



## Clinical Evaluation Summary

CES LX S01

### Lindhe - Xtend Connect

Warranty Period - 1 year

Weight Limit - 100kg

Quick Fit Unit	Base Unit
Tube clamp	Female pyramid adapter
4 - hole socket adapter	Male pyramid adapter
Female pyramid adapter	

This summary has been compiled from the results of a number of returned Clinical Evaluation forms, completed by both prosthetists and patients. It is an attempt to give an overview of the product based on our experience to date and should be read in conjunction with the product literature supplied by the manufacturer.

#### Evaluation Summary

The first structural component in the Lindhe Xtend range is the Xtend Connect, a compact, easy-to-use coupling device with a unique safety sprung button feature.

The Lindhe Xtend Connect provided a reliable means of changing limb configuration to all those who took part in the evaluation. Those fitted included both unilateral and bilateral, transfemoral and transtibial users testing the versatility in application of this product.

The device itself comes in two parts – the QuickFit and Base Units, including everything you need for fitting – there are no additional adapters needed. It is fitted 'inline' and appears no more intrusive than a standard tube clamp. Depending upon the application there are six different configurations available, and the device can be inverted, or mounted above or below a prosthetic knee joint.

Securing the Xtend Connect is easily achieved by tightening a threaded wheel mounted in the QuickFit Unit. Due to the design of the system it is not easily overtightened; and if for any reason the release knob is not secured, the unique safety sprung button acts to prevent the limb disconnecting accidentally. The releasing knob dial is available in black or bright orange.

#### Indications

- Lifestyle, environment or activity changes regularly, e.g. water-based activities to walking and snowboarding
- Bilateral transfemoral amputation with regular switching from stubbies to the use of prosthetic knee joints
- Difficulties manoeuvring in small spaces due to components
- Difficulties changing clothing/footwear over the prosthetic foot, e.g. slim trousers or boots.
- Regular changes between footwear with extremes differences in heel height
- Individual choice and ease of accessibility are a priority
- Component trial periods, that do not require second limb set

#### Contraindications

- Weight in excess of 100kg
- Use of a permanent cosmetic cover
- Diagnosis of dementia
- Lifting heavy weight that would exceed 100kg when considered in addition to their body weight
- High intensity/high impact running

## Evaluation Patients

### Patient Details

<b>Patient 1</b>	Unilateral Transtibial	90kg	36 year old female	Nurse Practitioner	Sigam F
<b>Patient 2</b>	Bilateral Transfemoral	78kg	38 year old male	Athlete	Sigam F
<b>Patient 3</b>	Unilateral Transtibial	82kg	49 year old male	Undisclosed	Sigam F
<b>Patient 4</b>	Unilateral Transtibial	95kg	73 year old female	Engineer	Sigam F

## Evaluation Result

### Current Prescription

<b>Patient 1 -</b>	TSB laminate socket with Össur 600 shuttle lock, Echelon/Rush foot with Ortho Europe Ferrier Coupler.
<b>Patient 2 -</b>	Bilateral Ischial Containment with Össur Seal-in liner, Ottobock X3 knees/None, Ottobock Tritons/Ossur Blades/Lindhe Xtends/CPI Sidekicks.
<b>Patient 3 -</b>	True Suction socket, Össur NOP4, Ottobock Torque Absorber, Freedom Innovations Senator Foot.
<b>Patient 4 -</b>	TSB laminate socket with OWW Limb Logic system & Flexsure Sleeve, Freedom Innovations Kinterra Foot.

### Prosthetist's Comments

- Patient 1 -** The patient was an existing Coupler user, meaning useful comparisons could be drawn. It was easy to fit, compact, safer and more secure than the previous device. I would routinely choose this device in future.
- Patient 2 -** The patient is very active and used his Sidekicks most regularly. Not having to travel with multiple limbs, and being able to easily change from knees to stubbies would be a great benefit and may promote the use of his prosthetic knees.
- Patient 3 -** This patient uses his water activity limb regularly, and finds the freedom of not having to remove his socket every time a great benefit.
- Patient 4 -** This patient prefers one of his sockets and enjoyed the freedom of swapping his feet based on activity rather than swapping limbs, though expressed concern at not having a backup socket like he has without this device.

### Patient's Comments

- Patient 1 -** The patient lacked confidence in the nylon pin used to secure her previous coupler, and found the stainless-steel material choice reassuring. She felt that changing feet became easier with the Xtend Connect.
- Patient 2 -** This very active patient has found the devices very useful and plans to use them in extreme environments; though occasionally he had difficulties engaging the release knob, but the safety sprung button gave him piece of mind.
- Patient 3 -** This gentleman was pleased with the ease and confidence he felt entering a wet environment with the Xtend Connect. Though the device added a little weight to his limb, he felt it was not troublesome at all. The device is also very useful for dressing and swapping clothes.
- Patient 4 -** The devices were ultimately rejected by the patient due to the weight limit. This patient is close to the weight limit of 100kg and he felt that it prevented him from carrying his grandchildren or doing any day to day activities that involved carry more than 5kg.

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