

GLOVE FOOT SUPPORT

Instructions For Use

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PRODUCT CODES & DESCRIPTIONS

All Glove Foot. Product codes prefixed with:

- GFOOT – Glove Foot

DEVICE DESCRIPTION:

The Glove Foot is a reusable support sling for the heel of a patient whilst they are in a wheelchair and attached to a hoist. The Glove Foot enables a patient's leg to be raised, to ease the fitting of a sling under their thigh.



For further information, support and product training requests visit: www.gbukgroup.com

PATIENT INFORMATION

The following information is provided for use by trained healthcare professionals, and carers, and those with the appropriate training or knowledge, however as the learned intermediary between the company and the patient, the trained healthcare professionals and carers, and those with the appropriate training or knowledge must convey the aspects they consider relevant to the individual patient. The patient must be informed of the potential adverse effects & residual risks contained within this document.

PATIENT TARGET GROUP(S)

The Glove Foot is intended for patients who require their leg to be raised and cannot do so themselves.

INTENDED USE

Intended for use with a compatible hoist to raise a patient's leg.

INTENDED USER(S)

The Glove Foot is intended to be used by trained healthcare professionals and carers, and those with the appropriate training or knowledge.

INDICATION

Indicated for use where a patient cannot raise their leg independently to allow the fitting of a sling under the thigh.

COMPATIBILITY

For use with all Non-Plus Glove Slings.

CONTRAINDICATIONS

Do not use on patients whose weight exceeds the safe working load limit of the sling.

WARNINGS & PRECAUTIONS

- A risk assessment must be carried out by a suitably qualified individual before selection and use, to ensure safety for the patient and handler. See 'RISK ASSESSMENT' section.
- Always carry out a visual check of the sling accessory prior to every use for any damage, rips, tears, wearing, loose stitching, material degradation, or any other general signs of wear and tear. Dispose of in accordance with the disposal instructions, if any of these are present, and select a new Glove Foot.
- Do not use with incompatible hoists.
- Follow local manual handling policy from your organization, National Back Exchange or HSE guidelines.
- All users must be trained or have the appropriate training or knowledge before using the Glove Foot.
- Inspect the Glove Foot, packaging and labelling prior to use and do not use if damaged.
- Do not bleach, iron or dry clean the Glove Foot. Do not use stain removers.
- Do not exceed maximum washing and drying temperatures.
- Do not wash below minimum washing temperature.
- Do not place the Glove Foot on hot pipes or heaters. Keep away from flames.
- Do not exceed SWL of the sling.
- The Sling is subject to Lifting Operations and Lifting Equipment Regulations (LOLER) Examinations. A LOLER

examination must be performed every 6 months, by trained and qualified persons.

- Repeated washing may lead to sling deterioration and/or discolouration to some materials or fading of labels.
- Where present, ensure any hooks and loops are closed prior to laundering.

EXPECTED LIFETIME

The expected performance and safety lifetime is at least 5 years; however the longevity of the Glove Foot may differ dependent on usage frequency and customer care. If any damage, rips, tears, wearing, loose stitching, material degradation, or any other general signs of wear and tear appear, the Glove Foot should be replaced.

MRI SAFETY INFORMATION

N/A – not intended to be used in the MR environment.

EXPECTED CLINICAL BENEFITS

The expected clinical benefits when used according to the instructions for use are:

- Raising of a patient's leg

PERFORMANCE CHARACTERISTICS

- 75kg SWL
- Easy cupping around the heel of a patient whilst in a wheelchair and attached to a hoist
- Improves ease of fitting a sling under a patient's thigh

DIRECTIONS FOR USE

Refer to 'Warnings & Precautions' and 'Risk Assessment' Sections prior to use.

Always support the foot until the straps have been adjusted to the correct position.

1. Place the user's heel in the aperture - see image below.
2. Attach the straps to the hoist.
3. Once the leg is in the correct position, adjust the sliders to hold the Glove Foot in place.

NOTE: Typically, a leg weighs 1/6, of the total body weight.

POTENTIAL ADVERSE EFFECTS & RESIDUAL RISKS

As with any procedure involving manual handling and use of manual handling aids, the typical risks associated apply. Failure during use may expose the patient and user to risks such as potential subsequent associated injury, and/or user exposure to sudden mechanical stress and potential associated pain and/or musculoskeletal injuries.

RISK ASSESSMENT

A risk assessment and visual inspection must be performed by competent person(s) before use. This should consider the following factors:

- The physical and medical status of the patient, including skin integrity,
- The status of the sling, including the presence of any damage, rips, tears, soil, loose stitching, or any other general signs of wear and tear,
- The compatibility of the hoist and sling, including if the correct size and type of the sling is being used,
- The capability of the users and,
- The situation in which it is being used

WARRANTY

The Glove Foot is covered by a lifetime warranty. Any manufacturing defect will be rectified free of charge. Product damage through wear and tear, neglect or accidental damage is not covered.

CLEANING

Routinely clean the Glove Foot, in accordance with these instructions.

- Where present, close hook & loop fastenings before washing to prevent damage to the fabric and webbing
- Wash gently at a minimum of 40°C and a maximum of 95°C.
- Use a mild soap solution or a non-biological detergent without bleaching additives.
- Do not add bleach or stain removers.
- Air dry, cabinet dry or tumble dry on a cool cycle (below 60°C). Do not tumble dry on a hot setting.

STORAGE CONDITIONS

Standard storage conditions. Keep off the floor. Keep out of direct sunlight. Keep dry.

DISPOSAL

No specific disposal requirements, handle contaminated items as clinical waste. Dispose of device in line with local and/or hospital policy.

COMPLAINTS


Any user who has a complaint or experiences dissatisfaction in the product quality, identity, durability, reliability, safety, usability, effectiveness, and/or performance, should notify the manufacturer and distributor immediately.

In the event of a serious incident involving the device, the user should report the event to the manufacturer (GBUK Group) and the competent authority of the member state in which the user and/or patient is established, immediately, by telephone, email (complaints@gbukgroup.com) or written correspondence.


When filing a complaint, provide the component(s) REF and SN number(s), your name and contact details, and the nature of the complaint.

In the event of a suspected device fault the user should report the event to GBUK Group with the above information and return the device to GBUK Group for examination.

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