VeriClean SEALS™
Your higher standard for clean seals

TECHNICAL WHITEPAPER
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MEDICAL DEVICES · DESIGN & RELIABILITY ENGINEERS

Elastomeric seal particulate contamination in medical device fluid paths: the uncontrolled variable your spec doesn't address.

As-received elastomeric seals carry 1,000–98,500 particles/cm² at ≥1.3 µm — and Cyclic Contamination Displacement™ delivers them into your fluid path through the same pressure cycling your device was designed to run under. No current specification measures it.

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PRP
Precision. Seals. Delivered.

Elastomeric seal particulate contamination in medical device fluid paths is real, measurable, and present in devices whose design history files have never recorded it. As-received elastomeric seals from standard commercial supply channels carry between 1,000 and 98,500 particles per square centimeter at ≥1.3 µm (SKU-average), with individual seals measured from 630 to more than 127,000 particles per square centimeter (PRP measurement data). In a microfluidic IVD cartridge with channel widths of 10 to 100 µm, a single dislodged particle in that upper range is not a soft performance anomaly. It is an obstruction.

Your compound is specified. Your extractables and leachables are characterized. Your USP Class VI compliance is on file. Your gland geometry is validated. Every variable in your fluid path that your design input requirements address has been addressed. The surface particulate burden on the seal itself — deposited through manufacturing, handling, and supply chain transit — is the one variable your specification has never reached. Not because it was evaluated and deemed acceptable. Because no standard has ever required you to reach it.

The Specification Gap

Understanding why this variable has no specification requires understanding what the existing standards were actually designed to do — and what they were not.

The standard was designed for a different problem

ISO 3601-3 specifies surface inspection at ×2 magnification. That standard was designed to detect molding defects — flash, tears, surface damage. It does that job. It is not designed to address fluid-path contamination. At ×2 magnification, particles at ≥1.3 µm — the size range directly relevant to your application — are structurally invisible. USP <381> and USP <382> address dimensional performance and biological reactivity. ISO 13485 and FDA 21 CFR Part 820 establish quality system requirements. EU MDR 2017/745 governs biocompatibility and general safety. USP <788> governs subvisible particulate at the finished device output level. ISO 11737-1 addresses microbiological populations on products.

None of these standards, individually or collectively, establishes a measurement method or acceptance criterion for surface-deposited subvisible insoluble particulate on an elastomeric seal at the component input level. This is not a gap that will be closed by reading the applicable standards more carefully. It is a structural absence.

Your supplier is compliant. That is the problem.

Your seal supplier ships seals that meet every published requirement. The certificate of conformance is accurate. The visual inspection passed. There is no negligence and no supply chain failure in the conventional sense. The seals are in spec.

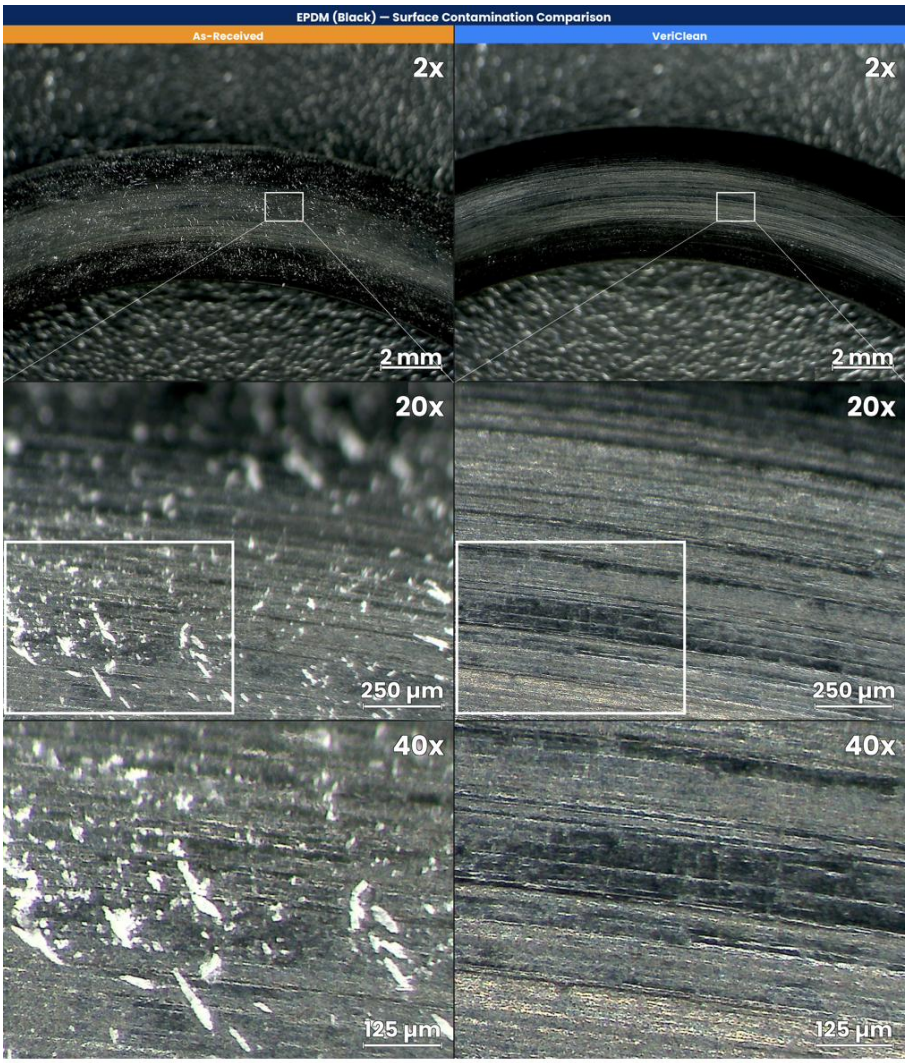
> *"The spec does not address what enters your fluid system. This is not fixable by finding a better supplier — every supplier operates to the same inadequate standard. Your seal supplier will ship seals in spec. The spec is the problem."*

