Omnilink Elite® Vascular Balloon-Expandable Stent System

Instructions for Use

℞ ONLY

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1.0 DEVICE DESCRIPTION

The Omnilink Elite Vascular Balloon-Expandable Stent System (Omnilink Elite Stent System) is a flexible, balloon-expandable L605 cobalt-chromium stent pre-mounted on the balloon of an over-the-wire (OTW) stent delivery system. The OTW stent delivery system is compatible with a 0.035" guide wire and comes in lengths of 80 cm and 135 cm. The stent is mounted on the balloon between the two radiopaque markers. The delivery system can be utilized to optimize the stent wall apposition post stent deployment. See Table 1 for stent dimensions.

Table 1: *In vitro Device Specifications**

Expanded Stent Diameter** (mm)	Stent Lengths (mm)	*In vitro** Stent Deployment Pressure (atm)	Rated Burst Pressure RBP (atm)	Recommended Minimum Sheath / Introducer*** (F)
6.0	12, 16, 19, 29, 39, 59	11	14	6
7.0	12, 16, 19, 29, 39, 59	11	14	6
8.0	19, 29, 39, 59	11	14	6
9.0	19, 29	11	14	6
9.0	39, 59	11	14	7
10.0	19, 29, 39, 59	11	14	7

* All data provided are based on *in vitro* testing. Assure full deployment of the stent. (Refer to *Clinician Use Information*) in Section 8.0 of the IFU) Deployment pressures should be based on lesion characteristics.
** The inflated balloon diameter of the system used to deploy the stent should approximate the diameter of the vessel.
***See individual manufacturer specifications for (F) equivalent on box label and pouch label.

2.0 HOW SUPPLIED

Sterile – This device is sterilized with electron beam radiation. Non-pyrogenic. Do not use if the package is open or damaged.
Storage – Keep dry, keep away from sunlight, temperature limitation 15°C – 30°C (59°F – 86°F).
Contents – One each: Omnilink Elite Stent System

3.0 INDICATIONS

The Omnilink Elite Stent System is indicated for the treatment of atherosclerotic iliac artery lesions with reference vessel diameters of ≥ 5.0 mm and ≤ 11.0 mm, and lesion lengths up to 50 mm.

4.0 CONTRAINDICATIONS

There are no known contraindications.

5.0 WARNINGS

- This device is intended for single-use only; do not reuse. Do not resterilize. Do not use if package is open or damaged.

- Since the use of this device carries the associated risk of subacute thrombosis, vascular complications, and / or bleeding events, judicious selection of patients is necessary.
- Persons allergic to L605 cobalt chromium alloy may suffer an allergic reaction to this implant.
- This device should be used only by physicians trained in angiography and percutaneous transluminal angioplasty and stent placement.
- The safety and effectiveness of multiple overlapping stents have not been established. However, when multiple stents are required, stent materials should be of similar composition to avoid the potential for dissimilar metal corrosion.
- Use of appropriate anticoagulant and / or antiplatelet therapy per standard of care is recommended for use with this stent system.

6.0 PRECAUTIONS

The device should be used only by physicians trained in angiography and percutaneous transluminal angioplasty and stent placement.

6.1 Stent Delivery System Handling – Precautions

- For single use only. Do not resterilize or reuse.
- Use the stent system prior to the “Use by” date specified on the package.
- Do not remove stent from its delivery balloon, as removal may damage the stent and / or lead to stent embolization.
- Carefully inspect the Omnilink Elite Stent System prior to use to verify that the stent has not been damaged in shipment and that the device dimensions are suitable for the specific procedure. Take care to avoid unnecessary handling.
- The Omnilink Elite Stent System is intended to perform as a system. The stent should not be removed for use in conjunction with other dilatation catheters, nor should the delivery system be used in conjunction with other stents.
- Refer to the instructions for use supplied with any interventional devices to be used in conjunction with the Omnilink Elite Stent System, for their intended uses, contraindications, and potential complications.
- Special care must be taken not to handle or in any way disrupt the stent on the balloon. This is most important during stent system removal from the packaging, placement over a guide wire and advancement through a guiding catheter or introducer sheath.
- Do not "roll" the mounted stent with your fingers, as this action may loosen the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon, as this may cause uneven expansion and difficulty in deployment of the stent.
- Do not advance the stent delivery system without the guide wire extending from the tip.

