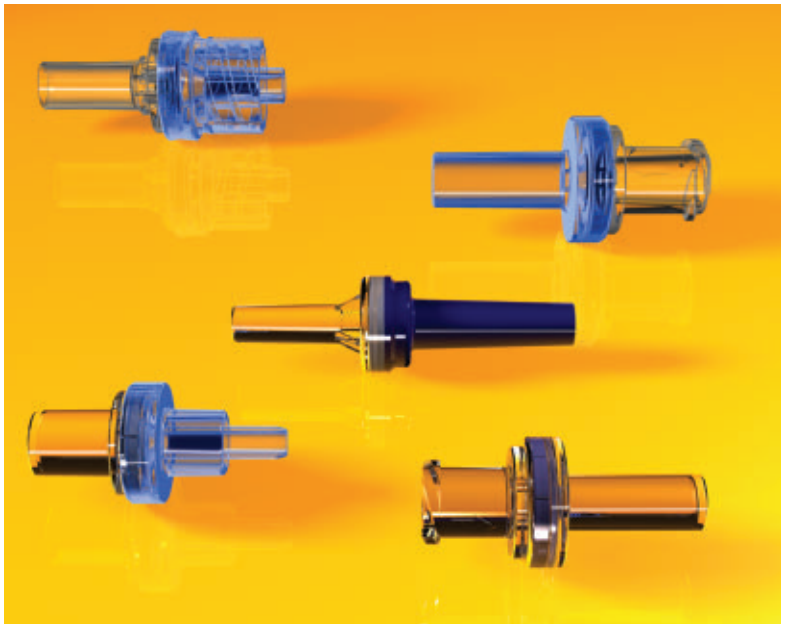
Versatile Check Valves
Enhance Medical Design Options

The latest plastic diaphragm check valves improve flexibility, flow control and safety in medical device applications.

by Ken Davis, Product Line Manager, Value Plastics, Inc., Fort Collins, Colo.

Improvements in the design of medical devices for more streamlined functionality and performance is influenced by a number of critical factors. The research, design, modeling, testing, prototyping and FDA and EU approvals of new devices, or the integration of changes to existing designs, usually represents a sizable capital investment of resources well before the equipment goes into serial production. Factored into medical device product development are many considerations, such as size of the equipment, speed of operation, heat generation, portability, handling of static or kinetic loads, power sources, measuring systems, vacuum and nonmagnetic requirements, sensors, machine controls, component part wear, diagnostics and patient and operator safety.

A key impetus influencing medical and bioresearch companies to engage upon involved product development cycles is the opportunity to capitalize on advances in technology for the manufacture of better operating, lower cost, more efficient and safer equipment and devices. One of these advances is in plastic tubing inline check valves, specifically diaphragm check valves, used for the transfer and management of fluids and gases in mission-critical medical applications.



The latest plastic diaphragm check valves offer more options for material selection, improved flow control, safety, flexibility and customized design.

Versatility in design

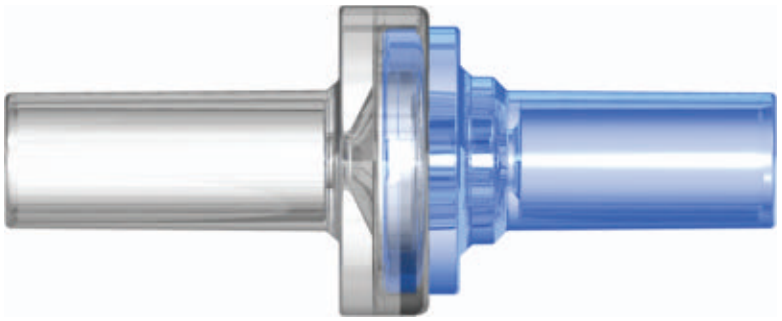
Plastic diaphragm check valves are two-port valves, meaning they have two openings—one for upstream fluid or gas to enter, and the other for the media to exit downstream. They use a flexing silicone diaphragm positioned to create a normally closed valve. Pressure on the upstream side must be greater than pressure on the downstream side by a designated amount, known as the pressure differential, for the check valve to open, allowing flow. Once positive pressure stops, the diaphragm then automatically flexes back to its original closed position.

To ensure a high level of safety, medical OEM designers rely on air, gravity and anti-siphon plastic diaphragm check valves to automatically control the directional flow of fluids and gases. This functionality helps to prevent backflow and provides a high level of assurance of proper operation by end users.

Plastic diaphragm check valves have become increasingly used in conjunction with medical devices for a wide spectrum of surgical operations, interventional cardiology, radiology procedures and pharmaceutical mixtures. A growing application is with endoscopic procedures for medical examinations of gastrointestinal (GI) tract organs and structures, such as the bladder, intestines and stomach. The endoscope, with the aid of a fiber optic camera, allows the operator to view and retrieve a small sample (biopsy) of the area being examined in order to more closely view the tissue under a microscope. Here, diaphragm check valves serve a critical function by simultaneously facilitating two precision activities: a) irrigating the incision, such as with a saline solution; and b) aspiration, by suctioning to remove blood from the surgery area and provide a cleaner view of the procedure. The plastic diaphragm check valve permits the flow path to go either way.

