

Contact:

Fon:

Fax:

Email:

vigilance_aag.de@aesculap.de

Internet:

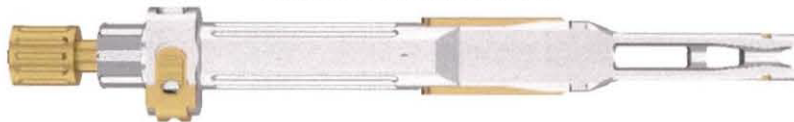
<http://www.bbraun.com>

Date:

July 31, 2018

Safety Notice – Product Recall

Product: Ennovate® Rod Persuader
Article-No.: SZ277R



Aesculap AG has received feedback from the market that the use of the **SZ277R – Ennovate® Rod Persuader** can lead to the loosening of individual components. To be more precise, pins, which are located at the lower portion of the gold-coloured threaded spindle, may loosen inside the instrument. Internal investigations have shown that with the current design of the Rod Persuader, a recurrence of the above mentioned topic cannot be ruled out. So far, there is no case in which an intra-operative release of the pins has been observed.

As a precautionary measure, Aesculap AG has decided to recall the affected product from the market.



The three fixation pins can be found at the lower portion of the gold-coloured threaded spindle

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

Executive Board:
Dr. Joachim Schulz
(Chairman)
Dr. Jens von Lackum

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 DEUTDE33
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

Figure 1: Disassembled instrument with reference to the position of the pins.

According to our internal distribution information, you have received one or more items of the affected product. Please check whether such instruments are used in your facility.

The Ennovate® Rod Persuader (SZ277R) is stored in the SZ251R – Ennovate® Tray Open Manipulation/Optional tray with an amount of four pieces (see marking, Figure 2).

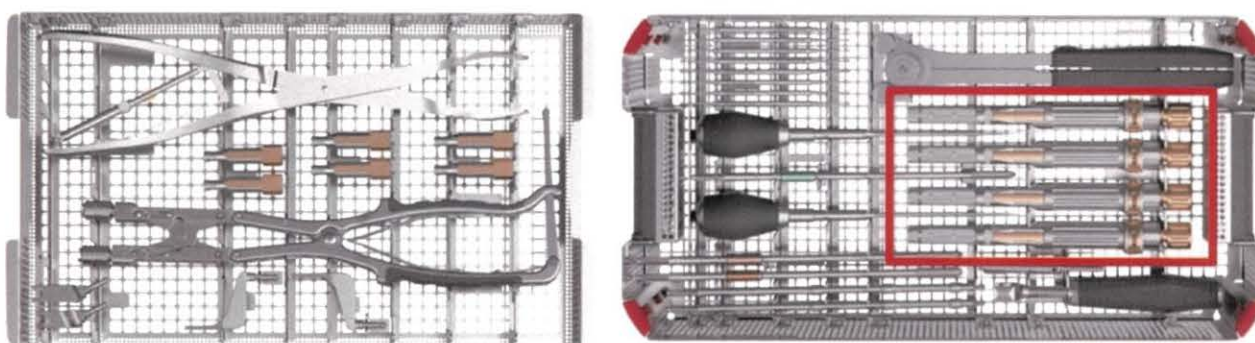


Figure 2: SZ251R tray – The Ennovate® Rod Persuader is stored in the lower layer of the tray.

In addition, the SZ251R tray is included in the following set configurations:

1. For consignment equipment:
SZ250 – Ennovate® Set Open Manipulation/Optional
2. For ELSA loan sets:
LSET-W0106 Ennovate® Open Instruments

Please follow the steps below when sending back the affected instrument:

1. You have identified an affected product:

- Please make sure that this instrument is not used any longer.
- Please send the identified products back with the enclosed "PRODUCT RECALL" return form to:

Aesculap AG
LRP
Siegfried Schwarz
Am Aesculap-Platz
D-78532 Tuttlingen

2. You were not able to identify any affected product:

- If you have not identified any affected product, please send us the enclosed feedback form back.

At this point, we would like to inform you that we have already started a redesign of the Ennovate® Rod Persuader in order to completely remedy the issue. In order to continue working with the open Ennovate® module without any limitations, we would like to provide you following alternatives.

1. SZ273R – Ennovate® Rod Pusher,

Tray SZ201R / Set no: SZ200– Ennovate® Set Open Implantation:

This instrument can be used in case of slight rod offsets.

2. SZ275R – Ennovate® Fork Rocker CVD,

TraySZ206R / Set no: SZ205– Ennovate® Open Connector Application:

This instrument can also be used for slight to medium rod offsets

3. SZ405R – Ennovate® FRI Downtube Short,

Trays SZ401R and SZ403R / Set no: SZ400 and SZ402 – Ennovate® Open MIS FRI:

This instrument can be used in the presence of slight to high rod offsets, for spondylolisthesis reduction (up to and including Meyerding Grade 2), and the reduction of fractures. All functionalities of the Ennovate® SZ277R Rod Persuader can thus be completely covered by this instrument.

Please note that this instrument is part of a separate module of the Ennovate® platform. This module is, with immediate effect, available on stock. We would be glad to explain this alternative solution to you in more detail. For this, we offer workshops or trainings, in order evaluate the usage of this alternative in your hospital.

If you have any questions regarding the return and alternative solutions, please do not hesitate to contact us. In such cases, please contact the following person:

Sandra Steinmeier (DE)

Best reachable by cell phone

☎ + 49 15156011473 (cell)

sandra.steinmeier@aesculap.de

Denis Ricci (EEA, ROW)

☎ + 49 7461- 95 – 2225

☎ + 49 175 – 5729638 (mobil)

denis.ricci@aesculap.de

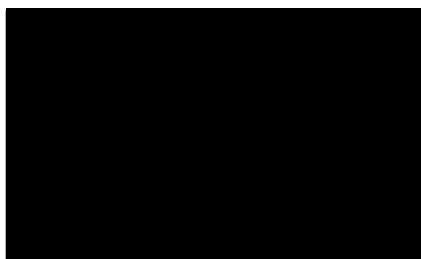
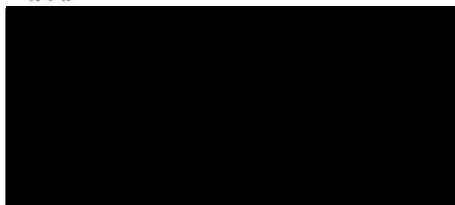
Please ensure that all users of the affected product are informed about this safety information in your organization. If you have distributed the products to a third party, please forward a copy of this information or inform the above mentioned contact person. The Competent Authority BfArM – Bundesinstitut für Arzneimittel und Medizinprodukte, has received a copy of this safety information.

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

With best regards,

Aesculap AG

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FEEDBACK FORM / FSCA**SZ277R – Ennovate® Rod Persuader**

Please send back this feedback form via fax or e-mail to:

Department QMV

Fax +49 7461-95 1555

vigilance_aag.de@aesculap.de

- ☐ We do not have affected product(s).
- ☐ We will return potentially affected product(s).

HOSPITAL _____ LOCATION _____

NAME _____ DEPARTMENT _____ PHONE _____

SIGNATURE _____ DATE _____



PRODUCT RECALL

Hygienic condition:

☐ new good

☐ used decontaminated

☐ used not decontaminated

pos. no.	part no. article no.	serial / lot-no.	quantity	remark
		n.a.		
		n.a.		
		n.a.		
		n.a.		
		n.a.		

RETURN ADDRESS :

Aesculap AG
LRP
Siegfried Schwarz
Am Aesculap-Platz
D-78532 Tuttlingen – Germany

ADDRESS / SENDER:

DATE / SIGNATURE :

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