



Product Portfolio Differentiators

www.biotronik.com

From Vision to Impact.
That's Excellence for Life.

 **BIOTRONIK**
excellence for life



We were born with purpose—to perfectly match technology to the human body. More than 55 years later, BIOTRONIK continues to develop innovative cardiovascular solutions that help our patients confidently experience everyday life.

BIOTRONIK is committed to excellence for life, and our solutions span cardiac rhythm management, vascular intervention and electrophysiology*.

We are proud of the positive impact we have on patients around the world through the relationships we have forged with physicians, health systems, and caregivers.

As a privately-held company, BIOTRONIK values excellence and reliability, not short-term gains.

BIOTRONIK FACTS:

BIOTRONIK solutions improve the lives of **more than 1.3 million people** annually.

Global headquarters in **Berlin, Germany**, with U.S. operations in **New York, NY** and **Lake Oswego, OR**.

Committed to **15% US market share** across all product lines by 2021.

More than **20 million BIOTRONIK CRM devices** have been implanted globally.

The Orsiro coronary drug-eluting stent (DES) system has been used to treat more than **one million patients worldwide**.

BIOTRONIK has not had a Class I recall in more than two decades in an industry that has had more than two dozen.

One in seven of our team members around the globe work in research and development and **more than 15%** work in quality assurance.

BIOTRONIK is the **first company to receive FDA approval** to transition from long-term prospective clinical data collection to a new **EP PASSION** Real-World Data methodology for post-approval lead studies.

BIOTRONIK has a presence in **more than 100 countries**, owning **22%** of the market outside the U.S.

ProMRI Technology

MRI AutoDetect: The ProMRI Advantage



REDUCING ADMINISTRATIVE BURDEN FOR DIAGNOSTIC MRI SCANS

Preparing Patients for the Future

- More than 500,000 patients receive an implanted cardiac device every year.
 - Up to 75% of cardiac device patients may need an MRI during their lifetime.¹
- A cardiac device should not keep patients from receiving necessary MRI scans.

Designed for patient safety

- Dedicated sensor automatically detects MRI environment
- Eliminates need for reprogramming after MRI scan
- 14 days of scheduling flexibility without requiring additional programming

Exceeding Standards

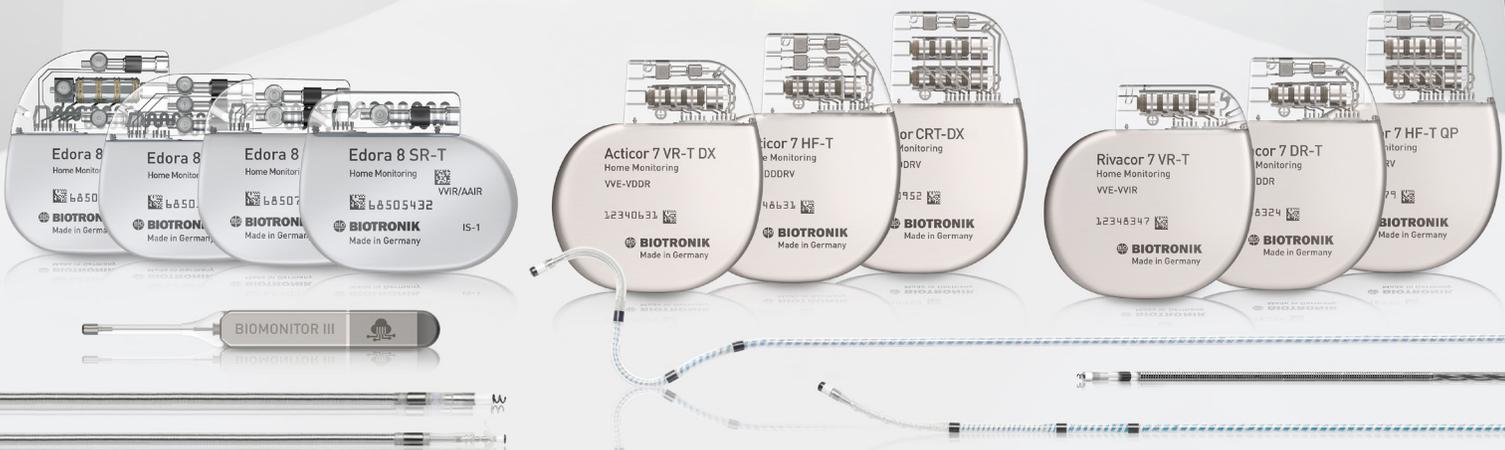
- All our device systems, including ProMRI, are tested to exceed ISO 10974 standards, and are clinically proven through FDA-mandated studies.

Only BIOTRONIK ProMRI systems offer these features

- Active MRI sensor in all therapy devices beginning in 2017 with Edora
- LV pacing during MRI mode in current HF-T devices
- ICD DX option
- Ultra-High Energy ICD option

MRI AutoDetect won the Cardiostim Innovation Award for Best Practice Improvement and was named a 2018 SXSW® Innovation Awards Finalist

1. Roguin A et al. *Europace*. 2008, 10(3).



DX Technology

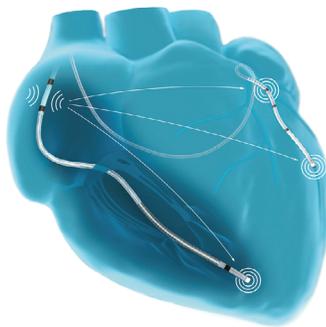
DR Smart. VR Simple. CRT Capable.



Complete atrial diagnostics without an atrial lead. DX and CRT-DX technology improve atrial fibrillation management with early detection while reducing inappropriate shocks.¹



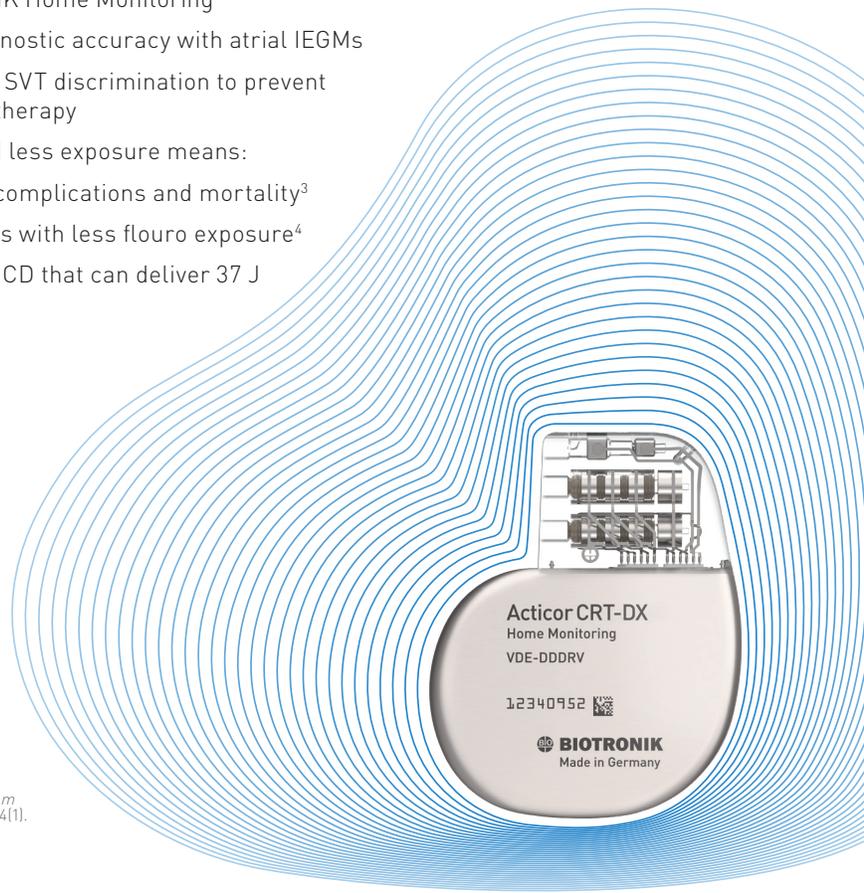
Clinical Value



- Superior performance to single chamber, and equivalent to dual chamber in AHRE* detection, while delivering zero inappropriate therapies (12-month follow-up)²
- Complete atrial monitoring and diagnostics, including:
 - Early identification of silent atrial arrhythmias with BIOTRONIK Home Monitoring®
 - Enhanced diagnostic accuracy with atrial IEGMs
 - Dual-chamber SVT discrimination to prevent inappropriate therapy
- Less hardware and less exposure means:
 - Reduced lead complications and mortality³
 - Faster implants with less fluoro exposure⁴
 - The only 3.0 T ICD that can deliver 37 J in 8 seconds

Economic Value

- DX technology helps:
 - Eliminate the cost of an atrial lead.
 - Reduce costs associated with increased complications.
 - Identify and intervene early to reduce hospitalizations due to atrial fibrillation, which is associated in 20% of all strokes in the U.S.⁵



* Atrial high rate episodes 1. Safak E et al. *Int J Cardiol.* 2016, 223. 2. Thomas G et al. *J Cardiovasc Electrophysiol.* 2019, <https://doi.org/10.1111/jce.14081>. 3. Dewland TA et al. *J Am Coll Cardiol.* 2011, 58(10). 4. Sticherling C et al. *Circ Arrhythm Electrophysiol.* 2011, 4(1). 5. Alkhouli M, et al. *JACC Clin Electrophysiol.* 2018, 4(5)..

Home Monitoring

Pioneers in telemedicine and remote monitoring.
Improving patient outcomes 24/7.



Enhancing efficiency for clinics and peace-of-mind for patients with worldwide cellular connectivity.



Reliable Early Detection with Daily Transmission Verification.

Clinically Proven Performance

BIOTRONIK Home Monitoring® delivers:

Lower Mortality

- The IN-TIME Trial shows that all-cause mortality can be reduced >60% in heart failure patients. This outcome can be achieved by following the IN-TIME protocol, based on daily transmissions.¹
- Reduces all-cause mortality for ICD patients by 38%.²

Reduced Utilization

- Reduces in-office visits by 45%.³
- Reduces hospitalizations for atrial arrhythmia and related stroke by 66%.⁴

Fewer Adverse Events

- May reduce device-related major adverse events.⁴
- Detects system-related events faster than conventional care.³
- Fewer inappropriate device shocks, which may result in longer device battery life.⁵

Powering Clinic Efficiency

Industry-Leading Adherence

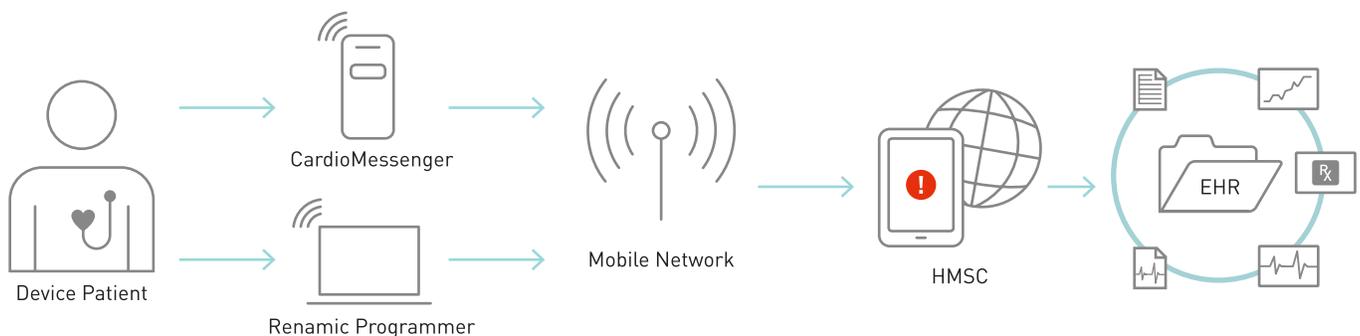
- >90% patient adherence to daily remote monitoring.³

"The clinical and economic benefits of remote monitoring have been well established over a decade of clinical studies. But these benefits are only realized if patients consistently use the technology. **When we make the remote monitoring process easy for patients, we increase the likelihood of patient adherence, which has been demonstrated to improve health outcomes.**"

- Dr. Niraj Varma,
Principal Investigator of the TRUST Study

EHR Data Sync

- Fully integrates BIOTRONIK Home Monitoring® with compatible EHR systems with support for discrete data and custom reports.



