



PRODUCT COMPLAINT QUESTIONNAIRE

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:

- ❶ Complete this form comprehensively, and attach the sterilized product to it. Any missing information will delay processing. All fields are mandatory, unless otherwise is written.
- ❷ If the case is an implant failure, please add radiographs before and after the event.

<p>Distributor Information</p> <p>Distributor name <input type="text" value="Alpha Implant Kft."/></p> <p>Distributor address <input type="text" value="9400 Sopron, Deák tér 45."/></p> <p>Distributor Country <input type="text" value="Hungary"/></p> <p>Patient Information</p> <p>Patient ID (not name, due to confidentiality) <input type="text"/></p> <p>Sex <input type="checkbox"/> Male <input type="checkbox"/> Female</p> <p>Patient Profile</p> <p><input type="checkbox"/> Bruxer <input type="checkbox"/> Smoker <input type="checkbox"/> Diabetic <input type="checkbox"/> Osteoporosis <input type="checkbox"/> Steroid therapy</p> <p><input type="checkbox"/> Current/previous radiation therapy in the area <input type="checkbox"/> Other <input type="text"/></p> <p>Product Information</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Part No. <input type="text"/></td> <td style="width: 33%;">Lot no. <input type="text"/></td> <td style="width: 33%;">Description <input type="text"/></td> </tr> <tr> <td>Part No. <input type="text"/></td> <td>Lot no. <input type="text"/></td> <td>Description <input type="text"/></td> </tr> </table>	Part No. <input type="text"/>	Lot no. <input type="text"/>	Description <input type="text"/>	Part No. <input type="text"/>	Lot no. <input type="text"/>	Description <input type="text"/>	<p>Practitioner Information</p> <p>Practitioner name (not mandatory) <input type="text"/></p> <p>Practitioner address (not mandatory) <input type="text"/></p> <p>Practitioner phone # (not mandatory) <input type="text"/></p> <p>Date of birth <input type="text" value="__-__-____"/> (dd - mm - yyyy)</p>
Part No. <input type="text"/>	Lot no. <input type="text"/>	Description <input type="text"/>					
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Case details

Occurrence of event: At Arrival During clinical procedure After clinical procedure

Case description:

- Labeling issue Packaging issue Trauma (external) Surface defect
- Non Osseo-integration Loss of Osseo-integrate Fracture during insertion Deformation
- Implant fracture after prosthetic restoration Handling - Loss of sterility (NOT USED)
- Dropped during surgery (NOT USED) Other

Describe event or problem (not mandatory)

Implantation date

Date of prosthetic attachment

Date of implant removal

Instruments/abutments failure date:

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 numbness?

Yes No

Did the pain/numbness disappear after the implant was removed?

Yes No

Would you like to receive a complaint investigation report?

Yes No

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

Thank you for your cooperation

Enclosures:

Radiographs

Product as Listed

Signature of the person who filed the report

Name:

Date Received at Alpha-Bio Tech:

Internal ABT tracking Number: