Time is Running Out

Importance of Environmental Conditions During Transport and Storage of Soiled Medical Devices

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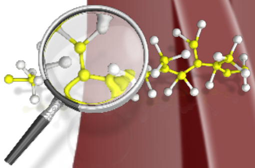
Objectives

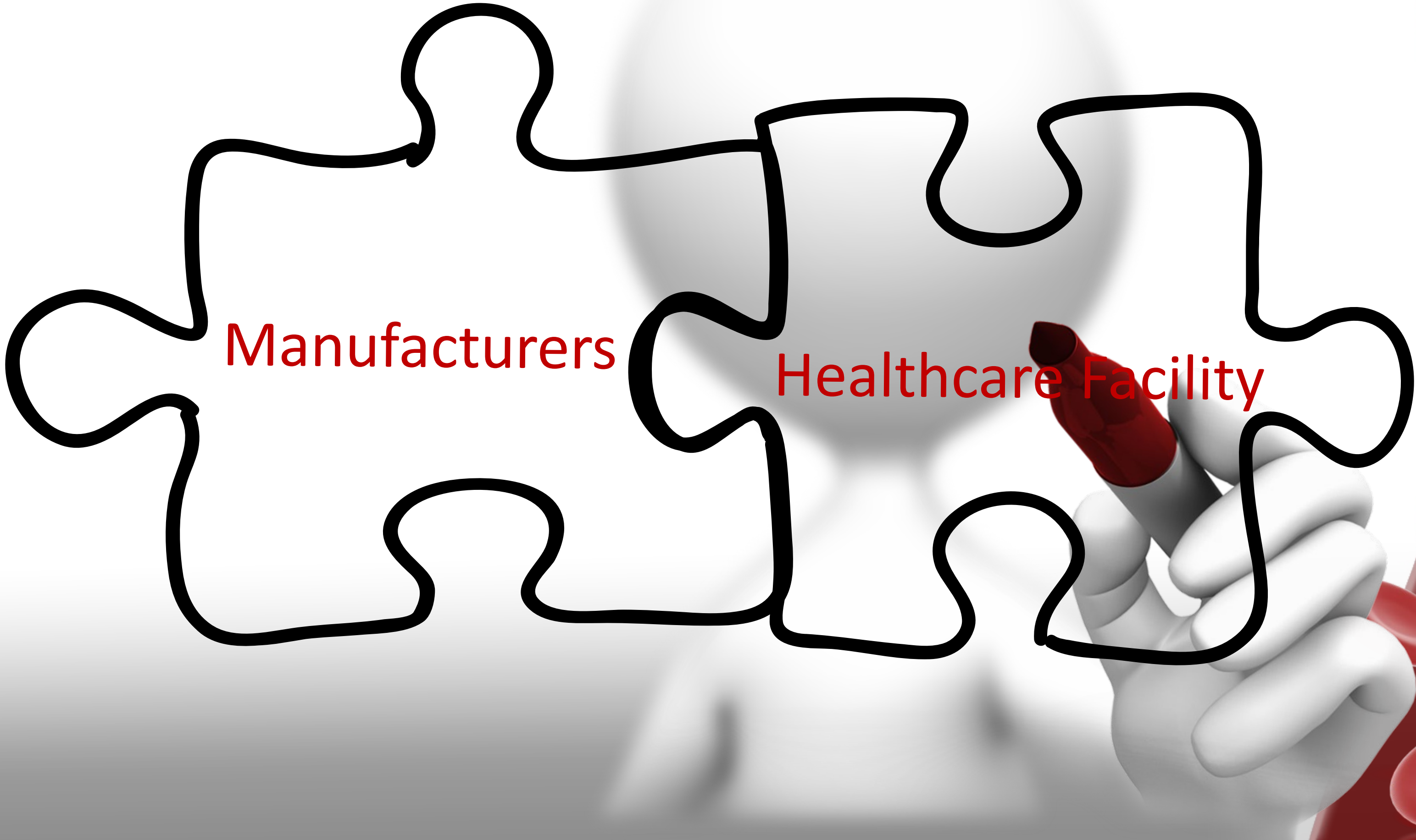
1. Risk of Dried Soil

2. Chemistry Changes

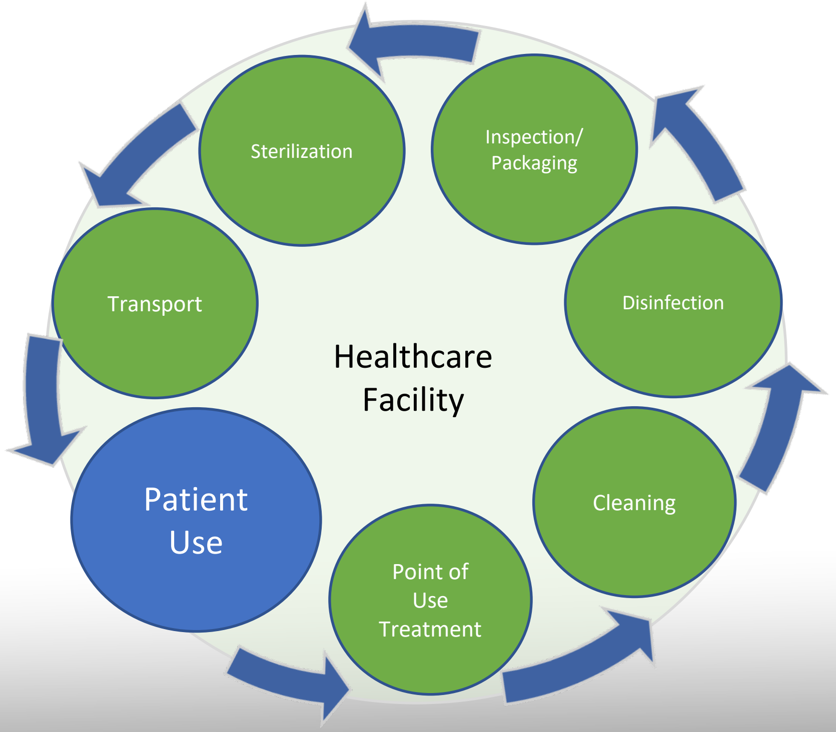


3. Environmental Impacts of Drying

Device Performance Responsibility



Device Processing Cycle



Decontamination Processes Manual Cleaning & Preparation for Mechanical Cleaning

- Remove gross soil
- Instruments opened & disassembled
- Use of fresh cleaning solution
- Use non-linting clean cloths & appropriately sized clean brushes
- Rinse with critical water
- Dry with clean non-linting cloths & critical final water rinse

Photo used with approval from Sue Klacik, HSPA

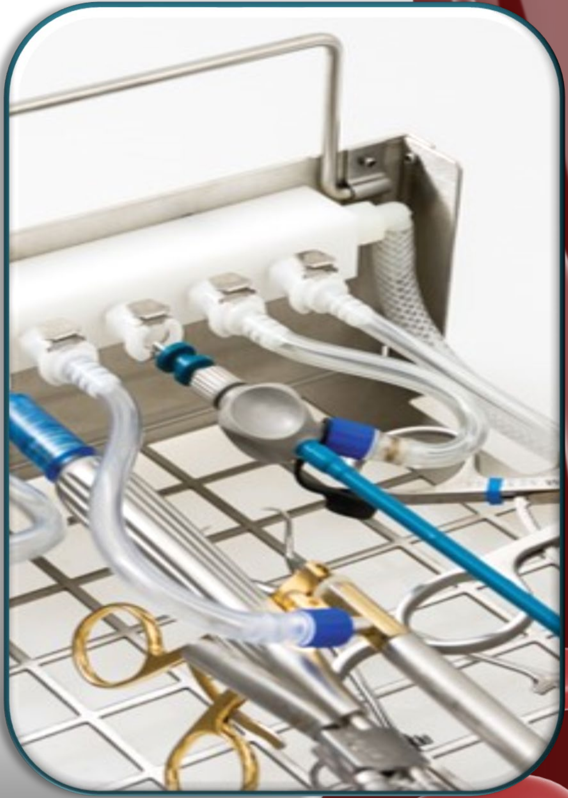
Process for Ultrasonic Cleaner

Used for fine cleaning to remove soil from joints, crevices, lumens, and other areas that are difficult to clean by other methods.

