ZIMMER BIOMET

zimmer dental

BIOMET 3i

For Zimmer Biomet Use Only Not to be Completed by the Reporter	CMP#:
	Aware Date:
	Replacement Order #:
	ZB employee filling out form:

PRODUCT EXPERIENCE REPORT

The inclusion of as many details as possible greatly aids the investigation process as well as provides useful information for continuous improvement. Additionally, it is needed to comply with Medical Device Manufacturer Regulatory Requirements. Missing information will delay processing. Required fields are denoted in ***bold italics***.

A. REPORTER INFORMATION

Complaint # _____

Person Submitting this Report: _____ ***Date of Report:*** _____

Is the person submitting this report a: ☐ Clinician ☐ Lab ☐ Distributor

Account Name: _____ ***Account #:*** _____

Address: _____ Doctor: _____

City, State, Zip, Country: _____

Phone #: _____ Fax: _____ e-mail: _____

Sales Rep: _____ Phone #: _____ Customer requesting a final report? ☐ Yes ☐ No

B. PRODUCT INFORMATION: One form should be used per complaint and/or patient. If more than one device is associated with a single event being reported, multiple Item numbers may be included below.

Item Number	***Lot / Serial #***	***Qty.***	***Is Product Being Returned?***	If No, Why? (i.e. retained by the hospital, scrapped, etc.)	***Has product been decontaminated?***	***Requested Replacement Item Number*** For Patient Specific Product, check if remake requested.
			☐ 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 that the above listed product has been decontaminated as stated above: (Sign/Date) _____

Method of decontamination: ☐ Autoclave ☐ Other (Specify): _____

Is destructive analysis permitted? ☐ Yes ☐ No

C. EVENT INFORMATION

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

Description of the Event (Check all that apply)

☐ Lack of Primary Stability ☐ Non-Integration (NI) ☐ Loss of Integration (LI) ☐ Infection ☐ Peri-implantitis ☐ Sinus Perforation
☐ Allergic Reaction ☐ Nerve Injury ☐ Cosmetic ☐ Fit ☐ Fracture ☐ Malfunction
☐ Other: _____

Discovered: ☐ During receiving / unpacking ☐ During clinical procedure ☐ During Laboratory Procedure ☐ Other: _____

Provide a detailed description of the reported problem (including procedure being performed, related products and settings used): _____

Was the surgery completed using another implant or another device? ☐ Yes ☐ No If Yes, please describe: _____

Was there any injury to the patient as a result of the event? ☐ Yes ☐ No If Yes, please describe: _____

Was surgical intervention necessary to preclude permanent impairment? ☐ Yes ☐ No If Yes, please describe: _____

Will the patient have to return for an additional dental appointment to complete the procedure? ☐ Yes ☐ No If Yes, explain: _____

Was there a delay in the surgical procedure? ☐ Yes ☐ No If Yes, what was the duration of the delay? _____

Note: This information is being gathered to assist in complying with regulatory requirements in the USA and other countries as applicable. Completion of this form does not constitute an admission that medical personnel, distributor, manufacturer, or product caused or contributed to the event.

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Describe what happened to the patient as a result of the event (Check all that apply): ☐ No Patient Impact	☐ Abscess ☐ Aspiration ☐ Bone Loss ☐ Dehiscence	☐ Edema ☐ Inflammation ☐ Ingestion	☐ Pain ☐ Paresthesia ☐ Other: _____
Other Relevant Patient History (Check all that apply):	☐ Smoker / Tobacco use ☐ Oral Hygiene: _____	☐ Bruxism ☐ Osteoporosis	☐ Clenching ☐ Diabetes ☐ Other: _____
Additional Information:	☐ Site Grafted If yes, describe material: Graft placement date: _____	☐ Autogenous ☐ Allograft ☐ Xenograft	☐ Alloplast ☐ Hybrid
	☐ Graft prior to implant placement ☐ Graft together with implant placement		

Was the implant restored (provisional or final)? ☐ Yes ☐ No ☐ N/A ☐ Provisional ☐ Final

If Yes, please check one: ☐ ***Immediate (within 48 hrs)*** ☐ ***Early (within 8 wks)*** ☐ ***Traditional (3-4 mos mandible, 4-6 mos maxilla)***

D. PATIENT INFORMATION

Patient Identifier: _____ ***Gender:*** ☐ Male ☐ Female ***Age at the time of the event:*** _____

Weight: _____ ☐ lbs ☐ kgs ☐ Unk ***Tooth Number:*** _____ ***Dental Notation Systems:*** ☐ Universal ☐ FDI ☐ Palmer

Bone Density Type: ☐ I ☐ II ☐ III ☐ IV ☐ Unk

Patient's Condition at the time of the event: _____

E. REGENERATIVE PRODUCT ONLY

Membrane used? ☐ Yes ☐ No How was it prepared? _____

Appearance at the time of insertion: _____

Appearance at the time of removal: _____

Bone Graft used? ☐ Yes ☐ No How was it prepared? _____

Appearance at the time of insertion: _____

Appearance at the time of removal: _____

Puros Product used? ☐ Yes ☐ No Specify Donor #: _____

F. PATIENT SPECIFIC PRODUCT BellaTek™ or ZFx™ Abutments ONLY

If related to a Lab Designed Abutment, include original file name submitted as part of the order: _____

Please check all that apply to the reported event and provide additional details:

☐ Incorrect analog placement/orientation ☐ Incorrect connection type ☐ Incorrect platform size (diameter) ☐ Incorrect material

☐ Missing requested design feature ☐ Fracture ☐ Incorrect margin style ☐ Incorrect margin depth

☐ Abutment does not seat in model ☐ Abutment does not seat in mouth

☐ Incorrect abutment height (clearance) ☐ Incorrect abutment orientation (rotated)

☐ Other: _____

Provide a detailed description of the reported problem:

_____

BellaTek™ or ZFx™ Bars:

Please check all that apply to the reported event and provide additional details:

☐ Incorrect analog placement/orientation ☐ Incorrect bar structure type ☐ Incorrect material

☐ Missing requested design feature ☐ Fracture ☐ Incorrect margin depth

☐ Incorrect bar-tissue spacing ☐ Incorrect bar height ☐ Incorrect bar width

☐ Bar not passive/rocking/movement) ☐ Bar does not seat on model ☐ Bar does not seat in mouth

☐ Other: _____

Provide a detailed description of the reported problem:

_____

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Instructions:

- Please return completed Product Experience Form(s) to the applicable Product Surveillance Department, see complaint handling contacts below. Complaint product(s) must be returned with complaint number(s), contact the complaint handling group to obtain the complaint number (CMP #).
- When returning product the following guidelines must be followed:
  1. Used product MUST be sterilized in pouches which display sterility (color change or other indicator) prior to shipping. Metal devices must be autoclaved; plastic devices must be cold sterilized.
  2. For non-Patient Specific Products, return only the complaint product.
  3. To ensure product identification and traceability the following information must be provided:
     - Primary Package: Each returned component or product has to be individually placed into a primary package (pouch) labeled with the product description and CMP #.
     - Secondary Package: The primary package should be packed in a box or a padded envelope, if necessary use bubble wrap. The primary package is then placed into the secondary package labeled with applicable complaint handling site address. Along with the complaint product, include customer contact information (include customer account #) with any additional product to be returned.
  4. Include a copy of the Product Experience Form with the applicable CMP # and any other supporting documentation (x-rays, intra-oral images, etc.).
- Due to regulatory requirements, please submit this form and the product immediately to the applicable complaint handling location listed below.

