

Diaphragms

The diaphragm is the most important component of the diaphragm valve.

Besides the valve body, the diaphragm is the only part which contacts the process medium.

The diaphragm separates the process medium from the actuator or top works and the external atmosphere.

In addition the diaphragm is the dynamic part which the flow rate of the process medium is controlled and stopped.

The developing of formulation of compound is done closely with a specialised company developing, producing and testing compounds since many years together with SED for our market.

The SED diaphragms have been developed and tested over years and are subject to stringent testing specification in our own test stands and third party. These tests are continuously performed with different specification to simulate as close as possible different real processes.

E.g. one of the testing is performed with a automatic saturated steam sterilisation loop. (see picture below). The tests result has an influence on the design, composition of the materials, valve body design, actuation and complete valve assemblies.

All diaphragms are produced with an embedded stainless steel compressor stud for the engagement at the valve operating mechanism except for the diaphragm dimension MA8 which is connected with the valve activation by an elastomer button.

All diaphragm materials of the same size have the same engagement with the valve operating mechanism and may be interchanged in the valve without changing the diaphragm compressor and spindle.



Test stand sterilization process simulation. Cycle and lifetime testing of diaphragms and valves with saturated steam

Material		EPDM		PTFE/EPDM		PTFE/EPDM
MA		8 - 100		25, 40, 50	8, 10	25 - 100
Design		One-piece molded open		One-piece molded open		two-pieces molded closed
Temperature range	(°C)	-40 to 150		-20 to 150		-20 to 160
	(°F)	-40 to 300		-4 to 300		-4 to 300
SED Code		20	28	30	51	44

The listed temperatures may apply to clean steam sterilization protocols and may not apply to continuous steam service. Upon request, other diaphragms are available with other materials, bigger sizes and for higher temperature up to 175°C/350°F.

Diaphragms



Elastomer



PTFE/EPDM

EPDM

Ethylene-propylene elastomer peroxide cured. The SED EPDM is a specifically developed compound reinforced with a vulcanized woven fabric inlay and is always manufactured in the molded open position. This diaphragm construction achieves higher stability for the diaphragm at elevated temperatures and pressures. In addition, the woven fabric inlay is vulcanized over the embedded compressor stud in order to strengthen the elastomer-metal connection. Thus, the EPDM diaphragm is ideal for vacuum applications.

PTFE (TFM)

These PTFE diaphragms have been designed and offer the highest degree of chemical resistance, increased stability, longer flex life, less porosity, reduced cold flow and superior performance through temperature fluctuations between hot and cold and steam sterilization cycles.

MA8 and MA10

The diaphragm dimensions MA8 and MA10 are designed as one-piece diaphragms: This means that the EPDM back is bonded with the PTFE.

The diaphragm is always manufactured in the molded open position. These one-piece diaphragms have less surface area and are subject to shorter linear strokes which explain the excellent performance that has proved itself over time.

MA8 diaphragm incorporates an elastomer button for assembly with the valve operating mechanism. The MA10 utilizes a threaded stud assembly with the valve operating mechanism. Both these features eliminate the potential for point loading at the center of the diaphragm.

MA25 to MA100

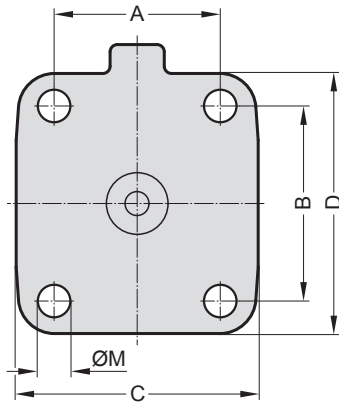
The diaphragm dimensions MA25 to MA100 are designed as two-piece diaphragms-consisting of a separate EPDM backing cushion and PTFE diaphragm. The diaphragm is always manufactured in the molded closed position. The advantage of this design for the MA25 to MA100 is that the diaphragm is in its molded shape while in the closed position of the valve. This reduces the force to close the valve and increases the life of the diaphragm.

In the two piece diaphragms the threaded stud connection is embedded in the PTFE of the diaphragm. To eliminate the potential of point loading at the center of the diaphragm, a floating suspension connection to the valve operating mechanism is utilized.

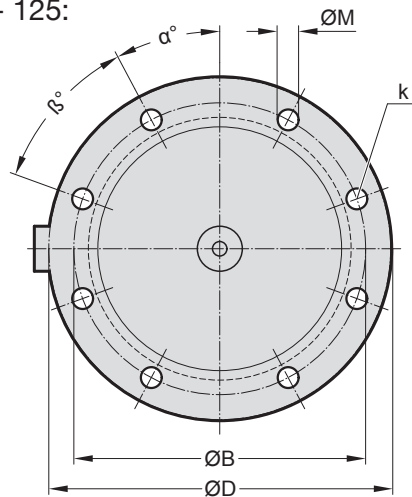
Note: Other diaphragm sizes and materials on request.

Diaphragms

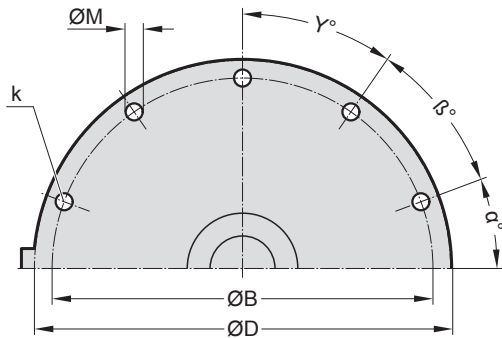
MA 8 - 80:



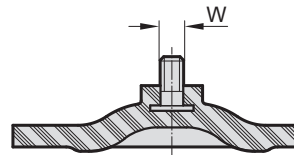
MA 100 - 125:



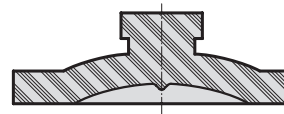
MA 150:



MA 10 - 150:



MA 8:

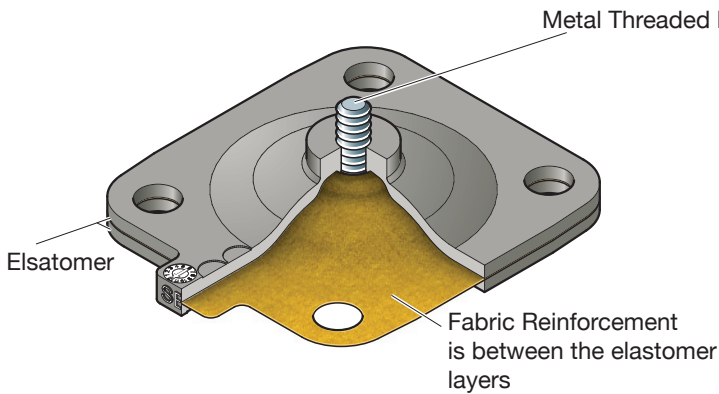


Dimensions (mm)

DN	NPS	MA	A	B	C	D	ØM	k	W	α	β	γ
4 - 15	1/4" - 1/2"	8	22	22	31,5	31,5	5,5	4	-	-	-	-
12 - 15	3/8" - 1/2"	10	42.5	37.5	52	47	5.5	4	M4	-	-	-
15 - 25	1/2" - 1"	25	46	54	67	72	9	4	1/4"	-	-	-
32 - 40	1 1/4" - 1 1/2"	40	65	70	90	100	13.5	4	1/4"	-	-	-
50	2"	50	78	82	106	124	13	4	1/4"	-	-	-
65	2 1/2"	65	95.3	101.6	131.9	144.4	14.3	4	5/16"	-	-	-
65 - 80	2 1/2" - 3"	80	114	127	156	186	18	4	5/16"	-	-	-
100	4"	100	-	194	-	228	14.5	8	5/16"	20	42	-
125	5"	125	-	222	-	254	17.5	8	3/8"	43.5	43.5	-
150	6"	150	-	273	-	298.5	17.5	10	3/8"	35	35	35

Diaphragms

Diaphragm Code 28

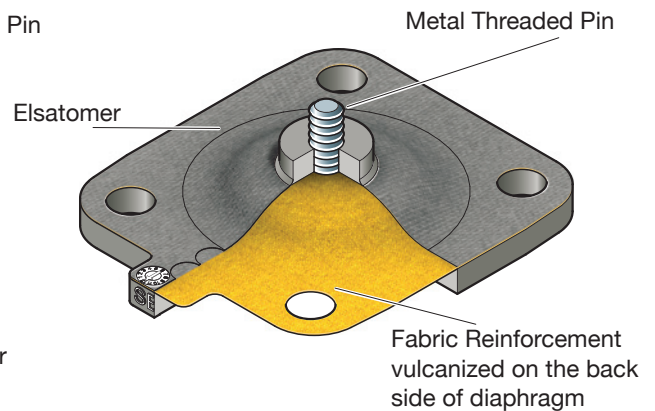


After a long and successful development accompanied by stringent testing, simulation of actual aseptic process applications and sterilization protocol, SED has released an improved elastomer formulation for our EPDM diaphragms. This EPDM diaphragm is produced out of an improved compound material targeting critical aseptic applications with SIP steam sterilizing cycles and processes.

Features:

- The elastomer formulation for our Code 28 EPDM diaphragm is identical to the Code 20 EPDM diaphragm which has a different design and manufacturing process.
- Woven fabric reinforcement is positioned between two elastomer layers.
- Increased lifetime expectancy under steam.
- All required approvals and conformities are available (See page 18).
- Diaphragm is interchangeable with all SED diaphragm valves.

