



**Medtronic International, Ltd. (Singapore Branch)**

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**URGENT MEDICAL DEVICE RECALL**

**Euphora™**

**Semi-Compliant Rapid Exchange Balloon Dilatation Catheters**

See Attachment 1 for Affected Model Numbers and Lot Information

4 September 2019

**Attention: Risk management Director and O.R Materials Management**

**CC: The Chairman Medical Board and relevant Head of Departments**

Dear Risk Manager or Healthcare Professional:

This letter is to inform you that Medtronic is voluntarily initiating a recall affecting a specific subset of Euphora™ Semi-Compliant Rapid Exchange Balloon Dilatation Catheters manufactured from 27-February-2019 through 31-July-2019. Potentially affected catheters were distributed worldwide under multiple model numbers and lot numbers (see Attachment 1). The Medtronic NC Euphora™ Non-Compliant RX Balloon Dilatation Catheters, and other Medtronic products, are **not** affected by this issue.

Medtronic has determined that some catheters have a slightly higher diameter stylette causing removal difficulties. If 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 injury.

Through 19-August-2019, Medtronic has received customer complaints related to stylette removal difficulties which represent 0.012% of affected product sold. Medtronic has received one (1) report of patient injury related to this matter.

As the potential inflation/deflation difficulty 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 your standard practice.

**Customer Instructions:**

Medtronic records indicate that your facility has received one or more of the affected lots of Semi-Compliant Euphora catheters. Therefore, Medtronic requests that you immediately take the following actions:

1. Identify and quarantine all unused affected product in your inventory.
2. Return all unused affected product in your inventory to Medtronic. Contact local Medtronic Representative to initiate a product return. Your local Medtronic Representative can assist you in the return of this product and in determining appropriate alternative products.
3. Complete the Customer Confirmation Form even if you no longer have the affected inventory

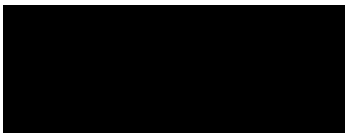
This notice needs to be forwarded to all those who need to be aware within your organization and to any organization where the affected product may have been transferred. This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations.

Per your facility's standard medical device complaint procedures, report any adverse reactions or quality problems if the quality issue described above has been observed.

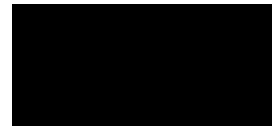
Please maintain a copy of this notice in your records. We are committed to patient safety and welcome any questions you may have regarding this communication. Please contact your Medtronic representative with questions.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,



Diana Teo  
QRA Lead  
SEA Region (Cluster 1)



Chloe Tan  
QRA Lead  
SEA Region (Cluster 2)

**Enclosures:**

- 1) *Attachment 1: Semi-Compliant Euphora Affected Product Model Numbers and Lot Information (US and OUS)*
- 2) *Customer Confirmation Form*

**Attachment 1: Euphora Affected Product Model Numbers and Lot Information (US and OUS)****Lot Manufacture Date Range: 27-Feb-2019 to 31-Jul-2019; Lot Expiration Date Range: 26-Feb-2021 to 30-Jul-2021**

