

















## Symbol-Legende Icon Legend

|  |  |
|--|--|
|  Achtung<br><i>Attention</i>   |  Europäischer Bevollmächtigter<br><i>European Authorized Representative</i> |
|  Artikelnummer<br><i>Article number</i>  |  CE-Kennzeichnung<br><i>CE marking</i>                                      |
|  einzelner Patient-<br>mehrfach anwendbar<br><i>single patient-<br/>multiple use</i> |  Übersetzung<br><i>Translation</i>  |
|  Reinigung<br><i>Cleaning</i>  |  Vertriebspartner<br><i>Distributor</i>                                     |
|  Hersteller<br><i>Manufacturer</i>   |  Importeur<br><i>Importer</i>   |
|  Nicht bleichen<br><i>Do not bleach</i>  |  Keine chemische Reinigung<br><i>No chemical cleaning</i>                   |
|  Nicht bügeln<br><i>Do not iron</i>  |  Nicht im Trockner trocknen<br><i>Do not tumble-dry</i>                     |
|  Umpacken<br><i>Repackaging</i>  |  Prothese<br><i>Prosthesis</i>  |

Qualität und Funktion

## Gebrauchsanweisung Instruction Manual

## Verschlussstück ShL20 Locking Device ShL20



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QR-Code Download IFU



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Rev.3-2025-02\_ShL20\_110750



Please read the IFU carefully before fitting. Only correct usage will warrant the function.

## 1. Intended Use



Socket fixations are used to securely connect the residual limb in the socket of a leg prosthesis.

## 2. Technical data

Locking: Clutch lock

**REF**

| Order No. | Material | Weight | Installation height | Article No.         |
|-----------|----------|--------|---------------------|---------------------|
| ShL20     | Plastic  | 118 g  | 40 mm               | 4 655 020 00 02 000 |

### 2.1 Scope of delivery

- 1 - Locking device
- 2 - Pin, 55 mm (gear rack)
- 3 - Dummy mechanism
- 4 - Plaster connection
- 5 - Dummy screw (plastic)
- 6 - O-ring for dummy screw
- 7 - Silicone sealing washer
- 8 - Patient's key



### 2.2 Individual and spare parts

| Order No. | Description                 | Article No.         |
|-----------|-----------------------------|---------------------|
| E-ShL16   | Wrench to tighten pin       | 4 147 009 59 00 000 |
| E-ShL17   | Clutchlock pin 55 mm        | 4 147 029 04 00 000 |
| E-ShL18   | Clutchlock pin 90 mm        | 4 147 029 05 00 000 |
| E-ShL56   | Mechanism for ShL20 / ShL5B | 4 655 029 00 01 000 |
| E-ShL57   | Dummy set ShL20             | 4 655 029 00 02 000 |
| E-ShL58   | Release push button         | 4 655 029 00 03 000 |

## 2.3 Adapter options

Direct fit to socket adapter A8-Ti and A9-Ti or laminating plates A28-Al and A29-Al is possible.

## 3. Indications/ Contraindications

Indications:

- Leg amputation
- Dismelia

Contraindications:

- sensitive distal end of residual limb

## 4. Side effects

Irritation at the end of the stump due to increased tensile stress.

## 5. General safety instructions



- This medical product is designed for single patient, multiple use.
- Fitting/ service of this medical device is only allowed by a certificated orthopedic professional.
- The patient must be instructed by the technician on correct use and informed about possible side effects/ residual risks.
- The patient should be instructed to don the liner so, that the distal pin is correctly aligned. If the pin is not aligned correctly, this could cause unsafe attachment to the locking device and/ or a jammed pin, what will be difficult to release, or that the pin will not be securely locked in the mechanism.
- We recommend an installation and function check by a specialist in case of malfunction, abnormalities such as external forces.
- Improper modification or application to the product is not allowed. In case of non-observance, the function of the product may be impaired, so that product liability is excluded.
- Avoid exposing the ShL to corrosives such as salt water, chlorinated water, ammonia, highly acidic, or highly alkaline agents. In case of contact, remove the mechanism, rinse with fresh water and after drying, thoroughly grease the freewheel bearing, pinion shaft and sleeve.



## 6. Residual risks

If the liner is applied inaccurately (incorrect alignment of the pin), locking problems can occur with the closure piece.

Despite proper installation and use of the fitting parts in a prosthesis, adverse circumstances can lead to insecurity (e.g. stumbling, loss of balance, falling).

## 7. Installation

### 7.1 Deep drawing

1. Grind the distal end of the positive plaster cast down to the height of plaster connection (4) and secure with 4 nails.
2. Unscrew the mechanism from the locking device (1), screw in the dummy for the mechanism (3), shorten the dummy screw (5) as required for the particular adaptation, and screw the locking device (1) to the plaster connection (4) ensuring everything is correctly oriented.
3. Draw the deep-drawing material over the model as per the processing instructions and vacuum.
4. Ensure the material in the surrounding groove has been sufficiently vacuumed away and, if necessary, tie with a loop.
5. Once everything has cooled down, grind until the dummies are free and remove; having finished the various grinding tasks, clean the thread, insert the mechanism, and tighten to 5 Nm.



Note: During final assembly, apply a little superglue to the middle of the mechanism's thread and tighten to 5 Nm.

Caution: Do not apply too much glue or you may cause the mechanism to become stuck.

### 7.2 Laminating

1. Grind the distal end of the positive plaster cast down to the height of plaster connection (4) and secure with 4 nails.
2. Draw the PVA foil over the model, tie to the groove provided in the plaster connection (4), and attach the sealing washer (7) to the foil once tied.
3. Unscrew the mechanism from the locking device (1), screw in the dummy for the mechanism (3), shorten the dummy screw (5) as required for the particular adaptation, and screw the locking device (1) to the plaster connection (4) ensuring everything is correctly oriented.
4. Tie the reinforcing materials, tailored to the patient's weight and activity, to the surrounding groove in the locking device (1) and the adaptor, if necessary.
5. Draw the second layer of PVA foil over and start the lamination process as normal.
6. Once everything has hardened, grind until the dummies are free and remove; having finished the various grinding tasks, clean the thread, insert the mechanism, and tighten to 5 Nm.



Note: During final assembly, apply a little superglue to the middle of the mechanism's thread and tighten to 5 Nm.

Caution: Do not apply too much glue or you may cause the mechanism to become stuck.

### 7.3 Shortening the release button

The aluminum release button can be shortened from the inside to the 4th groove.



The snap fastener must be secured with Loctite® 243.

Make sure that no Loctite penetrates the mechanism.



## 8. Maintenance and Cleaning



A 12 months check of the locking device is recommended. During maintenance, the locking shaft and sleeve must be greased (e.g. MM202 lithium grease).

Cleaning:

- Compressed Air up to 2 bar
- Soap and hand warm water
- Do not use aggressive solvents for cleaning.

## 9. CE-Conformity

The product satisfies the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) and bears the CE mark. All major incidents related to the product needs to be informed to Uniprox and the competence European Authority.

## 10. Warranty and Guarantee

Depending on the degree of usage, the locking device can generally be used for 5 years with regular maintenance.

Warranty is provided under the terms of sale and supply of Uniprox GmbH & Co. KG provided that the above conditions are met.

## 11. Storage and Disposal

This product has no special storage regulations.

Please note the country-specific disposal.

### Please direct any questions to:

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