URGENT: PRODUCT RECALL
HALYARD* CLOSED SUCTION SYSTEM FOR NEONATES/PEDIATRICS (5 Fr)

Manufacturer REF: FSCA-2019-004

REFERENCE: FSCA-2019-004 December 30, 2019

Dear Valued Distributor:

What is the Reason for this Recall?

This letter provides an update to the previous Product Advisory Notice dated November 4, 2019 and contains additional required actions.

Since the previous letter, Avanos Medical has identified three affected lots of product Catalog Code 195-5 that have an increased likelihood (up to approximately 0.075%) for full occlusion. **For these three lots that are directly associated with a potential full occlusion, Avanos Medical is voluntarily removing/recalling any remaining products from European distributors, customers, and associated inventories. Please refer to Table 1 for an overview of the affected lots.**

Note that Avanos Medical has received reports stating that the central lumen of some 5 Fr Neonate/Pediatric Closed Suction Catheters were occluded. This may cause the closed suction catheters (CSCs) to not suction secretions and/or saline fluids from the patient's airway to prevent oxygen desaturation. The risk of a CSC blockage to patient's health can be life threatening since the CSC is not able to suction out any fluids that may obstruct the airway/ ET tube.

Analysis of the returned samples identified that the occlusion may occur in the bushing adapter between the catheter tubing and the suction control button subassembly (see Figure 1). If an occlusion is present, the blockage is NOT visible to the user; however, a blockage is detectable before catheter use by assessing suctioning effectiveness using standard clinical practices.

Figure 1: Location where the potential occlusion was identified. The blockage is not visible to the user.

Which Products are being Removed/Recalled?

This Recall applies to the **HALYARD* Closed Suction System for Neonates/Pediatrics 5 Fr only.** The potentially affected product catalog codes and lot numbers are listed in the following table (see Table 1).

Table 1: Impacted Product to be recalled from inventories and customers.

9-Digit SAP Code	Catalog Code	Lot Number	Product Description
109838301 109838302	195-5	M18268T402 M18274T402 M18290T402	HALYARD* Closed Suction System for Neonates/Pediatrics, **5 Fr**, Y-Adapter

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Additional actions to mitigate risk associated with all 5 Fr Closed Suction Catheters
All other lots of 5 Fr CSCs are not directly associated with total occlusions but have a risk for partial occlusion. As a safety precaution, customers should always confirm that CSC products can adequately suction before use on a patient.

Testing the ability of the catheter to suction prior to use can be conducted by first connecting the CSCs proximal adapter to wall suction or to a suction unit. Advance the suction catheter, so the distal tip protrudes from the distal connector. Activate suction by depressing the thumb valve and:

- occlude the distal tip openings with a sterile glove to demonstrate an increase in the suctioning negative pressure, OR
- place distal tip into sterile water or saline to verify ability to suction fluid.

If the CSC appears occluded, users should not use and immediately replace the product. Always inform Avanos Medical if such a situation comes to your attention.

As this mitigation is considered a general safety precaution for this product in the intended patient population, the Instructions for Use will be updated to reflect this warning.

In addition, the current Instructions for Use (IFU) reminds clinicians to note any signs of suction intolerance during use which include oxygen desaturation, negative ventilator system pressures, patient stress, or excessive discomfort. Clinicians should also note that a differential diagnosis on the reason for the suction intolerance may be difficult with this issue, as these signs may also result from neonates not tolerating the therapy due to reasons other than occlusion.

Please refer also to the instructions for use to ensure adequate suction performance of the CSCs during its use and ensure that:

- CSC are appropriately irrigated after every use
- CSC are replaced at least every 24hrs.

Follow-up actions
If you have distributed any **HALYARD* Closed Suction System for Neonates/Pediatrics (5 FR)** devices from the Product Lot Numbers listed in Table 1, please follow the following instructions:

- If you received any of the impacted lot numbers, please complete the attached Distributor Recall Acknowledgement Form (Attachment 1).

  Please email the Acknowledgement Form in Appendix 1 to Avanos at **EMEAFieldAction@avanos.com**

- If you identify remaining products in your inventory from the impacted lot numbers, please contact Avanos Medical customer service through the email address below for replacement and return of the products for further investigation.

Please send the attached End-User/ Customer Recall Letter and Acknowledgment Form (Attachment 2) to all end-user customers who were potentially shipped any of the impacted product.

Please note that the precautions identified in the section “Additional actions to mitigate risk” are general safety precautions to be applied for each CSC. The IFU will be updated to reflect these warnings.

