

**Introduction:** Freeze Dryers come in two fundamental configurations, either with ice condenser plates/coils contained within the same chamber as the product shelves (an internal condenser) or with the condenser plates/coils contained in a vessel separate from the chamber and the product shelves (an external condenser). Mid-size to large freeze dryers, especially those used for production, tend to have the external condenser design. (Occasionally, smaller laboratory and pilot units are made in this way as well to provide for accurate and easier scaling up of the freeze-drying process.)

The chamber and external condenser must be connected by a relatively large pipe. This connection, called a "vapor line or port", provides a conduit for the water vapor to travel from the product chamber to the condenser. Vapor lines can range in size from 6 or 8 inches in diameter on the smallest of units to 36 inches in diameter or more on the largest of units.

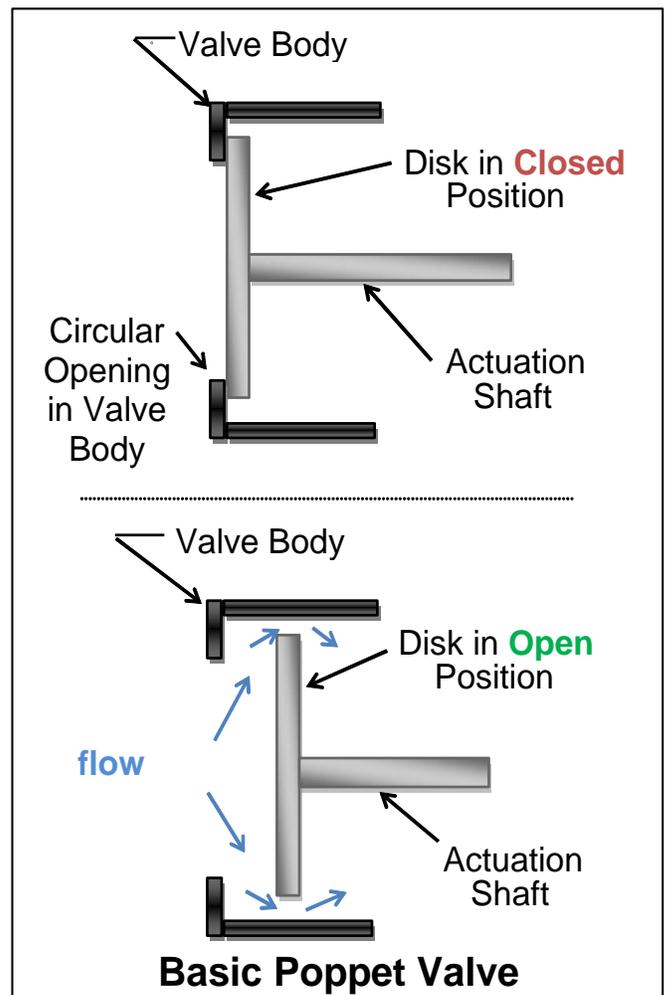
In order to maximize throughput of the production of freeze dried product it is desirable to isolate the product chamber from the external condenser in order to defrost it while unloading the product shelves. Leak testing of the freeze dryer is also done more effectively when isolating the shelf chamber from the condenser.

Most freeze dryer manufacturers install one of two major types of valves in the vapor line to isolate the chamber and the condenser: a butterfly valve or a poppet valve. Each valve has its own particular advantages and disadvantages. However, SP Scientific / Hull Brand has patented a unique valve called the "Rotary Disk Valve." The Rotary Disk Valve combines advantages of both the poppet and butterfly valves while doing away with the disadvantages of each. In order to understand how this valve works as well as its features, we will first examine the basic operations and properties of both the poppet and butterfly valves.

**The Poppet Valve**

The poppet valve has a disk that closes over a slightly smaller opening, much like a door (see Diagram 1). The seal between the two can be either an O-ring or gasket. For sanitary/parenteral applications, the single advantage of the poppet valve is its virtually non-existent particulate generation during sealing and unsealing. The O-ring or gasket is not rubbed in any way but simply compressed, thus eliminating a source of particulate generation.

However the poppet design has several disadvantages. First, the disk obstructs the line of sight flow path even when in a full open position. This forces the water vapor to flow in a somewhat torturous path around the valve disk that can result in significant pressure drops and a low Coefficient of Flow. Such a flow restriction can reduce the maximum freeze drying rate of the system which can in turn result in longer cycle times to dry product.<sup>1</sup>



**Diagram 1**

<sup>1</sup> See Jim Searles, "Observation and Implication of Sonic Water Vapor Flow During Freeze Drying," American Pharmaceutical Review (March/April 2004): 58-68+75.

The second disadvantage of the poppet type valve is the necessity of a shaft that must be used to move the disk. As is shown in Diagram 2 some configurations require that the actuation shaft must move through the entire external condenser/ ice trap where a linear actuator (such as a hydraulic or pneumatic cylinder) is connected. This design prevents a hinged, full opening condenser door, necessary for validation activities.

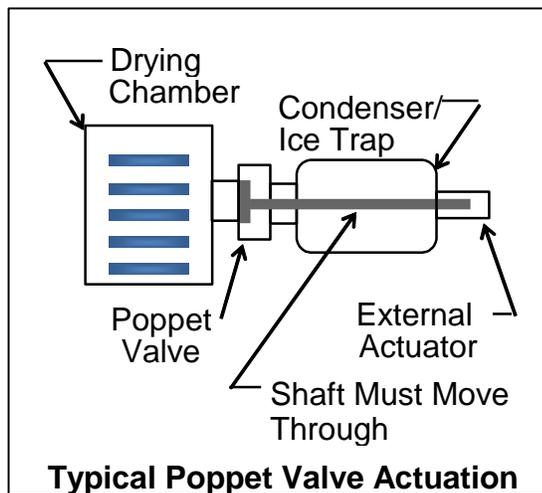


Diagram 2

### The Butterfly Valve

The typical butterfly valve has a central disk which seals by having its outside diameter come in complete contact with the inside diameter of an annular (cylindrical) seat (Diagram 3). The advantages of this design are several. First, the disk is rotary actuated, therefore the shaft need not enter a sterile process area. Second, since the disk rotates out of the flow path, butterfly valves have an inherently higher flow coefficient than poppet valves of similar size.

Butterfly valves are especially suited for open/close operation and low frequency usage that is typical of the freeze drying process. Additionally, they work best with clean gaseous media, such as water vapor typical of the freeze-drying process.

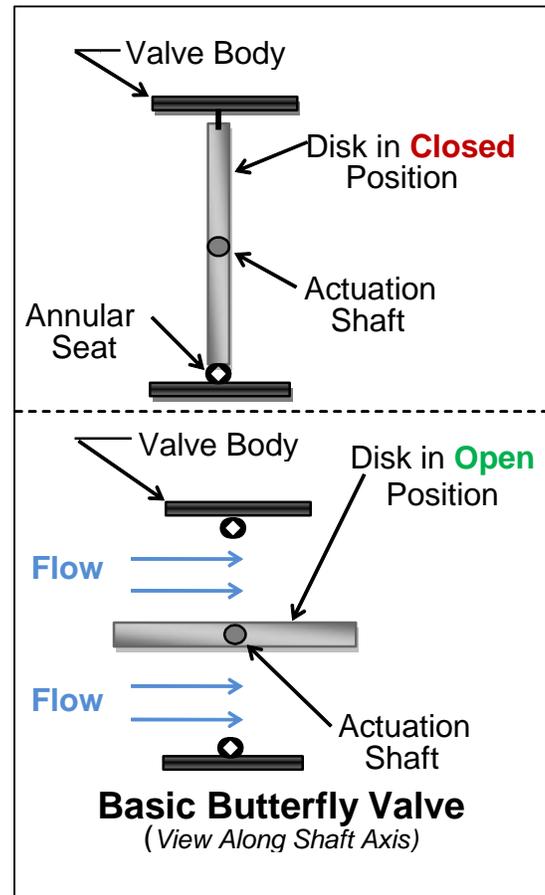


Diagram 3

On the other hand, like the poppet valve, butterfly valves have a number of disadvantages. The first and foremost consideration in light of a sanitary process is in the potential for particulate generation during sealing and unsealing. This is because the outside diameter of the disk rubs against the inside of the annular seal. A second disadvantage is that butterfly valves work best with positive pressure because it pushes the liner out toward the body. A common problem with large butterfly valves is that the vacuum level required for freeze drying sucks the liner away from the body, occasionally resulting in seal failure. Attempts to remedy this problem with vacuum taps or glues have met with limited success.

The major disadvantage of the butterfly design is that replacement of the valve liner requires the removal of the valve from the piping system. Although not a problem for small valves, removing 20 to 36 inch diameter butterfly valves from between two large

vessels and replacing their liners requires significant manpower and equipment. Replacement of the liner alone can be a two day process. Removal and installation of a butterfly valve takes about one-half day each. Finally, the system must be re-sterilized after install because removal of the valve exposes the interior of the chamber to the non-sterile machinery area. In total, four day down time on production equipment due to butterfly valve liner replacement is not uncommon.

