Saunders Type AFP Diaphragm Valves

Diaphragms for Aseptic Applications

The Diaphragm – Key to Successful Valve Performance

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.

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. As the innovator and leader in diaphragm valves, we continuously develop our diaphragm technology and remain the only manufacturer to have front to back ownership of all aspects of polymer research and development, diaphragm design and production.

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

All Saunders 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.

To assist in the validation process and to provide the highest level of reliability, security and regulatory compliance, Saunders provides 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 and regulatory conformance. Saunders 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 Saunders matches the quality and performance of its diaphragms with the highest standard of documentation and validation support available in the industry.

The main categories of aseptic diaphragms are:

Synthetic elastomer – black internally reinforced grades

- Grade 300 – Butyl
- Grade 325 – EPDM, peroxide cured
- Grade 425 – EPM, peroxide cured
- Grade E5 – EPDM, peroxide cured, post 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
- PTFE modified grade white, grade 214S with 325 or 425 backing

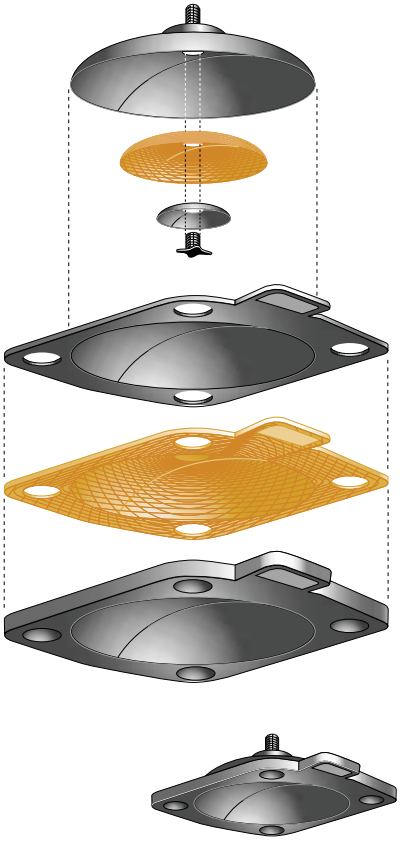
ALL DIAPHRAGMS CONFORM TO FDA REGULATIONS

Saunders Diaphragms

Diaphragm Design/Performance

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	Ethylene propylene (EPDM) diene-modified, peroxide cured	Black	DN8–DN200	-40 to 140	60–65°	12.5	✓	✓	✓
E5	Ethylene propylene (EPDM) diene-modified, peroxide cured, post cured	Black	DN8–DN100	-40 to 140	60–65°	12.5	✓	✓	✓
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	PTFE/EPDM backed	White facing, black backing	DN8–DN200	-20 to 160	–	32	✓	✓	✓
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	PTFE/EPDM backed for steam	White facing, black backing	DN8–DN200	-20 to 160	–	30	✓	✓	✓

Saunders Type AFP Diaphragm Valves

Diaphragm Traceability and 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
- 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.

