
4	Backload a guidewire (max. 0.014 inch) into the distal tip, holding the distal portion of the delivery system straight without any curving. Insert stent delivery system over guidewire through a large bore hemostatic valve adapter using conventional angioplasty techniques. Make sure the hemostatic valve adapter has a large bore and is fully open while passing stent through. Be careful not to exit the guidewire through the perfusion sideholes while backloading the guidewire.
5	Ensure guiding catheter stability before advancing the stent delivery system into the coronary artery. Carefully advance the stent delivery system into the hub of the guiding catheter.
6	Note: If the physician encounters resistance to the stent delivery system prior to exiting the guiding catheter, do not force passage. Resistance may indicate a problem and may result in damage to the stent if it is forced. Maintain guidewire placement across the lesion and remove the stent delivery system as a single unit. (see Stent/System Removal - Precautions)
7	Advance delivery system over the guidewire to the target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque markers on the balloon as a reference point. If the position of the stent is not optimal, it should be carefully repositioned or removed (see Stent/System Removal - Precautions). Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion segment of the vessel. (Stent markers should be located between balloon markers, refer to figure 1)
8	Optimal stent placement requires the distal end of the stent to be placed approximately 1 mm beyond the distal end of the lesion.
9	Sufficiently tighten the rotating hemostatic valve. Stent is now ready to be deployed

9.5 Deployment Procedure

Step	Action
1	Deploy stent by inflating balloon to nominal pressure to expand the stent. Note: Refer to product labeling and Table 6 for the proper stent inflation pressure. The Medtronic AVE BeStent™ 2 with Discrete Technology™ Rapid Exchange Coronary Stent Delivery System may be reinflated beyond nominal, without repositioning, up to rated burst, to assure complete apposition of the stent to the artery wall. Do not exceed Rated Burst Pressure. Do not expand the stent beyond the maximum allowable stent I.D. (see Table 1)
2	Maintain inflation pressure for 15-30 seconds for full expansion of the stent during which the guidewire may be retracted to the radiopaque marker proximal to the perfusion sideholes (see Figure 1) to allow for average flow of 2cc/min. of distal flow at nominal pressure. Note: The guidewire pull back should be performed only once during the recommended 15-30 seconds of deployment time. Note: During perfusion the use of pressures greater than the nominal (8 ATM) for stent deployment may compromise the perfusion capability and guidewire movement during inflation of the stent delivery system.
3	Reposition the guidewire across the lesion during deployment. Note: Be careful not to exit the guidewire through the perfusion sideholes. Do not exceed Rated Burst Pressure. Do not expand the stent beyond the maximum allowable stent I.D. (see Table 1)
4	Note: Under-expansion of the stent may result in stent movement. Care must be taken to properly size the stent to ensure the stent is in full contact with the arterial wall upon deflation of the balloon.

9.6 Removal Procedure

Step	Action
1	Deflate the balloon by pulling negative pressure on the inflation device. Allow adequate time, at least 20 seconds, for full balloon deflation. Longer stents may require more time for deflation.
2	Open the hemostatic valve to allow removal of the delivery system.
3	Maintain position of guiding catheter and guidewire to prevent it from being drawn into the vessel. Very slowly withdraw the balloon from the stent maintaining negative suction, allowing movement of the myocardium to gently dislodge the balloon from the stent.
4	After removal of the delivery system, tighten the hemostatic valve.
5	Repeat angiography and visually assess the vessel and the stent for proper expansion.
6	A second balloon inflation may be required to ensure optimal stent expansion. In such instances, a non-compliant, higher-pressure balloon of adequate size (the same size as the stent delivery system balloon or larger) and length may be used to accomplish this. Note: In smaller or diffusely diseased vessels, the use of high balloon inflation pressures may over-expand the vessel distal to the stent and could result in vessel dissection. Do not expand the Medtronic AVE BeStent™ 2 stent beyond the maximum allowable stent I.D. (see Table 1).
7	The final internal stent diameter should be equal to or slightly larger than the proximal and distal reference vessel diameters.
8	Repeat angiography to evaluate and determine procedure status or termination. Note: Should the need arise for placement of a second stent to adequately cover the lesion length, placement of the stent most distal in the artery should be done prior to placement of the proximal stent, if possible.
9	Note: Observation of the patient and angiographic evaluation of the stent site should be performed periodically within the first 30 minutes after stent placement. If stent placement is associated with the onset of thrombus or suspected thrombus in the region of the stented segment, intracoronary infusions of a thrombolytic agent is recommended.

