Medtronic

IN.PACT® Admiral®

PACLITAXEL-COATED PTA BALLOON CATHETER

Finally, an SFA Standard.

Innovating for life.

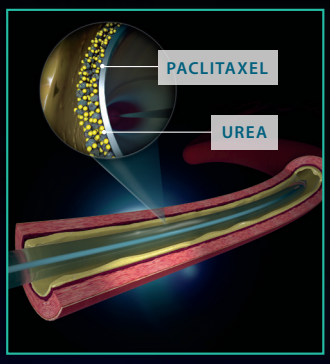
IN.PACT® ADMIRAL®
FINALLY, AN SFA STANDARD.

The IN.PACT Admiral drug-coated balloon (DCB) is a clinically-proven, primary endovascular therapy that enables physicians to confidently treat femoropopliteal disease, reduce reintervention, and preserve future treatment options.

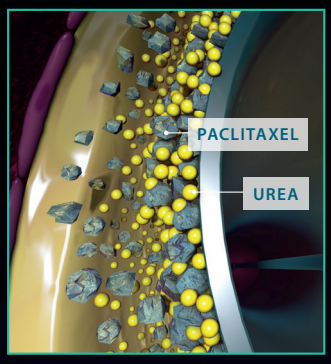
- **Incomparable Clinical Outcomes in the SFA**
- **Proven Primary Therapy in SFA Disease**
- **Differentiated DCB Design Intended to Maximize Safety and Efficacy**
- **Lowest Reported Reintervention Rate Offers Best-in-Class Patient Outcomes while Reducing Healthcare System Costs**

TECHNOLOGY HIGHLIGHTS

PLATFORM	DRUG	EXCIPIENT	COATING PROCESS
Medtronic	**Paclitaxel**	**Urea**	**Medtronic**
• Admiral® PTA balloon • 4 mm – 7 mm diameters • 40, 60, 80, 120 mm lengths	• Hydrophobic, lipophilic • Anti-proliferative drug • Therapeutic, efficacious dose (3.5ug/mm^2)	• Hydrophilic • Naturally-occuring • Non-toxic	• Uniform and stable • Controlled and scalable



1. IN.PACT Admiral is coated with a matrix of paclitaxel and an excipient, urea.



2. The coating comes into contact with water in the bloodstream upon inflation, hydrating the urea, which facilitates the release of paclitaxel at the target lesion.

3. Paclitaxel penetrates the vessel wall, where it remains at a therapeutic dose for over 180 days, addressing the causes of restenosis.

INCOMPARABLE CLINICAL OUTCOMES IN THE SFA

Outperforms All Other SFA Therapies

IN.PACT SFA Pivotal Trial

2.4%
CD-TLR
Lowest reported clinically-driven reintervention rate

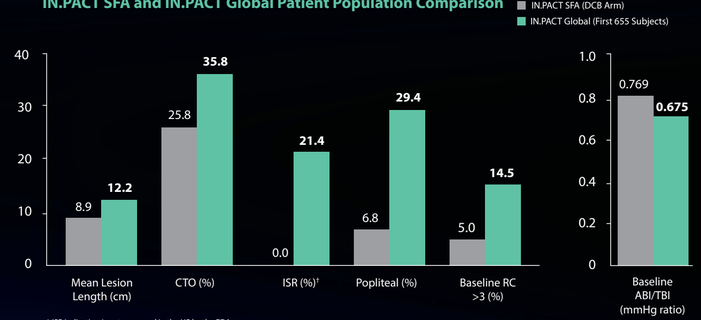
89.8%
PRIMARY PATENCY
Highest reported primary patency rate, while minimizing the use of durable implants

IN.PACT Global Single-Arm Study

8.7%
CD-TLR
Reproducible, positive outcomes in a complex, real-world population

IN.PACT Admiral demonstrates positive, consistent outcomes across a broad range of patient populations.

IN.PACT SFA and IN.PACT Global Patient Population Comparison



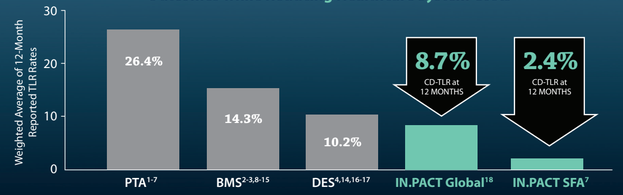
† ISR indication is not approved in the US by the FDA.

Extensive Clinical Portfolio

8 Presented Trials | **6** Published SFA Studies | **3,500+** Patients in Ongoing Trials

PROVEN PRIMARY THERAPY IN SFA DISEASE

Lowest Reported Reintervention Rate Offers Best-in-Class Patient Outcomes while Reducing Healthcare System Costs



Qualitative Comparison for Illustration Purpose Only. Not Meant for Head-to-Head Comparison.

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16. Lammer J et al. *J Vasc Surg.* 2011; 54:394-401
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Minimizing the Need for Durable Implants

- Metallic stents can be useful for the treatment of residual stenosis, flow-limiting dissection, and recoil, but the potential for chronic vessel injury and fracture remains an obstacle.
- Using DCB as a primary therapy with selective stenting may reduce the need for reintervention while preserving future treatment options.
- IN.PACT Admiral has demonstrated a low 7.3% provisional stenting rate.

IN.PACT Admiral SFA Treatment Strategy

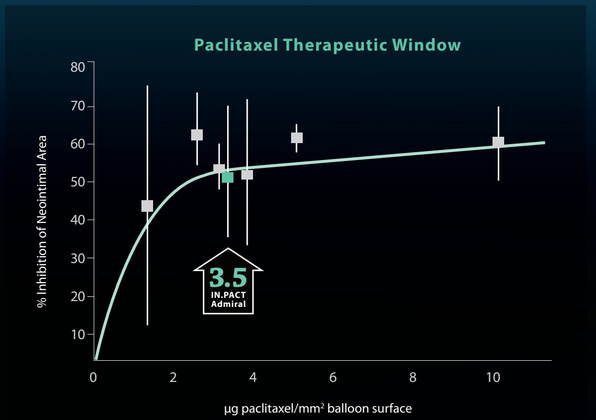
DCB	*Workhorse, primary therapy*
PTA	*Vessel pre- and post-dilatation*
BMS	*Treatment of suboptimal hemodynamic outcomes (recoil, residual stenosis, flow-limiting dissection, etc.)*
ATHERECTOMY	*Debulking and heavy calcium*

DIFFERENTIATED DCB DESIGN INTENDED TO MAXIMIZE SAFETY AND EFFICACY

Proprietary Balloon Coating Provides Efficacy while Maintaining Clinical Safety

- Paclitaxel dose of 3.5 µg/mm² for reduction of neointimal hyperplasia
- Naturally occurring excipient urea enables rapid drug transfer

Paclitaxel Therapeutic Window



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Exceptional Safety Profile

- 95.7% primary safety composite‡, proving superior safety to standard PTA
- Low, 1.4% and 3.8% thrombosis rates in IN.PACT SFA and IN.PACT Global, respectively

‡ Defined as freedom from device- and procedure-related death at 30 days and freedom from target limb major amputation and CD-TVR at 12 months.

ORDERING INFORMATION

IN.PACT ADMIRAL

Model Number (80cm Catheter)	Model Number (130cm Catheter)	Balloon Diameter (mm)	Balloon Length (mm)	Recom. Introducer Sheath (F)	RBP (atm)
ADM 040 040 08P	ADM 040 040 13P	4.0	40	5	14
ADM 040 060 08P	ADM 040 060 13P	4.0	60	5	14
ADM 040 080 08P	ADM 040 080 13P	4.0	80	5	14
ADM 040 120 08P	ADM 040 120 13P	4.0	120	5	14
ADM 050 040 08P	ADM 050 040 13P	5.0	40	6	14
ADM 050 060 08P	ADM 050 060 13P	5.0	60	6	14
ADM 050 080 08P	ADM 050 080 13P	5.0	80	6	14
ADM 050 120 08P	ADM 050 120 13P	5.0	120	6	14
ADM 060 040 08P	ADM 060 040 13P	6.0	40	6	14
ADM 060 060 08P	ADM 060 060 13P	6.0	60	6	14
ADM 060 080 08P	ADM 060 080 13P	6.0	80	6	14
ADM 060 120 08P	ADM 060 120 13P	6.0	120	7	14
ADM 070 040 08P	ADM 070 040 13P	7.0	40	7	14
ADM 070 060 08P	ADM 070 060 13P	7.0	60	7	14
ADM 070 080 08P	ADM 070 080 13P	7.0	80	7	14

Indications for Use:

The IN.PACT Admiral Paclitaxel-Coated PTA Balloon catheter is indicated for percutaneous transluminal angioplasty, after pre-dilatation, of de novo or restenotic lesions up to 180 mm in length in native 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 implanting 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 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.
- Potential interactions of the IN.PACT Admiral DCB with alternative therapies such as drug-eluting stents, lasers, atherectomy, cryoplasty, cutting/scoring balloons, and brachytherapy have not been evaluated and should be avoided whenever possible.
- 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

Potential Adverse Events

Adverse events that may occur or require intervention include, but are not limited to the following: 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 events observed with paclitaxel. There may be other potential adverse events that are unforeseen at this time.

Please reference appropriate product *Instructions for Use* for a detailed list of indications, warnings, precautions and potential adverse events. This content is available electronically at **www.manuals.medtronic.com**

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

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