Dear Sirs,

Within biomechanical testing Aesculap AG has identified that the S4 Cervical Cross Connectors (in the sizes listed above) show a reduced clamping force.

The products are recalled preventively, according to the current state of knowledge there is no acute danger for patients, users and third parties.

The S4 Cervical Cross Connectors are optional implant components of the S4 Cervical System supporting the overall stability when applied.
Due to the error pattern, the cross connector may migrate on the rods. A complete detachment is impossible. The additional rotational stability applied by the connector cannot be guaranteed in all cases.

To date, we are not aware of any effects on the clinical performance or incidents which apply to S4 Cervical Cross Connectors. Already implanted products do not need to be revised as a precautionary measure.

Aesculap AG is recalling the named product as a preventive action for the reasons given above.

According to our information you have received articles of the product concerned. Please check whether the products have been used in your institution.

In case you return the product, please enclose the return form "Product Recall" and address the shipment to:

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

In this case you will receive a credit note from us for all products you have purchased.

Your responsible sales specialist will inform you as soon as the cross connectors are available again.

In case you could not locate any affected product:

If you do not have any of the involved products, please send us the attached "Feedback Form" and tick the boxes as appropriate.
For questions related to the product and for further processing, our product management is at your disposal. Please contact:

Tamara Leder or Wolfgang Daiber
Tel.: +49 7461 95 - 31261 Tel.: + 49 7461 95-1505
E-Mail: tamara.leder@aesculap.de E-Mail: wolfgang.daiber@aesculap.de

Please ensure that all users of the affected product are informed about this safety information in your organization. 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 Federal Institute for Drugs and Medical Devices 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.V. i.A.

Georg Erhard Christian von der Grün
Safety Officer Medical Devices Head of Vigilance and Reporting
FEEDBACK FORM / FSCA 246
SW112T – S4C CROSS CONNECTOR FIXED 22MM
SW113T – S4C CROSS CONNECTOR FIXED 24MM
SW114T – S4C CROSS CONNECTOR FIXED 26MM
SW115T – S4C CROSS CONNECTOR VARIABLE 28–33MM
SW116T – S4C CROSS CONNECTOR VARIABLE 33–42MM
SW117T – S4C CROSS CONNECTOR VARIABLE 42–58MM

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

Department QMV / Recall Coordinator: [Hier eingeben] / [Hier eingeben]
Fax: +49 7461–95 1555
E-Mail: vigilance_aag.de@aeculap.de

Affected products were located on stock and will be returned.

☐ Yes ☐ No  Comment: __________________________________________
Quantity to return: __________

Affected products were implanted.

☐ Yes ☐ No  Comment: __________________________________________
Quantity implanted: __________

Vorsitzender des Aufsichtsrates:
Prof. Dr. Heinz-Walter Gruße

Verantwortlich:
Dr. Joachim Schulz
(Direktor)

Stelle: Vorsitzende
Dr. Jens vom Luckum

Sitze der Gesellschafts: Tuttingen
Reg. Gericht: Stuttgart HRB 730261
USG. O-Nr. DE812100059
WELT-Reg.-Nr. DE 65/109852

Bankverbindungen:
Deutsche Bank AG Tuttingen
BLZ 605 700 79 Konti 21 22 000 00
IBAN DE44 6057 7007 9212 2200 00
SWIFT / BIC DEUTDESS563

Rhein-Pfalz-Nagelbank
BLZ 605 501 01 Konti 497 1905
IBAN DE31 6057 0101 0004 8713 60
SWIFT / BIC SOALDE61

Hauptsitz:
Aesculap AG
Am Aesculap-Platz
72632 Tuttingen
Deutschland

Gesellschaftsform:
Aktiengesellschaft

Registergericht:
Stuttgart HRB 730261

Stelle der Gesellschaft:
Reg.-Nr. DE 65/109852

Bankverbindung:
Deutsche Bank AG Tuttingen
BLZ 605 700 79 Konti 21 22 000 00
IBAN DE44 6057 7007 9212 2200 00
SWIFT / BIC DEUTDESS563

Rhein-Pfalz-Nagelbank
BLZ 605 501 01 Konti 497 1905
IBAN DE31 6057 0101 0004 8713 60
SWIFT / BIC SOALDE61

Hauptsitz:
Aesculap AG
Am Aesculap-Platz
72632 Tuttingen
Deutschland
<table>
<thead>
<tr>
<th>pos. no.</th>
<th>part no.</th>
<th>article no.</th>
<th>serial / lot-no.</th>
<th>quantity</th>
<th>remark</th>
</tr>
</thead>
</table>

**PRODUCT RECALL**

- [ ] used not decontaminated
- [ ] used decontaminated

**RETURN ADDRESS:**

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

**ADDRESS / SENDER:**

**DATE / SIGNATURE:**