Magic Wallstent® Endoprosthesis

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

INSTRUCTIONS FOR USE

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1 DEVICE DESCRIPTION

The Magic Wallstent® Endoprosthesis includes:

- a stent composed of a biomedical superalloy wire with a radiopaque platinum alloy core. It is braided in a tubular mesh configuration and premounted on an over-the-wire delivery catheter which allows reconstrainment of the stent (when deployed ≤ 50%);

- radiopaque markers which aid in the accurate placement of the stent

MRI Safe: The Magic Wallstent® Endoprostheses have shown no deflection or torque in the area of maximum spatial gradient (450 gauss centimeter) of a 1.5 tesla MRI system under conditions that produced a Specific Absorption Rate (SAR) of 1.3 W/kg. Imaging artifacts affect the region of interest at the location of the device (artifact ratio 1.2 to 6.7), while areas away from the device appear unaffected by their presence.

Table 1. Stent Specifications

Stent Length (mm)	Stent Diameter (mm)	Minimum I.D. of Guide Catheter (inches)
14	3.5	.064
20	3.5	.064
20	4.0	.064
20	4.5	.064
30	3.5	.064
30	4.0	.064
30	4.5	.064
30	5.0	.064
30	5.5	.064
30	6.0	.064
40	3.5	.064
40	4.0	.064
40	4.5	.064
40	5.0	.064
40	5.5	.064
40	6.0	.064
60	4.0	.064
60	4.5	.064
60	5.0	.064
60	5.5	.064
60	6.0	.064

2 INDICATIONS and USAGE

The Magic Wallstent® Endoprosthesis is indicated for improving luminal diameter in the following:

- patients with symptomatic ischemic disease due to discrete *de novo* lesions in native coronary arteries (length ≤ 35 mm) with a reference vessel diameter of 3.0 to 5.5 mm;

- treatment of abrupt or threatened closure in patients with failed interventional therapy in lesions with reference diameters in the range of 3.0 to 5.5 mm.

(See 7.1 Individualization of Treatment).

3 CONTRAINDICATIONS

The Magic Wallstent® Endoprosthesis 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.

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4 WARNINGS and PRECAUTIONS

(see also 7.1 Individualization of Treatment)

WARNINGS

- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.
- Subacute thrombosis is more likely in patients with vessel diameter < 3.0 mm, vessel thrombosis, poor distal flow, and/or dissection following stent implantation
- Restenosis is more likely with smaller diameter vessels and longer lesions.
- Subsequent restenosis may require repeat dilation of the vessel segment containing the stent. The long-term outcome following repeat dilation of coronary stents is unknown at present.
- When multiple stents are required, stent materials should be of similar composition.

4.1 Stent Handling - Precautions

- **For single use only.** Do not resterilize or reuse. Note product "Use By" date.
- Do not expose delivery catheter to isopropyl alcohol. Exposure to isopropyl alcohol can cause delivery catheter plastics to become brittle.
- Carefully select stent size for the procedure using the Sizing Chart.

4.2 Stent Placement - Precautions

- The target lesion should be pre-dilated with a conventional balloon angioplasty catheter prior to stent deployment.
- Do not release the stent if unusual force is required. If the stent does not deploy easily, use another device.
- Do not advance the delivery catheter without the guidewire extending from the tip.
- Do not advance a partially deployed stent. Reconstrain and then move distally. Partially deployed stents can be pulled proximally if necessary.
- Implanting a stent may lead to dissection of the vessel distally, and/or proximally, to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g., CABG, further dilation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the more proximal lesion(s). Stenting in this order obviates the need to cross the proximal stent in placement of the distal stent and reduces the chances for dislodging the proximal stent.
- Do not fully deploy the stent if it is not properly positioned in the vessel.
- Placement of the stent has the potential to compromise side branch patency.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vascular site. Complications can include bleeding, hematoma or pseudoaneurysm.

4.3 Stent/System Removal - Precautions

- If Stent/System removal is required prior to full deployment, and when the stent is > 50% deployed, hold the T-connector securely on the stainless steel tube and cautiously withdraw the Stent/System into the guiding catheter. Pull the Stent/System back into the descending aorta toward the arterial sheath. As the distal end of the guiding catheter enters the arterial sheath, the catheter will straighten allowing safe withdrawal of the Stent/System into the guiding catheter and the subsequent removal of the Stent/System and the guiding catheter as a unit from the arterial sheath.

  Failure to follow these steps, and/or applying excessive force to the Stent/System can potentially result in loss of, or damage to the stent, or delivery system.

4.4 Post Implant - Precautions

- Care must be exercised when crossing a newly deployed stent with an intravascular ultrasound (IVUS), or a coronary guidewire, or a balloon catheter to avoid disrupting the stent geometry.

5 ADVERSE EVENTS

5.1 Observed Adverse Events

A total of 893 patients were enrolled in two multi-center studies as summarized in Table 2.

Table 2. Patient Enrollment in Clinical Studies
All patients in all studies (n=893)

	Wallstent® Endoprosthesis	PTCA	Patient Totals
Wellstent Registry (Europe)	105	-	105
WIN (Wallstent in Native) Trial			
Feasibility Study	132	-	132
WIN Randomized Trial	299	287	586
Post-randomization Registry	15	-	15
Magic Registry	55	-	55
PATIENT TOTALS	606	287	893

Patients from the WIN Randomized Trial form the basis of the observed adverse events in Table 3.

Table 3. Adverse Events during the First 6 Months
% [± 95% Confidence Interval] (Number) All patients in randomized trial (n=586)

Adverse Event	Wallstent® Endoprosthesis (n=299)	PTCA (n=287)	Difference [95% CI]
ANY Adverse Event	27.8% [22.8%, 33.2%] (83)	26.5% [21.5%, 32.0%] (76)	1.3% [-5.9%, 8.5%]
Early (in-hospital)	15.7% [11.8%, 20.3%] (47)	11.8% [8.3%, 16.2%] (34)	3.9% [-1.7%, 9.4%]
Out- of-hospital	12.7% [9.2%, 17.0%] (38)	15.3% [11.4%, 20.0%] (44)	-2.6% [-8.2%, 3.0%]
Non-Q-wave MI Total	6.0% [3.6%, 9.3%] (18)	3.8% [1.9%, 8.8%] (11)	2.2% [-1.3%, 5.7%]
Early (In-hospital)	5.4% [3.1%, 8.5%] (16)	3.8% [1.9%, 6.8%] (11)	1.5% [-1.9%, 4.9%]
Out-of-hospital	0.7% [0.1%, 2.4%] (2)	0% [0.0%, 1.3%] (0)	0.7% [-0.3%, 1.6%]
Q-wave MI Total	2.3% [0.9%, 4.8%] (7)	2.1% [0.8%, 4.5%] (6)	0.3% [-2.1%, 2.6%]
Early (in-hospital)	1.7% [0.5%, 3.9%] (5)	1.4% [0.4%, 3.5%] (4)	0.3% [-1.7%, 2.3%]
Out-of-hospital	0.7% [0.1%, 2.4%] (2)	0.7% [0.1%, 2.5%] (2)	0% [-1.4%, 1.3%]
CABG Total	1.3% [0.4%, 3.4%] (4)	1.0%[0.2%, 3.0%] (3)	0.3% [-1.5%, 2.0%]
Early (in-hospital)	0.7% [0.1%, 2.4%] (2)	0.7%[0.1%, 2.5%] (2)	0% [-1.4%, 1.3%]
Out-of-hospital	0.7% [0.1%, 2.4%] (2)	0.3% [0.0%, 1.9%] (1)	0.3% [-0.8%, 1.5%]
Stent Thrombosis Total	1.7% [0.5%, 3.9%] (5)	0.7% [0.1%, 2.5%] (2)	1.0% [-0.8%, 2.7%]
Early (in-hospital)	1.3% [0.4%, 3.4%] (4)	0% [0.0%, 1.3%] (0)	1.3% [0.0%, 2.6%]
Out-of-hospital	0.3% [0.0%, 1.8%] (1)	0.7% [0.1%, 2.5%] (2)	-0.4% [-1.5%, 0.8%]
Death Total	2.3% [0.9%, 4.8%] (7)	1.7% [0.6%, 4.0%] (5)	0.6% [-1.7%, 2.9%]
Early (in-hospital)	0% [0.0%, 1.2%] (0)	0.7% [0.1%, 2.5%] (2)	-0.7% [-1.7%, 0.3%]
Out-of-hospital	2.3% [0.9%, 4.8%] (7)	1.0% [0.2%, 3.0%] (3)	1.3% [-0.8%, 3.4%]
Bleeding Complications	4.0% [2.1%, 6.9%] (12)	1.7% [0.6%, 4.0%] (5)	2.3% [-0.4%, 5.0%]
Vascular Complications	7.7% [4.9%, 11.3%] (23)	8.4% [5.4%, 12.2%] (24)	-0.7% [-5.1%, 3.7%]
Cerebrovascular Accidents	0.7%[0.1%, 2.4%] (2)	0.7% [0.1%, 2.5%] (2)	0% [-1.4%, 1.3%]
Stent Delivery Failures	7.7% [4.7%, 10.7%] (23)	5.7% [1.3%, 10.2%] (6/105)	2.0% [-3.4%, 7.3%]

