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# From Vision to **Impact**

The BIOTRONIK Story

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# Born with a Purpose

## Perfectly Matching Technology with the Human Body

**In 1963, two young students, Max Schaldach and Otto Franke,** developed the first German implantable pacemaker in their Berlin apartment. So began the BIOTRONIK mission of perfectly matching technology with the human body to advance health and well-being for all people – providing excellence for life.

More than 50 years later, BIOTRONIK is a leading medical device company that saves and improves the lives of millions of patients every year, in over 100 countries. Over 20 million BIOTRONIK devices have been implanted, and we continue to innovate cardiovascular and endovascular solutions.

We invite you to browse through our story, and find out more about how we continue to shape the standard of care.

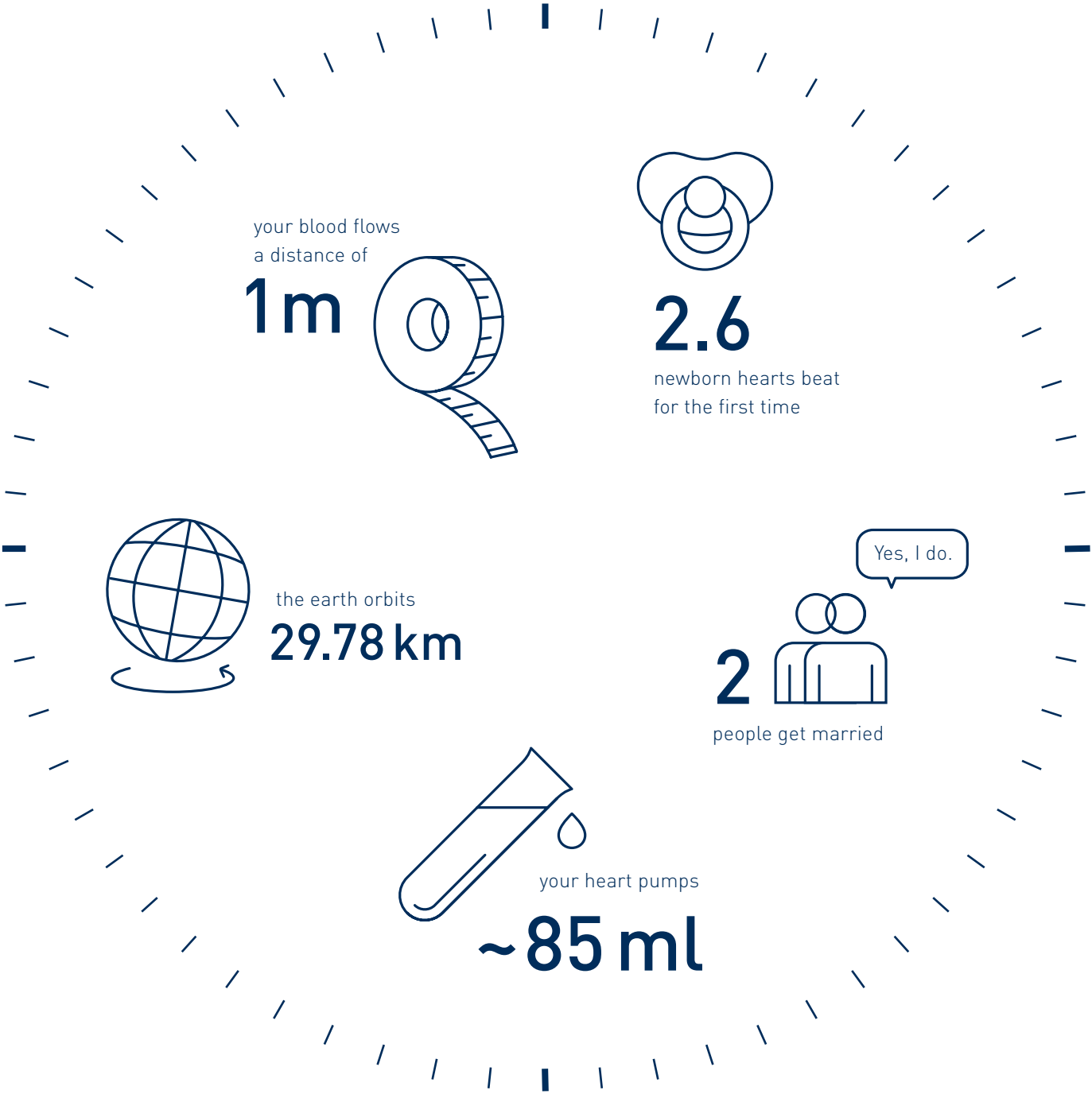


Max Schaldach with fellow students  
from Technical University, Berlin



# Realizing a **Vision**

Every Single Second...



## Making Every Second Count

A crucial moment occurs every time technology is matched with the human body, the very instant when technology begins to have an impact. **This moment changes a person's life.**

In 1963 we developed the first German pacemaker, our first such moment. We grew fast, and soon we impacted more than 10,000 per year. By 1998, we were changing more than 100,000 lives yearly. Today our technology improves more than 1.3 million lives every year.

We are committed to keep going. Our ultimate goal is to make this crucial moment happen every second of every day.

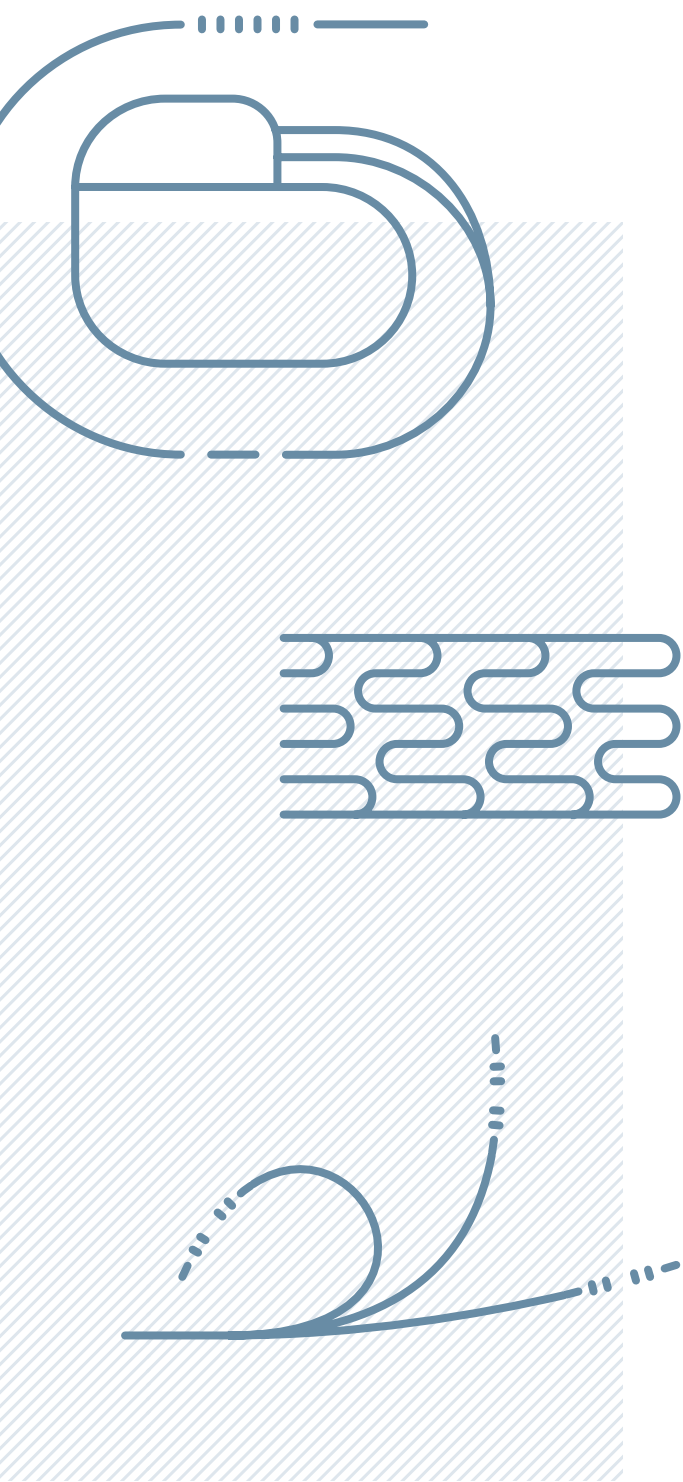
**Ambitious, you say?** Absolutely. But all big achievements start with a brave goal. That's why we promise to research, invent and validate until **we get there.**

**7,000,000,000+**  
human hearts beat



# Our Complete Cardiac Care Portfolio

From our beginnings in cardiac rhythm management (CRM), we have expanded into electrophysiology (EP) and vascular intervention (VI) to address today’s healthcare challenges.



