FCI OPHTHALMICS
30 Corporate Park Drive, Suite 310/320, Pembroke, MA 02359
TEL: 781.826.9060 * 800.932.4202 * **FAX:** 781.826.9062

a ZEISS company

COMPLAINT HANDLING FORM

CUSTOMER INFORMATION	
FACILITY NAME:	**SURGEON NAME:**
ADDRESS LINE 1:	**ACCOUNT NUMBER:**
ADDRESS LINE 2:	**CONTACT PERSON:**
CITY: **STATE:** **ZIP:**	**PHONE:**
CONTACT EMAIL:	

INCIDENT DESCRIPTION
Describe the incident in detail, including when it occurred (before, during or after surgery)?
Describe the patient's pathology, explain the context justifying the use of this device:

Complaints must be submitted within 48 hours of incident

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List any other devices, instruments and/or accessories that were used with the product during the case:
Following the incident, what immediate precautions were taken (use of another device of the same reference, use of another device, scheduling of a new procedure, etc)?
PATIENT IMPACT ☐ **YES** ☐ **NO** **If yes, please explain how the patient was impacted.**
CLINICAL CONSEQUENCES ☐ **YES** ☐ **NO** **If yes, please explain how the patient was treated and the date of treatment.**

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PRODUCT DETAIL
ITEM NUMBER:
ITEM DESCRIPTION:
LOT/SERIAL NUMBER:
EXPIRATION DATE:
INCRIMINATED QUANTITY:
DATE OF PROCEDURE:
Is the product available for return to FCI? ☐ YES ☐ NO
If the product is not available for return, is a photo of the product available to submit for review? ☐ YES ☐ NO
 **WHEN RETURNING A PRODUCT THAT HAS HAD PATIENT CONTACT, CUSTOMER MUST PROVIDE PROOF OF DECONTAMINATION.** **PLEASE HAVE PROOF CLEARLY MARKED ON BOX.**

_____ _____

CUSTOMER SIGNATURE **DATE**

CONFIRMS THAT THE INFORMATION PROVIDED HEREIN IS COMPLETE, ACCURATE AND TRUE.

To be completed by FCI Ophthalmics:

IMMEDIATE ACTION

Complaint Reported to Quality ☐ **YES** ☐ **NO**

Date Reported: _____

RMA Number Provided to Customer: _____

Completed By: _____

Complaints must be submitted within 48 hours of incident