

INSTRUCTIONS FOR USE

IFU CODE: 25

IB-ER
PROSTHETIC



**Silicon
Liner**



**Gel
Liner**



**Gel Suspension
Sleeve**

CE

INFORMATION

Last Update: 01-02-2023



- Please read this document carefully before using the product.
- Instruct the user in the appropriate and safe use of the product.
- Follow the safety instructions to abstain injuries and damage to the product.
- Please keep this document in a safe place.

Contents

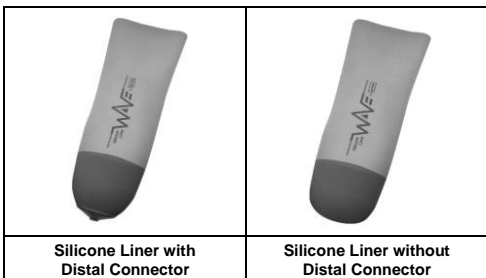
1 Silicone Liner System	1
2 Gel Liner System	6
3 Environmental Conditions.....	11
4 Service Life	12
5 General Safety Instructions	12
6 Maintenance	13
7 Warranty	13

1 Silicone Liner System

Made from Medical Grade Silicone Material. The silicones used have been tested for biocompatibility according to DIN EN ISO 10993-5 and DIN EN ISO 10993-10. High adhesion between liner and the skin. Seamless Fabric Cover.3 mm uniform thickness.2 different fabric cover has been used on outside. The fabric cover around the distal end has special "matrix" which prevents vertical stretch thus prevents the "pistoning movement". Perfect Pressure distribution. Suitable for nearly all locking devices.

Code		Distal Circumference
Silicone Liner with Distal Connector	Silicone Liner without Distal Connector	
SL-10-18	SL-18	18 cm
SL-10-20	SL-20	20 cm
SL-10-21	SL-21	21 cm
SL-10-22	SL-22	22 cm
SL-10-23,5	SL-23,5	23,5 cm
SL-10-25	SL-25	25 cm
SL-10-26,5	SL-26,5	26,5 cm
SL-10-28	SL-28	28 cm
SL-10-30	SL-30	30 cm
SL-10-32	SL-32	32 cm
SL-10-34	SL-34	34 cm
SL-10-36	SL-36	36 cm
SL-10-38	SL-38	38 cm

Code		Distal Circumference
Silicone Liner with Distal Connector	Silicone Liner without Distal Connector	
SL-10-40	-	40 cm
SL-10-42	-	42 cm
SL-10-45	-	45 cm



1.1 Adjustment of the Socket

Proper operation of the product largely depends on the fit of the head. The following points should be observed to ensure the highest level of comfort, grip and control.

- The patient can easily insert the socket without using lubricant.
- Air pockets should not form when the patient wears the liner.

- It is important to ensure full contact between the liner and the inner wall of the socket.
- Allows full movement without compromising distal adhesion.

CAUTION!



If user feedback indicates that one or more of the above conditions are not met, the socket should be redesigned or regenerated accordingly.

1.2 Wearing the Silicone Liner

1. Turn the silicone liner over. Expose the distal end of the liner as much as possible and place it against the stump. Avoid air pockets at this time.

2. Make sure the screw thread is flush with the stump and centered.

3. Then carefully roll the liner over the stump. To avoid annoying creases in the knee socket area, carefully pull the socket towards the back of the knee and put it back on the skin with a stretch.

Take special care not to damage the socket. The pin receptacle is positioned as central as possible.

4. Please avoid pulling from the upper end of the liner. Because this causes increased tension on the liner edge and the skin underneath. This is manifested by blisters, abrasions or similar symptoms. If wrinkles are formed during wearing of the liner, please repeat the procedure.

CAUTION!



If the patient has an open wound or broken skin
Cover the wound with a suitable wound dressing to
avoid direct contact between the wound and the liner.

1.3 Cleaning the Silicone Liner

- Clean the product daily after use and before first use.
- Turn the liner over. Hand wash the liner in warm water (30°C) with neutral soap. Use only soap and water for this, do not use other harsh cleaning liquids.
- Turn the liner again so that the outer/textile is on the outside.
- Tuck a towel inside the liner and lay the liner neatly to dry flat. Alternatively, a drying stand can be used. The product can also be machine washed with a mild detergent and low spin speed (40 °C).

CAUTION!



Fabric softener, bleach and other products/cleaning solutions may damage the product and should not be used. Using the wrong detergent may damage the product.

