

Post-Market Product Performance Monitoring

BACKGROUND INFORMATION

Boston Scientific CRM's post-market product performance monitoring system receives and investigates *product experience* reports from patients, health care professionals, field representatives, and others. Product experience reports include:

- Any expression of product deficiency.
- Possible product malfunction.
- Patient symptom, injury or death possibly associated with a product or its use.
- Unplanned or additional medical or surgical intervention possibly associated with the device or its use.
- General suggestions for product improvement.

CRM PRODUCTS REFERENCED

All ICDs, CRT-Ds, CRT-Ps and Pacing Systems

CRM CONTACT INFORMATION

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Tech.Services@bsci.com

Technical Services – Europe
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Product quality is extremely important in the implantable medical device business as quality of life and sometimes even life itself are dependent upon proper device function. **Quality** can be defined as “grade of excellence” or “fitness for use,” which encompasses both freedom from deficiencies as well as product features that meet customer needs. When a product is shipped to a hospital and patient, it has to fully meet design requirements *and* be capable of satisfying patient needs throughout the service life of the device.

Medical device companies must conduct significant research and testing on products to demonstrate safety and effectiveness to receive approval from regulatory bodies throughout the world. Following approval and distribution, it is vital that the products continue to be monitored while in service.

Reliability can be defined as “quality over time,” or “maintaining continuous customer satisfaction.” Boston Scientific CRM monitors the reliability of all active products, from the time they leave the manufacturing plant until they are removed from service; this is accomplished through the post-market product performance monitoring system.

Post-Market Product Performance Monitoring

Our post-market product performance monitoring system provides early warning signals to take necessary corrective and preventive action to ensure product safety and effectiveness, and provides feedback to design teams to improve future product performance and function. This is accomplished by obtaining information related to field clinical events, conducting a thorough investigation of each event, using the resulting data to improve overall product quality and reliability, and conveying important information to patients, physicians, and regulatory agencies. This system is based on feedback from our customers, which explains why Boston Scientific CRM strongly encourages customers to report product performance experiences and return explanted products.

The product performance monitoring system is comprised of four phases (Figure 1):

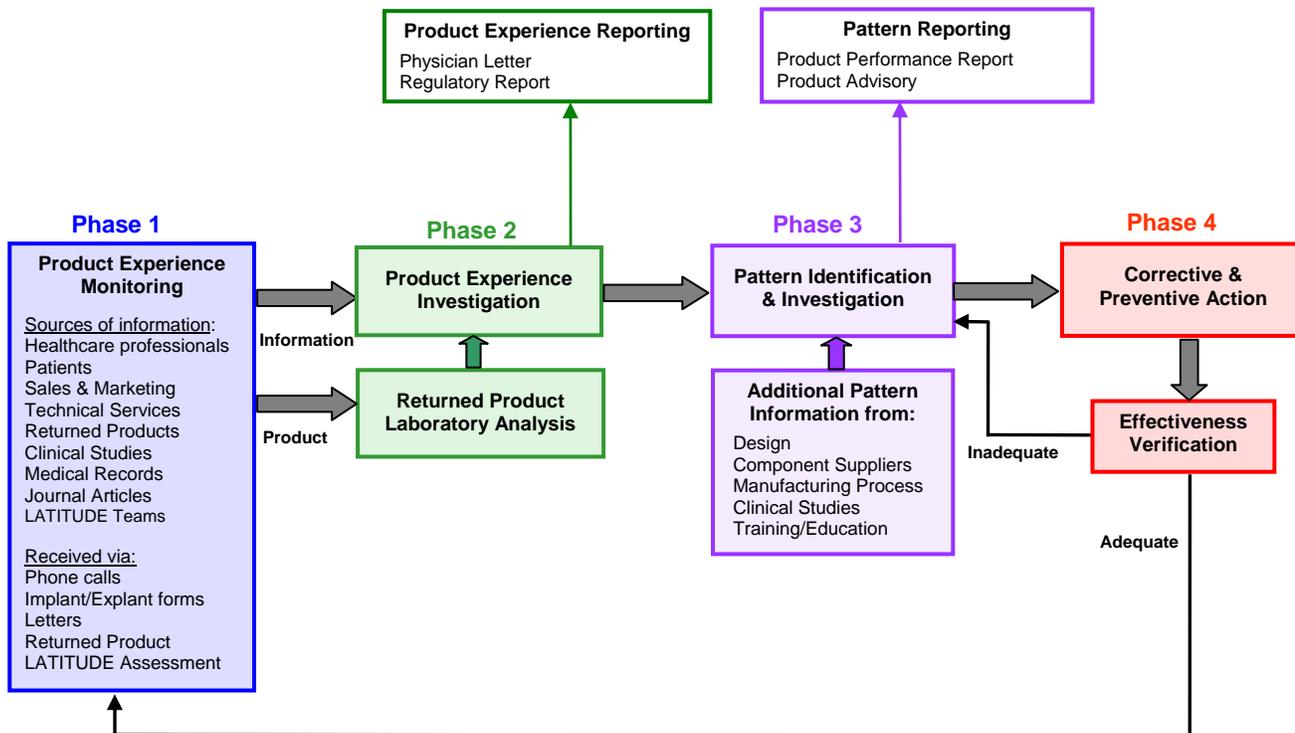
Phase 1. Product Experience Monitoring & Awareness

Phase 2. Product Experience Investigation

Phase 3. Pattern Identification & Investigation

Phase 4. Corrective & Preventive Action

Figure 1. Post-market product performance monitoring system.



Phase 1 – Product Experience Monitoring & Awareness

The term **product experience** is used to describe the main input into our monitoring system; a *product experience* includes expressions of product deficiencies (complaints), patient symptoms potentially associated with a product, and general suggestions for improvement. Healthcare professionals, patients, and field representatives are common sources of product experience reports and they typically convey the information to Technical Services. Information is received via telephone calls, letters, and returned product, with supporting documentation provided in the form of electrocardiograms (ECGs), X-rays, programmer print-outs, and other medical records. Clinical event details are important as they facilitate a more straightforward investigation of the product experience report during Phase 2.

Phase 2 – Product Experience Investigation

Reported product experiences and returned products are investigated to ensure that all observations have been correctly and completely described and understood. The investigation process may include consultation with field representatives and healthcare professionals to understand the clinical observation and to assess potential product involvement. The investigation may also include evaluation of supporting documentation such as X-rays, ECGs, device programming, and information obtained from device memory.

Laboratory analysis of returned product is a critical part of the investigation process. The programmed parameters and diagnostic information are reviewed, and battery usage is evaluated. Manufacturing tests can be repeated, comparing results to records created when the product was built to determine if current device behavior matches the original manufacturing performance. Specialized testing can also be conducted to focus on any areas specific to reported product experiences. In some situations, complete device disassembly is performed to determine root cause of a suspected malfunction. Furthermore, a detailed component analysis may be conducted, which often involves component suppliers.

Upon completion of individual product experience investigations, the results are provided to regulatory authorities (as needed), the involved physician(s), and his/her field representative (upon request). The results are also reviewed for similarity to other reported experiences.

Phase 3 – Pattern Identification & Investigation

The product experience investigation details are used to identify patterns in device behavior and to investigate process or component related issues. If a pattern (or suspected pattern) of similar product experiences is identified, the investigation is expanded and a cross-functional team is assembled to determine whether a pattern exists, followed by further investigation of the pattern to determine root cause. Typical pattern investigation analysis includes:

- Potential impact to the patient
- Root cause analysis
- Review of progress of the issue over time
- Impact on clinical performance and device longevity
- Comparison of the observed rate of occurrence to the rate predicted during design
- Projected rate of occurrence going forward

Phase 4 – Corrective & Preventive Action

If a pattern is identified during Phase 3, a corrective and preventive action (CAPA) plan is developed and implemented. Corrective and preventive action address three product groups: product currently in service, product manufactured today, and future product generations. The CAPA plan includes:

- Developing potential corrective actions (labeling update, device enhancement, manufacturing improvement, etc.)
- Determining the most effective and timely corrective actions
- Assigning personnel to implement corrective actions
- Scheduling corrective action
- Status reporting, including updates to the Product Performance Report and the possibility of a public Product Advisory communication
- Defining what constitutes completion of the corrective action
- Developing a method for verifying the effectiveness of the action

The corrective and preventative action(s) may include design changes in existing or subsequent generations, manufacturing and supplier process modifications, software updates, educational communications, and/or labeling changes. If corrective and/or preventive actions are implemented, field performance of product containing the corrective actions is monitored. If field data demonstrates that the pattern has been effectively addressed, team activities are brought to closure. The product is returned to normal monitoring, but the investigation will be reopened if field performance does not continue to meet expectations. A summary of pattern activities and their associated corrective and preventive actions are communicated to physicians and patients through our *Boston Scientific CRM Product Performance Report*, and as needed, to regulatory bodies.

Conclusion

Post-market product performance monitoring is an integral part of the life cycle of Boston Scientific CRM products. Products are continually reviewed to ensure safety and effectiveness, and to provide information for **quality** and **reliability** improvements for current and future product generations. In other words, this system makes our products better. In order for this system to work, we need input from our customers, both reports of product experiences and return of explanted product. If you have product experiences to report, please contact your local field representative or Boston Scientific CRM Technical Services. If you have product to return, a Returned Products Kit (Model 6499) that includes proper forms, shipping/packaging (biohazard bags), and a prepaid shipping label can be ordered at no charge through Customer Service at 1.800.CARDIAC (1.800.227.3422) or online at www.bostonscientific.com/ppr.