ZIMMER BIOMET

28th October 2016

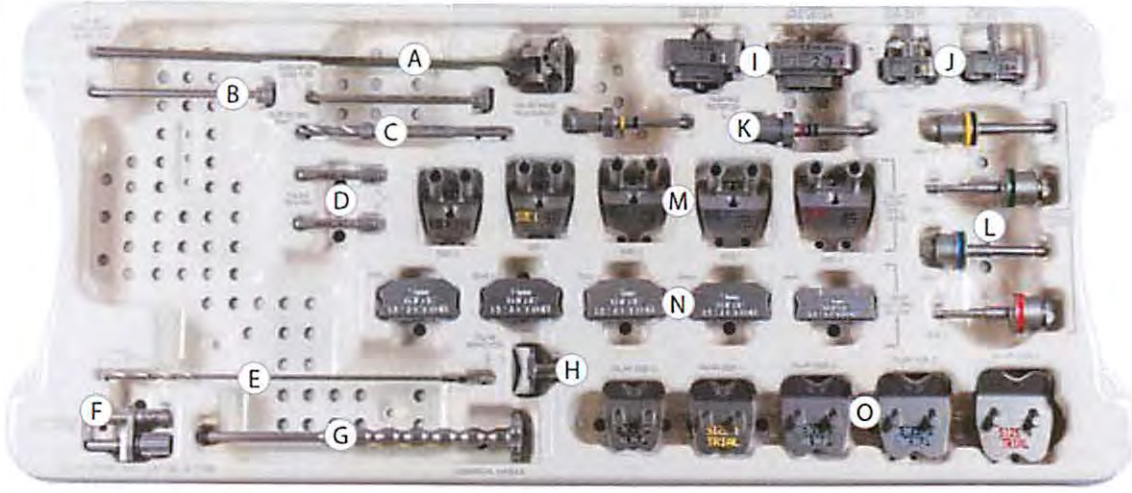
To: Risk Managers

Subject: URGENT FIELD SAFETY NOTICE

Affected Product:

Description	Item Number	Affected Serial or Lot Numbers	Tray Position
Rebalance Talar Ant Router Guide Size 0/1	407775	FS72117	I
Rebalance Talar Sulcus Guide Size 0/1	407776	FS72400	J
Rebalance Talar Sulcus Guide Size 0/1	407776	FS71394	J
Rebalance Talar Sulcus Guide Size 0/1	407776	FS69451	J
Rebalance Talar Ant Router Guide Size 2/3/4	407777	FS72119	I
Rebalance Talar Ant Router Guide Size 2/3/4	407777	FS71831	I
Rebalance Talar Ant Router Guide Size 2/3/4	407777	FS71397	I
Rebalance Talar Sulcus Guide Size 2/3/4	407778	FS72403	J
Rebalance Talar Sulcus Guide Size 2/3/4	407778	FS71400	J
Rebalance Talar Drill Guide Align Rod	407760	FS74140	A
Rebalance Talar Drill Guide Align Rod	407760	FS73505	A

Talar Instrument Tray - Top



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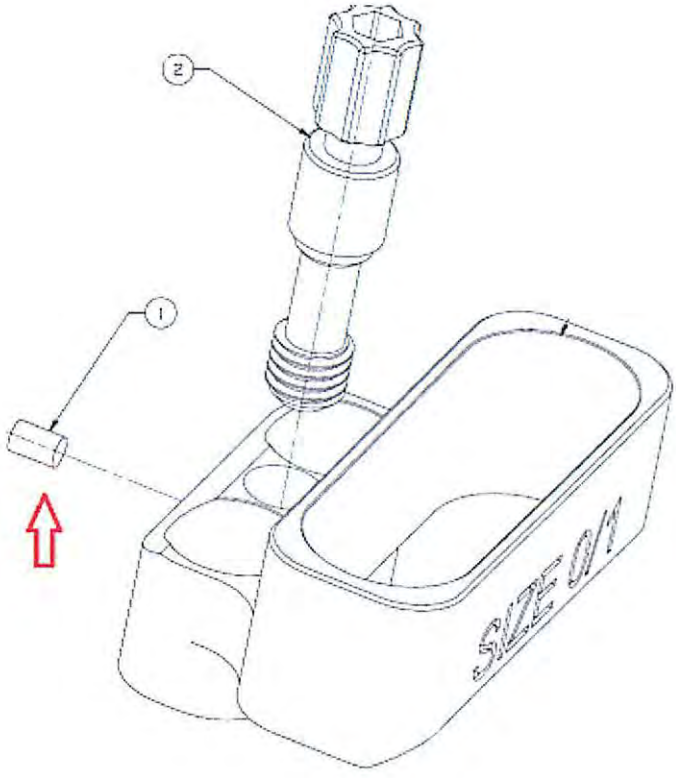
This notice is to inform you of an URGENT FIELD SAFETY CORRECTIVE ACTION that has been initiated by Biomet UK Ltd which involves the Rebalance instruments referenced above. Our records show that these instruments may have been distributed to your hospital as a single instrument and/or as part of the instrument set contained in kit number 407798. 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 an investigation that has revealed that it is possible that the pin (1) could become loose and disengage from the instrument.

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
	If the laser welded pin is loose and is detected to have fallen into the patient and is removed by the surgeon, then no immediate health consequence is expected other than a minor surgical delay.	OR staff recognize that an attachment screw is missing prior to surgery and surgery is then cancelled. This may result in the patient needing to be subjected to second round of anesthesia.
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	If pin is not detected to have fallen into the patient and is left within patient after surgical closure, then the pin could enter joint space and cause an increase in polyethylene wear, which could lead to a long term revision surgery Also if the attachment screw is loose then could lead to early loosening and revision due to inaccurate bone resections.	If pin is not detected to have fallen into the patient and is left within patient after surgical closure, then the pin could enter joint space and cause an increase in polyethylene wear, which could lead to a long term revision surgery Also if the attachment screw is loose then could lead to early loosening and revision due to inaccurate bone resections.

Please note that the applicable Instruction For Use for reprocessing reusable surgical instruments (Catalogue number 5401000246, version 2.3) states the following:-

All instruments should be visually checked for damage and wear.

Check for smooth movement of instruments without excessive "play"

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

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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 product.
3. Your Zimmer Biomet sales representative will remove the affected product 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.

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 device 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]

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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** [ ] **Surgeon** (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