

# Saunders®

## Hi-Steam Diaphragm

Cut the process downtime on arduous steam duties

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 over conventional designs on applications subject to steam sterilization regimes. Applying their core competence in polymer technology and diaphragm design, Crane Process Flow Technologies Ltd has applied recent advances in both areas to develop a unique solution to the industry's most arduous service conditions. The Saunders Hi-Steam range of diaphragms offer:

- Greater reliability and service lifetime due to the 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 Poly-tetrafluorethylene [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. Deformation associated with conventional PTFE diaphragms is greatly reduced over diaphragm life especially in vessel content transfer and sampling applications.

- 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. Documentation available to confirm specific batch number and critical manufacturing data. This aids validation, assists in troubleshooting and is a guarantee of product quality.
- 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.
- Crane Process Flow Technologies Ltd with in-house design and manufacture, has complete control over the development and formulation.



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### Typical Applications

Biopharmaceutical

- WFI (Water for Injection)
- Intermittent steam sterilisation
- Vacuum duties
- Acids and alkalis
- Process water/ pure water (cold)
- Cooling water
- De-ionised water
- Air/ Oxygen/ Nitrogen

### Special Applications

Specifically provides significant performance enhancement on intermittent steam duties and associated pure water duties.

### Specification

TFM (Modified PTFE) backed with a copolymer of Ethylene and Propylene monomers (EPM).

- TFM is specifically designed to give lower porosity, reduced permeability and reduced cold flow with a denser polymer structure.
- EPM is carbon black reinforced and peroxide cured and uniquely has a single bond structure to maximise chemical / temperature resistance.

### Nomenclature

Saunders Hi-Steam Diaphragm

- 214S / 425



### Temperature Range

-20° C to 165° C

### Pressure Range

Higher pressure rating up to 16 bar to meet validation test pressure protocols.

### Sizes

DN8, 15, 20, 25, 40 & 50 mm

1/4", 1/2", 3/4", 1", 1 1/2" & 2"

### Validation Support

- Formulated in accordance with FDA codes of Federal Regulations, Chapter 1, title 21, part 177, paragraph 2600 Rubber Articles and paragraph 1550 fluorocarbon resins for repeated use in contact with food (revised April 2003).
- USP Class V and VI Biological Reactivity Test conformance.
- Fully traceable to EN10203 3.1b.
- Certified to ADCF (Animal Derivative Component Free).

### FDA Compliance Assured

- A unique reference is moulded on the diaphragm for full batch traceability.
- Certificate of the physical properties of each batch is used to ensure consistency.
- A profile of the complete physical data of each batch is available for any verification against process conditions.
- Complete documentation package is available for all valve components in contact with

AFP/F03/01/03.03

Due to constant product improvements, details shown on this flyer are subject to change

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For further technical **information**, please contact the Crane Process Flow Technologies Ltd or your local supplier

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