



## Urgent Field Safety Notice

### Euphora™ and Solarice™ Rapid Exchange Balloon Dilatation Catheters Recall of specific Model and Lot Numbers

July 2017

Medtronic reference: FA779

Dear Risk Manager or Healthcare Professional:

At Medtronic, our top priority is product quality and most importantly, patient safety. This communication is to inform you of a voluntary recall of select lot numbers of the Medtronic Euphora™ and Solarice™ Semi-Compliant Rapid Exchange (RX) Balloon Dilatation Catheter due to reports of difficulties in removing the stylette. Availability of each of these products will vary by geography. A summary of the model numbers and lot numbers affected by this issue can be found in Appendix A of this communication. The Medtronic NC Solarice™ and NC Euphora™ Non-Compliant RX Balloon Dilatation Catheters are **not** affected by this issue.

The total number of customer reports relating to removal difficulties associated with this generation of Medtronic Semi-Compliant RX Catheters represent 0.1% of all affected units manufactured and distributed (since 12 January 2017). Medtronic has received one (1) report of patient injury related to this matter.

In the event that stylette removal difficulties are encountered, there is the potential for damage to the balloon or catheter due to excessive force being applied, and this may lead to balloon inflation or deflation challenges. Potential risks associated with balloon inflation and deflation difficulties include prolonged procedure time and the need for additional intervention. In addition, inflation or deflation difficulties or catheter damage during procedural use could result in vessel occlusion or injury.

**As this issue is experienced at the time of product use, there is no additional action related to this recall for patients who have previously been treated with potentially affected product. These patients should continue to be monitored in accordance with each facility's standard care protocols.**

**Customer Actions:** Medtronic's records indicate that your facility has received products potentially affected by this issue. As a result, Medtronic is asking that you immediately take the following actions:

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

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

Please share this notification with others in your organization as appropriate or to any organization where the potentially affected product may have been transferred. In case of any questions related to this Urgent Field Safety Notice contact your Medtronic Representative at [mohammed.jaha@medtronic.com](mailto:mohammed.jaha@medtronic.com).

We are committed to acting responsibly in the best interest of patient safety. We sincerely appreciate your patience as it relates to this matter.

Sincerely,

Mohammed N. Jaha

12/07/17



**Appendix A:**  
**Euphora™ and Solarice™**  
**Rapid Exchange Balloon Dilatation Catheter**  
Model and Lot Listing

Affected Lot Number Range: **212553130 to 213283557**

Affected Expiration Date Range: **4-Jan-2019 to 9-May-2019**

Model Numbers:

| <b>Euphora Semi-Compliant Rapid Exchange Balloon Dilatation Catheter</b> |           |           |           |           |           |           |           |
|--|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| EUP1506X   | EUP2015X  | EUP22520X | EUP2530X  | EUP3010X  | EUP32512X | EUP3520X  | EUP37525X |
| EUP1510X   | EUP2020X  | EUP22525X | EUP27506X | EUP3012X  | EUP32515X | EUP3525X  | EUP4006X  |
| EUP1512X   | EUP2025X  | EUP2506X  | EUP27510X | EUP3015X  | EUP32520X | EUP3530X  | EUP4010X  |
| EUP1515X   | EUP2030X  | EUP2510X  | EUP27512X | EUP3020X  | EUP32525X | EUP37506X | EUP4012X  |
| EUP1520X   | EUP22506X | EUP2512X  | EUP27515X | EUP3025X  | EUP3506X  | EUP37510X | EUP4015X  |
| EUP2006X   | EUP22510X | EUP2515X  | EUP27520X | EUP3030X  | EUP3510X  | EUP37512X | EUP4020X  |
| EUP2010X   | EUP22512X | EUP2520X  | EUP27525X | EUP32506X | EUP3512X  | EUP37515X | EUP4025X  |
| EUP2012X   | EUP22515X | EUP2525X  | EUP3006X  | EUP32510X | EUP3515X  | EUP37520X | EUP4030X  |

| <b>Solarice Semi-Compliant Rapid Exchange Balloon Dilatation Catheter</b> |           |           |           |           |           |          |
|---|-----------|-----------|-----------|-----------|-----------|----------|
| SLC1506X  | SLC2015X  | SLC22520X | SLC2530X  | SLC3015X  | SLC3512X  | SLC4012X |
| SLC1510X  | SLC2020X  | SLC22525X | SLC27512X | SLC3020X  | SLC3515X  | SLC4015X |
| SLC1512X  | SLC2025X  | SLC2506X  | SLC27515X | SLC3025X  | SLC3520X  | SLC4020X |
| SLC1515X  | SLC2030X  | SLC2510X  | SLC27520X | SLC3030X  | SLC3530X  | SLC4025X |
| SLC1520X  | SLC22506X | SLC2512X  | SLC27525X | SLC32512X | SLC37512X | SLC4030X |
| SLC2006X  | SLC22510X | SLC2515X  | SLC3006X  | SLC32515X | SLC37515X |          |
| SLC2010X  | SLC22512X | SLC2520X  | SLC3010X  | SLC3506X  | SLC37520X |          |
| SLC2012X  | SLC22515X | SLC2525X  | SLC3012X  | SLC3510X  | SLC4010X  |          |