Control No. _____

IMPLANT INCIDENT REPORT

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?		
Patient have any medical problems 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:	
Have you reported event to FDA: ☐ No ☐ Yes	

Procedure Information

***If Yes contact OCO Biomedical immediately**

1	Did incident cause or contribute to a death: ☐ No ☐ *Yes	
2	Did incident cause serious injury or illness to Patient that was Life Threatening: ☐ No ☐ *Yes	
3	Did incident result in permanent impairment of a body function or permanent damage to a body structure? ☐ No ☐ *Yes	
4	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:	
5	Date implant was placed:	Date implant was removed:
6	How soon after implant placement was problem detected?	
7	What was the problem (i.e.: pain, infection, tissue inflammation)?	
	If infection was present, how was it treated?	

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8	How was the problem initially treated?	
9	What quadrant of the mouth was the implant placed?	
10	How many implants were placed in conjunction with the unsuccessful implant?	
11	Was the implant immediately loaded/ put in function?	
12	Was the implant an immediate placement?	
13	What type of prostheses was placed?	
14	How many units did the implant support?	
15	Was there any grafting material used in conjunction with the implant? ☐ No ☐ Yes If yes, what was used?	
16	Was there any damage to the tissue? (physical trauma, infection tissue loss)?	
17	Was there any bone loss? ☐ No ☐ Yes	How much?
18	Were the buccal or lingual plates perforated during surgery?	
19	What was the normal drill speed(s) you used for the Final Drill?	
20	Was another implant placed after removal of the implant?	
21	In your opinion, what was the reason for the unsuccessful implant?	

Explanations/Comments/Clarification:

Please return report with implant, as well as x-ray or duplicate x-ray and anything else you think may 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

For OCO Biomedical Use Only

Date Received by OCO Biomedical: _____

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

Did implant INCIDENT contribute to event: ☐ No ☐ Yes Explain:
_____

Investigation Needed: ☐ No ☐ Yes If No, Reason: _____

Corrective and/or Preventive Action ☐ No ☐ Yes If No, Reason:

_____	_____	_____
Signature	Title	Date