

Durable symptom relief requires balance¹

No longer a choice
between conformability
or lumen expansion¹

Zilver Vena[®]

VENOUS SELF-EXPANDING STENT

Conforms to the vessel anatomy

Open-cell design provides flexibility and minimal foreshortening, adapting in a dynamic environment.^{1, 2, 3, 4, 5}

Durable patency

Open-cell design and nitinol self-expanding material provide sufficient lumen expansion without unnecessary force.^{1, 2, 3}

Controlled delivery

Low-profile pin-and-pull delivery system enables precise and smooth delivery.^{1, 2, 3, 4}



Zilver Vena[®]

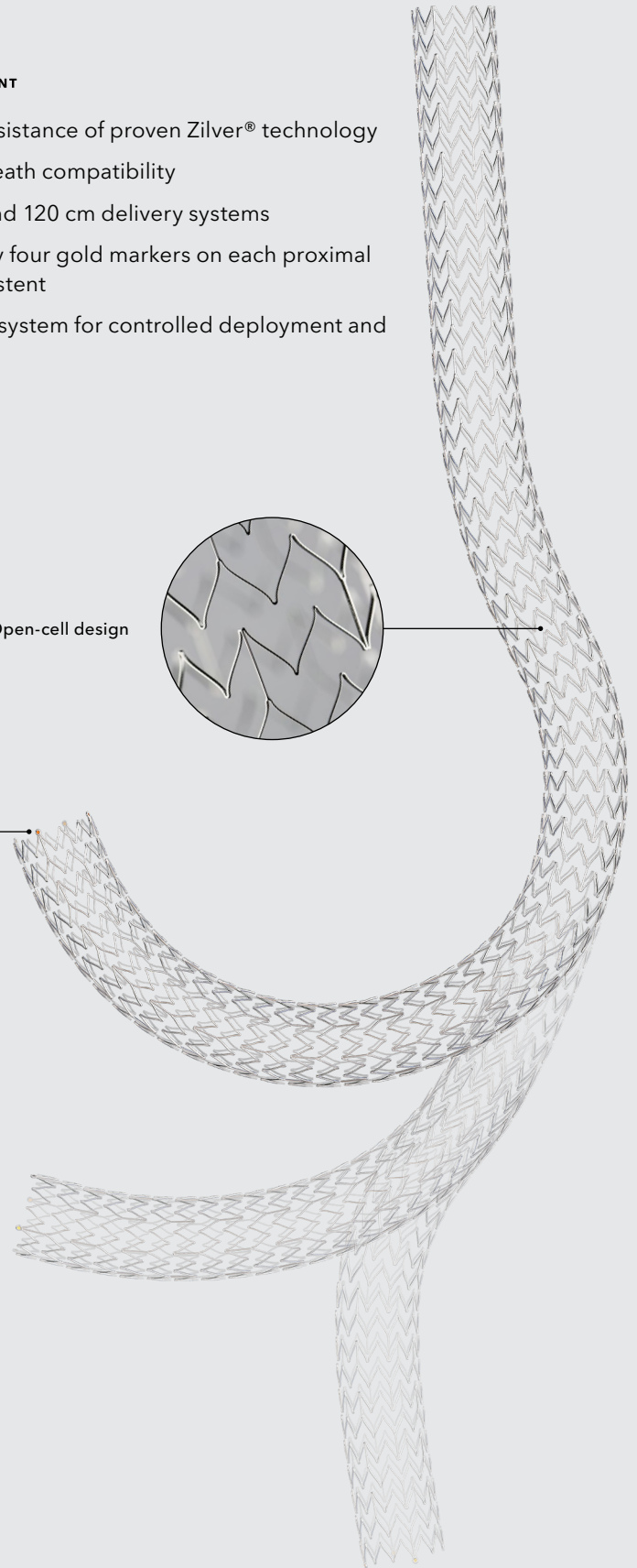
VENOUS SELF-EXPANDING STENT

- Flexibility and kink resistance of proven Zilver[®] technology
- 2.3 mm (7 French) sheath compatibility
- Deployment via 80 and 120 cm delivery systems
- Visibility enhanced by four gold markers on each proximal and distal end of the stent
- Pin-and-pull delivery system for controlled deployment and ease in placement^{4, 5}

