ZIMMER BIOMET

03 October 2017

To: Risk Managers and Surgeons

Subject: **URGENT MEDICAL DEVICE RECALL**

Affected Product: Sirus Drill Trauma Instrument and Flexible Shaft Hip & Anatomical Shoulder Instrument

Item Number	Lot Number	Item Description
02.00020.040	All Lots	Sirus Drill
75.80.04	All Lots	Flexible Shaft

Zimmer Biomet is conducting a medical device recall for the Sirus Drill and Flexible Shaft due to the potential that the instruments may not be adequately cleaned when utilizing the standard cleaning instructions. If an instrument is not adequately cleaned, this could result in infection and subsequent complications. As a result, the devices are being removed and as required being replaced with alternative instruments that can be adequately cleaned utilizing the standard cleaning instructions.

The Sirus implant system was discontinued in 2015, however the associated Drill 02.0020.040 has been included in this recall to ensure this is no longer in use. The Flexible Shaft is utilized with the Anatomical Shoulder implant system and alternative replacement instrument is available.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between 20 July 2004 and 25 October 2016.

Risk Manager Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to CorporateQuality.PostMarket@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your recall 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 call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to CorporateQuality.PostMarket@zimmerbiomet.com.
4. Retain a copy of the acknowledgement form with your recall 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 call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.

Other Information

This medical device recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing Zimmer.PER@zimmerbiomet.com.

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,

[redacted]
Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Sirus Drill and Flexible Shaft **Field Action Reference: ZFA2017-332**

Please check one as applicable:

☐ Hospital Facility ☐ Surgeon

Do you have affected product in your facility?
(Hospital Facility Only: Please mark the appropriate response.)

☐ **Yes**, we currently have one or more affected items in our facility.

☐ **No**, we currently have no affected items in our facility.

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

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 is closed for your account. It is important that you complete this form and email a copy to CorporateQuality.PostMarket@zimmerbiomet.com or fax to 574-372-4265.