Medical Device Advisory

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RISK OF INFECTION AND CONTAMINATION FROM THE USE OF REPROCESSED UROLOGICAL ENDOSCOPES

The Health Sciences Authority (HSA) would like to update healthcare professionals, users of urological endoscopes in hospitals and healthcare facilities and infection prevention teams on the potential risk of infection and contamination associated with the use of reprocessed **urological endoscopes**.

Risk of infection associated with endoscopes

2 Endoscopes are medical devices used for viewing and examining the various internal organs for diagnostic or monitoring purposes. There are different types of endoscopes such as laryngoscopes, bronchoscopes, duodenoscopes etc. and a common feature for all these endoscopes is the need for reprocessing these devices between use on patients. To prevent risk of infection or cross contamination between patients, high-level disinfection or sterilisation of these scopes and accessories is required between procedures. There have been reports of potential contamination associated with reprocessed endoscopes in the last few years and manufacturers have disseminated safety communications.

HSA's regulatory actions for endoscopes to date

3 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.

4 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:	

Reports of contamination in urological endoscopes

5 Urological endoscopes, which include cystoscopes, ureteroscopes, and cystourethroscopes, are used for viewing and accessing the urinary tract, from the urethra, bladder, ureters to the kidneys. Many of these scopes also have reusable accessory components, which need to be disassembled from the endoscopes and disinfected prior to reuse.

6 To date, HSA has not received any local reports of infection or cross-contamination involving urological endoscopes. 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 that there have been three deaths outside of the United States, of which these patients developed Pseudomonas aeruginosa infections post procedure[1]. Two of the death reports were associated with the use of an accessory component used to control water flow and enable access to the working channel of the urological endoscope. The third death involved a cystoscope that failed a leak test. A direct causality between patient death and infection from the use of the device could not be definitely established.

HSA recommends <u>strict adherence to reprocessing instructions</u> as per manufacturer's instruction for use (IFU)

7 HSA encourages healthcare professionals and staff performing reprocessing of reusable urological endoscopes to carefully follow reprocessing instructions described in the manufacturer's instruction for use. It is important to note that there are several discrete steps for the endoscopes as well as the associated reusable accessories:

i. pre-cleaning
ii. leak testing
iii. disassembly of the endoscope and other removable parts
iv. cleaning
v. disinfecting rinsing and drying; or sterilization

[1] The FDA Alert: Infections Associated with Reprocessed Urological Endoscopes - Letter to Health Care Providers https://www.fda.gov/medical-devices/letters-health-care-providers/infections-associated-reprocessed-urological-endoscopes-letter-health-care-providers?utm_medium=email&utm_source=govdelivery

8 HSA wishes to raise awareness among healthcare professionals and hospital staffs that reusable accessory may have separate reprocessing instructions. It is critical to follow the appropriate instructions to disassemble the endoscope and other components when reprocessing endoscopes. After which, the reprocessing procedures of endoscopes and reusable accessories should be carried out as per manufacturer's instructions for use, separately (where applicable).

9 Visual inspection of the endoscopes to ensure it is in working order must be carried out coupled with leak testing. Damaged or devices that have failed a leak test should not be used as they could increase the risk of infection or cross-contamination.

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. HSA recommends that the above best practices be extended to all endoscopes, not just urological endoscopes. 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 AE to HSA

11 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, Fax: 6478 9028, 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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How to report medical device adverse events?

Option 1. Complete our e-Form online:

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