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ORTONOM MEDICAL

CE 1984

Revision Knee Prosthesis System Instruction for Use (IFU)

1. Implant Description

In primary total knee and joint prosthesis applications, the need for revision arises due to loosening of one or more prostheses due to friction over time, wear and tear and infection, insufficient bone growth on the surface of the uncemented implant and patellar problems. The risk of infection in total knee replacement surgery is less than 1%, but knee revision surgery may be required when infection occurs. Revision Knee Prostheses are applied for patients with severe knee pain and disability caused by various reasons.

1.1. Revision Knee Femoral Component (COCR)

Revision Knee Prosthesis Femoral Component used for revision of the femoral defect.

System consists of 5 sizes for Right and Left: C / D / E / F / G / H

It is made from CoCrMo Alloy raw material, which complies with the ISO 5832-4.

1.2. Revision Tibia Component (Titanium and CoCr)

Revision Knee Prosthesis Tibia Plato used for revision of the tibial defect.

Compatible with the extension adapter and stem.

System consists of 6 sizes.

Manufactured with CoCrMo Alloy (ASTM F75 / ISO 5832-4) and Titanium (ISO 5832-3 / ASTM F 136) Material.

1.3. Revision Tibia Insert (UHMWPE)

It is used as a binder in revision knee prostheses to allow patients with favourable anatomy to have a wider range of knee flexion.

System consists of 6 sizes.

Manufactured with UHMWPE (ISO 5834-2) Material

1.4. Revision Tibia Insert Screw

The tibial insert screw is used to fix the tibial insert.

It has standard size. Manufactured with Titanium (ISO 5832-3/ASTM F 136) Material.

1.5. Femur / Tibial Extension Stem - Titanium

Femoral and Tibia stems are used in revision prosthesis knee applications to reduce the flexion force of the knee under load and spread it to the femur and tibia axes.

It is available in various diameters and lengths. Manufactured with Titanium (ISO 5832-3/ASTM F 136) Material.

1.6. Revision Offset Adaptor - Titanium

Offset Adaptor is an implant component used especially in revision knee prosthesis surgeries. These adaptors allow for more precise positioning of the femoral and tibial stems according to the patient's individual anatomy. The aim is to ensure optimal alignment of the implant and joint stability. Manufactured with Titanium (ISO 5832-3/ASTM F 136) Material. There are two different options: Straight and Offset

1.7. Wedges and Wedge Screws

Wedges are used to complete tibial and femoral defects.

Wedge Screws are used for fixing the wedges at the femoral/tibial component. Manufactured with Titanium (ISO 5832-3/ASTM F 136) Material.

2. Purpose of Implant

Reconstruction of degenerative knee joints.

Revision Knee Prosthesis System aims for pain relief and functional recovery of the knee joint. Degenerated joints are reconstructed appropriately for their anatomical structure with the aid of specialized surgical tools. For detailed information please refer to "Surgical Technique" section.

3. Indications

Revision Knee is indicated in;

- In primary total knee and joint prosthesis applications, the need for revision arises due to loosening of one or more prostheses due to friction over time, wear and tear and infection, insufficient bone growth on the surface of the uncemented implant and patellar problems. The risk of infection in total knee replacement surgery is less than 1%, but knee revision surgery may be required when infection occurs. Revision Knee Prosthesis is applied for patients with severe knee pain and disability caused by various reasons. Conditions that cause knee damage and/or disability;
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders and/or avascular necrosis of the femoral condyle.
- Moderate valgus, varus or flexion deformities.
- Previous unsuccessful surgical interventions or failure to achieve satisfactory stability in flexion.

4. Contraindications

- Past history of infection in the affected joint and/or local/systemic infection that may affect the prosthesis joint.
- Insufficient bone stock on the femoral or tibial surfaces.
- Skeletal immaturity
- Neuropathic arthropathy.
- Osteoporosis, any muscle wasting or neuromuscular disease
- Severe instability secondary to absence of collateral ligament integrity.
- Total knee arthroplasty is contraindicated in patients with rheumatoid arthritis (RA) and a history of ulceration of the skin or a recurrent breakdown of the skin because the risk of postoperative infection is higher. The risk of infection may also be increased in rheumatoid arthritis patients on steroids. Late infections in RA patients have been reported 24+ months postoperatively.

