

brands you trust.



Saunders[®] Aseptic Diaphragm Valves Overview



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Diaphragm Valves History

PK Saunders[®] Invented the Diaphragm Valve Concept

PK Saunders[®] invented and patented the diaphragm valve concept long before the emergence of the Life Science industry. However, the design features present in the original weir type diaphragm valve remain the reasons the aseptic diaphragm valve is recognized as the valve of choice for aseptic applications.

History of Innovation

Saunders[®] has led the way in the development of the diaphragm valve to meet ever increasing demands for hygienic performance and regulatory compliance. These innovations have included the introduction of:

- Introduction of forged 316L stainless steel bodies
- First compact pneumatic actuators
- First traceable diaphragms
- First modified PTFE diaphragms
- First controlled sulfur stainless steel bodies
- First compact modular actuators
- First interactive Bio-Block selection guide

Global Compliance

Aseptic Diaphragm Valves are supplied into critical process applications in the world's most closely regulated industries. Full compliance to all relevant Global Standards is an essential element of the product and cannot be taken for granted. Saunders[®] complies with all applicable Global Standards for diaphragm valves in the Life Science market, including:

- FDA CFR 177.1550 (PTFE), 177.2600 (Elastomer)
- USP Class VI, <87>, <88>
- Traceable to EN 10204 3.1
- 3A Certification
- Animal Derived Component Free (ADCF)
- ASME BPE
- Testing to BS EN 12266-1
- ISO 9001
- CE and PED 97/23/EC
- TUV-Merkblatt HPO Qualification



Aseptic Diaphragm Key Products





Diaphragm Valves Interactive Web-Based Tools

Saunders[®] has developed interactive web-based tools to facilitate selection of standard and customized valves. This includes our Biotech Process Map which saves time and effort in valve selection in an industry driven by time to market. Our P&ID Table of Orientations provides key design information such as drawings and datasheets for over 100 different valve orientations based on P&ID configuration. Also available is our drawing library which makes 2D pdfs available to all site visitors and 2D dwg and 3D stp files readily available to registered users.



Please visit www.saundersdrawings.com for current library of drawings in PDF, 2D DWG, and 3D STP formats.



Diaphragm Valves Body Design and Finish

Saunders[®] Body Range

Saunders[®] offers bodies with weld and clamp ends to meet all global tube and pipe specifications. This includes: OD tube, DIN, ISO, SMS and schedule pipe.



Standard body material for all forged bodies is stainless steel dual certified to 316L (ASTM A-182) and DIN 1.4435 with the additional requirement of controlled sulfur per ASME BPE Standard.

Cast bodies are available from 316L stainless steel. Bodies produced from alternate materials such as Hastelloy[®], AL6XN, 904L and Titanium are also available.

For further information about Saunders[®] body ranges, download applicable datasheets at: www.cranebiopharm.com.

Surface Finish

Saunders[®] valve bodies are available in all mechanically polished and electropolished surface finish options to match piping system specification. Saunders[®] valve bodies are also available in a complete range of ASME BPE compliant internal surface finishes.

Drainability

The diaphragm valve has outstanding self-draining characteristics and is capable of draining in both vertical and horizontal orientations.



Factors which affect drainability include:

- · Valve size and tube specification
- Internal surface finish
- Drain orientation
- Surface tension and viscosity of media
- Pipe run angle generally recommended at 2 to 3 degrees

Drainability in a process system is ultimately the responsibility of the system designer and end user as a result of the factors explained above.

Electropolishing

Electropolishing of mechanically polished product contact surfaces improves surface finish smoothness and corrosion resistance. Mechanical polishing or machining may leave numerous microscopic surface imperfections which can cause areas of differing electrical potential due to surface stresses.

	Product Contact (ID) Surface Finish Options								
Finish	Measurement					Body Type			
	Ra* (micro inch)	Ra* (micro meter)	ASME BPE SF Code	Saunders® Type	Forged	Machined	Cast		
Mechanical Only	30	0.8	SF3	N/A	Yes	Yes	Yes		
Mechanical Only	25	0.6	SF2	N/A	Yes	Yes	Yes		
Mechanical + EP	25	0.6	SF6	N/A	Yes	Yes	No		
Mechanical Only	20	0.5	SF1	Satin	Yes	Yes	Yes		
Mechanical + EP	20	0.5	SF5	Satin	Yes	Yes	No		
Mechanical Only	15	0.4	N/A	N/A	Yes	Yes	Yes		
Mechanical + EP	15	0.4	SF4	N/A	Yes	Yes	No		
Mechanical Only	10	0.25	N/A	Mirror	Yes	Yes	No		
Mechanical + EP	10	0.25	N/A	Mirror	Yes	Yes	No		

Saunders® Full Range of Surface Finish Options

*All Ra values are maximum.



Diaphragm Valves Standard 2-Way Bodies

Standard 2-Way Bodies

The standard 2-way valve body is the basic building block of diaphragm valve technology. CRANE ChemPharma, Saunders[®] 2-way forged bodies are manufactured from wrought 316L/1.4435 stainless steel bar with additional requirement of controlled sulfur per ASME BPE Standard.

The forging process results in a homogeneous surface that helps to eliminate porosity, inclusions, or shrinkage cavities. This surface is an ideal substrate for the high levels of mechanical and electropolished surfaces demanded by the clean processing industries to maintain sterility and optimize cleaning processes. CRANE ChemPharma, 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.



Valve Body Features

- Cavity-free and self-draining
- 2 Full traceability to EN 10204 3.1 and ASME BPE
- Serialized bodies for traceability and ASME BPE bodies are marked in accordance with DT 11-1

Forged Body Features:

- 1 Hash marks to indicate self drain angle
- 2 Integral weld and hygienic clamp ends
- 3 Controlled sulfur, 0.005-0.017% per ASME BPE Standard
- 4 Certified to ASTM A-182 and DIN 1.4435
- Full compliance with weld end tangent length as per DT-4.1.1 and with clamp end lay length per DT-4.4.1-1

2-Way Bodies					
Body Type	Size Range	Applications			
Forged Stainless Steel 2-Way	DN15 - DN80 (1/2" - 3")	Forged products are used where conformity is essential such as high purity Biopharm applications.			
Pure Performance (Bio-Seal) Forged Body	DN8 - DN15 (1/4" - 1/2")	Compact, space saving, high integrity, for critical applications. Process valve, sample, or drain port in hygienic system design.			
Machined from Block 2-Way Valve Body	DN100 - DN150 (4" - 6")	Larger size designations are machined from solid wrought stainless stee barstock. This construction brings the same level of surface integrity and metallurgical security as available with 2 Way Forged bodies.			
Investment Cast Stainless Steel 2-Way Bodies	DN8 - DN100 (1/4" - 4")	Ideal for clean industries where the requirements of the process are less critical.			



Diaphragm Valves Custom Valve Solutions



Custom Valve Solutions

Custom valve types may be welded tandem valve assemblies, machined from solid block types or manifolds that incorporate both technologies.

Custom Valve Solutions Benefits:

- Reduced wetted area to reduced dead legs
- Improved drainability and reduced design envelope over arrangements using individual 2-way valve bodies
- B Machined from solid bodies also offer increased security due to the elimination of internal fabrication welds.

Tandem Valves (Sterile Access Valves)

Tandem valves are designed to optimize drainability and meet process design requirements for minimum dead legs. A main valve is ported and a second access valve is welded to the main valve to create a tandem cluster.

Machined Tandem Valves

The Machined Tandem is a variation of the Serial Weir family.

This machined from solid Tandem Valve type offers several advantages over the welded tandem:

Machined Tanden Valve Benefits:

- Increased security no internal fabrication welds
- 2 Reduced dead leg depending on orientation
- Greater structural integrity

Valve Manifold / 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.

Optimum Process Fabrication Benefits:				
Tailor-made solutions to customer requirements				
2 Fully-tested assembled units manufactured under controlled conditions				
3 Full traceability of all components				
A Reduced on-site fabrication time and costs				

Diaphragm Valve Zero Dead Leg and Point-of-Use

Zero Dead Leg 'Tee' Pattern Range

The Zerostatic Tee valve combines a single weir with a tee pattern body. This design eliminates the dead leg present when a 2-way valve is welded or clamped to a tee fitting and has become a BioPharm standard. Essential for the elimination of dead legs in recirculating loops and designed to ease installation and validation, Saunders[®] Zerostatic Tee Valve enhances the integrity of critical systems.

