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**Urgent Field Safety Notice - Immediate Action Required**

**Affected Products:**

SB0570-50 Sterile Bud Trimmer Burs 70mm x 5mm

SB0570-60 Sterile Bud Trimmer Burs 70mm x 6mm

**FSCA identifier:** Mercian Surgical Supply Co. Ltd

**Type of Action:** Product Recall

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30<sup>th</sup> March 2021

**Details of affected devices:**

**Product Code(s) and affected Lot/Batch No's:**

SB0570-50 Sterile Bud Trimmer Burs 70mm x 5mm - Lot No's: BUD24850

SB0570-60 Sterile Bud Trimmer Burs 70mm x 6mm - Lot No's: BUD24851

**GTIN Codes:**

5056126880366

5056126896121

5056126880373

5056126896138

Catalogue image of the affected device(s):



**Description of the problem:**

The burs have been manufactured incorrectly. They will not fit inside the handpiece being used to carry out the surgical procedure.

Please be aware that there is a risk of dropping the device whilst attempting to insert the bur into the handpiece. Do not use force to insert the bur, as this may cause damage to the handpiece.

**Advise on action to be taken by the user:**

- Identify and quarantine the device(s).
- Complete and return the 'Confirmed receipt notice'.
- Inform Mercian of the quantity of burs affected. Mercian will arrange to collect the affected product via courier or local sales representative where possible.
- A credit note will be issued for the returned burs or an alternative product (50mm length) is available immediately as a replacement.

**Transmission of this Field Safety Notice:** (if appropriate)

This notice needs to be passed onto 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. (If appropriate)

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

**Contact reference person:**

Hayley Claridge - Quality and Compliance Manager

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

Telephone: +44 (0) 844 879 1133

Email: [Hayley.Claridge@merciansurgical.com](mailto:Hayley.Claridge@merciansurgical.com)

If you have any questions regarding this Field Safety Notice, please contact Mercian Surgical using the contact details provided above.

We can confirm that this notice has been notified to the appropriate Regulatory Agency

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**CONFIRM RECEIPT NOTICE**

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**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](mailto:Hayley.Claridge@merciansurgical.com)

[www.merciansurgical.com](http://www.merciansurgical.com)

**SB0570-50 Sterile Bud Trimmer Burs 70mm x 5mm**

**SB0570-60 Sterile Bud Trimmer Burs 70mm x 6mm**

**FIELD SAFETY NOTICE**

*Please complete the fields below and email back to the above*

Hospital Name/Healthcare Facility:	
Department:	
Contact Name:	
Job Title:	
Email Address:	
Telephone No:	
Quantity to return:	
Signature to confirm receipt of field safety notice:	
Date:	