TERUMO

2027-01 Rev.1

Misago™

RX Self-expanding Peripheral Stent

SE34X101-04

Rx ONLY

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

REF — Catalogue number

LOT — Batch code

Date of manufacture

Use-by date

Do not re-use

Contents

Manufacturer

Do not use if package is damaged and consult instructions for use

STERILE EO — Sterilized using ethylene oxide

Do not resterilize

MR — MR Conditional

Consult instructions for use or consult electronic instructions for use

Single sterile barrier system

Non-pyrogenic

Order No. — Order number

7440-48-4 — Contains hazardous substances (cobalt; CAS No. 7440-48-4)

Max Guide Wire O.D. — Max. outer diameter of guidewire

Ø — Unconstrained stent diameter

<L> — Stent length

<UL> — Usable length of delivery catheter

Reference vessel diameter

6Fr. — Recommended introducer sheath

Accessory (Syringe for flushing)

Hydrophilic Coating — Hydrophilic Coating

Keep away from sunlight

Keep dry

SFA & Iliac — Superficial femoral artery (SFA) & Iliac artery

Iliac — Iliac artery

Fragile,handle with care

Stacking limit by number

DESCRIPTION

The Misago RX Self-expanding Peripheral Stent ("stent system") consists of a self-expanding nitinol stent ("stent") pre-mounted on the distal portion of a rapid exchange delivery catheter system ("delivery catheter"). The stent is made of a nickel-titanium alloy with three (3) gold radiopaque markers located at each end for a total of six (6) markers. The delivery catheter is available in 135 cm and 200 cm usable lengths. The distal part of the delivery catheter has a coaxial construction and is constructed to allow coaxial passage of a guide wire that doesn't exceed 0.89 mm (0.035″) in diameter. The distal tip and sheath are coated with hydrophilic polymer which makes them lubricious by wetting. The intermediate shaft is blue to clearly distinguish the non-sliding part from the sliding part. The delivery catheter with 200 cm usable length has two depth markers, approximately 120 cm and 150 cm from the distal end of the catheter, which help to confirm how far the stent system has been advanced. Two inner shaft markers (radiopaque markers) are attached next to each end of the stent and allow confirmation under high-resolution fluoroscopy of the stent's position while in the patient's vessel before deployment. Stent deployment is initiated by pushing down and rolling back a thumbwheel in the deployment handle while holding the handle in place (see Fig. 1-3).

Fig. 1 Diagram of Stent System

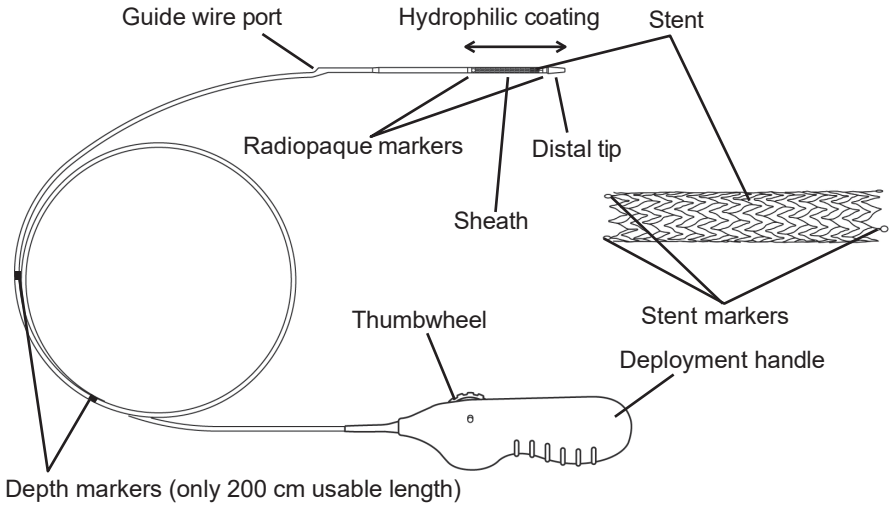


Fig. 2 Flushing Procedure

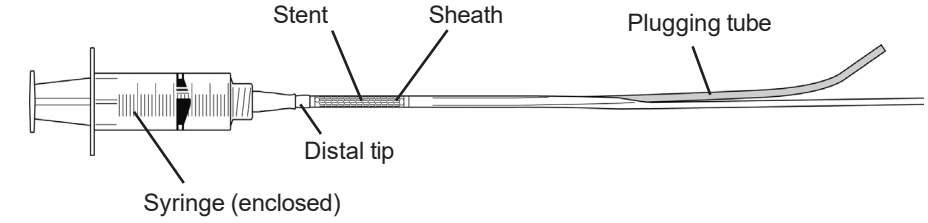
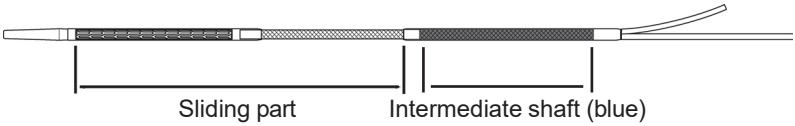


Fig. 3 The Sliding Part and the Intermediate Shaft of the Delivery Catheter



<Specifications>
• Usable length of delivery catheter: 135 cm and 200 cm
• Outer diameter of delivery catheter: 6Fr. (2.06 mm)/3Fr. (1.02 mm)
• Length of coaxial part (from distal tip to guide wire port):
Approximately 45 cm for 40 mm length stent
Approximately 47 cm for 60 mm length stent
Approximately 49 cm for 80 mm length stent
Approximately 52 cm for 100 mm length stent
Approximately 64 cm for 120 mm length stent
Approximately 67 cm for 150 mm length stent

<Specifications of Medical Devices Used Together>
• Maximum guide wire outer diameter: 0.89 mm (0.035″)
• Recommended introducer sheath: 6Fr.
• Minimum guiding catheter inner diameter: 2.16 mm

Table 1: Stent Size Selection Table and Percent foreshortening range

Stent Size Selection		Percent foreshortening range (%)*
Unconstrained stent diameter (mm)	Reference vessel diameter (mm)	
6.0	4.0	0 - 8.9
	5.0	0.1 - 3.6
7.0	5.0	0.9 - 8.6
	6.0	0 - 5.5
8.0	6.0	0 - 4.8
	7.0	0.7 - 6.5
9.0	7.0	0.5 - 6.4
	8.0	0.1 - 5.2
10.0	8.0	0.1 - 8.5
	9.0	0.4 - 7.8

*Percent foreshortening range =| L'-L | × 100/L
L': open stent length L: delivery stent length
Percentage based upon nonclinical testing of the 6.0mm and 10.0mm stent configurations.

INDICATIONS

The Misago RX Self-expanding Peripheral Stent is indicated

- to improve the luminal diameter in symptomatic patients with de novo or restenotic native lesions or occlusions of the superficial femoral artery (SFA) and/or proximal popliteal artery. The reference vessel diameters range from 4.0 mm to 7.0 mm and the lesion length is up to 150 mm.*[1]
- to improve the luminal diameter in patients with de novo, restenotic and/or occlusive atherosclerotic lesion(s) in the common and/or external iliac artery. The reference vessel diameters range from 4.0 mm to 9.0 mm and the lesion length is up to 120 mm.*[2]

Table 2: Stent Configurations and Indications

Length / Diameter	40 mm	60 mm	80 mm	100 mm	120 mm	150 mm
6.0 mm	X*[1, 2]	X*[1, 2]	X*[1, 2]	X*[1, 2]	X*[1, 2]	X*[1, 2]
7.0 mm	X*[1, 2]	X*[1, 2]	X*[1, 2]	X*[1, 2]	X*[1, 2]	X*[1, 2]
8.0 mm	X*[1, 2]	X*[1, 2]	X*[1, 2]	X*[1, 2]		
9.0 mm	X*[2]	X*[2]				
10.0 mm	X*[2]	X*[2]				

PATIENT TARGET GROUP

- Patients with de-novo, stenotic or occlusive lesions in the iliac or femoro-popliteal arteries.

CONTRAINDICATIONS

- Patients who exhibit angiographic evidence of severe thrombus in the target vessel or lesion site before/after undergoing Percutaneous Transluminal Angioplasty PTA procedure.
- Patients with contraindication to antiplatelet and/or anticoagulation therapy.
- Patients who are judged to have a lesion that prevents proper placement or deployment of the stent.
- A lesion that is within an aneurysm or an aneurysm with a proximal or distal segment to the lesion.
- A lesion through which a guide wire cannot pass.

WARNINGS

- The stent system has been sterilized by ethylene oxide gas, and is for single use only. **Do not** reuse. **Do not** resterilize. **Do not** reprocess as reprocessing may compromise the sterility, biocompatibility and functional integrity of this product.
- The stent system is sterile and non-pyrogenic in an unopened and undamaged unit package. **Do not** use if the unit package or the product has been damaged or soiled.
- Use this device prior to the expiry date indicated on the package.
- The stent **should not** come in contact with a previously placed non-nitinol stent. Contact of stents made from two dissimilar materials could possibly result in corrosion of the stents.
- **Do not** use in patients with known allergy to nickel-titanium alloy, gold or contrast media as this may result in an allergic reaction.
- Perform appropriate antiplatelet and/or anticoagulation therapy pre- and post- procedure.
- Insert the device into a guiding sheath or guiding catheter of adequate length to guide the device from the puncture site to the treatment site, failure to do so may cause thrombus on the vessel wall and/or plaque to flow through the blood stream, which may cause severe embolization and/or stroke especially in trans-brachial approach or trans-radial approach.
- This product can expose you to chemicals including cobalt, which is known to the State of California to cause birth defects or other reproductive harm or cancer. For more information go to www.P65Warnings.ca.gov

PRECAUTIONS

- Care should be taken when treating patients with known upper extremity vascular disease, extreme tortuosity, anomalous radial artery take off, severe subclavian artery stenosis or severe atherosclerosis.
- Care should be taken with patients with known Buerger's disease or Raynaud's phenomenon.
- Care should be taken when Arterio-venous Fistula is present.
- Care should be taken with patients with known anatomical abnormalities of the upper extremity arterial system /aorta.
- Care should be taken with patients with known dissecting thoracoabdominal aortic aneurysm.
- **Do not** use on pregnant patients or patients who may become pregnant.
- Patients for a peripheral intervention should be selected carefully. Operators should bear in mind that complications including (but **not** limited to) subacute thrombosis, vessel complication and hemorrhagic complications may result from peripheral intervention.
- This device should be used only at institutions where emergency surgery can be performed due to the risk of severe complications.
- This device should only be used by a physician who is familiar with, and well trained in, Percutaneous Transluminal Angioplasty (PTA) techniques, stent implantations, and, when using transradial approach, transradial access.
- Confirm that the design of the stent system meets the criteria of the procedure and the technique to be used.
- When delivering stent from a transradial approach, standard departmental radial artery protocol should be followed to prevent radial artery occlusion, injury or spasm.
- Prior to beginning radial artery access, conduct a screening test such as an Allen test to ensure the radial access is appropriate for the patient.
- Choose the appropriate stent size by considering the regions in which diagnosis is performed, and the anatomical aspects.

- Use delivery system of adequate usable length for patient anatomy to deliver the device from the puncture site to the treatment site.
- **Do not** use in highly tortuous or highly calcified lesions and/or vessels proximal to the lesion which could prevent proper pre-dilatation.
- To avoid resistance while inserting the guide wire into the delivery system, wipe off any foreign material (including blood) on the guide wire before delivering the stent system.
- **Do not** use agents containing organic solvent (e.g. alcohol) or oil-based contrast agents (e.g. fatty acid of poppy seed oil ethyl ester iodide), as this may cause the device to break or lose lubricity.
- Pre-dilatation of the target vessel is recommended.
- To assure optimal stent delivery, confirm that the pre-dilation is properly done before stenting patients who have highly tortuous or calcified lesions and/or vessels proximal to the lesion.
- To maintain sterility, the stent system should be used immediately after opening the package and be disposed of safely and properly after use.
- The entire operation should be carried out aseptically.
- Due to the diameter of the delivery system, buddy wire technique **cannot** be performed with a 6Fr. introducer sheath or guiding catheter. Choose the introducer sheath or guiding catheter with sufficient inner lumen.
- Manipulate the stent system carefully within the artery. If you feel any resistance, stop manipulating the stent system and under high-resolution fluoroscopy try to determine the cause of the problem. Continuing to manipulate the stent system may result in damage to the vessel and/or damage of the stent system. This may necessitate retrieval of fragments of the stent system.
- Stenting across a major vessel branch may lead to compromised future diagnostic or therapeutic procedures.
- Care should be taken when advancing the stent system through a previously placed stent. The stent system may be caught in the previously placed stent, and may cause deformation and/or dislodgement of the stent, damage to the blood vessel, and/or thrombo-embolism.
- A partially deployed stent **cannot** be repositioned or retracted into the sheath. Retraction, or repositioning of a stent by force, could cause deformation of the stent, damage to the blood vessel and/or to the delivery catheter. The stent **cannot** be removed after implantation.
- If you feel any resistance during withdrawal of the delivery catheter after stent implantation, stop the procedure and determine the cause of resistance in order to alleviate the risk of damaging the delivery catheter.
- Care should be given when additional devices and wires are delivered through a previously placed stent in order to prevent damage or dislodgement.

PRECAUTION FOR STORAGE

- This product has **no** special handling or storage requirements for temperature and humidity. Avoid exposure to water, direct sunlight.

MRI SAFETY INFORMATION

MR Conditional

Non-clinical testing has demonstrated Misago is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

Parameter	***Condition of Use/Information***
Static Magnetic Field Strength (B0)	1.5 T, 3 T
Static Magnetic Field Strength (B0) Orientation	Cylindrical Bore
Maximum Spatial Field Gradient (SFG)	40 T/m (4,000 gauss/cm)
RF Polarization	Circular Polarized (CP)
RF Transmit Coil	Integrated Whole Body Transmit RF coil
RF Receive Coil	Any Receive coil may be used.
MR System (RF) Operating Modes or Constraints	Device-Specific RF Operating Conditions
Whole-Body Averaged SAR	1.0 W/kg (1.5 T and 3 T)
Scan Duration and Wait Time	15 minutes of continuous RF exposure (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.

POTENTIAL ADVERSE EVENTS

Generally, complications to PTA are also complications for stent placement. Complications include, but are not be limited to:

- Allergic reaction
- Amputation of treated limb
- Arrhythmia
- Arterial dissection/perforation/rupture/injury
- Arterial embolism/thrombosis/occlusion
- Arterial spasm
- Arteriovenous fistula
- Bleeding/Hematoma
- Bradycardia/Palpitation
- Cerebral vascular accident
- Death
- Distal embolization
- Femoral pseudoaneurysm/ Pseudoaneurysm formation
- Fever
- Hemorrhage
- Hypotension/Hypertension
- Infection and pain at puncture site
- Leg Pain/Claudication
- Myocardial Infarction
- Renal failure
- Restenosis
- Sepsis
- Stent fracture
- Stroke
- Target lesion revascularization
- Thrombosis of target vessel

SUMMARY OF CLINICAL STUDIES

Following CE Mark approval of the Misago stent, several European prospective clinical studies and registries were conducted (MISAGO 1, MISAGO 2, E-MISAGO, and MISAGO ILIAC). This was later followed by a pivotal study (OSPREY) performed in the US and Asia that evaluated the Misago stent for the treatment of lesions in the superficial femoral artery (SFA) and/or proximal popliteal artery (PPA). The results of MISAGO 1, MISAGO 2, and OSPREY are based on clinical data using the femoral artery access route and are not based on data specifically related to transradial access.

A confirmatory pivotal study (OSPREY ILIAC) was also conducted, further expanding the clinical evidence base for the Misago stent in the treatment of iliac artery disease. The results of the OSPREY ILIAC trial are based on clinical data via femoral and radial artery access routes.

Pivotal Study:
The OSPREY: Occlusive/Stenotic Peripheral artery REvascularization studY: A US/Japan Multi-center trial of Misago for Superficial Femoral Artery evaluated the clinical effectiveness and safety of Misago for the treatment of narrowed or occluded superficial femoral arteries with comparison to historical study outcomes.

In the US, this was a multi-center, single-arm, non-randomized, prospective clinical trial to investigate the safety and effectiveness of the flexible Misago delivered via a rapid-exchange (RX) delivery system for the treatment of focal atherosclerotic disease in the superficial femoral artery (SFA). In Japan, there were two arms of the study: 50 subjects received Misago (stent arm) and 51 subjects received percutaneous transluminal angioplasty (PTA) with potential bailout stent implantation. This US/Japan pivotal study enrolled a total of 261 subjects who were implanted with Misago: 201 in the U.S., 50 in Japan (stent arm), as well as 10 additional subjects in Taiwan and South Korea.

Demographics:

The target population included men and women, ≥ 18 years of age, having symptomatic leg ischemia without tissue loss (Rutherford category 2, 3 or 4) and a resting ABI of < 0.9 arising from one or multiple de novo SFA lesion(s) with > 50% stenosis or occlusion with a total lesion length of ≥ 40 mm and ≤ 150 mm at least 3 cm above-the-knee. Baseline demographics and clinical characteristics are summarized in Table 3. It was determined that the data was poolable between sites in the US and outside the US (Japan, Taiwan and Korea) when including out-of-window DUS patency.

Table 3: Baseline Demographics and Clinical Characteristics

Characteristic	Mean±SD
Age at implant (years)	69.3 ± 10.0
Gender (% Male)	64.8% (169/261)
Race/Ethnicity	
Caucasian	69.0% (180/261)
Asian	23.0% (60/261)
Black	6.9% (18/261)
Hispanic	1.1% (3/261)
Diabetes Mellitus	47.9% (125/261)
Smoking history	
Yes, Current	42.1% (110/261)
Yes, Previous	40.6% (106/261)
BMI (kg/m^2)	28.2 ± 5.8
Rutherford score	
Rutherford – 2	48.3%(126/261)
Rutherford – 3	47.1%(123/261)
Rutherford – 4	4.6% (12/261)
ABI	0.7 ± 0.1
Percent of diameter stenosis (angiography)	86.5 ± 12.1
Lesion length (mm)	83.8 ± 41.3

Method:
The target lesion was to be predilated utilizing standard techniques if deemed necessary. Subjects underwent SFA stent placement according to the Instructions for Use. Following deployment of the stent, dilatation of the target lesion was required. Aspirin (81 to 325 mg) intake was required to be started within 24 hrs of the procedure. During the stenting procedure, use of supplemental anticoagulation was administered according to the investigator's discretion. Following the stenting procedure, subjects were prescribed daily aspirin (81 to 325 mg) and recommended daily antiplatelet agent for 1 month following the procedure. Table 4 presents baseline lesion characteristics assessed by the angiographic core laboratory.

Table 4: Baseline Lesion Characteristics (Core Lab Reported)

Parameter	Mean±SD or % (n/N)
Location	
Left	49% (128/261)
Right	51% (133/261)
Arterial segment	
Proximal SFA	12.3% (32/261)
Middle SFA	53.6% (140/261)
Distal SFA	33.3% (87/261)
Other	0.8% (2/261)
Lesion length (mm)	83.8 ± 41.3
Proximal Reference Vessel Diameter (mm)	5.1 ± 1.0
Distal Reference Vessel Diameter (mm)	5.1 ± 1.0
Segment Minimum Lumen Diameter (mm)	1.1 ± 0.9
Bend	80.1% (209/261)
Eccentricity	
Concentric	59.8% (156/261)
Eccentric	40.2% (105/261)

Parameter	Mean±SD or % (n/N)
Thrombus	
None	98.5% (257/261)
Possible	0.4% (1/261)
Small	0.0% (0/261)
Moderate	0.8% (2/261)
Large	0.4% (1/261)
Total occlusion	0.0% (0/261)
Calcification	
None	33.3% (87/261)
Moderate	35.2% (92/261)
Severe	31.4% (82/261)
Tortuosity	
None	100.0% (261/261)
Moderate	0.0% (0/261)
Severe	0.0% (0/261)
Ulceration	20.7% (54/261)
Aneurysm	1.1% (3/261)
Pre-TIMI flow	
0	24.1% (63/261)
1	1.9% (5/261)
2	0.8% (2/261)
3	67.8% (177/261)
NA	5.4% (14/261)
TASC II Classification	
TASC II type A lesions	55.6% (145/261)
TASC II type B lesions	37.5% (98/261)
TASC II type C lesions	6.9% (18/261)
TASC II type D lesions	0.0% (0/261)
Inflow tract stenosis	
< 50%	60.9% (159/261)
> 50%	8.8% (23/261)
NA	30.3% (79/261)
Distal runoff vessels	
1	27.2% (71/261)
2	32.2% (84/261)
3	20.3% (53/261)
NA	13.4% (35/261)
Patency of anterior tibial artery	46.5% (105/226)
Patency of posterior tibial artery	61.1% (140/229)
Patency of peroneal artery	69.0% (156/226)

Primary Endpoint Analysis:
Overall, the OSPREY data provide reasonable assurance of safety and effectiveness of Misago for use in the intended population.

The primary safety endpoint for this study was freedom from major adverse events (MAE) at 30 days post-procedure. MAE was defined as TLR, amputation of the treated limb, or death. Study success was based on the proportion of patients with freedom from MAE at 30 days post-procedure when tested against a performance goal of 88% using the lower bound of the 95% confidence interval. In both cohorts, the lower confidence interval exceeded the prespecified performance goal indicating the study met its primary safety endpoint. Table 5 summarizes the primary endpoints.

The primary effectiveness endpoint was defined as stent patency at 12 months as evidenced by a peak systolic velocity ratio < 2.0 from DUS obtained within the 12 months visit window. Because patency beyond the 12 months visit window may be considered as patency at 12 months, the out-of-window patency is imputed as treatment success. It also regarded missing data as loss of patency under the intention to treat (ITT) analysis. The ITT cohort included all 261 subjects, the modified intention to treat (mITT) cohort had 226 subjects (excluded subjects with unknown primary effectiveness endpoint) and the per protocol (PP) cohort had 222 subjects (excluded subjects that failed to meet all eligibility criteria).

In the ITT analysis 54.0% (141/261) of subjects met the primary effectiveness endpoint and were noted to have patent stents at 12 months as evidenced by peak systolic velocity ratio < 2.0 and freedom from TLR event. The primary effectiveness endpoint was met in 141/226 subjects (62.4%) in the mITT cohort and in 139/222 subjects (62.6%) in the PP cohort. The lower bound of the two-sided 95% confidence interval was 48.0% in the ITT cohort. The primary effectiveness objective was not met and a 12-month patency rate of 66% or less could not be ruled out.

Supplementary Primary Endpoint Analysis:
A supporting analysis conforming to FDA guidance using Kaplan-Meier methods avoided this issue by evaluating all available data in a time-to-event format and censoring subjects with missing data at the appropriate times. Kaplan-Meier freedom from loss of patency had a 12-month (360 day) estimate of 78.9% (see Fig. 4 and Table 6). Furthermore, Kaplan-Meier freedom from Target Lesion Revascularization (TLR) had a 12-month (360 day) estimate of 88.6% (see Fig. 5 and Table 7).

Although the primary effectiveness endpoint was not met by the protocol-defined analysis, when analyzed using the Kaplan-Meier method, the freedom from loss of patency at 12 months was 78.9%. Additional considerations may also be made using a more contemporary approach to evaluate stent patency using a peak systolic velocity ratio (PSVR) ≤ 2.4 (modified VIVA criteria). The freedom from loss of patency at 12 months was 60.5% and 69.9% in the ITT and mITT cohort, respectively. Furthermore, the Kaplan-Meier freedom from loss of patency at 12 months (360 days) estimate was 82.9%.

Table 5: Primary Endpoint (Including DUS data collected outside the 12-month visit window)

Primary Endpoint	% (n/N)	95% Confidence Interval	Performance Goal
Safety:			
Freedom from MAE at 30 Days post-enrollment (ITT)	99.2% (259/261)	97.1%, 100.0%	88%
Effectiveness (based on peak systolic velocity ratio < 2.0):			
Stent patent at 12 months (ITT)[1]	54.0% (141/261)	48.0%, 60.0%	66%
US - Stent patent at 12 months (ITT)	51.7% (104/201)		
OUS - Stent patent at 12 months (ITT)	61.7% (37/60)		
Stent patent at 12 months (mITT)	62.4% (141/226)		
Stent patent at 12 months (PP)	62.6% (139/222)		
Modified Effectiveness (based on peak systolic velocity ratio ≤ 2.4):			
Stent patent at 12 months (ITT)[1]	60.5% (158/261)		
Stent patent at 12 months (mITT)	69.9% (158/226)		
Stent patent at 12 months (PP)	69.8% (155/222)		

[1] Includes DUS data collected outside the 12-month visit window

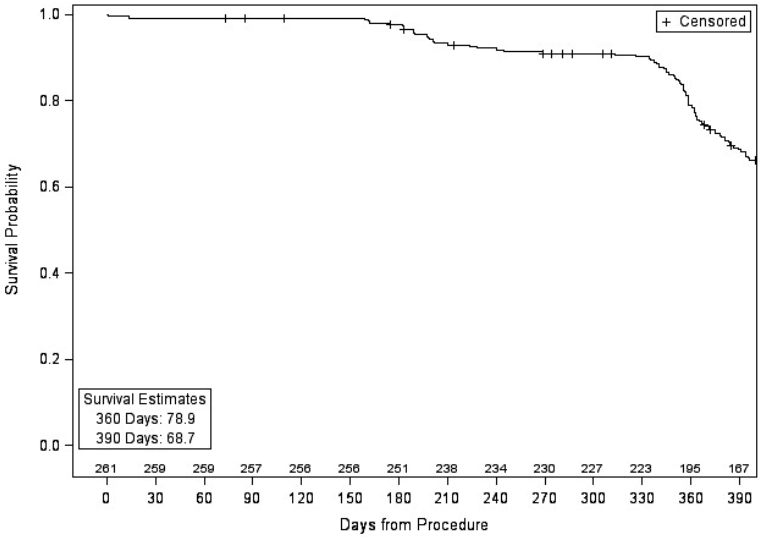


Fig. 4 Kaplan-Meier Freedom from Loss of Patency within 12 Months (PSVR ≥ 2.0 or TLR)

Table 6: Freedom from Loss of Patency (PSVR ≥ 2.0 or TLR)

Timepoint	[0, 90]	[90, 180]	[180, 270]	[270, 360]	[360, 390]
# At Risk[1]	261	257	251	230	195
# Events[2]	2	4	17	30	25
# Censored[2]	2	2	4	5	3
Survival %[3]	99.2	97.7	91.0	78.9	68.7
Standard Error[3]	0.5	0.9	1.8	2.6	2.9

[1]At beginning of interval
[2]Within interval
[3]At end of interval

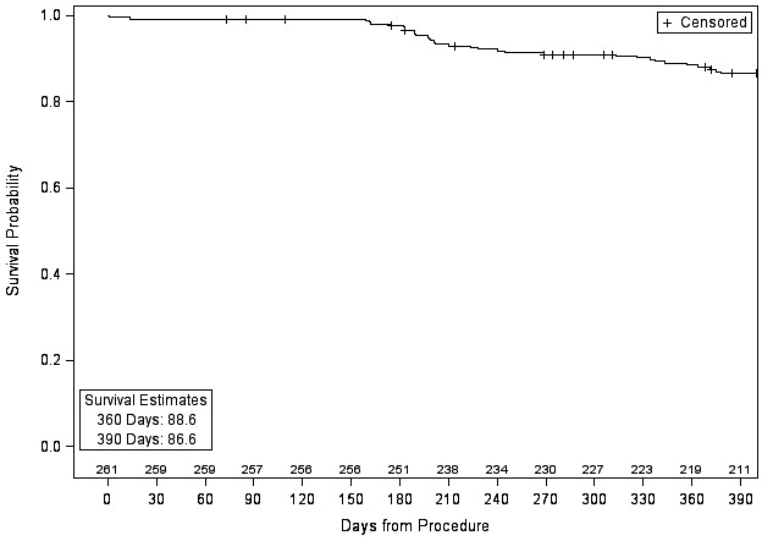


Fig. 5 Kaplan-Meier Freedom from TLR within 12 Months of Procedure

Table 7: Freedom from TLR within 12 Months of Procedure

Timepoint	[0, 90]	[90, 180]	[180, 270]	[270, 360]	[360, 390]
# At Risk[1]	261	257	251	230	219
# Events[2]	2	4	17	6	5
# Censored[2]	2	2	4	5	3
Survival %[3]	99.2	97.7	91.0	88.6	86.6
Standard Error[3]	0.5	0.9	1.8	2.0	2.2
[1]At beginning of interval [2]Within interval [3]At end of interval					

Secondary endpoints:
Multiple secondary effectiveness endpoints were defined for this study. Tables 8 and 9 summarize the secondary safety and effectiveness endpoints and subjects meeting each endpoint.

Table 8: Secondary Safety Endpoints

Secondary Safety Endpoint	% (n/N)
MAEs through 30 days	0.8% (2/261)
TLR	0.8% (2/261)
Amputation	0.0% (0/261)
Deaths through 30 days	0.0% (0/261)
MAEs through 12 months	16.1% (42/261)
TLR	13.0% (34/261)
Amputation	0.0% (0/261)
Device failures through 12 months	1.3% (3/234)
Failure/Malfunctions	0.4% (1/261)
Stent fracture evidenced by plain film X-ray at 12 months	0.9% (3/324 stents) 1.3% (3/234 subjects)
Device related peri-procedural complications	2.3% (6/261)
Significant distal embolization in target limb	2.3% (6/261)
Thrombosis of target vessel	0.4% (1/261)
Any device related adverse event	19.5% (51/261)

Table 9: Secondary Effectiveness Endpoints

Secondary Effectiveness Endpoint	Mean±SD or % (n/N)
Technical success	100.0% (261/261)
Successful delivery of stent at lesion site	100.0% (261/261)
Stent deployed in lesion with adequate lesion coverage	100.0% (261/261)
Procedural success	93.5% (244/261)
Clinical Success: relief or improvement from baseline symptoms as measured by the Rutherford score for chronic limb ischemia at 30 days as compared to baseline	90.0% (234/260)
Ankle-Brachial Index change from baseline to 30 days post-procedure	0.3 ± 0.2
Ankle-Brachial Index change from 30 days to 12 months post-procedure	-0.1 ± 0.2
Rutherford sustained (without increase of one or more in the score) at 12 months post-procedure from 30 days post-procedure	80.2% (190/237)
Clinically driven target lesion revascularization through 12 months post-procedure	13.0% (34/261)
Patency of target vessel based on systolic velocity ratio ≤ 2.4 and absence of TLR	69.9% (158/226)
Target lesion revascularization through 30 days	0.8% (2/261)
Target lesion revascularization through 12 months	13.0% (34/261)

Rutherford Becker (RB)

The majority of subjects had moderate-severe claudication (Rutherford Becker 2-3) at baseline. At 1 and 12 months post procedure, a majority of subjects were asymptomatic (see Table 10).

Table 10: Rutherford Becker Scale Analysis (Combined Cohort)

	Baseline % (n/N)	**30 days**	**12 Months**
Mean±SD	3.6 ± 0.6	1.6 ± 1.0	1.6 ± 0.9
Rutherford – 0	0.0% (0/261)	62.7% (163/260)	61.6% (146/237)
Rutherford – 1	0.0% (0/261)	19.6% (51/260)	22.4% (53/237)
Rutherford – 2	48.3% (126/261)	11.9% (31/260)	10.5% (25/237)
Rutherford – 3	47.1% (123/261)	4.6% (12/260)	5.5% (13/237)
Rutherford – 4	4.6% (12/261)	0.8% (2/260)	0.0% (0/237)
Rutherford – 5	0.0% (0/261)	0.0% (0/260)	0.0% (0/237)
Rutherford – 6	0.0% (0/261)	0.4% (1/260)	0.0% (0/237)

Ankle-Brachial Index (ABI)

There was an overall improvement in ABI from a mean of 0.7 at baseline to 0.9 at 12 months (see Table 11).

