

**Aesculap AG  
Quality Management**

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Date: October 27, 2016

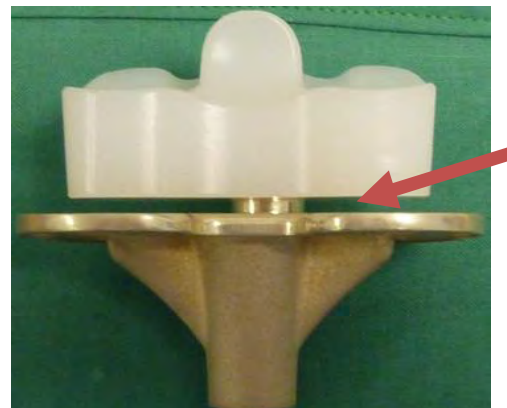
**Safety Notice – Product Recall**

**E.MOTION PS PRO MENISCAL COMPONENT F3L 20MM  
NX853 – Lot 51904621**

We were informed that the Meniscal Component, NX853, E.MOTION PS PRO MENISCAL COMPONENT F3L 20MM, could not be placed completely on a Tibia Plateau (see figures), during a surgery.



**Figure 1: Correctly assembled**



**Figure 2: Incorrectly assembled**

The initiated investigation resulted in the indication of a measurement deviation, caused by a singular failure within the production process.

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

**Executive Board:**  
Prof. Dr. Hanns-Peter Kraebel  
(Chairman)  
Dr. Jens von Lackum  
Dr. Joachim Schulz

**Corporate Office: Tuttlingen**  
Register Court: Stuttgart HRB 726261  
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 DE44 6537 0075 0212 2000 00  
SWIFT / BIC DEUTDE33  
**Baden-Württembergische Bank**  
BLZ 600 501 01 Konto 487 1905  
IBAN DE31 6005 0101 0004 8719 05  
SWIFT / BIC SOLADEST

**Address:**  
Aesculap AG  
Am Aesculap-Platz  
78532 Tuttlingen  
Germany

The deviation could exclusively be traced back to article No. NX853, lot 51904621.

Those implants cannot be used, since the resulting compartmental space would be too high, thus collateral ligaments would be stressed too much. This is why we decided to recall the affected products.

Please make sure that any user of the above mentioned product and any other person who should be informed within your organization, will take note of this safety information.

If you have forwarded the involved product to a third party, please provide a copy of this information to this party and also note Aesculap AG about this.

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

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

**Aesculap AG**  
**QMV**  
**Ms Mireille Suzy Eze**  
**Am Aesculap-Platz**  
**D-78532 Tuttlingen**

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

**Ms Brigitte Altermann**  
**☎ + 49 7461-95 1526**  
**☎ + 49 175 278 6784**  
**brigitte.altermann@aesculap.de**

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

With best regards,

Aesculap AG

[REDACTED]

[REDACTED]

**FEEDBACK FORM / FSCA**  
**E.MOTION PS PRO MENISCAL COMPONENT F3L 20MM**  
**(Batch 51904621)**

Please return this form by fax or e-mail to:

**Mireille Suzy Eze/ Department QMV**

**Fax +49 7461-95 1555**

**vigilance\_aag.de@aesculap.de**

Please tick as appropriate:

We do not have any of the affected products.

HOSPITAL \_\_\_\_\_ TOWN \_\_\_\_\_

NAME \_\_\_\_\_ DEPARTMENT \_\_\_\_\_ PHONE \_\_\_\_\_



## PRODUCT RECALL

Hygienic condition:

new good

used decontaminated

used not decontaminated

pos. no.	part no. article no.	serial / lot-no.	quantity	remark	expection	
					replacement of product	credit note
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>

### RETURN ADDRESS :

Aesculap AG  
QMV  
Ms Mireille Suzy Eze  
Am Aesculap-Platz  
D-78532 Tuttlingen – Germany

### ADDRESS / SENDER:

### DATE / SIGNATURE :

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(Chairman)  
Dr. Jens von Lackum  
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