SURGIKOR

Do Not Fill Out Boxes to the Right; For Office Use Only	CMP#:
	Aware Date:
	Replacement Order #:

PRODUCT EXPERIENCE REPORT

Required fields are indicated by ***bold italics***. However, providing as many details as possible will significantly assist our investigatory process, as well as our efforts to constantly improve. Such information is also needed to satisfy the Medical Device Manufacturer Regulatory Requirements. Processing of the report will be delayed by missing information.

INFORMATION ABOUT REPORTER

Name of Person Filing Report: _____ ***Report Date:*** _____ **Complaint #:** _____
Is the person submitting this report a: ☐ Distributor ☐ Lab ☐ Clinician
Address: _____ Doctor: _____
City, State, Zip, Country: _____
Phone #: _____ Fax: _____ e-mail: _____
Account Name: _____ ***Account No.:*** _____
Sales Rep Name: _____ Phone #: _____
Customer requesting a final report? ☐ Yes ☐ No

INFORMATION ABOUT PRODUCT: Use only one form per patient/complaint. If several devices are related to one event being report, you may list multiple item numbers below.

Item #	***Lot / Serial #***	***Qty.***	***Product being returned?***	If not, why (e.g., scrapped, etc.)?	***Product decontaminated?***	***# of Requested Replacement Item*** Check "remake" box if requesting patient specific product.
			☐ Yes ☐ No ☐ Unk		☐ Yes ☐ No ☐ Unk	☐ Remake
			☐ Yes ☐ No ☐ Unk		☐ Yes ☐ No ☐ Unk	☐ Remake
			☐ Yes ☐ No ☐ Unk		☐ Yes ☐ No ☐ Unk	☐ Remake
			☐ Yes ☐ No ☐ Unk		☐ Yes ☐ No ☐ Unk	☐ Remake
			☐ Yes ☐ No ☐ Unk		☐ Yes ☐ No ☐ Unk	☐ Remake

I hereby certify the product(s) listed above have been decontaminated per the above statement(s):
(Sign/Date) _____
Decontamination Method: ☐ Autoclave ☐ Other: _____
Destructive analysis allowed? ☐ Yes ☐ No Radiographs available? ☐ Yes ☐ No

INFORMATION ABOUT EVENT:

Date of Event: _____ **(mm / dd / yyyy)**
Date of Placement: _____ **(mm / dd / yyyy)**
Date of Removal: _____ **(mm / dd / yyyy)**

Event Description (Check all applicable boxes)
☐ Loss of Integration (LI) ☐ Cosmetic ☐ Non-Integration (NI) ☐ Fracture ☐ Malfunction ☐ Fit ☐ Other: _____
Discovered during: ☐ Clinical Procedure ☐ Laboratory Procedure ☐ Receiving / Unpacking ☐ Other: _____
Describe the reported issue in detail (list settings used, procedure being performed, and related products):

Was patient injured due to event? ☐ Yes ☐ No If yes, describe: _____

Note: The information being collected with this from is used for satisfying regulatory requirements of the United States of America and other countries as applicable. Completion of this form does not constitute an admission that the event was contributed to or caused by any medical personnel, distributors, manufacturers, or products.

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Was surgery necessary to prevent permanent damage? ☐ Yes ☐ No If Yes, please describe: _____
Will the patient need to return for another dental appointment to finish the procedure? If yes, explain: _____
Were there delays in the surgical procedure? ☐ Yes ☐ No If Yes, how long was the delay? _____

Describe what happened to the patient as a result of the event (Check all that apply): ☐ No Impact	☐ Allergic Reaction ☐ Aspiration ☐ Bone Loss ☐ Dehiscence ☐ Delayed Healing ☐ Edema	☐ Hemorrhage ☐ Hyperesthesia ☐ Hyperplasia ☐ Infection ☐ Inflammation ☐ Ingestion	☐ Nerve Damage ☐ Pain ☐ Paresthesia ☐ Other: _____
Other Patient History:	☐ Smoker / Tobacco use ☐ Oral Hygiene: _____	☐ Bruxism ☐ Osteoporosis	☐ Clenching ☐ Diabetes ☐ Other _____
Additional Information:	☐ Site Grafted If Yes, describe the material	☐ Autogenous ☐ Allograft ☐ Xenograft	☐ Alloplast ☐ Hybrid

Was the implant restored (final or provisional)? ☐ Yes ☐ No ☐ N/A
If Yes, when (please check one): ☐ ***Within 48 hours*** ☐ ***Within 8 weeks)*** ☐ ***3-4 mos mandible, 4-6 mos maxilla***

A. PATIENT INFORMATION

Patient Name: _____ ***Gender:*** ☐ Male ☐ Female ***Age at time of event:*** _____
Weight: _____ ☐ lbs ☐ kgs ☐ Unknown ***Tooth Number:*** _____ ***Dental Notation Systems:*** ☐ Universal ☐ FDI ☐ Palmer
Bone Density Type: ☐ I ☐ II ☐ III ☐ IV ☐ Unk
Patient's condition at time of event: _____

Instructions:

- You MUST follow the following guidelines when returning products:
  1. Sterilize used products in pouches that show sterility in some way (e.g., color change) prior to shipping.
  2. Autoclave metal items.
  3. Cold-sterilize plastic items.
  4. For primary packages, place each returned product or component or into a package labeled with the complaint number and product description. The primary package must be placed in a secondary package labeled with the contact information (account # is acceptable) with additional components or products that are to be returned.
  5. Include a copy of the Complaint Report and Complaint Number.
  6. For issues involving non-patient specific products, return only the products that are the subject of the complaint.
- Please do not return products without a Complaint Number. Please call a Customer Service Representative at 888-823-5553 to obtain this number before shipping any product that is the subject of a complaint.
- Please send this form and the product(s) to the address below immediately after the event occurs:

  Attn: Quality Assurance
  1299 West Jefferson Blvd.
  Los Angeles, CA 90007

- Please use the following contact information to get answers to any questions you may have in relation to this form and other relevant matters:

  Phone: 888-823-5553
  Email: info@surgikorimplants.com

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