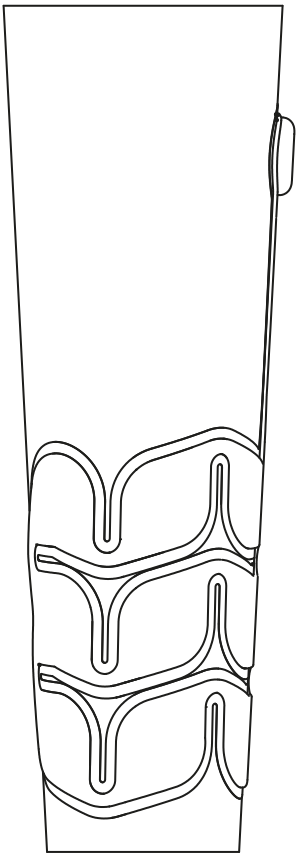
ETHNOCARE

Redefine people's mobility



Instructions for use

OVERLAY™

overlay
liner
other

Fig. 1

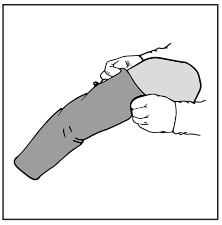


Fig. 2

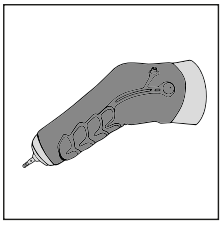


Fig. 3

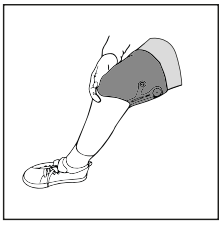


Fig. 4

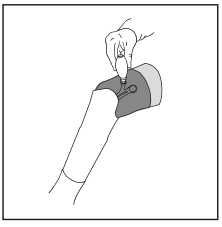


Fig. 5

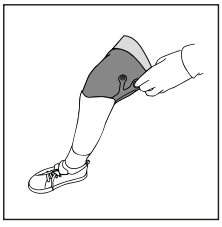


Fig. 6

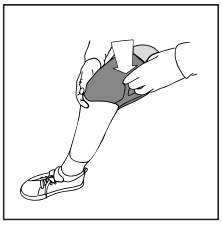


Fig. 7

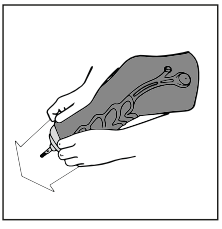


Fig. 8

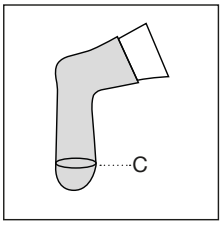
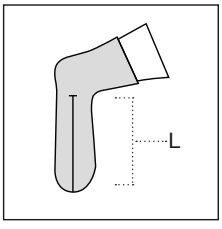


Fig. 9



Effective date : 2023-01-16
Document number : PDPROJ-01-UG
Rev. : 02

ENGLISH

READ THE FOLLOWING INSTRUCTIONS CAREFULLY IN THEIR ENTIRETY BEFORE USING THE DEVICE AND OBSERVE THE SAFETY INSTRUCTIONS. CORRECT INSTALLATION IS ESSENTIAL FOR THE PROPER FUNCTIONING OF THE DEVICE.

INSTRUCTIONS FOR USE :

These instructions are intended for the certified orthotist/prosthetist (CPO) fitting the device and the patients wearing the device. The OVERLAY is referred to as the “device” in this document. The device is intended for use by a licensed healthcare professional, the patient, or the caregiver providing care to the patient. The patient or the caregiver must be able to read and understand all instructions, warnings and precautions in the directions for use and be physically able to follow them.

1. INFORMATIONS :

1.1. Please read this entire document carefully before using the device and follow the safety instructions.

1.2. A healthcare professional must instruct the patient or the caregiver how to use this device safely.

1.3. Contact the manufacturer, or your healthcare professional if you are a patient or a caregiver, if you have any questions about the device or if you experience any problems or complaints or incidents including any worsening medical conditions.

