

PATIENT INFORMATION

OPRA™ Implant System
Transfemoral

 Integrum

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CAUTION

The OPRA™ Implant System may be used only in conjunction with the associated or recommended components and according to the instructions for use. Integrum AB does not authorize, or accept responsibility for, any use of the OPRA™ Implant System in any manner inconsistent with this Patient Information.

GENERAL INFORMATION

PURPOSE OF THE DEVICE

The OPRA™ Implant System is intended for use in patients with above-knee amputations due to trauma or cancer and who have rehabilitation problems with or cannot use a socket prosthesis.

The OPRA™ Axor™ device is designed to protect the OPRA™ Implant System from damage caused by overload. The Axor™ connects the Abutment and the prosthesis.

You may be a candidate for the OPRA™ Implant System if you have had a transfemoral (above the knee) amputation due to trauma (injury) or cancer and have difficulty wearing your socket prosthesis, high levels of pain when wearing your artificial leg prosthesis, or skin problems resulting from wearing your socket prosthesis.

DESCRIPTION OF THE DEVICES

OPRA™ IMPLANT SYSTEM

The OPRA™ Implant System is composed of parts that allow a prosthesis to attach directly to the femur (thigh bone). The system is designed so that any overload or complication will result in the release of the prosthesis to prevent damage to the surgically implanted parts of the OPRA™ Implant System.

The OPRA™ Implant System consists of seven components that are implanted during two surgeries:

1. Fixture – a titanium screw that will anchor the artificial leg prosthesis to the femur
2. Central Screw – a screw made of titanium that allows access to the bone without removing the Fixture
3. Healing Cylinder – a part made of titanium that prevents bone from growing into the Fixture opening
4. Healing Washer – a metal washer made of titanium that gives support to the bone graft
5. Graft Screw – a titanium screw inserted into the Healing Cylinder that holds the bone graft in place
6. Abutment – a titanium part that attaches to the Fixture and extends outside the skin to allow the attachment of the prosthesis
7. Abutment Screw – a screw made of titanium alloy that locks the Abutment to the Fixture

SURGERY PROCEDURE

In the first surgery (Stage 1), the Fixture is implanted in the femur (thigh bone) and the Central Screw is inserted into the Fixture. Next, the Healing Components are attached to the Fixture. The healing period for this surgery is 3-6 months, depending on bone quality. During this period, the bone grows onto the Fixture to anchor it in the femur. This bone growth process is called osseointegration.

After the healing period is complete, the patient is ready for the second surgery (Stage 2). In this surgery, the Healing Components are removed and the Abutment is attached to the Fixture. Part of the Abutment extends outside the skin to allow the prosthesis to be attached. An Abutment Screw is then attached to lock the Fixture and the Abutment together.

The OPRA™ Implant System components are shown in Figure 1 below.

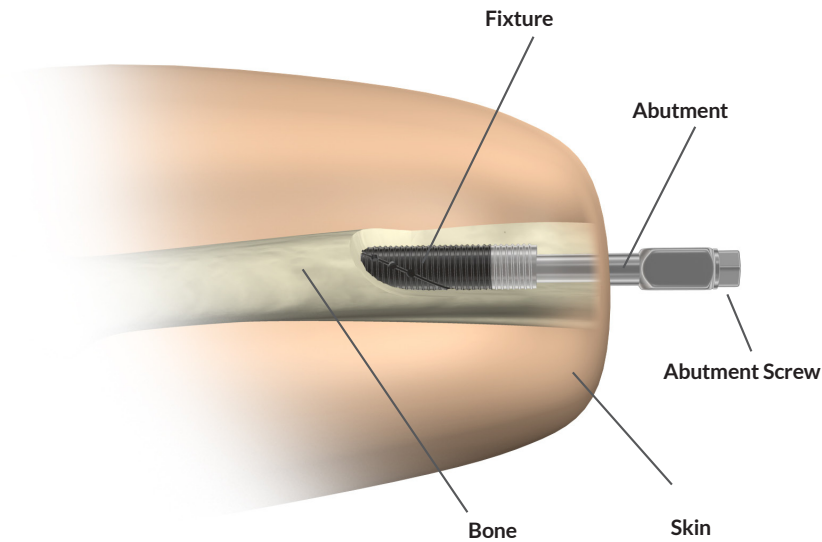


Figure 1: Illustration of the OPRA™ Implant System placed in the femur bone.

OPRA™ AXOR™

The OPRA™ Axor™ attaches to the Abutment square head that is outside of the skin and acts as a safety connection between the Abutment and the prosthesis. It is designed to prevent damage to the bone-anchored Fixture if it is overloaded. If an overload occurs, the Axor™ twists the prosthesis to protect the Fixture from damage. The OPRA™ Axor™ must be installed and serviced by a prosthetist.

For more information, see Axor™ Patient Information.



Figure 2: The OPRA™ Implant System, OPRA™ Axor™ and Artificial Leg and Foot.

INDICATIONS

- The OPRA™ Implant System is indicated for patients who have transfemoral (above the knee) amputation due to trauma (injury) or cancer and who have rehabilitation problems with, or cannot use, a regular socket prosthesis.
- The OPRA™ Implant System is intended for patients whose bone growth is complete.
- The patient experiences issues from a socket prostheses due to problems such as:
 - o Recurrent (repeated) skin infections and ulcerations (skin sores) in the socket contact area
 - o Pain
 - o Discomfort
 - o A short stump preventing the use of socket prosthesis
 - o Volume fluctuation (size change) in the stump
 - o Soft tissue scarring
 - o Extensive (large) area of skin grafting
 - o Socket retention problems (problems keeping the socket in place) due to excessive perspiration (sweating)
 - o Restricted mobility

There are other methods to reduce prosthetic problems. For each person, the best solution should be considered and evaluated by the treating team.

CONTRAINDICATIONS

The OPRA™ Implant System is not recommended for patients if any of the following is applicable:

- You have an atypical anatomy and/or immature skeleton that may affect treatment with OPRA™.
- You have osteoporosis (weak bones) that can affect the treatment with OPRA™.
- Your body weight is too high (this will be individually assessed by the treating team).
- You have suffered amputation due to vascular disease or diabetes.
- You are pregnant.
- You are smoking.

RISK/BENEFIT INFORMATION

BENEFITS

Having the prosthesis directly anchored into the bone reduces the problems of leg prosthesis attachment and improves the function of the prosthesis. This is shown by results from patients already treated with the OPRA™ Implant System. However, this attachment can never totally make up for or replace the lost leg.

Patients with the bone-anchored prosthesis report improved mobility, improved sitting comfort, improved prosthetic control, increased prosthesis use, increased ability to perform daily activities, a decreased feeling of being disabled and improved quality of life. Using the OPRA™ Implant System also decreases the risk of (mitigates) skin irritation problems that are common for prosthesis users.

RISKS

As in all surgical procedures, the OPRA™ treatment is associated with certain risks, which might lead to poor results. Improper use, such as failure to follow and complete the required training, excessive physical activity that overloads the device, or injuries such as falls will increase the risks.

The following risks were associated with the OPRA Implant System in a clinical study of 51 patients at 2 year follow up¹:

- Infection: 31 (61%) subjects had this effect
 - Superficial (skin) infection: 28 (55%) subjects had this effect
 - Deep infection: 3 (6%) subjects had this effect
- Loosening of the Fixture: 4 (8%) subjects had this effect
- Pain: 6 (12%) subjects had this effect
- Injury: 4 (8%) subjects had this effect
- Mechanical complications of the Abutment and/or Abutment Screw: 4 (8%) subjects had this effect
- Myositis (inflamed muscle): 1 (2%) subjects had this effect
- Soft tissue necrosis (soft tissue death): 2 (4%) subjects had this effect
- Blister: 1 (2%) subjects had this effect
- Skin necrosis (dead skin): 3 (6%) subjects had this effect
- Chills: 1 (2%) subjects had this effect
- Impaired (poor) healing: 1 (2%) subjects had this effect
- Fever: 2 (4 out of 100) subjects had this effect
- Wound necrosis (death of tissues): 1 (2%) subjects had this effect
- Fracture: 3 (6%) subjects had this effect
- Joint injury: 1 (2%) subjects had this effect
- Post surgical bruise: 1 (2%) subjects had this effect

Superficial infections around the skin-Abutment area are common and can be treated with appropriate cleaning. However, sometimes oral antibiotic treatment is required. Infections can be serious and should be treated. Patients with infections must be monitored regularly since there is a risk that treated infections will become active again. Deep infection can require long-term antibiotic treatment or removal of the implant.

Mechanical complications of Abutment and/or Abutment screw are common and can be exchanged with a minor surgery that requires a visit to the clinic.

If you notice any of the conditions mentioned in this section, contact your treating physician.

