

**Top tips on decontamination of phacoemulsification handpieces**

**Advice from the IHEEM Decontamination Technical Platform [DTP]**

**Introduction – This advice has been produced following MHRA Alert: Handpieces used in the phacoemulsification technique of cataract removal: need for careful cleaning (DSI/2021/009) and additionally incidence of sterility failure following reviews of practice within a number of reprocessing facilities. The purpose of the advice is to aid in the safe reprocessing of these devices.**

**1 Quality** – Ensure that all decontamination processes are controlled using an appropriate quality system e.g., BS EN ISO *13485 Medical devices. Quality management systems. Requirements for regulatory purposes* and that all equipment is operated and controlled in accordance with the manufacturer’s instructions. Also attaining best practice as required within UK versions of the Health Technical Memorandum 01-01, Health and Social Care Act Code of Practice and appropriate regulatory requirements within each of the devolved administrations

**2 Staff training** – Ensure all staff, including new staff, involved in the decontamination process are fully trained specifically in requirements of the precise methods for these intricate devices and that this training is regularly updated as appropriate (see Department of Health guidance https://www.england.nhs.uk/wp-content/uploads/2021/05/HTM0101PartA.pdf Policy and management). Staff working within devolved administrations should use the relevant documentation for their country.

**3 Instructions for use**- The device manufacturers are obliged to provide instructions for use, and these should be followed. To attain best practice both the manual and automated wash processes must be followed in full and any variations necessary, agreed through the relevant Medical Device / Decontamination groups within each healthcare facility and supported through agreed validation protocols using expertise such as the AE(D), decontamination lead and approval of the equipment manufacturer.

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

Audits should be conducted within the practice by independent persons, such as the AP(D) and/or AE(D) for evidence that these processes are working and recorded for security. It is recommended that Infection Prevention Audits are undertaken in support of the technical audits.

**5 Compatibility** – Ensure chemicals as used in the cleaning processes, and the agreed procedures are compatible with the phacoemulsification handpiece being processed. This will include all chemicals used in the wash process (some units are not compatible with ultrasonic pre-cleaning) and sterilization process.

**6 Decontamination –** the importance of removing soil as quickly as possible cannot be overstated. The manual flush and irrigation as detailed in the instructions for use is carried out immediately after use at the point of use. The handpiece and instruments must be kept moist during transportation and until further reprocessing commences. The handpiece should be manually cleaned upon arrival in the decontamination unit and then processed in an instrument washer-disinfector as soon as reasonably practicable, and the handpiece is sterilized as soon reasonably practicable within three hours of exiting the washer disinfector. Audit of the decontamination process, but particularly the manual cleaning, is necessary to evidence it is being undertaken correctly.

**7 Channel connection within the instrument washer-disinfector**. The channels/ lumens of a phacoemulsification handpiece must be connected to the load carrier which incorporates a specialist filter unit for the connection and washed only with ophthalmic instruments as detailed in the manufacturer’s instructions for use. Filters must be cleaned after every cycle. Variation to the above by risk assessment, agreed through the relevant Medical Device / Decontamination groups within each healthcare facility and supported through validation protocols using expertise such as the AE(D), decontamination lead and equipment manufacturer may allow mixed reprocessing.

**8 Process validation and audit**. All aspects of the reprocessing must be tested, validated, and audited, this includes proving the process is performed using the equipment, materials, and personnel to achieve the desired result. This can include residual soil detection, cleaning efficacy tests with a surrogate device, process residue test, performance qualification of sterilization including evidence of attainment of sterilisation parameters and dryness after processing.

**9 Preventative maintenance** – Have regular, planned preventative maintenance of all decontamination equipment in alignment with the decontamination equipment manufacturers requirements (technical manual) and records kept. These records must be presented for audit.

# **10 Risk, due diligence, and incident reporting** –All decontamination failures or incidents should be reported within the organization’s incident reporting, with oversight and review by the decontamination lead, decontamination committee or executive responsible for decontamination. It may be necessary to report failures with equipment to the MRHA. Responsibility for satisfactory decontamination ultimately always remains with the organisation using the device to ensure their patients are protected. Failure to attain best practice with these devices for any reason should be recorded on the organisation’s risk register.

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