

Legal Mfg:

 Complaint Number:

 Aware Date:

 RMA Number:

Submit this completed form to: complaints-international@wright.com **(Recommended submission is within 48 hours of becoming aware)**

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
					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-international@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.