GENERAL WARNINGS AND PRECAUTIONS

WARNINGS

- After you are implanted with the OPRA™ Implant System, if you have non-emergency surgery for any reason, you should take antibiotics to reduce the risk of infection.
- If you have a history of previous infection on the amputated side, you should communicate this with your treating physician.
- Joint problems that might make it difficult to walk, such as arthritis in your hip or other leg, may negatively affect this treatment.
- The following drugs may negatively affect bone growth onto the Fixture and cause loosening of the Fixture:
 - o Oral or injected steroids and
 - o Chemotherapy drugs
- The following drugs should not be used during the first year of treatment:
 - o NSAID (Non Steroid Anti Inflammatory Drugs) two weeks before surgery or for continued use after surgery
 - o Other drugs that might affect bone healing

PRECAUTIONS

- The OPRA™ Implant System is not intended for use with the following physical activities:
 - ! Do not run, jump or climb.
 - ! It is recommended to use a cane or crutches for long walks.
 - ! Do not lift or carry heavy items.
 - ! Avoid subjecting the OPRA™ Implant System to high torque (twisting motion or bending).
 - ! While riding a bike, your knee joint might lock in the fully stretched position. This can seriously damage the Fixture. Always position the bike seat low enough that your knee cannot fully extend while cycling. Never stand up while you are cycling. Consult with your treating team before riding a bike for the first time.
- If your bone quality is not the best, full weight bearing on the prosthesis should begin more gradually and at a reduced pace as determined by your physician.
- If your OPRA™ Axor™ is damaged in any way, contact your prosthetist.
- Never try to fix any problems with the device yourself. Never use any tools on the device as you might damage the OPRA™ Implant System.
- If the prosthesis is overloaded, the OPRA™ components could be severely damaged.
- Always check carefully that the prosthesis is adequately attached to the Abutment.
- Retightening of the Abutment Screw shall only be performed by professionals. If retightening is performed in an uncontrolled way (not performed by a professional according to protocol) there is a risk for mechanical complications with the Abutment and Abutment Screw.
- If the Abutment or Abutment Screw is replaced, the screw must be retightened by your treating physician. Additional appointments may be necessary to ensure that the system is working correctly.
- Be careful when you are in hot or cold places.
 - ! In the sauna, wrap a wet towel around the Abutment to protect it from heat.
 - ! Protect the amputated limb when in a cold environment.
- Avoid hurting yourself or others with the Abutment.
 - ! Protecting the Abutment during sleep is recommended. The protection will be provided by your prosthetist.

For the OPRA™ Implant System to perform as intended, it is critical that you comply with the treatment protocol, the warnings and precautions (as outlined in the section above) and follow the directions of your surgeon, prosthetist and physical therapist. In addition, it is important that you go to all follow-up appointments to have a successful OPRA™ Implant System treatment. It is also important to observe good hygiene (cleanliness) to minimize the risk of infection. For additional information, please see section, Hygiene Recommendations on page 13.

TREATMENT PROTOCOL

The OPRA™ Implant System for individuals with transfemoral amputations requires two surgeries, 3–6 months apart to insert the components into the residual limb and allow for proper osseointegration. Within three weeks following the second surgery you will begin the rehabilitation process. In about 180 days from this point the rehabilitation should be complete and you can use your bone anchored prosthesis with the limitations described in Precautions on page 10. More specific details are identified below:

1 PATIENT SCREENING

Each individual who would like to be considered for the OPRA™ Implant System should participate in a patient evaluation and intake process.

2 STAGE 1 SURGERY (S1)

The bone of the femur is prepared to receive the Fixture and it is precisely threaded into the medullary canal of the bone and once in place the soft tissues and skin are closed.

3 HEALING PERIOD

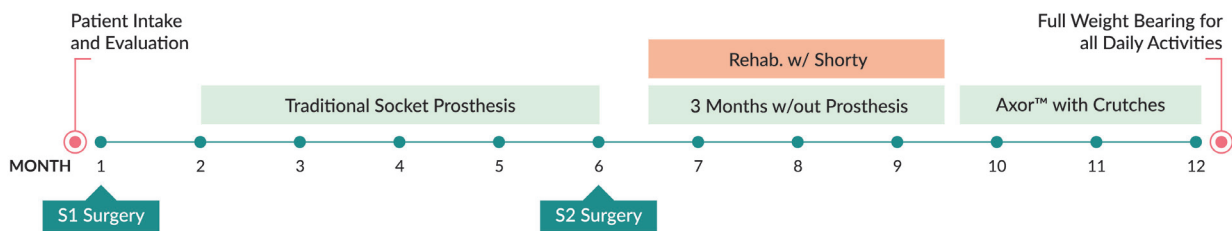
Following the S1 surgery a 3–6 month period of healing is achieved to allow the bone tissue to thoroughly integrate around the implant. During this healing period a traditional socket prosthesis can be utilized.

4 STAGE 2 SURGERY (S2)

In the S2 surgery the Abutment is attached to the Fixture and protrudes through the skin. The muscles of the limb are reattached near the end of the bone and the skin surrounding the area where the Abutment exits the skin is prepared in a meticulous surgical procedure. The wound is sutured closed and the Abutment protrudes through the skin.

