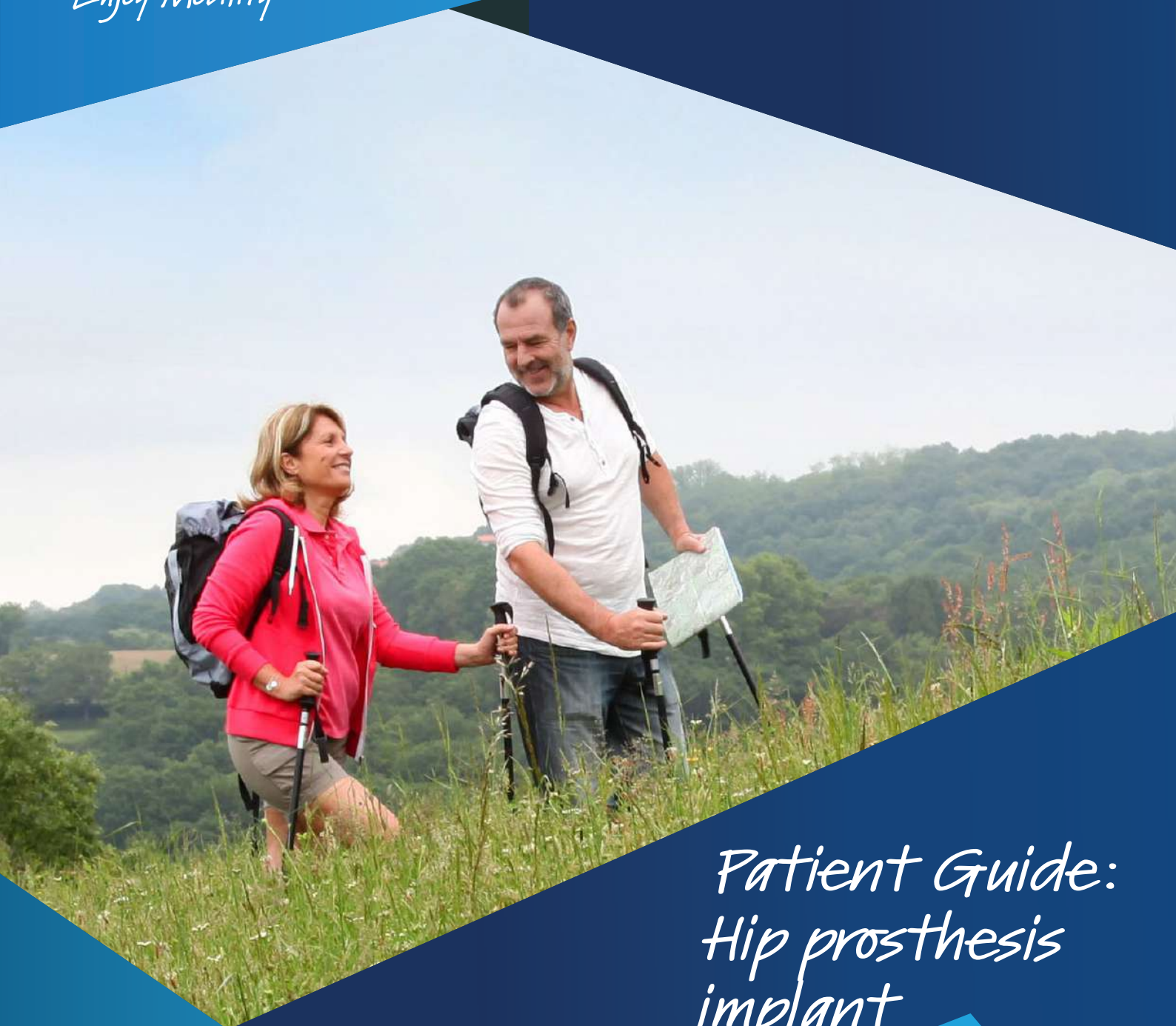




*Enjoy Mobility*



## *Patient Guide: Hip 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.

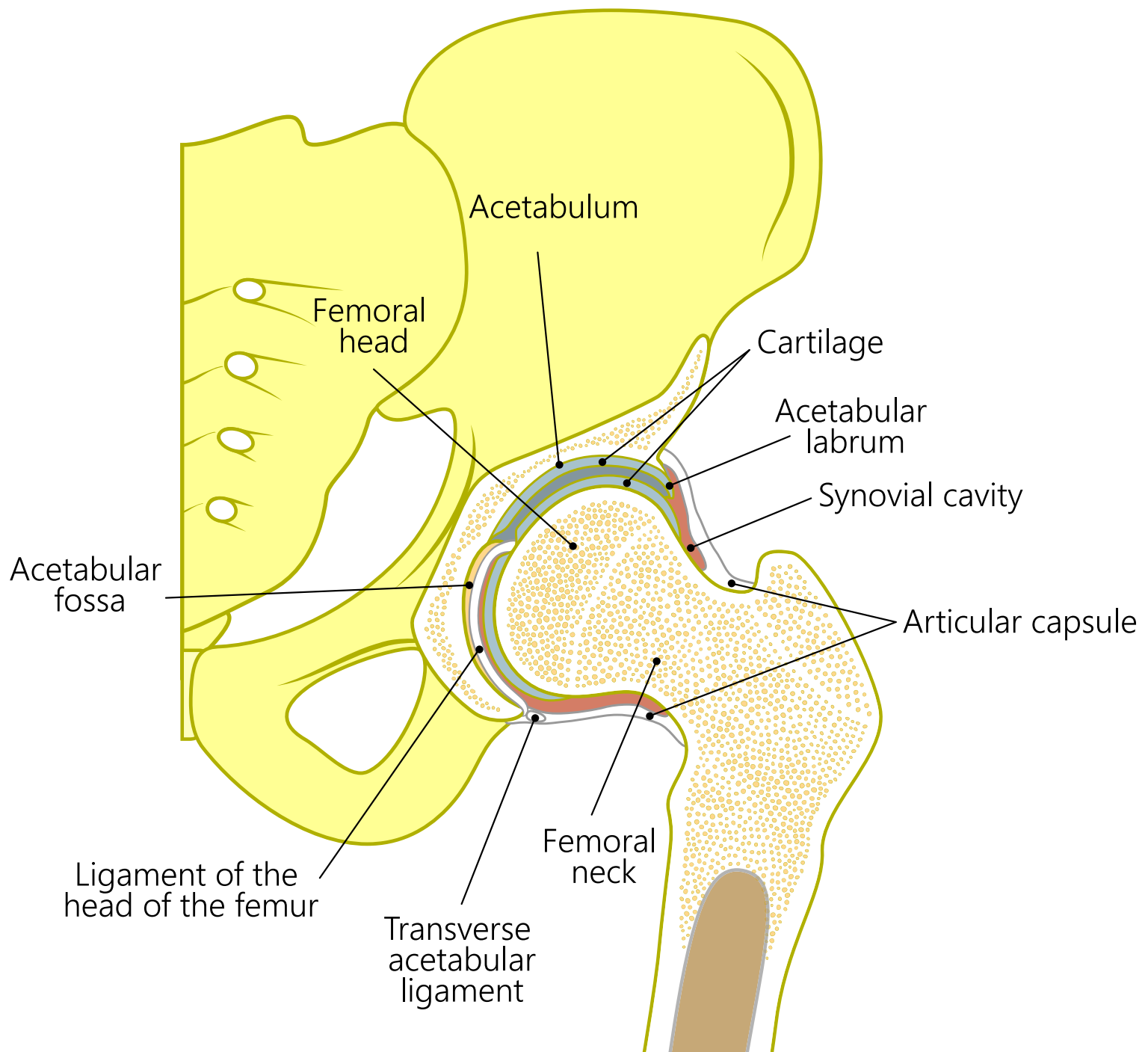
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# HIP ANATOMY



The two surfaces of the femur head and acetabulum are perfectly congruent and covered by cartilage, a structure that protects the bone and facilitates the sliding motion of the two articular elements. The femur head is not fully within the cavity of the acetabulum however.

The extreme stability of the joint is also ensured by the acetabular labrum, which extends the contact surface of the femur head by enveloping its entire circumference.

