

Time is Running Out

Emerging Risks with Spaulding's Classification

The Passion to Protect.

The Power to Prevent.

Disclaimer

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Learning Objectives – The WHAT

01

Explain how soil drying, device and tray design, and load configuration drive residual contamination and wet packs.

02

Identify high-risk features: narrow lumens, textured surfaces, hinges, and dense trays.

03

Apply risk-based criteria to point-of-use treatment, wet transport, and cleaning validation.

04

Describe mitigation strategies: timely cleaning, wet transport, better tray design, and audit metrics.

The Passion to Protect. The Power to Prevent.

Conversation Flow – The HOW



Stand Up

If you have a question, stand up — we will stop and answer questions.



Ask As We Go

We'd rather answer in the moment than save everything for the end.



Bring Your Reality

Your facility's water, constraints, and risks make this conversation better.

Conversation Leads – The WHO

Why these two voices, together

- Sarah Frank, BS — **frames the risks**: where device design and sterile processing practices break down, and what that means for cleaning, disinfection and sterilization outcomes.
 - Co-chair, AAMI WG-61 Chemical Sterilants Hospital Practices; J&J voting member for most AAMI standards groups focused on device processing.
- Terra Kremer, PhD, BS — brings the **industry research behind those risks**, studying microbial contamination control across the entire supply chain, from pharmaceutical and medical device manufacturing all the way to patient use.
 - Co-chair, AAMI WG-95 Water for Reprocessing; U.S. ISO expert (WG12, WG13); ASTM/AAMI/ISO and PDA TR70 contributor; PhD Microbiology, 20 years of lab and standards work.

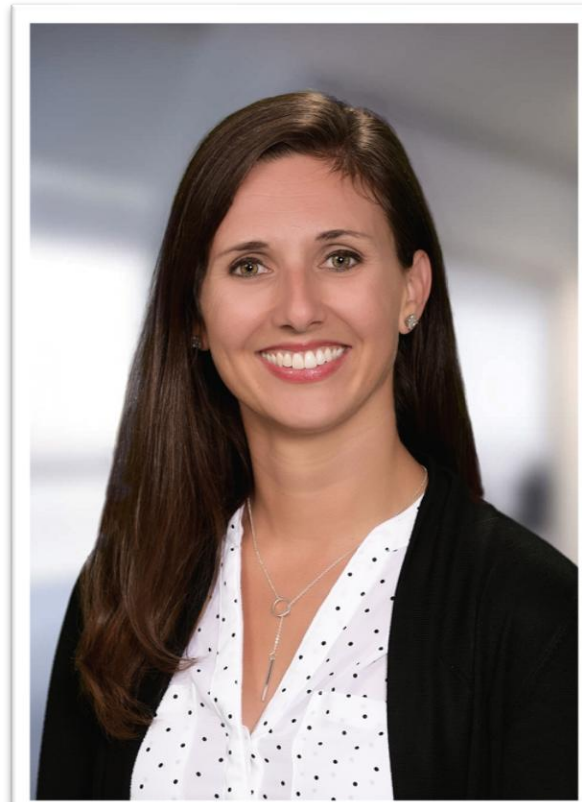
Sarah Frank

Manager, Device Processing



Terra Kremer

Director of Microbiological Quality

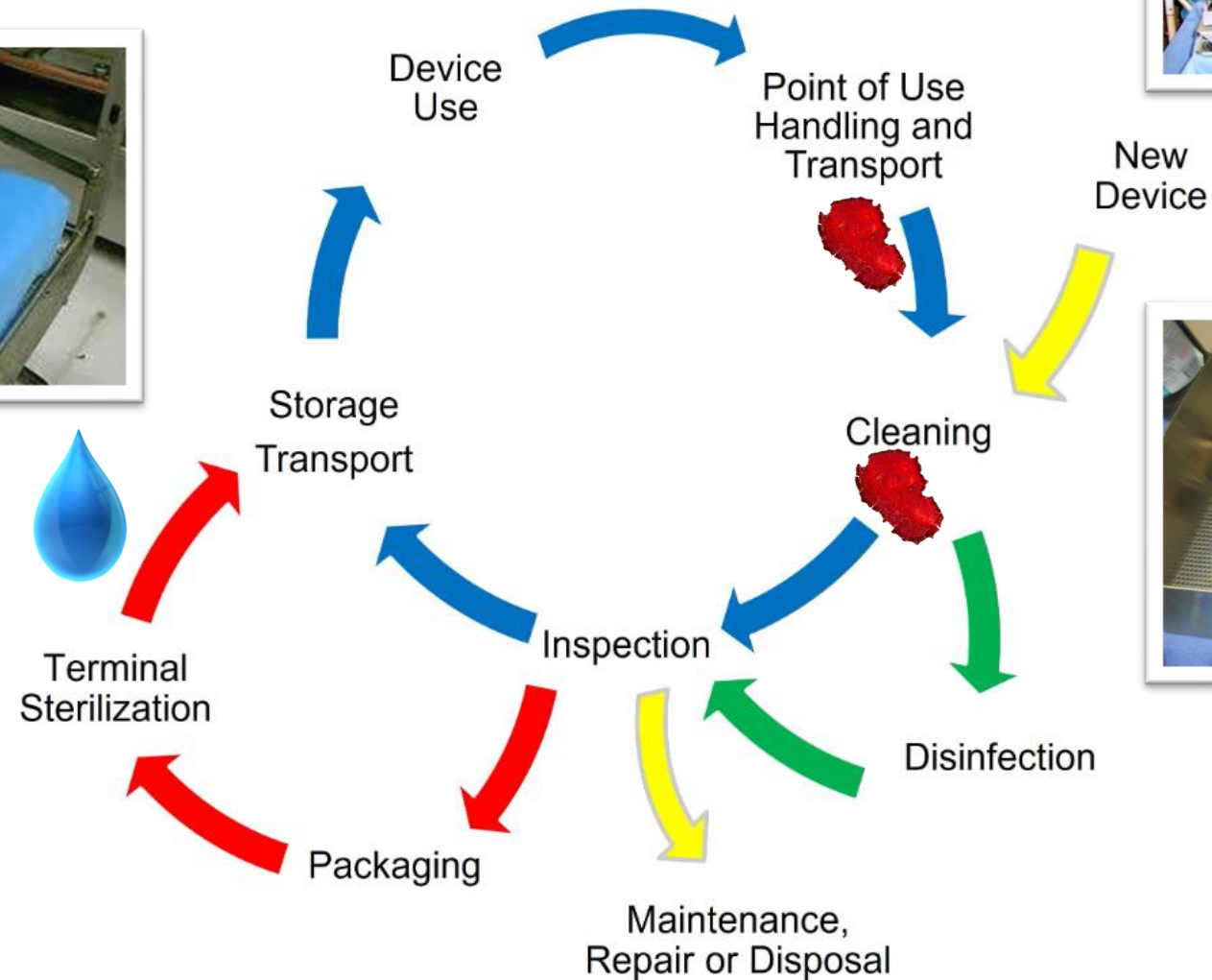


01

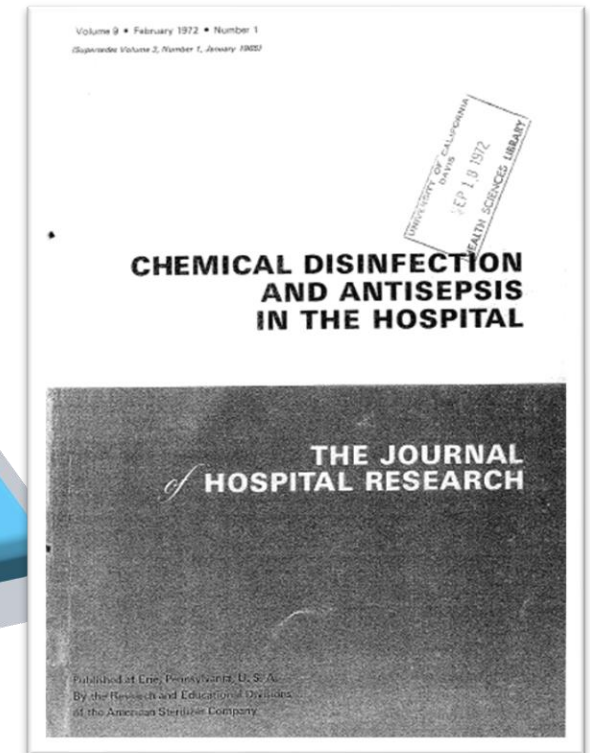
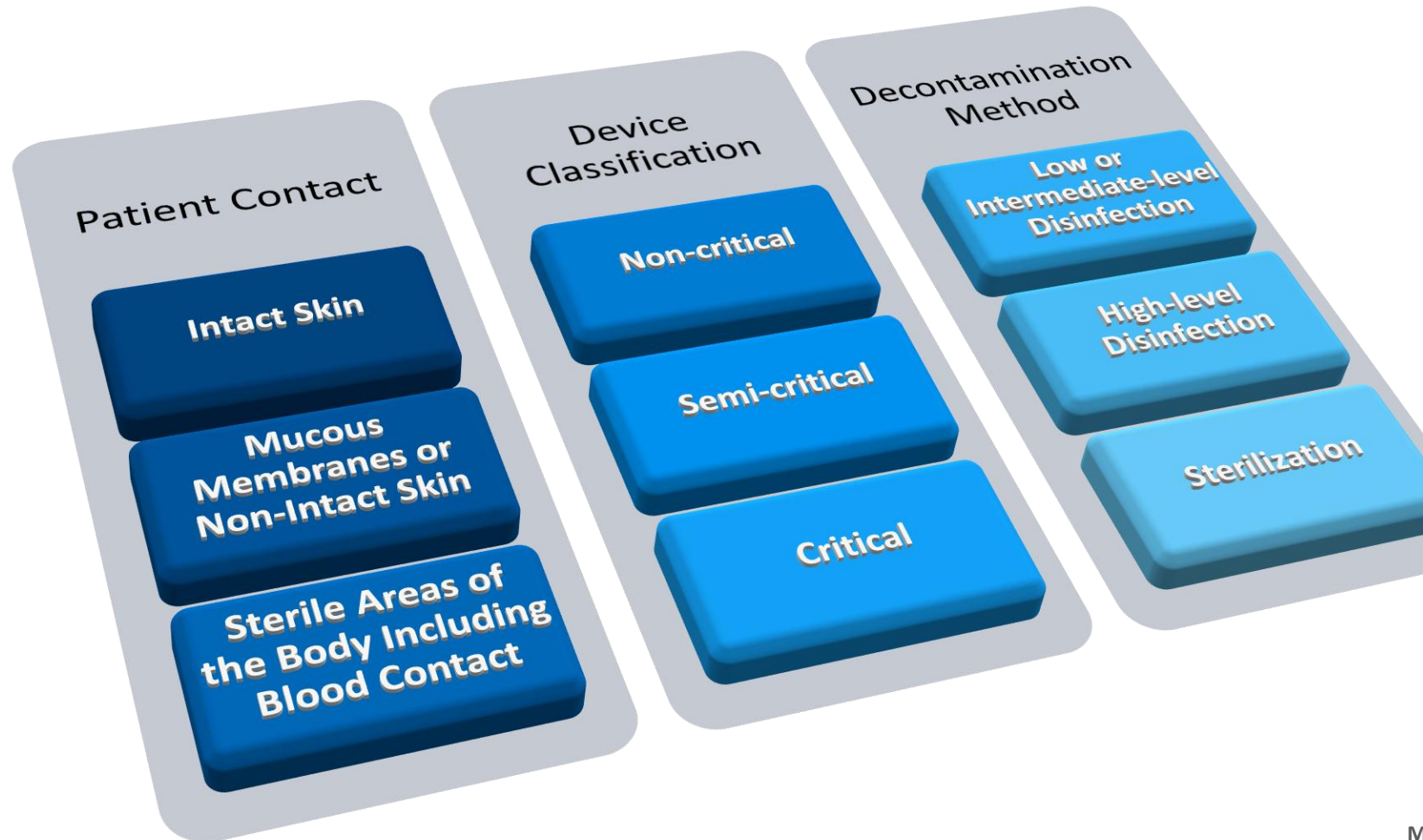
Explain how soil drying,
device and tray design,
and load configuration
drive residual
contamination and wet
packs.



Device Processing - CYCLE

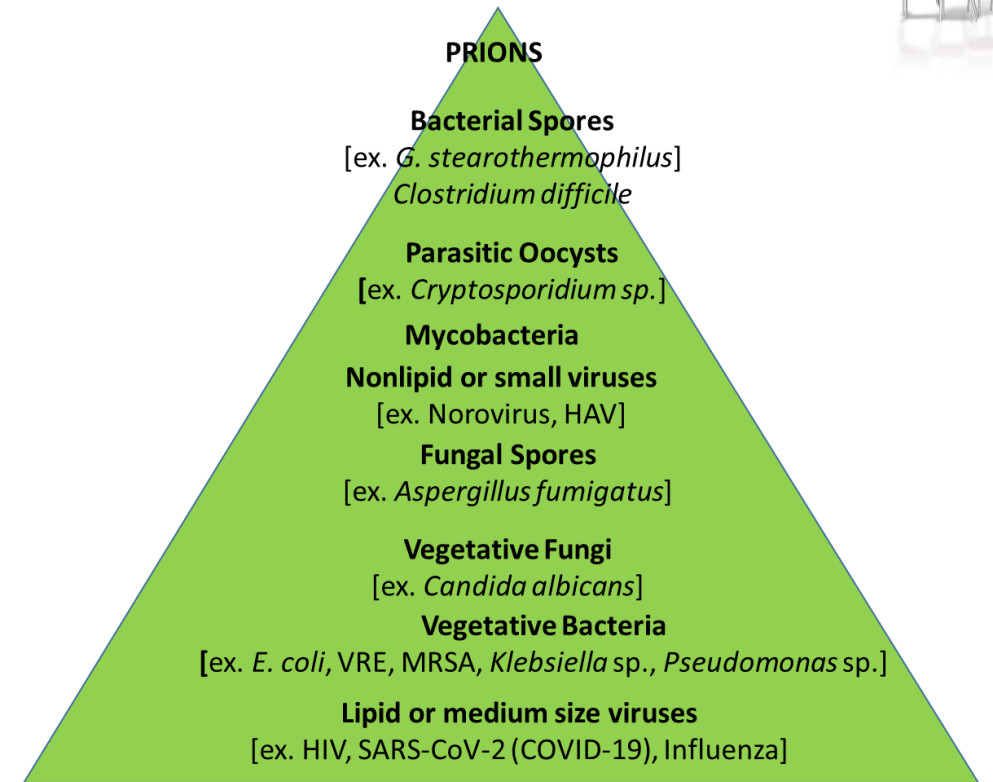


Spaulding Classification – MICROBIAL REDUCTION



Spaulding Classification - OPPORTUNITIES

- Remains as applicable today as it was 50 years ago.....but some opportunities
- Increased knowledge in microbiology (tolerance/resistance)
- It is a guide (varies depending on technology)
- Where things go wrong
 - Not applied correctly or concerns with device (including IFU) design
 - Cleaning problems



Opportunities - CLEANING

- Spaulding and associated guidelines have always highlighted cleaning is essential
- It is a requirement for new and reusable devices
- Impact of cleaning on patient safety
 - Reliability of disinfection and sterilization
 - Prevent device damage
 - Prevent device malfunction
 - Biocompatibility (toxicity risks)
- International harmonization of cleaning endpoints
- Continue to see reports of cleaning concerns in clinical practice

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Review

A review of Spaulding's classification system for effective cleaning, disinfection and sterilization of reusable medical devices: Viewed through a modern-day lens that will inform and enable future sustainability

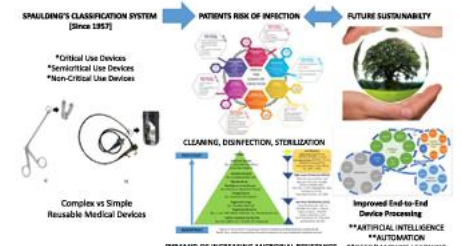
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HIGHLIGHTS

- Cleaning, disinfection and sterilization remain essential for mitigating patient risk from contaminated reusable medical devices
- Spaulding's classification of 1957 remains applicable, but it needs updating for modern-day challenges and opportunities
- Pressing need for new real-time monitoring and robust cleaning of devices enabled by automation
- Future design thinking of next-generation medical devices should address ease of cleaning, processing efficacy, and sustainability
- Quintuple Helix Hub concept (academia-industry-healthcare-regulators-society) will accelerate innovation and advance device safety

GRAPHICAL ABSTRACT



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Editor: Damià Barceló

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Patient risk, endoscopes, reprocessing

ABSTRACT

Despite advances in medicine and innovations in many underpinning fields including disease prevention and control, the Spaulding classification system, originally proposed in 1957, remains widely used for defining the disinfection and sterilization of contaminated re-usable medical devices and surgical instruments. Screening PubMed and Scopus databases using a PRISMA guiding framework generated 272 relevant publications that were used in this review. Findings revealed that there is a need to evolve how medical devices are designed, and processed by cleaning, disinfection (and/or sterilization) to mitigate patient risks, including acquiring an infection. This Spaulding Classification remains in use as it is logical, easily applied and understood by users (microbiologists, epidemiologists, manufacturers, industry) and by regulators. However, substantial changes have occurred over the past 65 years that challenge interpretation and application of this system that includes inter alia emergence of new pathogens (viruses, mycobacteria, protozoa, fungi), a greater understanding of innate and adaptive microbial tolerance to disinfection, toxicity risks, increased number of vulnerable patients and associated patient procedures, and greater complexity in design and use of medical devices. Common cited examples include endoscopes that enable non- or minimal invasive procedures but are highly sophisticated with various types of materials (polymers, electronic components etc), long narrow channels, right angle and

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Transport - TIME

Reality

- Internal – Transported in minutes to hours after use
- Transported by carts or containers
- Smooth floors
- External - Transported hours after use
- Transported by carts or containers
- Transported over roadways



Photo used with approval from Sue Klacik, HSPA





Decontamination - RECEIVING

Reality

Soiled instruments often wait hours before cleaning, letting protein dry and harden on surfaces



Photo used with approval from Sue Klacik, HSPA

Processing - DELAYS

Reality

- Unpredictable receiving volume
- Completion of surgical cases
- Receipt of loaned instrumentation
- Equipment from nursing units
- Instrumentation from nursing units
- L&D instrument sets
- Crash cart
- Instrumentation from clinics
- Flexible endoscope processing



Photo used with approval from Sue Klacik, HSPA



Processing - DELAYS

Reality

- Loaned Instrumentation
- Unpredictable receipt volume
- Unpredictable receiving time
- Complex instruments
- Vague IFUs
- Cleaned & transported in uncontrolled conditions
- If late delivery, rushed processing

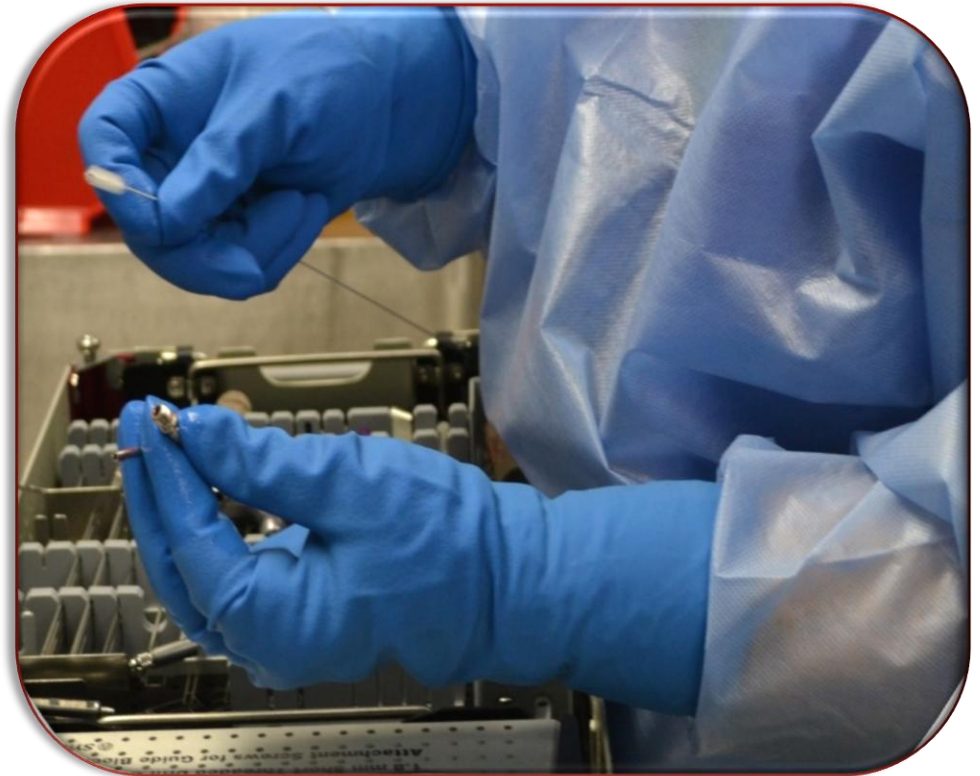


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Processing - DELAYS

Reality

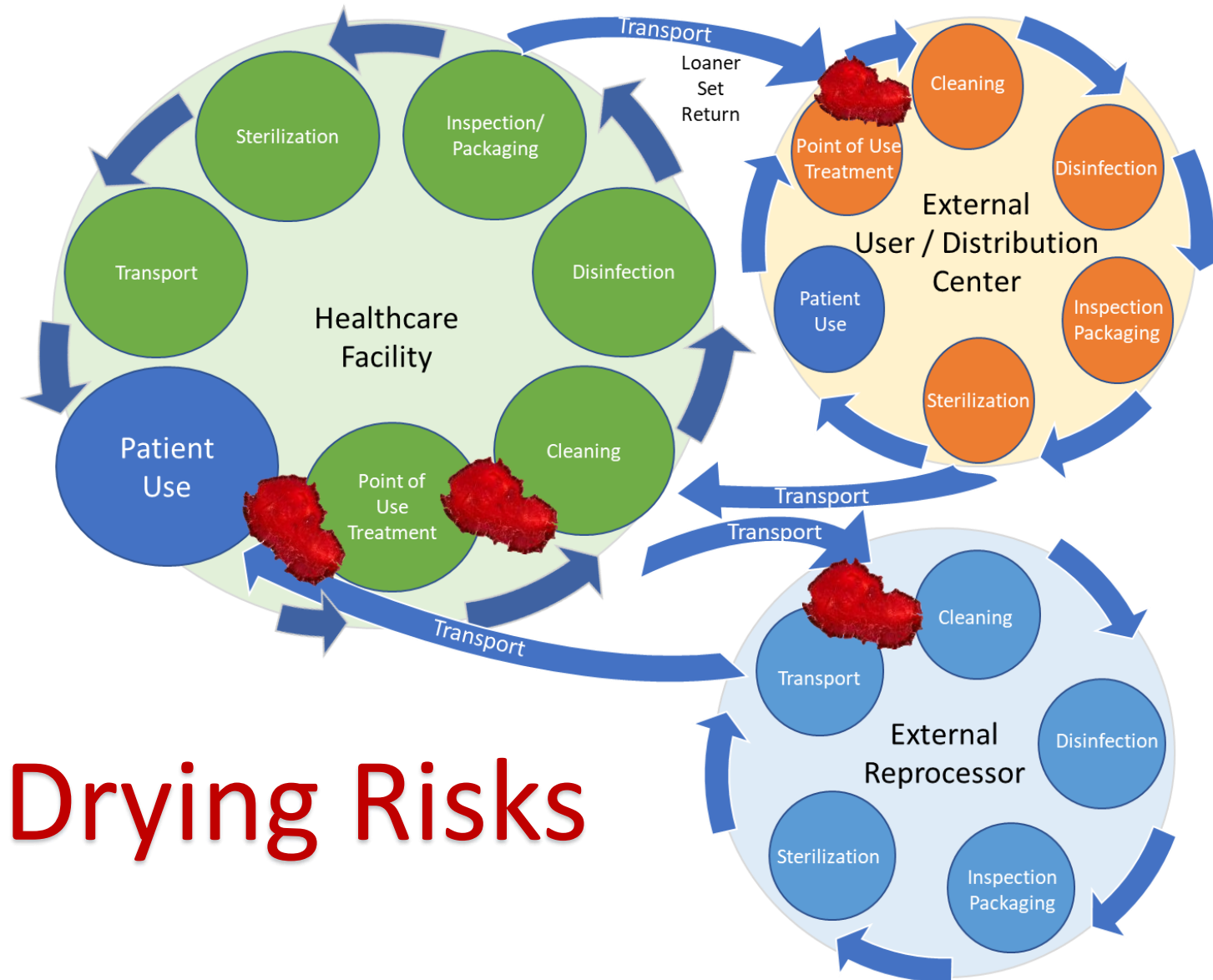
- Inadequate staffing due to:
- Staffing levels
- Priority issues
- Difficult to predict receipt of contaminated items
- Complex IFUs
- Time to don PPE



Photo used with approval from Sue Klacik, HSPA



Device Processing - END-TO-END CYCLE



Drying Risks



Transport - CONDITIONS

Reality

- Internal – Environmentally Controlled Areas
- External – Environmental Conditions Not Controlled or Monitored



External Transport of Instrument Trays and Associated Environmental Impacts

Katherine Olson, input information like below. *Corresponding author*

Cathy Castro, input information like below.

Tracy Raymond, input information like below.

Jen Barnickel, input information like below.

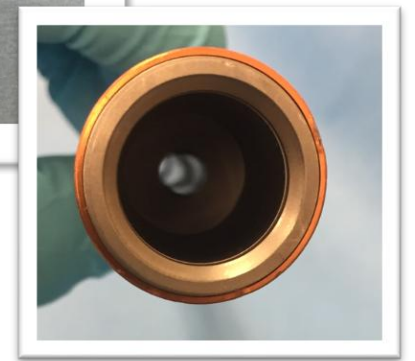
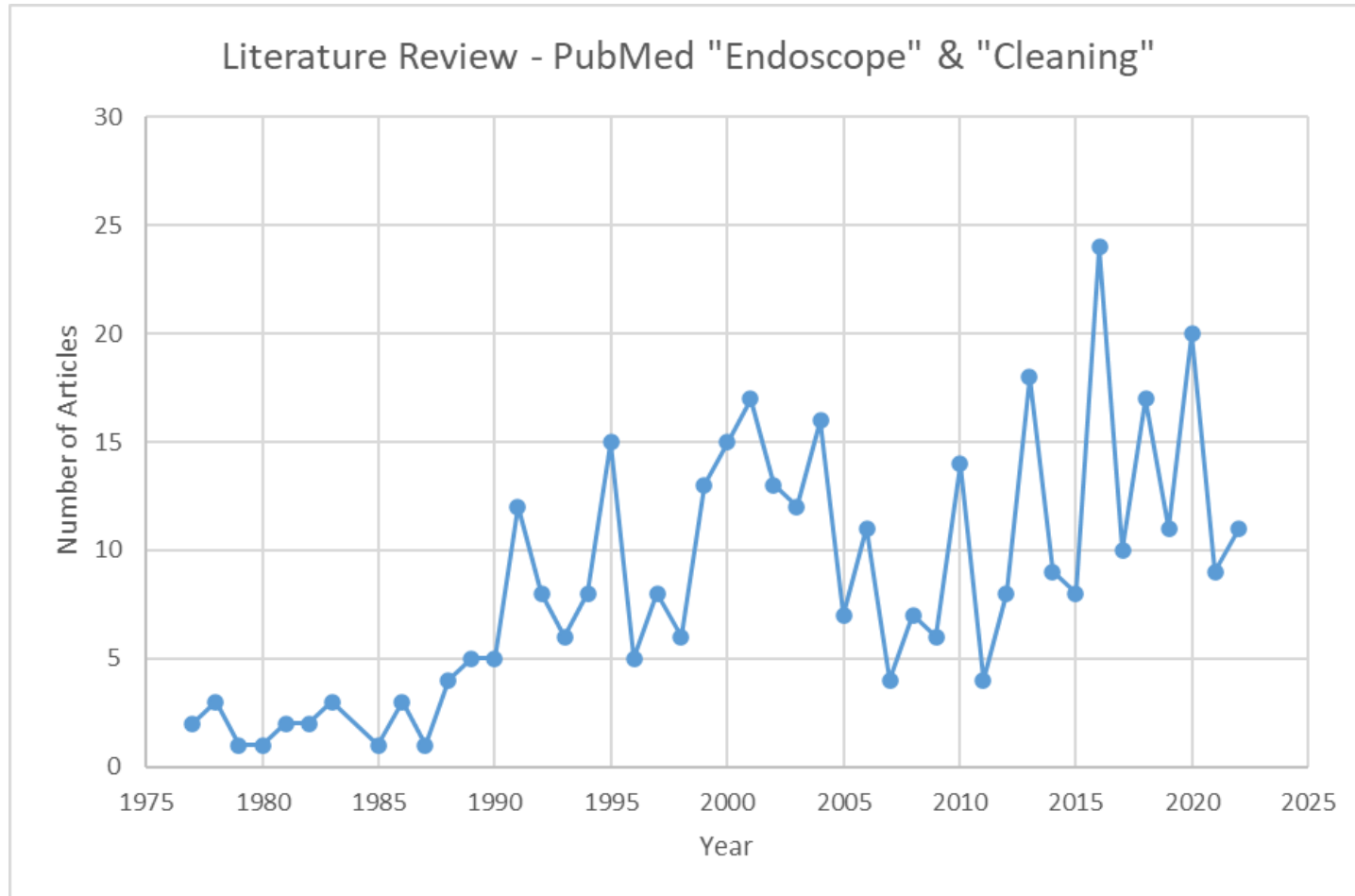
Terra A. Kremer, BS, PhD, is the director of Microbiological Quality within the Microbiological Quality & Sterility Assurance organization at Johnson & Johnson located in Raritan, NJ. Email: tkremer@its.jnj.com

Abstract:

In today's healthcare industry, healthcare facilities are needing to find ways to be more efficient, and sterile processing is one area of increasing focus. This is because facilities are being challenged to process an increasing volume of trays without increasing staffing levels or footprint. Similarly, many surgeries that were only done in hospitals, are now being moved to smaller ambulatory surgery centers that were not designed to handle the larger quantities of trays. This shift to the outpatient setting is especially true for reconstructive orthopedic surgery, which depends on instruments that many people believe are the most difficult to process. Moreover, this pressure on labor productivity is also compelling operators to prioritize the reduction of duplicate surgical instruments across a network of facilities. As a direct result of these trends, facilities are looking to offsite sterile processing facilities to handle the additional workload, which includes the cleaning and sterilization of manufacturer-owned loaner trays. This trend towards the establishment of off-site sterile processing centers is compelling people to ask whether or not instrument sterility can be impacted by transport between facilities. Observations into the practices of said facilities has suggested an increase in the transport of soiled surgical equipment to central facilities within a healthcare network, as well as more outsourcing to third parties who provide these services. While there is some guidance on the transport of sterile products inside the healthcare facility, the industry lacks standards for the external transport of sterile and soiled devices. In response, this study examined the impact of temperature change and humidity change on the sterility of orthopedic instruments traveling in sealed rigid containers. In addition to the industry-regulated parameters (e.g. temperature and humidity), this study also investigated the impact of dew point, moisture and prolonged vibration during transport. The primary objective was to determine the extent to which these environmental factors were able to affect instruments inside the rigid container, as well as the instrument trays. This serves as starting point to help address questions raised over the expanding use of external transportation to sister facilities, or from offsite sterile processing centers. This study confirmed that excursions are inevitable but can be successfully managed through the use of special purpose vehicles, suitable packaging, and real-time monitoring.



Improper Cleaning - RESIDUAL SOIL RISK



International Harmonization - ISO TC 198 WG13



- ISO 15883 series on washer-disinfectors
- ISO 15883-5:2020 Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy
- Defined 'clean'
 - visually free of soil and quantified as being below specified levels of analytes
- Harmonized test soil and test method requirements
- Defined analyte acceptance criteria for cleaning efficacy
 - Impacted other new standards such as ANSI/AAMI ST98:2022



International Harmonization - ISO 15883-5:2020*



Analyte	Alert Level	Action Level
Protein	$\geq 3 \mu\text{g}/\text{cm}^2$	$\geq 6.4 \mu\text{g}/\text{cm}^2$
Total Organic Carbon	$\geq 6 \mu\text{g}/\text{cm}^2$	$\geq 12 \mu\text{g}/\text{cm}^2$
Carbohydrate	$\geq 0.9 \mu\text{g}/\text{cm}^2$	$\geq 1.8 \mu\text{g}/\text{cm}^2$
Haemoglobin	$\geq 1 \mu\text{g}/\text{cm}^2$	$\geq 2.2 \mu\text{g}/\text{cm}^2$
ATP	≥ 10 femtomoles ATP/cm ²	≥ 22 femtomoles ATP/cm ²
Endotoxin	≥ 2.2 EU/device	≥ 20 EU/device

*Note, in addition devices are required not to have any associated process residuals (e.g., detergent residuals) that would be harmful or impair further processing (typically tested by cytotoxicity).

International Harmonization - ANSI/AAMI ST98:2022



Table 1—Acceptance criteria for endpoints

Clinically Relevant Analyte	Acceptance Criteria
Protein	$\leq 6.4 \mu\text{g}/\text{cm}^2$
Total Organic Carbon	$\leq 12 \mu\text{g}/\text{cm}^2$
Carbohydrate	$\leq 1.8 \mu\text{g}/\text{cm}^2$
Hemoglobin	$\leq 2.2 \mu\text{g}/\text{cm}^2$
Adenosine Triphosphate (ATP)	$\leq 22 \text{ femtomoles}/\text{cm}^2$

How were these DEFINED?

- Detailed literature review, including current regulatory requirements
 - Note: emphasis placed on protein as protein was determined to be the highest level of contamination on reusable device surfaces
- Expert knowledge within the standards committee, and peer review
- Impact on patient safety
 - Levels known not to impact disinfection/sterilization
 - Levels practically achieved using established cleaning methods
 - Clinically relevant and measurable
 - Ongoing research (e.g., link to toxicity risks)



Cleaning Analyte Concentrations vs PATIENT SAFETY



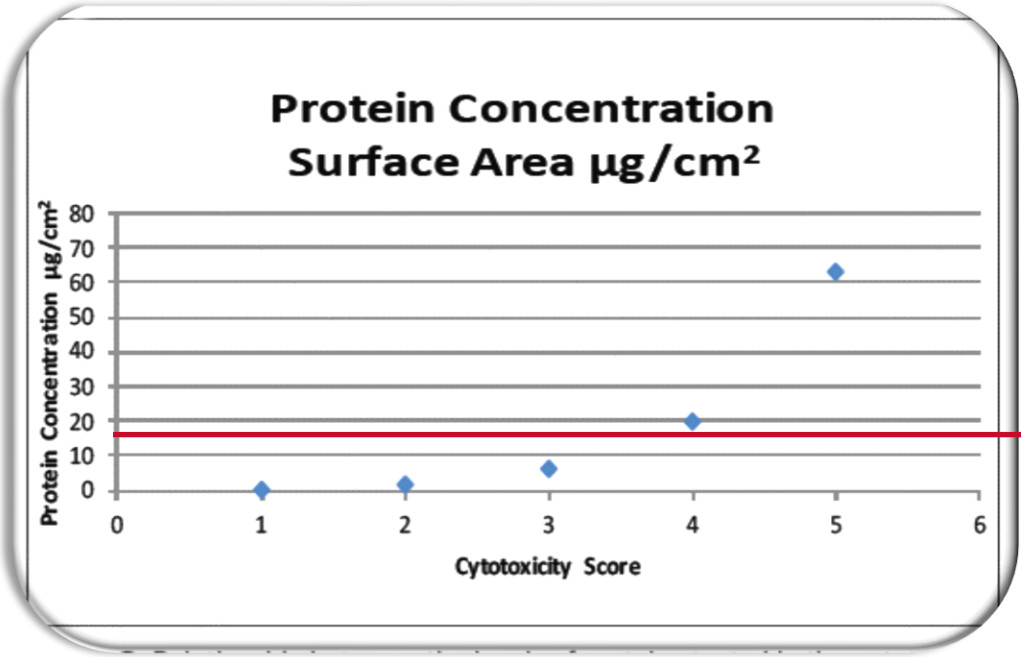
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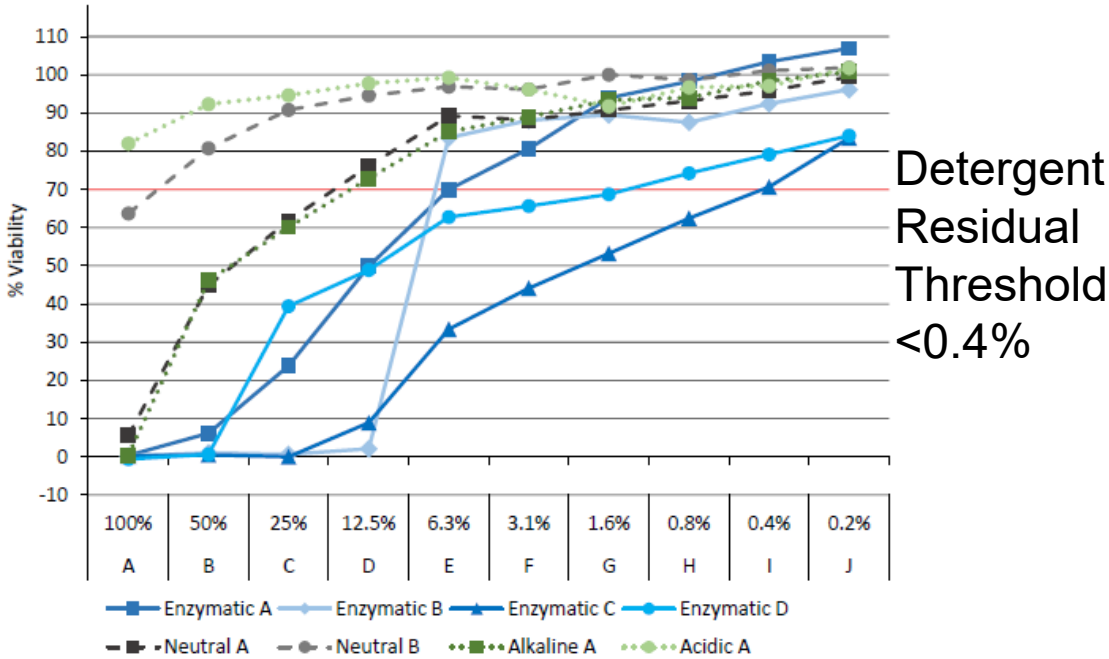
Acceptance Criteria Levels –
As low as practical based on literature

Verification Testing?