5. Performance Design

Angular motion between the components of Revision Knee Prosthesis System is designed to provide 0° - 130° movement. It is anticipated that the Revision Knee Prosthesis System will experience a certain degree of abrasion due to the physical effects of daily activities on the knee joint. However, it is expected for this abrasion to stay at acceptable levels and for Revision Knee Prosthesis System to remain serviceable for at least 15 years post implantation.

6. Side Effects

a) Abrasion or breakage of the UHMWPE insert component,
b) Tibial/femoral fracture,
c) Temporary peroneal nerve palsy following surgical intervention,
d) Partial or complete dislocation of the patella,
e) Instability, position changes or aseptic loosening of components,
f) Ligamentous laxity,
g) Non-union of components,
h) Infection,
i) Narrow range of motion,
j) Shortening of the extremities,
k) Sensitivity to metal

7. Safe Configuration Criteria

Original femoral, tibial and insert components are required in order to assure Revision Knee Prosthesis System safe and secure implementation. Additionally, the operation should be performed with original Revision Knee Prosthesis System surgical tools and as specified within the "Surgical Technique" document.

The dimensions specified in the table below can be used in conjunction with each other. The thickness of the insert component is not a determining parameter for this.

8. Expected Clinical Benefits

The Revision Knee Prosthesis System, including both primary and revision knee prostheses, is intended to improve knee function and reduce pain by replacing the damaged knee joint articulation in skeletally mature patients.

For revision cases, the system is designed to address complex conditions such as bone loss, implant loosening, instability, and joint deformities, while ensuring adequate fixation and support even in the presence of compromised bone structures

9. Patient Population

Patients presenting with a clinically diagnosed necessity for a Revision Knee Prosthesis System, compliant with the indications and not in conflict with the identified contraindications as defined in this packaging insert and who are musculoskeletally classified as adult.

No restrictions based on gender, ethnicity or stature (unless patient's physical condition would negatively impact the intended function or lifetime of the device). This device is not indicated for use with a paediatric population.

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The patient should present with no mental health issues which would undermine either the rehabilitation phase or longevity of the device due to non-compliance with any limitations to function defined by the surgeon or the medical device manufacturer. Furthermore, the patient should be considered mentally capable to undertake the physical rehabilitation regime prescribed by the physician.

10. Adverse Effects

- Cardiovascular disorders including venous thrombosis, pulmonary embolism and myocardial infarct can occur.
- Damaging of blood vessels or hematomas can be seen.
- Delayed wound healing: Deep wound infections (early or late) that might require the removal of the prosthesis can occur. Arthrodesis of the relevant joint or amputation of the extremity can be required in rare cases.
- Osteolysis (progressive bone lysis). Osteolysis can be asymptomatic, and therefore, periodic radiographic examinations are vitally important to prevent any possible severe complications in the future.
- Unwanted lengthening or shortening of the extremity can occur.
- Fatigue fractures of the components of the prothesis can arise from trauma, exhausting physical activity, misalignment, defective implantation, service period, loss of fixation, nonunion or overloading.
- As a potential result of surgical trauma resulting in pain or numbness in the affected extremity, temporary or permanent nerve damage, peripheral neuropathies or subclinical nerve damages can be seen.
- 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 sensitivity or allergic reaction to implant materials, particularly to metal ions. The material type of each implant is indicated on the product box label. As part of preoperative planning, the physician should assess potential risks related to sensitivity or allergy to implant materials and inform the patient accordingly.
- Do NOT resterilize the Revision Knee Prosthesis System under any circumstances.
- Do NOT use implants if sterility may have been compromised.
- Before surgery, the product packaging should be inspected for tears, damage, or any compromise of the sterile barrier. If the sterile barrier is compromised, the product must not be used and should be returned to Ortonom.
- Check the product label to verify the expiration date. Do not use the product after its expiration date.
- When unpacking the implant, verify the reference number and dimensions on the product box label and the inner labels.
- The Revision Knee Prosthesis System is for single use only. Used products must not be reused.
- Do not use prosthetic components from other knee systems with Ortonom knee components, as incompatible sizing and bearing surfaces may result in premature wear, malalignment, and failure.
- Before use, inspect each implant to ensure that there is no visible damage.
- Care should be taken to protect polished surfaces, especially convex and concave surfaces, from nicks and scratches. Contact with polished surfaces should be avoided.
- Do not expose the Revision Knee Prosthesis System to chemicals in the clinical environment. Do not clean the implant with alcohol or subject it to similar processes.
- Overweight patients may experience decreased implant performance.
- The prosthesis cannot fully replace normal healthy bone. The patient should be informed that the prosthesis may fracture or become damaged as a result of certain movements, trauma, strenuous activity, malalignment, incomplete implant placement, loss of fixation, non-union, long-term use, or excessive body weight. The expected service life of the prosthesis is limited, and replacement may be required in the future.
- If the Revision Knee Prosthesis System needs to be removed, refer to the Surgical Technique document.
- If the Revision Knee Prosthesis System needs to be disposed of, it should be considered medical waste and handled 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

