AVANOS

5405 Windward Parkway
Alpharetta, GA 30004

T 1-844-425-9273
avanosmedical.com

Date: 21st November 2019

FIELD SAFETY NOTICE: URGENT MEDICAL DEVICES RECALL

Reference Number: HSA 600:41/01-352/19/01_46

Product name: Halyard* Closed Suction System for Neonates/ Pediatrics (5Fr), Product Code 195-5

Products Impacted in Singapore

Product Code	Product Description	Lot Number	Quantity	Total (in units)
195-5	HALYARD* Closed Suction System for Neonates/ Pediatrics	M19030T401	2 cartons	2 x 20 = 40
		M19079T401	2 cartons	2 x 20 = 40
		M19191T407	2 cartons	2 x 20 = 40
		M19051T401	6 cartons	6 x 20 = 120

Shipment Date: 01 June 2018 through 23 October 2019

Problem/ Issue

Central lumen of some 5 Fr Neonate/Pediatric Closed Suction Catheters may be 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.

This recall does not affect any other lots of HALYARD* Closed Suction System for Neonates/ Pediatrics or any other Avanos Medical, Inc (currently known as) products. These lots have been distributed to Bluestone Corporation Pte Ltd since 1st June 2018 untill 23rd October 2019.

Actions

- Inspect your stock **immediately** and quarantine affected stock detailed with above listed lots and quantity on hand to prevent further use. Immediately cease all distribution and use of these products.
- If the product is in your stock and is to be discarded, Certificate of Destruction or photographs of destruction should be provided with reconciliation form.
- Fill out the reconciliation status table.
- Send this reconciliation form with Certificate of Destruction or photographs of Destruction to us once stock replacement is completed.
- If you are a distributor, you must notify your customers of the field action and ensure that these actions are carried out.

Please complete the attached acknowledgement form **immediately even if you do not have any affected stock and return the signed acknowledgement to us within 5 working days upon receipt of this notice.**

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Transmission of this Field Safety Notice:

Ensure relevant staff members are informed of this recall, including clinical staff in Emergency Room, Intensive Care, Respiratory Therapy, Home Health, and relevant healthcare professional.

If you have supplied or transferred any affected product to another facility or organisation, let that facility know of the recall **immediately** by providing a copy of this letter.

Name, Location, Telephone of Recalling Firm:

Avanos Medical, Inc. 5405
Windward Pkwy
Alpharetta, GA 30004
844-425-9273

Recall Contact and Public Contact:

Thomas Kozma, Ph.D. Director,
Regulatory Affairs Avanos Medical
5405 Windward Pkwy
Alpharetta, GA 30004
Phone: [redacted]
e-mail: [redacted]

Stock Replacement (For Distributor only)

Please send in your order for stock replacement by email to:

✉ shippingconcerns@avanos.com

Avanos is completing an investigation to prevent recurrence of this issue. Thank you for your assistance, and we apologize for any service disruptions this issue may have caused your distribution facility.

Sincerely,

[redacted]

Thomas Kozma, Ph.D. Director,
Regulatory Affairs

CC: Chairman Medical Board and relevant Head of Deparments

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URGENT MEDICAL DEVICES RECALL

If you received any of the impacted product codes, please complete the attached acknowledgement letter.

- Attachment 1 for Distributor
- Attachment 2 for End-User/ Customer/ Clinical Facilities

Please email Acknowledgement Form to Avanos:

In the US to: Avanos8446@stericycle.com
Outside the US to: Avanos8446OUS@stericycle.com

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

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

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

In the US to: Avanos8446@stericycle.com
Outside the US to: Avanos8446OUS@stericycle.com

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Sincerely,

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Thomas Kozma, Ph.D. Director,
Regulatory Affairs

Attachment 1 - Distributor Product Recall Acknowledgement Form

Attachment 2 - End-User/ Customer/ Clinical Faciities Product Recall Acknowledgment Form

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Attachment 1: Distributor Product Recall Acknowledgement Form

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 Recall Notice.

Table 1: Impacted Product Codes

Product Code	Product Description	Lot Number
195-5	HALYARD* Closed Suction System for Neonates/ Pediatrics	M19030T401
		M19079T401
		M19191T407
		M19051T401

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

Please return a copy of this Distributor Product Recall Acknowledgement by email to Avanos:

In the US send to: Avanos8446@stericycle.com
Outside the US send to: Avanos8446OUS@stericycle.com

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

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Attachment 2: End-User/ Customer/ Clinical Facilities Product Recall Acknowledgement Form

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Reconciliation Form (For Distributor to fill in only)

Affected Product Information

Product Code	Product Description	Lot Number
195-5	HALYARD* Closed Suction System for Neonates/ Pediatrics	M19030T401
		M19079T401
		M19191T407
		M19051T401

Quantities of Affected Products

Lot Number	**Total Quantities Received**	**Total Quantities Received (in units)**	**Quantities Consumed (in units)**	**Quantity Discarded (in units)**	**Remarks**
M19030T401	2 cartons	2 x 20 = 40			
M19079T401	2 cartons	2 x 20 = 40			
M19191T407	2 cartons	2 x 20 = 40			
M19051T401	6 cartons	6 x 20 = 120			

Total Quantities Received" shall be equal to sum of "Quantities consumed" and "Quantities discarded

REQUIRED ACTIONS

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Please tick the box

□ **I have read, understood and took the required actions.**

□ **I discarded all affected kits as per local guideline.**