

Diaphragms

ITT has manufactured diaphragm valves for nearly 50 years and takes great pride in its reputation for supplying the highest quality hygienic diaphragm valves to the Biopharm industry.

The diaphragm is the most critical component of a diaphragm valve. Diaphragms are the valve component that provide positive shut-off between process fluids, protects the process from the environment and in some cases protects the environment from the process.

Genuine ITT diaphragms feature:

- Designs specifically matched to Pure-Flo weire geometry
- Engineered safety
- Reliability
- Industry proven performance
- Reduced total cost of ownership
- Complete product range
- Pure-Flo Topworks compatibility
- Material traceability permanently marked on diaphragms
- Original Equipment Manufacturer (OEM) materials and specifications
- Global availability
- Global technical support
- Preventative maintenance program development assistance



Regulatory Compliance to:

- FDA 21CFR Part 177
- Latest edition of the US Pharmacopeia Class VI
- Pressure Equipment Directive 97/23/EC
- EMEA/410/01 - TSE/BSE (Transmitting Animal Spongiform Encephalopathy)

ITT Pure-Flo diaphragms are qualified and approved for use with Pure-Flo diaphragm valves. Other makes of diaphragms are not recommended and/or guaranteed by Pure-Flo for use with Pure-Flo valves.

Diaphragm Selection

The Pharmaceutical and Biotech industries consider a number of factors to determine the best diaphragm solution for a given process or application.

Key factors include:

- Regulatory Compliance
 - FDA
 - USP 31
- Biocompatibility
- Material extractibles
- Application temperatures
- Cleaning in place (CIP)
- Steaming in place (SIP)
- Passivation
- Failure mode



Applications within the Biotech industry are particularly sensitive to diaphragm materials because of the fact that many of the processes within the industry utilize living organisms. A balance or compromise must be struck between all of the key factors listed. Regulatory compliance in most cases is not sufficient by itself to guarantee a properly functioning system.

The worldwide network of ITT Pure-Flo technical resources are available to assist in determining the proper diaphragm for your application.

| Diaphragm Type | | Size | | Temperature | |
|----------------|--------------------|---------|--------|----------------------|----------------------|
| Grade | Material | Inch | DN | °F | °C |
| B | Black Butyl Rubber | 0.25-12 | 6-300 | -20-250 | -29-121 |
| 17, E1 | EPDM ¹ | 0.25-4 | 6-100 | -22-302 ² | -20-150 ² |
| P | Buna N | 0.50-12 | 15-300 | 10-180 | -12-82 |
| TM17 | PTFE | 0.25-6 | 6-150 | -4-329 | -20-165 |
| TM17E | PTFE | 0.25-6 | 6-150 | -4-329 | -20-165 |
| W1 | White Butyl Rubber | 0.50-8 | 15-200 | 0-225 | -18-107 |

| Diaphragm Type | | Compliance | | |
|----------------|--------------------|------------|------|-----|
| Grade | Material | FDA | USDA | USP |
| B | Black Butyl Rubber | ✓ | ✓ | |
| 17, E1 | EPDM | ✓ | | ✓ |
| P | Buna N | ✓ | ✓ | |
| TM17 | PTFE | ✓ | | ✓ |
| TM17E | PTFE | ✓ | | ✓ |
| W1 | White Butyl Rubber | ✓ | ✓ | |

¹ For high temperature and/or high cycle applications, contact ITT.

² Temperature range is as follows:

-4-194°F (-20-90°C) for liquid applications
 -22-285°F (-30-140°C) for continuous steam
 -22-302°F (-30-150°C) for intermittent steam

Diaphragm Design

Pure-Flo's two-piece PTFE diaphragms have proven through years of outstanding service to be a robust and forgiving design. The two-piece construction eliminates the delamination problems inherent in competitive "PTFE faced" diaphragms.

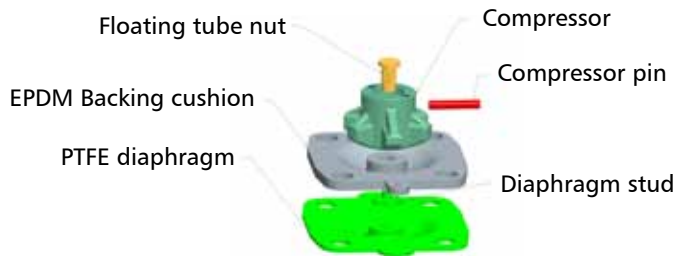
PTFE diaphragms utilize a floating tube nut connection. The floating tube nut design assures that downward closing forces will be

absorbed by the elastomer backing cushion and evenly distributed across the closing surface (weir) in the valve body.