- Wear and tear on the components can lead to increased loosening and bone damage. This may require revision surgery.
- Wear and tear of the components can lead to increased loosening and damage to the bone. This may require revision surgery.
- Due to trauma or excessive loading—particularly if the bone tissue is weak at the time of implantation—a hole may form or a fracture may occur in the femur or acetabulum.
- Cardiovascular disorders, including venous thrombosis, pulmonary embolism, or myocardial infarction.
- Fatigue fractures in the prosthetic component may occur as a result of trauma, strenuous activity, misalignment, improper implant placement, duration of use, loss of fixation, nonunion, or excessive weight.
- Patients should be advised that prostheses cannot replace normal, healthy bone; that prostheses may fracture or pose a risk as a result of certain movements or trauma; that their expected service life is limited; and that replacement of the prosthesis may be necessary in the future.
- Products are supplied sterile. Re-sterilization of the products is not recommended. Please report any products that have lost their sterility to the manufacturer.
- Check the expiration date. If you encounter a product past its expiration date, please contact the manufacturer.
- The devices are for single use only. Do not reuse a used product. This rule is clearly stated.

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. The expected product life of the implant is projected to last for the patient's lifetime, with a minimum of 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 Revision Knee 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 Revision Knee Prosthesis System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Revision Knee Prosthesis System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in

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injury or device malfunction. Ortonom products have not been evaluated for safety and compatibility in the MRI environment.

19. Disposal Implant

Please apply disposal procedure for implants accordance with hospital rules

20. Product Description and Implant Material

Component	Fixation Method	Material	ASTM Standard	ISO Standard
Revision Knee Femoral Component	It is cemented to the distal end of the femur.	CoCrMo Alloy	ASTM F75	ISO 5832-4
Revision Tibia Component	It is cemented to the proximal end of the tibia.	CoCrMo Alloy and Ti6Al4V Alloy	ASTM F75 ASTM F136	ISO 5832-4 ISO 5832-3
Revision Tibia Insert	It is secured with a screw by inserting it into the appropriate tibial component.	Ultra-High Molecular Weight (UHMWPE)	ASTM F648	ISO 5834-2
Femur / Tibial Extension Stem - Titanium	It is secured with a screw to the femoral or tibial component.	Ti6Al4V Alloy	ASTM F136	ISO 5832-3
Revision Offset Adaptor-Titanium	It is secured with a cone and a screw.	Ti6Al4V Alloy	ASTM F136	ISO 5832-3
Wedges and Wedge Screws	It is secured with a screw.	Ti6Al4V Alloy	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.*

24. 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 Ortonom + Hip and Knee Implant Systems . 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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