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## Field Safety Notice

**Date:** 13May2015

**Commercial Name:** Covidien Devon Light Gloves (Light handle covers)

**FSN Identifier:** FSN15D001

**Type of action:** Removal of the light handle covers (LHC)

### Attention:

This letter is to inform you of a Field safety notice initiated by Covidien

### Description of the Problem

Light handle covers MAY contain splits or holes

### Safety Action

Covidien has issued a Recall which indicates that all affected LHC's are to be removed from the market. ArcRoyal has placed the affected LHC into CPT's. ArcRoyal is issuing this Field safety notice to all their 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 CPT's which have been supplied to you from ArcRoyal that is affected by this Field Safety Notice. Unfortunately as Covidien have temporarily ceased manufacturing the LHC they have no equivalent LHC to offer us for replacement, therefore ArcRoyal cannot offer you an equivalent sterile LHC straight away. However ArcRoyal are working to supply an equivalent sterile LHC, we will be in a position to inform you of further details in due course.

### 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 CPT's
2. Place on Hold any CPT's 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 ([iarmstrong@arcroyal.ie](mailto:iarmstrong@arcroyal.ie))
5. On use of the CPT the affected Light handle cover (LHC) is to be removed
6. The affected Light handle cover (LHC) can be returned to ArcRoyal or destructed at the hospital
7. If the light handle cover (LHC) is destructed in the hospital appendix II must be completed and return to ArcRoyal



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**Transmission of this Field safety notice:**

Please immediately forward this information to all departments within your organisation in which the Light handle cover (LHC) may be stored. Additionally, please ensure that a copy of this information is provided to any other organisations to which the affected light handle covers (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,

A handwritten signature in blue ink that reads "Irene Armstrong".

Irene Armstrong  
Compliance Engineer  
ArcRoyal.



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### Appendix I

#### Advisory 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: iarmstrong@arcroyal.ie

I have checked our inventory and found the following number of CPT's with the affected LHC's in them. .

Product Number	Lot Number	Quantity left in stock of affected packs

This facility has read and understood the information supplied to us through the advisory notice issued by ArcRoyal in relation to the Covidien 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 FSN15D001 Instructions received from ArcRoyal.

Product Number	Lot Number	Qty Destroyed

**Authorized Signature:**

**Name:**

**Position:**

**Date:**

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