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.)\* |
| **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** |

**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. | 1. 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>=1.6m2902106 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 >= 1.6m2911000 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. | 1. 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 |

 |
|   | 1. 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. | 1. 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. | 1. Software version
 |
| N/A |
| 1. | 1. 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 To2900000; 32411113 324252252900005; 32413568 324223742900008; 32408874 324184912900009; 32423042 324242382900020; 32412443 324163452900023; 32408793 324238152900025; 32409820 324124492900027; 32410002 324100022900039; 32411065 324110652900047; 32410950 324109502900050; 32490239 324228612900051; 32410278 324102782900062; 32413456 324218972900076; 32412989 324153032900100; 32411800 324235222900102; 32414106 324242162900104; 32414690 324208672900106; 32414996 324220992900109; 32416439 324206422900110; 32414213 324211912901000; 32409539 324193482901007; 32422936 324229362901008; 32409279 324217282901009; 32415690 324241562901011; 32413306 324161762901012; 32416427 324164272901013; 32416068 324160682901021; 32416432 324200262901100; 32415608 324222772901102; 32421316 324091362901104; 32416528 324191502901105; 32415224 324170062901107; 32418963 324208682901109; 32418284 324213622901111; 32422568 324225682902000; 32403895 324202302902002; 32418628 324212762902012; 32413750 324137502902015; 32420647 324206472902017; 32417145 324171452902019; 32417089 324170892902021; 32417690 324186292902100; 32417392 324173922902102; 32417470 324232722902103; 32417791 324233932902104; 32420027 324204712902106; 32417235 324234482902111; 32417427 324229342903000; 32403502 324217072903005; 32418018 324153722903006; 32419034 324203792903007; 32417822 324190892903010; 32409172 324128562903015; 32418027 324180272903020; 32417471 324128852903027; 32417991 324234752903100; 32407945 324217752903101; 32417320 324228292910000; 32490385 324237582910100; 32409807 324098072911000; 32490384 324249052919016; 32417049 324221142919024; 32416958 324246292919032; 32417151 32424784 |
| 1. | 1. Associated devices
 |
| N/A. |

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| 1. **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. | 1. 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. | 1. 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. | 1. Further information to help characterise the problem
 |
| N/A |
| 2. | 1. 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. | 1. Other information relevant to FSCA

N/A |
|  | 1. **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:1. 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****.”*1. 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.

1. 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.lt 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. | 1. 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. | 1. Particular considerations for: N/A

Is follow-up of patients or review of patients’ previous results recommended? Not applicable. |
| 3. | 1. Is customer Reply Required? \*

(If yes, form attached specifying deadline for return) | Yes  |
| **3.** | 1. **Action Being Taken by the Manufacturer**

☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change  ☒ Other ☐ NoneWe have implemented corrective actions in manufacturing process to eliminate this problem for future supply.  |
| 3 | 1. By when should the action be completed?
 | Immediately but not later than 6 months from receipt of the FSN  |
| 3. | 1. Is the FSN required to be communicated to the patient /lay user?
 | No |
| 3 | 1. 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  |

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

(For contact details of local representative refer to page 1 of this FSN*)*  |
| * 1. Company Name
 | **Intersurgical Ltd.** |
| * 1. Address
 | **Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ** |
| * 1. Website address
 | **https://www.intersurgical.com/** |
| 4. | 1. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. \*
 |
| 4. | 1. List of attachments/appendices:
 | **Customer Reply Form** |
| 4. | 1. Name/Signature
 | **Ivan Seniut, Group Quality and Regulatory Affairs Director, Intersurgical** |
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|  |  |
|  | **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.