Medtronic

IN.PACT™ drug-coated balloons (DCB)

The premier choice.

IN.PACT™
AV DCB

IN.PACT™
018 DCB

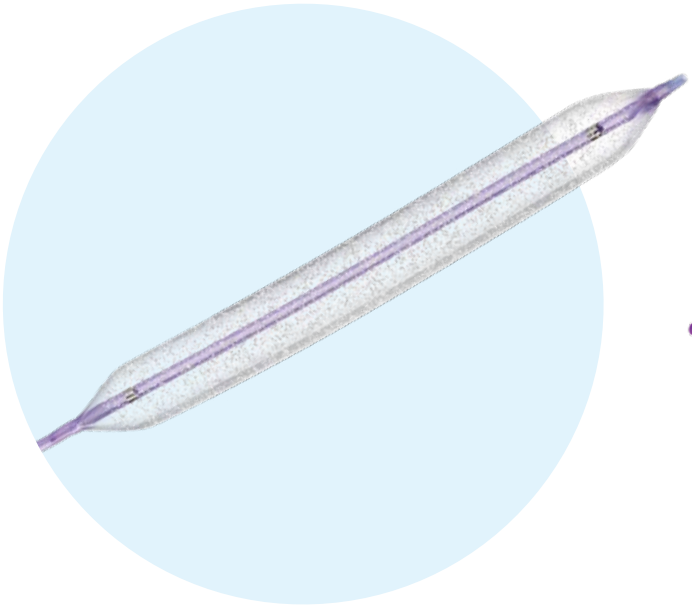
IN.PACT™
Admiral™ DCB

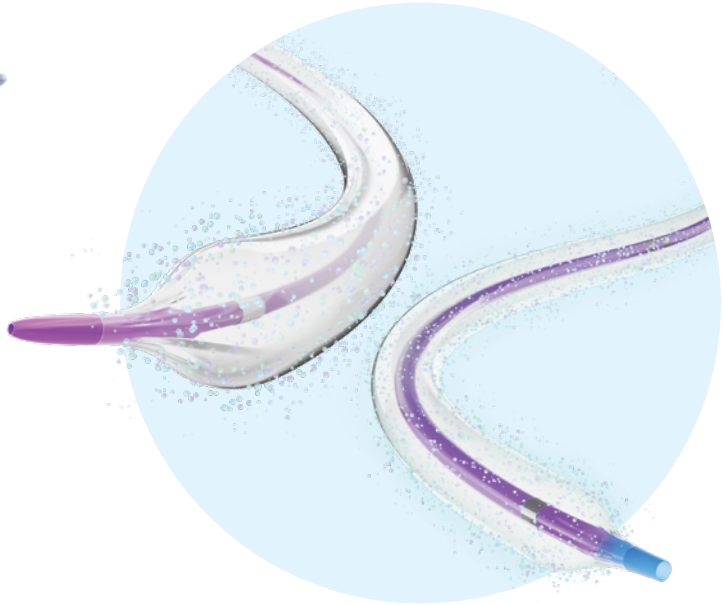
Your commitment to exceptional patient care deserves premier tools.

For treating peripheral arterial disease or AV fistula maintenance, the IN.PACT DCB portfolio checks all the boxes.

- **Unique mechanism of action**
- **Market-leader**
- **Lasting results**
- **Efficient inventory management**
- **Versatility**

The IN.PACT DCB portfolio includes:





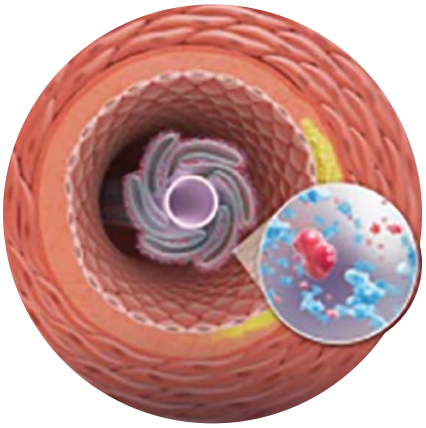
IN.PACT AV DCB

- Treat AV fistula lesions
- 4.0 to 12.0 mm balloon diameters
- 80 and 130 cm catheter lengths

