

# Transforming Care

**Our commitment to improving the lives of patients requires high levels of research, quality and innovation in every aspect of our operations.**

Boston Scientific teams collaborate across the company and with health care providers and other trusted external experts to design and make solutions for the health care challenges that matter the most. We are inspired by the people who have been helped by our products, and we are driven to serve those who need breakthroughs that have not yet been invented.



# Our Approach to Innovative and Quality Products

Boston Scientific product development teams follow a uniform, global approach that combines business, technical and quality processes. This allows us to monitor products over their life cycles, from concept and commercialization through next-generation designs. The data we gather and analyze helps us pursue new solutions that advance standards of care and address unmet customer and patient needs.

We have research and development sites in the United States, the European Union, Costa Rica, India and China. Some of the sites also serve as R&D Centers of Excellence where we identify successful practices and share them across the company to strengthen our overall R&D capability.



## Innovation Leadership

Our success in pursuing and developing life-changing innovations is recognized by leading institutions, as summarized on our website [awards page](#).

## Quality and Safety

Our commitment to meaningful innovation is matched by a customer- and patient-centric focus on quality and safety. The work and expertise of Boston Scientific global quality and safety teams is supported by:

- **Quality system training** for all employees.
- **A companywide plan** that prioritizes quality improvement projects and leads to higher quality products and better patient outcomes.

## GLOBAL QUALITY SYSTEM: ➔ DEVELOPING INNOVATIVE AND SAFE PRODUCTS



## SUSTAINABLE DEVELOPMENT GOALS:



- **A global quality system** that integrates customer feedback and regulatory requirements into our processes.
- **The Boston Scientific Best4 quality strategy** for delivering industry-leading culture, compliance, performance and agility.

Katie Crawford helps lead global processes that ensure quality and safety are incorporated into everything we do.

**"The global reach of our quality system is critical. Boston Scientific employees everywhere know they share responsibility for the quality and safety of our products. Each site has a comprehensive system for maintaining quality, which gives us agility in meeting new requirements such as the European Union Medical Device Regulation."**

**Katie Crawford**, manager, Quality Systems

## BEST<sup>4</sup> STRATEGY



## Best<sup>4</sup> Quality

culture + agility + performance + compliance

**Best culture:** Together we sustain a culture that makes the quality policy real for every employee. Our diverse quality team reinforces the importance of each role in improving patient lives.

**Best agility:** We add value by reducing complexity, removing obstacles and adapting to changing business needs. This means having intentional simplicity in our systems as well as lean practices and the right technology for process efficiency.

**Best performance:** We provide the best products, services and solutions for patients and customers, using a quality by design approach that emphasizes continuous improvement.

**Best compliance:** We comply with global laws and regulations using one global quality system. This work includes ongoing risk mitigation and an effective transition to the European Union Medical Device Regulation (EU MDR).

To ensure the safety and efficacy of our new technologies and tools, we follow a global design controls process that incorporates risk management and usability engineering. At every stage of development, our teams focus on the patients who will benefit from their efforts. This includes assessing component and device materials for quality and durability, availability, safety and efficacy. Our teams also take into consideration medical and environmental requirements and other regulations.

## Strategic Quality Process (SQP)

Boston Scientific manufacturing processes reinforce our quality policy and our overarching SQP, which is updated yearly and encompasses:

**Operations strategy:** How we establish our strategic goals and plans.

**Management systems:** How we prioritize and execute our work.

**Continuous improvement:** How we improve our work.

**Cascading metrics:** How we measure and connect performance.

**Recognition and engagement:** How we recognize teams and individuals.

To ensure cohesive quality throughout the enterprise, every one of our manufacturing sites uses the overarching SQP to develop its own SQP to support the facility's focus and performance objectives.

## A SHARED RESPONSIBILITY FOR QUALITY AND SAFETY



All Boston Scientific employees share responsibility for quality and safety in their work every day. This commitment is reinforced by:

- Completing a mandatory quality systems training course when hired.
- Completing an annual refresher training course.
- Signing and wearing a badge imprinted with the quality policy.

