**Product Name:** Passeo-18 Lux Drug-Eluting Balloon

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

**Description:**

- Based on Passeo-18, BIOTRONIK’s established 0.018 in. guidewire-based PTA balloon and is coated with a homogeneous layer of the drug
- Paclitaxel combined with a carrier for increased bioavailability and optimized antiproliferative effect

**Company/Sponsor:**

- BIOTRONIK

**Vessels:**

- Lower Limb Arteries
- Femoral-Popliteal Arteries (FemPop)

**General Modality:**

- Other Advanced Therapies

**Specific Modality:**

- Other Advanced Therapy Delivery Systems

**General Product Type:**

- Balloon Catheters

**Specific Product Type:**

- Paclitaxel Balloon Catheter

**Clinical Trials:**

4EVER Study - Investigating the Safety of the
- Full 4F Endovascular Treatment AppRoach of Infra-Inguinal Arterial Stenotic Disease
- BIOLUX 4EVER Trial - Physician-Initiated Trial Investigating the Efficacy of Endovascular Treatment of Femoropopliteal Arterial Stenotic Disease With the Biotronik Passeo-18 Lux Drug Releasing Balloon and the Biotronik Pulsar-18 Stent
- BIOLUX P-I Clinical Study
- BIOLUX P-II - First in Men Study of the Passeo-18 Balloon Catheter in Subjects Requiring Revascularization of Infrapopliteal Arteries
- BIOLUX P-III BENELUX All-Comers Registry
- BIOLUX P-III SPAIN All-Comers Registry
- BIOLUX-III Registry - All Comers Registry

**Commercial Approval:**

- Received FDA 510(k) Premarket Notification approval for Passeo-18 PTA Catheter Special on September 27, 2007
- On January 26, 2016, BIOTRONIK received CE Mark Approval for the smaller diameter versions of the Passeo-18 Lux Peripheral Drug-Eluting Balloon

**Development Status - Commercial Events:**

On January 21, 2014, BIOTRONIK announced the Europe-wide Release of Passeo-18 Lux Peripheral Vascular Drug Releasing Balloon in all countries accepting CE mark, following recent CE approval
- On January 26, 2016, BIOTRONIK received CE Mark Approval for the smaller diameter versions of the Passeo-18 Lux Peripheral Drug-Eluting Balloon

**Development Status - Clinical Trials:**

In October 2010, BIOTRONIK began the BIOLUX P-I Clinical Study to investigate the safety and performance of the BIOTRONIK Passeo-18 Lux, a drug-eluting balloon (DEB) catheter, versus a noncoated percutaneous transluminal angioplasty (PTA) catheter, for the treatment of lesions in the femoropopliteal segment
- In July 2012, BIOTRONIK began the BIOLUX P-II Clinical Study to investigate the safety and performance of the Passeo-18 Lux Paclitaxel releasing PTA balloon catheter versus the uncoated Passeo 18 PTA balloon catheter for the treatment of stenosis, restenosis or occlusion of the infrapopliteal arteries.

**Sources:**


September 8, 2011 --- "Commercial Approval" field - Added FDA approval indicated for dilatation of stenotic segments in peripheral vessels--- "Sources" field - <http://www.accessdata.fda.gov/cdrh_docs/pdf7/K072765.pdf> "Passeo-18