PRODUCT COMPLAINT QUESTIONNAIRE

QAOF-02A Rev 09

Please Return item(s) **sterilized** and packed separately!

Dear Healthcare Provider,

Thank you for purchasing Alpha-Bio Tec. products, which are manufactured to the highest quality standards and comply with the strictest international requirements.

In order to return the product in an orderly procedure, please follow the instructions below:

1. **Complete this form comprehensively and attach the sterilized product to it. Any missing information will delay processing. All fields are mandatory, unless otherwise written.**
2. **Please add radiographs before and after the event.**

1. Distributor Information			
Distributor Name	Alpha Implant Kft.		
Distributor Address	9400 Sopron, Deák tér 45.		
Distributor Country	Hungary		
2. Practitioner Information			
Practitioner Name			
Practitioner Address			
Practitioner Phone Number			
3. Product Information			
Part Number			
Lot Number			
Description			
4. Case Details			
Occurrence of event:	☐ At Arrival	☐ During clinical procedure	☐ After clinical procedure

Product Complaint Type:

☐ Failure to Osseo integrate	☐ Primary stability couldn't be achieved	☐ Loss of sterility (not used)
☐ Fractured part	☐ Wrong Size Chosen	☐ Packaging (please attach package & specify)
☐ Labeling (please specify)	☐ Deformation (please specify)	
☐ External trauma (e.g. car accident), please specify	☐ Surface defect (product), please specify	
☐ Other, please specify:		

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5. Surgery Information			
Implantation Date	__/__/____		
Date of prosthetic attachment	__/__/____		
Date of implant removal	__/__/____		
Instruments/abutments failure date	__/__/____		
6. Patient Information			
Patient Indicator (not name, due to confidentiality)		**Sex:**	☐ Male ☐ Female
Age	<20 20-50 50-70 >70		
Patient Profile	☐ Bruxer ☐ Smoker ☐ Diabetic ☐ Osteoporosis ☐ Steroid therapy ☐ Current/previous radiation therapy in the area ☐ Other _____		
7. Patient Injury*			
Patient Injury*	☐ Yes ☐ No	If yes, please explain: _____	
Date of event (dd/mm/yyyy)	__/__/____		
Permanent damage	☐ Yes ☐ No	If yes, please explain: _____	
Pain and numbness	Was the implant removed due to pain?		☐ Yes ☐ No
	Was the implant removed due to numbness?		☐ Yes ☐ No
	Did the pain/numbness disappear after the implant was removed?		☐ Yes ☐ No

***All unplanned surgical procedures are injuries and require an immediate report to your local ABT representative.**

Thank you for your cooperation!

FOR INTERNAL USAGE ONLY

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