

## URGENT FIELD SAFETY NOTICE

### NIM Flex™ EMG Endotracheal Tube

REF #'s: 8229960, 8229965, 8229970, 8229975, 8229980, 8229985

Lot #'s: 0205255342 through 0206371267 and 59716500 through 73826600

#### RECALL

#### Medtronic Reference: FA571

May 6, 2013

Dear Healthcare Professional (Physician, Hospital Administrator, OR Manager, and Risk Manager),

This letter is to inform you of a voluntary recall of the NIM Flex™ EMG Endotracheal Tube (Flex Tube).

#### Issue Description:

Our tube supplier has advised us that their tubes, used to manufacture the NIM Flex™ Endotracheal Tube product, may have the potential to delaminate. Our investigation has shown that such delamination can result in herniation of the inner lumen when the cuffs are over-inflated. Such herniation can constrict the inner lumen of the endotracheal tube resulting in a reduction of airflow to the patient.

Our records show that you were shipped affected product. We request your assistance by returning any affected devices that you may still have in your stock per the following procedure:

#### Action Requested:

1. Check your inventories for the affected products.
2. If you have any of the subject product, contact Medtronic ENT Customer Service at (insert local contact number) to arrange for returns and replacement or credit.

Your Sales Representative will be contacting you to facilitate the return of any affected NIM Flex™ EMG Endotracheal Tube you may have.

The Competent Authorities of your country has been notified of this action.

Please share this notification with others in your organization as appropriate.

Medtronic ENT regrets any inconvenience this matter may cause; however, we want to make sure that the products we provide to you are of the highest quality and reliability. We therefore ask for your cooperation in helping us to complete this product correction.

Please do not hesitate to contact your Medtronic Sales Representative at (insert local contact number) if you have any questions regarding the subject action or the content of this letter.

Sincerely,

Signature Country Manager or BU Manager.