



Vice President of Regulatory and Quality Assurance

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www.posey.com

## URGENT FIELD SAFETY NOTICE (CORRECTION)

September 12, 2008

Facility Name  
Address 1  
Address 2  
City State, Zip  
Country

**Special Attention:** Purchasing Department

**Product Names:** POSEY CONNECTING STRAPS/BELTS/ LOCKING CUFFS

**Posey Catalog Numbers:** 2320, 2330, 2346, 2350, 2351, 2355 and 2360/ 2208, 2209, 2210, 2211, 2212, 2213

**Please forward this notice to the appropriate Quality Assurance personnel for prompt action.** The purpose of this letter is to bring to your attention a labeling problem regarding the application of Posey Connecting Straps/Belts when used with an ambulatory patient. The application instructions described in the Posey 2008 catalog and Posey Locking Cuffs Application Instruction Sheet (I9273) differ from the Posey Connecting Straps/Belts application instructions. The problem affects all units.

The Posey 2008 Catalog (page 113) describes two "Alternative Application Techniques". The second Alternative incorrectly states:

Locking straps may be used in combination with Synthetic Leather (or Leather) Cuffs to create a waist belt that restrains the arms of ambulatory patients (see photo#1)

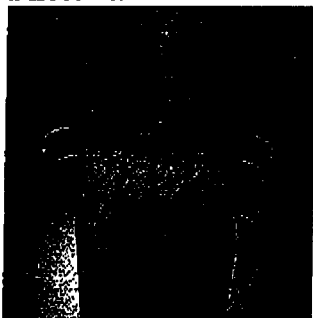
**This statement is incorrect.** In addition, the Posey Locking Cuffs Instruction Sheet (I9273) also includes the same incorrect picture. Posey Connecting Straps/Belts should NEVER be used to restrain an ambulatory patient's arms or legs. Attached is a replacement label to replace the picture in the Catalog. Please peel off the backing and affix the label over photo#1 in the Posey 2008 Catalog. The Posey Locking Cuffs Instruction Sheet (I9273) has been corrected and included with this letter. Please discard any old literature that does not contain the I9273 dated 080708.

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Please contact Posey Technical Support toll free at (800) 447-6739 and press "5" if you need additional labels or literature.

**Photo #1**



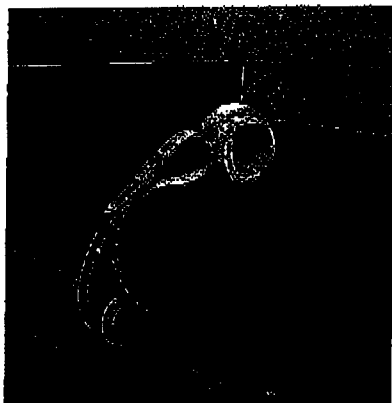
**INCORRECT APPLICATION**

**DO NOT** use a Posey Connecting strap around the waist as shown in this photo

A total of two complaints were received indicating that two different ambulatory patients were able to tear the 2360 strap at the adjustment notch when used in conjunction with a Posey Cuff attached around the waist as in **photo #1**. A patient may be able to catch the belt on a stationary object (wall, pipe, etc.) and use their body force to tear or break the strap, creating freedom of arm movement. In some patient populations (i.e. combative, agitated, psychiatric), such freedom of movement could pose an unwanted hazard of serious injury to a patient or caregiver. Posey has not had any reports of injury or death related to this labeling issue.

You may continue to use Posey Connecting Straps/Belts **ONLY** to restrain a patient in a bed as described in the Application Instruction Sheets (19254, 19270) provided with the products. The straps are intended to be wrapped once or more around the moveable frame of the bed (See **photo #2** for proper usage as a wrist restraint for a patient in bed). There have been no complaints or incidents of any Posey Connecting Straps/Belts tearing or breaking when used as pictured in **photo #2** and these connecting straps may be used as indicated with Posey Cuffs for wrist or ankle restrains in bed.

**Photo #2**



**CORRECT APPLICATION**

Posey connecting straps should only be used to connect wrist or ankle cuffs to the moveable frame of the bed.

Your account was identified as having either received the 2008 Posey Catalog or one or more units of Posey Connecting Straps/Belts, Posey Catalog Numbers 2320, 2330, 2346, 2350, 2351,

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2355, 2360 and/or Posey Locking Cuffs, Posey Catalog Numbers 2208, 2209, 2210, 2211, 2212, or 2213. Do NOT send the product back to Posey. Please fill out and fax back (626-443-5418) the Recall Reply Fax-Back Acknowledgment Form within 7 days [REDACTED] to confirm that you received the Recall letter.

Please adhere to the enclosed Application Instruction Sheets (I9254, I9270, and corrected I9273) provided. Do NOT use the second Alternative Application Technique listed in the Posey 2008 Catalog (page 113) and pictured in the Posey Locking Cuffs Instruction Sheet (I9273) originally received with the product.

If you are a distributor or if additional members in your facility received a Posey Catalog, please additionally forward a copy of this notice to each of your customers to whom you have further distributed the subject product.

We sincerely regret the confusion this may have caused. Please feel free to contact your Sales Representative with any questions [REDACTED]

Sincerely,

[REDACTED]  
[REDACTED]  
Vice President, Regulatory and Quality Assurance



Vice President of Regulatory and Quality Assurance

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Voluntary Device Recall (Correction)
POSEY CONNECTING STRAPS/BELTS/ LOCKING CUFFS
Reply Fax-Back Acknowledgment Form

Posey Customer No. :
Return Material Authorization No.:

Instructions:

- Please check the box below as applicable and fax or email back the REPLY FORM, even though you do not need to return any product to Posey. Please fax to: 626-443-5418

PLEASE COMPLETE THE REPLY FORM AND FAX or email back as soon as possible but no later than one week from receipt.

- 1. I verify that I have received and read and understand the recall notice for Posey Connecting Straps/Belts and Locking Cuffs.
2. I verify that I have received and read the recall notice for the Posey Connecting Straps/Belts and Locking Cuffs; however I would like a follow-up telephone call to further discuss the recall.

Authorized Signature Title Date
Telephone No. Fax No.
Account Name: Account No.: