Boston Scientific

Boston Scientific Position on FDA Update About Use of Paclitaxel-Coated Devices to Treat Peripheral Arterial Disease

On July 11, 2023, the U.S. Food and Drug Administration (FDA) published a letter to healthcare providers stating that, based on its review of the totality of the available data and analyses, the excess risk of mortality associated with paclitaxel-coated devices to treat peripheral arterial disease (PAD) is no longer supported. The letter recognizes the safety of paclitaxel-coated devices and provides updated guidance that eliminates the requirement for device manufacturers to include specific warning language within device labeling.

“We are pleased that, after continued analysis of data and collaboration among a broad set of stakeholders, the FDA has determined the large body of long-term clinical data do not support an excess mortality risk for paclitaxel-coated devices used to treat patients with PAD,” said Dr. Michael R. Jaff, chief medical officer and vice president, Peripheral Interventions, Boston Scientific. “We remain dedicated to helping physicians provide the best care possible for their patients through access to life-changing technologies, including the Eluvia™ Drug-Eluting Vascular Stent System (DES) and the Ranger™ Drug-Coated Balloon (DCB), both of which have demonstrated excellent safety profiles and very low revascularization rates in the hundreds of thousands of patients treated worldwide with these devices.”

Approximately 200 million people around the world are affected by PAD[i], a common circulatory problem in which plaque builds up and narrows arteries, consequently reducing blood flow to limbs.

The Ranger DCB has a low therapeutic drug dose and proprietary coating, which efficiently transfers the drug into the tissue, resulting in the highest primary patency rates from prior studies examining other peripheral DCBs.[ii],[iii],[iv] The low-profile platform of the balloon also assists clinicians in performing streamlined procedures and navigating through challenging anatomy in order to deliver consistent therapy.

The Eluvia DES, which features sustained release of the lowest dose of paclitaxel for peripheral drug-eluting devices, re-opens blocked arteries and restores blood flow while utilizing a drug-polymer combination to prevent excessive tissue regrowth. Eluvia has the highest primary patency and lowest revascularization rates among stents used to treat PAD in the superior femoral artery (SFA) and has shown superiority in two randomized controlled comparative effectiveness trials.[v],[vi],[vii],[viii]

For more information, visit the Eluvia and Ranger websites.

About Boston Scientific
Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 40 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit **www.bostonscientific.com** and connect on **Twitter** and **Facebook**.

CONTACTS:

Media:

Blake Rouhani

+1.763.494.2268

Blake.Rouhani@bsci.com

Investor Relations:

Lauren Tengler

+1.508.683.4479

BSXInvestorRelations@bsci.com

---

[i] Shu J, Santulli G. Update on peripheral artery disease: Epidemiology and evidence-based facts. Atherosclerosis. 2018;275:379-381.

[ii] RANGER II SFA Pivotal Trial Long Term Outcomes presented by Marianne Brodmann, M.D. LINC 2023, Leipzig, Germany Jun 6, 2023.
[iii] Sachar R, et al. JACC Cardiovasc Interv. 2021 May 24;14(10):1123-1133. doi: 10.1016/j.jcin.2021.03.021.
[iv] RANGER II SFA Randomized Trial: 2-Year Overall Results presented by Ravish Sachar, M.D. VIVA 2021, Las Vegas, NV Oct 2021.
[v] Gray W. 5-year Results from the IMPERIAL Randomized Study of Eluvia and Zilver PTX Drug-eluting Stents and Long Lesion Substudy for Femoropopliteal Artery Disease; CRT 2023, Washington DC Feb 27, 2023.
[vi] Gouëffic Y, Torsello G, Zeller T, et al. Efficacy of a Drug-Eluting Stent Versus Bare Metal Stents for Symptomatic Femoropopliteal Peripheral Artery Disease: Primary Results of the EMINENT Randomized Trial. Circulation. 2022;146(21):1564-1576. doi:10.1161/CIRCULATIONAHA.122.059606.
[vii] Gray WA, Lancet. 2018 Sep 24. pii: S0140-6736(18)32262-1.
[viii] Müller-Hülsbeck S, et al. Two-Year Efficacy and Safety Results from the IMPERIAL Randomized Study of the Eluvia Polymer-Coated Drug-Eluting Stent and the Zilver PTX Polymer-free Drug-Coated Stent. Cardiovasc Intervent Radiol. 2021;44(3):368-375. doi:10.1007/s00270-020-02693-1.

---

https://news.bostonscientific.com/Boston-Scientific-Position-FDA-Update-About-Use-Paclitaxel-Coated-Devices-Treat-Peripheral-Arterial-Disease