PATIENT LABELING

OPRA™ Implant System

Integrum

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GLOSSARY

OPRA™ - Osseoanchored Prostheses for the Rehabilitation of Amputees.

ABUTMENT - A skin-penetrating device connected to the Fixture for connection to the external prosthesis.

AMBULATION - Walking.

ARTIFICIAL LEG; FOOT - Part to replace a missing leg or foot.

BISPHOSPHONATES - Drugs to reduce bone loss.

COMPUTED TOMOGRAPHY - Radiographic method that provides cross sectional (slices) images of the body. Also known as CT or CAT scanning.

DRAINING - Fluid coming from wound after surgery.

DRESSING - Wound bandage.

FIXTURE - The device that is implanted into the thigh bone.

MECHANICAL FUNCTION – How the working parts operate.

NEUROPATHY OR NEUROPATHIC DISEASE - Abnormal sensations and pain due to nerve damage.

NSAIDs – Non-Steroidal Anti-Inflammatory Drugs – drugs such as ibuprofen and aspirin that reduce pain and inflammation.

RELEASE FUNCTION – The Axor™ II releases when subjected to high bending and/ or rotational moments in order to protect the OPRA™ Implant System from excessive loads.

OSSEO-ANCHORED - Bone growth to an implant.

OVERLOAD – Too much force on the OPRA™ Implant System which can be caused by climbing, jumping, kicking, carrying heavy items or other activities.

PHANTOM PAIN - Sensation related to a limb that is no longer part of the body.

PHYSICAL THERAPIST – Person who helps patients walk again, have less pain and be more active.

PROSTHESIS – Artificial leg and foot.

PROSTHETIST – A prosthesis specialist; a person who designs, fits or services a prosthesis.

RELEASE LEVEL – The load that causes the Axor™ II to release in bend or rotation by twisting the artificial foot

AXOR™ II - A prosthetic safety device connected to the Abutment.

SOCKET PROSTHESIS - A removable artificial leg and foot attached to the stump by a socket.

TRANSFEMORAL AMPUTATION - Amputation of the leg above the knee.

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 Labeling.

DESCRIPTIVE 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 or are anticipated to have rehabilitation problems with or cannot use a conventional (regular) artificial leg prosthesis.

The OPRA™ Axor™ II device is designed to protect the OPRA™ Implant System from damage caused by overloads. The Axor™ II connects the Abutment and the prosthesis. In the event of excessive twisting or bending of the prosthesis, the Axor™ II releases the prosthesis to prevent damage to the bone anchored Fixture. The Axor™ II is intended for daily use. However, you will need to complete the training program before you will be able to use your prosthesis for long periods of time. You should discuss your daily activities with your physician to make sure that they can be performed safely with this device.

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 or are anticipated to have difficulty wearing your socket prosthesis (artificial leg), high levels of pain when wearing your artificial leg prosthesis, or skin problems resulting from wearing your socket prosthesis.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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 moderate 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 where the Abutment will be placed during the second surgery. The Healing Cylinder is implanted during the first surgery and removed during the second surgery.

4. Healing Washer – a metal washer made of titanium that gives support to the bone graft. It is implanted during the first surgery and removed during the second surgery.

5. Graft Screw – a titanium screw inserted into the Healing Cylinder that holds the bone graft in place. It is implanted during the first surgery and removed during the second surgery.

6. Abutment - a titanium part that attaches to the Fixture and extends outside the skin to allow the attachment of the prosthesis. It is implanted during the second surgery.

7. Abutment Screw – a screw made of titanium alloy that locks the Abutment to the Fixture. It is implanted during the second surgery. Any retightening of this screw should only be performed by your physician or prosthetist.

The individual parts of the OPRA™ Implant System are shown in Figures 1 and 2.

FIRST SURGERY

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 Cylinder is attached to the Fixture. Then a bone graft (extra bone already removed from your thigh or bone from your hip bone) is placed and a Graft Screw is inserted in the Healing Cylinder to hold the bone graft in place. If needed, a Washer can be used to keep the bone graft in place. The healing period for this surgery is about 6 months. During this period, the bone grows onto the Fixture to anchor it in the femur. This bone growth process is called osseo-anchoring. The Healing Cylinder prevents bone from growing into the opening in the Fixture where the Abutment will be attached during the second surgery.