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

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If you require further assistance, please contact Avanos Medical customer service by email at:

Germany Austria, Switzerland customers please contact Avanos by email at:
Kundendienst@avanos.com

Belgium, Luxembourg and Netherlands customers please contact Avanos by email at:
BNL@avanos.com

UK and Ireland customers please contact Avanos by email at:
uk.ie@support.avanos.com

France customers please contact Avanos by email at:
ServiceClients@avanos.com

Other countries in the EU, please contact Avanos by email at:
CustomerService.Export@avanos.com

Please note that your respective National Competent Authority has been advised of the original FSCA and will be advised of this update including the recommendation to recall the affected lots.

Actions taken by Avanos Medical
Avanos Medical completed the investigation and identified the root causes of the potential for occlusion. Production of the affected subassembly and finished catheters was stopped when this issue became apparent. Several corrective actions in the manufacturing process and more sensitive measurement techniques have been implemented to avoid recurrence of this issue. The validation of these actions has been closed, and in mid-November regular production of the subassembly and finished catheters has been resumed with the updated manufacturing process. Thank you for your assistance, and we apologize for any service disruptions this issue may have caused your distribution facility.

Sincerely,

Thomas Kozma, Ph.D.
Director, Regulatory Affairs

Attachment 1 - Distributor Recall Acknowledgement Form

Attachment 2 - End-User/Customer Recall Letter and Acknowledgment Form

URGENT: PRODUCT RECALL
HALYARD* CLOSED SUCTION SYSTEM FOR NEONATES/PEDIATRICS (5 Fr)

Manufacturer REF: FSCA-2019-004

Attachment 1: Distributor Recall Acknowledgement Form

Avanos records indicate that the potentially impacted HALYARD* Closed Suction System for Neonates/ Pediatrics (identified in the Table below) was shipped to your Distribution Facility.

Please complete this form to acknowledge that you have received and understand this Recall and will notify your customers who were potentially shipped the impacted products.

9-Digit SAP Code	Catalog Code	Lot Number	Quantity Returned (specify cases or units)	Product Description
109838301 109838302	195-5	M18268T402		HALYARD* Closed Suction System for Neonates/Pediatrics, **5 Fr**, Y-Adapter
		M18274T402		
		M18290T402		

Distributor Account No.	Distributor Name
Contact Name	Phone Number
Signature	Date
PO Number	E-mail or fax number

Please return a copy of this Distributor Recall Acknowledgement by email to Avanos to **EMEAFieldAction@avanos.com**

Please Return within 5 business days of receipt of this notice.

Confidential - For intended recipients only.
Recall Acknowledgement Form

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Attachment 2 - End-User/Customer Recall Dated December 30, 2019

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Manufacturer REF: FSCA-2019-004

REFERENCE: FSCA-2019-004 December 30, 2019

Dear Valued Avanos Customer:

What is the Reason for this Recall?

This letter provides an update to the previous Product Advisory Notice dated November 4, 2019 and contains additional required actions.

Since the previous letter, Avanos Medical has identified three affected lots of product Catalog Code 195-5 that have an increased likelihood (up to approximately 0.075%) for full occlusion. **For these three lots that are directly associated with a potential full occlusion, Avanos Medical is voluntarily removing/recalling any remaining products from European distributors, customers, and associated inventories. Please refer to Table 1 for an overview of the affected lots.**

Note that Avanos Medical has received reports stating that the central lumen of some 5 Fr Neonate/Pediatric Closed Suction Catheters were occluded. This may cause the closed suction catheters (CSCs) to not suction secretions and/or saline fluids from the patient's airway to prevent oxygen desaturation. The risk of a CSC blockage to patient's health can be life threatening since the CSC is not able to suction out any fluids that may obstruct the airway/ ET tube.

Analysis of the returned samples identified that the occlusion may occur in the bushing adapter between the catheter tubing and the suction control button subassembly (see Figure 1). If an occlusion is present, the blockage is NOT visible to the user; however, a blockage is detectable before catheter use by assessing suctioning effectiveness using standard clinical practices.

Figure 2: Location where the potential occlusion was identified. The blockage is not visible to the user.

Which Products are being Removed/Recalled?

This Recall applies to the **HALYARD* Closed Suction System for Neonates/Pediatrics 5 Fr only.** The potentially affected product catalog codes and lot numbers are listed in the following table (see Table 1).

Table 1: Impacted Product to be recalled from inventories and customers.

9-Digit SAP Code	Catalog Code	Lot Number	Product Description
109838301 109838302	195-5	M18268T402 M18274T402 M18290T402	HALYARD* Closed Suction System for Neonates/Pediatrics, **5 Fr**, Y-Adapter

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Additional actions to mitigate risk associated with all 5 Fr Closed Suction Catheters
All other lots of 5 Fr CSCs are not directly associated with total occlusions but have a risk for partial occlusion. As a safety precaution, customers should always confirm that CSC products can adequately suction before use on a patient.