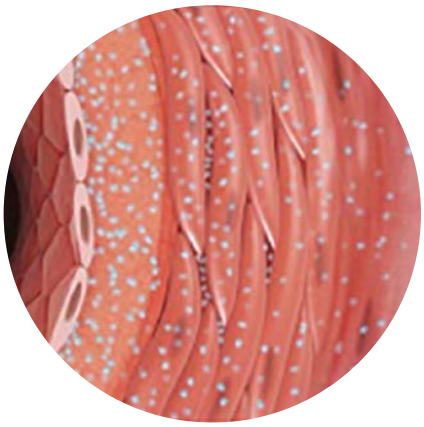
IN.PACT 018 and IN.PACT Admiral DCBs

- Treat superficial femoral popliteal disease
- 0.018" and 0.035" guidewire compatibility
- 200 cm catheter with IN.PACT 018 DCB for the option to treat via transradial access†
- Balloon lengths up to 250 mm

Uniquely formulated to suppress restenosis



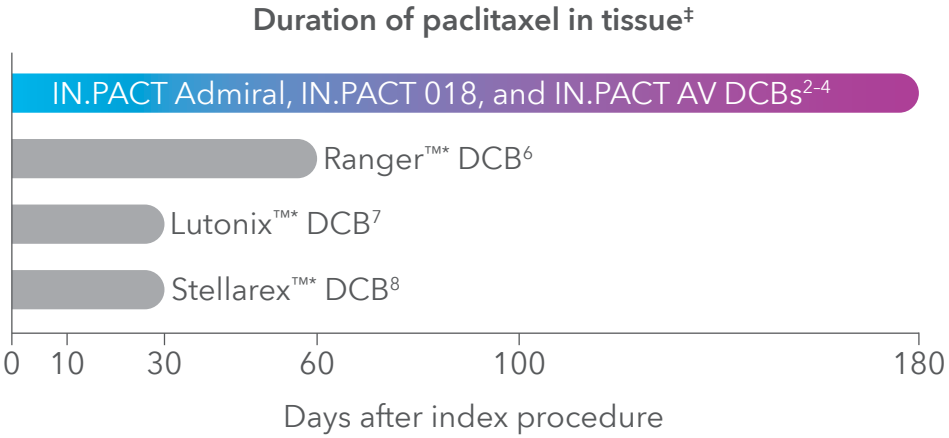
Efficient delivery
A proprietary combination of paclitaxel drug and urea excipient allows rapid transfer of the antiproliferative drug to the vessel wall.[1]



Sustained duration
Reservoirs of the drug stay in the vessel wall, making it capable of delivering effective paclitaxel levels by residing in the vessel for up to 180 days.[2-4]

Extended effect
By uniquely combining an appropriate amount of drug and time, IN.PACT DCBs reduce the need for repeat procedures.[3,5]

Only IN.PACT DCBs release drug into the tissue through the restenotic window, which is the time period the vessel is at highest risk of narrowing again.



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

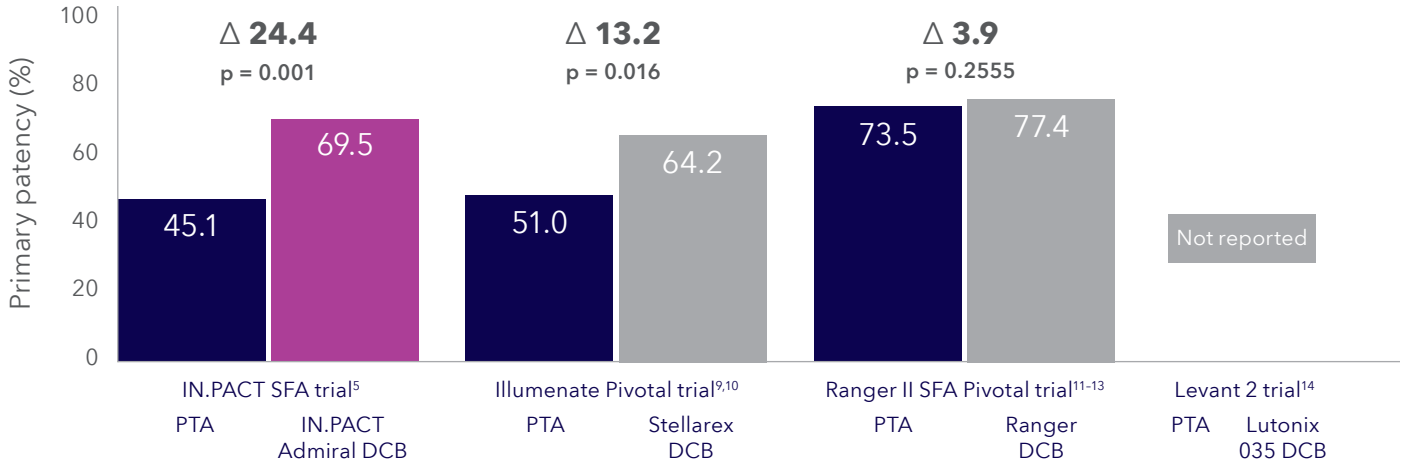
IN.PACT Admiral DCB
Proven to deliver lasting outcomes

In rigorous adjudicated studies, IN.PACT Admiral DCB demonstrates strong, consistent performance across all patient populations and lesion morphologies. IN.PACT 018 DCB uses the exact same drug formulation.

IN.PACT Admiral DCB is the only DCB that has:

- Demonstrated a statistically significant delta versus PTA for primary patency at three years[§,5]
- Demonstrated a statistically significant delta versus PTA for freedom from CD-TLR at five years[5]
- Five-year data on ISR, CTO, and long lesions[5]
- More than 30 sponsored publications[◊]

IN.PACT Admiral DCB has the greatest sustained patency benefit versus PTA through three years.[‡]



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

Risks may include: access site pain or infection; hemorrhage; thrombosis or embolic events; vessel dissection, perforation, or rupture; loss of permanent access (IN.PACT AV); amputation (IN.PACT Admiral/018); death.

The safety and effectiveness of the IN.PACT Admiral DCB (0.035 in guidewire compatible), as established in the clinical studies that were performed primarily via femoral access, can be considered supportive for the IN.PACT 018 DCB. The IN.PACT 018 DCB has not been evaluated in a clinical study.

IN.PACT AV DCB

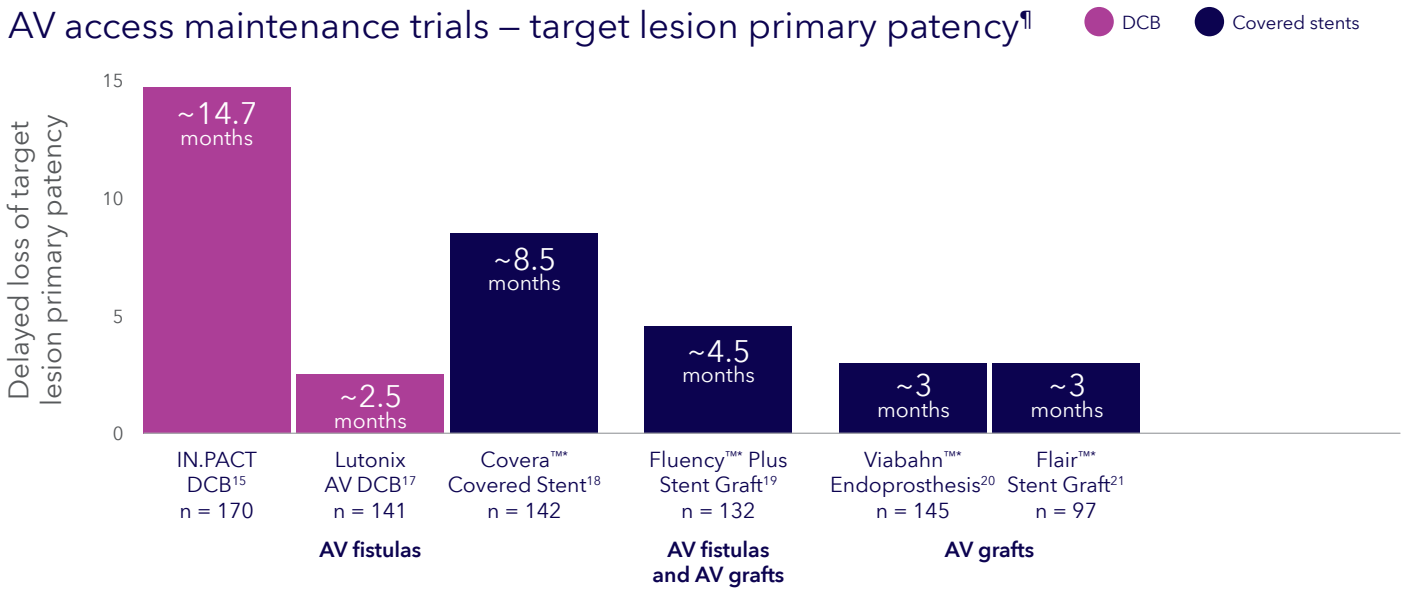
Proactive treatment, fewer reinterventions

IN.PACT AV DCB is the proactive treatment option that offers superior performance compared to PTA,[15] fewer reinterventions,[16] and a clear path for the dialysis lifeline.

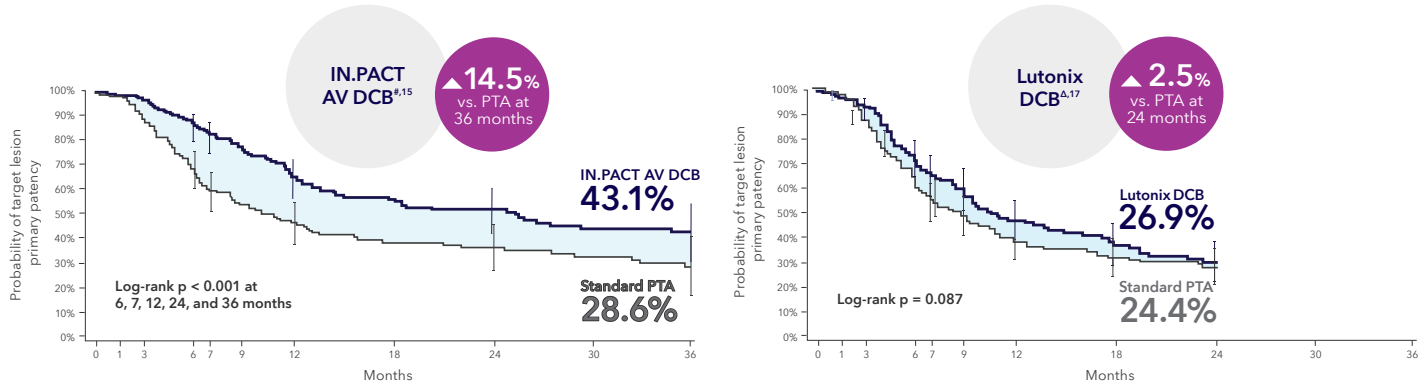
IN.PACT AV is the only DCB that:

- Met its primary efficacy endpoint[16]
- Extends the time between interventions by ~14.7 months[15]
- Offers the first and only DCB to show both superior and sustained performance compared to PTA through 36 months[15]
- Demonstrates 56% fewer reinterventions than PTA – enabling longer periods of uninterrupted dialysis[16]

AV access maintenance trials – target lesion primary patency¶



Separate trials evaluating target lesion primary patency for IN.PACT AV DCB at 36 months and Lutonix DCB at 24 months.¶



¶ Target lesion patency rates are defined differently; results are from different studies and may vary in head-to-head comparison; charts are for illustration purposes only.

Competitive review

More physicians choose IN.PACT DCBs than any other DCB on the market.[22] Here are a few of the reasons why.

DCBs for SFA

	Medtronic	DCB competitors			
	IN.PACT Admiral DCB	**Ranger DCB**	**Lutonix DCB**	**Stellarex DCB**	**Surveil DCB**
Drug dose	**3.5 µg/mm²**	**2.0**	**2.0**	**2.0**	**2.0**
Duration of drug in tissue	**180 days**[2-4]	60[6]	30[7]	30[8]	ND[∞]
Patency delta vs. PTA at 3 years[‡,§]	**24.4%**[5]	3.9%[13]	ND[∞]	13.2%[10]	N/A
5-year data on ISR, CTO, and long lesions	**Yes**[23]	No	No	No	No
Published studies[◊]	**32**	3	5	9	0
Indications	**SFA/popliteal**	SFA/popliteal	SFA/popliteal	SFA/popliteal	SFA/popliteal
	Lesions ≤ 360 mm	Lesions ≤ 180 mm	Lesions ≤ 300 mm	Lesions ≤ 180 mm	Lesions ≤ 180 mm
	ISR		ISR	ISR	

‡ Data comes from different individual studies and may different in a head-to-head comparison, and therefore may not be predictive of clinical results.
§ Primary patency not assessed after three years.
∞ Not disclosed.

DCBs for AV††

	IN.PACT AV DCB[15]	Lutonix DCB[‡‡,17]
Met primary effectiveness endpoint through 6 months	✓	✗
Statistically significant effectiveness at 1 year, compared to PTA (TLPP)	✓	✗
Statistically significant effectiveness at 2 year, compared to PTA (TLPP)	✓	✗
Statistically significant effectiveness at 3 year, compared to PTA (TLPP)	✓	N/A
3-year effectiveness data presented	✓	N/A

†† Primary patency endpoints are defined differently; results are from different studies and may vary in a head-to-head comparison; charts are for illustration purposes only.
‡‡ The safety and effectiveness of the Lutonix catheter is derived from the Lutonix AV study, a multicenter, 24-month pivotal IDE trial.

Outcomes Protection Program

The healthcare environment is ever-changing – managing costs and improving patient outcomes is more essential than ever as the population ages and obesity and chronic disease become more prevalent.

The IN.PACT drug-coated balloon Outcomes Protection Program is one way Medtronic is partnering with you to add value to your healthcare practice.

We believe in our DCBs and the clinical benefits they offer and stand behind our outcomes.

How the program works:

1 Treat

Treat your patients with IN.PACT Admiral, IN.PACT AV 018, or IN.PACT AV according to the IFU.

2 Qualifying event

IN.PACT Admiral and IN.PACT 018 DCBs:
If your patients return for a qualifying reintervention within one year, your facility is eligible for a rebate.

IN.PACT AV DCBs:
If your patients return for a qualifying reintervention within 180 days, your facility is eligible for a rebate.

3 Rebate

Simply submit the claim from within 30 days of the secondary intervention, and Medtronic will provide a $1,000 rebate to share in the cost of care.

Efficient inventory management

Streamline ordering and billing by sourcing all your DCBs from a single supplier.

Ordering information

IN.PACT 018 drug-coated balloon

Ref. number usable length 130 cm	Ref. number usable length 200 cm	Balloon diameter (mm)	Balloon length (mm)	Recommended introducer sheath (Fr)	Nominal pressure (atm)	RBP (atm)
IPU04004013P	IPU04004020P	4	40	5	8	10
IPU04006013P	IPU04006020P	4	60	5	8	10
IPU04008013P	IPU04008020P	4	80	5	8	10
IPU04010013P	IPU04010020P	4	100	5	8	10
IPU04012013P	IPU04012020P	4	120	5	8	10
IPU04015013P	IPU04015020P	4	150	5	8	10
IPU04020013P	IPU04020020P	4	200	5	8	10
IPU04025013P	IPU04025020P	4	250	5	8	10
IPU05004013P	IPU05004020P	5	40	5	8	10
IPU05006013P	IPU05006020P	5	60	5	8	10
IPU05008013P	IPU05008020P	5	80	5	8	10
IPU05010013P	IPU05010020P	5	100	5	8	10
IPU05012013P	IPU05012020P	5	120	5	8	10
IPU05015013P	IPU05015020P	5	150	5	8	10
IPU05020013P	IPU05020020P	5	200	5	8	10
IPU05025013P	IPU05025020P	5	250	5	8	10
IPU06004013P	IPU06004020P	6	40	5	8	10
IPU06006013P	IPU06006020P	6	60	5	8	10
IPU06008013P	IPU06008020P	6	80	5	8	10
IPU06010013P	IPU06010020P	6	100	5	8	10
IPU06012013P	IPU06012020P	6	120	5	8	10
IPU06015013P	IPU06015020P	6	150	5	8	10
IPU06020013P	IPU06020020P	6	200	5	8	10
IPU06025013P	IPU06025020P	6	250	5	8	10
IPU07004013P	IPU07004020P	7	40	6	8	10
IPU07006013P	IPU07006020P	7	60	6	8	10
IPU07008013P	IPU07008020P	7	80	6	8	10

IN.PACT Admiral drug-coated balloon

Ref. number usable length130 cm	Balloon diameter (mm)	Balloon length (mm)	Recommended introducer sheath (Fr)	Nominal pressure (atm)	RBP (atm)
ADM 040 040 13P	4	40	5	8	14
ADM 040 060 13P	4	60	5	8	14
ADM 040 080 13P	4	80	5	8	14
ADM 040 120 13P	4	120	5	8	14
ADM 040 150 13P	4	150	5	8	14
ADM 040 200 13P	4	200	5	5	11
ADM 040 250 13P	4	250	5	5	11
ADM 050 040 13P	5	40	6	8	14
ADM 050 060 13P	5	60	6	8	14
ADM 050 080 13P	5	80	6	8	14
ADM 050 120 13P	5	120	6	8	14
ADM 050 150 13P	5	150	6	8	14
ADM 050 200 13P	5	200	6	5	11
ADM 050 250 13P	5	250	6	5	11
ADM 060 040 13P	6	40	6	8	14
ADM 060 060 13P	6	60	6	8	14
ADM 060 080 13P	6	80	6	8	14
ADM 060 120 13P	6	120	6	8	14
ADM 060 150 13P	6	150	6	8	14
ADM 060 200 13P	6	200	6	5	11
ADM 060 250 13P	6	250	6	5	11
ADM 070 040 13P	7	40	7	8	14
ADM 070 060 13P	7	60	7	8	14
ADM 070 080 13P	7	80	7	8	14

