Aesculap AG
Quality Management

Postfach 40
78501 Tuttlingen
Germany

[redacted]

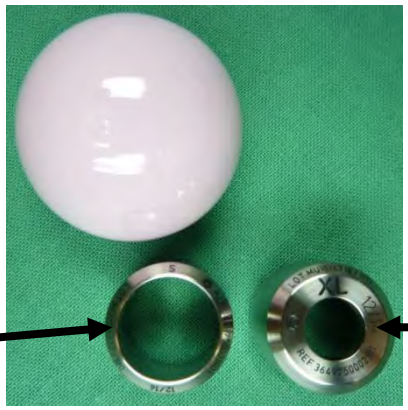
Date: 3/4/2016

Field Safety Corrective Action – Product Recall

Product: **NK535 – batch no. 52191195**
Product description: **BIOLOX DELTA REVISION HEAD 12/14 32MM S**

Due to feedback from two clinics, it appears that it is possible for size XL adapter sleeves to be in packages of size S Biolox Delta revision heads (see figure 1). This mistake occurs only in individual instances and is restricted to batch 52191195. The batch in question was recalled due to the incorrectly allocated adapter sleeves.

Correctly packaged adapter sleeve (size S)



Incorrectly packaged adapter sleeve (size XL)

Figure 1: Biolox Delta revision head with adapter sleeves (on the left, correctly packaged sleeves in size S, on the right the incorrectly packaged sleeves in size XL)

Since mounting the larger adapter sleeves would result in a length difference of 11.5 m, the danger of the mistake not being noticed during operation is estimated as being extremely small. Therefore, we do not assume there is increased patient risk. Patients already treated using the product are also not at increased risk, since a successful implantation requires that the length of the sleeve is correct for the treatment.

Using the attached return form, please send these articles to:

Aesculap AG
Building 12 – Department QMV / Product Recall
Attn. Jana Zibulski
Am Aesculap-Platz
DE - 78532 Tuttlingen

You will receive the choice of either credit or a replacement delivery. Please fill out the attached return form.

If you have any questions concerning this Field Safety Corrective Action, please contact our product management or our local marketing for orthopaedics/traumatology:

Mr. Thomas Güttler		**Mr. Dominik Kühne**	
Tel:	**+ 49 7461 95-2672**	**Tel.:**	**+ 49 7461 95-2653**
Fax:	**+ 49 7461 95-2522**	**Fax:**	**+ 49 7461 95-2131**
E-Mail:	**thomas.guettler@aesculap.de**	**E-Mail:**	**dominik.kuehne@aesculap.de**

Please notify all users of the above product and any other persons who need to be informed within your organisation 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. The Food and Drug Administration has received a copy of this *FSCA*.

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Please accept our apologies for the inconvenience caused by this action.

Kind regards,

Aesculap AG

FEEDBACK FORM / FSCA

BIOLOX DELTA REVISION HEAD 12/14 32MM S

Please return this form by fax or e-mail to:

Jana Zibulski / Department QMV

Fax +49 7461-95 1555

vigilance_aag.de@aesculap.de

We confirm having received the product recall of articles NK535. We will implement the recommended measures:

- ☐ We do not have any of the affected products in use.
- ☐ We send back the affected products from our establishment and wish to receive a:
  - ☐ credit note.
  - ☐ replacement delivery.

HOSPITAL _____

CITY _____

NAME _____

DEPARTMENT _____

PHONE _____

_____ _____

SIGNATURE DATE