URGENT FIELD SAFETY NOTICE: RA2020-2366861

April XX, 2020

FCA identifier:	2366861
Type of action:	Field Corrective Action: Recall
Description:	NileTM Alternative Fixation Spinal System Band
Affected Catalog Number(s):	5416-F03730-SG
Affected Lot(s):	HFNG-35650-166897, HFNG-35650-180445, HFNG-35650-182566, HFNG-35650-239505, HFNG-35650-239951, HFNG-35650-240245, HFNG-35650-268386 HFNG-35650-258790, HFNG-35650-258679, HFNG-35650-241425

Dear Customer,

Product description

The Nile Alternative Fixation System is a non-pedicle-based fixation technology that utilizes a band and clamp to provide fixation used in sublaminar, interspinous, or facet wiring techniques. The Band is 3mm wide with an overall length of 28.7". The band is attached to a rod using the rod clamp to secure the band.

Product issue

Stryker has identified that the expiration date of 2028-11-26, printed on patient (DO) labels and the secondary packaging label (i.e. outer packaging "carton") that are utilized for international shipments only, does not match the correct expiration date, 2023-11-26, printed on the product's primary packaging (i.e. inner packaging "blister").

As a result, the carton label and patient (DO) labels are printed with the incorrect expiration date. The product's primary packaging has the correct expiration date

Potential hazard

The potential hazard is the incorrect expiration date on the carton label is beyond the actual expiration date on the blister. If the product is used beyond the actual expiration date (2023-11-26), there is a potential to cause infection.

No adverse events have been reported for this issue.

Actions Needed:

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending to return to Stryker.
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organizations.
    a) Please provide contact details so that Stryker can inform the recipients appropriately.
    b) If you are a Distributor, note that you are responsible for notifying your affected customers.
5. Please inform Stryker of any adverse events concerning the use of the subject devices.

    Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.
6. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore, please complete even if you longer have any of the subject devices in your physical inventory.
7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA.
    a. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request that you respond to this notice within 7 calendar days from the date of receipt.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name:

Position:

Telephone:

E-mail:

In line with the recommendations of the Meddev Vigilance Guidance document Ref.2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be cause. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remaining on the market.

Yours Sincerely,

REPLY FORM: RA2020-2366861

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I acknowledge receipt of the Field Safety Notice for RA2020-2366861 and can confirm that:

We have not located any of these devices in our inventory: (please delete if not applicable)			
We have located the following devices:			
Catalog number	Description	Lot number	Qty
We have further distributed subject devices to the following organizations:			
Facility Name			
Facility Address			
Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organization		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE EMAIL, XX, OR FAX, XX