

ContexGel-Liner mit Textilbezug ContexGel-Liner with fabric cover



20L100	20L200	ContexGel.basic	ohne Außenmatrix	without outer matrix
21L100	21L200	ContexGel.soft	ohne Außenmatrix	without outer matrix
22L100	22L200	ContexGel.soft+	ohne Außenmatrix	without outer matrix
25L100	25L200	ContexGel.basic	mit Außenmatrix	with outer matrix
26L100	26L200	ContexGel.soft	mit Außenmatrix	with outer matrix
27L100	27L200	ContexGel.soft+	mit Außenmatrix	with outer matrix



D Anwenderinformation

GB Patient Information



Please read this instruction manual carefully before applying the ContexGel-Liner.

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Our general terms and conditions apply; they can be viewed anytime at www.streifeneder.com/op.



Please read this instruction manual carefully before applying the ContexGel-Liner.



Note

The sewn-in label with serial number / EAN Code must NOT be removed!



Important

The inside of the liner must be cleaned thoroughly with lukewarm water and cleaning lotion Skin-Care 10H2 prior to first skin contact.

1 Technical Data

Please refer to our latest catalogue „Prosthetics – lower extremities, socket comfort“ for available ContexGel-Liner sizes and qualities.

2 Description and Function

2.1 Application



Application according to Streifeneder walky-system:

The ContexGel-Liners 20L100, 20L200, 21L100, 21L200, 22L100, 22L200, 25L100, 25L200, 26L100, 26L200, 27L100 and 27L200 are used exclusively for prosthetic care and are approved for amputees with activity class (walky) 1 to 3.

2.2 Construction

Due to their construction, the ContexGel-Liners 20L100, 20L200, 21L100, 21L200, 22L100, 22L200, 25L100, 25L200, 26L100, 26L200, 27L100 and 27L200 feature following benefits for the user:

- Compression of the residual limb (edema prevention, less limb volume changes)
- Protection and care of the skin
- Shock absorption
- Improved adaption and increased safety by locking pin or vacuum system technology
- Protection of protruding areas by pressure distribution
- Simple handling and care (cleaning)
- Prosthetic fit with less restriction of movement (high supracondylar line or additional thigh corset are not necessary)
- Longevity
- Even for difficult residual limb conditions
- The ContexGel-Liners with outer matrix efficiently reduce the elongation during swing phase.

3 Indication

The ContexGel-Liner should be used mainly for following residual limb situations:

1. Poor coverage of soft tissue	Substitution of soft tissue by elastomer.
2. Bone protuberance	The gel flows around these pressure zones and increases the comfort of the limb embedding.
3. Burns (skin transplantations)	The liner absorbs a big part of the shear stress during walking, and consequently protects these sensitive skin areas to a great extent from mechanical overload.
4. Skin adhesions at the periosteum	

The ContexGel-Liner completes the possibilities of standard silicone liner care. The flow ability of the elastomer provides appropriate care for additional patient groups:

- Patients with arterical circulatory disorders and microangiopathies
- Patients with diabetes mellitus and its dermatological consequences

For these patients, it is important to carefully effect the volume reduction and to benefit from the good adhesion of the ContexGel-Liner.

4 Contraindication

Please carefully note the following exclusions!

1. Excessive soft tissue or overlapping soft tissue	The user „swims“ in the socket cup and shows an unsecure gait pattern.
2. Instable knee joint	All kinds of short prostheses will enhance instabilities of the knee joint and should only be applied with medical and physiotherapeutic supervision. A beneficial factor for these users is the application of soft, multi-axial foot constructions.
3. Users with high activity level	These users will complain about too much axial lift and too little rotation stability between socket and limb. Furthermore, the durability of the liner will be reduced considerably.
4. No residual limb end load possible	If the user cannot put load on the residual limb end, a ContexGel-Liner cannot be used. The limb end usually must be able to absorb 20 – 30 % of the body load.
5. Poor hygienic conditions	Please consider the instructions for cleaning the ContexGel-Liner.

6. Overly sensitive neuroma	If the user cannot put load on the residual limb end, a ContexGel-Liner cannot be used. The limb end usually must be able to absorb 20 – 30 % of the body load.
7. Allergic reactions / intolerance to the material(s)	If in doubt, consult your health care supply store resp. your orthopaedic technician in order to exclude possible hazards.
8. Contact with irritated or damaged skin	
9. Contact with open wounds	

5 Putting on the ContexGel-Liner



Attention!

We do not recommend to apply any type of lubricant to the residual limb or to the ContexGel-Liner. Petroleum jelly will damage the liner and should be avoided. The limb should be clean, dry, and free of soap residue.

1. Turn the ContexGel-Liner inside out so that the gel side is facing out.
2. With the logo and serial number in the front or anterior surface of the liner, place the end of the liner against the end of the limb. If you use a ContexGel-Liner with distal connection, center the pin attachment on the distal end of the limb.
3. Then carefully roll the liner onto the residual limb with the gel side facing the skin. For optimal comfort, place the seams away from any sensitive areas or bony prominences.



Attention!

Please take care to roll the liner onto the residual limb instead of pulling it onto it, which could stretch the skin and result in discomfort or skin irritation.

4. If the ContexGel-Liner is being put on for the first time, the user may find it somewhat tight. In order to achieve a more comfortable fit, proceed as follows:
Fold the upper edge of the ContexGel-Liner, then roll the liner almost all the way down the limb, so it looks like a thick sausage. Stop rolling down shortly before the distal end and then roll the line back on the limb. If the ContexGel-Liner still fits too tight, an additional customisation may become necessary. If in doubt, consult your health care supply store resp. your orthopaedic technician in order to exclude possible hazards.
5. Avoid wrinkles and air bubbles between residual limb and ContexGel-Liner.
6. If there is still space between the ContexGel-Liner and the socket, you should
 - Use a thicker ContexGel-Liner and a protecting stump socket or
 - Use an additional soft socket
7. Now let the user put on the prosthetic socket.

6 Perspiration

During the first weeks of use of a ContexGel-Liner, the user may complain about increased perspiration. Some orthopaedic technicians have found out that perfume-free antiperspirants or alum applied to the residual limb prior to putting on the ContexGel-Liner, are effective and gentle remedies to prevent increased perspiration. Please note the information on the package accordingly and never use these products on open wounds on the limb.



Attention

If the perspiration does not get back to normal within this time, 4 weeks, the user should consult an orthopaedic technician or a medical doctor.

7 Cleaning and care of the ContexGel-Liner



Attention!

Proper hygiene is extremely important when using the ContexGel-Liner. Please review these care instructions very thoroughly with the user.

The ContexGel-Liner must be thoroughly cleaned with cleaning lotion Skin-Care 10H2 at the end of each day of wear, and should be allowed to dry for at least 24 hours.

The use of two ContexGel-Liners is therefore recommended.

7.1 Daily Cleaning

1. Remove the liner by unrolling it from the residual limb so that it comes off the limb with the gel side facing out.
2. Immediately after removing the liner, with the gel side still facing outside, clean the ContexGel-Liner thoroughly with warm tap water and cleaning lotion Skin-Care 10H2 in order to prevent skin irritations.
Apply the cleaning lotion either by hand or with a clean, soft cloth or sponge.



Attention!

Do not scrub the ContexGel-Liner. Scrubbing can roughen the surface of the liner which may lead to skin irritations.

3. Take special care to rinse all washing lotion residue from the liner.
4. Dry the gel side of the liner with a clean, lint-free cloth.
5. Turn the liner inside out so that the fabric is on the outside, and the gel is on the inside.
6. Place the liner, with the fabric side out, onto the drying stand delivered with the liner.
7. Clean the residual limb.



Attention

Make sure that the ContexGel-Liner does not get in contact with foreign objects or substances, as they will settle in the gel and may cause skin irritations. In such cases, washing the liner may not be sufficient. Return the liner to the prosthetic shop, if it accidentally has got in contact with foreign objects or chemical substances.

The ContexGel-Liner must be checked daily for damages (tears, material abrasion).

7.2 Weekly Disinfection

1. Place a small amount (no more than 2 tbs.) of ethyl or isopropyl alcohol resp. 2 – 3 shots of Skin-Care-Spray 10H5 onto a soft, clean cloth
2. Lightly wipe the gel side of the liner with the cloth for two minutes. Rinse off any excess alcohol with water.
3. Place the liner, with the fabric side out, on the drying stand and let it dry.



Attention!

Do not immerse the ContexGel-Liner in ethyl or isopropyl alcohol. Extended contact with large amounts of ethyl or isopropyl alcohol will cause the ContexGel-Liner to stiffen.



