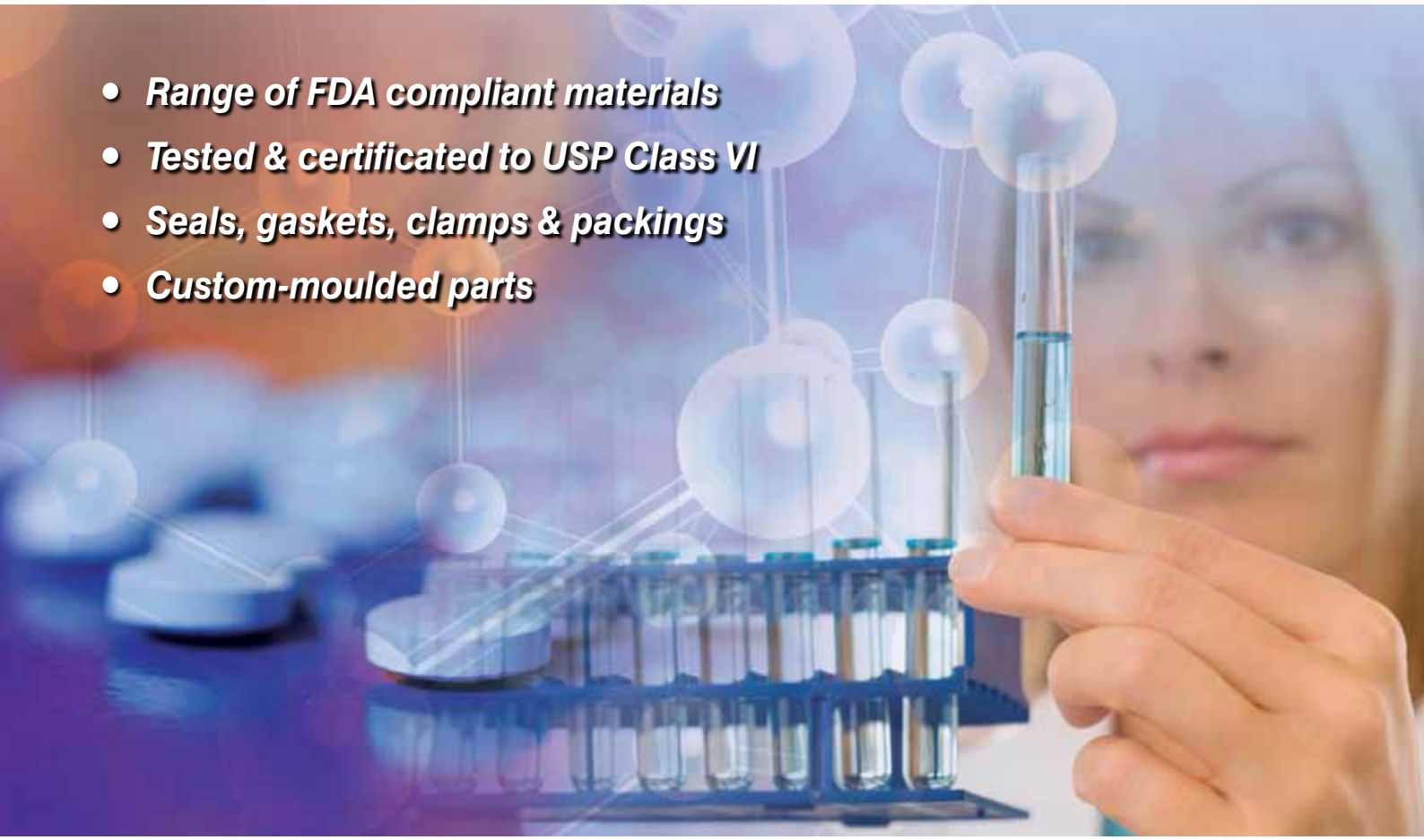
James Walker

Sealing products for the Pharmaceutical & Bioprocessing industries

Issue 2.2



- *Range of FDA compliant materials*
- *Tested & certificated to USP Class VI*
- *Seals, gaskets, clamps & packings*
- *Custom-moulded parts*