Early (in-hospital) refers to events during the hospitalization for the initial stent placement.
In cases where a patient experienced both an in-hospital event and an out-of-hospital event, they are counted once in each group, but only once in the event total. Hence, the sum of the in-hospital event rate and the out-of-hospital event rate may not equal the total event rate.
ANY Major Adverse Event includes death, Q wave MI, non-Q wave MI, emergent CABG, target lesion revascularization, stent thrombosis, bleeding complications, vascular complications and CVA
Stent Delivery Failures: stent misplacement, unable to cross lesion, unable to reach lesion

Nine (9) patients who received the Wallstent® Endoprosthesis died during the WIN Randomized Trial. Seven of these deaths occurred during the first six months and are included in Table 3 above. Of the nine deaths, one (1) death occurred within 30 days of stenting, but after hospital discharge, due to cardiac arrest. Eight (8) deaths occurred between 67 and 433 days due to arrythmia (n=4), cardiac arrest (n=1), encephalopathy (n=1), cancer (n=1) and unknown (n=1).

Two (2) patients died during the Feasibility study. Both deaths occurred between 250 and 357 days due to sudden

death (n=1) and cancer (n=1). No deaths occurred in the Magic and Post-Randomization Registry. Two (2) patients died during the Wellstent Registry, a non-cardiac death at 179 days and a sudden death at 321 days.

5.2 Potential Adverse Events

Adverse events (in alphabetical order) which may be associated with the use of a coronary stent in coronary vessels (including those listed in Table 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/or pain at the access site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident
- Total occlusion of coronary artery

6 CLINICAL STUDIES

A total of 893 patients were treated 26 North American investigational sites in the four parts of the WIN Trial and at 11 European investigational sites in the Wellstent Registry (Table 2). The WIN Trial is summarized below.

Primary Endpoint: The primary endpoint for the WIN Trial was MACE+CVA at 6 months. MACE+CVA was defined as a composite of death, nonfatal myocardial infarction, CVA, and clinically driven target lesion revascularization. An independent clinical events committee (CEC), adjudicated all of the major clinical endpoints.

Patients Studied: Eligible patients were candidates for percutaneous transluminal coronary angioiplasty (PTCA) with ischemic coronary artery disease and one or two *de novo* or restenotic lesions in native coronary arteries with maximum vessel diameter of 3.0 to 5.5 mm and lesion length ≤ 22 mm (3.0 mm – 4.0 mm vessels) or ≤ 35 mm (4.1 mm – 5.5 mm vessels).

Methods: In the WIN Randomized Trial, patients were prospectively randomized to treatment with the Wallstent® Endoprosthesis or PTCA. The patients underwent balloon angioplasty with an appropriate balloon diameter matching the reference vessel diameter. Post-stent deployment dilation with a high pressure, non-compliant balloon (balloon to artery ratio of 1:1) was recommended to hasten expansion of the stent. The goal was a residual stent diameter stenosis of less than 10%.

Patients in the PTCA arm received secondary treatment if acute results met one or more of the following abrupt or threatened closure conditions: TIMI flow < 3 which persisted after treatment with PTCA balloon and was related to mechanical dissection, or ≥ 50% residual stenosis, or any dissection grade C or higher.

