Tristel Duo™

NCU

Intermediate Level Disinfectant

RATIONALE FOR THE DISINFECTION OF SKIN SURFACE ULTRASOUND PROBES USED DURING HAEMODIALYSIS NEEDLE INSERTIONS

The prevailing National Standard which needs to be adhered to is AS 5369:2023 - Reprocessing of Reusable Medical Devices in Health Service Organisations.

There are several key parameters to be considered and met, including:

CLASSIFICATION OF THE MEDICAL DEVICE BEING USED

- AS 5369:2023 utilises the Spaulding Classification to categorise various medical devices into types, according to their intended use. The Spaulding Classification is clear on what constitutes a critical, semi-critical or non-critical medical device and is utilised across the world, including in Australia and New Zealand.
- Non-critical medical devices are those that "*only come into contact with intact skin and not mucous membranes*" (1.5.52).
- Semi-critical devices are "*a medical device that comes into contact with mucous membrane or non-intact skin*" (1.5.81).
- Critical medical devices are those that "*come into contact with the vascular system or sterile tissue*" (1.5.22).

The use of a skin surface ultrasound transducer in the placement of a haemodialysis needle does not enter sterile tissue or the vascular system, so it is **not a critical device**.

These skin surface ultrasound transducers do not contact mucous membranes or non-intact skin. The transducer is utilised to locate the vessel for guiding purposes. During the procedure, the transducer is positioned adjacent to the needle insertion point, not on top of it, contacting non-intact skin.

Should blood travel from the needle site and contact the transducer or the transducer cover, this would not constitute moving the transducer status from non-critical to semi-critical, because AS 5369 does not define contact with blood as semi-critical. The use of a disinfectant with efficacy against blood borne viruses would be prudent in this circumstance.

Skin surface transducers used for haemodialysis needle placement contact intact skin and are therefore non-critical medical devices.

Section 2.5.3.2 **Traceability Records** give further evidence of the types of devices that would be considered semi-critical. Examples of these devices are listed as "*e.g. trans-rectal ultrasound probes, colonoscopes, vaginal probes, endoscope.*" Note that all of these are in contact with mucous membranes and are all **intracavity/invasive** devices, entering the patient body. These are clearly of a different class to the skin surface ultrasound transducers which are not included as an example of the class of semi-critical devices.

Section 1.5.54 further states "*Non-invasive medical devices- A medical device which does not penetrate inside the body, either through a body orifice or through the surface of the body*". Skin surface ultrasound transducers used in haemodialysis needle placement do not penetrate the body in any way and and are therefore **non-invasive** medical devices.

LEVEL OF REPROCESSING REQUIRED FOR THE MEDICAL DEVICE BEING USED

- The Spaulding Classification is used by AS 5369:2023 to confirm the appropriate level of reprocessing for each of the three levels of medical device category "*on the basis of the risk to patient safety from contamination on a device*" (1.5.85).
- The Spaulding Classification clearly states that the appropriate reprocessing level required for a non critical device is "*Cleaning and this can be followed by low or intermediate level disinfection*" (1.5.52).
- **Semi-critical** medical devices require "*high-level disinfection at a minimum; however, sterilization of these items is strongly recommended*" (1.5.81).
- **Critical** medical devices "*require cleaning followed by sterilization*" (1.5.22).
- This status is referenced again in Table 5.1 within AS 5369 when highlighting the storage requirements of each of the levels of reprocessing- Page 37.

TYPE OF ASEPTIC FIELD USED DURING THE PROCEDURE

- AS 5369 makes reference to devices and aseptic fields in section 5.1.3, and in paragraph (e) it states "*RMDs that come into contact with sterile body cavities or are used on the critical aseptic field during invasive procedures shall be considered critical medical devices*".
- Placement of haemodialysis needles under ultrasound guidance are not performed in a critical aseptic field, but rather a designated clean site, utilising clean examination gloves, not sterile gloves. This setting does not lead to the determination that the ultrasound transducer be categorised as a critical medical device - it remains a **non-critical** medical device.
- This procedure is more akin to IV therapy. The Australian Guidelines for the Prevention and Control of Infection in Healthcare- Section 3 Standard and Transmission Precautions states in Table 11. "*That for IV therapy procedures a standard aseptic technique should be used, "Key-Parts can typically be protected by optimal Micro Critical Fields and non-touch technique. Key-Sites are small. Procedures are technically simple and <20 mins duration.*" Insertion of haemodialysis needles align with this definition.
- Table 11 also categorises PICC/CVC placement and surgery as requiring a surgical aseptic technique, further distancing the placement of dialysis needles away from these higher-risk, critical, invasive procedures which require "*Critical Aseptic Fields and full barrier precautions*". These high-risk procedure types are considered vastly different and the use of non-critical ultrasound transducers in a standard aseptic field does not elevate the transducer to the category of a critical medical device in any way.

THE OUTCOME ACHIEVED BY VARIOUS DISINFECTION LEVELS - LOW, INTERMEDIATE AND HIGH

- There are three levels of disinfection categorisation used in device reprocessing: high, intermediate and low, depending on the device's intended use. Critical devices require sterilisation.
- **Low level disinfection** is effective against bacteria and some larger viruses, but not smaller lipid viruses, mycobacteria, fungi or spores.
- **Intermediate level disinfection** is effective against bacteria, all viruses, mycobacteria and fungi, but not spores.
- **High level disinfection** is effective against bacteria, viruses, mycobacteria and fungi, as well as small numbers of bacterial spores.

AS 5369:2023 and TGO 54 agree on these definitions. The latter was recently sunsetted and is to be replaced by TGO 104, Australian Guidelines for the Prevention and Control of Infection in Healthcare.

DISINFECTANT REGISTRATIONS

- Under the Australian Regulator - the Therapeutic Goods Administration (TGA), a disinfectant to be allowed to be used for medical device reprocessing purposes must:
  - be an instrument grade disinfectant or sterilant - included, Class IIb medical device.
  - not be a hospital grade disinfectant (these may only be used for environmental surface disinfection, not medical device disinfection).

IN CONCLUSION

ULTRASOUND TRANSDUCERS USED IN HAEMODIALYSIS NEEDLE PLACEMENT ARE:

- non-critical devices
- non-invasive medical devices as they do not enter the body either by natural orifice, surgical intervention or the vascular system
- not used within critical aseptic fields, rather they are used in standard aseptic fields

The haemodialysis needle placement procedure is akin to I.V therapy, not PICC or CVC catheter placement (which is completed within a critical aseptic field.)

A reprocessing method including cleaning followed by intermediate level disinfection is sufficient to mitigate risk during these procedures.

TRISTEL DUO NCU:

- is a TGA approved Instrument Grade Class IIb-included medical device and is deemed appropriate for medical device reprocessing under all Australian regulatory standards
- eliminates organisms of concern including bacteria, viruses, mycobacteria and fungi
- is a point of care intermediate level disinfection foam that matches well with the requirements, the risk profile of the procedure and the nature of point of care ultrasound applications within the standard aseptic field

Where needle placement is akin to PICC or CVC catheter placement completed in a critical aseptic field, the Tristel Trio Wipes System is used to achieve high level disinfection.

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