Surfaces: A Foundational Issue in Infection Prevention

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Learning Objectives

- ✓ Identify how and why surfaces can support biofilm formation and microbial proliferation.
- ✓ Understand why cleaning better may increase patient risk.
- ✓ Learn the importance of asking critical questions BEFORE buying any products.

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Why are we talking about surfaces?

Because surfaces are FOMITES!

- The majority of surfaces within the healthcare environment **cannot be efficiently and effectively cleaned, disinfected, or sterilized.**
- Surfaces support the acquisition and transmission of microbes that cause deadly infections!
- In many cases, they harbor pathogens

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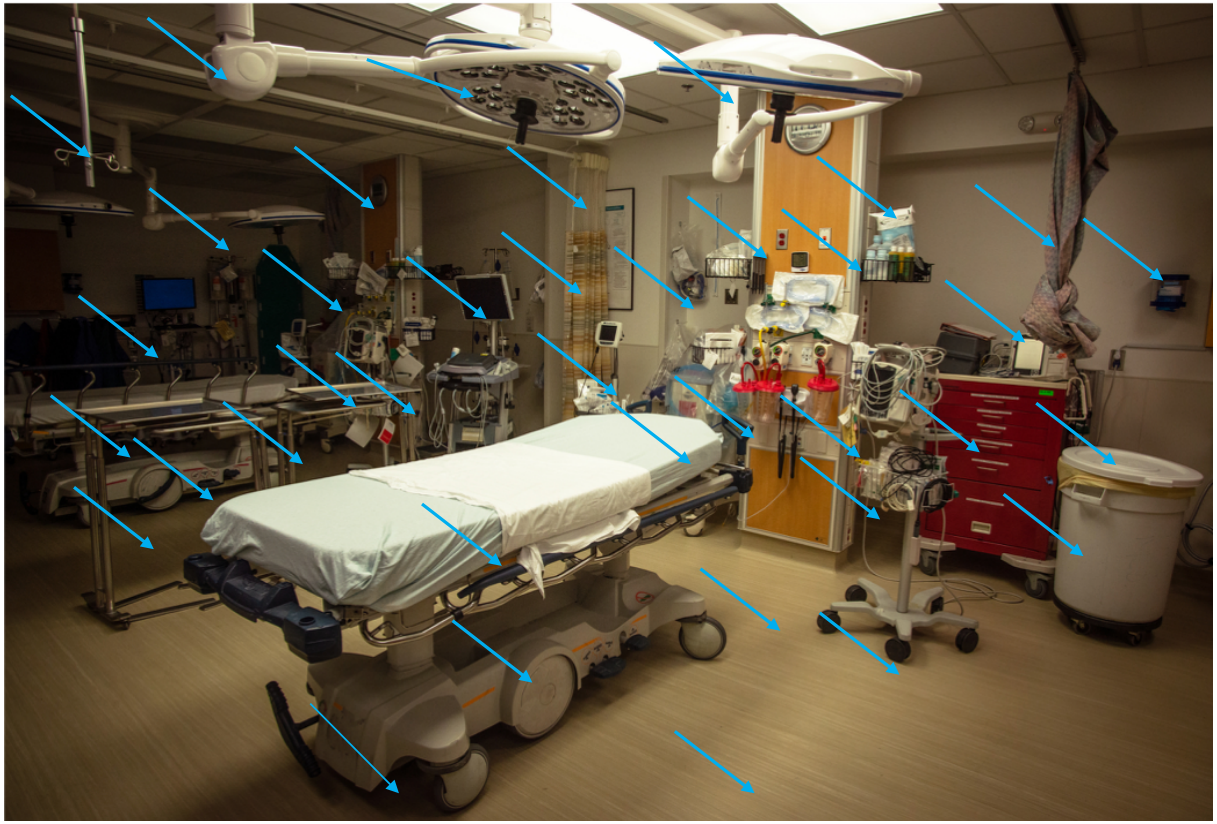
We don’t look at the surfaces!

How many surfaces do you see?

There are hundreds of surfaces in this room



- Combination soft, hard, smooth, textured, porous, and nonporous
- Different surfaces and connections
- Cannot all be cleaned and disinfected the same way
- Can they be cleaned in the allotted time for room turnover?

