THINK LONG.

IN.PACT™ Admiral™
Drug-Coated Balloon

GO THE DISTANCE FOR LONG-TERM OUTCOMES.
WORLDWIDE EVIDENCE SUPPORTS CLINICAL PRACTICE

Around the world, IN.PACT™ Admiral™ DCB has been used as a frontline therapy to effectively treat patients with peripheral arterial disease (PAD).

THINK CONSISTENT

In rigorous adjudicated studies, IN.PACT™ Admiral™ DCB has demonstrated strong, consistent performance across multiple trials, patient populations, and lesion morphologies.

PRIMARY PATENCY AT 1 YEAR

- IN.PACT SFA Global Study² (Complex Lesion Cohort): 89.1%
- IN.PACT SFA China Study⁴: 90.9%
- IN.PACT SFA Japan Trial³: 93.9%
- IN.PACT SFA Trial²: 87.5%
THINK DURABLE

IN.PACT SFA Trial

THE ONLY AVAILABLE DCB PROVEN THROUGH 5 YEARS

3 out of 4 patients treated with IN.PACT™ Admiral™ DCB remain reintervention-free through 5 years

IN.PACT™ Admiral™ DCB Freedom from CD-TLR

1 YEAR 97.2% 5 YEARS 74.5%

THINK SAFE

10 YEARS of proven experience

375,000+ PATIENTS safely treated worldwide

ZERO device or procedure-related deaths through 5 years in the IN.PACT SFA Trial
BACKED BY THE MEDTRONIC RISK-SHARE 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™ Admiral™ Drug-Coated Balloon Risk-share Program is one of the ways Medtronic is partnering with you to add value to your healthcare practice.

With our Risk-share Program, we believe in our product and the clinical benefits it offers that we are willing to stand behind our outcomes.

HOW THE PROGRAM WORKS

1. TREAT
   Treat your patient with IN.PACT™ Admiral™ DCB according to the IFU.

2. QUALIFYING EVENT
   For participating facilities: If patients return for a reintervention in the same vessel/lesion within a 12-month period, your facility qualifies for a rebate.

3. REBATE
   Simply submit the claim form within 30 days of the reintervention, and Medtronic will provide a $1,000 rebate to share in the cost of care.
GOING TO GREATER LENGTHS TO TREAT COMPLEX LESIONS

Available in 200 mm and 250 mm lengths.

The IN.PACT™ Admiral™ DCB enables physicians to treat long, complex lesions with longer balloon lengths, which helps reduce procedure time and costs.

THE VALUE OF IN.PACT™ ADMIRAL™ DCB

Clinical Performance
HIGHEST PRIMARY PATENCY1 89.1%

MEAN LESION LENGTH 28.74 cm

Clinical Efficiency
TREATING LONG LESIONS

SAVES TIME

LOWERS COST
Ordering Information

IN.PACT™ Admiral™ Drug-Coated Balloon

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References
1. Land JR. IN.PACT SFA 5-year Results: Presented at VIVA, 2018 Las Vegas, NV.
2. IN.PACT SFA Trial and IN.PACT SFA Global Study Complex Lesion Cohort: IN.PACT Admiral DCB IFU; MDS2524701 1 Rev. 1H.
4. IN PACT SFA China Study; Chen, Z. Twelve Month Results from the IN.PACT DCB in a Chinese Population. VEITH 2017.

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 360 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 anti-coagulant 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 of 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 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). 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 and effectiveness of using multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 34.854 mg of paclitaxel in a patient has not been clinically evaluated.

Precautions:
- This product is designed for single patient use only. Do not re-use, reprocess, or re-sterilize this product.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- Reuse, reprocessing, or re-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.
- 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.

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; hematomata; hemorrhage; hypotension/hypertension; inflammation; ischemia or infarction of tissue/gland; 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 spasm 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 leukopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthritis; 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 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 (USA) law restricts this device to sale by or on the order of a physician.