ZIMMER BIOMET

July 3, 2017

To: Surgeons/ Hospitals

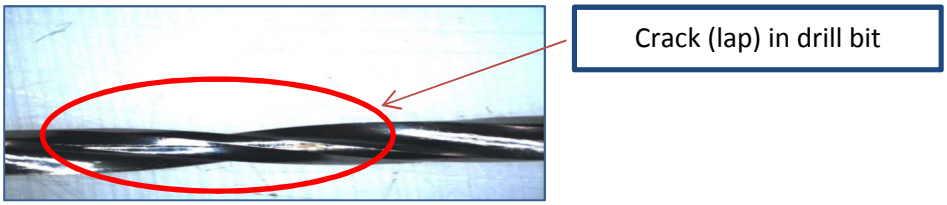
Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE- REMOVAL LOT SPECIFIC**

Affected Product: 1.0MM DRILL BIT MINI-QUICK CONNECT, FAST 1.1MM DRILLBIT MINIQUICK

Refer to Attachment 2-Affected Product List for the affected items/lot combinations.

Zimmer Biomet is conducting a medical device field action for specific lot numbers of the 1.0MM DRILL BIT MINI-QUICK CONNECT, FAST 1.1MM DRILLBIT MINIQUICK. A raw material anomaly was discovered during inspection at Zimmer Biomet, and an investigation by the supplier determined that four lots of raw material could have similar anomalies. The anomaly has the potential to be on or below the surface and can increase the risk of instrument fracture. Accordingly, all products manufactured with the affected raw material are being removed from the field.

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of May 2016 and May 2017.



Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Highest Severity*
	Extension of surgery < 30 minutes	*Extension of surgery > 30 minutes*
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Highest Severity*
	None	*Patient retains piece of fractured instrument leading to patient injury*

Surgeon/ Hospital 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 support the removal of 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 with your recall records in the event of a compliance audit of your facilities documentation.

5. If after reviewing this 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.

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

The undersigned confirms that this notice has been delivered to the appropriate Competent Authorities, as per MEDDEV 2.12-1 revision 8.

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

Sincerely,

[redacted]

ATTACHMENT 1
Certificate of Acknowledgement ZFA2017-199

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

[ ] **Hospital Facility** [ ] **Surgeon**

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.

Product Reference	Lot Reference	Number of returned instruments

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ATTACHMENT 2
Affected Product List ZFA2017-199

Part Number	Lot #	UDI #
231220200	045785	(01)00887868026973(10)045785
231220200	046151	(01)00887868026973(10)046151
231220200	047467	(01)00887868026973(10)047467
231220200	048461	(01)00887868026973(10)048461
231220200	048809	(01)00887868026973(10)048809
231220200	100016	(01)00887868026973(10)100016
231220200	102325	(01)00887868026973(10)102325
231220202	045790	(01)00887868026997(10)045790
231220202	048477	(01)00887868026997(10)048477
231220202	048811	(01)00887868026997(10)048811
231220202	100017	(01)00887680296997(10)100017
231220202	101028	(01)00887868026997(10)101028
231220202	102338	(01)00887868026997(10)102338
506265	1104161A	(01)00880304561915(17)261109(10)1104161A