VeriClean SEALS™
Your higher standard for clean seals

DISCOVERY LIFE SCIENCES · INSTRUMENT OEM ENGINEERS & PMS

Specifying seal surface cleanliness in laboratory instruments: a BOM parameter that didn't exist until now.

THE SPECIFICATION GAP · CCD · VARIABILITY

Instrument seal surface cleanliness specification is now a real BOM parameter — and VeriClean Seals™ is the first and only supplier infrastructure that makes it specifiable. As-received elastomeric seals carry 1,000–98,500 particles/cm² at ≥1.3 µm, with individual seals reaching more than 127,000 particles/cm². That particle load is present in every instrument you ship. Until now, it also had no solution.

PACIFICRUBBER.COM / VERICLEAN

PRP
Precision. Seals. Delivered.

Instrument seal surface cleanliness specification BOM is now a real parameter — and VeriClean Seals™ is the first and only supplier infrastructure that makes it specifiable. As-received elastomeric seals from standard commercial supply channels carry between 1,000 and 98,500 particles per square centimeter (SKU-average, ≥1.3 µm), with individual seals ranging from 630 to more than 127,000 particles per square centimeter (PRP measurement data). That particle load is present in every instrument you ship. It has no specification, no incoming measurement criterion, and no line item in the BOM. Until now, it also had no solution.

VeriClean Seals are backwards-compatible with existing BOM specifications. No requalification required. Processing does not alter compound, durometer, dimensions, leachables or extractables profile. For most OEM applications, it documents as a change to incoming component handling — not a design change.

The Specification Gap

The seal BOM is complete. That is the problem.

You have material certifications, dimensional conformance records, extractables panels, and a CoC for every seal in the instrument's fluid path. The supplier qualification record is accurate and thorough. What it does not contain — and what no supplier qualification record in the industry currently contains — is a single data point on surface particulate cleanliness. Not because anyone skipped it. Because no standard required it, and no measurement infrastructure existed at commercial scale to produce it.

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 relevant to analytical instrument fluid circuits — are structurally invisible.

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."*

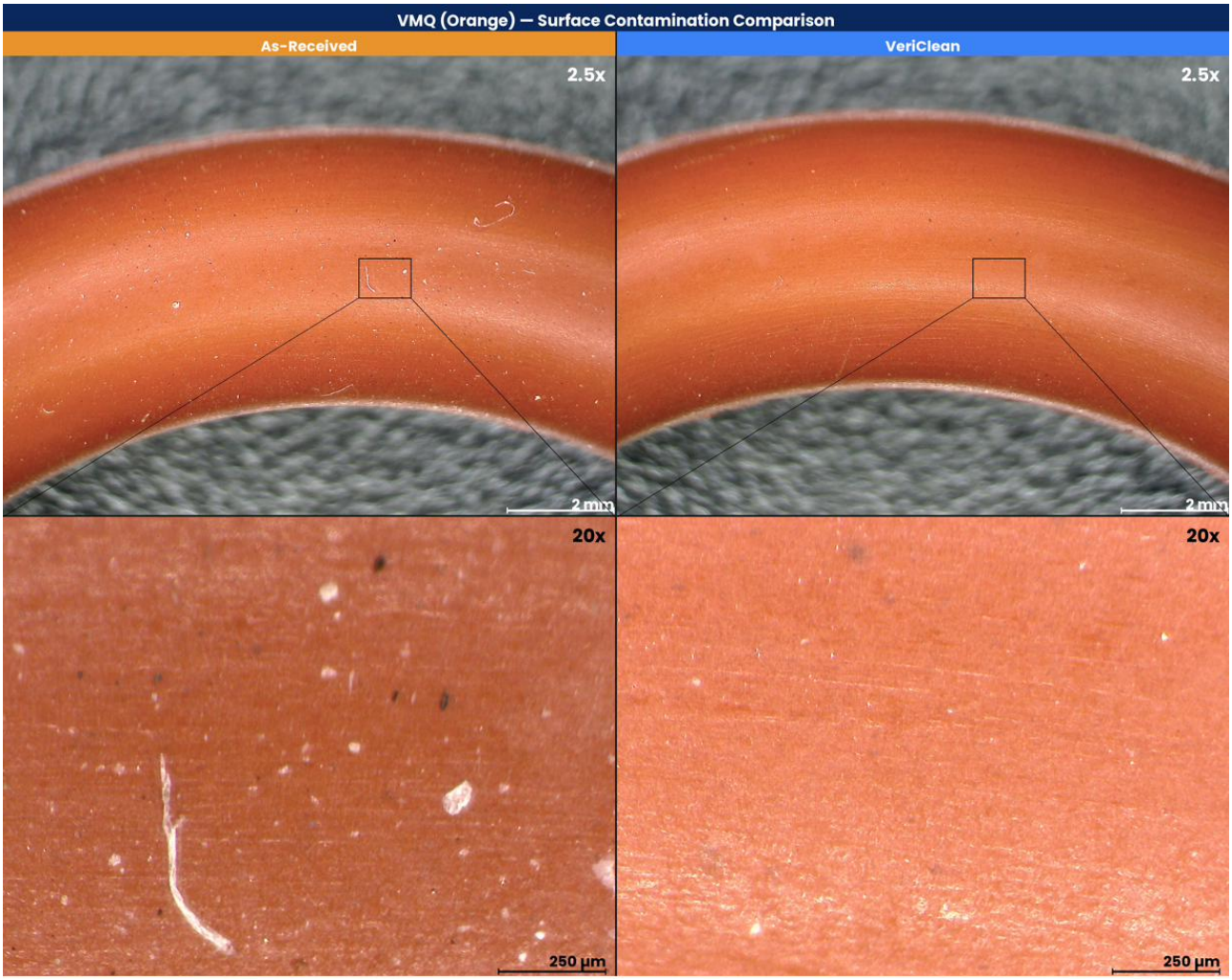
The contamination requires a methodology that doesn't exist

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. This is the Specification Gap.

The contamination on every seal reaching your dock is the predictable output of standard elastomeric manufacturing. Representative source classes include: talc (1–20 µm), used as a compounding filler and mold dusting agent; carbon black agglomerates (0.01–100 µm), liberated from the compound surface; skin squames (20–50 µm) deposited during operator handling; and textile fibers from packaging and PPE (50–

2,000 µm+). These are four of eleven contamination classes documented in full — see the full technical paper for the complete taxonomy.

What this contamination produces at the instrument level is quantified. As-received seals have been measured at 1,000 to 98,500 particles per square centimeter SKU-average (≥1.3 µm), with individual seals reaching more than 127,000 particles per square centimeter (PRP measurement data). Seal-to-seal variability within the same purchased lot exceeds 20-fold. A laboratory instrument seal supplier qualification record built on visual inspection and dimensional conformance alone is a reliability model with an uncharacterized input.



VMQ (silicone) seal surface — as-received (left) vs. VeriClean processed (right). Instrument OEMs currently specify seals on material and geometry. Surface cleanliness has not been a specifiable BOM parameter — because no supplier had the infrastructure to offer it. VeriClean changes that without requiring platform redesign or requalification. Scale bar: 250 µm.

CCD: Why the Contamination Gets In

A seal's static wetted footprint is a small fraction of its total surface area. This is by design — gland geometry, compression, and material compliance are engineered for sealing performance. The static contact zone is

the correct model for dimensional specification, leak rate, and extrusion resistance. It is not the correct model for contamination exposure.

Under pressurization, thermal cycling, and mechanical cycling — normal operating conditions — the effective wetted area expands 3:1 to 8:1 beyond the static footprint. The seal is functioning exactly as designed. That expansion brings previously dry gland surface — and its contamination load — into contact with the analytical fluid path. In a high-throughput LC/MS system processing samples continuously, every pump stroke is a contamination delivery event. In a gene sequencing platform cycling reagent over its service lifetime, contamination release is cumulative across hundreds of thousands of operating cycles.

