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Picture: Trelleborg

Nothing left to chance: PTFE O-rings are used in static axial seals in lids and flanges. Advantages: Almost universal chemical integrity, high thermal load. Available in all dimensions.

Sealing solutions in demand

The medical technology fields needs and expects high standards from sealing technology. This generally involves a complex blend of geometry, pressure, temperature, chemical integrity, hardness and a multitude of application-specific parameters. Whatever is needed – simple O-rings or complex sealing membranes – companies aiming to secure a place among the leading edge suppliers in the business need comprehensive expertise in materials, high precision manufacturing procedures and reliable quality assurance methods to stand even a chance of success.

Research is absolutely indispensable in the field of precision seals. Trelleborg Sealing Solutions maintains as many as seven research and development centres worldwide. Based in Stein am Rhein in Switzerland, the company processes liquid silicone and is one of the top producers of high-complexity moulded parts with a broad material mix. The reference list of customers ranges from energy generation companies, through the automotive

and machine construction industries to chemical and pharmaceutical industries. An important mainstay of the Swiss company's work is the fields of medical technology and life sciences.

Trelleborg works with materials which can be applied across the whole range of high tech sealing solutions. Elastomers, LSR (liquid silicone rubber), thermoplasts, PTFE and composite technologies are the ingredients needed in order to produce seals for critical

components and procedures such as therapeutic and diagnostic devices, infusion pumps, catheters, centrifuges and blood separators. The bulk of production output is generally closure seals for containers, tubing connections or seals in inhalation devices plus some specially designed seals that can cope with media containing oils and also Y and T connectors and flat seals

The Swiss company claims that one of its strengths is a special cleanliness



Sealing solution for knee prosthetics: Many applications in medicine require the materials used to have high wear resilience properties and system stability. Picture: Trelleborg

concept which qualifies the seals to satisfy particular hygiene standards. The company has developed and established cleanliness standards under the Flexclean banner. These lay down which defined technical cleanliness standards any seal satisfies and which test methods ensure that these cleanliness standards can be maintained with a high degree of reproducibility. Cleanliness class 1 allows a maximum particle size of 200 micrometres and a total impurity residue of less than ten micrograms. The corresponding values for cleanliness class 2 are 400 µm and 25 mg. Apart from that, there are also specifications for clean room class 5 seals, required in the main by the semiconductor industry.

Innovation by joint developments

Clean with regard to seals means seal production in clean room conditions. The US producer Parker has created the Parker Rayco Division for production in the medical and life science sector. This has designed its clean room facilities to meet the standards of the FDA, the US supervisory authority and the quality directives of DIN ISO 14644. The company's main customers are OEMs and end product manufacturers with customised O-rings and moulded parts for sealing tasks.

When special sealing solutions beyond the capabilities of standardised mass-produced articles are called for, Parker technicians and users get together to use computer simulations based on a finite element analysis (FEA) to arrive at the best material mixes and suitable component geometry. The advantage of such development partner-

ships is patently obvious. Even during the development stage, production planners can see how resources can be used efficiently and what the associated costs and savings opportunities are likely to be.

The secret star among the materials for critical sealing applications is PTFE (polytetrafluorethylene). This substance features very high chemical integrity, marked thermal resistance and good biocompatibility. Sometimes, when users consider the material's properties for sealing applications, it seems to square the circle. This begins with its surface roughness, which must be constituted to prevent colonisation by bacteria even after long periods of use and to form biofilms and ends with the tool-specific moulding process in which there must be no particle release whatsoever.



More than seals: Expertise in materials extends the life science product portfolio, as is shown for example by a blood separator for dialysis machines with stainless steel ball bearings. Picture: Trelleborg

The smaller the components, the more difficult the production process. For this reason, PTFE parts are frequently produced in a thermoplastic injection moulding process instead of cutting them to shape. The main feature of high-performance seals is high precision and a smooth surface for injection moulding. However, small margins and frequent tool changes drive the production costs up.

Another way of tailoring sealing material to special needs is to adopt finishing processes. Helix Medical Europe in Kaiserslautern works with classic, wet-chemical and plasma technical coatings which make it possible to customise the specifications of the surface properties. Purpose-designed treatment of seal surfaces achieves astonishing properties with regard to the media resistance of materials and their adhesion capabilities, so impurity and oil repellent properties can be purposefully built into a seal surface. Helix Medical Europe, part of the Freudenberg Group, develops and produces silicone and thermoplastic components for the medical technology, biotechnological and pharmaceutical industries.

The bandwidth of seal designs is huge. For example, O-rings can be covered by a protective sheath. These multi-component O-rings consist of a flexible silicone core which is covered by a thin FEP sheath (fluorinated ethylene propylene). In this way, an elastic seal is produced which also exhibits a high degree of media resistance – thanks to the protective coating.

Andreas Beuthner ←

German Summary

Dichtungsaufgaben im Medizintechnik-Umfeld sind anspruchsvoll. Meist handelt es sich um eine komplexe Matrix aus Geometrie, Druck, Temperatur, chemischer Beständigkeit, Härte und einer Vielzahl anwendungsspezifischer Parameter. Ob einfacher O-Ring oder aufwändige Dichtungs-Membran – wer nicht über umfassendes Werkstoff-Know-how, hochpräzise Fertigungsverfahren und zuverlässige Qualitätssicherungsmethoden verfügt, hat kaum Aussichten auf einen Stammplatz im tonangebenden Anbieterkreis. Der deutschsprachige Beitrag ist nachzulesen auf www.meditec-international.com/0312seal