6.2 Stent Placement – Precautions

- Do not prepare or pre-inflate balloon prior to stent deployment other than as directed. Use balloon purging technique described in the *Clinician Use Information* section.

- The inflated balloon diameter of the system used to deploy the stent should approximate the diameter of the vessel. Oversizing of the stent can result in a ruptured vessel. To ensure full expansion of the stent, the balloon should be inflated to a minimum of nominal pressure.

- Implanting a stent may lead to dissection of the vessel distal and / or proximal to the stent and may cause acute closure of the vessel, requiring additional intervention (surgical intervention, 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 in placement of 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.*)

- Stenting across a major bifurcation may hinder or prevent future side branch access.

- Balloon pressures should be monitored during inflation. Do not exceed Rated Burst Pressure (RBP) as indicated on product label. Use of pressures higher than specified on product label may result in a ruptured balloon with possible vessel damage or perforation.

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

- The Omnilink Elite Stent System is intended for deployment and post-deployment dilatation of the stent only and should not be used to dilate other locations.

- Do not attempt to pull an unexpanded stent back through the introducer sheath / guiding catheter; dislodgment of the stent from the balloon may occur.

- Once fully deployed, the stent cannot be repositioned.

6.3 Stent / System Removal – Precautions

Should unusual resistance be felt at any time during either lesion access or removal of the delivery system post-stent implantation, the entire system should be removed as a single unit.

When removing the delivery system as a single unit:

- DO NOT retract the delivery system into the introducer sheath / guiding catheter.
- Position the proximal balloon marker just distal to the tip of the introducer sheath / guiding catheter.
- Advance the guide wire in the anatomy as far distally as safely possible.

- Secure the delivery system to the introducer sheath / guiding catheter; then remove the introducer sheath / guiding catheter, guide wire and delivery system as a single unit.

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

If it is necessary to retain guide wire position for subsequent vessel access, leave the guide wire in place and remove all other system components.

6.4 Post Implant – Precautions

Exercise great care when crossing a newly deployed stent with a guide wire or balloon catheter to avoid disrupting the stent geometry.

Magnetic Resonance Imaging (MRI) Information

Non-clinical testing has demonstrated that the Omnilink Elite stent, in single and in overlapped configurations up to 100 mm in length, is MR Conditional as defined in ASTM F2503. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Spatial gradient field of 2500 Gauss/cm or less
- Maximum whole body average specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning per sequence for patient landmarks above umbilicus (Total duration of all scans may exceed 15 minutes)
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below umbilicus
- Transmit RF body coil should be used in normal operating mode, as defined in IEC 60601-2-33

MRI at 1.5 or 3 Tesla may be performed immediately following the implantation of the Omnilink Elite stent.

The Omnilink Elite stent should not migrate in this MRI environment. Magnetic force on the Omnilink Elite stent was tested according to ASTM F2052-06e. The deflection angle was measured to be 6° in a GE Signa 3T HDx MR system. Stent heating was derived by using the measured non-clinical, *in vitro* temperature rise according to ASTM F2182-09 in a GE Signa HDx 3 Tesla scanner and in a GE 1.5 Tesla coil in combination with the local specific absorption rates (SARs) in a digitized human model. For the SAR conditions above, the maximum *in vivo* temperature rise was calculated to be 6°C at 64 MHz (1.5 T) and 128 MHz (3T) for stent lengths 100 mm and less. These calculations do not take into consideration the cooling effects of blood flow.

The effects of MRI on overlapped stents greater than 100 mm in length or stents with fractured struts are unknown.

Image artifact may be present when scanning the Omnilink Elite stent as demonstrated in non-clinical testing performed according to ASTM F2119-07 in a GE Signa HDx 3 Tesla scanner. The image artifact (both inside and outside the device lumen) extends approximately 5 mm from the device, using the spin echo sequence, and 10 mm from the device, using the gradient echo sequence. MR image quality may be compromised if the area of interest is in the exact same

area, or relatively close to, the position of the Omnilink Elite stent. Therefore, it may be necessary to optimize the MR imaging parameters in the presence of Omnilink Elite stents.

7.0 POTENTIAL ADVERSE EVENTS

Potential complications associated with percutaneous iliac artery treatment, including the use of an iliac stent, may include, but are not limited to, the following:

- Acute myocardial infarction
- Allergic reaction (contrast medium, drug, or stent material)
- Aneurysm, pseudoaneurysm, or arteriovenous fistula
- Angina or coronary ischemia
- Arrhythmias, with or without the need for a temporary pacemaker
- Bleeding complications from anticoagulant or antiplatelet medication requiring transfusion or surgical intervention
- Death
- Detachment and / or implantation of a component of the system
- Embolization, arterial or other (air, tissue, plaque, thrombotic material, stent)
- Emergent or urgent surgery to perfuse limb or remove stent
- Fever
- Hematoma or hemorrhagic event
- Hypotension or hypertension
- Infection, local or systemic, including bacteremia or septicemia
- Ischemia or infarction of tissue or organ
- Pain (limb or catheter site)
- Pulmonary embolism
- Renal failure or insufficiency secondary to contrast medium
- Restenosis of vessel in stented segment
- Stent malapposition or migration
- Stent strut fracture
- Stent thrombosis or occlusion
- Stroke, cerebrovascular accident (CVA), or transient ischemic attack (TIA)
- Target limb loss (amputation of toe, foot, and / or leg)
- Vascular thrombosis or occlusion at puncture site, treatment site, or remote site
- Vessel dissection, perforation, or rupture
- Vessel spasm or recoil
- Worsening claudication or rest pain

8.0 CLINICIAL USE INFORMATION

8.1 MOBILITY Clinical Study

The safety and effectiveness of Omnilink Elite was evaluated in one of two arms of the MOBILITY clinical study. (**Note**: The second arm of the study is independently evaluating a different stent for use in the iliac artery.) The Omnilink Elite arm of the MOBILITY study is a prospective, non-randomized, multicenter study to demonstrate the safety and effectiveness of Omnilink Elite, when used to treat *de novo* and restenotic atherosclerotic lesions in the native common iliac artery and the native external iliac artery. A total of 153 subjects were enrolled in the Omnilink Elite arm at 44 clinical sites in the United States.

8.2 Subject Demographics

Subjects between the ages of 18 and 89 with symptomatic ischemic PAD (Rutherford Becker clinical category 2 – 4), with stenotic lesions ≥ 50% and ≤ 100% in the common iliac artery or ≥ 50% and ≤ 99% in the external iliac artery, with target vessel reference vessel diameters ≥ 5.0 mm and ≤ 11.0 mm by visual estimate, and lesion lengths between 10 mm and 50 mm for stenotic lesions in the common iliac artery or external iliac artery or ≤ 40 mm for total occlusions of the common iliac artery, were eligible for the MOBILITY study.

Both primary endpoint and secondary endpoints were analyzed for the intent-to-treat (ITT) and per-protocol (PP) populations. The primary analysis is based on the ITT population and is reported here. The ITT population includes all subjects enrolled into the study **(Table 2**).

Table 2: Baseline Demographics, Risk Factors, and Medical History

Subject Characteristics	**N = 153**
Age (in years) Mean ± SD (n) Median (Q1, Q3) Range (min, max)	 63.9 ± 9.0 (153) 63.8 (57.5, 70.8) (44.6, 86.0)
Male Female	57.5% (88/153) 42.5% (65/153)
Diabetes Type I Type II	30.7% (47/153) 4.3% (2/47) 95.7% (45/47)
Tobacco Use Former Current	91.5% (140/153) 43.8% (67/153) 47.7% (73/153)
Dyslipidemia Requiring Medication	79.1% (121/153)
Hypertension Requiring Medication	83.0% (127/153)
Coronary Artery Disease	58.9% (89/151)
Previous Myocardial Infarction	20.7% (31/150)
Congestive Heart Failure	7.9% (12/152)
Cerebrovascular Disease	24.0% (36/150)
Stroke	6.0% (9/151)
Chronic Obstructive Pulmonary Disease	29.4% (45/153)
Bilateral Lower Extremity Artery Disease	81.0% (124/153)
Multi-level Peripheral Lower Extremity Artery Disease	100% (153/153)
Lower Extremity Artery Disease (excluding iliac artery disease)	62.1% (95/153)
Previous Endovascular or Surgical Intervention to the Target Limb	12.4% (19/153)

Note: Denominators are based on available data.

8.3 Methodology

Pre-procedure assessments consisted of the following for each subject:

- Medical history, review of current medications
- Serum creatinine
- Thigh-brachial index (TBI) and ankle-brachial index (ABI) for both limbs
- Walking Impairment Questionnaire (WIQ) to determine subject's self-perception of walking distance, walking speed, and stair climbing
- SF-12® Health Survey (quality of life)
- Rutherford-Becker (RB) clinical category for both limbs

Subjects received pre-procedure antiplatelet therapy in the form of either aspirin or clopidogrel, or a combination of both drugs. Subjects unable to take clopidogrel could take ticlopidine instead. Subjects underwent iliac stent placement following standard procedures and according to the Instructions for Use. During the stent procedure, use of supplemental anticoagulation was per the investigator's standard of care. The protocol allowed planned use of one stent to treat the target lesion. Additional stents were allowed for bailout purposes only. Treatment of bilateral iliac lesions was allowed, provided both lesions met all eligibility criteria. Fifty (50) subjects had bilateral iliac artery treatment and 103 subjects had unilateral iliac artery treatment, resulting in a total of 153 subjects with 203 target lesions. Baseline target lesion characteristics (per angiographic core lab analysis) are detailed in **Tables 3** and **4** below.

Table 3: Anatomic and Lesion Morphology

Characteristics	Lesions = 203
Anatomic	
Unilateral artery treatment	50.7% (103/203)
Bilateral artery treatment	49.3% (100/203)
Target Artery	
Common iliac	84.2% (170/202)
Common & external iliac, or external iliac only	15.8% (32/202)
Preprocedure Morphology	
Eccentric	62.4% (126/202)
Ulceration	17.8% (36/202)
Calcification	
None / mild	9.9% (20/202)
Moderate	27.2% (55/202)

Severe	62.9% (127/202)
Thrombus	0.5% (1/202)
Postprocedure Morphology	
Dissection Grade	
0 (No dissection)	
A	0.0% (0/201)
B	2.0% (4/201)
C	0.0% (0/201)
D	0.0% (0/201)
E	0.0% (0/201)
F	0.0% (0/201)

[1]Only 202 procedural angiographic images were available for analysis.

Table 4: Angiographic Quantitative Analysis

Lesions = 203			
	Mean ±SD (n)	Median	Min, Max
Preprocedure Reference Vessel Diameter (mm)	8.1 ± 1.7 (202)	7.8	4.5, 12.7
Preprocedure Lesion length (mm)	21.8 ± 12.2 (202)	19.2	5.5, 82.6
Preprocedure Lesion Percent Diameter Stenosis (%)	68.3 ± 15.4 (202)	66.8	16.2, 100.0
Preprocedure Minimum Lumen Diameter (mm)	2.6 ± 1.4 (202)	2.6	0.0, 8.1
Postprocedure Lesion Percent Diameter Stenosis (%)	10.6 ± 11.7 (202)	10.3	-27.3, 50.5
Postprocedure Minimum Lumen Diameter (mm)	7.1 ± 1.4 (202)	6.9	4.2, 11.2

After discharge, subjects were followed at 1 month (23 – 44 days) and 9 months (249 – 326 days). At each of these visits, the following data were collected:

- Adverse events
- Current medications
- TBI and ABI for the treated limb(s)
- RB clinical category for the treated limb(s)
- WIQ and SF-12
- Duplex ultrasound (DUS) of the stented artery(ies)
- Arteriogram at 9-month visit (only if DUS was unreadable)

Follow-up visits will continue at 18 months and at 2 and 3 years post-procedure. At the 18-month telephone contact, data will be gathered for adverse events and current medications only; at the 2- and 3-year follow-up visits, the same data as above will be collected, with the exception of the arteriogram.

8.4 Results

8.4.1 Primary Endpoint

The primary endpoint for the MOBILITY clinical study was the major adverse event (MAE) rate at 9 months defined as: death due to any causes, myocardial infarction (MI), clinically-driven target lesion revascularization (TLR) (worsening Rutherford Becker clinical category that is clearly referable to the target lesion, and target lesion diameter stenosis ≥ 50%), and limb loss (major amputation only) on the treated side(s). The Performance Goal (PG) for this endpoint was developed from published literature from previous iliac artery stenting studies and was set at 19.5%.

