Urgent safety information
Field Safety Notification (FSN)
Product recall

to

Customized sets & treatment units
of the company Hell & Co. GmbH

Datum: 27.05.2021

Sender:

Michael Baumeister
Hell & Co. GmbH – Medical Devices - Am Käswasen 12 - 91456 Diespeck
Telefon: 09161/663397-0 / Fax: 09161/9657 / E-mail: info@hellco-gmbh.de

Addressee:

Customers and sales partner

Dear Ladies and Gentlemen,

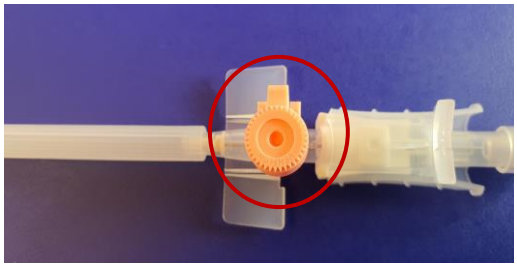
This letter is being sent in reference to products that have been used as components in the configuration of customised sets and treatment units and have been sterilised in the subsequent ethylene oxide (EO) sterilisation process. The possible non-compliant products are **Venflon Pro** from **BD**. An **urgent product safety notice MDS-21-4111** with **product recall** from BD **dated 17.05.2021** is available for these products.

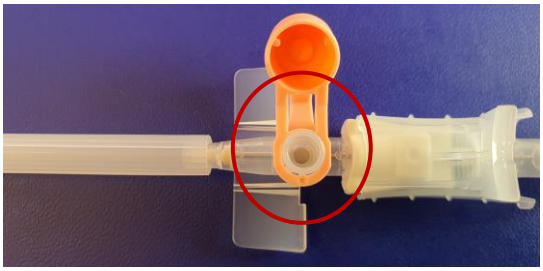
Identified risks for patients when using products from our set and treatment units are not tolerable. In this regard, the following risk minimisation measures have been taken by Hell & Co. GmbH:

Problem description, possible clinical effects and corrective measures:

Until the preparation of this urgent safety information, no feedback on non-conforming Venflon Pro in the customised sets and treatment units produced by Hell & CO. was reported by the customer. In this regard, the following contents of the problem description, as well as the possible clinical effects mentioned in the product safety communication MDS–21-4111 of our supplier BD, were relevant for the assessment:

The root cause identified by BD for reported leaks at the injection port of the BD Venflon Pro, was identified as a change made in 2019 to the dimensions of the injection port valve (see figures).
This change was made to allow for EO sterilisation.





If leakage from an injection port remains undetected for a prolonged period of time, this can have critical clinical consequences for the patient.
Due to possible blood loss or inadequate infusion of fluids and medications, this can lead to serious harm, life-threatening conditions or even death.

After evaluating the problem description, no hazards or negative influences on other products configured in the set and treatment units, as well as on the achievement and maintenance of the sterility status, could be determined.
As a result of a risk assessment and to ensure patient care, the set and treatment units can continue to be used without the Venflon Pro.

As a corrective measure by BD, the sterilisation process was changed from ethylene oxide (EO) to electron radiation (E-Beam).
Hell & Co. adapted its processes to this corrective measure as follows:

- With immediate effect, Venflon Pro in sets and treatment units, will no longer be configured, packaged and sterilised in an ethylene oxide sterilisation process..
- All Venflon Pro still in stock and affected by the recall have been identified and secured in the restricted warehouse for destruction as required by BD.
- Identification and recall of sets and treatment units containing Venflon Pro affected by the recall.
- Creation of an additional warning notice, which is issued to the affected customers together with the safety information.
- Separate labelling of transport boxes containing sets and treatment units affected by the recall. In addition, a warning notice is attached here.

Identification of affected products in produced sets and treatment units:

After evaluation and comparison of the article numbers reported by BD for the Venflon Pro, the following sets and treatment units produced by Hell & Co. were determined:

VENFLON PRO 22GA 1,1 MM AD 25MM L Artikelnummer: 393202

Designation of the set or treatment unit	Customer	Art. - No.:	Affected LOT numbers
IV-BLOCK-SET	[redacted]	170000205	20/1628
INFUSIONS-SET MRI		170000233	20/1503, 20/1853, 21/0153, 20/0242, 20/0850, 20/1038, 20/1503
IV-SET Nr.1		170000342	21/0398
IV-SET Nr.2		170000343	21/0428

VENFLON PRO 20GA 1,1 MM AD 32MM L Artikelnummer: 393204

Designation of the set or treatment unit	Customer	Art. - No.:	Affected LOT numbers
INVUSIONS-SET CT	[redacted]	170000230	20/1491, 20/0154, 20/0241, 20/0868

What measures are to be taken by the addressee?

