Decoding the Complexity of Instructions for Use (IFUs) for Reusable Medical Devices

Presented by:

Dr. Terra Kremer, Chris Ratanski, Jamie Fogarty, & Brian Flax

Disclaimer

- This presentation is intended for educational purposes only and does not replace independent professional judgment. Statements of fact and opinions expressed are those of the participant individually and, unless expressly stated to the contrary, are not the opinion or position of Johnson & Johnson or its affiliates.

Agenda

- Introduction to situation
- Workshop activity – IFU development
- Validation of cleaning instructions for use
- Transfer to healthcare facilities
- Establishing process families

Set & Setting

- Dorothy & friends are sterile processing engineers
- Traveled to Emerald City
- Scarecrow needs a brain to develop more efficient ways to clean reusable medical devices

Wizard of Oz

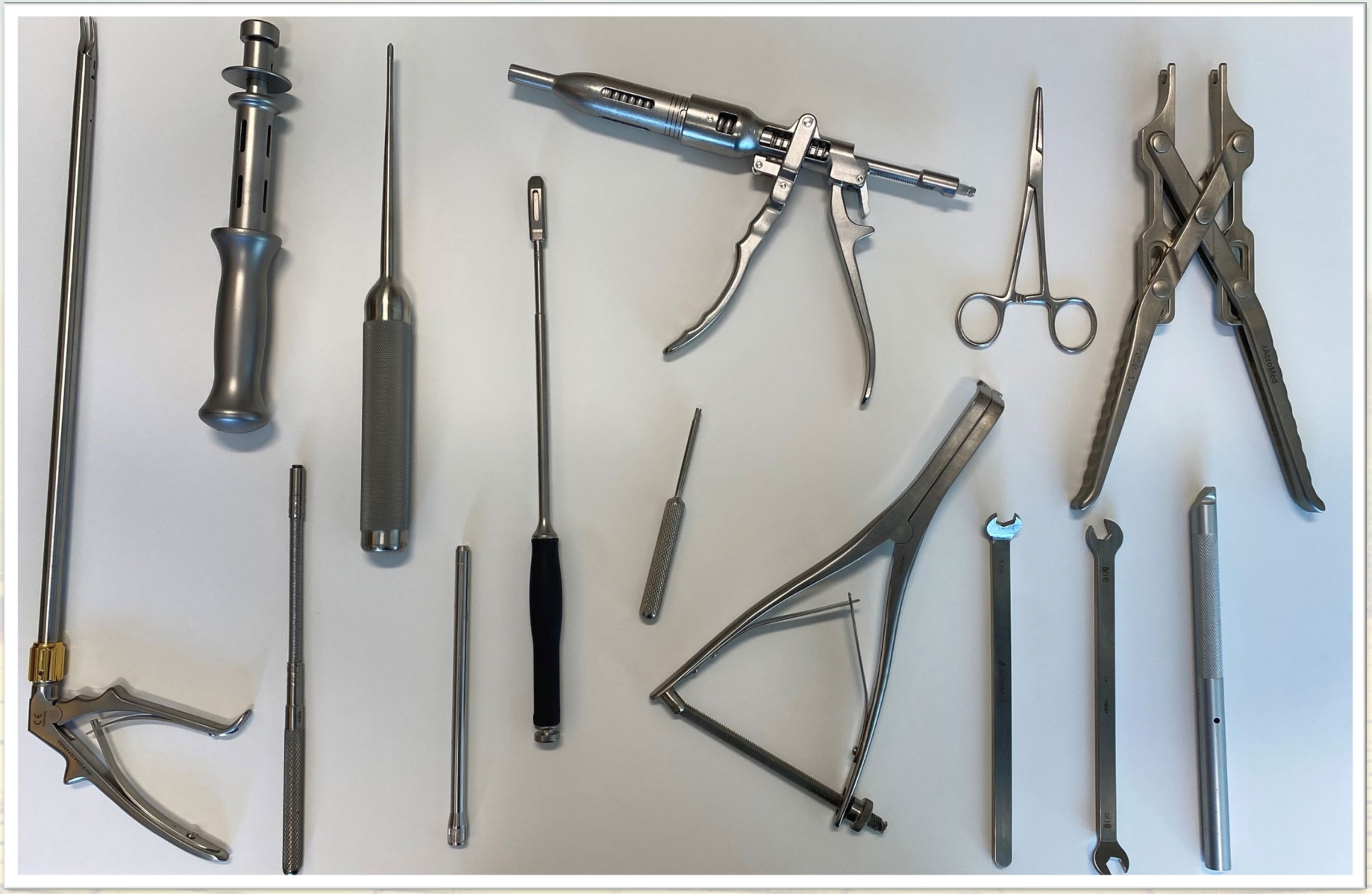
- Wizard is a medical device research & development (R&D) engineer
- Has a brain & implant surgical set
- Needs cleaning instruction for instrument set

Dr. Wicked Witch of the West

Cleaning IFU Requirements

- Developed
- Validated
- Used to process instrument set

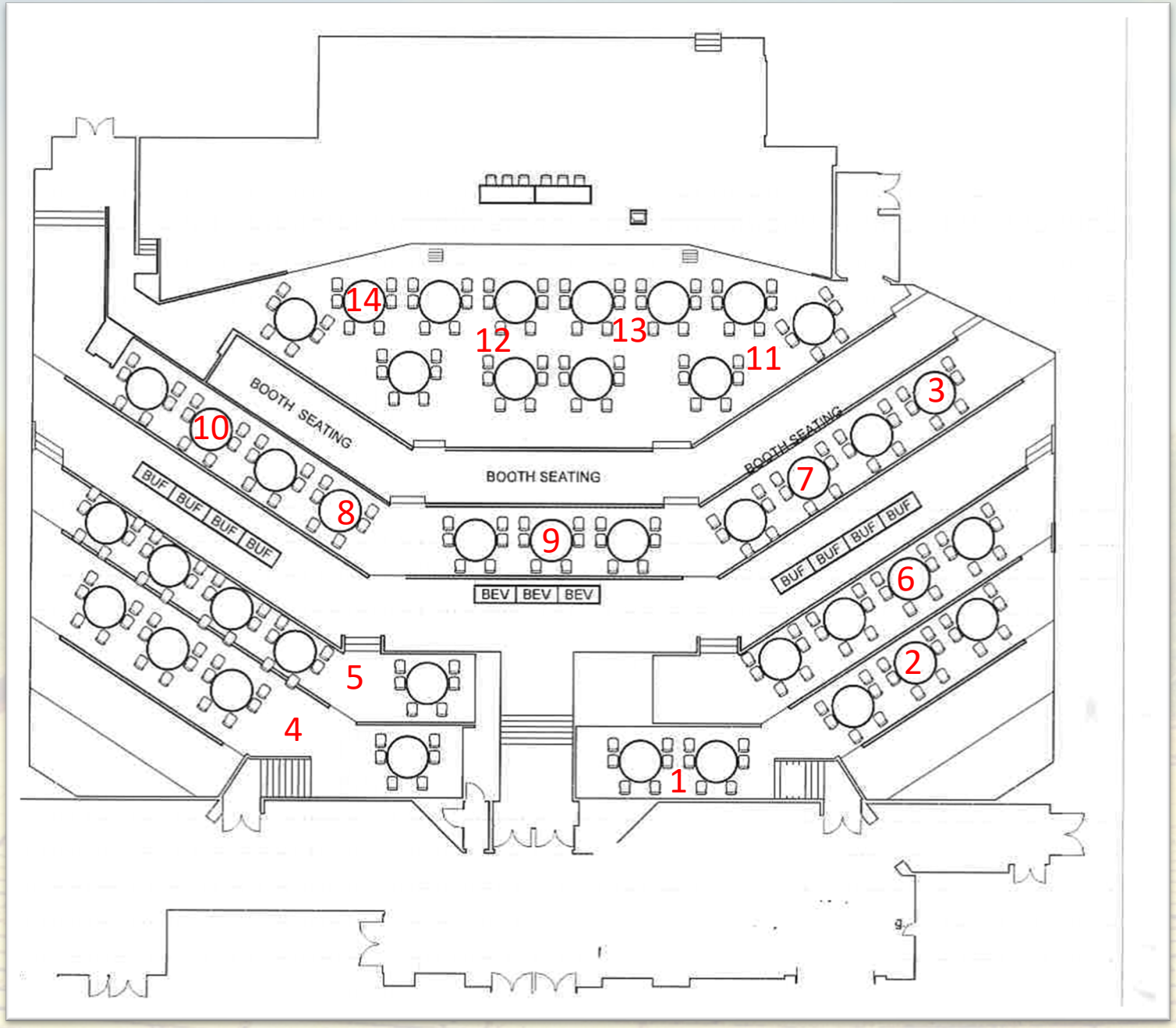
Brain Implant Surgical Set



Workshop Activity – 10 minutes

1. 14 Groups = ~15 people per group
2. One assigned instrument per group – Your instrument number is the same as your group number.
3. Complete page 17 of the IFU packet
4. Develop the automated cleaning instructions for your instrument

Groups


14
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BOOTH SEATING
BOOTH SEATING
BOOTH SEATING
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BUF BUF BUF BUF
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4
1

Workshop Activity – Report Out

Sit Down when you don't have a step: Manual Pre-Clean

Pre-Rinse	All devices with lumens need to be manually flushed to remove debris and brushed thoroughly using appropriately sized soft-bristled brushes and twisting action.

Soak	Prepare a neutral or mild alkaline cleaning solution (pH 7 to 9.5) in accordance to the detergent manufacturer's instructions. The temperature of the solution should be ≤40°C (104°F) for manual cleaning. Immerse devices and parts in the detergent solution, and soak for a minimum of 5 minutes.

Manual Brushing / Flushing	While immersed, use a soft non-metallic bristle brush (plastic bristles, like nylon) to thoroughly scrub all traces of blood and debris from all device surfaces for at least one minute. Ensure all lumens are thoroughly brushed. Push the brush through the entire length of the lumen using a twisting motion to remove debris from both ends for at least one minute. During cleaning, actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Ensure all lumens are flushed for at least one minute.

Sit Down when you don't have a step: Manual Pre-Clean

Intermediate Rinse	Rinse all devices by immersion in ambient, < 40°C (104oF), tap water for a minimum of one minute and until evidence of debris, soil, and cleaning solution are visually removed. Use a large syringe (e.g., 50ml or greater) filled to capacity with tap water to thoroughly flush lumens, blind holes, small clearances, and moving and intricate parts. Actuate joints, handles and other moveable device features to rinse thoroughly.

Ultrasonic Bath	Completely submerge the devices in an ultrasonic bath prepared with a neutral or mild alkaline pH detergent (pH 7-9.5), prepared in accordance with the manufacturer's instructions. Use a large syringe (50ml or greater) flush all lumens, blind holes, small clearances, and moving and intricate parts with the detergent solution to minimize the formation of air pockets or bubbles. Ultrasonically clean the device components for a minimum of 10 minutes.

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Sit Down when you don’t have a step: Automated

Washer-Disinfector Cycle Phase		
	Positioning (rack)	Load the device components in the washer-disinfector in accordance with manufacturer’s instructions, ensuring that the devices and lumens have maximum exposure to detergents and rinse water and can drain freely.
	Pre-Wash	02:00 min Cold tap water
	Enzyme Wash 1	01:00 min / <40°C / Neutral Enzymatic Cleaner
	Wash 2	05:00 min / 66°C / Neutral pH Detergent
	Rinse	02:00 min / >40°C / Tap Water
	Final Rinse	00:15 min / ambient / Critical Water
	Thermal Disinfection	01:00 min – 05:00 min / >90°C / Critical Water
	Dry Time	07:00 min / 115°C

Bump in the Yellow Brick Road

User Feedback

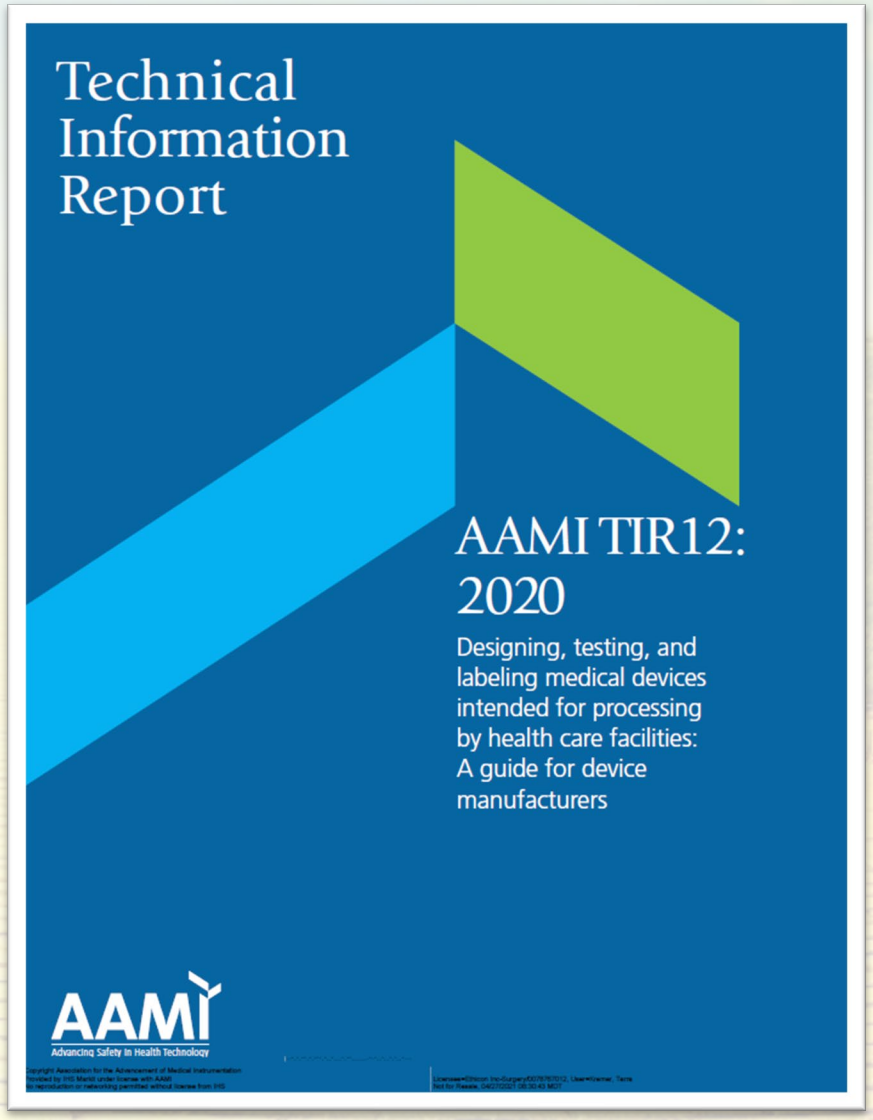
Cleaning-Disinfection Automated Method

1. Rinse soiled device under running cold tap water for a minimum of one minute. Remove gross soil using a soft-bristled brush or soft, lint-free cloth.
2. Manually clean device for a minimum of two minutes in a freshly prepared neutral or mild alkaline cleaning agent solution. Follow the cleaning agent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other moveable device features to expose all areas to cleaning agent solution, if applicable. Clean device under water to prevent aerosolization of contaminants. Note: fresh solution is a newly-made, clean solution.
3. Rinse device using ambient (≤40 °C) running tap water for a minimum of one minute. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water, if applicable.
4. Prepare a fresh cleaning agent solution for the ultrasonic bath using a neutral or mild alkaline cleaning agent. Follow the cleaning agent manufacturer's instructions for the correct dilution, temperature, water quality and exposure time. Note: fresh solution is a newly-made, clean solution.
5. Clean Synthes devices ultrasonically for a minimum of 15 minutes, using a minimum frequency of 38 kHz.
6. Rinse device using ambient (≤40 °C) DI or PURW water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. DI or PURW water must be used for final rinse.
7. Visually inspect device. Repeat steps 2–7 until no visible soil remains on device.
8. Automated washing shall be conducted in a validated washer-disinfector in compliance to ISO 15883-1 and -2, or to an equivalent standard. Load the device components in the washer-disinfector in accordance with manufacturer's instructions, ensuring that the devices and lumens can drain freely. Automated washing can be included as part of a validated washing, disinfection, and/or drying cycle in accordance to manufacturer's instructions. An example of a validated cycle used for cleaning validation included:

Cycle	Recirculation Time (minutes)	Water Quality/ Temperature	Type of Cleaning
Pre-wash	2	Cold tap water <40 °C	N/A
Wash I	2	Cold tap water <40 °C	Cleaning agent*
Wash II	5	Warm tap water >40 °C	Cleaning agent*
Rinse	2	Warm DI or PURW >40 °C	N/A
Thermal disinfection	5	Critical water (RO, DI or distilled water) ≥93 °C	N/A
Dry	40	≥90 °C	N/A

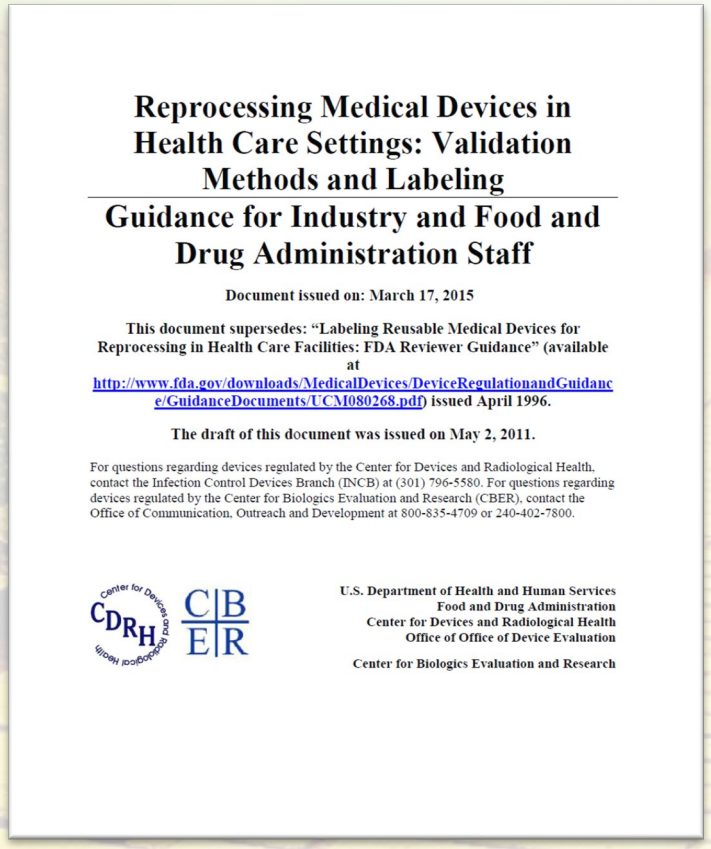
* see section Additional Information

Governing Standards for IFU Development



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

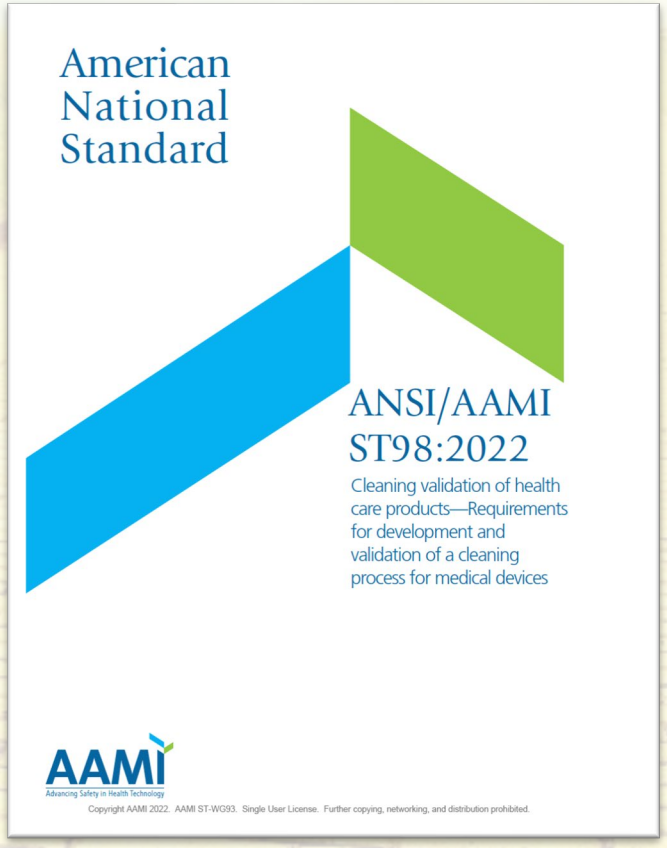
This document supersedes: "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance" (available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf) issued April 1996.

