

## Introduction

ITT Pure-Flo has developed a line of valve bodies that help address the needs of the Bioprocessing and Pharmaceutical industries for high quality, welded process systems.

By providing valve bodies with controlled sulfur 316L/1.4435 stainless steel material and weld tangents long enough to accept the most common orbital weld heads in the industry, we have eliminated two of the most common concerns in valve-to-tube welding known today.

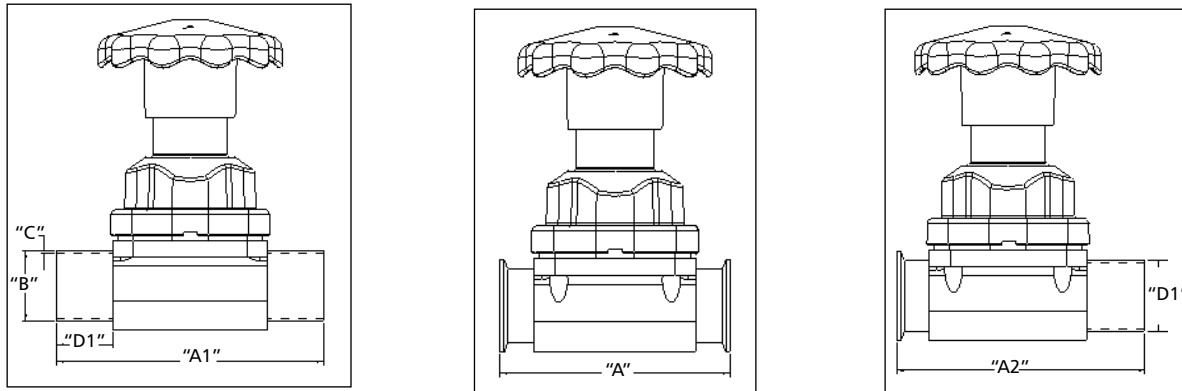
Automatic welding of 316L process components is greatly affected by the sulfur content of the mating process components. A disparity of sulfur content can result in reduced orbital weld quality and potentially incomplete fusion of the mating components. By controlling valve body sulfur content to the same chemistry as that required for ASME BPE fittings, welding problems due to material chemistry differences will be greatly reduced.



### 316L Sulfur Controlled Chemistry per ASME BPE Table DT-3

Element	% (316L)
Carbon (C)	0.035 max
Chromium (Cr)	16.00 - 18.00
Manganese (Mn)	2.00 max
Molybdenum (Mo)	2.00 - 3.00
Nickel (Ni)	10.00 - 15.00
Phosphorous (P)	0.045 max
Silicon (Si)	0.75 max
Sulfur (S)	0.005-0.017

## Body Dimension Charts



### Body Dimension Charts US & SMS

USOD (ANSI) Forgings & Castings										SMS	
B		A	A1	D1	A2	C				B	C
End Connection Size		Overall Length <sup>1</sup>	Overall Length	Weld Tangent	Overall Length	20 GA. 0.035"	18 GA. 0.049"	16 GA. 0.065"	14 GA. 0.083"		
IN	DN	Tri Clamp	Extended BW Forging	Extended BW Forging	TC x BW	Extended BW Forging	Extended BW Forging ASME BPE	Extended BW Forging	Extended BW Forging ASME BPE	BW Forging	
Forgings											
BP/BT 0.25"	DN8	2.5" (64) <sup>2</sup>	3.5" (89)	1 (25)	3.0	S	O				
BP/BT 0.375"	DN10	2.5" (64) <sup>2</sup>	3.5" (89)	1 (25)	3.0	S	O				
BP/BT 0.5"	DN15	2.5" (64) <sup>2</sup>	3.5" (89)	1 (25)	3.0		O	S			
0.5"	DN15	3.5" (89)	5.06" (128)	1.5" (38)	4.28	O	O	S	O		
0.75"	DN20	4" (102)	5.5" (140)	1.5" (38)	4.75	O	O	S	O		
1"	DN25	4.5" (114)	5.93" (156)	1.5" (38)	5.22		O	S	O	(25)	(1,2)
1.5"	DN40	5.5" (140)	6.8" (173)	1.5" (38)	6.15		O	S	O	(38)	(1,2)
2"	DN50	6.25" (159)	7.42" (188)	1.5" (38)	6.84			S	O	(51)	(1,2)
2.5" <sup>3</sup>	DN65	8.75" (222)	10" (254)	1.75" (44,5)	9.38			S		(63,5)	(1,6)
3"	DN80	8.75" (222)	10" (254)	1.75" (44,5)	9.38			S	O	(76,1)	(2)
4"	DN100	11.5" (292)	13" (330)	2.0" (51)	12.25			O	S		
Castings											
0.5"	DN15	3.5" (89)	N/A	N/A	3.5" (89)	O	O	S	O		
0.75"	DN20	4" (102)	N/A	N/A	4" (102)	O	O	S	O		
1"	DN25	4.5" (114)	N/A	N/A	4.5" (114)		O	S	O	(25)	(1,2)
1.5"	DN40	5.5" (140)	N/A	N/A	5.5" (140)		O	S	O	(38)	(1,2)
2"	DN50	6.25" (159)	N/A	N/A	6.25" (159)			S	O	(51)	(1,2)
2.5"	DN65	7.62" (194)	N/A	N/A	7.62" (194)			S	O	(63,5)	(1,6)
3"	DN80	8.75" (222)	N/A	N/A	8.75" (222)			S	O	(76,1)	(2)
4"	DN100	11.5" (292)	N/A	N/A	11.5" (292)			O	S		