Table 11: ABI and Change from Baseline in Combined Cohort Through 12 Months

ABI on Target Limb	Baseline	1 Month	6 Months	12 Months
Mean + SD (N)	0.70 ± 0.15 (259)	0.98 ± 0.16 (260)	0.92 ± 0.18 (253)	0.91 ± 0.17 (236)
Median	0.71	0.99	0.94	0.93
Min, Max	0.13, 1.12	0.39, 1.63	0.00, 1.42	0.43, 1.60

Patency

In the combined study cohort (US and Asian subjects), similar short and mid-length lesion effectiveness was observed (67.6% in lesions ≤ 60 mm, 63.3% in lesions 61-100 mm), while patency was reduced in lesions > 100 mm (54.8%). Tables 12, 13, and 14 summarize patency by lesion lengths. These tables include the DUS for 23 subjects that were obtained after the 12-month window; these subjects were used in the mITT analysis.

Table 12: 12-Month Efficacy (no TLR and PSVR < 2.0 and ≤ 2.4) by Core Lab Assessed Lesion Length Terciles – Combined Cohort *

	Lesion Length Terciles (Core Lab)		
	Lower (≤ 60) N=83	Mid (61-100) N=104	Upper (> 100) N=74
Pre-Procedure Lesion Length (mm) (core lab assessed)			
N	83	104	74
Mean ± SD	40.7 ± 12.6	80.3 ± 12.2	137.1 ± 26.1
Median	41.6	78.8	133.1
Min, Max	12.2, 60.0	61.2, 100.0	101.0, 227.5
Primary Effectiveness Endpoint (mITT)			
Primary Patency	67.6% (50/74)	63.3% (57/90)	54.8% (34/62)
PSVR < 2.0	71.8% (51/71)	75.9% (63/83)	60.3% (35/58)
No clinically driven TLR	90.4% (75/83)	84.6% (88/104)	86.5% (64/74)
Secondary Effectiveness Endpoint (mITT)			
Secondary Patency	73.0% (54/74)	71.1% (64/90)	64.5% (40/62)
PSVR ≤ 2.4	77.5% (55/71)	84.3% (70/83)	70.7% (41/58)
No clinically driven TLR	90.4% (75/83)	84.6% (88/104)	86.5% (64/74)

* Results are based on core lab reported lesion length and includes DUS data collected outside the 12-month visit window

Table 13: 12-Month Efficacy (no TLR and PSVR < 2.0 and ≤ 2.4) by Core Lab Assessed Lesion Length – Combined Cohort*

	Lesion Length by Core Lab Read Angiography	
	≤ 150 N=241	> 150 N=20
Primary Effectiveness Endpoint (mITT)		
Primary Patency	63.4% (135/213)	46.2% (6/13)
PSVR < 2.0	71.9% (143/199)	46.2% (6/13)
No clinically driven TLR	86.3% (208/241)	95.0% (19/20)
Secondary Effectiveness Endpoint (mITT)		
Secondary Patency	70.9% (151/213)	53.8% (7/13)
PSVR ≤ 2.4	79.9% (159/199)	53.8% (7/13)
No clinically driven TLR	86.3% (208/241)	95.0% (19/20)

* Results are based on core lab reported lesion length and includes DUS data collected outside the 12-month visit window

Table 14: 12-Month Efficacy (no TLR and PSVR < 2.0 and ≤ 2.4) by Core Lab Assessed Lesion Length – Combined Cohort*

	% (n/N)
Primary Effectiveness Endpoint (mITT)	
Core Lab Lesion Length	
≤ 60	67.6% (50/74)
61-100	63.3% (57/90)
101-150	57.1% (28/49)
> 150	46.2% (6/13)
Secondary Effectiveness Endpoint (mITT)	
Core Lab Lesion Length	
≤ 60	73.0% (54/74)
61-100	71.1% (64/90)
101-150	67.3% (33/49)
> 150	53.8% (7/13)

* Results are based on core lab reported lesion length and includes DUS data collected outside the 12-month visit window

Stent Fracture

X-rays of 324 stents (234 subjects) were available for analysis by the angiographic core laboratory to evaluate stent fractures at 12 months post-procedure. The stent fracture rate at 12 months was 0.9% (3/324 stents) and is summarized in Table 15 below. The per subject stent fracture rate was 1.3% (3/234).

Table 15: Summary of Stent Fractures by Stent

Parameter	At 12 Months % (n/N)
Stent fracture	0.9% (3/324)
Fracture type	
I – Single strut fracture only	0.3% (1/324)
II – Multiple single strut fractures that occur at different sites	0.0% (0/324)
III - Multiple strut fractures resulting in complete transection of the stent, without displacement of the stent segment	0.3% (1/324)
IV - Multiple strut fractures resulting in displacement of segments of the stent	0.3% (1/324)[1]
V - Spiral fractures that denotes a spiral dissection of a stent	0.0% (0/324)
Fracture location	
Proximal	0.3% (1/324)
Middle	0.3% (1/324)
Distal	0.3% (1/324)

[1]Caused by physician during non-study peripheral intervention

Adverse Events:

Table 16 provides a summary of the adverse events documented in the OSPREY study. The data are presented as a percentage of subjects experiencing an adverse event.

Table 16: Summary of Adverse Events

Adverse Event by SOC and PT	Overall % (n)	Within 30 Days % (n)	30 Days-6 Months % (n)	6 Months-12 Months % (n)
Any adverse event	85.1% (222)	45.2% (118)	53.3% (139)	55.9% (146)
Blood And Lymphatic System Disorders	6.1% (16)	0.8% (2)	3.1% (8)	3.1% (8)
Cardiac Disorders	16.1% (42)	3.8% (10)	6.5% (17)	9.6% (25)
Congenital, Familial And Genetic Disorders	0.4% (1)	0% (0)	0.4% (1)	0% (0)
Ear And Labyrinth Disorders	0.4% (1)	0.4% (1)	0% (0)	0% (0)
Endocrine Disorders	1.1% (3)	0% (0)	0.4% (1)	0.8% (2)
Eye Disorders	4.2% (11)	0.4% (1)	3.1% (8)	0.8% (2)
Gastrointestinal Disorders	17.2% (45)	4.6% (12)	8.4% (22)	8.0% (21)
General Disorders And Administration Site Conditions	18.4% (48)	8.4% (22)	6.1% (16)	6.9% (18)
Hepatobiliary Disorders	2.7% (7)	0.4% (1)	0.4% (1)	1.9% (5)
Immune System Disorders	2.3% (6)	1.1% (3)	0.4% (1)	0.8% (2)
Infections And Infestations	18.8% (49)	3.8% (10)	10.0% (26)	9.6% (25)
Injury, Poisoning And Procedural Complications	27.2% (71)	6.5% (17)	10.0% (26)	15.3% (40)
Investigations	3.1% (8)	1.9% (5)	0.4% (1)	1.1% (3)
Metabolism And Nutrition Disorders	6.5% (17)	0.8% (2)	2.7% (7)	3.1% (8)
Musculoskeletal And Connective Tissue Disorders	23.4% (61)	8.8% (23)	10.3% (27)	6.5% (17)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	4.6% (12)	0% (0)	2.3% (6)	2.3% (6)
Nervous System Disorders	15.7% (41)	2.3% (6)	6.9% (18)	7.3% (19)
Psychiatric Disorders	3.8% (10)	0.8% (2)	1.9% (5)	1.5% (4)
Renal And Urinary Disorders	4.6% (12)	0.4% (1)	2.3% (6)	2.3% (6)
Reproductive System And Breast Disorders	1.1% (3)	0% (0)	0% (0)	1.1% (3)
Respiratory, Thoracic And Mediastinal Disorders	11.9% (31)	1.9% (5)	3.8% (10)	6.1% (16)
Skin And Subcutaneous Tissue Disorders	10.0% (26)	3.4% (9)	3.8% (10)	3.8% (10)
Surgical And Medical Procedures	0.4% (1)	0% (0)	0.4% (1)	0% (0)
Vascular Disorders	38.3% (100)	18.4% (48)	14.6% (38)	16.9% (44)
MedDRA Preferred Terms shown where number of subjects with event is 5 or more				

Conclusion:

The primary safety endpoint of the OSPREY trial was met. While the pre-specified effectiveness endpoint was not met, the study results are similar to the results of other US marketed stents intended for use in patients with SFA lesions. Overall, the results of the non-clinical and clinical evaluations provide reasonable assurance that Misago is safe and effective. The benefits of Misago outweigh the risks when the device is used as indicated in accordance with the labeling and Instructions for Use (IFU).

***OSPREY Iliac Study*:**
A confirmatory pivotal clinical study called the OSPREY ILIAC- **O**cclusive/**S**tenotic **P**eripheral artery **RE**vascularization Stud**Y** for Common and/or External **ILIAC** Artery was performed to establish a reasonable assurance of safety and effectiveness for the Misago RX Self-expanding Peripheral Stent under IDE G160035. This study was conducted to expand the indications for the Misago stent to improve the luminal diameter in patients with de novo, restenotic and/or occlusive atherosclerotic lesion(s) in the common and/or external iliac artery with reference vessel diameters ranging from 4.0 mm to 9.0 mm and a lesion length up to 120 mm. The OSPREY ILIAC trial includes clinical data from procedures accessed via both femoral and radial arteries. A summary of the OSPREY ILIAC clinical study is presented below.

OSPREY ILIAC Study Design:
The OSPREY ILIAC study was a confirmatory, multi-center, single arm, non-randomized, prospective clinical study to evaluate the clinical effectiveness and safety of the Misago RX Self-expanding Peripheral Stent for the treatment of de novo, restenotic and/or occlusive atherosclerotic lesion(s) of the common and/or external iliac artery.

Patients were enrolled between December 01, 2022 and May 13, 2024. The database for this panel track supplement reflected data collected through May 02, 2025 and included 75 subjects at 9 clinical sites in the United States.

The primary endpoint evaluated stent safety immediately post-procedure, prior to hospital discharge (AEs only) and at 9 months post-procedure. A subject was considered enrolled into the study if the subject signed the informed consent form (ICF), met all eligibility criteria, including intra-procedure criteria, and the study device entered the vasculature.

The Intent-to-Treat (ITT) and Per-Protocol (PP) analysis sets are defined as follows:

ITT: Includes all enrolled subjects who met the protocol-defined enrollment criteria and in whom the study device entered the vasculature, regardless of subsequent protocol deviations or treatment received.

PP: Includes the subset of ITT subjects without major protocol deviations (i.e., protocol eligibility violations). Missed or out-of-window visits were not considered major protocol deviations.

Clinical Inclusion and Exclusion Criteria:
Enrollment in the OSPREY ILIAC study was limited to patients who met the following inclusion criteria:

Baseline:

1. Is ≥ 18 years old and of legal consent.
2. Is willing to comply with all follow-up evaluations at the specified times.
3. Subject or subject's legal representative has been informed of and understands the nature of the study and provides signed informed consent to participate in the study.
4. Has a Rutherford Clinical Category Score of 2, 3 or 4.