The intracapsular ligament, at the top of the femur head, anchors the femur head to the bottom of the acetabulum, thus acting as a further guarantee of joint stability.

The whole of the femur head is enveloped by the articular capsule, a structure attaching to the acetabular lip and delimiting the articular space.

Around the articular capsule there are numerous ligaments providing stability, while a number of muscles enable movement of the joint.

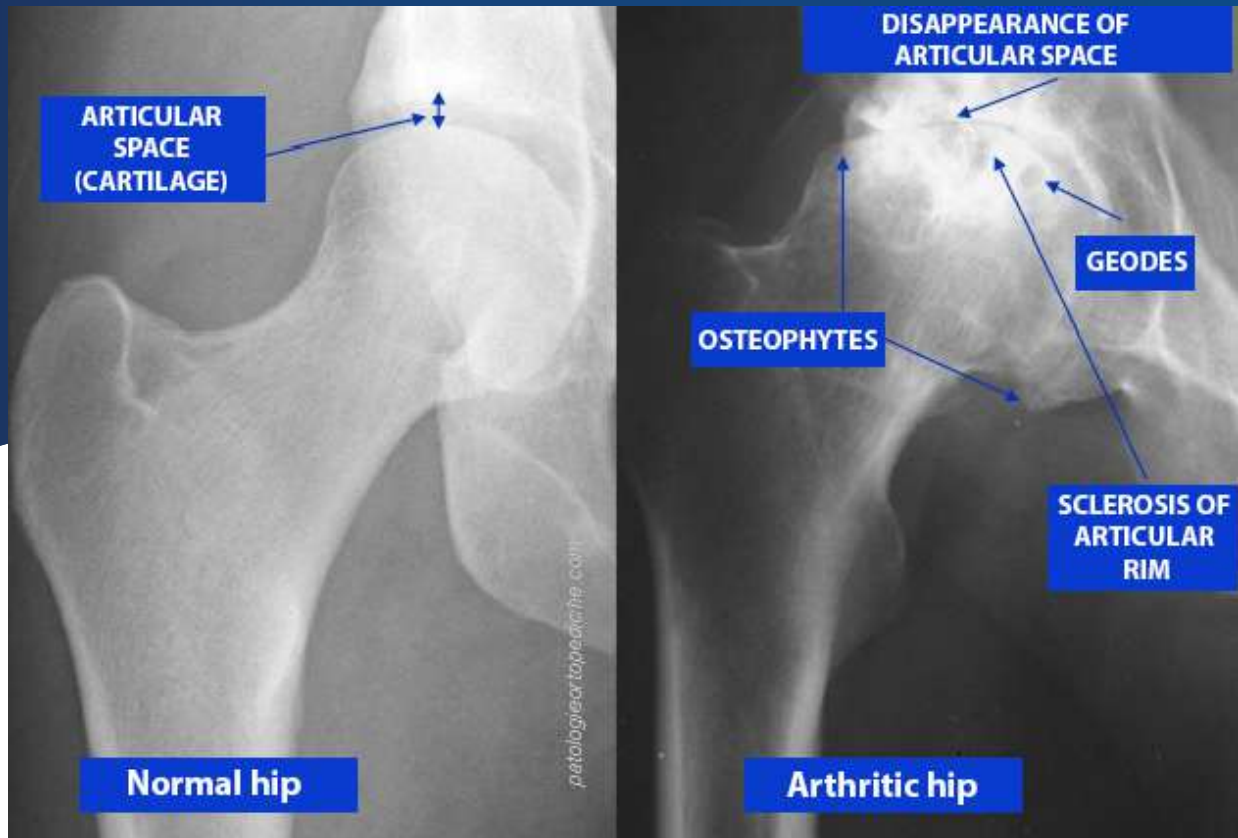
The HIP, or coxo-femoral joint, is one of the main joints in the human body.

It is formed by two spherical bone extremities:

- One concave: **ACETABULUM**
- The other convex: **FEMUR HEAD**, which move in all planes.

The femur head is thus free to turn inside the acetabulum.

# PATHOLOGIES



Various pathologies may affect the hip joint.

The most common are:

- **ARTHROSIS OF THE HIP OR COXARTHROSIS:** the consumption of the articular cartilage of the hip. It is a disease with progressive degenerative evolution that over time causes an increasing pain symptomatology and joint limitation.
- **FRACTURES** in older patients.

Arthrosis is a chronic degenerative disease that affects the capsule, ligaments and cartilage and gradually wears away the joint. Fracture of the femur is one of the most unpleasant events caused by osteoporosis, which is loss of quality of the bone occurring in older patients and also younger ones with metabolic disorders.

Diseases of the hip may also be diagnosed in young patients, examples including bursitis and tendinitis, caused by overloading or repeated stress, as in sports.

Hip arthroscopy has made early diagnosis of hip disorders much easier.

It has also made it possible to carry out preventive therapies, such as the repairing of small lesions or the correction of minor deformities to eliminate pain and prevent the onset of irreparable damage.

Other causes of hip pain are:

- **TROCHANTERIC BURSITIS** (or trochanteritis) caused by inflammation of the trochanteric bursa. The trochanteric bag is a structure that is interposed between the hip tendons and the bone with the function of “cushion”; made up of soft tissues, it has the function of decreasing the friction in the lateral region between the trochanter and the fascia lata.
- **CONGENITAL DYSPLASIA OF THE HIP (DDH)** is an evolutionary malformation that consists of a complex of developmental and modeling anomalies of the head of the femur and acetabulum. It originates during the fetal period and if it is not discovered promptly after birth it can lead to the gradual loss of relations between the head of the femur and the acetabulum, hesitating in the most serious cases in permanent dislocation of the hip, or in the ascent of the head of the femur above the acetabular cavity.
- **AVASCULAR NECROSIS OF THE FEMORAL HEAD (AVN)** consists in the death of cells in the bone in the apical portion of the femoral head. The area of cell death (or necrosis) can be variably extended. The consequence of necrosis is the alteration of the anatomy of the region with loss of strength of the bone scaffold which causes a collapse at the upper pole of the head. A depression is therefore created in the loading area with a deformation of the femoral head.
- **THE FEMORO-ACETABULAR CONFLICT (FAI, FEMORO ACETABULAR IMPINGEMENT)** is a pathology caused by an abnormal contact between the femoral head and the acetabulum during the joint excursion. It is a recently defined pathology that has been recognized as a cause of early osteoarthritis in young patients.
- **SNAPPING HIP SYNDROME:** it is characterized by a snap or snap sensation that the patient feels when the tendons near the hip joint slide over bony protrusions.

# COXARTHROSIS

**ARTHROSIS OF THE HIP (COXARTHROSIS)** involves consumption of the hip's articular cartilage. This is a gradual degenerative disease characterized by increasing pain and rigidity that limits joint movement.

Arthrosis may be primitive, ie. without a definite cause, or secondary, ie. caused by congenital (dysplasia) or infantile diseases of the hip, outcome of fractures, osteonecrosis, prior articular infections or other pathologies.

Onset of the primitive form usually occurs after 60, whereas secondary forms (especially as an outcome of dysplasia) may affect younger patients.

A typical onset of coxarthrosis would involve groin pain spreading eventually along the anterior face of the thigh. Some patients complain of pain in the buttocks or on the side of the thigh.

## LEVELS OF PAIN:

- Pain will initially follow prolonged effort and later also on resuming activity after a rest (getting out of bed or out of a chair).
- Pain may gradually become more frequent and lead to limited joint movement and limping.
- Being woken at night through pain is associated with severe arthrosis.

Standard radiography of the affected hip (anterior-posterior of the pelvis and lateral) is sufficient for diagnosing coxarthrosis.

Typical X-ray evidence of arthrosis of the hip includes:

- Depletion of the articular rim (caused by consumption of the cartilage, which is radiotransparent, ie. it appears as empty space inside the joint);
- Presence of osteophytes (small bone spurs near the articulation);
- Presence of geodes (areas of bone loss in the femur head or acetabulum);
- Presence of bone sclerosis (areas bone thickening underneath worn or suffering cartilage).

# NON SURGICAL THERAPIES

Therapy for coxarthrosis depends on the seriousness of the symptoms and the degree of cartilage degeneration.

Painkillers and anti-inflammatory drugs serve to alleviate symptoms in the initial phases of the disease. However, the side effects they may cause make them unsuitable for prolonged use.

Day to day habits like **PHYSICAL EXERCISE** (preferably with the limb unloaded, like cyclettes, swimming and water gymnastics) make it possible to maintain good muscle tone and retard the arthritic process.

**OVERWEIGHT PATIENTS MUST LOSE WEIGHT**, both to reduce overloading of the joint (and thereby slow down cartilage degeneration) and in view of arthroprosthesis surgery, to reduce possible complications and accelerate post-operative physiotherapy.

**VISCOSUPPLEMENTATION** is an infiltration therapy using hyaluronic acid to alleviate the symptoms and slow down the development of the disease. Hyaluronic acid occurs naturally in the synovial liquid, which is present in all the joints and provides local anabolic, anti-inflammatory and analgesic action.

**HYALURONIC ACID** is a large molecule whose physical characteristics of viscosity and elasticity produce the lubricant and shock absorbing effects of the synovial liquid.

In joints affected by osteoarthritis the synovial liquid is more diluted and less viscous than in healthy joints because its hyaluronic acid is in lower concentrations. This means the cartilage is more exposed to wear.

Viscosupplementation re-establishes and supplements normal levels of hyaluronic acid in the synovial liquid and exploits the molecule's lubricating, protective and anti-inflammatory properties. Another function of the molecule once introduced in the joint is that of re-activating synthesis of endogenous hyaluronic acid by the arthritic joint under treatment.

Viscosupplementation is only indicated in the initial phases of the disease, when cartilage degeneration is only partial.

**RADIOFREQUENCY NEUROLYSIS** is a pain therapy that desensitizes nerves in the articular capsule to interrupt transmission of pain. It is indicated exclusively for patients who cannot be treated surgically. Physical therapies, such as TENS, laser therapy and ultrasound therapy are rarely effective.

## ARTHROPLASTY IS THE ONLY EFFECTIVE THERAPY FOR COXARTHROSIS.

Surgery replaces the diseased joint and eliminate/reduce arthritic pain.

The hip replacement is the only possible therapy in cases of advanced degeneration of the joint.

The operation replaces the femur head and acetabulum with artificial components that reproduce all the movements of the affected joint as faithfully as possible.

Gruppo Bioimpianti devices are intended to be used for: Non-inflammatory degenerative joint disease such as primary or secondary osteoarthritis; Aseptic necrosis of the femoral head; Rheumatoid Arthritis; Post-traumatic Arthritis; Correction of functional deformity; Outcomes of fractures of the femoral neck; Outcomes of traumatic dislocations of the hip; Failures of osteotomy; Outcomes of arthrodesis.

The SMR stem is indicated in revision surgery of femoral components, following failure of primary cemented or un-cemented prosthesis with proximal bone loss, enlargement of the medullary canal and thinning of the cortical bone of the proximal femur. Revision of a mobilized femoral component, after sub prosthetic or periprosthetic fracture. Femoral reconstruction in cases of alterations of bone morphology after fractures or osteotomies. This stem is indicated for cementless implants.

Hip replacement – a routine operation in specialist clinics – involves the removal of the worn out cartilage in the acetabulum to prepare the portion of bone that will house the cotyle. The cotyle is then positioned inside the acetabulum so that it acts as a “lining” of the old bone surface. The second phase of the operation is to remove the consumed femur head and position the stem that will articulate with the cotyle to form the new joint inside the femoral channel. This is a total hip replacement as opposed to a partial arthroprosthesis or endoprosthesis, in which only the femur head is removed.

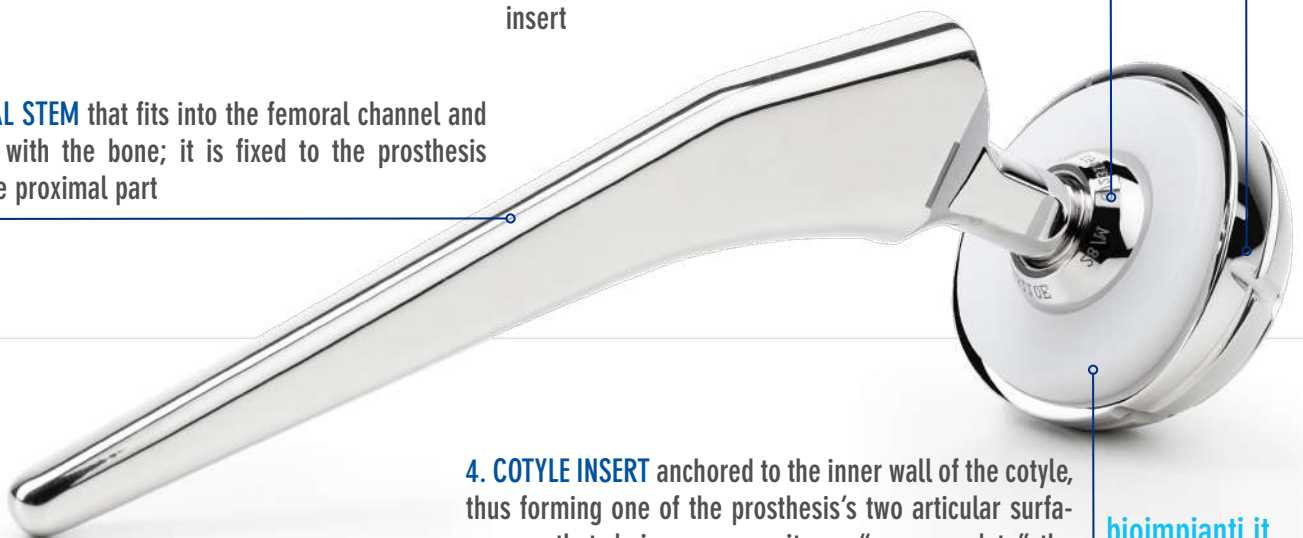
An endoprosthesis operation is indicated in the case of fractures to the femur neck when the cartilaginous surface is still healthy but the fractured bone is unlikely to heal. In this case it is sufficient to replace only the fractured part, ie. the neck and head the femur, with a stem whose head will articulate with the healthy acetabulum.

**1. CUP-FORM COTYLE**, replacing the acetabulum, inserted in direct contact with the bone

**2. FEMUR HEAD** (or “head”), fixed to the stem to articulate (thanks to its spherical shape) with the cotyle insert

**3. FEMORAL STEM** that fits into the femoral channel and integrates with the bone; it is fixed to the prosthesis head in the proximal part

**4. COTYLE INSERT** anchored to the inner wall of the cotyle, thus forming one of the prosthesis’s two articular surfaces, so that, being concave, it can “accommodate” the femur head fixed to the stem



# HIP PROSTHESIS

**CEMENTED KORUS** is a primary cemented straight femoral stem, that is fixed in position inside the femoral canal, using bone cement.

Material: High nitrogen content stainless steel

**UNCEMENTED KORUS** is a primary uncemented straight femoral stem that does not require cement, because it is totally covered with a porous coating.

Material: Titanium alloy Ti6Al4V Grade 5 ELI

Finishing: HA coating



# HIP PROSTHESIS

**SMR** is a revision modular femoral stem designed for prosthesis replacement in cases of serious bone loss.

Material: Titanium alloy Ti6Al4V Grade 5 ELI

**FIN II HA CUP** uncemented primary cup, characterized by three cranial fins.

Material: Titanium alloy Ti6Al4V Grade 5 ELI

Finishing: Ti-Growth-C® titanium Plasma Spray external coating and HA



# HIP PROSTHESIS

**LINERS** in Ceramic and XLPE are compatible with FIN II HA CUPS  
Materials: BioloX® DELTA ceramic liners (ISO 6474-1,-2), and XLPE cross-linked polyethylene (ISO 5834-2) liners with or without anti-luxation shoulder.

**FEMORAL HEADS** in Ceramic and CrCo alloy are compatible with FIN II HA CUPS and MULLER CUPS  
Materials: BioloX® DELTA ceramic liners (ISO 6474-1,-2) and CrCo-Mo (ISO 5832-12)



# HIP PROSTHESIS

**MULLER CUPS ACETABULAR SHELL** are characterized by their hemispherical shape made entirely of ultra-high molecular weight polyethylene (UHMWPE), they are designed to be cemented.

Material: ultra-high molecular weight polyethylene UHMWPE (ISO 5834-2)

**SNAP-FIT CEMENTED CUPS - ACETABULAR SHELL** are characterized by their hemispherical shape made entirely of ultra-high molecular weight polyethylene (UHMWPE), they are designed to be cemented.

Material: ultra-high molecular weight polyethylene UHMWPE (ISO 5834-2)



# DURATION OF THE IMPLANT

It is expected 15 years lifetime for Gruppo Bioimpianti's medical devices, as indicated also in the main orthopedic registries that provide survival rate of devices.

However, implantable device lifetime depends inevitably on different conditions, such as, implant surgery procedure and patient's health condition.

Performing radiological and clinical check ups is useful in order to detect potential signal.

It is inevitable, however, that in the long term there will be a loosening (or mobilization) of the main components of the prosthesis (cotyle and stem) provoking pain in the prothesized hip.

This may be caused mechanically, due to a lack of osteointegration between the host bone and the prosthesis, or biological, due to wear of the prosthetic component. Wear causes the formation of foreign-body tissue around the prosthesis that will erode the bone around the implant.

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.

Other factors causing a hip replacement to fail include:

- Recurrent dislocation of the prosthesis (which may provoke instability of the implant or wear of the cotyloid component)
- Breakage of a component of the prosthesis following a violent trauma or minor but repeated traumas, or bone fracture, whether of the cotyle or (more frequently) the femur.

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

The choice of stem, depends on the quality of the bone, the patient's age and the surgeon's experience: in the case of osteoporotic bone (poor bone quality) it's advisable to choose a cemented implant.

In young, active patients with good bone quality, the implant of a cementless stem is an indication endorsed in literature.

# DURATION OF THE IMPLANT



XRAY CONTROL 19 YEARS  
AFTER IMPLANT

# POST-OPERATIVE PRECAUTIONS

Detailed below are a number of precautions to take in the post-operative phase to avoid dislocation of the prosthesis in the first 6 weeks after a hip replacement operation and until the soft tissues have become stabilized. It is important in this delicate phase to comply with the doctor's recommendations.

## GOING HOME:

- In a car it is advisable to use the back seat (in 4-door cars) and recline the seat to a comfortable position, with one or two cushions behind the head. In the case of a 2-door car, sit in the front with two cushions and the seat reclined to reduce flexion of the hip to a minimum.

## AT HOME:

- In bed, place a cushion between the legs and keep them slightly flexed; this is because the legs must not cross or turn inwards.
- When getting up, do not lean forward in the chair: first move the hips forward, then get up. In general, **MAKE SURE THE SHOULDERS ARE NOT AHEAD OF THE HIPS WHEN SITTING DOWN OR GETTING UP.**
- Use a device to grip the blankets when in bed, don't bend forward to reach them.
- **DON'T CROSS THE LEGS WHEN SITTING**, standing or supine, when walking and especially not when turning.
- Avoid sitting in positions in which the knees are higher than the hips.
- **DON'T SIT ON TOILETS OR SEATS THAT ARE TOO LOW.** Use a toilet riser and raise low seats with cushions. Continue to use a toilet riser after leaving hospital and for as long as the doctor instructs (around 6-10 weeks).
- **DON'T STAND WITH FEET TURNED INWARDS**; when sitting, don't allow the knees to turn inwards.
- When sitting, keep the knees apart.
- Don't try getting into the bath without a bath seat; it's best to be helped by someone anyway.
- **DON'T LIE ON THE OPERATED SIDE UNTIL THE DOCTOR DECIDES IT IS POSSIBLE.** At night, lie in the part of the bed corresponding to the healthy limb (the right hand side of the bed if the left limb is the operated one). Avoid turning the trunk towards the side of the operated limb, which would be like turning the limb inwards.
- **AVOID SITTING FOR MORE AN HOUR WITHOUT GETTING UP OR DOING SOME STRETCHING.**

