Finding the right diaphragm valve for pharmaceutical applications

Like in Formula 1, success is often determined by design, material and maintenance

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Diaphragm valves in pharmaceutical plants are used for a variety of different media, and the right choice of valve and diaphragm is essential for long, reliable operation. The wrong choice of material or improper maintenance can quickly lead to high follow-up costs.

In pharmaceutical production, high-priced raw materials often have to be dosed precisely according to complex recipes. Reliability and dependable functionality are essential prerequisites for economical production, highest product quality and ultimately for regulatory approval. Diaphragm valves are typically used here. In order for them to work efficiently, the operating conditions need to be analyzed. Only with precise knowledge of material flows, switching frequency, the chemicals used and the media temperatures in play can a valve be selected that perfectly suits the requirements. During operation, professional maintenance is important to ensure that the diaphragms continue to meet the strict requirements over the long term.

Diaphragm valve Type 2103 with process controller (integrated air routing) for decentralized automation. (Source: Bürkert)

Diaphragm valves are suitable for a wide range of applications in which fluids must be guided using appropriate engineering processes. Whether it's fermentation or bioreactors, CIP/SIP systems, in filtration or filling, in chromatography or in the production of ultra-pure water, every application has its own special profile of requirements. Bürkert Fluid Control Systems (see the company box) therefore offers a wide range of diaphragm valve designs to go with matching actuator systems and solutions for easy automation. The modular system with versatile components ensures long, trouble-free operation and plannable maintenance intervals when configured correctly. But how do you find the right components?

Diaphragm valves are specialists

Modern diaphragm valves are multifunctional specialists that are designed precisely for their area of application in order to ensure reliable operation and handle the entire range of media and operating parameters. In particular, the choice of material for the diaphragms is an art – reminiscent of tyre choices in Formula 1. Only the right mix of materials makes it possible to bring the vehicle's potential onto the road given the conditions at hand. Rain tires are not suitable for dry roads. Slicks are not suitable for wet conditions. The tire selection poker game often determines victory or defeat. It is similar with diaphragm valves because, here too, not all application requirements are known in advance. You have to correctly assess them, evaluate them and then make your choice flexibly. The basis for efficient valve use is the service life of the diaphragm in contact with the medium. It must be

able to withstand the operating conditions both mechanically and chemically. This depends on the valve body, the actuator and of course the diaphragm material.

In addition to valve selection, things like switching cycles, temperature, media pressure and chemical composition also influence the choice of diaphragm materials. Even a small parameter change in production can lead to significant loss of service life if the same valve body is continuously in use.

Diaphragm selection requires know-how

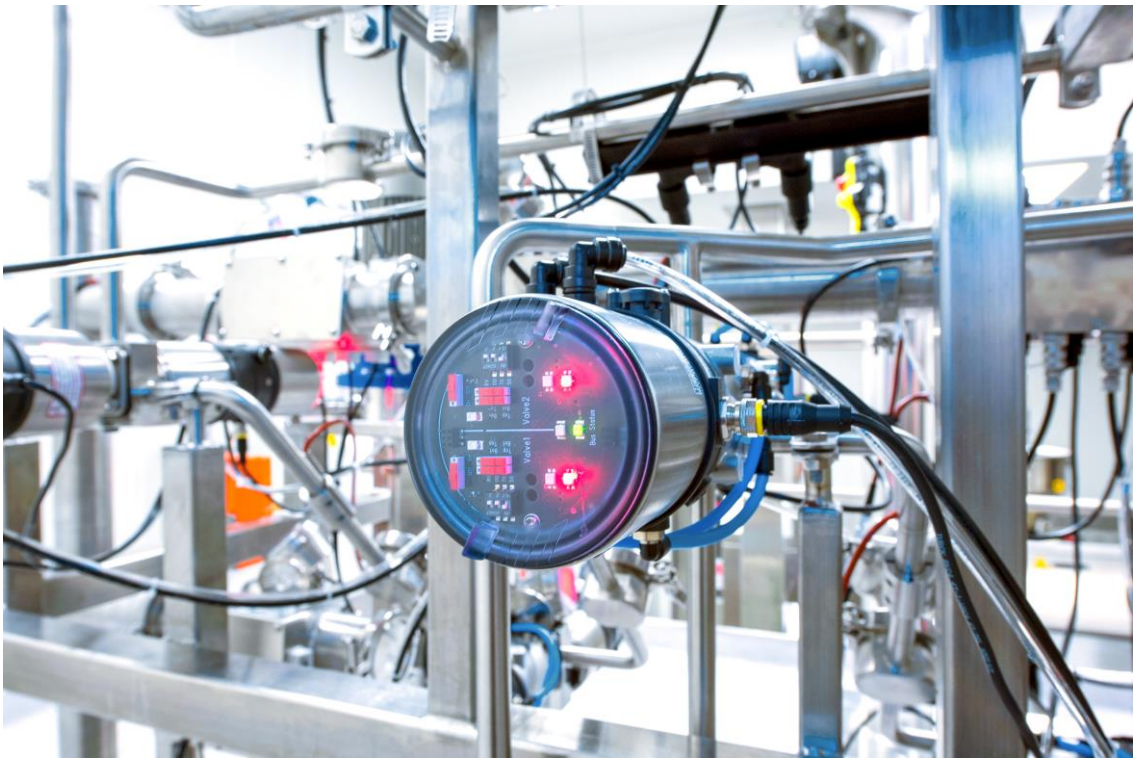
If all operating parameters are known, choosing the right diaphragm should not be an issue – in theory. As in Formula 1, however, very extensive know-how is required here. Depending on the track surface, it is not enough to run normal slicks at high temperatures; the additional abrasion caused by a rough road surface, for example, requires extra hard rubber compounds. The conditions for valve diaphragms in everyday operation are similar. Since only very specific basic substances are permitted for FDA and similar approvals, the mixtures must comply with these restrictions (see box text: Diaphragm materials). In addition, the principle of so-called traceability must also be kept in mind. With regard to the ingredients of the diaphragm compound, all of the ingredients need to be fully documented or comply with the provisions and approvals of the relevant regulations (e.g. USP 88).

Close-up of a diaphragm with stamp for traceability. (Source: Bürkert)

Consistent quality in production, composition and processing must be also ensured. The smallest changes in production processes, in the composition of the compounds, or in geometry must not be made without prior consultation with the end users – it can result in a revalidation of the diaphragms. Within the scope of documentation and traceability, the diaphragms and the valve body – the product that has contact with the components of a diaphragm valve – are subject to special requirements (Fig. 3). From the still huge amount of choices, it is now a matter of finding a suitable combination for the respective purpose.

Multi-port valve block with element actuator and process controller. (Source: Bürkert)

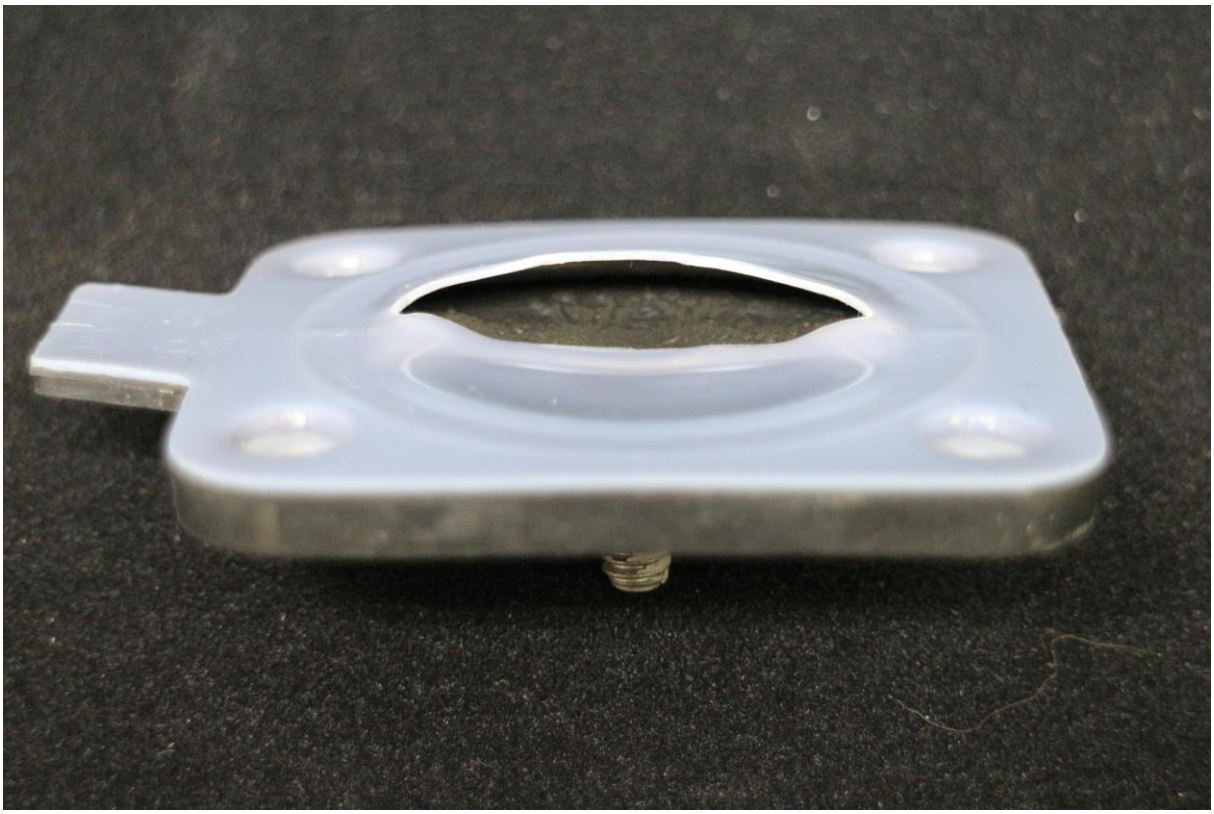
Once the mixture is fixed, the question arises: How is it further processed? When the diaphragm is pressed into shape and “vulcanized”, there are also a large number of influential parameters that either extend or restrict the range of applications. Only years and years of experience and constant learning can help here to produce durable, long-lasting and thus cost-effective diaphragms. The decades of experience of Bürkert’s fluid specialists in handling diaphragm valves, even in unusual applications, is therefore a good basis for a robust valve design.



