

**Aesculap AG  
Quality Management**

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Date: 11/09/2015

**Field Safety Corrective Action – Product Recall**

**Product: SJ607R, SJ706R, SJ723R  
– all batches**

**Product Description: FLEXIBLE BONE AWL; FLEXIBLE SCREW DRIVER;  
FLEXIBLE DRILL**

We have received reports from the market about defective flexible instruments used in lumbar spine stabilisation surgery. Parts of the flexible stem of the instruments can break intraoperatively. It cannot be ruled out that fragments may enter the surgical site and not be able to be recovered during the procedure. An increased risk for the patient cannot be ruled out in such a case.



**Picture1: SJ607R– Flexible Bone Awl**

**Chairman of Supervisory Board:**  
Prof. Dr. h.c. Ludwig Georg Braun

**Executive Board:**  
Prof. Dr. Hanns-Peter Knaebel  
(Chairman)  
Dr. Dirk Freund  
Dr. Joachim Schulz

**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



***Picture 2: SJ706R-Flexible Screw Driver***



***Picture 3: SJ723R- Flexible Drill***

By way of precaution, it has been decided to implement a product recall for all affected batches of the three flexible instruments.

Please send the affected articles from the set of Arcadius intervertebral implant' instruments in your possession together with the enclosed return form to:

**Aesculap AG**  
**Gebäude 12 – Abteilung QMV / Produktrückruf**  
**Kerstin Rothweiler**  
**Am Aesculap-Platz**  
**78532 Tuttlingen**

If you do not have any affected products in use at your hospital, please confirm this on the enclosed response form.

If you have any questions concerning this Field Safety Corrective Action, please contact our product management for spine surgery:

**Mr. Oliver Baumann**  
**Tel: + 49 7461 95- 31524**  
**Fax: + 49 7461 95- 1233**  
**E-Mail: [oliver.baumann@aesculap.de](mailto:oliver.baumann@aesculap.de)**

Please notify all users of the above product and any other persons who need to be informed within your organization about this FSCA. If you have provided the products to third parties, please forward a copy of this information to them or inform the contact person named below.

Please retain this information until the action is closed.

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Please accept our apologies for the inconvenience caused by this action.

Kind regards,

Aesculap AG

Thorsten Barthelmes  
Safety Officer Medical Devices  
Quality Management Vigilance

Kerstin Rothweiler  
Dpt. Safety Officer Medical Devices  
Quality Management Vigilance

**FEEDBACK FORM / FSCA**  
**ARCADIUS FLEXIBLE INSTRUMENTS: SJ607R, SJ706R, SJ723R**

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

**Kerstin Rothweiler / 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 in use.

HOSPITAL \_\_\_\_\_ TOWN \_\_\_\_\_

NAME \_\_\_\_\_ DEPARTMENT \_\_\_\_\_ PHONE \_\_\_\_\_

SIGNATURE \_\_\_\_\_

DATE \_\_\_\_\_