3. Hygienic design of closed systems

Accumulation of product residuals and build up of micro-organisms in processing lines should be prevented. This can be done by avoiding dead ends and cracks and crevices in process equipment and allow drainability of equipment.

3.1. Dead ends

The traditional way of mounting pressure gauges and temperature sensors in process lines results in dead spaces, which are not acceptable.

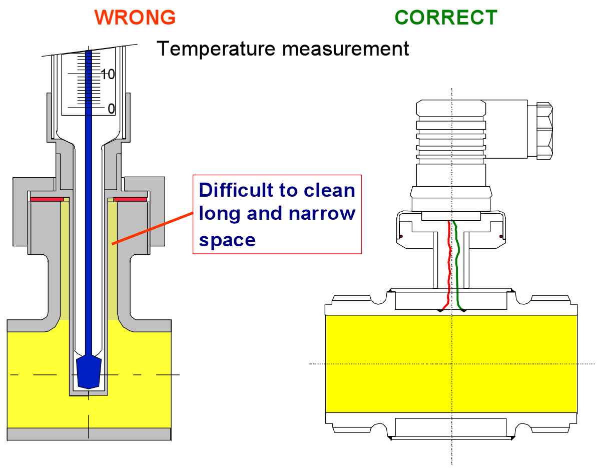


Figure 3.1 Two methods for mounting a temperature measuring device in a pipe.

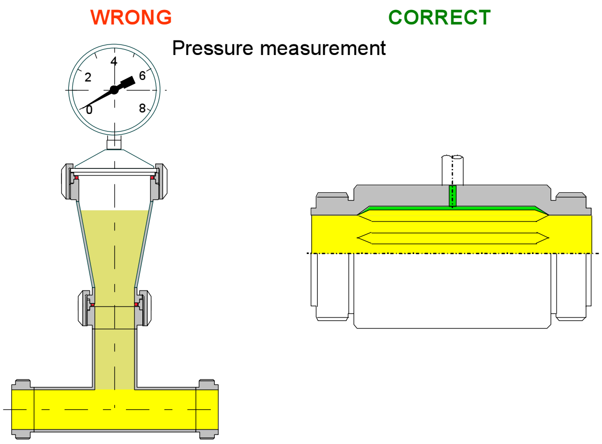


Figure 3.2 Two methods for mounting a pressure measuring device in a pipe.

In a hygienic design, these dead spaces are eliminated.

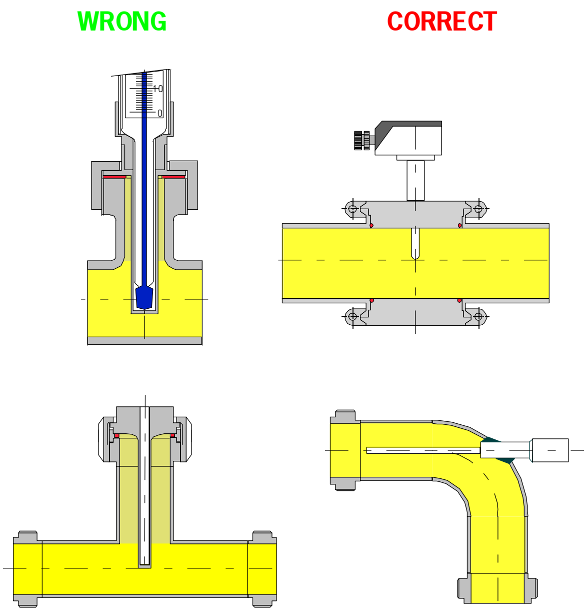


Figure 3.3 More examples of good and bad design of sensors.

Some examples are given below:

Figure 3.4 Traditional temperature sensor with unacceptable dead end.

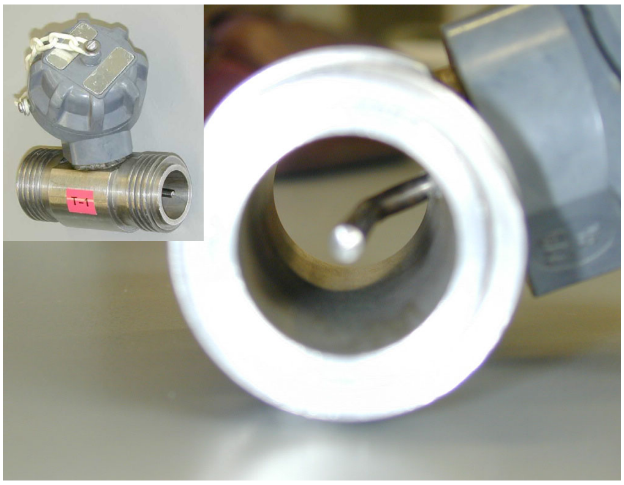
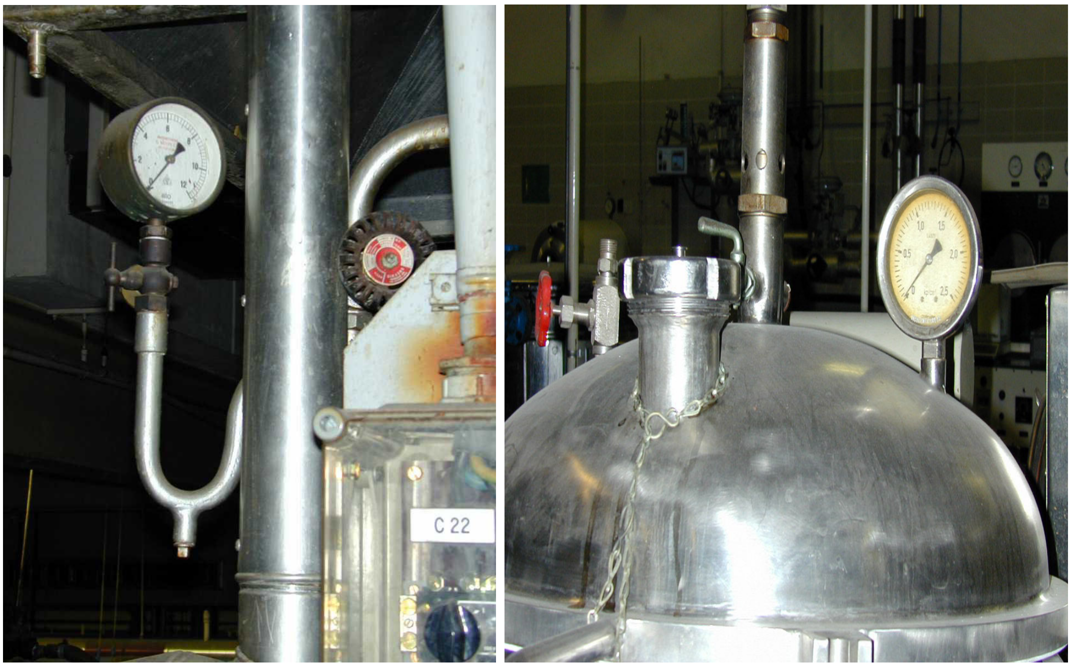
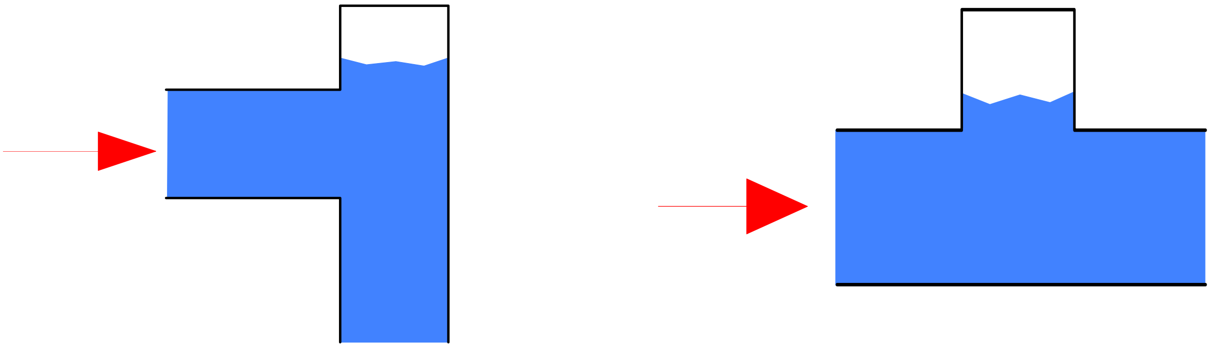


Figure 3.5 Hygienic design of a temperature sensor.

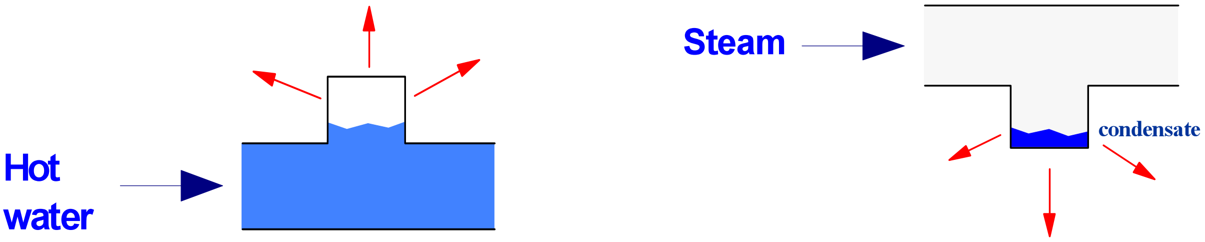
Badly designed pressure sensors:



Influence of dead ends on chemical disinfection:



Due to presence of dead ends, chemical solutions can not reach all places causing a decrease in cleaning efficiency. The same accounts for thermal inactivation:



Arrows indicate loss of heat, which in case of steam sterilisation causes condensation of water. If dead legs are unavoidable they must be as short as possible. For pipe diameters of 25 mm or longer the length of the dead end should be 28 mm at maximum. For smaller pipe diameters the length should be smaller than the diameter:

Figure 3.6 Unacceptably long dead end.

Furthermore, the position of the dead end influences the residence time in the dead end. Therefore, for most liquids the flow must be directed towards the dead end.

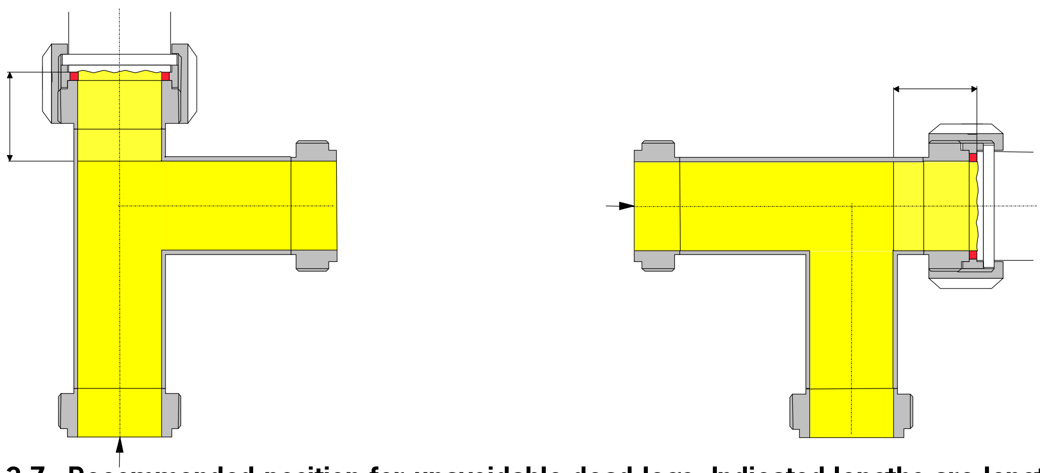


Figure 3.7 Recommended position for unavoidable dead legs. Indicated lengths are length ≤ 28 mm.

Installation of pumps should also be done in such a way that no product will be left standing still in a dead leg.

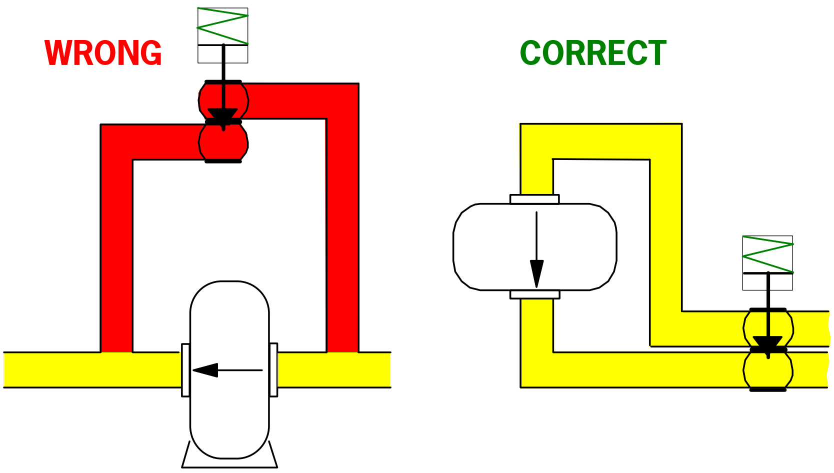


Figure 3.8 Wrong and correct way of installing a bypass for a pump. Both connections and the pump itself should be drainable.

By-pass of a pump to increase flow rate in the pipelines during cleaning. A small flow goes through the pump and the largest part of the cleaning solution goes directly through the pipelines. In the left picture a dead area is formed during production, where fluid is standing still.

3.2. Drainability

Equipment must be placed such that no accumulation is possible during production and that the equipment can be drained after cleaning.

3.2.1. Drainability of pumps

Examples of how to install a pump and how not to install a pump are given below.

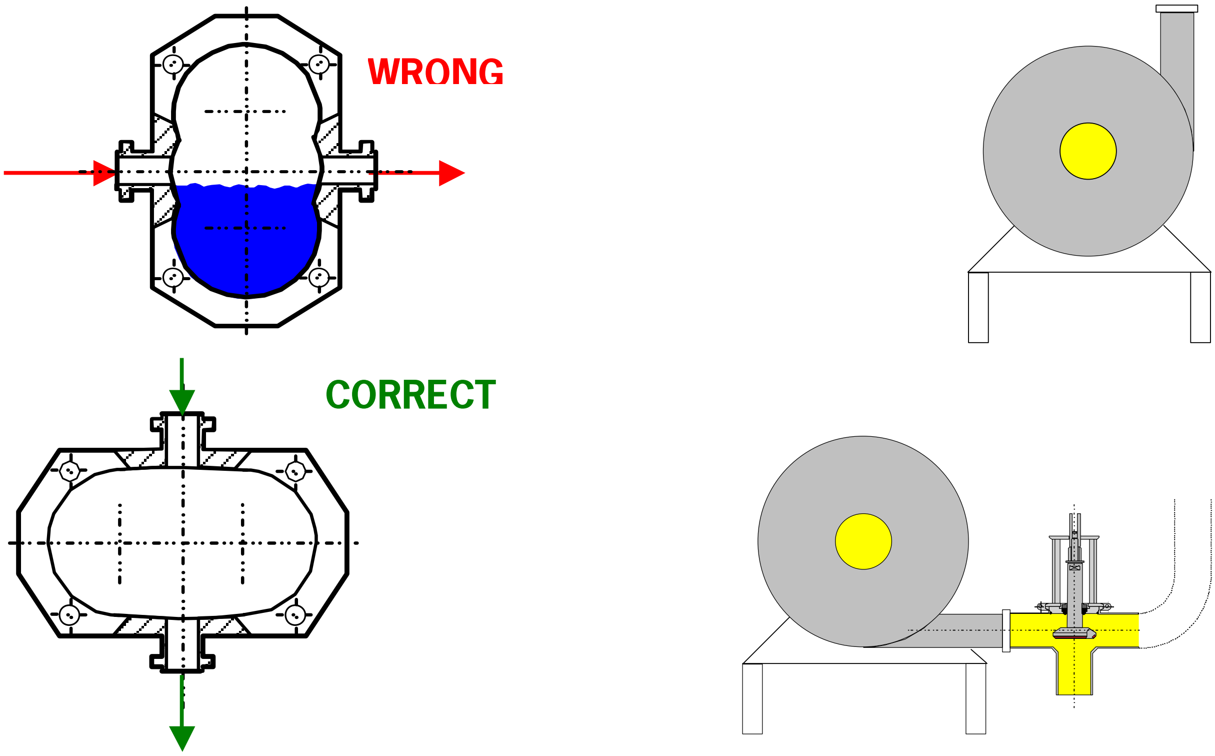


Figure 3.9 Wrong and correct ways to install displacement- and centrifugal pumps.

3.3. Drainability of pipework

Swept tees can be used to avoid dead areas but should be mounted vertically for better drainability.

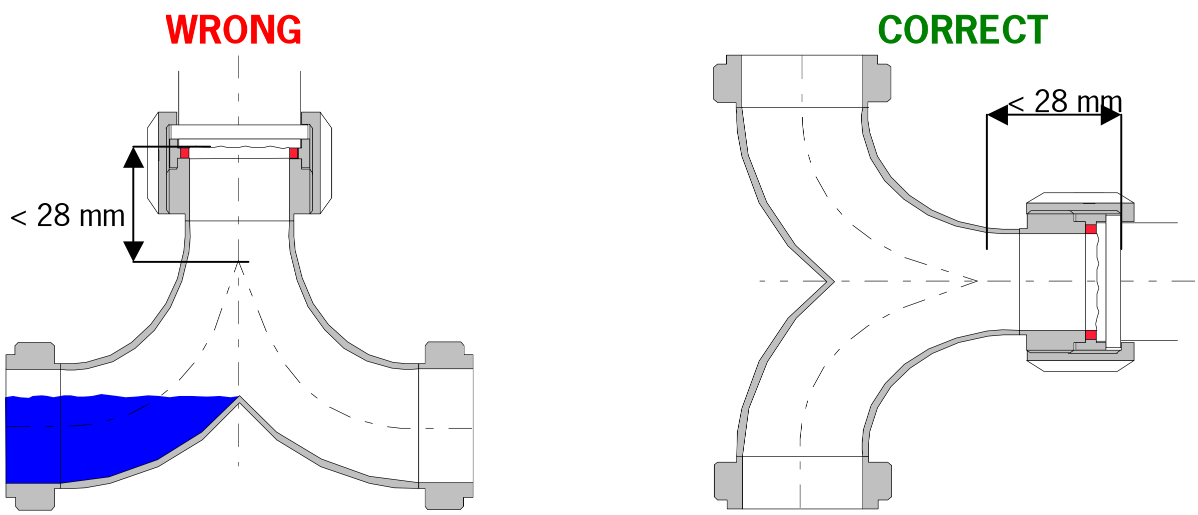


Figure 3.10 Incorrect and correct use of swept T-connection.

Tubing and piping should be installed in such a way that no undrainable sections are formed. Thus, in horizontal pipework, excentric reducers should be used (Figure 3.11). Also, flexible tubing should not be used for horizontal pipework, unless supported over its full length (Figure 3.12). Pipelines should slope around 3° to make drainage possible.

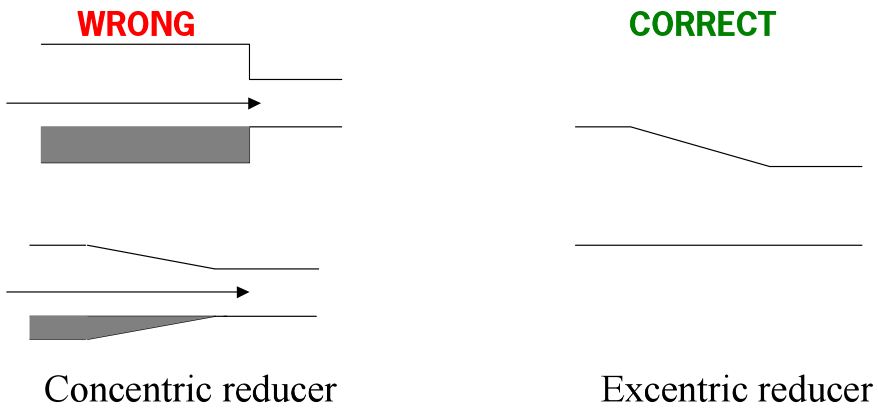


Figure 3.11 Use of reducers in horizontal pipework.

