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***.

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| 1. **Reporter Information** |
| ***Person Submitting this Report:***        ***Date of Report:***        Complaint #***:*** |
| 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 |

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| 1. **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 Are radiographs available?  Yes  No | | | | | | |

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| 1. **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)***  Non-Integration (NI)  Loss of Integration (LI)  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 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? If yes, explain: | | | | |
| Was there a delay in the surgical procedure?  Yes  No If Yes, what was the duration of the delay? | | | | |
| Describe what happened to the patient as a result of the event (Check all that apply):  No Patient Impact | | Allergic Reaction  Aspiration  Bone Loss  Dehiscence  Delayed Healing  Edema | Hemorrhage  Hyperesthesia  Hyperplasia  Infection  Inflammation  Ingestion | Nerve Damage  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 | Autogenous  Allograft  Xenograft | Alloplast  Hybrid |
| ***Was the implant restored (provisional or final)?***  Yes  No  N/A  ***If Yes, please check one:***  ***Immediate (within 48 hrs)***  ***Early (within 8 wks)***  ***Traditional (3-4 mos mandible, 4-6 mos maxilla)*** | | | | |

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| 1. **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: | | | | |

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| 1. **Patient Specific product only** | | | |
| **BellaTek™ or ZFx™ Abutment:** | | | |
| Was the abutment designed:  By the lab  By BellaTek™or ZFx™designer  Was the Impression taken:  Implant Level  Encode  Intra Oral Scan  Do you know if a radiograph was taken to ensure Encode healing abutments were completely seated at time of impression?  Yes  No  Unknown  Was the case remounted by BellaTek™ or ZFx™technicians?  Yes  No  Was the Analog Placed:  At the Lab  Robocast by BellaTek™ or ZFx™  If placed with Robocast, is tooth position correct?  Yes  No  Do you know if the Dr. cleared bone or tissue away from the platform of the implant?  Yes  No  Unknown  Was the abutment tried into the patient’s mouth or on the model?  Model  Patient – if Patient is selected, please answer the following questions:  • Was the abutment inserted into the patient’s mouth?  Yes  No  If yes, provide the following: Restorative Dr’s. Name        Phone Number  • Was the abutment seated in the patient’s mouth?  Yes  No  If yes, provide the following: Placement Date of Restoration        Removal Date of Restoration  If Abutment was not as requested, please indicate all that apply: | | | |
| **Abutment Seating /Fit:** | | | |
| Was the abutment seated? | | | |
| Yes | Was abutment rotated?  Yes  No  Unknown  When placing the abutment was the identification marker facing the buccal?  Yes  No  Unknown  Was the abutment fit:  Too Tight  Too Loose  Wrong Connection | | |
| No | Was the abutment rotated?  Yes  No  Unknown  When placing the abutment was the identification marker facing the buccal?  Yes  No  Unknown  Is the hex engaged?  Yes  No  Is there bone or tissue interference?  Buccal  Lingual  Mesial  Distal  Unknown | | |
| **Abutment Height (Clearance):**  Too Short (Large Clearance)  Too Tall (Small Clearance) | | | |
| **Angulation:**  Incorrect alignment with adjacent teeth  Yes  No  Multi-Units: Not Parallel  Yes  No  Direction of incorrect orientation Buccal  Lingual  Mesial  Distal | | | |
| Missing Design Feature?  Yes Describe:        No | | | |
| **Abutment Seating /Fit: Continued** | | | |
| **Margin:** Multi-unit / Single-unit:At placement was the identification marker facing the buccal?  Yes  No  Unk | | | |
| **Margin: Style** Not as requested –rec’d: Chamfer  Shoulder  Feather  **Margin: Geometry** Shape not as requested –rec’d: Anterior  Premolar  Molar  **Margin: Other**  Sharp Edges  Under Cuts | | | |
| **Margin –Depth**  Buccal:  Too low  Too High  Lingual:  Too low  Too High  Mesial:  Too low  Too High  Distal:  Too low  Too High | | **Margin –Tissue Displacement**  Buccal:  Less than desired  More than desired  Lingual:  Less than desired  More than desired  Mesial:  Less than desired  More than desired  Distal:  Less than desired  More than desired | |
| Zirconia Fracture?  Yes  No, If “Yes”, complete the following:   * What torque device was utilized? * Were recommended driver / driver tips utilized? (New driver/driver tips have a laser-marked dot next to the part number)  Yes  No  Unknown * Do you know what the abutment was torqued to?       Ncm   Was desired Material received?  Yes  No, if no please complete the following:  Material Desired  Zirconia  Nitride  Titanium  Material Received  Zirconia  Nitride  Titanium  Wrong Platform Size?  Yes  No What size was Received?       What size was desired?  Describe the Abutment Appearance  Other issue not described above: | | | |
| BellaTek**™ or ZFx™ Bars:** | | | BellaTek**™ or ZFx™ Coping:** |
| Was the bar tried into the patient’s mouth?  Yes  No  If Yes, please provide:  **Restorative Dr’s. Name**  **Phone Number**  Was the Bar Fractured?  Yes  No If yes, state the fracture location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Did the bar fit:   * the Patient?  Yes  No * the Model?  Yes  No   Was the Cast Verified?  Yes  No  Did you make a verification index?  Yes  No  Did the verification index fit the patient?  Yes  No | | | Was the coping tried into the patient’s mouth?  Yes  No  If yes**,** Placement Date of Coping:  Removal Date of Coping:  If coping was inserted into the patient’s mouth, please provide:  **Restorative Dr’s. Name:**  **Phone Number:**  Were you able to seat the coping:   * in the patient’s mouth?  Yes  No * on the model?  Yes  No   If Abutment / Coping was not as requested, please indicate all that apply:  **MARGIN**:  Too High  Too low  Open  **FIT**:  Too Tight  Too Loose  **Coping Height**  Too High  Too low  **Contact**   Open  Too Tight  **Fracture**  Yes  No  Other issue not described above: |

Instructions:

* Do not return product without Complaint #. Please call your Customer Service Representative to obtain this number prior to shipping complaint product.
* When returning product the following guidelines must be followed:

1. Used product MUST be sterilized in pouches which show sterility with color change or other indication prior to shipping. Metal items must be autoclaved; plastic items 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 labeled with the product description and Complaint #.
   * Secondary Package: The primary package is then placed in a secondary package labeled with the contact information (account # is suffice) with any additional components or product to be returned.
4. Include a copy of the Complaint Report and Complaint #.

* Due to regulatory requirements, please submit this form and the product to the below listed locations immediately after the event occurred.

# Send the complaint product to:

|  |  |  |  |
| --- | --- | --- | --- |
| **Israel**  ***Zimmer Dental***  Zimmer Dental Ltd  13 Amal St. Rosh A’ain  Building A, 3rd Floor  4809280 Israel  +972-3-6124242 |  |  |  |

**Patient Specific – Product**

**Email:** [es.3ipsp@biomet.com](mailto:es.3ipsp@biomet.com)

**Address:**

Biomet 3i Dental Ibérica

BellaTek Dept.

Islas Baleares 50, Polígono Fuente del Jarro

46988 Valencia

Tel.: +34 961379536 / 38 / 05