

Aesculap AG Quality Management Postfach 40 D-78501 Tuttlingen

e-mail: kerstin.rothweller@aesculap.de http://www.aesculap.de

Ihre 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

K0820T, K0822T, K0823T, K0824T, K0825T, K0826T, K0828T

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.

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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:

Dr. Andreas Doser

· 🖀 + 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
Fax: + 49 7461 95-1555
kerstin.rothweiler@aesculap.de

Aesculap AG

Quality Management Vigilance



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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

K0820T, K0822T, K0823T, K0824T, K0825T, K0826T, K0828T

1.			
2.			
User:			
	We have taken note of the safety information.		
Retaile	er:		
	We have forwarded the safety customer list.	le have forwarded the safety information to our customers and attach an according ustomer list.	
Facility		Location	
Name _			
Department		Tel.	
Signature		Date	