Aesculap AG
Quality Management

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Date: 09. August 2017

Safety Notice – Product Recall

FJ402R - CESPACE PEEK TRIAL IMPLANT 5° 16X12MM ANAT. ORDER-NO. 52230271

You are using in your facility instruments from the CeSPACE® PEEK System of the Aesculap AG. During the production process of one production unit, the CeSPACE® PEEK Trial implant 5° 16x12mm was labelled with an incorrect size on the caudal side of handle.

One order of the Trial implant FJ402R with the size 12-5° was falsely labelled with "10-5° caudal" on the caudal side of the handle. The other labels on the instrument are correct

The following picture shows the incorrect labelling.

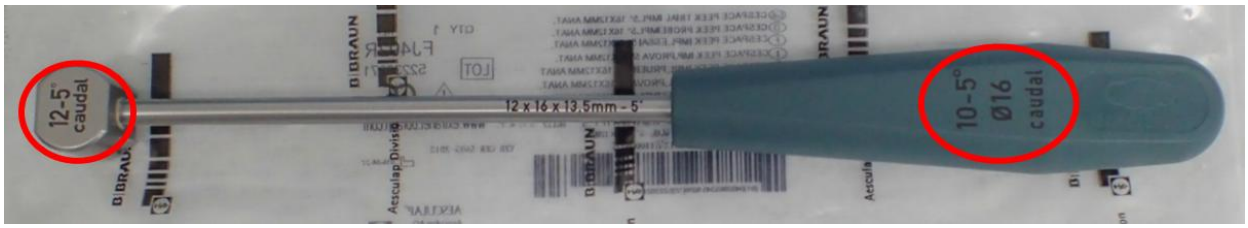

Figure 1: CeSPACE® PEEK Trial implant with incorrect labelling on handle

Our investigations have shown that the incorrect labelling can be limited to FJ402R and to Order-No. 52230271.

Trial implants with incorrect labeling can be identified by comparing cranial and caudal side.

If the Trial implant with the incorrect labelling was used and the error was not noticed, this could result in the implantation of a too small implant.

Please make sure not to continue using the affected device.

Should you have an affected product, please return it with the attached "**Product Recall Form**" to

Aesculap AG
LRP
Siegfried Schwarz
Am Aesculap–Platz
D-78532 Tuttlingen
vigilance_aag.de@aesculap.de

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

Oliver Baumann
☎ + 49 7461 95 31524
☎ + 49 151 12620739
oliver.baumann@aesculap.de

In the case you do not have any of the affected products, please send us the attached "**Feedback Form**" and tick as appropriate.

Please ensure in your organization and third party that all users of the affected devices be informed about this safety information. 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 this may cause and thank you very much for your support.

With best regards,

Aesculap AG

i.A. Kerstin Rothweiler
Team Leader Quality Management Vigilance
Dpt. Safety Officer Medical Device

i.A. Christian Strobel
Quality Management Vigilance
Vigilance Manager

FEEDBACK FORM / FSCA
CESPACE PEEK TRIAL IMPLANTAT 5° 16X12MM ANAT.
ORDER-NO. 52230271

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

Christian Strobel / Department QMV

Fax +49 7461-95 1555

vigilance_aag.de@aesculap.de

☐ We have no affected products in the application.

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	expection	
					replacement of product	credit note
					☐	☐
					☐	☐
					☐	☐
					☐	☐
					☐	☐

RETURN ADRESS :

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

ADRESS / SENDER:

DATE / SIGNATURE :