

James Walker[®]

Elast-O-Pure[®] Hygienic Clamp Gaskets

Issue 3

- ***FDA compliant material***
- ***Tested & certificated to USP Class VI***
- ***Compatible with CIP, SIP & WFI systems***
- ***Low intrusion***
- ***Exceptionally low extractables***
- ***ASME BPE Compliant***



High Performance Sealing Technology



Application specific development

Many seal designs and materials in use by the pharmaceutical and bioprocessing industries have their origins in the requirements of the Food & Dairy or Chemical Process Industries (CPI). Unfortunately these industries have lower demands on purity, lower or no requirements for traceability and less rigorous sanitisation and sterilising requirements.

In addition, the relatively low volume requirements of many pharmaceutical and bioprocessing requirements force most seal manufacturers to acquire 'off-the-shelf' compounds that are optimised for production rather than the needs of the customer.

These factors create a number of common operational issues for pharmaceutical and bioprocessing operations;

- Loss of process integrity due to seal failure, sometimes managed through retightening practices.
- Difficulty cleaning due to intrusion into the bore or excessive surface roughness.
- Excessive adhesion to stainless steel often resulting in equipment damage, operator injury or time consuming change-out practices.
- Marginal performance in common industry fluids and clean steam.
- Inconsistent service life.
- Lack of process and ingredient traceability in seal manufacture.
- Potential contamination of drug product or process utilities.

Elast-O-Pure®

The Elast-O-Pure® range of materials has been developed from first principles to meet the specific requirements of the pharmaceutical and bioprocessing industry.

James Walker possesses class-leading production and testing facilities, which receive regular praise from respected global operators in this sector, and is uniquely positioned in developing bespoke sealing materials such as the Elast-O-Pure® range of elastomers, specifically to match demanding biopharmaceutical application requirements.



Our highly controlled manufacturing process, with fully documented chain of custody, provides a reduced risk of failure due to consistent product quality and full traceability of the raw ingredients.

As a result, our Elast-O-Pure range of materials offers considerable operational benefits;

- 50% lower TOC extractables than typical EPDM used in this application, thereby minimising potential contamination of the product.
- Low adhesion to stainless steel even after thermal cycling, avoiding potential equipment damage and giving easy change-out.
- Biocompatibility tested via USP Class VI <87> and <88>.
- Engineered compatibility with common cleaning materials, process fluids and steam.
- Extremely low compression set (~6%) for long-term seal stress retention without retightening.
- Low intrusion provides predictable 'cleanability' throughout seal life.
- Formulae are Free of Animal Derived Ingredients.
- Longer service life offers extended preventative maintenance cycles.

Smooth joint transition is critical

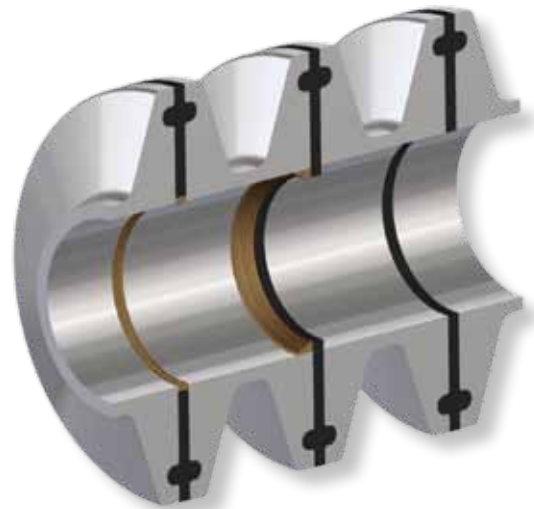
Why is a smooth bore joint transition critical?

The following risks are associated with intrusion and recess at the joint transition;

- System drainage and cleaning is compromised.
- Excess product held in system.
- Recess creates a microbial trap.
- Intrusion into the process stream creates damming and exposes the gasket to excessive shear.
- Accelerated failure of elastomer due to increased contact area subjected to aggressive CIP chemicals.
- Increased risk of process contamination from shearing of elastomer particulates.
- Recessed areas caused by oversized or undertightened gaskets create a trap at the clamp union.

