

**STANDARD FOR SURGICAL
IMPLANTS**

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REGISTRATION OF MODIFICATIONS

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1	14/12/99	MODIF § 7.3.5	
2	28/02/01	MODIF §2 §6 §7 §11	
3	21/08/03	REWRITING	
4	27/01/04	MODIF §7.2	
5	18/06/04	MODIF §5	
6	28/09/05	REWRITING	

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1. SCOPE :

This specification covers the requirements applicable to tubing supplied by MINITUBES to the manufacturers of surgical implants.

It does not give any guarantee regarding the ability of the tubing to perform adequately in its intended usage, which remains the full responsibility of the implant manufacturer.

Its object is to define a precise contractual basis between MINITUBES and its customers.

It defines the standard Minitubes prescriptions applicable to the non specified elements of the products.

Intended to meet implicit requirements, the indicated values can be significantly under the best possibilities.

Our sales department is at the customers' disposal to take into account and to discuss their specifications in order to best meet their needs.

Document levelling :

- level 1 : customer specification
- level 2 : current procedure at last revision applies if no specification or unspecified criteria

2. REFERENCE DOCUMENTS:

International standards on each used raw material (see table / 7.2)

3. REGULATORY REQUIREMENTS :

If regulatory requirements concerning the products have any impact on the supply, they have to be notified to us explicitly and be part of the requirements specified by the customer.

4. INFORMATION FEED-BACK :

Regarding vigilance referring to material, customers are required to notify us of all incidents or risks of incidents linked to our supply, to allow the initiation of adequate corrective and preventive actions.

5. MANUFACTURING CONTROL :

Medical products are manufactured according to ISO 13485 compliant rules. Process changes are allowed, as long as they do not affect the specified requirements, unless otherwise notified by the customers.

Classified clean rooms are not being used.

6. REQUIREMENTS ON THE RAW MATERIAL :

6.1 General requirements :

The raw material is purchased by MINITUBES according to its proprietary purchasing specification (specific to each material) and has to meet the requirements of the international standards on each used raw material.

MINITUBES shall request documented certification from its material supplier and will check compliance by a certification from an independent laboratory, on each batch of raw material ordered.

6.2 Chemical composition :

The heat analysis shall conform to the international standard on the used material.

7. REQUIREMENTS ON THE PRODUCT IN ITS SUPPLIED FORM :

7.1 Description :

Minitubes description	UNS description	International description
1 Alloy per ASTM F.138 and ISO 5832.1 and ASTM F.2257	S.31673	Fe-18Cr-14Ni-2.5Mo
2 Alloy per ASTM F.2229	S.29108	Fe-23Mn-21Cr-1mo-1N
3 Alloy per ASTM F562 and ISO 5832.6	R.30035	Co-35Ni-20Cr-10Mo
4 Alloy per ASTM F90	R.30605	Co-20Cr-15W-10Ni-1.5Mn
5 Alloy per ASTM F1314	S.20910	Fe-22Cr-12.5Ni-5Mn-2.5Mo
6 Alloy per ASTM F1058 and ISO 5832.7	R.30008	Co-19Cr-17Ni—14Fe-7Mo-1.5Mn

7.2 Metallurgical requirements :

Minitubes description	Chemical composition	Absence of delta ferrite	Resistance to intergranular corrosion	Inclusions ' rate	Grain size
1 Alloy per ASTM F.138 AND ISO 5832.1 AND ASTM F.2257	C, Si, P, S, Mn, Ni, Cr, Mo, Cu, N	ASTM F138 + Qi and sigma phases	ASTM A262 Practice E	ASTM E45 ISO 4967	ASTM E112 ISO 643 ≥ 6
2 Alloy per ASTM F.2229	C, Si, P, S, Mn, Ni, Cr, Mo, Cu, N	ASTM F.2229	ASTM A.262 practice E	ASTM E45 ISO 4967	ASTM E112 ISO 643
3 Alloy per ASTM F562 and ISO 5832.6	C, Si, P, S, Mn, Ni, Cr, Mo, Ti, Fe, B	NA	NA	ASTM E45 ISO 4967	ASTM E112 ISO 643
4 Alloy per ASTM F90	C, Si, P, S, Mn, Ni, Cr, Fe, Mo, W	NA	NA	NA	ASTM E112 ISO 643
5 Alloy per ASTM F1314	C, Si, P, S, Mn, Ni, Cr, Mo, N, Nb, V	NA	NA	ASTM E45 ISO 4967	ASTM E112 ISO 643
6 Alloy per ASTM F1058 and ISO 5832.7	C, Si, P, S, Mn, Ni, Cr, Mo, Co, N	NA	NA	ASTM E45 ISO 4967	ASTM E112 ISO 643

NA = non applicable

7.3 Mechanical properties :

The physical condition is stated on the order or in the customer's specification. Minitubes will measure the obtained mechanical properties (Rm, Rp 0.2 %, A %). The values in the table are typical features stated just for information and are not a contractual requirement. Contractual requirements are stated on the order or on the customer specification.

Minitubes description	Condition	Typical values			
		Rm (MPA)	Rp 0.2 % (MPA)	A %	Density (g/cm ³)
1 Alloy per ASTM F.138 and ISO 5832.1	Hard drawn	935	760	5 %	7.95
	Annealed	670	340	> 40 %	
2 Alloy per ASTM F.2229	Annealed	1 050	741	25 %	8.53
3 Alloy per ASTM F562 and ISO 5832.6	Hard drawn	1 400	990	4 %	8.43
	Annealed	940	500	> 40 %	
4 Alloy per ASTM F90	Annealed	> 965	> 483	> 40 %	9.10
5 Alloy per ASTM F1314	Annealed	827	448	> 40 %	7.88
6 Alloy per ASTM F1058 and ISO 5832.7	Hard drawn	1 450	1 300	8 %	8.30
	Annealed	950	450	> 40 %	

7.4 British units:

Minitubes description	Condition	Typical values			
		Rm (Ksi)	Rp 0.2 % (Ksi)	A %	Density (g/in ³)
1 Alloy per ASTM F.138 ISO 5832.1	Hard drawn	135	110	5 %	130.28
	Annealed	97	49	> 40 %	
2 Alloy per ASTM F.2229	Annealed	152	107	25 %	139.78
3 Alloy per ASTM F562 and ISO 5832.6	Hard drawn	203	144	4 %	138.14
	Annealed	136	73	> 40 %	
4 Alloy per ASTM F90	Annealed	140	70	> 40 %	149.13
5 Alloy per ASTM F1314	Annealed	120	65	> 40 %	129.13
6 Alloy per ASTM F1058 and ISO 5832.7	Hard drawn	210	189	8 %	136.01
	Annealed	138	65	> 40 %	

7.5 Dimensions, tolerances, surface finish and other features :

Criteria	Range	Tolerances
O.D.	$\varnothing < 3.00 \text{ mm}$	$\pm 0.010 \text{ mm}$
	$3.00 < \varnothing < 5.00 \text{ mm}$	$\pm 0.020 \text{ mm}$
	$5.00 \leq \varnothing \leq 15 \text{ mm}$	$\pm 0.025 \text{ mm}$
Circularity	$\varnothing < 3.00 \text{ mm}$	$< 0.005 \text{ mm}$
	$3.00 < \varnothing < 5.00 \text{ mm}$	Within OD tolerances
	$5.00 \leq \varnothing \leq 15 \text{ mm}$	Within OD tolerances
Wall thickness		$\pm 10 \%$ from nominal value with mini tolerance 0.008 mm
Concentricity		$\leq 7 \%$ from nominal wall thickness with mini limit 0.01 mm
Inside roughness	$\leq 0.6 \mu\text{m}$	(except for tubing with wall thickness $> 0.5 \text{ mm}$, internal $R_a \leq 2 \mu\text{m}$)
Outside roughness	$\leq 0.6 \mu\text{m}$	
Inside surface finish	Absence of drawing scratches visible under magnification X 15	/
Outside surface finish		
Length	0.8 to 2 meters	/
Straightness	The 2 meters maxi tubes have to roll down the totality of an inclined place at 5 % without assistance (a slight movement is tolerated to start the rotation of the tubes) A slight run-out is tolerated during the rotation of the tubes	
Cleanliness	The tubes have a final cleaning and their cleanliness is appraised by the absence of deposit and corrosion traces which could be observed with the naked eye.	
Quantity	/	$\pm 10 \%$ of the ordered quantity
Defects of internal and external surface according to ASTM F.2257	The size of defects shall not exceed 10 % of the wall thickness	

Sampling and inspection protocols are defined in the inspection schedule attached.

7.6 Other criteria or characteristics :

All other criteria not specified by the definition documents are not inspected.

8. PACKAGING :

Tubing are shipped within plastic tubes then within PVC case ensuring adequate protection and conservation under normal stocking and handling conditions.

Small pieces are delivered in bulk in variable batch size, in new polyethylene bags and cardboard boxes.

9. DOCUMENTATION :

MINITUBES shall supply with each delivery:

- extra requirements specified by the customer
- inspection report : shows actual values for specified dimensions, surface finish
- certificate of conformity according to ISO 4990
- test report : states the results of the tests performed on the raw material and the finished product
 - * chemical composition of the heat according to the certificate of the supplier
 - * certification number of the independent laboratory
 - * chemical composition of the product in its delivery condition
 - * test results (see table / 7.2)

NOTA : all delivery without full documentation on finished product (analysis lead time) requires a written agreement from the customer.

10. RECORD CONSERVATION :

All documents and records related to QA is conserved for 10 years with effect from the shipping date of the products.

If the life expectancy of the products requires a longer conservation of the data, the customer should inform us.

11. INSPECTION PLAN :

See attachment

The ANSi ASQC Z1.4 and NFX 06.022 norms are not suitable in case of tubes in variable length and no current standard complies correctly with this case.

The following features are conventionally applied:

Batch size: 1 piece = 1 tube.

Sampling 1 inspected piece = 1 area inspected on the tube (middle or one of its extremities)

12. SYNOPTIC AND ASSOCIATED PROCEDURES :

PHASES	INTERNAL DOCUMENTATION
Product definition	PRD018 and (or) customer specification
Customer requirement translation	ORG057
Manufacturing schedule preparation	ORG057
Inspection schedule preparation	F.I.217
Means of inspection arrangements	ORG010
Product manufacturing	FAB036 or specific procedure for an item to be qualified
No-conformity management	ORG001
Medical devices	ORG050 ORG051