

November 28, 2017

**To:** Surgeons/ Hospitals

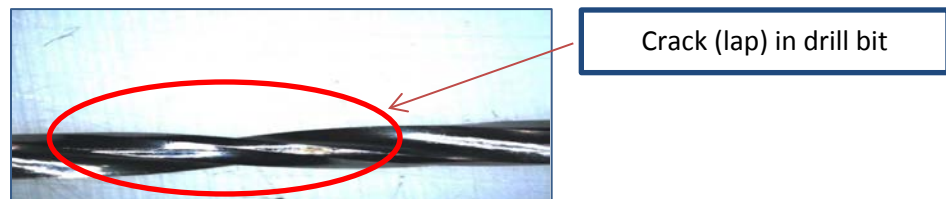
**Subject:** **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE- REMOVAL LOT SPECIFIC**

**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.



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



### **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.emea@zimmerbiomet.com](mailto:fieldaction.emea@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**

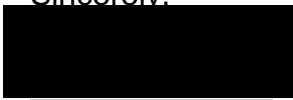
This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing [winterthur.per@zimmerbiomet.com](mailto:winterthur.per@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,



Kevin W. Escapule  
Post Market Surveillance & Regulatory Compliance Director



**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.emea@zimmerbiomet.com](mailto:fieldaction.emea@zimmerbiomet.com).**

Product Reference	Lot Reference	Number of returned instruments

**ATTACHMENT 2**  
**Affected Product List ZFA2017-199**

Part Number	Lot #	UDI #
231220200	45785	(01)00887868026973(10)045785
231220200	46151	(01)00887868026973(10)046151
231220200	47467	(01)00887868026973(10)047467
231220200	48461	(01)00887868026973(10)048461
231220200	48809	(01)00887868026973(10)048809
231220200	100016	(01)00887868026973(10)100016
231220200	102325	(01)00887868026973(10)102325
231220202	45790	(01)00887868026997(10)045790
231220202	48477	(01)00887868026997(10)048477
231220202	48811	(01)00887868026997(10)048811
231220202	100017	(01)008878680296997(10)100017
231220202	101028	(01)00887868026997(10)101028
231220202	102338	(01)00887868026997(10)102338