James Walker®

Sealing products for the Pharmaceutical & Bioprocessing industries

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

plus our Fluosele pharmaceutical grade compression packing.

All these products are independently tested and certificated to 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' situation 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.

A technical solution for example is little use if it is not economic, doesn't meet stringent legislation or fit in with existing maintenance schedules. To this end James Walker believes in developing a tailored solution package rather than supplying a compromise from a list of standard, off-the-shelf products.

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;

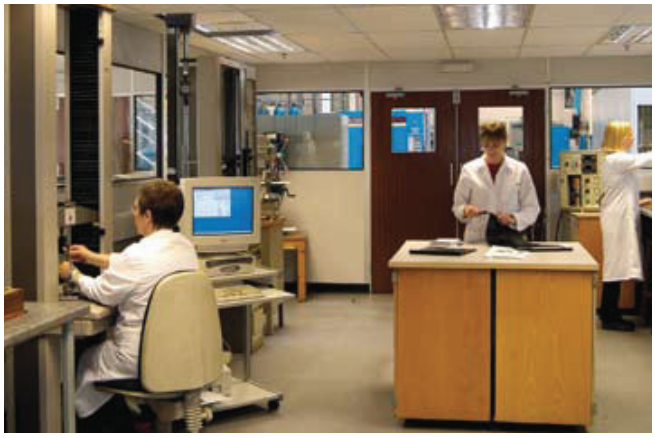
- Highly resistant to SIP / CIP cleaning regimes
- Independently certified to USP <87> and <88>, Class VI
- Full traceability and certification
- FDA compliance
- Very low compression set
- Class leading performance with regard to extractables
- Exceptionally clean release
- Proven longevity

Our in-house materials research and test facilities work in close co-operation with OEM and end user customers.

By no means have we developed these products in isolation however. James Walker applications and materials science teams have worked closely with OEM's and end-users to ensure that our product offerings work effectively on every level. 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 our clients in 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. Our dedicated sales, applications engineering and materials science team continues to develop potential new products and is now backed up by full Clean Manufacturing and inspection facilities at our Cockermouth site.



James Walker in-house materials development and testing laboratory facilities are complimented by independent, third party testing to industry standards.

As we said at the start of this introduction, every situation is different and the bespoke solution is very often the only true answer to a problem. 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.

James Walker

Products & materials

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 for money.
- 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-2005 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 8 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.

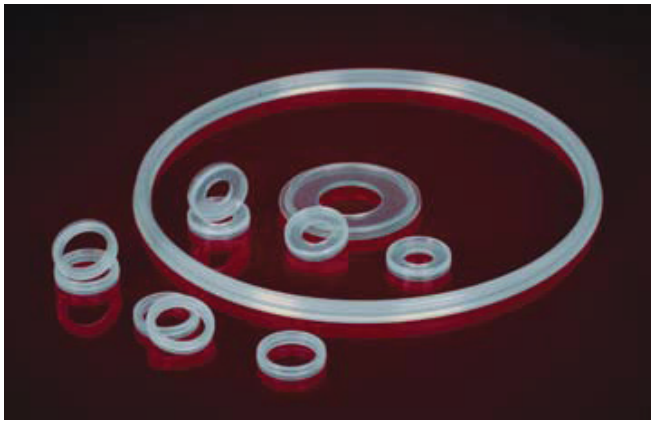
Elast-O-Pure® Sil70 Translucent — pharmaceutical grade silicone VMQ

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
- Non-toxic and low taint.
- 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 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 to Class VI.
- All materials are ADI free (No animal derived components).

Supplied as:
- BS4825 part 3 – 1991
- BS4825 – Non-Standard
- BS Schedule 5 Pipe
- ISO 2852

Additional size ranges to:
- BS Schedule 40
- ISO 1127
- ISO 2037
- Mini Series — Ultra Bore.

‘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® 6211 & 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® FFKM 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.

James Walker® Gylon® 3504

James Walker® Gylon® brings together two of the most respected names in sealing technology to provide the best modified PTFE sheet material 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 Pharmacopeia).

Special features of James Walker® 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 & 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″.

GORE™ Universal Pipe Gasket (Style 800)

Made from 100 per cent expanded PTFE (ePTFE) with multidirectional strength, this gasket type is recommended for sealing flange joints on steel, glass-lined steel and FPR systems. These gaskets are manufactured by WL Gore & Associates and supplied, along with GORE's full range of PTFE gaskets, by James Walker as a GORE™ Active Partner.

