

URGENT: FIELD SAFETY NOTICE

PDS® Plus Antibacterial Sutures
(Multiple Product Codes and Lot Numbers)

2 January, 2020

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

Ethicon have initiated a voluntary field notification regarding an Instructions for Use (IFU) leaflet not intended for Canada for the following product codes and associated lots, listed in Attachment 2, of PDS Plus Antibacterial Sutures. Through internal processes, Ethicon have identified certain product codes and lot numbers were distributed with IFUs that are not approved by Health Canada. The IFU includes an indication for the use in paediatric tissue. In Canada, PDS Plus Antibacterial Sutures are NOT indicated for use in paediatric tissue.

Ethicon is requesting that you review your inventory of this product to determine if you have impacted product. If you have impacted product, please reach out to your Ethicon sales representative for the correct Instructions for Use.

There is no product quality issue with the sutures and Ethicon has not received any reports of Adverse Events or Injuries related to this issue.

The scope of this notification includes 15 product codes and associated lots of PDS Plus Antibacterial Sutures listed in Attachment 2.

ACTION REQUIRED:

1. Ethicon is requesting that you examine your inventory to determine if you may have impacted product. Refer to Attachment 2 for the impacted product codes and lot numbers.
2. If any product subject to this notification has been forwarded to another facility, contact that facility to make the facility aware of the notification.
3. Complete the attached business reply form of this notice and hand it to your Ethicon sales representative within (3) business days.

If you have additional questions regarding this notification or to report any customer complaints, please contact your Ethicon sales representative.

Attachments:

Attachment 1: Business Reply Form

Attachment 2: List of product code & lot number

Yours sincerely,



Lee Ching Hwee
Manager, Regulatory Affairs

cc: Chairman Medical Board
Relevant Head of Departments

ATTACHMENT 1: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete this form and hand it to your Ethicon sales representative **within 3 business days**.

☐ I have read and understand the notification

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

Attachment 2: List of product code & lot numbers:

PRODUCT CODE	PRODUCT LOT
PDP304H	MMM208
	PAM282
	PC6658
	PEM983
	PGZ017
	PHZ969
	PJZ608
	PAK772
	PE5342
	PGK276
PDP315H	PDK455
PDP317H	PA6871
	PCK875
	PCZ062
	PGK005
	PGM938
	PH6807
PDP332H	MGZ322
	PAK593
PDP333H	MP6381
	PAK319
	PCZ127
PDP334H	MAM048
PDP338H	PBZ987

PRODUCT CODE	PRODUCT LOT
PDP346H	MBZ550
	MDM001
	MEK832
	MG5271
	MGZ523
	MKK696
	MLK346
	MMZ390
	PA5376
	PCK918
	PEK308
	PGZ096
PDP347H	MAK267
PDP352H	MPZ801
	PKK172
PDP371T	MAM124
	MAZ999
	MCM417
	MCZ883
	MDM597
	MDZ562
	MEM199
	MEZ181
	MG5024
	MGZ404
	MHM842
	MHZ827
	MJK774
	MJZ720
	ML5722
	ML5914

PRODUCT CODE	PRODUCT LOT
PDP371T	MMK132
	MMZ216
	MMZ486
	PA6616
	PAK580
	PC6701
	PCZ824
	PDK043
	PDK456
	PDM101
	PGZ544
	PGZ971
	PH6665
	PHK330
	PJM557
	PKZ926
PDP443H	PB5163
	PBU274
PDP463G	MMM223
PDP990G	PCK503
	PCM307
	PCZ071
	PCZ548
	PDM488
	PE5848
	PEK150
	PEK590
PDP990G	PGK624
	PHM764
	PJZ387

PRODUCT CODE	PRODUCT LOT
PDP991G	MAK599
	MAM448
	MC6737
	MD6700
	MEK931
	MEM239
	MH6538
	MJ5381
	MJZ645
	MKK883
	ML5925
	ML6600
	PA6475
	PBM178
	PC6801
	PCM155
	PGZ005
	PHM817
	PJZ335