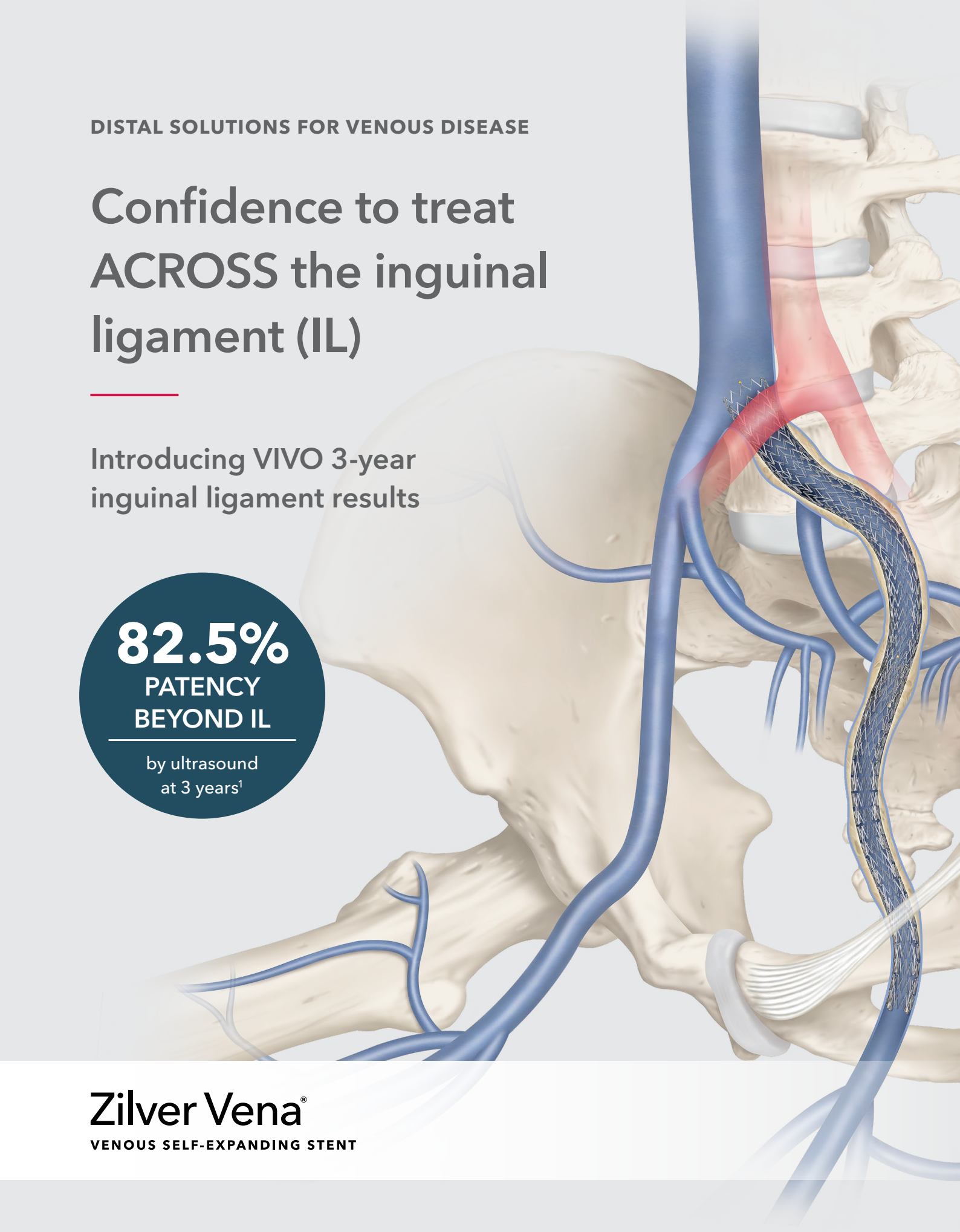
DISTAL SOLUTIONS FOR VENOUS DISEASE

Confidence to treat ACROSS the inguinal ligament (IL)

Introducing VIVO 3-year inguinal ligament results

82.5%
PATENCY BEYOND IL

by ultrasound at 3 years[1]

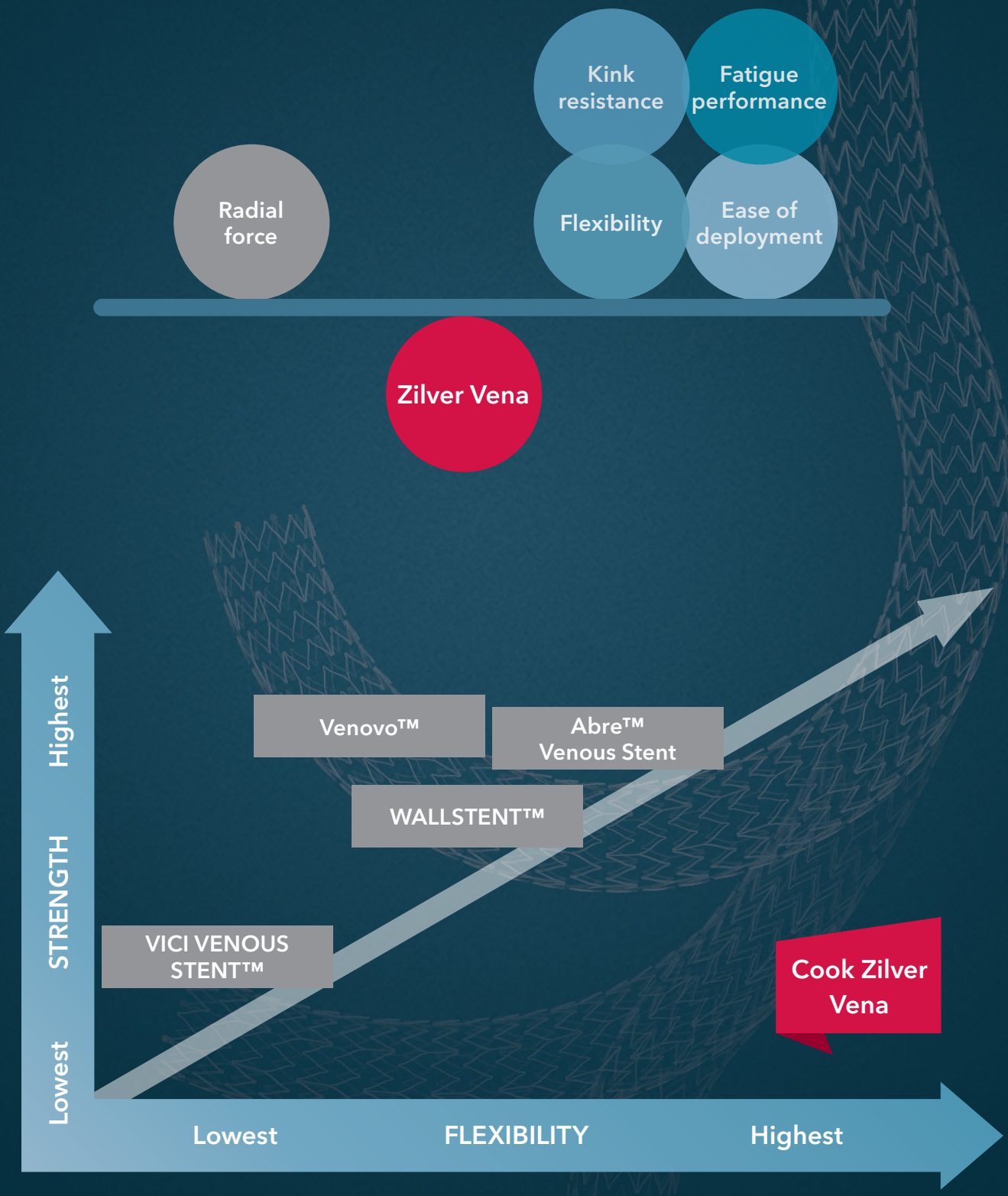


Zilver Vena®
VENOUS SELF-EXPANDING STENT

COOK® MEDICAL

The Zilver Vena difference

Comparison of radial force vs. flexibility[2,3]



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WALLSTENT and VICI VENOUS STENT are trademarks of Boston Scientific.

Abre is a trademark of Medtronic.

Patient demographics[1]

Current or past DVT and bleeding diathesis or coagulopathy were significantly more common among patients with stent extension below the inguinal ligament.

Demographic	Overall study population (N=243)	Patients without stent extension below the inguinal ligament (N=164)	Patients with stent extension below the inguinal ligament (N=79)	*P*-value
Age (years; mean ± SD)	53.0 ± 15.3 (243, 18–89)	53.7 ± 14.6 (164, 18–82)	51.4 ± 16.6 (79, 18–89)	0.27
Female	70.0% (170/243)	68.3% (112/164)	73.4% (58/79)	0.46
BMI (mean ± SD)	31.3 ± 8.5 (243, 17.5–64.8)	31.9 ± 9.2 (164, 17.5–64.8)	30.2 ± 6.8 (79, 20.5–53.8)	0.14
Current or past DVT	**67.5% (164/243)**	**56.7% (93/164)**	**89.9% (71/79)**	**<0.001***
Current or past PE	14.8% (36/243)	12.8% (21/164)	19.0% (15/79)	0.25
Bleeding diathesis or coagulopathy	**7.0% (17/243)**	**3.0% (5/164)**	**15.2% (12/79)**	**<0.001***
History of cancer	16.9% (41/243)	16.5% (27/164)	17.7% (14/79)	0.86

*Statistically significant by Fisher test at a *p*-value < 0.05.

Baseline lesion characteristics[1]

Longer lesion and total occlusion at baseline were more common among patients with stent extension below the inguinal ligament.

Outcome	Overall study population (N=243)	Patients without stent extension below the inguinal ligament (N=164)	Patients with stent extension below the inguinal ligament (N=79)	*P*-value
Mean lesion length (mm)	98.6 ± 68.8 (232, 3.5–319)	71.3 ± 48 (157, 3.5–227.4)	**155.9 ± 73.7 (75, 13.1–319)**	<0.001*
Total occlusion of target lesion	22.3% (52/233)	11.4% (18/158)	**45.3% (34/75)**	<0.001*

*Statistically significant by Fisher test at a *p*-value < 0.05.

155.9 +/- 73.7 mm

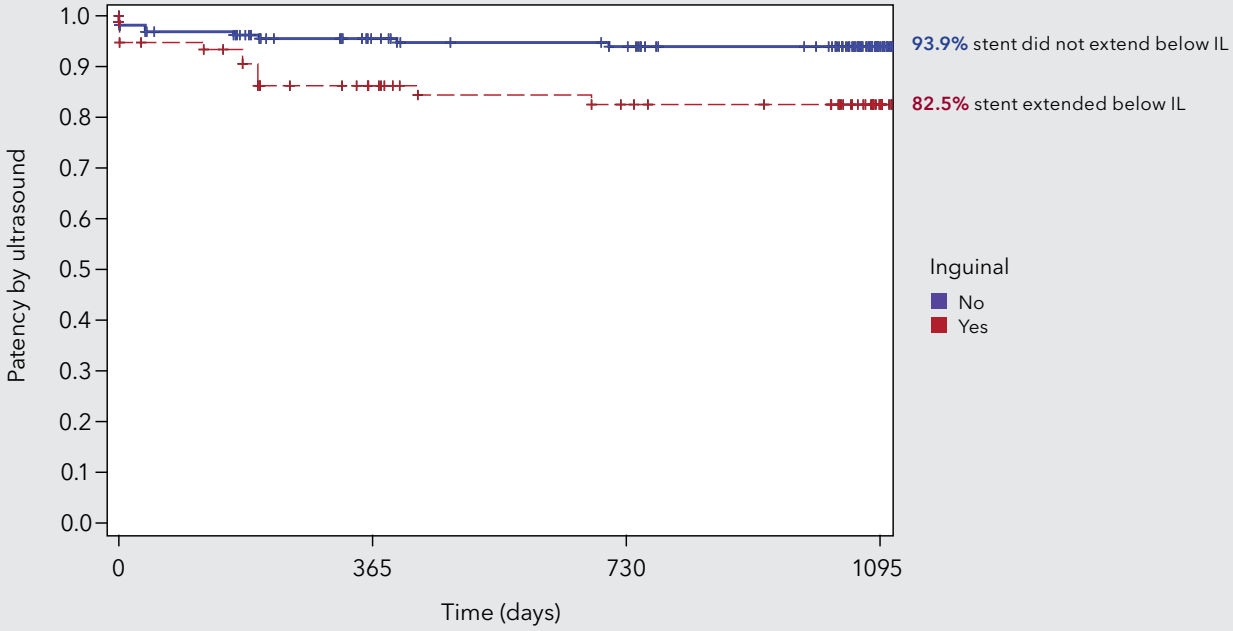
mean lesion length[1]

