Johnson&Johnson MedTech

Ethicon

URGENT: FIELD SAFETY NOTICE

GYNECARE TVT EXACT®

–Field Safety Corrective Action (Product Recall/Removal) –

[Date]

Dear Customer:

Records indicate that you have ordered or received product subject to this recall as indicated in the table below.

EFFECTIVE IMMEDIATELY – DO NOT USE, IMPLANT OR DISTRIBUTE THE FOLLOWING PRODUCT LOTS. REFER TO ACTION REQUIRED FOR FURTHER INSTRUCTIONS.

Product Name	Product Code	Product Lots				UDI
GYNECARE TVT EXACT®	TVTRL	5000013	5000023	5000025	5000027	10705031062375
		5000032	5000036	5000037	5000039	

PLEASE DISTRIBUTE THIS INFORMATION WITHIN YOUR FACILITY TO ALL STAFF WHO USE HANDLE, STORE, PURCHASE, DISTRIBUTE, MANAGE GYNECARE TVT EXACT®.

THIS INCLUDES OPERATING ROOM, MATERIALS MANAGEMENT, RISK MANGEMENT, QUALITY AND PHYSICIAN/SURGEON TEAMS AS APPLICABLE.

Purpose of this Letter

Ethicon Sarl has initiated a medical device recall (removal) of eight lots of GYNECARE TVT EXACT®, product code TVTRL.
This letter provides information about the affected product, the reason for the action, the potential risk to health, and the action required by customers.

Reason for the Recall (Removal)

Ethicon Sarl has received complaints for GYNECARE TVT EXACT®, product code TVTRL, regarding white particulate observed in the sterile barrier. Our investigation determined that the white particulate originated from the adhesive layer applied to the Tyvek lid of the product packaging.

We have identified the root cause of the manufacturing issue associated with this recall and have implemented corrective actions and controls to prevent recurrence.

Risk to Health

Ethicon Sarl has not received any reports of injuries related to this issue as of the date of the recall initiation.

The particulates come from packaging materials which are not cytotoxic, not genotoxic, not expected to sensitize or irritate or be systemically toxic, and are unlikely to affect device functionality.

The white particulates are visible to the naked eye and likely would be detected during package inspection and opening in the operating room by trained personnel. Surgical delay may occur if a surgeon opts not to use the product, but there is no expected direct harm associated with this issue.

The potential impact is limited to products with the particulates in sterile barrier issue. Other product lots in the field are unaffected. Health care practitioners who have treated patients using impacted product lots should follow those patients post-operatively in the usual manner with no additional action required.

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Actions Required –

1. Review your inventory immediately to determine if you have product subject to this recall on hand and quarantine such product(s). If you have product subject to this recall, please maintain a copy of this notice with the quarantined product and keep a copy for your records.
2. Stop use, implantation, and distribution of affected product immediately.
3. Quarantine any affected product identified in your inventory. Maintain a copy of this notice with the quarantined product and keep a copy for your records.
4. Communicate this recall/removal notice to all relevant personnel within you facility, including operating room, materials management personnel, or anyone else in your facility who needs to be informed.
5. If affected product was transferred, distributed to another facility / department, physician, distributor or customer, promptly forward this notice to them and request they complete the required actions.
6. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and fax or email to [Enter Information] within three (3) business days. **Please return the BRF even if you do not have product subject to this recall**.
7. Customers are required to return all unused product subject to this recall that are in inventory immediately. To receive credit reimbursement, customers must return product subject to this recall no later than **August 31, 2026** to [Enter Information]. Any non-affected product and any product returned after the date specified will not receive credit reimbursement.
8. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to [Enter Information].
9. If you require any assistance with returning product, please contact [Enter Information] at [Enter Information].
10. As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your Sales Representative, or your National Health Authority. If you have any further questions related to this notice or if you need any additional communications, please contact your local Sales Representative

Other Information

At Ethicon Sarl, our first priority is to our customers and their patients, and that includes the safe and effective use of our products. We recognize Field Safety Corrective Action may be disruptive to your facility and we appreciate your assistance in this matter.

If you have additional questions, please contact [Enter Information].

