PAGINA 0

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A clinical review of drug-coated balloons (DCB)

The IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter provides unparalleled effectiveness and safety, with 75% of patients re-intervention free at five years.[1]

Indications, Safety, and Warnings

Overview

Data comes from different individual studies and may differ in a head-to-head comparison, and therefore may not be predictive of clinical results.

- Highest patency benefit versus PTA
- Consistency in outcomes
- Clinical evidence

Highest patency benefit versus PTA

When comparing long-term durability of DCBs to PTA, IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter has the highest patency benefit and sustained delta through three years.

IN.PACT SFA Trial

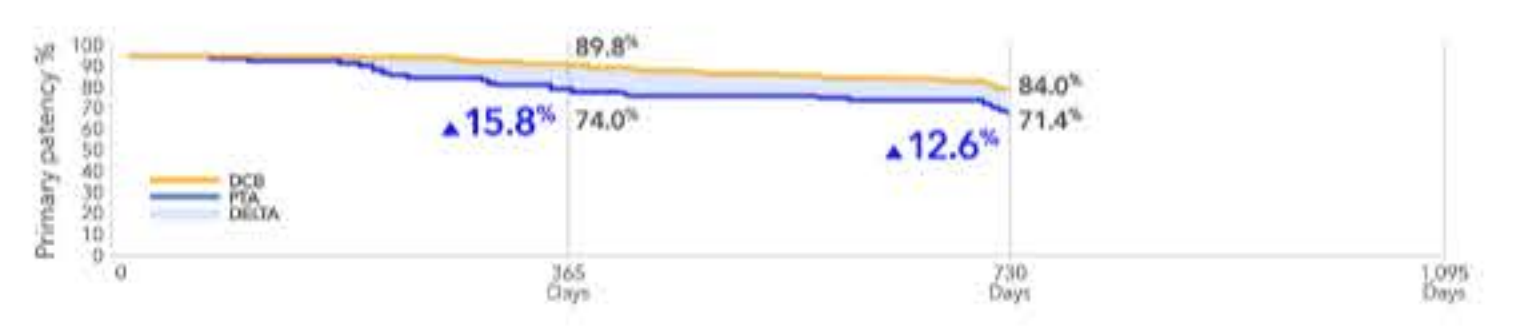
IN.PACT™ Admiral™ Paclitaxel-coated PTA
STELLAREX™* DCB†4,5

LEVANT 2 Trial

LUTONIX™* 035 DCB†6

RANGER II SFA Global Study

RANGER™* DCB†7,8



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Consistency in outcomes

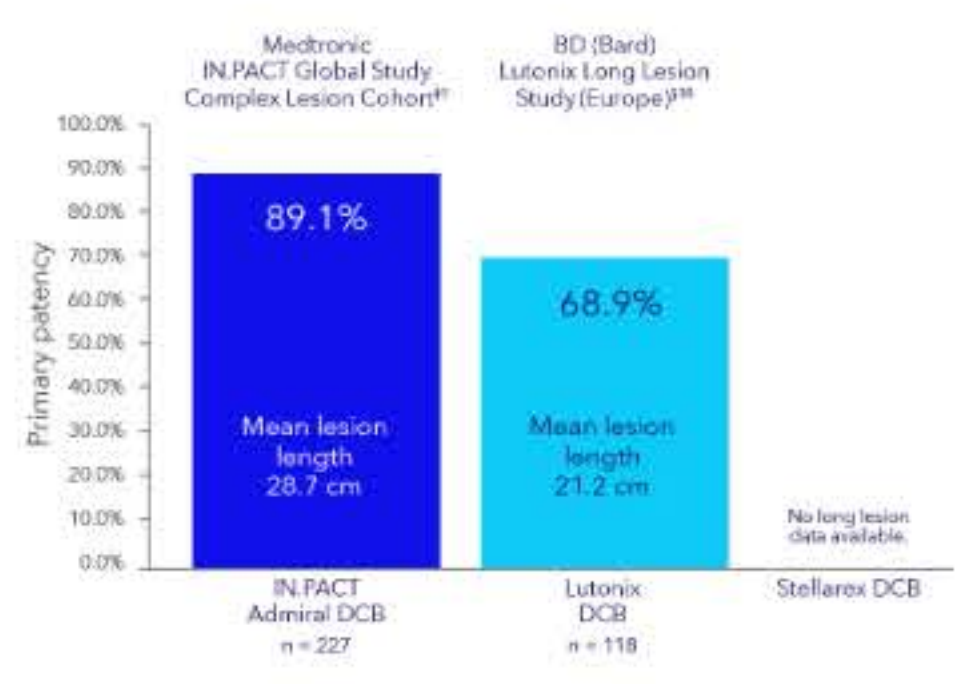
IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter demonstrates consistent performance across lesion complexity and patient diversity.

IN.PACT Global pre-specified cohorts: freedom from CD-TLR through five years[2]

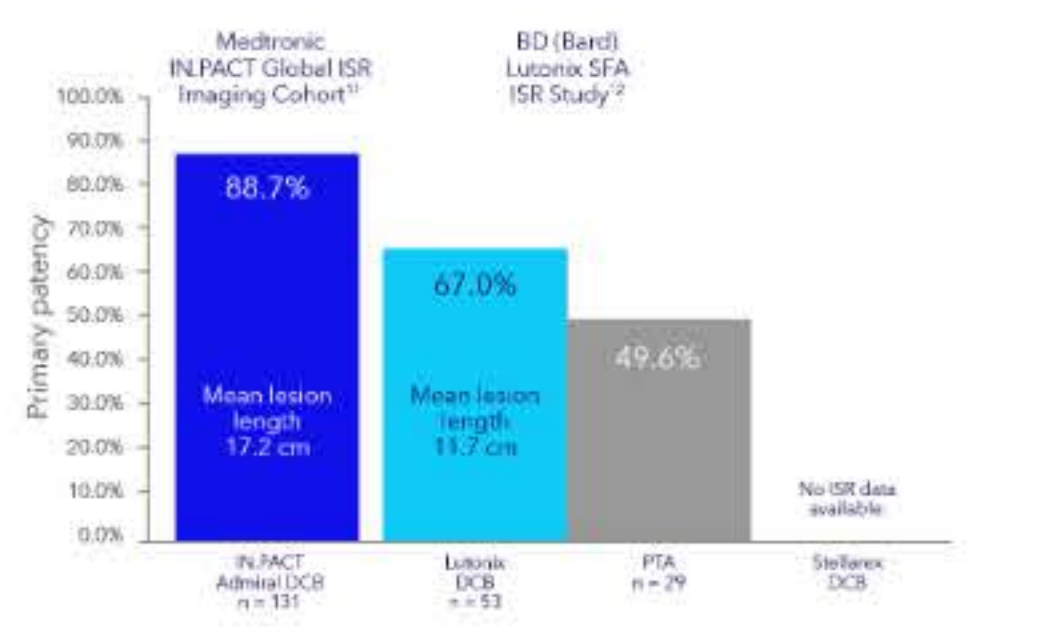
IN.PACT global full cohort five-year freedom from CD-TLR rate: 69.4%[2]

EXPLORE THE DATA

12-month primary patency in long lesions

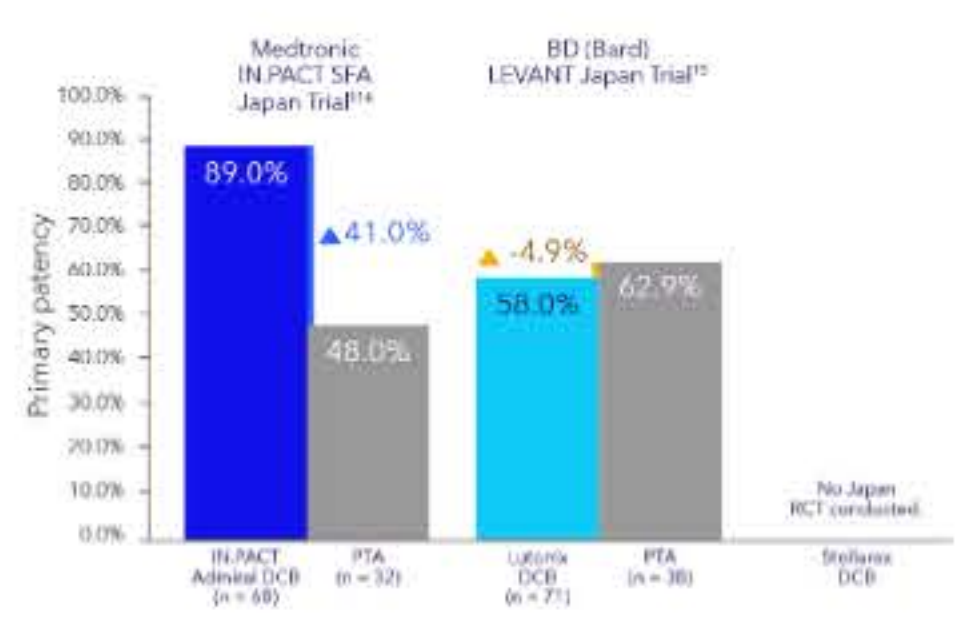


12-month primary patency in in-stent restenosis (ISR)