Clinical follow-up was performed at 6 weeks, six months and one year. Six-month angiographic follow-up was requested of all patients. Anticoagulation included aspirin 325-mg/day for at least one year for all patients. Stent patients also received ticlopidine 500-mg/day for 30 days. If optimal results (≤ 10% residual stenosis) were not achieved at stent implantation, the physician had the option to add an antithrombin agent.

Results: Of the 299 patients randomized to the Wallstent® Endoprosthesis in the WIN Randomized Trial there were 256 patients with *de novo* lesions and 43 patients with restenotic lesions. Baseline characteristics were similar for the two treatment groups in the randomized trial. All patients were included in the intent-to-treat efficacy analysis. The MACE+CVA rate at 6 months was 24% for patients with *de novo* lesions and 14% for patients with restenotic lesions with an associated difference of 10% and 95% confidence interval of [-2.1%, 21%]. Table 4

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shows the results for both groups (restenosis and *de novo* lesions combined). Figure 1 shows the actuarial freedom from MACE+CVA.

Table 4. Principal Effectiveness and Safety Results
All Patients in the WIN Randomized Trial (n=586)

Efficacy Measures	Wallstent® Endoprosthesis (n=299)	PTCA (n=287)	Difference [95% CI]
Device Success	96% (286/298)	60% (158/265)	36%* [30%, 43%]
Procedure Success	97% (289/298)	96% (258/268)	0.7% [-2.3%, 3.7%]
Post-procedure In-Lesion %DS	19% ± 13% (298)	26% ± 13% (268)	-7.1%* [-9.2%, -4.9%]
Range (min, max)	(-26%, 98%)	(-11%, 100%)	
6 Months Follow-up In-Lesion %DS	45% ± 20% (229)	46% ± 20% (196)	-0.9% [-4.8%, 2.9%]
Range (min, max)	(-1%, 100%)	(5%, 100%)	
6 Months Follow-up In-Lesion Binary Restenosis Rate	38% (87/229)	38% (75/196)	-0.3% [-9.5%, 9.0%]
TLR-free at 6 Months (K-M)	87% [83%, 91%]	85% [81%, 90%]	1.8% [-3.9%, 7.5%]
TVR-free at 6 Months (K-M)	84% [80%, 89%]	84% [79%, 88%]	0.9% [-5.2% 7.0%]
MACE+CVA-free at 6 Months (K-M)	80% [75%, 84%]	80% [75%, 85%]	-0.4% [-6.9%, 6.2%]
MACE+CVA rate at 6 Months	20% (60/294)	20% (56/279)	0.3% [-6.2%, 6.9%]
Safety Measures			
In-Hospital Major Clinical Events	8.0% (24/299)	5.9% (17/287)	2.1% [-2.0%, 6.2%]
Out-of Hospital Major Clinical Events	12.0% (36/299)	13.9% (40/287)	-1.9% [-7.3%, 3.5%]
Bleeding Complications	4.0% (12/299)	1.7% (5/287)	2.3% [-0.4%, 5.0%]
Vascular Complications	7.7% (23/299)	8.4% (24/287)	-0.7% [-5.1%, 3.7%]
Stent Thrombosis	1.7% (5/299)	1.9% (2/105)	-0.2% [-3.2%, 2.8%]
Subacute Closure	1.3% (4/299)	1.4% (4/287)	-0.1% [-1.9%, 1.8%]

Numbers are % (counts/sample size) or Mean ± standard deviation. CI is Confidence Interval. RR is relative risk.
Device Success: attainment of < 50% residual stenosis using assigned device without using a device outside the assigned treatment strategy.
Procedure Success: < 50% residual stenosis and freedom from in-hospital death, Q-wave MI, or emergent CABG.
%DS: percent diameter stenosis; TLR: target lesion revascularization; TVR: target vessel revascularization
CVA: cerebral vascular accident; MACE: death, Q-wave or non-Q-wave MI, TLR (PTCA or CABG)
Major Clinical Event: death, MI, TLR (PTCA or CABG) or CVA
Subacute closure: abrupt closure occurring after index procedure completed and patient out of catheterization laboratory, but within 30 days.
Stent thrombosis: total thrombotic stent occlusion documented by angiography or cardiac death occurring in the first 30 days after stenting.
Bleeding complications: transfusion of blood products due to blood loss resulting from the percutaneous revascularization procedure, or blood loss resulting in change in anticoagulation regimen.
Vascular complications: occurrence of hematoma, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure-related transfusion, and vascular surgical repair.
K-M indicates Survival estimates by Kaplan-Meier method; Standard Error estimates by Greenwood formula.
* Difference statistically significant ($p<0.05$) by Chi square or t-test

