

Ansprechpartner: Miriam Hossfeld

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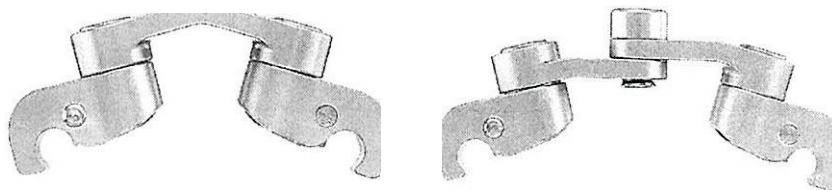
E-Mail: [vigilance\\_aag.de@aesculap.de](mailto:vigilance_aag.de@aesculap.de)

Internet: [http:// www.aesculap.de](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 Sir s,

Within biomechanical testing Aesculap AG has identified that the 54 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 54 Cervical Cross Connectors are optional implant components of the 54 Cervical System supporting the overall stability when applied.

Vorsitzender des Aufsichtsrats:  
Prof. Dr. Heinz-Walter Grob

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

Sitz der Gesellschaft: Tuttlingen  
Reg. Gericht: Stuttgart HRB 726261  
USt. Id.-Nr.: DEB12160059

WEEE-Reg.-Nr. DE 65109852

**Bankverbindungen:**  
**Deutsche Bank AG Tuttlingen**  
BIC: 6S370075 Konto 21 22 000 00  
IBAN DE 44 6537 0075 0212 2000 00  
SWIFT / BIC: DEUTDE33HAN33  
**Baden-Württembergische Bank**  
BLZ 600 501 01 Konto 487 1905  
IBAN DE31 6005 01010004 8719 05  
SWIFT / BIC: SOLADE33

**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.

Vorsitzender des Aufsichtsrats;  
Prof. Dr. Heinz-Walter Grob

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

**Sitz der Gesellschaft:** Tuttlingen  
Reg. Gericht: Stuttgart HRB 726261  
USt. Id.-Nr. OE812160059

WEEE-Reg.-Nr. OE 6 5109852

**Bankverbindungen:**  
**Oeutsche Bank AG** Tuttlingen  
BLZ 653 700 75 Konto 21 2200000  
IBAN DE 44 6537 0075 0212 2000 00  
SWIFT / BIC OEUTDE33

Baden-Württembergische Bank  
BLZ 600 501 01 Konto 487 1905  
IBAN OE31 600501010004 8719 05  
SWIFT / SIC SOLADEST

Hausanschrift:  
Aesculap AG  
Am Aesculap-Platz  
78532 Tuttlingen  
Deutschland

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.

XXX

i.A.

XXX

**Vorsitzender des Aufsichtsrates:**  
Prof. Dr. Heinz-Walter GroOc

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Dr. Joachim Schulz  
(Vorsitzender)  
Dr. Jens van Iackum  
(Stellv. Vorsitzender)  
Dr. Kattin Sternberg

Sitz der Gesellschaft: Tuttlingen  
Reg. Gericht: Stuttgart HR8 726261  
USt. Id.-Nr. DEB12160059

WEEE-Reg.-Nr. DE 65109852

**Bankverbindungen:**  
**Deutsche Bank AG Tuttlingen**  
BIZ 6 53 700 75 Konto 21 22 000 00  
IBAN DE 44 6537 0075 0212 2000 00  
SWIFT/BIC DEUTDE33  
**Baden-Württembergische Bank**  
BIZ 600 50 1 01 Konto 487 1905  
IBAN DE 51 6005 0101 00048719 05  
SWIFT/BIC SOLADEST

**Hausanschrift:**  
Aesculap AG  
Am Aesculap-Platz  
78532 Tuttlingen  
Deutschland

## FEEDBACKFORM/FSCA246

SW112T - S4C CROSS CONNECTOR FIXED 22MM  
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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](mailto: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: \_\_\_\_\_

Vorsitzender des Aufsichtsrates:  
Prof. Dr. Heinz-Walter Grol3c

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:  
Oesterreichische Bank AG Tuttingen  
BLZ 653 700 75 Konto 21 22 000 00  
IBAN DE 44 6537 0075 0212 2000 00  
SWIFT / BIC OESB3333  
Baden - Württembergische Bank  
BLZ 600 501 01 Konto 487 1905  
IBAN OEJL 6005 0101 00048719 OS  
SWIFT / BIC SDLADEST

Hausanschrift:  
Aesculap AG  
Am Aesculap-Platz  
78532 Tuttlingen  
Deutschland

# BIBRAUN

Seite 5 zum Schreiben vom 09. Juli 2020

HOSPITAL \_ \_ \_ \_ \_

LOCATION - - - - -

NAME \_\_\_\_\_

DEPARTMENT \_ \_ \_ \_ \_

PHONE \_ \_ \_ \_ \_

SIGNATURE - - - - -                      DATE - - - - -

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

**Vorstand:**  
Or. Joachim Schulz  
**(Vorsitzender)**  
Or. Jens von Luckum  
**(Stellv. Vorsitzender)**  
Or. Katrin Steinhilber

Sitz der Gesellschaft : Tuttlingen  
Reg. Gericht: Stuttgart HRB726261  
USt. Id.- Nr. OE812160059  
  
WEEE- Reg.- Nr. DE 65109852

**Bankverbindungen:**  
**Deutsche Bank AG** Tuttlingen  
BLZ 653 700 75 Konto 2122 000 00  
18 AN DE 44 6537 0075 0212 2000 00  
SWIFT / BIC DEUTDE33  
**Baden-Württembergische Bank**  
BLZ 600 501 01 Konto 487 1905  
IBAN DE 31 6005 0101 0004 8719 05  
SWIFT / SIC SOLADES1

**Hausanschrift:**  
Aesculap AG  
Am Aesculapplatz  
78532 Tuttlingen  
Deutschland



## PRODUCT RECALL

Hygienic condition:

new good

used decontaminated

used not decontaminated

pos. no.	part no. article no.	serial / lot-no.	quantity	remark
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### RETURN ADDRESS :

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

ADRESS / SENDER:

DATE / SIGNATURE: