

URGENT: FIELD SAFETY NOTICE

Velosorb Fast Surgical Suture 20200803

6 August, 2020

Dear Customer:

This is to inform you of a field safety corrective action (FSCA) involving Velosorb Fast Surgical Suture used in soft tissue approximation of the skin and mucosa. Product was distributed on July 8, 2020.

Product information is provided below:

PN	Item	Lot#
CV1213	Covidien Velosorb 5/0 Undyed 30" CV-23 Taper	20052817X
CV2279	Covidien Velosorb 4/0 Undyed 30" KV-15 TaperCutting	20060928X
CV2293	Covidien Velosorb 5/0 Undyed 30" KV-11 TaperCutting	20060118X
CV3100	Covidien Velosorb 4/0 Undyed 30" CV-25 Taper	20052720X
CV3110	Covidien Velosorb 3/0 Undyed 30" CV-25 Taper	20061108X
CV3110	Covidien Velosorb 3/0 Undyed 30" CV-25 Taper	20051916X
CV416G	Covidien Velosorb 3/0 Undyed 30" V-20 Taper	20052815X
CV417G	Covidien Velosorb 2/0 Undyed 30" V-20 Taper	20051406X
CV4731	Covidien Velosorb 0 Undyed 36" GS-11 Cutting	20060204X
CV486	Covidien Velosorb 1 Undyed 36" GS-12 Cutting	20052102X
CV604	Covidien Velosorb 0 Undyed 36" GS-25	20060812X
CV605	Covidien Velosorb 1 Undyed 36" GS-25	20060201X
CV605	Covidien Velosorb 1 Undyed 36" GS-25	20060927X
CV916	Covidien Velosorb 3/0 Undyed 36" KV-34 TaperCutting	20060120X
CV919	Covidien Velosorb 0 Undyed 36" KV-34 TaperCutting	20051311X
CV946	Covidien Velosorb 0 Undyed 36" GS-21 Taper	20060203X
CV947	Covidien Velosorb 1 Undyed 36" GS-21 Taper	20052816X
CV9975G	Covidien Velosorb 2/0 Undyed 30" GS-20	20060930X
SV2239	Covidien Velosorb 3/0 Undyed 30" SC-1	20052701X
SV2294	Covidien Velosorb 4/0 Undyed 30" C-12 Cutting	20051405FX
SV2295	Covidien Velosorb 3/0 Undyed 30" C-12 Cutting	20060202FX
SV2298	Covidien Velosorb 3/0 Undyed 30" C-13 Cutting	20061715FX
SV32	Covidien Velosorb 6/0 VL 18" P-10	20052702FX
SV426	Covidien Velosorb 4/0 Undyed 30" P-12 Cutting	20061012FX
SV426	Covidien Velosorb 4/0 Undyed 30" P-12 Cutting	20060813FX
SV426	Covidien Velosorb 4/0 Undyed 30" P-12 Cutting	20051216FX
SV487G	Covidien Velosorb 3/0 Undyed 30" PC-11	20060814X
SV4893	Covidien Velosorb 6/0 Undyed 30" P-10 Cutting	20052703FX
SV496	Covidien Velosorb 4/0 Undyed 18" P-12 Cut	20060116FX
SV496G	Covidien Velosorb 4/0 Undyed 18" P-12 Cutting	20052721FX



SV497G	Covidien Velosorb 3/0 Undyed 18" P-12 Cutting	20060929FX
SV6830	Covidien Velosorb 3/0 Undyed 18" P-14 Cutting	20051814FX
SV835G	Covidien Velosorb 4/0 Undyed 18" PC-10	20060119X
SV935	Covidien Velosorb 3/0 Undyed 30" P-14 Cutting	20061504FX
SV935	Covidien Velosorb 3/0 Undyed 30" P-14 Cutting	20051215FX
SV9911G	Covidien Velosorb 4/0 Undyed 18" P-24	20051815FX
SV9913	Covidien Velosorb 6/0 Undyed 18" P-10 Cutting	20050709FX
SVP2251	Covidien Velosorb 4/0 Undyed 30" P-14	20060117FX
SVP2294	Covidien Velosorb 4/0 Undyed 30" P-11	20052017FX
SVP2295	Covidien Velosorb 3/0 Undyed 30" P-11	20060205FX

See enclosed product label. Suture packs with lot numbers not listed in the table above are not affected by this recall.

Reason for the FSCA:

Riverpoint Medical is performing a product removal of Velosorb Fast Surgical Suture. The product involved in this removal is non-sterile. Product pallets labeled “non-sterile” were inadvertently shipped to the Riverpoint Medical customer. To date, Riverpoint Medical has received no complaints or adverse effects noted during surgical use of the device.

Risk to Health:

Use of a non-sterile suture could compromise the sterile field, increase risk of a surgical site infection, and increase break strength retention. Prompt surgical site follow-up is recommended to reduce the risk of potentially severe complications.

Actions to be taken by the Customer:

Customers who received the product listed above should:

- Immediately examine your inventory and quarantine product subject to the FSCA.
- Discontinue selling product listed above and return any existing stock to Riverpoint Medical.
- Complete and return the enclosed response form as soon as possible to quality@rpmed.com. Mark the return shipments with RGA#010820VZB.
- Provide recall information to any customers to whom you may have distributed or forwarded affected product. You may include a copy of this recall notice with your customer notification.

If you have any questions, call Riverpoint Medical at (503) 517-8001.

Other Information:

This FSCA has been notified to the appropriate Competent Authorities.

Thank you for your assistance in the matter.

6 August, 2020

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Label Images





Acknowledgement Letter

**Riverpoint Medical 20200803 FSN Return Response
Acknowledgment and Receipt Form**

Customer Name: _____

Customer Address: _____

PN	Item	Lot#	Box_QTY	each	Box QTY Returned
CV1213	Covidien Velosorb 5/0 Undyed 30" CV-23 Taper	20052817X	33	3DZ.	
CV2279	Covidien Velosorb 4/0 Undyed 30" KV-15 TaperCutting	20060928X	33	3DZ.	
CV2293	Covidien Velosorb 5/0 Undyed 30" KV-11 TaperCutting	20060118X	34	3DZ.	
CV3100	Covidien Velosorb 4/0 Undyed 30" CV-25 Taper	20052720X	170	3DZ.	
CV3110	Covidien Velosorb 3/0 Undyed 30" CV-25 Taper	20061108X	220	3DZ.	
CV3110	Covidien Velosorb 3/0 Undyed 30" CV-25 Taper	20051916X	238	3DZ.	
CV416G	Covidien Velosorb 3/0 Undyed 30" V-20 Taper	20052815X	256	DZ.	
CV417G	Covidien Velosorb 2/0 Undyed 30" V-20 Taper	20051406X	464	DZ.	
CV4731	Covidien Velosorb 0 Undyed 36" GS-11 Cutting	20060204X	34	3DZ.	
CV486	Covidien Velosorb 1 Undyed 36" GS-12 Cutting	20052102X	34	3DZ.	
CV604	Covidien Velosorb 0 Undyed 36" GS-25	20060812X	33	3DZ.	
CV605	Covidien Velosorb 1 Undyed 36" GS-25	20060201X	49	3DZ.	
CV605	Covidien Velosorb 1 Undyed 36" GS-25	20060927X	85	3DZ.	
CV916	Covidien Velosorb 3/0 Undyed 36" KV-34 TaperCutting	20060120X	34	3DZ.	
CV919	Covidien Velosorb 0 Undyed 36" KV-34 TaperCutting	20051311X	85	3DZ.	
CV946	Covidien Velosorb 0 Undyed 36" GS-21 Taper	20060203X	34	3DZ.	
CV947	Covidien Velosorb 1 Undyed 36" GS-21 Taper	20052816X	85	3DZ.	
CV9975G	Covidien Velosorb 2/0 Undyed 30" GS-20	20060930X	102	DZ.	
SV2239	Covidien Velosorb 3/0 Undyed 30" SC-1	20052701X	33	3DZ.	
SV2294	Covidien Velosorb 4/0 Undyed 30" C-12 Cutting	20051405FX	151	3DZ.	
SV2295	Covidien Velosorb 3/0 Undyed 30" C-12 Cutting	20060202FX	51	3DZ.	
SV2298	Covidien Velosorb 3/0 Undyed 30" C-13 Cutting	20061715FX	255	3DZ.	
SV32	Covidien Velosorb 6/0 VL 18" P-10	20052702FX	34	3DZ.	
SV426	Covidien Velosorb 4/0 Undyed 30" P-12 Cutting	20061012FX	207	3DZ.	
SV426	Covidien Velosorb 4/0 Undyed 30" P-12 Cutting	20060813FX	33	3DZ.	
SV426	Covidien Velosorb 4/0 Undyed 30" P-12 Cutting	20051216FX	238	3DZ.	



SV487G	Covidien Velosorb 3/0 Undyed 30" PC-11	20060814X	100	DZ.	
SV4893	Covidien Velosorb 6/0 Undyed 30" P-10 Cutting	20052703FX	34	3DZ.	
SV496	Covidien Velosorb 4/0 Undyed 18" P-12 Cut	20060116FX	68	3DZ.	
SV496G	Covidien Velosorb 4/0 Undyed 18" P-12 Cutting	20052721FX	103	DZ.	
SV497G	Covidien Velosorb 3/0 Undyed 18" P-12 Cutting	20060929FX	103	DZ.	
SV6830	Covidien Velosorb 3/0 Undyed 18" P-14 Cutting	20051814FX	85	3DZ.	
SV835G	Covidien Velosorb 4/0 Undyed 18" PC-10	20060119X	103	DZ.	
SV935	Covidien Velosorb 3/0 Undyed 30" P-14 Cutting	20061504FX	289	3DZ.	
SV935	Covidien Velosorb 3/0 Undyed 30" P-14 Cutting	20051215FX	271	3DZ.	
SV9911G	Covidien Velosorb 4/0 Undyed 18" P-24	20051815FX	102	DZ.	
SV9913	Covidien Velosorb 6/0 Undyed 18" P-10 Cutting	20050709FX	220	3DZ.	
SVP2251	Covidien Velosorb 4/0 Undyed 30" P-14	20060117FX	34	3DZ.	
SVP2294	Covidien Velosorb 4/0 Undyed 30" P-11	20052017FX	51	3DZ.	
SVP2295	Covidien Velosorb 3/0 Undyed 30" P-11	20060205FX	34	3DZ.	

Has the customer read and understood the recall instructions provided in the letter dated 6 August 2020?

YES NO

Were there any adverse events associated with the recall product?

YES NO

If Yes, Please explain:

Please fill out the return quantity in the table above.

Customer Representative <Print> Customer Representative <Sign> Title Date