

G. Diagnostic socket fitting It is advisable to assess the fit with a clear diagnostic socket prior to fabrication of the final socket.

Items to assess during the fitting:

Volume: • Total contact under load.
• Shuttle lock should engage easily, but require force to be fully connected.

Trim-lines:

- Intimate fitting. No areas causing the laminated socket wall to cut the liner.
- Full knee flexion possible.
- Appropriate relief for Hamstring Tendons.

Suspension: • Little or minimal pistoning.
• No visible movement with pull.

Control: • Rotational Stability.
• Comfortable Flexion and Extension.
• M/L stability.

Before using liner:

- If there is any damage to the packaging, the liner should be cleaned with mild soap and rinsed thoroughly prior to initial fitting.
- Clean with mild soap and rinse thoroughly before each use.
- Inspect the liner for rips, tears, or holes daily.
- Insure that pin or lanyard is firmly threaded into the liner.

Warnings and Contraindications:

- The Parydonn™ liner should not be used on more than one patient, due to the risks associated with cross-contamination.
- If you experience a rash or allergic reaction while wearing the liner, discontinue use and consult a physician.
- Wearing a damaged liner may result in injury. Inspect the liner before each use.
- Only industry standard 10mm distal connectors (i.e., pin or lanyard) should be used with the Parydonn™ liner.
- Do not use the liner if the pin or lanyard connection is loose.
- If the prosthesis or liner causes pain or injures you in any way, discontinue use immediately and see your physician and/or prosthetist.
- Do not use the liner if it causes cramping or numbness in the residual limb. These are signs of a disruption in circulation. See your prosthetist or physician.



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R-720-068 Parydonn™ Liner, Prosthetist's Instructions, Rev. C

I. INTRODUCTION Thank you for choosing a high quality silicone liner from Freedom Innovations. The *Parydonn* Liner is the industry's most hygienic, user-friendly socket interface available today. It is comfortable, durable, odor-resistant and promotes healthy skin. To ensure and maximize each of these product benefits, please familiarize yourself with the following instructions before fitting a patient with the liner. Remember that informing the patient concerning proper handling and care of the liner, as set forth in these instructions, is important to achieve maximum patient comfort and product life.

II. PRODUCT SELECTION AND FITTING

A. Sizing To determine the correct liner size:

1. Measure the circumference of the residual limb 4cm proximal from the distal end.
2. Choose the liner size which corresponds equally to the measurement OR, if the exact measurement is not an available size, choose the size immediately below the indicated measurement.

NOTE: Never choose a liner size that exceeds the measurement or round up to a higher size.

EXAMPLE: If the residual limb measures 24.5cm at the indicated location choose size 23.5 NOT size 25. Selecting the correct size is very important. If the liner is too tight, the amputee could experience pistoning and/or constriction of blood flow in the residual limb that may cause cramping or numbness. If the liner is too loose, increased perspiration and/or movement of the limb inside the liner may occur. Perspiration and movement can lead to blisters and rashes. If any of the above symptoms or any other indications of improper fit are noted, the user should be instructed to contact his/her physician or prosthetist immediately.

NOTE: On transtibial applications the stabilizing matrix should cover at least 4cm of bony structures. Do not allow the matrix to extend higher than the fibula head. Similar principles apply to transradial applications, and the matrix should not extend higher than the medial condyle.

B. Trimming *Parydonn*™ liners may be trimmed for user preference and to increase range of motion. Do not cut the liner below the level of the matrix or below the proximal trim-lines of the socket. Excessive trimming may reduce the natural suction between the liner and limb and/or compromise suspension.

C. Donning Due to the Parylene Coating, two donning options are available. You may reflect and roll on the liner OR simply pull it on like a sock. When rolling

on the liner, reflect the liner over itself and roll it on to the residual limb, taking care to ensure proper pin placement. After exposing as much of the distal end of the liner as possible, position it against the residual limb and with light compression roll upward onto the limb. Roll the liner all the way up the limb, taking care not to damage it with fingernails. Regardless of donning procedure, it is important to confirm that no air pockets are present. No lubricants are required to aid in the donning process.

