Improving life

OUR VISION IS TO CONTINUOUSLY LEAD THE IMPROVEMENT OF MEDICAL DEVICES USING EVIDENCE BASED DEVELOPMENT

Anchoring a prosthesis directly to the body, results in an amazing improvement in quality of life for individuals with amputations.
A significant increase in function and mobility, gives patients with bone-anchored prostheses a new opportunity to return to normal life.

REHABILITATION OF INDIVIDUALS WITH AMPUTATIONS

OUR VISION IS TO CONTINUOUSLY LEAD THE IMPROVEMENT OF MEDICAL DEVICES USING EVIDENCE-BASED DEVELOPMENT

The trauma of losing a limb changes life dramatically. Adapting to the new situation is often very demanding for patients and their families. With the aim of returning to their lifestyle before amputation, the choice of rehabilitation method must therefore be individually selected based on the needs of the patient.

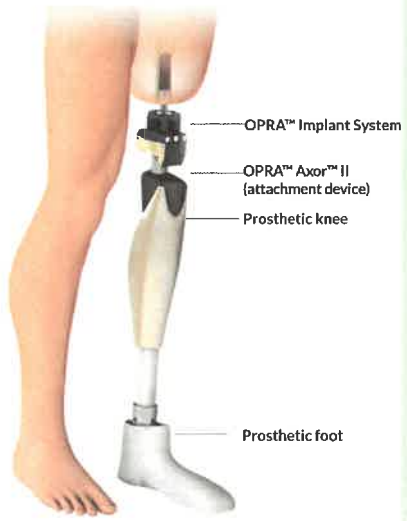
SOCKET PROSTHESES

Individuals with amputations are traditionally fitted with a socket prosthesis attached to the amputation stump. Problems related to the socket prosthesis often include discomfort, sores and pain in the residual limb. Moreover, the procedure of attaching/detaching the prosthesis is often cumbersome. A comfortable and firmly attached prosthesis that can be used all day, is generally hard to achieve, why patients may even choose not to use a prosthesis at all.

BONE-ANCHORED PROSTHESES

An alternative to the conventional socket is a bone-anchored prosthesis, allowing direct connection of an artificial limb to the skeleton. A bone-anchored prosthesis is firmly attached through a quick connection. Since it is not in contact with the skin, all issues related to the sockets are eliminated. This allows wearing the prosthesis continuously with greater comfort. Furthermore, only a bone-anchored prosthesis provides the liberating possibilities of free movement and sensory feedback (e.g. feeling the ground you are walking on).

Bone-anchorage of prostheses is a pioneering treatment, based on long term documentation of osseointegration that improve the quality of life for individuals with amputations and their families.



OPRA™ transfemoral patient.

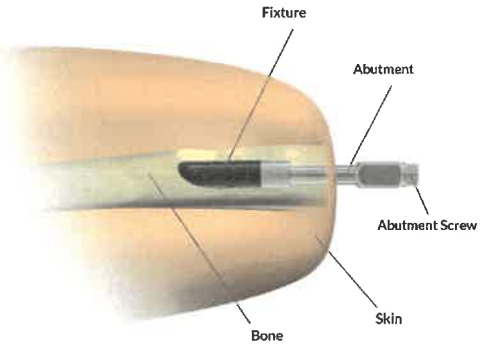
BENEFITS OF BONE-ANCHORED PROSTHESES COMPARED TO SOCKET PROSTHESES

- Increased range of motion
- Eliminates pressure, sores and pain caused by the socket
- Stable attachment
- Easy attachment and detachment
- Better mobility
- Improved osseoperception (Feel the ground under your feet)
- Can be worn all day, every day
- Improved comfort while sitting
- No socket adjustments required
- Suitable for short amputation stumps

...all contributing to **improving quality of life.**

OPRA™ IMPLANT SYSTEM

The OPRA™ Implant System is a bone-anchored prosthesis system based on osseointegration, where the prosthesis is directly attached to the bone and therefore avoiding the use of a socket. The system consists of three parts; an anchoring element (the Fixture) and a skin penetrating connection (the Abutment), secured with a screw (the Abutment Screw)



A REVOLUTIONARY CHANGE

Since the first patient was treated in 1990, more than 500 patients with amputations around the globe have been treated, showing functionality for more than 25 years after treatment. The treatment has been successfully used for several amputation levels such as above/below knee, above/below elbow, fingers and thumbs.

