

Please complete this form with as much details as possible. If appropriate, attach the product(s) in sterile condition and any relevant radiographs or clinical photos to this form.

PLEASE NOTE:

- Product(s) must be returned within 30 days of the date of the event.
- Returned product must be autoclave sterile (to protect our employees) but not cleaned, packaged in protective pouch and labelled "sterile".
- Only signed and properly documented Warranty Questionnaires will be considered.
- Only one replacement implant per day and per tooth qualifies for replacement.

Z-SYSTEMS USE ONLY	
Complaint/ Feedback N°:	
Product returned and sterile?	<input type="radio"/> yes <input type="radio"/> no
Complaint (C) or feedback (F)?	<input type="radio"/> C <input type="radio"/> F
Reportable event?	<input type="radio"/> yes <input type="radio"/> no
Information complete:	<input type="radio"/> yes <input type="radio"/> no
Date:	Signature:

CUSTOMER INFORMATION

Clinician: _____	Facility: _____
Address: _____	City: _____
Phone: _____	E-Mail: _____

PATIENT INFORMATION for privacy DO NOT use patient's name

Patient ID: _____	<input type="radio"/> Smoker	<input type="radio"/> Bruxism	<input type="radio"/> Compromised immunity
Age: _____	<input type="radio"/> Drug or alcohol abuse	<input type="radio"/> Xerostomia	<input type="radio"/> No significant findings
Gender: <input type="radio"/> m <input type="radio"/> f <input type="radio"/> div.	<input type="radio"/> Diabetes mellitus	<input type="radio"/> Limited oral hygiene	<input type="radio"/> Other: _____

PRODUCT INFORMATION

REF-Number	Lot Number	Placement Date / Event date	Regio
_____	_____	____/____/____	_____
_____	_____	____/____/____	_____

SURGERY INFORMATION

Time of implantation	Bone quality	Bone defects	Insertion mode/torque	Protection
<input type="radio"/> immediate implantation	<input type="radio"/> D1	<input type="radio"/> horizontal	<input type="radio"/> manual/_____Ncm	<input type="radio"/> long-term prov. restoration
<input type="radio"/> early implantation	<input type="radio"/> D2	<input type="radio"/> vertical		<input type="radio"/> prosthesis
<input type="radio"/> late implantation	<input type="radio"/> D3	<input type="radio"/> no information	<input type="radio"/> mechanical/_____Ncm	<input type="radio"/> protective splint
<input type="radio"/> no information	<input type="radio"/> D4			<input type="radio"/> other
Sinus elevation	Augmentation	Was primary stability achieved?		<input type="radio"/> yes <input type="radio"/> no
<input type="radio"/> yes <input type="radio"/> no	<input type="radio"/> yes <input type="radio"/> no	Was osseointegration achieved?		<input type="radio"/> yes <input type="radio"/> no

PROSTHESIS INFORMATION

Temporary restoration/Date: _____	Final restoration/Date: _____
<input type="radio"/> long-term provisional	<input type="radio"/> crown
<input type="radio"/> bridge	<input type="radio"/> bridge
<input type="radio"/> other _____	<input type="radio"/> other _____

EVENT INFORMATION

Were any of the following conditions involved in the event?	At the time of the event/implant removal:
<input type="radio"/> Trauma/Accident	<input type="radio"/> Inflammation
<input type="radio"/> Peri-implantitis	<input type="radio"/> Mobility
<input type="radio"/> Sinus perforation	<input type="radio"/> Asymptomatic
<input type="radio"/> Infection	<input type="radio"/> Swelling
<input type="radio"/> Implant fracture	<input type="radio"/> Pain
<input type="radio"/> Abutment fracture	<input type="radio"/> Bleeding
<input type="radio"/> Poor bone quality	<input type="radio"/> Fistula
<input type="radio"/> Poor bone quantity	<input type="radio"/> Increased sensitivity
<input type="radio"/> Chipping during insertion	<input type="radio"/> Numbness
<input type="radio"/> Biomechanical overload	<input type="radio"/> Hypersensitivity
<input type="radio"/> Bruxism	<input type="radio"/> Abscess
<input type="radio"/> Bone augmentation	<input type="radio"/> other: pls describe below

Please describe the event: Why do you think the event occurred?

Before sending the complaint (please tick the box when read):

We hereby confirm that the product was used according to the instructions for use (IFU).

We hereby confirm that the warranty conditions are read and accepted.

Autoclave all products, but do NOT clean them, and mark them STERILE.

Send the product and this completed form to your local distributor.

Complete this template, including name, date and signature and send it including x-rays by e-mail to quality@zsystems.com.

Name: _____

Date: _____ Signature: _____

CONTACTS

If you have any queries, please contact your Z-Systems Territory Manager or Support: support@zsystems.com.

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