



Urgent Field Safety Notice

TLC Self-Retraining Retractor System

2016-01-04

Return of a medical device to the manufacturer

Date: January 5, 2016

Attention: Medical Device Liason Officer

Details on affected devices:

- Type of Device: TLC Self-Retraining Retractor System
- Device Names: TLC Self-Retraining Retractor System; TLC Self-Retraining Retractor Frames; Wilson Penile Implantation System
- Product Codes: TLC200, TLC300, TLC5042-I
- Lot Numbers: See page3 titled "Applicable Lot Numbers".

Description of the problem:

Applied Medical Technology, Inc. has received customer complaints indicating some devices subject to this recall may contain open sterile pouch seals. In each reported case, the pouch opening was obvious and discovered prior to use of the device in a surgical procedure. No injuries associated with this problem have been reported.

Applied Medical Technology, Inc. conducted a health risk assessment related to this problem and found that the use of the device with an open pouch could result in a possible post-operative infection. The patient populations most at risk are those patients unable to resist infection. The hazard associated with the use of a device with an open pouch is limited, and the probabilities of a serious health risk or a medical reversible health risk are each not likely. The health risk assessment found that this problem did not pose a significant threat to public health.

Advise on action to be taken by the user:

Applied Medical Technology, Inc. requests that customers IMMEDIATELY TAKE THE ACTION and perform a visual inspection of the straight pouch seal opposite the chevron seal of all devices in inventory and subject to this recall. Look for an open or damaged seal.

1. Open the outer box.
2. Remove the sterile pouch.
3. Visually inspect the seal opposite the chevron seal.

- **Do not use any device with a pouch seal that is open or appears damaged.**

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Website: www.AppliedMedical.net | Email: CS@AppliedMedical.net

- Complete and return to Applied Medical Technology the enclosed RECALL NOTIFICATION ACKNOWLEDGMENT via fax or send mail.
- Return to Applied Medical Technology any devices with open pouches or damaged pouch seals. Return the device with all available packaging and labeling.
- Not all devices subject to this recall may have open pouches. Devices with pouch seals that pass a visual inspection are sterile and may be properly used.
- Customers should continue to inspect and prepare any devices prior to use according to its standard operating procedures and good medical practices.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

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The undersign confirms that this notice has been notified the appropriate Regulatory Agency.



Dan Filler

Applicable Lot Numbers

The following tables provide lot numbers and related information associated with this recall.

Table 1: TLC5042-I

Lot Number
13092465

Table 2: TLC200

Lot Numbers				
13013236	13080476	14040252	14104555	15062732
13021255	13081545	14044133	14113449	15070461
13040364	13083129	14051689	14120607	15070515
13042592	13102212	14053107	15011648	15080317
13044498	13111529	14053108	15011659	15090148
13050721	13120989	14060348	15020188	15090422
13060533	14020121	14070239	15032061	15092264
13060623	14020591	14070329	15034503	
13062950	14022730	14081538	15040520	
13073907	14031951	14092857	15041108	
13080455	14031977	14093927	15050175	

Table 3: TLC300

Lot Numbers				
13010035	13062360	13123457	14053115	15023291
13011623	13062951	14013957	14062474	15034509
13012464	13070300	14020123	14091274	15053401
13012615	13081450	14020197	14091365	15054441
13021643	13090299	14020917	14092856	15064578
13031502	13100436	14022810	14100564	15070470
13040391	13100448	14023322	14100566	15070490
13040392	13103900	14040251	14112492	15081541
13042531	13104409	14044097	14123036	15082695
13043413	13111530	14053109	15020186	15090147
13060531	13120990	14053112	15020189	
13060537	13123456	14053114	15021929	