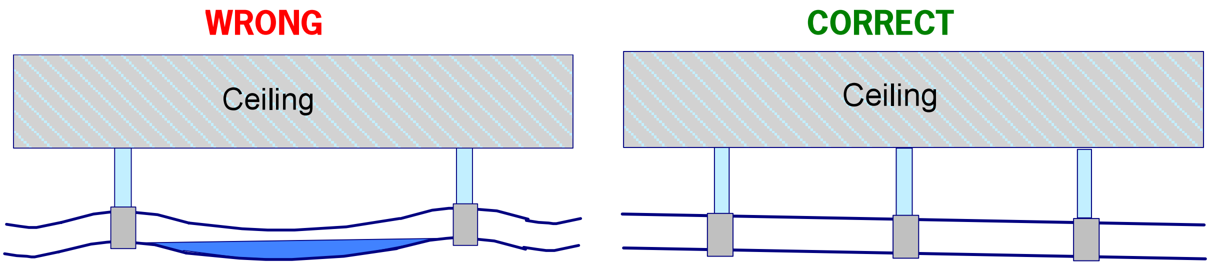


Figure 3.12 Hanging of pipework from ceilings.

Examples of non-drainable situations:

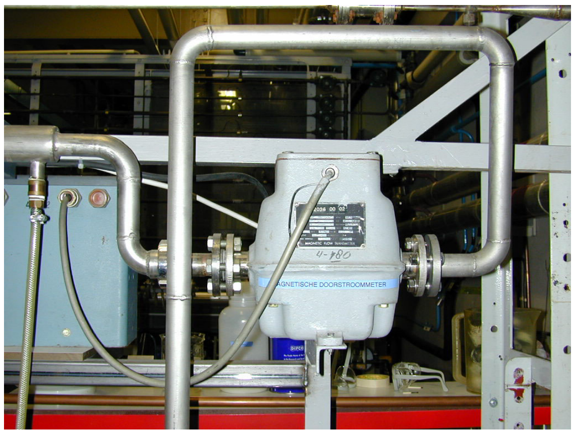


Figure 3.13 Incorrect installation of pipework: pipes can not be drained completely.

3.3.1. Drainability of tanks

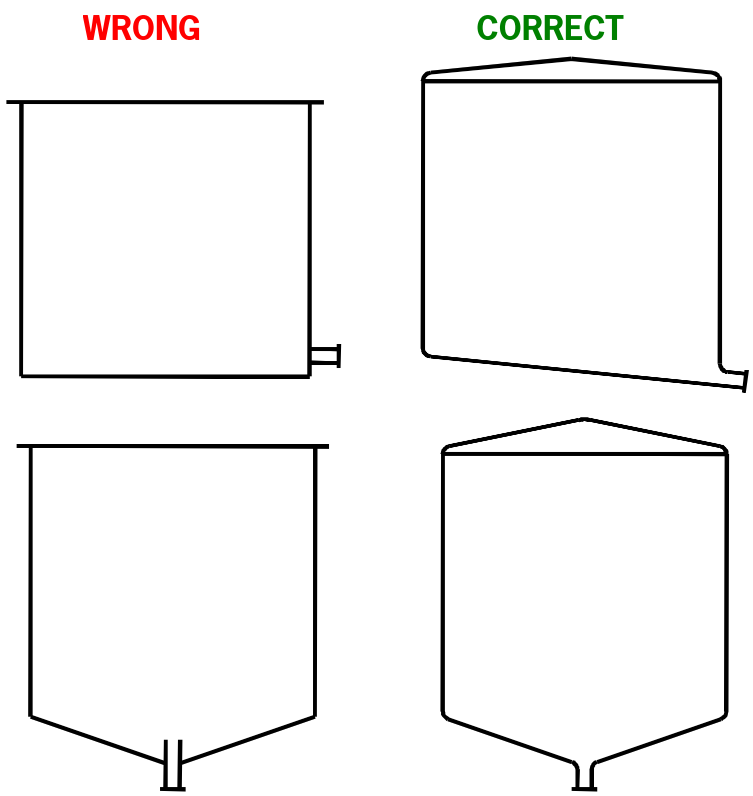


Figure 3.14 correct (right) and incorrect placement of drains in holding tanks).

3.3.2. Drainability of valves:

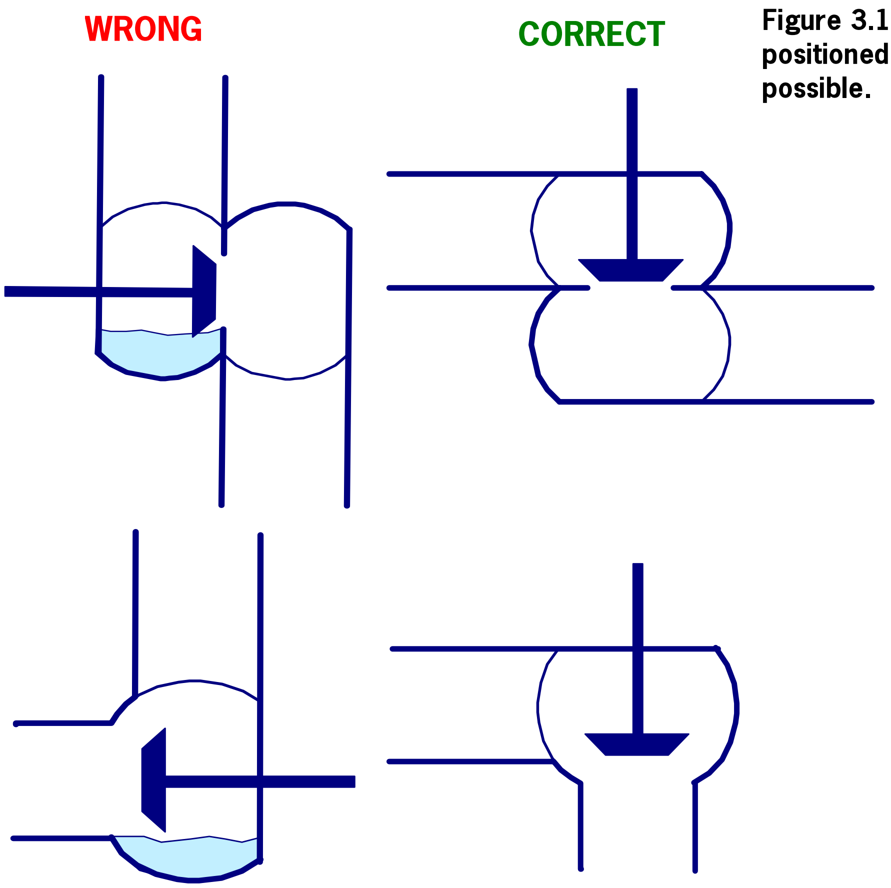


Figure 3.15 Lip-seal valves must be positioned such that drainage is possible.

