

Urgent Field Safety Notice

Date: 30 August 2017

Reference: CC17-014

Action: Advisory

Our records indicate that your facility received one or more of the products subject to this field safety notice. The table below gives a full list of the affected products.

Affected Product	Part Number	Lot number
5/10112mm Armoured Swin to	YA512STSA	703340

Description of the problem:

This field safety notice gives notification of a labelling error on the product listed above.

The devices are sterile, however the label states non-sterile.

The label on the device (primary packaging) is labelled incorrectly and states "non-sterile" (see figure 1).

Figure 1



The label on the carton (secondary packaging) is correct and states "sterile" (see figure 2).

Figure 2



This does not impact the quality of the product, the product is sterile and there is **no** risk to patient safety. A steri-dot (red in colour) is applied to each primary and secondary packaging to indicate the batch has been sterilised.

Customer Instructions:

- Please read this notice.
- Complete the attached acknowledgement, even if you no longer have any of the product.
- Please return the completed end user and distributor acknowledgement to shazia.chaudhry@surginno.co.uk within 5 working days.
- Please pass this notice onto all users of the product listed within your organisation.
- Surgical Innovations is not requesting return or removal of these products as a result of this field safety notice, this notice is advisory.

Although Surgical Innovations is not recalling any of the products listed above, your National Competent Authority will be notified of this Field Safety Notice.

If you have any questions please contact Surgical Innovations on the contact details below.

Contact reference person:

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Thank you for your consideration.