NOTE: Be very careful that the inside of the liner is clean, dry and free from any foreign objects that could cause skin irritation.

D. Liner Care Proper product care is important. The liner needs to be washed inside and out every day, following use. The amputee should be instructed to remove the liner, turn the liner inside out and wash it with mild soap. After cleaning, the patient should rinse the liner thoroughly with water and wipe both sides dry with a lint-free cloth. A *Parydonn*TM Liner may be used directly after washing. It does not need to dry over night. Always return the liner to its normal position with the distal attachment facing out as soon as possible after cleaning.

*Parydonn*TM Liners should always be checked for damage or wear before use. Any damage may weaken the effectiveness of the liner and should be reported to the user's prosthetist immediately. Misuse may result in loss of suspension, allergic reactions, and/or injury to the residual limb if worn while damaged.

E. Skin Care Daily cleaning of the residual limb is also essential. We recommend use of a mild liquid soap, and rinsing the liner well with fresh water to remove soap residues which could cause a rash or other allergic reaction. Do NOT apply lotion to the residual limb immediately prior to donning the liner.

III. CASTING PROCEDURE

A. Introduction The successful fitting of a transtibial prosthesis is dependent on the fit of the hard socket. Appropriate socket design is fundamental for comfort, control and suspension to be achieved. Casting may be approached in a number of ways. The following hand casting instructions are intended as a recommendation to help create a proper socket when a *Parydonn*TM Liner is being used. *Parydonn*TM Liners provide comfort and protection of residual limb tissues, allowing the user secure suspension whilst maintaining optimal convenience and simplicity. Please read the following instructions carefully before beginning the process of casting for and fitting the prosthesis.

B. Equipment

- Plaster of Paris bandages (non elastic)
- Plastic bag or wrap
- One ply casting sock
- Indelible pencil
- Tape measure
- Water.
- Lanyard or casting weight
- Scissors

C. Preparation If required, carry out full amputee assessment. Collect relevant prosthetic history and standard measurements. Inspect the residual limb and note anatomical landmarks, scarring and sensitive areas to aid in socket fitting.

Apply the plastic bag or wrap over the *Parydonn*TM liner and ensure all areas are covered. Attach lanyard or casting weight and apply tension until distal shape stabilizes. If excessive movement is observed, confirm correct liner selection and donning technique.

Note:

An undersized liner may cause:

- Increased pistoning movement
- Compression of distal residuum
- Difficulty in donning
- Cramping or poor circulation

An oversized liner may cause:

- Air pockets
- Increased perspiration

Apply a wet casting sock over the plastic barrier and hold firmly in place with an elastic waist strap if necessary. Identify and mark the following anatomical landmarks:

- Patella and patellar tendon.
- Fibula head and distal fibula.
- Tibial crest, tubercle, and distal tibia.
- Other bony areas which may contact the socket wall.
- Neuromas or other sensitive areas.
- Alignment reference lines

Record circumference at 2cm intervals, distal measures should be taken with the liner under distal tension. Record the length from MTP to distal end.

D. Casting Ensure the amputee's knee is extended but relaxed. Begin the casting process by placing a wet splint of plaster bandage over the distal end of the liner, ensuring accurate definition of the distal profile. Wrap the remainder of the remainder of the cast in a figure eight pattern making sure to ensure even pressure of the plaster bandage over the liner. Smooth the plaster cast and mold the plaster to capture bony prominences and weight bearing areas until plaster begins to set.

Note: Attach the weight or lanyard and apply tension along the axis of the limb until distal shape stabilizes prior to the plaster hardening. It may be helpful to have the amputee stand if using a casting weight and/or have an assistant to keep tension on the lanyard during the casting procedure. Once the plaster is set, carefully remove and trim the negative mold.

E. Modification Fill the negative model with plaster of Paris in preparation for modification, strip the negative cast, and ensure that all indelible pencil marks have transferred to the positive model. Compare measurements with recorded measurement.

F. Recommended Volume Reduction Procedure If utilizing a Total Surface Bearing Socket design, reduce Proximally by 3-5%. Reduce Distally to recorded measurement (0% reduction)