Teleflex Medical
IDA Business & Technology Park

Dublin Road, Athlone
Co. Westmeath, Ireland

27th of August 2014

URGENT - FIELD SAFETY NOTICE

Dear Customer,

TYPE OF ACTION:	Advisory Notice	
TELEFLEX REFERENCE:	2014-02 Rev 2	
Commercial Name	**Material**	**Batch**
Nelaton and Nelaton Robinson Catheters	402100	13431-14311
	402101	13261-14311
	402140	13271-14311
	403300	13261-14311
	403340	13291-14311
	403900	13261-14311
	404300	13261-14311
	410200	13261-14311
	410201	13261-14311

1. Details of affected devices

Teleflex has initiated a voluntary Field Safety Advisory Notice for the above listed products.

2. Description of the problem

Teleflex is issuing this advisory for the above listed products, because although they are labelled as “soft rubber,” the unit label does not contain the FDA CFR statement or specific ISO symbol stating that the devices contain dry natural rubber latex.

Since our sales brochure information for this product family regarding latex is quite clear and you intentionally ordered these products we assume that staff within your hospital are already aware that latex products are used.

We would nonetheless like to point out that the Nelaton and Nelaton Robinson Catheters mentioned above which bear the marking ‘Soft rubber’ do contain dry natural rubber latex and contact with latex products can cause allergic reactions in patients with latex sensitivity.

As a precautionary measure Teleflex is issuing this Advisory Notice.

3. ADVISORY NOTICE CORRECTIVE ACTION INSTRUCTIONS:

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

We request that you check your inventory for product within the scope of this field safety advisory action.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

If you are a distributor, provide this field safety advisory notice to all of your customers who have received product in scope of this Field Action.

Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in 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/TK area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

4. Teleflex

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

5. Transmission of this Field Safety Advisory Notice

This notice should be passed on to all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice.

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:

Contact: Shane Kenny **Telephone:** +353 (0)90 6460869
Fax: +353 (0)1 4370773 **Email**: orders.intl@teleflex.com

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.

For and on behalf of Teleflex,

Karen Boylan

Karen Boylan
VP Global RA/QA