<sup>1</sup> For 2.5" overall length does not comply with ASME BPE dimensions  
<sup>2</sup> BT TC x BW and TC x TC bodies are 2.5" (64) overall length with 0.5" (13) tangent  
<sup>3</sup> 2.5" size uses 3" topworks

Note: Extended Weld Tangents are available only with USOD (ANSI) end connections.  
 Dimensions in ( ) are mm  
 S = Standard, O = Optional, BT = Bio-Tek Body, BP = Bio-Pure

## Body Dimension Charts

### ISO/DIN Forgings

End Connection Size	Topworks Size	ISO										DIN Series 1		DIN Series 2		DIN Series 3	
		A	D	B	C							B	C	B	C	B	C
		mm	mm	mm	1	1,2	1,6	2	2,3	2,6	2,9	mm	mm	mm	mm	mm	mm
DN6	Bio-Tek	89 <sup>1</sup>	25 <sup>1</sup>	8	S	O						8	1				
DN8	Bio-Tek	89 <sup>1</sup>	25 <sup>1</sup>	13,5	O		S	O				10	1				
DN10	Bio-Tek	89 <sup>1</sup>	25 <sup>1</sup>	17,2	O		S	O				12	1	13	1,5	14	2
DN15	0.5"	106	25	21,3			S	O				18	1	19	1,5	20	2
DN20	0.75"	118	25	26,9			S	O				22	1	23	1,5	24	2
DN25	1"	127	25	33,7			O	S				28	1	29	1,5	30	2
DN32	1.5"	174	35	42,4			O	S				34	1	35	1,5	36	2
DN40	1.5"	174	35	48,3			O	S				40	1	41	1,5	42	2
DN50	2"	191	35	60,3				S	O	O	Cast Only	52	1	53	1,5	54	2
DN65	3"	254	44.5	76,1				O	S	O		70	2				
DN80	3"	254	44.5	88,9					S	O		85	2				
DN100	4"	330	51	114,3					S	O		104	2				

<sup>1</sup> BT TC x BW and TC x TC bodies are 64 mm overall length with 13 mm tangent

Note: All measurements are mm unless otherwise noted.

S = Standard, O = Optional

### Benefits of the new Pure-Flo Body:

- No welded tube extensions required for most welding equipment
  - Less over-all valve body length compared to welded tube extensions
  - Fewer welds in the process system
  - Less validation paperwork due to fewer material certifications
  - Higher quality field welds
  - No narrow or off-set weld heads required.
- All these benefits add up to lower installation costs and improved production schedules.

### End Connections

Pure-Flo Diaphragm Valve bodies are available in a variety of end connections:

- Tri-Clover Tri-Clamp®
- 14, 16, 18, 20 O.D. Gauge Tubing
- Schedule 5, 10, 40 Piping
- ISO Ends
- SMS 1146 Ends
- DIN 11850 Ends

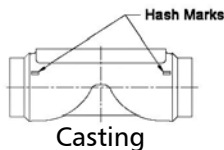
### Drainability

Pure-Flo diaphragm valves may be installed in vertical or horizontal lines as required. Drain marks are provided as standard on cast and forged bodies to facilitate installation and optimize drainability. One mark must be located in the vertical plane, cutting the centerline of the pipe.