US Semi-Compliant Euphora Rapid Exchange Balloon Dilatation Catheters	
Model	Lot Numbers
EUP1506X	217238068, 217354645, 217638054, 217833021
EUP1510X	217225186, 217238070, 217371289, 217602408, 217610624, 217656465, 217804976
EUP1512X	217282749, 217290758, 217518423, 217791032, 217833023
EUP1515X	217225187, 217379139, 217638060, 217727985, 217786006, 217961583
EUP1520X	217253539, 217313635, 217488906, 217791033, 217875827
EUP2006X	217290755, 217325279, 217602407, 217646822, 217791029, 217913568
EUP2010X	217313603, 217371290, 217465238, 217535671, 217656461, 217728347, 217860167
EUP2012X	217325272, 217339173, 217347821, 217379135, 217418683, 217465237, 217479184, 217518421, 217535675, 217646823, 217668159, 217713354, 217728346, 217848884, 217922641, 217939733
EUP2015X	217325281, 217371288, 217435218, 217479183, 217526980, 217646821, 217682079, 217727984, 217766423, 217850428, 217889499
EUP2020X	217325273, 217347761, 217418685, 217488908, 217535680, 217668162, 217786010, 217860170
EUP2025X	217313631, 217465231, 217602164, 217646819, 217727983, 217804979
EUP2030X	217313592, 217488910, 217721630, 217860171
EUP22506X	217232723, 217325275, 217465230, 217610620, 217713347, 217850426, 217939732
EUP22510X	217238067, 217479181, 217646820, 217799181
EUP22512X	217225189, 217379136, 217646817, 217786009, 217860169
EUP22515X	217282748, 217290757, 217479185, 217675576, 217713357
EUP22520X	217239782, 217418946, 217721627
EUP22525X	217262441, 217465234, 217881225
EUP2506X	217239781, 217505523, 217859380, 217932670
EUP2510X	217347818, 217505524, 217535673, 217668157, 217766421, 217842269
EUP2512X	217313594, 217325278, 217339176, 217347760, 217371292, 217404066, 217435216, 217465241, 217488907, 217506606, 217526982, 217535681, 217638062, 217656456, 217675571, 217705253, 217713358, 217791031, 217875835, 217884491, 217905889
EUP2515X	217325276, 217339175, 217347822, 217402505, 217418947, 217465240, 217518424, 217535677, 217656458, 217675572, 217850427, 217860175, 217889498, 217932666, 217990295
US Semi-Compliant Euphora Rapid Exchange Balloon Dilatation Catheters	
Model	Lot Numbers
EUP2520X	217313633, 217355447, 217418684, 217479182, 217526983, 217646818, 217713349, 217842272
EUP2525X	217290756, 217325283, 217535674, 217675577, 217859382
EUP2530X	217339174, 217638056, 217721629, 217875830
EUP27506X	217313629, 217903665
EUP27510X	217290753, 217379133, 217602406, 217668158, 217859381, 217932045
EUP27512X	217239783, 217435214, 217905887
EUP27515X	217238066, 217465239, 217638057
EUP27520X	217347759, 217675573, 217848883
EUP3006X	217239780, 217379140, 217804984, 217884490, 217990288
EUP3010X	217313590, 217505525, 217535676, 217859383, 217932668

EUP3012X	217325274, 217355446, 217435215, 217518420, 217535678, 217656460, 217705254, 217804981, 217860172, 217922643
EUP3015X	217325282, 217371291, 217465235, 217505522, 217526984, 217638059, 217842273, 217889500
EUP3020X	217313600, 217465236, 217518422, 217535679, 217668156, 217721628, 217875834
EUP3025X	217313605, 217488845, 217804978, 217884488
EUP3030X	217290754, 217325277, 217526981, 217675575, 217791030, 217860166
EUP32506X	217325280, 217465232, 217875829
EUP32510X	217602165
EUP32512X	217253537, 217435213, 217610623, 217833020, 217875833, 217980918
EUP32515X	217262437, 217339172, 217505518, 217610618, 217713351, 217842271
EUP32520X	217347819, 217875836
EUP32525X	217675570, 217859379
EUP3506X	217253538, 217347820, 217713348, 217859378, 217913569, 217990290
EUP3510X	217225123, 217290752, 217347817, 217505519, 217602409, 217610622, 217705251, 217742946, 217799182, 217875831
EUP3512X	217225125, 217238069, 217379138, 217799180
EUP3515X	217225188, 217379137, 217713353, 217804982
<b>US Semi-Compliant Euphora Rapid Exchange Balloon Dilatation Catheters</b>	
<b>Model</b>	<b>Lot Numbers</b>
EUP3520X	217239784, 217404067, 217766420, 217860173
EUP3525X	217290747, 217465233, 217713084, 217859385
EUP3530X	217225124, 217379134, 217848882, 217903664
EUP37510X	217262438, 217505520, 217705248, 217764489, 217833019, 217922640
EUP37512X	217313596, 217842270, 217913570
EUP37515X	217371287, 217833022, 217913571
EUP37520X	217290750, 217610621, 217804977, 217881224
EUP37525X	217742784
EUP4006X	217262439, 217347816, 217786008, 217889494
EUP4010X	217290749, 217379132, 217535670, 217668161, 217786007, 217875828, 217932043
EUP4012X	217232725, 217526979, 217638058, 217668160, 217799179, 217860168
EUP4015X	217262440, 217313627, 217488909, 217848885, 217922642
EUP4020X	217232724, 217535672, 217721626, 217875832, 217997964
EUP4025X	217465229, 217638061, 217766419, 217913572
EUP4030X	217313598, 217602163, 217638055, 217905886, 217998766
<b>OUS Semi-Compliant Euphora Rapid Exchange Balloon Dilatation Catheters</b>	
<b>Model</b>	<b>Lot Numbers</b>
EUP1506X	217291131, 217473721, 217473914, 217506615, 217576082, 217876349
EUP1510X	217262907, 217396792, 217451079, 217473910, 217473911, 217518609, 217630776, 217704793, 217704794, 217803293, 217817346, 217939845, 217960062
EUP1512X	217282165, 217291003, 217396342, 217451080, 217584296, 217728406, 217803295, 217817347, 217876348
EUP1515X	217216700, 217216702, 217270937, 217291129, 217291133, 217387047, 217396791, 217451566, 217518610, 217518611, 217584297, 217601078, 217630784, 217728244, 217775695, 217777586, 217791230, 217960063
EUP1520X	217270929, 217270933, 217339009, 217370779, 217387049, 217427611, 217444053, 217480193, 217506621, 217518608, 217518614, 217577127, 217682939, 217775696
EUP2006X	217473906, 217506617, 217601073, 217616434, 217682942, 217721594

