

Putting Patient Safety First





At Boston Scientific, we provide innovative medical solutions that improve the health of more than 25 million patients around the world each year. Patient safety is our priority and our constant focus in helping our customers care for patients living with complex, debilitating and often life-threatening conditions. We rely on collaboration with physicians, patients and industry partners to inform our work, and provide physicians with data from clinical trials as well as routine clinical use to support physician/patient treatment decisions.

Rigorous Patient Safety Monitoring

Safety monitoring is a constant process that begins with product design and development, is built into clinical trials and continues after our products are introduced to the market.

- ✓ **Every day, we monitor and review multiple sources of information to track product safety**, including post-market surveillance studies, patient registry information, quality systems feedback and real-world evidence.
- ✓ **Whenever there is a concern, we conduct thorough investigations and analyses** and take corrective and preventative actions to address adverse trends.
- ✓ **We issue recalls and alerts as needed to protect patient safety** and in compliance with all applicable regulatory requirements.
- ✓ **We have a strong safety record, with an average annual complaint rate across our entire product range of less than 0.15%**, and an even lower rate of adverse events.

MEASURES TO PROTECT PATIENT SAFETY

-  **Interaction with Regulatory Bodies:** We provide information regarding product specifications, R&D testing results, clinical data and patient impact to regulatory bodies throughout product development and following approval. Regulatory authorities regularly audit our processes, policies and facilities to ensure compliance with all applicable regulations.
-  **Global Field Action:** Global Field actions are field activities taken as a result of an assessment of risk to patient or user health, or a risk to regulatory compliance regulations. Our field action process is uniform, rigorous and industry-leading, and complies with all country-specific regulations where we distribute products.
-  **Recalls:** If a recall is necessary, we communicate with all customers and regulatory bodies in markets where impacted products are available. We provide customers with an overview of the issue as well as any recommended actions.
-  **Healthcare professionals confirm receipt and action:** Because patient information is generally kept confidential under privacy rules, we direct physicians to relay pertinent information to their affected patients. We also request that physicians confirm that the field action notice has been received and acted upon.

Our Commitment to Ethics and Transparency

Working in collaboration with physicians and other health care providers is critical to driving innovation and advancing patient care. These collaborations may include inventing new devices and therapies, developing educational materials, conducting clinical research or providing training on how to implement our technology. Our global compliance programs ensure ethical, patient-focused collaboration, transparent disclosure, and physician funding that meets strict criteria for serving an educational need or advancing innovation.

- ▶ All Boston Scientific employees are expected to abide by our [Code of Conduct](#). Our Code ensures that honesty and integrity are fundamental to how we conduct business.
- ▶ Our established compliance training curriculum is designed to ensure employees understand our policies, remain compliant with applicable country laws, and are aware of resources for questions or concerns.

We utilize feedback from physicians, employees and all new regulatory guidelines to continuously evaluate and improve our compliance and quality processes.