Medical Product Information Report

L005-20 (Rev E0, 2019-02-18)

Submit this form to FHC Quality and Regulatory via: Email: regulatory@fh-co.com Fax: +207-666-8292.

An email will be sent to confirm receipt of this form within 24 hours. Please contact us at +1-800-326-2905 if you have any questions or do not receive confirmation.

Customer Information

Physician/Contact Name: _____ Telephone Number: _____

Hospital/Facility: _____ Email: _____

Address: _____

Product Information

Product Number	Serial or Lot Number	Who was product purchased from?	Will Product be sent back for Evaluation? Y/N

Any Additional product information

Event Information

Date of Incident: _____ Date reporter became aware of product issue: _____

Was product used with a patient? ☐ Yes ☐ No

Outcome: ☐ Minimal Impact ☐ Procedure Delays ☐ Patient Injury ☐ Death

Has event been reported by customer to governing regulatory authority? ☐ Yes Date: _____ ☐ No

Description of event: Please provide as much details as possible

Reporters Information

Prepared by: _____ Company: _____ Date: _____

Telephone: _____ Email: _____

Address: _____

Signature: _____

All information above is required to submit this form. Please fill out completely.

Optional Next Action:

Customer requests: ☐ Credit ☐ Replacement ☐ Product has already been replaced: Qty. _____ Lot# _____ Date _____

All credits and replacements are subject to product evaluation by FHC.
Contact FHC Customer Support at +207-666-8190 for RMA# and return shipping instructions.

RN# _____
For internal FHC documentation

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