Closed Loop Stimulation (CLS)

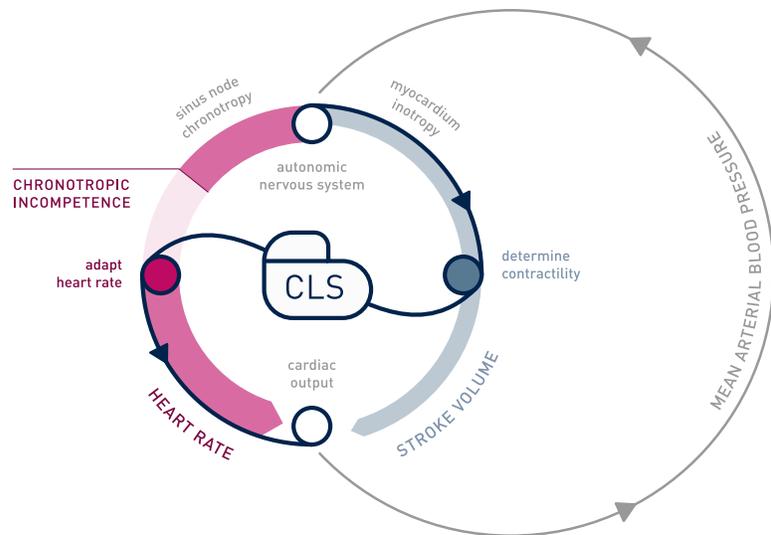
Physiologic rate adaptation in every device.



CLS is a primary rate adaptation sensor, built on a beat-to-beat architecture, and it is automated with machine learning. Cardiac devices with CLS adapt a patient's heart rate in the most physiological way possible.

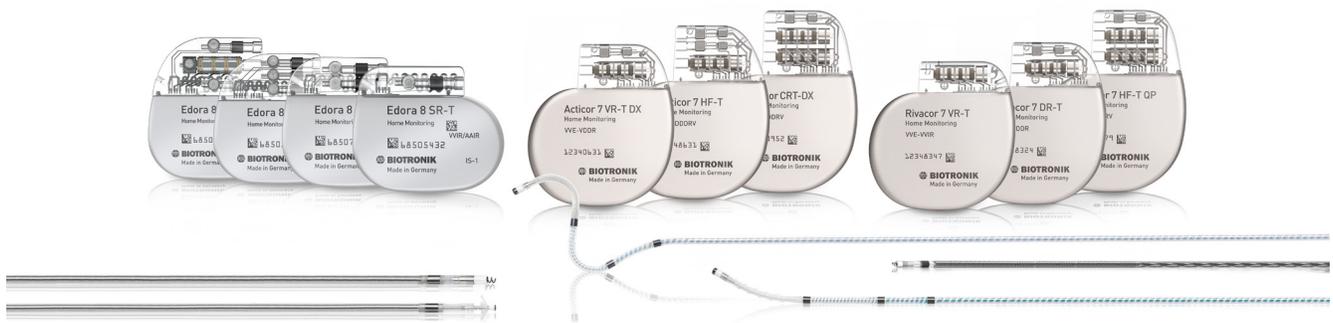
Enabling physiologic rate adaption in pacemaker, ICD and CRT patients

- The only rate-adaptive algorithm that responds to physiologic demands independent of body movement or respiratory rate.
- Responds to acute mental stress via signals from the autonomic nervous system.
- Algorithm continuously learns and adjusts to the human body.
- Available across the entire BIOTRONIK CRM product portfolio.



Clinical Value:

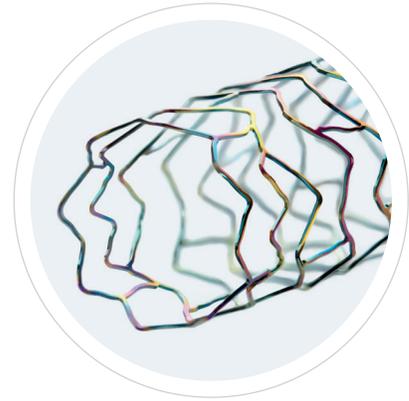
- 75% reduction in the prevalence of orthostatic hypotension.¹
 - Orthostatic hypotension occurs in 30–50% of elderly persons.²
- Wider heart rate distribution³ and closely mimics physiological heart rate variability.^{4,5}
 - Decreased heart rate variability is a risk factor for HF mortality.⁶



1. Abi-Samra FM et al. *Europace*. 2013, 15(6). 2. Mader SL. *Expert Rev Cardiovasc Ther*. 2012; 10(3). 3. Orlov M et al. *Am Heart J*. 2010, 159(2). 4. Quaglione R et al. *Europace*. 2005, 7(4). 5. Beliaev OV, et al. *Prog Biomed Res*. 1999, 4. 6. Sandercock G et al. *PACE*. 2006, 29(6).

