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ORTONOM MEDICAL

Hip Prosthesis System Instruction for Use (IFU)

CE 1984

1. Implant Description

General Description

Hip prostheses are medical devices used to restore joint mobility and stability when the natural hip joint is damaged or loses function. Hip prosthesis implants are designed and manufactured with different materials and configurations to suit the patient's bone structure and clinical needs. The product portfolio includes total hip prostheses, partial hip prostheses, revision hip prostheses, and additional implants for femoral fractures.

a. Total Hip Prostheses (THP)

Total hip prostheses are intended to replace the articulation of the damaged hip joint in patients with insufficient bone support for component placement and fixation due to degenerative joint diseases, traumatic hip fractures, hip dysplasia, or avascular necrosis. These prostheses consist of the following components;

- Ortohip Acetabular Cup (Ti+HA Coated) Cementless (COCR/Ti),
- Ortohip Acetabular Cup (Ti+HA Coated) Dual Mobilty Cemented/ Cementless (COCR/Ti),
- Ortohip Acetabular Cup Cemented (UHMWPE)

b. Partial Hip Prostheses (PHP)

Partial hip prostheses are used to replace the articulation of the damaged hip joint in patients with an intact or undeformed acetabulum and sufficient bone support for the femoral stem.

These prostheses consist of the following components:

- Ortohip Bipolar Cup (COCR/Ti)

c. Femoral (Hip) Stems

The femoral stems used in hip prostheses are designed in different configurations to suit the patient's bone structure and clinical requirements:

- Ortohip Square Cross-Section Stems (COCR/Ti) , Cemented/Cementless
- Ortohip Calcar Replacement Stems (COCR/Ti) , Cemented/Cementless
- Ortohip Femoral Stem Standard (COCR/Ti) , Cemented/Cementless
- Ortohip Modular Calcar Replacement Stem (COCR), Cemented

d. Revision Hip Prosthesis (RHP)

Revision hip prostheses are used when a previously implanted total hip prosthesis needs to be replaced due to loosening, wear, or infection. Revision systems are designed to meet anatomical and biomechanical requirements and include the following components:

- Ortohip Femoral Revision Stem Standart (COCR/Ti) , Cemented
- Ortohip K2 Modular Revision Stem (Ti), K2 Modular Revision Stem Gövde (Ti), Cemented/Cementless
- Ortohip Modular Calcar Replacement Stem (Ti), Cementless

e. Plates

The cable hook plate and cable flat plate are designed to stabilize femoral fractures and facilitate proper bone healing by providing secure fixation.

2. Purpose of Implant

The Hip Prosthesis System is designed to restore joint function, relieve pain, and improve patient mobility by replacing damaged hip structures with biocompatible implants. The system aims to deliver a durable, functional, and patient-specific solution for hip joint disorders, enhancing quality of life and surgical outcomes. For detailed information please refer to "Surgical Technique" section.

3. Indications

Hip prostheses are indicated for patients with severe hip joint dysfunction causing pain and disability due to:

- Degenerative Joint Diseases: Primary or secondary osteoarthritis.
- Inflammatory Arthritis: Rheumatoid arthritis or other inflammatory arthropathies.
- Avascular Necrosis: Femoral head necrosis with bone collapse.
- Fractures & Trauma: Femoral neck or acetabular fractures, hip dislocations.
- Congenital & Developmental Disorders: Developmental dysplasia of the hip (DDH).
- Post-Traumatic Joint Damage: Joint configuration loss, instability, patellofemoral erosion.
- Moderate-Severe Deformities: Valgus, varus, or flexion deformities.
- Failed Previous Hip Arthroplasty (Revision Cases): Implant loosening, wear, infection, or instability.

Revision hip arthroplasty is indicated for patients with failure or complications of a primary total hip replacement, leading to pain, loss of function, or implant instability due to:

- Aseptic Implant Loosening:
- Mechanical loosening due to osteolysis or wear.
- Loss of fixation in cemented or cementless implants.
- Periprosthetic Infection:
- Acute or chronic infection requiring implant removal and replacement.
- Periprosthetic Fractures:
- Fractures around the femoral or acetabular component affecting implant stability.
- Recurrent Dislocation or Instability:
- Malalignment, soft tissue imbalance, or implant failure causing repeated dislocations.
- Severe Polyethylene Wear & Osteolysis:
- Extensive wear of the acetabular liner leading to bone loss.
- Implant Malalignment or Failure:
- Incorrect positioning or early implant failure.
- Severe Bone Loss (Paprosky Type II-III, AAOS Classification):
- Significant femoral or acetabular bone defects requiring reconstruction.

