Intersurgical Ltd.

Rev 1: September 2018
FSN Ref: 323168

FSCA Ref: 323168

Date: 03/06/2021

# Urgent Field Safety Notice
# INTUBE TRACHEAL TUBE, WIRE REINFORCED CUFFED, 7MM

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

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
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| 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)
# INTUBE TRACHEAL TUBE, WIRE REINFORCED CUFFED, 7MM
# Risk addressed by FSN

| | 1. Information on Affected Devices* |
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| 1. | 1. Device Type(s)* |
| | **INTUBE TRACHEAL TUBE, WIRE REINFORCED CUFFED, 7MM, STERILE** |
| 1. | 2. Commercial name(s) |
| | **INTUBE TRACHEAL TUBE, WIRE REINFORCED CUFFED, 7MM** |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | N/A |
| 1. | 4. Primary clinical purpose of device(s)* |
| | Securing and maintaining a patent airway. To provide and/or support a conduit for the delivery of respiratory gases to the patient. |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | 8060070 |
| 1. | 6. Software version |
| | N/A |
| 1. | 7. Affected serial or lot number range |
| | 306062 |
| 1. | 8. Associated devices |
| | N/A |

| | 2 Reason for Field Safety Corrective Action (FSCA)* |
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| 2. | 1. Description of the product problem* |
| | The following product problem have been identified. 1) Loose connectors; 2) Excess glue; 3) Excessive gap between the end of the connector and the wire-reinforced coil. |
| 2. | 2. Hazard giving rise to the FSCA* |
| | 1) The loose connector may easily become detached from the tube leading to a loss of a secure airway. If not rapidly identified and a secure airway re-established, complications associated with inadequate ventilation and oxygenation may develop. 2) The glue could detach and be ingested or aspirated, which may require medical intervention. If in the interior of the tube, there is a risk this could occlude the airway device, leading to airway obstruction and its associated complications; 3) The gap may increase the risk of the tube kinking, leading to possible airway obstruction, hypoxia and associated airway complications. |
| 2. | 3. Probability of problem arising |
| | Probability of problem arising in the indicated lot is up to 100%. |
| 2. | 4. Predicted risk to patient/users |
| | There is a potential for life threatening incidents. |
| 2. | 5. Further information to help characterise the problem |
| | Include any further relevant statistics to help convey the seriousness of the issue. |
| 2. | 6. Background on Issue |
| | The product problem is a result of non-conformity within the manufacturing process of connector gluing. The lot was identified as containing defective product, unfortunately |

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| | small quantities of potentially affected devices have been placed on the market. We are urgently reviewing our processes to identify a resolution to the issue. |
| 2. | 7. Other information relevant to FSCA |
| | This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA. |

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| | **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<br>☐ On-site device modification/inspection<br>☐ Follow patient management recommendations<br>☐ Take note of amendment/reinforcement of Instructions For Use (IFU)<br>☐ Other ☐ None<br>Stop the use of all affected devices. Ensure that all of the affected devices in stock are quarantined. Check stock and complete the enclosed Customer Reply Form and return it to the contact at the top of the Response Form. Ask for credit to be arranged with the local distributor as required. Continue to report any adverse events involving this product to Intersurgical. | |
| 3. | 2. By when should the action be completed? | ASAP |
| 3. | 3. Particular considerations for: Choose an item.<br>Is follow-up of patients or review of patients' previous results recommended? Choose an item.<br>Provide further details of patient-level follow-up if required or a justification why none is required | |
| 3. | 4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) | Yes |
| **3.** | **5. Action Being Taken by the Manufacturer**<br>☒ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ None<br>Return all affected products to the local distributor, credit will be arranged as required. | |
| 3 | 6. By when should the action be completed? | Specify where critical to patient/end user safety |
| 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? | |

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| | Choose an item. Choose an item. |

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| | **4. General Information*** | |
| 4. | 1. FSN Type* | New |
| 4. | 2. For updated FSN, reference number and date of previous FSN | Provide reference and date of previous FSN if relevant |
| 4. | **3.** For Updated FSN, key new information as follows: | |
| | Summarise any key difference in devices affected and/or action to be taken. | |
| 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: | |
| | Eg patient management, device modifications etc | |
| 4 | 6. Anticipated timescale for follow-up FSN | For provision of updated advice. |
| 4. | 7. Manufacturer information<br>(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. | 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** |
| 4. | 10. 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)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>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.