5 REHABILITATION

Approximately three weeks following the completion of the S2 surgery the partial loading of the limb with a “shorty” prosthesis begins and continues for about 6 weeks. At this point, the use of the definitive prosthesis with the Axor™ is initiated and within an additional twelve weeks of progressive loading individuals are free to use their bone-anchored prosthesis for all daily activities.



FOLLOW-UP OF MECHANICAL FUNCTION

In the case of overload, the outer parts of the OPRA™ Implant System (Abutment and Abutment Screw) might be damaged. These parts can be replaced under sterile conditions in the operating room. General anesthesia might be required. In most cases, you will be able to return to walking within a few days.

WHEN TO CONTACT YOUR TREATING PHYSICIAN

For your safety and comfort, and for the anchoring and prosthesis to function without problem, it is important to follow certain instructions and advice as follows.

YOU MUST IMMEDIATELY CONTACT YOUR TREATING PHYSICIAN IF:

- You experience pain from your leg and increased body temperature (fever).

ALWAYS CONTACT YOUR TREATING PHYSICIAN IF:

- You have pain in your leg.
- You identify Abutment Screw loosening.
- You have signs of infection which include but are not limited to:
 - o The area where the Abutment extends out of the skin becomes red or irritated
 - o Increasing amount of body fluid leaks from the area where the Abutment extends out of the skin or there is a bad smell coming from that area
 - o Dark discoloration increases in the area where the Abutment extends out of the skin
 - o You notice black or greyish leakage from the area where the Abutment extends out of the skin

The parts should be inspected daily for cracks and signs of wear. Signs of wear in the connection between Fixture and Abutment include dark colored fluid or skin.

Contact your physical therapist if you have any questions related to your rehabilitation program.

Contact your prosthetist if you have any questions related to your prosthesis.

HYGIENE RECOMMENDATIONS

It is important to inspect and clean the skin penetration area (the area where the Abutment extends out of the skin) every morning and evening. Good hygiene decreases the risk of infections. It is preferable to use an alcohol-based hand rub before inspection and cleaning. If an alcohol rub is not available, wash hands thoroughly prior to inspecting and cleaning the area. A hand mirror may be useful for inspecting the skin penetration area. You should not let other people touch the area immediately around the Abutment.

There are no restrictions regarding bathing and swimming if carried out according to instructions for protection of the skin penetration area (see below).

INSTRUCTIONS FOR CLEANING THE SKIN PENETRATION AREA

- Moisten a clean gauze bandage or a compress with sterile saline solution (0.9% NaCl). Wrap the bandage or compress around the device, press it gently against the skin and clean the skin with a circular movement (as with dental floss). Repeat this cleaning twice daily, e.g. morning and evening.
- If there is dry, flaking skin immediately around the device this may be removed using a dry swab or a swab moistened with sterile saline solution (0,9 % NaCl).
- If the skin area next to the device becomes dry and chapped, apply a thin layer of an ointment, e.g. Vaseline, twice a day.
- It is not unusual for fluid to drain from the skin penetration area, especially after vigorous physical activity. If a small amount of clear fluid leaks out, wrap a clean gauze bandage or compress around the Abutment and change it daily.
- For bathing or swimming, Vaseline should be gently applied to the skin penetration area and a silicon liner (provided by your prosthetist) should be used as a "bathing cap". It is very important to clean the the skin penetration area carefully after bathing or swimming. Axor™ cannot be used during bathing or swimming.

IN CASE OF IRRITATION OR INFECTION

- If you have a cold, the skin penetration area may become irritated. Prior to cleaning this area, it is important for you to carefully clean your hands with an alcohol-based rub.
- At early signs of irritation or infection such as redness, or mild pain, you must clean the skin penetration area one or more times extra during the day.
- If irritation continues along with flushing, swelling, fever and/or aching, or unclear fluid draining from the skin penetration area, you should consult your treating physician.
- **IN CASE OF HIGH FEVER AND/OR SEVERE PAIN, YOU SHOULD IMMEDIATELY GO TO THE HOSPITAL EMERGENCY ROOM.**

TRAVEL

During security screenings, your metal implant may be detected by a metal detector or other screening device which may trigger additional screening procedures including a pat down to ensure that the implant is the only reason for indication of metal at the screening.

EXPECTED LIFETIME

The OPRA™ Implant System is designed to have an expected lifetime of at least 10 years. However, failure to follow and complete the required training, excessive physical activity that overloads the device or traumas such as falls may cause the OPRA™ Implant System to require replacement sooner than expected. It is the patient's responsibility to follow the recommendations in this document. It is the responsibility of the treating physician to ensure that all protocols for the OPRA™ Implant System treatment are followed correctly and performed by professionals only. Integrum AB is responsible for the OPRA™ Implant System performance only when the system is used in accordance to Patient Information and Instructions For Use.

It is important to understand the warnings and precautions (as outlined in this document) and follow the directions of your treating team.

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