

Durability of Antimicrobial Claims in Photopolymer Devices: Depletion, Fouling, Cleaning, Resistance and Test Design

Longitudinal qualification of efficacy across depletion, fouling, cleaning and resistance pressure

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ER-259 · Engineering Review · Version 0.2 · 22 September 2026

Abstract

Antimicrobial performance is often reported from a clean, newly prepared surface under a single laboratory protocol, while real photopolymer devices experience extraction, sorption, wear, protein fouling, repeated cleaning, disinfectant exposure, humidity changes and microbial adaptation. This review defines antimicrobial durability as preservation of a specified effect across a declared use-state history, not as a one-time log-reduction result. It separates releasable, contact-active and anti-adhesive mechanisms; identifies depletion, masking, surface reconstruction and cleaning damage as distinct failure modes; and proposes a non-compensatory qualification matrix linking antimicrobial efficacy to chemistry, surface state, biofilm challenge, cleaning cycles, mechanical integrity and resistance-selection risk. The central conclusion is that an antimicrobial claim is durable only when the claimed mechanism and effect remain demonstrated after the relevant conditioning sequence and when loss of activity, leachables and selection pressure are explicitly bounded.

Keywords: antimicrobial surfaces; photopolymers; biofilm; depletion; fouling; cleaning; resistance; durability; medical devices; qualification

1. Significance and scope

An antimicrobial label is not a material constant. In a photopolymer device, the active state is created by formulation, conversion, post-cure, extraction, finishing and subsequent use. A fresh coupon can therefore show strong inhibition while a clinically relevant surface later presents lower active-agent concentration, altered wettability, adsorbed proteins, scratches or a mature conditioning film. This review owns the durability question: whether an antimicrobial or anti-biofilm claim persists after the histories that the device is expected to encounter. It does not define biocompatibility acceptance limits, sterilisation validation or a universal antimicrobial formulation recipe.

1.1 Claim ownership and boundary

ER-259 treats the claim as a coupled property of mechanism, surface state, environment and time. ER-14 retains antimicrobial photopolymer mechanisms, efficacy testing, leaching and baseline durability architecture; ER-192 retains skin-contact state and biofilm qualification; ER-42 retains sterilisation; and ER-175 retains printer changeover, cleaning validation and cross-contamination control. ER-259 therefore owns the narrower longitudinal question of whether a declared antimicrobial claim survives depletion, fouling, repeated cleaning and resistance pressure across the stated use history. Antimicrobial chemistry alone is insufficient. Biofilm biology, cleaning, abrasion, extraction and resistance pressure must be connected to the same specimen history. A pass in one domain cannot compensate for failure in another.

2. Mechanism classes and what can decay

Three broad mechanism classes require different durability logic [2,3]. Releasing systems depend on a reservoir and transport path; their activity can fall as the mobile species is consumed, trapped or extracted. Contact-active systems depend on chemical groups or surface-bound species remaining accessible; adsorption, oxidation, abrasion or reconstruction can mask them even if bulk composition is unchanged. Anti-adhesive or antifouling surfaces depend on interfacial chemistry and hydration; contamination, protein adsorption and mechanical damage can destroy the low-adhesion state without changing nominal antimicrobial content. Hybrid systems can fail through more than one route and should be decomposed into these mechanisms before testing.

3. Depletion, leaching and extraction

A releasable antimicrobial creates an inherent time axis [2,3]. Early high flux can produce a strong assay result while shortening useful lifetime and increasing exposure to released species. Conversely, a highly immobilised active group may remain chemically present but become inaccessible after fouling. Qualification should therefore measure both biological effect and a mechanism-relevant chemical observable after conditioning. Depending on the design, this may include released mass, residual surface concentration, extractables, mass loss or spectroscopic markers. The objective is not to prescribe a universal threshold, but to prove that the claimed effect is supported by the surface state that exists at the declared service point.

4. Fouling and biofilm as masking processes

Proteins, lipids, salts and extracellular polymeric substances can form a conditioning layer [3] between the antimicrobial surface and the microorganism. This is especially important for contact-active surfaces, for which the active moiety must remain physically accessible. Biofilm also changes local diffusion, pH and metabolic state. A durability programme should therefore include a fouling challenge representative of the intended contact environment and should distinguish planktonic kill from prevention of attachment, reduction of viable biofilm and removal after cleaning. A single endpoint cannot represent all four.

5. Cleaning, disinfection and mechanical cycling

Repeated cleaning can remove contamination and restore function, but it can also extract mobile components [8], swell the network, alter surface energy, scratch the device or leave detergent residues. For reusable devices, the conditioning sequence should reproduce the declared chemistry, contact time, temperature, rinsing, drying and number of cycles. Mechanical handling should be added when abrasion, flexure or contact pressure are credible. The antimicrobial assay belongs after the conditioning sequence, not only before it. Cleanability and antimicrobial activity should be treated as coupled controls because residues can either suppress or inflate the apparent effect.

