TRIAD
GROUP

December 22, 2010

URGENT MEDICAL DEVICE RECALL

PSS World Medical
PO Box 550560
Jacksonville, FL 32255

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

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