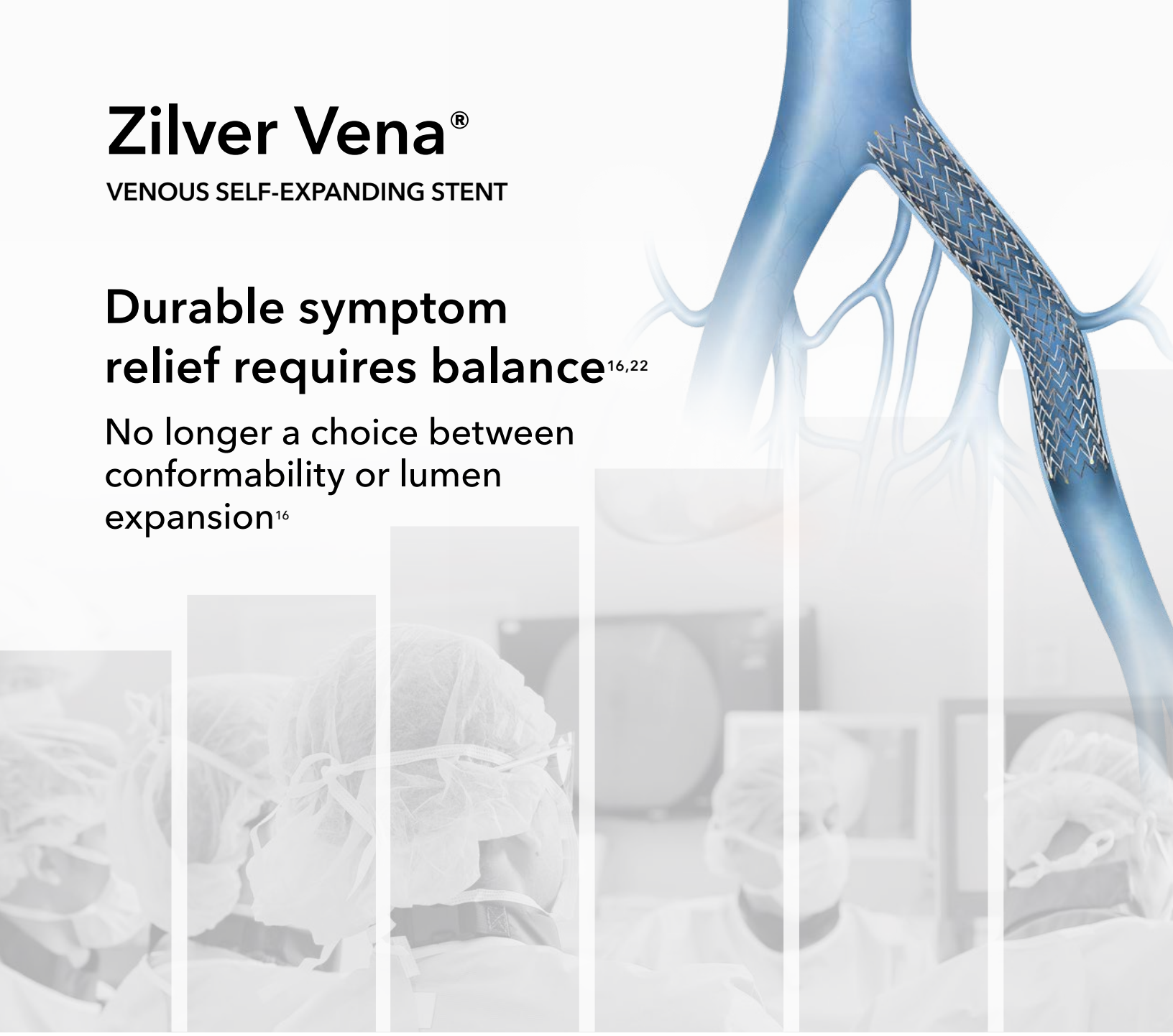
Zilver Vena®

VENOUS SELF-EXPANDING STENT



Durable symptom relief requires balance[16,22]

No longer a choice between conformability or lumen expansion[16]

COOK® MEDICAL

VALUE ANALYSIS AND PRODUCT INFORMATION PACKET

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Product overview

Cook recognizes that venous disease is complex, progressive and unpredictable[20], and that each patient is unique. The Zilver Vena® Venous Self-Expanding Stent offers physicians a purpose-built stent designed specifically for iliofemoral venous outflow obstruction. Cook is committed to continuing to develop venous therapies to benefit patients.

The Zilver Vena stent is used in interventional procedures to treat symptomatic iliofemoral outflow obstruction (deep venous obstruction), which can occur due to thrombotic (acute and post-thrombotic) and nonthrombotic disease (referred to as NIVL). Untreated venous disease could potentially lead to debilitating effects and could adversely affect the patient's quality of life.[2,3] Further, untreated venous disease could potentially put more stress on the healthcare system by requiring additional time, resources and money.[2,9]

Key product features and benefits

Conforms to the vessel anatomy

- The open-cell design provides flexibility and minimal foreshortening and adapts to a dynamic environment.[4,5,6,16,21,22,29]

Durable patency

- An 89.9% 12-month primary quantitative patency rate resulted from the data collected under the VIVO Clinical Study.[6]
- Sustained patency by ultrasound through 3 years: 92.0% patency at 12 months and 90.3% patency at 3 years.[22*]
- The open-cell design and nitinol self-expanding material provide sufficient lumen expansion without unnecessary force.[6,16,21,22]

Controlled delivery

- Lowest profile (7 Fr) venous stent on the market.
- The low-profile, pin-and-pull delivery system enables precise and smooth delivery.[6,16,21,22]

The Zilver Vena stent is designed to provide value.	
Patients	Patients with symptomatic iliofemoral venous outflow obstruction include a high percentage of women and often present at a younger age (i.e., 20-45 years).[6,22,26,28] The VIVO Clinical Study shows improved quality of life and ability to perform daily tasks.[6,22]
Healthcare providers	Cook provides a full portfolio of solutions to fill deep venous needs, including the stent, specialty catheters to help support crossing vascular obstructions (TriForce®), and procedural tools.
Hospitals	The Zilver Vena stent can provide positive clinical outcomes, and it is available in lengths up to 140 mm. Its longer stent-length options may keep costs lower by potentially requiring fewer stents.
Payers	The longer stent length options (up to 140 mm) may reduce the number of stents needed for treatment, leading to cost savings. Additional cost savings can be gained because this minimally invasive treatment option can be used in an outpatient setting.[1,9]

*Patency by ultrasound was the presence of flow or no flow on ultrasound.

Key considerations for your value analysis

The product

The Zilver Vena stent is a self-expanding nitinol stent loaded in a pin-and-pull delivery system that allows for precise deployment. The Zilver Vena stent's combination of nitinol material, stent design, and delivery system results in minimal foreshortening, which potentially avoids complications associated with deployment errors.[6,21,22] It is available in lengths up to 140 mm, which means potentially fewer stents need to be placed.

The financial impact

The Zilver Vena stent provides precise deployment and minimal foreshortening which can lead to fewer stents being used during the procedure.[6] The Zilver Vena stent can also be placed in a minimally invasive procedure that can be performed in an outpatient setting.[1,9,16,21,22]

Note: References are found on page 19 of this packet.

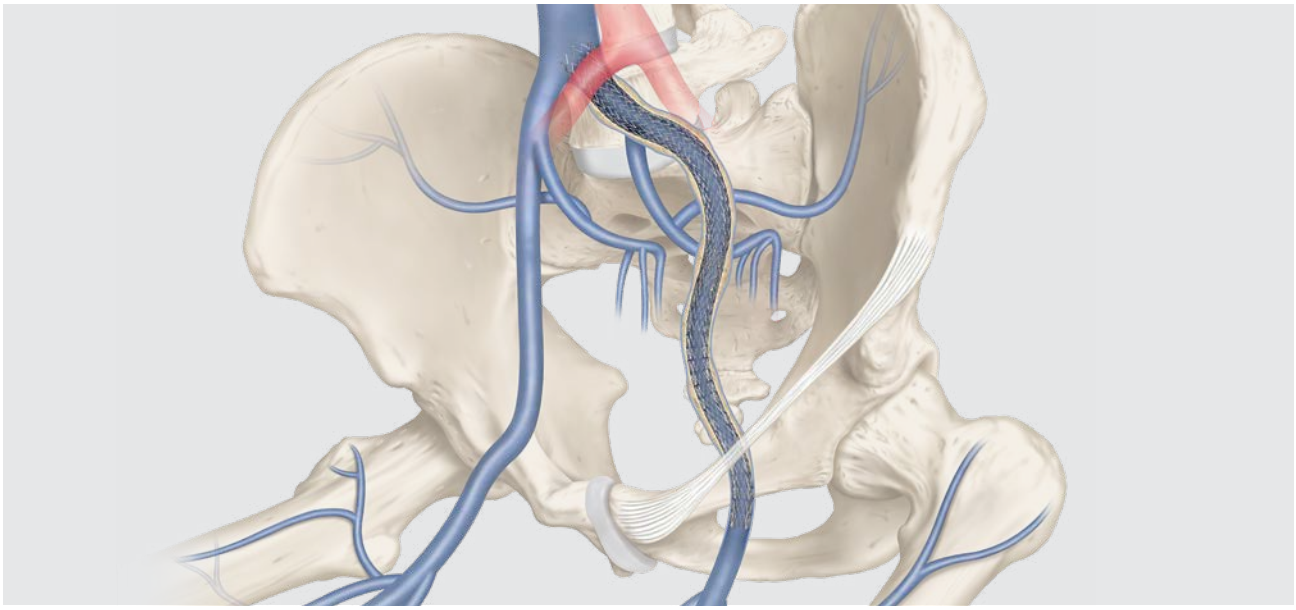
Product information

Product design

The Zilver Vena stent is a flexible, open-cell nitinol stent. After deployment, the stent is designed to exert outward radial force on the vessel lumen, establishing patency in the stented region.

Upon deployment, the stent provides support, while maintaining conformability within the vessel.

The stent comes preloaded in a 2.3 mm diameter (7.0 Fr) delivery catheter. A radiopaque marker on the distal tip of the delivery system is used to visualize the positioning for deployment of the stent. The device is available in 10, 12, 14, and 16 mm diameters and 40*, 60, 100, and 140 mm lengths. The Zilver Vena stent is compatible with 7 Fr sheaths and is deployed via 80 or 120 cm long delivery systems. The Zilver Vena stent provides sufficient lumen expansion while conforming to the vessel.[16,21,22]



Product intended 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.

***Note:** Only available in 10 and 12 mm diameters.

Value analysis

Overview

Using cost, quality, and clinical outcomes to make evidence-based decisions.

Healthcare professionals understand the importance of having high-quality products that also make economic sense. In this ever-changing healthcare landscape, healthcare providers must focus not only on the best clinical option for their patients but also the most cost-effective option. They can no longer focus solely on the individual procedure, they must also focus on the total care of the patient, including follow-up, return to work, and overall quality of life.

This value analysis for the Zilver Vena stent focuses on the variable that can be controlled—venous stent choice—in order to allow healthcare providers to make evidence-based decisions to treat their patients.

The Zilver Vena stent is designed to provide value.	
Patients	Patients with symptomatic iliofemoral venous outflow obstruction include a high percentage of women and often present at a younger age (i.e., 20-45 years).[6,22,26,28] The VIVO Clinical Study shows improved quality of life and ability to perform daily tasks.[6,22]
Healthcare providers	Cook provides a full portfolio of solutions to fill the deep venous needs, including the stent, specialty catheters to help support crossing vascular obstructions (TriForce®), and procedural tools.
Hospitals	The Zilver Vena stent can provide positive clinical outcomes, and it is available in lengths up to 140 mm. Its longer stent-length options may keep costs lower by potentially requiring fewer stents.
Payers	The longer stent length options (up to 140 mm) may reduce the number of stents needed for treatment, leading to cost savings. Additional cost savings can be gained because this minimally invasive treatment option can be used in an outpatient setting.[1,9]

Instructions for Use (IFU)

Venous stent placement and related procedures can put the patient at additional risk. For the list of potential adverse events associated with venous stent procedures please refer to the IFU.

Note: For the most up-to-date IFU please reference the Zilver Vena stent product page (https://www.cookmedical.com/products/f3af274c-42cc-42cd-a0db-e5715ad57cc4/).

Economic value analysis

Economic value and device selection for symptomatic iliofemoral venous outflow obstructions

Alternatives to the Zilver Vena stent include other venous-indicated stents. These stents tend to have a higher radial force[5,25] than the Zilver Vena stent. However, there is no clinical evidence that these higher radial forces lead to better outcomes. The Zilver Vena stent has an open-cell design and is characterized by a balance of radial force and flexibility, which allows the stent to conform to the vessel anatomy.[5,16,21,22] Additionally, the Zilver Vena stent demonstrated an 89.9% primary quantitative patency rate at 12 months.[6,22] The Zilver Vena stent is associated with a freedom from clinically driven reinterventions of 95.3% at 12 months and 92.6% at 3 years.[6,22] In addition to stent choice, the overall cost of care must be considered as part of the value analysis.

- The mean cost of a **hospital outpatient** placement of venous stents without complications is **approximately $10,183.30**[g]
- Venous stenting procedures are reimbursed on average **$10,258.59** by Medicare[a] in the outpatient setting.
- Thus, the total reimbursement rate per procedure is only slightly higher than the average hospital outpatient cost per procedure.

Scenarios

Assume your hospital performs 100 venous stenting procedures per year.

	Zilver Vena	Other stents*
Estimated average cost per year[b,c]	$924,939.00	$930,101.00[c]
1-Year Patency Rate[d,e]	89.90%[d]	86.76%[e]
Estimated number of patient's that are patent at 1 year	89.9	86.1
Estimated number of clinically driven reinterventions needed	10.1	13.9
Estimated cost of additional interventions[f]	$59,839.07	$82,352.77
Total cost to treat your population (initial procedure plus reintervention costs)	$984,778.07	$1,012,453.77
By eliminating approximately 4 reinterventions at 1-year you could save your facility $27,675.71		

Note: Performing more than 100 venous stenting procedures per year may increase the savings your hospital experiences.

Example: 200 venous stenting procedures per year may eliminate approximately 8 reinterventions and could save your facility $55,351.42 at 1 year.

For more information on this economic value analysis and to further understand the use of the Zilver Vena stent and/or accessories, please contact your local Cook Medical representative.

