

IMPORTANT NOTICE

January 2008

To Whom It May Concern,

Re: Applix Smart enteral feeding pump

Further to a recent medical devices notice in the U.K on the Applix Smart enteral feeding pump, Fresenius Kabi would like to bring to your attention the potential risk of free flow when giving sets are incorrectly fitted during set up. The risk applies to all enteral feeding pumps and as such, it is imperative that all staff and users are adequately trained and competent in using enteral feeding pumps.

In order to avoid possible incorrect fitting of the giving set, we would like to remind users that the Instructions for Use (IFU) should be followed. In particular, it is important to ensure that the giving set is inserted in a straight line and slightly stretched through the tube guides (see excerpt from IFU below). Furthermore, staff and users should always visually check that the device is functioning correctly, prior to leaving the device unattended.

In addition, it should be ensured that all staff and users of the enteral feeding pump are adequately trained and assessed prior to use. The IFU should be available to end users at all times and users should adhere to the guidance provided. To this end, Fresenius Kabi provides the following training aids:

1. Instruction for Use Manual (IFU)
2. Quick Reference Guides
3. Audio Visual Training Aid (DVD Guide)
4. Tube Feeding at Home Booklet

We have enclosed a sample of each of these and an order form should you require more. Fresenius Kabi provides education and training sessions for all users of the Applix Smart enteral feeding pump. If you have any training needs or require more of our training aids, please do not hesitate to contact our head office at 01-841 3030 or you local Fresenius Kabi representative.

Yours sincerely,



Tony Rigden

Regulatory & Clinical Services Manager

Applix Smart Enteral Feeding Pump

Instructions for Use (Excerpt)

Installing the giving set in the pump

1. Unlock and open the pump door with the door lever.
2. Insert the tube clamp on the giving set into the pump in accordance with the arrow marking, with the clamp lever pointing upwards.
3. Guide the giving set over the pump mechanism and fix it in the lower tube guide ensuring that it is in a straight line and slightly stretched but not elongated.
4. Push the pump door shut and ensure that it engages properly.

