Rev 1: October 22, 2025
FSN Ref: 25-018 FSCA Ref: 25018

Date: 24.10.2025

Urgent Field Safety Notice
DART Intranasal Mucosal Atomization Device

For Attention of*:Distributors, pharmacists, hospitals, clinics, and healthcare professionals across the EU/EEA.

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 Tamara Lefevers Vice President, Regulatory Affairs & Quality Assurance Pulmodyne, Inc. 2055 Executive Drive Indianapolis, Indiana 46241 USA Email: tlefevers@engmedsys.com Tel. No. +1 317-246-5500 ext.113

Urgent Field Safety Notice (FSN)
DART Intranasal Mucosal Atomization Device

Risk addressed by FSN

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	Various DART Intranasal Mucosal Atomization Devices
1.	2. Commercial name(s)
	Intranasal Mucosal Atomization Device 3ml Syringe Intranasal Mucosal Atomization Device 1ml Syringe Intranasal Mucosal Atomization Device 3ml Syringe Viral Adaptor Intranasal Mucosal Atomization Device No Syringe
1.	3. Unique Device Identifier(s) (UDI-DI)
	00841470100308 00841470100292 00841470100674 00841470100285
1.	4. Primary clinical purpose of device(s)*
	For atomizing solutions across the naso and oropharyngeal mucous membranes.
1.	5. Device Model/Catalogue/part number(s)*
	DART100 DART110 DART140 DART300
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	DART100 – Lot numbers 240116, 240203, 240207, 240307, 240209 DART110 – Lot numbers 240203, 24240207, 24240508 DART140 – Lot numbers 240124, 24240203, 240205, 240226 DART300 – Lot numbers 240124, 240209, 240227, 240322, 240402, 240419, 240515, 240522, 240611 ** To confirm, any lot number with a prefix of 2410-- is not affected as these lots were manufactured after actions were taken by the manufacturer to prevent the problem.
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 leakage occurring when using the device as shown below.

	
2.	2. Hazard giving rise to the FSCA*
	Although devices exhibiting this leakage are expected to perform by atomizing solutions as intended, if leakage occurs, this might lead to the patient not receiving a small amount of the solution intended to be delivered. If additional solution needs to be administered due to the leakage, this additional dosing could represent a delay in treatment.
2.	3. Probability of problem arising
	We have determined there is a potential for nearly all devices in the affected lots to develop the fault.
2.	4. Predicted risk to patient/users
	Although the device has been confirmed to atomize solutions as intended, the defect may result in under-delivery of the intended dose. This could lead to delayed treatment or sub-therapeutic dosing, potentially causing a potential deterioration in a patient's health.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Pulmodyne, Inc. has identified a potential issue with certain Pulmodyne DART 300 devices manufactured before October 2024. The root cause is sidewall cracking due to a tighter interference fit between components, which may subject the device to increased stress over time. A corrective action was implemented in production in October 2024, and all devices manufactured after this date are not affected.
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 Forward this Field Safety Notice to all distributors and potential users of the DART Intranasal Mucosal Atomization devices listed above to ensure their awareness of the potential problem and to carry out the following actions. To ensure the safety of patients the following actions are required.

<table>
<tr><td></td><td colspan="2">1. Identify any potentially affected products from the affected codes and lot numbers listed above, stop using and quarantine them.

2. If there is an immediate need to use any of the affected codes or lot numbers listed above, devices can continue to be used as long as the user is aware of the following potential:

The device has been confirmed to atomize solutions as intended. However, there is a potential that a small amount of the solution may leak and saturate the foam nasal cone as shown below, and therefore a potential of a portion the solution may not get delivered to the patient as intended.

 

3. If you have any potentially affected products listed above and there is no immediate need to continue to use the affected lots, please detail the quantities for each code and lot numbers in the Reply Form provided below. Upon confirmation of the reply form, replacements will be arranged/provided at no cost and affected lots shall be returned or destroyed based on the quantity affected.

4. Please complete and return the Reply Form provided below within 30 days of awareness of this FSN to the contacts listed above to confirm receipt of this notice and to confirm what actions have been taken.

Please continue to report to Pulmodyne any adverse events involving this product.</td></tr>
<tr><td>3.</td><td>2. By when should the action be completed?</td><td>Immediately on receipt of this FSN, and awareness of this FSN should be ongoing until all potentially affected stock listed in this FSN have been removed from use or used up if following the instructions.</td></tr>
<tr><td>3.</td><td colspan="2">3. Particular considerations for: N/A

Is follow-up of patients or review of patients' previous results recommended?

Not Applicable</td></tr>
<tr><td>3.</td><td>4. Is customer Reply Required? *
(If yes, form attached specifying deadline for return)</td><td>Yes
Return the completed reply form within 30 days of awareness of the FSN confirming the affected products have been removed or used up.</td></tr>
</table>

<table>
<tr><td>3.</td><td colspan="3">5. Action Being Taken by the Manufacturer

☒ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other ☐ None

Product shall be removed or discarded onsite (depending on quantity affected). Replacement product shall be provided at no cost.

We have already implemented corrective actions in manufacturing process to eliminate this problem for future supply.</td></tr>
<tr><td>3</td><td>6. By when should the action be completed?</td><td colspan="2">Upon receipt of the notification</td></tr>
<tr><td>3.</td><td colspan="2">7. Is the FSN required to be communicated to the patient /lay user?</td><td>No</td></tr>
<tr><td rowspan="2">3</td><td colspan="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?</td></tr>
<tr><td colspan="3">N/A</td></tr>
</table>

	4. General Information*	
4.	1. FSN Type*	New
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	Pulmodyne Inc.
	b. Address	2055 Executive Drive, Indianapolis Indiana 46241 USA
	c. Website address	www.pulmodyne.com
4.	8. The Competent (Regulatory) Authority has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	N/A
4.	10. Name/Signature	Tamara Lefevers Vice President, Regulatory Affairs & Quality Assurance
		Tamara Lefevers

	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*	25-018
FSN Date*	October 22, 2025
Product/ Device name*	DART
Product Code(s)	DART100 DART110 DART140 DART300
Batch/Serial Number (s)	DART100 – Lot numbers 240116, 240203, 240207, 240307, 240209 DART110 – Lot numbers 240203, 24240207, 24240508 DART140 – Lot numbers 240124, 24240203, 240205, 240226 DART300 – Lot numbers 240124, 240209, 240227, 240322, 240402, 240419, 240515, 240522, 240611

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 affected devices - enter number of devices to be returned.	Customer to complete with reference number(s), lot number(s), Quantity or enter N/A
☐	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 complete or enter N/A
Print Name*		
Signature*		

Date*	

4. Return acknowledgement to sender	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form*	Return the completed reply form within 30 days of awareness of the FSN confirming the affected products have been removed or used up.

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.