Qualität und Funktion

Gebrauchsanweisung **Instruction Manual**



Verschlussstücke ShL5B, ShL50B **Locking Device** ShL5B, ShL50B







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. Technische Daten

with clutch lock

ShL5B: max. body weight 100 kgShL50B: max. body weight 125 kg



Order No.	Material	Weight	Install. height	Art. no.
ShL5B	Aluminium	146 g	40 mm	41470300011001
ShL50B	Aluminium	200 g	30 mm	46550500002000

2.1 Service Parts

Order No.	Description	Art.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 00 01 000
E-ShL56	Mechanics ShL20 a. ShL5B	4 655 029 00 01 000
E-ShL58	Push Button-Set ShL	4 655 029 00 03 000

2.2 Adapter options

proximal (ShL5B, ShL50B): A19St, A20St, A21St

distal (only with ShL5B): A22St, A22Ti, A23St, A23Ti, A25Ti

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.

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6. Application information

The locking device must be screwed-on all the way down to the surface of the lamination anchor. The Locking Device can be turned-out max. 270° in order to place it in the required position. Breakage of the housing can occur if it is unscrewed more than the above mentioned amount.

After positioning the Locking Device, tighten the securing cap screw of the lamination anchor to a torque of 8 Nm.

Secure with Loctite 222 when finishing the prosthesis.

The release push button can be shortened depending on the size of the socket and cosmetics. Remove the push button from the mechanism and cut to length from the inside and remove any burrs. The push button can maximally be shortened until the last rotation groove. Finally the push button must be secured to the locking shaft with Loctite 222.

Caution: Do not use too much adhesive to prevent sticking of the mechanism!

In addition, the following must be observed with the **ShL5B**:

The distal threaded adaptor must be screwed-on up to the surface of the ShL 5B. The threaded attachment adaptor can be secured with the M4 screw ONLY for trial purposes. Bond the screw with the included UHU adhesive.

7. 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 an 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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