



## Stainless Steel – A Family of Medical Device Materials

A report by

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Stainless steel is the term used to describe an extremely versatile family of engineering materials. Selected primarily for their corrosion and heat resistance, these materials offer a wide range of physical and mechanical properties coupled with inert, easily cleaned, surfaces capable of accepting a variety of aesthetically pleasing finishes. Hence, stainless steels find a broad range of applications in industries where hygiene is a major requirement (eg food and beverage processing, pharmaceutical production, drinking water systems, etc).

### ***What makes the stainless steel family “stainless”?***

Alloys of iron containing 10.5% chromium form a protective, adherent and coherent, oxide film that envelops the entire surface of the material. This oxide film, known as the passive or boundary layer, is very thin (~2 nanometres thick) and forms as chromium in the surface layer reacts with oxygen and moisture in the environment. The passive layer exhibits a truly remarkable property: when damaged (e.g. abraded), it self-repairs as chromium in the steel reacts rapidly with oxygen and moisture in the environment to reform the oxide layer.

Increasing the chromium content beyond the minimum of 10.5% confers still greater corrosion resistance. Further improvement in corrosion resistance and a wide range of properties may be achieved by the addition of nickel. The addition of other chemical elements may be used to enhance resistance to specific corrosion mechanisms or to develop desired mechanical and physical properties. For example, molybdenum further increases resistance to pitting corrosion, while nitrogen increases mechanical strength as well as enhancing resistance to pitting.

### ***The Stainless Steel Family***

The stainless steel family may be described in a variety of ways. Perhaps the most accurate way is by reference to the metallurgical phases present in their microscopic structures:

- Austenitic
- Ferritic
- Martensitic (including precipitation hardening steels)
- Duplex (consisting of a mixture of ferrite and austenite)

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Within each of these groups, there are a number of “grades” of stainless steel defined according to their chemical compositions. These grades are specified in European and International standards, and within its specified range of chemical composition, each grade will exhibit the desired properties (e.g. corrosion resistance, heat resistance, machinability).

***Ferritic stainless steels*** consist of primarily of chromium (typically 12.5% or 17%) and iron. Generally, ferritic stainless steels contain very little nickel (typically <1%). Their minimal carbon content prevents hardening by heat treatment, but confers superior corrosion resistance to martensitic stainless steels. They possess good resistance to oxidation, are ferromagnetic and, although subject to an impact transition (i.e. become brittle) at low temperatures, possess adequate formability. Their thermal expansion and other thermal properties are similar to conventional steels. Ferritic stainless steels are readily welded in thin sections, but suffer grain growth with consequential loss of properties when welded in thicker sections.

***Martensitic stainless steels*** consist of carbon (0.2-1.0%), chromium (10.5-18%) and iron. These materials may be heat treated, in a similar manner to conventional steels, to provide a range of mechanical properties. Their corrosion resistance may be described as moderate (ie their corrosion performance is poorer than other stainless steels of the same chromium and alloy content). They are ferromagnetic, subject to an impact transition at low temperatures and possess poor formability. Their thermal expansion and other thermal properties are similar to conventional steels. They may be welded with caution, but cracking can be a feature when matching filler metals are used.

***Austenitic stainless steels*** consist of primarily of chromium (16-26%), nickel (6-12%) and iron. However, as previously stated, other alloying elements (e.g. molybdenum) may be added in order to develop desired properties. For example, copper is added to improve resistance to acids and/or for the improved deformation needed in the cold heading of fasteners). This subgroup contains more grades, used in greater quantities, than any other category of stainless steel. Austenitic stainless steels exhibit superior corrosion resistance to both ferritic and martensitic stainless steels. Corrosion performance may be varied to suit a wide range of service environments by careful adjustment of their compositions. These materials cannot be hardened by heat treatment and are strengthened by work-hardening. Unlike ferritic and martensitic stainless steels, austenitic grades do not exhibit a yield point. They offer excellent formability and their response to deformation can be controlled by the nickel and copper content. They are not subject to an impact transition at low temperatures and possess high toughness down to cryogenic temperatures. They exhibit greater thermal expansion and heat capacity, with lower thermal conductivity than other stainless or conventional steels. They are generally readily welded, but care is required in both the selection of consumables and the welding practice used for more highly alloyed grades. Austenitic stainless steels are often described as non-magnetic, but may become slightly magnetic when machined or worked.

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**Duplex stainless steels** consist of chromium (18-26%) nickel (4-7%), molybdenum (0-4%), copper and iron. These stainless steels have a microstructure consisting of austenite and ferrite, which provides a combination of the corrosion resistance of austenitic stainless steels with greater strength. Duplex stainless steels are weldable, but care must be exercised to maintain the correct balance of austenite and ferrite. They are ferromagnetic and subject to an impact transition at low temperatures. Their thermal expansion lies between that of austenitic and ferritic stainless steels, while other thermal properties are similar to plain carbon steels. Formability is reasonable, but higher forces than those used for austenitic stainless steels are required. Duplex stainless steels cannot be hardened by heat treatment.

#### ***Surgical steels***

There is a popular misconception that special “surgical” steels are used for all medical devices. However, as medical devices represent approximately 1% of the total production tonnage of stainless steel, there is little justification for the development of special surgical steels. Furthermore, stainless steel medical devices are produced in low volume, batch processes or in high volume processes utilising small quantities of material. Most non-implant medical devices (eg dental and surgical instruments, kidney dishes, theatre tables, etc) are, therefore, manufactured from commercial grade stainless steels. These stainless steels adequately meet clinical requirements where contact with human tissue is transient.

However, implant applications are an exception to this generalisation. Stainless steels used for implants must be suitable for close and prolonged contact with human tissue (ie in warm, saline conditions). These clinical requirements were the driver for the development of special “implant” steels. These materials, now produced with enhanced chemical compositions, were originally developed from commercial grade 1.4401 (AISI 316) stainless steel. Specific requirements for resistance to pitting corrosion, and the quantity and size of non-metallic inclusions apply to implant grade stainless steels, which do not apply to commercial stainless steels. Hence, special production routes (ie vacuum melting or electroslag refining) are required to produce implant steels.

#### ***Non-Implant Medical Devices***

ISO 7153-1 specifies stainless steel for surgical and dental instruments, and also provides an indication of medical device applications for each grade. It should be stressed that, although the grades listed in ISO 7153-1 are generic, they can be related to European and National steel standards for readily available, steels intended for commercial applications. These steel grades are used, throughout the world, in non-implant medical devices.

Austenitic stainless steels find applications in medical devices where good corrosion resistance and moderate strength are required. For example, canulae, dental impression trays, guide pins, hollowware, hypodermic needles, steam sterilisers, storage cabinets and work surfaces, thoracic retractors, etc. These applications often require a material that is easily formed into complex shapes.

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Martensitic stainless steels are used extensively for dental and surgical instruments. These stainless steels can be hardened and tempered by heat treatment. Thus, they are capable of developing a wide range of mechanical properties (i.e. high hardness for cutting instruments and lower hardness with increased toughness for load-bearing applications). For example, bone curettes, chisels and gouges, dental burs, dental chisels, curettes, explorers, root elevators and scalers, forceps, haemostats, retractors, orthodontic pliers, and scalpels.

Ferritic stainless steels, however, find few applications in medical devices. Examples are solid handles for instruments, guide pins and fasteners.

Duplex stainless steels have yet to make an impact in healthcare and, in fact, the author was unable to find any examples of their use medical devices.

#### ***Implants***

ISO standards 5832-1 and 5832-9 specify wrought (austenitic) stainless steel and high-nitrogen (austenitic) stainless steel, respectively, for surgical implants. Examples of implant applications are aneurysm clips, bone plates and screws, femoral fixation devices, intramedullary nails and pins, and joints for ankles, elbows, fingers, knees, hips, shoulders and wrists.

#### ***Surface Finish***

Non-implant medical devices are produced with smooth, often highly polished, surfaces that are easily cleaned, resist corrosion and reduce the tendency to accumulate debris. However, knurled areas are often provided on dental and surgical instruments to increase grip. Polished surfaces are produced by mechanical polishing techniques and may be further enhanced by electropolishing. Electropolished surfaces have the advantage of being chemically clean and free from residual polishing compounds. Highly reflective surfaces can, however, cause glare under operating lights and many producers now offer non-glare finishes. In the production of non-glare surface finishes, the standard mechanical polishing route is followed until the last operation, where a Scotchbrite mop is used instead of a polishing mop.

Implants have very specific surface finish requirements. In many cases, the surfaces are mechanically polished to a high finish and/or electropolished. Polished surfaces offer enhanced corrosion resistance and, in the case of an electropolished finish, a chemically clean surface. Furthermore implants are subject to stringent cleaning regimes designed to remove debris from manufacturing processes as well as microbiological contamination.

#### ***Innovation***

In the case of non-implant medical devices, innovation tends to be limited to new applications for commercial grade stainless steels. For example, a precipitation hardening stainless steel has been used for the shaft and gripping mechanism of forceps used in keyhole surgery. As precipitation hardening stainless steels may be hardened, after forming and machining, by heat treatment at relatively low temperatures (~500 °C). Thus, precipitation hardening stainless steels are less prone

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to distortion other hardenable stainless steels and advantages are gained in both assembly and function. Manufacturers of non-implant medical devices continue to work with highly innovative medical professionals to meet new design challenges by adapting existing commercial grade stainless steels to new applications.

In recent years, innovation in implant applications has tended to concentrate on further improvement of their bio-compatibility by the application of special surface coatings that encourage bone attachment.

#### *From Manufacture to Disposal*

The European stainless steel industry promotes selection and use of appropriate grades of stainless steel to maximise the benefits of their unique properties throughout their life cycle. As stainless steels are relatively expensive raw materials, the industry has made use of life cycle costing to develop the market by highlighting the advantages of using a material with low maintenance costs. This may be demonstrated by the fact that, due to their passive film, stainless steels do not require protective surface coatings (eg paint) and, thus, considerable savings in maintenance costs may be achieved.

The high intrinsic value of stainless steel scrap, derived from its constituents nickel and chromium, coupled with economic advantages obtained by melting scrap stainless steel in electric arc furnaces, has led to a well-established, international recycling network. European stainless steel producers routinely incorporate more than 50% stainless steel scrap in their melting processes and, in addition, it is estimated that more than 95% of the total stainless steel production is recycled. Nevertheless, there continues to be an increase in the annual demand for virgin materials for the production of stainless steel. This increase is due to an average annual growth in the stainless steel market of ~5% and an average service life of 30 years for stainless steel products.

The average service life of stainless steel medical devices varies from single use (eg hypodermic needles, scalpel blades, etc) to decades of service for dental extraction forceps, kidney dishes, thoracic retractors, etc. Disposal of medical devices is governed by the need to prevent infection and thus inhibits the extent to which stainless steel medical devices are recycled. However, the stainless steel industry in the UK has shown an interest in recycling of single use instruments intended to prevent the spread of CJD. At the time of preparing this article, the challenges presented by these proposals remain to be resolved.

In summary, stainless steels offer a family of cost effective engineering materials, with good corrosion resistance and a range of mechanical/physical properties, well-suited to a wide variety medical device applications. Since their development over sixty years ago, stainless steels have made invaluable contributions to the health and well-being of mankind. This trend is set to continue into the future by meeting the needs of healthcare in developing countries with cost effective reusable medical devices as well as in the continued development of sophisticated medical products for developed countries.

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