Sterisets®
Medical Products

13th October 2025

URGENT: FIELD SAFETY NOTICE

CitraLock Syringe 4%

REF: 3591S2 **Batch Number:** 2502149, 2502045, 2502173

FSCA-Identifier: 2025/01

Type of Action: Field Safety Corrective Action - update

This letter contains important information which requires your immediate attention.

Description of the problem:

On the 24th of July, Sterisets Manufacturing S.A. has conducted a Field Safety Corrective Action (FSCA) to **quarantine** the specific batch number **2502149** of **CitraLock Syringe 4%**, REF: 3591S2, following several reports of adverse reactions in patients, in Belgium and in Portugal, potentially related with the administration of 4% sodium citrate, prefilled syringe from batch 2502149.

This Field Safety Notice (FSN) intends to update the previous Field Safety Corrective Action (FSCA) by requesting the **collection and return** of the specific batch number **2502149** of **CitraLock Syringe 4%**.

Furthermore, considering that the root cause is inconclusive and still under investigation, Sterisets Manufacturing S.A. is initiating a **voluntary recall** of batches **2502045** and **2502173** as well, as they have been manufactured with the same raw material as batch 2502149. Laboratory tests conducted by the Portuguese and Belgian Competent Authorities on samples from batches 2502149 and 2502173 showed non-compliant results with regard to endotoxins in some of the samples tested.

Additionally, and if available, all other batches manufactured prior to batch **2507149** that are within the expiration date must also be recalled, as per the following list.

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Table 1. List of batches:

Batch
2401201
2401236
2402022
2405019
2405086
2405152
2408055
2409140
2409141
2409142
2411196
2412030
2502045
2502149
2502173
2503093
2504122
2505071

For batches produced after **2505071**, we inform you that additional in-process controls were implemented during production. These include representative hourly sampling to assess batch homogeneity.
Therefore, and specifically in relation to batch **2507149**, it will not be subject to recall, since it was released after this exhaustive sampling plan mentioned above.

Clinical risk:

This updated Field Safety Corrective Action (FSCA) aims to address the potential risk of endotoxin contamination, now involving a larger number of batches, given the information available above and considering that the root cause is inconclusive and still under investigation. To date, Sterisets Manufacturing S.A. has only received reports of serious incidents involving batch 2502149, with reported symptoms including fever, headaches, tremors, cyanosis of the extremities, and general malaise.

End Users Actions:

1. Cease use of any affected product - *CitraLock Syringe 4%, REF: 3591S2, batch:* ***2502149, 2502045, 2502173 and other batches mentioned on Table 1 above;***
2. Identify and **return** all affected products;
3. Complete and return the End User Reply Form (Annex A) even if you no longer have any inventory remaining in your facility by 27th October 2025;
4. Circulate this notice to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred;
5. If you experience any issues, please report as an incident as per your normal procedure.

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Distributor Actions:

1. Cease distribution of any affected product - *CitraLock Syringe 4%, REF: 3591S2, batch:* ***2502149, 2502045, 2502173 and other batches mentioned on Table 1 above;***
2. Identify and **return** the affected products;
3. Identify the facilities where you have distributed affected product and notify them immediately of this notice;
    a. Make sure your customers complete and return the appropriate Reply form (Annex A or Annex B) to your organization for reconciliation purposes by 27th October 2025;
4. Complete and return the Distributor Reply Form following completion of your reconciliation activities;
5. If you experience any issues, please report as a complaint as per your normal procedure.

Contact reference:

If you have any questions about this, please contact your distributor which will be in contact with us or e-mail QA.PT@sterisets.com.

We confirm that we are informing the appropriate regulatory agencies about these actions.

We kindly ask you to remain attentive to this notice and apologize for any inconvenience it may cause.

Sterisets Manufacturing S.A. remains firmly committed to delivering high-quality products, with patient safety as our foremost priority.

Sincerely,

Joana Pereira

Quality & Regulatory Affairs Director

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Annex A

End User (Hospital/Clinic) Reply Form

Field Safety Notice – FSCA Identifier 2025/01

CitraLock Syringe 4%, REF: 3591S2, Batch Number: 2502149, 2502045, 2502173 and other batches mentioned on Table 1 above

It is essential that you complete and return this form to enable Sterisets Manufacturing S.A. to finalize the end user notification process.

Please **return the completed form** by email to QA.PT@sterisets.com as soon as possible and **no later than 27th October 2025.**

Company Name		
Company Address		
Email Address		
Telephone Number		
Name and Job title		
☐	I confirm receipt of the Field Safety Notice and have read and understood its content.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	Affected devices REF: 3591S2, Batch Number: 2502149, 2502045, 2502173 and other batches listed on table 1 have been returned	Please provide quantity, per batch:
☐	I do not have any affected devices.	
Print Name		
Signature		
Date		

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Annex B

Distributor Reply Form

Field Safety Notice – FSCA Identifier 2025/01

CitraLock Syringe 4%, REF: 3591S2, Batch Number: 2502149, 2502045, 2502173 and other batches mentioned on Table 1 above

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Please **return the completed form** by email to QA.PT@sterisets.com as soon as possible and **no later than 27th October 2025.**

Company Name		
Company Address		
Email Address		
Telephone Number		
Name and Job title		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I have identified customers that received or may have received this device.	
☐	I have informed the identified customers of this FSN.	Date of communication:
☐	I have received confirmation of reply from all identified customers.	
Print Name		
Signature		
Date		

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