**Product Name:** Lutonix Drug Coated Balloon Catheter (Formerly Lutonix® MOXY DCB)

**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, Lower Limb In-Stent Restenosis - LL ISR**

**Description:**
- Combines the advantages of angioplasty balloons (a mechanical technique of widening narrowed or obstructed arteries) and drug-releasing stents, to treat Peripheral Arterial Disease (PAD) in the femoral and popliteal arteries.

**Company/Sponsor:**
- Lutonix, Inc.
- C. R. Bard (BD - Becton, Dickinson and Company)
- Bard Peripheral Vascular, Inc (BD - Becton, Dickinson and Company)

**Vessels:**
- Femoral-Popliteal Arteries (FemPop)

**General Modality:**
- Other Advanced Therapies

**Specific Modality:**
- Other Advanced Therapy Delivery Systems

**General Product Type:**
- Balloon Catheters

**Clinical Trials:**
- Bard LifeStent and Lutonix DCB for Treatment of Long Lesions in Femoropopliteal Arteries
- BTK Registry - Registry Investigating the Clinical Use and Safety of the Lutonix Drug Coated Balloon
- Balloon for Treatment of Below-the-Knee Arteries
- CONFIRM Study - Lutonix Drug Coated Balloon for Treatment of Femoropopliteal Arteries in United States Females
- DCB-SFA Study - Randomized Comparison of Drug-Coated Balloons for the Treatment of Superficial Femoral and Popliteal Peripheral Artery Disease
- Freeway vs. Lutonix DEBATE-BTK Post-hoc Study - Drug Eluting Balloon in peripheral inTervenion for Below-The-Knee Arteries With Freeway and Lutonix
- HEROES-DCB Trial - Lutonix or Impact for the Treatment Of Femoropopliteal Stenosis
- LEG - LUTONIX® Lower Extremity Global (LEG) Registry
- LEVANT 2 Registry - Access Registry
- LEVANT 2 Registry - Safety Registry
- LEVANT 2 Study - A Prospective, Multicenter, Single Blind, Randomized, Controlled Trial
- Comparing the Lutonix (Moxy) Drug Coated Balloon vs. Standard Balloon Angioplasty for Treatment of Femoropopliteal Arteries
- LEVANT CHINA - A Prospective, Multicenter, Single Arm Trial Evaluating the BARD Lutonix Drug-Coated Balloon (LTX DCB) for Treatment of Femoropopliteal Arteries
- LEVANT I Study - The Lutonix Paclitaxel-Coated Balloon for the Prevention of Femoropopliteal Restenosis
- Lutonix DCB for Treatment of Long Lesions in Femoropopliteal Arteries

**Commercial Approval:**
- On September 7, 2018, BD announced that it has received FDA approval for the 220-mm length of its Lutonix 035 drug-coated balloon (DCB) for the treatment of long superficial femoral artery (SFA) lesions in patients with peripheral artery disease (PAD).
- On June 28, 2018 CR Bard received PMA application approval for Lutonix 035 DCB PTA for a change in the frequency of endotoxin monitoring.
- On February 7, 2017 CR Bard received PMA application approval for Lutonix 035 DCB PTA for appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions up to 300 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.
- On March 7, 2017 CR Bard received PMA application approval for Lutonix 035 DCB PTA for Modifications to the preparation method for the coating solution.
- On February 6, 2018 CR Bard received PMA application approval for Lutonix 035 DCB PTA for revised protocol for the post approval study (PAS) protocol.
- On June 15, 2018 CR Bard received PMA application approval for Lutonix 035 DCB PTA for minor updates to the Instructions for Use.
- On August 29, 2018 lutonix received PMA approval for an extension of the product matrix to include balloon lengths up to 220 mm for all diameters of the Lutonix 035 Drug Coated Balloon.
- On December 16, 2016 Bard received PMA approval for Lutonix DCB for its Modifications to annual stability monitoring protocol and associated test methods.
- On October 13, 2014 -- Lutonix 035 Drug Coated Balloon (DCB) Catheter became the first Drug Coated Balloon approved by the U.S. Food and Drug Administration (FDA).
- On December 18, 2018 BD (Becton, Dickinson and Company) announced that it has received FDA approval for its 0.018-inch–guidewire-compatible Lutonix 018 drug-coated balloon (DCB) for the treatment of long superficial femoral artery lesions in patients with peripheral artery disease.
- On November 21, 2016 CR Bard received PMA application approval for Lutonix 035 DCB PTA for shelf life extension from 24 to 36 months.
- On June 3, 2019 BD (Becton, Dickinson and Company) announced that the FDA has approved expanded sizes of the company's Lutonix 018 drug-coated balloon (DCB) to treat long superficial femoral artery lesions in patients with peripheral artery disease. The new lengths are 80, 100, 150, and 220 mm.
- Awarded a CE Mark, June 28th 2011.
- On November 25, 2013, Bard submitted final PMA module for Lutonix DCB.
- On February 14, 2019 Lutonix received PMA approval for a shelf life extension to 24 months for devices with balloon sizes 4 x 220 mm and 5 x 220 mm (standard balloon) and 6 x 220 mm (low profile balloon).

**Development Status - Commercial Events:**
Development Status - Clinical Trials:

On July 27, 2009 Lutonix announced their DCB Catheter was involved in three clinical trials: The PERVIDEO I Registry, The LEVANT I Trial, and The Lutonix De Novo Pilot Study; Both the PERVIDEO I Registry and De No Pilot Study are testing treatment in coronary lesions, while the LEVANT I is testing treatment in preventing restenosis in the femoropopliteal arteries.

Sources:


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