October 1, 2018

To: Surgeons/ Hospitals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE – REMOVAL**

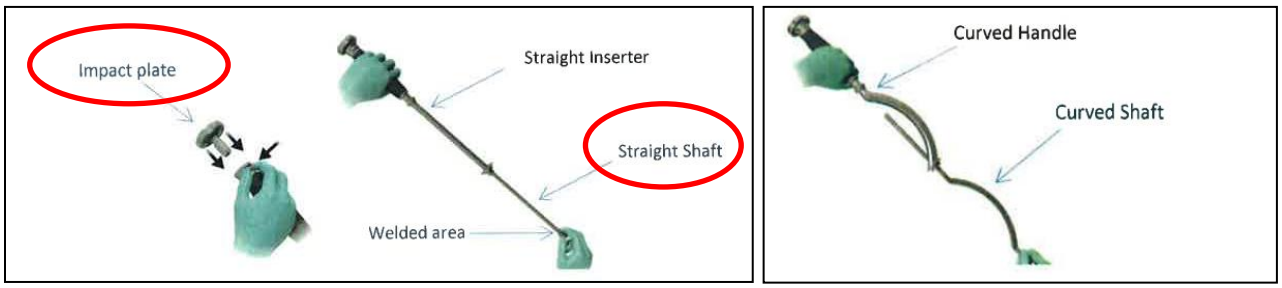
Reference: **ZFA2018-00369 & ZFA2018-00374**

The above two Field Safety Correction Actions (FSCA) are combined in one Field Safety Notice (FSN), because they both involve the Avantage Acetabular Shell Inserter Instrument for hip. This instrument consists of various parts (see picture 1). Two parts of the instrument have to be removed and the removal is intended to be conducted at the same time.

Item Number	Part Description	FSCA Reference
110027769	Avantage THRD Shaft Straight	ZFA2018-00369 (Part 1 of the letter)
110028874	Avantage Straight Impact Plate	ZFA2018-00374 (Part 2 of the letter)

Please note that the following parts are **not** affected by these two FSCAs (Field Safety Corrective Actions):

Item Number	Part Description
110031337	Avantage Curved Handle
110031338	Avantage Curved Shaft
110031174	Avantage Straight Inserter



Picture 1: View of the complete Avantage instrument configuration

Part 1- ZFA2018-00369

Affected Parts: Avantage Threaded Shaft Straight

Reference #	Description	Batch #
110027769	AVANTAGE THRD SHAFT STRAIGHT	120200
		120210
		129360
		129480
		178580
		359140
		375280
		437700
		513450
		596980
		725740
		950970
		ZBCRUK1610

Affected Parts

As a precautionary measure Biomet France SARL is conducting a medical device Field Safety Corrective Action (removal) for one specific part of the Avantage Acetabular Shell Inserter. This specific removal deals with the Avantage Thread Shaft Straight part with reference 110027769 (see picture 1 for the instrument configuration) and for the batch numbers as listed above. The removal is due to a potential dissociation of the welded part (see picture 2). No adverse events have been reported to date for this issue.

Picture 2: View of the issue with the straight shaft

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Highest Severity
	Extension of surgical time less than 30 minutes to get alternative instrument.	Extension of surgical time more than 30 minutes in order to retrieve the block in the patient.
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Highest Severity
	None	Potential consequences due to prolongation of the anaesthesia time.

Our records indicate that you may have received one or more of the affected parts. The affected parts were distributed between April 2016 and April 2018 (local deployment dates might defer).

Surgeons/ Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected parts at your facility, assist your Zimmer Biomet sales representative and quarantine all affected parts. Your Zimmer Biomet sales representative will remove the affected parts from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.emea@zimmerbiomet.com. This form must be returned even if you do not have affected parts at your facility.
4. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet representative.

Part 2- ZFA2018-00374

Affected Parts: Avantage Impact Plate

Reference #	Description	Batch #
110028874	AVANTAGE IMPACT PLATE	129690
		181350
		181360
		191750
		191760
		466310
		722190
		860580
		874100

Affected parts

Biomet France SARL is conducting a medical device Field Safety Corrective Action (removal) for one specific part of the Avantage Acetabular Shell Inserter. This specific removal deals with the Avantage Impact plate with reference 110028874 (see picture 1 for the instrument configuration) and for the batch numbers as listed above. The removal is due to the fact that the Avantage Impact Plate may get stuck in the Avantage Curved Handle (with reference 110031337) or in the Straight Inserter (with reference 110031174) due to the material of the Impact Plate. The issue might be detectable prior use during the functional testing conducted during the maintenance of the complete instrument No adverse events have been reported to date for this issue.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Highest Severity
	None (Issue discovered prior surgery).	The instrument is stuck in the implant. Short movements are needed to release instrument. If the positioning of the shaft is questioned, alternate instrument is needed. In case of bone damage, new implant is needed. > 30 min surgical time extension.
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Highest Severity
	None	The primary anchoring of the implant is damaged during the removal of the blocked instrument and this can lead to early loosening of the implant.

Our records indicate that you may have received one or more of the affected parts. The affected parts were distributed between March 2016 and April 2018(local deployment dates might defer).

Surgeons/ Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected parts at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected parts from your facility.
3. Complete **Attachment 2 – Certificate of Acknowledgement** and send to fieldaction.emea@zimmerbiomet.com. This form must be returned even if you do not have affected parts at your facility.
4. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet representative.

Note:
Three options can be followed to perform surgery without the referenced instrument parts affected in this FSN, as per surgical technique reference 0023.1-EMEA-en-REV0316 (English version); see Fig 24 & 37/38:

1. Use of the Shell Positioner available in the same kit (ref. 110027772 and 110027771)
2. Use of the assembly usually used for the cemented shell insertion.
3. Use of the legacy instrumentation, if available.

Important: Both Acknowledgement forms (1 and 2) must be separately filled corresponding to each instrument and sent back.

Other Information (for both FSCA)

This 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 parts or any other Zimmer Biomet product by emailing fr.complaints@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,

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: AVANTAGE THRD SHAFT STRAIGHT

Field Action Reference: ZFA2018-00369

Please return the completed form to your Zimmer Biomet contact person:
fieldaction.emea@zimmerbiomet.com

☐ I received and understood the Field Safety Notice.

Regarding the parts:

☐ All inventories for the affected parts have been checked and following parts are to be returned:

Reference	Lot Reference	Number of parts returned

OR

☐ The affected parts which are unavailable for return have been: ☐ discarded ☐ lost ☐ other: _____

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

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

Printed Name: _____ **Signature:** _____ **Date:**____/____/____

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

Facility Name: _____ **Facility Address:** _____

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

ATTACHMENT 2
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: AVANTAGE Impact Plate

Field Action Reference: ZFA2018-00374

Please return the completed form to your Zimmer Biomet contact person:
fieldaction.emea@zimmerbiomet.com

☐ I received and understood the Field Safety Notice.

Regarding the parts:

☐ All inventories for the affected parts have been checked and following parts are to be returned:

Reference	Lot Reference	Number of parts returned

OR

☐ The affected parts which are unavailable for return have been: ☐ discarded ☐ lost ☐ other: _____

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

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

Printed Name: _____ **Signature:** _____ **Date:**____/____/____

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

Facility Name: _____ **Facility Address:** _____

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