
















## Symbol-Legende Icon Legend

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

 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](mailto:info@uniprox.de)



Rev 4-2023-07\_L01,L14,L15,L03,L20

Qualität und Funktion

## Gebrauchsanweisung Instruction Manual

**Silikon-Kontaktkissen (L14, L15)**  
**Distal-Cup (L01)**  
**Silikon-Liner (L03, L20)**  
*Silicone Distal End Pad (L14, L15)*  
*Distal-Cup (L01)*  
*Silicone-Liner (L03, L20)*





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

## 1. Intended use

The silicone products (L01, L03, L14, L15, L20) are used to bed the residual limb.

## 2. Technical data

### 2.1 Distal Cup

- Distal thickness: appr. 6 mm
- Length: 150 mm
- soft, transparent silicone



Order No.	Distal circumference in cm	Silicone liner size	Article No.
L01-6	6	14	4 143 070 00 00 060
L01-7	7	16	4 143 070 00 00 070
L01-9	9	18	4 143 070 00 00 090
L01-11	11	20 / 21	4 143 070 00 00 110
L01-12	12	22	4 143 070 00 00 120
L01-14	14	23,5	4 143 070 00 00 140
L01-16	16	25	4 143 070 00 00 160
L01-17	17	26,5	4 143 070 00 00 170
L01-19	19	28	4 143 070 00 00 190
L01-20	20	30	4 143 070 00 00 200
L01-22	22	32	4 143 070 00 00 220

## 2.2 Silicone Distal End Pad

For knee disarticulations, convex (for intercondylar fossa)



Order No.	Condylar circumference in cm	Article No.
L14-1	31 – 36	4 156 020 01 00 360
L14-2	38 – 40	4 156 020 01 00 400

For knee disarticulations, concave



Order No.	Condylar circumference in cm	Article No.
L15-1	31 – 36	4 156 020 02 00 360
L15-2	38 – 40	4 156 020 02 00 400

## 2.3 Silicone Liner

- Thickness: 2,5 mm
- L03 - size in cm: 16/ 18 / 20 / 21 / 22 / 23,5 / 25 / 26,5 / 28 /30/ 32 / 34 / 36 / 38 / 40 / 42 / 45
- L20 – size in cm: 20 / 21 / 22 / 23,5 / 25 / 26,5 / 28 /30/ 32 / 34 / 36 / 38 / 40 / 42 / 45
- soft cushioning of the stump
- transparente silicone
- good guiding properties of the silicone
- also for immediate postoperative fittings



Order No.	Distal connection	Shore hardness	Length	Article No.
L03 - [size]	with	50 Shore A	350 mm	4 143 010 10 00 xxx
L20 - [size]	without	50 Shore A	350 mm	4 143 010 00 00 xxx

### 3. Indications/ Contraindications

#### Indications:

- after amputation of lower extremities
- knee disarticulations (L14, L15)
- distal volume compensation for conically shaped residual limbs (L01)

#### Contraindications:

- allergic reactions of the amputees own sweat
- problematic or unhealed wounds
- skin necrosis
- other skin problems

### 4. Side effects

Due to increased adhesion of the silicone to the skin and the stress caused by movements in the socket, irritations may occur on a sensitive skin. To protect the skin, we recommend fat-free care products such as PS06 Allpremed® hydro INTENSIV.

### 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 professional should instruct the correct use of the device to the user
- Avoid contact of the silicone products with open wounds and broken skin areas!
- Select the size that matches the measured circumference! Do not choose a large size, as this will cause an instable distal fitting.
- Do not apply the liner like a stocking! Though turn inside out and roll-on.
- Be careful not to damage the liner with your fingernails!
- It is not allowed to dry the silicone products in the tumble dryer. Only use a lint-free towel to rub.
- Keep in mind that many soaps, deodorants, perfumes, aerosols and alcohol sprays can cause irritation to the skin.
- Do not use fatty creams for skin care while using!
- Do not store the liner inside out, as the silicone could damage. We recommend the use of the liner stand E-LSG.
- For easy donning, the use of a lubricant (like Isopropyl-alcohol) on the outside of the liner is recommended.

### 6. Application information

#### 6.1 Distal-Cup

##### Size selection

To select the right size of the Distal-Cup measure the circumference of the residual limb 4 cm proximal to the distal end.

##### *Pulling on of the Distal-Cup:*

Before pulling on the Distal-Cup, turn it inside out. For easy donning, a little water on the outside of the cup is recommended. Expose the distal end of the Distal-Cup as far as possible and place it distally on the residual limb by taking care to avoid any trappings of air. Take care that the Distal-Cup is positioned centrically on the limb. Then roll it carefully over the residual limb. Dry the outer side of the Distal-Cup carefully and then roll on the Silicone Socket over the Distal-Cup and your residual limb as usual.

#### 6.2 Silicone Distal End Pad

##### Size selection

Condylar circumference

##### *Usage*

Place the pad in the socket (distally) as a residual limb bedding. The pad can be fixed with a silicone glue like M22-0,1.

#### 6.3 Silicone Liner

To select the right size of the Liner measure the circumference of the residual limb 4 cm proximal to the distal end. Choose a smaller size from the range instead of a larger size, when the measured circumference varies from the offering.

Example: Measured circumference: 27 cm, choose size: 26,5.

##### *Trimming the liner*

The liner can be trimmed to the individual needs of the patient. Cut the liner by starting with small amounts until the desired length is obtained. If available, use a wave shape cutter or - scissors. Do not cut the liner too short!

##### *Donning the liner*

- Apply a suitable lubricant (e.g. isopropyl alcohol) to the outside of the liner for easier donning.
- Roll the liner inside out. Place the distal end of the liner to the end of the residual limb.

- Slide the liner with both hands over the residual limb without pulling.
- Check if no air will be captured between the skin and liner whilst donning.
- If there is a liner plate it should be aligned in extension of the residual limb (especially when using a liner with distal connection) and the logo on the outer fabric should face posterior. If not fitted correctly, roll down the liner and start again.

## 7. Maintenance and Cleaning



The silicone products should be cleaned after every use with a silicone cleaner or mild soap at least once a day. Rinse with warm water.

The silicone products should be checked regularly for damage (e.g. cracks in the silicone).

## 8. Care of the residual limb

Clean the residual limb daily by using neutral soap. Water based skin lotions are recommended for dry skin. To protect the skin, we recommend fat-free care products such as PS06 Allpremed® hydro INTENSIV.

## 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

We recommend to change/ renew the liner after 6 month of usage.

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

Do not store the liner inside out, as the silicone could damage.

We recommend the use of the liner stand E-LSG.

Please note the country-specific disposal.

### 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](mailto:export@uniprox.de)