

GLOVE DETACHABLE HEAD SUPPORT

Instructions For Use

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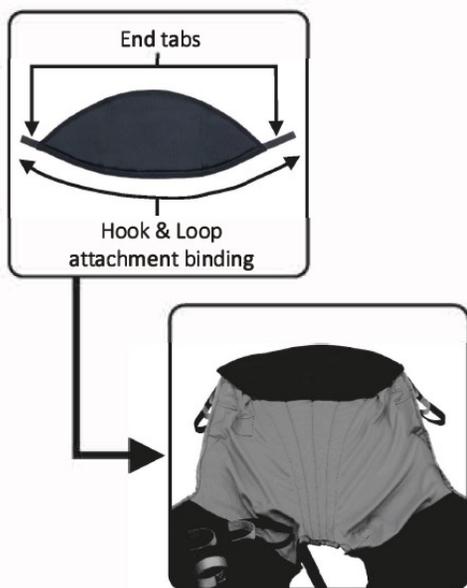
PRODUCT CODES & DESCRIPTIONS

All Glove Detachable Head Support. Product codes prefixed with:

- GH – Glove Detachable Head Support

DEVICE DESCRIPTION:

Padded, reusable, soft-knit polyester Head Support for use with all Non-Plus Glove Slings, to provide additional head support.



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 Detachable Head Support is intended for patients fitted with a Non-Plus Glove Sling, who require additional head support.

INTENDED USE

Intended for use with a compatible Non-Plus Glove Sling, for additional head support.

INTENDED USER(S)

The Glove Detachable Head Support 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 requires additional head support.

COMPATIBILITY

For use with all Non-Plus Glove Slings.

CONTRAINDICATIONS

Do not use on patients who are not fitted with a Non-Plus Glove 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 Detachable Head Support.
- Do not use with incompatible slings.
- 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 Detachable Head Support.
- Inspect the Glove Detachable Head Support, 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 Detachable Head Support on hot pipes or heaters. Keep away from flames.
- Repeated washing may lead to deterioration and/or discolouration to some materials or fading of labels.

EXPECTED LIFETIME

The expected performance and safety lifetime is at least 5 years; however the longevity of the Glove Detachable Head Support 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 Detachable Head Support should be replaced.

PERFORMANCE CHARACTERISTICS

- Easy attachment to Non-Plus Glove Slings

DIRECTIONS FOR USE

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

It is recommended that the Head Support is attached to the compatible sling body before sling fitting.

1. With the label side of the Head Support facing the rear, line up the corresponding Hook & Loop binding with that on the sling.
2. Press firmly along the join to fix the Head Support to the sling.
3. Secure the Head Support by folding the end tabs around to attach to the back of the sling's head section.

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 using the sling. This should consider the following factors:

- The physical and medical status of the patient, including skin integrity,
- Compatibility with the patients sling,
- The capability of the users and,
- The situation in which it is being used

WARRANTY

The Glove Detachable Head Support 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 Detachable Head Support, in accordance with these instructions.

- 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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