

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

D-Special Product Codes of PROLENE® Polypropylene Suture
and D-Special PRONOVA® Poly (Hexafluoropropylene - VDF) Suture
(D-Special Product Codes D10027, D10031, D5981, D5988, D6416, D7748,
D7768, D7879, D8292, D8647, D8881, D9067, D9662, D9746, D9844, D9995,
DC631)

May 10, 2019

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

**PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY
WHO USE D-Special Product Codes of PROLENE® Polypropylene Non-Absorbable
Suture and PRONOVA® Poly (Hexafluoropropylene - VDF) Suture**

At Ethicon, Inc. ("Ethicon"), our first priority is to our customers and their patients, and that includes the safe and effective use of our products.

Ethicon Inc., ("Ethicon") has initiated a medical device recall (removal) of the D-Special product codes of PROLENE® Polypropylene Suture and D-Special PRONOVA® Poly (Hexafluoropropylene - VDF) Suture listed in the table below. The needle associated with these certain suture product codes has the potential to perforate the packaging due to a packaging design issue. This issue pertains specifically to the D-Special codes referenced below and is bounded to an expiration date period from 3/31/2021 to 2/28/2023.

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT CODES:

PRODUCT NAME	PRODUCT CODE	EXPIRY DATE	DESCRIPTION/SIZE
D-Special PROLENE® Polypropylene Suture	DC631	3/31/2021 to 2/28/2023	PROLENE® SUTURE BLUE 18" 7-0 D/A BV-1 Taper Point 3/8C
D-Special PROLENE® Polypropylene Suture	D5981	3/31/2021 to 2/28/2023	PROLENE® SUTURE BLUE 4X90CM M1.5 USP 4/0 DA RB-1 +P
D-Special PROLENE® Polypropylene Suture	D5988	3/31/2021 to 2/28/2023	PROLENE® SUTURE 4-36"(90CM) 4-0 BLUE BB Taper Point 3/8C
D-Special PROLENE® Polypropylene Suture	D6416	3/31/2021 to 2/28/2023	PROLENE® SUTURE 4-36" (90CM) 3-0 BLUE SH Taper Point 1/2C
D-Special PROLENE® Polypropylene Suture	D7748	3/31/2021 to 2/28/2023	PROLENE® SUTURE 30"(75CM) 4-0 BLUE SH-1 Taper Point 1/2C



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PRODUCT NAME	PRODUCT CODE	EXPIRY DATE	DESCRIPTION/SIZE
D-Special PROLENE® Polypropylene Suture	D7768	3/31/2021 to 2/28/2023	PROLENE® SUTURE 36"(90CM) 4-0 BLUE SH-1 Taper Point 1/2C
D-Special PROLENE® Polypropylene Suture	D7879	3/31/2021 to 2/28/2023	PROLENE® SUTURE BLUE 4X18"5/0 DA RB-2 +PLG
D-Special PROLENE® Polypropylene Suture	D8292	3/31/2021 to 2/28/2023	PROLENE® SUTURE 30"(75CM) 8-0 BLUE BV175-6 Taper Point 3/8C
D-Special PROLENE® Polypropylene Suture	D8647	3/31/2021 to 2/28/2023	PROLENE® SUTURE 30"(75CM) 6-0 BLUE C-1 Taper Point 3/8C
D-Special PROLENE® Polypropylene Suture	D8881	3/31/2021 to 2/28/2023	PROLENE® SUTURE 24"(60CM) 7-0 BLUE BV-1 Taper Point 3/8C
D-Special PROLENE® Polypropylene Suture	D9067	3/31/2021 to 2/28/2023	PROLENE® SUTURE 36"(90CM) 4-0 BLUE SH Taper Point 1/2C
D-Special PROLENE® Polypropylene Suture	D9662	3/31/2021 to 2/28/2023	PROLENE® SUTURE 4"(10CM) 8-0 BLUE BV130-5 Taper Point 3/8C
D-Special PROLENE® Polypropylene Suture	D9746	3/31/2021 to 2/28/2023	PROLENE® SUTURE BLUE 48" 4-0 D/A SH-1 Taper Point 1/2C
D-Special PROLENE® Polypropylene Suture	D9844	3/31/2021 to 2/28/2023	PROLENE® SUTURE 36"(90CM) 3-0 BLU SH-1 Taper Point 1/2C
D-Special PROLENE® Polypropylene Suture	D9995	3/31/2021 to 2/28/2023	PROLENE® SUTURE MONO BLUE BV1755 Taperpoint 3/8C
D-Special PROLENE® Polypropylene Suture	D10031	3/31/2021 to 2/28/2023	PROLENE® SUTURE MONO BLUE - BV1755 Taper Point 3/8C
D-Special PRONOVA® Poly (Hexafluoropropylene - VDF) Suture	D10027	3/31/2021 to 2/28/2023	PRONOVA® SUTURE BLUE MONO POLY - SH-1 Taperpoint 1/2C

Please be aware that a perforated package has the potential to cause a soft tissue injury to a healthcare professional handling the subject product or a patient infection due to a breach of sterility within the packaging if it goes unnoticed by the healthcare professional.

To date, Ethicon has not received any reports of Adverse Events associated with the product subject to this recall (removal).

Health care professionals that have treated patients using the product codes of the D-Special PROLENE® Polypropylene Suture and D-Special PRONOVA® Poly (Hexafluoropropylene - VDF) Suture listed above subject to this recall should continue to follow those patients post-operatively in the usual manner.

At Ethicon, our first priority is to our customers and their patients, and that includes the safe and effective use of our products.

IDENTIFICATION OF PRODUCT SUBJECT TO THIS RECALL (REMOVAL):

Product subject to the recall (removal) in your inventory can be identified by product code and expiry date (see product code listing above). All unused D-Special PROLENE® Polypropylene Suture & D-Special PRONOVA® Poly (Hexafluoropropylene - VDF) Suture products subject to this recall (removal) are required to be returned. The D-Special product codes can be determined by using the Product Identification Tool within 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 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.
3. If any product subject to this recall (removal) has been forwarded to another facility, contact that facility to arrange return.
4. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and return 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 your Ethicon Sales Representative. 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 all unused D-Special PROLENE® Polypropylene Suture & D-Special PRONOVA® Poly (Hexafluoropropylene - VDF) Suture product subject to this recall (removal) returned by September 21, 2018 will be eligible for credit reimbursement. Any product subject to this recall (removal) returned after September 21, 2018 will not be eligible for credit reimbursement.
7. To return product subject to this recall (removal), photocopy the completed BRF, place it in the box with the product, and return to 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 D-Special PROLENE® Polypropylene Suture & D-Special PRONOVA® Poly (Hexafluoropropylene - VDF) Suture 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.



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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

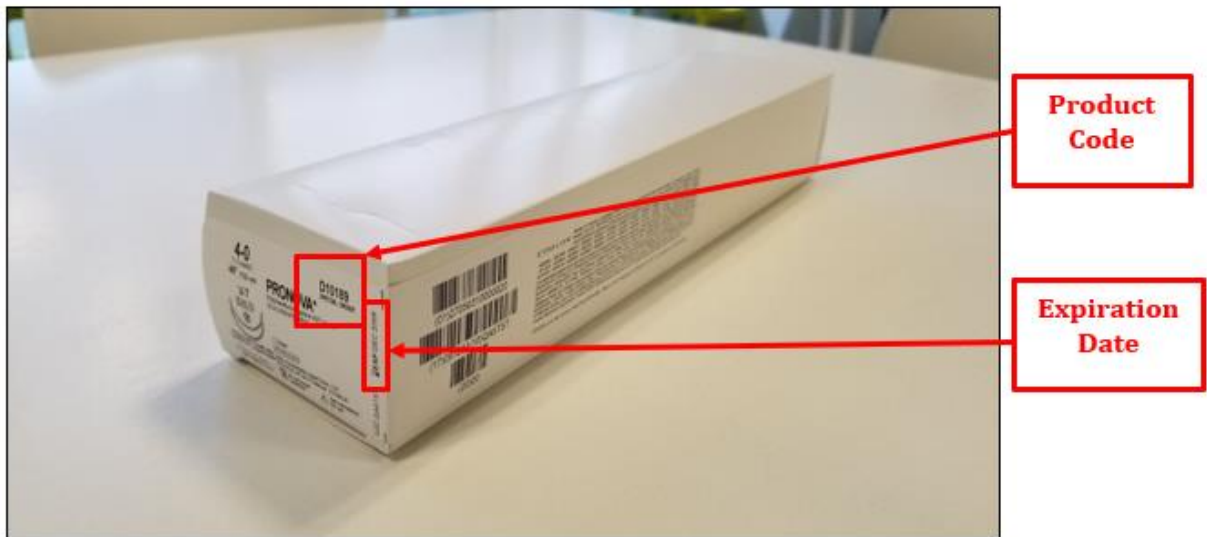
ATTACHMENT 1: Product Identification Tool for D-Special PROLENE™ Polypropylene Non-Absorbable Suture & D-Special PRONOVA™ Suture

This tool will help customers identify the product subject to this recall (removal) by using the package labels. While the pictures below are in reference to the D-Special PRONOVA® Poly (Hexafluoropropylene - VDF) Suture, the packaging is congruent for the D-Special PROLENE® Polypropylene Suture.

