

Urgent safety information

Field Safety Notification (FSN)

Product recall

to

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

Datum: 12.05.2021

Sender:

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,

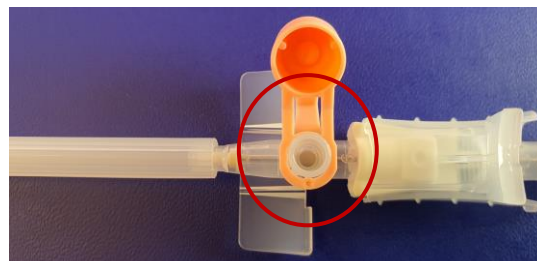
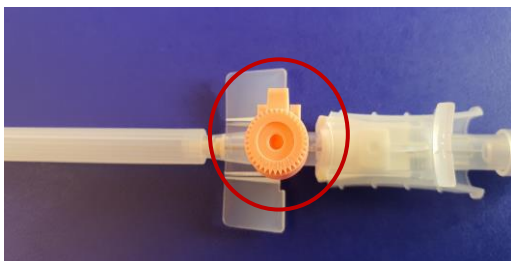
This letter is being sent in reference to products that have been used as components in the configuration of customised sets and treatment units and have been sterilised in the subsequent ethylene oxide (EO) sterilisation process. The possible non-compliant products are **Venflon Pro Safety (VPS) safety intravenous catheters** from **BD**. An **updated urgent product safety notice MDS-20-3801** with **product recall** from **BD dated 29.04.2021** 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 Safety (VPS) safety intravenous catheters 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 updated product safety communication MDS-20-3801 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 Safety cannulae, 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 Safety (VPS) safety intravenous catheters.

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 Safety (VPS) safety intravenous catheters, in sets and treatment units, will no longer be configured, packaged and sterilised in an ethylene oxide sterilisation process..
- All Venflon Pro Safety (VPS) safety intravenous catheters 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 Safety (VPS) safety indwelling cannulae 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 sets and treatment units:

After evaluation and comparison of the article numbers reported by BD for the Venflon Pro Safety (VPS) safety indwelling cannulae, the following sets and treatment units produced by Hell & Co. were determined:

Designation of the set or treatment unit	Customer	Art. - No.:	Affected LOT numbers
SET CT (blau)		170000062	20/0413, 20/0671, 20/1544
SET CT (rosa)		170000063	19/2270, 20/0311, 20/0438, 20/0670, 20/1543, 21/0277
SET IRM petit		170000067	20/0276, 20/0728, 20/1607
SET CT analyse créatinine 18G (vert)		170000106	19/2024, 19/2134, 20/0127, 20/0287, 20/0878, 20/0958, 20/1350, 20/1595, 20/1852, 21/0147
SET CT analyse créatinine 20G (rose)		170000107	19/1961, 20/0128, 20/0367, 20/0919, 20/1382, 20/1704, 20/1757
SET IRM		170000108	19/1983, 20/0140, 20/0346, 20/0930, 20/1169, 20/1606, 21/0113
SET PET-CT		170000109	20/0016, 20/0239, 20/0745, 20/0957, 20/1374, 20/1611, 21/0066, 21/0367
SET D' ACCÈS VEINEUX		170000173	19/1882, 20/0176, 20/1110, 20/1191, 20/1780, 21/0159
SET DE PERFUSION INTRA VEINEUX		170000174	20/0072, 20/0990, 20/1493, 21/0020, 21/0387
IV - SET		170000247	19/1731, 19/1933, 19/1934, 19/2235, 20/0098, 20/0361, 20/0590, 20/0873, 20/0956, 20/1103, 20/1562, 20/1703, 21/0296, 21/0534
VERWEILKANÜLENSSET		170000269	19/1905, 19/2220, 20/0202, 20/0464, 20/0955, 20/1211, 20/1654, 20/1781
RÖNTGENPUNKTION-SET		170000293	19/2006, 20/0193, 20/0699, 20/1041, 20/1373, 21/0160, 21/0531

Designation of the set or treatment unit	Customer	Art. - No.:	Affected LOT - numbers
		170000314	19/1650, 19/1691, 19/1849, 19/1851, 19/2025, 19/2072, 19/2098, 19/2130, 19/2264, 20/0142, 20/0155, 20/0550, 20/0660
IV-SET		170000326	20/0715, 20/0758, 20/1235, 20/1237

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 - 3 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 4 – 6.

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 pages 4 - 6) **by 11.06.2021.**

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:

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Article - No.:	LOT – Number:	Quantity:	Destroyed:
17000062	20/0413		
	20/0671		
	20/1544		
17000063	19/2270		
	20/0311		
	20/0438		
	20/0670		
	20/1543		
	21/0277		
17000067	20/0276		
	20/0728		
	20/1607		
170000106	19/2024		
	19/2134		
	20/0127		
	20/0287		
	20/0878		
	20/0958		
	20/1350		
	20/1595		
	20/1852		
	21/0147		
170000107	19/1961		
	20/0128		
	20/0367		
	20/0919		
	20/1382		
	20/1704		
	20/1757		
170000108	19/1983		
	20/0140		
	20/0346		
	20/0930		
	20/1169		
	20/1606		
170000109	21/0113		
	20/0016		
	20/0239		
	20/0745		
	20/1374		
	20/1611		
	21/0066		
21/0367			

Article - No.:	LOT – Number:	Quantity:	Destroyed:
170000173	19/1882		
	20/0176		
	20/1110		
	20/1780		
	21/0159		
170000174	20/0072		
	20/0990		
	20/1493		
	21/0020		
	21/0387		
170000247	19/1731		
	19/1933		
	19/1934		
	19/2235		
	20/0098		
	20/0361		
	20/0590		
	20/0873		
	20/0956		
	20/1103		
	20/1562		
	20/1703		
	21/0296		
21/0534			
170000269	19/1905		
	19/2220		
	20/0202		
	20/0464		
	20/0955		
	20/1211		
	20/1654		
20/1781			
170000293	19/2006		
	20/0193		
	20/0699		
	20/1041		
	20/1373		
	21/0160		
21/0531			
170000314	19/1650		
	19/1691		
	19/1849		
	19/1851		
	19/2025		
	19/2072		
	19/2098		
	19/2130		
	19/2264		
	20/0142		
	20/0155		
	20/0550		
20/0660			

Article - No.:	LOT – Number:	Quantity:	Destroyed:
170000326	20/0715		
	20/0758		
	20/1235		
	20/1237		

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