

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.

Integrum

Rehabilitation of individuals with amputations

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

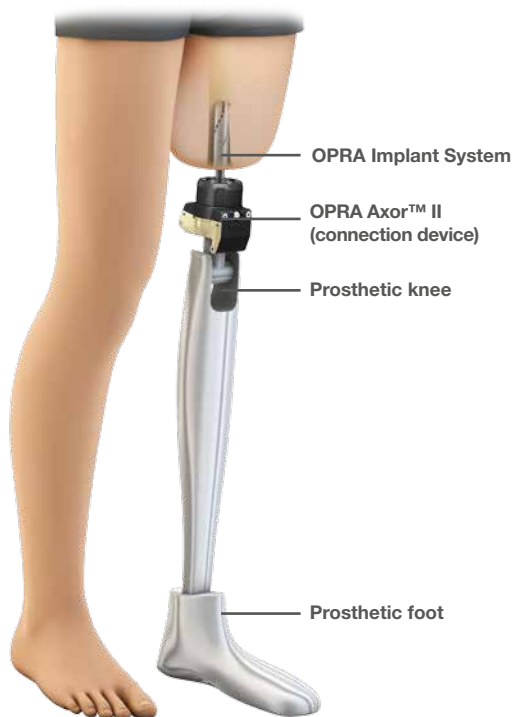
Socket prostheses

Individuals with amputations are traditionally fitted with a socket prosthesis suspended to the amputation stump. Problems related to the socket include discomfort, sores and pain of 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 the direct connection of an artificial limb to the skeleton. A bone-anchored prosthesis is firmly attached through a quick connection. Since it is not supported over the skin, all issues related to the sockets are eliminated. This allows wearing the prosthesis continuously with higher 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, built on experienced concepts that improve the quality of life for individuals with amputations and their families.



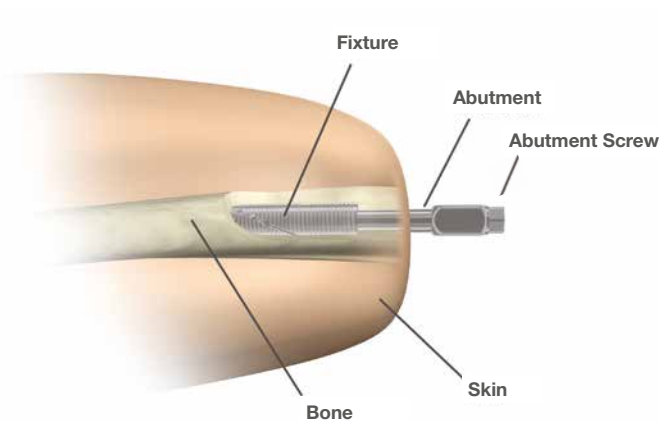
Benefits of bone-anchored prostheses compared to socket prostheses

- Increased range of motion
- Eliminates pressure, sores and pain caused by the socket
- Stable attachment
- Easy attachment and detachment
- Better walking ability
- Improved osseoperception (sensory feedback)
- Can be worn all day, every day
- Improved sitting comfort
- No socket adjustments required
- Suitable for short amputation stumps

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

OPRA Implant System

The OPRA Implant System for bone-anchored prostheses serves as a stable and direct connection to the amputation prosthesis. The system consists of 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 400 patients around the globe with amputations have been treated, showing functionality for more than 20 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 of 92% at 2 years follow-up (Brånemark et al, 2014 Jan)¹. The study showed statistically significantly increased prosthetic use, better prosthetic mobility, fewer problems, a better overall amputation situation and improved quality of life. Results from in-depth interviews reported by Lundberg et al (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.'

Treatment protocol

The implant components are surgically inserted into the bone of the amputation stump in two separate surgical sessions. The patient can continue to use a socket prosthesis between the two sessions.

The patient's prosthesis is then attached to the outer part of the Abutment through the Axor™, a load control device that protects the implant from accidental loads in both bending and rotational directions by means of a release mechanism.



References:

¹ Brånemark R, Berlin Ö, Hagberg K, Bergh P, Gunterberg B, Rydevik B. A novel osseointegrated, percutaneous prosthetic system for treatment of patients with transfemoral amputation. A prospective study of 51 patients. Bone Joint J 2014;96-B:106-13.

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

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 12 clinical centres. Performing continuous 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.



Countries where the OPRA treatment has been performed: Sweden, Australia, Belgium, Chile, Denmark, France, Great Britain, Hungary, Jordan, Netherlands, Portugal and Spain.

For more information, visit our website; www.integrum.se

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. P.I. Brånemark in 1952. Other applications successfully used include dental implants, craniofacial prostheses, bone-anchored hearing aids and joint replacements.

Humanitarian Device

Authorized by Federal law for use in patients with transfemoral amputation due to trauma or cancer and who has rehabilitation problems with or cannot use a conventional socket prosthesis. The effectiveness of this device for this use has not been demonstrated.

The Axor prosthetic connection component is pending FDA approval and not available for sale within the United States.



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