**Product Name:** IN.PACT Admiral Paclitaxel-Eluting Drug-Coated Balloon

*(Peripheral Vascular Therapeutics - In Development, Lower Limb Advanced Arterial Therapeutics, Pathway Clinical Trial MarketTracks, Medtronic PV Lower Limb Advanced Arterial Therapeutics)*

**Description:**
The In.Pact Admiral Drug-Eluting Balloon utilizes Invatec's proven PTA full balloon line, combined with Paclitaxel and Medtronic's proprietary coating technology to treat de novo lesions, in-stent restenosis, BTK lesions and combination therapies of debulking plus DEB.

**Company/Sponsor:**
- Invatec (Medtronic)
- Medtronic Vascular

**Vessels:**
- Femoral Arteries (SFA/Superficial)
- Lower Limb Arteries

**General Modality:**
- Medical Devices

**Clinical Trials:**
Combined treatment of heavy calcified femoropopliteal lesions using directional atherectomy and a paclitaxel coated balloon: One-year single centre clinical results
- **COMPARE I Pilot Study** - Prospective, Randomized, Multi-Center Study for the Treatment of Subjects With Symptomatic Femoropopliteal Artery Disease With the Ranger Paclitaxel Coated PTA Balloon
- **DCB-SFA Study** - Randomized Comparison of Drug-Coated Balloons for the Treatment of Superficial Femoral and Popliteal Peripheral Artery Disease
- **DEBATE SFA Study** - Drug Eluting Balloon in peripheralAr inTervention
- **DEBATE-ISR** - Drug Eluting Balloon in Peripheral Intervention for In-Stent Restenosis
- **Disrupt PAD III Study** - Shockwave Medical Peripheral Lithoplasty System Study for PAD
- **FAIR** - Femoral Artery In-Stent Restenosis FORTEZ Study - Prospective Study for the Treatment of Atherosclerotic Lesions in the Femoral and/or Popliteal Arteries Using the FLEX Scoring Catheter Plus DCB
- **HEROES-DCB Trial** - Lutonix or Inpact for tHE Use of a new fixture for proximal connector tube flaring.
- **IN.PACT Global clinical study**
- **IN.PACT SFA I Trial** - European Trial: Randomized Trial of IN.PACT Admiral(TM) Drug Eluting Balloon vs Standard PTA for the Treatment of SFA and Proximal Popliteal Arterial Disease
- **IN.PACT SFA II Trial** - Randomized Trial of IN.PACT (Paclitaxel) Admiral DEB vs Standard Percutaneous Transluminal Angioplasty (PTA) for the Treatment of Atherosclerotic Lesions in the SFA and/or PPA
- **IN.PACT SFA Study** - randomized trial of IN.PACT Admiral DCB vs. Standard PTA for the treatment of atherosclerotic lesions in the SFA and/or PPA
- **INPCFTLEXION Study** - In.Pact Flexion Study

**Product Image:**
![Product Image](Image)

**Commercial Approval:**
- On December 14, 2016 Medtronic received PMA approval for IN PACT Admiral in order conduct incoming inspections of materials used in manufacturing the catheter body subassembly at an alternate manufacturing site
- On January 26, 2017 Medtronic received PMA approval for IN PACT Admiral for minor modifications to the incoming inspection of the active pharmaceutical ingredient to include expiry dates of the solutions
- On March 7, 2017 Medtronic Inc received PMA approval for IN PACT Admiral for automation of the calculation of analytical test methods results
- On March 30, 2017 Medtronic Inc received PMA approval for IN PACT Admiral for Use of European Pharmacopeia paclitaxel reference standard for lot release and stability testing.
- On May 11, 2017 Medtronic Inc received PMA approval for IN PACT Admiral for Modification to a manufacturing aid material.
- On June 23, 2017 Medtronic Inc received PMA approval for IN PACT Admiral for Use of a new fixture for proximal connector tube flaring.
- On July 6, 2017 Medtronic received PMA approval for IN PACT Admiral for Approval for a shelf life extension to 36 months.
- On September 8, 2017 Medtronic announced that the IN.PACT Admiral Drug-Coated Balloon (DCB) received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for the treatment of peripheral artery disease (PAD)
- On January 05, 2018 Medtronic received PMA approval for IN.PACT Admiral Drug-Coated Balloon (DCB) for to implement an alternate drug coater for the manufacturing of the IN.PACT Admiral Paclitaxel-Coated Balloon Catheter
- On April 23, 2018 Medtronic announced that that it has received U.S. Food and Drug Administration (FDA) approval for the IN.PACT(TM) Admiral(TM) Drug-Coated Balloon (DCB) to treat long superficial femoral artery (SFA) lesions up to 360mm in patients with peripheral artery disease (PAD).
- On June 15, 2018 Medtronic receives FDA Approval for 200mm & 250mm IN.PACT Admiral Drug Coated Balloons to treat long superficial femoral artery (SFA) lesions in patients with peripheral artery disease (PAD).
- Medtronic Inc received PMA approval for IN PACT Admiral on October 5, 2018 for to implement a new labeling system at the Galway facility.
- Awarded a CE Mark On May 19, 2009 for the treatment of Peripheral Arterial Disease (PAD), including the Peripheral Femoral Artery (SFA)
- On December 2014, the IN.PACT Admiral Paclitaxel-Elluting Drug-Coated Balloon has received FDA Approval to be marketed as treatment designed to open up blocked or narrowed arteries in the thigh and knee.
- On July 13, 2016, IN PACT Admiral drug coated balloon (DCB) received FDA approval for 150mm length balloon, which will provide greater treatment options for long lesions in patients with peripheral artery disease (PAD)
- On February 14, 2017 Medtronic IN PACT DCB received Health Canada licence, in order to market the device in Canada.
- On October 31, 2016 Medtronic received PMA approval for IN PACT for modifications to the potency and related substances test method to include relative retention time and correction factors.

**Development Status - Commercial Events:**
Investigating the In.Pact Admiral DEB for Popliteal Lesions
• JET RANGER Trial - JETStream Atherectomy With Adjunctive Paclitaxel-Coated Balloon Angioplasty vs Plain Old Balloon Angioplasty Followed by Paclitaxel Coated Balloon MDT-2113 (IN.PACT Admiral) SFA Japan Trial - MDT-2113 (IN PACT Admiral) Drug-Eluting Balloon vs. Standard PTA for the Treatment of Atherosclerotic Lesions in the Superficial Femoral Artery Medtronic IN.PACT Drug Eluting Balloon Angioplasty Versus Nitinol Stent Implantation in the Superficial Femoral Artery Paclitaxel-coated balloon angioplasty for lower extremity revascularization: better way to fight restenosis? PHOTOPAC - Photoablation Followed by a Paclitaxel-Coated Balloon to Inhibit Restenosis in In-stent Femoropopliteal Obstructions REALITY - DiRectional AthErectomy + Drug-coAted BaLloon to Treat Long, CalciFed Femoropopliteal Artery Stenoses REALITY Study - DiRectional AthErectomy + Drug CoAted BaLloon to Treat Long, CalciFed Femoropopliteal Artery Lesions Safety and Tissue Level of Paclitaxel in Patients With Critical Limb Ischemia (CLI) and Femoropopliteal Occlusive Disease The IN.PACT SFA Clinical Study for the Treatment of Atherosclerotic Lesions in the Superficial Femoral Artery and/or Proximal Popliteal Artery Using the IN.PACT Admiral™ Drug-Eluting Balloon in a Chinese Patient Population TOBA III Study - Tack Optimized Drug Coated Balloon Angioplasty Study of the Tack Endovascular System™ in Femoropopliteal Arteries Total IN.PACT Pooled Imaging and Propensity Analyses TRANSCEND Trial - Safety and Efficacy of the SurVeil™ Drug-Coated Balloon

**Please Note:** All links will open in the current window - to open a link in a new window please right click the link and select "Open in New Window" or "Open in New Tab"

Sources:


On August 15, 2018 Medtronic announced full commercial launch of the IN.PACT(TM) Admiral(TM) Drug-Coated Balloon (DCB) in Japan. On April 21, 2010 Medtronic announced the completion of their acquisition of Invatec and Invatec's affiliated companies On August 15, 2013, MEDTRONIC, Inc announced the submission of its first Pre-Market Approval module to the U.S. Food and Drug Administration for the IN.PACT Admiral drug-elution balloon


November 10, 2016 --- "Development Status" field - Added FDA PMA approval for modifications to the potency and related substances test method to include relative retention time and correction factors. --- "Sources" field - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140010S018>


November 15, 2010 --- "Commercial Approval" field - Added FDA approval is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae --- "Sources" field - <www.accessdata.fda.gov/cdrh_docs/pdf6/K062809.pdf> "510-K"; FDA, October 18, 2006.


Last Update: October 11, 2018