ZIMMER BIOMET

June 27, 2019

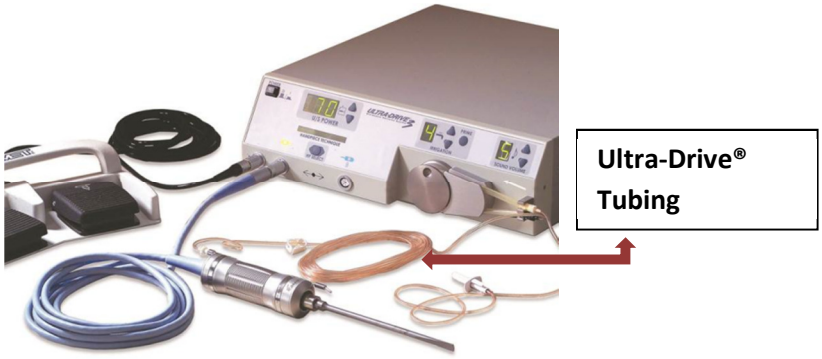
To: Hospital and Surgeons

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

Reference: ZFA2018-00634

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

Item Number	Description	Lot Numbers					
423833	Ultra-Drive® Hose/Drape Assembly	221437	219825	218921	217766	216610	216610
		216550	211324	214994	214545	214315	213350
		213612	212877	212670	211638		
423834	Ultra-Drive® Irrigation Tubing Assembly	217761	215048	212966	210002	211237	211325
		216489	215524	212622	210867	210848	209586
		219913	212928	215445	215329	210566	214051
		220935	214669	218667	215623	210972	210488
		219661	211172	217767	217556	214499	214995
		217370	212076	214005	214546	214255	214822
		216611	212488	214118	219305		



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.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	*Extension of Surgery < 30 minutes while another tubing set is obtained or alternative method is used*
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	*Infection, surgical interventions (Biologic Response)*

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.emea@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.emea@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,

[redacted]

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.emea@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:

Product Reference	Lot Reference	Number of products returned

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.emea@zimmerbiomet.com