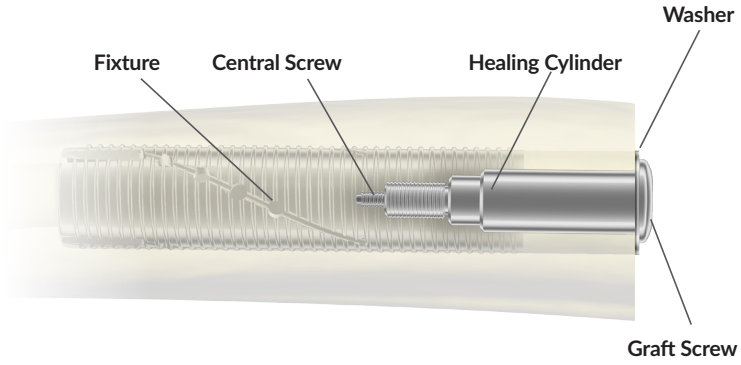

Figure 1: OPRA™ Implant System Parts Implanted in First Surgery.

SECOND SURGERY

After the healing period is complete, the patient is ready for the second surgery (Stage 2). In this surgery, the Healing Cylinder, Washer and Graft Screw 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 parts are shown in Figure 2 below. For more information on surgeries, please see the section Surgery Procedure.

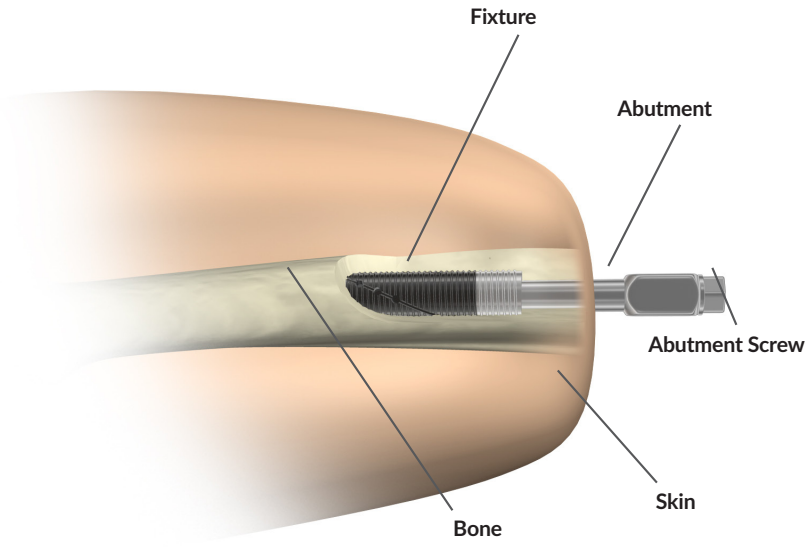

Figure 2: Illustration of the Fixture and Abutment parts of the OPRA™ Implant System placed in the femur bone of the amputation stump.

OPRA™ AXOR™

The OPRA™ Axor™ II attaches to the Abutment end 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™ II twists the prosthesis to protect the Fixture from damage. The OPRA™ Axor™ II must be installed and serviced by a prosthetist (person who specializes in prostheses).

The Axor™ II releases when subjected to high bending and/or rotational moments in order to protect the OPRA™ Implant System from excessive loads.

Release modes:

- In the *bending/flexion* direction the Axor™ II is opened according to Figure 3.
- In the *rotational direction* the Axor™ II rotates around its axis in both clockwise and counterclockwise directions according to Figure 4.

The two release mechanisms are the normal and fundamental functions of the Axor™ II and can be reset by the patient without using any tools. The Axor™ II has been tested to pass numerous release/reset procedures without any change of the settings.

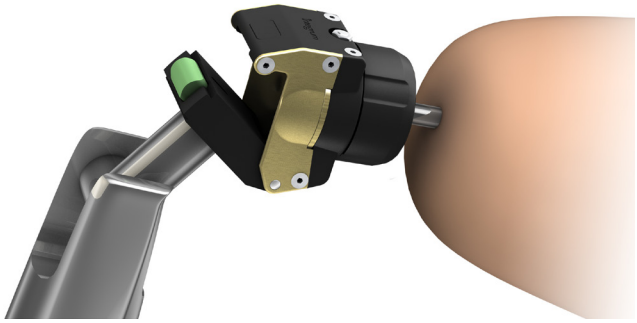

Figure 3. Bend release.

Figure 4. Rotation release.

Your prosthetist (prosthesis specialist) has adjusted the release level setting for the OPRA™ Axor™ II to suit you. You should NEVER change the settings yourself.

If the release level is exceeded, the OPRA™ Axor™ II will release in bend or rotation by twisting the foot or releasing the foot. You can avoid overloading the OPRA™ Axor™ II by following and completing the training plan and discussing your post-operative activities with your physician.

If OPRA™ Axor™ II has released by twisting your foot or stumbling, you may reset it to yourself. Your prosthetist (prosthesis specialist) will show you the proper procedure. It is important to reset the prosthetic foot back to its exact original position. After you reset the OPRA™ Axor™ II, you should not continue performing the same activity that caused the device to release.

After your OPRA™ Axor™ II released in bend and/or rotation your prosthetist (prosthesis specialist) will give you a OPRA™ Axor™ II Report Form to fill in if the product does not function as intended. A copy of the OPRA™ Axor™ II Report Form is provided in Appendix 1.

The OPRA™ Axor™ II should be removed before laying down on a couch, bed or other flat surface.

The OPRA™ Implant System, the OPRA™ Axor™ II and the prosthesis are shown in Figure 5. The OPRA™ Implant System, the OPRA™ Axor™ II and the prosthesis are shown on a person in Figure 6.

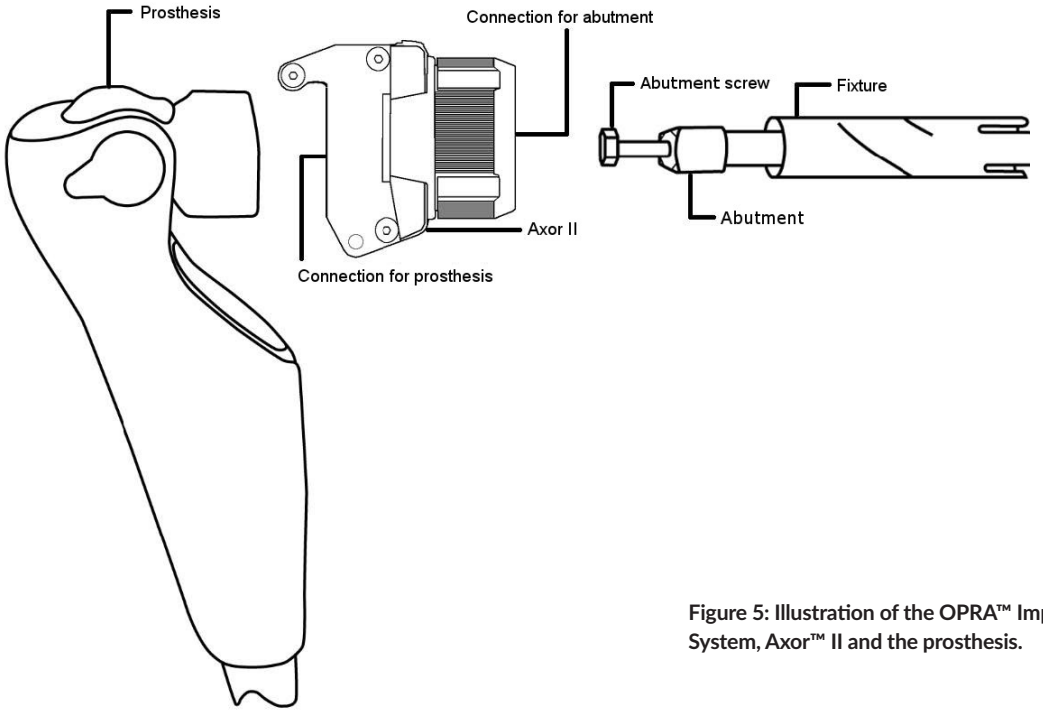

Figure 5: Illustration of the OPRA™ Implant System, Axor™ II and the prosthesis.

Figure 6: The OPRA™ Implant System, OPRA™ Axor™ II Device and artificial leg and foot

CONTRAINDICATIONS

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

- The patient's bone growth is not complete based on X-ray examination.
- The patient has bone anatomy that is not typical and may affect treatment with OPRA™.

  Examples of bone anatomy that is not typical:

  - o Bone measurements outside defined interval.
  - o Unexpected development.
  - o Conditions which are not favorable for device to be installed such as deformities, fracture, infection.
- The patient would have less than 2 mm of remaining cortex bone available around the implant, if implanted.
- The patient has osteoporosis (weak bones).
- The patient is older than 65 years or younger than 22 years.
- The patient's body weight is higher than 220 lbs including the prosthesis.
- The patient suffers from other diseases that might affect treatment with OPRA™. Examples of other diseases are:
  - o Severe peripheral vascular (blood vessels outside the brain and heart) disease.
  - o Diabetic mellitus (diabetes) with complications.
  - o Skin disorders involving the stump.
  - o Neuropathy or neuropathic disease (damage or disease to nerves) and severe phantom pain.
  - o Active infection or dormant (currently not active) bacteria.
  - o Metabolic bone disease and/or metastatic lesions in the residual femur.
- The patient is pregnant.
- The patient is not expected to be able to follow the treatment and follow up rules.

