Product Name: Eluvia Peripheral Vascular Drug-Eluting Stent System

(Lower Limb Advanced Arterial Therapeutics, Pathway Clinical Trial MarketTracks, Peripheral Arterial Occlusion Therapeutics - In Development, Medtronic PV Lower Limb Advanced Arterial Therapeutics)

Description: designed to treat peripheral vascular lesions in arteries above the knee, specifically the superficial femoral artery (SFA) and proximal popliteal artery (PPA)

Company/Sponsor: Boston Scientific Corporation, Inc.

Vessels: Femoral Arteries (SFA/Superficial) Popliteal Arteries

General Modality: Medical Devices

Specific Modality: Stents

General Product Type: Drug-Eluting

Clinical Trials:
- EMINENT Trial - Comparing ELUVIA Versus Bare Metal Stent in Treatment of Superficial Femoral and/or Proximal Popliteal Artery
- IMPERIAL Trial - A Randomized trial comparing Eluvia dDrug-eluting Stent vs. Zilver PTX Stent for treatment of Superficial femoral and/or proximal popliteal arteries
- K - ELUVIA Registry - Korean Multicenter Registry of ELUVIA Stent for Femoropopliteal Artery Disease
- MAJESTIC Trial - Eluvia DES Clinical Stenting Trial to Treat SFA/PPA Lesions

**Please Note: All links will open in the current window - to open a link in a new window please right click the link and select "Open in New Window" or "Open in New Tab"

Commercial Approval:
- On March 18, 2019 Boston Scientific Corporation received PMA approval for Eluvia Drug Eluting Vascular Stent System for the addition of an alternate nitinol tubing supplier
- On February 11, 2019 Boston Scientific Corporation announced that it has received reimbursement approval in Belgium for its Eluvia drug-eluting vascular stent system for treating superficial femoral artery and/or proximal popliteal artery lesions.
- On December 14, 2018 Boston Scientific announced that FDA approved its Premarket Approval (PMA) application to market the Eluvia™ Drug-Eluting Vascular Stent System for a change to parameters associated with the stent laser cutting process.
- On December 11, 2018 Boston Scientific announced that FDA approved its Premarket Approval (PMA) application to market the Eluvia™ Drug-Eluting Vascular Stent System for to implement a modification to the stent inspection steps.
- On December 06, 2018 Boston Scientific announced that FDA approved its Premarket Approval (PMA) application to market the Eluvia™ Drug-Eluting Vascular Stent System for a modification to the stent electropolishing process.
- On October 1, 2018 Boston Scientific announced that the U.S. Food and Drug Administration (FDA) has approved its Premarket Approval (PMA) for Eluvia Drug eluting vascular stent.
- On September 24, 2018 Boston Scientific Corporation announced that FDA approved its Premarket Approval (PMA) application to market the Eluvia™ Drug-Eluting Vascular Stent System.
- Received CE Mark in March of 2016
- On September 18, 2018 Boston Scientific Corporation received PMA approval for Eluvia Drug Eluting Vascular Stent System for improving luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters (RVD) ranging from 4.0 - 6.0 mm and total lesion lengths up to 190 mm.

Development Status - Commercial Events:
- In May of 2012, Innova DES begins European launch
- In May of 2012, Boston Scientific Corp, Inc began European launch of Innova DES
Development Status - Clinical Trials:

The MAJESTIC Trial, began in July 2013, is designed to evaluate the safety and performance of the first Boston Scientific peripheral drug-eluting stent system in the SFA/PPA lesions. 55 patients will be enrolled in 15 centers in Europe and New Zealand.

Nine-month data from the MAJESTIC trial demonstrated the following:

- a primary patency rate of 94.4 percent;
- a target lesion revascularization (TLR) rate of 3.6 percent; and
- no deaths or amputations.

IMPERIAL trial will assess the safety and efficacy of the Eluvia Stent System compared to the Zilver® PTX® Stent manufactured by Cook Medical. Enrollment began in Q4 2015 and the study will include approximately 485 patients in 75 sites worldwide.

Sources:

March 18, 2019 --- "Commercial Approval" - updated with FDA approval for PMA --- "Source"
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180011S005>

February 11, 2019 --- "Commercial Approval" - updated with reimbursement approval in Belgium --- "Source"

December 14, 2018 --- "Commercial Approval" - updated with FDA approval for PMA --- "Source"

December 11, 2018 --- "Commercial Approval" - updated with FDA approval for PMA --- "Source"
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180011S003>

December 6, 2018 --- "Commercial Approval" - updated with FDA approval for PMA --- "Source"
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180011S001>

October 1, 2018 --- "Commercial Approval" - updated with FDA approval for PMA --- "Source"

September 24, 2018 --- "Commercial Approval" - updated with FDA approval for PMA --- "Source"

September 18, 2018 --- "Commercial Approval" - updated with FDA approval for PMA --- "Source"
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180011>


Last Update: March 28, 2019