

WHITEPAPER PFAS-ban, TA Luft 2021 and the consequences

Solutions for sealing of connections in the
process industry

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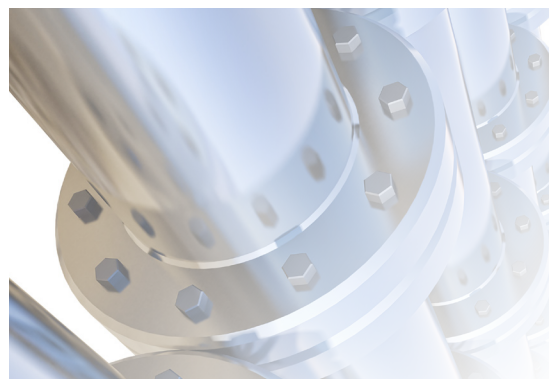
Of equal weight, two current exciting topics are fostering creativity in process system operators in the chemical and life science industries: the impending PFAS-ban and the more stringent limits of the new TA Luft. This throws the question of how, in the future, tube connections can be safely sealed in compliance with the regulations into sharp focus. In this Whitepaper, the problems posed for the pharmaceutical, biotechnology, food processing and chemical industries, together with the hydrogen industry will be described and solutions put forward. Elastomer-free connections also form a particular area of interest.



The combination of more stringent thresholds caused by TA Luft 2021 and the impending PFAS-ban has significant consequences for tube connection seals in corporations in the chemical, pharmaceutical and food processing industries. TA Luft, in force since December 2021, stipulates that emissions by volatile organic compounds (VOC) from tube connections in the chemical, pharmaceutical and food processing industries must be reduced significantly. Owing to their chemical resistance, biocompatibility and sliding properties, seals made from fluoropolymers are often used in these applications.

However, in the European Union, a comprehensive ban on perfluorinated and polyfluorinated alkyl compounds (PFAS) is currently under discussion, which could result in fluoropolymers/fluoroelastomers no longer being available in the future. Against the background of these developments, it is advisable for operators and system builders to consider the sealing concepts for their systems.

The PFAS problem



Chlorofluorocarbons are among the strongest chemical compounds in organic chemistry. Chlorofluorocarbon compounds are consequently particularly resistant - whether in seals, functional clothing or coatings on frying pans. However, what is practical in everyday use also has a down side: Chlorofluorocarbons are difficult to break down - the term “forever chemicals” is in common use - and these can be dangerous to health. Many of the some 10,000 perfluorinated and polyfluorinated alkyl substances (PFAS) pose health risks: They can weaken the immune-system, cause hormonal imbalance and are suspected of causing cancer, as well as damage to the liver and kidneys. And, owing to their long life

PFAS in the environment are broken down only very slowly: If they accumulate in the groundwater, the drinking water supply is endangered. The problems have been known for a long time: Even at this early stage, the international community has decided in the Stockholm Convention to ban the use of perfluorooctanesulphonic acid and its derivatives (PFOS) - in the EU, their use was restricted with EU Directive 2006/122. Perfluorooctane acid (PFOA) and its salts have been banned since July 2020 (2020/784/EU). Since August 2023, perfluorohexanesulphonic acid (PFHxS) and its salts have been banned in the EU. Other perfluorinated carbonic acids (C9 to C21) are also to be eliminated worldwide.

The national authorities of Germany, Denmark, the Netherlands, Norway and Sweden are also proposing a restriction which covers a wide range of PFAS uses. In January 2023, they submitted their proposal to the European Chemicals Agency ECHA, where this is now being assessed by scientific committees. The ECHA is recommending in the current PFAS draft of February 2023 that the manufacture, use and marketing of several thousand fluoralkyl substances be banned. Public consultations have been in progress since March 2023 and the European Commission is to decide on the proposal in 2025.

However, the issue is by no means unique to Europe: In the USA, the discussion on restricting PFAS is already in full flow. The consequences for technology are serious: Fluorine compounds that are made from PFAS and used in many areas - including polymer and elastomer seals - are virtually unavoidable.



In chemical, pharmaceutical and biotechnology systems, PTFE or FEP is used as a

coating for elastomers, for example for O-rings, as a sealing material.

Planners, operators, system and mechanical engineers are consequently rapidly searching for alternatives.

