



MEDICAL SUPPLY BULLETIN

HHS SUPPLY SERVICE CENTER

PERRY POINT, MD 21902

We Service the World

Steven Pearson, Director

David Wernek, Q.A. Specialist, Editor

BULLETIN NO. 3

January 20, 2011

RECALL NOTICE

Dear Valued Customer:

Triad Group, the manufacturer of the Foley Insertion Tray, has issued a recall notice concerning **Sterile Lubricating Jelly** which is **one** of the components in the Foley Insertion Tray. The Sterile Lubricating Jelly is being recalled due to concerns regarding the validation of the gamma radiation sterilization cycles for these products. Be aware that if unsterile lubricating jelly is used it could lead to patient infection.

Components of the Foley Insertion Tray Kit:

- A Graduated Collection Basin And Moisture-Proof Underpad
- Graduated Collection Basin
- **Lubricating Jelly Packet**
- Inflation Syringe
- Underpad
- Wrapped Gloves
- Fenestrated Drape
- Aloetouch 3G Gloves
- Csr Wrapped Tray 10Cc Syringe, 3-Pk Pvp, And Specimen Container with Id label



If you have the tray listed above, locate the lot number on the packaging to determine if the tray is affected by the recall. All lots starting with 08, 09, or 10, followed by a letter (A-Z) in the third position **are affected by this recall**. If the lot number starts with 08, 09, or 10, and then followed by another number, the product **is not affected by this recall**.

For example:

- Lot # 082010A is not affected by the recall.
- Lot # 08DA0452 is affected by the recall.

If you have an affected lot, do not open the Foley Insertion Tray Kit and remove the Sterile Lubricating Jelly until lubricating jelly is replaced and the kit is about to be used. Doing so will compromise the sterility of the tray. The Supply Service Center will verify the information provided in your response form and arrange to have the lubricating jelly replaced by the manufacturer.

SSC has stocked this product under **Catheterization Set, Ureth, St, 20's**, NSN: 6515-00-000-2033. We are asking for your cooperation in taking the following action:

- Please examine your inventory immediately, and if you have the recalled product in question immediately cease distribution / use.
- FAX the "Recall Response Form" to 410-642-2616, attention Quality Assurance, or e-mail it to Dave.Wernek@psc.hhs.gov.
- Please return the "**Recall Response Form**" before February 20, 2011 to expedite processing of your replacement of lubricating jelly from manufacturer.

If you have any questions about this recall, please contact David Wernek, Quality Assurance Specialist at 1-800-642-0263 ext. 1130. We apologize for any inconvenience and appreciate your prompt attention to this recall.



Steven Pearson

Recall Response Form

HHS Supply Service Center

The following product has been identified as previously being stocked by HHS Supply Service Center with the manufacturer of this product being Triad Group.

Catheterization Set, Ureth, St, 20's NSN: 6515-00-000-2033

Point of Contact (POC): _____.

Customer Number: _____.

Telephone Number: _____.

Organization: _____.

Date: _____.

Product Description	Quantity Disposed
Catheterization Set, Ureth, St, 20's NSN: 6515-00-000-2033	

Please FAX the "Recall Response Form" to 410-642-2616, attention Quality Assurance, or e-mail it to Dave.Wernek@psc.hhs.gov. The "Recall Response Form" must be received by or before **February 20, 2011** to expedite processing the replacement of your lubricating jelly from the manufacturer.