INTERSURGICAL®
COMPLETE RESPIRATORY SYSTEMS
Quality, innovation and choice

Intersurgical Ltd, [redacted]
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Rev 1: September 2018

FSN Ref: 385183-A

Date: 01/12/2022

Urgent Field Safety Notice

NEONATAL, NASAL CANNULA WITH CURVED PRONGS AND TUBE, 2.1M – REF: 1164000

PLEASE NOTE: THIS NOTICE SUPERCEDES THE PREVIOUS FIELD SAFETY NOTICE 385183 ISSUED ON 23/11/2022

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

Contact details of local representative (name, e-mail, telephone, address etc.)*
[redacted] **Customer Resolution and Relationship Manager** **Intersurgical UAB** **Arnioniu str 60, LT-18170 Pabrade Lithuania** **Email:** [redacted] **Tel.** [redacted] **or** **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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Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Basic Nasal Oxygen Cannula
1.	2. Commercial name(s)
	NEONATAL, NASAL CANNULA WITH CURVED PRONGS AND TUBE, 2.1M
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	To deliver oxygen into a patient's nose.
1.	5. Device Model/Catalogue/part number(s)*
	1164000
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	32101838 32103910 32104363 32105886 32107401 32107969 32108492 32108661 32113543 32114272 32115031 32115516 32116417 32117131 32118980 32121015 32121426 32122791 32200213 32201328 32203136 32204165 32205503 32205602 32207055 32208628 32209416 32210009 32210465 32210778 32211422 32213464 32214035 32214784 32215283 32215951 32217487 32218056
1.	8. Associated devices
	N/A

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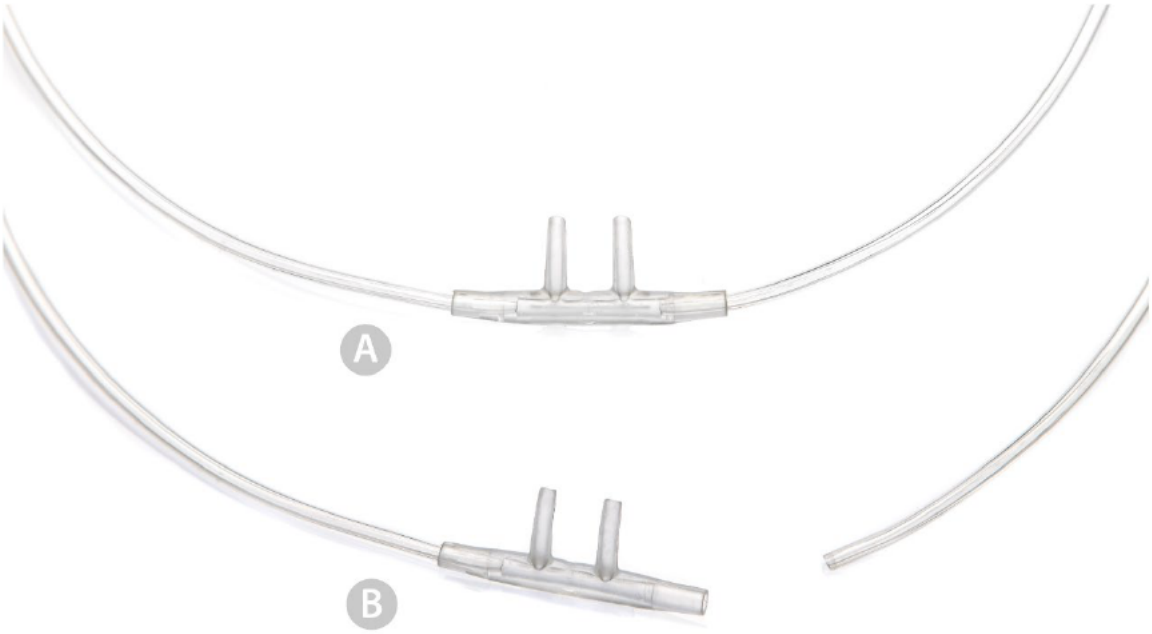
	2 **Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	We have received reports related to disconnection of the tube from the nasal prong section while using our Neonatal Nasal Cannula with curved prongs and tube. Image A, below, shows the correct configuration, and image B demonstrates the reported disconnection. The purpose of this FSN is to advise you that Intersurgical is issuing a Safety Notice for the removal of the potentially affected products. This safety notice applies to all distributed products with the Lot Numbers indicated above 
2	2. Hazard giving rise to the FSCA*
	If the oxygen tubing, which is connected to the nasal prong part of the device, becomes detached (see image B above), oxygen will not be delivered to the patient. There is a risk of oxygen desaturation/hypoxaemia, which could cause life-threatening incidents.
2.	3. Probability of problem arising
	1:1,000,000 - 1:10,000
2.	4. Predicted risk to patient/users
	There is a potential for a major effect on the patient health, however it has been assessed as unlikely/rare to occur.

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2.	5. Further information to help characterise the problem
	See section 2.3 above
2.	6. Background on Issue
	We have received reports from two hospitals of disconnection of the tube from the nasal prongs whilst in use on patients.
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
	Identify and Immediately quarantine all affected lot numbers listed above and do not use these devices. Please complete the Reply Form to confirm the products have been disposed of locally or to arrange collection of the devices and a credit. If you have no affected devices in stock, please confirm this using the Reply Form. Return the completed Reply Form to [redacted] (local contact e-mail address).
	Please continue to report to Intersurgical any adverse events involving this product.

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	PLEASE NOTE: The potentially affected products must be removed from use as soon as replacement or alternative stock is available. We have provided these important excerpts from the IFU to help minimise the specific risk of disconnection if the products are required for use until replacement or alternative products are available. Please refer to the IFU provided for full details. PRE USE CHECK Ensure all components are undamaged and attached securely. IN USE CHECKS Patient monitoring (SaO2) must be used with this device. Ensure that nasal prongs remain inserted into the nares. Caution: 1. For use by appropriately trained personnel only. 2. Ensure that trained personnel are familiar with the contents of this instruction. 3. Always perform pre-use checks.		
3.	2. By when should the action be completed?	Immediately on receipt of this FSN and ongoing until no affected stock listed in this FSN is remaining.	
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No 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 Users are advised to follow the Instructions For Use provided with the product if needing to use potentially affected products whilst alternative products are obtained.		
3	6. By when should the action be completed?	One month of receipt of the FSN	
3.	7. Is the FSN required to be communicated to the patient /lay user?		Yes

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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?
	No

	4. General Information*	
4.	1. FSN Type*	Revised FSN
4.	2. For updated FSN, reference number and date of previous FSN	Superseding FSN Ref: 385183
4.	**3.** For Updated FSN, key new information as follows:	
	Previous advisory FSN Ref: 385183 has now been superseded by this FSN 385183A.	
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:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Intersurgical Ltd.**
	b. Address	[redacted], **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	[redacted], **Group Quality and Regulatory Affairs Director, Intersurgical**
		[redacted]

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	Transmission of this Field Safety Notice
	This notice needs to be passed on to 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.

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Customer Reply Form

PLEASE NOTE: THIS RECALL NOTICE REPLY FORM SUPERCEDES THE PREVIOUS FIELD SAFETY NOTICE 385183 ISSUED ON 23/11/2022

1. Field Safety Notice - RECALL (FSN) information	
FSN Reference number*	385183A
FSN Date*	01/12/2022
Product/ Device name*	Neonatal Nasal Cannula with Curved prongs and Tube, 2.1M
Product Code(s)	**1164000**
Batch/Serial Number (s)	32101838 32103910 32104363 32105886 32107401 32107969 32108492 32108661 32113543 32114272 32115031 32115516 32116417 32117131 32118980 32121015 32121426 32122791 32200213 32201328 32203136 32204165 32205503 32205602 32207055 32208628 32209416 32210009 32210465 32210778 32211422 32213464 32214035 32214784 32215283 32215951 32217487 32218056

2. Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
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
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A
☐	The information and required actions have	Customer to complete or enter N/A

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	been brought to the attention of all relevant users and executed.			
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
☐	Other Action (Define):			
☐	I do not have any affected devices.	Customer to complete or enter N/A		
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query		
Print Name*				
Signature*				
Date*				

4. Return acknowledgement to sender	
Email	
Customer Helpline	N/A
Web Portal	
Fax	
Deadline for returning the customer reply form*	03/01/2023

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.