Ordering information

IN.PACT AV drug-coated balloon

Ref. number usable length 80 cm	Ref. number usable length 130 cm	Balloon diameter (mm)	Balloon length (mm)	Recommended introducer sheath (Fr)	Nominal pressure (atm)	RBP (atm)
IAV04004008P	-	4.0	40	5	8	14
IAV04006008P	-	4.0	60	5	8	14
IAV04008008P	-	4.0	80	5	8	14
IAV04012008P	-	4.0	120	5	8	14
IAV05004008P	-	5.0	40	6	8	14
IAV05006008P	-	5.0	60	6	8	14
IAV05008008P	-	5.0	80	6	8	14
IAV05012008P	-	5.0	120	6	8	14
IAV06004008P	-	6.0	40	6	8	14
IAV06006008P	-	6.0	60	6	8	14
IAV06008008P	-	6.0	80	6	8	14
IAV06012008P	-	6.0	120	6	8	14
IAV07004008P	-	7.0	40	7	8	14
IAV07006008P	-	7.0	60	7	8	14
IAV07008008P	-	7.0	80	7	8	14
IAV08004008P	IAV08004013P	8.0	40	7	8	10
IAV08006008P	IAV08006013P	8.0	60	7	8	10
IAV08008008P	IAV08008013P	8.0	80	7	8	10
IAV09004008P	IAV09004013P	9.0	40	7	8	10
IAV09006008P	IAV09006013P	9.0	60	7	8	10
IAV09008008P	IAV09008013P	9.0	80	7	8	10
IAV10004008P	IAV10004013P	10.0	40	7	6	9
IAV12004008P	IAV12004013P	12.0	40	9	6	9

To place an order, contact your Medtronic field representative.

The safety and effectiveness of the IN.PACT Admiral DCB (0.035 in guidewire compatible), as established in the clinical studies that were performed primarily via femoral access, can be considered supportive for the IN.PACT 018 DCB. The IN.PACT 018 DCB has not been evaluated in a clinical study.

† Complications associated with radial access may include but are not limited to: abrupt vessel closure, vessel spasm, perforation or rupture of the artery, dissection, pseudoaneurysm, hematoma, thrombosis, and stroke.
‡ Data comes from different individual studies and may differ in a head-to-head comparison and therefore may not be predictive of clinical results.
§ Primary patency not assessed after three years.
◊ List of publications on file with Medtronic.
¶ Target lesion patency rates are defined differently; results are from different studies and may vary in head-to-head comparison; charts are for illustration purposes only.
# IN.PACT AV Access Trial: Target Lesion Primary Patency Rate was defined as freedom from clinically driven target lesion revascularization (CD-TLR) or access circuit thrombosis measured through 36 months (1,080 days) post-procedure.
Δ Lutonix AV Clinical Trial: Target Lesion Primary Patency was defined as freedom from clinically driven reintervention of the target lesion or access thrombosis measured through 24 months.
∞ Not disclosed.
†† Primary patency endpoints are defined differently; results are from different studies and may vary in a head-to-head comparison; charts are for illustration purposes only.
‡‡ The safety and effectiveness of the Lutonix catheter is derived from the Lutonix AV study, a multicenter, 24-month pivotal IDE trial.

1. GLP preclinical study PS747. Medtronic data on file.
2. GLP preclinical study FS201. Medtronic data on file.
3. IN.PACT™ AV drug-coated balloon (DCB) instructions for use (IFU). Medtronic. Results from the IN.PACT™ AV Access Clinical Trial found in the IN.PACT™ AV DCB IFU.
4. PMA P140010: Summary of safety and effectiveness data. FDA. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p140010. October 15, 2024.
5. Laird JA, Schneider PA, Jaff MR, et al. Long-Term Clinical Effectiveness of a Drug-Coated Balloon for the Treatment of Femoropopliteal Lesions. *Circ Cardiovasc Interv.* June 2019;12(6):e007702.
6. PMA P190019: Summary of safety and effectiveness data. FDA. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190019. October 15, 2024.
7. Yazdani SK, Pacheco E, Nakano M, et al. Vascular, downstream, and pharmacokinetic responses to treatment with a low dose drug-coated balloon in a swine femoral artery model. *Catheter Cardiovasc Interv.* January 1, 2014;83(1):132–140.
8. PMA P160049: Summary of safety and effectiveness data. FDA. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160049. Accessed September 2024.
9. Mathews SJ. 1- and 2-Year Outcomes. Presented at: NCVH 2018; May 30–June 1, 2018; New Orleans, LA.
10. Lyden SP, Faries PL, Niazi KAK, et al. No Mortality Signal With Stellarex Low-Dose Paclitaxel DCB: ILLUMENATE Pivotal 4-Year Outcomes. *J Endovasc Ther*. December 2022;29(6):929–936.
11. Sachar R, Soga Y, Ansari MM, et al. 1-Year Results From the RANGER II SFA Randomized Trial of the Ranger Drug-Coated Balloon. *JACC Cardiovasc Interv*. May 24, 2021;14(10):1123–1133.
12. Sachar R. 2 Year Outcomes. Presented at: VIVA 2021; October 3–7, 2021; Las Vegas, NV.
13. Broadman M. 3 year outcomes. Presented at: LINC 2023; June 6–9, 2023; Graz, Austria.
14. Primary Patency is listed as reported in the IFU. Lutonix BAW1387400r9 Section 10.3.5 Table 7.
15. Lookstein RA, Haruguchi H, Suemitsu K, et al. IN.PACT AV Access Randomized Trial of Drug-Coated Balloons for Dysfuntional Arteriovenous Fistulae: Clinical Outcomes through 36 Months. *J Vasc Interv Radiol*. December 2023;34(12):2093–2102.e7.
16. Lookstein RA, Haruguchi H, Ouriel K, et al. Drug-coated balloons for dysfunctional dialysis arteriovenous fistulas. *N Engl J Med*. August 20, 2020;383(8):733–742. Highlighted results reported at both 180 and 210 days.
17. Trerotola SO, Saad TF, Roy-Chaudhury P. The Lutonix AV Randomized Trial of Paclitaxel-Coated Balloons in Arteriovenous Fistula Stenosis: 2-Year Results and Subgroup Analysis. *J Vasc Interv Radiol.* January 2020;31(1):1–14.e5.
18. Dolmatch B, Cabrera T, Pergola P, et al. Prospective, randomized, multicenter clinical study comparing a self-expanding covered stent to percutaneous transluminal angioplasty for treatment of upper extremity hemodialysis arteriovenous fistula stenosis. Kidney Int. July 2023;104(1):189–200.
19. Falk A, Maya ID, Yevzlin AS. A Prospective, Randomized Study of an Expanded Polytetrafluoroethylene Stent Graft versus Balloon Angioplasty for In-Stent Restenosis in Arteriovenous Grafts and Fistulae: Two-Year Results of the RESCUE Study. *J Vasc Interv Radiol.* October 2016;27(10):1465–1476.
20. Vesely T, DaVanzo W, Behrend T, Dwyer A, Aruny J. Balloon angioplasty versus Viabahn stent graft for treatment of failing or thrombosed prosthetic hemodialysis grafts. *J Vasc Surg.* November 2016;64(5):1400–1410.e1.
21. Flair Endovascular Stent Graft Instructions for Use. Bard; 2007.
22. U.S. only. QSight market share data for drug-coated balloons. QSight. October 2024.
23. Tepe G, Brodmann M, Micari A, et al. 5-Year Outcomes of Drug-Coated Balloons for Peripheral Artery In-Stent Restenosis, Long Lesions, and CTOs. J*ACC Cardiovasc Interv*. May 8, 2023;16(9):1065–1078.

IN.PACT™ 018 Paclitaxel-coated PTA Balloon Catheter and IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter

Indications for Use: The IN.PACT Admiral Paclitaxel-coated PTA Balloon Catheter and IN.PACT 018 Paclitaxel-coated PTA Balloon Catheter are indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4–7 mm. **Contraindications:** The IN.PACT Admiral DCB and IN.PACT 018 DCB are contraindicated for use in: Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries • Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy • Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system • Patients with known allergies or sensitivities to paclitaxel • Women who are breastfeeding, pregnant, or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure. **Warnings:** Use the product prior to the Use-by Date specified on the package. • Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened. • Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution). • Do not move the guidewire during inflation of the IN.PACT Admiral DCB or IN.PACT 018 DCB. • Do not exceed the rated burst pressure (RBP). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection. [IN.PACT Admiral DCB: The RBP is 14 atm (1419 kPa) for all balloons except the 200 and 250 mm balloons. For the 200 and 250 mm balloons the RBP is 11 atm (1115 kPa) – IN.PACT 018 DCB: The RBP is10 atm (1013 kPa) for all balloons.] • The safety and effectiveness of using multiple IN.PACT Admiral DCB, or multiple IN.PACT 018 DCB, with a total drug dosage exceeding 34,854 µg of paclitaxel in a patient has not been clinically evaluated. **Precautions:** • The safety and effectiveness of the IN.PACT Admiral DCB (0.035 in guidewire compatible), as established in the clinical studies that were performed primarily via femoral access, can be considered supportive for the IN.PACT 018 DCB. Vessel preparation using only pre-dilatation was studied in the IN.PACT Admiral DCB clinical studies. Other methods of vessel preparation, such as atherectomy, have not been studied clinically. The IN.PACT 018 DCB has not been evaluated in a clinical study. • The IN.PACT Admiral DCB and IN.PACT 018 DCB should only be used by physicians trained in percutaneous transluminal angioplasty (PTA). • The IN.PACT Admiral DCB and IN.PACT 018 DCB are designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. • Assess risks and benefits before treating patients with a history of severe reaction to contrast agents. • The safety and effectiveness of the IN.PACT Admiral DCB or IN.PACT 018 DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated • The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content. • The use of the IN.PACT Admiral DCB and IN.PACT 018 DCB carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events. • The IN.PACT Admiral DCB and IN.PACT 018 DCB are not intended for the expansion or delivery of a stent. **Potential Adverse Effects:** The potential adverse effects (e.g., complications) associated with the use of the device are: abrupt vessel closure; access site pain; allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (materials, drugs, and excipients); amputation/loss of limb; arrhythmias; arterial aneurysm; arterial thrombosis; arteriovenous (AV) fistula; death; dissection; embolization; fever; hematoma; hemorrhage; hypotension/hypertension; inflammation; ischemia or infarction of tissue/ organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the dilated artery; sepsis or systemic infection; shock; stroke; systemic embolization; vessel spasms or recoil; vessel trauma which requires surgical repair. Potential complications of peripheral balloon catheterization include, but are not limited to: 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. Although systemic effects are not anticipated, potential adverse events that may be unique to the paclitaxel drug coating include, but are not limited to: allergic/immunologic reaction; alopecia; anemia; gastrointestinal symptoms; hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthralgia; myelosuppression; peripheral neuropathy. Refer to the Physician's Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time. Please reference appropriate product Instructions for Use for a detailed list of indications, warnings, precautions, and potential adverse effects. This content is available electronically at manuals.medtronic.com. **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