4. Contraindications

- Conditions that block/tend to block adequate support of the implant or prevent use of an implant with suitable measures, including, for example:
- Limited blood supply;
- Poor bone quality and amount; for example, osteoporosis or other metabolic disorders that weaken bone formation and osteomalacia;
- Infections or other conditions leading to advanced bone resorption.
- Mental or nervous disorders deteriorating the ability or and motivation of the patient to limit their physical activities.
- Patients with active or suspicious infection in the area surrounding the hip joint,
- Physical conditions and movements resulting in the overloading of implants, for example, Charcot joints, missing muscles, multiple joint motility losses, etc.
- Skeletal immaturity,
- Patients with any vascular insufficiency, muscular atrophy or serious neuromuscular disorders,
- Patients with known medium- or serious renal insufficiency,
- Patients with suppressed immune systems because of AIDS or use of corticosteroid in high dosages,
- Physical disorders such as morbid obesity or limited motility,
- Failure of the patient in following the instructions for postoperative care,
- Contra-indications can be relative or definitive. Patients must be examined very carefully, and alternative procedures must be used where possible, including for example, nonsurgical treatment, osteosynthesis, arthrodesis, femoral osteotomy, pelvic osteotomy, resection arthroplasty, half arthroplasty and others.
- Conditions involving high risks include the following: osteoporosis, metabolic disorders preventing bone formation and osteomalacia.

5. Performance Design

The Hip Prosthesis System is designed for stability, durability, and optimal biomechanical performance to restore hip function and mobility.

Anatomical design ensures natural joint movement and load distribution.

Cemented & cementless fixation options provide secure implant stability.

High-strength materials (CoCr, Titanium, UHMWPE) enhance wear resistance and longevity.

Modular components allow customized fit and revision solutions.

Low-friction articulation reduces wear, minimizing complications. This design prioritizes long-term function, patient safety, and improved quality of life.

6. Side Effects

a) Postoperative Pain & Swelling – Normal inflammatory response after surgery.

b) Limited Mobility & Stiffness – Temporary movement restriction due to soft tissue healing.

c) Muscle Weakness & Fatigue – Reduced muscle strength due to surgical intervention and immobility.

d) Bruising & Mild Hematoma – Minor bleeding under the skin at the surgical site.

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e) Inflammatory Response – Mild local swelling and warmth around the implant.

f) Temporary Numbness – Due to minor nerve irritation or compression during surgery.

g) Mild Leg Length Discrepancy – Perceived or temporary limb length differences due to soft tissue adaptation.

h) Increased Joint Temperature – A sensation of warmth in the joint as part of the healing process.

i) These side effects are generally mild, transient, and self-limiting, resolving within a few weeks after surgery. However, if persistent or severe, they may indicate adverse effects requiring further medical evaluation.

7. Safe Configuration Criteria

The dimensions specified in the table below can be used in conjunction with each other.

		Femoral Head	
		22	28
Bipolar Cup	38	X	
	40	X	
	42		X
	44		X
	46		X
	48		X
	50		X
	52		X
	54		X
	56		X
	58		X
	60		X
	62		X

		Femoral Head		
		28	32	36
Cemented Acetabular Cup	42	X		
	44	X		
	46		X	
	48		X	
	50		X	
	52		X	
	54			X
	56			X
	58			X
	60			X
	62			X

		Femoral Head		
Cementless Acetabular Cup	Acetabular Liner	28	32	36
42	42-44	X		
44	42-44	X		
46	46-48	X		
48	46-48	X		
50	50-52		X	
52	50-52		X	
54	54-56			X
56	54-56			X
58	58-60-62			X
60	58-60-62			X
62	58-60-62			

8. Expected Clinical Benefits

TOTAL HIP REPLACEMENT

In total hip arthroplasty, replacement of the damaged hip joint articulation in skeletal adult patients with evidence of sufficient bone to seat and support the components is expected to increase patient mobility and reduce pain.

PARTIAL HIP REPLACEMENT

In partial hip replacements, replacement of the damaged hip joint articulation in skeletal adult patients with evidence of a satisfactory native acetabulum and adequate bone seating to support the femoral stem is expected to increase patient mobility and reduce pain.

9. Patient Population

It is used in adult individuals who have completed their bone development. Implants are not preferred for very old people with superior osteoporosis. It is not preferred for use in pregnant and lactating patients. It is not possible to set a maximum age limit for orthopedic implant use.

The appropriate type and size of the implant should be determined by taking into consideration the patient's age, activity level, body weight, bone and muscle condition, history of previous surgery, and other relevant anatomical and biomechanical factors.

10. Adverse Effects

– Hip arthroplasty, like any surgical procedure, carries potential adverse effects that may arise intraoperatively or postoperatively. These risks should be carefully assessed to ensure patient safety and optimal outcomes.

– Surgical & Immediate Postoperative Risks

– Infection – Superficial or deep periprosthetic infection.

– Bleeding & Hematoma Formation – Excessive blood loss requiring transfusion.

– Thrombosis & Pulmonary Embolism (DVT/PE) – Increased risk of clot formation post-surgery.

– Nerve or Vascular Injury – Sciatic, femoral, or obturator nerve damage leading to weakness or numbness.

– Leg Length Discrepancy – Due to soft tissue imbalance or surgical positioning errors.

– Wound Healing Complications – Delayed healing, dehiscence, or necrosis.

– Implant-Related Complications

– Aseptic Loosening – Bone resorption or mechanical instability leading to implant failure.

– Dislocation & Instability – Occurs due to improper implant positioning or soft tissue laxity.

– Periprosthetic Fractures – Bone fractures around the implant due to trauma or stress.

– Heterotopic Ossification – Abnormal bone formation around the joint, restricting mobility.

– Implant Wear & Osteolysis – Polyethylene wear causing bone loss and implant loosening.

– Metal Sensitivity & Allergic Reactions – Adverse response to implant materials.

– Systemic & Long-Term Risks

– Chronic Pain & Stiffness – Persistent pain despite a well-positioned implant.

– Muscle Atrophy & Weakness – Due to prolonged immobilization.

– Reoperation or Revision Surgery – Required due to implant failure, infection, or complications.

– Systemic Inflammatory Response (ALVAL, Pseudotumors) – Rare hypersensitivity to metal debris in metal-on-metal implants.

– Sensitivity against the metal or histological or allergic reactions or adverse foreign material reaction can occur as a result of implantation of a foreign material.

– Macrophages against the implant or tissue reactions containing foreign material reactions can be seen around the implant.

– Embolism can occur in patients who have extreme sedentary lifestyle.

11. Warnings:

- There may be patient sensitivities or allergies to the materials of the implants, especially metal ions. The type of material for each implant is indicated on the box label. As part of preoperative planning, the physician should assess and inform the patient of possible risks related to sensitivities to implant materials.
- The patient should be warned about the surgical risk and be aware of possible side effects. The patient should be warned that the implant does not replace normal healthy bone, that the implant may be broken or damaged as a result of high physical activity or trauma, and that it may need to be replaced in the future because it has an expected finite lifespan.

– Components from different manufacturers should not be used together.

– These metals should never be joined on non-joint contact surfaces.

– Patient selection should consider the following factors that can lead to an increased risk of failure and may be critical to the ultimate success of the procedure: the patient's weight, activity level, and occupation. Implant life and stability can be affected by these variables. A heavy patient can produce high loads on the prosthesis, which can cause the prosthesis to fail. The surgeon must consider the patient's ability and willingness to follow instructions and control their weight and activity level. Patients with high activity levels, poor bone quality, or excess weight may not be candidates for a narrow femoral implant. Any joint replacement system, including the implant/bone interface, cannot be expected to withstand activity levels and loads like normal healthy bone, and will not be as strong, reliable, or durable as a natural human joint. The patient should not have unrealistic functional expectations for occupations or activities that involve significant walking, jogging, lifting, or muscle strain.

– The Hip Prosthesis System is presented sterilized with gamma radiation and should always be stored unopened in its protective boxes. Before use, inspect the packaging for damage that could compromise puncture. Do not use implants if the packaging is opened or damaged

– Do not re-sterilize the Hip Prosthesis System for any reason. Do not use implants that may have impaired sterility

– Inspect the labels to verify that they have not expired. Do not use implants if the product has expired.

– When unpacking the implant, verify the reference number and dimensions on the label on the product box and the labels inside.

– Surgical technical information is available upon request. The surgeon must be familiar with the technique. Medical or manufacturer literature should be consulted for specific product information

– Intraoperative fracture or breakage of instruments may occur. Tools that experience heavy use or excessive force are susceptible to breakage. Instruments should be

inspected for wear or damage prior to surgery.

- Choosing the right neck length and shell, and root positioning, is important. Muscle laxity and/or material position of the components may result in loosening, partial/complete dislocation, and/or fracture of the components. Increasing neck length and varus positioning will increase the stress that must be borne by the root. The component must fit snugly with the component adding tools.
- Modular starts and femoral components must be from the same manufacturer to avoid taper mismatch. The modular femoral head component must fit snugly to the femur component to prevent separation.
- Use caution when positioning and drilling screw and peg holes to avoid damage to vital neurovascular structures. Do not put a screw in the middle hole of the acetabular prosthesis. The bone screws must fit completely into the holes of the shell to ensure proper locking for the acetabular lining.
- Surgical debris, including tissue, should be removed from surfaces before modular components are seated. These debris, including bone cement, can interfere with the component locking mechanism. Make sure that soft tissue does not interfere with the shell/liner interface during liner insertion. Modular components must be securely assembled to prevent disassembly. Failure to properly fit the acetabular liner into the shell may cause the liner and shell to separate.
- Avoid repeated assembly and disassembly of modular components as this may compromise the critical locking action of the locking mechanism.
- Previously installed implants should never be reused, as invisible stress accumulations can cause premature bending and breakage.
- For the correct removal of the Hip Prosthesis System, see the Surgical Technique document.
- If the Hip Prosthesis System needs to be destroyed, it should be considered as medical waste and treated accordingly.
- Products of different manufacturers must not be used together.

Components that can be used together according to EN ISO 21534 Annex-C:

- CoCrMo Alloy (ISO 5832-4)/ Titanium Alloy (ISO 5832-3)
- CoCrMo Alloy (ISO 5832-4)/ CoCrMo Alloy (ISO 5832-4)
- Implant Steel (ISO 5832-1)/Titanium Alloy (ISO 5832-3)
- Implant Steel (ISO 5832-1)/Implant Steel (ISO 5832-1)

Components that are incompatible with each other:

- Implant Steel (ISO 5832-1)/ CoCrMo Alloy (ISO 5832-4)

12. Residual Risks

- Before the operation, it should be checked for tears or hazard to the packages. If the sterile barrier is broken, send the product back to Ortonom
- Wear of the components can lead to increased loosening and hazard to the bone. This situation may require revision
- Femoral or acetabular perforation/ fracture may occur due to trauma or overload, especially in the presence of weak bone stock while implantation
- Cardiovascular disorders can occur, including venous thrombosis, pulmonary embolism, or myocardial infarction.
- Fatigue fracture of the Prostheses component may occur as a result of trauma, strenuous activity, misalignment, incomplete implant placement, length of service, loss of fixation, non-boiling or excessive weight.
- The patient should be warned that the Prostheses cannot replace the normal healthy bone, the Prostheses may be broken or hazardd as a result of some movements or trauma, the expected period of use is limited, and there may be a need for its replacement in the future.
- Products are offered sterile. It is not convenient to re-sterilize products. Please inform the manufacturer of the sterile degraded products. the phrase.
- Please check the expiration date. Expiration Date of an expired product in case, please contact the manufacturer.
- The devices are disposable. Do not reuse the used product. It is defined as.
- Ortonom products have not been evaluated for safety and compatibility in the MRI environment.

13. Removal Of The Implant:

The period of the implant within the patient's body can change according to the daily activity of the patient. Product life of this implant has been determined as 15 years. Implants can be removed according to the surgeon's decision.