6. Resistance and tolerance as a durability hazard

Durability also has an evolutionary dimension. Antimicrobial surfaces that generate sublethal exposure can create selection pressure, particularly when activity decays gradually. Laboratory evolution has produced bacterial populations with markedly increased survival on metallic copper surfaces [4], showing that surface-mediated killing cannot be assumed evolution-proof. This does not mean that every antimicrobial surface will select resistance in use; it means that the hazard should be considered when the mechanism produces persistent gradients or declining concentrations. Resistance testing is therefore a risk-based extension, not a mandatory universal assay.

7. Test design: state history before endpoint

The core design principle is to define the specimen history first. A useful sequence is: manufacture → post-cure/extraction → baseline chemistry and mechanics → ageing or soak → fouling → cleaning/disinfection cycles → mechanical cycling where relevant → antimicrobial or biofilm challenge → post-test chemistry and surface inspection. Parallel unconditioned controls establish initial efficacy, while conditioned negative controls reveal effects caused by the history itself. Temperature, humidity, inoculum, contact geometry and recovery method must be fixed because antimicrobial results can be highly environment-dependent [1,5].

8. Non-compensatory qualification matrix

No weighted average should convert failure of a safety-critical durability dimension into a pass. The matrix below is deliberately non-compensatory.

Gate	Required evidence	Failure meaning
G1 Initial effect	Defined organism, inoculum, contact time, recovery and control surface	No supported baseline claim
G2 Mechanism state	Chemical or surface marker linked to proposed mechanism	Biological result not mechanistically anchored
G3 Conditioned effect	Repeat antimicrobial/biofilm assay after declared ageing and cleaning history	Claim not durable for declared history
G4 Surface integrity	Visual/chemical/mechanical evidence after cycling	Loss may reflect damage rather than chemistry alone
G5 Extractables/depletion	Risk-based release or residual-active measurement	Unbounded depletion or exposure
G6 Resistance risk	Risk assessment; targeted serial-passages or adaptation test when justified	Selection hazard not bounded

9. Minimum reporting set

Report material and surface identity, build orientation when it changes exposure or surface state, post-cure and extraction history, conditioning media, cleaning chemistry, cycle count, storage conditions, antimicrobial mechanism, organism and strain, inoculum, contact time, humidity or wetness state, recovery method, detection limit, replicate structure, acceptance rule and raw log-reduction or viable-count data. For biofilm claims, report the attachment and maturation period and the method used to separate viable biomass from total material. For releasing systems, report the time point at which the biological result is linked to the release state.

10. Degradation trajectories and acceptance models

Durability should be represented as a trajectory rather than a binary initial/final comparison. For releasing systems, measure at enough time points to distinguish rapid burst loss, diffusion-controlled decline and abrupt exhaustion. For contact-active or antifouling systems, intermediate states can reveal masking or damage before complete failure. A practical acceptance model defines a minimum claimed effect at the declared end-of-history state and also limits unacceptable monotonic deterioration when that trend predicts early failure. Apparent stability must be interpreted against analytical and microbiological uncertainty. A plateau within assay variability is not proof that the underlying active state is unchanged. Where the mechanism is measurable, chemical or surface-state data should be evaluated alongside the biological endpoint so that loss of efficacy can be attributed rather than merely observed.

11. Sampling, variability and false durability

Antimicrobial testing is sensitive to biological variability, specimen heterogeneity and recovery efficiency. Replicates should span independently manufactured specimens when manufacturing variability is part of the claim, not only repeated inoculations on one coupon. Surface roughness and build orientation can alter fouling and accessible area; these factors should be blocked or explicitly randomised. Censored data at the detection limit require transparent treatment because substituting zero survivors can exaggerate log reduction. The test should also guard against false durability caused by residual disinfectant carried into the assay after cleaning. Neutralisation and recovery controls are therefore essential when conditioning chemicals can continue killing during enumeration.

12. Change control and requalification triggers

A durability claim should be reopened when a change can alter the mechanism or the relevant state history [7]. Examples include antimicrobial concentration or immobilisation chemistry, photopolymer conversion, post-cure, washing, surface finish, supplier or raw-material lot specification, cleaning instructions, intended service life or contact environment. Requalification can be bounded to the affected gates when equivalence is demonstrated, but the rationale must be explicit. A purely administrative version change need not trigger biology; a change that shifts release, surface accessibility or fouling behaviour does.

13. Knowledge boundary and limitations

ISO 22196 provides a standardized method for antibacterial activity on treated non-porous surfaces, but the standard itself does not establish service-life durability, biofilm prevention, cleaning compatibility or resistance risk. Evidence from metals, coatings and polymeric devices is mechanistically informative but cannot be transferred automatically to a specific photopolymer formulation. No universal number of cleaning cycles, minimum log reduction, leachate limit or resistance protocol is justified here. Those values must follow intended use, risk analysis and the specific claim.

14. Conclusions

A durable antimicrobial claim is a longitudinal claim. It requires preservation of effect after the relevant sequence of depletion, fouling, cleaning, environmental and mechanical challenges, with the mechanism still demonstrably present and safety-relevant release or resistance

hazards bounded. Testing only a pristine coupon establishes initial activity, not durability. The strongest qualification architecture couples conditioned efficacy, surface chemistry, device integrity and risk-based resistance assessment without allowing success in one domain to compensate for failure in another.

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