Instruments placed:

- in an open position & disassembled
- remove rubber or silicone mats
- when required, connect lumen devices to flushing ports by tubing and adapters

Photos used with approval from Sue Klacik, HSPA



Process for Washer-Disinfector

- Instruments opened & disassembled
- Instruments placed into wire baskets
- Separate multi-level sets
- Items placed for spray cleaning & drainage
- Hold down screens used for lightweight items
- Spinning arms checked for clearance and spray obstruction
- Correct cycle selected

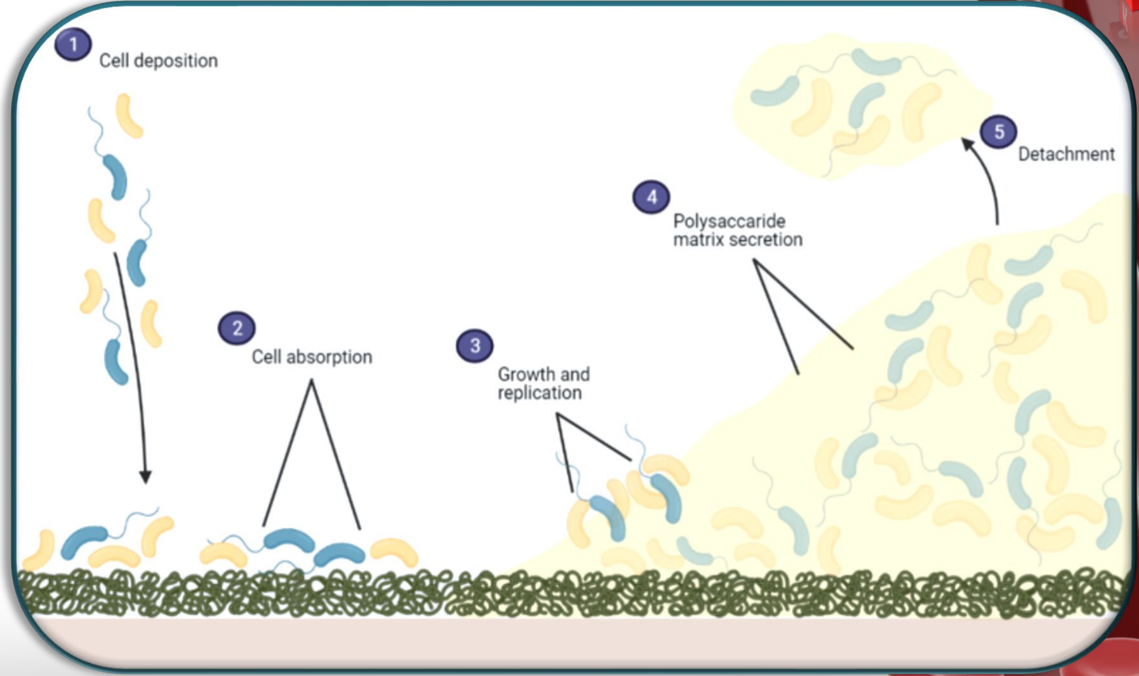
Photo used with approval from Sue Klacik, HSPA

Bottleneck Washer Capacity Issues

- Automated washer cycle time averages 35 minutes
- Average amount of instrument sets per load 6-8
- Loaned sets are completely disassembled including the outer containment system & lid are processed separately.

Photo used with approval from Sue Klacik, HSPA

What is Bioburden?

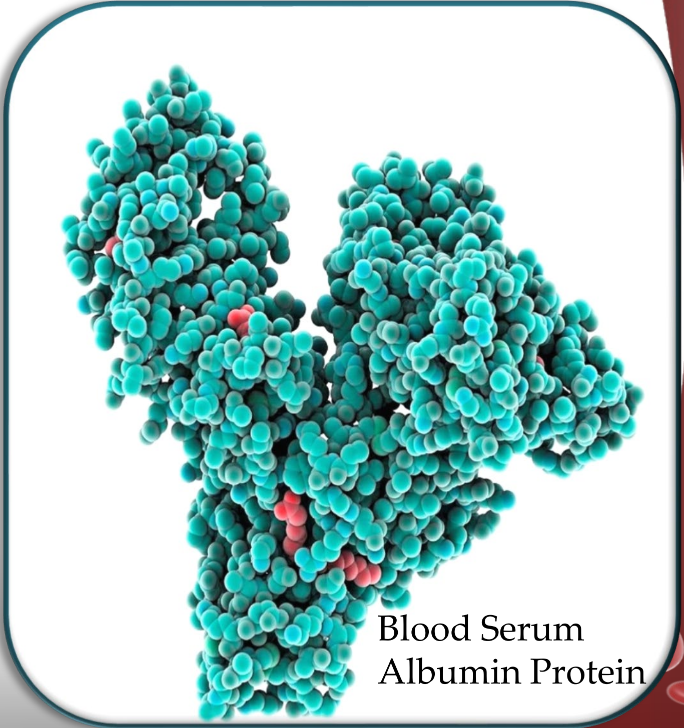


Open-source image: https://particle3d.com/biofilms-and-their-medical-importance/

Patient Safety - Disease

Microorganism

Residual Soil



Blood Serum
Albumin Protein

How Clean is Clean?

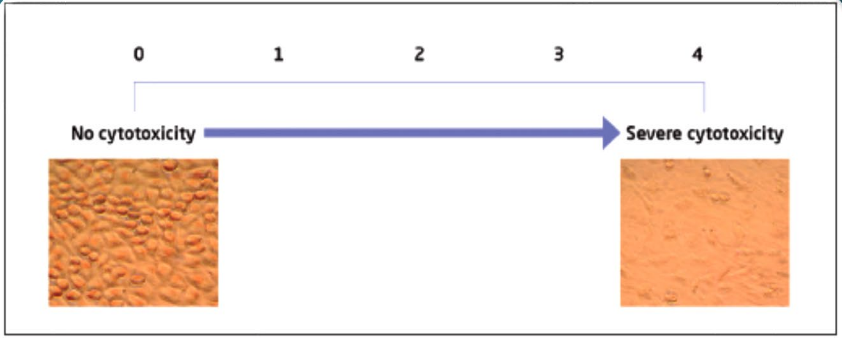
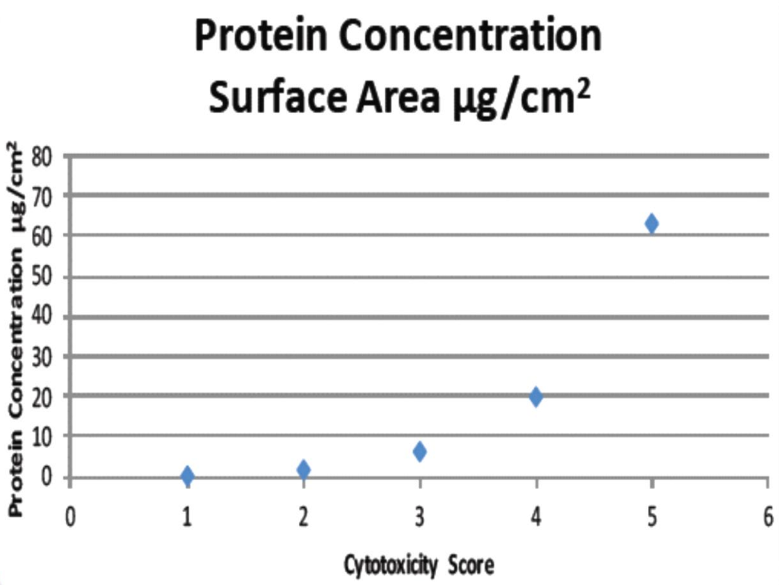
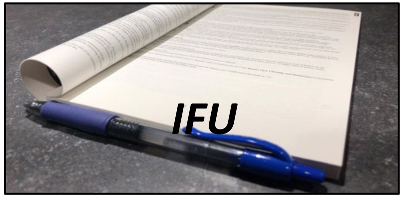


Figure 1: A summary of the cytotoxicity scale, based on the test methodology defined in ISO 10993-5. Note that a score of <2 is typically considered non-cytotoxic (11).

