



**Indiana State
Department of Health**
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: January 14, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: *Laurie Kidwell*
Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Wallcur - RECALL [Drug]

AFFECTED PRODUCT: Wallcur's Practi-0.9% sodium chloride IV bag and Practi-0.9% sodium chloride 100 mL IV solution bag with sterile distilled water.

SUMMARY: Unclassified Recall; The recall has been initiated because recently some of Wallcur's training products were not used for their intended purpose. Specifically, despite the fact that the products are intended "for clinical simulation" only, we are aware of reports that these products have been used outside of their intended use and administered to patients. Because these products are not intended for human or animal administration, and are not sterile, administration of these products could result in adverse events.

Wallcur's Practi-0.9% sodium chloride IV bags supplied in 50 mL, 250 mL, 500, mL, and 1000 mL sizes and the Practi-0.9% sodium chloride 100 mL IV solution bag with sterile distilled water.

We began shipping this product on May 22, 2014. Immediately examine your inventory, quarantine the products subject to recall, and return them to Wallcur. In addition, if you are a Wallcur distributor, or have further distributed or sold this product, please provide Wallcur with a list of your customers the products were distributed or sold to, 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 along with a copy of the enclosed product labels to make the products easily identifiable at the user level. Please also notify your customers that have purchased these products that the products are for demonstration, training, and educational purposes only, and not for human or animal use.

They products were distributed nationwide.

SUGGESTED ACTION: For consumer inquiry only. Please complete and return the enclosed response form as soon as possible. If you have any questions call Carla Sanderson at 619-702-4333.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.



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To promote and provide
essential public health services.

*Wallcur Practi-0.9% Sodium Chloride-IV Bags 50 mL, 250 mL, 500, mL,
and 1000 mL Wallcur Practi-0.9% Sodium Chloride-IV Bag with
Distilled Water 100 mL*

Contact:

Consumer:
619-702-4333

FOR IMMEDIATE RELEASE — January 7, 2015 — San Diego, CA — This letter is to notify you of a product recall involving Wallcur's Practi-0.9% sodium chloride IV bags supplied in 50 mL, 250 mL, 500, mL, and 1000 mL sizes and the Practi-0.9% sodium chloride 100 mL IV solution bag with sterile distilled water.

As you know, all of Wallcur's products are intended for training, simulation, and educational purposes only. Recently some of Wallcur's training products were not used for their intended purpose. Specifically, despite the fact that the products are intended "for clinical simulation" only, we are aware of reports that these products have been used outside of their intended use and administered to patients. Because these products are not intended for human or animal administration, and are not sterile, administration of these products could result in adverse events.

We began shipping this product on May 22, 2014. Immediately examine your inventory, quarantine the products subject to recall, and return them to Wallcur. In addition, if you are a Wallcur distributor, or have further distributed or sold this product, please provide Wallcur with a list of your customers the products were distributed or sold to, 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 along with a copy of the enclosed product labels to make the products easily identifiable at the user level. Please also notify your customers that have purchased these products that the products are for demonstration, training, and educational purposes only, and not for human or animal use.

Your assistance is appreciated and necessary to prevent use of these products in humans or animals. Please complete and return the enclosed response form as soon as possible. If you have any questions call Carla Sanderson at 619-702-4333.

This recall is being carried out with the knowledge of the U.S. Food and Drug Administration.

In addition to the recall, as a precautionary measure, if you are a Wallcur distributor or reseller, we are requesting that you ensure your websites, catalogues, and other print materials advertising these products and any other Wallcur products prominently display the following language:

"THIS PRODUCT IS FOR TRAINING PURPOSES ONLY. NOT FOR HUMAN OR ANIMAL INJECTION."

Wallcur intends to add product enhancement labels containing similar language to the IV bags prior to future distribution.

*Wallcur Practi-0.9% Sodium Chloride-IV Bags 50 mL, 250 mL, 500, mL,
and 1000 mL Wallcur Practi-0.9% Sodium Chloride-IV Bag with
Distilled Water 100 mL*

Photo







