

URGENT: FIELD SAFETY NOTICE

BALLARD* Multi-Access Port (MAP) Closed Suction System for Adults and BALLARD* Seal Cassette

FSN REF: FSCA-2021-006

23 November 2021

«Customer_Name»

Dear Valued Avanos Customer:

Avanos Medical (formerly Halyard Health) is issuing a field safety notice for BALLARD* Multi-Access Port Closed Suction System for Adults and 'BALLARD* Seal Cassette. This field safety notice is being issued because there is an incorrect expiration date printed on the labels.

What is the reason for this Field Safety Notice?

Avanos has detected through a regular review of the Label Room Spreadsheet that on the Label Room Spreadsheet (a password protected document) some codes of the MAP Catheter products had been assigned the incorrect expiry date.

The correct shelf life for these products is 3 years, but instead a shelf life of 5 years was used to print the expiry date on the labelling.

All of the affected products were manufactured in 2021. Each lot should have been labelled with a 3-year expiry date (i.e., 2024), but were erroneously labelled with a 5-year expiry date (i.e., 2026). Therefore, no products are expired at this time.

Which products are impacted?

This FSN pertains to the Avanos products identified in Table 1.

Table 1: Impacted Product Codes

REF Code	Material Description	Lot Number
24013-5	BALLARD* Seal Cassette Replacement for Multi-Access Port (MAP) Catheter	30143745
24014-5	BALLARD* Multi-Access Port Catheter, Double Swivel Y Elbow,Adult, 14 Fr,	20065842
		30135996
		30135999
		30137463
		30140309
		30138711
		30137463
		30141360

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		20065842
		30135999
		30135996
240168-5	BALLARD* Multi-Access Port (MAP) Catheter, Double Swivel Y- Adult, 16 Fr, DSY, MDI	30135997
		30137462
		30138710
		30140310
		30141359
		30138710
		30141359
		30140310
		30137462
		30135997

What should I do in response to this Field Safety Notice?

Our ship history records show that your facility has received one or more lots of the affected products. As the products are currently not expired, Avanos requires that you take the following actions:

- **CHECK** all storage and usage locations to determine if any impacted product remains within your possession and complete the acknowledgement form in Annex 1.

Unused Inventory

- **SEGREGATE** the devices according to your facility's procedures.
- Avanos personnel will contact you and schedule a site visit to apply warning labels with a corrected expiry date to all affected products in your inventory.
- Alternatively, when it is not possible to obtain access to the devices at your site, please indicate that you wish to return the product(s) to Avanos on the acknowledgement form in Annex 1. We will contact you to make the return arrangements.

Inventory Already Used

- Since the products are not passed the correct expiry date, there is no risk related to devices that are already used.

Please respond within five (5) business days of receipt of this letter.

If you require further assistance, please contact Avanos via email: EMEAfieldaction@avanos.com.

The Competent Authority of your country has been informed about this Field Safety Notice.

Please maintain a copy of this letter for your records.

Avanos has taken the necessary steps to prevent future shipment of the affected products.

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Please share this communication within your organization, with other organizations where affected devices have been transferred, and any other associated organizations that may be impacted by this action.

We thank you for your assistance and appreciate your prompt attention in this matter.

We apologize for any disruptions to patient care this issue may cause your clinical facility.

Sincerely,

Klien van Dam,

Director Quality Assurance and Regulatory Affairs, EMEA

DRAFT

«Customer_Name»

Annex 1

INSTRUCTIONS:

RETURN the completed Annex 1 via email to EMEAFieldAction@avanos.com within five (5) business days of receipt of this letter.

Avanos shipping records indicate you have received the following affected product.

TICK one of these statements and complete the table below:

- We would like to RETURN the products available to be reworked at Avanos
- We would like Avanos to REWORK the products available at our facility

Product Code	Lot Number	Quantity Sent	Quantity Available
«Product_Code»	«Lot_Number»	«Quantity_Sent»	

PROVIDE your contact details as indicated below.

Please complete this form to acknowledge that you have received and understand this Field Safety Notice letter.

Customer Name _____ Title _____

Telephone _____ Email _____

Date _____

«Customer_Name»