Attention

It is most important that the ContexGel-Liner is not exposed to corrosive chemicals and substances such as salt water, acids, dust or sand! If these rules are not obeyed, the warranty and any claims towards Streifeneder ortho.production GmbH will be void.

8 Storage of the ContexGel-Liner

When the liner is not in use, it should be stored in a cool and dry place. If the ContexGel-Liner is not in use for a longer time period, we recommend storing it placed on the drying stand while covered with a clean plastic bag.

9 Service Directions and Recommendations

Generally, a visual and functional check must be done every 6 months.

10 Use

The ContexGel-Liner requires qualified and individual adaption to the patient according to medical indication. All adjustments must be done by qualified professional staff.

10.1 Restriction of Use

Due to the customisation and for hygienic reasons, please note that the product must only be used by the wearer it has been customised for and must not be transferred to any other user.

10.2 Misuse of Product

The ContexGel-Liner are exclusively constructed for the activity level (walky) 1-3 and is not suitable for sportive activities like jumping, running, e. g.



Attention!

We are pointing out, that the ContexGel-Liner are tested and released only in combination with all other Streifeneder modular parts.

10.3 Product Life Cycle

The product life cycle is limited on 3 years.

11 Guarantee

The following guarantee bond shall apply in conjunction with any legal statutory warranty claims and completely independent thereof. It is provided in lieu of any other expressed or implied warranties or suitabilities for a particular purpose (to the extent permitted by law).

11.1 Conditions

Claims resulting from this manufacturers guarantee can only be asserted, if the relevant product was installed or adjusted by or under the direction of a certified / licensed orthopedic technician AND if the product has been properly and regularly maintained by a trained technician within the provided intervals - as far as such maintenance and inspection intervals are predefined by Streifeneder ortho.production GmbH. The conducted maintenance and service checks must be confirmed with the date, official stamp and signature of the performing specialist company. The corresponding verifications shall be submitted to Streifeneder ortho.production GmbH without request, upon the assertion of claims under this Guarantee.

11.2 Guarantee and Preclusion period

The duration of our manufacturers guarantee varies depending on the product. However, the duration of the Guarantee starts in any case upon delivery to the customer. The special terms and conditions of the Guarantee for this particular product are:

Guarantee Duration for the 20L100, 20L200, 21L100, 21L200, 22L100, 22L200, 25L100, 25L200, 26L100, 26L200, 27L100 and 27L200 = 6 months

Claims under this Guarantee must be asserted immediately in writing to Streifeneder ortho.production GmbH, at the latest within one month after knowledge of the existence of the preconditions for claims under this Guarantee. Rights to assert guarantee claims are expressly excluded after the expiry of this time limit.



Note

The sewn-in label with serial number / EAN Code must NOT be removed!

11.3 Scope of Guarantee and Exclusion

It is guaranteed that the product is free from defective material and / or workmanship.

The Guarantee does not cover damages resulting from

- faulty installation,
- operating errors,
- inappropriate application (especially contrary to existing manufacturer specifications / instructions)
- normal wear and tear
- external influences such as force majeure or interventions by third parties.

Likewise not included are merely optical impairments without influence on the functionality of the relevant product, as well as defects arising from the installation of damaged components, the application of spare parts not approved by Streifeneder ortho.production GmbH and / or interventions or repair works conducted by distributors / specialist companies not authorized by Streifeneder ortho.production GmbH.

This Guarantee does not create a liability of Streifeneder ortho.production GmbH with regard to consequential loss or damage of any kind or other claims for compensation with the exception of mandatory legal provisions according to which Streifeneder ortho.production GmbH can be held accountable as manufacturer beyond the scope of this voluntary Guarantee.

11.4 Guarantee service

If all preconditions of this Guarantee are met, Streifeneder ortho.production GmbH will, at its sole discretion, either repair or replace the product free of charge.

12 Declaration of Conformity

Streifeneder ortho.production GmbH declares as manufacturer in sole responsibility, that the ContexGel-Liner 20L100, 20L200, 21L100, 21L200, 22L100, 22L200, 25L100, 25L200, 26L100, 26L200, 27L100 and 27L200 complies with the requirements of directive 93/42/EWG.

13 Disposal

The product must be disposed of or recycled according to your regional or national regulations.



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20L-P/G 2016-09