URGENT Field Safety Notice (FSN)

Product Name: Britepro Solo Single-Use Fiber Optic Laryngoscope

Ref: FSCA 2024-001 **Date:** 23 May 2024

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

Description of the problem:

BritePro Solo Laryngoscope handles have been found not to illuminate. Flexicare Ltd has been made aware of incidents that BritePro Solos have failed to illuminate when preparing for intubation during emergency situations.

As with all single-use BritePro Solo Laryngoscopes it is a requirement to carry out a pre-use illumination check. The method of detection is visual, the user can ascertain if handle is illuminating while still in the packing, therefore not compromising the sterility.

BritePro Solo Laryngoscopes should be available alongside backup devices and it is common practice to test functionality daily.

Only devices with the below lot number are affected and included in this recall.

Details on affected devices:

Flexicare Part Number	LOT Number	Expiry Date
040-310	200600284	**2025-05**
040-333	200503144	**2025-04**
040-333	200101078	**2024-12**
040-333	191002181	**2024-09**
040-334	220301692	**2027-04**
040-334	200503144	**2025-04**
040-334	200600287	**2025-05**
040-334	200600288	**2025-05**
040-343	200700560	**2025-06**
040-344	201001784	**2025-09**

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flexicare

Registered Number: 9109193 • VAT Registration Number: GB 310 726 243

While the occurrence of the device not illuminating is low, and will be observed during pre-use check, it is recommended that all other back-up devices be checked for functionality, to prevent a delay in treatment and/or a difficult/unsuccessful intubation.

Advise on action to be taken:

1) If you have purchased this device; please locate and quarantine the devices with lot numbers listed in the table above. The lot number can be found on both the outer box label and the individual packaging.

2) Please ensure this Field Safety Notice has been communicated to all users including those listed in the Attention section on page 1.

3) If you have any devices as listed, please complete and return the Acknowledgment and Response Form (page 3) of this notice to Flexicare Medical Limited, indicating the quantities. Arrangements for return and subsequent credit/replacement of these devices will then be given.

4) If you have no affected devices, you are still requested to complete and return the Acknowledgment and Response Form (page 3) of this notice to Flexicare Medical Limited, indicating zero stock.

Transmission of this Urgent Field Safety Notice (FSN)**:**
This notice is to be passed on to all those who need to be aware within your organisation and to any organisation 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

Digitally signed by Gurge Phull
DN: cn=Gurge Phull, o=Flexicare Medical Ltd, ou=QARA Dept, email=gurge.phull@flexicare.com, c=GB
Date: 2024.05.23 16:17:49 +01'00'

Dr Gurge Phull,

Regulatory / Quality Director

Flexicare Medical Limited

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URGENT MEDICAL DEVICE FIELD SAFTEY NOTICE (FSN) ACKNOWLEDGEMENT FORM

Flexicare Part Number	LOT Number	Quantity Quarantined (pieces)
040-310	200600284	
040-333	200503144	
040-333	200101078	
040-333	191002181	
040-334	220301692	
040-334	200503144	
040-334	200600287	
040-334	200600288	
040-343	200700560	
040-344	201001784	

☐ I acknowledge receipt and understanding of this medical device Field Safety Notice (FSN) and can confirm that I have forwarded this 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 notices to you.

☐ I acknowledge receipt and understanding of this medical device Field Safety Notice (FSN) and have units for Collection & Return as per instructions. (quantities specified in the above table)

☐ I acknowledge receipt and understanding of this medical device Field Safety Notice (FSN) and have identified that we do not have any of the listed product lot numbers

Customer Name:_____ Position:_____

Facility Name _____

Facility Address:_____

Email:_____

Please complete this form by 17 June and return to quality@flexicare.com

Flexicare Use Only

Reviewed By: Date:

Comments

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