

INSTRUCTION FOR USE KNEE PROSTHESIS SYSTEM

IMPORTANT NOTE:

The HIPKNEE Knee system (Proknee -Orthoknee) is a reconstructive knee system intended for patients suffering from pain and/or deformity of the knee joint.

DESCRIPTION OF THE SYSTEM:

HIPKNEE manufactures this Knee System in a variety of sizes to accommodate differing surgeon and patient requirements.

The Knee System consists of:

- **Femoral components** (Cemented and Uncemented) manufactured from cast Cobalt Chromium alloy conforming to ISO 5832-4 - ASTM F 75
- **Tibial components** (Cemented and Uncemented) manufactured from cast Cobalt Chromium alloy conforming to ISO 5832-4 - ASTM F 75
- **Tibial Component Stem** manufactured from Titanium Alloy conforming to ISO 5832-3
- **Tibial inserts** manufactured from UHMWPE /Cross Linked UHMWPE conforming ISO 5834-2
- **Patella components** manufactured from UHMWPE conforming ISO 5834-2

Description of the component material is provided on the labels
Each Knee Component is designed as part of a system and does not allow the substitution of components from other systems or manufacturers. All implantable devices are designed sterile and for Single-Use only.

The Hydroxyapatite or Titanium Plasma / Porous coatings applied to implant surfaces are intended for uncemented arthroplasty.

Indications:

Knee Systems are indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- 2) Inflammatory degenerative joint disease including rheumatoid arthritis;
- 3) correction of functional deformity;

POSSIBLE ADVERSE EFFECTS

The general principles of good patient selection and sound surgical judgment apply to the total knee procedure. Preoperative planning and meticulous surgical technique are essential to achieve optimum results. Considerations of anatomic loading, soft-tissue condition, and component placement are critical to minimize a variety of postoperative complications.

1. Osteolysis (progressive bone resorption). Osteolysis can be asymptomatic, and therefore, routine periodic radiographic examination is vital to prevent any serious future complication
2. Particulate generation leading to increased wear rates necessitating early revision. Soft tissue imbalance leading to excessive wear;
3. Allergic reactions to materials; metal sensitivity that may lead to histological reactions;
4. Delayed wound healing; deep wound infection (early or late) which may necessitate removal of the prosthesis. On rare occasions, arthrodesis of the involved joint or amputation of the limb may be required;
5. A sudden drop in blood pressure intra-operatively due to the use of bone cement;
6. Damage to blood vessels or hematoma;
7. Temporary or permanent nerve damage, peripheral neuropathies and subclinical nerve damage as possible result of surgical trauma resulting in pain or numbness of the affected limb;
8. Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
9. Dislocation, migration and/or subluxation of prosthetic components from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity;
10. Periarticular calcification or ossification, with or without impediment to joint mobility;
11. Varus-valgus deformity;
12. Traumatic arthrosis of the knee from intraoperative positioning of the extremity;
13. Inadequate range of motion due to improper selection or positioning of components, periarticular calcification, flexion contracture;
14. Femoral, tibial or patellar bone or component fracture intraoperatively or postoperatively; fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
15. Undesirable shortening or lengthening of the limb;
16. Aggravated problems of the affected limb or contralateral extremity by leg length discrepancy, excess femoral medialization, or muscle deficiency;
17. Pain.

Contraindications

1. Tibia, femur or patella fractures.
2. Blood Circulatory constriction such as arteriosclerosis
3. Known allergic reaction to CoCr
4. Infection
5. Children or patients with skeletal immaturity
6. Tumors, cysts in the distal femur, proximal tibia

WARNINGS AND PRECAUTIONS

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the devices do not replace normal healthy bone, and that the implant can break or become damaged as a result of strenuous activity or trauma, and has a finite expected service life and may need to be replaced in the future. Higher rates of wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components. Loosening, bending, cracking, or fracture of implant components; fracture of the implant can occur as a result of trauma, strenuous activity.

The potential long-term biological effects of metal wear debris and metal ion production are not known. Questions regarding carcinogenicity have been raised in literature; no studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.

MEANING OF SYMBOLS (According to EN ISO 15223-1:2016)



: Consult the user manual.



: Lot numbers



: Product code number (Catalog number)



: Manufacturer name and address



: Sterilized by Gamma Irradiation



: Use on time (Expiration date)



: Not reusable



: European union symbol of conformity



: Production date

Ligament stability , based on maintained isometry throughout knee of motion. Designed to maintained collateral stability throughout the range of motion.

Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the surgical technique, implants and instruments prior to performing surgery.

Preoperative:

1. Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, occupation and lifestyle.

