Sealing products for the Pharmaceutical & Bioprocessing industries

- Range of FDA compliant materials
- Tested & certificated to USP Class VI
- Seals, gaskets & clamps
- Custom-moulded parts
We have built a respected global reputation for our materials science capabilities in formulating and compounding materials for use in critical applications across many industries.

This brochure offers an insight into the services we offer in material formulation and compounding, product design and re-engineering plus the manufacture and supply of components for the bioprocessing and pharmaceutical industries.

To the best of our knowledge, we are the only component manufacturer able to offer total in-house control from material formulation to finished product.

For over 30 years we have applied our expertise in specialised elastomers to the pharmaceutical sector. Our experience of the biopharm industry extends to work on ASME BPE sub-committees covering polymer materials and seal performance, which provide updates to the BPE Standard. We have also worked closely with industry groups such as the BioPhorum Operations Group (BPOG) in developing solutions to key sealing issues.

By taking the time and trouble to understand customer and industry issues we are able to be more targeted in our development of a solution, ensuring that the result of our work addresses the problem on every level.

With this in mind we encourage you to talk to us, so that together we may advance our knowledge and understanding and develop new ideas that will be a positive move forward for the pharmaceutical and bioprocessing industries.
Contents

Materials development 4
Product testing 5
Traceability 6-7
Elast-O-Pure® EP75 Black 8-9
Elast-O-Pure® GF75 Black 10
Elast-O-Pure® SIL70 11
Kalrez® perfluoroelastomer 12
PTFE materials 13

Hygienic clamps & gaskets 14-15
PTFE envelope gaskets 16
O rings and encapsulated O rings 17
Component manufacture in engineering thermoplastics 18
Literature and technical papers 19
Contact details 20

Images courtesy of National Institute for Bioprocessing Research and Training.
Our position as a leader in material science and compound development is only half the story in our creation of effective sealing solutions.

In many cases, improving performance is not simply a matter of using a better material – it requires a detailed understanding of the forces and dynamics at work in the application.

James Walker application and design engineers possess not only the necessary tools but more importantly the experience required to find the root cause of problems and through re-engineering seals, housing designs and other elements of the equation, develop a successful solution.

**Material science**

Probably a unique position among manufacturers of seals for the biopharmaceutical industry, James Walker develops its own elastomer compounds in-house. This capability and experience helps ensure material performance is optimised not only for the customer application but also throughout the manufacturing process.

Having the capability to develop compounds and adjust formulations also provides additional options when trying to solve sealing issues. Where many suppliers can only call upon 'off-the-shelf' alternatives, James Walker can literally go all the way back to a clean sheet and start again with the basic material ingredients.

**Design**

Working from a clean sheet in partnership with an OEM or solving a problem retrospectively on a working plant, James Walker has built a respected reputation as a leading force in sealing engineering.
Material development and seal design

Our engineers have amassed years of experience across a broad range of industries and applications. This experience instinctively points them in the right direction when looking for solutions and, combined with the latest CAD, FEA and 3D computerised simulation and design tools, offers a capability few companies can match.

Testing and validation

Although our materials have proven themselves in the laboratory it is important for our customers to know that the end products made from those materials will perform to the required levels under operational conditions.

Running accelerated tests as part of our validation process enables us to provide strong indicators with regard to product behaviour and lifespan and provides our customers with the confidence and peace of mind they are seeking when looking at any potential process change.

Bespoke test facilities

Our research and development in the field of sanitary valve diaphragms would not have been possible without our investment in a purposebuilt test rig.

Fully computer controlled, this rig is capable of replicating regimes involving steam, water and chemical cleaning cycles and can therefore match our customers' regimes exactly, allowing us to carry out performance benchmarking and comparative testing under identical conditions. The system allows us to subject a range of products including clamp gaskets and diaphragms to operational trials.
Laser marking capability
Batch number, part number, manufacturing date and any desired customer information can be laser marked onto every finished product – allowing the entire production journey to be traced, right back to raw ingredients.

Full packaging identification
All products are packaged in accordance with food regulations and carry detailed product / material information including batch numbers and production dates.

Comprehensive validation pack
A comprehensive validation pack can be supplied for each product covering material and product testing, statements of compliance and material data.

