

Urgent Field Safety Notice

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

13 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 <XXXX>.

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,

Local /BU Manager



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:

Euphora Semi-Compliant Rapid Exchange Balloon Dilatation Catheter							
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

Solarice Semi-Compliant Rapid Exchange Balloon Dilatation Catheter						
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	