Medical Procedure Packs and Products

FSN Ref:2020FSN10606914_06jul2020 FSCA Ref: 2020FSCA10606914_06jul2020

Date: 06-07-2020

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

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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)
	Hemo dialysis start-stop set
	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 1912047
	6. Associated devices
	REF:14363 - Syringe NaCl 0,9% Luer Lock 10 ml, with label

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2 Reason for Field Safety Corrective Action (FSCA)*

1. Description of the product problem*

The syringe tip broke

2. Hazard giving rise to the FSCA*

Inadequate performance characteristics - broken tips

3. Probability of problem arising

Likely to occur six times in the last 12 months
Reference: 10606914
Sales volume (2020): 100.352 units
Number of the Incidents (2020): 1 Incident
% incident in = 0,00099%

4. Predicted risk to patient/users

The *Severity vs Probability evaluation* is the tool used to predict the impact of each risk– *Low impact; Medium Impact; High Impact* and *Extreme Impact.* The *table* shows the contribution of each variable on risk evaluation based on a 5 x 5 matrix for the estimation of the risks:

Probability (P)	Severity (S)				
	Trivial 1	Minor 2	Moderated 3	Major 4	Severe 5
Frequent 5	L	H	H	E	E
Occasional 4	L	M	H	H	E
Possible 3	L	M	M	H	E
Improbable 2	L	M	M	H	H
Rare 1	L	L	M	M	H

In this case, the predicted risk to patient/users is *High impact.*
Probability – 4 (Likely to occur)
Severity – 3 (Potential of injury – reversible)

5. Further information to help characterise the problem

It is recommended in the Instructions for use that excessive force is not exerted. In addition, the instructions for use do alert the end user to not use the medical device if the syringe tip cap is damaged in any way that suggests or indicates syringe leakage. Therefore, in order to ensure patient safety, it is important that the end user/health professional verify the integrity of the syringe tip before use.

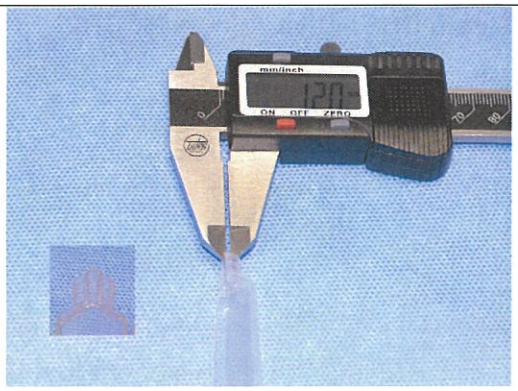
6. Background on Issue

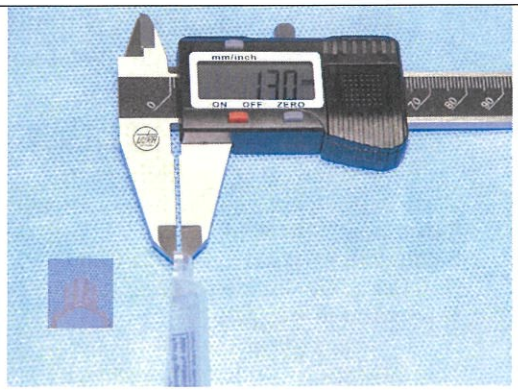
The cap closure process during the manufacturing process is of critical importance when filling and closing the prefilled syringes. If the cap and syringe are not aligned by the time of closure, the inner tip of the syringe powerfully touches the cap causing the inner tip to become weak, due to the strength input from the filling machine.

Following the syringes filling process, these are 100% inspected. During the inspection procedure, the plunger is being slightly pressed in order to check for any leaks which could be originated from a broken tip, and also checking for cap defects which would indicate that both syringe and cap would not be aligned.

However, after a thorough investigation, and due to the alerts on the Instructions for Use of the affected Medical Device, it is apparent that this incident might be a case of misuse of the medical device. This is backed up by the fact that only 0,00099% of the total quantity of the same medical device placed in the market in 2020 (100.352 units) has been affected, meaning that this is not an issue on the syringe design, otherwise a bigger percentage or even the whole batch(es) would have been affected.

A continuous improvement process is in place at the Steripack S.A., the legal manufacturer (trading as Sterisets Medical Products), and, therefore, in 2019 an improvement has been implemented on the design of the syringe in order to strengthen the syringe tip. The plastic injection technology has been changed so that a stronger syringe tip could be achieved. This improvement has now been implemented on batches manufactured since March 2020 (after the current affected batch) which are already in the market. Please refer to the below pictures where on the left hand side a thinner tip wall (measured using a calibrated caliper) can be seen. This corresponds to the previous syringe design which, apart from the possible misuse of the device, could have led to the current incident.
On the right hand side, it can be seen an improved thicker syringe tip wall which corresponds to the improved syringe design implemented in March 2020.





In addition to the investigation, the production records of the affected batch has been reviewed and showed that there were no issues during the manufacture of the product that would contribute to this defect condition and product was manufactured according to the procedure.

According to the scientific literature, the syringes´ design may well contribute towards an inherent weakness of the syringe tip, which renders it prone to break. Syringes differ in the barrel shape and tip length which could have an effect on the strength of the tip, causing it to break.

Adding to the investigation, a continuous risk management is implemented at Steripack S.A., and risk control options will be to increase the sampling plan according to ISO 2859 and carry out a simulation of the final purpose in vascular access devices.

It is important to note that patient safety is not at risk as there is no description of acutely unwell patients.

7. Other information relevant to FSCA

In addition to the mentioned above, and although this might be considered a case of misuse due to the very low number of affected syringes, due to the cautions already present on the instructions for use of the medical device and the described steps which must be taken to use the device safely, additional corrective actions have and are due to be implemented by the manufacturer. Please see list below:

- Improvement on the syringe tip design (already implemented in March 2020)
- During the investigation it became apparent that although the medical device itself did have the symbol "Caution" added to the labelling as per ISO15223-1 (Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements), the primary, secondary and tertiary packaging did not have the referred symbol. Therefore, labelling will be updated. **This symbol indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.** – Due in September 2020
- On the Instructions for Use of the affected Medical Device, step 6 already describes that the connection of the luer-lock syringe to the vascular access device must be done taking care, however, an improvement in the wording will be done in order to reinforce that this connection must be done carefully – Due in September 2020
- On the same Instructions for Use of the affected Medical Device, step 7 will be enhanced so that the end user is alerted to the fact that an excessive force when connecting the luer-lock syringe must not be exerted – Due in September 2020
- During the manufacturing process of the medical device and during the 100% inspection, a sampling plan according to ISO 2859 will be implemented in order to carry out a simulation of the final purpose in vascular access devices, so that any weakness of the syringe tip batch being inspected could be detected and a decision on batch approval taken – Due in September 2020

For the corrective actions presented above an internal non-conformance will be opened within the Quality Management System of Steripack S.A. in order to closely monitor and follow up on the implementation, closure and effectiveness check of the corrective actions.

This event will be accounted for and monitored via post market surveillance activities and risk assessment to ensure that our products corresponds with the highest standards of quality and to avoid similar situations.

In order to ensure patient safety and until further corrective actions are implemented, it is important that the end user/health professional verify the integrity of the syringe tip before use and that the instructions for use are consulted before the use of the medical device.

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

In order to ensure patient safety and until further corrective actions are implemented, it is important that the end user/health professional verify the integrity of the syringe tip before use and that the instructions for use are consulted before the use of the medical device

2. By when should the action be completed?	Specify where critical to patient/end user safety
This action should be performed before use. **It is important that the user consults the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.**	None

3. Particular considerations for: Choose an item.

Is follow-up of patients or review of patients' previous results recommended?
No
In order to ensure patient safety and until further corrective actions are implemented, it is important that the end user/health professional verify the integrity of the syringe tip before use and that the instructions for use are consulted before the use of the medical device.

4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) **06-08-2020**	Yes

5. **Action Being Taken by the Manufacturer**

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

Please refer to section 7.

	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	**2020FSN10606912_06jul2020**
	3. For Updated FSN, key new information as follows:	
	Please refer to section 7	
	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:	
	Please, return samples of the affected product to the manufacturer	
	6. Anticipated timescale for follow-up FSN	**N/A**
	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

	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.

Steripack
Medical Procedure Packs and Products

Contact manufacturer

Steripack S.A
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Web site: www.sterisets.eu
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Acknowledgment of receipt
Sterisets Medical Products requires an acknowledgment of receipt of this notice.

With regards,

Steripack S.A
Nuno Felix - Quality Director