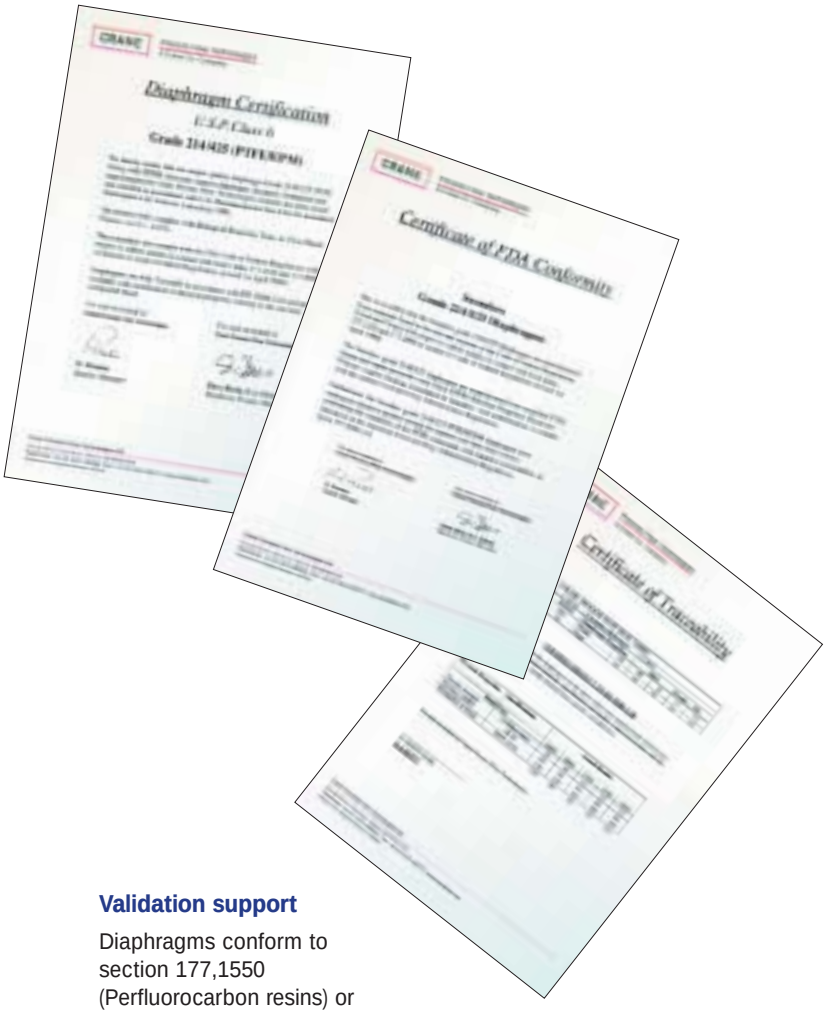
Expert and independent verification

- 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 biopharm processes. This has led the Saunders product to be taken still one step further, and through its range of fully traceable diaphragms provides its valve users with uniquely 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

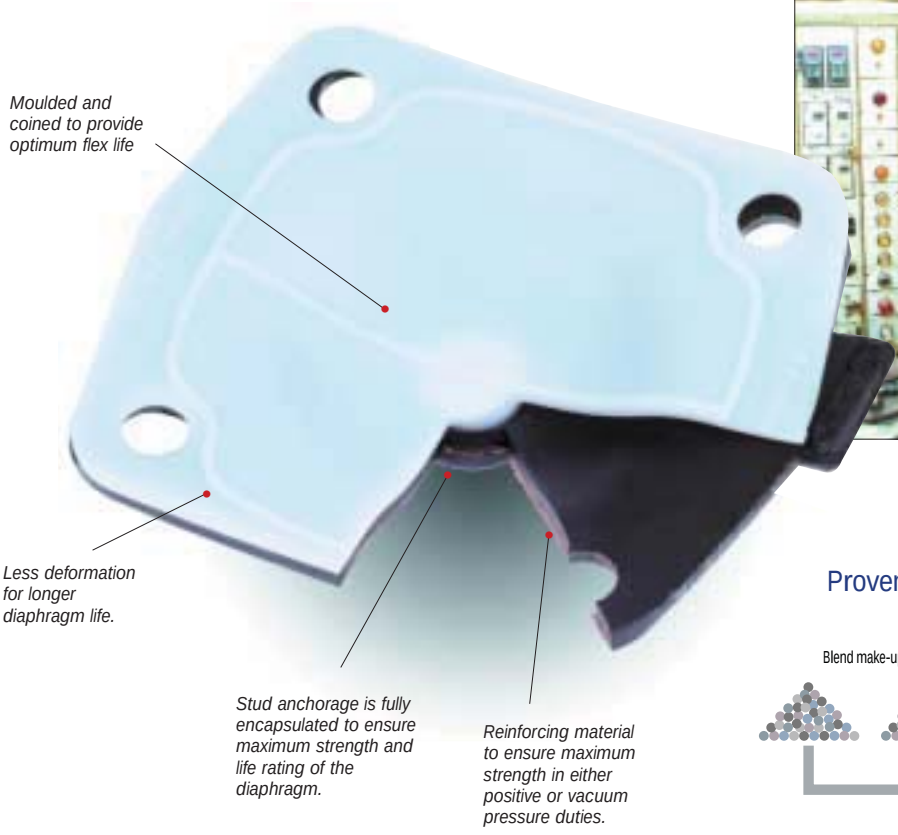
Diaphragms conform to section 177,1550 (Perfluorocarbon resins) or 177.2600 (Rubber Articles) in Chapter 1 Title 21 of the FDA Regulations (revised 1st April 2001) USP Class V and VI.

Traceable to EN10204 3.1b (was DIN 50049 3.1b)

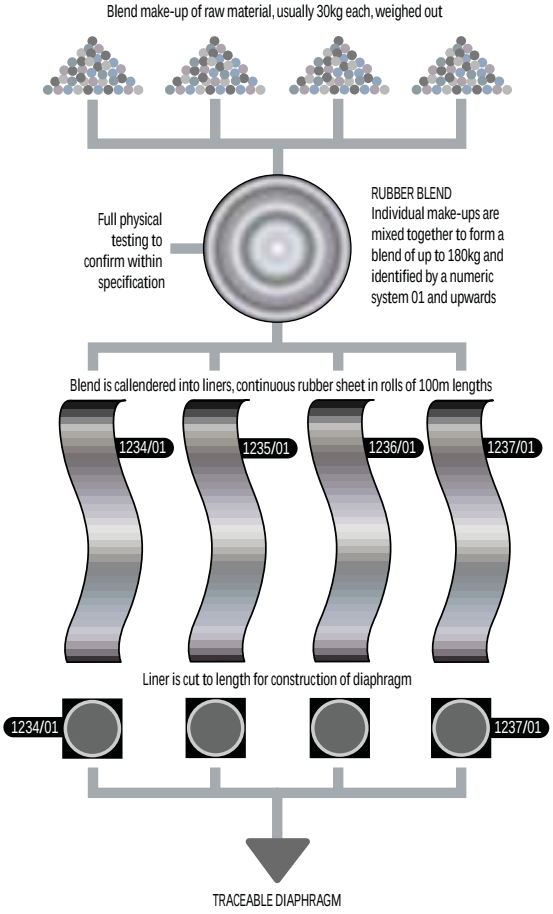
VALIDATION PACK INCLUDES:

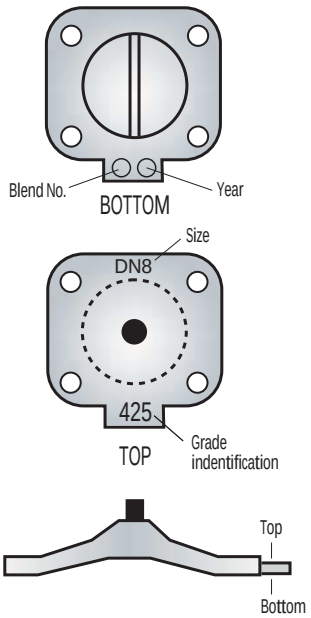
Saunders Type AFP Diaphragm Valves

Diaphragm Traceability and Validation



Proven manufacturing process





Saunders Type AFP Diaphragm Valves

Diaphragms – USP Approval, EPDM and EPM Grades

USP Approval

Saunders aseptic range now 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 from Crane Process Flow Technologies. We are proud to declare that we are almost unique in having polymer scientists engaged in research, development and manufacture of our diaphragm range. This enables us to manufacture all elements of the diaphragm in-house and gives us total control of every aspect of material content, design and production. It also assures customers that they are using products of unrivalled reliability that extend service life and minimise downtime.

