

**Aesculap AG
Quality Management**

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Date: February 11, 2019

Field Safety Notice - Safety Information

NP462R - ENDURO SPECIAL KEY TIB.LOCK.RING F1/10MM

NP454R - ENDURO KEY F/TIBIAL LOCKING RING



NP462R



NP454R

Aesculap AG has received customer feedback that the assembly of Enduro Tibia components and the replacement of the PE gliding surfaces can lead to the bending or breaking of the metal pins of the tibial locking ring key.

This bending or breaking of the metal pins on the tibial locking ring key is the result of a possible tilting of the NP462R or NP454R wrench during use.

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

Management Board:
Dr. Joachim Schulz
(Chair)
Dr. Jens von Lackum
(Deputy Chair)
Dr. Katrin Sternberg

Company headquarters: Tuttlingen
Reg. Court: Stuttgart Commercial
Register B 726261
VATIN DE812160059
WEEE Reg. No. DE 65109852

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

Street address:
Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
Germany

As part of ongoing product improvement, the system has been modified and added. Assembly and changing the PE sliding surfaces was simplified by the use of the new modified instrument NQ839R in combination with NP144PM and NP141R (only in combination with the modified version of the wrench NP462RM). The NQ839R - ENDURO TIBIA PLATEAU HOLDING KEY makes it easier to hold the tibia components in place when changing the PE gliding surfaces (including the axis components). Tilting of the wrench during use is prevented.

Please check that the instruments you are using are the latest versions. Please only use these new versions in the future. In the table below you will find an overview of the modified and added system instruments. In order to also avoid the scenario described above when using the NP454R, Aesculap AG recommends to use this tibial locking ring key only in combination with the new modified instruments.

A detailed description of its use can be found in the operating technique instructions O38602.

If you do not yet have the latest version of the instruments at your facility, please contact our product management to organize an exchange. If required, Aesculap AG will provide a new storage tray and a corresponding packing template.

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

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Zentraleuropa

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Old instruments	OLD	Action	New/ modified instrument	NEW
NP462R		Modified with Hexagon	NP462RM	
NP144P		Modified with thread	NP144PM	
NQ830R		Replaced by	NQ839R	
		New Holding down clamp for NP462RM	NP141R	
NP454R		No change	NP454R	

Please make sure that all users of the above products and other people who should be informed at your organization receive this information.

If you have given the products to third parties, please forward a copy of this information or inform Aesculap AG (vigilance_aag.de@aesculap.de).

The German Federal Institute for Drugs and Medical Devices has received a copy of this safety information.

Please return the feedback form attached to this letter as acknowledgment of receipt of this safety information.

Aesculap AG

i.V.



Thorsten Barthelmes
Safety Officer Medical Devices
Director Quality Project and Risk Management

i.V.



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

FEEDBACK FORM
Field Safety Notice
NP462R - ENDURO SPECIAL KEY TIB.LOCK.RING F1/10MM
NP454R - ENDURO KEY F/TIBIAL LOCKING RING

_____ We acknowledge the receipt of the Field Safety Notice from B. Braun Aesculap / Germany.

Please mark:

We have take notice.

HOSPITAL _____ TOWN _____

NAME _____ DEPARTMENT _____ TELEPHONE _____

_____ SIGNATURE _____

DATE _____

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

Fax: +49 7461-95 1555

E-Mail: vigilance_aag.de@aesculap.de