



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 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 style="width: 100%;" type="text"/></p> <p>Distributor address <input style="width: 100%;" type="text"/></p> <p>Distributor Country <input style="width: 100%;" type="text"/></p> <p>Patient Information</p> <p>Patient ID (not name, due to confidentiality) <input style="width: 100%;" 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 <input type="checkbox"/> Current/previous radiation therapy in the area <input type="checkbox"/> Other <input style="width: 150px;" type="text"/> </p> <p>Product Information</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Part No. <input style="width: 100%;" type="text"/></td> <td style="width: 33%;">Lot no. <input style="width: 100%;" type="text"/></td> <td style="width: 33%;">Description <input style="width: 100%;" type="text"/></td> </tr> <tr> <td>Part No. <input style="width: 100%;" type="text"/></td> <td>Lot no. <input style="width: 100%;" type="text"/></td> <td>Description <input style="width: 100%;" type="text"/></td> </tr> </table>	Part No. <input style="width: 100%;" type="text"/>	Lot no. <input style="width: 100%;" type="text"/>	Description <input style="width: 100%;" type="text"/>	Part No. <input style="width: 100%;" type="text"/>	Lot no. <input style="width: 100%;" type="text"/>	Description <input style="width: 100%;" type="text"/>	<p>Practitioner Information</p> <p>Practitioner name (not mandatory) <input style="width: 100%;" type="text"/></p> <p>Practitioner address (not mandatory) <input style="width: 100%;" type="text"/></p> <p>Practitioner phone # (not mandatory) <input style="width: 100%;" type="text"/></p> <p>Date of birth <input style="width: 100%; text-align: center;" type="text" value="-- - - - -"/> (dd - mm - yyyy) </p>
Part No. <input style="width: 100%;" type="text"/>	Lot no. <input style="width: 100%;" type="text"/>	Description <input style="width: 100%;" 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 Tec:

Internal ABT tracking Number: