Product Fact Sheet

IN.PACT Admiral Drug-Coated Balloon

Drug-coated balloons are a breakthrough therapy for the treatment of peripheral artery disease (PAD) in the upper leg, specifically in the arteries in the thigh (superficial femoral artery) and behind the knee (popliteal artery).

Developed by Medtronic, the **IN.PACT® Admiral® drug-coated balloon (DCB)** is a medical device designed to help restore blood flow in the upper leg by reopening narrowed or blocked arteries and delivering a proven, safe, and effective anti-restenotic drug dose to the artery walls.

A New Primary Therapy for PAD in the Upper Legs

Minimally-invasive, catheter-based procedures like percutaneous transluminal angioplasty (PTA), atherectomy, and stents have traditionally been used to treat PAD in the upper legs, after exercise and medical management have failed. However, these types of treatments have been associated with the need for repeat procedures within six to 12 months because the plaque returns to the vessel wall. The introduction of IN.PACT Admiral offers a new minimally-invasive therapy for this type of PAD that decreases the need for repeat procedures, as shown by lower clinically-driven target lesion revascularization (CD-TLR) rates. It is also associated with the highest reported rates of restored blood flow in the treated artery as determined by primary patency.

Technology Features

Proven Platform

- IN.PACT Admiral is a differentiated drug-coated balloon built on Medtronic's proven Invatec PTA balloon platform, which leverages a long history of PTA innovation and experience in the treatment of PAD
- The device is available in 40, 60, 80 and 120 mm lengths and can accommodate vessels ranging from 4-7 mm in diameter

Proprietary Drug Coating

- IN.PACT Admiral is coated with a proprietary formulation of the anti-restenotic drug paclitaxel and an excipient called urea designed to maximize safety and efficacy
- Paclitaxel is the drug that is transferred to the artery wall to help prevent restenosis and is delivered in a 3.5 $\mu g/mm^2$ dose to maximize therapeutic benefit
- Urea is a hydrophilic, naturally occurring substance that facilitates the release of paclitaxel when the balloon comes into contact with the artery wall

Established Drug

- Paclitaxel is a well-characterized chemotherapy drug that halts cancer cell growth by preventing cell division and replication
- Doctors have successfully used paclitaxel-coated stents to treat PAD in the upper legs for several years as the medication provides a strong anti-restenotic benefit and prevents the re-narrowing of the artery due to plaque build-up
- Similarly, paclitaxel has become well-established as a primary drug used in drug-eluting stents to treat coronary artery disease since the early 2000s

How It Works[i]

- The IN.PACT Admiral DCB is inserted along a flexible wire through a very small incision made near the upper thigh and guided to the location of the plaque that is blocking blood flow.
- As the balloon inflates, the plaque is pushed against the side of the artery and the paclitaxel is transferred to and absorbed into the artery wall

- The balloon is then removed with only the drug left behind, and the newly opened blood vessel enables restored blood flow through the treated artery
- The drug absorbed into the vessel wall will remain at therapeutic doses for 180+ days, continuing to fight the progression of disease

Clinical Leadership

IN.PACT Admiral is supported by a robust body of clinical evidence demonstrating the best reported outcomes of all existing therapies for PAD in the upper leg, and suggest IN.PACT Admiral as the primary therapy option for the treatment of this common form of the condition. It is the most studied drug-coated balloon to date with ongoing clinical studies involving more than 3,500 patients worldwide that demonstrate positive, consistent results across a broad range of patient populations, both in real-world and rigorously controlled settings.

Fewer Repeat Procedures[ii]

- IN.PACT Admiral is associated with the lowest reported CD-TLR rate ever reported in this vessel bed
- Only 2.4% of patients required a repeat procedure at one year in the pivotal IN.PACT SFA Trial, compared to 20.6% of patients treated with PTA

Restored Blood Flow[ii]

- IN.PACT Admiral has the highest reported patency rates of any medical device used to treat SFA disease
- In the IN.PACT SFA Trial, rates of primary patency, or adequately restored blood flow, were 89.8% in the DCB group, compared to 66.8% in the PTA group at 12 months (per Kaplan-Meier Day 360 estimates)

Exceptionally Safe[ii]

- IN.PACT Admiral has an exceptional safety profile, with a 95.7% primary safety composite*, proving superior safety to standard PTA
- It has also demonstrated a low thrombosis rate of 1.4%, according to one-year pivotal data from IN.PACT SFA Trial

*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.

Economic Benefit[iii]

- Due to the fact that IN.PACT Admiral reduces the need for expensive repeat procedures, the new therapy is also economically attractive
- Results from an interim economic analysis of the IN.PACT SFA Trial revealed treatment with IN.PACT Admiral is cost-effective compared to balloon angioplasty at one year, despite higher initial hospital costs
- These findings indicate IN.PACT Admiral may lower overall healthcare costs over the longer-term

Regulatory Status

Since receiving CE (Conformité Européenne) Mark in 2009, IN.PACT Admiral has become the most widely used DCB by European physicians. IN.PACT Admiral was approved by the U.S. Food and Drug Administration in December 2014, offering a new primary therapy to patients and physicians in the U.S.

For more information about IN.PACT Admiral, visit: www.medtronic.com/dcb.

###

[i] IN.PACT Admiral Drug-Coated Balloon. Instructions for Use. Data on file at Medtronic
[ii] Tepe, G Charing Cross Symposium. 2014; London, UK
[iii] Salisbury, AC Transcatheter Cardiovascular Therapeutics. 2014; Washington, DC