14. Sterilization:

Implants are submitted as sterile. Sterilization method will be shown on the packaging. All implants sterilized by gamma irradiation are exposed to a minimum of 25 kGy and a maximum of 45 kGy of gamma radiation. Sterile products will remain so unless the integrity of the package is broken. The products are presented as sterile. Re-sterilization of the product is not recommended.

Please inform the manufacturer about any products with impaired sterility although offered as sterile.

15. Shelf Life:

The shelf life for Hip Prosthesis System sterilized with Gamma sterilization is 5 years.

Please check the expiry date. Please contact the manufacturer for products expired.

16. Storage And Maintenance Conditions:

Implants must be maintained in a dry and clean environment and protected from direct sunlight, excessive heat and humidity.

17. Severe Events:

Any severe events arising in relation with the implant must be notified to the manufacturer and used and/or authorized entity of the member state that the patient is a citizen of.

18. MRI Compatibility

The Hip Prosthesis System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of The Hip Prosthesis System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

19. Disposal Implant

Please apply disposal procedure for implants accordance with hospital rules

20. Product Description and Implant Materials

Component	Fixation Method	Material	ASTM Standard	ISO Standard
Ortohip Acetabular Cup (Ti+HA Coated)	Cementless	CoCr/Ti	ASTM F136 / ASTM F75	ISO 5832-3 / ISO 5832-4
Ortohip Acetabular Cup (Ti+HA Coated) Dual Mobility	Cemented/Cementless	CoCr/Ti	ASTM F136 / ASTM F75	ISO 5832-3 / ISO 5832-4
Ortohip Acetabular Cup Cemented (UHMWPE)	Cemented	UHMWPE	ASTM F648	ISO 5834-2
Ortohip Bipolar Cup	Cemented/Cementless	CoCr/Ti	ASTM F136 / ASTM F75	ISO 5832-3 / ISO 5832-4
Ortohip Square Cross-Section Stems	Cemented/Cementless	CoCr/Ti	ASTM F136 / ASTM F75	ISO 5832-3 / ISO 5832-4
Ortohip Calcar Replacement Stems	Cemented/Cementless	CoCr/Ti	ASTM F136 / ASTM F75	ISO 5832-3 / ISO 5832-4
Ortohip Femoral Stem Standard	Cemented/Cementless	CoCr/Ti	ASTM F136 / ASTM F75	ISO 5832-3 / ISO 5832-4

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Ortohip Modular Calcar Replacement Stem	Cemented/Cementless	CoCr	ASTM F75	ISO 5832-4
Ortohip Femoral Revision Stem Standard	Cemented/Cementless	CoCr/Ti	ASTM F136 / ASTM F75	ISO 5832-3 / ISO 5832-4
Ortohip K2 Modular Revision Stem	Cemented/Cementless	Titanium	ASTM F136	ISO 5832-3
Ortohip K2 Modular Revision Stem Body	Cemented/Cementless	Titanium	ASTM F136	ISO 5832-3
Ortohip Modular Calcar Replacement Stem	Cemented/Cementless	Titanium	ASTM F136	ISO 5832-3
Cable Hook Plate	Fixation with Cables	Titanium	ASTM F136	ISO 5832-3
Cable Flat Plate	Fixation with Cables	Titanium	ASTM F136	ISO 5832-3

21. Raw Materials Information

CoCrMo raw material is produced in accordance with ASTM F75 and ISO 5832-4 standard. Raw material content is given in the table below.

Element	*Composition, % ISO 5832-4*	*Composition, % ASTM F75*
Chromium (Cr)	26,5 - 30,0	27,0 - 30,0
Molybdenum (Mo)	4,5 - 7,0	5,0 - 7,0
Iron (Fe)	1,0 max.	0,75 max.
Manganese (Mn)	1,0 max.	1,0 max.
Silicon (Si)	1,0 max.	1,0 max.
Carbon (C)	0,35 max.	0,35 max.
Nickel (Ni)	1,0 max.	0,50 max.
Nitrogen (N)	0,25 max.	0,25 max.
Cobalt (Co)*	Balance	Balance
Tungsten	-	0,20 max.
Phosphorous	-	0,020 max.
Sulfur	-	0,010 max.
Aluminum	-	0,10 max.
Titanium	-	0,10 max.
Boron	-	0,010 max.

