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

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	CE #: _____

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)*

☐ Abutment / Bar Fit	☐ Allergic Reaction	☐ Bone loss	☐ Bent
☐ Damaged Hex	☐ Damaged Threads	☐ Does not assemble	☐ Does not disengage / release (Stuck)
☐ Fracture (Broken)	☐ Infection	☐ Lack of Primary Stability	☐ Loosening
☐ Loss of Integration (LI)	☐ Nerve Injury	☐ Non-Integration (NI)	☐ Packaging
☐ Peri-implantitis	☐ Shipping Damage	☐ Sinus Perforation	☐ 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: _____			
Bone Density Type*	☐ I ☐ II ☐ III ☐ IV ☐ 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.

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. 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.)
				☐ ***Universal*** ☐ ***FDI*** ☐ ***Palmer***		☐ Yes ☐ No	☐ Discarded ☐ Used ☐ Remains Implanted ☐ Other:
				☐ ***Universal*** ☐ ***FDI*** ☐ ***Palmer***		☐ Yes ☐ No	☐ Discarded ☐ Used ☐ Remains Implanted ☐ Other:
Is destructive analysis permitted?*	☐ Yes ☐ No						

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

D. PATIENT INFORMATION	
Patient Identifier*	
Gender*	☐ Male ☐ Female ☐ Intersex ☐ Transgender ☐ Prefer not to disclose
Age at the time of the event*	
Weight	_____ ☐ kg ☐ 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); 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.

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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

Canada
Biomet 3i & Zimmer Dental
ZimVie – Zimmer Biomet Dental Canada Inc.
2345 Argentia Road Suite #106
Mississauga, Ontario L5N 8K4
Email: DentalComplaints@zimvie.com

Chile
Zimmer Dental
Zimmer Dental Chile SPA
Luis Thayer Ojeda 0130
Oficina 901/902
Providencia Santiago, Chile
Email:
DentalInternationalComplaints@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

India
Biomet 3i & Zimmer Dental
ZimVie India Private Limited
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

China
Zimmer Dental
ZimVie (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

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

Belgium and Luxembourg
Biomet 3i
Zimvie Belgium N.V
For product return please contact customer service
Phone: +32 80050311
Email: 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

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

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

Switzerland
Biomet 3i & Zimmer Dental
ZimVie Switzerland 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

Italy
Zimmer Dental
ZimVie Italy srlViale Italia 205/D
31015 Conegliano (TV), Italy
Phone: +39 0438 37681
Email:
zimvie.italy@zimvie.com

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

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

UK and Northern Ireland
Biomet 3i & Zimmer Dental
ZimVie UK LtdReading 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

Spain, Portugal and Republic of Ireland
Biomet 3i & Zimmer Dental
ZimVie Spain 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

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