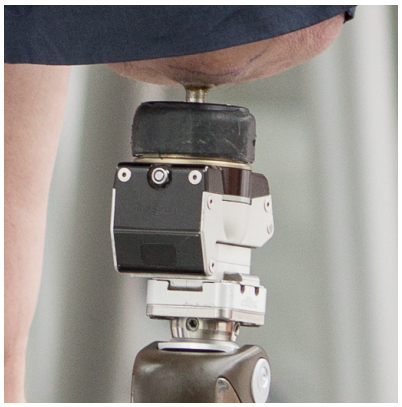
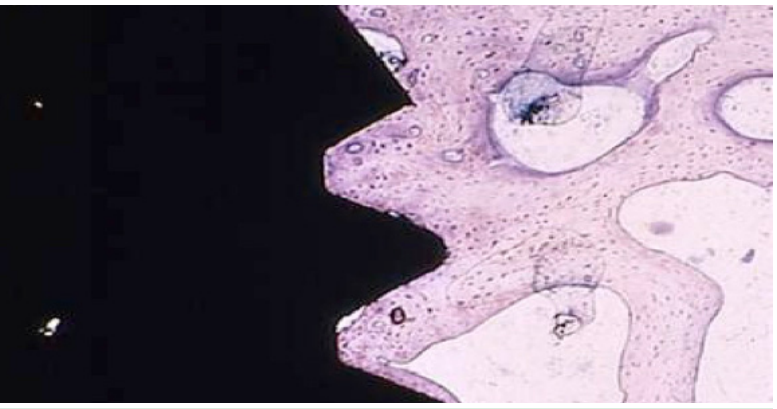
OPRA™ IMPLANT SYSTEM

BONE ANCHORED PROSTHETICS – ELIMINATING THE NEED FOR SOCKETS





Mr. Erik Ax,
OPRA™ Implant System user since 1999, Hyggen, Norway

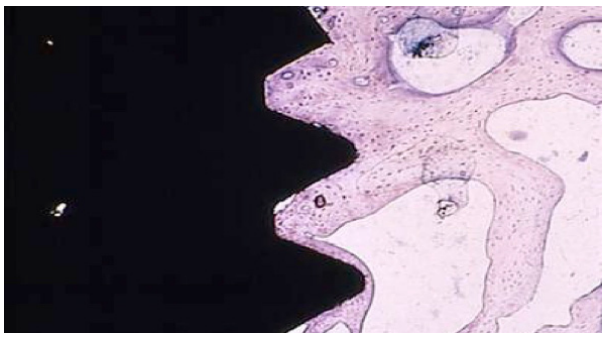
Integrum

BONE ANCHORED PROSTHETICS

The science behind bone anchored prosthetics is powered by the principles of osseointegration. Osseointegration relates to the ability for certain implant materials to interact with bone in a way which makes the interface between bone and implant basically indiscernible. An invisible interface between the implant and the patient's bone produces solid fixation.

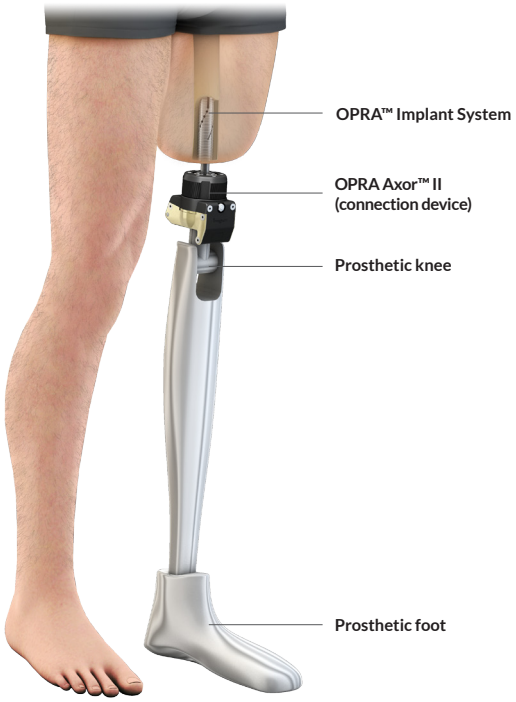
The entire field of osseointegration was established by the pioneering work of Prof PI Brånemark, who in 1962 identified complete titanium integration into bone while studying microcirculation in the bone of an animal model. Over the past 50 years this discovery has lead to new treatments and entirely new fields of medicine. The impact of osseointegration has helped millions of individuals with the technology applied to restoration of teeth by way of the modern dental implant and the bone-anchored hearing aid.

