OCO BIOMEDICAL

Work Form		
Document Title	Document Description	Version No.
FRM-13-01	**IMPLANT INCIDENT REPORT**	**0**

Control No: _____

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

Please answer all questions and return with implant

Patient Information

Patient Identifier:	Sex:	Age:
General Health: Good ☐ Fair ☐ Poor ☐ Smoker ☐ Non-smoker ☐		
Patient on regular recall? Interval?		
Does patient have any medical problems or is taking any medication that could have been a factor in the implant failing?	Explain:	

Product Information

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

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 implant was placed:	Date implant was removed:
How many implants were placed in addition to the unsuccessful implant?	
What was the final torque value used when placing the implant?	
How soon after implant placement was problem detected?	
What was the problem (i.e.: pain, infection, tissue inflammation)?	
If infection was present, how was it treated?	
How was the problem initially treated?	

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What quadrant of the mouth was the implant placed?
How many implants were placed in conjunction with the unsuccessful implant?
Was the implant immediately loaded/ put in function?
Was the implant an immediate placement?
What type of prostheses was placed?
How many units did the implant support?
Was there any grafting material used in conjunction with the implant? ☐ No ☐ Yes If yes, what was used?
Was there any damage to the tissue? (physical trauma, infection, tissue loss)
Was there any bone loss? ☐ No ☐ Yes How much?
Were the buccal or lingual plates perforated during surgery?
What was the normal drill speed(s) you used for the Final Drill?
Was another implant placed after removal of the implant?
Was a tissue flap reflected?
In your opinion, what was the reason for the unsuccessful implant?
Explanations/Comments/Clarification:
Please return this report with implant, as well as pre and post-op x-rays 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 Implant: ☐ 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-31-01; Implant Incident Report Form; Version No.: **0**