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

14th June 2010

Urgent
Field Safety Notice

Commercial Name of Affected Product:	ANTIREFLUX VALVE URETERAL STENT SETS FOR CHILDREN
Type of action:	Recall

AFFECTED PRODUCT:

Part Number	335403-000030	335404-000030	335405-000030	335405-000030
Lot Numbers	100 599 396	100 604 870	100 611 593	100 636 759

Dear Customer,

1. Details of affected devices
Teleflex Medical has issued a voluntary field safety corrective action for specific lot/batch numbers of the **ANTIREFLUX VALVE URETERAL STENT SETS FOR CHILDREN** product as identified above.

2. Description of the problem
Teleflex Medical is conducting a voluntary field corrective action for the **ANTIREFLUX VALVE URETERAL STENT SETS FOR CHILDREN** products identified above. Ureter Stents are intended for use to prevent or treat obstruction of urine flow from the kidney.

Teleflex Medical have received reports of difficulty in inserting the spring wire guide into the catheter. No patient injuries have been reported due to this issue. The potential consequences to the patient, of failure to insert the spring wire guide into the catheter, include extended procedure time as the physician has to replace the catheter. In the event that the phys cian has to remove the catheter and guidewire together, consequences could include: infection and loss of an access site.

3. FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

Instructions for Hospitals/Medical Staff/Customers

Our records indicate you have received product included in the scope of this recall. In order to provide the highest level of quality product to our customers, we are notifying our Customers to take the following action:

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- Check your stock for the products included within the scope of this recall. Cease use and distribution, and quarantine all affected product immediately.

- 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.

- 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.

- 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]

- 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.

Instruction for Distributors of affected product

If you are a distributor, Teleflex Medical requires that you communicate this field safety corrective action notice to your customers who received product within the scope of this field safety corrective action by providing:

- A copy of this Field Safety Notice to them.
- A copy of the Acknowledgement Form.

The Acknowledgement Form is required to be completed in its entirety, signed and returned to you (the Distributor).

As a Distributor, it is your responsibility to provide Teleflex Medical International with confirmation that all of your consignees have been contacted under this field safety corrective action. Please forward the completed Acknowledgement Form to **[insert local customer service number here]**.

4. Teleflex Medical

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

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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.

6. Contact reference person

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

For Customer Service
[insert local customer service details here].

For Product Specific Queries:
[insert local product manager contact details here]

This field safety corrective action is voluntary and all affected 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]***

Signed by:

[redacted]
VP Quality Assurance & Regulatory Affairs EMEA

Attachments as follows:

Appendix A *Acknowledgement Form*

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APPENDIX A
ANTIREFLUX VALVE URETERAL STENT SETS FOR CHILDREN

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT AND STOCK STATUS FORM

Please check the appropriate box and return this form by Fax/email to the number below.

☐ We have no inventory within the scope of this field safety corrective action.	☐ We have the following affected product at our facility *(Please detail clearly below the stock you have under your control)*

Part Number	335403-000030	335404-000030	335405-000030	335405-000030
Lot Numbers	100 599 396	100 604 870	100 611 593	100 636 759
Quantity				

Return Authorisation No _____

Customer Number _____

Complete this Acknowledgement Form and immediately fax/email to Teleflex Medical at the number given below.

Print Name/Title _____ **Date** _____ **Institution Name** _____

Signature _____ **Telephone Number** _____ **Address** _____

City, State, Zip Code _____

RETURN BY FAX/email to: Customer Service FAX /email [insert local fax/email no here]