ITT

Manufacturing Methods

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

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, metalographic 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.

Castings

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. Ferrite content may vary considerably depending on several variables including wall thickness, metallurgy of the material, etc. ITT has established a specification of 12% norm based on ASTM A800 analysis techniques. 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.

Forgings:

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%. The ferrite measurement method employed by ITT is the more accurate and labor intensive metalographic technique of ASTM E-562.

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Wrought

The 4" Pure-Flo wrought body, 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. However, most standard product is less than 3%.

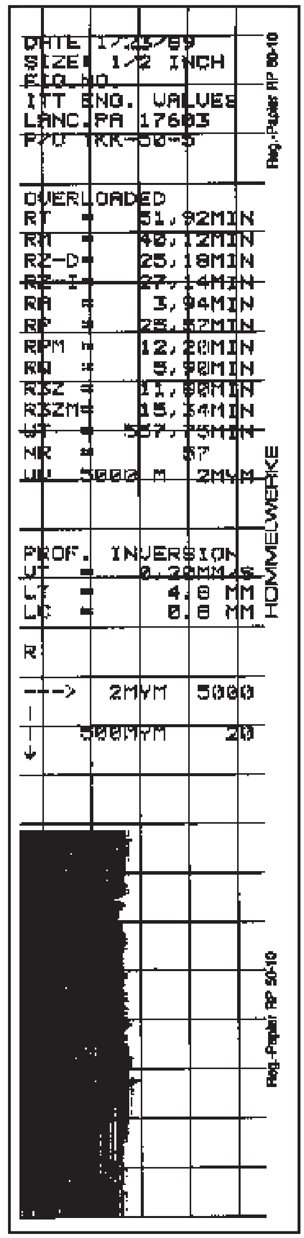
The Pure-Flo product line offers a complete line of Cast, Forged and Wrought bodies to meet the needs and requirements of your process application. The size range, dimensional standards, as well as stainless alloys available for the various body types are as follows:

		Forged	**Wrought**	**Cast**
Size Range	**ANSI**	1/2" - 4"	1/2" - 6"	1/2" - 6"
	DIN/ISO	DN 15 - DN50	DN 15 - DN150	DN 15 - DN50
316L Stainless Alloy		Tri Certified to ASTM A182 Grade 316L,S9, DIN 17440, 1.4435, BN2	ASTM A479, A240, 316L DIN 17440, 1.4435, BN2	ASTM A351 Grade CF 3M
Special Alloys*			C22, C276, AL6XN	
Dimensional Standards		USOD Tubing, Pipe, ISO/DIN/SMS	USOD Tubing, Pipe, ISO/DIN	USOD Tubing, Pipe, ISO/DIN
Ferrite content		< 0.5%	< 3%	<12%

* other materials available upon request

Mechanical Polishing

The method for describing interior surface finishes for stainless process components (i.e., tube, fittings, valves, etc.) has become more articulate as the concern for surface quality and consistency has heightened in the Pharmaceutical and Bioprocessing Industries. Initially, interior surfaces were described by polish numbers such as #4 or #7. Polish numbers gave manufacturers a great deal of breadth on the interior finish supplied. For example, depending on the polishing technique, a #4 interior finish may vary from an 80 grit to a 150 grit finish.



Polish numbers have typically been replaced by grit numbers as a means for describing interior surface finishes more accurately. Grit numbers are the number of silicon carbide particles per square inch of abrasive pad. Another definition equates grit number with the number of scratches per linear inch. In general grit numbers attempt to link surface roughness with the number of scratches on a particular surface. The higher the grit number, the finer and more numerous the scratches and the smoother the finish. However, the method of polishing, devices employed, and surface hardness encountered (i.e., castings, forgings, extrusions, etc.) all have a bearing on the surface roughness achieved. The Pharmaceutical and Bioprocessing Industries are now applying a more articulate means of describing surface roughness. The surface roughness is actually measured in

Mechanical Polishing

micro inches, or microns, by a surface profilometer. Surface roughness is normally described utilizing two arithmetic derivations: Rq-root mean square or Ra-arithmetic mean (see Surface Roughness chart).

When utilizing a quantitative measuring technique, all the variables inherent in polishing are eliminated. An end user can now specify a specific surface roughness (ex. 25 μin Ra) and the vendor must now determine how to effectively achieve the finish required. The result is a consistent, verifiable surface finish. ITT utilizes a Hommelwerke T-20 surface roughness device as a quality assurance mechanism and can provide, per request, a tape detailing the interior surface characterization of valve bodies on a statistical basis.

To specify a maximum surface roughness:

Roughness Chart		
Micro Inch μ in	Micron μ m	Grit # (Reference only)
35	0.89	150
25	0.64	180
20	0.51	240
11	0.28	320

Note: Values expressed in Ra

Surface Roughness

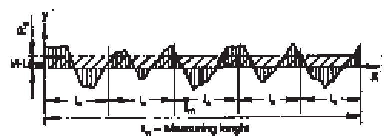
Parameter: Ra (CLA)
Description: Arithmetic means roughness value
Specification: DIN 4768/1, DIN 4762/1, Draft, ISO/DIS, 4287/1, Draft

Definition:

$$R_a = \frac{1}{l_m} \int_{x=0}^{x=l_m} |y| \, dx$$

The arithmetical average value of all absolute distances of the roughness profile R from the centre line within the measuring length l_m.

Diagram:



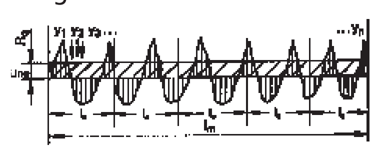
Parameter: Rq (RMS)
Description: Root means square roughness value
Specification: DIN 4762/1, Draft, ISO/DIS, 4287/1, Draft

Definition:

$$R_q = \sqrt{\frac{1}{l_m} \int_{0}^{l_m} y^2 (X) \, dx}$$

(An alternative to R_a.) R_q is defined as the RMS value of a profile calculated over a single sampling length, but can be expressed as the mean result of 5 consecutive sampling lengths.

Diagram:



Electropolishing

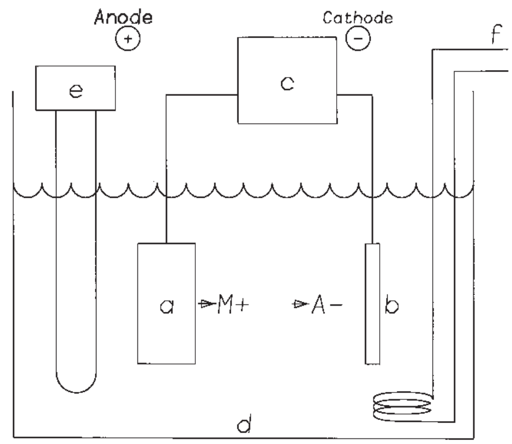
Electropolishing, simply stated, is the electrochemical method of removing metal from a surface. Formally, electropolishing is defined as anodic dissolution in the presence of an electrolyte and an imposed current potential.

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 lusterous, 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 1/4–6 (DN 8–150).

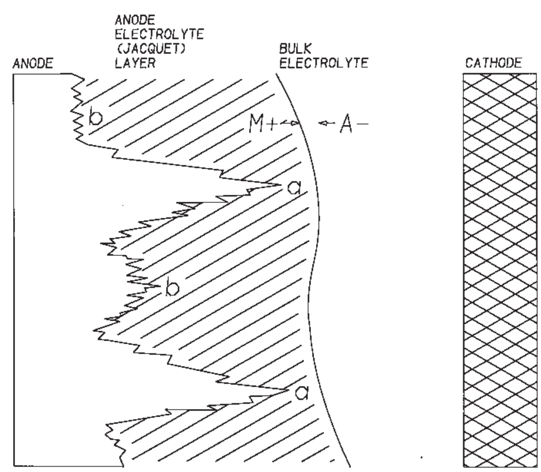
Diagram of a Typical Electropolising Cell



Legend

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

Diagram Illustrating Micropolishing and Macropolishing



Legend

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