Do not use bleach, salt water or objects such as harsh chemicals, acids, dust or sand as they may damage the fabric or silicone surface outside the liner. Dry the liner textile side out to prevent damage.

- Do not store your socket unwashed or bent. The spare socket is very useful in this case, provides additional security and ease of use.
- Worn liners are generally softer than new liners.



CAUTION!

When using your silicone socket, be careful not to damage it with your nails or sharp objects such as the lock pin.

1.4 Care of Stump and Perspiration

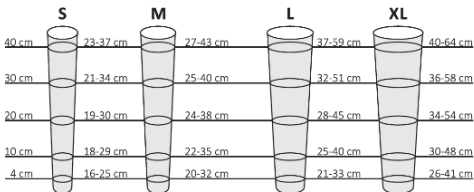
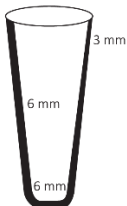
The stump should be thoroughly washed daily with neutral soap. We recommend using a mild, pH-neutral, fragrance-free and dye-free soap. For dry skin, apply a pH-balanced, dye-free and fragrance-free lotion to soften and condition the skin.

You may experience increased sweating at the beginning of your application with the silicone liner. However, this will decrease significantly after one to two weeks because there is virtually no friction between the skin and the housing, unlike more conventional fittings. Sweating may still occur with increased physical exertion.

In case of sensitive skin, skin irritation can sometimes occur. In this case, consult your medical supply store or your doctor.

2 Gel Liner System

Made from Medical Grade TPE Gel Material. Non-uniform Gel Thickness (3 mm Posterior and 6 mm Anterior). With and without Distal Connector systems are available. The Gel Material used have been tested for biocompatibility according to DIN EN ISO 10993-5 and DIN EN ISO 10993-10.



2.1 Gel Liner with Distal Connector

Code	Thickness	Size
GL-S-6-10	S	6 mm to 3 mm
GL-M-6-10	M	
GL-L-6-10	L	
GL-XL-6-10	XL	



2.2 Gel Liner without Distal Connector

Code	Thickness	Size
GL-S-6	S	6 mm to 3 mm
GL-M-6	M	
GL-L-6	L	
GL-XL-6	XL	



2.3 Gel Suspension Sleeve

Made from Medical Grade TPE Gel Material.

The Gel Material used have been tested for biocompatibility according to DIN EN ISO 10993-5 and DIN EN ISO 10993-10.

3 mm uniform thickness. Total length of the sleeve is around 340 mm.



Code	Size	Lower Circumference	Top Circumference
KP-S	S	15-22 cm	23-34 cm
KP-M	M	21-30 cm	29-43 cm
KP-MP	MP	24-35 cm	33-47 cm
KP-L	L	28-42 cm	36-51 cm
KP-LP	LP	31-46 cm	39-55 cm

2.4 Usage

2.4.1 Wearing the Gel Liner

CAUTION!



Do not apply any grease or lubricant to the liner or the stump.

Petroleum jelly can damage the liner. The use of petroleum jelly must be avoided. The stump must only be clean, dry and free of soap residue.

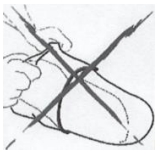
1. First, position the liner so that the logo is in front of the liner.

2. Turn the liner over with the gel side facing out. Then insert the tip of the liner into the distal stump tip. If using a liner with a distal connector, center the pin seat at the distal stump end.

3. Then carefully roll the liner over the stump with the gel side facing the skin.

Please be sure the liner is rolled up and not pulled onto the stump. If the liner is pulled over the stump, this will stretch the skin and cause an uncomfortable fit.

Pulling the liner over the stump stretches the skin and causes an uncomfortable fit.



4. Avoid trapped air and wrinkles between the stump and the liner.
5. If there is still space between the liner and the socket, you should either use a stump stocking or thicker liner.
6. Then proceed to the prosthetic socket. If you are using a liner with a distal connector, please follow the relevant instructions for the locking mechanism you are using.

2.4.2 Daily Controlling of Gel Liner

The liner should be carefully checked each time you wear it. Conspicuous spots on the seam, gel or fabric surface may indicate a change in socket fit.

In order to maintain the warranty terms and provide you with the best possible wearing comfort, please consult your treating prosthetist as soon as possible. If you are using a locking liner, please make sure the locking pin is still closely connected to the liner.

