

Rev 1: January 2025



FSN Ref: FSN202601

FSCA Ref: 2026/003/023/601/005

Date: 20.03.2026

## **Urgent Field Safety Notice Safety Needle**

For Attention of\*:GBUK Group Ltd.

Contact details of local representative (name, e-mail, telephone, address etc.)\*

**Emily, Emily.Kay@gbukgroup.com, +44 (0) 1757 606 981, Woodland House,  
Blackwood Hall Business Park, North Duffield, Selby, North Yorkshire, YO8  
5DD, UK**



**Urgent Field Safety Notice (FSN)**  
**Safety Needle**  
**Risk addressed by FSN**

<b>1. Information on Affected Devices*</b>	
1	1. Device Type(s)* 25G x 5/8"(0.5 x 16mm)
1	2. Commercial name(s) Safety Needle
1	3. Unique Device Identifier(s) (UDI-DI)* 06971911299132
1	4. Primary clinical purpose of device(s)* The safety needle is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose. After remove needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.
1	5. Device Model/Catalogue/part number(s)* SHN250625
1	6. Software version /
1	7. Affected serial or lot number range Lot number: 20251125, 20251020
1	8. Associated devices /

<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2	1. Description of the product problem* The needle of the product is blocked, preventing normal aspiration of liquid.
2	2. Hazard giving rise to the FSCA* Needle blockage will cause operational issues, preventing normal aspiration of liquid.
2	3. Probability of problem arising Frequent
2	4. Predicted risk to patient/users Hazard Risk Level: 10, Investigate Further Risk Control (IFRC)
2	5. Further information to help characterise the problem Current investigation results indicate that batches 20251125 and 20251020 are affected by the needle blockage issue.
2	6. Background on Issue On March 12, 2026, we received a customer complaint regarding blockage of the safety needle. We conducted tests on all products in inventory and confirmed that for the safety needle with specification 25G x 16mm, batches 20251125 and 20251020, some products did exhibit the issue of needle blockage. We immediately notified the customer to quarantine and recall the same batch of products already in the market. Subsequent root cause analysis revealed that the blockage was caused by the solidification of silicone oil inside the needle cannula. Further investigation determined that the silicone oil solidification resulted from a malfunctioning air valve on the needle production line, leading to insufficient air pressure. Consequently, the silicone oil inside the needle

	cannula could not be effectively blown out, accumulated within the cannula, and solidified after a period of time following shipment. Corrective action has now been implemented: an observation port has been installed on the production line's air pressure valve, allowing for real-time monitoring of the air pressure value to prevent similar incidents from recurring.
2	7. Other information relevant to FSCA
.	This incident will only render the product unusable and will not cause personal injury.

<b>3. Type of Action to mitigate the risk*</b>	
<b>3.</b>	<p><b>1. Action To Be Taken by the User*</b></p> <p> <input type="checkbox"/> Identify Device                        <input type="checkbox"/> Quarantine Device                        <input checked="" type="checkbox"/> Return Device                        <input type="checkbox"/> Destroy Device                 </p> <p> <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Follow patient management recommendations  <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)  <input type="checkbox"/> Other                      <input type="checkbox"/> None                 </p> <p>Provide further details of the action(s) identified.</p>
3.	<p>2. By when should the action be completed?                      Specify where critical to patient/end user safety</p>
3.	<p>3. Particular considerations for:                      Choose an item.</p> <p>Is follow-up of patients or review of patients' previous results recommended? Choose an item.</p> <p>Provide further details of patient-level follow-up if required or a justification why none is required</p>
3.	<p>4. Is customer Reply Required? *                      No (If yes, form attached specifying deadline for return)</p>
<b>3.</b>	<p><b>5. Action Being Taken by the Manufacturer</b></p> <p> <input checked="" type="checkbox"/> Product Removal                      <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Software upgrade                      <input type="checkbox"/> IFU or labelling change  <input type="checkbox"/> Other    <input type="checkbox"/> None                 </p> <p>Provide further details of the action(s) identified.</p>
3	<p>6. By when should the action be completed?                      Specify where critical to patient/end user safety</p>
3.	<p>7. Is the FSN required to be communicated to the patient /lay user?                      Choose an item.</p>
3	<p>8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? Choose an item.                      Choose an item.</p>

<b>4. General Information*</b>	
4.	1. FSN Type* <span style="float: right;">New</span>
4.	2. For updated FSN, reference number and date of previous FSN <span style="float: right;">Provide reference and date of previous FSN if relevant</span>
4.	3. For Updated FSN, key new information as follows: Summarise any key difference in devices affected and/or action to be taken.
4.	4. Further advice or information already expected in follow-up FSN? * <span style="float: right;">Not planned yet</span>
4	5. If follow-up FSN expected, what is the further advice expected to relate to: Eg patient management, device modifications etc
4	6. Anticipated timescale for follow-up FSN <span style="float: right;">For provision of updated advice.</span>
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name <span style="float: right;">Jiangsu Micsafe Medical Technology Co., Ltd</span>
	b. Address <span style="float: right;">Xituan Industrial Park, Dafeng District, Yancheng, 224125, Jiangsu, P.R. China</span>
	c. Website address <span style="float: right;">www.micsafe.com</span>
4.	8. The Regulatory Authority of your country has been informed about this communication to customers. * Yes
4.	9. List of attachments/appendices: <span style="float: right;">If extensive consider providing web-link instead.</span>
4.	10. Name/Signature <i>Leon Liang PRRC</i> <i>2026.03.23</i> <span style="float: right;">Leon Liang, PRRC</span>

<b>Transmission of this Field Safety Notice</b>	
	<p>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. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*</p>

Note: Fields indicated by \* are considered necessary for all FSNs. Others are optional.