



Aesculap AG
Quality Management

Postfach 40
78501 Tuttlingen
Deutschland

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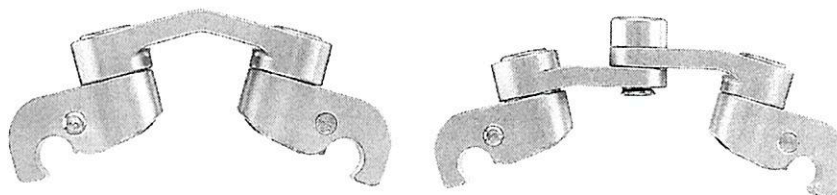
E-Mail: vigilance_aag.de@aesculap.de

Internet: <http://www.aesculap.de>

Datum: 09. Juli 2020

Safety Information – Product recall

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



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.

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

Vorstand:
Dr. Joachim Schulz
(Vorsitzender)
Dr. Jens von Lackum
(Stellv. Vorsitzender)
Dr. Katrin Sternberg

Sitz der Gesellschaft: Tuttlingen
Reg. Gericht: Stuttgart HRB 726261
USt. Id.-Nr. DE812160059
WEEE-Reg.-Nr. DE 65109852

Bankverbindungen:
Deutsche Bank AG Tuttlingen
BLZ 653 700 75 Konto 21 22 000 00
IBAN DE 44 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

Hausanschrift:
Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
Deutschland

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.

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78532 Tuttlingen
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For questions related to the product and for further processing, our product management is at your disposal. Please contact:

Tamara Leder
Tel.: +49 7461 95 - 31261
E-Mail: tamara.leder@aesculap.de

or

Wolfgang Daiber
Tel.: + 49 7461 95-1505
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,

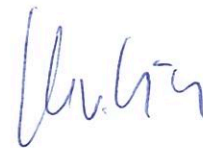
Aesculap AG

i.V.



Georg Erhard
Safety Officer Medical Devices

i.A.



Christian von der Grün
Head of Vigilance and Reporting

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FEEDBACK FORM / FSCA 246

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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@aesculap.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: _____

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HOSPITAL _____

LOCATION _____

NAME _____

DEPARTMENT _____

PHONE _____

SIGNATURE _____

DATE _____

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PRODUCT RECALL

Hygienic condition:

new good

used decontaminated

used not decontaminated

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

RETURN ADDRESS :

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

ADRESS / SENDER:

DATE / SIGNATURE :