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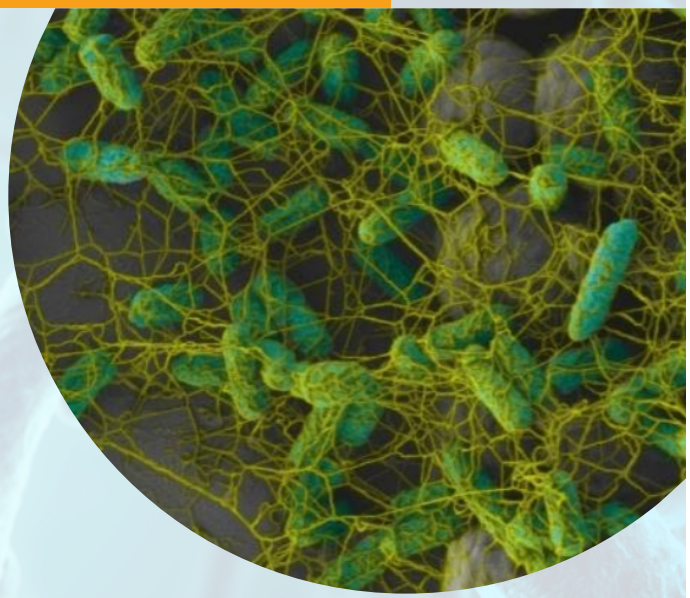
Surfaces harbor unseen pathogens

Biofilm formation



- Biofilms are structured microbial communities attached to surfaces, wet or dry
- It is formed as a result of the microorganism's surface sensing (initial adhesion to surfaces)
- Followed by adhesion and production of extracellular matrix (protection)
- Motility of microbes – can move independently using metabolic energy
- Think of surfaces as microbial reservoirs that support microbial attachment and biofilm formation

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Toilet plume?

How many surfaces are contaminated?

Microbial Attachment

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Surface materials support attachment

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Can the surfaces be cleaned and disinfected?

How do we know?

- There are no guidelines or standards that validate that surfaces can be effectively cleaned and disinfected without causing damage
  - Evaluation must begin with raw materials before design of products
  - Evaluate before construction of the healthcare environment
- Many cleansers and disinfectants are actually damaging the surfaces they are meant to clean and disinfect.
- One of the leading ways microbes move within a healthcare setting is via surfaces

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Transmission of microbes

Cross-contamination occurs in so many ways!

- Floors
- Gurneys
- Wheelchairs
- Medical devices - including IV poles
- Clothing - Healthcare workers and visitors
- Shoes
- Human behavior is unpredictable

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How many different patient care devices do you see?

- Gurney
  - Metal frame
  - Mattress cover
  - Mattress core
  - Sheets
- Backboard – straps
- Rolling cabinets – drawer pulls
- Lights
- Medical devices – monitors

How many types of surface materials and textiles?

Cleaning? Disinfection?

Can all surfaces be cleaned and disinfected the same way in 20-30 minutes to turn the room over?

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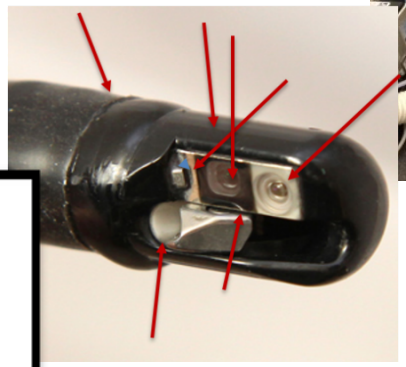
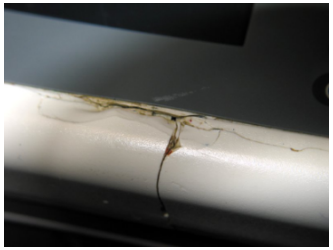
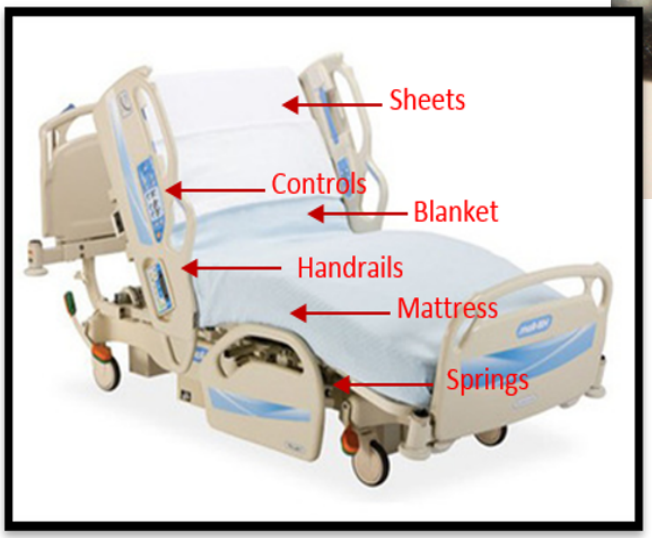
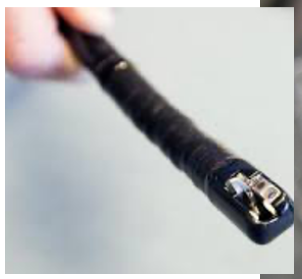
Problem: Microbes cannot be seen

