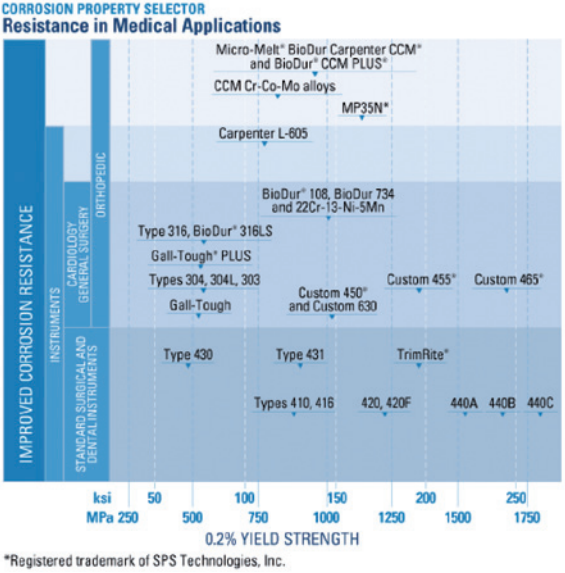
INSTRUMENT MANUFACTURING

Experience shows that this domain has its specific and multidisciplinary aspects, often not well known by implant manufacturers.

How to make properly a surgical instrument ?

It must be resistant, mechanically, but it also needs to undergo treatment throughout its life (cleaning, sterilization, transportation, etc.). The instruments will always remain an essential part of surgery!



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A surgical instrument is composed of one or more materials, and associated treatments, but how to choose the most suitable material, across a myriad of choices offered by manufacturers? Diagrams exist like the one shown above, but from the viewpoint of the designer, the choice is not that simple. Depending on the use, the choice may be relevant or not! Everyone wants to use the absolute best material at the lowest cost, which resists everything, in short, universal. This material does not exist yet, but we selected three materials based on their specifications that must reach the final instrument. This article does not pretend to scan all materials, but restrict our choice to the most common used material in surgical instrumentation.

Instruments with common strength

For the majority of surgical instruments in orthopedics, 17-4PH (1.4542, 630, UNS S17400, X5CrNiCuNb 16-4) proved to be a very good compromise between mechanical strength and corrosion resistance. The machinability of this alloy is correct because it contains copper, and its finishing is easy. Also the heat treatment which gives it its final strength is particularly easy to integrate without complex equipment. It means that this alloy is economically attractive. Mechanical strength of 44 ± 2 HRc (or 1500MPa), is suitable in most cases. However more and more instruments are "miniaturized" and require mechanical strength equivalent.

To meet these new requirements, using materials more resistant is essential. The following paragraph highlights two main.

Instruments with increased strength

The Custom 455 (1.4543, XM16, UNS S45500, X2CrNiTiNb 16-2), combines the workability and post processing of 17-4PH, with increased mechanical strength. Indeed, the hardness can be from 47 to 50HRC (nearly 1700MPa), about 15% more than a 17-4PH.

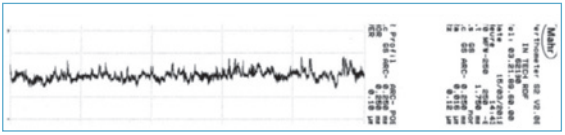
Instruments with flexible parts

In cases where parts of instruments or entire instruments must include elastic parts, such as leaf springs or scissors clamp arms, the use of a martensitic steel such as 420 (1.4028, 420B, UNS S42000, X30Cr13) or 301-302 (1.4310, 301-302, UNS S30200, X10CrNi18-8) is essential. Indeed their elongation after treatment is more important than the steels mentioned above. The weak point of 420, remains its corrosion resistance (lower than other steels).

Treatments after machining

For an instrument to resist external environment, it is critical that the finishing operations, are perfectly controlled,

to avoid the risks of structural and / or visual damage. Heat treatment is an essential element of this chain, but not only. Indeed, the following treatments are also critical; including, for example, mechanical and electrochemical polishing, allowing to have a lower roughness. Without forgetting cleaning and passivation, which brings up stainless steel material characterics.



Identification, laser etching

There are essentially two ways of performing a laser etching on instruments, one is called “deep etching” and the other “superficial etching”. The two etchings don’t behave the same throughout the instrument life. When one looks better cosmetically than the other, it is actually less resistant to repeated cycles of sterilization: it is a question of compromise. Several factors are involved in marking, besides the quality of the surface, four parameters must be controlled:

frequency, power, speed and recovery rate (depending on material and surface condition).

A solution that improves the durability of the engraving, is a chromium coating before etching. This coating has several functions, such as keeping a clean etching, but also improve the corrosion resistance in extreme cases. This also greatly limit the visual aging of the instrument.

Maintenance / recommendation

Cleaning operations are more and more difficult due to complex geometries instruments involved. From the beginning, the designer must focus on integrating the systematic dismantling of the hidden parts and removing deep blind holes.

Here are recommendations to follow:

- During cleaning cycles in decontamination treatment centers, be sure that validated treatments (method - products) are strictly followed; it is often the risk of premature failure of the instruments (corrosion, galling). In particular, do not soak the product during a prolonged time, wipe and dry instruments immediately.

- Avoid treating damaged instruments with newest instruments. Avoid shocking instruments together, at risk to damage the passivation layer. And finally, a critical part of maintenance, often forgotten, is to lubricate the joints and other contact points.

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