Medical Device Advisory

Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-03 Helios
Singapore 138667
Website: www.hsa.gov.sg
Fax: 6478 9028

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RISK OF INFECTION AND CONTAMINATION FROM THE USE OF REPROCESSED FLEXIBLE BRONCHOSCOPES

The Health Sciences Authority (HSA) would like to remind healthcare professionals, users of endoscopes in healthcare facilities and infection prevention teams on the risk of infection and contamination associated with the use of reprocessed flexible bronchoscopes.

Risk of infection associated with reusable flexible bronchoscopes

2 Flexible bronchoscopes are endoscopes with a flexible inserted portion for endoscopic procedures of the airways and tracheobronchial tree (i.e., bronchoscopy). It is inserted through the mouth or nose during bronchoscopy for diagnostic or therapeutic purposes. To prevent risk of infection or cross contamination between patients, high-level disinfection or sterilisation of these scopes and accessories is required between procedures. In addition, there is a potential risk of spreading microorganism through air through aerosolization or from the surface of the bronchoscope when using and reprocessing a bronchoscope.

3. In view of the above and the current COVID19 situation, healthcare professionals and users are advised to consider the use of single-use bronchoscopes, where available, especially in situations where there is an increased risk of spreading infection or when bronchoscopy is required for immunocompromised patients.

HSA's regulatory actions for endoscopes to date

4 HSA has been working with endoscope manufacturers on this issue for some years now. For reusable endoscopes, manufacturers provide specific reprocessing instructions in the device information for use (IFU) regarding cleaning and disinfecting the devices after each use to ensure they are free from any contamination. The users should strictly adhere to these instructions to ensure that the endoscopes and accessories remain free from contamination during reuse.

5 In the last three years, there have been a number of post-market actions conducted by endoscope manufacturers in consultation with HSA to correct device related issues identified during real world clinical use. These actions could include recall of defective devices, inclusion of new warnings or precautions, strengthening reprocessing instructions in IFU etc. These cover various brands and different types of endoscopes and communications have been disseminated to hospitals and healthcare facilities to remind users to strictly follow reprocessing instructions in the device IFUs. These communications (i.e. field safety notices) can be accessed online at:

• FSCAs initiated before 6 January 2020:	
• FSCAs initiated on 6 January 2020 or after:	

6 HSA has published a Medical Device Advisory on the risk of infection and contamination from the use of reprocessed urological endoscopes on 15 April 2021.

Reports of contamination in flexible bronchoscopes

7 To date, HSA has not received any local reports of infection or cross-contamination involving reusable flexible bronchoscopes. However, there have been reports of contamination related to other endoscopes and automated endoscope reprocessors (AER). There have been global reports of infection post-procedures or contamination. The US FDA reports numerous reports of infections or device contamination associated with reusable flexible bronchoscopes, which has been attributed to factors such as failure to follow manufacturer instructions, continued use of devices even when signs of damage or maintenance issues were identified.

HSA advises strict adherence to manufacturer's validated reprocessing instructions as per the Instructions for use (IFU)

8 HSA emphasizes the importance of carefully following the manufacturer's validated reprocessing instructions in accordance with the IFU. Staff responsible for reprocessing should follow through each and every step of the reprocessing instructions described in the manufacturer's instruction for use, including:

1. Pre-cleaning	• Surface wiping and channel flushing should take place at point of use immediately following procedure to prevent drying of biological fluids, tissues or debris, which may lead to build-up of bioburden and development of biofilms
2. Leak testing	• Carry out leak testing as per manufacturer's instructions. • Remove any damaged devices (e.g. scopes with loose parts, holes, cracks, kinks or bends in tubing) or devices that fail leak test from service/use.
3. Cleaning	• Use cleaning accessories, enzymatic cleaning agents and detergent, as specified in the IFU, which has been validated by the manufacturer.
4. High-level disinfection (HLD) or sterilization	• Consider using sterilization instead of HDL, *where possible*. • Follow manufacturer's recommended HLD or sterilization protocols. • For HLD, use manufacturer-specified high-level disinfectants, followed by recommended rinsing and drying steps, meticulously.

9 The bronchoscopes should be visually inspected for signs of damage such as loose parts, holes, cracks, kinks or bends in tubing during reprocessing. After reprocessing, proper storage of the bronchoscopes is also important in reducing the risk of contamination. Bronchoscopes should be stored in accordance with manufacturer's instruction, which minimizes the collection and retention of moisture within the flexible bronchoscopes.

10 All reusable medical devices carry a significant risk of infection and cross-contamination. It is advised that hospitals develop schedules for routine inspection and periodic maintenance of these devices, especially reusable endoscopes in accordance with manufacturer's instructions. Hospitals should follow manufacturer's recommendations for preventive maintenance and repair of the device or contact manufacturers directly for additional information on maintenance and repair services.

11 HSA recommends that the above best practices be extended to all endoscopes, not just reusable flexible bronchoscopes. If users perform reprocessing in an AER, do refer to the user manual of the AER for specific instructions from the manufacturer. The above best practises should still be followed through systematically to ensure safe and effective use of these devices.

When to report an adverse event (AE) to HSA

12 The confirmation of the causality of the AE is not a prerequisite for reporting to HSA. As long as there is a suspicion 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, or report online at https://www.hsa.gov.sg/adverse-events/healthcare-professionals'-guide-to-adverse-events-reporting.

Thank you.

Yours faithfully,

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DR SETHURAMAN RAMA
DIRECTOR (MEDICAL DEVICES BRANCH)
MEDICAL DEVICES CLUSTER
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

How to report medical device adverse events?

Option 1. Complete our e-Form online:

Option 2. Complete our Medical Device Adverse Event Reporting Form: