Steripack
Medical Procedure Packs and Products

FSN Ref:2020FSN10606914_07Oct2020 FSCA Ref: 2020FSCA10606914_07Oct2020

Date: 07-10-2020

Urgent Field Safety Notice
Hemo dialysis start-stop set Rev, incl flushing Saline

For Attention of*:End User

Contact details of local representative (name, e-mail, telephone, address etc.)*
H. Dam Kaergaard, Gammel Kongevej 601850 Frederiksberg Denmark

STERIPACK S.A. Zona Industrial 1 - Lote 11 a 14 - 4560-164 Guilhufe, Penafiel - PORTUGAL - Phone: +351 255 729 090 www.sterisets.com

Steripack
Medical Procedure Packs and Products

Urgent Field Safety Notice (FSN)
Hemo dialysis start-stop set Rev, incl flushing Saline

1. Information on Affected Devices*	
	1. Device Type(s)*
	Hemo dialysis start-stop set Rev, incl flushing Saline
	2. Commercial name(s)
	Haemodialyse start-stop saet
	3. Unique Device Identifier(s) (UDI-DI)
	5608120SETSDIALYSO-7WU
	4. Primary clinical purpose of device(s)*
	These sets are intended to be used in non-invasive dialyse procedures
	5. Affected serial or lot number range
	REF: 10606914 and LOT 1912155
	6. Associated devices
	REF:14363 - Syringe NaCl 0,9% Luer Lock 10 ml, with label

STERIPACK S.A. Zona Industrial 1 - Lote 11 a 14 - 4560-164 Guilhufe, Penafiel - PORTUGAL - Phone: +351 255 729 090 www.sterisets.com

2 Reason for Field Safety Corrective Action (FSCA)*

1. Description of the product problem*

Syringe is broken when set is opened. There is liquid out in the set.

2. Hazard giving rise to the FSCA*

Sterile fluid leaked from the syringe

3. Probability of problem arising

Likely to occur six times in the last 12 months
Reference: 10606914
Sales volume (2020): 168.224 units
Number of the Incidents (2020): 4 Incidents
% incident in 2020 = 0,0023%

4. Predicted risk to patient/users

Predicted risk to patients/users is classified as improbable.

5. Further information to help characterise the problem

If the syringe is broken, please discard the set.

6. Background on Issue

The customers have noticed that the syringe is broken when they opened the set. There is liquid out in the set.

7. Other information relevant to FSCA

It was not possible to identify a specific root cause. It was likely to be related to the sterilisation process or shipping conditions.

3. Type of Action to mitigate the risk*

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
☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

2. By when should the action be completed? **This action should be performed before use.**	Specify where critical to patient/end user safety None

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

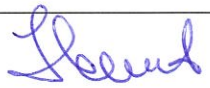
4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) **07-11-2020**	Yes

5. Action Being Taken by the Manufacturer

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other ☒ None

Steripack
Medical Procedure Packs and Products

	6. By when should the action be completed? **N/A**	Specify where critical to patient/end user safety	
	7. Is the FSN required to be communicated to the patient /lay user?		**No**
	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?		
	N/A		

	4. General Information*	
	1. FSN Type*	**New**
	2. For updated FSN, reference number and date of previous FSN	**2020FSN10606914_07Oct2020**
	3. For Updated FSN, key new information as follows:	
	4. Further advice or information already expected in follow-up FSN? *	**No**
	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
	6. Anticipated timescale for follow-up FSN	**07-11-2020**
	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	Steripack S.A	Only necessary if not evident on letter-head.
	Zona Industrial 1, Lote 11 a 14 4560-164 Guilhufe, Penafiel Portugal	Only necessary if not evident on letter-head.
	nfelix@sterisets.eu	Only necessary if not evident on letter-head.
	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * **Yes**	
	9. List of attachments/appendices:	If extensive consider providing web-link instead.
	10. Name/Signature	Nuno Felix - Quality Director/ Isabel Nascimento – Quality and Regulatory Affairs Manager
		

	Transmission of this Field Safety Notice
	This notice needs to be passed on to all end users who need to be aware of this Field Safety Notice. Please maintain awareness on this notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action

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

Medical Procedure Packs and Products

Contact manufacturer

Steripack S.A
Att.: Mr. Nuno Félix – Quality Director
Zona Industrial 1, Lote 11 a 14
4560-164 Guilhufe, Penafiel
Portugal
Tel.: +351 255 711 355
Fax: +351 255 711 357
Web site: www.sterisets.eu
E-mail: nfelix@sterisets.eu

Acknowledgment of receipt
Sterisets Medical Products requires an acknowledgment of receipt of this notice.

With regards,

Steripack S.A
Nuno Felix - Quality Director/ Isabel Nascimento – Quality and Regulatory Affairs Manager