Four gold markers on each proximal and distal end of the stent



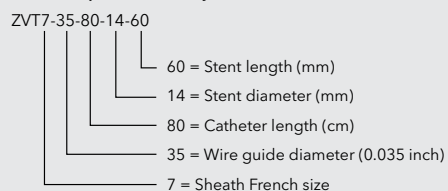
Open-cell design



Order Number	Reference Part Number	Accepts Wire Guide Diameter inch	Stent Diameter mm	Stent Length mm	Minimum Sheath mm/Fr
80 cm Over-the-Wire Delivery System					
G57428	ZVT7-35-80-10-40	0.035	10	40	2.3/7
G57429	ZVT7-35-80-10-60	0.035	10	60	2.3/7
G57430	ZVT7-35-80-10-100	0.035	10	100	2.3/7
G57431	ZVT7-35-80-10-140	0.035	10	140	2.3/7
G57432	ZVT7-35-80-12-40	0.035	12	40	2.3/7
G57433	ZVT7-35-80-12-60	0.035	12	60	2.3/7
G57434	ZVT7-35-80-12-100	0.035	12	100	2.3/7
G57435	ZVT7-35-80-12-140	0.035	12	140	2.3/7
G57444	ZVT7-35-80-14-60	0.035	14	60	2.3/7
G57445	ZVT7-35-80-14-100	0.035	14	100	2.3/7
G57446	ZVT7-35-80-14-140	0.035	14	140	2.3/7
G57447	ZVT7-35-80-16-60	0.035	16	60	2.3/7
G57448	ZVT7-35-80-16-100	0.035	16	100	2.3/7
G57449	ZVT7-35-80-16-140	0.035	16	140	2.3/7
120 cm Over-the-Wire Delivery System					
G57436	ZVT7-35-120-10-40	0.035	10	40	2.3/7
G57437	ZVT7-35-120-10-60	0.035	10	60	2.3/7
G57438	ZVT7-35-120-10-100	0.035	10	100	2.3/7
G57439	ZVT7-35-120-10-140	0.035	10	140	2.3/7
G57440	ZVT7-35-120-12-40	0.035	12	40	2.3/7
G57441	ZVT7-35-120-12-60	0.035	12	60	2.3/7
G57442	ZVT7-35-120-12-100	0.035	12	100	2.3/7
G57443	ZVT7-35-120-12-140	0.035	12	140	2.3/7
G57450	ZVT7-35-120-14-60	0.035	14	60	2.3/7
G57451	ZVT7-35-120-14-100	0.035	14	100	2.3/7
G57452	ZVT7-35-120-14-140	0.035	14	140	2.3/7
G57453	ZVT7-35-120-16-60	0.035	16	60	2.3/7
G57454	ZVT7-35-120-16-100	0.035	16	100	2.3/7
G57455	ZVT7-35-120-16-140	0.035	16	140	2.3/7

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Distribution for details.

Reference part number key



1. Shamimi-Noori SM, Clark TWI. Venous stents: current status and future directions. *Tech Vasc Interv Radiol.* 2018;21(2):113-116.
2. PMA reference number P200023.
3. View the Instructions for Use for the Zilver Vena Venous Self-Expanding Stent for a thorough examination of the procedural instructions, intended use, contraindications, warnings, precautions, and potential adverse events.
4. Engineering testing: D00206124 and D00244797.
5. Engineering testing: D00250996, D00261847, and D00250585.

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.

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AI, ESC, IR, OHNS, PI, RH, SUR-8.5X11