

Genay, **July 20th, 2018**

URGENT : FIELD SAFETY NOTICE

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (if appropriate)

Our Ref.: EN 020/F/ **217251300**

Dear Customer,

Details on affected devices

This is to inform you of a product recall involving TRENDHIP STEM STD 12/14 B-BRAUN T2S / GL-HET HS402 / batch 217251300 manufactured by Groupe lépine.

Description of the problem

This recall has been initiated due to a mistake on a size 1S batch labelling. This batch have been labelled as a Size 2S.

Advise on action to be taken by the user

- immediately examine your inventory and quarantine product subject to recall within **July 27th, 2018**,
- maximum identified risk are dislocation and/or loosening of the implant.
- complete and return the enclosed response form as soon as possible (by fax or mail),
- contact the export assistant of Groupe lépine to deal with exchange,
- In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall.

Sincerely yours,

Laurence FISCUS

Head of Regulatory and Medical Affairs
Vigilance Officer

RECALL RETURN RESPONSE FORM

TRENDHIP STEM STD 12/14 B-BRAUN T2S / GL-HET HS402 / batch 217251300

Please check ALL appropriate boxes.

- I have read and understand the recall instruction provided in the 'reference' letter
- I have checked my stock and have quarantined inventory consisting of:
- No more stock
 - Quantity left:

Reference	Lot number	Quantity

- Indicate disposition of recalled product:
- Returned
 - Destroyed
- I have identified and notified my customers that were shipped or may have been shipped this product.

Name: _____

Position: _____

Firm Name: _____

Address: _____

Please fax or mail completed return response form to:

Groupe Lépine

Laurence Fiscus – Vigilance officer

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