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Hip Femoral Stem Patient Information Leafllet

This Information Leaflet is for patient that have undergone a total hip prosthesis surgery with an implant designed and manufactured by Evolutis.

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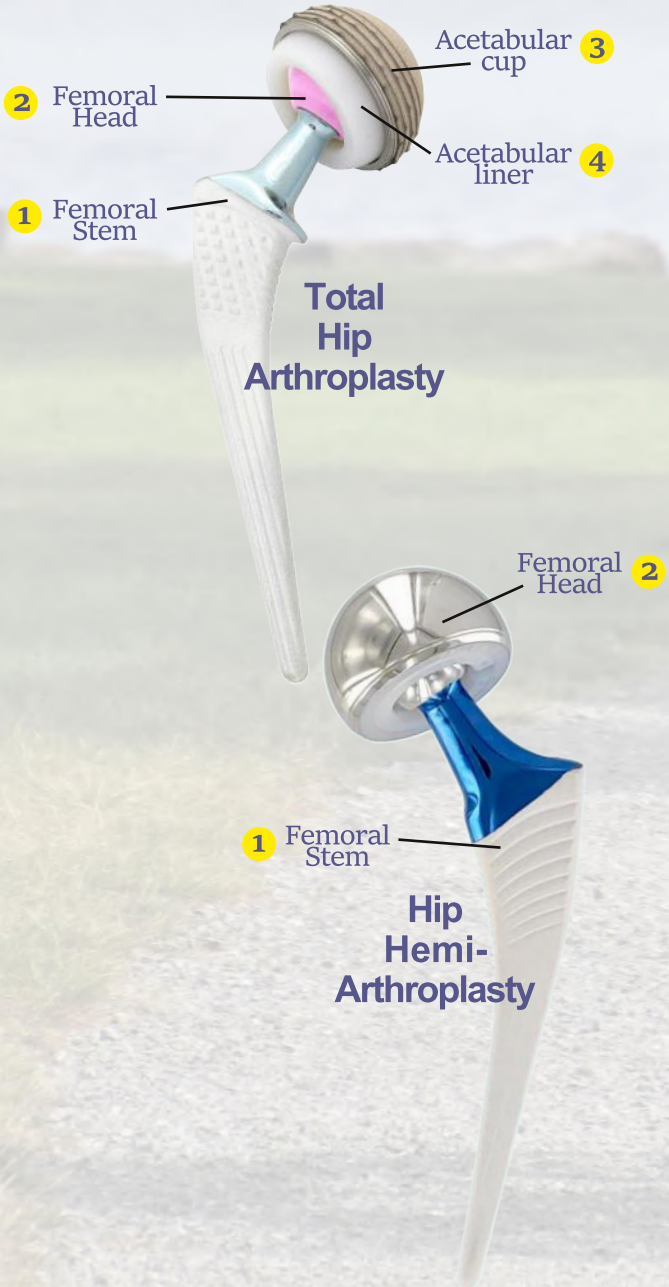
MOTION INSIDE

You have been implanted with a Total Hip Arthroplasty following discussion and analyses with your surgeon. Your surgeon has proposed to replace your deseased of fractured hip with prosthetic joint with goals of reducing you articular pain and help you recover a normal activity.
Your surgeons as the person who knows best your patient's profile and expectations, has selected implants designed and manufactured by Evolutis, in France, for your surgery.
Evolutis, which has been manufacturing orthopedic implants since 1999 and distributing them in more than 40 countries around the world, is very concerned about the well-being and preservation of your functional performance with your prosthesis.
This leaflet aims to help you adopt the right behaviours to maintain your comfort and autonomy as long as possible.



What is a Total Hip Arthroplasty?

A Total Hip Arthroplasty is when both sides of your hip joint are replaced with prosthetic components: a femoral stem on the femoral side, and an acetabular cup on the pelvic side.
A hip replacement prosthesis is composed of a femoral stem 1 , a femoral head 2 , and an acetabular cup 3 and liner 4 . The femoral stem is implanted in the femur and the acetabular cup is implanted in the pelvis of the patient. These two components are fixed to the bone either by means of an orthopaedic bone cement, or via a biologically enhanced fixation. The biologic fixation is when the bone of the patients grows on the surface of the implant, and therefore takes more time than a cemented fixation which is immediate after surgery.
In between the femoral stem and the acetabular cup, a femoral head is fixed on the femoral stem, and a liner fixed into the cup, and both components articulate one with the other to enable the articulation.
The lifetime of a Total Hip Arthroplasty will be dependent of the reason for surgery, of the health status and of the level of activity of the patient. According to the 2020 Report of the AOA the prosthesis will last a minimum of 15 years for 9 patients out of 10 (1).

What is a Hemi Hip Arthroplasty?

The Hemiarthroplasty of the hip is when only the femoral side of the hip joint is replaced with a prosthetic implant. The femoral stem 1 fixed to the bone is fitted with a large femoral head 2 of the same diameter as your pathological femoral head, and the new prosthetic large head articulates directly within your natural acetabulum. Hemi-arthroplasty can be justified for neck fractures of the hip when the cartilage of the acetabulum is still intact. Hemi-arthroplasty is not possible when you suffer from arthritis and that the cartilage surface of your acetabulum is worn out.

(1) Cumulative percent Revision of Primary Total Hip Replacement: 9.5% - CI (9.3; 9.7). AOA 20th Annual Report 2019, page 82

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When should a Hip Arthroplasty not be used?

Placement of a total or hemi hip prosthesis can be contraindicated temporarily or sometimes definitively for patient-related reasons. Such contraindications include infection, mental deficiency, neuromuscular disease, neurologic or vascular problems, addiction to alcohol or drugs, level of professional or sports activity which may stress the implant above the mechanical resistance of the prosthesis, overweight, or bone loss or demineralisation which may compromise the fixation of the implants to the bone.

What is a femoral implant (stem and head) used for?

The femoral implant (stem and modular head) is used to replace the femoral anatomic head and neck when the patient suffers from pain which is so dense and frequent that pain killer medication has become unsufficient to stop, or when the patient suffers from a femoral neck fracture.

What is a femoral implant -component of a Total Hip Arthroplasty?

The femoral implant (stem and modular head) includes the femoral prosthetic stem that will be fixed into the femoral bone and will replace the anatomic femoral neck, and the femoral prosthetic head that will be connected to the top of the femoral stem and will replace the anatomic femoral head.
According to the informed decision of your surgeon, the femoral stem can be fixed into the femur with an orthopaedic bone cement, or with a biologic fixation. The biologic fixation may require more precaution in the post-operative care.

HACTIV® and STEMSYS® femoral stems supplied by Evolutis in Australia are designed for biologic fixation.

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Materials

The HACTIV® femoral stem is made of TA6V4 titanium alloy compliant with ISO 5832-3 standard and is surface coated with synthetic calcium hydroxyapatite.

The STEMSYS® femoral stem is made of TA6V4 titanium alloy compliant with ISO 5832-3 standard and is surface coated with synthetic calcium hydroxyapatite.

The femoral head is made of Cobalt-Chromium alloy compliant with the ISO 5832-4 standard or Composite Ceramic compliant with the ISO 6474-2 standard.

Implant card

The patient will be handed out an implant card mentioning important information about his (her) prosthesis. The information includes the brand name of the device, the designation, the product code and batch number, the material and its UDI-DI reference. This implant card can should be kept available by the patient at all time and should be presented to any healthcare professional before consultation or exam.

MRI Imaging exam of the patient

Non-clinical testing has demonstrated that this prosthesis is MRI Conditional. The patient can be safely scanned in an MRI system meeting the following conditions:

- *Static magnetic field of 3T or less*
- *Maximum spatial gradient magnetic field of 19 T/m*
- *Maximum MRI System reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (normal operating mode)*

Under the scan conditions defined above, the product is expected not to produce a clinically significant temperature rise after 15 minutes of continuous scanning.
The appearance of an artifact caused by this device remains possible.
The patient having been implanted with a total hip prosthesis must inform the healthcare staff before any MRI examination of the presence and site of implantation of his/her prosthesis.
The patient can present the implant card on which all the necessary information is provided.
The restrictions on use are available in the instructions for use (IFU) downloadable from www.evolutisfrance.com - ImplantCard section, then enter the UDI-DI number from your ImplantCard.

RECOMMANDATIONS AND PRECAUTIONS

During the preoperative consultation, the surgeon will evaluate if the the health and activity status of the patient is compatible with the implantation of a Hemi or Total Hip Arthroplasty. The surgeon will explain the risks of the surgery, the mechanical limitations of the implant and the post-operative care and physiotherapy program. Because anticipating a complication will always be better than treating it, regular follow-up examinations will be planned, meaning that the patient will have to regularly visit his (her) surgeon even if the prosthesis works perfectly. The surgeon will decide of the proper frequency but usually the follow-up examinations are planned between 3 and 6 months, 2 years, 5 years, 10 years and 15 years after surgery. These consultations are necessary to confirm the security and performance of the prosthesis and make sure the quality of life of the patient is preserved.
In case the patient notices a change in the performance of the prosthesis or pain in between two evaluation periods, the patient should contact his surgeon without notice, and in cases the evaluation shows the prosthesis is responsible of a reduction in performance or outcomes, the surgeon will discuss the options with the patient and plan all necessary actions.

ADVERSE EFFECTS

Although the placement of a total hip arthroplasty has become a well-mastered, very frequent, and secure operation, any surgery involves risks that the patient must know before making his decision. Surgical risk include haematoma, thrombosis, pulmonary embolism, cardiovascular disturbances, severe nervous, tendinous or venous risk factors, excessive peri-prosthetic ossification, tissue reaction to the material of the implant, post-operative pain at the surgery site, bone fracture, breakage of the implant, bone wear, prosthetic wear, limb length discrepancy, implant noise (squeaking), implant loosening, dislocation or infection.

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For additional information, refer to the IFU available on request or on www.evolutisfrance.com *(ImplantCard section, enter the UDI code number)*.
In case of serious incident contact EVOLUTIS (Manufacturer) and the Therapeutic Good Administration (TGA)

TGA (Therapeutic Goods Administration)
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