

**Aesculap
Quality Management**

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Contact:

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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 $\varnothing 8.0\text{mm}$ was laser marked with an incorrect diameter.

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

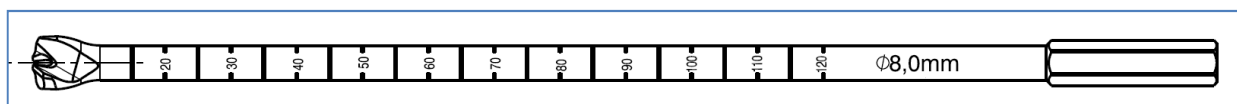


Figure 1: Headed Reamer with correct labeling

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	$\varnothing 8,0\text{mm}$	correct labeling
FO087R	$\varnothing 6,0\text{mm}$	incorrect labeling
FO083R	$\varnothing 6,0\text{mm}$	correct labeling

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

Executive Board:
Prof. Dr. Hanns-Peter Knaebel
(Chairman)
Dr. Jens von Lackum
Dr. Joachim Schulz

Corporate Office: Tuttlingen
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SWIFT / BIC DEUTDE33
Baden-Württembergische Bank
BLZ 600 501 01 Konto 487 1905
IBAN DE31 6005 0101 0004 8719 05
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Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
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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 Ø6,0mm 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

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

With best regards,

Aesculap AG

