Urgent security information

Field Safety Notification (FSN)

to

Customized sets & treatment centers from Hell & Co. GmbH

Date: 20.07.2020

sender:

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

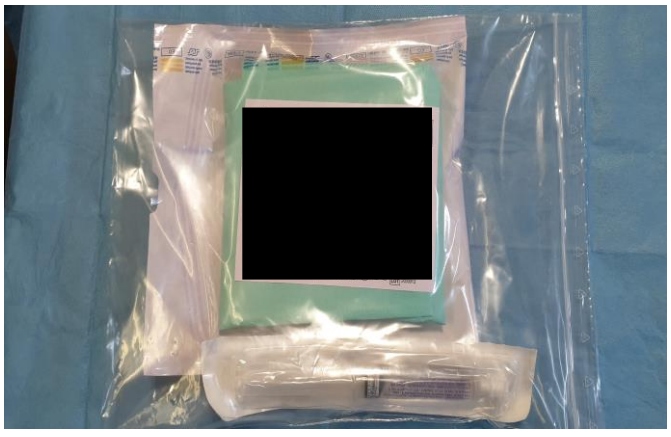
addressee:

Customers and sales partners

Dear Sir or Madam,

After consultation with our notified body and the BfArM, this urgent safety information refers to a possible non-compliant product that was used as a sterile accessory pack for the configuration of customer-specific treatment centers. The non-compliant product is the **PosiFlush10ml XS syringe REF: 306572 from BD**. An updated **urgent product safety notification MDS-20-1971 with product recall from BD from 07/03/2020** is available for this product. In their intended use at Hell & Co. as sterile accessories, possible non-conforming products could have been configured unchanged in their original manufacturer packaging, together with sterile sets and finally together in protective packaging, as treatment units desired by the customer and user.
See the following pictures:

Representation of the possible non-compliant product in the configuration step



Presentation of the possible non-compliant product in the completed and delivered treatment center

Risk identified by Hell & Co. GmbH for the patient if the non-compliant product is used:

If a possible non-sterile syringe is used while the entire treatment center is being used on the patient, cross-contamination with the sterile products in the set can occur.
This serious deviation from the required sterility status of the set products used could then lead to an acute health hazard to the patient with regard to a possible infection.
This risk for the patient is not tolerable for Hell & Co. GmbH.
In this regard, the following corrective measures to minimize risk on the part of Hell & Co. GmbH company:

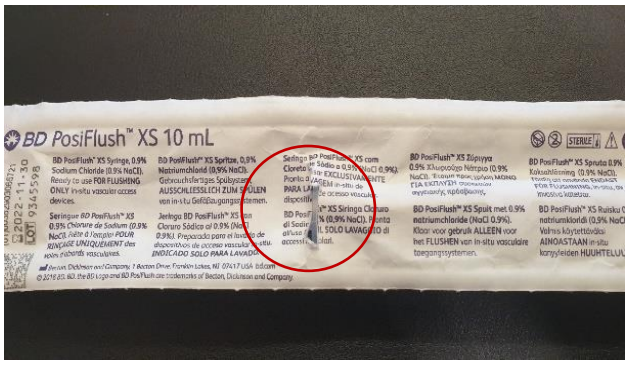
Identification of affected sets and treatment centers:

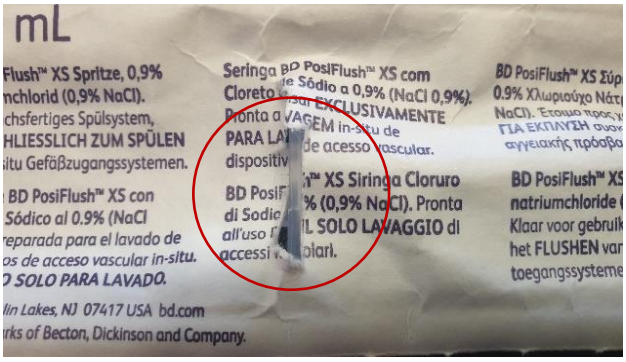
After evaluation and comparison of the LOT numbers reported by BD for the PosiFlush10ml XS syringe REF: 306572, the following listed treatment units produced by Hell & Co. were determined:

Name of the treatment center	customer	item number	Affected LOT numbers
SET D´ ACCÈS VEINEUX	[redacted]	170000173	19/1882
PUNKTIONS-SET PORT		170000188	19/1869, 19/2152, 19/2118, 20/0284, 20/0334
IV-BLOCK-SET		170000205	19/2066
SET INJECTION 20G,		170000219	19/0283
SET BLOCS PERIPHERIQUES / ULTRASONS		170000225	19/1880, 19/2126, 20/0343, 20/0437
IV-SET		170000247	19/1934, 19/1933, 19/2235
PORT A CATH SET		170000300	19/2095, 19/2207
SET ponction		170000314	19/1849, 19/1851, 19/2098, 19/2072, 19/2130, 19/2264, 20/0155
IV-SET [redacted]		170000326	20/0406

Description of the problem including the identified cause:

Irrespective of the current, updated urgent safety information from BD, internal quality controls of the product packaging are generally carried out as a requirement from the QM system.
As a result, damage to the original packaging of PosiFlush10ml XS syringes could already be determined in the manufacturing process for the manufacture of treatment units at Hell & Co. GmbH, and affected non-compliant products could be disposed of.
See the example below:





Despite internal quality controls being carried out in the configuration process, it cannot be ruled out that PosiFlush 10ml XS syringes with damaged product packaging are in the identified treatment centers due to the residual risks mentioned below

Presentation of existing residual risks to justify the need to destroy the enclosed PosiFlush 10 ml XS syringes from the identified treatment units:

- Possible damage to the product packaging could be in the microscopic size range, so that it was not recognized during internal quality controls in the configuration process of the treatment center
- Product packaging cannot be recognized by the customer and user based on previous statements regarding possible damage in the microscopic area

What measures are to be taken by the addressee?

- Pass on the urgent safety message to all users of the treatment center within your organization
- Compare your inventory with those identified by Hell & Co. GmbH and treatment units listed on page 4
- If appropriate treatment units are determined by you, please inform us of the number immediately in order to provide you with appropriate replacement products
- If appropriate treatment units are determined by you, destroy the possible non-conforming product enclosed by Hell & Co.

- Even if there is no macroscopic damage to the product packaging, the products must be destroyed
- Only open the sterile set after the possible non-conforming product has been destroyed in order to rule out cross-contamination with the sterile articles in the set
- The sterile set can continue to be used after this step
- Processing and returning the customer response form on page 4

Contact Person:

The Hell & Co. GmbH, the safety officer, Mr. Baumeister, will be happy to answer any questions you may have.

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

Customer response form

Date: .....

Customer / address data:

.....

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.....

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customer: .....

Item number:	LOT – number:	number of pieces	Annihilated:
170000173	19/1882		
170000188	19/1869		
170000188	19/2152		
170000188	19/2118		
170000188	20/0284		
170000188	20/0334		
170000205	19/2066		
170000219	19/0283		
170000225	19/1880		
170000225	19/2126		
170000225	20/0343		
170000225	20/0437		
170000247	19/1934		
170000247	19/1933		
170000247	19/2235		
170000300	19/2095		
170000300	19/2207		
170000314	19/1849,		
170000314	19/1851		
170000314	19/2098		
170000314	19/2072		
170000314	19/2130		
170000314	19/2264		
170000314	20/0155		
170000326	20/0406		

Return response

by fax to Hell & Co. GmbH: 09161 / 663397-20

by email 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 destroyed them

Place and date: **Signature:** **Signature in block letters:**