AESCULAP®

ACCOUNT INFORMATION ***(NOTE: CONTACT PERSON REQUIRED FOR REPLACEMENT)***

Customer Facility:_____ Account Number:_____

Contact Person:_____ Title:_____

Address:_____

Address 2:_____

Phone:_____ Email:_____

SAMPLE/PRODUCT INFORMATION ***(NOTE: SET NUMBER, WHERE APPLICABLE, IS REQUIRED TO REMOVE THE ITEM FROM THE ACCOUNT)***

Catalog #:_____ Lot #:_____ Set #:_____ Qty. Affected: _____ Qty. Returned: _____
Is the device available for evaluation? ☐Yes ☐No

Catalog #:_____ Lot #:_____ Set #:_____ Qty. Affected: _____ Qty. Returned: _____
Is the device available for evaluation? ☐Yes ☐No

Catalog #:_____ Lot #:_____ Set #:_____ Qty. Affected: _____ Qty. Returned: _____
Is the device available for evaluation? ☐Yes ☐No

COMPLAINT INFORMATION ***(NOTE: CONTACT THE QUALITY GROUP BY PHONE IF ANY PATIENT INJURY IS REPORTED)***

Did the incident occur in surgery? ☐Yes ☐No If not, where? *(i.e. Central Sterile)*

Did this incident cause or contribute to serious injury or death? ☐Yes ☐No
If yes, who was impacted? *(i.e. staff, patient)*

Did this incident cause or contribute to a delay in surgery? ☐Yes ☐No ☐Unknown
If so, how long?
(NOTE: IF EXACT TIME IS UNKNOWN, PLEASE ESTIMATE, I.E. LESS THAN FIVE MINUTES, FIVE TO TEN MINUTES, ETC.)

DETAILED DESCRIPTION OF INCIDENT ***(NOTE: IF NECESSARY ATTACH SEPARATE SHEETS)***

Please provide a brief description of what was happening during the incident. ***(NOTE: REPORT FACTS ONLY)***

Was additional intervention needed?
(i.e. X-ray, piece retrieval or additional medicine)

Date of Surgery: _____
Type of Procedure: _____

FIELD INFORMATION

Date of Occurrence: _____

Representative: ☐**Aesculap, Inc.** ☐**Aesculap Implant Systems, LLC** ☐**Distributor Rep** ☐**Unknown**

Sales Rep. Name:_____ **Regional Manager:**_____

FAX COMPLETED COMPLAINT FORM AND DIRECT ALL INQUIRIES TO:
CUSTOMER COMPLAINT COORDINATOR (PHONE: 888-237-2852, EXT. 5938)
FAX: 484-821-9116 – PLEASE NOTE: QA WILL CONTACT SUBMITTER UPON RECEIPT OF FORM OR DEVICE.
PRE-NOTIFICATION OF COMPLAINT SHIPMENT BY FAX IS APPRECIATED.

MAIL PRODUCT TO:
AESCULAP, INC. - ATTN: QA – 615 LAMBERT POINTE DRIVE – HAZELWOOD, MO 63042
(INCLUDE RGR# ON BOX IF APPLICABLE) - IMPORTANT INFORMATION: INCLUDE A COPY OF THIS FORM. DEVICES THAT HAVE BEEN USED MUST BE DECONTAMINATED BEFORE RETURNING TO AESCULAP WITH ACCOMPANYING DECONTAMINATION FORM.

***TO SUBMIT ELECTRONICALLY, GO TO** www.aesculapusa.com/QualityAssurance **AND CLICK "COMPLETE ON-LINE COMPLAINT FORM".**