Rev 1: September 2018
FSN Ref: 448955 FSCA Ref: 448955

Date: 04.09.2024

Urgent Field Safety Notice

IPPB Flextube™ breathing system

For Attention of*: MDSOs, All clinical staff, Managers and users of the above product

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)

IPPB Flextube™ breathing system

Risk addressed by FSN

Please note: This is not a Recall

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	IPPB breathing systems
1.	2. Commercial name(s)
	IPPB Flextube™ breathing system
1.	3. Unique Device Identifier(s) (UDI-DI)
	05030267001873
1.	4. Primary clinical purpose of device(s)*
	IPPB breathing systems are for short-term, intermittent use with spontaneously breathing patients for the purpose of assisting lung expansion and delivering medication in a hospital environment.
1.	5. Device Model/Catalogue/part number(s)*
	1416000
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	1416000 - 32104658, 32110163, 32110431, 32203905, 32205904, 32207328, 32210033, 32214289, 32215185, 32215610, 32317105, 32318867, 32319758, 32321069, 32322754, 32401829.
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*

1. We have received a report of loose connections between the nebuliser and supply line T-Piece in one of our IPPB breathing systems (see figure1 below). When the system is pressurised, there is the possibility that the T-Piece can detach from the nebuliser.
See Actions 1. and 2. in Sec. 3.1 below.

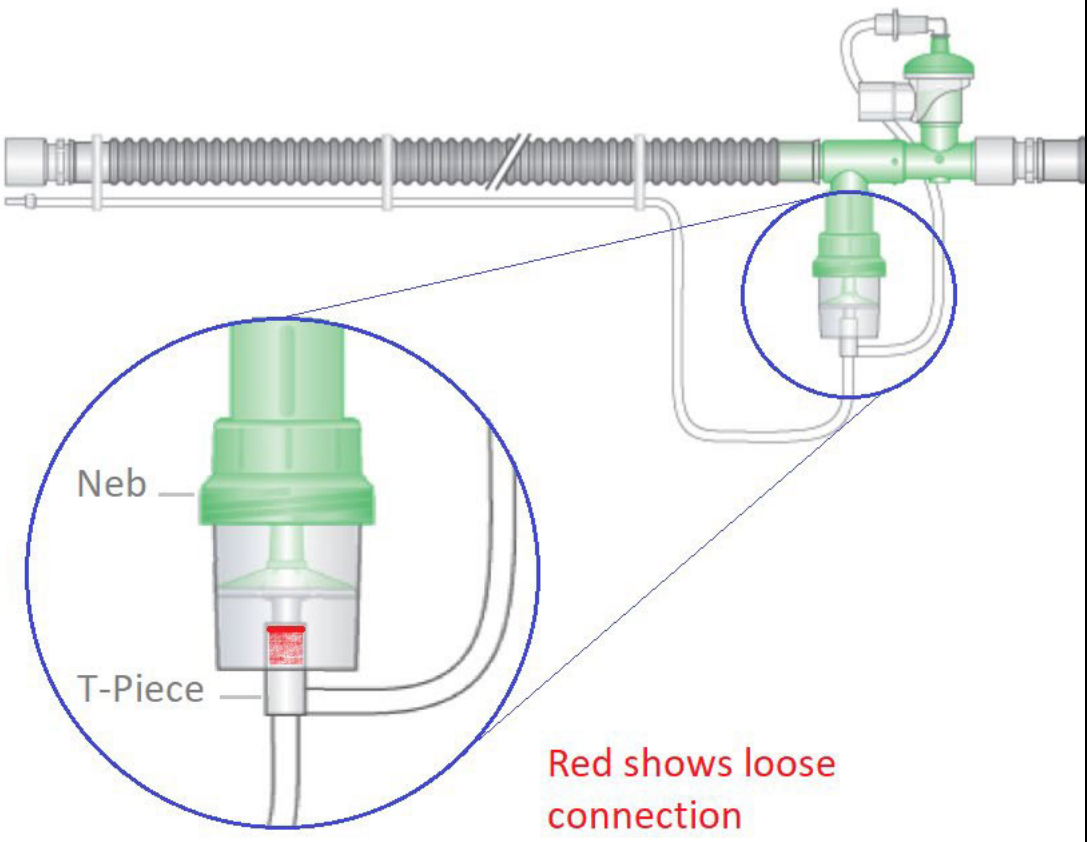


***Figure 1**: IPPB Breathing system schematic showing zoom detail of nebuliser and supply line T-Piece connection*

2. As a result of the reported problem, we have identified the opportunity to improve the current Instruction For Use provided with these products. The Pre-Use Checks section will in future include the following warning;
*"WARNING: Every component of the breathing system must be visually inspected and checked for function, leakage and occlusions, immediately before use on each patient. Ensure that connections are secure **using a push and twist action.**"*

See Action 2. In Sec. 3.1. below.

