



URGENT: PRODUCT ADVISORY NOTICE HALYARD CLOSED SUCTION KITS WITH FLEX CONNECTOR

15 March 2018

ATTENTION: HALYARD HEALTH PRODUCT DISTRIBUTOR
cc Chairman of Medical Board and all relevant Head(s) of Department

Dear Inventory/Field Action Coordinator:

Please review the attached Voluntary Product Advisory Notice to customers regarding Halyard Closed Suction Kits with Flex Connector, and forward a copy of the letter to each of your direct customers who may have received the potentially impacted products.

Which products are impacted?

Please see attached Voluntary Product Advisory Notice for a list of all potentially affected product codes. Please note that impacted products began shipping to your distribution facility on August 01, 2017 to present.

As a Distributor, what should I do in response to this Product Advisory Notice?

Please distribute the attached Voluntary Advisory Notice to each of your direct customers who may have received the potentially impacted products.

Please complete the Distributor Acknowledgement Form, which is also attached, and return it **within five (5) business days of receipt** via Fax: **+44 20808 91412** or Email: halyard8795OUS@stericycle.com

If you require further assistance, please contact your Halyard Health Representative.

Thank you for your assistance.

Sincerely,

Halyard Health


Laleetha Devi

Regulatory & Quality Assurance Director
15 March 2018

ATTACHMENTS

- Product Advisory Acknowledgement Form (Distributors)
- Product Advisory Notice (Letter to Direct Customers with Customer Acknowledgement Form)



URGENT: PRODUCT ADVISORY NOTICE
HALYARD CLOSED SUCTION KITS WITH FLEX CONNECTOR

Product Advisory Notice Acknowledgement Form (DISTRIBUTORS)

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

Please FAX a copy of this form to +44 20808 91412 or e-mail to halyard8795OUS@stericycle.com within 5 business days of receipt of this notice.

Distribution Facility Name	Contact Phone Number

Distribution Facility Address

[] I certify that this facility has read and understood the information provided in this Product Advisory Notice.

(Signature) (Date)

(Name of Person Completing Form – print)

(Title – print)

URGENT: PRODUCT ADVISORY NOTICE

HALYARD CLOSED SUCTION KITS WITH FLEX CONNECTOR

15 March 2018

ATTENTION: RESPIRATORY THERAPY DEPARTMENT

cc Chairman of Medical Board and all relevant Head(s) of Department

Dear Valued Halyard Health Customer:

What is the reason for this Voluntary Product Advisory Notice?

Recently, we have received reports indicating that certain Flex Connectors supplied with **Halyard Closed Suction Kits with Flex Connector** may become loose or disconnect *before use or during use*. If disconnection occurs *during use*, it will result in an open respiratory circuit and interruption of patient ventilation. To date, there have been no reports of patient injury.

Although the reported risk of occurrence is low (i.e., less than 1 per million), this notice is intended to inform all users of **Halyard Closed Suction Kits with Flex Connector** products about this potential issue and provide steps to help prevent this issue from occurring *during use*.

Which products are impacted?

See tables below that list all potentially affected product codes.

Halyard* Closed Suction System for Adults, Double Swivel Elbow (DSE)

Product Code	Product Description
2160	HALYARD* 12FR DSE 21.3IN/54CM (WHITE)
2160-5	HALYARD* 12 FR TRACH CARE DSE ENDO
21603	HALYARD* 12FR DSE 12IN/30.5CM (WHITE)
21603-5	HALYARD* 12FR TRACH CARE DSE TRACH
2210	HALYARD* 14FR DSE 21.3IN/54 CM (GREEN)
2210-5	HALYARD* 14FR TRACH CARE DSE ENDO
22103	HALYARD* 14FR DSE 12IN/30.5 CM (GREEN)
22103-5	HALYARD* 14FR TRACH CARE DSE TRACH
221036	HALYARD* 14FR DSE 12IN/30.5CM (GREEN)
221036-5	HALYARD* 14FR TRACH CARE WET PAK* DSE TRACH
221037	HALYARD* 14FR DSE 12IN/30.5 CM (GREEN)
221038	HALYARD* 14FR DSE 12IN/30.5 CM (GREEN)
2210386-5	HALYARD* 14FR TRACH CARE WET PAK* DSE MDI TRACH
22106	HALYARD* 14FR DSE 21.3IN/54 CM (GREEN)
22106-5	HALYARD* 14FR TRACH CARE WET PAK* DSE ENDO
221069-5	HALYARD* 14FR TRACH CARE WET PAK* DSE DIR TIP ENDO
22107	HALYARD* 14FR DSE 21.3IN/54 CM (GREEN)
22107-5	HALYARD* 14 FR TRACH CARE DSE DUAL LUMEN ENDO
22108	HALYARD* 14FR DSE 21.3IN/54 CM (GREEN)
22108-5	HALYARD* 14FR TRACH CARE DSE MDI ENDO
22108130	HALYARD* 14FR DSE 21.3IN/5 4CM (GREEN)
22108147	HALYARD* 14FR DSE 21.3IN/54 CM (GREEN)
22108148	HALYARD* 14FR DSE 22.2IN/56 CM (GREEN)
22109	HALYARD* 14FR DSE 22.2IN/56 CM (GREEN)
22109-5	HALYARD* 14FR TRACH CARE DSE DIR TIP ENDO

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HALYARD CLOSED SUCTION KITS WITH FLEX CONNECTOR

Product Code	Product Description
2260	HALYARD* 16FR DSE 21.3IN/54CM (ORANGE)
2260-5	HALYARD* 16FR TRACH CARE DSE ENDO
22606	HALYARD* 16FR DSE 21.3IN/54CM (ORANGE)
22606-5	HALYARD* 16FR TRACH CARE WET PAK* DSE ENDO
8223	HALYARD* 14FR DSE 12IN/30.5 CM (GREEN)
8224	HALYARD* 14FR DSE 21.3IN/54 CM (GREEN)

Halyard* Turbo-Cleaning Closed Suction System for Adults, Double Swivel Elbow (DSE)

Product Code	Product Description
227	HALYARD* TURBO-CLEANING 14FR DSE 21.3IN/54 CM (GREEN)
227-5	HALYARD* TRACH CARE-72 DSE ENDO 14FR
22701356-5	HALYARD* TRACH CARE-72 WET PAK* 14FR
2270156-5	HALYARD* TRACH CARE-72 WET PAK* T-PIECE SWVL/FLEX ENDO 14FR
22703	HALYARD* TURBO-CLEANING 14FR DSE 12IN/30.5 CM (GREEN)
22703-5	HALYARD* TRACH CARE-72 DSE TRACH 14FR
227036-5	HALYARD* TRACH CARE-72 WET PAK* DSE TRACH 14FR
227101-5	HALYARD* TRACH CARE-72 DSE ENDO 10FR
2271013	HALYARD* TURBO-CLEANING 10FR DSE 12IN/30.5CM (BLACK)
2271018-5	HALYARD* TRACH CARE-72 DSE MDI BUILT IN ENDO 10FR
2271218-5	HALYARD* TRACH CARE-72 DSE MDI BUILT IN ENDO 12FR
22712183	HALYARD* TURBO-CLEANING 12FR DSE 12IN/30.5CM (WHITE)
22712186-5	HALYARD* 72 DSE MDI BUILT IN ENDO 12FR
227121863-5	HALYARD* 72 DSE TRACH CARE 12FR
2271418	HALYARD* 14FR DSE 22.2IN/56CM (GREEN)
2271418-5	HALYARD* TRACH CARE-72 DSE MDI BUILT IN ENDO 14FR
22714183	HALYARD* TURBO-CLEANING 14FR DSE 12IN/30.5CM (GREEN)
22714183-5	HALYARD* TRACH CARE-72 DSE MDI BUILT IN TRACH 14FR
22714186	HALYARD* TC-72 WET PAK* DSE MDI ENDO 14FR
22714186-5	HALYARD* TC-72 WET PAK DSE MDI ENDO 14FR
227141863-5	HALYARD* TC-72 WET PAK DSE 14FR
227147	HALYARD* TURBO-CLEANING 14FR DSE 21.3IN/54CM (GREEN)
22716	HALYARD* TURBO-CLEANING 12FR DSE 21.3IN/54 CM (WHITE)
22716-5	HALYARD* TRACH CARE-72 DSE ENDO 12FR
2271603	HALYARD* TURBO-CLEANING 12FR DSE 12IN/30.5CM (WHITE)
2271603-5	HALYARD* TRACH CARE-72 DSE TRACH 12FR
22716036-5	HALYARD* TRACH CARE-72 WET PAK* DSE TRACH 12FR
227161	HALYARD* TURBO-CLEANING 16FR DSE 21.3IN/54CM (ORANGE)
227161-5	HALYARD* TRACH CARE-72 DSE 16FR 21.3IN/54CM
2271613-5	HALYARD* TRACH CARE-72 DSE TRACH 16FR
2271616-5	HALYARD* TRACH CARE-72 DSE ENDO 16FR
2271618-5	HALYARD* TRACH CARE-72 DSE MDI BUILT IN ENDO 16FR
22716183-5	HALYARD* TRACH CARE-72 DSE MDI BUILT IN TRACH 16FR

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HALYARD CLOSED SUCTION KITS WITH FLEX CONNECTOR

Product Code	Product Description
22716186-5	HALYARD* TRACH CARE-72 DSE MDI ENDO 16FR
227161863-5	HALYARD* TRACH CARE-72 DSE 16FR
227166-5	HALYARD* TRACH CARE-72 WET PAK* DSE ENDO 12FR
2276	HALYARD* TURBO-CLEANING 14FR DSE 21.3IN/54CM (GREEN)
2276-5	HALYARD* TURBO-CLEANING 14FR DSE Endo

Halyard* Multi-Access Port Closed Suction System for Adults

Product Code	Product Description
24010-5	HALYARD* MULTI-PORT, DSY, ENDO 10FR
240121-5	HALYARD* MULTI-PORT, DSY, ENDO 12FR
240128-5	HALYARD* MULTI-PORT, DSY, ENDO, MDI 12FR
24014-5	HALYARD* MULTI-PORT, DSY, ENDO 14FR
240143-5	HALYARD* MULTI-PORT, DSY, TRACH 14FR
2401436-5	HALYARD* MULTI-PORT, DSY, TRACH, WP 14FR
2401438-5	HALYARD* MULTI-PORT, DSY, ENDO, MDI 14FR
240146-5	HALYARD* MULTI-PORT, DSY, ENDO, WP 14FR
240146-5N	HALYARD* MULTI-PORT, DSY, ENDO, WP 14FR
240148-5	HALYARD* MULTI-PORT, DSY, ENDO, MDI 14FR
240168-5	HALYARD* MULTI-PORT, DSY, ENDO, MDI 16FR

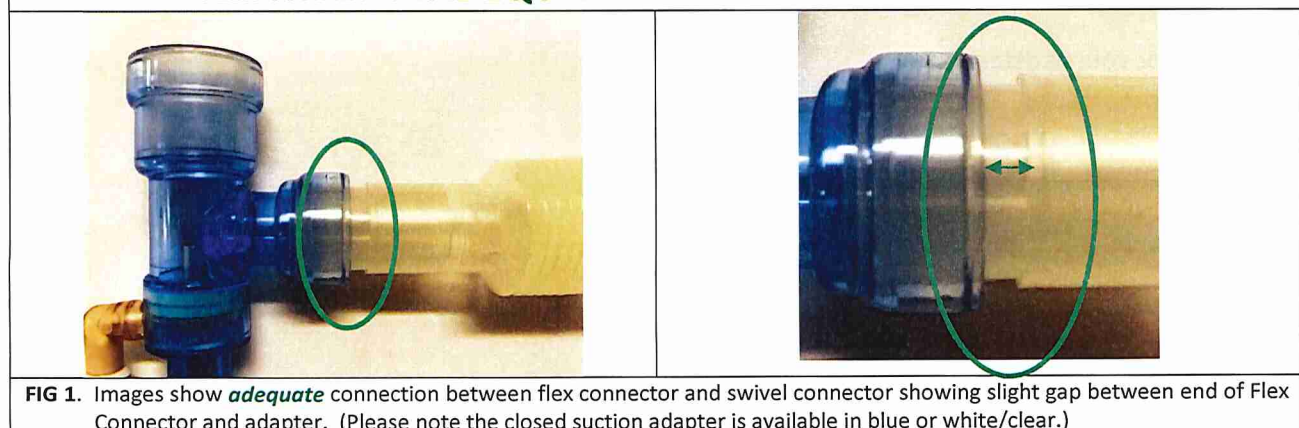
What should I do in response to this Product Advisory Notice?

Please ensure adequate connection of the Flex Connector to Swivel Connector *before use*.

BEFORE USE:

- Before using the Flex Connector evaluate its connection to the Swivel Connector of the Closed Suction adapter to ensure an **ADEQUATE** connection. Evaluation of the connection can be accomplished by pushing the Flex Connector onto the Swivel Connector.
 - An **adequate** connection (FIG. 1) is defined when a tight fit is achieved on the Swivel with the Flex Connector advanced approximately three-quarters over the Swivel, so a gap remains visible.
 - An **inadequate** connection (FIG. 2) is defined when the bottom of the Flex Connector advances all the way to the end of the Swivel Connector, where a gap is no longer visible.

FLEX CONNECTOR **ADEQUATELY** ATTACHED TO SWIVEL CONNECTOR



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HALYARD CLOSED SUCTION KITS WITH FLEX CONNECTOR

FLEX CONNECTOR **INADEQUATELY** ATTACHED TO SWIVEL CONNECTOR

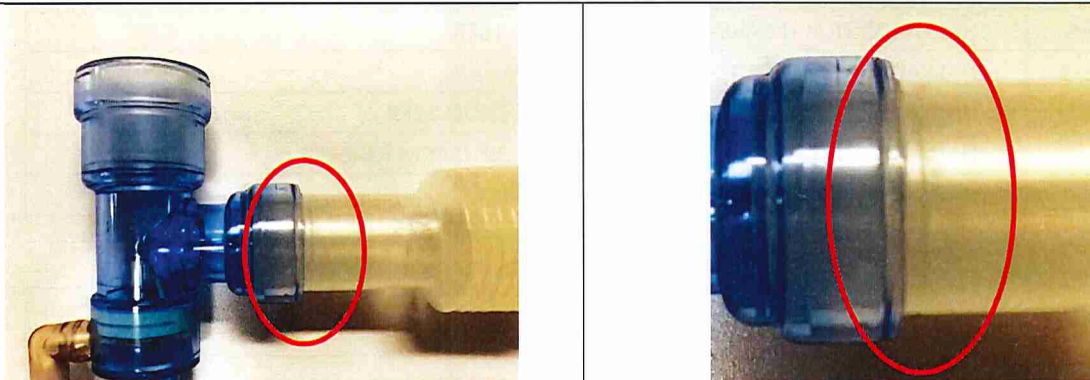


FIG 2. Image depicts **inadequate** connection between flex connector and swivel connector. The flex connector has *bottomed-out*, and a gap between end of flex connector and adapter is not visible. Please note the closed suction adapter is available in blue or white/clear.

- If an **inadequate** connection is observed, the Flex Connector may be replaced with a new, sterile Flex Connector (e.g. HYH Product # 1115) and the system connection should be re-evaluated.
- If use of a Flex Connector with the ventilator circuit is optional, the closed suction Swivel Connector can be connected directly to the ventilator circuit.

DURING USE:

- If a disconnection between the Flex Connector and Swivel Connector is observed *during use*, replace the Flex Connector with a new, sterile Flex Connector (e.g. HYH Product # 1115) and ensure adequate connection as described in this notice.

If an inadequate connection occurs, please save the Flex Connector and report it to Halyard via the Product Complaint Process (PIQ). Your local Halyard Sales Representative can assist you with this process.

Please distribute this Advisory Notice to all clinicians within your facility who may use the impacted Closed Suction Kits with Flex Connector.

Please complete the Acknowledgement Form attached and return it **within five (5) business days of receipt** via Fax: +44 20808 91412 or Email: halyard8795OUS@stericycle.com

If you require further assistance, please contact your Halyard Health Representative.

Thank you for your assistance.

Sincerely,

Halyard Health


Laleetha Devi
Regulatory & Quality Assurance Director
15 March 2018



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Product Advisory Notice Acknowledgement Form (Clinical Facilities)

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Please FAX a copy of this form to +44 20808 91412 or e-mail to halyard8795OUS@stericycle.com within 5 business days of receipt of this notice.

Clinical Facility Information	Contact Phone Number

Facility Address

[] I certify that this facility has read and understood the information provided in this Product Advisory Notice.

(Signature)

(Date)

(Name of Person Completing Form – print)

(Title – print)