

Aesculap AG  
Quality Management  
Postfach 40

Contact:

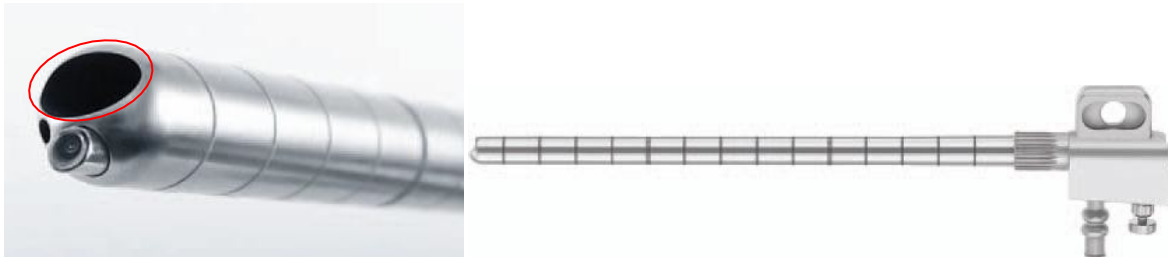
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Date: March 06, 2017

## Safety Notice – Product Recall

### **FH620R - MINOP INVENT 30° TROCAR D8.3MM L150MM**

We were informed that the insulation of an electrode has been damaged intraoperatively when pulling it out of the MINOP INVENT TROCAR, FH620R.



The initiated investigation showed that the distal working end of the trocar was not clear from burrs. The failure was caused by a deviation in the production process which could be traced back to a limited period of time. There is a possibility that other MINOP INVENT TROCARS, FH620R, which were manufactured during that period of time might also be defective.

We cannot exclude that due to the damage of the electrode insulation, particles would dissolve.

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Corporate Office: Tuttlingen  
Register Court: Stuttgart HRB 726261  
VAT reg. no. DE812160059  
WEEE-Reg.-No. DE 65109852

Bank Account:  
**Deutsche Bank AG Tuttlingen**  
BLZ 653 700 75 Konto 21 22 000 00  
IBAN DE44 6537 0075 0212 2000 00  
SWIFT / BIC DEUTDESS653  
**Baden-Württembergische Bank**  
BLZ 600 501 01 Konto 487 1905  
IBAN DE31 6005 0101 0004 8719 05  
SWIFT / BIC SOLADEST

Address:  
Aesculap AG  
Am Aesculap-Platz  
78532 Tuttlingen  
Germany

As a measure of precaution, Aesculap AG has decided to recall the products which may be affected.

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 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 enclosed “**Product Recall Form**”

Should you have any question concerning this Field Safety Corrective Action, please contact

**Ms. Kerstin Rothweiler**  
**Tel: +49 7461 95-2182**  
**Fax: +49 7461 95-1555**  
**E-Mail: [vigilance\\_aag.de@aesculap.de](mailto:vigilance_aag.de@aesculap.de)**

For any product related request, do not hesitate to contact our product manager „Neurosurgery“:

**Mr. Jürgen Honer**  
**Tel: +49 7461 95-1599**  
**Fax: +49 7461 14614**  
**E-Mail: [juergen.honer@aesculap.de](mailto:juergen.honer@aesculap.de)**

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

With best regards

Aesculap AG

i.V.

i.A.

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

**FEEDBACK FORM / FSCA**  
**MINOP INVENT 30° TROCAR D8.3MM L150MM**  
**FH620R**

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

**Kerstin Rothweiler**

**QMV**

**Fax +49 7461-95 1555**

**vigilance\_aag.de@aesculap.de**

We do not have any of the affected products.

HOSPITAL \_\_\_\_\_ TOWN \_\_\_\_\_

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