

For Zimvie Use Only Not to be Completed by the Reporter	CE #:
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## PRODUCT EXPERIENCE REPORT

The inclusion of as many details as possible greatly aids the investigation process, continuous improvement and is necessary to comply with Medical Device Manufacturer Regulatory Requirements. Missing information will delay processing. Required fields are identified with an asterisk(\*).

<i>Document if a Complaint # has been previously assigned</i>		CE #:	
A. EVENT INFORMATION	Placement Date*: (dd/mmm/yyyy)	Event Date*: (dd/mmm/yyyy)	Removal Date*: (dd/mmm/yyyy)
<b>Discovered*:</b> <input type="checkbox"/> During receiving / unpacking <input type="checkbox"/> During clinical procedure <input type="checkbox"/> During Laboratory Procedure <input type="checkbox"/> Other: _____			
<b>Description of the Event (Check all that apply)*</b>			
<input type="checkbox"/> Abutment / Bar Fit	<input type="checkbox"/> Allergic Reaction	<input type="checkbox"/> Bone loss	<input type="checkbox"/> Bent
<input type="checkbox"/> Damaged Hex	<input type="checkbox"/> Damaged Threads	<input type="checkbox"/> Does not assemble	<input type="checkbox"/> Does not disengage / release (Stuck)
<input type="checkbox"/> Fracture (Broken)	<input type="checkbox"/> Infection	<input type="checkbox"/> Lack of Primary Stability	<input type="checkbox"/> Loosening
<input type="checkbox"/> Loss of Integration (LI)	<input type="checkbox"/> Nerve Injury	<input type="checkbox"/> Non-Integration (NI)	<input type="checkbox"/> Packaging
<input type="checkbox"/> Peri-implantitis	<input type="checkbox"/> Shipping Damage	<input type="checkbox"/> Sinus Perforation	<input type="checkbox"/> Other, please detail: _____
<b>Provide a detailed description of the reported problem (including procedure being performed, related products and settings used)*:</b>			
<b>At the time of the event or implant failure/removal, was there ...? (Check all that apply)*:</b>		<input type="checkbox"/> No Patient Impact <input type="checkbox"/> Abscess <input type="checkbox"/> Ingestion <input type="checkbox"/> Pain <input type="checkbox"/> Inflammation <input type="checkbox"/> Aspiration <input type="checkbox"/> Paresthesia <input type="checkbox"/> Edema <input type="checkbox"/> Other: _____	
<b>Was surgical and/or medical intervention necessary to preclude permanent impairment?*</b>		<input type="checkbox"/> Yes <input type="checkbox"/> No    If Yes, please describe:	
<b>Was there a delay during the procedure?*</b>		<input type="checkbox"/> Yes <input type="checkbox"/> No    If Yes, please describe:	
<b>Will the patient have to return for an additional dental appointment to complete the procedure?*</b>		<input type="checkbox"/> Yes <input type="checkbox"/> No    If Yes, please describe:	
<b>Was the procedure completed using another implant or another device?*</b>		<input type="checkbox"/> Yes <input type="checkbox"/> No    If Yes, please describe:	
<b>Other Relevant Patient History (Check all that apply)*:</b>		<input type="checkbox"/> Bruxism <input type="checkbox"/> Diabetes <input type="checkbox"/> Smoker / Tobacco use <input type="checkbox"/> Clenching <input type="checkbox"/> Osteoporosis <input type="checkbox"/> Inadequate Oral Hygiene <input type="checkbox"/> Other: _____	
<b>Bone Density Type*</b>	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Unknown		

*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.*

**PRODUCT EXPERIENCE REPORT**

<b>Additional Information:</b>	<input type="checkbox"/> Grafted prior to implant placement <input type="checkbox"/> Grafted together with implant placement	<input type="checkbox"/> Site Grafted If Yes, Describe Material Graft placement date: _____	<input type="checkbox"/> Allograft <input type="checkbox"/> Alloplast <input type="checkbox"/> Autogenous <input type="checkbox"/> Hybrid <input type="checkbox"/> Xenograft
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**B. PRODUCT INFORMATION:** One form should be used per event and/or patient. If more than, one device is associated with a single event being reported, multiple Item numbers may be included below. Additional rows may be added, or additional information included as necessary.

