Rev 1: September 2018
FSN Ref: 487911 FSCA Ref: 487911

Date: 03/06/2025

Urgent Field Safety Notice (RECALL)

i-View Video Laryngoscope

For Attention of*: MDSO's, All clinical staff, Managers and users of the above products, including those who may use them remotely.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Giedrius Budrys **Customer Resolution and Relationship Manager** **Intersurgical UAB** **Arnioniu str 60, LT-18170 Pabrade Lithuania** **Email: giedriusb@intersurgical.lt** **Tel. +370 387 66611** **Fax: +370 387 66622** **or** **This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages**

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Urgent Field Safety Notice (FSN)

i-View Video Laryngoscope

Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Video Laryngoscope
1.	2. Commercial name(s)
	i-View Video Laryngoscope
1.	3. Unique Device Identifier(s) (UDI-DI)
	05030267LARYNAB
	4. Primary clinical purpose of device(s)*
	To facilitate laryngoscopy.
1.	5. Device Model/Catalogue/part number(s)* REF: 8008000
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range Lot 1240555 Lot 1240793 Lot 1241142
1.	8. Associated devices
	N/A.

	2. Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	We have received a number of reports of faulty devices resulting from depleted batteries.

2.	2. Hazard giving rise to the FSCA*
	The instructions for use provided with i-View, include the pre-use check to turn on the device and check there is a visible light at the distal end of the blade and that the screen and camera are working correctly. The device must be discarded if it cannot be successfully switched on and off. It also includes the warning to ensure a backup plan is in place, in case of difficulty or emergency while performing the procedure. The risk associated to the highlighted problem is therefore assessed as low providing the pre-use checks in the instructions for use are followed. However, in view of the number of reports already received for these devices manufactured between January and July 2024, we believe it is necessary to carry out FSCA by removing the potentially affected products from the market to minimise inconvenience to users and possible delays to treatment.
2.	3. Probability of problem arising
	High in the affected Lot number range.
2.	4. Predicted risk to patient/users
	The risks associated with the identified fault have been reviewed, where the probability of harm is low, but due to the higher rate of possible occurrence we feel it is essential to address the issue promptly to further reduce the risk of any potential delays to treatment and any patient harm.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	The batteries and the assembled device are tested for performance during the manufacturing process. However, following customer reports from the market and subsequent analysis of internal stock, we have identified faulty batteries in some products where the batteries have depleted sometime after manufacture.
2.	7. Other information relevant to FSCA N/A
	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***
	☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Please distribute this Field Safety Notice to all potential users of the i-View devices listed above, within your facility. This is for their awareness of the potential problem and to carry out the following actions.

	1. Identify and immediately quarantine any potentially affected products from the affected code and lot numbers listed above. 2. Please complete the Reply Form below to confirm the products you have identified, to arrange collection of the devices and a credit. 3. If you have no affected devices in stock, please confirm this using the Reply Form below. 4. Please return the Reply Form provided below to to giedriusb@intersurgical.lt or local contact e-mail address, to confirm receipt of this notice and that the necessary actions have been taken. **Please note**: This is a Recall. Please continue to report to Intersurgical any adverse events involving this product.	
3.	2. By when should the action be completed?	Immediately on receipt of this FSN and ongoing until no affected stock listed in this FSN is remaining.
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? Not applicable.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	One month from receipt of the FSN
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	N/A	

	4. General Information*	
4.	1. FSN Type*	New – Recall Notice
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
	5. If follow-up FSN expected, what is the further advice expected to relate to:	

4	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Intersurgical Ltd.**
	b. Address	**Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ**
	c. Website address	**https://www.intersurgical.com/**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**Customer Reply Form**
4.	10. Name/Signature	**Ivan Seniut, Group Quality and Regulatory Affairs Director, Intersurgical**
		

	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

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Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	487911
FSN Date*	02/06/2025
Product/ Device name*	i-View Video Laryngoscope
Product Code(s)	REF: 8008000
Batch/Serial Number (s)	Lot 1240555 Lot 1240793 Lot 1241142

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.			
☐	The information and required actions have been brought to the attention of all relevant users and executed.			
☐	I do not have any affected devices.			
☐	We have quarantined the following potentially affected stock we wish to return for credit/replacement. (Please enter the quantity for each Code and Lot number).	**Code:**	**Lot:**	**Qty:**
		Code:	**Lot:**	**Qty:**
		Code:	**Lot:**	**Qty:**
		Code:	**Lot:**	**Qty:**
		Code:	**Lot:**	**Qty:**

☐ Any Other comments:	
Print Name*	Customer print name here
Signature*	Customer sign here
Date*	

4. Return acknowledgement to sender	
Email	priority@intersurgical.co.uk
Customer Helpline	N/A
Postal Address	Intersurgical Ltd., Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ
Web Portal	N/A
Deadline for returning the customer reply form*	04/07/2025

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.