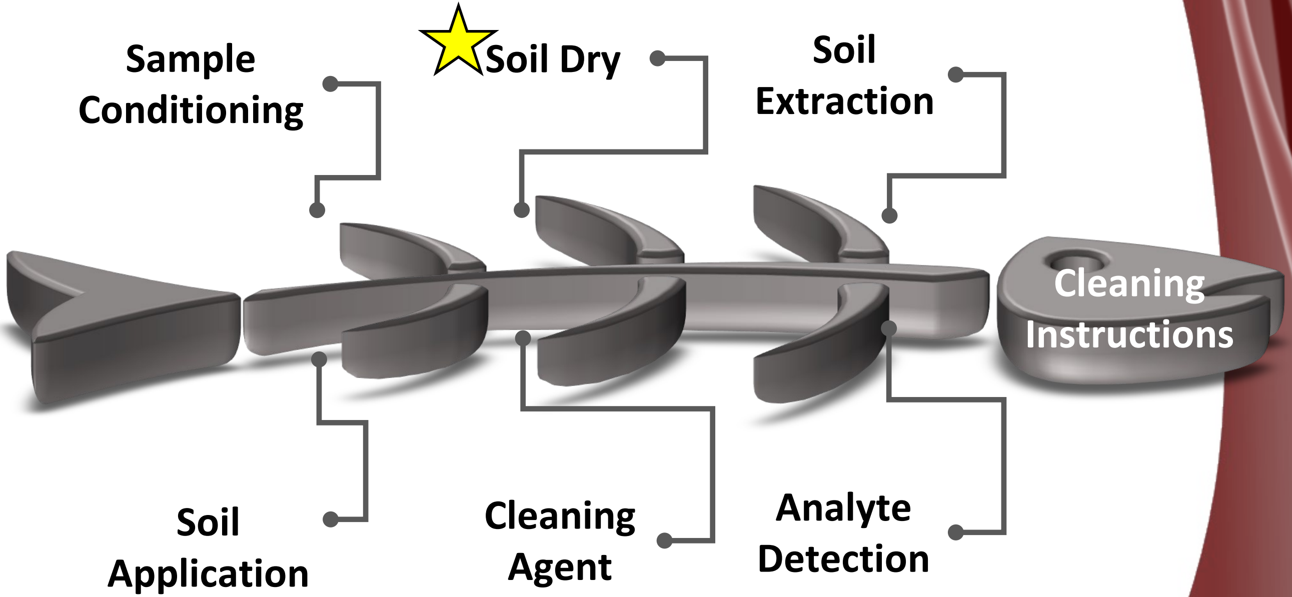


Kremer et. al., Protein Residuals on Reusable Medical Devices and Patient Safety Impact. Zentralsterilization. 27 (3). 2019. 178-183

Mitigating Risk



*Validation Excludes Point of Use Cleaning

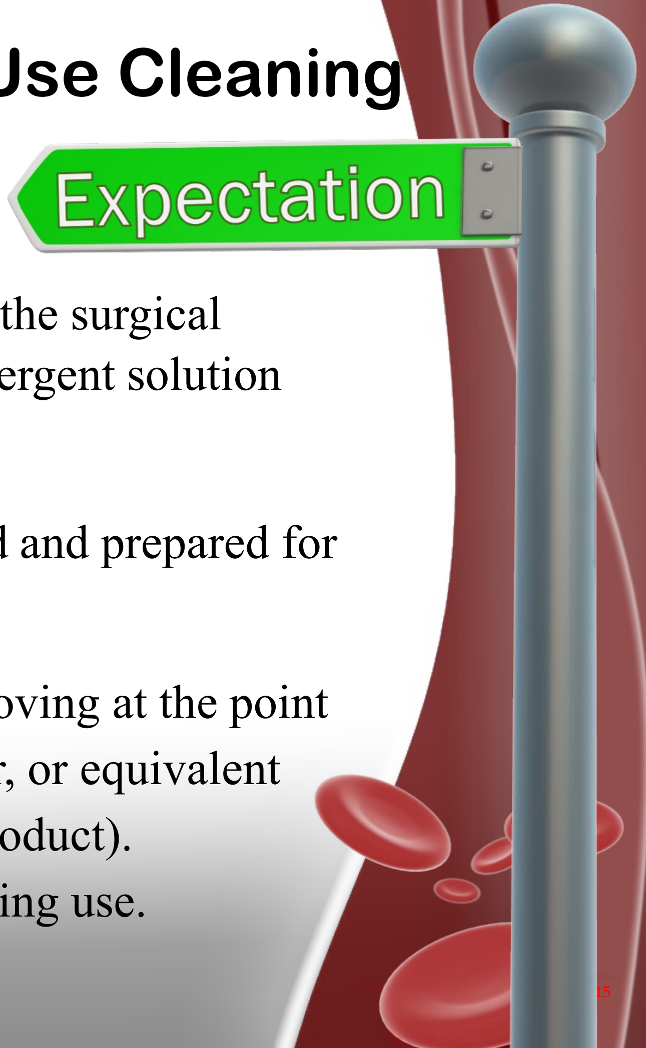


Manufacturer’s Cleaning Validation


Reality
Expectation

IFU Example Wording – Point of Use Cleaning

Don't let the soil dry!



- Remove visual blood and/or debris from device following the surgical procedure by wiping and/or immersion with water or a detergent solution labelled and prepared for use for devices

- Flush all lumens with water or a detergent solution labelled and prepared for use for devices

- Prevent residual soil from drying on surfaces by either removing at the point of use, covering with a towel dampened with purified water, or equivalent procedure (e.g., immersion in water or a detergent-based product). Reprocessing should be initiated as soon as possible following use.

How Dry is Dry in a Cleaning Validation?

Minimum of 1hr

Visually Dry

Dry to the Touch

No Cracking / Lifting

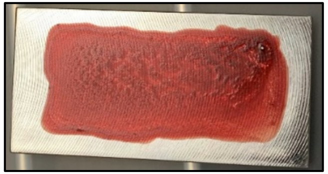
How Dry is Dry Really?

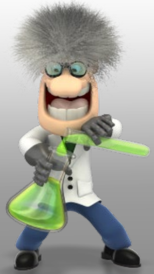
Reality

Problem Statement: How long does is take for water to evaporate from soil under ambient conditions?

Surrogate Device

Coupon





Step 1: Devices Prepped
- Cleaned Devices
- Weighed

Step 2: Devices Soiled
- Max thickness – 0.22g
- Worst Case Soil – Modified Coagulated Blood

Step 3: Devices Dried
- N=25 for each time point
- Time (hr.)= 0.5, 1 ,2, 3, 4, 6, 19, 24, 48, 72

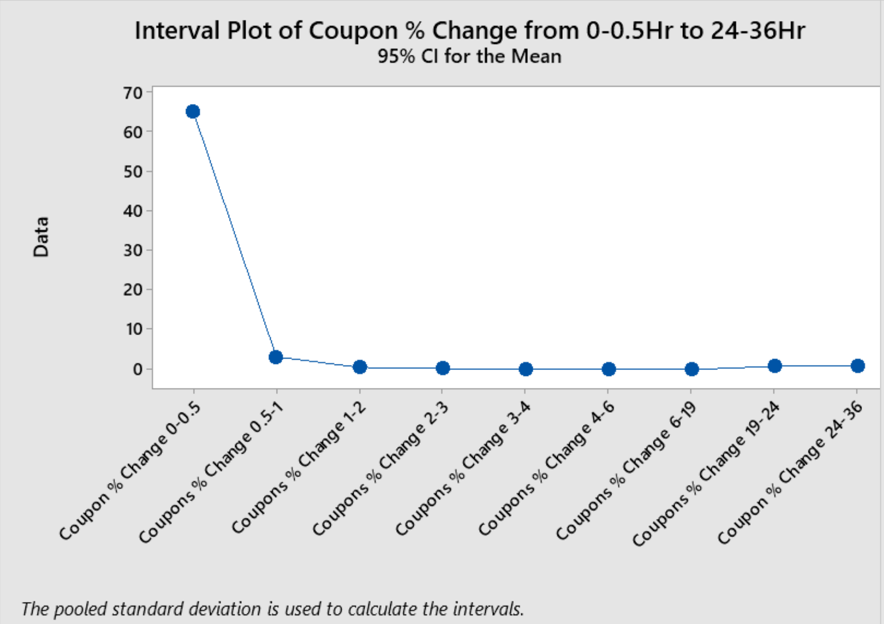
Step 4: Devices Weighed
- Weighed at each time point tested

