

ETHNOCARE

Overlay Product Description

Features and Benefits

The Ethnocare Overlay is a **prosthetic device** that allows users to instantly **adjust the fit of their prosthetic socket** to accommodate for **limb volume fluctuation**, and activity level changes throughout the day thus **maintaining appropriate socket fit** without having to doff the prosthesis.

The Overlay is intended to be **worn over the liner** and slid **inside the existing socket**. It features a breathable **circumferential textile structure** with an **integrated air expansion system**, located on the product's posterior, medial and lateral aspects, ensuring proper surrounding and alignment of the limb inside the socket. A proximally positioned **built-in pump and release valve** enable the **patient** to effortlessly **self-manage the fit quality and comfort of their socket** by **inflating or deflating the air expansion system**. An external air pump is also provided for faster inflation.

The air expansion system consists of a series of **interconnected cells** that **allow air to flow evenly within the socket, filling spaces only where necessary**. Since certain regions of the limb experience greater variability in volume, the use of air, a compressible and easily moveable fluid, effectively compensates for these fluctuations and creates a uniform fit inside the socket .



The Overlay helps clinicians and patients **efficiently address fitting issues** caused by **daily volume fluctuations** and/or **transitions and variations in the size and shape** of the patient's residual limb. It serves as an effective alternative to prosthetic socks, adjustable sockets, and internal socket padding by **filling voids***, **improving fit***, **enhancing suspension***, **relieving pressure points** (especially at the distal end), and **reducing potential skin irritations and friction**. This reduces socket issues that can disrupt ADLs. *Badaire, P., Robert, M. T., & Turcot, K. (n.d.). The Overlay: A solution for volume variations in transtibial amputation. (Cirris), Université Laval. <https://hubs.ly/Q02BZC570>
*Ethnocare. (2023). Clinical Evaluation Report Overlay. <https://hubs.ly/Q02BVPxF0>

The Overlay is **compatible with most liners** and **sockets** and **can be used with** different suspension methods, such as **distal fixation (pin)**, **sleeve**, and both **active and passive vacuum systems**.

Proven Results

A *case study conducted in Canada that included 24 transtibial patients indicates the Overlay demonstrated effective volume management and benefits for patients, including: **Improved socket fit; enhanced cushioning; pain reduction; ease of use** compared to the traditional use of prosthetic socks; and **overall improvement in user comfort and satisfaction**.

Significant results over traditional methods of socket volume management include:

1. Users reported a **↑24% improvement in socket fit** with the Overlay
2. Users experienced **↑46% better cushioning** when using the Overlay
3. Patients indicated their **pain sensation decreased by ↓24%** when wearing the Overlay
4. Users found the Overlay **↑52% easier to use** than adding prosthetic socks.

*Ethnocare. (2023). Evaluation Overlay [Case study] <https://hubs.ly/Q02YVhJL0>

Patient Populations - The Overlay is **suitable for patients at all functional levels K1 to K4 (K-levels)**.

1. **Mature Amputees:** Patients often have atrophied limbs with sensitive areas, making socket fit challenging. The Overlay provides targeted cushioning and expansion to offload pressure from sensitive areas and apply it to pressure-tolerant ones.
2. **Newly Amputees:** Commonly, newly amputated limbs undergo a reduction in size, shape, and volume at an accelerated rate. The Overlay can be used to help manage these more consistent and rapid volume changes as opposed to having to make up for this loss with numerous sock layers.
3. **Diabetes or Vascular Disease Patients:** Patients with these conditions can experience challenges with the management of prosthetics socks and socket fit. The ease of use of the Overlay can benefit those patients.
4. **Traumatic Amputees:** Traumatic amputations often result in more scar tissue and irregularly shaped residual limbs, making optimal socket fitting more challenging.
5. **Dialysis Patients:** Dialysis patients experience important limb volume fluctuations between and after dialysis treatments.
6. **Cancer Patients:** Patients with amputation due to cancer often return to their pre-diagnosis activity level. However, cancer medications often cause fluctuations in limb volume.
7. **Patient that experiences "Bell clapping"** (Distal portion of the socket is loose and the proximal portion fits snugly). The Overlay provides targeted cushioning to reposition bony anatomy and accommodate distal limb volume.