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Reusable Medical Device Cleaning Validation: Soiling Considerations

Background

The reusable medical device cleaning process is the process of physically removing contaminants from a device to ensure the safety and effectiveness at the point of use. The validation of the cleaning process, including relevant soils and soil markers used in the soiling and analytical testing, must also be validated and executed as part of reusable medical device testing.

Device surface area

While it may seem counterintuitive, understanding and properly calculating surface area is the first critical step to appropriate soiling and the eventual calculation of residual soil markers post processing.

Vital aspects of a cleaning validation that are directly or indirectly impacted by device surface area include:

- How much soil is applied (and where) to appropriately soil the device to worst-case
- Calculating soil recovery efficiency
- Determining the volume of extractant used to ensure recovered soils are not overdiluted
- Calculations used to determine passing or failing residual soil levels on devices

The surface area utilized should include all extractable surfaces. This will include both external and internal surface areas of the device or representative worst-case component parts. Areas of cleaning challenge, such as threads, lumens, mated surfaces, hinges/joints, dead ends, etc. must be included in testing as they represent the most challenging areas to clean during reprocessing. A successful validation will need to demonstrate these areas are able to be cleaned, even after going through multiple use and cleaning conditioning cycles.

While it is possible to exclude non-patient contacting internal surface areas not meant to contact clinical soil or reprocessing chemicals, doing so would involve demonstrating fluid soils are not able to penetrate the interior of the device. This may require repeated soiling and cleaning steps followed by disassembly or destructive testing to open the device. Once disassembled or destructively opened, a visual inspection followed by residual soil marker testing can be completed to confirm whether or not the interior surfaces show any ingress of soil. It is often difficult or impossible to prevent ingress of soil because fluid soils will very easily wick into the interior and other challenge areas of devices during use. It is ideal to design the device to be easily cleaned or, if needed, disassembled and cleaned thereby avoiding this challenge altogether.

Clinically relevant soil

Choosing an appropriate soil is a key aspect of the reusable device cleaning validation. Ensuring that the soil utilized during validation recreates or simulates the natural clinical soil demonstrates the cleaning process will be able to remove the soils seen in clinical use. The soils chosen are therefore based on clinical use of the device and attributes of the clinical soil, such as soil components, viscosity, adherence of soil to the device, and water solubility.

There are a wide variety of soil ingredients that help represent clinical soils and even special recipes to recreate certain soil types. Some of the various soil components used to simulate clinical soils are blood, egg, mucin, bone, albumin, and muscle tissue. Custom simulated clinical soils can be created based on specific needs.

Worst-case soiling

It is important to apply soil to test reusable medical devices at worst-case. This means that soiling of validation test devices and positive controls is not done to mimic what is typically seen in clinical use, but instead they are soiled to the 'worst-case'that could be anticipated to occur in a clinical setting. This robust approach will demonstrate that even the dirtiest clinical device seen by thehospital reprocessing unit will come out of the validated and recommended cleaning process fit for re-use.

Soil markers

It is required to choose two relevant soil markers that can be quantitatively tested to demonstrate that any residual simulated soil, cleaning chemistries, or other soil have been removed to asatisfactory level. These markers should be relevant to:

- The device. For instance, it would only be beneficial to demonstrate the removal of carbohydrate during cleaning if the device was likely to encounter carbohydrate during clinical use, such as with an endoscope.

FOR MORE INFORMATION

STERIS Applied Sterilization Technologies
www.steris-ast.com
Email: ast_info@steris.com
(EMEA-APAC) is +44 330 236 8344
(Americas) +1 877.783.7479

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- The chosen soil. For example, the simulated soil must haveenough of the intended test marker/analyte to make it viable to test for it in both the positive control devices and the cleaned test devices

Soil marker analysis

Surface area is used to calculate the reported residual soil on test devices. All residual soil in the extractant from a test device is divided across the total device surface area tested to evaluate the soil per surface area (ex. µg of soil per cm^2 of surface area).

Conclusion

Having a good rationale on what surface area is being tested and why, along with an accurate surface area calculation will provide more confidence in the calculated residual soil determinations. It will also demonstrate the efficacy of the validation and recommended cleaning process.

- When initiating a cleaning validation, the following items are helpful to have determined and prepared in advance:
- An up-to-date surface area calculation
- Rationale for the chosen representative device (if family of devices are in scope of the study)
- List of devices within the product family (if applicable)
- A minimum of one representative device

Having this information and at least one sample device early in the process will keep the project moving quickly into the protocol drafting stage, helping to ensure a successful validation.

References

ANSI/AAMI ST98: Cleaning validation of health care products. Requirements for development and validation of a cleaning process for medical devices

BS EN ISO 15883-5: Washer-disinfectors — Performance requirements and test method criteria for demonstrating cleaning efficacy

ASTM F3208-20: Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices

BS EN ISO 17664-1: Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices — Critical and semi-critical medical devices

BS EN ISO 17664-2: Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices — Non-critical medical deviceS

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Email: ast_info@steris.com
(EMEA-APAC) is +44 330 236 8344
(Americas) +1 877.783.7479

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