

20 March 2014

URGENT - FIELD SAFETY NOTICE

TYPE OF ACTION:	Recall	
TELEFLEX REFERENCE:	40004241A	
COMMERCIAL NAME	PART	LOT
Bondek Plus	EP4049N	02A1003137
DEKLENE® II Polypropylene Suture	E7-4578	02D0901672
	ED-6072	02C1002218
		02E1002342
		02J0902517
	ED-6276	02F0902457
	ED-6896	02C0900661
		02C1002207
		02D0900634
		02D1100186
		02E0901921
		02E0902608
		02E1301581
		02J0900501
		02K0901590
		02K0902406
02L0900676		
02M0901869		
ED-853	02G1002594	
ED-863	02D0902457	
	02M0901348	
POLYLENE Polyester Suture	E13-6351	02F0902446
	E13-6354	02F0902439
	E13-6399	02F0902436
silky' II POLYDEK® Polyester Suture	E6-545	02F0902443

Dear Customer,

1. Details of affected devices

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

2. Description of the problem

Teleflex is recalling the products referenced above because they did not meet minimum needle attachment strength requirements. If affected product is used and failure occurs, delay in procedure, injury infection and bleeding may occur requiring medical and/or surgical intervention.

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 of affected product and quarantine immediately.
2. If you do not have stock in scope of this field action as referred to in above table then mark the according checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or e-Mail-address mentioned there.
3. If you have stock from the affected product as referred to in above table, mark the according checkbox on the Acknowledgement form (Appendix 1). Contact customer service by calling the phone number mentioned in section 6 who will issue you with 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. Return this form immediately to Customer Service.
5. Teleflex (or your local dealer) 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 Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
3. 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.
4. 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 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. 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:

Customer Service: Contact: Shane Kenny
FAX: +353 (0)1 4370773

Telephone: +353 (0)90 6460869
E-mail: Recalls.intl@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.

For and on behalf of Teleflex,

Padraig Hegarty

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Senior Director of Quality International.