PHILIPS

Stellarex

Drug coated 0.035” and 0.014” OTW angioplasty balloon family

The clear DCB choice

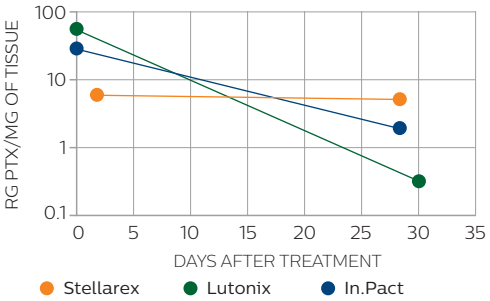
Featuring **EnduraCoat** technology

Differentiated technology – next-generation EnduraCoat

Stellarex EnduraCoat has proven performance in severely calcified lesions and complex patients with multiple comorbidities.

- Hybrid paclitaxel offers prompt drug transfer and sustained tissue residency through 28 day restenotic window[1]
- Excipient polyethylene glycol (PEG) offers excellent adhesion and durability to protect low dose paclitaxel[2,3]
- Reduces drug loss during transit, relieving clinicians of transit time requirements[4,5]

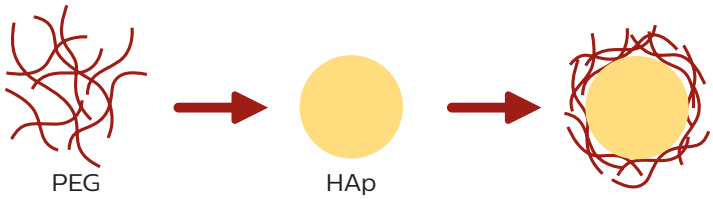
High transfer efficiency and effective residency[6]



Based on animal testing

- PEG forms strong ionic bonds with hydroxyl apatite (HAp), the primary component of calcified atherosclerotic lesions.[7]
- 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.

Proven performance in calcium



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[9-12]. Stellarex is the only low dose DCB with a statistically significant treatment effect in femoropopliteal lesions **beyond 2 years**[13].

2 µg/mm²

Only low DCB drug dose still effective in SFA at 3 years[13]

- In.Pact has a 75% higher drug dose than Stellarex[4,8]
- Compared to Stellarex, In.Pact loses 2.7 times more drug (µg) during tracking to the deployment site[5]
- In.Pact coating visually flakes off during device prep[5]
- Lutonix low dose is mostly amorphous paclitaxel, which may lead to short-term tissue residency[2]

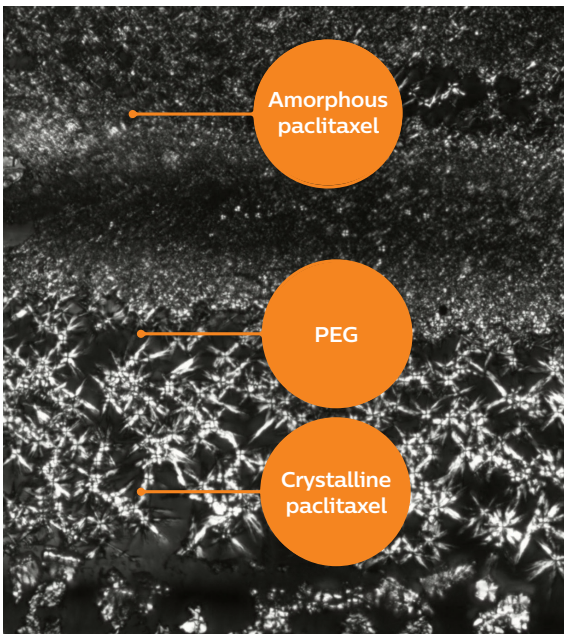


Image on file at Philips..

