Boston Scientific

Boston Scientific Responds to the FDA's Guidance on Use of Peripheral Paclitaxel Devices for Treatment of PAD

On August 7, 2019, the U.S. Food and Drug Administration (FDA) published guidance to physicians about the benefit-risk profile of peripheral paclitaxel devices intended for the treatment of peripheral artery disease (PAD).

The guidance notes doctors should discuss the risks and benefits of all available PAD treatment options and may determine the benefits of paclitaxel devices outweigh the risks of late mortality in individuals at high risk for restenosis and repeat interventions. Clinicians should work with patients to make informed treatment decisions based on the available data and individual patient needs.

We are pleased physicians will have continued access to the Eluvia™ Drug-Eluting Vascular Stent (DES) System, which has demonstrated an excellent safety profile and a very low revascularization rate of 12.9% at two years in the pivotal IMPERIAL trial – including many complex PAD patients – representing a statistically significant improvement when compared to the control group with a competitor's paclitaxel-coated stent.[i],[ii]

We look forward to collaborating with the FDA and industry partners, as appropriate, on the revised labeling changes, data collection requirements and informed consent protocols to ensure treatment options are available for the 8.5 million patients in the U.S. suffering from PAD.[iii]

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[i] Boston Scientific Data on File. As-treated ELUVIA and Zilver PTX Control data from IMPERIAL RCT.

[ii] As presented at FDA Circulatory System Devices Panel Meeting. June 2019. www.fda.gov.

[iii] https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_pad.htm

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https://news.bostonscientific.com/response-FDA-guidance