Design Benefits:

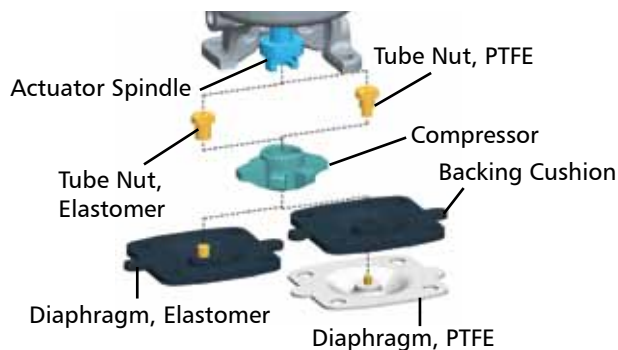
- Reduced cold flow
- Improved sealability
- Longer diaphragm life
- Reduced point loading
- Eliminates stud pullout

PTFE Diaphragm Compressor Assembly Showing Floating Tube Nut Design for Advantage, 903, and 913 (963 prior to 2010)

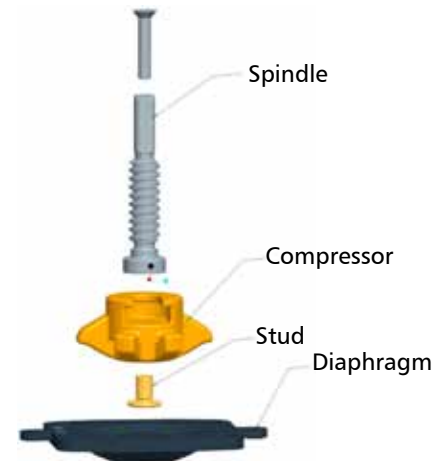


Note: Not available in Bio-Pure or Bio-Tek product line

Diaphragm Compressor Assembly with Modular Compressor Design for AXS and Advantage 2.0

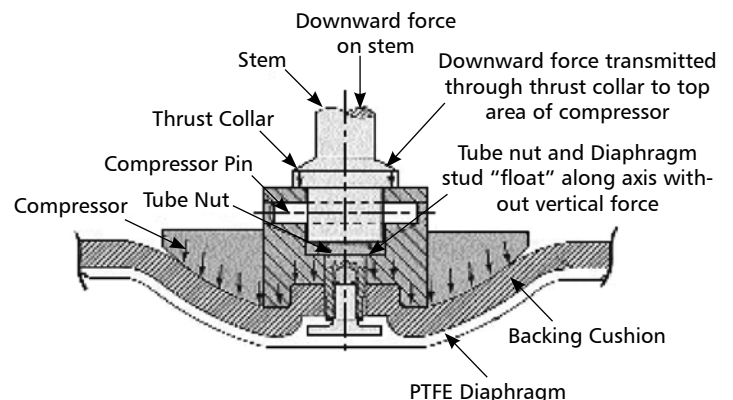


PTFE Diaphragm Compressor Assembly Showing T-slot Design for 970 and 963 with stainless compressor



Principle of Operation

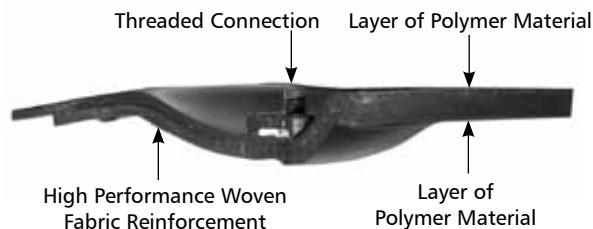
Downward force on top of compressor by-passed by tube nut and transformed to distributed pressure on bottom area of compressor. Compressor presses diaphragm over weir area of valve body.



Elastomer Diaphragm Construction

Pure-Flo elastomer diaphragms are produced by a compression molding process. The completed elastomer diaphragm is of a one-piece design. The diaphragm is constructed with layers of polymer material and a high performance woven fabric reinforcement for maximum strength and durability.

Elastomer diaphragms utilize a threaded connection to the valve compressor. PTFE and Elastomer diaphragm threads are not interchangeable.



Qualification Testing

Quality, performance and reliability of all Pure-Flo diaphragms is assured through extensive testing and comprehensive controls on the diaphragm material manufacturing process. Pure-Flo has years of experience in the development of diaphragm materials for use in the challenging applications within the Pharmaceutical and Bioprocessing industries. This knowledge is applied to each new material development. Successful completion of all appropriate regulatory requirements and operational performance benchmarks must be met before any new diaphragm material is released to the industry.

Typical conformance and performance tests:

- FDA extraction per 21CFR177.2600 (Elastomers)
- FDA extraction per 21CFR177.1550 (PTFE)
- USP Class VI <87> and <88> (70°C and 121°C¹)
- Cycle testing using air, water, and steam
- Cycle testing against vacuum and positive pressure at 100% and 0% ΔP conditions
- Cycle testing at ambient, cold, and elevated temperatures

¹ For PTFE Diaphragms

Note: ITT Pure-Flo diaphragms are qualified and approved for use with Pure-Flo diaphragm valves. Other makes of diaphragms are not recommended and/or guaranteed by Pure-Flo for use with Pure-Flo valves.

Diaphragm Development



USP Class VI

Pure-Flo PTFE diaphragms are tested to USP standards at 70°C and 121°C to provide assurance that diaphragm materials do not affect the process when subjected to typical protocols.

Grade TM17E PTFE

Grade TM17E combines the performance of the Grade TM PTFE diaphragm with a Grade 17 EPDM backing cushion that has been specifically processed to enhance material properties. Backing cushion compression and extrusion has been minimized with these changes. As a result diaphragm performance is improved in thermal cycling applications that are common place in the BioPharm industry.

The new backing cushion material is designated Grade 17E EPDM. As this new backing cushion utilizes the same materials of construction as the long used Grade TM17, validation efforts should be minimized.

Type: TM17E

Size Range: BT-6" (DN6 - DN150)

Temperature Rating:
-4°F to 329°F (-20°C to 165°C)

Pressure Rating:
See Pressure & Temperature chart on page D-10

Material (2 Piece Construction):
Product Contact Surface: Modified PTFE with PPVE*
Backing Cushion: Grade 17 EPDM

Regulatory Compliance:
21CFR 177.1550 (a)
USP Class VI, Chapter <87>, <88>
(70°C and 121°C)
21CFR177.2600 (Backing cushion)

*TM17 Material is considered a homopolymer according to ISO 12086, ASTM D-4894 due to < 1% perfluoropropyl vinyl ether (PPVE) modification



Grade TM17 PTFE

ITT Pure-Flo has developed a modified PTFE diaphragm to better withstand the critical process protocols associated with the Pharmaceutical and Bioprocessing industries, resulting in increased performance and longer life.

Type: TM17

Size Range: BT-6" (DN6 - DN150)

Temperature Rating:

-4°F to 329°F (-20°C to 165°C)

Pressure Rating:

See Pressure & Temperature chart on page D-10

Material (2 Piece Construction):

Product Contact Surface: Modified PTFE with PPVE*

Backing Cushion: Grade 17 EPDM

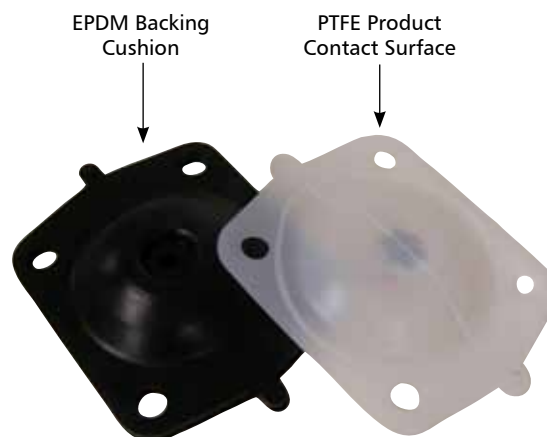
Regulatory Compliance:

21CFR 177.1550 (a)

USP Class VI, Chapter <87>, <88>
(70°C and 121°C)

21CFR177.2600 (Backing cushion)

*TM17 Material is considered a homopolymer according to ISO 12086, ASTM D-4894 due to < 1% perfluoropropyl vinyl ether (PPVE) modification



Pure-Life NGE Diaphragms - Grade E1

Created with the latest advanced technology polymer science. The NGE (E1) diaphragm was developed specifically for the intense applications of the Biopharmaceutical industry, the Pure-Life NGE diaphragm outperform all previous classes of EPDM and EPM diaphragms in these applications. Testing in extreme conditions both at ITT's state of the art diaphragm development laboratory and prominent Biopharm end users has shown order of magnitude performance gains over current generation of EPDM diaphragms.

Type: E1

Size Range: BT-6" (DN6 - DN150)

Temperature Rating:

- -4-194°F (-20-90°C) for liquid applications¹
- -22-285°F (-30-140°C) for continuous steam¹
- -22-302°F (-30-150°C) for intermittent steam¹

Pressure Rating:

See Pressure & Temperature chart on page D-10
Consult factory for steam rating

Material:

Ethylene Propylene Diene Monomer
Peroxide Cured (EPDM)

Regulatory Compliance:

21CFR 177.2600
USP Class VI, Chapter <87>, <88>

¹ For high temperature and/or high cycle applications, contact ITT.

Benefits:

- Reduced total cost of ownership
- Extended service life
- Improved uptime
- Ease of validation
- Improved resistance to steam, WFI and commonly used CIP chemicals
- Maintains ITT valve warranty



Certifications:

USP Class VI standard, Chapters <87> , <88> compliant
FDA 21CFR177.2600 compliant
Animal Derived Ingredient Free
EMEA /410/01 TSE/BSE (Transmitting Animal Spongiform Encephalopathy) compliant



Grade 17 EPDM

Grade #17 is comprised of a high molecular weight EPDM elastomer, which provides increased mechanical properties while reducing compression set. In addition, the diaphragm is peroxide cured* enhancing the biocompatibility of the material.

Type: Grade 17

Size Range: BP/BT, 0.5–6" (DN6 - DN150)

Temperature Rating:

- -4–194°F (-20–90°C) for liquid applications¹
- -22–285°F (-30–140°C) for continuous steam¹
- -22–302°F (-30–150°C) for intermittent steam¹

Pressure Rating:

See Pressure & Temperature chart

Material:

Ethylene Propylene Diene Monomer
Peroxide Cured (EPDM)

Regulatory Compliance:

21CFR 177.2600

USP Class VI, Chapter <87>, <88>

Benefits:

- Improved biocompatibility
- Better mechanical properties
- Reduced compression set
- Improved steam resistance (intermittent)

* Peroxide has replaced sulfur as the preferred method of EPDM curing as sulfur was found to be a biocide which could adversely affect sensitive bioprocesses.

¹ For high temperature and/or high cycle applications, contact ITT.



European Pressure Equipment Directive 97/23/EC

Diaphragm valves must comply with European Union Pressure Equipment Directive 97/23/EC. Valves must meet certain Essential Safety Requirements and design criteria. This includes diaphragms as they are an integral component of the valve pressure boundary.

The PED requires the manufacturer to maintain a technical file primarily consisting of:

- Design calculations or proof test
- Material testing
- Performance testing
- Declaration of Compliance to the PED 97/23/EC (available on request)

An excerpt from a guideline for the Pressure Equipment Directive 97/23/EC states:

“Pressure equipment which has been subject to important modifications that change its original characteristics, purpose and/or type after it has been put into service has to be considered as a new product covered by the directive.”¹

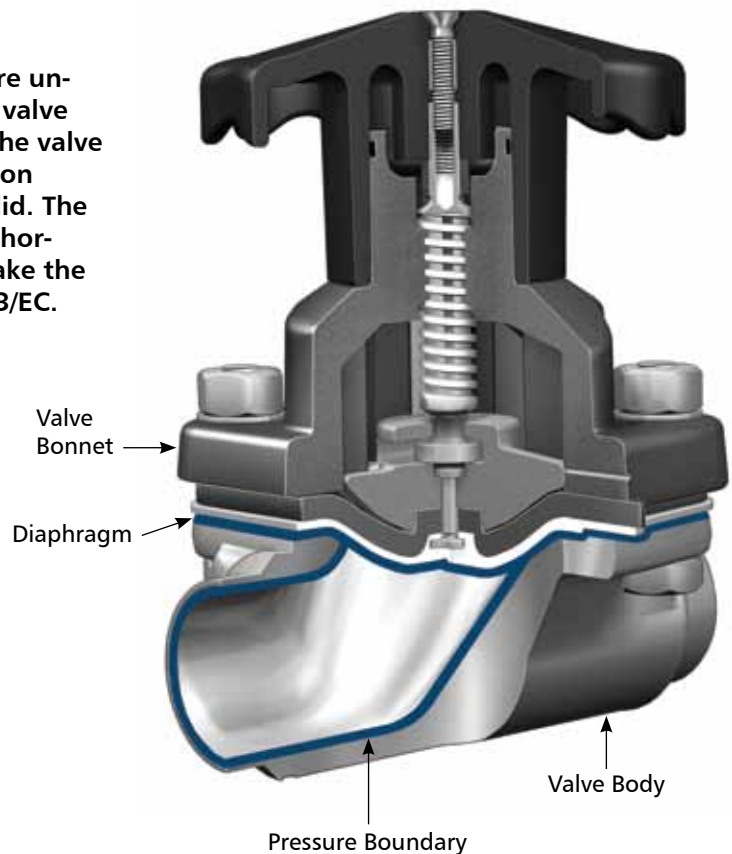
Note:

The use of unauthorized and therefore undocumented components within the valve constitutes a major modification to the valve and renders the original ITT Declaration and compliance to the Directive invalid. The end user or the supplier of the unauthorized replacement component must take the responsibility for compliance to 93/23/EC.

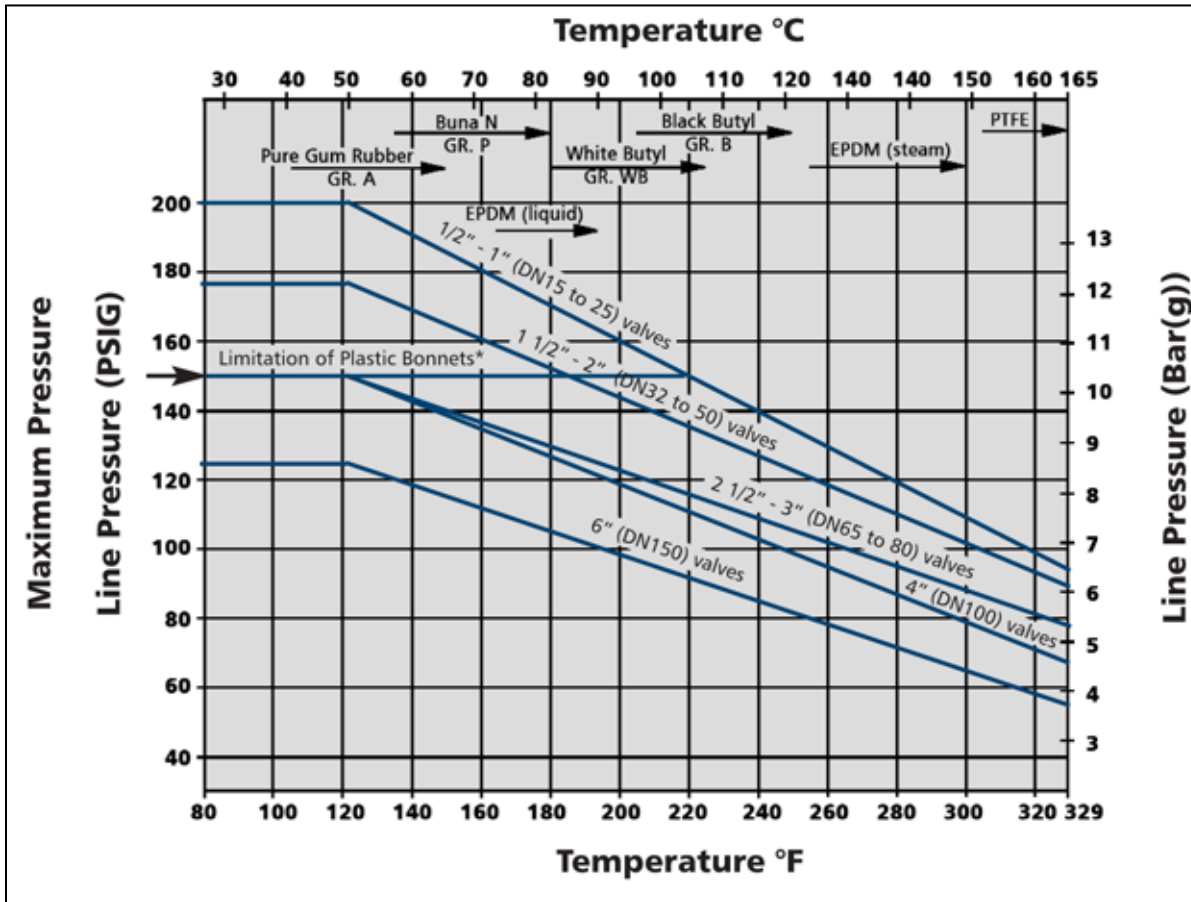
¹ http://europa.eu.int/comm/enterprise/pressure_equipment/ped

Pressure Boundary

The diaphragm is a critical pressure boundary component of a typical diaphragm valve in conjunction with the valve body, fasteners and manual or actuated bonnet. These components are designed, manufactured and tested to achieve specific pressure ratings and performance criteria. Changes in materials, dimensions or even tolerances of any of these components can have an adverse affect on the overall performance and safety of the valve. ITT Pure Flo conducts extensive testing to support the performance of the valve and pressure boundary.

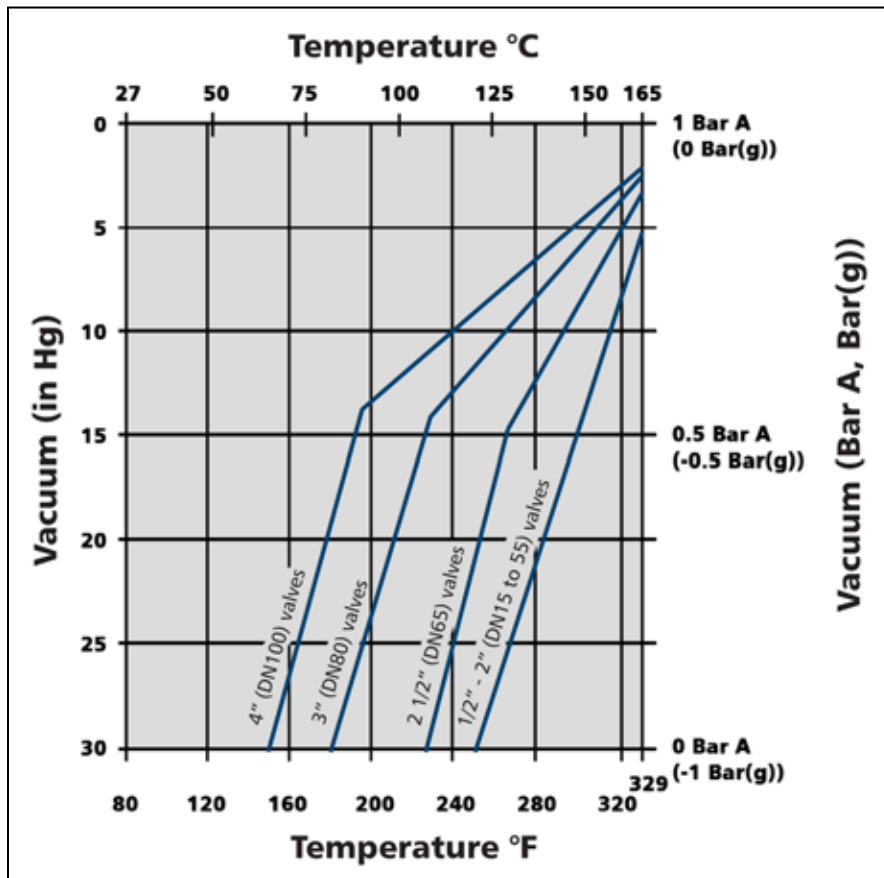


Pressure/Temperature Recommendations



* This line shows the limitation of plastic bonnets including the 963 and Advantage Actuators.
 Note: Elastomer diaphragms may be used in vacuum service within above temperature recommendations. For services exceeding charted pressure/temperature recommendations, consult factory. The chart does not pertain to steam or corrosive services. Consult ITT DV-06 Technical Manual and Service Guide for specific recommendations.

PTFE Diaphragms for Vacuum Service



Notes:

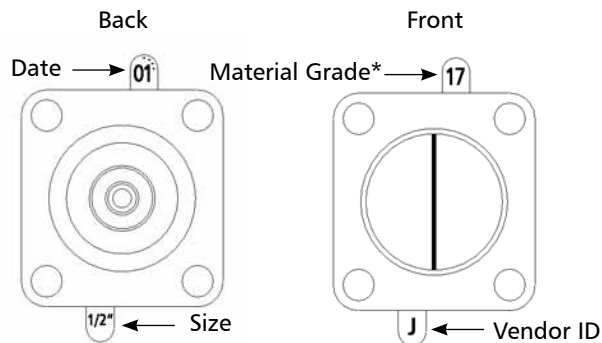
1. Service conditions falling to the right of these lines will require bonnet evacuation.
2. PTFE-Diaphragms, 6" (DN 150) size and larger, will not withstand full vacuum at any temperature unless bonnets are evacuated.
3. With evacuated bonnets any size PTFE-Diaphragms can be used up to 329°F (165°C).
4. See below for elastomer diaphragms for vacuum service

Elastomer Diaphragms for Vacuum Service

The standard Pure-Flo diaphragm valve is ideally suited for vacuum service, providing dependable performance and good service life from atmospheric pressure down to nearly full vacuum (-30 in Hg, 0 Bar A) The diaphragm is bi-directional and presents a smooth face with no hidden voids on either side of the valve, whether open, closed or throttling.

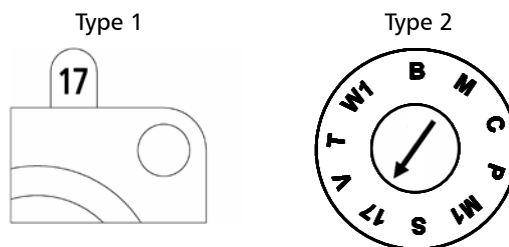
Diaphragm Traceability

All diaphragm materials and physical properties are batch traceable via permanent codes molded into the diaphragm tabs. The molding date, material grade, and diaphragm size provide traceability to original batch records.



Elastomer Material Grade Codes

Elastomer material grades are listed on page D-2 (Type 1). For diaphragms with a clock (Type 2) the arrow points to the material grade.



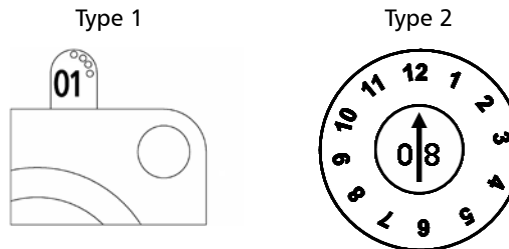
Elastomer Date Codes

The date is a two digit year code and dots corresponding to months

Type 1: April 2001

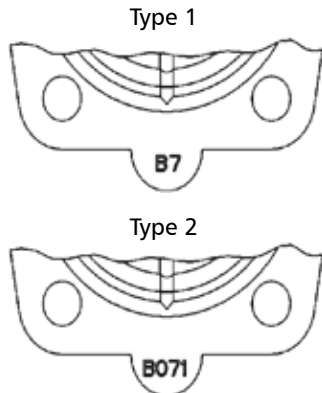
For diaphragms with a clock, the two digits in the middle are the year and the arrow points to the month.

Type 2: December 2008



PTFE Date Codes

The first letter identifies the month the lot was manufactured. For a two digit code, the second digit is the year (Type 1: B7 = February 2007). For a four digit code, the next two digits indicate the year, and the last number indicates the batch number (Type 2: B071 = February 2007, batch 1).



| PTFE Code - Months | |
|--------------------|-----------|
| A | January |
| B | February |
| C | March |
| D | April |
| E | May |
| F | June |
| G | July |
| H | August |
| I | September |
| J | October |
| K | November |
| L | December |

| PTFE Code - Year | | |
|------------------|--------------|--------------|
| Year | 4 Digit Code | 2 Digit Code |
| 2005 | 05 | 5 |
| 2006 | 06 | 6 |
| 2007 | 07 | 7 |
| 2008 | 08 | 8 |
| 2009 | 09 | 9 |
| 2010 | 10 | 0 |
| 2011 | 11 | 1 |
| etc. | etc. | etc. |

Packaging

All Pure-Flo diaphragms are sealed in individual tamper evident packages to prevent damage and contamination during transportation, handling and storage. Tamper evident packaging provides an extra level of assurance that the diaphragm has not been exposed to potential contamination during storage or maintenance activities prior to installation.