- Pass on the urgent safety message and the additional warning to all users of the set and treatment units within your organisation.
- Compare their situation inventories with those identified by Hell & Co. GmbH identified and listed on page 2 sets and treatment units.
- If you identify corresponding sets and treatment units, please inform us of the number as soon as possible so that we can provide them with corresponding replacement products, depending on BD's delivery capacity.
- If you identify corresponding sets and treatment units, destroy the possible non-compliant product before using it on the patient.
- Processing and returning the customer response form on page 3.

We kindly ask you to **take note of** and **confirm** receipt of this safety information and to report any existing stock quantities on **the enclosed customer response** form.
(see page 3) **by 17.06.2021**.

Contact:

If you have any questions, please contact Hell & Co. GmbH, the safety officer Mr. Baumeister, will be happy to answer your questions.

Hell & Co. GmbH – Medical devices - 91456 Diespeck, Am Käswasen 12
Telefon: 09161/663397-0 / Fax: 09161/9657 / E - mail: info@hellco-gmbh.de

The company Hell & Co. GmbH apologises for any inconvenience this may cause.

Customer reply form **Date:** ……

Customer / Address data:

……
……
……
……

Article - No.:	LOT – Number:	Quantity:	Destroyed:
170000205	20/1628		
170000233	20/1503		
	20/1853		
	21/0153		
	20/0242		
	20/0850		
	20/1038		
	20/1503		
170000067	20/0276		
	20/0728		
	20/1607		
170000342	21/0398		
170000343	21/0428		
170000230	20/1491		
	20/0154		
	20/0241		
	20/0868		

Return reply

per Fax to Hell & Co. GmbH: 09161 / 663397-20

per Mail to Hell & Co. GmbH: info@hellco-gmbh.de

Please specify:

☐ We had no stock of the product mentioned

☐ Yes, we still had goods with the batch affected by the product recall in stock and have destroyed them.

Place / Date **Stamp / Signature** **Signature in block letters**

Hell & Co. GmbH – Medical devices - At the Käswasen 12 - 91456 Diespeck
Phone: 09161/663397- 0 / Fax: 09161/9657 / e - mail: info@hellco-gmbh.de

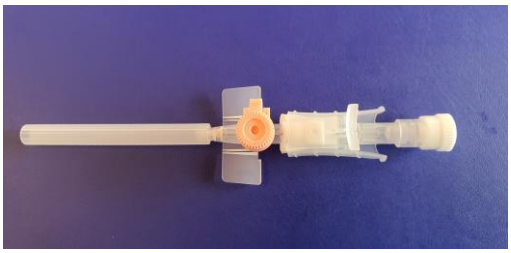
Attention Warning!

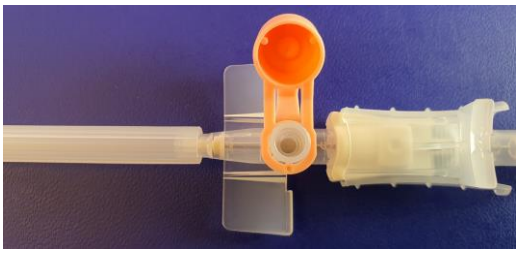
In customised sets & treatment units of the company Hell & Co. GmbH include Venflon Pro indwelling cannulae from BD from BD and dispose of them!

Dear customer,

You have received urgent safety information from Hell & Co. GmbH with urgent safety information regarding customised sets and treatment units containing sterile Venflon Pro cannulae that have been recalled by BD.
The Venflon Pro cannulae affected by the recall were identified on the basis of available article numbers and the product name as well as a batch tracing carried out and could be assigned to the affected sets and treatment units.
See here the detailed listing in the urgent safety information available to them.

The customised sets and treatment units affected by the recall contain non-conforming Venflon Pro cannulae manufactured by BD,
see the following illustration of a product example:





The non-conforming Venflon Pro cannulae contained in the sets and treatment units must not be used and must be disposed of.

In order to avoid a supply shortage in the current COVID 19 pandemic and as a result of a risk assessment carried out internally for FSCA notification, the sets and treatment units may continue to be used after the Venflon Pro Safety (VPS) safety cannulae have been removed.
Possible hazards of further set components, with regard to the maintenance of the sterility status as well as a safe use within the scope of their intended purpose on or in the patient, could not be determined in the risk assessment.

Please observe this warning before using Hell& Co. sets and treatment units.

Thank you for your support and cooperation!

Diespeck, den 27.05.2021

Hell & Co. GmbH