Rev 2: February 2020
FSN Ref: WF-FSN-2021-1 FSCA Ref: WF-FSCA-2021-1

Date: 2021-12-01

Field Safety Notice
Chemo-Sure Infusion Set

For Attention of*: [redacted]

[redacted]

Field Safety Notice (FSN)
Chemo-Sure Infusion Set
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Spirit Medical Chemo-Sure Infusion Set (with or without valve) is a secure infusion device that is supplied sterile. It is used for administration and rinsing of medicinal solutions. (Refer to Annex A – Chemo Sure Product Photos)
1.	2. Commercial name(s)*
	SM-CHEMO-SURE
1.	3. Unique Device Identifier(s) (UDI-DI)
	SM-CHEMO-SURE-01P (9555864700593), SM-CHEMO-SURE-05P (9555864700616), SM-CHEMO-SURE-V-01P (9555864700586), SM-CHEMO-SURE-V-05P (9555864700609)
1.	4. Primary clinical purpose of device(s)*
	SM-Chemo-Sure infusion set is sterile, non-pyrogenic and for single use
1.	5. Device Model/Catalogue/part number(s)*
	SM-CHEMO-SURE-01P, SM-CHEMO-SURE-05P, SM-CHEMO-SURE-V-01P, SM-CHEMO-SURE-V-05P
1.	6. Software version
	NA
1.	7. Affected serial or lot number range
	Refer to Annex 1
1.	8. Associated devices
	NA

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Risk of leakage on one connection point between 2 components of the Chemo-Sure set, as observed during the preparation stage.
2.	2. Hazard giving rise to the FSCA*
	Leaks seen during use of the IV sets detected by customer during preparation stage.
2.	3. Probability of problem arising
	High.
2.	4. Predicted risk to patient/users
	None. Problem can be detected during preparation stage.
2.	5. Further information to help characterise the problem
	Risk of leakage on one connection point between 2 components of the Chemo-Sure set, as observed during the preparation stage.
2.	6. Background on Issue
	11 incidents of leakage were reported by customer during preparation stage. Fluid leakage prior to connection to an intravenous administration set may potentially cause delay of infusion or exposure to hazardous medications. Root cause: Insufficient glue at connection point. Why this FSCA affect

	only to the listed lots? Only these lots are having these defects. Actions to prevent this from happening in future: Extra tests and inspections being conducted.
2.	7. Other information relevant to FSCA
	NA

3. Type of Action to mitigate the risk*		
3.	**1. Action To Be Taken by the User***	
	☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification / inspection ☐ Follow patient management recommendations ☐ Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Immediately
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer***	
	☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Recall products from customer location	
3.	6. By when should the action be completed?	By end of December
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No Choose an item.	

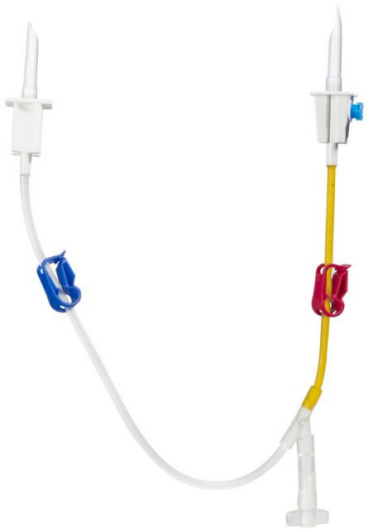
4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	NA
4.	3. For Updated FSN, key new information as follows:	
	NA	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	NA	
4.	6. Anticipated timescale for follow-up FSN	NA
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Welford Manufacturing (M) Sdn Bhd
	b. Address	No.25, BRP 9/1B, Putra Industrial Park, 47000 Sungai Buloh, Selangor Darul Ehsan, Malaysia
	c. Website address	www.welfordmedical.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * France: National Agency for the Safety of Medicine and Health Products Belgium: Federal Agency for Medicines and Health Products (Location of Authorised Representative) Germany : The Federal Institute for Drugs and Medical Devices	
4.	9. List of attachments/appendices:	Annex A - SM-Chemo Sure product photos, Annex 1 - List of SM-CHEMO-SURE affected lot numbers
4.	10. Name/Signature	[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.*

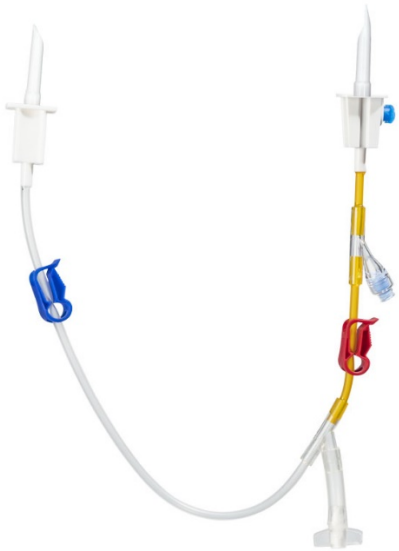
Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Annex A

SM-Chemo Sure product photos



SM-CHEMO-SURE-V-01P & SM-CHEMO-SURE-V-05P



SM-CHEMO-SURE-01P & SM-CHEMO-SURE-05P

Annex 1

List of SM-CHEMO-SURE affected lot numbers

Manufacturer's Product Number	Lot/Serial Number
SM-CHEMO-SURE-01P	SM47-S08-21F
SM-CHEMO-SURE-05P	SM49-S08-21F
SM-CHEMO-SURE-V-01P	SM46-S08-21F
SM-CHEMO-SURE-V-05P	SM48-S08-21F