Important safety information

The Stellarex 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 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 which 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 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

1. Krishnan P, et al. Circulation. 2017;136:1102-1113.
2. Schroeder H, et al. Circulation. 2017;135:2227-2236.
3. Jaff M. Drug-coated balloon treatment for patients with intermittent claudication: insights from the In.Pact Global full clinical cohort. Oral Presentation at: VIVA 2016; September 19-22, 2016; Las Vegas, NV. In.Pact Summary of Safety and Effectiveness Data (SSED).
4. Rosenfield K, Jaff MR, White CJ, et al. NEJM 2015; 373:145-153. Lutonix Summary of Safety and Effectiveness Data (SSED).
5. Roch-Singh, et al. Cath and Cardiovasc Intervent. 2014;83:E212-E220.
6. Holden. Comparing trial data in the management of calcified arteries. Charing Cross 2018. April 24-26, 2018; London, UK.
7. Venkatasubbu GD, et al. Surface modification and paclitaxel drug delivery of folic acid modified polyethylene glycol functionalized hydroxyapatite nanoparticles. Powder Technology. 2013;235:437-442.
8. Mark J, et al. Physical Properties of Polymers. Cambridge University Press. 3rd ed. 2004.
9. Rocha-Sing. DCB Potential Beyond the Selected SFA Lesions Types Studied in Trials to Date. What We Know About the 'Real World'. LINC 2017. January 24-27, 2017; Leipzig, Germany.
10. Rocha-Singh CCI. 2014;83:E212-E220.

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PHILIPS

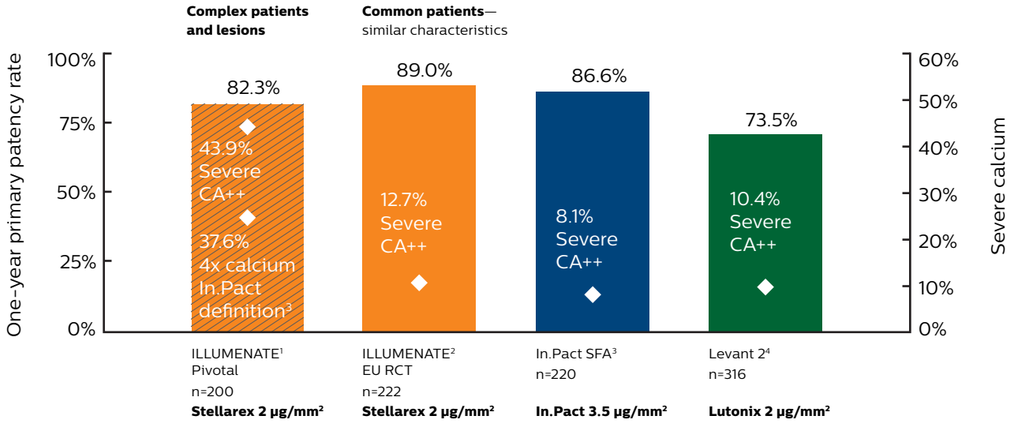
Stellarex

Drug-coated 0.035"
angioplasty balloon

Stellarex in calcium analysis

Top-tier patency
with the highest rates of severe calcium

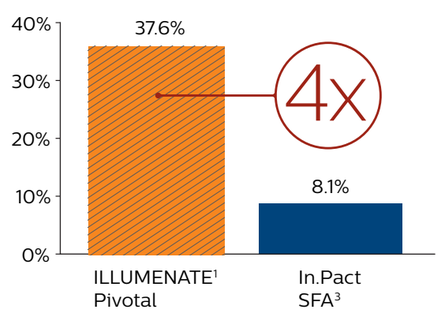
Philips Stellarex is the only DCB to demonstrate top-tier patency in the highest rates of severely calcified lesions in an RCT, regardless of definition. The prevalence of calcified lesions increases with age and diabetes[5], making Stellarex the clear treatment choice for today's PAD patients.



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.