## Cardiac Rhythm Management

**Attention to Every Detail**  
We specialize in innovative technologies that bring the human heart back into normal rhythm. Our comprehensive portfolio includes pacemakers, implantable defibrillators, leads, insertable cardiac monitors and digital health solutions like BIOTRONIK Home Monitoring® technology – a pioneer innovation in connected cardiac care.

## Vascular Intervention

**Engineering at the Highest Level**  
BIOTRONIK has developed innovations now considered to be industry benchmarks, like the resorbable magnesium scaffold and drug-eluting stent. We are proud to offer a comprehensive portfolio of stents, balloon catheters and guide wires to treat patients suffering from vascular diseases of the heart and body.

## Electrophysiology

**Pioneering Unique Innovation**  
With our GoldTip ablation technology at the center of a growing EP portfolio, we cover all aspects of irrigated and non-irrigated cardiac radiofrequency ablation with a wide range of diagnostic catheters, integrated external devices and accessories.

# Making an Impact

We believe in uncompromised safety, trustworthy expertise, independent strength, challenging the status quo and profound integrity. These five core principles shape how we turn aspirations into clear impacts and results.

**From Vision to Impact. That’s Excellence for Life.**  
Yesterday. Today. Tomorrow.



1

Impact on Safety



2

Impact on Performance



3

Impact on Reliability



4

Impact on Outcomes



5

Impact on Society



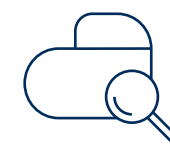
# Impact on Safety

## Designing Secure and Resilient Products

In today's interconnected world, every company is responsible for developing products with cybersecurity in mind. As the pioneer of remote monitoring in 2001, we take this responsibility seriously. BIOTRONIK has integrated cybersecurity into its quality management system, considering it at every step of research and development. Cardiac devices with BIOTRONIK Home Monitoring are resilient when delivering therapy and collecting diagnostic information outside the clinical environment, during remote follow-up, and when using programming and patient devices.

**"We never compromise on safety.** It is and will remain our number one priority. We invest the time and resources necessary to ensure that every product we bring to market is one that we can stand by confidently."

## Taking the Time to Get Things Right



Defibrillators and pacemakers are tested for **40,000 hours**.



**12,000 samples** are used in more than 80 tests to develop new stents and balloons.



**Over 15%** of all employees in Berlin headquarters are employed in specific quality assurance roles.



A carefully designed process **identifies and controls cybersecurity risks** in our products and remote monitoring system.



**“We provide solutions based on competence** and support the medical community with proven expertise in product research, innovation and implementation. Our employees are approachable and highly knowledgeable – that’s the simple secret behind our long-lasting customer relationships and sales success.”

## Impact on Performance

### Service

We believe doing business is not just about making the sale, but about a commitment to service.



Providing in-person customer support **within 24 hours globally**



**Directly answering** patients’ questions and concerns



Offering **24/7 technical support** to healthcare professionals worldwide



## A Partner of the Medical Community

BIOTRONIK invests in extensive programs to share knowledge and train physicians. We develop tailored solutions based on customer feedback and provide sound advice for non-clinical decision makers. In workshops, courses and hands-on events, we train physicians on solutions and new products to diagnose and treat cardiovascular and endovascular diseases.

### Trust via Partnerships

#### Developing tailored solutions based on customer feedback

At BIOTRONIK, physician feedback is paramount. That is why we offer programs, such as iBIO, that connect physicians with our engineers to develop a common understanding so we can provide solutions that respond to clinical needs.