Track

PEG offers exceptional durability during handling, tracking and inflation, helping prevent premature drug loss[2,5]

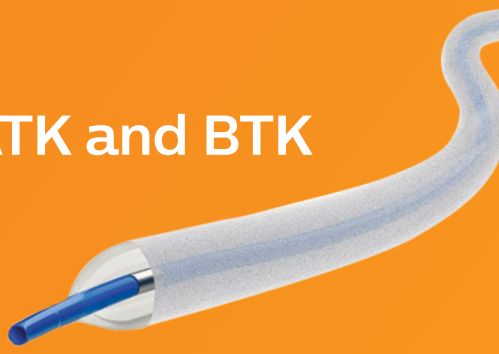
Deliver

EnduraCoat achieves uniform and efficient drug transfer[1]

Sustain

Hybrid paclitaxel provides prompt drug availability with amorphous and sustained tissue Residency with crystalline formulation[1]

Stellarex robust clinical program **for ATK and BTK**



Core-lab adjudication and over
2500 patients treated in clinical trials

Illumenate Clinical Program

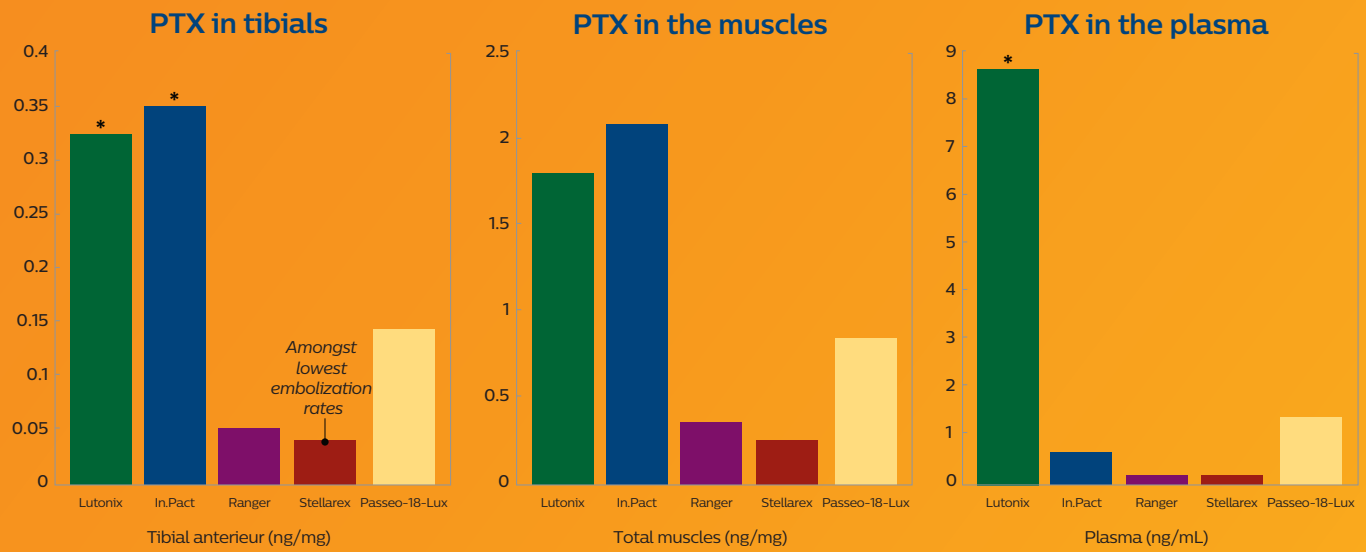
ILLUMENATE FIH	80 patients	3 sites	
ILLUMENATE EU RCT	328 patients	18 sites	
ILLUMENATE Pivotal	300 patients	43 sites	
ILLUMENATE Global	371 patients	37 sites	
ISR Cohort	130 patients	26 sites	
ILLUMENATE PK	25 patients	2 sites	
ILLUMENATE BTK	354 patients	37 sites	Enrolling
ILLUMENATE EU BTK POST MARKET	75 patients	10 sites	Enrolling
SAVER-E-Registry	1,500+ patients	70 sites	Enrolling

● United States ● Europe ● Australia/New Zealand

Minimal PTX embolization with Stellarex shown in an independent pre-clinical study [14]

- Fully independent pre-clinical study confirms low embolization rates with Stellarex.
- Results may have implications while choosing a DCB, especially for BTK and/or CLI.

Blinded evaluation of ptx particles and dose



Courtesy of R. Coscas, Boitet A., oral presentation, LINC 2018.
Based on animal testing: Rabbit model / DCB deployed in Aorta. Blinded evaluation of ptx particles and dose by HPLC (5 different DCBs, n=25)

Top-tier patency and safety with the lowest effective drug dose in all SFA patients – common to complex*†

Common patients in EU RCT study[13]:
- Only low dose DCB reporting 3yr patency
- Statistically significant improvement over PTA (67.5% vs. 59.9%, p=0.05)[13]

Complex patients in US Pivotal study[13] - Stellarex effective in calcium:
- Statistically superior patency even in most complex patients studied in DCB RCT (64.2% vs. 51.0%, p=0.016)[13]
- Highest rate of severely calcified lesions: five times the rate of severe calcium studied in competitive trials[15]
- Clinically relevant difference in CD-TLR at 4 years: 28.2% Stellarex vs. 34.1% PTA (p=0.343)[16]

Top-tier primary patency in complex patients with up to

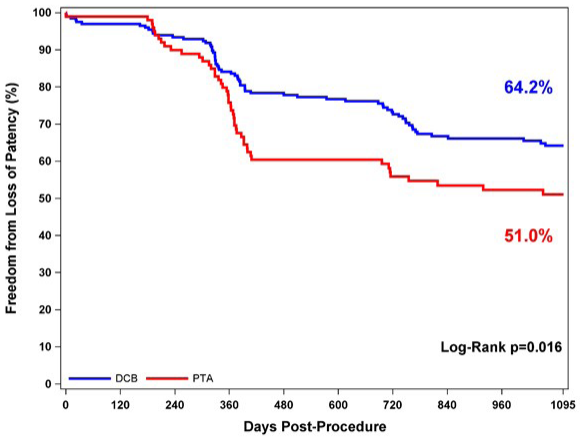
43%

less drug load[8,13]

2 ILLUMENATE RCTs: primary patency through 3 years[13,16]

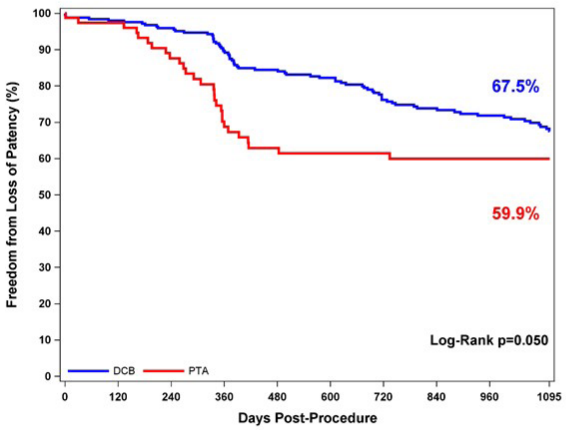
Complex patients*

ILLUMENATE Pivotal



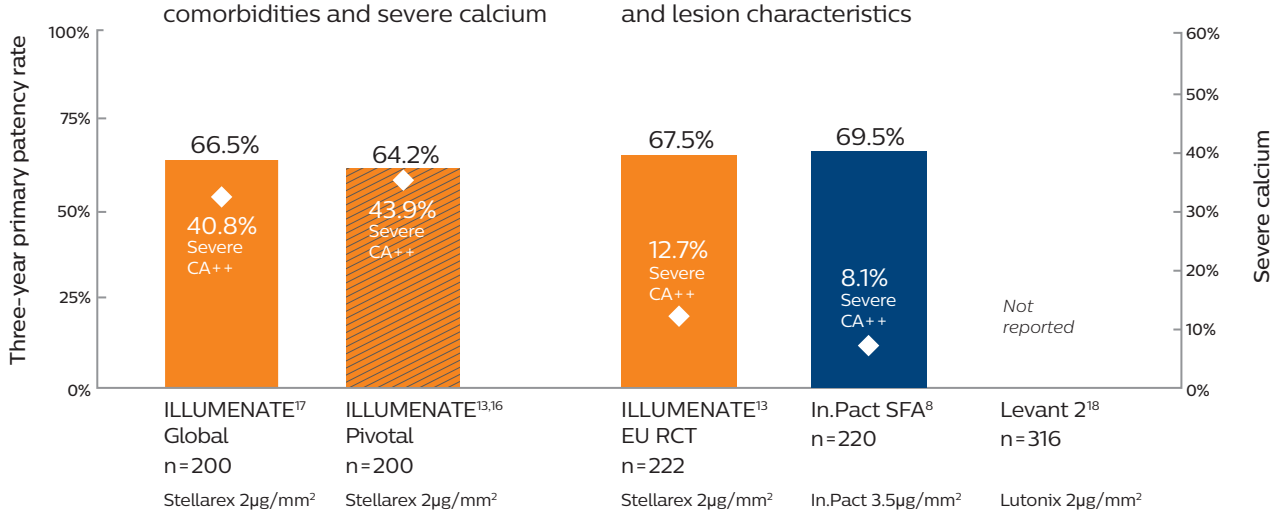
Common patients

ILLUMENATE EU RCT



Complex patients* - more comorbidities and severe calcium

Common patients - similar patient and lesion characteristics



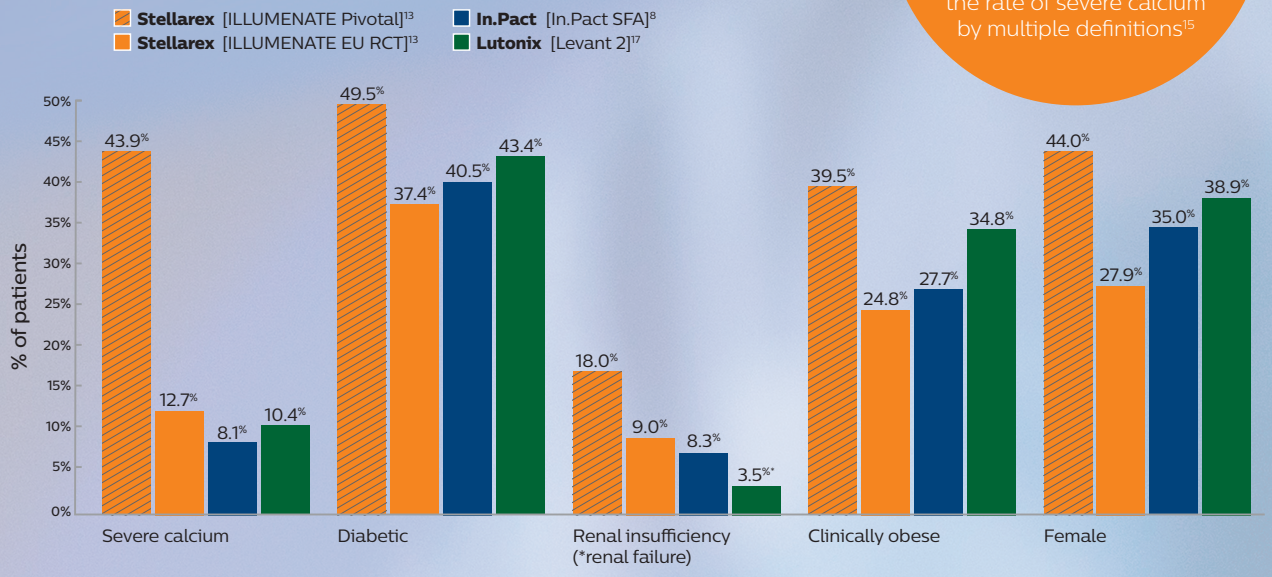
Competitor studies are independent clinical trials with different protocols and definitions. Therefore, they are not head-to-head comparisons, and data presented cannot be directly compared. Calcium definitions may vary from study to study, and the rates presented here are based on those used and reported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

*Complex patients refers to high rates of severe calcium, diabetes and renal insufficiency. Primary patency based on Kaplan-Meier estimates.

