Teleflex

Teleflex

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Urgent Field Safety Notice

Commercial name of the affected product: **T.A.L.O.N.® (Tactically Advanced Lifesaving Intraosseous Needle)**
FSCA-identifier: **DK-12MAY2015**
Type of action: **Field Safety Corrective Action (FSCA)**

Date: May 12, 2015

Attention: Danish Health and Medicines Authority

Dear Sir or Madam,

Details on the affected devices:

Specific details of the affected product are as follows:

- T.A.L.O.N.® (Tactically Advanced Lifesaving Intraosseous Needle)
- Reference Number: 9081-VC-006
-

Affected Product Lot Codes			
3103376	3547157	3986753	4011996
3103377	3693167	3991994	4023525
3103378	3843307	3991995	4040723
3524557	3868998	3999583	4040724

Description of the problem:

This is to inform you that the product referenced above is being recalled by Teleflex-Vidacare Business Unit because the needle packaging may be compromised. If the needle becomes separated from the needle cover, there may be the potential for the packaging to be damaged thereby compromising the sterility of the product. If non-sterile products are used, there is a possible risk of infection.

The resulting risk category based on the estimated frequency of occurrence and the clinical consequence is shown below. The risk profile for the TALON FSCA is a, Vidacare Category III risk assessment is not acceptable based upon the risk profile for this device.

Advise on action to be taken by the user:

The products subject to this notification were manufactured from September 17, 2013 through April 27, 2015. Please examine and quarantine your stock of the affected lot codes, immediately.

Customers in possession of quarantined product from affected lot codes should contact Teleflex Customer Service to coordinate return of product – see contact details below.

In addition, if you have further distributed the products subject to this Field Safety Notice, please identify your customers and notify them at once. Notification may be accompanied by including a copy of this notification letter to further assist with your customer notifications. This notification should be carried out to the user level to prevent potential breach of sterile barrier or injury to the user.

Transmission of this Field Safety Notice:

This notice should be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Coordination for the return of affected product, please contact:

Teleflex Customer Service
Shane Kenny
Phone: +353 (0)90 6460869
Fax: +353 (0)1 4370773
orders.intl@teleflex.com

All other inquiries please contact:

Marisa Walsh
Senior Regulatory Affairs Specialist
Teleflex – Vidacare Business Unit
4350 Lockhill Selma Rd., Suite 150
Shavano Park, TX 78249
USA
Telephone: 210.375.8500
Fax: 210.375.8537
marisa.walsh@teleflex.com

The undersigned confirms that this notice has notified the appropriate Regulatory Agency.

Sincerely,

Marisa Walsh
Senior Regulatory Affairs Specialist
Teleflex – Vidacare Business Unit