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 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

AAMI
Advancing Safety in Health Technology

- Automated Cleaning Validation ~ 30K
- Two quantitative analytes
  - Protein ≤ 6.4 µg/cm^2
  - Total Organic Carbon (TOC) ≤ 12 µg/cm^2
- Data Variability
  - Standard deviation added to the highest value must be less than acceptance criteria

Bump in the Yellow Brick Road

All devices are visibly clean ✓

All extractions less than acceptance criteria ✓

Data variability is less than acceptance criteria ✗

Need additional cleaning instructions to revalidate

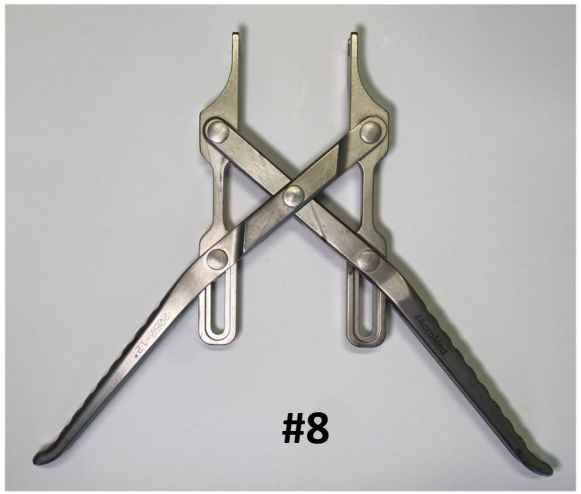
No Time for Redesign

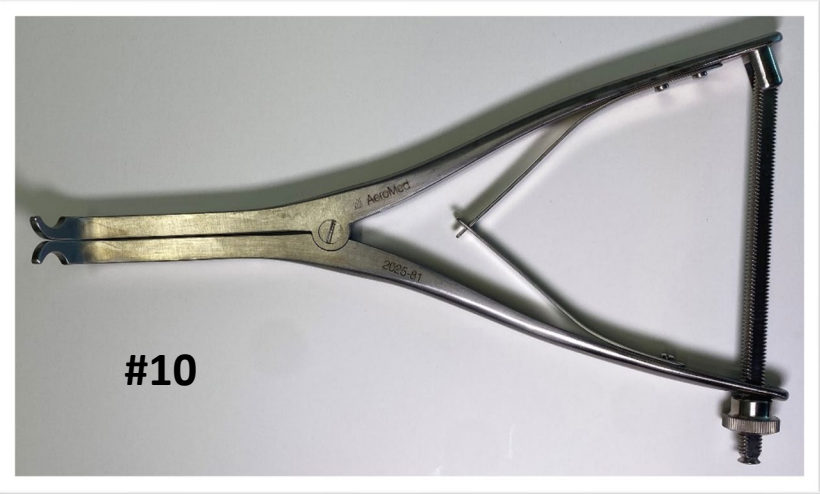
Workshop Activity – 10 minutes

1. Reform your 14 Groups = ~15 people per group
2. Complete pages 18 - 19 of the IFU packet
3. Identify the hardest to clean device in the instrument set
4. Group to develop changes to IFU to achieve a passing cleaning validation

Hardest to Clean Device – Audience Vote

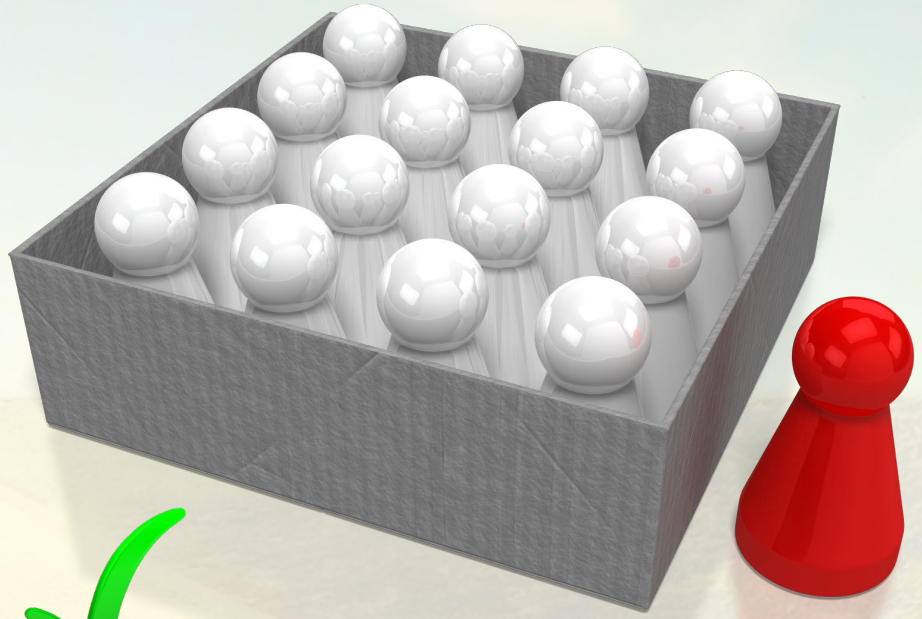
Hardest to Clean Device – Audience Vote

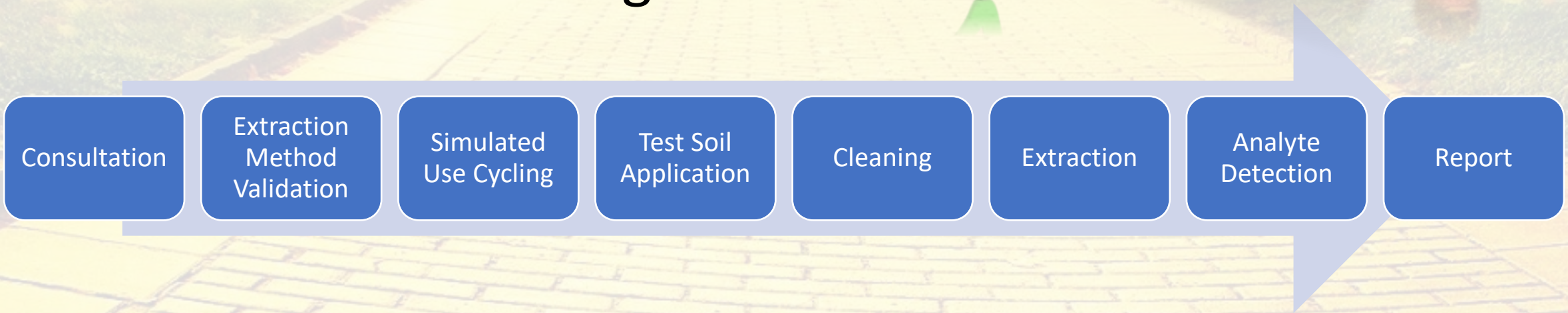




Cleaning Re-Validation

- New cleaning steps
  - Repeat cleaning validation
    - Cleaning validation

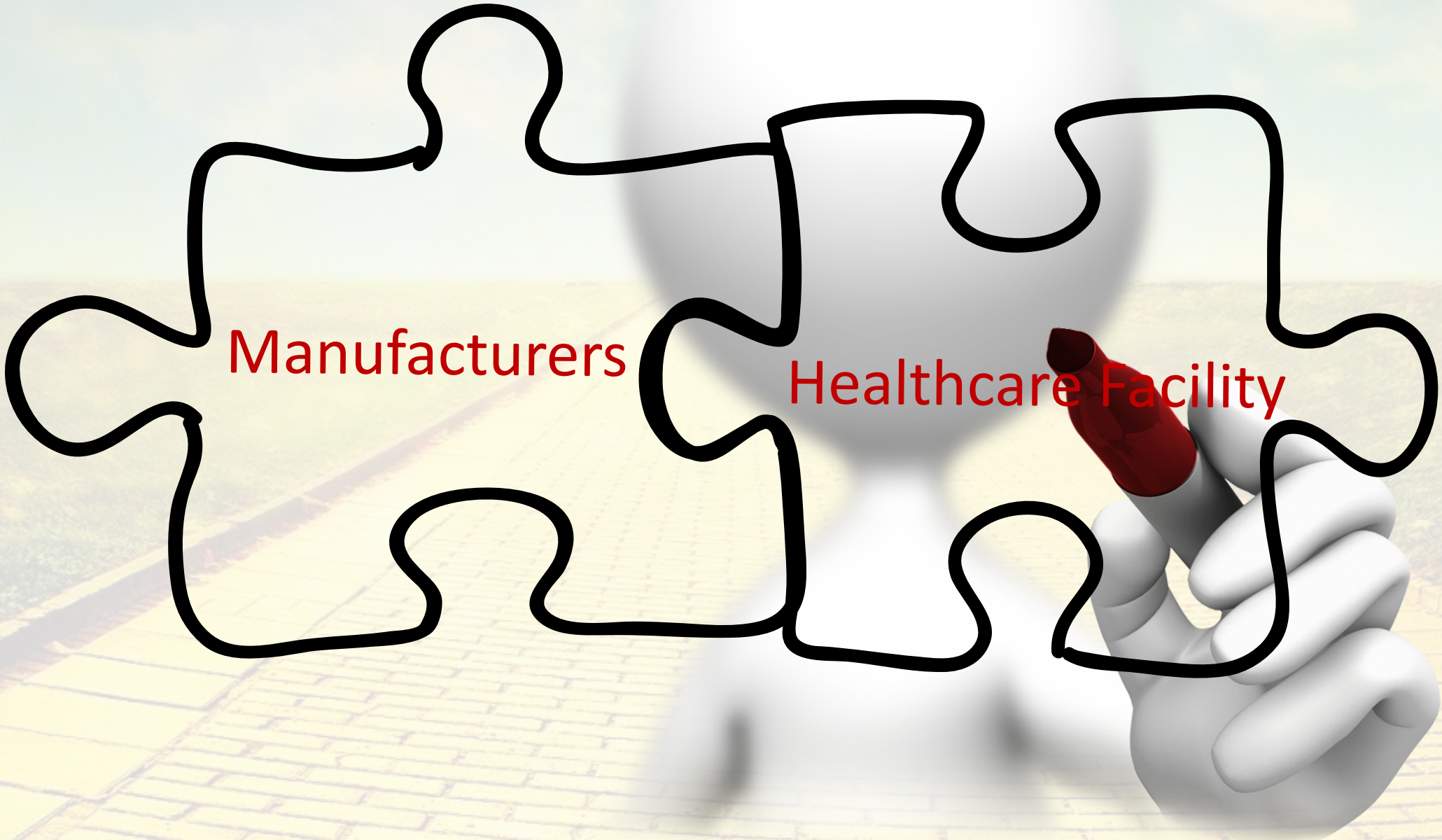




Ready to Reprocess

- Delivered instruments to sterile processing w/ validated cleaning IFU

Device Performance Responsibility

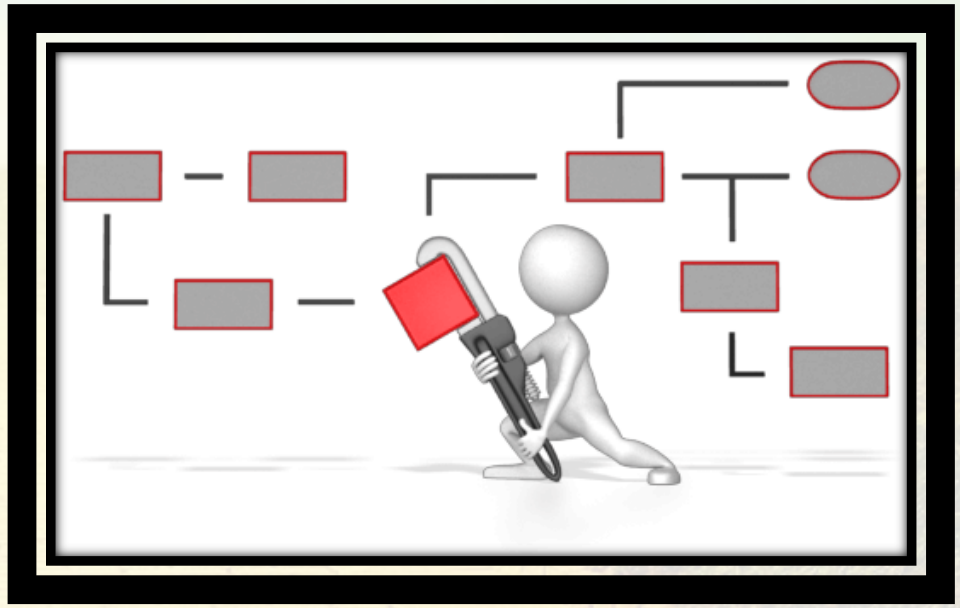


Workshop Activity – 10 minutes

1. 14 Groups = ~15 people per group
2. Complete page 20 of the IFU packet
3. List considerations that need to be taken to ensure a successful transfer of the cleaning IFU to Sterile Processing.

Cleaning Instruction Considerations

- Established cleaning processes – Can new set be adopted into an established process?
- Training – Is training offered / required?
- Supplies – Are special tools / supplies needed to perform cleaning?
- Equipment – Is specified equipment (e.g., washer rack, sonic irrigator) needed to perform cleaning?



Bump in the Yellow Brick Road

On Your Own…

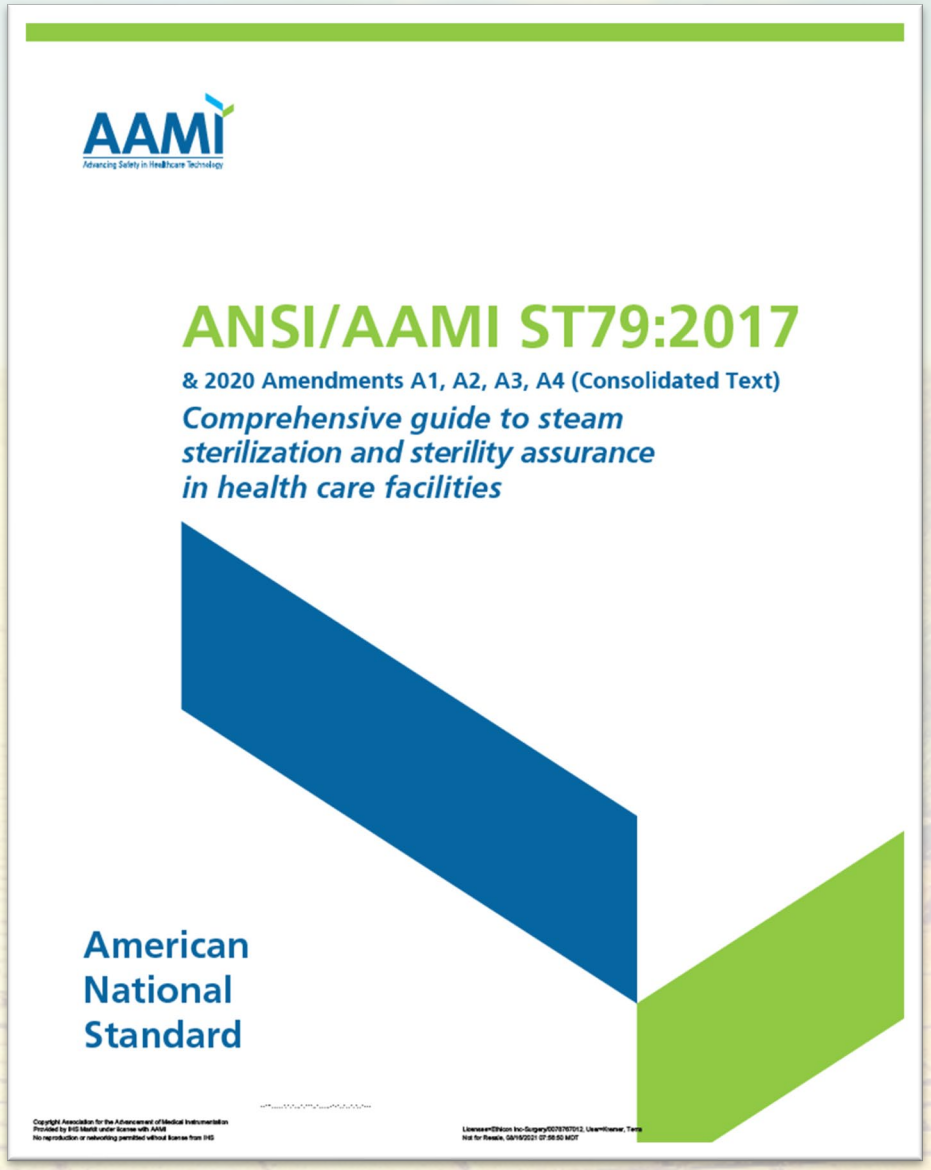
You had the power the whole time!

You had the power the whole time!

13.9.3 Product Families

The concept of product families may be used in the product quality assurance testing program for the following purposes:

a) To group routinely processed items that are similar in construction, materials, size, and packaging into a product family. Other considerations could include design configuration, number of components, need for disassembly, surface finish or texture, the presence of lumens, and the written IFU for reprocessing provided by the manufacturer.



Tools to develop cleaning process families…

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Journal of Hospital Infection

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

Review

A proposed cleaning classification system for reusable medical devices to complement the Spaulding classification

T. Kremer [a,d,*], N.J. Rowan [a,b,c], G. McDonnell [d]

[a] Centre for Sustainable Disinfection and Sterilization, Bioscience Research Institute, Technological University of the Shannon Midlands Midwest, Athlone, Ireland
[b] Department of Nursing and Healthcare, Technological University of the Shannon Midwest Mideast, Athlone, Ireland
[c] SFI-funded CURAM Centre for Medical Device Research, University of Galway, Galway, Ireland
[d] Microbiological Quality and Sterility Assurance, Johnson & Johnson, Raritan, NJ, USA

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SUMMARY

A central tenet in infection prevention is application of the Spaulding classification system for the safe use of medical devices. Initially defined in the 1950s, this system defines devices and surfaces as being critical, semi-critical or non-critical depending on how they 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 risk of infection. However, a focus on microbial inactivation is insufficient to address this concern, which has been particularly highlighted in routine healthcare facility practices, emphasizing the underappreciated importance of cleaning and achieving acceptable levels of cleanliness. A deeper understanding of microbiology has evolved since the 1950s, which has led to 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 micro-organisms, 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. 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 healthcare facilities, and improve established cleaning practices. This new cleaning classification system

* Corresponding author. Address: Microbiological Quality and Sterility Assurance, Johnson & Johnson, 1000 Route 202 S Building 930, East Raritan, NJ 08869, USA.
E-mail address: tkremer@its.jnj.com (T. Kremer).

