

Sterility Assurance & Quality Risk Management Conference





Residue Management as a Key Step in Contamination Control Strategy

Proactive solution to prevent residue, rust & rouge

Presentation by
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Introduction & Context

- Sterile pharmaceutical manufacturing relies on strict contamination control
 - Disinfection is applied repeatedly to maintain low bioburden
- However, accumulation of chemical residues is often excluded from CCS risk assessments
 - Residues are the “hidden threat” often overlooked
- Even when residue risk is acknowledged, it is difficult to manage





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The Big Picture

Sterility assurance depends on:



Microbial Control



Surface Integrity



Particulate Control

Residues threaten all three



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Regulatory & Guidance Alignment

- **FDA:** Expect robust Contamination Control Strategy (CCS) including residue considerations
- **EU GMP Annex 1:** Emphasizes “visually clean” & residue control
- **ICH Q9(R1):** Residue management = proactive risk control, not reactive CAPA

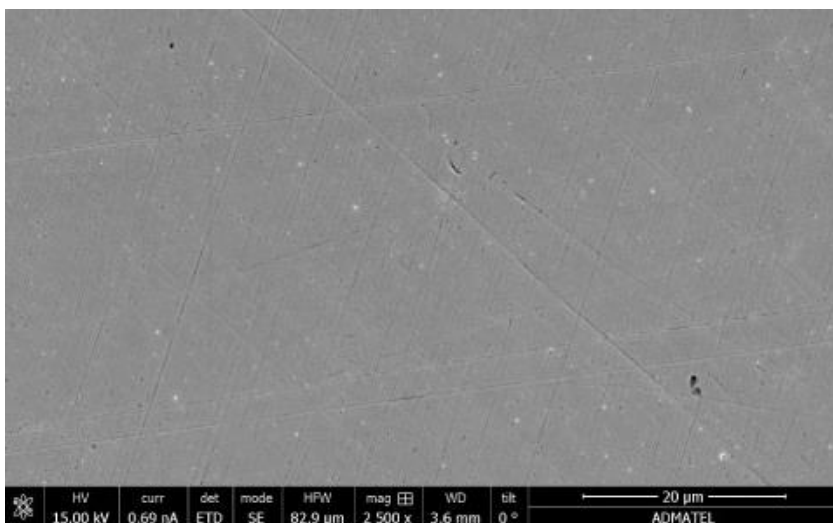


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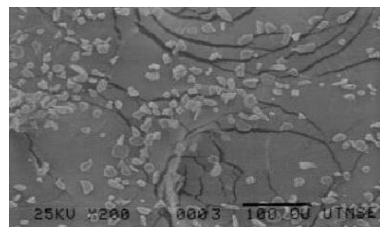
Brand New 316 Stainless Steel

What Are Disinfectant & Sporicidal Residues?

- Accumulation of quats, peroxides, chlorine, alcohols after repeated cycles
- Remain on: stainless steel, pass-throughs, carts, walls, floors, autoclaves
- Often invisible until late stage accumulation



