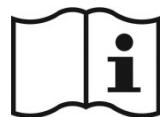




A DIRECT HEALTHCARE GROUP COMPANY

User's guide

Tergo®Glide
Tergo®Belt



See also:

How to use Tergo®Glide and Tergo®Belt (Video-URL, in Finnish)



<https://www.youtube.com/watch?v=9VwQ3KsOrZ4>

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1 Description of symbols used

1.1 Device and packaging symbols



Manufacturer



Do not use if
the packaging
is damaged or
has been opened



Product code



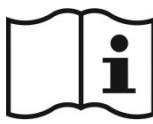
Date of
manufacture
(yyymmdd)



Store away from
heat



Lot number



See user's
guide



Keep protected
from rain



Warning



Class 1 medical device
under the Medical
Device Regulation
2017/745 (MDR)

2 Introduction

2.1 Intended use

(Tergo®Glide) The intended use of the product is repositioning, lateral transfer, gliding and/or lifting of patients lying down and whose moving capability is compromised. Incontinence protector pad.

(Tergo®Belt) Accessory for Tergo®Glide. Supporting the operator in transfer situations.

2.2 Operating environment

Used in professional or domestic healthcare environments.

2.3 User profile

Professional healthcare personnel or lay person, who is instructed by a professional healthcare personnel.

2.4 Target patients

Patients in the above-mentioned environments for whom a healthcare professional has determined the need for treatment support and evaluated the medical device as appropriate for the patient and the particular treatment situation.

2.5 Indications

Tergo®Glide acts as a transfer aid for a patient who needs to be transferred or moved by lateral transfers, sliding, or lifting. Tergo®Glide's absorbent properties protect the patient's skin from moisture.

2.6 Contraindications

No known contraindications.

2.7 Products whose use is described in this guide

- Transfer aid with incontinence protector pad
 - Tergo®Glide (S/M), (L/XL)
 - Accessory: Tergo®Belt



Read this guide carefully before starting to use the product. Persons who have not read this user's guide or cannot understand its content may not use the products independently.



Keep this guide.



Any serious incident that has occurred in relation to the device described in the user's guide that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat; should be reported to the manufacturer and the competent authority of the Member State or Sovereign State in which the user and/or patient is established.

2.8 Warnings



- If you have any questions regarding the commissioning of the products, contact the reseller.
- Contact the reseller if any part of the product is damaged or works in an unusual way. Do not attempt to repair damage before contacting the reseller.
- Do not use the device if the configuration is incomplete or any of its components is broken, worn or contaminated. Worn, missing and broken parts must be replaced and contaminated ones cleaned.

- Do not modify the product without the manufacturer's permission. Unauthorised modifications and connections may pose a danger to the user of the product.
- The user is responsible for any and all consequences of the use of the device in a manner inconsistent with its intended purpose or resulting from maintenance, repair or modification carried out by a party other than the manufacturer or reseller.
- Use only original accessories from the manufacturer.
- The operability of the product must always be ensured before a treatment situation.
- (Tergo®Glide) Is not to be used with mechanical lifting devices.
- (Tergo®Glide) It is forbidden to use a product that has broken in the handles or support structures under them. To ensure the safety of the patient and caregiver, a product whose support structures have broken down must be taken out of service immediately.
- (Tergo®Glide) Comply with occupational safety regulations laid down in terms of the maximum weight/lifting a person.
- (Tergo®Glide) In the treatment situation, a healthcare professional is responsible for implementing an ergonomically suitable and correct lifting and transferring method in accordance with the support given in the user's guide.
- (Tergo®Glide) Always have at least 4 people, 2 people per side when lifting. Lifting is always the responsibility of the user.
- (Tergo®Glide) The maximum permissible weight limit when lifting a patient is 250 kg.
- (Tergo®Belt) It is forbidden to use a product with broken buckles or support structures. To ensure the safety of the patient and caregiver, a product whose support structures have broken down must be taken out of service immediately.
- (Tergo®Belt) It is prohibited to use Tergo®Belt in lifting a patient.
- If the surface materials are exposed to urea (sweat and urine) for a prolonged period, the molecular structure of polyurethane may break down, damaging the materials. Clean the product immediately if exposed to urea.
- Do not clean the products using solvents, phenols or clean alcohols.
- After washing and cleaning, ensure that the product is entirely dry before commissioning it.
- In each step of the washing, it must be ensured that the product is not exposed to contact with heat that damages it, for example via metal parts in the devices.
- If the product is used in violation of the instructions specified in the user's guide, or it is not cleaned of body secretions containing urea in particular, or the product is used by a prominently sweating or mobile patient, the estimated life cycle of the product may be shortened. This does not extend the product warranty.

- Contaminated products must be cleaned before disposal or, if cleaning is not possible, disposed of in accordance with official regulations pertaining to contaminated healthcare waste.
- The products must always be cleaned in accordance with the cleaning instructions described in this guide. The warranty does not apply to a product that has been cleaned in violation of the instructions.
- Any serious incident that has occurred in relation to the device described in the user's guide that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat; should be reported to the manufacturer and the competent authority of the Member State or Sovereign State in which the user and/or patient is established.

3 Tergo®Glide

3.1 Contents of the sales package



If the delivery set is damaged or incomplete, do not commission the product. Immediately contact the product reseller.



Figure 1: Tergo®Glide.

Depending on the configuration, the sales package includes:

- Tergo®Glide (S/M or L/XL)
- User's guide (KOHJ-D-EN2)

3.2 General description

Tergo®Glide is an ergonomic aid with handles, which is intended for transferring and turning patients with disabilities. The product has an integrated incontinence protection pad.

Tergo®Glide consists of a bed pad in several layers and the sliding and handle constructions specified below. The long sides of the product have 6 handles per side.

The fabric under Tergo®Glide slides across the sheet, which among other things makes it easier for the patient to turn independently and assisted. Correspondingly, friction occurs longitudinally in the fabric, which means that Tergo®Glide slows down sliding downwards when the backrest is folded up.

3.3 Commissioning and operation

- 1) The product is delivered wrapped in packaging plastic. Carefully remove the packaging plastic so that no sharp objects, such as box cutters or scissors, come in contact with the product. Sharp objects may damage the product.
- 2) Check that the product you received is undamaged and matches the order. Product identification information is indicated on the labels.
- 3) Place Tergo®Glide evenly in bed without the patient. The Tergo®Glide is placed on the bed on top of the sheet immediately under the patient. The gray sliding side down, the green bed protector facing up towards the user. The integrated lifting handles will always be placed alongside the length of the bed, as shown in the picture below.



- 4) When placed correctly the Tergo®Glide extends over the patient's shoulders shown in the picture below.

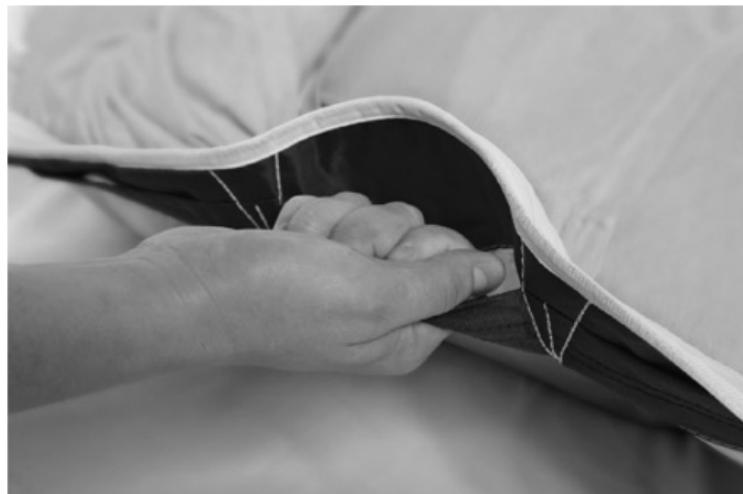


3.4 Transfers and lifting

- 1) Before the transfer, adjust the bed to a suitable height, the operator's fingers approximately level to the top of the bed, as shown in the pictures below.



- 2) The user's grip on the handles must be chosen according to the requirements for the transfer task, so that as little load as possible is directed at their joints. The picture below illustrates a reverse grip.



- 3) The transfers are made using weight transfer.



4) Turning the patient.



5) Assisting the patient to a sitting position.



- 6) Moving upwards in bed with the help of two caregivers.



See also:

How to use Tergo®Glide and Tergo®Belt (Video-URL, in Finnish)



<https://www.youtube.com/watch?v=9VwQ3KsOrZ4>



The operability of the product must always be ensured before a treatment situation.



It is forbidden to use a product that has broken in the handles or support structures under them. To ensure the safety of the patient and caregiver, a product whose support structures have broken down must be taken out of service immediately.



Comply with occupational safety regulations laid down in terms of the maximum weight/lifting a person.

- !** Always have at least 4 people, 2 people per side when lifting. Lifting is always the responsibility of the user.
- !** Comply with occupational safety regulations laid down in terms of the maximum weight/lifting a person.
- !** In the treatment situation, a healthcare professional is responsible for implementing an ergonomically suitable and correct lifting and transferring method in accordance with the support given in the user's guide.
- !** The maximum permissible weight limit when lifting a patient is 250 kg.
- !** Tergo®Glide is not to be used with a mechanical lifting device.

4 Tergo®Belt

4.1 Contents of the sales package



If the delivery set is damaged or incomplete, do not commission the product. Immediately contact the product reseller.



Figure 2: Tergo®Belt (Tergo®Glide in the picture is not included in the sales package).

Depending on the configuration, the sales package includes:

- Tergo®Belt
- User's guide (KOHJ-D-EN2)

4.2 General description

Tergo®Belt is an accessory (adjustable belt) for the transfer aid Tergo®Glide and it has been designed to make patient transfers more efficient and easier.

4.3 Commissioning

- 1) The product is delivered wrapped in packaging plastic. Carefully remove the packaging plastic so that no sharp objects, such as box cutters or scissors come in contact with the product. Sharp objects may damage the product.
- 2) Check that the product you received is undamaged and matches the order. Product identification information is indicated on the labels.
- 3) The product is ready for use with Tergo®Glide.

4.4 Operation

- 1) Slip the end of the belt through the handle on the Tergo®Glide transfer aid. Fold down the buckle and slip it through the D-link to a suitable distance, as shown in the picture below.



- 2) Attach the other end of the belt in the same way. The fastening loops are now firmly in place.



- 3) Step between the belt loop and the patient. Take a firm grip on the belt at the patient's shoulders and hips. Place yourself in position, with your back straight. Move using the weight transfer.



- 4) Transferring from one bed to another. If necessary, two people can perform the transfer. Note! Check that the beds are at the same height and their wheels locked.



See also:

How to use Tergo®Glide and Tergo®Belt (Video-URL, in Finnish)



<https://www.youtube.com/watch?v=9VwQ3KsOrZ4>

 The operability of the product must always be ensured before a treatment situation.

 It is forbidden to use a product that has broken buckles or support structures under them. To ensure the safety of the patient and caregiver, a product whose support structures have broken down must be taken out of service immediately.

 Comply with occupational safety regulations laid down in terms of the maximum weight/lifting a person.

 It is forbidden to use this product when lifting patients.

 In the treatment situation, a healthcare professional is responsible for implementing an ergonomically suitable and correct lifting and transferring method in accordance with the support given in the user's guide.

5 Maintenance and storage

5.1 Cleaning

The products must be cleaned in accordance with these instructions whenever

- there is suspicion that any part of the product is contaminated
- there is visible dirt or secretions on the product
- the patient is changed to another

 Do not clean the products using solvents, phenols or clean alcohols.

 If the surface materials are exposed to urea (sweat and urine) for a prolonged period, the molecular structure of polyurethane may break down, damaging the materials. Clean the product immediately if exposed to urea.

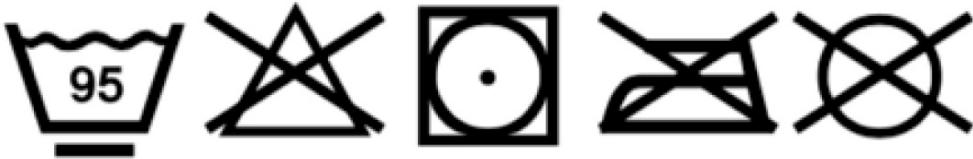
Wiping (Tergo®Belt only)

- Wipe with a cleaning agent with pH value of about 10.
- When wiping with a disinfecting cleaning agent, do not use corrosive agents.

Machine wash

- Heat disinfecting recommendation 10 min at 70°C
- Max. washing temperature 95°C
- Hang to dry (or use 1-point tumble dry in a washing bag)
- Ensure that the product is entirely dry before commissioning it
- (Tergo®Belt) Use a washing bag
- Do not chlorine bleach
- Do not iron
- Do not dry wash
- Do not use conditioners
- Washable in soft laundry

- Do not wash with hard or sharp objects (eg. Velcro fastenings, zips)



Drying and finishing (Tergo®Glide)

- Sheet program (optional):
 - Use 1-point tumble dry.
 - The product is dried until damp, after which hot mangling at max. 150 °C.
 - When mangle the green absorbing side always faces the heated roller.
- Terrycloth program (optional):
 - Use 1-point tumble dry.
 - The product is dried until dry, after which folded.
 - When using the terrycloth program, the product remains wrinkled.



