June 27, 2019

To: Hospital and Surgeons

Subject: URGENT MEDICAL DEVICE FIELD SAFETY NOTICE- REMOVAL

Reference: ZFA2018-00634

Affected Product: Ultra-Drive® Hose/Drape Assembly and Ultra-Drive® Irrigation Tubing Assembly

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<thead>
<tr>
<th>Item Number</th>
<th>Description</th>
<th>Lot Numbers</th>
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<tbody>
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<td>423833</td>
<td>Ultra-Drive® Hose/Drape Assembly</td>
<td>221437 219825 218921 217766 216610 216610</td>
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<td>Ultra-Drive® Irrigation Tubing Assembly</td>
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Zimmer Biomet is conducting a medical device field action (removal) for the Ultra-Drive® Hose/Drape Assembly and Ultra-Drive® Irrigation Tubing Assembly due to insufficient data to support the labeled shelf life of 10 years.
Our records indicate that you may have received one or more of the affected products. The affected units were distributed between September 2009 and March 2018 (local deployments may differ).

**Hospital 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 fieldaction.export@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 field action 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 contact your Zimmer Biomet representative.

**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 fieldaction.export@zimmerbiomet.com
4. Retain a copy of the acknowledgement form with your field action 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 contact your Zimmer Biomet Representative.
Other Information

This 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 as per MEDDEV 2.12-1 in Europe.

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 or to your local Zimmer Biomet contact.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.
The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

We would like to thank you for your co-operation 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

**IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED**

**Affected Product:** Ultra-Drive® Hose/Drape Assembly and Ultra-Drive® Irrigation Tubing Assembly

**Field Action Reference:** ZFA 2018-00634

Please return the completed form to your Zimmer Biomet contact person:

fieldaction.export@zimmerbiomet.com

☐ I received and understood the Field Safety Notice.

Regarding the products:

☐ All inventories for the affected products have been checked and following products are to be returned:

<table>
<thead>
<tr>
<th>Product Reference</th>
<th>Lot Reference</th>
<th>Number of products returned</th>
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OR

☐ The affected products which are unavailable for return have been: ☐ discarded ☐ lost ☐ other:

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: __________________________ Date: /_ /_

Title: ________________________________ Telephone: ( ) -

Facility Name: __________________________ Facility Address: __________________________

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 fieldaction.export@zimmerbiomet.com