Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

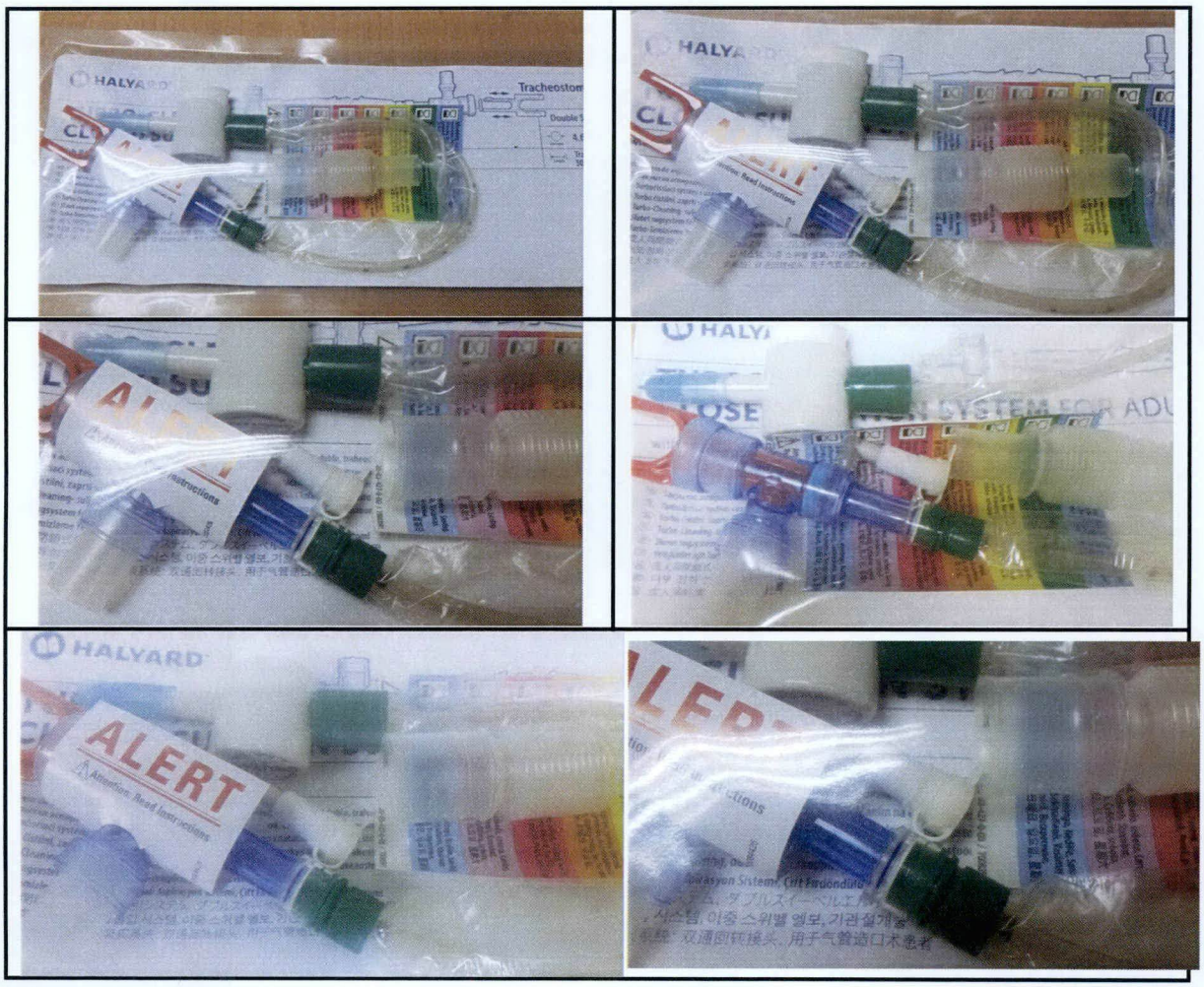
03 MAY 2018

FDA ADVISORY
No. 2018-162

TO: **THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED PROFESSIONALS**

SUBJECT: **PRODUCT ADVISORY NOTICE OF HALYARD HEALTH INC.**

The Food and Drug Administration (FDA) informs the public and all healthcare concerned professionals that Halyard Health, Incorporated manufacturer of halyard closed suction kits with connector and Panamed Philippines Inc. as their distributor has voluntarily submit a product advisory notice for the products with DVR number of 7454 and 7452.



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Panamed Philippines Inc. inform the FDA that Halyard Health Inc. received reports that certain Flex Connectors supplied with **Halyard Closed Suction Kits with Flex Connectors** may become loose or disconnect before use or during use.

Risk to health:

If disconnection occurs during use, it will result in an open respiratory circuit and interruption of patient ventilation.

Although the reported risk of occurrence is low, this advisory is intended to inform the general public and all the healthcare professionals about this potential issue and provide steps to help prevent this issue from occurring during use.

Specific Instruction Before Use:
Please ensure adequate connection of the Flex Connector to Swivel Connector before use.

- Before using the Flex Connector evaluate its connection to the Swivel Connector of the Closed Suction adapter to ensure 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.
- If an inadequate connection is observed, the Flex Connector may be replaced with a new, sterile Flex Connector and the system connection should be re-evaluated.
- If use of a Flex Connector with ventilator circuit is optional, the closed suction Swivel Connector can be connected directly to the ventilator circuit.

Figure 1

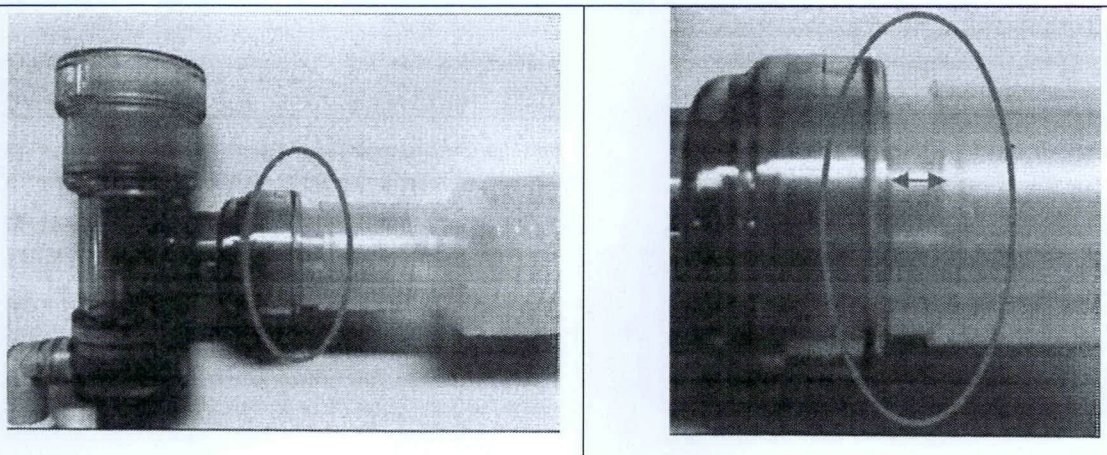
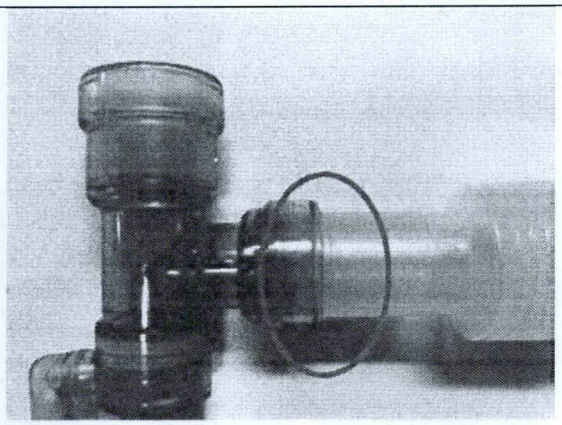
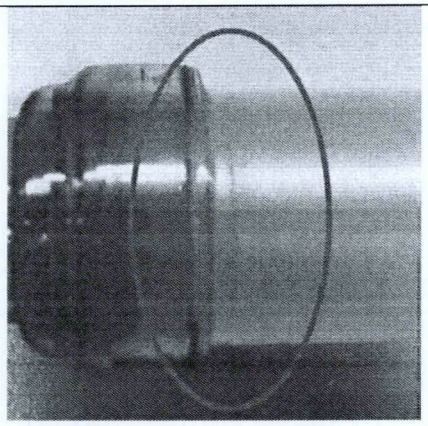


Figure 2





Specific Instruction 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 and ensure adequate connection as described in this notice.

Distributors, retailers, hospitals and all healthcare professionals / users are advised to coordinate with Panamed Philippines Inc.

For more information and inquiries, please e-mail us at cdrrhr_prsdd@fda.gov.ph. or call us at the Center for Device Regulation, Radiation Health and Research (CDRRHR) hotline (02) 857-1900 local 8301.

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Director General

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