1.4. Please keep this document.

2. USE OF SYMBOLS

Symbols	Symbols titles	Explanatory text
	Manufacturer	Indicates the medical device manufacturer.
	Europeen authorized representative	Indicates who is the manufacturer's Europeen authorized representative.
	CE Mark	Indicate that the medical device is compatible with the Europeen regulations.
	Packaging integrity	Indicates to not use the device if the packaging is damaged.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalog #	Indicates the manufacturer's catalog # so that the medical device can be identified.
	Quantity	Indicates the # of units per package.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	Medical device	Indicates that the item is a medical device.
	Single patient - Multiple use	Indicates that the medical device can be used multiple times, but only on one patient.

Symbols source : ISO 20417:2021

3. PRESENTATION OF THE DEVICE :

3.1. DEVICE DESCRIPTION :

This device is a medical device for patients with transtibial amputations. It is composed of a fabric and integrates an air cushion that can be activated by a pump integrated on the device and/or a pump external to the device (bulb pump - accessory) as

well as a manual release valve in order to allow a daily volumetric adjustment. (see instruction for use at page 10)

3.2. TABLE OF COMPONENTS :

3.2.1. Textile
3.2.2. Air bladder
3.2.3. Outlet valve
3.2.4. External pump (accessory)
3.2.5. Integrated pump

3.3. LIST OF MATERIALS :

3.3.1. Nylon
3.3.2. Elasthanne
3.3.3. TPU (Thermoplastic Polyurethane)
3.3.4. Spring steel
3.3.5. Silicone

Material applicable standard : ISO 10993-1

4. OPERATION :

The device creates additional support and volumetric fit in a tibial exoprosthesis (external limb prosthesis) by creating a uniform tightness using an air cushion. The device needs to be positioned between the prosthesis's liner and the socket. The device must be used in combination with a liner. It is intended for use with exoprosthesis and liners that are compatible with the device such as any transtibial liners and sockets approved by a healthcare professional. To inflate the device, the patient or healthcare professional should use the integrated pump or the external pump (accessory), the external pump needs to be connected to the exit valve in order to pump air into the air expansion system. To release the air, the patient or the healthcare professional needs to press on the metal part of the exit valve in order to activate the release mechanism.

NOTICE! The patient should keep their leg straight in order to easily inflate or deflate the device.

5. CONTENTS OF THE DELIVERY :

Qty.	Description	REF.
1	Instructions for use	PDPROJ-01-UG

Qty.	Description	REF.
1	Overlay	-
1	External pump	-

6. DEVICE SELECTION AND ADAPTATION

6.1. SELECTION OF THE DEVICE SIZE

6.1.1. Width

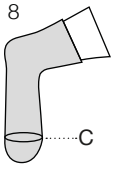
The size of the device should be chosen according to the size of the patient's residual limb with their liner put on.

Due to the stretchability of the device, the sizes are suitable for a large number of residual limb sizes per increment.

C = Circumference at 4cm of distal extremity with the liner on.

C (cm)	Denomination of the product
23,5 to 28,5	OV23
28,5 to 35,5	OV28
35,5 to 43,5	OV35

Fig. 8



6.1.2. Length

The length of the device should be selected according to the distance measured between the distal end and the popliteal fossa. (Figure 9).

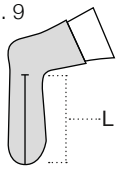
Steps :

1. Have the patient assume a sitting position.
2. Have the patient position the residual limb at a 90-degree angle.
3. Measure the distance from the distal end to the popliteal fossa.
4. Select the length of the device according to this measurement (see table below).

L = Length from poplitea fossa to tibial distal end with the liner on and the leg at 90°.

L (cm)	Length of the product
14 to 20	SH
20+	LG

Fig. 9



6.1.3. Orientation

The orientation denomination of the device is based on the user's preference for pump use. (not dependent on the side of the amputation)

User's preference	Orientation
The pump is to the right when the product is worn	R
The pump is to the left when the product is worn	L

6.1.4. Complete nomenclature

Example: OV23-LG-R (Overlay size 23 of length LG of right orientation (R)).

7. INTENDED USE / PURPOSE :

7.1. Intended use : This device is intended for use under the supervision of a healthcare professional. Determination of when to use the device and the frequency and duration of use is at the sole discretion of the treating physician. The device intends to provide additional support for and volumetric fit of a tibial exoprosthesis.

