Flexicare Medical Limited

URGENT: MEDICAL DEVICE RECALL

Ref: FSCA 2019-001 **Date:** 25th October 2019

Product Name: BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Macintosh Blade Size 3

Part Number: 040-333

Flexicare Medical has received a limited number of reports of issues relating to a specific lot number of the above products and is issuing a voluntary recall as a precautionary measure for potentially affected devices remaining unused with customers.

Attention:
All users of the listed products including Operating Room, Resuscitation, Intensive Care, Anaesthetic Department and Emergency Medicine clinicians, managers, nurses, paramedics and support staff.

Description of Problem:
The potential for the spring-loaded bearings that secure the blade in position when engaged on the laryngoscope handle to become separated from the blade block and possibly fall into the oral cavity if the blade is disengaged over the patient's open mouth.

Part Number, Description and Lot Numbers of devices involved in this Field Safety Notice:

Part Number	Product Description	Lot Numbers
040-333	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Macintosh Blade Size 3	180900401
		181201031

Action to be taken:

1) Immediately locate and quarantine any devices with a lot number in that table above. The lot number can be found on both the outer box label and on the individual packaging.
2) Complete and return the Acknowledgement and Response Form to Flexicare Medical Limited to arrange return and credit/replacement of these devices. If you have no affected devices, please indicate this on the Acknowledgement and Response Form.

+44(0)1443 474647 +44(0)1443 474222 enquiries@flexicare.com www.flexicare.com
Registered Office: Flexicare (Group) Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER UK
Registered Number: 9109193 VAT Registration Number: GB 197 124 784

Corrective Action taken by Flexicare Medical:
The cause of the potential loose parts was identified as the use of out of specification components that could lead to the spring expelling the bearing and retaining ring from the blade block. Production was placed on hold, all components dimensionally checked, and any the out of specification parts withdrawn. Following completion of these actions and validation of the changes, production recommenced.

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 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 our Quality Team by email at Quality@Flexicare.com.

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

Richard Downs
Group Product Surveillance Manager
Flexicare Medical Limited

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FLEXICARE MEDICAL Ltd PRODUCT RECALL

Acknowledgement and Response Form

Response is Required

BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Macintosh Blade Size 3
Part Number: 040-333

☐ I have read and understood the instructions in the Product Recall letter dated 25th October 2019

☐ I have communicated this Product Recall to all end users

☐ I have identified that we do not have any of the listed product lot numbers

or

☐ I have removed from service and quarantined the quantities listed in the table below and await your instructions for return:

Part Number	Product Description	Lot Numbers	Quantity Quarantined (units)
040-333	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Macintosh Blade Size 3	180900401	
		181201031	

Name: _____

Position: _____

Organisation: _____

Address: _____

Telephone: _____

Email: _____

Please complete this form and return to: Quality@Flexicare.com

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Flexicare use only

Reviewed by: Date:

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