Recall:	April 2025 OTW/PIOC/POC
Start Date:	10 April 2025
Product Families:	TufTex® Over-the-Wire Embolectomy Catheter Pruitt® Irrigation Occlusion Catheter Pruitt® Occlusion Catheter
Description:	LeMaitre has observed some packages to have incomplete seals (sterile barrier) during internal product testing. Seal integrity testing has found a compromised package on approximately 1% of devices, which could allow microorganisms to enter and contaminate the device, leading to potential infection transmitted by the compromised device. LeMaitre conducted a comprehensive investigation and identified the following issues: • Sink marks on the procured trays used for packaging products. Sink marks are surface depressions in molded plastic components, often caused by uneven cooling and shrinkage. • Sealing process issue due to inadequate support at the tray tube connection area leading to incomplete seals. 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. If identified prior to use, there is a risk of delayed treatment due to locating another usable unit. Although there have been no complaints about this issue and no reports of infection to date, there is still a potential risk for infection, and products have been distributed globally; therefore, LeMaitre is removing all impacted products from all regions. **Please Take the Following Actions**: 1. Ensure the contents of this Voluntary Product Recall communication are read and understood by those within your organization. 2. Do not use the devices. Check your inventory against the list of lots in **Attachment 1**. Immediately quarantine any recalled devices. 3. If an affected device was previously used on a patient without incident, no further action is necessary. 4. Complete the attached Customer Response Form. ***Please note that you must return the form even if you have no devices in inventory.*** 5. Scan the reply form and send it to recalls@lemaitre.com. *(If you have checked your inventory and have none of the recalled devices, you may simply email us with that information to recalls@lemaitre.com.)* 6. Upon receipt of your completed form, a LeMaitre Vascular representative will contact you to provide return instructions. 7. When a recalled device has been returned to LeMaitre, a customer service representative will generate a replacement order for the received device(s). 8. If you have transferred devices to another facility, please forward a copy of this letter to them.