PHILIPS

Important safety information
Drug-Coated Angioplasty Balloon Catheter – Stellarex

Indications for Use

The Stellarex 0.035" OTW Drug-coated Angioplasty Balloon is indicated for percutaneous transluminal angioplasty (PTA), after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions up to 180 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-6 mm.

Contraindications

The Stellarex™ 0.035" OTW Drug-coated Angioplasty Balloon is contraindicated for use in:

- Patients with known hypersensitivity to paclitaxel or structurally related compounds.
- Patients who cannot receive recommended antiplatelet and/or anticoagulation therapy.
- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children.
- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system.

Potential Adverse Events

Possible adverse effects associated with the balloon dilation procedure include, but are not limited to: Abrupt vessel closure; Allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (drug, excipients, and materials); Amputation/ Loss of limb; Arrhythmias; Arterial aneurysm; Thrombosis; Arterio-venous fistula (AVF); Bleeding; Death; Embolism/Device embolism; Fever; Hematoma; Hemorrhage; Hypertension/Hypotension; Infection or pain at insertion site; Inflammation; Ischemia or infarction of tissue/organ; Occlusion; Pain or tenderness; Peripheral edema; Pseudoaneurysm; Renal insufficiency or failure; Restenosis; Sepsis or systemic infection; Shock; Stroke/Cerebrovascular accident; Vessel dissection, perforation, rupture, spasm, or recoil; Vessel trauma which requires surgical repair.

Potential complications of peripheral balloon catheterization include, but are not limited to: Balloon rupture; Detachment of a component of the balloon and/or catheter system; Failure of the balloon to perform as intended; Failure to cross the lesion.

Potential complications which may be associated with the addition of paclitaxel to the balloon include, but may not be limited to the following: Allergic/immunologic reaction to paclitaxel; Alopecia; Anemia; Gastrointestinal symptoms (diarrhea, nausea, pain, vomiting); Hematologic dyscrasia (including neutropenia, leucopenia, thrombocytopenia); Hepatic enzyme changes; Histologic changes in vessel wall including inflammation, cellular damage, or necrosis; Myalgia/Arthralgia; Myelosuppression; Peripheral neuropathy.

Caution: Federal law restricts this device to sale by or on the order of a physician.