Date: 17 August 2023
FSCA reference number 2023-01

Urgent Field Safety Notice (FSN)
Sedana Medical's FlurAbsorb 26096

Attention! For all distributors and users of the below product manufactured by Sedana Medical.

REF number	Product name	Affected lot #	Recall reason	Action to take
26096	FlurAbsorb (Medical Device)	23061368-23071425	Manufacturing defect	Stop using the device and inform Sedana Medical

1. Information on Affected Devices

1.1	**Device Type**
	FlurAbsorb is an active carbon filter, developed by Sedana Medical to capture waste anaesthetic gases from the exhaust of the ventilator. The FlurAbsorb is comprised of a plastic container with a series of holes placed in the bottom to allow airflow through the device. Various filters are placed throughout the device to contain the activated carbon. The inlet on top of the FlurAbsorb is connected to the exhaust of the ventilator using the flex tube and adapters from the FlurAbsorb Accessory Kit. The materials used in the FlurAbsorb and the FlurAbsorb Accessory Kit are compatible with volatile anaesthetics.
1.2	**Commercial name**
	FlurAbsorb
1.3	**Unique Device Identifier (UDI-DI)**
	539153029026003FJ
1.4	**Primary clinical purpose of the device**
	Scavenging of waste anaesthetic gases
1.5	**Device Model/Catalogue/part number**
	26096
1.6	**Affected serial or lot number range**
	23061368-23071425

2. Reason for Field Safety Corrective Action (FSCA)

2.1	**Description of the product problem**
	The underlying problem stems from an assembly error, where an incorrect inner lid (retainer) was utilised during manufacturing. The lid chosen was incorrect, which makes the FlurAbsorb create a large pressure drop to the ventilator, rendering the waste anaesthetic absorption process ineffective. This issue impacts products manufactured between June 7, 2023, and July 27, 2023. Sedana Medical's attention was drawn to this matter on August 14th during an analysis of a sample linked to a customer complaint from Germany. Upon connecting it to testing equipment, an unusually high-pressure drop was observed. Subsequent examination of the FlurAbsorb device revealed that the Inner Tub Lid (inner retainer) differed from the intended specification. It's crucial to note that the reported incident in Germany did not result in any harm to patients. Sedana Medical is recalling the affected product/s and is advising users to segregate affected devices for retrieval as they should not be employed for patient usage. Unaffected stock will be

	available from 25 August. For urgent situations, 26094 (smaller FlurAbsorbs) are available as a temporary replacement.
2.2	**Hazard giving rise to the FSCA**
	Due to increased pressure drop, FlurAbsorb is blocked, which may lead to hazards including ventilator alarms and treatment cessation and environmental concerns such as waste gas release.
2.3	**Probability of problem arising**
	The likelihood of encountering the issue is significant for any user of the device, as it arises from a manufacturing error affecting all affected batches. This error involves a cover on the upper inlet, causing internal resistance within the device and effectively preventing the entry of gases into FlurAbsorb.
2.4	**Predicted risk to patient/users**
	No serious patient consequences - The patient's anaesthetic dosage and sedation depth will remain unchanged, consequently preserving their recovery time. Both the fresh gas volume and the recirculation of CO2 to the patient will remain consistent, eliminating any potential risk of hypoxia or hypercarbia.
2.5	**Background on Issue**
	We received a non-serious complaint from Germany indicating that upon connecting the FlurAbsorb to the Evita ventilator, the expiration function of the ventilator ceased to operate. Subsequently, the FlurAbsorb was promptly replaced, leading to the restoration of normal functionality. Upon receipt, Sedana Medical subjected the affected device to in-house laboratory testing, revealing that when connected to testing equipment, the pressure drop exceeded acceptable levels. Further investigation of the FlurAbsorb unit unveiled that the Inner Tub Lid (inner retainer) differed from the expected specification.

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?	The initiation of device returns occurs immediately. However, it's important to note that managing all the returns might take some time, possibly extending until the end of September.
3.3	Is customer Reply Required?	Yes. Please confirm receiving this information to Sedana Medical (office.de@sedanamedical.com), customerservice@sedanamedical.com). Make an inventory of your storage to find out if you have any of the affected batches and contact (office.de@sedanamedical.com or customerservice@sedanamedical.com) one of these mail addresses for return information/shipment.
3.4	Action Being Taken by Sedana Medical ☒ Product Removal	
3.5	By when should the action be completed?	The initiation of device returns occurs immediately. However, it's important to note that managing all the returns might take some time, possibly extending until the end of September.
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 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 or 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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