

Product Information Healthcare



ENOVA® PREMIUM TAPER POINT, MICRO-POINT, FLAT & SQUARE BODY - ENOVA® PREMIUM CUTTING & XTRASHARP Surgical NEEDLES

CHEMICAL COMPOSITION

All ENOVA® needles are made in 300 steel series, according to the standard ASTM F899.

UNS Type	CAS nbr.	Carbon Max.	Manganese Max.	Phosphorus Max.	Sulfur Max.	Silicon Max.	Chromium	Nickel	Other Elements
S30200	12671-80-6.	0.15	2.00	0.045	0.030	1.00	17.00–19.00	8.00–10.00	N 0.10 max
S30100		0.15	2.00	0.045	0.030	1.00	16.00–18.00	6.00–8.00	
S30400		0.07	2.00	0.045	0.030	1.00	17.00–19.00	8.00–11.00	N 0.10 max

STANDARD*

NF EN ISO 10993 Biocompatibility tests (Cytotoxicity, Intracutaneous irritation, Sensitization)

European Pharmacopoeia (Bacterial contamination)

ASTM F899 (Standard Specification for Wrought Stainless Steels for Surgical Instruments)

ASTM F1089 (Standard Test Method for Corrosion of Surgical Instruments)

AVAILABILITY RANGES*

Wire sizes 0.28 to 1.58 mm

Length 10 to 90 mm

Hole sizes 0.15 to 1.30 mm

For USP 6/0 to 7

The SUTUREX & RENODEX Company certifies that all needles are coated with medical grade silicon.

INTERNAL PROTOCOLS*

I739 – Dimensional Measurement Protocol

I740 – CuSO4 Test Protocol (corrosion resistance)

I741 – Basic NaCl Test Protocol (corrosion resistance)

I742 – Bending Strength and Ductility Measurement Protocol

I743 – Penetration Strength Measurement Protocol

I744 – Hardness Measurement Protocol

MECHANICAL PROPERTIES

Bending: ●●●●●

Ductility: ●●●●●

Penetration force: ●●●●●

Corrosion resistance: ●●●●●

INTERNAL SPECIFICATIONS*

D013 - SPECIFICATIONS PENETRATION AIGUILLES PCC XTRASHARP

D147 - SPECIFICATIONS PENETRATION AIGUILLES TAPER POINT (ET & ETS)

D148 - SPECIFICATIONS PENETRATION AIGUILLES PREMIUM CUTTING (RCP, ICP & SCP)

D154 - SPECIFICATIONS PENETRATION AIGUILLES MICRO POINT (EY & EYS)

D248 - Spécifications Flexion et Ductilité - Aiguilles Corps Ronds ENOVA® - Machine FLEX V.1.0

D249 - Spécifications Flexion et Ductilité - Aiguilles Corps Triangulaire ENOVA® - Machine FLEX V.1.)

D250 - Spécifications Flexion et Ductilité - Aiguilles Corps Triangulaires Inversés ENOVA® - Machine FLEX V.1.0

D251 - Spécifications Flexion et Ductilité - Aiguilles Corps Carré ENOVA® - Machine FLEX V.1.0

PRODUCT SPECIFICATIONS

Wire size: -0,01/+0,01 mm (.28 < ws. < .98 mm) - -0,02/+0,025 mm (≥ .98 mm)

Length: -1/+1,2 mm

Hole size / Hole depth: D127 - DIAMETRE ET PROFONDEUR DE FORAGE 420, XFLEX® et ENOVA®*

Hardness: 550Hv0.5 to 770Hv0.5

Curvature:

Round needles

130° < **135°** < 140°

155° < **160°** < 168°

175° < **180°** < 190°

220° < **225°** < 230°

Cutting needles

125° < **135°** < 145°

150° < **160°** < 170°

170° < **180°** < 190°

(*) Documents available upon request

SILICON COATING

Most of Suturex & Renodex's surgical needles are coated with our advanced needle coating technology, by using silicone medical grade coating*. Our Silicon coating maintains needle sharpness from start to finish over multiple passes. Silicon covers entire surgical needle offering consistent needle penetration pass after pass and needle to needle.

IMPORTANCE NOTICE

Suturex & Renodex neither represents nor test this material for specific medical application since we do not supply a medical device. Our products are non-sterile and for further processing only. Purchaser is fully responsible to determine end-use suitability.

MANUFACTURING ENVIRONMENT

ENOVA® needles are manufactured, tested and packaged under strict quality control. The quality system is in compliance with ISO 13485 registered.

ATTACHING PRECAUTIONS

The attaching machines must have an appropriate size of dies to attach needles on thread.

Suturex & Renodex takes no responsibility for such needle hole selection.

DESCRIPTION AND USE

Traditional suture needles are sharp, usually curved, and used to thread sutures through the patient's skin or other tissues to close wounds. They come in a variety of designs, including those with cutting tips, or those with tapered non-cutting tips.

INJURY RISK

Injuries can occur before use (when preparing the needle in the needle holder, passing between staff), during use (it is quite common for surgeons to pierce their own fingers whilst suturing), and after use/during disposal

Suturex & Renodex provide only disposable, single-use needles for sutures to avoid any cross-contamination.

HANDLING PRECAUTIONS

During transport and in factory:

Needle tips are fragile. Handle the product with care. The needle is held securely in a needle holder

In surgical application:

- The needle holder must be an appropriate size instrument for the size needle selected.
- Needles should be grasped in an area about 1/3 to 1/2 of the distance from the swaged area to the point. Avoid placement on or near the swaged area.

- The needle should be placed securely in the tip of the needle holder jaws.
- Do not damage taper points or cutting edges when using the needle holder to pull the needle out through the tissue. Grasp as far as possible.
- If the needle is held too tightly in a sharp or hard jawed or defective needleholder, the needle may be damaged or notched in such a manner that it will have more of a tendency to bend or break on successive passes through tissue.

STORAGE

The products should be stored, if possible, in original and closed package, in dry condition.

SHELF LIFE

Suturex & Renodex guarantees that the supplied products meet our internal specifications and the sales specifications in effect at the time of shipment. A wrong storage could affect performances of the products.

The traceability records of each of the production batches are kept after 10 years from the manufacturing date.

DELIVERY FORMS

The needles are delivered in lots in plastic boxes of 250, 500, and 1000 needles (depend of the needle size).

Small quantities of samples are available upon request.

The customer shall inspect the packaging immediately upon delivery for completeness and absence of defects.

LIMITED WARRANTY INFORMATION – PLEASE READ CAREFULLY

The information contained herein is offered in good faith and is believed to be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customer's tests to ensure that our products are safe, effective, and fully satisfactory for the intended end use.

Suggestions of use shall not be taken as inducements to infringe any patent.

Suturex & Renodex's sole warranty is that our products will meet our internal specifications and the sales specifications in effect at the time of shipment. Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other as warranted.

All documents are available upon request. For further information, please see our website, www.suturex-renodex.com or contact us.

(*) Documents available upon request