VeriClean SEALS™
Your higher standard for clean seals

TECHNICAL WHITEPAPER
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MEDICAL DEVICES · REGULATORY & COMPLIANCE SPECIALISTS

Elastomeric seal contamination control under 21 CFR Part 820 and EU MDR: the component-level gap your next audit may find.

THE SPECIFICATION GAP · CCD · DOCUMENTED CONTROL

"We didn't know" is not a defensible audit response. No broadly adopted standard requires component-level surface cleanliness data for elastomeric seals — and the contamination that enters your fluid path through Cyclic Contamination Displacement™ is operating in every device you ship.

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PRP
Precision. Seals. Delivered.

"We didn't know" is not a defensible audit response. Medical device seal contamination control under 21 CFR Part 820 and EU MDR has a structural gap that no current standard requires you to close: no broadly adopted industry standard requires component-level surface cleanliness data for elastomeric seals. Your design history file documents material biocompatibility, extractables and leachables profiles, dimensional conformance, and sterilization validation. The contamination control section names the sources addressed and the controls applied. One component-level variable is absent from every DHF in your device category — not because it was evaluated and accepted, but because no standard has ever required it.

As-received elastomeric seals from standard commercial supply channels carry a measurable surface particulate burden: 1,000 to 98,500 particles per square centimeter at SKU average (≥1.3 µm), with individual seals ranging from approximately 630 to more than 127,000 particles/cm² (PRP measurement data). These particles are not detectable by visual inspection. They are not documented on any Certificate of Conformance your quality system has received. And they enter the fluid path of the device through a mechanism that operates continuously across every pressure transient, thermal cycle, and actuation event across the service life of the device — not as a commissioning artifact, but as a persistent contamination input.

The VeriClean Seals™ Cleanliness Qualification (VCQ) from Pacific Rubber & Packing, Inc. closes this gap. It generates the first quantitative characterization of what is actually on your seal surfaces — before and after VeriClean Seals™ processing — and produces a documented dataset that belongs in your design history file, your Device History Record, and your supplier qualification record.

The Specification Gap

The standard your supplier operates to was not designed for this problem. ISO 3601-3 specifies surface inspection at ×2 magnification. It is an effective standard for the seal defects it was designed to detect: molding flash, tears, surface damage visible under low magnification. It does that job. It was not designed to address fluid-path contamination. At ×2 magnification, particles at ≥1.3 µm — the size range directly relevant to medical device fluid paths — are structurally invisible. The unaided human eye cannot resolve below approximately 40 to 50 µm under normal lighting conditions. ISO 3601-3 was not designed to address this contamination class and does not.

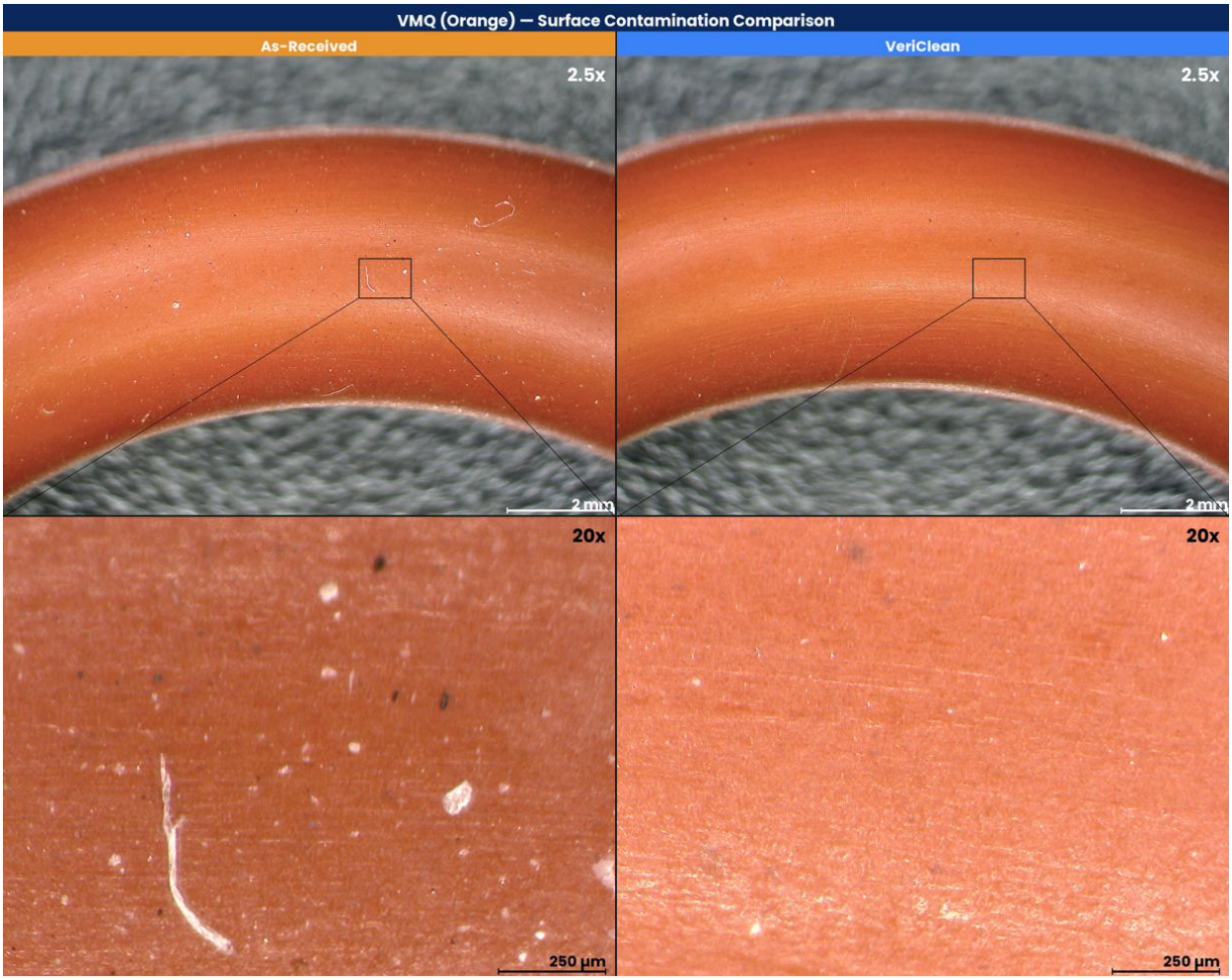
> *Your seal supplier will ship seals in spec. The spec is the problem.*

Your supplier's Certificate of Conformance is accurate. The visual inspection passed. There is no supply chain failure in the conventional sense. The seals meet every published requirement — dimensional conformance, material certification, durometer, compression set, whatever chemistry certifications your specification requires. What the CoC does not contain, and what no current standard requires, is a surface particle count. The specification has no entry for it. The incoming test does not exist. This is not fixable by finding a better supplier — every supplier operates to the same standard, and the standard does not address what enters your fluid system.

Detecting the contamination of concern requires extraction, counting, and documentation at ≥1.3 µm. That methodology did not exist at the component level anywhere in the industry — until now. This is the Specification Gap.

The contamination present on an as-received commercial elastomeric seal is not the output of a process deviation. It is the predictable product of a supply chain optimized for dimensional and mechanical performance in which surface cleanliness was never a controlled variable. Contamination classes include talcum powder (1–20 µm), carbon black agglomerates (0.01–100 µm), skin squames from operator handling (20–50 µm), and textile fibers from packaging and PPE (50–2,000+ µm). Eleven contamination source classes are documented in full — see the full technical paper for the complete taxonomy with morphology, size ranges, supply chain origin, and fluid-path impact.

As-received particle burden ranges from 1,000 to 98,500 particles/cm² at SKU average (≥1.3 µm), with individual seals measured from approximately 630 to more than 127,000 particles/cm² (PRP measurement data). Within a single purchased lot, seal-to-seal variability of 20-fold or more has been observed under identical measurement conditions. Your incoming inspection cannot find the outliers. They are in the box with the compliant ones.



