

URGENT: FIELD SAFETY NOTICE

Disposable Infusion Set

Type of Action: Field Work

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel, Purchasing Managers

This letter contains important information which requires your **immediate** attention.

Dear customer,

MEDCAPTAIN LIFE SCIENCE CO., LTD., as the Legal Manufacturer, is issuing a Field Safety Corrective Action for **Disposable Infusion Set.** According to distribution records your organization may have received the impacted product in Table 1.

Manufacturer's SRN: CN-MF-000006656

Legal Manufacturer: MEDCAPTAIN LIFE SCIENCE CO., LTD.

Catalog Number (REF)	Trade Name	UDI-DI	LOT	Intended Purpose
300-00011-01	Disposable Infusion Set	06972991866993	205375KS	Disposable infusion set, it is mainly used to administer fluids to a patient's vascular system by connecting with IV pump. It is applicable for patients with high precision control requirements.

Table 1: Impacted product

This Field Safety Notice is limited to the product codes listed in Table 1. No other product codes are affected.

Description of the problem

On August 20, 2025, We, MEDCAPTAIN LIFE SCIENCE CO., LTD., received an incident (P300-327-2025) from the authority in Slovenia regarding our disposable infusion sets (Model: A211M1F, Lot number: 205375KS) leakage occurred during the use process in a medical institution in Slovenia (UNIVERZITETNA KLINIKA ZA PLJU Cne BOLEZNI IN ALERGIJO GOLNIK).

The leakage issue of this lot led to five incidents (Reference number: P300-586/2025, P300-564/2025, P300-561/2025, P300-337/2025 and P300-250/2025) involving the infusion devices manufactured by MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

This issue affected the following products:

Model: A211M1F Lot number: 205375KS

No other lots are impacted.

Clinical risk

1. If leakage occurs during infusion, it may result in patients not receiving sufficient drug dosage and also cause drug waste.
2. The leakage of the medication caused malfunctions in other related sophisticated medical devices.

Clinical User Actions

1. Stop using the following lots of disposable infusion sets:
Legal manufacturer: MEDCAPTAIN LIFE SCIENCE CO., LTD.
Model: A211M1F, Lot number: 205375KS
2. Contact the distributor to replace the products with those from other lots.

Corrective Actions

- 1 MEDCAPTAIN LIFE SCIENCE CO., LTD., as the Legal Manufacturer, recall the lot of products located with importers, distributors and end customers to prevent the lot of products from continuing to circulate and be used.
- 2 Provide qualified alternative lots of disposable infusion sets for relevant economic operators and end users.

Customer Actions:

- Review the information in Table 1 .to determine if the impacted Disposable Infusion Sets are in your possession.
- Complete and return the Customer Response Form by January 31, 2026, **even if you no longer have any inventory remaining in your facility**
- Circulate this notice to all those who need to be aware within your organization or to any organization where the potentially affected product has been transferred.
- If you experience any issues, please report as a complaint as per your normal process.

Contact reference person

If you have any questions or require assistance relating to this Field Safety Notice, please contact at e-mail **dream.du@medcaptain.com**.

We confirm that the appropriate regulatory agencies have been informed of these actions.
Sincerely,

Customer Response Form - FSN Number: FSN-202512-001
Disposable Infusion Set

Return to [dream.du@medcaptain.com] as soon as possible or **no later than the [January 31, 2026]**.

By signing below, you confirm this Field Safety notice has been read, understood and that all recommended actions have been implemented as required.

Account/Organization Name:	
Department (if applicable):	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Name of your supplier for this product (if not direct from Medcaptain Life Science)*	
Signature:	Date:

This form must be returned to Medcaptain before this action can be considered closed for your account.

*If you were forwarded this Field Safety Notice via a distributor/3rd party, please return your completed form to that organization for reconciliation purposes.

Please confirm **ONE** of the following options:

I have one or more affected product(s) within my organization.

Please provide a contact name of a representative from your organization who will be the point of contact to organize product remediation, if different from above:

<i>Name:</i>	<i>Telephone No:</i>	<i>Email:</i>	<i>No. of Impacted product:</i>

OR

I confirm that our facility **does not have any** of the affected product listed in this Field Safety Notice.

All product that is not available for remediation will be considered as dispositioned at your location and therefore physically unavailable unless otherwise specified.