Ultrathin Struts

Engineering at the highest level.



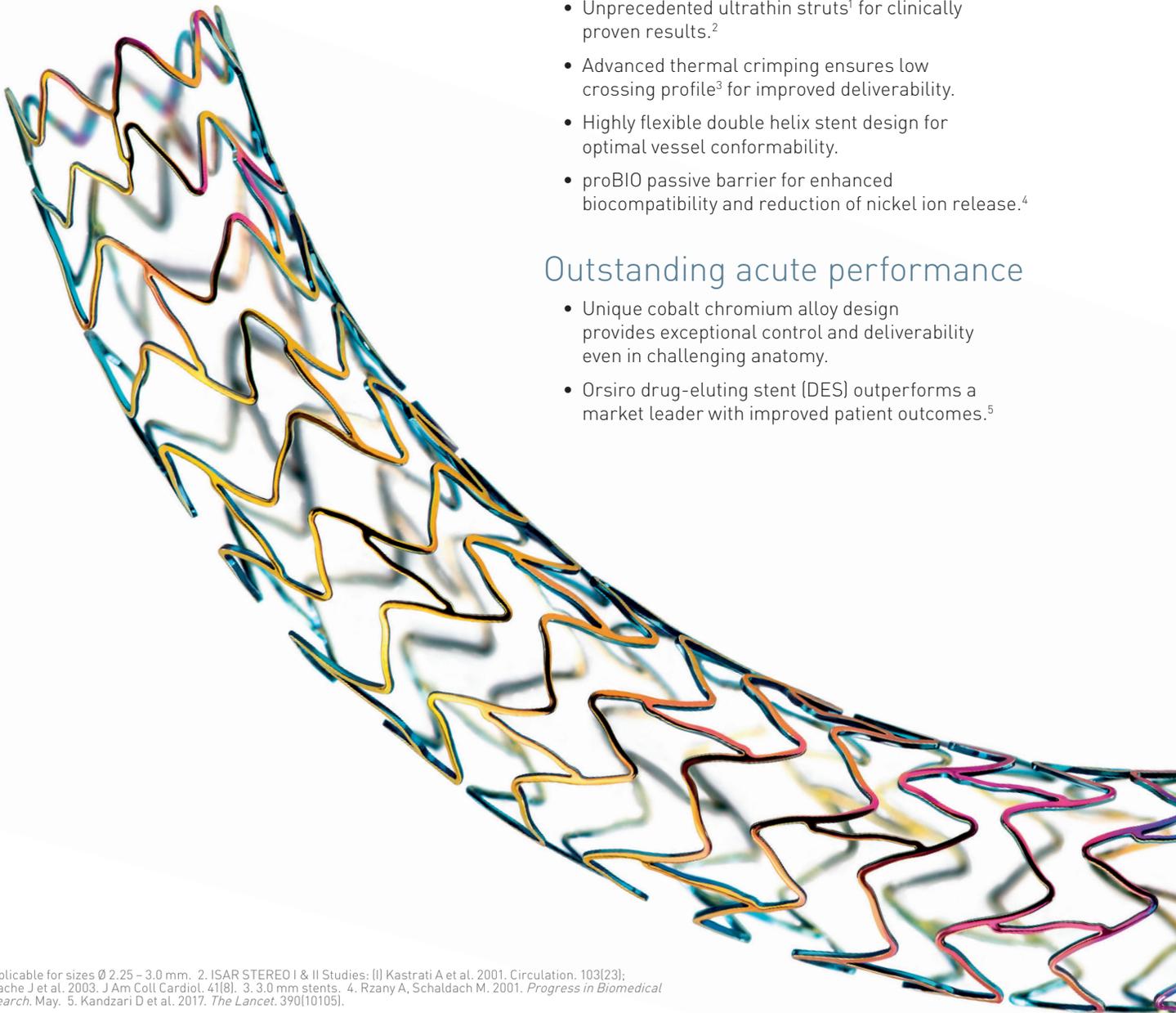
THE COMBINED POWER OF ADVANCED STENT DESIGN, EXCEPTIONAL DELIVERY AND BIOCOMPATIBILITY IS AT YOUR FINGERTIPS.