Special diaphragm designs like the one in the patented Robolux valve allow two independent process switching functions in one diaphragm, thereby minimizing the number of valves and diaphragms required. (Source: Bürkert)

Caution during maintenance!

Once all of the components – from the valve body to the optimum diaphragm design – have been selected and are in operation, the valve will eventually need to be serviced and the diaphragm replaced. Unfortunately, this is precisely where avoidable mistakes happen that can lead to lofty and unwanted follow-up costs. If the new diaphragms are tightened too much, premature wear and even failure may occur. All diaphragms are to be fitted properly and then the screws are to be screwed in by hand. Then it is imperative to operate the valve three to four times while empty so that the diaphragm can seat itself precisely without getting jammed on the valve flange. Only then can the screws be tightened in the correct sequence to the specified torque. If all of these things don't happen, even the most resistant diaphragm can be completely destroyed after just a few switching cycles and, in the worst case, the valuable end products may be unusable.



Diaphragm damage – the damage pattern does not always indicate the cause. (Source: Bürkert)

The main causes of premature failure in certified quality manufacturing processes these days is improper maintenance or replacement. Looking at it critically, failures after approximately four weeks of operation due to installation errors are avoidable and unfortunate when compared with problem-free operation for over a year for the 98 to 99% correctly installed diaphragms. After the initial selection, correct maintenance is the most important and "cheapest element" in long, trouble-free operation.

For economical system operation it is important right from the start to assemble the right diaphragm valve components for the respective application. In the event of changes to the mode of operation – higher clocking, temperature, etc. – it is advisable as a precaution to check the suitability of the components for the new conditions. If users also follow the prescribed steps during maintenance, nothing stands in the way of reliable system operation, even in difficult applications.

More information available here:

https://www.burkert-usa.com/en/Products-Applications/Customised-Solutions/Applications/Automated-fluidics-solutions-for-machines-in-the-pharmaceutical-industry

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Technology Box:

Properties of common diaphragm materials:

EPDM: Ethylene propylene diene rubber is a synthetic rubber with a wide range of applications. The material is very compatible with hot and cold water, alkaline media as well as diluted acids and is therefore often used in hygiene applications. Application range: -10 to +143 °C, steam sterilisation +150 °C for 60 min.

PTFE: Synthetic fluoropolymer made from tetrafluoroethylene is particularly inert to reactive and corrosive chemicals such as concentrated alkalis and acids. The material tends to yield or deform under tension (cold flow). A small degree of flow distension means that PTFE seals can fit better to a given mating surface than most other plastic seals. However, if the material deforms too much at over +130 °C, or due to temperature fluctuations (heating/cooling), the system tightness is at risk. Diaphragms are therefore often designed in two parts: The PTFE shield on the media side is supported with a back made of EPDM. Application range: -10 to +130 °C, steam sterilisation +140 °C for 60 min.

Advanced PTFE is a performance-enhanced PTFE variant that deforms considerably less even under heavier loads (cold flow). In comparison with conventional PTFE, this material is less affected by high temperatures and temperature fluctuations. The compacted polymer structure also reduces permeation in the diaphragm. Application range: -5 to +143 °C, steam sterilisation +150 °C for 60 min.

GYLON is the brand name of a diaphragm material that is considered the third generation of polytetrafluoroethylene (PTFE). PTFE and fillers are restructured in a special manufacturing process for even less cold flow and permeation. The material is highly resistant to temperature and chemicals and is ideal for processes such as CIP (Cleaning in Place) and SIP (Sterilisation in Place) as well as processes where downtimes result in high costs. Application range: -5 to +130 °C, steam sterilisation +140 °C for 60 min.

About Bürkert Fluid Control Systems

Bürkert Fluid Control Systems is one of the world's leading manufacturers of measuring, control and regulating systems for liquids and gases. Bürkert solutions are used in a wide range of industries and applications – ranging from breweries and labs to medical, bio-engineering and aerospace technology. With a portfolio of more than 30,000 products, Bürkert is the only supplier to offer all fluid control system components, from solenoid valves to process and analytical valves, from pneumatic actuators to sensors.

With its headquarters in Ingelfingen in southern Germany, the company has a wide-ranging sales network in 36 countries and more than 3,000 employees worldwide. Bürkert continuously develops customized solutions and innovative products at its five Systemhaus locations in Germany, China, and the USA, and in four research centers.

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