



Dirinco BV  
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**Subject:** Urgent Field Safety Notice  
FSCA 18-12-2015  
Return of the Medical Device to the manufacturer

**Date Issued:** 18<sup>th</sup> December 2015, 15:30 P.M.

**Audience**

Hospital and clinic administrators, purchasing departments, distributors, pharmaceutical offices.

**Product**

Citra-Lock S 4% is a sterile Catheter lock solution, anti-clotting and antimicrobial prefilled syringe available in the market with the references 359, 3591S2 and 3592S.

**Purpose**

To alert health care professionals and facilities to stop using all batches of Citra-Lock S 4% manufactured from January 2015 through December 2015 due to a still yet non identified suspicion of unknown foreign matter.

The affected batches are as follows:

REF	Product name	Batch	Qty
3591S2	Syringe 3 ml with 4% Tri sodium citrate, filled with 2,5 ml, 2 pcs /pack	1504195	38.400
		1505377	19.200
		1508168	9.600
		1511077	28.800
3592S	Syringe 10 ml with 4% Tri sodium citrate, filled with 5 ml, 1 pcs/pack	1506108	38.400
		1508057	38.400
		1511013	19.200

**Summary of problem and scope**

Sterisets Medical Products is a contract manufacturer of medical devices used in Hospitals and Clinics, we produce sterile prefilled syringes with the outmost care and concern regarding quality in our products. We believe that our environmental





monitoring, cleaning procedures and the performance of sterility testing and endotoxin testing is a more than good enough rationale (since it is the GMP approved procedures) to exclude environmental contaminants.

**Advice on action to be taken by the user**

The products have been manufactured by Sterisets Medical Products and sold to Dirinco B.V. only.

Sterisets Medical Products is responsible to initiate the return of the products (recall) and therefore requires the products to be placed in quarantine.

Dirinco B.V. assures that the products will be in quarantine at Dirinco`s facilities, this includes all batches that have been distributed to his customers.

**Forward-Looking Statements**

Sterisets Medical Products expect to release forward-looking statements of our investigation that are based on hard evidence from our laboratory testing results that will allow us to conclude on this issue.

**Transmission of this Field Safety Notice**

This notice needs to be passed on all those who need to be aware within Dirinco`s organization and to other organizations on which this action has an impact (Dirinco`s customers).

The Dutch Healthcare Inspectorate will be advised of this FSCA.

**Contact manufacturer**

**Sterisets Medical Products**

Att.: Mrs. Isabel Nascimento – QAM

Dr. João Quirino - Pharmacist

Address:

Zona Industrial 1 – lote 11 a 14 4560-164 Guilhufe Penafiel

Portugal

T +351 255 729 090

Sales office address:

**Sterisets International B.V.**

Ketelmeer 3

5347 JX Oss

The Netherlands

T +31 (0) 412 667755

**Acknowledgment of receipt**

**Sterisets International B.V./Sterisets Medical Products, requires an acknowledgment of receipt of this notice.**

With regards,

**Sterisets International B.V./Sterisets Medical Products**

Mrs. Isabel Nascimento – QAM

Dr. João Quirino - Pharmacist

**Sterisets International B.V.**

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