* BD/Bard Venovo™ Venous Stent System, and Boston Scientific-Vici Venous STENT® System

a. The 2022 Medicare reimbursement rate was calculated by using CPT code 37238.

b. Cost calculated with the following formula: ((Mean Cost of CPT code 37238 - Device Related Portion of CPT code 37238)+((Device related portion of CPT code 37248 [venous angioplasty only code] + average list price of Zilver Vena [$1650]) multiplied by average number of stents used [1]) multiplied by number of procedures per year [100]).

c. Cost calculated with the following formula: ((Mean Cost of CPT code 37238 - Device Related Portion of CPT code 37238)+((Device related portion of CPT code 37248 [venous angioplasty only code] + average price from ECRI data [$1701.62]) multiplied by average number of stents used [1]) multiplied by number of procedures per year [100]). Abre cost data not available at time of calculation.

d. VIVO clinical study. ClinicalTrials.gov Web site. https://clinicaltrials.gov/ct2/show/results/NCT01970007. Published October 25, 2013. Updated April 8, 2021. Accessed April 8, 2021.

e. BARD® The VENOVO™ Venous Stent Study for Treatment of Iliofemoral Occlusive Disease (VERNACULAR) clinical study results. ClinicalTrials.gov identifier: NCT02655887. https://clinicaltrials. gov/ct2/show/NCT02655887. Updated February 4, 2021. Accessed November 19, 2020. VIRTUS: An Evaluation of the Vici™ Venous Stent System in Patients With Chronic Iliofemoral Venous Outflow Obstruction (VIRTUS). ClinicalTrials.gov identifier: NCT02112877. https://clinicaltrials.gov/ct2/show/NCT02112877. Updated April 15, 2021. Accessed November 19, 2020. Abre Venous Self-Expanding Stent System. Food and Drug Administration Web site. https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200026B.pdf. Accessed December 3, 2020.

f. Calculated with the following formula: Estimated number of reinterventions needed multiplied by the mean cost from CPT code 37248 [venous angioplasty only]

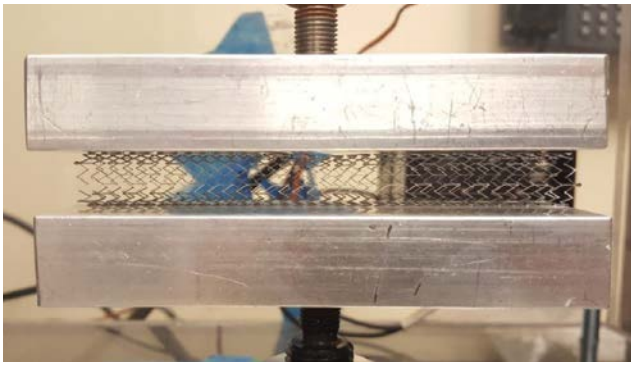
g. The procedure cost is the geometric mean cost of CPT code 37238 from the CY2022 Hospital Outpatient Prospective Payment System (OPPS) Final Rule (Medicare program: changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs). Centers for Medicare & Medicaid Services Web site https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientpps/cms-1753-fc. Published 2021. Accessed December 15, 2021.

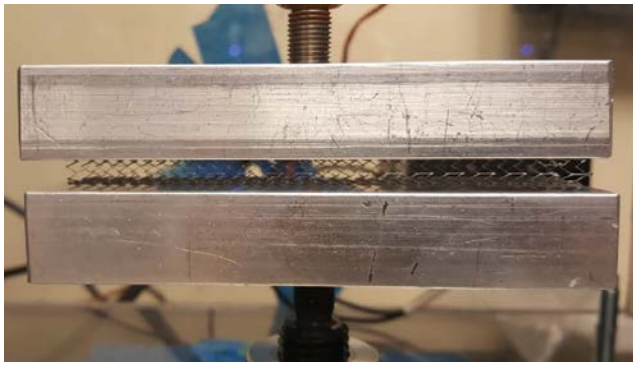
Preclinical data analysis

The venous system is a lower pressure environment than the arterial system, in which the vessel walls are thinner, are less elastic and pliable, and contain valves to help facilitate blood flow toward the heart. Although healthy veins are more compliant than arteries, the impact of using oversized, high radial force, non-conforming stents on inflamed/diseased vessel walls must be investigated further in order to understand the full consequences in deep venous stenting. Furthermore, high radial force stents are more rigid[25] with a greater potential for fracture[27] and a recent study has shown that tapering and poor alignment between the connecting stents is observed more frequently among more rigid stents, potentially resulting in increased duration of anticoagulant use.[5]

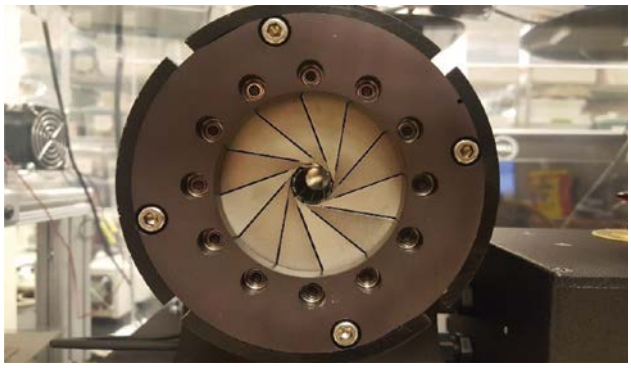
The Zilver Vena stent devices have been tested for crush resistance with parallel flat plates and radial force. Pictures of utilized equipment are provided below to illustrate the testing.

