

Saunders the first name in diaphragm valve technology

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in diaphragm valve technology



The Saunders name has been synonymous with the diaphragm valve since we invented the technology over 75 years ago.

Today, the Saunders brand is the standard for excellence and performance in diaphragm valve technology and is widely recognised in the process industries as a leader in quality and innovation. Our expertise in diaphragm valves is equally apparent in standard two-way valves as it is in custom designed, multi-valve arrangements machined from a single block of stainless steel. Innovation is partnered with manufacturing excellence to drive advances in product development. The first to bring a forged body to market, the first to introduce BPE compliant controlled sulphur forgings as standard, and the first to offer fully traceable diaphragms are all examples of how the brand continues to challenge the potential for improvements in diaphragm valve technologies. Looking to the future, the Saunders brand will be linked to cutting-edge developments such as the revolutionary Simflex[™] liner valve, designed for single use systems.

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We are committed to surpassing accepted levels of service and quality through investment and dedicated customer support.

Saunders is a brand of Crane Process Flow Technologies, a company within the global Crane Corporation. Drawing on the strengths of our parentage and building on an already well-established position in highly demanding process industries, we are continually researching and implementing ways to develop diaphragm valve technology.

At a product level, we employ advanced computer-aided engineering (CAE) and computational fluid dynamic (CFD) software platforms that allow us to design and manufacture products to optimise valve performance and flow conditions.

At a service level, we have realigned our structure to bring our customers closer to the support and decisions they need. By streamlining these channels and focusing resources we aim to better address our customers' global specification and purchasing processes.

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The Saunders brand name guarantees product quality and continuity of supply, giving you complete control of your process.



The diaphragm is the real heart of the valve. Saunders stainless steel bodies are complemented by high-quality butyl, EPM, EPDM, silicone or PTFE diaphragms that are manufactured in-house from

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FDA and USP conforming raw materials to the highest specification using our proprietary knowledge of polymer technology.

By managing the production of every diaphragm from start to finish, we provide full batch traceability. This gives customers validation of the reliability of the diaphragm, supported by certification of regulatory compliance as well as physical property data for complete confidence in valve performance.

Saunders brand products are manufactured in an environment of Operational Excellence that provides a framework for product quality and reliability. Incorporating Six Sigma methodologies, employing tools such as Kaizen, Operational Excellence gives us the continuous process improvement needed to ensure world class production standards. Through a combination of knowledge and experience, we understand the relationship between a diaphragm valve and its application.

technology

The purity and performance inherent in the Saunders brand makes our diaphragm valves ideally suited to demanding aseptic applications in the pharmaceutical and biopharmaceutical sectors. Our revised product portfolio also includes diaphragm valves to meet the specification necessary for various other clean applications, such as food processing.

A fully comprehensive product range ensures that we can deliver a product precisely optimised for your situation, incorporating elements such as temperature, pressure, regulatory compliance and aesthetic design. From sealed, electropolished stainless steel bonnet assemblies to remotely operated, compact pneumatic actuators, each component of the diaphragm valve is fit for purpose.

For applications that cannot be precisely satisfied by a standard product, our experience of customisation ensures the path between specification and solution is as smooth as possible.



We are exclusively dedicated to the manufacture, supply and support of the highest quality diaphragm valves.

At every stage, Saunders customers have access to our knowledgeable and flexible business development and product engineering teams. These have been streamlined to make the resources you need available exactly where you need them, when you need them.

To aid the specification and purchasing process, we have also developed e-tools that can produce a fully coded 3D graphic of the valve and provide 3D "envelope" dimensions in PDMS format. This allows the system designer to select the optimum orientation for their requirements that can be translated to process layouts and manufacture quickly and easily.

Both standard and custom valve bodies are complemented by Saunders proven diaphragms, bonnets, actuators and a range of accessories to maintain system performance.

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Our unrivalled expertise in diaphragm valves is backed by global presence in process control.

As part of Crane Process Flow Technologies, the Saunders brand belongs to a wider group of companies that provides solutions to the diversified process industries through the development, production and distribution of valves, actuators, pumps and related flow components.



strength

Crane Process Flow Technologies in turn draws upon the heritage and manufacturing experience of the Crane Corporation to provide customers with a worldwide understanding of local quality standards and legislative requirements. This, coupled with a long-established network of independent distribution partners, ensures a global network that provides the structure to design, manufacture and deliver world-class products with world-class service.



HC4 AFP-Type Standard 2-Way Diaphragm Valves



The standard 2-way valve body is the basic building block of diaphragm valve technology. Its design and characteristics make it the ideal choice for all categories of "clean" processing systems. Optional materials, surface finish specifications (in compliance with ASME BPE) and international tube designations are all available to suit your application/specification criteria.

Standard 2-Way Bodies

Saunders invented the diaphragm valve concept and then pioneered the development of the first true high purity diaphragm valve with the introduction of the AFP forged 316L/1.4435 body range. The entrapment free design and self-draining characteristics of the diaphragm valve body make it the ideal choice for both aseptic processes and systems that must be cleaned in place. Top entry design allows maintenance while the valve is installed and permits the valve to be welded in place reducing the required number of mechanical joints and enhancing system security.

Saunders Valve Body Highlights

- Cavity free and self draining.
- Isolating diaphragm, top entry design, and positive closure.
- Controlled sulphur forged bodies (0.005% – 0.017%) meets ASME BPE DT-3 requirement for low sulphur content.
- Low maintenance costs.
- Readily incorporated into valve cluster and access valve/fitting fabrications.
- Materials of construction compatible to entire system.
- Bubble tight closure against both pressure and vacuum.
- Bi-directional flowpath.
- Diaphragm valves are recognised by the biopharm industry as the only truly aseptic valve.

Drainability

The diaphragm valve has outstanding self draining characteristics when compared with other valve types and this feature has contributed to making the valve a standard for hygienic/aseptic application requirements. Factors which affect drainability are:

- Valve size and end specification
- Internal surface finish
- Drain orientation (as shown)
- Surface tension and viscosity of media
- Pipe run angle generally recommended at 2 to 3 degrees

Valves with body orientation indicators are available on request (the marks must be located in a plane cutting the vertical centreline of the pipe).



