

**URGENT: MEDICAL DEVICE RECALL (REMOVAL)**  
**VICRYL Suture, VICRYL Plus Suture, PDS Suture and PDS Plus Suture Products**  
**(Multiple Product Codes/Lot Numbers)**

March 13, 2019

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery:

Ethicon has initiated a voluntary recall (removal) of specific product codes and lots of **VICRYL Suture, VICRYL Plus Suture, PDS Suture and PDS Plus Suture Products**, as listed in the table below. The lots and codes above may contain product that does not match the sales unit carton and foil label. The mixed suture may be a different size or type than indicated on the label. The physical product inside the suture tray matches the product noted on the lid of the tray inside the foil pouch.

**EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT LOTS BELONGING TO VICRYL Suture, VICRYL Plus Suture, PDS Suture and PDS Plus Suture Products (ONLY SPECIFIC LOT BELOW). REFER TO ACTION REQUIRED FOR FURTHER INSTRUCTIONS:**

PRODUCT NAME	DESCRIPTION/SIZE	PRODUCT CODE	PRODUCT LOT
PDS PLUS Suture	PDSPLUS VIO 8X45 M3.5 CT-1 CR	PDP740Z	MHK321
	PDSPLUS VIO 8X45 M2 CP-2 CR	PDP761Z	MJZ670
	PDSPLUS VIO 8X45 M3 CP-2 CR	PDP762D	MHZ077
	PDSPLUS VIO 8X45 M1.5 SH-1 CR	PDP771Z	MGK883
			MKZ732
	PDSPLUS VIO 8X45 M1.5 SH CR	PDP773Z	MKZ578
	PDSPLUS VIO 8X45 M2 SH CR	PDP774Z	ME6981
	PDSPLUS VIO 8X45 M3.5 CTB-1 CR	PDPB740Z	MJM347
	PDSPLUS VIO 8X45 M3 SHB CR	PDPB775Z	MGK709
	PDSPLUS VIO 8X45 M3.5 CTXB CR	PDPB776Z	MHK366
PDS Suture	PDSPLUS VIO 8X45 M3 CTB-2 CR	PDPB9928Z	MH6730
	PDSII MONO VIO	D10056	MGZ487
	PDS*II VIOLET MONO	D10063	MG6867
	PDS II SUTURE 18"(45CM) 3-0 VIO	D7725	MKZ458
	PDS II SUTURE 27"(70CM) 4-0 VIO	D8461	MKM099
	PDS II SUTURE 18"(45CM) 2-0 VIO	Z739D	MGM110
		Z712Z	MGZ637
		Z771Z	MGM777



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			MK5092
			MK6777
			MKK001
			MKM109
	PDS II SUTURE 8-18" (45CM) 0 VIO	ZB750Z	MJ6626
Vicryl Plus Suture	VCL+ UD 8X18IN 1 S/A CTB-1 CR	VCPB841Z	MG2588
			MH2687
	VCL+ VIO 8X18IN 1 S/A CTX CR	VCP765Z	MJK812
	VCL+ VIO 8X18IN 3-0 S/A RB-1 CR	VCP713Z	MJM545
	VCL+ VIO 8X18IN 3-0 S/A SH CR	VCP774Z	MH2283
	VCL+ VIO 8X18IN 3-0 S/A X-1 CR	VCP790Z	MHM862
	VICRYL PLUS SUTURE 18"(45CM) 0 UND	VCP724D	MJM852
		VCPB724Z	MGM632
		VCPB840Z	MJZ668
	VICRYL PLUS SUTURE 18"(45CM) 0 VIO	VCP727D	MH2267
		VCP740D	MH2821
		VCP752DCN	MEK088
			MGM249
			MGM428
			MGZ565
			MHM580
			MHM670
			MJ5257
			MJM345
			MJM949
			MKM319
			MLM986
	VICRYL PLUS SUTURE 18"(45CM) 1 UND	VCP841D	MG2339
		VCPB725D	MHZ771
		VCPB725Z	MGK913
			MJM549
VICRYL PLUS SUTURE 18"(45CM) 1 VIO	VCP753D	MGM113	
VICRYL PLUS SUTURE 18"(45CM) 2-0 UND	VCP762D	MGK480	
		MK5042	
		MKK981	
	VCP839D	ME2930	
		MK2929	