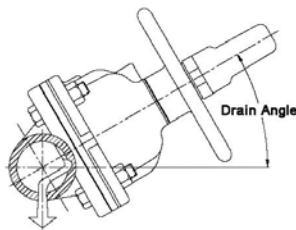
The slope of process piping must be designed to provide proper pitch in order to optimize drainability. Drainability in a process system is ultimately the responsibility of the system designer end user.



Forging/Wrought



Casting



### Weld Installation

Bio-Pure and Bio-Tek valves, 1/4"–1/2" (DN 8–15) and ISO End valves have minimum 1" (25 mm) cutbacks and generally do not require tube extensions for standard TIG orbital welding equipment.

Pure-Flo valves, 0.5–6" (DN15–150) have ASME BPE fitting compatible outbacks and generally can be welded without disassembly using most standard TIG orbital welding equipment.

### Drain Angles

Valve Size		Forging			Investment Casting	
Inch	DN	ANSI <sup>5</sup>	ISO	DIN	ANSI	ISO
0.25 <sup>1</sup>	8 <sup>1</sup>	30° <sup>2</sup>	20°	20°	N/A	N/A
0.375 <sup>1</sup>	10 <sup>1</sup>	30° <sup>2</sup>	20°	20°	N/A	N/A
0.50 <sup>1</sup>	15 <sup>1</sup>	30° <sup>2</sup>	20°	20°	N/A	N/A
0.50	15	30°	13°	16°	30°	17°
0.75	20	30°	21°	25°	30°	18°
1.00	25	30°	22°	26°	31°	20°
1.25	32	N/A	22°	25°	N/A	28°
1.50	40	28°	17°	22°	30°	20°
2.00	50	23°	16°	19°	25°	19°
2.50	65	26° <sup>3</sup>	23°	23°	19°	N/A
3.00	80	20°	14°	18°	25°	N/A
4.00	100 <sup>4</sup>	16°	11°	14°	20°	N/A
6.00	150	N/A	N/A	N/A	20°	N/A

<sup>1</sup> Bio-Pure and Bio-Tek sizes.

<sup>2</sup> Bodies manufactured prior to 2010 have a 20° drain angle for the Bio-Tek buttweld bodies with 1" (25.4 mm) cutbacks and a 30° drain angle for Bio-Tek TC bodies. Consult engineering drawings for drain angles on Bio-Tek fabrications. Bio-Pure and Bio-Tek forgings have been standardized on 30° draing angle regardless of body type.

<sup>3</sup> 3" forged body with 2.5" end connection.

<sup>4</sup> DN 100 bodies to DIN/ISO dimensions are wrought.

<sup>5</sup> Forging drain angles apply to all end connections.

Note: As a rule of thumb drain angle tolerances of +/- 2° will assure optimal drainability. Consult Pure-Flo product engineering for specific drain angle tolerances.

## Manufacturing Methods

### Ferrite

The selection of process components in the Pharmaceutical/Bioprocessing Industry, especially in cell culture applications, demonstrates a distinct movement toward lower ferrite materials. However, in many applications the use of higher ferrite content components may have no effect on the product, service life, or performance of the component and the inherent cost of the component is reduced. The nature of the process, utility protocols (i.e. passivation, cleaning, sterilization, fabrication), as well as additional surface preparation of the material such as electropolishing, will impact the extent of the components corrosion resistance. ITT provides customers a choice in body types based on the needs and requirements of the customers process application.

Ferrite can be defined as the ferromagnetic, body-centered, microstructural constituent of variable chemical composition in iron-chromium-nickel alloys. This may be formed upon solidification from molten metal (delta ferrite) or by transformation from austenite or sigma phase on cooling in the solid state (alpha ferrite). The formation of ferrite is therefore a natural occurrence in stainless alloy products. Ferrite levels can be determined utilizing several techniques including chemical analysis, metallographic examination and magnetic attraction. As one can see from the below comparisons, ferrite is depleted as the material is worked, i.e. castings having the highest content and forgings having the lowest. Free delta ferrite contained in components in a process system may or may not be of concern to the end user.

### Metallurgy

ITT Pure-Flo customers have a choice of valve body types based on the needs and requirements of the process application. Pure-Flo standard body material for forged bodies is 316L, 1.4435 sulfur controlled to ASME BPE Table DT-3.

Applications may require special alloys or materials to provide a desired performance. Consult a Pure-Flo representative for availability and application information.

Wrought bodies are available in 316L, 1.4435 or other special materials. Biopharmaceutical ap-

All valve bodies are fully material heat traceable to EN 10204 3.1B. Certified Mill Test Reports are provided as standard.

## Manufacturing Methods (cont.)

### Forged

Pure-Flo bodies are produced from round stock or plate which has been processed from an ingot. The round stock or plate is compressed between two halves of a forging tool at elevated temperatures. The result is a shape which is then machined to create the shape required. Machining required is more extensive than a casting. Ferrite content for the ANSI Pure-Flo and ISO/DIN forged product lines is 0.5%.



### Wrought

The tank bottom valves, divert valves and block body fabrications are produced from wrought material. Wrought material is worked material such as plate or round stock. Rather than forging a shape between two halves of a tool, as in the case of a forged body, the shape required is machined directly from wrought material. Ferrite content in wrought material may vary depending primarily on the metallurgy of the material used.



### Cast

Pure-Flo bodies are produced utilizing the lost wax or investment cast method. A wax impression is created for the shape required. The wax impression is dipped or sprayed with ceramic material and then fired in a kiln. The wax evaporates leaving behind a hard ceramic shell into which molten material is poured. The solidification of molten metal may cause sub-surface porosity, which varies in occurrence depending on casting techniques, machining and interior finish specifications. The result is a product complete with flow path, bolt holes,

drain marks and body identification marks cast into the required shape. Machining is, therefore, minimal. Pure-Flo castings go through a rigorous qualification program to ensure the highest attainable quality is achieved. The levels of porosity are the absolute minimum possible.



## Surface Finish

Pure-Flo valve bodies are available in a complete range of mechanically polished and electropolished internal surface finishes to satisfy system design requirements. Pure-Flo valves are available in a complete range of ASME BPE compliant internal surface finishes.

ITT Pure-Flo provides a complete range of both internal and external electropolish options. Electropolish surface finishing creates a superior surface finish for biopharmaceutical applications. Electropolishing improves corrosion resistance, removes inclusions and contaminants, and improves the over-all surface for cleaning and sterilization.

### Surface Finishes per ASME BPE

Mechanical Polished Surface Finish (Interior Only)

Code	R <sub>a</sub> , MAX	
	μ-in	μm
SF1	20	0.51
SF2	25	0.64
SF3	30	0.76

General Notes:

1. All Ra readings are taken across the lay, wherever possible.
2. No single Ra reading shall exceed the Ra max. value in this table.
3. Other Ra readings are available if agreed upon between owner/user and manufacturer, not to exceed values in this table.

### Mechanical Polish Surface Finish (Interior Only)

Code	Non-EU Service Microinch Max	EU Service Micron Max
0	No Mechanical Polish	No Mechanical Polish
2	35 Ra	0.8 Ra
6	25 Ra	0.6 Ra
8	20 Ra	0.5 Ra
7	15 Ra	0.38 Ra
9	11 Ra	0.28 Ra
10	10 Ra	0.25 Ra

### Electropolish Surface Finish (Interior & Exterior)

Code	Surface Finish
0	No Electropolish
2	Exterior Electropolish only
3	Both Interior and Exterior Electropolish
4	Interior Electropolish only

Mechanical Polished & Electropolished Surface Finish (Interior Only)

Code	R <sub>a</sub> , MAX	
	μ-in	μm
SF4	15	0.38
SF5	20	0.51
SF6	25	0.64

## Electropolishing

Electropolishing is the electrochemical method of removing metal from a surface. Formally, electropolishing is defined as anodic dissolution in the presence of an electrolyte and an imposed current potential.

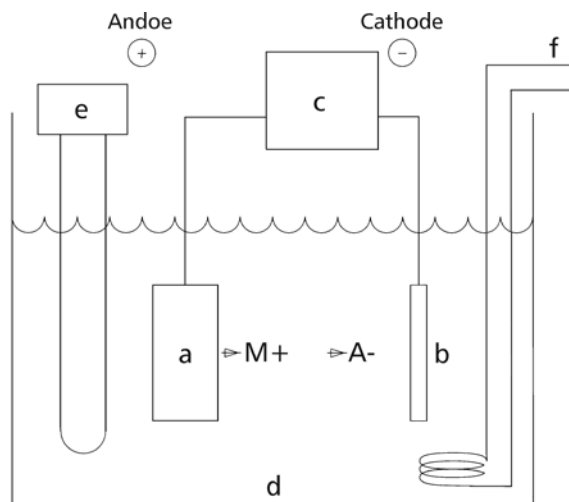
The inherent benefits derived from electropolishing are as follows:

- Provides a continuous, tenacious, chromium-rich oxide layer on the surface resulting in an excellent passive film enhancing corrosion resistance
- Surface leveling reduces the total surface height and relieves much of the surface tension inherent in mechanical polishing
- Enhances the optimization of cleanability and sterilization

- Provides a quality control mechanism exposing surface pits and defective welds
- Exposes and removes impurities within the surface layer
- Provides a lustrous, aesthetically pleasing appearance

For the reasons mentioned, the use of electropolishing over a mechanically polished surface is becoming more prevalent on the surfaces of system components in critical pharmaceutical and bioprocessing applications. The Pure-Flo product line is available with electropolished interior and exterior surfaces, sizes 0.25–6" (DN 8–150).

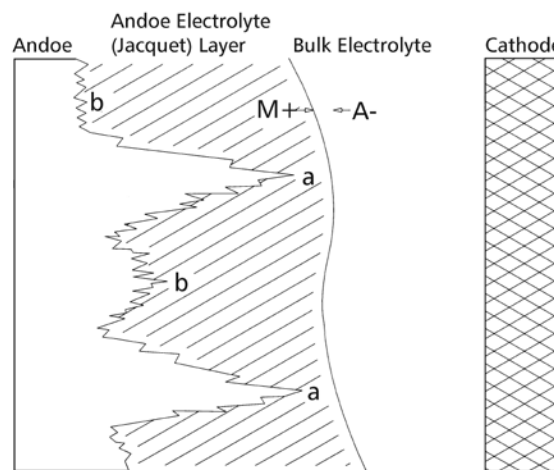
Diagram of a Typical Electropolishing Cell



Legend

- a Anode
- b Cathode
- c Power Source
- d Electrolyte
- e Heater and Temperature Regulator
- f Cooling Coil
- M+ Metal Ion
- A- Anion

Diagram Illustrating Micropolishing and Macropolishing



Legend

- a Region of Macropolishing
- b Region of Micropolishing
- M+ Metal Ion
- A- Anion

## Marking

Pure-Flo valve bodies are marked directly on the valve body, typically on the bottom of the valve or underside of the bonnet flange. Additional information such as customer tag number is available upon request.

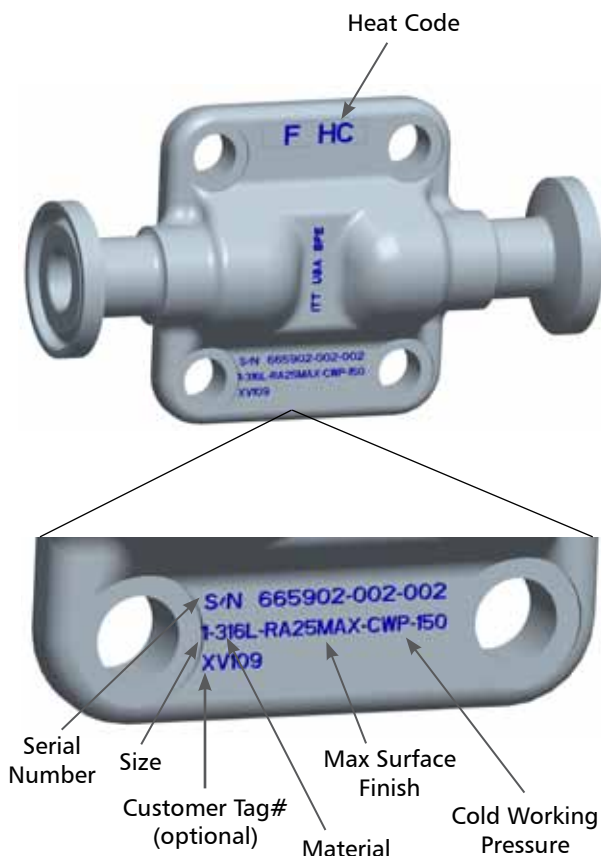
### Validation

ITT Pure-Flo provides critical validation information to meet the needs of the Pharmaceutical and Bioprocessing industries.

### Certified Mill Tests Reports

All Pure-Flo Valve bodies contain a heat number traceable per EN 10204 3.1. Certified Mill Test Reports (CMTRS) are provided as standard on all Pure-Flo valves.

### Standard Marking



### Certificate of Compliance to Specifications

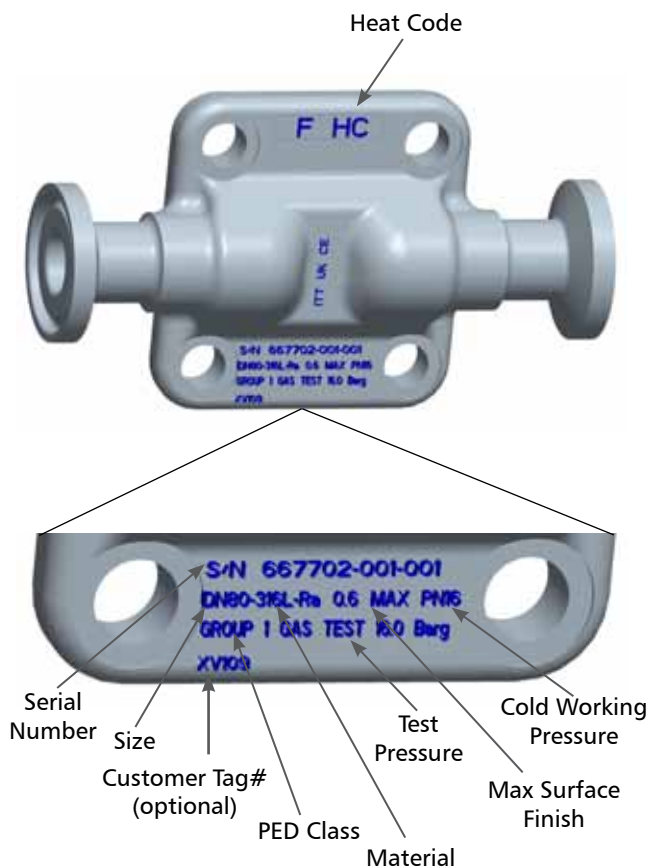
A Certificate of Compliance to customer specification is provided as a standard on all Pure-Flo valves.

- Certification of compliance to CFR Title #21 section 177
- Certification to USP Class VI compliance and/or physical testing document

Additional Validation information available on request

- Interior Surface Characterization documentation
- Quality assurance manual
- ISO 9001 certification
- Certification of testing to MSS-SP-88

### European Union Service Marking



Pure-Flo valves comply with the European Union (EU) Pressure Equipment Directive (PED) 97/23/EC Category 1. Valve bodies are CE marked per the 97/23/EC when EU service is requested.

## Process Fabrications

Process fabrications consist of multiple 2-way valves ported in various ways to fit the application. The intent is to reduce hold up volume and improve drainability versus using standard valves and fittings. Process fabrications minimize the distance between valves improving cleanability and reducing risk of contamination. Fabrications are utilized when hold up volumes are a consideration but not critical. Many process fabrication combinations can comply with the cGMP requirements.

There are three styles of standard two valve fabrications:

### GMP Option:

The GMP fabrication is typically oriented in the vertical position. The design is utilized to reduce dead legs on point-of-use outlets in a typical WFI distribution loop.

### Sterile Access Option:

The Sterile Access orientation is designed for use when the orientation of the main valve is horizontal and the secondary or purge valve or outlet is in the vertical position. The main valve is ported at the low point of the main valve waterway to achieve optimum drainability when the main valve is on its drain angle.

### Horizontal Sterile Access Option:

The Horizontal Sterile Access orientation is similar in configuration to the Sterile Access configuration, but is employed when both the main valve and secondary valve have horizontal orientation.

### Typical Applications:

Sampling, steam condensate drain, divert port, and block and bleed.

### Size Range

0.25–6" (DN8–150) main valve  
0.25–6" (DN8–150) purge valve

### Body Material

316L Stainless Steel wrought, ASTM A479  
316L Stainless Steel Forging, ASTM A-182  
Other materials available upon request

### End Connections

Buttweld:

- 14, 16, 18, 20 Gauge O.D. Tubing
- Schedule 5, 10, and 40 Pipe
- DIN/ISO Ends

Hygienic clamp ends:

