Qualität und Funktion

Gebrauchsanweisung Instruction Manual

Verschlussstück ShL20 **Locking Device** ShL20





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

#### 1. Intended Use

The locking devices are used to fix a liner in the socket of a leg prosthesis.

#### 2. Technical data

Locking: Clutch lock



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 0-ring for dummy screw
- 7 Silicone sealing washer
- 8 Patient's key



# 2.2 Service 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	Dummyset 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. Indication/Contraindication

#### Indication:

- Limb amputations
- When using liners with pin connection (Locking liners)

#### Contraindication:

- When using liners without pin connection (Cushion liners)
- Sensitive distal end of the residual limb

#### 4. Side effects

There are no known side effects.

# 5. General safety instructions





- This medical device is designed for single patient, multiple use.
- Fitting/service of this medical device is only allowed by a certificated orthopedic professional.
- The professional should instruct the correct use of the device to the user.
- 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.
- 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 nonobservance, 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.

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# 6. Application information

# 6.1 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.

# 6.2 Laminating

- 1. Grind the distal end of the positive plaster cast down to the height of plaster connection (4) and secure with 4 nails.
- 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 casting process as normal.
- 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. 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.

#### 8. 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.

#### 9. 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.

# 10. Storage and Disposal

This product has no special storage regulations.

The product is disposable with standard household garbage.

## Please direct any questions to:

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