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A new quantitative method for determining patient risk for reusable medical device categorization based on using and interpreting Kremer's cleaning classification system

T. Kremer [a,c,*], N.J. Rowan [a,b], G. McDonnell [c]

[a] Centre for Sustainable Disinfection and Sterilization, Bioscience Research Institute, Technological University of the Shannon Midlands Midwest, Athlone Campus, Ireland
[b] SFI-funded CURAM Centre for Medical Device Research, University of Galway, Galway, Ireland
[c] Microbiological Quality & Sterility Assurance, Johnson & Johnson, NJ, USA

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Keywords:
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SUMMARY

Background: The cleaning of reusable medical devices involves inherent challenges that can impact on the effectiveness of the cleaning process; consequently, the subsequent safety of patients. Fluid dynamics play a critical role in determining the flow and distribution of cleaning agents where the design of the device can either facilitate or hinder this important process. Complex geometries, narrow channels, or irregular surfaces can impede effective flushing of contaminants leading to incomplete cleaning that creates a greater likelihood for patient contamination risks.
Methods: Device features ($N = 23$) were exposed to the most challenging cleaning conditions to find the point of failure in both fluid dynamics and soil retention. Experimental results obtained from the aforementioned along with associated compound risks were used to assign a risk value. Using the 'hardest to clean' device feature approach as the base risk value, the total quantitative risk score was calculated for different reusable medical devices from numerical values obtained from addressing 14 questions focusing on variability in geometry, material use, types of cleaning, and intended patient use. Patient risk values for devices with different features were calculated from using Kremer's cleaning categories based on position within value ranges.
Findings: Occurrences less than 18 correspond to minimal risk devices while a total risk score between the values of 18 and 39 are moderate and ≥40 scores corresponds to the maximal category.
Conclusion: Application of this quantitative assessment approach will facilitate appropriate mitigation of risk for cleaning reusable medical devices by informing use of targeted effective interventions. Future use of this Kremer cleaning classification will complement and augment disinfection and sterilization modalities.

* Corresponding author. Address: 1000 Route 202 S, Building 930, East Raritan, NJ 08869, USA. Tel.: +1 801 631 7953.
E-mail address: tkremer@its.jnj.com (T. Kremer).

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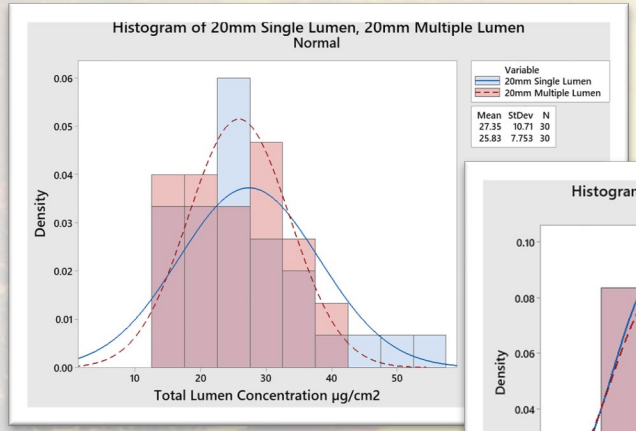
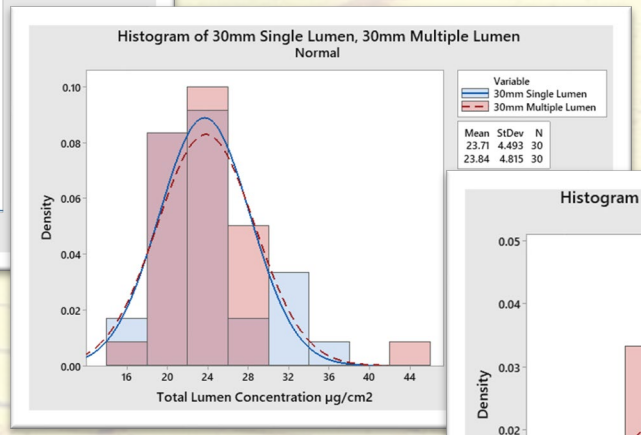
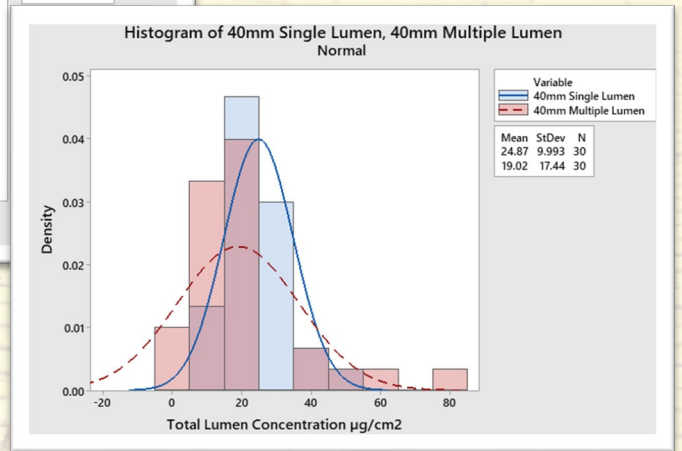
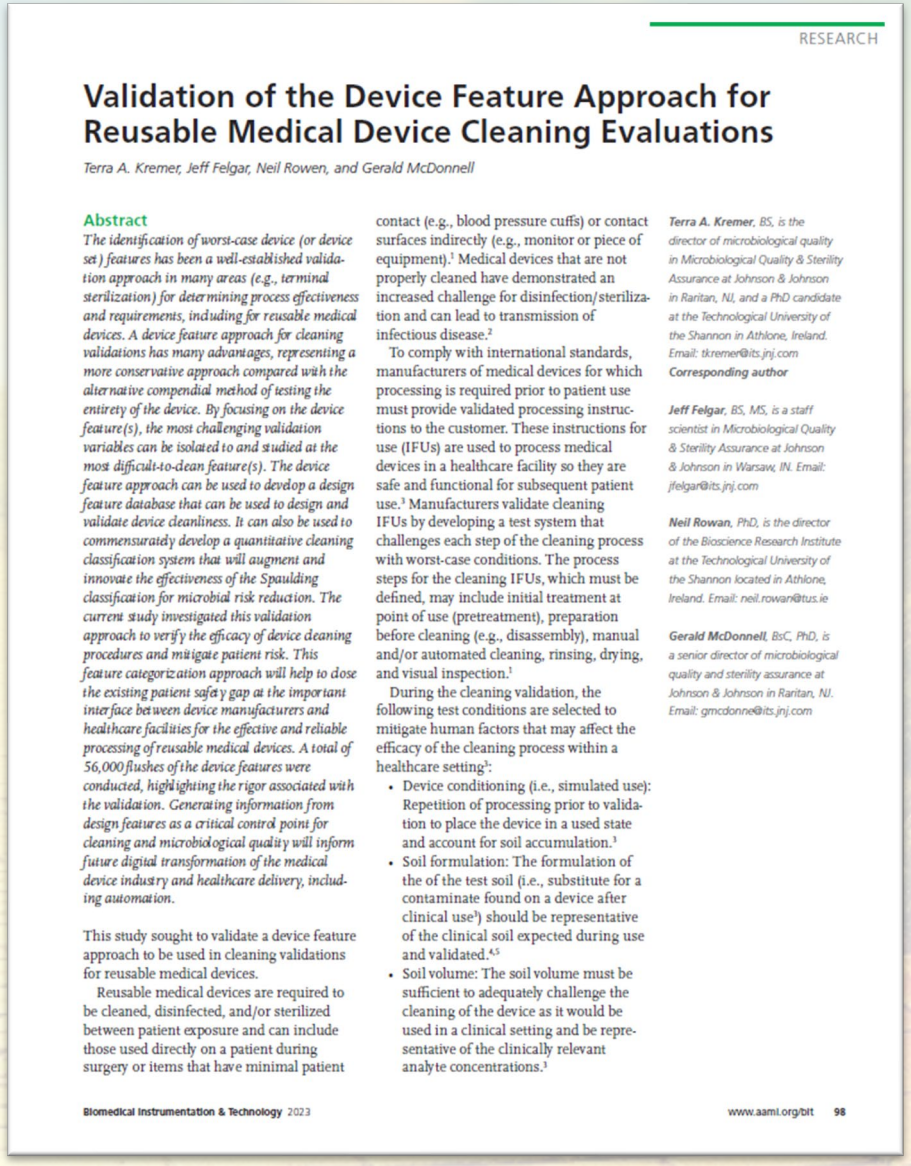
Validation of the Device Feature Approach

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









RESEARCH

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

Terra A. Kremer, Jeff Felgar, Neil Rowen, 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[3]:

- 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 of the test soil (i.e., substitute for a contaminate found on a device after clinical use[3]) 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.[3]

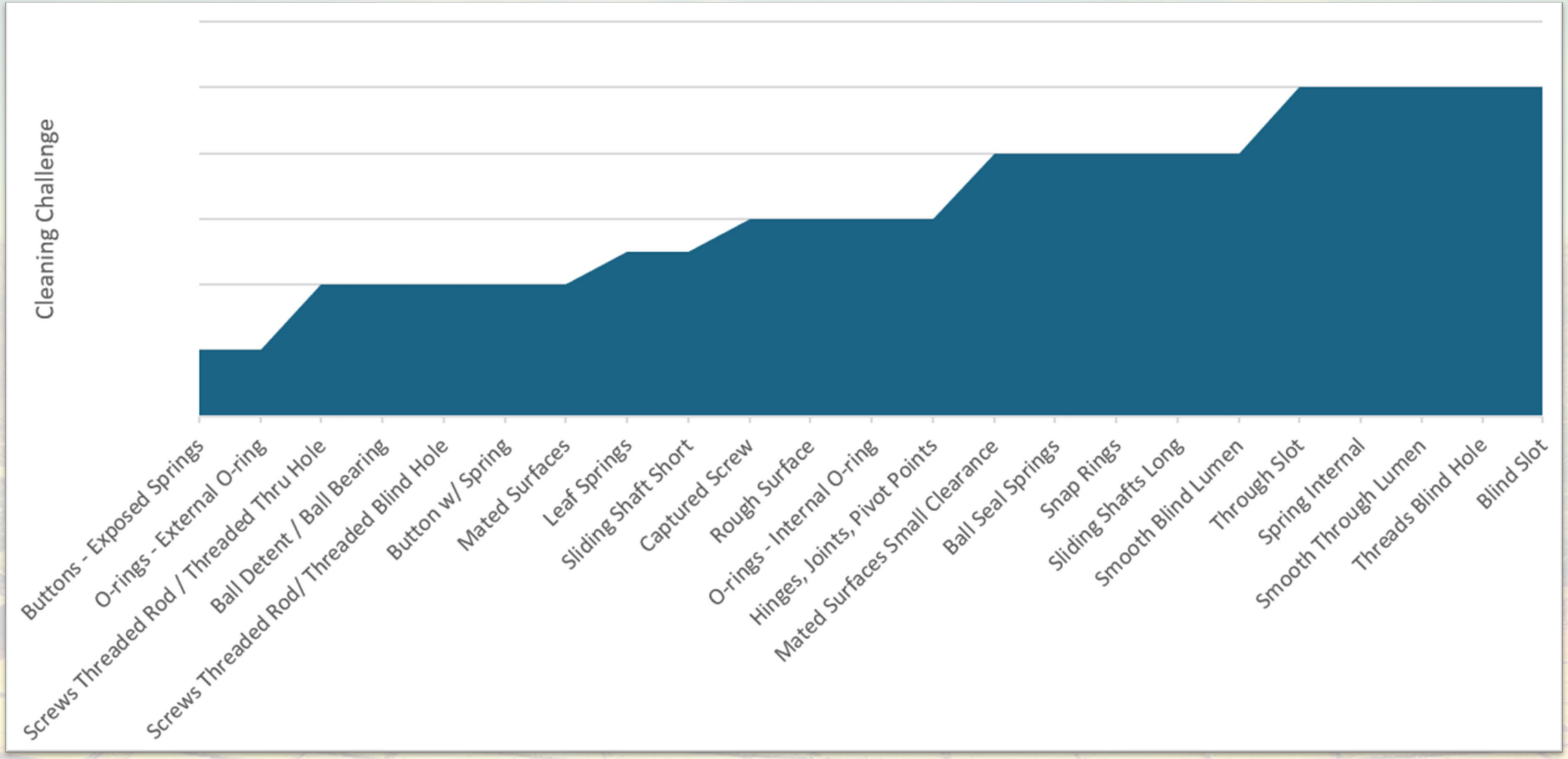
***Terra A. Kremer**, BS, is the director of microbiological quality in Microbiological Quality & Sterility Assurance at Johnson & Johnson in Raritan, NJ, and a PhD candidate at the Technological University of the Shannon in Athlone, Ireland. Email: tkremer@its.jnj.com*
Corresponding author

***Jeff Felgar**, BS, MS, is a staff scientist in Microbiological Quality & Sterility Assurance at Johnson & Johnson in Warsaw, IN. Email: jfelgar@its.jnj.com*

***Neil Rowan**, PhD, is the director of the Bioscience Research Institute at the Technological University of the Shannon located in Athlone, Ireland. Email: neil.rowan@tus.ie*

***Gerald McDonnell**, BsC, PhD, is a senior director of microbiological quality and sterility assurance at Johnson & Johnson in Raritan, NJ. Email: gmcdonne@its.jnj.com*

Validation of the Device Feature Approach



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

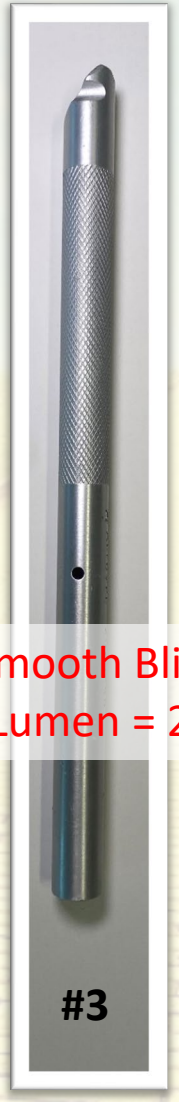
Device Feature	Total Risk Categorization
Rough Surface	8
Screws Threaded Rod / Threaded Thru Hole	5
Screws Threaded Rod/ Threaded Blind Hole	16
Sliding Shaft Short	12
Sliding Shafts Long	15
Smooth Blind Lumen	20
Smooth Through Lumen	24
Snap Rings	12
Spring Internal	25
Threads Blind Hole	24
Through Slot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

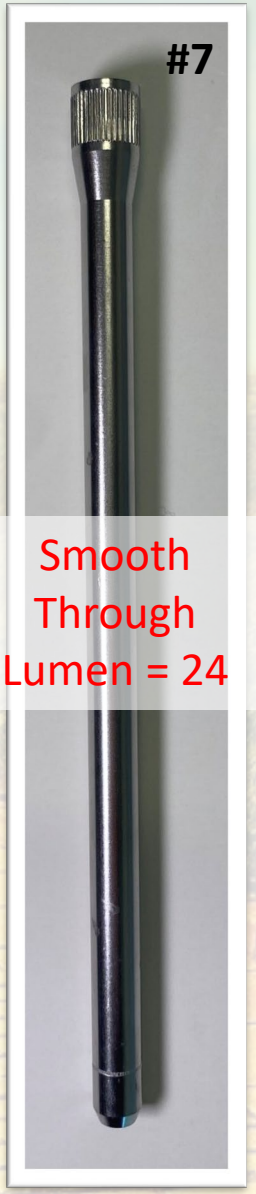
Workshop Activity – 10 minutes

1. 14 Groups = ~15 people per group
2. One assigned instrument per group – Your instrument number is the same as your group number.
3. Using page 21 – 24, complete page 25 of the IFU packet
4. Define the hardest to clean feature and assign ranking

Device #	Hardest to Clean Feature	Rank

Hardest to Clean Feature w/ Risk Value

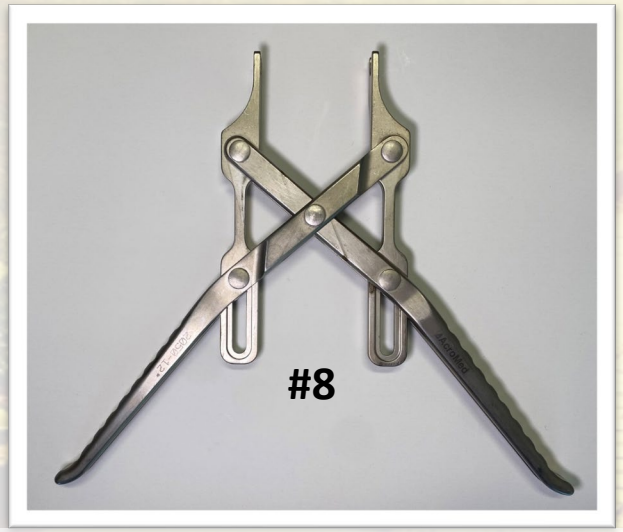




Hardest to Clean Feature w/ Risk Value

What if device has multiple features?

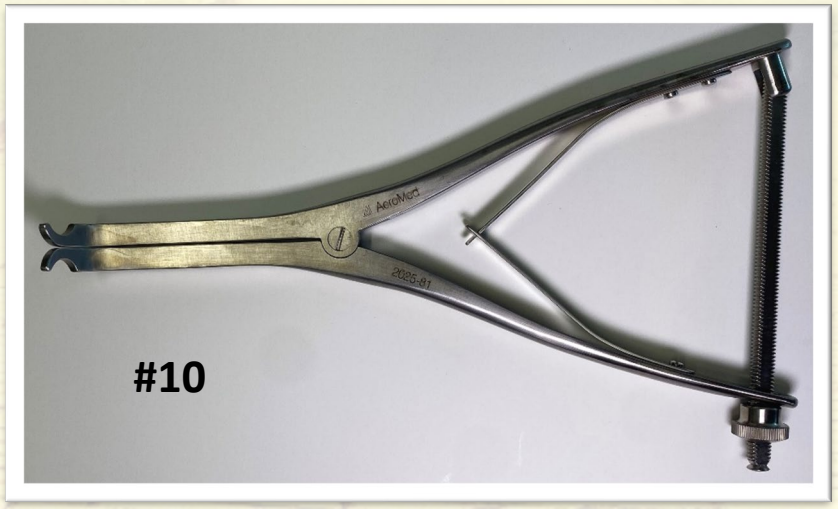
1. Identify all features
2. Assign risk value
3. Assign highest value for family grouping



Hinges, Joints, Pivot Points = 18

Through Slot = 25

Captured Screw = 12



Leaf Spring = 9

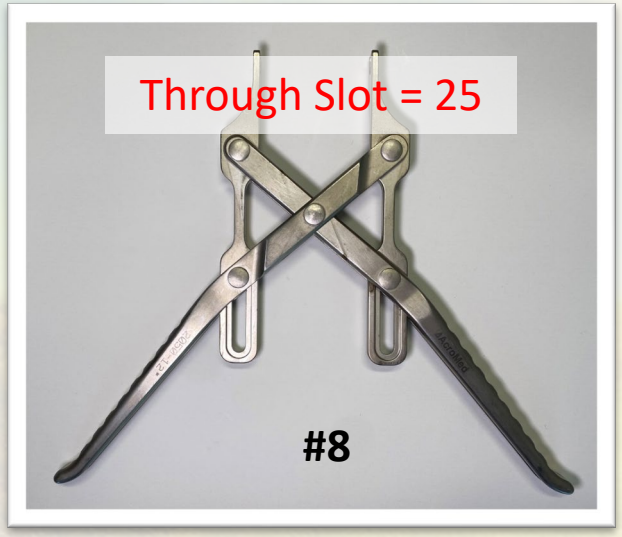
Screws Threaded Rod / Through Hole = 5

Captured Screw = 12

Spring Internal = 25

Smooth Through Lumen = 24

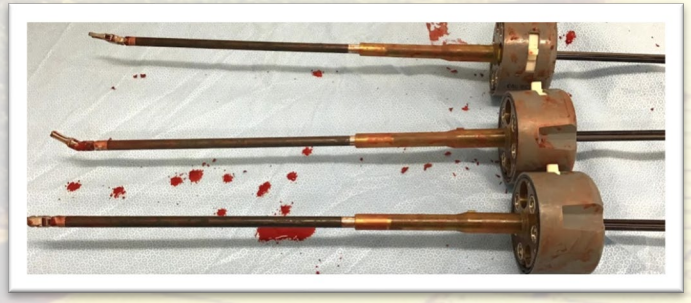
Hardest to Clean Feature w/ Risk Value



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

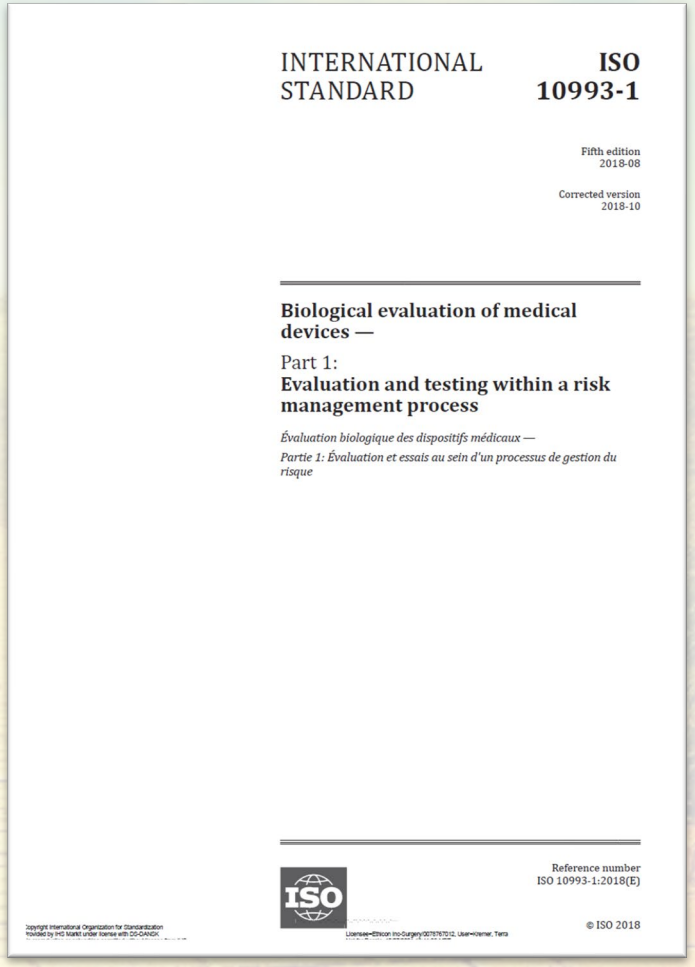
Risk Question	Answer	Value	Risk for Likelihood of Occurrence
Does the device contain a housing that cannot be removed or accessed by fluid without flushing for cleaning where soil can migrate?	Yes	10	Frequent – Serious/Critical
	No	0	Remote/Improbable – Negligible/Minor

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 - 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



INTERNATIONAL STANDARD **ISO 10993-1**

Fifth edition
2018-08

Corrected version
2018-10

Biological evaluation of medical devices —

Part 1:
Evaluation and testing within a risk management process

Évaluation biologique des dispositifs médicaux —

Partie 1: Évaluation et essais au sein d'un processus de gestion du risque

Reference number
ISO 10993-1:2018(E)

Compounding Hazards - 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 - Use

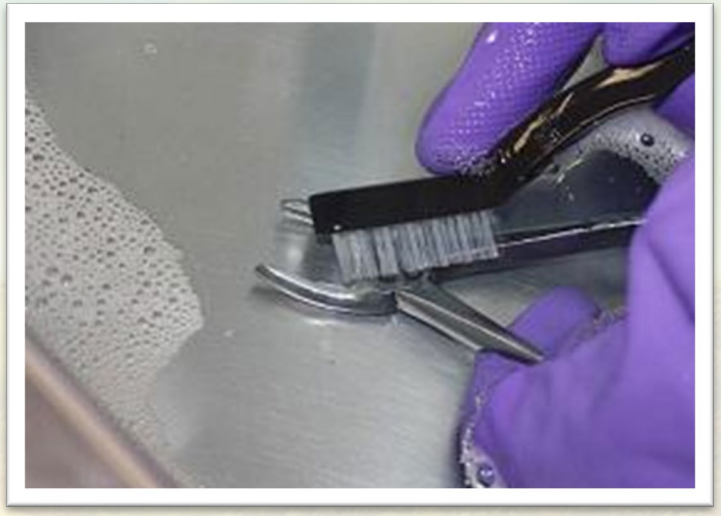
Risk Question	Answer	Value	Risk for Likelihood of Occurrence
Does the device come in contact with high-risk tissue such as the brain, spinal cord, and eye?	Yes	1	Remote/Improbable – Serious/Critical
	No	0	Remote/Improbable – Minor/Serious

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

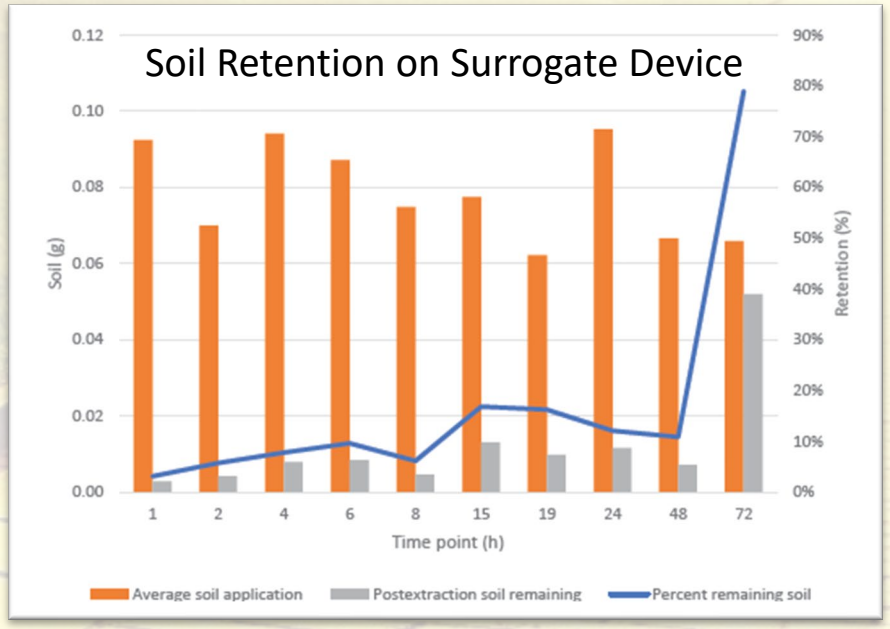
Risk Question	Answer	Value	Risk for Likelihood of Occurrence
Can the device be fully submerged (Facilitation of water exposure to residual soil)?	Yes	0	Remote/Improbable – Negligible/Minor
	No	5	Frequent/Probable – Minor/Serious



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

Soil Dry Time

- Most Cleaning Validations are performed when soil is dry to the touch ~1hr
- Cleaning challenge increases as soil dries.



A. Kimble, C. Ratanski and T. Kremer, "Chemical Changes Over Time Associated with Protein Drying," *Biomedical Instrumentation & Technology,* pp. 52-57, 2023.

T. Kremer, C. Carfaro and S. Klacik, "Effects of Time, Temperature, and Humidity on Soil Drying on Medical Devices," *Biomedical Instrumentation & Technology,* pp. 58-66, 2023.

Chemical Changes Over Time Associated with Protein Drying

Allan Kimble, Christopher Ratanski, and Terra A. Kremer

Abstract

remaining on a device after processing.

***Allan Kimble**, MS, is a principal*

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

Terra A. Kremer, Christopher Carfaro, Sue Klacik

Abstract

In the healthcare environment, delays can occur that prevent reusable devices from being processed within the specified time outlined in manufacturers' instructions for use. It has been suggested in the literature and industry standards that residual soil components, such as proteins, may undergo a chemical change when they are exposed to heat or experience prolonged drying times under ambient conditions. However, little experimental data are available in the literature to document this change or how is may be addressed for cleaning efficacy. This study presents the effects of time and environmental conditions on contaminated instrumentation from the point of use until the cleaning process begins. It demonstrates that soil drying after a period of eight hours changes the solubility of the soil complex, with a significant change occurring after 72 hours. Temperature also contributes to chemical changes in protein. Although no significant difference occurred between 4°C and 22°C, temperatures greater than 22°C demonstrated a decrease in soil solubility in water. An increase in humidity prevented the soil from completely drying and prevented the chemical changes affecting solubility from occurring.

Most reusable medical devices are intended to be cleaned immediately after use or stored in a way that does not allow for the remaining clinical soil (e.g., blood, mucus, tissue) to dry on surfaces. These point-of-use treatment instructions are conveyed in medical device instructions for use (IFU) and are intended to be performed by healthcare personnel (e.g., perioperative staff).

However, following these instructions may not always be possible, resulting in soil drying on a device. Guidance documents (e.g., the Association of periOperative Registered Nurses' *Guidelines for Perioperative Practice*,[1] ANSI/AAMI ST79:2017[2]) suggest that changes to soil may occur if it's allowed to dry, but little evidence exists within the literature for how soil drying may affect the cleaning process. In the current study, a series of experiments were conducted to elucidate how time, temperature, and humidity may affect the solubility of soil, if allowed to dry.

Review of Literature

The microbiological quality of a product is defined as all activities that provide confidence that the product is microbiologically safe according to its intended use.[3] This is particularly important in critical situations, such as perioperative practices. It is important to understand that product quality goes beyond whether a product contains microorganisms and the associated risk of infection.

