



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

November 4, 2019

Dear Valued Avanos Customer:

**What is the Reason for this Product Advisory Notice?**

Avanos Medical has received reports stating that the central lumen of some 5 Fr Neonate/Pediatric Closed Suction Catheters may be occluded (approximately 0.045% based on complaints of distributed units). 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.

If an occlusion is present, the blockage is NOT visible to the user; however, a blockage is detectable before catheter use by testing suctioning effectiveness. 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.

**Customers should confirm that the potentially impacted 5 Fr CSC products can adequately suction before use on a patient and/or before introducing saline. *If the CSC appears occluded, users should not use and immediately replace the product.*** The Instructions For Use (IFU) reminds the clinician to note any signs of suction intolerance, which include oxygen desaturation, negative ventilator system pressures, patient stress, or excessive discomfort and may require the use of an alternate suction technique.

**Which Products are Impacted?**

This Product Advisory Notice applies to the **HALYARD\* Closed Suction System for Neonates/Pediatrics (5 Fr only)**. The potentially affected product codes are listed in the following table (see Table 1). Please note that all potentially affected lots were shipped beginning June 1, 2018 and ending October 23, 2019.

*Table 1: Impacted Product Codes*

| <b>9-Digit SAP Finished Product Code</b> | <b>Catalog Code</b> | <b>Product Description</b>   |
|--|---------------------|--|
| 109382303                                | 195                 | HALYARD* Closed Suction System for Neonates/Pediatrics, <b>5 Fr</b> , Y-Adapter                |
| 109382803                                | 201                 | HALYARD* Closed Suction System for Neonates/Pediatrics, <b>5 Fr</b> , with BALLARD* Technology |
| 109382903                                | 202                 | HALYARD* Closed Suction System for Neonates/Pediatrics, <b>5 Fr</b> , Elbow                    |
| 109838302                                | 195-5               | HALYARD* Closed Suction System for Neonates/Pediatrics, <b>5 Fr</b> , Y-Adapter                |

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If you have received any **HALYARD\* Closed Suction System for Neonates/Pediatrics (5 FR)** devices from the Product Codes listed above, please follow the instructions below:

Please evaluate your unused inventory of HALYARD\* Closed Suction System for Neonates/Pediatrics (5 Fr) to determine if any impacted products remain in inventory. Please distribute this notice to all clinicians within your departments who may use any of the potentially impacted Closed Suction System (5 Fr) devices. This may include the following clinical staff: Emergency Room, Intensive Care, Respiratory Therapy, Home Health, etc.

*Before using the Impacted product, users can review the Instructions for Use (IFU). If the CSC appears occluded, users should not use the product.*

Next, please complete the attached Product Advisory Notice Acknowledgement Form (Enclosure) and email to Avanos:

- In the US send to: [Avanos8446@stericycle.com](mailto:Avanos8446@stericycle.com)
- Outside the US send to: [Avanos8446OUS@stericycle.com](mailto:Avanos8446OUS@stericycle.com)

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

If you require further assistance, please email Avanos:

- In the US send to: [Avanos8446@stericycle.com](mailto:Avanos8446@stericycle.com)
- Outside the US send to: [Avanos8446OUS@stericycle.com](mailto:Avanos8446OUS@stericycle.com)

Avanos is completing an investigation to prevent recurrence of this issue. 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

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Enclosure – Product Advisory Notice Acknowledgement Form



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**ENCLOSURE: Product Advisory Notice Acknowledgement Form (Clinical Facilities)**

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

Please complete this form to acknowledge that you have received and understand this Product Advisory Notice.

*Table 1: Impacted Product Codes*

| 9-Digit SAP Finished Product Code | Catalog Code | Product Description  |
|-----------------------------------|--------------|--|
| 109382303                         | 195          | HALYARD* Closed Suction System for Neonates/Pediatrics, 5 Fr, Y-Adapter                |
| 109382803                         | 201          | HALYARD* Closed Suction System for Neonates/Pediatrics, 5 Fr, with BALLARD* Technology |
| 109382903                         | 202          | HALYARD* Closed Suction System for Neonates/Pediatrics, 5 Fr, Elbow                    |
| 109838302                         | 195-5        | HALYARD* Closed Suction System for Neonates/Pediatrics, 5 Fr, Y-Adapter                |

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

Please return a copy of this Product Advisory Notice Acknowledgement by email to Avanos:

- In the US to: [Avanos8446@stericycle.com](mailto:Avanos8446@stericycle.com)
- Outside the US to: [Avanos8446OUS@stericycle.com](mailto:Avanos8446OUS@stericycle.com)

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

Confidential - For intended recipients only.  
Product Advisory Notice Acknowledgement Form