INSERT KAPLAN-MEIER Graph and Table for MACE+CVA through 360 days

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Secondary treatment was necessary in a high percentage of patients in the PTCA group (105, 37%). Secondary treatment in all cases was stent implantation (71 Wallstent® Endoprosthesis, 31 other stents, and 3 unsuccessful stenting attempts). Baseline patient variables were similar between the two subgroups. Lesion length (mean ± SD) was significantly different (13 ± 6 mm for PTCA Only group, 17 ± 10 mm for PTCA+Stent group, p<0.0001). In the PTCA+Stent group, the MACE+CVA rate at 6 months was 24% for patients with the Wallstent® Endoprosthesis and 23% for patients with other stents, with an associated difference of 0.8% and 95% confidence interval of [-6.1%, 7.7%]. Table 5 shows the results for PTCA Only vs. all secondary treatment cases combined.

Table 5. Principal Effectiveness and Safety Results
All Patients in the WIN Randomized Trial PTCA Group (n=287)

Efficacy Measures	PTCA Only (n=182)	PTCA + Stent (n=105)	Difference [95% CI]
Device Success	96% (158/165)	0% (0/100)	96%* [93%, 99%]
Procedure Success	95% (159/167)	98% (99/101)	-2.8% [-7.0%, 1.4%]
Post-procedure In-Lesion %DS	30% ± 12% (167)	19% ± 12% (101)	11%* [8.2%, 14%]
Range (min, max)	(2%, 100%)	(-11%, 56%)	
6 Months Follow-up In-Lesion %DS	45% ± 19% (128)	47% ± 22% (68)	-1.8% [-7.8%, 4.2 %]
Range (min, max)	(5%, 100%)	(12%, 100%)	
6 Months Follow-up In-Lesion Binary Restenosis Rate	39% (50/128)	37% (25/68)	2.3% [-12%, 17%]
TLR-free at 6 Months * (K-M)	87% [82%, 92%]	83% [75%, 91%]	3.6% [-5.1%, 12%]
TVR-free at 6 Months * (K-M)	85% [80%, 90%]	81% [73%, 89%]	3.9% [-5.2%, 13%]
MACE+CVA-free at 6 months * (K-M)	82% [76%, 88%]	77% [68%, 85%]	5.2% [-4.6%, 15%]
MACE+CVA rate at 6 Months	18% (32/177)	24% (24/102)	-5.5% [-15%, 4.5%]
Safety Measures			
In-Hospital Major Clinical Events	3.8% (7/182)	9.5% (10/105)	-5.7%[-12%, 0.6%]
Out-of Hospital Major Clinical Events	13.7% (25/182)	14.3% (15/105)	-0.5% [-8.9%, 7.8%]
Bleeding Complications	1.6% (3/182)	1.9% (2/105)	-0.3% [-3.5%, 2.9%]
Vascular Complications	8.8% (16/182)	7.6% (8/105)	1.2% [-5.4%, 7.7%]
Stent Thrombosis	0% (0/182)	1.9% (2/105)	-1.9% [-4.5%, 0.7%]
Subacute Closure	1.1% (2/182)	1.9% (2/105)	-0.8% [-3.8%, 2.2%]

Numbers are % (counts/sample size) or Mean ± standard deviation. CI is Confidence Interval. RR is relative risk.
Device Success: attainment of < 50% residual stenosis using assigned device without using a device outside the assigned treatment strategy.
Procedure Success: attainment of < 50% residual stenosis and freedom from in-hospital death, Q-wave MI, or emergent CABG.
%DS: percent diameter stenosis; K-M: Kaplan-Meier estimate; TLR: target lesion revascularization; TVR: target vessel revascularization
CVA: cerebral vascular accident; MACE: death, Q-wave or non-Q-wave MI, TLR (PTCA or CABG)
Major Clinical Event: death, Q-wave or non-Q-wave MI, TLR (PTCA or CABG) or CVA
Subacute closure: abrupt closure occurring after index procedure completed and patient out of catheterization laboratory, but within 30 days.
Stent thrombosis: total thrombotic stent occlusion documented by angiography or cardiac death occurring in the first 30 days after stenting.
Bleeding complications: transfusion of blood products due to blood loss resulting from the percutaneous revascularization procedure, or blood loss resulting in change in anticoagulation regimen.
Vascular complications: occurrence of hematoma, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure-related transfusion, and vascular surgical repair.
K-M indicates Survival estimates by Kaplan-Meier method; Standard Error estimates by Greenwood formula.
*** Difference statistically significant (p<0.05) by Chi square or t-test**