All Pure-Flo Diaphragm packages contain important information necessary for validation and maintenance.

- Diaphragm part number
- Description
- Material
- Pack date
- Cure date
- Installation graphic

Storage Recommendations

- Storage temperature should be between 40-75°F (5-25°C). Higher temperatures may affect overall service.
- Diaphragms should be stored in a cool dry environment so that condensation does not occur.
- Diaphragms should be protected from direct sunlight and Ultra Violet light sources.
- Where possible diaphragms should be protected from circulating air. Storage in bags or other air tight containers is recommended for longest service life.
- Physical properties and performance of rubber diaphragms can deteriorate when stored for long periods. The diaphragm may become unsuitable for service due to environmental, physical, and chemical factors.

Shelf Life

| Material | Grade | Shelf Life |
|-------------------|--------|------------|
| Butyl | B, W1 | 10 |
| EPDM | 17, E1 | 6 |
| Buna N | P | 6 |
| PTFE ¹ | TM17 | 10 |

¹ PTFE diaphragm face only.

Application

Pure-Flo diaphragms are suitable for a wide range of utility and process applications utilized in the Pharmaceutical and Biotech industries. However, not all diaphragm materials are suitable for all processes and conditions. The accompanying tables should be used as a reference.

The worldwide network of ITT Pure-Flo technical resources are available to assist in determining the proper diaphragm for your application.

Typical Process Applications:

- WFI
- Purified water
- Product solutions
- Buffer solutions
- Cell culture solutions
- Media
- Solvents
- Protein solutions
- Ultra filtration

Typical Utility Applications:

- Passivation protocols
- Cleaning protocols
- Sterilization protocols

Passivation

| | Nitric Acid 15% ¹ | Phosphoric 10% ¹ | Citric Acid 15% ¹ | Mixed Chelants ² |
|----------|------------------------------|-----------------------------|------------------------------|-----------------------------|
| PTFE | R | R | R | R |
| EPDM | U | R | R | R |
| Butyl | R | R | R | R |
| Silicone | U | U | R | R |

¹ At 60°C/140°F

² Amonium citrate Base at 80°C/176°F

R = Resistant

U = Unsatisfactory

Cleaning

| | Sodium Hydroxide NaOH | Sodium ypochlorite NaOCl | Potassium Hydroxide KOH | Phosphoric Acid H3PO4 | Hydrogen Peroxide H2O2 |
|----------|-----------------------|--------------------------|-------------------------|-----------------------|------------------------|
| PTFE | R | R | R | R | R |
| EPDM | R | R | R | R | R |
| Butyl | R | R | R | R | U |
| Silicone | R | R | U | U | R |

Consult factory for specific temperature and concentration limitations.

Sterilization

| | Saturated Steam ¹ | | | Dry Heat ² | Ozone ³ |
|----------|------------------------------|-------------------|-------------------|-----------------------|--------------------|
| | 20 psi 1.4 Bar(g) | 30 psi 2.1 Bar(g) | 40 psi 2.8 Bar(g) | | |
| PTFE | R | R | R | R | R |
| EPDM | R* | R* | R* | U | R |
| Butyl | R* | R* | R* | U | R |
| Silicone | U | U | U | U | R |

1 20psi/1.4 Bar(g) = 259°F/126°C

30psi/2.1 Bar(g) = 274°F/135°C

40psi/2.8 Bar(g) = 286°F/142°C

2 338°F/170°C

3 3% at 80°F/27°C

* Limited life and undesirable failure mode

Bio-Pure Diaphragm

Interchangeability

All Bio-Pure valves feature a common diaphragm connection. Elastomer and PTFE diaphragms can be interchanged as required on both the manual and actuated bonnets.

Installation

Bio-Pure diaphragm installation is simplified by utilizing a bayonet diaphragm connection. The diaphragm is inserted into the compressor and turned 90°. The bayonet design provides float to eliminate point loading on PTFE diaphragms.

