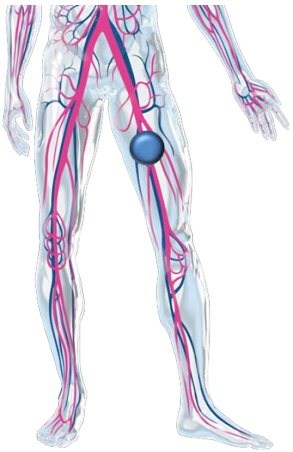
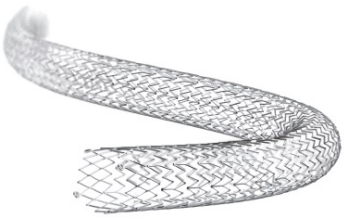
Eluvia™ Stent System – Factsheet



Eluvia™ is the **first polymer-based, drug-eluting stent designed to treat and restore blood flow in the peripheral arteries above the knee – specifically the superficial femoral artery (SFA) and the proximal popliteal artery (PPA).** The Eluvia Stent System utilises the anti-restenotic drug paclitaxel in conjunction with a polymer.

This drug and polymer combination is intended to facilitate sustained release of the drug over the period of time when narrowing (restenosis) is most likely to occur in the vessel, preventing tissue growth that might otherwise block the stented artery. This is often the cause of pain and disability for people diagnosed with **peripheral artery disease (PAD)**.

The Eluvia Stent System is built on the Innova™ Stent System platform, consisting of a self-expanding nitinol stent and a 6F low-profile triaxial delivery system for added support and placement accuracy. The innovative **stent architecture** features a closed-cell design at each end of the stent for more predictable deployment, and an open-cell design along the stent body for improved **flexibility, strength and fracture resistance**.



Why a stent specifically designed for arteries above the knee?

Flexibility
Arteries in the legs like the SFA are subject to strong and complex movements. An SFA stent must have the ability to track through tortuous, dynamic anatomy and conform to the vessel.

Strength
The Eluvia Stent is strong enough to stay open within the challenging and dynamic SFA, even during vessel movement and external pressure.

Fracture Resistance
The SFA is subject to unique mechanical forces like compression and bending, which cause fatigue fractures in stents.[1] Thanks to its structure, custom materials and processing practices, including high purity Nitinol and enhanced stent polishing, the Eluvia Stent is designed to withstand multiple deformation modes including elongation, extreme bending and axial compression.

Clinical data

CE mark approval was based on data from the **MAJESTIC trial**, a prospective, multicentre clinical trial, which assessed the safety and performance of the Eluvia Stent System and reflected a primary patency rate (vessels remained open, providing sufficient blood flow) of more than 96%.[2] The trial included a high

percentage of complex lesions, with 46% of lesions classified as total occlusions and 65% identified as severely calcified.
12-month data included:

- 94% of people presented with no or minimal claudication at 12 months
- 96.1% primary patency at 12 months
- 3.8% target lesion revascularization (TLR) rate (no new TLRs between 9 and 12 months)
- No stent fractures at 12 months
- No deaths or amputations

Boston Scientific received an Investigational Device Exemption (IDE) to conduct a global, prospective trial called the IMPERIAL trial, which will assess the safety and efficacy of the Eluvia Stent System compared to the Zilver® PTX® Stent manufactured by Cook Medical. Enrolment began in late 2015 and the study will include approximately 485 people in 75 sites worldwide.

In the U.S., the Eluvia Stent System is an investigational device and is not available for sale.

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References

[1] Bench testing conducted by Boston Scientific Corporation. Data on file. Bench test results may not necessarily be indicative of clinical.
[2] Müller-Hülsbeck, S. Presented at CIRSE 2015. Primary patency defined as PSVR ≤ 2.5 and the absence of TLR or bypass. n=57