Grade 425 EPM Diaphragms

Designed specifically for the most demanding biopharmaceutical applications, the 425 EPM elastomer diaphragm provides optimum process security. Manufactured from EPM (a copolymer of ethylene-propylene monomers), this compound uses the latest vulcanisation technology coupled with the inherent stability of the copolymer to eliminate 'weak points' associated with traditional solutions. Used widely in biopharm on aqueous media, CIP fluids, dilute acids and steam duties.

** United States Pharmacopeia*

Purity for Demanding Biopharm Processes

Saunders EPDM diaphragms

Ethylene propylene diene monomer (Grade 325) has good mechanical properties and is resistant to ageing, ozone, oxygen and ultra-violet radiation. The diaphragm is cured with an organic peroxide rather than the more commonly used sulphur to optimise product purity.

Used in biotech and pharmaceutical industries on aqueous media with good resistance to steam and CIP fluids, chlorinated caustic and dilute acids.

Approved to USP Class V and VI. Fully traceable to EN 10204 3.1b

The range also includes the E5 EPDM elastomer diaphragm which gives complete confidence that process product is free from leachables and extractables. Manufactured from EPDM (Ethylene Propylene Diene Monomer), the diaphragm is subjected to a post curing process to enhance polymer cross-linking and reduce the level of extractables. The result is improved product purity with minimal or zero contamination. Lasting longer than conventionally produced elastomer diaphragms, the E5 EPDM also provides better reliability and therefore less disruption to your processes.

The E5 EPDM has more quality approvals than any other grade of diaphragm available today. It actually exceeds current FDA inspection criteria, which means it can replace existing EPDM type diaphragms without any need for FDA revalidation.

The E5 EPDM has been specifically designed in conjunction with leading pharmaceutical manufacturers to:

- Overcome the problem of sulphur leachables which can be introduced through conventional vulcanisation process
- Improve product purity
- Provide a longer life alternative to traditional diaphragms
- Fully support and simplify the validation process.

Diaphragms

PTFE Grades

Type 214 PTFE (polytetrafluoroethylene) diaphragms

- 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

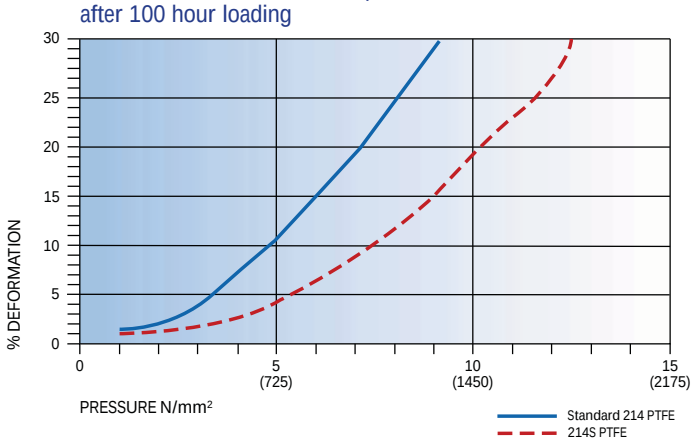
The PTFE 214S diaphragm has been designed specifically to improve performance in applications where steam is present. It displays improved elastic modulus at high temperature, resulting in less movement due to the effects of cold and hot flow. Indeed, the increased resistance to creep and cold flow of 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.

Improved life rating

Users of diaphragm valves within the biopharm industry can achieve major processing advantages using the PTFE 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.

PTFE – % Deformation under pressure at 150°C after 100 hour loading



By virtue of its material properties, standard PTFE tends to creep or flow into the body of the valve following steam sterilisation. This occurs when a vacuum is created in the system as the steam condenses. The resulting deformation, over time, reduces the valve's flow capacity, necessitating regular changes of the diaphragm.

