

Urgent safety information

Field safety notification (FSN)

RECALL of products



We hereby refer to the following products, which are used as components for the customer-specific treatment units manufactured by us and then with ethylene oxide (EO) - sterilization processes have been sterilized.

The non-compliant products are “Venflon Pro Safety (VPS)” safety vein catheter from BD. For these products, there is an updated urgent product safety notification MDS-20-3801 with a product recall by BD from 29.04.2021.

To minimize risks, CeMed GmbH, Neufra does the following:

Description of the problem, possible clinical effects and corrective measures:
Until this urgent safety information, recall was created, no Complaints about non-compliant “Venflon Pro Safety (VPS)” indwelling safety vein catheters in the customer-specific sets and treatment units produced by CeMed GmbH were reported by customers. Due to ongoing market monitoring, a re-evaluation and further discussions with the European authorities, BD has decided to update this measure from a safety notice to a product recall of all products still available that have been sterilized with ethylene oxide (EO).

A change in the dimensions of the injection port valve carried out in 2019 was identified as the root cause, identified by BD via reported leaks at the injection port of the BD Venflon intravenous catheter (see figures).

This change was made to enable ethylene oxide (EO) sterilization procedure.



If the leakage at an injection port remains undetected for an extended period of time, this can have critical clinical consequences for the patient.

Due to possible blood loss or insufficient infusion of fluids and medication, this can lead to serious damage, life-threatening conditions or even death.

After the evaluation and assessment of the present description of the problem, no hazards or negative influences on other products configured in treatment units or on the achievement and maintenance of the sterility status could be determined.

As a result of a carried out risk assessment and to ensure patient care, the delivered treatment units can continue to be used without the „Venflon Pro Safety (VPS)“ intravenous catheters.

As a corrective measure by BD, the sterilization process was changed. This involved switching from ethylene oxide (EO) to electron beams (e-beam).

CeMed GmbH adapts its processes to this corrective measure as follows:

With immediate effect, no more Venflon Pro Safety (VPS) safety vein catheters affected by the recall will be configured, packaged and sterilized in an ethylene oxide sterilization process in treatment units.

- All “Venflon Pro Safety (VPS)” safety vein catheters in stock and affected by the recall were identified and secured in the quarantine warehouse for destruction as requested by BD and then properly disposed of.
- Identification and recall of treatment centers containing the recalled “Venflon Pro Safety (VPS)” indwelling vein catheters have been carried out.
- Creation of an additional warning, which is issued to the customers concerned in addition to the safety information.

Identification of affected treatment units:

After evaluating and comparing the article numbers reported by BD for the “Venflon Pro Safety (VPS)” indwelling safety vein catheters, the treatment units included in the table below were identified, determined.

SetNr	Set-Bezeichnung	ChB/LOT
0041140	Innova-Set PDT Jules Gonin	69099
SetNr	Set-Bezeichnung	ChB
0041083	Innova-Set, Voie veineuse Vision Clinique	66596
0041083	Innova-Set, Voie veineuse Vision Clinique	67244
0041083	Innova-Set, Voie veineuse Vision Clinique	68163
0041083	Innova-Set, Voie veineuse Vision Clinique	70156
0041083	Innova-Set, Voie veineuse Vision Clinique	71063
0041083	Innova-Set, Voie veineuse Vision Clinique	71218
0041083	Innova-Set, Voie veineuse Vision Clinique	71239

The recipient of this safety notification (FSN) must take the following measures:

- Pass on the urgent safety message and the additional warning to all users of The treatment centers within your organization.
- If you determine appropriate treatment units, please inform us of the number as soon as possible so that we can provide you with appropriate replacement products, depending on BD's ability to deliver.
- If you identify appropriate treatment units, destroy the possibly non-conforming product before clinical use.
- Processing and sending back the customer response form in the attachment

We kindly ask you to take note of and to confirm that you have received this safety information and to report back any inventory quantities on the enclosed Customer response form until June 7th, 2021.

Contact Person:

If you have any questions, please contact CeMed GmbH, the Responsible person reg. (EU)2017/745, article 15: Mr. Lang.

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We apologize for the inconvenience this caused.

Warning

Dear customer,

You have received urgent safety information from CeMed GmbH regarding customer-specific sets and treatment units, which contain a recall from BD sterile "Venflon Pro" intravenous catheters.

The "Venflon Pro" indwelling venous catheters affected by the recall were identified on the basis of the available article numbers and the product name as well as a batch tracing process and could be assigned to the affected sets and treatment units.

See here the detailed list in the urgent safety information available to you. The customer-specific sets and treatment units affected by the recall contain non-compliant "Venflon Pro IV" catheters from BD,

The non-compliant "Venflon Pro" intravenous catheters contained in the sets and treatment units must not be used and must be disposed of / destroyed.

In order to avoid a supply bottleneck in the current COVID 19 pandemic and as a result of a risk assessment carried out internally for the FSCA report, the sets and treatment units may continue to be used after the "Venflon Pro" indwelling catheters have been removed.

Possible hazards to other set components with regard to maintaining the sterility status and safe use within the scope of their intended use on or in the patient could not be determined in the risk assessment.

Please read this warning before using "Innova sets" and "treatment units".

Thank you for your help and cooperation!