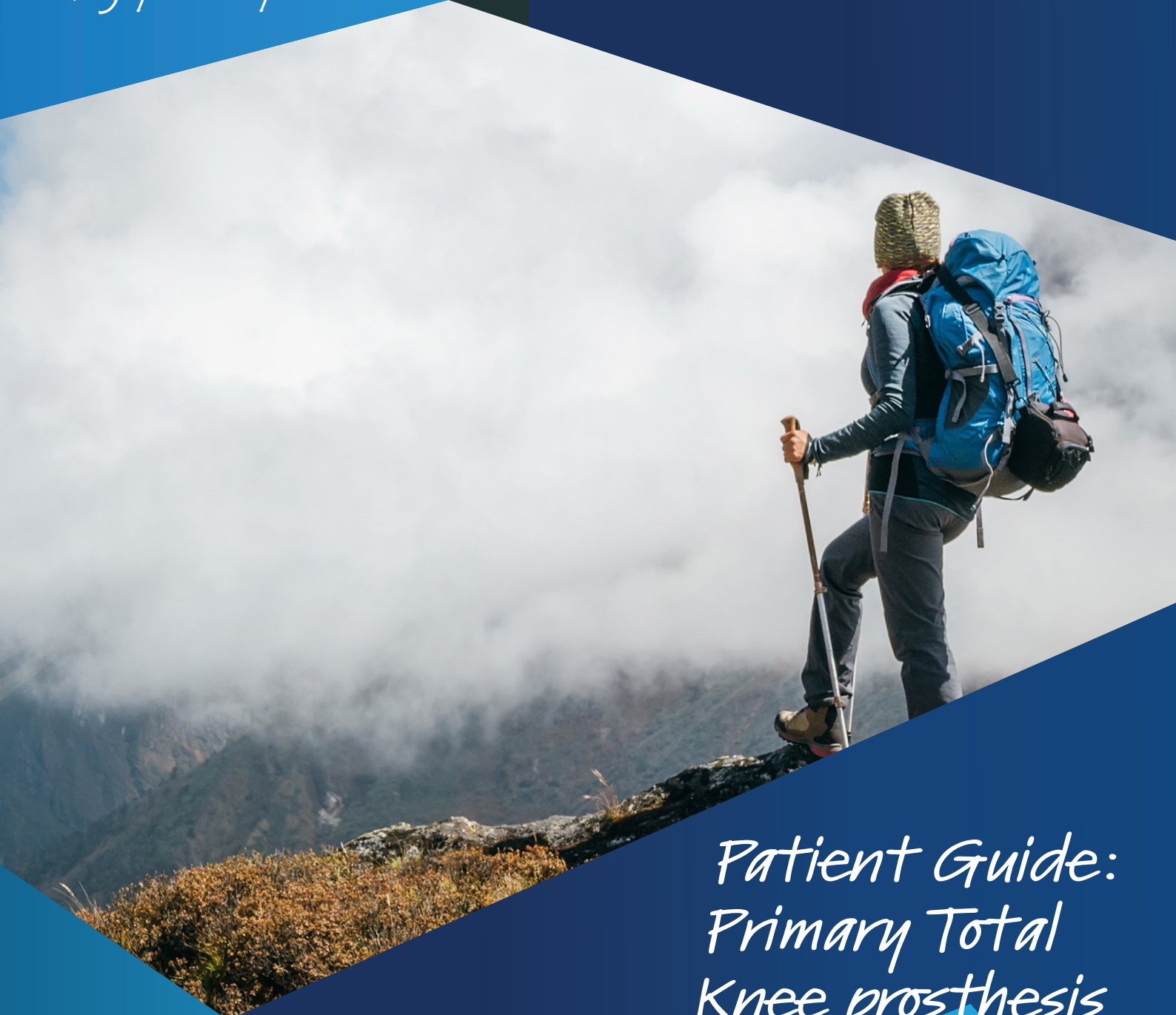




Enjoy Mobility



*Patient Guide:
Primary Total
Knee prosthesis
implant*



IMPORTANT

This document does not constitute medical advice, it does not dispense medical recommendations and it does not convey any diagnostic or therapeutic information.

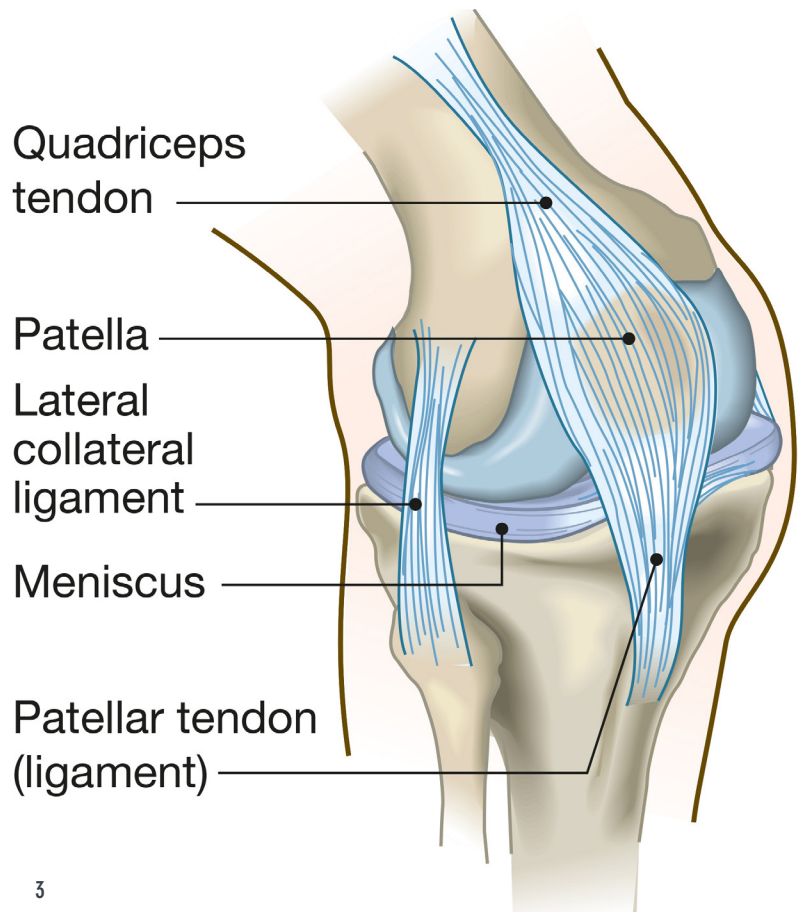
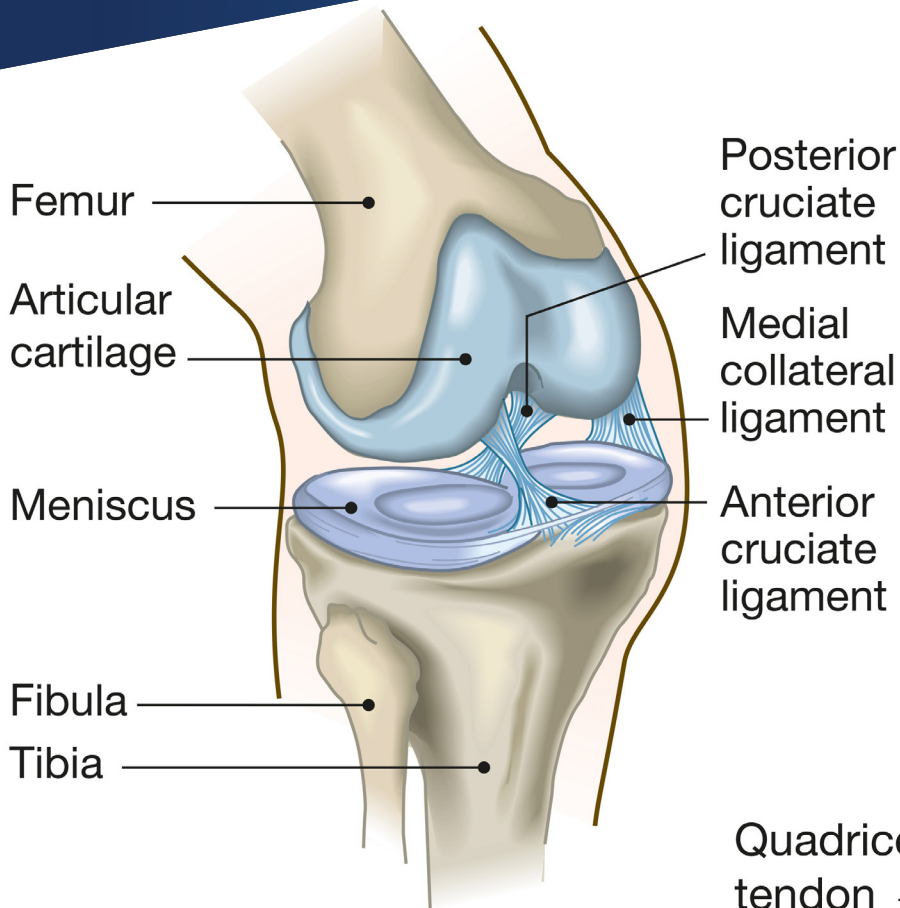
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KNEE ANATOMY



The knee is a hinged joint allowing flexion and extension movements.

THE THREE BONE SEGMENTS MAKING UP THE JOINT ARE THE FEMUR, TIBIA AND PATELLA.

The flexion-extension mechanism is performed by the rolling and sliding of the convex surface of the femur on the concave surface of the tibial plateaus.

The **PATELLA** is in the anterior part of the knee, having an anterior surface and a posterior surface that slides during flexion-extension inside the intercondylar notch in the anterior wall of the femur between the femoral and medial condyles.

The joint as a whole is covered by the articular capsule, a robust membrane containing the synovial liquid. In addition to the muscles, that reinforce the joint and enable its movement, the knee's "scaffolding" is provided by the ligaments, which counter the forces of stress and render it stable.

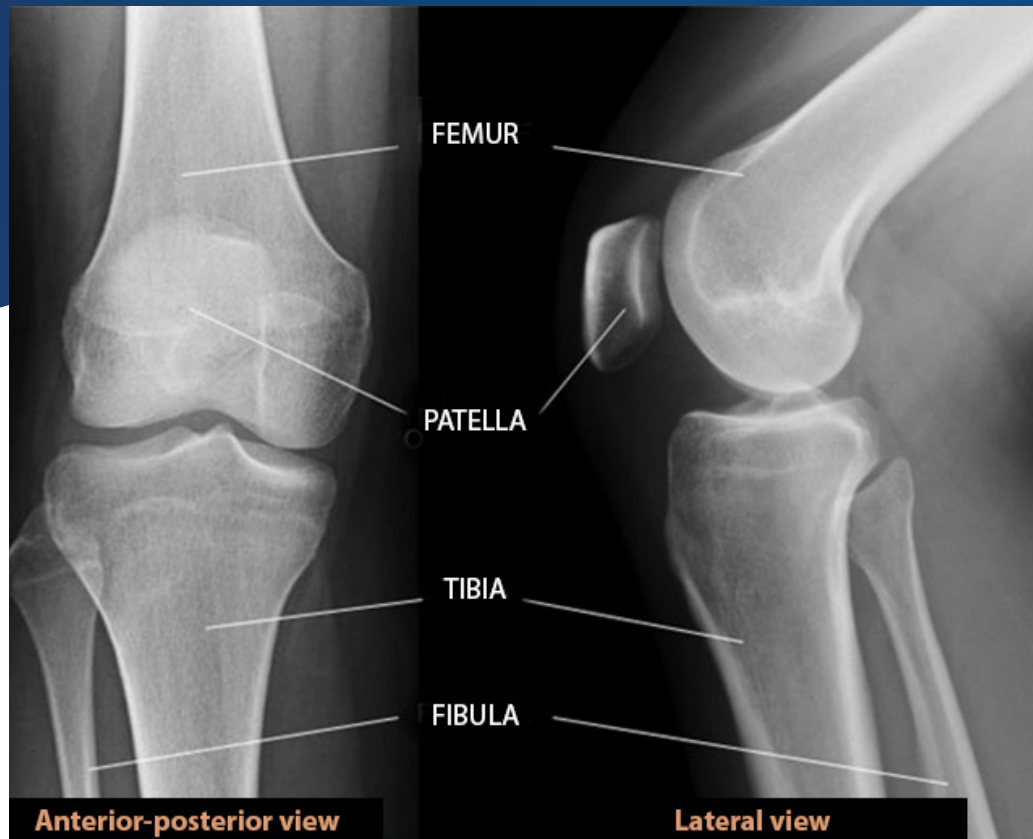
The **CRUCIATE LIGAMENTS** are in the middle of the knee and stabilize the femur and tibia in the anterior-posterior plane. The collateral ligaments are at the sides of the knee and stabilize the femur and tibia against inward and outward bending forces (varus and valgus).