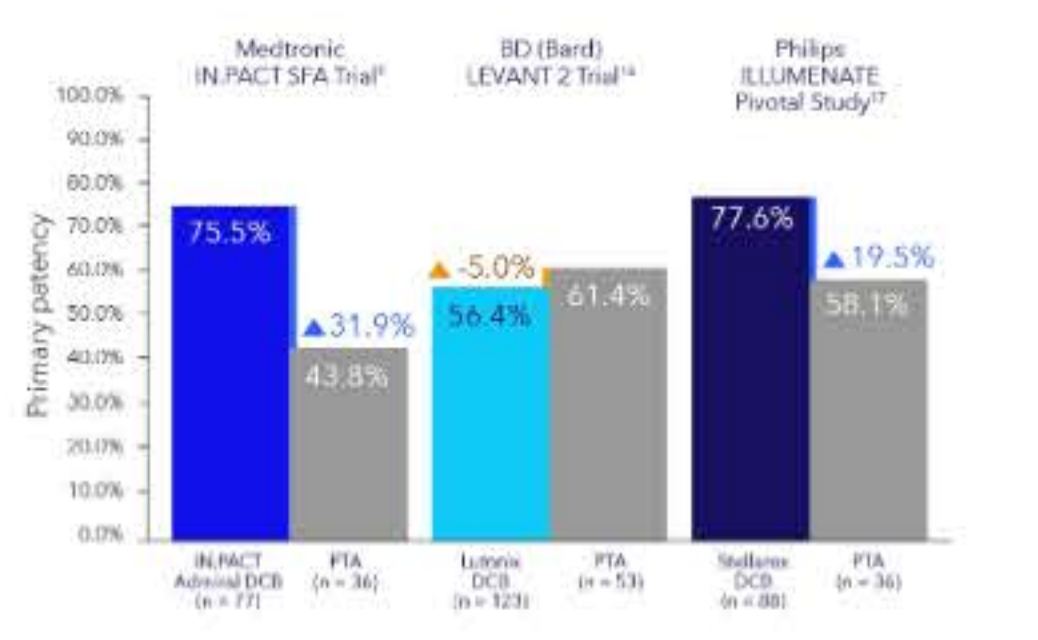


Note: Provisional stent rate for IN.PACT Admiral is 42.5% and is for Lutonix 65.2%.[9,13]

