Teleflex Medical Tuttlingen GmbH

Gansacker 36

D-78532 Tuttlingen

Germany

10 July 2012

URGENT
FIELD SAFETY NOTICE

COMMERCIAL NAME OF AFFECTED PRODUCTS:	Pilling Cannula 1.2 x 69mm with sharp Mandrin Pilling Cannula 1.2 x 79mm with sharp Mandrin
COMMON NAME	Duisburg Needle
TELEFLEX REFERENCE	603831
TYPE OF ACTION	**Market Withdrawal**

AFFECTED PRODUCT

PART	LOT	PART	LOT	PART	LOT	PART	LOT
LR9171N	F1	LR9281N	C1	MR8181N	E1	NGR-6N	K1
LR9181N	C1		JO		LO		L1
LR9271N	G0	MR8171N	K1	MR9271N	D1		LO
	L0		LO	MR9281N	D1	NGR-7N	J1
							LO

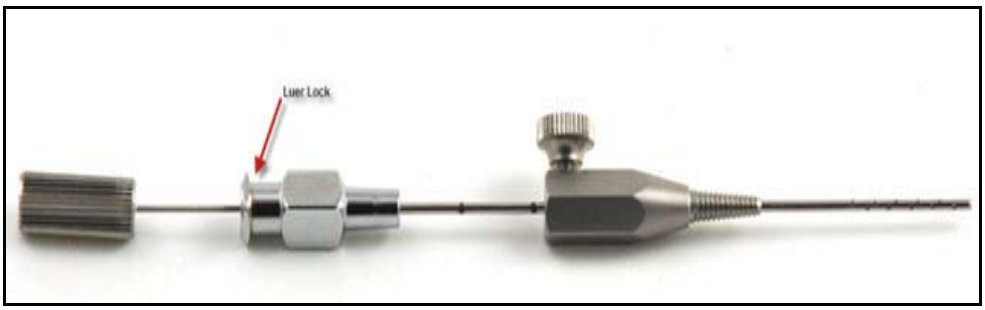
Dear Customer,

1. Details of affected devices

Teleflex has initiated a voluntary Field Action for the above listed products.

2. Description of the problem

Teleflex has become aware that the female luer lock connector of the Pilling Cannula may be oversized. Because of this it may not be easily connected to the male luer lock connector of the external drainage tubing which may result in procedural delay.



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3. 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 from the affected lot numbers and quarantine all products from the affected lot numbers immediately.

2. If you do not have stock from the affected part or lot numbers as referred to in above table then mark the according checkbox on the Acknowledgement form (see Appendix 1) and send the form to the fax number or e-Mail-address mentioned there.

3. If you have stock from the affected part/lot numbers as referred to in above table, mark the according checkbox on the Acknowledgement form (see Appendix 1). Contact customer service by calling the phone number mentioned in section 6 and you will be given a return number. Write this return number into the respective field in the Acknowledgement form.

4. Complete 'Appendix 1' for all products in your possession and under control for return and send this information immediately to the following fax number: **07151 406 – 566** or provide a completed copy to your local Sales Representative. This helps us to confirm your notification and to register the amount of products under your control.

5. Return of the affected product with the Teleflex Customer Service (or your local dealer).

6. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

Instruction for Distributors of affected product

If you are a distributor, provide this field safety notice to all of your customers which have received product of the Field Actioned batches. Send the customers the following documents:

- A copy of this Field Safety Notice
- A copy of the Acknowledgement Form (see Appendix 1)

The Acknowledgement form has to be filled in completely by your customer and returned to you.

As a Distributor you are required to confirm to Teleflex that you have informed all of your customers affected by the Field Action. Please forward the completed Acknowledgement Form (Appendix 1) to the following fax number: **07151 406 – 566**

Please be advised that all European Economic Area/Switzerland (EEA/CH and Turkey) Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex.

If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH and Turkey area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

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4. Teleflex

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

5. Transmission of this Field Safety Notice

This notice should be passed on all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Maintain awareness of this notice until all required actions have been completed in your organisation

6. Contact reference person

Should you require any further information or support concerning this issue, please contact:

For Customer Service:

Herrn Horst Erbe
Tel.: 07151 / 406 – 431
Mobil: 0172 / 74 33 713
e-mail: horst.erbe@teleflex.com

For Product Specific Queries:

Frau Babette Goldhammer
Mobil: 0172-8232078
e-mail: babette.goldhammer@teleflex.com

Please be advised that all European Economic Area/Switzerland (EEA/CH and Turkey) Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex.

Teleflex 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 local sales representative or Customer Service at **horst.erbe@teleflex.com**

If you have further questions please feel free to contact our customer service or sales representatives.

For and on behalf of Teleflex,

[redacted]

Senior Director of Quality, EMEA, QA

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Appendix 1

Customer No
_____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

RETURN COMPLETED FORM IMMEDIATELY TO: horst.erbe@teleflex.com or by fax on 07151 / 406-566

☐ Our inventory does not include products affected by this Field Action.	☐ Our inventory does include products affected by this Field Action. The use and further distribution of the affected products is stopped. All product is put on hold and the amount below will be returned.	
Return Authorisation No: _____	☐ Replacement	☐ Credit note

PLEASE PRINT QUANTITY NUMBERS CLEARLY

COMMERCIAL NAME OF AFFECTED PRODUCTS:	Pilling Cannula 1.2 x 69mm with sharp Mandrin Pilling Cannula 1.2 x 79mm with sharp Mandrin	
COMMON NAME	Duisburg Needle	
Part Number:	**Lot Number:**	**QUANTITY**

PRINT NAME / TITLE		**DATE**	
SIGNATURE:		**TELEPHONE #**	
INSTITUTION NAME		**CITY**	
ADDRESS		**ADDRESS**	