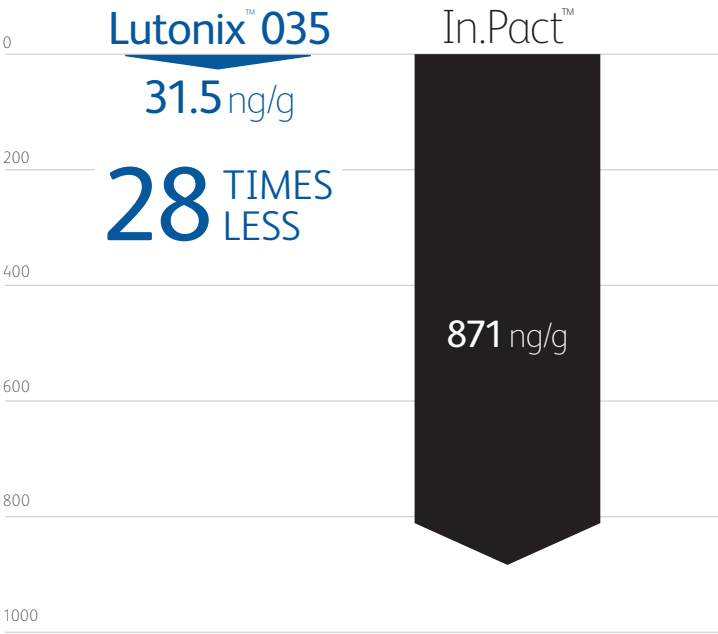
Downstream Paclitaxel Concentration Levels

Lutonix™ 035 DCB vs. In.Pact™

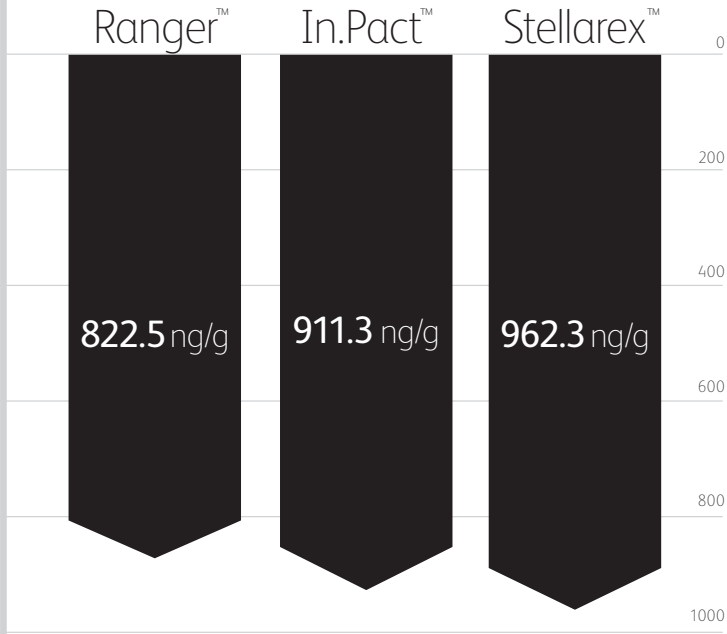
Pre-Clinical Study as Published in JVIR*



Coronary Band Hoof of the swine at 28 days

In.Pact™ DCB vs. Stellarex™ DCB & Ranger™ DCB

Pre-Clinical Study**



Coronary Band Hoof of the swine at 28 days

Lutonix™ 035

Drug Coated Balloon PTA Catheter

* November 2016. Journal of Vascular and Interventional Radiology: Comparison of Particulate Embolization after Femoral Artery Treatment with IN.PACT Admiral versus Lutonix 035 Paclitaxel-Coated Balloons In Healthy Swine. Limitations associated with this pre-clinical study include: Pathologic findings are limited to healthy swine and do not account for the fact that human PAD presents with co-morbidities; and transferring pre-clinical findings in healthy animal arteries to humans with peripheral arterial disease is complex, as lesions can be complicated fibrosis, necrosis and calcification. Data presented as median (interquartile range). This study was funded by Lutonix, Inc. (New Hope, Minnesota). Article available at: https://www.jvir.org/article/S1051-0443(16)30338-4/pdf.

** Pre-Clinical head-to-head comparison of vascular changes (inflammation, smooth muscle cell necrosis, fibrinoid necrosis, nuclear pykosis). 3x balloons. 1 minute inflation. Data presented are median (interquartile range). Pre-clinical safety comparison study of and downstream paclitaxel level of treatment with different Drug Coated Balloon Catheters in a swine femoral model and may not be indicative of clinical performance. Data on file, Bard Peripheral Vascular, Inc. March 2017.

In August 2019, the U.S. Food and Drug Administration (FDA) issued an updated letter to health care providers noting an increased risk in late mortality (2-3 years post-treatment) with paclitaxel-coated devices when used to treat peripheral arterial disease in the femoropopliteal artery as compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients. BD will continue to work collaboratively with FDA and industry for additional safety data collection and inform labeling as appropriate. These communications as well as information about the FDA Panel meeting can be found at: https://www.fda. gov/medical-devices/letters-health-care-providers/august-7-2019-update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel Pre-Clinical data sets from different studies are not comparable. Different test methods may yield different results. Please consult product labels and instructions for use for indications, contraindications, hazards, warnings and precautions.

BD

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