



**Vygon (UK) Ltd**  
 The Pierre Simonet Building  
 V Park, Gateway North  
 Latham Road  
 Swindon  
 Wiltshire SN25 4DL

27<sup>th</sup> March 2018

**FIELD SAFETY NOTICE  
 (ISSUED FOR VYGON (UK) LTD CUSTOMERS IN SCOTLAND)**

***HALYARD HEALTH CLOSED SUCTION KITS WITH FLEX CONNECTOR***

**FSN – Identifier:**        ***1803/41537/00***

**Type of Action:**        ***AWARENESS***

**Details of Affected Devices:** ***Closed Suction Systems***

**Product Codes:**

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

<b>Product Code</b>	<b>Product Description</b>
<b><i>VKC2160</i></b>	<b><i>KV CSS DSE ENDO 12F</i></b>
<b><i>VKC21603</i></b>	<b><i>KV CSS DSE TRACH 12F</i></b>
<b><i>VKC2210</i></b>	<b><i>KV CSS DSE ENDO 14F/54CM</i></b>
<b><i>VKC22103</i></b>	<b><i>KV CSS DSE TRACH 14F</i></b>
<b><i>VKC221036</i></b>	<b><i>KV CSS DSE WP TRACH 14F</i></b>
<b><i>VKC221038</i></b>	<b><i>KV CSS DSE WP TRACH MDI 14F</i></b>
<b><i>VKC2210386</i></b>	<b><i>KV CSS WP TRACH MDI 14F</i></b>
<b><i>VKC22106</i></b>	<b><i>KV CSS WP ENDO 14F</i></b>
<b><i>VKC221069</i></b>	<b><i>KV CSS WP ENDO DIR TIP 14F</i></b>
<b><i>VKC22107</i></b>	<b><i>KV CSS DSE ENDO D-LUM 14F</i></b>
<b><i>VKC22108</i></b>	<b><i>KV CSS DSE ENDO MDI 14F</i></b>
<b><i>VKC22109</i></b>	<b><i>KV CSS DSE ENDO DIR TIP 14F</i></b>
<b><i>VKC2260</i></b>	<b><i>KV CSS DSE ENDO 16F</i></b>
<b><i>VKC22606</i></b>	<b><i>KV CSS WP ENDO 16F</i></b>

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

<b>Product Code</b>	<b>Product Description</b>
<b>VKC227</b>	<b>KV TURBO CSS DSE ENDO 14F</b>
<b>VKC22701356</b>	<b>KV TURBO CSS T-PC WP TRACH 14F</b>
<b>VKC2270156</b>	<b>KV TURBO CSS T-PC WP ENDO 14F</b>
<b>VKC22703</b>	<b>KV TURBO CSS DSE TRACH 14F</b>
<b>VKC227036</b>	<b>KV TURBO CSS WP TRACH 14F</b>
<b>VKC227101</b>	<b>KV TURBO CSS DDSE ENDO 10F</b>
<b>VKC2271013</b>	<b>KV TURBO CSS DSE TRACH 10F</b>
<b>VKC2271018</b>	<b>KV TURBO CSS DSE ENDO MDI 10F</b>
<b>VKC2271218</b>	<b>KV TURBO CSS DSE ENDO MDI 12F</b>
<b>VKC22712183</b>	<b>KV TURBO CSS DSE TRACH MDI 12F</b>
<b>VKC22712186</b>	<b>KV TURBO CSS DSE WP ENDO MDI</b>
<b>VKC227121863</b>	<b>KV TURBO CSS DSE WP TRACH MDI</b>
<b>VKC2271418</b>	<b>KV TURBO CSS DSE ENDO MDI 14F</b>
<b>VKC22714183</b>	<b>KV TURBO CSS DSE TRACH MDI 14F</b>
<b>VKC22714186</b>	<b>KV TURBO CSS DSE WP ENDO MDI</b>
<b>VKC227141863</b>	<b>KV TURBO CSS DSE WP TRACH MDI</b>
<b>VKC22716</b>	<b>KV TURBO CSS DSE ENDO 12F</b>
<b>VKC2271603</b>	<b>KV TURBO CSS DSE TRACH 12F</b>
<b>VKC22716036</b>	<b>KV TURBO CSS DSE WP TRACH 12F</b>
<b>VKC227161</b>	<b>KV TURBO CSS DSE ENDO 16F</b>
<b>VKC2271613</b>	<b>KV TURBO CSS DSE TRACH 16F</b>
<b>VKC2271616</b>	<b>KV TURBO CSS DSE WP ENDO 16F</b>
<b>VKC2271618</b>	<b>KV TURBO CSS DSE ENDO MDI 16F</b>
<b>VKC22716183</b>	<b>KV TURBO CSS DSE TRACH MDI 16F</b>
<b>VKC22716186</b>	<b>KV TURBO CSS DSE WP ENDO MDI</b>
<b>VKC227161863</b>	<b>KV TURBO CSS DSE WP TRACH MDI</b>
<b>VKC227166</b>	<b>KV TURBO CSS DSE WP ENDO 12F</b>
<b>VKC2276</b>	<b>KV TURBO CSS DSE WP ENDO 14F</b>

**Lot Number(s):**     **ALL**

**Description**

The manufacturer, Halyard Heath, has received reports indicating that certain Flex Connectors supplied with the Closed Suction Kits may become loose or disconnected 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 the Halyard Health Closed Suction Kits with Flex Connector products about this potential issue and provide steps to help prevent this issue from occurring during use.

**Field Safety Notice (FSN) Instructions:**

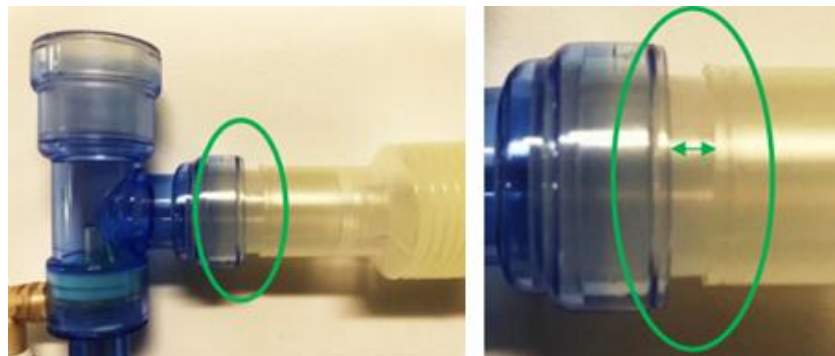
**Advice on action to be taken by Medical Staff**

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

**BEFORE USE:**

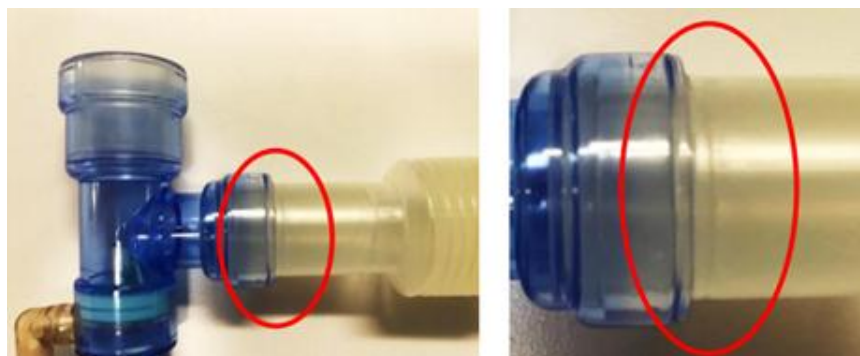
- Before using the Flex Connector evaluate its connection to the Swivel Connector of the Closed Suction adaptor to ensure an **ADEQUATE** connection. Evaluation of the connection can be accomplished by pushing the Flex Connector onto the Swivel Connector.
  - An **adequate** connection (FIG 1.) is defined 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**



**Fig 1.** Images show **adequate** connection between Flex Connector and Swivel Connector showing slight gap between end of Flex Connector and adaptor (please note the closed suction adaptor is available in blue or white/clear).

**FLEX CONNECTOR **INADEQUATELY** ATTACHED TO SWIVEL CONNECTOR**



**Fig 2.** Images depicts **inadequate** connection between Flex Connector and Swivel Connector. The Flex Connector has bottomed-out and a gap between end of Flex Connector and adaptor is not visible (please note the closed suction adaptor 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. product code: VKC1115) 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.

2. Please ensure adequate connection of the Flex Connector to Swivel Connector *during use*:

#### **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. product code: VKC1115) and ensure adequate connection as described in this notice.
- If an inadequate connection occurs, please save the Flex Connector and report it to the Vygon (UK) Ltd. Technical Department on 01793 748940 or at [technical@vygon.co.uk](mailto:technical@vygon.co.uk)

3. Please confirm receipt of this FSN by completing the attached fax back form and returning it to Vygon (UK) Ltd. using the following fax number: 01793 748899 or email: [technical@vygon.co.uk](mailto:technical@vygon.co.uk)

4. Please complete actions by **27<sup>th</sup> April 2018**

#### **Instruction for Distributors of affected product codes**

Please provide this FSN to all your customers who have received the affected product codes. Please send your customers the following documents:

- A copy of this FSN
- A copy of the FSN fax-back form

The FSN fax-back form should be completed by your customers and returned to you.

As a distributor you are required to confirm to Vygon (UK) Ltd. that you have received this FSN by completion and return of the attached fax back form. Please forward all completed FSCA Fax Back Forms to the following fax number: 01793 748899 or email: [technical@vygon.co.uk](mailto:technical@vygon.co.uk).

Please complete actions by **27<sup>th</sup> April 2018**

#### **Vygon (UK) Ltd**

Vygon (UK) Ltd. has informed all customers in Scotland, employees of Vygon (UK) Ltd. and distributors of this FSN.

## **Transmission of this FSN**

This notice needs to be passed on to all recipients/users of this product within your organisation, in particular, the following:

- MHRA Liaison Officer
- Risk Managers
- Medical Device Safety Officer
- Medical Directors
- Nursing Directors
- Respiratory Unit
- Intensive Care unit
- High Dependency Unit
- Infection Prevention & Control
- Coronary Care Unit
- Procurement/

Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this FSN.

## **Contact Person**

Tara Pawley  
Technical Support Department  
Vygon (UK) Ltd.  
The Pierre Simonet Building  
V Park, Gateway North  
Latham Road  
Swindon  
Wiltshire  
SN25 4DL

Telephone: 01793 748940  
Email: [technical@vygon.co.uk](mailto:technical@vygon.co.uk)

Vygon (UK) Ltd. apologise for any inconvenience this FSN may cause.

This FSN has been communicated to the MHRA.



Tara Pawley  
Technical Advisor  
Email: [tara.pawley@vygon.co.uk](mailto:tara.pawley@vygon.co.uk)

**FSN FAX/EMAIL BACK FORM**

**FIELD SAFETY NOTICE REF. NO: 1803/41537/00**

**DATE: 27/03/18**

**PRODUCT:**

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

Product Code	Product Code
VKC2160	VKC22106
VKC21603	VKC221069
VKC2210	VKC22107
VKC22103	VKC22108
VKC221036	VKC22109
VKC221038	VKC2260
VKC2210386	VKC22606

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

Product Code	Product Code
VKC227	VKC22714186
VKC22701356	VKC227141863
VKC2270156	VKC22716
VKC22703	VKC2271603
VKC227036	VKC22716036
VKC227101	VKC227161
VKC2271013	VKC2271613
VKC2271018	VKC2271616
VKC2271218	VKC2271618
VKC22712183	VKC22716183
VKC22712186	VKC22716186
VKC227121863	VKC227161863
VKC2271418	VKC227166
VKC22714183	VKC2276

**LOT: ALL**

Please complete this form and return it to the Vygon (UK) Ltd., Technical Support Department using Fax Number 01793 748899 or email: [technical@vygon.co.uk](mailto:technical@vygon.co.uk)

I/we acknowledge receipt of the above FSN and that the information contained in this FSN has been shared with all recipients/user of the above products within our organisation:

Name: \_\_\_\_\_ Mr/Mrs/Miss/Other: \_\_\_\_\_

Designation: \_\_\_\_\_

Organisation: \_\_\_\_\_

Department: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

Post code: \_\_\_\_\_

Telephone No: \_\_\_\_\_

E-mail: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_