OPRA™ PATIENT INFORMATION SHEET

OPRA™ Implant System Description and General Considerations

The Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA™) Implant System is intended for use in patients with above knee (transfemoral) amputations due to trauma or cancer and who have or are anticipated to have rehabilitation problems with or cannot use a conventional (socket-based suspension) prosthesis.

The OPRA™ Implant System is composed of parts that allow a prosthesis to be attached directly to the femur (thigh bone). The OPRA™ Implant System consists of seven components that are implanted during two surgeries. In the first surgery (Stage 1), the Fixture is implanted in the femur (thigh bone) and the Central Screw is inserted into the Fixture. *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. After the healing period is complete, the patient is ready for the second surgery (Stage 2). In this surgery, the Abutment is attached to the Fixture. Part of the Abutment extends outside the skin to allow the external prosthesis to be attached (Figure 1). An Abutment Screw is then attached to lock the Fixture and the Abutment together. *The healing period for this surgery is about 6 months.* Overall time commitment to surgery and recovery from surgery is anticipated to be greater than one year including rehabilitation.

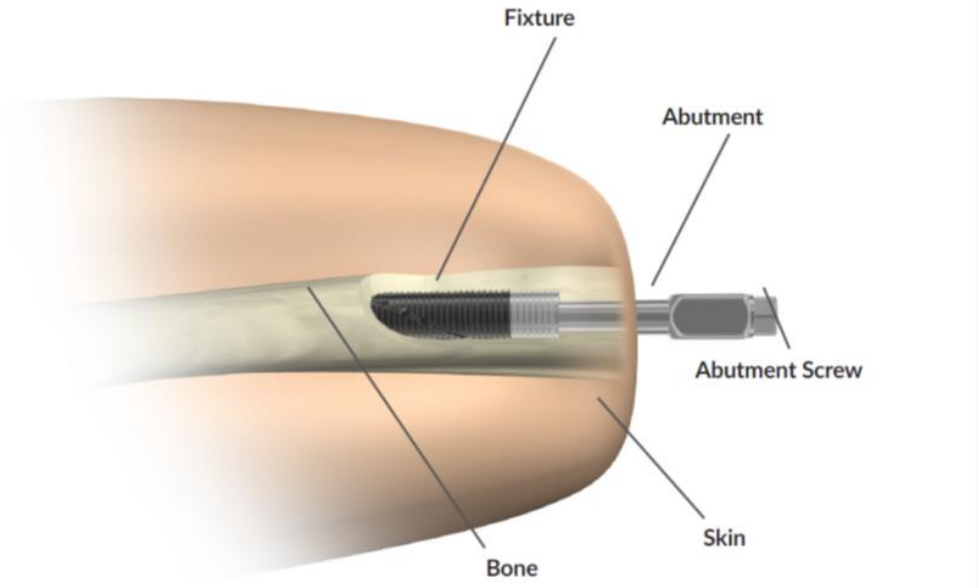

Figure 1. Fixture and Abutment Parts of the OPRA™ Implant System placed in the Femur Bone of the Amputation Stump. (Courtesy Integrum)

Am I a candidate?

The Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA™) Implant System is intended for use in patients with above knee (transfemoral) amputations on one or both sides due to trauma or cancer and who have or are anticipated to have rehabilitation problems with or cannot use a conventional (socket-based suspension) prosthesis. The OPRA™ Implant System is intended for skeletally mature patients who failed to receive benefit from socket prostheses or is expected to not tolerate socket

To be fit with an OPRA™ Implant System, the surgical and rehabilitation teams will consider the following:

- problems with recurrent skin infections and skin sores in the socket contact area,
- pain in the socket contact area,
- a short stump preventing the use of socket prosthesis,
- volume fluctuation (size change) in the stump,
- socket retention problems due to excessive sweating, or
- restricted mobility.

You may not be with a candidate for the OPRA™ Implant System if you have:

- incomplete bone maturity,
- femur (thigh) bone anatomy or deformity that would not allow placement of the implant,
- moderate to severe osteoporosis (weak bones),
- age greater than 65 years or younger than 22 years,
- body weight higher than 220 lbs. including the prosthesis,
- medical conditions that might affect treatment with OPRA™ such as severe peripheral vascular disease, diabetic mellitus (diabetes) with complications, skin disorders involving the residual limb, neuropathy or neuropathic disease, compromise of the immune system, active infection or dormant (currently not active) bacteria, and/or are pregnant.

NOTE: The OPRA™ Implant System is intended for use with commercially available non-microprocessor controlled prosthetic knees and microprocessor controlled prosthetic knees that do not include powered activation of flexion and extension of the prosthetic knee and prosthetic foot and ankles that do not include powered activation of plantarflexion.

Potential Benefits

Having the prosthesis directly anchored into the bone reduces the challenges of leg prosthesis attachment using a traditional socket 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 skin irritation problems that are common for socket-based prosthesis users.

Risks

As in all surgical procedures, the OPRA™ treatment is associated with certain risks which can lead to poor results. Some risks are minor in nature and may not require treatment or limit use of the implant system whereas other risks may be more serious and can result in the need to remove the implant system.

Improper use such as failure to follow and complete the required training, excessive physical activity creating an overload on 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) implant site infection in 28 (55%) subjects.
- Deep infection at the implant site in 3 (6%) subjects.
- Loosening of the Fixture in 4 (8%) subjects.
- Pain in 6 (12%) subjects.
- Injury in 4 (8%) subjects.
- Mechanical complication of the Abutment and/or Abutment Screw in 4 (8%) subjects.
- Myositis (inflamed muscle) in 1 (2%) subject.
- Soft tissue necrosis (soft tissue death) in 2 (4%) subjects.
- Blister in 1 (2%) subject.
- Skin necrosis (dead skin) in 3 (6%) subjects.
- Chills in 1 (2%) subject.
- Impaired (poor) healing in 1 (2%) subject.
- Fever in 2 (4%) subjects.
- Wound necrosis (death of tissues) in 1 (2%) subject.
- Fracture in 3 (6%) subjects.
- Joint injury or post-surgical bruise in 1 (2%) subject.

Importance of Following A Care Regimen

For the OPRA™ Implant System to perform as intended, it is critical that you understand the risks and potential benefits 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 ongoing monitoring in the15-20 years after implantation. It is also important to observe good hygiene (cleanliness) to minimize the risk of infection.

Evaluation and Fitting Requirements

Your local amputation care team will conduct an initial screening. If you meet the criteria noted above, you will be referred to the National Medical Director for the VHA Amputation System of Care. Next, the OPRA Specialty Team will conduct additional screening which will include a chart review, telephone interview, and either a telehealth or in-person evaluation.

Following completion of initial screening, determination will be made whether you are an appropriate candidate to proceed with evaluation. If you are determined to be appropriate, further pre-surgery screening will be completed. Travel and lodging eligibility and requirements will be determined. Scheduling for surgery will take place when all the prior steps have been completed.

Travel and Housing Requirements

Depending on where you live, you may be required to travel to a specialty center for your surgery and for your rehabilitation following the surgery. When you are ready to proceed with initial prosthesis fitting following stage 2 surgery, you may need to travel and to lodge for approximately 4 weeks at a VA OPRA Specialty Program site. Travel and lodging arrangements will be coordinated once the initial fitting and rehabilitation date is confirmed. A Veteran's local VA medical center and the VA OPRA Specialty Program site are the main points of contact for travel and Beneficiary Travel regulations are to be followed if travel is necessary.

Who do I contact for more information?

To request additional information or to be considered for the OPRA™ Implant System, please contact Joseph B. Webster, M.D.; National Medical Director for the VHA Amputation System of Care at (804) 675-5648 or by email joseph.webster@va.gov. For more information about the Amputation System of Care go to Amputation System of Care (ASoC) - Rehabilitation and Prosthetic Services (va.gov).