Rev 1: September 2018
FSN Ref: 464552 FSCA Ref: 464552

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.)*
Miriam Nolan **Managing Director** **Intersurgical Ireland Ltd** **253 Corporate Park 2** **Blanchardstown** **Dublin 15** **Mobile: 0870685089** **Email: mn@intersurgical.ie**

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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/CONNM/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 05030267117833 05030267127559 05030267136988 05030267137008 05030267144945 05030267153602 05030267040599 05030267075935 05030267107124 05030267121359 05030267138951 05030267140213 05030267029020 05030267088812 05030267089819 05030267094776 05030267118052 05030267120208 05030267122899 05030267144624 05030267040605 05030267103300 05030267107148 05030267119356 05030267125210 05030267136315 05030267140190 05030267029846 05030267040377 05030267091768 05030267109999 05030267113996 05030267119509 05030267146826 05030267040612

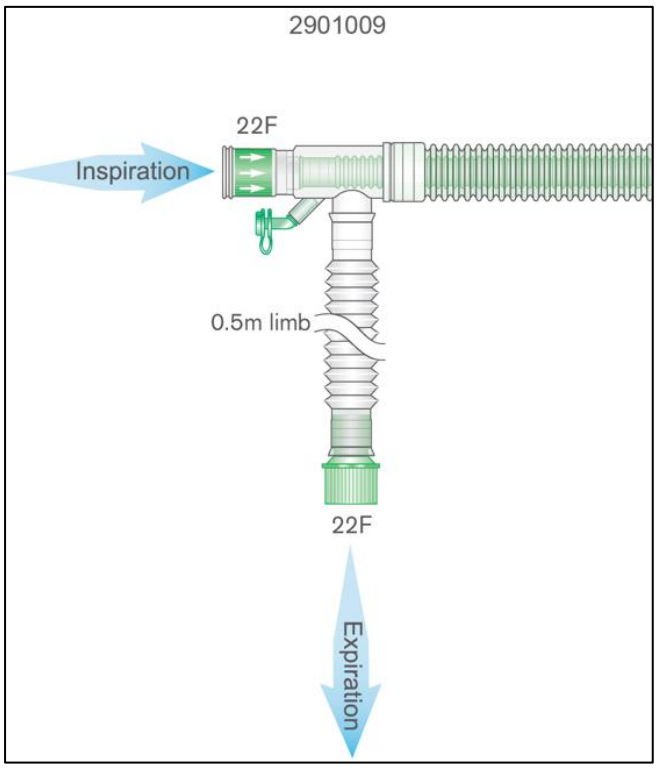
	05030267043590 05030267043583 05030267045310 05030267125364 05030267107162 05030267029839 05030267048830 05030267109975 05030267113873 05030267144907 05030267124770 05030267144136 05030267156399 05030267040629 05030267047857 05030267029037 05030267040636 05030267033508 05030267162628 05030267162680 05030267162666
	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

	2900110 2901000 2901007 2901008 2901009 2901011 2901012 2901013 2901021 2901100 2901102 2901104 2901105 2901107 2901109 2901111 2902000 2902002 2902012 2902015 2902017 2902019 2902021 2902100 2902102 2902103 2902104 2902106 2902111 2903000 2903005 2903006 2903007 2903010 2903015 2903020 2903027 2903100 2903101 2910000 2910100 2911000 2919016

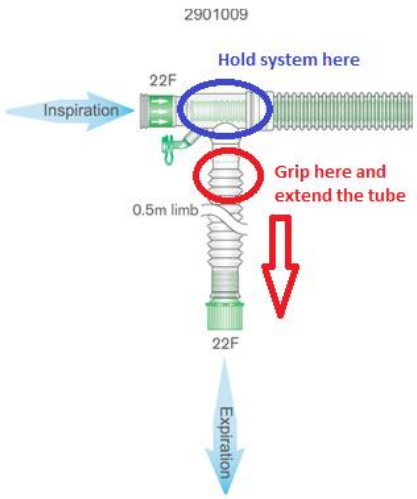
	2919024 2919032
1.	6. Software version
	N/A
1.	7. Affected lot numbers— all within the range below, from the first lot produced after the change to the last one manufactured before the issue was noticed (e.g., code 2900000; from lot 32411113 to 32425225): Code From To 2900000; 32411113 32425225 2900005; 32413568 32422374 2900008; 32408874 32418491 2900009; 32423042 32424238 2900020; 32412443 32416345 2900023; 32408793 32423815 2900025; 32409820 32412449 2900027; 32410002 32410002 2900039; 32411065 32411065 2900047; 32410950 32410950 2900050; 32490239 32422861 2900051; 32410278 32410278 2900062; 32413456 32421897 2900076; 32412989 32415303 2900100; 32411800 32423522 2900102; 32414106 32424216 2900104; 32414690 32420867 2900106; 32414996 32422099 2900109; 32416439 32420642 2900110; 32414213 32421191 2901000; 32409539 32419348 2901007; 32422936 32422936 2901008; 32409279 32421728 2901009; 32415690 32424156 2901011; 32413306 32416176 2901012; 32416427 32416427 2901013; 32416068 32416068 2901021; 32416432 32420026 2901100; 32415608 32422277 2901102; 32421316 32409136 2901104; 32416528 32419150 2901105; 32415224 32417006 2901107; 32418963 32420868 2901109; 32418284 32421362 2901111; 32422568 32422568 2902000; 32403895 32420230 2902002; 32418628 32421276 2902012; 32413750 32413750 2902015; 32420647 32420647 2902017; 32417145 32417145 2902019; 32417089 32417089 2902021; 32417690 32418629 2902100; 32417392 32417392 2902102; 32417470 32423272 2902103; 32417791 32423393

	2902104; 32420027 32420471 2902106; 32417235 32423448 2902111; 32417427 32422934 2903000; 32403502 32421707 2903005; 32418018 32415372 2903006; 32419034 32420379 2903007; 32417822 32419089 2903010; 32409172 32412856 2903015; 32418027 32418027 2903020; 32417471 32412885 2903027; 32417991 32423475 2903100; 32407945 32421775 2903101; 32417320 32422829 2910000; 32490385 32423758 2910100; 32409807 32409807 2911000; 32490384 32424905 2919016; 32417049 32422114 2919024; 32416958 32424629 2919032; 32417151 32424784
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.	3. Probability of problem arising
	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%).
2.	4. Predicted risk to patient/users
	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.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	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.
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 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. To ensure the safety of patients we recommend the following actions.

	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 mn@intersurgical.ie 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.

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.	
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	**Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ**
	c. Website address	**https://www.intersurgical.com/**
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	**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.