PHILIPS

Stellarex

Drug-coated 0.035"
angioplasty balloon

The clear DCB choice

Featuring **EnduraCoat** technology

Top-tier outcomes with the lowest therapeutic drug dose in all patients–**common to complex.**

In common patient populations

89.0%

patency[2]

In highly complex patients

82.3%

patency[2]

The Stellarex **difference**

Hybrid paclitaxel **+** PEG excipient **=** Top-tier clinical outcomes

EnduraCoat technology

- Efficient drug transfer
- Effective tissue residency
- High coating durability
- Minimal particulate loss

> Stellarex technology in one word, **predictability**—predictable results, clinical efficacy that's sustained over time and no safety concerns.

Juan F. Granada, MD, FACC
CRF Skirball Center for Innovation, Orangeburg, NY

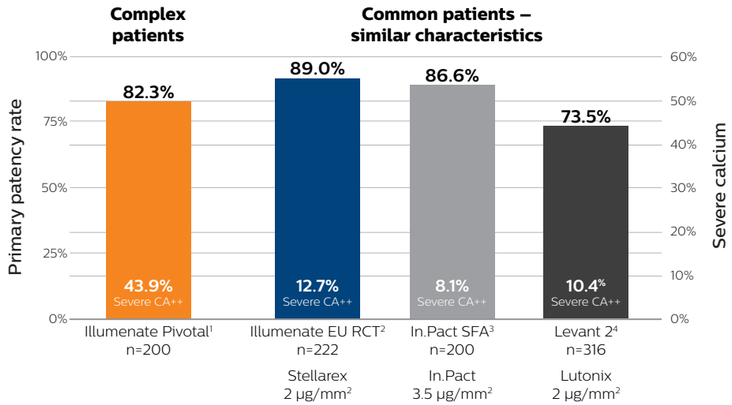
Choose **efficacy**

Top-tier patency

Stellarex has the highest patency rate of any DCB in a randomized controlled trial, with up to 43% less drug load.

- 89% primary patency in common patients with similar characteristics[1]
- 82.3% patency in a complex patient population with the highest reported rate of severe calcium
- The only commercially available DCB with two reported randomized controlled trials

Competitor studies are independent clinical trials with different protocols and definitions. Therefore, they are not head-to-head comparisons, and data presented cannot be directly compared. Calcium definitions may vary from study to study, and the rates presented here are based on those used and reported in each respective study. Complex patients refers to high rates of severe calcium, diabetes and renal insufficiency. Primary patency based on Kaplan-Meier estimates.



Highest primary patency in similar patients with up to

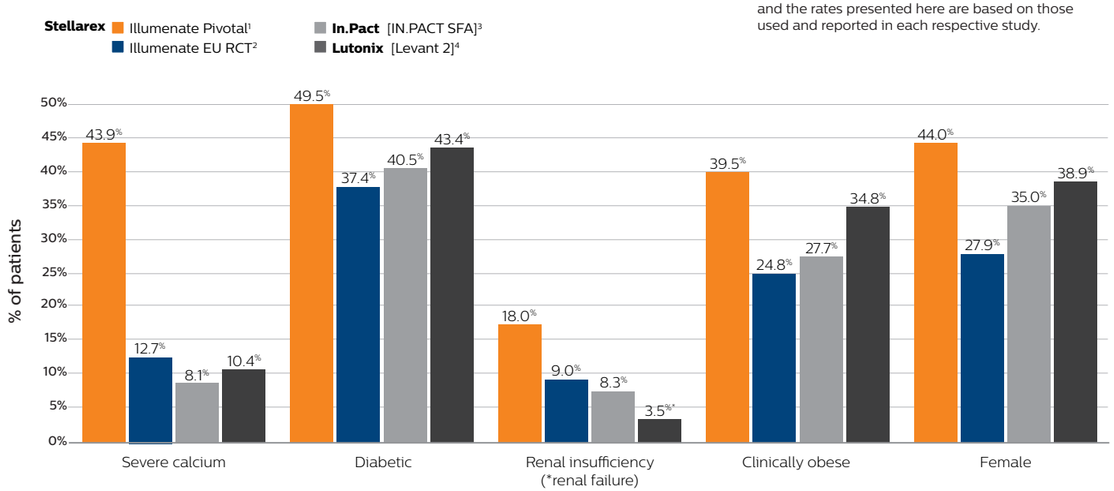
43%

Less drug load[1,3]

Highly complex patients

Stellarex delivers top-tier outcomes in more highly complex lesions and patient comorbidities than any DCB RCT—like the patients you see every day.