TA Luft 2021 makes sealing system requirements more stringent

In addition, an updated administrative regulation is immensely significant for planners and operators of process systems: The new version of the Technical Instruction for air pollution control (TA Luft) has been in force since 1st December 2021. This defines patently higher criteria for the sealing of some 50,000 systems in Germany. On one hand, because many thresholds have been made

on the other, because new materials and new system types have been included in the administrative regulation. The fact that operators have so far felt little of its effect is in the nature of the administrative regulation: This is aimed at Approval and Supervisory Authorities, which supervise the implementation of the Federal Immission Protection Code (BImSchG). The new TA Luft

then becomes relevant if, owing to a new build or a system change, a special examination under environmental law is needed for approval. Operators are also well advised to reconcile the thresholds set in the existing approval with the new TA Luft and to take measures to comply with the requirements in future.



Problems posed by the sealing of systems with hygiene requirements



Tube connections and process instrumentation are neuralgic interfaces, which have to be reassessed against the background of stricter thresholds and the impending cut-off for fluorelastomers. Independent of these current developments, there is something to look out for when selecting and using connections and sealing systems - above all, if product hygiene is crucial. This is particularly relevant in the pharmaceutical industry, in biotechnological processes, the food processing industry or cosmetics manufacture. Even in the chemicals industry, microbiology or protection against cross-contamination can be relevant. Welded connections compared to interconnected system components or pipelines are the safest methods. However, detachable connections are frequently necessary. These have to fulfil a whole range of requirements: They are intended to separate outer and inner spaces hermetically. Usually, seals are used for this. In construction and

when using detachable connections, contact between seal and medium should be minimised. So that no dead spaces arise at the seal, sealing and compression forces must be checked: If flanges are not tightened sufficiently, it can be that an elastomer seal does not occupy the flange gap completely and dead spaces arise. In contrast, if the seal is pressed too tightly on to the flange by

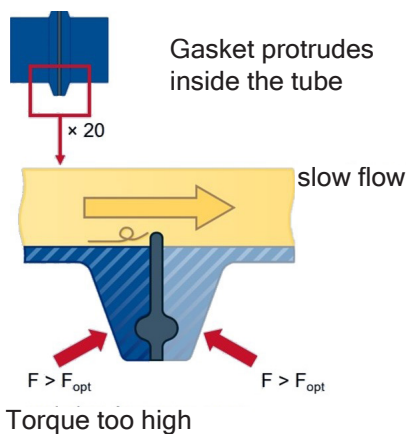
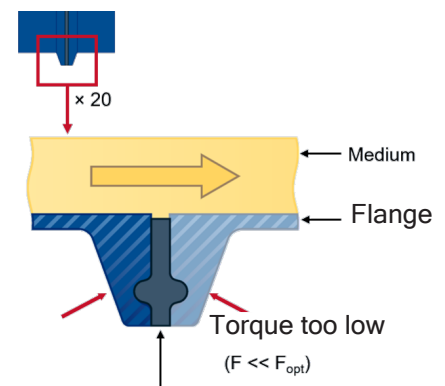
excessive screw forces, it sometimes protrudes into the pipeline, which may cause areas with low flow speeds - so-called dead spaces upstream and downstream of the sealing seal. The consequence can be microbiological contamination. Other requirements of detachable connections on the design are a self-draining construction, together with excellent ease of cleaning and sterilisation.



Contamination hazards at Tri-Clamp connections

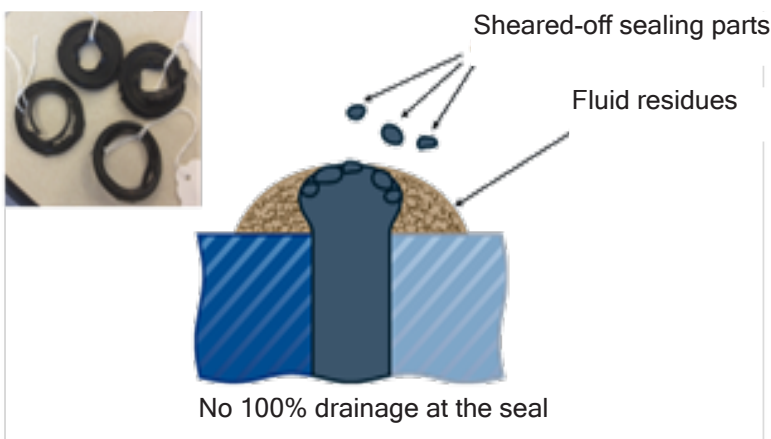
Tri-Clamp connections are a favoured solution in the pharmaceutical and food processing industries. Here, an elastomer seal is inserted between two symmetrically shaped clamp ferrules with a sealing groove. The two ferrules are then pressed together in an undefined manner using a clamping mechanism. Again, in this case

the principal problem is that safe functioning is guaranteed only if the seal is compressed ideally with a defined force. This force is again dependent on the age and condition of the seal. Because Tri-Clamp connections do not have a mechanical stop, the fitter or operator cannot adequately control the tightening torque.

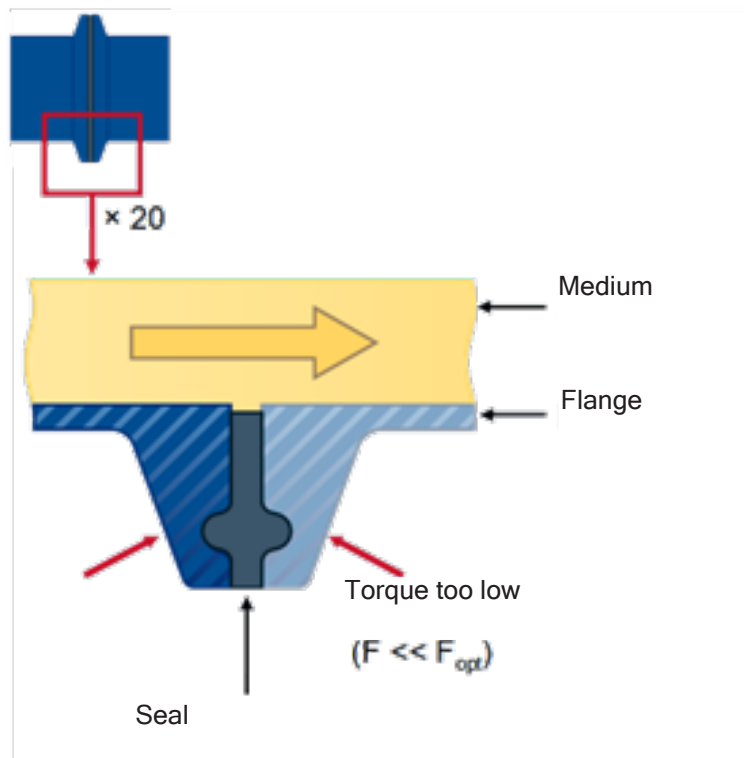


If the tightening torque is excessive, the seal is crushed, so that a sealing, which protrudes into the pipeline cross-section and thus into the product flow, occurs.

A break in flow at the seal can occur wherein a low movement area arises behind the seal, in which microorganisms can bond. This means that, even with a vertical configuration, the line is no longer self-draining. There is also a risk that parts of the gasket are sheared off by the flow - in particular if the medium to be conveyed contains solid components.



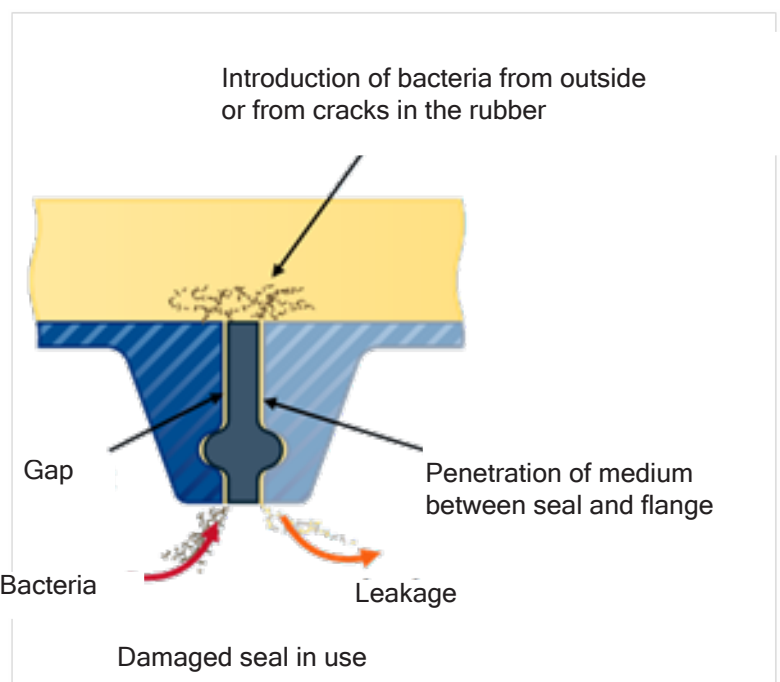
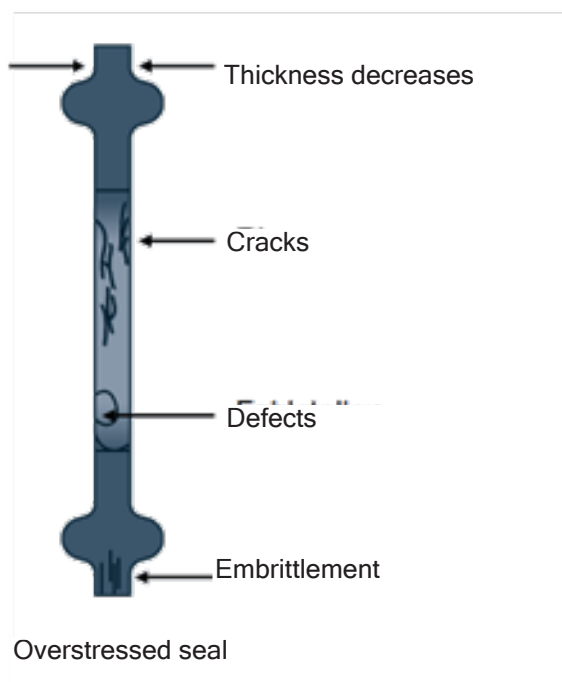
If the tightening torque is too low, the seal does not sit completely on the flange area. On one hand, there may be leaks to the outside and, on the other, a dead space arises inside the tube, because the seal is no longer flat with the tube wall.



