Aesculap AG Quality Management

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1hre Zeichen

Unsere Zeichen QMV-kro

Tel. (+49 74 61) 95-2182 Fax (+49 74 61) 95-**1555**  Datum 2013-11-22

## Safety Information

**Product:** 

TARGON FN TELESCREWS

KO820T, KO822T, KO823T, KO824T, KO825T, KO826T, KO828T

Internal tests have shown that Targon FN screws can occasionally be difficult to screw into the Targon FN femoral plates. In order to avoid any uncertainty in the use of the product, we would like to inform you of the following facts.

It is an inherent feature of the system that the screw heads of the TeleScrews may protrude when they are screwed into the Targon FN plate. This does not have any functional effects, as the screw depth is only conditionally a criterion for the stability of the screw connection.

Due to the design, the required tightening torque of 8 Nm can be achieved after just half a turn of the screw, depending on the tolerance of the TeleScrew and plate. To ensure a secure connection between the Targon FN plate and the TeleScrews, it is generally recommended to check that the threads of both the Targon FN plate and the TeleScrew are free from any bone particles, blood or tissue before screwing them in. In case of doubt and if you encounter any problems screwing the TeleScrew into the plate, take the TeleScrew out again and clean the thread of the plate and the TeleScrew.

According instructions have also been added to the operating manual. Your Aesculap Consultant for Medical Devices will provide you with the updated version as soon as it is available. If you have any questions, please contact one of the following people:

Vorsitzender des Aufsichtsrates:

Prof. Dr. h.c. Ludwig Georg Braun

Vorstand: Prof. Dr. Hanns-Peter Knaebel (Vorsitzender) Dr. Harald Stallforth (stellv. Vorsitzender) Dr. Joachim Schulz **Sitz der Gesellschaft: Tuttlingen** Reg. Gericht: Stuttgart HRB 726261 USt. Id.-Nr. DE812160059

WEEE-Reg.-Nr. DE 65109852

**Bankverbindungen:**Deutsche Bank AG Tuttlingen

BLZ 653 700 75 Konto 21 22 000 00

IBAN DE44 6537 0075 0212 2000 00

BLZ 633 700 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

Hausanschrift: Aesculap AG Am Aesculap-Platz 78532 Tuttlingen

Deutschland

page 2 Safety Information dated 22.11.2013

Dr. Andreas Doser

**2** + 49 7461-95 2236

Mr. Robert Weber

**2** + 49 07461-95 2605.

Please make sure that each user of the above mentioned product and any other person that has to be informed within your organization, will take notice 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 circumstance.

Please acknowledge the receipt of the safety information to:

Aesculap AG Dept. QMV Ms Kerstin Rothweiler Am Aesculap-Platz DE-78532 Tuttlingen + 49 7461 95-1555

kerstin.rothweiler@aesculap.de

Aesculap AG

Quality Management Vigilance

Please complete this form and return to Ms Kerstin Rothweiler, Dept. QMV Fax: +49 7461-95 1555 or E-mail: kerstin.rothweiler@aesculap.de

## Ackowledgement Safety Information TARGON FN TELESCREWS

KO820T, KO822T, KO823T, KO824T, KO825T, KO826T, KO828T

1.	We acknowledge receipt of the safety information.			
2.	Please m	e mark accordingly:		
Use	er:			
		We have taken note of the safety information.		
Ret	tailer:			
		We have forwarded the safety information to our list.	customers and attach an according custome	
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