

ArcRoyal uc

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

p +353 (0) 46 928 010

Field Safety Notice

For Mediplast Suction Set Medina Midi mouthpiece with three slits, 26cm, tubing 3.5m that is included in Vingmed CPT DV5125

Type of Action: Advisory
FSN-23-B-001

22 February 2022

Dear Valued Customer,

ArcRoyal has been informed of an Advisory Field Safety Notice for Mediplast Suction set. Mediplast has noted a variation in the strength of the attachment between the hand piece and the suction tip. ArcRoyal place this Suction Set into Vingmed CPT DV5125 that may be in your inventory.

Details:

Mediplast has noted a variation in the strength of the attachment between the hand piece and the suction tip. No serious incident has occurred, but Mediplast is choosing to provide information about this, as low strength in the attachment between the hand piece and the suction tip could cause these to separate from each other. ArcRoyal therefore wish to provide notice that, in relation to the suction set contained in the lots of DV5125 listed below; there may be an increased risk of the suction tip separating from the actual hand piece attachment

Details of affected devices

ArcRoyal supply Vingmed with the affected Mediplast Suction set in the below lots of DV5125;

Table 1:

ArcRoyal Code	Mediplast Code	Description	Pack Code	Work Order/Lot
10-007476	68122	Mediplast Suction Set Medina Midi mouthpiece with three slits, 26cm, tubing 3.5m	DV5125	768969 765328 766971 767639

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

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departments within your organisation. Attached is the Advisory Field safety notice issued by Medioplast with the instructions to notify all end users that the suction tip is at risk of separating from the handle piece.

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 Medioplast Suction Set listed in the above table.

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,

 22 Feb 2023

Ciarán McCurtin
ArcRoyal General Manager

ArcRoyal uc

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Appendix I
FSN-23-B-001
(Mediplast reference Field Safety Notice FSN 23-2423)
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-B-001 (Mediplast reference FSN 23-2423)

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 Field Safety Notice issued by ArcRoyal in relation to CPT DV5125 containing the affected Mediplast Suction Set, ArcRoyal Code 10-007476.

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