2.	2. Hazard giving rise to the FSCA*

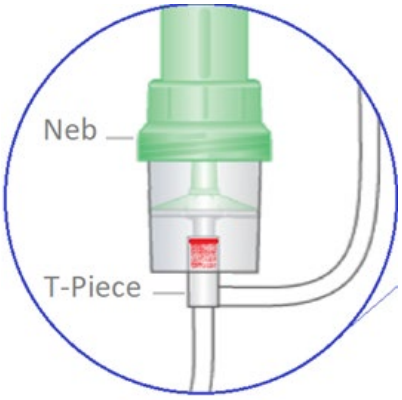
	The disconnection of the nebuliser/ exhalation valve control T-Piece during use would cause a minor delay or interruption of treatment. As the issue has been shown to occur immediately at set-up or very shortly after first use, a clinician will be present. If a secure reconnection cannot be achieved, a replacement product will be needed to continue treatment. A short delay or interruption to treatment will result in an extended procedure time, which has been evaluated as a **minor risk.** In rare situations, i.e. a combination of patient condition and timely unavailability of IPPB replacement, an alternative form of therapy may be needed e.g. Non-invasive Positive Pressure Ventilation or an alternative cough assist machine. This has been evaluated as a **moderate risk.**
2.	3. Probability of problem arising
	Delay or interruption of treatment resulting in extended procedure time: It is likely to occur frequently in the potentially affected range of products. **An alternative procedure may be required e.g. Non-invasive Positive Pressure Ventilation**: It is unlikely / rare to occur.

2.	4. Predicted risk to patient/users
	The risks associated with the identified fault have been reviewed, and whilst it is unlikely there will be any impact beyond a short delay to treatment, we believe it is essential to address the issue promptly to further reduce the risk of any potential patient harm and to avoid the further risk of product availability if removed from the market
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	To date this issue has only been reported by one customer. The problem was identified before use on the patient. Analysis of manufacturing records has confirmed the loose connection is possibly affecting the product codes and lot numbers listed above.
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 Any Defective Devices ☒ Return any Defective Devices ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Please distribute this Field Safety Notice to all potential users of the IPPB breathing systems listed above, within your facility. This is for their awareness of the potential problem and to carry out the following actions. **<u>Action 1. Stock of the potentially affected Lots:</u>** To ensure the safety of patients we recommend the following immediate actions with any existing stock you may have of the Lot numbers listed above.

1. Identify any potentially affected products from the affected codes and lot numbers listed above.

2. The security of connection between the Nebuliser and T-Piece can be checked by hand through the packaging. Secure connection should be possible using the push and twist action as detailed in the device Instructions For Use.



Please isolate any products you identify with loose connections, and return them to us.

<u>Action 2. All Users of these products</u>:

1. All users must perform a thorough visual inspection and functional test before use of the products and lot numbers listed above, as detailed in the device Instructions For Use, Pre-use Checks:
   - *WARNING Every component of the breathing system must be visually inspected and checked for function, leakage and occlusions, immediately before use on each patient. Ensure that connections are secure.*
   - *WARNING Perform a self-test of the ventilator after full assembly of the breathing system and associated accessories before use on each patient.*

   Additionally to the current instructions for use, you must confirm a secure connection can be achieved between the nebuliser and gas supply, using a push and twist action. This new instruction is currently being added to the IFU for the future.

2. If a secure connection cannot be achieved with a device, remove from use, quarantine the product and please return to us immediately.

Please complete and return the Reply Form provided to giedriusb@intersurgical.lt , to confirm receipt of this notice and that the necessary actions are being taken.

The copy of this FSN will be available on the Intersurgical website, Support section, for the duration of this Field Safety Corrective Action.
Direct link - https://customers.intersurgical.com/ProductDocumentation

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 awareness of this FSN should be ongoing until all potentially affected stock listed in this FSN has been used up.

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 We have implemented corrective actions in manufacturing process to eliminate this problem for future supply. We will also be introducing further clarification to the device Instruction For Use which will be included within the existing Pre-Use Checks, in line with the recommended actions above: *"WARNING: Every component of the breathing system must be visually inspected and checked for function, leakage and occlusions, immediately before use on each patient. Ensure that connections are secure **using a push and twist action.**"*	
3	6. By when should the action be completed?	4 months 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
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
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	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	[redacted]

	c. Website address	[redacted]
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, Distributor Reply Form
4.	10. Name/Signature	[redacted]

	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.