

Legal Mfg:

Complaint Number:

Aware Date:

RMA Number:

Submit this completed form to: [complaints-international@wright.com](mailto:complaints-international@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 |
|              |       |              |            |          | 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](mailto: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.