Stellarex™ Drug-coated 0.035" Angioplasty Balloon

Featuring EnduraCoat™ Technology

The Clear DCB Choice
Top-tier outcomes with the lowest therapeutic drug dose in all patients—common to complex.

89.0% patency\(^2\) in common patient populations

82.3% patency\(^1\) in highly complex patients

The Stellarex Difference.
EnduraCoat™ Technology

Hybrid Paclitaxel + PEG Excipient = Top-Tier Clinical Outcomes

Efficient Drug Transfer + Effective Tissue Residency + High Coating Durability + Minimal Particulate Loss
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

![Top-Tier Patency Graph](image)

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.

**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.

![Highly Complex Patients Graph](image)

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

**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.

**Low Particulate Loss**

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

"THE 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
The Stellarex Difference.

EnduraCoat™ Technology = Hybrid Paclitaxel + 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 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

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.

LOW DRUG DOSE OF 2 µg/mm²

HIGHEST RATED BALLOON PRESSURES

LONG CATHETER WORKING LENGTH OF 135 cm

TREAT LONG LESIONS UP TO 180 mm

EASY-TO-REMOVE PROTECTIVE SHEATH
# Stellarex 0.035" OTW Drug-coated Angioplasty Balloon

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<th>Product Catalog Number</th>
<th>Sheath Size (Fr)</th>
<th>Balloon Diameter (mm)</th>
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<th>Shaft Length (cm)</th>
<th>Nominal Pressure (atm)</th>
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## 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:
- Abdominal pain
- Abrupt vessel closure
- Arterial rupture
- Balloon rupture
- Detachment of a component of the balloon and/or catheter system
- 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
- Arterial rupture
- 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

## References


## Corporate Headquarters

The Spectranetics Corporation, 9965 Federal Drive, Colorado Springs, CO 80921

Learn more and come visit us at [www.stellarexdcb.com](http://www.stellarexdcb.com)