SAFETY COMMUNICATION

PFA_2438233

Affected Product: Osteosynthesis Compression Staple EasyClip and EasyClip Xpress implants

Legal Manufacturer: Stryker GmbH, Bohnackerweg 1, 2545 Selzach, Switzerland

FSCA Identifier: PFA_2438233

Type of Action: Safety Communication

Products Affected:

Catalog Number	Product Description	Lot Number
See attachment	Osteosynthesis Compression Staple EASY CLIP	All
	EASY CLIP XPRESS	All

September 2020

Dear Customer,

The purpose of this notification is to advise you that Stryker Trauma GmbH (Trauma & Extremities Division) has identified a risk of a nickel release above the acceptable Margin of Safety for EasyClip implants.

It was determined that pediatric patients with a body weight of less than 20 kg should have a maximum of 2 Easyclip staples implanted to remain in the acceptable Margin of Safety. Therefore, the current IFU will be updated, a contraindication will be added “Do not implant more than 2 EasyClip devices in pediatric patients.”

This risk was proactively identified following an update of the toxicological risk assessment for the Osteosynthesis Compression Staple EasyClip and EasyClip Xpress products.
As of the date of this communication, Stryker is not aware of any complaints or incidents related to this potential risk.

Risk to Health
The risk to health can be considered as very low with a potential elevated development of nickel ion hypersensitivity in the future.

Mitigating Factors
Allergies due to Nickel release are mentioned in the EasyClip IFU V15082 - PRECAUTIONS FOR USE section "The implants contain metals which may stimulate allergic hypersensitive responses by the immune system”.

Allergies due to Nickel release are mentioned in the EasyClip Xpress IFU V15221 - PRECAUTIONS FOR USE section " The implants contain metals which may stimulate allergic hypersensitive responses by the immune system. In the specific case of metallic alloys composed of Nickel and Titanium (Ni and Ti), some preoperative testing should be conducted when sensitivity is suspected. A surgeon should not attempt clinical use of an implant before reviewing instructions for use and/or rehearsing the installation procedure in a skills laboratory.”

Recommendations for patients already treated with an affected device
As the release is reduced to almost zero after a month and with the highest release occurring in the first days it is very unlikely that the existing threshold value will be exceeded and therefore no action has to be recommended in these cases.

Potential Alternative Products
This is not an action to remove devices. The product can be used according to the instructions for use, with the limitation of a maximum of two implants in pediatric patients.

Actions to be taken by the Customer/User
Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions.

1. Inform individuals within your organization who need to be aware of this safety communication.
2. Maintain awareness of this notice internally.
3. 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.
4. Complete the attached customer response form (acknowledgement form). 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.
5. Return the completed form to your nominated Stryker Distribution Centre (indicated below) for this Action.

We request that you **respond to this notice within 7 calendar days** from the date of receipt. We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter.

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: *Sharun Thavarajan*
Position: *Senior RAQA Specialist*
E-mail: *sharunyan.thavarajan@stryker.com*
Phone: *+44(0)7929 021 221*

We confirm that the competent national authorities in your country have been informed of this safety corrective action in accordance with regulatory requirement in 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 the 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 faithfully,

Sharun Thavarajan
Regulatory Affairs and Quality Assurance

MEDICAL DEVICE SAFETY NOTICE
Acknowledgement and Receipt Form

Please sign and return this form to acknowledge receipt of product notice.

Osteosynthesis Compression Staple EasyClip and EasyClip Xpress implants

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See attachment	Osteosynthesis Compression Staple EASY CLIP	All
	EASY CLIP XPRESS	All

I acknowledge receipt of the Safety Communication for PFA 2438233 and understand the safety notice provided in this letter.

Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

We have **further distributed** subject devices to the following organizations. I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of the devices noted in this letter. (IF APPLICABLE).	
Facility Name	
Facility Address	

PLEASE COMPLETE THIS FORM WITHIN **7 CALENDAR DAYS** AND RETURN IT BY USING THE EMAIL: **raqa.uk@stryker.com**