Aesculap AG
Quality Management

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Date: October 24, 2017

Safety Notice – Product Recall

NR485K - COLUMBUS REV FEMUR SPACER DISTAL F5 15MM – BATCH 51468773 | 51577362
NR486K - COLUMBUS REV FEMUR SPACER DISTAL F6 15MM – BATCH 51447588 | 51503765 | 51586632
NR487K - COLUMBUS REV FEMUR SPACER DISTAL F7 15MM – BATCH 51447589 | 51468302
NR585K - COLUMBUS REV FEMUR SPACER POST.F5 15MM – BATCH 51447595 | 51503760 | 51589205
NR586K - COLUMBUS REV FEMUR SPACER POST.F6 15MM – BATCH 51447596 | 51571394 | 51586634
NR587K - COLUMBUS REV FEMUR SPACER POST.F7 15MM – BATCH 51447597 | 51585136

As part of the continuous product improvement, the dimensions of the above articles have been modified as follows.

The following figure shows the difference between the initial and the modified version of the component.

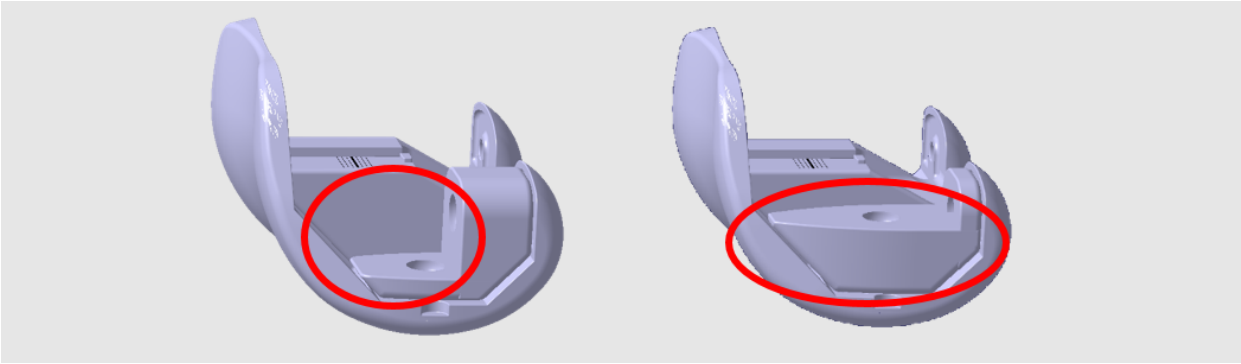

Figure 1: Difference between the initial and the modified version of the Columbus® Revision implant

The modified version of the articles is not compatible with the components of the previous version of the **Columbus® Revision System**.
According to our research, your facility has received affected articles from the **Columbus® Revision System**.

The joint application of both versions can result in intraoperative removal of more bone material than necessary. As a result, more bone cement has to be used than planned, which can lead to a early loosening of the prosthesis. To date, we have not received any market feedback on such incident.

Our investigations have shown that the articles which are affected, can be limited to the above mentioned batches.
The affected implants can clearly be identified by comparing the batch numbers.

Please ensure that the affected implant components are no more used.

Should you have an affected product, please return it with the attached "**Product Recall Form**" to

Aesculap AG
LRP
Siegfried Schwarz
Am Aesculap–Platz
D-78532 Tuttlingen
vigilance_aag.de@aesculap.de

For any product-related request, kindly do not hesitate to contact our product manager:

Denis Hoeffgen
☎ + 49 7461 95 1785
☎ + 49 151 12635913
denis.hoeffgen@aesculap.de

In the case you do not have any of the affected products, please send us the attached "**Feedback Form**" and tick as appropriate.

Please ensure in your organization that all users of the affected devices are informed about this safety information. If you have distributed the products to a third party, please forward a copy of this information or inform the above mentioned contact person. The Competent Authority BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte, has received a copy of this safety information.

We apologize for any inconvenience this may cause and thank you very much for your support.

With best regards,

Aesculap AG

i.A.

Kerstin Rothweiler
Team Leader Quality Management Vigilance
Dpt. Safety Officer Medical Device

i.A.

Miriam Hoßfeld
Quality Management Vigilance
Vigilance Manager

FEEDBACK FORM / FSCA

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Please sent back this feedback form via fax or e-mail to:

Department QMV

Fax +49 7461-95 1555

vigilance_aag.de@aesculap.de

☐ We have no affected products.

☐ We will return the affected products.

☐ The affected products were successfully implanted.

HOSPITAL _____ LOCATION _____

NAME _____ DEPARTMENT _____ PHONE _____

SIGNATURE _____ DATE _____

PRODUCT RECALL

Hygienic condition: ☐ new good ☐ used decontaminated ☐ used not decontaminated

pos. no.	part no. article no.	serial / lot-no.	quantity	remark		

RETURN ADRESS :

Aesculap AG
LRP
Siegfried Schwarz
Am Aesculap–Platz
D-78532 Tuttlingen – Germany

ADRESS / SENDER:

DATE / SIGNATURE :