7.2. Requirements for use

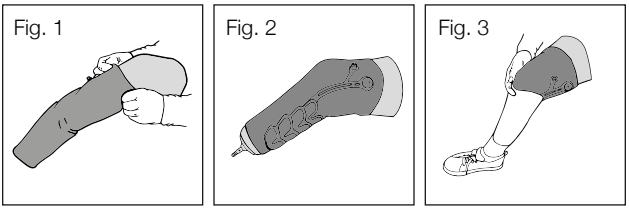
The device must be used between a socket and a prosthetic liner.

7.3. Steps required to put on the device :

NOTICE! Before putting on the device, it is strongly recommended to verify that the air cushion is airtight and that both pumps and the valve are working properly.

1. The patient is initially in a sitting position
2. The patient puts the prosthetic liner on their residual limb.
3. The patient orientates the air cushion of the device at the back of their residual limb (at the level of the calf) by positioning the visual mark on their tibia. (Figure 1)
4. The patient puts on the device by sliding it over their prosthetic liner (Figure 2)

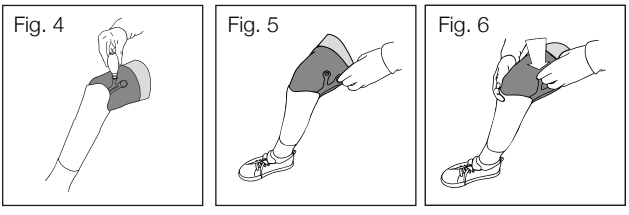
5. The patient makes sure that the device is positioned uniformly (no creases, folds or excess thickness) on the prosthetic liner.
6. The patient inserts their residual limb (covered by the prosthetic liner and the device) into the socket (Make sure the air cushion is below the trim line of the socket). (Figure 3)



(If the patient uses a distal fixation)

7. The patient lightly presses their residual limb (covered by the prosthetic liner and the device) to snap the distal attachment of their prosthetic liner into the ratchet system of the prosthesis

8. Still in the seated position, the patient uses the external (Figure 4) or integrated (Figure 5) pump to inject ambient air into the air cushion and create a tightening inside the socket.
9. It is recommended to use the external pump if there is a large volume to be filled and to use the integrated pump for micro adjustments. The air cushion inflates and creates a tightening between the prosthetic liner (which covers the residual limb) and the socket. The patient stops using the pump when the residual limb is comfortable and when the socket is evenly tightened.



NOTICE Wrongful usage of the pumps or release valve could cause harm to the patient such as soft tissue wounds. Please refer to Figure 4-5-6 on how to use those components.

(If the patient uses a suspension sleeve)

10. The patient puts on, at this moment, their suspension sleeve

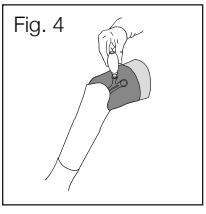
11. The patient then stands with their prosthesis.

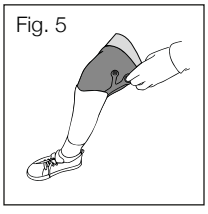
Steps required to use the device on a daily basis:

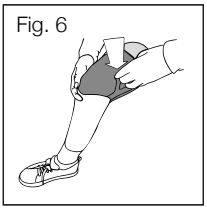
1. When the patient feels that a gap has been created in their socket or that the tightness between their residual limb and their socket is too high, he momentarily stops their activities.

(If the patient uses a suspension sleeve)

2. The patient must first be in a sitting position. The patient must then unroll the suspension sleeve covering their or her thigh from top to bottom to gain access to the device.
3. If a gap is created, the patient uses the integrated pump, without removing the prosthesis, to inject ambient air into the air cushion and recreate a uniform and comfortable tightening inside the socket. The air cushion inflates and recreates a tightening between the prosthetic liner and the socket. (Figure 5)
4. If the gap is important, to accelerate the inflation of the cells, the patient can, if he wishes, use the external pump (Figure 4)
5. If too much tightness is felt, the patient uses the release valve, without removing the prosthesis, to remove air from the air cushion to recreate a uniform and comfortable tightness inside the socket. (Figure 6)

