

MATERIALS USED IN PRODUCT MANUFACTURING

Surgimax is using different types of material for manufacturing of surgical instruments, in below you can find detailed information about the material and their properties:-

What is AISI?

AISI stands for American Iron and Steel Institute. AISI operates in the United States and North America only. AISI is concerned with steel and iron product. There are different materials which are being used in surgical instruments manufacturing i.e. AISI 304 or AISI 410.

What is ASTM?

ASTM stands for American Society for Testing and Materials. This was founded in the late 1800s and has become one of the largest standards developers in the world. They develop and produce standards for both metallic and non-metallic materials. Some materials will have an AISI number as well as an ASTM number.

Austenitic Stainless Steel

Austenitic or nonmagnetic stainless steels, are classified in the 300 series, with 18% chromium and 2% to 20% nickel for enhanced surface quality, formability, increased corrosion and wear resistance, and are nonhardenable by heat treating because carbon percentage is very low which is only 0.08%. These steels are the most popular grades of stainless produced due to their excellent formability and corrosion resistance but these will not hold a strong cutting edge. Austenitic stainless steel grades include are type 301, 304, 305, 309S, 316, 316L, and 321.

Martensitic Stainless Steel

Martensitic, or hardenable stainless steels, are classified in the 400 series, usually with 11.5% chromium up to 18% chromium, with higher levels of carbon than austenitic, and are capable of being heat treated to a wide range of hardness and strength levels. This series is used in most O.R quality instruments, cutting and non-cutting, because it has a high tensile strength, can hold edge for a long time and is corrosion resistant. However, as there is little or no nickel in this series it is susceptible to corrosion if not looked after properly. Commercially produced AISI grades of this class are type 410, 410H, 420, and 420HC.

Applicable International standards

ISO 7153-1
BS 5194: Part 1
DIN 58298

Stainless Steels

Stainless steel is an alloy of Iron with a minimum of 10.5% Chromium. Chromium produces a thin layer of oxide on the surface of the steel known as the 'passive layer'. This prevents any further corrosion of the surface. Increasing the amount of Chromium gives an increased resistance to corrosion. Stainless steel also contains varying amounts of Carbon, Silicon and Manganese. Other elements such as Nickel and to enhanced formability and increased corrosion resistance. It comes in sheets and bars which are being used in surgical instruments manufacturing.

Stainless Steel Type AISI 304

This material is easy to machine and form. Instruments or components that do not need to be hardened, such as speculums, retractor blades, hollow handles, hospital hollow wares, nuts, screws and pins etc, are usually made from this grade.

Stainless Steel Type AISI 316L

It is a very high purity alloy. 'L' stands for low carbon. It is also called SMO. It is a preferred material for making most orthopaedic implants, such as plates and screws, nails, staples, prostheses and aneurysm clips etc. Certain instruments that have prolonged contact with implants also utilize this material to avoid transfer of dissimilar metal particles which could cause galvanic corrosion reaction on the implants. It is however important to know that metal implants and prostheses can sooner or later fail since no metal has yet been developed that will equal the revitalizing durability of living bone.

Stainless Steel Type AISI 410

This is a most commonly used grade for the manufacture of non-cutting instruments. Typical examples are hemostats, assorted forceps, retractors and so on. It is easy to work with and has Rockwell Hardness in the range of C-40 to C-45. It is a misconception that this grade is inferior in any way as it clearly complies with the British, German and International Standards for application in surgical instruments.

Stainless Steel Type AISI 420 & 440

These are useful grades for cutting instruments such as scissors, knives, chisels, ronguers, bone cutters, bone drills and taps etc. AISI 420 can get Rockwell Hardness in the range of C-48 to C-50 but if hardness around C-55 is required then grade AISI 440 with more carbon is appropriate.

Titanium

Type ASTM F67 - Commercially Pure grades 1,2 and 4. It has the same strength as steel but weighs only 60 percent of the steel. It is highly corrosion resistant but very difficult to work with. Some microsurgery instruments, mandibular implants and weight bearing hip prostheses are made from it. Its biocompatibility is far more superior than any other currently employed implant material. It can be finished in a distinct blue colour but repeated autoclaving may give it a reddish tinge.

Tungsten Carbide

GRADE GC20 This is the hardest man made material, sometime also referred to as diamond. It has a Rockwell of C-86. Cemented carbide is often called hard metal. Its inserts are entered in the jaws of high wearing instruments such as needle holders, scissors and wire cutters. Traditionally these instruments are partly gold-plated for recognition.

Other Metals

There are also many non-ferrous materials that are used in instruments for their specific properties. They may be easier to machine or form and more suitable for procedures or budget.

Aluminum

There are many hard and soft grades. With its excellent heat dissipation capacity along with durability and lightweight it is employed for making the container system for sterilization and storage. Surgimax offer a durable yet economical system, please see our catalogue. Aluminum requires a protective layer by hard anodizing that can also be in different colours for identification. Some instrument handles, mallet heads and splints are also made of aluminum.

German Silver

An alloy of silver and nickel that is less expensive and is used as an alternative to Sterling Silver. It is also more durable and does not turn black after autoclaving.

Brass and Copper

Free cutting brass type 360 and nickel-copper Class A or B are easily formed, moulded and welded therefore useful for making instruments that are otherwise hard to make from steel or require malleable features. Certain instruments made traditionally in these soft metals are proctoscopes, malleable uterine sounds and retractor blades, catheters and cannulas. In order to enhance surface wear these are usually plated.

Sterling Silver

It is 92.5 percent pure silver (Ag). Current uses include trachea tubes, probes for eyes and haemostatic clips. Silver will turn black with oxide. This does not interfere with the function of the instrument. A bit of rub with or without silver polish or elbow grease will bring the original shine back. These instruments should be handled carefully as they are expensive as well as delicate.

Non-metal Materials

Rubber, Plastic, Silicon and Teflon are increasingly used in a wide variety of application, both reusable and disposable. Some of the useful characteristics are toughness, flexibility, resilient, resistant to chemicals, insulating, no moisture absorption, heat deformation, high impact strength, easy fabrication and low cost etc. In fact the possibilities are endless.

Plastic items are gradually enabling a new wave of convenience and cost reduction in the operating room, a trend that will undoubtedly continue to grow with the passage of time. The use of latex rubber, however, has been discouraged because it contains certain protein that is said to cause skin allergy to some patients and hospital staff. No significant hazards are expected from silicon products under normal conditions of handling and use.

Plating

Carbon steel and non-ferrous metals instruments are protected from staining or discolouring by plating of various types. Until the advent of stainless steel most surgical instruments were plated. However many instruments are still more economical or effective to make plated. Mixing of plated instruments with stainless steel instruments in the reprocessing cycle should be avoided as it may result in transference of chrome to stainless that will look like stains. All plated instruments should be routinely checked to ensure there is no cracks or worn areas in the surface. In recent years the use of ultrasonic cleaning has hastened the demise of plated instruments as it tends to strip the plating from the base metal.

Nickel Plating

Nickel adheres very well to carbon steel and is not removed easily. The surface is made free from all flaws or defects which will be detrimental to the final finish. Cutting edges are ground to remove all plating. There are not many instruments made with carbon steel these days, except perhaps for veterinary use or some general-purpose scissors. Moisture will act rather quickly to first stain and then corrode these instruments.

Silver Plating

Instruments or components made of copper or brass can be plated with silver by electrodeposited coating. To enable the final silver deposit to adhere it will follow a primary coating of silver strike solution, nickel or copper plating. The silver plating shall not be less than 0.0010 inch in thickness. It is especially suitable on malleable instruments because the layer of silver plating is so thin it does not crack or chip when instrument is bent. Silver plating may turn black with silver oxide and may be given a good rub to get the shine back.

Chrome Plating

Carbon steel, copper and brass are all base metals that can be chrome plated. Finish on all edges and surfaces shall be uniform and free from burrs, sharp edges (except where required), crevices, grind marks, rough areas, cracks and overlaps. Chrome plating often has a layer of copper or nickel underneath and therefore protects instruments longer from corrosion and discolouration.

Different Finishes

Surgimax is supplying surgical instruments in different finishes depending on customer requirements which are enlist below.

Mirror

A mirror finish is highly polished finish which makes the instruments surface very resistant to correction. This finish does not spot and discolor as easily as other finishes. However it reflects the light during usage and this glare can be distraction for surgeon or an obstruction to visibility.

Satin

An anodized finish, sometime referred to as a satin finish, is dull and no reflective. Protective coatings of chromium and nickel are deposited electrolytically and reduce glare at the wound site but tend to stain and spot more frequently as compared to mirror finish.

Sand

This type of finish is also being used for surgical instruments which eliminates glare completely. This is attained by a sandblasting technique utilizing glass beads or silicone. This finish offer the surgeon better color contrast because they do not reflect the color of tissues.

Ebonizing

It is achieved by placing the instruments in a chemical bath. It is a nonglare finish primarily used for laser surgery. This finish is a black, microscopically irregular surface which scatters and absorbs laser energy. The black or ebonized finish is achieved by dipping in a sodium salt solution and then baking in oven. It keeps the energy from bouncing onto tissue surrounding the intended target and damaging the healthy tissue. Surgimax has therefore abandoned this process and may only be able to offer instruments ebonized in Europe if necessary.

Titanium Nitride Coating

Titanium nitride coating is used to provide improved performance on surgical instruments and dental and medical implants providing an inert surface barrier that protects the products from corrosion and improves the wear resistance maintaining the integrity of the cutting edge longer. The reduced friction coefficient provided by the coating reduces the edge build-up and helps to prevents tissue from adhering to the instruments.



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