Aesculap AG
Quality Management

Postfach 40
78501 Tuttlingen
Germany

Contact: Christian Strobel

Fon: +49 7461 95-31926
Fax: +49 7461 95-1555
Email: vigilance_aag.de@aesculap.de
Internet: http://www.bbraun.com

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Safety Notice – Product Recall

OM040R - DOYEN-COLLIN MOUTH GAG 120MM

The Aesculap AG received knowledge about the possibility that the plastic sleeves of a DOYEN-COLLIN MOUTH GAG 120MM – OM040R could stick together after reprocessing.

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

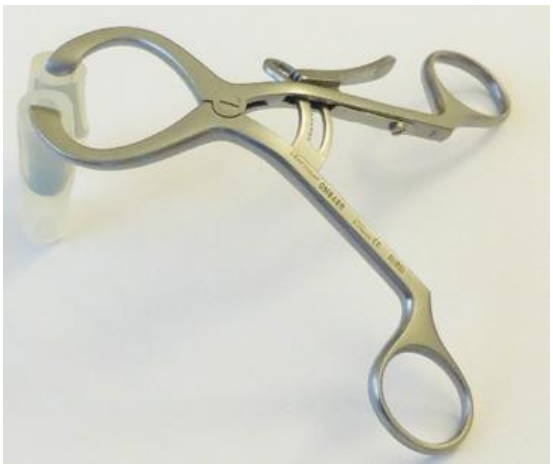

Figure 1: OM040R – MOUTH GAG

It has been determined that the used plastic sleeves of the 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.

An affected product OM040R can be clearly identified by two options:
Identification on the basis of the labelled production date **(from 02 16 to 10 17 inclusively).**
Identification on the basis of the labelled encoding **(from 000330 to 000449 inclusively)**.

As soon as at least one of the two identification options is possible, it shall be assumed that the product is affected.

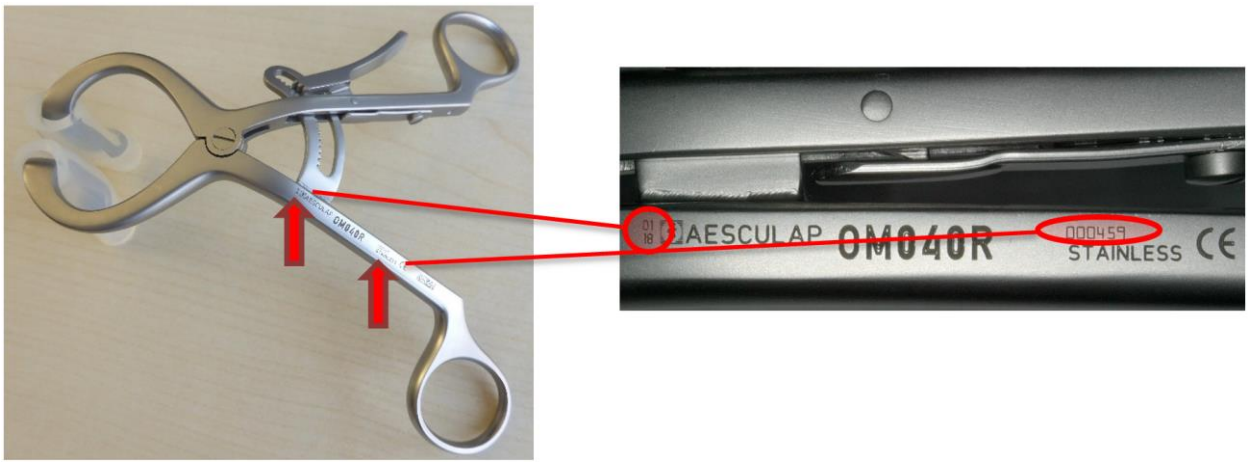

Figure 2: OM040R – LABELLING OF MOUTH GAG

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 units 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 the involved products are no longer used.

Should you have an involved 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,

Aesculap AG

i. V.

Thorsten Barthelmes
Director Product Risk & Vigilance Management
Safety Officer Medical Device

i. A.

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

FEEDBACK FORM / FSCA

OM040R - DOYEN-COLLIN MOUTH GAG 120MM

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 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 ADRESS :

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

ADRESS / SENDER:

DATE / SIGNATURE :