Aesculap AG Quality Management

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Christian Strobel

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Date:

09. August 2017

<u>Safety Notice – Product Recall</u>

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.

Chairman of Supervisory Board: Prof. Dr. h.c. Ludwig Georg Braun **Executive Board:** Dr. Joachim Schulz (Chairman) Dr. Jens von Lackum 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 DEUTDESS653

 Baden-Württembergische Bank

 BLZ 600 501 01 Konto 487 1905

 IBAN DE41 6005 0101 0004 8719 05

 SWIFT / BIC SOLADEST

Address: Aesculap AG Am Aesculap-Platz 78532 Tuttlingen Germany Page 2 to the letter of August 09, 2017

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 2 + 49 7461 95 31524 2 + 49 151 12620739 <u>oliver.baumann@aesculap.de</u>

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 Page 3 to the letter of August 09, 2017

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 ______ PHONE ______

SIGNATURE _____

DATE _____

PRODUCT RECALL



Hygienic condition:

new good

used decontaminated

used not decontaminated

pos.	part no.	serial /	quantity	remark	expection	
no.	article no. lot-no.	replacement of product	credit note			

RETURN ADRESS :

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

ADRESS / SENDER:		
DATE / SIGNATURE :		

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

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 Corporate Office: Tuttlingen
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 Acsculap AG

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