Send the complaint product to:

US

Biomet 3i & Zimmer Dental
Email:
DomesticComplaints@zimmerbiomet.com

Attn: Complaints Handling
4555 Riverside Drive
Palm Beach Gardens, FL 33410
Phone: 1.800.443.8166

Canada

Biomet 3i & Zimmer Dental
Email:
DomesticComplaints@zimmerbiomet.com

Zimmer Dental Corp.
2323 Argentia Road
Mississauga, Ontario L5N 5N3
Phone: 514-956-9843

Chile

Zimmer Dental
Email:
3IPBG-IntComplaint@zimmerbiomet.com

Zimmer Dental Chile SPA
Luis Thayer Ojeda 0130
Oficina 901/902
Providencia Santiago, Chile

International (APAC & Non-European):

Biomet 3i
Email:
3IPBG-IntComplaint@zimmerbiomet.com

Biomet 3i
Attn: Complaints Handling
4555 Riverside Drive
Palm Beach Gardens, FL 33410
Phone: 561.776.6918

China
Email:
3IPBG-IntComplaint@zimmerbiomet.com

Zimmer Dental
Zimmer Dental
1003 Fosun International Center
273 North Chao Yang Road,
Chao Yang District Beijing
100020 China

Australia: ***Phone:*** +61 2 9855 4444
Mexico: ***Phone***: +52 55 2282 0120

Europe

Non- Patient Specific Product

Austria:
Zimmer Biomet Austria GmbH
Großmarktstraße 7a
1230 Wien, Austria
Phone: +43 (0) 8000 700 17
Fax: +43 (0) 8000 700 18
Email: 3iEUComplaints@zimmerbiomet.com

Belgium and Luxembourg:
Biomet 3i
Biomet 3i
TAV: Customer Service
Prins Boudewijnlaan 24C
2550 Kontich, Belgium
Phone: +32 80050311
Email: 3iEUComplaints@zimmerbiomet.com

France:
Biomet 3i & Zimmer Dental
Zimmer Dental S.A.S.
2 Place Gustave Eiffel,
94150 Rungis, France
Phone: +33(0) 800 91 67 86
Email:
3iEUComplaints@zimmerbiomet.com

Germany:
Biomet 3i & Zimmer Dental
Zimmer Dental GmbH
Wilhelm-Wagenfeld-Straße 28
80807 München, Germany
Phone: +49 (0) 800 184 0271 /
+49 (0) 800 101 6420
Fax: +49 (0)800 313 11 11
Email: 3iEUComplaints@zimmerbiomet.com

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Israel

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Vicenza, Italy
Phone: +39 0444 913 410
Email: info@biomax.it

Netherlands:
Biomet 3i
Biomet 3i Netherlands
TAV: Customer Service
Toermalijnring 600
3316 LC Dordrecht, Netherlands
Phone: +31 078 62 92 800
Email: 3iEUComplaints@zimmerbiomet.com

Spain and Portugal:
Biomet 3i and Zimmer Dental

Email:
3iEUComplaints@zimmerbiomet.com

Biomet 3i Dental Ibérica, S.L.
WTC Almeda Park, Ed.4, Planta 2
C/Tirso de Molina, 40
08940 Cornellà de LLobregat
(Barcelona) Spain
Spain Phone: 900 800 303
Portugal Phone: 800 827 836

Switzerland:
BIOMET 3i Schweiz GmbH
Grüzefeldstrasse 41
CH-8404 Winterthur, Switzerland
Phone: +41 (0)800 24 66 38
F***ax***: +41 (0)800 24 66 39
Email: 3iEUComplaints@zimmerbiomet.com

UK and Ireland:
Biomet 3i
Biomet 3i UK
1 Bell Street Maidenhead
Berkshire, UK SL6 1BU, United Kingdom
Email: 3iEUComplaints@zimmerbiomet.com
UK:
Phone: +44 (0) 800 652 1233
Ireland:
Phone: +353 1800 552752

Patient Specific Product

Email: es.3ipsp@biomet.com
Address:
Biomet 3i Dental Ibérica
BellaTek Dept.
Islas Baleares 50, Polígono Fuente del Jarro
46988 Valencia
Téléphone : +34 961379536 / 38
Fax: +34 961379505

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