Approved by/date: Claude Borgeaud / 22.09.05

GENERAL PRODUCT SPECIFICATION FOR OUR HYPODERMIC AND MEDICAL TECHNIQUE NEEDLES

1 MATERIALS

The selected stainless steels can be used, according to ISO 9626 (1991) International Standard, in the manufacture of hypodermic needle cannulae, and according to ISO 7153-1 (1991) International Standard in the manufacture of surgical instruments.
As for brass, it can be used, according to DIN 13097 (1979) German Standard, in the manufacture of hubs and knobs for hypodermic needles.

1.1 NEEDLE MOUNT (HUB) AND STYLET KNOB

Can be made of free cutting brass, nickel and chrome plated or austenitic stainless steel AISI 303.

Chemical composition:

Brass

Cu	56 to 61 %	
Pb	1.5 to 3.5 %	
Al	0.1 %	max.
Fe	0.5 %	max.
Mn	0.3 %	max.
Ni	0.5 %	max.
Sb	0.02 %	max.
Sn	0.4 %	max.
Zn	remainder	

Stainless Steel AISI 303

C	0.15 %	max.
Si	1 %	max.
Mn	2 %	max.
P	0.20 %	max.
S	0.15 %	min.
Cr	17 à 19 %	
Ni	8 à 10 %	
Fe	remainder	

1.2 NEEDLE TUBE (CANNULA)

Made of austenitic stainless steel, either AISI 304 (or DIN 1.4301), AISI 316L (or DIN 1.4404 or DIN 1.4435) or AISI 316Ti (or DIN 1.4571).

Chemical composition:

AISI 304

C	0.08 %	max.
Si	1 %	max.
Mn	2 %	max.
P	0.045 %	max.
S	0.03 %	max.
Cr	18 to 20 %	
Ni	8 to 10.5 %	
Fe	remainder	

AISI 316L

C	0.03 %	max.
Si	1 %	max.
Mn	2 %	max.
P	0.045 %	max.
S	0.03 %	max.
Cr	16 to 18 %	
Mo	2 to 3 %	
Ni	10 to 14 %	
Fe	remainder	

AISI 316Ti

C	0.08%	max.
Si	1.00 %	max.
Mn	2.00 %	max.
P	0.045 %	max.
S	0.030 %	max.
Cr	16.5-18.5	
Mo	2.00-2.50	
Ni	10.5-13.5	
Ti	]5x%C∗0.80	
Fe	remainder	

1.3 MANDRIL (STYLET/OBTURATOR)

Made of austenitic stainless steel, either AISI 302 (or DIN 1.4310), AISI 303 (or DIN 1.4305) or AISI 304 (or DIN 1.4301).

Chemical composition:

AISI 302			AISI 303			AISI 304		
C	0.15 %	max.	C	0.15 %	max.	C	0.08%	max.
Si	1 %	max.	Si	1 %	max.	Si	1 %	max.
Mn	2 %	max.	Mn	2 %	max.	Mn	2 %	max.
P	0.045 %	max.	P	0.20 %	max.	P	0.045 %	max.
S	0.03 %	max.	S	0.15 %	min.	S	0.03 %	max.
Cr	17 à 19 %		Cr	17 à 19 %		Cr	18 à 20 %	
Ni	8 à 10 %		Ni	8 à 10 %		Ni	8 à 10.5 %	
Fe	remainder		Fe	remainder		Fe	remainder	

1.4 PLASTIC HANDLES OF UNIGRIP-SYSTEM

Made of APPRYL 3050 MN1 Polypropylene which is a food compatible material according FDA (USA) 21 CFR of 01.04.1991 § 177-1520 and EEC Directive 90/128 and 92/39 (Annex II Section A).

2 INSPECTION PROCEDURE

- Statistical control of all the measurements,
- 100 % visual inspection of the tube ends and points, according to Unimed standard procedure.

3 STERILIZATION

The products are supplied non-sterile with a cleanliness consistent with the requirements of the international standard ISO 7864 § 4.
The metallic products must be cleaned and sterilized prior to initial and subsequent uses according to specific procedure. The plastic handle of the Unigrip-System must be cleaned and sterilized only by steam (max. 135 °C) or EtO gas.

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