

URGENT - Field Safety Notice



To all users of the Disposable Syringe 10CC Luer Slip Lot No: 21121310S50 and 22010310S50

Re: Disposable Syringe 10CC Luer Slip – “soft” flange and plunger with gasket easily dislodged from barrel

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to user when using the Disposable Syringe 10CC Luer Slip (Lot No: 21121310S50 and 22010310S50).

Our recent investigation has confirmed through customer complaints that the potential malfunctions may be occurred as follows:

1. The flanges bend during injection procedure due to insufficient of silicone oil inside the barrel.
2. The plunger might feel like it is easily pushed with just minimum resistance and can be fully dislodge from the barrel due to smaller undercut.

The above malfunctions may cause liquid spilled out during aspiration or injection process.

Pharmaniaga Logistic Sdn Bhd (PLSB) is our customer who distribute these batches. As such, we seek PLSB to;

1. Immediately discontinue distribution of affected lot numbers listed above.
2. Determine if any stock of the affected lots remain in inventory and quarantining the medical device.
3. Notify all the affected PLSB's customers if the stock still available, they will need to return to PLSB.
4. Complete the Acknowledgement of Receipt Form.
5. Notify Selia-tek Industries Sdn. Bhd. (STISB) the quantity to be exchanged with new batch.

Selia-Tek Industries Sdn. Bhd. (STISB) is preparing for product exchange of Disposable Syringe 10CC Luer Slip and that will stop the use of possible malfunctions syringe. The field exchange will be available upon receipt of details stock information from PLSB

We appreciate your understanding and cooperation with this Field Safety Notice and request you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instructions for use. Your personnel should maintain awareness over an appropriate defined period.

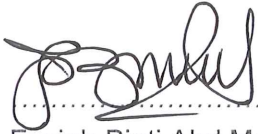
The **Medical Device Authority** will be informed of this notice.

SELIA-TEK INDUSTRIES SDN BHD
(199531-V)

Lot 18, Jalan Teknologi 3/5, Taman Sains Selangor, Kota Damansara,
47810 Petaling Jaya, Selangor Darul Ehsan
Tel: +603-6151 8056, 6151 8057, 6151 8058, 6151 8059 Fax: +603-6150 1771, 6143 7523
email: enquiry@selia-tek.com website: www.selia-tek.com

Reference No: FSN-FCA-001/23

Sincerely Yours



Foziah Binti Abd Majid

Senior Manager,

Quality Assurance,

Selia-Tek Industries Sdn. Bhd.

15 February 2023

Contact person of this notification

Name : Ailyna Binti Hazizul Hasan

Department : QMS Section

Telephone : 0122520873

E-mail : ailyna@seliatek.com

Acknowledgement of Receipt

Please fill in the information below so that we may acknowledge your receipt of this notification and revert the completed form upon receipt, but no later than 30 days.

I hereby confirm as the owner / responsible operator of the **Disposable Syringe 10CC Luer Slip** with the Lot No.: **21121310S50** and **22010310S50** that I received the Field Safety Notice.

- No affected product received.
- I am aware of the information about the field action concerning the above reference product(s) and have proceeded according to the instructions issued by Selia-Tek Industries Sdn. Bhd.

Product	Affected Lot Number	Quantity
Disposable Syringe 10CC Luer Slip		

I have read and understood the attached notice & will share this Field Safety Notice with all users within my facility.

Facility Name : _____
Full Address : _____

Contact Name : _____
Phone Number : _____
E-mail : _____

Signature : _____ Date : _____