#### Providing sound advice for non-clinical decision makers

Today's health systems put enormous pressure on hospitals to deliver exceptional care while also managing costs. BIOTRONIK's programs, such as iHEAR, work to bring high-ranking executives together to discuss challenges and collaborate on potential solutions.

### Sharing Knowledge

**We are passionate about education** – informed by deep expertise – that empowers clinicians to provide exceptional care in an ever-evolving healthcare environment. For this, we offer training locally, regionally and through digital platforms. Meanwhile, our global programs aim to connect experts around the world to develop best practices.

#### The International Fellows Program for Physicians (IFP)

provides world-class physician education in the latest issues in electrophysiology and cardiac rhythm management.

#### The EPIC Alliance for Women in Research and Medicine

is a global network of over 200 female electrophysiologists and cardiac device specialists.

#### The European Physician Education Program (E-PEP)

supports physicians in becoming European Heart Rhythm Association (EHRA) certified cardiac device specialists.

#### The Global Ambassador Program (GAP)

is a network of informed local experts in all aspects of BIOTRONIK vascular intervention products.

#### The Cardiac Device Expert App

is a digital education tool that allows customers to test their knowledge and experience anytime, anywhere with over 70 programmed cases and regular webinars.





## Impact on Reliability

### **“We build upon our own talent and resources.**

Being an independent and privately owned company sets us apart. Since the very beginning, we believe in our own resources and above all, the power of talent. Fully vertically integrated, we build all products and critical components in-house to achieve the very best results.”



**Privately  
owned**

### Stability through Independent Strength

Being a privately owned company that develops its own resources allows us to take the time to get things right and make crucial, long-term investments, without compromising our values. Thanks to this independence, we can uphold our commitment to the highest levels of safety and quality.



4  
manufacturing  
sites in high-tech  
countries

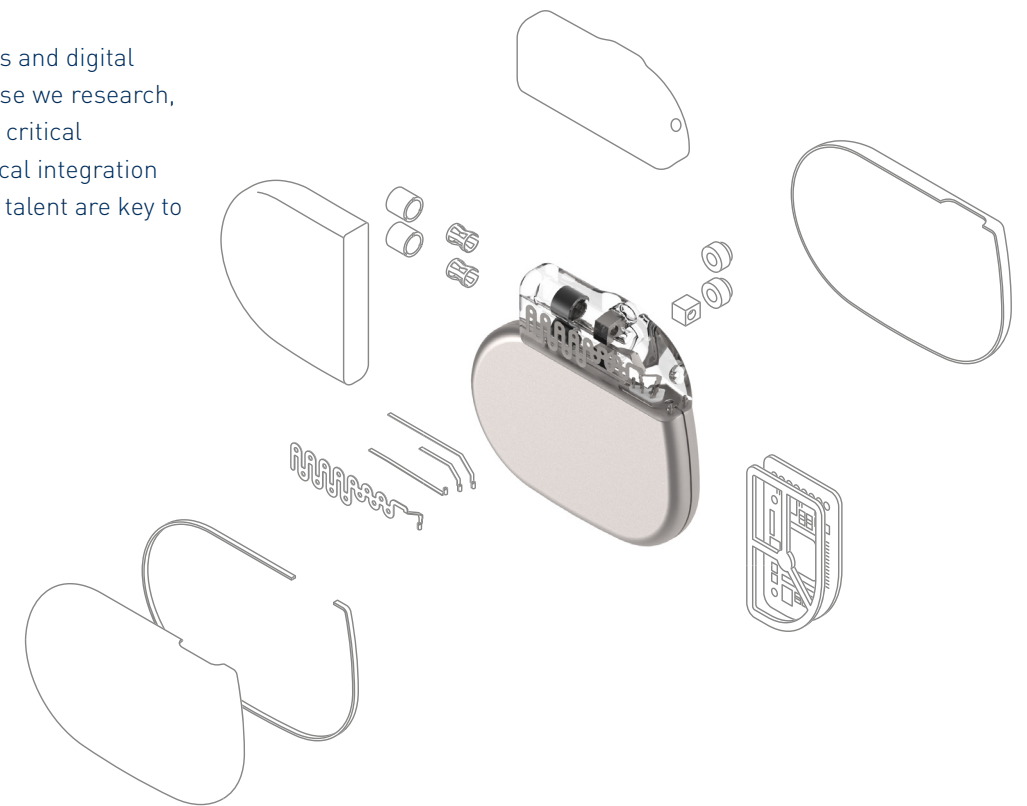
## Independent Resources for a Top Safety Record

We research, develop and manufacture exclusively in four high-tech countries. This means we can assure customers that our products are made by the most qualified talent in the industry:

- **German** engineering
- **Swiss** precision
- **American** ingenuity
- **Singapore** sophistication

## Top Talent: From Idea to Product

We can stand by our products and digital solutions confidently because we research, develop and manufacture all critical components ourselves. Vertical integration and continuing to attract top talent are key to our business success.



## A Culture Defined by Excellence

A company's success is always based on the success of its employees. We take pride in educating specialists and managers from the fields of computer science, engineering and natural sciences, preparing them to be one step ahead of advances in cardiovascular and endovascular therapy.

BIOTRONIK's globally renowned drive for innovation and quality has created a deep and sustainable corporate culture that values our employees as our greatest asset.

Meeting our corporate objectives demands both an extraordinary degree of dedication and a continuous commitment to learning, which is why we place particular emphasis on encouraging employees to expand their skill sets.





## Impact on Outcomes

**“We challenge the status quo.** We aim high and push to improve current industry standards and provide the best and most trusted solutions on the market. Because our goal is to help patients live life to the fullest, our search for innovation never rests.”

## Improving Patient Care and Outcomes

Innovating medical technology is one of our core principles. BIOTRONIK pioneers innovations. We place the utmost importance on research and development in order to continuously improve the diagnosis, treatment and prevention of diseases. Our breakthroughs aim to improve workflows between health care professionals, leading to improved clinical outcomes and cost efficiencies.

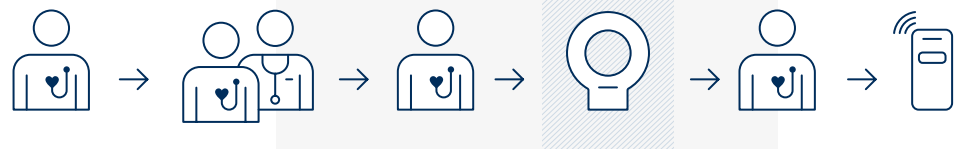


# Industry Leading Breakthroughs

## BIOTRONIK Home Monitoring®

Physicians should be able to detect potential cardiac events earlier.

BIOTRONIK pioneered telemedicine with its award-winning Home Monitoring technology, which automatically sends clinically-relevant information from a patient's device to their physician on a daily basis. As proven in several landmark trials, BIOTRONIK Home Monitoring significantly reduces patient mortality and hospitalization at no extra cost.<sup>1</sup>



## MRI AutoDetect

A cardiac device should not keep patients from necessary MRIs.

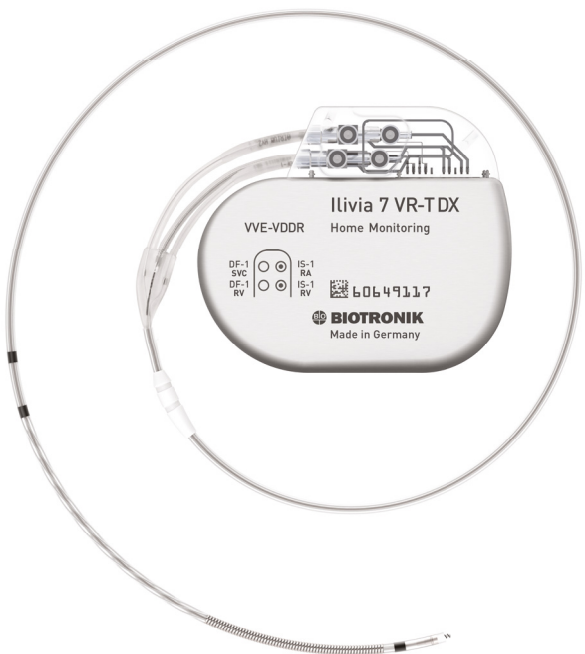
From this strong conviction, we developed a complete portfolio of MR conditional products, including pacemakers, implantable defibrillators, cardiac resynchronization devices, leads and cardiac monitors. Our latest feature MRI AutoDetect, a sensor that automatically recognizes when a patient is in an MR environment, received the Cardioslim Innovation Award for Best Practice Improvement.



