**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 5147596 | 5171394 | 5158634  
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
Please send 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

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## RETURN ADDRESS:
Aesculap AG  
LRP  
Siegfried Schwarz  
Am Aesculap–Platz  
D–78532 Tuttlingen – Germany

## ADDRESS / SENDER:

## DATE / SIGNATURE:

Chairman of Supervisory Board:
Prof. Dr. h.c. Ludwig Georg Braun

Executive Board:
Dr. Joachim Schulz  
(Chairman)  
Dr. Jens von Lackum

Corporate Office: Tuttlingen  
Register Court: Stuttgart HRB 72861  
VAT reg. no. DE812160059  
WEEE-Reg.-No. DE 65109852

Bank Account:
Deutsche Bank AG Tuttlingen  
BLZ 653 700 75 Konto 21 22 000 00  
IBAN DE84 6537 0075 0212 0000 00  
SWIFT / BIC DEUTDESS653

Baden-Württembergische Bank  
BLZ 600 501 01 Konto 487 1905  
IBAN DE05 6005 0103 0004 8719 05  
SWIFT / BIC SOLADEST

Address:
Aesculap AG  
Am Aesculap–Platz  
78532 Tuttlingen  
Germany