High Performance Sealing Technology

James Walker

Sealing products for the pharmaceutical & bioprocessing industries

Introduction

Only the highest quality sealing products, materials, services and technical advice are provided by James Walker to the pharmaceutical and bioprocessing sector. With over 30 years of service to this industrial area, our client base now covers:

- Pharmaceutical producers
- Bioprocessing sector
- Original equipment manufacturers
- Drug formulation R&D
- Powders handling containment
- Chemical producers

This document provides an overview of the most popular products that we supply for applications within the pharmaceutical and bioprocessing environments. These include pharmaceutical grade elastomers:

- Elast-O-Pure® EP75 Black ethylene-propylene-diene (EPDM)
- Elast-O-Pure® GF75 Black fluorocarbon elastomer (based on Viton® GF-600S)
- Elast-O-Pure® SIL70 Translucent platinum-cured silicone

All these products are independently tested and certificated to United States Pharmacopoeia (USP) Class VI.

The capability we have developed for our many clients in these specialised sectors includes an extensive range of liquid and gas sealing products, on-site and off-site technical advice, full technical support, and product training.

About James Walker

James Walker works constantly at the forefront of materials science and fluid sealing technology to create engineered solutions to industry's problems.

We can demonstrate unrivalled experience in the design, development and manufacture of a wide range of general and high performance elastomers. In these areas, the in-house expertise of the James Walker Technology Centre is backed by academic bodies, technological centres of excellence and commercial laboratories.

It is our experience that the best answer to many of the problems faced by our clients often lies in a bespoke solution. With our own, in-house laboratory, testing facilities and research production unit, all processes are under one roof – from compound formulation and manufacture through to product design, manufacture and testing. This allows us to provide the flexibility of service required to find and produce those bespoke solutions.

Whether the answer lies in a reformulated compound or complex, precision moulding, we have the expertise, facilities and resources on hand. Our clients are therefore working with dedicated, compact teams assuring efficient project turnaround and total confidentiality.

Materials expertise

We are constantly reviewing material performance and seeking to develop new compounds and variants that will address the operational problems faced by our clients and the industry sectors we serve. Across industries as diverse as aerospace, power generation and bioprocessing, James Walker technical ability and expertise has helped create what are now recognised as class-leading, best practice products and solutions.

In-house compound manufacturing provides total control and traceability for all products.

For over 30 years we have applied our expertise in specialised elastomers to the pharmaceutical sector. We have also developed and supplied elastomer-based sealing materials to the food, beverage and semiconductor industries for 20 years.

Sealing products for the pharmaceutical & bioprocessing industries

Our experience of the pharmaceutical sector extends to work on ASME BPE sub-committees covering polymer materials and seal performance, which provide updates to the BPE Standard.

Understanding our customers

We can't begin to solve our customers' problems if we don't understand their business, the legislative framework in which they must operate, their operational constraints and manufacturing processes. By taking the time and trouble to understand our customers' situations 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 we may, together, advance our knowledge and understanding and develop new ideas that will be a positive move forward for the pharmaceutical and bioprocessing industries.

Partners with industry

Our in-depth understanding of the requirements of the pharmaceutical and bioprocessing industries has enabled us to develop class-leading elastomer compounds that deliver on every level:

- Highly resistant to SIP / CIP cleaning regimes
- Independently certified to USP <87> and <88>, Class VI
- Full traceability and certification
- FDA compliance
- Very low compression set
- Class leading performance with regard to extractables
- Exceptionally clean release
- Proven longevity
- ADI free

By no means have we developed these products in isolation however. James Walker applications and materials science teams have worked closely with OEMs and end-users to ensure that our product offerings work effectively in every aspect. Our customers therefore receive a long-term, economic solution, which in turn offers them a competitive advantage.

Investing for a future in pharmaceuticals and bioprocessing

Our commitment to the pharmaceutical and bioprocessing industries can be seen at every level within the James Walker organisation. We have invested heavily in both manpower and technology, and continue to do so.

We have invested in purpose-built ISO Class 7 / Class 10,000 Clean Manufacturing and Inspection facilities to ensure that product for critical pharmaceutical and bioprocessing applications will meet the most stringent of customer specifications. The new facilities include metal to elastomer bonding capabilities and a further clean production cell dedicated to silicone product manufacture.

James Walker commitment to the pharmaceutical and bioprocessing industry includes investment in a full clean manufacturing and inspection facility.

