Observation/Complication/Out-of-Service Reporting Form

Submit by E-mail | 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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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).