Intrusion into the process flow will cause a build-up of product on the downstream side of the gasket. This will be difficult to remove and create a potential contamination hazard.

With a greater surface area of the gasket exposed to flow and cleaning processes there is also an increased risk of contamination from particles of sealing material.



Dimensional stability & dead space avoidance

The excellent long-term dimensional stability of Elast-O-Pure® EP75 Black, when under load, minimises any tendency for our Hygienic Clamp Gaskets to intrude into the product flow area or, conversely, to shrink back to form recesses.

Such defects could lead to dead spaces where contaminants from previous product flow might accumulate.

Intrusion testing in accordance with ASME BPE-2009

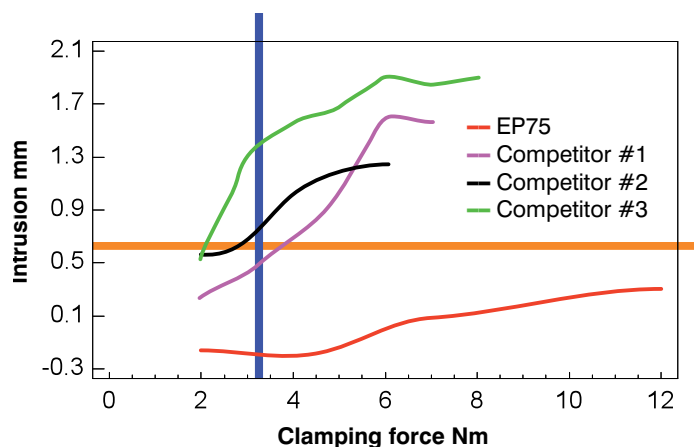
*(Typical values, where +value is intrusion into flow line and -value indicates a recess)**

Clamp size** (inch)	Intrusion (mm)	ASME BPE-2009 SG-2.4.1; Category I allowable intrusion	ASME BPE-2009 SG-2.4.1; Category II allowable intrusion
---.5	-0.20	+/- 0.6 mm	+/- 0.2 mm
0.75	0.00	+/- 0.6 mm	+/- 0.2 mm
1	0.05	+/- 0.6 mm	+/- 0.2 mm
1.5	-0.13	+/- 0.6 mm	+/- 0.2 mm
2	-0.21	+/- 0.6 mm	+/- 0.2 mm

Intrusion is categorised according to ASME BPE-2009 SG-2.4.1; measured at room temperature after being clamped for 10 minutes.

(Clamps and ferrules supplied by Advanced Couplings Limited.)
(** A clamping force of 5Nm was applied for all clamp sizes.)*

A recess at the joint will create a microbial trap, holding product that will not be removed by cleaning processes.



This chart, compiled from James Walker test data on 1" clamp gaskets, demonstrates rates of seal intrusion plotted against clamping force for James Walker Elast-O-Pure EP75 and the three closest competitor materials. The traces clearly show that only Elast-O-Pure remains within ASME Category 1 for intrusion specification (0.6mm) as clamping forces are increased from the ASME recommended clamping force of 3.3Nm.

Elast-O-Pure® Hygienic Clamp Gaskets

Elast-O-Pure® EP75 Black

Our highly developed pharmaceutical grade of ethylene - propylene - diene elastomer possesses significantly enhanced properties in comparison to other EPDM compounds. The wealth of special features it offers includes;

- Compliance with FDA 21 CFR 177.2600.
- Independently tested and certificated to **USP Class VI**.
- Compounded to give extremely low extractables.
- Long-term dimensional stability with very low compression set, which gives our clamp gaskets excellent long-term sealability.
- Compatibility with a wide range of process chemicals, including acids and alkalis used in CIP systems.
- Excellent resistance to steam — ideal for SIP sterilisation systems.
- Low adhesion to stainless steel — providing clean release and disassembly after long use.
- Exceptionally wide temperature range.
- ADI Free (Animal Derived Ingredient Free).

Typical properties of Elast-O-Pure® EP75 Black

Property	Units	Value
Temperature (max)	°C / °F	+135 / +275, with excursions to +180 / +356 in steam for SIP
Temperature (min)	°C / °F	-40 / -40
Hardness	IRHD	76
Tensile strength	MPa / psi	16.0/2320
Elongation at break	%	130

Compression set

(After 25% compression at specified time and temperature followed by 30 minutes recovery.)

Time (hours)	Temperature		
	100°C / 212°F	125°C / 257°F	150°C / 302°F
48	4.2%	6.1%	10%
168	6.0%	11.4%	22%
336	8.1%	18%	37%
672	11%	31%	65%

(These results display the excellent long-term sealing efficiency of Elast-O-Pure® EP75 Black.)

Biocompatibility

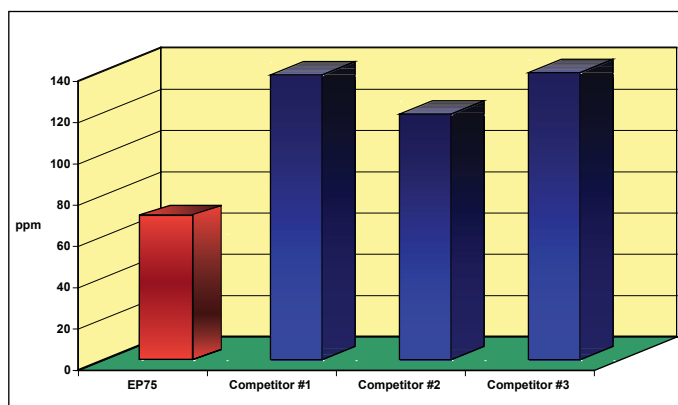
Elast-O-Pure® EP75 Black has been independently tested in accordance with, and fully complies with, the requirements of United States Pharmacopoeia (USP) 30 Class VI.

Full reports of the testing against the various aspects of compliance are available to customers on request.



Total Organic Carbon value

When independently tested, following extraction procedures in accordance with USP 381, Elast-O-Pure EP75 Black demonstrated significant, class-leading performance in comparison to its three main competitors.



Whilst there is no specified limit stated in the USP document, this remarkably low TOC value minimises any potential for contamination.

Elast-O-Pure® Hygienic Clamp Gaskets

Industry specific immersion testing

Purified water

(Conductance at 25°C / 77°F = 5µS/cm max)

	Units	4 weeks at 125°C / 257°F	4 weeks at 180°C / 356°F
Volume change	%	+2.7	+3.2
Change in tensile strength	%	+48	+26
Change in elongation at break	%	+7	+31
Change in hardness	IRHD	-1	-3

Water For Injection (WFI)

	Units	4 weeks at 80°C / 176°F
Volume change	%	+1.9
Change in tensile strength	%	+8.5
Change in elongation at break	%	+11
Change in hardness	IRHD	-2

(These results show that Elast-O-Pure® EP75 Black displays exceptional resistance to purified water, even at elevated temperatures.)

CIP 100®*

(4% by volume in de-ionised water)

	Units	4 weeks at 60°C / 140°F
Volume change	%	+2.6
Change in tensile strength	%	-9.7
Change in elongation at break	%	-7
Change in hardness	IRHD	-2

(Manufactured by Steris — based on potassium hydroxide. CIP 100® is a registered trademark of Steris Corporation.)*

CIP 200®*

(4% by volume in de-ionised water)

	Units	4 weeks at 20°C / 68°F
Volume change	%	+0.1
Change in tensile strength	%	-24
Change in elongation at break	%	-16
Change in hardness	IRHD	0

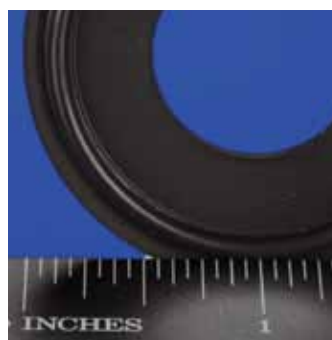
(Manufactured by Steris — based on phosphoric acid. CIP 200® is a registered trademark of Steris Corporation.)*

Immersion of EP75 in 6% Hydrogen Peroxide for 48 hours at 23°C

	Original	After immersion	% Change
Shore A	77	76	-1
Tensile Strength, MPa	16.4	15.4	-6.1
Elongation at Break, %	143.5	148.5	+3.5
Modulus at 25%	1.9	1.9	0.0
Modulus at 50%	3.4	3.5	+2.9
Modulus at 100%	9.1	9.3	+2.2
Volume Swell			-0.1%

Resistance to steam cycling

To check the adhesion resistance of our Elast-O-Pure® EP75 Black gaskets we have performed customer trials under a steam cleaning regime; subjecting the gaskets to 500 thermal cycles from clean steam at 130°C / 266°F in a line assembly.



Each cycle comprised one hour in clean steam and a return to room temperature before re-exposure to steam.

On completion of 500 cycles, the assembly was dismantled and the gasket was removed cleanly with no sticking and without leaving any residue on the metal surfaces.

Photograph shows an Elast-O-Pure® EP75 Black gasket after removal following 500 steam cycles.

Other pharmaceutical elastomers

In addition to Elast-O-Pure® EP75 Black, we also manufacture seals, gaskets and components in other USP Class VI elastomers, including;

- Elast-O-Pure® GF75 Black — Genuine Viton® pharmaceutical grade fluoroelastomer FKM
- Elast-O-Pure® EP70 White — peroxide cured EPDM pharmaceutical grade elastomer

(Viton® is a registered trade mark of DuPont Performance Elastomers)

Elast-O-Pure® Hygienic Clamp Gaskets

Elast-O-Pure® Sil70 Translucent — pharmaceutical grade silicone (VMQ)

Silicone elastomer does not readily support microbiological growth. This makes it ideal for use in clean environments and the manufacture of medical devices. Our platinum-cured Elast-O-Pure® Sil70 Translucent pharmaceutical grade of silicone is available in a hardness grade of 70 IRHD, making it suitable for a wide variety of fluid sealing duties.

Specifications

- Compliant with FDA 21 CFR 177.2600.
- Independently tested and certificated to **USP Class VI**.
- ADI Free (no animal derived components).

Special features of Elast-O-Pure® Sil70 Translucent

- Platinum-cured.
- High temperature resistance — up to 200°C constant with dry heat.
- Low levels of the extractables that can leach from material to promote contamination in a pharmaceutical process.
- Translucent.

Chemical properties

Suitable for sterilisation with SIP systems at up to 130°C and most CIP systems. Resistant to WFI systems at up to 80°C.



How supplied

Standard components — including 'O' rings and hygienic clamp seals — to any size, shape and international standard. Complex custom shapes by precision moulding. Full materials traceability provided for all items; an attribute that is highly desirable for critical applications.

Elast-O-Pure® Envelopes

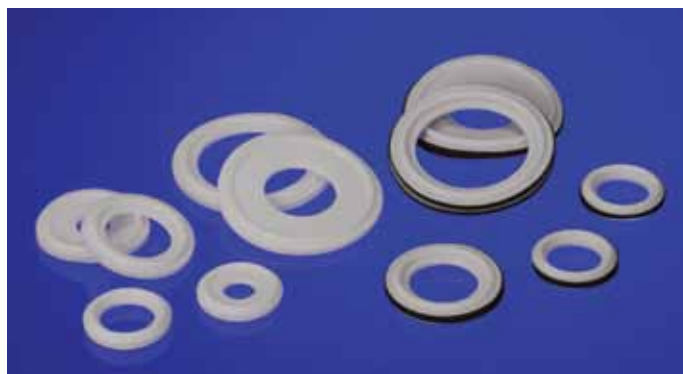
James Walker PTFE envelope gaskets for pharmaceutical and bioprocessing applications are available in a broad range of sizes and provide positive, trouble-free sealing in most applications.

- The PTFE envelope provides a full PTFE coverage, from the ID to the OD of the seal.
- The products are manufactured from PTFE with filler material of Elast-O-Pure® EP75 Black, Elast-O-Pure® GF75 Black or Elast-O-Pure® Sil70 Translucent.
- All materials meet FDA requirements and are certified to **USP Class VI**.
- Custom configurations are available to order.

The PTFE envelope provides excellent non-adhesion properties, allowing for easy removal during maintenance, yet combines with the filler to provide excellent formability for low compressive clamp loading. Ideal applications include alloy, standard steel, plastic, ceramic and glass-lined flanges.

Specifications

- Compliant with FDA 21 CFR 177.2600 & CFR 21 177.1550 for PTFE.
- Materials are independently tested and certificated to **USP Class VI**.
- ADI Free (no animal derived components).



Special features

- Recommended for high purity applications in the pharmaceutical and food processing industries.
- Combine the resilience and sealing ability of rubber with the chemical resistance of PTFE.
- Low contamination from extractables.

Chemical properties

- Resistant to aggressive water (WFI) and other critical systems.
- Resistant to SIP sterilisation systems.
- Resistant to strong cleaning agents used in CIP systems.

Available with fill material of Elast-O-Pure® EP75 Black, Elast-O-Pure® GF75 Black or Elast-O-Pure® Sil70 Translucent.

Serving the pharmaceutical & bioprocessing industries

Extensive size range available

In addition to the features provided by our Elast-O-Pure® materials, all our Hygienic Clamp Gaskets offer the following benefits;

- Long service life for best value and lowest total cost of ownership (TCO) in operation.
- Sizes available from 1/2" to 12".
- Full batch traceability — with elastomer compounding and gasket moulding undertaken in house by James Walker.
- Supplied in size ranges including: BS4825 part 3, 1991; BS4825 Non-Standard; BS Schedule 5 Pipe; BS Schedule 40; ISO 2852; ISO 1127; ISO 2037; Mini Series Ultra Bore.
- Custom sizes manufactured to order.

Global expertise – local support

We have more than 50 production, engineering, distribution and customer support facilities worldwide — backed by extensive IT networks, e-commerce systems and logistics operations — to serve customers in over 100 countries.

Our world-leading area of expertise is high performance fluid sealing. Activities range from research, development and manufacture, to product application and plant refurbishment.

Expert technical resources

Materials technologists and sealing specialists in our Technical Services and Pharmaceutical Industry Support teams are readily available to discuss processing applications for our products and materials, and are able to provide all relevant documentation on request.

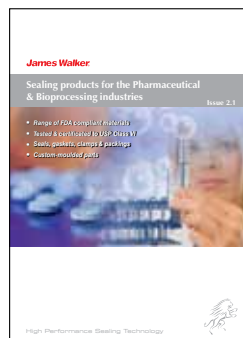
We regularly work in partnership with equipment manufacturers and end users to develop, prototype and evaluate materials and specific components for custom applications, always under strict confidentiality agreements.

Quality — our prime consideration

Quality design, quality manufacture and quality service are paramount throughout our worldwide operations. We start with the best raw materials and use advanced manufacturing techniques with strict quality control. This culture is reinforced by top-level technical support, logistics networks and a multitude of customised services.

Our quality standards are third-party registered to BS EN 9100:2003 and ISO 9001:2008. We are also regularly assessed and quality approved by a wide range of industry bodies and individual clients including multinational corporations, utilities and government organisations.

These guides give detailed technical information on the products and services supplied by James Walker to the pharmaceutical and bioprocessing industries. Please ask for your copies, or visit our website www.jameswalker.biz where many of them can be downloaded in pdf form.



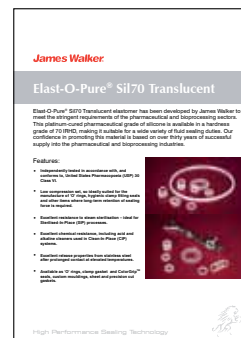
Sealing Guide



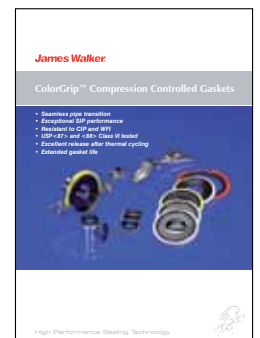
Elast-O-Pure® EP75 Black



Elast-O-Pure® GF75 Black



Elast-O-Pure® Sil70



ColorGrip™

James Walker companies worldwide

James Walker & Co

Tel: +44 (0)1270 536000
Fax: +44 (0)1270 536100
Email: csc@jameswalker.biz

James Walker Australia

Tel: +61 (0)2 9721 9500
Fax: +61 (0)2 9721 9580
Email: sales.au@jameswalker.biz

James Walker Benelux (Belgium)

Tel: +32 3 820 7900
Fax: +32 3 828 5484
Email: sales.be@jameswalker.biz

(Netherlands)

Tel: +31 (0)186 633111
Fax: +31 (0)186 633110
Email: sales.nl@jameswalker.biz

James Walker Brasil

Tel: +55 21 2220 2152
Fax: +55 21 2531 1704
Email: sales.br@jameswalker.biz

James Walker China

Tel: +86 21 6876 9351
Fax: +86 21 6876 9352
Email: sales.cn@jameswalker.biz

James Walker Deutschland

Tel: +49 (0)40 386 0810
Fax: +49 (0)40 389 3230
Email: sales.de@jameswalker.biz

James Walker France

Tel: +33 (0)437 497 480
Fax: +33 (0)437 497 483
Email: sales.fr@jameswalker.biz

James Walker Iberica

Tel: +34 94 447 0099
Fax: +34 94 447 1077
Email: sales.es@jameswalker.biz

James Walker Ireland

Tel: +353 (0)21 432 3626
Fax: +353 (0)21 432 3623
Email: sales.ie@jameswalker.biz

James Walker Italiana

Tel: +39 02 257 8308
Fax: +39 02 263 00487
Email: sales.it@jameswalker.biz

James Walker Mfg (USA)

Tel: +1 708 754 4020
Fax: +1 708 754 4058
Email: sales.jwmfg.us@jameswalker.biz

James Walker New Zealand

Tel: +64 (0)9 272 1599
Fax: +64 (0)9 272 3061
Email: sales.nz@jameswalker.biz

James Walker Norge

Tel: +47 22 706800
Fax: +47 22 706801
Email: sales.no@jameswalker.biz

James Walker Oil & Gas (USA)

Tel: +1 281 875 0002
Fax: +1 281 875 0188
Email: oilandgas@jameswalker.biz

James Walker Singapore

Tel: +65 6777 9896
Fax: +65 6777 6102
Email: sales.sg@jameswalker.biz

James Walker South Africa

Tel: +27 (0)31 304 0770
Fax: +27 (0)31 304 0791
Email: sales.za@jameswalker.biz

General information

Health warning: If PTFE or fluoroelastomer (eg, FKM, FFKM, FEPM) products are heated to elevated temperatures, fumes will be produced which may give unpleasant effects, if inhaled. Whilst some fumes are emitted below 250°C from fluoroelastomers or below 300°C from PTFE, the effect at these temperatures is negligible. Care should be taken to avoid contaminating tobacco with particles of PTFE or fluoroelastomer, or with PTFE dispersion, which may remain on hands or clothing. Material Safety Data Sheets (MSDS) are available on request.

Information in this publication and otherwise supplied to users is based on our general experience and is given in good faith, but because of factors which are outside our knowledge and control and affect the use of products, no warranty is given or is to be implied with respect to such information. Unless governed by type approval or contract, specifications are subject to change without notice. Statements of operating limits quoted in this publication are not an indication that these values can be applied simultaneously.

To ensure you are working with the very latest product specifications, please consult the relevant section of the James Walker website: www.jameswalker.biz.

James Walker & Co Ltd

Pharmaceutical Industry Support Team
1 Millennium Gate, Westmere Drive
Crewe, Cheshire CW1 6AY, UK
Tel: +44 (0)1270 536 000
Fax: +44 (0)1270 536 100
Email: pharma@jameswalker.biz

www.jameswalker.biz



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