Medtronic

Engineering the extraordinary

IN.PACT™ AV Access Trial

The first & only

AV DCB Randomised Controlled Trial to meet primary effectiveness and safety endpoints in AV Fistula lesions versus PTA.

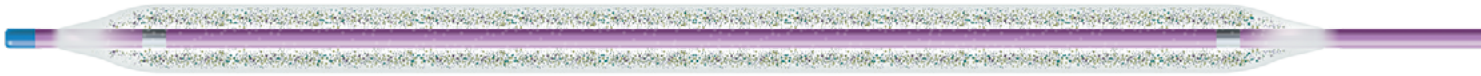
Contact us

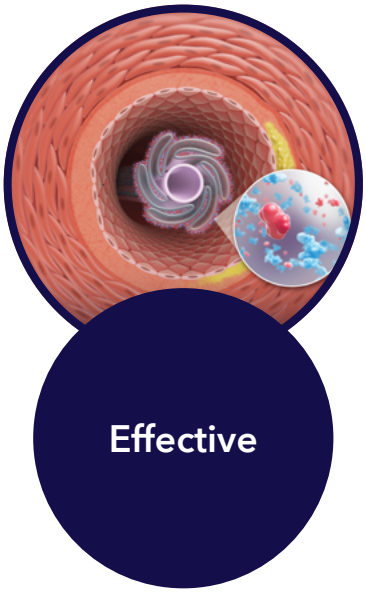
Click here to request more information

Statistically significant difference between two groups in the primary analysis with continued trend through 36 months (no adjustment made for multiple comparisons).

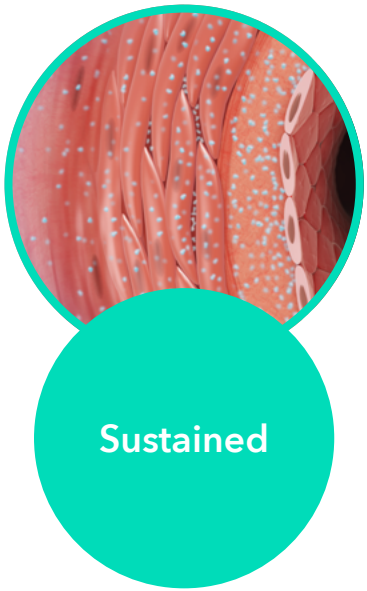
IN.PACT™ Admiral™ DCB For Fistula

Paclitaxel-coated PTA Balloon Catheter

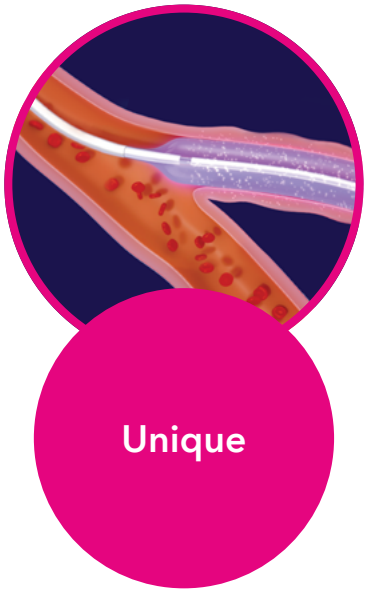




Effective



Sustained



Unique

IMPACT

for your End Stage Renal Disease (ESRD)
fistula patients

IN.PACT™ AV Access Trial

Objective and Study Characteristics[1]

The aim of the trail is to evaluate the safety and effectiveness of the IN.PACT™ DCB compared to PTA for treatment of de novo or restenotic obstructive lesions of native arteriovenous fistulae (AVF) in the upper extremity

Design	Prospective, global, multicenter, 1:1 randomized, single - blinded study of 330 participants
Sites	29 Global Sites in The United States, Japan and New Zealand
Adjudication	Independent and blinded Duplex Ultrasound Core Lab‡, Angiographic Core Lab §, and Clinical Events Committee Ω
Primary Safety Endpoint	**Serious Adverse Event Rate within 30 Days** Defined as the Serious Adverse Event (SAE) rateinvolving the AV access circuit through 30 days post-procedure
Primary Effectiveness Endpoint	**Target Lesion Primary Patency Rate through 6 Months** Defined as freedom from clinically-driven target lesion revascularization or access circuit thrombosis measured through 6 months post-procedure
Long-term Outcomes	**Through 36 months** Target lesion primary patency, access circuit primary patency, number of reinterventions, mortality **Through 60 months** Mortality with vital status follow-up

Risks may include: access site pain or infection; hemorrhage; local or distal embolic events; perforation or rupture of the artery; amputation; death.

