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.)*
Chris Randall **Wokingham Site Quality Manager** **Intersurgical Ltd.** **Crane house** **Molly Millars Lane** **Wokingham** **Berkshire** **RG41 2RZ** **Email: priority@intersurgical.co.uk** **Tel. No: 0118 9656 300**

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Urgent Field Safety Notice (FSN)

VARIOUS UNIFLOW COAXIAL BREATHING SYSTEMS

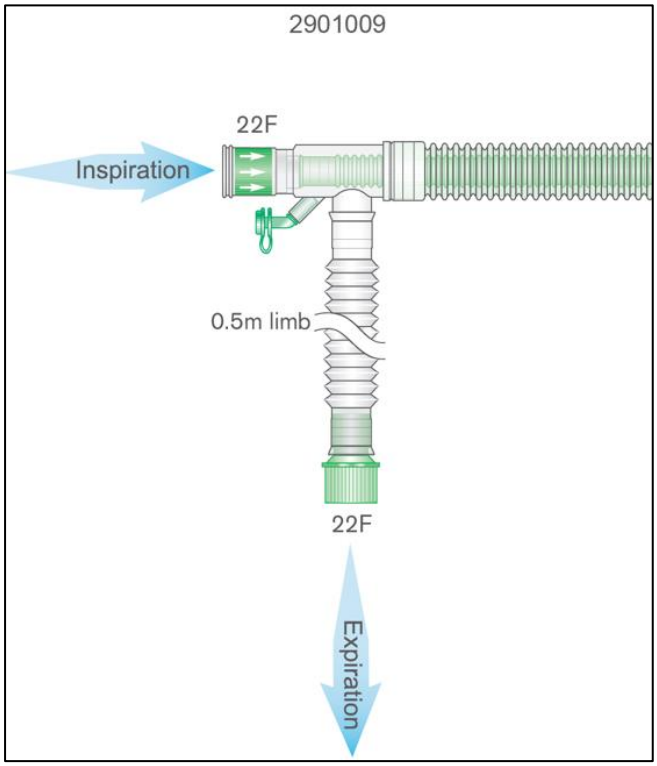
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Various Uniflow Coaxial Breathing Systems
1.	2. Commercial name(s)
	▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH LUER ELBOW AND LIMB, ≥ 1.6M ▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH LUER ELBOW, AND LIMB, ≥ 3.2M ▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH LUER ELBOW, AND LIMB, ≥ 4.8M ▪ 30MM UNIFLOW BREATHING SYSTEM FOR USE WITH GE MACHINES WITH 2L BAG, LUER ELBOW, MONITORING LINE, AND LIMB, ≥ 1.6M ▪ 30MM UNIFLOW SILVER KNIGHT ANTI-MICROBIAL COAXIAL BREATHING SYSTEM WITH 2L BAG, LUER ELBOW, AND LIMB, ≥ 1.6M ▪ 30MM UNIFLOW SILVER KNIGHT COAXIAL B/SYSTEM FOR USE WITH GE MACHINES WITH 2L BAG, FILTER, SPIRO/SET, AND LIMB, ≥ 1.6M ▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH LUER ELBOW, AND LIMB, ≥ 2.4M ▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH 2L BAG, LUER ELBOW, AND LIMB, ≥ 2.4M ▪ 30MM UNIFLOW SILVER KNIGHT ANTI-MICROBIAL COAXIAL BREATHING SYSTEM WITH LUER ELBOW, ≥ 2.4M ▪ 30MM SILVER KNIGHT UNIFLOW CO-AXIAL SYS,3M ADULT SPIROMETRY ▪ 30MM UNIFLOW SILVER KNIGHT ANTI-MICROBIAL COAXIAL B/SYSTEM WITH 2L BAG, LUER ELBOW, SPIRO/SET, AND LIMB, ≥ 2.4M ▪ 30MM UNIFLOW SILVER KNIGHT COAXIAL B/SYSTEM FOR GE MACHINES WITH 2L BAG, FILTER, SPIROMETRY SET, AND LIMB, ≥ 2.4M ▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH LUER CONNECTOR, INTEGRAL MONITORING LINE, AND ELBOW, ≥ 1.6M ▪ 30MM UNIFLOW SILVER KNIGHT COAXIAL BREATHING SYSTEM WITH LUER CONNECTOR, INTEGRAL MONITORING LINE, AND ELBOW, ≥ 1.6M ▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH LUER CONNECTOR, INTEGRAL MONITORING LINE, AND ELBOW, ≥ 2.4M ▪ 30MM UNIFLOW COAXIAL B/SYSTEM WITH 2L BAG, LUER CONN, INTEGRAL MON LINE, ELBOW, FILTER, AND LIMB, ≥ 2.4M ▪ 30MM SILVER KNIGHT ANTI-MICROBIAL UNIFLOW COAXIAL BREATHING SYSTEM WITH INTEGRAL MONITORING LINE AND LIMB, ≥ 2.4M ▪ 30MM UNIFLOW SK COAXIAL B/SYSTEM WITH 2L BAG, LUER CONN, INTEGRAL MON LINE, ELBOW, AND LIMB, ≥ 2.4M ▪ 30MM SILVER KNIGHT ANTI-MICROBIAL UNIFLOW DELUXE COAXIAL BREATHING SYSTEM, 2L BAG, INTEGRAL MONITORING LINE,1.6M ▪ 30MM UNIFLOW SK COAXIAL BREATHING SYSTEM WITH 2L BAG, LUER CONNECTOR, INTEGRAL MONITORING LINE, AND ELBOW, ≥ 1.6M ▪ 30MM UNIFLOW SK COAXIAL B/SYSTEM WITH 2L BAG, LUER CONN, INTEGRAL MONITORING LINE, AND ELBOW, ≥ 2.4M ▪ 30MM UNIFLOW SK COAXIAL B/SYSTEM WITH 2L BAG, LUER CONN, INTEGRAL MONITORING LINE, AND ELBOW, ≥ 3.2M

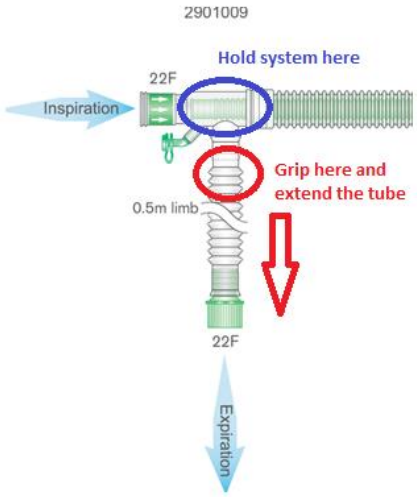
1.	3. Unique Device Identifier(s) (UDI-DI)
	05030267029013 05030267040551 05030267092918 05030267106424 05030267075935 05030267138951 05030267029020 05030267089819 05030267040605 05030267125210 05030267136315 05030267140190 05030267029846 05030267040612 05030267029839 05030267156399 05030267040629 05030267047857 05030267040636 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 2900023 2900027 2900102 2900109 2901000 2901008 2901100 2901107 2901109 2901111 2902000 2902100 2903000 2903027 2903100 2903101 2910100 2919016 2919024 2919032
1.	6. Software version
	N/A
1.	7. Affected lot numbers ▪ 2900000 – Lot 32412799, 32413873, 32420947. ▪ 2900005 – Lot 32413568, 32419363, 32419716. ▪ 2900023 – Lot 32408793, 32409993, 32413567, 32421253. ▪ 2900027 – Lot 32410002. ▪ 2900102 – Lot 32414106, 32418017, 32421913. ▪ 2900109 – Lot 32416439, 32418763, 32420642. ▪ 2901000 – Lot 32409539, 32411235, 32411863, 32414251, 32414597, 32416613, 32418490. ▪ 2901008 – Lot 32410680, 32419257. ▪ 2901100 – Lot 32415608, 32417060, 32419318, 32420491, 32421309. ▪ 2901107 – Lot 32418963, 32420868. ▪ 2901109 – Lot 32418284, 32421362, 32422737. ▪ 2901111 – Lot 32422568. ▪ 2902000 – Lot 32404597, 32406348, 32410021, 32410864, 32412262, 32413827, 32414498, 32416742, 32418517, 32418647, 32420041, 32420230. ▪ 2902100 – Lot 32417392, 32417392, 32417588. ▪ 2903000 – Lot 32403502, 32404788, 32406188, 32407881, 32408370, 32409169, 32410001, 32411289, 32412099, 32412746, 32413316, 32414199, 32414759, 32415161, 32416897, 32417294, 32417515, 32418130, 32418288, 32418765, 32419259, 32419640, 32419992, 32421707, 32424533. ▪ 2903027 – Lot 32417991, 32418010, 32418955, 32420149, 32423475. ▪ 2903100 – Lot 32407945, 32408794, 32409455, 32410460, 32412717, 32413803, 32415471, 32415806, 32417205, 32421132, 32421775. ▪ 2903101 – Lot 32417320, 32419037, 32421192, 32422147, 32422278, 32422829. ▪ 2910100 – Lot 32409807, 32422339. ▪ 2919016 – Lot 32417049, 32420261, 32422114. ▪ 2919024 – Lot 32416958, 32417596, 32420409, 32420966, 32421776, 32422256, 32424629. ▪ 2919032 – Lot 32417151, 32418467, 32420859, 32422020, 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.

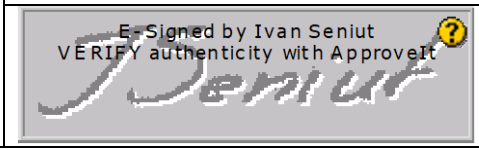


2.	2. Hazard giving rise to the FSCA*
	If the insecure connection of the expiratory gas tube is not identified during set-up and pre-use checks, detachment in use could result in gross leakage and reduced circulating gas volume which would have a negative impact upon ventilation.
2.	3. Probability of 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 below to priority@intersurgical.co.uk 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.

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?	One month 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.

Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	464552
FSN Date*	30/01/2025
Product/ Device name*	▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH LUER ELBOW AND LIMB, ≥ 1.6M ▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH LUER ELBOW, AND LIMB, ≥ 3.2M ▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH LUER ELBOW, AND LIMB, ≥ 4.8M ▪ 30MM UNIFLOW BREATHING SYSTEM FOR USE WITH GE MACHINES WITH 2L BAG, LUER ELBOW, MONITORING LINE, AND LIMB, ≥ 1.6M ▪ 30MM UNIFLOW SILVER KNIGHT ANTI-MICROBIAL COAXIAL BREATHING SYSTEM WITH 2L BAG, LUER ELBOW, AND LIMB, ≥ 1.6M ▪ 30MM UNIFLOW SILVER KNIGHT COAXIAL B/SYSTEM FOR USE WITH GE MACHINES WITH 2L BAG, FILTER, SPIRO/SET, AND LIMB, ≥ 1.6M ▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH LUER ELBOW, AND LIMB, ≥ 2.4M ▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH 2L BAG, LUER ELBOW, AND LIMB, ≥ 2.4M ▪ 30MM UNIFLOW SILVER KNIGHT ANTI-MICROBIAL COAXIAL BREATHING SYSTEM WITH LUER ELBOW, ≥ 2.4M ▪ 30MM SILVER KNIGHT UNIFLOW CO-AXIAL SYS,3M ADULT SPIROMETRY ▪ 30MM UNIFLOW SILVER KNIGHT ANTI-MICROBIAL COAXIAL B/SYSTEM WITH 2L BAG, LUER ELBOW, SPIRO/SET, AND LIMB, ≥ 2.4M ▪ 30MM UNIFLOW SILVER KNIGHT COAXIAL B/SYSTEM FOR GE MACHINES WITH 2L BAG, FILTER, SPIROMETRY SET, AND LIMB, ≥ 2.4M ▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH LUER CONNECTOR, INTEGRAL MONITORING LINE, AND ELBOW, ≥ 1.6M ▪ 30MM UNIFLOW SILVER KNIGHT COAXIAL BREATHING SYSTEM WITH LUER CONNECTOR, INTEGRAL MONITORING LINE, AND ELBOW, ≥ 1.6M ▪ 30MM UNIFLOW COAXIAL BREATHING SYSTEM WITH LUER CONNECTOR, INTEGRAL MONITORING LINE, AND ELBOW, ≥ 2.4M ▪ 30MM UNIFLOW COAXIAL B/SYSTEM WITH 2L BAG, LUER CONN, INTEGRAL MON LINE, ELBOW, FILTER, AND LIMB, ≥ 2.4M

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Product Code(s)	2900000 2900005 2900023 2900027 2900102 2900109 2901000 2901008 2901100 2901107 2901109 2901111 2902000 2902100 2903000 2903027 2903100 2903101 2910100 2919016 2919024 2919032
Batch/Serial Number (s)	▪ 2900000 – Lot 32412799, 32413873, 32420947. ▪ 2900005 – Lot 32413568, 32419363, 32419716. ▪ 2900023 – Lot 32408793, 32409993, 32413567, 32421253. ▪ 2900027 – Lot 32410002. ▪ 2900102 – Lot 32414106, 32418017, 32421913. ▪ 2900109 – Lot 32416439, 32418763, 32420642. ▪ 2901000 – Lot 32409539, 32411235, 32411863, 32414251, 32414597, 32416613, 32418490. ▪ 2901008 – Lot 32410680, 32419257. ▪ 2901100 – Lot 32415608, 32417060, 32419318, 32420491, 32421309. ▪ 2901107 – Lot 32418963, 32420868. ▪ 2901109 – Lot 32418284, 32421362, 32422737. ▪ 2901111 – Lot 32422568. ▪ 2902000 – Lot 32404597, 32406348, 32410021, 32410864, 32412262, 32413827, 32414498, 32416742, 32418517, 32418647, 32420041, 32420230. ▪ 2902100 – Lot 32417392, 32417392, 32417588. ▪ 2903000 – Lot 32403502, 32404788, 32406188, 32407881, 32408370, 32409169, 32410001, 32411289, 32412099, 32412746, 32413316, 32414199, 32414759, 32415161, 32416897, 32417294, 32417515, 32418130, 32418288, 32418765, 32419259, 32419640, 32419992, 32421707, 32424533. ▪ 2903027 – Lot 32417991, 32418010, 32418955, 32420149, 32423475.

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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.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I do not have any affected devices.	Customer to complete or enter N/A		
☐	We are continuing to use the potentially affected stock we have, whilst following the instructions provided to check for the problem.	Customer to complete or enter N/A		
☐	We have 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*	01/03/25

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.