45.3% (34/75)

total occlusion of target lesion[1]

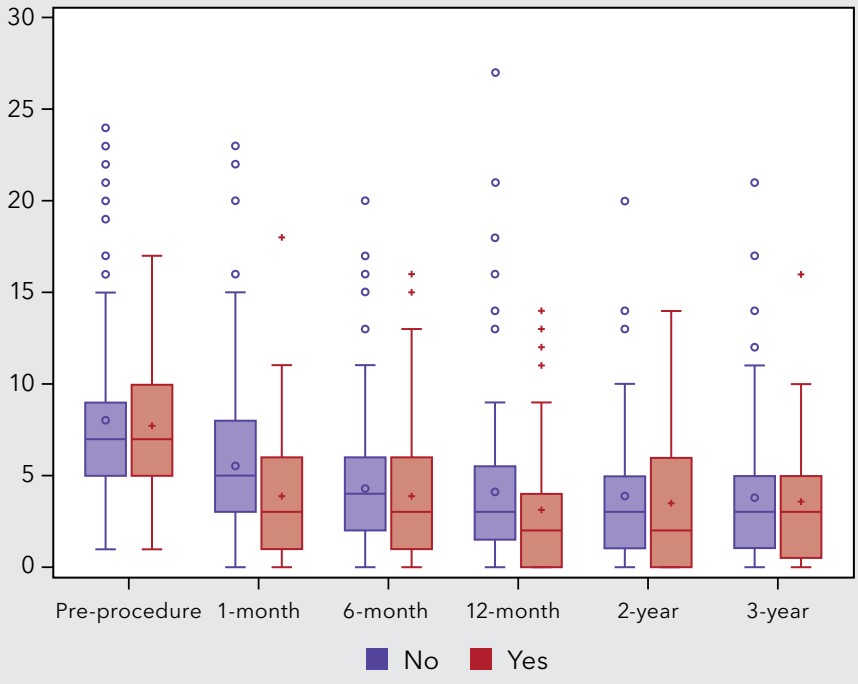
Stent patency below the inguinal ligaments[1]

Stent did not extend below inguinal ligament. **Stent extended below** inguinal ligament.



Improvement in VCSS among patient cohorts[1]

Clinical improvement in VCSS was similar among patients with and without stent extension below the inguinal ligament. **Stent did not extend below** inguinal ligament. **Stent extended below** inguinal ligament.



Stent fracture[1]

There were no fractures among 243 patients in the overall cohort (365 Zilver Vena stents), **including the 79 patients (32.5%) with stents extending below the inguinal ligament.**

Stent measure	Parameter	365 days	730 days	1095 days
Core laboratory-reported freedom from fracture	Number at risk	140	128	57
	Cumulative events	0	0	0
	Cumulative censored	16	28	99
	Kaplan-Meier estimate	**100%**	**100%**	**100%**

Zilver Vena inguinal ligament stenting case study

Courtesy of Dr. Abdulrahman Salem

A 55-year-old male patient with hypertension and diabetes experienced a left leg iliofemoral DVT and a pulmonary embolus three months earlier. The patient received anticoagulation therapy and an IVC filter to protect against recurrent pulmonary embolism. The patient presented with chronic edema and pain with prolonged standing. Conservative measures such as compression stockings and venotonics did not sufficiently reduce the patient's symptoms.

A duplex ultrasound scan demonstrated a recurrent iliofemoral DVT with no flow. The patient was prescribed above-the-knee Class II compression stockings and venotonics for one month. At one month, the patient showed persistent symptoms and secondary varicose veins indicating venous hypertension and chronic venous insufficiency.

