T-ZIV7/6/5

IMPORTANT INFORMATION: PLEASE READ PRIOR TO USE

Zilver® Vascular Stent

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ZILVER® VASCULAR STENT

These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

DEVICE DESCRIPTION

The Zilver® Vascular Stent is a self-expanding stent made of nitinol. It is a flexible, slotted tube that is designed to provide support while maintaining flexibility in the vessel upon deployment. Post-deployment, the stent is designed to impart an outward radial force upon the inner lumen of the vessel, establishing patency in the stented region.

The Zilver® Vascular Stent is available in the following sizes:

Stent Outer Diameter (mm)	5 Fr Delivery System					6 Fr Delivery System					7 Fr Delivery System				
	Stent Length (mm)														
	20	30	40	60	80	20	30	40	60	80	20	30	40	60	80
6	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×
7	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×
8	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×
9	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×
10	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×

The Zilver® stent comes preloaded in 7.0, 6.0, and 5.0 French delivery catheters. Hand-loading of the stent is not possible. Stent deployment is controlled by retraction of the handle while holding the metal cannula stationary.

INDICATIONS FOR USE

The Zilver® Vascular Stent is intended for use as an adjunct to percutaneous transluminal angioplasty (PTA) in the treatment of symptomatic vascular disease of the iliac arteries up to 100 mm in length, with a reference vessel diameter of 5 to 9 mm. Patients should be suitable candidates for PTA and/or stent treatment.

CONTRAINDICATIONS

- There are no contraindications known at this time based on the clinical data.

WARNINGS

- Persons allergic to nitinol (nickel titanium) may suffer an allergic reaction to this implant.

PRECAUTIONS

- This product should only be used by physicians trained and experienced in diagnostic and interventional vascular techniques. Standard techniques for interventional vascular procedures should be employed.
- Manipulation of the Zilver® Vascular Stent requires fluoroscopic control.
- Do not use power injection systems with the delivery system.
- Before insertion of the dilation catheter appropriate antiplatelet and anticoagulant therapy should be administered.
- Use in patients with a history of contrast sensitivity is not recommended unless the patient can be adequately premedicated.
- Bench testing suggests that an increased potential for strut fracture may be associated with overlapping of Zilver® Vascular Stents in the peripheral vasculature, while animal studies involving implantation of overlapped Zilver® Vascular Stents in iliac arteries did not result in any detected strut fractures. Clinical data characterizing the incidence of fractures in implanted Zilver® Vascular Stents are not available.
- The long term outcome following repeat dilatation of endothelialized stents is unknown at present.
- Safety and effectiveness has not been demonstrated in:
    - Patients with a history of bleeding diathesis or coagulopathy
    - Patients with a history of iliac aneurysm
    - Patients with a known pregnancy
    - Lesions located within or beyond a bypass graft
    - Pediatric patients

Stent Handling

- Do not attempt to remove the stent from the delivery system before use.
- Do not expose any part of the delivery system to organic solvents (e.g. alcohol).
- The device is intended for single use only. Do not resterilize and/or reuse this device.
- Carefully inspect the sterile package and stent system prior to use to verify that neither has been damaged during shipment.
- Use the stent system prior to the expiration date specified on the package.

Stent Placement

- Ensure that the red safety lock is not removed until ready for final stent release.

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- Deploy the stent over an extra stiff or ultra stiff wire guide.
- Do not push the hub toward the handle during deployment.
- Do not rotate any part of the system during deployment.
- Avoid stent placement that may obstruct access to a vital side branch.
- If placement of multiple stents is required in a patient, to cover the length of the lesion, the distal area of narrowing should be stented first, followed by the proximal locations, (i.e., a second stent should be placed proximally to the previously placed stent). Stents placed in tandem must overlap to allow for complete coverage of the lesion.
- When more than one stent is required, resulting in stent-to-stent contact, stent materials should be of similar composition to avoid the possibility of dissimilar metal corrosion.
- Once stent deployment has begun, the stent must be fully deployed.
- Repositioning of the Zilver® Vascular Stent is not possible since the delivery system's outer sheath cannot be re-advanced over the stent once deployment begins.
- Overstretching of the artery may result in rupture and life threatening bleeding. Do not overstretch the stent.

Stent/System Removal

- Do not advance sheath after stent has been deployed. Delivery system can be removed without the need to recapture tip.

