FSN Ref: MDS-22-4419 FSCA Ref: CAPA-22-SKP-012

Date: 2022-07-26

Urgent Field Safety Notice
For procedure pack according to MDD Article 12

For Attention of*: End users as well as the customers of Sengewald Klinikprodukte GmbH.

Contact details of local representative (name, e-mail, telephone, address etc.)*
mpö GesmbH in Klagenfurt, Austria
SMS medipool GmbH in Gauting, Germany
NORDMED Medical Produkte GmbH in Garbsen, Germany

FSN Ref: MDS-22-4419 FSCA Ref: CAPA-22-SKP-012

Urgent Field Safety Notice (FSN)
For procedure pack according to MDD Article 12

	1. Information on Affected Devices
1.	a) Device Type(s)
	There is a risk of leaks in the three-way valve from Becton Dickinson. The FSN number from Becton Dickinson is MDS-22-4419. The item recalled is a medical device class IIa in a procedure pack according to MDD Article 12. The legal manufacturer of the affected item is Becton Dickinson. This FSCA is listed in our company under the number 22-SKP-012.
1.	b) Commercial name(s)
	CAVA Set Modell SMZO; S6676272-08 Kleinteile Set Gefäß Krankenhaus Agatharied, S66827277-03 Vitrektomie Set Modell Braunschweig, S6628099-12 Gefäß-Set Krankenhaus Agatharied Hausham, S66820329-08
1.	c) Affected serial or lot number range
	S6676272-08: 422612 & 427986 S66827277-03: 425234 S6628099-12: 425708 S66820329-08: 427667
1.	d) Associated devices
	BD Connecta™ Dreiwegehahn blau ohne Verlängerung Sengewald Nr.: B350065 BD Nr.: 394602 BD Lot Nr.: 1090039

	2. Reason for Field Safety Corrective Action (FSCA)
2.	a) Description of the product problem
	BD has confirmed through customer feedback that BD Connecta™ three-way valves and the BD Nexiva™ IV closed access system with BD Connecta™ three-way valve may have leakage at the body portion of the isolation valve.
2.	b) Hazard giving rise to the FSCA
	With the BD Connectra three-way valves and the BD Nexiva IV closed access system with BD Connecta, leaks may occur and treatment delay or interruption, exposure of infusion solutions, medications, and biohazards, under-dosing or under-infusion, contamination, and/or air entrainment may occur.
2.	c) Other information relevant to FSCA
	For further descriptions, see FSN from BD with the number MDS-22-4419.

FSN Ref: MDS-22-4419 FSCA Ref: CAPA-22-SKP-012

	3. Type of Action to mitigate the risk	
3.	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 Informing the customer of the product safety notification from Becton Dickinson. Feedback on the stock level of the specified lot numbers. Providing sterile 3-way stopcocks to the customer.	
3.	By when should the action be completed?	2022-06-17
3.	Is customer Reply Required? * Customers were sent the FSN Customer Reply Form (FORM-054-01) with all relevant information.	Yes

	4. General Information	
4.	FSN Type	New
4.	Further advice or information already expected in follow-up FSN?	Not planned yet
4.	The Competent (Regulatory) Authority of Austria and Germany has been informed about this communication to customers.	
4.	Name/Signature	[redacted] **PMS & Vigilance Specialist** [redacted]

	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..*