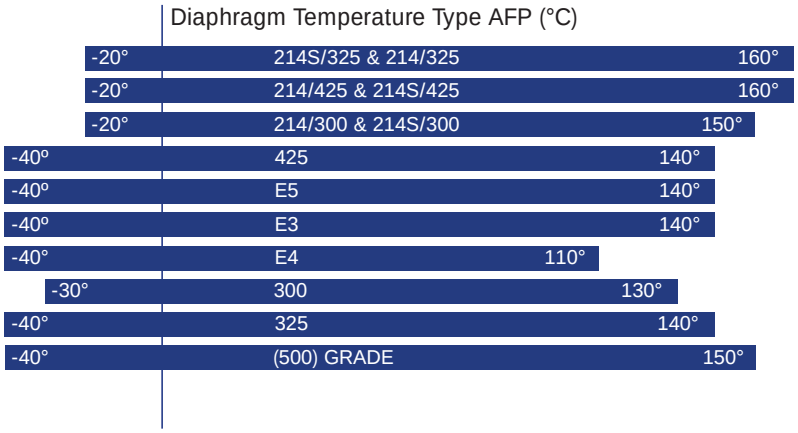
Diaphragms

Diaphragm Design/Performance

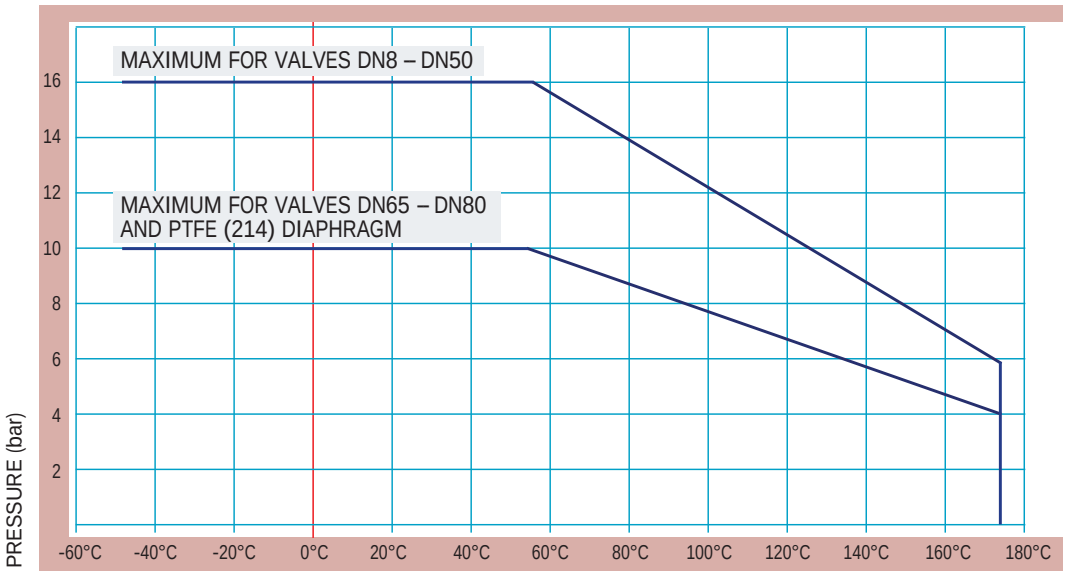
Temperature and pressure are the major limitations of valve operating capability although there can be many other aspects of a process specification that could affect both valve and diaphragm life. It is therefore essential with any valve selection to provide the fullest process and operating details such as operating cycles, speed of temperature fluctuations, sterilising fluids, steam sterilisation temperatures or any other parameter that may be present.

The Saunders aseptic diaphragm range has the following temperature and pressure characteristics: –

- Moulded and coined to provide optimum flex performance.
- Reinforcing material to ensure maximum strength in either positive or vacuum pressure duties.
- Optimum stud anchorage, to provide maximum bond strength and increased life rating of the diaphragm.



Valve Body Temperature/Pressure Relationship



Type AFP – Maximum rated Working Pressure (bar)

					25	40	50	65	80
PTFE – (214)	10	10	10	10	10	10	10	10	10
All rubber types	16	16	16	16	16	16	16	10	10