			ML7047
		VCP726D	MG2667
		VCP751DCN	MGM435
			MHZ913
			ML5846
			ML6940
			MLK806
			MMM159
		VCP775D	ML2512
		VICRYL PLUS SUTURE 18"(45CM) 3-0 UND	VCP864D
			MK2923
			MKZ730
		VCPB864Z	MM6491
		VICRYL PLUS SUTURE 18"(45CM) 3-0 VIO	VCP713D
			MJ6586
			VCP738D
			MJ7656
			MM2920
			MG7595
			MH2680
			MH2706
			MJ7608
			MK2968
			MM2283
			MM2309
		VCP772Z	MH2256
			MK2943
		VICRYL PLUS SUTURE 18"(45CM) 4-0 UND	VCP714D
			MJZ386
			VCP714Z
		VICRYL PLUS SUTURE 18"(45CM) 4-0 VIO	MGK613
			MEK354
			MEK713
			MGM845
			MGM903
			MH6853
			MHK620
			MJM459
			MJM522
			MJZ381
		VCP773D	MGZ815
			MM6814

		VICRYL PLUS SUTURE 27"(70CM) 0 UND	VCPP41D	MK6415
				ML5418
		VICRYL PLUS SUTURE 27"(70CM) 2-0 UND	VCPP42D	MG6757
		VICRYL PLUS SUTURE 27"(70CM) 2-0 VIO	VCP785D	MK6998
		VICRYL PLUS SUTURE 27"(70CM) 3-0 VIO	VCP784D	ME5053
				MEK314
				MJM663
		VICRYL PLUS VL BR 18	D10083	MLK269
		VICRYL SUT 18IN(45CM) 4-0 VIO	VCP771ZCC	MKM347
				ML5031
				MLM281
VICRYL Suture	COATED VICRYL SIZE 3-0 VIOLET 8X18" SH CONTROL RELEASE	J774Z		MGZ447
				MHZ850
				MJK246
				MJZ255
				ML5160
	VCL CT UD 8X18IN 1 S/A CT-1 CR	J841D		MEK194
				MGK749
				MMM998
	VCL CT UD 8X18IN 2-0 S/A CP-2 CR	J762D		MJZ094
				MLZ026
	VCL CT UD 8X18IN 3-0 S/A SH CR	J864D		MEK524
				MGZ556
				MHZ379
				MHZ475
				MJK262
	VCL CT UD 8X18IN 4-0 S/A RB-1 CR	J714Z		MGM427
				MHM437
				MKM951
				ML5552
				MMK560
	VCL CT VIO 8X18IN 0 S/A CT CR	J752Z		MGZ129
	VCL CT VIO 8X18IN 3-0 S/A RB-1 CR	J713Z		MJK054
				MKZ237
				MLK164
	VCL CT VIO 8X18IN 3-0 S/A SH-1 CR	J772D		MHZ196
	VCL CT VIO 8X18IN 4-0 S/A SH-1 CR	J771Z		MEK056

			MGM463
			MH6722
			MJ5357
			MJZ980
			MK6618
			MKK504
			MKM463
			MKM465
			ML5428
			ML5788
			MMZ654
	VCL CT VIO 8X18IN 4-0 S/A TF CR	J743Z	MHK791
			MMM333
	VCL CT VIO 8X27IN 3-0 S/A SH CR	J784V	MGK078
	VICRYL CT UD 8X18IN 0 S/A CT-1 CR	J840D	MEK770
			MGK812
			MJK773
			MM6633
	VICRYL CT UD 8X18IN 2-0 S/A CT-1 CR	J839D	MG2349
			MG2593
			MG2666
			MG7585
			MK2820
	VICRYL CT UD 8X27IN 0 S/A CT-1 CR	JJ41G	ME5281
			MGZ466
			MGZ563
			MHK212
	VICRYL CT VIO 8X18IN 0 S/A CT-1 CR	J740D	ME6539
			MJM523
	VICRYL CT VIO 8X18IN 2-0 S/A SH CR	J775D	MLZ864
	VICRYL CT VIO 8X27IN 0 S/A CT-1 CR	JJ31G	MJK828
		JB724	MEK410
	VICRYL SUTURE 18"(45CM) 0 UND	JB840	MEK959
			MGM275
			MGM643
			MM6544
	VICRYL SUTURE 18"(45CM) 0 VIO	D6043	MKM683

			ML5314
		J701D	MJ6796
		J727D	MHZ777
		VICRYL SUTURE 18"(45CM) 1 UND	JB725
		VICRYL SUTURE 18"(45CM) 1 VIO	MEZ999
			MGZ624
		VICRYL SUTURE 18"(45CM) 2-0 UND	MJ5193
			MJM912
		VICRYL SUTURE 18"(45CM) 2-0 VIO	D6226
			D9142
			MKK700
			J726D
		J739D	ME5454
			MGZ324
		VICRYL SUTURE 18"(45CM) 3-0 VIO	MJM399
			J713D
			MGK411
			MHZ574
			MJK204
			MJM181
			MJZ973
			MK6914
			MKK571
			ML5676
			MLZ621
			MMK185
		VICRYL SUTURE 18"(45CM) 4-0 UND	J714D
			ME5059
		VICRYL SUTURE 27"(70CM) 0 VIO	MKM907
		VICRYL SUTURE 27"(70CM) 1 UND	JJ81G
		VICRYL SUTURE 8-18" (45CM) 1 VIO	JJ40G
		VICRYL UND 8X45CM	ME6809
		VICRYL VIO 6X45CM	JB753Z
		VICRYL VIO 8X45CM	MLM422
			8PB2643YD
			MGZ072
			V703D
			MMK012
			V797D
			MGZ085

This voluntary recall (removal) does NOT affect any other product codes or lots for VICRYL Suture, VICRYL Plus Suture, PDS Suture and PDS Plus Suture Products.

Our records indicate that you may have ordered or received product subject to this recall (removal). The product families include Coated VICRYL® (polyglactin 910) Suture, Coated VICRYL® Plus Antibacterial (polyglactin 910) Suture, PDS® (polydioxanone) Suture and PDS® Plus Antibacterial (polydioxanone) Suture. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE VICRYL Suture, VICRYL Plus Suture, PDS Suture and PDS Plus Suture Products.**



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If the mix results in the incorrect suture being used, the tensile strength or absorption profile may be inadequate for the procedure. Suture breakage could occur during surgery or post operation. Intra operative suture breakage requires an alternative device to be used to complete the procedure. If suture breakage occurs post operation prior to complete wound healing, wound dehiscence and impaired healing may happen, requiring additional surgical and/or medical intervention to prevent further injury or permanent impairment of body structure/function.

To date, Ethicon has not received any reports of adverse events associated with the issue that led to this recall (removal). Health care practitioners who have treated patients using **VICRYL Suture, VICRYL Plus Suture, PDS Suture and PDS Plus Suture Products** should follow those patients post-operatively in the usual manner with no additional action required.

We have identified the root cause and we have implemented immediate corrective actions to address the issue.

Refer to Attachment 1 for assistance in identifying the product lot subject to this recall (removal).

This voluntary medical device recall (removal) has been communicated to the Health Sciences Authority (HSA).