Post Implant

- Appropriate antiplatelet/anticoagulant therapy should be administered post procedure.
- Use caution when re-crossing a stent to avoid stent damage or migration.

MRI CONDITIONS

Non-clinical testing has demonstrated that the Zilver® Vascular Stent is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient field of 720 Gauss/cm or less
- Whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg (for a single stent at 1.5 Tesla) and 3 W/kg (for a single stent at 3 Tesla and a pair of overlapping stents at 1.5 and 3 Tesla) for 20 minutes (for a single stent at 1.5 Tesla) and 15

minutes of scanning (for a single stent at 3 Tesla and a pair of overlapping stents at 1.5 and 3 Tesla), respectively.

In non-clinical testing, the Zilver® Vascular Stent produced maximum temperature rises of 0.1, 3.8, 0.8, and 0.1 degrees C (for a single stent at 1.5 Tesla, a pair of overlapping stents at 1.5 Tesla, a single stent at 3 Tesla, and a pair of overlapping stents at 3 Tesla, respectively) at whole body averaged specific absorption rates (SAR) of 1.5 W/kg (for a single stent at 1.5 Tesla) and 3 W/kg (for a single stent at 3 Tesla and a pair of overlapping stents at 1.5 and 3 Tesla) for 20 minutes (for a single stent at 1.5 Tesla) and 15 minutes (for a single stent at 3 Tesla and a pair of overlapping stents at 1.5 and 3 Tesla) of MR scanning in a 1.5 Tesla/64 MHz General Electric MR scanner, a 1.5 Tesla Magnetom Siemens Medical Solutions MR Scanner (to evaluate a pair of overlapping stents), and a 3 Tesla Excite General Electric MR scanner.

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 Zilver® Vascular Stent. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

Heating in the MRI environment for stents with fractured struts is not known.

POTENTIAL ADVERSE EVENTS

Potential adverse events that may occur include, but are not limited to, the following:

- Abrupt stent closure
- Allergic reaction to nitinol
- Amputation
- Angina/coronary ischemia
- Arrhythmia
- Arterial aneurysm
- Arterial rupture
- Arteriovenous fistula
- Atheroembolization (Blue Toe Syndrome)
- Death
- Embolism
- Fever
- Hematoma/hemorrhage
- Hypersensitivity reactions
- Hypotension/hypertension
- Infection/abscess formation at access site
- Intimal injury/dissection

- Ischemia requiring intervention (bypass or amputation of toe, foot or leg)
- Myocardial infarction (MI)
- Pseudoaneurysm formation
- Pulmonary embolism
- Renal failure
- Restenosis of the stented artery
- Septicemia/bacterimia
- Stent malapposition
- Stent migration
- Stent strut fracture
- Stroke
- Spasm
- Tissue necrosis
- Worsened claudication/rest pain

SUMMARY OF CLINICAL INVESTIGATIONS

A pilot study of the safety of the Zilver® Vascular Stent enrolled 20 patients at four investigative sites and provided justification for initiation of a pivotal study to assess the safety and effectiveness of the Zilver® Vascular Stent.

A total of 151 patients at 24 U.S. investigative sites were enrolled in a pivotal study to evaluate the safety and effectiveness of the Zilver® Vascular Stent for use as an adjunct to percutaneous transluminal angioplasty (PTA) in the treatment of symptomatic vascular disease of the iliac arteries. The following is a summary of the pivotal study.

Study Endpoints

This prospective, non-randomized study of the Zilver® Vascular Stent for the treatment of stenotic or occlusive lesions of the external or common iliac arteries was intended to establish the rate of major adverse events (MAE) at nine-month clinical follow-up as the primary study endpoint compared to an Objective Performance Criterion (OPC) derived from literature of recent studies in similar patient populations. The MAE rate of the OPC was set to be not greater than 16%, with a 9% delta. Secondary endpoints included acute procedure success, 30-day clinical success, nine-month patency rate based on ultrasound examination, ankle-brachial index, and nine-month functional status as measured by the walking impairment questionnaire.

Patient Population

Patients eligible to enroll in this study had up to two documented stenotic (≤10 cm long) or occluded (≤5 cm long) atherosclerotic lesions of the external iliac or common iliac

artery on opposite sides. Lesions could be either *de novo* or restenotic. Patients with previously stented lesions were excluded. Characteristics of the patients enrolled in this study including age, gender, medical history as well as angiographic characteristics of the treated lesions (pre-procedure) are included in Tables 2 and 3.

