Designing with inflatable seals for the medical industry

Seals are central parts of the design of medical equipment with moveable, interlocking parts that must be secured for sanitary, thermal, or radioactive reasons.

Designing with inflatable seals requires the inclusion of a source of compressed gas, which is used to inflate seals in the medical device industry and it is often already available on the plant floor, in a laboratory, or medical environment. It is also possible to inflate with liquids rather than gas in demanding applications, and water would be an acceptable inflation media in this sector, although not common. For some low-temperature applications, a seal may be inflated with a blend of glycerine and water.

Designing with inflatable seals

Seals used on doors and openings should be part of the early phases of product design. In some cases, contact seals may be effective, but they often require substantial force be applied to load the seal, which impacts product design and increases manufacturing cost. Inflatable seals enable more cost-effective machinery fabrication for two reasons:

1. Inflatable seals are more forgiving because the seal can inflate to close a gap between structural members and achieve equal sealing pressure around the flange as long if the gap falls within a broad tolerance. An inflatable seal will work whether the gap spans 3mm or 10mm, for instance. A compression seal or other contact seal will not be effective unless the seal and flange contact each other with great precision, which can be difficult to achieve on new equipment. Even a robust and precision-manufactured machine with well-designed flanges will lose some of its geometric integrity as hinges and other components deform or bend over years of use. Throughout the course of the equipment lifecycle, a contact seal may become problematic and exhibit leakage.

2. Inflatable seals enable lighter and more affordable methods of equipment fabrication.
The force exerted on the chassis of a piece of equipment means doors and related components must be thicker, and perhaps machined instead of welded. These components are typically made of stainless steel, and inflatable seals might be attractive due to lowered material costs.

Which equipment needs inflatable seals?

- **Isolators** — where a leak-tight enclosure can be critical for environmental health protection due to hazardous substances or processes. — can secure glove boxes, access gates, transfer systems and filtration systems that handle toxic or sterile components.
- **Sterilizers** — which may rely on heat, chemicals, irradiation, or filtration — may be suitable for desktop autoclave sterilizers, sterilizing tabletop autoclaves and static air depyrogenation sterilizers.
- **Dryers and freeze dryers** – used to sterilize everything from machine components to glassware.
- **Material handling functions** – to raise, lower, or grasp objects.

Standard vs. advancing materials

Seals are often exposed to temperature extremes and mechanical stresses, and a well-engineered elastomer inflatable seal will maintain its structural integrity and flexibility over millions of duty cycles. While silicone is the standard material for inflatable seals, new advanced products include materials innovations designed to prolong life and mitigate operational risk. Silicone rubber impregnated with a silver ion helps the material resist the growth of bacteria.

Another new technology is designed to make silicone rubber less permeable. Silicone is not porous, but has the highest permeability of all rubber compounds. If it is immersed in water long enough, there will be some gas that escapes, forming bubbles. Treatments are now available that decrease the permeability of silicone used in an inflatable seal, preventing absorption of foreign substances, prolonging the life of the seal, and preventing cross-contamination. The treatment may also result in a seal with a better friction co-efficient, ensuring the seal moves easily in its groove and avoiding any sticking between the surface of the seal and the flange.

Advanced design

Once a machinery designer chooses an inflatable seal, they must choose a cross section that is right for the specific application. Sometimes, the customer seeks high pressure on an large extension to close a wide gap, expects the highest performance, and wants to use a rough, grippy seal face, even though the application in the pharmaceuticals industry
Inflatable seals require a polished face. The elements of this design would place the seal under stress, and consulting a seal manufacturer during the early product design process will ensure the design conforms to the requirements of the industry, the performance characteristics of the material, and the sealing system.

If extremely tight tolerances are required for the finished component, annealing (also known as stress relieving), is often required to stabilize the material. This process involves placing the sintered material into an oven and applying a controlled heat to the molding that exceeds the service temperature of the finished part. The molded shape is held at this temperature for a calculated period of time, after which the temperature is slowly brought back down to ambient. The material is not heated past the melt temperature of the polymer during this process.

The location of the seal is also important. In washing machines for example, bottles, vials or other glass objects can break and cut the seal, so proper location of the seal can mitigate against damage. In other cases, improper seal location can cause retention of product or other material in the groove of the seal, even if it is a lip seal with a smooth surface. Avoiding retention becomes very important when using a cross-section like an accordion seal, where designers need to avoid retention of material, water, or even drops of liquid or condensation in the seal itself.

More than just closure

Inflatable seals are most often used to seal openings, but they can also be used in designs such as an airlifting bag or in other settings to initiate or halt motion. In a surgical theater, for example, lights extending from the ceiling need to be positioned and repositioned securely by the surgeon, and a manufacturer may use an engineered length of an inflatable seal to lock the light in place. The surgeon can press a handle to deflate the seal, and as soon as he or she releases the handle, the seal will re-inflate and lock the light into position. This also offers a cushioning action because the seal absorbs vibrations in the building that may be caused by foot traffic, equipment on the floor above, or nearby vehicle traffic.

Regardless if they are used for sealing or for material handling applications, supply chain integrity and traceability for the processes and components that go into the seal should be a primary focus during selection and specification. Ideally, each seal should include a laser marking that will allow the manufacturer to reverse-engineer the raw material batch, extrusion, mixing, installation of the fitting valve, manufacturing batch, the lot of stainless steel used for fitting the valve and more.

Conclusion

Inflatable seals should be up for consideration for the medical designer’s list of a broad class of equipment. Reduced pressure requirements allow for lower cost fabrication.
methods because the equipment can be less robust and need not hold precise flange tolerances over its lifecycle. They work even as equipment falls out of specification during its lifecycle, and new innovations in silicone material design can help reduce risk of contamination and meet regulator demands. Involving the sealing system manufacturer in the early stages of design is crucial to ensuring optimal performance of the equipment, and the supply chain management practices of the vendor should be subject of careful due diligence.

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**Considerations**

1. Specify the seal early, as it can allow you to value-engineer the design, saving cost. Early consultation will also help you specify the correct seal profile.
2. Consider new innovations in sealing materials, including silver ion impregnation, which prevents microbial growth.
3. Ask hard questions about supply chain integrity and traceability. The seal is only as trustworthy as the materials it is manufactured from and the processes that go into it.

For more information about inflatable seals, or sealing devices for medical equipment, contact Gallagher Fluid Seals today.

This original article can be found on Technetics website, and was written by Bruno Rouchouze.