Zilver® PTX® vs. Eluvia™ size offering and indication*

ZILVER PTX[1]

DIAMETER	LENGTH 40	60	80	100	120	140
5	✔	✔	✔	✔	✔	✔
6	✔	✔	✔	✔	✔	✔
7	✔	✔	✔	✔	✔	✔
8	✔	✔	✔	✔	✔	

Indication for lesion length – **up to 300 mm**

ELUVIA[2]

DIAMETER	LENGTH 40	60	80	100	120	150
5						
6	✔	✔	✔	✔	✔	
7	✔	✔	✔	✔	✔	
8						

Indication for lesion length – **up to 190 mm**

COOK® MEDICAL

* Chart represents sizes available at time of printing.

1. Refer to the Instructions for Use ([IFU0118]) for a clinical data overview.
2. Refer to the Instructions for Use (IFU50565157-01) for a clinical data overview.

Zilver® PTX® Drug-Eluting Peripheral 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® PTX® Drug-Eluting Peripheral Stent is indicated for improving luminal diameter for the treatment of *de novo* or restenotic symptomatic lesions in native vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameter from 4 mm to 7 mm and total lesion lengths up to 300 mm per patient.

CONTRAINDICATIONS: Women who are pregnant, breastfeeding, or plan to become pregnant in the next 5 years should not receive a Zilver PTX Drug-Eluting Peripheral Stent. It is unknown whether paclitaxel will be excreted in human milk, and there is a potential for adverse reaction in nursing infants from paclitaxel exposure. • Patients who cannot receive recommended anti-platelet and/or anti-coagulant therapy. • Patients judged to have a lesion that prevents proper placement of the stent or stent delivery system.

WARNINGS: A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients. See SUMMARY OF CLINICAL INVESTIGATIONS section in the complete Instructions for Use for further information. • Persons with allergic reactions to nitinol, or its components, nickel and titanium, may suffer an allergic reaction to this implant. • Persons allergic to paclitaxel or structurally-related compounds may suffer an allergic reaction to this implant. • The inner package should not be opened or damaged prior to use to maintain sterility; do not use if inner package is opened or damaged. • The use of this Drug-Eluting Peripheral Stent carries the risks associated with peripheral artery stenting, including vascular complications, and/or bleeding events. • The safety and effectiveness of implanting multiple Zilver PTX Drug-Eluting Peripheral Stents with a total drug coating quantity of greater than 3 mg paclitaxel (i.e., an additive stent length greater than 160mm per limb) has not been established.

PRECAUTIONS: To avoid involvement of the common femoral artery, the most proximal stent end should be placed at least 1 cm below the origin of the superficial femoral artery. To avoid involvement of the below-the-knee popliteal artery, the most distal stent end should be placed above the plane of the femoral epicondyles. • This product is intended for use by physicians trained and experienced in diagnostic and interventional vascular techniques. Standard techniques for interventional vascular procedures should be employed. • Manipulation of the Zilver PTX Drug-Eluting Peripheral Stent requires fluoroscopic control. • Do not try to push the delivery system through stenoses that cannot be dilated to permit passage of the introducer catheter. • If resistance is met during advancement of the delivery system, do not force passage. Remove the delivery system and replace with a new device. • Do not try to remove the stent from the introducer system before use. • Ensure that the red safety lock is not inadvertently depressed before stent deployment is desired. • A 0.035 inch (0.89mm) diameter wire guide should be used during tracking, deployment, and removal in order to ensure adequate support of the system. If hydrophilic wire guides are used, they must be kept fully activated. • Do not use excessive force to deploy the stent. If excessive resistance is felt when beginning deployment, remove the delivery system without deploying the stent and replace with a new device. • Do not expose the delivery system to organic solvents (e.g., alcohol). • Do not use power injection systems with the delivery system. • Do not torque the delivery system during introduction or deployment. • The device is intended for single use only. Attempts to reprocess, resterilize and/or reuse may lead to device failure and/or transmission of disease. • Appropriate antiplatelet/anticoagulant therapy should be administered pre- and post-procedure (**see section entitled PRE- and POST-PROCEDURE ANTIPLATELET REGIMEN in the complete Instructions for Use**). Use in patients who are unable to tolerate the appropriate antiplatelet therapy is not recommended. • Safety and effectiveness of the Zilver PTX Drug-Eluting Peripheral Stent has not been demonstrated in patients with a history of bleeding disorders. • Use of the Zilver PTX Drug-Eluting Peripheral Stent in an arterial vessel where leakage from the artery could be exacerbated by placement of the stent is not recommended. • A low incidence of stent fracture has been reported (0.9% at 12 months in the randomized pivotal study). Although no clinical sequelae were associated with stent fracture in the randomized study through 12 months, the long-term clinical consequence of stent fracture is not yet established. The majority of stent fractures were associated with stent elongation ≥ 10% at deployment. Therefore, care should be taken when deploying the stent to minimize the risk of stent fracture due to elongation at implant. • After stent deployment begins, the stent retraction sheath cannot be re-advanced and the stent cannot be re-captured. • If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol). • Do not use the stent after the "Use By" date specified on the package. • Flow restrictions remaining after stent deployment (e.g., residual proximal or distal stenosis or dissection, or poor distal outflow) may increase the risk of stent thrombosis. Inflow and outflow should be assessed at procedure completion and additional measures considered (e.g., additional PTA, adjunctive stenting, or distal bypass) if necessary to maintain good inflow and outflow. • Following stent deployment, if resistance is met during the withdrawal of the delivery system, carefully remove the delivery system and wire guide as a unit. If resistance is still encountered during removal of the delivery system and wire guide as a unit, remove the wire guide, delivery system and introducer sheath together as a unit.

POTENTIAL ADVERSE EVENTS: Potential adverse events that may occur include, but are not limited to, the following: Allergic reaction to anticoagulant and/or antithrombotic therapy or contrast medium • Allergic reaction to nitinol • Atheroembolization (Blue Toe Syndrome) • Arterial aneurysm • Arterial rupture • Arterial thrombosis • Arteriovenous fistula • Death • Embolism • Hematoma/hemorrhage • Hypersensitivity reactions • Infection • Infection/abscess formation at access site • Ischemia requiring intervention (bypass or amputation of toe, foot, or leg) • Pseudoaneurysm formation • Renal failure • Restenosis of the stented artery • Stent embolization • Stent malapposition • Stent migration • Stent strut fracture • Vessel perforation or rupture • Worsened claudication/rest pain. Although systemic effects are not anticipated, refer to the Physicians' Desk Reference for more information on the potential adverse events observed with paclitaxel. Potential adverse events, not described in the above source, may be unique to the paclitaxel drug coating: • Allergic/immunologic reaction to the drug coating • Alopecia • Anemia • Blood product transfusion • Gastrointestinal symptoms • Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia) • Hepatic enzyme changes • Histologic changes in vessel wall, including inflammation, cellular damage, or necrosis • Myalgia/Arthralgia • Myelosuppression • Peripheral neuropathy

See Instructions for Use for full product information.

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