Class II Medical Device Recall: Triad Group, Triad Sterile Lubricating Jelly

U.S. Food & Drug Administration

Recall Class: Class II

Date Recall Initiated: December 23, 2010

Products: Sterile Lubricating Jelly, packaged in:

- 5 gram tubes
- 2 ounce and 4 ounce tubes
- 4 ounce bottles
- 3 and 5 gram packets

This recall affects all Triad lubricating jelly packages with lot numbers beginning with the numbers 7, 8, 9, or 0. If these packages are part of kits, packs, or trays, the lot numbers will only appear on the lubricating jelly packages.

The Triad lubricating jelly products were distributed by Triad from January, 2007 through December 2010. These products may be contained in kits, packs, or trays that have been packaged after December 2010 by other firms.

FDA will update this webpage when additional information is available.

The following table provides brand names, distributors, and product identifiers (catalog or reorder numbers) known at present:

BRAND NAMES	FIRM NAMES	CATALOG/ REORDER #s	PRODUCTS
Allegiance	Cardinal Health	LJT2 LJF3 LJT4 LJT5	Net Wt. 2 oz. Net Wt. 3g Net Wt. 4 oz. Net Wt. 5g
Select Medical Products	PSS World Medical, Inc.	137 136	3g/packet 4 oz.
Novaplus	Novation, Inc.	V10-8344 V10-8919 V10-8917	Net Wt. 3g Net Wt. 4 oz. Net Wt. 2 oz.
Triad Triad Plus	Triad Group, Inc.	10-8917 10-8946 11-8344 11-8472	Net Wt. 2 oz. Net Wt. 5g Net Wt. 3g Net Wt. 5g

		10-8919 10-8500	Net Wt. 4 oz. Net Wt. 4 oz.
IMCO	Independent Medical Co-op, Inc.	8919-IMC	Net Wt. 4 oz.
McKesson Medi-Pak Performance	McKesson Corporation, McKesson Surgical	66-8919	Net Wt. 4 oz.
Henry Schein	Henry Schein, Inc.	104-9637	Net Wt. 4 fl. oz.

Under **Useful Links** below, see also firm recall letter and recall webpage**,** relatedFDA News Release on non-sterile alcohol prep pads, and related firm Press Releaseon Alcohol Prep Pads, Alcohol Swabs, and Alcohol Swabsticks.

Use: This product helps to provide easy insertion of a medical device (such as a catheter or an endoscope) or gloved fingers into body openings.

Recalling Firm:
H & P Industries, Inc., doing business as, Triad Group
700 West North Shore Drive
Hartland, Wisconsin 53029-8358

Reason for Recall: This product may not be sterile. Patients, who are immuno-compromised, such as those with diabetes, cancer and certain other chronic diseases, may be at potential risk for infection.

Public Contact: Customers with questions may contact Triad Group Customer Service at 1-262-538-2900 ext. 2761, Monday through Friday, from 8:30 AM through 4:00 PM, Central Time or your distributor.

FDA District: Minneapolis

FDA Comments:

On December 22, 2010, the company sent an “Urgent Medical Device Recall” letter to all its customers by certified mail. The letter described the issue, identified the affected products with the lot numbers beginning with the digits 7, 8, 9, or 0, as well as the action to be taken by the customers.

Triad Customers (Distributors, and kits, packs, or trays’ manufacturers) were instructed to:

- **IMMEDIATELY EXAMINE** their inventory.
- **QUARANTINE only** lubricating jelly products.
- **IMMEDIATELY NOTIFY** their customers if the recalled product was further distributed.
- **COMPLETE AND RETURN** the enclosed Recall Acknowledgement form by FAX at 1-262-538-2947 or mail to: Recall Coordinator, Triad Group, 700 West

North Shore Drive, Harland, Wisconsin 53029, **OR**
- **RETURN** the recalled product to the appropriate company, if not the Triad Group.

Additional Information:

Triad sterile lubricating jelly products have been incorporated into a variety of procedural and convenience kits, packs, or trays with other medical devices and/or drug products.

Healthcare facilities: IMMEDIATELY CONTACT yourkit, pack or tray suppliers to determine whether the products stocked at your facility are impacted by the Triad recall**.** Your supplier should provide you with documentation on whether your products are affected by the recall.

FDA is instructing manufacturers and repackers who have incorporated the recalled products into their kits, packs or tray to **PROMPTLY CONDUCT A SUB-RECALL** and submit their recall strategiesto their FDA District Office.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

Useful Links:

- Triad Recall Letter [2] [3]
- Triad Recall Webpage [4] [3]
- FDA News Release - Safe Use of Non-Sterile Alcohol Prep Pads [5]
- Firm Press Release on Alcohol Prep Pads, Alcohol Swabs, and Alcohol Swabsticks [6]

SOURCE [7]

Source URL (retrieved on *03/06/2015 - 5:45pm*):
http://www.mdtmag.com/news/2011/02/class-ii-medical-device-recall-triad-group-triad-sterile-lubricating-jelly

Links:
[1] http://www.fda.gov/Safety/MedWatch/default.htm
[2] http://www.triad-group.net/media/pdf/LJ_Recall_Ltr_FINAL.pdf
[3] http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm
[4] http://www.triad-group.net/index.php?option=com_content&view=section&layout=blog&id=1&Itemid=58

[5] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm241750.htm
[6] http://www.fda.gov/Safety/Recalls/ucm239219.htm
[7] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm243399.htm