Stellarex 0.035" well suited for complex patients*†

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

Stellarex is the only DCB to be proven in **4x** the rate of severe calcium by multiple definitions[15]



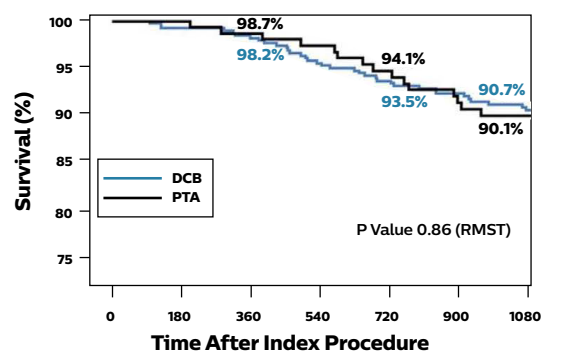
Data overview for informational purposes only and not for head-to-head comparison. Calcium definitions may vary from study to study, and the rates presented here are based on those used and reported in each respective study.
* Complex patients refers to high rates of severe calcium, diabetes and renal insufficiency.

Proven safe in SFA patients in the long run†

- Zero device-related death‡ reported in over 2,300 clinical SFA patients through 3 years [19]
- No mortality signal†† in pooled ILLUMENATE RCT analysis[19,20]
- No differences in all-cause mortality through 4 years in ILLUMENATE US Pivotal[16]

Published patient-level meta-analysis shows no significant differences in mortality rates through 3 years[20]

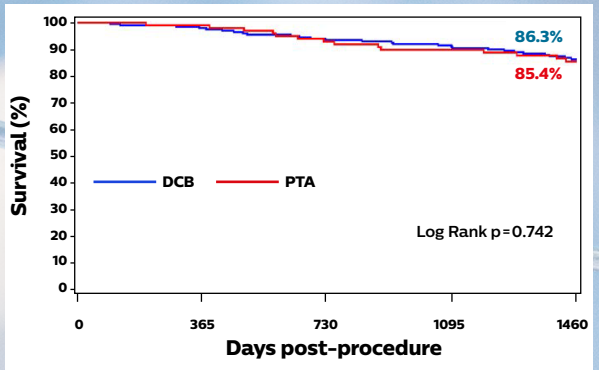
Survival at 3 years in the pooled ILLUMENATE RCT analysis



Patients at Risk							
DCB	419	397	384	363	353	333	301
PTA	170	160	156	148	142	134	115

No mortality signal continues at 4 years[16]

Survival through 4 years in ILLUMENATE US Pivotal[16]



Patients at Risk						
DCB	100	196	186	181	126	
PTA	200	99	91	85	62	

†† No statistically significant difference in mortality
‡Data from independent CEC (clinical events committee) adjudication of all events resulting in death across all studies.

