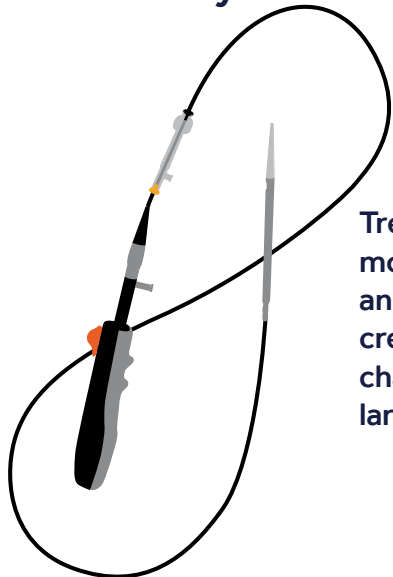


IMPRESSIVE ALONE. BETTER TOGETHER.

HawkOne™ Directional Atherectomy



Treats all morphologies and can create a small channel or large lumen.

IN.PACT™ Admiral™ Drug Coated Balloon (DCB)



The only DCB proven through five years with 75% of patients reintervention-free.¹



A NEW REALITY.

The REALITY Study, sponsored by the VIVA Physicians,² demonstrates how optimizing the combination of HawkOne™ Directional Atherectomy and IN.PACT™ Admiral™ DCB in treating peripheral artery disease can help achieve excellent patient outcomes.

LESION CHARACTERISTICS:^{*}



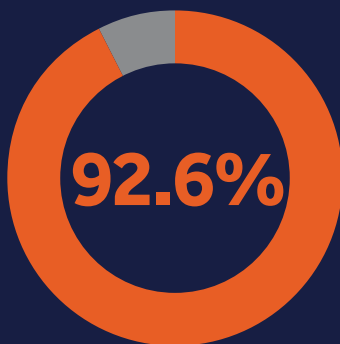
86.2% Bilateral Calcium [PACSS 3+4]

67.6% Bilateral Calcium ≥5 cm [PACSS 4]

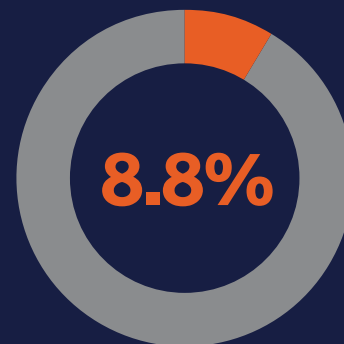
17.9 cm Average Lesion Length

39.0% Chronic Total Occlusions at Baseline

OUTCOMES IN COMPLEX, LONG, HEAVILY CALCIFIED LESIONS:³



12-MONTH FREEDOM FROM CD-TLR**



BAILOUT STENT RATE

To learn more, visit
[medtronic.com/RealityStudy](https://www.medtronic.com/RealityStudy)

Medtronic
Further, Together

* This image is an example of a REALITY Study lesion, it is for illustrative purposes only, and is not representative of an exact lesion from a patient in the study.

** 12-month data reported includes patients beyond the follow-up window.

¹ Laird JA, Schneider PA, Jaff MR, et al. Long-Term Clinical Effectiveness of a Drug-Coated Balloon for the Treatment of Femoropopliteal Lesions. *Circ Cardiovasc Interv.* June 2019;12(6):e007702.

² The REALITY Study was independently sponsored and conducted by the VIVA Physicians. The study prospectively enrolled 102 participants whose treatment outcomes were independently adjudicated by angiographic and duplex ultrasound core labs and a clinical events committee. The research was funded by Medtronic.

³ Rocha-Singh K. Data presented at VIVA 2020.

HawkOne™ Directional Atherectomy System

Important Information: Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.

Indications for Use: The HawkOne™ peripheral directional atherectomy system is intended for use in atherectomy of the peripheral vasculature. The HawkOne catheter is indicated for use in conjunction with the SpiderFX™ embolic protection device in the treatment of severely calcified lesions. The HawkOne catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.

Caution: Federal (USA) law restricts this product for sale by or on the order of a physician.

BRIEF STATEMENT

IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter

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 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

- **A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2–3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients.**
- 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 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 µg of paclitaxel in a patient has not been clinically evaluated.

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.
- 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 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 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 manuals.medtronic.com.

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

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