

**Aesculap AG
Quality Management**

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Date: 20/08/2015

Field Safety Notice

Product: NC077T NC078T NC079T NC087T NC088T
NC089T NC097T NC098T NC099T – all batches
Product name: METHA **TITANIUM** CONE ADAPTER (NECK)

On 06/12/2006 we communicated a Field Safety Notice for the stop of implantations with the above articles due to the first breakages of the product. As of January 2007, the **titanium alloy cone adapters** for the modular system were replaced by cobalt-chrome cone adapters and the monoblock version.

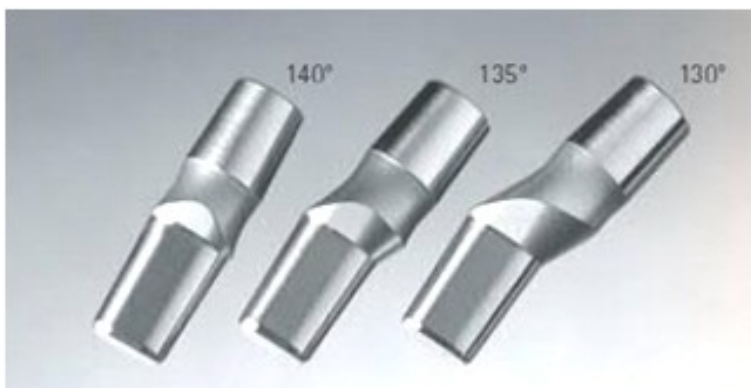


Figure 1: Metha titanium cone adapters – different CCD angles

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

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Address:
Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
Germany

Over the past years, we have regularly kept you informed of our experiences with failure cases of the modular titanium adapters in the form of user information. To inform all users once again about the current situation, we are sending you a further Field Safety Notice.

Based on the total number of implanted titanium cone adapters and the failure cases known to date, the current average failure rate for all article numbers is 6.74 % for the entire period since the first breakage event in 2006.

Based on the data available to date relating to the Metha titanium cone adapter breakages, the failure rates of the titanium cone adapters with different CCD angles are currently as follows:

CCD angle	Failure rate
METHA NECK 12/14 130°	12.87 %
METHA NECK 12/14 135°	4.17 %
METHA NECK 12/14 140°	0.66 %

Figure 2: Failure rates of Metha titanium cone adapters according to CCD angle

At 12.87 %, the adapters with a CCD angle of 130° show a significantly higher breakage rate than the variants with angles of 135° and 140°.

The entire risk population concerned includes a high proportion of male patients with an average body weight of 100 kg. The proportion of female patients with an average body weight of 92 kg is currently 10.43 % of all patients affected to date. Patients of a normal weight have also been affected by breakages of the Metha titanium cone adapter, meaning that body weight cannot be regarded as the sole risk factor in terms of implant load.

Based on the data currently available, we recommend that users inform their patients treated with Metha titanium cone adapters of the risk, even though early detection of potential failures through radiology is not possible.

Page 3 to the letter of August 20, 2015

If you have any questions regarding this Field Safety Notice, please contact our product management for hip replacements:

Herr Thomas Güttler

☎ + 49 7461- 95 26 72

☎ + [REDACTED]

thomas.guettler@aesculap.de

If one of your patients is affected by a breakage of a Metha cone adapter, we will continue to support you by providing you with special explantation instruments. These can be requested by calling telephone number [REDACTED]

Please ensure within your organisation that all users of the above products and any other persons who need to be informed of this safety information are made aware of it. 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
NC077T NC078T NC079T NC087T NC088T
NC089T NC097T NC098T NC099T - all batches
METHA TITANIUM CONE ADAPTER (NECK)

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 confirm receipt and acknowledge the safety information.

HOSPITAL _____ TOWN _____

NAME _____ DEPARTMENT _____ TELEPHONE _____

SIGNATURE _____

DATE _____