



5635 Peck Road Arcadia, CA 91006 USA  
P 626.443.3143 or 800.447.6739  
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www.posey.com

## URGENT FIELD SAFETY NOTICE

3 June 2009

██████████  
MDSS GmbH  
Schiffgraben 41  
30175 Hannover  
Germany

**Manufacturing Dates Affected: February, March, April, 2009**

**Distributors and Products Affected:**

Product Number	Product Description	Distributor	Shipping Date	Quantity Shipped
235036	POSEY POLYPROPYLENE STRAP	Diframed	9 February 2009	96
235048	POSEY POLYPROPYLENE STRAP	Diframed	9 February 2009	60
2798	SINGLE STRAP TAT	Diframed	9 February 2009	48
1337	POSEY SWEDISH BELT-THREE	NOOTENS S A	9 April 2009	16
2798	SINGLE STRAP TAT	NOOTENS S A	9 April 2009	2
2799	SINGLE STRAP TAT	NOOTENS S A	9 April 2009	2

**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 problem with certain Posey product units which were manufactured using an incorrect key lock buckle. The incorrect key lock buckle is similar in appearance to, but functionally different from, the correct locking buckle. This problem only affects a limited number of units of certain product catalog numbers **manufactured between February 2009 and April 2009.** Only the product catalog numbers identified above have been linked to your account.

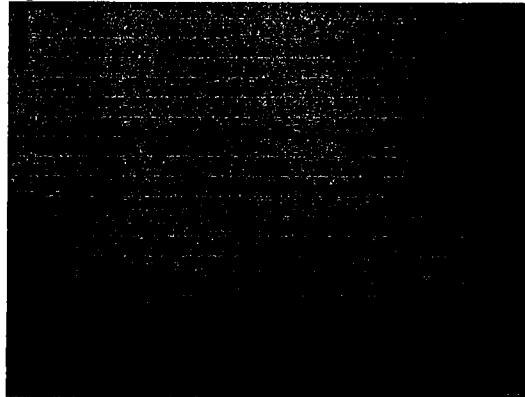
Posey product units manufactured with the incorrect buckle may not perform according to our specifications for strength. This nonconformance may allow the strap (webbing) of a product unit to become damaged and/or slip through the unit's buckle. This could permit a patient freedom of movement which could then lead to an injury to the patient or a caregiver. As a result, these product units are subject to a product recall. Please immediately cease further distribution or use of these products and return them to Posey. The product identified in this recall notice must be returned to Posey for inspection to identify units with the incorrect buckle.

If you have additional units of the product catalog numbers identified above that were not manufactured within the specified timeframe, it is not necessary to return these items. All Posey key lock products manufactured outside the February – April, 2009 time frame are still safe and effective for use and should NOT be returned.

To determine the manufacturing date of your product units, please select the most applicable method below.

**Method #1: If the product is still in the original packaging:**

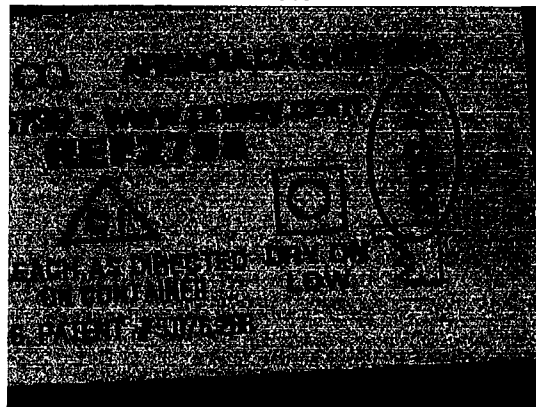
A bar code label affixed to the outside of each individual box will have a 5-digit number in the lower right corner of the label. The product is considered to be part of this recall if the number on the label falls within the range of '09056 – 09110'. See Photo 1



**Photo 1**

**Method #2: If the product is not in the original packaging:**

Each unit has a hand stitched wash label affixed to the device. On the right side of the wash label, there is a date. The product is considered to be part of this recall if the date on the wash label is '2009-02, 2009-03 or 2009-04'. See Photo 2



**Photo 2**



# Posey® Company

June 2, 2009

Page 3

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Your account was identified as having received one or more units of the product catalog numbers identified above and manufactured in the specified timeframe. Please fill out and return the Recall Reply Fax-Back Form within 7 days. You can fax the form to Posey at (626) 443-5418 or mail it (with self-enclosed envelope) to Posey at 5635 Peck Road, Arcadia, CA 91006. Again, please immediately return to Posey all units of the product catalog numbers identified above which were manufactured between February 2009 and April 2009 A pre-paid Automatic Return Service (ARS) label containing your RMA number is enclosed for your convenience.

If you are a distributor, please forward a copy of this recall notice and Recall Reply Fax-Back Form to each of your customers to whom you have further distributed product units subject to the recall. Please ask them to fill out and return the reply form to Posey and to contact Posey for a pre-paid shipping label with RMA number for return of product to Posey.

Upon inspection of the returned product units, Posey will promptly return all unaffected product units that already have the correct key lock buckle back to you. Any product unit found to have the incorrect buckle will be repaired with the correct buckle and returned to you at no charge or a replacement unit will be provided to you at no charge

Posey has not had any complaints or reports of injury or death related to this issue. Only the products identified above and manufactured during the timeframe indicated are subject to the recall. All other Posey products remain safe and effective for their intended use.

The relevant National Competent Authorities have been informed about the Field Safety Corrective Action with the affected products.

We sincerely regret the inconvenience this will cause you. Please feel free to contact your Sales Representative with any questions or concerns or you may contact Tarun Bhardwaj directly at any time at 626-443-3143 Ext. 111.

Sincerely

Regulatory & Quality Senior Specialist