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The recently released Standard AS5369 **'Reprocessing of reusable medical devices and other devices in health and non-health related facilities'** (2023) provides clear guidance on reprocessing of reusable medical devices, including manual processes and decentralisation. Tristel products are designed for manual disinfection of a variety of medical devices.

Here, we answer some commonly asked questions.

1. Does AS5369 allow for manual high-level disinfection (HLD) processes for semi-critical reusable medical devices (RMDs)?

Yes, AS5369 specifically allows for manual HLD processes for semi-critical RMDs.

Section 6.3.5 references heat-labile, semi-critical RMDs and other devices, and states that these devices shall undergo high-level disinfection in accordance with their IFU. It notes that where a semi-critical RMD/other device is manually immersed in a high-level instrument grade disinfectant, procedures for handling, storage and use of the disinfectant shall be documented.

To further reinforce the allowance of manual HLD processes, Table 7.2 provides guidance on the quality of water to be used in the final rinse, specifically for manual cleaning, manual disinfection, and washer-disinfectors.

2. Is HLD sufficient for semi-critical, reusable RMDs?

The Introduction of AS5369 states that semi-critical, reusable RMDs shall be high-level disinfected at a minimum. Section 3.3.1 repeats that a high-level, instrument grade disinfectant is the minimum requirement, with clear definitions provided in Table 5.1.

While sterilisation is recommended for semi-critical devices, many of these are unable to withstand the process, and require a validated HLD solution.

3. Can reprocessing occur outside of a specific sterilisation department, or is centralisation required?

AS5369 is designed to cover reprocessing of **ALL** reusable medical devices. Many medical devices are designed for and best suited to central reprocessing, and it is often a requirement for specific RMDs. However, other devices are better suited to decentralised reprocessing; in Section 2.4.3, AS5369 references that reprocessing can occur in areas separate to a central department, such as endoscopy units, outpatient departments, day surgeries or radiology etc. This is likely due to unique design, specificity, turnaround requirements or low equipment inventory.

Section 5.6.1 states that RMDs should be reprocessed in a centralised and dedicated reprocessing facility wherever practicable. Centralised reprocessing may not be practicable for a number of reasons; there may be limited inventory of expensive and specialist devices, and no capacity to invest in expanding. Transportation and slow turnaround times for central reprocessing may impact device availability. If centralised reprocessing impacts service provision, then the practice is not practicable and therefore remote department reprocessing via a suitable method is valid and supported within AS5369.

Further, AS5369 highlights in Section 2.4.3 that reprocessing can occur in spaces separate to a central department and provides examples including outpatient and radiology clinics.

4. Is a digital means of tracking reprocessing activities a requirement?

Section 9.4 of AS5369 states that facilities should be working towards electronic traceability, but not that they must use electronic traceability systems.

Traceability systems – digital or manual – are required to record the type of device and its unique identifier, date and time of reprocessing, the person responsible, method of reprocessing and relevant parameters, and unique cycle. Other records – such as test strips, expiration dates, disinfection time, rinsing etc – may be kept if required by the manufacturer of the reprocessing agent.

5. Is a validation of my HLD process required?

Under Section 6.3.5, AS5369 states that a heat-labile, semi-critical medical device that is reprocessed manually shall have documented procedures for handling, storage and use of the disinfectant.
Further, it states to follow the disinfectant manufacturer's instructions in relation to monitoring and recording process parameters - such as temperature, contact or pH – if these are required.

Section 8.3 covers monitoring and control of manual, chemical high-level disinfectants, and highlights that documentation is required for temperature (if applicable), contact time, and rinse water volume (in line with disinfectant manufacturer IFUs). The MRC (Minimum Required Concentration) is required to be checked for reusable disinfectants using a chemical indicator, but there is no requirement for single use chemistries. Chemical Indicators confirm the presence of chemistry, but not that it was effective.

In addition, Table 9.1 highlights that a chemical disinfection process needs disinfectant agent concentration, exposure time, temperature and rinsing to conform with process specifications for release from reprocessing.

All of these features can be tracked either digitally or manually, and constitute validation.

6. If I use a cover on my device, do I still need to perform HLD?

AS5369 Section 5.1.3(e) states that a single-use sheath, sleeve or protective barrier shall not be used as a substitute for cleaning, disinfection or sterilisation. Within ultrasound, a probe cover is designed to contain the conduction medium and has a secondary benefit of preventing significant soiling of the probe with bodily fluids. The required level of decontamination is still mandated for the device even if a dedicated cover is used.

7. My RMD has blood on it; do I need to perform HLD?

AS5369 uses the Spaulding Classification to class medical devices. Under this universal system, a non-critical device touches intact skin, a semi-critical device contacts broken skin or mucosal surfaces, and a critical device is introduced into or has direct contact with the vascular system or areas of the body that are ordinarily sterile. These three device classes require cleaning followed by LLD or ILD (non-critical), high-level disinfection (semi-critical) and sterilisation (critical) respectively.

There is no mention of blood, and blood does not dictate device reprocessing requirements. Within healthcare, many non-critical devices contact blood and are not required to undergo HLD – while LLD is sufficient, ILD has a greater range of efficacy against micro-organisms. If an RMD is used on intact skin (and does not directly contact broken skin) and becomes contaminated with blood, HLD is not required under AS5369.

The implementation of AS5369 requires healthcare professionals to understand the requirements for reprocessing RMDs as they transition to the new Standard.

Tristel is committed to ensuring clarity and education, and to facilitate understanding of how manual disinfection with Tristel products continues to play an important role in meeting Standards for device reprocessing.

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