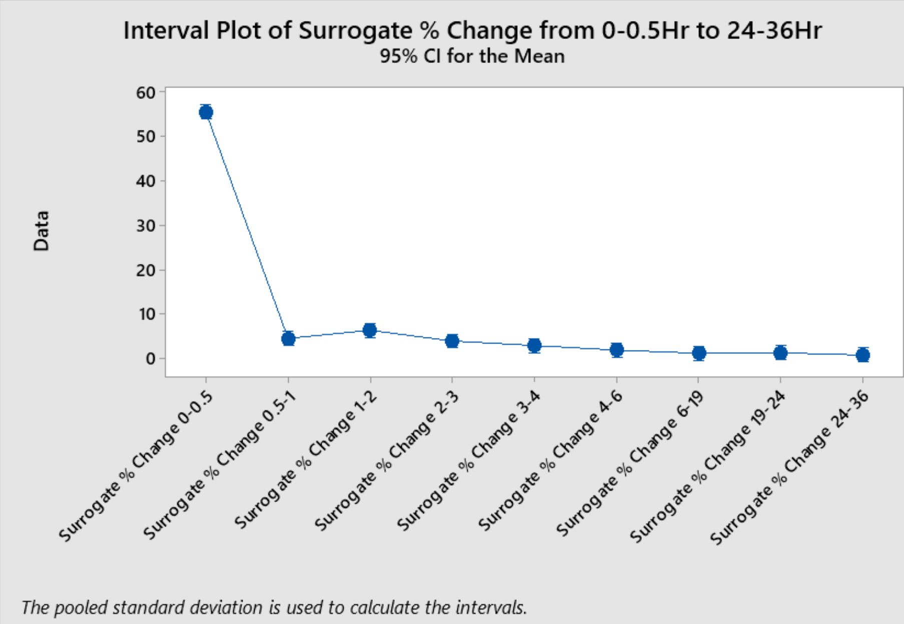
Step 5: Loss on Drying Calculation
- At what point does the weight become statistically stable?

How Dry is Dry Really?

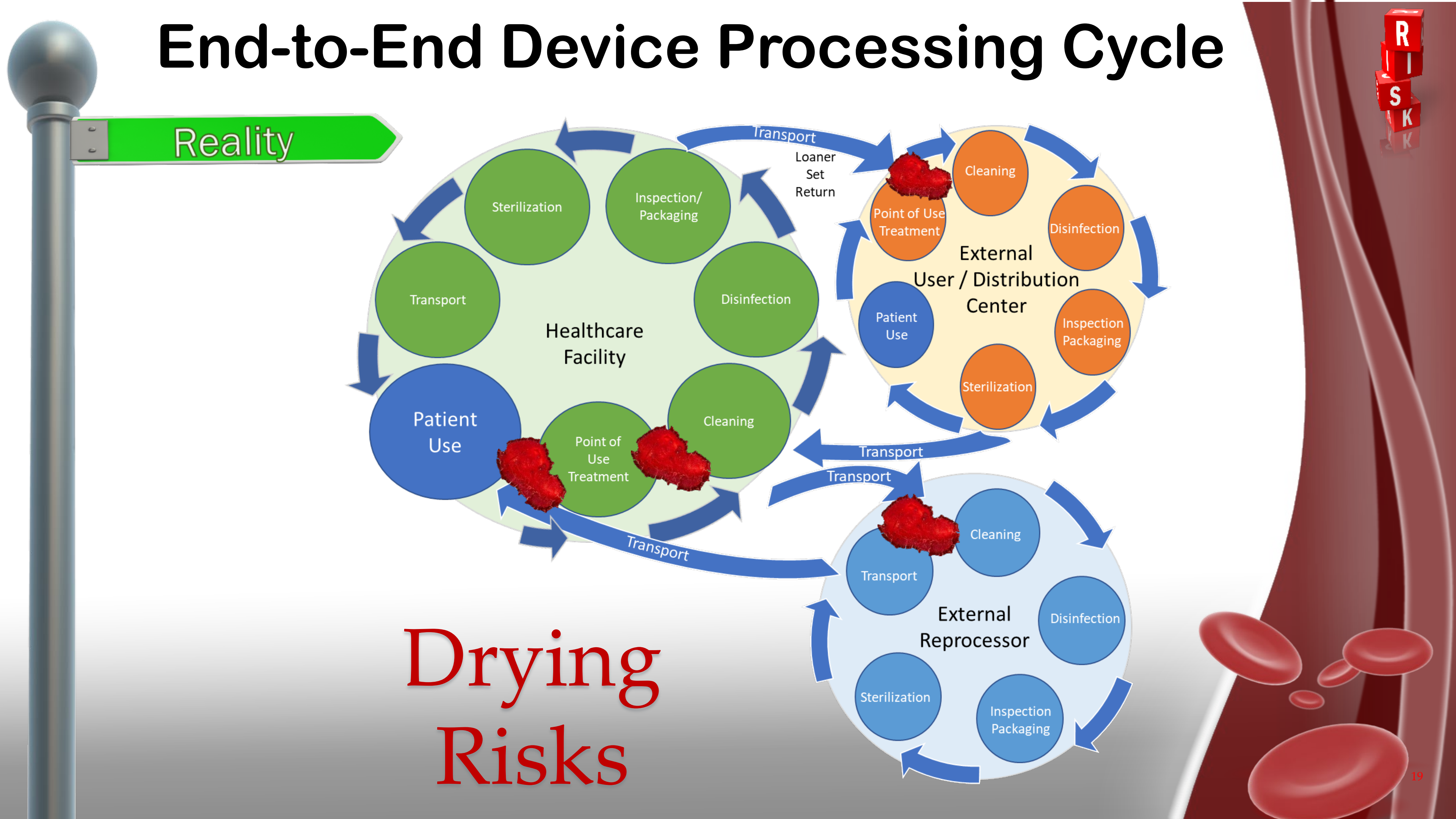
Most water evaporates from the soil during the first 30 minutes.

Experiment Conclusion: No statistical difference for change in moisture after 1 hour dry (p-value= 0.134) for the coupons and 4 hours dry (p-value= 0.277) for surrogate device.





End-to-End Device Processing Cycle



Drying Risks

Receiving in Decontamination

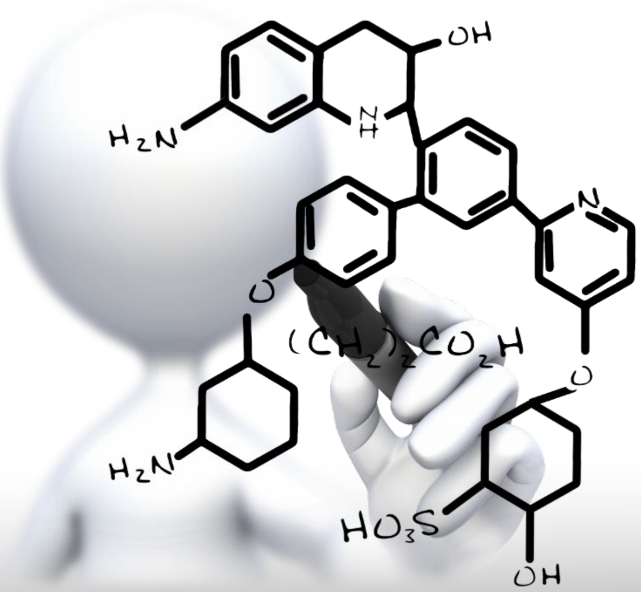
Reality

Contaminated instruments may sit for long periods of time before undergoing cleaning processes to remove protein

Photo used with approval from Sue Klacik, HSPA

Does DRY time matter for Cleaning?

