SUTUREX & RENODEX
SURGICAL NEEDLES

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STAINLESS STEELS INFORMATION FOR SURGICAL NEEDLES APPLICATIONS

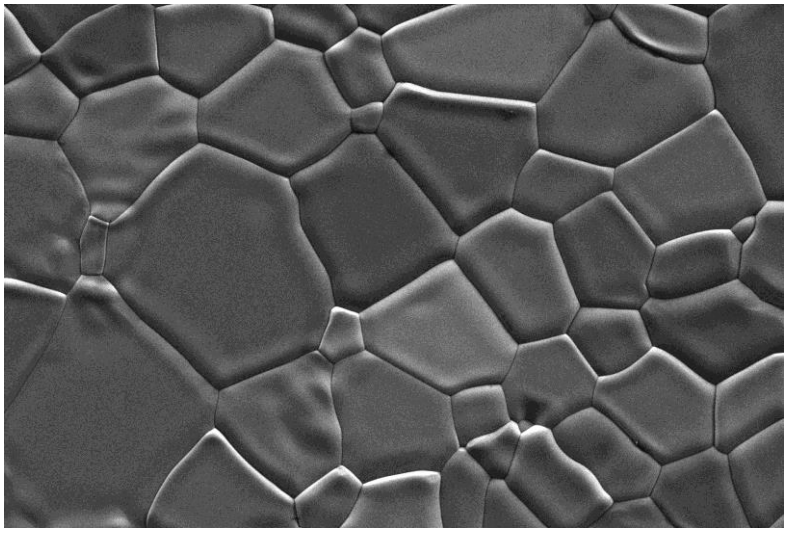
The different stainless steels on the market

INTRODUCTION

Nowadays, all over the world, the production of surgical needles is usually made of stainless steels. A stainless steel means a steel containing chromium (Cr). The main function of this chromium addition is to increase the corrosion resistance of the steel.

Surgical needles have complicated shape and should present the best compromise between higher final strength, no breakage during use, good attaching for the suture thread and good constant penetration in the tissues.
In order to manufacture surgical needles, we can find 3 main stainless steels families:

- **Martensitic**
- **Maraging**
- **Austenitic**



WHICH FAMILY?

- ***Martensitic***

AISI 420 and 420 F series
Suturex & Renodex (**420**$^{+}$)

- ***Maraging***

AISI 455 series

- ***Austenitic***

AISI 301 - 302 - 304
Suturex & Renodex (**ENOVA®**)

The above is not an exhaustive list of the steels available on the market.

*Suturex & Renodex certifies that needle manufactured in 420 or ENOVA® 300 complies with **ASTM F899***

MARTENSITIC STAINLESS STEELS

Examples:

AISI 420: Z 35 C14 **AISI 420 F:** Z 22 CD 13-1

Their general chemical composition is:

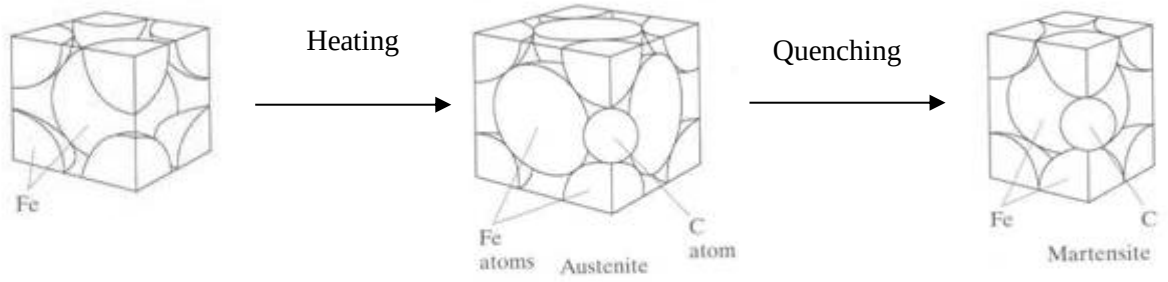
CARBON: From 0,1 to 0,4 %

CHROMIUM: From 11,5 to 14,5 %

Some additional elements can be added to slightly modify the performance of the stainless steel. Sulphur provides an easier drillability and molybdenum increases the corrosion resistance.

Thanks to their very good formability and drillability, the martensitic chromium stainless steels have been the most widely used in the market.
This stainless steel family reaches its mechanical characteristics, and its corrosion resistance after heat treatment.
The hardening process is obtained by heating and air quenching (quick cooling) the metal, followed by a tempering operation.

After quenching: we obtain a martensitic microstructure.



KEY INFORMATION

1. The basic stainless steel of the market
2. Certainly the easiest machinability
3. **Main drawback:**
   The choice of parameters that balances the different performances (High Bending Resistance, Ductilty, Easy attaching, Good Corrosion Resistance) is very limited.

PRECIPITATION HARDENABLE ALLOYS (MARAGING)

Maraging steels were developped in the 1960's.

Examples:

Custom 455®

Their general chemical composition is:

CARBON:	Low content
NICKEL:	From 4 to 12 %
CHROMIUM:	From 10 to 17 %

Additional elements are used for the precipitation hardening as:
Titanium, Copper, Molybdenum, Nobium, Aluminium

Both chromium and molybdenum increase corrosion resistance. Nickel content helps keeping a good formability and ductility.

The formability and drillability of the maraging family, is more difficult than the martensitic stainless steels.
Indeed, the microstructure of the wire in delivery condition is already martensitic.
This stainless steel achieves hardening by precipitation of intermetallic compounds like Ni_3Ti inside the martensitic matrix.

Let's take a comparison from the building industry:
The regular concrete is the martensitic stainless steel, while the reinforced concrete is the maraging super alloy.

In order to reach the best performances, the 2 most critical parameters are:

1. The adequate choice of the raw material
2. To master the precise parameters of the manufacturing process (know-how of the needle manufacturer)

KEY INFORMATION

1. More difficult machinability
2. **Main advantage:**
3. The choice of parameters that balances the different performances (High Bending Resistance, Ductilty, Easy attaching, Good Corrosion Resistance) is very large
4. High Bending Resistance

AUSTENITIC STAINLESS STEELS

This the family of the AISI 300 Stainless steels, used in the ENOVA® range of needles.

Examples:

AISI 304 : X5 Cr Ni 18-10 **AISI 302** : X10 Cr Ni 18-8

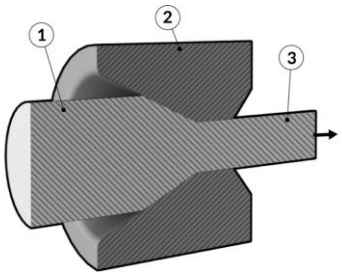
Their general chemical composition is:
CARBON: < 0,15 %
NICKEL: From 6 to 13 %
CHROMIUM: From 17 to 2 %

Additional elements: Molybdenum, Copper, Manganese

Due to their chemical composition, the structure of these stainless steel grades is fully austenitic at low and high temperatures.
It is the austenitic structure that gives the ductile comportment of the needle.

Thanks to the important chromium content, these steels have an excellent corrosion resistance. For example, they can be used in surgical implants.

The mechanical resistance of the austenitic stainless steels is given by a strong cold working.
During a strong cold working, the carbon atoms penetrate the austenic structure, creating a solid solution that strongly strengthens the wire.



❶Soft austenite ❷Draw plate ❸Hard austenite

It is its specific structure that gives the 300 stainless steels their excellent mechanical performances for needle application. These performances are today the best on the market.

The formability and the drillability of such stainless steels is really difficult, and need a specific process. To achieve the perfect adequacy between high tensile strength and ductility, a perfect knowledge of the raw material elaboration linked to the specific know-how of the needle manufacturer is required.

The ENOVA® needle bending resistance is improved by more than 40% compared to a classical 420F martensitic taper point needle, while maintaining an excellent ductility.

KEY INFORMATION

1. The **best steel** on the market
2. Most difficult machinability
3. **Main advantage:**
   Combine high bending resistance with high ductility.

CONCLUSION

- The ENOVA® needle bending resistance is **improved by more than 40% compared** to a classical 420F martensitic taper point needle, with an excellent ductility.

- **ENOVA®: the highest quality needle.**

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