The patient was scheduled for CT venography and possible iliofemoral vein stent placement. The left popliteal vein was accessed. CT venography showed good inflow with a patent popliteal vein, distal femoral vein, and profunda vein. An occlusion with significant collaterals was shown in the iliofemoral segment. The IVC was patent with no flow restriction observed in the IVC filter.

The patient was taken to the cath lab for a diagnostic venogram and possible stent placement. The patient was placed under general anesthesia because venoplasty of chronic venous lesions can be quite painful.

Subtraction venography showed an occlusion in the common iliac, external iliac, and common femoral veins. The lesion was crossed with a stiff hydrophilic .035 inch wire and support catheter. Re-entry of the wire into the IVC was confirmed with venography.

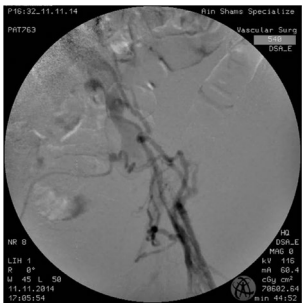
After crossing the lesion, segmental balloon venoplasty was performed in the diseased segments with a 12 mm high-pressure balloon. A 16 mm x 100 mm Zilver Vena stent was placed in the common iliac vein. Because Zilver Vena does not shorten on placement, the physician was able to use the pin-and-pull delivery system to place the proximal end of the stent at the iliocaval confluence. A second 14 mm x 100 mm was placed in the external iliac with approximately 20 mm of overlap.

Follow-up venography showed that the disease extended into the common femoral vein underneath the inguinal ligament. A third Zilver Vena stent was placed that was 14 mm x 100 mm. Post-stent dilatation was performed. Post-stenting venography demonstrated brisk flow into and through the stented segment. Venography also demonstrated a significant reduction of collateral vein flow.

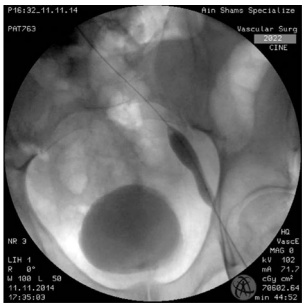
The patient was placed on an oral anticoagulant for six months and Plavix® for three months. The patient was seen at one month, three months, six months, and annually for duplex ultrasound scan and clinic visit.

The patient had a complete resolution of symptoms post-procedure. Follow-up visits showed no worsening of symptoms through four years. At the five-year follow-up, the patient presented with mild worsening of symptoms. Venous duplex showed a 60% stenosis in one of the stents. A balloon venoplasty was performed in the stenotic region to improve luminal flow. The patient had immediate relief of symptoms. The patient remains asymptomatic through eight years of follow-up.

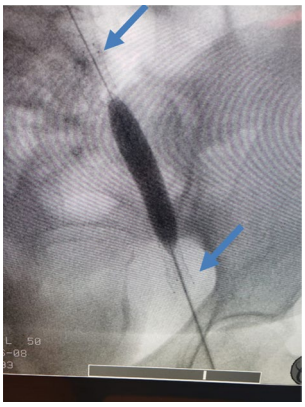
Plavix is a registered trademark of Sanofi.



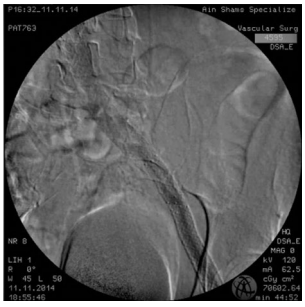
Diagnostic venography



Predilation of the lesion



Postdilation of Zilver Vena



Completion venogram

Images courtesy of
Dr. Abdulrahman Salem

Zilver Vena® Venous Self-Expanding Stent

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

INDICATIONS FOR USE: The Zilver Vena® Venous Stent is indicated for improving luminal diameter in the iliofemoral veins for the treatment of symptomatic iliofemoral venous outflow obstruction.

CONTRAINDICATIONS: The Zilver Vena Venous Self-Expanding Stent System is contraindicated for use in: • Patients who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system. • Patients who cannot receive intraprocedural anti-coagulation therapy.

WARNINGS: Nitinol (nickel-titanium) may cause allergic reactions in some patients. • The device is designed for single use only. Attempts to reprocess, re-sterilize, and/or reuse may lead to device failure and/or transmission of disease. This may also increase the risk of contamination. • Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Inspect the product to ensure no damage has occurred. • This device is a permanent implant. • Selection of inappropriate stent diameter and length based on lesion and vessel characteristics could lead to stent migration. It is important to select the appropriate stent size after a complete diagnostic evaluation. As described in the Stent Selection section, the diameter of the stent should be oversized 1-4 mm with respect to the estimated vessel diameter and the length of a stent(s) should cover the length of the lesion and secure adequate wall apposition in the adjacent normal vein (the stent should extend 5-10 mm into adjacent normal tissue). Stent migration may be more likely to occur in Non-thrombotic Iliac Vein Lesions (NIVL). For common iliac vein lesions, extension of the stent into the external iliac vein may enhance wall apposition. Stent migration or stent movement could also result from a deployment that does not result in a fully expanded stent. Post-deployment dilatation along the stent length may enhance wall apposition. Attention to the post stent deployment venogram and other imaging modalities as appropriate is important.

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 Vena Venous Stent requires high-resolution fluoroscopic control. • Do not use power injection systems with the delivery system. • Prior to the procedure, the patient's underlying condition should be assessed for compatibility with anticipated procedural and post-procedural antiplatelet/anticoagulation therapy. • Use in patients with a history of contrast sensitivity is not recommended unless the patient can be adequately premedicated. • Safety and effectiveness of the Zilver Vena Venous Stent for use in the arterial system has not been established. • 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. • The potential effects of phthalates on pregnant/nursing women or children have not been fully characterized and there may be concern for reproductive and developmental effects. **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). • Use the stent system prior to the expiration date specified on the package. **Stent Placement** • Ensure that the safety lock is not inadvertently removed prior to stent release. • Do not rotate any part of the system during deployment. • Repositioning of the device once deployment has begun (i.e., the stent markers begin to flower) is not possible because the outer sheath cannot be re-advanced over the stent. • Repositioning of the delivery system to the intended deployment location can be carried out up until the stent markers begin to flower. • If excessive resistance is felt when beginning deployment, do not force deployment. Remove the delivery system without deploying the stent and replace with a new device. • Ensure the handle remains in a stabilized position while deploying the stent. Tension to remove the slack outside the patient's body should be applied; however, do not apply excessive tension on the system as stretching of the stent may occur. • Once stent deployment has begun, the stent must be fully deployed. **Stent/System Removal** • Do not advance outer sheath after stent has been deployed. Delivery system can be removed without the need to recapture tip. **Post Implant** • Antiplatelet/anticoagulant therapy should be administered during and after procedure according to institutional standard of care. • Use caution when re-crossing a stent to avoid stent damage or migration (i.e., the use of a balloon has the potential to get caught).

POTENTIAL ADVERSE EVENTS: Potential adverse events that may occur include, but are not limited to, the following: • Abdominal or back pain • Abrupt stent closure • Allergic reaction to anticoagulant and/or antithrombotic therapy or contrast medium • Allergic reaction to nitinol (nickel-titanium) • Amputation • Aneurysm • Arrhythmia • Arteriovenous fistula • Bleeding associated with anticoagulation • Death • Embolism • Fever • Hematoma/hemorrhage at access site • Hypersensitivity reactions • Hypertension • Hypotension, nausea or symptoms of a vasovagal response • Infection/abscess formation at access site • Intimal injury/dissection • Myocardial infarction (MI) • Pseudoaneurysm formation • Pulmonary embolism • Renal failure • Restenosis, occlusion, or thrombosis of the stented vein • Septicemia/bacteremia • Stent malapposition • Stent migration or embolization • Stent strut fracture • Stroke • Tissue necrosis • Vasospasm • Vessel perforation/rupture • Worsened pain

See Instructions for Use for full product information.

AB_IFU0091_REV3

1. Gagne P. VIVO clinical study 3 year results: cohort analysis of longer term outcomes in patients with stent extension below the inguinal ligament. Presented at: Charing Cross International Symposium; 26–28 April 2022; London, UK.
2. Non-clinical test reports: D00206124, D00204576, D00244797, D00250996, D00261847, and D00250585
3. Dabir D, Feisst A, Thomas D, et al. Physical properties of venous stents: an experimental comparison. *Cardiovasc Intervent Radiol.* 2018;41(6):942-950.

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