Zerostatic Tee Valve Benefits:

- Compact design providing excellent drainage characteristics and absence of dead leg
- 2 Machined block construction with no internal fabrication welds offer optimum security
- Sampling/injection points on high purity water systems

Point-of-Use Options (Zerostatic Valve with '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 re-circulating 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 minimize dead areas and fully drain all associated tubing.

Diaphragm Valves Bio-Block and Compound Solutions

Bio-Block Valves

Bio-Block valves offer the foremost expression of aseptic diaphragm valve technology. Bio-Block designs are machined from solid bar or billet to create tee configurations or clusters of two or more weirs with shared chambers that result in a single design with reduced wetted area, optimum drainability and the highest level of integrity.

Bio-Block Compound Solutions

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

Saunders[®] Sales and Engineering is pleased to work with you to identify and select the ideal valve design to optimize the performance of your system. Please contact your local distributor or CRANE ChemPharma sales office for support.

Bio-Block Categories Machined From Solid Options

- 1. Zerostatic Weir: Tee fitting and weir combined
- 2. Serial Weir: Two weirs sharing a common chamber
- 3. Multiple Weir: Three or more weirs with a common chamber
- 4. Tank Weir: Weir integrated into tank bottom
- 5. **Compound Bio-Block:** Combination of Bio-Block types into one assembly

Diaphragm Valves Multi-Port and Tank Bottom

Multi-Port Diverter Valves - Zero Dead Leg Options

The family of Multi-Port valves includes the Diverter Valve range. These valves include 2-way diverters on through to clusters that have up to eight outlets.

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

Multi-Port Deverter Valve Benefits:

- Machined block construction, free from fabrication welds to enhance structural integrity
- Minimal dead leg design will reduce risk of process contamination
- **3** Excellent drainage characteristics for quick and effective sterilization
- Reduced space requirement provides greater flexibility in system design and simplified installation
- Fully-certified range, with comprehensive validation support documentation on request

Please visit www.saundersdrawings.com for current library of drawings in PDF, 2D DWG, and 3D STP formats.

Tank Bottom Valves

The Saunders[®] tank bottom valve incorporates the performance and features of a diaphragm valve into a machined from solid tank outlet design. These valves are free from fabrication welds and dead legs, enhancing structural integrity and reducing the potential for process contamination. The absence of dead legs also improves drainability, and facilitates effective mixing.

Sample valves, purge valves and ports are easily incorporated into the tank bottom design to achieve the desired performance.

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. This process, combined with our manufacturing expertise, results in custom valve configurations that combine utility and performance.

Diaphragm Valves Pneumatic Actuator S360

Saunders® S360

The S360 is a compact, lightweight, piston-type pneumatic actuator which has been developed to deliver superior performance for sterile BioPharm applications.

Key Features and Benefits

- Modular range delivers optimum dimensional envelope and closure performance
- Full 360° rotation of actuator allows flexible installation and air port alignment
- Smooth corrosion resistant profile optimizes cleanability

Saunders® S360 Lite

The Saunders[®] S360 Lite range provides standard closure for spring-to-close applications in a very compact, lightweight package and is ideal for most applications and is available through sizes DN8 – DN50 (0.25" – 2.00").

The S360 Lite range is a very compact actuator that offers shutoff performance in line with standard industry applications. The S360 Lite is available in spring-to-close operation with optimum spring force to closure to minimize stress on diaphragms. Suitable for 10 bar line pressure at 100% Delta P (both PTFE and Elastomer diaphragm).

Saunders® S360 Power

The Saunders[®] S360 Power range offers higher operating closure performance in a compact package for high operating pressure or atypical closing conditions with high pressure on both sides of the weir. The S360 Power spring-to-close actuator is available through sizes DN15 – DN50 (0.50" – 2.00").

The Saunders[®] S360 actuator is also available in spring-to-open and double acting modes. Suitable for 16 bar line pressure at 100% Delta P (both PTFE and Elastomer diaphragm).

Easy Compressor Change

The Saunders[®] S360 has a unique compressor attachment that permits easy conversion of the compressor between rubber and PTFE diaphragms.

Full 360° Rotation

The Saunders[®] S360 features the ability to fully rotate the actuator head by 360°, enabling flexible installation and air port alignment.

This in turn reduces installation cost and optimizes incorporation into compact valving arrays or skid arrangements.

Diaphragm Valves Pneumatic Actuators EC and ECX

Saunders[®] pneumatic actuators permit remote operation of the valve, either as an alternative to manual operation or as an integral part of a control system.

EC Actuator

The EC is a compact, lightweight piston-type pneumatic actuator developed specifically for BioPharm applications. The housing is manufactured from PES (polyethersulphone), a high performance thermoplastic. PES is known for its outstanding strength, chemical resistance and thermal properties. The EC features compact size and a smooth exterior profile that includes shrouded fastener design for 2-way bodies and slotted base for use on block type bodies.

EC actuators are available in sizes DN8 - DN50 (0.25" – 2.00"). All three operating modes: double acting, spring-to-close and spring-to-open use the same housing and share the same reduced overall size.

Key Features

- EC offers direct connection to accessories including switches and positioners to eliminate hysteresis and inaccuracy
- Stainless steel compressor, air port connections and body fastener inserts
- Operating temperature -10° C to +100° C, and autoclavable to 150 C

Note: For actuator sizing information please visit: www.cranebiopharm.com for applicable datasheet information.

ECX Actuator

Saunders[®] ECX type actuators are designed to offer an extension to the EC size range while maintaining a compact envelope size. The ECX is available in sizes DN65–DN150 (2.50" – 6.00"). The housing is manufactured

in coated silicon aluminum for optimum chemical resistance and long life. With an extensive range of spring packs available, Saunders® offers 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.

Diaphragm Valves Sensors, Switches and Controls

Limit Open Stop

Adjustable limit open stops can be supplied for all Saunders[®] actuators.

Mini Positioner

For control application on the EC and S360, the VIAPOS mini offers pneumatic, electro-pneumatic and digital inputs with sensor feedback options and linear mounting design providing a compact control solution.

Module Switchbox

This highly modular switchbox option is available for EC and 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.

I-VUE Valve Sensor

The Saunders[®] I-VUE offers advanced "intelligent" valve sensing technology and is designed specifically for aseptic diaphragm valve applications in the Life Science industry. Compatible with Pointto-Point (P2P), AS-i, and DeviceNet control systems, the Saunders[®] I-VUE offers substantial benefits over standard switch controls.

Key Features and Benefits

- Enhance Reliability and Accuracy with Saunders[®] I-VUE solid state continuous sensing technology that provides precise position readings for the entire valve range from 0.25" to 4.00" (DN8 to DN100).
- Simplify Installation by utilizing automated valve calibration without opening the IP67 rated polycarbonate sensor enclosure, reducing set up times to 3 minutes or less.
- Eower Maintenance Costs by applying factory or user defined device settings to monitor valve cycle count and end point tolerance limits, preventing false alarms and unnecessary diaphragm replacement.

Opti-SET Switchbox

The Opti-SET switchbox is a compact option for valves sizes DN8- DN50 (0.25'' - 2.00'') that features:

- Lightweight Nylon 66 housing
- NEMA 4X enclosure, ATEX approvals
- Self-setting with mechanical switches and proximity Sensor options
- Networking capable with AS-i and DeviceNet option
- Bright yellow visual position indication

Diaphragm Valves Manual Bonnets Overview

Key Features and Benefits

- Clean external profile to facilitate wash down and cleaning regimes
- Suitable materials, corrosion resistant polymer and stainless construction
- **3** FDA conforming lubricants
- Compact design easily integrated into process system
- Autoclavable types for valves subject to repeated autoclaving
- 6 Modular options including limit open and limit closed stops, padlocking device and switches