Vascular innovations that set the industry standard

- Unprecedented ultrathin struts¹ for clinically proven results.²
- Advanced thermal crimping ensures low crossing profile³ for improved deliverability.
- Highly flexible double helix stent design for optimal vessel conformability.
- proBIO passive barrier for enhanced biocompatibility and reduction of nickel ion release.⁴

Outstanding acute performance

- Unique cobalt chromium alloy design provides exceptional control and deliverability even in challenging anatomy.
- Orsiro drug-eluting stent (DES) outperforms a market leader with improved patient outcomes.⁵



1. Applicable for sizes \varnothing 2.25 – 3.0 mm. 2. ISAR STEREO I & II Studies: (I) Kastrati A et al. 2001. *Circulation*. 103(23); (II) Pache J et al. 2003. *J Am Coll Cardiol*. 41(8). 3. 3.0 mm stents. 4. Rzany A, Schaldach M. 2001. *Progress in Biomedical Research*. May. 5. Kandzari D et al. 2017. *The Lancet*. 390(10105).

BIOTRONIK

Premium Product Portfolio



Pacemakers Defibrillators CRT-Ds CRT-Ps Diagnostics

MRI Capabilities	Full body 1.5/3.0 T Single/Dual	Full body 1.5/3.0 T DX/Dual DF1 & DF4	Full body 1.5/3.0 T DF1 & DF4	Full body 1.5/3.0 T IS1/IS4	Full body 1.5/3.0 T
Home Monitoring	Automatic, daily, including HF trends, online alert programmability.	Automatic, daily, including HF trends, online alert programmability.	Automatic, daily, including HF trends, online alert programmability.	Automatic, daily, including HF trends, online alert programmability.	Automatic, daily, including HF trends, online alert programmability.
Rate Response	Accelerometer Closed Loop Stimulation	Accelerometer Closed Loop Stimulation	Accelerometer Closed Loop Stimulation	Accelerometer Closed Loop Stimulation	
Effective Therapies	I-Opt; Vp Supression	DX Technology Ultra High Energy	CRT AutoAdapt, LV Polarites Management with 20 polarities, IN-TIME Template, Quick Check	I-Opt; Vp Supression	

Vascular Intervention



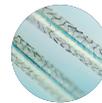
Orsiro Drug-Eluting Stent System

- Improved patient outcomes¹
- Only ultrathin DES in the US²
- Excellent deliverability, with lowest crossing profile³ and up to 72% more force from hub to tip³



PK Papyrus**

- The only 5 F compatible⁴ covered coronary stent available in the US
- First FDA approved 2.5 mm diameter covered coronary stent⁵
- Designed to deliver more like a conventional stent^{6,7}



PRO-Kinetic Energy

- Thinnest struts—pericard
- Exceptional deliverability
- Best-in-class clinical data



Pantera Pro & Pantera LEO

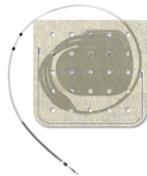
Workhorse and Non-Compliant Balloons



Galeo Pro

Family of high-tensile stainless steel Guide Wires

Partner Alliances



CanGaroo® Envelope

Constructed of a Small Intestine Submucosa (SIS) Extracellular Matrix (ECM) rich in growth factors, structural proteins, and collagens.* The ECM supports remodeling into vascularized, native healthy tissue for the life of the device.*



Zero-Gravity®

Suspended radiation protection system designed to increase the level of radiation protection while at the same time eliminating the weight burden for the operator

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*Animal model. **Humanitarian Device. Authorized by Federal law for use in the treatment of acute perforations of native coronary arteries and coronary bypass grafts in vessels 2.5 to 5.0 mm in diameter. The effectiveness of this device for this use has not been demonstrated. 1. Kandzari D et al. *J Am Coll Cardiol*, 2018, 72(25). 2. When compared to FDA approved Drug Eluting Stents. BIOTRONIK data on file. 3. BIOTRONIK data on file; IIB[P]24/2018. 4. For 2.5-4.0 mm diameter compared to Graftmaster; 6F compatible for 4.5-5.0 mm. 5. FDA Humanitarian Device Exemption (HDE) Database: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm>; last accessed September 14, 2018. 6. Compared to Graftmaster 2.8/16 (BIOTRONIK data on file). 7. Compared to Jostent Graftmaster 3.0/16 (BIOTRONIK data on file).