This is Cyclic Contamination Displacement™ (CCD). It is not a manufacturing defect and not a supply chain failure. It is contamination release from a seal doing exactly what it was designed to do. The mechanism does not self-resolve after commissioning. CCD-released contamination enters the fluid stream progressively over the instrument's deployed service life — well after the qualification flush, well after ship, well after the instrument is at the customer's bench. Filtration cannot solve it: in every analytical instrument, at least one seal exists downstream of the last filtration stage. Contamination from those seals bypasses filtration entirely.

> 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. Seal-to-seal variability within a single purchased lot exceeds 20-fold (PRP measurement data). Lot-to-lot variability within the same SKU runs 3× or more. A statistically normal approved lot — one that passed every incoming inspection criterion on dimensional conformance and material certification — can contain a subset of seals at the high end of the burden distribution generating field failure rates inconsistent with any BOM prediction.

The price-cleanliness relationship offers no alternative: correlation between seal price, visual grade, and contamination burden runs at R=0.47 across the PRP supply chain database. A premium-priced analytical instrument fluid path seal is not a cleaner seal. Seal selection based on material performance and extractables compliance — the correct selection criteria — conveys no information about surface particulate burden.

This variability means that lot-average results and periodic sampling cannot characterize the high-burden seals in a population. The only resolution is a documented, repeatable measurement methodology applied at the SKU level, to the full population. No current industry standard provides that methodology at component level.

What This Means for Instrument OEM Product Managers

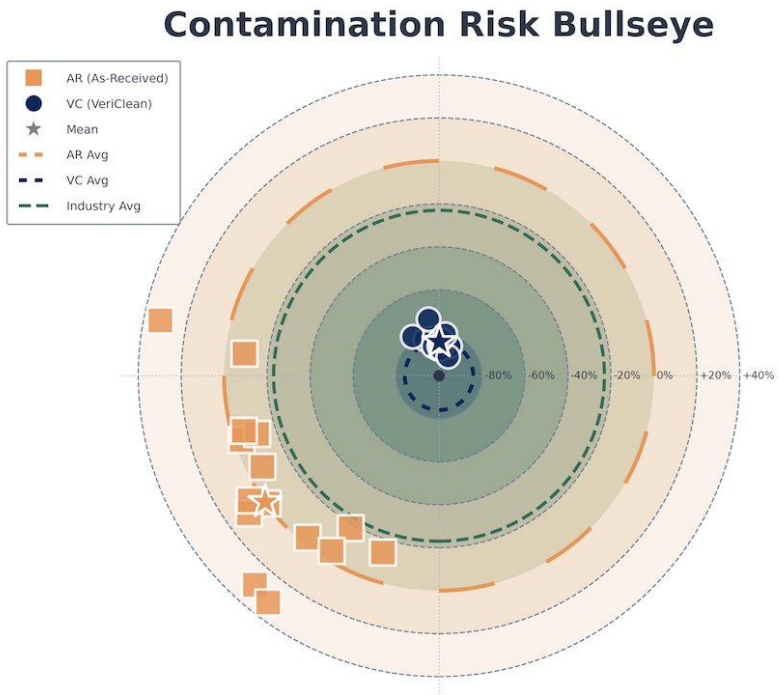
An unspecified BOM variable is a liability with no corrective action lever. Seal surface contamination is present in every analytical instrument fluid path, releases progressively through normal operating cycles, and produces field failure modes — fouled flow cells, degraded pump performance, blocked capillaries, elevated

background noise — that do not trace back to the seal in standard field failure analysis. The result is warranty cost absorbed to non-specific causes and a field reliability model that excludes a real input. VeriClean Seals close that gap without platform redesign or sourcing change. Specifying seal surface cleanliness in your BOM is now a decision, not an infrastructure problem.

What's Inside the Full Technical Paper

The complete 20-page technical paper provides the mechanism, the dataset, and the measurement methodology behind every claim in this document.

- 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: ISO 3601-3, OEM quality system requirements, supplier CoC frameworks, and system suitability testing — coverage assessment for surface particulate at component level
- 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 (92–100%, ISO 11737-1 validation) reflects process characterization data. It is not a batch-monitored VCQ deliverable or guarantee. Results vary by elastomer compound and initial contamination state.

VeriClean Seals™ and Cyclic Contamination Displacement™ are trademarks of Pacific Rubber & Packing, Inc.