TECHNICAL INFORMATION

RS | Resilience Socket

EN

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 Tool Set. Please familiarize yourself with the 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**

Package Contents

- 1x Resilience Socket Material Cone
- 1x Technical Information

Indications and Contraindications

The Resilience Socket is contraindicated for patients who do not meet the inclusion criteria or present any of the exclusion criteria listed below.

Inclusion Criteria	Exclusion Criteria
Amputation Level Transtibial	**Amputation Level** Symes, Knee Disarticulation, Transfemoral
Liner Size and Weight Limit Resilience Pediatric: 12–20 (Max Weight 60kg) Resilience Small: 16–23 (Max Weight 80kg) Resilience Medium: 20–38 (Max Weight 125kg)	**Liner Size and Weight Limit** Resilience Pediatric: < 12 or > 20 (body weight above 60 kg) Resilience Small: < 16 or > 23 (body weight above 80 kg) Resilience Medium: < 20 or > 38 (body weight above 125 kg)
Residual Limb Length Up to 27 cm	**Limb Shape** Bulbous residual limbs
	Tissue Sensitivity Hypersensitive residual limb

Technical Data

Suspension: The socket may be used with a Passive Vacuum System, Elevated Vacuum, or Pin Lock System, depending on the chosen suspension. The socket is compatible with Amparo suspension units, but their use is not mandatory. Other clinically approved suspension systems may be used as directed by a qualified prosthetist, provided they do not compromise the structural integrity of the socket, as this may void the product warranty.

Size	Pediatric	Small	Medium
Reference Number	RS-PE-*	RS-S-*	RS-M-*
Weight Limit	60 kg	80 kg	125 kg
Liner Size	12-20	16-23	20-38
Maximum Residual Limb Length	27 cm	27 cm	27 cm
Pre-Fitting Socket Weight*	700 g	700 g	1.080 g
Internal Color	Black or White	Black or White	Black or White
External Color	Black Carbon, Dark Marble (with black internal)	Black Carbon (with black internal) Dark Blue Carbon, Light Blue, Camo or Custom (with white internal)	Black Carbon (with black internal) Dark Blue Carbon, Light Blue, Camo or Custom (with white internal)
Required Accessories	Insulation Cap Pediatric (IC-P) Vacuum Adapter Pediatric (PEH)	Insulation Cap Small (IC-S)	Insulation Cap Medium (IC-M)

*During fitting 100-400g will be removed depending on residual limb length.

⚠ 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.
- Heat sensitivity:
    - Do not place near heat sources.
    - Avoid direct sunlight.
    - Do not exceed 120°F / 48°C.
- Do not use abrasive cleaning agents or solvents.
- Check residual limb daily for irritation or discomfort.

Maintenance

Form Changes

Up to 5 re-moldings before replacement.

Cleaning

Warm water (≤ 100°F / 38°C) with mild soap or alcohol.
Do not use abrasive cleaners.

Storage

Store in a cool, dry place, away from sunlight.

Disposal

Dispose of the socket according to local medical waste regulations.

Malfunction or Damage

In case of cracking, deformation, malfunction, or any unexpected change in the socket's structure or performance, discontinue use immediately and contact your clinician and Amparo Support: **support@amparo.world.**

Legal Notice

Warranty

This product is covered by a 2-year warranty against defects in materials and workmanship, provided it is used according to these instructions and for its intended purpose.

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.

Declaration of Conformity

This product complies with the requirements of Regulation (EU) 2017/745 on medical devices (MDR). 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.

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