2. The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or trauma, has a finite expected service life, and may need to be replaced at some time in the future. The patient should also be advised of other risks that the surgeon believes should be disclosed. The patient should be advised that any noise or unusual sensation should be reported to the surgeon as it may indicate implant malfunction.

3. Use care in handling and storing of implant components. Cutting, bending, or scratching the surfaces of components can significantly reduce the strength, fatigue resistance and/or wear characteristics of the implant system. These in turn may induce internal stresses that are not obvious to the eye and may lead to fracture of the component.

4. Surgical information is available upon request. The surgeon should be familiar with the technique.

5. An adequate inventory of implant sizes should be available at the time of surgery.

6. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear and damage prior to surgery.

Intraoperative:

1. The correct selection of the implant is extremely important. The appropriate type and size should be selected for patients with consideration of anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, etc. Generally, the largest cross-section component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum size component may result in loosening, bending, cracking, or fracture of the component and/or bone.

2. Modular components must be assembled securely to prevent disassociation. Avoid repeated assembly and disassembly of the modular components which may compromise a critical locking action of the components. Surgical debris must be cleaned from components before assembly. Debris may inhibit the proper fit and locking of modular components leading to early failure of the procedure.

3. Prior to closure, the surgical site should be thoroughly cleaned of bone chips , extraneous cement, etc.; foreign particles at the metal and/or plastic interface may cause excessive wear and/or friction.

4. An implant should never be reused. While it may appear undamaged, imperfection may exist which would reduce the service life of the implant.

Extramedullary alignment metot:

Rotational alignment can be achieved by aligning the ankle clamp attachment shaft with second toe. You can choose 5 degree or 0 degree posterior angle on resection guide.

Postoperative:

1. The patient must be advised of the limitations of the reconstruction and the need for protection of the prosthesis from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma

affecting the joint replacement have been implicated with failure of the reconstruction by loosening, fracture and/or wear of the prosthetic components. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.

2. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.

3. Periodic postoperative x-rays are recommended for close comparison with early post-op conditions to detect long term evidence of changes in position, loosening, bending, or cracking of components

4. HIPKNEE Knee Systems have not been evaluated for safety and compatibility in the Magnetic Resonance Imaging environment. The HIPKNEE Knee Systems have not been tested for heating or migration in the MRI environment.

PACKAGING AND LABELING

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. Products cannot be reused as indicated on the label.

STERILIZATION / RESTERILIZATION

All implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a minimum of 25 kiloGrays of gamma radiation. Inspect packages for punctures or other damage prior to surgery. If the sterile barrier has been broken, return the component to HIPKNEE. If metal products are out of use after opening, they cannot be sterilized again. HIPKNEE accepts no responsibility for the use of implants resterilized after contact with body tissues or fluids. Polyethylene products cannot be resterilized.

INSTRUCTION FOR USE HIP PROSTHESIS SYSTEM

IMPORTANT NOTE:

The goals of HIPKNEE hip replacement system (Prohip –Orthohip) are to decrease pain, increase function, and increase mobility.

DESCRIPTION OF THE SYSTEM:

The Hip System consists of Femoral components, Acetabular components, Fixation screws, Femoral Heads. These components can be utilized in a variety of configurations to assemble the final construct. *All implantable products are sterile and for single use only.*

Femoral Components(Cemented&Uncemented):

Materials: Titanium TiAlV6 –ISO 5832-3 and CoCrMo Alloy ISO 5832-4 - ASTM F75

All Femoral stems have a 12 /14 Morse taper.

Femoral Heads & Bipolar Cups

Materials: CoCrMo Alloy ISO 5832-4 - ASTM F75 . Heads are highly polished for reduced friction and hence reduced wear.

Acetabular Screws:

Materials: Titanium TiAlV6 –ISO 5832-3

Acetabular Components:

Materials: Titanium TiAlV6 –ISO 5832-3 and Polyethylene -UHMW-PE ISO 5834-2 +Cross Linked
Acetabular components can be one-piece all Polyethylene or two-piece components consisting of metal Acetabular shell and a Polyethylene Liner. Femoral components and femoral heads are designed for use with any HIPKNEE polyethylene acetabular component or polyethylene-liners with metal backed acetabular component having an appropriately sized inside diameter. Acetabular screws are sterilized in the same box with Acetabular cups.
The Hydroxyapatite or Titanium Plasma / Porous coatings applied to implant surfaces are intended for uncemented arthroplasty.

INDICATIONS:

Intended Use: HIPKNEE Hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulating surface in Adult patients where there is evidence of sufficient sound bone to seat and support the components.

