

TECHNICAL INFORMATION

USER MANUAL FOR TECHNICIANS

1. INTENDED USE

The Confidence 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 Confidence 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 Confidence 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 Confidence Socket TT Material Cone
- 1x User Manual for Technicians

3. CONTRAINDICATIONS

The Confidence 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 23 cm (for S) / less than 30 cm (for L)
- a distal residual limb circumference with liner greater than 34 cm (for S), 45 cm (for L)
- a residual limb length greater than 27 cm

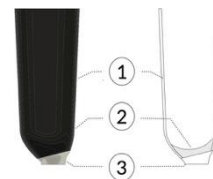
4. TECHNICAL DATA User: Transtibial amputees

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

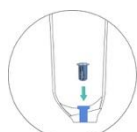
SIZE	SUCTION SUSPENSION		PIN LOCK SUSPENSION	
	SMALL	LARGE	SMALL	LARGE
Reference Number	CSBK-V-S	CSBK-V-L	CSBK-P-S	CSBK-P-L
Weight Limit	125 kg	150 kg	125 kg	150 kg
Distal Circumference	23-34 cm	30-45 cm	23-34 cm	30-45 cm
Maximum Residual limb Length	27 cm	27 cm	27 cm	27 cm
Socket Weight*	1.100 g	1.320 g	1.040 g	1.300 g
Suspension Unit Weight	20 g	20 g	180 g	180 g
Color	black	black	black	black
Mobility Grade	1-3	1-3	1-3	1-3

*During fitting 200-800g will be removed depending on residual limb length. Confidence Socket TT Material Cone

1. Low Temperature Thermoplastic Cone
2. Distal Pad or Pin Guide
3. Pre-Lateralized
- 4-Bolt Aluminum Mounting Plate



Sold with either



One-way Valve

OR



Pin-lock Unit

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 Confidence Socket can be remolded up to 5 times before replacement.

6.2. Cleaning

The Confidence 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.