

ArcRoyal uc

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

p +353 (01) 46 928 0100

Field Safety Notice

Date: 08 Jan 2020

Commercial Name: Custom Procedure Trays containing Insufflation Tubing Set with Gas Filter ArcRoyal Code 10-005212, Supplier Code 031222-10

Identifier: FSN-20-A-001

Type of Action: Removal of Karl Storz Insufflation Tubing Set with Gas Filter ArcRoyal Code 10-005212, Supplier Code 031222-10

Attention: This letter is to inform you of a Field Safety Notice initiated by Karl Storz.

ArcRoyal received a Field Safety Notification from Karl Storz on the 27th of December 2019. The notification detailed that Karl Storz has initiated a recall of specific product codes and lot numbers of Insufflation Tubing Set with Gas Filter.

The Field Safety Notice Recall issued by Karl Storz states:

Problem Description:

“It is suspected that the listed products had increased residues of the sterilization gas ethylene oxide (EO) at the time of delivery because a validation parameter (temperature during outgassing) had not been monitored. If these products are used further, there is no risk that patients may come into unnecessary contact with ethylene oxide (EO).

Due to the relatively short duration of application and the expected low ethylene oxide exposure to the patient, no further measures are required for patients who have already been treated.”

Safety Action: Karl Storz have initiated a recall that indicates that specific batch numbers of Insufflation Tubing Set with Gas Filter are to be removed from the market. ArcRoyal has placed the Insufflation Tubing Set with Gas Filter into Custom Procedure Trays (CPTs). ArcRoyal is issuing this Field Safety Notice to all Customers to provide instructions on how to control the affected Insufflation Tubing Set with Gas Filter ArcRoyal Code 10-005212, Supplier Code 031222-10

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Details of affected items:

The Insufflation Tubing Set with Gas Filter ArcRoyal Code 10-005212 is used in the following CPTs listed in Table 1 below.

Table1 List of affected CPTs

Product Code	ArcRoyal Lot Number	Supplier Lot Number	# of cases	# of trays	Expiry Date
GE1499	674165	W-028719	12	60	30/04/2021
GE1499	674659	W-028719	4	20	30/04/2021
GE1499	675281	W-028719	4	20	30/04/2021
GE1499	676468	W-028719	8	40	30/05/2021
GE1499	678015	W-028719	4	20	30/05/2021
GE1499	679048	W-028707	4	20	30/07/2021
GE1499	680201	W-028707	12	60	30/07/2021
GE1513	678153	W-028707	4	16	30/07/2021
NL0180	677704	W-028719	4	20	06/11/2021
NL0180	678668	W-028707	8	40	25/11/2021
NL0183	676563	W-028719	12	72	23/10/2021
		& W-028719			
NL0183	677705	W-028707	12	72	11/11/2021
NL0183	679914	W-028707	12	72	14/11/2021
NL0183	681365	W-028707	8	48	08/12/2021
NL0183	682790	W-028707	4	24	10/12/2021

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. Complete the attached verification form Appendix I
This should be done even if you have no affected product
3. Return the completed Field Safety Corrective Action Response Form Appendix I to ArcRoyal (elaine.lynn@owens-minor.com)
4. On use of the CPT the Insufflation Tubing Set with Gas Filter ArcRoyal Code 10-005212 is to be removed.

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The affected Insufflation Tubing Set with Gas Filter ArcRoyal Code 10-005212 can be returned to ArcRoyal or disposed of at the end users facility.

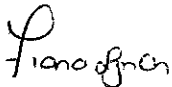
5. If the Insufflation Tubing Set with Gas Filter ArcRoyal Code 10-005212 is disposed of at the hospital Appendix II must be completed and returned to ArcRoyal
6. Ensure a copy of this notification is included with each case of CPT's

Transmission of this Field safety notice:

Please immediately forward the information to all departments within your organisation in which the Insufflation Tubing Set with Gas Filter ArcRoyal Code 10-005212 may be stored. Additionally, please ensure that a copy of this information is provided to any other organisations to which the affected items 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,



Fiona Lynch
Quality Manager
ArcRoyal uc, an Owens and Minor Company

ArcRoyal uc

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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: elaine.lynch@owens-minor.com

I have checked our inventory and found the following number of CPTs containing the affected Insufflation Tubing Set with Gas Filter ArcRoyal Code 10-005212

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 Insufflation Tubing Set with Gas Filter ArcRoyal Code 10-005212

Facility Name	
Facility Address	
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 FSN-20-A-001 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: