GEA Tuchenhagen VESTA® Sterile Technology

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Introduction

As one of the world's leading process component manufacturers, GEA Tuchenhagen has been supplying products to the pharmaceutical, biotechnology, fine chemistry, cosmetics and healthcare industries for the past 75 years.

One of the basic requirements in such industries is the ability to meet the highest hygiene and sterility standards. GEA Tuchenhagen takes account of these factors right from the initial design phase, ensuring they are consistently implemented.

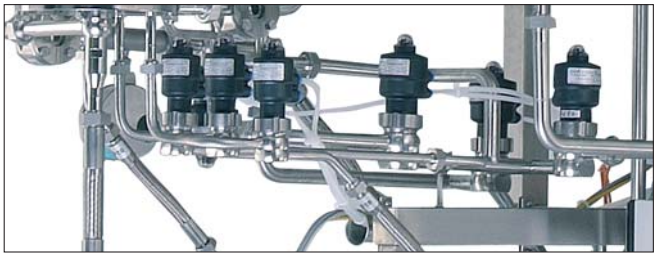
The name GEA Tuchenhagen stands for customised systems that can be configured from amongst the company's wide product range to create innovative, cGMP-compliant solutions.

A leader in the field in hygienic valve technology, GEA Tuchenhagen enjoys a worldwide reputation for products which have contributed significantly towards making process technology what it is today.

GEA Tuchenhagen's many years of experience in the manufacture of hygienic stainless steel instruments give the company an enormous knowledge base to draw on in developing all its innovative products.

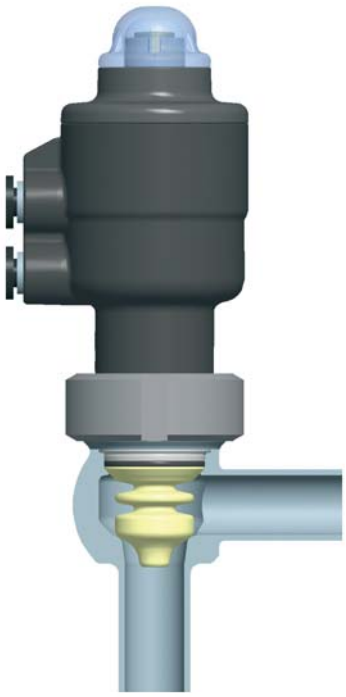
Pocket-free instrumentation

The ideal configuration for a processing system is a straight pipe linking each of the process components. Lack of space, however, invariably makes pipe fittings a prominent feature in system design, not only rendering assembly more difficult but also necessitating more planning and qualification work. For several decades now, GEA Tuchenhagen has been addressing the challenge that this trend presented, developing an inline-based range of pocket-free, self-draining valves. GEA Tuchenhagen is specialised in developing stainless steel valves for sterile and hygienic applications. Specialisation is the one factor that enables us to consolidate our advanced position as developers at a level necessary to assure steady growth, addressing more sophisticated demands on the product as well as intensifying competition. By continuing to develop its valve technology at an intensive pace, GEA Tuchenhagen is also able to anticipate future requirements in terms of dependability and safety.



VESTA® Technology

VESTA® sterile valves have been developed specifically for use in pharmaceutical processes and are designed for applications ranging from laboratory use to complex processing systems. By preventing the ingress of product contaminants, VESTA® sterile valves form the basis for a sterile, reliable process system. VESTA® sterile valves feature the following design characteristics:

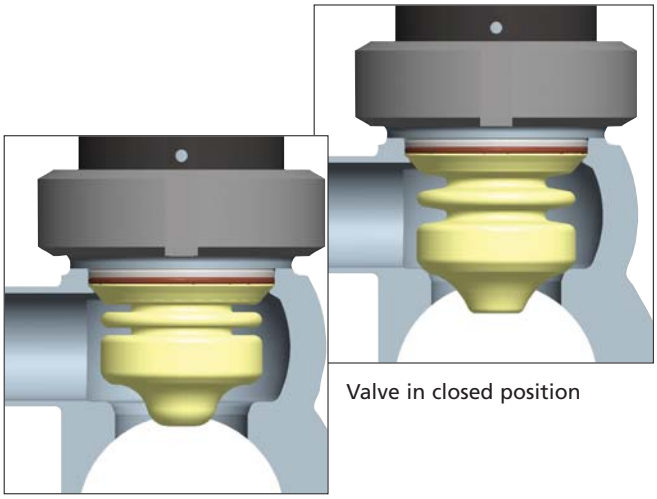


Features

- Small, compact design combined with high flow rate
- Inside contour flow-optimised body acc. to EHEDG/cGMP
- Valve bodies designed for natural draining
- Pocket-free body
- One-part, homogeneous PTFE bellows-type seals for hermetic sealing action
- Extremely long lifetime of PTFE bellows
- Easy, safe maintenance with no loose parts

Benefits of VESTA sterile valve technology

VESTA® sterile valves represent a full range of process technology valves. As sterile production processes demand that any migration of substances between the processing zone and its ambient area be prevented, a hermetically secure sealing system is essential. VESTA® sterile valves meet that requirement by utilising a bellows-type sealing element. Conventional shut-off valves are unsuitable on account of the valve spindle's reciprocating motion ('shuttle' effect). The bellows offers a means of sealing the inner processing zone hermetically, keeping it permanently separate from the surrounding area. Aseptic bellows seals ensure the integrity of the processing zone and compensate for the valve stroke.

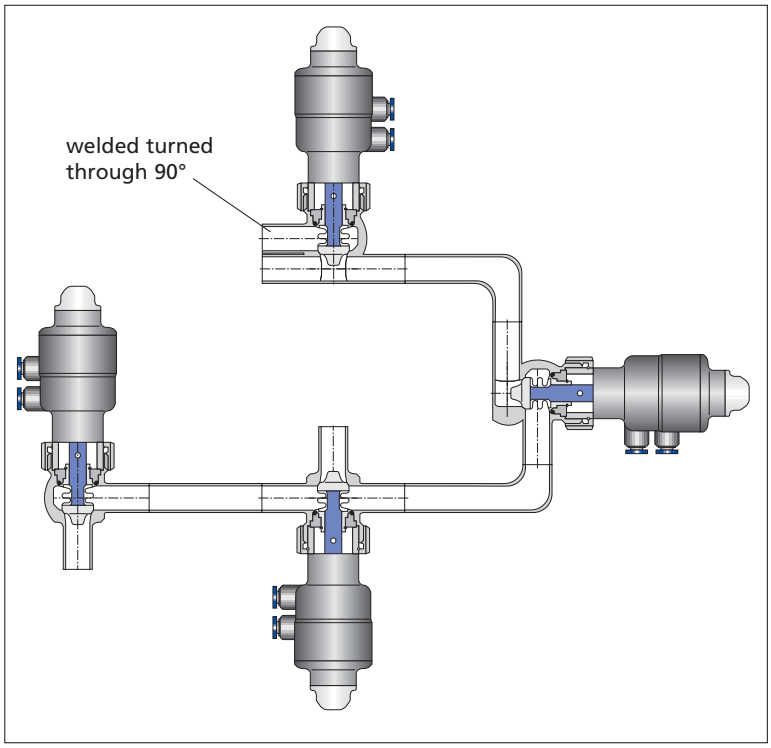


Valve in closed position

Valve in open position

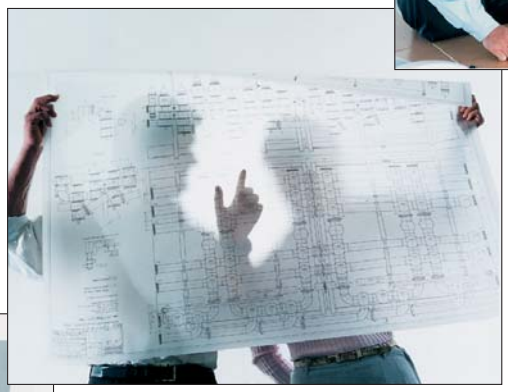
Small, compact design

Small and compact, VESTA® sterile valves are specially shaped to permit high-volume flowrates despite their small size. Seat valves have a small sealing area, allowing them to achieve high performances even with small actuators. Due to their circular sealing cone geometry, even a slight lift exposes a large-sectioned orifice. A relatively short lift is enough to open the orifice to its full cross-section. This results in low flow resistance, as reflected by the high Cv figures. The comparatively short stroke minimises deformation of the active bellows, prolonging the sealing element's service life. With its circular cross-section, the bellows is mechanically extremely stable. Using a seat valve structure allows the sealing cone to be dimensioned to practically the same size as the pipe cross section. Benefits include a sealing surface with minimal product contact as well as small actuators. Due to its conical shape, process pressure only acts on one side of the seal when in the closed position. Any reverse pressure will support the valve's closing action, positioning the cone securely in the seat. In seat-type valves it is impossible for a buildup of reverse pressure to open the cone by mistake. Using this operating principle maximises the production process's dependability.

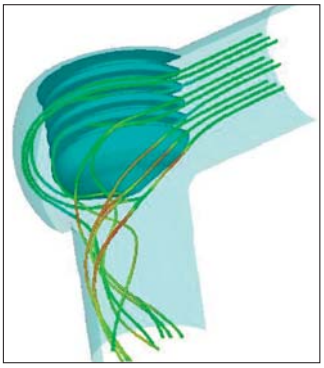


Development and conception

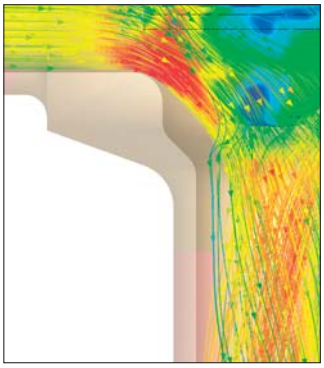
Our work is constantly focused on finding solutions to new challenges and the special needs of customers who frequently offer suggestions. Cooperation between customer care, engineering and design staff is close, enabling such challenges to be implemented in the shortest possible time.



The valve bodies' flow-optimised inside contour is developed using modern design systems. VESTA® sterile valves are developed and designed combining our experience with CAE (Computer Aided Engineering). We design our bodys with the CAE system which simultaneously presents them as three-dimensional objects on the screen, allowing component shapes to be optimised while still in the design phase. The steps which follow the design phase include hydrodynamic analysis and final testing, milestones which our components are required to achieve before they go into the field. During these phases it is possible to reduce flow resistance and minimise the effects of the flow on the wall surfaces and sealing elements.
VESTA® sterile valves undergo extensive testing before being integrated in the processing system. We operate a testing bay where VESTA® sterile valves are tested under real life conditions to ensure dependable, uninterrupted operation.



CAE engineering system



Flow simulation

Natural draining action

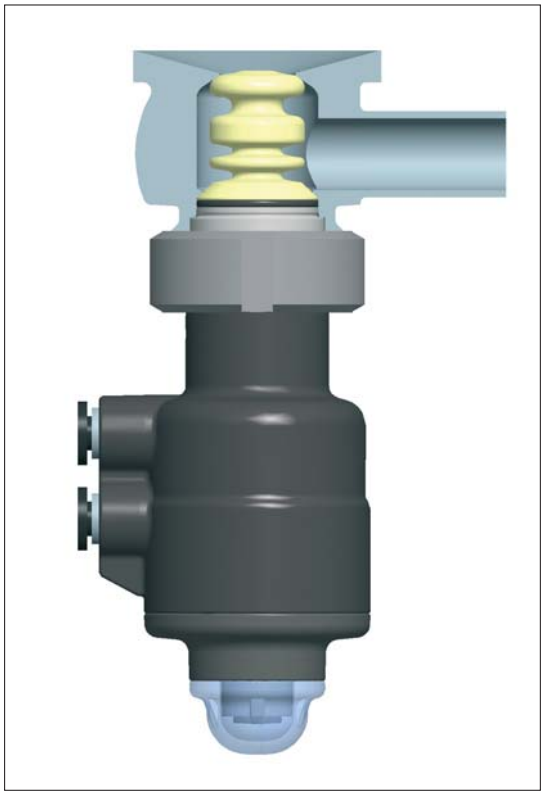
Unlike other valve types, seat valves possess a natural draining action. The sectional diagram illustrates the way the valve seats are configured to ensure a natural gradient between the valve connectors.

Being on a level with the piping, the body's inside contour and the natural gradient between the body levels combine to ensure that the valve body drains completely.

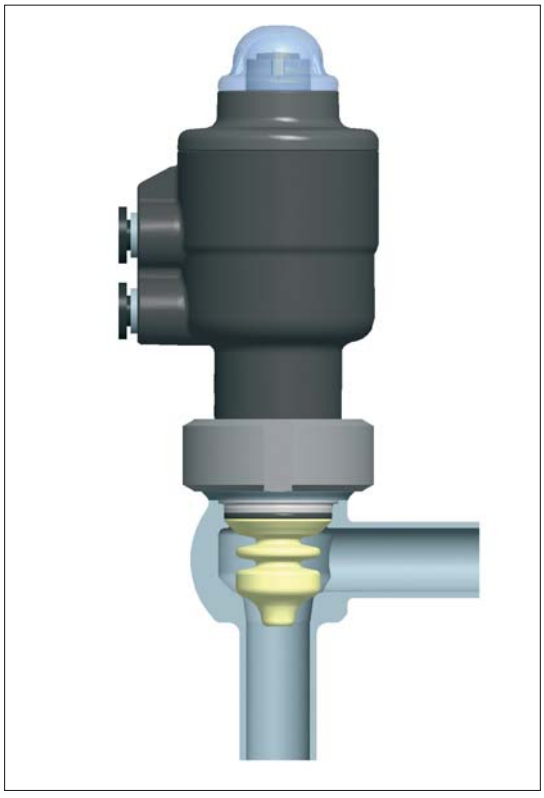
Seat valves feature no barriers that could obstruct the drainage of residual fluid, allowing it to accumulate and form a breeding ground for microorganisms.

Inside surfaces all feature wide-radius geometry to assist fluid drainage.

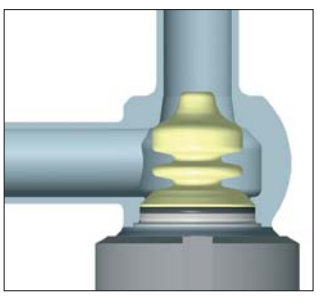
The VESTA® sterile valve is designed with a self-draining shape. The unit's design with its right-angled connector arrangement and the body portion between the pipe levels ensures easy, foolproof alignment when fitting.



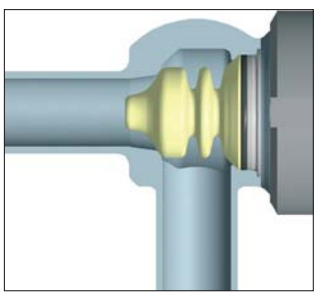
Sectional view of VESTA® body type HLA/T



Sectional view of VESTA® body type L, upright



Sectional view of VESTA® body type L, inverted



Sectional view of VESTA® body type L, horizontal

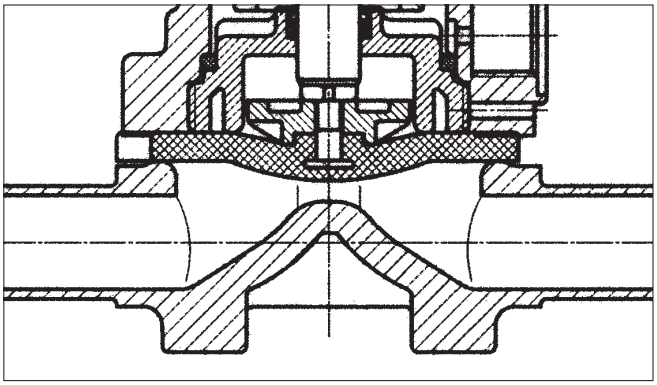
VESTA® Technology

Seat valve technology is a choice that enables to begin saving costs right from the planning stage.

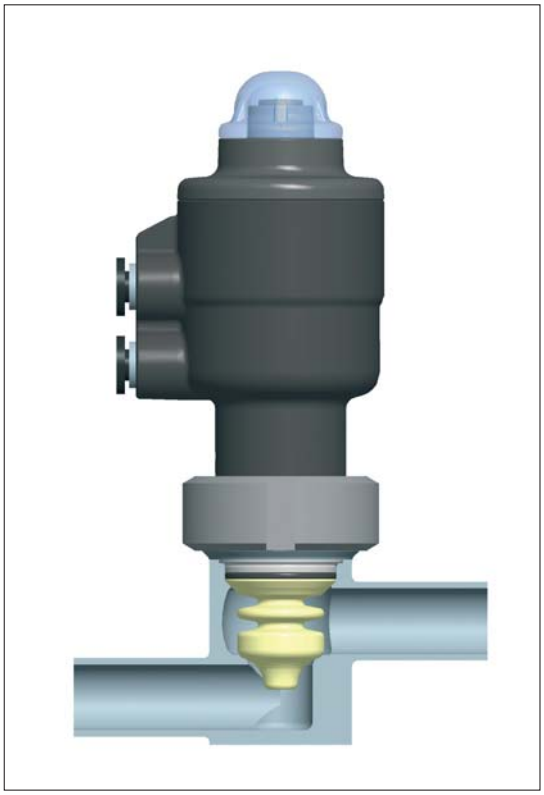
The valves offer foolproof alignment as well as easy integration. These units can help to reduce costs, featuring integrated fittings for simple assembly plus right-angled orientation and easy monitoring to facilitate plant qualification. All VESTA® valve bodies are self-draining both in the upright position and at throughflow level.

Valve bodies come in a variety of versions, providing a wide choice of bodys suitable for integration in horizontal as well as vertical lines. Each is designed for independent, reliable self-draining action. Low product surface tension assists self-draining.

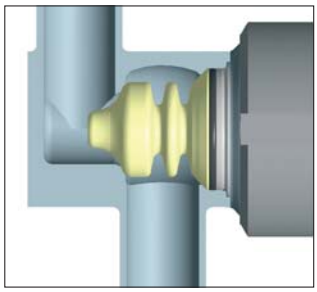
Liquids with a high surface tension tend to form droplets and adhere to surfaces. Venting with sterile air is therefore absolutely essential to ensure the processing system is completely dried.
Even sterile air, however, will not adequately dry liquid held up in dead zones in pipe connectors and sharp-edged corners. This is why it is vital to provide a wide radius, particularly at the point where the body meets the sealing diaphragm.



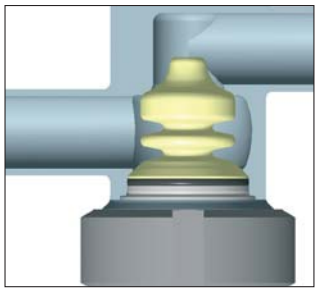
Sectional view of a diaphragm valve



Sectional view of VESTA® body type B, upright



Sectional view of VESTA® body type B, horizontal



Sectional view of VESTA® body type B, inverted

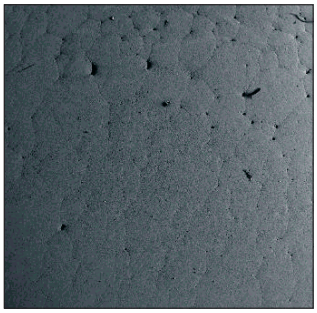
VESTA bellows

The core element of all VESTA® sterile valves is a bellows made of TFM 1705 material. Its characteristics include resistance to practically all media, a high-grade surface (Ra ≤ 0.8 µm), the ability to form a crevice-free hermetic seal and a wide pitch between bellows folds for optimum CIP/SIP cleaning. GEA Tuchenhagen's patented bellows seal system also ensures that the inner processing area is kept hermetically sealed off from the surrounding atmosphere in all processing phases including critical ones. The bellows design has been configured using a CAD system. Fold geometry, number of bellows folds relative to nominal size and valve stroke, alternating strain (compression/stretching) are factors with a major influence on continuous, dependable valve function. During valve actuation, the bellows geometry deforms within the elastic limits. This forms the basis for an extremely long lifetime.

Properties of TFM 1705

TFM 1705 belongs to the latest generation of modified PTFE materials. Initially, TFM 1705 is a powdery material. It is compression moulded into semi-finished products which are used as the raw material for manufacturing PTFE bellows. Compared with conventional PTFEs, this material's significantly lower melting point ensures particularly high homogeneity and density levels and smooth surfaces when sintered. The photographs below illustrate how the material textures differ, TFM 1705 clearly exhibiting more homogeneity (SEM photos; approx. 50x magnification). The material's homogeneous composition makes it practically impossible for microorganisms to gain a hold. The material also stays consistently homogeneous over long periods of use, even when subjected to limit stresses (pressure/temperature/media effects/alternating strain).

TFM 1705's advantages also include excellent mechanical properties, slow flow behaviour and a high degree of flexibility. TFM 1705 is an approved material according to the Code of Federal Regulations, Title 21 § 177.1550 "Perfluorcarbon resins" of the Food and Drug Administration (FDA), which simultaneously documents its biocompatibility as specified by USP Class VI.



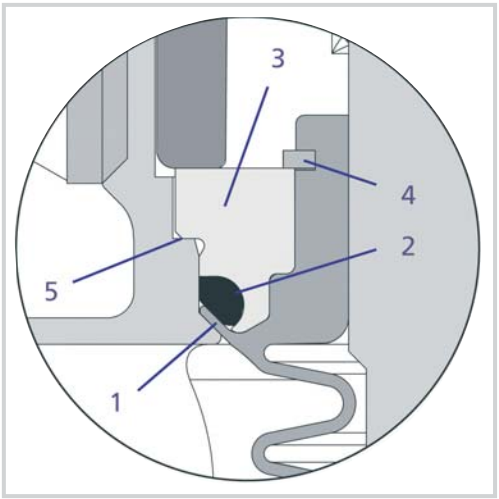
Conventional PTFE

TFM™ 1705 PTFE

How PTFE bellows are manufactured

The raw material used to make PTFE bellows consists of compressed and sintered rods. Products are manufactured using an ultra-modern CNC machining process. Many years of experience in manufacturing bellows are the factor that guarantees top quality and dimensional stability plus excellent finish. Products are continuously monitored right through the manufacturing process to the final quality check, ensuring that high quality standards are maintained. This also gives plant operators the assurance of dependable production process operation even after a change of the bellows. A unique feature of the PTFE bellows for VESTA sterile valves is the fact that they are made with guaranteed material properties (tensile strength/elongation at break/raw density). Material acceptance test certificates to EN 10 204 / 3.1 can be provided on request.

Patented bellows sealing system
GEA Tuchenhagen's patented bellows sealing system ensures that the interior of the valve is kept hermetically sealed off from the atmosphere in all processing phases including critical ones. The elastomer O-ring (2) is only



The unique features of this bellows sealing system:
1 Sealing by a thin-walled sealing diaphragm
2 Permanent compression by an elastomer O-ring
3 Under excess pressure conditions, product forces are compensated by a metallic thrust collar
4 Under vacuum conditions, protection is provided by a circlip
5 Defined pretension by metallic stop

provided to keep the sealing lip (1) of the PTFE bellows under pressure and is positioned away from the product. Long-term sealing system integrity is obtained by applying extremely narrow manufacturing tolerances, and in this context the elastomer O-ring, a precision-made component with a low CS (compression set) value, plays a central role. The groove geometry for the elastomer O-ring is designed to ensure that the O-ring will not be overstressed even when subjected to temperature limit stress levels.

An important feature is the fact that static and dynamic stress on the PTFE bellows, as opposed to diaphragm valves, are kept strictly separate. In diaphragm valves, the sealing diaphragm is clamped in an "undefined" position within the body and the added material needed to perform the lifting action (contouring) produces significant dynamic stress at the fixing point. Each time the valve is actuated, the extreme flexing action strains the material to levels up to and beyond its property limits. These strains on the diaphragm combine to reduce its service life. VESTA® bellows, on the other hand, feature static sealing within the body which means that absolutely no dynamic strain occurs during actuation. Neither actuation itself nor hydro–dynamic factors can place the seal under dynamic strain. This configuration ensures a durable inside-to-outside seal plus a much longer service life compared with diaphragm-type seals.

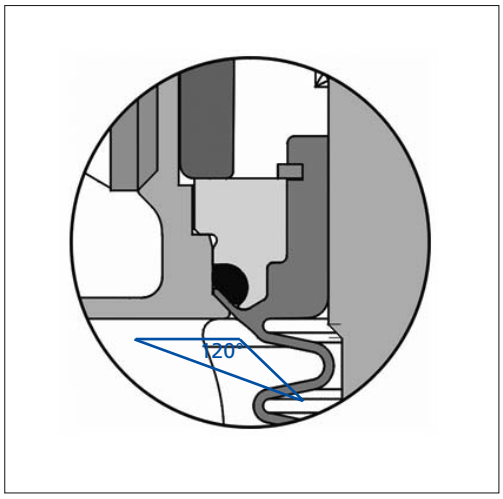
PTFE bellows – their features
PTFE bellows are suitable for universal applications, particularly the highly sensitive, complex processes encountered in the pharmaceutical industry.

Here is a list of the features which make PTFE bellows unique:
- One-piece component
- Products are manufactured using an ultra-modern CNC machining process – no extra seals within the product zone.
- Wide pitch between folds for optimum CIP/SIP cleaning
- Low particulate adhesion tendency
- Excellent chemical resistance to practically all media
- Smooth surfaces (Ra ≤ 0.8 µm)
- Good hydrodynamic properties
- Easy, safe maintenance

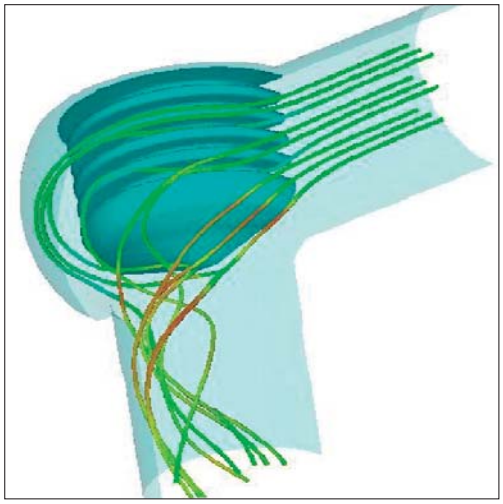
Hydrodynamically designed inner contour

Due to their inline design, VESTA® sterile valves are ideally shaped for cleaning and extremely reliable. Their inner contours feature no edges, domes or crevices. That also applies to the way the bellows element is integrated.

The bellows element is sealed to the body using GEA Tuchenhagen's patented sealing system to ensure that the PTFE sealing lip is kept under static pressure, forming a durable seal against the body. The PTFE sealing lip allows the process medium to pass along the bellows at an obtuse angle of about 120°. VESTA® sterile valve technology is specially designed to ensure gentle flow, featuring easily accessible inner surfaces and wide-radius geometry for simple, most efficient cleaning.



Sealing edge in VESTA® sterile valve

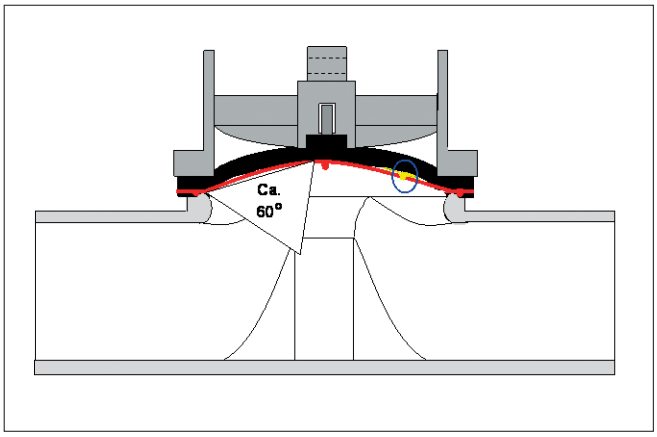


CAE engineering system

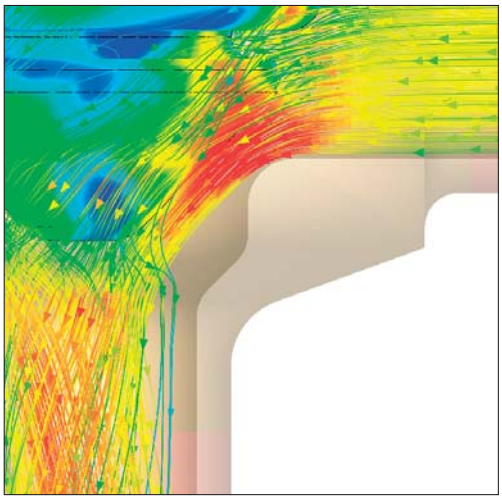
VESTA® bellows are simple to handle due to the PTFE material's non-stick properties, the wide gap between folds and their one-piece design with no additional connecting elements. Years of hard service in day-to-day operation have proven this bellows to be a durable, dependable sealing system.

The point where a diaphragm valve is clamped to the flange forms a sealing edge with crevices which are difficult to access for cleaning.

The lifting action of the diaphragms can draw product residues into the diaphragm's clamping area.



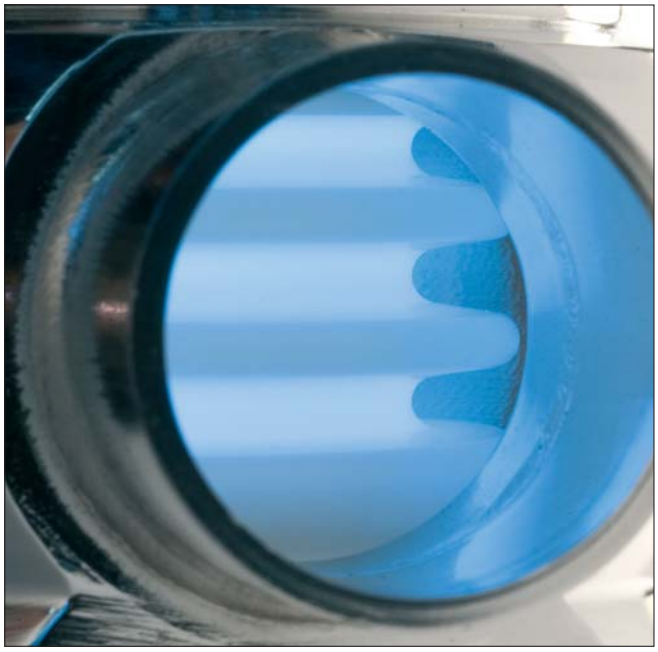
Sharp sealing edge in a diaphragm valve



Flow simulation

Bellows monitoring

Unlike other sealing systems, PTFE bellows feature a wear indicator to show when the bellows has been in place for a long period. When the material begins to show signs of fatigue, the surface texture turns white. This is the first sign that the material is weakening. Due to its toughness, PTFE is a material that is unlikely to tear suddenly. Microscopic surface damage cannot cause fatigue notching. These factors allow the bellows to be monitored and maintenance intervals to be scheduled. A bellows in perfect condition is identified by its homogeneous white colour. The bellows texture can easily be inspected using a torch.



View through bellows

Bellows versus diaphragms

Bellows exhibit advantages which make them clearly superior to ordinary diaphragm seals.

	VESTA® bellows seals	Diaphragm seals
Clamping to body	separately located static and dynamic seals	combined strain
Sealing system	patented sealing design ensures defined, durable seal	flange compression seal
Sealing edge/rib	very low sealing edge, easy to clean, lines meet in valve seat	sharp sealing edge at transition to body, entrapment of product residues, severe compression at sealing rib
Sealing element	thin-walled, flexible bellows, very long service life	rigid, thick-walled sealing diaphragm, liable to crack
Seal positioning	self-centring valve insert	4-hole flange
Body	self-draining inline body	valve body with barrier, angled to drain, liquid hold-up area between sealing rib and diaphragm In order to increase to lifetime of the diaphragm certain torques for the srews need to be respected.

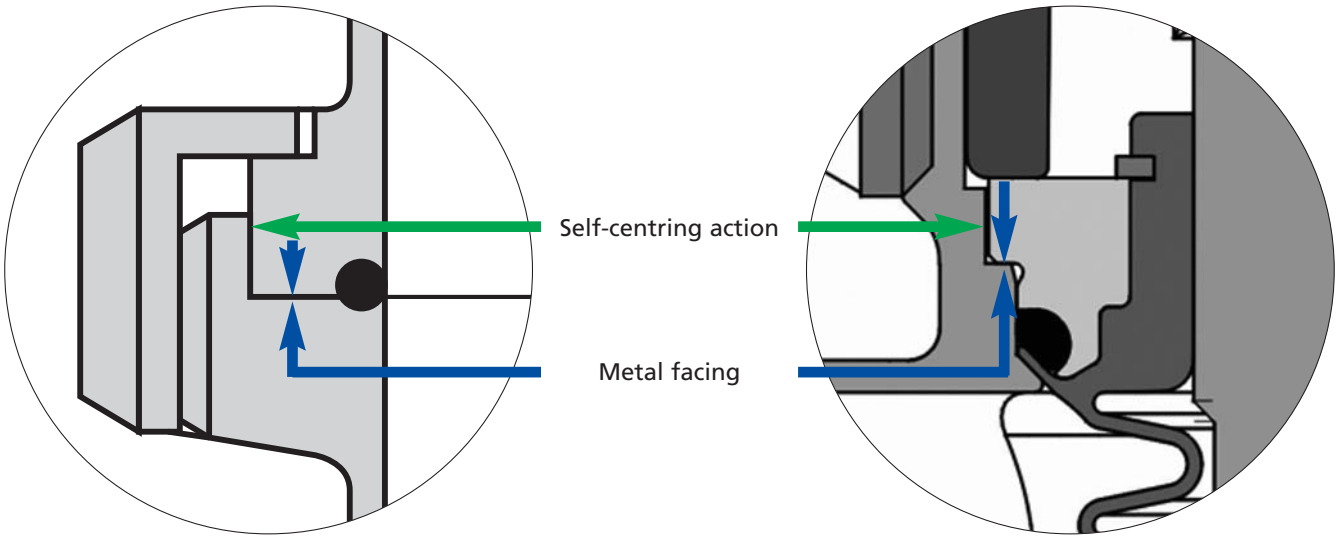
Groove nut connections

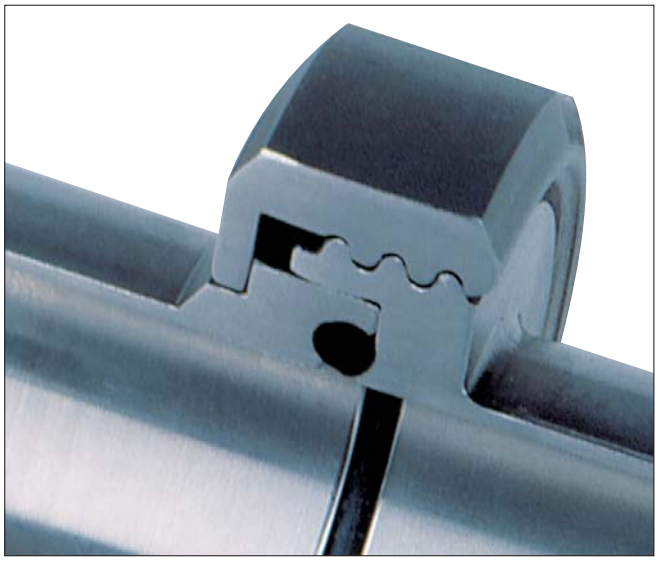
The central groove nut connection featured in VESTA® sterile valves is a type of connector standardised to DIN 11864 and recommended in ASME-BPE. In a VESTA® sterile valve, the groove nut is used as an easy-to-service central screw connecting the actuator and the valve body. Central screw connectors exhibit the following features:

a. Sealing by a thin-walled sealing diaphragm
b. Permanent compression by an elastomer O-ring
c. Under excess pressure conditions, product forces are compensated by a metallic thrust collar
d. Under vacuum conditions, protection is provided by a circlip
e. Defined pretension by metallic stop

Sealing system in ASME-BPE groove nut connectors

The sealing function in a VESTA® sterile valve is performed by a thin product-oriented PTFE lip. An O-ring located behind the sealing lip ensures a constant pretensioning force.





Maintenance

Quick, simple handling is a major feature of these valves when carrying out servicing and maintenance jobs on site. Routine checks and replacement of the PTFE bellows involve no more than to loose the groove nut and taking the whole valve insert out of the body. VESTA® sterile valves have no loose attachments and the groove nut is connected to the valve insert.

Standard tools are suitable for all servicing work including bellows replacement as well as actuator system maintenance. VESTA® sterile valves are fitted with a groove nut linking the body to the actuator.
The self-centring valve insert helps to ensure that the bellows element is effectively and durably sealed inside the body. They are practically impossible to assemble wrongly. The parallel guide provided inside the body for the valve insert ensures repeatable, dependable sealing action. The groove nut is attached to the valve insert and serves as a simple, secure fixing element. The groove nut has a self-locking thread to prevent loosing. The metal stop between each of the load-bearing structures distributes the load evenly amongst sealing elements and prevents excessive strain by restraining the groove nut. VESTA® sterile valves are absolutely tight as soon as they have been assembled. Easier assembly resulting from fewer parts– no more screws, nuts, washers and pressure rings to handle, just one component. As the fitting position is exactly defined, it is practically impossible for damage to occur to the clamping area. Using a groove nut to form a secure connection between the body and the drive facilitates assembly as well as maintenance work.

The central groove nut is an ASME-recommended type which provides reliable protection against inadvertent opening. To perform maintenance jobs, the groove nut is slackened. Any residual pressure inside the process cavity is released safely.
The actuator's spring tension relaxes as soon as the groove nut is opened. Once the spring has de-tensioned, the actuator element can be removed by fully unscrewing the groove nut.

Slacken groove nut and withdraw valve insert

Unscrew bellows

Check bellows

No loose parts – just assemble the valve and...

... you're done!

Manufacturing technology

Modern processing equipment for the pharmaceutical industry is almost manufactured exclusively using the orbital welding technique, a method that offers the benefit of repeatable weld quality in addition to preserve component material quality.

This process is practically unaffected by external factors like the operator or the weld position. The automatic welding operation can be performed repeatable in a short time and fine-tuned to suit the material and the workpiece. As orbital welds take a short time to perform, they introduce less heat than manual welding operations, producing a reduced, narrow heat effect zone.

They reduce oxidation effects on the surface as well as solidification (recrystallisation) after melting.

The purpose of the welding gas is to keep the melt protected from oxygen and to add gas that will improve

the quality of the weld. Orbital welding heads provide effective shielding from the oxygen-rich atmosphere and maintain a continuous flow of welding gas to the seam.

Orbitally weldable components can of course also be processed using conventional manual welding.

Orbital welding technology and automated welding processes on mechanical turning equipment are today's most dependable methods as far as repeatability is concerned.

Stainless steel welding involves a wide variety of factors that can affect the quality of the weld and the heat-affected zone. The following is a description of the most important influencing factors which will help readers to understand each stage of the work in context.

Factors affecting the welding process

Ferrites are the ferromagnetic or body centred structural constituents in stainless steels with a high iron content. Within the series of stainless steel materials, the proportion of austenite that occurs while solidifying increases in relation to higher proportions of austenite formers in the alloy (e.g. Ni, C, N). Austenitic solidification means that the Δ-Fe percentage stays small. Machining processes such as turning and grinding can cause changes in a material's structure. They can turn a material that was originally austenite into a material known as martensite. The latter is magnetic, a property that can be measured using a ferritoscope. This method, however, cannot be used to identify whether the material is Δ-ferrite or martensite.

The Δ-ferrite percentage as defined by the Basle Standard covers magnetic constituents in the stainless steel which consists not only of the steel's ferritic solidification form but also of martensite. The parameter measured is the magnetism of the material, consisting of martensite and ferrite.

Material	**Crystallisation forms** (solidification forms)
1.4404	Austenite +ferrite
1.4435	Austenite +ferrite
1.4529	Austenite
1.4539	Austenite
2.4819 (C276)	Nickel base material

The tendency to form ferrites can be counteracted using suitable flux agents and processing steps.

During welding, the crystallising action (e.g. austenitic or ferritic) can be influenced using high-alloy welding fillers and inert gas containing nitrogen. The steel's various alloy constituents also affect the melt's crystallising behaviour.

Examples:
Chromium tends to solidify in a ferritic form.
Nickel tends to solidify in an austenitic form.
Iron tends to solidify in a ferritic form.
Titanium stabilises the austenitic solidification process, its preferred titanium carbide formation preventing the formation of chromium carbide.
Carbon promotes austenitic solidification.

The effect of temperature
The elements in chrome nickel stainless steel alloys react with the oxygen in the air from temperatures of 250 °C upwards. This oxidation of the alloy constituents in the weld area is visible as a slightly yellowish to violet discolouration, indicating a change in the material's surface in the heat-affected area. In practical terms this means that flooding the weld with inert gas before and after welding is just as important as forming during the welding operation. To put it a different way: As long as the temperature of the material is above 250 °C, oxygen must be expelled from the ambient atmosphere.

Effects of the gas mixture
The purpose of the inert welding gas is to shield the melt from oxygen. It also promotes current transfer when in an ionised state and influences the weld's solidification behaviour. Inert gases used for welding are usually argon-based mixtures. Pure argon is used as well as argon-hydrogen and argon-nitrogen mixtures. Nitrogen promotes the formation of austenitic structures.

Effects of the alloy constituents
Steel's different alloy constituents affect it in different ways. Titanium (Ti) binds carbon (C) which has a stabilising effect. Carbon (C) can react with chromium (Cr) to form chromium carbide (CrC), thereby reducing the chromium content. The reduction in chromium content increases corrodibility. Silicon (Si) reinforces the crystalline structure.

Traces of phosphor (P) occur as an impurity deriving from the manufacturing process. Traces of sulphur (S) also occur as an impurity deriving from the manufacturing process (Marangonie effect). Oxygen (O2) occurs as residual oxygen deriving from the manufacturing process and as a deposit adhering to the material's surface. This is why polished hex nipples are sometimes used to reduce discolouration on the weld. The polish smooths the outer surface, making it difficult for oxygen to adhere.

Weld preparation
Pipes, bends, flanged joints and pipe sleeves to be welded together should have matching thicknesses and diameters, sharp edges and be aligned as flush as possible. Misalignment or gaps will cause the pipe material to liquefy during welding, resulting in thinning of the wall. The current rules and regulations give concrete information on permitted tolerances.

Gaps
As no filler is used in orbital welding, gaps must be kept to a minimum (not over 0.1-0.2 mm, depending on pipe diameter), otherwise wall thinning or collapsed seams could occur in the welding area.

Welding fillers
Closed standard-type welding heads operate without filler rod feed. Manual welds are normally finished using higher-alloy fillers to counteract alloy depletion.

Welding
- Permit
  EN 729-2 / AD2000 HP0
- Welding procedure test
  EN 288-3 / AD2000 HP2/1 / 97/23/EG
- Welding supervision
  EN 719 / AD HP3
- Welders
  EN 287-1 / AD2000 HP3 / 97/23/EG
- Machine operators
  EN 1418 / AD2000 HP3 / 97/23/EG
- Re-stamping arrangement with TÜV Nord
- Certified examiners for endoscopy and radiography assessment

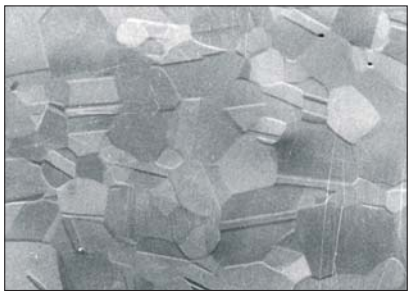
Dokumentation
- Conforms to pressure equipment directive and customer specification
- Drafts, drawings and parts lists generated on CAE systems
- Welded seams documented using as-built single-line isometry and recorded seam parameters
- Material certificates

WIG orbital welding system with enclosed cartridge system

Due to the mobility of ultramodern welding techniques and trained staff, seam welding is now a dependable, tried-and-trusted element in a processing plant. Orbital welding is a versatile technology, delivering reliable, consistent results that meet top quality standards.

Materials

Steel is generally regarded as a homogeneous material. Viewed through an SEM (scanning electron microscope), stainless steel will be seen to consist of numerous closely juxtaposed crystals. These crystals are characterised by a structure which is inherently uniform, the crystalline structure, which in turn depends on the melt's composition and the proportions of the substances present in it. This uniform crystalline structure is interrupted at the grain boundaries. The size of the crystals and their composition are the factors that determine a material's corrosion behaviour. The chromium-nickel-molybdenum stainless steels used in the pharmaceutical and biotechnology industries have different crystal forms.



Electropolished stainless steel surface

The primary form is austenite. Austenite describes the material quality. Stainless steel's magnetic constituents, collectively known as ferrite, represent an undesirable crystal form from the point of view of corrosion resistance. Ferrites are high-iron, low-chromium crystal forms which are much less corrosion-resistant than austenite. This is quoted as an indicator for corrosion resistance. Investigations into stainless steel's corrosion behaviour have shown that corrosion resistance can weaken if the crystal structure contains ferrite in proportions upwards of 1%. The ferrite phase proportion drops as the percentage of alloy in the steel rises.

There are rolled and wrought steels obtainable on the market with a defined ferrite percentage of < 1%, and these are able to satisfy the required level of corrosion resistance in the pharmaceutical industry. Materials that come in rod, rolled and as forged form have a compressed, homogeneous structure which is practically free of gas bubbles.

Castings, due to the way they are made, are liable to include gas bubbles which appear as holes on the surface when they are subsequently machined. Holes like these should be avoided as they can harbour microorganisms.

Grade 1.4435 (316L) stainless steel in rod, tube and sheet form, the material used to manufacture VESTA sterile valves, is origin an extremely high quality material as its ferrite content helps to testify. The large number of machining operations performed on the surface and the resulting deformation of its structure may raise the proportion of ferrite slightly. Machining the workpieces at a slow speed is therefore a crucial factor in maintaining the material's quality.

The material used by GEA Tuchenhagen always meets Grade 1.4435 and conforms to ASME-BPE Standard 316L. It is possible to achieve that quality by applying narrower tolerances to the flux materials Cr, Ni and Mo and by limiting the sulphur content to between 0.005 and 0.017%. This enables the material to meet the requirements specified by DIN 11866 and ASME-BPE.

VESTA® Manufacturing

Commercially available semi-finished Grade 316L austenitic products with no special restrictions are obtainable with ferrite percentages between 3% and 7%. The lower the ferrite content, the greater the homogeneity of the accompanying constituents in the stainless steel. Stainless steels with particularly low ferrite percentages exhibit consistently good material properties which play a significant role in the processing steps that follow.

The ferrite percentage is a measure of a material's corrodibility. Generally, stainless steels are regarded as corrosion-resistant steel materials. The more chromium and nickel it contains, the greater is the material's corrosion resistance.

If the orbital welding method is used to process modern stainless steel components, more than just the high-grade welding system itself is required to obtain good results. All associated processes need to be coordinated.

- Homogeneous material quality
- Minimal, consistent presence of accompanying constituents in the material
- Minimal thermal influence during welding
- Same thermal behaviour in any two components to be joined
- Exclusion of athmosphere

Together, the process steps needed to produce these characteristics form the basis of VESTA® sterile valve manufacturing, their target being consistent high quality. Perfect welding technique is a major factor in ensuring maximum product dependability.

Ferrite content measurement is part of the quality assurance procedure

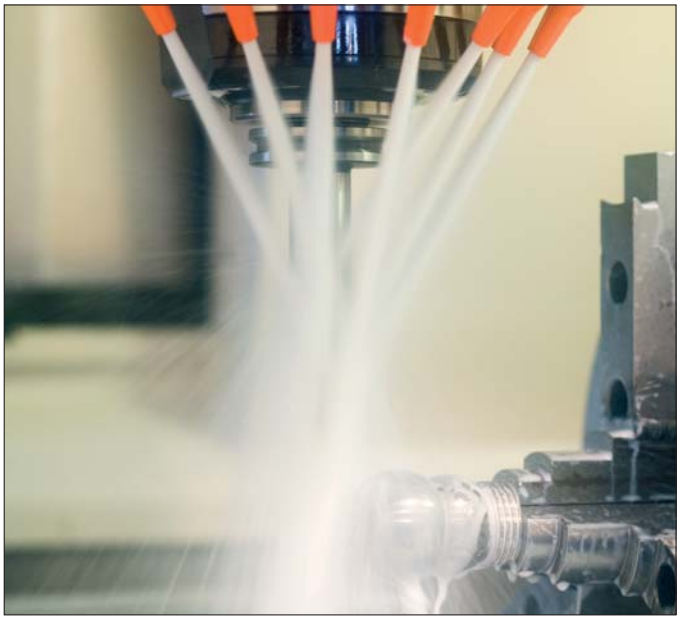
Stainless steel and its composition

DIN	AISI	DIN	C	Cr	Mo	Ni	Others
1.4301	304	X 5 CrNi 18 10	<0.07	17.0 to 19.0	2.0 to 2.5	8.5 to 10.5	0
1.4571	316Ti	X 6 CrNiMo Ti 17 12 2	<0.08	16.5 to 18.5	2.0 to 2.5	10.5 to 13.5	Ti 5%C to 0.8 Nb %C
1.4404	316L	X 2 CrNiMo 17 13 2	<0.030	16.5 to 18.5	2.0 to 2.5	11.0 to 14.0	0
1.4435	316L	X 2 CrNiMo 18 14 3	<0.030	17.0 to 18.5	2.0 to 3.0	12.5 to 15.0	S <0.025

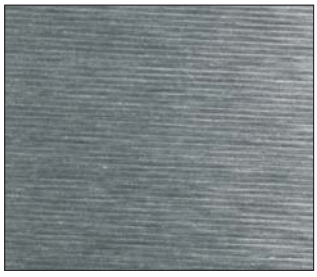
Surface treatment

Cleanability is regarded as essential for aseptic processes. Apart from other general requirements that demand a hygienic design, surface quality has an important role to play particularly in applications destined for use in the pharmaceutical industry. Surface quality is defined by its R_a value. The R_a value is the arithmetic mean of the roughness profile and is determined as specified in DIN/ISO 4287/1. The R_a value is obtained by taking the surface enclosed by the roughness profile and dividing it by the measured length.

Depending on what production process is used, a surface can take a large number of processing steps to create. Components to be used in the pharmaceutical industry are manually reworked using different grit abrasives depending on their original roughness to obtain the required surface quality. An important factor when working the surface is to ensure that the job is done in several steps using different, appropriately graded grits.

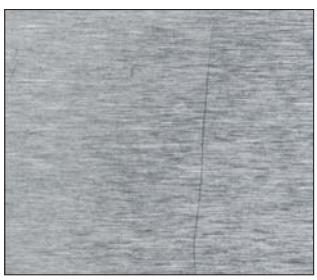


Stainless steel surfaces



Surface finish: machined, Ra 1.2 µm

Surface finish: fine-machined, Ra 0.8 µm

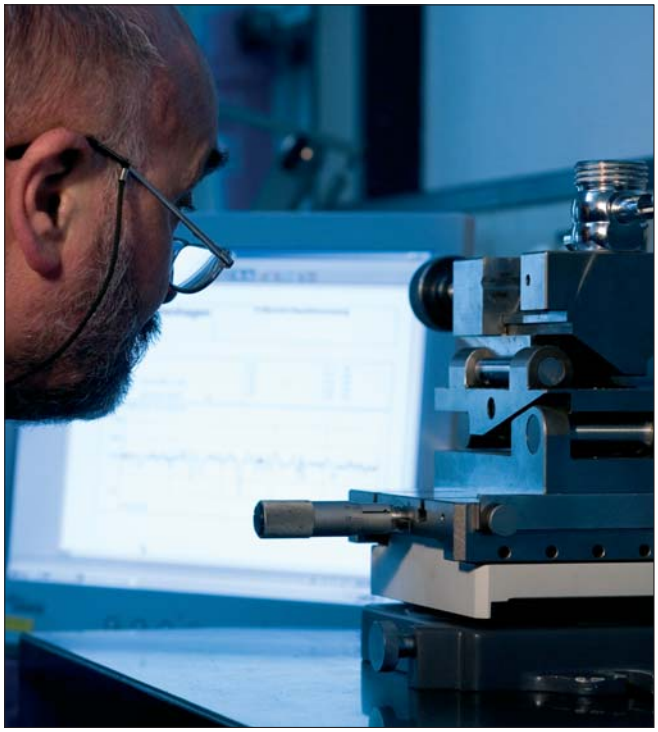


Surface finish: fine-machined and grinded, Ra 0.4 µm

Surface finish: fine-machined and grinded, Ra 0.2 µm

The grit is equivalent to the number of smallest lines per centimetre, becoming finer as the number increases. A manually executed surface ($R_a \leq 0.8$ µm) is usually produced in 3 grinding operations. Determining its roughness involves measuring the surface profile and calculating the roughness value using defined formulas. The most frequently cited values are average peak-to-valley height (R_a) and height root mean square (R_q).

A smaller degree of roughness goes some way towards facilitating the removal of bacteria from the surface and also reduces the tendency of deposits to adhere to it. Beyond a certain threshold this effect is reversed. Surfaces with a minor degree of roughness exhibit a thin laminar boundary layer, offering only poor protection against a turbulent flow. This threshold value is therefore economically speaking the best compromise between a surface's roughness value and its cleanability.

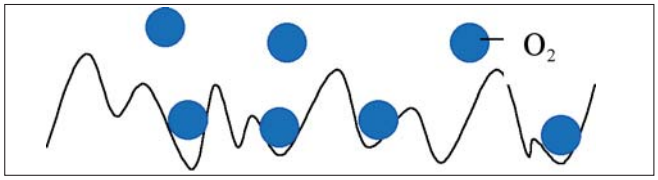


Surface requirements

Criterion	Surface features
Weld faults	To DIN EN, Group B
Scratches	Free of scratches
Visible boundaries	< 5% of the total surface, R_a value met
Notches	Notch-free
Grinding lines	Ra value met
Scratches	Diameter < 0.5 mm, Shiny base
Scratches	Length < 6 mm, depth < 0.1 mm, R_a value met
Surface cracks	Free of surface cracks
Surface inclusions	Ra value met, no penetration by test fluid
Surface residues	Free of surface residues

Influence of roughness

The roughness of material surfaces in pharmaceutical processing equipment has a major effect on processing and on the process in which the surface is integrated. Smooth surfaces not only facilitate cleaning and discourage microbiological deposits but also resist the tendency of atmospheric gases like the oxygen in the air to attach themselves. On account of its larger specific surface, a rough surface offers good conditions for oxygen to adhere.



Adhesions of oxygen molecules on a rough stainless steel surface area

A smooth surface means less oxygen attachment and short rinse times before and after the welding process as well as less discolouration. VESTA® sterile valves are electrochemically polished to obtain extra surface smoothness. This gives them the best prerequisites for perfect processing.

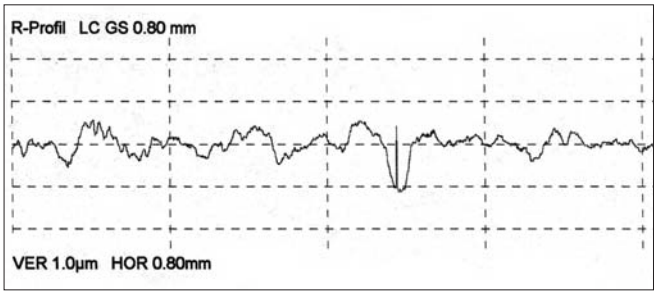
The mathematics of roughness

Designation	Description	Regulations
R_q	av. p.-to-v. height	DIN EN ISO 4287 ASME B46.1

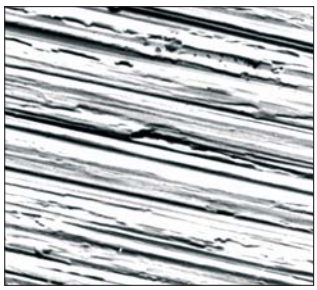
$$R_a = \frac{1}{l}\int_0^l |z(x)|dx$$

R_q	height root mean square	DIN EN ISO 4287 ASME B46.1

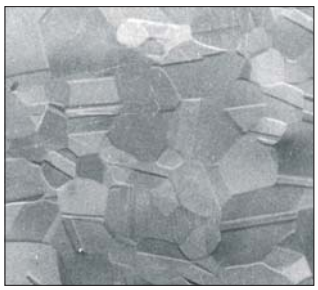
$$R_q = \sqrt{\frac{1}{l}\int_0^l z^2(x)dx}$$



Part of a surface measurement recording

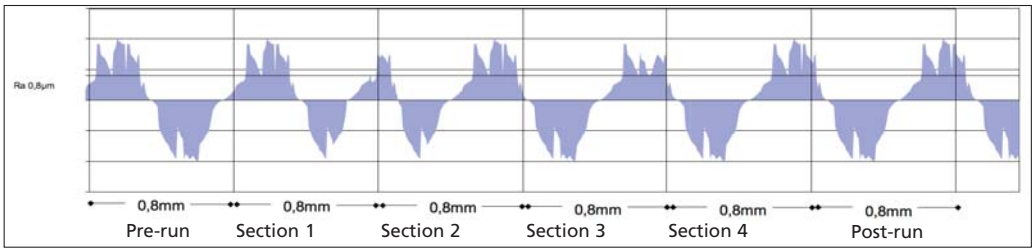


Stainless steel surface ground with Grit 400



Stainless steel surface ground with Grit 400 and electropolished

Quality check – Surface measurement determining its R_a value

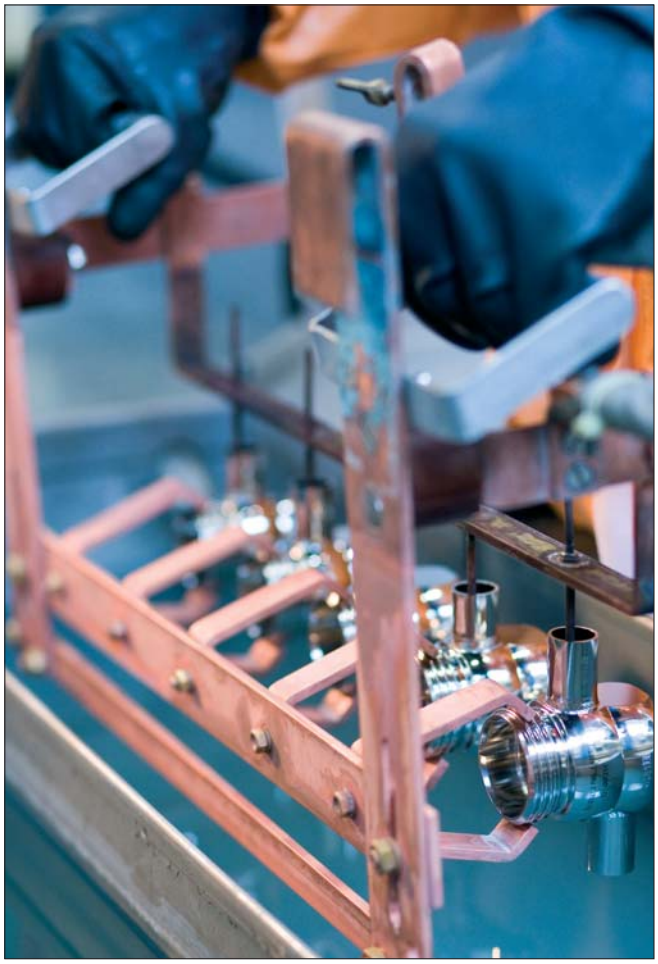


Surface measurement graph

Electropolishing

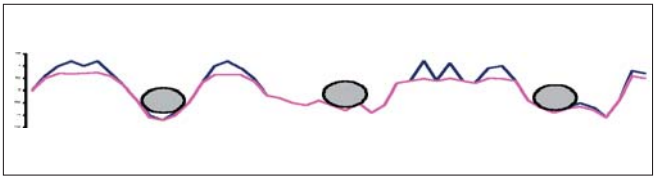
The process of grinding metal surfaces mechanically produces a rough structure with a profile which corresponds to the size of the grit. The ground surface texture allows

Workpieces on a holder being dipped in an electropolishing bath



Workpieces being immersed in water

microorganisms to gain a hold, to burrow from cleaning agents and the fluid flow. A method that can do yet more to optimise the surface is electrochemical polishing. Electropolishing is a galvanic process which removes the peaks on the material's surface electrochemically, producing a profile with rounded peaks. Its effect is to reduce the surface's roughness. Levelling the peak profile makes it much more difficult for contaminants and microorganisms to adhere. The material abraded from the surface is proportional to the electric charge introduced to it.



Bacteria on a stainless steel material surface ground to $R_a < 0.8$ µm and electropolished

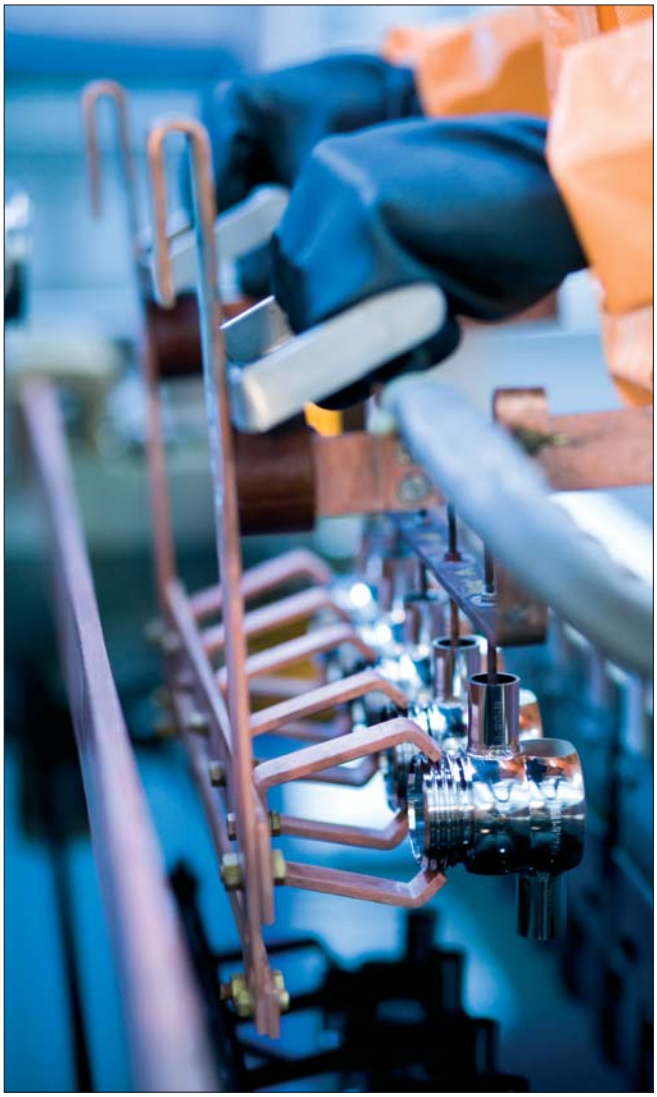
Rinsing the workpieces

Faraday's Law

$$m = \frac{M(Fe,Cr,Ni) \times I \times t}{z \times 96485C / mol}$$

m = mass of deposited substance [Kg]
M = molar mass of deposited substance [Kg/mol]
I = current strength [A]
t = time [s]
z = equivalence number [n]
(Example: Cr3+, equivalence number 3)

Electropolishing is a process that involves electrochemically removing material from a surface in an electrolyte with a voltage applied to it. More material is removed from the peaks than from the valleys. This is because the peaks are a different distance away from the electrode. Effective electropolishing requires the surface to be mechanically prepared as needed to obtain the intended quality. The surface is smoothed by removing the peaks caused by grinding, not only inhibiting microbiological contamination but also considerably improving corrosion resistance. Electropolishing electrochemically levels out the crystalline surface texture, which may cause it to coat with an inert "oxide layer" (passive layer).



VESTA® sterile valves

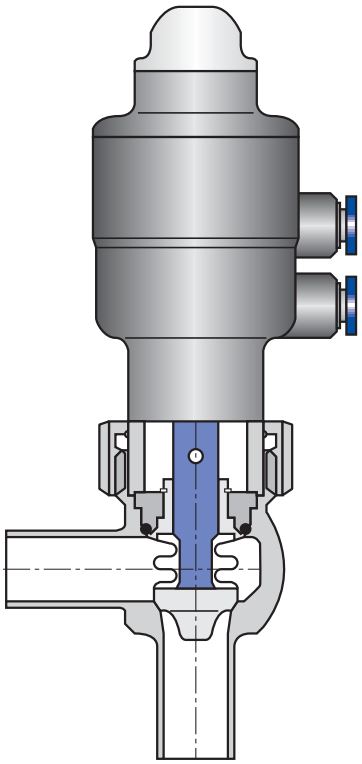
In the pharmaceutical, biotechnology, cosmetics and food industries, maximum process reliability and product quality are targeted by setting high standards for process components. Rules and regulations like FDA, cGMP and EHEDG as well as qualification and validation procedures now play an increasingly important role.

In presenting the VESTA® sterile valve series, GEA Tuchenhagen opens up a whole new range of alternatives to diaphragm valves. Apart from the unique details featured in VESTA® sterile valves, they are also capable of being used in ways which are unprecedented both from an economical and from a technical point of view. VESTA® sterile valves meet the most exact requirements for processes where the safety factor is the highest priority, ensuring that top quality can be produced.

Innovative valve design

VESTA® sterile valves represent a series of valves which GEA Tuchenhagen offers for applications ranging from laboratory use to complex processing systems. By preventing the product contamination, VESTA® sterile valves ensure process system sterility. VESTA® sterile valves feature the following design characteristics:

- Pocket-free design, without domes and sump
- PTFE bellows for universal use as a shut-off element
- Patented bellows sealing system for hermetic inside-to-outside valve cavity sealing
- Actuator systems specially redeveloped for compact design
- Flow-optimised design for highly efficient CIP/SIP cleaning
- Hygienic external design, EHEDG/cGMP-compliant
- Most simple, safe maintenance



Plastic pneumatic actuator, body type **L**

Plastic pneumatic actuator, body type **T**

Stainless steel pneumatic actuator, body type **B**

Stainless steel pneumatic actuator, body type **C**

Plastic and stainless steel pneumatic actuators

For use in automated processes GEA Tuchenhagen offers pneumatic actuators made of heavy-duty PPS. This is a chemically highly stable plastic material capable of resisting temperatures up to 180 °C which exhibits strong mechanical properties in addition to being extremely age-resistant. The actuator is maintainable and designed to prevent the hazard of the spring releasing when taken apart. The actuator's action is reversible and can easily be converted to the reverse control function on site.
VESTA® series pneumatic actuators feature integrated air connectors dimensioned for Ø 6x1 mm/ 1/4" plastic hosing and a visual valve status indicator. The actuator and product cavities are separated by a pressure relief hole which simultaneously rules out the possibility of contamination in addition to acting as a leak hole in the case of actuator defects or a broken bellows. GEA Tuchenhagen's VESTA® sterile valves are also obtainable with stainless steel pneumatic actuators with the same design features as the plastic actuators. Autoclavable stainless steel actuators are also available on request.

Manual actuation

Manual actuated VESTA® sterile valves are available for use in manually operated processes. Their special feature is technical design. An integrated spring assembly ensures a defined compression of the PTFE bellows in the closed position, preventing inadvertent bellows deformation. The spring pressure does not become active until the valve reaches the closed position, and in intermediate positions these manually actuated valves can be operated with a minimum of effort. Even when a valve is subjected to thermal extremes it is not necessary to adjust the closed position manually – the spring automatically readjusts. Manual operated VESTA® sterile valves can be placed under seal additionally.

Technical data

- Polyphenylene sulphide (PPS) pneumatic actuators
- 1.4301/AISI 304 stainless steel pneumatic actuators
- Maximum operating pressure 6 bar (depends on operating temperature), higher pressure rates on request
- Control air pressure
  - NC actuation min. 5 bar(72.5 psi), max. 10 bar (145 psi)
  - NO actuation min. 5 bar (72.5 psi), max. 6 bar (87 psi)
- Operating temperature -10 °C(+14° F) to max 135 °C (max. 275° F), (depends on operating pressure)
- Maximum sterilisation temperature 150 °C (302° F)

T.VIS® V-1 and V-20 electrical position indicator / control head

The T.VIS® concept (GEA Tuchenhagen Valve Information System) now complements the pneumatic VESTA® sterile valve series with a smart, modular system for valve monitoring, actuation and control – adapted to the hygienic design of the sterile valve.

T.VIS® V-1

T.VIS® V-1 with solenoid valve

The T.VIS® V-1 / V-20 is an electrical position indicator with feedback system and optionally integrated solenoid valves for linear process valves with a stroke up to 30 mm.

The luminous cap integrated in the control head indicates the status of the process valve – clearly to be identified locally. The information is transferred to the PLC via the 3 binary outputs, integrated as a standard feature.

This means that the OPEN and the CLOSED position of the process valve and the failures or faults are constantly monitored.

T.VIS® V-20

	Yellow LED	OPEN position
	Green LED	CLOSED position
	Red LED	Fault / Failures

The automated end position programming for the T.VIS® V-1 / V-20 can be activated alternatively using the buttons or the programming input (integrated as a standard feature) in just a few seconds. Due to the buttons and plug-in connections it is not necessary to open the T.VIS® V-1 / V-20.

Thanks to its modular design, the T.VIS® V-1 / V-20 can be customized to the customer's specific requirements:

- without solenoid valve
- with one solenoid valve (for single-acting actuators – with spring, only T.VIS® V-1)
- with two solenoid valves (for double-acting actuators – without spring, only T.VIS® V-1)

Benefits

- Automated end position programming
- Easy and safe operation without tools, no need to open the module
- Modular design
- Manual operation of the process valve is possible
- OPEN and CLOSED feedback signals as standard
- Accuracies can be set
- Option: AS Interface & DeviceNet(T.VIS® V-1 / V-20)

The T.VIS® P-1 / P-20 is a position controller for pneumatic process valves.

By specifying a setpoint (4-20 mA), transferred e.g. by the PLC, the process valve can be brought to any position.

A setpoint can also be entered locally with buttons to bring the process valve to the required position. This is achieved by internally adjusting the actual position of the process valve (actual value) to the setpoint.

The position is detected by a position sensor and adjusted by two integrated solenoid valves.

The local LEDs indicates clearly the status of the valve:

Yellow LED	OPEN position
Green LED	CLOSED position
Blue LED	Position adjusted
Flashing blue LED	Position not adjusted
Red LED	Fault / Failures

Of course all these messages can also be evaluated in the PLC via the actual value output as well as optional available three binary outputs, provided as standard features.