Clean manufacturing process
Manufacturing takes place under strictly supervised manufacturing conditions and does not involve the use of potentially cytotoxic mould release agents or bonding agents.

Specification testing & quarantine
All materials are quarantined until tested and approved to specification before they are permitted to be used in any product manufacturing process.

A unique position
At James Walker we not only manufacture elastomeric components; we also formulate and compound our own materials, giving us total control over every stage of the manufacturing process.

What does this mean to the end-user?
By formulating specifically for biopharmaceutical use we make sure that our compounds are designed to minimise leachables and extractables without affecting performance and, unlike component manufacturers purchasing ready-made compounds off the open market, we are able to trace and verify every ingredient.

**Compound mix recording**
A lot number is created that can be linked back to the in-house controlled mixing of each batch of compound, detailing the full ingredient mix.

**FDA & USP compliance**
Every ingredient is screened to ensure full compliance with FDA 21 CFR 177.2600 and finished parts are tested to USP Class VI.

**ADI free assurance**
Written assurances throughout the raw material supply chain confirm that no animal derived elements are present in the individual ingredients.

**Certificate of analysis**
Certificates of analysis are available to audit for each and every batch of ingredient that is put into any compound.

**Ingredient batch recording**
The exact weight and lot number of each individual ingredient is recorded for every batch of compound.
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 include;

- 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 (no animal derived components)

Typical properties of Elast-O-Pure® EP75 Black

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

Compression set

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

<table>
<thead>
<tr>
<th>Time (hours)</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100°C / 212°F</td>
</tr>
<tr>
<td>48</td>
<td>4.2%</td>
</tr>
<tr>
<td>168</td>
<td>6.0%</td>
</tr>
<tr>
<td>336</td>
<td>8.1%</td>
</tr>
<tr>
<td>672</td>
<td>11%</td>
</tr>
</tbody>
</table>

(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 <643>, 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.
Industry specific immersion testing

**Purified water**

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

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

**Water For Injection (WFI)**

<table>
<thead>
<tr>
<th></th>
<th>Units</th>
<th>4 weeks at 80°C / 176°F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume change</td>
<td>%</td>
<td>+1.9</td>
</tr>
<tr>
<td>Change in tensile strength</td>
<td>%</td>
<td>+8.5</td>
</tr>
<tr>
<td>Change in elongation at break</td>
<td>%</td>
<td>+11</td>
</tr>
<tr>
<td>Change in hardness</td>
<td>IRHD</td>
<td>-2</td>
</tr>
</tbody>
</table>

(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)

<table>
<thead>
<tr>
<th></th>
<th>Units</th>
<th>4 weeks at 60°C / 140°F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume change</td>
<td>%</td>
<td>+2.6</td>
</tr>
<tr>
<td>Change in tensile strength</td>
<td>%</td>
<td>-9.7</td>
</tr>
<tr>
<td>Change in elongation at break</td>
<td>%</td>
<td>-7</td>
</tr>
<tr>
<td>Change in hardness</td>
<td>IRHD</td>
<td>-2</td>
</tr>
</tbody>
</table>

(* 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)

<table>
<thead>
<tr>
<th></th>
<th>Units</th>
<th>4 weeks at 20°C / 68°F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume change</td>
<td>%</td>
<td>+0.1</td>
</tr>
<tr>
<td>Change in tensile strength</td>
<td>%</td>
<td>-2.4</td>
</tr>
<tr>
<td>Change in elongation at break</td>
<td>%</td>
<td>-16</td>
</tr>
<tr>
<td>Change in hardness</td>
<td>IRHD</td>
<td>0</td>
</tr>
</tbody>
</table>

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

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

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

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® GF75 Black — Pharmaceutical grade fluorocarbon elastomer based on Viton® GF-600S

Elast-O-Pure® GF75 Black is a fluorocarbon elastomer based on Viton® GF-600S polymer from DuPont™ Performance Elastomers. James Walker developed Elast-O-Pure® GF75 Black to meet the stringent requirements of the pharmaceutical and bioprocessing sectors. It provides excellent resistance to steam and strong mineral acids and exhibits very low Total Organic Carbon (TOC) levels.

Special features of Elast-O-Pure® GF75 Black
- Based on Viton® GF-600S polymer from DuPont™ Performance Elastomers
- Independently tested and certificated to USP Class VI
- ADI free (no animal derived components)
- Excellent resistance to a wide range of chemicals
- Very low compression set
- Exceptionally clean release after prolonged contact
- Exceptional low-temperature flexibility
- Very high working temperature capability
- Contains very low levels of extractables

Typical properties of Elast-O-Pure® GF75 Black

<table>
<thead>
<tr>
<th>Property</th>
<th>Unit</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature (max)</td>
<td>°C / °F</td>
<td>230 / 446</td>
</tr>
<tr>
<td>Temperature (min)</td>
<td>°C / °F</td>
<td>0 / 32</td>
</tr>
<tr>
<td>Hardness</td>
<td>IRHD</td>
<td>74</td>
</tr>
<tr>
<td>Tensile strength</td>
<td>MPa / psi</td>
<td>30 / 4350</td>
</tr>
<tr>
<td>Elongation at break</td>
<td>%</td>
<td>220</td>
</tr>
<tr>
<td>Compression set (24 hours at 200°C / 392°F)</td>
<td>%</td>
<td>13</td>
</tr>
<tr>
<td>Total Organic Carbon (TOC)*</td>
<td>ppm</td>
<td>8.4</td>
</tr>
</tbody>
</table>

(*Independent test report available on request.)

Industry specific immersion testing

Water for injection (WFI)

<table>
<thead>
<tr>
<th>Property</th>
<th>Units</th>
<th>4 weeks at 80°C / 176°F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume change</td>
<td>%</td>
<td>+3.2</td>
</tr>
<tr>
<td>Change in tensile strength</td>
<td>%</td>
<td>+4</td>
</tr>
<tr>
<td>Change in elongation at break</td>
<td>%</td>
<td>-1.7</td>
</tr>
<tr>
<td>Change in hardness</td>
<td>IRHD</td>
<td>-2</td>
</tr>
</tbody>
</table>

(These results show that Elast-O-Pure® GF75 Black displays exceptional resistance to WFI, even at elevated temperatures.)

Chemical properties
- Resistant to aggressive water (WFI) systems
- Resistant to SIP sterilisation systems – very low swell and minimal loss of mechanical properties after repeated steam cycling
- Resistant to strong cleaning agents used in CIP systems

How supplied
Standard components, including O rings and flange gaskets cut to any size, shape and international standard. Complex custom shapes by precision moulding or CAD/CAM waterjet cutting of sheet material. Full materials traceability provided for all items; an attribute that is highly desirable for critical applications.

CIP 100**
(4% by volume in de-ionised water)

<table>
<thead>
<tr>
<th>Property</th>
<th>Units</th>
<th>4 weeks at 60°C / 140°F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume change</td>
<td>%</td>
<td>+0.9</td>
</tr>
<tr>
<td>Change in tensile strength</td>
<td>%</td>
<td>+3.2</td>
</tr>
<tr>
<td>Change in elongation at break</td>
<td>%</td>
<td>-6.0</td>
</tr>
<tr>
<td>Change in hardness</td>
<td>IRHD</td>
<td>-2</td>
</tr>
</tbody>
</table>

(*Manufactured by Steris — based on potassium hydroxide. CIP 100® is a registered trademark of Steris Corporation.)
Elast-O-Pure® SIL70 Translucent — Platinum-cured 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

Typical properties of Elast-O-Pure® SIL70 Translucent

<table>
<thead>
<tr>
<th>Property</th>
<th>Unit</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardness</td>
<td>IRHD</td>
<td>73</td>
</tr>
<tr>
<td>Tensile strength</td>
<td>MPa</td>
<td>9.6</td>
</tr>
<tr>
<td>Elongation at break</td>
<td>%</td>
<td>600</td>
</tr>
<tr>
<td>Compression set (24 hours at 100°C / 212°F)</td>
<td>%</td>
<td>6.5</td>
</tr>
<tr>
<td>Compression set (24 hours at 125°C / 257°F)</td>
<td>%</td>
<td>7.5</td>
</tr>
<tr>
<td>Tear Strength</td>
<td>N/mm</td>
<td>65</td>
</tr>
</tbody>
</table>

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.
DuPont™ Kalrez®

Kalrez® 6221, 6230 & LS205 — pharmaceutical grade perfluoroelastomers (FFKM)

James Walker is an authorised distributor in the UK, Ireland and France for the design, supply and technical support of sealing and fluid handling items made from DuPont™ Performance Elastomers’ range of Kalrez® perfluoroelastomers.