- Measured by TOC
- Measured by Protein
- Measured by Protein



Protein
Safety
Threshold
<10μg/cm²



Detergent
Residual
Threshold
<0.4%

Source: Kremer, et. al. Protein Residuals on Reusable Medical Devices and Patient Safety. Zentral Sterilization. 2019

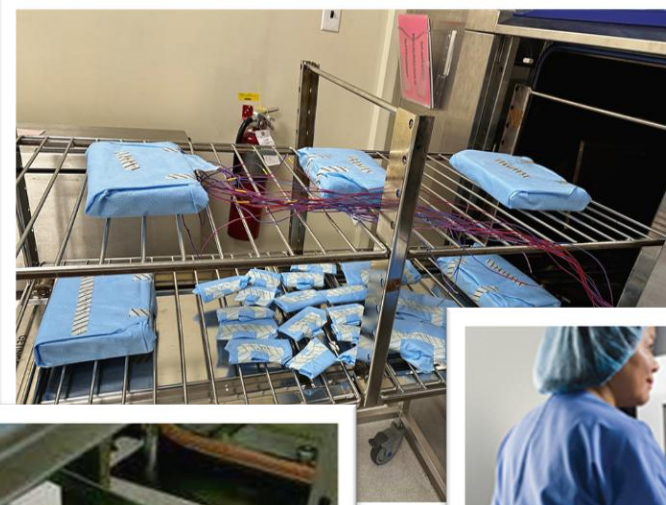
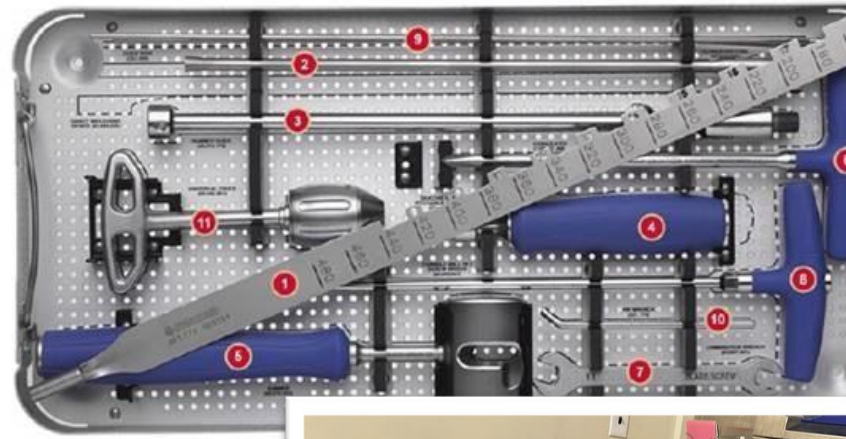
Source: Kremer, et. al. Assessing Detergent Residuals for Reusable Device Cleaning Validations. Biomedical Instrumentation & Technology. 2021

Post Sterilization – WET PACKS

- Moisture breaks the sterile barrier
- Wicking lets microbes travel into the pack
- Sterility cannot be assumed — load is not released

Causes: overloading, dense trays, poor drying, cold spots

Impact: delays, reprocessing costs, patient risk



Wet Pack- DELAYS

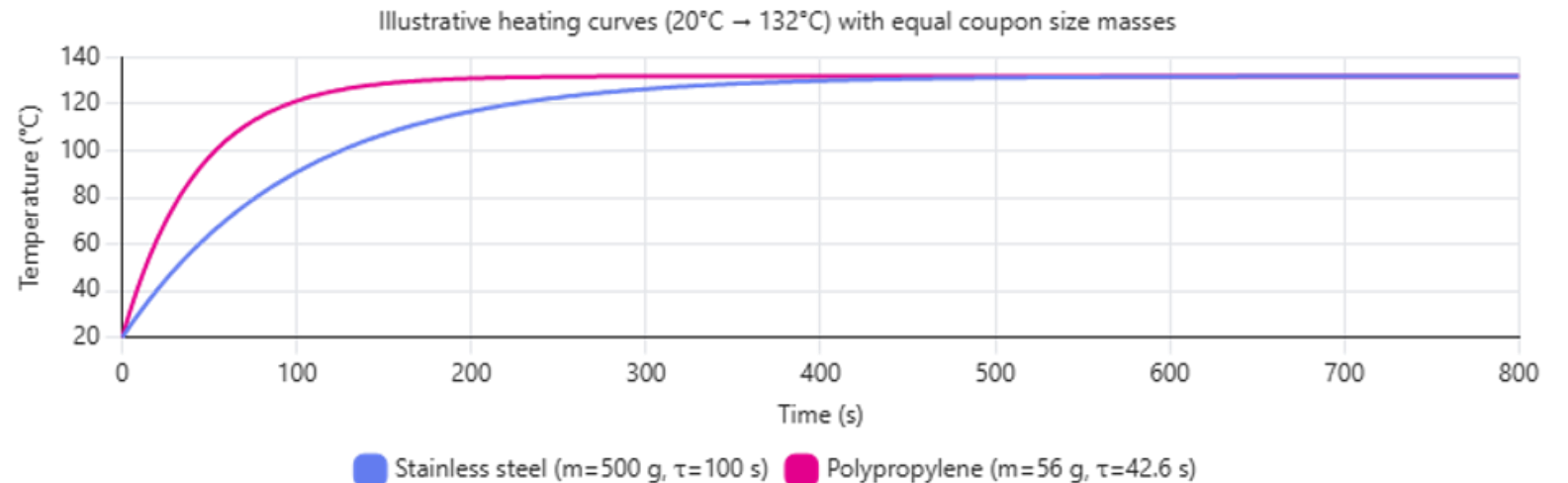
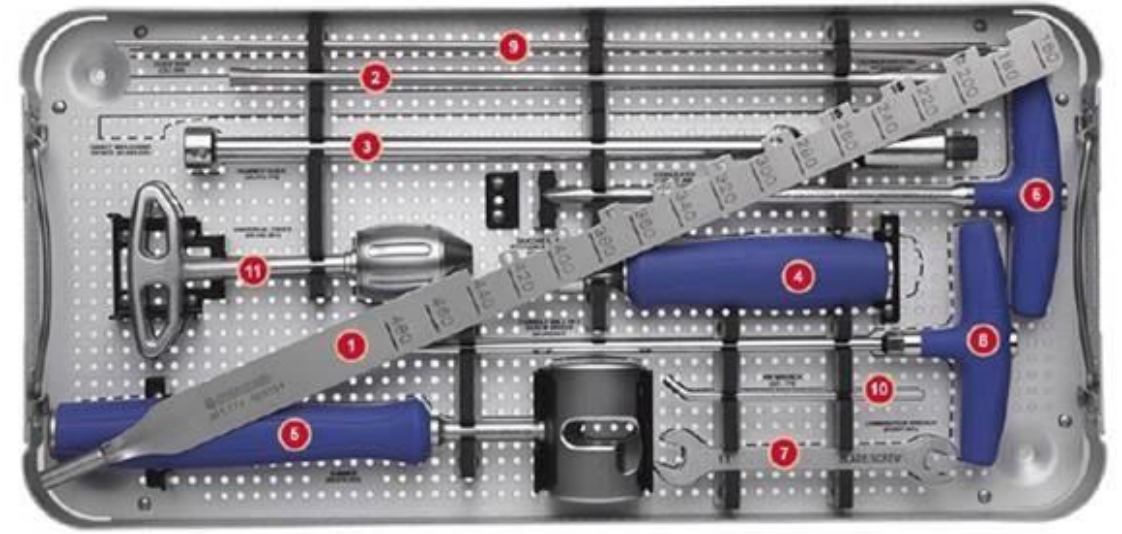
Reality

- Wet pack not always visible in SPD
- Moisture seen after opening wrap
- Devices returned to SPD
- If late delivery, rushed processing



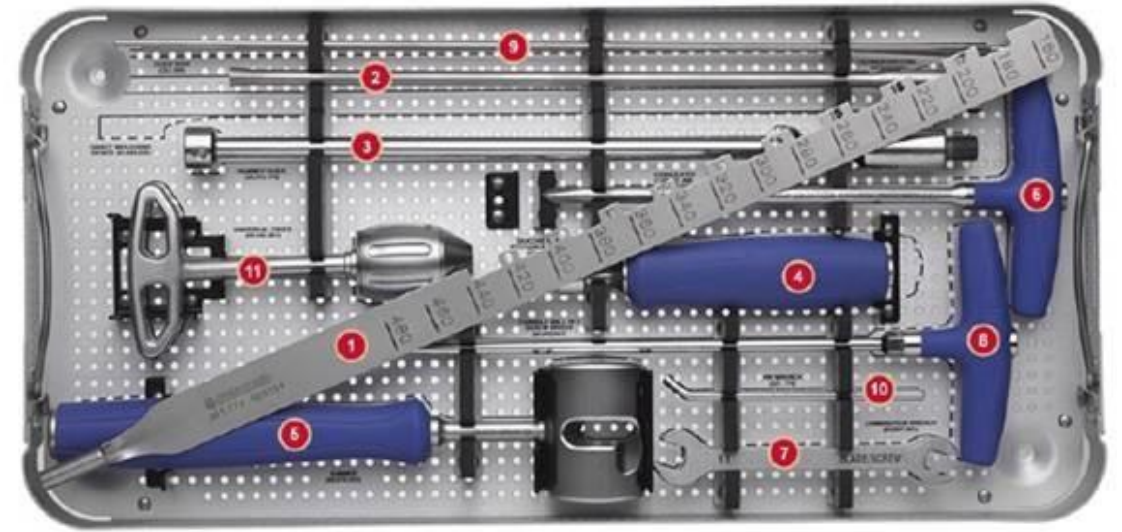
Opportunities - DRYING

- Condensate forms when cold surfaces meet steam
- Key drivers: total load mass, thermal conductivity
- Non-metallics (silicone, plastics) are insulators
 - Low thermal conductivity – greater risk for condensate



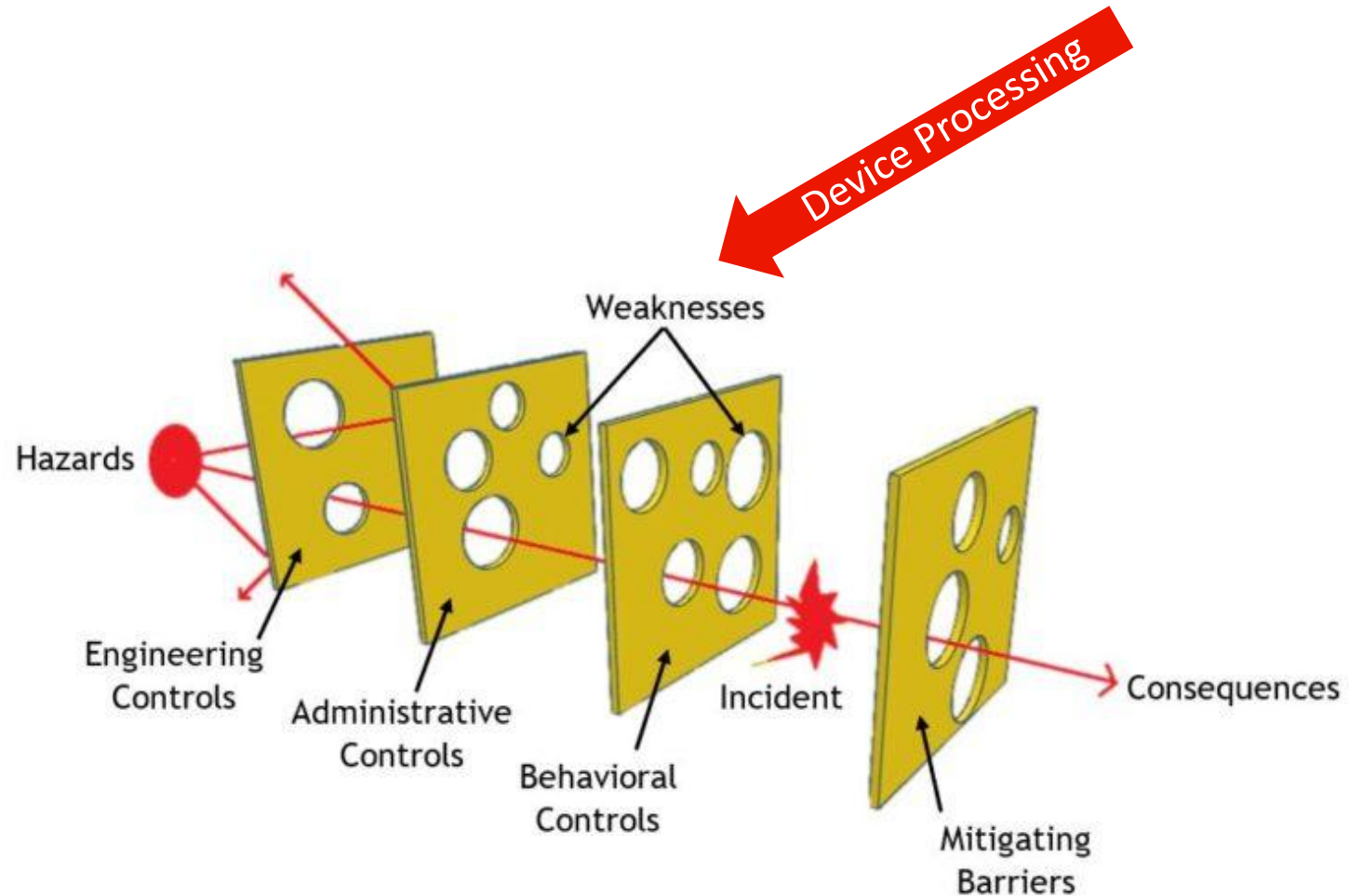
Opportunities - DRYING

- Cooling time matters
 - Exterior of case cools faster than internal components
 - Handling a warm container can act as a point of condensation
 - See ANSI/AAMI ST79 9.7 and 10.3.1

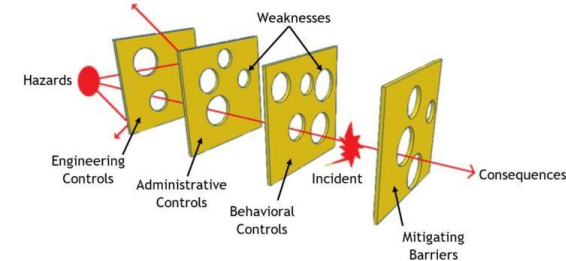


02

Identify high-risk features: narrow lumens, textured surfaces, hinges, and dense trays.



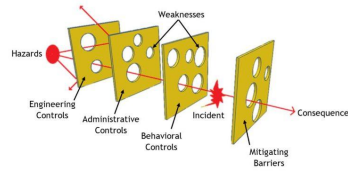
Device Performance - RESPONSIBILITY



Manufacturers

Healthcare Facility

Manufacturer's Responsibility - CLEANING VALIDATION



Consultation

Extraction
Method
Validation

Simulated
Use Cycling

Test Soil
Application

Cleaning

Extraction

Analyte
Detection

Report

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 17, 2015

This document supersedes: "Labeling Reusable Medical Devices for
Reprocessing in Health Care Facilities: FDA Reviewer Guidance" (available
at
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf>) issued April 1996.

The draft of this document was issued on May 2, 2011.

For questions regarding devices regulated by the Center for Devices and Radiological Health,
contact the Infection Control Devices Branch (INCB) at (301) 796-5580. For questions regarding
devices regulated by the Center for Biologics Evaluation and Research (CBER), contact the
Office of Communication, Outreach and Development at 800-835-4709 or 240-402-7800.



