WITH THE REQUEST FOR IMMEDIATE FORWARDING TO THE SENIOR DOCTORS AND OP MANAGEMENT OF ORTHOPEDICS / TRAUMATOLOGY SURGERY

URGENT PRODUCT SAFETY NOTICE

Affected products: hip stems of the ANA.NOVA® system
Article no.: all article numbers
Lot/Serial No.: all lot numbers
Our reference number: IT2021-09

Dear Customer!
In March 2021, ImplanTec GmbH started a product safety action at the user for the above products and batch numbers. The purpose of this letter is to inform you of all known potential hazards associated with the issue listed below and the mitigation measures associated with the use of the product.

Problem and possible danger:

This notice is intended to inform the implanting and/or treating surgeons and other healthcare professionals that ImplanTec GmbH has updated the Instructions for Use for the ANA.NOVA® Hip System.

The reason for the change in the instructions for use is that ImplanTec GmbH has added a safety notice regarding intraoperative damage to the implant and its effects.

Risk reduction:
The instructions for use and the surgical techniques for the ANA.NOVA® system have been updated with the information regarding the risk of damage to the implants as follows:

Damage to the implant weakens the material and thus increases the risk of breakage! If the implant is damaged intraoperatively or there are nicks or scratches when the ball head is removed, or if the structure of the material changes as a result of contact with the electrocautery, the strength of the stem neck is significantly reduced.

An additional follow-up check or monitoring of the patients outside of the usual postoperative care of patients is not necessary. Closer follow-up of the patients would neither allow an early diagnosis nor an early detection of clinical problems.

Our records indicate that you have been supplied with the product(s) listed above. As the manufacturer, ImplanTec GmbH is responsible for ensuring that all customers who may have been supplied with the affected products also receive this important information.

- ensure that copies of this product safety information are distributed internally to all affected users.

ImplanTec GmbH
Grenzgasse 38a
2340 Mödling
Österreich

Tel: +43-2236-864 194
Fax: +43-2236-864 234
E-Mail: info@implan-tec.at
BIC: BCAUATWW

Bankverbindung:
UniCredit Bank Austria AG
BLZ 12000 Konto-Nr. 51854058893
IBAN: AT 381200051854058893

ARA-Lizenz Nr. 6819
UID Nr. ATU 67464237
Firmenbuch FN 386699a
HG Wiener Neustadt

- Display the information in a clearly visible place until all necessary measures have been taken in the facility.
- Complete the attached Customer Response Form to acknowledge receipt of this notice

We have reserved February 28th, 2022 for the receipt of your reply. ImplanTec GmbH continues to strive to develop, manufacture and sell products of the highest quality for surgeons and patients.

We apologize for any inconvenience this user corrective action may cause and thank you for your cooperation on our request.

If you have any questions, please contact your responsible sales representative, by email to qm@implan-tec.at or by telephone on +43 2236 864 194.

Kind regards

Dr. Reingard Huber-Wurzinger
PRRC/CEO
ImplanTec GmbH

Michael Bohdal
Quality Manager
ImplanTec GmbH

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RESPONSE

URGENT PRODUCT SAFETY NOTICE

Affected products: hip stems of the ANA.NOVA® system
Article no.: all article numbers
Lot/Serial No.: all lot numbers
Our reference number: IT2021-09

Hospital _____

ZIP / City _____

Name of Lead Physician _____

Phone number _____

I confirm that I have received the information about a corrective action regarding the above products from ImplanTec GmbH. I have taken note of the changed instructions for use for the above product.

_____ _____

Date signature and stamp

Please return this reply form electronically to qm@implan-tec.at, by fax to +43 2236 864234 or by post to ImplanTec GmbH, Grenzgasse 38a, A-2340 Mödling

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