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Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland

16th September 2009

Urgent
Field Safety Notice

Commercial Name of Affected Product:	**Nephrostomy Catheter**
Type of action:	**PRODUCT RECALL**
Teleflex Medical FSCA case #:	**2009_0010_Nephrostomy**

Please pass this notice to the Risk Management Division or Director of Purchasing for your institution

Dear Customer,

1. Details on affected devices

Teleflex Medical has issued a voluntary recall for the specific lot number of the **Nephrostomy Catheter Set** shown in the table below.

Catalog Number	Description	Lot #
340012-000060	Nephrostomy Catheter Set 6 Ch	100621613

2. Description of the problem

The Nephrostomy Catheter set is used in Percutaneous Nephrostomy procedures. A Nephrostomy is an artificial opening created between the kidney and the skin which allows for the drainage of urine directly from the upper part of the urinary system (renal pelvis). The issue for the affected lot is that the puncture cannula has a lower internal diameter than required. As a result some difficulty/resistance may be encountered when advancing the guide wire through the cannula. This may result in a delay in the procedure, or in the event that a new nephrostomy puncture set is used, a second puncture procedure, thus increasing the potential for infection and/or bleeding. The product in its packaging and an illustration of the puncture cannula are depicted on the next page.

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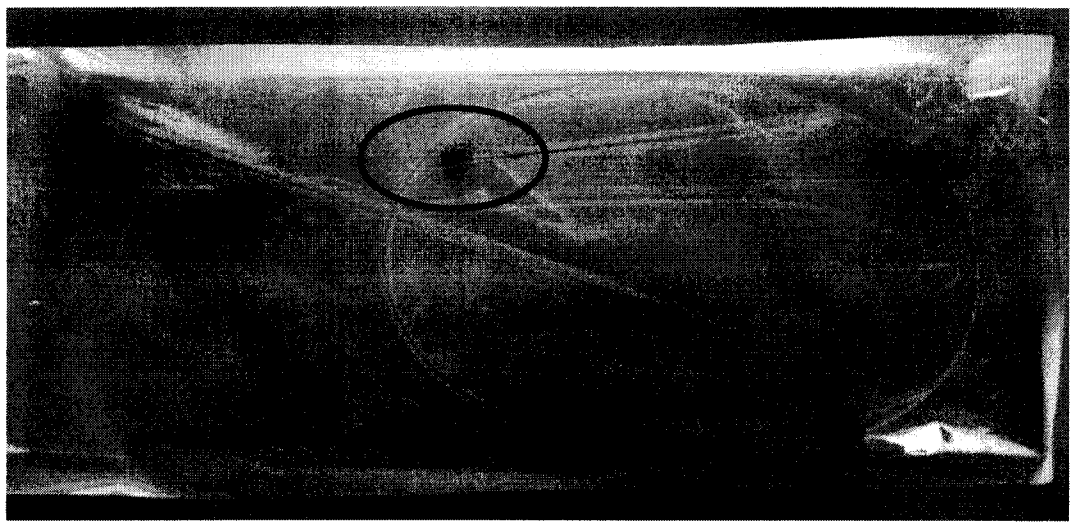

Figure 1
Nephrostomy Catheter Set 6 Ch

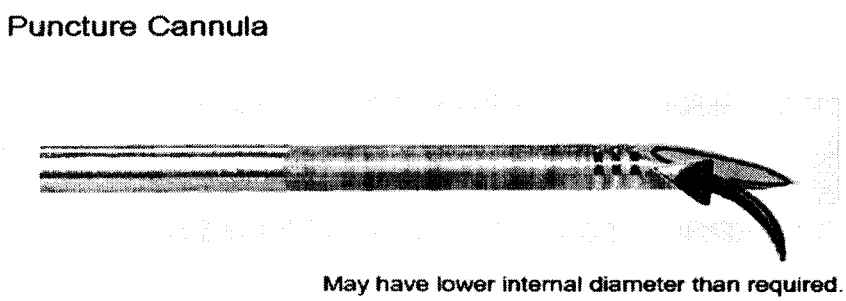

Figure 2

Nephrostomy Catheter: Puncture Cannula

3. Advice on action to be taken by Medical Staff

Our records indicate you have received product included in the scope of this recall. We are notifying our Customers to take the following action:

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RECALL INSTRUCTIONS:

Instructions for Hospitals/Medical Staff/Customers

1. **Check your stock for the lot of product in this recall. Cease use and distribution, and quarantine all affected product immediately.**

2. **Contact Teleflex Medical Customer Service Department at** [insert local customer service number here] **for a Return Authorization Number. Once you have received the Return Authorization Number, please enter it in the space provided on the attached Recall Acknowledgement & Stock Status Form.**

3. **Complete the enclosed Recall Acknowledgement & Stock Status Form and immediately fax back to Teleflex Medical, Fax number:** [insert local customer service number here]**, Attn: Customer Service. This will allow us to document your receipt of this letter and the amount of product you have on hand for return.**

4. **Return any affected product freight collect, along with the original completed Recall Acknowledgement & Stock Status Form to the following:**

   [insert local customer service contact details here including name of contact person]

   Note: Teleflex Medical can provide either replacement product at no charge or credit your account when the product is returned. Please indicate which you desire on the Recall Acknowledgement & Stock Status Form.

Instructions for Distributors

If you are a distributor, communicate this recall notice to your customers who received product within the scope of this recall by providing a copy of this recall notification to them. Also provide a copy of the Acknowledgement Form. This form should be completed in its entirety, signed and returned to you (the Distributor). As a Distributor, it is your responsibility to provide Teleflex Medical with a certification that all of your consignees have been contacted under this recall.

If you have any other questions, please feel free to contact your local sales representative or the Teleflex Medical Customer Service available at:

[Insert local customer service details here]

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5. Teleflex Medical Action

Teleflex Medical is notifying any potentially affected Customers, Teleflex Medical employees and Distributors of this Field Safety Notice.

6. 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.

7. Contact reference person

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

[insert local contact details here]

This recall is voluntary and the relevant Competent Authorities have been advised of this Field Safety Corrective Action.

Teleflex 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 local sales representative or Customer Service at *[insert local contact details here]*

VP Quality Assurance & Regulatory Affairs, EMEA

Attachments:
Appendix A: Acknowledgement Form