RISK/POTENTIAL BENEFIT INFORMATION

POTENTIAL 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 amputees 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, quality of life, perception of where and how their steps are placed, increased ability to perform daily activities, and a decreased feeling of being disabled. Using the OPRA™ Implant System also lessens the risk of (mitigates) skin irritation problems that are common for prosthesis users.

The OPRA™ study has shown the following benefits:

- an improved range of movement around the hip joint, not stopped by a socket brim;
- increased prosthetic use, level of function and mobility, including longer walking distances and increased sitting comfort;
- improved quality of life; and
- eliminated socket related issues.

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 2-year clinical study of 51 patients:

- 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 complication 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%) subject had this effect.
- Skin necrosis (dead skin): 3 (6%) subjects had this effect.
- Chills: 1 (2%) subject had this effect.
- Impaired (poor) healing: 1 (2%) subject had this effect.
- Fever: 2 (4 out of 100) subjects had this effect.
- Wound necrosis (death of tissues): 1 (2%) subject had this effect.
- Fracture: 3 (6%) subjects had this effect.
- Joint injury: 1 (2%) subject had this effect.
- Post surgical bruise: 1 (2%) subject had this effect.

Similar events have been observed to 5-years post-surgery.

If any of these complications occur, they must be treated promptly by your physician. 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 (up to 6 months) or removal of the implant. In the study, 4 subjects had deep infection, and in one subject the implant was removed. Complications such as loosening of an implant or bone infection, may occur over the long-term use of the system, so your physician should be contacted immediately if you notice any of the conditions referenced in section When to Contact Your Doctor, on page 16.

The components of the OPRA™ Implant System are designed to be replaceable if they wear or break. Long-term success of the OPRA™ system has not yet been established, so there is a risk that all of the components of the implant system would have to be removed and that the stump would need to be shortened an additional 4 inches.

INDICATIONS

- The OPRA™ Implant System is indicated for patients who have transfemoral amputation due to trauma or cancer and who have or are anticipated to have rehabilitation problems with, or cannot use, a conventional socket prosthesis. The OPRA™ Implant System is intended for skeletally mature patients.
- The patient failed to receive benefit from socket prostheses or is expected to not tolerate socket use due to problems such as:
    - o Recurrent (repeated) skin infections and ulcerations (skin sores) in the socket contact area
    - o Pain
    - 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 (cannot move fully)

OTHER WAYS TO REDUCE PROSTHETIC PROBLEMS

There are other methods to reduce prosthetic problems. One method is one or more plastic surgery operations to adjust the shape of the amputated limb. Another method is to avoid using a prosthesis. For each person, the best solution should be considered and evaluated.

GENERAL WARNINGS AND PRECAUTIONS

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the OPRA™ Implant System is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static Magnetic field of 1.5 and 3.0 T.
- Maximum spatial field gradient of 4500 gauss/cm (45 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (normal operation mode) when the implant is at least 20 cm out of isocenter.

RF heating tests of the OPRA™ Implant System showed high expected temperature increase for a wbSAR of 2W/kg after 15 minutes of continuous scanning when at the isocenter. Moving the device 20 cm out of iso center, as listed in the conditions above, reduced heating to 3.9°C.

In non-clinical testing, the image artifact caused by the device extends approximately up to 45 mm from the OPRA™ Implant System when imaged with a gradient echo pulse sequence and a 3.0 T MRI system. It is likely that clinical MR protocols may show smaller artifacts.

WARNINGS

- Smoking negatively impacts bone growth onto the Fixture device.
- Healing problems can occur in obese patients.
- After you are implanted with the OPRA™ Implant System, if you have non-emergency surgery for any reason, you should notify your physician of your implant and consider taking antibiotics to reduce the risk of infection. Do not self-administer antibiotics.
- Patients with both unilateral (one leg) and bilateral (two leg) amputations have been treated with the OPRA™ Implant System. As only a small number of bilateral patients have been treated, results in bilateral patients are unknown and definite conclusions cannot be made from study results.
- If you have a history of previous infection on the amputated side, you should be carefully evaluated with blood work to determine that you do not have an on-going infection. Also, bone cultures (examination of bone marrow) should be done to make sure that no inactive infection is present.
- 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.
- You will typically not be a suitable candidate for treatment with the OPRA™ Implant System if:
    - o You are using the prosthesis every day more than 13 hours; or
    - o You do not report more than moderate trouble and moderate reduction of quality of life.

    In these instances, alternative treatments, such as socket modifications (changes), general amputee rehabilitation (physical therapy), or soft tissue or bone surgery might better address your rehabilitation problems.
- The following drugs should not be used during the first year of treatment:
    - o NSAID (Non Steroid Anti Inflammatory Drugs) such as ibuprofen and aspirin two weeks before surgery or for continued use after surgery; and
    - o Bisphosphonates (drugs to reduce bone loss).
- Contact your treating physician immediately if you have pain from your leg and increased body temperature (fever).

