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.
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
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

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**RETURN ADRESS:**
Aesculap AG
QMV
Ms Mireille Suzy Eze
Am Aesculap-Platz
D-78532 Tuttlingen – Germany

**ADDRESS / SENDER:**

**DATE / SIGNATURE:**