MOBILITY met the primary objective of the study demonstrating the safety and effectiveness of Omnilink Elite in the treatment of iliac artery stenosis. The primary endpoint of MAE rate at 9 months (270 days) is 5.4% (8/149), with the upper one-sided 95% confidence interval (CI) of 9.5%, which is significantly below the pre-specified PG of 19.5% ($p < 0.0001$, one-sided exact binomial test).

Table 5 details the individual subject counts for each of the MAE components.

Table 5: Non-hierarchical MAE at 270 Days – Per Subject Analysis

Events	**0 – 30 Days**	**0 – 270 Days**
Total Major Adverse Event (MAE) Rate	0.7% (1/151)	5.4% (8/149)
Death	0.0% (0/151)	0.7% (1/149)
Myocardial infarction	0.0% (0/151)	0.7% (1/149)
Major amputation of the treated limb(s)	0.0% (0/151)	0.0% (0/149)
Clinically-driven TLR	0.7% (1/151)	4.0% (6/149)

Note: Data available for 149 subjects

8.4.2 Key Secondary Endpoints

8.4.2.1 Device, Technical, and Procedure Success

Acute success is comprised of device, technical, and procedural success (Table 5). Study device success, on a per device basis, was 98.6% (208/211). Technical success, on a per lesion basis, was 93.1% (189/203). Procedure success, on a per subject basis was 91.5% (140/153).

Table 6. Acute Success

Effectiveness	**N = 153 Patients M = 203 Lesions**
Study Device Success[1]	98.6% (208/211)
Technical Success[2]	93.1% (189/203)
Procedure Success[3]	91.5% (140/153)

[1] Device success is defined, on a per-device basis, as the achievement of successful delivery and deployment of the assigned device(s), and successful removal of the delivery system as intended to the designated location.
[2] Technical success is defined, on a per-target lesion basis, as device success and attainment of a final in-stent residual stenosis < 30% by quantitative angiogram (QA), or as reported by the investigator if the assessment by QA is not available.
[3] Procedure success is defined, on a per-patient basis, as technical success without any of the following complications: death due to all causes, myocardial infarction, major amputation of the treated limb(s), stent thrombosis, and target lesion revascularization of the treated limb(s), within two days after the index procedure or at hospital discharge, whichever is sooner.

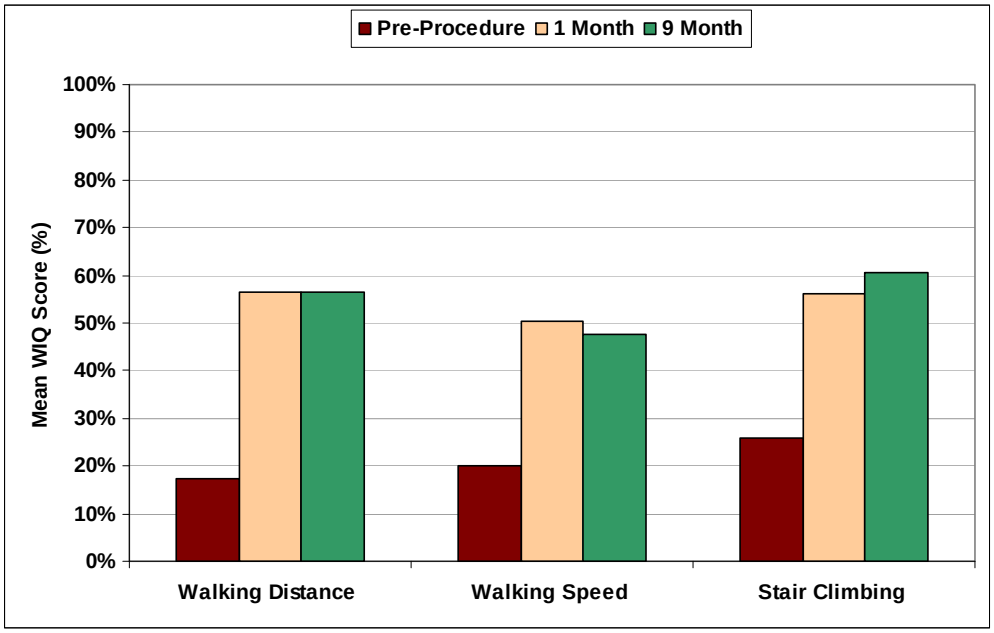
8.4.2.2 Thigh Brachial Index (TBI) and Ankle Brachial Index (ABI)

The majority of limbs, 93.4% (170 / 182), had 9-month hemodynamic success, defined as TBI or ABI improvement by > 0.1 compared to baseline, or had no deterioration by ≤ 0.15 compared to post-procedure values.

