TSC LIFE

Innovation with purpose

Subject: Recall Fluido® Trauma sets 671500

24 April 2024

Dear Valued Business Partner,

The Surgical Company International BV is conducting the removal of specific batches of Fluido® Trauma sets which were manufactured between April 2022 and September 2022. A review of our records reveals that you were in receipt of affected batch(es).

The Surgical Company International BV has identified that a temporary change to a manufacturing technique has resulted in the production of a number of individual Fluido® Trauma sets with an unstable connection junction (as indicated in Figure 1). This can result in leakage from the set connection leading to unreliable infusion during use. While the incident is related to batch number 70220741, The Surgical Company International BV has decided to recall all batches manufactured between April 2022 and September 2022 which have been produced with the same manufacturing technique. The affected batch numbers are listed in Appendix 1.

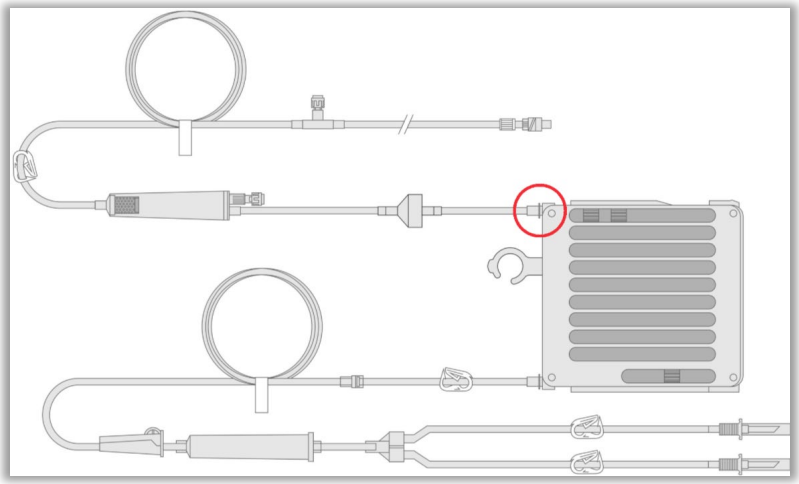

Figure 1 Schedule of Fluido trauma set with indicated unstable connection.

Please note that only the listed batch numbers are affected. No other products manufactured by The Surgical Company International BV are affected by this Field Safety Notice.

Immediate actions to be taken:

1. Please immediately discontinue the use of any remaining products from lots reported in Appendix 1 and remove all the affected units from your inventory. Segregate the products in a secure place pending return to The Surgical Company International BV.

2. Please complete the attached form even if you do not have any product to return. If you are a Distributor, please pass this notice on to any other healthcare facility that needs to be informed, and to any other organization to which you have distributed this product. As a distributor, you will need to recall remaining devices from these facilities in accordance with this Field Safety Notice, for this you can use the attached response form for the hospital.

3. When complete, please return the Product response form to our quality department: quality@tsc-life.com but no later than April 30, 2024.

4. On receipt of the completed form, The Surgical Company International BV will arrange collection of the recalled devices and replacement products will be sent to your facility to replace the remaining affected products.

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 your local The Surgical Company International BV representative.

Appendix 1
The following batches are subject to this recall:

Article number	Description	Lot number	Expiration date
671500	Fluido® Trauma Set	70220424	2025-04
671500	Fluido® Trauma Set	70220428	2025-04
671500	Fluido® Trauma Set	70220430	2025-04
671500	Fluido® Trauma Set	70220431	2025-05
671500	Fluido® Trauma Set	70220433	2025-05
671500	Fluido® Trauma Set	70220435	2025-05
671500	Fluido® Trauma Set	70220436	2025-05
671500	Fluido® Trauma Set	70220437	2025-05
671500	Fluido® Trauma Set	70220438	2025-05
671500	Fluido® Trauma Set	70220439	2025-05
671500	Fluido® Trauma Set	70220565	2025-06
671500	Fluido® Trauma Set	70220737	2025-06
671500	Fluido® Trauma Set	70220738	2025-06
671500	Fluido® Trauma Set	70220739	2025-07
671500	Fluido® Trauma Set	70220740	2025-07
671500	Fluido® Trauma Set	70220741	2025-07
671500	Fluido® Trauma Set	70220742	2025-07
671500	Fluido® Trauma Set	70220743	2025-07
671500	Fluido® Trauma Set	70220744	2025-07
671500	Fluido® Trauma Set	70220745	2025-07
671500	Fluido® Trauma Set	70220746	2025-07
671500	Fluido® Trauma Set	70220747	2025-08
671500	Fluido® Trauma Set	70220749	2025-09
671500	Fluido® Trauma Set	70220750	2025-09