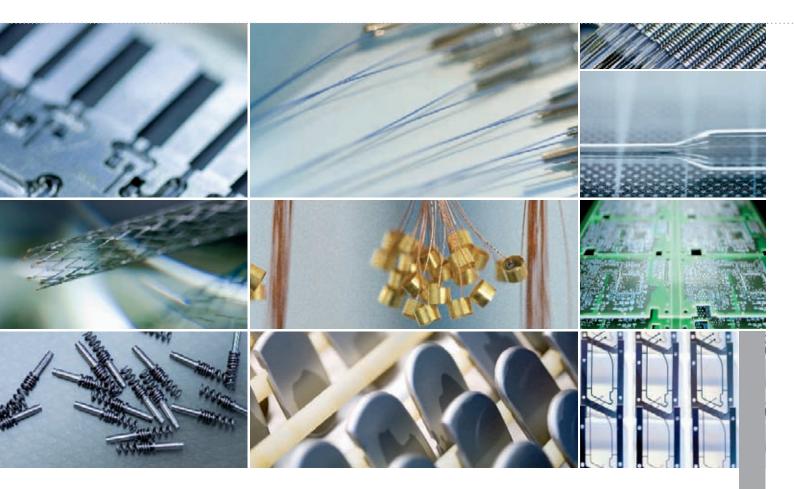
#### BIOTRONIK

#### Quality in every detail





"Quality isn't something that can be argued into an article or promised into it. It must be put there. If it isn't put there, the finest sales talk in the world won't act as a substitute."

> C.G. Campbell US Scientist

# Quality in every detail

#### A history of firsts:

From creating one of the world's
smallest ICDs, to launching the
first remote monitoring system,
to the revolutionary BIOTRONIK
Home Monitoring of today, we are
a company that continually strives
to break new ground.

"We are what we repeatedly do. Excellence, then, is not an act, but a habit."

Aristotle, Greek philosopher

#### Dedicated to life. Passionate about quality.

BIOTRONIK is in the business of maintaining lives, enhancing lives, saving lives. And since the day we started back in 1963, quality has walked hand in hand with those aspirations. Now, more than two million devices later, we continue to reinforce this commitment through research, collaboration, and master craftsmanship. This is why patients and physicians alike trust our expertise. Because at BIOTRONIK, quality, reliability, and progress are not just words; they are words to live by.

## Our finger is on the pulse

#### Listening is the way forward.

Our priorities are clearly defined. The well-being of patients is always in the forefront. We are equally as committed to meeting the needs and expectations of the physicians and healthcare professionals we work so closely with. This is why we continuously strive for better communication and the sharing of ideas through global forums, annual panels, scientific surveys, workshops, and extensive educational programs. With so many bright minds at our disposal, it is obvious to see why we are in the position to create innovation after innovation.

> For our expert panel, we annually involve numerous technical and clinical experts from around the world to exchange ideas and experiences that facilitate continuous enhancement of therapy concepts.

### "Experience is the

best teacher."

Proverb

"Progress lies not in enhancing what is, but in advancing toward what will be."

Khalil Gibran Lebanese–American writer

# Progress backed by quality

#### Innovative solutions straight from the heart.

BIOTRONIK is the pioneer in wireless monitoring technology. In fact, we were the first company to develop and introduce an internet-based remote monitoring system into the market. Since then, we have continued to push the boundaries with innovative, cutting-edge technologies in Home Monitoring. It is this pioneering spirit coupled with extensive customer research that continues to set us apart. Today, BIOTRONIK Home Monitoring is available in over 55 different countries, optimizing patient management in more than 3,800 clinics around the world.

2000 Introduction of BIOTRONIK Home Monitoring®



DEUTSCHER ZUKUNFTSPREIS Preis des Bundespräsidenten für Technik und Innovation

- 2003 First internet-based Home Monitoring system
- 2006 First bidirectional telemetry and IEGM-Online HD®

#### 2009 First intelligent traffic light system

First and only FDA and CE approved remote monitoring system to safely replace in-office follow-ups and to provide early detection

Nominated for the prestigious German Federal President's Innovation Award ("Deutscher Zukunftspreis")

# Expect more than a product

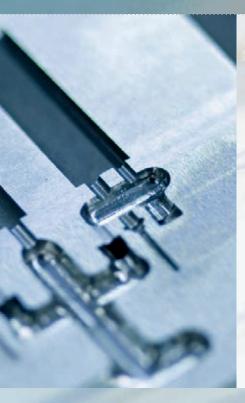
#### Quality is not an end result, it is a process.

At BIOTRONIK, we constantly seek out top-notch talents and provide them with regular access to the most recent and relevant educational programs. They add to our ever-expanding team of experts providing research, development, distribution, and customer service all over the world. It is precisely this extensive talent pool that enables us to continually develop new and fascinating technologies.

# 

- The fractal coating of our lead tip is 100 times thinner than a single human hair but has the capacity to increase the electrically active surface by a factor of over 1,000.
- Simply put, a 2 mm<sup>2</sup> geometric surface can provide an electrically active area the size of a magazine cover.





### "By the work one knows

the workman."

Jean de La Fontaine French poet

"Everything should be made as simple as possible ... but not simpler."

> Albert Einstein German-born US physicist

# Tried and tested – a thousand times over

#### Every second step - a quality step.

Each and every BIOTRONIK employee is well aware that every other step during the production process is nothing less than a quality check. This is why every single component, every process, and every specification is tested and monitored over and over again. For one lead alone, there are over 80 manufacturing steps backed up by over 300 quality checks. At BIOTRONIK, we do not just comply with industry quality standards, we create new ones:

#### Mechanical shock tests ensure that devices can withstand mechanical shocks during the implant procedure

	Standard test <sup>1</sup>	BIOTRONIK test	
Acceleration	1 x 500 g in 6 directions	5 x 500 g in 6 directions	
		+ 5 x 1,000 g in 6 directions	

#### Barometric pressure tests ensure that implants are resistant to changes in atmospheric pressure

#### during storage and transportation

	Standard test <sup>1</sup>	Additional BIOTRONIK test
Low pressure <sup>2</sup>	1 hour @ 700 mbar ≙3,000 m height	24 hours @ 250 mbar ≙ 10,000 m height
High pressure <sup>2</sup>	static	cyclic
1.000	1 hour @ 1,500 mbar≙5m water depth	up to 4,500 mbar≙35 m water depth

# Expertise equals success

#### Vascular intervention based on integrity, quality, and trust.

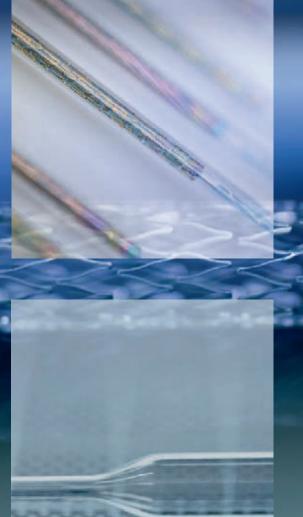
It takes dedication, know-how, and superior engineering to create a sophisticated, high-quality device. But that is only half the equation. Improving patient care is the other half. This is the reason why we make sure that our cutting-edge products stay ahead of the trends with a perfect balance of flexibility and strength. We even go above and beyond industry standards to ensure you are getting the highest quality products on the market.

#### Tensile strength tests for peripheral balloon catheters

- The standard test for .018" peripheral balloon catheters requires a tensile strength of 10 Newton.<sup>1</sup>
- BIOTRONIK's Passeo-18 device exceeds the safety target by up to 300%.

#### Rated fatigue tests for balloon catheters

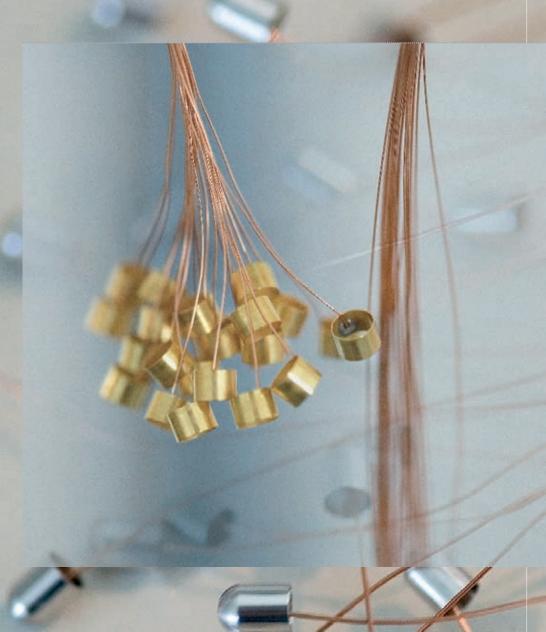
	Standard test <sup>2</sup>	BIOTRONIK test
Repeated inflation and	10 times	20 times
deflation cycles up to		
rated burst pressure		



### "If there is no worker involvement, there is no quality system."

Lloyd Dobyns and Clare Crawford-Mason US authors "The secret of greatness is simple: do better work than any other man in your field - and keep on doing it."

Wilfried A. Peterson US writer



# Pinpoint accuracy, unmatched safety

#### Setting the gold standard in electrophysiology.

At BIOTRONIK, quality is not just part of the big picture, it is part of the smallest detail as well. From the first mapping catheter to today's sophisticated gold-tip ablation catheters, BIOTRONIK continues to break new ground in electrophysiology. Each of our high-precision catheters is designed to optimize performance, control, and safety, ultimately leading to more successful treatments.

