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

18 February, 2010

# Urgent
# Field Safety Notice

| | |
|---|---|
| **Commercial Name of Affected Product:** | **Bondek Absorbable Suture** |
| **Type of action:** | **FSCA - Recall** |

**AFFECTED PRODUCT:**

| Part Number | Lot Number |
|---|---|
| **EP1081P** | 02A0802800 |
| | 02A0801448 |
| | 02A0802802 |

Dear Customer,

## 1. Details of affected devices

Teleflex Medical has issued a voluntary recall for the above Bondek Absorbable Sutures:

## 2. Description of the problem

Teleflex Medical has identified a packaging error where an incorrect outer box label was used to package Bondek Absorbable Sutures. The outer box label identifies the product as Bondek Plus Absorbable Synthetic Sutures, Part Number EP1081P but the product inside the package is one of either Bondek absorbable synthetic suture (part number EP1101P), Bondek absorbable synthetic suture (part number EP2087P) or Bondek Plus absorbable synthetic suture (EP2053P) This labeling error may cause confusion to the end user, since the sutures inside the box are of different catalog numbers than labeled on the outer box.

If the suture is not recognized as an incorrect suture and is used in a procedure for which it is not suitable, there is a moderate potential for injury including wound dehiscence, bleeding, needle breakage, intraoperative delay, or the need to re-do parts of the operation.

## 3. FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

### Advice on action to be taken by Hospitals/Pharmacies

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

- Immediately discontinue use and quarantine any products identified within this notification.
- Complete and return the Field Safety Acknowledgement Form in Appendix A as directed and a Customer Service Representative will contact you with a Return Goods Authorization (RGA) Number.

- Return the product to Teleflex Medical.
- Teleflex Medical will replace your inventory from the affected lots at no charge.

## 4. Teleflex Medical

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

## 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:***

*Attachments as follows:*

*Appendix A* *Acknowledgement Form*

APPENDIX A

# Bondek Absorbable Suture

## FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT AND STOCK STATUS FORM

| ☐ We have no inventory within the scope of this field safety corrective action. | ☐ We have the following affected product at our facility |
|---|---|

Return Authorisation No: _____

| Part No. EP1081P | | |
|---|---|---|
| **Lot No.** 02A0802800 | **Lot No.** 02A0801448 | **Lot No.** 02A0802802 |
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**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]