Intra-procedure:

5. De novo, restenotic, and/or occlusive target lesion(s) located within the

native common and/or external iliac artery.

6. Radiographic evidence of ≥ 50% stenosis or restenosis (from PTA or adjunct therapy, not including stents or stent grafts), or occlusion of target lesion(s) in the common iliac artery and/or external iliac artery.
7. Total combined length of lesion(s) is ≤ 120 mm as determined by the investigator and is amenable to stenting.
8. Reference vessel diameter is ≥ 4.0 mm and ≤ 9.0 mm.
9. At least one patent infrapopliteal artery to the ankle not requiring intervention (i.e., < 50% stenosis).

Patients were <u>not</u> permitted to enroll in the OSPREY ILIAC study if they met any of the following exclusion criteria:

**Criteria marked with an asterisk were reviewed intra-procedurally*

1. Has had previous stent or stent-graft implantation in the target lesion(s).
2. Has a contraindication or known untreatable allergy to antiplatelet therapy, anticoagulants, thrombolytic drugs or any other drug used during the study according to the protocol.
3. Has known hypersensitivity to contrast material that cannot be adequately pretreated.
4. Has known hypersensitivity to nickel-titanium (nitinol).
5. In the opinion of investigator, has bleeding diathesis, coagulopathy, and/or known hypercoagulable condition making the patient unsuitable for study participation.
6. Refuses blood transfusion.
7. Is female currently breastfeeding, pregnant, or of childbearing potential not using adequate contraceptives measures or refuses to use contraception throughout the duration of the study.
8. Has life expectancy of less than 1 year.
9. Has planned use of thrombectomy, atherectomy, brachytherapy, cryotherapy or laser devices to treat the common and/or external iliac arteries during the index procedure.
10. Has any planned surgical intervention (requiring in-patient hospitalization) 14 days before or 30 days after the index procedure.
11. Is currently participating in an investigational drug or other device study that has not yet reached the primary endpoint analysis.
12. Has known aortic disease requiring intervention within 9 months post index procedure.
13. In the opinion of the investigator, has one or more of the following co-morbid conditions that may impact the subject's safety and/or participation in the study:
    - History of severe liver disease (i.e. ascites, esophageal varices, liver transplant).
    - Known or suspected active systemic infection or infection within the target limb.
    - Undergoing immunosuppressant therapy following organ transplant.
    - Chronic Kidney Disease Stage IIIB or worse (i.e., GFR < 45 mL/min).
    - New York Heart Association Classification of III or IV with hospitalization for decompensated heart failure within 30 days of

index procedure.

- Recent (within 30 days of index procedure) myocardial infarction.
- Recent (within 30 days of index procedure) hemorrhagic or ischemic stroke.
- Acute thrombophlebitis or deep venous thrombosis in the index limb to be treated.
- Any other co-morbid condition that in the judgment of the investigator precludes safe percutaneous intervention.

14. Guide wire cannot successfully cross the target lesion(s) and re-enter true vessel lumen beyond the lesion(s), and study device cannot be deployed so that its proximal and distal ends will be within the true vessel lumen. *
15. Aneurysmal target vessel. *
16. Presence of an acute intraluminal thrombus of the proposed lesion site(s). *
17. Perforation, flow-limiting dissection, or other injury requiring additional stenting or surgical intervention prior to the start of target lesion treatment. *

Follow-up Schedule:

Subjects were evaluated prior to discharge (within 7 days of the index procedure), and at 30 days, 9 months, 12 months, and 24 months post-procedure. The follow-up procedures are documented in Table 17 below.

Table 17: Study Follow-up Plan

Assessment	Pre-discharge	30-Day Follow-up	9-Month Follow-up	12- and 24-Month Follow-up
Adverse Events (AEs)	X	X	X	X
Concomitant antiplatelet and anticoagulant medications only	X	X	X	X
Vital Signs	X	X	X	
Rutherford Classification		X	X	
Ankle-Brachial Index		X	X	
QoL- WIQ		X	X	
Radial artery DUS[1]		X		
Iliac DUS			X	

[1] *Procedural access side only and only for subjects treated via radial artery access.*

Clinical Endpoints:

The primary endpoint of the study was defined as freedom from the composite major adverse events (MAE), which includes peri-procedural death (through 30 days), amputation of the target limb and clinically driven target-lesion revascularization (CD-TLR) assessed at 9 months post-procedure. CD-TLR was defined as a re-intervention of the target lesion in the presence of ≥ 50% stenosis accompanied by worsening symptoms, or ≥ 70% stenosis in the absence of symptoms. As this was a confirmatory study, the endpoints were evaluated with descriptive statistics.

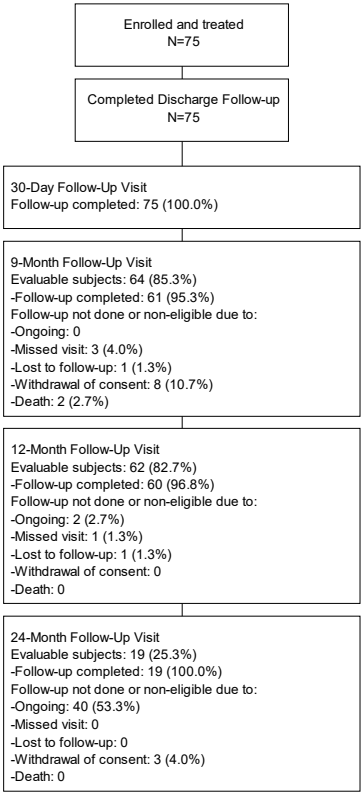
Secondary endpoints in this study included the following:

1. Freedom from Major Adverse Events at 30 days, and 12- and 24-months post-procedure. MAE is defined as a composite of peri-procedural related death, amputation of the target limb, and clinically driven TLR.

2. Target lesion primary stent binary patency at 9 months defined by duplex ultrasound peak systolic velocity ratio ≤ 2.4 at the stented target lesion and absence of TLR.
3. Technical Success defined by the following conditions:
   - Successful delivery of the stent at the lesion site.
   - Stent(s) successfully deployed in the lesion with adequate lesion coverage.
4. Procedural Success: Attainment of < 30% residual stenosis of the target lesion and no peri-procedural complications defined as: death, stroke, myocardial infarction (MI), emergent surgical revascularization, significant distal embolization in target limb, and thrombosis of target vessel. Peri-procedural complication is defined as complications after the performance of a medical procedure before hospital discharge.
5. Clinical Success: Relief or improvement (without increase of one or more in the score) from baseline symptoms as measured by the Rutherford score for chronic limb ischemia at 30 days as compared to baseline.
   - Rutherford sustained (without increase of one or more in the score) at 9 months post-procedure from 30 days post-procedure for durability of results.
6. Ankle-Brachial Index (ABI) change from baseline at 30 days post-procedure
   - ABI change from 30 days to 9 months post-procedure for durability of results.
7. Clinically driven Target Vessel Revascularization (TVR) at 30 days and 9-, 12- and 24-months post-procedure defined as any re-intervention or artery bypass surgery involving the target vessel in which the subject has ≥ 50% diameter stenosis with worsening symptoms, or ≥ 70% stenosis without symptoms. The target vessel is defined as the vessel containing the treated lesion (e.g., common and/or external iliac artery).
8. Clinically driven TLR through 30 days and 9-, 12- and 24-months post-procedure.
9. Quality of Life Measurement: Walking Impairment Questionnaire (WIQ) change from baseline (pre-procedure) at 30 days and 9 months post procedure.
10. Evaluation of all AEs at pre-discharge, 30 days, and 9-, 12- and 24-months post-procedure.
11. Evaluation of access site complications including severe bleeding, hematoma, and pseudoaneurysm, occurring prior to hospital discharge.
12. Occurrence of device deficiency.
13. Device Related Complications (DRCs) through 9 months post-procedure. DRCs are defined as any of the following events: amputation of the treated limb, arterial dissection, perforation, rupture, or injury; arterial embolism, thrombosis, or occlusion; arterial spasm; arteriovenous fistula; death; distal embolization; hemorrhage; hypotension; leg pain or claudication; TLR; or thrombosis of the target vessel.

Clinical outcomes were also stratified according to key baseline clinical and anatomical characteristics to assess potential differences in treatment response among subgroups. These stratifications will allow for a detailed evaluation of clinical outcomes across relevant subpopulations.

Accountability of PMA Cohort:
At the time of database lock, 75 patients were enrolled in the PMA study. Of these, 64/75 [85.3%] patients were available for analysis of the primary endpoint at the 9 months post-operative visit.



Note: Evaluable subjects for the follow-up period were defined as enrolled subjects who either completed their follow-up visit or who remained enrolled in the study during the visit window end date. At the time of database lock, 12- and 24-month follow-up visits were in progress.

Fig. 6: Study Subject Disposition

Study Population Demographics and Baseline Parameters:
The demographics of the study population are typical for a study of SFA occlusive disease in the US. The target population included men and women, ≥ 18 years of age, with ≥ 50% stenosis or occlusion of the target lesion(s) located within the native common and/or external iliac artery. Subjects required a Rutherford Clinical Category Score of 2, 3 or 4 and a total combined lesion length of ≤ 120 mm (Table 18).

Table 18: Baseline Demographics

Demographics	Total Mean ± SD or n/N (%)
Age (years)	69.3 ± 6.76
Gender (% Male)	61.3%
Race	
American Indian or Alaska Native	0
Asian	2/75 (2.7%)
Black or African American	14/75 (18.7%)
Native Hawaiian or Pacific Islander	0
White	58/75 (77.3%)
Not reported	1/75 (1.3%)
BMI (kg/m2)	28.0 ± 5.93
Rutherford Category*	
Category 2: Moderate claudication	6/74 (8.1%)
Category 3: Severe claudication	43/74 (58.1%)
Category 4: Ischemic pain at rest	25/74 (33.8%)

** Rutherford category missing for 1 subject.*

Table 19: Baseline Medical History in ITT Population

Medical History	Total N = 75 Subjects
Risk Factors	
Coronary/Peripheral Disease	71/75 (94.7%)
Diabetes mellitus	31/75 (41.3%)
Type 1	2/31 (6.5%)
Type 2	29/31 (93.5%)
Diabetes Treatment	
Untreated	2/31 (6.5%)
Oral Agents	15/31 (48.4%)
Insulin	7/31 (22.6%)
Insulin and Oral Agents	7/31 (22.6%)
Dyslipidemia	35/75 (46.7%)
Hypertension	68/75 (90.7%)
History of Chronic Kidney Disease	15/75 (20.0%)
Smoking Status[1]	56/75 (74.7%)
Current	22/56 (39.3%)
Former	34/56 (60.7%)
Medical History	
Cardiovascular Disease	59/75 (78.7%)
Angina Pectoris	7/75 (9.3%)
Stable	6/7 (85.7%)
Unstable	1/7 (14.3%)
Asymptomatic	0
Coronary Artery Disease	43/75 (57.3%)
Heart Failure	4/75 (5.3%)
NYHA Class I	0
NYHA Class II	2/4 (50.0%)
NYHA Class III	1/4 (25.0%)
NYHA Class IV	0
NYHA Class Missing	1/4 (25.0%)
Myocardial Infraction (MI)	14/75 (18.7%)
Cerebrovascular Disease	4/75 (5.3%)
Hemorrhagic Stroke	1/75 (1.3%)
Transient Ischemic Attack	3/75 (4.0%)

Medical History	Total N = 75 Subjects
Ischemic Stroke	1/75 (1.3%)
CFA Occlusive Disease/Significant Aortic Occlusive Disease	6/75 (8.0%)
History of Acute Limb Ischemia	3/75 (4.0%)
[1] Smoking Status, 'Former' means the patient has had a history of smoking at any previous timepoint in their life.	