Specifications *(please ask for data sheet)*
- Compliant with FDA 21 CFR 177.1550.

Special features of GORE™ Universal Pipe Gasket (Style 800)
- Seals efficiently at low bolt load.
- Seals all types of standard piping.
- Not subject to ageing; can be stored indefinitely.

Chemical properties
- Resistant to all media in the range pH 0-14, except molten alkali metals and elemental fluorine.
- Resistant to aggressive water (WFI) systems.
- Resistant to SIP sterilisation systems.
- Resistant to strong cleaning agents used in CIP systems.

How supplied
Cut gaskets to ASME/ANSI 150 & 300 Classes, from 0.5 inch to 24 inch nominal pipe flanges.

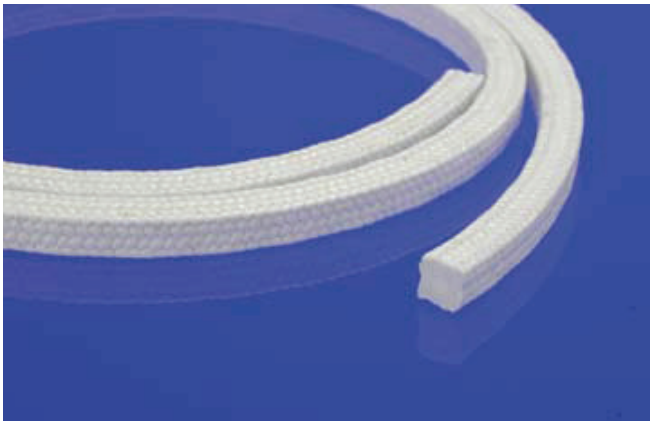
Fluosele pharmaceutical grade gland packing

This PTFE-based length-form compression packing has been developed by James Walker specifically for use where simple-to-install gland sealing products are needed in pharmaceutical and bioprocessing environments.

It is recommended for valve stems, rotary and reciprocating pumps, mixers, agitators, centrifuges, filter dryers and other vessels handling high purity or chemically aggressive fluid media. It is also suitable for sealing lids and access doors.

Specifications *(please ask for data sheet, see p11)*
- Compliant with FDA 21 CFR 177.1550.
- Tested and certificated to ***USP 28 Class VI*** — it is probably the first gland packing to gain this certification.

Special features of Fluosele gland packing
- Long-term high integrity fluid sealing.
- Inherently clean, non-toxic and non-tainting.
- Comprises PTFE yarns cross-plaited over a central core of white elastomer, and impregnated with a pharmaceutical grade lubricant.
- Elastomeric core gives resilience for long-term sealing under arduous mechanical conditions. Enables packing to withstand repeated opening/closing cycles of lids and access doors.



Chemical properties
- Compatible with media in the range pH 0-14.
- 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
As standard, in all popular sections from 3mm to 25mm, boxed in 8m lengths. Also available as split preformed rings and sets. Full fitting instructions are included.

Fluolion SEQUEL® gland packing

This non-contaminating packing is made by James Walker from WL Gore & Associates' highly developed GORE™ SEQUEL® yarn of ePTFE and entrapped white solid lubricant. It is ideal for dynamic applications in the pharmaceutical industry, including pumps, mixers, agitators and filter dryers.

Specifications *(please ask for Compression Packings guide, see p11)*
- Made from materials compliant with FDA 21 CFR 177.1550.

Special features of Fluolion SEQUEL®
- Clean, non-contaminating and graphite free.
- Long maintenance-free service life.
- Minimal shaft wear and leakage.
- Superior performance over most other pure white packings.

Chemical properties
- Compatible with media in the range pH 1-14, *excluding* strong oxidising agents and molten alkali metals.

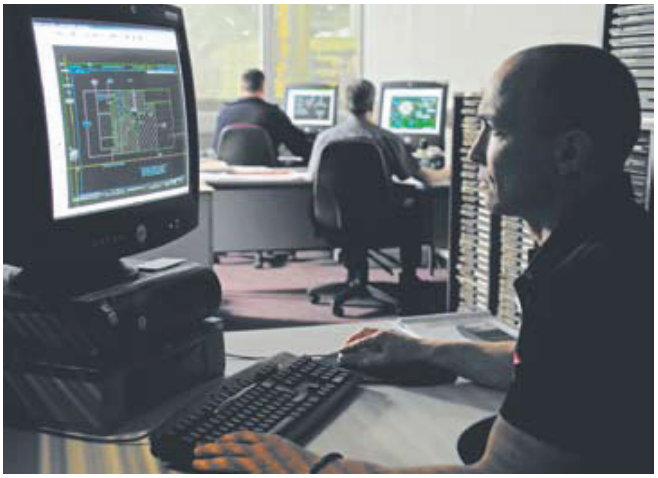
How supplied
In all popular sections from 3mm to 25mm, boxed in 8m lengths. Customers are recommended to use sets of preformed rings for optimum performance, fitting ease and economy. Full fitting instructions are included.

