

## URGENT FIELD SAFETY NOTICE

### NIM TriVantage™ EMG Endotracheal Tube

**REF #'s:** 8229705, 8229706, 8229707, 8229708, 8229709, 8229735, 8229736, 8229737, 8229738, and 8229739

**Lot #'s:** 205830052 to 206486732 and 0206516104, 0206516105, 0206516106, 0206516108, 0206520224, 0206520225, 0206520226, 0206520227, 0206520228, 0206520358, 0206542163, 0206545356, 0206545502

#### RECALL

#### Medtronic Reference: FA567

March 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 TriVantage™ EMG Endotracheal Tube (TriVantage product).

#### Issue Description:

We have determined that the TriVantage product may experience cuff leakage. Such leakage may result in intraoperative cuff deflation which then requires re-inflation or replacement of the deflated tube in order to ensure the continued ventilation of 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 TriVantage™ 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 recall.

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,