Guideline drain orientation angles for individual size and tube specifications are readily available on request. Please note that drainability in a process system is ultimately the responsibility of the system designer and/or end user as a result of the variance factors denoted above.

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Saunders HC4 AFP-Type Diaphragm Valves

Standard 2-Way Bodies

Standard 2-Way Valves	
Pure performance forged valves*	8 – 15 mm
Forged stainless steel valves*	15 – 80 mm
Solid block stainless steel valves	100 – 150 mm
Cast stainless steel valves	8 – 100 mm

* Compliant with ASME BPE Table DT-3 for low sulphur requirement





Pure Performance (Bio-Seal) Forged Bodies (DN8–DN15)

Saunders Pure Performance fractional valve bodies offer a compact, space saving, high integrity solution for critical applications. Manufactured from a 316L/1.4435 stainless steel forging, the valve is used widely as a sample or drain port in hygienic system design. All major tube designations (O.D., butt weld, Tri-Clamp, DIN/ISO) are machined integrally from the forging and cover sizes, DN8, DN10 and DN15. This flexibility is achieved by utilisation of the same DN8 body design for all options and machining inlet/outlet ports to the desired end specification. This allows the valve to utilise the same size (DN8) diaphragm, bonnet and actuator across all specification requirements regardless of end connection size.

Forged Stainless Steel Bodies (DN15-DN80)

Saunders standard AFP body is forged from wrought 316L/1.4435 stainless steel bar. The forging process results in a homogeneous surface that is free of defects such as porosity, inclusions or shrinkage cavities. This defect free surface is an ideal substrate for the high levels of mechanical and electropolished surfaces demanded by the clean processing industries to maintain sterility and optimise cleaning processes. Saunders forged bodies are manufactured to achieve low ferrite levels of less than 0.5% maximum. This reduces the potential for migration of oxides through a high purity water system. These bodies are fully FDA compliant, meet all existing ASME BPE (American Society of Mechanical Engineers Bioprocessing Equipment) standards and cGMP (current Good Manufacturing Practice) principles and are ideal for all high purity applications.



Saunders HC4 AFP-Type Diaphragm Valves

Standard 2-Way Bodies



Investment Cast Stainless Steel Bodies (DN8–DN100)

The Saunders investment cast range uses high quality materials and selective casting processes to provide an economical solution for the food, beverage, dairy, and bioprocess industries. Available in all major international tube designations including, O.D. tubing, Tri-Clamp, DIN and ISO. Stringent quality control is employed to minimise any risk of porosity and ensure a finished product of the highest integrity.

Chemical C	omposition – HC4	AFP Forgings
1.4435/316L EN	N 10222-5 ASTM A-182	ASME BPE Table DT-3
Element	%	%
Carbon	0.03 max.	0.03 max.
Silicon	1.00 max.	1.00 max.
Manganese	2.00 max.	2.00 max.
Phosphorus	0.04 max.	0.04 max.
Sulphur	0.025 max.	0.005/.017 🔇
Chromium	17.0/18.0	17.0/18.0
Nickel	12.5/13.5	12.5/13.5
Molybdenum	2.5/3.0	2.5/3.0
Nitrogen	0.11	0.11



Machined from Block Standard Valve Bodies (DN100–DN150)

Larger size designations are now machined integrally from solid wrought stainless steel barstock. This construction brings the same high level of surface integrity and metallurgical security as available with the AFP forgings. We can support the increasing demand for special alloys ((Hastelloy, Titanium, AL6, XN etc.) with an economic and flexible solution, even for small volumes, because we machine from solid barstock.



Controlled Sulphur Forged Bodies (DN8–DN80)

316L/1.4435 forgings are now available with sulphur composition between 0.005% and 0.017%, conforming to ASME BPE Table DT-3. Conventional bodies average 0.03% sulphur.

These controlled sulphur bodies eliminate the need to incorporate costly tube-end extensions, so reducing lead time and paperwork requirements. Additional benefits include improved dimensional stability of weld ends and improved electro-polish finish.

Saunders HC4 Diaphragm Valve Features

Handwheel High integrity handwheel with ergonomic design ensures comfortable, precise control.

Position Indication

Highly visible from a distance with positive indication of valve position.

FDA Conforming

Both PES bonnet shell and internal components are fully FDA conforming.

Top Entry

Designed for in-line maintenance essential for welded systems.

End Connections

Body is machined from single forging with integral ends. Butt weld ends have sufficient turnback for orbital weld installation. Now available with weld chemistry to ASME BPE Table DT-3 with sulphur level between 0.005% and 0.017%.

Forged Bodies

All HC4 valve bodies are profiled for low turbulence flow. Forged in 316L/1.4435 stainless steel to maximum ferrite content level 0.5%. Cavity free design eliminates entrapment areas and enhances diaphragm life.

Contoured

Contoured design to optimise external washdown and cleanability.

Sealed Bonnet

'O' Ring sealed bonnet as standard to prevent ingress from external environment.

Performance Bonnet Assembly

Polyethersulphone (PES) suitable for wash-down with detergents, sodium hydroxide, hypochlorite, alcohols, dilute acids and autoclaving at up to 160°C.

Shrouded

Shrouded bonnet construction covers body fasteners for clean exterior profile.

Diaphragms

Saunders unique FDA/USP conforming diaphragms are totally manufactured from raw polymer in-house. All diaphragms are fully traceable back to physical characteristics of the rubber blend.

Modular Options

Alternative modular options available including padlocking facility, proximity sensors and limit open stop versions.

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HC4 Standard Machined Block Valves

The Saunders range of HC4 Standard Machined Block valves uniquely provides the user with compact, minimum deadleg construction, full drainability, flexible high-integrity configuration and, ultimately, security of processing.

Zero Deadleg 'T' Pattern

Essential for the elimination of dead legs and designed to ease installation and validation, Saunders Zero Deadleg T pattern range (ZDT) enhances the integrity of critical systems.

Machined integrally from a forging, the ZDT normally features three common ports with the same bore dimensions and incorporates a valve body and tee fitting into a single solution. ZDT valves form the ideal solution for feeding laterals off recirculating loops, sample points or use point applications. The bodies can be supplied with weld or hygienic clamp end connections or included in a U-bend configuration for point-of-use service.

Major benefits of the range include:

- Virtual elimination of deadleg to enhance process integrity
- Highly compact, space saving design providing ideal solution where space is a concern
- Excellent drainage characteristics to facilitate quick and effective sterilisation
- Patented design to aid validation for FDA and cGMP compliance
- Machined integrally from Stainless Steel 316L/1.4435 forging (no welds)
- Available in size range DN15–DN50 with full range of FDA conforming diaphragm/bonnet/actuation options





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HC4 Standard Machined Block Valves

Close-Coupled Branch Valves

The Saunders Close Coupled Branch Valve (CCBV) compliments the patented ZDT design by facilitating larger main line size options. They provide the ideal solution when the main process line is at least one size larger than the valve/branch size. The unique tee construction is engineered from a machined billet to enhance structural integrity and ease installation and validation.

The CCB valve provides a straight through unobstructed main line flow path and will eliminate the deadleg normally associated with welding a conventional two-way valve to a T-piece. By virtue of the weir size, the CCB offers a compact, flexible and economic design solution.





Major benefits of the range include:

- Compact flexible design providing excellent drainage characteristics and absence of deadleg
- Machined block construction provides security of installation, rapid sterilisation and easier regulatory compliance
- Ideal solution when main process line is larger than valve/branch size (i.e. main line DN50 valve/branch DN25) utilises DN25 diaphragm/bonnet/ actuator
- Sampling/injection points on high purity water systems

Point-of-Use Options (Close-Coupled Branch Valve 'U' Bend)

One of the most sensitive applications in a WFI loop is the use point valve. These valves represent the barrier between the safety of the recirculating loop and the potential hazards of the environment and function as the take off point for consumption of WFI. Valves for this application need the highest level of design security, integrity and cleanliness. Saunders point-of-use valves are engineered to minimise dead areas and fully drain all associated tubing.

Saunders Point-of-Use Valve

Horizontal or vertical drain port. Significantly reduces the hold-up volume and necessary site welds associated with conventional 'U' bends and branch tee assemblies. Sampling or injection points on high integrity systems.





Multi-port Diverter Valves

Modern machining technology is employed in the design and manufacture of Saunders range of Bio-Block diverter valves.

This product brings two or more weirs or control points together in a single configuration that is manufactured from a single block of stainless steel. The result is a single valve without internal fabrication welds for maximum strength, with reduced holdup volumes and without stagnant areas. On one side of the weirs there is a common chamber and on the other side of the weir the flow is divided and split into multiple control points. Diverter valve designs are ideal solutions whenever a process line needs to be divided into two or more process streams or when multiple lines are combined into one.

Two weir diverter valves drain in horizontal and vertical orientation. Diverter valves with three or more weirs only drain vertically. Diverter valves can be supplied with either autoweld or hygienic clamp ends arranged to meet system design requirements.



Saunders multiport diverter valves have significant advantages over conventional multiple valve assemblies.

- Machined Block construction, free from fabrication welds to enhance structural integrity
- Minimal deadleg design to reduce risk of process contamination
- Inlet machined integrally eliminates a potential source of contamination (many other designs employ bolted inlet)
- Excellent drainage characteristics for quick and effective sterilisation
- Reduced space requirement provides greater flexibility in system design and simplified installation
- Complete solution including FDA compliant diaphragms, manual bonnets and actuators
- Fully certified range, with comprehensive validation support documentation on request



E Tools

The Saunders diverter software selection programme supports the multi-port diverter range. Like the tandem valve programme, this electronic tool enables our customers to select the ideal multi-port valve solution including end selection and valve arrangement and then print the selection in a 3D format.



HC4 Standard Machined Block Valves

Integral Sampling Ports

Saunders Close Coupled Branch Valves (both T and U bend) can be supplied with optional integral sample ports to permit real-time sampling of WFI without breaking a sterile use point connection.

This provides a number of key process advantages:

- Minimum product envelope
- Minimum deadleg
- Less system welds

Integral ports can be positioned on main line or branch connections (see section views) according to user requirements.

Alternate use point designs can be manufactured to accommodate special centre line dimensions, reduced envelope requirements and other design considerations (see image of CCB 90° to reduce centre dimensions).



Sample quality directly from water loop with integral back sample option.



Sample port positioned integrally on branch connection.

vessel agitation. Ask for further details.

Tank Bottom Valves



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HC4 Customised Fabrication Options

For applications where a standard machined block valve is not sufficient, but a full custom solution is not required, there is a wide variety of fabricated options that will provide the optimum valve configuration.

Tandem Valves (Sterile Access Valves)

Welded Valve Fabrications

The first and still most common customised valve concept is the tandem valve or valve and fitting combination.

A main valve is ported and a section of tube is welded to the port to create an access point into the valve. This tube can in turn be welded to a second valve forming a two-valve cluster, or the tube can be turned into a weld end, hygienic clamp or other type of fitting. The fabrication weld is polished to match the required surface finish specification. The resulting assembly is designed to optimise drainability and meet standard process considerations including cGMPs for dead legs.



Applications include flow diversion, sampling, steam injection or condensate drain and block and bleed applications. The following rules help define the possible orientation of tandem valves:

- The main valve and access valve may be installed to drain in either the horizontal or vertical position. When installed in a horizontal run the valve must be rotated into the self-drain position to drain.
- Allowance must be made to permit access to bonnet or actuator fasteners and for diaphragm maintenance.
- The access valve can be any size including the same size as the main valve.
- The amount of dead leg between main and access valves will vary depending on respective valve sizes and orientation. Virtually all combinations fall within cGMP requirements.
- 'Handwheel opposite' designs generally have shorter tangents than configurations with the handwheel of the main and access valves in the same quadrant.
- All Saunders welded valve fabrications are 100% hydro-tested before and after all welding and polishing processes to ensure mechanical integrity. Full material certification of all tube and fittings utilised is standard.
- Saunders bonnets, actuators and diaphragms fit fabricated valve assemblies without adaptors or distance pieces.



Tandem Valve Orientation Options

- Full range of horizontal and vertical, drainable options
- Can be configured to your exact pipe layout with minimum deadlegs
- Product transfer, purging, steam sterilisation, condensate drains, CIP systems

Horizontal main at drain angle/vertical tandem



Horizontal main at drain angle/vertical tandem



Horizontal main/vertical tandem



Vertical main/tandem at drain angle



Horizontal main and tandem at drain angle





E Tools

Electronic tools exist to assist customers in the selection and orientation of these fabrications. Saunders Tandem Valve Selection Programme enables engineers and design detailers to select the optimum orientation to suit system requirements and produce a fully coded 3D graphic for immediate translation to valve manufacture.





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ZDL Zero Deadleg Valve 'L' Pattern

The Saunders ZDL 'L' pattern diaphragm valve is typically installed in a vertical line. The functions of a 90 degree fitting and a take-off valve are combined within the valve body. The bore of the third port is situated in line with the point of seal where the diaphragm meets the weir. This ensures low point drainability and elimination of deadlegs.

The ZDL valve is available with tri-clamp or butt-weld end connections in sizes DN8–DN100.

Common applications include WFI (Water for Injection) point of use, CIP manifolds and vertical inlet/outlet piping to process equipment requiring low point drainage.





HC4 Customised Fabrication Options

Valve Manifolds/Clusters

Configuration of optimum process fabrication presents system designers with an ongoing challenge. Minimum space envelope, reduced hold up areas, reduced cost and facilitating ease of installation are all key considerations.

Our expert customisation service is designed to create the optimum valve configuration for customers' specific processes. Working from your sketch details or Piping and Instrumentation Drawings (P+IDs), our engineers will propose the solution, realised in a fully detailed CAD drawing for you to verify and approve. This straightforward process ensures that the product we make matches customer requirements in every respect.

The benefits of such fabrications include:

- Manufactured under stringent ISO 9001:2000 quality control
- Tailor-made solutions to customer requirements
- Fully tested assembled units manufactured under controlled conditions
- Full traceability of all components

All Saunders process fabrications utilise either forgings or machined barstock components to ensure process integrity.





Specialised steam manifold



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HC4 Bio-Block Customised Design Solutions



Almost every process system includes a unique piping challenge that does not lend itself to conventional solutions. Saunders custom designed HC4 Bio-Block valves replace welded clusters, manifolds and valve/fitting combinations and offer the most compact, minimum deadleg design for optimum process integrity.

Computer Aided Design Capability (CAE)

Bio-Block Standard & Compound Valves

Our design teams work closely with customers to create unique machined valve designs that we call Bio-Blocks. These 'outside of the box' solutions may be driven by process, space constraints, regulatory issues or other specific requirements.

The key element in producing Bio-Block valve solutions has been the development of advanced CAE (Computer Aided Engineering) design and manufacturing tools that enable our engineers to convert concept into reality. This approach to manufacturing provides custom machined valve products with the shortest possible lead times in design and production. We work closely with customers to co-ordinate solutions to unique application challenges.

All custom Bio-Block valve bodies accept Saunders standard diaphragms, bonnets and actuators without modification or adaptors. The compact design of the EC actuator range enables us to produce the most space-efficient solutions in the industry.

Machined Bio-Blocks have the advantages of reduced wetted area and dead-legs, no internal fabrication welds and reduced documentation for installation and validation. Faster and easier installation of process manifolds can be achieved using advanced "machined from solid" valves. Converting vision into reality



Engineering team with client



Tool path verification



Five axis machining centre



Advanced Valve Design Tools

It is important that all aspects of the application be properly communicated between customer and designer to ensure that the resulting design meets expected performance criteria. Saunders has adopted advanced electronic tools to configure unique and often complex concepts such as compound Bio-Block designs.

Foremost of these is the use of 3D modelling software. This program produces a 3D model of a proposed valve complete with a viewer in an e-mailable format that can be shared easily between the Saunders design and



applications engineering teams and our customers. The 3D representation of the valve design is derived from the same program file that is used to design and manufacture the final product.

Using this software our customers can select from five isometric 3D views, or freely rotate the valve to confirm flow paths or drainability.

Additional features include zoom and the facility to 'wire frame' the view and access the internal configuration.

Computational Fluid Dynamics (CFD)

We routinely use Computational Fluid Dynamics software to ensure that flow characteristics including Cv (Kv), pressure drop and flow paths meet client requirements. Actual flow paths can be viewed to eliminate low flow areas or potential cavitation.





CFD analysis of Bio-Block five-way diverter

CFD analysis of standard AFP forging

Trained and experienced sales and engineering staff are ready to work with you to develop unique Bio-Block valve solutions. The Saunders brand delivers excellence in the application, design and manufacture of custom machined valve solutions as reflected in its innovative and evolving range of Bio-Block valves.

Conceptual Approach

Bio-Block Compound Valve Solutions

Many of today's most challenging applications cannot be addressed by one valve configuration. Instead, a combination of two or more valve concepts must be machined from a single block of stainless steel to meet system requirements.

The resulting valve types are a hybrid or compound solution that entails the use of more than one valve concept. For example combining a tank bottom valve with an access valve, a multi-port valve with access valves to perform as steam and condensate port or a point-of-use valve together with a sample valve. Highly trained and experienced engineering staff and modern CAD design tools combined with our manufacturing expertise result in custom valve configurations that combine utility and performance.

Converting vision into reality



There are some key considerations when configuring custom "machined from solid" valves.

- Valve centrelines
- Drain point of body bore and any associated tubing
- Drain point of weirs
- Centre to face dimensions
- Allowance for bonnet or actuator assembly and diaphragm maintenance
- Internal flow patterns and drain paths
- Minimise deadleg area
- Meet cGMP requirements



Conceptual Approach

Bio-Block Machined Tandem Valves (Serial Weir)

This design is a solid version of the welded valve-to-valve or tandem valve assembly. Machined from a single block of wrought stainless steel it provides several benefits.

- Absence of internal fabrication welds enhances product integrity
- Hold up volumes can be reduced
- Dead legs minimised
- Reduced number of material certificates required



These advantages are especially realised in the smaller sizes where valve geometry makes it difficult to achieve cGMP requirements for minimum dead legs.

Bio-Block Integral Steam, Purge and Condensate Porting (Tank Weir)

Rather than control steam supply and condensate drain by means of 'stand off' welded access valves that may entail large design envelopes or dead legs, Saunders Bio-Block valves can be machined with integral weirs and/or ports.



Bio-Block tank manifold arrangement. Combining conventional tank bottom and ZDT technology into a high integrity machined block configuration for bio-pharm vessel applications. Cleanability, is facilitated by purging into offset weirs (sterile barrier).



Bio-Block Serial Weir Option

This concept puts two weirs in line, but 180° apart and sharing a common chamber. This allows the common chamber to be sterilised and form a barrier between two process flow streams. Our customers have incorporated this concept in requirements as diverse as Point-of-Use, Tank Outlet and in 'Mix-Proof' applications.



Bio-Block Controlled Inlet Option (Multiple Weir)

Generally associated with multi-port designs, this option involves machining a weir at the inlet to the common chamber of a Bio-Block valve. This design permits control of flow entering into the multi-port valve. The controlled inlet option can be included in any number of compound Bio-Block solutions to comply with specific system requirements.

HC4 Bio-Block Customised Design Solutions

Conceptual Approach

Bio-Block Chromatography Valves (Multiple Weir)



Bio-Block Specification and Selection

Our unique Bio-Block design and specification manual is available on request. This provides a mechanism for rapid, efficient and accurate communication of Bio-Block designs. It allows the customer to specify and select a fully-coded 3D design to meet P+ID system requirements without an on-going exchange of 2D drawings, rough sketches and data which may be confusing. Containing over 100 product designs in coded 3D representation, the manual includes a detailed explanation of design principles and valving terminology, P+ID coding structure and categorised 3D design options. Bio-Block specification/selection data sheets are also available.

Design and Installation Advantages

Bio-Block machined valve solutions are the ideal compliment to modular component design and construction.

- One Bio-Block valve can replace a welded piping manifold comprising several valves and fittings
- Reduced design envelope and installation times giving overall cost savings
- Fewer welds and less documentation required



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HC4 Diaphragms

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The critical component of any diaphragm valve is the diaphragm itself, due to its function as a dynamic seal and its continuous contact with highly valuable process media. Through continuous in-house development of our core expertise in this area, the Saunders brand provides customers with class-leading, traceable solutions to meet the most stringent process needs.

The Diaphragm – Key to Successful Valve Performance

The diaphragm is the key performance component within a diaphragm valve. The diaphragm forms both the differential and atmospheric seal and isolates the topworks from the process media.

Saunders continues to lead the diaphragm valve industry in the development and manufacture of elastomer components based on our in-house core competence in rubber and plastic technologies. We remain the only manufacturer to have front to back ownership of all aspects of polymer research and development, diaphragm design and production.

We offer a full range of diaphragm selections engineered to meet the exacting demands of the pharmaceutical industry. PTFE, TFM and elastomer types are available to suit individual system requirements.

All Saunders brand aseptic diaphragms are formulated in-house and manufactured from FDA conforming materials to meet the requirements of CFR (Code of Federal Regulations) Chapter 1 Title 21 and are tested and certified to USP Classes V and VI. Certificates of Conformity to FDA and USP are available upon request.

All diaphragms within the range are certified ADCF (Animal Derivative Component Free).

The main categories of aseptic diaphragms are:

Synthetic elastomer – black internally reinforced grades

- Grade 300 Butyl
- Grade 425 EPM, peroxide cured
- Grade E3 EPM, peroxide cured, post cured

Synthetic elastomer – white internally reinforced grades

- Grade 500 Silicone
- Grade E4 EPDM peroxide cured

PTFE

- PTFE virgin grade white, grade 214 with either 300, 325 or 425 backing support
- TFM white, grade 214S with 325 or 425 backing

All Diaphragms conform to FDA Regulations

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Diaphragm Construction



• Rubber diaphragm screw fixing

Rubber Diaphragms

The polymer material is bonded with a high strength woven reinforcement to ensure maximum strength and durability.







PTFE diaphragm bayonet fixing

PTFE Diaphragms

PTFE diaphragms are two piece construction backed with a rubber diaphragm to increase their pressure rating and durability. PTFE faced diaphragms are fitted with a bayonet fitting to ensure reliable installation and maximum life rating.

Grade	Material	Colour Size Range Continu Lower-Upper Temper Range S	Size Range	Continuous	Hardness	Tensile	Approvals		
			Temperature Range °C	ature IRHD °C	Strength Mpa	FDA	3A Class IV	USP Class V & VI	
300	Resin cured butyl rubber (isobutylene/isoprene)	Black	DN8-DN200	-30 to 130	62–68°	12.9	1	1	√
425	Ethylene Propylene, co-polymer peroxide cured	Black	DN8-DN100	-40 to 140	61–67°	12	√	1	 Image: A start of the start of
325	SUPERCEDED BY NEW ENHANCED EPM								
E5	SUPERCEDED BY NEW ENHANCED E3								
E3	Ethylene Propylene, co-polymer peroxide cured, post cured	Black	DN8-DN100	-40 to 140	61–67°	12	√	1	1
E4	Ethylene propylene (EPDM) diene-modified, peroxide cured	White	DN8-DN100	-40 to 110	60–66°	11	✓	-	-
214/300	PTFE/Butyl backed	White facing, black backing	DN8-DN200	-20 to 150	-	32	1	1	 Image: A second s
214/425	PTFE/EPM backed	White facing, black backing	DN8-DN200	-20 to 160	-	_	✓	1	1
214S/425*	PTFE/EPM backed for steam	White facing, black backing	DN8-DN200	-20 to 160	-	-	1	1	 Image: A start of the start of
214/325	SUPERCEDED BY NEW ENHANCED 214/425								
500	Silicone DBPH cured	White	DN8-DN200	-40 to 150	67–73°	7.1	1	1	-
214S/300	PTFE/Butyl backed for steam	White facing, black backing	DN8-DN200	-20 to 150	-	30	✓	 Image: A second s	 Image: A second s
214S/325		SUPERCEDED	BY NEW EN	HANCED 21	4S/425				

* DN8-50 conforms to new Hi-Steam design



Diaphragms

Type 425 Grade EPM diaphragms

Delivers highest levels of performance and security for the most demanding biopharmaceutical applications.

Ethylene propylene based elastomer is the most commonly used diaphragm material in the Pharmaceutical industry. Saunders EPM diaphragms offer enhanced performance for the demanding application criteria found in the Biopharmaceutical environment.



- Manufactured from inherently stable EPM (A copolymer of Ethylene and Propylene monomers)
- Uses the latest vulcanisation technology
- Enhanced temperature performance and chemical resistance due to the elimination of any double bond active sites as displayed with EPDM molecular structure
- Improved steam life cycle and flex life
- Longer lasting diaphragm provides better reliability with less disruption to pharmaceutical processes
- Fully complies with all international standards for toxicity and purity as defined by regulatory bodies such as FDA, USP and ISO is confirmed by independent laboratory studies
- Full traceability documentation available to confirm specific batch number and critical data. This aids validation, assists in trouble shooting and is a guarantee of product quality
- Certified as ADCF (Animal Derivative Component Free) to ensure maximum product purity and integrity

Full Traceability

To assist in the validation process and to provide the highest level of reliability, security and regulatory compliance, we provide full batch traceability for all grades of aseptic diaphragms.

Key elements in diaphragm design and selection include:

- Media compatibility
- Levels of extractables
- Flex and closure performance
- Resistance to compression set
- Longevity
- Regulatory conformance

Our elastomer technology and application engineering specialists are available to consult on specifics of material selection.

The Saunders range of FDA conforming diaphragms has been designed to meet the highest standards of performance and reliability based on current elastomer and plastics technology. Equally important is the associated documentation support to assist regulatory compliance and aid plant and system validation.

Only the Saunders brand matches diaphragm quality and performance with the highest standard of documentation and validation support.

Diaphragms



Type 214S TFM diaphragms (DN65-250)

Improved life rating

Users of diaphragm valves within the biopharm industry can achieve major processing advantages using the TFM 214S diaphragm. An innovative formulation means that it can stay in service up to four times longer than conventional PTFE diaphragms without deformation. The net result is less time spent routinely replacing diaphragms and, consequently, fewer interruptions in process run time.

- Fully fluorinated carbon backbone
- Widest temperature range of any polymer
- Inert to corrosive chemicals, only attacked by molten alkali metals, fluorides of chlorine or oxygen and free fluorine
- Low co-efficient of friction good anti-stick properties

Less Deformation for Longer Diaphragm Life

The TFM 214S diaphragm has been designed specifically to improve performance in applications where steam is present. It displays improved elastic modulus at high temperature, resulting in less movement due to the effects of cold and hot flow. Indeed, the increased resistance to creep and cold flow of the 214S grade at elevated temperatures make the 214S diaphragm the optimum choice for environments, which call for intermittent steam.

The Saunders range of FDA, USP Class V and VI diaphragms, which includes the PTFE 214S, has been designed to meet the highest standards of reliability and quality today. Equally importantly, however, they are supplied with supporting material that will help you meet your regulatory requirements in full. Only Saunders aseptic diaphragms match the quality of its products with this high standard of documentation to provide all round support in smoothing the demands of FDA validation of plant and process.

Hi-Steam TFM Diaphragms (DN8-50)

Delivers the best performance and security for steam duties in biopharmaceutical applications.

Saunders Hi-Steam TFM diaphragms offer the biopharmaceutical industry a major improvement in service life and reliability. Applying core competence in polymer technology and diaphragm design, the Saunders Hi-Steam diaphragm benefits from recent advances to uniquely address the problem posed by intermittent steam sterilisation when combined with small surface area of diaphragm.

The range offers:

- Significant reduction in cold flow deformation typically associated with conventional PTFE components present in biopharmaceutical systems.
- Significant performance improvement under aggressive steam sterilisation and pure water based media.
- Manufactured from TFM (modified Polytetrafluorethylene [PTFE]) backed with EPM (a copolymer of Ethylene and Propylene monomers) from raw polymer ingredients employing Crane Process Flow Technologies Ltd's unique moulding competence.
- Significant improvement in valve flow capacity to maintain processing efficiency.
- Energizer ribs moulded into the EPM backing material assist diaphragm closure under demanding operating conditions by directing closure loads on the weir area minimising deformation and compression set and lowering the amount of force required to effect closure.
- All formulation, blending and processing is performed in-house allowing full production control and lot traceability.
- Fully complies with all international standards for toxicity and purity as defined by regulatory bodies such as FDA, USP and ISO and confirmed by independent laboratory testing.
- Certified as ADCF (Animal Derivative Component Free) to ensure maximum product purity and integrity.

This Product Leaflet is one of a set detailing the complete range of Saunders brand Diaphragm Valves, Diaphragms and Accessories. For further information, or to request additional data, please contact us. Due to constant product improvements, details shown in this publication are subject to change. Saunders[®] is a registered trademark of Crane Process Flow Technologies Ltd. Crane[®] is a registered trademark of Crane Corporation.

CRANE

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HC4 Top Works Manual Bonnets, Actuators & Accessories

6

The Saunders HC4 range of manual and actuated Top Works provides industry-leading features with ergonomic, compact design. Ease of operation and high temperature resistant materials (polymer and stainless steel) compliment a wide choice of modular options.

HC4 Manual Bonnets

Black PES Performance Bonnet

Black PES (Polyethersulphone) Perfomance Bonnet

Designed for the most demanding applications and featuring PES, a high performance thermoplastic material with excellent chemical resistance, to ensure long life and high reliability.

Fully autoclavable, the PES bonnet is available across the size range DN15–DN80.

The PES Performance Bonnet offers several key features:

- High integrity, ergonomic handwheel.
 Design ensures comfortable operation and precise control
- Fully autoclavable to 140°C
- 'O' Ring seal prevents both the escape of product and the potential ingress of contaminates
- Shrouded bonnet construction provides maximum containment and diaphragm support for critical applications
- Modular options available including padlocking facility, proximity sensors, 'V' notch vent plugs and limit open stop version
- Fully FDA conforming materials of construction
- Limit closing stop to provide process/flow control option



Padlock Option

The padlocking facility can be supplied to order or is available in kit form for retro-fitting to the bonnet sub-assembly or whole valve.

Limit open stop option

Limit open stop bonnet to facilitate effective running of system under normal capacity.

Limit closing stop option

A fully adjustable limit closing stop is fitted as standard to all 'Performance' bonnets. The limit closure stop is located under the handwheel and is adjusted by first removing the handwheel fixing screw and the handwheel assembly.



HC4 Manual Bonnet Assemblies

The best all-round choice for your application

The unique needs of the Clean Processing Industries have been considered in every aspect of design. Our manual bonnet range incorporates:

- Hi-tech polymer materials that are lightweight and corrosion resistant
- Truly autoclavable models
- Modular options to suit all application needs
- Stainless steel and polymer options that are contoured for ease of cleaning

Stainless Steel Bonnet Assembly

resistance.

Constructed from materials which fulfil all FDA requirements, this bonnet offers the best possible levels of security, durability and corrosion



- Represents a high integrity solution for situations where coated or plastic bonnets would be unacceptable
- Features smooth contours and an electropolished surface to eliminate bug traps
- Fully autoclavable up to 140°C to ensure maximum levels of sterility
- Supplied with PES (polyethersulphone) handwheel to offer high temperature performance and excellent chemical resistance
- Available in size range DN15–DN150
- Suitable for Steam-in-Place (SIP)

Stainless Steel Sealed Bonnet Assembly

Meeting all FDA requirements, this is the optimum solution in bonnet assemblies for the Biopharm market.

Thrust pad and 'O' rings apart. completely constructed from stainless steel ensuring long life and providing the ultimate in security, reliability and corrosion resistance



- Fully sealed, with a primary seal that provides absolute containment for critical applications
- Electropolished to meet both aesthetic and aseptic requirements
- Operational at temperatures up to 160°C
- Suitable for Steam-in-Place (SIP)
- Available in size range DN15–DN80

White Epoxy Coated **Bonnet**

This consistently popular bonnet is the economic solution for applications which do not require high temperature steam autoclaving.

- Suitable for washing externally with semicorrosive fluids
- Engineered in sizes DN15–DN100 with a white epoxy coating
- Features an easily cleaned surface, which is free from pits or crevices
- Suitable for Steam-in-Place (SIP)



Pure Performance Bonnet

Available only in size DN8 (4 bolt), this bonnet is produced in PPS (Poly-phenylenesulphide). Features include:

- Built in overclosure stop for greater process control
- O' Ring seal preventing ingress of foreign material and providing containment of process media
- 4-Bolt design providing optimum sealing capability
- Fully autoclavable up to 140°C



HC4 Pneumatic Valve Actuation

Compact Actuators that provide reliable remote control

Saunders EC and SSC Pneumatic Actuators facilitate remote operation of the valve, either as a simple alternative to manual bonnet assemblies or as an integral part of the control system. Both are compact piston style actuators with excellent chemical and temperature resistance.

The versatile and robust design derived from the use of high technology materials of construction, results in an actuator suitable for a wide range of process industry applications.

EC Actuator

The EC is manufactured by injection moulding in PES (polyethersulphone), which has a temperature range of -10° to +100°C ambient (autoclave maximum 150°C). Actuators can be supplied as spring close, spring open or double acting with various spring pack options for a variety of pressure requirements.



 EC Actuator mounted on a ZDT valve Size range: DN8 – DN50

All three operation modes, double acting, spring to close and spring to open feature the same physical dimensions for a given valve size. This provides uniform compact envelope dimensions and outstanding economic benefits particularly for spring return failsafe actuation.

Field conversion of manual valves to power actuation can be readily achieved 'in-line' without special tools or modification.

C, SSC & EC

SSC Actuator

With the same flexibility as the EC Actuator, the SSC has been manufactured with a 316L stainless steel investment cast housing. Suitable for a wide range of demanding applications the SSC provides excellent resistance to both chemical and steam duties.



SSC Actuator Size range: DN8 – DN50

ECX Actuator

Saunders ECX type actuators are designed to offer an extension to the EC size range whilst still maintaining the compact envelope size. The housing is manufactured in coated silicon aluminium for optimum chemical resistance and long life. With an extensive range of spring packs available we can offer an actuator to suit a wide range of pressure and flow variations.

Available in spring close, spring open and double acting modes of operation to suit process needs. A wide range of options including switches, positioners, limit stop and visual open/close indication are also available.



 ECX Actuator with visual indicator
 Size range: DN65 – DN150



ECX Actuator with Module Switchbox Size range: DN65 – DN150

Pneumatic Actuators for Larger Valves

The EV and ES actuator range directly replaces manual bonnet assemblies and may be ordered as part of a whole valve or separately to convert a manual valve to automatic operation. Installation may be carried out with the valve body in the pipeline.

Saunders EV and ES actuators are designed with close coupled bonnet assemblies and have complete flexibility of performance. Several different actuator models may be provided for each valve size to suit different application requirements. The range allows valve closure against the maximum valve working pressures and can be successfully used for modulating control duties in addition to more normal isolation functions.



EV Actuator
 Size range:
 DN15 – DN150

EV & ES Modular

Failsafe closing actuators are fully adjustable, i.e. spring compression can be externally adjusted to provide optimum diaphragm forces and hence provide extremely long diaphragm life in service.

Many accessory options are available which include solenoid valves, remote indication devices (switches or sensors) to suit environmental conditions such as hazardous services. Limit stops and positioners and many other devices may be offered to allow usage within particular control systems. EV and ES actuators are provided with a tough epoxy coating which gives maximum durability, even in exposed locations.



ES Modular Size range: DN15 – DN200

Actuation Accessories

Overview ſ MODEL SIZE RANGE STYLE MATERIAL DN8-50 A, AFP PES FC 1 V X X 316 C12 **SSC** DN8-50 A, AFP 1 √ X 1 1 ECX DN65-150 A, AFP 1 X V X SiAI Coated 1 EV DN15-150 A, AFP, KB SiAl Coated 1 1 1 1 X SiAI Coated ES DN15-200 A, AFP, KB 1 1 1 1

Available X = Not available

Mini Positioner

For control application on the EC and SSC the VIAPOS mini offers both pneumatic, electro-pneumatic and digital inputs with sensor feedback option and linear mounting design providing a compact control solution.



