Aesculap
Quality Management

Postfach 40
78501 Tuttlingen
Germany

Contact:

[redacted]

Internet: http://www.aesculap.de

Date: December 15, 2016

Safety Notice – Product Recall

POSITION HEADED REAMER SCALED D8.0MM

FO087R – Lot 52194770

You are using in your facility the instruments for the Position ACL reconstruction system. During the production process of one batch, the Position Headed Reamer scaled ∅8.0mm was laser marked with an incorrect diameter.

The headed reamer FO087R with a diameter of ∅8,0mm was wrongly marked with „∅6,0mm“. The following drawing shows the drill with the correct labeling (figure 1):

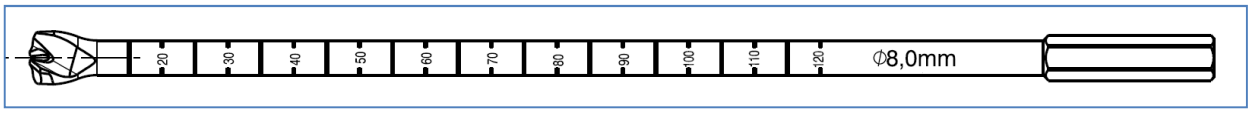

Figure 1: Headed Reamer with correct labeling

A headed reamer with an incorrect diameter labeling can be identified by comparing the marked diameter and part number with the help of the table below:

Labeling on headed reamer		
Art.-Nr.	**Drill diameter**	
FO087R	∅8,0mm	correct labeling
FO087R	**∅6,0mm**	**incorrect labeling**
FO083R	∅6,0mm	correct labeling

Should the deviation not be detected in a timely manner, a too large channel can be drilled resulting in an insufficient press fit between transplant and bone . The deviation could exclusively be traced back to the article No FO087R with the lot 52194770.

The lot number is not marked on the product.

Please make sure that any headed reamer with an incorrect drill diameter, which can be recognized by the labelling ∅6,0mm in combination with the article number FO087R, is no longer used in your facility.

Please make sure that any user of the above mentioned product and any other person who should be informed within your organization, will take note of this safety notice information.

If you have forwarded the involved product to a third party, please provide a copy of this information to this party and also note Aesculap AG about this.

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

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

Aesculap AG
QMV
Mireille Suzy Eze
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

Marcus Schäfer
☎ **+ 49 7461 95 2913**
☎ **+ 49 171 44 33 732**
marcus.schaefer@aesculap.de

We apologize for any inconvenience this may cause and thank you very much for your support.

With best regards,

Aesculap AG

[redacted]