

Date: 30.01.2025

Urgent Field Safety Notice

VARIOUS UNIFLOW COAXIAL BREATHING SYSTEMS

For Attention of*: MDSO's, All Clinical staff, Managers and users of the above product

Contact details of local representative (name, e-mail, telephone, address etc.)*

[Redacted contact details]

or

This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

Urgent Field Safety Notice (FSN)**VARIOUS UNIFLOW COAXIAL BREATHING SYSTEMS****Risk addressed by FSN**

1. Information on Affected Devices*	
1.	1. Device Type(s)* Various Uniflow Coaxial Breathing Systems
1.	2. Commercial name(s)

2900000	30mm UNIFLOW B/S LUER/ELB =>1.6m
2900005	30mm UNIFLOW B/S LUER/ELB >= 3.2M
2900008	30mm UNIFLOW B/S LUER/ELB LIMB >= 2m
2900009	30mm UNIFLOW B/S 3L/B LUER/ELB F >= 1.6m
2900020	30mm UNIFLOW B/S 2L/B LUER/ELB LIMB >= 1.6m
2900023	30mm UNIFLOW B/S LUER/ELB >= 4.8m
2900025	30mm UNIFLOW B/S 2L/B LUER/ELB LIMB >= 2m
2900027	30mm UNIFLOW B/S 2L/B LUER/ELB M/LINE LIMB >= 1.6m
2900039	30mm UNIFLOW B/S 2L/B LUER/ELB SPIRO/SET LIMB >= 1.6M
2900047	30mm UNIFLOW B/S 2L/B LUER/ELB M/LINE LIMB >= 2m
2900050	30mm UNIFLOW B/S LUER/ELB >= 1.8m
2900051	30mm UNIFLOW B/S LUER/ELB >= 2.7M
2900062	30mm UNIFLOW B/S M/LINE >= 1.8m
2900076	30mm UNIFLOW B/S LUER/ELB S/LIMB >= 3.2M
2900100	30mm UNIFLOW SK B/S LUER/ELB >= 1.6m
2900102	30mm UNIFLOW SKB/S 2L/B LUER/ELB LIMB >= 1.6m
2900104	30mm UNIFLOW SK B/S 2L/B LUER/ELB BAG LIMB >= 1.6m
2900106	30mm UNIFLOW SK B/S 3L/B LUER/ELB >= 1.6m
2900109	30mm UNIFLOW SKB/S 2L/B F SPIRO/SET LIMB >= 1.6m
2900110	30mm UNIFLOW SKB/S 2L/B LUER/ELB LIMB >= 1.6m
2901000	30mm UNIFLOW B/S LUER/ELB >= 2.4m
2901007	30mm UNIFLOW B/S LUER/ELB LIMB >= 2.4m
2901008	30mm UNIFLOW B/S 2L/B LUER/ELB LIMB >= 2.4m
2901009	30mm UNIFLOW B/S 2L/B LUER/ELB M/LINE LIMB >= 3.2m
2901011	30mm UNIFLOW B/S 2L/B LUER/ELB SPIRO/SET LIMB >= 2.4m
2901012	30mm UNIFLOW B/S 2L/B LUER/ELB LIMB >= 2.4m
2901013	30mm UNIFLOW B/S 2L/B LUER/ELB LIMB >= 2.4m
2901021	30mm UNIFLOW B/S 2L/B LIMB >= 2.4m
2901100	30mm UNIFLOW SKB/S LUER/ELB >= 2.4m
2901102	30mm UNIFLOW SKB/S 2L/B LUER/ELB BAG LIMB >= 2.4m
2901104	30mm UNIFLOW SKB/S 2L/B LUER/ELB BAG LIMB >= 2.4m
2901105	30mm UNIFLOW SKB/S 2L/B LUER/ELB LIMB >= 2.4m
2901107	30mm UNIFLOW SK B/S 2L/B LUER/ELB SPIRO/SET LIMB >= 2.4M
2901109	30mm UNIFLOW SKB/S 2L/B LUER/ELB SPIRO/SET LIMB >= 2.4m
2901111	30mm UNIFLOW SKB/S 2L/B F SPIRO/SET LIMB >= 2.4m
2902000	30mm UNIFLOW B/S LUER/CONN M/LINE ELB >= 1.6M
2902002	30mm UNIFLOW B/S 2L/B LUER/CONN M/LINE ELB BAG LIMB >= 1.6m
2902012	30mm UNIFLOW B/S 2L/B LUER/CONN M/LINE LIMB >= 1.6m
2902015	30mm UNIFLOW B/S 2L/B LUER/CONN BAG LIMB >= 1.6m
2902017	30mm UNIFLOW B/S LUER/CONN M/LINE >= 1.6m
2902019	30mm UNIFLOW B/S ELB M/LINE >= 2M
2902021	30MM UNIFLOW B/S 2L/B LUER/CONN M/LINE ELB LIMB >= 1.6m
2902100	30mm UNIFLOW SK B/S LUER/CONN M/LINE ELB >= 1.6m
2902102	30mm UNIFLOW SKB/S 2L/B M/LINE ANA FM LIMB >= 1.6m
2902103	30mm UNIFLOW SK B/S 2L/B LUER M/LINE ANA FM LIMB >= 2.4m
2902104	30MM UNIFLOW SK B/S 2L/B LUE/CON ELB M/LINE ANAFM LIMB>=1.6m
2902106	30mm UNIFLOW SKB/S 2L/B M/LINE ANA FM LIMB >= 1.6m
2902111	30mm UNIFLOW SK B/S 2L/B LUER/CONN M/LINE BAG LIMB >= 1.6m
2903000	30mm UNIFLOW B/S LUER/CONN M/LINE ELB >= 2.4M
2903005	30mm UNIFLOW B/S LUER/CONN M/LINE ELB >= 3.2m
2903006	30mm UNIFLOW B/S 2L/B LUER/CONN M/LINE ELB BAG LIMB >= 2.4m
2903007	30mm UNIFLOW B/S LUER/CONN M/LINE ELB >= 2.4m
2903010	30mm UNIFLOW B/S LUER/CONN M/LINE ELB >= 3.2M

	2903015	30mm UNIFLOW B/S 2L/B LUER/CONN M/LINE ELB LIMB >= 2.4M
	2903020	30mm UNIFLOW B/S 2L/B LUER/CONN M/LINE ELB BAG LIMB >= 2.4M
	2903027	30mm UNIFLOW B/S 2L/B LUER/CONN M/LINE ELB F LIMB >= 2.4M
	2903100	30mm UNIFLOW SK B/S LUER/CONN M/LINE ELB >= 2.4M
	2903101	30mm UNIFLOW SK B/S 2L/B LUER/CONN M/LINE ELB LIMB >= 2.4M
	2910000	30mm UNIFLOW DELUXE B/S 2L/B LUER/CONN M/LINE LIMB >= 1.6m
	2910100	30mm UNIFLOW SK DL B/S 2L/B LUER/CONN M/LINE ELB APL >= 1.6m
	2911000	30mm UNIFLOW B/S 2L/B LUER/CONN M/LINE ELB APL >= 2.4M
	2919016	30mm UNIFLOW SK B/S 2L/B LUER/CONN M/LINE ELB >= 1.6m
	2919024	30mm UNIFLOW SK B/S 2L/B LUER/CONN M/LINE ELB >= 2.4m
	2919032	30mm UNIFLOW SK B/S 2L/B LUER/CONN M/LINE ELB >= 3.2M
1.	3. Unique Device Identifier(s) (UDI-DI)	

05030267029013
05030267040551
05030267042340
05030267045440
05030267089796
05030267092918
05030267099221
05030267106424
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05030267127559
05030267136988
05030267137008
05030267144945
05030267153602
05030267040599
05030267075935
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05030267136315
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	4. Primary clinical purpose of device(s)* To deliver and remove anaesthetic and respiratory gases to and from a patient via a breathing system comprised of tubing and connectors.
1.	5. Device Model/Catalogue/part number(s)* 2900000 2900005 2900008 2900009 2900020 2900023 2900025 2900027 2900039 2900047 2900050 2900051 2900062 2900076 2900100 2900102 2900104 2900106 2900109

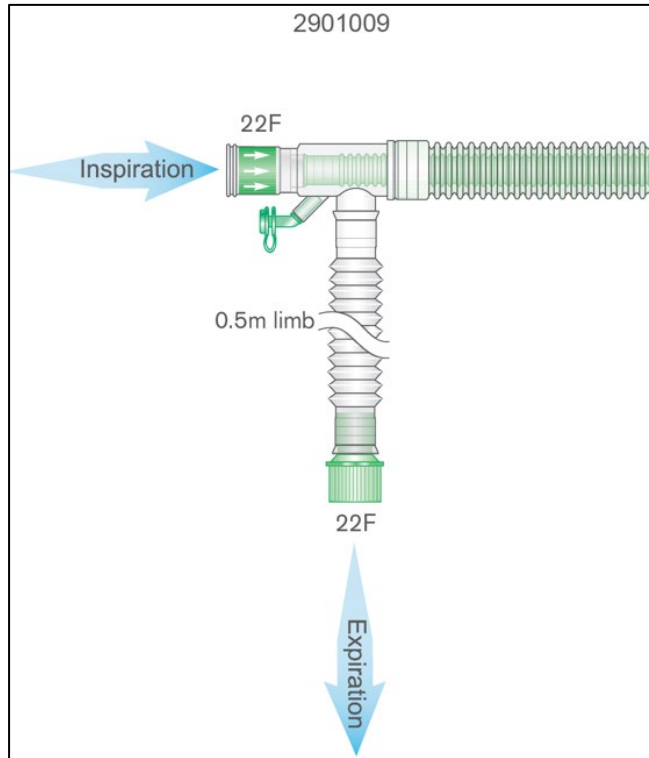
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1.	6. Software version																																																																																																																																										
	N/A																																																																																																																																										
1.	7. Affected lot numbers— all within the range below, from the first lot produced after the change to the last one manufactured before the issue was noticed (e.g., code 2900000; from lot 32411113 to 32425225):																																																																																																																																										
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1.	8. Associated devices
	N/A.

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

We have received some reports of the extendable expiratory gas tubing disconnecting from the system T-piece as shown below, due to insecure connection of the two mating parts.



2. 2. Hazard giving rise to the FSCA*

	If the insecure connection of the expiratory gas tube is not identified during set-up and pre-use checks, detachment in use could result in gross leakage and reduced circulating gas volume which would have a negative impact upon ventilation.
2.	<p>3. Probability of problem arising</p> <p>We have determined that as many as 5% could be affected by this problem, but the probability of the problem not being identified prior to use is assessed as possible (<0.1%).</p>
2.	<p>4. Predicted risk to patient/users</p> <p>The risks associated with the identified fault have been reviewed, and If the fault of potential disconnection is not identified before use, it could result in failure of ventilation and accumulation of Carbon Dioxide, hypercapnia could result in respiratory and metabolic acidosis. If acidosis is left untreated it can lead to organ failure, shock and death. Whilst we believe the fault is most likely to be identified before use, we believe it is essential to address the issue promptly to further reduce the risk of any potential patient harm.</p>
2.	<p>5. Further information to help characterise the problem</p> <p>N/A</p>
2.	<p>6. Background on Issue</p> <p>Following customer reports from the market and subsequent thorough inspection and analysis of internal stock, we have identified a potential safety concern related to various Uniflow Coaxial breathing systems as listed above. Unfortunately some products have been manufactured with the extendable expiratory gas tubing not fully and securely connected to the T-piece. This could result in detachment of the tubing with resulting gross leakage, reduced circulating gas volume, which would have a negative impact upon delivery of prescribed ventilation.</p>
2.	<p>7. Other information relevant to FSCA</p> <p>N/A</p>
	3. Type of Action to mitigate the risk*
3.	<p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input checked="" type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Please distribute this Field Safety Notice to all potential users of the Uniflow Coaxial breathing systems listed above, within your facility. This is for their awareness of the potential problem and to carry out the following actions.</p> <p>To ensure the safety of patients we recommend the following actions.</p>

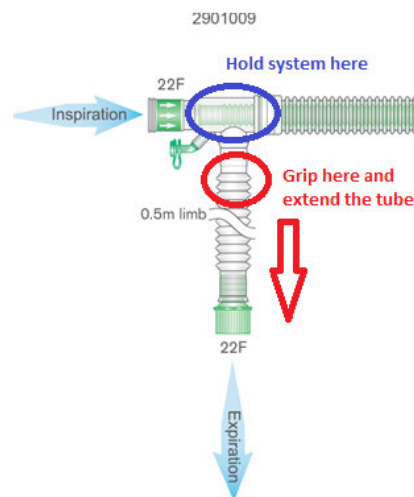
1. Identify any potentially affected products from the affected codes and lot numbers listed above and quarantine them.

2. If there is an immediate need to use any of the affected codes or lot numbers listed above, please follow these instructions:

A) Carry out the Pre-Use Checks as per the instructions for use provided, paying particular attention to the following instruction:

*“Following attachment the breathing system and all accessories must be checked for leaks and occlusions prior to use **and that all connections are secure.**”*

B) As an additional specific check, hold the inspiratory gas tubing at the connection point and extend the expiratory gas tubing as shown below, to confirm the tube is securely attached and does not disconnect.



C) If you identify any affected systems as a result of the checks above, please retain them and report to us immediately.

3. If you have any potentially affected products listed above for return to us for credit/replacement, please detail the quantities for each code and lot number in the Reply Form provided below.

4. Please complete and return the Reply Form provided to giedriusb@intersurgical.it or local contact e-mail address to confirm receipt of this notice and to confirm what actions have been taken. This will enable us to arrange any necessary replacements or credits.

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 removed from use, or used up if following the instructions for checking the product.
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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 <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other <input type="checkbox"/> None We have implemented corrective actions in manufacturing process to eliminate this problem for future supply.	
3	6. By when should the action be completed?	Immediately but not later than 6 months from receipt of the FSN
3.	7. Is the FSN required to be communicated to the patient /lay user? 8.	No
3	9. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? 10.	
	N/A	

4. General Information*		
4.	1. FSN Type*	New – Recall
4.	2. For updated FSN, reference number and date of previous FSN 3.	N/A
4.	4. For Updated FSN, key new information as follows: N/A	
4.	5. Further advice or information already expected in follow-up FSN? * 6.	No
4	7. If follow-up FSN expected, what is the further advice expected to relate to: N/A	
4	8. Anticipated timescale for follow-up FSN 9.	N/A
4.	10. 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.	11. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	12. List of attachments/appendices:	Customer Reply Form
4.	13. Name/Signature	[Redacted]

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.</p>

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