Please note: The labels listed below are used for illustration purposes only. Refer to the table listed above for a list of product codes and associated expiration dates subject to this recall (removal).

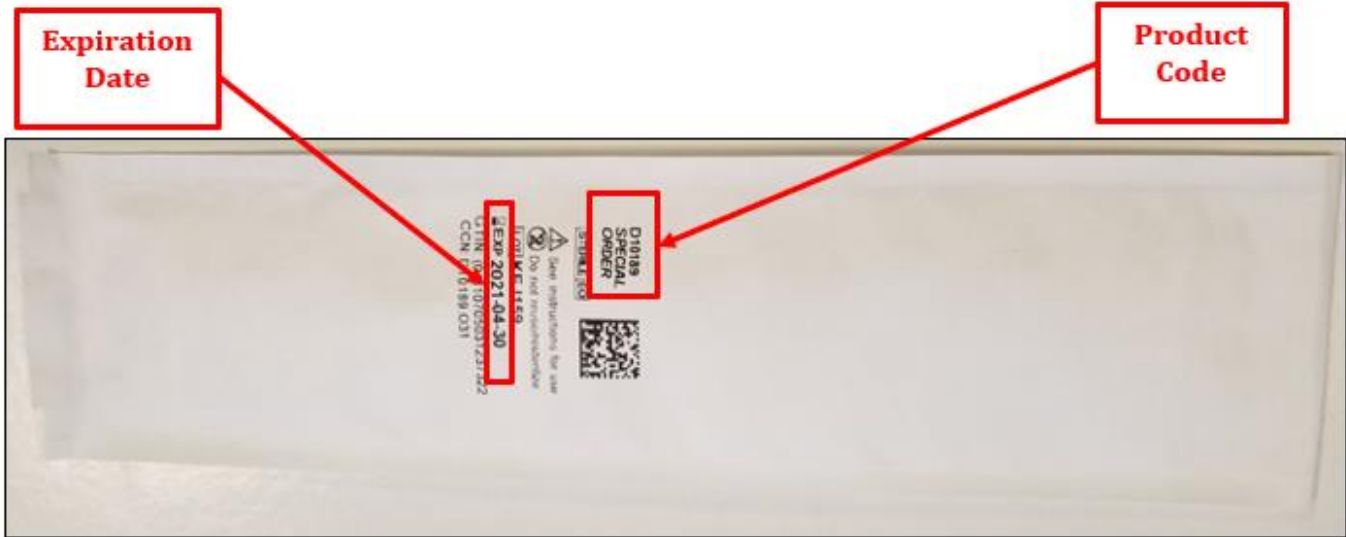
D-SPECIAL PRONOVA® POLY (Hexafluoropropylene-VDF) SUTURE **SALES UNIT CARTONS (CONTAINING 12 EACHES)**

FRONT AND SIDE OF SALES UNIT CARTON (PRODUCT CODE D10189)



D-SPECIAL PRONOVA® POLY (Hexafluoropropylene-VDF) SUTURE POUCH
(CONTAINING 1 EACH)

BACK SIDE OF D-SPECIAL TYVEK POUCH (CONTAINING PAPER FOLDER)
(PRODUCT CODE D10189)



ATTACHMENT 2: 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, even if you do not have product subject to this correction.**

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 D-Special PROLENE® Polypropylene Suture & D-Special PRONOVA® Poly (Hexafluoropropylene - VDF) Suture** subject to this recall (removal).
- ☐ We have **D-Special PROLENE® Polypropylene Suture & D-Special PRONOVA® Poly (Hexafluoropropylene - VDF) Suture** subject to this recall (removal) and are returning the following products:

Device Name	Product Code	Expiry Date	Quantity Returning (in “Eaches”)
D-Special PROLENE® Polypropylene Suture	DC631	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D5981	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D5988	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D6416	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D7748	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D7768	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D7879	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D8292	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D8647	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D8881	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D9067	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D9662	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D9746	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D9844	3/31/2021 to 2/28/2023	



D-Special PROLENE® Polypropylene Suture	D9995	3/31/2021 to 2/28/2023	
D-Special PROLENE® Polypropylene Suture	D10031	3/31/2021 to 2/28/2023	
D-Special PRONOVA® Poly (Hexafluoropropylene - VDF) Suture	D10027	3/31/2021 to 2/28/2023	

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

