Medical Device Advisory

Health Sciences Authority
Health Products Regulation Group
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CROSS CONTAMINATION ASSOCIATED WITH MULTI-PATIENT USE ENDOSCOPE CONNECTORS

The Health Sciences Authority (HSA) would like to remind users of endoscope devices regarding risks associated with endoscope connectors that are intended for use with multiple patients over the course of 24 hours without reprocessing. Following several global reports regarding backflow of substances such as blood, stool or other patient fluids from the endoscope irrigation channels into the water bottle or irrigation tubing, HSA had worked with local companies with endoscopes registered with HSA to ensure that only multi-patient use endoscope connectors with backflow prevention features were available in Singapore. The backflow of substances could result in cross contamination between patients. Primarily, the complaints received globally were mainly for endoscope connectors which did not have any back-flow prevention features in their design, such as back-flow prevention valves.

Risk of Cross contamination

2. This reported risk of cross-contamination applies to all brands of the reusable endoscope connectors without back-flow prevention features. There are a few models of multi-patient use endoscopy port-connectors currently registered with HSA. Registered models of endoscope connectors should include backflow prevention valve as part of their design when used with endoscopes, which would mitigate the risk of cross-contamination.

3. The manufacturers of such devices have recommended in their instructions for use (IFU) that users should use these connectors with designated tubing sets with backflow prevention features, such as valves, as part of the tubing sets. The risk of cross-contamination is expected to be minimised for these devices by users following these recommended instructions for use. The risk of cross contamination continues to be present if users do not adhere closely to the manufacturer's instructions for use when using these devices.

Recommendations for Healthcare Institutions and End-users

4. HSA has not received any local reports of cross-contamination or other issues related to the use of these multi-patient port connector devices so far.

5. HSA encourages healthcare professionals and staff performing gastrointestinal endoscopy to use single-use disposable connectors with backflow prevention features where possible. Alternatively, use reusable connectors with backflow prevention features during the procedures and adhere to the manufacturer's instructions for use when using these endoscope connectors in your facility.

6. HSA encourages healthcare professionals and staff performing gastrointestinal endoscopy to report any adverse events associated with the use of endoscope connectors. The confirmation of the causality of the AE is not a prerequisite for reporting. If a healthcare professional suspects that a medical device may be related to a serious adverse event, an AE report may be submitted. Please report any adverse events and/or suspected adverse reactions associated with the affected devices to the Medical Devices Branch, Health Products Regulation Group, HSA at Tel: 6866 1048, Fax: 6478 9028, or report online at www.hsa.gov.sg/ae online.

Thank you.

Yours faithfully,

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