Field Safety Notice for NORDYX PLACL Threads

To our customers:

Following the NOMA inspection of Amedica dated 12th and 13th February 2025, we have been required to notify of incorrect information over the last 2 years regarding the medical device NORDYX PLACL Threads. The reason for this field safety notice is that we introduced unauthorized changes to the manufacturer's labeling and instructions for use. Our information has resulted in us assuming manufacturer responsibility for the medical device.

Amedica AS does not have the legal or practical ability to fulfill the manufacturer's responsibility on behalf of Yurim Medical in Korea. We apologize for this error.

For this reason, we are issuing this Field safety notice regarding the shipment of Nordyx products from August 20, 2023 to July 29, 2025. An overview of available Nordyx products at Amedica AS to which this applies is attached.

All affected devices that have not been put into use should be used in accordance with the attached corrected instructions for use. This is the correct instructions for use for the use of NORDYX PLACL threads, from the manufacturer Yurim Medical Co., Ltd.

Below we describe the changes that Amedica AS made during this period.

Correct intended use:

Amedica AS has changed the description of the intended use of the device in the Norwegian instructions for use. Correct intended use is:

«This device is used for correction surgery by fixing the sub dermal tissue in an elevated position for injured tissue, or reconstructed position of damaged tissue(especially sub dermal in face) for patient after damage or an accident.»

Warnings:

Amedica AS has changed the following warnings in the Norwegian instructions for use:

-Warnings regarding the use of anticoagulant/blood thinning medication were changed from instructions that the patient should stop taking them approximately one week before surgery to three days before surgery.

-Contraindication was changed from "diabetes" to "unregulated diabetes".

-The absorption time was changed from the original claim of “more than 28 weeks”

[equivalent to more than approx. 7 months] to “12-18 months”.

The use of the threads outside the stated indications may pose a risk to patients. We recommend that the threads are used according to the manufacturer’s recommendations. Attached is new English instruction manual from the **manufacturer.**

Information about the manufacturer and authorized representative: Amedica AS has removed the name and address of the manufacturer and authorized representative from the Norwegian instruction manual. The manufacturer’s name and address were also removed from the labeling on the outer packaging for some of the devices.

Contact information for the manufacturer is:

Yurim Medical Co., Ltd. 43, Jeongjung 3-gil, Osong-eup, Heungdeok-gu Cheongju-si, Chungcheongbuk-do, Republic of Korea,

Yurim Medical Co.,ltd.
Mobile/Whatspp : +82-10-2105-5430
Tel : +82-43-231-9788
Fax : +82-43-231-9789

e-mail: sales@yrmedi.com

Contact information for **Authorized Representative** is:

KTR Europe GmbH, Mergenthalerallee 77, Eschorn, Hessen, 65760, Germany

Tel) +49(0)6196-887170 / FAX) +49(0)6196-8871728

E-mail: ktreurope@ktreurope.de

We kindly ask that all recipients of this message acknowledge that it has beenreceived, read and understood. Please respond with your inventory of the relevant equipment.

For questions or further information, please contact us:

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Træleborgodden 6

3112 Tønsberg

Norge

Tel: 400 15 086/920 99 350 Mail: hei@amedica.no/ragni@amedica.no

Enclosed:

English IFU

Nordyx product list