Solenoid Valves

A wide range of locally mounted banjo solenoid valves can be fitted to the Saunders actuator range with a manual override option and various hazardous area classifications. The solenoid range is designed to cover all requirements.

Module Switchbox

This highly modular switchbox option is available for EC/SSC & ECX actuator ranges. The switchbox offers a wide range of V3 mechanical and proximity sensors with space for up to 4 switch, integral solenoid valve & ASI* interface. *ASI Interface can be retrofitted.



SSC Manual Over-Ride

For extra security the SSC can be supplied with an emergency manual over-ride manufactured from stainless steel. Contact us for further information.



Opti-SET

Suitable for EC and SSC actuators. It is a unique valve position monitoring unit designed for use with Saunders EC actuated diaphragm valve sizes DN8 to DN50. It provides quick and easy installation and commissioning, compactness and reliability. The Opti-SET unit automatically sets by stroking the actuator, significantly reducing installation cost and validation time.





ES Positioner

Providing precise control of the flow through the valve. This long life corrosion resistant range suits a wide variety of applications with reliability and accuracy. Available as pneumatic, electro pneumatic, intrinsically safe and explosion proof, together with a variety of feedback options.

EC & SSC Limit Open Stop

The EC/SSC limit open stop can be supplied to order and offers a fully adjustable travel stop. With the removal of the plastic indicator the limit stop is easily accessible.

007 Switchbox

Manufactured from polyester coated aluminium. This switchbox is used for the ES and EV linear actuators. It has the capability for up to 4 switches and can incorporate internal solenoid valve and ASI system.



Shown mounted to ES Actuator





Shown mounted to ES Actuator

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HC4 Quality Standards, Traceability & Validation

Through continuous focus on quality, the Saunders brand offers the clean processing industries complete peace of mind. All international standards and conformances are rigidly adhered to throughout the HC4 product portfolio to assist the user in achieving secure, repeatable and reliable processing when using Saunders brand valves.

Quality Statements and Approvals

The Complete Approach to Quality

Quality Management system registered to ISO 9001:2000 standard in which our R & D and manufacturing process are optimised to maintain our product quality and service.



- TUV AD2000 Merkblatt HPO and A4 Qualifications for our product manufacturing and certification.
- CE marked products for compliance to European Directive ATEX 94/9/EC for Group II, Categories 2 and 3 applications.
- Certified compliance to the European Pressure Equipment Directive 97/23/EC authorising Saunders to CE mark relevant valve products.
- International product approval from authorities such as Bureau Veritas, American Bureau of Shipping.
- Polymer/Rubber materials certified as meeting the requirements of FDA, 3A, WRAS and USP.

Validation Documentation

Saunders can supply the following validation documentation on request:

- Certification of chemical composition to EN 10204 for body material
- Traceability certification for diaphragm grade
- Full validation manual (polymers)
- Surface trace certification
- USP Class V and VI diaphragm certification
- FDA conformance certification for all biopharm diaphragm grades
- Certificate of conformity to order specification
- ISO 9001:2000 certification
- Certification of testing to BS 6755-1



FDA	
USP	
ISO 9001:2000	

CRANE

HC4 Diaphragm Traceability & Validation

Validation support – from raw materials to your system

- All ingredients base polymer, filler, accelerators, etc – are manufactured from FDA conforming materials
- All diaphragms are fully batch traceable and carry a unique moulded batch identification number
- All diaphragms can be issued with a certificate of FDA conformity to assist in FDA validation and internal quality controls
- All diaphragm grades certified ADCF (Animal Derivative Component Free)
- Physical property data is also available upon request

Saunders diaphragms offer enhanced performance with more confidence

The integrity of the product and the quality of your process is assured. All extractables are fully identified and guaranteed to meet FDA limits. Access to all physical data is available upon written request.

Expert and independent verification

Saunders has worked with the Rubber and Plastics Research Association (RAPRA) to provide complete and detailed identification of extractables and leachables – leading the way and reaffirming our commitment to our customers and the industry.

Full traceability and product validation

The Saunders valve range is acknowledged right across industry as being a leader in quality assurance techniques and design criteria for clean processes. The Saunders product, through its range of fully traceable diaphragms provides its users with valuable support in the validation process.

- A unique moulded reference number gives precise batch traceability
- Access is available to all relevant physical data
- Diaphragms that meet the most stringent validation requirements
- A certificate of the physical properties of each batch is issued to ensure consistency and support validation on request
- A profile of the complete physical data of each batch is available to help trouble shooting
- Complete documentation package is available for all valve components in contact with the process fluids (EN 10204 3.1b certification).



Validation support

- Diaphragms conform to section 177,1550 (Perfluorocarbon resins) or 177.2600 (Rubber Articles) in Chapter 1 Title 21 of the FDA Regulations (revised 1st April 2001) USP Class V and VI.
- Traceable to EN10204 3.1b (was DIN 50049 3.1b)





HC4 Diaphragm Traceability & Validation





Proven manufacturing process



Diaphragms - USP Approval, PTFE, EPDM and EPM Grades

USP Approval

Saunders aseptic range incorporates a full range of Elastomer and PTFE FDA conforming diaphragms that fulfil the rigorous requirements of USP Class V and VI accreditation which indicates that products are fit for medical use (implant or injectable).

The stringent systemic and implant toxicity testing regimes associated with USP Class VI means that customers can be fully confident in the quality of their processing. For added confidence, however, and to give further assurance that the polymer element of the valve as well as the valve body itself meet the highest standards of integrity, toxicity testing was undertaken by an independent authority.

USP Class VI approval applies to Saunders' Elastomer and PTFE diaphragms already in service as well as those that may be installed in the future, and adds one more benefit to the established advantages of using Saunders products. We manufacture all elements of the diaphragm in-house with total control of every aspect of material content, design and production. This assures products of unrivalled reliability that extend service life and minimise downtime.



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