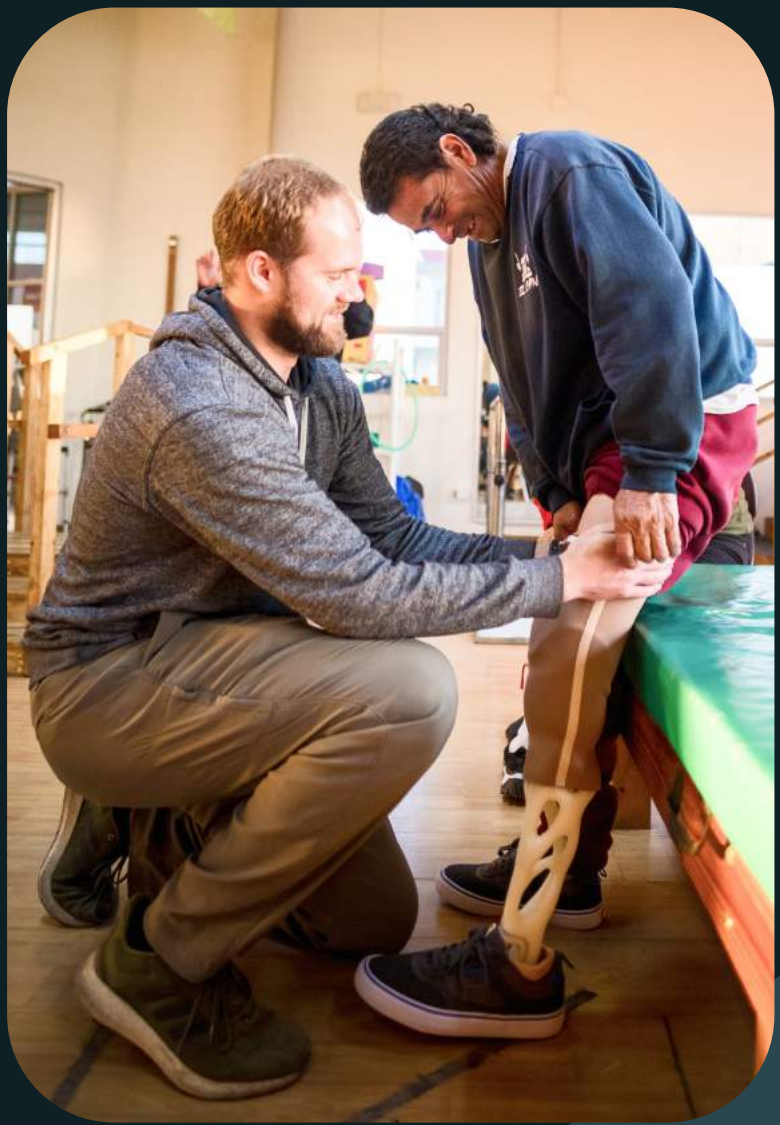
Limber P&O

LIMBER Prosthetics & Orthotics, Inc.

UniLeg CPO Manual



This document provides information about the LIMBER UniLeg for prosthetists.

20-LIM-000008 Rev B

Information for a Prosthetist Receiving a LIMBER UniLeg Prosthesis

Who is LIMBER?

LIMBER Prosthetics & Orthotics Inc. is a prosthetic manufacturing company that works directly with clinics to offer a one-piece, 3D printed prosthetic device. Only ABC/BOC-Certified Prosthetists (Providers) may order a UniLeg for their patients (End-User). LIMBER does not sell directly to the End-User.

What is the LIMBER UniLeg?

The LIMBER UniLeg is a below-knee (transtibial) prosthetic limb that is custom designed for each End-User based on three-dimensional scan data and other measurements. The device boasts dynamic performance that enables a high level of comfort and functionality.

The LIMBER UniLeg is intended for use with K1, K2, and K3 activity level patients.

MD

This device has passed ISO 10328:2016 mechanical tests for safety. Every LIMBER UniLeg is designed and manufactured under the supervision of an ABC/BOC-Certified Prosthetist.

What are LIMBER's responsibilities?

LIMBER is responsible for manufacturing the UniLeg and will support prosthetists through the scanning and fitting process. LIMBER does not interact directly with patients.

What are your responsibilities?

The Provider is responsible for measuring and fitting the End-User with the prosthesis. The prosthetist is responsible for all direct communication with the End-User, and if necessary, will reach out to LIMBER with any questions or concerns. The Provider is responsible for verifying proper socket fit and UniLeg alignment.

What are the End-User's responsibilities?

The patients who receive a LIMBER UniLeg are responsible for their own safe use of the device. End-Users **must** follow all recommendations in the following pages and all recommendations from their prosthetist and should reach out to their prosthetist immediately with any concerns or questions. Mandatory duties include good hygiene and reporting fitting issues or socket discomfort immediately to their prosthetist.

LIMBER Instructions for Providers

GETTING STARTED WITH LIMBER

Create a Clinic Account:

- Contact a LIMBER representative to initiate the account setup process for your clinic.
- The LIMBER representative will create an account not only for your clinic but also for all prosthetists who will be working with LIMBER. This step ensures that your entire team is seamlessly integrated into the LIMBER platform.

Download LIMBER PatientHub App:

- Visit the Apple App Store.
- Search for the "LIMBER PatientHub" app and click the download button to install it on your mobile device.

Log In to the App and WebPlatform:

- Open the LIMBER app after it's successfully downloaded and installed.
- You'll be prompted to log in with the account details provided by the LIMBER team during the account setup process.
- Enter your clinic or CPO account credentials to gain access to the LIMBER app, where you can begin utilizing its features and services.
- Use the same credentials to log in to the LIMBER web platform at clinic.limberprosthetics.com

START A NEW PATIENT/ORDER

Select Services:

- When you start a new order you will be able to select from a menu of services such as socket design, bilateral patient, and the 3D printing of the UniLeg.
- Select the services you desired for this order and press continue.

Basic Info:

- **LIMBER does not collect Personal Identifiable Information (PII) such as name, address, etc.** Instead we will create an Order ID that you can use to ensure devices are delivered to the correct patient.
- Begin by entering essential patient information, such as age, height, weight, amputation type, amputation side, functional level and date of amputation.

Preparation Work:

- Follow the preparation instructions provided in the app. You will be instructed on how to prepare the residual limb for measurements and scanning.

- Following the instructions in the app, illustrate the important anatomic landmarks.

Scanning:

- Utilize the COMB scanning embedded in the LIMBER app using your iPhone to capture the patient's residual limb for the prosthetic design. Make sure you upload the resultant scan files following the instructions in the app.

- If you prefer using an alternative scanning technology, upload that scan file using the LIMBER web platform at clinic.limberprosthetics.com

Measurements:

- Record precise measurements using a tape measure and a set of calipers to ensure proper customized fit for the patient's UniLeg. Measurements include residual limb circumference, length of fibula, tibia and residual limb, as well as caliper measurements of the M-L Knee Center and A-P patellar tendon.

- Other additional measurements will be taken from the sound side such as Mid Patella Tendon to floor, foot length, shoe size, heel height, toe-in and toe-out.

- Administer the Thomas Test and record the range of motion for the sound side and residual limb side.

Alignment:

- In order to provide LIMBER CPOs with the proper alignment directions, you will be asked to take pictures from a lateral, anterior and posterior view.

- Upload the images in the app or web portal following the instructions provided.

- You will also have the opportunity to provide additional design information such as desired modification method, suspension method, tissue level and the percent reduction.

- Finally, you will have the option of selecting coating and any other addons.

Submit Order:

- Once all the necessary details are entered, add your desired delivery address for this order and proceed to checkout.

- Review the checkout screen to ensure the proper options and services were selected.

- If everything is correct, proceed by submitting the order. You will receive a confirmation via email and on the app, as well as in the web-portal with the order ID for your records.

IMPORTANT: The Order ID is the only way to track the device to the corresponding patient. This will be the clinic's responsibility as LIMBER does not gather any personal patient information.

Track Orders:

- Keep track of all patient orders using the LIMBER app and web portal.

Shipping, Delivery, Reviews and Re-Prints:

- Monitor the shipping and delivery of the UniLeg using the app and web portal.
- In the App and web portal you will be asked to confirm the receipt of orders.
- You will have the option of reviewing each order, and when necessary, order a reprint.

