Document name	FSN FLuido Trauma/ Standard set
Date	16 AUG 2024
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Field Safety Notice Fluido® Trauma (671500)/ Standard (671200) set

Affected devices: Fluido® Trauma set 671500/ Fluido® Standard set 671200
Type of action: Correction
Date: 16 AUG 2024
Attention: End-users, Nurses, Clinicians, Physicians, Field Safety Coordinators, Distributors

URGENT FIELD SAFETY NOTICE

Fluido® Trauma sets 671500 Fluido® Standard sets 671200

Dear valued business partner,

The purpose of this notice is to inform you that TSC International B.V. has identified an increase in levels of production related particulates at their supplier of the cassettes as part of Fluido® Trauma sets (671500) and Standard sets (671200) and is providing an additional priming instruction to users to ensure continued safe use of the devices.

The Fluido® disposable sets are classified as class IIa devices according to EU Medical Device Directives (MDD). The sets are used in combination with the Fluido® Airguard System (article code: 655230-C) and are used in high blood loss surgical procedures, trauma, and any situation where replacement of warmed blood or replacement of fluid is required.

Indications for use:
- Infusion of crystalloid, colloid or blood product, including packed red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery.
- Infusion of warmed fluid to patients with the ability to prevent hypothermia.

This Urgent Field Safety Notice is intended to inform on the issue and further instructions of the devices.

Recent quality control testing revealed a proportion of the tested samples have a presence of elevated levels of non-toxic particulates in Fluido® single use sets. The presence of elevated levels of non-toxic particulates where present in quantities which exceed maximum allowable thresholds. These non-toxic particulates may enter the blood and fluid warming system and therefore could enter the patient's bloodstream. This FSCA is intended to mitigate any potential risks to patients and ensure compliance with relevant standards and regulations.

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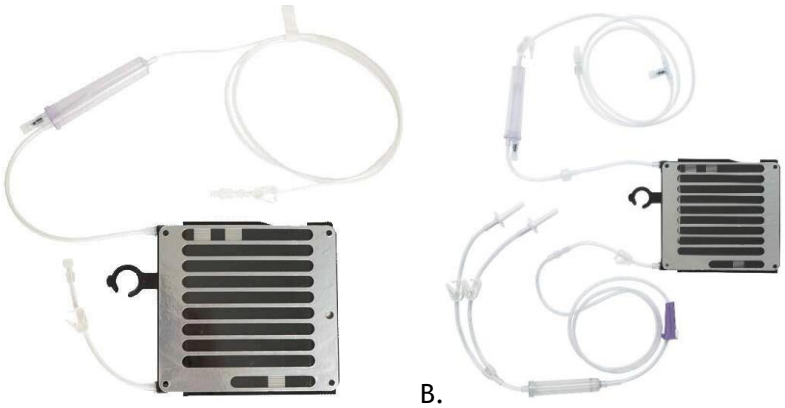
Affected products

Affected products are listen in the table below

Component	REF. No.	Function
Disposable components		
Fluido® Standard Set	REF 671200	Define a sterile pathway for the fluids to be administered to the patient, with adjustable flow rates. Allow heating of fluids when used with the Fluido Blood and Fluid Warmer device.
Fluido® Trauma Set	REF 671500	



A. B.

Figure 1: Fluido® Single use Sets. (A) Standard Set (REF 671200). (B) Trauma Set (REF 671500).

There are no specific lot numbers impacted. This Field Safety Notice applies to **all non-expired products**. **No other products manufactured by TSC International B.V. are affected by this Field Safety Notice.**

Please note that this is an advisory notification and not a product removal.

Note that: TSC International B.V. has not identified any complaints, or reports of injury or death associated with this issue. This FSN is a direct consequence of TSC International B.V.'s continuous quality control monitoring.

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Instruction for all customers and users

All customers who purchased Fluido® Trauma sets (671500) and Standard sets (671200) are requested to identify these products in their possession and refer to the detailed information below:

Instructions for end users:

1. Acknowledge receipt of FSN and extended priming instructions by returning the acknowledgement form provided in Annex ll to fsca@tsc-life.com

2. **Before IV fluid administration** of Fluido® Trauma sets (671500) and Standard sets (671200) Extended Priming instructions as provided in Annex l should be followed

3. Healthcare facilities can report issues arising from device availability or any of the implementation actions requested in this FSN to TSC Life via fsca@tsc-life.com

Instructions for distributors:

1. Acknowledge receipt of FSN and extended priming instructions by returning the acknowledgement form provided in Annex ll to fsca@tsc-life.com.

2. Notify Hospitals/ end users with current stock on FSN and extended priming instructions.

3. Add extended priming instructions to stock on the outer box of the products in warehouse before sending to hospital/ end users.

4. Distributors can report issues arising from device availability or any of the implementation actions requested in this FSN to TSC Life via fsca@tsc-life.com.

We regret any inconvenience that this Field Safety Corrective Action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or require any further assistance with this Field Safety Corrective Action, please contact fsca@tsc-life.com. .

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ANNEX l Extended priming instructions

1.Purpose

The purpose of the extended priming instructions is to eliminate the possibility of an elevated level of particulates being present in the Fluido® Trauma (671500) and Standard (671200) single-use sets. Please, complete priming instructions as described in the Fluido® AirGuard System FAS User Manual INT-R757-XXX. In addition to standard priming instructions you must complete the extended priming instructions as provided in **section 2 below.**

2.Extended priming instructions

The purpose of the extended priming procedure is to use a higher volume of fluid to eliminate the possibility of an elevated level of particulates being present in the Fluido® Trauma (671500) and Standard (671200) single-use sets. Please conduct **before IV administration** to patient.

1. Use a hospital IV bag of at least 500 ml for the priming.
2. Prime the set according the normal procedure, as described in the User Manual **(INT-R757-XXX)**
3. Open in-line clamps to flush remaining fluid (at least up to the 500ml) from the IV bag out of the patient line and dispose of this fluid. The IV bag is allowed to be pressurized for this step.
4. The set is now primed and ready for use.

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Annex ll Acknowledgement response form

URGENT

Distributor/ Hospital	
Country	

PRODUCT:

I acknowledge that:

☐ **the receipt of FSN and extended instructions and return of this form to fsca@tsc-life.com**
☐ **FSN and instructions are understood and provided to the relevant roles/ department of the receiving organization**

Name:		**Signature:**	
Title:		**Date:**	

Please complete this Acknowledgement Response Form and send in return to:

TSC Life
C/o FSCA TSC-Life
Email: fsca@tsc-life.com