PRECAUTIONS

- For at least 6 months after Stage 1 (S1) surgery, you must not put your full weight on the prosthesis. Putting full weight on the prosthesis is normally allowed about 6 months after the Stage 2 (second) surgery, following a check-up by the treatment physician.
- Standing and walking must be done according to individualized training programs.
- The OPRA™ Implant System is intended for use with normal physical activity.
- If your bone quality is inadequate, full weight bearing on the prosthesis should begin more gradually and at a reduced pace as determined by your physician.
- If your OPRA™ Axor™ II is damaged in any way, contact your prosthetist (prosthesis specialist).
- If your OPRA™ Axor™ II has been immersed in water, contact your prosthetist (prosthesis specialist).
- You should take special care of your OPRA™ Implant System:

  o Never try to fix any problems with the OPRA™ Implant System yourself. Never use any tools on the OPRA™ Implant System as you might damage the Abutment, Abutment Screw and the Fixture

  o If the OPRA™ Implant System is overloaded, the Fixture could be severely damaged.

  ! Never run, jump or climb.

  ! Always use a cane or crutches for longer walks.

  ! Never lift or carry heavy items.

  ! Never subject the OPRA™ Implant System to high torque (twisting motions).

  o Always check carefully that the prosthesis is adequately attached to the Abutment.

  o 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 stretch out while cycling. Never stand up while you are cycling.

  o Retightening of the Abutment Screw shall only be performed by professionals. If the retightening is performed in an uncontrolled way (not performed by a professional according to protocol) there a risk for mechanical complications with the Abutment and Abutment Screw.

  o 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.

  o Always 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.

  o Always avoid damaging yourself or others with the Abutment.

  ! Protecting the Abutment during sleep is recommended. The protection will be provided by your prosthetist (prosthesis specialist).

IMPORTANCE OF FOLLOWING A CARE REGIMEN

For the OPRA™ Implant System to perform as intended, it is critical that you understand the warnings and precautions (as outlined in the section above) and follow the directions of your surgeon, prosthetist (prosthesis specialist), and physical therapist (person who helps patients walk again). In addition, it is important that you go to all follow-up appointments as the OPRA™ Implant System requires on-going monitoring in the15-20 years after implantation. 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 17.

OPERATING INFORMATION

PREOPERATIVE ASSESSMENTS

A team of an orthopedic surgeon, physical therapist (person who helps patients walk again) and prosthetist (prosthesis specialist) will determine if you are a candidate for the OPRA™ Implant System. The decision is based on clinical examination, radiographic examination, and your amputation status.

The radiographic evaluation includes x-rays to determine bone quality, make measurements and look for any abnormalities, as well as CT scans to determine the correct Fixture length and to verify thigh bone length.

If you have a medical history of previous infection on the amputated side, laboratory analysis will be done at specific times as defined by your surgeon to make sure that you do not have an ongoing infection.

If you are a candidate for the OPRA™ Implant System, your kidney and liver function will be tested to see if you are able to safely take oral or intravenous (given into a vein) antibiotics. If you receive the OPRA™ Implant System, you will be given antibiotics starting on the day of each surgery until 2 days after your sutures are removed. The purpose of the antibiotics is to reduce your risk of infection. Additionally, if you have an infection after surgery or later during the long-term use of this device, you may be given antibiotics.

SURGERY PROCEDURE

The treatment consists of two surgeries. The surgeries are performed under anesthesia. After each surgery you will spend 5-7 days in the hospital.

STAGE 1

During the first surgery (Stage 1, S1), a screw-like anchor (Fixture) is inserted in the inner canal of the thigh bone. After surgery, the Fixture is not used for at least 6 months to improve bone healing. During this period, some patients might be able to use their socket prostheses.

STAGE 2

During the second surgery (Stage 2, S2), the Abutment is attached to the end of the Fixture. The Abutment goes through the skin and makes it possible to attach the prosthesis to the OPRA™ Implant System. Approximately 4-6 weeks after the surgery, mobilization (movement) is carried out under the supervision of a physical therapist (person who helps patients walk again). Full weight bearing with a leg prosthesis is normally allowed approximately 6 months after Stage 2, see section Precautions on pages 12.

POST-OPERATIVE MANAGEMENT AFTER STAGE 1 SURGERY

After the S1 surgery, your sutures (stitches) will be removed after about 3 weeks, and after 6 weeks, you will normally be allowed to use a socket prosthesis and return to your pre-surgery activities. Your socket prosthesis should be adjusted by a prosthetist (prosthesis expert) so that the socket does not touch the end of the bone in your stump; otherwise, healing may be reduced or delayed.

