# Fact Sheet

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BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin, Germany
Tel +49 (0) 30 68905-1414
Fax +49 (0) 30 68905-961414
www.biotronik.com

## Orsiro Ultrathin Drug-Eluting Stent System

A stent is a small mesh tube used to treat narrowed arteries. It is placed in an artery as part of percutaneous coronary intervention, a procedure to restore blood flow through narrowed or blocked arteries. After implantation, the stent helps supporting the inner wall of the artery in the months or years after the procedure[1].

Drug-eluting stents like Orsiro®[2] are coated with an anti-proliferative drug that is slowly and continuously released. Orsiro is designed to treat de novo coronary stenosis – new lesions that occlude coronary arteries – and in-stent restenosis – lesions that have reformed inside a stent. Orsiro reopens the artery and releases a controlled dose of a limus drug that helps prevent re-narrowing of the artery (restenosis).

### Orsiro's safety and efficacy

The ultrathin Orsiro drug-eluting stent (DES), launched in the CE-market in 2011 and approved by the FDA in 2019, features the latest development in BIOTRONIK stent technology – a unique solution that combines passive and active components. proBIO passive coating encapsulates the stent and minimizes interaction between the metal stent and the surrounding tissue. BIOlute active coating contains a highly biocompatible polymer that delivers a limus drug via a bioabsorbable matrix. These coatings are layered on top of the PRO-Kinetic Energy stent platform, which has a strong and flexible ultrathin strut design and is highly deliverable.

Safety, efficacy and clinical performance of the Orsiro stent have been investigated in clinical studies with more than 48,500 patients enrolled to date.[3] Significantly lower rates of target lesion failure (TLF) and target vessel myocardial infarction (TV-MI) were observed at 12 months in the BIOFLOW-V study.[4] In addition, according to newly released data from the BIOSTEMI trial, Orsiro has demonstrated superiority over DP-EES* with respect to TLF rates at 12 months in patients presenting with ST-segment elevation myocardial infarction (STEMI).[5]

Orsiro is the first current generation DES with a proven superiority over another current generation DES in STEMI patients.

For more information please visit www.orsiro.com.

### References:

[1] The US National Heart, Lung and Blood Institute: www.nhlbi.nih.gov/health/health-topics/topics/stents
[2] Orsiro is a trademark or registered trademark of the BIOTRONIK group of companies
[3] Status: January 2019
[4] Kandzari D et al. Ultrathin bioresorbable polymer sirolimus-eluting stents versus thin durable polymer everolimus-eluting stents. JACC. 2018 Dec 17;72(25):3287-97.
[5] Iglesias JF et al. Biodegradable polymer sirolimus-eluting stents versus durable polymer everolimus-eluting stents in patients with ST-segment elevation myocardial infarction (BIOSTEMI): a single-blind, prospective, randomised superiority trial. The Lancet. Published online: September 2, 2019. DOI: https://doi.org/10.1016/S0140-6736(19)31877-X

*Durable Polymer Everolimus Eluting Stent
For indications please see Instructions For Use.
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