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Center for Biologics Evaluation and Research

American
National
Standard



ANSI/AAMI
ST98:2022

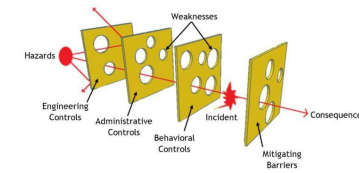
Cleaning validation of health
care products—Requirements
for development and
validation of a cleaning
process for medical devices



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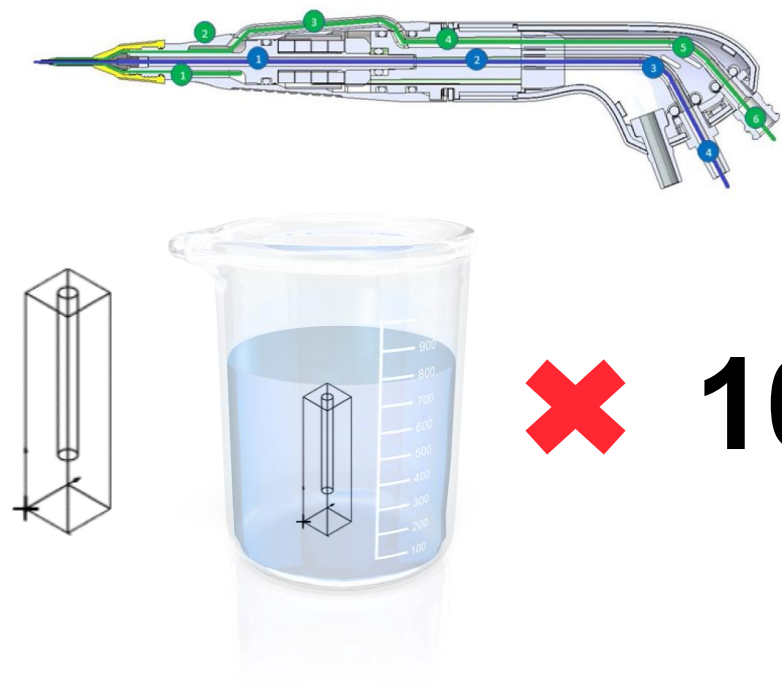
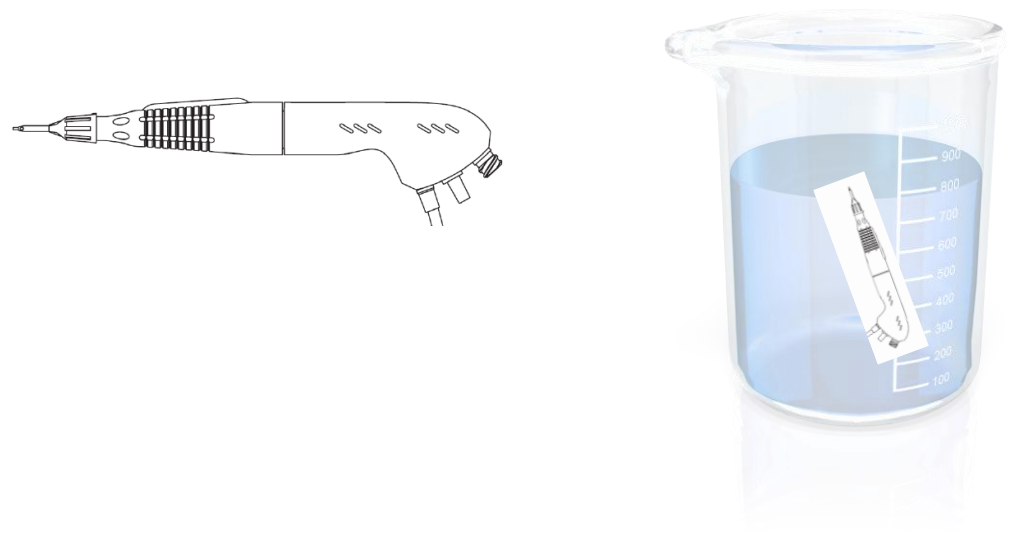
- Automated Cleaning Validation ~ 30K
- Two quantitative analytes
 - Protein $\leq 6.4 \mu\text{g}/\text{cm}^2$
 - Total Organic Carbon (TOC) $\leq 12 \mu\text{g}/\text{cm}^2$
- Data Variability
 - Standard deviation added to the highest value must be less than acceptance criteria

Device Feature Cleaning Validation – The APPROACH



Current Practice: Whole Device Surface Area

Future Practice: Cumulative Device Feature

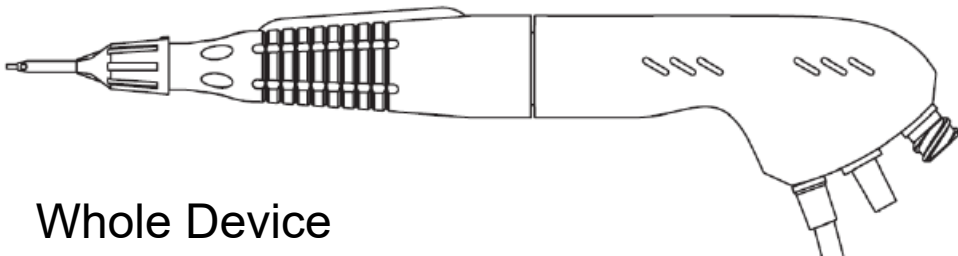
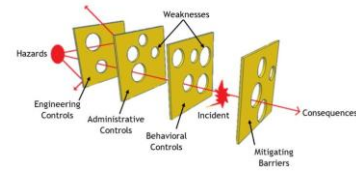


✖ 10

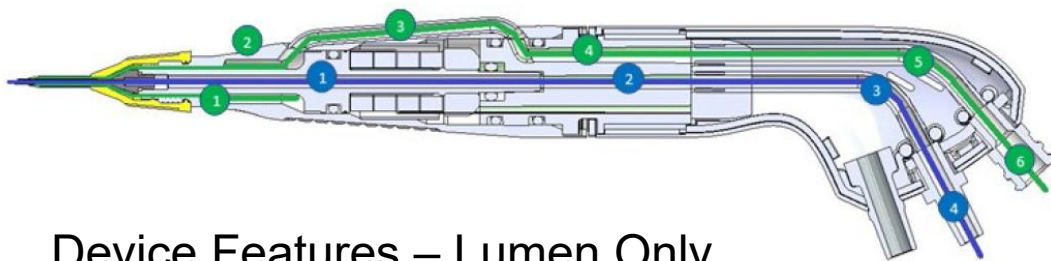
May **DILUTE DETECTION** in worst case location

WORST Case

Device Testing vs FEATURE TESTING

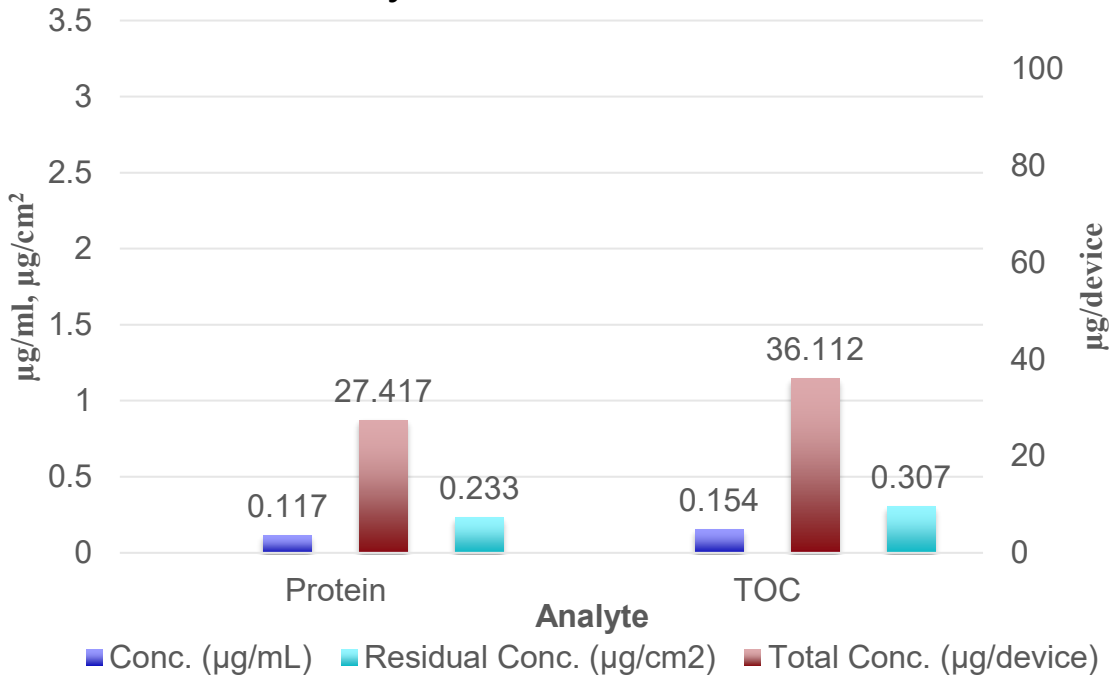


Whole Device
Surface Area = 117.86 cm²

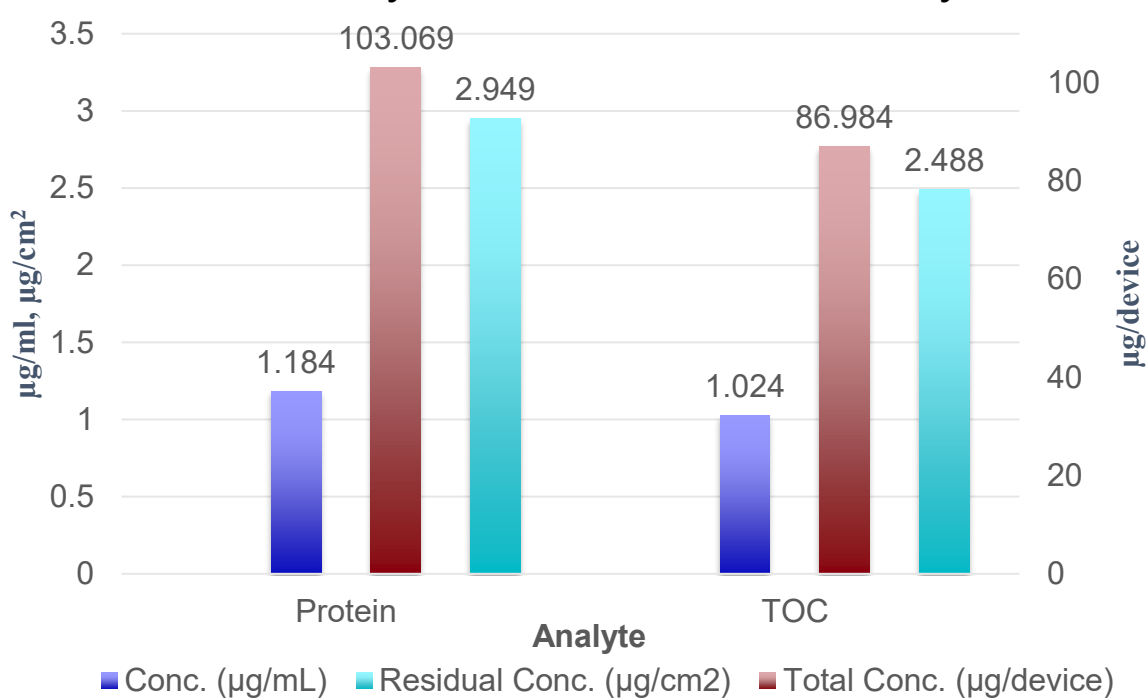


Device Features – Lumen Only
Surface Area = 34.96 cm²

Extraction Analyte Residual – Whole Device



Extraction Analyte Residual – Lumen Only



*Device images are for illustrative purposes only

Device Feature Approach - VALIDATION

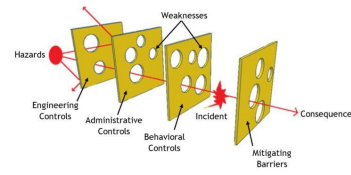


Image 1: Single Feature

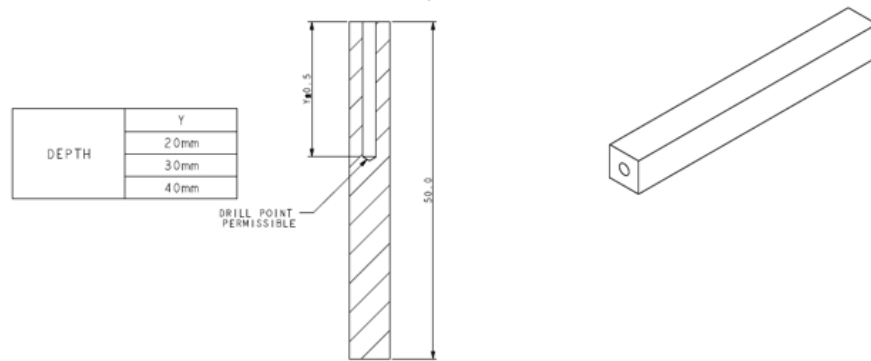
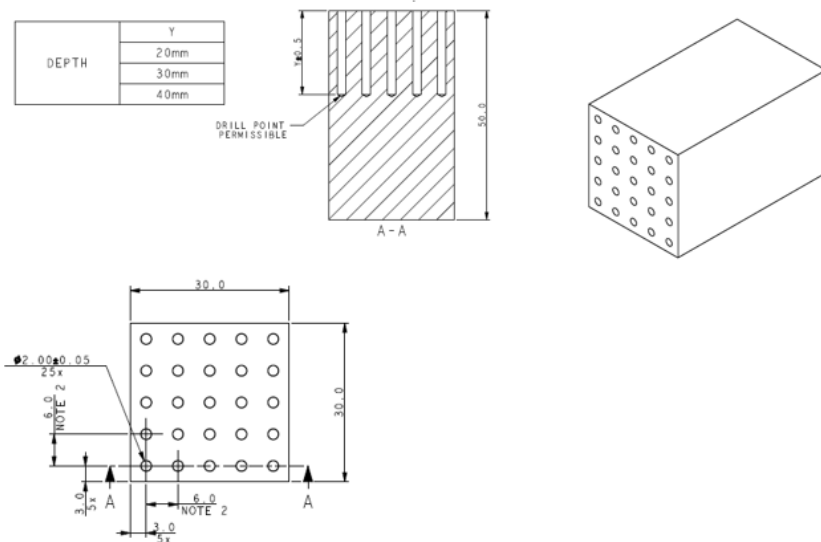
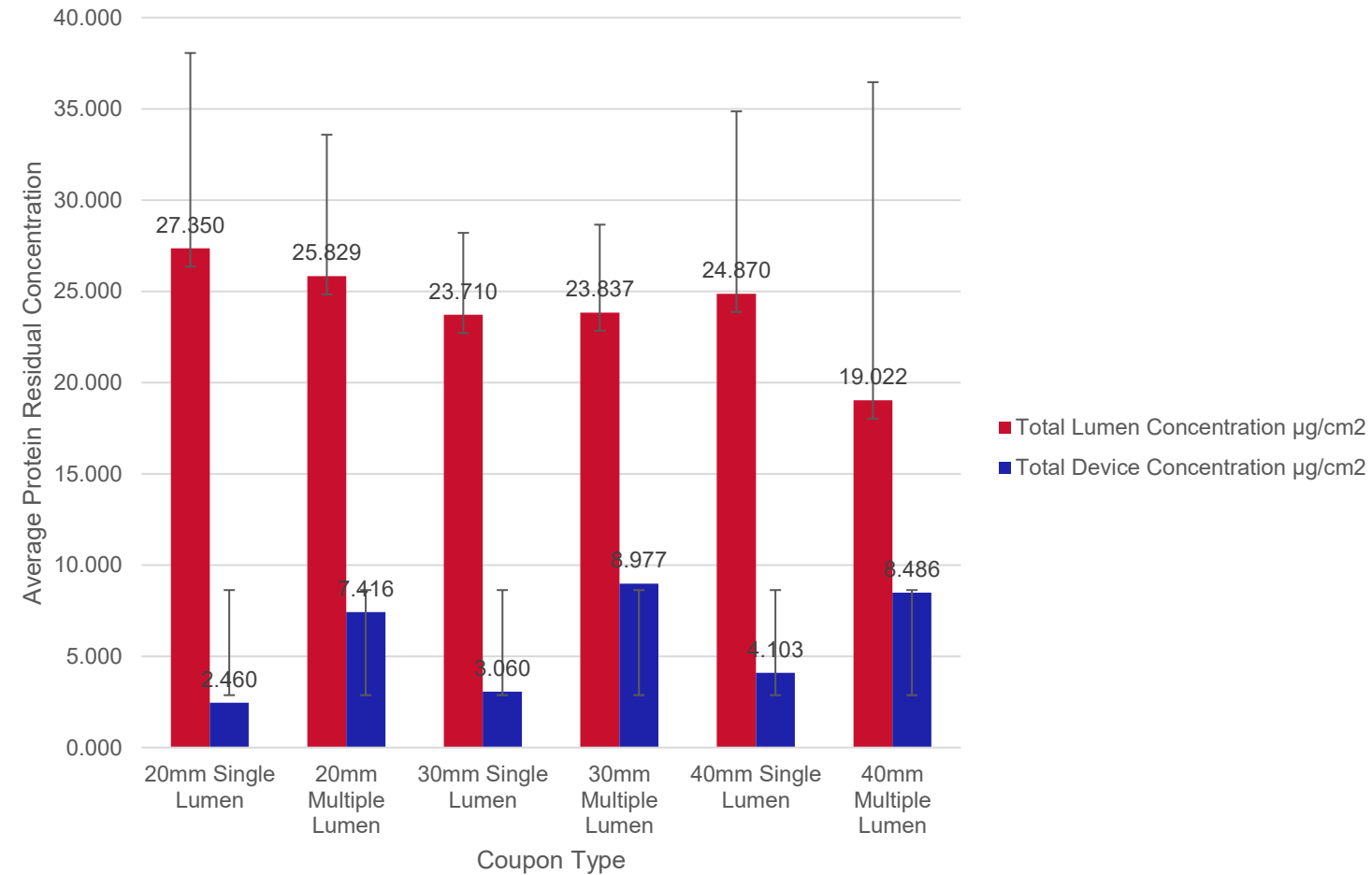


Image 2: Multiple Feature



Protein Residual Concentration: Design Feature Approach vs Compendial Method



Test Soil - SELECTION

Test Soil	Recipe
Modified Coagulated Blood Soil	100 ml fresh egg yolk, 0.1 ml heparin per 100 ml of sheep blood and 2 g dehydrated hog mucin mixed using a blender. Soil should be stored at 4°C to 8°C and brought to room temperature prior to coagulation. Pour the mixture into a bowl, add ~0.05 ml of protamine sulphate to each 5 ml of blood and mix well. Blood should be applied immediately and coagulate in approximately 10 min to 15 min.

- Demonstrated to be the most challenging soil
- Validated using Annex B of ISO 15883-5
- Contains both water soluble and non-water-soluble proteins (fibrin)

T. Kremer, A. Tortora, Y. Yeung and G. McDonnell, "Material Adhesion Comparison of Test Soils for Reusable Device Cleaning Efficacy," *Zentralsterilization*, vol. 29, no. 3, pp. 166-172, 2021.

T. Kremer, R. Bancroft, Z. Patel, M. Owen, G. McDonnell, "A Standardized Method for Evaluating Test Soils Used to Demonstrate Cleaning Efficacy," *Journal of Hospital Infection*, pp. 52-55, 2022.

MAIN ARTICLES | Comparison of Test Soils for Reusable Device Cleaning

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From the Field

Material Adhesion Comparison of Test Soils for Reusable Device Cleaning Efficacy

T.A. Kremer^{a,*}, A. Tortora, Y. Yeung, G. McDonnell Johnson & Johnson, Raritan, NJ, USA

Corresponding author:

TA Kremer BS

■ Abstract

tein, carbohydrate, and lipids associat-

Journal of Hospital Infection 126 (2022) 52–55

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevier.com/locate/jhin

A standardized method for evaluating test soils used to demonstrate cleaning efficacy

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Reusable device

Test soil

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Washer-disinfectant

SUMMARY

Background: Cleaning and associated validation requirements are essential for the safe use of reusable devices. In the past, test methods and associated endpoints for cleaning validations have varied worldwide. Recent international standards have updated the requirements to include cleaning endpoints and requirements for the use of test soils for demonstrating cleaning efficacy of washer-disinfectors.

Methods: A quantitative comparison of test soils used in cleaning efficacy studies was conducted using a new standardized test method as published in Annex B ISO 15883–5:2021. Test soils included Artificial Test Soil (ATS 2015), Blood Test Soil (BTS), Coagulated Blood, Defibrinated Blood Soil (DBLSO), Modified Coagulated Blood Soil, Two Component Blood Test Soil and the UK Test Soil (Edinburgh Soil).

Conclusion: All the test soils demonstrated acceptable performance in accordance with the standard.

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Introduction

The safe and effective use of reusable medical devices is an important consideration for infection prevention in healthcare facilities. Central to infection prevention is the standardization of requirements for the preparation of a new or clinically used healthcare product, referred to as device processing [1]. This includes the demonstration of cleaning effectiveness prior to terminal disinfection and/or sterilization. This is important to ensure expected microbiological endpoints, but also in the overall safe use of reusable devices, to include usability and biocompatibility expectations. The standardization of validation requirements in this area requires a collaborative effort and has resulted in performance requirements documented in

country-specific, regional, and international consensus standards, to include labelling (e.g., ISO 17664–1 [2]), cleaning and disinfection (e.g., ISO 15883–1 and –5), and sterilization (e.g., ISO 17665–1 for steam sterilization [3]). There has been greater focus in the last 10 years on the standardization of cleaning requirements, as they are essential to device safety and ensuring that terminal antimicrobial processes are reproducibly effective [4]. Standardization allows for both washer-disinfectant manufacturers and clinical users to validate, monitor for routine control, and re-validate the equipment to effectively measure performance [5].

Acceptable levels of device cleanliness have been established when using an automated washer-disinfectant under the ISO 15883 series of standards originally published in the 2000s [5]. These specified for the first time the cleanliness requirements internationally, based on individual country and regional specifications. Cleaning efficacy performance of washer-disinfectors and their associated loads were considered in

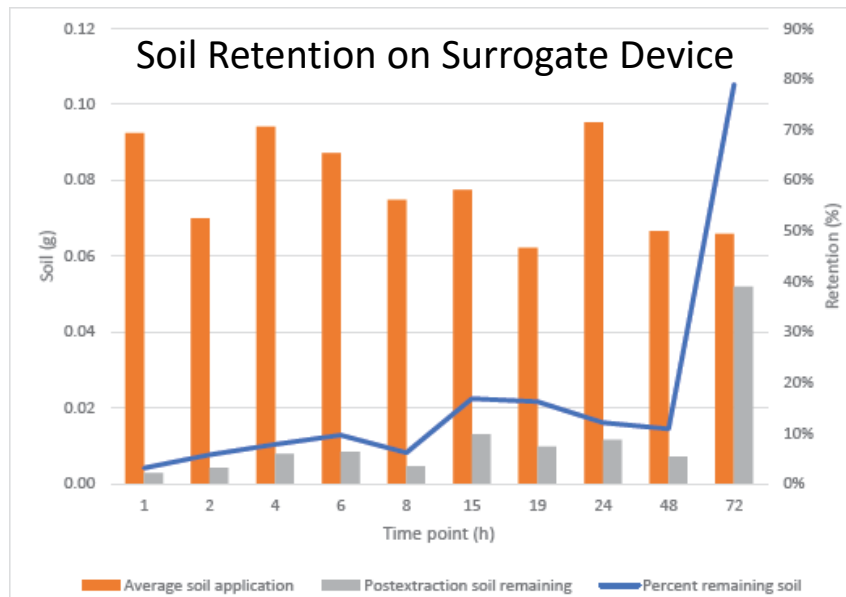
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Soil Dry Time - SELECTION

- Most Cleaning Validations are performed when soil is dry to the touch ~1hr
- Solubility is statistically similar from 1hr to 8hr ($p_{\text{value}}=0.066$)
- 72hr Soil Dry results in lowest soil solubility



Chemical Changes Over Time Associated with Protein Drying

Allan Kimble, Christopher Ratanski, and Terra A. Kremer

Effects of Time, Temperature, and Humidity on Soil Drying on Medical Devices

Terra A. Kremer, Christopher Carfaro, Sue Klack

Abstract

within the literature for how soil drying may Terra A. Kremer, BS, is the

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scientific reports

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OPEN Left to dry: unseen risks lurking on reusable medical devices

Terra A. Kremer^{1,2}, Gerald McDonnell¹, Jamie Fogarty¹, Cindy Rodriguez¹, Christopher H. Ratanski¹ & Neil J. Rowan^{2,3}

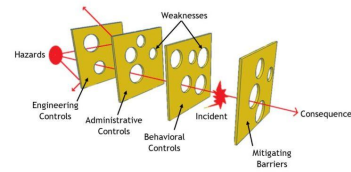
In this study, the intricate relationship between the complexity of reusable medical devices and their cleaning efficacy is explored to the point of cleaning failure. The results identified complex device features that require manual cleaning regardless of soil drying time, as well as device designs (i.e., features) that are appropriate for a fully automated cleaning process. All features were evaluated for cleaning performance under conditions where the soil was not allowed to dry, as well as replacing manual cleaning steps with non-manual methods, (i.e., substituting manual brushing and flushing with soaking and sonication). Findings revealed that soil drying on reusable medical devices can increase the cleaning challenge specific to the device feature. Devices engineered with visually accessible challenging geometries, as opposed to those with enclosed or concealed features, successfully met the requirements for soil drying times and semi-automated cleaning evaluations. However, device features with occluded geometries such as ball bearings, leaf springs, threaded screws, and mated surfaces proved more challenging to clean effectively. Since device features vary in their cleaning complexity, each device should be assessed based on their features. By recognizing the risks associated with soil drying on reusable devices, healthcare facilities can implement appropriate practices that streamline more effective cleaning processes that will inform patient safety along with paving the way for future automation.

Keywords Reusable medical devices, Device features, Cleaning regimes, Drying time, Patient safety

As the bright lights blur and consciousness fades during the countdown to surgery, most people are unlikely to be pondering the odds of an unsterilized instrument being used^{1,2}. The US FDA³ noted that "infections can occur through multiple situations including inadequate cleaning, disinfection and sterilization of reusable medical devices". For example, an estimated risk of infection transmitted by endoscopy is 1 per 1.8 million procedures, and infectious agents such as *Helicobacter pylori*, *Salmonella* spp., *Pseudomonas aeruginosa*, *Strongyloides stercoralis*, and hepatitis B and C viruses have been attributed to gastrointestinal endoscopy⁴. However, due to a number of factors such as inadequate or no surveillance and low occurrence or absence of clinical symptoms, the true risk of infection is difficult to estimate⁵. Hospital-Acquired Infections (HAIs) are infections that occur 48 h or more after a patient is admitted to a healthcare facility, which were neither present nor incubating at the time of admission¹. It was observed that on any given day, about one in 31 patients has at least one HAI⁶. Moreover, in the 2015 HAI Hospital Prevalence survey, the CDC reported that about 72,000 of the estimated 687,000 (or 10.48%) patients with HAIs died during their acute hospital stay in the US⁷.

The occurrence of HAIs has a direct medical cost impact on hospital finances and many researchers have performed analysis to understand the economic benefits of investing in an infection prevention and control

Extraction Method - ADDITIVE EXTRACTION



ANALYSIS

Additive Extraction = 1st Extraction w/ Water + 2nd Extraction w/ Alkaline SDS

- Soil contains both water-soluble and non-water-soluble proteins.
- Water alone is not sufficient
- Other analytes (e.g., TOC, ATP) are not compatible with pH 10 SDS
- Additive extraction results in total protein remaining

T. Kremer, A. Kimble and C. Ratanski, "Improving Protein Assay Methods to More Accurately Assess Medical Device Cleanliness," *Biomedical Instrumentation & Technology*, pp. 29-35, 2023.

Improving Protein Assay Methods to More Accurately Assess Medical Device Cleanliness

Terra A. Kremer, Allan Kimble, Christopher Ratanski

Abstract

Protein assays commonly used to evaluate reusable device cleanliness do not always accurately measure the low concentrations of protein that are expected on reusable medical devices after processing. Methods often are adapted to provide an estimation of protein concentration; however, sensitivity issues in the portion of standard curves at the acceptance criteria of 6.4 µg/cm² protein have been reported. Using analytical validation criteria, method improvements for the micro-bicinchoninic acid assay for protein residuals are demonstrated by incorporating a standard addition method, increasing the well volume, and changing the working reagent ratio. These improvements increased method sensitivity and accuracy in the reliable detection of protein levels for device cleaning validations.

How clean is clean? This is a common question when evaluating the cleaning efficacy for medical devices intended to be processed within a healthcare facility. Cleaning instructions are validated by the manufacturer to ensure cleaning efficacy under the most challenging conditions. Cleaning validation requirements have evolved during the previous 20 years, transitioning from microbial reduction studies to quantitative analytical chemistry methods, which have been adapted to evaluate unknown concentrations of residual analytes. Protein is the most prevalent analyte found in clinical soil and, if not cleaned to the appropriate degree, can cause negative adverse reactions among patients. Therefore, protein often is included as the primary analyte in cleaning validations.¹

The three most common protein assays used within cleaning validations are the Bradford assay, ortho-phthalaldehyde assay (OPA), and bicinchoninic acid assay (BCA).² The biochemical reaction within these assays uses ultraviolet-visible (UV-VIS) spectrophotometry as the detection method, but this method is sensitive to interference from

processing chemicals (e.g., cleaning agents)³ or device materials.⁴ For example, in the study by Wehrl et al.,⁵ two protein methods were used to challenge the cleaning efficacy of a robotic instrument. Although both methods provided comparable results, interfering compounds eluting from the tungsten cables resulted in false-positive results protein results. On the other hand, in a study by Hubert et al.⁶ comparing the OPA and BCA protein assays for cleaning agent interference, OPA was found to be more susceptible to interference from cleaning detergents.

Another limitation of these protein assays is the sensitivity of the spectrophotometer. To establish the lowest point of instrument sensitivity, the test method must be validated. Validation requirements for analytical methods supporting similar assays include the following elements⁴:

- Linearity/range. The linearity is assessed by preparing protein standards in a concentration curve that spans the range of expected protein concentration. This process should include method acceptance criteria. The linearity, measured by the R² value of the line, should be greater than 0.9900. For range, the protein residual acceptance criteria of at least 6.4 µg/cm² should be in the portion of the curve that demonstrates the best accuracy and precision, with the upper and lower points of the curve being both accurate and precise.⁷
- Accuracy. Accuracy is expressed as the closeness of agreement between the reference value and calculated value. It is determined by comparing the calculated (actual) concentration from the calibration curve with that of the nominal (theoretical) concentration of the protein standard, using the following equation:

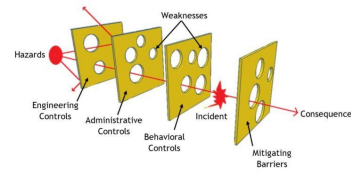
$$\text{Accuracy} = 100 - \left(\frac{[\text{Nominal}] - [\text{Calculated}]}{[\text{Nominal}]} \right) \times 100$$

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Device Feature Approach Validation - CONCLUSIONS



- Most conservative validation approach
- Most challenging feature is representative of a whole device challenge
- Cleaning validation data is normally distributed

Validation of the Device Feature Approach for Reusable Medical Device Cleaning Evaluations

Terra A. Kremer, Jeff Felgar, Neil Rowan, and Gerald McDonnell

Abstract

The identification of worst-case device (or device set) features has been a well-established validation approach in many areas (e.g., terminal sterilization) for determining process effectiveness and requirements, including for reusable medical devices. A device feature approach for cleaning validations has many advantages, representing a more conservative approach compared with the alternative compendial method of testing the entirety of the device. By focusing on the device feature(s), the most challenging validation variables can be isolated to and studied at the most difficult-to-clean feature(s). The device feature approach can be used to develop a design feature database that can be used to design and validate device cleanliness. It can also be used to commensurately develop a quantitative cleaning classification system that will augment and innovate the effectiveness of the Spaulding classification for microbial risk reduction. The current study investigated this validation approach to verify the efficacy of device cleaning procedures and mitigate patient risk. This feature categorization approach will help to close the existing patient safety gap at the important interface between device manufacturers and healthcare facilities for the effective and reliable processing of reusable medical devices. A total of 56,000 flushes of the device features were conducted, highlighting the rigor associated with the validation. Generating information from design features as a critical control point for cleaning and microbiological quality will inform future digital transformation of the medical device industry and healthcare delivery, including automation.

This study sought to validate a device feature approach to be used in cleaning validations for reusable medical devices.

Reusable medical devices are required to be cleaned, disinfected, and/or sterilized between patient exposure and can include those used directly on a patient during surgery or items that have minimal patient

contact (e.g., blood pressure cuffs) or contact surfaces indirectly (e.g., monitor or piece of equipment).¹ Medical devices that are not properly cleaned have demonstrated an increased challenge for disinfection/sterilization and can lead to transmission of infectious disease.²

To comply with international standards, manufacturers of medical devices for which processing is required prior to patient use must provide validated processing instructions to the customer. These instructions for use (IFUs) are used to process medical devices in a healthcare facility so they are safe and functional for subsequent patient use.³ Manufacturers validate cleaning IFUs by developing a test system that challenges each step of the cleaning process with worst-case conditions. The process steps for the cleaning IFUs, which must be defined, may include initial treatment at point of use (pretreatment), preparation before cleaning (e.g., disassembly), manual and/or automated cleaning, rinsing, drying, and visual inspection.¹

During the cleaning validation, the following test conditions are selected to mitigate human factors that may affect the efficacy of the cleaning process within a healthcare setting:⁴

- Device conditioning (i.e., simulated use): Repetition of processing prior to validation to place the device in a used state and account for soil accumulation.³
- Soil formulation: The formulation of the test soil (i.e., substitute for a contaminant found on a device after clinical use⁵) should be representative of the clinical soil expected during use and validated.^{4,5}
- Soil volume: The soil volume must be sufficient to adequately challenge the cleaning of the device as it would be used in a clinical setting and be representative of the clinically relevant analyte concentrations.¹

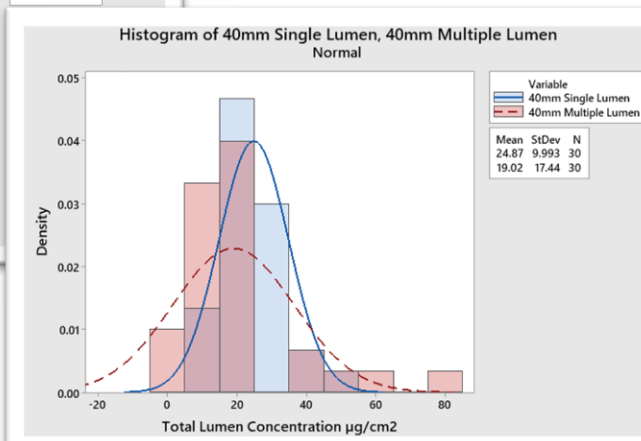
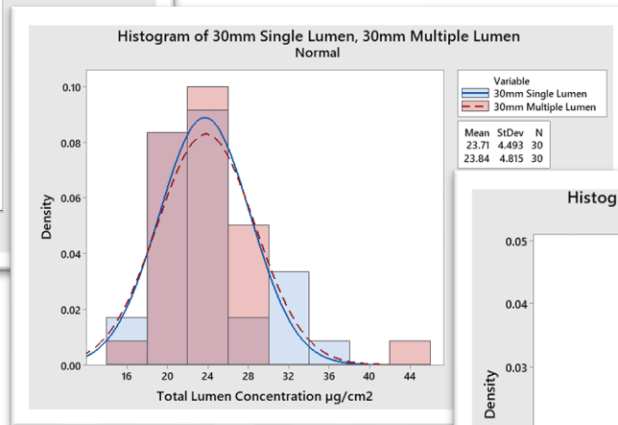
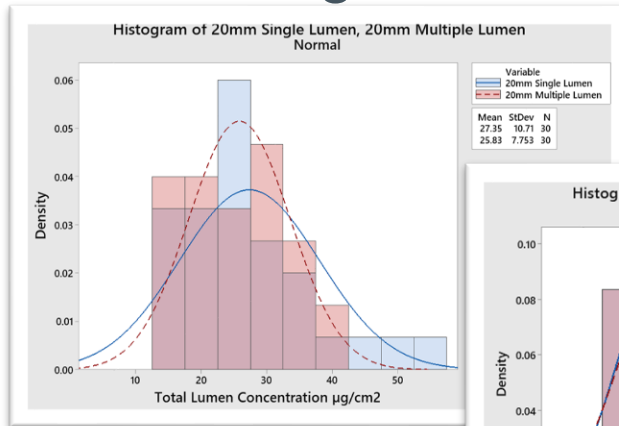
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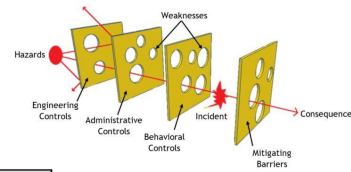
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23 Features – Challenge to Point of Failure

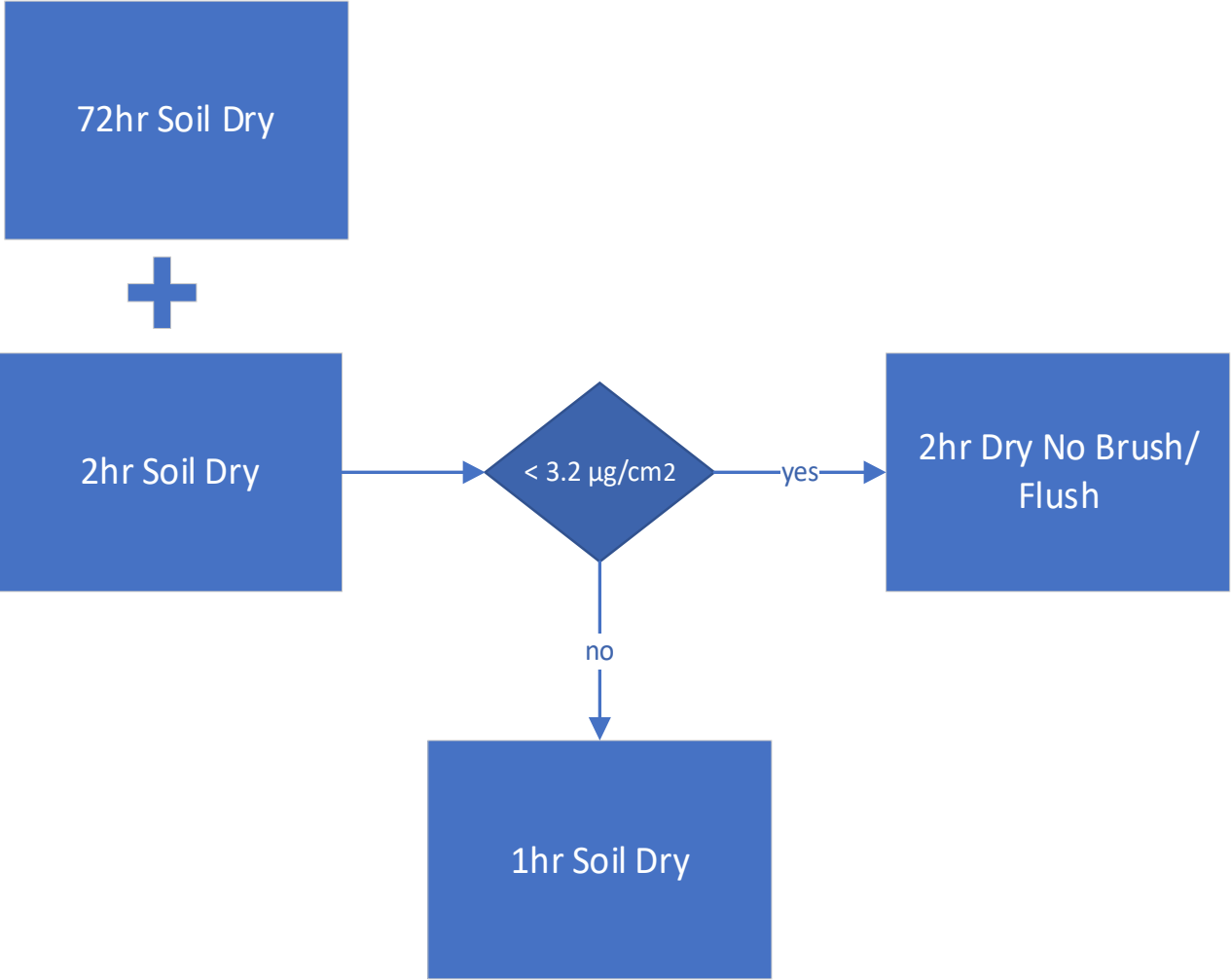
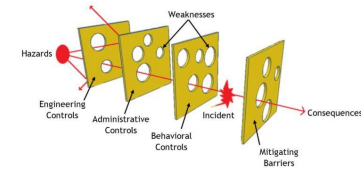