- Seams and connection points
- Formation of microbial reservoirs
- Chemical exposure









We rely on visual assumptions

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It’s complicated

There are many aspects to the problem

- Many different silos of expertise each
  - Raw materials, surface manufacturers, device vendors, disinfectant/chemical companies, environmental managers, facilities, value analysis, etc.
- Conflicting definitions and guidelines for cleaning and disinfection
  - Porous, non-porous, clean, disinfect, sanitize?
- Many different standards organizations and test methods
- Disparities between test methods and pathogens used to validate products
- Fragmented information and guidance

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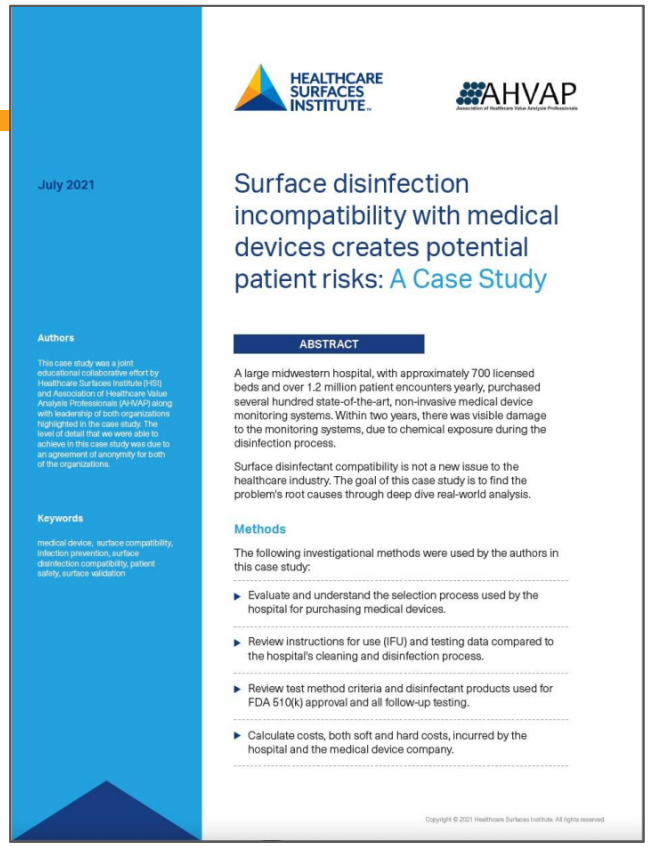
Case study

Discover root causes and gaps

Key findings:

- ✓ Develop a minimum standard
- ✓ Designate a single point of contact
- ✓ Establish a greater understanding of real-life challenges
- ✓ Build awareness around how critical surface selection is
- ✓ Create guidelines for product review and checklists
- ✓ Medical device manufacturers must provide training, including nurses



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AHVAP

July 2021

Surface disinfection incompatibility with medical devices creates potential patient risks: A Case Study

Authors

This case study was a joint educational collaborative effort by Healthcare Surfaces Institute (HSI) and Association of Healthcare Value Analysis Professionals (AHVAP) along with leadership of both organizations highlighted in the case study. The level of detail that we were able to achieve in this case study was due to an agreement of anonymity for both of the organizations.

