Medtronic

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 <and sign and return the customer confirmation form included with this letter>.

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.
3. <Please complete and return the customer confirmation form, even if you do not have affected product.

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.

Sincerely,
Ayman Doughan
senior business manager, cranial spine, APS
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

Medtronic

FA948

RETURN VERIFICATION FORM

ARES Catheter Pouches with Sterility Breach

Please complete this form and return it to Medtronic even if you do not have affected inventory

December 10, 2020

Customer Contact Details	**Medtronic Contact Details**
Hospital Name: **Medtronic Account Number:**	**To:** **Medtronic APS RA Team**
Account Address: Street: Postal Code: City: **Department:** Contact Person at Point of Collection: Opening Hours: **Name of person completing this form:**	**Address:** **Office 1, 12 Floor, Abraj Al-Tawuniya, South Tower** **King Fahad Road, Olaya, Riyadh, Saudi Arabia**
Telephone:	**Telephone: 00966118384761**
Fax:	**Fax: NA**
E-mail:	**E-mail: nahar.s.alsurayi@medtronic.com**

Please list the quantity of affected product at your facility, if you have **no** inventory, please tick the box below.

No Inventory (Please tick): ☐

Item Code	**Invoice or Despatch Note (if available)**	**Lot number**	**Quantity (Eaches or Cases) Please specify**

Information for the courier:

Number of parcels to collect: _____

Number of these parcels that weigh more than 45 KG: _____

By signing this form, I confirm that I have read and understand the Field Safety Notice regarding the ARES Catheter Pouches with Sterility Breach dated November 2020.

I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of the ARES Catheter Devices noted in this letter.

_____ _____ _____

Name: (print) Signature: Date:

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.
- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.