Product Experience Report, F-720-007

1 REPORT INITIATION

Initiated by:	☐ Tightline Development ☐ Customer
Complainant Name/Function:	
Complainant Contact:	
Initiation Event:	

2 PRODUCT INFORMATION

Part Number:	
Lot #:	
Part Description:	
Product Return (if this event has product that can be returned, please return for investigation):	☐ Product returned to One Glenlake Pkwy, Suite 650 Atlanta, GA ☐ Product discarded ☐ Product return refused

3 EVENT INFORMATION:

Notification Date:	
Event Date:	
Hospital Name / Address:	
Describe event in detail (include information on the impact to the patient, user, and/or malfunction; detail any information available regarding surgery delays and/or additional devices used):	
Were there any patient repercussions due to deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of Tightline Development product?	☐ Death ☐ Additional Medical Intervention ☐ No, surgery was completed ☐ Unknown Comments:

4 ADDITIONAL INFORMATION (TIGHTLINE DEVELOPMENT USE ONLY)

☐ All information is complete for Sections 2 & 3.

☐ Any additional information from the previous sections on this form left blank or marked "Unknown" have been requested from the hospital/surgeon/reporter and it was confirmed there is NO ADDITIONAL INFORMATION that is reasonably available for this event.

How and when was it communicated that no information was available?	☐ Phone ☐ Other: ☐ Email Date: _____
Who provided you the detail which specified that no additional information is available?	

5 EVALUATION (TIGHTLINE DEVELOPMENT USE ONLY)

Complaint #	
CAPA required?	☐ Yes (any of the following conditions are satisfied) • CAPA is requested from complaint source • dFMEA does not capture failure mode • dFMEA Severity of 4 or 5 (refer to P-722 Risk Management) • Complaint trend for similar product that warrants investigation • Reportable event per P-820 Post Market Surveillance and Product Recall ☐ No, CAPA criteria not met
Justification for complaint closure: ☐ N/A - CAPA required	

5.1 APPROVALS

Function	Name	Signature	Date
Development			
Quality			