## GLOBAL QUALITY PROCESS: 8 PILLARS

- 1 Quality system management**
- 2 Documents, records and data control**
- 3 Design controls**
- 4 Product approvals**
- 5 Material controls**
- 6 Production and process controls**
- 7 Post-market support**
- 8 Corrective action, preventive action**

## OUR QUALITY POLICY AND QUALITY MISSION



Our Quality Policy is printed on employee badges and is highly visible in our facilities:

**"I improve the quality of patient care and all things Boston Scientific."**

Our Quality Policy is complemented by our Quality Mission:

**"We exceed expectations with customer-centric quality solutions that transform patient lives."**

## PRODUCT INNOVATION:

## LISTENING TO OUR CUSTOMERS

**"Customer insights are a key resource as we work to improve our products and introduce new devices. That's how new generations of products are born."**

Alejandra Hernandez, senior engineer, Quality Systems



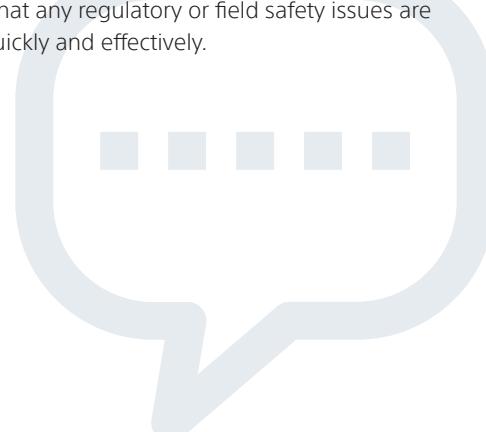
## Measuring and Monitoring Quality and Compliance Effectiveness

We conduct regular audits to verify that our global quality system meets internal and external requirements and that it is implemented and maintained effectively. We follow up with activities that include re-auditing prior observations and confirming that the requisite actions were taken. Regulatory agencies also review our performance to ensure quality and compliance.

In 2020, to adapt amid the pandemic, our global quality team acted quickly to shift from in-person to virtual audit processes. We partnered with vendors to pilot new technologies for remote auditing and obtained legal and privacy approvals for camera and recording activity. This approach meant we were able to secure key regulatory approvals safely and on time.

## Product Performance

Boston Scientific teams review customer and patient feedback and monitor experiences with our devices. This information is valuable for our quality system and for future product iterations and innovations. We follow a preventive action process to identify root causes for potential compliance and quality issues, and to develop preventive solutions. We initiate field actions as needed to ensure that any regulatory or field safety issues are resolved quickly and effectively.



## ELEVATING QUALITY: EVERYONE MAKES AN IMPACT

Our annual Everyone Makes an Impact events take place at Boston Scientific sites around the world to celebrate patients who overcome health challenges and highlight how each and every employee is helping to advance patient care. In 2020, thousands of employees across the globe attended a virtual event, and several patients joined to talk about how their lives changed after being successfully treated with Boston Scientific solutions.



Valentina Arango of Bogota, Colombia discussed how doctors used the SpyGlass™ DS Direct Visualization System to treat potentially cancerous liver fibrosis, destroy stones in her intrahepatic duct and collect a biopsy.

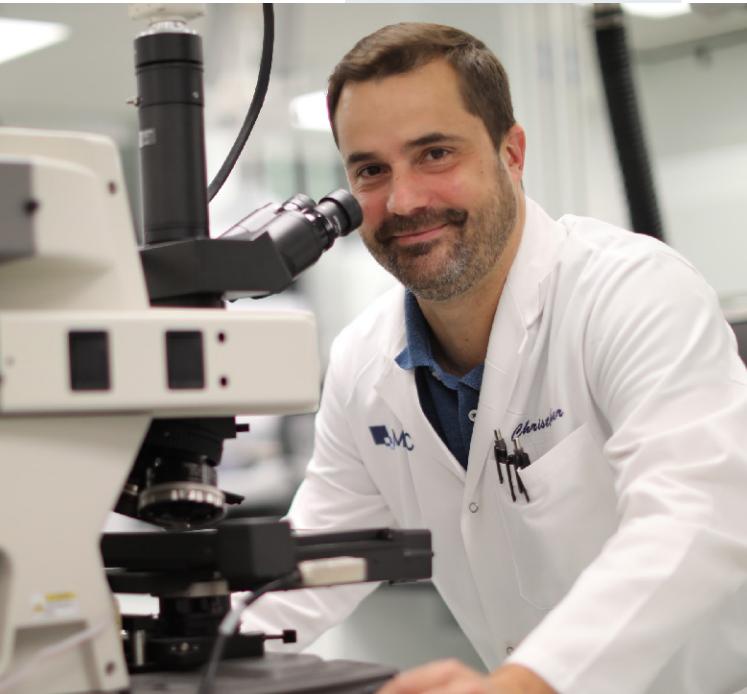


Rahul Mathur, an employee in our Gurgaon, India office was successfully treated for a cardiac condition with a Promus ELITE™ stent. He talked about what it feels like to be helped by a device he knows was made with quality and care.



## Pre-Clinical Sciences

We conduct extensive research into the safety and efficacy of our devices before progressing to human clinical trials. This pre-clinical research sets stringent standards that govern our training practices, product testing and regulatory compliance. In 2020, we made significant investments in our Research and Technology Center in Minnesota, including the latest in advanced imaging technology to help ensure device compatibility – an investment that will enhance R&D initiatives across all our businesses.



To meet the highest safety standards, on occasion we use animal testing in our R&D efforts. For instance, when we use new materials in medical devices, the U.S. Food and Drug Administration (FDA) may require evidence of animal testing prior to human clinical trials. Boston Scientific is committed to the humane care and treatment of laboratory animals. Whenever it is feasible, appropriate and scientifically valid, we use alternative testing. Our facilities meet applicable laws and regulatory standards, often exceeding the latter. We are routinely audited by internal experts and government agencies, including by the FDA, the U.S. Department of Agriculture, and the Association for Assessment and Accreditation of Laboratory Animal Care.

## Clinical Trials

Our clinical trials are scientifically rigorous and generate the data we need to document that Boston Scientific products are safe and effective. We disclose the outcome of all primary and pre-specified secondary endpoints in trials we sponsor, regardless of whether the results are positive, negative or inconclusive. Our clinical teams adhere to criteria established by the International Committee of Medical Journal Editors for authorship on clinical trial publications. In publications pertaining to research that has been supported by Boston Scientific, our teams disclose the company's involvement, whether as a sponsor or supporter.

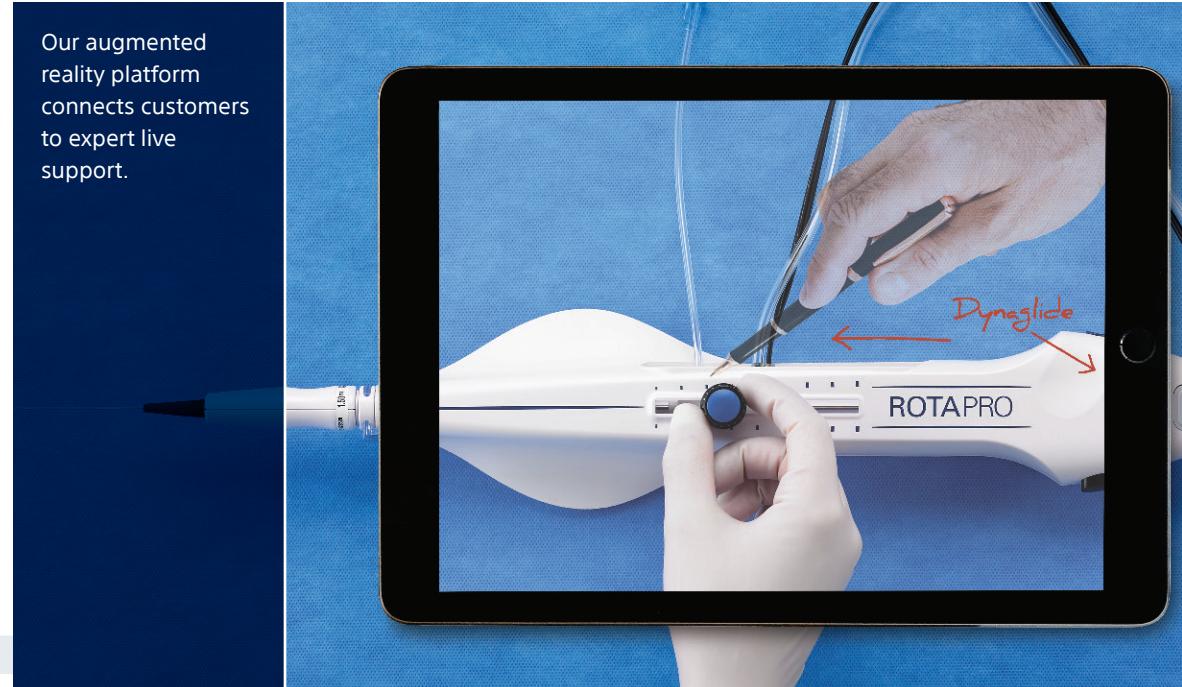
In 2020, we strengthened and refined our operating procedures to ensure we meet or exceed EU MDR requirements by the required deadlines.

