

ArcRoyal uc

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## Field Safety Notice

Vostra Tampon Nasal included in Halyard CPT Q98458 Nasenset

**Type of Action:** Updating the instructions for use  
FSN-23-L-001

12 December 2023

Dear Valued Customer,

**Commercial Name:** Halyard Nasenset CPT Q98458 containing Vostra Tampon Nasal  
ArcRoyal Code 10-008651, Supplier Code 12480205

**ArcRoyal Identifier:** FSN-23-L-001

**Vostra:** FSN Ref: U473, FSCA Ref: 36063/23

**Type of Action:** Updating the instructions for use (IFU) for ArcRoyal Code 10-008651,  
Supplier Code 12480205, contained within Halyard Nasenset CPT Q98458

**Attention: This letter is to inform you of a Field Safety Notice initiated by  
Vostra**

ArcRoyal received an official Field Safety Notification from Vostra on the 7<sup>th</sup> of Dec 2023. The notification detailed that Vostra is conducting a Field Safety Corrective Action to update their IFU for the Tampon Nasal.

### Details and Clinical Risk:

As part of the PMS activities, VOSTRA has become aware of a case of use with the product RHINOTAMP in which a user pulled on the reinforcing threads with his hands, contrary to the instructions in the instructions for use. In this case, a tamponade / tamponade component remained in situ after detamponation.

The complaint is due to two application errors/errors in use, as the user acted contrary to the warnings in the instructions for use and did not take into account the state of the art and good clinical practice. During detamponation, the reinforcement threads were pulled, which can lead to disintegration of components of the tamponade, so that component parts can enter the site in an uncontrolled manner. Correct consideration of the state of the art and Good Clinical Practice would have been sufficient even if the instructions for use - "Do not pull out Rhinotamp by the reinforcement threads! Removal after application with forceps or similar instruments." - would have completely prevented the event in question. This is achieved by appropriate follow-up checks of the site and completeness checks of all tamponade components after detamponation has been completed.

The FMECA considers the error and application case. However, this takes into account the state of the art and the GCP. The FSCA is intended to provide the user with revised

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instructions for use that now explicitly provide implicit information from the state of the art and the GCP. Change in IFU: Addition of the warning: After removing the tamponades, check that all tamponades or tamponade components have been completely removed.

**Details of affected devices**

ArcRoyal supply Halyard with the affected Tampon Nasal set in the below lots of Q98458;

**Table 1: Affected product**

ArcRoyal Code	Vostra Code	Description	Pack Code	Work Order/Lot
10-008651	12480205	Tampon Nasal	Q98458	754033
				755604
				758123
				746051
				747958
				749388
				752125
				759039
				762306
				763691
				764896
				768127
				771328
				773254
				776682
				778878
				781599
782640				
783133				
786556				
787302				
792137				

The affected listed code is contained within Halyard custom procedure tray Q98458. All other components within the CPT are safe to use as normal and are not impacted by this field safety notice.

**Actions for customers to take:**

Based off the FSN received from Vostra, ArcRoyal requires that the following actions are taken:

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1. Ensure the contents of this Field Safety Notice are read and understood by those within your organization who may use the Vostra Tampon Nasal listed in the above table 1.
2. Inspect your inventory, locate and identify any units of the impacted lot numbers as per those detailed in Table 1. Please remove the existing IFU and replace with the attached IFU FB\_4.2.3.2\_IFU-RT\_Rev5, revision 5 of 10.11.2023.
3. If you have further distributed the product, identify those facilities, notify them of the new IFU FB\_4.2.3.2\_IFU-RT\_Rev5, revision 5 of 10.11.2023.
4. Ensure a copy of this notification along with updated IFU is included with each case of CPT's before sending to the end users facility.
5. Complete and return the Field Safety Corrective Action Response Form, Appendix I, to ArcRoyal ([ArcRoyal.QARAQueries@owens-minor.com](mailto:ArcRoyal.QARAQueries@owens-minor.com)) confirming receipt of this notification.

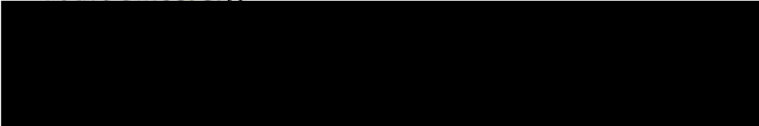
**NOTE:** If you no longer use the product or it is no longer in your inventory, it is still important that you return the Customer Response Form for our reconciliation purposes.

#### 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 Field Safety Notice issued by Vostra.

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,

  
ArcRoyal Quality Manager

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**Appendix I**  
**FSN-23-L-001**  
**(Vostra: FSN Ref: U473, FSCA Ref: 36063/23)**  
**Field Safety Corrective Action Response Form**

Please complete this form as acknowledgement that you have received, read and understood the actions to be taken in relation to ArcRoyal FSN-23-L-001.

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 Q98458 containing the affected Vostra Tampon Nasal ArcRoyal Code 10-008651, Supplier Code 12480205

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