SAFETY COMMUNICATION

PFA_2438233 Version 7

Affected Product: Osteosynthesis Compression Staple EasyClip and EasyClip Xpress implants

September 2020

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

Recipients: Health Care Professionals, Operators of Medical Devices, Distributors

Type of Action: Safety Communication

PFA Identifier: PFA_2438233

Identification of the Affected Product(s):

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

Dear Customer,

Purpose of this letter

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 Center (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.

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.

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: Per Maegaard
Position: Senior Manager Post Market Safety
Email: per.maegaard@stryker.com
Telephone: +41 799043871

Yours Sincerely,

Signature

MEDICAL DEVICE SAFETY NOTICE RETURN RESPONSE

Acknowledgement and Receipt Form

Response is Required

Osteosynthesis Compression Staple EasyClip and EasyClip Xpress implants

PFA Identifier: Product Field Action PFA_2438233

Type of Action: Safety Communication

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

Product name: Osteosynthesis Compression Staple EasyClip and EasyClip Xpress implants

Catalog Number	Product Description	Lot Number
See attachment	See attachment	See attachment

I acknowledge receipt of the SAFETY NOTICE

We have further distributed subject devices to the following organizations:				
Facility Name				
Facility Address				
Form completed by:				
Contact Name				
Contact address		**Contact Position**		

_____ **Contact Tel No** _____

_____

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

I have read and understand the SAFETY NOTICE provided in the <date of> letter. ☐Yes ☐No

Date_____Signature of Receipt _____

PLEASE FAX COMPLETED RESPONSE FORM TO: Tel. # , ATTN:
OR MAIL TO: FIRM NAME AND ADDRESS