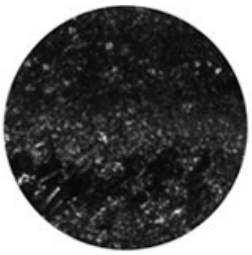
(https://www.stellarexdcb.com/)

Stellarex EnduraCoat technology

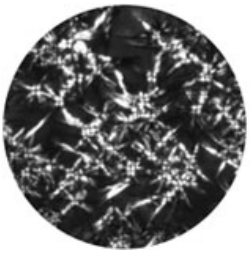
Patented Stellarex EnduraCoat is a differentiated technology designed for performance in complex and severely calcified lesions and patients with multiple comorbidities.

Hybrid paclitaxel + polyethylene glycol = top-tier outcomes

Hybrid paclitaxel (PTX) formulation + PEG excipient



Amorphous PTX
enhances coating durability and prompt drug availability for immediate action and short-term residency[7] (https://www.stellarexdcb.com/atk/references/)



Crystalline PTX
forms drug depots that dissolve into tissue slowly for sustained residency[7]
(https://www.stellarexdcb.com/atk/references/)

Polythene glycol (PEG) excipient
PEG's durability, adhesion, flexibility, elongation and elasticity may help prevent premature drug loss during handling, tracking and inflation

Stellarex Paclitaxel Animation

PHILIPS
Stellarex
(https://www.stellarexdcb.com/)

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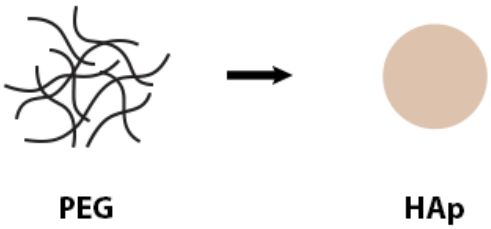

Designed for performance in calcium

- PEG forms strong ionic bonds with hydroxyl apatite (HAp),[12] (https://www.stellarexdcb.com/atk/references/) the primary component of calcified atherosclerotic lesions, which may limit PTX washout in the presence of calcium
- PEG may protect PTX, giving it time to be absorbed into vessel when calcium is present

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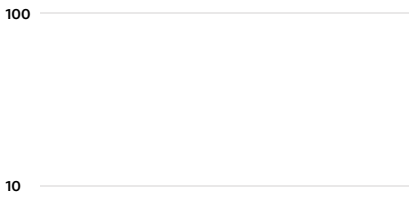
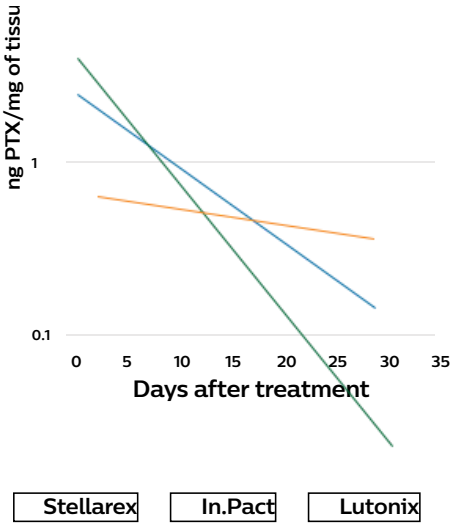
High transfer efficiency and effective residency[9,11] (https://www.stellarexdcb.com/atk/references/)

Stellarex EnduraCoat technology achieves uniform and acute drug transfer and sustained tissue residency at therapeutic levels through 28 days, minimizing restenosis.

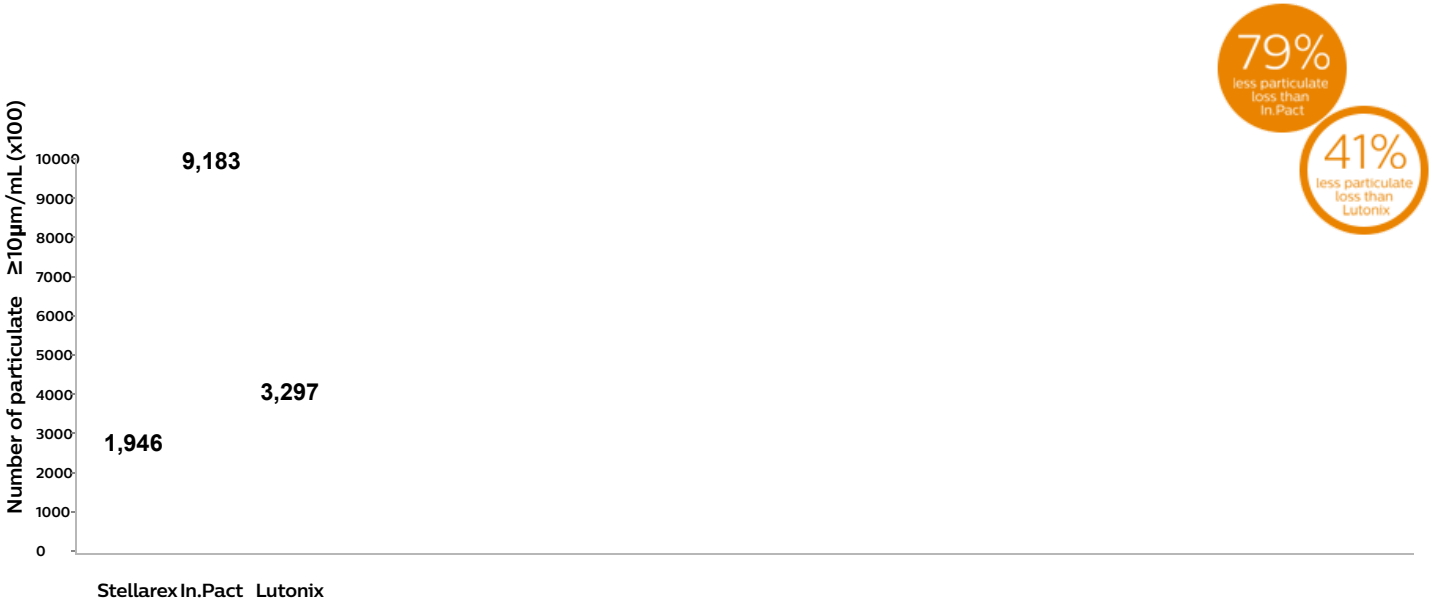


(https://www.stellarexdcb.com/)



Low particulate loss

Stellarex demonstrates low particulate loss,[9] (https://www.stellarexdcb.com/atk/references/) which may reduce the risk of downstream embolization and, at the same time, enable a low therapeutic drug dose.



Based on bench study and results may not be indicative of clinical results

Anti-restenotic effect

A comparative study of Stellarex versus PTA in a swine model of in-stent restenosis demonstrates Stellarex DCB's efficacy at 28 days, indicated by minimal luminal loss and consistent treatment effect.[9] (https://www.stellarexdcb.com/atk/references/)

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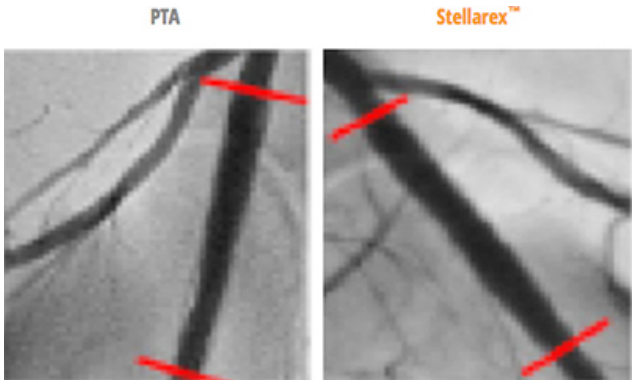
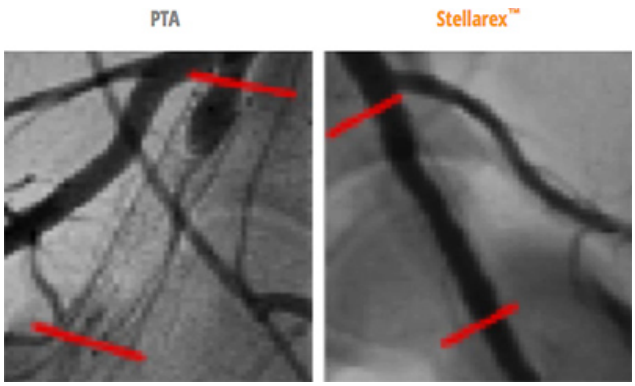


Day 28



See more about the Stellarex difference

Download info sheet (https://www.stellarexdcb.com/wp-content/uploads/2017/06/Stellarex-EnduraCoat-Technology-Brochure.pdf)

(https://www.usa.philips.com/healthcare)

DISCLAIMER: This website is intended for physician education only. Patients should consult with their physician with questions related to PAD.

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

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

- rteries, renal arteries and supra-aortic/cerebrovascular arteries
- dged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system

(https://www.stellarexdcb.com/)

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 that requires surgical repair; 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.

Additional complications that 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, leukopenia, 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