HYGIENIC CLASSES FOR PROCESS VALVES

A guideline for users

GEA Engineering for a better world.

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HYGIENIC CLASSES FOR PROCESS VALVES

Customers for process valves are always faced with the challenge of evaluating suitable solutions for complex production requirements. GEA's aim with this brochure is to provide current and future decision-makers with a guide for selecting the right valve technology.

Constantly increasing product variety, longer production cycles, different market conditions – all this makes plant designs more complex for producers. At the same time, there is an increase in consumer expectations and higher legal requirements for producers and products. For engineers, this results in an increased need for consulting services to offer manufacturers a suitable solution offer.

Application examples

Dairy
Milk, cream, desserts and baby food

Beverages
beer, juices, soft drinks, ready-to-drink coffee and tea

Pharma & healthcare
Medical food, liquid medicine and WFI

Food
Liquid food, dietary supplements, New Food, oils and fats

Home & personal care
Home care and personal care products

The German Engineering Federation (VDMA) has published various technical papers on hygienic classes, especially in the field of filling technology, which have established helpful guidelines for the industry. The concept of hygienic classes provides a suitable link for hygienic requirements between the machine and the product to be processed. GEA Flow Components is now transferring this concept to process valves.

As usual from the VDMA, valves are divided into hygienic classes I – V; from Hygienic (I – III) through UltraClean / ESL (IV) to Aseptic (V). For filling machines, the sterilization rate in the sterile chamber and the packaging material are particularly critical factors. In the case of process valves, possible contamination risks and their detection possibilities are decisive. Underlying the classification in both areas is based on the properties that the producer expects from the product to be marketed.

This brochure is intended to provide a practical introduction to the subject of hygienic classes and to classify common valve concepts, particularly with regard to microbial contamination risks. The contents and arguments are intended to stimulate dialog. The aim is to equip your plant with tailor-made valves for your products and your market. GEA Flow Components can draw on more than 80 years of valve technology and over 35 years of aseptic experience. Our portfolio also includes hygienic pumps and tank cleaning equipment.

Please contact us – we will be happy to discuss with you the right valve solution for your application.

Microbiology determines the classification

The hygienic classes can be described by microbiological, physicochemical and resulting sensory properties. An important parameter for the classification of products to be produced is the minimum shelf life.

The labeled minimum shelf life depends primarily on the microbiological stability of the product, and also on the planned distribution logistics. The matrix below serves as a guide for classification into the classes Hygienic, UltraClean / ESL and Aseptic, whereby one characteristic can already be decisive and the transitions are fluid.

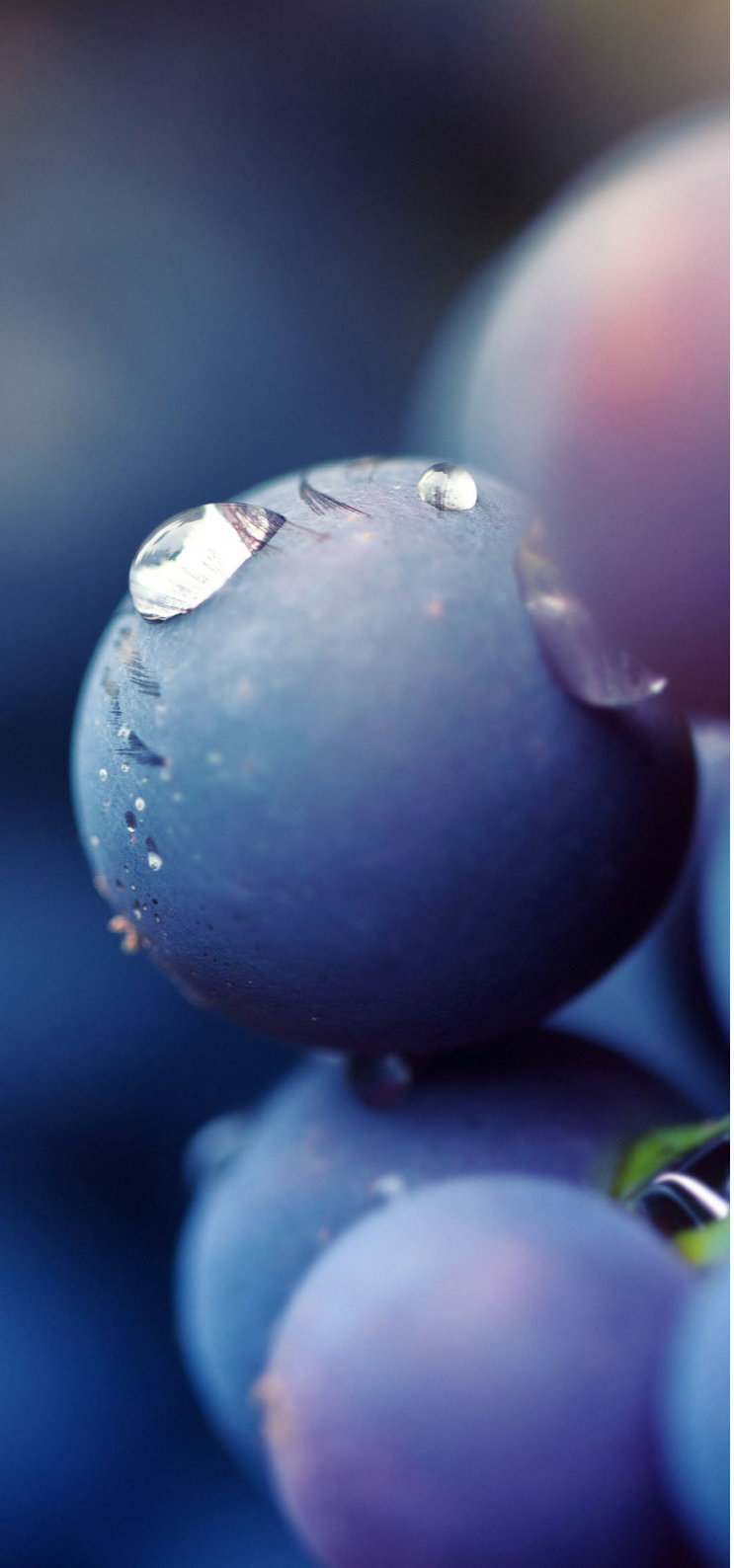
Important decision-making criteria are therefore the type of food and its suitability as a breeding ground for microorganisms. Here, a distinction is made between pathogenic, i.e. food poisoners, and non-pathogenic organisms. The latter have no direct influence on human health, but may very well have undesirable effects on the food itself. The consumer ultimately judges the manufacturer and brand by the taste, odor and appearance of the products. In view of the important product image, product safety and the required process reliability are of paramount importance.

The germ reduction required for microbial stability and minimum shelf life, measured in the logarithmic reduction of the germ count, is primarily achieved by direct or indirect heat treatment. The required microbial reduction must be achieved by taking into account the heat resistance of relevant microorganisms, measured by D and Z values. These values are specific to microorganisms and can also be influenced by the food matrix present, especially by fat and protein. Microorganisms can also occur in different forms, vegetative and non-vegetative, and can influence the microbial reduction within the food through the process. The goal is to have as little negative impact as possible on the physicochemical, nutritional and sensory properties of the product.

This is, as mentioned, usually achieved by classical heat treatment, sometimes combined with other unit operations, such as mechanical separation, electro-magnetic-induced forces or filtration. The process valves and components are an important part as well, as they can help avoid or minimize the risk of microbial contamination. This is already valid before the microbial load reduction, as the initial cell count is an important parameter for the reduction kinetics of microorganisms and, thus, for process and product safety and quality.

Classification in the hygienic classes

Parameter	Hygienic (I–III) / UltraClean / ESL (IV)	Aseptic (V)
pH-value	< 4.5	> 4.5
a_w-value	< 0.85	> 0.85
Minimum shelf-life	< 3 weeks	> 3 weeks
Distribution	chilled	ambient temperature
Preservatives	yes / no	no



THE HYGIENIC CLASS HYGIENIC

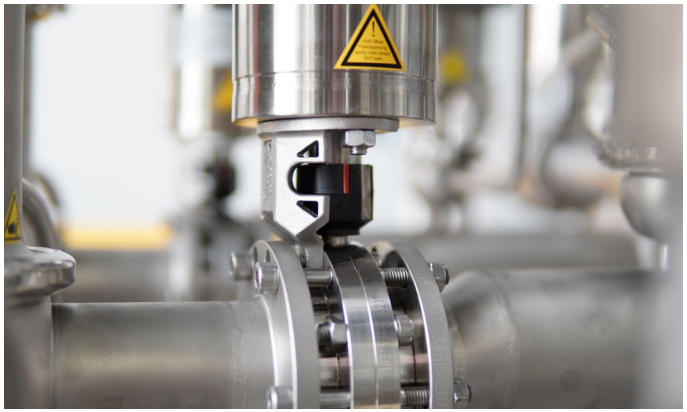
The essential requirement for process valves in direct contact with food is their hygienic design.

In order to meet the basic requirement, the Machinery Directive stipulates that the design must be such that any risk to health is excluded. In particular, it must be possible to clean the materials used before each use, and surfaces in contact with the product must not provide any space for microorganisms to settle, e.g. raised areas, recesses or edges. The background to this requirement is the indispensable need to be able to produce food safely and in consistent quality with an appropriate shelf life.

Ensuring a permanently consistent and controlled process system is the key to achieving this high goal. This is achieved in hygienic plants by means of a cleaning process tailored to the product and the system, which reliably returns the plant to a desired initial condition before each production run. Hygienic-class valves are designed to be as reliably and completely cleaned in this process as the connected piping system.

The distinguishing feature of valves in the Hygienic class is not the cleanability per se, but often the efficiency of cleaning. The hygienic design of the valves determines the necessary intensity of the cleaning process and thus the use of the four parameters of Sinner‘s circle, namely time, temperature, chemistry and mechanics, to clean the valve completely. The efficient way to clean a valve is also underlined by its compliance with relevant guidelines, such as EHEDG, 3-A, etc. These standards all promote the hygienic design of components, and in the case of EHEDG, the cleanability of a valve is tested against a reference pipe under controlled and standardized conditions.

Hygienic-class valves are used in numerous applications in food and beverage production (and related industries) where there are no stringent requirements regarding germ reduction or shelf life for sensitive products – primarily in large parts of brewery, dairy, beverage, and food production plants. Outside the food and beverage industry, hygienic valves are often found in pharmaceutical, health-care, biotechnology, fine chemicals and cosmetics plants.



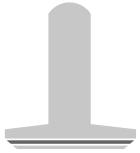
Hygienic valves

Hygienic valves are characterized by the use of high-quality materials and the possibility of seamless cleanability of all components and surfaces that come into contact with the product.

A hygienic valve ensures complete cleanability in the course of pipeline system cleaning (CIP – Cleaning In Place), so there is no need to remove the valve for cleaning reasons.

Butterfly valves
Butterfly valves are the most widespread and simplest form of hygienic valves on the market. This type of valve is particularly popular due to the cost-effective possibility of shutting off the product flow within a pipeline.

Microbiological contamination risk	Possible sources of failure	Possibility of detection
Product residues at shaft connection	Insufficient cleaning caused by bad sealing designs	none
Valve shaft sealing	Malfunctioning sealing at the shaft connection caused by high stress	Visual detection
Surface damages	High mechanical stress caused by occuring torsion forces	Conditional visual detection



Seat valves
Seat valves are used to shut off a pipeline. The valve is characterized in particular by the low product-contacting sealing surface compared to the butterfly valve and its torsion-free loading with defined compression. In addition, seat valves allow two pipelines lying one above the other to be safely shut off from each other, which leads to a considerable increase in productivity in the process.

Microbiological contamination risk	Possible sources of failure	Possibility of detection
Elevator effect	Microorganisms seated on the valve stem are brought into the product area while activating the valve	none
Contamination behind seals	Badly designed sealing concepts can lead to contamination behind a product wetted seals	none

THE HYGIENIC CLASS ULTRACLEAN / ESL

The UltraClean / ESL hygienic class has long been known in the field of filling technology for food processing companies and is defined primarily by the requirements placed on the product to be processed.

The requirements primarily concern the declared shelf life, which is largely determined by product-specific pH and a_w values. In addition, sensory and certainly increasingly logistical parameters play a decisive role. Another advantage of this process technology is the reduced or even eliminated use of preservatives while maintaining product shelf life.

