Sealing solutions for biopharmaceutical processes

James Walker Elast-O-Pure® high performance elastomers

int2 solutions offers James Walker Elast-O-Pure® hygienic clamp gaskets and O-rings developed specifically for pharmaceutical and bioprocessing applications. Low extractables, lasting sealing performance, and clean release help address purity and productivity needs.

James Walker compounds its sealing materials with traceability from formulation to finished product. int2 connects you with material selection and technical expertise for your process.



Materials at a glance

Material	Elastomer	Key characteristics
Elast-O-Pure® EP75 Black	EPDM	50% lower Total Organic Carbon (TOC) extractables than typical EPDMs used in this application, helping minimize potential product contamination.
Elast-O-Pure® GF75 Black	Fluorocarbon	Excellent resistance to steam and strong mineral acids, with very low TOC levels.

Performance and process benefits

- **Low extractables:** Independently tested TOC values are significantly lower than comparative materials, reducing contamination risk.
- **Long term sealability:** Very low compression set and dimensional stability help retain sealing forces through repeated process cycles and reduce the need for re-torquing after CIP and SIP.
- **Steam and chemical resistance:** Suited to steam sterilization in Sterilize-In-Place (SIP) processes and acid and alkaline cleaners used in Clean-In-Place (CIP) systems.
- **Clean release:** Low adhesion to stainless steel supports disassembly after prolonged contact at elevated temperatures.
- **Low intrusion:** Designed to provide low levels of seal intrusion in hygienic clamp applications.

Available product forms

Hygienic clamp gaskets, O-rings, custom moldings, sheet, and precision cut gaskets.

int2 solutions is the exclusive North American distributor for James Walker's biopharmaceutical product range.

Applications and technical support

Sealing components for upstream and downstream processes

Process area	Typical sealing applications
Upstream	Hygienic clamp seals, O-rings, and manway seals on offline media preparation vessels; CIP, water, and buffer supply.
Centrifugation and filtration	Main vessel or equipment seals (O-rings) and hygienic clamp seals.
Chromatography columns	Dynamic and static O-rings.

Compliance and traceability

Material documentation includes FDA compliance with 21 CFR 177.2600; biological reactivity testing to USP <88>; non-cytotoxicity to USP <87>; low TOC levels to USP <643>; and heavy metals testing to USP <381>. ADIF documentation, certificates of compliance, and extended traceability are also available. Contact int2 for material-specific certificates.

EP75B steam cycle study

The reported study evaluated James Walker EP75B seals after 100 and 500 steam cycles using ASME-BPE compliant fittings.



Test method: Ten samples of each seal size were assembled in a sample block with Advanced Couplings SH-Type clamps tightened to 30 in-lb. Blocks were pressure tested at 45 psig for one hour with an acceptance criterion of no more than 0.5 psig loss.

Each steam cycle consisted of one hour at 130°C, followed by cooling below 25°C with clean, dry air. After the required cycles, blocks were retested at 45 psig for one hour. Intrusion measurements and visual inspection for cracks, tears, and deformation were performed by James Walker. Additional information was recorded under Integra protocol ENG-303-TP, Rev. 00.

Reported results: No cracks, tears, or other deformation were observed. All seals released cleanly from the ferrules with minimal adhesion. Contact int2 for the full report and data analysis.

Engineering and application support

Through James Walker, int2 connects you with component design and re-engineering, prototyping, tool manufacture, and production molding across elastomer materials. Support includes elastomer change-outs, onsite technician training, and application consultation informed by experience across global biopharmaceutical facilities.

Connect with int2 solutions

Discuss your sealing application, select a material, or request product documentation and the full steam-cycle test report.

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