To aid product development and materials research we have also invested in a series of test rigs which allow our research engineers to replicate operational conditions as closely as possible – an invaluable aid in helping us to identify the source of product performance and application problems.

James Walker is one of a very limited number of companies with such test facilities, including a multi-channel steam rig on which we are able to examine SIP performance. This investment in our application testing and quality regimes aims to give our customers the confidence that James Walker products are not just compliant with industry materials specifications but have been practically and fully tested to meet the required application conditions.

Elast-O-Pure® EP75 Black — pharmaceutical grade EPDM

This specially developed high-purity material from James Walker is based on an ethylene-propylene-diene terpolymer (EPDM) elastomer that is highly regarded by the pharma and biotech sectors for its many invaluable features. With a nominal hardness of 75 IRHD, it is a medium hardness grade suitable for many high-integrity fluid sealing applications.

Specifications *(please ask for data sheet, see p11)*
- Compliant with FDA 21 CFR 177.2600
- Independently tested and certificated to ***USP Class VI***
- Statement of compliance available on request
- ADI free (no animal derived components)

Special features of Elast-O-Pure® EP75 Black
- Outstanding solvent and amine resistance
- Excellent resistance to a wide range of chemicals
- Resistance to ageing
- Long service life
- Exceptional low-temperature flexibility
- Clean, easy release from ferrules
- Excellent value in service
- Contains very low levels of extractables

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 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.

ColorGrip™

ColorGrip™ combines the ultimate in mechanical design with Elast-O-Pure® EP75 Black, the ideal EPDM elastomer, to provide the most reliable sanitary gasket available for critical bio-processing applications.

Specifications *(please ask for data sheet, see p11)*
- ASME BPE-2009 compliant
- FDA listed materials
- USP <87> and <88> Class VI tested
- ADI free (no animal derived components)

Special features of ColorGrip™ with Elast-O-Pure® EP75 Black
- Locator ring available in eight colours for easy process and product segregation or simplification of maintenance procedures
- Gripping design gives proper alignment and frees hands for clamp assembly
- Compression stop extends service life of seal
- Seamless pipe transition (<0.008'' / 0.20mm intrusion or recess)
- Very low compression set – ideal for long-term retention of sealing forces
- Excellent release properties even after thermal cycling
- Exceptional autoclave and SIP performance

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

Elast-O-Pure® GF75 Black — pharmaceutical grade fluorocarbon elastomer based on Viton® GF-600S

Specifications *(please ask for data sheet, see p11)*
- Compliant with FDA 21 CFR 177.2600
- Independently tested and certificated to **USP Class VI**
- Statement of compliance available on request
- ADI free (no animal derived components)

Special features of Elast-O-Pure® GF75 Black
- Based on Viton® GF-600S polymer from DuPont Performance Elastomers
- 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

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.

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.

Products & materials

Hygienic clamps and gaskets

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

The gaskets are manufactured in a wide 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
- Elast-O-Pure® GF75 Black fluorocarbon elastomer based on Viton® GF-600S to Class VI
- Colorgrip™ with Elast-O-Pure® EP75 Black ethylene-propylene-diene (EPDM) to Class VI
- All materials are ADI free (no animal derived components)

Supplied as:
- BS 4825 part 3 – 1991
- BS 4825 – Non-Standard
- BS Schedule 5 Pipe
- ISO 2852

Additional size ranges to:
- BS Schedule 40
- ISO 1127
- ISO 2037
- Mini Series — Ultra Bore
- Custom sizes manufactured to order

‘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, plus FEP encapsulated ‘O’ rings for applications 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.

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

James Walker is 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.

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 and 6230
- 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
- Thermally stable up to 260°C, which permits their use in applications such as Stage II sterilisation
- 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

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.

