April 2025 TufTex OTW / POC / PIOC Recall

This form must be returned even if you have zero devices in inventory.
Email completed form to recalls@lemaitre.com.

Account #	Customer Name	Address

Contact Name	Contact Email	Contact Phone
Signature and Date:		

Contact Information for Ongoing and Future Communications. Input your hospital's risk management contact information below (*e.g., riskmanagement@xyzhospital.org*). Please do not include an email address for an individual.

Contact Name	Contact Email

I have read and understand the recall instructions provided in this letter. Yes ☐ No ☐

Any adverse events associated with recalled product(s)? Yes ☐ No ☐

If yes, please explain:

_____

_____

_____

Do you have any recalled devices at your facility? ☐ Yes ☐ No

If Yes, please complete the table below.

- If you have checked your inventory and have no recalled devices, you may simply email ***recalls@lemaitre.com*** to indicate that "I have checked our inventory and we have none of the recalled devices."

  NOTE: Distributors must complete the entire form.

- **If you have transferred affected devices to another facility, please send them a copy of this recall letter. If possible: list the facility information, including contact information.**

REF (Catalog) #	LOT #	QUANTITY ON HAND

ADDRESS TO WHICH REPLACEMENT DEVICES SHOULD BE SENT :

FOR DISTRIBUTORS ONLY:

☐ I have checked my stock and have quarantined inventory consisting of _____ units.

☐ I identified and notified all of my customers that are affected by this recall.

☐ If the product was distributed outside the US, I have notified that country's medical device regulatory agency about this recall.

☐ I did not notify the regulatory agency. The rationale is listed below.

Rationale:

Name / Title:	
Telephone:	
Email Address:	

Please scan the completed form and email it to recalls@lemaitre.com.

Thank you for your cooperation.

This section is for LeMaitre use only:

RMA #		REPLACEMENT ORDER #	