

**DURABLE.
CONSISTENT.
SAFE.**

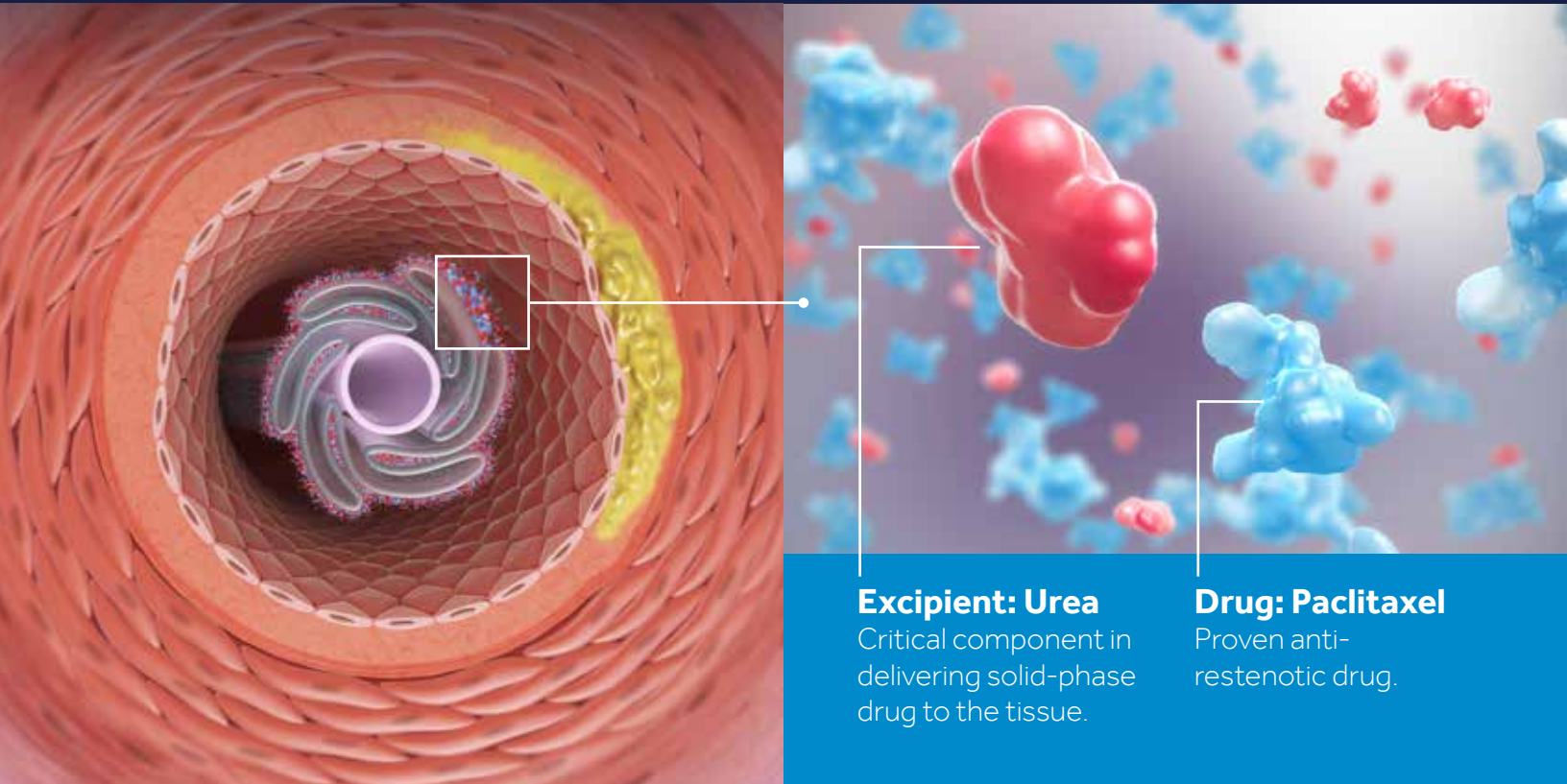
IN.PACT™ Admiral™
Drug-Coated Balloon



Medtronic
Further, Together

THE SCIENCE BEHIND THE OUTCOMES

IN.PACT™ Admiral™ DCB has proven, long-term durable outcomes across multiple clinical trials, as well as across complex patient and lesion types. This strong clinical data may be explained by the mechanism of action.