# Building Digital Capability

Our recent investments in digital platforms gave us capabilities that were critical for providing remote customer support in 2020. Highlights include:

- Aided practitioners remotely using our [augmented reality platform](#) to offer expert guidance on product use and assist with setup and troubleshooting for devices and procedures.
- Partnered with a wearable technology company to pilot a smart glasses device that enables 225 customers in Latin America to receive real-time remote guidance from Boston Scientific clinical specialists – assistance that helped nearly 1,200 patients.
- Developed and launched provider [tools and resources](#) for re-engaging with patients in the wake of the pandemic.
- Offered [on-demand webinars](#) and telehealth resources for providers on COVID-19-related legislation, regulations and protocols.
- Used our [Heart Connect™](#) system to conduct over 13,000 remote follow-up device checks with customers.

Our augmented reality platform connects customers to expert live support.



The company's digital capabilities also allowed many employees to work remotely during the pandemic. We established new operating procedures and launched online tools so our employees could collaborate virtually with colleagues inside and outside the company.

## ACCELERATING DIGITAL SOLUTIONS



We are working closely with the FDA on their new [Digital Health Software Precertification Pilot Program](#). The goal of the program is to offer precertified companies a streamlined premarket review that will ultimately result in faster patient access to safe and effective software-based medical innovations.

In October, Boston Scientific hosted our annual Recognize Success event, where we celebrated cross-functional teams that are making outstanding contributions to improve quality, patient care and operational effectiveness.



## Innovation in a Virtual World

Throughout 2020, we remained steadfast in our commitment to transform lives. Using virtual platforms, we continued internal innovation initiatives such as:

- **Recognize Success**, a program that celebrates contributions by teams that have innovated to improve quality, efficiency and agility at Boston Scientific.
- **Recognize Development Excellence**, an initiative that honors cross-functional teams that develop meaningful innovations for customers, patients and our company.

- **ImagineIt**, an internal venture capital-style approach to funding breakthrough employee ideas which could have a positive impact on any aspect of our company.

In addition, Boston Scientific launched the COVIDea portal in March to collect employee ideas on how to help slow the spread of the coronavirus and support relief efforts. We received more than 100 submissions and pursued several proposals to develop and donate personal protective equipment and medical equipment, many of which are featured in this report.

## SUPPORTING DIGITAL INNOVATION: THE CONNECTED PATIENT CHALLENGE

Digital health solutions that improve patient and caregiver quality of life at home was the theme of the fifth annual Boston Scientific Connected Patient Challenge. The external competition, co-sponsored by Massachusetts Life Sciences Center and others, promotes the development of digital innovation to address complex health care challenges. In early 2020, six finalists participated in a live pitch event with life science professionals and industry experts. The winning submission was the VaGenie, a connected pelvic floor muscle training device that can help prevent issues related to having a weak pelvic floor, including incontinence and lower back pain.



# Collaborating with Customers

Boston Scientific is deeply committed to helping health care providers meet patient needs. We gather customer feedback in several ways to inspire future product iterations and develop solutions collaboratively. For example, our anatomical model lab in Minnesota enables engineers and physicians to evaluate new product concepts on-site or remotely using new collaboration and visualization tools.