Data overview for informational purposes only and not for head-to-head comparison. Calcium definitions may vary from study to study, and the rates presented here are based on those used and reported in each respective study.

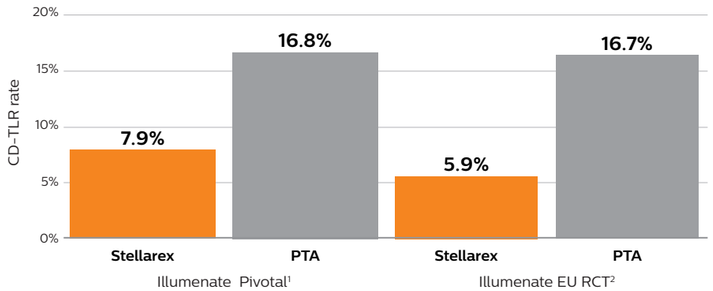


Choose **safety**

Low CD-TLR

Consistently low clinically driven target lesion revascularization rates demonstrate the safety of Stellarex across common to complex patients.

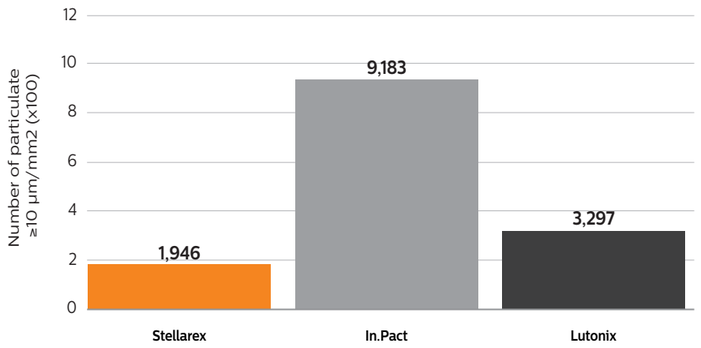
- Safe treatment for the patients you see every day
- Low CD-TLR rates in both Stellarex RCTs
- Clinically proven effect



2 µg/mm²
Low drug dose

Why low dose matters

To lower the likelihood of any potential—and potentially harmful— dose excess and particulate downstream effect possibly resulting in a delay of wound healing, loss of microcirculation and creation of aneurysms.



Bench test may not be indicative of clinical results.

Low particulate loss

In a bench test, Stellarex demonstrates minimal particulate loss,[5] reducing the risk of downstream embolization. Stellarex coating stability enables low therapeutic drug dose.

79% Less particulate loss than In.PACT

41% Less particulate loss than Lutonix

The Stellarex **difference**

EnduraCoat technology equals hybrid paclitaxel plus PEG

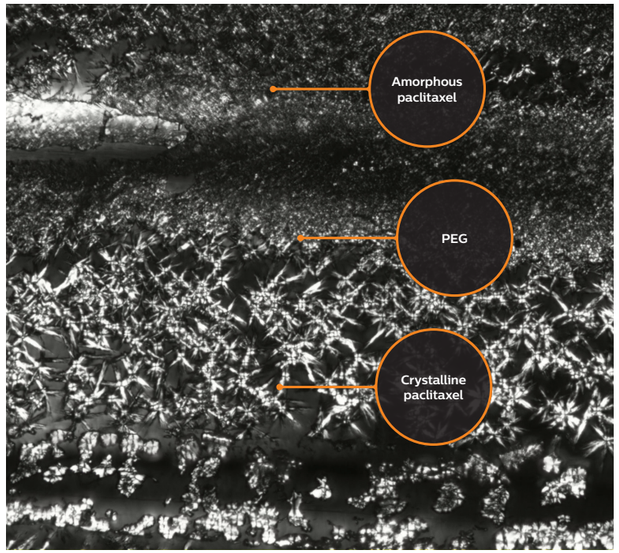
Stellarex with EnduraCoat Technology offers a critical balance of hybrid paclitaxel with Polyethylene Glycol (PEG) excipient—to provide efficient drug transfer and effective tissue residency with high coating durability and minimal particulate loss.

