

Urgent Field Safety Notice

Antibiotic Impregnated (ARES™) Catheters

Model Numbers - 91101, 93092, 95001

December 2020

Medtronic Reference: FA948

Dear Healthcare Provider,

Medtronic is voluntarily recalling specific lots of the ARES™ Antibiotic Impregnated Shunt Catheter products. Please review the information contained in this letter, quarantine any affected product in your inventory for return and replacement by Medtronic.

Issue Description:

During routine post-sterilization inspection, Medtronic identified that there is a potential for a defect on the seal of the outer pouch of specific lots of the ARES™ Catheters. Internal testing has shown that approximately 3 percent of pouches are potentially impacted by this condition. This defect may compromise the sterility of the pouch contents, which may increase the risk of post-operative infection, requiring further medical intervention. To date, Medtronic has not received any reports of patient harm or any complaints related to this issue.



Patient Management:

Patients implanted with affected devices should be monitored in accordance with your medical facility's standard care protocols. Elective explantation or revision is **not** recommended for this issue.

Required Actions:

1. Identify, segregate, and quarantine affected products within your inventory. The list of affected lots is included.
2. Contact your Medtronic representative to return affected product and to receive replacement.

Additional Information:

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

We sincerely regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

If you have questions related to this issue, please contact your local Medtronic representative directly or via Tel No: 01 511 1400.

Sincerely,



Keith Taverner
Regulatory Affairs Manager UK & Ireland

Attachment: Appendix A, Affected Models and Lot Numbers.

Appendix A: Affected Models and Lot Numbers.

ARES Catheter Affected Model Numbers and Lot Numbers
91101 - CATHETER 91101 VENTRICULAR ANTIMICROBIAL
0010052549, 0010369362, 0010052552, 0010149011, 0010149013, 0010258434, 0010265136, 0010353504, 0010336618, 0010265137, 0010265138, 0010278408, 0010278409, 0010289827, 0010289828, 0010289829, 0010305921, 0010289830, 0010289831, 0010289833, 0010289834, 0010297686, 0010305919, 0010297689, 0010297691, 0010297693, 0010297696, 0010305912, 0010305920, 0010305923, 0010305926, 0010316955, 0010316956, 0010316957, 0010316958, 0010336617, 0010336619, 0010353500, 0010353501, 0010353502, 0010353503, 0010369364, 0010369365, 0010376787, 0010376788, 0010376789, 0010376790, 0010384892, 0010384893, 0010384894, 0010384895, 0010384896, 0010393213, 0010393215, 0010393216, 0010393814, 0010393839
93092 - CATHETER 93092 DISTAL ANTIMICROBIAL
0010369367, 0010258435, 0010353507, 0010273889, 0010273890, 0010273891, 0010273893, 0010278418, 0010278427, 0010281384, 0010281390, 0010316959, 0010281391, 0010281392, 0010305929, 0010289835, 0010297678, 0010289836, 0010305937, 0010312360, 0010312361, 0010312362, 0010316960, 0010316961, 0010316963, 0010336620, 0010353505, 0010369366, 0010376784, 0010376785, 0010376786, 0010384897, 0010384900, 0010384901, 0010384903, 0010393220, 0010393221
95001 - CATHETER 95001 KIT ANTIMICROBIAL
0010369357, 0010038455, 0010061294, 0010061295, 0010083617, 0010083618, 0010083619, 0010083620, 0010083622, 0010083623, 0010097240, 0010097241, 0010097249, 0010097250, 0010316973, 0010097251, 0010305905, 0010258429, 0010258430, 0010258433, 0010265129, 0010265130, 0010265131, 0010265133, 0010265134, 0010297675, 0010265135, 0010278428, 0010278430, 0010281382, 0010289822, 0010281383, 0010289819, 0010289823, 0010297674, 0010297676, 0010297683, 0010305904, 0010305906, 0010305907, 0010305908, 0010305909, 0010316967, 0010316968, 0010316971, 0010316972, 0010336621, 0010336622, 0010336623, 0010353498, 0010353499, 0010369358, 0010369359, 0010376779, 0010376781, 0010376782, 0010376783, 0010384872, 0010384874, 0010384881, 0010384888, 0010393228, EB00006085, EB00006086, EB00006166, EB00007496, EB00007537, EB00009476