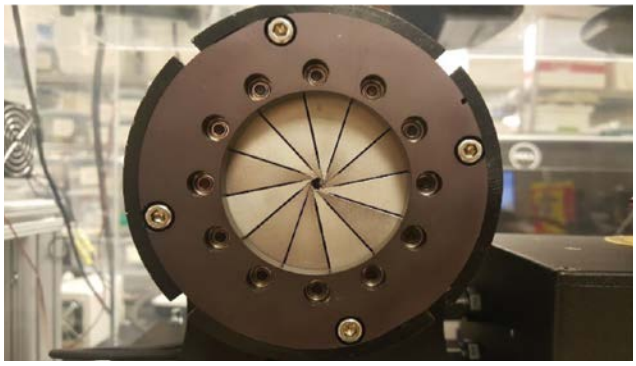
Crush resistance with parallel flat plates



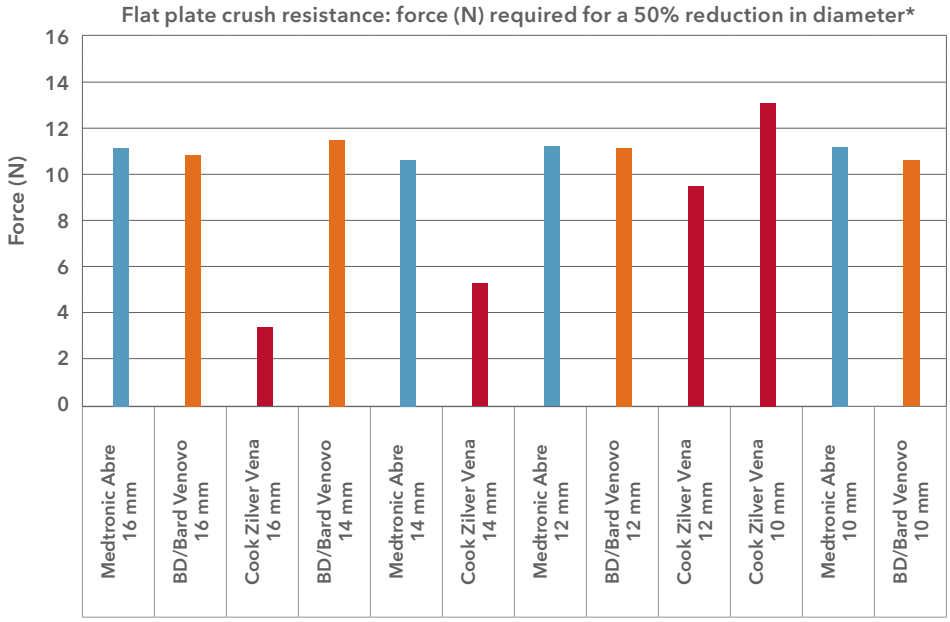


Radial force testing

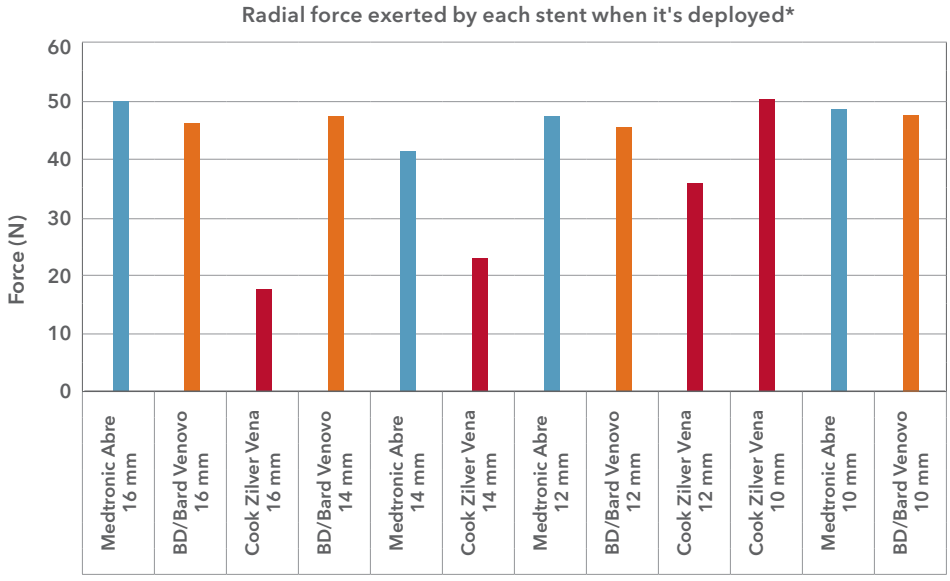




Iliofemoral venous outflow obstructive disease requires treatment solutions that offer optimized radial force that expands the vessel lumen while maintaining flexibility to conform to the native anatomy. The Zilver Vena stent design offers the flexibility to conform to native venous anatomy, while providing adequate radial strength and crush resistance to support the vein wall.* Even with the lowest radial strength and crush resistance results among competitor devices, the Zilver Vena stent demonstrated high primary quantitative patency (89.9%) and sustained 3-year ultrasound patency (90.3%) among a diverse patient population.[6] Ultimately, the Zilver Vena stent offers lumen expansion for restored blood flow.



Note: Assumes a 100 mm stent length



Note: Values are for when stents were deployed in vessels 2 mm smaller than nominal stent diameter.

Note: Assumes a 100 mm stent length

***Data on file with manufacturer. Reference document numbers:** FS150163, FS160488, FS210077, TS180328, and TS190297

Summary

Treating symptomatic venous outflow obstruction can be complicated because of the complex and progressive nature of the disease.[20] Furthermore, venous disease can be unpredictable, but timely intervention can provide symptom relief and help patients improve their quality of life by alleviating obstruction and associated symptoms, stopping disease progression.[6,23]

Cook Medical has an entire venous therapy program devoted to improving outcomes for every patient. The data referenced throughout this document, can help healthcare providers make evidence-based decisions. By using this cost, quality, and clinical outcomes information, providers can determine if the Zilver Vena stent is ideal for their patients.

The Zilver Vena stent is designed to provide value.	
Patients	Patients with symptomatic iliofemoral venous outflow obstruction include a high percentage of women and often present at a younger age (i.e., 20-45 years).[6,22,26,28] The VIVO Clinical Study shows improved quality of life and ability to perform daily tasks.[6,22]
Healthcare providers	Cook provides a full portfolio of solutions to fill deep venous needs, including the stent, specialty catheters to help support crossing vascular obstructions (TriForce®), and procedural tools.
Hospitals	The Zilver Vena stent can provide positive clinical outcomes, and it is available in lengths up to 140 mm. Its longer stent-length options may keep costs lower by potentially requiring fewer stents.
Payers	The longer stent length options (up to 140 mm) may reduce the number of stents needed for treatment, leading to cost savings. Additional cost savings can be gained because this minimally invasive treatment option can be used in an outpatient setting.[1,9]

The key considerations for your value analysis include:

1. The product

The Zilver Vena stent is a self-expanding nitinol stent loaded in a pin-and-pull delivery system that allows for precise deployment. The Zilver Vena stent's combination of nitinol material, stent design, and delivery system results in minimal foreshortening, which potentially avoids complications associated with deployment errors.[6,21,22] It is available in lengths up to 140 mm, which means potentially fewer stents need to be placed.

2. Specialties impacted

- Vascular surgery
- Interventional radiology
- Interventional cardiology

3. The financial impact

- The Zilver Vena stent provides precise deployment with minimal foreshortening, which can lead to fewer stents being used during the procedure.[6] The Zilver Vena stent can also be placed in a minimally invasive procedure that can be performed in an outpatient setting.[1,9]

4. Impact on patients

With a minimally invasive procedure, patients will have a quicker recovery time and be able to experience less pain, less disability, and improved quality of life.[6]

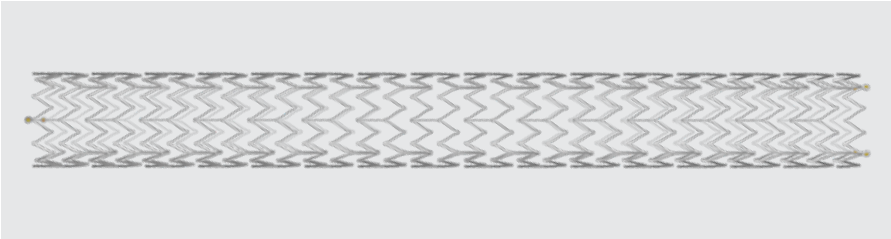
Note: References are found on page 19 of this packet.

Materials management information

Ordering numbers and sizing

Zilver Vena® Venous Self-Expanding Stent

Indicated for improving luminal diameter in the iliofemoral veins for the treatment of symptomatic iliofemoral venous outflow obstruction.

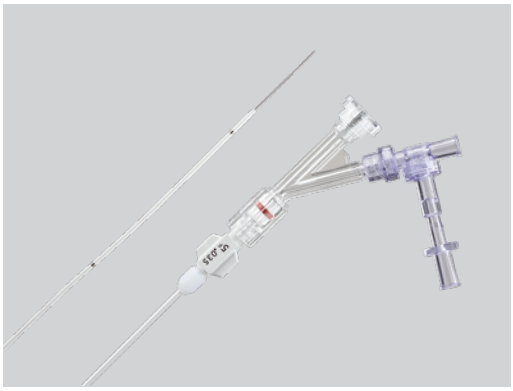


Order Number	Reference Part Number	Accepts Wire Guide Diameter inch	Stent Diameter mm	Stent Length mm	Minimum Sheath Fr
80 cm Over-the-Wire Delivery System					
G57428	ZVT7-35-80-10-40	0.035	10	40	7.0
G57429	ZVT7-35-80-10-60	0.035	10	60	7.0
G57430	ZVT7-35-80-10-100	0.035	10	100	7.0
G57431	ZVT7-35-80-10-140	0.035	10	140	7.0
G57432	ZVT7-35-80-12-40	0.035	12	40	7.0
G57433	ZVT7-35-80-12-60	0.035	12	60	7.0
G57434	ZVT7-35-80-12-100	0.035	12	100	7.0
G57435	ZVT7-35-80-12-140	0.035	12	140	7.0
G57444	ZVT7-35-80-14-60	0.035	14	60	7.0
G57445	ZVT7-35-80-14-100	0.035	14	100	7.0
G57446	ZVT7-35-80-14-140	0.035	14	140	7.0
G57447	ZVT7-35-80-16-60	0.035	16	60	7.0
G57448	ZVT7-35-80-16-100	0.035	16	100	7.0
G57449	ZVT7-35-80-16-140	0.035	16	140	7.0
120 cm Over-the-Wire Delivery System					
G57436	ZVT7-35-120-10-40	0.035	10	40	7.0
G57437	ZVT7-35-120-10-60	0.035	10	60	7.0
G57438	ZVT7-35-120-10-100	0.035	10	100	7.0
G57439	ZVT7-35-120-10-140	0.035	10	140	7.0
G57440	ZVT7-35-120-12-40	0.035	12	40	7.0
G57441	ZVT7-35-120-12-60	0.035	12	60	7.0
G57442	ZVT7-35-120-12-100	0.035	12	100	7.0
G57443	ZVT7-35-120-12-140	0.035	12	140	7.0
G57450	ZVT7-35-120-14-60	0.035	14	60	7.0
G57451	ZVT7-35-120-14-100	0.035	14	100	7.0
G57452	ZVT7-35-120-14-140	0.035	14	140	7.0
G57453	ZVT7-35-120-16-60	0.035	16	60	7.0
G57454	ZVT7-35-120-16-100	0.035	16	100	7.0
G57455	ZVT7-35-120-16-140	0.035	16	140	7.0

