For contact information, please refer to the last page of this document. Please provide the form to the appropriate contact site within 2 business days of the event.
You will be contacted if information is missing, unclear, or insufficient.

A. REPORTER INFORMATION:

Reporter Name: ***Distributorship Name:***	***Reporter Address:***
Reporter Email Address:	***Phone:***
If Additional information is needed about this reported event, follow-up questions will be sent to the reporter. If questions should be directed to someone else, please provide information below (Reporter is the person filling out this form).	
Additional Contact Name:	***Additional Contact Address:***
Additional Contact Email Address:	***Additional Contact Phone:***

B. EVENT INFORMATION

Has the FDA or another government agency been notified of this event? ☐ Yes ☐ No ☐ Unknown	
Notification Date *(i.e. date when ZimVie becomes aware of event):*	
Date when event occurred:	***Country in which event occurred:***
For implant: ***date implanted*:**	For explant: ***date removed*:**
Describe alleged event in detail (Include information on the impact to the patient or user and/or malfunction, if known):	
Did the event occur during a surgery? If the event did not occur during surgery explain when the event occurred? *(Explain if the event occurred prior to surgery, outside of operation room, with the distributor or site etc.)*	☐ Yes ☐ No ☐ Unk
List any device(s) that were used to complete the procedure: ***(If additional ZimVie product was used please include part number/lot numbers, if applicable)***	
Was this an Initial or Revision Surgery/Procedure?	☐ Initial ☐ Revision
If this is a revision surgery:	Reason for revision surgery: Was fusion present at the initial level? Was the patient involved in a fall, accident, or similar type of event?

C. PRODUCT INFORMATION (Product Identified in Event)

Qty	***Item Number***	***Lot/Serial#***	***UDI Unique Device Identification (if applicable)***	***Item Description/Brand Name***	***Will Product be returned for Evaluation?***
					☐ Yes ☐ No ☐ Unk

					☐ Yes ☐ No ☐ Unk
					☐ Yes ☐ No ☐ Unk
					☐ Yes ☐ No ☐ Unk
					☐ Yes ☐ No ☐ Unk

If the product cannot be returned, please provide explanation ☐ Discarded ☐ Not released by hospital ☐ Other reason:

****If this event has product involved that can be returned, DO NOT discard or place back in kit. Please return to ZimVie Spine for investigation per instructions on the last page of this document.***

Has product been cleaned and/or disinfected? ☐ Yes ☐ No ☐ Unk

If yes, method of disinfecting: ☐ Autoclave ☐ Alcohol ☐ Other:

Tracking number (if known):

D. HOSPITAL/COMPLAINANT INFORMATION

Did the complainant request a response? ☐ Yes ☐ No

Hospital/Clinic Name:	***Surgeon Name:***
ADDRESS SECTION: ☐ Hospital/Clinical ☐ Physician ☐ Patient ☐ Other:	
Address:	
City:	***State:*** ***Zip Code:***
Country:	***Phone:***
Email Address:	

E. PATIENT INVOLVEMENT:

Was there patient involvement? *(If no skip Patient Information Section)* ☐ Yes ☐ No

If YES, there was patient involvement, please include the following documents:

X-rays, Surgery or Revision records, Pictures and other detailed documents of patient involved surgery/procedure.

If no documents are available, provide rationale:

PATIENT INFORMATION

Patient Name or Initials: _____
First *Last*

☐ Not allowed by country regulations

Date of Birth: _____ ***Age at Time of Event:*** _____	☐ Male ☐ Female ☐ Other:
Weight: ☐ Pounds ☐ Kilograms	***Height:*** ☐ Inches ☐ Centimeters

1. ***Was there a death or impact to patient?*** ☐ Death ☐ Injury ***If Yes, Clearly Describe:***	☐ Yes ☐ No ☐ Unk
2. ***Was there additional medical intervention?*** (e.g. revision surgery, additional treatment, prescription drugs provided, additional appointments to see a medical professional, etc.) ***If Yes, Clearly Describe:***	☐ Yes ☐ No ☐ Unk
3. ***Was this medical intervention for correction of an infection that occurred within one (1) year post operatively?*** ***If Yes, Clearly Describe:***	☐ Yes ☐ No ☐ Unk
4. ***Did the event cause a delay to the procedure?*** ***If Yes, add Delay in Minutes:*** ***If Yes, Clearly Describe Reason for Delay:***	☐ Yes ☐ No ☐ Unk
5. ***Were there any contributing conditions related to the event?*** (e.g. trauma, illness, previous surgery, related non-compliance, patient anatomy, infection, etc.) ***If Yes, Clearly Describe:***	☐ Yes ☐ No ☐ Unk

Instructions for returning complaint product:

Explants

The handling of explants should be performed as described below in order to not destroy any potential evidence and to protect the personnel handling these explanted products:

1. Rinse implant directly after removal under tap water and dry it.
2. Protect implant by wrapping in i.e. lint-free tissues, cushioning foil etc.
3. Pack each part separately and label it with the respective complaint number, if available.
4. If larger part of bone or tissue is attached to the implant then it should be stored in 4% formalin solution in a leak proof container i.e. analysis bottle, and labeled.
5. Put all parts belonging to one case in one labeled bag / transport box with identification. Enclose any relevant documentation which cannot be transmitted electronically.
6. Send to the respective site indicated below.

Instruments

The handling of these instruments should be performed as described below in order to not destroy any potential evidence and to protect the personnel handling these products:

1. Instruments need to be decontaminated and/or sterilized.
2. Pack each instrument separately and label with complaint number, if available. Sharp components, i.e. drills etc. must be protected.
3. Send to the respective site indicated below.

NOTE: Used and/or contaminated regenerative product shall not be returned to the ZimVie contact site.

Austria:
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
Biomet 3i Belgium
Building MC Square
Schaliënhoevedreef 20T
2800 Mechelen, Belgium
Phone: +32 80050311
Email: emeacomplaints@zimvie.com

France :
LDR Medical
Quartier Europe de l'Ouest
5, rue de Berlin
Sainte-Savine 10300
France
Phone: +33 3 25 82 32 63
Email: emeacomplaints@zimvie.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: emeacomplaints@zimvie.com

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: emeacomplaints@zimvie.com

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Email: emeacomplaints@zimvie.com

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

Spain and Portugal:
Biomet 3i and Zimmer Dental
Email: emeacomplaints@zimvie.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

UK and Ireland:
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Email: emeacomplaints@zimvie.com