Porous or cracked seals pose a frequent problem: Not only does ageing affect elastomer seals, but also high temperatures in sterilisation processes (SIP) and aggressive chemicals - such as those used for CIP cleaning. With Clean-in-

Place cleaning alkaline and acid cleaning solutions are used, alternating with high temperatures. With time, seals, which are subjected to mechanical, thermal or chemical stresses, lose their elasticity - their return torque deteriorates. The

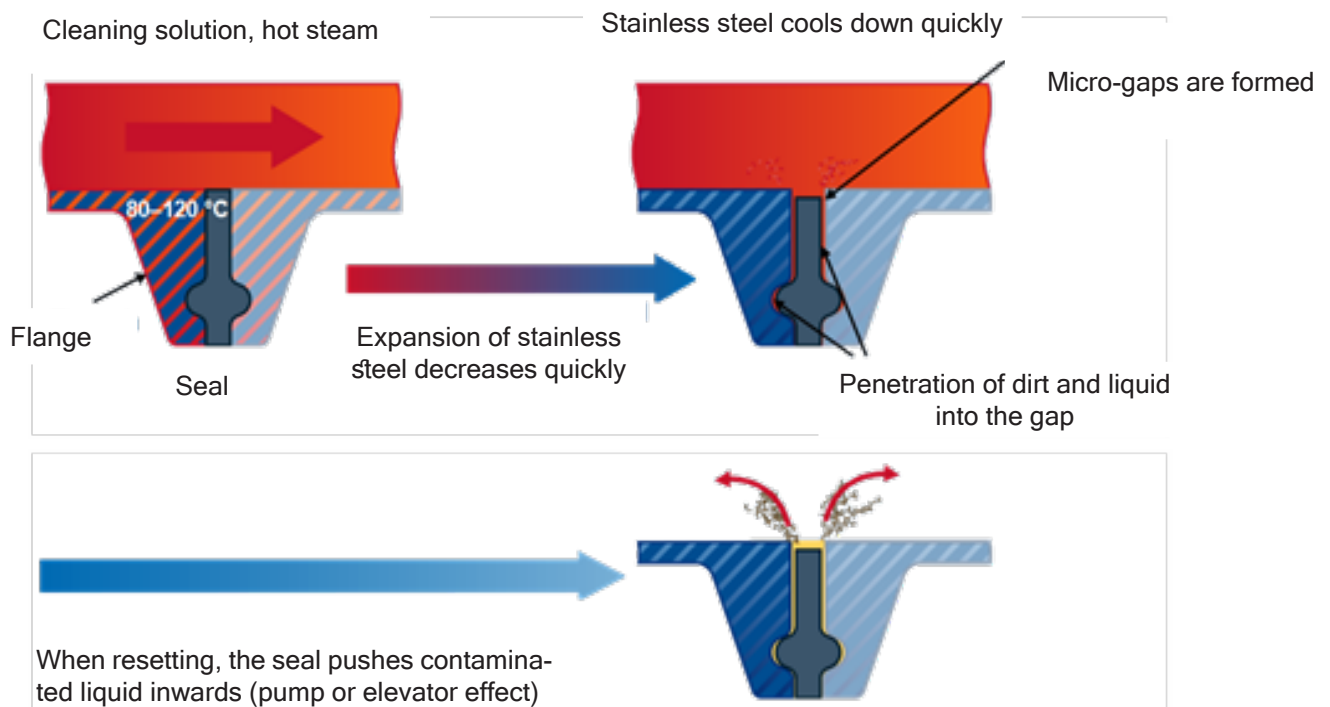
return torque is the ability of a seal to return to its original shape after distortion or stress. This means that bacteria can be pulled into the process from outside or from cracks in the elastomer.



