Saunders

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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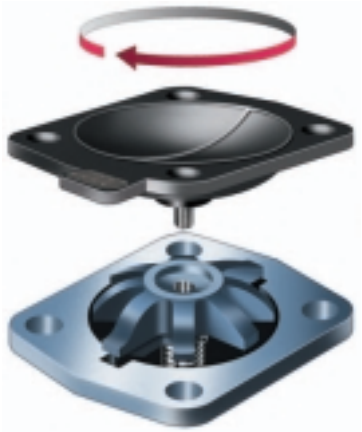
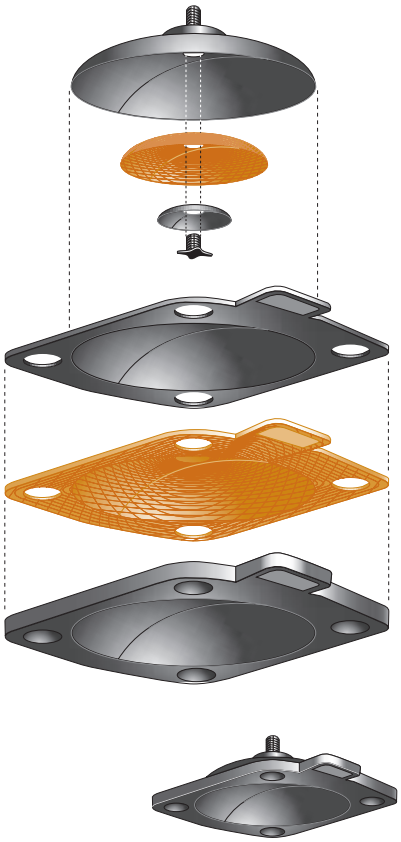
Diaphragm Construction



Rubber diaphragm screw fixing



PTFE diaphragm bayonet fixing

Rubber Diaphragms

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

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 Lower–Upper	Continuous Temperature Range °C	Hardness IRHD	Tensile Strength Mpa	Approvals 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	✓	✓	✓
425	Ethylene Propylene, co-polymer peroxide cured	Black	DN8–DN100	-40 to 140	61–67°	12	✓	✓	✓
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	✓	✓	✓
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	✓	✓	✓
214/425	PTFE/EPM backed	White facing, black backing	DN8–DN200	-20 to 160	–	–	✓	✓	✓
214S/425*	PTFE/EPM backed for steam	White facing, black backing	DN8–DN200	-20 to 160	–	–	✓	✓	✓
214/325	SUPERCEDED BY NEW ENHANCED 214/425								
500	Silicone DBPH cured	White	DN8–DN200	-40 to 150	67–73°	7.1	✓	✓	–
214S/300	PTFE/Butyl backed for steam	White facing, black backing	DN8–DN200	-20 to 150	–	30	✓	✓	✓
214S/325	SUPERCEDED BY NEW ENHANCED 214S/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.

HC4 Diaphragms

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.

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