Table 2: Characteristics of Patients Implanted with the Zilver® Vascular Stent

Baseline Characteristics		Patients (N=151)	
Age (Mean years +/- SD)		67 ± 8.9	
Male Gender		93	61.6%
Smoking Status	Past	79	52.3%
	Current	65	43.0%
Diabetes		46	30.5%
Hypercholesterolemia		109	72.2%
Hypertension		117	77.5%
Carotid Disease		49	32.5%
Renal Disease		23	15.2%
Pulmonary Disease		50	33.1%
Use of antiplatelets		116	76.8%
CHF Class 3 or 4		7	4.6%
Previous MI		47	31.1%

Table 3: Angiographic Characteristics of the Lesions Prior to Treatment with the Zilver® Vascular Stent

Angiographic Characteristics	Lesions (n=177)	Mean ± S.D.
Lesion Length (mm)	168	32.9 ± 18.8
RVD (mm)	171	7.4 ± 1.5
In-Stent MLD (mm)	171	2.7 ± 1.4
% Diameter In-Stent Stenosis	171	64.5 ± 15.2

Methods

All patients underwent PTA (predilatation) of the target lesion prior to deployment of the stent. Up to two lesions per patient on opposite sides were stented with no more than two stents per lesion. Patients had an angiogram prior to and immediately following stent placement. Duplex ultrasound to assess patency of the stented artery and common femoral artery was performed no more than three days following the

procedure. The protocol recommended each hospital follow their standard protocol with respect to pre- and post-procedure medication; based on previous published studies clopidogrel was suggested before and post procedure for 6 months. Patients underwent clinical follow-up at 1 and 9 months post-procedure. Clinical follow-up at 1 month included measurement of ABI on the treated side as well as completion of a walking impairment questionnaire. Follow-up at 9 months included measurement of ABI on the treated side as well as completion of the walking impairment questionnaire, and an ultrasound to evaluate patency. In addition, patients were contacted by telephone at 6 months post-procedure. All data were recorded on case report forms at the investigative sites. Independent core laboratories were to analyze angiographic and ultrasonic imaging.

Results

The primary study endpoint is the major adverse event (MAE) rate occurring within nine months post-procedure. Major adverse events include death, MI (non-Q-wave and Q-wave), target lesion revascularization, and limb loss on the same side as the treated lesion. Success of the study required that the MAE rate be less than or equal to a predetermined objective performance criterion (OPC) of 16%. All MAEs were also adjudicated with respect to their relationship to the study device by an independent Clinical Events Committee.

Table 4 presents the adverse events and complications reported in the pivotal study. Events that occurred while the patients were hospitalized and cumulative events through 9 months post-implant are presented. There were a total of 8 deaths, 3 myocardial infarctions (MI), 1 target lesion revascularization, and 1 limb loss. Two patients experienced two events each as discussed below. All patients have completed their nine-month follow-up or reached a study endpoint. Five (5) of the 151 patients (3.3%) have been confirmed as withdrawn or lost to follow-up. Therefore, there were 146 evaluable patients available for assessment of MAE within the entire 9-month follow-up period. This number (146) exceeds the sample size of 130 patients determined *a priori* to be necessary to provide at least 80% power for this measure.

Table 4: Adverse Events/Complications Observed in Patients Implanted with the Zilver® Vascular Stent

Adverse Event/Complication	In-Hospital	Cumulative thru 9 Months
Death[(1)]	2.6% (4/151)	5.3% (8/151)
MI (Non-Q-Wave and Q-Wave) [(1)]	0.7% (1/151)	2.0% (3/151)
Total Lesion Revascularization	0.0% (0/151)	0.7% (1/151)
Limb Loss[(1)]	0.0% (0/151)	0.7% (1/151)
Arterial Aneurysm/Rupture	0.0%(0/151)	0.0%(0/151)
Blood Loss Requiring Transfusion	3.3%(5/151)	4.6%(7/151)
Blue Toe Syndrome	0.0%(0/151)	0.7%(1/151)
Drug/Allergic Reactions Requiring Antibiotics	0.7%(1/151)	0.7%(1/151)
Embolism	0.0%(0/151)	0.0%(0/151)
Hematoma at Access Site Requiring Intervention	1.3%(2/151)	1.3%(2/151)
Hemorrhagic Stroke with Deficit	0.0%(0/151)	0.0%(0/151)
Iliac Artery Spasm	0.0%(0/151)	0.0%(0/151)
Iliofemoral Bypass Graft Surgery	0.0%(0/151)	1.3%(2/151)
Infection/Abscess Formation	0.0%(0/151)	3.3%(5/151)
Pseudoaneurysm or AV Fistula at the Access Site	2.0%(3/151)	3.3%(5/151)
Thrombosis of Culprit Lesion	0.0%(0/151)	0.7%(1/151)
Tissue Necrosis Requiring Debridement	0.7%(1/151)	4.0%(6/151)
Worsened Claudication/Rest Pain	0.7%(1/151)	7.3%(11/151)

