

Adapt, Parasil, Hydro, Premier Liner IFU



MD Medical Device



PRACTITIONER / PATIENT IFU:

Please carefully review and follow these instructions before fitting a patient with the liner. Remember that informing the patient concerning proper handling and care of the liner, as set forth in these instructions, is important to achieving patient comfort and maximum product life.

PRODUCT SELECTION AND FITTING

Part number:	TT locking	TT cushion	TF locking	TF cushion
Adapt	3012L-XX	3012C-XX	3092L-XX	
Parasil	3020L-XX	3020C-XX	3070L-XX	3070C-XX
Hydro (*)	3030-XX		3050-XX	
Premier (*)	3040-XX		3060-XX	

(*) denotes Maglock Magliner with steel button

Liner sizing

To determine the correct Liner size:

1. Measure the circumference of the residual limb at 4 cm from the distal end. (*Trans Femoral and Trans Tibial figure above*)
2. Choose the Liner size, which corresponds to the measurement or which, is immediately below the indicated measurement.
3. Never choose a liner size larger than the measurement, or round up.

Example: If the residual limb measures 24.5 cm at the indicated location, choose Maglock Liner size 23.5 **not** size 25.

Selecting the correct size is very important.

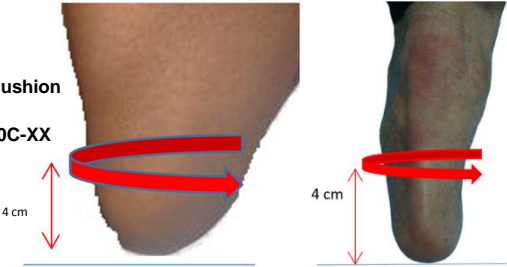
If the liner is too tight, this may cause pistoning and/or numbness and blistering.

If the liner is too loose, increased perspiration and/or movement of the limb inside the liner may occur. Perspiration and movement can lead to blisters and rashes.

If any of the above symptoms or any other indication of improper fit are noted, the user should be instructed to contact his/her prosthetist immediately.

Note: On transtibial applications the stabilizing matrix should cover at least 4 cm of bony structures.

Do not allow the matrix to extend higher than the fibula head!



Intended use

Indications for use: The product is to be used solely for lower limb prosthetic fittings.

Service life: The product is a wear part, which means it is subject to normal wear and tear, and comes with a 6 month warranty. For single user use only, not to be reused on a different user.

Trimming a Liner

ST&G Liners may be trimmed for user preference and to increase range of motion.

The Liners should be cut with a smooth non-jagged edge, which will minimize the risk of skin irritation and/or tears of the liner.

Do not cut the liner below the level of the matrix or below the proximal trim-lines of the socket. Excessive trimming may reduce the natural suction between the liner and limb, compromise suspension, or increase the instance of skin irritation if too short.

Recommended tools for liners with textile cover: Scissors for synthetic fibers or conventional straight edge scissors

Recommended tools for liners without textile cover: Conventional straight edge scissors

NOTICE! Do not use wave edge scissors.

TT liner: Cut the liner horizontally at the required length. Make sure a smooth cutting edge is obtained to prevent the material from tearing.

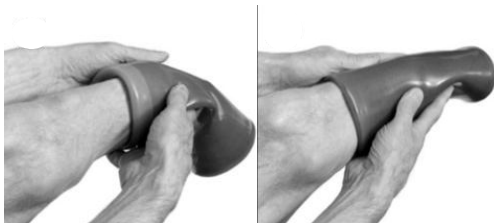
TF liner: Cut the liner according to the trim line.

The liner always has to end outside the prosthetic socket

Donning the Liner When donning the liner, turn the liner inside out and grip it as shown in the illustrations shown right.

If you are donning any of the liners make sure that the distal cap is close to the desired location on the bottom of the limb before applying the upper liner.

Note: Be very careful that the inside of the liner is clean, dry and free from any foreign objects that can cause skin irritation.



After exposing as much of the distal end of the liner as possible, position it against the residual limb and with light compression roll up onto the limb.

Check that no air pockets are present on the bottom of the limb as you start to roll liner up.

Roll the liner all the way up the limb, taking care not to pull the liner and damage it with fingernails.

Do not tug, stretch, or pull.

When using a Hydro or Parasil liner without a textile cover

The low friction outer coating that is applied to the Hydro or Parasil liner facilitates easy donning. The coating will actually slide on itself without any lubricant or powder being necessary.

Distal shape of the limb

Off the shelf liner Distal Cups can help to provide enhanced shape and comfort for conical limbs with poor soft tissue coverage. They can also be used as a fitting tool in conjunction with the Liners to ensure total contact between the silicone and residual limb.

