Nester® Embolization Coils and Microwires

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 Microwires are intended for arterial and venous embolization in the peripheral vasculature.

CONTRAINDICATIONS: None known.

WARNINGS: Positioning of Embolization Coils and Microwires should be done with particular care. Coils should not be left too close to the inlet of arteries and should be interlaced with previously placed coil(s) if possible. A minimal but sufficient arterial blood flow should remain to hold the coils against the previously placed coils until a solid clot ensues permanent fixation. The purpose of these suggestions is to minimize the possibility of loose coils becoming dislodged and obstructing a normal or essential arterial channel. Nester Embolization Coils and Microwires 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 0.018 inch Nester Embolization Microwire, ensure that the delivery catheter has an internal diameter (ID) of 0.18 to 0.23 inch.

See instructions for use for full product information.

Tornado® Embolization Coils and Microwires

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 Microwires are intended for arterial and venous embolization in the peripheral vasculature.

CONTRAINDICATIONS: None known.

WARNINGS: Positioning of Embolization Coils and Microwires should be done with particular care. Coils should not be left too close to the inlet of arteries and should be interlaced with previously placed coil(s) if possible. A minimal but sufficient arterial blood flow should remain to hold the coils against the previously placed coils until a solid clot ensues permanent fixation. The purpose of these suggestions is to minimize the possibility of loose coils becoming dislodged and obstructing a normal or essential arterial channel.

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.

See instructions for use for full product information.

Zilver® PTFE Drug-Eluting Peripheral Stent

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

INDICATIONS FOR USE: The Zilver® PTFE Drug-Eluting Peripheral Stent is indicated for improving tinalmural diameter for the treatment of de novo or restenotic symptomatic lesions in native vascular disease of the above-listed femoropopliteal arteries having reference vessel diameter of 6 mm to 7 mm and total lesion length 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 PTFE 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 antplatelet and/or anticoagulant 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-coating 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 revascularizations. 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 information on dose, frequency, and potential adverse events related to this implant. - Persons allergic to paclitaxel or structurally-related compounds may experience 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 percutaneous transluminal angioplasty, including vascular rupture, dissection, and vascular stenosis. - The safety and effectiveness of implanted vascular stents for femoropopliteal peripheral arteries has not been established.

PRECAUTIONS: To avoid involvement of the femoral arterial wall in the most distal stent end should be placed above the plane of the femoral epicondylar condyles. 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 PTFE 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 introducer catheter and replace with a new device. - Do not try to remove the stent from the introducer system before use. - Ensure that the safety lock(s) are 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 stent. - If the stent guidewire is 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, reseal, reseal, and/or reuse may lead to device failure and/or transmission of disease. - Appropriate antplatelet/anticoagulant therapy should be administered pre- and post-procedure (see section entitled PRE- AND POST-PROCEDURE ANTIPATELET REGIMEN in the complete instructions for use). - Use in patients who are unable to tolerate the appropriate antplatelet therapy is not recommended. - Safety and effectiveness of the Zilver PTFE Drug-Eluting Peripheral Stent has not been demonstrated in patients with a history of bleeding disorders. - Use of the Zilver PTFE Drug-Eluting Peripheral Stent in an arterial vessel where leakage from the artery could be demonstrated by placement of the stent is not recommended. - A few incidence of stent fracture has been reported (0.3%) at 12 months in the randomized pivotal study). - Although in clinical studies were associated with stent fracture in the randomized study through 12 months, the long-term clinical consequence of stent fracture has 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.

See instructions for use for full product information.
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