#### **IDENTIFICATION OF PRODUCT SUBJECT TO THIS RECALL (Removal):**

**Product subject to the recall (removal) in your inventory can be identified by product code and lot number (see product code listing above). All unused VICRYL Suture, VICRYL Plus Suture, PDS Suture and PDS Plus Suture product subject to this recall (removal) are required to be returned. The product code and lot number can be determined by using the Product Identification Tool attached at Attachment 1.**

#### **ACTION REQUIRED:**

1. Examine your inventory immediately to determine if you have product subject to this recall (removal) on hand and quarantine such product(s).
2. Remove the product subject to this voluntary recall (removal) and communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed. Do not open foil pouches to confirm contents.
3. If any product subject to this recall (removal) has been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this recall (removal) letter when communicating.
4. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and hand it to your Ethicon Sales Representative within three (3) business days. **Please return the BRF even if you do not have product subject to this recall (removal).**

5. Keep this notice visibly posted for awareness until all product subject to this recall (removal) has been returned to Johnson & Johnson Medical Singapore. While processing your returns, please maintain a copy of this notice with the product subject to this recall (removal) and keep a copy for your records.
6. Customers are required to return unused impacted **VICRYL Suture, VICRYL Plus Suture, PDS Suture and PDS Plus Suture Products** subject to this recall (removal) that are in their inventory immediately. To receive replacement product, customers must return product subject to this recall (removal) by July 31, 2019. **Any non-affected product and any product returned after the date specified will not be replaced.**
7. To return product subject to this recall (removal), please contact your Ethicon Sales Representative.

If you require any assistance with returning product, please contact your Ethicon Sales Representative.

We recognize the recall (removal) of the **VICRYL Suture, VICRYL Plus Suture, PDS Suture and PDS Plus Suture Products** may be disruptive to your facility and we apologize for any inconvenience this may cause.

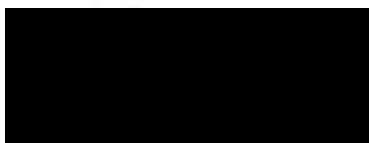
If you have additional questions regarding this recall (removal) or to report any customer complaints, please contact your Ethicon Sales Representative.

