

**Aesculap AG
Quality Management**

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78501 Tuttlingen
Germany

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Email:

vigilance_aag.de@aesculap.de

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<http://www.bbraun.com>

Date:

September 26, 2019

Safety Notice – Product Recall

SW202T – S4C OCCIPITAL PLATE SMALL 5 HOLES



Based on market feedback, it has been established that the connectors of the S4C OCCIPITAL PLATE SMALL 5 HOLES were incorrectly assembled during the manufacturing process..

The OCCIPUT PLATE is used together with a posterior cervical screw-rod system to fix the occipital bone to the cervical spine. The defect can be detected by the user prior to implantation or, at the latest, when the rods are inserted into the plate's connectors.

It was possible to limit the affected articles to the S4 Cervical OCCIPUT PLATE with article number SW202T and batch number 52433451. Aesculap AG has decided to recall the product as a precaution.

According to internal distribution tracking, you received articles of the affected product. Please check whether such products are in use at your facility. Identification can be clearly made using the label on the packaging or the marking on the implant itself (see Figure 1 REF and LOT encircled in red).

Due to the deviation from the product specification, an intraoperative exchange of the affected plate may become necessary and lead to an extension of the surgical time. The manufacturer recommends having four different sizes on the set, which should generally provide a replacement plate.



Fig. 1: OCCIPUT plate – batch 52433451

Chairman of Supervisory Board:
Prof. Dr. Heinz-Walter Große

Executive Board:
Dr. Joachim Schulz
(Chairman)
Dr. Jens von Lackum
(Deputy Chairman)
Dr. Katrin Sternberg

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

In case you have located an affected product at your facility, please return the product using the "Product Recall Form" to:

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

If you return a product to us, we will send you a credit note.

In case you could not locate any affected product:

In the case you **do not have** an involved product, please send us the attached "**Feedback Form**" and tick as appropriate.

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

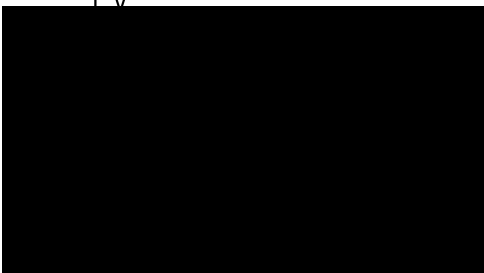
**Aesculap AG
DSI
Tamara Leder
Am Aesculap-Platz
D-78532 Tuttlingen
Tel.: +49 7461 95-31261**

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 Competent Authority BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte, has received a copy of this safety information.

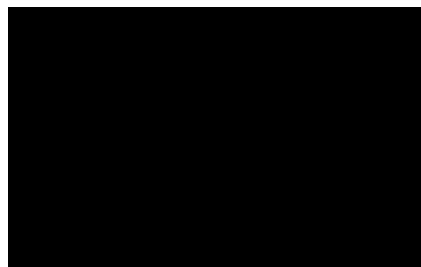
We apologize for any inconvenience these measures may cause and thank you very much for your support.

With best regards,
Aesculap AG

i. V.



i. A.



FEEDBACK FORM / FSCA
SW202T – S4C OCCIPITAL PLATE SMALL 5 HOLES
BATCH 52433451

Please send back this feedback form via fax or e-mail to:

Department QMV

Fax +49 7461-95 1555

vigilance_aag.de@aesculap.de

We do not have affected product(s).

We will return affected product(s).

HOSPITAL _____ LOCATION _____

NAME _____ DEPARTMENT _____ PHONE _____

SIGNATURE _____

DATE _____



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 :

Chairman of Supervisory Board:
 Prof. Dr. Heinz-Walter Große

Executive Board:
 Dr. Joachim Schulz
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 Dr. Jens von Lackum
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Baden-Württembergische Bank
 BLZ 600 501 01 Konto 487 1905
 IBAN DE31 6005 0101 0004 8719 05
 SWIFT / BIC SOLADEST

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 Am Aesculap-Platz
 78532 Tuttlingen
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