Another problem with Tri-Clamp connections is the so-called elevator effect: this is based on the phenomenon that flange and seal materials expand differently during heating and cooling processes. Accordingly, the stainless steel flange

patently expands faster and more strongly during sterilisation processes than the elastomer seal does. If the sterilisation process has ended, microscopic gaps are formed between seal and flange, because the ferrules are cooled more quickly and are

together. This allows dirt and liquids to penetrate. During the resetting of the seal, this presses the contaminated liquid inwards and a pump or elevator effect occurs.

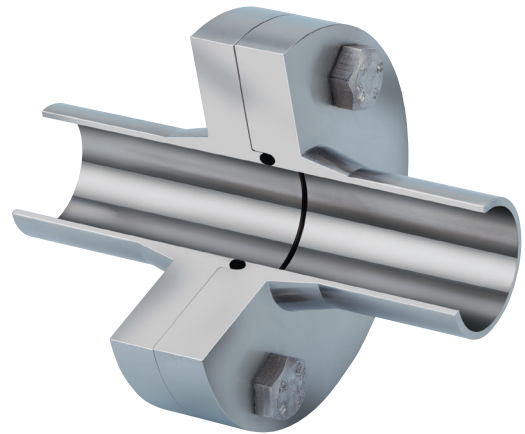


The problem fields described indicate that the economical and commonplace Tri-Clamp connections are suitable only

for standard applications. In this case, above all, where stringent demands for leak proofing and the purity of the

products are made, connection technologies which avoid the problems posed above are necessary.

BioConnect© gives cross-contamination no chance

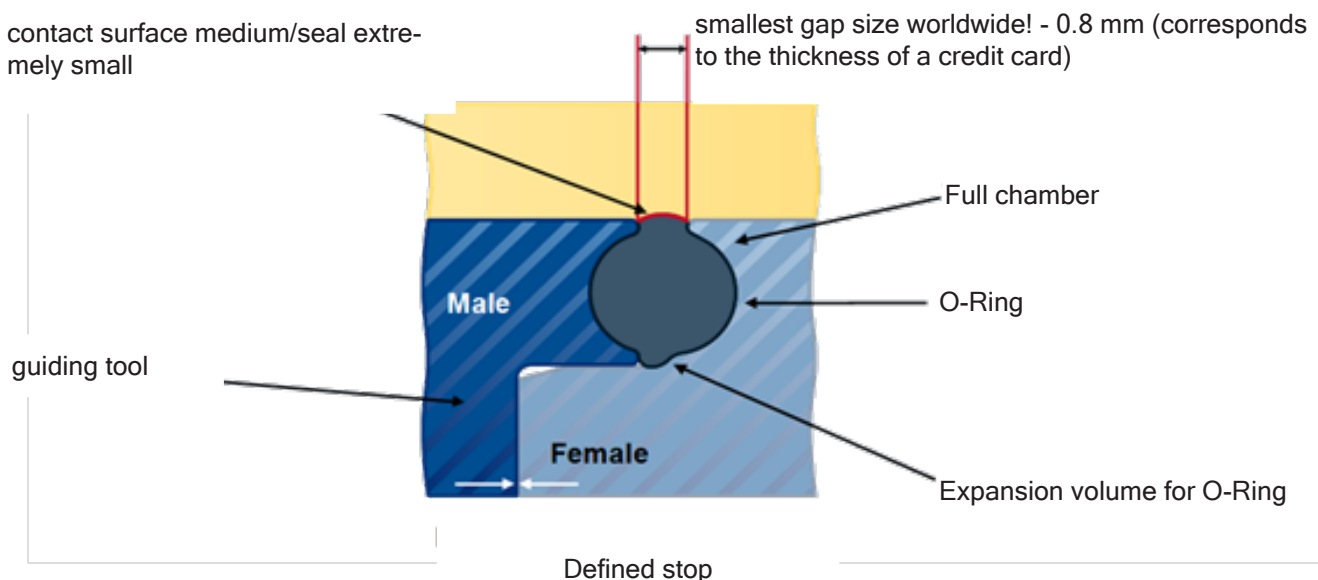


In order to address the above mentioned problem areas concerning hygienic and aseptic connections, NEUMO has developed the BioConnect© aseptic connection. Since its introduction at the beginning of the 2000's, in the interim already more than 1.5 million units of the connection are in use worldwide - in the pharmaceutical industry, biotechnology and in food processing. The tube connection

