RECALL ALERT

DRAP ALERT NO. Nº I/07-23-28

RECALL OF SURGEE DISPOSABLE INFUSION SET (BATCH # IV0523)

(MANUFACTURED BY M/S. REHMAN RAINBOW (PVT), LAHORE)

Date: 27th July 2023

Target Audience:

- Healthcare Professionals particularly working in the critical care areas of hospitals including Physicians, Pharmacists, and Nurses.
- Procurement Officers at Hospitals and Healthcare Institutions.
- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores.

Alert Summary:

Central Drugs Laboratory, Karachi received samples of Surgee Disposable Infusion Set manufactured by the M/s Rehman Rainbow (Pvt) Ltd , Industrial Estate, Kot Lakhpat, Lahore for testing which after testing had been declared substandard for not complying the sterility criteria. Accordingly, the manufacturing company had been directed to recall all the defective product from the market.

The detail of the affected Medical device is as under:

Product Name	**Product Description**	**Batch No**	**Manufacturer name**
Surgee Disposable Infusion Set Mfg Lic No 000510 Reg No 071602	Intravenous Infusion set	Batch No IV0523 Mfg date 05.2023 Exp 04.2028	M/s Rehman Rainbow (Pvt) Ltd 82-M, Industrial Estate, Kot Lakhpat, Lahore

Risk Statement:

Use of Non sterile IV set poses a serious risk of patient harm and due to non-sterility may lead to bacteremia and sepsis.

Action Initiated: -

The manufacturing company in Pakistan has initiated a recall of the affected batch of Medical Device from the market where it was distributed. All healthcare professionals working in critical care units of hospitals as well as pharmacists and chemists working at distributions and pharmacies should **immediately check** their stocks and stop supplying these lots of the product. The remaining stock should be quarantined and returned to the supplier/company. The regulatory field force of all federating units (DRAP and Provincial Health Departments) has also increased surveillance to monitor the recall progress to ensure effective recall.

Advice for Healthcare Professionals: -

DRAP requests to enhance **vigilance** within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by these defective lots of the Medical Device. Patient using the affected device should immediately contact their doctors for further guidance.

Adverse reactions or quality problems experienced with the use of this product may be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link

Advice for Consumers / General public: -

Consumers should stop using this product bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to using this Medical Device, and report the incident to National Pharmacovigilance Centre of Drug Regulatory Authority of Pakistan, through MedSafety Mobile Application, or online at Med Vigilance E Reporting System.

All therapeutic goods must be obtained from the licensed pharmacies, and other authorized retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professional in case of any doubt.

Drug Regulatory Authority of Pakistan
محفوظ، موثر اور معیاری اشیائے علاج

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