Diaphragm Code 20



Typically a diaphragm is manufactured with a woven fabric reinforcement positioned in the middle of the EPDM elastomer diaphragm to improve the mechanical properties, strength and durability. This is accomplished by vulcanizing the woven fabric reinforcement between two elastomer layers.

A specific manufacturing process has been developed to vulcanize the woven fabric reinforcement on the back side of the EPDM diaphragm. With this manufacturing process the diaphragm achieves better performance in SIP steam sterilizing cycles and processes with reliability in critical sterile processes.

Features:

- The elastomer formulation for our Code 20 EPDM diaphragm is identical to the Code 28 EPDM diaphragm.
- The fabric has a maximum distance from the media contact surface.
 - Damage to the fabric can be easily observed.
- Friction between the compressor and the back of the diaphragm is minimized.
 - Therefore reduced wear and longer cycle lifetime.
- Better load distribution because the height of pure elastomer is maximized when the fabric is on the back side.
- Process safety increases because of only one fabric layer. The position of the fabric on the back side is exactly geometrically defined.
- Production control is easier when the fabric is on the back side.
- All required approvals and conformities are available (See page 18).
- Diaphragm is interchangeable with all SED diaphragm valves.

Diaphragms

Certification and Compliance for Validation

At SED, we recognize the importance of the validation process in the aseptic industry.

This has led to an internal awareness and specific restructuring within the company to provide the highest level of reliability and regulatory compliance through the complete supply chain to provide a complete package of documentation for all components in contact with the process fluid.

Related to it the key performance component in the diaphragm valve is the diaphragm.

- All resin and additives used in the manufacturing process are FDA compliant.
- Compounding, physical properties and manufacturing process are documented
- Certificate of Conformance with FDA for all diaphragms
 - 21CFR177.2600 for Elastomers
 - 21CFR177.1550 for Perfluorocarbon resins
- Certificate of Conformance with USP 28 Class VI, Chapter 87 In-Vitro and Chapter 88 In-Vivo
- Testing for extractable organic substances on the basis of ISO 10993-18 (detection by GC-MS)
- Certificate of Conformance with 3-A
- TSE/BSE (ADCF) Certification of Compliance to EMEA/410/01 "Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medical Products"
- Certificate of Traceability according EN 10204 3.1 of compounding and molding process with material analysis
- Test data available upon request
- REACH-Verordnung (EU) 1907/2006/EG is observed
- RoHS Directive 2011/65/EU is observed

Substanz	CECL	CECL	CECL
1	21.348	0.141	0.263
2	1.170		
3	1.69.000	76.333	0.375
4	1.300		
5	1.300	7.000	0.200
6	1.300	4.497	0.307
7	1.300	18.000	0.316
8	1.300	14.347	0.260
9	1.300	244.437	3.385
10	1.300	0.300	0.140

Diaphragms

Diaphragm Traceability

All diaphragms are clearly identified and the material is batch traceable by a set of unique codes molded into the diaphragm body.

Information provided on the order and shipping documents as well as on the packaging is described by the following. With the request of the Material Analysis Traceability Certificate DIN EN 10204 3.1 for manufacturing and formulation the additionally provided information is shown in bold type.

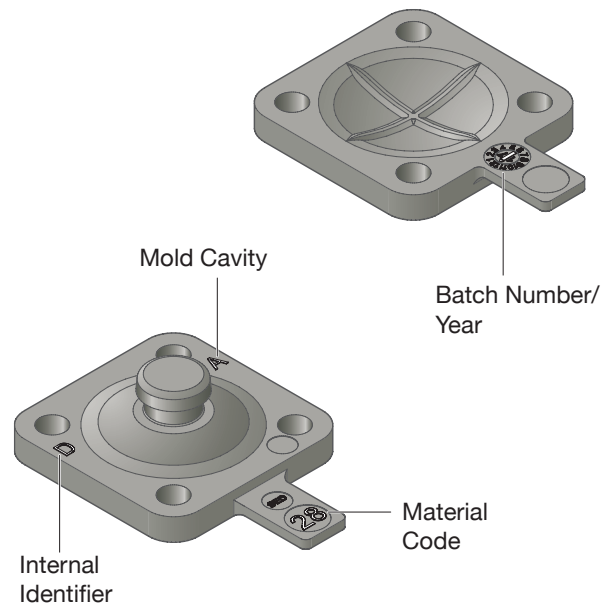
... on the order and shipping documents:

- SED article number, material code with description
- Customer article number on request
- **Batch number**
- **Shelf Life**

... on packaging in which the diaphragm is bagged and sealed in plastic:

- SED article number, material code with description
- Internal order series number
- Packaging quantity
- Customer article number on request
- **Batch number**
- **Shelf Life**

Example markings MA8



Example markings MA50

