


Qualität und Funktion

Gebrauchsanweisung
Instruction Manual

Verschlussstück
ShL1
Locking Device
ShL1



Rev. 4-2021-05_ShL1_101687

 Uniprox GmbH & Co.KG
H.-Heine-Str.4
07937 Zeulenroda-Triebes

Tel. +49 (0) 36628-66-33 00
Fax +49 (0) 36628-66-33 55
E-Mail info@uniprox.de





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

Smooth pin with grooved / corrugated tip

REF

| Order No. | Material | Weight | Install. height | Art. No. |
|-----------|-----------|--------|-----------------|---------------------|
| ShL1 | Aluminium | 78 g | 23 mm | 4 147 110 01 00 000 |

2.1 Scope of delivery

- 1 - Locking piece
- 2 - Pin smooth with serrated tip
- 3 - Funnel \varnothing 58 mm
- 4 - Dummy for funnel with silicone sealing ring (\varnothing 14 mm)
- 5 - Dummy for pin (8.5 mm) with silicone sealing ring (\varnothing 9 mm)
- 6 - Dummy for release mechanism with silicone sealing ring (\varnothing 14 mm)
- 7 - Distance washer for connection of shaft adapter A9-Ti or sprue washer A28-Al/A29-Al



2.2 Service Parts

| Order No. | Description | Article No. |
|-----------|-------------------------------|---------------------|
| E-ShL02 | Smooth Pin 55 mm | 4 147 019 00 00 002 |
| E-ShL03 | Smooth Pin 90 mm | 4 147 019 00 00 003 |
| E-ShL54 | Smooth pin with grooved tip | 4 620 009 00 33 001 |
| E-ShL06 | Push button | 4 147 019 00 00 006 |
| E-ShL07 | Spring with silicone base | 4 147 019 00 00 007 |
| E-ShL08 | Clamp disks, 2 pieces | 4 147 019 00 00 008 |
| E-ShL09 | Mechanism for ShL1 | 4 147 019 00 00 010 |
| E-ShL10 | Lamination dummy set for ShL1 | 4 147 019 00 00 010 |
| E-ShL11 | Funnel 58 mm for ShL1 | 4 147 019 08 00 000 |
| E-ShL12 | Funnel 76 mm, for ShL1 | 4 147 019 09 00 000 |

Tooling for ShL1

| Oder No. | Description | Article No. |
|----------|-----------------|---------------------|
| E-ShL13 | Two-hole wrench | 4 147 019 10 00 000 |

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

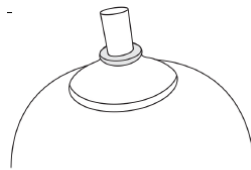


- This medical device is designed for single patient, multiple use.
- Fitting/service of this medical device is only allowed by a certificated orthopedic professional.
- The professional should instruct the correct use of the device to the user.
- The patient should be instructed to don the liner so, 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 non-observance, the function of the product may be impaired, so that product liability is excluded.
- When screwing in the unlocker, the technician must ensure that the clamping washers are correctly seated to ensure proper function. This must be checked before use on the patient with a pin inserted by hand.

6. Installation

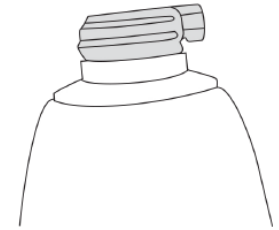
Work step 1

The dummy must be attached to the plaster positive. A hole of 8 mm must be drilled on the positive side. The dummy is ideally already placed in the plaster negative and then filled with plaster. This saves a work step and time. The average value from the silicone seal of 14 mm is finally slid over the pin of the dummy.



Work step 2

The clamping washers, the clamping spring and the release mechanism must be removed from the locking piece, the inside of the housing with thread must be lightly greased and the dummy for the release mechanism must be screwed on. Make sure that the silicone sealing ring \varnothing 14 mm is seated on the thread of the dummy.



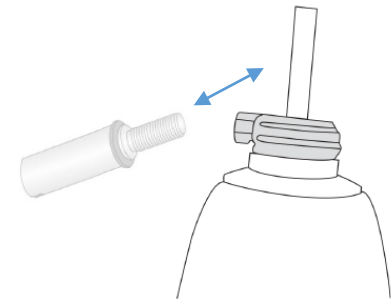
Fix the funnel (\varnothing 58 mm) on the ShL1 and place the closure piece on the dummy. (Alternately a funnel of average 76 mm can be ordered, see 2.2. at spare parts).



Work step 3

The dummy for the pin is then screwed through the locking piece into the already fixed dummy funnel.

Also make sure that the silicone sealing ring \varnothing 9 mm is seated on the dummy. The bottom film is pulled over the model and the silicone seal of the funnel and housing is set.

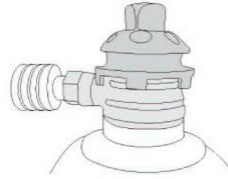


The overlapping foil is cut to just under 2 mm and additionally fixed to the housing with adhesive tape. Open areas (e.g. slots of dummies) are closed with plasticine.

The reinforcement of the socket must match the weight and mobility of the patient.

6.1 When using the A8-Ti shaft adapter:

The shank adapter A8-Ti was specially developed for mounting ShL1.



After steps 1 and 2, the dummy for pin black (supplied with the A8-Ti) is screwed into the dummy for funnel. The A8-Ti shank adapter is then placed on the dummy for pin and screwed in place with the 6 M3x20 countersunk screws. Place the special rubber laminate protector included in the scope of delivery on the A8-Ti (also on the A9-Ti), sealing the transition with plasticine if necessary. The laminate must be firmly tied to the milled groove of the A8-Ti so that the necessary stability of the adapter in the laminate is achieved.

6.2 Use of A9-Ti shaft adapter or A28-AL/A29-AL sprue washers



A9-Ti



A28-AL



A29-AL

If shank adapter A9-Ti or sprue washer A28-AL/A29-AL is in use the included the spacer washer will be needed (see 2.1 Nr. 7) .

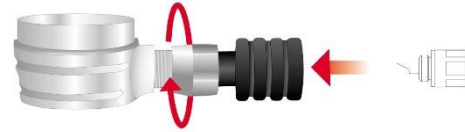
It must be placed between the locking piece and the stem adapter or the sprue screw and ensures the necessary distance to the unlocker.

The shaft adapter or sprue screw is then screwed to ShL. The laminate must be firmly tied to the milled groove of the respective adapter so that the necessary stability of the adapter in the laminate is achieved.

6.3 Inserting the release mechanism

After casting and hardening of the prosthetic socket, the plastic dummies can be milled free and removed. After that, release mechanism can be inserted.

Please take note for a simple fitting:



1. Place the release mechanism in the correct position (see picture) and insert the opening of ShL.
2. When screwing in, keep the knob of the mechanism slightly pressed.
3. Unscrew the cover inside the shaft with the two-hole wrench and remove it with the plastic funnel. Insert the clamping spring and the clamping washers (The beveled clamping disk must be on top so that the phase is visible) Take note that the washers are located under the hold-down screw and the unlocker tip. Slight loosening of the unlocking screw makes it easier to thread in the discs. Then tighten the screw connection with an open-end wrench while pressing the release button.
4. Screw the cover tight with the two-hole wrench and insert the funnel.

7. Maintenance and Cleaning



A 12 months check of the locking device is recommended. Depending on the degree of usage the clamp disks (E-ShL08) or the pin have to be renewed. With the aid of the two-hole wrench (E-ShL13), the cover of the ShL1 can be unscrewed and the individual parts can be cleaned.

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:

Customer Service: + 49 (0) 36628-66-33 70

Fax: + 49 (0) 36628-66-33 77

E-mail: export@uniprox.de