In each step of the washing, it must be ensured that the product is not exposed to contact with heat that damages it, for example via metal parts in the devices.

5.2 Checking the operability of the products

To maintain the operational reliability of the products, you need to monitor their condition throughout their life cycle as follows.

5.2.1 Life cycle of products

The estimated life cycle of the products, when properly cleaned and in their normal intended use, has been assessed to be about two (2) years.



If the product is used in violation of the instructions specified in the user's guide, or it is not cleaned of body secretions containing urea in particular, or the product is used by a prominently sweating or mobile patient, the estimated life cycle of the product may be significantly shortened. This does not extend the product warranty.

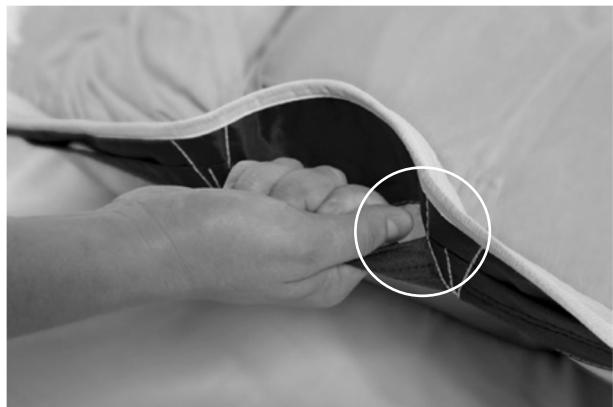
5.2.2 Inspection intervals

The condition of the products must be checked as follows:

- When commissioning the product
- When transferring the product between treatments
- When cleaning
- Whenever there is reason to believe the device has had an accident
- If you suspect that the product is broken or the interior is contaminated
- When the patient is changed to another

5.2.3 Inspection areas

- (Tergo®Glide) In particular, check the handles and support structures below it (see picture) to detect any cracks and cracked seams.



- (Tergo®Belt) Condition on buckles and buckle seams (cracks, stretch marks).
- Product water permeability / leakage (condition of the polyurethane film).
- The product's natural wear, such as worn edges, cracked surface seams or pilling of satin (silk), do not constitute an obstacle to using the product.



It is forbidden to use a product that has broken in the handles or support structures under them. To ensure the safety of the patient and caregiver, a product whose support structures have broken down must be taken out of service immediately.

5.3 Storage and transport

- Store in a clean, dry place.
- Do not place sharp or heavy objects on or near the products.
- Do not store near heat sources.

6 Disposal of products



Contaminated products must be cleaned before disposal or, if cleaning is not possible, disposed of in accordance with official regulations pertaining to contaminated healthcare waste.

6.1 Product

The product can be disposed of as burnable matter or in mixed waste. Paper can be disposed of in waste paper collection.

6.2 Packaging

Plastic packaging can be sorted into plastic packaging collection.

7 Warranty

The products have a warranty of one (1) year from the date of purchase. The warranty covers all faults resulting from defects in materials or workmanship.

For warranty questions, please contact the seller of the product.



The limited manufacturer warranty does not apply to situations where the product has been used or cleaned in violation of the user's guide.

8 Technical specifications

Basic-UDI-DI (GMN)	642981059150TEGW6 642981059151TEBW3	Tergo®Glide Tergo®Belt
REF group identifiers	50TEG 51TEB	Tergo®Glide Tergo®Belt
Weight limit for use (Tergo®Glide)	max. 250 kg (EN ISO 10535:2006 sub clause 8.3)	
Absorbency (Tergo®Glide)	30 dl/m ²	
Dimensions (W x L x H) - total weight	Tergo®Glide: 88 x 120 cm (S-M) - 815 g, 105 x 120 cm (L-XL) - 980 g Tergo®Belt: 4 x 240 cm / 4 x 345 cm - ~200 g	
Materials	Tergo®Glide Multi-layered structure: PE (velour/fleece)/PU	
	Tergo®Belt Fabric: PU/PES Buckles: PE	
Flammability	EN ISO 12952-1:2010 + EN ISO 12952-2:2010	
Design standards	EN ISO 10535:2006 sub clause 8.3 (Tergo®Glide only) EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 10993-1:2018 EN ISO 15223-1:2016 EN ISO 3758:2012	
	Class I medical devices under the Medical Device Regulation 2017/745 (MDR) (Rule 1 - Non-invasive devices).	
Patent (Tergo®Glide)	European Patent No 2 787 950	

9 Contact details of the manufacturer



Manufacturer:

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