DuPont™ Kalrez® perfluoroelastomer parts made from compounds 6221, 6230 & LS205 provide superior chemical resistance and low contamination from extractables in pharmaceutical and food handling applications where FDA compliance is required. DuPont™ Kalrez® 6221, 6230 & LS205 are especially suited for Water For Injection (WFI) systems, Steam-in-Place (SIP) cleaning and other critical systems.

Specifications (please ask for data sheets)
• Compliant with FDA 21 CFR 177.2600
• Tested and certificated to USP Class VI

Special features of Kalrez® 6221, 6230 & LS205
• Recommended for high purity applications in the pharmaceutical and food processing industries
• Combine the resilience and sealing ability of rubber with almost universal chemical resistance
• Low contamination from extractables

Typical Physical Properties**

<table>
<thead>
<tr>
<th>Typical Physical Properties</th>
<th>Kalrez® LS205</th>
<th>Kalrez® 6221</th>
<th>Kalrez® 6230</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>White</td>
<td>White</td>
<td>Black</td>
</tr>
<tr>
<td>Maximum Application Temperature, °C (°F)</td>
<td>225 (437)</td>
<td>260 (500)</td>
<td>260 (500)</td>
</tr>
<tr>
<td>Durometer, Shore A³</td>
<td>75</td>
<td>70</td>
<td>75</td>
</tr>
<tr>
<td>100% Modulus¹, MPa (psi)</td>
<td>7.57 (1099)</td>
<td>7.24 (1050)</td>
<td>7.03 (1020)</td>
</tr>
<tr>
<td>Tensile Strength at Break (Tb), MPa (psi)</td>
<td>21.11 (3062)</td>
<td>15.16 (2200)</td>
<td>16.54 (2400)</td>
</tr>
<tr>
<td>Elongation at Break (E₄), %</td>
<td>170</td>
<td>150</td>
<td>170</td>
</tr>
<tr>
<td>Compression Set, Pellet, 70 hr at 204°C (400°F)</td>
<td>21</td>
<td>27</td>
<td>24</td>
</tr>
<tr>
<td>FDA</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>USP &lt;87&gt; and &lt;88&gt; Class VI at 121°C</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

¹ Not to be used for specification purposes ² DuPont proprietary test method ³ ASTM D2240 (plied sheet test specimen) ⁴ ASTM D412, 500 mm/min ⁵ ASTM D395B1

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

How supplied
Standard components, including O rings, flange gaskets and diaphragms to any size, shape and international standard. Complex custom mouldings. Full materials traceability provided for all items; an attribute that is highly desirable for critical applications.
GORE® STA-PURE™ sheet gasketing  
(Style 1200)

GORE® STA-PURE™ Style 1200 sheet gasketing has a unique proprietary design of 100% expanded PTFE (ePTFE). It excels at sealing irregular surfaces and maintaining a tight seal under demanding processing and system conditions.

Specifications
• USP Class VI <88> Biocompatibility
• US food contact compliance: 21 CFR 174.5(d)
• (EC) No 1935/2004

Prime features
• Suitable for pharmaceutical processing duties
• Resistant to creep and cold flow
• Maintains a reliable, durable seal
• Dimensionally stable
• Conforms easily - seals irregular flanges
• Retains tightness - minimum re-torque
• Documented lot traceability

Chemical properties
Resistant to all media in the range pH 0-14, excluding alkali metals and elemental fluorine, particularly at elevated temperatures.

How supplied
Standard thicknesses: 1.5mm & 3.0mm. Standard sheet size: 1524mm x 1524mm

GORE® STA-PURE™ pipe gasket  
(Style 1500)

GORE® STA-PURE™ Style 1500 gaskets feature a unique proprietary design of 100% expanded PTFE (ePTFE) with multidirectional strength. These gaskets meet the needs of many different piping and flange materials to provide a highly durable and creep-resistant joint.