A clinical investigation of 51 subjects with transfemoral amputation (above knee), treated with OPRA™, reported functionality with a cumulative survival rate at 5 years was 92% and the revision-free survival rate was 45%[1]. Thirty-four patients had 70 superficial infections. Eleven patients had 14 deep infections. Fifteen patients had mechanical complications. Four fixtures were removed (ie, one deep infection and three loosening). Patient-reported (PRO) outcome measures, showed significant improvements including longer and more frequent use of the prosthesis, better mobility, fewer issues and improved physical health-related quality of life (all $P < 0.0001$) compared with baseline. Conclusion: Individuals with transfemoral amputations at 5-year follow-up had significant improvement in PRO measures, but increase in deep infections and mechanical complications are concerning. Results from in-depth interviews reported by Lundberg, Hagberg & Bullington (2011)[2], showed that patients using a bone-anchored prosthesis experienced a revolutionary change that went beyond the functional gains, to improve quality of life. One of the patients expressed this in the following way:

"The other prosthesis ruled my life, it was my master in a way, it's inevitable... it affected my mood and my interest in doing things that I knew would demand an extra effort. You had to weigh the pros and cons and that's all gone now. Now it's actually me... I am in command and not the left leg (socket prosthesis) and that's a big difference."

THE OPRA™ IMPLANT SYSTEM

- Only FDA approved bone-anchored prosthesis system
- Modular design allows future upgrades and access to technical advancements

References:

[1] Brånemark, R., Hagberg, K. Kulbacka-Ortiz, K., Berlin, Ö., Rydevik, B. (2018). Osseointegrated percutaneous prosthetic system for the treatment of patients with transfemoral amputation: A prospective five-year follow-up of patient-reported outcomes and complications. J Am Acad Orthop Surg, doi: 10.5435/JAAOS-D-17-00621

[2] Lundberg, M., Hagberg, K., & Bullington, J. (2011). My prosthesis as a part of me: a qualitative analysis of living with an osseointegrated prosthetic limb. Prosthet Orthot Int, 35(2), 207–14v

THE OPRA™ 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 without limitations. 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

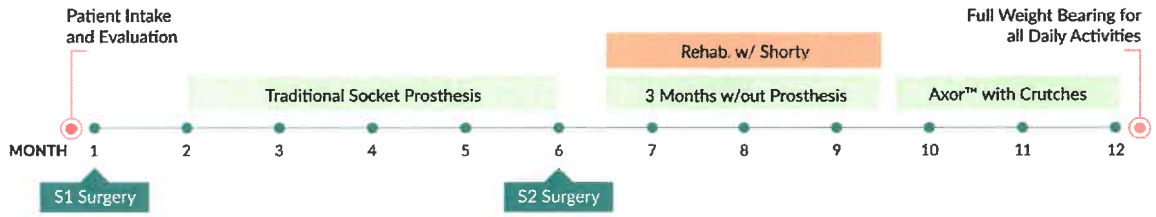
Following the S1 surgery a 3–6 month period of healing is achieved to allow the bone tissue to thoroughly integrate around the implant. During this healing period a traditional socket prosthesis can be utilized.

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 re-attached 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.



HELPING PATIENTS WORLDWIDE

Integrum has since the start in 1998 been helping individuals with amputations towards an improved quality of life. A thorough experience in osseointegration has generated a system for bone-anchored prostheses – a beneficial alternative to the traditionally used socket prosthesis. Integrum is world leading in this area, with patients from all parts of the world treated in well renowned clinical centres. Performing continous research and development, Integrum aims at providing safe medical devices and supporting a more active life-style. In order to meet individual needs, custom-made solutions are developed in close collaboration with scientists and clinicians.

OSSEOINTEGRATION

The technology of bone-anchored prostheses is based on the principle of osseointegration, which is the ability of titanium to naturally integrate with bone, and thereby stay fixated to the body. Osseointegration was discovered in Gothenburg by Prof. PI. Brånemark in 1952. Other applications successfully using osseo-integration include dental implants, craniofacial prostheses, bone-anchored hearing aids and joint replacements.

INTEGRUM AB

Krokslätts Fabriker 50
SE-431 37 Mölndal, Sweden
PHONE: +46 (0)31-760 10 60
EMAIL: info@integrum.se
WEBSITE: www.integrum.se

INTEGRUM INC

100 Montgomery Street, Suite 1780
San Francisco, CA 94104, USA
PHONE: +1(800) 805-8073
EMAIL: info-US@integrum.se
WEBSITE: www.integrum.se

Doc.No: 004 005-06 ENG. 2021-08