GRUPPO BIOIMPIANTI

Enjoy Mobility

PATIENT INFORMATION LEAFLET

HIP ARTHROPLASTY

EN

bioimpianti.it

INFORMATION FOR THE PATIENT

The following document contains information regarding your implant: read it carefully and keep a copy in case of future need.
In case of doubts or further questions regarding what it is described in the document, consult your doctor and, in any case, follow the instructions given to you at discharging from the hospital.
In conjunction with the surgery, you were given a "Patient Implant Card", which contains fundamental information regarding your prosthesis.

NAME OF PROSTHESIS

Component	Name of Prosthesis
Steli femorali	**Korus System** stems: Cemented Korus stem (ISO 5832-9), Cemented Korus stem with distal centralizer (ISO 5832-9), Uncemented Korus stem with HA (ISO 5832-3 e ISO 13779-2), Uncemented Korus stem with HA with collar (ISO 5832-3 e ISO 13779-2), Korus Titan stem with Titanium Y367 (ISO 5832-3 e ISO 13179-1)
	Fin Short stem with TiGrowth® C (ISO 5832-3 e ISO 13179-1)
	Saphir stems: Uncemented Saphir stem with TiGrowth® C and HA (ISO 5832-3, ISO 13179-1 e ISO 13779-2), Cemented Saphir stem (ISO 5832-9), Uncemented Saphir stem with TiGrowth® C (ISO 5832-3 e ISO 13179-1)
	SMR Modular revision stem (ISO 5832-3)
	SMR Resection Modular resection stem (ISO 5832-3)
	SMR 100's stem (ISO 5832-3)
	S-TAPER stems: S-TAPER Uncemented stem (ISO 5832-11), S-TAPER Mirror Cemented stem (ISO 5832-9), S-TAPER Mirror Long Cemented stem (ISO 5832-9)
Cotili acetabolari	**FIN CUPS System**: FIN II cup with TiGrowth® C (ISO 5832-3 e ISO 13179-1), FIN MB cup with Titanium Y367 (ISO 5832-3 e ISO 13179-1), FIN II HA cup with TiGrowth® C and HA (ISO 5832-3, ISO 13179-1 e ISO 13779-2), FIN DMD cup (ISO 5832-3, ASTM F3001), FIN DMD Multihole cup (ISO 5832-3, ASTM F3001)
	JANUS Bipolar cup (5832-1)
	DUALIS System cups: Uncemented Dualis Double mobility acetabular cup with Titanium Ti SPS and HA (ISO 5832-9, ISO 13179-1 e ISO 13779-2), Cemented Dualis Double mobility acetabular cup (ISO 5832-9), Uncemented Dualis Tripod Double mobility acetabular cup with Titanium Ti SPS and HA (ISO 5832-9, ISO 5832-1, ISO 13179-1 e ISO 13779-2)
	CEMENTED ACETABULAR CUPS: Standard Cemented Muller Cup, Cemented Muller Cup with anti-dislocation shoulder, Cemented Muller Cup with snap-fit, Cemented Muller Cup with double snap-fit (ISO ISO 5834-2 e ISO 5832-1)
Inserti acetabolari	**FIN CUPS System acetabular inserts**: Insert in UHWMPE (ISO 5834-2, ASTM F648), Insert in XLPE (ISO 5834-2, ASTM F648), Insert in XLPE + VIT. E (ISO 5834-2, ASTM F648 e ASTM F2695), Insert in BIOLOX® DELTA Ceramic (ISO 6474-2), Insert in ZTA Ceramic (ISO 6474 -2), Double Mobility Insert in XLPE (ISO 5834-2, ASTM F648), Double Mobility Insert in XLPE + VIT. E (ISO 5834-2, ASTM F648 e ASTM F2695), Double Mobility Insert in CrCo (ISO 5832-12), Double Mobility Insert in CrCo and TiNbN (ISO 5832-12)
	DUALIS System acetabular inserts (ISO 5834-2, ASTM F648)
	JANUS acetabular inserts (ISO 5834-2, ASTM F648)
Testine femorali	**FEMORAL HEADS** in CrCo (ISO 5832-12), Femoral head in Stainless steel (ISO 5832-9), Femoral heads in BIOLOX® DELTA ceramic (ISO 6474-2), Femoral heads in ZTA ceramic (ISO 6474-2)
Altro	**Acetabular reinforcement cage** (ISO 5832-1)
	Acetabular reinforcement ring (ISO 5832-1)
	Cancellous screws for **FIN CUPS System** 6.5mm (ISO 5832-3)
	Cortical screws for **DUALIS TRIPOD** 4.5mm (ISO 5832-1)
	Distal centralizer in UHMWPE (ISO 5834-2)
	Wedge for FIN CUPS System (ISO 5832-3, ASTM F3001)
	Wedge for S-TAPER (ISO 5832-1)

INDICATIONS FOR USE

The indications are tied to hip pathologies that require a primary arthroplasty to reduce or eliminate pain compared to pre-operative levels and/or improve joint function.
For more information on hip replacement, we invite you to visit the dedicated page on the Gruppo Bioimpianti website: **https://bioimpianti.it/en/patients/**

PRECAUTIONS FOR USE

The precautions for use regarding your prosthetic implant depend on your own condition and your doctor has provided you with a series of instructions and indications to follow, dedicated to you. Your doctor has also provided you with a series of information on how resume some activities as best as possible and avoid others and on maintaining a healthy lifestyle and an adequate body weight.
Not following the directions, information and precautions provided by your doctor could lead to complications and the potential need for further surgery.

DURATION OF THE IMPLANT

The life of the implant can be reduced or prolonged based on the level of activity or due to events independent of the prosthesis (accidents, trauma, falls).
It is inevitable that in the long term there will be a loosening (or mobilization) of the main components of the prosthesis, causing pain in the hip with prosthesis.
In case of mobilization of one or all components, these can be removed and replaced with a new prosthesis.

INTERACTION WITH METAL DETECTORS FOR SECURITY CHECKS

The metal detectors used for security checks detect the presence of the prosthetic implant in your body.
The presence of a prosthetic implant does not prevent the possibility of travel; simply make the presence and position of the prosthesis known to the security controllers at the time of the checks.

INTERACTION WITH MAGNETIC RESONANCE

Non-clinical tests and in vitro electromagnetic simulations have demonstrated that the medical devices produced by Gruppo Bioimpianti S.r.l., are MRI conditional (MRI is the acronym for magnetic resonance imaging); which means that it is possible to undergo a magnetic risonance after a prosthetic surgery.
Before undergoing a magnetic risonance, consult your doctor and show him your “Patient Implant Card”.
For safe use of the medical device, the patient must be scanned in an MRI system under the following conditions:

- Static magnetic field equal to 3.0 T;
- The spatial gradient of the magnetic field must be less than 229 T/m (extrapolated value);
- The product of the static magnetic field and the spatial gradient of the magnetic field must be less than 435 T2/m (extrapolated value);
- The MRI system recorded a whole-body average specific absorption rate (SAR) of 2.4 W/kg for 15 minutes of scanning under normal MRI system operating conditions.

Under the above scanning conditions, the prosthesis is expected to produce a maximum temperature increase of up to (4.2 ±0.1)°C after 15 minutes of continuous scanning in a static magnetic field of 3.0 T.
Nonclinical testing has shown that the resulting image artifact produced by the prosthesis can extend up to approximately 12.1mm when imaged using a gradient echo sequence and a 3.0 T MRI system.
The above conditions are applicable to all medical devices with the exception of the Korus Stem size 10 in all its variants, as this specific size has not been tested in terms of heating, migration or image artefacts in the MR environment. Its safety in MRI environments is unknown. Scanning a patient with these devices can cause patient injury.

POSSIBLE SIDE EFFECTS

No surgical operation is without risk and your doctor has provided you with information in this regard.
Contact your doctor if you have any further concerns or if you think you may have side effects related to the device or surgery. There may be problems that can shorten the life of the implant and lead to early revision surgery. These may include, but are not limited to:

- Early or late infection on the surface of the incision or within the wound, which may result in the need to remove the implant
- Allergic reactions: some people may experience allergic reactions to the metals used to make the implant
- Intraoperative bone fractures
- During the surgery it is possible that blood vessels and/or nerves may be damaged. Injuries can cause temporary or permanent numbness
- Unwanted variation in limb length and/or reduction in range of motion due to incorrect choice of components or inadequate positioning of the implant during surgery
- Peri-articular calcification or ossification may occur, with or without limitation of range of motion
- Corrosion of the interface between the components due to fragments of cement, of bone or of metal produced by the intervention
- Noise audible during movement, more or less transient
- Dislocation, migration and/or subluxation of the implant due to trauma, incorrect fixation, loss of fixation, incorrect alignment, incorrect positioning, bone resorption, soft tissue laxity, movement sudden and/or unnatural and/or excessive activity. These risks are more likely in younger and more active patient or in heavier patients
- Progressive bone resorption may occur which, being asymptomatic, can only be assessed through periodic radiographic checks
- In case of prolonged pain, consult your doctor
- Additional possible side effects include: slow wound healing and/or accumulation of necrotic tissue in the wound area, blood clots in the legs and/or lungs, irregular heartbeat rhythm
- Knee or ankle problems of the affected limb or the contralateral limb aggravated by a limb length discrepancy, too much femoral medialization, or muscle deficiencies

IMPLANT MATERIAL

The materials used to make the products marketed by Gruppo Bioimpianti comply with the international regulations of the sector which guarantee, to date, the best levels of biocompatibility.

MATERIALS AND COMPOSITION

Ti6Al4V (ISO 5832-3) Titanium 6 Aluminum 4 Vanadium Alloy

Element	Composition (%)
Aluminum	5.5 ÷ 6.75
Vanadium	3.5 ÷ 4.5
Iron	Max. 0.30
Oxigen	Max. 0.20

Element	Composition (%)
Carbon	Max. 0.08
Nitrogen	Max. 0.05
Hydrogen	Max. 0.015
Titanium	Balance

Ti6Al4V (ASTM F3001, ISO 5832-3) Titanium 6 Aluminum 4 Vanadium Alloy for Additive Manufacturing

Element	Composition (%)
Aluminum	5.5 ÷ 6.5
Vanadium	3.5 ÷ 4.5
Iron	Max. 0.25
Oxigen	Max. 0.13
Carbon	Max. 0.08
Nitrogen	Max. 0.05
Hydrogen	Max. 0.012

Element	Composition (%)
Yttrium	Max. 0.005
Other elements, each	Max 0.10
Other elements, total	Max. 0.40
Titanium	Balance

Ti6Al 7Nb (ISO 5832-11) Titanium 6 Aluminum 7 Niobium Alloy

Element	Composition (%)
Aluminum	5.5 ÷ 6.5
Niobium	6.5 ÷ 7.5
Tantalum	Max. 0.50
Oxigen	Max. 0.20

Element	Composition (%)
Carbon	Max. 0.08
Iron	Max 0.25
Nitrogen	Max 0.05
Hydrogen	Max 0.009
Titanium	Balance

Stainless steel (ISO 5832-1) Stainless steel products contain nickel[a]: if you are allergic to nickel or think you may be allergic to nickel, consult your surgeon before surgery.

Element	Composition (%)
Carbon	Max 0.03
Silicon	Max 1.0
Manganese	Max 2.0
Nickel	13.0 ÷ 15.0
Chromium	17.0 ÷ 19.0
Molybdenum	2.25 ÷ 3.0

Element	Composition (%)
Sulfur	Max 0.01
Phosphorus	Max 0.025
Copper	Max 0.50
Nitrogen	Max 0.10
Iron	Balance

Stainless steel with high Nitrogen content(ISO 5832-9) Stainless steel products contain nickel[a]: if you are allergic to nickel or think you may be allergic to nickel, consult your surgeon before surgery.

Element	Composition (%)
Carbon	Max. 0.08
Silicon	Max. 0.75
Manganese	2 ÷ 4.25
Nickel	9 ÷ 11
Chromium	19.5 ÷ 22
Molybdenum	2.0 ÷ 3.0
Niobium	0.25 ÷ 0.8

Element	Composition (%)
Sulfur	Max 0.01
Phosphorus	Max 0.025
Copper	Max 0.25
Nitrogen	0.25 ÷ 0.5
Iron	Balance
Residues, each	Max 0.1
Residues, total	Max 0.4

CrCoMo (ISO 5832-12) Cobalt Chromium Alloy Cobal Chromium alloy products contain nickel[a]: if you are allergic to nickel or think you may be allergic to nickel, consult your surgeon before surgery.