Through the Motion Medical joint innovation accelerator with the Mayo Clinic, we made progress developing minimally invasive treatments for conditions that impede quality and longevity of life. In 2020, we refined two prototype devices, one for patients with cancer and another for patients with structural heart disease. In 2021, these projects are proceeding to final verification, validation and preclinical testing.



## INNOVATING WITH URGENCY DURING THE PANDEMIC

To support demand for ventilators and personal protective equipment (PPE), we teamed up with customers and health care industry peers to develop and distribute innovative solutions to address critical medical needs in our communities.

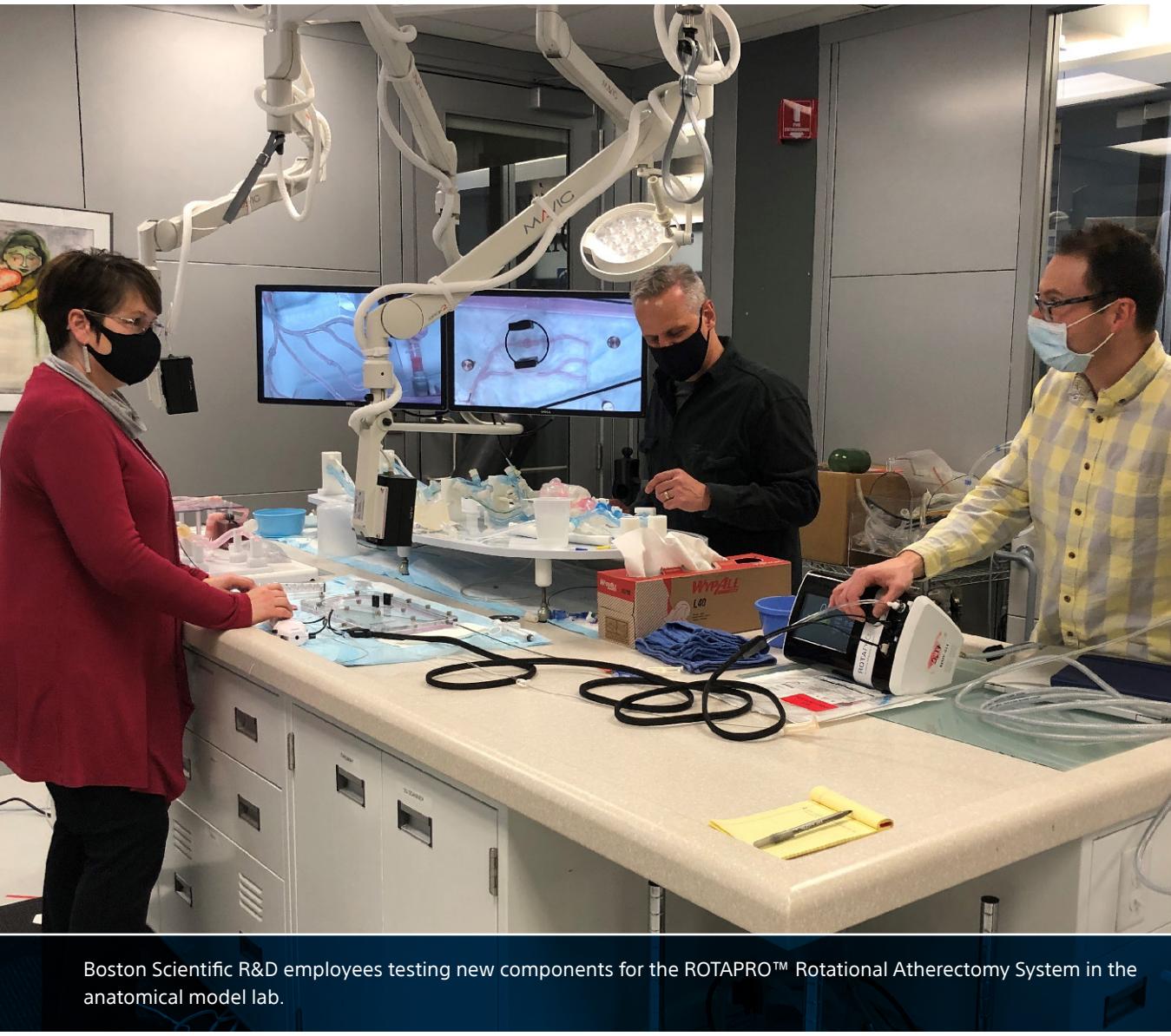
**Ventilator Alternatives.** We collaborated with the University of Minnesota Bakken Medical Device Center and industry partners to bring the [Coventor](#) resuscitator to market, with less than 60 days from concept meeting to production completion. The machine pumps a resuscitation bag at regular intervals, replacing the need for manual respiration in emergency settings. After receiving FDA Emergency Use Authorization in April 2020, our partnership delivered nearly 3,000 Coventor resuscitators to health care providers.



**PPE.** Working with Stanford University and an international coalition of medical experts, clinicians and industry leaders, we developed the [Pneumask™](#) Face Shield in 38 days and received FDA Emergency Use Authorization shortly thereafter. The device combines a full-face mask and a Boston Scientific custom-molded adapter that attaches to a medical-grade air filter. We donated over 1,500 Pneumask Face Shields to hospitals across the United States and have given other manufacturers access to design details for future production.



Nearly 3,000 Coventor resuscitators were delivered to health care providers



Boston Scientific R&D employees testing new components for the ROTAPRO™ Rotational Atherectomy System in the anatomical model lab.

## INNOVATION COLLABORATION



Boston Scientific collaborates with a variety of academic institutions, research organizations and accelerators around the globe to promote innovations in health care, including:

**gBETA Medtech**, a free Minnesota-based accelerator that helps early-stage health care startups.

**MEDX Xelerator**, a medical device and digital health incubator, based in Israel, that's focused on innovations across multiple disease states.

**PracticePoint**, a membership-based health care R&D facility operating at Worcester Polytechnic Institute in Massachusetts.

**BiolInnovate**, a program at the National University of Ireland Galway that fosters medical device innovation using a needs based approach from Stanford University Biodesign.

**Avicenna Alliance**, an industry and academic collaboration to promote an EU framework embracing in-silico methods, computer modeling and simulation.

**HuaXi-Boston Scientific Joint Innovation Center**, a collaboration with Huaxi Hospital in Chengdu, China launched in September 2020 to bring innovative solutions to patients via remote education.

**Medical Device Innovation Consortium**, a public-private partnership with the FDA to advance solutions that promote patient access to innovative medical technologies.

## Global Customer Care

In 2020, our global customer care team expanded its framework and capabilities to improve customer support. These enhancements enabled us to shift more resources to manage customer relationships, anticipate product needs and advise on solutions.

- We introduced Salesforce.com Service Cloud in 16 countries to better serve customers and increase online collaboration.
- In the EU, we invested in technology to increase automated ordering to more than 80 percent of volume, allowing employees to spend less time handling orders and more time talking with customers about their needs.
- Using robotic process automation shipping, we reduced cycle time for sales and sales support agents and improved field inventory levels.

PERSPECTIVES ON ADVANCING CUSTOMER CARE:  HANS WILLEMS

**"Technology solutions represent a huge opportunity for our customers to provide better care to patients. Our teams are focused on what's going to help providers and patients the most."**

**Hans Willems**, vice president, Global Customer Care and EMEA Supply Chain



More than **750** dedicated  
Customer Care team members  
across **40** unique sites



## **Value-Based Health Care**

A [global Boston Scientific team](#) is dedicated to studying health economics to demonstrate the value of our technologies and increase market access for providers and patients through policy and reimbursement advocacy.

Chronic conditions among an aging population present challenges to health care access and affordability. [A study in the Journal of the American Heart Association](#) showed significant cost savings when patients who are at risk

for stroke due to atrial fibrillation undergo a one-time, minimally invasive procedure to implant the WATCHMAN™ Left Atrial Appendage Closure Device rather than receive lifelong anticoagulant treatment.

We use a combination of science and technology to help identify patients who are likely to become sick or experience a sudden health event, giving providers more opportunities to take preventive action and keep patients healthier at more affordable costs.

The Boston Scientific HeartLogic™ Heart Failure Diagnostic technology is embedded within implantable defibrillators and uses multiple sensors to collect and analyze patient physiological data. The technology has been proven to [predict heart failure events an average of 34 days before they happen](#), which enables proactive care and helps reduce patient hospitalizations and readmissions.