MOBILIZATION AFTER STAGE 1 SURGERY

Joint movement, strength and fitness training instruction will be provided to you and supervised by your physical therapist (person who helps patients walk again). When the skin is healed enough, patients who used prosthesis before the OPRA™ treatment can begin using an adapted prosthesis 1-3 weeks after suture removal.

POST-OPERATIVE MANAGEMENT AFTER STAGE 2 SURGERY

After the S2 surgery, the bandage applied to the wound should be changed 2 times per week until the skin has healed. Your treating physician will prescribe antibiotics to reduce your risk of infection. Approximately 3 weeks after the surgery, your physician will remove your sutures (stitches).

FOLLOW-UP PROGRAM AFTER STAGE 2 SURGERY

After surgery, your will return to your treating physician for follow-up exams that will include clinical, mechanical and X-ray evaluations.

CHECK-UP SCHEDULE

You should follow up with your treating physician at the times following surgery shown in Table 1.

Table 1: Follow-up Times with Actions

Action	Day 21	Month 3	Month 6	Month 12	Ongoing
Amputation status	●	●	●	●	Every 6 months
Inspection of components	●	●	●	●	Every 6 months
X-ray			●	●	Years 2, 3, 5, 7, 10, 15 etc.

If you have significant pain, you should rest completely from all kinds of training or walking and contact your treating physician for further instructions.

REHABILITATION AFTER STAGE 2 SURGERY

After the second surgery, your physical therapist (person who helps patients walk) and prosthetist (prosthesis specialist) will instruct you on rehabilitation (physical therapy). You will be provided instructions for at home exercise and training.

When appropriate, the leg prosthesis will be attached to the Abutment through a quick connection Axor™ II device. During the first stage of rehabilitation, a specially designed training prosthesis is used before moving on to the full-length prosthesis. At first, you should be very cautious when initially putting weight on the prosthesis.

Approximately 6 months after the second surgery, you can start using the leg prosthesis normally as directed by your physician.

TRAINING PROGRAM

An overview of the training program after Stage 2 follows.

Initial training after Stage 2 Surgery

WEEK 3 POST-OP

Your physical therapist (person who helps patients walk) will guide you through active movement training of your hip joint.

WEEK 6 POST-OP

A short training prosthesis will be attached to the OPRA™ Implant Systen and you will begin placing weight on the prosthesis. The load will be increased slowly until full bodyweight is reached. You will need to exercise for 15 minutes at a time, 2 times a day increasing to 30 minutes at a time, 2 times a day as directed by your physical therapist (person who helps patients walk).

If you have significant pain, your physical therapist (person who helps patients walk) will evaluate your pain level according to a scale. If your pain level is too high, you will be instructed to rest from all training for 1-2 days. If your pain has decreased after rest, training will resume at a lower weight bearing amount. If your pain remains high according to the pain scale, you should contact your treating physician.

WEEK 10-14 POST-OP AFTER STAGE 2 SURGERY

If full body weight bearing is reached and you are able to train without pain, you will begin general fitness exercises including kneeling on all fours and kneeling down. At this point, your physician will decide if you can begin to use a full-length prosthesis.

Training with full-length prosthesis after Stage 2 Surgery

The schedule for training with a full-length prosthesis is listed below. Please note that the Week intervals overlap as some patients will complete a level of training and be ready to start the next level after only 2 or 3 weeks. Your physical therapist (person who helps patients walk) and treating physician will tell you when to move to the next training level.

WEEK 10-14 POST-OP

Your physical therapist (person who helps patients walk) will start your training with a full-length prosthesis and a low weight bearing amount. Over a two week period, you will train indoors with the prostheses for no more than 60 minutes at a time and no more than 2 times a day. The weight bearing amount will be increased slowly over time as you do walk exercises with parallel bars and with 2 crutches.

If you have significant pain, your physical therapist (person who helps patients walk) will evaluate your pain level according to a scale. If your pain level is too high, you will be instructed to rest from all training for 1-2 days. If the pain has decreased after rest, training will resume at a lower level of weight bearing. If pain remains high according to the pain scale, you should contact your treating physician.

WEEK 12-16 POST-OP

During these weeks, you will receive training on balance and walking patterns using 2 crutches at all times. Exercises during this stage include the stair climbing, fitness cycling with a light load, sitting down, and standing up.

WEEK 14-18 POST-OP

As time progresses, you might be able to use the prosthesis the entire day. You will also work on transferring your body weight while standing and walking uphill with two supports.