Prof PI Brånemark and Prof B Rydevik performed the first surgery in 1990, rehabilitating a female transfemoral amputee who had been unable to use a traditional socket prosthesis. Dr. Rickard Brånemark, orthopaedic surgeon and Integrum's Founder, expanded upon his father's pioneering work and applied the principles of osseointegration to rehabilitation of transfemoral amputees.



Bone is shown in purple (right) against the titanium implant in black. Note the tight interface between bone and implant, this is visible evidence of osseointegration.

A cell is attaching to the titanium surface initiating the osseointegration process.



BENEFITS OF THE OPRA™ IMPLANT SYSTEM

- Elimination of Socket Related Problems (Hagberg et al 2014)
  - Skin irritations, ulcers and perspiration – all eliminated
  - Allows volume fluctuation and weight gain/loss
  - Greater comfort during sitting
- Enhanced Proprioception & Osseoperception (Häggström et al 2013)
  - Intuitive awareness of limb positioning in space
  - Increased sense of feel through the prosthesis
- Easy Prosthetic Attachment (Carroll et al 2006)
  - Donning and Doffing in less than 10 seconds
  - Extremely easy and the same way every time
- Increased Range of Motion and Limb Strength (Hagberg et al 2008)
  - Wear time and daily steps increase
  - Improved force production in residuum

Hagberg, K., Hansson, E., Brånemark, R., (2014) Outcome of percutaneous osseointegrated prostheses for patients with unilateral transfemoral amputation at two-year follow up. Arch Phys Med Rehabil, 95, 2120-7

Häggström, E., Hagberg, Rydevik, B, Brånemark R., (2013). Vibrotactile evaluation: Osseointegrated versus socket-suspended transfemoral prostheses. J Rehabil Res Dev, 50 (10), 1423-34

Carroll, K, Edelstein, J (2006). Prosthetics and Patient Management: a Comprehensive Clinical Approach. (pg. 236) SLACK Inc.

Hagberg, K., Brånemark, R., Gutenberg, B., Rydevik, B., (2008). Osseointegrated trans-femoral amputation prostheses: prospective results of general and condition-specific quality of life in 18 patients at 2 year follow-up. Prosthet Orthot Int, 32(1), 29-41

OPRA™ IMPLANT SYSTEM INDICATIONS

The device is indicated for use in patients with transfemoral amputation due to trauma or cancer and who has rehabilitation problems with or cannot use conventional socket prosthesis.

OPRA™ consists of an anchorage element (Fixture) and a skin-penetrating device (Abutment). The Fixture is surgically inserted in the medullary canal of the remaining femoral skeleton and, after a healing time of six months, the Abutment is connected to the Fixture. The amputation prosthesis is then attached directly to the external part of the Abutment, via the OPRA™ Axor™. For further information, please see the OPRA™ Axor™ Manual.

The postoperative rehabilitation is standardized with controlled levels of loading. Full weight bearing with the definitive prosthesis is normally achieved approximately 6 months after S2 surgery.

The OPRA™ Implant System PMA approval by FDA, 2020, was based on an analysis[1] performed with a group of 65 patients, which included an earlier OPRA™ study of 51 patients[2] 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:

- Physical function
- Prosthetic use
- Walking ability
- Fewer problems

At 5 years, 28 patients (43.1%) did not have issues that required another surgery and no more than 3 superficial infections.

[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] Brånemark, R., Berlin, Ö., Hagberg, K., Bergh, P., Gunterberg, B., & Rydevik, B. (2014). **A novel osseointegrated percutaneous prostheic system for the treatment of patients with transfemoral amputation A prospective study of 51 patients.** Bone & Joint Journal, 96(1), 106-113.