Feature Name	Most Challenging Geometry	Coupon Image
Rough Surface	Medium Knurl (21 Pitch)	
Through Slot	Depth = 30.0 mm Width = 1.0 mm	
Blind Slot	Depth = 24.9 mm Width = 1.0 mm	
Smooth Through Lumen	Length = 277.2mm Diameter = 1.2 mm	
Smooth Blind Lumen	Depth = 6.0 mm Diameter = 1.0 mm	
Sliding Shaft - Short	Sliding Length = 25.4 mm Minimal Clearance = 0.02 mm (diametrical clearance of 0.04mm)	
Mated Surfaces – Small Clearance	Minimal Clearance = 0.10 mm	

Feature Name	Most Challenging Geometry	Coupon Image
Threads – Blind Hole	Internal thread – Minor diameter - 2.599 mm Thread Depth – 25.4 mm Hole Depth – 35.0 mm	
Screws- Threaded Rod/Threaded Thru Hole	Minor Diameter: 6.912 mm Thread Length – 108.32 mm Mated Length – 25.4 mm	
Screws- Threaded Rod/Threaded Blind Hole	Minor diameter - 6.912 mm Thread Length – 108.32 mm Thread Depth – 25.4 mm Hole Depth – 35.0 mm	
Sliding Shafts - Long	Sliding Length = 127.0 mm Minimal Clearance = 0.0381 mm (diametrical clearance of 0.0762mm)	
Ball Detent/Ball Bearing	Ball Diameter = ≥ 1.1 mm	
Button w/ Spring	Deep internal springs	
Buttons - Exposed Springs	Exposed Springs	
Spring - Internal	Internal Springs	

Feature Name	Most Challenging Geometry	Coupon Image
Leaf Springs	The challenging geometry is observed among all leaf springs.	
Ball Seal Springs	External Ball Seal Spring	
O-rings, External O-ring	External O-ring	
O-rings, Internal O-ring	Internal O-ring	
Snap Rings	External Snap Ring	
Captured Screw	Captured screw held in place with an external snap ring	
Hinges, Joints, Pivot points	Rongeur Hinge	
Mated Surfaces	Zero Clearance	

Challenge to Point of Failure - 23 FEATURE TEST PLAN



23 Features

Feature Name	Most Challenging Geometry	Coupon Image
Rough Surface	Medium Knot (21 Pitch)	
Through Slot	Depth = 30.0 mm Width = 1.0 mm	
Blind Slot	Depth = 24.9 mm Width = 1.0 mm	
Smooth Through Lens	Length = 277.2mm Diameter = 1.2 mm	
Smooth Blind Lens	Depth = 6.0 mm Diameter = 1.0 mm	
Sliding Shaft - Short	Sliding Length = 25.4 mm Maximal Clearance = 0.02 mm (diametrical clearance of 0.04mm)	
Mated Surfaces - Small Clearance	Maximal Clearance = 0.10 mm	
Threads - Blind Hole	Internal thread - Minor diameter = 1.599 mm Thread Depth = 25.4 mm Hole Depth = 35.0 mm	
Screws - Threaded Rod Threaded Thru Hole	Minor Diameter = 6.912 mm Thread Length = 108.32 mm Thread Depth = 25.4 mm Hole Depth = 35.0 mm	
Screws - Threaded Rod Threaded Blind Hole	Minor diameter = 6.912 mm Thread Length = 108.32 mm Thread Depth = 25.4 mm Hole Depth = 35.0 mm	
Sliding Shafts - Long	Sliding Length = 127.0 mm Maximal Clearance = 0.0381 mm (diametrical clearance of 0.0762mm)	
Ball Detent Ball Bearing	Ball Diameter = 21.1 mm	
Buttons w/ Spring	Deep internal springs	
Buttons - Exposed Springs	Exposed Springs	
Spring - Internal	Internal Springs	
Leaf Springs	The challenging geometry is observed among all leaf springs	
Ball Seat Springs	External Ball Seat Spring	
O-rings, External O-ring	External O-ring	
O-rings, Internal O-ring	Internal O-ring	
Isap Rings	External Isap Ring	
Captured Screw	Captured screw held in place with an external snap ring	
Hinges, Joints, Pivot points	Longest Hinge	
Mated Surfaces	Zero Clearance	

03

Apply risk-based criteria to point-of-use treatment, wet transport, and cleaning validation.





Risk Assessment - QUALITATIVE

1. Subjectivity:

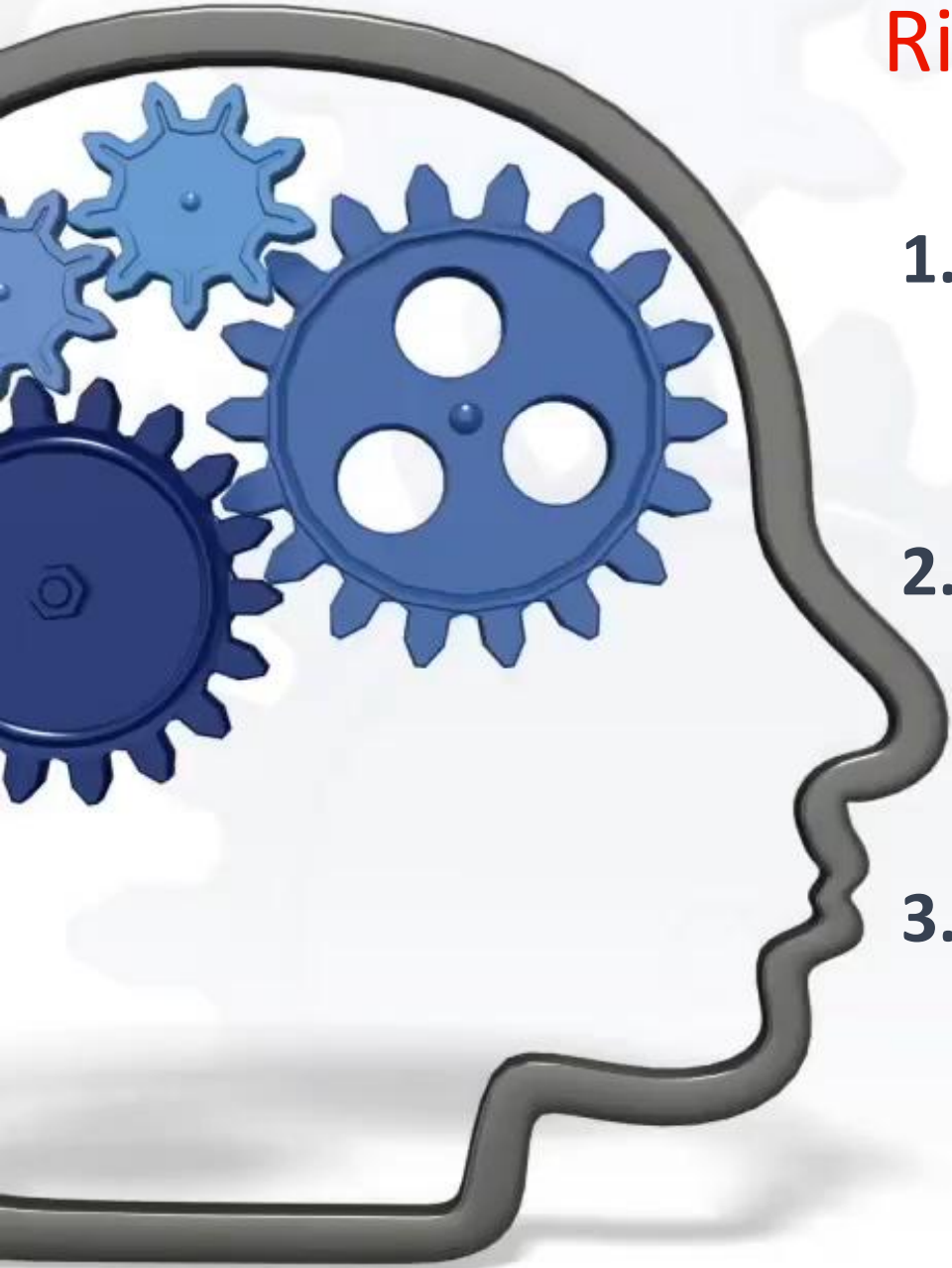
The qualitative approach is more subjective, and different experts may perceive risks differently, leading to potential inconsistencies.

2. Lack of Precision:

Qualitative assessments may lack precision in estimating the magnitude and likelihood of risks. This can make it challenging to prioritize and allocate resources effectively.

3. Limited Quantitative Data:

It may not fully leverage available quantitative data, potentially missing out on valuable insights that can be obtained through numerical analysis.



Risk Assessment - QUANTITATIVE



1. Precision:

Provides a more precise and quantitative measure of risks, allowing for better prioritization and allocation of resources based on numerical data.

2. Objective Analysis:

Quantitative assessments are generally more objective and less dependent on individual judgments, reducing the impact of biases.

3. Data-Driven Decision-Making:

Enables data-driven decision-making by incorporating numerical data, which can be especially beneficial in complex situations involving multiple variables.

4. Comparative Analysis

Allows for the comparison of risks across different scenarios, facilitating a more comprehensive understanding of the overall risk landscape.

Quantitative Cleaning Classification - DEVELOPMENT

- Collaboration between Johnson & Johnson & The Technological University of the Shannon (TUS)
- <200 Cleaning Validations
- \$2.4M Endowment from J&J
- Open Access Supporting Publications
- Open Access PhD Dissertation
 - Literature Review
 - Materials & Methods
 - Results
 - Justification of Classification



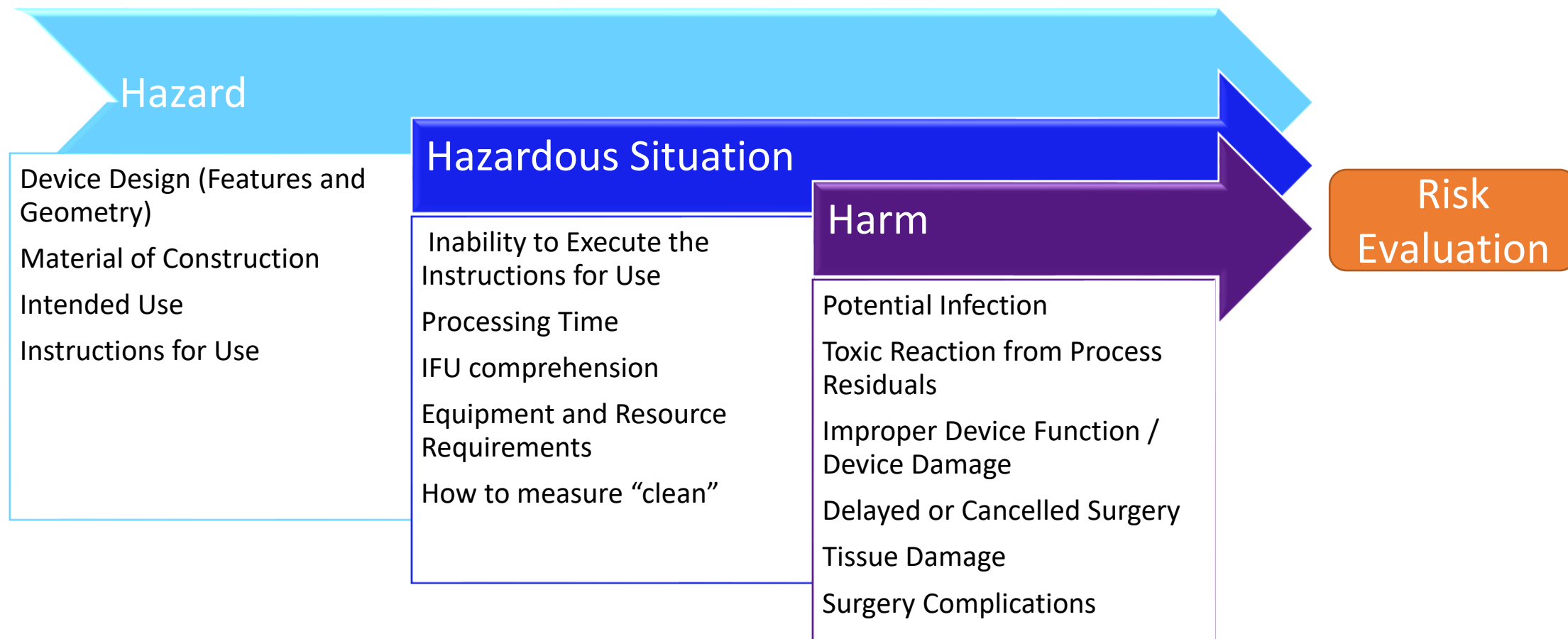
Summary

A central tenet in infection prevention is the application of the Spaulding classification system for the safe use of medical devices. Initially defined in the 1950's, this system defines types of devices and surfaces as being critical, semi-critical, and non-critical depending on how it will be used on a patient. Different levels of antimicrobial treatment, defined as various levels of disinfection or sterilization, are deemed appropriate to reduce patient risks of infection. However, a focus on microbial inactivation is insufficient to address this concern that has been particularly highlighted in routine healthcare facility practices emphasizing the underappreciated importance of cleaning and achieving acceptable cleanliness levels. A deeper understanding of microbiology has evolved since the 1950s that has led to a re-evaluation of the Spaulding classification along with a commensurate emphasis on achieving appropriate cleaning. Albeit underappreciated, cleaning has always been important as the presence of residual materials on surfaces can interfere with the efficacy of the antimicrobial process to inactivate microorganisms, as well as other risks to patients including device damage, malfunction, and biocompatibility concerns. Unfortunately, this continues to be relevant as attested by reports in the literature on the occurrence of device-related infections and outbreaks due to failures in processing expectations. This reflects in part increasing sophistication in device features and reuse, along with commensurate manufacturer's instructions for use (IFU). Consequently, this constitutes the first description and recommendation of a new cleaning classification system to complement use of the traditional Spaulding definitions to help address these modern-day technical and patient-risk challenges. This quantitative risk-based classification system highlights the challenge of efficient cleaning based on the complexity of device features present as an isolated variable impacting cleaning. This cleaning classification can be used in combination with the Spaulding Classification to improve communication of cleaning risk of a reusable medical device between manufacturers and health care facilities and improve established cleaning practices. This new cleaning classification system will also inform future creation, design-thinking and commensurate innovations for the sustainable safe reuse of important medical devices.

[Source: T. Kremer, N. Rowan and G. McDonnell, "A proposed cleaning classification system for reusable medical devices to complement the Spaulding Classification," Journal of Hospital Infection, 2023]



ISO 14971 - RISK RUBRIC



Compounding - RISK RUBRIC



	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	MEDIUM	MEDIUM	HIGH	HIGH	HIGH
Probable	LOW	MEDIUM	MEDIUM	HIGH	HIGH
Occasional	LOW	LOW	MEDIUM	MEDIUM	HIGH
Remote	LOW	LOW	LOW	MEDIUM	HIGH
Improbable	LOW	LOW	LOW	LOW	MEDIUM



Device Feature - Risk Value

- Performed using additive extraction (2nd extraction with pH 10 SDS)
- Minimum N=5 (passing results were run in duplicate n=10)
- T-test performed to calculate 99% confidence interval of the data set
- High value of confidence interval used as worst case to assign risk value

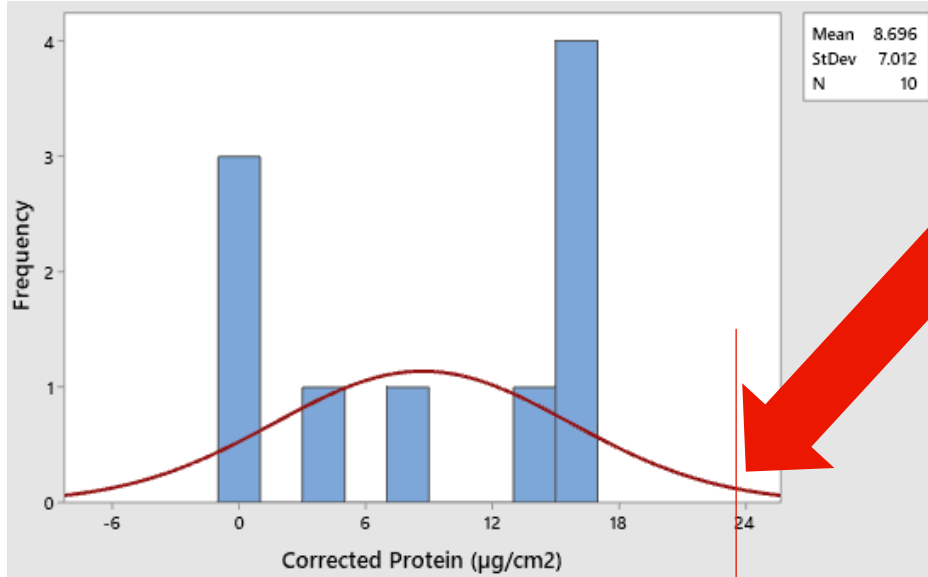


Table A.4 — Risk Evaluation for Cleaning Efficacy (except No Brush/Flush)

