DTR Medical ltd
17 Clarion Court
Enterprise Park
Swansea
SA6 8RF
United Kingdom

13th August 2020

URGENT – FIELD SAFTEY NOTICE

Commercial Name of Effected Product:	**Tibbs Arterial Cannula, Large cone. Various product codes Refer to appendix 2 TAC2003 & TAC20LC**
Type of Action:	**Recall**
DTR Medical Refence:	**CC459 - 13/08/2020**
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, TAC2003 & TAC20LC 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 connecter 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

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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 21st August 2020.
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 21st August 2020.
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 21st August 2020.
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: Kelsey Allen Telephone: +44 (0) 1792 797910
FAX: +44 (0) 1792 797955 Email: info@dtrmedical.com
ADDRESS: 17 Clarion Court, Enterprise Park, Swansea, UK SA6 8RF
WEBSITE: www.dtrmedical.com

The under sign 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,

Emily Rees, Quality Manager

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Appendix 1

FIELD SAFTEY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

Customer No. _____

PRODUCT FIELD ACTION BY DTR MEDICAL LTD – IMMEDIATE ATTENTION REQUIRED BY 21st AUGUST 2020

REF. CC459 – 13/08/2020

DATE: 13th August 2020

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

☐ 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	☐ 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. _____

PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	TAC2003 & TAC20LC Tibbs Arterial Cannula, Large Cone	
PRODUCT CODE	LOT/BATCH NUMBER	QUANTITY (Returning)

- 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	

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CC459 – Appendix 2

Product Code	Description	Lot /batch number
TAC2003	Tibbs Arterial Cannula Set of 3 sizes	531788 532233
TAC20LC	Tibbs Arterial Cannula, Large Cone standard length	530227 530537 530657 531229 531790 531568 532067