**September 27, 2016**

**To:** **Hospital Risk Managers**

**Subject:** **URGENT MEDICAL DEVICE REMOVAL NOTICE**

**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** | |

In follow-up to the July 13, 2016 recall correction notice, Zimmer Biomet Surgical is initiating phase II of the applicable voluntary recall of the Zimmer Air Dermatome II Handpieces and Zimmer Air Dermatome II Width Plates due to the potential for the surface coating applied to the device to blister, peel, and discolour after usage over time. Replacement Zimmer® Air Dermatomes are now available.

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) are included in this removal. Zimmer Biomet Surgical 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, these devices are being recalled to prevent future complaints.

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.<br>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**

1. Review the notification and ensure affected personnel are aware of the contents.
2. **Locate and quarantine all affected product identified in table above.**
3. Carry out a physical count and sterilize all of the affected product in your hospital/clinic and complete Attachment 1 – Certificate of Acknowledgment and Sterilization (enclosed). Email a completed copy of Attachment 1 to Fieldaction.Emea@zimmerbiomet.com.
4. Your Zimmer Biomet sales representative will remove the recalled product from your facility.
5. The model 8851 Zimmer® Air Dermatome II has been discontinued. Please contact your local Zimmer Biomet distributor or representative to order replacement devices.
6. **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.

**Note:**
Where applicable, the 8801 Zimmer Air Dermatome system can be provided, however the specific instruction for cleaning and sterilization should be carefully reviewed as the 8801 Zimmer Air Dermatome has not been designed for automated washing. Please contact your Zimmer Biomet representative for more information and support.

# Attachment 1
# Certificate of Acknowledgement and Sterilization

**Affected Product:**

| Description | Item Number | Affected Serial or Lot Numbers |
|---|---|---|
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By signing below, I acknowledge that the required actions (Responsibility Section) have been taken in accordance with the Recall Notice. Additionally, I acknowledge that the non-sterile devices listed below have been cleaned and sterilized prior to being returned.

Describe the method of sterilization: _____

**Identify re-sterilized devices by item, serial/lot number, and quantity or attach an Excel spreadsheet containing same information.**

| Item | Serial/Lot Number | Quantity | Comments |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

*Note: Zimmer Biomet Surgical will credit your account for returned devices only.

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.**

**Do not return recalled product with other returns.**
**In order to receive proper credit, please include a copy of this Certificate of Acknowledgement and Sterilization with the shipment.**

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