



2, Place Berthe MORISOT
Parc technologique
69800 SAINT PRIEST
France

FSN Ref: FSN_2020_001 // RIRCVM_2020_013

Saint Priest, 07/10/2020

Subject: URGENT – FSN

MEDICAL DEVICE: KHEIRON Spinal Fixation System – Surgical technique

Legal Manufacturer: SMAIO - 2, Place Berthe MORISOT - Parc Technologique - 69800 SAINT-PRIEST - FRANCE

Dear Customer,

SMAIO is writing this document on purpose in order to provide an important safety information related to the surgical technique followed during the installation of the KHEIRON fixation system, a spinal fixation system intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

Context :

Intraoperatively, during 4 surgeries involving the use of sacral plates, the threaded plate extension and nut were damaged while tightening the nut to the plate.

Safety rationale:

2 surgeons informed SMAIO of the threaded extension and nut breaking when tightening the sacral plate nut. Upon investigation, it was found that reducing the cranial screws first and then the plate increased the stress on the threads of the extensions and nuts.

This information was transmitted to the 2 surgeons who informed us of this type of incident. For now, no other incident of this kind has been reported to us by these 2 surgeons, who are now following the instructions described below (see: action to be taken).

A 3rd surgeon informed SMAIO of this kind of incident, which led SMAIO to set up an FSN in order to clarify the reduction method to be conducted.

Action to be taken

Based on our traceability information, you are identified as a customer who has the KHEIRON system in his inventory. We request you to comply with the following instructions in order to avoid any risk of tearing of the threaded extension of the sacral plate and nut's thread.

When a sacral plate is used in an assembly, the rod on the sacral plate must be reduced in a first time, then the rod must be connected and reduced on the pedicle screws from the most caudal vertebra to the most cranial vertebra.

For information: the reverse technique (reduction of the rod on the vertebrae then reduction of the rod on the sacrum) will increase the stress on the threads of the extensions and the nuts. When the nut is straddling the first threads of the second part of the threaded extension and the breaking groove, only a few threads are engaged which increases the risk of the engaged threads breaking.



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Therefore, it is important:

- First of all, lower the connector of the sacred plate as much as possible while keeping the polyaxiality of the connector and the sliding of the rod in the latter if necessary (unscrew a quarter of a turn from the stopper then a second quarter of turn if necessary).
- Reduce the connectors of the cranial pedicle screws.

Please feel free to report any new occurrence of this incident to SMAIO in order that the appropriate actions can be taken.

Action to be taken for products already in use

As the incident occurs intraoperatively, no special action is to be taken for patients operated with the medical devices concerned by this FSN.

The receipt of the Acknowledgment Form assures that SMAIO has effectively communicated this Field Safety Notice to affected customers.

Please note that your country's Competent Authority has been informed regarding this Field Safety Notice.

Thank you for your cooperation in carrying out this action and for returning the attached acknowledgment of receipt.

For any questions or additional information, please contact Aurélie FRETAY ALTARE, Quality Director or Jean Charles ROUSSOULY, Vice-President of Operations at the following address: vigilance@smaio.com

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Dear Customer,

SMAIO is writing this document on purpose in order to provide an important safety information related to the surgical technique followed during the installation of the KHEIRON fixation system, a spinal fixation system intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

This record confirms that you have received and understood the instructions to be implemented in order to avoid any risk of the threaded extension and the nut tearing:

- First of all, lower the connector of the sacred plate as much as possible while keeping the polyaxiality of the connector and the sliding of the rod in the latter if necessary (unscrew a quarter of a turn from the stopper then a second quarter of turn if necessary).
- Reduce the connectors of the cranial pedicle screws.

Instruction:

- 1) Please complete the acknowledgment of receipt attached
- 2) To return it by email to SMAIO at the following address Email: vigilance@smaio.com without delay
- 3) Please communicate this notice to any healthcare professional using the KHEIRON system

We regret any issue generated by this action and appreciate your understanding as we act to ensure patient safety and customer satisfaction.

Please, feel free to report any new occurrence of this incident to SMAIO in order that the appropriate actions can be taken.

For any questions or additional information, please contact Aurélie FRETLY ALTARE, Quality Director or Jean Charles ROUSSOULY, Vice-President of Operations at the following address: vigilance@smaio.com

Regards,

Annex: acknowledgment of receipt

AURELIE FRETLY ALTARE
Directrice Qualité
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Subject: URGENT – FSN

MEDICAL DEVICE: KHEIRON Spinal Fixation System – Surgical technique

Acknowledgment of receipt

Please complete the information hereafter and return this acknowledgment of receipt by email to SMAIO at the following address Email: vigilance@smaio.com without undue delay

Customer

Name	
Position	
Adress	
Zip	
Town	
country	
Phone	
Email	
Signature	

Vigilance contact:

Name	
Position	
Phone	
Email	

By this form, I confirm that I have received, read and understood the information provided. I am committed to :

- Initially, lower the connector of the sacred plate as much as possible while keeping the polyaxiality of the connector and the sliding of the rod in the latter if necessary (unscrew a quarter of a turn from the stopper then a second quarter of turn if necessary).
- Reduce the connectors of the cranial pedicle screws.