### The Hull Rotary Disk Valve

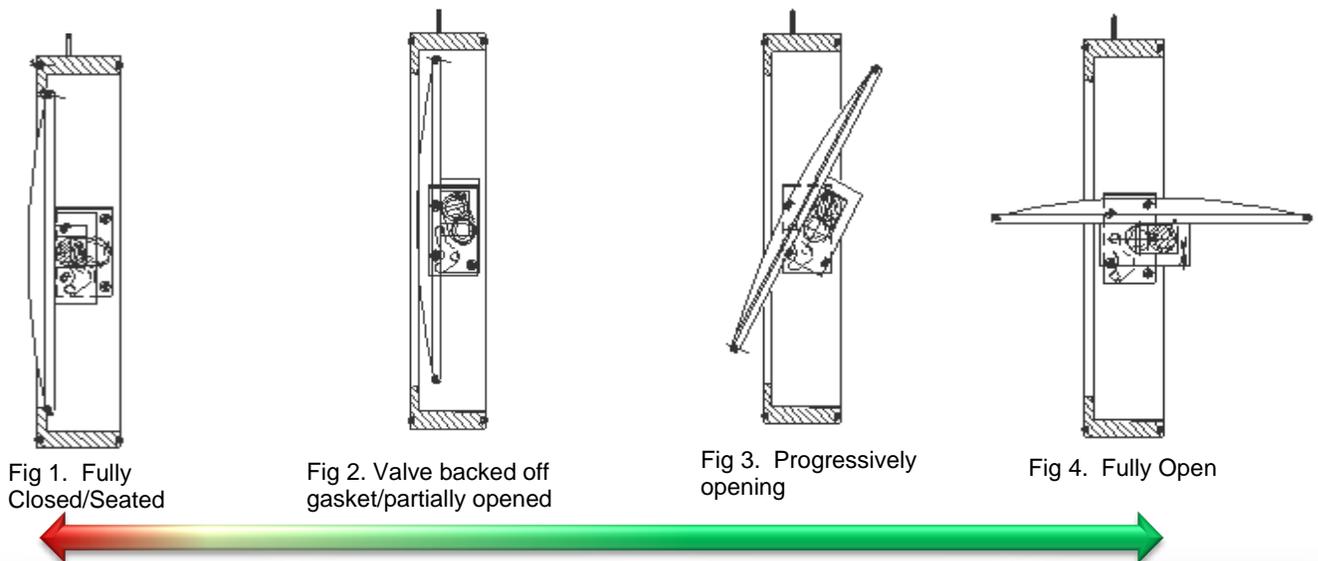
The Hull Rotary Disk Valve was designed to combine the advantages of both the poppet and butterfly valves without the disadvantages. This is accomplished by having the valve disk seat by compressing an o-ring like a poppet valve and then rotating the valve disk out of the flow path like a butterfly valve. In addition, a rotating shaft effects all motion of the valve disk.

Figure 1 in the following diagram shows the Rotary Disk Valve in the closed position. As the crankshaft begins to rotate as shown in Figure 2, the valve disk pulls back horizontally from the seal surface without rubbing, just like a poppet valve.

After the crank has rotated about 90 degrees the disk contacts the crankshaft links. Because of this contact, further rotation of the crankshaft causes rotation in the disk as shown in figure 3. As the crankshaft rotates 180 degrees from its starting position, the valve disk rotates 90 degrees to the full open position as shown in Figure 4.

Thus the Rotary Disk Valve combines the major advantages of the poppet and butterfly valves without the disadvantages. It seals and unseals without rubbing a liner like a poppet valve, thus eliminating/minimizing particulate generation, while at the same time its disk turns 90 degrees to allow the high flow rates of a butterfly valve.

In turn, the Rotary Disk Valve has none of the disadvantages of either. Rotary actuation means that no shaft need enter the sterile boundary and the absence of an actuator on the condenser door allows for full validation access to the condenser.



In addition, all components are exposed, which allows complete sterilization by steam or other media. Finally, the Hull Rotary Disk Valve is interchangeable with most major brands of butterfly and poppet valves and can be retrofitted to any system with standard 20, 24, 30 or 36 inch vapor line piping as well as metric line sizes.

*Charles D. Dern is a Project Engineer for SP Industries and Hull/SP Scientific and an inventor of the Rotary Disk Valve*