

June 27, 2018

To: Surgeons/ Hospital

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (REMOVAL)**

Affected Product: Dermatome AN

Reference: ZFA 2018-00215 & 2018-00170

Attachment 2 – Affected Product List



Zimmer Biomet is conducting a medical field action (removal) for specific serial numbers of Dermatome AN. The affected devices could potentially have a loose control bar, which could compromise the ability to control the thickness of the graft. The affected devices could also potentially have a loose width plate that if undetected, could result in an imperfect, yet still usable graft.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	<p>Loose Control Bar: Harvesting a skin graft of a thickness much greater than intended such that it is described as patient gouged.</p> <p>Loose Width Plate: Minor delay of surgery (<30 minutes) to retrieve replacement device</p>	<p>Loose Control Bar: Harvesting a skin graft of a thickness much greater than intended such that it is described as patient gouged.</p> <p>Loose Width Plate: The graft may be sub-optimal but usable.</p>
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	<p>Loose Control Bar: Prominent scarring due to gouging.</p> <p>Loose Width Plate: None</p>	<p>Loose Control Bar: Prominent scarring due to gouging.</p> <p>Loose Width Plate: None</p>



Our records indicate that you may have received one or more of the affected products. The affected units were distributed between June 2017 and March 2018.

Surgeon/ Hospital Responsibilities:

1. Review this notification for awareness of the contents.
2. Assist your Zimmer Biomet sales representative to quarantine immediately all affected instruments.
3. Your Zimmer Biomet sales representative will remove the affected instruments from your facility.
4. Complete **Attachment 1 – Certificate of Acknowledgement**.
 - a. Return a digital copy to fieldaction.emea@zimmerbiomet.com.
 - b. Retain a copy of the Certificate of Acknowledgement with your field action records in the event of a compliance audit of your documentation.
5. If after reviewing the notice you have further questions or concerns please contact your Zimmer Biomet representative.

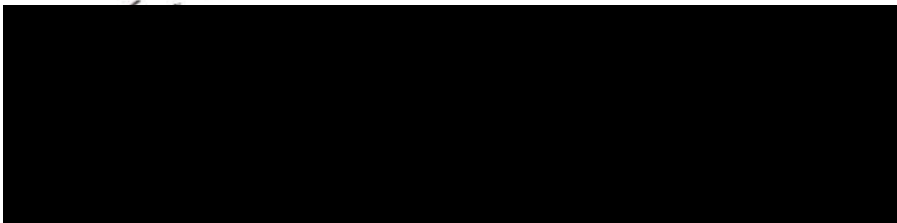
Other Information

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 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,





ATTACHMENT 1 Certificate of Acknowledgement

Affected Product: Dermatome AN

ZFA Number: ZFA 2018-00215 & ZFA 2018-00170

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Hospital Facility Surgeon (Please check one as applicable)

Printed Name: _____ Signature: _____

Title: _____ Telephone: () _____ - _____ Date: ____/____/____

Facility Name: _____

Facility Address: _____

City: _____ ZIP: _____ Country: _____

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.

Even if you have no product to return, this form must be completed, signed and returned.

Choose the following options:

All received products were discarded or lost by the clinic/ hospital

Or complete the chart below for remaining products:

Product Reference	Lot Reference	Number of products returned

Comments (if needed): _____



Please do not return affected product with other returns.

ATTACHMENT 2 Affected Product List

Item Number	Lot Number	Serial Number	Item Description
88710100	63578134	700141	Dermatome AN
88710100	63578134	700142	Dermatome AN
88710100	63578134	700143	Dermatome AN
88710100	63578134	700144	Dermatome AN
88710100	63578134	700145	Dermatome AN
88710100	63578134	700146	Dermatome AN
88710100	63578134	700147	Dermatome AN
88710100	63578134	700148	Dermatome AN
88710100	63578134	700149	Dermatome AN
88710100	63578134	700150	Dermatome AN
88710100	63578134	700151	Dermatome AN
88710100	63578134	700152	Dermatome AN
88710100	63578134	700153	Dermatome AN
88710100	63578134	700154	Dermatome AN
88710100	63578134	700155	Dermatome AN
88710100	63578134	700156	Dermatome AN
88710100	63578134	700157	Dermatome AN
88710100	63578134	700158	Dermatome AN
88710100	63578134	700159	Dermatome AN
88710100	63578134	700160	Dermatome AN
88710100	63578135	700161	Dermatome AN
88710100	63578135	700162	Dermatome AN
88710100	63578135	700164	Dermatome AN
88710100	63578135	700165	Dermatome AN
88710100	63578135	700167	Dermatome AN
88710100	63578135	700171	Dermatome AN
88710100	63578135	700172	Dermatome AN
88710100	63578135	700174	Dermatome AN
88710100	63578135	700175	Dermatome AN
88710100	63578135	700177	Dermatome AN
88710100	63592351	700182	Dermatome AN
88710100	63592351	700183	Dermatome AN
88710100	63592351	700184	Dermatome AN

Item Number	Lot Number	Serial Number	Item Description
88710100	63592351	700185	Dermatome AN
88710100	63592351	700186	Dermatome AN
88710100	63592351	700187	Dermatome AN
88710100	63592351	700191	Dermatome AN
88710100	63592351	700193	Dermatome AN
88710100	63592351	700194	Dermatome AN
88710100	63592351	700195	Dermatome AN
88710100	63592351	700197	Dermatome AN
88710100	63592351	700198	Dermatome AN
88710100	63618116	700201	Dermatome AN
88710100	63618116	700202	Dermatome AN
88710100	63618116	700203	Dermatome AN
88710100	63618116	700205	Dermatome AN
88710100	63618116	700206	Dermatome AN
88710100	63618116	700207	Dermatome AN
88710100	63618116	700208	Dermatome AN
88710100	63618116	700209	Dermatome AN
88710100	63618116	700211	Dermatome AN
88710100	63618116	700216	Dermatome AN
88710100	63618116	700218	Dermatome AN
88710100	63618116	700219	Dermatome AN
88710100	63646910	700221	Dermatome AN
88710100	63646910	700222	Dermatome AN
88710100	63646910	700224	Dermatome AN
88710100	63646910	700226	Dermatome AN
88710100	63646910	700227	Dermatome AN
88710100	63646910	700228	Dermatome AN
88710100	63646910	700229	Dermatome AN
88710100	63646910	700230	Dermatome AN
88710100	63646910	700231	Dermatome AN
88710100	63646910	700233	Dermatome AN
88710100	63817639	700243	Dermatome AN
88710100	63817639	700250	Dermatome AN

ATTACHMENT 3

Certificate of Decontamination

Affected Product: Dermatome AN ZFA Number: ZFA 2018-00215 & 2018-00170

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: ____/____/____

Attachment 3, Certificate of Sterilization, 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.