Element	Composition (%)
Chromium	26 ÷ 30
Molybdenum	5 ÷ 7
Iron	Max. 0.75
Manganese	Max. 1.0
Nitrogen	Max. 0.25

Element	Composition (%)
Silicon	Max 1.0
Carbon	Max 0.14
Nickel	Max 1.0
Cobalt	Balance

Biolox® Delta Ceramic and ZTA Ceramic (ISO 6474-2)

Properties	Unit of measurement	ISO 6474-2 type X
Averange relative bulk density	%	≥99
Chemical composition		
• Alumina Matrix Al2O3	Ma.-%	60-90
• Zirconia ZrO2+HfO2	Ma.-%	10-30
• Amounts of HfO2 in ZrO2	Ma.-%	≤ 5
• Intended additives	Ma.-%	≤ 10
• Limits of impurities	Ma.-%	≤0.2

[a] *Nickel is classified as a skin sensitiser in the EU chemicals legislation Medical Device Regulation (Regulation (EU) 2017/745, MDR)*

UHMWPE (ISO 5834-1, ISO 5834-2, ASTM F648) Ultra high molecular weight polyethylene; XLPE (ISO 5834-1, ISO 5834-2, ASTM F648) Crosslinked Ultra high molecular weight polyethylene; XLPE with Vitamine E (ISO 5834-1, ISO 5834-2; ASTM F648, ASTM F2695) Crosslinked Ultra high molecular weight polyethylene with Vitamine E

The ultra high molecular weight polyethylene has "Chirulen 1020 UHMWPE, ISO 5834-1, Type 1, low calcium grade" as its base material, which is then processed to comply with the requirements of the ISO 5834-2 standard.
In the case of XLPE the material is then subjected to a cross-linking process while in the case of XLPE + Vitamin E it is subjected to a cross-linking process and then it's added with Vitamin E, useful for preventing the oxidation of the UHMWPE.

Element	Unit	Maximum quantity allowed [mg/Kg]
Powder	Ppm	125 Max
Titanium	Ppm	40 Max
Aluminum	Ppm	20 Max
Calcium	Ppm	5 Max
Chlorine	Ppm	30 Max
Particulate	\	10 Max

TiNbN PVD Coating of Titanium-Niobium Nitride (No reference standard available)

Parameter	Element	Mass fraction percentage
TiNbN Composition	Nitrogen	Max 0.03 wt %
	Carbon	Max 0.1 wt %
	Hydrogen	Max 0.015 wt %
	Iron	Max 0.3 wt %
	Oxigen	Max 0.25 wt %
	Niobium	30+/-1 wt %
	Residues, each	Max 0.1 wt %
	Residues, total	Max 0.4 wt %
	Titanium	Balance

Hydroxyapatite HA - Osprovit® - Coating (ISO 13779-2)

Element	Maximum limit [mg/kg]
Cadmium	5.0
Mercury	5.0
Arsenic	3.0
Lead	30.0
Heavy Metals total	50.0

Features	Requirements (min-max)
CaP ratio	1.61 ÷ 1.76

Porous Titanium APS Coating - Ti SPS, Y367 (ISO 13179-1)

Element	Composition limits (mass fraction)
Carbon	≤0.10%
Hydrogen	≤0.30%
Iron	≤0.60%

Element	Composition limits (mass fraction)
Nitrogen	≤5.0%
Oxigen	≤10.00%
Titanium	Balance

Porous Titanium VPS Coating - TiGrowth® C (ISO 13179-1)

Element	Composition limits (mass fraction)
Carbon	≤0.10%
Hydrogen	≤0.30%
Iron	≤0.60%

Element	Composition limits (mass fraction)
Nitrogen	≤0.5%
Oxigen	≤1.00%
Titanium	Balance

PATIENT IMPLANT CARD

In conjunction with the implantation of the orthopedic device, a “Patient Implant Card” is also delivered, which contains fundamental information regarding your orthopedic device.
The implant card contains the labels of the implant: keep it with you.

LEGEND

1 Section dedicated to the application of labels

2 Patient's name and surname

3 Date of implantation

4 Name and address of the Healthcare Structure and/or provider

5 Name and address of the manufacturer of device

REPORTING SIDE EFFECTS OR INCIDENTS

It is essential to report any incidents or problem or side effects to your doctor and to the manufacturer (contact details below).

MANUFACTURER'S DATA

Gruppo Bioimpianti Srl
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ITALIA
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info@bioimpianti.it

You can find a copy of this document and download it from the Gruppo Bioimpianti website, in the patients section:
https://bioimpianti.it/en/patients/

The information contained in this document does not constitute medical advice nor does it provide medical advice as a substitute for the opinion of a doctor.
Under no circumstances this information replaces a consultation, visit or diagnosis made by your doctor

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