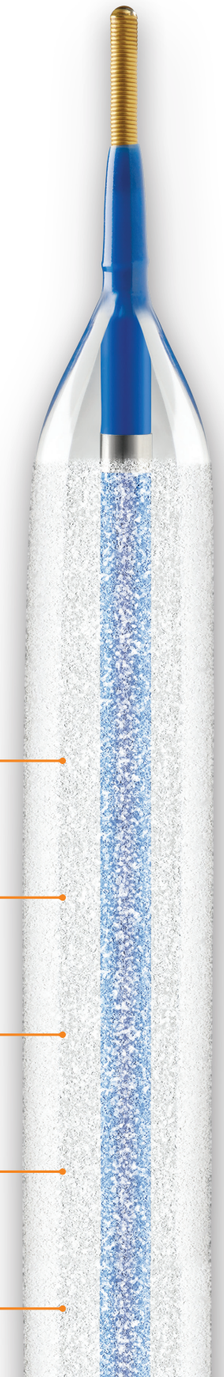
- Hybrid formulation offers the advantages of coating durability and prompt drug availability by the amorphous paclitaxel and the sustained tissue release of crystalline paclitaxel
- PEG's high molecular weight offers excellent adhesion, flexibility, elongation and elasticity[6] for adaptability during balloon deformation such as flexion, torsion and compression
- Exceptional durability during handling, tracking and inflation to prevent premature drug loss
- PEG may limit the amount of drug washout in the presence of calcium due to its affinity to HAp (hydroxyl apatite), the primary component of calcified atherosclerotic lesions[7]

Exceptional balloon performance

Low tip profile (0.039") and high pushability facilitate trackability and lesion crossing, even in challenging anatomies and through previously deployed stents.

Stellarex EnduraCoat technology under optical microscopy[5]





Stellarex 0.035" OTW drug-coated angioplasty balloon

Product catalog number	Sheath size (Fr)	Balloon diameter (mm)	Balloon length (mm)	Shaft length (cm)	Nominal pressure (atm)	Rated burst pressure (atm)
AB035SX040040080	6	4	40	80	10	20
AB035SX040060080	6	4	60	80	10	20
AB035SX040080080	6	4	80	80	10	20
AB035SX040120080	6	4	120	80	10	20
AB035SX050040080	6	5	40	80	10	18
AB035SX050060080	6	5	60	80	10	18
AB035SX050080080	6	5	80	80	10	18
AB035SX050120080	6	5	120	80	10	16
AB035SX060040080	6	6	40	80	8	14
AB035SX060060080	6	6	60	80	8	14
AB035SX060080080	6	6	80	80	8	14
AB035SX060120080	6	6	120	80	8	12
AB035SX040040135	6	4	40	135	10	20
AB035SX040060135	6	4	60	135	10	20
AB035SX040080135	6	4	80	135	10	20
AB035SX040120135	6	4	120	135	10	20
AB035SX050040135	6	5	40	135	10	18
AB035SX050060135	6	5	60	135	10	18
AB035SX050080135	6	5	80	135	10	18
AB035SX050120135	6	5	120	135	10	16
AB035SX060040135	6	6	40	135	8	14
AB035SX060060135	6	6	60	135	8	14
AB035SX060080135	6	6	80	135	8	14
AB035SX060120135	6	6	120	135	8	12

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 180 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-6 mm.

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

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.

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