is supplied in three types (flanged connection, clamp connection, screwed union) and uses four precision radii, in which a closely toleranced O-ring is inserted as the sealing element. The seal geometry ensures that the inserted O-ring is always positioned exactly. The flange is designed so that both flange ends abut with a defined stop. In order to avoid the above mentioned expansion or elevator effects, an expansion

chamber is formed on the rear face of the O-ring insertion. This takes up the additional volume of the O-ring, if this expands due to heating. The O-ring used is restricted in tolerances for diameter and string thickness, so that a precise, reproducible seal unit arises through the metallic stop. Accordingly, assembly is completely reproducible and a jump in or jump back, as can arise with Tri-Clamp connections, is avoided.

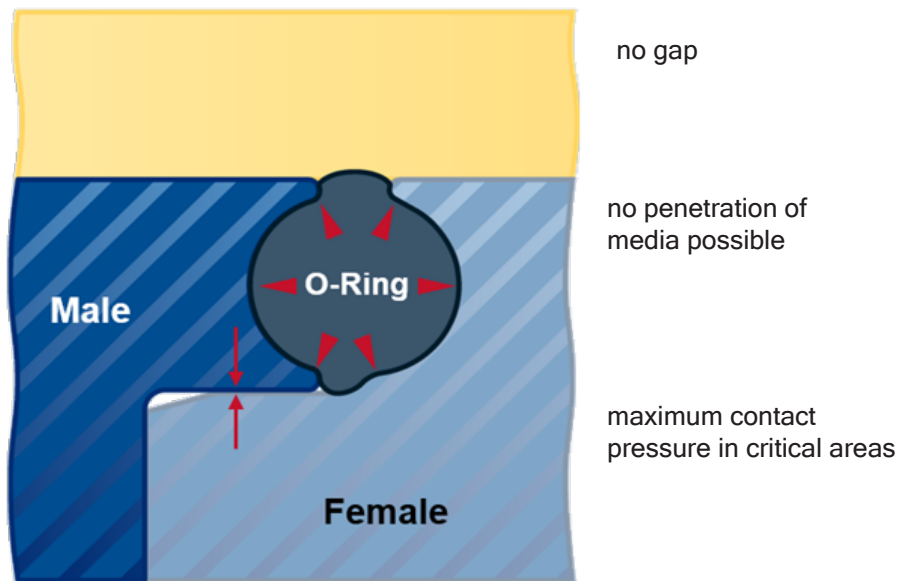
contact surface medium/seal extremely small



Compared with connections to DIN 11864, the dead volume arising and the gap is clearly less, as the thickness of the string of the O-ring with Bio-Connect© is only half as large

and the O-ring is almost completely chambered. In addition, blowing the seal off is not possible - if the internal pressure in the pipeline rises, the compression pressure at the O-ring also

rises. Due to the narrow gap, the seal cannot be pressed out. The connection thus withstands a pressure of up to 100 bar.

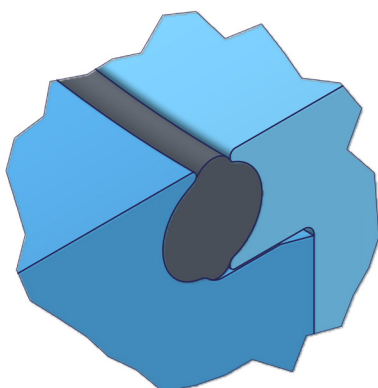


The even pressure of the seal, which reaches a maximum compressive pressure at critical points, ensures that the medium, even with rapid temperature changes, cannot penetrate behind the seal - the pump or elevator effect and the resultant cross-contamination are thus safely avoided.

