Aesculap AG
Quality Management

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Date: 11/09/2015

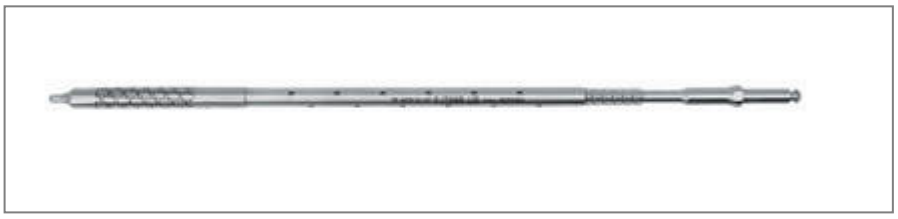
Field Safety Corrective Action – Product Recall

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

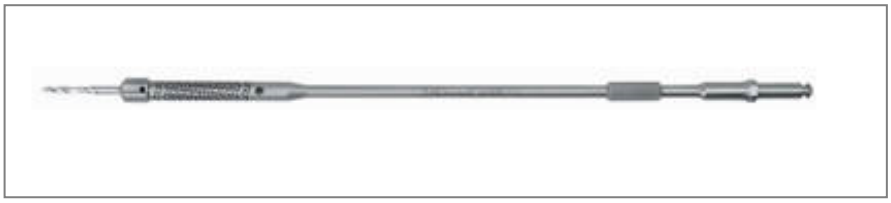
Product Description: **FLEXIBLE BONE AWL; FLEXIBLE SCREW DRIVER; FLEXIBLE DRILL**

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



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

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.

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 _____