# POST-OPERATIVE PRECAUTIONS

## THE FIRST FEW WEEKS:

- **IT'S POSSIBLE TO START DRIVING AGAIN SIX WEEKS AFTER** the operation only if effective control of the operated hip has been regained and if the foot can be moved from accelerator to the brake with minimum effort. Use a device to grip the blankets when in bed, don't bend forward to reach them.
- Try lying down in bed without a pillow for at least 15-30 minutes a day to prevent the onset of rigidity in the anterior part of the hip.
- **CONTINUE TO USE CRUTCHES OR A WALKER FOR AS LONG AS INSTRUCTED BY THE DOCTOR.**
- If you think that the swelling of the limb has increased since returning home, try raising the foot (remembering to lean back). If the swelling persists, contact your doctor. Also call the doctor if you feel pain in the calf. It should be remembered that until full weight can be rested on the limb, the muscles cannot perform their pumping function, so the leg will tend to swell until capable of taking the full load. Swelling usually disappears at night.
- **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.

Sport may only be resumed with great care, because certain repeated movements may favour wear of the implant. Many activities are compatible with a hip replacement however. Detailed in the table below are the activities recommended in the long term following a total hip or knee replacement.

Very good, highly recommended	Cyclette, Ballroom dancing, Dancing, Golf
Good, recommended	Bowling, Fencing, Rower, Speed walking
Requiring certain abilities, previous experience	Cycling (road), Rowing, Horse riding, Ice skating
With care, subject to doctor's advice	Aerobics, Calisthenics, Jazz dancing, Tennis (doubles), Stepper, Climbing, Water exercises
Avoid	Baseball, Basketball, Football, Softball, Handball, Squash, Football, Tennis (singles), Volleyball

# POST-OPERATIVE PRECAUTIONS



## ADVERSE EVENTS:

- Any serious incident in relation to the device should be reported to your surgeon, the manufacturer, and the Australian Therapeutic Goods Administration (<https://www.tga.gov.au/reporting-adverse-events>)

## 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
- Gruppo Bioimpianti's hip prosthesis implants 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 these hip prosthesis implants in the MR environment is unknown. Scanning a patient who has these devices may result in patient injury.

# POST-OPERATIVE PRECAUTIONS



# POST-OPERATIVE PRECAUTIONS

## POSSIBLE ADVERSE EFFECTS

The possible adverse effects that may result from the use of a prosthetic system, are the classics that may result from a hip arthroplasty and include the following:

1. Osteolysis (progressive bone resorption). Osteolysis can be asymptomatic and therefore routine periodic radiographic examination is essential to prevent any serious future complication
2. Particles leading to increased wear rates necessitating early revision;
3. Early or late deep infection which may necessitate the removal of the prosthesis,
4. Allergic reactions;
5. Intra-operative bone fractures particularly in the presence of low bone density due to osteoporosis, bone defects resulting from previous surgeries, bone resorption, or insertion of the device;
6. Damage to blood vessels or hematoma
7. Dislocation, migration and / or subluxation of the prosthetic components due to trauma, incorrect attachment, loss of fixation, misalignment, improper positioning, bone resorption, soft tissue laxity, sudden movement and / or natural and / or excessive activity;
8. Peri-articular calcification or ossification, with or without impediment to joint mobility;
9. Undesirable variation of the length of the limb;
10. Reduced Range of Movement due to an incorrect choice of the components or a inadequate placement of the implant, or femoral impingement;
11. Fatigue fracture of the prosthetic components can occur as results of loss of fixation or uncomplete fixation, strenuous activity, trauma, misalignment or excessive weight.
12. Corrosion at the interface between components;
13. Wear and / or deformation of the articular surfaces;
14. Pain;
15. Post-operative bone fracture post-operative and / or post-operative pain;
16. Audible sounds during motion.
17. Nerve damage;
18. Throchanteric avulsion or non-union as result of excess muscular tension, early weight bearing, or inadequate reattachment;
19. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.



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