Stainless steel: an aseptic remedy

With technological advancements, humankind is successfully developing optimal and healthy solutions to combat several serious diseases. The use of stainless steel in medical science has given birth to the marvel called surgical steels, often known as medical steels, which are passive, corrosion-resistant, and suitable for the human body in all conditions. With increasing thrust on R&D in medical technology, stainless steel is paving the way for new uses in internal and external medical applications.

By Mr. K K Pahuja, President, Indian Stainless Steel Development Association (ISSDA)

Surgical or medical steels are grades of stainless steel with at least 13% chromium content and 0.2% carbon, and may additionally contain more carbon, nickel or molybdenum, depending on the end-use. Chromium is added to improve corrosion resistance, while adding nickel reduces brittleness. Along with this, stainless steel is inherently inert in nature. This allows medical stainless steels to be hypoallergenic, which means that they are unlikely to cause an allergic reaction. Owing to this property, such stainless steels can come in direct contact with the human body during pharmaceutical preparations and as medical devices, implants, and bone fixation devices without the risk of causing any infection. It is noteworthy that stainless steel implants do not assume any toxicity which could otherwise be caused due to corrosion or wear and tear.

Stainless steel and the medical industry

According to the British Stainless Steel Association, medical devices consume approximately 1% of the total production tonnage of stainless steel. The production of stainless steel medical devices occurs in low volumes in batch processes, or in high volumes while utilising small quantities of the material. Most non-implant medical devices (for example, dental and surgical instruments, kidney dishes, operation theatre tables, wall claddings, etc.) are, therefore, manufactured from commercial grade stainless steels. These stainless steels adequately meet clinical requirements where contact with human tissue is transient. On the other hand, specialized higher grades of stainless steel are used for more critical medical instruments (like scissors, scalpels, hypodermic needles, tongue depressor, etc.) to ensure the best hygiene standards.

Applications of stainless steel as a safe alloy

On marrying the unique properties of stainless steel with the dynamics of the human body, one gets special medical stainless steels that provide corrosion resistance to body fluids, bio-compatibility, and an excellent strength-to-weight ratio for designing efficient surgical instruments. The bio-compatibility of medical stainless steel has proven to be the most effective till date in its ability to perform specific functions inside the human body, especially during implants. Stainless steel has been used traditionally for dental, surgical, and reconstruction purposes, apart from being useful in invasive devices in the medical field, such as cannulae, hypodermic needles, guide pins, thoracic retractors, etc. Non-invasive medical devices such as dental impression trays, hollowware, steam sterilizers, storage cabinets and work surfaces, etc. are also made of stainless steel. Hardened or martensitic stainless steel is used for bone curettes, chisels and gouges, dental burs, dental chisels, explorers, root elevators and scalers, forceps, haemostats, retractors, orthodontic pliers, and scalpels. Examples of implant applications are aneurysm clips, bone plates and screws, femoral fixation devices, intra-medullary nails and pins, and joints for ankles, elbows, fingers, knees, hips, shoulders, and wrists. For implants, wear- and fatigue-resistance are crucial in determining the longevity of an implant. Medical stainless steels also meet the stringent design and fabrication criteria that are typically required in medical devices of various shapes and sizes. The average service life of stainless steel medical devices varies from single-use (eg. hypodermic needles, scalpel blades, etc.) to decades of service (eg. dental extraction forceps, kidney dishes, thoracic retractors, etc.)

“Grade 304 is the most commonly used stainless steel grade for manufacturing medical devices and instruments.”

304 as medical stainless

As per International Stainless Steel Federation (ISSF), elementary chromium (Cr) is a critical constituent of any stainless steel as it is

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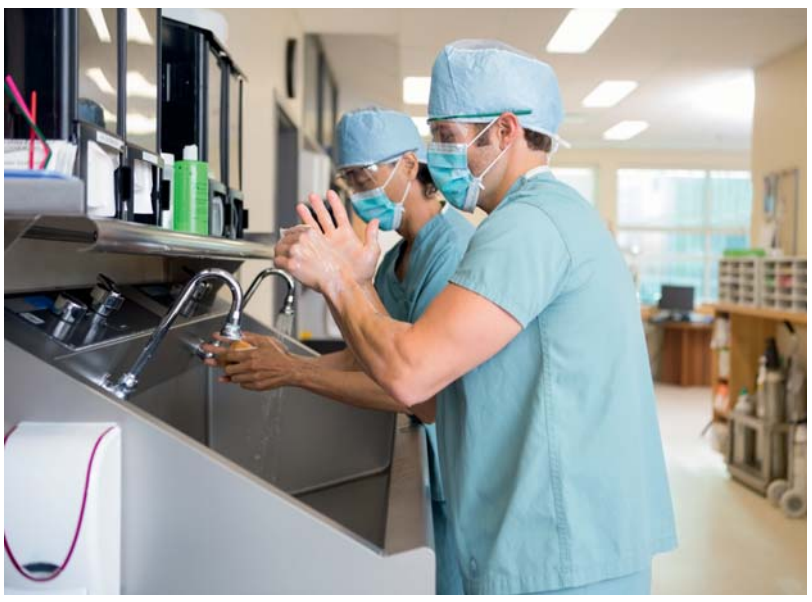
Mechanical and chemical properties of SS 304 are shown in the following tables:

MECHANICAL PROPERTIES					
Grade	Tensile Strength (MPa)- min	Yield Strength 0.2% Proof (MPa)- min	Elongation (% in 50mm)-min	Hardness Rockwell B (HRB)- max	Brinell (HB)- max
304	515	205	40	92	201
316	515	205	40	95	217
316L	485	170	40	95	217

CHEMICAL PROPERTIES									
Grade	%C (max)	%Mn (max)	%Si (max)	%P (max)	%S (max)	%Cr (max)	%Ni (max)	%N (max)	%Mo (max)
304	0.07	2.00	0.75	0.045	0.03	19.50	10.50	0.10	–
316	0.08	2.00	0.75	0.045	0.03	18.00	14.00	0.10	3.00
316L	0.03	2.00	0.75	0.045	0.03	18.00	14.00	0.10	3.00

MEDICAL STAINLESS



Stainless steel is valued in the medical field for its sanitary design principles.

biologically inert, remains unabsorbed in body tissues, and has no nutritional value. Grade 304 (SS 304) is the most commonly used stainless steel grade for manufacturing medical devices and instruments. SS 304 is highly corrosion-resistant and has low carbon content, which makes it an ideal choice for medical applications. The sterile nature of SS 304 allows for high sanitation standards and makes sure that the metal does not react with body tissues. In another study, ISSF mentions that stainless steel, regardless of its grade can be easily disinfected given its chemically inert and non-toxic nature. Additionally a smooth surface of stainless steel resists HAI (Hospital Acquired Infection) bacteria to flourish. This makes it the perfect choice for surgical and paramedical equipment.

The steel used in medical instruments must necessarily be curable and ductile. Moreover, medical steel should not contain sulfur, copper, or other additives which might be toxic for the human body in certain levels. Good metallurgy is a prerequisite for all surgical equipment and implants. Since medical steels come in contact with human tissue, they have to mandatorily comply with the international instruments and implants standards of ISO (International Organization for Standardization) and ASTM (American Society for Testing and Materials). A series of daily experiences prove that stainless steel is safe when it comes in contact with the human body.

The advantages of SS 304 include high corrosion-resistance, antibacterial properties, easy cleanability, and reusability. Further, this grade is non-magnetic and hence, is perfect for operating theatres or implants within the body. It is interesting to note that once work-hardened, SS 304 will keep its shape. Stainless steel grade 316 is also used in the manufacture and handling of food and pharmaceutical products where metallic contamination is a pertinent challenge. 316L stainless steel is a chromium, nickel and molybdenum alloy. It is a low carbon version of 316 grade stainless steel and is a common choice for biomedical implants, as well as body piercings and body modification implants.

Over the years, stainless steel has made significant contribution to the health and well-being of the human race. Not only is it suitable for high hygiene and sanitation standards, stainless steel today is enabling medical science to tackle several infectious diseases head-on. What's more is that stainless steel does not require regular maintenance and enjoys a low life cycle cost. These properties further validate stainless steel's mettle to meet the future needs in healthcare services in an efficient and cost-effective manner.

Case study: experimental design

In recent years, attempts have been made to improve the surface properties of metals and alloys used in biomedical applications. Namely, 316 L stainless steel is being widely used in orthopedic implants, dental implants, and cardiovascular stents, but manufacturing constraints make working with 316 L SS a difficult task. By refining the parameters of wire electric discharge machining, Dr. P. Raju has recently demonstrated the effectiveness of machining implants from 316 L SS, introducing yet another effective use of stainless steel for medical applications.