BOSTON SCIENTIFIC
PACLITAXEL-ELUTING DEVICES

Approximately 8.5 million people in the United States are affected by peripheral artery disease (PAD), which is a circulatory problem in which narrowed arteries or blockages reduce blood flow to parts of the body, such as legs and feet, due to a buildup of a fatty or calcified material called plaque.¹

Physicians may recommend a medical procedure to place stents, which are small mesh tubes, or balloons in the arteries to open these arteries and restore blood flow to the previously blocked arteries. A common complication that may follow these procedures is restenosis, or re-narrowing of the artery after treatment, caused when plaque or scar tissue builds up in the treated area. This may be more likely to happen with bare metal stents or plain balloons, which do not have a special drug coating that helps prevent restenosis.

Paclitaxel in devices used to treat peripheral artery disease

To decrease the likelihood of restenosis occurring following the procedure, physicians use drug-eluting stents (DES) or drug-coated balloons (DCB), which are coated with a medicine called paclitaxel that can help limit tissue regrowth and prevent vessel re-narrowing.

Endovascular devices with paclitaxel have significantly reduced restenosis rates by up to 50% compared to non-paclitaxel devices and have helped hundreds of thousands of PAD patients avoid additional potentially dangerous and costly treatments and walk longer without pain.²

While some recent data analyses suggest increased mortality in patients who received DES or DCB, these findings have not been confirmed. These devices have benefited patients by improving blood flow to the legs, helping to reduce leg and resting pain and to improve quality of life and the ability to walk and move around. Additionally, it is important to know that Boston Scientific devices were not part of the analyses.
Eluvia™ Drug-Eluting Vascular Stent System

At Boston Scientific, the health and safety of patients is our top priority. We are committed to innovation in order to help improve patient care, and our Eluvia™ Drug-Eluting Vascular Stent (DES) System – approved by the U.S. Food and Drug Administration (FDA) in 2018 – represents a major advancement in endovascular devices with paclitaxel.iii

The Eluvia Drug-Eluting Vascular Stent System is fundamentally different from other endovascular drug-coated stents and is more like our portfolio of FDA-approved coronary stents, which have been safely used for nearly 20 years. Like our TAXUS coronary stents, the Eluvia stent combines paclitaxel with a polymer, which is a coating that carries and protects the drug during the procedure and helps control drug release once the stent is implanted. Paclitaxel is then released over time, helping to slow the re-narrowing of the blood vessel by limiting the overgrowth of tissue within the stent.

Eluvia has the lowest drug dose of any endovascular drug coated device on the market.

Eluvia is the only endovascular stent approved by the FDA that has a polymer, which controls how and when the drug is released. This polymer matrix – studied in more than 100,000 patients in clinical trials and implanted in more than 20 million vessels – plays a critical role in coating integrity and stability, further enhancing the safety of Eluvia.iv.v

The low-dose drug on the Eluvia stent is released initially, at the time of implantation and then gradually over the course of several months to prevent re-narrowing of the artery.

Our goal is to ensure the safety of every patient who is treated with a Boston Scientific device. We monitor safety in an ongoing process that begins with product design and development, is built into our clinical trials, and continues after our products are introduced to the market. We work with the FDA to ensure the safety and effectiveness our products demonstrated in controlled clinical trials continue in real-world use.


As you consider your therapy options, there are three key questions to ask your physician:

1. What treatments are available, and what are the benefits and risks of each?
2. Which of these treatment options do you recommend for my specific case and why?
3. What are the odds of coming back for a repeat procedure with the various treatment options?

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i https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_pad.htm
ii Boston Scientific Corp. FDA Executive Summary: Circulatory Systems Device Panel Meeting 36-37 (2019).
iii Boston Scientific currently has another device available outside the United States called the Ranger™ Paclitaxel-Coated PTA Balloon Catheter.
iv Data on file at Boston Scientific Represents total global sales of PROMUS (Boston Scientific) and XIENCE (Abbott) stents since 2006.
v Data on file at Boston Scientific Represents total population of patients studied in the PROMUS and XIENCE series of clinical trials.