VMQ (silicone) seal surface — as-received (left) vs. VeriClean processed (right). Standard supplier qualification criteria — material certification, dimensional conformance, extractables/leachables data — do not require or detect surface particulate contamination of this type. VCQ deliverables document it. Scale bar: 250 µm.

CCD — The Mechanism

Cyclic Contamination Displacement™ (CCD) is not a manufacturing defect. It is a consequence of the seal doing exactly what it was designed to do.

The static gland model — the standard engineering framework for seal performance evaluation — is correct for leak rate, extrusion resistance, and chemical compatibility. It is not correct for contamination exposure. Real fluid systems cycle. Under pressurization, thermal shifts, and mechanical cycling — normal operating conditions — the fraction of the seal surface that contacts the process fluid expands substantially beyond the static gland geometry.

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. Under operating cycles, the effective wetted area expands 3:1 to 8:1 beyond the static footprint. The seal is functioning as designed. That expansion brings previously dry gland surface — and the contamination load it carries — into contact with the fluid. In dynamic and semi-dynamic sealing applications, seal translation under pressure differential liberates the particle layer adhered to the surface by mold release oils and other surface films through mechanical shear at the seal-gland interface. Process fluid film entrained in the gland then carries liberated particles into the bulk fluid stream without requiring direct bulk fluid contact with the contaminated surface.

Contamination release through CCD is cumulative and ongoing — not a one-time commissioning event. The flush that intercepts freely mobile contamination at startup does not intercept contamination that has not yet been liberated from the seal surface. In an implantable drug delivery system, that bulk fluid is the drug product, and CCD operates across years of service life and thousands of actuation cycles. In a diagnostic instrument executing 10,000+ fluid path cycles per year, CCD delivers a continuous contamination input into precision flow cells, optical windows, and valve seats. In a microfluidic lab-on-chip device, a single particle at the right size is an assay failure — not a performance anomaly, but a physical obstruction at the scale of the channel itself.

Filtration cannot close this gap. In any real fluid path, at least one elastomeric seal exists downstream of the last filtration stage — contamination from those seals bypasses filtration entirely. And CCD-released contamination that enters the fluid stream progressively over service life was not present at the time any commissioning filtration event occurred. 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. The variability data makes this explicit.

Lot-to-lot variability for the same SKU reaches 3× across the PRP supply chain database (PRP measurement data). Within a single purchased lot, individual seals have been observed to differ in particle burden by more than 20-fold from the same bag, measured under identical conditions (PRP measurement data). More than 25% of SKUs in the database exhibit within-population count spreads of 3× or greater. A representative sample of an incoming lot — even a statistically well-designed sample — cannot characterize the distribution of contamination burden across that lot. The outlier seals are real, they are in the lot, and standard incoming inspection cannot find them.

The correlation between price, visual grade, and contamination burden is weak (R=0.47 across the PRP database). A premium-priced seal is not a cleaner seal. Specifying a higher-grade or medically sourced elastomeric component does not specify surface cleanliness — it specifies dimensional and chemical performance. The surface particulate profile is not controlled by compound grade, supplier qualification status, or CoC review. It is controlled only by a documented, repeatable measurement methodology applied at the SKU level.

No current industry standard provides that methodology at the component level. Not ISO 3601-3. Not ISO 13485. Not FDA 21 CFR Part 820.70. Not EU MDR 2017/745 Annex I. Not USP 381, 382, or 788. Each of these standards is doing the job it was designed for. None of them was designed for this one.

What This Means for Regulatory / Compliance Specialists

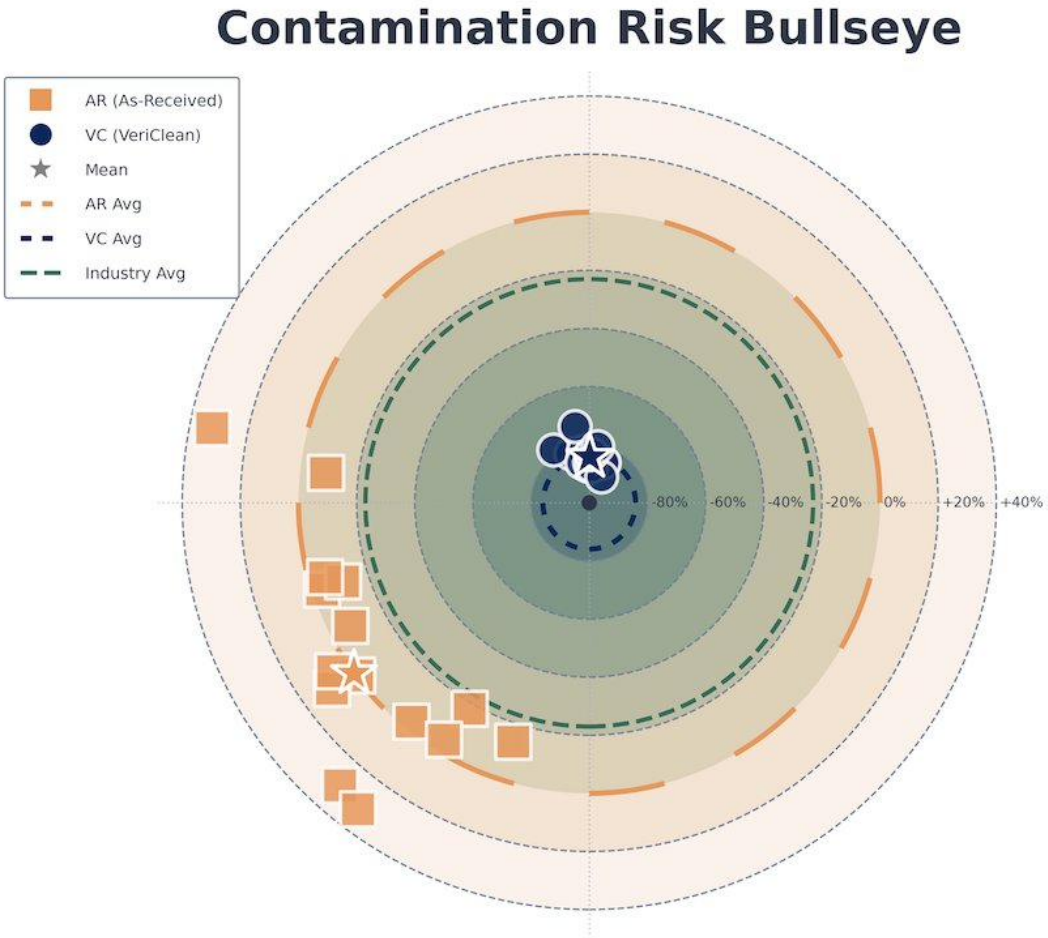
Your design history file is complete by every current standard — and silent on a contamination variable that operates in every device your facility ships. The audit answer to "how is seal surface particulate characterized and controlled at incoming?" is currently: not characterized at this level. Under ISO 13485 Section 7.4, FDA 21 CFR 820.70, and EU MDR 2017/745 Annex I GSPR, that answer is not a cited nonconformance today — because no standard creates the requirement. It is, however, an unaddressed contamination control risk that a competent auditor can identify without any standard prompting them to look. The VCQ converts that answer. The DHF entry changes from a documentation gap to a characterized, documented contamination control step — particle count data tied to a specific production lot, with a processing record that belongs in your supplier qualification file.

What's Inside the Full Technical Paper

The complete 20-page technical paper — *'Surface Particulate Contamination on Elastomeric Seals'* — contains the full dataset, mechanism documentation, and standards landscape analysis. 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) (PRP measurement data)
- 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 Annex I GSPR, ISO 11737-1 — coverage gaps mapped at the component level
- VeriClean Seals™ 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 testing. It is not a batch-monitored VCQ deliverable or guarantee. Results vary by elastomer compound and initial contamination state.

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