

**December 16, 2015**

**To: Risk Managers and Surgeons**

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

**FSN/FSCA: FA 2015-09**

**Affected Product: Original M.E. Müller® Low Profile cup (see attachment 1)**

Zimmer GmbH is initiating a voluntary recall of certain batches of above referenced M.E. Müller cup, because of a labeling issue.

Following a complaint alleging a mix-up of the labelling, it was determined that a M.E. Müller Low Profile cup was labelled as a M.E. Müller Full Profile cup.

Further investigation discovered that some products show an incorrect patient, product and barcode label (see attachment 1 - Group A) while others present only an incorrect Print On Demand (POD) label (see attachment 1 - Group B). There are also two batches that present both incorrect labels (see attachment 1 - Group C).

Our records indicate that you may have received one or more of the affected products from October 19<sup>th</sup> 2015 through November 9<sup>th</sup> 2015.

For reference purposes please see below the pictures of the incorrect (pictures 1, 3, 5) and the correct (picture 2, 4, 6) original M.E. Müller Low Profile cup labels.

 <p>REF 63.32.44    LOT 0123456789    </p> <p>Original M.E. Müller® Original M.E. Müller®, full profile cup, cemented, 44/32</p> <p>STERILE R    2023-10</p> <table border="1"> <tr> <td>CEMENTED</td> <td>CUP</td> <td>44/32</td> </tr> </table> <p>***H8446332441/233040123456789K155*** (FORMER CENTERPULSE)</p> <p>If this seal is broken, the product may not be returned for credit!</p> <p>Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician. UHMW Polyethylene (Sulene®-PE) ISO 5834-2 C.P. Titanium (Protasul®-Ti) ISO 5832-2</p> <p>***H8446332441/233040123456789K155***</p> <p> <b>CE</b> only 0086    STERILE R    2023-10    2015-11</p> <p>Zimmer GmbH, Sulzerallee 8, 8404 Winterthur, Switzerland</p> <p>REF 63.32.44    EDI: 633244 LOT 0123456789    Qty. 001 DE: Original M.E. Müller®, Pflanne Vollprofil, zementiert, 44/32 FR: Original M.E. Müller®, cupule à profil complet, cimenté, 44/32 IT: Original M.E. Müller®, coppa a profilo pieno, cementata, 44/32 ES: Original M.E. Müller®, cotilo de perfil completo, cementado, 44/32</p>	CEMENTED	CUP	44/32	 <p>REF 63.32.44    LOT 0123456789    </p> <p>Original M.E. Müller® Original M.E. Müller®, low profile cup, cemented, 44/32</p> <p>STERILE R    2023-10</p> <table border="1"> <tr> <td>CEMENTED</td> <td>CUP</td> <td>44/32</td> </tr> </table> <p>***H8446332441/233040123456789K155*** (FORMER CENTERPULSE)</p> <p>If this seal is broken, the product may not be returned for credit!</p> <p>Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician. UHMW Polyethylene (Sulene®-PE) ISO 5834-2 C.P. Titanium (Protasul®-Ti) ISO 5832-2</p> <p>***H8446332441/233040123456789K155***</p> <p> <b>CE</b> only 0086    STERILE R    2023-10    2015-11</p> <p>Zimmer GmbH, Sulzerallee 8, 8404 Winterthur, Switzerland</p> <p>REF 63.32.44    EDI: 633244 LOT 0123456789    Qty. 001 DE: Original M.E. Müller®, Pflanne Flachprofil, zementiert, 44/32 FR: Original M.E. Müller®, cupule à profil partiel, cimenté, 44/32 IT: Original M.E. Müller®, coppa a profilo basso, cementata, 44/32 ES: Original M.E. Müller®, cotilo de perfil bajo, cementado, 44/32</p>	CEMENTED	CUP	44/32
CEMENTED	CUP	44/32					
CEMENTED	CUP	44/32					
<p>Picture 1: incorrect product labels</p>	<p>Picture 2: correct product labels</p>						

<p>REF 63.32.44      EDI: 633244  <b>LOT 0123456789</b>      Qty: 001</p> <p>Original M.E. Müller® full profile cup, cemented, 44/32  Original M.E. Müller® Flanne Vollprofil, zementiert, 44/32  Original M.E. Müller® cupule à profil complet cimenté, 44/32  Original M.E. Müller® coppa a profilo pieno, cementata, 44/32  Original M.E. Müller® cápsula de perfil completo, cementado, 44/32</p> <p><b>STERILE R</b> 2023-10 2015-11</p> <p>Zimmer GmbH, Sulzerallee 8, 8404 Winterthur, Switzerland  (FORMER CENTERPULSE)</p>	<p>REF 63.32.44      EDI: 633244  <b>LOT 0123456789</b>      Qty: 001</p> <p>Original M.E. Müller® low profile cup, cemented, 44/32  Original M.E. Müller® Flanne Flachprofil, zementiert, 44/32  Original M.E. Müller® cupule à profil partiel, cimentée, 44/32  Original M.E. Müller® coppa a profilo basso, cementata, 44/32  Original M.E. Müller® cápsula de perfil bajo, cementado, 44/32</p> <p><b>STERILE R</b> 2023-10 2015-11</p> <p>Zimmer GmbH, Sulzerallee 8, 8404 Winterthur, Switzerland</p>
Picture 3: Incorrect barcode label	Picture 4: Correct barcode label

<p>REF 63.32.44      EDI: 633244  <b>LOT 0123456789</b>      Qty: 001</p> <p>Original M.E. Müller® full profile cup, cemented, 44/32  UHMW Polyethylene (Sulene®-PE) ISO 5834-2  C.P. Titanium (Protasul®-Ti) ISO 5832-2</p> <p><b>STERILE R</b> 2023-10 2015-11</p> <p>Zimmer GmbH, Sulzerallee 8, 8404 Winterthur, Switzerland</p>	<p>REF 63.32.44      EDI: 633244  <b>LOT 0123456789</b>      Qty: 001</p> <p>Original M.E. Müller® low profile cup, cemented, 44/32  UHMW Polyethylene (Sulene®-PE) ISO 5834-2  C.P. Titanium (Protasul®-Ti) ISO 5832-2</p> <p><b>STERILE R</b> 2023-10 2015-11</p> <p>Zimmer GmbH, Sulzerallee 8, 8404 Winterthur, Switzerland</p>
Picture 5: Incorrect patient label	Picture 6: Correct patient label

### Risk

- The implantation of the M.E. Müller Cup Low Profile cup instead of the intended M.E. Müller Cup Full Profile Cup is not associated with an increased risk to the patient.
- If the incorrect product is detected before the surgery, a slight delay in the surgery time could result in order to obtain another product.

### Your Responsibilities

1. Review the notification immediately and ensure affected personnel are aware of the contents without delay.
2. Assist your Zimmer Biomet sales representative with the quarantine of any device mentioned above.
3. Your Zimmer Biomet sales representative will remove the affected device, if any, from your facility.
4. Complete the Certification of Acknowledgement from (Attachment 2) and return to [fielddaction.emea@zimmerbiomet.com](mailto:fielddaction.emea@zimmerbiomet.com).
5. **If after reviewing this notification you have further questions or concerns please contact your local Zimmer Biomet representative.**



**Vigilance 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 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](mailto:winterthur.per@zimmerbiomet.com), or to your local Zimmer Biomet representative.

Kind regards,

..... Zimmer Biomet \_\_\_\_\_



### Attachement 1

Material	Batch	Device Name	Group
63.22.36	2828904	Original M.E. Mueller Low Profile Cup Sulene 22/36	A
63.22.38	2828915	Original M.E. Mueller Low Profile Cup Sulene 22/38	A
63.22.40	2830749	Original M.E. Mueller Low Profile Cup Sulene 22/40	A
63.22.42	2828916	Original M.E. Mueller Low Profile Cup Sulene 22/42	A
63.22.44	2828917	Original M.E. Mueller Low Profile Cup Sulene 22/44	A
63.22.48	2830750	Original M.E. Mueller Low Profile Cup Sulene 22/48	A
63.28.42	2828389	Original M.E. Mueller Low Profile Cup Sulene 28/42	A
63.28.42	2830751	Original M.E. Mueller Low Profile Cup Sulene 28/42	A
63.28.44	2830803	Original M.E. Mueller Low Profile Cup Sulene 28/44	A
63.28.46	2827478	Original M.E. Mueller Low Profile Cup Sulene 28/46	A
63.28.46	2829594	Original M.E. Mueller Low Profile Cup Sulene 28/46	A
63.28.48	2827465	Original M.E. Mueller Low Profile Cup Sulene 28/48	A
63.28.48	2830747	Original M.E. Mueller Low Profile Cup Sulene 28/48	A
63.28.50	2828395	Original M.E. Mueller Low Profile Cup Sulene 28/50	A
63.28.50	2830748	Original M.E. Mueller Low Profile Cup Sulene 28/50	A
63.28.52	2828396	Original M.E. Mueller Low Profile Cup Sulene 28/52	A
63.28.54	2830804	Original M.E. Mueller Low Profile Cup Sulene 28/54	A
63.28.56	2830805	Original M.E. Mueller Low Profile Cup Sulene 28/56	A
63.28.60	2828397	Original M.E. Mueller Low Profile Cup Sulene 28/60	A
63.32.44	2828398	Original M.E. Mueller Low Profile Cup Sulene 32/44	A
63.32.44	2830806	Original M.E. Mueller Low Profile Cup Sulene 32/44	A
63.32.44	2830807	Original M.E. Mueller Low Profile Cup Sulene 32/44	A
63.32.44	2832541	Original M.E. Mueller Low Profile Cup Sulene 32/44	A
63.32.46	2828399	Original M.E. Mueller Low Profile Cup Sulene 32/46	A
63.32.46	2828415	Original M.E. Mueller Low Profile Cup Sulene 32/46	A
63.32.46	2828416	Original M.E. Mueller Low Profile Cup Sulene 32/46	A
63.32.46	2830808	Original M.E. Mueller Low Profile Cup Sulene 32/46	A
63.32.46	2830809	Original M.E. Mueller Low Profile Cup Sulene 32/46	A
63.32.46	2832542	Original M.E. Mueller Low Profile Cup Sulene 32/46	A
63.32.48	2827462	Original M.E. Mueller Low Profile Cup Sulene 32/48	A
63.32.48	2828417	Original M.E. Mueller Low Profile Cup Sulene 32/48	A
63.32.48	2829806	Original M.E. Mueller Low Profile Cup Sulene 32/48	A
63.32.48	2830796	Original M.E. Mueller Low Profile Cup Sulene 32/48	A
63.32.50	2828418	Original M.E. Mueller Low Profile Cup Sulene 32/50	A
63.32.50	2828419	Original M.E. Mueller Low Profile Cup Sulene 32/50	A
63.32.50	2829807	Original M.E. Mueller Low Profile Cup Sulene 32/50	A
63.32.50	2830798	Original M.E. Mueller Low Profile Cup Sulene 32/50	A
63.32.50	2830799	Original M.E. Mueller Low Profile Cup Sulene 32/50	A

Material	Batch	Device Name	Group
63.32.52	2827463	Original M.E. Mueller Low Profile Cup Sulene 32/52	C
63.32.52	2828431	Original M.E. Mueller Low Profile Cup Sulene 32/52	A
63.32.52	2828432	Original M.E. Mueller Low Profile Cup Sulene 32/52	A
63.32.52	2830800	Original M.E. Mueller Low Profile Cup Sulene 32/52	A
63.32.52	2830801	Original M.E. Mueller Low Profile Cup Sulene 32/52	A
63.32.54	2827464	Original M.E. Mueller Low Profile Cup Sulene 32/54	A
63.32.54	2828430	Original M.E. Mueller Low Profile Cup Sulene 32/54	A
63.32.54	2830802	Original M.E. Mueller Low Profile Cup Sulene 32/54	A
63.32.56	2827468	Original M.E. Mueller Low Profile Cup Sulene 32/56	C
63.32.56	2830815	Original M.E. Mueller Low Profile Cup Sulene 32/56	A
63.32.58	2830816	Original M.E. Mueller Low Profile Cup Sulene 32/58	A
63.32.60	2832543	Original M.E. Mueller Low Profile Cup Sulene 32/60	A
63.28.44	2822044	Original M.E. Mueller Low Profile Cup Sulene 28/44	B
63.28.46	2822050	Original M.E. Mueller Low Profile Cup Sulene 28/46	B
63.28.48	2818949	Original M.E. Mueller Low Profile Cup Sulene 28/48	B
63.28.48	2822549	Original M.E. Mueller Low Profile Cup Sulene 28/48	B
63.28.50	2818251	Original M.E. Mueller Low Profile Cup Sulene 28/50	B
63.28.50	2822555	Original M.E. Mueller Low Profile Cup Sulene 28/50	B
63.28.52	2813783	Original M.E. Mueller Low Profile Cup Sulene 28/52	B
63.28.52	2822895	Original M.E. Mueller Low Profile Cup Sulene 28/52	B
63.28.54	2825076	Original M.E. Mueller Low Profile Cup Sulene 28/54	B
63.28.54	2819199	Original M.E. Mueller Low Profile Cup Sulene 28/54	B
63.28.56	2808999	Original M.E. Mueller Low Profile Cup Sulene 28/56	B
63.28.58	2809000	Original M.E. Mueller Low Profile Cup Sulene 28/58	B
63.28.62	2823628	Original M.E. Mueller Low Profile Cup Sulene 28/62	B
63.32.44	2822042	Original M.E. Mueller Low Profile Cup Sulene 32/44	B
63.32.44	2822882	Original M.E. Mueller Low Profile Cup Sulene 32/44	B
63.32.46	2582815	Original M.E. Mueller Low Profile Cup Sulene 32/46	B
63.32.46	2827466	Original M.E. Mueller Low Profile Cup Sulene 32/46	B
63.32.46	2825078	Original M.E. Mueller Low Profile Cup Sulene 32/46	B
63.32.48	2822556	Original M.E. Mueller Low Profile Cup Sulene 32/48	B
63.32.48	2825820	Original M.E. Mueller Low Profile Cup Sulene 32/48	B
63.32.48	2821497	Original M.E. Mueller Low Profile Cup Sulene 32/48	B
63.32.50	2822560	Original M.E. Mueller Low Profile Cup Sulene 32/50	B
63.32.50	2825063	Original M.E. Mueller Low Profile Cup Sulene 32/50	B
63.32.50	2825821	Original M.E. Mueller Low Profile Cup Sulene 32/50	B
63.32.50	2822558	Original M.E. Mueller Low Profile Cup Sulene 32/50	B
63.32.50	2822559	Original M.E. Mueller Low Profile Cup Sulene 32/50	B
63.32.52	2580788	Original M.E. Mueller Low Profile Cup Sulene 32/52	B
63.32.52	2822570	Original M.E. Mueller Low Profile Cup Sulene 32/52	B



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Material	Batch	Device Name	Group
63.32.52	2822564	Original M.E. Mueller Low Profile Cup Sulene 32/52	B
63.32.54	2580790	Original M.E. Mueller Low Profile Cup Sulene 32/54	B
63.32.54	2822574	Original M.E. Mueller Low Profile Cup Sulene 32/54	B
63.32.54	2822575	Original M.E. Mueller Low Profile Cup Sulene 32/54	B
63.32.54	2825822	Original M.E. Mueller Low Profile Cup Sulene 32/54	B
63.32.56	2822886	Original M.E. Mueller Low Profile Cup Sulene 32/56	B



ZIMMER BIOMET

## Attachement 2 Certificate of Acknowledgement

FSN/FSCA: FA 2015-09

**Affected Product: Original M.E. Müller® Low Profile cup**

Please email or fax the completed form to your local Zimmer Biomet contact

Fax / Email \_\_\_\_\_ / \_\_\_\_\_

By signing below, I acknowledge that I have received and understand the content of the Urgent Field Safety Notice – Removal, and that the required actions have been taken in accordance with the notice.

Printed Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Hospital Name: \_\_\_\_\_

Hospital Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

**Please maintain a copy of your completed form with your internal records.**

ZFA 2015-159