2.4.3 Perspiration

During the first weeks of wearing the liner, increased sweating may occur. Unscented antiperspirants or alum applied onto the stump before wearing the liner. They are effective tools to prevent excessive sweating. Please follow the relevant instructions of your prosthetist. Never use these products on open wounds on the stump.

2.4.4 Cleaning of Gel Liner

The liner should be thoroughly cleaned and dried after wearing.

Daily Cleaning

1. Roll the liner from the stump with the gel side facing out.
2. Remove the liner with the gel side still facing out. Clean with lukewarm tap water and pH-neutral soap immediately afterwards.

Apply the soap by hand or with a clean soft cloth or sponge.

CAUTION!



Do not treat the liner with a brush. This can roughen the surfaces of the primer causing skin irritations.

Do not use bleaching agents as they may damage the fabric on the outside of the liner. This voids the warranty.

3. Please make sure to rinse all soap residue from the liner afterwards.
4. Wipe the gel side of the liner with a clean, lint-free cloth and towel.
5. Let the liner dry with the fabric side facing out.
6. Then clean your stump.

Weekly Cleaning for Disinfection

1. Apply a small amount of ethyl or isopropyl alcohol to a soft, clean cloth.
2. Gently wipe the gel side of the liner with an alcohol-based cloth.

3. Place the liner with the fabric side out, on the drying stand provided separately.

ATTENTION!



Do not soak the liner in ethyl or isopropyl alcohol as this prolonged contact with larger amounts of ethyl or isopropyl alcohol may cause the liner to harden. This voids the warranty.

2.4.5 Storage of Gel Liner

If you do not wear the liner, it should be stored with the fabric side facing out. If you are not going to use the liner for a longer time, please put it in a clean plastic bag.

3 Environmental Conditions

Acceptable Environmental Conditions
Temperature use range: -10 °C to +45°C
Humidity: Allowable relative humidity 20% to 90%, non-condensing

Unsuitable Environmental Conditions
Fresh water, salt water, sweat, urine, acids e.g.
Sand, dust, highly hygroscopic particles (e.g., talcum)
Mechanical vibrations, impacts

Storage and Transportation
Temperature range: -20 °C to +55°C
Keep the product away from open fire or other heat sources
If the products are left unused for a long time, they should be stored at room temperature in a dry place away from direct sunlight.

4 Service Life

The service life of the product is about 12 months. This duration depends on the daily activity of the user.

5 General Safety Instructions

CAUTION!



To avoid the risk of injury and product damage, do not use for longer than the service life of the product.

The suitability of the liner to the patient and the prosthesis should be evaluated by a healthcare professional.

Avoid using this product in unsuitable environmental conditions. If the product has been exposed to unsuitable environmental conditions, check for damage.

Do not use the product that is damaged, has limited functionality or is in doubtful condition. Ensuring that appropriate measures are taken (e.g. control, cleaning, repair, replacement by the authorized workshop or manufacturer).

To prevent damage, be careful and caution when working the product.

Use the product for a single patient to avoid injuries and product damage.

Products should be used in appropriate combinations. Using the product with unsuitable combinations may result in possible injury.

Be careful not to wear a liner on injured skin!

It should not be worn on broken skin or used by people prone to skin inflammation.

The liner and its functional components should be checked regularly by an orthopedic technician for function, possible wear and tear, and possible damage.

6 Maintenance

This silicone liner is subject to natural wear and tear during continued use and should therefore be checked at regular intervals and replaced if necessary.

- After the first 30 days of use, the prosthesis parts should be visually inspected and function checked.
- Check the complete prosthesis for wear during normal inspection.
- Perform annual security checks.

7 Warranty

IB-ER company provides the warranty for the products in case of material and production flaws. Warranty duration for the above-mentioned products are individually mentioned at below.

Product	Duration After The IB-ER Invoice Date
Silicone Liner System	6 Months
Gel Liner System	
Gel Suspension Sleeve	

This warranty covers on only replacement and repair of failed products after assemblies performed by qualified individuals and competent institutions. This warranty is not applicable in case of following points:

- Improper use of the product, using with unsuitable conditions and fault assembly.
- Issues arising from replacement of our products with other products.



İB-ER Makina A.Ş
Selvilitepe OSB Mah. OSB 2006. Cad. No: 13/1
45400, Turgutlu - Manisa / Turkey

Phone : +90 (236) 312 32 00

Fax : +90 (236) 312 32 06

info@ib-er.com

www.ib-er.com



Ercan Gozuacik
Reinickendorfer Str 45 13347 Berlin GERMANY
(for regulatory affairs only)