Cleaning is Chemistry

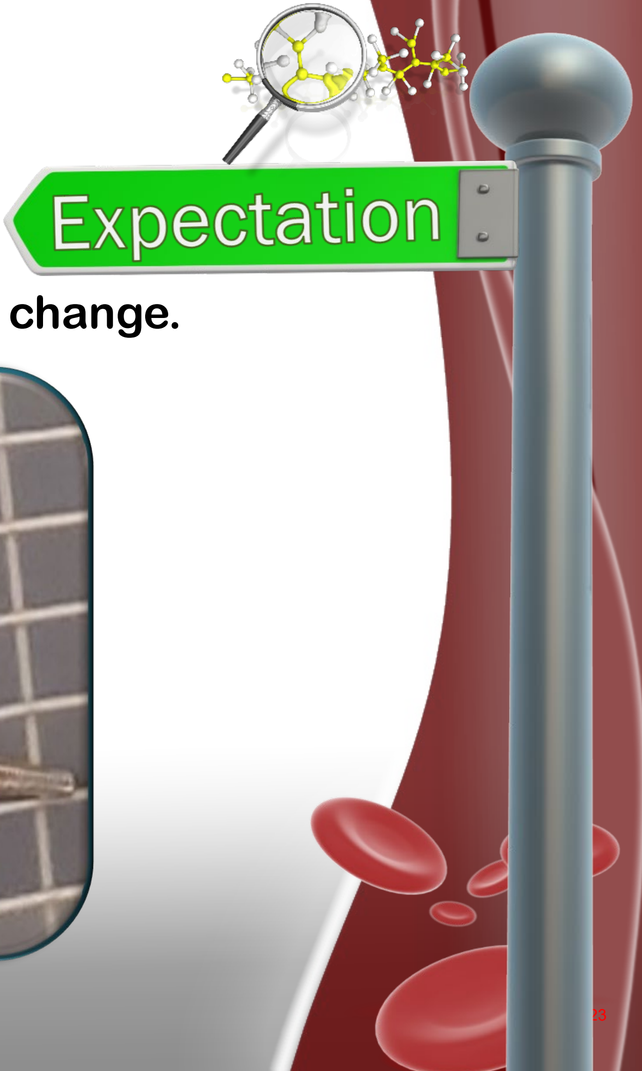


- Soil Composition
- Water
- Cleaning Agents

Solubility: The ability to be dissolved, especially in water.

Dry is Dry

Once soil is dry the challenge to cleaning does not change.

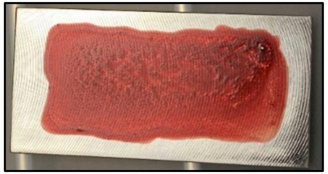


Is Dry Really Dry?

Problem Statement: What effect does time have on the solubility of dry soil?

Surrogate Device

Coupon



Step 1: Devices Prepped
- Cleaned Devices
- Weighed

Step 2: Devices Soiled
- Max thickness – 0.22g
- Worst Case Soil – Modified Coagulated Blood

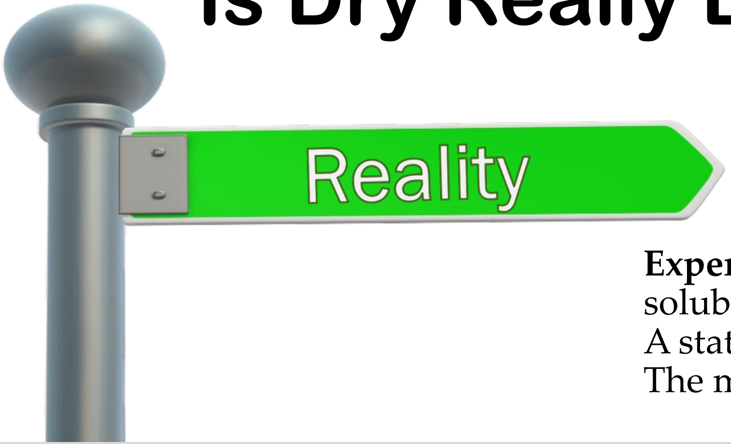
Step 3: Devices Dried
- N=12 for each time point
- Time (hr.)= 1 ,2, 4, 6, 8, 15, 19, 24, 48, 72

Step 4: Solubility
- Devices Weighed
- Soak devices in 45°C water for 60 min

Step 5: Post Extraction
- Dried samples >24 hours
- Devices Weighed

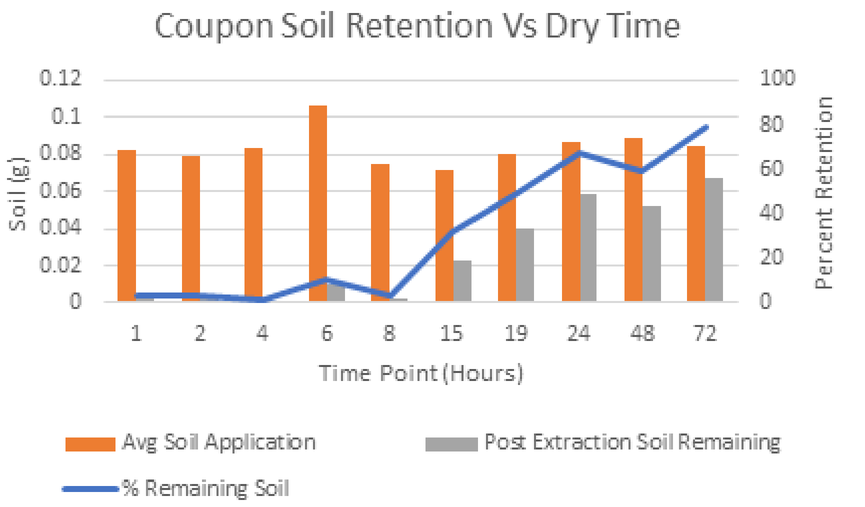
Step 6: % Soil Remaining
- Calculate % soil remaining.

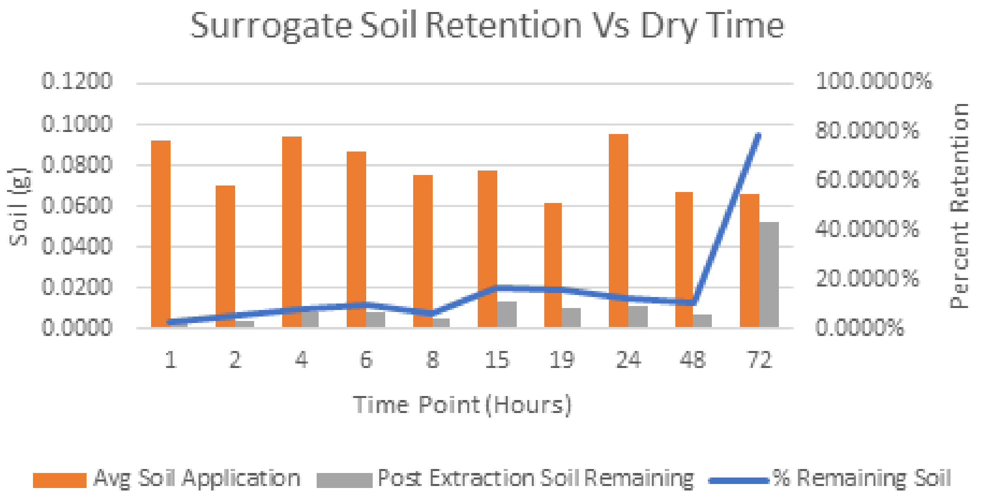
Is Dry Really Dry?



Dry is dry for the first 8 hours, and then the solubility of soil changes.

Experiment Conclusion: No statistical difference for change in solubility between 1 and 8 hours of dry (p_{value} =0.041 for surrogate). A statistical difference was demonstrated between 8 and 15 hours. The most retention of the soil was observed at 72 hours.





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

Processing Delays

Reality

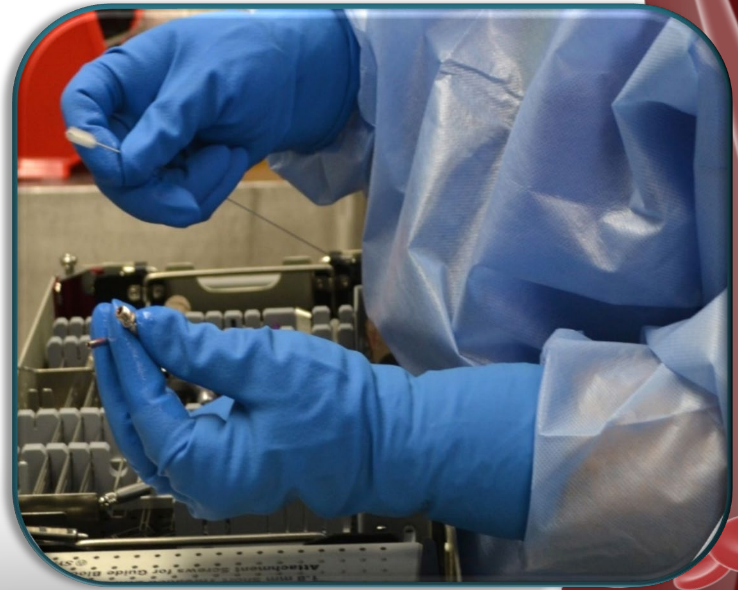
- Unpredictable receiving volume
- Completion of surgical cases
- Receipt of loaned instrumentation
- Equipment from nursing units
- Instrumentation from nursing units
- L&D instrument sets
- Crash cart
- Instrumentation from clinics
- Flexible endoscope processing

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

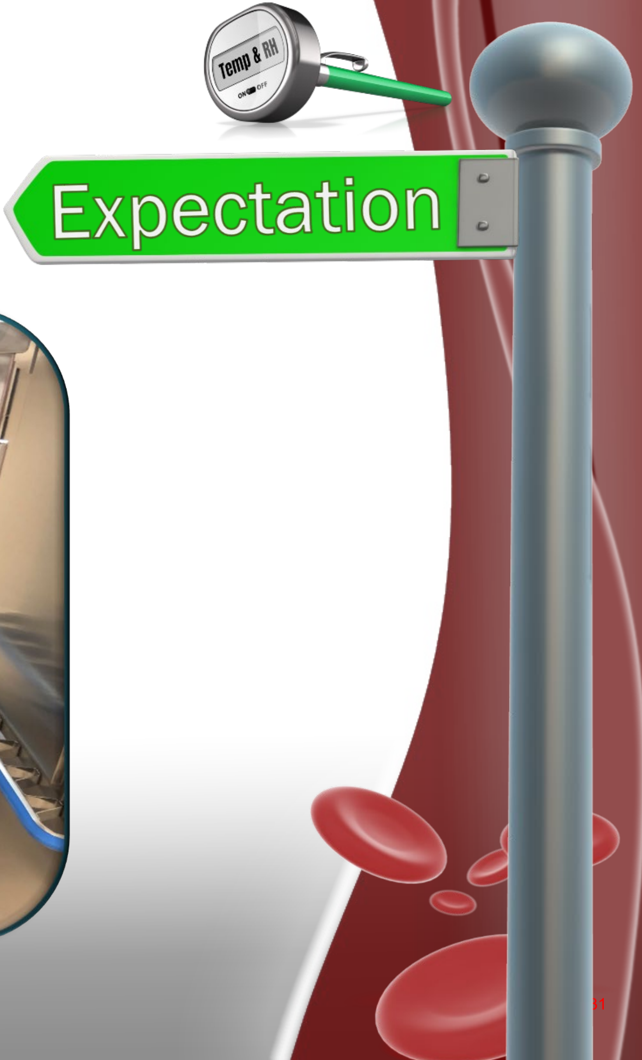
- Inadequate staffing due to:
- Staffing levels
- Priority issues
- Difficult to predict receipt of contaminated items
- Complex IFUs
- Time to don PPE

Photo used with approval from Sue Klacik, HSPA

Do Environmental Conditions Matter for Cleaning?

Ambient Conditions

Devices are stored under ambient conditions during all phases of device processing cycle.



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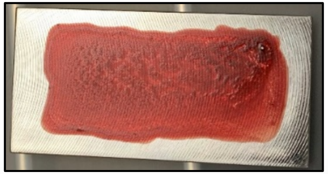
Does Temperature Matter?

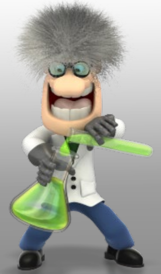
Reality

Problem Statement: What effect does temperature have on the solubility of dry soil?

Surrogate Device

Coupon





Step 1: Devices Prepped
- Cleaned Devices
- Weighed
- N=25 for each temp

Step 2: Devices Soiled
- Max thickness – 0.22g
- Worst Case Soil – Modified Coagulated Blood

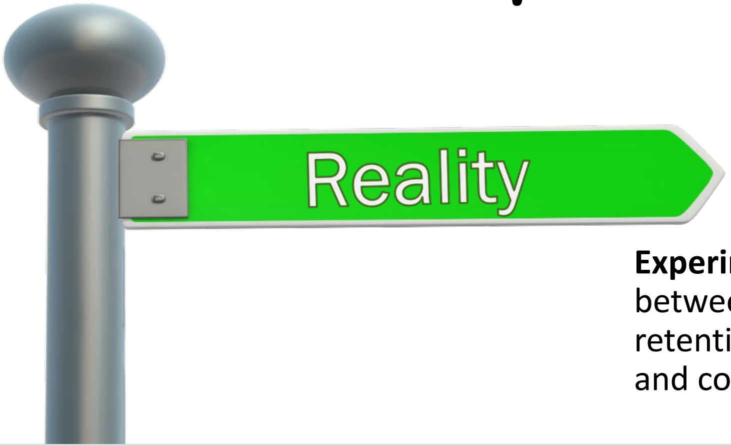
Step 3: Devices Dried 24hr / 50%RH
- Temp (°C)= 4, 11, 22, 35, 45, 55
- Temp (°F)= 39, 51, 71, 95, 113, 131

Step 4: Solubility
- Devices Weighed
- Soak devices in 45°C water for 60 min

Step 5: Post Extraction
- Dried samples >24 hours
- Devices Weighed

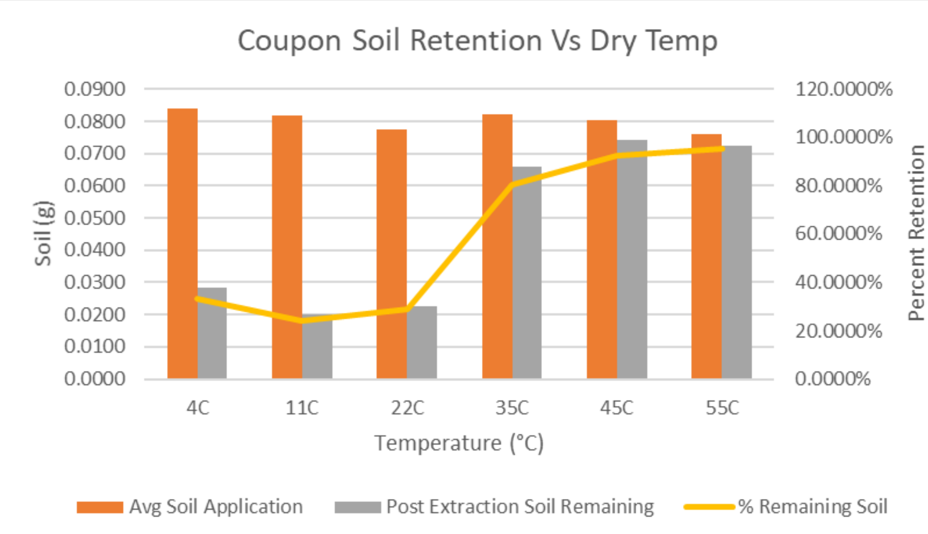
Step 6: % Soil Remaining
- Calculate % soil remaining.

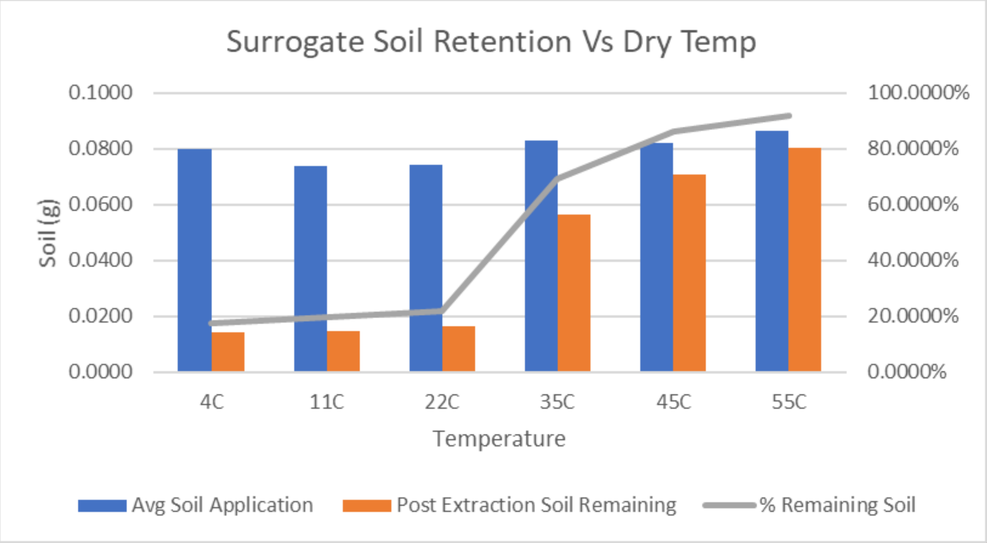
Does Temperature Matter?



