December 15, 2017

To: Surgeons/ Hospitals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (Removal)**

Reference: **FA 2017-05 (ZFA2017-404)**

Affected Product: REVITAN® MODULAR RASP DISTAL CURVED

Item Number	Product Name
01.00409.612	MOD RASP DISTAL CURVED 14/140
01.00409.613	MOD RASP DISTAL CURVED 16/140
01.00409.614	MOD RASP DISTAL CURVED 18/140
01.00409.615	MOD RASP DISTAL CURVED 20/140
01.00409.616	MOD RASP DISTAL CURVED 22/140
01.00409.617	REVIT RASP DISTAL CURVE 24/140
01.00409.622	MOD RASP DISTAL CURVED 14/200
01.00409.623	MOD RASP DISTAL CURVED 16/200
01.00409.624	MOD RASP DISTAL CURVED 18/200
01.00409.625	MOD RASP DISTAL CURVED 20/200
01.00409.626	MOD RASP DISTAL CURVED 22/200
01.00409.627	MOD RASP DISTAL CURVED 24/200
01.00409.628	REVIT RASP DISTAL CURVE 26/200
01.00409.629	REVIT RASP DISTAL CURVE 28/200
01.00409.633	MOD RASP DISTAL CURVED 16/260
01.00409.634	MOD RASP DISTAL CURVED 18/260
01.00409.635	MOD RASP DISTAL CURVED 20/260
01.00409.636	MOD RASP DISTAL CURVED 22/260
01.00409.637	MOD RASP DISTAL CURVED 24/260
01.00409.638	REVITAN RASP DSTL CURV 26/260
01.00409.639	REVITAN RASP DSTL CURV 28/260

Table 1: Affected products

Picture 1: Revitan Rasp

Zimmer GmbH is conducting as a precautionary measure a voluntary medical device “phased” Field Safety Corrective Action (removal) involving certain Revitan Rasp instruments, which were manufactured by a specific vendor in the time period between 2002 and 2008. (Please see attachment 2 for the list of affected lots).

The current issue deals with potential breakage of the instrument intra-operatively after an extensive use over time. There is a potential risk for breakage of the rasps during the surgery as indicated in the chart hereafter. The cause for the reported breakage can be multifactorial.

Trending of complaint data showed that the fracture rate for these lots are found to be higher (0.54%) than the fracture rate for the Revitan rasp instruments manufactured by a different vendor (0.038%).

Zimmer Biomet would like to emphasize the importance of adhering to the applicable surgical technique, Instruction for Use (IFU) and Orthopaedic Reusable Device Instructions.

As per the applicable surgical technique *06.01169.012 - Revitan Curved Revision Hip System*, the preparation of the implant bed can be achieved by the use of medullary canal reamers, followed by rasp preparation or exclusively rasp preparation. In both techniques, progressive rasping is recommended, starting with either the smallest rasp size and progressively increasing in size or starting at least two sizes smaller than the medullary canal or prosthesis size as measured during preoperative planning. It should also be ensured that no cement residue or osseous obstacles obstruct the free movement of the rasps.

As per the applicable IFU (D011500192 (2015-12_87-6204-050-23)):

- Do not use cutting/sharp instruments with dull or deformed edges or instruments/provisionals that are deformed, corroded, damaged or worn. They may not perform as intended.

Precautions

- Inspect all instruments/ provisionals carefully prior to use
- Rasps – A rasp must advance each time it is struck with a mallet. There is a higher risk of bone fracture or rasp impaction when it does not advance or if the rasp is dull.

As per the applicable Orthopaedic Reusable Devices Instructions for Care, Cleaning, Maintenance and Sterilization (97-5000-170-00 Rev. 6);

Inspection, Maintenance, Testing and Lubrication

- Visually inspect for completeness, damage and/or excessive wear.

Note: If damage or wear is noted that may compromise the function of the instrument, contact your Zimmer Representative for a replacement.

In case of any breakage intra-operatively, the following risks have been identified and evaluated:

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Worst Case*
	Coupling part of the curved rasps breaks, the rasp body remains stuck within the femur as the remaining bolt cannot be connected to a handle anymore. Additional medical surgical intervention outside of planned procedures is necessary. The remaining rasps can be removed from the femur and the surgery can be continued with a bigger size of the rasps. Extended surgery time less than 60min.	Coupling part of the curved rasps breaks, the rasp body remains stuck within the femur as the remaining bolt cannot be connected to a handle anymore. Additional medical surgical intervention outside of planned procedures is necessary. The remaining rasps cannot be easily removed from the femur and the broken rasps needs to strike out via a distal window in the femur. This could also lead to a breakage of the femur itself. Extended surgery time more than 60min.
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Worst Case*
	A distal window in the femur was necessary to remove the broken rasp which could lead to pain and resulting in an insufficient connection between the implant and the femur of the patient.	Insufficient connection between the implant and the femur of the patient due to the additional medical surgical intervention outside of planned procedures during surgery could lead to a revision surgery.

