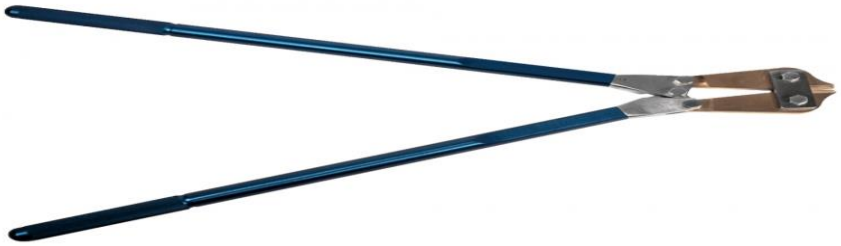
November 20, 2020

To: Distributors, Sales Representatives, and Distributor Operation Managers

Subject: **URGENT MEDICAL DEVICE RECALL AND NOTICE OF DISCONTINUATION**

Affected Product: Spinal Rod Cutter Maximum Pin Diameter ¼ Inch (6.4M)

Item Number	Description	Lot Number
00-3925-002-00	Spinal Rod Cutter	All Lots



Zimmer Biomet is conducting a medical device recall for all lots of 00-3925-002-00 Spinal Rod Cutter Maximum Pin Diameter ¼ Inch (6.4M) due to the potential for fracture during use. The cutter is primarily used in spine procedures to cut stainless steel rods. If the pin cutter were to fracture during use, it would be easily recognized. The associated risks are set out below. The highest severity event may result if the cutters were to fracture intra-operatively in an internal fixation procedure and a fragment creates a puncture wound that resulted in permanent impairment of a body function or damage to a body structure.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Non-clinically significant extension of surgery to find another readily available product	*Results in permanent impairment of a body function or damage to a body structure.*
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	*Results in permanent impairment of a body function or damage to a body structure.*

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between June 1992 and June 2020. This product is being discontinued and will no longer be available.

Your Responsibilities

1. Review this notification and ensure that affected team members are aware of the contents.
2. Immediately locate and quarantine affected product in your inventory.
3. Immediately return all affected product from your distributorship and from affected hospitals within your territory.
   a. Complete **Attachment 1 – Inventory Return Certification Form** and send to CorporateQuality.PostMarket@zimmerbiomet.com within three (3) days. This form must be returned even if you do not have affected products available to return in your territory.
   b. For each return, send a copy of Attachment 1 to CorporateQuality.PostMarket@zimmerbiomet.com.

c. Include a hardcopy of Attachment 1 in each carton of your return shipment for immediate processing.
d. Include a copy of **Attachment 2-Certificate of Sterilization**
e. Mark "RECALL" on the outside of the returned cartons.

4. Return the **Additional Accounts** form to CorporateQuality.PostMarket@zimmerbiomet.com.
   a. Review the list of hospitals included with the email notification sent to your facility, which includes a list of hospitals that have already been notified of this recall.
   b. Identify whether there are any additional hospitals that Zimmer Biomet has *not* notified and list these accounts on the Additional Accounts form. Please provide the form in **Excel format**.
   c. If there are no additional accounts to notify, please indicate that there are no additional accounts, or indicate "None" or "NA" on the form.
5. Retain a copy of your Inventory Return Certification and product return forms for your records in the event of a compliance audit of your facility.
6. 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 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.
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- 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-0178Under 21 CFR 803, manufacturers are 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 product.experience@zimmerbiomet.com.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. Your urgent cooperation is needed. The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.
Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,

[redacted]

Kevin Escapule

Director, Post Market Surveillance

ZIMMER BIOMET

ATTACHMENT 1 - Inventory Return Certification Form

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: Spinal Rod Cutter Maximum Pin Diameter ¼ Inch (6.4M) ZFA Number: ZFA 2020-00270

Territory Number: _____ Account Number: _____

Account Name: _____

Account Address: _____

Please return the affected product to the appropriate address below with a spreadsheet containing item number, lot number, and quantity:

Zimmer Biomet
Product Service Department
ATTN: RECALLS
1777 West Center Street
Warsaw, IN 46580

OR

Zimmer GmbH
Biomet Global Supply Chain Center B.V.
Hazeldonk 6530
Dock 20
Breda 4836 LD, Netherlands

	Check one of the following:	
This is the final return for the entire territory. **An exhaustive search has been performed for the affected products.**	**Yes** ☐	**No** ☐

Note: Any product not returned or found in your territory is considered consumed/lost and unavailable for use.

☐ **Credit My Account**

Item Number	Lot Number	Quantity Returned

Complete this table for all affected items returned. If additional space is needed, please provide a spreadsheet and return it to CorporateQuality.PostMarket@zimmerbiomet.com with this form.

Certificate of Acknowledgement:

By signing below, I acknowledge that I have received, read, and understand the contents of this recall communication. All required activities are complete or are being completed.

Printed Name: _____ Signature: _____

Title: _____ Tel: ( ) _____ Ext. _____ Date: _____

Note: This form and affected product must be returned to Zimmer Biomet before this action is considered closed for your account. It is important that you complete this form and email a copy to CorporateQuality.PostMarket@zimmerbiomet.com.

Please do not return affected product with other returns.

ATTACHMENT 2 - Certificate of Decontamination

Affected Product: Spinal Rod Cutter Maximum Pin Diameter ¼ Inch (6.4M) ZFA Number: ZFA 2020-00270

By signing below, I acknowledge that the instrumentation being quarantined has been cleaned and sterilized prior to being returned to Zimmer Biomet.

Describe method of disinfecting: _____

Printed Name: _____ Signature: _____

Title: _____ Phone: ( ) _____-_____ Date: _____/_____/_____

Note: Attachment 2 Certificate of Decontamination is only required when returning used instruments from the field or when returning product that has been removed from its sterile packaging and held in a clinical environment where there is a potential for exposure to biological contamination.