

# **User Manual: Silicone Prosthetic Liners**

## **Safety Instructions**

- **Read Carefully:** Before using the product, read this document thoroughly.
- **Safety First:** Follow the safety instructions to avoid injury and product damage.
- **User Training:** Ensure users are properly instructed in the safe use of the product.
- **Reporting Incidents:** Report any serious incidents related to the product to the manufacturer and the competent authorities.
- **Document Storage:** Keep this document in a safe place.

## **1. Description**

The product is a silicone liner designed for use with prosthetic limbs, providing a contact surface between the residual limb and the prosthetic socket. It is available in two types:

- **Locking Liner:** Features a distal connection option, which may have a fixed or removable distal connector.
- **Cushion Liner:** Lacks a distal port and requires a sleeve for vacuum hold.

## **2. Indicated Use**

The silicone liners are intended exclusively for the prosthetic fitting of the lower extremities, serving as the interface between the residual limb and the prosthetic socket. The suitability of the device must be evaluated and adjusted by a healthcare professional.

### **Functions:**

- Attaches the prosthesis to the limb stump using pin locking or vacuum system technology.
- Provides residual limb compression to prevent edema and reduce volume fluctuations.
- Protects and cares for the skin.
- Absorbs shock and provides cushioning.

### **2.1 Indication**

The silicone liners are to be used for prosthetic restoration following amputation or congenital deficiency of the lower extremities.

### **2.2 Contraindications**

Do not use the product in the following conditions:

- Excessive soft tissues or soft tissue overhangs.
- Unstable knee joint or impossible stump load.
- Poor hygiene.
- Very sensitive neuromas.
- Allergy or intolerance to the material.
- Contact with irritated, sick skin, or open wounds.

## 5. Size Selection

### 5.1 How to Choose the Correct Liner Size

1. **Measure Circumference:** Measure the residual limb's circumference 4 cm from the distal end. For transtibial liners, the knee should be slightly bent.
2. **Select Size:** Choose the liner size corresponding to this measurement or the next smaller size.
3. **Size Limitation:** Do not choose a liner exceeding the measurement taken and avoid reducing by more than one liner size to prevent high compression.

**Notice:** A liner with a connector often has a matrix integrated that should end below the fibula head to avoid knee flexion issues.

### Importance of Correct Size

- **Too Tight:** Can cause pistoning, numbness, and blisters.
- **Too Loose:** May lead to increased perspiration, stump rotation, blisters, and skin rashes.
- **Contact Prosthetist:** If any symptoms or issues occur, contact your prosthetist.

### Threaded Liners

- **Matrix:** Prevents excessive elongation with minimal radial extensibility restriction.
- **Application Area:** Liners with distal area matrix suit TT prostheses; full-length matrix liners are used for TF prostheses.

## 6. Adjustment of the Liner

### Inspection

- **Thorough Check:** Inspect the product for defects before fitting.

### 6.1 Trimming of a Liner

- **Caution:** Do not follow socket edge. Cut around at an equal height above the socket edge.
- **Avoid Zigzag Scissors:** To prevent tearing at serrated areas.
- **Trim Carefully:** Do not trim below the matrix edge or proximal stem cut lines to maintain adhesion.

### 6.2 Adjustment of the Socket

- **Proper Fit:** Ensure complete contact between the liner and socket wall without air pockets.
- **Ease of Use:** The patient should put on the socket easily without lubricants.
- **Full Movement:** Ensure full movement without compromising distal adhesion.
- **Redesign if Necessary:** Redesign or remanufacture the socket if conditions are not met.

## Cushion Liner Specifics

- **Airtight Socket:** Ensure the socket is airtight for vacuum fixation with a sleeve.

### 6.3 Optional: Installing the Pin

- **Threading the Pin:** Screw the pin into the distal end of the liner, using medium-strength Loctite on the thread.
- **Tighten:** Tighten the pin carefully with 3-4 Nm.