Phenol



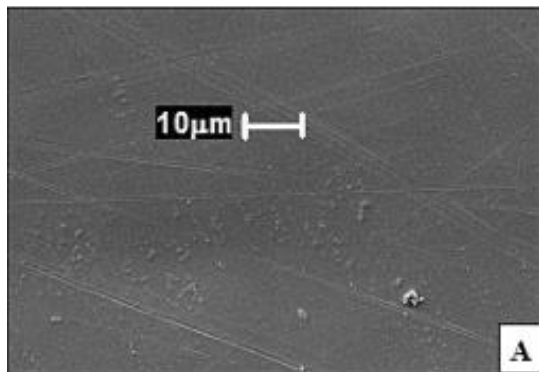
Sodium Hypochlorite



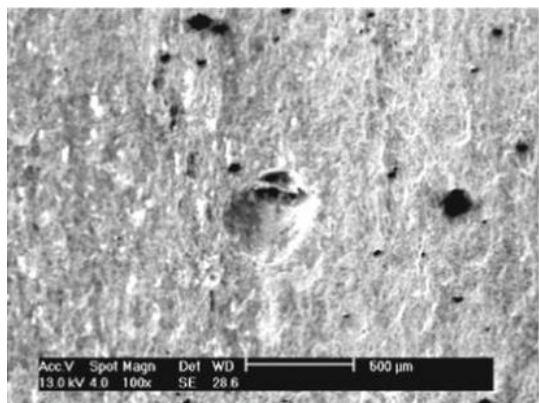
Quaternary Ammonium



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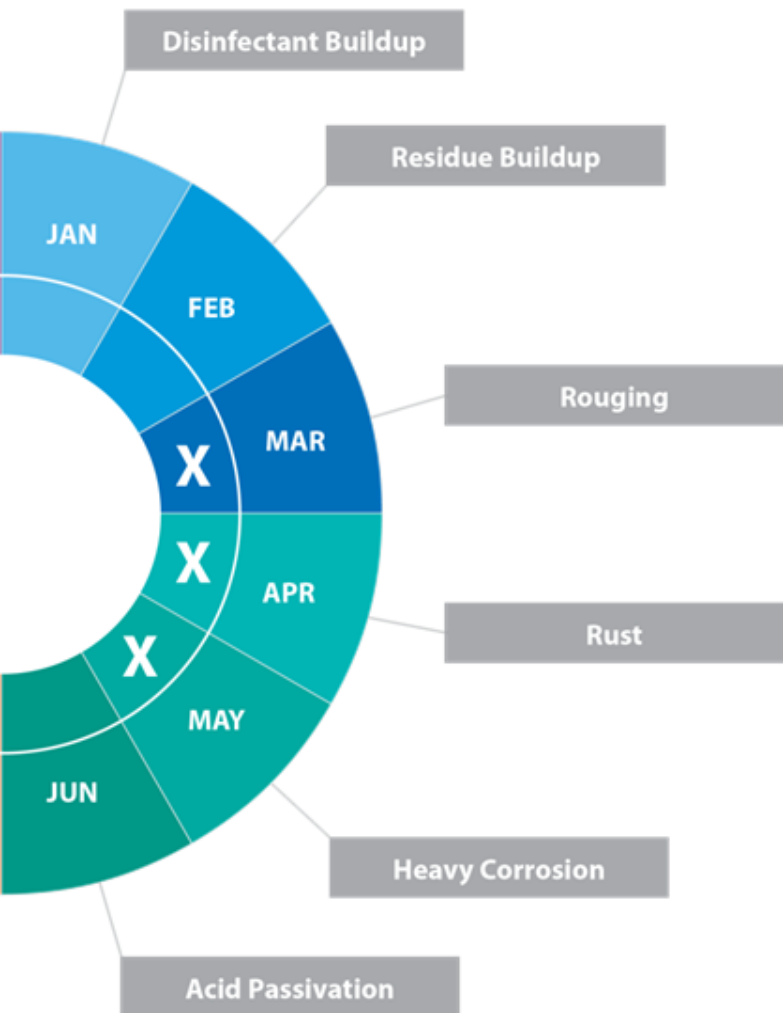
New Stainless Steel Surface



Pitted Stainless Steel Surface

Risks of Residue Accumulation

- Harborage sites for microorganisms
- Accelerated surface degradation (rouging, rust, corrosion)
- Nonviable particle generation → adds particulate load
- Creates blind spots for environmental monitoring (EM)



The Current Residue to Rust Cycle on Stainless Steel

- Disinfectant build up leads to residue buildup which degrades the self passivation layer of stainless steel leading to rouge and eventually rust
- Once rust is detected, acid passivation is followed prompting a facility shutdown
- X = Risk of Contamination and Audit Failures



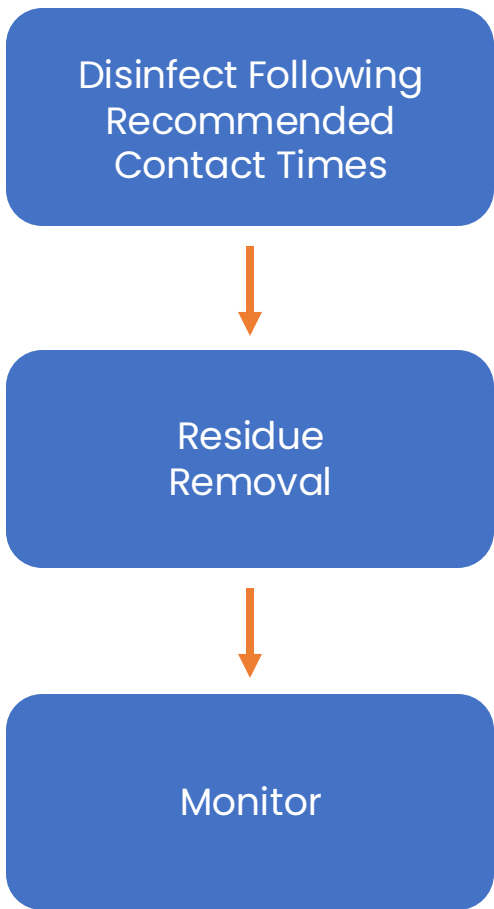


Foamtec's 2 Step Proactive Solution



- Step 1 - Using an abrasive cleanroom foam wipe to dislodge and scrub the stainless steel surface
- Step 2 - Perform a wipedown with our advanced cleanroom microfiber wipe to entrap and remove disinfectant residues
- Removes the disinfectant residue before it becomes rouge/rust
- Note: Only 70% IPA and DI Water are needed (no additional detergents or chemicals)





Implementing a Residue Strategy

- Add dedicated residue removal step after disinfection cycles
- Remove chemical layers before they degrade or entrap soil
- Focus on root cause elimination, not just symptom control





Implementation Framework

- Risk assessment of high-residue zones (floors, high-traffic areas)
- Define cleaning frequencies and validated methods
- Use cleanroom consumables that are designed to meet all cleaning and disinfecting requirements, plus disinfectant residue removal
- Integrate into SOPs and training





Why do Cleaning Materials Matter?



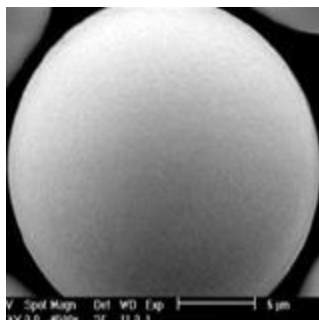
MiraWIPE® picks up what Polyester wipes cannot.



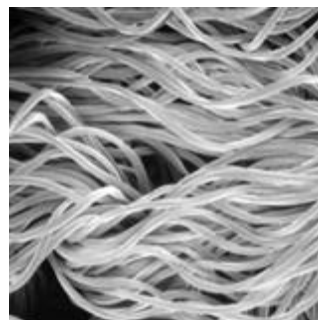
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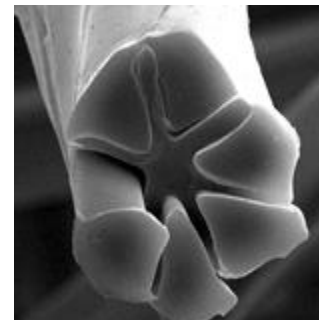
Polyester Vs. Microfiber Characteristics



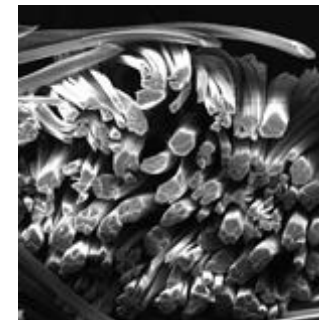
Polyester Fiber



Polyester Fiber Bundle



Woven Microfiber



Woven Microfiber Bundle

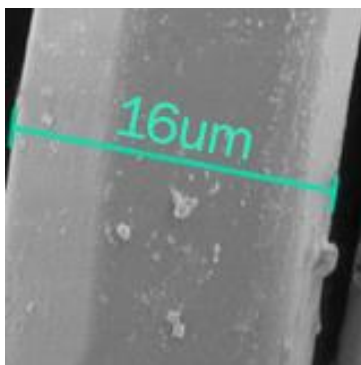
Star-shaped microfiber traps and removes particles; where standard Polyester round fibers push particles around. A tighter bundle means better pick up, greater absorbency, and superior abrasion resistance.



