LeMaitre Vascular, Inc.

14 APR 2025

URGENT: MEDICAL DEVICE RECALL

TufTex® Over-the-Wire Embolectomy Catheter
Pruitt® Irrigation Occlusion Catheter
Pruitt® Occlusion Catheter

Dear Device Customer/Distributor,

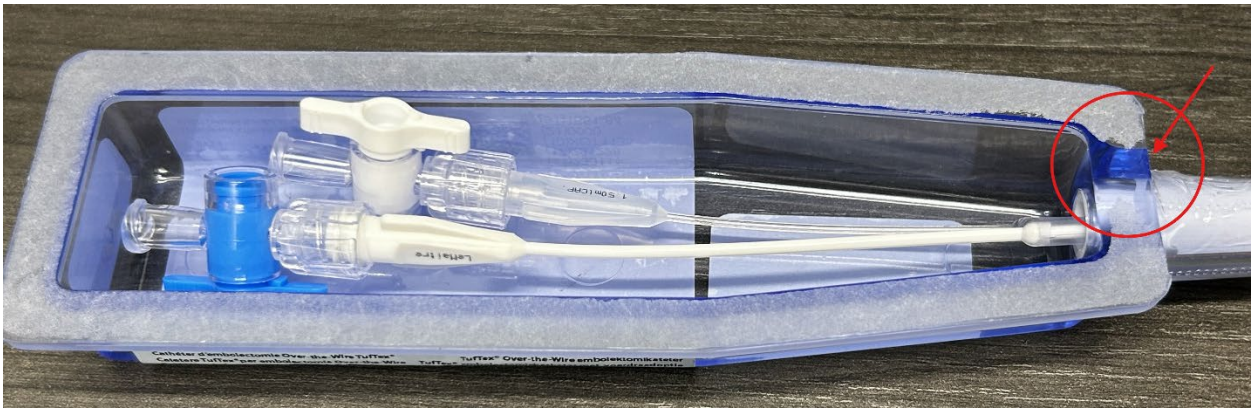
(1) Purpose of this letter

The purpose of this letter is to advise you that LeMaitre Vascular, Inc. is voluntarily recalling all lots of the following devices. This table includes a list of impacted lot numbers.

Product Line	Catalog Numbers	Lot Numbers
TufTex® Over-the-Wire Embolectomy Catheter	1651-38, 1651-48, 1651-68, 1651-78, 1651-84, 1651-88	OTW4185, OTW4297, OTW4312, OTW4322, OTW4330, OTW4332, OTW4342, OTW4350, OTW4374, OTW4393, OTW4402, OTW4409, OTW4413, OTW4458, OTW4498, OTW4504A, OTW4550A, OTW4601, OTW4614, OTW4638, OTW4643, OTW4662, OTW4707, QOT1034, QOT1038, QOT1043, QOT1046, QOT1048, QOT1070, QOT1077, QOT1094, QOT1099, QOT1115, QOT1121, QOT1174, QOT1187, QOT1214, QOT1218, QOT1227, QOT1231, QOT1232, QOT1261, QOT1271, QOT1320, QOT1409, QOT1412, QOT1417, QOT1429, QOT1451, QOT1482, XOT00001602, XOT00001612, XOT00001621, XOT00001629, XOT00001639, XOT00001689, XOT00001717, XOT00001736, XOT00001745, XOT00001917, XOT00002029, XOT0032, XOT1022, XOT1037, XOT1070, XOT1097, XOT1108, XOT1119, XOT1133, XOT1169, XOT1217, XOT1218, XOT1241, XOT1251, XOT1256, XOT1265, XOT1271, XOT1283, XOT1286, XOT1289, XOT1294, XOT1299, XOT1301, XOT1330, XOT1360, XOT1364, XOT1367, XOT1368, XOT1369, XOT1380, XOT1384, XOT1385, XOT1387, XOT1392, XOT1401, XOT1430, XOT1432, XOT1454, XOT1465, XOT1466, XOT1519, XOT1523, XOT1525, XOT1541, XOT1567
Pruitt® Occlusion Catheter	2103-36, 2103-46, 2103-56	POC1883, POC1967, POC2003, QPO1154, POC1929, POC1936, POC1968, QPO1124, XPO1006, QPO1149
Pruitt® Irrigation Occlusion Catheter	2102-09	QPI1051, XPI1069, XPI1080, XPI1082, XPI1089, XPI1093, XPI1099

(2) Reason for the Voluntary Recall

During internal product testing, we observed some packages to have incomplete seals (sterile barrier) as depicted in the picture below:



(3) Risk to Health:
If the sterile barrier of the packaged device is broken, there is a risk of contamination of the device and subsequent risk of infection if used. So far, there have been no reports of infection.

(4) Actions to be taken by the Customer/User:
- Check your inventory against the list of products in this letter. Immediately quarantine any recalled devices.
- Complete the form at the end of this letter. ***Please note that you must return the form even if you have no devices in inventory.***
- Scan the reply form and send it to your in-country Sales Representative at his/her relevant email address. *(If you have checked your inventory and have none of the recalled devices, you may simply email us with that information to your Sales Representative at his/her relevant email address)*
- When a recalled device has been returned to LeMaitre Vascular, a replacement device will be provided.
- If you have transferred devices to another facility, please forward a copy of this recall letter to them.

(5) Product and Distribution Information:
Refer to the tables mentioned earlier in the letter.

(6) Type of Action by the Company:
LeMaitre Vascular has opened a corrective action to address the root causes of the issue. Some actions will be short term, and others will require extensive validation and will therefore be longer term measures.

(7) OTHER INFORMATION:
Authorized by:

Jeffrey Oddy
Sr. Engineer, Post Market Surveillance
Recall Coordinator
Joddy@lemaitre.com
If you have any questions, contact **Jeffrey Oddy** Monday through Friday, 9:00 AM to 5:00 PM, ET.

14 Apr 2025 Recall
TufTex Over-the-Wire Embolectomy Catheters, Pruitt Occlusion Catheters, Pruitt Irrigation Occlusion Catheters

This form must be returned even if you have zero devices in inventory.
Email completed form to your in-country Sales Representative at his/her relevant email address

Account #*	Customer Name*	Address
«Customer_»	«Customer_Name»	«Address_1»«Address_2» «City», «State» «Zip»

**If you are not the customer listed here, please list your facility information.*

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*).

Contact Name	Contact Email	Contact Phone

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 ***in-country Sales Representative at his/her relevant email address*** to indicate that "I have checked our inventory at «Customer_», «Customer_Name» 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, 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 your in-country Sales Representative at his/her relevant email address.

Thank you for your cooperation.

This section is for LeMaitre use only:

RMA #		**REPLACEMENT ORDER #**	