T.VIS® P-1

T.VIS® P-20

Technical data of the T.VIS® monitoring systems

- Operating voltage: 24 V DC
- Binary outputs (CLOSED / OPEN / Fault): 24 DC / 200 mA
- Setpoint input (T.VIS® P-1 / P-20): 4 -20 mA
- Actual value output (T.VIS® P-1 / P-20): 4-20 mA
- Pressure range: 0-8 bar / 0-116 psi (temporarily 9 bar)
- Protection class: IP66 / IP67
- Ambient temperature: -20 (-4° F) to +70 °C (158° F)(without solenoid valve)
  -10 (14° F) (P-20 ±0 °C / 32° F) to +50 °C (122° F) (with solenoid valve)
- Housing material: PA / PET / TPE
  resistant to the typical cleaning agents and disinfectants

Benefits of T.VIS® control systems

- Automatic limit position programming
- Easy, safe operation requiring no tools, no opening necessary
- Modular structure
- Manual process valve operation
- OPEN and CLOSED feedback signals provided as standard
- Adjustable accuracy settings
- Optional: AS interface (T.VIS® V-1)

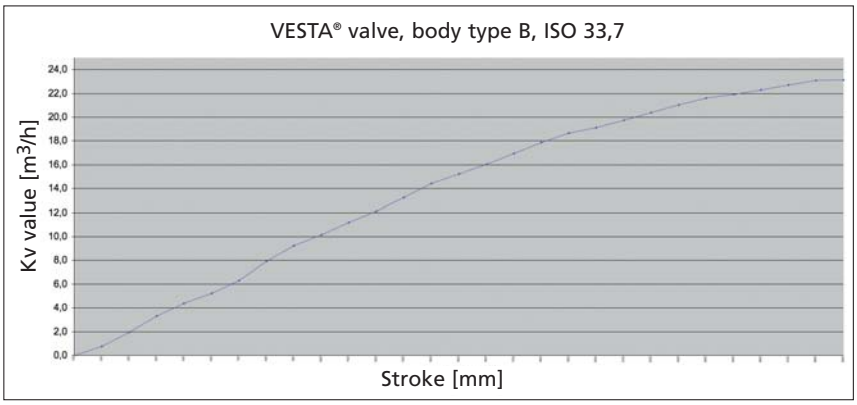
Technical data for T.VIS® control systems

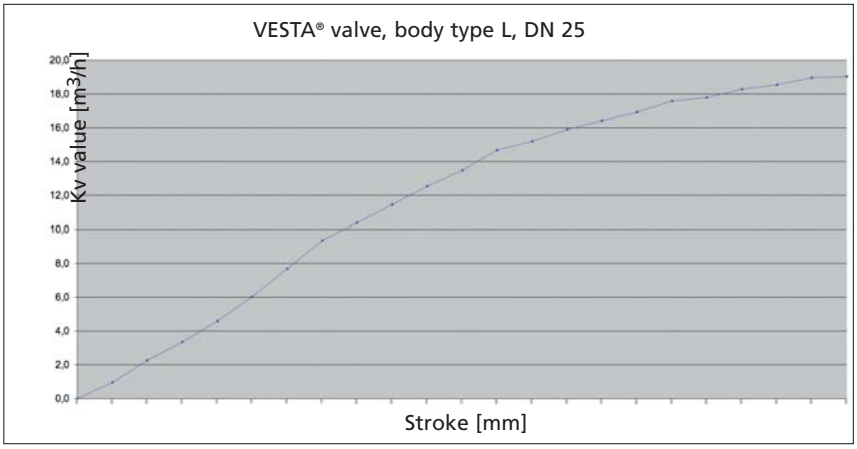
- Operating voltage 24 V DC
- 3 binary outputs 24 V DC / 200 mA
- Setpoint input (T.VIS® P-1) 4-20 mA
- Actual value output (T.VIS® P-1) 4-20 mA
- Pressure range 0-8 bar / 0-116 psi (temporarily 9 bar / 130.5 psi)
- Protected to IP65 / IP67
- Ambient temperature
  -20 (-4° F) to +70 °C (158° F) (without pilot valve)
  -10 (14° F) to +50 °C (122° F) (with pilot valve)

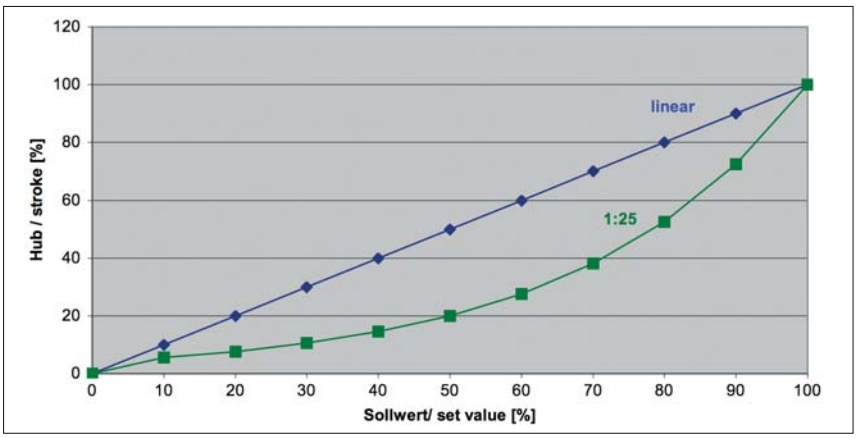
Control characteristic

On account of their design, seat valves have a reproducible control characteristic.
The annular gap between the bellows and the valve seat becomes proportionately wider as the valve lifts. The shape of the standard bellows in a VESTA® sterile valve makes it possible to obtain exact Kv values throughout the entire range due to the practically linear run of the characteristics.

The menu of the **T.VIS® P-1** allows a setting to be performed to obtain a control characteristic with the same percentage in addition to the linear one.

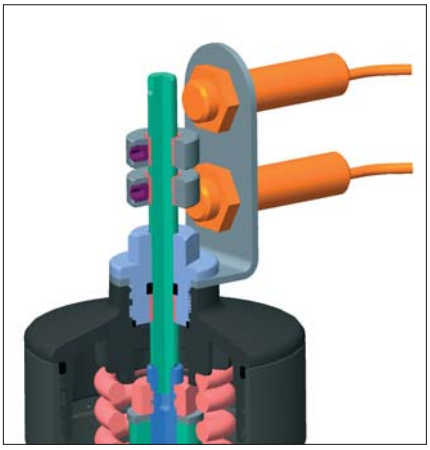






Control characteristic of the VESTA® sterile valve with position controller.

Stainless steel proximity switch assembly



Position monitoring

Apart from T.VIS® control systems, proximity switches are also available to monitor the pneumatically operated VESTA® sterile valves. These units are fitted to the top of the actuator with a stainless steel bracket and are easy to adjust subsequently. Proximity switches are obtainable for an operating voltage of 10 – 30 V DC (3 conductors) or for an operating voltage of 8 V DC (2-conductor type to NAMUR, DIN 19234 / EEx i).
The switches have integrated LEDs to indicate operating status and valve position.

VESTA® valve bodies

All bodies are manufactured from 1.4435 stainless steel (barstock material). Using modern manufacturing methods it is possible to make high-grade valve bodies with a perfectly finished surface and repeatable body quality. Manual finishing work such as grinding is no longer required as the surfaces are already turned to an extremely fine finish. Extensive automation ensures a fully repeatable process. All valve bodies are manufactured with material certification to EN 10204/3.1 and are marked as specified in AD Sheet A4. Valve bodies all feature orbital weldable pipe connections and are weldable using enclosed orbital cassette systems.

VESTA® sterile valves are available with a variety of different bodys suitable for a wide range of applications. All body shapes feature a selfdraining, pocket-free design. They are specially designed for horizontal as well as vertical use.

Body type L

Body type T

Body type B

Body type C

VESTA® Sterile Valves

Technical data

- Parts in contact with the media
  - Body 1.4435/AISI 316L
  - PTFE bellows TFM 1705
- Maximum operating pressure 6 bar

Sizes

The VESTA range of sterile valves includes small sizes in a variety of pipe classes.

DIN – DN 10 up to DN 65
Outside diameter to DIN 11850 Series 2 / DIN 11866, Series A

OD – OD 0.5" up to OD 2.5"
Outside diameter to DIN EN ISO 1127 / DIN 11866, Series B

ISO – ISO 13.5 up to 76.1
Outside diameter to ASME BPE / DIN 11866, Series C

other sizes on request

Design features

- Single-part block-type body made of solid material
- PTFE bellows for universal use as a shut-off element
- Patented bellows sealing system for hermetic inside-to-outside valve cavity sealing
- Can be fitted in any orientation
- Compact design
- Self-locking groove nut connection

Benefits

- Pocket-free design
- Self-draining
- Flow-optimised design for exellent CIP/SIP cleaning
- Extremly long PTFE bellows service life
- Pipe level sealing
- Use of standard pneumatically and manually operated VESTA valve inserts
- Simple, safe maintenance

VESTA® Mix-Matched sterile valves

VESTA® mix-matched sterile valves featuring Type C bodies are mainly used as branch valves in piping systems or for media distribution. Branching at pipe level ensures a pocket-free, self-draining body. Inline (zero dead leg) technology enables all applications to be implemented with pocket-free valve bodys. The VESTA® sterile valve with mix-matched connections is suitable for all applications where different connections are technically necessary in throughflow and branch lines. Shut-off takes place directly at the loop. Mix-matched VESTA® sterile valves allow small amounts of product to be easily and simply removed from wide-diameter pipes.

The pipe width rating can be individually tailored to suit the requirements of the process. The stepped down line cross section on the branch side helps to prevent process media losses. The body's inline design allows the system to be configured with no dead zones and significantly increases cleaning efficiency. Their integrated inline design also obviates the need for unwanted pipe fittings and complicated fitting work.

VESTA® Mix-Matched Sterile Valves

VESTA® sterile valve, Type HCA mix-matched, DN 50 / 25

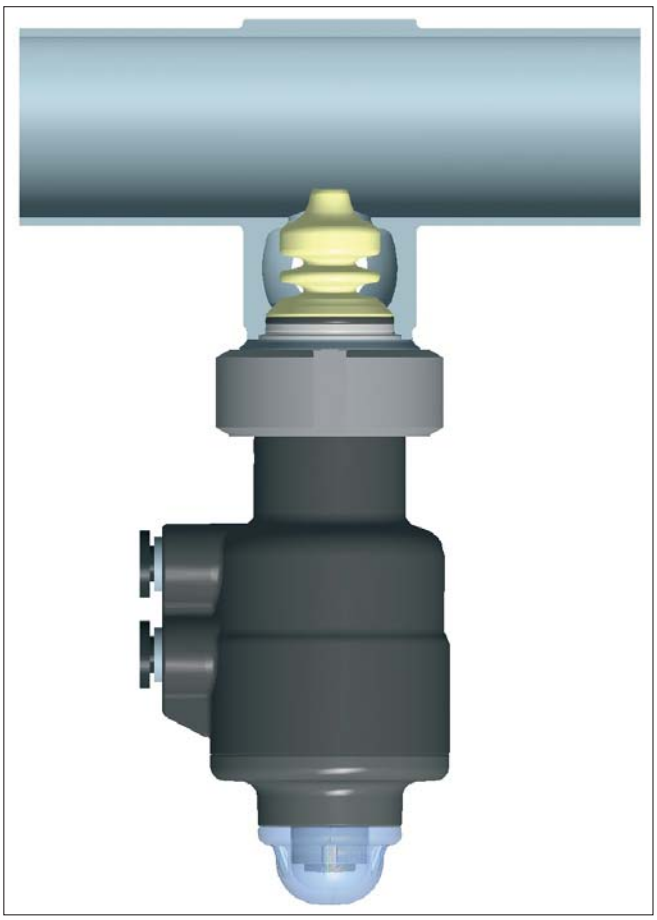
VESTA® type HCA mix-matched sterile valves are available in the following nominal widths:

DIN Series	DN 15 up to DN 100 (loop) - DN 10 up to DN 65 (branch)
ISO Series	ISO 17.2 up to 114.3 (loop) - ISO 13.5 up to ISO 76.1 (branch)
OD Series	0.75“ OD up to 4“ OD (loop) - 0.5“ OD up to 2.5“ OD (branch)

Other mix-matched combinations on request.

VESTA® type HCA mix-matched sterile valves are designed without domes, can be fitted in any orientation and cleaned effeciently.
VESTA® type HCA mix-matched sterile valves can provide technically the best possible solutions to your processing system's design challenges.

Upright orientation



Upright orientation

VESTA® block valves

VESTA® block valves are compact, general-purpose sterile valves featuring two independent operating actuators. The one-piece body is designed to allow different media flows to be joined, separated or diverted within an extremely confined space. VESTA® block valves offer optimum flow management with minimised dead zones. Major design features include a significant reduction in pipe volume plus more efficient draining action than conventional diaphragm technology can offer. Bodies are available in various configurations to enable plant layouts to be implemented with maximum flexibility while at the same time significantly reducing costs. VESTA® block valves – ideally complementing the VESTA® range of sterile valves – are designed for process reliability and extremely easy maintenance. The single-part body is machined from solid material. This ensures a consistently excellent surface quality within extremely narrow tolerance limits.

VESTA® block valves are available as standard in two different body configurations:

- **Type HWA – body with 3 connections**
- **Type HXA – body with 4 connections (central throughflow)**

Other configurations such as bodies with differently dimensioned connectors can be made to order.

There are many applications that can be implemented using VESTA® block valves as they can be either used singly or combined to create compact media distribution blocks.

VESTA® Block Valves

Unlike layouts incorporating single valves, system solutions featuring VESTA® block valves minimise the number of pipe fittings and welded joints required, thus helping to keep plant design economical.

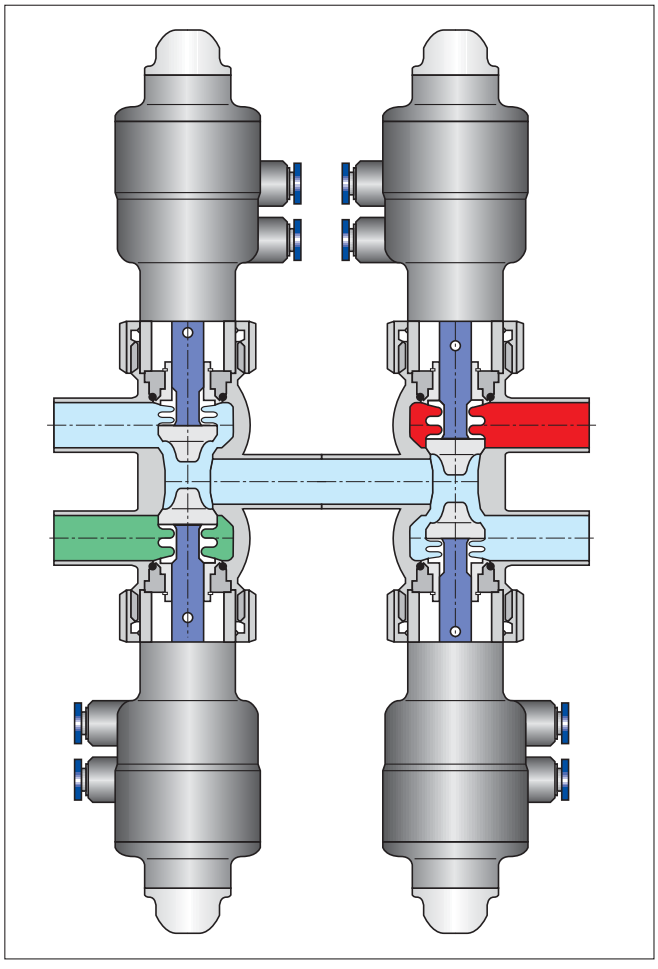
VESTA Block® Valve, Type HWA
Body with 3 connections

VESTA® Block Valve, Type HXA
Body with 4 connections
(central throughflow)

VESTA® Sterile Blocks can be used to implement complex valve configurations in confined spaces. VESTA® Type HWA block valves can be directly linked, for instance, forming a compact sterile gateway. Apart from ensuring that the installation has no dead zones, the connector linking the blocks allows media to be completely exchanged. No extra cleaning routes are required, enabling much less complex valve technology to be used.

- Dependable separation of media
- Low-mass body with even equal wall thicknesses
- Short heating rate
- Small, compact design
- Low process volume

are the characteristic features of VESTA® block valves. Practical solutions for nearly every application can be configured by combining them with the various body types.



Basic diagram: Sterile gateway for biopharmaceutical applications

VESTA® tank bottom valves

VESTA® tank bottom valves are used to drain the flow of liquid media from vessels and tanks. Preferably they should be fitted at the lowest point of the tank bottom. The distinguishing feature of these valves is their ability to shut off the flow at tank bottom level with absolutely no sump.

Their pocket-free design ensures complete tank drain and optimum CIP/SIP cleaning. The body and its connecting flange are shaped for stability, allowing it to be welded without warping. Due to their extremely compact design, VESTA® tank bottom valves can be used in very confined spaces. It is also possible to fit them in the side of a tank (e.g. as sample valve).

VESTA® tank bottom valves are also available in various designs to suit specific purposes. Examples include extra valves for CIP/SIP or drainage featuring flush-to-front shut-off (zero dead leg configuration).

VESTA® tank bottom valves are available in the following versions:

- **housing to weld**
- **housing to flange**

Body versions:

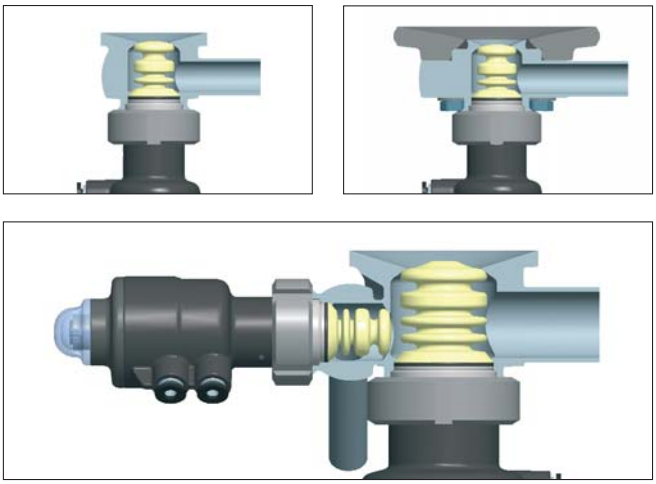
- **L shape (1 outlet)**
- **T shape (2 outlets) for ring lines.**

VESTA® Tank Bottom Valves

VESTA® Tank Bottom Valve with SIP valve (customised solution)

VESTA® Tank Bottom Valve, weldable body

VESTA® Tank Bottom Valve, flangeable body



Sectional views

Connecting flange

Design features

- Shut-off flush with the tank bottom, sump free
- Dead space free design
- Self draining, even when installed within the tank wall
- Optimized for CIP/SIP cleaning
- Distorsion free welding by stable design

Benefits

- Tank bottom level shut-off without sump
- Self-draining even when fitted in the side of a tank
- Flow-optimised design for exellent CIP/SIP cleaning
- Extremely long PTFE bellows service life
- Use of standard pneumatically and manually operated VESTA® valve inserts
- Ideally integratable into downstream piping system
- Simple, safe maintenance

VESTA® Multiport

Manufacturing sensitive products economically in the pharmaceutical and biotechnology industries demands increasingly complex processes, presenting enormous engineering challenges particularly with respect to process dependability throughout such systems. In this context, regulations (FDA, cGMP), basic regulatory rules like EU regulations and concepts like qualification and validation now play an increasingly prominent role. Processes involving different operating, cleaning and sterilising media are amongst the applications frequently encountered in sterile process technology. Currently, processes like these are often implemented using diaphragm valves in conventional configurations featuring single valves or so-called valve blocks.

Conventional solutions of the welded type using single diaphragm valves are notoriously work-intensive. Apart from the lengthy assembly work they involve, the required valves, fittings and pipe components take up more space. Some dead space has to be accepted as it is unavoidable in configurations like these. Valve blocks featuring blocked diaphragm valves machined from solid material may be compact, but they are not entirely free of pockets. Also, valve blocks of this type only feature "optimised draining" – the system never drains fully. Due to their very thick walling, such systems not only heat very slowly and create heavy condensation during sterilisation but also take an extremely long time to cool down. Up till now there has been practically no alternative but to use diaphragm valve systems for processes such as these. Now, GEA Tuchenhagen's newly developed VESTA® Multiport meets that need.

VESTA® Multiport is a system incorporating VESTA® sterile valves which features no dead legs, a CIP-friendly design and complete draining action and will also fit into very confined spaces.

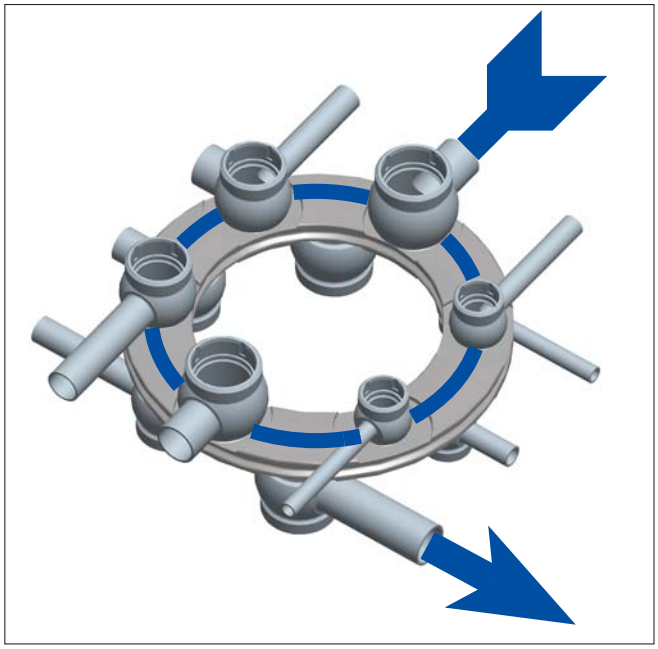
VESTA® Multiport

Operating principle

The VESTA® Multiport's basic structure consists of a circular ring with an inner channel. The channel cross section is dimensioned to suit the valve size and is approximately 50% of the valve inlet cross section. This ensures optimum throughflow and a continuous exchange of media. The valves are positioned on the ring faces (its upper and lower surfaces) in whichever configuration is needed for the process. Multiports should preferably be fitted in a horizontal position with the valve actuators upright or inverted to ensure complete draining.

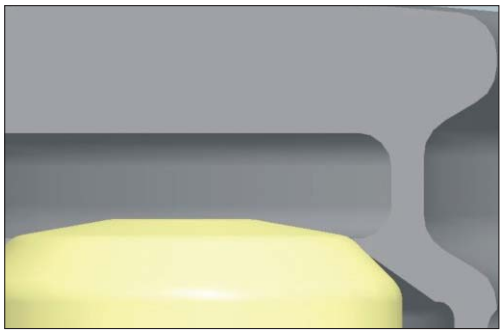
The system's annular shape offers:

- complete media exchange
- exellent cleaning
- minimal process volume



Example showing how the ring distributor operates

VESTA® Multiport



With its modular structure, the VESTA® Multiport can be individually configured to suit a particular purpose. Up to 6 shut-off valves can be incorporated in the supply and return lines. The valves' shut-off action is equal with the ring channel. The valve bodies are TIG-welded to the ring.

The system's outer dimensions depend on the configuration and the valve sizes. VESTA® Multiport has been designed as a modular system.

The valve bodys can be arranged on the ring so that their connectors are oriented to suit individual structural requirements. A special advantage of the VESTA® Multiport over conventional solutions is the fact that pipe connections can be made in different directions. Pipe grid can be defined at an early
stage in planning.

Design features

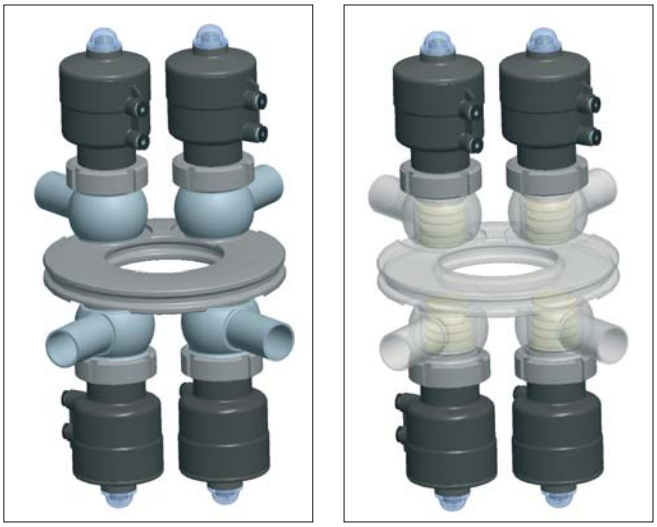
- Modular, compact design
- Basic modules are the ring and the valve bodys
- Flush-to-front shut-off at ring channel
- Allows individual valve configurations
- Piping can be oriented to suit structural requirements
- Fixed pipe grid
- Use of VESTA® sterile valve actuators

Benefits

- Allows early planning of pipe routing with fixed grids between supply and return lines
- VESTA® Multiport can be preconfigured for complete unit delivery with defined interfacing for integration within the processing system
- Allows early planning of 2- and 3-dimensional space requirements
- Qualification (DQ / IQ) can be completed at manufacturer's factory
- Reduction of assembly and fitting work (no special pipe fittings required)
- Less time needed for planning, delivery, assembly and commissioning.

VESTA® Multiport

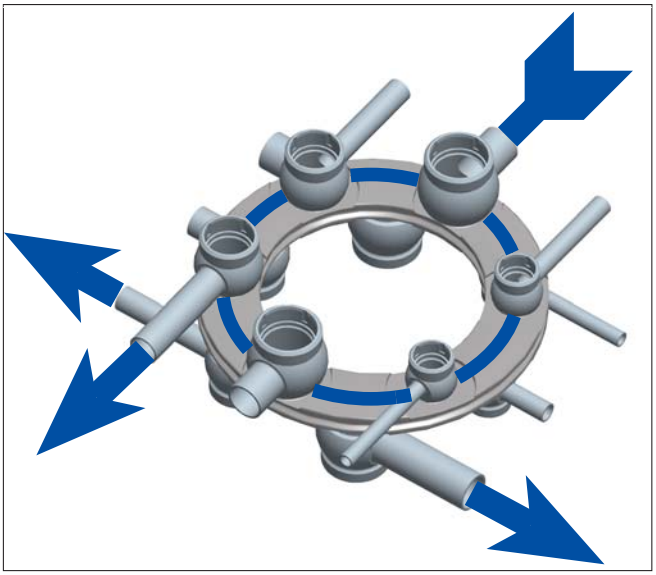
The VESTA® Multiport ring distributor is structured for cyclic operation, permitting pocket-free operation without mixed phases. The split flow in the ring channel allows media to be completely exchanged. The medium divides into two half-volume streams in the ring channel. No-flow areas can be ruled out. The processing system is cleaned following the same direction as the production flow. No extra cleaning routes are required, enabling much less complex valve technology to be used.

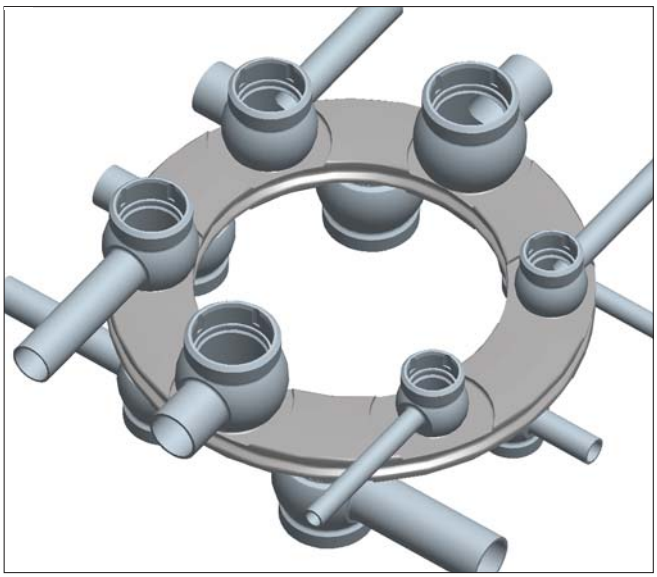


VESTA® Multiport ring distributor, Type 2/2

Individually configurable

The VESTA® Multiport is designed to allow a choice of individual configurations for different process requirements. Up to 12 valves (6 valves on the upper side, 6 valves on the lower side) can be positioned on ring. The valves can be configured in any way, with a different number in each. A special advantage of the VESTA Multiport is that different valve sizes (nominal widths) can be combined with each other.





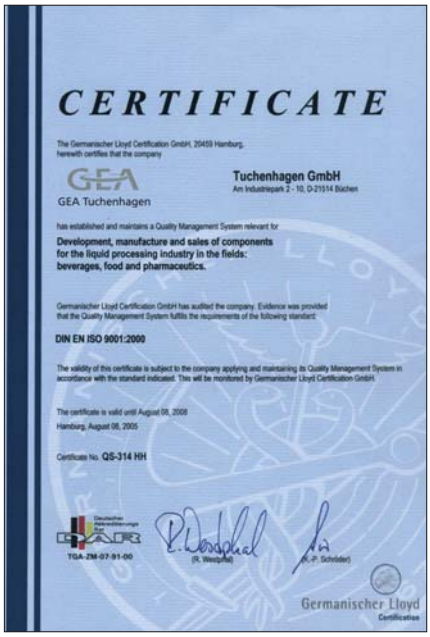
Example showing how the ring distributor operates

Repeatable manufacturing quality

The most stringent quality criteria are applied when manufacturing VESTA® sterile valves. GEA Tuchenhagen uses certification according to the DIN ISO 9001 quality assurance system as a basis. Quality assurance measures include constant quality checking during manufacture, coding of all components plus function and integrity tests, to mention just a few; all factors that contribute to consistently high quality in addition to enabling users to identify the required components confidently when spares are needed.

VESTA sterile valves can be supplied with the following proven quality attributes:

- Product-contacting valve body with material acceptance test certificate to EN 10 204 / 3.1
- Works certificate to EN 10 204 as proof of surface roughness
- Works certificate to EN 10 204 as proof of delta ferrite content
- Works certificate to EN 10 204 for PTFE bellows (TFM 1705), conformity certificate as required by FDA 21 § 177.1550
- Certificate for PTFE bellows proving biocompatibility to USP Class VI
- Welded seam documentation - cGMP-compliant, including items such as weld report, weld location plan, endoscopy report, etc.