Protein Residual	Risk Value
<3µg/cm ²	1
3 µg/cm ² – 6.4 µg/cm ²	2
>6.4 µg/cm ²	3

Table A.6 — Risk evaluation for cleaning efficacy for no brush/flush

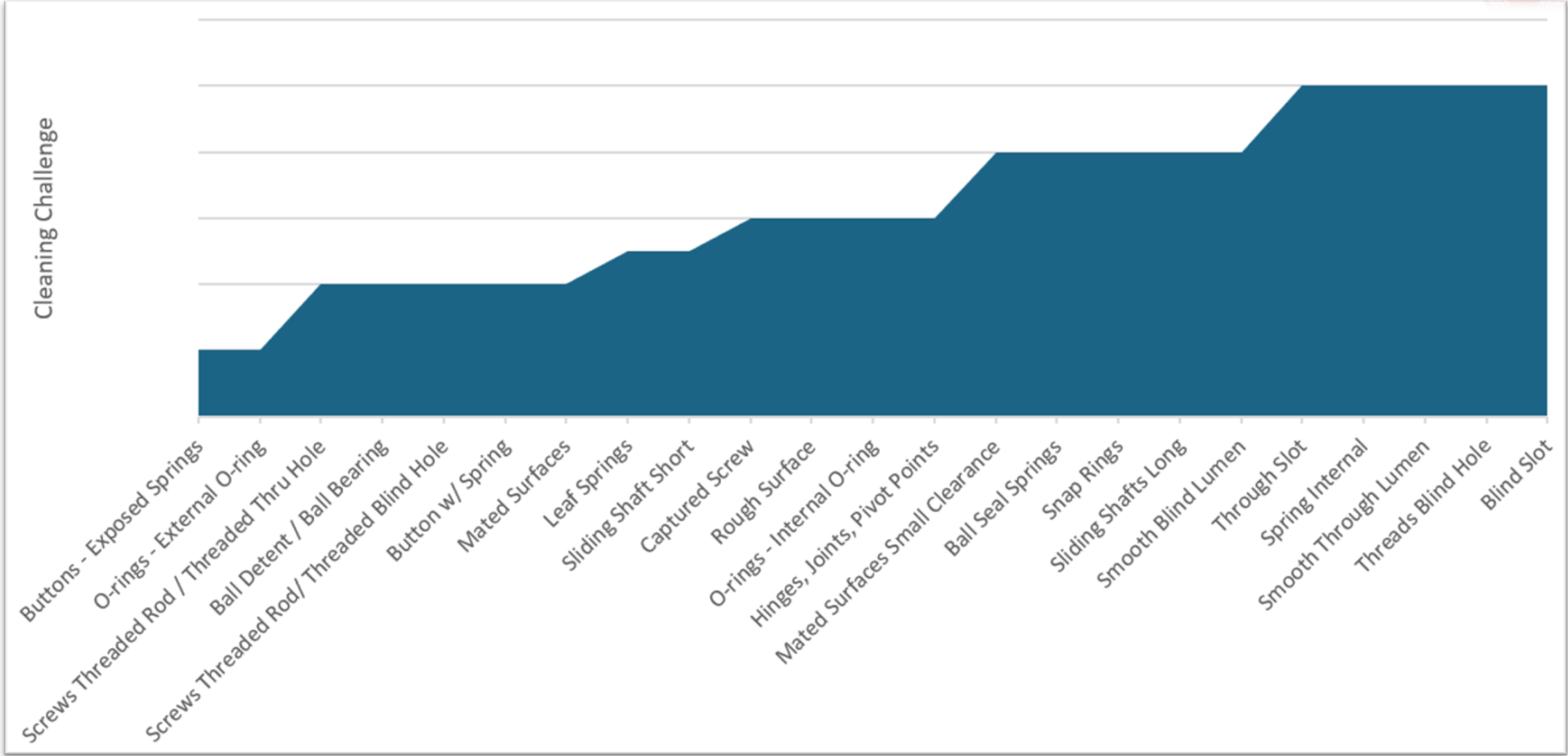
Protein residual	Risk value
<3µg/cm ²	-2
3 µg/cm ² – 6.4 µg/cm ²	-1
>6.4 µg/cm ²	0



Device Feature Risk Calculation - EXAMPLE

Device Feature	72hr Dry Water Only Extraction Efficiency 99% CI (low)	Extraction Efficiency Categorization	Requires Flushes	Cleaning 72hr Dry - Water Protein 99% CI (high)	72hr Water Cleaning Categorization	Cleaning 72hr Dry - Additive Protein 99% CI (high)	72hr Additive Cleaning Categorization	Cleaning 2hr Dry Water- Protein 99% CI (high)	2hr Cleaning - Water Categorization	Cleaning 2hr Dry Additive- Protein 99% CI (high)	2hr Cleaning - Additive Categorization	Cleaning 1hr Dry - Water Protein 99% CI (high)	1hr- Water Cleaning Categorization	Cleaning 1hr Dry - Additive Protein 99% CI (high)	1hr- Additive Cleaning Categorization	Cleaning No Brush/Flush - Water Protein 99% CI (high)	No Brush/Flush - Water Cleaning Categorization	Cleaning No Brush/Flush - Additive Protein 99% CI (high)	No Brush/Flush - Additive Cleaning Categorization	Total Risk Categorization
Ball Detent / Ball Bearing	67.310%	4	5	40.710	3	33.300	3	1.171	1	3.139	2	NA	0	NA	0	4.637	-1	25.74	0	17
Ball Seal Springs	55.170%	5	0	15.010	3	15.340	3	0.379	1	4.113	2	NA	0	NA	0	0.05533	-2	6.516	0	12
Buttons - Exposed Springs	45.750%	6	0	0.885	1	2.935	1	0.058	1	4.881	2	NA	0	NA	0	0.058	-2	4.231	-1	8
Hinges, Joints, Pivot Points	79.900%	3	0	112.400	3	202.700	3	5.565	2	8.530	3	2.946	1	7.820	3	NA	0	NA	0	18

Device Feature Cleaning Challenge - RANKING



Ranking of Device Feature Performance



Device Feature	Total Risk Categorization
Ball Detent / Ball Bearing	17
Ball Seal Springs	12
Blind Slot	25
Button w/ Spring	15
Buttons - Exposed Springs	8
Captured Screw	12
Hinges, Joints, Pivot Points	18
Leaf Springs	9
Mated Surfaces	15
Mated Surfaces Small Clearance	8
O-rings - External O-ring	4
O-rings - Internal O-ring	18

Device Feature	Total Risk Categorization
Rough Surface	8
Screws Threaded Rod / Threaded Thru Hole	5
Screws Threaded Rod/ Threaded Blind Hole	16
Sliding Shaft Short	12
Sliding Shafts Long	15
Smooth Blind Lumen	20
Smooth Through Lumen	24
Snap Rings	12
Spring Internal	25
Threads Blind Hole	24
Through Slot	25

04

Describe mitigation strategies: timely cleaning, wet transport, better tray design, and audit metrics.



Microbiological Control Level (MQL) – 4 ELEMENTS



1. Use Quality Risk Management (QRM) to minimize the probability of microbiological contamination
2. Ensure the product's Critical Quality Attributes (CQA) are achieved
3. Quantify the State of Control by measuring the microbiological risk associated with independent steps of the manufacturing process
4. Demonstrate reduced microbiological risk to the patient through process control

Slide courtesy of Stephen Langille, PhD
Senior Microbiology Consultant - ValSource

Kremer's Cleaning Classification - MITIGATING RISK

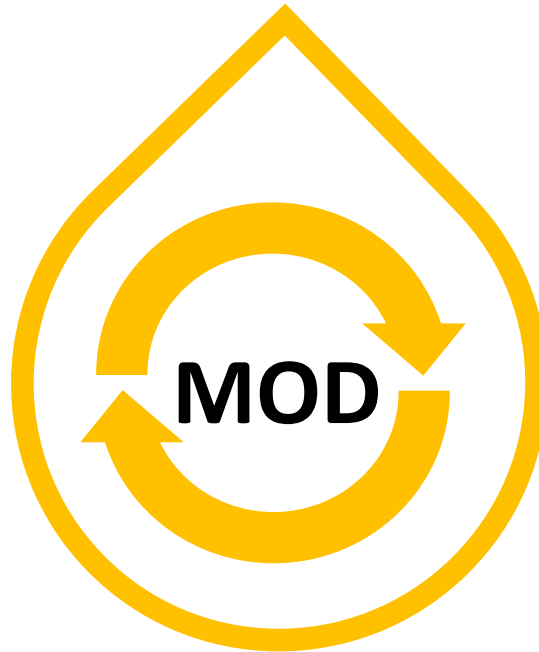


Minimal



Low risk: all surfaces exposed for cleaning

Moderate



Intermediate risk: device features requiring specific intervention (e.g., lumens and mated surfaces)

Maximal

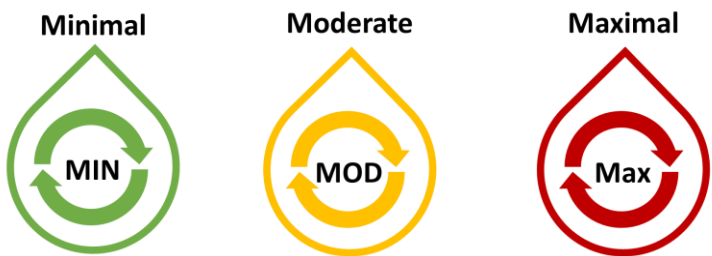


High risk: complex features with high risk of soil retention

Cleaning in Device Processing - RISK CLASSIFICATION



- 1. Risk value assigned to each question.
- 2. Sum of risk values deliver total risk value.



Classification Category	Category Description	Total Risk Value
Minimal	Low risk reusable medical devices where all features are exposed without specific intervention for cleaning.	<20
Moderate	Accessible device features that require specific intervention (e.g., brushing or flow through lumens, mated surfaces requiring disassembly or opening/closing to ensure access).	20 - 39
Maximal	Complex device features with a high probability of soil accumulation with a medical device.	>40

Question
What is the most challenging to clean medical device feature that is exposed to soil?
Is the material in the most challenging feature absorbing (e.g., Stainless steel, Nitinol, Aluminum, Titanium) or repelling (e.g., silicone, PEEK, Delrin)?
What contact does the feature have with the patient?
Does the device come in contact with high-risk tissue (e.g., the brain, spinal cord and eye)?
How is the soil exposed to the most challenging feature?
Will the soil be exposed to heat (e.g., cauterization)?
Will the soil be exposed to chemical during use (e.g., saline, chlorine, iodine, simethicone)?
Does the device have a lumen length greater than 270mm?
Does the device contain a housing that cannot be removed or accessed by fluid without flushing for cleaning where soil can migrate?
Is the device powered (Powered instruments, which can entrap debris that can later be aerosolized during a surgical procedure)?
Does the device have internal movable parts such as multiple cables (e.g., robotic instruments, elevator shaft) that may have exposure to soil?
Is the device a microsurgical instrument?
Can the device be fully submerged? (Facilitation of water exposure to residual soil)
Do the cleaning instructions as part of the IFU contain instructions that prevent soil from drying on the device while awaiting full decontamination processes?

Compounding Hazards - DESIGN



Risk Question	Answer	Risk Value	Risk for Likelihood of Occurrence
Is the material in the most challenging feature absorbing (e.g., stainless steel, nitinol, aluminium, titanium) or repelling (e.g., silicone, peek, Delrin)?	Absorbing	1	Remote/Improbable - Serious/Critical
	Repelling	0	Remote/Improbable - Minor/Serious



Risk Question	Answer	Value	Risk for Likelihood of Occurrence
Does the device have a lumen greater in length than 270mm?	Yes	10	Frequent - Serious/Critical
	No	0	Remote/Improbable - Negligible/Minor



Risk Question	Answer	Value	Risk for Likelihood of Occurrence
Does the device have internal movable parts such as multiple cables (e.g., robotic instruments, elevator shaft, interior lumen) that may have exposure to soil?	Yes	10	Frequent - Serious/Critical
	No	0	Remote/Improbable - Negligible/Minor

Risk Question	Answer	Value	Risk for Likelihood of Occurrence
Does the device contain a housing that cannot be removed or accessed by fluid without flushing for cleaning where soil can migrate?	Yes	10	Frequent - Serious/Critical
	No	0	Remote/Improbable - Negligible/Minor

Compounding Hazards - CONTAMINATION



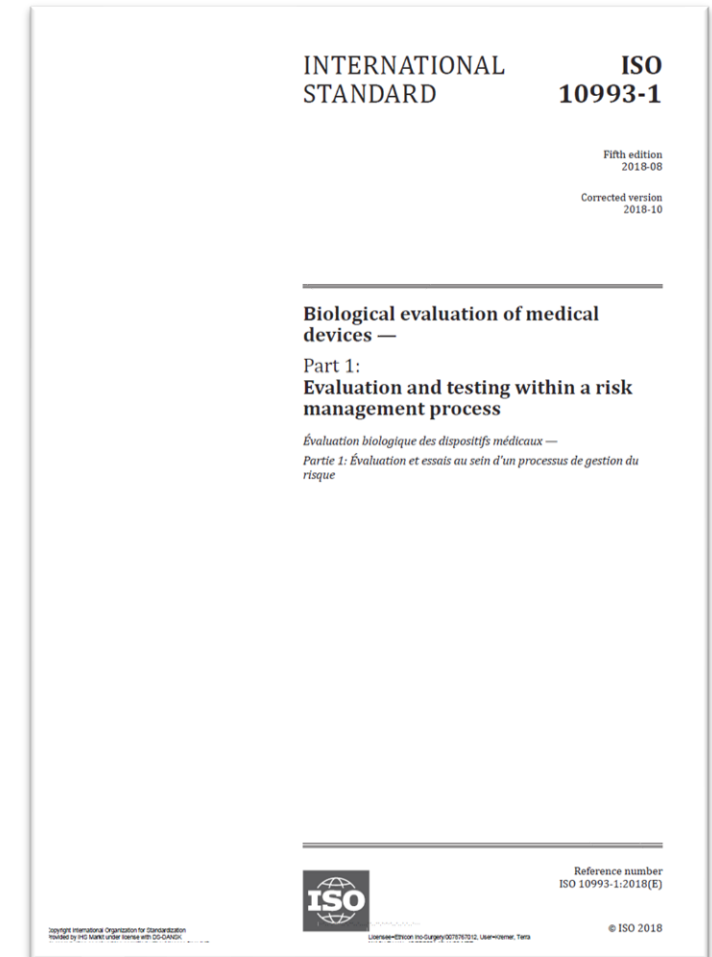
Risk Question	Answer	Value	Risk for Likelihood of Occurrence
How is the soil exposed to the most challenging feature?	Handled with Soiled Gloves	1	Remote/Improbable - Minor/Serious
	Partially Soiled	2	Remote/Improbable - Serious/Critical
	Vacuum	2	Remote/Improbable - Serious/Critical
	Partial Submersion	3	Occasional/Remote - Serious/Critical
	Flushing	4	Probable/Occasional - Minor/Serious
	Full Immersion	5	Frequent/Probable - Minor/Serious



Compounding Hazards – PATIENT USE



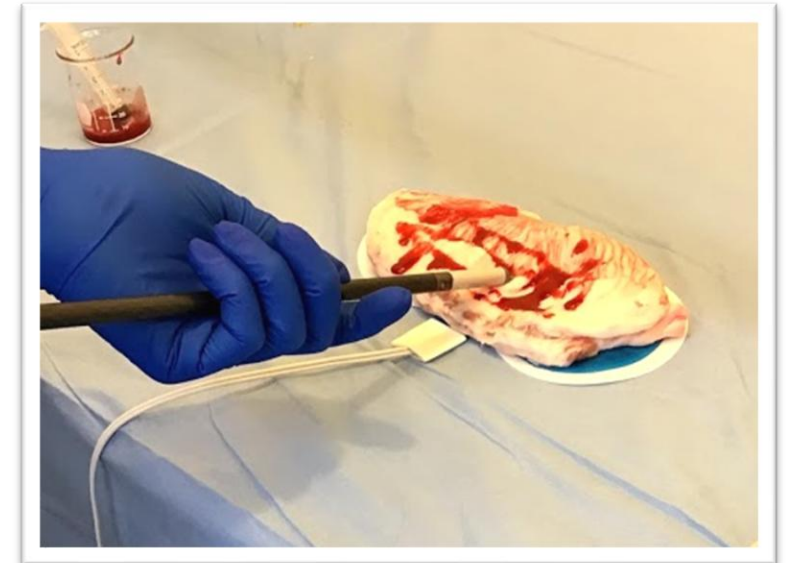
Risk Question	Answer	Risk Value	Risk for Likelihood of Occurrence
What contact does the feature have with the patient?	Non-patient Contacting	0	Remote/Improbable – Minor/Serious
	Intact Skin	0	Remote/Improbable – Serious/Critical
	Mucosal Membranes	1	Occasional/Remote – Minor/Serious
	Breached or compromised surfaces	2	Occasional/Remote – Serious/Critical
	Blood path, indirect	3	Probable/Occasional – Minor/Serious
	Tissue/Bone/Dentin	4	Probable/Occasional – Serious/Critical
	Circulating Blood	5	Frequent/Probable – Minor/Serious



Compounding Hazards – CLINICAL USE



Risk Question	Answer	Value	Risk for Likelihood of Occurrence
Will the soil be exposed to heat (e.g., cauterization)?	Yes	1	Remote/Improbable – Serious/Critical
	No	0	Remote/Improbable – Negligible/Minor
Will the soil be exposed to chemical during use (e.g., saline, chlorine, iodine, simethicone)?	Yes	1	Remote/Improbable – Serious/Critical
	No	0	Remote/Improbable – Negligible/Minor



Compounding Hazards – CLINICAL USE



Risk Question	Answer	Value	Risk for Likelihood of Occurrence
Does the device come in contact with high-risk tissue such as the brain, spinal cord, and eye?	Yes	1	Remote/Improbable – Serious/Critical
	No	0	Remote/Improbable – Minor/Serious

Risk Question	Answer	Value	Risk for Likelihood of Occurrence
Is the device powered (Powered instruments, which can entrap debris that can later be aerosolized during a surgical procedure)?	Yes	5	Frequent/Probable – Minor/Serious
	No	0	Remote/Improbable – Negligible/Minor

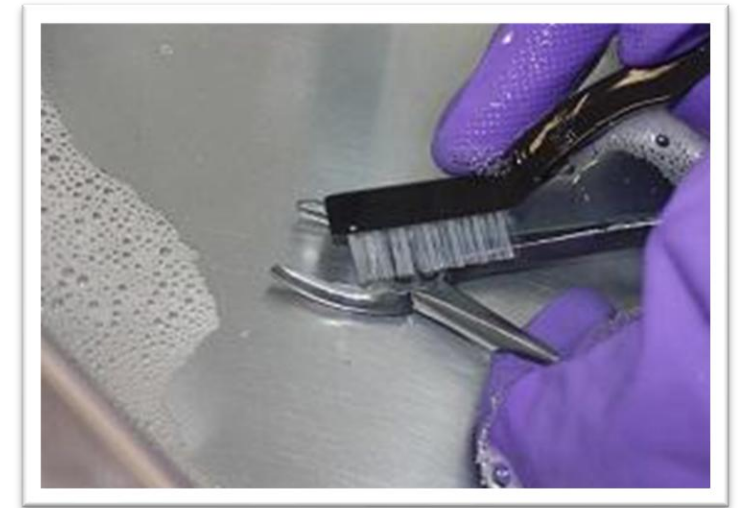


Risk Question	Answer	Value	Risk for Likelihood of Occurrence
Is the device a microsurgical instrument?	Yes	10	Frequent – Serious/Critical
	No	0	Remote/Improbable – Negligible/Minor

Compounding Hazards - CLEANING



Risk Question	Answer	Value	Risk for Likelihood of Occurrence
Can the device be fully submerged (Facilitation of water exposure to residual soil)?	Yes	0	Remote/Improbable - Negligible/Minor
	No	5	Frequent/Probable - Minor/Serious

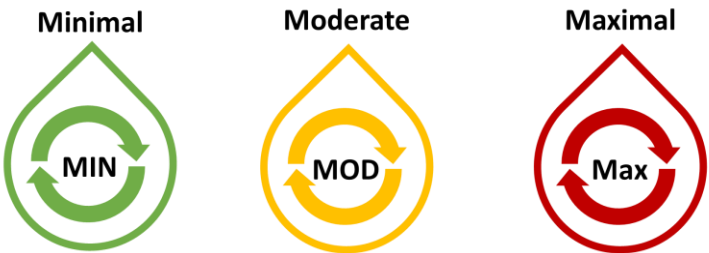


Risk Question	Answer	Value	Risk for Likelihood of Occurrence
Do the cleaning instructions as part of the IFU contain instruction that prevent soil from drying on the device while awaiting full decontamination processes?	Yes	-5	Remote/Improbable - Negligible/Minor
	No	0	Frequent/Probable - Minor/Serious

Cleaning in Device Processing - RISK CLASSIFICATION



- 1. Risk value assigned to each question.
- 2. Sum of risk values deliver total risk value.



