



Longitude™ Stem

Above Knee Osseointegration



What is Osseointegration ?

Osseointegration is a surgical procedure for amputees that allows an external surgical implant to be directly attached into the bone. The surgery is a two-stage process over a 6-8 week period with a post-surgery rehabilitation program.

Stage 1: Insert Femoral Implant

The femoral implant is inserted into the femur during the first surgery.

Stage 2: Insert External Prosthesis

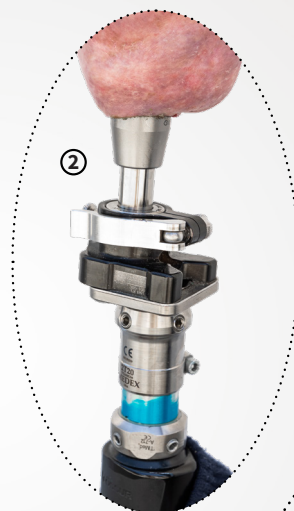
After the patient recovers for 6-8 weeks and the implant undergoes osseointegration, the external prosthesis is inserted into the stub.

What is an endo-exo prosthesis ?

An endo-exo prosthesis is a modular prosthesis designed to osseointegrate with the intermedullary canal of the femur to act as a transcutaneous, distal intramedullary device, with a distal external coupling system which serves to connect with the above knee amputation (AKA) prosthetic.

It consists of:

- 1) An endo-exo femoral prosthesis that provides a secure and durable fixation within the femur.
- 2) A distal hard-point attachment that exits through the skin that allows an attachment to a prosthetic limb, providing direct transmission of load to the external component.



Latitude™ Stem
Below Knee Osseointegration

Longitude™ Stem
Above Knee Osseointegration



Indications for an endo-exo implant ?

You may be considering an osseointegration implant if you are an amputee who had experienced:

- Traumatic injury.
- Infection in a joint replacement that did not respond to antibiotics or alternative treatments.
- Cancer where tumours are formed around the bone or muscle.
- Neuroma when a nerve issue is thickened.
- Frostbite.
- Burns.

Surgical Technique

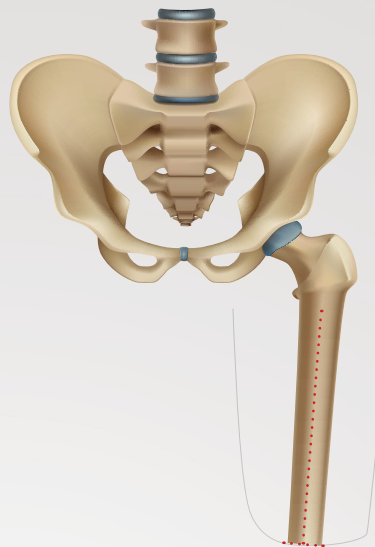
Full Surgical Technique on

<https://www.signatureortho.com.au/Osseointegration/>

STAGE 1

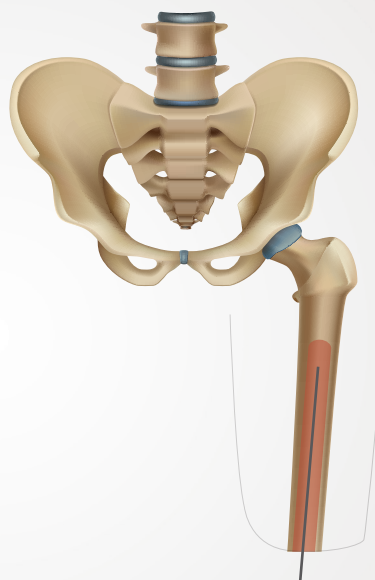
01 Femoral Preparation

Preparation of the soft tissue and uncovering of the distal femur.



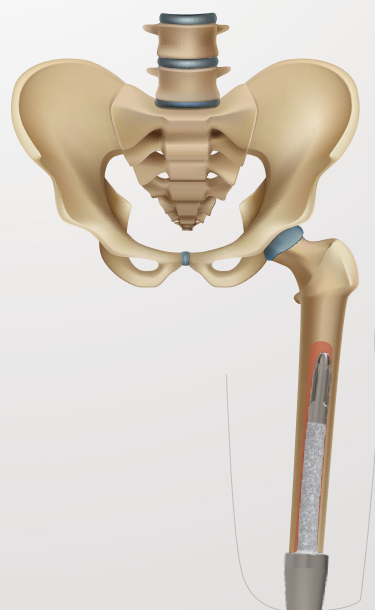
02 Canal Reaming

Using a modular Olive reamer. Ream the medullar cavity to the predetermined diameter



03 Implant Insertion

Insert the implant into the bone using the Stem Impactor.



Surgical Technique

Full Surgical Technique on

<https://www.signatureortho.com.au/Osseointegration/>

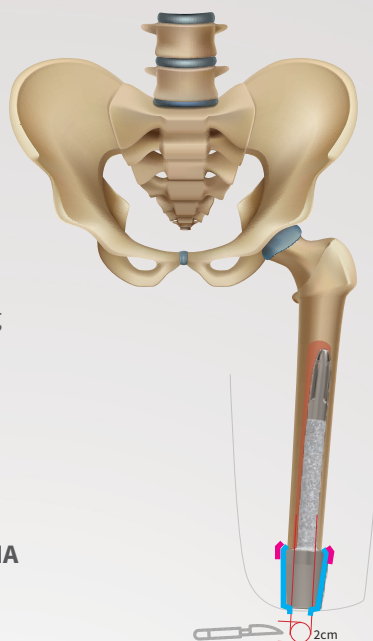
STAGE 2

04 Preparation for Component Insertion

Locate the end of the implant and using a scalpel cut a Ø20mm hole, to fit the post center of the stem.

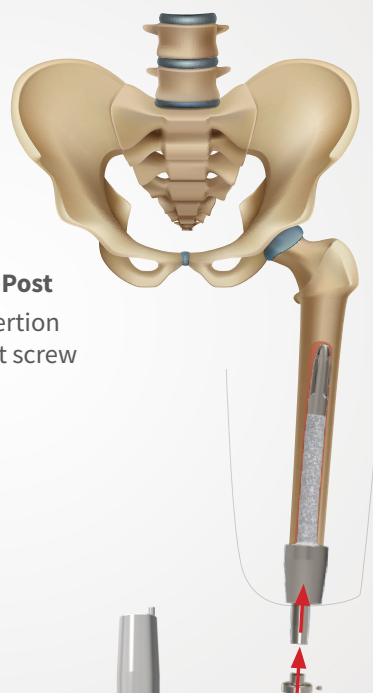
(Soft Tissue interface: stoma/skin)

- OLD Fashion : **WET STOMA**
- CURRENT Best Practice : **DRY STOMA**



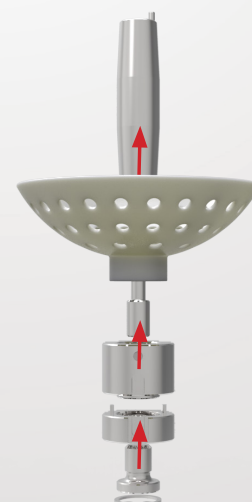
05 Insertion and assembly of Dual Taper Post

Insert the Dual Taper Post using the Insertion Tool and fasten with the Dual Taper Post screw to specified torque



06 Assembling the Silicon Cap and the Preparatory Sleeve and Cap

Gently push the Silicon Cap over the assembly to hold the gauze. Then assemble the Preparatory Sleeve and the Preparatory Cap to protect the Taper.



STAGE 3

Prosthesis connection after rehabilitation and implant full implant integration.



Longitude™ Stem Features

Signature Orthopaedics' Longitude™ and Latitude Implant System is a solution that offers improved functionality and lifestyle of an amputee over conventional prosthetic devices.

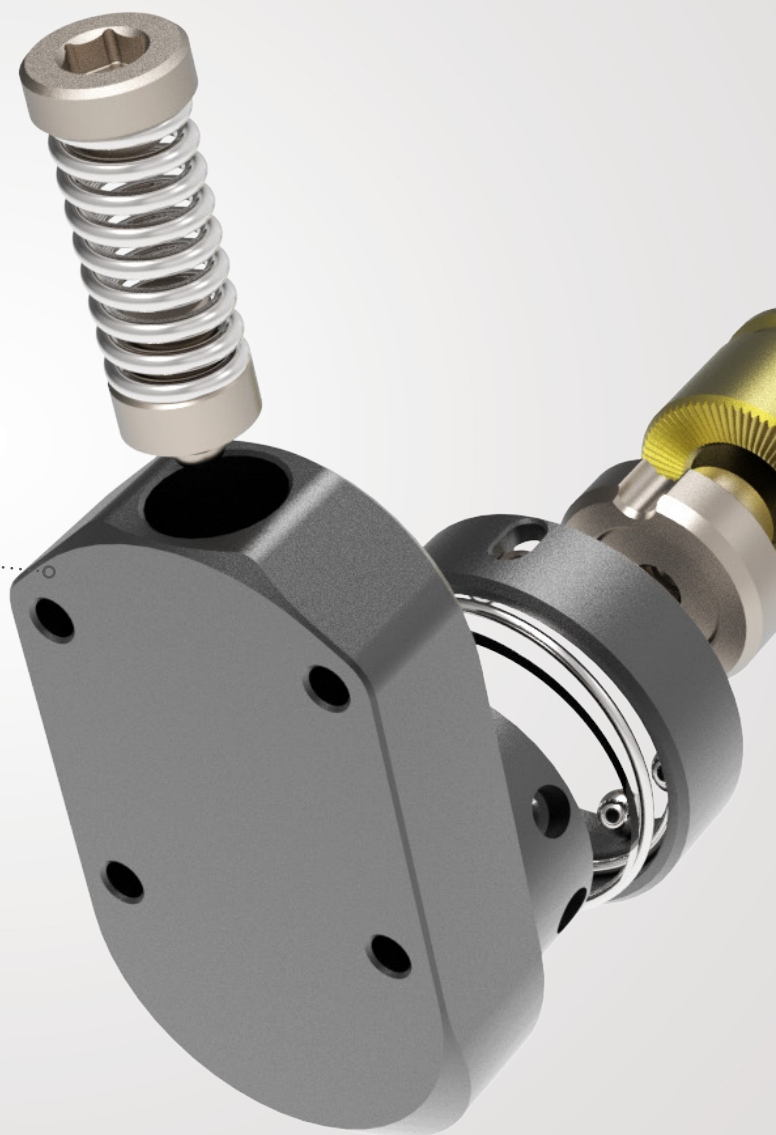


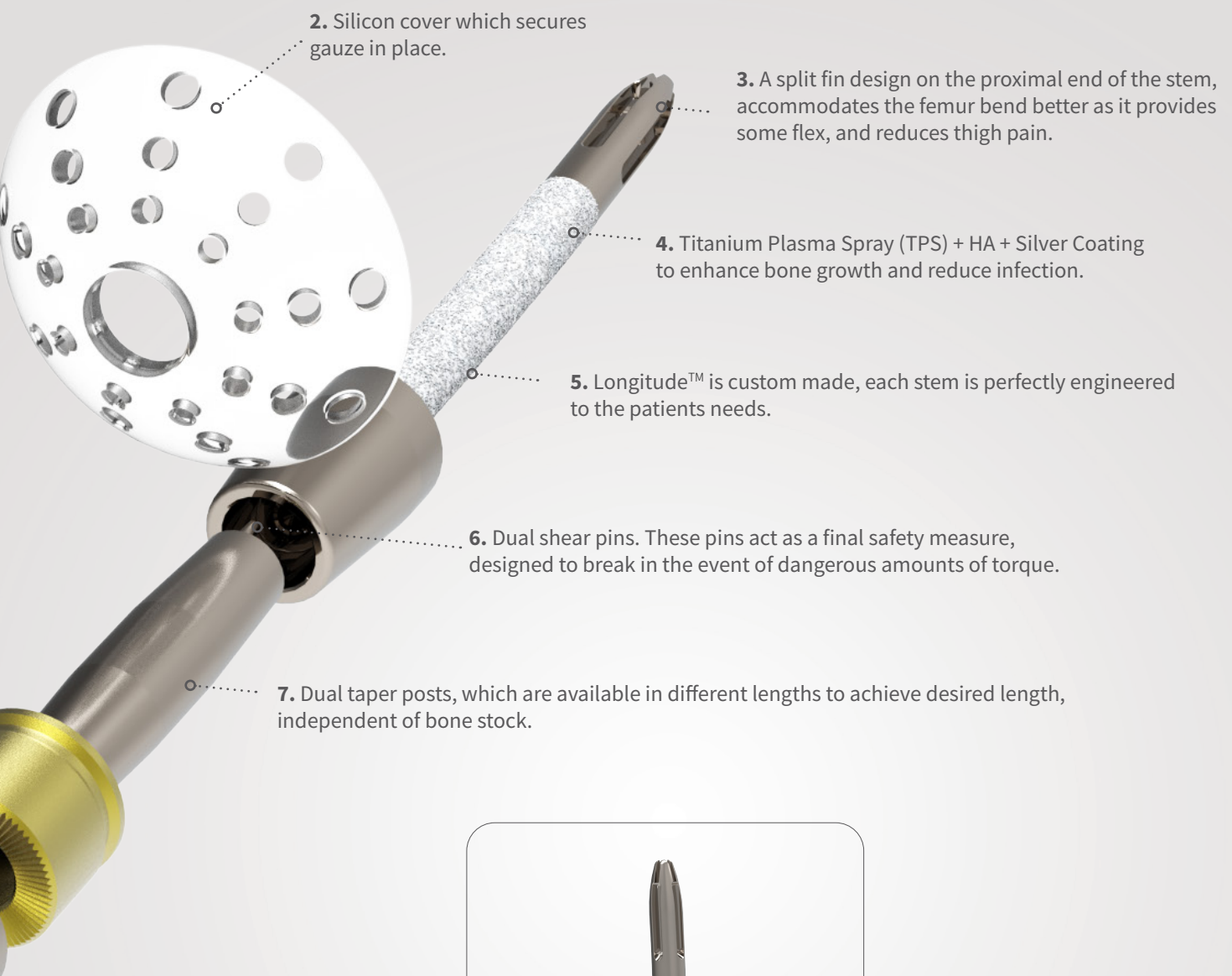
..... **An endo-exo femoral prosthesis**

that provides a secure and durable fixation within the femur

..... External Attachment

1. The Longitude™ stem is designed to work with various 3rd party leg adaptors in addition to our own. SignatureOrtho leg adaptor includes safety limits and quick release levers as standard.





What are the benefits?

Signature Orthopaedics' state-of-the-art osseointegration implants aim to help amputees achieve a new level of mobility, control and comfort over conventional prosthetic devices.

Increased joint range of motion

Long-term muscular development is improved with increased range of motion.

Stability

Direct load transmission from bone to prosthesis restoring full control and stability of the limb.

Longer periods of endurance and improved sureness of walking compared with shaft prosthesis.

Improved gait symmetry

A more natural gait and mobility are achieved with increased muscle use.

Accommodating weight changes

Changing body weight and the resulting modified stump form.

Pain improvement

An overall pain improvement is achieved with reduced energy expenditure.

Regenerate proprioception

Perception of the position and movement of the body is restored as awareness of ground and general surfaces improves.

Comfort

All socket problems such as discomfort, bruising, rubbing, and sweating are eliminated.

Lack of dependence on already existing scars.

Easy to operate

Simple second-stage procedure that involves a single screw attachment that can be done in seconds.

Fast rehabilitation

Post-surgery rehabilitation program reduces overall recovery period by 4 to 6 weeks.

Cost-effective

Save significantly on cost as regular socket re-fittings are no longer needed.

What is the clinical summary of endo-exo prosthesis?

Clinical outcomes from a case series¹

	Current Study	Current Study	Hagberg and Branemark 2001		Hagberg et al 2014	Hagberg et al 2008	Branemark et al 2014
	OI (Unilateral Only)	OI	Amputee	Match-general population	Amputee	Amputee	Amputee
Sample size	8	9	97	1067	39	17	51
Physical Functioning	46.9, 34.2, 59.6, 43 (30-85)	42.8, 29, 56.6, 40	46.45, 41.4, 51.5	86.35, 85.2, 87.5	35.7, 29.0, 42.4, 30	31, 21, 41	35, 29.0, 41.0, 30
Role Functioning-Physical	56.3, 25.9, 86.6, 63 (0-100)	50.0, 20.6, 79.4, 50	49.5, 40.6, 58.4	81.5, 79.5, 83.5		38, 16, 60	41, 34.9, 47.1, 25
Bodily Pain	61.9, 50.8, 72.9, 64 (45-90)	55.0, 38.4, 71.6, 58	50, 45.2, 54.8	72.1, 70.5, 73.7		53, 36, 71	55, 47.9, 62.1, 51
General Health	83.1, 71.5, 94.7, 85 (60-100)	78.3, 64.4, 92.2, 80	65.4, 60.8, 70.8	72.7, 71.2, 74.1		75, 64, 86	78, 73.1, 82.9, 82
Vitality	71.3, 59, 83.5, 75 (35-85)	63.3, 44.4, 82.2, 75	56.0, 51.2, 60.8	67.0, 65.0, 68.9		61, 50, 72	60, 54.5, 65.5, 60
Social Functioning	78.1, 63.7, 92.6, 88 (50-100)	69.4, 48.2, 90.7, 88	76.7, 72.0, 81.4	87.0, 85.7, 88.3		80, 74, 96	78, 71.1, 84.9, 88
Role Functioning-Emotional	79.2, 51.7, 106.6, 100 (0-100)	70.4, 40.7, 100.1, 100	70.5, 62.4, 78.6	85.1, 83.3, 86.90		78, 61, 95	75, 64.2, 85.8, 100
Mental Health	81.5, 66.5, 96.5, 90 (32-100)	76.9, 60.9, 92.9, 88	72.9, 68.6, 77.2	80.1, 78.9, 81.3		76, 68, 84	74, 68.2, 79.8, 80
PCS	62.0, 49.3, 74.7, 66 (36-86)	56.5, 41, 72.1, 63			32.1, 29.2, 35.0, 30.5	31, 27, 35	74, 68.2, 79.8, 80
MCS	77.5, 64.3, 90.7, 88 (53-96)	70.0, 51.3, 88.7, 88				55, 51, 59	53, 49.4, 56.6, 57

Discussion:

This prospective case series sought to evaluate a unique OI device and its impact on recipient patients' quality of life and function. Study group patients were evaluated for differences in quality of life based on the SF36 and Q-TFA, prosthetic use, residual limb pain, back pain, and overall satisfaction in transfemoral amputees relative to their peers. The results were consistent with previously published literature comparing patients treated with OI. (cite) Although not all findings were statistically significant, all metrics measured were found to be trending higher than those reported by peers not treated with OI. The improvements in scores are likely due to clear expectations, risks and benefits of the device, proper skin care, patient motivation, and previously failed use of a traditional socket suspended prosthesis.

191-042-100 Osseointegration Design Rationale and Surgical Technique REV B

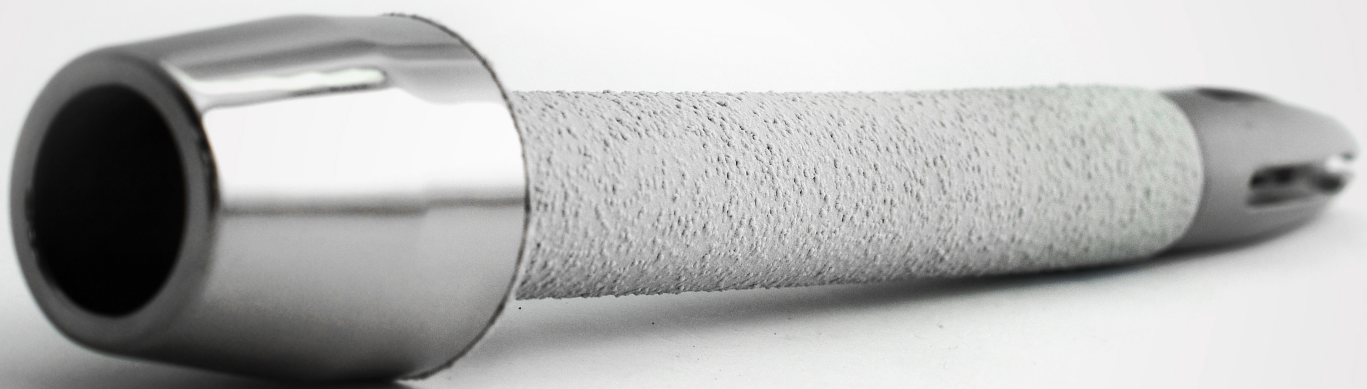
What Makes Us Different?

1. **SignatureOrtho™** Endo-Exo prosthesis uses a clinically proven cylindrical press fit porous coated design. A traditional approach to fix internal prostheses where on-growth of bone is important. The principles of this design are derived from femoral hip prosthesis.
2. **SignatureOrtho™** Endo-Exo prostheses are coated with an Acusure Ag® coating. This innovative surface coating, which harnesses the anti-microbial properties of silver to significantly reduce infection rates following implant surgery. Implants treated with Acusure Ag® technology have been shown to remain clear of biofilm formation, and clinical data from the field of tumour implants has shown a demonstrable reduction in infection rates in patients treated with Acusure Ag® coated implants.
3. Unique proximal tip geometry allowing for a better fit, and reduced thigh pain.







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