THE OPRA™ TREATMENT PROTOCOL

The OPRA™ Implant System for individuals with transfemoral amputations requires two surgeries, six months apart to insert the components into the residual limb and allow for proper osseoanchoring. The six months healing allows for a strong bone bond to form. Within three weeks following the second surgery the individual begins the rehabilitation process. In about 180 days from this point the rehabilitation should be complete and amputees can use their bone anchored prosthesis without limitations. More specific details are identified below:

1 PATIENT SCREENING

Each individual that 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 (threaded cylinder implant) 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

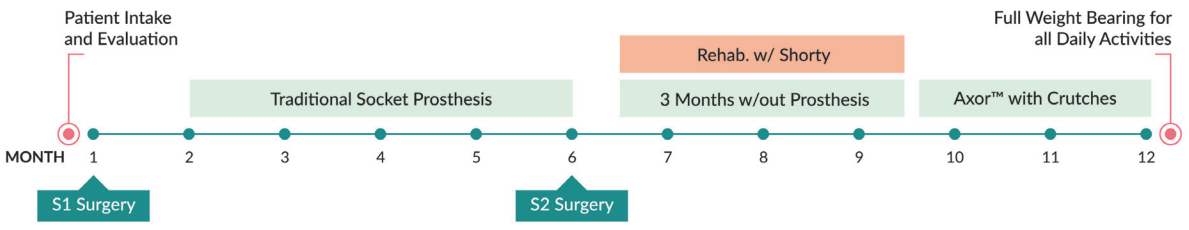
Following the S1 surgery a six month period of healing is achieved to allow the bone tissue to thoroughly integrate around the implant. During this healing period a traditional socket prosthesis can be utilized.

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 reattached 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 now 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. 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

In December 2020, Integrum became the first and only company to receive, by FDA, PMA approval in the United States for its Osseoanchored Prosthesis for the Rehabilitation of Amputees or OPRA™ Implant System for above knee amputees.

Integrum was founded in 1998 with the goal of improving the quality of life for amputees through use of bone anchored prosthetic technology. Since the early 1990's the procedure, instrumentation, implants and rehabilitation protocol have been meticulously evaluated and further refined. This work lead to the introduction of the OPRA™ Implant System, a solution for suffering transfemoral amputees that is available in the US and worldwide.

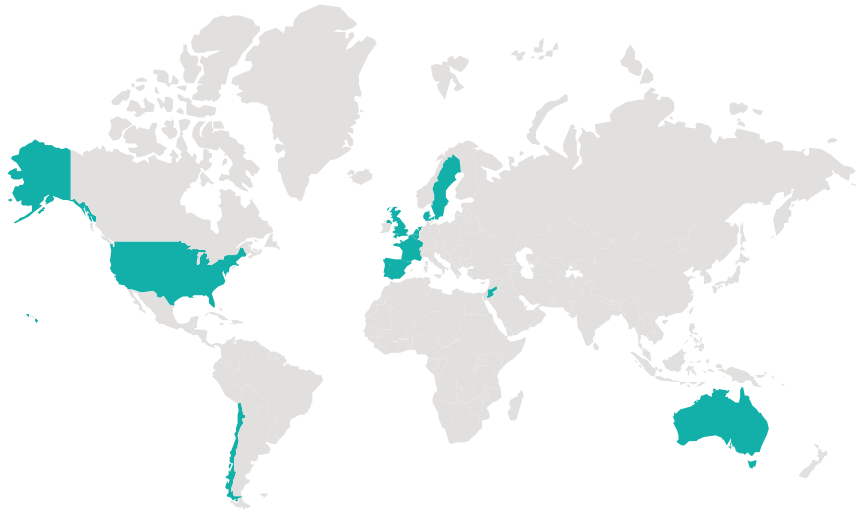
A partial list of countries where the OPRA™ Implant System has been used is as follows: Australia, Belgium, Chile, Denmark, France, Great Britain, Hungary, Jordan, Netherlands, Portugal, Spain, Sweden and USA.

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

"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 and that's a big difference"

Transfemoral OPRA™ Implant System User
(Lundberg et al 2011)

Lundberg, M, Hagberg, K, & Bullington, J.,(2011) My prosthesis as a part of me: a qualitative analysis of living with an osseointegrated prosthetic limb. Prosthetics and Orthotics International 35(2) 207–214.



FDA-Approved Humanitarian Device.

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

FDA Approval P190009: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190009

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Doc.No: 008 287-01 ENG, 2021-08