This versatility of plastic diaphragm check valves is permitted to a large degree by their ability to operate in any spatial orientation, to prevent the free-flow of fluids or gases under gravity. During a medically invasive procedure, the capability to defy gravity while performing a precision aspiration or irrigation activity, without interruption of the fluid or gas flow, is an important benefit. Plastic diaphragm check valves are uniquely designed to deliver a one-directional flow without backflow.

Bi-directional capability of some plastic diaphragm check valves also accentuates their versatility. The DCV Series of plastic diaphragm double check valves, developed by Value Plastics, for example, is designed to transfer clean fluid from a supply vessel to a use site. The fluid supply vessel is connected to the valve supply port (chimney) using a luer connection or tubing. The fluid is withdrawn from the supply vessel by a syringe or other device connected to the aspiration port. When the syringe is compressed, the fluid is then



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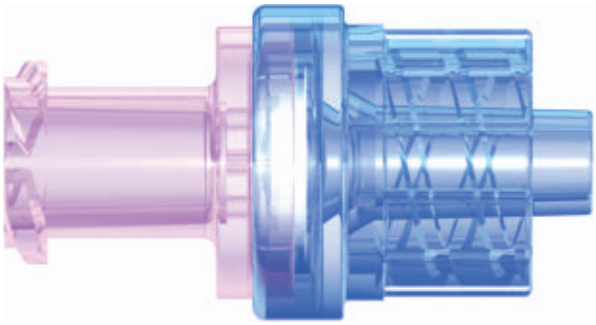
transferred through the exit port to the use site without adulterating the fluid.

Precise flow control, enhanced safety

The inherent design of latest generation plastic diaphragm check valves exhibit functionality critical to exceptional performance. The plastic diaphragm double check valve itself is typically a rubber disc with a small slit in it. As directional pressure in the form of a fluid or gas is applied, the disc flexes toward that flow and opens the slit, allowing for very precise movement.

More advanced diaphragm discs are composed of a latex-free silicone membrane set in a closed, standby position for improved positional performance, delivering a seal mechanism that avoids a retrograde flow even at the lowest backflow rates of 0.1 mL/hr. This feature provides several benefits: a) protection of a flowline from back pressure caused by a pinched tube or closed roller clamp; b) avoidance of cross-contamination from one part of the line to another; c) better prevention of unwanted free-flow under gravity; and d) air-vent functionality for applications such as enteral feeding.



An example of an anti-siphon check valve.

A key attribute of the diaphragm is its ability to provide extremely low cracking pressure compared to other check valve types, like umbrella, duckbill and lift check valves. An important concept in check valve performance, crack pressure defines the minimum upstream pressure at which the valve will operate. Cracking pressure ranges for the more advanced latex-free silicone membrane dia-

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phragms are: one-way check valves: <=12 mBar (.174 psig); and anti-siphon valves: 100 to 300 mBar (1.450 to 4.351 psig).

Plastic diaphragm check valves also excel at removing air bubbles from their downstream flow path. This is exemplified in the SCV Series of plastic diaphragm check valves, also from Value Plastics, which integrate a low priming volume capability that is particularly effective in clearing bubbles from the flow path.

The importance of clearing bubbles from the flow path is a key concern for medical device designers when evaluating the suitability of a check valve. For example, when performing cataract surgery of the eye, an incision is made into the cornea, the lens capsule is severed and the material of the lens is fragmented and aspirated by a needle. In the process of subsequent irrigation of the eye, it would be undesirable to have air bubbles blowing into the cut open, exposed outer layer of the cornea. With the latest generation plastic diaphragm check valves, the possibility of this condition occurring is greatly minimized.

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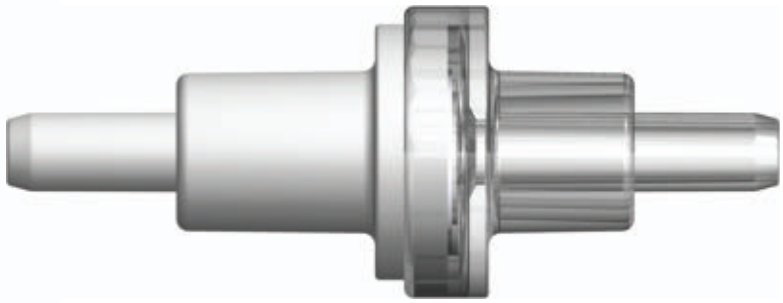
Options for designers

Plastic diaphragm check valve manufacturers generally produce a range of options for designers, but some provide more of a custom manufacturing capability. Plastic check valves can be manufactured from ABS, SAN and polycarbonate resins. Some check valves are DEHP- and latex-free, in accordance with USP Class VI and ISO 10993 standards, and can be specified to withstand EtO (ethylene oxide) and gamma radiation, and can even be autoclavable.



Some suppliers provide a wide variety of end fitments, including single barbs, tubing pockets, sockets and male and female luers that comply with ISO 594-1 and 594-2 standards. Sizes can be made to fit with 0.118, 0.122, 0.161 and 0.165" tubing IDs.

The latest plastic diaphragm check valves offer more options for material selection, improved flow control, safety, flexibility and customized design than at any time prior. These improvements enhance the medical OEM's ability to optimize features and better achieve peak performance in the equipment and devices being designed.

CONTACT

For more information, visit Value Plastics, Inc. at www.valueplastics.com, or call 970-267-5200.