

TECHNICAL INFORMATION USER MANUAL FOR TECHNICIANS

1. INTENDED USE

The Resilience Socket is designed for use by lower limb amputees. It is intended to be used for patients who would benefit from an efficient fitting process, mobile prosthetic care and/or socket adjustability. The Resilience Socket can be molded directly to the amputee's residual limb or to a plaster mold. It should be used by a single user only. The device can be reheated and remolded multiple times and should be used in combination with other standardized prosthetic components. For the socket fitting we highly recommend utilizing the Amparo Mobile Clinic and Tool Set. Please familiarize yourself with the Resilience Socket fitting process. To assist you with this, we have prepared a step-by-step guide and a video tutorial: <https://amparo-prosthetics.com/trainings/>. For further training possibilities please contact Amparo at hello@amparo.world.

2. PACKAGE CONTENTS

- 1x Resilience Socket Material Cone
- 1x User Manual for Technicians

3. CONTRAINDICATIONS

The Resilience Socket is currently only suitable for patients with lower limb amputations. It is not suitable for patients with:

- a distal residual limb circumference with liner less than 20 cm
- a distal residual limb circumference with liner greater than 38 cm
- a residual limb length greater than 27 cm

4. TECHNICAL DATA User: Transtibial amputees

- Suspension: Passive Vacuum System, Pin Lock System or elevated vacuum depending on chosen product

SIZE	Medium
Reference Number	RS-M-*
Weight Limit	270 lbs (125 kg)
Distal Circumference (w/ Liner)	20-38 cm
Maximum Residual limb Length	27 cm
Socket Weight*	1.300 g
Color	Black Carbon, Dark Blue, Light Blue, Camo, or Custom
Mobility Grade	1-3

*During fitting 200-800g will be removed depending on residual limb length. Resilience Socket

Sold with one of the following suspension products:

- RVK - Resilience Button Valve Kit
- EVK - Resilience Elevated Vacuum Kit
- PLU-R - Pin-lock Unit for Resilience Socket

5. RISKS AND WARNINGS

Socket fittings and adjustments should only be performed by Amparo-trained clinicians. Each socket should only be used by a single amputee.

The product is heat-sensitive and must not be:

- placed near a heat source (e.g. fireplace, radiator, etc.).
- stored in direct sunlight (e.g. in the car on a sunny day!).
- exposed to temperatures higher than 120°F/48°C (sauna, hot bath, car trunk in summer, etc.).

6. MAINTENANCE

6.1. Form changes

The Resilience Socket can be completely remolded up to 5 times before replacement.

6.2. Cleaning

The Resilience Socket can be cleaned with warm water (up to 100°F/38°C) and mild soap or alcohol.

7. LEGAL NOTICE

7.1. Disclaimer

The manufacturer's liability for this product is limited to the proper use as outlined in our usage guides. No liability can be accepted for damages that are caused by other components of the prosthesis or the interaction with these.

7.2. Declaration of Conformity

This product complies with the requirements of Directive MDR 2017/745. According to the classification of criteria referred to in Annex IX to this Directive, the product is classified in class 1. According to FDA classification criteria, the product is classified in Class 1. The manufacturer declares conformity in accordance with Annex VII in sole responsibility.