Doc. No. F/QA/08-01
Supersedes – 00, 01.06.2020
Date of Issue – 01.05.2024

URGENT FIELD SAFETY NOTICE

Medical Devices Vigilance System

Date:	19-12-2025	
Attention (Contact Person):	Hardik Bhan	
Name of the affected product:	I.V. Cannula 22G	
Brand Name (if any):	(Vencare - Zentrum)	
Date of Field Safety Corrective Action (FSCA):		19-12-2025
Type of Action Required:	Return of the affective device	☐
	Device Modification	☐
	Device Exchange	☐
	Device Destruction	☐
	Retrofit by purchaser of MANUFACTURER's modification or design change	☐
	Advice given by MANUFACTURER regarding the use of the device and/or the follow up of patients, users or others	☐
	Quarantine the goods immediately	☑

Details on affected devices:

Affected Lot No(s):

IV Cannula with wings & with injection port (Vencare-Zentrum), LOT 231305, DoC/07.10.2021, EC Certificate G1 109029 001 issued by NB 0123 on 2021-0-20, correspondent Invoice/ 20.01.2025.

Description of the problem:

In the hospital wards and emergency rooms of the hospital, events were identified - catheter phlebitis and/or solemn chills occurring in patients who were infused (10 events in the previous week). Initially, the infused solutions were suspected, but they were different (physiological saline from different manufacturers and glucose solutions) and we ruled out this option. Cultures were made (under sterile conditions) from the catheters used and from the infusers. The affected patients (the 5 who are still hospitalized) have a local inflammatory reaction and, in laboratory tests, an increased PCR without leukocytosis/neutrophilia and with negative procalcitonin (within the normal range). In the cultures performed in the hospital laboratory, Staph. Epidermidis and Staph. Coagulase-negative were grown from the used swabs. We mention that 2 series of branules from the same batch were incubated, in the repeated series of cultures/seedings there were other branules (another producer) for which there was no bacterial growth.

Advice on action to be taken by the user:

- Identifying and quarantining the device, ☑
- Method of recovery, disposal or modification of device
- Recommended patient follow up, e.g. implants, IVD
- Timelines.
- Confirmation form to be sent back to the manufacturer if an action is required (e.g. return of products)

As a safety measure, all the unused I.V. cannulas in the stock should be immediately quarantined.

We the manufacturer of I.V. Cannula Lot No. 231305 has received information from a healthcare facility reporting multiple clinical events, including catheter-associated phlebitis and/or chills, observed in patients following infusion using I.V. Cannula from the above-mentioned batch.

Microbiological cultures performed at the hospital laboratory on used catheters and infusion assemblies reportedly identified coagulase-negative staphylococci (including staphylococcus epidermidis). Infusion solutions from different manufacturers were used and have been ruled out at the hospital level. Parallel cultures using catheters from another manufacturer reportedly showed no bacterial growth.

This investigation at our end is ongoing.

Potential risk to patients:

The potential risks associated with this issue may include:

- local inflammatory reactions (e.g. phlebitis),

- transient systemic symptoms such as chills.

To date, no confirmed cases of bacteremia or sepsis have been reported to the manufacturer.

Actions to be taken by users / healthcare facilities:

Please take the following actions immediately:

- stop using the affected batch/lot listed above.
- quarantine all remaining stock from the affected batch/lot and clearly label it as “do not use.”
- do not discard the quarantined products until further instructions are provided by the manufacturer.
- ensure this notice is shared with all relevant departments, including wards, emergency rooms, and infection control teams.
- continue to monitor patients who have received the affected device in accordance with your internal clinical protocols.
- report any additional adverse events or concerns to the manufacturer using the contact details below.

Transmission of this Field Safety Notice:

- This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which this action has an impact.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Mr. Hardik Bhan
(Sr. QA/RA Executive & MR)
Disposafe Health and Life Care Limited
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Sector-59, Ballabgarh, Faridabad
Haryana (INDIA)
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Web: www.disposafe.com

The undersign confirms that this field safety notice has been issued in accordance with applicable vigilance requirements and in coordination with the relevant regulatory authorities.

Signature:	**Stamp:**
Hardik Bhan Sr. QA/RA Executive & MR *Disposafe Health and Life Care Limited* **Mobile:** +91 9311816791 **Phone:** +91 129 4170 201, Ext:701 **Email:** mr@disposafe.com **Office:** A-30/B-1, First Floor Mohan Co-operative Industrial Estate New Delhi 110024, India **Factory:** Plot 1 & 2, Sector-59, Phase-2 Faridabad, Haryana 121004 **Website:** www.disposafe.com	DISPOSAFE HEALTH AND LIFE CARE LTD.

NOTE: Kindly acknowledge the receipt of the field safety notice by e-mail or fax.