(1) Two patients experienced multiple major adverse events. One patient had a non-Q-wave MI on day 87 followed by a limb loss on day 119; and another had an MI on day 3 followed by death on day 8.

Rates for CEC-adjudicated related events as well as total events are shown in Table 5. Of primary interest is the MAE rate at 9 months post-procedure for events adjudicated by the Clinical Events Committee as related to the device or the procedure. This rate is 2.7% (4/146). For related and non-related events combined, the total MAE rate is 7.5% (11/146). These study results demonstrate that the MAE rate of the Zilver Vascular Stent is not greater than the target value of 16%.

Table 5: Summary of Protocol Defined Major Adverse Events Observed in 146 Patients Implanted with the Zilver® Vascular Stent

Major Adverse Event	Related Events (CEC Adjudicated)		All Events	
	N	%	N	%
Death [1]	3	2.0	8	5.5
MI (Non-Q-Wave and Q-Wave)	0	0.0	1	0.7
TLR	1	0.7	1	0.7
Limb Loss [2]	0	0.0	1	0.7
Total	4	2.7	11	7.5

[1] One patient experienced a MI 5 days prior to the death.

[2] One patient experienced a non-Q-wave MI 32 days prior to the limb loss.

Table 6 focuses on all (related and non-related) observed major adverse events and demonstrates that for evaluable patients (n=146), the MAE rate is 7.5% (11 of 146). A more conservative analysis of all evaluable patients counts all patients who withdrew from the study and all who were lost to follow-up as Major Adverse Events. In this conservative approach, the MAE rate becomes 10.6% (16 of 151). By both methods of analysis, the MAE point estimate rate is below the OPC target value of 16%. This indicates that the primary study endpoint was met.

Table 6: Rates for All Major Adverse Events within 9 months post-procedure

	Pivotal Study Result		OPC	
	Point Estimate	2-sided 95% CI Upper Bound	Target Value	Upper Limit
All enrolled patients [1]	16/151 (10.6%)	16.6%	16%	25%
Evaluable patients [2]	11/146 (7.5%)	13.1%		

[1] 5 patients who could not be assessed at 9 months (i.e., 1 withdrawn and 4 lost to follow up) were imputed as experiencing MAE as a worst case analysis.

[2] Major adverse events in 7 of the 11 patients reported with MAE were adjudicated by an independent Clinical Events Committee as not related to the device or the procedure.

Effectiveness of the Zilver® Vascular Stent was confirmed by clinical and imaging assessment post-procedure and at follow-up time points. Effectiveness measures included acute procedure success, thirty-day clinical success, ankle-brachial index, patency, and nine-month functional status measured by the walking impairment questionnaire. These measures are summarized in Table 7.

Table 7: Effectiveness Measures for Patients Implanted with the Zilver® Vascular Stent

Effectiveness Measure	Pre-Procedure	Post-Procedure	One-Month	Nine-Month
Acute Procedure Success		93.3% (140/150)[1]		
30-day Clinical Success			94.0% (141/150)	
ABI[2]	0.68 ± 0.23 (N=154)	0.88 ± 0.29 (N=152)	0.86 ± 0.20 (N=140)	0.87 ± 0.21 (N=137)
Patency of Stented Lesion		99.2% (123/124)		92.9% (105/113)
Walking Distance Score	20.1 ± 28.8 (N=147)		63.5 ± 38.3 (N=138)	55.8 ± 40.1 (N=124)
Walking Speed Score	25.6 ± 29.2 (N=141)		63.1 ± 37.4 (N=131)	56.7 ± 37.5 (N=119)

[1] One patient was excluded from the analysis due to placement of a non-study stent during the procedure.
[2] There were 177 treated lesions in the study that occurred in 170 limbs. N = number of limbs treated.

Acute procedure success was defined in the protocol as "vessel with <30% residual stenosis determined angiographically immediately after stent placement and no major clinical events before discharge." Furthermore, patients with multiple treated vessels are considered to be acute procedure failures if any of their treated vessels are ≥ 30% stenosed. The acute procedure success was 93.3% for the pivotal study. Ten patients experienced acute procedure failure. Six of the 10 failures had ≥ 30% residual stenosis, and the remaining 4 patients experienced major adverse events (3 deaths and 1 MI) prior to hospital discharge. Two of the three deaths, and the MI, were adjudicated as procedure-related by the Clinical Events Committee.

Thirty-day clinical success was defined in the protocol as "vessel with <30% residual stenosis immediately after stent placement and no major clinical events within 30 days of implant." Thirty-day clinical success was 94.0% for the pivotal study. Nine patients out of the ten patients that were considered to be acute procedure failures were also thirty-day clinical failures.

ABIs were measured pre-procedure, post-procedure, and at one- and nine-month follow-up. ABI was seen to improve from pre- to post-procedure, as well as from pre-procedure to one-month and nine-month follow-ups. After the procedure, ABI was little changed at one-month follow-up and nine-month follow-up relative to the post-procedure value. These findings suggest that the improvement achieved immediately after stent placement is maintained up to nine months post-procedure.

Ultrasound was performed no more than three days post-procedure and at nine-month follow-up to assess treated vessel patency within the stented region. Patency rates

were high both post-procedure and at the nine-month follow-up (99.2% and 92.9%, respectively). Imaging was not performed, or was inadequate for assessment, for 53 lesions immediately post-procedure and for 52 lesions at follow-up.

The Walking Impairment Questionnaire is a measure of patient-perceived walking performance for patients with PAD and/or intermittent claudication. Distance and speed scores are calculated by expressing each patient's score as a percentage of the maximum score possible, with higher scores indicating a patient's perception of greater walking distance and/or speed. Table 6 presents the walking distance and speed scores pre-procedure, at one-month follow-up, and nine-month follow-up. The walking distance and speed both increased from pre-procedure to one-month follow-up, and from pre-procedure to nine-month follow-up. From one- to nine-month follow-up there is a slight decrease in both scores. These decreases may be due to progression of the disease rather than directly related to stent performance. More importantly, walking distance and speed at 9-month follow-up continues to be improved relative to pre-procedure values.

Sub-analysis of Patients with Overlapping Stents

According to the study protocol, patients were eligible to receive up to two stents per lesion. As a result, some patients received overlapping stents to treat a single lesion. Twenty-four patients (15.9%) received at least one pair of overlapping stents. Comparisons were made between results from patients with non-overlapping stents and patients with overlapping stents. Patients with overlapping stents were slightly older with a greater proportion of males. Although patients with overlapping stents had a lower incidence of diabetes, they had a greater incidence of high cholesterol, hypertension, and carotid, renal, and pulmonary disease. Of the 11 major adverse events that occurred within nine months post-procedure, four of the events occurred in patients with overlapping stents. However, according to the CEC, none of these four events were iliac repair related. Acute procedure success rate and 30-day clinical success were 87.5% and 91.7%, respectively, for patients with overlapping stents. Trends in ABIs were similar to patients with non-overlapping stents, showing an increase in ABI pre-procedure to post-procedure and maintenance of ABI post-procedure to nine-month follow-up. Treated vessel patency was high for patients with overlapping stents post-procedure and at nine-month follow-up (100% and 82.4%, respectively). Of those patients with overlapping stents, imaging was not performed, or was inadequate for assessment, for 13 lesions immediately post-procedure and for 11 lesions at follow-up. Walking impairment scores including distance and speed improved for patients with overlapping stents from pre-procedure to one-month follow-up and pre-procedure to nine-month follow-up. From one- to nine-month follow-up time points, patients with overlapped stents had no significant changes in their walking distance and

speed scores. In summary, despite more prevalent comorbid conditions, effectiveness measures such as acute procedure success, 30-day clinical success, ABIs, patency, and walking distance and speed scores were improved for patients with overlapping stents. These measures are summarized in Table 8.

