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***.

|  |
| --- |
| 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 |

|  |
| --- |
| 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 |

|  |  |  |  |
| --- | --- | --- | --- |
| 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)*** |

|  |
| --- |
| 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:        |

|  |
| --- |
| 1. **Patient Specific product only**
 |
| **BellaTek™ or ZFx™ Abutment:** |
| Was the abutment designed: [ ]  By the lab [ ]  By BellaTek™or ZFx™designerWas the Impression taken: [ ]  Implant Level [ ]  Encode [ ]  Intra Oral ScanDo you know if a radiograph was taken to ensure Encode healing abutments were completely seated at time of impression? [ ]  Yes [ ]  No [ ]  UnknownWas the case remounted by BellaTek™ or ZFx™technicians? [ ]  Yes [ ]  NoWas the Analog Placed: [ ]  At the Lab [ ]  Robocast by BellaTek™ or ZFx™If placed with Robocast, is tooth position correct? [ ]  Yes [ ]  NoDo you know if the Dr. cleared bone or tissue away from the platform of the implant? [ ]  Yes [ ]  No [ ]  UnknownWas 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 [ ]  NoIf yes, provide the following: Restorative Dr’s. Name        Phone Number        • Was the abutment seated in the patient’s mouth? [ ]  Yes [ ]  NoIf 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 [ ]  UnknownWhen placing the abutment was the identification marker facing the buccal? [ ]  Yes [ ]  No [ ]  UnknownWas the abutment fit: [ ]  Too Tight [ ]  Too Loose [ ]  Wrong Connection |
| [ ]  No | Was the abutment rotated? [ ]  Yes [ ]  No [ ]  UnknownWhen placing the abutment was the identification marker facing the buccal? [ ]  Yes [ ]  No [ ]  UnknownIs the hex engaged? [ ]  Yes [ ]  NoIs 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 [ ]  NoMulti-Units: Not Parallel [ ]  Yes [ ]  NoDirection 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 HighLingual: [ ]  Too low [ ]  Too HighMesial: [ ]  Too low [ ]  Too HighDistal: [ ]  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 [ ]  TitaniumMaterial Received [ ]  Zirconia [ ]  Nitride [ ]  TitaniumWrong 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 [ ]  NoIf 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 [ ]  NoDid you make a verification index? [ ]  Yes [ ]  NoDid the verification index fit the patient? [ ]  Yes [ ]  No | Was the coping tried into the patient’s mouth? [ ]  Yes [ ]  NoIf 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 [ ]  NoOther 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 Ltd13 Amal St. Rosh A’ainBuilding A, 3rd Floor4809280 Israel +972-3-6124242 |  |  |  |

 **Patient Specific – Product**

**Email:** 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