Excipient: Urea

Critical component in delivering solid-phase drug to the tissue.

Drug: Paclitaxel

Proven anti-restenotic drug.

Delivery

93% of delivered paclitaxel is retained in solid phase at 24 hours, critical to ensuring prolonged tissue response.

Duration

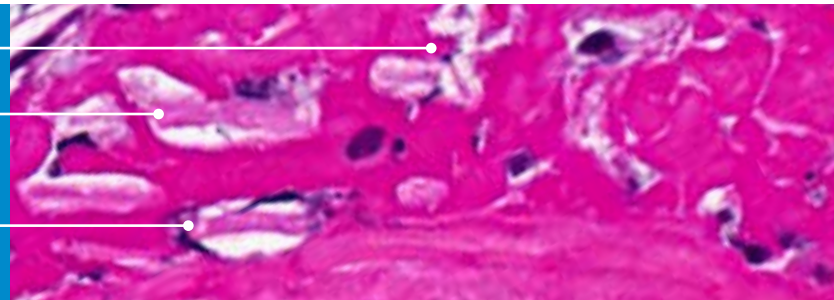
Solid-phase paclitaxel remains in tissue at therapeutic levels through 90 days.

Effect

IN.PACT™ Admiral™ DCB demonstrates continued trend of smooth muscle cell loss, managing restenosis through 90 days.

Paclitaxel reservoirs 28 days following drug delivery

Presence of solid-phase paclitaxel "reservoirs" enables prolonged anti-restenotic effect.

