June 10, 2015

Dear Loyal Halyard Customer,

ON-Q* Pump with ONDEMAND® Bolus Button - Red Tab Removal

The enclosed Technical Bulletin is provided to reinforce the product’s Instructions for Use (IFU) on the correct method for removing the red tab from the bolus device. Please note the importance of following the correct method, to ensure patient safety.

If you have any questions regarding this information, please, please call Halyard Customer Service (8:00AM – 5:00PM U.S., Pacific Standard Time): 800-448-3569/949-923-2400 or the Halyard 24-hour Product Support Hotline, 1-800-444-2728.

Yours sincerely,

Shelly Harris
Associate Director, Regulatory Affairs
Halyard Health, Inc.

43 Discovery, Suite 100
Irvine, CA 92618
USA
800.448.3569
949.923.2400 DIRECT
949.923.2401 FAX
halyardhealth.com
ONDEMAND* Bolus Device Red Tab Removal

The following references important instructions related to removal of the red tab on ON-Q* pumps with the ONDEMAND* bolus device. For complete instructions, please refer to the product Instructions for Use.

⚠️ WARNING:
- Dosing - Total Flow Rate refers to bolus + basal. To reduce potential adverse effects, medication dosing should be based on the Total Flow Rate.
- Red tab must be removed before use. If red tab is not removed before use or breaks while removing continuous delivery will occur. The delivery may be significantly greater than the Total Flow Rate (bolus + basal).

ONDEMAND Bolus Device Red Tab Removal

FIG. 1
- Remove the ONDEMAND* device red tab by pulling straight out. (FIG. 1)
- It is important to remove red tab completely and ensure it does not break. (FIG. 2) The ONDEMAND* bolus device will begin to fill.
- Do not pull the red tab upwards as breakage could occur. (FIG. 3)

FIG. 2
- Red tab after removal
- The patient or clinician should give a bolus as soon as possible after the infusion has started to ensure the bolus device is working properly. The bolus button should pop up within a few minutes and the orange indicator should begin to move towards the top.

⚠️ WARNING: If the bolus button will not latch, close the clamp. Continuous medication delivery may be occurring. This delivery may be significantly greater than the Total Flow Rate.

There are inherent risks in all medical devices. Please refer to the product labeling for Indications, Cautions, Warnings and Contraindications. Failure to follow the product labeling could directly impact patient safety. Physician is responsible for prescribing and administering medications per instructions provided by the drug manufacturer. Refer to www.halyardhealth.com for additional product safety Technical Bulletins.

Please contact the Clinical Services Department at 800-444-2728 or 949-923-2400 if you have any questions regarding this information.

*Registered Trademark or Trademark of Halyard Health or its affiliates. © 2015 H&Y. All Rights Reserved.

MK-00826
05/2015
Page 1 of 1