Yes - As the temperature rises after 22°C/71.2°F the solubility decreases.

Experiment Conclusion: No statistical difference for change in solubility between 4°C and 22°C (p_{value}= 0.214 for surrogate). After 22°C soil retention increased from 21.9% to 69.3% (surrogate) at the 35°C mark and continued to increase at higher temperatures .





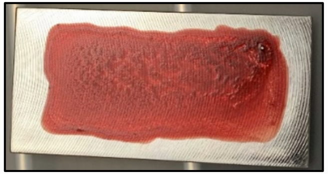
Does Humidity Matter?

Reality

Problem Statement: What effect does humidity have on the solubility of dry soil?

Surrogate Device

Coupon



Step 1: Devices Prepped
- Cleaned Devices
- Weighed
- N=25 for each temp

Step 2: Devices Soiled
- Max thickness – 0.22g
- Worst Case Soil – Modified Coagulated Blood

Step 3: Devices Dried 24hr / 45°C
- Humidity = 30%, 50%, 80%, 100%

Step 4: Solubility
- Devices Weighed
- Soak devices in 45°C water for 60 min

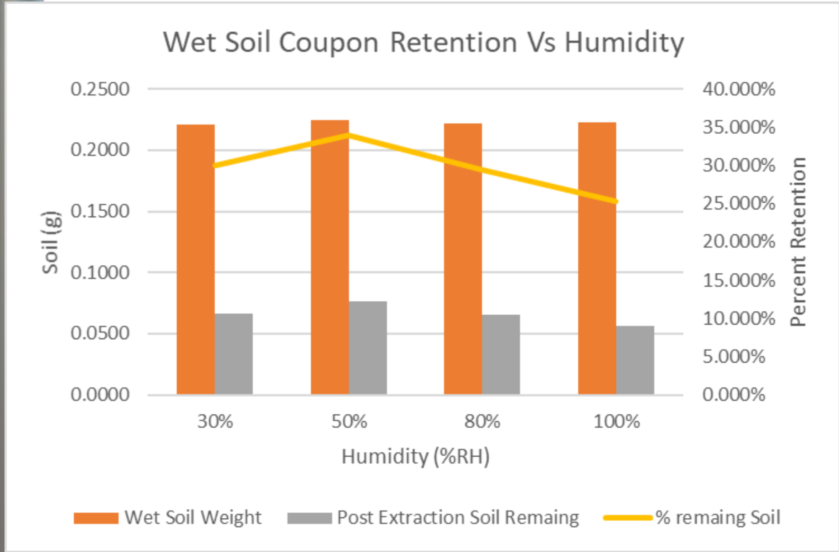
Step 5: Post Extraction
- Dried samples >24 hours
- Devices Weighed

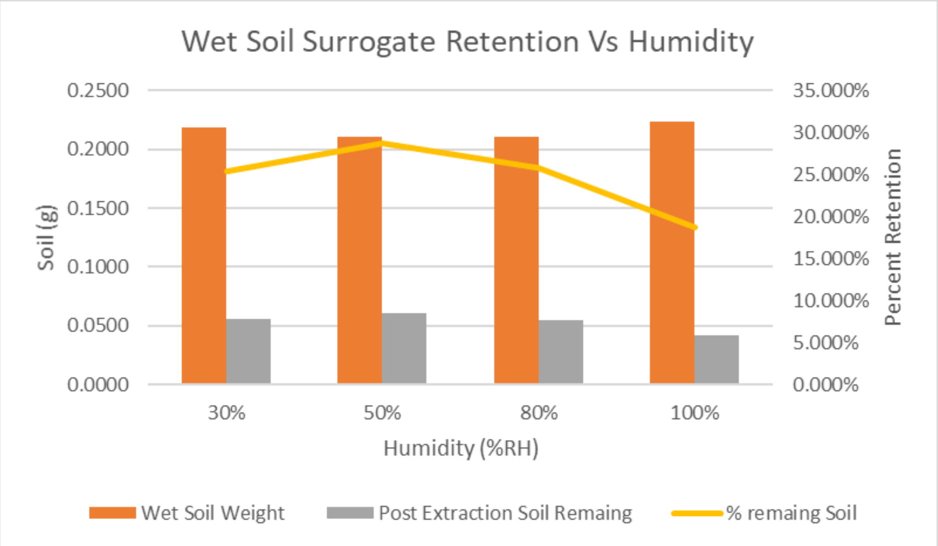
Step 6: % Soil Remaining
- Calculate % soil remaining.

Does Humidity Matter?

Yes - As the humidity increases after 50% RH the solubility increases.

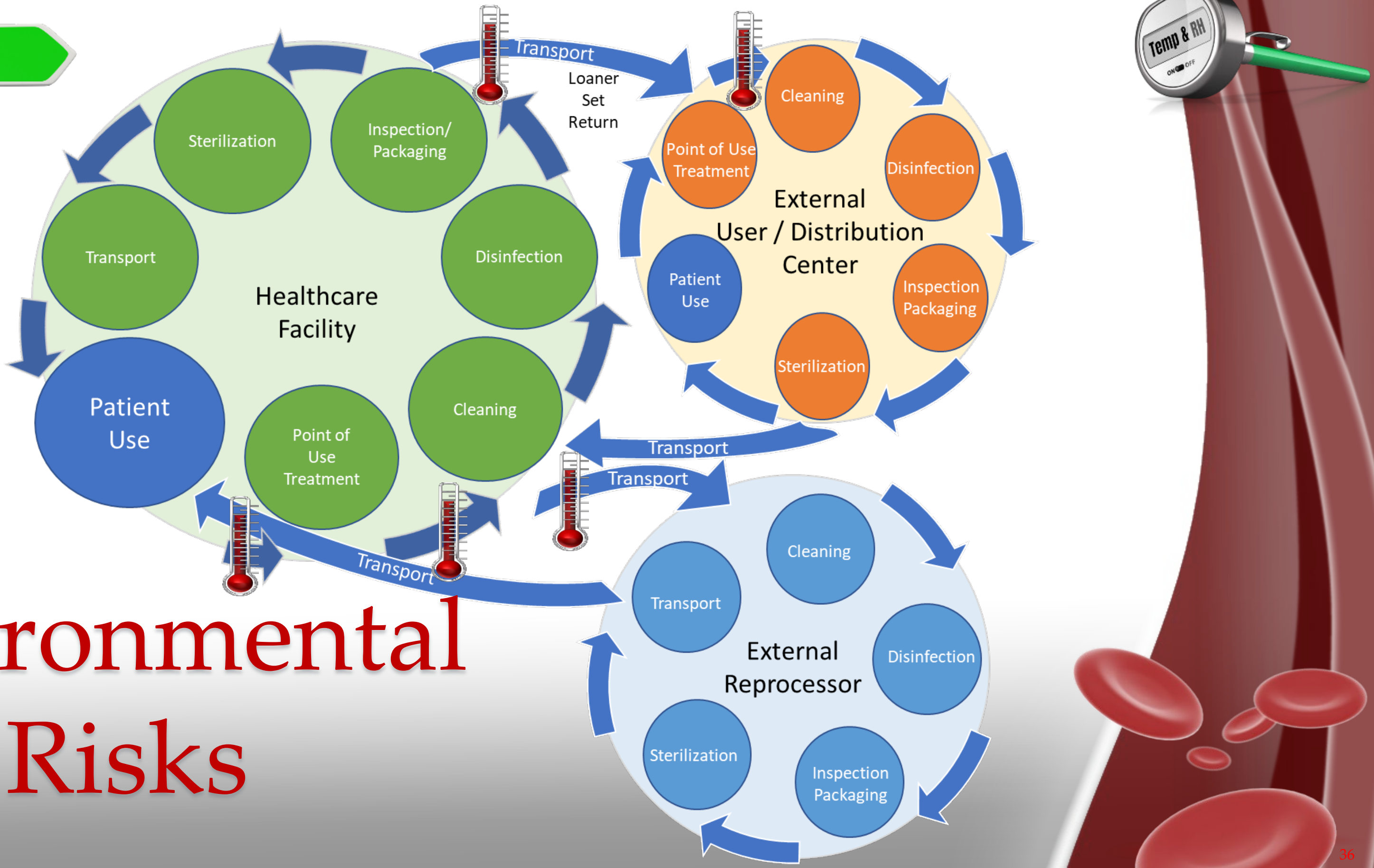
Experiment Conclusion: After 50% RH the soil retention decreases with a negative correlation to increase in humidity. At 100% humidity the soil did not dry.





