

**FOR USA
ONLY**

**INSTRUCTIONS FOR USE
PHYSICA KNEE SYSTEM**

**SOLAMENTE
PARA EEUU**

**INSTRUCCIONES DE USO
SISTEMA DE PRÓTESIS DE
RODILLA PHYSICA**

NOTE: a larger print version of this IFU is available on www.limacorporate.com in the specific product section.

NOTA: una versión más completa de las instrucciones de uso se encuentra disponible en el sitio www.limacorporate.com en la específica sección de productos.



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preoperatorio no se puedan usar.

La selección correcta del implante así como su adecuada colocación y asentamiento son de extrema importancia. Una elección, posicionamiento, alineamiento y fijación inadecuadas de los componentes del implante pueden generar condiciones de tensión inusuales que, a su vez, pueden repercutir en el rendimiento y duración del implante.

Los componentes de los sistemas originales de Lima Corporate se deben integrar según la técnica quirúrgica y se deben usar solo para las indicaciones recogidas en las etiquetas.

Use solo instrumentos y pruebas de prótesis específicamente diseñados para su uso con los implantes correspondientes. El uso de instrumentos de otros fabricantes o el uso de instrumentos diseñados para combinarse con otros sistemas puede resultar en una preparación inadecuada del entorno del implante y un posicionamiento, alineamiento y fijación incorrectos de los dispositivos. Esto podría provocar que el implante se afloje, pierda funcionalidad y/o dure menos, y la necesidad de una cirugía posterior.

Se debe extremar el cuidado para proteger las superficies de acoplamiento entre componentes (acoplamiento cómico entre base tibial y vástago tibial y acoplamiento entre base tibial e inserto tibial); las superficies articulares de los implantes se deben proteger para que no sufran ralladuras o cualquier otro daño. Todas las superficies de los componentes que se acoplan se deben limpiar y secar antes de montarlas. La estabilidad de los componentes combinados se debe comprobar tal como se describe en la técnica quirúrgica.

3.3 CUIDADO POSTOPERATORIO

El cirujano o el personal médico debidamente cualificado deberán prestar el cuidado postoperatorio adecuado. Se recomienda el seguimiento mediante radiografías periódicas postoperatorias para detectar posibles cambios en la posición o estado de los implantes o de los tejidos circundantes.

El cirujano debe concienciar al paciente de las limitaciones en la función de la extremidad después de la artroplastia de rodilla y las precauciones necesarias, especialmente en el período post-operatorio. El exceso de actividad física o un traumatismo en la rodilla afectada puede conducir al fallo prematuro debido a aflojamiento, fractura o desgaste anormal de los implantes protésicos. El cirujano debe poner en guardia al paciente para que realice actividades acordes a su condición y avisarle de que los implantes pueden fallar a consecuencia de un desgaste articular excesivo. Entre las advertencias al paciente, el cirujano debe insistir especialmente en las precauciones siguientes:

- evitar levantar cargas pesadas de forma repetitiva;
- mantener el peso controlado; condiciones de sobrepeso pueden afectar negativamente a los resultados del reemplazo articular;
- evitar picos de carga repentinos (resultantes de actividades como correr o esquiar) o movimientos susceptibles de acabar con un frenazo repentino o giros bruscos;
- evitar posiciones que puedan aumentar el riesgo de dislocación.

La falta de instrucciones de rehabilitación adecuadas y de cuidado postoperatorio puede repercutir de forma negativa en el resultado del procedimiento quirúrgico.

3.4 POSIBLES EFECTOS ADVERSOS

Los efectos adversos que pueden ocurrir en la artroplastia de rodilla incluyen:

- los componentes de la prótesis se aflojan;
- dislocación e inestabilidad de la prótesis;
- daño en el implante protésico;
- inestabilidad del sistema por un inadecuado equilibrio con los tejidos blandos;
- disociación debida a un acoplamiento incorrecto de los dispositivos;
- infección;
- reacción del tejido al material del implante o abrasión;
- hipersensibilidad local;
- dolor local;
- fracturas periprotésicas;
- daño nervioso temporal o permanente;
- contractura en flexión;
- rango de movimiento limitado;
- alargamiento o acortamiento de la pierna;
- fracturas de los dispositivos;
- desgaste excesivo de los componentes de UHMWPE debido a superficies articulares dañadas o a la presencia de partículas;
- cirugía adicional.

Algunos efectos adversos pueden provocar la muerte.

Las complicaciones generales incluyen trombosis venosa con o sin embolismo pulmonar, perturbaciones cardiovasculares o pulmonares, hematomas, reacciones alérgicas sistémicas y dolor sistémico.

4. ESTERILIZACIÓN

a. Implantes

Todos los componentes implantables del sistema de rodilla Physica se suministran estériles con un Nivel de Garantía de Esterilidad (SAL) de 10⁻⁶. Los componentes metálicos se esterilizan mediante radiación o EtO y los componentes de UHMWPE (polietileno de peso molecular ultra elevado [PEPMUE]) mediante EtO.

SYMBOLOGY



Single use | Un solo uso



Use By | Fecha de caducidad



Lot Number | Número de lote



Reference number | Número de referencia



Caution | Consulte las instrucciones de uso



Consult instructions for use | Atención



Manufacturer | Fabricante



Keep away from sunlight
No exponer a la luz solar Mantener seco



Keep dry | Mantener seco



Do not use if package is damaged
No usar si el paquete está deteriorado



Sterilized using Irradiation
Esterilizado mediante Irradiación



Sterilized using Ethylene Oxide
Esterilizado mediante Oxido de etileno

**CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE
ON OR BY THE ORDER OF A PHYSICIAN.**

**ATENCIÓN: LA LEY FEDERAL ESTADOUNIDENSE RESTRIGE LA
VENTA DE ESTE DISPOSITIVO A LA PRESCRIPCION PREVIA DE UN
MÉDICO.**

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ENGLISH**INSTRUCTIONS FOR USE - PHYSICA KNEE SYSTEM****Intended for cemented fixation**

Before using a Limacorporate product, the surgeon should carefully study the following recommendations, warnings and instructions, as well as the available product-specific information (e.g.: product literature, surgical technique).

1. PRODUCT INFORMATION

The main goal of a knee joint prosthesis is to reproduce the articular anatomy. The joint prosthesis is intended to reduce pain and give articular mobility to the patient. The degree of pain reduction and mobility depends in part on the pre-operative situation, intra-operative options and on the post-operative rehabilitation.

Physica knee system is a modular knee replacement system. The CR (cruciate retaining) and KR (kinematic retaining) designs are intended to be used in patients with a preserved and well functioning posterior cruciate ligament. The PS (posterior stabilized) design is intended to be used in situations where the posterior cruciate ligament is absent or cannot be preserved. All the three versions (CR, KR and PS) require preserved and well functioning collateral ligaments.

Physica knee system includes femoral components, tibial implants with tibial stems, tibial liners and patellar components. These devices are intended for cemented use only.

The components should not be used alone as single components, or with components from other manufacturers.

1.1 MATERIALS

Components	Material
Femoral component	CoCrMo
Tibial plate	Ti6Al4V
Tibial liner	UHMWPE
Tibial stem	Ti6Al4V
Patella	UHMWPE
Tibial plate plug	UHMWPE
Material Standards	

Ti6Al4V (ISO 5832-3 - ASTM F1472) - CoCrMo (ISO 5832-4 - ASTM F75)
- UHMWPE (ISO 5834-2 - ASTM F648)

Some patients may be hypersensitive or allergic to the implant materials; this should be appropriately considered by the Surgeon.

Follow the instructions of the manufacturer of bone cement (PMMA) for preparing the bone and applying the bone cement for prosthesis fixation.

1.2 HANDLING AND STORAGE

All devices are provided sterile and should be stored at ambient temperature (indicative range 0-50°C / 32-122°F) in their protective closed packaging in controlled rooms, protected from exposure to light, heat and sudden changes in temperature.

Once the package is opened check that both the model and size of the implant correspond exactly to the description printed on the labels. Avoid any contact between the implant and objects or substances that can alter the sterile condition or the surface integrity. Careful visual examination of each implant is recommended before use in order to verify that the implant is not damaged. Components removed from the package should not be used if they are dropped or suffer other accidental impacts. Devices should not be modified in any way.

The device's code and lot number should be recorded in the patient's case history by using the labels included in the components packaging.

The disposal of medical devices is to be performed by the hospitals in conformity with applicable laws.

Re-use of previously implanted devices must be absolutely avoided. Risks associated with reuse of single use devices are:

- infection;
- early or late failure of the device or device fixation;
- lack of appropriate coupling between modular junctions (e.g. taper connections);
- device wear and wear debris associated complications;
- transmission of diseases (e.g. HIV, hepatitis);
- immune system response / rejection.

2. GENERAL INFORMATION ON INDICATIONS, CONTRAINDICATIONS AND RISK FACTORS**2.1 INDICATIONS**

Physica total knee system is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease: including osteoarthritis, traumatic arthritis, or avascular necrosis;
- Inflammatory degenerative joint disease including rheumatoid arthritis;
- Correction of functional deformity;

- Revision procedures where other treatments or devices have failed; and
- Treatment of fractures that are unmanageable using other techniques. In patients with preserved and well functioning collateral ligaments, Physica PS components are also for:

- Absent or not-functioning posterior cruciate ligament;
- Severe antero-posterior instability of the knee joint.

Physica knee system is intended for cemented fixation.

2.2 CONTRAINDICATIONS

Common contraindications for Physica CR, KR and PS versions include:

- severe instability of the knee joint secondary to the absence of collateral ligament integrity and/or function;
- local systemic infection;
- important bone loss on femoral or tibial joint side;
- progressive tumour diseases;
- known incompatibility or allergy to the product materials;
- septicaemia;
- persistent acute or chronic osteomyelitis;
- open epiphyses (immature patient with active bone growth).

Specific contraindications for Physica CR and KR versions include:

- important joint instability;
- deficiency of posterior cruciate ligament.

The relative contraindications are:

- vascular or nerve diseases affecting the concerned limb;
- bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/ or fixation to the prosthesis;
- metabolic disorders which may impair fixation and stability of the implant;
- any concomitant disease and dependence that might affect the implanted prosthesis;
- metal hypersensitivity to implant materials;
- rephant osteoporosis, haemophilic disease;
- intrinsic problems with high risk for surgery;
- skeletal immaturity.

2.3 RISK FACTORS

The following risk factors may result in poor results with this prosthesis:

- overweight;
- strenuous physical activities (active sports, heavy physical work);
- fretting of modular junctions;
- incorrect implant positioning;
- insufficient bone to support the femoral and/or tibial components;
- medical disabilities which can lead to an unnatural gait and loading of the knee joint;
- muscle deficiencies;
- multiple joint disabilities;
- refusal to modify postoperative physical activities;
- patient's history of infections or falls;
- systemic diseases and metabolic disorders;
- local or disseminated neoplastic diseases;
- drug therapies that adversely affect bone quality, healing, or resistance to infection;
- drug use or alcoholism;
- marked osteoporosis or osteomalacia;
- patient's resistance to disease generally weakened (HIV, tumour, infections);
- severe deformity leading to impaired anchorage or improper positioning of implants.

3. WARNINGS**3.1 PRE-OPERATIVE PLANNING**

Limacorporate products should be implanted only by surgeons familiar with the joint replacement procedures described in the specific surgical techniques.

The permitted combinations of femur and tibia sizes for Physica systems are shown in this table.

Tibial Liner										
Femoral Component	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
#1	✓	✓	✓							
#2	✓	✓	✓	✓						
#3	✓	✓	✓	✓	✓					
#4	✓	✓	✓	✓	✓	✓				
#5		✓	✓	✓	✓	✓	✓			
#6		✓	✓	✓	✓	✓	✓	✓		
#7			✓	✓	✓	✓	✓	✓		
#8				✓	✓	✓	✓	✓		
#9					✓	✓	✓	✓		
#10						✓	✓	✓		

Pre-operative planning, through radiographic templates in different formats, provides essential information regarding the type and size of components to be used and the correct combination of required devices based on the anatomy and specific conditions of each patient. Inadequate pre-operative planning can lead to improper selection of the implants and/ or incorrect implant positioning.

Complications or failures of the total knee replacement are more likely to

occur in heavy and highly active patients. The surgeon should perform a careful evaluation of the patient's clinical condition and level of physical activity before performing knee replacement.

Limacorporate specialized technical staff is available to provide advice regarding pre-operative planning, the surgical technique, and product and instrumentation assistance both prior to and during surgery.

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, that it has a finite expected implant life, and may need to be replaced at some time in the future.

The possible impact of the factors mentioned in sections 2 and 3.4 should be considered preoperatively and the patient informed as to what steps he/ she can take to reduce the possible effects of these factors.

Implants are single use devices; do not re-use implants that were previously implanted in another patient. Do not re-use an implant that has previously come into contact with the body fluid or tissue of another person.

Surgical instruments are subject to wear with normal usage. After extensive use or excessive loads, instruments are susceptible to fracture. Surgical instruments should be used only for their specific purpose. Before use, the functionality of surgical instruments should be checked since the use of damaged instruments may lead to early failure of the implants. Damaged instruments should be replaced before surgery.

4. STERILITY**a. Implants**

All implantable components of the Physica knee system are provided sterile with a Sterility Assurance Level (SAL) of 10⁶. Metal components are sterilized by radiation or ETO and UHMWPE components by ETO. Do not use any component from a package that has been previously opened or appears to be damaged. Do not use implants after the expiration date printed on the label.

b. Instruments

Instruments are supplied non sterile and must be cleaned, disinfected and sterilized before use according to appropriate validated methods (refer to the "Instrument Care, Cleaning, Disinfection and Sterilization" brochure for validated sterilization parameters; this brochure is available on request or downloadable from www.limacorporate.com in the Products section). Users should validate their specific cleaning, disinfection and sterilization processes and equipments.

3.3 INTRAOOPERATIVE

The use of trial devices is recommended to check the correct site preparation, size and positioning of the implants to be used. It is recommended that additional implants are available during surgery for use in those cases requiring prostheses of different sizes or when the preoperatively selected prostheses cannot be used. The correct selection as well as the correct seating/placement of the implant is extremely important. Improper selection, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may affect system performance and survival of the implant.

The components forming original Limacorporate systems must be assembled according to the surgical technique and used only for the labelled indications.

Use only instruments and prosthesis trials specifically designed for use with the implants being used. The use of instruments from other manufacturers or the use of instruments designed for use with other systems can lead to inappropriate preparation of the implant site, incorrect positioning, alignment and fixation of the devices followed by loosening of the system, loss of functionality, reduction of the durability of the implant, and the need for further surgery.

Care must be taken to protect the surfaces involved in the coupling between components (taper coupling between the tibial plate and the tibial stem and coupling between the tibial plate and the tibial liner); the articular surfaces of the implants should be protected from scratches or any other damage. All component coupling surfaces should be clean and dry before assembly. The stability of component couplings should be verified as described in the surgical technique.

3.3 POST-OPERATIVE CARE

Adequate post-operative care should be provided by the surgeon or other suitably qualified medical staff. Regular postoperative x-ray follow up is recommended to detect possible changes in position or condition of the implant or surrounding tissues.

The surgeon should make the patient aware of the limitations of limb function after knee arthroplasty and that caution is needed, especially in the post-operative period. Excessive physical activity or trauma to the involved knee can lead to premature failure through loosening, fracture, or abnormal wear of the prosthetic implants. The patient should be cautioned by the surgeon to govern activities accordingly and advised that the implants may fail due to excessive joint wear. In particular the following precautions should be presented to the patient by the surgeon:

- avoid repeated high weight lifting;
- keep body weight under control, overweight conditions may adversely affect the outcomes of joint replacement;
- avoid sudden peak loads (consequences of activities, such as running and skiing) or movements which can lead to sudden stops or twisting;
- avoid positions that can increase the risk of dislocation.

Lack of appropriate post-operative rehabilitation instructions and care can negatively influence the outcome of the surgical procedure.

3.4 POSSIBLE ADVERSE EFFECTS

Adverse effects that can occur in knee arthroplasty include:

- loosening of the prosthetic components;
- prosthesis dislocation and instability;
- damage to the prosthetic implant;
- instability of the system because of inadequate soft tissue balancing;
- dissociation due to incorrect coupling of the devices;
- infection;
- tissue reaction to the implant material or abrasion;
- local hypersensitivity;
- periprosthetic fractures;
- temporary or permanent nerve damage;
- flexion contracture;
- limited range of motion;
- lengthening or shortening of the leg;
- fracture of the devices;

- excessive wear of UHMWPE components due to damaged articular surfaces or the presence of particles;
- additional surgery.

Some adverse effects can lead to death.

General complications include venous thrombosis with/without pulmonary embolism, cardiovascular or pulmonary disturbances, hematomas, systemic allergic reactions and systemic pain.

1.2 MANIPULACION Y ALMACENAMIENTO

Todos los dispositivos se suministran esterilizados y se deben almacenar a temperatura ambiente (intervalo indicativo: 0-50°C / 32-122°F) en sus embalajes protectores cerrados y en salas controladas y protegidas frente a la exposición solar, el calor excesivo y los cambios de temperatura repentina.

Una vez abierto el envoltorio, compruebe que el modelo y el tamaño corresponden exactamente con la descripción impresa en las etiquetas. Evite cualquier contacto entre el implante y objetos o sustancias que pudieran alterar su esterilización o la integridad de su superficie. Se recomienda realizar un examen visual meticoloso de cada implante antes de usarlo para comprobar que no esté dañado.

Los componentes extraídos del envoltorio no se deben usar si se han caído o han sufrido algún impacto accidental. Los dispositivos no se deben alterar en modo alguno.

