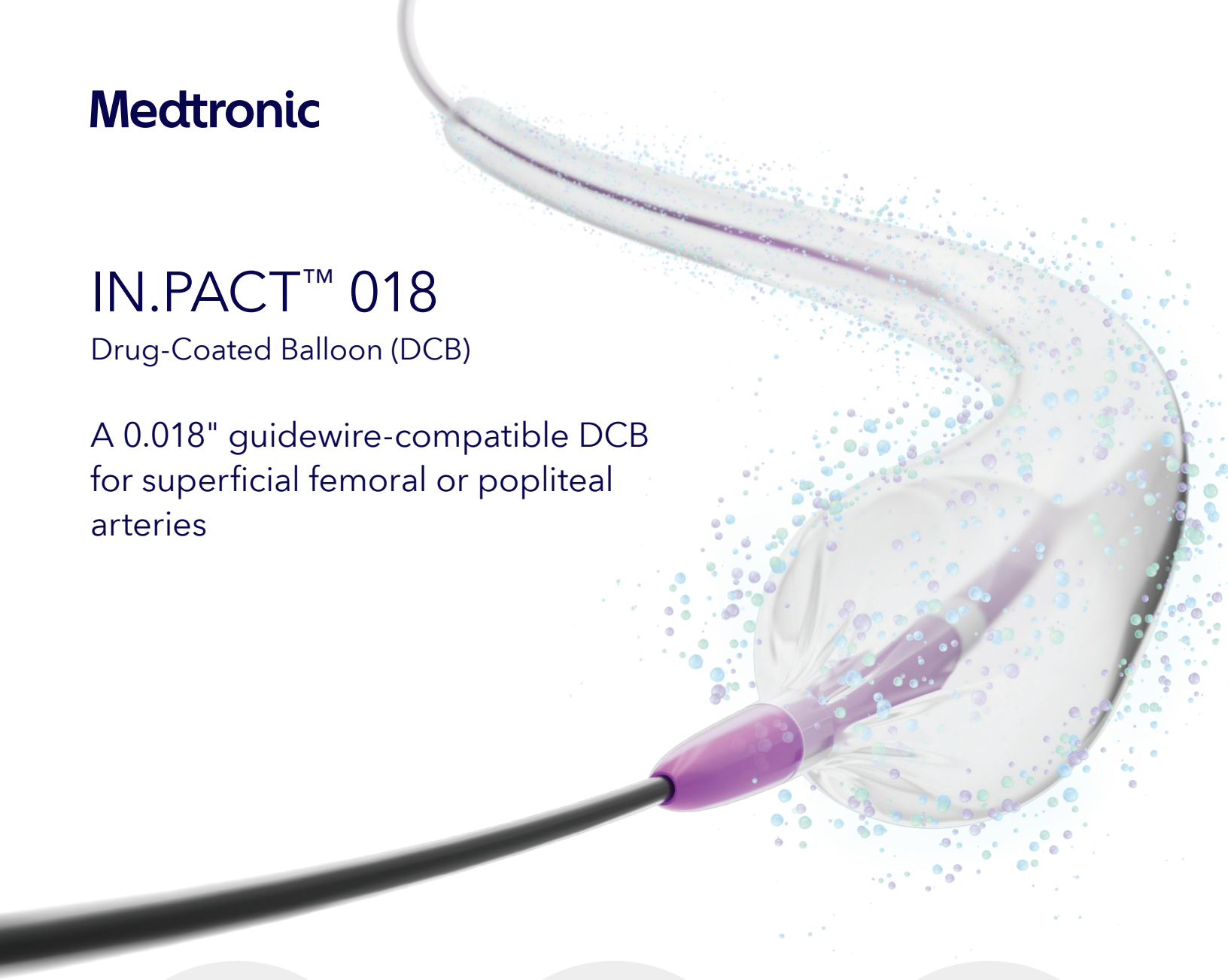
Medtronic

IN.PACT™ 018

Drug-Coated Balloon (DCB)

A 0.018" guidewire-compatible DCB for superficial femoral or popliteal arteries



Low-profile design

Engineered to cross tight lesions and provide better deliverability.[1]

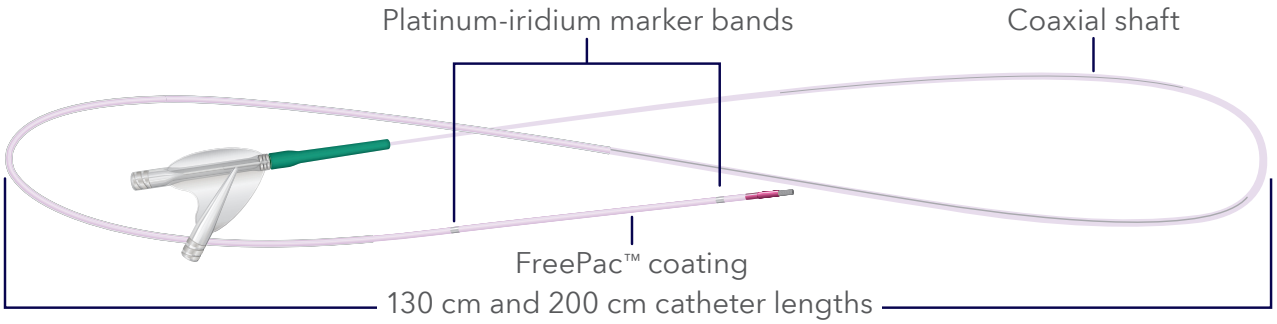
Proven technology

Utilizes the same proven drug formulation as the market-leading DCB, IN.PACT™ Admiral™.

Alternative access

Provides physicians the option to treat via femoral or radial access with 130 cm and 200 cm catheter lengths.

medtronic.com/INPACT018



130 cm catheter length

	Size matrix	40 mm	60 mm	80 mm	100 mm	120 mm	150 mm
5 F	4 mm	IPU04004013P	IPU04006013P	IPU04008013P	IPU04010013P	IPU04012013P	IPU04015013P
	5 mm	IPU05004013P	IPU05006013P	IPU05008013P	IPU05010013P	IPU05012013P	IPU05015013P
	6 mm	IPU06004013P	IPU06006013P	IPU06008013P	IPU06010013P	IPU06012013P	IPU06015013P
6 F	7 mm	IPU07004013P	IPU07006013P	IPU07008013P			

200 cm catheter length

	Size matrix	40 mm	60 mm	80 mm	100 mm	120 mm	150 mm
5 F	4 mm	IPU04004020P	IPU04006020P	IPU04008020P	IPU04010020P	IPU04012020P	IPU04015020P
	5 mm	IPU05004020P	IPU05006020P	IPU05008020P	IPU05010020P	IPU05012020P	IPU05015020P
	6 mm	IPU06004020P	IPU06006020P	IPU06008020P	IPU06010020P	IPU06012020P	IPU06015020P
6 F	7 mm	IPU07004020P	IPU07006020P	IPU07008020P			

[1]Data on file with Medtronic. Report numbers: 10191378DOC, 10644925DOC, D00261893.

Disclaimer: The safety and effectiveness of the IN.PACT Admiral DCB (.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.

Brief Statement
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 is 10 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.

Medtronic

medtronic.com/INPACT018