The **MENISCI** perform a very important function within the structure of the knee. They are two fibrous cartilage disks between the two femoral condyles and the two tibial plateaus. The medial and lateral menisci, in the form of an inward facing C, have a triangular section and increase the congruence between the articular surfaces of the femur and tibia, thus acting as protective "bearings" for the cartilage.

Functionally speaking, there are three compartments in the knee joint:

- the **MEDIAL COMPARTMENT**, formed by the articulation between the medial femoral condyle and the medial tibial plateau;
- the **LATERAL COMPARTMENT**, formed by the articulation between the lateral femoral condyle and the lateral tibial plateau;
- the **FEMOROPATELLAR ARTICULATION**, formed by the anterior surface of the femur (intercondylar notch) and the posterior surface of the patella.

PATHOLOGIES



Various pathologies involve the knee joint.

The most common, **ARTHROSIS**, affects older patients and is an chronic degenerative disease affecting the capsule, ligaments and cartilage and brings about a gradual wearing down of the joint.

Pathologies of the knee may also diagnosed in younger patients, such as **MENISCAL LESIONS** or **RUPTURES OF THE ANTERIOR CRUCIATE LIGAMENT** caused by traumas or repeated stress, as occurring in sport for example. Pain may also be felt in the knee due to overload pathologies or post-trauma pathologies such as **BURSITIS** or **TENDINITIS**.

Other causes of knee pain are:

- **ANTERIOR CRUCIATE LIGAMENT (ACL) INJURY** is a tear or sprain of the anterior cruciate ligament (ACL). The anterior cruciate ligament, with the medial collateral ligament, represents the ligament structure of the knee most frequently affected by traumatic injuries. The traumatic mechanism consists more frequently in a twist of the knee (falls in rotation such as in basketball, volleyball, skiing) or for a forced flexion or maximum extension.
- **MENISCAL INJURIES** are observed in young people, athletes, often caused by distorting traumas or “unnatural” movements of the knee. The injury is caused by the failure of the meniscus to slip between the two articular surfaces which causes the “pinching” of the fibrocartilage which creates the laceration or net rupture. The same mechanism of injury can occur in non-sports individuals due to sudden efforts or movements. With increasing age, the meniscus slowly undergoes dehydration and degeneration. After 55-60 years of age meniscal lesions have a degenerative component but are in any case in most cases responsible for painful symptoms. Generally the lesions in patients with 65-70 years are instead to be included in the set of arthritic changes in the knee and rarely the painful symptoms are exclusively of meniscal origin.
- **PATELLOFEMORAL STRESS SYNDROME** includes a group of problems that cause anterior knee pain that worsens with activities that increase the load on the patellofemoral joint. The pain is related to the inflammation of the cartilage both of the patella surface and of the femoral intercondylar throat. This inflammation is linked to bad patellar sliding during knee flexion-extension.
- **PATELLAR TENDINITIS** is one of the most frequently encountered pathologies in sportsmen. The patellar tendon is part of the extensor apparatus of the knee, originates soon from the lower pole of the patella and is inserted on the tibial tuberosity. The contraction of the quadriceps muscle traction soon tracts the patella and with it the patellar tendon and the tibia causing the extension of the knee.
- **THE ILIO-TIBIAL BAND SYNDROME** is an overuse injury of the connective tissues that are located on the outer thigh and knee.

GONARTHROSIS



ARTHROSIS OF THE KNEE (GONARTHROSIS) consists in the consumption of the knee joint cartilage. It is a progressive degenerative disease that over time causes an increasing pain symptomatology and a stiffness with joint limitation.

Osteoarthritis can be primitive, or without a definite cause, or secondary, or caused by axis deviations (varus or valgus knee), fracture outcomes, osteonecrosis, inveterate lesions of the anterior cruciate ligament, results of meniscectomy (performed with surgery open as happened until the 80s) previous joint infections or other pathologies.

Osteoarthritis of the knee can be **SPREAD TO THE ENTIRE JOINT**, it can only affect the **MEDIAL OR LATERAL FEMORO-TIBIAL COMPARTMENT** (single compartment arthrosis) or only affect the **PATELLOFEMORAL JOINT** (patellofemoral arthrosis).

SYMPTOMS

Pain is the main symptom. Initially it is referred to as retro-patellar, in correspondence of the anterior region; generally it is in the early stages of a pain that is not well defined, exacerbated by the use of stairs, especially downhill, or evoked by mobilization after a prolonged sitting or squatting position.

From the clinical point of view in case of patellofemoral hyperpressure the pain is caused by the pressure of the patella in the lateral region. If the patella tends to move laterally during flexion (subluxation) or comes out of the intercondylar throat (dislocation), the abnormal sliding of the joint can be assessed by the specialist. The misalignment over time causes a real consumption of cartilage.

NON SURGICAL THERAPIES

As in all cases of osteoarthritis, therapy depends on the severity of the symptoms and the degree of cartilage degeneration.

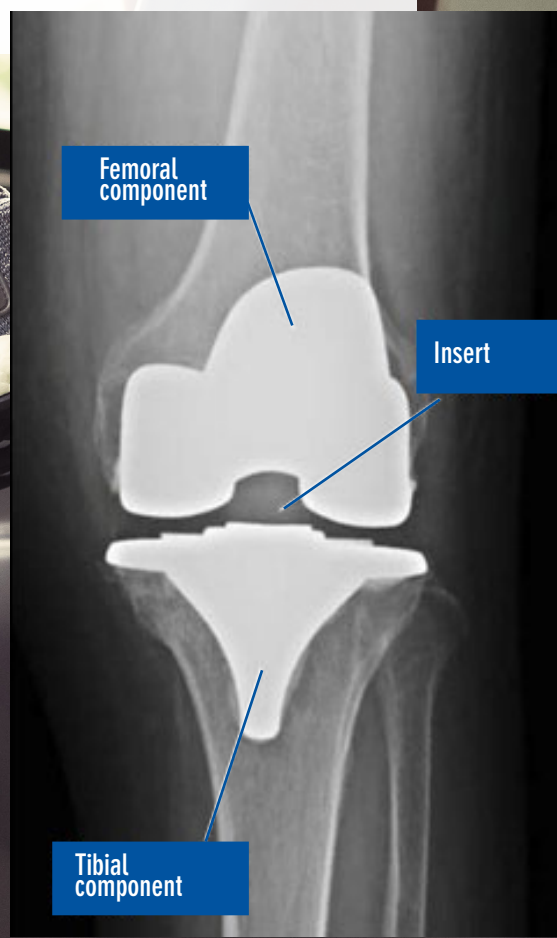
Painkillers or anti-inflammatory drugs are useful in alleviating the symptoms in the early stages of the disease. However, the side effects that can cause chronic therapies with anti-inflammatory drugs do not allow their prolonged use.

Life habits such as **EXERCISE** (possibly in unloading such as the exercise bike, swimming and gymnastics in the water), allow you to maintain good muscle tone and slow down the arthritic process. In particular, maintaining a good tone in the quadriceps muscle contributes to slowing down instability.

WEIGHT LOSS is a must in overweight patients, both to decrease the overload on the joint and therefore slow down cartilage degeneration, and in anticipation of an arthroplasty intervention in order to reduce possible complications and accelerate post-operative physiotherapy.

Physical therapies such as **TENS, LASER THERAPY, ULTRASOUND THERAPY ARE RARELY EFFECTIVE.**

INFILTRATIVE THERAPY improves symptoms and slows the progression of the disease. There are two categories of drugs used for infiltrative therapy: cortisone and hyaluronic acid. Cortisone infiltrations are indicated in case of significant pain symptoms. The drug inside the joint capsule acts against inflammation of the joint capsule, decreasing or eliminating joint pain. In case of too prolonged therapies, the intraarticular cortisone has a degenerative action on the cartilage itself, which is why it is not indicated in young patients. Infiltrations with hyaluronic acid are indicated only in the early stages of the disease, i.e. when the cartilage degeneration is only partial.



KNEE REPLACEMENT IS THE ONLY POSSIBLE THERAPY IN THE CASE OF ADVANCED DEGENERATION OF THE JOINT.

It involves surgical replacement of the articular surfaces of the femur and tibia with artificial components capable of reproducing as faithfully as possible all the movements of the arthritic joint.

Total knee replacement (an operation carried out everyday in specialist clinics) involves the removal of worn cartilage from the articular surfaces of the femur and tibia with techniques that prepare the bone to receive the components, and the positioning of the femoral and tibial component on the two surfaces so that they "line" the old surface. The insertion of the tibial insert renders the two surfaces congruent, thus enabling the new joint to move.