When using a Liner in combination with a Distal Cup, the liner measurement (4 cm from the distal end) should be made with the Distal Cup in place (i.e. over the Distal Cup). Choose the correct Liner size based on the measurement obtained with the Distal Cup in place.

Liner Care

Proper product care is important. The liner needs to be washed inside and out every day, following use. Remove the liner, turn the liner inside out and wash it with pH balanced, 100% fragrance- and dye-free soap. After thorough cleaning, the patient should repeatedly rinse the liner thoroughly with water, then wipe both sides dry with a lint-free cloth. Always return the liner to its normal position with the distal cushion, maglock cap, or attachment facing out as soon as possible after cleaning. The liner should always be checked for damage or wear (such as punctures or tears). Any damage may weaken the effectiveness of the liner and should be reported to the user's prosthetist immediately.

Misuse may result in potential loss of suspension, which can cause a fall, or possible skin breakdown if there is a tear. Note: Care must be taken by both the prosthetist and the patient not to expose a liner to glass or carbon fibers or other foreign particles, not even baby powder. Such substances can become embedded in the silicone causing aggravation of the skin. Washing alone may not be sufficient to eliminate the problem and the patient should be instructed to return the liner to the prosthetist if the liner is inadvertently exposed to any foreign substances or chemicals.

All ST&G Liners have silicone that contain Mineral Oil. This acts as a natural moisturizer and is known for its active soothing effects on skin. For this reason, the liner should not be left inside out for extended period or exposed to excessive heat or sunlight.



Storage

Store at room temperature, and avoid extremely hot, cold, or moist storage environments.

Do not store with liner inverted! This can void warranty!

Be sure to limit UV exposure, as it can start to degrade fabric prematurely.

Contact with heat, heat, embers or fire Injuries (e.g. burns) caused by melting of the material and damage to the product.

▲ Keep the product away from open flames, embers and other sources of heat.

▲ Do not expose the product to temperatures above +80 °C or below -20 °C.



Skin Care

Daily cleaning of the residual limb is also essential. It is recommended to use a mild liquid, pH balanced, 100% fragrance and dye-free soap. If dry skin is noted, apply a pH balanced, 100% fragrance- and dye-free lotion to nourish and soften the skin. Lotions with Aloe Vera extract are preferred to help with skin conditioning.

Do not apply lotion to the residual limb immediately prior to donning the liner or to an open wound.

▲ **Note:** Many common household or bath products, including soaps, deodorants, perfumes, aerosol or alcohol sprays or abrasive cleaners may cause or contribute to skin irritation and the patient should be so advised.

▲ **Note:** It may be necessary to remove liner and dry the liner and allow the limb to dry depending on activity or weather conditions. Do not allow sweat to pool up inside the liner.

▲ **Note:** Use of a lubricating gel/lotion may be necessary along the top edge of the liner should there be potential for skin abrasion due to scarring, skin graft, or occasional activity that may produce excessive pulling or friction.

CAUTION:

Reuse on other persons and improper cleaning Skin irritation, formation of eczema or infections due to contamination with germs

▲ The product may be used by one person only.

▲ Clean the product regularly.

CAUTION:

Incorrect or excessively tight application of the product to the body Risk of pressure points and constriction of blood vessels and nerves due to improper application

▲ Ensure that the product is applied properly and fits correctly.

▲ Do not continue to use the product if there are problems with the correct fit.

CAUTION: Use of the product on damaged skin

Skin irritation, formation of eczema or infections due to contamination with germs

▲ Only use the product on healthy skin.

Maintenance instructions

Depending on the amputee's activity there is a service life of three to five years. We recommend carrying out bi-annual inspection / safety checks. Do not reuse components on a different prosthesis after the life expectancy has passed.

Legal information

▲ Substances in sweat containing Sulphur may cause discoloration. This discoloration has no effect on the function or durability of the liner but cannot be removed. Sulphur may enter sweat through food, for example, protein products, cabbage, nuts, legumes and Sulphured products (e.g. dried fruit). Discoloration of the liner does not justify customer complaint claims.

Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregard of this document, particularly due to improper use or unauthorized modification of the product, or if reusing on a different prosthesis than originally intended for.

CE conformity

This product meets the requirements Council EU 2017/745 (MDR) for medical devices. This product has been classified as a class I device according to the classification criteria outlined in Annex IX of the directive. The declaration of conformity was therefore created by the manufacturer with sole responsibility according to Annex VII of the directive.

Warranty

The manufacturer warrants this device for 6 months from the date of purchase. The warranty covers defects that can be proven to be a direct result of flaws in the material, production or construction and that are reported to the manufacturer within the warranty period. Signs of abuse will not be a covered event, such as finger nail tears, tears propagating from improper trimming (liner trimming should generally follow the contours of the brim, but without any severe contours), or lack of following cleaning instructions.

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