

## Medical Devices

**GBUK Healthcare**

Woodland House, Blackwood Hall Business Park  
North Duffield, Selby, North Yorkshire YO8 5DD

T +44 (0) 1757 288 587  
W [www.gbukhealthcare.com](http://www.gbukhealthcare.com)  
E [info@gbukhealthcare.com](mailto:info@gbukhealthcare.com)

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## Field Safety Notice

**Product:** GBUK Chest Drain Bottle

**FSCA-Identifier:** 2023/001/031/601/024

**Type of action:** Immediate attention required.

**Date:** 30<sup>TH</sup> JANUARY 2023

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**Attention - Risk/ Safety Managers, Clinicians, Nursing, Theatre staff and Anaesthesia, ICU, HDU, Paediatrics and other users of these devices.**

### Information on Affected Devices:

**Device Type/Intended Use:** The chest drainage system consists of a chest drainage bottle (1800ml capacity) and a tubing set. The tubing set is intended to allow connection of the patient's drainage catheter/s to the chest drainage bottle. The device is intended to be used on any patient requiring intrapleural drainage. The chest drainage system is intended for intrapleural drainage.

**Indications:** For drainage of air and/or fluid from the pleural space and/or mediastinum.

**Contraindications:** Only to be used as indicated above. There are no known contraindications.

Product Code	NHSSC NPC	Batch Number
CDB-001	FSW1437	22016414
		22017952

**Affected LOT Numbers:** Only the above batch numbers are impacted by this Field Safety Notice.

**Website:** <https://gbukgroup.com/brands/gbuk-healthcare/chest-drainage/gbuk-chest-drain/gbuk-chest-drain/>

### Reason for Field Safety Corrective Action (FSCA):

**Description of the problem** – It has been identified in GBUK chest drain bottles CDB-001 that there are a number of cracks in the base. This is an identifiable fault.

**Associated Hazard/Risk to Patient:** The crack could potentially allow the movement of air through it. Therefore, the device would not be a closed circuit. This may result in the following scenarios:

1. Air could be forced into the body. This could be a significant impact on patient health and may be fatal if undetected.
2. Air and fluid may not be removed effectively from the chest cavity. This could be a significant impact on patient health and may be fatal if undetected.
3. Leakage of biologically hazardous material from the bottle could occur. This could lead to cross contamination and infection to the patient and persons in the environment.

**Background /Probability of Problem Arising:** GBUK Group have become aware of this problem due to customer complaints. There have currently been no reported injuries that have been attributed to this product fault. We do not believe that the fault is in all bottles however, the current results from internal inspections predict approximately a 30% failure rate.

#### **Type of Action to Mitigate the Risk:**

##### **Action to be taken by the user:**

- Identify Device  Quarantine Device  Return Device
- Destroy Device
- On-site device /inspection
- Follow patient management recommendations
- Take note of amendment/reinforcement of Instructions for Use (IFU)
- Other  None

**Action be Completed:** Immediately

**Patient Follow Up:** No patient follow up is required.

**Customer Reply Required:** Yes (form attached)

##### **Action to be taken by the manufacturer:**

- Product Removal
- Onsite Device Modification/Inspection
- Software Upgrade
- IFU or labelling change
- Other
- None

GBUK Group are in the process of recalling any impacted stock from the market. 100% inspection will be performed on any further GBUK Chest Drain Bottles being placed on the market that could be impacted by this fault.

**Action be Completed:** Immediately

This FSN is not required to be communicated to the patient.

**General Information:**

This is a new FSN, no further FSN is expected to be required. The MHRA has been informed about this communication to customers.

**Transmission of this Field Safety Notice** - This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency  
Yours sincerely,



Lynsey Pack  
GBUK Enteral Ltd, Woodland House, Blackwood Hall, North Duffield, Selby, North Yorkshire, YO8 5DD.

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## Acknowledgement of Field Safety Notice

**Product:** GBUK Chest Drain Bottle CDB-001

**FSCA-Identifier:** TBC

**Type of action:** Immediate attention required.

**Date:** 30TH JANUARY 2023

Upon receipt of the attached information please confirm your receipt and understanding in the boxes below. Please return this sheet to GBUK Healthcare by email to [complaints@gbukgroup.com](mailto:complaints@gbukgroup.com), fax +44(0)1757 600545 or by post to the following address:

Complaints Department- 6663  
 Woodland House,  
 Blackwood Hall Business Park,  
 North Duffield,  
 Selby,  
 North Yorkshire,  
 YO8 5DD.

Head Office Telephone Number - +44 (0) 1757 288 587

Check One Box ✓	
	<b>Yes</b> – I confirm receipt and I understand this Field Safety Notice and the required actions.
	<b>No</b> – I do not understand this Field Safety Notice. I would like a representative of GBUK Healthcare to contact me

<b>Customer Name:</b>	
<b>Address:</b>	
<b>Phone Number:</b>	
<b>Email Address:</b>	

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Customer Signature

\_\_\_\_\_

Date

