

















## 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	 Prothese Prosthesis

QR-Code Download GA



QR-Code Download IFU



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Ein Unternehmen der Bauerfeind Gruppe – [www.uniprox.de](http://www.uniprox.de)

Rev.0-2024-02\_Softskin(Air)

Qualität und Funktion

## Gebrauchsanweisung Instruction Manual

# Softskin SoftskinAir®



unique prosthetic solutions  
A company of the Bauerfeind Group

 uniprox®



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

### 1. Intended Use



Liners and silicone products are used to bed the residual limb in a leg prosthesis.

### 2. Technical data

The SoftSkin liner with air function allow body sweat to be drained away from the skin through micropores incorporated into the material.

#### 2.1 SoftskinAir® Sport

- Thickness: appr. 3mm
- Length: 370 mm
- Sizes in cm: 20 / 22 / 23,5 / 25 / 26,5 / 28 / 30

**REF**

Order No.	Distal Connector	Shore hardness	Article No.
Sport-[Size]-Air	with	40 Shore A	4 164 030 40 00 XXX

#### 2.2 Softskin SC30, SC40 (Air®)

- Thickness: appr. 3 mm
- Lengths: until size 26,5 appr. 370 mm, from size 28 appr. 400 mm, from size 36 appr. 430 mm
- Sizes in cm: 23,5 / 25 / 26,5 / 28 / 30 / 32 / 34 / 36 / 38 / 40 / 42 / 45

**REF**

Order No.	Distal Connector	Shore hardness	Article No.
SC30-[Size]	without	30 Shore A	4 168 010 30 50 XXX
SC30-[Size]-Air	without	30 Shore A	4 168 020 30 50 XXX
SC40-[Size]	without	40 Shore A	4 168 010 40 50 XXX
SC40-[Size]-Air	without	40 Shore A	4 168 020 40 50 XXX

#### 2.3 Softskin S30, S30CL, S40, S40CL, S50, S50CL, S-2L (Air®)

- Thickness: appr. 3 mm
- Length: 370 mm
- Sizes in cm: 16 / 18 / 20 / 21 / 22 / 23,5 / 25 / 26,5 / 28 / 30 / 32 / 34 / 36 / 38 / 40 / 42 / 45

**REF**

Order No.	Distal Connector	Shore hardness	Order No.
S30-[Size]	with	30 Shore A	4 164 010 30 00 XXX
S30-[Size]-Air	with	30 Shore A	4 164 020 30 00 XXX
S30CL-[Size]	without	30 Shore A	4 168 010 30 00 XXX
S30CL-[Size]-Air	without	30 Shore A	4 168 020 30 00 XXX
S40-[Size]	with	40 Shore A	4 164 010 40 00 XXX
S40-[Size]-Air	with	40 Shore A	4 164 020 40 00 XXX
S40CL-[Size]	without	40 Shore A	4 168 010 40 00 XXX
S40CL-[Size]-Air	without	40 Shore A	4 168 020 40 00 XXX
S50-[Size]	with	50 Shore A	4 164 010 50 00 XXX
S50-[Size]-Air	with	50 Shore A	4 164 020 50 00 XXX
S50CL-[Size]	without	50 Shore A	4 168 010 50 00 XXX
S50CL-[Size]-Air	without	50 Shore A	4 168 020 50 00 XXX
S-2L-[Size]	with	30 / 50 Shore A	4 164 010 35 00 XXX
S-2L-[Size]-Air	with	30 / 50 Shore A	4 164 020 35 00 XXX

#### 2.4 Softskin (Air®) TF

- Thickness: appr. 3 mm
- Lengths: 350 mm
- Sizes in cm: 28 / 30 / 32 / 34 / 36 / 38 / 40 / 42 / 45 / 50 / 55

**REF**

Order No.	Distal Connector	Shore hardness	Article No.
STF-[Size]	with	40 Shore A	4 165 010 60 00 XXX
STF-[Size]-Air	with	40 Shore A	4 165 020 60 00 XXX
STF-2L-[Size]	with	30 / 40 Shore A	4 165 010 30 00 XXX
STF-2L-[Size]-Air	with	30 / 40 Shore A	4 165 020 30 00 XXX

### 3. Indications/ Contraindications

Indications:

- Leg amputation

Contraindications:

- general: extreme stump shape
- Liner with pin: sensitive butt end

### 4. 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 patient must be instructed by the technician on correct use and informed about possible side effects/residual risks. Avoid contact of the liner 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.
- A liner that is trimmed too short proximal, could reduce the vacuum effect with a CL-Liner or cause incorrect fitting with a Locking liner.
- 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 liner 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 the liner!
- Do not store the liner inside out, as the silicone could damage. We recommend the use of the liner stand E-LSG.

### 5. Residual risks

Despite proper use of the liner in a leg prosthesis, in individual cases adverse circumstances can lead to insecurities (e.g. stumbling, loss of balance, falls) as well as skin irritation and pressure points.

To protect the skin, we recommend fat-free care products, such as PS06 Allpremed® hydro INTENSIVE.

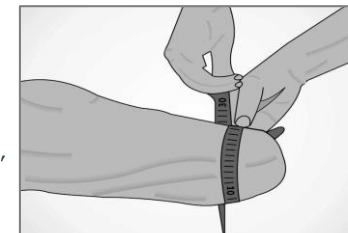
In the event of negative changes (e.g. skin irritations) during the prescribed period Please contact your doctor or orthopedic specialist workshop immediately.

### 6. Application information

#### 6.1 Size selection

To select the right size of the Softskin-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.)

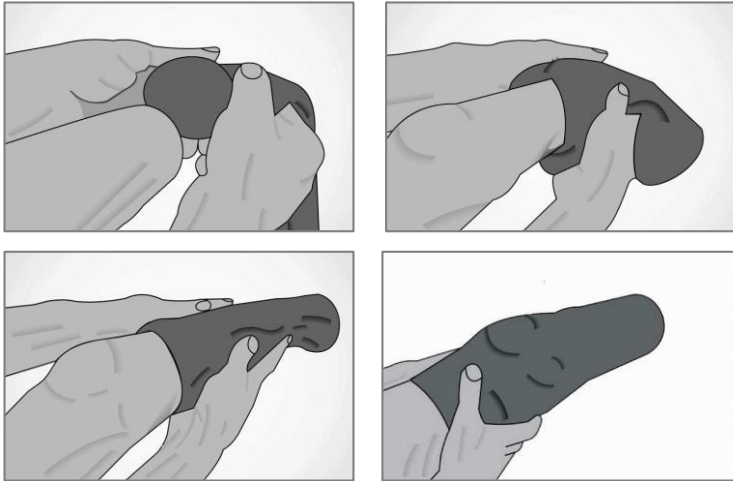


#### 6.2 Trimming the liner

The Softskin 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!

### 6.3 Donning the liner

- 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.



*(Pictures show donning of a liner for transtibial fitting; it is equal for transfemoral amputation)*

### 6.4 Activation of the micro-pores (only SoftskinAir®)

All SoftskinAir® liner models have micro-pores in the silicone material to transport moisture and/ or air away from the skin. With a newly used liner, it may happen that this initially does not work properly. The cause lies in the inherently high adhesion tendency of the silicone material.

The storage period of the liners from production to application on the patient can lead to closing of the micro-pores by the sticking habits of the silicone. By pouring water in the liner, you can easily test whether moisture penetrates through the micro-pores (see point 4).

Activation procedure:

1. Roll the liner several times from different sides onto the liner stand.



2. Twist the liner several times in alternating directions.



3. Turn the inside of the liner outward and twist the liner several times in alternating directions.



4. Fill the liner half (maximum) with water. Roll the upper end to close the liner until pressure occurs on the trapped water.



5. With successful activation of the micro-pores, water drops will leak on the outside.





## 7. Maintenance and Cleaning



The Softskin liner should be cleaned after every use, at least once a day. Place the liner inside out and clean it thoroughly with a Silicone Cleaner or with a mild soap. Rinse with warm water. The Softskin liner can also be washed in the washing machine using mild detergents at 30°C (86°F). Please use a cotton bag to protect the liner. The liner 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 observe the local disposal regulations.

### Please direct any questions to:

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