8.4.2.3 Walking Capacity

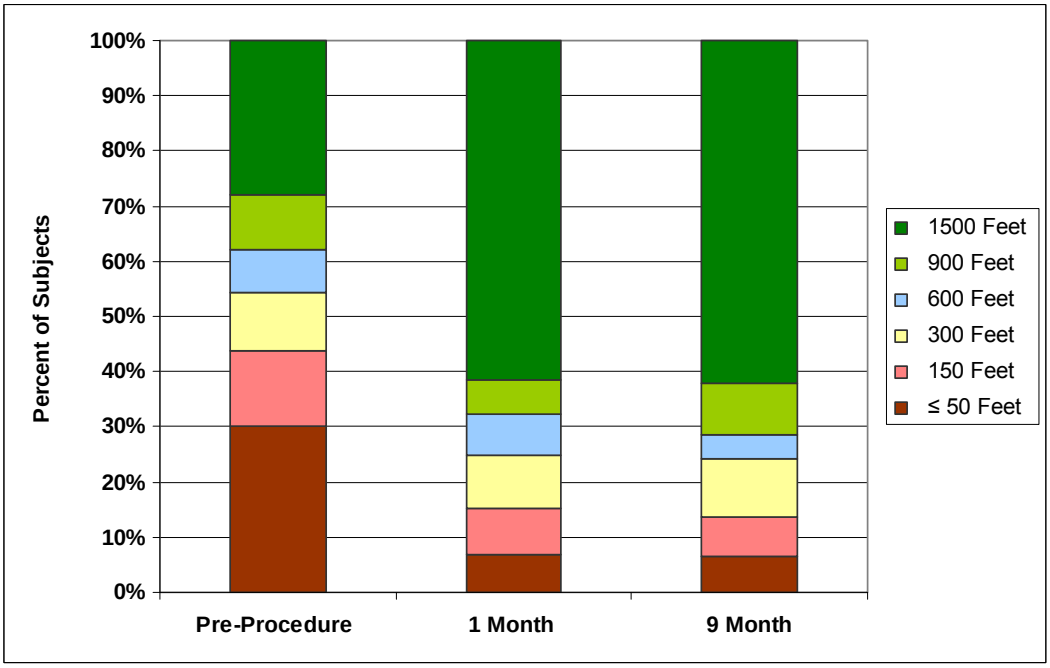
The WIQ was used to assess walking distance, walking speed and stair climbing for study subjects. The walking distance mean score increased from 17.5 ± 22.7% at baseline to 56.6 ± 38.6% at 9 months. The walking speed and stair climbing mean scores also increased from 20.1 ± 24.0% and 26.0 ± 25.8%, respectively, at baseline, to 47.6 ± 33.2% and 60.4 ± 35.9%, respectively, at 9 months (**Figure 1 below**).

Figure 1: WIQ Score Changes – Per Subject Analysis
(Omnilink Elite: Intent-to-Treat Population)



Prior to intervention, 30.1% (46/153) of the subjects could walk ≤ 50 feet, 13.7% (21/153) could walk 150 feet, while 28.1% (43/153) could walk 1500 feet. There was an improvement in maximum walking distance; at 9 months, 6.4% (9/140) were limited to walking ≤ 50 feet, 7.1% (10/140) were limited to walking 150 feet, and 62.1% (87/140) of subjects could walk 1500 feet (**Figure 2**).

Figure 2: Walking Distances



8.4.2.4 Rutherford Becker (RB) Clinical Category

At 9 months, 89.0% (162/182) of limbs had improved ≥ 1 RB clinical category.

8.4.2.5 Restenosis

Restenosis, defined as ≥ 50% stenosis by duplex ultrasound or arteriography, occurred in 9.0% (16/178) of lesions at 9 months.

