ZIMMER BIOMET

16th January 2017

To: Risk Managers

Subject: URGENT FIELD SAFETY NOTICE

Affected Product: Accu-Cut Saw Blade AO Drive.

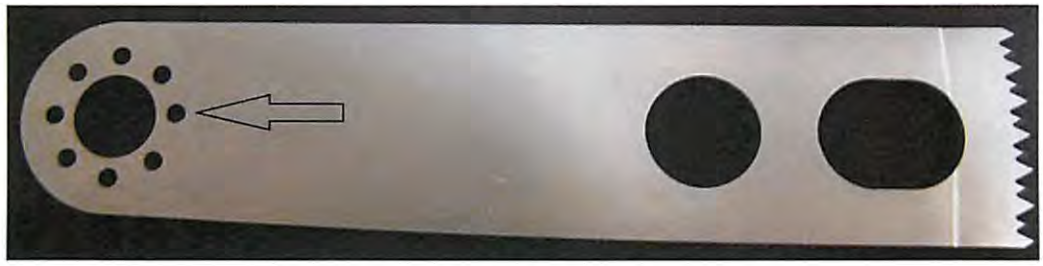
Item Number	Lot Number	Lot Number
32-401168	*3187381*	3499793
	3298383	*3499794*
	3318061	*3499795*
	3346309	*3564294*
	3346753	*3564295*
	3405282	*3571752*
	3408366	*3571753*
	3411380	

This notice is to inform you of a VOLUNTARY URGENT FIELD SAFETY CORRECTIVE ACTION that has been initiated by Biomet UK Ltd which involves the **Accu-Cut Saw Blades** referenced above. Our records show that these instruments may have been distributed to your hospital and are a **Single Use Only** instrument. We are requesting that you immediately locate and discontinue use of the instruments with the above item/lot numbers.

Biomet UK Ltd has initiated this action following a single complaint where the surgeon was unable to assemble a saw blade to the electrical power saw.

The investigation has revealed that the saw blade did not assemble to the electrical power saw due to one miss-aligned hole on the blade fitment. As a precautionary measure Biomet UK Ltd has decided to recall all lots manufactured using the same process as the complaint item.

Example Item shown below



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Risks

Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	Extended operation time of less than 30 minutes whilst the surgeon sources a correct saw blade or potentially a new power tool/ sawblade that is suitable	Extended Operation time of greater than 30 minutes whilst the surgeon sources an alternative solution if no equivalent saw blade is made available.
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	No long range health consequences are anticipated.	Increased infection risk, risks associated with prolonged anesthesia. Delayed recovery due to lack of blood supply for longer due to extended operation time.

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

Risk Manager Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative quarantine all affected products.
3. Your Zimmer Biomet sales representative will remove the affected products from your facility.
4. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy to fieldaction.uk@zimmerbiomet.com
    b. Retain a copy of the Acknowledgement Form within your records in the event of a compliance audit of your facilities documentation.
5. If after reviewing this Urgent Field Safety Notice you have further questions or concerns please contact your local Zimmer Biomet representative.

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Other Information

This voluntary Urgent Field Safety Notice will be reported to Competent Authorities, Notified Bodies, and Regulatory Authorities as required under the applicable regulations.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 or any relevant requirements to the local Regulatory Authority in your country.

Please keep Biomet UK Ltd informed of any adverse events associated with this instrument or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at per.uk@zimmerbiomet.com, or to your local Zimmer Biomet representative.

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

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this Urgent Field Safety Notice.

Sincerely,

[redacted]

ATTACHMENT 1
Certificate of Acknowledgement

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

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

Printed Name: _____ **Signature:** _____

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

Facility Name: _____

Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

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.uk@zimmerbiomet.com