

Urgent Field Safety Notice – Immediate Action Required

Affected product: Sterile Caspar Distraction Screws
FSCA identifier: Mercian Surgical Supply Co. Ltd - 14th April 2017
Type of action: Product Recall

19th April 2017

Details on affected devices:

SP3006-14 - Sterile Caspar Distraction Screws 14mm (Batch No: DIS18426)

www.merciansurgical.com

Description of the problem:

The screw has been manufactured with a flat square end not round, therefore the screws do not fit into the screwdriver correctly.

The product cannot be secured into the screwdriver as intended, the screw will remain loose and fall out. There are no hazards or risk to the patient, this will be highlighted by the device user when assembling the product prior to use.

Action to be taken by the user:

- Identify and quarantine the affected device
- Complete and return 'confirmed receipt notice'.
- Inform Mercian of quantities affected. The manufacturer will arrange to collect the product and replace via courier or by the sales representative for the local area.
- All product will be collected and replaced by Friday 28th April 2017.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

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

Contact reference person:

John Duffy / Hayley Claridge

Mercian Surgical Supply Co. Ltd. 10 Topaz Way, Topaz Business Park, Bromsgrove, B61 0GD

Telephone: 0844 879 1133

Email(s): John.Duffy@merciansurgical.com and Hayley.Claridge@merciansurgical.com

If you have any questions regarding this information please contact Mercian Surgical on the details provided above.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

Signature:



CONFIRMED RECEIPT NOTICE

Mercian Surgical Supply Co. Ltd

10 Topaz Way, Topaz Business Park, Bromsgrove, Worcestershire, B61 0GD
Tel: 0844 879 1133
Fax: 0844 879 1155
Email: Hayley.Claridge@merciansurgical.com

CASPAR DISTRACTION SCREWS

FIELD SAFETY NOTICE

Please complete the fields below and fax or email to the above

HOSPITAL OR TRUST:

NAME:

TITLE:

DEPARTMENT:

CONTACT TELEPHONE NUMBER:

CONTACT EMAIL ADDRESS:

SIGNATURE TO CONFIRM RECEIPT OF FIELD SAFETY NOTICE:

DATE: