WRIGHT
FOCUSED EXCELLENCE

Complaint Initiation Form (US)

Legal Mfg: | Complaint Number:

Aware Date: | RMA Number:

Submit this completed form to: complaints-US@wright.com

All Information below to be fully completed by Complaint Reporter (For help filling out form reference, GLOBAL-WI-0001):

Reporter/Contact Person: | Reporter Phone/Email:

Reporter Address: | Distributor/Organization:

Physician/User's Name: | Facility/Hospital:

Physician/User Address: | City/State/Zip/Country:

Product Name	Part#	Lot#/Serial#	UDI Number	Quantity	Will Product Be Returned?
					◯ Yes ◯ No
					◯ Yes ◯ No
					◯ Yes ◯ No
					◯ Yes ◯ No

Complaint Device from a Kit? ◯ Yes ◯ No Kit Part/Lot/Serial Number:

Incident Date: | Was Product Revised? ◯ Yes ◯ No Implant Date: | Explant Date:

Where was the issue identified? *(ie, in surgery, set inspection)*

Describe in Detail the Problem Encountered: *(attach any applicable photographs)*

If Problem Occurred during Surgery: How was surgery completed? Was a backup device available? Impact to Patient? *(N/A if issue identified outside of surgery)*

Did issue cause a delay that required additional anesthesia, medication, surgical procedure, or the use of unintended equipment? *(N/A if issue identified outside of surgery)*

Patient Info: [i.e., Patient ID, Date of Birth, Weight (lbs./kg), Height (in/cm), Sex, or condition] *(N/A if issue identified outside of surgery)*

Would you like a response after the issue is investigated *(if yes, please include email address)* ◯ Yes ◯ No

DEVICE RETURN: Submit complaint form via email to complaints-US@wright.com, request an RMA number, and instructions for device return. A hard copy of this completed form should be enclosed in the shipping carton.

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