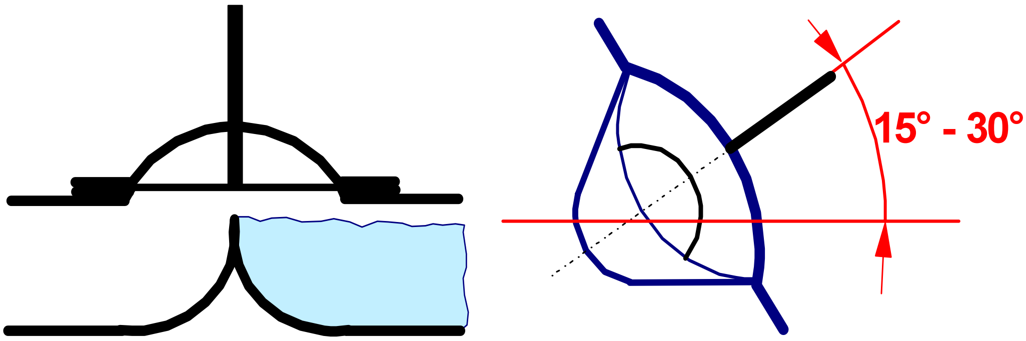


Figure 3.16 Positioning of membrane valve in order to allow for drainability.

Membrane valves should be positioned in an angle to allow drainage of the swept tee legs. Positioning a membrane valve like shown on the right is not a hygienic design.

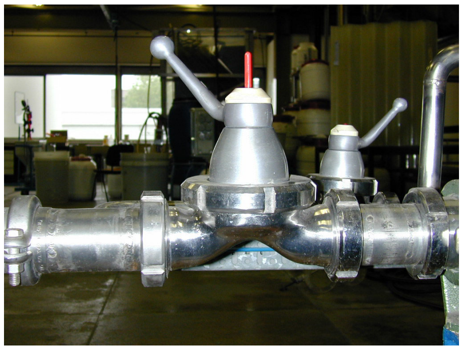


Figure 3.17 Membrane valve installed horizontally.

3.4. Hygienic design of valves

Besides good drainability of valves, the valves themselves should be designed hygienically.

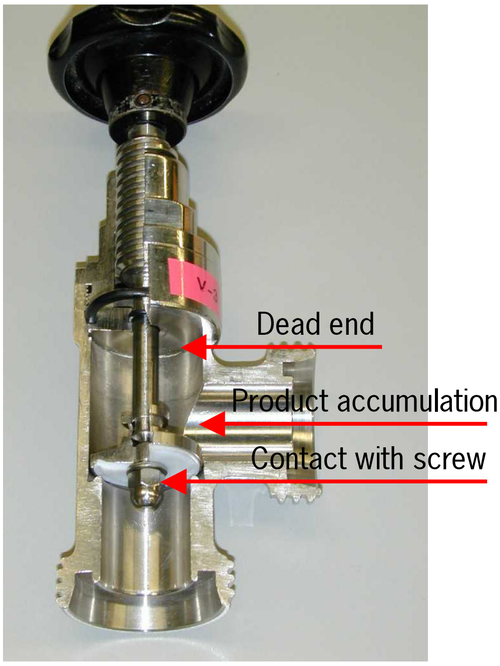


Figure 3.18 Valve, showing dead ends in closed position. Product also can get in the screw head and into the mechanism

Valves should not contain dead ends (Figure 3.18), but should also prevent accumulation of product residues. For that reason, the valve type below is not suitable for hygienic applications.

When these valves are closed the inside is being turned. Part of the product stream ends up in the valve body. Once the valve is opened again the product residues stored in the valve body are returned into the (cleaned) process line. The valve can only be cleaned when dismantled.

Example of a hygienic valve:

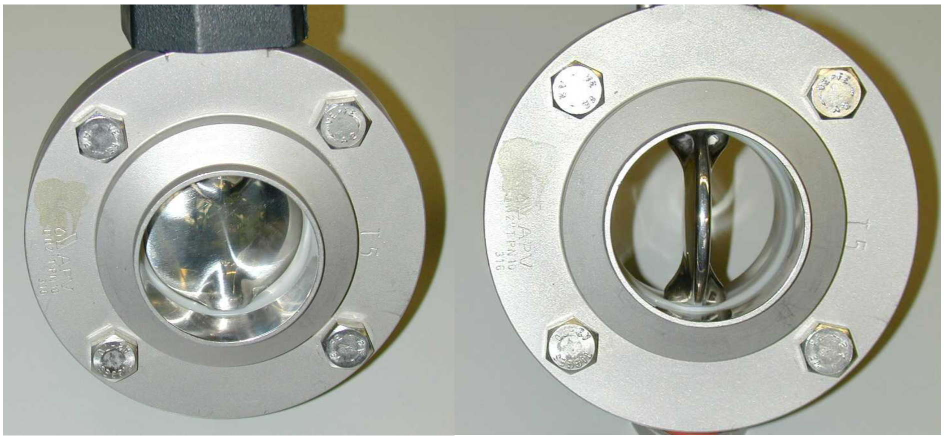


Figure 3.19 Butterfly valve in closed and open position.

The butterfly valve is a hygienic valve. No product can accumulate in it, and the valve is easily cleanable.

Example of an aseptic valve:

Figure 3.20 Aseptic valve.

This valve contains a membrane that results in bacteria-tightness of the valve: it prevents re-entrance of product materials or micro-organisms in the process line. If there is a leak somewhere in the valve, this is visible at the tap.

For certain specific purposes, specific valves were designed, like for instance **flow diversion valves**, as applied in for example pasteurisers. The working mechanism of this type of valves is explained in Chapter 6.

Double seat valves were designed to separate two process lines. The working mechanism of this type of valve is explained in Chapter 5.

More information on valves can be found in document 14 (EHEDG).

3.5. Hygienic design of pipe couplings

When a stainless steel pipeline is to be connected with a flexible hose, clamps are used. These clamps should be applied correctly, such that no product residues can be trapped causing contamination.

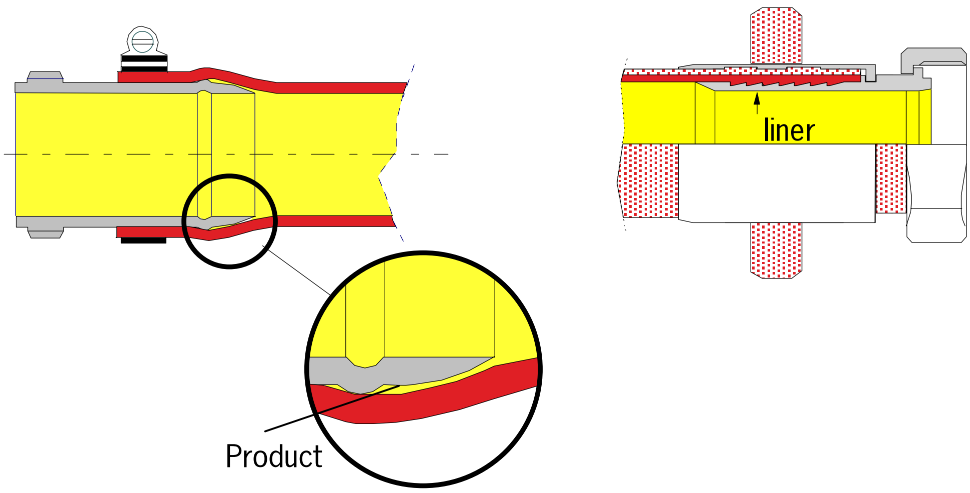


Figure 3.21 Clamping of a flexible hose to a pipe. Left : wrong, right: correct.

When two stainless steel pipelines are connected, the best design is a permanent connection provided with good hygienic welding (see chapter 2.1.2). Don't do as shown in Figure 3.22.

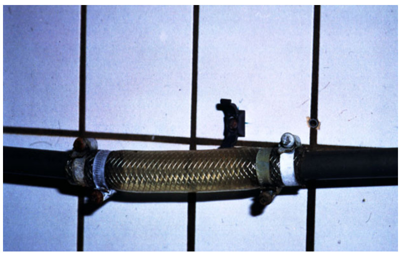


Figure 3.22 "Quick and Dirty" pipe coupling: not hygienic.

When dismountable pipe couplings are unavoidable (for example when connecting pumps, valves or vessels) this should be done hygienically.

Care must be taken that no metal-to-metal joints are used, since these can cause cracks and crevices promoting accumulation of micro-organisms (Figure 3.23). Metal-to-metal joints can not provide complete sealing. Such a coupling is therefore not aseptic: bacteria can migrate from one side to the other and cause contamination.

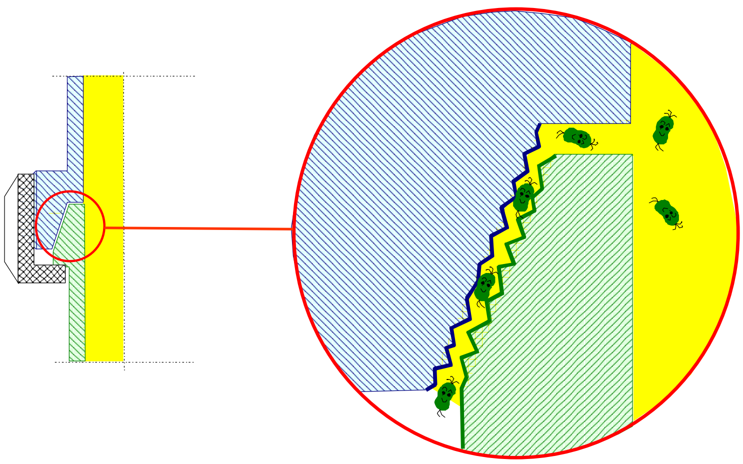


Figure 3.23 Connection of two metal pipes.

Connections should be made either by welding, or by using couplings using some kind of gasket. O-rings are commonly used tfor this purpose. They can fill the gap between metal-to-metal joints and result in bacteria tightness of the coupling.

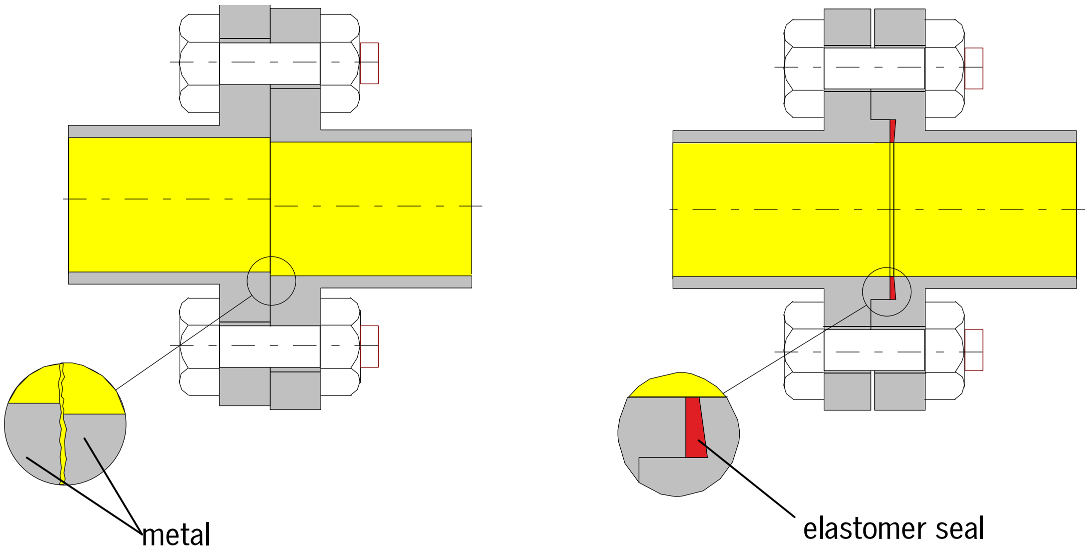


Figure 3.24 Left: misalignment and metal-to-metal joint causing crevices. Right: alignment of coupling and gasket used for bacteria tightness.

If gaskets are used, their design must be such that no crevice exist where soil residues may be trapped and bacteria can accumulate and multiply.

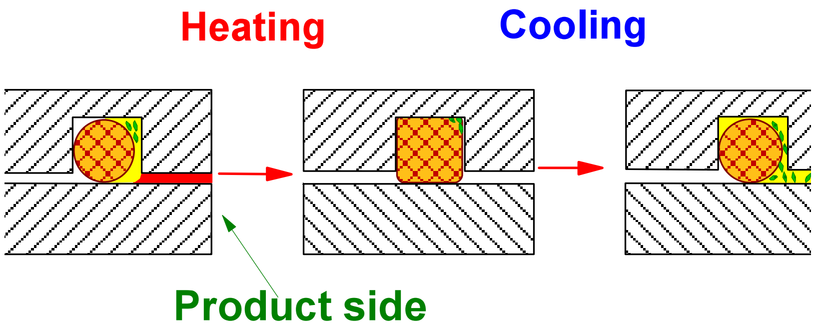


Figure 3.25 Gasket deformation resulting in protection of trapped bacteria.

When O-rings do not fit tightly, bacteria can accumulate. During heat treatment of the equipment, the O-ring protects the bacteria so that they can survive a cleaning procedure and recontaminate the product (Figure 3.25)

The type of material used for sealing must be able to withstand a variety of conditions such as low and high temperatures and a variety of products like alkaline or acid products, oils etc. Polytetrafluorethylene (PTFE) is often used for its temperature and corrosion resistance. However, this material is nonresilient: a heat treatment changes the shape of the material causing gaps where bacteria can accumulate (Figure 3.26).

Elastomers that are used in hygienic design are: ethylene propylene diene monomer (EPDM, which is not oil or fat resistant), nitrile rubber, nitrile butyl rubber (NBR), silicon rubber or fluorestomer (Viton) (doc 8, EHEDG).

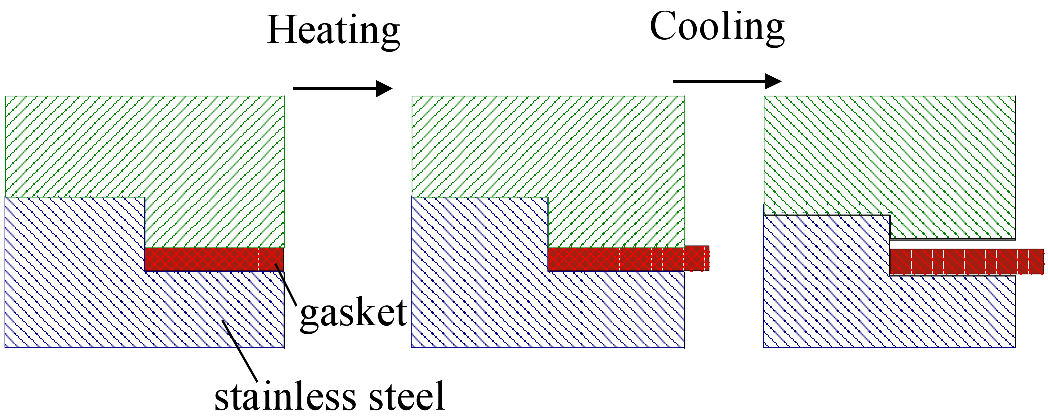


Figure 3.26 Development of a microbial leak due to differences in thermal expansion between stainless steel and nonresilient gasket material. During heating, both materials expand. Subsequent cooling gives shrinkage of the stainless steel whereas the gasket material remains in its former shape causing a gap between the two materials.

Even when resilient material is used, ageing and crack formation can occur. Ageing is promoted by:

- Deformation. For example, sharp corners give compressive stress causing cracks in the gasket material. Compression should be limited to 20-25% of the original thickness. Special gaskets can prevent overcompression:

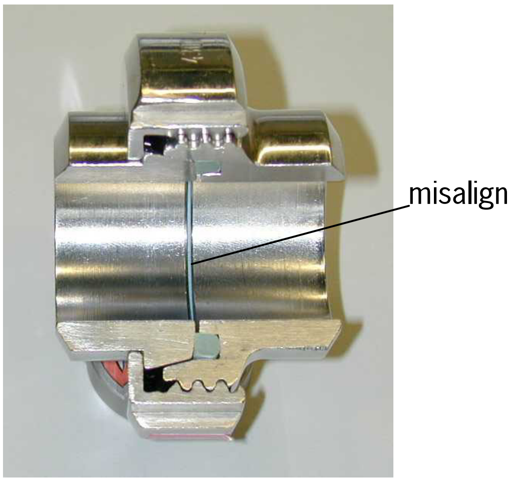


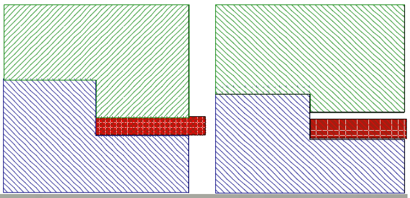
Figure 3.27 DIN 11851.

Figure 3.28 ISO 2853 coupling with T-gasket (red circle) that improves alignment and controls compression of the gasket.

Friction: Friction between stainless steel and elastomers can be very high under dry conditions which causes deformations (leaving gaps between stainless steel and elastomer) and damage of the gasket.

Thermal expansion: Heating and cooling can cause damage to the gasket. This can be prevented by allowing expansion of the gasket at the non-product side.

- Exterior forces: For example when couplings are connected too tight, gaskets can be damaged. Left: over compression (gasket protruding in product area). Right: insufficient compression



This can be prevented by allowing expansions in 2 directions and preventing too tight connections by using metal-to-metal contact.

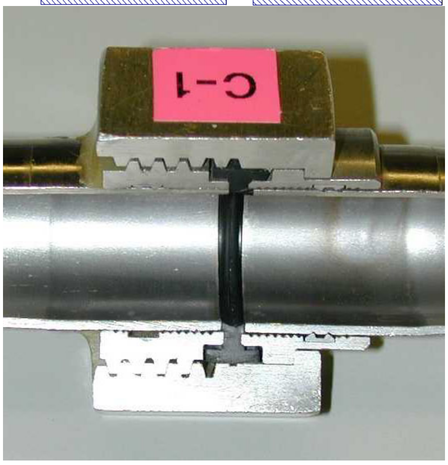


Figure 3.29 ISO 2853. By tightly screwing the coupling on the pipeline the gasket can get over compressed causing damage.

Two types of pipe couplings with elastomer gaskets have been approved by EHEDG as being aseptic: the APV designed profiled gasket sealed coupling and the Tuchenhagen designed coupling. In the first one a diamond shaped seal allows expansion in two directions and metal-to-metal contact prevents too tight connection of the coupling (Figure 3.30). In the second one a round gasket is applied and again metal to metal contact prevents overtightening (Figure 3.31).

Further information on pipe couplings and elastomer gaskets can be found in EHEDG documents 10 and 16.

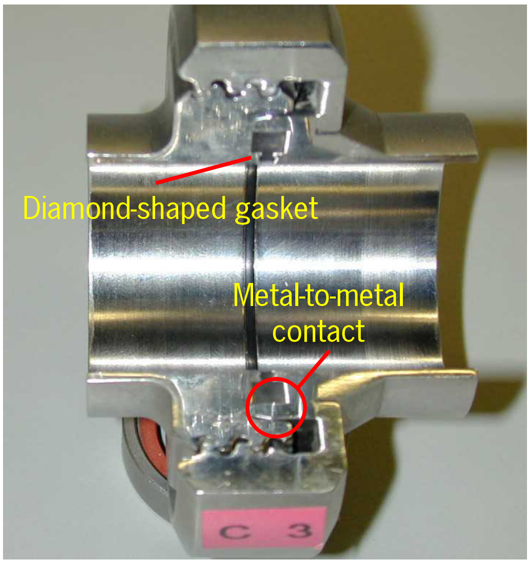


Figure 3.30 APV-designed profiled gas-ket. .

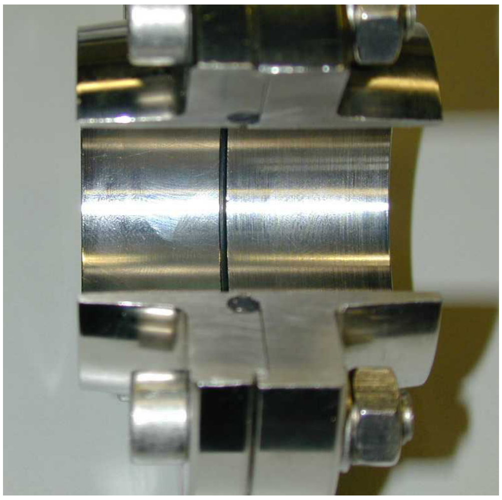


Figure 3.31 Tuchenhagen designed O-ring gasket in a screwed coupling version (DIN 11864). .

3.6. *Dynamic seals*

Dynamic seals are used in centrifugal or high-pressure pums, homogenisers etc. The use of such seals should not promote accumulation of product residues and microorganisms. Therefore, the space around the seal should be as wide as possible to prevent dead spaces. The use of single dynamic seals will not prevent passage of micro-organisms and will be (if properly designed) hygienic but not aseptic:

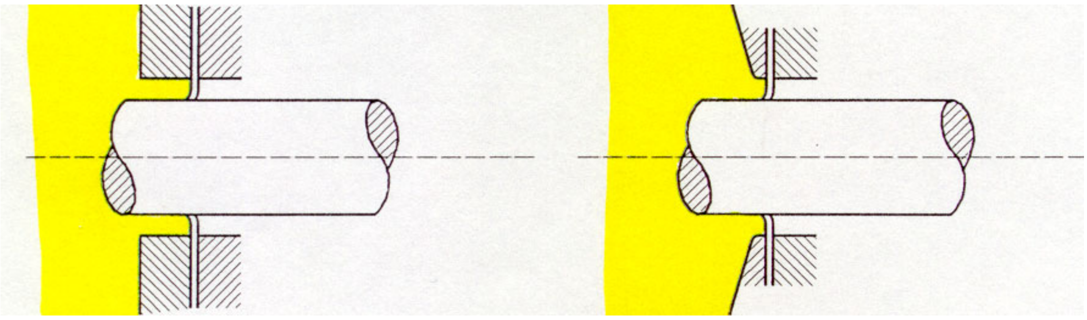


Figure 3.32 Moving axis with single dynamic seal. Right: space around the seal should be as wide as possible.

For aseptic equipment dynamic seals should be avoided by using bellows or diaphragms that separate the seal from the product side. If that is not possible double seals must be used.

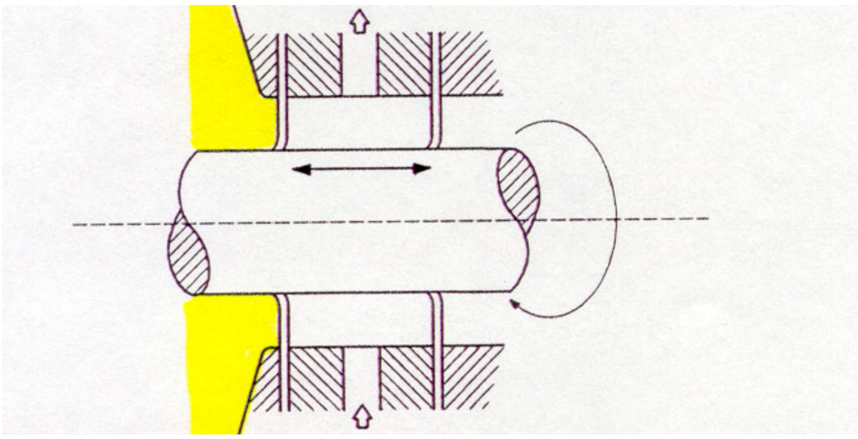


Figure 3.33 Double shaft seal. White arrows indicate flow of antimicrobial fluid. Black arrow indicates stroke of the shaft, which should be smaller than the space between the seals.

When using a double seal, the space between the seals must be flushed with antimicrobial fluids or sterile water to remove any micro-organisms that enter the space between the seals. The distance between the seals must be larger than the stroke of the shaft to increase contact time between micro-organism and antimicrobial fluids.

3.7. *Further reading*

1. H.L.M. Lelieveld (2000). Hygienic design of factories and equipment. In: Lund, B.M., Baird-Parker, T.C. and Gould, G.W. Microbiological safety and quality of food 2. Aspen Publishers Inc. Gaithersburg, 1656-1690

2. Anonymous (1994). Hygienic plant engineering requirements, SHE 8, Hygienic Processing Working Party, Unilever

3. ISO 14159. Safety of machinery-Hygiene requirements for the design of machinery

4. EN 1672 (1997). Food processing machinery-Basic concepts-Part 2: Hygiene requirements

EHEDG guidelines:

5. Document 8: Curiel, G.J., Hauser, G., Peschel.P et al. (1993). Hygiene equipment design criteria. Trends in Food Science & Technology 4(7), 225-229

6. Document 10: Curiel, G.J., Hauser, G. Peschel, P. et al. (1993). Hygienic design of closed equipment for processing of liquid food. Trends in Food Science & Technology 4(11), 375-379

7. Document 14: Abram, I., Baumback, F., Curiel, G.J. et al. (1994). Hygienic requirements on valves for food processing. Trends in Food Science & Technology 5(5), 169-171

8. Document 16: Baumbach, F., Dubois, J.P., Grell, W. et al. (1997). Hygienic pipe couplings. Trends in Food Science & Technology 8(3), 88-92