Smith+Nephew

FIELD REPORT

EXCEPTION # _____
(TO BE COMPLETED BY COMPLAINT ADMINSTRATOR)

PLEASE NOTE THAT ALL FIELDS MARKED WITH AN ASTERISK (*) ARE REQUIRED.

Report Information

Date of Event*	Reported by*	Title*

Customer Information

Healthcare Facility Name*	Country*	

Address	City	State

Attending Surgeon*

Representative Present*

Patient Information

☐ Information Unavailable

Patient Identifier

Age

Weight

Gender
☐ Male ☐ Female ☐ Unknown

Product Information

Cart Serial Number*

Software Version*

Suspect Part Name(s)/Number(s)*

Suspect Part Serial Number(s)*

Suspect Part Unique Device Identifier (UDI)

Product*
- ☐ NAVIO
- ☐ CORI

Returning (select all that apply)*
- ☐ N/A
- ☐ Log Files/Patient Archive
- ☐ Equipment Return
- ☐ Other:

Procedure
- ☐ N/A
- ☐ UKR
- ☐ TKA
- ☐ PFA
- ☐ OTHER

Event Description

Describe what happened in detail* (Include pictures on page 2, log files, and Patient Archive for error messages or unexpected behavior)

What was the impact on the case?*
- ☐ None
- ☐ Delay (<30 min)
- ☐ Delay (>30 min)
- ☐ Case Aborted
- ☐ Injury (Patient, explain below)
- ☐ Injury (Other, explain below)
- ☐ Retained Material
- ☐ Other (explain):

How did you recover?*
- ☐ N/A
- ☐ Equipment Swap
- ☐ Reboot
- ☐ Manual Procedure
- ☐ Case Cancelled
- ☐ User/Medical Intervention (explain):

At which time of the procedure was the problem noticed?*
- ☐ Before
- ☐ During (patient under anesthesia)
- ☐ After
- ☐ Unknown
- ☐ Preventative Maintenance
- ☐ Lab/Demo
- ☐ Other (explain):

Replacement Request

Requesting Replacement?*
- ☐ Yes – please fill out this section
- ☐ No

What part(s) is/are being requested?

Deliver by date

Please return the device to:
Smith & Nephew, Inc.
Attn: Customer Complaints
Ref.: C-######## (if available)
2875 Railroad Street
Pittsburgh, PA 15222

Shipping Address for parts requested if different from above

Special shipping instructions

Email this completed form to fieldreports.robotics@smith-nephew.com or submit via FLUIX
Share log files via OneDrive with fieldreports.robotics@smith-nephew.com

PLEASE NOTE THAT ALL FIELDS MARKED WITH AN ASTERISK (*) ARE REQUIRED.

Field Report Pictures

PLACE PICTURES ON THIS PAGE I.E. PICTURE OF ERROR CODE ON SCREEN, DAMAGED COMPONENT.

PROVIDE A DESCIPTION OF PICTURES BELOW: