

MEDICAL DEVICE NOTICE

30th of October 2020

Steriflush® Prefilled 0.9% Sodium Chloride Syringes and Procedure Packs Containing Steriflush® Prefilled 0.9% Sodium Chloride Syringes

Dear Valued Customer,

Steripack S.A., trading as Sterisets Medical Products, part of STI Group is contacting you as potentially affected product has been supplied to your organisation.

Purpose of this Letter:

The purpose of this letter is to advise you that Steripack S.A. is voluntarily asking you to return product Steriflush® Prefilled 0.9% Sodium Chloride Syringes and Procedure Packs Containing Steriflush® Prefilled 0.9% Sodium Chloride Syringes intended for flushing of intravascular catheters and to maintain the patency of indwelling intravascular catheters.

Please note that **no serious injuries and/or deaths have occurred** or could occur due to the failure mode associated with this notice.

Reason for this notice:

Following a thorough investigation on the unlikely presence (<0,1%) of trace metals in the syringe stopper used in the Steriflush® Prefilled 0.9% Sodium Chloride Syringes, which could potentially generate extremely small brown particles, Steripack S.A. has decided to advise you on the following.

Actions Required:

1. CHECK all storage and usage locations to confirm if you have any units of the affected item codes in your possession as per Annex I
2. SEGREGATE and QUARANTINE all products on-hand that are confirmed to be affected with batch numbers up until 1809XXX (batch number is YYMM123)
3. RETURN the affected products to the legal manufacturer
4. NOTIFY any customers to whom you may have distributed or forwarded product affected by this notice. You may include a copy of this notice with your customer notification

The health risk associated with this issue is small as no incident or patient safety has ever been involved. Sterisets Medical Products will continue to work closely on this issue and soon it will be solved so that we can continue safely supplying Steriflush® Prefilled 0.9% Sodium Chloride Syringes.

We sincerely apologize for the hardship this notice has caused your staff and patients.

Sincerely,



Jos van der Kwartel

CEO

ANNEX I

Manufacturer's Product Reference Number	Product Name	Manufacturer's internal code
14363SAL	Syringe NaCl 0,9% Luer Lock 10 ml	14363SAL
14360S	Syringe 3 ml with 0,9% sodium chloride sterile	14360S
14361S	Syringe 5 ml with 0,9% sodium chloride (3ml fill) sterile	14361S
14366S	Syringe 10 ml with 0,9% sodium chloride (5ml fill) sterile	14366S
14362S	Syringe 5 ml with 0,9% sodium chloride	14362S
14363S	Syringe 10 ml with 0,9% sodium chloride	14363S
14364S	Syringe 20 ml with 0,9% sodium chloride	14364S
TP-50-10	Prefilled syringes 0,9% Natriumchloride(0,9%NaCl)	14363STA
14363SNSAL	Syringe NaCl 0,9% Luer Lock 10 ml	14363SNSAL
14365SNSF	Syringe LL 10 ml NaCl 0,9% (3ml fill) sterile White Cap	ZZZ14365SNSF
14360SNS	Syringe 3 ml with 0,9% sodium chloride sterile/non sterile	14360SNS
14361SNS	Syringe 5 ml with 0,9% sodium chloride (3ml fill) sterile/non sterile	14361SNS
14362SNS	Syringe 5 ml with 0,9% sodium chloride sterile/non sterile	14362SNS
14363SNS	Syringe 10 ml with 0,9% sodium chloride sterile/non sterile	14363SNS
14364SNS	Syringe 20 ml with 0,9% sodium chloride sterile/non sterile	14364SNS
14365SNS	Syringe 10 ml with 0,9% sodium chloride (3ml fill) sterile/non sterile	14365SNS
14366SNS	Syringe 10 ml with 0,9% sodium chloride (5ml fill) sterile/non sterile	14366SNS
100470	Na-und Abschluss-Set / homepump	10606915
10606912	Dialysis fistel saet	10606912
10606914	Haemodialyse start-stop saet	10606914
10606902	Aansluitset Dialyse	10606902
10606913	Dialyse aansluitset	10606913
10606901	Afsluitset dialyse	10606901
10606911	Disconnection set dialysis home care incl. Flushing saline	ZZZ10606911
10609006	Oncology set	10609006
10601030	Port Skiftesaet	10601030
10609007	Connectionset oncologic	10609007
10605810	Picc-line saet	10605810