

**Aesculap AG
Quality Management**

Postfach 40
78501 Tuttlingen
Germany

Contact:

Fon: +49 7461 95-2182
Fax: +49 7461 95-1555
Email: kerstin.rothweiler@aesculap.de
Internet: <http://www.bbraun.com>

Date: June 1, 2015

FSN - Safety Information

Product: FW103R
Product name: S4C OCCIPUT TORQUE WRENCH F/SET SCREW

We have been informed by a customer that during the use of a torque wrench FW103R as part of an Occiput procedure, a screw broke off during an intervention. The cause of the fracture was found to be the release mechanism of the torque wrench, which applies a defined torque of 2.8Nm, failing to release and therefore too high a torque was applied.

The surgery was completed successfully with a new screw and a different torque wrench which was available. According to our records, you also use the torque wrench FW103R at your facility.

The torque wrench FW103R comes in three parts and can be disassembled for reprocessing. Assembly/disassembly is described in the current instructions for use using an exploded drawing among other things. (See Figure 1: Exploded drawing in instructions for use)

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

Executive Board:
Prof. Dr. Hanns-Peter Knaebel
(Chairman)
Dr. Dirk Freund
Dr. Joachim Schulz

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

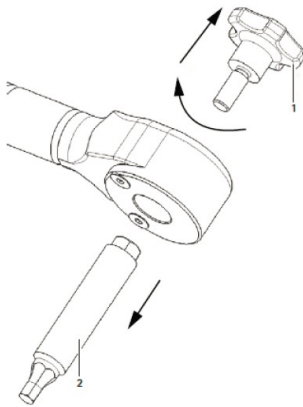


Figure 1: Exploded drawing in instructions for use

In the case in question, the torque wrench was not assembled correctly after reprocessing.

To prevent any future confusion, we have decided to produce this additional safety information describing the assembly/disassembly process once again in detail.

There are two versions of the torque wrench FW103R currently available on the market. Both versions of the FW103R torque wrench can be disassembled, as shown in the following illustrations.

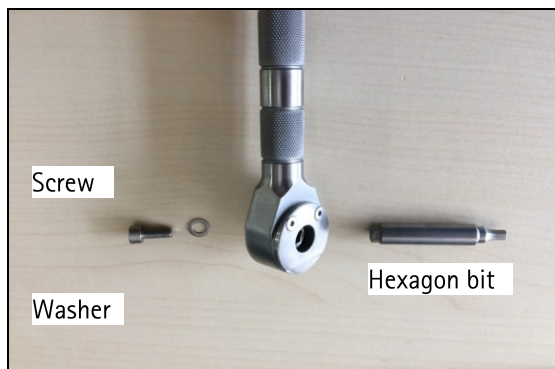


Figure 2: FW103R - Version 1, disassembled



Figure 3: FW103R - Version 2, disassembled

After cleaning, care must be taken to assemble the individual parts of the FW103R correctly to ensure that the correct torque of 2.8 Nm is applied during surgery. Note that the hexagon bit must be inserted on the inner surface of the torque wrench. The inner surface of both torque wrench versions can be identified by the integrated screws. (See Figure 4 and Figure 6)

With version 1, the screw is then screwed on with the washer, and with version 2, the star screw is screwed on from the direction of the smooth outer surface of the torque wrench.

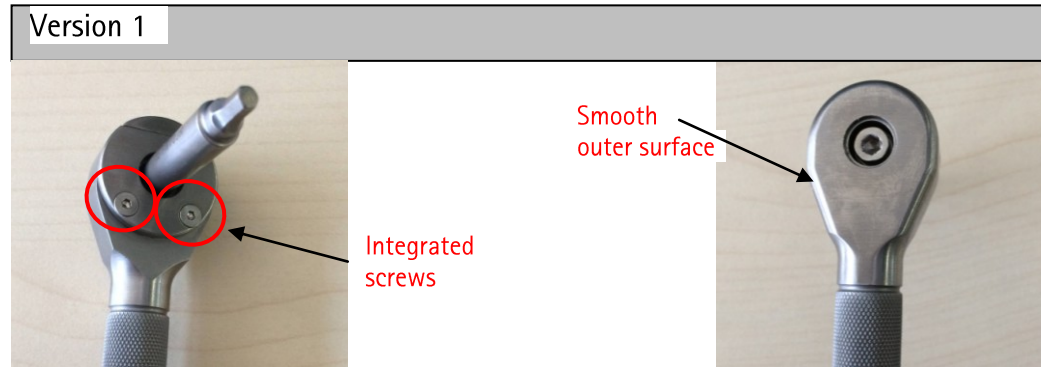


Figure 4 (left): Inner surface of the torque wrench with hexagon bit inserted.

Figure 5 (right): Smooth outer surface of the torque wrench with inserted screw and washer

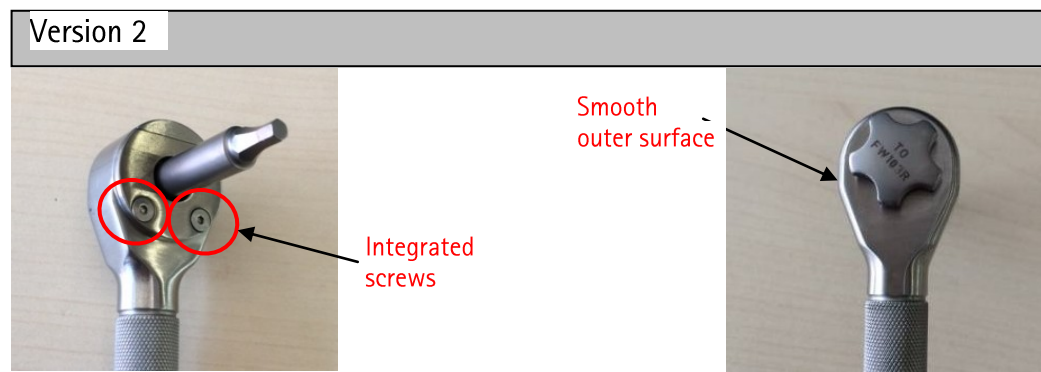


Figure 6 (left): Inner surface of the torque wrench with hexagon bit inserted.

Figure 7 (right): Smooth outer surface of the torque wrench with star screw inserted

Please notify all users of the above product and any other persons who need to be informed within your organization about this safety information. If you have passed on the products to third parties, please forward this information to these persons. The Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this safety information.

Kind regards,

Aesculap AG

FEEDBACK FORM / FSCA

FW103R

S4C OCCIPUT TORQUE WRENCH F/SET SCREW

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

Kerstin Rothweiler / QMV Department

Fax +49 7461-95 1555

kerstin.rothweiler@aesculap.de

Please tick as appropriate:

- ☐ We do not use any of the affected products in our establishment.
- ☐ We confirm receipt and acknowledge the safety information.

HOSPITAL _____ TOWN _____

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SIGNATURE _____ DATE _____