Stellarex for above-the-knee (ATK) treatment

0.035" (0.89mm) OTW drug-coated angioplasty balloon

Product catalogue number	Sheath size (Fr)	Balloon diameter (mm)	Balloon length (mm)	Shaft length (cm)	Nominal pressure (atm)	Rated burst pressure (atm)
A35SX040040080	6	4	40	80	10	20
A35SX040060080	6	4	60	80	10	20
A35SX040080080	6	4	80	80	10	20
A35SX040100080	6	4	100	80	10	20
A35SX040120080	6	4	120	80	10	20
A35SX040150080	6	4	150	80	10	20
A35SX040200080	6	4	200	80	10	20
A35SX050040080	6	5	40	80	10	18
A35SX050060080	6	5	60	80	10	18
A35SX050080080	6	5	80	80	10	18
A35SX050100080	6	5	100	80	10	18
A35SX050120080	6	5	120	80	10	16
A35SX050150080	6	5	150	80	10	16
A35SX050200080	6	5	200	80	10	16
A35SX060040080	6	6	40	80	8	14
A35SX060060080	6	6	60	80	8	14
A35SX060080080	6	6	80	80	8	14
A35SX060100080	6	6	100	80	8	14
A35SX060120080	6	6	120	80	8	12
A35SX060150080	6	6	150	80	8	12
A35SX060200080	6	6	200	80	8	11
A35SX040040135	6	4	40	135	10	20
A35SX040060135	6	4	60	135	10	20
A35SX040080135	6	4	80	135	10	20
A35SX040100135	6	4	100	135	10	20
A35SX040120135	6	4	120	135	10	20
A35SX040150135	6	4	150	135	10	20
A35SX040200135	6	4	200	135	10	20
A35SX050040135	6	5	40	135	10	18
A35SX050060135	6	5	60	135	10	18
A35SX050080135	6	5	80	135	10	18
A35SX050100135	6	5	100	135	10	18
A35SX050120135	6	5	120	135	10	16
A35SX050150135	6	5	150	135	10	16
A35SX050200135	6	5	200	135	10	16
A35SX060040135	6	6	40	135	8	14
A35SX060060135	6	6	60	135	8	14
A35SX060080135	6	6	80	135	8	14
A35SX060100135	6	6	100	135	8	14
A35SX060120135	6	6	120	135	8	12
A35SX060150135	6	6	150	135	8	12
A35SX060200135	6	6	200	135	8	11

Stellarex for below-the-knee (BTK) treatment

0.014" (0.3589mm) **OTW drug-coated angioplasty balloon**

Product catalogue number	Sheath size (Fr)	Balloon diameter (mm)	Balloon length (mm)	Shaft length (cm)	Nominal pressure (atm)	Rated burst pressure (atm)
AA14SX025040090	4	2.5	40	90	8	14
AA14SX025080090	4	2.5	80	90	8	14
AA14SX025150090	4	2.5	150	90	8	14
AA14SX030040090	4	3	40	90	8	14
AA14SX030080090	4	3	80	90	8	14
AA14SX030150090	4	3	150	90	8	14
AA14SX020040150	4	2	40	150	8	14
AA14SX020080150	4	2	80	150	8	14
AA14SX020150150	4	2	150	150	8	14
AA14SX025040150	4	2.5	40	150	8	14
AA14SX025080150	4	2.5	80	150	8	14
AA14SX025150150	4	2.5	150	150	8	14
AA14SX030040150	4	3	40	150	8	14
AA14SX030080150	4	3	80	150	8	14
AA14SX030150150	4	3	150	150	8	14
AA14SX035040150	4	3.5	40	150	8	14
AA14SX035080150	4	3.5	80	150	8	14
AA14SX035150150	4	3.5	150	150	8	14
AA14SX040040150	4	4	40	150	8	14
AA14SX040080150	4	4	80	150	8	14
AA14SX040150150	4	4	150	150	8	14

- 0.014" DCB built on a clinically proven SFA enduracoat coating technology.
- Low tip profile (0.46 mm) designed to support trackability and lesion crossing in distal vessel beds.
- High coating stability and low dose may fulfil requirements specific to BTK and CLI disease.

† All discussed clinical results refer to patients with femoropopliteal lesions

Important Safety Information

Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

INDICATIONS FOR USE

The Stellarex 0.035" OTW drug-coated angioplasty balloon is indicated for the treatment of de-novo or restenotic lesions up to 220 mm in length in the superficial femoral or popliteal arteries to establish blood flow and to maintain vessel patency.

The Stellarex 0.014" OTW drug-coated angioplasty balloon is indicated for the treatment of de-novo or restenotic lesions up to 270mm in length (single-vessel) or 320mm in length (multi-vessel) in native popliteal and infra-popliteal arteries to establish blood flow and to maintain vessel patency.

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