End-to-End Device Processing Cycle

Reality



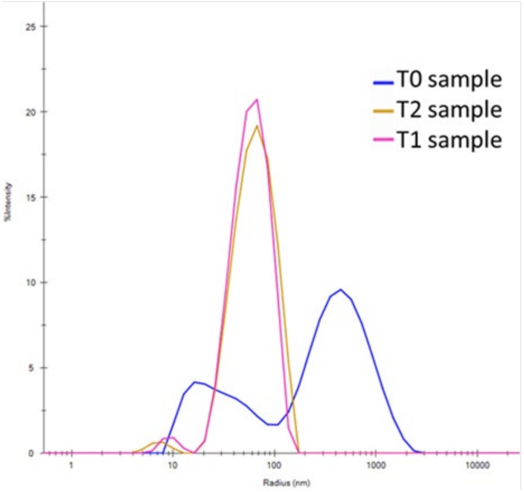
Environmental Risks

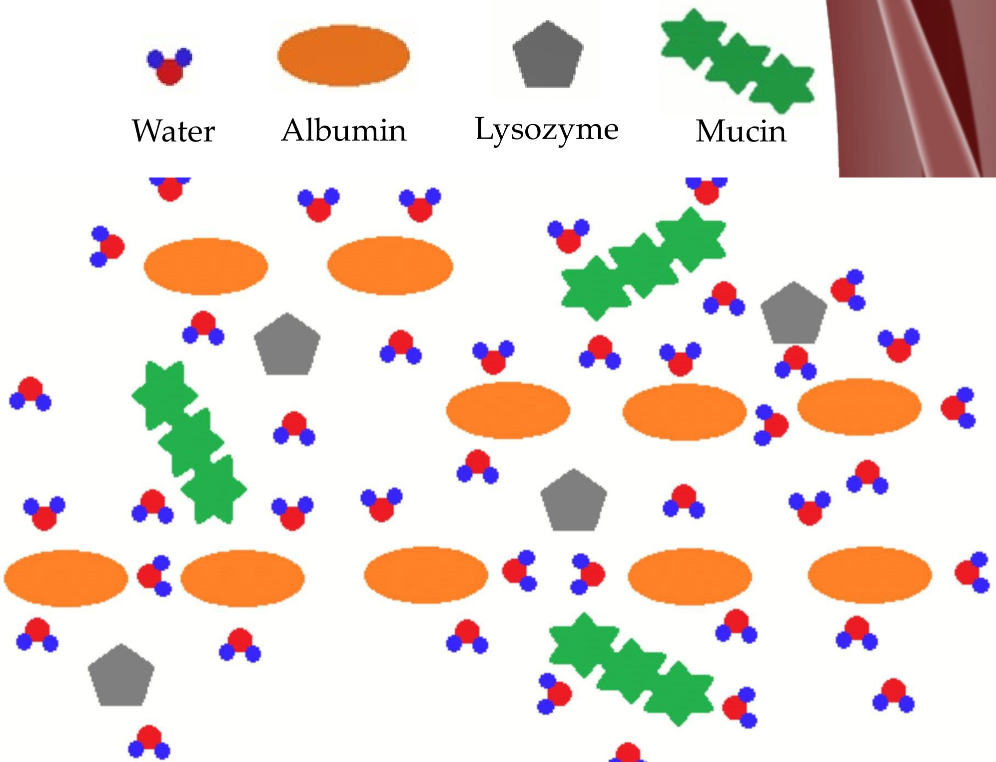
Transport - Conditions

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

Photo used with approval from Sue Klacik, HSPA

How is the Soil Chemistry Changing?





The drying process is a combination of degradation, polymerization and aggregation as water is removed and protein-protein interactions are enabled. The molecular weight distribution changes over time affecting the solubility.

The Domino Effect of Change:

1. Change to IFU instruction validation plan (dry time/ temp) = **More Processing Steps**
2. Increase to cleaning process for Sterile Process = **Longer Cleaning Times**
3. Less throughput in SPD = **More Resources Needed To Process The Same Number Of Cases**

Key Lessons…

Expectations	Reality
Align with manufacturer's cleaning validation for cleaning at point of use	Don't Let Soil Dry
Clean dried soil immediately	Dried soil should be cleaned within 8 hours.
Temperature & Humidity should be controlled	Control Conditions during transport

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/cm², 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

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Chemical Changes Over Time Associated with Protein Drying

Allan Kimble, Christopher Ratanski, and Terra A. Kremer

Abstract

Upon drying, physical changes of the characteristics of proteins are observed by coagulation, but the nature and chronology of these changes have not been well studied. Coagulation changes the structure of protein from liquid to a solid or a thicker liquid by heat, mechanical action, or acids. Changes may have implications regarding the cleanability of reusable medical devices; therefore, an understanding of the chemical phenomena associated with drying of proteins is essential to ensuring adequate cleaning and mitigation of retained surgical soils. Using a high-performance gel permeation chromatography analysis with right-angle light-scattering detector at 90°, it was demonstrated that as soils dry, the molecular weight distribution changes. From the experimental evidence, the molecular weight distribution trends over time with drying to higher values. This is interpreted as a combination of oligomerization, degradation, and entanglement. As water is removed through evaporation, the distance between proteins decreases and their interactions increase. Albumin will polymerize into higher-molecular-weight oligomers, decreasing its solubility. Mucin, commonly found in the gastrointestinal tract to prevent infection, will degrade in the presence of enzymes releasing low-molecular-weight polysaccharides and leaving behind a peptide chain. The research described in this article investigated this chemical change.

The current research investigated the nature of chemical changes that occur when proteins are dried in a manner similar to that which may occur in a clinical processing scenario. By understanding the fundamental changes that occur when soils are dried onto medical device surfaces, the nature of soil solubility changes can be better understood and the processing of reusable medical devices used in surgical procedures adjusted to ensure that more effective removal of surgical soils can be achieved, thereby lowering the patient risk of residual soil remaining on a device after processing. Inadequate cleaning of soiled instruments can result in the retention of blood, tissue, and other biological soils. The debris can allow microorganisms to survive the subsequent disinfection or sterilization process. This can lead to healthcare-associated infections.[1]

Review of Literature

Surgical soils can be a complex combination of liquids, semisolids, and solid materials. Water is essential in the stability, structure, dynamics, and function of proteins and other biomolecules.[2] When these soils are in contact with medical devices, particularly those intended to be cleaned, sterilized, and reused, their removal becomes a primary concern. Depending on how the device is used, a variety of chemical constituents from tissues can remain on the device after patient use. Tissue, including cells, is made up of four biomolecules: proteins, lipids, carbohydrates, and nucleic acids.

Protein is a common constituent found in, for example, bacteria, blood cells, tissue, human secretions, and bone fragments and has been studied to measure the concentration of the soil components after surgical use.[3] Proteins are polymer chains of amino acids that combine to form highly complex structures for which amino acids will interact to form specific folds (e.g., α-helices, β-sheets) called "secondary structures." The secondary structures yet again combine in an additional fold to form a tertiary structure.[4] Surgical soils are chemically diverse mixtures of proteins, carbohydrates, lipids, water, ionic species, and other organic matter.

In their native state (i.e., wet), soils are more manageable with regards to removal. However, almost immediately after their relocation to a device and exposure to the external environment, changes begin to occur that, over time, will render the soils more difficult to remove as they dry. A soiled

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Questions?

The Passion to Protect.
The Power to Prevent.