

📍 Europe



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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 \(/xd-en/healthcare-professionals/products/cvg-emea-indication-safety-warning.html\)](/xd-en/healthcare-professionals/products/cvg-emea-indication-safety-warning.html)

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 Balloon Catheter†³

ILLUMENATE PIVOTAL Study

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 years²

de novo ISR

Long lesion

CTO

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

EXPLORE THE DATA (OPENS NEW WINDOW)

(/CONTENT/DAM/EMC/FOLIO/PUBLIC/FOLIOAPPCONTENT/CVG/PERIPHERAL/IPA-PRE-SPECIFIED-COHORT-TEPE-VIVA2021.PDF)

12-month primary patency in long lesions

Note: Provisional stent rate for IN.PACT Admiral is 42.5% and is for Lutonix 65.2%.^{9,13}

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

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 \(/xd-en/healthcare-professionals/products/cardiovascular/drug-coated-balloons/inpact-drug-coated-balloon.html\)](/xd-en/healthcare-professionals/products/cardiovascular/drug-coated-balloons/inpact-drug-coated-balloon.html)
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*

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†

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.

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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.

References

¹ Laird JA, Schneider PA, Jaff MR, et al. Long-Term Clinical Effectiveness of a Drug-Coated Balloon for the Treatment of Femoropopliteal Lesions. 5-year results from the IN.PACT SFA Trial. *Circ Cardiovasc Interv.* June 2019;12(6):e007702.

² Tepe G. 5-year results from the IN.PACT Global Study Prespecified Cohorts: ISR, CTO and Long Lesions. Presented at VIVA, 2021.

³ Schneider PA, Laird J, Tepe G, et al. Treatment Effect of Drug-Coated Balloons Is Durable to 3 Years in the Femoropopliteal Arteries: Long-Term Results of the IN.PACT SFA Randomized Trial. *Circ Cardiovasc Interv.* January 2018;11(1):e005891.

⁴ Mathews SJ. 1- and 2-Year Outcomes. Presented at NCVH 2018. New Orleans, LA.

⁵ Mathews SJ. 3-Year Outcomes. Presented at NCVH 2019. New Orleans, LA.

⁶ Primary Patency is listed as reported in the IFU. Lutonix BAW1387400r9 Section 10.3.5 Table 7.

⁷ Brodmann M. 1 Year Outcomes. Presented at LINC 2020; Leipzig, Germany.

⁸ Sachar R. 2 Year Outcomes. Presented at VIVA 2020; Las Vegas, NV.

⁹ IN.PACT Admiral IFU M052624T001. Rev. 1G.

¹⁰ Lutonix IFU:BAW1387400r3, Primary patency per KM analysis at day 365.

¹¹ Brodmann M, Keirse K, Scheinert D, et al. Drug-Coated Balloon Treatment for Femoropopliteal Artery Disease: The IN.PACT Global Study De Novo In-Stent Restenosis Imaging Cohort. *JACC Cardiovasc Interv.* October 23, 2017;10(20):2113-2123.

¹² Lutonix IFU: BAW1387400r9.

¹³ Lutonix IFU BAW1387400r9 - Table 33: Procedural Data (Bailout Spot Stent used Post-DCB Dilatation, 65.2% (45/69).

¹⁴ Iida O, Soga Y, Urasawa K, et al. Drug-Coated Balloon vs Standard Percutaneous Transluminal Angioplasty for the Treatment of Atherosclerotic Lesions in the Superficial Femoral and Proximal Popliteal Arteries: One-Year Results of the MDT-2113 SFA Japan Randomized Trial. *J Endovasc Ther.* February 2018;25(1):109-117.

¹⁵ Bard Data: 1-year outcomes from the LEVANT Japan Trial. Pharmaceuticals and Medical Devices Agency. Available at:

http://www.pmda.go.jp/medical_devices/2017/M20170830001/780045000_22900BZX00252000_A100_1.pdf(opens new window) (http://www.pmda.go.jp/medical_devices/2017/M20170830001/780045000_22900BZX00252000_A100_1.pdf).

(in Japanese). Accessed March 23, 2022.

¹⁶ Lutonix IFU: BAW1387400r5.

¹⁷ Stellarex IFU No. P011966.

DCB publication landscape

Medtronic IN.PACT Admiral DCB

¹⁸ Tepe G, et al. *Circulation.* 2015;131:495-502.

¹⁹ Iida O, et al. *J Endovasc Ther.* 2018;25:109-117.

²⁰ Chen Z, et al. *J Endovasc Ther.* 2019;26:471-478.

²¹ Zeller T, et al. *Circ Cardiovasc Interv.* 2019;12:e007730.

²² Shishehbor MH, et al. *J Vasc Surg.* 2019;70:1177-1191.e9.

²³ Kobe DS, et al. *J Invasive Card.* 2020;32:243-248.

²⁴ Laird JR, et al. *J Am Coll Cardiol.* 2015;66:2329-2338.

²⁵ Iida O, et al. *Catheter Cardiovasc Interv.* 2019;93:664-672.

²⁶ Schneider PA, et al. *Circ Cardiovasc Interv.* 2018;11:e005891.

²⁷ Soga Y, et al. *J Endovasc Ther.* 2020;27:946-955.

²⁸ Laird JA, et al. *Circ Cardiovasc Interv.* 2019;12:e007702.

²⁹ Schneider PA, et al. *J Am Coll Cardiol.* 2019;73:2550-2563.

³⁰ Brodmann M, et al. *JACC Cardiovasc Interv.* 2017;10:2113-2123.

³¹ Scheinert D, et al. *Circ Cardiovasc Interv.* 2018;11:e005654.

- ³² Tepe G, et al. *JACC Cardiovasc Interv.* 2019;12:484-493.
- ³³ Ansel GM, et al. *J Endovasc Ther.* 2018;25:673-682.
- ³⁴ Reijnen MMPJ, et al. *J Endovasc Ther.* 2019;26:305-315.
- ³⁵ Micari A, et al. *JACC Cardiovasc Interv.* 2018;11:945-953.
- ³⁶ Salisbury AC, et al. *JACC Cardiovasc Interv.* 2016;9:2343-2352.
- ³⁷ Pietzsch JB, et al. *Cardiovasc Intervent Radiol.* 2022;45:298-305.
- ³⁸ Torsello G, et al. *J Endovasc Ther.* 2020;27:693-705.
- ³⁹ Kohi M, et al. *J Vasc Interv Radiol.* 2020;31:1410-1418.e10.
- ⁴⁰ Schneider PA, et al. *Catheter Cardiovasc Interv.* 2020;96:1087-1099.

BD Lutonix DCB

- ⁴¹ Rosenfield K, et al. *N Engl J Med.* 2015;373:145-153.
- ⁴² Scheinert D, et al. *J Endovasc Ther.* 2016;23:409-416.
- ⁴³ Scheinert D, et al. *JACC Cardiovasc Interv.* 2014;7:10-19.
- ⁴⁴ Thieme M, et al. *JACC Cardiovasc Interv.* 2017;10:1682-1690.
- ⁴⁵ Ouriel K, et al. *JACC Cardiovasc Interv.* 2019;12:2515-2524.

Philips Stellarex DCB

- ⁴⁶ Krishnan P, et al. *Circulation.* 2017;136:1102-1113.
- ⁴⁷ Schroeder H, et al. *Circulation.* 2017;135:2227-2236.
- ⁴⁸ Schroë H, et al. *Catheter Cardiovasc Interv.* 2018;91:497-504.
- ⁴⁹ Brodmann M, et al. *JACC Cardiovasc Interv.* 2018;11:2357-2364.
- ⁵⁰ Schroeder H, et al. *Catheter Cardiovasc Interv.* 2015;86:278-286.
- ⁵¹ Grey WA, et al. *Circulation.* 2019;140:1145-1155.
- ⁵² Lyden SP, et al. *J Endovasc Ther.* Published online January 8, 2022.
- ⁵³ Lyden SP, et al. *J Vasc Surg.* 2022;75:600-607.

Boston Scientific Ranger DCB

- ⁵⁴ Sachar R, et al. *JACC Cardiovasc Interv.* 2021;14:1123-1133.
- ⁵⁵ Steiner S, et al. *JACC Cardiovasc Interv.* 2018;11:934-941.

⁵⁶ Lichtenberg M, et al. *J Cardiovasc Surg (Torino)*. 2018;59:45-50.

⁵⁷ Steiner S, et al. *Eur Heart J*. 2020;41:2541-2552.



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