Specifications
• UPS Class VI <88> Biocompatibility
• US food contact compliance: 21 CFR 174.5(d)
• (EC) No 1935/2004

Prime features
• Suitable for pharmaceutical processing duties
• Low bolt-load sealing for use with the most fragile flanges
• Dimensionally stable - resistant to creep and cold flow
• Maintains durable, reliable seal
• Standardise across a plant - use one gasket type, system-wide
• Documented lot traceability

Chemical properties
Resistant to all media in the range pH 0-14, excluding alkali metals and elemental fluorine, particularly at elevated temperatures.

How supplied
Gaskets for 1/2-inch through to 12-inch nominal pipe flanges (NPS) per ASME B16.21 Class 150 & 300. DN 10 - 300, PN2.5, PN6, PN10, PN16 & PN40 per EN1514
Hygienic clamps and gaskets

High-performance gaskets

We provide hygienic clamps, plus the special gaskets needed by the many pipe coupling systems used extensively in the pharmaceutical and bioprocessing sectors.

The gaskets are manufactured in a variety of high performance elastomer grades, including:

- Elast-O-Pure® EP75 Black ethylene-propylene-diene (EPDM) to Class VI
- Elast-O-Pure® SIL70 Translucent platinum-cured silicone (VMQ) to Class VI

All materials have a validation pack including statement of compliance and MSDS available on request and are;

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

Our gaskets are supplied to BS 4825 Part 3 specification and are compliant to ASME BPE 2012. (Sizes and configurations outside these standards are available to customer specification).

Clamps, ferrules and blanks

James Walker offers a wide range of pharmaceutical clamps, ferrules and pharmaceutical blanks manufactured in high quality stainless steel. The TUV certified range includes single and double hinged clamps plus heavy-duty variants.

We cater for most standards used world-wide covering BS, DIN, ISO, SMS plus a vast range of international sizes;

- BS4825 Part 3
- BS4825 Non Standard
- BS Schedule 5 Pipe
- ISO 2852
- BS Schedule 40
- ISO 1127
- ISO 2037
- Mini Series Ultra Bore

In addition, custom sizes and configurations can be manufactured and supplied to order.

Accu-Tite™ Torque Tool

Proper compression of a gasket is critical to creating a proper seal. Achieving this correct compression couldn't be easier than with the Accu-Tite™.

- Prevents leaks
- Eliminates over-tightening
- Calibrated to +/-4%

Accu-Tite™ is designed to quickly and accurately tighten hygienic clamps to a fixed torque to improve reliability, prevent leaks and reduce ergonomic issues associated with tightening clamps.
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

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-2012

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

<table>
<thead>
<tr>
<th>Clamp size** (inch)</th>
<th>Intrusion (mm)</th>
<th>ASME BPE-2012 SG-2.4.2: Category I allowable intrusion</th>
<th>ASME BPE-2012 SG-2.4.2: Category II allowable intrusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>---.5</td>
<td>-0.20</td>
<td>+/- 0.6 mm</td>
<td>+/- 0.2 mm</td>
</tr>
<tr>
<td>0.75</td>
<td>0.00</td>
<td>+/- 0.6 mm</td>
<td>+/- 0.2 mm</td>
</tr>
<tr>
<td>1</td>
<td>0.05</td>
<td>+/- 0.6 mm</td>
<td>+/- 0.2 mm</td>
</tr>
<tr>
<td>1.5</td>
<td>-0.13</td>
<td>+/- 0.6 mm</td>
<td>+/- 0.2 mm</td>
</tr>
<tr>
<td>2</td>
<td>-0.21</td>
<td>+/- 0.6 mm</td>
<td>+/- 0.2 mm</td>
</tr>
</tbody>
</table>

Intrusion is categorised according to ASME BPE-2012 SG-2.4.2: 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.)

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.

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 Black 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.
Envelope gaskets

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 & FDA 21 CFR 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
O Rings

James Walker has a vast range of stock sizes and existing moulds for O rings, which can be moulded in an equally broad range of materials including Elast-O-Pure® materials, Kalrez® and other pharmaceutical grade elastomers.

We also supply O rings in fluorocarbon or silicone where conditions are not suitable for standard ranges. These rings are used in the pharmaceutical and food processing industries, and other sectors where high levels of chemical resistance and hygiene are required.

Special features
• Suit many static and dynamic duties
• Occupy little space
• Seal efficiently in both directions
• Appropriate material selection provides compatibility with most fluid media
• Can work between -65°C and +315°C according to material type
• Can function at temperatures down to -200°C when made of PTFE

Chemical properties
• Dependent upon chosen material. Material Safety Data Sheets and Statements of Compliance, where appropriate, are available to customers on request

How supplied
• As O rings to any international standard and size.