Keywords

medical device, surface compatibility, infection prevention, surface disinfection compatibility, patient safety, surface validation

ABSTRACT

A large midwestern hospital, with approximately 700 licensed beds and over 1.2 million patient encounters yearly, purchased several hundred state-of-the-art, non-invasive medical device monitoring systems. Within two years, there was visible damage to the monitoring systems, due to chemical exposure during the disinfection process.

Surface disinfectant compatibility is not a new issue to the healthcare industry. The goal of this case study is to find the problem's root causes through deep dive real-world analysis.

Methods

The following investigational methods were used by the authors in this case study:

- Evaluate and understand the selection process used by the hospital for purchasing medical devices.
- Review instructions for use (IFU) and testing data compared to the hospital's cleaning and disinfection process.
- Review test method criteria and disinfectant products used for FDA 510(k) approval and all follow-up testing.
- Calculate costs, both soft and hard costs, incurred by the hospital and the medical device company.

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Manufacturer's frustrations

- Confusion for them as well
  - Testing is expensive
  - No guidelines for minimum standards
  - Not sure how to write Instructions of Use (IFUs)
- Don't completely understand what happens in the healthcare setting
  - Different infection prevention protocols and guidelines
  - Damaged equipment because hospitals don't use what they were told to use
  - Repair and replacement costs are their own

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Confusion in healthcare

- Not all healthcare professionals are included in product purchase discussions
  - Value Analysis Professional
  - Infection Prevention
  - Biomed
  - EVS
  - Directors of Nursing
  - Facilities Management
- Not necessarily a single point of contact
- How many people will be involved with infection prevention and cleaning and disinfection? Are they all trained the same way?

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Infection prevention guidelines

- Accountable Care Act
  - Time Requirements patient care
- Room turnover times
- Daily cleaning
- Outbreak disinfection
- Terminal cleaning

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Seven Aspects of Surface Selection

1. Material and textile selection
   - Compatible with standard EPA-registered hospital-grade disinfectant categories
   - Healthcare facilities set infection prevention, cleaning, disinfection, and reprocessing guidelines. Can those be followed without causing damage to the surfaces in the built environment and equipment used for patient care?
2. Surface assemblies
   - Surfaces are always combined with other surfaces to create a product. That product must be cleaned and disinfected.
3. Location
   - How often are surfaces and medical devices cleaned? Can material withstand those guidelines without damaging materials and products?
   - In high traffic, turnover areas require frequent but effective cleaning and disinfection.
4. Microbiology
   - High contamination, such as ED

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Seven Aspects of Surface Selection

5. Human behavior
   - A focus on high-touch surfaces leaves highly touched surfaces out of the equation
6. Cleaning and disinfection
   - Surface disinfection compatibility and infection prevention guidelines
   - Case study
7. Manufacturer warnings
   - Often have to ask for these, not necessarily in care and maintenance documents and IFU

To create a healing environment, surfaces and products must be able to be cleaned without damage.

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Infection Prevention Guidelines

Instructions for use and care and maintenance

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Manufacturer instructions for use (IFUs)