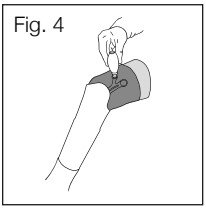


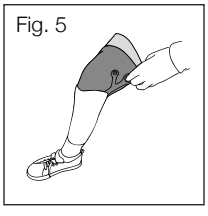


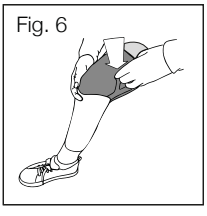


(If the patient uses a distal fixation)

6. If a gap is created, the patient uses the integrated pump, through their clothes and without removing their prosthesis, to inject ambient air into the air cushion and recreate a uniform and comfortable tightening inside the socket. (Figure 5)
7. If the gap is important and to accelerate the inflation of the cells, the patient can, if he/she wishes, make a transition to a sitting position and inflate the air cushion with the external pump. (Figure 4)
8. If too much pressure is felt, the patient uses the release valve, through their clothes and without removing their prosthesis, to remove ambient air from the air cushion to recreate a uniform and comfortable pressure inside the socket. (Figure 6)







7.4. Steps required to remove the device :

1. The patient must first be in a sitting position.

(If the patient uses a suspension sleeve)

2. The patient must unroll the suspension sleeve covering their or her thigh from top to bottom to gain access to the device.

3. The patient uses the release valve to release air from the air cushion and create a gap inside the socket. The patient stops using the release valve when he/she no longer feels any tightness in the socket. (Figure 6)

(If the patient uses a distal fixation)

4. The patient presses the release mechanism of the fixation system located on the prosthesis.

5. The patient removes the residual limb (covered by the liner and device) from the socket.
6. The patient removes the device from the liner by pulling it from the distal end. (Figure 7)

Fig. 6

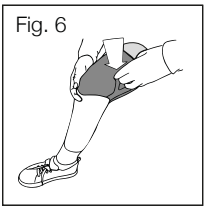
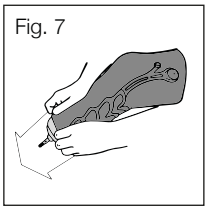


Fig. 7



7.5. Contraindications

7.5.1. Do not use this device if you are allergic to the materials listed.

7.5.2. Do not use this device on any type of amputation other than a transtibial amputation.

7.5.3. Do not use this device on a patient who is unable to communicate physical discomfort.

7.6. Useful life

This device is intended to be used for a period of 6 months of normal use.

8. PERFORMANCE INFORMATION :

The device can replace up to 15 ply of prosthetic socks

9. SECURITY :

9.1. Symbols

Symbols	Definitions
Warning	Warning indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
Caution	Caution indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.
Notice	Warning against possible technical damage.

9.2. General safety instructions

9.2.1. WARNING

9.2.1.1. Risk of serious injury:

- Keep the device out of the reach of children. There is a choking hazard if the device is placed over the mouth and nose.

9.2.2. CAUTION

9.2.2.1. Risk of injury and risk of damage to the device :

- Keep the device away from flames, embers or other sources of heat.
- Do not use in a MRI.
- Do not expose the device to temperatures above +60°C or below -20°C.
- Ensure that the device is properly placed and adjusted.
- Incorrect or overly tight placement can cause pressure and compression of blood vessels and nerves.
- Discontinue use of the device if there are problems with the fit of the device on the residual limb.
- At high altitudes or when exposed to extreme heat, the air in the air cushion will expand and cause the pressure to vary.
- Do not use the device if it seems too tight or too large for the patient. Inform the patient to contact the Orthotist/ Certified Prosthetist (CPO) immediately.
- Do not use the device if the patient is using an adjustable socket.
- Do not use the device if there are wounds on the residual limb.
- Do not use on patients with neuropathy without physician aprobation.

- 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).
- If you experience pain, swelling, altered sensation or other abnormal reactions when using this device, contact a healthcare professional immediately.
- Not inflating the device when required could cause skin tissue and soft tissue wounds from the lack of cushioning inside the exoprosthesis.
- Small metal part inside the release valve could fail if overpressurized and result in moderate injuries, make sure the release valve body is in good condition before using the device.
- The product is susceptible to normal wear and tear. Check the product before each use and do not wear the product if damaged.
- Do not use the device with exoprosthesis that are incompatible with the device. Make sure that the use of the device is approved by a healthcare professional before using it with any additional exoprosthesis.
- Instruct the patient to contact their orthotist/certified prosthetist (CPO) if the device is damaged. The device is unusable if the built-in valve or pump does not function properly or if the air cushion is not 100% airtight. Also, if the bonding between the fabric and the air cushion is damaged or if the fabric itself is damaged, it can affect the performance of the system and its durability. A damaged device cannot be used safely and may result in injury.

9.2.2.2. Skin irritation, eczema, infections, germ contamination

- The device is for single patient use and is not to be shared for use with other patients.
- Follow the cleaning instructions to avoid germs, bacterias and infections.
- Do not use the device directly on the skin.
- Do not over-inflate the air cushion. Improper inflation of the air cushion may cause significant skin irritation in patients with diabetic neuropathy or other neurological condition as determine by prescribing physician. This condition is determined by the medical specialist. Reduce air cushion compression as soon as skin changes occur or discomfort is felt.
- Patients with decrease or loss of normal sensation (i.e., neuropathy, etc.) should be monitored frequently (as determine by prescribing physician) for skin lesions, skin irritation, or wound management.

9.2.2.3. Adverse Effect

- May cause skin redness
- Alergic reaction to materials
- May cause pressure points

9.2.2.4. Use of powder (e.g. talc)

- Risk of skin irritation to the residual limb and loss of functionality of the device due to particle blockage.
- Keep the device away from the powder.

9.2.3. NOTICE

- Do not modify the device or use it in any way other than intended.
- Do not use this device if it is damaged and/or if the package has been opened.
- Before each use, check the device for damage.
- Do not use the device if its functions are limited.
- If needed, take the necessary measures (e.g. replacement, check by the manufacturer's service department, etc.).

10. CLEANING, MAINTENANCE AND STORAGE:

10.1. Cleaning of the device :

1) Remove the device from the liner.

2) Be sure the integrated pump hole is covered when expose to fluid (i.e. covering with a finger). Clean the device once a day only 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)
NOTICE! Do not put in the washing machine and do not wring out the device to avoid damage.

3) Rinse the device thoroughly with clean warm water to remove all soap residues.
NOTICE! Do not expose the integrated pump to water.

4) Insert a towel into the device and air dry.
NOTICE! Do not place it in a dryer or use any other heat source for drying.

5) The device can be used only when completely dry.

10.1.1. Use of unsuitable detergents

NOTICE! The use of unsuitable detergents may cause the device to deteriorate and void the warranty.

10.2. Environmental conditions

The device is intended for indoor and outdoor use.
NOTICE! Avoid using during activities involving contact with a lot of water (i.e. swiming)

10.3. Failure to follow these instructions will void the warranty.

11. WASTE DISPOSAL :

Do not dispose of this device anywhere with unsorted household waste. Incorrect disposal can have negative effects on the environment and health. Follow the regulations of the applicable authorities in your municipality regarding return, collection and recycling procedures. In this regard, all components of the device and its packaging must be disposed of in accordance with applicable national environmental regulations. Patients should contact their local authorities for information on how to dispose of these items.

12. LEGAL INFORMATION

All legal conditions are subject to the local and other applicable law and may vary accordingly.

12.1. Responsibility

The manufacturer accepts no liability for damages resulting from failure to comply with this document, in particular from improper uses, unintended uses, uses outside the devices specified use conditions or unauthorized modification of the device. The device must be maintained in accordance with the operating instructions. Abuse or improper use of the device may result in decreased functionality. The manufacturer cannot be held responsible for damage resulting from improper maintenance or caused by components not authorized by the manufacturer. The manufacturer's distribution company responsible in your country will provide you with further information on the conditions of the commercial guarantee.

12.2. Commercial Warranty

The manufacturer grants a commercial warranty for this device from the date of fitting. The warranty period is 6 months. The commercial warranty covers proven defects in material, workmanship or construction. These defects must be reported to the manufacturer within the period of validity of the commercial warranty. Further information on the warranty terms and conditions can be obtained from the manufacturing company.

Note: While all advanced techniques have been used to achieve the maximum level of compatibility of function, strength, durability and comfort, there is no guarantee that the use of this device will prevent injury.

Exclusive South African Distributor:

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ETHNOCARE

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