

ArcRoyal uc

Virginia Road,
Kells,
Co. Meath
A82 R862, Ireland

p +353 (0) 46 928 010

Field Safety Notice

For Dispo Medical Bacterial Filter Slime Line (Insufflation Set 300cm) placed in procedure pack CHA229 and Q01574

Type of Action: Advisory

FSN-23-J-001

30 November 2023

Dear Valued Customer,

ArcRoyal has been informed of an Advisory Field Safety Notice for Dispo Medical Bacterial Filter Slime Line (Insufflation Set 300cm). Dispo Medical has issued an Advisory notice regarding the possible presence of blocked connectors. ArcRoyal place this device into procedure packs listed in Table 1.

Details:

Dispo Medical has identified that an error occurred during the injection moulding process of one of the filter connectors they use (figure 1). A relatively small part of these connectors appears to be impenetrable and is blocked from the inside by an occluding fleece (figure 2). These faulty connectors may have ended up in some of their medical devices. There is no immediate danger to the patient, but the product will not function because gas cannot flow through it. A blocked connector will cause discomfort during use and will delay the procedure using the medical device in question.

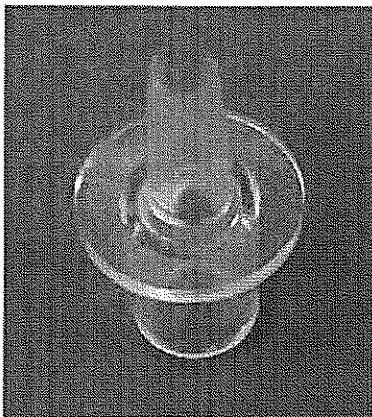


Figure 1: Filter connector

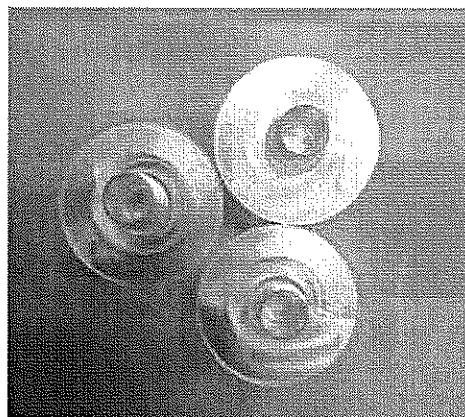


Figure 2: Incorrect filter connectors with occluding fleece

ArcRoyal therefore wish to provide notice that, in relation to the Bacterial Filter Slime Line (Insufflation Set 300cm) contained in procedure pack lots listed in Table 1; there may be some blocked connectors.

Recommendations for Use:

Before using the device mentioned, we request that you check whether the connector is open. If you encounter a blocked connector, please report this to us as soon as possible via ArcRoyal.QARAQueries@owens-minor.com

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Details of affected devices

ArcRoyal supply the affected Dispo Medical device included in the below lots of CHA229 and Q01574;

Table 1:

ArcRoyal Code	Dispo Medical Code	Description	Pack Code	Work Order/Lot
10-008981	73272	Bacterial Filter Slime Line (Insufflation Set 300cm)	CHA229	790728 785541 786805 787717 788551
			Q01574	790968 786186 787064

All other components within the CPT are safe to use as normal and are not impacted by this field safety notice.

Transmission of this Advisory

ArcRoyal are committed to patient safety and would appreciate your immediate attention and cooperation to this matter. Please immediately forward this information to all departments within your organisation. Attached is the Advisory Field safety notice issued by Dispo Medical with the instructions for users of this device.

Advice on action to be taken by the user

Ensure the contents of this Field Safety Notice are read and understood by those within your organization who may use the affected device in the procedure packs listed in the above Table 1.

Please return a completed Appendix I as acknowledgment of receipt of this Field Safety Notice to ArcRoyal.QARAQueries@owens-minor.com. If you are no longer in possession of or no longer use the device listed above, please indicate so in a response to your customer representative so we may update our records.

We sincerely apologize for any inconvenience that this may cause and thank you for your business and continued support. If you have any questions or concerns, please do not hesitate to contact your ArcRoyal representative.

Yours Sincerely,



Mary O'Reilly
ArcRoyal Quality Manager

ArcRoyal uc

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Appendix I
FSN-23-K-001
Field Safety Notice Response Form

Please complete this form as acknowledgement that you have received, read and understood the actions to be taken in relation to FSN-23-K-001 regarding Dispo Medical device.

The completed response form should be immediately returned via email to:
ArcRoyal.QARAQueries@owens-minor.com

This facility has read and understood the information supplied to us through the Advisory Field Safety Notice issued by ArcRoyal in relation to CHA229 and Q01574 containing the affected Bacterial Filter Slime Line (Insufflation Set 300cm), ArcRoyal Code 10-008981, Vendor Code 73272

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

