

# Clinical Guide

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Product: Overlay

## **!! Be sure to read the Instruction for use before using the Overlay. !!**

This document summarizes how to use the Overlay and frequently asks questions about the device. That said, it is not a complete user manual; you should always refer to the instructions for use.

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## **A detailed description of the Overlay**

- The Overlay is a breathable fabric sleeve with an integrated air expansion system that the wearer can adjust for maximum, personalized comfort. It's a new type of adjustment device that uses air to manage the changes in limb volume, ensuring that the users always have a snug fit in their prosthesis.

## **Target patients :**

- Transtibial amputee, K1 to K4 activity level
- Have volumetric variation during the day and/or a loose socket. At least 2 plys.
- The product is compatible with most suspension methods: suspension sleeve, passive vacuum, active vacuum and distal fixation

## **Scenario of Use :**

### **To Put on the Overlay:**

1. The patient must be in a sitting position and must first put on their prosthetic liner.
2. The patient can slide the Overlay over their liner. They need to orient the air cushion of the Overlay at the back of their residual limb (at the level of the calf).
3. The patient puts on the Overlay by sliding it over the prosthetic liner
4. The patient can wear their socket by ensuring the air cells are below the trim line.
5. Still, in the seated position, the patient uses the external or integrated pump to create a tightening inside the socket. The patient stops using the pump when the residual limb is comfortable and the socket is evenly tightened.
  - a. It is recommended to use the external pump if there is a large volume to be filled and to use the integrated pump for minor volume adjustments.
  - b. To facilitate inflation, the air canal linking the pump to the air cells should be as straight as possible. To achieve that, the leg of the user should be straight, and the Overlay itself should not be folded.

### **To adjust the pressure in the Overlay throughout the day:**

When the patient feels a gap has been created in their socket or the tightness between their residual limb and socket is too high, he momentarily stops his activities.

### **For patients with **suspension sleeve** or **vacuum system****

1. The patient must first be in a sitting position.
2. To access the device, the patient must unroll the suspension sleeve covering their thigh from top to bottom.
3. The patient can use the integrated or external pump to recreate a uniform and comfortable fit in their prosthesis without removing it.
4. If too much tightness is felt, the patient uses the release valve, without removing the prosthesis, to remove air from the circuit to recreate a uniform and comfortable tightness inside the socket.
  - a. To facilitate the deflation, the air canal linking the valve to the air cells should be as straight as possible. To achieve that, the leg of the user should be straight, and the Overlay itself

should not be folded. Also, the limb must be in the socket when the release valve is pressed.

#### **For patients with distal fixation**

1. If a gap is created, the patient uses the integrated pump through their clothes without removing their prosthesis to recreate a uniform and comfortable tightening inside the socket.
2. If too much tightness is felt, the patient uses the release valve, without removing the prosthesis, to remove air from the circuit to recreate a uniform and comfortable tightness inside the socket.

#### **To remove the Overlay**

*For patients with suspension sleeve or vacuum system*

1. The patient must first be in a sitting position.
2. To access the device, the patient must unroll the suspension sleeve covering their thigh from top to bottom.
3. The patient press on the silver part of the release valve to release air from the air cushion and create a gap inside the socket.
4. The patient can now remove their socket.

*For patients with suspension sleeve or vacuum system*

1. The patient must first be in a sitting position.
2. The patient press on the silver part of the release valve the release valve to release air from the air cushion and create a gap inside the socket.
3. The patient presses the release mechanism of the fixation system located on the prosthesis.
4. The patient can now remove their socket.

#### **Sizing:**

As far as sizing is concerned, there are currently 12 sizes of Overlay available, which can accommodate almost all amputees:

- 3 circumferences (OV23, OV28, OV35)
- 2 lengths (SH, LG)
- 2 orientations (Right, Left)

Two measurements must be done to select the right size Overlay for the patient.

- Measure the circumference of the limb at 4 cm from the distal end over the liner to determine the width.
- Measure the length of the residual limb from the distal end to the popliteal fossa to determine the length.
  - SH stands for a limb from 14 cm to 20 cm in length.
  - LG addresses a limb that is over 20 cm in length.
- Orientation (R or L) is only based on the user's preference for pump use. It's not linked to the side of amputation.

## **Benefits of the Overlay**

### **For the user:**

- Much simpler and easier to use than socks and other volume management solutions like prosthetic socks
- The use of air creates cushioning, significantly improving comfort.
- The air cushion's design has been optimized to create a uniform fit and an optimal alignment in the socket.
- The product can accommodate different residual limb morphologies and is compatible with most suspension methods, sockets, and liners.
  - Suspension sleeve, distal fixation, passive and active vacuum system
- The product can fill a variation of up to 15 plys.
- Users have fewer materials to carry along the day to ensure comfort and fit.
- Users can now adjust their fit more precisely; there is no more "in between ply" fit.
- Users take fewer pauses to take off the socket to recreate a fit resulting in a more active life.
- Users spend more time using their prostheses.
- Users can adjust their fit without taking off their prostheses and clothes.
- User gain in mobility and knee flexion because there is no material accumulation in the popliteal fossa

### **For the professional:**

- The Overlay is an effective and easy solution for volume management.
  - It reduces the number of follow-up appointments for volume variation management (Saving time and Cost)
  - No changes are required in the prosthesis manufacturing method to use the Overlay.
  - The product is retrofitted with existing equipment. It can be used without modifying the socket, liner, or suspension method.
  - Less frequent prosthetic socket replacement / Less socket fabrication so clinics can focus on care.
  - Clinics can see more patients.

### **Cleaning and maintenance:**

- Cleaning of the device:
  - Remove the device from the liner.
  - Be sure the integrated pump hole is covered when exposed to fluid (i.e. covering with a finger). Clean the device daily with approved cleansing products, including neutral soap or mild detergent that is pH balanced, fragrance, bleach, and dye-free. Clean the device in warm water 30°C (86°F)
- Do not put it in the washing machine, and do not wring out the device to avoid damage.
  - Rinse the device thoroughly with clean, warm water to remove all soap residues.
- Do not expose the integrated pump to water.

- Insert a towel into the device and air dry.
- Do not place it in a dryer or use any other heat source for drying.
  - The device can be used only when completely dry.
- Use of unsuitable detergents
  - Using unsuitable detergents may cause the device to deteriorate and void the warranty.

**Contraindication:**

- Do not use this device on patients with leather thigh straps (Cuffs, Straps and Belts) if they interfere with the pump or valve of the Overlay.
- Do not use this device on patients who have a wound or very sensitive skin.
- Do not use this device on any type other than a transtibial amputation.
- Do not use this device on patients who cannot communicate physical discomfort.

**Cautions for use:**

- The Overlay might not be suitable for all patients with a supracondylar socket (the data on the compatibility with this type of system is insufficient)
- The Overlay corresponds to a thickness of approximately two (2) plies. Thus, this device should be worn by patients who wear more than two (2) plies.
- The sizing is different for patients with a sealing ring positioned at the distal end of their liner. If those patients wear the Overlay, it must be placed above their seal ring. We advise testing the product case by case for those types of patients to ensure a good fit and that the product suits them.
- Do not use the device if the length of the residual limb is less than 14 cm (vertical measurement in a sitting position between the popliteal fossa and the distal end). All the air cells need to be inside the socket.
- Only use the device if it seems tight enough for the patient. If the fit is incorrect, it can cause the product to malfunction and damage the product.
- Stop using the Overlay if the product is not 100% airtight / if the product is leaking air. A damaged device cannot be used safely and may result in injury.
- The device is for single-patient use and should not be shared with other patients.
- The device should not be used directly on the skin. We suggest wearing it over a liner.
- Do not over-inflate the air system. Improper air cushion inflation may cause skin irritation and monitor patients with diabetic neuropathy. Reduce air cushion pressure when skin changes occur, or discomfort is felt.
- Patients with a decrease or loss of normal sensation (i.e. neuropathy, etc.) should be monitored frequently for skin lesions, skin irritation, or wound management. The medical specialist determines this condition.



## FAQ

### 1. **Warranty period | What does it cover?**

- a. The warranty is six months, and it covers the entire product. If a part of the product is damaged, the entire product will be replaced with a new one. Further information on the warranty terms and conditions can be obtained from the manufacturing company. You can reach the Ethnocare support team by mail at [Clinics@ethnocare.ca](mailto:Clinics@ethnocare.ca) or phone at +1 418-934-5669.

### 2. **What is the lifespan?**

- a. The minimal expected lifespan is six months. The product has been designed to withstand extreme loads and be highly durable. Extreme users (over 350 lbs and/or really active users) have worn it for more than eight months without any significant damage to the product. Each component was also tested through several bench tests to ensure they were highly durable and withstand extreme loads. After several months, the fabric might start to wear out, as is usually the case with liners.

### 3. **What prevents the product from slipping?**

- a. The Overlay is a stretchable fabric sleeve that integrates silicone bands inside to prevent slipping and ensure a snug fit on the liner.

### 4. **Does it work with any type of suspension method?**

- a. The Overlay works with most suspension methods, such as suspension sleeves, passive & active vacuum and distal fixation. The Overlay might only be suitable for some patients with a supracondylar socket (the data on the compatibility with this type of system is insufficient).

This device can't be used on patients with leather thigh straps (Cuffs, Straps and Belts) if they interfere with the pump or valve of the Overlay.

### 5. **How can I inflate the Overlay?**

- a. There are two ways to inflate the Overlay; The user can adjust the fit with an external pump for a more significant increment or the integrated pump for smaller increments. To facilitate inflation, the air canal that links the pump and valve to the air cells should be as straight as possible when the user is trying to inflate the product. To achieve that, the user's residual limb should be straight, and the Overlay should not be folded.

### 6. **What is the pump cover in the packaging of the Overlay?**

- a. The pump cover is meant to go over the integrated push pump. It can facilitate the use of the integrated pump when pressed through clothing. This accessory is not necessary for the functionality of the product. If the user doesn't want to add this part.

## **7. How do you completely deflate the Overlay ?**

- a. To release the air properly, the user should deflate the product when their residual limb is still in the socket. The air canal linking the pump and valve to the air cells should also be as straight as possible when the user is trying to release the air. To achieve that, the leg of the user should be straight, and the Overlay itself should not be folded. If those steps are followed, most of the air should release because of the pressure the socket creates and the user's weight.
- b. If the product is out of the socket, like an air mattress, if no pressure is applied to the air expansion system, it won't deflate as easily as within the socket. To release all the air, you should:
  1. Gently push the air from the farthest cells to the release valve area to create some pressure below the release valve.
    - a. To move the air to the release valve area, you can fold the air cells.
  2. You can then press the release valve to release the air.
  3. You may have to repeat those steps a couple of times to deflate the product completely.

## **8. Why is the air expansion system / the air cells positioned at the back?**

- a. The Overlay compensates volume where there is a need to. Most of the volumetric variation will occur at the back of the limb, so the air expansion system is located posteriorly. It is intended to keep the limb in position with the initial reference point of the socket. If you have more questions about how the Overlay's air expansion system works and inflates, feel free to reach the Ethnocare support team by mail at [Clinics@ethnocare.ca](mailto:Clinics@ethnocare.ca) or by phone at +1 418-934-5669

## **9. Does it require any adjustment on the prosthesis?**

- a. The Overlay is a retrofit solution; it doesn't require modifying the existing equipment. However, the patient trying out the Overlay must have a small initial gap (at least 2 plys) in their prosthesis to put it on.

## **10. What happens if my Overlay Breaks?**

- a. You can reach the Ethnocare support team by mail at [Clinics@ethnocare.ca](mailto:Clinics@ethnocare.ca) or by phone at +1 418-934-5669 and we'll send you a new Overlay. Ethnocare grants a commercial warranty for this device from the date of fitting. The warranty period is six months. The commercial warranty covers proven defects in material, workmanship or construction. These defects must be reported to the manufacturer within the commercial warranty's validity period. Further information on the warranty terms and conditions can be obtained

from the manufacturing company.

**11. Which type of activities the Overlay is made for?**

- a. Any activities besides one's with high water exposure, like swimming.

**12. How can I have customer support?**

- a. You can reach Ethnocare support team by mail at [Clinics@ethnocare.ca](mailto:Clinics@ethnocare.ca) or by phone at +1 418-934-5669

**13. Is the Overlay suitable for a particular patient population and/or a medical condition?**

- a. Do not use the device if there are wounds on the residual limb. Do not use it on patients with neuropathy without physician approbation. Do not use the device if the length of the residual limb is less than 14 cm (vertical measurement in a sitting position between the popliteal fossa and the distal end). Contact a healthcare professional immediately if you experience pain, swelling, altered sensation or other abnormal reactions when using this device. Do not over-inflate the air cushion. Improper air cushion inflation may cause skin irritation in patients with diabetic neuropathy or other neurological conditions, as determined by prescribing physicians. The medical specialist determines this condition. Reduce air cushion compression when skin changes occur, or discomfort is felt. Patients with a decrease or loss of normal sensation (i.e., neuropathy, etc.) should be monitored frequently (as determined by the prescribing physician) for skin lesions, skin irritation, or wound management. See the instruction for use to have more in-depth information and or reach Ethnocare support team by mail at [Clinics@ethnocare.ca](mailto:Clinics@ethnocare.ca) or by phone at +1 418-934-5669

**14. What kind of maintenance or cleaning is required for the Overlay and how often must it be performed?**

- a. The Overlay should be hand-washed with mild soap every day. It needs to be completely dry before using again. More information about maintenance and cleaning in the instruction for use in the section "Cleaning, Maintenance and Storage" If this section lacks information, feel free to reach Ethnocare support team by mail at [Clinics@ethnocare.ca](mailto:Clinics@ethnocare.ca) or by phone at +1 418-934-5669

**15. Are there any safety considerations or precautions that healthcare professionals and patients should know when using the Overlay?**

- a. User and healthcare professionals should always read the Instruction for Use before using the Overlay. You'll find all the information about safety in the section "general safety instructions". If this section lacks information, feel free to reach Ethnocare support team by mail at [Clinics@ethnocare.ca](mailto:Clinics@ethnocare.ca) or by phone at +1 418-934-5669

**16. Is there a version for transfemoral amputees? Do you have any other products coming out soon ?**

- a. Ethnocare's mission is to challenge the Status Quo in the orthopedic field; naturally, many products are in creation and aim to offer better comfort and mobility for their users. That said, Ethnocare is developing a transfemoral adaptation of the Overlay; if you want to hear

more or participate in the development process, feel free to contact by mail at [Clinics@ethnocare.ca](mailto:Clinics@ethnocare.ca) or by phone at +1 418-934-5669

**17. Can the exit valve break or pierce the suspension sleeve?**

- a. Even though we receive this question many times, it never happens to any user of the Overlay, even after 8 months of use with highly active users. If you have any questions or concerns, feel free to contact us by mail at [Clinics@ethnocare.ca](mailto:Clinics@ethnocare.ca) or by phone at +1 418-934-5669