Drug Coated Balloons: The Evidence is Black and White

**FreePac Formulation**
Medtronic In.Pact Admiral™ & Amphirion

**LUTONIX® Formulation**
ALL LUTONIX® DCB Products

12% Downstream Necrosis
In.Pact™ Admiral™
in Pre-Clinical Downstream Findings at 90 Days

0% Downstream Necrosis
LUTONIX® 035 DCB
in Pre-Clinical Downstream Findings at 90 Days

2013 All Market DCB BTK Voluntary Product Recall
In.Pact™ Amphirion™
due to increased rate of major amputations and no efficacy improvement

OR

None

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1 Downstream skeletal muscle necrosis in swine arterial tissue at 90 days with 3x dosing. Dr. Virmani preclinical data, on file at Bard Peripheral Vascular Inc., Tempe, AZ. Preclinical results may not be indicative of actual clinical performance. Different test methods may yield different results.


3 No LUTONIX® DCB clinically-driven efficacy or safety-related recalls.

Note: the LUTONIX® 035 DCB Coated Balloon and the In.Pact™ Admiral™ paclitaxel-coated PTA balloon indications for use differ slightly. Please consult product labels and instructions for use relevant to your geography for indications, contraindications, hazards, additional warnings and precautions. EU Indications for use: The Lutonix® 035 Drug Coated Balloon Catheter is intended for use as a PTA catheter to dilate stenotic or obstructive vascular lesions in the lower extremities, and native or synthetic arteriovenous fistulae, for the purpose of improving limb perfusion and decreasing the incidence of restenosis. Bard, Advancing Lives and the Delivery of Health Care, and Lutonix are registered trademarks of C. R. Bard, Inc. All other trademarks are the responsibility of their respective owners. Not for distribution in USA, France, Italy, Belgium, or Japan.