WEEK 16-24 POST-OP

Training continues with walking exercises using one support at the physical therapist's office and at home. At this stage, you should always use 2 crutches for longer walks outdoors. Your training will also include walking slightly uphill, in rough terrain, over obstacles, turning, and fitness training with full-length prostheses.

WEEK 22-26 POST-OP

During training, if full body weight bearing is reached without pain, you will be instructed to return to visit your treating physician. At this point, your physician will decide if you can use one support more frequently while walking and your training will include walking without any support.

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.

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 screw is working correctly.

WHEN TO CONTACT YOUR DOCTOR

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 suddenly have pain in your leg during or after weight bearing.
- You have increased pain in your leg during or after weight bearing.
- You have signs of infection which include but are not limited to:
    - o The area where the Abutment device extends out of the skin becomes red or irritated.
    - o Increasing amount of body fluid leaks from the area where the Abutment device 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 device extends out of the skin.
    - o You notice black or greyish leakage from the area where the Abutment device extends out of the skin.
    - o You notice any change in the way the Axor™ II or prosthesis connection feels.

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 (person who helps patients walk) if you have any questions related to your rehabilitation program.

Contact your prosthetist (prosthesis specialist) 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 device meets 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 as long as carried out according to instructions for protection of the skin penetration area (see below).

INSTRUCTIONS FOR CLEANING THE AREA WHERE THE ABUTMENT DEVICE EXTENDS OUT OF THE SKIN

- Moisten a clean gauze bandage or a compress with sterile saline solution (0.9% salt). 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 % salt).
- If the skin area next to the device becomes dry and chapped, apply a thin layer of an ointment, e.g. Vaseline Petroleum Jelly, twice a day.
- It is not unusual for a small amount of clear fluid to seep from the area where the device extends out of the skin, 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 Petroleum Jelly should be gently applied to the area where the device extends out of the skin and a silicon liner (provided by your prosthetist) should be used as a "bathing cap". It is very important to clean the area where the device extends out of the skin carefully after bathing or swimming.

IN CASE OF IRRITATION OR INFECTION

- If you have signs of infection, notify the health care provider. Do not self-administer antibiotics.
- If you have a cold, the area where the device extends out of the skin 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 area where the device extends out of the skin one or more times extra during the day.
- If irritation continues along with flushing, swelling, fever and/or aching, or non-clear fluid draining from the area where the device extends out of the skin, you should consult your treating physician.
- **IN CASE OF HIGH FEVER AND/OR SEVERE PAIN, YOU SHOULD IMMEDIATELY GO TO THE HOSPITAL EMERGENCY ROOM.**

CLINICAL RESULTS

ORIGINAL 51-PATIENT OPRA™ STUDY

The OPRA™ Implant System and OPRA™ RotaSafe used with an artificial leg and foot was evaluated in a study with a historical control, as the study was not randomized. During the 2-year study, early loosening was the most common complication that required surgical removal of the OPRA™ Implant System. Removal was normally performed within the first two years after the Stage 2 surgery. No cases of implant fracture have been reported with the OPRA™ Implant System in the OPRA™ study within 5-years of Stage 2 surgery.

The OPRA™ Implant study showed the following results to 24 months:

- Increased use and function at 12 and 24 months compared to the use of previous prosthetics system.
- 45 (89%) of the subjects in the study reached full weight bearing by the time the study ended 24 months after the second surgery.
- The most often reported adverse event was superficial (surface) infection.
- The most often reported serious adverse event that required surgery was mechanical (working parts) failure of the device, which was treatable. A serious adverse event was any event that:
    - o Resulted in death.
    - o Was life-threatening.
    - o Required inpatient hospitalization or increased the time of an existing hospitalization.
    - o Resulted in permanent or significant disability/incapacity.
- 4 (8%) subjects had their implants removed due to loosening or persistent pain.

Subjects from the OPRA™ study were also asked the following question: “Do you think the advantages outweigh the disadvantages when you add up surgeries and rehabilitation and possible complications (e.g., complications as abutment changes, superficial infections, etc.)?” This question was asked 5 years and an average 8.5 years after stage 2 surgery. Responses were recorded using a 5-point scale of “no, highly” to “yes, highly.” The vast majority of responses at both time points were that patients “highly” thought the advantages outweighed the disadvantages of the OPRA™ Implant System.

The adverse events (complications) that were related to the device and reported most often are:

- 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 complication of the Abutment and/or Abutment Screw: 4 (8%) subjects had this effect.

Table 2 summarizes all adverse events that were either related or possibly related to use of the OPRA™ device.