FEP encapsulated O rings

In addition to full ranges of O rings in our Elast-O-Pure® materials, Kalrez® and other pharmaceutical grade elastomers, we also supply rings of fluorocarbon or silicone that are completely covered with a seamless sheath of FEP fluoropolymer.

These rings are used in the pharmaceutical and food processing industries, and other sectors where high levels of chemical resistance and hygiene are required.

Special features of FEP encapsulated O rings
• For use when a standard elastomeric O ring has inadequate chemical resistance, or a solid PTFE O ring has insufficient elasticity for reliable, long-term sealing
• Excellent resistance to a wide range of chemical media
• Fully interchangeable with standard elastomeric O rings
• Low friction and low 'stick-slip' effect
• Due to the FEP sheath, these rings are less flexible than normal elastomeric O rings. They may need auxiliary tools to facilitate efficient fitting

How supplied
As O rings to any international standard and size.
Alternative materials

Thermoplastic engineering

James Walker has the capabilities to mould, cast, extrude and machine a broad range of thermoplastic materials.

Our application and materials engineering teams work with customers to design seals and components for specific application requirements using the most suitable and cost-effective materials including:

ABS
Acetal Copolymer and Homopolymer
Arnitel®
Devlon®
Dupont™ Hytrel®
Evathane®
HD polystyrene
Nylon – filled & virgin
PEEK™
Polycarbonate
Polypropylene
PTFE – filled & virgin
PVC
Santoprene™
Thermoplastic and thermoset PU
Thermoplastic rubbers
TPE
UHMWPE

Our facilities can produce anything from a single bespoke item machined out of solid billet to millions of injection moulded components, all with the back-up of 3D design, FEA analysis and rapid prototyping facilities.

• 3D CAD and FEA design tools
• All processes fully in-house
• Total traceability of process and materials

With total in-house control of the entire process, from casting to final machining and testing, we have the capability to produce complex components from 10mm to over 2500mm OD, and weighing up to 1000kg with total traceability of production methods and materials.
These guides and technical papers give detailed technical information on the products and services supplied by James Walker to the pharmaceutical, biotech and general industrial sectors. Please ask for your copies, or visit our website www.jameswalker.biz where many of them can be downloaded in pdf form.

Total material traceability

Extractables & leachables

O Ring guide

Gaskets & jointings guide

General information

**Health warning:** If PTFE or fluoroeastomer (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 fluoroeastomers 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 fluoroeastomer, 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.

Trademark acknowledgements

James Walker acknowledges the following trademarks as mentioned in this publication. All other names bearing the ® symbol are trademarks of James Walker.

- Accu-Tite™: Integra Companies
- Arnitel®: DSM Engineering Plastics
- Evathane®: Arkema Inc.
- GORE™: WL Gore & Associates
- Hytrel®: DuPont™ Company
- Karez®: DuPont™ Performance Elastomers
- Peek™: Victrex plc.
- Santoprene™: ExxonMobil Corporation
- Viton®: DuPont Performance Elastomers

Environmental statement: This brochure is manufactured using advanced environmentally friendly technologies and follows the strict environmental standard BS EN ISO 14001. Made from chlorine-free pulp (ECF) with post-consumer recycled fibre obtained from sustainable wood forests, and printed using vegetable-based inks, by Binfield Printers Ltd.

For those who wish to reduce further their impact on the environment, this publication is also available as a PDF from: www.jameswalker.biz
### James Walker worldwide support & distribution