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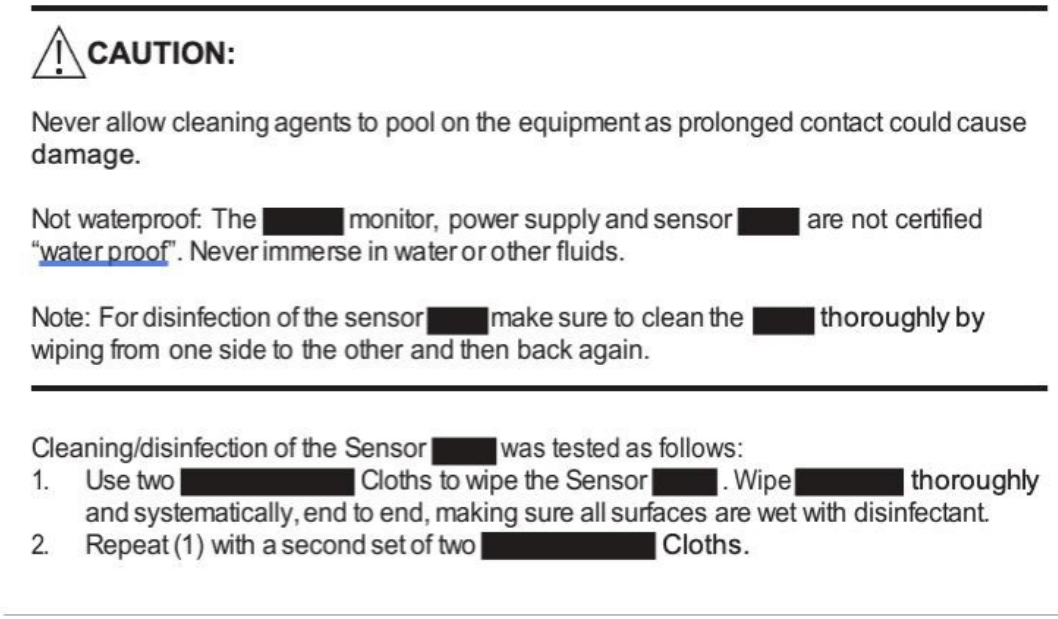
Figure 1. *Monitoring system’s cleaning and disinfection instructions from 2017 instructions for use (IFU)*



⚠ CAUTION:

Never allow cleaning agents to pool on the equipment as prolonged contact could cause damage.

Not waterproof: The [redacted] monitor, power supply and sensor [redacted] are not certified “water proof”. Never immerse in water or other fluids.

Note: For disinfection of the sensor [redacted] make sure to clean the [redacted] thoroughly by wiping from one side to the other and then back again.

Cleaning/disinfection of the Sensor [redacted] was tested as follows:

1. Use two [redacted] Cloths to wipe the Sensor [redacted]. Wipe [redacted] thoroughly and systematically, end to end, making sure all surfaces are wet with disinfectant.
2. Repeat (1) with a second set of two [redacted] Cloths.

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User manual care and maintenance

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Additional information for cleaning agents that were proven to not damage the product (Figure 2), shown through internal repeated cleanability testing, were provided in the user manual.

Figure 2. Monitoring system’s approved cleaning and disinfection agents from the 2017 user manual

The following agents have been tested and can be used to safely clean the [redacted] monitor, power supply, and sensor [redacted] without damaging the equipment.

Agents	[redacted] Monitor	Power Supply	Sensor [redacted]
1% Sodium hypochlorite bleach	✓*	✓*	✓
70% Isopropyl alcohol solution	✓	✓	✓
1.4% Hydrogen peroxide		✓	✓

* Bleach may cause corrosion of the USB, serial port and power socket of the [redacted] monitor. It may also cause corrosion to the power supply connector, which attaches to the monitor. These components can be cleaned with 70% Isopropyl alcohol solution.

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Different infection control guidelines

DECONTAMINATION OF ENVIRONMENT & EQUIPMENTS

NO	ITEMS	CLEANING PROCESS	STAFF RESPONSIBLE
1	Airways/ ventilator tubes	Disposable or disinfect with 100ml of Clorox in 900ml water solution dip for 10 minutes.	Nursing staff
2	Ambu bags	Disposable or disinfect with 100ml of Clorox in 900ml water solution dip for 5 minutes.	Nursing staff
3	Baby Baths	Clean bath after use with detergent and water. Disinfect with 100ml of Clorox in 900ml water solution spray.	House-keeping personnel
4	Bed frames, cradles etc.	Disinfect with 100ml of Clorox in 900ml water solution spray.	Housekeeping personnel
7	Blood-pressure cuff Tourniquets	Clean with damp cloth soaked in detergent and water, dry thoroughly. If contaminated with blood/ body fluids spray with 100ml of Clorox in 900ml water solution.	Nursing staff
8	Ceilings	When visibly soiled, wash with detergent and water.	Maintenance Department
9	Commodes/ urinal	Clean with detergent and water and disinfect with 250 ml of Clorox (pure) contact time 2 minutes.	House-keeping personnel
10	Curtains	Should be laundered at least 6 monthly and when visibly soiled. Some curtains may need to be laundered more regularly (high risk area) If unable to send to central laundry clean with detergent and water.	Nursing staff & Laundry Dept
11	Dressing trolleys	Wash with detergent and hot water and dry before and after use. If contaminated with blood/ body fluids or used for a patient with a transmissible infection refer to policy / guidance. 70% alcohols wipes can be used to disinfect trolley between uses if visibly clean/ use 100ml Clorox in 900ml of water solution spray.	Nursing staff

Generated by **Dr Anjum Hashmi** MBBS, CCS (USA), MPH. Infection Prevention & Control Director and Employees Health Director EAST NAJRAN HOSPITAL, MINISTRY OF HEALTH, NAJRAN KSA. Reviewed By **Al Scoggins** CEO Janus Solutions USA.
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Cleaning and Disinfection

Material	Sodium Hypochlorite (bleach 10%)	Isopropyl Alcohol	Glutaraldehyde (Cidex Plus)
PVC	Good	Good	Good
TPE/TPR	Excellent	Excellent	Excellent
TPU	Poor	Poor	Good
Silicone	Good	Excellent	Good

DILUTION INSTRUCTIONS FOR PRECEPT DISINFECTANT TABLET

KINDS OF INFECTIONS & OTHER PROTECTIVE USAGE	DILUTION RATE / MEASUREMENTS			ADDITIONAL INSTRUCTIONS & PROCEDURES
	0.5 grms.	2.5 grms.	5.0 grms.	
Blood Spillage / Body Fluids	18 Tablets in 0.5 liters water	7 Tablets in 1 liter water	9 Tablets in 2.5 liters water	Pour over blood. Using gloves wipe up with disinfectant saturated disposable cloth.
Pipette Jars	9 Tablets in 1 liter of water	9 Tablets in 5 liters of water	9 Tablets in 10 liters of water	Drop tablets into water filled pipette jar. Discard daily
Gen.Laboratory / Invironmental Use	4 Tablets in 1 liter of water	4 Tablets in 5 liters of water	3.5 Tablets in 10 liters of water	Wipe down surfaces with disposable disinfectant saturated disposable cloth.
Stainless Steel Instruments	1 Tablet in 0.5 liters water	1 Tablet in 2.5 liters of water	1 tablet in 10 liters of water	Immerse for 1 hour.
Baby Bottles Teats / Stainless Steel Utensils, Porcelain, Glassware, Rubber & Plastic Tube	1 Tablet in 2 liters of water	1 Tablet in 10 liters of water	1 Tablet in 20 liters of water	Immerse for 1 hour.
Eating Utensils & Crokery	1 Tablet in 2 liters of water	1 Tablet in 10 liters of water	1 Tablet in 20 liters of water	Rinse for 1 to 2 minutes
Soiled or Infected Linen	1 Tablet in 2 liters of water	1 Tablet in 10 liters of water	1 Tablet in 20 liters of water	Immerse for 1 hour prior to washing
Work Surfaces, Closets, Floors, etc..	1 Tablet in 2 liters of water	1 Tablet in 10 liters of water	1 Tablet in 20 liters of water	Wash down
Dish Cloths, Mops, etc	1 Tablet in 4.6 liters of water (1 gal.)	1 Tablet in 23 liters of water (5 gals.)	1 Tablet in 46 liters of water (10 gals.)	Soak to bleach clean and deodorize.

Cleaning and disinfection products

And WHO is doing the cleaning and disinfecting?

- No library of disinfection products
  - Cleaning and disinfection process based on microbes
- Number of products on Environmental Services professionals' cart
- Nursing #1 focus – patient care
- Visitors grab cloths, wipes

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A typical cleaning cart has limited products

What works for some surfaces doesn't work for others.

"Provide me with the name of the disinfectant you use, and I will put it on our letterhead."