Lesion length was a significant predictor for some measures of clinical restenosis in both arms (see 7.1 Individualization of Treatment). The MACE+CVA rate at 6 months was 20% for the Wallstent® Endoprosthesis group and 20% for the PTCA group with an associated difference of 0.3% and 95% confidence interval of [-6.2%, 6.9%]. Lesion length (mean ± SD) was 15 ± 9 mm for the Wallstent® Endoprosthesis group and 14 ± 8 mm for the PTCA group with an associated difference of 1 and 95% confidence interval of [-0.4, 2.4]. Relationships between lesion length and major efficacy/safety measures at six months for all patients in the WIN Randomized Trial are shown in Table 6.

Table 6. Lesion Length Analysis, WIN Randomized Trial (Wallstent® Endoprosthesis + PTCA)
All Patients in the WIN Randomized Trial (n=586)

Efficacy/Safety Measures at 6 Months	Lesion Length (0-10 mm)	Lesion Length (11-20 mm)	Lesion Length (>20 mm)
%DS in-lesion	41% ± 19%	47% ± 20%	51% ± 21%
Binary Restenosis rate in-lesion	28% (41/149)	42% (88/208)	49% (33/67)
TLR	16% (33/209)	25% (67/271)	27% (25/94)
TVR	21% (44/209)	29% (78/271)	31% (29/94)
MACE	23% (49/209)	32% (87/271)	36% (34/94)

TLR: target lesion revascularization; TVR: target vessel revascularization; MACE: death, Q-wave or non-Q-wave MI, TLR (PTCA/CABG)

The Magic Registry was conducted to demonstrate the safety through discharge of the new over-the-wire Magic delivery system as compared to the rolling membrane over-the-wire delivery catheter used in the WIN Randomized Trial. The in-hospital rate for any major clinical event was 5.5% in the Magic Registry, compared with 8.0% for Wallstent® Endoprosthesis group in the WIN Randomized Trial, difference 2.6% [-4.2%, 9.3%].

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 the Magic Wallstent® Endoprosthesis. Patient selection factors to be assessed should include a judgment regarding risk of prolonged anticoagulation. Stenting is 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 increased 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. The relation of baseline and procedural variable to MACE+CVA was examined. The only two significant predictors of MACE+CVA were pre-procedural reference vessel diameter and lesion length. As has been reported for PTCA, MACE+CVA was less likely with larger vessel diameter and shorter lesion lengths.

Thrombosis following stent implantation is effected by several baseline angiographic and procedural factors. These include vessel diameter < 3.0 mm, vessel 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 because stent thrombosis may occur during this period.

7.2 Specific Patient Populations

The safety and effectiveness of the Magic Wallstent® Endoprosthesis has not been established for patients with any of the following characteristics:

- Patients with recent acute myocardial infarction.
- Patients with unresolved vessel thrombus at the lesion site.
- Patients with coronary artery reference vessel diameter < 3.0 mm.
- Patients with restenotic lesions.
- 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 lesion(s).
- Patients with more than two overlapping stents due to risk of thrombus or poor flow.
- Patients for longer than 6 months follow-up.

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

8 HOW SUPPLIED

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

CONTENTS:

One (1) Magic Wallstent® Endoprosthesis
One (1) envelope containing patient materials and tracking information
One (1) Instructions for Use Manual

STORAGE: Store in a cool, dry, dark place. Do not expose to organic solvents or ionizing radiation.

9 OPERATOR'S INSTRUCTIONS

9.1 Inspection Prior to Use

Step	Action
1	Measure the vessel diameters adjacent to the target stenosis and the length of the segment to be stented. Exact calibration measurements are recommended.
2	Select the proper stent model using Sizing Chart (see 9.7 Sizing).
3	Carefully inspect the sterile package before opening. Do not use after the "Use By" date. If the integrity of the sterile package has been comprised prior to the product "Use By" date (e.g., damage of the package), contact your local SCIMED Representative for return information. Do not use if any defects are noted.
4	Remove the Magic Wallstent® Endoprosthesis from its protective packaging and visually check that the stent and the distal X-ray marker are fully covered by the distal end of the outer sheath. Do not use if any defects are noted.

9.2 Materials Required (not included in the package)

Quantity	Material
	Appropriate guiding catheter(s) (see Table 1, Stent Specifications), PTFE inner liner recommended
1	10 ml sterile syringe for flushing
1	Small basin containing heparinized sterile isotonic saline
1	0.014 inch x 300 cm length extra support guidewire
1	Rotating hemostatic valve
	Diluted contrast medium 1:1 with normal heparinized saline
1	Pre-deployment dilation catheter with inflation device
Optional	Three-way stopcock

9.3 Preparation of the Stent/System

Flush Annular Space

Step	Action
1	Attach a 10-ml syringe filled with sterile heparinized saline to the stopcock on the T-connector.
2	Open the stopcock and vigorously inject the sterile saline into the annular space between the shafts until it comes out of the outer sheath.

Guidewire Lumen Flush

Step	Action
1	Attach a 10-ml syringe filled with heparinized saline to the proximal luer lock injection/hub,
2	Inject the saline solution through the guidewire lumen until it comes out of the catheter tip.

9.4 Delivery Procedure

Step	Action
1	Prepare the 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. Check the stenosis dimensions after balloon dilatation to confirm that the correct stent model has been selected.
3	Backload Stent/System onto proximal portion of guidewire while maintaining guidewire position across target lesion. Note: If shaft kinks during insertion over guidewire, remove the Stent/System and use a another one.
4	Loosen the hemostatic valve to allow easy movement when advancing or retracting the Stent/System, and during deployment.
5	Ensure guiding catheter stability before advancing the Stent/System into the coronary artery. Carefully advance the Stent/System into the hub of the guiding catheter. Note: If resistance to the Stent/System is encountered prior to exiting the guiding catheter, do not force passage. Resistance may indicate a problem and may result in damage to the Stent/System. Maintain guidewire placement across the lesion and remove the Stent/System as a single unit.
6	Advance Stent/System over the guidewire to target lesion under direct fluoroscopic visualization. Maintain the delivery catheter as straight as possible outside of the body.
7	Place the proximal and distal X-ray markers of the inner shaft to overlap both sides of the stenosis, with the proximal marker closer to the proximal end of the stenosis.

9.5 Deployment Procedure and Removal

Step	Action
1	Immobilize the stainless steel tube by holding it firmly with right hand, placing your fingers on the black marker. Then grasp the sliding T-connector with the other hand and gently slide it back towards the luer lock injector/hub. **CAUTION: Do not push the stainless steel tube. Pushing the stainless steel tube will cause misalignment of the stent and possible vessel damage.** Deploy the stent a few millimeters at a time, repositioning the delivery catheter as required until the stent is approximately 50% deployed, that is, until the T-connector reaches the black release marker on the stainless steel tube. Note: During deployment the X-ray marker placed in the outer sheath is retracted from the distal marker, allowing fluoroscopic guidance while releasing the stent. **CAUTION: Do not deploy the stent if unusual force is required. Remove Stent/System and use a different one.** **CAUTION: Do not deploy more than 50% of the stent (beyond the black release marker) until correct position is confirmed. Further deployment could lead to premature release of the stent. Keeping the fingers of your right hand on the black release marker can help prevent premature deployment.**
2	Check the position of the partially deployed stent to ascertain its correct alignment with the stenosis. Note: Contrast medium can be injected through the guiding catheter for fluoroscopic guidance, if desired. Vessel perfusion is maintained throughout stent placement. If position is correctly aligned go to Step 5.
3	**Proximal** repositioning of a partially deployed stent (≤ 50%) can be achieved by carefully retracting the entire Stent/System in the vessel. Hold the T-connector securely on the stainless steel tube and carefully retract the entire Stent/System while checking the position of the X-ray markers.

4	**Distal** or proximal repositioning of the partially deployed stent (≤ 50%) can be achieved by re-covering the stent. Hold the sliding T-connector stationary with your left hand and pull back the stainless steel tube with your right hand. This action pulls the inner shaft, and the stent, back into the outer sheath. The entire Stent/System can now be repositioned distally or proximally. If Stent/System removal is required prior to full deployment, but when the stent is > 50% deployed, hold the T-connector securely on the stainless steel tube and cautiously withdraw the Stent/System into the guiding catheter. Pull the Stent/System back into the descending aorta toward the arterial sheath. As the distal end of the guiding catheter enters the arterial sheath, the catheter will straighten allowing safe withdrawal of the Stent/System into the guiding catheter and the subsequent removal of the Stent/System and the guiding catheter as a unit from the arterial sheath. **Note:** The re-covering procedure should be performed carefully. It can be seen easily on fluoroscopy and should be stopped when a slight resistance is noted and the distal X-ray marker reaches the position of the X-ray marker on the outer sheath. **Re-covering of the stent should not be performed more than twice. Do not continue re-covering if unusual force is required.**
5	For complete deployment, immobilize the stainless steel tube with your right hand, grasp the T-connector with your left hand and gently slide it up the immobilized stainless steel tube back towards the luer lock injector/hub until the stent is completely deployed. **Note:** If stent system removal is required prior to full deployment, but when > 50% deployed, hold the T-connector securely on the stainless steel tube and cautiously withdraw the Stent/System into the guiding catheter. (see **4.3 Stent/System Removal – Precautions**).
6	Withdraw the delivery catheter under fluoroscopic guidance leaving the guidewire in place. If the tip of the delivery catheter catches the distal stent filaments, perform gentle movements in order to free it.

9.6 Post Delivery System Removal

Step	Action
1	Perform routine post-procedural angiography. **Note:** If the stent does not adequately cover the entire stenosis, a second stent should be implanted overlapping the first (overlap at least 5 mm).
2	Perform balloon dilation inside the stent(s) using either a non-compliant balloon catheter with known maximum diameter, or a semi-compliant balloon catheter, where the ratio between balloon diameter and balloon pressure is clearly documented. Attain a stent diameter that matches the referenced vessel diameter as closely as possible. Ensure that the balloon length will not exceed the length of the implanted stent.
3	Perform routine post-procedural angiography again to verify results. Upon confirmation of desired results, remove all devices from the patient.

9.7 Sizing

Stent diameter selected should be approximately 0.5 mm to 1 mm larger than the calculated vessel diameter. Select a stent with an implanted length longer than the calculated lesion length so adequate lesion coverage is provided (an additional 4 mm on each end of lesion is recommended).

Table 7. Estimated Implanted Stent Lengths							
Order No.*	Fully Open Stent Diameter Ø mm	Stent Length Descriptor	Constrained Stent Length mm	Estimated Stent Length Implanted in Vessel Vessel Ø mm	Stent Length mm	Estimated Stent Length Implanted in Vessel Vessel Ø mm	Stent Length mm
MAG-64490	3.5	mini	15	3.0	11		
MAG-64491		extra short	20		15		
MAG-64492		short	30		23		
MAG-64493		medium	40		30		
MAG-64500	4.0	extra short	20	3.5	15	3.0	17
MAG-64501		short	30		23		25
MAG-64502		medium	40		31		34
MAG-64503		long	60		44		48
MAG-64510	4.5	extra short	20	4.0	15	3.5	17
MAG-64511		short	30		22		24
MAG-64512		medium	40		30		33
MAG-64513		long	60		44		48
MAG-64520	5.0	short	30	4.5	22	4.0	24
MAG-64521		medium	40		29		32
MAG-64522		long	60		43		47
MAG-64530	5.5	short	30	5.0	22	4.5	24
MAG-64531		medium	40		29		32
MAG-64532		long	60		43		47
MAG-64544	6.0	short	30	5.5	22	5.0	24
MAG-64541		medium	40		28		31
MAG-64542		long	60		43		47

10 PATIENT INFORMATION

In addition to this Instructions for Use, the Magic Wallstent® Endoprosthesis is packaged with a Patient 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:

Physicians will be provided separately copies of a Patient Guide which includes information on coronary artery disease, the implant procedure and the Magic Wallstent® Endoprosthesis.