Bard Limited (now part of BD)
Forest House, Tilgate Forest
Business Park
Brighton Road, Crawley
West Sussex, RH11 9BP
England, UK

June 29th 2020

URGENT: FIELD SAFETY NOTICE – MDS-20-1979

BARD SafeStep™ Huber Needle Sets

REF & Lot Numbers: Refer to Table 1 below

Type of Action: Product Removal

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your immediate attention.

Dear Customer,

BD is issuing this Field Safety Notice to remove specific lots of **BARD SafeStep™ Huber Needle Sets** as listed in Attachment 1 (page 4). According to our distribution records your organisation may have received these devices which were shipped from BD between February 2020 and May 2020.

Description of the Problem

Through customer feedback, BD has discovered that the specific lots of BARD SafeStep™ Huber Needle Sets listed in Attachment 1 have the potential to develop cracks or breaks in the tubing near the Luer or Y site of the device.

If a crack or break develops there are potential health risks to the User including exposure to chemicals such a chemotherapeutics or biohazard material (e.g., blood) through leakage. A crack or break could result in potential blood loss, catheter occlusion, air embolism, under or interrupted infusion, or site contamination which could lead to infection.

Advice on actions to be taken by the user:

1. Inspect your inventory, locate and quarantine any units of the impacted devices listed in Attachment 1.

2. If you have further distributed the product, please identify those facilities, notify them at once of this product removal and have them destroy any unused units of the affected product.

3. Destroy any unused units of the affected product.

4. Complete the customer response form on page 3, together with Attachment 1 on page 4, as applicable, indicating:
   - the quantities destroyed **OR**
   - that your organisation does not have any impacted units left in inventory

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5. Return the completed Customer Response Form (page 3) and attachment 1 (page 4) for a credit to your account to BDUKFieldAction@bd.com **as soon as possible or no later than 23rd July , 2020.**

Should you have any questions or require assistance relating to this Field Safety Notice, please contact your Local BD representative or Isabelle Herz at Isabelle.Herz@bd.com

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Yours sincerely,

William David
Senior Director, Quality Compliance EMEA

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Customer Response Form – MDS-20-1979

BARD SafeStep™ Huber Needle Sets

Please read in conjunction with Field Safety Notice MDS-20-1979 and return, completed and signed, as soon as possible or **no later than 23RD July, 2020** to BDUKFieldAction@bd.com

- **I confirm this notice has been read, understood and that all recommended actions have been implemented as required.**

Tick the appropriate box below

☐ We do not have any of the affected product as listed in Attachment 1 in our possession.

OR

☐ We have units of the affected product as listed in Attachment 1 in our possession and I confirm that the units have been destroyed *(Please complete Attachment 1 with the quantity of units destroyed. Then complete the table below with your contact information and return **both** pages 3 and 4 - to the email address listed above)*

Account/Organisation Name:	
Department *(if applicable)*:	
Address:	
Postcode:	**City:**
Contact Name:	**Job Title:**
Contact Telephone Number:	**Contact E-mail Address:**
Signature:	**Date:**

This form must be returned to BD before this action can be considered closed for your account.

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Attachment 1: Impacted Product Codes & Lot Numbers

REF	Description	LOT	Quantity Destroyed
LH-0029	SafeStep, 22 x 0.75, straight	ASDYF071	
LH-0030	SafeStep, 22 x 1, straight	ASDXF020	
LH-0030YN	SafeStep, 22 x 1, Needleless Y	ASDWF065	
LH-0031	SafeStep, 20 x 0.75, straight	ASDXF053	
		ASDXF070	
		ASDXF092	
		ASDXF096	
		ASDXF101	
		ASDYF001	
		ASDYF004	
		ASDYF006	
		ASDYF010	
		ASDYF015	
		ASDYF019	
		ASDYF023	
		ASDYF029	
		ASDYF033	
		ASDYF037	
		ASDYF044	
		ASDYF050	
		ASDYF054	
		ASDYF060	
		ASDYF061	
		ASDYF074	
LH-0031YN	SafeStep, 20 x 0.75, Needleless Y	ASDYF034	
		ASDYF055	
		ASDYF066	
		ASDYF075	
		ASDYF078	
		ASDYF087	
LH-0032	SafeStep, 20 x 1, straight	ASDVF052	
		ASDXF052	
		ASDXF061	
		ASDXF091	
		ASDXF107	
LH-0032YN	SafeStep, 20 x 1, Needleless Y	ASDZF014	
		ASDZF023	
		ASDZF034	
LH-0033	SafeStep, 19 x 0.75, straight	ASDSF025	
LH-0036	SafeStep, 22 x 1.5, straight	ASDRF062	
LH-0036YN	SafeStep, 22 x 1.5, Needleless Y	ASDRF007	
		ASDRF008	
LH-0039	SafeStep, 19 x 0.5, straight	ASCXF003	