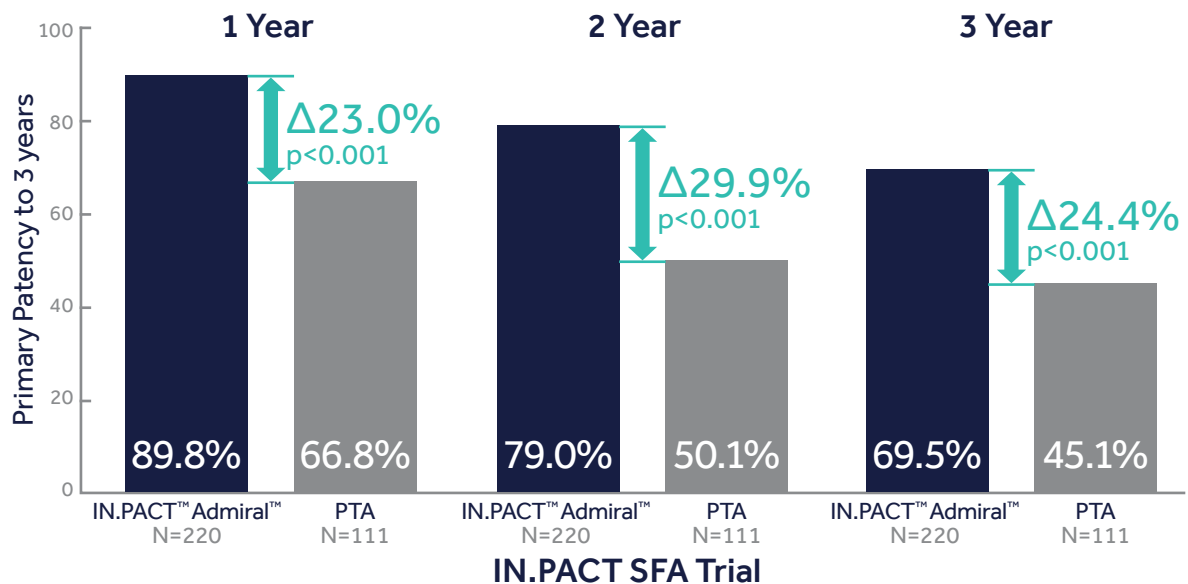


SUSTAINED DRUG = SUSTAINED BENEFIT

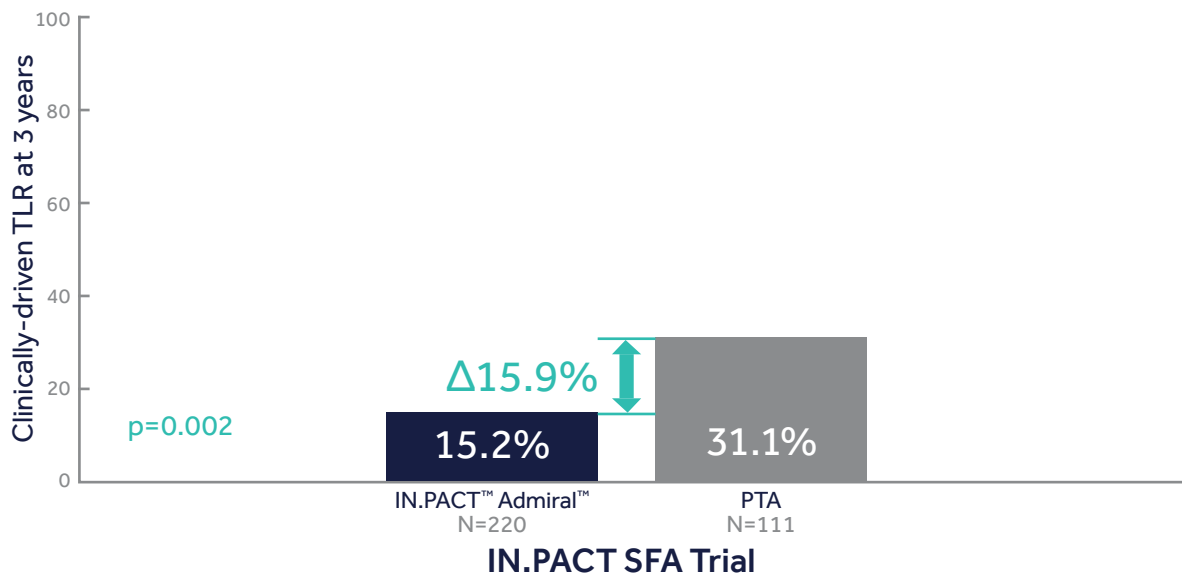
DURABLE.

IN.PACT™ Admiral™ drug-coated balloons demonstrate best-in-class clinical outcomes with durable performance through 3 years.

IN.PACT™ Admiral™ DCB shows durable outcomes in primary patency out to 3 years, relative to the PTA control arm.†



IN.PACT™ Admiral™ DCB had a low reintervention rate of 15.2%, half that found in the PTA control arm at 3 years.‡



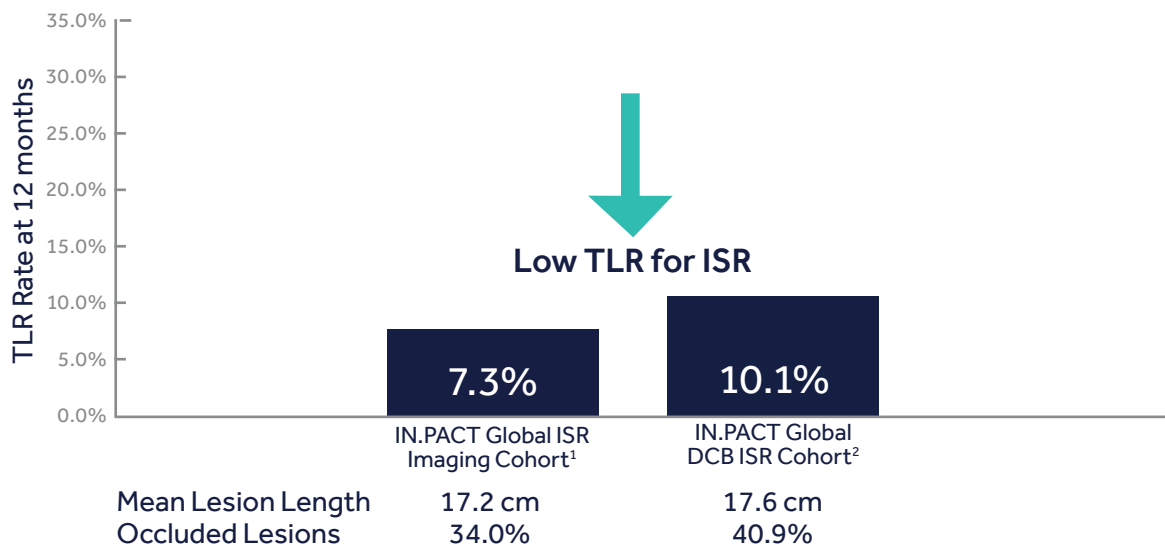
† Primary Patency: Freedom from clinically driven TLR or freedom from restenosis as determined by Duplex ultrasound peak systolic velocity ratio ≤ 2.4 at 12 months and reported again at 24 and 36 months. The 36-month primary patency was calculated based on Kaplan-Meier estimate.

‡ Clinically-driven TLR adjudicated by an independent Clinical Event Committee, blinded to the assigned treatment based on any re-intervention at the target lesion due to symptoms or drop of ABI of $\geq 20\%$ or >0.15 when compared to post-procedure baseline ABI.

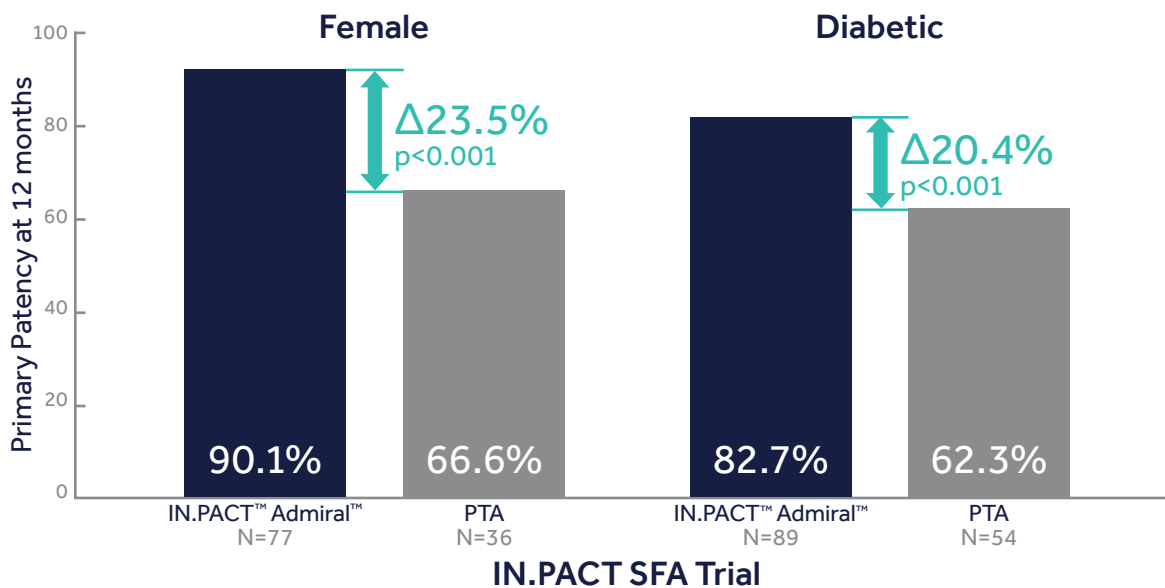
CONSISTENT.

IN.PACT™ Admiral™ drug-coated balloons demonstrate positive, consistent outcomes across trials, complex patients and lesion subgroups.

IN.PACT™ Admiral™ DCB provides high primary patency and consistently low TLR rates for ISR at 12 months.



IN.PACT™ Admiral™ DCB performs consistently across a range of complex patient types at 12 months.



TLR and Mean Lesion Length may be calculated differently, and therefore may not be directly comparable; chart is for illustration only. Overlap exists between the patient populations in the IN.PACT Global ISR Imaging Cohort and the IN.PACT Global ISR Cohort.

