Updated March 29, 2018

*By Electronic Mail*

March 28, 2018

Thomas Volder Anderson

Blue Surgical

VIRUMVEJ 64

VIRUM, DK-2830

DENMARK

**Urgent Regulatory Field Action Notice**

**Commercial name of affected products :** Blue Suture Grasper

**FSCA :-**Ranfac001

**Type of action:** Medical Device Destruction

Attention Thomas Volder Anderson,

**Details on affected devices:**

The product listed below and the subject of our “Notice to Distributors” date March 14, 2018 now needs to be Scrapped.

Blue Suture Grasper lot #38487,149 boxes shipped 1/24/18,

Blue Suture Grasper lot#39020, 13 Boxes shipped 1/24/18

Blue Suture Grasper lot#39398, 200 Boxes Shipped 2/27/18

**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.
* All product not already used must be scrapped.
* Please complete the attached Confirmation Form (Attachment 1) confirming which devices have been scrapped and which devices have been used.

**Please confirm once these devices have been scrapped.**

**Transmission of this Field Action Notice:**

Blue Surgical has indicated that these identified devices have been further distributed to other distributors or end users, as indicated in your email of March 24, 2018 in the three excel spread sheets. 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**

**CONFIRMATION FORM**

**Please indicate on this form the quantity of devices scrapped and quantity of devices used for:**

**Blue Suture Grasper lot #38487,149 boxes**

**Blue Suture Grasper lot#39020, 13 Boxes**

**Blue Suture Grasper lot#39398, 200 Boxes**

**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 scrapped in the column identified as “Qty Scrapped”.
* Please indicate the total number used in the column identified as “Qty Used”.

| Dato | Antal | Partnr | Serienr | Modtager | Reference | Notification Provided | Qty Scrapped | Qty Used |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 13-03-2018 | -10 | RSG-14-13 | 38487 | Denmark hospital | F-015574 / 2416994 |  |  |  |
| 09-03-2018 | -10 | RSG-14-13 | 38487 | Sweden Hospital | F-015530 / OR750231588 |  |  |  |
| 09-03-2018 | -10 | RSG-14-13 | 38487 | Sweden Hospital | F-015539 / OR750231684 |  |  |  |
| 09-03-2018 | -100 | RSG-14-13 | 38487 | Ireland distributor | F-015531 / PO32375 |  |  |  |
| 08-03-2018 | -10 | RSG-14-13 | 38487 | Sweden Hospital | F-015519 / OR750231330 |  |  |  |
| 06-03-2018 | -50 | RSG-14-13 | 38487 | Germany Distributor | F-015488 / 600687 |  |  |  |
| 02-03-2018 | -10 | RSG-14-13 | 38487 | Denmark hospital | F-015463 / 3400535282 |  |  |  |
| 01-03-2018 | -20 | RSG-14-13 | 38487 | Sweden Hospital | F-015458 / PR.MAIL |  |  |  |
| 28-02-2018 | -10 | RSG-14-13 | 38487 | Denmark hospital | F-015455 / 105575544 |  |  |  |
| 28-02-2018 | -20 | RSG-14-13 | 38487 | Denmark hospital | F-015446 / 3400534898 |  |  |  |
| 26-02-2018 | -150 | RSG-14-13 | 38487 | Ireland distributor | F-015424 / PO32238 |  |  |  |
| 26-02-2018 | -10 | RSG-14-13 | 38487 | Italy distributor | F-015426 / 90085814 |  |  |  |
| 23-02-2018 | -30 | RSG-14-13 | 38487 | Sweden Hospital | F-015404 / OR750229694 |  |  |  |
| 23-02-2018 | -10 | RSG-14-13 | 38487 | Sweden Hospital | F-015399 / OR750229505 |  |  |  |
| 23-02-2018 | -30 | RSG-14-13 | 38487 | Finland distributor | F-015408 / 22022018 |  |  |  |
| 21-02-2018 | -200 | RSG-14-13 | 38487 | UK Distributor | F-015392 / 7766 |  |  |  |
| 20-02-2018 | -30 | RSG-14-13 | 38487 | Sweden Hospital | F-015379 / 010-LJA 015 |  |  |  |
| 20-02-2018 | -20 | RSG-14-13 | 38487 | Sweden Hospital | F-015374 / IN180220-132 |  |  |  |
| 20-02-2018 | -20 | RSG-14-13 | 38487 | Sweden Hospital | F-015373 / ST18080118 |  |  |  |
| 15-02-2018 | -100 | RSG-14-13 | 38487 | Austria distributor | F-015350 / 3541 |  |  |  |
| 13-02-2018 | -10 | RSG-14-13 | 38487 | Sweden Hospital | F-015336 / EH5221032 |  |  |  |
| 13-02-2018 | -50 | RSG-14-13 | 38487 | Ireland distributor | F-015330 / PO32035 |  |  |  |
| 12-02-2018 | -10 | RSG-14-13 | 38487 | Denmark hospital | F-015325 / 2405449 |  |  |  |
| 08-02-2018 | -10 | RSG-14-13 | 38487 | Denmark hospital | F-015303 / 3000958094 |  |  |  |
| 08-02-2018 | -60 | RSG-14-13 | 38487 | Denmark hospital | F-015285 / 3400530145 |  |  |  |
| 08-02-2018 | -10 | RSG-14-13 | 38487 | Denmark hospital | F-015298 / 3400530726 |  |  |  |
| 06-02-2018 | -40 | RSG-14-13 | 38487 | Denmark hospital | F-015265 / 3400529723 |  |  |  |
| 30-01-2018 | -100 | RSG-14-13 | 38487 | Ireland distributor | F-015228 / PO31823 |  |  |  |
| 26-01-2018 | -200 | RSG-14-13 | 38487 | UK Distributor | F-015131 / 7733 |  |  |  |
| 26-01-2018 | -150 | RSG-14-13 | 38487 | Spain Distributor | F-015172 / PO18-00102 |  |  |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dato | Antal | Partnr | Serienr | Modtager | Reference | Notification Provided | Qty Scrapped | Qty Used |
| 14-03-2018 | -10 | RSG-14-13 | 39020 | Sweden Hospital | F-015576 / IN180313-311 |  |  |  |
| 09-03-2018 | -100 | RSG-14-13 | 39020 | Austria distributor | F-015538 / 3558 |  |  |  |
|  | 20 | RSG-14-13 | 39020 |  |  |  |  |  |

| Dato | Antal | Partnr | Serienr | Modtager | Reference | Notification Provided | Qty Scrapped | Qty Used |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 12-03-2018 | -200 | RSG-14-13 | 39398 | UK Distributor | F-015554 / 7792 |  |  |  |
|  | 1800 | RSG-14-13 | 39398 |  |  |  |  |  |

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* Please complete this Form confirming which devices have been scrapped and which devices have been used.

**Blue Surgical \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_DATE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Please email back to** **bzimble@ranfac.com**

**Thank you,**

Barry H. Zimble

Executive Vice President & General Manager