

URGENT FIELD SAFETY NOTICE / RECALL

Product Name: 040-734 BriteBlade Pro Single-use Flexible McCoy Type Blade Size 4

Ref: FSCA 2023-001 **Date:** 12 June 2023

Attention: All users of the product including Operating Room, Intensive Care, Emergency Departments, Obstetric units and Anaesthetic Department clinicians, managers, nurses, and support staff.

Details on affected devices:

Flexicare Part Number	Product Description	LOT Number
040-734	BriteBlade Pro Single-use Flexible McCoy Type Blade Size 4	230204048
		230304082

Description of the problem: *There is potential this product is not provided sterile as indicated on product packaging. Laryngoscope blades are not commonly provided as sterile and therefore it is believed the risk to patients who have or will receive treatment using this device is low.*

Only devices with the above lot numbers are affected.

Advise on action to be taken:

- 1) If you have purchased this device; locate and quarantine the devices with a lot number listed in the table above. The lot number can be found on both the outer box label and the individual packaging.
- 2) Acknowledge receipt and understanding of this field safety notice and have communicated this field safety notice to all end users
- 3) Complete and return the Acknowledgment and Response Form to Flexicare Medical Limited to arrange return and/ credit/replacement of these devices.
- 4) If you have no affected devices, please indicate this when returning the Acknowledgment and Response Form.

Transmission of this Field Safety Notice / Recall:

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

Flexicare Medical would like to apologise for any inconvenience this matter may cause you.

If you have any questions, please contact your local Flexicare Medical representative or email our Quality Team at Quality@Flexicare.com.

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

Dr Gurge Phull
Regulatory / Quality Director
Flexicare Medical Limited

FIELD SAFETY NOTICE – ACKNOWLEDGEMENT FORM

PRODUCT CODE	DESCRIPTION	LOT	Quantity Quarantined (pieces)
040-734	BriteBlade Pro Single-use Flexible McCoy Type Blade Size 4	230204048	
		230304082	

- I acknowledge receipt and understanding of this field safety notice and have identified that we do not have any of the listed product lot numbers
- I acknowledge receipt and understanding of this field safety notice and can confirm that I have forwarded this field safety notice to all end users and have asked them to complete and send back to me and once received, I will forward the completed end users field safety notices to you.
- I acknowledge receipt and understanding of this field safety notice and have _____pieces for Collection & Return as per instruction of this Field Safety Notice.

Customer Name: _____

Position: _____

Address: _____

Telephone: _____

Email: _____

Please complete this form by 30 June 2023 and return to Quality@flexicare.com

Flexicare use Only

Reviewed By:

Date:

<p>Comments</p> <hr/> <hr/> <hr/> <hr/>