Proven in four times the number of patients with severe calcium

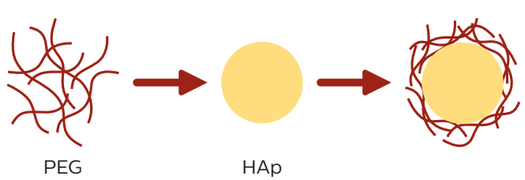
Using In.Pact's definition of severe calcium, Stellarex enrolled four times the number of patients with severely calcified lesions as In.Pact SFA.[6]



Designed for performance in calcium

Stellarex's proprietary low dose EnduraCoat technology was designed with the excipient polyethylene glycol (PEG). PEG has a natural affinity to hydroxyl apatite, the primary component of calcified lesions.[7] PEG's affinity to HAp may limit drug washout in the presence of calcified lesions.

PEG's large molecular weight[8] may protect the hybrid paclitaxel, giving it time to be absorbed into the vessel even when calcium is present.

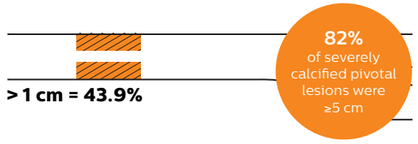


The clear choice even by In.Pact SFA's definition

Inconsistent calcium definitions are used across PAD trials, making it difficult to interpret outcomes or put data in context.

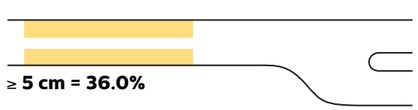
Objective
Assess the level of correlation across different definitions of severe calcium through an independent quantitative analysis.

Severe calcium definitions
Even when severe calcium definitions are more stringent, a high percentage of Stellarex lesions are consistently classified as severe.



BIDMC[1] (ILLUMENATE Pivotal and Global): both sides of the arterial wall and extending more than 1 cm of length prior to contrast injection or digital subtraction angiography.

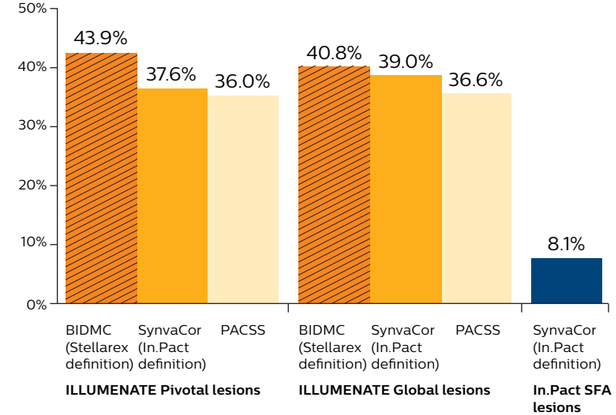
SynvaCor[9] (IN.PACT SFA): visible along both sides of the arterial wall, covers 2 cm or greater of the target lesion area, encompasses 50% of the total target lesion treatment area by visual estimate and/or the calcium is circumferential in nature or classified as exophytic calcification, which significantly impedes blood flow in the vessel.



PACSS[10] Grade 4: Bilateral calcification ≥ 5 cm
- Intimal calcification
- Medial calcification
- Mixed type

Study design
- Angiograms from the Stellarex ILLUMENATE Pivotal and Global trials were reevaluated by BIDMC Core Laboratory
- A novel algorithm permitted cross classification comparisons for each calcium definition
- Classifications included:
  - BIDMC (ILLUMENATE Pivotal & Global)
  - SynvaCor (IN.PACT SFA)
  - PACSS
- Independent database management and data analysis

Portion of severely calcified lesions across definitions[6]
Rates of severe calcification in ILLUMENATE Pivotal and Global were similar across BIDMC, SynvaCor/In.Pact and PACSS definitions. In ~90% of lesions, the severity of calcium was the same when using the SynvaCor/In.Pact definition.



Conclusions
- Only Stellarex has the top-tier results in the highest rates of complex patients and severely calcified lesions
- The frequency of severe calcium was four times higher in ILLUMENATE Pivotal and Global even when using the In.Pact SFA definition