SPINE PRODUCT EXPERIENCE REPORT (PER)

After completing all fields, send the form to SpineComplaints@highridgemedical.com ***within 2 business days*** of the event. If information is missing, unclear, or insufficient, you will be contacted for clarification.

A. REPORTER INFORMATION:

Reporter Name: ***Distributorship Name:***	***Reporter Address:***
Reporter Email Address:	***Phone:***
If Additional information is needed about this reported event, follow-up questions will be sent to the reporter. If questions should be directed to someone else, please provide information below.	
Additional Contact Name:	***Additional Contact Address:***
Additional Contact Email Address:	***Additional Contact Phone:***

B. EVENT INFORMATION

Has the FDA or another government agency been notified of this event? ☐ Yes ☐ No ☐ Unknown	
Notification Date *(date when Highridge Medical becomes aware of event):*	
Date when event occurred:	***Country in which event occurred:***
For implant: ***date implanted***:	For explant: ***date removed***:
Describe alleged event in detail (Include information on the impact to the patient or user and/or malfunction, if known):	
Did the event occur during a surgery? *If not, please describe when and where event occurred (i.e. sterilization, inspection, etc.):*	☐ Yes ☐ No ☐ Unk
Was the procedure completed using the reported device? If not, was it completed using an additional device? Please describe: *(If additional Highridge Medical product was used, please include part number/lot numbers, if applicable)*	
Was this an Initial or Revision Surgery?	☐ Initial ☐ Revision ☐ N/A
If this is a revision surgery:	Reason for revision surgery: Was the patient involved in a fall, accident, or similar type of event? ☐ Yes ☐ No ☐ Unknown

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C. PRODUCT INFORMATION (Product Identified in Event)

Qty	Item Number	Lot/Serial #	Item Description/Brand Name	Will Product be returned for Evaluation?
				☐ Yes ☐ No ☐ Unk
				☐ Yes ☐ No ☐ Unk
				☐ Yes ☐ No ☐ Unk
				☐ Yes ☐ No ☐ Unk
				☐ Yes ☐ No ☐ Unk

If the product cannot be returned, please provide justification: ☐ Discarded ☐ Not released by hospital ☐ Remains implanted ☐ Other reason:

****If this event has product involved that can be returned, DO NOT discard or place back in kit. Please return for investigation to Highridge Medical per instructions from Complaint Team.***

Has product been cleaned and/or disinfected? ☐ Yes ☐ No ☐ Unk

If yes, method of disinfecting: ☐ Autoclave ☐ Alcohol ☐ Other:

D. HOSPITAL/COMPLAINANT INFORMATION

Please email the complaints team if a response letter is requested.

Hospital/Clinic Name:	***Surgeon Full Name:***
ADDRESS SECTION: ☐ Hospital/Clinic ☐ Physician ☐ Patient ☐ Other:	
Address:	
City:	***State:*** ***Zip Code:***
Country:	***Phone:***
Email Address:	

E. PATIENT INVOLVEMENT:

Was a patient present when the event occurred? *(If no, skip below)* ☐ Yes ☐ No

Patient Name or Initials: _____
First *Last*
☐ Not allowed by country regulations

Note: For events occurring within the US; device manufacturers are allowed to have patient information per HIPAA: http://www.hhs.gov/ocr/privacy/hipaa/faq/public_health_uses_and_disclosures/490.html

Date of Birth: _____
Age at Time of Event: _____

☐ Male ☐ Female ☐ Unknown ☐ Other:

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Weight: ☐ Pounds ☐ Kilograms	***Height:*** ☐ Inches ☐ Centimeters

1. Was there a death or impact to patient? ☐ Death ☐ Injury ***If Yes, Clearly Describe:***	☐ Yes ☐ No ☐ Unk
2. Was there additional medical intervention? (e.g. revision surgery, additional treatment, prescription drugs provided, additional appointments to see a medical professional, etc.) ***If Yes, Clearly Describe:***	☐ Yes ☐ No ☐ Unk
3. Was this medical intervention for correction of an infection that occurred within one (1) year post operatively? ***If Yes, Clearly Describe:***	☐ Yes ☐ No ☐ Unk
4. Did the event cause a delay to the procedure? ***If Yes, add Delay in Minutes:*** ***If Yes, Clearly Describe Reason for Delay:***	☐ Yes ☐ No ☐ Unk
5. Were there any contributing conditions related to the event? (e.g. trauma, illness, previous surgery, related non-compliance, patient anatomy, infection, etc.) ***If Yes, Clearly Describe:***	☐ Yes ☐ No ☐ Unk

Please include the following documents, if available:

X-rays, Surgery or Revision records, Pictures and other detailed documents of patient involved surgery/procedure.

F. ADDITIONAL INFORMATION

Please provide any additional comments that you believe to be relevant to this event: