



2, Place Berthe MORISOT
Parc technologique
69800 SAINT PRIEST
France

Ref: FSCA_2020_002 – FSN_2020_002 R2022449

Saint-Priest, 08/12/2020

Subject: URGENT – RECALL

Legal manufacturer : S.M.A.I.O - 2, Place Berthe MORISOT - Parc Technologique - 69800 SAINT-PRIEST - FRANCE

Dear Customer,

S.M.A.I.O is writing this document on purpose in order to report a **recall of 2 batches of S2 screw securing cap (formerly designed by “Breakable securing nut for S2 screw”) from 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.

Our records indicate that your facility received the concerned product. Please note that only the devices listed below are affected.

Designation	Reference	Batch number(s)
Breakable securing nut for S2 Screw	25SN55005	200052
S2 screw securing cap	25SN55005	200053

Context :

13 non-conforming products referenced 25SN5505 S2 screw securing cap (formerly designed by “Breakable securing nut for S2 screw”) from the batch 20051 were detected during the final quality check before release (this is a sampling control). After investigation, it turns out that :

- The 100% control at the end of production was not realized according to the control plan
- Batches 200052 and 20053 put on the market did not reveal any non-conforming products during the sampling control. However, the 100% control of the cap thread at the end of the production was not performed according to the control plan.

Consequently S.M.A.I.O decides to recall in their totality the batches 200053 and 200052 which are still on the market in order to perform a 100% final release control and to put the conforming products back on the market.

Safety rationale:

Internal controls have shown that some securing nuts could be “smaller” than minimally tolerance thread according to the device’s drawing, indeed the NOGO control threaded device assembles tight on the nut (the observed gap is about one hundredth millimeter).

An additional control showed that external diameter is conform to the specification, therefore only the depth of the thread is non-conform.

This non-conformity has no consequence on the mechanical performances of the devices.

Action to be taken

Based on our traceability information, you are identified as a customer detaining the batch(s) 200052 and/or 20053 of the 25SN55005 of S2 screw securing cap (formerly designed by “Breakable securing nut for S2 screw”) reference. Please conform to the recall instructions which are reported in the document FSCA_2020_002 RECALL.

1) To ensure that the affected devices can not be used, please put the affected stock in quarantine zone.

2) Please complete the attached Acknowledgement form and return it to S.M.A.I.O by Email to vigilance@smaio.com as soon as possible.



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3) As soon as S.M.A.I.O will receive your inventory, the S.M.A.I.O logistic members will contact you to organize the affected devices return.

Action to be taken for products already in use

No specific action is to be taken for products already in use.

Please, feel free to report any incident regarding KHEIRON fixation system to S.M.A.I.O in order that the appropriate actions can be taken.

S.M.A.I.O regrets any inconvenience that this action may cause and appreciates your understanding as S.M.A.I.O acts to ensure patient safety and customer satisfaction. Thank you for your cooperation in carrying out this action. The sending to S.M.A.I.O of the receipt of the Acknowledgment Form attached assures that S.M.A.I.O has effectively communicated this recall to affected customers.

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

Your sincerely,

AURELIE FRETY ALTARE
Directrice Qualité
Quality Director
+33(0) 6 13 34 48 99
aurelie.frety.altare@smaio.com

Attachment: Acknowledgement form



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ACKNOWLEDGEMENT FORM

Please fill in information below and send it to vigilance@smaio.com as soon as possible.

Customer		Name	
Street address		Zip code	
City		Country	
Phone		Email	
Position		Signature	

Vigilance contact:

NAME		Position	
Phone		Email	
Signature			

With this form I confirm that I have received, read and understood the information provided. I have identified all products, concerned. Hereafter, the result of my inventory put in quarantine.:

Inventaire - Inventory

Designation	Reference	Batch number(s)	Quantity
Breakable securing nut for S2 Screw	25SN55005	200052	
S2 screw securing cap	25SN55005	200053	

Note: The recall will end for you when information above will be sent and the devices received (100% reconciliation).