8.5 Adverse Events

An independent Clinical Events Committee (CEC) adjudicated all cases of death, amputation, MI, TLR, target vessel revascularization (TVR), and stent thrombosis that occurred within 9 months of the index procedure, as well as all instances of TLR that occurred within 3 years. Clinical sites also reported all adverse events that occurred. Serious adverse events that occurred within the first 30 days and between 31 to 326 days post procedure are listed in **Tables 7** and **8**.

Table 7: Serious Adverse Events through 30 Days

Adverse Event	**N = 153**
Blood Dyscrasia	
Anemia	0.7% (1/153)
Gastrointestinal	
GI Bleed	0.7% (1/153)
Nausea	0.7% (1/153)
Infection	
Other: Cellulitis	0.7% (1/153)
Pneumonia	1.3% (2/153)
Metabolic	
Other: Hyponatremia	0.7% (1/153)
Miscellaneous	
Edema (non pulmonary)	0.7% (1/153)
Neurologic other than stroke	
Mental Status Change	0.7% (1/153)
Transient Ischemic Attack	0.7% (1/153)
Procedure-related	
Dissection	1.3% (2/153)
Distal Emboli	0.7% (1/153)
Renal	
Renal Failure	0.7% (1/153)
Respiratory	

Other: COPD Exacerbation	0.7% (1/153)
Stroke	
Other: Cerebral Vascular Accident	0.7% (1/153)
Vascular	
Occlusion	0.7% (1/153)
Other: Deep Vein Thrombosis	0.7% (1/153)

Table 8: Serious Adverse Events between 31 Days and 326 Days (Event Rate > 1%)

Adverse Event	**N = 153**
Blood Dyscrasia	
Anemia	2.0% (3/153)
Cancer	
Cancer	3.3% (5/153)
Cardiac	
Congestive Heart Failure	1.3% (2/153)
Other: Coronary Artery Disease	3.9% (6/153)
Cardiac / Hemodynamic	
Bradycardia	1.3% (2/153)
Gastrointestinal	
GI Bleed	1.3% (2/153)
Other: Cholecystitis	1.3% (2/153)
Infection	
Pneumonia	2.0% (3/153)
Miscellaneous	
Musculoskeletal	3.9% (6/153)
Neurologic other than stroke	
Transient Ischemic Attack	1.3% (2/153)
Respiratory	
Respiratory Failure	1.3% (2/153)
Vascular[1]	
Restenosis	3.9% (6/153)
Stenosis	6.5% (10/153)
Surgery / Interventional Procedure	1.3% (2/153)

[1]Includes any lesion within the vasculature

The adverse events reported within the Omnilink Elite arm of the MOBILITY study were as anticipated for the study population and are considered acceptable.

8.6 Conclusion

In conclusion, the MOBILITY study results support the safety and effectiveness of the Omnilink Elite Vascular Balloon-Expandable Stent System in subjects with atherosclerotic *de novo* or restenotic iliac artery stenoses. The MOBILITY study demonstrated a MAE rate of 5.4%. Iliac stenting with Omnilink Elite is safe as shown by the low MAE rate at 270 days and absence of any death and MAE through 30 days. TBI, ABI, and RB clinical category all improved at 9 months. Additionally, walking scores and distance, as measured by WIQ, were improved. The restenosis rate of 9.0% is acceptable and consistent with other stents that are used for iliac intervention even with 62.9% of the lesions having severe calcification.

9.0 OPERATOR'S INSTRUCTIONS

9.1 Stent Inspection Prior to Use

Prior to using the Omnilink Elite Stent System, carefully remove the system from the package and inspect for bends, kinks, and other damage. Verify that the stent is located between the radiopaque balloon markers. Do not use if any defects are noted.

9.2 Materials Required

- Introducer sheath / guiding catheter in the appropriate size and configuration for the selected stent delivery system (refer to **Table 1**).
- 2 – 3 syringes (10 – 20 cc)
- 1,000 u/500 cc normal saline
- 0.035" guide wire of appropriate length
- 60% contrast diluted 1:1 with normal saline
- Inflation device
- Three-way stopcock
- Torque device (if applicable)
- Guide wire introducer

9.3 Lesion Preparation

1. Standard percutaneous technique should be used to place the introducer sheath / guiding catheter in the vessel. An appropriate size (0.035") guide wire should be advanced across the lesion and into the common vessel.

2. Pre-dilate the lesion with an appropriate size balloon dilatation catheter to closely match the lumen diameter proximal and distal to the lesion.

3. Withdraw the balloon dilatation catheter leaving the guide wire in place.

9.4 Guide Wire Lumen Flush

1. Remove the protective cover from the tip.

2. Attach the syringe with HepNS to the guide wire port.

3. Flush until fluid exits the distal tip.

9.5 Stent Delivery System Preparation

1. Prepare an inflation device / syringe with diluted contrast medium
2. Attach the inflation device / syringe to the stopcock; attach to the inflation port.
3. With the tip down, orient the delivery system vertically.
4. Open the stopcock to the delivery system; pull negative for 30 seconds; release to neutral for contrast fill.
5. Close the stopcock to the delivery system; purge the inflation device / syringe of all air.
6. Repeat steps 3 through 5 until all air is expelled. **Note:** If air is seen in the shaft, repeat *Delivery System Preparation* steps 3 through 5 to prevent uneven stent expansion.
7. If a syringe was used, attach a prepared inflation device to stopcock.
8. Open the stopcock to the delivery system, leave on neutral.

9.6 Stent Delivery Procedure

1. Wipe the exposed guide wire with heparinized saline to remove residual blood or contrast medium.
2. Fully open the hemostatic valve. Maintain neutral pressure on the inflation device.
3. Backload the delivery system onto the proximal portion of the guide wire while maintaining guide wire position across the target lesion.
4. Advance the delivery system over the guide wire to target lesion. Utilize radiopaque balloon markers to position the stent across the lesion; perform angiography to confirm stent position. If applicable tighten the hemostatic valve.

   Note: If during the process of moving the delivery system into position you notice the stent has moved on the balloon, do not deploy the stent. The entire system should be **removed as a single unit.** See *Stent / System Removal – Precautions* section for specific removal instructions.
5. The stent is now ready to be deployed.

9.7 Stent Deployment Procedure

CAUTION: Refer to product label for expanded stent outer diameter, deployment pressure, and RBP.

1. Slowly inflate the delivery balloon to low pressure; hold until balloon inflation is observed both proximally and distally to the stent. Continue balloon expansion to the specified stent deployment pressure. Confirm complete expansion of the stent / balloon fluoroscopically. If necessary, the delivery balloon can be used to post dilate the stent to optimize stent apposition.

   Do not exceed RBP: A larger PTA catheter may be used to dilate the stent. Do not expand the 6 – 7 mm stent beyond 8 mm. Do not expand the 8 – 10 mm stent beyond 11 mm.

2. Deflate the balloon by pulling negative pressure on the inflation device. Ensure that the balloon is fully deflated.

3. With the inflation device on **negative pressure**, carefully withdraw the delivery catheter with the guide wire remaining across the lesion.

   Note: Should **unusual resistance** be felt **at any time** during either lesion access, or removal of an undeployed stent, the Stent System, wire, and guiding catheter should be **removed as a single unit**. See *Stent / System Removal – Precautions* section for specific removal instructions.

4. Confirm optimal stent apposition using standard angiographic techniques. If necessary, post-dilate within stent. Post dilatation balloon diameters should closely match vessel reference diameter.

9.8 Removal Procedure

1. Maintain **negative pressure** to allow the balloon to remain fully deflated during removal through the sheath.

2. With the inflation device on **negative pressure**, carefully withdraw the delivery catheter with the guide wire remaining across the lesion.

   Note: Should unusual resistance be felt at any time during lesion access or removal of delivery system post-stent implantation, the entire system should be removed as a single unit See *Stent / System Removal – Precautions* section for specific removal instructions.

3. Confirm optimal stent apposition using standard angiographic techniques. If necessary, post-dilate within stent. Post dilatation balloon diameters should closely match vessel reference diameter.

10.0 REFERENCES

The physician should consult current literature on current medical practice on balloon dilatation and placement of balloon expandable stents.

11.0 PATENTS AND TRADEMARKS

This product and / or its use may be covered by one or more of the following United States Patents: 5,514,154; 5,569,295; 5,649,952; 5,759,192; 5,780,807; 6,131,266; 6,139,525; 6,221,425; 6,217,547; 6,224,803; 6,368,301; 6,369,355; 6,572,813; 6,568,235; 6,620,193; 6,835,059; 6,908,479; 7,828,766. Other U.S. patents pending. Foreign patents issued and pending.

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