FSN Ref: FSN001-2025 FSCA Ref: FSCA001-2025

Date: 15/04/2025

Urgent Field Safety Notice

GBUK Arterial Cannula Kit 4 Fr x 10 cm

For Attention of*:N/A

Contact details of local representative (name, e-mail, telephone, address etc.)*
GBUK Group Ltd Woodland House, Blackwood Hall Business Park, Cornelius Causeway, Selby YO8 5DD – ph. + 44 (0) 1757 288 587 - soiena.gorman@gbukgroup.com

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Urgent Field Safety Notice (FSN)

GBUK Arterial Cannula Kit 4FR x 10cm
Component Incompatibility

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	GBUK Arterial Cannula Kit 4 Fr x 10 cm – is set of medical devices, provided in a unique package, intended to allow the placement of the Single Lumen Catheter in the peripheral vein or arteria, through the Seldinger Technique. Once the Single Lumen Catheter is in place, it is intended to remain into the vein or arteria for a short term timing.
1.	2. Commercial name(s)
	GBUK Arterial Cannula Kit 4 r x 10 cm
1.	3. Unique Device Identifier(s) (UDI-DI)
	Primary packaging: 0 803224860005 8 – Secondary packaging: 3 803224860005 9 – Shipping carton: 5 803224860005 3
1.	4. Primary clinical purpose of device(s)*
	Kit formed by a Polyurethane Single lumen catheter, a stainless steel short guidewire and by an introducer needle. Normally intended for continuous use for between 60 minutes and 30 days (short term). The device could remain in situ for 72-96 hours. The Device is intended to allow the placement of the Single Lumen Catheter in the peripheral vein or arteria, through the Seldinger Technique.
1.	5. Device Model/Catalogue/part number(s)*
	394101100322
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	30847S2803, 31491S2806, 31818S2808
1.	8. Associated devices
	N/A

2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	The needle provided is too narrow so the guidewire will not go down it to complete the Seldinger procedure.
2.	2. Hazard giving rise to the FSCA*
	Inability to use the device, inability to perform the Seldinger technique (a medical procedure used to gain safe access to blood vessels or other hollow organs through a needle), inability to complete the procedure correctly, blood loss and need to replace the device with another one with consequent re-cannulation with associated patient discomfort.
2.	3. Probability of problem arising
	Based on incident data, the probability of the problem occurring is specific to the reported batches, as it only affects devices from this lots. The issue is not expected to occur in other batches.

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2.	4. Predicted risk to patient/users
	Blood loss, need to replace the device with another one with consequent re-cannulation with associated patient discomfort.
2.	5. Further information to help characterise the problem
	The issue has been observed in just one case where the device failed to work as intended, leading to delays and complications.
2.	6. Background on Issue
	The line was ineffective in a haemorrhaging hypertensive trauma patient who required prompt arterial blood pressure assessment and management while receiving large-volume blood resuscitation. The root cause is identified as the needle being too narrow. Containment measures are in place to limit the issue to only the affected devices. Ongoing investigation is being carried out, and corrective actions are planned.
2.	7. Other information relevant to FSCA
	No additional information at this time

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Return Process: Return products as indicated below. Before proceeding with the return, contact our Customer Service department to notify them of the return and receive detailed instructions. You can reach us via email at info@deltamed.numantec.eu or by phone at +39 0375 785915. Returned products must be properly packaged and clearly identified as return materials. Please refer to this notice and include a copy of the acknowledgment form within the shipment. Return products to: **Delta Med S.p.A.** Via Guido Rossa, 20 – 46019 Viadana (MN), Italy	
3.	2. By when should the action be completed?	20 calendar days from the receipt of this notification - 05/05/2025
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? No The follow-up on patients is not required as the product is not usable due to the incompatibility between the components of the kit, and therefore, it is not being used. In any case, given the nature of the device, which is neither implantable nor intended for prolonged patient contact, follow-up is not foreseen.	

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3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	10/05/2025
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	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?	
	N/A N/A	

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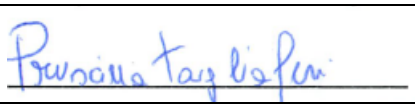
	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Delta Med S.p.A.**
	b. Address	Via Guido Rossa, 20 – 46019 Viadana (MN), Italy
	c. Website address	https://deltamed.pro/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Ref. to Customer acknowledgment form_2025
4.	10. Name/Signature	**Priscilla Tagliaferri** **QA&RA Manager** 

	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. (As appropriate) *Please transfer this notice to other organisations on which this action has an impact. (As appropriate)* *Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.* *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..**

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