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|---|-------------------------------|
| 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 | |
|--|---|
| Person Submitting this Report: _____ | Complaint # _____ |
| Is the person submitting this report a: <input type="checkbox"/> Clinician <input type="checkbox"/> Lab <input type="checkbox"/> Distributor | Date of Report: _____ |
| Account Name: _____ | Account #: _____ |
| Address: _____ | Doctor: _____ |
| City, State, Zip, Country: _____ | |
| Phone #: _____ Fax: _____ e-mail: _____ | |
| Sales Rep: _____ Phone #: _____ | Customer requesting a final report? <input type="checkbox"/> Yes <input type="checkbox"/> 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 <small>For Patient Specific Product, check if remake requested.</small> |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk | <input type="checkbox"/> Remake |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk | <input type="checkbox"/> Remake |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk | <input type="checkbox"/> Remake |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk | <input type="checkbox"/> Remake |
| | | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk | <input type="checkbox"/> 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: _____ <small>(dd/mmm/yyyy)</small> | Event Date: _____ <small>(dd/mmm/yyyy)</small> | Removal Date: _____ <small>(dd/mmm/yyyy)</small> |
|---|---|---|---|
| Description of the Event (Check all that apply) | | | |
| <input type="checkbox"/> Lack of Primary Stability <input type="checkbox"/> Non-Integration (NI) <input type="checkbox"/> Loss of Integration (LI) <input type="checkbox"/> Infection <input type="checkbox"/> Peri-implantitis <input type="checkbox"/> Sinus Perforation <input type="checkbox"/> Allergic Reaction <input type="checkbox"/> Nerve Injury <input type="checkbox"/> Cosmetic <input type="checkbox"/> Fit <input type="checkbox"/> Fracture <input type="checkbox"/> Malfunction <input type="checkbox"/> Other: _____ | | | |
| Discovered: <input type="checkbox"/> During receiving / unpacking <input type="checkbox"/> During clinical procedure <input type="checkbox"/> During Laboratory Procedure <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please describe: _____ | | | |
| Was there any injury to the patient as a result of the event? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please describe: _____ | | | |
| Was surgical intervention necessary to preclude permanent impairment? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please describe: _____ | | | |
| Will the patient have to return for an additional dental appointment to complete the procedure? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, explain: _____ | | | |
| Was there a delay in the surgical procedure? <input type="checkbox"/> Yes <input type="checkbox"/> 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.



| | | | |
|---|--|---|--|
| Describe what happened to the patient as a result of the event (Check all that apply): <input type="checkbox"/> No Patient Impact | <input type="checkbox"/> Abscess <input type="checkbox"/> Aspiration <input type="checkbox"/> Bone Loss <input type="checkbox"/> Dehiscence | <input type="checkbox"/> Edema <input type="checkbox"/> Inflammation <input type="checkbox"/> Ingestion | <input type="checkbox"/> Pain <input type="checkbox"/> Paresthesia <input type="checkbox"/> Other: _____ |
| Other Relevant Patient History (Check all that apply): | <input type="checkbox"/> Smoker / Tobacco use <input type="checkbox"/> Oral Hygiene: _____ | <input type="checkbox"/> Bruxism <input type="checkbox"/> Osteoporosis | <input type="checkbox"/> Clenching <input type="checkbox"/> Diabetes <input type="checkbox"/> Other: _____ |
| Additional Information: | <input type="checkbox"/> Site Grafted If yes, describe material: Graft placement date: _____ | <input type="checkbox"/> Autogenous <input type="checkbox"/> Allograft <input type="checkbox"/> Xenograft | <input type="checkbox"/> Alloplast <input type="checkbox"/> Hybrid |
| <input type="checkbox"/> Graft prior to implant placement <input type="checkbox"/> Graft together with implant placement | | | |
| Was the implant restored (provisional or final)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Provisional <input type="checkbox"/> Final If Yes, please check one: <input type="checkbox"/> Immediate (within 48 hrs) <input type="checkbox"/> Early (within 8 wks) <input type="checkbox"/> Traditional (3-4 mos mandible, 4-6 mos maxilla) | | | |

| | | |
|--|--|---|
| D. PATIENT INFORMATION | | |
| Patient Identifier: _____ | Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female | Age at the time of the event: _____ |
| Weight: _____ <input type="checkbox"/> lbs <input type="checkbox"/> kgs <input type="checkbox"/> Unk | Tooth Number: _____ | Dental Notation Systems: <input type="checkbox"/> Universal <input type="checkbox"/> FDI <input type="checkbox"/> Palmer |
| Bone Density Type: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Unk | | |
| Patient's Condition at the time of the event: _____ | | |

| | |
|--|----------------------------|
| E. REGENERATIVE PRODUCT ONLY | |
| Membrane used? <input type="checkbox"/> Yes <input type="checkbox"/> No | How was it prepared? _____ |
| Appearance at the time of insertion: _____ | |
| Appearance at the time of removal: _____ | |
| Bone Graft used? <input type="checkbox"/> Yes <input type="checkbox"/> No | How was it prepared? _____ |
| Appearance at the time of insertion: _____ | |
| Appearance at the time of removal: _____ | |
| Puros Product used? <input type="checkbox"/> Yes <input type="checkbox"/> 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: | | | |
| <input type="checkbox"/> Incorrect analog placement/orientation | <input type="checkbox"/> Incorrect connection type | <input type="checkbox"/> Incorrect platform size (diameter) | <input type="checkbox"/> Incorrect material |
| <input type="checkbox"/> Missing requested design feature | <input type="checkbox"/> Fracture | <input type="checkbox"/> Incorrect margin style | <input type="checkbox"/> Incorrect margin depth |
| <input type="checkbox"/> Abutment does not seat in model | <input type="checkbox"/> Abutment does not seat in mouth | | |
| <input type="checkbox"/> Incorrect abutment height (clearance) | <input type="checkbox"/> Incorrect abutment orientation (rotated) | | |
| <input type="checkbox"/> 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: | | |
| <input type="checkbox"/> Incorrect analog placement/orientation | <input type="checkbox"/> Incorrect bar structure type | <input type="checkbox"/> Incorrect material |
| <input type="checkbox"/> Missing requested design feature | <input type="checkbox"/> Fracture | <input type="checkbox"/> Incorrect margin depth |
| <input type="checkbox"/> Incorrect bar-tissue spacing | <input type="checkbox"/> Incorrect bar height | <input type="checkbox"/> Incorrect bar width |
| <input type="checkbox"/> Bar not passive/rocking/movement) | <input type="checkbox"/> Bar does not seat on model | <input type="checkbox"/> Bar does not seat in mouth |
| <input type="checkbox"/> 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 | Canada | Chile | International (APAC & Non-European): |
|--|--|--|--|
| Biomot 3i & Zimmer Dental Email: DomesticComplaints@zimmerbiomet.com Attn: Complaints Handling 4555 Riverside Drive Palm Beach Gardens, FL 33410 Phone: 1.800.443.8166 | Biomot 3i & Zimmer Dental Email: DomesticComplaints@zimmerbiomet.com Zimmer Dental Corp. 2323 Argentia Road Mississauga, Ontario L5N 5N3 Phone: 514-956-9843 | Zimmer Dental Email: 3IPBG-IntComplaint@zimmerbiomet.com Zimmer Dental Chile SPA Luis Thayer Ojeda 0130 Oficina 901/902 Providencia Santiago, Chile | Biomot 3i Email: 3IPBG-IntComplaint@zimmerbiomet.com Biomot 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: Biomot 3i Biomot 3i TAV: Customer Service Prins Boudewijnlaan 24C 2550 Kontich, Belgium Phone: +32 80050311 Email: 3iEUComplaints@zimmerbiomet.com | France: Biomot 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: Biomot 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

Zimmer Dental

Zimmer Dental Ltd
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Italy

Zimmer Dental

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Phone: +39 0438 37681
Email:
zimmerdental.italy@zimmerbiomet.com

Biomet 3i (Biomax)

BIOMAX SPA
Via Zamenhof, 615
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
Fax: +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

Email: es.3iipsp@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

Patient Specific Product

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