

URGENT MEDICAL DEVICE RECALL

**Locking Mechanism on GRASEBY™ 3300 Pump,
Pole Clamp, and Security Cover**

Affected Devices: GRASEBY™ 3300 Pump and GRASEBY™ 3000 Series Accessories

Type of Action: Recall – Correction and Removal

Date: August 24, 2017

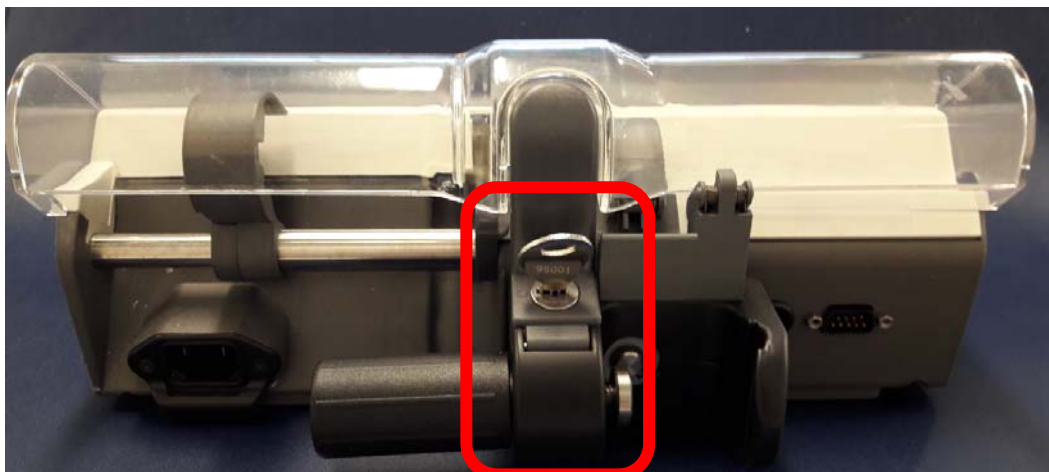
Attention: Clinicians who oversee the use of the GRASEBY™ 3300 Pump.

Affected devices: **Locking Mechanism on GRASEBY™ 3300 Pump (0128-0001 and 0128-0025:Lock Assembly), Pole Clamp (0128-0135 and 0128-0136), and Security Cover Kit (0128-0451)**

Dear Valued Customer,

The purpose of this letter is to advise you that Smiths Medical has initiated a voluntary recall of certain GRASEBY™ 3300 pumps and GRASEBY™ 3000 series accessories.

REASON FOR RECALL:



Smiths Medical has become aware that in certain cases, the lock and key supplied with Graseby™ 3300 pumps and accessories does not match the standard GRASEBY™ 3300 key. Affected Graseby™ products were either serviced in our service center or manufactured between 30-OCT-2015 and 06 -APR-2016. In affected cases, the key provided will operate the lock, but key cannot be shared between affected pumps and other GRASEBY™ 3300 pumps as it should. The key is needed to unlock the pump's security cover to allow programming of infusion, changing of program settings, restarting infusion that has been stopped, or allow clinician overrides. The key is also needed for operation of the ratcheting type pole clamp (described as the "locking" type): the lock must be operated to remove the pump from the pole and to reposition the pump on the pole.

This recall is being performed with the knowledge of the appropriate regulatory authorities.

RISK TO HEALTH:

A mismatch between the lock and key has the potential to delay the delivery of pain medication and lead to an increase in pain. In cases of severe, uncontrolled pain, rapid shallow respirations, increased blood pressure, and increased heart rate may occur.

Smiths Medical has not received any reports of deaths or serious injuries related to under delivery with GRASEBY™ 3300 Pump and GRASEBY™ 3000 Series Accessories.

INSTRUCTIONS TO CUSTOMERS:

**PLEASE TAKE THE FOLLOWING ACTIONS TO HELP US PROPERLY
EXECUTE THIS RECALL**

1. Locate all keys associated with GRASEBY™ pumps and locking accessories
2. Visually inspect keys to ensure keys are labeled “95001” (Example 1)
3. Ensure all personnel with Graseby keys are using key “95001”
4. Collect and isolate any keys not labeled “95001” (Example 2 – Non-Conforming Key)
5. Using the “95001” key, unlock and relock the locking mechanism on all GRASEBY™ pumps or locking accessories in your possession. (Enclosure 1 – list of known Serial Numbers repaired for you, Example 3 – Location of product Serial Number)
6. If the “95001” key does not successfully operate the locking mechanism, or if you do not have a “95001” key, discontinue use of the pump.
7. Complete the urgent Medical Device Recall Response Form (Enclosure 1) and return to smithsmedicalgrasebylock@stericycle.com. Return the form even if you do not have any affected devices in your possession.
8. If you are a distributor, please immediately notify your customers to whom you have distributed this product.

Example 1 - Conforming Key



Example 2 – Non-Conforming



Example 3: Where to find serial number:

The GRASEBY™ serial number
can be found on the base of the pump.



If you have any questions regarding this notification, please contact Stericycle via email at smithsmedicalgrasebylock@stericycle.com.

Smiths Medical is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may cause.

Sincerely,

Christine Thomas
Vice President, Quality Systems
Smiths Medical ASD, Inc.

Enclosures: Enclosure 1 – Urgent Medical Device Recall Response Form