Adresse établissement

FSN VERSION 1 Genay, le

URGENT - MEDICAL DEVICES RECALL
For the attention of the Materiovigilance Correspondent for distribution to:
- Orthopedic Surgeons
- Pharmacists
- Operating room supervisors

MAIA STEM S8s
Reference: M100 0018 Batch: 275277600 expiry date: 31/06/2035

Subject: ***Voluntary recall: MAIA STEM S8s Reference: M100 0018 Batch: 275277600 expiry date: 31/06/2035***

Dear,

Groupe Lepine has decided to voluntarily recall the devices **MAIA STEM S8s Reference: M100 0018 Batch: 275277600 expiry date: 31/06/2035**

Description of the incident:

An incident was reported by a healthcare facility in Switzerland during a surgical procedure (intra-operative detection). During implantation, it was observed that the neck could not be assembled/connected to the metacarpal stem (neck/stem connection impossible), which prevented implantation of the device and resulted in a failure to implant.
The affected device, which was not implanted, was returned to Groupe Lepine. Upon receipt, the issue was confirmed:

- functionally, through the impossibility to assemble the neck onto the stem, and
- dimensionally, through a three-dimensional analysis highlighting a non-conformity.

The defect is not systematic across all devices from the affected lot. To date, the issue has been observed on one device only; the other devices implanted from this lot did not present any assembly issue.
An investigation is currently ongoing to identify the origin of the defect. At this stage, no confirmed root cause has been formally established. As a precautionary measure, and to prevent any potential recurrence, the manufacturer has decided to recall the affected lot(s).

Actions to be taken by the customer / user:

Healthcare facilities and distributors are requested to:

1) Immediately identify and quarantine all affected products in their inventory (stock, consignment stock, operating theatre storage, etc.).
2) Stop using any device from the affected lot(s).
3) Inform all relevant personnel (orthopaedic surgeons, operating theatre staff, sterilisation department, purchasing, logistics, etc.) within your organisation about this FSN.
4) Return the affected products to Groupe Lepine (or local representative/distributor). We will contact you to organize the return of these products and their replacement at our expense.

5) Complete the product return form attached and return it to us as quickly as possible (by fax or mail
6) Complete and return the FSN acknowledgement form to confirm receipt and implementation of the required actions.

Consequences and recommendations in the event of a MAIA METACARPAL STEM S8s devices Reference: M100 0018 Batch: 275277600 expiry date: 31/06/2035 is used (potential risk):

For devices from the affected lot(s), the neck/stem assembly cannot be performed due to the absence of the cone interface, resulting in an inability to implant the device as intended.
This may lead to:
- inability to complete the planned implantation procedure with the intended implant,
- prolongation of the surgical procedure,
- need to use an alternative implant and/or additional instrumentation,
- potential change in surgical strategy and associated patient risk related to extended operating time.

No implantation of the affected device occurred in the reported case. The issue is 100% detectable intra-operatively during assembly prior to implantation

We also remind you of the need to report any adverse effects associated with these devices in particular or any other device manufactured by Groupe Lépine to the following email address: Materiovigilance@groupe-lepine.com and to the National Safety Agency of medicines and health products – Surveillance Department – by email to materiovigilance@ansm.sante.fr or by fax to +33 (0)1 55 87 37 02.
In accordance with Article L. 1111-2 of the Public Health Code, it is up to the surgeon or health professional to consider the methods of informing patients with the implants concerned.

Other information

This safety action relating to a medical device is reported to the relevant competent authorities, to the notified body in charge of the product and to all relevant regulatory authorities, as required by the medical device regulations.

The undersigned confirms that this notification has been transmitted to the competent health authorities.

Please excuse us for any inconvenience this may cause you and thank you for your trust, please accept, Madam, Sir, the expression of our distinguished consideration.

Laurence Fiscus
Quality/Regulatory Affairs Director
Vigilance Officer

RETURN FORM
FOLLOWING PRODUCT RECALL

MAIA STEM S8s
Reference: M100 0018 Batch: 275277600 expiry date: 31/06/2035

Please tick the appropriate boxes.

❑ I have received and read the recall instructions relating to the letter referenced

❑ I have checked my stock and isolated the corresponding products:
- ❑ Out of stock
- ❑ Remaining quantity:

Reference	Batch number	Quantity

❑ The products concerned are
- ❑ Returned
- ❑ Destroyed

❑ I have identified and alerted my customers affected by this product recall

Name: _____

Position: _____

Establish: _____

_____

Address: _____

_____

<u>To be sent as soon as possible to the attention of</u>:
Groupe Lépine
Laurence Fiscus – Medical Device Vigilance Correspondent
175 RUE JACQUARD – CS 50307 – 69727 GENAY CEDEX – FRANCE
Tel: +33 (0)4 72 33 02 95 – Fax: + 33 (0)4 72 35 96 50

Or by email at: Materiovigilance@groupe-lepine.com