Our records indicate you may have received one or more of the affected instruments.

Surgeon/ Hospital Responsibilities:

1. Review this notification for awareness of the contents.
2. Assist your Zimmer Biomet sales representative to locate affected instruments.
3. Your Zimmer Biomet sales representative will schedule with you the swapping of the affected instruments from your facility.
4. There are no specific patient monitoring instructions related to this Field Safety Corrective Action beyond your existing follow up schedule. . As a manufacturer of medical devices Zimmer Biomet is not licensed to practice medicine. It is up to healthcare professionals to assess the risk and to decide on any patient monitoring,
5. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy to fieldaction.emea@zimmerbiomet.com.
    b. Retain a copy of the Certificate of Acknowledgement with your field action records in the event of a compliance audit of your documentation.
6. If after reviewing the notice you have further questions or concerns please contact your Zimmer Biomet representative.

Other Information

This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@zimmerbiomet.com or to your local Zimmer Biomet contact.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this field action.

Sincerely,

_____

Matthias Bürger

Zimmer Biomet Vice President QARA EMEA

ATTACHMENT 1
Certificate of Acknowledgement FA2017-05 (ZFA2017-404)

By signing below, I acknowledge that the required actions have been taken in accordance with the Recall Notice.

[ ] **Hospital Facility** [ ] **Surgeon** (Please check one as applicable)

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** ( ) ____-_____ **Date:**____/____/____

Facility Name: _____

Facility Address: _____

City:_____ **ZIP:**_____ **Country:**_____

Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to: fieldaction.emea@zimmerbiometcom.

Product Reference	Lot Reference	Number of products identified	Number of products to replace

ZIMMER BIOMET

Attachment 2: Scope of affected instruments

Item Number	Lot Number	Item Number	Lot Number
01.00409.612	06252212	01.00409.625	05.144479
01.00409.612	05.183284	01.00409.625	04.131144
01.00409.612	05.179192	01.00409.625	04.126290
01.00409.612	05.144479	01.00409.625	04.115639
01.00409.612	04.131144	01.00409.625	04.108358
01.00409.612	04.126290	01.00409.625	03.096551
01.00409.612	04.115639	01.00409.625	03.086042
01.00409.612	04.108358	01.00409.625	03.080100
01.00409.612	03.096551	01.00409.625	02.059994
01.00409.612	03.086042	01.00409.625	02.029994
01.00409.612	03.080100	01.00409.625	02.059989
01.00409.612	02.059994	01.00409.626	05.183284
01.00409.612	02.059989	01.00409.626	05.179192
01.00409.613	05.183284	01.00409.626	05.177483
01.00409.613	05.176050	01.00409.626	05.144479
01.00409.613	05.179192	01.00409.626	04.131144
01.00409.613	05.144479	01.00409.626	04.126290
01.00409.613	04.131144	01.00409.626	04.115639
01.00409.613	04.126290	01.00409.626	04.108358
01.00409.613	04.115639	01.00409.626	03.096551
01.00409.613	04.108358	01.00409.626	03.086042
01.00409.613	03.096551	01.00409.626	03.080100
01.00409.613	03.086042	01.00409.626	02.059994
01.00409.613	03.080100	01.00409.626	02.059989
01.00409.613	02.059994	01.00409.627	05.179192
01.00409.613	02.059989	01.00409.627	05.183284
01.00409.614	06252212	01.00409.627	05.177483
01.00409.614	05.183284	01.00409.627	05.144479
01.00409.614	05.179192	01.00409.627	04.131144
01.00409.614	05.144479	01.00409.627	04.126290
01.00409.614	04.131144	01.00409.627	04.115639
01.00409.614	04.126290	01.00409.627	04.108358
01.00409.614	04.115639	01.00409.627	03.096551
01.00409.614	04.108358	01.00409.627	03.086042
01.00409.614	04.103296	01.00409.627	03.080100
01.00409.614	03.096551	01.00409.627	02.059994
01.00409.614	03.086042	01.00409.627	02.059989

Item Number	Lot Number	Item Number	Lot Number
01.00409.614	03.080100	01.00409.628	04.126290
01.00409.614	02.059994	01.00409.628	04.103296
01.00409.614	02.059989	01.00409.629	04.126290
01.00409.615	06244962	01.00409.629	04.103296
01.00409.615	05.183284	01.00409.633	05.183287
01.00409.615	05.179192	01.00409.633	05.179192
01.00409.615	05.144479	01.00409.633	05.144479
01.00409.615	04.131144	01.00409.633	04.131144
01.00409.615	04.126290	01.00409.633	04.126290
01.00409.615	04.115639	01.00409.633	04.115639
01.00409.615	04.108358	01.00409.633	04.108358
01.00409.615	03.096551	01.00409.633	04.105808
01.00409.615	03.086042	01.00409.633	03.096551
01.00409.615	03.080100	01.00409.633	03.086042
01.00409.615	02.059994	01.00409.633	03.080100
01.00409.615	02.059989	01.00409.633	02.059994
01.00409.616	06250007	01.00409.633	02.059989
01.00409.616	05.183284	01.00409.634	06.255334
01.00409.616	05.179192	01.00409.634	06255334
01.00409.616	05.144479	01.00409.634	05.183287
01.00409.616	04.131144	01.00409.634	05.179192
01.00409.616	04.126290	01.00409.634	05.144479
01.00409.616	04.115639	01.00409.634	04.131144
01.00409.616	04.108358	01.00409.634	04.126290
01.00409.616	03.096551	01.00409.634	04.115639
01.00409.616	03.086042	01.00409.634	04.108358
01.00409.616	03.080100	01.00409.634	03.096551
01.00409.616	02.059994	01.00409.634	03.086042
01.00409.616	02.059989	01.00409.634	03.080100
01.00409.617	07299883	01.00409.634	02.059994
01.00409.617	04.126290	01.00409.634	02.059989
01.00409.617	04.103296	01.00409.635	06.250007
01.00409.622	06226062	01.00409.635	06250007
01.00409.622	05.183284	01.00409.635	05.183287
01.00409.622	05.179192	01.00409.635	05.179192
01.00409.622	05.144479	01.00409.635	05.144479
01.00409.622	04.131144	01.00409.635	04.131144
01.00409.622	04.126290	01.00409.635	04.126290
01.00409.622	04.115639	01.00409.635	04.115639
01.00409.622	04.108358	01.00409.635	04.105808

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Item Number	Lot Number	Item Number	Lot Number
01.00409.622	03.096551	01.00409.635	04.108358
01.00409.622	03.086042	01.00409.635	03.096551
01.00409.622	03.080100	01.00409.635	03.086042
01.00409.622	02.059994	01.00409.635	03.080100
01.00409.622	02.059989	01.00409.635	02.059994
01.00409.623	06250007	01.00409.635	02.059989
01.00409.623	05.183284	01.00409.636	06.255334
01.00409.623	05.179192	01.00409.636	06255334
01.00409.623	05.144479	01.00409.636	05.183287
01.00409.623	04.131144	01.00409.636	05.179192
01.00409.623	04.126290	01.00409.636	05.144479
01.00409.623	04.115639	01.00409.636	04.131144
01.00409.623	04.108358	01.00409.636	04.126290
01.00409.623	04.105808	01.00409.636	04.115639
01.00409.623	03.096551	01.00409.636	04.108358
01.00409.623	03.086042	01.00409.636	03.096551
01.00409.623	03.080100	01.00409.636	03.086042
01.00409.623	02.059994	01.00409.636	03.080100
01.00409.623	02.059989	01.00409.636	02.059994
01.00409.624	06.250007	01.00409.636	02.059989
01.00409.624	06250007	01.00409.637	07265997
01.00409.624	05.183284	01.00409.637	05.183287
01.00409.624	05.179192	01.00409.637	05.179192
01.00409.624	05.144479	01.00409.637	05.144479
01.00409.624	04.149104	01.00409.637	04.149104
01.00409.624	04.131144	01.00409.637	04.131144
01.00409.624	04.126290	01.00409.637	04.126290
01.00409.624	04.115639	01.00409.637	04.115639
01.00409.624	04.108358	01.00409.637	04.108358
01.00409.624	04.105808	01.00409.637	03.096551
01.00409.624	03.096551	01.00409.637	03.086042
01.00409.624	03.086042	01.00409.637	03.080100
01.00409.624	03.080100	01.00409.637	02.059994
01.00409.624	02.059994	01.00409.637	02.059989
01.00409.624	02.059989	01.00409.638	04.126290
01.00409.625	06255334	01.00409.638	04.103296
01.00409.625	05.183284	01.00409.639	04.126290
01.00409.625	05.172716	01.00409.639	04.103296
01.00409.625	05.179192	-	-