FSCA Ref: 2025-01

Date: 14 January 2025
FSCA reference number 2025-01

Urgent Field Safety Notice (FSN)
Sedana Medical's Sedaconda Syringe 1026022

Attention! Users of the below product manufactured by Sedana Medical.

REF number	Product name	Affected lot #	Recall reason	Action to take
1026022	Sedaconda Syringe	Potentially F000036-65. No complaints were registered after batch F000065. Current production batch F000124	N/A	Refer to the latest Sedaconda ACD and Syringe IFU (Instructions For Use Sedaconda ACD Rev 5, specifically 5.3 Point 6 and Instructions For Use Sedaconda Syringe Rev 1, specifically Picture 3) regarding tightening of the syringe to the agent line by following this link: Sedaconda ACD IFU and Sedaconda Syringe IFU

1. Information on Affected Devices

1.1	**Device Type**
	The Sedaconda Syringe is a device designed for the safe and accurate administration of volatile anaesthetics, such as isoflurane or sevoflurane, during inhaled sedation via the Sedaconda ACD

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Reg. no 551564 VAT. no. IE3330914UH

	(Anaesthetic Conserving Device). The syringe ensures controlled dosing and minimizes waste of anesthetic agents.
1.2	**Commercial name**
	Sedaconda Syringe
1.3	**Unique Device Identifier (UDI-DI)**
	UDI-DI for SKU (box of syringes) 05391530290692
1.4	**The primary clinical purpose of the device**
	Administration of isoflurane or sevoflurane when using Sedaconda ACD
1.5	**Device Model/Catalogue/part number**
	1026022
1.6	**Affected serial or lot number range**
	Potentially F000036-65. No complaints were registered after batch F000065. Current production batch F000124.

2. Reason for Field Safety Corrective Action (FSCA)	
2.1	**Description of the product problem**
	A potential issue has been identified with the connection between the syringe (filled with isoflurane or sevoflurane) and the delivery line to the Sedaconda ACD. In some cases, this connection may experience leakage, leading to reduced or interrupted delivery of the drug. This could result in inadequate sedation, causing the patient to wake prematurely. The issue has been traced to variability in the connector, which can be resolved by ensuring proper tightening, when the connection is loose this can compromise the integrity of the link between the syringe and the agent line. Updates to the Instructions for Use (IFU) and additional training materials regarding the same have been implemented to address this issue.
2.2	**Hazard giving rise to the FSCA**
	The identified issue with the syringe-to-line connection may result in leakage of Isoflurane, leading to insufficient delivery of the anaesthetic. This could cause inadequate sedation, resulting in the patient waking prematurely. If not promptly addressed, this may pose a risk of patient discomfort, psychological stress, or, in severe cases, unintended movement or self-extubation, potentially compromising patient safety.
2.3	**Probability of problems arising**
	The probability of the problem occurring is low, as the issue is linked to variations in the sizing of components, which has been rectified. Implemented corrective actions, including updated training and instructional materials, have further reduced the likelihood of recurrence of similar incidents in these batches.
2.4	**Predicted risk to patient/users**
	The overall risk is low, as this issue is rare and can be managed with prompt intervention. Since 2022, three isolated incidents of inadequate sedation have been reported. Through this FSN, we aim to remind users that following the instructions helps prevent psychological harm to patients. Corrective actions have minimized recurrence and associated risks. While an issue was identified with the Sedaconda ACD syringe that could lead to a slight leakage of the drug and inadequate sedation, to date there has been no actual patient harm reported.
2.5	**Background on Issue**
	An issue was identified with the syringe-to-line connection in the Sedaconda ACD syringe, leading to potential drug leakage and insufficient sedation. The problem arose due to variations in component size. Corrective actions, including updates to the IFU, training materials, and customer communication, have been implemented to address this issue in these batches.

	Previously, manual leak testing was performed, but now 100% of the devices undergo automatic testing. For updated instructions, scan the QR code or follow the provided link to access the Instructions for Use.

3. Type of Action to mitigate the risk		
3.1	Action To Be Taken by the User ☒ Identify Device ☐ Return Device	
3.2	By when should the action be completed?	Affected customers are provided with immediate access to the updated IFU and e-guide. Instructions For Use Sedaconda ACD Rev 5, specifically 5.3 Point 6 and Instructions For Use Sedaconda Syringe Rev 1, specifically Picture 3.
3.3	Is customer Reply Required?	No
3.4	Action Being Taken by Sedana Medical ☐ Product Removal ☒ Updated IFU and e-Learning	
3.5	By when should the action be completed?	15 February 2025
3.6	Is the FSN required to be communicated to the patient /lay user?	No

4. General Information		
4.1	FSN Type	New
4.2	Further advice or information already expected in follow-up FSN?	No
4.3	Manufacturer information	
	Company Name	Sedana Medical Ltd
	Address	Unit 2A, The Village Centre, Two Mile House, Co. Kildare, W91 PWH5, Ireland
	Website address	www.sedanamedical.com
4.4	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	

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.
- Please transfer this notice to other organisations on which this action has an impact.
- Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.
- Please report all device-related incidents to the manufacturer, distributor local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Quality questions
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We apologize for the inconvenience this action causes, and we thank you for your cooperation.

Sincerely,
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