

Safety Notice – Product Recall

EF401R – STRAUSS PENIS CLAMP 130MM

The Aesculap AG received feedback from the market that the plastic sleeves of a STRAUSS PENIS CLAMP 130MM – EF401R had stuck together after reprocessing.

The following image shows an affected product (see Figure 1)

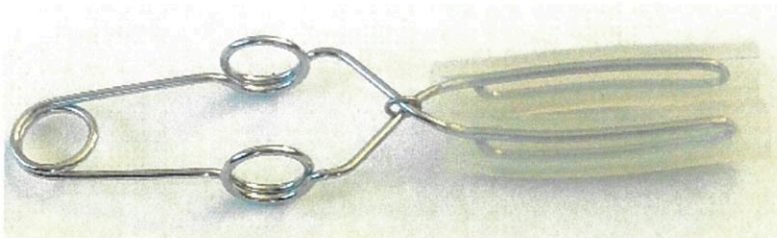


Figure 1: EF401R – PENIS CLAMP

During complaint investigation it has been determined that the plastic sleeves of the returned instrument do not meet the valid specification. Instead of the specified material silicone, the material PVC was used for the manufacturing of the sleeves. This could render affected instruments unusable after reprocessing.

Internal investigation conducted at the manufacturing plant revealed that the reported failure can be limited to the production period from February 2016 to October 2017.

A definite identification of an affected product is not possible without the help of suitable equipment. We therefore ask you to consider all of your existing STRAUSS PENIS CLAMP 130MM – EF401R to be potentially affected.

The results of investigation revealed that there is no increased risk expected for patients who have been treated with the affected product.

According to our internal distribution information your facility received applicable unit/s manufactured within the above mentioned production period. We kindly ask you to check if an affected instrument is currently in use at your facility.

In case you have located an affected product:

Please ensure that these instruments are no longer used.

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

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

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

Andreas Lauer
☎ + 49 7461 95 2479
☎ + 49 171 73 24 907
andreas.lauer@aesculap.de

In case you could not locate any affected product:

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

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 this may cause and thank you very much for your support.

With best regards,



FEEDBACK FORM / FSCA**EF401R - STRAUSS PENIS CLAMP 130MM**

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 potentially 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
		n.a.		
		n.a.		
		n.a.		
		n.a.		
		n.a.		

RETURN ADDRESS :

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

ADDRESS / SENDER:

DATE / SIGNATURE :

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 653 700 715 Konto 21 22 0000 00
 IBAN DE44 6537 0075 0212 2000 00
 SWIFT / BIC DEUDES653
Baden-Württembergische Bank
 BLZ 600 501 01 Konto 487 1905
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 SWIFT / BIC SOLADEST

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 78532 Tuttlingen
 Germany