UHMWPE raw material is produced in accordance with ISO 5834-2 standard. Raw material content is given in the table below.

Element	**Maximum Quantity Permitted (mg/kg)**
Ash	125
Titanium	40
Calcium	5
Chlorine	30
Aluminium	20

Ti6Al4V ELI raw material is produced in accordance with ISO 5832-3 standard. Raw material content is given in the table below.

Element	*Composition, %*
Nitrogen (N), max	0.05
Carbon (C), max	0.08
Hydrogen (H), max	0.012
Iron (Fe), max	0.25
Oxygen (O), max	0.13
Aluminum (Al)	5.5-6.50
Vanadium (V)	3.5-4.5
Titanium (Ti)	Kalan

22. CMR Description

RS Identifier	RS Description	Risk
	Cobalt: CAS No. 7440-48-4 EC No. 231-158-0	This device or one or more of its components contain the substance defined as **CMR 1B** at a concentration of more than **0.1% by weight**. Existing scientific evidence and biocompatibility studies support that **medical device made from cobalt alloys or stainless-steel alloys do not increase the risk of cancer or cause adverse effects on reproduction**.

23. Preoperative Planning and Postoperative Care

***See Surgical Technique document.*

Symbols Shown on the Label

SYMBOL DESCRIPTION		
CE	European Medical Device Directive 93/42/EEC (as amended by Directive 2007/47/EC), Article 17 European Medical Device Regulation 2017/745, Article 20	CE Symbol
1984	European Medical Device Directive 93/42/EEC (as amended by Directive 2007/47/EC), Article 17 European Medical Device Regulation 2017/745, Article 20	NB Number
MD	ISO 15223-1 (Section 5.7.7*)	Medical device
LOT	ISO 15223-1 (Section 5.1.5) ISO 7000 (Symbol No. 2492)	Batch code
REF	ISO 15223-1 (Section 5.1.6) ISO 7000 (Symbol No. 2493)	Catalogue number
UDI	ISO 15223-1 (Section 5.7.10*)	Unique Device Identifier
	ISO 15223-1 (Section 5.4.3) ISO 7000 (Symbol No. 1641) ISO 15223-1 Annex A / A.15	Consult instructions for use
	ISO 15223-1 (Section 5.1.1) ISO 7000 (Symbol No. 3082)	Manufacturer
	ISO 15223-1 (Section 5.1.11) ISO 7000 (Symbol No. 2497)	Country of manufacture
	ISO 15223-1 (Section 5.1.4) ISO 7000 (Symbol No. 2607)	Use-by date
	ISO 15223-1 (Section 5.2.12*) ISO 7000 (Symbol No. 3704)	Double sterile barrier system
STERILE R	ISO 15223-1 (Section 5.2.4) ISO 7000 (Symbol No. 2502)	Sterilized using irradiation
	ISO 15223-1 (Section 5.4.2) ISO 7000 (Symbol No. 1051)	Do not re-use

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	ISO 15223-1 (Section 5.2.6) ISO 7000 (Symbol No. 2608)	Do not resterilize
	ISO 15223-1 (Section 5.2.8) ISO 7000 (Symbol No. 2606)	Do not use if package is damaged and consult instructions for use
	ISO 15223-1 (Section 5.3.2) ISO 7000 (Symbol No. 0624)	Keep away from sunlight
	ISO 15223-1 (Section 5.4.4) ISO 7000 (Symbol No. 0434A)	Caution
	ISO 15223-1 (Section 5.4.10)	Contains hazardous substances

Information supplied with the device

The Summary of Safety and Clinical Performance (SSCP) is available in the European Database on Medical Devices (Eudamed, https://ec.europa.eu/tools/eudamed) or you can access it via the manufacturer's website: www.ortonom.com.tr

e-IFU

You can access the e-IFU at https://ortonom.com.tr/qrdirected-010. You can also access the e-IFU via the QR code on the label and box. If you cannot access the e-IFU, please contact the manufacturer.

Implant Card

The implant card is physically located inside the product box within the device packaging. The implant card is contained in the Level 2 package inside the box. If you are unable to locate the physical implant card, please contact Ortonom Medikal.

Manufacturer

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