



Precision instruments for specialized applications

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.

RANFAC CORP. | PO BOX 635 | 30 DOHERTY AVE | AVON, MA 02322 | USA
Phone: 508-588-4400 | 800-272-6322 | Fax: 508-584-8588 | Email: info@ranfac.com
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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

RANFAC CORP. | PO BOX 635 | 30 DOHERTY AVE | AVON, MA 02322 | USA
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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			

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Dato	Antal	Partnr	Seriernr	Modtager	Reference	Notification Provided	Qty Scrapped	Qty Used
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	Seriernr	Modtager	Reference	Notification Provided	Qty Scrapped	Qty Used
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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					

- 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.
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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