URGENT Device RECALL

Flexiflo DURA-Peg ™ Kit
List # M606 & List # M607

(Insert Date)

Re: Flexiflo DURA-PEG Bumper Degradation

Dear Doctor:

Abbott Laboratories would like to inform you that we are recalling certain lots of Flexiflo DURA-PEG Kit that were distributed between 2004 and 2006. Please review the information carefully and take the necessary actions outlined below.

ONLY THE LOTS LISTED BELOW ARE AFFECTED

List Number	Product Description	Lot Numbers
M606	Flexiflo 10 Fr DURA-PEG Kit	20721VM, 21752VM, 22934VM, 23166VM, 26573VM, 29957VM, 32241VM, 33428VM
M607	Flexiflo 16 Fr DURA-PEG Kit	26702VM

BACKGROUND
Abbott has initiated this voluntary recall in response to an increased number of complaints of DURA-PEG product bumper degradation.

Abbott has received 28 medical complaints related to degradation of the DURA -PEG internal bumper since the product was introduced in 1999 and discontinued in 2006 (0.9 incidents per 1,000 tubes distributed).

Abbott has received 28 reports of non-elective endoscopies related to this issue. There have been no reports of abdominal surgery or intestinal obstruction due to this bumper degradation.

The potential consequences of bumper degradation include the tube falling out, small pieces of the bumper becoming detached, the entire bumper becoming detached, and inflammation, infection or bleeding in and around the site of tube placement.

RECOMMENDATIONS
If you have any DURA-PEG product in your facility that has not been used, please do not use and return to Abbott.

Please consider the information above in evaluating future patient management for any patient in whom the DURA-PEG is currently placed. Additionally, patients with any gastrostomy tube, including a DURA-PEG tube, in place should be routinely monitored by a health care professional or caregiver to ensure proper tube position and tube function. DURA-PEG labeling and supporting educational materials include the following statement:

> *Note: Check tube placement before each feeding and administering medication. If the tube has been pulled, cannot rotate easily or does not move slightly in and out of the skin, DO NOT USE. CALL THE PHYSICIAN IMMEDIATELY. The tube may be out of position. Correct placement must be verified before the tube is used further.*

Care and use of the tubes according to these instructions will help to prevent any potential problems with the tubes and will facilitate the identification of problems in a timely manner.

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Thank you for taking the time to review this information. Abbott Laboratories regrets any inconvenience that this may have caused. If you have any questions regarding these products, please contact *(insert local contact name or department and telephone number)*, Monday through Friday between the hours of ___ a.m. and ___ p.m. As always, we request that any serious adverse events be reported to *(insert local contact name or department and telephone number)*.

Sincerely,

(Insert Name and Title)
(Insert Local Address)