Products & materials

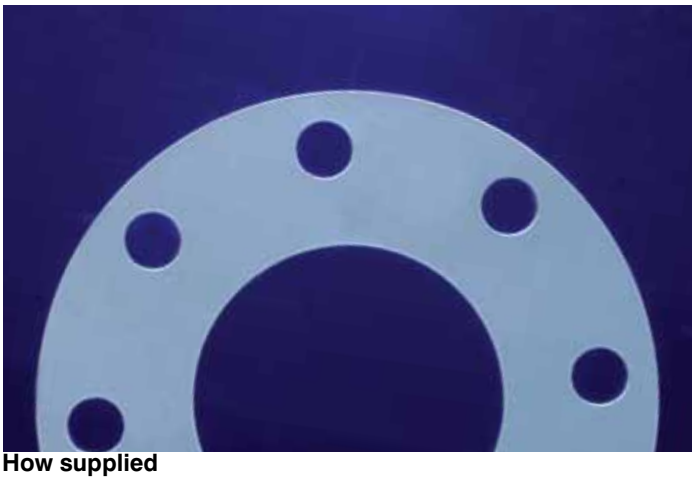
Gylon® 3504

Gylon® is recognised as one of the best modified PTFE sheet materials available for an extensive range of applications, particularly where aggressive chemicals are being handled or hygiene is a top priority.

Specifications
- Meets specifications of ABS (American Bureau of Shipping), FDA (Food and Drug Administration) and USP (US Pharmacopoeia)

Special features of Gylon® 3504
- Highly compressible form of Gylon, this version is particularly suited to applications that are sensitive to bolt loads such as glass-lined, enamelled or plastic flanges
- Improved performance over conventional PTFE
- Excellent resistance to cold flow/creep
- Suitable for high temperature/pressure applications
- Improved seal and excellent bolt torque retention
- Outstanding dimensional stability under thermal stress

Chemical properties
- PTFE with glass microspheres
- Resistant to moderate concentrations of acids and some caustics, hydrocarbons, solvents, water, refrigerants, and cryogenics



How supplied
Precision cut gaskets to any shape, size or quantity. Also in sheets. Thicknesses 1/32″, 1/16″, 1/8″.

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.

Thermoplastic products for the pharmaceutical and bioprocessing industries

James Walker has the capabilities to mould, cast, extrude and machine a broad range of thermoplastic materials, many of which are WRAS approved and FDA compliant.

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.

Metallic gaskets and components for the pharmaceutical and bioprocessing industries

Semi-metallic gaskets
These exceptionally versatile gaskets solve many flange sealing problems for industry. They have either a metal core with sealing materials on both flat surfaces, or a pliable core encased in a thin metallic casing.

Spiral wound gaskets
James Walker Metaflex® gaskets will seal flanges where temperature, pressure, vibration and flow rates are beyond the capability of conventional jointing materials. They are used worldwide for pipelines and pressure vessels on steam, petrochemical, nuclear, marine and hydraulic plant, as well as on heat exchangers.

Kammprofile-type gaskets
Our Metakamm® gaskets are now widely specified for high temperature/pressure pipework and vessels where spiral wound gaskets were previously used. Robust metal core with concentric grooves on either side plus soft layers of sealing material.

- Better leak-tightness than spiral-wound gaskets
- Safer and easier to handle than spiral-wound
- Operate at up to 1000°C or 25MPa/250bar

James Walker also possesses the facilities and skills required for precision machining of exotic alloys, producing high-specification, proprietary components for the oil & gas, chemical processing and defence industries.

We have considerable experience in working with materials including Inconel®, Incoloy®, Hastelloy®, nickel, titanium and all grades of stainless steel – many of these materials being held in stock.

Machined components can be finished in a wide range of coatings including Xylan® fluoropolymer, silver, gold and zinc. We also have the capability to bond metal with other materials to form metallic-elastomeric composites, providing customers with versatile metal and rubber seals and components for a range of applications.

James Walker

Services to the pharmaceutical & bioprocessing industries

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.

Clients seeking solutions to sealing problems have full access to the expertise of the James Walker design teams.

We are willing to partner with equipment manufacturers and end users to develop, prototype and evaluate materials and specific components for custom applications.

Global expertise – local support

James Walker is a dynamic global manufacturing organisation that supplies a vast range of specialised products and services to virtually every industrial sector.

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.

Together with associated knowledge-based services, our sealing application expertise and specialised products help to keep global industry running safely and efficiently, year-in and year-out.

James Walker maintains its position as an industry leader through investment in the latest production technology, including ISO Class 7 / Class 10,000 Clean Manufacturing facilities.

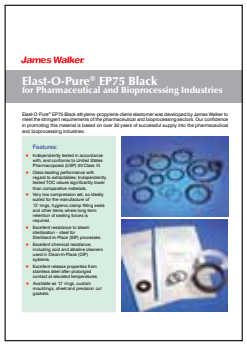
Quality — our prime consideration

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.

