SEDANAMEDICAL
Pioneering volatile anaesthetic delivery

Sedana Medical Ireland Ltd
Unit 1-2 The Village Centre
Twomilehouse, Co Kildare
W91 PWH5, Ireland
+353 (0)45 87 90 81
www.sedanamedical.com

Urgent Field Safety Notice

Date: 22.01.2020
Commercial name of the affected product: AnaConDa-S (Ref:26050)
FSCA – Identifier = FSCA 01
Type of Action: Return of Medical Device to Manufacturer

Attention:
Name of Hospital:
Request: Please pass this Field Safety Notice (FSN) onto all relevant personnel who needs to be aware of its existence and maintain awareness over an appropriate period.

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

The following authorized and notified bodies have been informed of this FSN and they are as follows:
The Health Products Regulatory Authority (HPRA), British Standards Institute (BSI), Federal Institute for Drugs and Medical Devices (BfArM), National Agency For The Safety of Medicine and Health Products.(ANSM), Federal Institute for Drugs and Medical Devices (AEMPS), Austrian Agency for Health and Food Safety (AGES), Medicines And Healthcare Products Regulatory Agency(MHRA),Danish Medicines Agency.

Please kindly provide acknowledgement receipt of this FSN by way of an email to contact persons listed below.

Details on effected devices:
Type of device = Anaesthetic delivery device.
Model name of device = AnaConDa – S (Ref:26050)
Effected batch / Lot numbers = N001254, N001262, N001279.

Description of the problem:
Sedana Medical received complaints from a hospital, Klinikum Wolfsburg Germany, notifying that batch number N001254 had a loose fit between the Covidien tube extension (REF 352/5985) and the patient side of AnaConDa-S. An evaluation of the complaint sample showed that there was a loose fit between the tube extender and AnaConDa-S. 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.

Advise on action to be taken by user:
Stop usage and return of all AnaConDa-S product with the following batch numbers: N001254, N001262, N001279
Sedana Medical will be in contact immediately with all users/hospitals to recover the product with above batch Numbers.

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Transmission of this field Safety Notice:

Head of ICU
Head of Purchasing (Purchasing Department of Hospital)
Materiovigilance Department of Hospital

Contact reference person:

Auindrila Das
Regulatory Affairs Specialist
auindrila.das@sedanamedical.com
+353 873751599

Steven Prendergast
QA Engineer
steven.prendergast@sedanamedical.com
+353 873593312

Signature:

Auindrila Das

Steven Prendergast

Date:

22 Jan 2020

22 JAN 2020