Procedural Characteristics:

Initial procedural access was to be assessed in the radial artery. If radial access was not feasible or was unable to be established, it was acceptable to choose another point of procedural access. The radial access site was utilized for 88.0% of subjects; the femoral access site was utilized for 12.0% of subjects. The target lesion was to be predilated utilizing standard techniques, if necessary. Subjects underwent iliac stent placement according to the Instructions for Use. Following deployment of the stent, dilation of the target lesion was required. Aspirin intake was recommended to be started within 24 hours of the procedure. During the stenting procedure, use of supplemental anticoagulation was administered according to the investigator's discretion. Post-procedure, subjects were to receive the appropriate anticoagulation at the discretion of the investigator, and it was recommended that all subjects receive aspirin daily to be continued indefinitely.

A total of 83 lesions were treated across 75 subjects: 51.8% of lesions were in the common iliac artery and 39.8% of lesions were in the external iliac artery. Seven subjects (8.4%) had lesions that extended across both arterial segments. All target lesions were de novo with a mean target lesion length was 37.9 mm and a mean initial stenosis of 68.2%. Table 20 presents target lesion characteristics assessed by the angiographic core laboratory.

Table 20: Target Lesion Characteristics (Core Lab Reported)

Core Lab Angiography	Total N = 83 Lesions Mean ± SD or n/N (%)
Target Lesion Location	
Common Iliac Artery (CIA)	43/83 (51.8%)
External Iliac Artery (EIA)	33/83 (39.8%)
Common Iliac, External Iliac	7/83 (8.4%)
Target Limb by Lesion	
Left	42/83 (50.6%)
Right	41/83 (49.4%)
Pre-Treatment Arteriogram*	
Target Lesion Length (mm)	37.9 ± 29.47
Reference Vessel Diameter (RVD) (mm)	7.3 ± 1.48
Minimal Lumen Diameter (MLD) (mm)	2.4 ± 1.65
Stenosis [%]	68.2 ± 20.12
Post-Treatment Arteriogram*	
Total Treated Lesion Length (mm)	60.2 ± 24.59
Max Stent Diameter (mm)	8.6 ± 1.26
Stent MLD (mm)	6.3 ± 1.31
Stenosis [%]	16.0 ± 9.84
* Pre- and post-treatment arteriograms were conducted on 82 lesions; 1 arteriogram was non-diagnostic.	

Safety and Effectiveness Results

Primary Composite Safety and Effectiveness Endpoint Analysis:
The primary endpoint of the study was defined as freedom from the composite Major Adverse Events (MAE), which included periprocedural death, amputation of the target limb, and clinically driven target lesion revascularizations (TLR), assessed at 9 months post-procedure. CD-TLR was defined as a re-intervention of the target lesion in the presence of ≥50% stenosis accompanied by worsening symptoms, or ≥ 70% stenosis in the absence of symptoms.

Among the evaluable subjects who completed the 9-month follow-up visit or remained enrolled at the end of the 9-month visit window, 64 subjects were analyzed. Eleven of the 75 subjects were not included in the 9-month analysis population due to death (n=2), loss to follow-up (n=1), or withdrawal of consent prior to the 9-month visit (n=8). The 2 deaths were unrelated to the device or procedure (i.e. lung cancer and influenza B).

Of these, 63 subjects (98.4%) were free from MAEs at 9 months post-procedure. No peri-procedural related deaths or amputations of the target limb were reported. Clinically driven TLR was observed in 1 subject (1.6%), with 63 subjects (98.4%) remaining free from TLR. Table 21 summarizes the primary safety endpoint analysis.

Table 21: Primary Endpoints in Evaluable Subjects at 9-months Follow-up

	n/N (%)
Subjects without MAE at 9 Months Post-Procedure	63/64 (98.4%)
Subjects without Peri-Procedural Related Death	64/64 (100.0%)
Subjects without Amputation of the Target Limb	64/64 (100.0%)
Subjects without Clinically Driven Target Lesion Revascularization (TLR)	63/64 (98.4%)

Note: Evaluable subjects for the 9 months follow-up (64) were defined as enrolled subjects who either completed their 9-month follow-up visit or who remained enrolled in the study on their 9-month visit window end date.

Secondary Endpoint Analysis:
Secondary endpoints in this study included a comprehensive evaluation of clinical, procedural, and device-related outcomes at 30 days and/or 9 months post-procedure. Table 22 below summarizes the secondary safety endpoints in the ITT population and in the per protocol (PP) population. At each time point, high rates of event-free survival were observed across all assessed endpoints.

Table 22: Secondary Safety Endpoints

	ITT Population		PP Population	
	30 Days Follow-up	**9 Month Follow-up**	**30 Days Follow-up**	**9 Month Follow-up**
Subjects without MAE	75/75 (100.0%)	63/64 (98.4%)	75/75 (100.0%)	63/64 (98.4%)
Subjects without Peri-Procedural Related Death	75/75 (100.0%)	64/64 (100.0%)	75/75 (100.0%)	64/64 (100.0%)
Subjects without Amputation of the Target Limb	75/75 (100.0%)	64/64 (100.0%)	75/75 (100.0%)	64/64 (100.0%)
Subjects without Clinically Driven Target Lesion Revascularization (TLR)	75/75 (100.0%)	63/64 (98.4%)	75/75 (100.0%)	63/64 (98.4%)
Subjects without Clinically Driven Target Vessel Revascularization (TVR)	75/75 (100.0%)	63/64 (98.4%)	75/75 (100.0%)	63/64 (98.4%)

Table 23 summarizes the secondary effectiveness endpoints in the ITT population.

Table 23: Secondary Effectiveness Endpoints

Secondary Effectiveness Endpoint(s)	Total Mean ± SD or % (n/N)
Primary Stent Patency at 9 months defined as a binary duplex ultrasound PSVR ≤ 2.4 or stenosis category <50% and absence of TLR [1]	94.5% (52/55)
Clinical success, defined as relief or improvement without an increase of one or more in Rutherford score, at 30 days compared to baseline	98.6% (71/72)
Clinical success, defined as relief or improvement without an increase of one or more in Rutherford score, at 9 months compared to baseline [2]	96.6% (56/58)
Site reported technical success, defined by successful delivery of the stent at the lesion site and the stent(s) successfully deployed in lesion with adequate lesion coverage.	100.0% (75/75)
Core lab reported technical success, defined by successful delivery of the stent at the lesion site and the stent(s) successfully deployed in lesion with adequate lesion coverage.	97.3% (72/74)
Procedural Success, defined as the attainment of < 30% residual stenosis of the target lesion and no peri-procedural complications	94.6% (70/74)
Ankle-Brachial Index (ABI) change from baseline to 30 days post-procedure	0.20 ± 0.23
Target Limb Ankle-Brachial Index (ABI) change from baseline to 9 months post-procedure	0.19 ± 0.24
Walking Impairment Questionnaire (WIQ) Score Improvement from baseline to 30 days	22.3 ± 30.02
Walking Impairment Questionnaire (WIQ) Score Improvement from baseline to 9 months	22.3 ± 28.51

Subjects without Clinically Driven Target Lesion Revascularization (TLR) at 9 months post-procedure	98.4% (63/64)
Subjects without Clinically Driven Target Vessel Revascularization (TVR) at 9 months post-procedure	98.4% (63/64)

[1]Three subjects did not achieve primary stent patency at 9 months due to either a PSVR >2.4, ≥50% stenosis, or target lesion revascularization (TLR). DUS assessments were evaluable for 55 subjects, meaning that diagnostic-quality iliac artery ultrasound images and the required measurements were available for core laboratory assessment of vessel patency.
[2]Two subjects did not achieve clinical success at 9 months because their Rutherford Classification scores worsened compared with baseline. Fifty-eight subjects were considered evaluable for clinical success since both baseline and 9-month Rutherford Classification assessments were available.

Table 24 summarizes the device-related complications and device deficiencies in the ITT population through 9 months.

Table 24: Device-Related Complications and Device Deficiencies through 9 MonthsSecondary Endpoint(s)	**Total % (n/N)**
Subjects with Device-Related Complications	2.7% (2/75)
Subjects with Device Deficiencies	1.3% (1/75)

Adverse Events:
Table 25 provides a summary of the non-serious adverse events, as reported by sites, documented in the OSPREY ILIAC study. The data are presented as a percentage of subjects experiencing non-serious adverse events.

Table 25: Non-Serious Adverse Events (Site Reported)

Adverse Event	**N (%) subjects with ≥1 condition / number of events**		
	Within 30 days (0-30 days)	**9 months (31-270 days)**	**Overall (0-270 days)**
Evaluable Subjects	N=75	N=69	N=75
Any Adverse Events	33 (44.0%) / 63	53 (76.8%) / 135	59 (78.7%) / 198
Non- Serious Adverse Events	31 (41.3%) / 52	44 (63.8%) / 81	54 (72.0%) / 133
Incidence of Adverse Event by SOC/PT			
Vascular disorders	19 (25.3%) / 21	14 (20.3%) / 15	29 (38.7%) / 36
General disorders and administration site conditions	7 (9.3%) / 7	11 (15.9%) / 11	16 (21.3%) / 18
Musculoskeletal and connective tissue disorders	5 (6.7%) / 5	9 (13.0%) / 9	13 (17.3%) / 14
Cardiac disorders	-	6 (8.7%) / 9	6 (8.0%) / 9
Respiratory, thoracic and mediastinal disorders	1 (1.3%) / 1	6 (8.7%) / 8	6 (8.0%) / 9
Infections and infestations	3 (4.0%) / 3	6 (8.7%) / 7	8 (10.7%) / 10
Injury, poisoning and procedural complications	7 (9.3%) / 8	1 (1.4%) / 1	8 (10.7%) / 9
Nervous system disorders	1 (1.3%) / 1	4 (5.8%) / 5	5 (6.7%) / 6

Gastrointestinal disorders	1 (1.3%) / 1	4 (5.8%) / 4	5 (6.7%) / 5
Renal and urinary disorders	1 (1.3%) / 1	4 (5.8%) / 4	4 (5.3%) / 5
Blood and lymphatic system disorders	1 (1.3%) / 1	1 (1.4%) / 1	2 (2.7%) / 2
Metabolism and nutrition disorders	2 (2.7%) / 2	2 (2.9%) / 2	3 (4.0%) / 4
Reproductive system and breast disorders	-	1 (1.4%) / 1	1 (1.3%) / 1
Investigations	-	1 (1.4%) / 1	1 (1.3%) / 1
Skin and subcutaneous tissue disorders	-	1 (1.4%) / 1	1 (1.3%) / 1
Ear and labyrinth disorders	-	1 (1.5%) / 1	1 (1.3%) / 1
Hepatobiliary disorders	-	-	-
Psychiatric disorders	1 (1.3%) / 1	-	1 (1.3%) / 1
Surgical and medical procedures	-	1 (1.4%) / 1	1 (1.3%) / 1

Note: Evaluable subjects include those who are enrolled and either completed the follow-up visit within the protocol-defined visit window or were evaluable for adverse event reporting during the corresponding adverse event reporting period.