ALIGNMENT VIA THERMOFORMING

Dynamic Alignment of the UniLeg via Thermoforming:

Introduction to Thermoforming:

Thermoforming is a technique used to adjust the fit and alignment of prosthetic devices such as the UniLeg. It involves the precise heating and shaping of thermoplastic materials to provide final alignments in accordance with a patient's residual limb. This process is essential to ensure that the UniLeg aligns perfectly with the patient's specific needs, providing comfort, stability, and functionality.

The Role of the Fixture:

In the thermoforming process, a specially designed fixture plays a crucial role. The fixture is a framework created to secure the UniLeg during the thermoforming procedure. It is constructed with careful attention to alignment to guarantee that the UniLeg is molded accurately according to the patient's requirements. The fixture serves as the foundation for achieving the dynamic alignment of the UniLeg.

How to Thermoform:

1. **Preparation:** There are two fixing points: One at the ankle/foot connection and one at the socket/pylon connection. To initiate the thermoforming process, ensure that the UniLeg components are securely fastened within the fixture at these two locations.
2. **Heating:** This process involves heating a thermoplastic material to a pliable state using a heat source. The heating process requires precise control to prevent overheating and ensure safety.

3. **Molding/Aligning:** Once the thermoplastic material reaches the correct temperature, it can be realigned using the handles on the fixture for translation and rotation. Heat softens the material, allowing the alignment to be adjusted with limited resistance. The fixture provides scales for precise control of modifications.
4. **Cooling:** The aligned UniLeg is then allowed to cool, which locks in the shape and ensures the alignment. This step is critical in achieving the desired fit and functionality.
5. **Fitting:** The UniLeg is now ready to fit again to the patient and re-test for proper gait. This process can be repeated multiple times, if necessary.

Device Instructions

LIMBER UniLeg Fitting

- The UniLeg must always have a liner installed between the UniLeg Socket and residual limb.
- The UniLeg is designed to support specified pin-locking systems, expulsion valves, and suspension sleeves which are selected by the prosthetist.
- The Provider is responsible for verifying proper socket fit and UniLeg alignment.

Single Patient – Multiple use

Environmental conditions

- Keep It Dry: Avoid prolonged exposure to moisture outside the allowable humidity range of 10% to 95%. While the UniLeg is water-resistant, extended exposure to moisture can lead to material deterioration. Ensure to thoroughly dry the UniLeg if it becomes wet and avoid leaving it submerged in water to prevent potential damage.

Suitable for submersion

- Protect from Extreme Temperatures: Store the UniLeg away from extreme heat or cold within the allowable temperature range of -20°C to 50°C (-4°F to 122°F). High temperatures can weaken plastics, while extreme cold may affect the flexibility of materials. For example: Do not leave the UniLeg inside a car on a hot summer day for prolonged periods of time.
- Prevent Chemical Exposure: Avoid contact with harsh chemicals or solvents, as they can cause damage to the materials. Clean the UniLeg using only mild soap and water as recommended.
- Proper Storage: When not in use, store the UniLeg in a clean, dry place, ideally in a bag or case to protect it from environmental elements.

Expectations when Receiving a LIMBER UniLeg Prosthesis

What risks are associated with using a LIMBER UniLeg?

The risk of using the LIMBER UniLeg is not significantly different from those risks assumed using other lower-limb prosthetic devices. Potential risks include, but are not limited to, acute trauma to the residual limb, skin breakdown, abrasion, bruising, falls, and discomfort.

What benefits can your patient expect?

The LIMBER UniLeg offers End-Users a comfortable, customized fit and lightweight design. Built to withstand the demands of daily use, the LIMBER UniLeg is durable and reliable, providing long-lasting performance. The LIMBER UniLeg's water-resistant design and easy-to-clean features make it suitable for aquatic activities and outdoor adventures, ensuring durability and functionality even in challenging environments.

Who can you call if you have questions?

Please reach out to LIMBER P&O with any questions or concerns at sales@limberprosthetics.com

Limber P&O

Creating the future of accessible prosthetic care

LIMBER Prosthetics & Orthotics, Inc.
info@limberprosthetics.com
Tel: + 1 858 321 8001
4883 Ronson Court, Ste G
San Diego, CA, 92111
United States of America

For further information please visit
www.limberprosthetics.com

© LIMBER Prosthetics & Orthotics, Inc. 2024. All rights reserved.
20-LIM-000007 Rev B

Consult instructions for use

Rx ONLY Prescription use only

UDI Unique device identifier