

Field Safety Notice

URGENT - Field Safety Notice

Date : 27 October 2023

To : Distributor, Customer (Doctors and Nurses who uses the Transfer sets for PD patients) & End users

Device : Transfer set: 'You-wei' brand

This letter is to inform you of several incidents of leakages from the transfer sets during use. The exact cause(s) is yet to be established, but initial investigation points to a potential malfunction associated with the possible use of the following chemicals on particular batches. These chemicals, in direct contact, may induce potential damage to the tubing and hence hazard to patients when using the transfer set.

The following chemicals may cause the potential malfunction:

- Cleaning agents containing alcohol and/or
- Disinfectant agents containing alcohol.
- Povidone Iodine

Affected Device:

Product Identifier	Description	Lot
530-001-03	Transfer Set	All lots manufactured between May 2022 to Jun 2023

Malfunction and potential risks:

Damage to the silicon tubing from weakening of the tube molecular structure could potentially lead to leakages in the transfer set over time. This may predispose patients to treatment interruptions or adverse events.

Action to be taken by Customer/User to avoid the potential risk of this issue:

If you are using one of the above-mentioned cleaning agents or antiseptics, please avoid direct contact of the chemicals with the silicone tube of the Transfer Set. This is to avoid any direct and residual effect of the above-mentioned chemicals. Saline solution may be used to wipe down the tube.

If there is no observed leakage from the transfer set in use by the patients, the use may be continued, provided the above instruction is adhered to. The transfer set shall be changed within the prescribed period of use.

Action taken by the Supplier

Unless absolutely necessary, all transfer sets not yet in use should be kept on hold, out of abundance of prudence. These shall be exchanged with new sets. New transfer sets will be made available to all PD units no later than 4 weeks from the date of this Field Safety Notice.

The **Medical Device Authority** has been informed of this notice.

Sincerely Yours,



Liyana Abd Ghani
Regulatory Affairs



Contact person of this notification
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Acknowledgment of receipt:

I hereby confirm as user of the Transfer Set that I received the following the Field Safety Notice on the Transfer Set.
