December 22, 2010

URGENT MEDICAL DEVICE RECALL

Professional Hospital
42500 Winchester Road
Temecula, CA 92590

Dear Customer:

This is to inform you of a product recall involving Sterile Lubricating Jelly manufactured by Triad Group.

This recall has been initiated due to concerns expressed by the Food and Drug Administration regarding the validation of the gamma radiation sterilization cycles for these products. We are initiating this recall because use of inadequately sterilized product might result in patient infection.

This recall extends to all Lots of Sterile Lubricating Jelly remaining within their labeled expiration dating (three years), including all Lot numbers beginning with the digits 7, 8, 9, or 0. We began shipping the Lots of product subject to this recall in January, 2007.

Please immediately examine your inventory and quarantine product subject to recall – any stock of Sterile Lubricating Jelly manufactured by Triad Group. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

This recall should be carried out to the user level. Your assistance is appreciated and necessary to prevent potential patient harm.

Please complete and return the enclosed response form as soon as possible and return the recalled product to Triad Group.

If you have any questions please call Triad Group Customer Service Monday through Friday, between the hours of 8:30 A.M. and 4:00 P.M. Central Time: 262-538-2900 ext 2761.

This recall is being made with the knowledge of the Food and Drug Administration.

Yours truly,

Jack Waterman
Jack Waterman
Regulatory Affairs Manager
URGENT NOTICE
SUPPLIER DEVICE RECALL

Recall # 505

SUBJECT: PRODUCT RECALL / FIELD CORRECTION

NOTICE DATE: January 4, 2011

PRODUCT DESCRIPTION: STERILE LUBRICATING JELLY

SUPPLIER NUMBER: SEE OFFICIAL RECALL NOTICE

LOT NUMBER: SEE OFFICIAL RECALL NOTICE

CUSTOM PACKS AFFECTED: X PACK NUMBER: SEE DMR AND LOT # LIST ENCLOSED.
LOT NUMBER:

REASON FOR RECALL: See attached Recall Notice.

CORRECTIVE ACTION: Remove products from inventory. Return affected products to PHS.

REPLACEMENTS: Contact PHS Customer Service at 800-944-3195.

PLEASE COMPLETE THE FOLLOWING QUESTIONNAIRE REGARDING THIS NOTICE

1. Did your facility find affected product on hand? If Yes, PLEASE CONTACT PHS CUSTOMER SERVICE AT 800-944-3195 TO RETURN PRODUCT.

☐ Yes  ☐ No

COMPLETED BY: ____________________________________________

PHONE NUMBER: __________________________________________

FACILITY NAME: __________________________________________

ADDRESS: ________________________________________________

CITY / STATE / ZIP: ________________________________________

Print Name _______________________________________________

Position _________________________________________________

Signature ________________________________________________

Date _____________________________________________________

Please return via FAX to PHS – (951) 296-2622 Attention: Recall Coordinator