9.7 In vitro information.

Table 7: Medtronic AVE BeStent™ 2 Stent Inner Diameter (mm) vs. Inflation Pressure (ATM)

Stent Diameter (mm)	MEDTRONIC AVE BeSTENT™ 2 STENT INNER DIAMETER (MM) Deployed stent inner diameter following balloon deflation												
	6 ATM	7 ATM	8* ATM	9 ATM	10 ATM	11 ATM	12 ATM	13 ATM	14 ATM	15** ATM	16*** ATM	17 ATM	18 ATM
3.0	2.80	2.90	3.00	3.05	3.10	3.15	3.20	3.25	3.30	3.35		3.45	3.50
3.5	3.30	3.40	3.50	3.55	3.60	3.65	3.70	3.75	3.80	3.85		3.95	4.00
4.0	3.80	3.90	4.00	4.05	4.10	4.15	4.20	4.25	4.30		4.40	4.45	

* Nominal Deployment Pressure (8 ATM)

** Rated Burst Pressure for 4.0 mm diameter devices (15 ATM). DO NOT EXCEED.

*** Rated Burst Pressure for 3.0 mm and 3.5 mm diameter devices (16 ATM). DO NOT EXCEED.

Note: 95 percent of all data points will fall within ± 10 percent of table values at nominal deployment pressure. The nominal in vitro device specification does not take into account lesion resistance. Stent sizing should be confirmed angiographically.

Note: Do not expand the stent beyond the maximum allowable stent I.D. (see Table 1)

Note: Balloon pressures should be monitored during inflation. Do not exceed Rated Burst Pressure as specified on product label as this may result in a ruptured balloon with possible intimal damage and dissection.

10. PATIENT INFORMATION

In addition to the Instructions for Use, the Medtronic AVE BeStent™ 2 with Discrete Technology™ Rapid Exchange Coronary Stent Delivery System is packaged with additional specific information which include:

- A Patient Guide which includes information on Medtronic AVE, Inc., the implant procedure and Medtronic AVE, Inc. coronary stents.
- A Coronary Stent Implant Card that includes both patient information and stent implant information. All patients will be instructed to keep this card in their possession at all times for procedure/stent identification. (Note: The Coronary Stent Implant Card is located in the back of the Patient Guide.)

REFERENCES

The physician should consult recent literature on current medical practice on stent deployment, such as published by the American College of Cardiology / American Heart Association.

The revision number, month and year of these instructions is included for the user's information on the first page of these instructions. In the event 2 years have elapsed between this date and product use, the user should contact AVE Ireland Ltd., to see if additional information is available.

PATENTS

Product(s) and/or methods of manufacture under one or more of the following United States Letters Patent: 4,581,017; 5,728,067; 5,776,161; 5,836,965; 5,980,486; 6,090,127. Other U.S. Patents pending. Foreign Patents granted and pending. Licensed under at least one or more of the following United States Letters Patent: 4,748,982; 4,762,129; 5,040,548; 5,061,273; and/or any other patents or patent applications which claim priority thereto or therefrom.

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NOTE: ALTHOUGH THE CORONARY STENT DELIVERY SYSTEM, HEREAFTER REFERRED TO AS "PRODUCT," HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC AVE, INC. HAS NO CONTROL OVER CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC AVE, INC., THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC AVE, INC. 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 AVE, INC. TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

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