FIELD SAFETY NOTICE:
Safety Information (FSN)

December 10th, 2021

Name of the trademark: NEMOST – Growing Domino

Reference	Designation
A304013051	Growing Domino - Ø5.5 mm – Extension 50mm - Length 300 mm
A304013081	Growing Domino - Ø5.5 mm – Extension 80mm - Length 300 mm

FSCA Ref.: FSCA-2021-02

Type of measure: Safety Information

Batch number affected: Tous

Dear Sir/Madam,

By this letter, EUROS inform you about an important communication linked with product safety of our products listed above.
According to our records, at least one of the products concerned, which are listed above, has been delivered to you and is concerned by this action.

Incident description

Following trend analysis in complaints related to NEMOST device, EUROS has decided to issue a voluntary safety notice to all users of NEMOST device to clarify/restrict indications of the device in Instructions For Use.

Post-Market Surveillance data collected by Euros have highlighted a rate of "migration" (rod sliding) of the device higher than expected in our Risk Management File, although overall performance (benefit/risk balance) remains higher than state of the art.
Analyzes performed have determined higher rate is mainly linked to particular indications including revision surgery, an inadequate level of bone maturity and per-operative excessive stress

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www.euros-orthopaedics.com

As part of this safety notice, Euros wishes to communicate the following new elements concerning the instructions for use and the operating technique and relating to:

- Any assembly comprising Nemost device must be performed bilaterally (including visual examples on the operating technique),
- The limitations of indications (*RISSER 0 and in first line*) and precision of contraindications (*do not use in revision of spine having already been instrumented or fused*),
- More precise precautions regarding preoperative examination,
- Addition of recommendations on post-operative manipulations.

The modification of the instructions and the operating technique aims to reduce the rate of occurrence of these "migrations" (sliding of the rod).

Measures to be taken by the user

Please carefully read this notice and take the measures listed below:

- Read Field Safety Notice in its entirety and make sure all users within establishment are informed of this Field Safety Notice,
- If products have been supplied to third party, please disseminate this Field Safety Notice,
- Complete Acknowledgement Receipt Form and send it back to Euros by mail (qualite@euros.fr) or fax (+33442714280)
- Maintain copy of completed Acknowledgement Receipt Form in your vigilance file as may be requested in case of audit of documentation within your establishment.

Please reply to this notice within 7 days following its receipt.

Transmission of this Field Safety Notice

This notice has been sent to you because the records indicate that your organization has received this device with the affected batch number referenced above. This notice must be given to all those who need to be aware of it inside your organization or any organization where these products may have been transferred.

According to European Medical Device Directive 93/42/EEC (and European Medical Device Regulation 2017/745) and applicable vigilance guidelines (MEDDEV reference 2.12/1), we confirm that French Competent Authority (ANSM) and any other concerned Competent Authorities have been informed of this field safety corrective action.

We sincerely thank you for your help and cooperation in the application of this action and we are sorry for any inconvenience caused. We would like to confirm that EUROS is committed to ensuring patients safety and to commercializing reliable and efficient products.

Should you have any question, please do not hesitate to contact Mrs ANGELI Carine, EUROS Quality, Regulatory Affairs and Clinical Director.

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Carine ANGELI
Quality, Regulatory affairs & Clinical Director

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Acknowledgement Receipt Form

This form acknowledges receipt of Field Safety Notice (FSCA-2021-02) transmitted by EUROS regarding the devices NEMOST.

Please tick and fill in the boxe(s) that concern(s) you:

❒ I confirm that I have received, read and understood this urgent safety notice and acknowledge the recommendation concerning the limitation of indications and associated information communicated.

❒ I hereby acknowledge that all required staff or customers have been informed of the recommendation regarding the limitation of indications and associated information communicated:

Form filled in by:

Name and profession:

Establishment:

Phone number:

Email address:

Signature and date:

Please fill in this document and send it by:
Mail : qualite@euros.fr
Fax : +33 4.42.71.42.80