Robust evidence

Rigorous and unbiased

Durability of outcomes

1. Lookstein R et al. N Engl J Med 2020;383:733-42.
AVF, arteriovenous fistula; DCB, drug-coated balloon; IDE, investigational device exemption; PTA, percutaneous transluminal
‡ VasCore DUS Core Laboratory
§ SYNTACTX Angiographic Core Laboratory
Ω SYNTACTX Clinical Events Committee

Effective

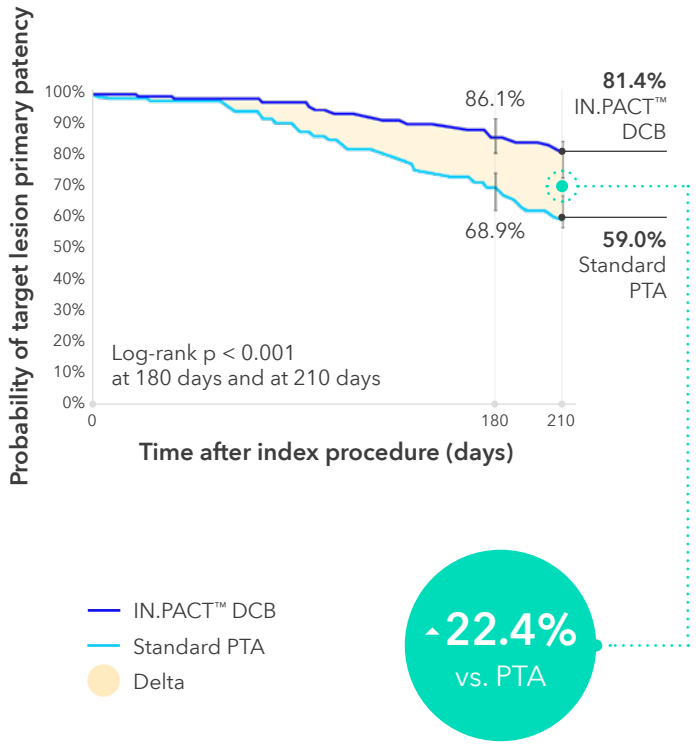
Outcomes at 6 months[2]

The FIRST and ONLY DCB in AVF Trial that achieved primary safety and effectiveness endpoints

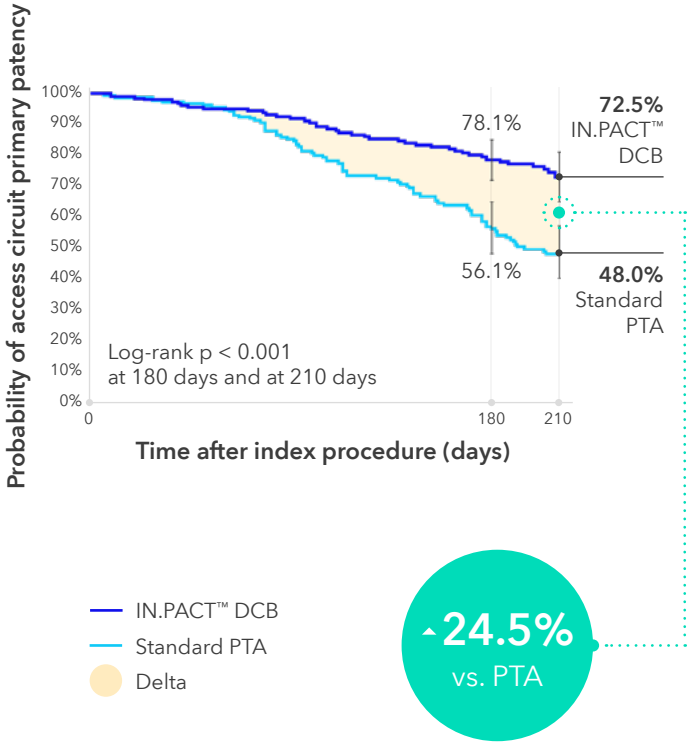
Published on

The NEW ENGLAND JOURNAL of MEDICINE

Target lesion primary patency†



Access circuit primary patency†

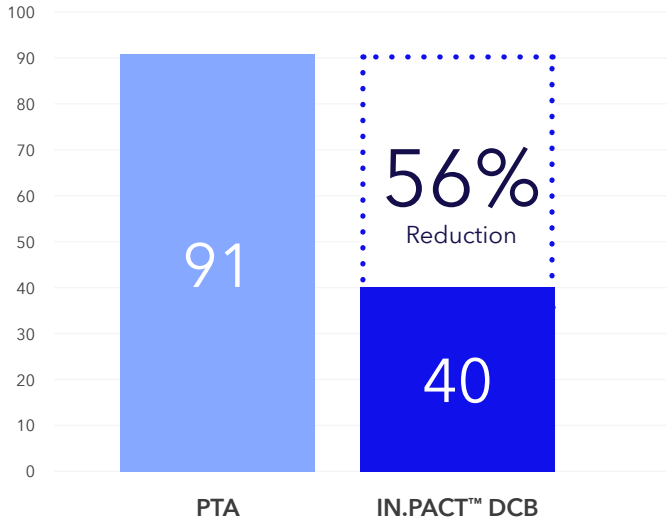


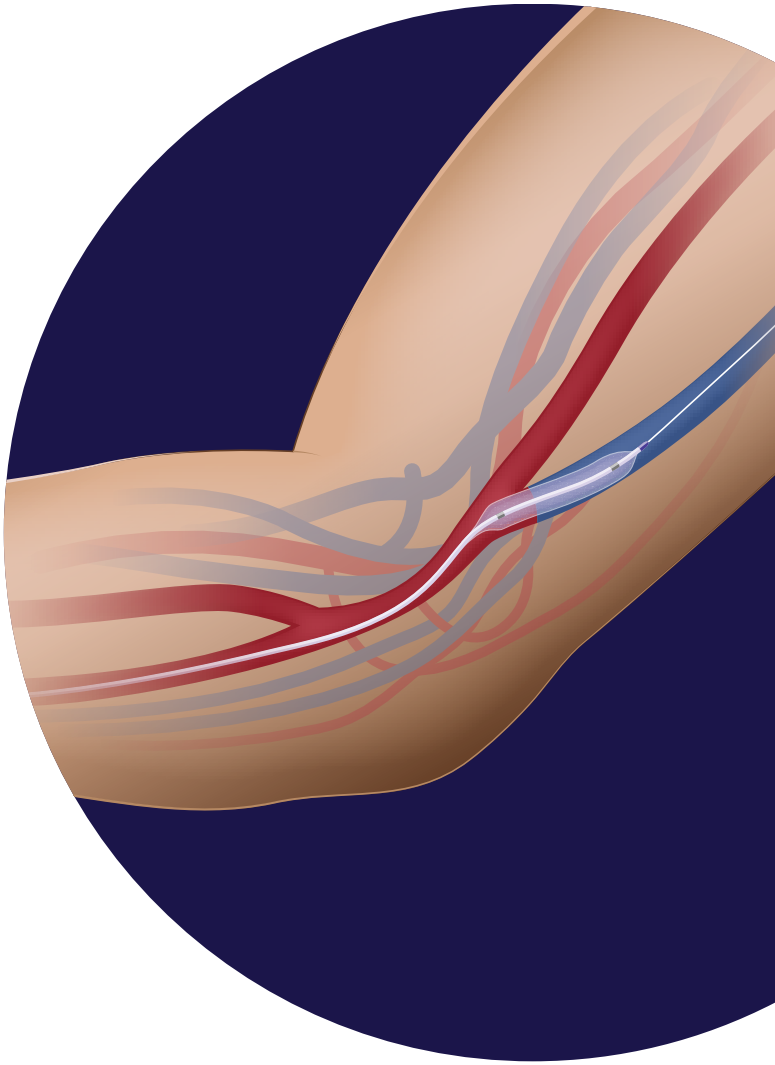
2. Results from the IN.PACT AV Access clinical trial found in the IN.PACT AV drug-coated balloon (DCB) Instructions for Use (IFU).
† IN.PACT AV Access trial: Target lesion primary patency rate was defined as freedom from clinically driven target lesion revascularization (CD-TLR) or access circuit thrombosis measured through 210 days post-procedure. Access circuit patency rate was defined as freedom from reintervention in the access circuit or access circuit thrombosis measured through 210 days post-procedure.

Effective

Outcomes at 6 months
Key secondary endpoint

Number of reinterventions
required to maintain target lesion primary patency[3]





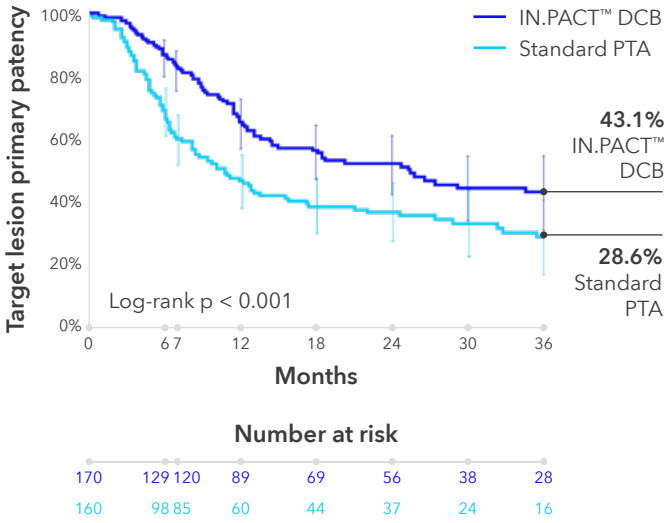
3. Lookstein RA, et al. Drug-Coated Balloons for Dysfunctional Dialysis Arteriovenous Fistulas. N Engl J Med 2020;383:733-42. DOI: 10.1056/NEJMoa1914617. Highlighted results reported at both 180 and 210 days.

Sustained

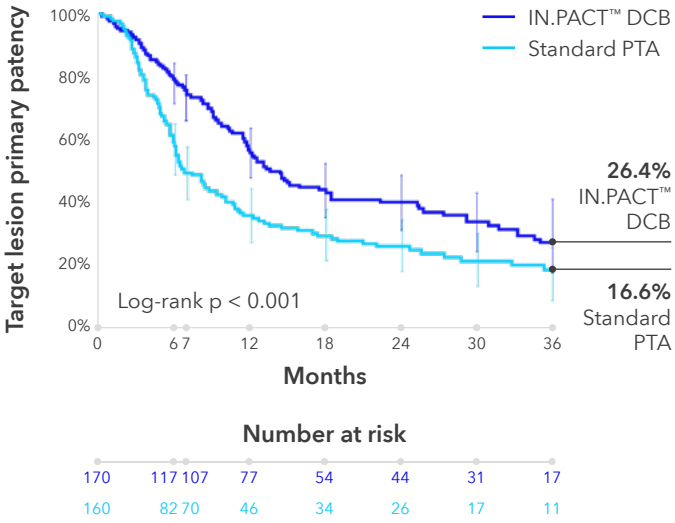
Outcomes at 3 years[4]

Proven superiority of IN.PACT™ DCB vs PTA through 3 years

Target lesion
primary patency†



Access circuit
primary patency†



17.3% Reduction in reinterventions with DCB use

16.3% Reduction in reinterventions with DCB use

Statistically significant difference between two groups in the primary analysis with continued trend through 36 months (no adjustment made for multiple comparisons).

4. Lookstein RA, Haruguchi H, Suemitsu K et al. IN.PACT AV Access Randomized Trial of Drug-Coates Balloons for Dysfunctional Arteriouvenous Fistulae: Clinical Outcomes through 36 months. J Vasc Interv Radiol. December 2023;34(12):2093-2102.e7.

† IN.PACT AV Access trial: Access circuit patency rate was defined as freedom from clinically driven access circuit revascularization (CD-TLR) or access circuit thrombosis measured through 720 days post-procedure