El código del dispositivo y el número de lote se deben anotar en el historial del paciente refiriéndose para ello a las etiquetas incluidas con el componente.

La eliminación de los dispositivos médicos tiene que ser realizada por los hospitales en conformidad con las leyes pertinentes.

Debe evitarse absolutamente la reutilización de un implante.

Riesgos asociados a la reutilización de un dispositivo de un solo uso:

- infección;
- fallo prematuro o tardío del implante o de la fijación del implante;
- falta de acoplamiento apropiado entre las uniones modulares (p. ej. conexiones cónicas);
- complicaciones asociadas al desgaste del implante y a material de desgaste;
- transmisión de enfermedades (p. ej. VIH, hepatitis);
- respuesta del sistema inmunitario / rechazo.

2. INFORMACIÓN GENERAL SOBRE INDICACIONES, CONTRAINDICACIONES Y FACTORES DE RIESGO**2.1 INDICACIONES**

El sistema de rodilla Physica está indicado para su uso en arthroplastia de la rodilla en pacientes que han alcanzado la madurez esquelética con las siguientes afecciones:

- Enfermedades degenerativas no inflamatorias de las articulaciones: incluida la artrosis, la artritis traumática o la necrosis avascular;
- Enfermedades degenerativas inflamatorias de las articulaciones, incluida la artritis reumatoide;
- Corrección de deformidad funcional;
- Procedimientos de revisión donde otros tratamientos o elementos han fallado;
- Tratamiento de fracturas que no se pueden tratar usando otras técnicas.

En pacientes con ligamentos colaterales en buen estado y buen funcionamiento, los componentes Physica PS también están indicados para:

- Ausencia o mal funcionamiento del ligamento cruzado posterior;
- Instabilidad anteroposterior grave de la articulación de la rodilla.

El sistema de rodilla Physica está diseñado para la fijación con cemento.

2.2 CONTRAINDICACIONES

Las contraindicaciones comunes para las versiones Physica CR, KR y PS incluyen:

- fuerte inestabilidad de la articulación de la rodilla secundaria a la falta de integridad y/ o función de los ligamentos colaterales;
- infección local o sistémica;
- pérdida ósea importante en la articulación femoral o tibial;
- enfermedades tumorales progresivas;
- incompatibilidad conocida o alergia a los materiales del producto;
- septicemia;
- osteomielitis crónica o aguda persistente;
- epifisis abiertas (paciente inmaduro con crecimiento óseo activo).

Las contraindicaciones específicas para las versiones Physica CR y KR incluyen:

- inestabilidad articular importante;
 - deficiencia del ligamento cruzado posterior.
- Las contraindicaciones relativas son:
- enfermedades vasculares o nerviosas que afectan a la extremidad en cuestión;
 - reserva ósea comprometida por enfermedad, infección o implantación previa que no puede proporcionar el apoyo adecuado y/ o la fijación de la prótesis;
 - desórdenes metabólicos que puedan perjudicar la fijación y la estabilidad del implante;
 - cualquier enfermedad y dependencia concomitante que pudiera afectar a la prótesis implantada;
 - hipersensibilidad a los metales de los implantes.
 - osteoporosis importante, hemofilia;
 - problemas de medicina interna de alto riesgo quirúrgico;
 - inmadurez esquelética.

2.3 FACTORES DE RIESGO

Los factores de riesgo siguientes podrían causar resultados inferiores a los esperados con esta prótesis:

- sobrepeso;
- actividades físicas intensas (deporte activo, trabajo físico pesado);
- fricción de las uniones modulares;
- incorrecta colocación del implante;
- hueso insuficiente para el apoyo de los componentes femoral y/ o tibial;
- discapacidades médicas que conlleven a un modo no natural de caminar o cargar la articulación de rodilla;
- deficiencias musculares;
- discapacidades en diferentes articulaciones;
- rechazo a modificar las actividades físicas postoperatorias;
- historia de caídas o infecciones del paciente;
- enfermedades sistémicas y desórdenes metabólicos;
- neoplasias locales o diseminadas;
- terapias farmacológicas que perjudican la calidad, curación y resistencia a la infección del hueso;
- consumo de drogas o alcohol;
- osteoporosis acentuada u osteomalacia;
- resistencia del paciente a enfermedades debilitadas de forma generalizada (VIH, tumores, infecciones);
- grave deformidad que pueda perjudicar el anclaje o impedir el correcto posicionamiento de los implantes.

Inserto Tibial										
Componente	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
#1	✓	✓	✓							
#2	✓	✓	✓	✓						
#3	✓	✓	✓	✓	✓					
#										