

Urgent Field Safety Notice

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

September 2019

Medtronic reference: FA886

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™ and Solarice™ 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™ and NC Solarice™ 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 and Semi-Compliant Solarice 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. Your local Medtronic Representative can assist you in the return of this product and in determining appropriate alternative products.

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. 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 Medtronic Representative.

Sincerely,

Enclosed: Attachment 1: Affected Product Model Numbers and Lot Information

Attachment 1: Affected Product Model Numbers and Lot Information

Lot Manufacture Date Range: **27-Feb-2019 to 31-Jul-2019;**

Lot Expiration Date Range: **26-Feb-2021 to 30-Jul-2021**

Euphora Affected Product Model Numbers and Lot Information:

| Semi-Compliant Euphora Rapid Exchange Balloon Dilatation Catheters Model Numbers | |
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| Model | Lot Numbers |
| 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 |
| 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 |
| EUP2520X | 217225192, 217253644, 217253669, 217262909, 217262911, 217270936, 217270938, 217282827, 217291128, 217291136, 217385684, 217396796, 217444061, 217451084, 217473909, 217602588, 217602591, 217616454, 217713123, 217762422, 217762423, 217763785, 217765231, 217775588, 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, 217775589, 217922813 |
| EUP3015X | 217253666, 217253671, 217282162, 217291127, 217291134, 217387050, 217451085, 217480326, 217713122, 217762420, 217765226, 217803294, 217803296, 217842276, 217913826, 217922820, 217940338, 217962032 |
| EUP3020X | 217282829, 217396795, 217427610, 217444055, 217451077, 217480201, 217499988, 217527336, 217527340, 217557960, 217584302, 217721595, 217775702, 217775587, 217817352 |
| EUP3025X | 217261363, 217396789, 217817350, 217940326 |
| EUP3030X | 217480200, 217506613, 217765229, 217832639 |
| EUP32510X | 218033199 |
| EUP32512X | 217396788 |
| EUP32515X | 217396339, 217506614, 217849836, 217891538 |

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| 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 |

Solarice Affected Product Model Numbers and Lot Information:

| Semi-Compliant Solarice Rapid Exchange Balloon Dilatation Catheters Model Numbers | |
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| Model | Lot Numbers |
| SLC1506X | 217427355 |
| SLC1510X | 217253572, 217298666, 217387126, 217427354, 217487816 |
| SLC1512X | 217218112, 217253582, 217387128, 217487818, 217542634, 217859789 |
| SLC1515X | 217246455, 217253577, 217306789, 217415822, 217427365, 217823443, 217859165, 217940024 |
| SLC1520X | 217253580, 217306787, 217427359, 217542633, 217646425, 217668582, 217799249, 217859164 |
| SLC2006X | 217435326, 217913786 |
| SLC2010X | 217253573, 217297545, 217387127, 217427356, 217646867, 217668585, 217676631, 217905820 |
| SLC2012X | 217253578, 217298670, 217306788, 217415824, 217434925, 217602539, 217668687, 217799250, 217859791, 217940066 |
| SLC2015X | 217218115, 217253574, 217271254, 217298669, 217306223, 217404046, 217418812, 217418907, 217427706, 217435327, 217498815, 217615647, 217646871, 217668584, 217713076, 217721607, 217777612, 217799251, 217884509, 217913790 |
| SLC2020X | 217218110, 217246457, 217253575, 217271253, 217298667, 217306220, 217387130, 217404047, 217418908, 217487822, 217498821, 217676628, 217713075, 217727927, 217799252, 217850364, 217905822 |
| SLC2025X | 217271251, 217542635, 217905821 |
| SLC2030X | 217218119, 217427363, 217602538, 217704778, 217777614 |
| SLC22510X | 217487815, 217646423 |
| SLC22515X | 217427362, 217646422 |
| SLC22520X | 217721606, 217913787 |
| SLC22525X | 217415820, 218025488 |
| SLC2506X | 217823441 |
| SLC2510X | 217218122, 217401003, 217427357, 217693881, 217913792, 218034774 |
| SLC2512X | 217271257, 217306225, 217415825, 217434924, 217498822, 217606584, 217695006, 217859787, 217913793 |
| SLC2515X | 217253581, 217306786, 217401005, 217418813, 217418906, 217427709, 217487819, 217498813, 217542636, 217602540, 217646866, 217693884, 217859788, 217905823, 218045287 |
| SLC2520X | 217271256, 217387129, 217404048, 217418909, 217434922, 217487821, 217498819, 217542632, 217646868, 217695009, 217859162, 217913794 |
| SLC2525X | 217218108, 217675585 |
| SLC2530X | 217246456, 217434923, 217498814, 217615649, 217704782, 217777613 |
| SLC27512X | 217427360, 217602535, 217695007, 217850362 |
| SLC27515X | 217542631, 217602534, 217646421, 217713071, 217799248 |
| SLC27520X | 217298668, 217387131, 217704783, 217832948 |
| SLC3010X | 217271255, 217693880, 217850363 |
| SLC3012X | 217306224, 217415821, 217498812, 217646869, 217704781, 217850360 |
| SLC3015X | 217246458, 217253579, 217306790, 217418910, 217498816, 217615646, 217693885, 217832949, 217913791 |
| SLC3020X | 217253571, 217297544, 217306222, 217401004, 217498818, 217646872, 217695008, 217859163 |
| SLC3025X | 217306221, 217487817 |
| SLC3030X | 217218124, 217427708, 217602537, 217850358 |
| SLC3506X | 217246454, 217713072 |
| SLC3510X | 217668583 |
| SLC3512X | 217913789 |

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| SLC3515X | 217271252, 217415823, 217498817, 217668580, 217913788 |
| SLC3520X | 217646424, 217676626, 217832947, 217850361 |
| SLC3530X | 217940068 |
| SLC4010X | 217246459 |
| SLC4012X | 217668581, 217905819 |
| SLC4015X | 217498820, 217615648, 217859790 |
| SLC4020X | 217427353, 217487820, 217606585 |
| SLC4025X | 217823440 |
| SLC4030X | 217823444 |