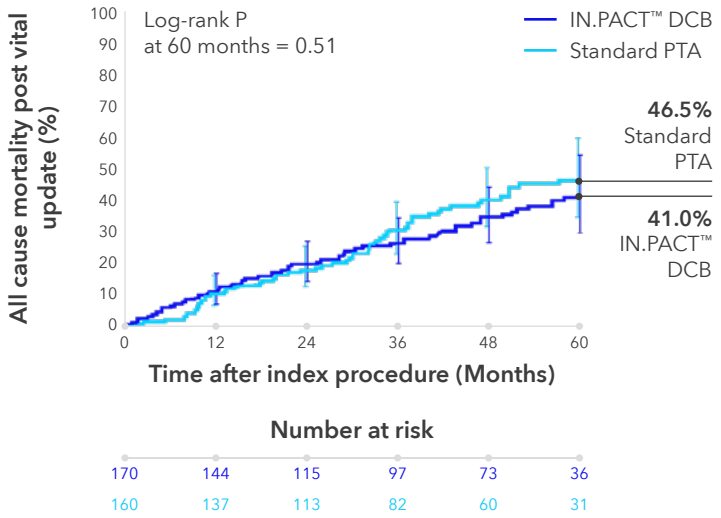
Sustained

Outcomes at 5 years

Proven superiority of IN.PACT™ DCB vs PTA through 5 years

Incidence of all-cause mortality

post vital status update[5]



60.4% Mortality rate of patients on hemodialysis in the US through 5 years*.

*dialysis onset 2017; includes COVID-19 pandemic†

Confirming safety

of DCB at 5 years with no differences in the incidence of all-cause mortality following a vital status update

5. Vital status collection only legal to collect in US. DCB, drug-coated balloon; IDE, investigational device exemption; PTA, percutaneous transluminal angioplasty.

† USRDS 2023 Annual Report, Figure 6.7. https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/6-mortality. Adjusted survival of incident ESRD patients after onset of ESRD in patients treated with hemodialysis with the year of ESRD onset being 2017 (same numbers for 2007 onset are 23.0% at 1 year, 35.0% at 2 years, 44.9% at 3 years, 53.5% at 4 years and 60.6% at 5 years; 2012 onset is 20.8% at 1 year, 32.1% at 2 years, 41.9% at 3 years, 50.5% at 4 years and 58.3% at 5 years).

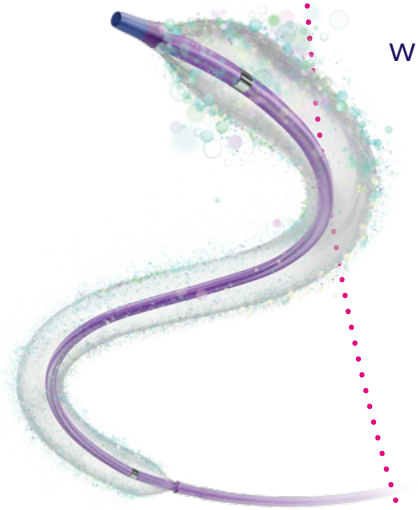
Unique

A unique DCB design
conceived to address your AV Access procedural needs

Diameter [mm]	Balloon Length [mm]						
	40	60	80	120	150	200	250
4.0	14	14	14				
5.0	14	14	14				
6.0	14	14	14				
7.0	14	14	14				
8.0	10	10	10				
9.0	10	10	10				
10.0	9						
12.0	9						

- 5 French
- 6 French
- 7 French
- 9 French

Shaft Lenghts	Introducer Sheath Compatibility
40, 80, 130cm	5 Fr / 6 Fr / 7 Fr / 9 Fr



Large diameter
Up to 12 mm to increase treatment options across anatomies

Short shaft
allowing use of shorter wires to save procedure time

Unique

A unique design and drug coated formulation
is the reason behind results

Superior impact

56% Fewer reinterventions in DCB vs. PTA arm at 6 months[6]

Sustained effectiveness

43% Highest reported target lesion primary patency at 3 years[7]

Proven safety

5 years — Follow up confirming DCB's safety profile[8]

IN.PACT™ Admiral™ DCB
Treating the causes of fistula stenosis, not just the symptoms

6. Lookstein RA, et al. Drug-Coated Balloons for Dysfunctional Dialysis Arteriovenous Fistulas. N Engl J Med 2020;383:733-42. DOI: 10.1056/NEJMoa1914617. Highlighted results reported at both 180 and 210 days.
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8. Holden A. IN.PACT AV Access Outcomes: We know which DCB to use! Presented at Charing Cross 2024.

This material should not be considered the exclusive source of information, it does not replace or supersede information contained in the device manual(s). Please note that the intended use of a product may vary depending on geographical approvals. See the device manual(s) for detailed information regarding the intended use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For a MRI compatible device(s), consult the MRI information in the device manual(s) before performing a MRI. If a device is eligible for eIFU usage, instructions for use can be found at Medtronic's website manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser. For any further information, contact your local Medtronic representative and/or consult Medtronic's websites.

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