Testing the ability of the catheter to suction prior to use can be conducted by first connecting the CSCs proximal adapter to wall suction or to a suction unit. Advance the suction catheter, so the distal tip protrudes from the distal connector. Activate suction by depressing the thumb valve and:

- occlude the distal tip openings with a sterile glove to demonstrate an increase in the suctioning negative pressure, OR
- place distal tip into sterile water or saline to verify ability to suction fluid.

If the CSC appears occluded, users should not use and immediately replace the product. Always inform Avanos Medical if such a situation comes to your attention.

As this mitigation is considered a general safety precaution for this product in the intended patient population, the Instructions for Use will be updated to reflect this warning.

In addition, the current Instructions for Use (IFU) reminds clinicians to note any signs of suction intolerance during use which include oxygen desaturation, negative ventilator system pressures, patient stress, or excessive discomfort. Clinicians should also note that a differential diagnosis on the reason for the suction intolerance may be difficult with this issue, as these signs may also result from neonates not tolerating the therapy due to reasons other than occlusion.

Please refer also to the instructions for use to ensure adequate suction performance of the CSCs during its use and ensure that:

- CSC are appropriately irrigated after every use
- CSC are replaced at least every 24hrs.

If you have received any **HALYARD* Closed Suction System for Neonates/Pediatrics (5 FR)** devices from the Product Code Lots listed in Table 1, please follow the following instructions:

- Please evaluate your unused inventory of HALYARD* Closed Suction System for Neonates/Pediatrics (5 Fr) to determine if any impacted product lot number remain in inventory.

- If you identify any affected product lot codes, please DO NOT USE these products and contact Avanos Medical customer service through the email address below for replacement and return of the products for further investigation.

- Please distribute this notice to all clinicians within your departments who may use any of the impacted Closed Suction System (5 Fr) devices. This may include the following clinical staff: Emergency Room, Intensive Care, Respiratory Therapy, Home Health, etc.

- Please email the Acknowledgement Form in the enclosure to Avanos at **EMEAFieldAction@avanos.com**

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

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If you require further assistance, please contact Avanos customer service by email at one of the following addresses:

Germany Austria, Switzerland customers please contact Avanos by email at:
Kundendienst@avanos.com

Belgium, Luxembourg and Netherlands customers please contact Avanos by email at:
BNL@avanos.com

UK and Ireland customers please contact Avanos by email at:
uk.ie@support.avanos.com

France customers please contact Avanos by email at:
ServiceClients@avanos.com

Other countries in the EU, please contact Avanos by email at:
CustomerService.Export@avanos.com

Actions taken by Avanos Medical

Avanos Medical completed the investigation and identified the root causes of the potential for occlusion. Production of the affected subassembly and finished catheters was stopped when this issue became apparent. Several corrective actions in the manufacturing process and more sensitive measurement techniques have been implemented to avoid recurrence of this issue. The validation of these actions has been closed, and in mid-November regular production of the subassembly and finished catheters has been resumed with the updated manufacturing process.

Thank you for your assistance, and we apologize for any disruptions to patient care this issue may cause your clinical facility.

Sincerely,

Thomas Kozma, Ph.D.
Director, Regulatory Affairs

Enclosure – Recall Acknowledgement Form

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HALYARD* CLOSED SUCTION SYSTEM FOR NEONATES/PEDIATRICS (5 Fr)

Manufacturer REF: FSCA-2019-004

ENCLOSURE: Recall Acknowledgement Form (Clinical Facilities)

Please complete this form to acknowledge that you have received and understand this updated Field Safety Action and recall.

Avanos records indicate that the impacted HALYARD* Closed Suction System for Neonates/Pediatrics 5FR was shipped to your clinical facility. Please evaluate your unused inventory of HALYARD* Closed Suction System for Neonates/Pediatrics (5 Fr) to determine if any impacted product lot number identified below remain in your inventory.

9-Digit SAP Code	Catalog Code	Lot Number	Quantity Returned (specify cases or units)	Product Description
109838301 109838302	195-5	M18268T402		HALYARD* Closed Suction System for Neonates/Pediatrics, **5 Fr**, Y-Adapter
		M18274T402		
		M18290T402		

Account No.	Name
Contact Name	Phone Number
Signature	Date
PO Number	E-mail or fax number

Please return a copy of this Recall Acknowledgement by email to Avanos at:
EMEAFieldAction@avanos.com

Please Return within 5 business days of receipt of this notice.

Confidential - For intended recipients only.
Recall Acknowledgement Form