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Virginia Road, Kells,
Co Meath, Ireland

Tel: +353 (0)46 928 0100

Fax: +353 (0)46 928 0110

Advisory Notice

Date: 26 October 2016

Commercial Name: 10-00478 Devon Light Glove

Identifier: FSN16J001

Type of action: Labelling Update

Attention:

This letter is to inform you of an advisory notice initiated by Medtronic

Description of the Problem:

Customers have reported that on rare occasion (complaint rate of less than 20/100,000 or 0.0017%), the Devon Light Glove may split upon application to the Devon Light Handle Adapter. A subset of these splits reportedly resulted from a difficult application of the glove to the handle adapter. A split in the glove can potentially lead to a breach in the sterile barrier between the glove and the handle adapter.

Safety Action

Medtronic have issued a field safety notice detailing that addition of the statement "After application, inspect the Light Glove for barrier integrity" will be added to their IFU in order to help OR staff ensure that the sterile field is maintained.

As ArcRoyal has placed Devon Light Handle Covers into our Procedure Trays ArcRoyal and is issuing this advisory notice to all of our customers to provide instructions to inspect the Devon Light Glove after application. The instruction to customer is "After application, inspect the Light Glove for barrier integrity".

Details of affected items

The instruction that "after application, inspect the Light Glove for barrier integrity" should be applied to ArcRoyal part code, 10-004723, Devon light handle cover for all trays produced after 01 May 2015.



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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 Procedure Trays
2. Complete the attached response form Appendix I **This should be done even if you have no affected product**
3. Return the completed Advisory Notice Action Response Form Appendix I to ArcRoyal (emma.russell@owens-minor.com)
4. The affected Procedure Trays can still be used, with instruction that "After application, inspect the Light Glove for barrier integrity".

Transmission of this advisory notice:

Please immediately forward this information to all departments within your organisation in which the Procedure Trays may be used. Additionally, please ensure that a copy of this information is provided to any other organisations to which the affected Procedure Trays may 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 do not hesitate to contact me.

Yours Sincerely,

A black rectangular box redacting the signature of Emma Russell.

Emma Russell
Quality Compliance Engineer



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Appendix I

Advisory Notice 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

This facility has read and understood the information supplied to us through the advisory notice issued by ArcRoyal in relation to the Procedure Trays containing the Devon light handle cover.

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