

Rev 3: March 2020

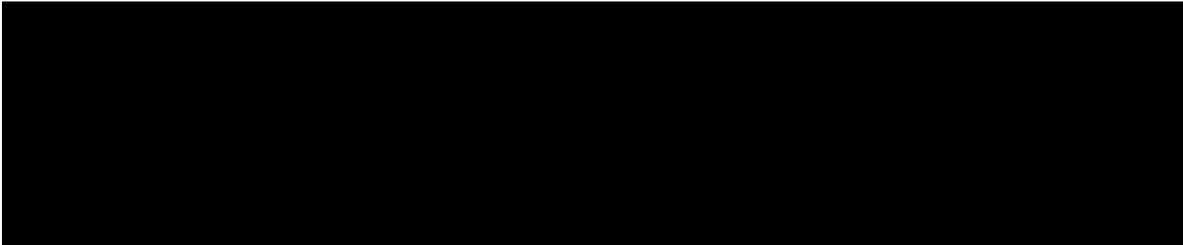
FSN Ref: FSCA01_FSN01

FSCA Ref: FSCA 01

Date: 24 MAR 2020

Urgent Field Safety Notice
AnaConDa-S
DRAFT

For Attention of*:Hospital/Clinic/Risk Manager /Device Safety Officer/Purchasing Dept./Head of ICU



Urgent Field Safety Notice (FSN)**AnaConDa-S****Risk addressed by FSN**

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	AnaConDa-S (Anaesthetic Conserving Device), Ref No: 26050 is an anaesthetic delivery system developed for the administration of volatile anaesthetics such as Isoflurane or Sevoflurane to invasively ventilated patients.
	
1	2. Commercial name(s)
.	AnaConDa-S
1	3. Unique Device Identifier(s) (UDI-DI)
.	Complete when this becomes available.
1	4. Primary clinical purpose of device(s)*
.	The AnaConDa (Anaesthetic Conserving Device) is intended for administering and recirculation of isoflurane and sevoflurane to mechanically ventilated patients. Administration of isoflurane and sevoflurane using Anaconda should only be done in a setting fully equipped for the monitoring and support of respiratory and cardiovascular function and by persons specifically trained in the use of inhalational anaesthetic drugs and the recognition and management of the expected adverse effects of such drugs, including respiratory and cardiac resuscitation. Such training must include the establishment and maintenance of a patent airway and assisted ventilation. Anaconda 50ml and 100ml are intended for single use only and needs to be replaced every 24 hours or when needed e.g. at unexpected events like sudden blockage of the airways because of secretion.
1	5. Device Model/Catalogue/part number(s)*
.	26050
1	6. Affected serial or lot number range
.	N001254, N001262, N001273, N001275, N001279, N001282, N001286
1	7. Associated devices
.	Not applicable.

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	Sedana Medical received a complaint from a hospital, notifying of a loose fit between a tube extension and the patient side of AnaConDa-S. An evaluation of the complaint sample showed that there was a loose fit between the tube extension and AnaConDa-S.
2	2. Hazard giving rise to the FSCA*
.	The potential hazard is that the AnaConDa and the respiratory circuit could potentially disconnect from the endotracheal tube when there is loose fit between AnaConDa-S and the extension tube. This implies a temporary loss of ventilation and positive end expiratory

	pressure (PEEP), which may affect gas exchange. The hazard resembles the situation when staff performs endotracheal suctioning, but it is unplanned and undesirable.
2	<p>3. Probability of problem arising</p> <p>Sedana Medical's Contract Manufacturer (CMO) has acquired a new supplier for manufacturing of the AnaConDa component to address the loose fit between a tube extension and the patient side of AnaConDa-S. This new supplier has been fully evaluated and qualified by Sedana Medical's expert team.</p> <p>Stringent controls have been placed on the incoming inspection process at the CMO. The above-mentioned steps will mitigate the risk of this issue's reoccurrence in future.</p> <p>The Drager ErgoStar CM 50 has been tested and validated for compatibility with the AnaConDa-S devices which were quarantined due to the complaint. Sedana Medical will create a procedure pack (REF 26150) which will co-package these two devices and provide a letter informing the user that the two devices must be used in combination. Once the AnaConDa-S is used with the ErgoStar CM 50, the risk of disconnection is mitigated.</p>
2	<p>4. Predicted risk to patient/users</p> <p>The potential hazard for patients is deemed to be moderate to potentially serious, due to the temporary loss of ventilation and oxygenation and positive end expiratory pressure, even if this is readily detected by bedside staff, typically at the time of fitting the AnaConDa and tube extension. The patient may require additional procedures, such as lung recruitment manoeuvres after reconnection of the respiratory circuit. There is a potential risk to users in the vicinity of a leaking device from inadvertent exposure to volatile anaesthetics. However, this risk is considered of low grade as the volatile anaesthetic concentrations that disconnection of the circuit implies for healthcare professionals is relatively low.</p> <p>This potential hazard is mitigated when the Drager ErgoStar CM 50 is connected to the AnaConDa-S patient side port. The ErgoStar CM 50 ensures a tight connection to the AnaConDa which mitigates the risk of a loose fit.</p>
2	<p>5. Background on Issue</p> <p>Sedana Medical received a complaint from a hospital, notifying that batch number N001254 was found to have a loose fit between tube extension and the patient side of AnaConDa-S which was noticed at the time of connecting the two devices. An evaluation of the complaint sample showed that there was a loose fit between the tube extender and AnaConDa-S.</p> <p>Sedana has conducted an evaluation of all batches of AnaConDa-S in stock. The evaluation determined that three batches had a dimensional variant that could potentially cause a disconnection when used in conjunction with the above referenced tube extension. A further four batches were found to be potentially non-conforming and were also placed in quarantine, bringing the total number of quarantined batches to seven, as outlined in section 1.5.</p>

	3. Type of Action to mitigate the risk*
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<p>3.</p>	<p>1. Action To Be Taken by the User*</p> <p> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input checked="" type="checkbox"/> Other <input type="checkbox"/> None </p> <p>The user should use the AnaConDa-S and Drager ErgoStar CM 50 device together to mitigate the risk of disconnection. These devices shall be co-packaged and provided to the user under the new reference number 26150, named “<i>AnaConDa Flex Tube Kit</i>”. This procedure pack will contain 8 AnaConDa-S devices and 8 Drager ErgoStar CM 50 devices. The pack will be labelled with information restricting use of the lot numbers identified in section 1.5 only with the ErgoStar CM 50. The package will also contain an information letter which explains the combination of the two devices. This procedure pack (REF 26150) shall only be supplied to the German market for a limited period of time.</p>	
<p>3.</p>	<p>2. By when should the action be completed?</p>	<p>Specify where critical to patient/end user safety Immediate</p>
<p>3.</p>	<p>3. Patient level follow up not required because Administration of isoflurane and sevoflurane using AnaConDa should only be done in a setting fully equipped for the monitoring and support of respiratory and cardiovascular function and by persons specifically trained in the use of inhalational anaesthetic drugs and the recognition and management of the expected adverse effects of such drugs, including respiratory and cardiac resuscitation. Patients are typically sedated and cared for by healthcare professionals who have the patient under continuous observation and are trained to manage any adverse events.</p> <p>The combination of the Drager ErgoStar CM 50 and AnaConDa-S mitigates the risk to the patient and prevents unwanted disconnection of the devices.</p>	
<p>3.</p>	<p>4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</p>	<p>No</p>
<p>3.</p>	<p>5. Action Being Taken by the Manufacturer</p> <p> <input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other <input type="checkbox"/> None </p> <p>All of the AnaConDa-S devices noted in section 1.5 have been removed from all markets and placed in quarantine. These devices will be co-packaged with the Drager ErgoStar CM 50 and provided to the end users as part of a procedure pack, Reference 26150 “<i>AnaConDa-S Flex Tube Kit</i>”. The combination of the AnaConDa-S and ErgoStar CM 50 mitigates the risk of loose connection.</p>	

3	6. By when should the action be completed?	Immediately
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

4. General Information*	
4.	1. FSN Type* Update
4.	2. For updated FSN, reference number and date of previous FSN 02 February 2020 FSN: Reference Number: FSCA 01_FSN01
4.	3. For Updated FSN, key new information as follows: Updated information related to repackaging and release of quarantined AnaConDa-S devices which mitigate the risk to the patient and user
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * BfArM, Germany
4.	5. Name/Signature Insert Name and Title here and signature below

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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..*</p>

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.