Medtronic

Urgent Field Safety Notice

AFFINITY® NT Cardiotomy/Venous Reservoir (CVR) Stand-Alone

All non-expired Lot Numbers of Product Code: 540 and 540T

Recall

January 2018

Medtronic reference: FA799

Dear Health Care Professional, Risk Manager,

The purpose of this letter is to advise you that Medtronic is conducting a recall for all lot numbers with remaining shelf life of the above listed product.

Issue Description:
During internal testing, Medtronic identified the potential for a breach of the sterile barrier in all lot numbers of the above listed products. Other packaging configurations, such as integrated Affinity NT Hollow Fiber Oxygenator/Cardiotomy Venous Reservoirs and Perfusion Tubing Packs with Affinity NT Cardiotomy Venous Reservoirs **are not affected by this issue**. No other Medtronic products are affected by this issue.

Through January 4, 2018, there have been zero (0) complaints received for the affected products reporting damage or a breach of the sterile barrier in the packaging, or any adverse patient effects or harms related to this issue.

Potential patient harm is infection, which can also result in secondary harms, which can occur if a breach in the sterile barrier packaging is not detected prior to use.

Potential patient harm is infection, which can also result in secondary harms if a sterile barrier breach in the packaging is present, but not detected prior to use.

For patients who were treated using one of the potentially affected products, there are no recommendations for special follow-up, physician communication or a change in patient management beyond routine practice.

Our records indicate that one or more affected product(s) were distributed to your facility. As a result, Medtronic requests that you take the following actions:

1. Immediately identify and quarantine all unused affected product in your inventory.
2. Return all affected product in your inventory to Medtronic. Your Medtronic Representative can assist you in the return and replacement of this product as necessary.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred. Please maintain a copy of this notice in your records.

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

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your MedtronicRepresentative.

Sincerely,

Medtronic Saudi Arabia