

Symbol-Legende Icon Legend



Achtung
Attention



Artikelnummer
Article number



einzelner Patient-
mehrfach anwendbar
single patient-
multiple use



Reinigung
Cleaning



Hersteller
Manufacturer



Nicht bleichen
Do not bleach



Nicht bügeln
Do not iron



Umpacken
Repackaging



Europäischer Bevollmächtigter
European Authorized Representative



CE-Kennzeichnung
CE marking



Übersetzung
Translation



Vertriebspartner
Distributor



Importeur
Importeur



Keine chemische Reinigung
No chemical cleaning



Nicht im Trockner trocknen
Do not tumble-dry



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Ein Unternehmen der Bauerfeind Gruppe – www.uniprox.de

Rev.3-2023-04_SoftskinAir

Qualität und Funktion

Gebrauchsanweisung Instruction Manual

SoftskinAir®

S30/ S30CL

S40/ S40CL

S50/ S50CL

SoftskinAir® S-2L

SoftskinAir® Sport

SoftskinAir® Cushion

SC30-Air

SC40-Air

SoftskinAir® TF



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

The SoftSkin Liners are the connection between the prosthetic socket and the residual limb. The SoftSkin Liners with Air function have additional transportation of moisture from the skin through the liner wall.

2. Technical data

2.1 SoftskinAir® / SoftskinAir® S-2L

- Thickness: appr. 3mm
- 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]-Air	with	30 Shore A	4 164 020 30 00 XXX
S30CL-[Size]-Air	without	30 Shore A	4 168 020 30 00 XXX
S40-[Size]-Air	with	40 Shore A	4 164 020 40 00 XXX
S40CL-[Size]-Air	without	40 Shore A	4 168 020 40 00 XXX
S50-[Size]-Air	with	50 Shore A	4 164 020 50 00 XXX
S50CL-[Size]-Air	without	50 Shore A	4 168 020 50 00 XXX
S-2L-[Size]-Air	with	30 / 50 Shore A	4 164 020 35 00 XXX

2.2 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

2.3 SoftskinAir® Cushion

- 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]-Air	without	30 Shore A	4 168 020 30 50 XXX
SC40-[Size]-Air	without	40 Shore A	4 168 020 40 50 XXX

2.4 SoftskinAir® 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]-Air	with	40 Shore A	4 165 020 60 00 XXX

3. Indications/ Contraindications

Indications:

- After amputation of lower extremities
- Residual limbs with insufficient distal weight bearing (CL-and Cushion-liner only)
- Residual limbs with sensitive/ sensible skin (S-2L only)
- A-symmetrical distal end of the residual limb (CL-and Cushion-liner only)
- knee disarticulation (Cushion-liner only)
- exclusively transfemoral amputation (STF only)

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

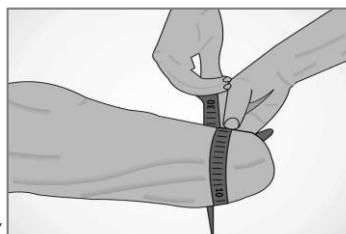


- This medical product is designed for: single patient, multiple use.
- Fitting/ service of this medical device is only allowed by a certificated orthopedic professional.
- The professional should instruct the correct use of the device to the user
- Avoid contact of the liner with open wounds and broken 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.

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.)

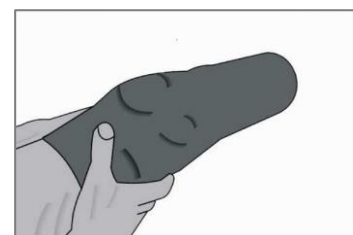
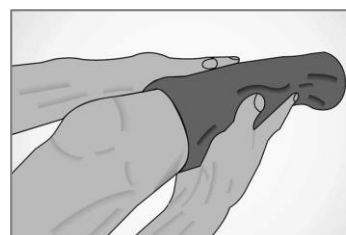
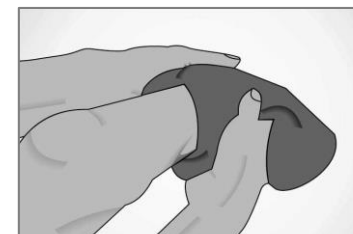
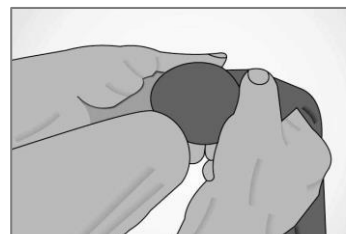


6.2 Trimming the liner

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

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.

The product is disposable with standard household garbage.

Please direct any questions to:

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