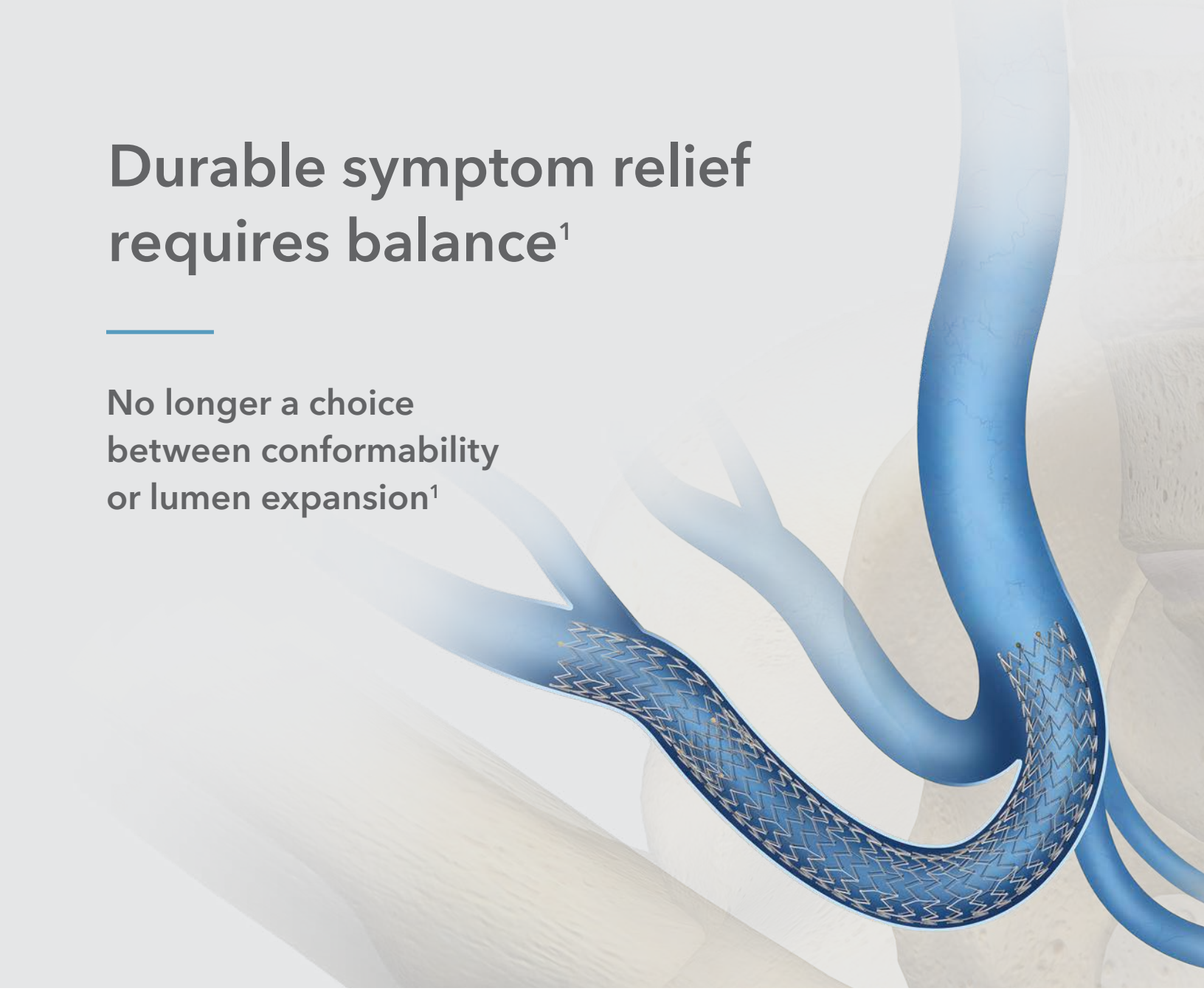
Durable symptom relief requires balance[1]

No longer a choice between conformability or lumen expansion[1]



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 provides 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]

COOK® MEDICAL

Zilver® Vena™

VENOUS SELF-EXPANDING STENT

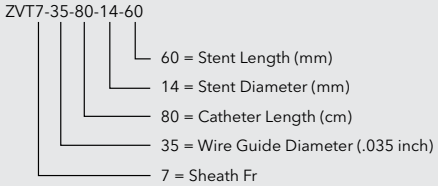
- Flexibility and kink resistance of proven Zilver® technology
- 2.3 mm (7 French) sheath compatibility
- Deployment via 80 and 120 cm delivery systems
- Visibility enhanced by four gold markers on each proximal and distal end of the stent
- Pin-and-pull delivery system allows for controlled deployment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

*Engineering testing: D00206124, D00244797 and D00250996

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 Service for details.

Reference Part Number Key



1. Shamimi-Noori SM, Clark TWI. (2018). Venous Stents: Current Status and Future Directions. *Tech Vasc Interv Radiol.* 2018;21(2):113-116.

2. PMA reference number [P200023]

3. Zilver® Vena™ View the Instructions for Use for a thorough examination of the procedural instructions, intended use, contraindications, warnings and precautions and potential adverse events. Some products or part numbers may not be available in all markets.

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 or 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.

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) • Pseudyaneurysm 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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