PHILIPS

Stellarex

Drug-coated 0.035"
angioplasty balloon

The clear DCB choice

Featuring **EnduraCoat** technology

Calcium can be beat

Stellarex is the only DCB reported to have durable patency at 2 years in severely calcified lesions—showing patients with severe calcium can have a meaningful treatment effect with Stellarex.

- 67.8% two-year patency in severely calcified lesions
- Demonstrates a robust treatment effect over PTA in severely calcified lesions[1]
- 82% of severely calcified segments are ≥ 5 cm long[4]

Stellarex is the only DCB to be proven in

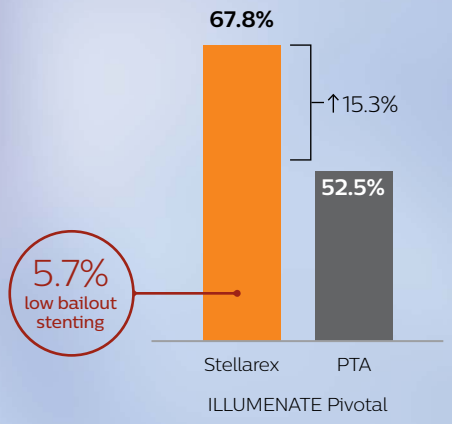
4x

the rate of severe calcium by multiple definitions[4]

The smart treatment choice for today's PAD patients

The prevalence of calcified lesions increases with age and diabetes.[5] Shown to work in calcium, Stellarex is the clear treatment choice for PAD.

Two-year primary patency in severely calcified lesions[1]



ILLUMENATE Pivotal

Pay for the DCB that works in calcium

Only Stellarex gives you confidence that your DCB use and spend in severely calcified lesions will be worthwhile and beneficial to patients.

	Incidence of severe calcium in RCT	Two-year patency rate in severe Ca++	DCB shown effective in RCT with severe Ca++	DCB provides treatment confidence in severe Ca++
Stellarex[1]	43.9%	67.8%	Yes	Yes
In.Pact[3]	8.1%	N/A	?	?
Lutonix[6]	10.4%	N/A	?	?

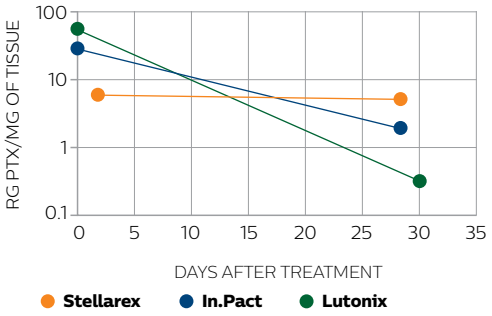
Overview is provided for informational purposes only and not for head-to-head comparisons. Protocols and definitions may vary from study to study.

Differentiated technology— next-generation EnduraCoat

Stellarex EnduraCoat was designed for performance in complex and severely calcified lesions and patients with multiple comorbidities.

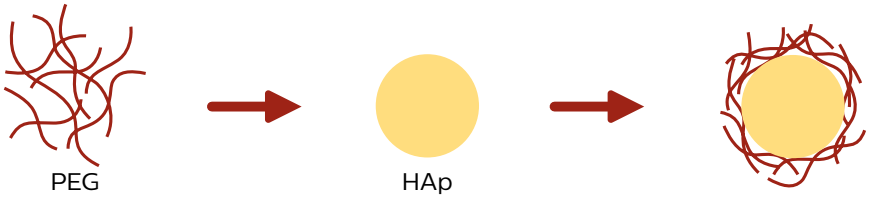
- Hybrid paclitaxel offers prompt drug transfer and sustained tissue residency through 28 day restenotic window[12]
- Excipient polyethylene glycol (PEG) offers excellent adhesion and durability to protect low dose paclitaxel[11]
- Reduces drug loss during transit, relieving clinicians of transit time requirements[8,10]

High transfer efficiency and effective residency[13]



Based on animal testing.

Designed for performance in calcium



PEG forms strong ionic bonds with hydroxyl apatite (HAp), the primary component of calcified atherosclerotic lesions.[9]

PEG's affinity for HAp may result in limited PTX washout in the presence of calcium.

PEG may protect PTX, giving it time to be absorbed into vessel when calcium is present.