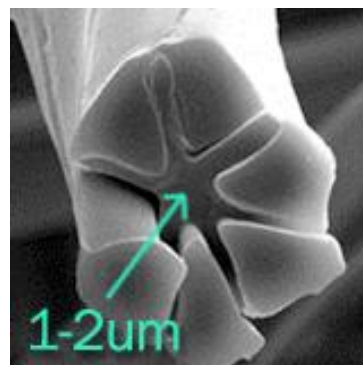


How the Microfiber in MiraWIPE® Works

The microfiber 1-2um star-shape characteristic is able to reach into the micro scratches on all surfaces, giving the microfiber the ability to remove the sub .2um particles gathered within micro scratches. Contaminants, soil and even Bleach residue can be lifted by the microfiber wipe.



Polyester Fiber



Woven Microfiber



An Acute Angle Of Divided Monofilament Of Woven Microfiber Can Scoop Out entrapad partirles





Non-Viable Surface Particle Analysis Via Q3 Surface Particle Counter

ISO Class 7 Suite	5 micron/cm ²	0.5 micron/cm ²
Rusted 316L	567	14589
Rouged 316L	456	16783
Stained 316L	4759	200,129
Sahara Remediated 316L	34	467
Stained Windows	2344	125,167
Sahara Cleaned Windows	22	345

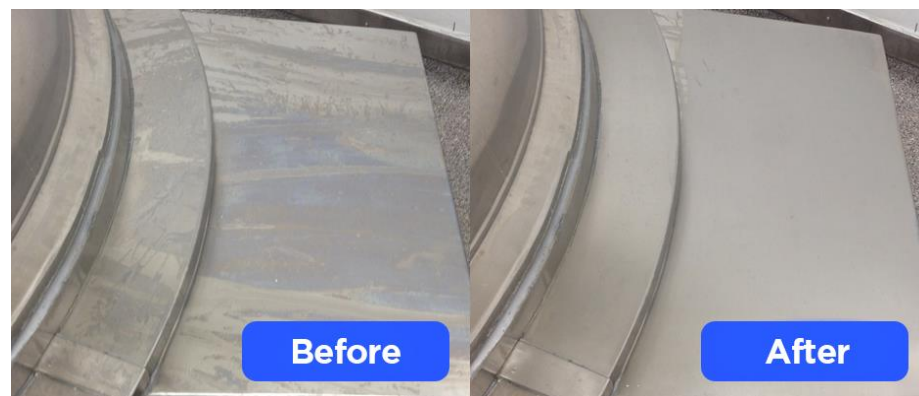




Case Examples

Residue-Driven Corrosion

- Oxidizing disinfectant left layers on stainless steel
- Disinfectant residues were removed before they could become rouge and rust.





Electropolish Panel



Cleaned with Polyester & 70% IPA



Cleaned with MiraWIPE® & 70% IPA





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Autoclave Panel



Before



After



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Benefits of Residue Removal

- Eliminates root cause, not just symptoms
- Extends surface/equipment life
- Lowers particle counts & EM deviations
- Strengthens sterility assurance
- Only requires 70% and DI Water





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Key Takeaways

- Residues are an underestimated contamination source
- Routine disinfection does not mitigate residue-related risks
- Dedicated residue removal is a preventive control that closes a known CCS gap
- Enables a shift from reactive CAPA to proactive risk mitigation
- High quality microfiber wipes are highly effective for removing residues, whereas polyester wipers often fail to remove and may spread residues



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Q&A



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Thank You!



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