OCO BIOMEDICAL

Work Form		
Document Title	Document Description	Version No.
FRM-13-02	**PRODUCT INCIDENT REPORT**	**0**

Control No: _____

Doctor's Name:		
Street Address:		
City:	State:	Zip
Phone:	Fax:	

Please answer all questions and return with product

Product Information

Catalog Number:	Lot Number:
Invoice & Date purchased?	
If unknown: Description of Product:	
Product used for: Treatment or Diagnosis	Explain:
Nature of Complaint:	

Patient Information (If Applicable)

Did the incident involve a specific patient? __ Yes* __ No	*Please Explain:

Procedure Information

***If Yes contact OCO Biomedical immediately**

Have you reported event to FDA: ☐ No ☐ Yes
Did incident cause or contribute to a death: ☐ No ☐ *Yes
Did incident cause serious injury or illness to patient that was life threatening: ☐ No ☐ *Yes
Did incident result in permanent impairment of a body function or permanent damage to a body structure? ☐ No ☐ *Yes
Did incident necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure? ☐ No ☐ *Yes
*Explain any **Yes** answers to Questions 1-4 and contact OCO Biomedical immediately:
Date of Incident:
In your opinion, what was the reason for the incident?

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Explanations/Comments/Clarification:

Please return this report with product to help us diagnose the problem. Thank you.	
Report prepared by:	Date:

Please mail this report to:

OCO Biomedical
9550 San Mateo Blvd. NE, Suite C
Albuquerque, NM 87113

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For OCO Biomedical Use Only

Date Received by OCO Biomedical: _____

Was event caused by Product: ☐ No ☐ Yes Explain:
_____

Investigation Needed: ☐ No ☐ Yes If Yes give reason:
_____

Corrective and/or Preventive Action ☐ No ☐ Yes If Yes give reason:
_____

Reportable to FDA or Health Canada: ☐ FDA ☐ Health CANADA ☐ N/A

OCO Biomedical will report adverse events FDA and Health Canada within the following timelines:

FDA: 5 days, if event poses immediate risk to cause substantial harm to public health. 21CFR803.53
FDA: 30 days, any adverse event that may have contributed to death or serious injury. 21 CFR803.50

Health Canada: 10 Days, if event led to death or serious deterioration of patient or user health. SOR/98-282.60
Health Canada: 30 Days, if event could lead to death or surgery. SOR/98-282.60

_____ _____ _____
Signature Title Date

To be filled out by Sales:
Notes for follow-up:

_____
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_____ _____ _____
Signature Title Date

Work Form Reference: FRM-08-01; Label Template Form; Version No.: **0**