Classification Category	Category Description	Total Risk Value
Minimal	Low risk reusable medical devices where all features are exposed without specific intervention for cleaning.	<20
Moderate	Accessible device features that require specific intervention (e.g., brushing or flow through lumens, mated surfaces requiring disassembly or opening/closing to ensure access).	20 - 39
Maximal	Complex device features with a high probability of soil accumulation with a medical device.	>40

Question
What is the most challenging to clean medical device feature that is exposed to soil?
Is the material in the most challenging feature absorbing (e.g., Stainless steel, Nitinol, Aluminum, Titanium) or repelling (e.g., silicone, PEEK, Delrin)?
What contact does the feature have with the patient?
Does the device come in contact with high-risk tissue (e.g., the brain, spinal cord and eye)?
How is the soil exposed to the most challenging feature?
Will the soil be exposed to heat (e.g., cauterization)?
Will the soil be exposed to chemical during use (e.g., saline, chlorine, iodine, simethicone)?
Does the device have a lumen length greater than 270mm?
Does the device contain a housing that cannot be removed or accessed by fluid without flushing for cleaning where soil can migrate?
Is the device powered (Powered instruments, which can entrap debris that can later be aerosolized during a surgical procedure)?
Does the device have internal movable parts such as multiple cables (e.g., robotic instruments, elevator shaft) that may have exposure to soil?
Is the device a microsurgical instrument?
Can the device be fully submerged? (Facilitation of water exposure to residual soil)
Do the cleaning instructions as part of the IFU contain instructions that prevent soil from drying on the device while awaiting full decontamination processes?

Classification Example – SCALPEL



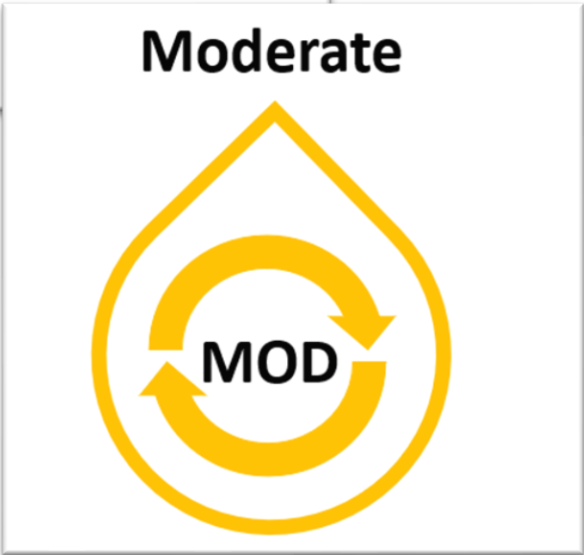
Device:	Scalpel		
#	Question	Answer	Risk Value
1	What is the most challenging to clean feature that is exposed to soil?	Rough Surface	8
2	Is the material in the most challenging feature adsorbing (e.g., Stainless steel, Nitinol, Aluminum, Titanium) or repelling (e.g., silicone, PEEK, Delrin)?	adsorbing	1
3	What contact does the feature have with the patient?	Circulating Blood	5
4	Does the device come in contact with high-risk tissue such as the brain, spinal cord and eye?	Yes	1
5	How is the soil exposed to the most challenging feature?	Partial Submersion	3
6	Will the soil be exposed to heat (e.g., cauterization)?	No	0
7	Will the soil be exposed to chemicals during use (e.g., saline, chlorine, iodine, simethicone)?	No	0
8	Does the device have a lumen greater in length than 270mm?	No	0
9	Does the device contain a housing that cannot be removed or accessed by fluid without flushing for cleaning where soil can migrate?	No	0
10	Is the device powered (Powered instruments, which can entrap debris that can later be aerosolized during a surgical procedure)?	No	0
11	Does the device have internal movable parts such as multiple cables (e.g., robotic instruments, elevator shaft) that may have exposure to soil?	No	0
12	Is the device a microsurgical instrument?	No	0
13	Can the device be fully submerged? (Facilitation of water exposure to residual soil)	Yes	0
14	Do the cleaning instructions as part of the IFU contain instruction that prevent soil from drying on the device while awaiting full decontamination processes?	Yes	-5
Total Risk Value			13



Classification Example – FEMORAL REAMER



Device:	Femoral Reamer		
#	Question	Answer	Risk Value
1	What is the most challenging to clean feature that is exposed to soil?	Smooth Through Lumen	24
2	Is the material in the most challenging feature absorbing (e.g., Stainless steel, Nitinol, Aluminium, Titanium) or repelling (e.g., silicone, PEEK, Delrin)?	Absorbing	1
3	What contact does the feature have with the patient?	Tissue/Bone/Dentin	4
4	Does the device <u>come in contact</u> with high-risk tissue such as the brain, spinal cord and eye?	No	0
5	How is the soil exposed to the most challenging feature?	Full Immersion	4
6	Will the soil be exposed to heat (e.g., cauterization)?	No	0
7	Will the soil be exposed to saline?	No	0
8	Does the device have a lumen greater than 270mm?	No	0
9	Does the device contain a housing that cannot be removed or accessed by fluid without flushing for cleaning where soil can migrate?	No	0
10	Is the device powered (Powered instruments, which can entrap debris that can later be aerosolized during a surgical procedure)?	No	0
11	Does the device have internal movable parts such as multiple cables (e.g., robotic instruments, elevator shaft) that may have exposure to soil?	No	0
12	Is the device a microsurgical instrument?	No	0
13	Can the device be fully submerged? (Facilitation of water exposure to residual soil)	Yes	0
14	Do the cleaning instructions as part of the IFU contain instruction that prevent soil from drying on the device while awaiting full decontamination processes?	Yes	-5
Total Risk Value			28



Intermediate risk: device features requiring specific intervention (e.g., lumens and mated surfaces)

Classification Example – DUODENOSCOPE



Device:	Duodenoscope		
#	Question	Answer	Risk Value
1	What is the most challenging to clean feature that is exposed to soil?	Smooth Through Lumen	24
2	Is the material in the most challenging feature absorbing (e.g., Stainless steel, Nitinol, Aluminium, Titanium) or repelling (e.g., silicone, PEEK, Delrin)?	Repelling	0
3	What contact does the feature have with the patient?	Mucosal Membranes	1
4	Does the device come in contact with high-risk tissue such as the brain, spinal cord and eye?	No	0
5	How is the soil exposed to the most challenging feature?	Flushing	5
6	Will the soil be exposed to heat (e.g., cauterization)?	No	0
7	Will the soil be exposed to saline?	No	0
8	Does the device have a lumen greater than 270mm?	Yes	10
9	Does the device contain a housing that cannot be removed or accessed by fluid without flushing for cleaning where soil can migrate?	No	0
10	Is the device powered (Powered instruments, which can entrap debris that can later be aerosolized during a surgical procedure)?	No	0
11	Does the device have internal movable parts such as multiple cables (e.g., robotic instruments, elevator shaft) that may have exposure to soil?	Yes	10
12	Is the device a microsurgical instrument?	No	0
13	Can the device be fully submerged? (Facilitation of water exposure to residual soil)	Yes	0
14	Do the cleaning instructions as part of the IFU contain instruction that prevent soil from drying on the device while awaiting full decontamination processes?	Yes	-5
Total Risk Value			45



High risk: complex features with high risk of soil retention

Reusable Medical Devices - MICROBIOLOGICAL QUALITY RISK



Spaulding

Patient exposure risk-based approach

- Microbiological
 - **Critical**: Sterilization
 - **Semi-critical**: Sterilization (where high-level disinfection can be acceptable, when applicable)
 - **Non-critical: Disinfection**
 - Based on risk
 - Effective cleaning may be appropriate
 - Efficacy against blood-borne pathogens in higher-risk applications



Kremer

Device feature risk-based approach

- Cleaning
 - **Maximal** (High risk): complex features (high risk of soil retention)
 - **Moderate** (Intermediate risk): device features requiring specific intervention (e.g., lumens and mated surfaces)
 - **Minimal** (Low risk): all surfaces exposed for cleaning

Minimal



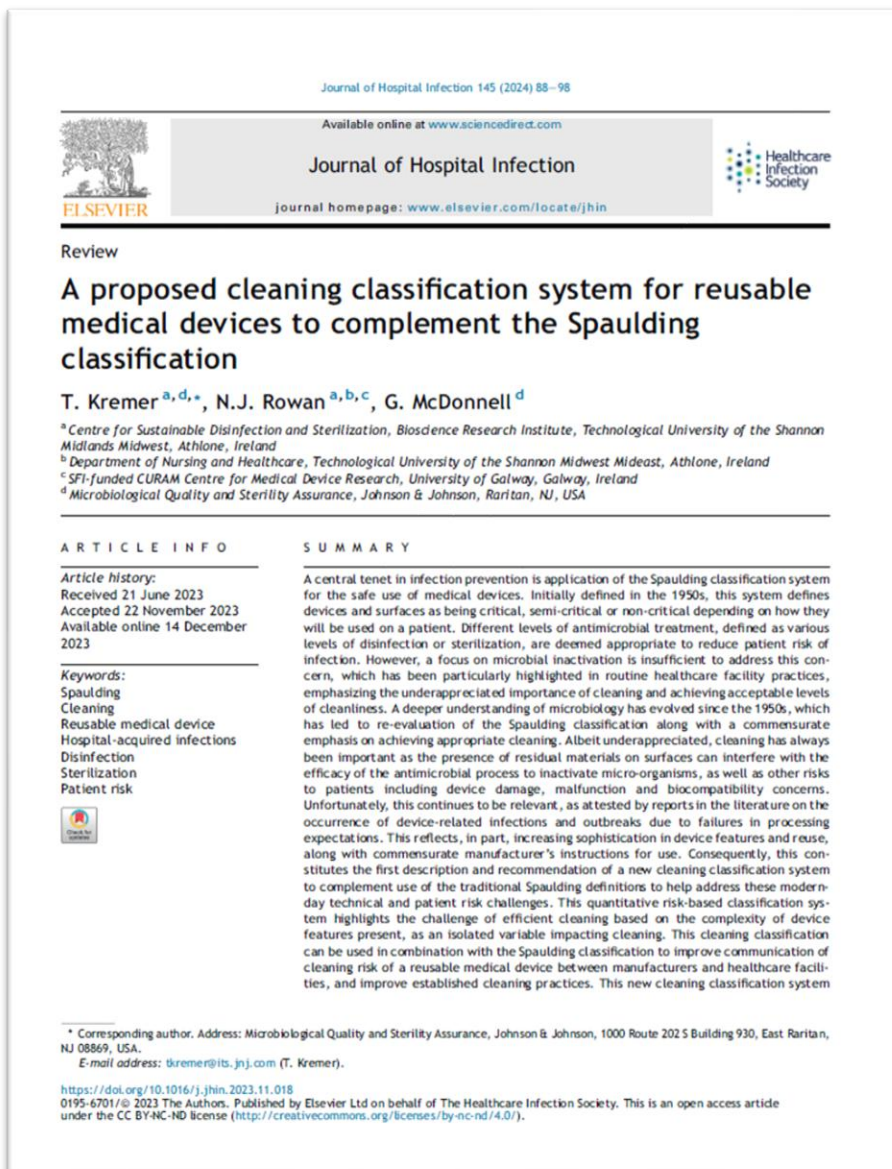
Moderate



Maximal



Kremer's Classification - SUPPORTING PUBLICATIONS





Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices

Part 3: Guidance on the designation of a reusable medical device to a cleaning classification

Part 3: Guidance on the designation of a reusable medical device to a cleaning classification

This document gives guidance on designating medical devices to cleaning classification categories, attributes used for medical device cleaning classification category, and designation of a cleaning process.

The cleaning classification category is comprised of two parts:

- designate medical devices to a product family;
- designate product families to cleaning processes.

NOTE 1 This allows grouping of medical devices into cleaning classification categories during cleaning and identification of master products during cleaning validation.

This document is applicable to manufacturers devising cleaning methods and instructions for processing. It also applies to any processing facility where medical devices are cleaned.

This document does not cover processing of single-use medical devices provided as sterile before use and textile devices.

NOTE 2 Manual cleaning steps before automated cleaning do not include steps that are considered point of use treatment that can be specified.

NOTE 3 Microbiocidal processes (sanitization, disinfection, sterilization) are not in the scope of the medical device cleaning classification categories.

ISO 17664-3 - CONCEPTS TO CONSENSUS

PD CEN ISO/TS 17664-3:2026

ISO/TS 17664-3:2026(en)



PD CEN ISO/TS 17664-3:2026

BSI Standards Publication

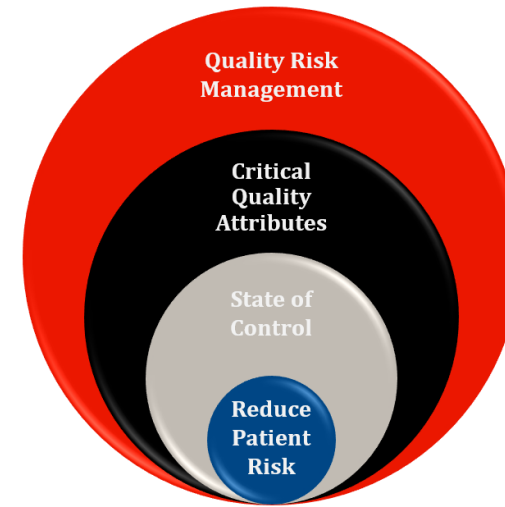
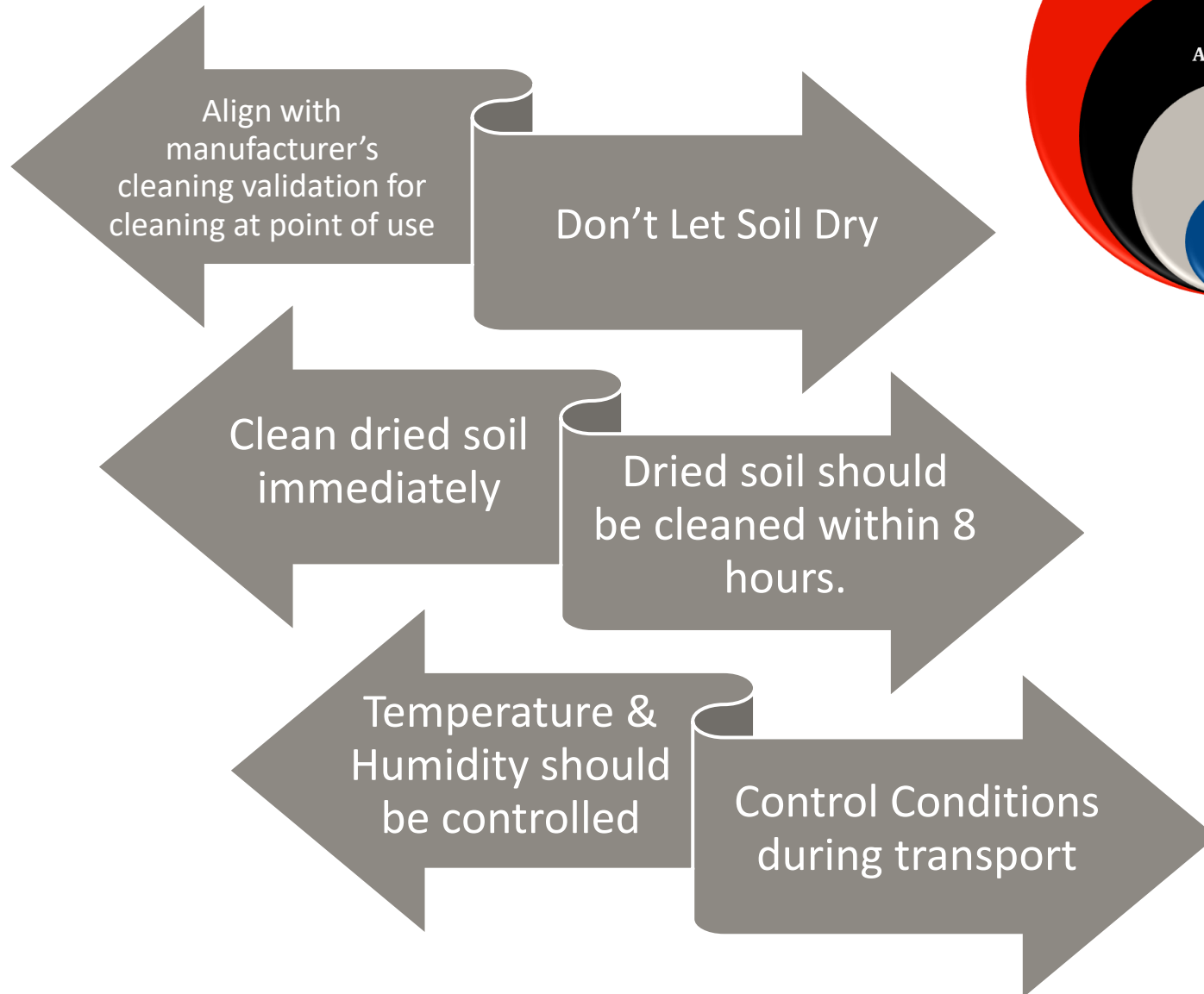
Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices

Part 3: Guidance on the designation of a reusable medical device to a cleaning classification

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- [11] US FDA Reprocessing Guidance, Section VI, Criterion 5

Key LESSONS



Questions?

