Observation/Complication/Out-of-Service Reporting Form

Submit by Email | Print Form

Fax: 651.582.3126

Please transmit this form to Boston Scientific to report any and all observations, complications, or patient deaths associated with Boston Scientific devices . US regulations require Boston Scientific to report such events to regulatory bodies.

Use the tab key to quickly move from field to field. Hover the cursor over any field to display a completion hint. Print form and place labels of product information, if desired.

Patient Information

Last Name: First Name: Middle: Suffix: Gender: ☐ Male ☐ Female

Street: City: State: Country: ZIP+4:

Phone: SSN: DOB: Weight: MR #:

Patient Status (select one):

☐ Patient death Date of death:

Was device active at onset of terminal event? ☐ No ☐ Yes

Was onset of terminal event witnessed? ☐ No ☐ Yes

Was device explanted? ☐ No ☐ Yes

Was device interrogated *in situ*? ☐ No ☐ Yes

Enter cause of death:

Death classification (select one):

If the selected death classification is preceded by *, submit a Product Experience Report (PER) or contact Boston Scientific.

Health Care Facility

Facility Name: Country: Phone:

Street: City: State: ZIP+4: Fax:

Physician Information

Physician Last Name: First Name: Middle: Suffix: Specialty: Phone:

Street: City: State: ZIP+4: Country:

Out-of-Service Information

Check all that apply: ☐ Normal battery depletion ☐ Elective replacement ☐ Heart transplant ☐ Other/non-product experience

If any selection is preceded by *, submit a PER or contact Boston Scientific. ☐ * Advisory/recall ☐ * Dissatisfied with product ☐ * Product performance issue

☐ Other observation/complication (describe):

Out-of-service device:

Manufacturer: Model: SN: Date Out Of Service: Status:

Status of out-of-service device (select one):

☐ Entire system was removed from service. No further response required.

☐ Portions of the system were removed or modified. Complete section below for each device affected.

Manufacturer: Model: SN: Date out of service: Status:

Reason:

Manufacturer: Model: SN: Date out of service: Status:

Reason:

Manufacturer: Model: SN: Date out of service: Status:

Reason:

Replacement device: Manufacturer: Model: SN: Implant Date:

Comments:

Form completed by: Name: Phone: Date:

Position/Title: Company:

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Boston Scientific CRM considers all information provided on this form to be confidential. We maintain physical, electronic, and procedural safeguards that maintain the confidentiality of this information. All information provided on this form will be handled in a manner described in our company's Code of Business Conduct and confidentiality policies. Within Boston Scientific CRM, we restrict access to confidential information to only those employees or agents who need access in order to provide products and services to our customers; to those who need access to perform quality, regulatory, operational, or compliance functions; and to those whose access to confidential information is required by law or regulation.

Privacy of patient information during transmittal to Boston Scientific is the responsibility of the sender.

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This form is the online version of 355434-003.

Thank you for providing us with this information. If you have any questions or comments, please contact Boston Scientific at 1.800.PATDATA (1.800.728.3282).