<table>
<thead>
<tr>
<th>Region</th>
<th>Country</th>
<th>Tel</th>
<th>Fax</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>James Walker Asia Pacific</strong></td>
<td></td>
<td>+65 6267 4788</td>
<td>+65 6267 4980</td>
<td><a href="mailto:sales.sg@jameswalker.biz">sales.sg@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker Australia</strong></td>
<td></td>
<td>+61 (0)2 9721 9500</td>
<td>+61 (0)2 9721 9580</td>
<td><a href="mailto:sales.au@jameswalker.biz">sales.au@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker Benelux</strong></td>
<td>(Belgium)</td>
<td>+32 3 820 7900</td>
<td>+32 3 828 5484</td>
<td><a href="mailto:sales.be@jameswalker.biz">sales.be@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker Benelux</strong></td>
<td>(Netherlands)</td>
<td>+31 (0) 186 633111</td>
<td>+31 (0) 186 633110</td>
<td><a href="mailto:sales.nl@jameswalker.biz">sales.nl@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker Brasil</strong></td>
<td></td>
<td>+55 11 4392 7360</td>
<td>+55 11 4392 5976</td>
<td><a href="mailto:sales.br@jameswalker.biz">sales.br@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker China</strong></td>
<td></td>
<td>+86 21 6876 9351</td>
<td>+86 21 6876 9352</td>
<td><a href="mailto:sales.cn@jameswalker.biz">sales.cn@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker Deutschland</strong></td>
<td></td>
<td>+49 (0) 40 386 0810</td>
<td>+49 (0) 40 389 3230</td>
<td><a href="mailto:sales.de@jameswalker.biz">sales.de@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker France</strong></td>
<td></td>
<td>+33 (0) 437 497 480</td>
<td>+33 (0) 437 497 483</td>
<td><a href="mailto:sales.fr@jameswalker.biz">sales.fr@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker Iberica</strong></td>
<td></td>
<td>+34 94 447 0099</td>
<td>+34 94 447 1077</td>
<td><a href="mailto:sales.es@jameswalker.biz">sales.es@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker Inmarco (India)</strong></td>
<td></td>
<td>+91 (0)22 4080 8080</td>
<td>+91 (0)22 2859 6220</td>
<td><a href="mailto:info@jwinmarco.com">info@jwinmarco.com</a></td>
</tr>
<tr>
<td><strong>James Walker Ireland</strong></td>
<td></td>
<td>+353 (0)21 432 3626</td>
<td>+353 (0)21 432 3623</td>
<td><a href="mailto:sales.ie@jameswalker.biz">sales.ie@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker Italiana</strong></td>
<td></td>
<td>+39 02 257 8308</td>
<td>+39 02 263 00487</td>
<td><a href="mailto:sales.it@jameswalker.biz">sales.it@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker Mfg (USA)</strong></td>
<td></td>
<td>+1 708 754 4020</td>
<td>+1 708 754 4058</td>
<td><a href="mailto:sales.jwmfg.us@jameswalker.biz">sales.jwmfg.us@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker New Zealand</strong></td>
<td></td>
<td>+64 (0)9 272 1599</td>
<td>+64 (0)9 272 3061</td>
<td><a href="mailto:sales.nz@jameswalker.biz">sales.nz@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker Norge</strong></td>
<td></td>
<td>+47 22 706800</td>
<td>+47 22 706801</td>
<td><a href="mailto:sales.no@jameswalker.biz">sales.no@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker Oil &amp; Gas (USA)</strong></td>
<td></td>
<td>+1 281 875 0002</td>
<td>+1 281 875 0188</td>
<td><a href="mailto:oilandgas@jameswalker.biz">oilandgas@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker South Africa</strong></td>
<td></td>
<td>+27 (0)31 304 0770</td>
<td>+27 (0)31 304 0791</td>
<td><a href="mailto:sales.za@jameswalker.biz">sales.za@jameswalker.biz</a></td>
</tr>
<tr>
<td><strong>James Walker UK</strong></td>
<td></td>
<td>+44 (0)1270 536000</td>
<td>+44 (0)1270 536100</td>
<td><a href="mailto:sales.uk@jameswalker.biz">sales.uk@jameswalker.biz</a></td>
</tr>
</tbody>
</table>

**UK sales & support**

James Walker UK Ltd  
Gawsworth House  
Westmere Drive  
Crewe  
CW1 6XB  
United Kingdom  
Tel: + 44 (0)1270 536 000  
Fax: + 44 (0)1270 536 100  
Email: sales.uk@jameswalker.biz

**International sales & support**

James Walker Ireland Ltd  
3 Richfield Business Park  
Ballycurren  
Kinsale Road  
Cork  
Ireland  
Tel: +353 (0)21 432 3626  
Fax: +353 (0)21 432 3623  
Email: pharma@jameswalker.biz

www.jameswalker.biz