Table 26 provides a summary of the serious adverse events (SAEs), as reported by sites, documented in the OSPREY ILIAC study. The data are presented as a percentage of subjects experiencing serious adverse events.

Table 26: Serious Adverse Events (SAEs) (Site Reported)

Adverse Event	N (%) subjects with ≥1 condition / number of events		
	Within 30 days (0-30 days)	9 months (31-270 days)	Overall (0-270 days)
Evaluable Subjects	N=75	N=69	N=75
Any Adverse Events	33 (44.0%) / 63	53 (76.8%) / 135	59 (78.7%) / 198
Serious Adverse Events	7 (9.3%) / 11	25 (36.2%) / 54	29 (38.7%) / 65
Incidence of Adverse Event by SOC/PT			
Vascular disorders	4 (5.3%) / 5	15 (21.7%) / 23	17 (22.7%) / 28
Infections and infestations	2 (2.7%) / 2	5 (7.2%) / 7	7 (9.3%) / 9
Cardiac disorders	1 (1.3%) / 1	3 (4.3%) / 3	4 (5.3%) / 4
Renal and urinary disorders	1 (1.3%) / 1	4 (5.8%) / 4	5 (6.7%) / 5
Gastrointestinal disorders	-	3 (4.3%) / 3	3 (4.0%) / 3
General disorders and administration site conditions	1 (1.3%) / 1	1 (1.4%) / 1	2 (2.7%) / 2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (1.3%) / 1	2 (2.9%) / 2	3 (4.0%) / 3
Nervous system disorders	-	3 (4.3%) / 3	3 (4.0%) / 3
Respiratory, thoracic and mediastinal disorders	-	1 (1.4%) / 2	1 (1.3%) / 2

Eye disorders	-	2 (2.9%) / 2	2 (2.7%) / 2
Injury, poisoning and procedural complications	-	2 (2.9%) / 2	2 (2.7%) / 2
Hepatobiliary disorders	-	1 (1.4%) / 1	1 (1.3%) / 1
Musculoskeletal and connective tissue disorders	-	1 (1.4%) / 1	1 (1.3%) / 1
Psychiatric disorders	-	-	-

Note: Evaluable subjects include those who are enrolled and either completed the follow-up visit within the protocol-defined visit window or were evaluable for adverse event reporting during the corresponding adverse event reporting period.

Among the 75 subjects in the ITT population, safety outcomes through the 9-month follow-up window (day 0–270), which corresponds to the primary endpoint timepoint, demonstrated a low incidence of serious procedure- and device-related adverse events.

A total of 19 events were adjudicated by the Clinical Events Committee in 15 subjects (20.0%), including procedure- or device-related events, SAEs, and TLRs. Of these, 5 events in 3 subjects (4.0%) were adjudicated as procedure related, and 3 events in 2 subjects (2.7%) were adjudicated as device related.

Subgroup Analyses:
Clinical outcomes were stratified according to key baseline clinical and anatomical characteristics to assess potential differences in treatment response among subgroups (e.g., diabetic versus non-diabetic status, female versus male gender, lesion location in the common iliac artery versus the external iliac artery).

Subgroup analyses were only performed for the primary endpoint (MAE within 9 months post-procedure). Due to the low Major Adverse Event (MAE) rate within 9 months post-procedure, no meaningful comparisons could be made across subgroups.

Conclusion
Findings from the OSPREY ILIAC Study, including primary and secondary endpoint outcomes and cumulative adverse event data, support the conclusion that Misago® RX Self-expanding Peripheral Stent is both safe and effective for improving the luminal diameter of de novo, restenotic and/or occlusive atherosclerotic lesion(s) in the common and/or external iliac artery up to 120 mm in length with reference vessel diameters (RVDs) between 4.0 and 9.0 mm.

MISAGO 1 was a prospective, multicenter, non-randomized study conducted in Europe. The study evaluated a newly developed self-expanding nitinol stent with rapid exchange delivery catheter for the treatment of stenotic or occluded superficial femoral (SF) or popliteal arteries. There were a total of 5 sites which enrolled 55 subjects with the implantation of 81 stents. The primary endpoint was restenosis rate at 6 months assessed by duplex sonography. The technical success rate was 100% while the procedural success rate was 98.2% without death, MI, stroke, or major bleeding. At 6 months follow-up the restenosis rate was 8.5%. Rutherford index at 6 months demonstrated improvement of 73%, without any subjects having symptom deterioration. One case of stent fracture was observed. The results from this first-in-man study indicated acceptable clinical outcomes.

MISAGO 2 was a post-market clinical study to confirm the performance and long term safety of the device for the treatment of occluded or stenotic SFA or popliteal arteries. This multicenter, non-randomized, prospective, observational registry evaluated the absence of clinically driven target lesion revascularization (TLR) at 6 and 12 months. The study enrolled 744 subjects in 76 European and South American sites. At the 12 months follow-up completion, 671 (90.2%) subjects were evaluated. The overall freedom from TLR and freedom from TLR per subject were 96.9% and 97.0% at 6 months, and 89.9% and 91.4% at 1 year, respectively. Total event-free survival rate estimates were 93.2% at 6 months and 84.9% at 1 year. Ischemic symptoms improved since 691 (92.1%) subjects enrolled were symptomatic at baseline and only 136 (21.3%) reported ischemic symptoms at 1 year ($p < 0.001$). Pain-free walking distances significantly increased and mean ABIs in the target limb revealed improvement of ≥ 0.1 or more in 76% of subjects at 12 months ($p < 0.001$). The Rutherford classification improved in 87.5% of subjects or remained stable in 8.0%.

DIRECTIONS FOR USE

Refer to Fig. 1 – 3 and Table 27 for instructions.

1. Preparation prior to stent implantation

1-1 Insert into the blood vessel an introducer sheath of at least 6 Fr., a guiding sheath, or a guiding catheter with an internal diameter of at least 2.16 mm.

1-2 Introduce an angiographic catheter into the blood vessel.

1-3 Image the lesion site by angiography.

1-4 Choose a stent size according to the stent size selection Table below (see Table 27).

Table 27: Stent Size Selection Table

Unconstrained stent diameter (mm)	Reference vessel diameter (mm)
6.0	4.0 - 5.0
7.0	5.0 - 6.0
8.0	6.0 - 7.0
9.0	7.0 - 8.0
10.0	8.0 - 9.0

1-5 Prepare the device according to standard practice.

1-6 Pre-dilatate the lesion site according to standard practice.

PRECAUTIONS

- Before use, confirm that **all** devices including the stent system function correctly, **are not** damaged, **are not** beyond their expiry date, and are suited for the purpose and procedure.
- **Do not** insert the stent system directly into the vessel without an introducer sheath, guiding sheath, or guiding catheter. (Inserting the stent system directly into the vessel can potentially damage the blood vessel and/or the stent system.)
- Confirm that the guide wire outer diameter **does not** exceed 0.89 mm (0.035 inches). If a larger guide wire has been used, exchange the guide wire.
- **Do not** use a stent smaller than the blood vessel diameter.
- Use guiding sheath or guiding catheter with enough length for each approach such as trans-femoral, trans-brachial, or trans-radial.

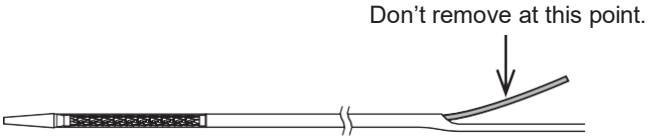
2. Preparation of the stent system

2-1 Carefully remove the stent system from its holder.

PRECAUTIONS

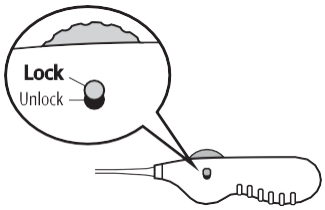
- Confirm that the stent system **is not** damaged and that the sterility **has not** been compromised.
- **Do not** remove the green plugging tube at this stage. Unplug the plugging tube immediately before the insertion of a guide wire into the distal tip of the delivery catheter (see Fig. 7).

Fig. 7



2-2 Confirm that the thumbwheel on the deployment handle is in the "Lock" position (see Fig. 8).

Fig. 8



PRECAUTIONS

- Stop using the stent system immediately if the thumbwheel **is not** in the "Lock" position at this stage.
- **Do not** depress the thumbwheel until just before stent deployment.

2-3 Fill the enclosed syringe with heparinized physiological saline solution and then connect the syringe to the distal tip (see Fig. 9).

Fig. 9

2-4 Flush with the heparinized physiological saline solution to remove air bubbles (see Fig. 10).

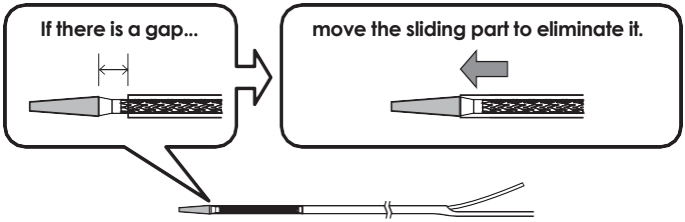
Fig. 10

PRECAUTIONS

- Confirm that the air bubbles have been removed by flushing until the heparinized physiological saline solution comes out of the proximal and distal ends of the sheath.
- Repeat step 2-4 if the solution **does not** come out. (Inadequate removal of air bubbles can result in occlusion of the peripheral blood vessels.)

2-5 If you see a gap between the sliding part and the distal tip, move the sliding part to eliminate the gap (See Fig. 11).

Fig. 11

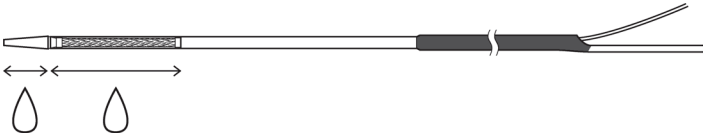


PRECAUTION

- Stop using the stent system immediately if the gap **cannot** be eliminated by moving the sliding part. (This could cause adverse events, such as vessel damage.)

2-6 Wet surface of distal tip and sheath enough with heparinized physiological saline solution to keep them lubricated (See Fig. 12).

Fig. 12



3. Insertion of the stent system

3-1 Maintaining the position of the guide wire in the lesion, remove the dilatation catheter.

3-2 Unplug the plugging tube from the delivery catheter (see Fig. 13).

Fig. 13

3-3 Pass the proximal end of the guide wire through from the distal tip and advance the stent system in line with the guide wire.

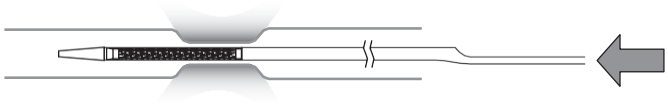
3-4 Maintaining the position of the guide wire in the lesion, insert the stent system into the introducer sheath, guiding sheath, or guiding catheter. For 200 cm usable length, the depth marker on the shaft will help confirm how far the stent system has been advanced.

PRECAUTIONS

- **Do not** insert the stent system without a guide wire support. (This could cause adverse events, such as blood vessel damage.)
- The rapid exchange delivery system **will not** allow guide wire exchanges once the device is inside the patient. (If the guide wire is removed, carefully remove the stent system and re-insert a guide wire and stent system.)
- Loosen the hemostatic valve of the Y-connector attached to the introducer sheath or guiding sheath when inserting the stent system.
- **Do not** advance the stent system by force if you feel any resistance during insertion. (The stent system can catch on and damage the hemostatic valve.)

3-5 Insert the stent system into the blood vessel along the fixed guide wire under high-resolution fluoroscopy and advance the stent system through the pre-dilatated lesion (see Fig. 14).

Fig. 14

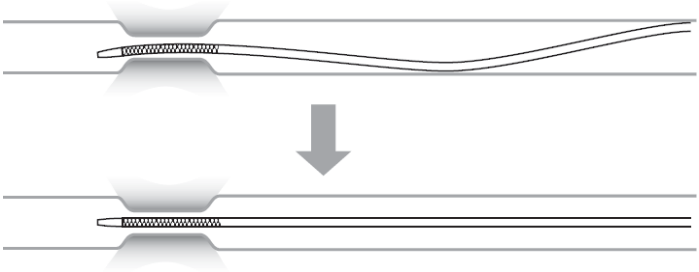


Then, by pulling back the stent system, position the stent within the stenotic lesion while observing the radiopaque markers under fluoroscopy (see Fig. 15).

Fig. 15

At this point, remove the slack in the delivery catheter (see Fig. 16).

Fig. 16

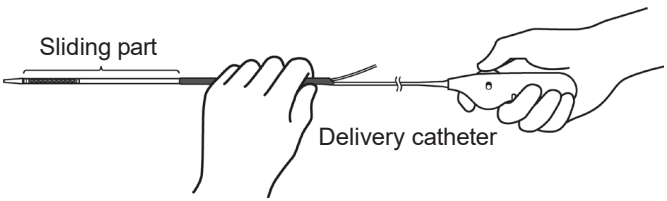


PRECAUTIONS

- Repeat the pre-dilatation step if you feel any resistance (Advancing the stent system by force can potentially damage the blood vessel and/or break or damage the stent system.)
- **Do not** deploy the stent until it is properly positioned. (If the stent is deployed in an incorrect position, it **may not** expand fully.)
- Ensure that the stent **is not** positioned within the introducer sheath, guiding sheath, or guiding catheter. (Deploying the stent within the introducer sheath, guiding sheath, or guiding catheter may deform the stent or damage the delivery catheter.)
- Avoid deploying the stent in positions that could hamper access to major vessel branches. (This could compromise future diagnostic or therapeutic procedures.)
- The stent **should not** come into contact with non-nitinol stents. (Contact between stents made from two different materials can result in potential corrosion of the stents.)

3-6 To maintain the position of the delivery catheter while rotating the thumbwheel, grip the delivery catheter by hand at the operator side (proximal) of the intermediate shaft and **do not** move the delivery catheter at the operator side of the intermediate shaft (see Fig. 17).

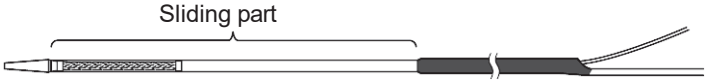
Fig. 17



PRECAUTIONS

- Eliminate any slack in the delivery catheter and fix in position. (The stent can become compressed or elongated during deployment.)
- **Do not** pull the delivery system tight during stent deployment. (The stent can become elongated during deployment.)
- **Do not** hold the sliding part of the delivery catheter (see Fig. 18). (The stent can become compressed during deployment.)

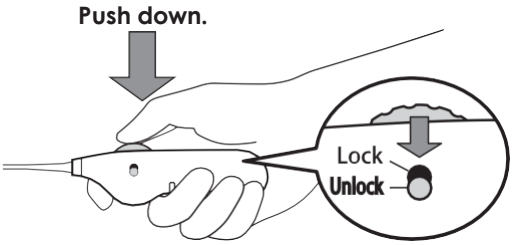
Fig. 18



4. Stent deployment

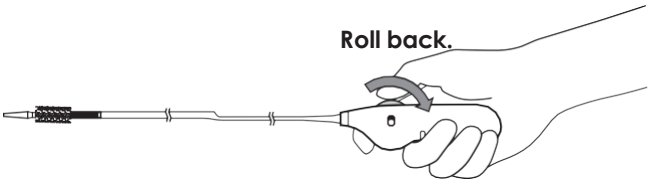
4-1 Grasp the deployment handle firmly and depress the thumbwheel until it clicks (see Fig. 19).

Fig. 19



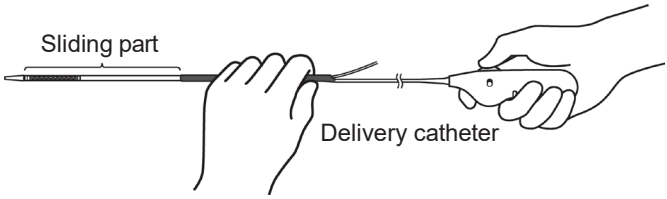
4-2 While observing the stent under high-resolution fluoroscopy, slowly roll back the thumbwheel using the thumb (with successive click sounds). The stent will start to deploy gradually from the distal end (see Fig. 20).

Fig. 20



If the radiopaque markers are observed moving distally, grip with a force commensurate with the force of the forward movement, using the movement of the radiopaque markers as a guide. If the radiopaque markers are observed moving proximally, move the delivery catheter until it is in the appropriate location. Then, grip firmly so that the delivery catheter **does not** move and deploy again by turning the thumbwheel (see Fig. 21).

Fig. 21



PRECAUTION

- When adjusting the position of the stent, always advance the stent system first and then pull it back to position the stent. (The stent can become shortened or elongated during deployment due to flexure of the delivery catheter within the vessel.)

4-3 Continue rolling back the thumbwheel until the stent deployment is completed.

PRECAUTIONS

- Securely fix the delivery catheter so that it **does not** get drawn forward. (The stent can be compressed if the delivery catheter is drawn forward in reaction to resistance on the sliding part (Fig. 3) from vessel occlusion or tortuosity.)
- Ensure that the radiopaque markers for the delivery catheter **do not** move during stent deployment.
- If the sliding part is located at the hemostatic valve or connector, the delivery catheter can slip distally during deployment and the stent may become compressed.
- As a guide, stent deployment commences on rolling back the thumbwheel 5–10 clicks for stents up to 100 mm long and 10–15 clicks for stents at least 120 mm long. Carefully roll back the thumbwheel one click at a time and adjust the position of the stent just prior to deployment if necessary (otherwise the stent can be deployed in the wrong position).
- Ensure that the introducer sheath, guiding sheath, or guiding catheter **does not** move while the stent is deploying. (The stent could become compressed during deployment).
- Deploy the stent completely, even if the delivery catheter bends and corrugates. (Removal of the delivery catheter prior to full deployment of the stent could cause the stent to deploy in an unexpected site.)
- If the stent **does not** start to deploy when the thumbwheel is rolled back, if **no** corrugations can be seen in the delivery catheter, stop rolling the thumbwheel, observe using high-resolution fluoroscopy, and then carefully remove the stent system. (The stent system could become unrecoverable.)
- A partially deployed stent **cannot** be retracted into the sliding part or repositioned. (Retraction or repositioning by force could cause deformation of the stent or damage to the blood vessel and/or delivery catheter.)
- Where multiple stents are deployed in one patient, deploy the stent within the distal lesion first and ensure that there is more than 5 mm but less than 10 mm overlap between the stents by observing the position of the radiopaque markers

fluoroscopically.
- Stop rotating the thumbwheel when stent deployment is complete. (Excessive rotation of the thumbwheel after deployment is complete will cause deformation of the inner shaft, which may prevent removal of the delivery catheter due to increased resistance to the guide wire.)
- **Do not** rotate the thumbwheel in a forward direction. (This could damage the stent system.)

4-4 Observe that the deployed stent has expanded sufficiently under high-resolution fluoroscopy.

PRECAUTION

- **Do not** remove the delivery catheter until the stent has expanded sufficiently. (The stent could move from the desired position.)

5. Removal of the delivery catheter

5-1 Confirm under high-resolution fluoroscopy that the stent expands sufficiently so that the distal tip can pass through it.

5-2 Remove the delivery catheter slowly while allowing the guide wire to maintain the position within the lesion site.

PRECAUTION

- If you feel any resistance during withdrawal of the delivery catheter, confirm the cause under high-resolution fluoroscopy and resolve the issue. Remove the delivery catheter, introducer sheath or guiding sheath, and guide wire as one unit. (Removal by force could deform or move the stent, damage the site of deployment, and/or damage or break the delivery catheter.)

5-3 Perform angiography through the introducer sheath, guiding sheath, or guiding catheter to assess the dilated lesion site and to confirm that the stent has expanded to an appropriate diameter compared to that of the reference vessel.

5-4 Take appropriate steps if high-resolution fluoroscopy shows inadequate stent expansion after deployment.

PRECAUTIONS

- Where post-dilatation is needed, use a dilatation catheter with a balloon shorter in length than the stent and an expansion diameter roughly consistent with the reference vessel diameter. After post-dilatation, perform angiography to confirm adequate expansion.
- **Do not** force the dilatation catheter if you feel any resistance during the procedure. (This could deform or move the stent, damage the site of deployment, and/or damage or break the dilatation catheter.)

5-5 Remove the guide wire and perform appropriate hemostatic procedures.

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