Field Safety Notice

Safety pin no. 3, 1 piece per pouch Ref. 331016S (Batch 1810069)
FSCA: 12 April 2019
Field Safety Notice to all end users regarding the use of the device with the reference 331016S (Batch 1810069)

Date: 25 April 2019

Attention: End users

Details of affected device:
Product REF 331016S, Name: Safety pin no. 3, 1 piece per pouch, Batch 1810069

Description of the problem:
On the 12th of April 2019, Aichele Medico AG has reported that Sterisets Medical Device product with the reference 331016S (Safety pin no. 3, 1 piece per pouch), batch number 1810069 was found with rust residue inside the sterile pouch.

Steripack SA has assessed the issue carefully, and advises the end users that, prior to use, the user visually verify that the referred defect (rust residue) is not present.

The affected batch number was already put in quarantine by the distributor and the manufacturer.

Steripack SA has identified the batch numbers of the safety pin used in the affected lot and a supplier complaint has been performed. No non-conformances were identified during the product realization process at Steripack SA following review of the batch documentation.

Steripack SA has had the responsibility for initiating the return of the product (recall) and has asked the customer to return the product to Steripack SA facilities. This Field Safety Notice is addressed to all end users. End users are asked to act as follows.

Sterisets International B
P.O. Box 474 - 5340 AL Oss - The Netherlan
Phone: +31 (0)412 667 755 - Email: info@sterisets.
www.sterisets.co

Actions to be taken by the end user:

- Prior to use medical device with the reference 331016S, please visually verify that the referred defect is not present.
- Please identify the medical device with the reference 331016S, Batch 1810069 and quarantine it
- Please return the affected products back to the manufacturer
- Please send back the attached Acknowledgment Form to Steripack SA via email to nfelix@sterisets.eu

Transmission of this Field Safety Notice:

This notice needs to be passed on all end users who need to be aware of this Field Safety Notice.

Please maintain awareness on this notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Nuno Felix

Steripack S.A.

Zona Industrial 1 – Lote 11 a 14
4560 – 164 Guilhufe, Penafiel
PORTUGAL

From the Steripack SA concern, the present Field Safety Notice is also being sent to the following Regulatory Authorities:

- Portuguese Competent Authorities
- Swiss Competent Authorities
- Dekra Certification – Notified Body CE0344

Maintaining a high level of safety and quality is our highest priority and we are diligently working to return to the normal use of the product.

With regards,
Sterisets Medical Products / Steripack SA

Nuno Felix
Quality Director
25th April 2019

Sterisets International B
P.O. Box 474 - 5340 AL Oss - The Netherlan
Phone: +31 (0)412 667 755 - Email: info@sterisets.
www.sterisets.co

Field Safety Notice Acknowledgement Receipt

I acknowledge the receipt of the Field Safety Notice issued on the 25th of April 2019 with the following subject:

- Incident with Safety pin no. 3, 1 piece per pouch
  (Batch 1810069)
  Incident description: rust residue inside the sterile pouch

Company/End User	Print Name	Signature	Date

Note: Please send the signed *Field Safety Notice Acknowledgement Receipt* via email to nfelix@sterisets.eu

Sterisets International B
P.O. Box 474 - 5340 AL Oss - The Netherlan
Phone: +31 (0)412 667 755 - Email: info@sterisets.e
www.sterisets.co