Table 8: Effectiveness Measures for Patients Implanted with overlapping Zilver® Vascular Stents

Effectiveness Measure	Pre-Procedure	Post-Procedure	One-Month	Nine-Month
Acute Procedure Success		87.5% (21/24)		
30-day Clinical Success			91.7% (22/24)	
ABI[1]	0.65 ± 0.24 (N=24)	0.84 ± 0.28 (N=23)	0.86 ± 0.26 (N=23)	0.80 ± 0.24 (N=18)
Patency of Stented Lesion		100% (20/20)		82.4% (14/17)
Walking Distance Score	20.7 ± 30.7 (N=24)		53.5 ± 43.3 (N=24)	52.8 ± 40.0 (N=17)
Walking Speed Score	17.2 ± 25.0 (N=20)		55.9 ± 44.3 (N=22)	48.3 ± 42.8 (N=16)

[1] N = number of limbs treated.

PRODUCT RECOMMENDATIONS

This product is intended for use by physicians trained and experienced in diagnostic and interventional vascular techniques. Placement of this vascular stent requires advanced skills in interventional vascular procedures. The following instructions will give technical guidance, but do not obviate formal training in the use of the device.

Upon removal from package, inspect the product to ensure no damage has occurred. If it is suspected that sterility or the integrity of the device has been compromised, it should not be used.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product tc ensure no damage has occurred.

ZILVER® VASCULAR STENT AND DELIVERY SYSTEM

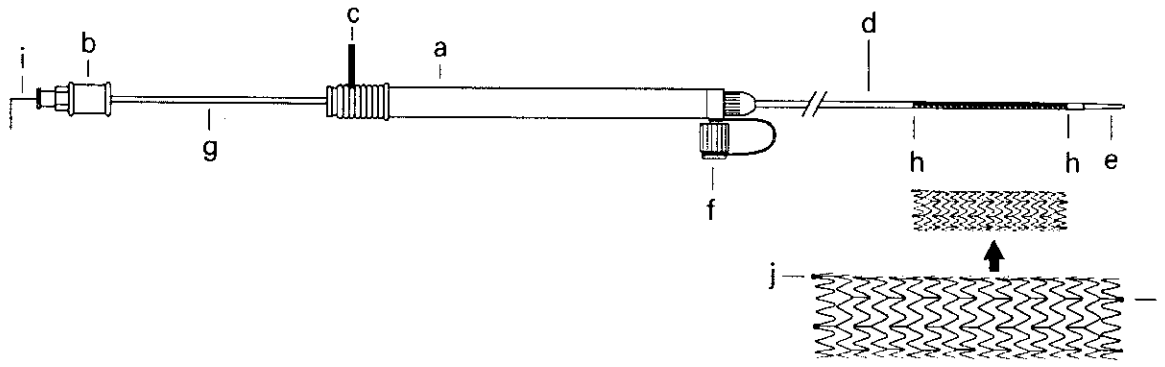

Figure 1

a. Handle
b. Hub
c. Safety Lock
d. Delivery System: Outer Sheath
e. Tip of Delivery System Inner Catheter
f. Side-arm Flushing Port
g. Metal Cannula
h. Radiopaque Markers on the Delivery System (635 has no proximal radiopaque marker)
i. Inner Support Stylet
j. Gold Radiopaque Markers

INSTRUCTIONS FOR USE

1. Determine the proper stent size after complete diagnostic evaluation. The stent deployment must be performed under fluoroscopic control. Measure the length of the target lesion to determine the length of the stent required. Allow for the proximal and distal aspects of the stent to cover the entire target area.

Note: If multiple stents are required to cover the length of the lesion, please refer to the Multiple Stent Placement Section below for further recommendations.

The Zilver® Vascular Stent is designed not to shorten upon deployment. Bench testing has shown that the post-deployment unconstrained length varies from the unconstrained length shown on the package label by -3.7% to +3.0%. Measure the diameter of the reference vessel (proximal and distal to the lesion) and use the LARGEST reference diameter as your basis for choosing the appropriate stent size (See Table 9).

Table 9: Stent Size Selection Table

Reference Vessel Diameter	Nominal Stent Diameter
5.0 mm	6.0 mm
5.0-6.0 mm	7.0 mm
6.0-7.0 mm	8.0 mm
7.0-8.0 mm	9.0 mm
8.0-9.0 mm	10.0 mm

2. Introduce the extra or ultra stiff wire guide (7 and 6 French system accepts 0.035 inch wire guide, 5 French system accepts 0.018 inch wire guide) through the access catheter across the distal segment of the target lesion.
3. Remove the access catheter, leaving the wire guide in place.
4. Predilatation of the lesion was required by protocol during the U.S.clinical study and is recommended.
5. Remove the inner support stylet from the hub of the delivery system's handle.
6. Immediately before placing the delivery system into the body, use the 1 cc syringe included in the inner package to flush the delivery system with saline through the side-arm flushing port. Flush only until a few drops of saline exit the distal tip, between the introducer catheter and sheath.

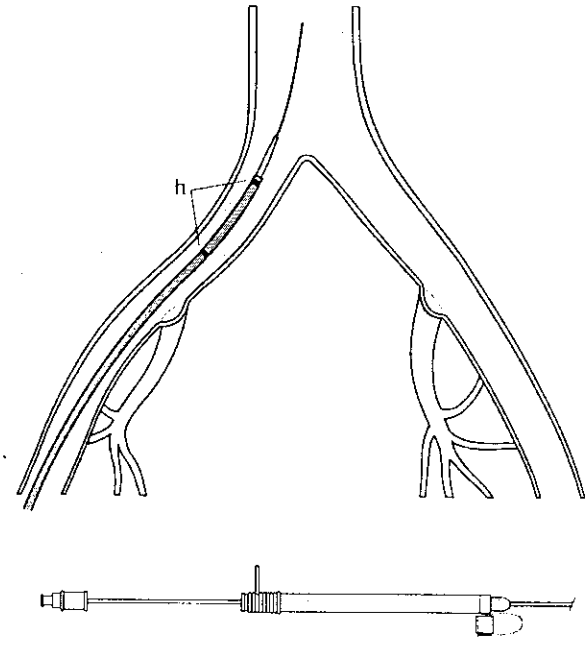

Figure 2

7. Place the delivery system under fluoroscopy to determine that the radiopaque markers on the delivery system (h) are at the desired position. The stent is now ready to be deployed. (**Fig. 2**)

Deployment of the Stent

1. Before deployment, it is important to straighten the proximal part of the delivery system as much as possible and to keep the handle in a stable position.
2. The stent expansion must be performed under fluoroscopic control.

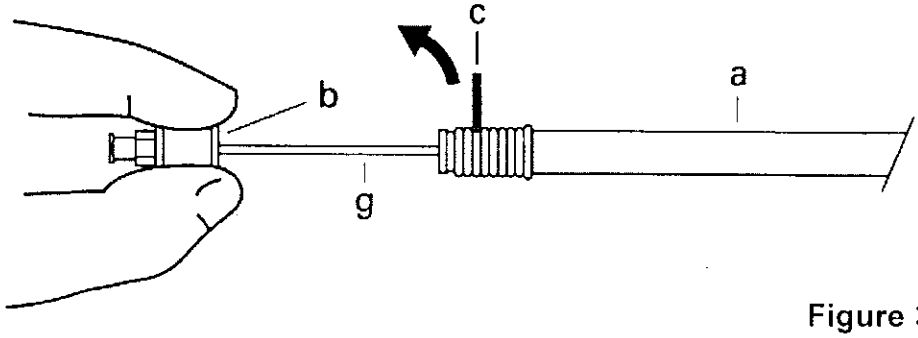

Figure 3

3. Hold the hub (b) on the metal cannula (g) steady. To deploy the stent, remove the red safety lock (c). (**Fig. 3**)

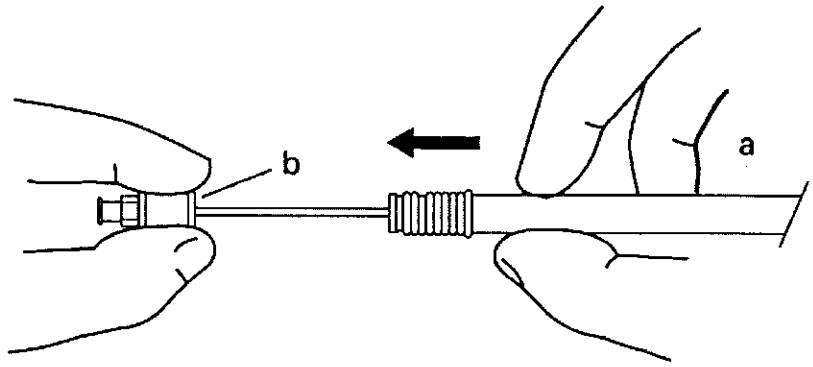

Figure 4

Hold the hub end stationary. The stent will be deployed as you pull the handle (a) toward the hub (b). (**Fig. 4**)

NOTE: Full deployment of the stent length will occur when the distal end of the sheath has been retracted past the proximal part of the stent.

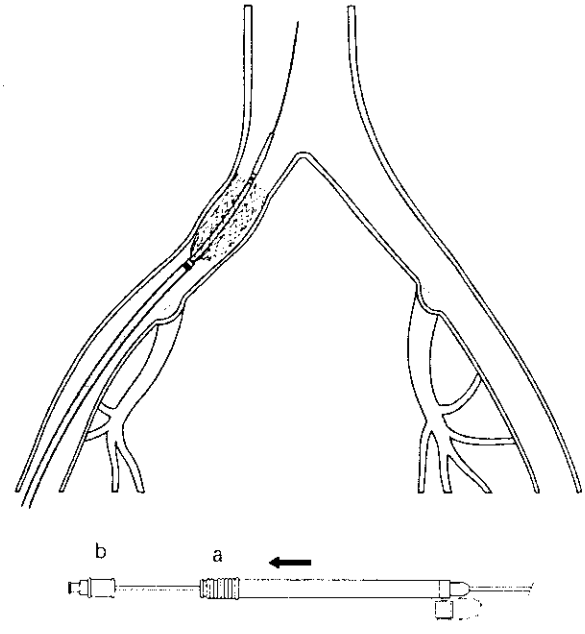

Figure 5

4. As deployment occurs, continue sliding the handle (a) toward the hub (b) in a slow, smooth and consistent fashion. (**Fig. 5**)

NOTE: ***Once stent deployment has begun, the stent must be fully deployed. Repositioning of the Zilver® Vascular Stent is not possible since the delivery system's outer sheath cannot be re-advanced over the stent once deployment begins. Refer to the*** *Multiple Stent Placement* ***section of these instructions for use for information on missed lesions.***

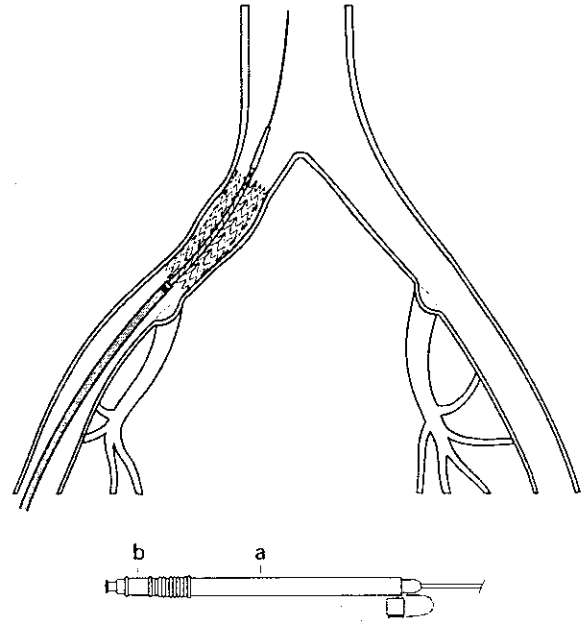

Figure 6

5. The stent is fully deployed when the handle (a) reaches the hub (b). (**Fig. 6**)

6. Remove the delivery system.

7. Perform an arterial angiogram to verify full deployment of the device.

If incomplete expansion exists within the stent at any point along the lesion, post-deployment balloon dilatation (standard PTA) can be performed at the discretion of the physician.

Multiple Stent Placement

If placements of multiple stents are required in a patient, to cover the length of the lesion, the following recommendations should be considered:

- In relation to the lesion site, the distal area of narrowing should be stented first, followed by the proximal locations, i.e. a second stent should be placed proximally to the previously placed stent.
- Stents placed in tandem must overlap to allow for complete coverage of the lesion.

REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information on available literature.