July 13, 2016

To: **Distributors and Sales Representatives**

Subject: **URGENT FIELD SAFETY NOTICE - CORRECTION**

Affected Products:

Description	Item Number	Affected Serial or Lot Numbers
Zimmer® Air Dermatome II Handpiece	**00-8851-001-00**	**All serial numbers**
Zimmer® Air Dermatome II Handpiece w/o Hose	**00-8851-001-01**	
Zimmer® Air Dermatome II Handpiece Loaner	**01-8851-001-00**	
Zimmer® Air Dermatome II Width Plate, 1 in.	**00-8851-201-00**	**All lot numbers**
Zimmer® Air Dermatome II Width Plate, 1.5 in.	**00-8851-215-00**	
Zimmer® Air Dermatome II Width Plate, 2 in.	**00-8851-202-00**	
Zimmer® Air Dermatome II Width Plate, 3 in.	**00-8851-203-00**	
Zimmer® Air Dermatome II Width Plate, 4 in.	**00-8851-204-00**	

Issue:

Zimmer Biomet Surgical is initiating a Medical Device Correction (followed by a phased removal) for all serial numbers of the Zimmer Air Dermatome II Handpieces and all lot numbers of the Zimmer Air Dermatome II Width Plates distributed between March 2012 and August 2015 (including loaner devices).

Zimmer Biomet Surgical has received product complaints reporting that the surface coating applied to the device is blistering, peeling and discoloring after usage over time (see Image 1). There have been no injuries associated with the reported complaints. In addition, an independent assessment determined that the blistering, peeling and potentially flaking of the surface coating is not expected to result in any long range health consequences. Given that the frequency of this surface coating condition can worsen with age, Zimmer Biomet Surgical is currently making preparations for replacement activities to follow in order to prevent future complaints. This document is provided to alert all users of the potential for the surface coating to exhibit blistering, peeling, and discoloring after usage over time. A separate recall removal notice will be issued to facilities, in phases, with detailed instructions in August 2016. **Your sales representatives will be notified when a replacement is ready. Do not return product at this time as part of this action.**

Image 1. Blistering on Zimmer Air Dermatome II

Risks:

Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	Use of the device with the surface characteristics (blistering/peeling) could result in gray coating flakes on the skin graft and/or donor site, resulting in the opportunity for the operating team to see the gray coating flakes. In which case, copious irrigation with saline should remove the flakes easily from both skin graft and donor site.	Theoretically, coating flakes could contact both the harvested skin graft as well as the donor site. The coating composition contains nonvalent chromium that is not readily absorbed by the skin. If coating flakes were not detected and remain on the skin graft, the skin graft would not "take" in the areas where the flakes were present, resulting in small open wounds that would eventually close once the flakes were no longer present. Likewise, a donor site that had coating flakes adherent might not re-epithelialize in the usual 1-2 week timeframe focally where the flakes blocked keratinocyte proliferation. Eventually, either the flakes would be removed by an external agent or the patient's body would eventually expel the flakes and the small focal wounds would eventually close on their own.
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	Use of the device with the surface characteristics (blistering/peeling) could result in gray coating flakes on the skin graft and/or donor site, resulting in the opportunity for the operating team to see the gray coating flakes. In which case, copious irrigation with saline should remove the flakes easily from both skin graft and donor site. With such brief contact with skin graft or donor, no long range consequences are likely.	Given the chemical composition of the surface coating, no long range health consequences would be expected.

Your Responsibilities:

If your territory has current users of the Zimmer Air Dermatome II Handpieces and Width Plates that were directly notified of this update, we ask for your support during the Medical Device Recall.

1. Please carefully review this letter.
2. Inspect the Zimmer Air Dermatome II devices within your possession and indicate on the attached Certificate of Acknowledgment the condition of the device. Please complete and sign the attached Certificate of Acknowledgment and return it to Fieldaction.Emea@zimmerbiomet.com .

You will receive copies of notification sent directly to hospital risk managers in your territory. As necessary, review and facilitate understanding of this notification by those entities. The notification sent to the hospital risk managers identifies the following as the responsibilities of the facility:

1. Please carefully review this letter and ensure all users of the Zimmer Air Dermatome II at your facility have been informed of this notice.
2. Inspect the Zimmer Air Dermatome II devices within your facility and indicate on the attached Certificate of Acknowledgment the condition of the device. Please complete and sign the attached Certificate of Acknowledgment and return it to Fieldaction.Emea@zimmerbiomet.com.
3. Before each use, continue to examine the surface coating for blistering/peeling.

a. If the blistering/peeling characteristics are not present, you may continue to use. Immediately after each use, re-examine the surface coating for blistering/peeling.
b. If the blistering/peeling characteristics are present, discontinue use. In the event that alternate devices or therapies are not available, surgeons may, at their discretion, determine the use of the device as a medical necessity and continue to use. After use, follow your facility's wound irrigation protocol or Zimmer Biomet recommends copious irrigation with a normal saline solution or immersion of the graft in a bowl of normal saline. Zimmer Biomet recommends irrigating the donor site with saline as well. Carefully examine the skin graft and donor site for gray coating flakes and continue to irrigate as necessary. Please report this as an adverse event to Zimmer Biomet Surgical at winterthur.per@zimmerbiomet.com.

If after reviewing this notification you have further questions or concerns please contact your local Zimmer Biomet representative.

Vigilance/ Reporting Information

This voluntary notification will be reported to the local Competent Authorities.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 or any relevant requirements to the local health authority in your country.

Please keep Zimmer GmbH informed of any adverse events associated with this device or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at winterthur.per@zimmerbiomet.com, or to your local Zimmer Biomet representative.

ZIMMER BIOMET

Attachment 1
Certificate of Acknowledgement

Please inspect the Zimmer Air Dermatome II devices within your facility and indicate the condition of the device below:

Item	Serial/Lot Number	Quantity	Condition of the Device	
			Blistering/Peeling NOT Present	Blistering/Peeling Present

By signing below, I acknowledge that the required actions (Responsibility Section) have been taken in accordance with the Recall Notice.

Printed Name: _____ Signature: _____

Title: _____ Telephone: _____ Date: _____

Facility Name: _____

Account Number: _____

Facility Address: _____

City: _____ State: _____ Zip: _____

Note: It is important that you complete this form and email a copy to: Fieldaction.Emea@zimmerbiomet.com**.**
Please keep a copy for your records.

Important: If you have further transferred affected product please provide the customer's information below, or on an attachment, so that we may notify them:

Facility Name: _____ Telephone: _____

Account Number: _____

Facility Address: _____

City: _____ State: _____ Zip: _____

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