Japan Trial 12-month primary patency



Females 12-month primary patency



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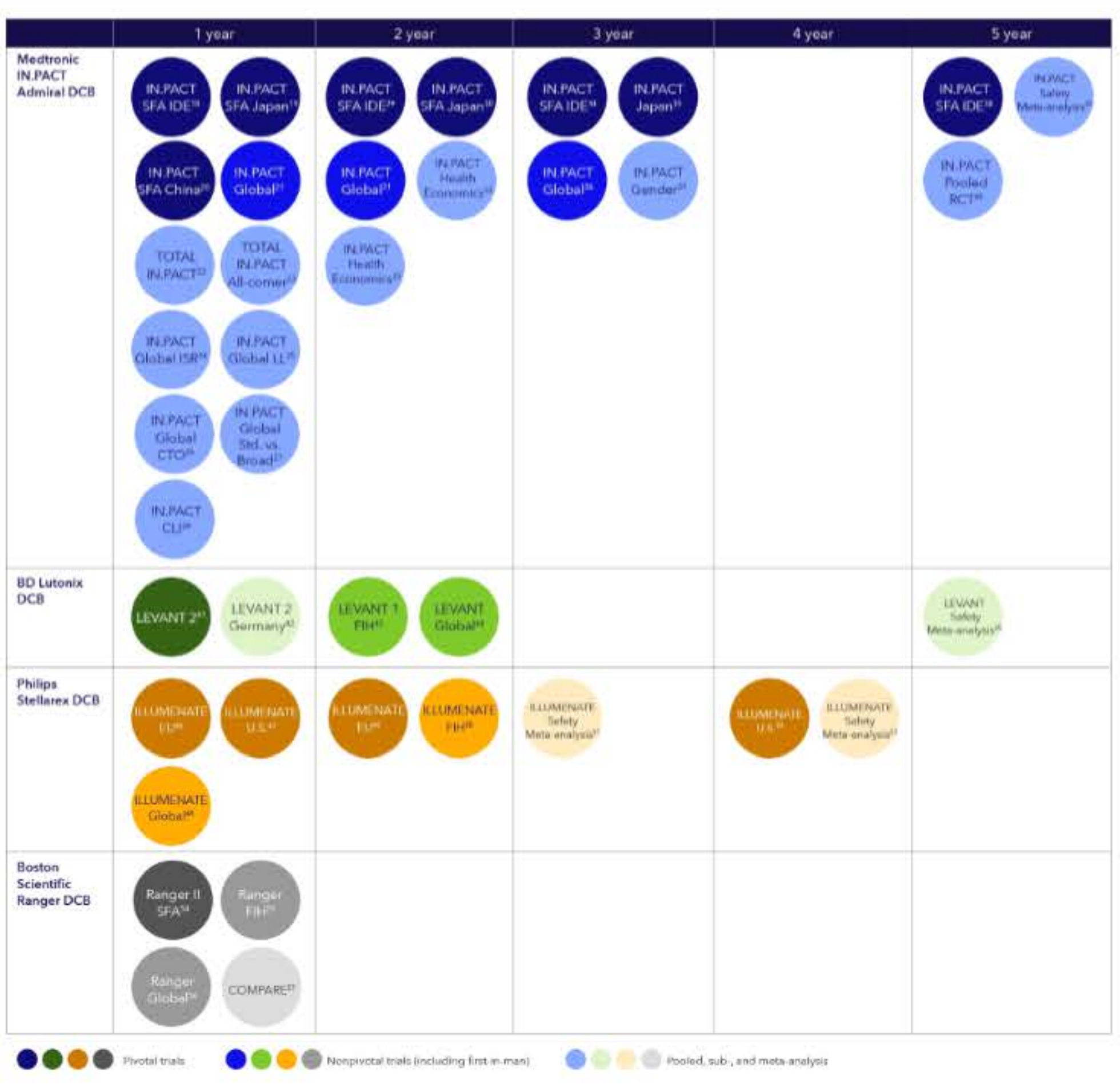
Clinical evidence

Published data from the IN.PACT trials demonstrates our commitment to clinical evidence.



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Additional resources

Related pages

- IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter
- Clinical outcomes
- Paclitaxel safety

Related products

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- Cardiovascular products

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* ™Third party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company. The approved product name for the drug-coated balloon is IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter.

† Patency rates from clinical trials may be calculated differently. Chart is for illustrative purposes only and results may differ in head-to-head comparison, and therefore may not be predictive of clinical results.

‡ Primary patency is defined as freedom from CEC-adjudicated clinically driven TLR and from core lab-adjudicated binary restenosis. Patency per Kaplan-Meier estimates at 12 months (day 365).

§ Primary patency based on intent-to-treat (ITT) analysis. Primary patency is defined as freedom from clinically driven target lesion revascularization and freedom from restenosis as determined by duplex ultrasound-derived PSVR ≤ 2.4. Indication statement for IN.PACT Admiral (Japan): This device, IN.PACT Admiral Drug Coated Balloon Catheter, is indicated for percutaneous transluminal angioplasty of de novo and non-stented restenotic lesions with length ≤ 200 mm in superficial femoral and popliteal arteries with reference vessel diameters of ≥ 4 mm and ≤ 7 mm.

‖ Primary patency based on intent-to-treat (ITT) analysis. Primary patency per Kaplan-Meier estimate is not available. Primary patency is defined as the absence of binary restenosis (as adjudicated by a blinded core lab) and freedom from target lesion revascularization. Indication statement for Lutonix (Japan): This device, Lutonix Drug-Coated Balloon Catheter, is indicated for treatment of de novo or restenotic lesion with a reference vessel diameter ≥ 4 mm and ≤ 6 mm and a length ≤ 15 cm in the native femoropopliteal artery (excluding in-stent lesion) to improve luminal diameter and to reduce restenosis.

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