ZIMMER BIOMET

For Zimmer Biomet Use Only Not to be Completed by the Reporter	CMP#:

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 #: _____

A. EVENT INFORMATION	***Placement Date**:* _____ (dd/mmm/yyyy)	***Event Date**:* _____ (dd/mmm/yyyy)	***Removal Date**:* _____ (dd/mmm/yyyy)

***Discovered**:* ☐ During receiving / unpacking ☐ During clinical procedure ☐ During Laboratory Procedure ☐ Other:_____

Description of the Event (Check all that apply)*

☐ Allergic Reaction	☐ Infection	☐ Nerve Injury	☐ Peri-implantitis
☐ Bone Loss	☐ Lack of Primary Stability	☐ Non-Integration (NI)	☐ Sinus Perforation
☐ Fracture	☐ Loss of Integration (LI)	☐ 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) *:	☐ No Patient Impact			
	☐ Abscess ☐ Aspiration	☐ Ingestion ☐ Paresthesia	☐ Pain ☐ Edema	☐ Inflammation ☐ Other: _____
Was surgical and/or medical intervention necessary to preclude permanent impairment?*	☐ Yes ☐ No If Yes, please describe:			
Was there a delay during the procedure?*	☐ Yes ☐ No If Yes, please describe:			
Will the patient have to return for an additional dental appointment to complete the procedure?*	☐ Yes ☐ No If Yes, please describe:			
Was the procedure completed using another implant or another device?*	☐ Yes ☐ No If Yes, please describe:			
Other Relevant Patient History (Check all that apply)*:	☐ Bruxism ☐ Clenching	☐ Diabetes ☐ Osteoporosis	☐ Smoker / Tobacco use ☐ Inadequate Oral Hygiene	
	☐ Other: _____			

Tooth Number*	_____ ☐ Universal ☐ FDI ☐ Palmer	***Bone Density Type****	☐ I ☐ II ☐ III ☐ IV ☐ Unknown
Tooth Number*	_____ ☐ Universal ☐ FDI ☐ Palmer		

Additional Information:	☐ Grafted prior to implant placement ☐ Grafted together with implant placement	☐ Site Grafted If Yes, Describe Material Graft placement date: _____	☐ Allograft ☐ Alloplast ☐ Autogenous ☐ Hybrid ☐ Xenograft

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.

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.)
				☐ Yes ☐ No	☐ Discarded ☐ Used ☐ Remains Implanted ☐ Other:
				☐ Yes ☐ No	☐ Discarded ☐ Used ☐ Remains Implanted ☐ Other:

Is destructive analysis permitted?*		☐ Yes ☐ No

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.

C. REPORTER INFORMATION	
Reporter Name*	
Date of Report*	
Is the person submitting this report a	☐ Clinician ☐ Lab ☐ Distributor ☐ Sales Representative
Account Name	
Account #*	
Address	
City, State, Zip, Country	
Contact Name*	
Phone #*	
E-mail*	

D. PATIENT INFORMATION	
Patient Identifier*	
Gender*	☐ Male ☐ 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.
4. If a Serious Adverse Event related to Human Tissue occurs in the UK, the customer 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.

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ZIMMER BIOMET

Complaint Handling Contacts:

International (APAC & Non-European):

US
Biomet 3i & Zimmer Dental
Email:
DomesticComplaints@zimmerbiomet.com

Attn: Complaints Handling
4555 Riverside Drive
Palm Beach Gardens, FL 33410
Phone: 1.800.262.2702

Canada
Biomet 3i & Zimmer Dental
Email:
DomesticComplaints@zimmerbiomet.com

Zimmer Dental Corp.
2323 Argentia Road
Mississauga, Ontario L5N 5N3
Phone: 514-956-9843

Chile
Zimmer Dental
Email:
3IPBG-IntComplaint@zimmerbiomet.com

Zimmer Dental Chile SPA
Luis Thayer Ojeda 0130
Oficina 901/902
Providencia Santiago, Chile

Biomet 3i & Zimmer Dental
Email:
3IPBG-IntComplaint@zimmerbiomet.com

Biomet 3i & Zimmer Dental
Attn: Complaints Handling
4555 Riverside Drive
Palm Beach Gardens, FL 33410
Phone: 561.776.6918

India
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

China
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

Australia: ***Phone:*** +61 2 9855 4444
Mexico: ***Phone***: +52 55 2282 0120

Europe

Non- Patient Specific Product

Austria:
Zimmer Biomet Austria GmbH
Wienerbergstrasse 11/12a
1100 Wien, Austria
Phone: +43 (0) 8000 700 17
Fax: +43 (0) 8000 700 18
Email:
3iEUComplaints@zimmerbiomet.com

Belgium and Luxembourg:
Biomet 3i
Biomet 3i Belgium
Building MC Square
Schaliënhoevedreef 20T
2800 Mechelen, Belgium
Phone: +32 80050311
Email:
3iEUComplaints@zimmerbiomet.com

France and Luxembourg:
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

Germany:
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

Israel
Zimmer Dental
Zimmer Dental Ltd
13 Amal St. Rosh Haa'yin
Building A, 3rd Floor
Ramat Gan 52523, Israel

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

Italy
Zimmer Dental
Zimmer Dental Italy srl
Viale Italia 205/D
31015 Conegliano (TV), Italy
Phone: +39 0438 37681
Email:
zimmerdental.italy@zimmerbiomet.com

Biomet 3i (Biomax)
BIOMAX SPA
Via Zamenhof, 615
Vicenza, Italy
Tel: +39 0444 913 410
Email: info@biomax.it

Netherlands:
Biomet 3i
Biomet 3i Netherlands
Marten Meesweg 25-G
3068 AV Rotterdam, Netherlands
Phone: +31 078 62 92 800
Email: 3iEUComplaints@zimmerbiomet.com

UK and Ireland:
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

Spain and Portugal:
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

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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