Nester® Embolization Coils and Microcoils

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

INTENDED USE: Nester Embolization Coils and Microcoils are intended for arterial and venous embolization in the peripheral vasculature.

CONTRAINDICATIONS: None known.

WARNINGS: Positioning of Embolization Coils and Microcoils should be done with particular care. Coils should not be left too close to the inlets of arteries and should be intermeshed with previously placed coils if possible. A minimal but sufficient arterial blood flow should remain to hold the coils against the previously placed coils until a solid clot ensures permanent fixation. The purpose of these suggestions is to minimize the possibility of loose coils becoming dislodged and obstructing a normal and essential arterial channel. • Nester Embolization Coils and Microcoils are not recommended for use with polyurethane catheters or catheters with sideports. If a catheter with sideports is used, the embolus may lodge in the sideport or pass inadvertently through it. Use of a polyurethane catheter may also result in lodging of the embolus within the catheter. • If difficulties occur when deploying the embolization coil, withdraw the wire guide, coil and angiographic catheter simultaneously as a unit.

PRECAUTIONS: The product is intended for use by physicians trained and experienced in embolization techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed. • Perform an angiogram prior to embolization to determine correct catheter position. • Prior to introduction of the embolization coil, flush the angiographic catheter with saline. • **If using a .018 inch Nester Embolization Microcoil, ensure that the delivery catheter has an internal diameter (ID) of .018 to .025 inch.**

See instructions for use for full product information.

AB_T_NEC2_REV0

Tornado® Embolization Coils and Microcoils

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

INTENDED USE: Tornado Embolization Coils and Microcoils are intended for arterial and venous embolization in the peripheral vasculature.

CONTRAINDICATIONS: None known.

WARNINGS: Positioning of Embolization Coils and Microcoils should be done with particular care. Coils should not be left too close to the inlets of arteries and should be intermeshed with previously placed coils if possible. A minimal but sufficient arterial blood flow should remain to hold the coils against the previously placed coils until a solid clot ensures permanent fixation. The purpose of these suggestions is to minimize the possibility of loose coils becoming dislodged and obstructing a normal and essential arterial channel. • Tornado Embolization Coils and Microcoils are not recommended for use with polyurethane catheters or catheters with sideports. If a catheter with sideports is used, the embolus may lodge in the sideport or pass inadvertently through it. Use of a polyurethane catheter may also result in lodging of the embolus within the catheter. • If difficulties occur when deploying the embolization coil, withdraw the wire guide, coil and angiographic catheter simultaneously as a unit.

PRECAUTIONS: The product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed. • Perform an angiogram prior to embolization to determine correct catheter position. • Prior to introduction of the embolization coil, flush the angiographic catheter with saline. • **If using a .018 inch Tornado Embolization Microcoil, ensure that the delivery catheter has an internal diameter (ID) of .018 to .025 inch.**

See instructions for use for full product information.

AB_T_TEM2_REV0

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.

AB_IFU0118_REV4

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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