Top Ten Tips

Endoscope Decontamination

1. **Quality** – Ensure that all processes are controlled using an appropriate quality system e.g. BS EN ISO 13485:2012 ‘Medical devices. Quality management systems. Requirements for regulatory purposes’ and that all equipment is operated and controlled in accordance with the manufacturer’s instructions.

2. **Staff training** – Ensure all staff, including new staff, involved in the decontamination process are fully trained* and that this training is regularly updated as appropriate (see Department of Health publication ‘Choice Framework for local Policy and Procedures 01-06 – Decontamination of flexible endoscopes: Policy and management’). Staff working within devolved administrations should consider the relevant documentation for their country.

3. **Compatibility** – Ensure compatibility with the existing hospital decontamination processes, including compatibility with the decontamination equipment. Do not reprocess single-use devices. Use pre-purchase questionnaires that require input and acceptance from decontamination and/or infection control teams prior to purchase.

4. **Identification** – Identify all endoscopes and decontamination equipment used in the hospital to ensure they are being maintained and that the correct decontamination process is being used. Ensure endoscopes can be tracked throughout the decontamination process and traced to the patients on which they were used.

5. **Channel connection** – Check the number of channels in each endoscope and ensure that they can all be connected to the automated endoscope reprocessor using the correct connectors/connection sets provided by the manufacturer.

6. **Manual cleaning** – Ensure endoscopes and accessories are manually cleaned prior to processing in an automated endoscope reprocessor or washer disinfector, including the flushing of all channels even if they have not been used during the procedure.

7. **Chemical compatibility** – Use only chemicals compatible with the endoscope, its accessories and the automated endoscope reprocessor. Chemicals must be used at the correct concentration, temperature and contact times as recommended by the manufacturer throughout the decontamination process. See ‘Choice Framework for local Policy and Procedures 01-06’.

8. **Process validation** – Use only validated processes following the manufacturer’s instructions and the appropriate standards e.g. the BS EN ISO 15883 series ‘Washer-disinfectors’.

9. **Preventative maintenance** – Have regular, planned preventative maintenance in place with records kept for all endoscopes and decontamination equipment.

10. **Incident reporting** – Report any problems relating to endoscope decontamination equipment or associated chemicals to the MHRA via our [website](http://www.mhra.gov.uk). Report identified problems with any decontamination process to the local consultant in communicable disease control (CCDC) at your local health protection unit.

---

Products claiming to remove/inactivate prion protein from contaminated medical devices: It is important that, until the efficacy of these products and technologies is established fully against human prions, clinicians ensure they follow the current Department of Health guidelines.

*Manufacturers of endoscopes and decontamination equipment and other external organisations provide courses in endoscope decontamination.

Note: The importance of decontamination needs to be clearly understood at all levels throughout the organisation. There could be legal implications if failures in this process are identified.