Blink Medical Ltd
Radway Road
Shirley, Solihull
B90 4NS, UK

A KATENA BRAND blink medical

Urgent Field Safety Notice

Date: **09/09/20**

Field Safety Corrective Action [FSCA] Ref. No. **#362**

Type of Action: Return of Medical Device to Blink Medical

1. Details on Affected Devices

Product Code	Product Description	Lot No.
HR620	Cannula Liposuction 30cm x 6mm	206087 207454 209181
HR621	Cannula Liposuction 30cm x 5mm	175511 201581 206088 212244 214495 215439
HR622	Cannula Liposuction 30cm x 4mm	175512 179592 180637 201582 204077 206089 207455 209182 210765 214494 215440
HR623	Cannula Liposuction 30cm x 3mm	175513 178286 179593 181504 201583 204078 206090 207456 209183 215441
HR624	Cannula Liposuction 15cm x 4mm	179594 201584 207457 209184 215442
HR625	Cannula Liposuction 15cm x 3mm	176620 179595 181505 204079 206091 207458 209185 210766 214492 215443
HR626	Cannula Liposuction 15cm x 2mm	175514 178287 179596 201585 207459 209186 210767 212245 214491

Additional Information:
Should product be identified from a lot number not listed above, where there is evidence of discolouration around the handle to shaft area of the cannula – then this product should be returned to Blink Medical in accordance with the requirements of this Field Safety Notice.

2. Description of the Problem:

In reference to the Liposuction Cannula product range, and the product codes & lot numbers listed above, there is the potential for foreign matter contamination to be evident on these devices presenting as brown discolouration in and around the handle / upper shaft section of the instrument.

At this time there are no substantiated health risks associated with the presence of this contamination.

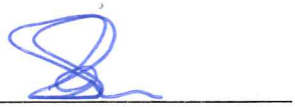
3. Advise on Action to be taken [by user]:
Blink Medical request that you check all relevant instrument inventory for products within the scope of this Field Safety Notice; and cease further use and/or distribution of these products, quarantining them immediately. Where stock of potentially affected product is identified, please complete the form within the appendix of this Field Safety Notice with the relevant details (product code; lot number & quantity) and return the form to the email address below by 30 September 2020. Once this form is received Blink Medical Customer Services will contact yourselves and make the necessary arrangements the return of the products to Blink Medical. Blink Medical will issue credit notes upon receipt of all product returned in accordance with the requirements of this Field Safety Notice. Where there is not stock of the potentially affected product identified, please complete the form within the appendix of this Field Safety Notice with the relevant details and return the form to the email address below by 30 September 2020.

FSN Communication:
This Field Safety Notice needs to be passed on to 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 all relevant personnel within your organisation and any 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.

4. Blink Medical Contact Information:	
Contact Name(s):	Kelly Dutson
Contact E-Mail:	kelly@blinkmedical.com
Address [inc. Country]:	**Blink Medical** Radway Road Shirley, Solihull UK
Postcode:	B90 4NS
Contact Telephone:	+44 (0) 121 386 8433

Alternate Contact Information:	
Contact E-Mail:	compliance@blinkmedical.com

The undersigned confirms that this notice has been notified to the appropriate regulatory agencies & competent authorities, for and on behalf of Blink Medical:



Stuart Smith
Blink Medical
Quality Assurance Manager

Blink Medical Ltd
Radway Road
Shirley, Solihull
B90 4NS, UK

Appendix:

Field Safety Corrective Action [FSCA] Ref. No. **#362**

Type of Action: Return of Medical Device to Blink Medical

Please complete this form in accordance with the requirements of **Field Safety Notice (#362)**, and return to Blink Medical at:

- Kelly Dutson kelly@blinkmedical.com
- Alternate Contact compliance@blinkmedical.com

Please include a copy of this form with any returned product – thank you.

Organisation Details:			
Name:			
Customer Address:			
Tel:		Email:	

Form Completed By:	Name & Sign:			
	Position Held:		Date:	

☐ We confirm receipt & acknowledgment of this Field Safety Notice and having undertaken the actions requested by Blink Medical confirm that **there were no products** affected by this Field Safety Notice identified within our inventory.

☐ We confirm receipt & acknowledgment of this Field Safety Notice and having undertaken the actions requested by Blink Medical confirm that **there were quantities of products** affected by this Field Safety Notice identified within our inventory, with these products listed in the table below for the subsequent return to Blink Medical.

We confirm that no further use and/or distribution of the products will take place, with all products appropriately quarantined pending return to Blink Medical.

Product Code	**Lot Number**	**Quantity**

Note: please attach additional pages if needed to record all product identified for return to Blink Medical.