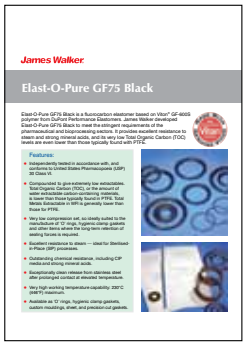
Our quality standards are third-party registered to BS EN 9100 and BS EN ISO 9001. We are also regularly assessed and quality approved by a wide range of industry bodies and individual clients including multinational corporations, utilities and government organisations.

Technical guides & data sheets

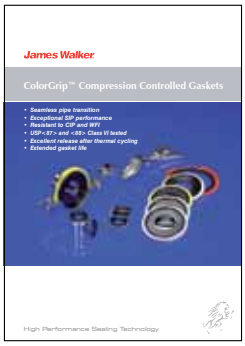
These guides give detailed technical information on the products and services supplied by James Walker to the pharmaceutical, biotech and general industrial sectors. Please ask for your copies, or visit our website *www.jameswalker.biz* where many of them can be downloaded in pdf form.



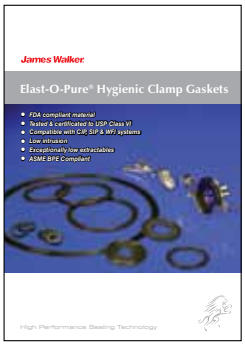
Elast-O-Pure® EP75 Black



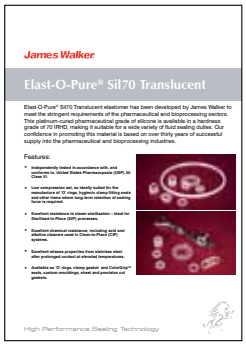
Elast-O-Pure® GF75 Black



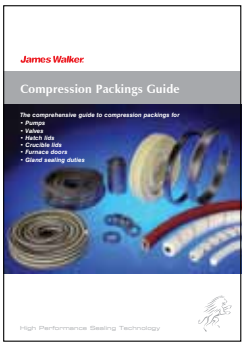
ColorGrip™



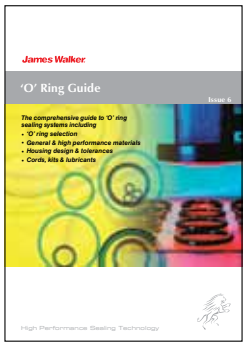
Elast-O-Pure® Hygienic Clamp Gaskets



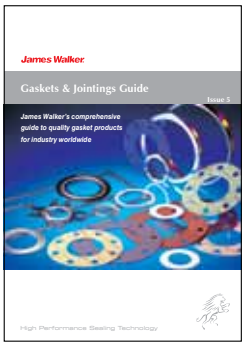
Elast-O-Pure® SIL70 Translucent



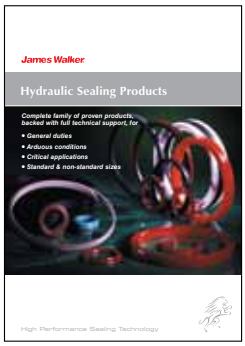
Compression packings



'O' rings



Gaskets & Jointings



Hydraulic seals

Confidentiality

Much of our high-level work on special materials and customised products for use within pharmaceutical processing is confidential. We are accustomed to operating under these conditions and fully respect the security issues involved.

We therefore gratefully acknowledge the permissions granted by clients to publish the technical data on our materials that were derived from independent evaluation tests performed on their specific items.

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.

Trademark acknowledgements

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Arnitel®	DSM Engineering Plastics
ColorGrip™	Integra Companies Inc.
Evathane®	Arkema Inc.
GORE™	WL Gore & Associates
Gylon®	Garlock Sealing Technologies
Hastelloy®	Haynes International
Hytrel®	DuPont Company
Incoloy®	Special Metals Corporation
Inconel®	Special Metals Corporation
Kalrez®	DuPont Performance Elastomers
Peek™	Victrex plc.
Santoprene™	ExxonMobil Corporation
Viton®	DuPont Performance Elastomers
Xylan®	Whitford Corp

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