IN.PACT™ AV Drug-coated PTA Balloon Catheter

Indications for Use: The IN.PACT™ AV Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, for the treatment of obstructive lesions up to 100 mm in length in the native arteriovenous dialysis fistulae with reference vessel diameters of 4 to 12 mm. **Contraindications:** The IN.PACT AV DCB is contraindicated for use in the following anatomy and patient types: • Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries • Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy • Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system • Patients with known allergies or sensitivities to paclitaxel • Women who are breastfeeding, pregnant, or are intending to become pregnant, or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure. **Warnings:** Use the product prior to the Use-by date specified on the package. • Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened. • Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution). • Do not move the guidewire during inflation of the IN.PACT AV DCB. • Do not exceed the rated burst pressure (RBP). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection. • The safety of using multiple IN.PACT AV DCBs with a total drug dosage exceeding 15,105 µg paclitaxel has not been evaluated clinically. **Precautions:** • This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA). • Assess risks and benefits before treating patients with a history of severe reaction to contrast agents. Identify allergic reactions to contrast media and antiplatelet therapy before treatment and consider alternatives for appropriate management prior to the procedure. • This product is not intended for the expansion or delivery of a stent. • Do not use the IN.PACT AV DCB for pre-dilatation or for post-dilatation. • This product is designed for single patient use only. Do not reuse, reprocess, or resterilizethis product. Reuse, reprocessing, or resterilizationmay compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death • The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events. • The safety and effectiveness of the IN.PACT AV DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure has not been evaluated. • The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content. • Appropriate vessel preparation, as determined by the physician to achieve residual stenosis of ≤ 30%, is required prior to use of the IN.PACT AV DCB. Vessel preparation of the target lesion using high-pressure PTA for pre-dilatation was studied in the IN.PACT AV Access clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT AV DCB.

Potential Adverse Effects: Potential adverse effects which may be associated with balloon catheterization may include, but are not limited to, the following: abrupt vessel closure, allergic reaction, arrhythmias, arterial or venous aneurysm, arterial or venous thrombosis,death, dissection, embolization, hematoma, hemorrhage, hypotension/hypertension, infection, ischemia or infarction of tissue/organ, loss of permanent access, pain, perforation or rupture of the artery or vein, pseudoaneurysm, restenosis of the dilated vessel, shock, stroke, vessel spasms, or recoil. Potential complications of peripheral balloon catheterization include, but are not limited to, the following: 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. These complications may result in adverse effects. Although systemic effects are not anticipated, potential adverse effects not captured above that may be unique to the paclitaxel drug coating include, but are not limited to, the following: allergic/immunologic reaction, alopecia, anemia, gastrointestinal symptoms, hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia), hepatic enzyme changes, histologic changes in vessel wall, including inflammation, cellular damage, or necrosis, myalgia/ arthralgia, myelosuppression, peripheral neuropathy. Refer to the Physicians' Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time. Please reference appropriate product Instructions for Usefor a detailed list of indications, warnings, precautions, and potential adverse effects. This content is available electronically at www.manuals.medtronic.com. **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Medtronic.com/INPACT

Medtronic