Cook Medical’s perspective on FDA Panel Meeting on paclitaxel coated medical devices

Lead Author: none given

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Cook Medical

Last week, during FDA’s public meeting of the Circulatory System Devices Panel, there was an important discussion on patient safety and mortality rates associated with paclitaxel coated medical devices. During the meeting, Cook Medical** presented 5-year clinical data on our Zilver® PTX® drug eluting stent**. We appreciated the breadth of perspectives shared during the meeting, as well as the passion for patient safety and care that was displayed by everyone involved.

The panel unanimously agreed that the aggregate data showed a mortality signal. However, there was uncertainty regarding the signal magnitude, primarily due to the small number of trials with 5-years follow-up and high levels of missing data. Read the full FDA summary of the panel meeting here.

Cook Medical has shared, and will continue to share, the data we’ve gained over the past 25 years researching and developing paclitaxel coated devices. More than 300,000 Zilver PTX stents have been used over the past decade to treat patients around the world suffering from peripheral arterial disease (PAD). When comparing patients treated with the Zilver PTX stent to patients treated with angioplasty or bare metal stents, our randomized trial data and real-world post market studies showed no difference in mortality rates. The Zilver PTX stent has been shown to provide greater than 40% reduction in restenosis and reintervention through 5 years.¹

As FDA, device manufacturers, medical societies, and healthcare providers move forward to address the panel’s recommendations, collaboration and information are key to ensuring PAD patients receive the best care possible. We are committed to working with all stakeholders to continually improve data collection and data analysis methods. We are also committed to providing physicians and patients what they need to make informed decisions on treatment options. Finally, we will continue to fight this disease and help to improve the quality of life for PAD patients.

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