**Attachments:**

Attachment 1: Product Identification Tool

Attachment 2: Business Reply Form

Yours sincerely,



Lee Ching Hwee  
Manager, Regulatory Affairs

cc: Chairman Medical Board  
Relevant Head of Departments



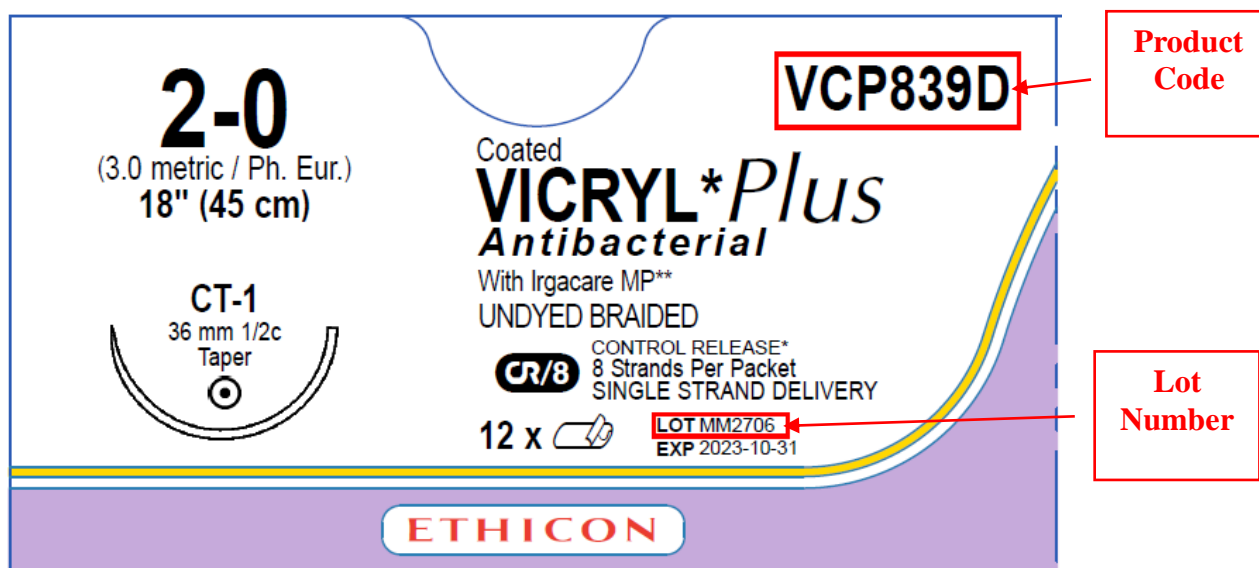
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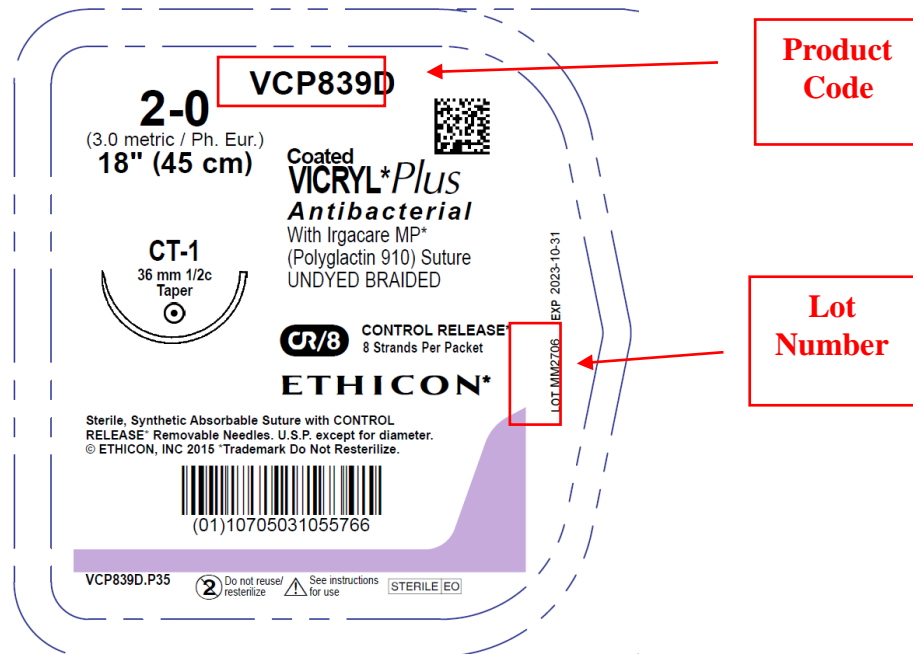
## ATTACHMENT 1: Product Identification Tool for VICRYL Suture, VICRYL Plus Suture, PDS Suture and PDS Plus Suture Products

This tool will help customers identify the impacted product subject to this recall (removal). This document applies to the sales unit carton and foil packaging for specific product codes and lots for VICRYL Suture, VICRYL Plus Suture, PDS Suture and PDS Plus Suture Products. While the labeling below is an example and is representative of an impacted product code/lot, sutures within each product family have very similar labeling and the product codes and lot numbers can be identified using the same images below.

### FRONT OF SALES UNIT CARTON (Representative Sample)



**FOIL PACKAGE (Representative Sample)**



## ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Complete this form and hand it to your Ethicon Sales Representative within three (3) business days. **Please return the BRF even if you do not have product subject to this recall (removal).**

If you have product subject to this recall (removal) to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

### Product Inventory – *please check one*

- ☐ We have **NO** VICRYL Suture, VICRYL Plus Suture, PDS Suture and PDS Plus Suture Products subject to this recall (removal).
- ☐ We have VICRYL Suture, VICRYL Plus Suture, PDS Suture and PDS Plus Suture Products subject to this recall (removal) and are returning the following products:

Product Code	Lot #	Quantity Returning (Eaches) <sup>1</sup>	Produce Code	Lot #	Quantity Returning (Eaches) <sup>1</sup>

<sup>1</sup>Note: Each Sales Unit Box contains (3) eaches / devices.

Print Name of Person Completing Business Reply Form:	Sign & Date:
Customer Account Details (Name and Address)	