Rev 1: September 2018
FSN Ref: 418344 FSCA Ref: 418344

Date: 07.07.2023

Urgent Field Safety Notice

Intersurgical NIV Angled Mouthpiece with Notch 22M/15F

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]**@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**

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Urgent Field Safety Notice (FSN)

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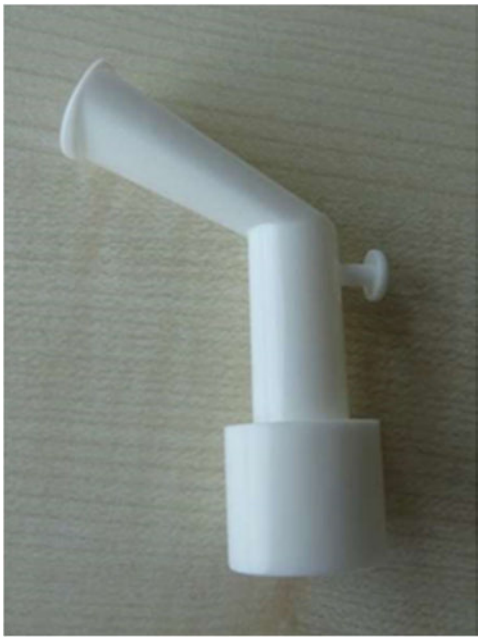
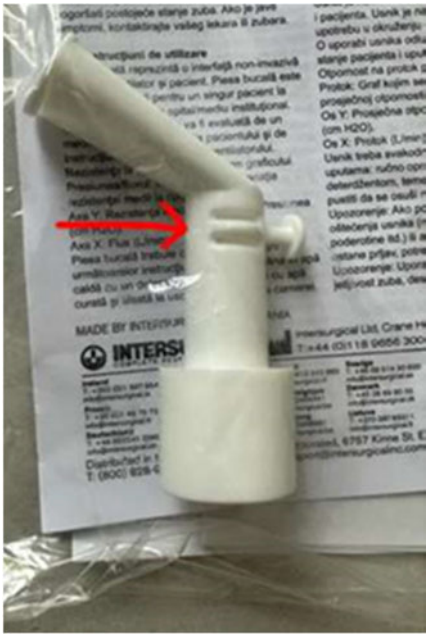
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Respiratory Mouthpiece
1.	2. Commercial name(s)
	NIV Angled Mouthpiece with Notch 22M/15F
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	A device intended for partial insertion into a patient's mouth (in between the lips) to facilitate access to the respiratory system. It is typically attached, either directly or through other tubes/adaptors, to diagnostic and/or therapeutic respiratory devices (e.g., ventilator, inhaler, incentive spirometer, aerosol equipment, breath analyser, breath collector). This is a single-use device.
1.	5. Device Model/Catalogue/part number(s)*
	Ref: 1938000
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lots: 32304444, 32305269, 32306017, 32307438, 32311265
1.	8. Associated devices
	N/A.

	2. Reason for Field Safety Corrective Action (FSCA)*
	1. Description of the product problem*

2.	As a result of a nonconformity during manufacture, the mouthpiece has been produced with unintended open slits on the side of the mouthpiece body (see photos below). This unfortunately allows some of the respiratory gas to escape and so reduces the effectiveness.  **Correct – No slits**  **Incorrect - Slits**
2.	2. Hazard giving rise to the FSCA*
	The device does not function as per its intended use.
2.	3. Probability of problem arising
	100% in the listed Lot numbers.
2.	4. Predicted risk to patient/users
	Minor risk of harm with very likely occurrence.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Intersurgical has received a report, where slits have been found on the side of the mouthpiece body that would result in the unintended escape of the respiratory gas during use. This issue has resulted from a nonconformity during manufacture of the mouthpiece.
2.	7. Other information relevant to FSCA Only the listed Lot numbers are affected.

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 giedriusb@intersurgical.lt (local contact e-mail address). 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 ongoing until no affected stock listed in this FSN is remaining.
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	
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?	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?	
	No	

	4. General Information*	
4.	1. FSN Type*	New - Recall
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
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	**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	[redacted], **Group Quality and Regulatory Affairs Director, Intersurgical** [redacted]

	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*	418344
FSN Date*	10/07/2023
Product/ Device name*	NIV Angled Mouthpiece with Notch 22M/15F
Product Code(s)	1938000
Batch/Serial Number (s)	Lots: 32304444, 32305269 and 32306017

2. Customer Details	
Account Number	
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 been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	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:	
☐	No affected devices are available for return/	Customer to complete or enter N/A		

	destruction	
☐	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*		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
Fax	0118 9656 356
Deadline for returning the customer reply form*	10/08/2023

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.