¹ M. Brodmann, VIVA 2015. CD-TLR Rate. ² Medtronic IN.PACT™ Admiral™ DCB IFU. Kaplan Meier 360-day TLR rate.

SAFE.

IN.PACT™ Admiral™ drug-coated balloons have an excellent safety profile, with superior results relative to PTA.

3-Year Safety Outcomes

	IN.PACT™ Admiral™ (n=220)	PTA (n=111)	p-value*
Primary safety composite ¹	81.2% (160/197)	64.1% (66/103)	<0.001 [†]
Device- and procedure-related death	0.0% (0/197)	0.0% (0/103)	N/A
Target limb major amputation	0.0% (0/197)	0.0% (0/103)	N/A
Thrombosis	2.0% (4/197)	4.9% (5/103)	0.283

Thousands of patients around the world have been treated with IN.PACT™ Admiral™ DCB, the established global market leader in drug-coated balloons.

150,000+ PATIENTS TREATED WITH IN.PACT™ ADMIRAL™**

21 TOTAL SFA STUDIES

3,500+ PATIENTS REGISTERED IN CLINICAL STUDIES

Values are % (n/N); *p values are based on Fisher exact test for superiority with significance level of 0.05

¹ Freedom from 30-day device- and procedure-related death and target limb major amputation and clinically driven TVR within 36 months

[†] 10% Non-inferiority Test Margin with one-sided 97.5005% CI

** Based on sales and use of IN.PACT™ Admiral™ DCB globally.

Ordering Information

IN.PACT™ Admiral™ Drug-Coated Balloon

Ref. Number Usable Length 80 cm	Ref. Number Usable Length 130cm	Balloon Diameter (mm)	Balloon Length (mm)	Recommended Introducer Sheath (F)	Nominal Pressure (atm)	RBP (atm)
ADM 040 040 08P	ADM 040 040 13P	4	40	5	8	14
ADM 040 060 08P	ADM 040 060 13P	4	60	5	8	14
ADM 040 080 08P	ADM 040 080 13P	4	80	5	8	14
ADM 040 120 08P	ADM 040 120 13P	4	120	5	8	14
ADM 040 150 08P	ADM 040 150 13P	4	150	5	8	14
ADM 050 040 08P	ADM 050 040 13P	5	40	6	8	14
ADM 050 060 08P	ADM 050 060 13P	5	60	6	8	14
ADM 050 080 08P	ADM 050 080 13P	5	80	6	8	14
ADM 050 120 08P	ADM 050 120 13P	5	120	6	8	14
ADM 050 150 08P	ADM 050 150 13P	5	150	6	8	14
ADM 060 040 08P	ADM 060 040 13P	6	40	6	8	14
ADM 060 060 08P	ADM 060 060 13P	6	60	6	8	14
ADM 060 080 08P	ADM 060 080 13P	6	80	6	8	14
ADM 060 120 08P	ADM 060 120 13P	6	120	7	8	14
ADM 060 150 08P	ADM 060 150 13P	6	150	6	8	14
ADM 070 040 08P	ADM 070 040 13P	7	40	7	8	14
ADM 070 060 08P	ADM 070 060 13P	7	60	7	8	14
ADM 070 080 08P	ADM 070 080 13P	7	80	7	8	14

Indications for Use

The IN.PACT™ Admiral™ Paclitaxel-Coated PTA Balloon catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of *de novo*, restenotic, or in-stent restenotic lesions with lengths up to 180 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.

Contraindications

The IN.PACT Admiral DCB is 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.
- Do not exceed the rated burst pressure (RBP). The RBP (14 atm [1419 kPa]) 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 and effectiveness of using multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 20.691 µg of paclitaxel in a patient has not been clinically evaluated in the IN.PACT SFA Trial.

Precautions

- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or sterilize this product. Reuse, reprocessing, or sterilization 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 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 this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events.
- Vessel preparation using only pre-dilatation was studied in the clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT Admiral DCB.
- This product is not intended for the expansion or delivery of a stent.

Potential Adverse Events

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 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.

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 www.manuals.medtronic.com.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician

FTSOP113326-32 Rev 1E

Medtronic

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