The design ensures that a aseptic connection, free of dead space arises, which achieves safe draining of the connection. The BioConnect© system includes liners and male ferrules, flanges and clamp ferrules with male and female parts, the corresponding blind flanges and

blind clamps, as well as seals, screw kits, nuts and clamps. All connections can be orbitally welded according to DIN 11866 in range A (DIN) and B (ISO), as well as in range C (OD/ASME-BPE). Surface quality standard is inside Ra <0.8 µm (higher qualities as well as electro-polished

surfaces are also available. Standard material is 1.4435/316L (higher qualities, for example 1.4539/904L, 1.4529/6Mo, 2.4602/Alloy22, titanium, and many more, can also be supplied). The seals can be supplied in the materials EPDM or VI 780 with FDA- and USP Class VI.



CleanLip© - metallic sealing element replaces elastomers

An ideal addition to the BioConnect© aseptic connection by NEUMO, used for many years in the aseptic field, is the metallic CleanLip© sealing element.

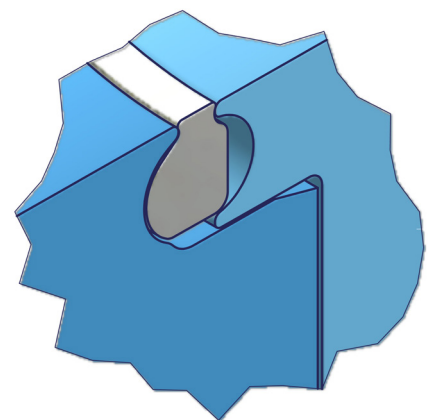
This replaces the elastomer seals used in the BioConnect© connection and can be retrofitted to existing BioConnect© flanged connections.

CleanLip© is made of stainless steel material 1.4435/ 316L and is, for example, used in clean steam systems, as well as generally in other applica-

tions in the pharmaceutical industry and biotechnology. The sealing element is distinguished by its high thermal and chemical resistance - particle friction does not occur in the medium. The much greater working life, in comparison to elastomer seals and the resultant very low maintenance and servicing costs lead to clear benefits in life cycle cost (Total Cost of Ownership). CleanLip© therefore represents, in particular for existing systems with BioConnect©



flanged connections, a simple and cost-effective solution, to counter the impending PFAS-ban with a change of the sealing element.



ConnectS© - metallic sealing connection without additional sealing element



The subsequent continued development of the metallic sealing connection is the ConnectS©. This enters the market without additional sealing elements and is thus, even in light of the impending PFAS-ban, an option aimed at the future: In addition to an ideal ease of cleaning and sterility, there are hardly any restrictions during the cleaning process for the user when using ConnectS©: The system is distinguished by its high resistance to alkalis and acids. Because both flange ends are made from the same material, there are no materials with different coefficients of expansion in the connection - hence there are no thermal limitations in use.

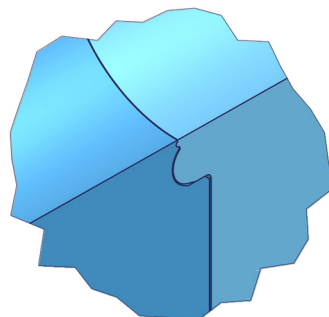
ConnectS© comprises two ex-

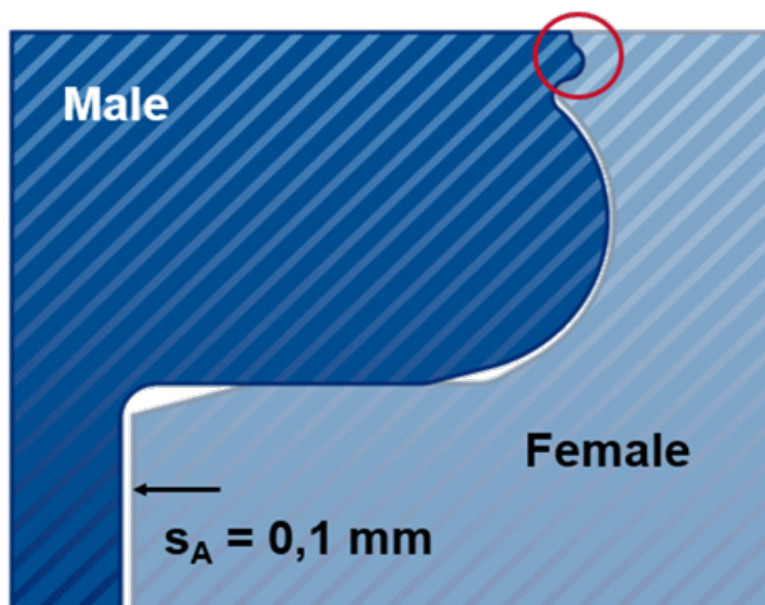
tremely precise machined flanges, in which the stainless steel surfaces are connected with each other so that the flange connection remains sealed even after it has been assembled and dismantled on a number of occasions. The design is based on a very precisely shaped sealing contour with dual S-bends. The actual sealing contour, the “small S”, is protected by a second, preconnected S-contour. The contact line between male and female flanges are designed so that it jumps back from the media space only minimally. The pressing of the stainless steel is defined so that the strength index $R_p 0.2$ (expansion limit with 0.2% plastic expansion) is not exceeded.

The connection is thus always moved in the elastic range of the stainless steel.

The connection can be opened and closed at any time without impairing the functionality.

ConnectS© is used with ease anywhere you want to have a tube connection to be “forgotten” to best effect, e.g. in double-skin ceilings, wall connections and points that are difficult to access. A metallic stop is also obligatory, such as a TÜV design approval, together with bacteriological investigations by research institutes and users. Typical uses include clean steam lines for critical media, for which absolute purity is a given: active ingredient production, in biopharmaceutical production, as well as in downstream processing for the pharmaceutical industry. The metallic sealing connection is available as flanged and clamp version and can be autoclaved.





Fitted with orbital welding ends, the dimensions are available to DIN 11866 ranges A (DIN), B (ISO) and C (OD/ASME-BPE). The standard surface quality is inside $R_a < 0.8 \mu\text{m}$ (higher qualities, as well as electro-polished surfaces are also available); standard material is 1.4435/316L (higher qualities, for example 1.4539/ 904L or 1.4529/6Mo can also be supplied). In addition to the positive properties of ConnectS© in light of a dead space-free and hygienic con-

nection, the system is also characterised in use by its flexibility regarding products and conditions of use. Because the seals don't wear out and have to be exchanged regularly, not only is reduced the risk of contamination fall, but maintenance expenditure is also reduced, which increases system availability. Thus, in particular in the regulated range, it is possible to simplify validation of the manufacturing process, cleaning and sterilisation. Operating costs thus fall significantly.

In addition, there is no expenditure for the procurement and storage of replacement seals. ConnectS© is available with diameters from DN 10 to 100 (on request, up to DN 150). The pressure strength is equal to standard PN 16; an approval up to 100 bar is available.

BioControl© creates the connection for sensors and process instruments



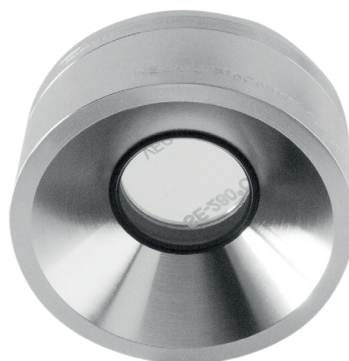
The installation of sensors and process instruments is often a neuralgic point in systems and demands cleverly designed connection systems. For the hygienic connection of measuring and control equipment in systems for the food processing and pharmaceutical industries, as well as biotechnological production workshops, NEUMO has developed the BioControl© connection system. The standardised connections provide flexibility in adapting instruments or sight

glasses in systems.

In conventional T-pieces or Ingold ferrules, as are frequently on the agenda when installing sensors, BioControl© connections are designed without a dome. Together with the very small contact area between seal and medium, this produces ideal ease of cleaning (CIP/SIP) and thus a cGMP-compliant design low in dead space. Again, with BioControl©, the elastomer seal used is controlled under pressure - the seal is fitted without rebound.

In order to avoid the disadvantages that occur with use of elastomer seals completely, the BioControl© connection system is also available as elastomer-free version (BioControlCS©). This reduces the already comparatively low maintenance costs still further and increases system availability.

BioControl© is available in two housing shapes as inline or angle housing. For installation in vessels, standardised block flanges and special solutions are available.



SUMMARY:

Elastomer-free connection systems are future-proof

More stringent emission thresholds and the impending PFAS-ban mean system planners and operators must reconsider the sealing technology used in their systems. In particular, in hygiene-sensitive processes, the design related to dead spaces plays an important role, in addition to sealing. These can also arise, caused by ageing elastomer seals. In this Whitepaper, the problems posed with sealing systems are illustrated and possible solutions are set out. In addition, the use of metallic sealing elements (BioConnect© with CleanLip©) or sealing systems without an additional sealing element (ConnectS©) allows a way out of the PFAS problems. Accordingly, systems can be produced not only future-proof against any material bans and harsher emission thresholds, but also with their handling safety enhanced. In addition, metallic sealing connections are characterised by low maintenance costs and high system availability - aspects that also gain in significance against the background of the increasing scarcity of specialists in this field.

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