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

Why an effective low drug dose matters

Dose excess and particulate downstream possibly results in a delay of wound healing, loss of microcirculation and creation of aneurysms. Stellarex is the only low dose DCB with a statistically significant treatment effect at two years.

2 µg/mm²

Only low drug dose still effective at 2 years[1-3,6]

- In.Pact has a 75% higher drug dose than Stellarex[3,8]
- Compared to Stellarex, In.Pact loses 2.7 times more drug (µg) during tracking to the deployment site[10]
- In.Pact coating visually flakes off during device prep[10]
- Lutonix low dose is mostly amorphous paclitaxel, which may lead to short-term tissue residency[11]

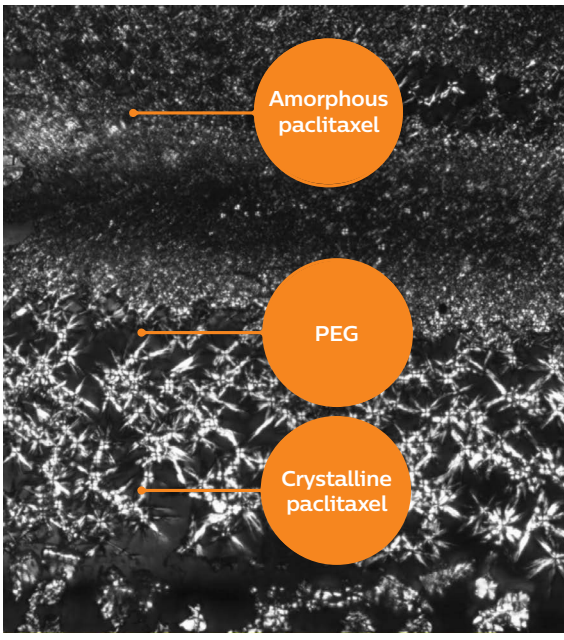


Image on file.

Track

PEG offers exceptional durability during handling, tracking and inflation, helping prevent premature drug loss[10,11]

Deliver

EnduraCoat achieves uniform and efficient drug transfer[13]

Sustain

Hybrid paclitaxel provides prompt drug availability and sustained tissue residency[12]

Treatment that endures
even in complex patients

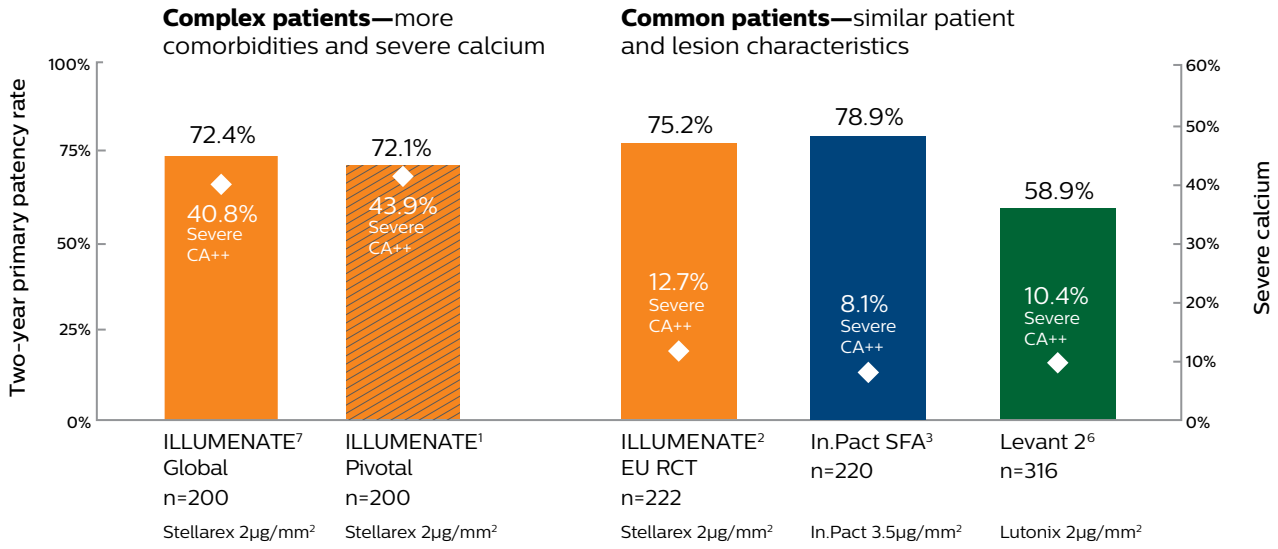
Stellarex exhibits consistent two-year patency across trials—even in the most complex cases. Now, all patients can experience the power of proven results:

- 72.1% patency in ILLUMENATE Pivotal proves only durable two-year RCT results in complex lesions
- 43.9% severe calcium is four or five times the rate of severe calcium studied in competitive trials[4]

Top-tier primary patency in complex patients with up to

43%

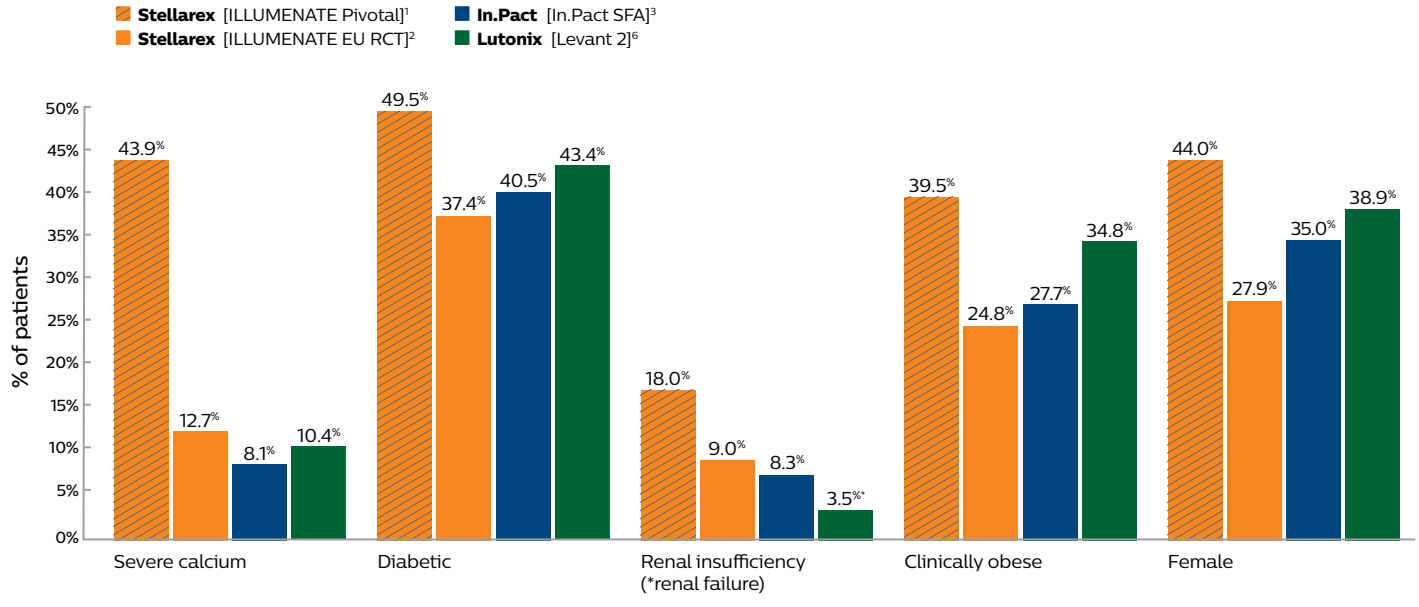
less drug load[1,3]



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.

Show complex patients a better way

Stellarex continues to perform in patients with the highest rates of complex comorbidities—even through two years.



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.

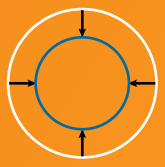
More ease of use, **more efficiencies**

Stellarex enhances time savings—even in challenging anatomies and previously deployed stents. Decide on the DCB designed for ease of use, and feel the difference in your hands.

Product and procedure differences	Lutonix[6]	In.Pact[3]	Stellarex[8]
No transit time requirements limits rushing		✓	✓
Lowest tip profile (0.039") supports ease of trackability and lesion crossing[10]			✓
Tip more tightly hugs 0.035" guide wire design for easy tracking[10]			✓
Lowest tip flaring or "fishmouthing" when traveling around tortuous anatomy[10]			✓
Lowest inflation hold time requirement of 60 seconds			✓
Highest rated burst pressure for complex lesions			✓
Longest catheter working length of 135cm to reach more distal lesions			✓

Efficiency as easy as **1-2-3**

1. **Limit wire exchanges—**Stellarex tracks easily over your choice of guide wire, including 0.035, 0.018 and 0.014, potentially reducing the need for guide wire exchanges.



Stellarex
Over guide wire

2. **Fast tracking—**Stellarex distorts less in tight bends, and the strong low-profile tip inhibits flare, minimizing catch on lesions and maximizing pushability and trackability.[10]

Stellarex
Lateral view

Stellarex
Axial view

In.Pact
Axial view

In.Pact
Lateral view

3. **Less waiting—**At just 60 seconds, Stellarex recommends the shortest inflation hold time of any DCB

Stellarex
1-minute inflation hold

Lutonix
2-minute inflation hold

In.Pact
3-minute inflation hold

"I believe that Stellarex is more deliverable than In.Pact. I specifically have noticed better deliverability when advancing the balloon over 0.014" wires, which makes a clinical difference when treating complex lesions."

Ehrin Armstrong, MD MSc MAS FACC FSCAI FSVM

Director, Interventional Cardiology
VA Eastern Colorado Healthcare System

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)
AB35SX040040080	6	4	40	80	10	20
AB35SX040060080	6	4	60	80	10	20
AB35SX040080080	6	4	80	80	10	20
AB35SX040100080	6	4	100	80	10	20
AB35SX040120080	6	4	120	80	10	20
AB35SX040150080	6	4	150	80	10	20
AB35SX040200080	6	4	200	80	10	20
AB35SX050040080	6	5	40	80	10	18
AB35SX050060080	6	5	60	80	10	18
AB35SX050080080	6	5	80	80	10	18
AB35SX050100080	6	5	100	80	10	18
AB35SX050120080	6	5	120	80	10	16
AB35SX050150080	6	5	150	80	10	16
AB35SX050200080	6	5	200	80	10	16
AB35SX060040080	6	6	40	80	8	14
AB35SX060060080	6	6	60	80	8	14
AB35SX060080080	6	6	80	80	8	14
AB35SX060100080	6	6	100	80	8	14
AB35SX060120080	6	6	120	80	8	12
AB35SX060150080	6	6	150	80	8	12
AB35SX060200080	6	6	200	80	8	11
AB35SX040040135	6	4	40	135	10	20
AB35SX040060135	6	4	60	135	10	20
AB35SX040080135	6	4	80	135	10	20
AB35SX040100135	6	4	100	135	10	20
AB35SX040120135	6	4	120	135	10	20
AB35SX040150135	6	4	150	135	10	20
AB35SX040200135	6	4	200	135	10	20
AB35SX050040135	6	5	40	135	10	18
AB35SX050060135	6	5	60	135	10	18
AB35SX050080135	6	5	80	135	10	18
AB35SX050100135	6	5	100	135	10	18
AB35SX050120135	6	5	120	135	10	16
AB35SX050150135	6	5	150	135	10	16
AB35SX050200135	6	5	200	135	10	16
AB35SX060040135	6	6	40	135	8	14
AB35SX060060135	6	6	60	135	8	14
AB35SX060080135	6	6	80	135	8	14
AB35SX060100135	6	6	100	135	8	14
AB35SX060120135	6	6	120	135	8	12
AB35SX060150135	6	6	150	135	8	12
AB35SX060200135	6	6	200	135	8	11

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.

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

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3. Laird, et al. *J Am Coll Cardio.* 2015;66:2329-2338. In.Pact Summary of Safety and Effectiveness Data (SSED). Medtronic In.Pact Instructions for Use, M052624T001 Rev 1F.
4. Holden. Comparing Trials Data in the Management of Calcified Arteries. Charing Cross 2018. April 24-26, 2018; London, UK.
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7. Zeller. ILLUMENATE Global: 2-year results with the Stellarex DCB in femoropopliteal lesions. Linc. 2018. Leipzig, Germany.
8. Stellarex IFU. P011966-D.
9. 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.
10. Data on file. D044595-00.
11. Mark J, et al. Physical properties of polymers. Cambridge University Press. 3rd ed. 2004.
12. Granada JF. Future directions, clinical applications and local drug delivery technologies. Presented at the Transcatheter Cardiovascular Therapeutics (TCT) 25th Annual Scientific Symposium; October 27-November 1, 2013; San Francisco, California. Slide 7, 15.
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