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.

Quality — our prime consideration

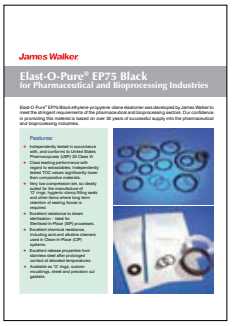
Quality design, quality manufacture and quality service are paramount throughout our worldwide operations. We start with the best raw materials and use advanced manufacturing techniques with strict quality control. This culture is reinforced by top-level technical support, logistics networks and a multitude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

State of the art, automated inspection systems complement the visual inspection process carried out by our experienced quality control teams. Our quality control ensures individual inspection of 100% of critical application products.

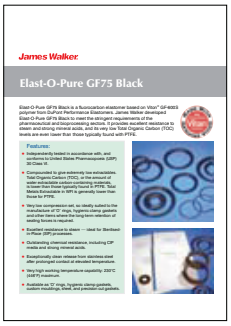
Our quality standards are third-party registered to BS EN ISO 9001:2000. We are also regularly assessed and quality approved by a wide range of industry bodies and individual clients including multinational corporations, utilities and government organisations.

Technical guides & data sheets

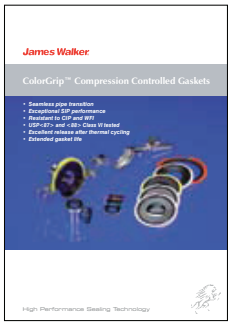
These guides give detailed technical information on the products and services supplied by James Walker to the pharmaceutical, biotech and general industrial sectors. Please ask for your copies, or visit our website *www.jameswalker.biz* where many of them can be downloaded in pdf form.



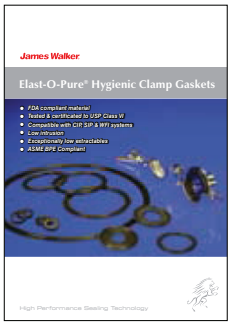
Elast-O-Pure® EP75 Black



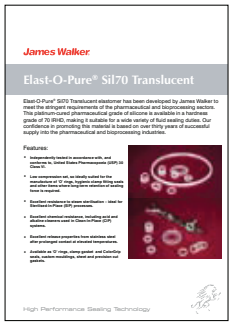
Elast-O-Pure® GF75 Black



ColorGrip™

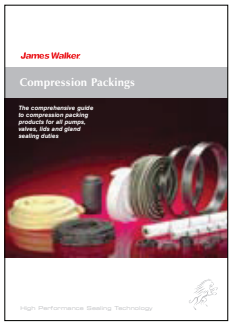


Elast-O-Pure® Hygienic Clamp Gaskets

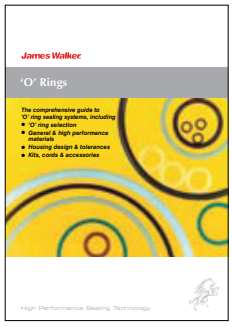


Elast-O-Pure® Sil70 Translucent

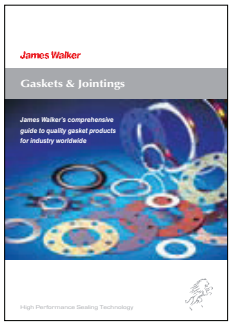
Fluosele gland packing



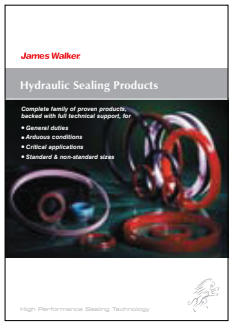
Compression packings



'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.

Trademark acknowledgements

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

GORE™	WL Gore & Associates
Kalrez®	DuPont Performance Elastomers
SEQUEL®	WL Gore & Associates
Viton®	DuPont Performance Elastomers
ColorGrip™	Integra Companies Inc.
Gylon®	Garlock Sealing Technologies

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. 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.