Contact your local Cook representative or Customer Support & Distribution for details.

Multi-Sideport Catheter Infusion Set

Intended to administer infusions of various therapeutic solutions and contrast media into the peripheral vasculature.



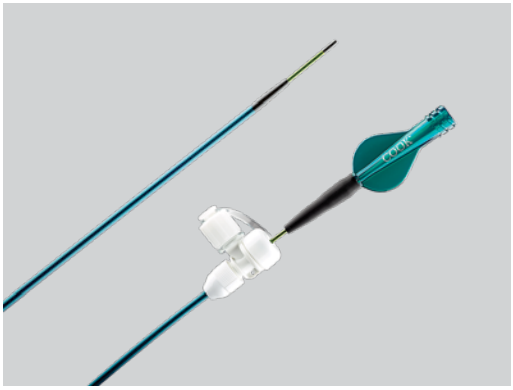
Order Number	Reference Part Number	Fr	Accepts Wire Guide Diameter inch	Length cm	Sideports	Infusion Segment Length cm
Set						
G06416	**MCIS-5.0-35-65-7.0**	5.0	0.035	65	14	7
G06420	**MCIS-5.0-35-65-15.0**	5.0	0.035	65	30	15
G06417	**MCIS-5.0-35-100-7.0**	5.0	0.035	100	14	7
G06422	**MCIS-5.0-35-100-15.0**	5.0	0.035	100	30	15
G06423	**MCIS-5.0-35-130-7.0**	5.0	0.035	130	14	7
G06425	**MCIS-5.0-35-130-15.0**	5.0	0.035	130	30	15
G08704	**MCIS-5.0-35-130-20.0**	5.0	0.035	130	40	20

Set includes the catheter, a Tuohy-Borst sidearm adapter, a catheter tip occluder, a dual check valve, and a syringe.

Contact your local Cook representative or Customer Support & Distribution for details.

TriForce® Peripheral Crossing Set

Intended to be percutaneously introduced into blood vessels and support a wire guide while performing percutaneous peripheral interventions. This device is also intended for injection of radiopaque contrast media for the purpose of angiography.



Order Number	Reference Part Number	Catheter Fr/Length cm	Sheath Length cm	Sheath Tip Fr	Accepts Wire Guide Diameter inch
Set with Straight Tip Sheath and Straight Tip Catheter					
G56412	KCXS-5.0-35-65-RB-0/0-HC	4.0/65	55	4.0	0.035
G56416	KCXS-5.0-35-100-RB-0/0-HC	4.0/100	90	4.0	0.035
Set with Straight Tip Sheath and Curved Tip Catheter					
G56413	KCXS-5.0-35-65-RB-0/DAV-HC	4.0/65	55	4.0	0.035
G56417	KCXS-5.0-35-100-RB-0/DAV-HC	4.0/100	90	4.0	0.035
Set with Curved Tip Sheath and Straight Tip Catheter					
G56414	KCXS-5.0-35-65-RB-MPB/0-HC	4.0/65	55	4.0	0.035
G56418	KCXS-5.0-35-100-RB-MPB/0-HC	4.0/100	90	4.0	0.035
Set with Curved Tip Sheath and Curved Tip Catheter					
G56415	KCXS-5.0-35-65-RB-MPB/DAV-HC	4.0/65	55	4.0	0.035
G56419	KCXS-5.0-35-100-RB-MPB/DAV-HC	4.0/100	90	4.0	0.035

Contact your local Cook representative or Customer Support & Distribution for details.

For information on additional Cook Medical products, please visit cookmedical.com/products.

Product specifications

The Zilver Vena stents are are intended for use in the venous system to improve luminal diameter in the iliofemoral veins for the treatment of symptomatic iliofemoral venous outflow obstruction.

Material composition

The device features a flexible, self-expanding stent made from nitinol and is available in 10, 12, 14, and 16 mm diameters and 40*, 60, 100, and 140 mm lengths. The Zilver Vena stent is compatible with 7 Fr sheaths and is deployed via 80 or 120 cm delivery systems. The Zilver Vena stent provides lumen expansion.[16, 21,22]

Coding and reimbursement

For the most up-to-date information, please visit cookmedical.com/reimbursement and click the interventional cardiology, interventional radiology, or vascular surgery tab under "Coding and Reimbursement Guides," and then click "Zilver Vena Venous Stent".

***Note:** Only available in 10 and 12 mm diameters.

FDA premarket approval (PMA) letter

This document is also available at accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200023.

U.S. FOOD & DRUG ADMINISTRATION

October 9, 2020

Cook Ireland Ltd.
Jennifer Brown
Director Global Regulatory Science
O'Halloran Road
National Technology Park
Limerick, Ireland

Re: P200023
Trade/Device Name: Zilver® Vena™ Venous Self-Expanding Stent
Product Code: QAN
Filed: April 13, 2020
Amended: July 9, 2020, August 20, 2020

Dear Jennifer Brown:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Zilver Vena Venous Self-Expanding Stent. This device is indicated for improving luminal diameter in the iliofemoral veins for the treatment of symptomatic iliofemoral venous outflow obstruction. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 3 years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should

be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

Be advised that failure to comply with any post-approval requirement, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" https://www.fda.gov/media/81431/download.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at

https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product post-marketing safety reporting is available at (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet Home Page located at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Sevan Oungoulian at 301-796-9631 or Sevan.Oungoulian@fda.hhs.gov.

Sincerely,

Brian D. Pullin -S

Brian Pullin
Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Solutions portfolio

Clinical

Vista® training and education programs

Cook Medical's Vista Training and Education programs set a high standard for product education. Vista programs incorporate qualified Cook selected faculty, Cook-specific content training, and peer-to-peer interaction in every session.

Visit https://vista.cookmedical.com for more information or talk to your local Cook Medical representative for upcoming events in your area.

Reimbursement

Cook's policy is to offer information that is complete, accurate, straightforward, and consistent with the statutes and regulations of the federal government and well-accepted coding guidelines as established by the Centers for Medicare and Medicaid Services (CMS), the American Medical Association (AMA), the American Hospital Association (AHA), and other relevant professional societies.

Cook's reimbursement assistance team can provide Medicare reimbursement rates, assessment of Medicare and commercial insurance coverage policies, and coverage appeals support.

Purchasing

Digital catalog

Cook can provide a URL to an image for each product in the Cook Medical catalog. These URLs are delivered to a customer in a spreadsheet that can be uploaded to display the images in the customer's purchasing platform (ERP) or clinical information system. Product images allow end users to view and validate the items.

E-commerce

We can help you order electronically. E-commerce is an automated, paper-free method of transacting purchase orders, acknowledgements, invoices, and dispatch and receiving notifications. Cook offers value-added-network (VAN), direct EDI, XML, and web-based methods of e-commerce transactions and ordering.

GS1

GS1 is an international, not-for-profit association that creates and implements standards to bring efficiency and visibility to supply chains across multiple industries. The GS1 standards for healthcare focus on improving patient safety and supply-chain efficiency. They do this by providing unique product identification (GTINs), clean data (GDSN), and location information (GLNs) numbers.

All our products are GS1 compliant. Having GS1-compliant products gives systems improved visibility in the supply chain.

Customer Support & Distribution

Distribution support

At Cook Medical, we partner with health systems to identify the distribution model that best fits their needs. We're glad to discuss the possibility of shipping Cook Medical items through a third-party distributor or a customer's self-distribution center.

Shipping

Standard shipping is included for most orders, although Cook may require a minimum order quantity or dollar amount. Expedited shipping may be available and subject to an additional cost which will be prepaid by Cook and invoiced to the customer. Cook's shipping policy is subject to change and may be updated from time to time. Please refer to cookmedical.com/support/ordering-returns for current order requirements and further information about shipping options.

Item master clean-up

Cook Medical can perform an item master clean-up for its customers. This includes but is not limited to helping customers correct pricing discrepancies, discover unit of measure discrepancies, and locate unavailable or invalid part numbers; providing GTINs; and offering contract information. Performing an item master clean-up will ensure that the ordering process between the customer and Cook Medical is seamless.

Product use and SKU reduction

Cook Medical can provide cross-referencing to all customers who request it. This includes cross-referencing between a competitor and Cook and between Cook's stock and nonstock items.

Consolidated packaging

Cook's consolidated packaging program combines separate product orders in clear, heat-sealed plastic bags that will ensure that the integrity of each purchase order (PO) is maintained. A packing slip with scannable barcode is included in each heat-sealed pack. Our process includes placing individually bagged POs into as few boxes as possible by using a mutually agreed-upon order cutoff time. Fewer boxes received means a more streamlined receiving process, reduced shipping and freight costs, and reduced cardboard recycling waste and expense.

Sustainability

At Cook, we strive to perform in an environmentally responsible manner by incorporating the best management practices, fostering the sustainable use of natural resources, promoting pollution prevention, reducing waste generation, and recycling and reusing materials where possible within our operations. Cook has a corporate sustainability team responsible for finding new ways to reduce waste for our customers and for us. Currently, our sustainability strategy is focused mainly on improving the environmental performance of our facilities, packaging, and recycling.

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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

Customer Service

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