**NOTE:** 1) Please make sure product listed below has been properly decontaminated. 2) For non-Patient Specific Products, return only the complaint product. 3) For ZFX products please indicate Order number if possible:

Item Number* (if available, affix patient record label)	Lot / Serial Number*	Qty*	Replacement Requested	Tooth numbering System	Tooth #	Is Product Being Returned ?*	If No, Why?* (i.e. retained by the hospital, scrapped, etc.)
				<input type="checkbox"/> Universal <input type="checkbox"/> FDI <input type="checkbox"/> Palmer		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Discarded <input type="checkbox"/> Used <input type="checkbox"/> Remains Implanted <input type="checkbox"/> Other:
				<input type="checkbox"/> Universal <input type="checkbox"/> FDI <input type="checkbox"/> Palmer		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Discarded <input type="checkbox"/> Used <input type="checkbox"/> Remains Implanted <input type="checkbox"/> Other:
<b>Is destructive analysis permitted?*</b>			<input type="checkbox"/> Yes <input type="checkbox"/> No				

**C. REPORTER INFORMATION**

<b>Reporter Name*</b>	
<b>Date of Report*</b>	
<b>Is the person submitting this report</b>	<input type="checkbox"/> Clinician <input type="checkbox"/> Lab <input type="checkbox"/> Distributor <input type="checkbox"/> Other Health Professional <input type="checkbox"/> Sales Representative
<b>Account Name</b>	
<b>Account #*</b>	
<b>Address</b>	
<b>City, State, Zip, Country</b>	
<b>Contact Name*</b>	
<b>Phone #*</b>	
<b>E-mail*</b>	

**D. PATIENT INFORMATION**

<b>Patient Identifier*</b>	
<b>Gender*</b>	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Intersex <input type="checkbox"/> Transgender <input type="checkbox"/> Prefer not to disclose
<b>Age at the time of the event*</b>	
<b>Weight</b>	_____ <input type="checkbox"/> kg <input type="checkbox"/> lbs

With respect to patient personal data, should the customer include such data on the PER form, the customer guarantees to: (i) ensure and document properly the appropriate lawful basis for such a disclosure; (ii) inform the data subjects about this circumstance, including the provision of the ZimVie Privacy Policy (you may access by visiting: [www.zimvie.eu/en/privacy-notice.html](http://www.zimvie.eu/en/privacy-notice.html)); and (iii) share with us exclusively the information that is complete, accurate and strictly necessary to achieve our purposes of processing of this form. The customer will be the only one responsible in case of breach of said guarantees.

*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.*

**Instructions for returning complaint product:**

1. Complete the Product Experience Report (PER) editable PDF per event/patient, save and email to the appropriate ZimVie complaint handling contact email (see page 3). The complaint handling contact will reply with the complaint number (CE #(s)) and the product return instruction.
2. If a Serious Adverse Event related to Human Tissue occurs in the UK, the reporter has an obligation to notify Biomet3i UK, Ltd within 24 hours of event's discovery. Complaint Contact details are located on page 3 of this form.
3. Contaminated product shall be sterilized and identified as **STERILE**.
4. Return product labeled with the CE# in an appropriate shipping container along with a copy of this completed PER form to the addresses provided and/or indicated on page 3 of this form.
5. Used and/or contaminated regenerative product shall **not** be returned to the Zimmer Biomet complaint handling contact site.

**Complaint Handling Contacts:**

**International (APAC & Non-European):**

**US**

**Biomet 3i & Zimmer Dental**  
Attn: Complaints Handling  
4555 Riverside Drive  
Palm Beach Gardens, FL 33410  
**Phone:** 1.800.262.2702  
**Email:**  
[DentalComplaints@zimvie.com](mailto:DentalComplaints@zimvie.com)

**Canada**

**Biomet 3i & Zimmer Dental**  
ZimVie – Zimmer Biomet Dental Canada Inc.  
2345 Argenta Road Suite #106  
Mississauga, Ontario L5N 8K4  
**Email:** [DentalComplaints@zimvie.com](mailto:DentalComplaints@zimvie.com)

**International**

**Biomet 3i & Zimmer Dental**  
Attn: Complaints Handling  
4555 Riverside Drive  
Palm Beach Gardens, FL 33410  
**Phone:** 1.800.262.2702  
**Email:**  
[DentalInternationalComplaints@zimvie.com](mailto:DentalInternationalComplaints@zimvie.com)

**China**

**Zimmer Dental**  
Zimmer Dental (Shanghai) Medical Device Co Ltd  
Room 2001, Metro Plaza 555 Lou Shan Guan  
Road,  
Shanghai 200051 China  
**Phone:** 086 21 222 05180  
**Email:**  
[DentalInternationalComplaints@zimvie.com](mailto:DentalInternationalComplaints@zimvie.com)

