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Virginia Road, Kells,  
Co Meath, Ireland

Tel: +353 (0)46 928 0100

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### Field Safety Notice

**Date:** 13 Jan 2017

**Commercial Name:** Medtronic Devon Light Gloves (Light Handle Covers)

**FSN Identifier:** FSN17A001

**Type of action:** Removal of the Light Handle Covers (LHC)

**Attention:** This letter is to inform you of a Field Safety Notice initiated by Medtronic

**Description of the Problem:** Light handle covers may split on application to the Devon Light Handle Adapter.

**Safety Action:** Medtronic has initiated a recall which indicates that all affected LHCs are to be removed from the market. ArcRoyal has placed the affected LHC into Custom Procedure Trays (CPTs). ArcRoyal is issuing this Field Safety Notice to all Customers to provide instructions on how to control the affected LHC.

**Details on affected items:**

Reference	Description	Lot Number
10-004723	Light handle cover	All Lots

Attached is a list of all CPTs which have been supplied to you by ArcRoyal that are affected by this Field Safety Notice. We can offer a sterile equivalent LHC for short term replacement. If you wish to avail of this equivalent replacement, please communicate your request to us.



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**Advice on Action to be taken by the user:**

To minimize disruption and ensure continuous patient care, ArcRoyal is recommending the following:

1. Check your inventory to identify affected CPTs
2. Place on hold any CPTs that are affected
3. Complete the attached verification form Appendix I **This should be done even if you have no affected product**
4. Return the completed Field Safety Corrective Action Response Form Appendix I to ArcRoyal (emma.russell@owens-minor.com)
5. On use of the CPT the affected Light Handle Cover (LHC) is to be removed
6. The affected LHC can be returned to ArcRoyal or disposed of at the hospital
7. If the LHC is disposed of at the hospital Appendix II must be completed and returned to ArcRoyal

**Transmission of this Field safety notice:**

Please immediately forward this information to all departments within your organisation in which the LHC may be stored. Additionally, please ensure that a copy of this information is provided to any other organisations to which the affected LHC have been transferred. Please maintain awareness on this notice and resulting corrective action for an appropriate period to ensure effectiveness of the corrective action

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience that this may cause you. Should you have any questions or concerns about the matter, please don't hesitate to contact me.

Yours Sincerely,

Emma Russell  
Compliance Engineer  
ArcRoyal uc, an Owens and Minor Company



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### Appendix I

#### Field Safety Notice Corrective Action Response Form

Please acknowledge that you have received, read and understood the actions to be taken by completing the information below.

The completed response form should be immediately returned via fax or email to

Fax: 00353469280110

Email: emma.russell@owens-minor.com

I have checked our inventory and found the following number of CPTs containing the affected Medtronic Light Handle Cover.

Product Number	Lot Number	Quantity left in stock of affected packs

This facility has read and understood the information supplied to us through the Field Safety Notice issued by ArcRoyal in relation to CPTs containing the affected Medtronic Light Handle Cover

Facility Name	
Facility Address	
Your Printed name and Title	
Signature and Title	
Phone Number/Fax Number	



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**Appendix II**

**Certificate of Destruction**

I certify that the product(s) listed in the table below have been destroyed and removed from inventory records as a result of product Field Safety Notice FSN17A001 Instructions received from ArcRoyal.

Product Number	Lot Number	Quantity Destroyed

**Authorized Signature:**

**Name:**

**Position:**

**Date:**

**Destruction of the medical devices listed above was completed on**