A manufacturer rep of medical device

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Case Study: FDA Recall of Medical Device

Date Initiated by Firm	January 07, 2022
Create Date	February 08, 2022
Recall Status[1]	Open[3], Classified
Recall Number	Z-0570-2022
Recall Event ID	89327
510(K)Number	K152675
Product Classification	Set, administration, for peritoneal dialysis, disposable - **Product Code** KDJ
Product	Baxter MiniCap Extended Life PD Transfer Set (Easy-Lock), 5C4449
Code Information	All lot numbers within expiry
Recalling Firm/ Manufacturer	Baxter Healthcare Corporation 1 Baxter Pkwy Deerfield IL 60015-4625
For Additional Information Contact	Center for One Baxter 800-422-9837
Manufacturer Reason for Recall	Cleaning products, containing, but not limited to, hydrogen peroxide, bleach, alcohol, or antiseptic agents and solvent, such as those containing acetone, toluene, xylene, or cyclohexanone may cause damage, such as leaking or cracking, to the MiniCap Extended Life PD transfer sets.
FDA Determined Cause [2]	Other
Action	Baxter disseminated a Urgent Medical Device Correction letter on 7 January 2022 to peritoneal dialysis centers and will follow with notice to the patients on 12 January 2022. The notices warned that the use of cleaning products and solvents may cause damage (for example, leaking or cracking), if they come into direct contact with the transfer set. Baxter will be updating the Instructions for Use (IFU) to include a warning against the use of these cleaning products and solvents. For general questions regarding this communication, contact Baxter Corporate Product Surveillance at 800-437-5176.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=191272

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How do we facilitate change to address the issue?

Through collaboration, testing and standards

- We need to bring together all the different groups working on surfaces to improve the situation: raw materials, manufacturers, healthcare workers, researchers, testing labs, and more.

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5 steps you can take now

1. **Designate a single point of contact within your healthcare organization** to facilitate collaboration between manufacturers and healthcare professionals, and to communicate important matters to all parties. Typically a value analysis professional.
2. **Create guidelines for product review before purchase and checklists** for healthcare selected teams within the healthcare setting that provides them with needed information for product value analysis professionals.
3. **Ask hard questions at the design, review and evaluation stage** of any equipment, material, device or surface to be used in the facility. Ask questions about cleaning and disinfection compatibility.
4. **Push your manufacturers to show research done on the surface materials** and how the materials were used in real-world settings, not just laboratory clean rooms.
5. **Ask your Medical device suppliers to provide maintenance training** as well as cleaning and disinfection review for healthcare professionals.

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Your checklist

- ❑ Do you have scientific testing data that validates claims?
  a. What test methods were used?
  b. What microbes were used?
  c. UV and other no touch technology testing?
- ❑ Have all categories of EPA registered disinfectants been tested and are surfaces compatible?
- ❑ Review IFU's – Do they support infection prevention protocols?
- ❑ Review care and maintenance documents
- ❑ Review manufacturer warnings
- ❑ Review the warranties
- ❑ Review the cleaning and disinfectant supplies being used

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What HSI is doing

- Education and research
- Case studies- What is happening in healthcare
- Working across the “supply chain” and industry to develop standards and common definitions
- Implementing a patent-pending certification testing methodology, starting with raw materials and assembly testing
- Ultimately the collaboration will provide sustainable solutions to real problems.4

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How you can get involved

1. Become a member
2. Have your company become a corporate sponsor
3. Donate
4. Drive change in your organization

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Thank you!

Linda Lybert, Founder and Executive Director
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February 15, 2023	*(FREE South Pacific Teleclass)* **PREVALENCE, COST AND PREVENTION OF HEALTHCARE ASSOCIATED INFECTIONS IN NEW ZEALAND** Speaker: **Dr. Arthur Morris**, Auckland City Hospital, New Zealand
February 23, 2023	*(FREE Teleclass ... Denver Russell Memorial Teleclass Lecture)* **USING ELECTRONIC SYSTEMS TO MONITOR HAND HYGIENE: STRATEGIES TO PROMOTE UPTAKE** Speaker: **Prof. Dinah Gould**, City University, London
March 7, 2023	*(European Teleclass)* **AUTOMATING THE SURVEILLANCE OF HEALTHCARE-ASSOCIATED INFECTIONS: MAKING SENSIBLE SENSE OF ELECTRONIC HEALTH RECORD DATA** Speaker: **Dr. Maaike van Mourik**, University Medical Center, Utrecht, The Netherlands
March 9, 2023	**HOMECARE & HOSPICE - STANDARDIZING INFECTION SURVEILLANCE** Speaker: **Mohamed Adawee**, Sparrow Health, Michigan
March 23, 2023	**THE ENVIRONMENT, THE TICK, AND THE PATHOGEN - IT'S AN ENSEMBLE**

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