**Chile**

**Zimmer Dental**  
Zimmer Dental Chile SPA  
Luis Thayer Ojeda 0130  
Oficina 901/902  
Providencia Santiago, Chile  
**Email:**  
[DentalInternationalComplaints@zimvie.com](mailto:DentalInternationalComplaints@zimvie.com)

**India**

**Biomet 3i & Zimmer Dental**  
ZB dental India Pvt. Ltd.  
Unit No. 904 & 905, A-Wing, Damji Shamji  
corporate Square,  
Off. Ghatkopar Andheri Link Road, Laxmi Nagar,  
Ghatkopar East,  
Mumbai, 400075, India.  
**Phone :** 18002669920 / + 91 022 6901 3700  
**Email:** [info.india@zimvie.com](mailto:info.india@zimvie.com)

**Australia:** **Phone:** +61 2 9855 4444

**Mexico:** **Phone:** +52 55 2282 0120

**Europe**

**Austria**

**Biomet 3i & Zimmer Dental**  
Zimvie Austria GmbH  
Wienerbergstrasse 11/12a  
1100 Wien, Austria  
**Phone:** +43 (0) 8000 700 17  
**Fax:** +43 (0) 8000 700 18  
**Email:**  
[EMEAComplaints@zimvie.com](mailto:EMEAComplaints@zimvie.com)

**Belgium and Luxembourg**

**Biomet 3i**  
Zimvie Belgium N.V  
For product return please contact customer  
service  
**Phone:** +32 80050311  
**Email:** [EMEAComplaints@zimvie.com](mailto:EMEAComplaints@zimvie.com)

**France and Luxembourg**

**Biomet 3i & Zimmer Dental**  
Zimvie France S.A.S.  
19 rue d'Arcueil  
94150 Rungis, France  
**Phone:** +33(0) 800 91 67 86  
**Email:** [EMEAComplaints@zimvie.com](mailto:EMEAComplaints@zimvie.com)

**Germany**

**Biomet 3i & Zimmer Dental**  
Zimvie Germany GmbH  
Kopernikusstraße 15,  
85221 Dachau, Germany  
**Phone:** +49 (0) 8131 27171 0  
**Fax:** +49 (0) 8131 27171 59  
**Email:** [EMEAComplaints@zimvie.com](mailto:EMEAComplaints@zimvie.com)

**Israel**

**Zimmer Dental**  
Zimmer Dental Ltd  
13 Haamal St.Afeq Industrial Park  
Building A, 3rd Floor,  
Rosh Haayin 4809280, Israel  
**Email:** [zvil-cs@zimvie.com](mailto:zvil-cs@zimvie.com)

**Italy**

**Zimmer Dental**  
Zimmer Dental Italy S.R.L  
Viale Italia 205/D  
31015 Conegliano (TV), Italy  
**Phone:** +39 0438 37681  
**Email:**  
[zimmerdental.italy@zimvie.com](mailto:zimmerdental.italy@zimvie.com)

**Netherlands**

**Biomet 3i**  
Zimvie Netherlands B.V Marten Meesweg 25-G  
3068 AV Rotterdam, Netherlands  
**Phone:** + 31 107 98 79 70  
**Email:** [EMEAComplaints@zimvie.com](mailto:EMEAComplaints@zimvie.com)

**Spain, Portugal and Republic of Ireland**

**Biomet 3i & Zimmer Dental**  
Biomet 3i Dental Ibérica, S.L.U  
and Zimvie Portugal Lda  
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  
**Republic of Ireland Phone:** +353 1800  
552752  
**Email:** [EMEAComplaints@zimvie.com](mailto:EMEAComplaints@zimvie.com)

**Switzerland**

**Biomet 3i & Zimmer Dental**  
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:** [EMEAComplaints@zimvie.com](mailto:EMEAComplaints@zimvie.com)

**Biomet 3i (Biomax)**

Biomax SPA  
Via Zamenhof, 615  
Vicenza, Italy  
**Phone:** +39 0444 913 410  
**Email:** [info@biomax.it](mailto:info@biomax.it)

**UK and Northern Ireland**

**Biomet 3i & Zimmer Dental**  
Biomet 3i UK, Ltd  
Reading Business Centre,  
Suite 807, 8th Floor Fountain House  
2 Queens Walk,  
Reading, Berks, RG1 7QF,  
United Kingdom  
**UK Phone:** +44 (0) 800 652 1233  
**Ireland Phone:** +353 1800 552752  
**Email:** [EMEAComplaints@zimvie.com](mailto:EMEAComplaints@zimvie.com)

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