en

ADLER ORTHO
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PATIENT INFORMATION

1. General information

It is important to note that, despite progress made in development of materials and surgical management, and the undoubted percentage increase in optimal results, joint replacement devices still require continual monitoring, and their performance greatly depends on the patient's own personal characteristics like body weight, eating habits and physical exercise.

For further information it is recommended that you consult your own referring physician.

2. Materials

Biocompatible materials used for the manufacture of implant medical devices provide excellent resistance to corrosion and conform to the following international norms:

- stainless steel ISO 5832 -1 or ISO 5832-9
- titanium alloy [Ti6Al4V] ISO 5832 – 3
- cobalt-chrome-molybdenum alloy [CoCrMo] ISO 5832 – 4 or ISO 5832-12
- alumina ceramic ISO 6474
- ultra-high-molecular weight polyethylene ISO 5834 - 1 and ISO 5834-2
- unalloyed titanium, ISO 5832 – 2 standard, symbol: Ti.

The full list of Adler Ortho® prosthesis components and the materials of which they are composed can be found on the website www.adlerortho.com on the same page on which this document appears.

3. Metal sensitivity

The patient is advised to inform his/her own referring physician of any suspected or confirmed sensitivity to the following materials:

- Nickel [Ni]
- Chrome [CoCrMo] 

- Other heavy metals

so that the most appropriate treatment can be recommended.

4. Use of diagnostic apparatus

As set out in paragraph 2, materials for the manufacture of Adler Ortho prostheses comply with current standards.

In any event, it is advisable to inform the radiologist that you have a prosthesis, so that any possible contra-indications or effects on medical tests can be verified.

It will be the responsibility of the facility that will perform the possible MRI examination to verify possible contraindications or the effects that the constituent materials of the DM may have on the examination.

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5. Possible Complications, Side-effects

Apart from possible per-operation complications, a prosthetic implant can also be subject to:

- Peri-prosthetic infection with or without loosening
- Movement of one or several prosthetic elements due to mechanical overloading, osteoporosis, etc.
- Dislocation or bone fracture due to traumatism
- Extra-articulatory pathology: phlebothrombosis, pulmonary embolism, etc.
- fatigue fracture of prosthetic components can occur as a result of : trauma, strenuous activity, improper alignment or duration of service.

6. Contra-indications

Contra-indications may be relative or absolute.
The articular problems must be evaluated case by case, taking into account alternative surgical options (osteosynthesis, excision of radial epiphysis, amputation, et.).
The following examples are regarded as contra-indications:

- infection, septicaemia, and osteomyelitis constitute cases of absolute contraindication;
- serious metabolic, cardiovascular, respiratory or neurological pathologies;
- serious osteoporosis;
- rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
- neurogenic arthropathy (Charcot joint);
- skeletally immature patients;
- female patients of childbearing age, for whom a negative pregnancy test is not obtained;
- high patient activity which could lead to overloading of the implant.

7. Expected useful life of the device

The expected useful life of the device is a parameter subject to several factors. Below is the most important distinction, depending on the type of use of the prosthesis:

- Primary prostheses: it is possible, through registry data such as RIPO[i], to estimate the useful life of the device in 90% of cases at 10 years.
- Non-primary prostheses (revision, "limb salvage", "rare indications"): the parameters influencing the useful life of the device are many and are mainly attributable to the characteristics of the patient.

In all cases, the patient is advised to consult the treating physician, who is aware of the patient's condition and can reasonably estimate the expected useful life of the device.

[i] https://ripo.cineca.it/authzssl/Reports.html

Please refer to the following link for the material of the prosthesis: MATERIALS

To find out the analytical composition of the constituent materials of the plants refer to the following:

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Material	Specifications
Stainless Steel M30NW	*ISO 5832-9*

Table 1 — Chemical composition

Element	Mass fraction %
Carbon	0,08 maximum
Silicon	0,75 maximum
Manganese	2,00 to 4,25
Nickel	9,0 to 11,0
Chromium	19,5 to 22,0
Molybdenum	2,0 to 3,0
Niobium	0,25 to 0,80
Sulfur	0,01 maximum
Phosphorus	0,025 maximum
Copper	0,25 maximum
Nitrogen	0,25 to 0,50
Iron	Balance
Residuals	—
Each	0,1 maximum
Total	0,4 maximum

Material	Specifications
Inox Steel AISI 316L	*ISO 5932-1*

Table 1 — Chemical Composition

Element	Mass fraction %
Carbon	0,030 max.
Silicon	1,0 max.
Manganese	2,0 max.
Phosphorus	0,025 max.
Sulfur	0,010 max.
Nitrogen	0,10 max.
Chromium	17,0 to 19,0 max.
Molybdenum	2,25 to 3,0
Nickel	13,0 to 15,0
Copper	0,50 max.
Iron	Balance

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Material	Specifications
Alumina Ceramics	ISO 6474-1 and ISO 6474-2

Table 1 — Limits for material properties

Property	Unit	Property category	Requirement Type A	Requirement Type B	Subclause	References
Average bulk density	$kg/m^3 \times 10^3$	1	≥ 3,94	≥ 3,90	6.1	ISO 18754 EN 623–2
Chemical composition:						
Basic material, Al_2O_3	% mass fraction	1	≥ 99,7	≥ 99,5		
Sintering additive, MgO	% mass fraction	1	≤ 0,2	≤ 0,2	6.2	ISO 12677 EN 725-1
Limits of impurities, total amount of $SiO_2 + CaO + Na_2O$	% mass fraction	1	≤ 0,1	≤ 0,3		
Microstructure:						
Linear intercept grain size	µm	1	≤ 2,5	≤ 3,5	6.3	ISO 13383-1 ASTM E112 EN 623-3
Relative standard deviation linear intercept grain size	%	1	≤ 25	≤ 25		
Material strength; alternatives 1) or 2):					6.4	
1a) Mean biaxial flexural strength	MPa	1	≥ 300	≥ 150	6.4.2	ASTM C1499
1b) Weibull modulus	—	1	≥ 8	≥ 8	6.4.4	ISO 20501 EN 843–5 ASTM C1239
2a) Mean 4-point flexural strength	MPa	1	≥ 500	≥ 250	6.4.3	ISO 14704 EN 843–1 ASTM C1161
2b) Weibull modulus	—	1	≥ 8	≥ 8	6.4.4	ISO 20501 EN 843–5 ASTM C1239
Young's modulus	GPa	2	≥ 380	≥ 370	6.5	ISO 17561 EN 843–2 ASTM C1331 ASTM C1198 ASTM C1259
Fracture toughness, alternatives 1) to 3)					6.6	
1) SEVNB	$MPa\sqrt{m}$	2	≥ 2,5	n.a.	6.6.2	ISO 23146 CEN/TS 14425-5
2) SEPB	$MPa\sqrt{m}$	2	≥ 2,5	n.a.	6.6.3	ISO 15732
3) SCF	$MPa\sqrt{m}$	2	≥ 2,5	n.a.	6.6.4	ISO 18756 ASTM C1421

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Table 1 *(continued)*

Property	Unit	Property category	Requirement		Subclause	References
			Type A	Type B		
Hardness, Vickers HV1	GPa	2	≥ 18	≥ 17	6.7	ISO 14705 EN 843-4 ASTM C1327
Wear		2	Info	n.a.	6.8	e.g. ISO 14242-1
Cyclic fatigue: 10 million cycles endurance limit strength in 4-point bending	MPa	2	No failure at 200 MPa	n.a.	6.9	ISO 22214

Table 1 — Limits for material property category 1

Property	Unit	Property category	Requirement		Subclause	References
			Type X	Type S		
Average relative bulk density	%	1	≥99	≥99	6.1	ISO 18754 EN 623-2
Chemical composition:						
Alumina, Al_2O_3	% mass fraction	1	60 to 90	60 to 90	6.2	ISO 12677
Zirconia, $ZrO_2 + HfO_2$	% mass fraction	1	10 to 30	10 to 30		
Amount of HfO_2 in ZrO_2	% mass fraction	1	≤5	≤5		
Intended additives	% mass fraction	1	≤10	≤10		
Total amount of impurities	% mass fraction	1	≤0,2	≤0,2		
Microstructure:						
Alumina linear intercept grain size	µm	1	≤1,5	≤1,5	6.3	ISO 13383-1 EN 623-3
Relative standard deviation alumina linear intercept grain size	%	1	≤25	≤25		
Zirconia linear intercept grain size	µm	1	≤0,6	≤0,6		
Relative standard deviation zirconia linear intercept grain size	%	1	≤40	≤40		
Material strength; alternative 1) or 2):					6.4	
1 a) Mean biaxial flexural strength	MPa	1	≥600	≥450	6.4.2	ASTM C1499
1 b) Weibull modulus		1	≥8	≥8	6.4.4	ISO 20501 EN 843-5 ASTM C1239
2 a) Mean 4-point flexural strength	MPa	1	≥1 000	≥750	6.4.3	ISO 14704 EN 843-1 ASTM C1161
2 b) Weibull modulus		1	≥8	≥8	6.4.4	ISO 20501 EN 843-5 ASTM C1239

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Table 2 — Limits for material property category 2

Property	Unit	Property category	Requirement		Subclause	References
			Type X	Type S		
Radioactivity (measured on raw materials)						
Zirconia Other intended additives	Bq/kg	2 See 6.5	≤200	≤200	6.5	ISO 13356
Fracture toughness, alternatives 1) to 3)					6.6	
1) SEVNB	MPa $\sqrt{m}$	2	≥4,0	≥3,5	6.6.2	ISO 23146 CEN/TS 14425-5
2) SEPB	MPa $\sqrt{m}$	2	≥4,0	≥3,5	6.6.3	ISO 15732
3) SCF	MPa $\sqrt{m}$	2	≥4,0	≥3,5	6.6.4	ISO 18756 ASTM C1421
Hardness, Vickers HV1	GPa	2	≥16,0	≥15,5	6.7	ISO 14705 EN 843-4 ASTM C1327
Young's modulus	GPa	2	≥320	≥320	6.8	ISO 17561 EN 843-2 ASTM C1331 ASTM C1198 ASTM C1259
Cyclic fatigue: Cyclic loading in 4-point bending, 10^7 cycles		2	No failure at 400 MPa	No failure at 300 MPa	6.9	ISO 22214
Accelerated ageing: 10 h in autoclave (0,2 MPa, 134 °C) after autoclaving:					6.10	
Strength		2	Degradation ≤ 20 % in comparison to value before autoclaving *and* conformity with values given in Table 1		6.10.2	See 6.4
Cyclic loading in 4-point bending, 10^7 cycles		2	No failure at 320 MPa	No failure at 240 MPa	6.10.3	See 6.9
Wear		2	Increase ≤ 20 % in comparison to value before autoclaving		6.10.4	ISO 14242-1 ISO 14243-1 or other tests

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Material	Specifications
PMMA (Polymethyl Methacrylate)	ISO 5833

Table 1 — Requirements and test methods for setting properties of liquid-powder mixtures

Mixture	Doughing time			Setting time		Maximum temperature		
	Average min	Maximum deviation from average min	Test method	Average min	Test method	Average °C	Maximum deviation from average °C	Test method
Syringe usage (see clause 5)	—	—	—	6,5 to 15	Annex C	90	± 5	Annex C
Dough state usage (see 6.1)	⩽ 5	1,5	Annex B	3 to 15	Annex C	90	± 5	Annex C

Table 2 — Requirements and test methods for set and polymerized cement

Average compressive strength		Bending modulus		Bending strength	
MPa	Test method	MPa	Test method	MPa	Test method
⩾ 70	Annex E	⩾ 1 800	Annex F	⩾ 50	Annex F

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Material	Specifications
CoCrMo Alloy	ISO 5832-4 and ISO 5832-12

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Table 1 — Chemical composition

Element	Compositional limits % (m/m)
Chromium	26,5 to 30,0
Molybdenum	4,5 to 7,0
Nickel	1,0 max.
Iron	1,0 max.
Carbon	0,35 max.
Manganese	1,0 max.
Silicon	1,0 max.
Cobalt	Balance

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Table 1 — Chemical composition

Element	Mass fraction %	
	Alloy 1 Low carbon	Alloy 2 High carbon
Chromium	26,0 to 30,0	26,0 to 30,0
Molybdenum	5,0 to 7,0	5,0 to 7,0
Iron	0,75 maximum	0,75 maximum

Element	Mass fraction %	
	Alloy 1 Low carbon	Alloy 2 High carbon
Manganese	1,0 maximum	1,0 maximum
Silicon	1,0 maximum	1,0 maximum
Carbon	0,14 maximum	0,15 to 0,35
Nickel	1,0 maximum	1,0 maximum
Nitrogen	0,25 maximum	0,25 maximum
Cobalt	Balance	Balance

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Material	Specifications
UHMWPE (Ultra High Molecular Weight Polyethylene)	*ISO 5834-1 and ISO 5834-2*

Table 2 — Maximum ash and trace element content

Element	Maximum quantity permitted mg/kg			Test method according to subclause
	Type 1	Type 2	Type 3[a]	
Ash	125	125	300	8.3
Titanium	40	40	150	8.4
Calcium	5	5	50	8.4
Chlorine	30	30	90	8.4
Aluminium	20	20	100	8.4

[a] Type 3 polymer is no longer manufactured. However, in order to cover existing supplies held in stockpile, this Type 3 material is retained in this document until the next revision.

Material	Specifications
Ti6Al4V Alloy	*ISO 5832-3*

Table 1 — Chemical composition

Element	Compositional limits % (*m/m*)
Aluminium	5,5 to 6,75
Vanadium	3,5 to 4,5
Iron	0,3 max.
Oxygen	0,2 max.
Carbon	0,08 max.
Nitrogen	0,05 max.
Hydrogen	0,015 max.[1)]
Titanium	Balance

1) Except for billets, for which the maximum hydrogen content shall be 0,010 % (*m/m*).

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Material	Specifications
Unalloyed Titanium	ISO 5832-2

Table 1 — Chemical composition

Element	Maximum compositional limits percent mass fraction				
	Grade 1 ELI	Grade 1	Grade 2	Grade 3	Grades 4A and 4B
Nitrogen	0,012	0,03	0,03	0,05	0,05
Carbon	0,03	0,08	0,08	0,08	0,08
Hydrogen	0,012 5[a]	0,012 5[a]	0,012 5[a]	0,012 5[a]	0,012 5[a]
Iron	0,10	0,20	0,30	0,30	0,50
Oxygen	0,10	0,18	0,25	0,35	0,40
Titanium	Balance	Balance	Balance	Balance	Balance

[a] Except for billets, for which the maximum hydrogen content shall be 0,010 0 % (mass fraction) and for flat products for which the maximum hydrogen content shall be 0,015 % (mass fraction).