ATTACHMENTS:

Attachment 1: Product Identification Tool

Attachment 2: Business Reply Form (BRF)

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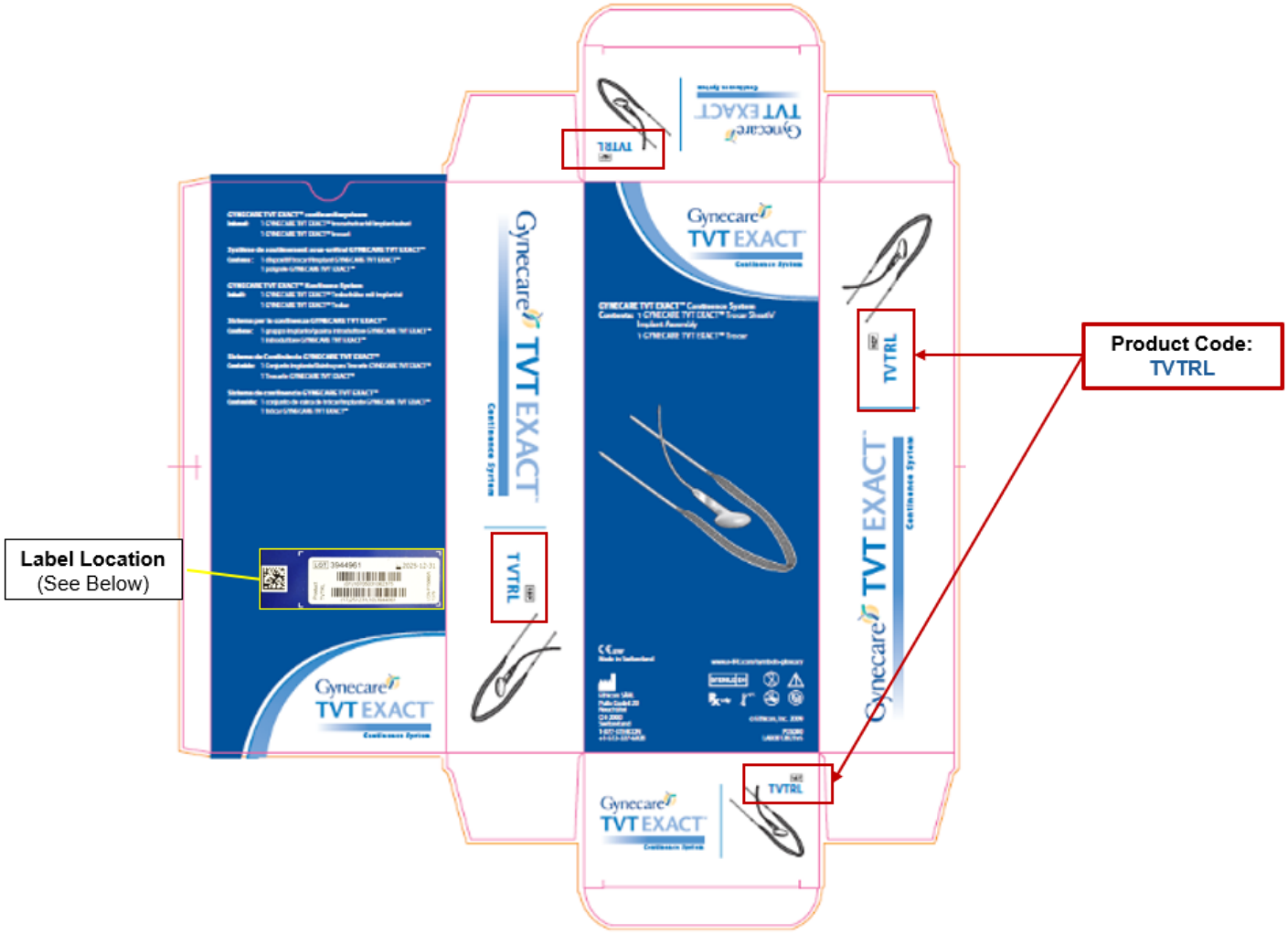
Attachment 1: Product Identification Tool

Please refer to the representative sample pictures below to identify the location of the subject product code and lots for impacted products by using the packaging labels.

TVT Exact Box



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Label

(Labeling behind box)

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Attachment 2: Business Reply Form (BRF)

Business Reply Form (BRF)

Your timely response to this recall notification is requested. Please complete this form and fax or email it to [Enter Information] or e-mail the form to [Enter Information] **within 3 business days, even if you do not have product subject to this recall to return.**

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

[Account Name]
[Account Address]

Print Name of Person Completing Business Reply Form:	Telephone Number:
Account Number (number used to order product):	Date:
Email Address:	
Reference PO for credit, if needed.	
Signed*: **Your signature provides confirmation that you have received and understood this notification*	
Your comments are welcome.	

Product Inventory – *please check one*

☐	We have NO inventory of product subject to this recall (removal).
☐	We have product subject to this recall (removal).

PRODUCT CODE	Product Lot		Quantity in Inventory	Quantity Returning (Eaches)
TVTRL	☐	5000013		
	☐	5000023		
	☐	5000025		
	☐	5000027		
	☐	5000032		
	☐	5000036		
	☐	5000037		
	☐	5000039		