An immune response can occur from microbiological contamination and other toxic compounds on the surface or eluting from the device. As an example, the potential toxicity of protein concentrations were measured using cytotoxicity tests, and it was found that when the concentration of known toxic proteins was increased to greater than 8 µg/cm^2, cell death occurred.[4] Although this was a potentially exaggerated response, as the L29 mouse cells used in the study had no immune system, the evidence demonstrates that residual protein can be cytotoxic. Other studies also have demonstrated that chemical residue, such residual cleaning agent, can be cytotoxic.[5,6]

Overall, the microbiological and chemical contamination on a product, which includes residual chemicals and particulates, may elicit an immune response in a patient. Manufacturers are responsible for ensuring that medical devices are manufactured with the intended microbiological quality and delivered to the healthcare facility with the appropriate instructions, thereby allowing for safe and effective use throughout a device's lifetime.

During the previous 25 years, country-specific and global standardization committees

Terra A. Kremer**, BS, is the director of microbiological quality in Microbiological Quality & Sterility Assurance at Johnson & Johnson in Raritan, NJ. Email: tkremer@its.jnj.com **Corresponding author

***Christopher Carfaro**, BS, is a laboratory supervisor in Microbiological Quality & Sterility Assurance at Johnson & Johnson in Raritan, NJ. Email: carfarochris@gmail.com*

***Sue Klacik**, BS, is a clinical educator at the Healthcare Sterile Processing Association in Chicago, IL. Email: sklacik@myhspa.org*

Cleaning Classification to Mitigate 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

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 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?	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**

Moderate

MOD

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**

Microbiological Quality for Reusable Medical Devices

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

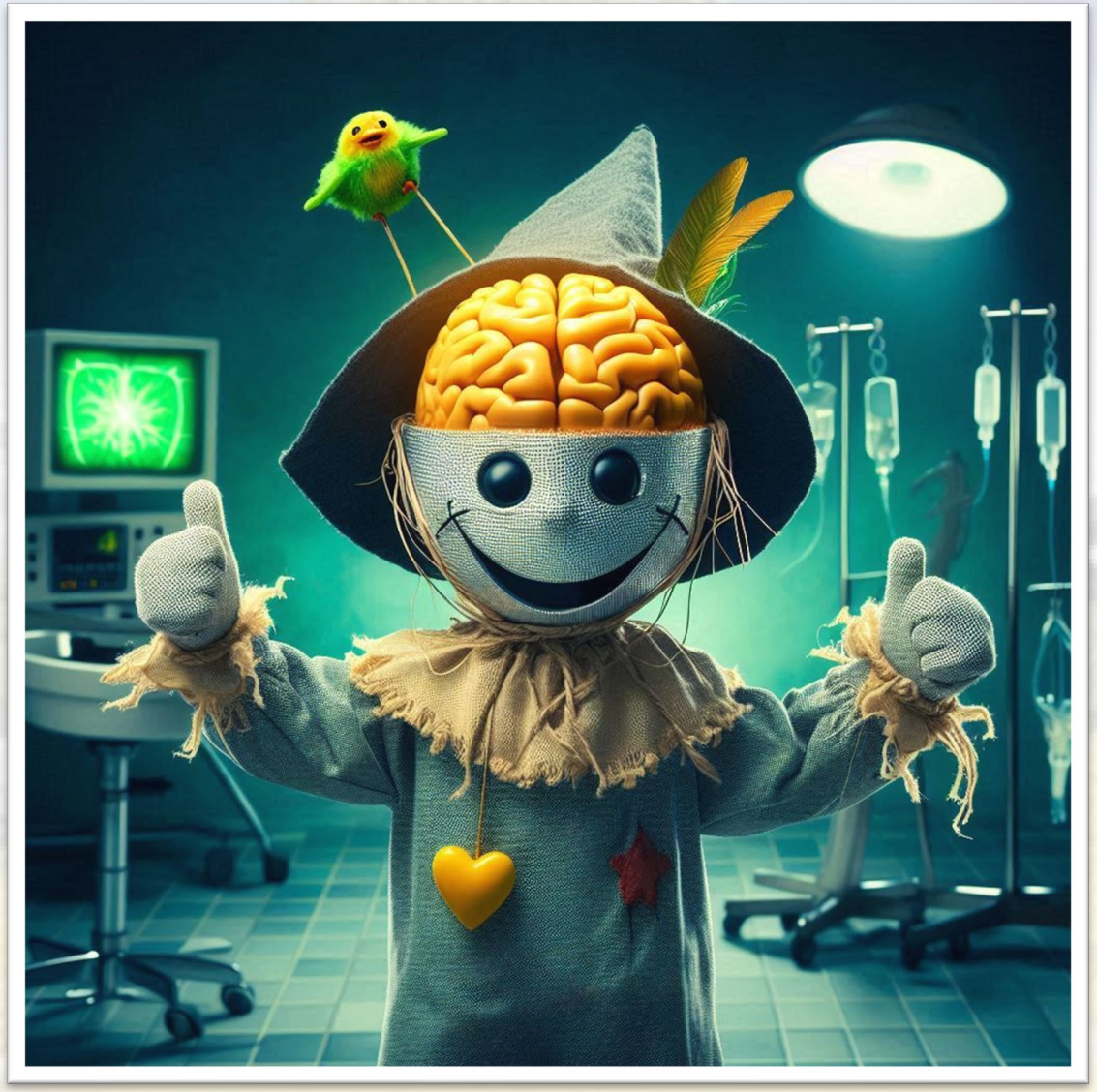
- Cleaning
  - Maximal (High risk): complex features (high risk of soil or microbial retention)
  - Moderate (Intermediate risk): device features requiring specific intervention (e.g., lumens and mated surfaces)
  - Minimal (Low risk): all surfaces exposed for cleaning

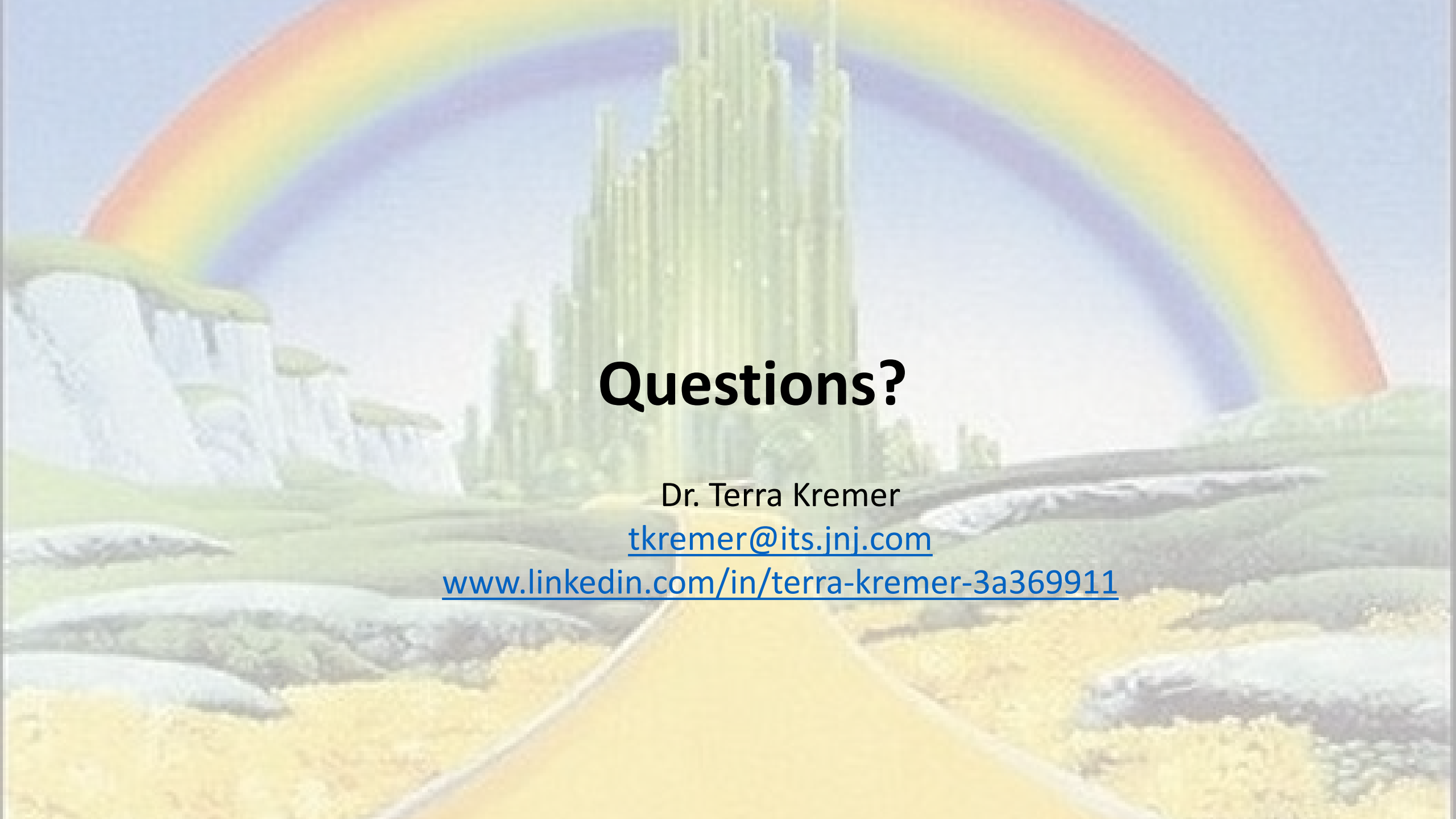
Cleaning Families Established

Kremer Classification Benefits

- Increased processing efficiencies and compliance within Sterile Processing Departments
- Complement the Spaulding Classification to ensure cleaning focus and develop cleaning families
- Communication of cleaning risks with reusable medical devices
- Improve and standardize instructions for use (IFU)

Conclusion





Questions?

Dr. Terra Kremer
tkremer@its.jnj.com
www.linkedin.com/in/terra-kremer-3a369911