

## URGENT FIELD SAFETY NOTIFICATION

### RE: Stryker 2-Stage and 3-Stage I.V. Poles

**ATTENTION: Materials Manager, Risk Manager, Recall Coordinator**

October 22, 2015

**FSCA identifier:** Product Field Action RA2015-014

**Type of Action:** Field replacement

**Description:** Stryker 2-Stage and 3-Stage I.V. Poles distributed on beds, stretchers. This product field action is limited to I.V. Poles distributed between 01/07/2014 - 06/24/2014.

**Product owner:** Stryker Medical, 3800 East Centre Ave. Portage, Michigan 49002, USA

The following I.V. Pole option numbers have been distributed in Singapore with Models 1105, 1105X stretchers and S3 bed

Option Number	Product Description
1105-035-341	30" IV POLE, 2 STAGE HE, PR
1105-035-368	30" IV POLE 2 STAGE HE PR
1105-035-641	26" IV POLE, 2 STAGE HR
2035-113-000	26", 3 Stage IV Pole Assembly

#### Dear Distributor/Customer

The purpose of this letter is to advise you that Stryker Singapore Pte Ltd, on behalf of Stryker Medical, is voluntarily recalling in Singapore the Stryker 2-Stage and 3-Stage I.V. Poles distributed on beds, stretchers listed above.

**Product Description** Two-stage and three-stage I.V. poles are shipped as an optional accessory to a bed or stretcher. The safe working load of the two-stage permanently attached I.V. pole is 40 lb. (3005-009-001 Rev E). To avoid damage to the three-stage I.V. pole, the weight of the I.V. bags should not exceed 12 lb. while the weight of any one item attached to each stage of the three-stage permanently attached I.V. pole should not exceed 9.3 lb. (Operations Manual 1105-109-001 Rev D).

The I.V. poles are stationary, height adjustable stands intended to hold infusion liquids, infusion accessories, and/or other medical devices. They may be used on the following "parent" devices: Model 2030 (EPIC II), model 3005 S3 beds and stretcher models 1105, 1105E, 1105X, 1105XE, 1115, 1115E, 1115X, 1115XE, 1125E, 1125X and 1125XE.



Figure 1. S3 Hospital bed with 2-Stage I.V. Pole



Figure 2. Prime Zoom Stretcher with 3-Stage I.V. Pole

### Product Issue

It was identified by a customer complaint that some I.V. poles were retracting/lowering from an extended position to the low height unexpectedly. An investigation was initiated which identified that the I.V. Latch Housing was nonconforming.

### Potential Hazard

We have identified the following potential hazards:

- Suspended I.V. pole retracts unexpectedly
- Suspended I.V. pole retracts unexpectedly with pump/bags attached

Our medical risk assessment has determined that the probability of harm requiring medical intervention associated with these hazards is negligible for patients and remote for individuals other than patients.

### Actions Needed

1. Locate the bed(s) and/or stretcher(s) listed by serial number on the attached business reply form.
2. Place the I.V. pole(s) in the lowest position.
3. Hang the enclosed label in a visible manner on one of the hooks of the I.V. Pole.
4. A Stryker Representative will contact your facility to schedule a time for repair.
5. Return a copy of the enclosed business reply form to confirm receipt of this notification to the undersigned or to your local Stryker representative.
6. If you have further distributed the I.V. Poles listed in this letter, please forward a copy of this notice to the new users and advise us of their new location..

\*For additional information, please, refer to the product's operations and/or maintenance manuals.

Please report any adverse events or product quality problems associated with this device to Stryker. You may also report any suspected adverse events associated with these devices to the Vigilance Branch, Health Products Regulation Group, HAS as indicated on [www.hsa.gov.sg/ae\\_online](http://www.hsa.gov.sg/ae_online) by mail, fax or email to

Vigilance Branch  
Health Products Regulation Group  
11 Biopolis Way  
#11-03 Helios  
Singapore 138667  
Fax: (65) 6478 9069  
Email: [HSA\\_productsafety@hsa.gov.sg](mailto:HSA_productsafety@hsa.gov.sg)  
Tel: (65) 6866 3538

We apologize for any disruption that this notification may cause. We strive to make products that meet our customer's expectations for quality and durability.

On behalf of Stryker Medical,

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