

02nd March 2021

URGENT – FIELD SAFETY NOTICE

Commercial Name of Affected Product:	Tibbs Arterial Cannula, Micro Olive. Refer to Appendix 2 TAC20MO
Type of Action:	Recall
DTR Medical Reference:	CC474 - 25/02/2021
Product Codes/Lot Numbers:	Refer to Appendix 2

Dear Customer,

Details of affected devices

DTR Medical is issuing a recall for the above listed product, TAC20MO for the batches listed in Appendix 2.

Description of the problem

DTR Medical is recalling the product referenced in Appendix 2 due to the cone end of the Tibbs device separating from the luer connector needle (fig.1). If this failure happens in use there could be a serious risk of patient harm. The risk to the patient if separation occurs in use is the potential for the cone to get lodged in the Artery/Vein or travel to another part of the body, where further surgical intervention could be required to remove. In the event of separation this is immediately evident so if the failure has not been observed there is no risk to patient safety. No patient injuries have been reported relating to this issue. There is no risk to patients that are associated with previous use of the defective device.

Our records indicate your facility has received product in scope of this field safety notice.



Fig. 1 Showing visual of the defect noted above

FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

1. We request that you check your inventory for product within the scope of this field action. Users should cease use and distribution of stock of the affected product batch and quarantine immediately.
2. If you do not have stock in the scope of this field action as referred to in Appendix 2, then mark the according checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or the email address mentioned below by 12th March 2021.
3. If you have stock from the affected product as referred to in Appendix 2, then mark the according checkbox on the Acknowledgement form (Appendix 1). Contact customer service by calling the phone number mentioned below who will issue you with a return number. Write this return number into the respective field in the Acknowledgement form in Appendix 1.
4. Complete Appendix 1 for all products still in your possession and under control. Return this form immediately to customer service or by 12th March 2021.
5. DTR Medical will issue a credit note upon receipt of the returned affected product.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

1. If you are a distributor, provide this field safety notice to all of your customers who have received product in scope of this Field Action. Your customer is then required to complete the acknowledgement form and return this to you.
2. As a distributor you are required to confirm to DTR Medical that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement form to Customer Service by 9th March 2021.
3. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TK area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to DTR Medical.

Please be aware that all European Economic Area/Switzerland (EEC/CH) and Turkey Member State Competent Authorities in which DTR Medical distribute directly will be notified by DTR Medical.

DTR Medical

DTR Medical informs all customers, employees of DTR Medical and distributors on this Field Action.

Transmission of this Field Safety Notice

This 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 other organisations on which this action has an impact. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. until all required actions have been completed in your organisation.

Contact reference person

Should you require any further information or support concerning this issue, please go to our website noted below or contact:

Customer Service

Contact: Kayley Marsh
FAX: +44 (0) 1792 797955

Telephone: +44 (0) 1792 797910
Email: info@ltrmedical.com

ADDRESS: 17 Clarion Court, Enterprise Park, Swansea, UK SA6 8RF
WEBSITE: www.ltrmedical.com

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

DTR Medical is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your Business Manager or Customer Service.

For and on behalf of DTR Medical Ltd,



Kelly Gittins, Quality Manager

Appendix 1

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT
FORM

Customer No.
HSL01

PRODUCT FIELD ACTION BY DTR MEDICAL LTD – IMMEDIATE ATTENTION REQUIRED BY 12th March 2021

REF. CC474 - 25/02/2021
DATE: 02nd March 2021

RETURN COMPLETED FORM IMMEDIATELY TO:
FAX: +44 (0) 1792 797955 Email: info@dtrmedical.com

<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does NOT include products affected by this Field Action	<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory DOES include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned. Return Authorisation No. <u>CC474/O</u>
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	Tibbs Arterial Cannula, Micro Olive. TAC20MO	
PRODUCT CODE	LOT/BATCH NUMBER	QUANTITY (Returning)
TAC20MO	534231	
TAC20MO	534470	
TAC20MO	533976	

- Include a copy of the completed Acknowledgement Form in the returns package with the returned units
- Ensure the Return Authorisation number is clearly visible on the returns package.
- Please label returns as "Field Action Returns"

Complete this Acknowledgement form and return immediately by using the fax number or email address above.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	Phone / Fax
FORM COMPLETED BY:	Stamp
PRINT NAME: _____	
SIGNATURE: _____	
DATE	

CC474 – Appendix 2

Product Code	Description	Lot /batch number
TAC20MO	Tibbs Arterial Cannula, Micro Olive.	532379 532421 532733 533257 533801 533976 534231 534238 534381 534470