Process technology

Microbial growth
Microbes require various conditions to grow. Within the area of process technology, microbial growth can be influenced via the following factors:
- Temperature (cleaning/sterilisation) above the levels that permit growth
- Chemical environment, pH value above/below the levels that permit growth
- Stress/turbulence, high flow rate causes stress and prevents cell division
- Nutrients
- Places where microbes can lodge, allowing them to breed
- Moisture is a basic necessity for microbial growth; cell division ceases when moisture is removed

Self-draining system design
As a general rule: Hygienic processing systems should be designed and the piping configured in such a way that the system can be completely drained without any dismantling. This has the following advantages:
- Cleaning is fast and cost-effective as the pipes are fully drained with minimal mixed-phase formation
- Reduced microbial growth during breaks in production as the system is kept in a dry state
- Elimination of pooling minimises condensation formed during steam sterilisation

To ensure self-draining action, the piping should be fitted with an inclination of 1% – 3%. Valves or components carrying flowing media should be fitted with the in- or outflow connector pointing downwards. If that is not possible, a drain valve must be fitted at the lowest point to ensure component drainage.

Short pipe branch connectors
- ensure that flow fills the entire pipe without creating lee-side eddies
- prevent undesirable microbial growth in slow-flow areas
- minimise the tendency of bubbles to collect in domes by entraining air with the main flow

Standards and regulations

USP United States Pharmacopoeia

CFR Code of Ferderal Regulations
Seal materials,
soft seals to 21 CFR 177.2600
PTFE materials to 21 CFR 177.2400

GMP Good Manufacturing Practice,
issued by the FDA

DAB 12 Deutsches Arzneimittel Buch 12
(German Pharmacopoeia 12)

Directives
- Pressure equipment directive

DIN standards
- DIN 2632 Welding neck flanges, 10 bar pressure rating
- DIN 2633 Welding neck flanges, 16 bar pressure rating
- DIN 6601 Resistance of materials used in steel containers/tanks to liquids
- DIN 11850 Pipes made of stainless steels
- DIN 11864-1, aseptic screw-type pipe connectors
- DIN 11864-2, aseptic flanged connectors
- DIN 11865, pipe fittings made of stainless steel for aseptic, chemical and pharmaceutical applications
- DIN 11866, pipes made of stainless steel for aseptic, chemical and pharmaceutical applications
- DIN 28004, flow diagrams for processing plants
- DIN 28011, torispherical heads
- DIN 32767, clamp connectors for pipes made of stainless steel
- DIN 17457, welded circular tubes of austenitic stainless steels for special requirements (delivery criteria)

DIN EN standards
- DIN EN 558-1, overall lengths of metal instruments designed for fitting to pipe lines with flanges
- DIN EN 1127-1, explosion protection
- DIN EN 10204, test certificate types, general pressure equipment directive 2000
- DIN EN 12296, appliances and equipment, testing for cleanability
- DIN EN 45014, general criteria for conformity declarations given by suppliers

SMS Standard
- SMS 3008, pipes made of stainless steels as specified by ISO/R 2037

British Standard
- BS 4825, Part 1:1991, stainless steel tubes and fittings for the food industry and other hygienic applications

ISO Standard
- ISO 2037, stainless steel tubes for the food industry

Basle Standard
- Baseler Norm (Basle Standard) BN2, (‰ ferrite) BCI Baseler Chemische Industrie (Basle Chemical Industry)

TRB ordinance
- Technical regulations pertaining to the (German) Pressure Vessel Ordinance

VDI regulations
- VDI 2440, reduction of emissions in mineral oil refineries (with reference to "TA-Luft" clean air regulations)

DIN EN 10204, acceptance test certificate 3.1-BN2
The acceptance test certificate 3.1 to BN2 is a certificate issued for a specific test performed in accordance with BN2 (Basle Standard 2) testing methods. All other requirements as given under certificate to 3.1. The Basle Standard was created around 20 years ago by the BCI (Baseler Chemische Industrie), a body representing the three largest Basle-based chemical companies. It is no longer an officially valid standard, having meanwhile been superseded by the DIN and DIN EN standards. Quote: This standard describes the technical requirements for materials used in products made of austenitic stainless steel with molybdenum, basically 1.4435 steel to DIN 17440 or 316L to AISI but with narrower analysis tolerances and a defined ferrite content. This is intended to ensure that the material's corrosion resistance stays constant even if products originating from different places and batches are used.

Handling of materials with a 3.1 certificate
The making of a product certified to DIN EN 10204, acceptance test certificate 3.1, begins with purchasing the raw or semi-finished material. The semi-finished material can come in tube, round, sheet or similar form ready for processing. The steel mill is required to provide quality assurance by carrying out the material tests specified in the DIN standard. Before making a component that is to be material-tested to DIN EN 10204, 3.1, the semi-finished material always receives an unambiguous code. This requirement is met by obtaining a copy of the batch certificate when purchasing the semi-finished material which bears a numeric code. The numeric code remains clearly visible on the workpiece throughout all stages in the manufacturing process. Ideally it should be punched on to the semi-finished material. If a part is to be taken off a semi-finished product, a specially authorised staff member applies the same code to the part to be removed. At GEA Tuchenhagen this code is called the "B Code" and accompanies each workpiece from the raw materials receipt area to the finished product. VESTA valve bodies bear this code on the spherical body and on the pipe connectors. It is not possible to mark a component after completion as non-marked workpieces cannot be uniquely allocated.

GEA Tuchenhagen GmbH purchases European-made semi-finished stainless steel materials in rod, sheet, tube and other forms and buys only from certified manufacturers and dealers. It is standard policy to purchase all main materials with 3.1 or 3.1 / AD-W2 certificates. Arriving goods are always checked to verify the certificates and records are kept to document the fact that they correspond to the goods delivered. Our QA department ensures that all documents are properly archived.

Glossary

A

AB (DAB)
Arzneimittelbuch (Deutsches Arzneimittelbuch) – (German) pharmacopoeia
ANSI
American National Standards Institute (US)

Aqua
Water

Aqua ad injectabile
Water for injection purposes

Aqua demineralisata
Demineralised water, water with a reduced mineral content

Aqua purificata
Purified water

Aseptic
Free of germs

B

Bacteria
Single-cell microorganisms without a nucleus. They propagate by simple mitosis (cell division). There are three known basic forms:
Rod-shaped, Ø 0.5-1 x 2-5 µm, typical names: clostridium, -bacillus, pseudomonas Spherical, Ø usually 1 µm, typical names: -coccus Bacteria spores are an extremely resistant form which certain bacteria can adopt under adverse growth conditions. They are capable of developing and measure Ø <1µm.

Bacteriostatic
Inhibiting bacterial growth

Batch
A product manufactured in one or more stages which is considered to be homogeneous.

Biotechnology
Use of living organisms or their constituents or catabolic products to make, convert or decompose substances for the purpose of obtaining active substances for use in foodstuffs, pharmaceuticals or pesticides.

Bubble Point Test
Integrity test used in the pharmaceutical industry for filter elements. The filter element is wetted and an increasing gas differential pressure is applied. The bubble point is the point at which the first gas bubbles pass through the filter element. If the pressure is lower than a comparative value, the filter element is defective.

C

Certification
Confirmation of a circumstance or a characteristic

CFR- Code of Federal Regulations (US)
Binding regulations issued by the FDA that apply to drug production.

CFU – Colony Forming Units
Number of microorganisms present in a sample

cGMP
Current Good Manufacturing Practice

Chromatography
Method of physically separating mixed substances which utilises their different interaction between a liquid/gas phase and a solid phase.

CIP - Cleaning In Place
Cleaning a system by circulating cleaning and rinsing agents through it without dismantling the system first.

Corrosion-resistant material
Material which retains its original surface characteristics when used in the intended way.

D

DAB – Deutsches Arzneimittelbuch = German pharmacopoeia.

Dome
Slow-flow area in which air is trapped or can only escape in an uncontrolled manner.

Decontamination
Removal of undesirable substances or impurities from surfaces.

Disinfection
Killing or inactivating microbes and pathogenes on contaminated objects to interrupt the chain of infection.

Documenting
Recording process data in writing as evidence of an activity or a process and its results.

E

Endotoxins
Endotoxins occur in the cell walls of gram-negative bacteria and blue-green algae. Biochemically these belong to the lipopolysaccharides (LPS). Endotoxins are thermostable and sterilising will not inactivate them. They can cause fever, drops in blood pressure and other symptoms.

H

High-purity water
Same as WFI water – water that contains no organisms or their spores and is also demineralised. See DAB for production details.

L

Limulus Test
Test procedure used to determine the presence of endotoxins by producing a yellow colour.

M

MHD - Mindeshaltbarkeitsdatum (sell-by date)

Microorganisms
Bacteria, mould, yeasts, algae. (viruses), bacteriophages

P

Pasteurisation
Heat treatment to reduce the germ count in a product. Categorised according to the duration and temperature of the process.

Pocket
Area in which media such as product, cleaning agents, disinfectants or dirt are entrapped or held up.

Pool
Area which cannot be drained.

Pyrogenic
Substances causing fever, for instance endotoxins and exotoxins deriving from different cell membranes or other substances of highly varying chemical structure.

Q

Qualification
Qualification is the recording of a work sequence or a process. Nowadays many processes in industry such as organisational structures, production processes and work sequences are qualified. Qualification provides a clear written definition of a process, thereby contributing towards process and quality assurance. The qualification document is freely accessible by all staff involved, ensuring consistent information and process handling. In a plant engineering context, the following planning sequences for drafting a plant are normally qualified.

Design Qualification DQ
DQ provides proof that the drafted processing equipment meets the required quality standard in respect of type and implementation and that account has been taken of the design of the building and the services system. The DQ document forms the basis for installation and function qualification. It describes the media flows to be handled by the system, the specifications which the equipment is required to meet and the selected items of equipment.

Glossary

Installation Qualification IQ
The IQ provides proof that all items of equipment and systems have been installed in accordance with the plans and specifications approved by the customer and the statutory safety requirements. It involves verifying the scope of supply and checking that it concurs with the equipment (components and their documentation) drafted and defined in the DQ.

Operation Qualification OQ
The OQ provides proof that critical items of equipment and systems operate as intended, not only within but also beyond the normal operating ranges defined by the setting parameters. OQ's for devices are generally performed without product or using a placebo. The system is tested to determine technical performance and operation as intended. Components are tested, measuring instruments calibrated and the software validated.

Process Qualification PQ
PQ is used to check and record the production process.

R

Ra value
The average peak-to-valley height Ra is the arithmetic mean of all a roughness profile's profile values as defined by DIN 4762, 4768 and ISO 4287/1 (there are many more roughness-related values. Ra is the commonest)

RO - Reverse Osmosis
Reversible separation method used to desalinate water by passing it through a membrane. The method utilises the osmotic behaviour of saline solutions.

S

Sanitising
Cleaning followed by disinfection.

Scratch
A sharp-edged, irregular, shallow indentation which is detrimental to a surface's cleanability.

SIP
Steaming in place. Sterilisation by steam.

Spores
Dormant type of microorganism formed when conditions for propagation are adverse. Spores can germinate when conditions improve, forming bacteria capable of multiplying. They are able to withstand heat up to 75°C applied over a period of 20 min.

Sterile
Free of microorganisms capable of multiplying and active viruses.

Sterilisable
An object is sterilisable if at least one method, which must be defined, can be used to sterilise it.

T

Test certificates
DIN EN 10204 (test certificate types) provides an overview of test certificate types and contents. Generally a large number of test parameters can be applied and these are described in the following standards. The most frequently cited standards are:

- DIN EN 10204, test certificate types, general pressure equipment directive 2000
- DIN 11866, pipes made of stainless steel for aseptic, chemical and pharmaceutical applications
- DIN 17457, welded circular tubes of austenitic stainless steels for special requirements (delivery criteria)
- BS 4825, Part 1:1991, stainless steel tubes and fittings for the food industry and other hygienic applications
- ISO 2037, stainless steel tubes for the food industry
- Baseler Norm (Basle Standard) BN2, (delta ferrite) BCI Baseler Chemische Industrie (Basle Chemical Industry)

DIN EN 10204, factory certificate 2.2
A factory certificate 2.2 is purely a manufacturer's declaration regarding the material.
It certifies that the product is the one described in the specification (delivery terms).
Certificate in which the manufacturer confirms that the supplied products meet the specifications agreed in the order, stating the results obtained from non-specific tests.

DIN EN 10204, acceptance test certificate 3.1
The acceptance test certificate 3.1 is a certificate for a specific test performed in accordance with specific testing methods which is issued by a specialist at the manufacturer's factory who is not involved in the production process. It certifies that the product has the same attributes as specified by the customer in the order and that testing is performed under precisely defined test conditions. Issued by a department independent of the manufacturing department and endorsed by a specifically authorised specialist at the manufacturer's factory who is also independent of the manufacturing department ("factory specialist").

DIN EN 10204,
acceptance test certificate 3.1-AD2000-W2
The acceptance test certificate 3.1 to ADW2 is a certificate issued for a specific test performed in accordance with AD (Arbeitskreis Druckbehälter, pressure vessel working group) testing methods. All other requirements as given under acceptance test certificate 3.1. AD-W2 defines the guidelines as per AD Instruction Sheet, Appendix W2, for the specific test referring to the relevant DIN EN standards.

GEA Tuchenhagen Material Test Certificates
As specified in DIN EN 10204, test certificates and reports are issued for the material the workpiece is made of. DIN EN 10204 states that it is generally possible for a customer to ask for other characteristics to be tested in addition, but these need to be previously defined.

U

UF – Ultrafiltration
Membrane separation method involving the application of pressure. It allows substances to be separated according to particle size. Mol weight approx. 1,000 – 2 million, equivalent to 0.1µm – 0.001µm.

UHT – Ultra High Temperature
Pasteurising method using ultra high temperatures above 135°C

USP – United States Pharmacopoeia
Pharmacopoeia used in the United States of America

V

Validation
Confirmation that the requirements for intended use have been met, accompanied by proof provided in the form of a documented investigation. Validation is the basis for a defined, repeatable process.

VE water
"Vollentsalztes" (fully desalinated) water, same as aqua demineralisata.
Water from which all mineral ions have been removed by an ion exchanger.

W

WFI – Water for Injection
Production is described in the USP and in the DAB. Currently obtained by distilling with droplet separation to avoid microbe entrainment or occasionally by reverse osmosis and sterile filtration.

Notes

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GEA Group is a global mechanical engineering company with multi-billion euro sales and operations in more than 50 countries. Founded in 1881 the company is one of the largest providers of innovative equipment and process technology. GEA Group is listed in the STOXX Europe 600 Index.

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