PES Performance Bonnet

Sealed Stainless Steel Bonnet

Para Bonnet

Stainless Steel Bonnet

Bonnet Type	Size Range	Shell MOC	Handwheel MOC	Compressor MOC	Autoclavable	SIP	Chemical Resistance
Stainless Steel	DN15 - DN150 (½"- 6")	Stainless Steel	PES (Polyethersulphone)	Stainless Steel	\checkmark	\checkmark	\checkmark
Para	DN15 - DN50 (½" - 2")	PARA (Polyaryl Amide)	PARA (Polyaryl Amide)	Stainless Steel		\checkmark	\checkmark
PES Performance	DN15 - DN80 (½" - 3")	PES (Polyethersul- phone)	PES (Polyethersulphone)	Stainless Steel	~	\checkmark	\checkmark
Stainless Steel Sealed	DN15 - DN80 (½" - 3")	Stainless Steel	Stainless Steel	Stainless Steel	✓	\checkmark	\checkmark
Bioseal Polymer	DN8 (¼")	PPS (Polyphenylene Sulphide)	PPS (Polyphenylene Sulphide)	Stainless Steel	~	\checkmark	\checkmark
Bioseal Stainless Steel	DN8 (¼")	Stainless Steel	PPS (Polyphenylene Sulphide)	Stainless Steel	\checkmark	\checkmark	\checkmark

Diaphragm Valves PTFE Diaphragms

Saunders[®] PTFE type diaphragms utilize bayonet attachment to compressor to reduce point loading, improve sealing performance and facilitate installation.

PTFE Diaphragms

Saunders[®] Life Science PTFE diaphragms are robust two piece leaf type. This design uses a wetted PTFE face backed with a fabric reinforced rubber diaphragm. Critical performance factors include: resistence to compression set, mechanical strength, and thermal resistance properties.

Saunders® has front-to-back ownership of all phases of diaphragm development and manufacture. This includes the sintering and coining of PTFE diaphragm faces as well as the compounding, calendering and compression molding of elastomer diaphragms and backing cushions.

Saunders® EX Endurance Diaphragms

Key Features

- EX Endurance Diaphragms offers outstanding high temperature performance and is resistant to prolonged exposure to high temperature steam up to 175° C (347° F)
- EX Endurance is ideal for steam distribution and supply, sterile barrier and block and bleed applications
- Improved Seal to Atmosphere performance and reduced requirements for re-torqueing of fasteners after thermocycling

Type 214/425 PTFE Diaphragms

Key Features

- 100% virgin PTFE product contact face which is inert and unaffected by media common to bioprocess applications
- Industry conforming low levels of extractables and leachables
- B Fabric reinforced EPM backing

Type 214S/425 Modified PTFE Diaphragms

Key Features

- Reduction in cold flow deformation typically associated with conventional PTFE components present in BioPharm systems
- Improved performance under aggressive steam sterilization and pure water-based media
- B Fabric reinforced EPM backing

Diaphragm Valves Elastomer Diaphragms

Elastomer Diaphragms

The Saunders[®] diaphragm is an Intricate design and not a simple injection molded part. Layers of proprietary blended and calendared (rolled into sheet form) rubber is vulcanized with high strength woven reinforcement.

Type EE Grade EPDM Diaphragms

The EE grade diaphragm is constructed from Ethylene propylene diene monomer (EPDM) base polymer. Originally developed to meet BioPharm customer requirements for an EPDM grade, this diaphragm has demonstrated excellent performance on the full range of bio-process applications. The EE grade diaphragm has full industry compliance. Available post cured variation designated as grade EF.

Type 500 Grade Silicone Diaphragms

The 500 grade diaphragm uses a dicumyl cured silicone that is fabric reinforced to optimize flex life. This is a white grade of diaphragm which offers very low levels of extractables and leachables. Silicone is ideal for low temperature environments and applications. Like all Life Science Diaphragms, the 500 grade Silicone Diaphragm is FDA conforming and USP Class VI tested and certified.

Type PV Grade Passivation Diaphragms

The Saunders PV passivation diaphragm has been developed specifically for use during the passivation of stainless steel systems reducing installation and set up costs for the end user.

Key Features

- 1 Reduced cost versus single use PTFE diaphragm
- High visibility tag reduces risk of diaphragm not being replaced
- 100% interchangeable with Saunders Life Science PTFE diaphragm range

Type 425 Grade EPM Diaphragms

Manufactured from inherently stable EPM (a copolymer of Ethylene and Propylene monomers)

Key Features

- Organic peroxide-cured for reduced extractables and leachables
- Enhanced temperature performance and chemical resistance due to fully saturated hydrocarbon backbone with no double bonds
- 3 Available post cured variation designated as grade E3

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