Indications For Use: HIPKNEE Hip arthroplasty may be used for the following conditions, as appropriate:

1. Degenerative osteoarthritis of the hip.
2. Inflammatory arthritis of the hip.
3. Secondary arthritis of the hip, such as may follow trauma (e.g. fracture of the femoral neck, or fracture and/or dislocation of the hip or acetabulum), or congenital conditions (e.g. developmental dysplasia of the hip).
4. Displaced intracapsular femoral neck fractures where there is a high risk of nonunion or avascular necrosis and bone collapse.
5. Avascular Necrosis of the femoral head.

CONTRAINDICATIONS

- 1) Conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately-sized implant eg,;
 - a) blood supply limitations;
 - b) insufficient quantity or quality of bone support, e.g., osteoporosis, or metabolic disorders which may impair bone formation, and osteomalacia;
 - c-) infections or other conditions which lead to increased bone resorption.
2. Mental or neurological conditions which tend to impair the patient's ability or willingness to restrict activities.
3. Physical conditions or activities which tend to place extreme loads on implants, e.g., muscle deficiencies, multiple joint disabilities, etc.
4. Skeletal immaturity.
- 5-The use is contraindicated in cases with active or recent joint sepsis, insufficient bone stock, skeletal immaturity, Charcot's disease; Inflammatory Degenerative Joint Disease, or where loss of musculature or neuromuscular disease would render the procedure unjustifiable. The use is also contraindicated for pregnant because of loss of adequate clinical research.

POSSIBLE ADVERSE EFFECTS

The general principles of good patient selection and sound surgical judgment apply to the total hip procedure. Preoperative planning and meticulous surgical technique are essential to achieve optimum results. Considerations of anatomic loading, soft-tissue condition,

and component placement are critical to minimize a variety of postoperative complications.

- 1) Osteolysis (progressive bone resorption). Osteolysis can be asymptomatic and therefore routine periodic radiographic examination is vital to prevent any serious future complication.
- 2) Particulates leading to increased wear rates necessitating early revision.
- 3) Allergic reactions to materials; metal sensitivity; or reactions to wear debris that may lead to histological reactions, pseudotumor and aseptic lymphocytic vasculitis-associated lesions (ALVAL).
- 4) Delayed wound healing; Deep wound infection (early or late) which may necessitate removal of the prosthesis. On rare occasions, arthrodesis of the involved joint or amputation of the limb may be required.
- 5) A sudden drop in blood pressure intra-operatively due to the use of bone cement;
- 6) Damage to blood vessels or hematoma;
- 7) Temporary or permanent nerve damage, peripheral neuropathies and subclinical nerve damage as possible result of surgical trauma resulting in pain or numbness of the affected limb;
- 8) Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
- 9) Fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, incomplete implant seating, duration of service, loss of fixation, non-union, or excessive weight;
- 10) Dislocation, migration and/or subluxation of prosthetic components from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity;
- 11) Periarticular calcification or ossification, with or without impediment to joint mobility;
- 12) Trochanteric non-union due to inadequate reattachment and or early weight bearing;
- 13) Trochanteric avulsion as a result of excess muscular tension, early weight bearing, or inadvertent intraoperative weakening;
- 14) Traumatic arthrosis of the knee from intraoperative positioning of the extremity;
- 15) Inadequate range of motion due to improper selection or positioning of components, by femoral impingement, and periarticular calcification;
- 16) Femoral or acetabular perforation or fracture; femoral fracture while seating the device; femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
- 17) Undesirable shortening or lengthening of the limb;
- 18) Aggravated problems of the affected limb or contralateral extremity by leg length discrepancy, excess femoral medialization, or muscle deficiency;
- 19) Pain.

WARNINGS AND PRECAUTIONS

The patient should be warned of surgical risk, and made aware of possible adverse effects. The patient should be warned that the device does not replace normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that it has a finite expected service life and may need to be replaced in the future. Do not mix components from different manufacturers.

NEVER combine these metals in NON-ARTICULATING contact surfaces:

- Stainless Steel /Cobalt Chrome alloy.

- Stainless Steel / unalloyed Titanium (Pure Titanium).

The potential long-term biological effects of metal wear debris and metal ion production are not known. Questions regarding carcinogenicity have been raised in literature; no studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.

Preoperative

1. Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, and occupation. Implant longevity and stability may be affected by these variables. A heavy-weight patient can produce high loads on the prosthesis, which can lead to failure of the prosthesis. The surgeon must consider the ability and willingness of the patient to follow instructions and to control their weight and activity level. Patients with high activity levels, poor bone quality, or heavy 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 as would 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 include substantial walking, running, lifting, or muscle strain.
2. The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or

trauma, has a finite expected service life, and may need to be replaced at some time in the future. The patient should also be advised of other risks that the surgeon believes should be disclosed. The patient should be advised that any noise or unusual sensation should be reported to the surgeon as it may indicate implant malfunction.

3. Use extreme care in handling and storage of implant components. Cutting, bending or scratching the surface of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These in turn may induce internal

stresses that are not obvious to the eye and may lead to fracture of the component. Implants and instruments should be protected from corrosive environments such as salt air during storage.

4. Do not allow the HA/Ti Plasma coated surfaces to come in contact with cloth or other fiber-releasing materials.

5. Surgical technique information is available upon request. The surgeon should be familiar with the technique. Refer to medical or manufacturer literature for specific product information.

6. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage prior to surgery.

Intraoperative

1.The general principles of patient selection and sound surgical judgment apply. The correct selection of the implant is extremely important. The appropriate type and size should be selected for patients with consideration of anatomical and biomechanical factors such

as patient age and activity levels weight, bone and muscle conditions , any prior surgery and anticipated future surgeries, etc. Generally, the largest cross-section component which will allow adequate bone support to be maintained is preferred.

2. Correct selection of the neck length and shell, and stem positioning, are important. Muscle looseness and/or mal-positioning of components may result in loosening, subluxation, dislocation, and/or fracture of components. Increased neck length and varus positioning will increase stress which must be borne by the stem. The component should be firmly seated with the component insertion instruments.

3.Care should be taken not to scratch, bend or cut implant components during surgery for the reasons stated in Number three of the "Pre-Operative" section of "Warnings and Precautions."

4.Modular heads and femoral components should be from the same manufacturer to prevent mismatch of tapers.

5.Clean and dry stem taper prior to impacting the femoral head or taper sleeve. The modular femoral head component must be firmly seated on the femoral component to prevent disassociation.

6.Take care, when positioning and drilling screw and peg holes, to avoid damage to vital neurovascular structures.. Do not place a screw in the center hole of the acetabular prosthesis. Bone screws must be completely seated in the holes of the shell to allow proper locking for the acetabular liner.

7.Prior to seating modular components, surgical debris including tissue must be cleaned from the surfaces. Debris, including bone cement, may inhibit the component locking mechanism. During liner insertion, make sure soft tissue does not interfere with the shell /

liner interface. Modular components must be assembled securely to prevent disassociation. Failure to properly seat the acetabular liner into the shell can lead to disassociation of the liner from the shell.

8.Avoid repeated assembly and disassembly of the modular components which could compromise the critical locking action of the locking mechanism.

9.Implants previously implanted should never be reused, since internal stresses which are not visible may lead to early bending or fracture of these components.

Postoperative

1.The patient must be advised of the limitations of the reconstruction and the need for protection of the prosthesis from full weight bearing until adequate fixation and healing have occurred. The patient should be cautioned to limit activities and protect the replaced

joint from unreasonable stresses and possible loosening, fracture and/or wear, and follow the instructions of the physician with respect to follow-up care and treatment. Loosening of the components can result in increased production of wear particles, as well as damage

to the bone, making successful revision surgery more difficult.

2.Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone. Periodic postoperative x-rays are recommended for close comparison with early post-op conditions to detect

long term evidence of changes in position, loosening, bending, or cracking of components.

3.HIPKNEE Hip Systems have not been evaluated for safety and compatibility in the Magnetic Resonance environment. The

HIPKNEE Hip Systems have not been tested for heating or migration in the MR and CT environment.

4.Postoperative warnings to patients by physicians, and patient care, are extremely important.

5.Patients should be warned against unassisted activity, particularly use of toilet facilities and other activities requiring excessive motion of the hip.

6.Use extreme care in patient handling. Support should be provided to the operative leg when moving the patient. While placing the patient on bedpans, changing dressings and clothing, and similar activities, precautions should be taken to avoid placing excessive load on the operative part of the body.

7.Postoperative therapy should be structured to regain muscle strength around the hip a gradual increase of activities.

8. when implant needs to be removed from patient, Revision surgery must be performed by The surgeon should be familiar with the general revision surgery technique. Removed implants must be treated as biological hazards and are required to be treated or

disposed of according to the country's waste regulations where the implant is removed

PACKAGING AND LABELING

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. Products cannot be reused as indicated on the label

STERILIZATION

All implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a minimum of 25 kiloGrays of gamma radiation. Inspect packages for punctures or other damage prior to surgery, if the sterile barrier has been broken, return the component to HIPKNEE. If metal products are out of use after opening, they cannot be sterilized again. HIPKNEE accepts no responsibility for the use of implants resterilized after contact with body tissues or fluids. Polyethylene products cannot be resterilized.

MEANING OF SYMBOLS:



: Consult the user manual.



: Lot numbers



: Product code number (Catalog number)



: Manufacturer name and address



: Sterilized by Gamma Irradiation



: Use on time (Expiration date)



: Not reusable



: European union symbol of conformity



: Production date