Table 2: Related and Possibly Related Adverse Events

Adverse Events	Total Subjects = 51		
	AEs	Number of Subjects with AEs	Percentage of Subjects with AEs
Any Adverse Event	84	44	86%
General complications	20	12	24%
Chills	1	1	2%
Impaired (poor) healing	1	1	2%
Mechanical (working parts) complication of Abutment and/or Abutment Screw	9	4	8%
Pain	6	6	12%
Fever	2	2	4%
Wound necrosis (death of tissues)	1	1	2%
Infection	44	31	61%
Superficial (skin)	40	28	55%
Deep	4	3	6%
Injury and surgical complications	13	13	26%
Loosening of the fixture resulting in device removal/failure	4	4	8%
Fracture	3	3	6%
Injury*	4	4	8%
Joint injury	1	1	2%
Post surgical bruise	1	1	2%
Muscle and tissue complications	3	3	6%
Myositis (inflamed muscle)	1	1	2%
Soft tissue necrosis (death of tissue)	2	2	4%
Skin complications	4	4	8%
Blister	1	1	2%
Skin necrosis (dead skin)	3	3	6%

*** 4 events of trauma resulting from falls**

ADDITIONAL ANALYSIS WITH 65 PATIENTS

Another analysis has been performed with a larger group of 65 patients, which includes the original OPRA™ study 51 patients above and 14 additional patients who were treated at the same hospital. Patients' results 2 and 5 years after stage 2 surgery were included in this analysis. This analysis demonstrated:

- Increased prosthetic use, prosthetic mobility, and fewer problems 2 and 5 years after surgery compared to the use of the previous prosthetics system.
- In 4 of the 65 patients the implant failed and was removed. In the remaining 61 patients no radiological signs of implant failure was observed at 2 and 5 years follow up.
- At 2 years, 44 patients (67.7%) did not have issues that required another surgery and no more than 2 superficial infections.
- Overall, most patients had improvements in the following areas 2 and 5 years after surgery:
    - o Physical function.
    - o Prosthetic use.
    - o Walking ability.
    - o Fewer problems.
- At 5 years, 28 patients (43.1%) did not have issues that required another surgery and no more than 3 superficial infections.

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.

If you have specific questions regarding air travel to and from the United States, you may contact the Transportation Security Administration on the TSA Cares toll free line (1-855-787-2227) or find more information on their web page (www.tsa.gov) under Travelers with Disabilities and Medical Conditions.

EXPECTED SERVICE LIFE

The OPRA™ Implant System is designed to have an expected service life 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 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 with patient labeling and Instructions For Use.

It is important to understand the warnings and precautions (as outlined in this document) and follow the directions of your surgeon and prosthetist (prosthesis specialist).

CONTACT INFORMATION

For additional information, please contact:

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APPENDIX 1: OPRA™ AXOR™ II REPORT FORM

REPORTER INFORMATION

Company/Clinic	Name
Address	
Phone	E-mail (for feedback reporting)

Note that information on when you should contact your doctor and the hygiene recommendations for your device are provided at the end of this form.

PRODUCT INFORMATION

Name /Ref No	Serial No	Lot No
Product return	☐ Yes	☐ No

PATIENT RELATED INFORMATION

Name initials or coded identity		Serial No on abutment	
Date of Axor™ II installation			
Axor™ II failure	☐ First fault	☐ Repeated fault	
Body height (cm)		Body weight (kg)	
Stump length	☐ Short (< 15 cm)	☐ Medium (15- 25 cm)	☐ Long (> 25 cm)

COMPLICATION REPORT

Date for removal of components

Failure type	☐ Problems to attach the Axor™ II to the Abutment	☐ Rotational release value to low/high
	☐ Problems to detach the Axor™ II from the Abutment	☐ Bend release value to low/high
	☐ Axor™ II locked in resting position	☐ Movement/play
		☐ Sound (click, rattling)
		☐ Other (please specify)
Probable cause	☐ Trauma	☐ Patient gait pattern
	☐ Body fluids/ poor cleaning	☐ Contraindication
	☐ Normal wear	☐ Other (please specify in description section)

Additional Products used

Description of Complication(s). Specify date(s) of event(s) if available. If several, clearly separate the events.

Signature: Date: Feedback required: ☐ Yes ☐ No

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CE 2797

WHEN TO CONTACT YOUR DOCTOR

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 suddenly have pain in your leg during or after weight bearing.
- You have increased pain in your leg during or after weight bearing.
- You have signs of infection which include but are not limited to:
    - o The area where the Abutment device extends out of the skin becomes red or irritated.
    - o Increasing amount of body fluid leaks from the area where the Abutment device extends out of the skin or there is a bad smell coming from that area.
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Doc.No: 003 401 06 ENG, 2021-03