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

23 May 2014

# URGENT - FIELD SAFETY NOTICE

| TYPE OF ACTION: | Recall | |
|---|---|---|
| REFERENCE | FA2014-10 | |
| COMMERCIAL NAME | PART | LOT |
| BONDEK | BON100 | 02D1101137 |
| | | 02F1103013 |
| | | 02H1302839 |
| | | 02J1101705 |
| TEVDEK | TEV100 | 02G1101500 |

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**
   BARD, acting as distributor, is implementing an FSCA for the above listed product codes. Teleflex, acting as manufacturer, 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:**
   - Please check your inventory for product within scope of this field action. Users should cease use and distribution of stock of affected product and quarantine immediately.
   - Complete the *Reply Effectiveness Check Form* and return to BARD customer service.
   - 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 *Reply Effectiveness Check Form* and return this to you. As a Distributor you are required to confirm to BARD that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed *Reply Effectiveness Check Form* to BARD Customer Service.
   - Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which BARD 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.

4. **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

5. **Contact reference person**

   Should you require any further information or support concerning this issue, please contact BARD Customer Service

   Teleflex is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations.

***For and on behalf of Teleflex,***

*Padraig Hegarty*

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*Senior Director of Quality International.*