Product Name: Zilver® PTX Drug Eluting Peripheral Stent

(Peripheral Vascular Therapeutics - In Development, Lower Limb Advanced Arterial Therapeutics, Pathway Clinical Trial MarketTracks, Medtronic PV Lower Limb Advanced Arterial Therapeutics, Lower Limb Critical Limb Ischemia - CLI)

Product Image:

Description:
- Paclitaxel-eluting stent for use in above-the-knee femoropopliteal artery

Company/Sponsor:
- Cook Medical, Inc

Vessels:
- Lower Limb Arteries
- Femoral-Popliteal Arteries (FemPop)

General Modality:
- Medical Devices

Specific Modality:
- Stents

General Product Type:
- Drug-Eluting

Specific Product Type:
- Antiproliferative-eluting Stents

Clinical Trials:
- Angioscopic Assessment of Early Phase Arterial Repair After Paclitaxel-Coated Nitinol Drug-Eluting Stent Implantation in the Superficial Femoral Artery
- BATTLE Trial - Bare Metal Stent Versus Paclitaxel Eluting Stent in the Setting of Primary Stenting of Intermediate Length Femoropopliteal Lesions
- DEBATE in SFA Trial - Drug Eluting stent implantation vs Bare metal stent implantation in treatment of SFA
- DESPERADO SFA Study- Drug Eluting Stent for the Management of Peripheral Arterial Disease Of the SFA Evaluation of Paclitaxel Eluting Stent vs Paclitaxel Eluting Stent
- PAVE Study- Balloon Treating Peripheral Artery Disease Of the Femoral Artery Evaluation of the Long Zilver PTX Drug-Eluting Peripheral Stent for Treatment of Lesions of the Above-The-Knee Femoropopliteal 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
- PARADISE II - Comparison of the PrimAry Long Versus Short Coverage With Drug-Eluting Stents for Long Femoropopliteal Artery Disease
- PESEMA - Paclitaxel Eluting Stent or Exercise for Thigh Atherosclerosis
- REAL PTX - Randomized Evaluation of the Zilver PTX Stent vs. Paclitaxel-Eluting Stent for Treatment of Symptomatic Peripheral Artery Disease of the Femoropopliteal Artery
- STELLA-PTX - Treatment of TASC C and D Femoropopliteal Lesions with Paclitaxel eluting Stents
- XPEDIT Study - Paclitaxel-coated Peripheral Stents Used in

Commercial Approval:
- On September 24, 2018 Cook Medical received FDA approval for a new 5 mm diameter version of Zilver® PTX Drug Eluting Peripheral Stent
- On August 23, 2018 Cook Medical received PMA approval for Zilver PTX Drug eluting Peripheral stent for modifications to raw material specifications, test methods, and frequency of testing.
- On August 29, 2018 Cook Medical received PMA approval for Zilver PTX Drug eluting Peripheral Stent for Addition of a delivery system component specification and changes to a supplier's extrusion line.
- On June 26, 2018 Cook Medical received PMA approval for Zilver PTX Drug eluting Peripheral stent for an alternate manufacturing aid used for stent crimping.
- On December 16, 2016 Cook Medical received PMA approval for Zilver PTX Drug eluting Peripheral stent for its Additional quality control inspections.
- On December 28, 2016 Cook Medical received PMA approval for Zilver PTX Drug eluting Peripheral Stent which is used for the treatment of de novo or restenotic symptomatic lesions in native vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameter from 4 mm to 7 mm and total lesion lengths up to 300 mm per patient.
- On April 4, 2017 Cook Medical received PMA approval for Zilver PTX Drug eluting Peripheral Stent for its supplier modifications to the stent component processing.
- On May 2, 2017 Cook Medical has received PMA Approval for Zilver PTX for Approval for the extension of the shelf life of the Zilver PTX Drug-Eluting Peripheral Stent to 24 months.
- On January 11, 2018 Cook Medical received a PMA approval for Zilver PTX Drug eluting Peripheral Stent for approval for a 140 mm stent length.
- Cook Medical received PMA approval for Zilver PTX Drug Eluting Peripheral Stent on November 8, 2018 for an extension to the raw material restet period.
- On December 20, 2018 Cook Medical received FDA approval for an update the labeling to include post-approval study clinical data.
- Awarded a CE Mark on July 24, 2009 for the treatment of peripheral vascular disease
- Filed Pre-Marketing Approval (PMA) Application as of June 11, 2010
- Received FDA clearance announced on October 13, 2011
- FDA approves first drug-eluting stent to treat peripheral arterial disease Nov. 15, 2012
- April 24, 2013 - Based on its investigation into a small number of complaints that the delivery system of the device had separated at the tip of the inner catheter, Cook Medical has initiated a nationwide/global voluntary recall of its Zilver® PTX® Drug Eluting Peripheral Stent
- August 7, 2013 - Cook Medical is again shipping its Zilver® PTX® Drug-Eluting Peripheral Stent to medical centers in the U.S., Japan, Europe and other major markets. The shipments follow a brief period of unavailability due to a voluntary recall by Cook related to an issue with the stent's delivery catheter that has been resolved.

Development Status - Commercial Events:
- As of December 2007, it is an investigational device not approved for sale
- Received FDA clearance announced on October 13, 2011
- FDA approves first drug-eluting stent to treat peripheral arterial disease
- August 23, 2013 - Effective October 1, Cook Medical's Zilver® PTX® Drug-Eluting Peripheral Stent qualifies for new-technology add-on payments under Medicare's hospital inpatient prospective payment system.
- On March 16, 2015, Cook received CE Mark for the new rotating thumbwheel deployment system on the Zilver PTX Drug-Eluting Peripheral Stent.
- As of September 22,2016, Zilver PTX with Thumbwheel Delivery System was launched in France
- As of February 23, 2017 Cook has extended its Zilver PTX product portfolio with a 140mm drug-eluting stent.
the Treatment of Femoropopliteal Stenoses ZEPHYR - Zilver PTX for the Femoral Artery and Proximal Popliteal Artery
Zilver PTX China Study - Evaluation of the Zilver® PTX® Drug-Eluting Peripheral Stent for Treatment of Lesions of the Above-the-Knee Femoropopliteal Artery (China)
Zilver PTX Delivery System Study
Zilver PTX Paclitaxel-Eluting Stent: Sustained Effectiveness for Treating SFA Lesions in Diabetic Patients
Zilver PTX Post-Market Study in Japan
Zilver PTX Randomized Controlled Trial (Zilver RCT) - Evaluation of the Zilver PTX Drug-Eluting Stent in the Above-the-Knee Femoropopliteal Artery
Zilver PTX Registry - Evaluation of the Zilver PTX Drug-Eluting Stent in the Above-the-Knee Femoropopliteal Artery
Zilver® PTX® V Clinical Study ZILVERPASS Study - The Cook Zilver PTX Drug-Eluting Stent Versus Bypass Surgery for the Treatment of the Cook Zilver PTX Drug-Eluting Stent Versus Bypass Surgery of Femoropopliteal TASC C&D 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"

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**Development Status - Clinical Trials:**

On June 26, 2019 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-year follow-up and high levels of missing data.

On November 04, 2014 data from the Zilver® PTX® Randomized Controlled Trial of Paclitaxel-Eluting Stents for Femoropopliteal Disease showed 5-year primary patency of 66.4 percent in the superficial femoral artery (SFA) for patients treated with Cook’s paclitaxel-eluting stent. This compares to 43.4 percent patency for patients with balloon angioplasty or provisional bare metal stent placement.

First International Trial of Paclitaxel-Eluting Peripheral Artery Stent Results Encouraging Nine-Month Data for ZILVER® PTX Drug-Eluting Stent Trial at International Symposium on Endovascular Therapy (ISET)

Cook Medical’s Zilver PTX Paclitaxel-Eluting Stent (DES) trial results demonstrated no stent fractures. The major adverse event (MAE) rate was equivalent to conventional balloon angioplasty treatment at its six-month follow-up point, as reported by the trial’s national principal investigator today. January 2007

On May 3, 2005 Cook announced they will begin the first international trial of a paclitaxel-eluting stent for Peripheral Artery Disease using the Zilver PTX DESTINY trial: will investigate the use of the Zilver PTX in the above-the-knee femoropopliteal artery

Will be conducted initially at 10 U.S. medical facilities and will enroll 60 patients

First clinical trial approved by the FDA to study the effectiveness of the DES in the peripheral arteries

ZILVER PTX trial: investigates the use of the Zilver PTX paclitaxel-eluting stent in the above-the-knee femoropopliteal artery

On August 8, 2018 Cook Medical has introduced the 140 mm-length Zilver® PTX® Drug-Eluting Peripheral Stent in both 6 and 7 mm diameters in the U.S. The longer length comes after an expanded indication approval by FDA to treat total lesion lengths up to 300 mm per patient. In addition, the product also received an extended shelf life of two years by the FDA.

Announced that the Zilver PTX was launched with limited availability on July 24, 2009 in Europe with the first use after its CE Mark occurring on August 11, 2009

**Comments:**

- First clinical trial approved by the FDA to study the effectiveness of the DES in the peripheral arteries

**Sources:**

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<tr>
<th>Date</th>
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April 2, 2015 --- "Commercial Approval" field - Added CE Mark --- "Sources" field -

January 23, 2015 --- "Clinical Trials" field - Updated clinical trials --- "Sources" field -

May 9, 2013 --- "Commercial Approval" field - Added FDA approval --- "Sources" field -

March 1, 2013 --- "Commercial Approval" field - Added FDA approval --- "Sources" field -
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm327068.htm> "FDA approves first drug-eluting stent to treat peripheral arterial disease"; fda.gov, Nov. 15, 2012.

October 18, 2011 --- "Commercial Approval" field - Added FDA clearance --- "Sources" field -

September 9, 2010 --- "Commercial Approval" field - Added PMA filing on June 11, 2010 --- "Sources" field -

September 7, 2010 --- "Product Image" field - Added product image --- "Sources" field -

August 12, 2009 --- "Development Status - Commercial Events" field - Added first use after CE Mark --- "Sources" field -

July 24, 2007 --- "Product Name, Product Description" field - Added Zilver PTX --- "Sources" field -
<http://www.businesswire.com/portal/site/google/index.jsp?ndmViewId=news_view&newsId=20070716005199&newsLang=en> "The first U.S. patients in the pivotal Phase II trial of a potentially revolutionary new type of drug-coated stent designed to prevent blockages in arteries outside the heart were treated at Tri-City Medical Center in Oceanside, Calif., Cook Medical announced today..."; BusinessWire, July 16, 2007.

February 15, 2007 --- "Development Status - Clinical Trials" field - Added notes on Zilver PTX clinical trial history and pivotal Phase II trial --- "Sources" field -