

## Instruction For Use Leg Trough (THS/THS-43/THS-61) CE



**Product Name(s):** Leg Trough (THS/THS-43/THS-61)

**Intended Purpose and Design:** The leg trough is a U-shaped foam trough heel elevator, recommended for use with individuals assessed as being At High Risk of developing a pressure ulcer and/or those with Stage I and II pressure ulcers\*.

The leg trough provides pressure relief by completely offloading the heel from the surface of the bed, allowing the heel to 'float'. The leg trough is designed in such a way as to allow pressure to be spread evenly along the full length of the calf, reducing the pressure on the Achilles tendon and popliteal vein. The THS-43 also allows for a slight flexion of the knee, in order to reduce the risk of popliteal vein compression and Deep Vein Thrombosis (DVT)\*\*.

The leg trough is made of combustion modified polyurethane and is covered in a wipe clean multi-stretch vapour-permeable fabric. The THS is consistent in height and width through the length of the leg trough, whilst the THS-43 and THS-61, taper from knee to ankle in height and width.

**Operator Qualifications:** Those responsible for the storage, transportation, usage, cleaning and disinfecting of the leg trough should be fully trained and competent. Choice of heel suspension device should be determined by a qualified health professional, following a comprehensive and holistic assessment using both formal and informal assessment methods. The leg trough should only be used for its intended purpose, as specified in this instruction guide. In addition to the information in this guide, operators must adhere to local health and safety and manual handling policies.

## Instructions for Use (IFU):

**Prior To Use:** Upon receipt of the leg trough all packaging should be removed and visual checks should be carried out to ensure:

- The contents are complete
- The leg trough has not been damaged in transit
- All fittings operate correctly
- Ensure the leg trough is suitable for the intended user in terms of pressure care risk
- The label should not be removed

**Storage:** When the leg trough is not in use it should be stored in a protective covering and should be in a secure location away from the general public. For ease of storage leg troughs can be stacked on top of one another. However, to avoid damage to the leg trough, never store other items on top of the leg trough, do not store the leg trough directly on the floor and do not store the leg trough next to radiators or other heat sources.

**Servicing:** The leg trough should be visually inspected weekly and/or between users to check for material degradation, damage, misuse or tampering. Check for any signs of tearing and/or punctures, check all the seams for any signs of splitting, check the zip(s) for any signs of damage and check for any signs of permanent staining. Unzip the leg trough and check the foam inners for any signs of fluid ingress/strikethrough. If following the visual inspection, there are any signs of contamination, the leg trough should be withdrawn from use until the cover and/or the inner foam is replaced. If the cover or foam inner is replaced, then it is important that the correct corresponding cover/foam inner is re-ordered as leg trough covers must not be used on other foam inners. Contaminated covers/inner foams, should be disposed of safely and in line with local infection prevention and control policies.

## During Use:

- Ensure the bed is clear of debris
- Ensure that the leg trough is positioned on the bed and is the correct way up
- Although the leg trough completely offloads the heel from the surface of the bed, it is important to remove the device and check for skin integrity and perfusion status regularly (at least twice a day).

**Aftercare:** The THS, THS-43 and THS-61 are reusable, therefore, the following processes should be undertaken to allow for re-use.

- **Visual Inspection:** The leg trough should be inspected weekly and/or between users as per previous recommendations.
- **Cleaning:** The covers should be cleaned regularly including between patients in accordance with The Revised Healthcare Cleaning Manual 2009, BHTA Protect, Rinse and Dry 2016, local infection prevention and control policies and the guidance below:
  1. Wipe the whole surface of the leg trough with soap and water, rinse with clean water and allow to dry completely before re-use. A non-abrasive cloth can be used for more stubborn soiling
  2. If a disinfectant wipe is applied, the leg trough must be allowed to dry completely
  3. If the cover is heavily soiled a 0.1% Chlorine Solution (1,000ppm) and cold water can be used. If the cover has been exposed to bodily fluids, such as blood, a 1% Chlorine Solution (10,000ppm) and cold water can be used. All

sides, including under and around the zip must be cleaned. Rinse thoroughly with clean water and a damp single use wipe

4. The cover is machine washable up to 95°C for 15 minutes and should then be followed by a cold rinse
5. Line dry in an indoor, clean environment or tumble dry on a low heat setting not exceeding 40°C and not for longer than 10 minutes
6. Leg trough covers must be thoroughly dried before re-use
7. Always ensure the correct cover is returned to its corresponding foam inner. Covers must not be used on other inner foam inserts

#### General Warnings Precautions and Limitations:

- Only qualified professionals should be involved in leg trough selection
- Only use the leg trough for its intended purpose
- Ensure the leg trough is suitable for the intended user in terms of pressure care risk
- Remove the device and check for skin integrity and perfusion status regularly (at least twice a day).
- Take care not to puncture the cover, to avoid fluid ingress/strikethrough
- Do not place sharp objects such as scissors, needles, syringes, scalpels or other sharps on the leg trough surface
- Advise operators, users and visitors to remove or cover hand jewellery including rings with sharp edges
- Take extra care when using medical equipment near the leg trough
- Do not drag along the floor, do not transport in roll cages unless completely protected from sharp edges and do not scrape against walls, door frames, door catches or locks
- Avoid any protruding and sharp objects
- Frequent or prolonged exposure to higher concentration disinfectant solutions may prematurely age the fabric cover of the leg trough
- The cover must be thoroughly rinsed and dried between and after cleaning or disinfection. The cover is more susceptible to physical damage when wet and will remain susceptible for a period of time after being dried
- Abrasive cleaners and sponges must not be used to avoid ingress of fluids/strikethrough
- Dimethyl formamide (DMF), tetrahydrofuran (THF), concentrated inorganic acids, concentrated alkalis, and phenol/cresol based chemicals should never be used

#### Technical Information:

Cushion/ Quality	THS	THS-43	THS-61
<b>Cover</b>	Blue multi-stretch vapour-permeable fabric	Blue multi-stretch vapour-permeable fabric	Blue multi-stretch vapour-permeable fabric
<b>Foam Inner</b>	Combustion modified polyurethane	Combustion modified polyurethane	Combustion modified polyurethane
<b>Dimensions (Max)</b>	43 x 22 x 20cm	43 x 28 x 18cm	61 x 28 x 18cm

**Contact Details:** If you require any further information please contact us at:

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Please take time to read the contents of this information guide. Any actions that are inconsistent with this guide, are done so at the operators risk and Thorpe Mill Ltd will not be liable for injury or damage. In addition to the information in this guide, operators should use the product specified with due consideration of applicable international, national and local regulations, guidance and policies. Safe and correct use of this product is solely at the discretion of the operators.

If a serious incident does occur during use, this should be reported to Thorpe Mill Ltd using the above contact details.

\*A strategy for offloading the heel should be discussed with children, young people, and adults at High Risk of developing a heel pressure ulcer and for neonates, infants, children, young people and adults with a heel pressure ulcer, as part of their individualised care plan (NICE, 2014). Specifically, heel elevators designed for heel suspension, a pillow or foam cushion are recommended for individuals at risk of heel pressure injuries and/or those with Category/Stage I or stage II pressure injuries. The heel should be offloaded completely in such a way as to distribute the weight of the leg along the calf without placing pressure on the Achilles tendon and popliteal vein (NPUAP, EPUAP, & PPPIA, 2019). Choice of heel suspension device should be determined by a qualified professional, following a comprehensive and holistic assessment using both formal and informal assessment methods.

\*\* Implementation considerations for heel elevators suggest that the knee should be in slight flexion to avoid the risk of compression of the popliteal vein and risk of Deep Vein Thrombosis (Huber et al. 2009; NPUAP, EPUAP, & PPPIA, 2019)