WillowWood®

LIMBLOGIC®

Prosthetist Instructions

WHAT'S IN THE BOX

LimbLogic M

Proximal Gasket (2)

M6 X 50 mm Socket Head Capscrews (4)

Split Washer

LimbLogic 4-Hole Adapter

Forming Plate with 4 M6 X 10 mm Capscrews

Poron Filter

Instructions

- LimbLogic M Prosthetist Instructions
- LimbLogic M Patient Instructions
- LimbLogic M Fabrication Instructions

The LimbLogic M is an elevated vacuum suspension system that operates by compressing with each step and is completely integrated into the prosthesis without the annoyances of tubes in the socket.

WillowWood®

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Unauthorized changes or modifications to the pump or accessories may impair their function resulting in injury or death, will void the warranty, and may prevent their compliance with relevant standards.

This pump is only designed to move air; use of Vaseline® or similar lubricating creams inside the socket will clog the pump. Do not allow foreign substances to be pulled through the pump. This may impair function of your vacuum system.

LimbLogic is designed for use by a single patient only. Use on more than one patient may result in cross-contamination potentially causing a serious infection.

LimbLogic pumps cannot compensate for failures in the associated prosthetic socket or sealing system. Only use LimbLogic pumps with commercially proven socket and sealing systems. Use with other sealing systems may result in loss of suspension resulting in injury or death.

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PATIENT CRITERIA

Indications

Patients who meet the following criteria should be considered for this system.

- Patients who are transtibial amputees.
- Patients who comment about lack of suspension or feeling insecure in their current prosthesis.
- Patients who exhibit high cognitive function and are "in tune" with prosthetic fit.
- Community ambulators whose activity level is at least Level 2. (Level 2: The patient has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs or uneven surfaces. This is typical of the limited community ambulator.)
- Patients who prefer simple non-electrical solutions.
- Patients who could benefit from vertical shock reduction.

Contraindications

Patients with any of the following conditions should not be considered for this system:

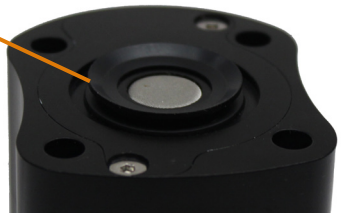
- Patients other than transtibial amputees.
- Patients who require the ability to turn off the vacuum pump or greatly vary the vacuum level.
- Patients who need an audible indication of a leak in their system.
- Patients who weigh less than 100 lb (45 kg), because they will be unable to activate the pump
- Patients who weigh more than 330 lb (150 kg) for U.S. Acitivity Level K2-K3, or more than 300 lb (135 kg) for U.S. Activity Level K4.

FITTING INSTRUCTIONS

1. Attach the pump to the prosthesis (refer to page 5).
2. Adjust the spring stiffness (refer to page 7).
3. Adjust the vacuum level if desired (refer to page 9).
    - For low vacuum mode, turn the 4 mm hex screw counterclockwise until it comes to a stop (approximately 3/4 of a turn). For the lowest possible vacuum level, increase the spring stiffness.
    - To return to high vacuum mode, turn the 4 mm hex screw clockwise until it comes to a stop (approximately 3/4 of a turn). For the highest possible vacuum level, decrease the spring stiffness.

ASSEMBLY

1. Fabricate a laminated socket using the LimbLogic 4-Hole Adapter. Follow the fabrication instructions provided with the adapter.
2. Apply the proximal gasket to proximal surface of the pump.



You should be able to turn the pump upside down without the gasket falling off. If the gasket falls off, it was not properly seated into the recess.

Be sure to fully seat the gasket onto the inlet before attaching the pump to the socket. **Failure to properly seat the gasket may result in leaks.**

3. Using the four M6 x 50 mm socket head screws provided, attach the pump to the socket with the logo facing anterior.

OR

If the prosthesis requires a hose barb connection instead of a direct mount, attach the pump to a LimbLogic Vacuum Pyramid (LLV-01044) using the four M6 x 50 mm socket head screws provided.

Apply Loctite 242 (or equivalent) and tighten the screws to 9 ft-lbs (12 Nm).

The proximal end of the pump must be attached to either the LimbLogic 4-Hole Adapter (LLV-01041) or to the LimbLogic Vacuum Pyramid (LLV-01044).

4. Install the mating pyramid receiver component of your choice onto the pyramid at the distal end of the pump. Once alignment has been achieved, follow the torque and threadlocker specifications provided by the manufacturer of the pyramid receiver.

ROTATION ADJUSTMENT

To make a rotation adjustment before assembling the prosthesis, use an adjustable wrench to rotate the pyramid to the desired position.

To make a rotation adjustment after assembling the prosthesis:

1. Loosen two adjacent 8 mm setscrews on the pyramid receiver.
2. Turn the prosthesis to rotate the pyramid to the desired position.
3. Tighten the 8 mm setscrews using the torque and thread-locker specifications provided by the manufacturer of the pyramid receiver.

STIFFNESS ADJUSTMENT

1. In order to maintain alignment, make a reference mark to indicate the rotation of the pyramid on the distal end of the pump.
2. Disconnect the pyramid receiver from the pyramid.
3. Insert a 4 mm Allen wrench into the hole on the distal end of the pyramid.

4. Turn the wrench as follows:
   - Turn the wrench **clockwise** to make the pump feel **stiffer** and to reduce deflection.
   - Turn the wrench **counterclockwise** to make the pump feel **softer** and to increase deflection.
5. Reinstall the pyramid receiver to the pyramid on the distal end of the pump. Follow the torque and thread-locker specifications provided by the manufacturer of the pyramid receiver.

If desired, use the included split washer to observe the amount of pump deflection:

1. Open the split washer and apply it to the pump shaft.

2. Push the split washer up as proximal as possible on the shaft.

3. Ask the patient to take several steps.

4. When the amputee stops walking, the washer will remain at its fullest deflection, indicating the maximum travel of the pump.

5. Remove the split washer when the evaluation is complete.

Keep fingers and toes away from the pump while walking.

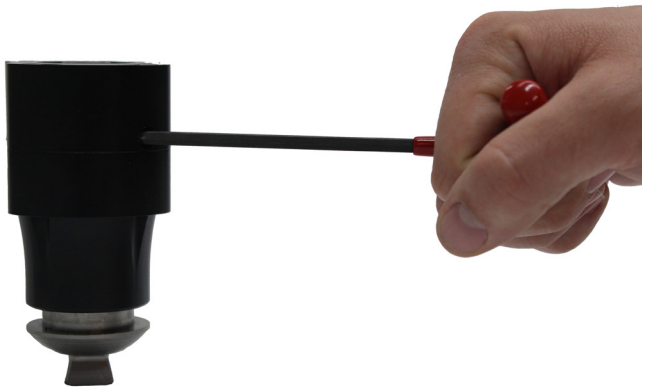
VACUUM LEVEL ADJUSTMENT

The LimbLogic M features two settings for the vacuum level: **Low** and **High**. The pump is shipped with the setting at **High**.

To change the Vacuum Level Setting to **Low**:

1. Locate the exposed 4 mm hex screw on the posterior side of the pump.

2. Using a 4 mm Allen wrench, rotate the screw **counterclockwise** until it comes to a stop (approximately 3/4 of a turn).



The pump is now in low vacuum mode. The vacuum level for an average user will not exceed 16 inHg.

To change the Vacuum Level Setting back to **High**:

1. Locate the exposed 4 mm hex screw on the posterior side of the pump.

2. Using a 4 mm Allen wrench, rotate the screw **clockwise** until it comes to a stop (approximately 3/4 of a turn).

PATIENT BRIEFING

The LimbLogic M has been designed and tested for durability and usage in common environments. While unlikely to result in unsafe performance, there are extreme conditions which may affect the LimbLogic M's function.

Be sure to train patients:

- Not to use their LimbLogic M in corrosive environments, such as salt water.
- Not to use the LimbLogic M outside of its specified range of environmental conditions. (Refer to "Performance Characteristics" on page 15.)
- How to release the vacuum in their socket.
- To obtain medical attention in the event of an open wound on their residual limb.
- To keep fingers and toes away from pump while compressing the pump.
- How to contact you, as WillowWood's representative to this patient, in the event that they have questions about the configuration, use, or maintenance of their LimbLogic M.

POTENTIAL HOME USE CHALLENGES

The pump is unlikely to be damaged by exposure to lint, dust, or light.

While not necessary, outside surfaces can be cleaned by wiping with a water-dampened cloth.

Do not allow children or pets to play with LimbLogic M or its accessories. While designed for durability, they may be damaged if exposed to untrained or rough handling.

MAINTENANCE

Wipe the inside of the socket as needed to prevent the pump from drawing in debris.

Do not add oil or grease to the pump.

EXPOSURE TO WATER

Do not submerge the LimbLogic M in liquid.

SUPPORT

If you encounter problems that you cannot solve, or encounter unexplained behaviors, contact WillowWood at 800.848.4930 for support.

Under normal conditions, you should not need to flush or sanitize your pump. If a pump starts to smell, or if you suspect contamination, contact WillowWood for support. Do not flush the pump unless you are directed to do so by WillowWood.

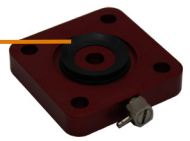
DIAGNOSTIC KIT

The Diagnostic Kit (LLM-11001) can be used to evaluate the vacuum level of the system to diagnose the source of a leak.

The kit contains a Diagnostic Plate, M6 x 60 mm bolts, a proximal gasket, a tube, a Diagnostic Disc, and a vacuum gauge.

1. Remove the pump from the socket.

2. Place a gasket on the Diagnostic Plate.



3. Place the Diagnostic Plate with the gasket on top of the pump inlet and gasket.

4. Bolt the pump onto the socket with the M6 x 60 mm bolts.

5. Install the gauge.

   Ask the amputee to activate the pump by shifting their weight on and off of the prosthesis. Observe the vacuum level with the gauge.

- If the vacuum level is adequate, remove the Diagnostic Plate and reinstall the pump with the M6 x 50 mm bolts.
- If a leak is detected:

a. Remove the pump. Install the Diagnostic Disc as shown.

b. Bolt the pump onto the socket with the M6 x 60 mm bolts.

c. Install the gauge.

Ask the amputee to activate the pump by shifting their weight on and off of the prosthesis. Observe the vacuum level with the gauge.

- An adequate vacuum level indicates that the leak is in the sleeve or the socket.
- If a pump leak is detected, call WillowWood Customer Care at 800.848.4930.

6. Remove the Diagnostic Plate and Diagnostic Disc before allowing the patient to leave with the prosthesis.

OPERATION AT HIGH ALTITUDE

At high altitude, the pump will operate at a reduced efficiency, reducing the amount of vacuum provided and increasing the amount of steps required to achieve vacuum.

SERVICE LIFE

The LimbLogic M pumps are designed for a reliable service life of at least two years.

WARRANTY

The warranty for the LimbLogic M is two years from fit date. Use of the LimbLogic M for amputees whose adjusted body weight is more than 330 lb or 150 kg (or more than 300 lb or 135 kg for U.S. Activity Level K4*) or who engage in extremely high and abusive activity is against WillowWood's recommendations and will void the warranty. Adjusted body weight is defined as the weight of the amputee plus any loads normally or routinely carried by the amputee. "Extremely high and abusive activities" are defined as activities such as skydiving, karate, and judo; activities that could result in injury to an individual's natural limbs; and activities that expose the prosthesis to corrosives such as salt water.

*Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

WARRANTY DISCLAIMER

WillowWood warrants that each product manufactured will, at the time of delivery, be of workmanlike quality and substantially free of defects. WILLOWWOOD MAKES NO OTHER WARRANTY, IMPLIED, OR EXPRESSED, AND MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. This warranty shall terminate immediately upon an action to combine our products with other materials or in any manner to change the nature of our products. The sole remedy is replacement of the products or credit for the products. WillowWood's liability shall not exceed the purchase price of the product. WillowWood shall not be liable for any indirect, incidental, or consequential damage.

WILLOW WOOD RETENTION OF RIGHTS

WillowWood retains all intellectual property rights reflected or incorporated in its physical products, regardless of the transfer of the physical products to another party or parties.

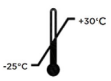
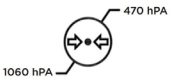
There are no field-serviceable parts inside the Vacuum Pump. Opening the Vacuum Pump will void the warranty.

REGULATORY INFORMATION

Return this product to the factory for proper disposal.

Essential performance

The distally mounted pump is designed to provide structural support when assembled into a prosthesis and complies to ISO 10328 for this function.

Symbol	Definition
	Acceptable temperature range for long term storage.
	Acceptable humidity range for long term storage.
	Acceptable pressure range for long term storage.
	Consult instructions for use.
	Adjacent to Manufacturers name and address.
	This product complies with applicable standards for sale and use in EC countries.

LimbLogic M Vacuum Pump

Blocking or plugging the exhaust port of the vacuum control assembly will prevent proper operation of the vacuum pump.

The LimbLogic M Vacuum Pump is intended for use on a single patient. Use of the system with multiple patients could lead to cross contamination between patients.

The LimbLogic M vacuum system has been designed for and clinically tested as a suspension aid. It has not been clinically tested for wound healing or other uses. WillowWood does not currently support the use of the LimbLogic M for uses other than suspension and shock absorption.

Use only the bolts supplied by WillowWood. All testing for the LimbLogic M vacuum system has been tested with the bolts included with the system. Use of other bolts could result in mechanical failure.

USER PROFILE

Prosthetist user

LimbLogic M is intended to be used for assembly of prosthetic devices by a certified prosthetist or prosthetic technician.

Patient user

LimbLogic M is intended for use by patients meeting the following conditions.

- Age: Any. Determined by clinician's evaluation of patient competence and health.
- Minimum weight to activate the pump: 100 lb (45 kg)
- Maximum weight: (Body weight plus any loads normally or routinely carried cannot exceed these weight limits.)
  - <330 lb (150 kg) for U.S. Activity Level K2-K3
  - <300 lb (135 kg) for U.S. Activity Level K4
- Health: Activity Level K2-K4
- Mentally competent to operate system as judged by prosthetist.

PERFORMANCE CHARACTERISTICS

Restrictions

- Though this WillowWood component is resistant to fresh water splashes, light sprays and sanitizing with damp cloths, it is not rated for prolonged exposure to moisture and liquids such as partial or total immersion in water (as in swimming, bathing and showering). This product is also not rated for pressure sprays, any salt water contact as well as exposure to chlorinated water, soaps and any liquid with chemical content.

PHYSICAL MEASUREMENTS

Dimensions (mm): 62L x 51W x 105H

Weight (gms): 475