

James Walker®

Elast-O-Pure® Hygienic Clamp Gaskets

- ***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



Elast-O-Pure[®] Hygienic Clamp Gaskets

James Walker has developed its Elast-O-Pure[®] Hygienic Clamp Gaskets, based on Elast-O-Pure[®] EP75 Black ethylene-propylene-diene elastomer, to meet the stringent requirements of the pharmaceutical and bioprocessing sectors.

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	16.4 / 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.)

Elast-O-Pure[®] Hygienic Clamp Gaskets

In addition to the features provided by our Elast-O-Pure[®] EP75 Black elastomer, our Hygienic Clamp Gaskets offer the following benefits:

- Long service life for best value and economy in use.
- 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.



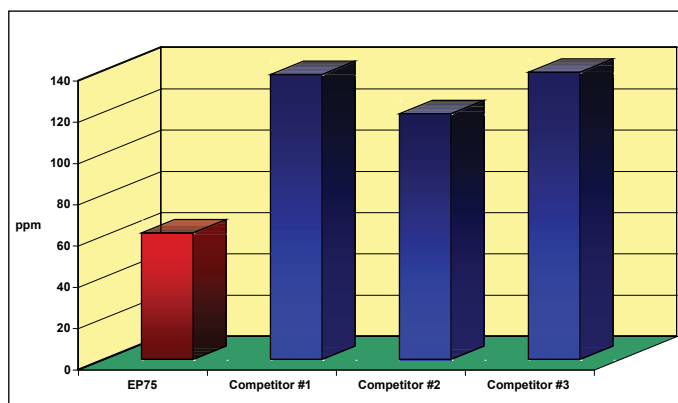
Biocompatibility

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

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-2007

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

Clamp size** (inch)	Intrusion (mm)	ASME BPE-2007 SG-2.4.1; Category I allowable intrusion	ASME BPE-2007 SG-2.4.1; Category II allowable intrusion
0.5	-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-2007 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.)

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®*

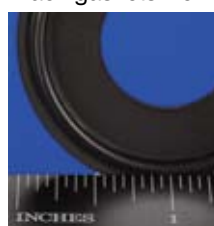
(4% by volume in de-ionised water)

	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.)

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® Sil70 Translucent — platinum-cured pharmaceutical grade silicone VMQ

Viton® is a registered trade mark of DuPont Performance Elastomers

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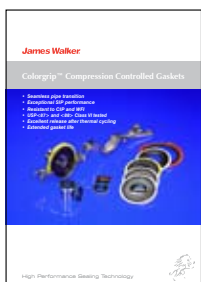
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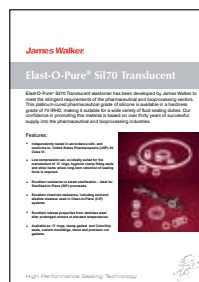
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GF75 Black



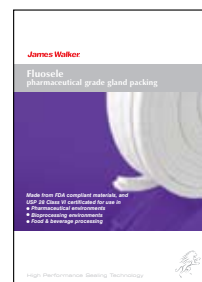
ColorGrip™



Sealing products for the
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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.

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