- Every catheter is fabricated to demanding specifications. Each year, more than 250,000 electrodes are fitted and soldered with uncompromising accuracy.
- We use over 275,000 m of copper wire and 2.1 kg of gold annually in catheter manufacturing, which is continuously monitored for precise mechanical and electrical specifications.

# From our hands to you

#### Quality through and through.

As an independent, privately held company, we believe the best way to retain superior quality is to stay in charge of the entire process. This is why all of the critical components that go into our products are made by our own highly experienced manufacturers in both Germany and the U.S. From the smallest component to the most sophisticated technologies, we control all parts of the process. It is just another level of trust and reliability we can offer our customers.

 BIOTRONIK has established and will sustain full ownership of and access to all mission-critical technologies.

### "There is no substitute for knowledge."

W. Edwards Deming US management theorist



### "Quality means doing it right when no one is looking."

Henry Ford US industrialist

# A long track record of reliability

#### The proof is in the percentages.

It is one thing to claim reliability. It is another to prove it. At BIOTRONIK, that is just what we have been doing since our company was founded in 1963. We view every customer as our only customer. And in return they have come to trust and rely on our long history of quality, reliability, and safety. After all, when it comes to our customers, reliability is nothing less than essential.

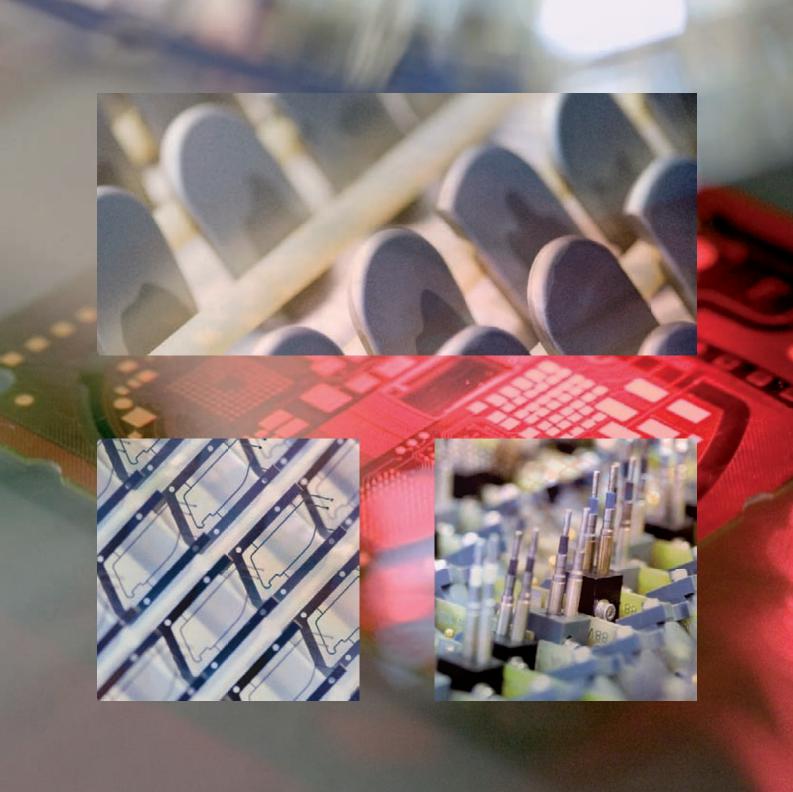
Lumax ICD family: With more than
 100,000 implanted devices, we demonstrate
 a reliability rate greater than 99.8%.

The patient relies on 630 million pacemaker

stimuli over a 10-year period.

# Who we are at a glance

BIOTRONIK is one of the world's leading cardiovascular medical device companies providing cutting-edge solutions in the areas of cardiac rhythm management, electrophysiology, and vascular intervention. Priding ourselves on engineering excellence, we are represented in over 100 countries and have a global workforce of over 5,000 employees.



# Index



Silicone injection molding tool



Shock coils, ICD leads



Shock coil wiring, ICD leads



Formed balloon



Self-expanding stent



Catheter ring electrodes



Circuit board



Active fixation screws



Pacemaker shells



Home Monitoring antenna



Pacemakers



Lead wires



Home Monitoring antenna



lodine, pacemaker battery



Header casting, pacemaker



Final acceptance test, pacemaker



Welding protection ribbon



Assembly tool, pacemaker



Balloon-expandable stents



Self-expanding stent



Ablation catheter tips



Part of the lead tip



Silicon wafer



Subassembly, ICD



Lead coil manufacturing



Printed circuit board, pacemaker



Test adapter, active implants

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