EUP2010X	217506623, 217542638, 217557954, 217584304, 217602587, 217616444, 217682944, 217728410, 217891539
<b>OUS Semi-Compliant Euphora Rapid Exchange Balloon Dilatation Catheters</b>	
<b>Model</b>	<b>Lot Numbers</b>
EUP2012X	217225194, 217246462, 217270930, 217282164, 217291005, 217339010, 217339011, 217379610, 217379612, 217387051, 217387053, 217451567, 217557965, 217584406, 217602590, 217630783, 217704795, 217713408, 217728243, 217728408, 217729333, 217799312, 217832637, 217922811, 217940331, 217940334
EUP2015X	217370780, 217396344, 217473724, 217473913, 217480203, 217527338, 217527339, 217558106, 217577128, 217584305, 217601083, 217616442, 217630780, 217682938, 217704798, 217728242, 217729332, 217742357, 217762424, 217775697, 217786014, 217876353, 217884478, 217905104, 217913833
EUP2020X	217216701, 217225191, 217246460, 217246463, 217262442, 217262443, 217270932, 217270934, 217282826, 217282828, 217291002, 217291135, 217385682, 217444057, 217451078, 217473723, 217473916, 217480199, 217506622, 217527334, 217542637, 217557950, 217576083, 217584293, 217601079, 217602592, 217616447, 217630781, 217682943, 217683711, 217741585, 217742358, 217742360, 217777590, 217876356, 217905926, 217932681, 217960064
EUP2025X	217584408, 217601077, 217832632
EUP2030X	217370772, 217473907, 217518612, 217682945, 217775705, 217824429, 217932675
EUP22506X	217473720, 217535800, 217832634, 217876347
EUP22510X	217370782, 217713407, 217775701
EUP22512X	217480196, 217535801, 217704797, 217884481
EUP22515X	217396793, 217584301, 217601075, 217704796, 217742355, 217791228, 217884480
EUP22520X	217370778, 217601084, 217713406
EUP22525X	217535799, 217799308, 217876346
EUP2506X	217370777
EUP2510X	217262906, 217262910, 217282160, 217291001, 217444060, 217451568, 217602586, 217616437, 217630777, 217721598, 217765233, 217940329
EUP2512X	217225193, 217253645, 217282161, 217291126, 217385685, 217396345, 217444058, 217444065, 217451083, 217451570, 217473912, 217480327, 217584298, 217601081, 217616449, 217630782, 217762421, 217765228, 217791227, 217791233, 217803297, 217832636, 217876355, 217891540
EUP2515X	217253667, 217262908, 217270931, 217282163, 217291004, 217291130, 217379611, 217385683, 217396794, 217444059, 217451081, 217473725, 217473908, 217480204, 217480205, 217499989, 217499990, 217557957, 217576085, 217584295, 217601080, 217602589, 217616452, 217713409, 217721600, 217765227, 217765232, 217768796, 217775700, 217786013, 217824430, 217905105, 217913827, 217922819, 217922821, 217940339

OUS Semi-Compliant Euphora Rapid Exchange Balloon Dilatation Catheters	
Model	Lot Numbers
EUP2520X	217225192, 217253644, 217253669, 217262909, 217262911, 217270936, 217270938, 217282827, 217291128, 217291136, 217385684, 217396796, 217444061, 217451084, 217473909, 217602588, 217602591, 217616454, 217713123, 217762422, 217762423, 217763785, 217765231, 217777588, 217786011, 217799314, 217832638, 217851624, 217940330
EUP2525X	217473722, 217584292, 217721597, 217832635, 217932684
EUP2530X	217480194, 217480329, 217499987, 217884479
EUP27506X	217253668, 217339008
EUP27510X	217253643, 217396340, 217630775, 217799310, 217913830
EUP27512X	217557961, 217940337
EUP27515X	217270928, 217270935, 217387046, 217427612, 217630778, 217713124, 217786015, 217851678
EUP27520X	217396343, 217480192, 217535797, 217777591
EUP27525X	217370775, 217535804, 217911684
EUP3006X	217396786
EUP3010X	217370773, 217480195, 217518607, 217584299, 217775703
EUP3012X	217246461, 217262444, 217291132, 217339012, 217387052, 217444063, 217584410, 217764524, 217777589, 217922813
EUP3015X	217253666, 217253671, 217282162, 217291127, 217291134, 217387050, 217451085, 217480326, 217713122, 217762420, 217765226, 217803294, 217803296, 217842276, 217913826, 217922820, 217940338, 217962032
OUS Semi-Compliant Euphora Rapid Exchange Balloon Dilatation Catheters	
Model	Lot Numbers
EUP3020X	217282829, 217396795, 217427610, 217444055, 217451077, 217480201, 217499988, 217527336, 217527340, 217557960, 217584302, 217721595, 217775702, 217777587, 217817352
EUP3025X	217261363, 217396789, 217817350, 217940326
EUP3030X	217480200, 217506613, 217765229, 217832639
EUP32510X	218033199
EUP32512X	217396788
EUP32515X	217396339, 217506614, 217849836, 217891538
EUP32520X	217535798, 217584291, 217682936
EUP3506X	217506620
EUP3510X	217557953, 217683707
EUP3512X	217480198, 217480202, 217536446, 217576084, 217616439, 217922816
EUP3515X	217396797, 217480197, 217480328, 217557958, 217558107, 217601085, 217728245, 217743066, 217891541
EUP3520X	217246464, 217246465, 217387048, 217427609, 217444062, 217451569, 217506625, 217518613, 217518615, 217791229, 217842274, 217851676, 217980581
EUP3525X	217370774, 217506624

EUP3530X	217370771, 217601076, 217728407, 217799309
EUP37506X	217601074
EUP37512X	217370781
EUP37515X	217851674
EUP4006X	217396787, 217932678
EUP4010X	217396341, 217444056, 217444066
EUP4012X	217370776, 217535803, 217584409, 217775698, 217922815
EUP4015X	217261364, 217444054, 217557955, 217584407, 217683709, 217775704, 217922817
EUP4020X	217225190, 217396790, 217535796, 217940335
EUP4030X	217584300, 217765230



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**URGENT MEDICAL DEVICE RECALL**

**Euphora™**

**Semi-Compliant Rapid Exchange Balloon Dilatation Catheters**

**ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY**

Customer Contact Details	Medtronic Contact Details
<b>Physician:</b>	<b>Name:</b>
	<b>Contact:</b>
<b>Address:</b>	<b>Email:</b>
<b>Phone no:</b>	
<b>E-mail:</b>	

**Even if you have no affected stock to returned, please complete this form and table; return to your local Medtronic contacts stated above**

Please tick (either one) only:

- ☐ No, no affected inventory to be returned.
- ☐ Yes, affected inventory to be returned (Please fill up the below table if chosen)

Item code	Product Description	Lot number	QTY (Each)

**By signing this form, I confirm that I have read the Urgent Medical Device Recall Letter, dated 4 September 2019 from Medtronic regarding the Euphora and/or Solarice Semi-Compliant Rapid Exchange Balloon Dilatation Catheters and have taken appropriate action.**

Name: \_\_\_\_\_ (print) Signature: \_\_\_\_\_ Stamp: \_\_\_\_\_ Date: \_\_\_\_\_