

**Aesculap AG  
Quality Management**

P.O. Box 40  
78501 Tuttlingen  
Germany

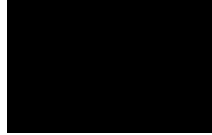
Contact:

Phone:

Fax:

E-mail:

Internet:



[vigilance\\_aag.de@aesculap.de](mailto:vigilance_aag.de@aesculap.de)

<http://www.aesculap.de>

Date:

18 December 2019

## **Security information**

**Product: SZ380R**

**Product name: ENNOVATE MIS REMOVAL KEY SHORT**



Aesculap AG received customer feedback that during loosening of Ennovate MIS and FRI downtubes (SZ378R, SZ405R), the fixation arms are increasingly broken, which are used to anchor the screw head.

Breaking the fixation arms may result from incorrect application of the Ennovate removal key SZ380R. In the instructions for use it is described that the key must be rotated by 90° in order to spread the shanks of the downtube and thus loosen the fixation arms from the screw head. A rotation above or below 90° causes the fixation arms to anchor again in the screw head and the downtube cannot be removed. If this is not noticed and the downtube is removed by applying additional forces, there may be fractures of the fixation arms.

**Chairman of the Supervisory Board:**  
Prof. Dr. Heinz-Walter Große

**Board:**  
Dr. Joachim Schulz  
(Chairman)  
Dr. Jens von Lackum  
(Stellv. Chairman)  
Dr. Katrin Sternberg

**Registered office of the company:**  
**Tuttlingen**  
Reg. Court: Stuttgart HRB 726261  
Vat. Id.-No. DE812160059  
WEEE-Reg.-Nr. EN 65109852

**Bank account:**  
**Deutsche Bank AG Tuttlingen**  
BLZ 653 700 75 Account 21 22 000  
00  
IBAN DE 44 6537 0075 0212 2000 00  
SWIFT / BIC DEUTDE33  
**Baden-Württemberg Bank**  
BLZ 600 501 01 Account 487 1905  
IBAN DE31 6005 0101 0004 8719 05  
SWIFT / BIC SOLADEST

**Address:**  
Aesculap AG  
At Aesculap Square  
78532 Tuttlingen  
Germany

If you have any further questions about this safety information, please contact our product management / marketing management:

**Denis Ricci**

Product Management  
Product Manager Global Marketing DSD  
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**Wolfgang Daiber**

Marketing Management  
Director Global Marketing & R&D  
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Please ensure in your organization that all users of the affected product and other persons to be informed are aware of this safety information.

If you have handed over the product to third parties, please forward a copy of this information or inform Aesculap AG ( [vigilance\\_aag.de@aesculap.de](mailto:vigilance_aag.de@aesculap.de) ).

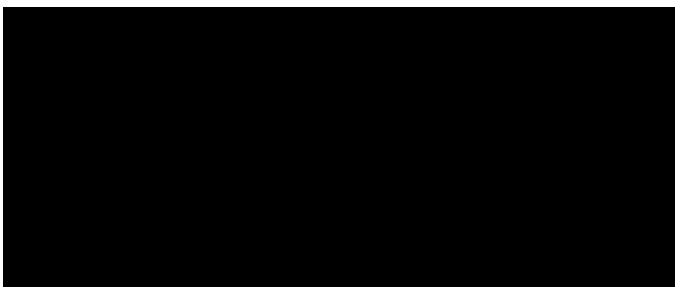
The Federal Institute for Medicinal Products and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) has received a copy of this safety information.

In order to confirm the knowledge of this security information, we kindly ask you to return the feedback form attached to this letter.

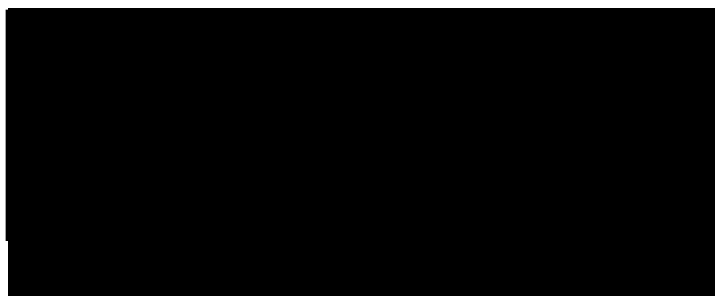
Yours sincerely

Aesculap AG

i.V.



i.V.



**REGISTRATION FORM**  
**Field Safety Notice**  
**SZ380R - ENNOVATE MIS DISTANCE KEY**

We have taken note of the content of the security information

HOSPITAL \_\_\_\_\_ LOCATION \_\_\_\_\_

NAME \_\_\_\_\_ DEPARTMENT \_\_\_\_\_ PHONE \_\_\_\_\_

SIGNATURE \_\_\_\_\_ DATE \_\_\_\_\_

Please send the confirmation of the knowledge to:

Fax: +49 7461-95 1555  
Email: [vigilance\\_aag.de@aesculap.de](mailto:vigilance_aag.de@aesculap.de)