## Closed Loop Stimulation

A cardiac device should adapt a patient's heart rate in the most physiological way possible.

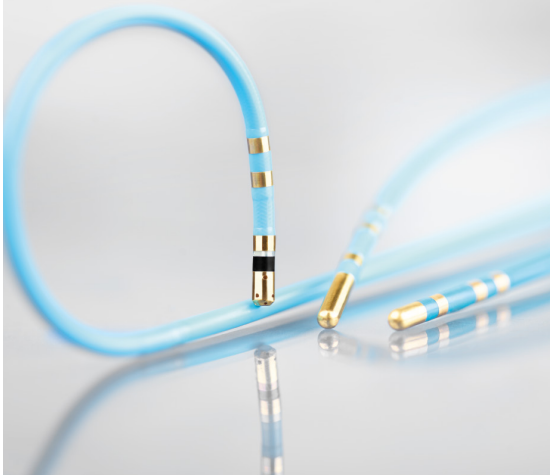
Strong emotions or mental stress? Closed Loop Stimulation (CLS) matches technology with the human body by responding to acute mental stress in the autonomic nervous system, rather than simply an increase in movement. CLS is also an algorithm that continuously learns from and adjusts to the human body, improving its reaction over time.



## GoldTip Ablation

Radiofrequency ablation therapy should be as safe as possible for patients and physicians.

Unique GoldTip ablation has thermal conductivity up to four times greater than conventional catheters, with faster, more efficient cooling, making AlCath Flux eXtra Gold one of the most effective and safe therapies for patients with atrial fibrillation.



## DX System

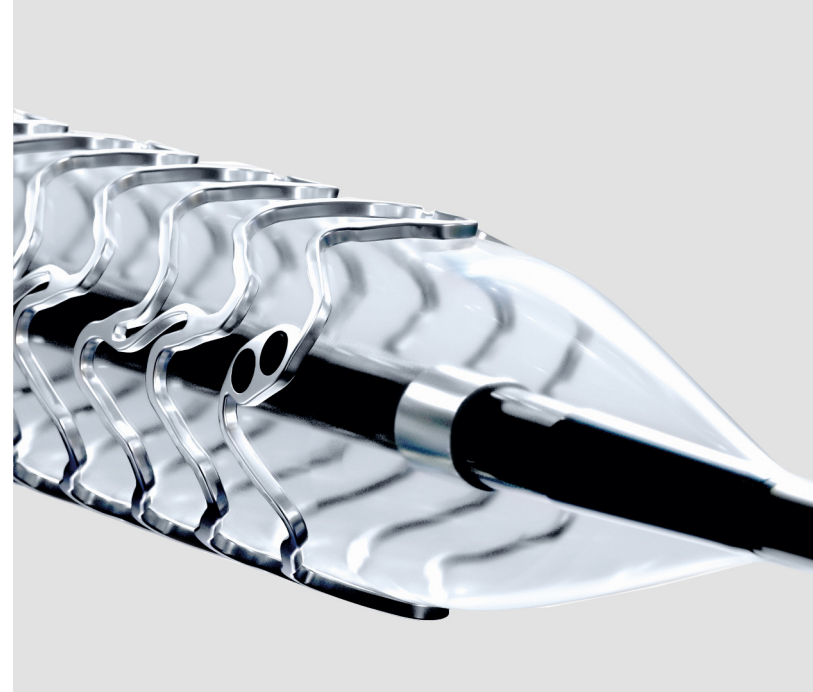
ICD patients should have fewer inappropriate shocks.

The DX system is the world's only single-chamber defibrillator that can specifically detect atrial fibrillation. Using a single lead, the system can precisely detect rhythm disturbances in the atria and ventricles, so the patient receives fewer inappropriate shocks.



There should be a way to overcome limitations of conventional permanent metallic stents, such as late events.

BIOTRONIK's new approach to treat patients with coronary artery disease does not require a permanent stent. Magmaris is a type of naturally dissolving stent called a resorbable scaffold that has opened a new horizon in the vascular therapeutic field. Made of magnesium and coated with a drug to keep the vessel open. Magmaris is almost completely resorbed in the body within 12 months (95% of magnesium). Clinical studies<sup>1</sup> show no evidence of scaffold thrombosis.

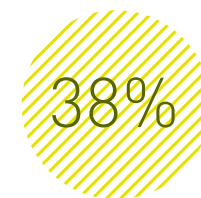


It should be easier to apply medication over time exactly where it is needed.

Orsiro, the first hybrid drug-eluting stent with a bioabsorbable coating, delivers better pushability and easier crossability than competing devices. Ultrathin 60µm struts allow less disrupted flow and arterial injury, leading to improved formulation of endothelial tissue and reduced risk of restenosis and thrombosis.<sup>2</sup>

## Clinical Research to Find Tomorrow's Answers

We are proud to contribute to scientific breakthroughs in our field. BIOTRONIK works with the medical community to help close gaps in care and improving treatment decisions and guidelines, such as European Society of Cardiology (ESC) recommendations.



reduction in mortality & hospitalization

**"Can AF Ablation Effectively Reduce Mortality in Heart Failure Patients?"**

**Yes.** The **CASTLE-AF study** showed that catheter ablation of atrial fibrillation in heart failure patients is associated with a significant reduction (38%) of the composite of mortality and hospital admissions for worsening heart failure.<sup>3</sup> BIOTRONIK's clinical contribution adds ablation to cardiac resynchronization therapy (CRT) and remote monitoring as a way to manage advanced heart failure.



mortality reduction

**"Can Remote Monitoring Improve Patient Outcomes?"**

**Yes.** The **IN-TIME study** showed a reduction in all-cause mortality of over **50%**.<sup>5</sup> ESC added a clear remote monitoring recommendation in their guidelines.

0%  
thrombosis

**"Are Resorbable Magnesium Scaffolds Safe and Effective?"**

**Yes.** Magmaris is the first scaffold on the market made of the natural element magnesium. Its safety and efficacy were demonstrated in the **BIOSOLVE-II study** which observed a 0% definite/probable scaffold thrombosis up to 24 months.<sup>4</sup>

<sup>1</sup> Waksman R. Safety and Clinical Performance of the Drug Eluting Absorbable Metal Scaffold in the Treatment of Subjects with de Novo Lesions in Native Coronary Arteries at 12-month follow-up – BIOSOLVE-II and BIOSOLVE-III. Presented at tct 2017; October 31, 2017; Denver, USA  
<sup>2</sup> Ielasi A and Tespili M. EMJ Int Cardiol. 2014(1). <sup>3</sup> Marrouche NF et al. N Engl J Med. 2018, 378.  
<sup>4</sup> Haude M et al. EuroIntervention. 2017, 13(4). <sup>5</sup> Hindricks G et al. Lancet. 2014, 384 (9943).





## Impact on Society

### **“We do what we say and we say what we do.**

We are in a business built on long-term relationships and trust. We earn this trust by being open about our intentions, keeping our word, and making ourselves accountable to deliver on our mission of advancing health for all people.”

## Social and Environmental Responsibility

Saving lives, contributing to our community and protecting the environment go hand-in-hand at BIOTRONIK. By supporting the long-term projects of local and international partners, we help economically disadvantaged patients access lifesaving medical care, fund leading medical research and provide education informed by deep expertise.





## Reducing our Carbon Footprint

Our Berlin production site's air conditioning system moves up to 950,000 m<sup>3</sup> of air per hour – air that needs to be heated, cooled, moistened and dried. We have set out to **reduce energy consumption** – saving enough energy to power 650 single-person and 75 family homes – by 850 tons of CO<sup>2</sup> emission by 2020.



## Lifesaving Donations

BIOTRONIK has partnered with the non-profit foundation Heartbeat International (HBI) since 2010. We have donated more than 9,000 urgently needed lifesaving devices to date, helping HBI save patients in developing countries who would otherwise not be able to afford care.