Precision instruments for specialized applications

Updated March 29, 2018
By Electronic Mail

March 28, 2018

<Contact Name>
<Organization>
<Address>
<Address>
<Address>

Urgent Regulatory Field Action Notice

Commercial name of affected products : Blue Suture Grasper
FSCA :-Ranfac001
Type of action: Medical Device Return to Supplier / Medical Device Destruction

Attention <Contact Name>,

Details on affected devices:
The product listed in the attached Confirmation Form, and the subject of our "Notice to Distributors" date March 14, 2018 now needs to be returned or scrapped.

Reason for request:
This field action notice comes due to the expiration of the Product Quality Assurance certificate number CE 01760. The identified products were imported into the EU after the expiration of this certificate. Ranfac has completed an assessment and there is no inherent impact to product safety or performance.

Advise on action to be taken by users:
It is requested that the following actions be taken:

- All product must be identified and quarantined
- All quarantined product and product identified as already used must be documented and communicated to bzimble@ranfac.com.
- Please complete the attached Confirmation Form (Attachment) to identify the quantity and location of these devices.
- Based upon the information provided regarding the identification, quantity and location of the identified product, Ranfac will decide if the product should be scrapped or returned.
- Disposal instructions will be provided by Ranfac upon receipt of product identification communication and will include instructions to either scrap the product or will include shipping and RMA information.
- Please complete the attached Confirmation Form (Attachment) confirming which devices have been returned, scrapped and which devices have been used.

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Transmission of this Field Action Notice:
In the event that these identified devices have been further distributed to other distributors or end users, it is requested that this Field Action Notice be provided to all other relevant organizations as soon as possible and before Wednesday, April 2, 2018.

Please confirm that this notification has been provided to these relevant organizations.

It is further requested that these organizations notify Ranfac of all product that has been used and scrapped for traceability.

Contact reference person:

Barry H. Zimble
Ranfac Corp.
30 Doherty Ave.
Avon, MA 02322
USA
(508) 588-4400

The undersign confirms that the appropriate Regulatory Agencies have been advised of this notice.

Thank you for your prompt cooperation in this matter.

Sincerely,

Barry H. Zimble

Barry H. Zimble
Executive Vice President & General Manager

cc: Emergo Europe – vigilance@emergogroup.com

Attachment

Ranfac

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CONFIRMATION FORM

Please indicate on this form the location of the devices, quantity of the devices at each location, and confirmation that this Field Action Notice has been provided.

Instructions:

- Please indicated Yes (Y) or No (N) in the "Notification Provided" column to indicate if this notification has been provided to the other relevant organizations identified in the below spreadsheet.
- Please indicate the total number returned in the column identified as "Qty Returned".
- Please indicate the total number scrapped in the column identified as "Qty Scrapped".
- Please indicate the total number used in the column identified as "Qty Used".

Catalog / Part #	Total Qty (boxes) Shipped after 21.01.18	Lot #	Location	Notification Provided	Qty Returned	Qty Scrapped	Qty Used
RSG-14-13	40	38487	Ireland				

Distributor Signature _____DATE_____

Please email back to bzimble@ranfac.com

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