

Qualität und Funktion

Gebrauchsanweisung Instruction Manual

Verschlussstück ShL40A, ShL40B Locking Device ShL40A, ShL40B



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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: - ShL40A with smooth pin
- ShL40B with clutch lock

Weight limit: max. body weight 150 kg

REF

Order No.	Material	Weight	Installation height	Article No.
ShL40A	Aluminium	247 g	38 mm	4 655 040 00 01 000
ShL40B	Aluminium	252 g	42 mm	4 655 040 00 02 000

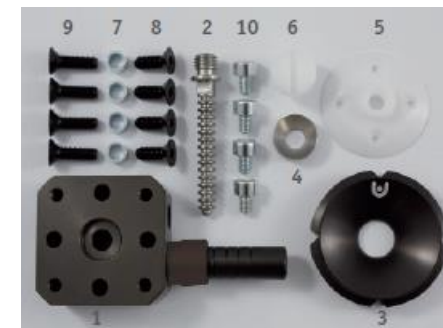
2.1 Scope of delivery ShL40A

- 1 - Locking device
- 2 - Pin, smooth, 55 mm with nurlled tip
- 3 - Lamination attachment plate
- 4 - Pin guide, stainless steel
- 5 - Plaster connection
- 6 - Bolt for dummy
- 7 - Spacers
- 8 - Countersunk head screws 6 x 20 (12.9)
- 9 - Countersunk head screws M6 x 30 (12.9)
- 10- Cylinder head screws M6 x 8



2.2 Scope of delivery ShL40B

- 1 - Locking device
- 2 - Pin, 55 mm (gear rack)
- 3 - Lamination attachment plate
- 4 - Pin guide, stainless steel
- 5 - Plaster connection
- 6 - Bolt for dummy
- 7 - Spacers
- 8 - Countersunk head screws M6 x 20 (12.9)
- 9 - Countersunk head screws M6 x 35 (12.9)
- 10 - Cylinder head screws M6 x 8



2.3 Service parts ShL40A

Bestell-Nr.	Bezeichnung	Artikelnummer
E-ShL40	Mechanism	4 147 149 00 00 004
E-ShL02	Pin, smooth 55 mm	4 147 019 00 00 002
E-ShL03	Pin, smooth, 90 mm	4 147 019 00 00 003
E-ShL54	Pin, smooth with grooved tip	4 620 009 00 33 001
E-ShL06	Push button black	4 655 049 00 06 000
E-ShL61	Replacement kit for ShL40A	4 655 049 00 05 000
E-ShL60	Dummy set for ShL 40A, ShL40B	4 655 049 00 07 000

2.4 Service parts ShL40B

Order No.	Description	Article No.
E-ShL16	Patient's key	4 147 009 59 00 000
E-ShL17	Pin, Clutch 55 mm	4 147 029 04 00 000
E-ShL18	Pin, Clutch 90 mm	4 147 029 05 00 000
E-ShL58	Lower part of the mechanics for ShL40B	4 655 029 00 03 000
E-ShL59	Dummy kit for ShL40A, ShL40B	4 655 049 00 04 000
E-ShL60	Dummy set for ShL 40A, ShL40B	4 655 049 00 05 000
E-ShL62	Sprue washer ShL40	4 655 049 00 07 000

2.5 Adapter options

Direct connection optional by the following socket adapters: A10m A11, A13 or A14

3. Indication/ Contraindicationen

Indication:

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

Contraindicationen

- 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 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 mal-function, 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 product to corrosives such as salt water, chlorinated water, ammonia, highly acidic, or highly alkaline agents. In case of exposure, rinse with fresh water and allow to thoroughly dry.

6. Application information

6.1 Deep drawing

- Grind the distal end of the positive plaster cast down to the height of plaster connection (5) and secure with 4 nails.
- Place the lamination attachment plate (3) on the plaster connection (5), making sure everything is correctly oriented, and screw down with the dummy screw (6).

- Screw the cylinder head screws M6x8 (10) provided into the lamination attachment plate (3).
- Draw the deep-drawing material over the model as per the processing instructions and vacuum. Ensure the material in the surrounding groove has been sufficiently vacuumed away and, if necessary, tie with a loop.
- Once everything has cooled down, grind until the dummy screws and cylinder head screws are free.
Caution: Only grind until things are level!
- Remove the dummy and cap screws, and insert the spacers (7) provided and the pin guide (4) into the openings provided.
- Place the locking device (1) on the lamination attachment plate (3) and screw it down using the 4 countersunk head screws M6 x 30 (9) (12 Nm).



Note: The various screws used for assembly purposes must be secured with Loctite 222.

6.2 Laminating

- Grind the distal end of the positive plaster cast down to the height of plaster connection (5) and secure with 4 nails.
- Draw the PVA foil over the model and tie to the groove provided in the plaster connection (5).
- Grease the funnel on the lamination attachment plate (3) with silicone grease.
- Place the lamination attachment plate (3) on the plaster connection (5), making sure everything is correctly oriented, and screw down with the dummy screw (6).
- Screw the cylinder head screws M6x8 (10) provided into the lamination attachment plate (3) and insulate the cylinder head screw and dummy screw with Plastilin modeling clay.
- Tie the reinforcing materials, tailored to the patient's weight and activity, to the surrounding groove in the lamination attachment plate (3). Avoid direct contact between aluminium and carbon.



Aluminium + Carbon + Moisture = Galvanic Corrosion!

- Draw the second layer of PVA foil over and start the casting process as normal.
- Once everything has hardened, grind until the dummy screws and cylinder head screws are free. Caution: Only grind until things are level!

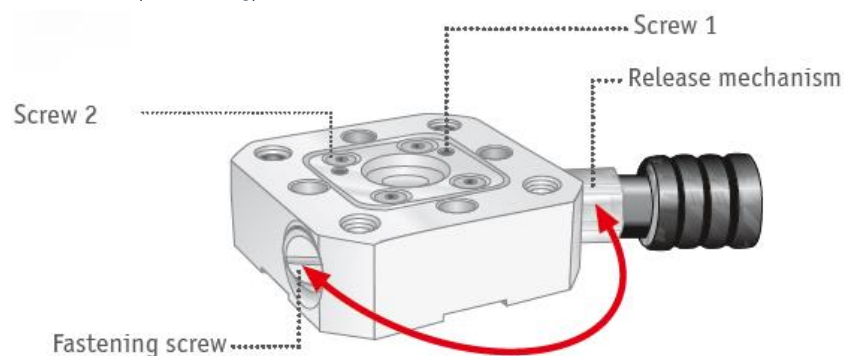
- Remove the dummy and cap screws, and insert the spacers (7) provided and the pin guide (4) into the openings provided.
- Place the locking device (1) on the lamination attachment plate (3) and screw it down using the 4 countersunk head screws M6 x 30 (9) (12 Nm).



Note: The various screws used for assembly purposes must be secured with Loctite 222.

6.3 Changing the release mechanism (only ShL40A)

The release mechanism can be screwed into the locking device on either the left or on the right (standard). The following steps must be followed when replacing the mechanism: (seedrawing)



- Unscrew the release mechanism from the locking device.
- Screw in bolt 1 as far as it will go (the bolt is inside the ShL40A).
- Remove the fastening screw and screw it into the opening of the previously removed release mechanism.
- Screw in the release mechanism on the side on which the fastening screw was screwed in. Tighten the mechanism with an open-end wrench.
- Unscrew bolt 2 (inside the ShL40A) completely and secure with slight pressure against the cover.



Caution: The bolt (Bolt 1 or 2) lying opposite the release mechanism must always be screwed in as far as it will go. The other bolt must always be screwed against the cover. The stiffness of the bolts (thread locking compound) is intentional in order to prevent them becoming loose on their own. Please follow these instructions carefully to ensure the pin is held securely in place.

7. Maintenance and Cleaning



A 12 months check of the locking device is recommended.

For ShL40A: During the annual service, check and if necessary replace (depending on usage impact) the clamp discs (E-ShL61) and pin.

For ShL40B: 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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