

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 (*).

Document if a Complaint # has been previously assigned	CMP #: _____
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A. EVENT INFORMATION	Placement Date*: _____ (dd/mmm/yyyy)	Event Date*: _____ (dd/mmm/yyyy)	Removal Date*: _____ (dd/mmm/yyyy)
Discovered*: <input type="checkbox"/> During receiving / unpacking <input type="checkbox"/> During clinical procedure <input type="checkbox"/> During Laboratory Procedure <input type="checkbox"/> Other: _____			
Description of the Event (Check all that apply)*			
<input type="checkbox"/> Allergic Reaction		<input type="checkbox"/> Infection	
<input type="checkbox"/> Bone Loss		<input type="checkbox"/> Lack of Primary Stability	
<input type="checkbox"/> Fracture		<input type="checkbox"/> Loss of Integration (LI)	
		<input type="checkbox"/> Nerve Injury	
		<input type="checkbox"/> Non-Integration (NI)	
		<input type="checkbox"/> Other, please detail: _____	
Provide a detailed description of the reported problem (including procedure being performed, related products and settings used)*: _____ _____ _____ _____			
At the time of the event or implant failure/removal, was there ...? (Check all that apply)*:		<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: _____	
Was surgical and/or medical intervention necessary to preclude permanent impairment?*		<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please describe: _____	
Was there a delay during the procedure?*		<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, please describe: _____	
Was the procedure completed using another implant or another device?*		<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please describe: _____	
Other Relevant Patient History (Check all that apply)*:		<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: _____	
Tooth Number* _____ <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"/> Unknown		
Tooth Number* _____ <input type="checkbox"/> Universal <input type="checkbox"/> FDI <input type="checkbox"/> Palmer			
Additional Information:	<input type="checkbox"/> Grafted prior to implant placement <input type="checkbox"/> Site Grafted <input type="checkbox"/> Grafted together with implant placement 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

B.	C. 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.				
Item Number* (if available, affix patient record label)	Lot / Serial Number*	Qty.*	Replacement Requested	Is Product Being Returned?*	If No, Why?* (i.e. retained by the hospital, scrapped, etc.)
				<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"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Discarded <input type="checkbox"/> Used <input type="checkbox"/> Remains Implanted <input type="checkbox"/> Other: _____

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.

Is destructive analysis permitted?*	<input type="checkbox"/> Yes <input type="checkbox"/> No
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C. REPORTER INFORMATION	
Reporter Name*	
Date of Report*	
Is the person submitting this report a	<input type="checkbox"/> Clinician <input type="checkbox"/> Lab <input type="checkbox"/> Distributor <input type="checkbox"/> Sales Representative
Account Name	
Account #*	
Address	
City, State, Zip, Country	
Contact Name*	
Phone #*	
E-mail*	

D. PATIENT INFORMATION	
Patient Identifier*	
Gender*	<input type="checkbox"/> Male <input type="checkbox"/> Female
Age at the time of the event*	

Instructions for returning complaint product:

1. Contaminated product shall be Sterilized and identified as STERILE.
2. Please return product in an appropriate package along with this completed form to the addresses listed in the next page.
3. 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):	
<u>US</u> Biomet 3i & Zimmer Dental Email: DomesticComplaints@zimmerbiomet.com Attn: Complaints Handling 4555 Riverside Drive Palm Beach Gardens, FL 33410 Phone: 1.800.443.8166	<u>Canada</u> Biomet 3i & Zimmer Dental Email: DomesticComplaints@zimmerbiomet.com Zimmer Dental Corp. 2323 Argentia Road Mississauga, Ontario L5N 5N3 Phone: 514-956-9843	<u>Biomet 3i</u> Email: 3IPBG-IntComplaint@zimmerbiomet.com Biomet 3i Attn: Complaints Handling 4555 Riverside Drive Palm Beach Gardens, FL 33410 Phone: 561.776.6918	<u>China</u> Zimmer Dental Email: 3IPBG-IntComplaint@zimmerbiomet.com Zimmer Dental (Shanghai) Medical Device Co Ltd Room 2001, Metro Plaza 555 Lou Shan Guan Road, Shanghai 200051 China Phone: 086 21 222 05180
<u>Australia:</u> Phone: +61 2 9855 4444 <u>Mexico:</u> Phone: +52 55 2282 0120	<u>Chile</u> Zimmer Dental Email: 3IPBG-IntComplaint@zimmerbiomet.com Zimmer Dental Chile SPA Luis Thayer Ojeda 0130 Oficina 901/902 Providencia Santiago, Chile	<u>India</u> Biomet 3i & Zimmer Dental Email: CustomerCare.IndiaDental@zimmerbiomet.com 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	
Europe			
Non- Patient Specific Product			
<u>Austria:</u> 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	<u>Belgium and Luxembourg:</u> Biomet 3i Biomet 3i TAV: Dental Division Meyskensstraat 224 1780 Wemmel, Belgium Phone: +32 80050311 Email: 3iEUComplaints@zimmerbiomet.com	<u>France and Luxembourg:</u> Biomet 3i & Zimmer Dental Zimmer Dental S.A.S. 19 rue d'Arcueil 94150 Rungis, France Phone: +33(0) 800 91 67 86 Email: 3iEUComplaints@zimmerbiomet.com	<u>Germany:</u> 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
<u>Israel</u> Zimmer Dental Zimmer Dental Ltd 13 Amal St. Rosh Haa'yin Building A, 3rd Floor Ramat Gan 52523, Israel	<u>Italy</u> Zimmer Dental Zimmer Dental Italy srl Viale Italia 205/D 31015 Conegliano (TV), Italy Phone: +39 0438 37681 Email: zimmerdental.italy@zimmerbiomet.com	<u>Netherlands:</u> Biomet 3i Biomet 3i Netherlands TAV: Customer Service Toermalijnring 600 3316 LC Dordrecht, Netherlands Phone: +31 078 62 92 800 Email: 3iEUComplaints@zimmerbiomet.com	<u>Spain and Portugal:</u> Biomet 3i and Zimmer Dental Email: 3iEUComplaints@zimmerbiomet.com Biomet 3i Dental Ibérica, S.L.U 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
<u>Switzerland:</u> 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	<u>Biomet 3i (Biomax)</u> BIOMAX SPA Via Zamenhof, 615 Vicenza, Italy Tel: +39 0444 913 410 Email: info@biomax.it	<u>UK and Ireland:</u> Biomet 3i Biomet 3i UK, Ltd Reading Business Centre, Suite 807, 8th Floor Fountain House 2 Queens Walk, Reading, Berks, RG1 7QF, United Kingdom Email: 3iEUComplaints@zimmerbiomet.com UK: Phone: + 44 (0) 800 652 1233 Ireland: Phone: +353 1800 552752	
Patient Specific Product			
Biomet 3i Dental Ibérica BellaTek Dept. Islas Baleares 50, Polígono Fuente del Jarro 46988 Valencia Spain Tel.: +34 961379536 / 38 Fax: +34 961379505 Email: es.3ipsp@biomet.com			

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