The contamination requires a methodology that doesn't exist

Particles at ≥1.3 µm require extraction, counting, and documentation to detect. That methodology does not exist at the component level anywhere in the industry. Visual inspection cannot contribute meaningful contamination control for this class of contaminant — the lower limit of unaided visual resolution is approximately 40 to 50 µm under normal lighting conditions, and the contaminants of primary concern begin well below 10 µm.

The contamination arrives through identifiable supply chain mechanisms. Talc particles (1–20 µm) from compounding filler and mold dusting. Carbon black agglomerates (0.01–100 µm) liberated from the polymer matrix. Skin squames (20–50 µm) from operator handling in non-controlled environments. Textile fibers (50–2,000 µm+) from garment shedding during packaging. These are four of eleven contamination classes documented in full — see the full technical paper for the complete taxonomy.

As-received elastomeric seals have been measured across a SKU-average range of approximately 1,000 to 98,500 particles/cm² (≥1.3 µm). Individual seals within those populations range from approximately 630 to more than 127,000 particles/cm² (PRP measurement data). Within a single purchased lot, seal-to-seal particle burden has been observed to differ by more than 20-fold, measured under identical conditions (PRP measurement data). This is the Specification Gap: a contamination variable that is present, measurable, and consequential — and for which no standard has ever required documentation.



EPDM seal surface — as-received (left) vs. VeriClean processed (right). At ×2 magnification (ISO 3601-3 inspection standard), both surfaces appear acceptable. At ×20 and ×40, crystalline contamination on the as-received surface is clearly visible at scale. In microfluidic and diagnostic fluid paths, particles of this morphology and size are sufficient to obstruct channels or interfere with assay performance. Scale bar: 125 µm.

The Delivery Mechanism: Cyclic Contamination Displacement™

The contamination present on as-received seal surfaces does not remain static once the device enters service. The mechanism by which it enters the fluid path is Cyclic Contamination Displacement (CCD): the progressive mobilization of surface-bound contamination through the normal operating mechanics of pressurization, thermal cycling, and mechanical actuation. CCD is not a manufacturing defect. It is a direct consequence of the seal's designed function.

A seal's static wetted footprint — the surface area initially in contact with process fluid — is a small fraction of its total surface area. At 15 to 25% cross-sectional deflection, the ratio of total seal surface to initial fluid contact zone is typically 3:1 to 8:1 (PRP measurement data). The static gland model that informs your design verification accounts for the initial footprint. It does not model what happens across operating cycles.

Under pressurization, the seal translates toward the low-pressure side of the gland, exposing previously dry surfaces to process fluid contact. Thermal cycling introduces differential expansion and contraction at the seal-gland interface, progressively exposing additional surface area. Mechanical actuation under load liberates the particle layer adhered to the seal surface through mold release oils and other surface films.

The consequence for your device is temporal. In an implantable pump with a multi-year service life and thousands of cumulative actuation cycles, the temporal distribution of contamination release is a design variable — one that is not currently characterized. In a microfluidic diagnostic cartridge, CCD-driven release of a single particle in the 10 to 100 µm range does not produce an obvious failure. It produces a measurement artifact: shifted results, false negatives, irreproducible replicates, elevated background — anomalies that don't correlate with reagent lot, column lot, or operator, because none of those is the source.

CCD is not a flaw. It is contamination release from a seal doing exactly what it was designed to do. Only surface cleanliness control solves it.

> For full CCD mechanism visualization — including wetted area expansion diagrams, operating cycle analysis, and the complete contamination class dataset — download the full technical paper: *'Surface Particulate Contamination on Elastomeric Seals'* at pacificrubber.com/resources.

Particle load variability and documented control

The contamination problem cannot be managed by visual inspection or lot-level assumptions.

Particle burden across different purchased lots of the same SKU shows 3× variability at the lot-average level (PRP measurement data). Within a single bag from the same lot, individual seals have been observed to differ in burden by more than 20-fold under identical measurement conditions (PRP measurement data). The relationship between price, visual grade, and contamination burden is weak — the correlation across the PRP database is R=0.47. A premium-priced seal is not a cleaner seal.

This variability is attributable to differences in handling environment, packaging occasion, and processing history — not compound or dimensional differences. A change in supplier lot is not visible in material certification. It does not trigger a design change review. But it may introduce a meaningfully different contamination population into the device fluid path.

This variability requires a documented, repeatable measurement methodology applied at the SKU level — not lot level, not visual inspection, not supplier assertion. No current industry standard provides this methodology at the component level.

What this means for Design / Reliability Engineers

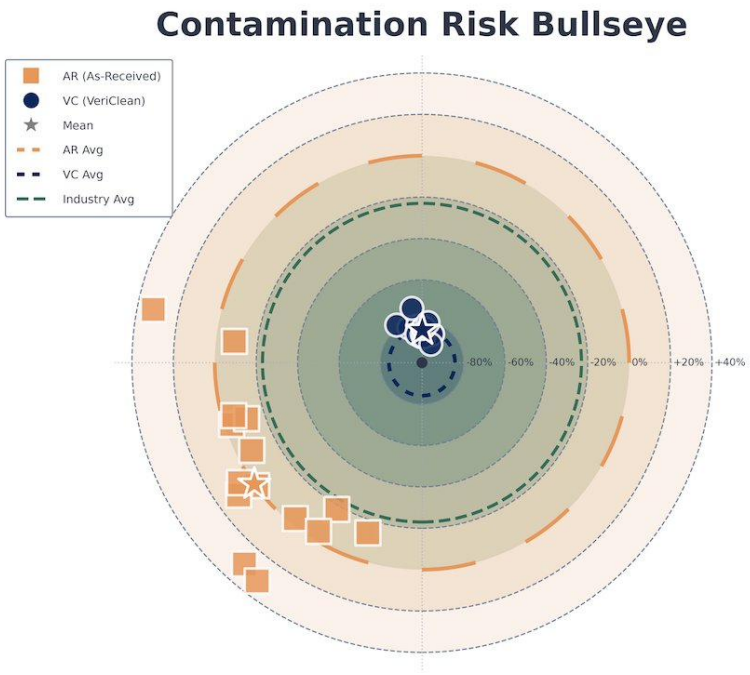
For design and reliability engineers who own the design input requirements governing a medical device fluid path, the Specification Gap is a documentation gap with regulatory consequence. Your design history file is complete by every current standard and entirely silent on seal surface cleanliness — not because the variable was evaluated and accepted, but because no standard has required characterization and no supplier

has had the measurement infrastructure to offer data. In a microfluidic device where a single particle is an assay failure, or in an implantable pump where CCD-driven contamination release is a design variable across thousands of actuation cycles and years of service life, the first answer an auditor or failure investigator receives should not be "not characterized at this level." VeriClean Seals™ processing and the VeriClean Cleanliness Qualification (VCQ) convert that answer to "characterized and controlled — see design history file section X."

What's inside the full technical paper

'Surface Particulate Contamination on Elastomeric Seals' is the complete 20-page technical paper behind every claim in this document. Access the full paper at pacificrubber.com/resources.

- 11 contamination source classes — full taxonomy with morphology, size ranges (0.01 µm to 2,000+ µm), supply chain origin, and fluid-path impact
- Complete particle count dataset: 1,000 to 98,500 particles/cm² SKU-average; individual seals 630 to more than 127,000 particles/cm² (≥1.3 µm)
- Particle volume density analysis across 16 size buckets: 45,000 µm³/cm² to more than 5.4 million µm³/cm² SKU-average
- Within-lot variability: 3× lot-to-lot; 20× seal-to-seal within same bag
- Full CCD mechanism with wetted area expansion ratios (3:1 to 8:1) and operating cycle analysis
- Standards landscape mapping for medical devices: ISO 3601-3, USP <381>/<382>, ISO 13485, 21 CFR Part 820, EU MDR 2017/745, USP <788>, ISO 11737-1 — scope and surface particulate gap for each
- VeriClean processing methodology and performance data
- 20 pages · 5,300 words · 24 cited references



VeriClean Qualification (VCQ) — Contamination Risk Bullseye, one of several visual analytical outputs in the VCQ report.

About the bullseye. The Contamination Risk Bullseye shown here is one of several visual analytical outputs in the VCQ report. Each marker represents independent particle extraction and quantification for an individual seal: n=15 as-received measurements and n=15 VeriClean-processed. The distribution of as-received markers across the chart reflects the seal-to-seal variability within a single submitted lot, and positions that population against the same compound family average from PRP's full supply chain dataset. The complete VCQ report delivers this and other visualizations alongside all raw particle count and volume data across 16 size bins.

The full data is available. The full paper is accessible now.

'Surface Particulate Contamination on Elastomeric Seals' — 20 pages · 5,300 words · 24 cited references. The complete mechanism, the complete dataset, and the measurement methodology that closes the Specification Gap.

Download at pacificrubber.com/resources

VeriClean Seals™ bioburden reduction of 92–100% is a process characterization finding per ISO 11737-1 validation. It is not a batch-monitored VCQ deliverable or guarantee. Results vary by elastomer compound and initial contamination state.

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