

# OSSEOINTEGRATION AND THE VA OPRA™ IMPLANT SYSTEM PROGRAM

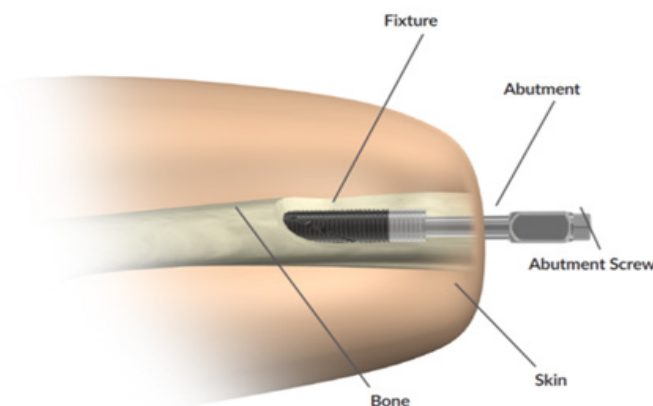
The Department of Veterans Affairs (VA) is now offering osseointegration and the Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA™) Implant System to qualified Veterans

## Osseointegration General Description

Osseointegration provides a mechanism for the direct skeletal attachment of an artificial limb to the residual limb of a person with an amputation and eliminates the need for a socket. Compared to socket suspension techniques, direct skeletal attachment of a prosthetic limb through osseointegration offers many potential advantages including improved mechanical transfer of motion, reduced skin irritation from a prosthetic socket, improved joint range-of-motion, and enhanced comfort. Osseointegration also presents the risk of serious complications such as infection, failure of the implant, and bone fracture. In addition, the osseointegration surgical procedure requires not using a prosthesis for a period of time along with an extensive period of rehabilitation.

## OPRA™ Implant System Description and General Considerations

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. The overall time commitment for surgery, recovery and rehabilitation is anticipated to be greater than one year.



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## Am I a candidate?

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The 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.

## Potential Benefits and Risks

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Having the prosthesis directly anchored into the bone reduces the challenges of using a traditional socket. This is shown by results from amputees already treated with the OPRA™ Implant System. 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.

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.

## Who do I contact for more information?

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To request additional information or to be considered for the OPRA™ Implant System, please contact your local amputation care provider at the VA Medical Center where you receive services. You may also contact Joseph B. Webster, M.D.; National Medical Director for the VHA Amputation System of Care at 804-675-5000 extension 7036 or [Joseph.Webster@va.gov](mailto:Joseph.Webster@va.gov) or Patty Young, MSPT, CP; National Program Manager for the VHA Amputation System of Care at 804-676-8929 or [Patricia.Young8@va.gov](mailto:Patricia.Young8@va.gov).