The valve technology used for UltraClean / ESL processes prevents or reduces the introduction of germs by protecting the valve stem with steam or by hermetically sealing it against the atmosphere using a membrane. UltraClean / ESL valves are used for milk-based, lactic acid or also ESL milk products. Due to an acidic product environment or the constantly guaranteed cold chain, an improved product quality with also extended shelf life can be produced.

Another important area of application is fruit juices and other fruit-based beverages. The pH value of the product to be manufactured serves as the basis for the decision. If this is below the known limit of pH 4.5, the use of UltraClean / ESL valve technology is recommended.

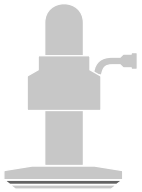
In addition, water-based mixed drinks such as spritzers and mixed beer drinks are possible applications for UltraClean / ESL valve technology. The growing sector of sports and wellness drinks as well as sauces and delicatessen foods also lend themselves to this hygienic class. Of course, UltraClean / ESL valves can also be used as a valve-side upgrade for classic hygienic processes such as in the brewing industry.

An important factor in UltraClean / ESL applications is also the question of whether the product to be processed (dairy-based foods excluded) can withstand repeated heat input in terms of quality, should unwanted contamination occur – in other words, whether process errors are forgivable or lead to complete product loss.

UltraClean / ESL valves

UltraClean / ESL valves are characterized by increased safety against contamination from the environment and thus ensure the microbial stability of the product throughout the entire process.

The increased safety of the UltraClean / ESL valve concepts lies in the protection of the moving valve stem or other interfaces to the atmosphere – either by a zone closed by means of steam or, similar to aseptic valves, by hermetically sealing the valve stem by means of a diaphragm. Analogous to the other valve types, the same hygienic design principles apply to UltraClean / ESL valves as to all valves used in food applications.



Valves with sterile lock

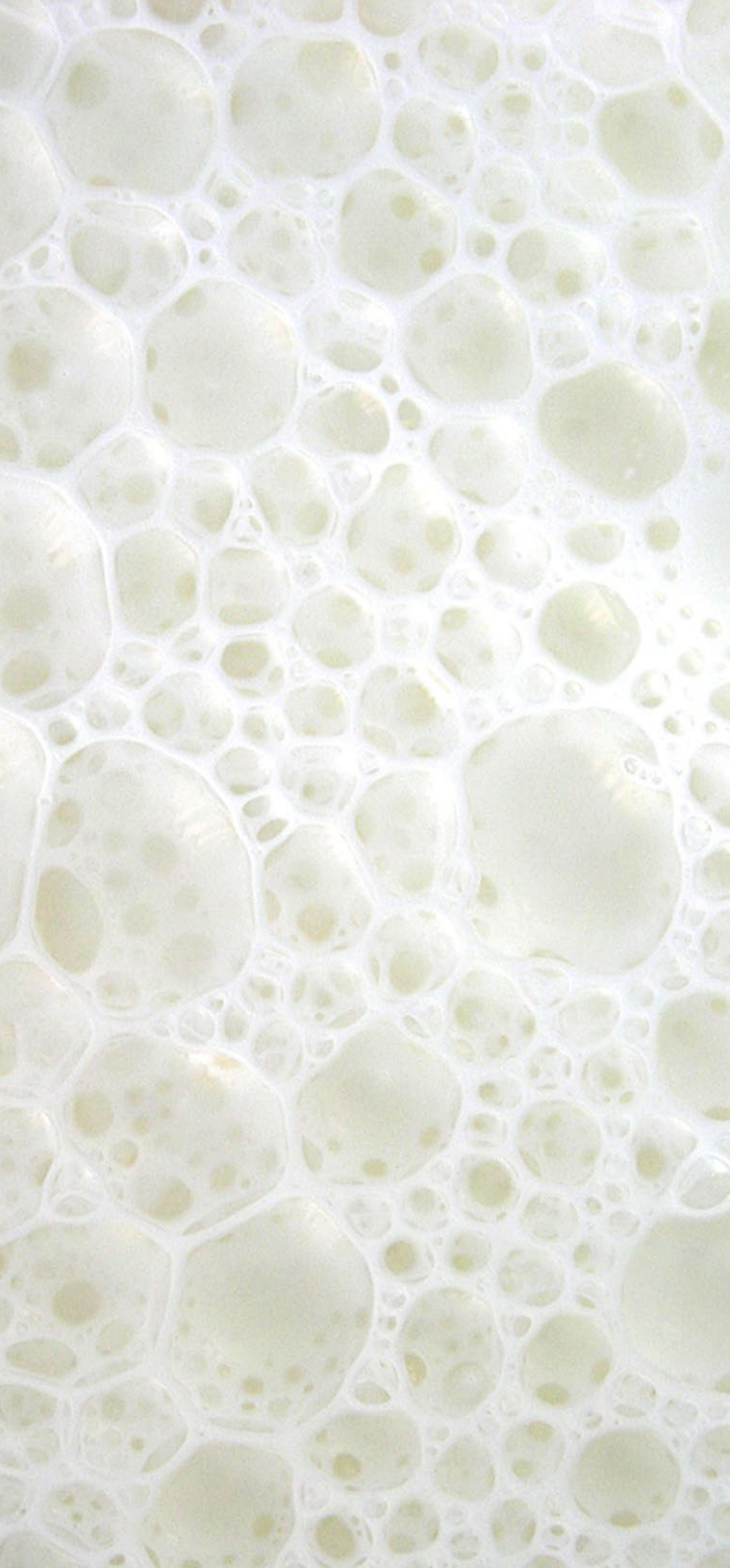
The sterile lock can be mounted on existing hygienic valves in order to upgrade these installations to UltraClean processes. In this concept, the valve stem is protected by a steam barrier. Generally, this only allows a steaming of the interface to the atmosphere. Normally, there is not an enclosed system to allow sterilization temperatures, this is why the solution cannot be seen as equally safe as a hermetical sealing of the valve stem.

Microbiological contamination risk	Possible sources of failure	Possibility of detection
No sterilization of valve stem	• No active steam circulation end, thus no sterilization	none
Valve stem sealing	• No permanent steam barrier recommended (life time of the seal, product burn-ons) • Unintentional inoculation of the product with contaminated condensate	none
Loss of steam barrier	• Power loss • Problems with steam production	Temperature monitoring

Diaphragm and stem diaphragm

Both diaphragm and stem diaphragm valves are well known in the industry. Normal diaphragm valves are usually used in pharmaceutical processes; stem diaphragm valves, on the other hand, are frequently used in food-related applications. The diaphragm is sealing the product area hermetically against the atmosphere. Accordingly, this valve type complies with the requirements of aseptic processes. Due to the limited detection possibilities of the diaphragm material and the dynamically stressed fixation points between stainless steel and synthetic material, GEA primarily classifies the diaphragm technology as UltraClean.

Microbiological contamination risk	Possible sources of failure	Possibility of detection
Membrane deformation	• Occuring blisters because of unfavorable sterilization cycles	none
Surface damage	• Micro scratches • Insufficient heat transfer caused by low heat conductivity of the material	none
Dynamically stressed fixation points	• Undefined conditions at seal fixation points (e.g. temperature influences) • Detachable connection in product area	Conditional visual detection
Hollow space in the membrane	• Composites (e.g. multi-layer membrane)	none
Cracked membrane	• Fatigue fracture • Precedent membrane deformations / surface damages • Hydraulic or thermal pressure hammer	Visual detection



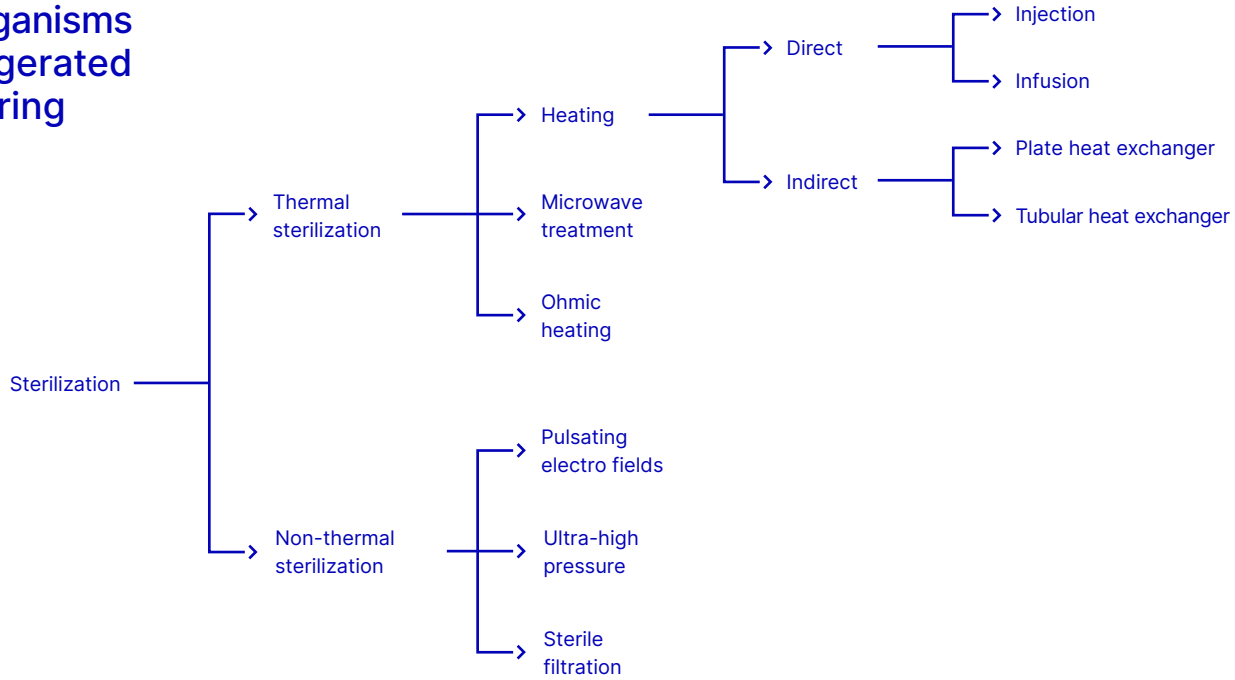
HYGIENIC CLASS ASEPTIC

In the Aseptic hygienic class, everything revolves around the commercial sterility and the endeavor to prevent any introduction of germs after product sterilization under all circumstances.

Aseptic applications focus on three areas of equipment: sterilizing products, conveying / holding products in a sterile state, and filling products in a sterile state. Aseptic processes stand for long-life and / or highly refined products, manufactured specifically for specific consumer groups. In addition to classic UHT milk products, medical nutrition and baby food also fall into this hygienic class.

“Commercial sterility means the absence of microorganisms capable of growing in the food at normal non-refrigerated conditions at which the food is likely to be held during manufacture, distribution and storage.”

Codex Alimentarius Commission (WHO/FAO) CAC/RCP 40-1993



Product sterilization

Sterilization of a product can be achieved by a wide variety of processes. The diagram shows an overview, but combinations of processes are also being investigated time and again, which, in the sense of the “hurdle concept”, aim at an overall reduced treatment of the product with complete sterilization. As a general rule, the more valuable the product and the more heat-labile the food matrix, the more complex the technologies used, from sterilization to valves to filling machines.

Maintaining sterility

In order to keep a product sterile, the installation needs to be highly automated and always kept in a defined overpressure. Furthermore, the installation has to be perfectly cleaned and sterilized in-place. If the product gets stored in a tank before filling, the tank needs to be maintained under pressure by means of sterile gas. Aseptic process components greatly contribute to the aseptic operation of an installation.

Sterile filling

Aseptic product filling is a complex field and takes various criteria into account. Nevertheless, any aseptic filling machine must fulfill several factors: In the area of the filling valves, the machine must operate in clean-room conditions with filtered air, and a laminar flow against the container filling direction has to be ensured. On-place cleaning and sterilization complete the basic criteria. To ensure aseptic filling across the production chain, the container and cap of a commercially sterile product must be pre-sterilized and kept sterile until the final hermetic seal.

Aseptic valves

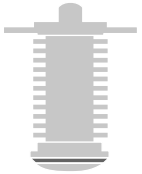
Aseptic valves are characterized in particular by their uncompromising hermetic sealing of the valve stem and the minimization of contamination risks.

Unlike the lower hygienic classes, hermetic sealing of the product chamber against the environment (atmosphere) is mandatory for aseptic valves. In addition, the expected contamination risks are lowest. In combination with the detection possibilities that are particularly given with metal bellows, this results in the highest rating. Aseptic valves are subject to special requirements in the plant due to the regular sterilization cycles and thus frequently changing temperatures.

PTFE bellow

Valves equipped with PTFE bellows are well known in the aseptic market. The main difference between PTFE and stainless steel bellows is their possibility of failure detection. Other than with stainless steel bellows, and similar to the diaphragm / membrane technology, a deformation and / or partial damage of the hermetic seal is more likely to occur than a full crack. In contrast to the diaphragm / membrane, this valve concept does not include dynamically forced sealing connections, and due to the fabrication method the risk of blistering is considerably reduced.

Microbiological contamination risk	Possible sources of failure	Possibility of detection
Bellow deformation	• Flow combined with high temperature • Cold flow in the seat area • Valve activation during sterilization • Hydraulic, thermal or mechanical pressure hammer	none
Surface damage	• Micro-scratches • Insufficient heat transfer caused by low heat conductivity of the material	none
Cracked bellow	• Fatigue fracture • Precedent bellow deformations / surface damages • Hydraulic, thermal or mechanical pressure hammer	Visual detection



Stainless steel bellow

Aseptic valves with stainless steel bellows are considered the highest class of aseptic valves. This is due to the material and the permanent joint at both sides of the bellow, as well as the bellow monitoring in the process.

Microbiological contamination risk	Possible sources of failure	Possibility of detection
Cracked bellow	• Fatigue fracture • Hydraulic, thermal or mechanical pressure hammer	• Visual detection • Optional via temperature with steam barrier • Optional via level with liquid, sterile medium

THE RIGHT VALVE FOR EVERY PROCESS

The choice of the right valve technology is based on sound knowledge of the product and process. Both the intrinsic product factors and the extrinsic factors during storage and transport, as well as the respective consumer target group, are decisive.

It is clear that a final decision on the optimum valve technology must be made anew for each installation, taking into account the respective process.

The table on the next page shows an exemplary list of typical products for the hygiene classes and should serve as an initial orientation in a decision-making process. The symbol shown indicates the minimum valve standard to be considered in the respective process steps. A valve-side upgrade of the installation can be achieved by equipping process steps with valves that meet a higher hygienic standard than the minimum recommended.

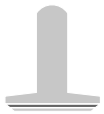
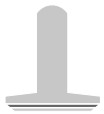
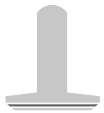
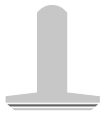
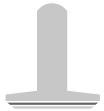
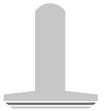
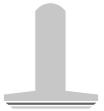
Hygienic classes

Aseptic valves with stainless steel bellow
Aseptic valves with PTFE bellow

Stem diaphragm
Hygienic seat valves with sterile lock

Hygienic seat valves
Hygienic butterfly valves

VDMA Hygienic classes:
I – III: Hygienic, IV: UltraClean / ESL, V: Aseptic

	Product	pH value	Distribution	Shelf-life	Storage	Preparation	Preservation	Filling
Aseptic (V)	UHT milk, UHT cream	> 4.5	ambient temperature	> 3 months				
	Ice tea (still)	> 4.5	ambient temperature	> 12 months				
	Soft drinks (still)	> 4.5	ambient temperature	several months				
UltraClean / ESL (IV)	Fruit juice	≤ 4.5	ambient temperature	several months				
	Ice tea (still)	≤ 4.5	ambient temperature	> 6 months				
	Fruit yoghurt heat-treated	≤ 4.5	ambient temperature	> 5 weeks				
Hygienic (I – III)	Fruit yoghurt	≤ 4.5	chilled	2 – 4 weeks				
	Beer	≤ 4.5	ambient temperature	> 6 months				
	Wine	≤ 4.5	ambient temperature	> 1 year				

Decision-making

The final classification of valves into hygienic classes is always subject to further evaluation on the basis of the requirement profiles and feature weightings known only to the user. In addition to the factors already mentioned, particular consideration must be given to the influence on follow-up costs, including the maintenance and inspection work to be carried out in order to be able to continuously guarantee reliable production. Just as in all other areas of an installation, it is also necessary to assess which valve concept is best suited to the existing conditions for the process valves. From this point of view, there are sometimes fluid transitions between the hygienic classes described, which must be evaluated by the plant operator and the person responsible for the product alone. With our comprehensive product portfolio and many years of experience, we at GEA Flow Components aim to support current and future decision-makers in these considerations and to provide the right valve technology for every process.

Engineering for a better world.

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