Knee implants are either cemented in position or 'press-fit' into place without cement

A total knee replacement comprises the following: **THE FEMORAL COMPONENT**, which replaces the articular surface of the femur; it is inserted in direct contact with the bone after removal of the arthritic cartilage and reproduces the anatomical shape of the femoral condyles; **THE TIBIAL COMPONENT**, which replaces the articular surface of the tibial plateau; this is fixed to the tibia after removal of the articular cartilage; **THE TIBIAL INSERT**, which is fixed to the tibial component and, being congruent with the femoral condyles, articulates with the femoral component; **THE PATELLAR COMPONENT**, which is applied to the articular surface of the patella after removal of the articular cartilage.

All Gruppo Bioimpianti devices are made of biocompatible materials and they comply with the main standards of the sector. Tibial and femoral components made in CrCoMo alloy comply with ISO 5832-4, tibial components made in Titanium alloy (Ti6Al4V) comply with ISO 5832-3.



1. **FEMORAL COMPONENT** replacing the femur, inserted in direct contact with the bone

2. **TIBIAL INSERT**, to articulate with the femoral component

3. **TIBIAL COMPONENT** replacing the tibia, inserted in direct contact with the bone



POST-OPERATIVE PRECAUTIONS

An articular recovery and rehabilitation programme after the implanting of a total knee replacement must be agreed with the orthopaedic surgeon who carried out the operation on the basis of the type of prosthesis implanted and the technique used.

In general, if the patient's condition and the type of prosthesis allow it, rehabilitation in the weeks following the operation is designed to achieve full extension and 90° flexion.

The exercises indicated by the therapist are often accompanied by passive mobilization (CPM) using apparatus to guide the movement of the leg.

GOING HOME:

- To get into a car it's advisable to put a cushion on the seat, sit down keeping the legs out of the car and then bring the operated leg inside first and then the sound one. To facilitate this movement, if the left leg is the operated one, it's best to sit to the right of the driver; if the operated leg is the right one, sit behind the driver.

AT HOME:

- **FULL LOADING OF THE OPERATED KNEE MAY BE DONE IMMEDIATELY WITH THE HELP OF A WALKER.**
- **DON'T BEND THE KNEES EXCESSIVELY.**
- When taking a shower it's advisable to use an anti-slip mat. Put a stool in the shower and use it with your back against the wall.
- If you don't have a shower, use an appropriate bathtub seat. Sit on the edge of the seat, put the operated leg in the bath first, then the other one.
- In the period when crutches are used, it's best to brush hair, shave and brush teeth in a sitting position.
- Use firmly stable chairs, preferably with armrests. On sitting down, open the legs out slightly and rest your hands on the armrests or on your thighs and sit down slowly keeping your knees wide apart and your feet parallel.
- To get up from a chair, slide forward to the edge of the chair and rise with the help of the armrests.
- Wear closed shoes with anti-slip soles.
- You can safely sleep on your back, on either side, or on your stomach.

POST-OPERATIVE PRECAUTIONS

THE FIRST FEW WEEKS:

- **IT IS ONLY POSSIBLE TO START DRIVING AGAIN WHEN YOUR SPECIALIST HAS GIVEN CLEARANCE.**
- **CONTINUE TO USE CRUTCHES OR A WALKER FOR AS LONG AS INSTRUCTED BY THE DOCTOR.**
- You may have moderate to severe swelling in the first few days or weeks after surgery. You may have mild to moderate swelling for about 3 to 6 months after surgery. To reduce swelling, elevate your leg slightly and apply ice. Wearing compression stockings may also help reduce swelling. Notify your doctor if you experience new or severe swelling, since this may be the warning sign of a blood clot.
- **GOING UPSTAIRS:** lead with the healthy leg, keeping the crutches on the step below until both legs are on the step above, then bring up both crutches onto the step. Lean against the handrail if possible.
- **GOING DOWNSTAIRS:** put the crutches on the step below, lead with the operated leg and follow with the healthy leg. Here too, lean against the handrail if possible.
- Long-term use of a crutch or stick in the hand opposite the operated side is advisable to minimize the forces acting daily on the hip prosthesis and to lengthen the life of the implant.

POST-OPERATIVE PRECAUTIONS

THE REHABILITATION PERIOD VARIES FROM CASE TO CASE.

On completion of the rehabilitation programme patients can normally carry out most day-to-day activities. The patient should communicate to the physician any noise or unusual sensation, because they could be due to implant malfunctioning.

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.

Sport may only be resumed with great care, because certain repeated movements may favour wear of the implant.

Many activities are compatible with a knee replacement however. Detailed in the table below are the activities recommended in the long term following a total knee replacement.

Recommended	Low-impact aerobics, Bowling, Golf, Dancing, Walking, Swimming
Recommended with experience	Cycling Hiking, Rowing, Cross-country skiing, Stationary skiing, Speed walking, Doubles tennis, Ice skating
Not recommended	Racquetball, squash, Contact sports (Football, Hockey, Soccer) Rock climbing, Jogging, Running, Singles tennis, Waterskiing, Baseball, Softball, Handball, Martial arts

L.A. Vogel, G. Carotenuto, J.J. Basti, W. N. Levine, Physical Activity After Total Joint Arthroplasty, Sports Health. 2011 Sep; 3(5): 441–450

POST-OPERATIVE PRECAUTIONS

ADVERSE EVENTS:

Any serious incident in relation to the device should be reported to your surgeon and the manufacturer.

POSSIBLE ADVERSE EFFECTS

The possible adverse effects of the K-MOD and K-MONO systems are similar to those occurring with any total knee replacement, both revision and primary surgeries, and include the following: General Complications related to surgical interventions, medications, other instruments used, blood etc. Particulate wear debris from metallic and polyethylene components may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis which can lead to the implant loosening; Early or late postoperative infection and allergic reaction; Intraoperative bone fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device; Loosening, migration or fracture of the implants can occur due to trauma, loss of fixation, malalignment, mal position, bone resorption, unusual and/or awkward movement and/or excessive activity; Periarticular calcification or ossification, with or without impediment of joint mobility; Inadequate range of motion due to improper selection or positioning of components; Variation in the leg length; Dislocation or subluxation due to: inadequate fixation, malalignment or mal position, unusual and or excessive movement, trauma, obesity, weight gain. Muscle and soft tissue laxity; Fatigue fracture of a component can occur as a result of loss of fixation, strenuous activity, trauma, malalignment, or excessive weight; Corrosion at the interfaces between components; Wear and/or deformation of articulating surfaces; Varus-valgus deformity; Patellar tendon rupture and ligamentous laxity; Intraoperative or postoperative bone fracture, and/or postoperative pain; Hematomas and delayed wound healing; Temporary or permanent neuropathies; Venous thrombosis and pulmonary embolism; Cardiovascular disorders; Occasional and permanent nerve dysfunction.

FURTHER POST-OPERATIVE PRECAUTIONS

- **ALWAYS KEEP THE PATIENT IMPLANT CARD** containing information about implanted medical devices that will make information easily available and accessible to the particular patient
- The K-MOD and K-MONO Systems have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artefact in the MR environment. The safety of the K-MOD and K-MONO System in the MR environment is unknown. Scanning a patient who has these systems may result in patient injury.

DURATION OF THE IMPLANT

The duration of an implant depends on a great many factors, including the patient's age, weight, gender, bone quality and activity. It is expected 10 years lifetime for Gruppo Bioimpianti's knee prosthesis, as indicated also in the main orthopedic registries that provide survival rate of devices.

The main cause of long-term failure of knee endoprotheses is wear of the tibial insert. Wear (or debris) may compromise the functionality and durability of the implant, not just because it causes alteration of the articular surfaces but also because the worn away particles favour bone resorption, the main cause of aseptic mobilization.

Such mobilization consists of a loosening of the main components of the prosthesis (femoral and tibial), which provokes pain in the prosthesised knee.

In the event of mobilization of one or both components, they may be removed and replaced with a new prosthesis (prosthetic revision). For complex revision operations, orthopaedic surgeons are provided with special prosthesis models to remedy the shortage of bone preventing the implant of a traditional prosthesis.

PERIODICAL CLINICAL AND RADIOGRAPHIC CONTROL OF THE PROSTHESIZED KNEE ARE USEFUL FOR PICKING UP INITIAL SIGNS OF MOBILIZATION AND PREVENTING THE SERIOUS BONE DAMAGE THAT A LOOSENED PROSTHESIS MAY CAUSE BY ITS MOVEMENTS.



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