GLOVE BOLSTER NECK PILLOW

Instructions For Use

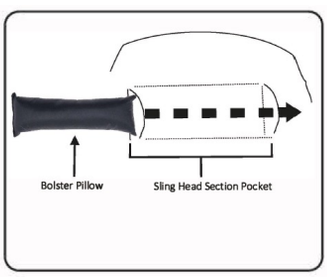
Please read these instructions befor

Care Independence
A GBUK COMPANY

INSTRUCTIONS FOR USE
Please read these instructions before use.

PRODUCT CODES & DESCRIPTIONS
All Glove Bolster Neck Pillow. Product codes prefixed with:
- GAIRBOL – Glove Bolster Neck Pillow

DEVICE DESCRIPTION:
Polyester reusable Neck Pillow compatible with Plus Variant Glove Slings. The Glove Bolster Neck Pillow slots into the two-ended pocket integrated in the head section of the Plus Variant Glove Slings.



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

PATIENT INFORMATON
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 Bolster Neck Pillow is intended for patients who require additional support to the neck, following a suitable risk assessment.

INTENDED USE
Intended for use with Plus Variant Glove Slings to provide additional neck support.

INTENDED USER(S)
The Glove Bolster Neck Pillow 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 has insufficient neck support.

COMPATIBILITY
For use with Plus Variant Glove Slings only.

CONTRAINDICATIONS
Do not use on patients who are not fitted with a Plus Variant Glove Sling

SAFE WORKING LOAD (SWL)
The SWL is provided on the label(s) directly attached to the device.

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 Bolster Neck Pillow.
- 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 Bolster Neck Pillow.
- Inspect the Glove Bolster Neck Pillow, packaging and labelling prior to use and do not use if damaged.
- Do not bleach, iron or dry clean the Glove Bolster Neck Pillow. Do not immerse in water, use stain removers or tumble dry.
- Do not place the Glove Bolster Neck Pillow on hot pipes or heaters. Keep away from flames.
- Wipe clean in accordance with the instructions provided in 'CLEANING' section.

EXPECTED LIFETIME
The expected performance and safety lifetime is at least 5 years; however the longevity of the Glove Bolster Neck Pillow 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 Bolster Neck Pillow should be replaced.

PERFORMANCE CHARACTERISTICS
- SWL as stated on label(s)
- ISO 21856 and ISO 10535 compliant

DIRECTIONS FOR USE
Refer to 'Warnings & Precautions' and 'Risk Assessment' Sections prior to use.
It is recommended that the Glove Bolster Neck Pillow is inserted into the two-ended pocket integrated in the head section of the Plus Variant Glove Slings, prior to fitting the sling.

1. Locate the opening at either end of the two-ended pocket integrated in the head section of the Plus Variant Glove Slings.
2. Slide the Glove Bolster Neck Pillow into the opening until it is in a central position. The Glove Bolster Neck Pillow can be inserted from either end of the two-ended pocket.

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,
- 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, using the equipment; and,
- The situation in which it is being used

WARRANTY
The Glove Bolster Neck Pillow 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 wipe the Glove Bolster Neck Pillow, in accordance with these instructions.

1. Gently wipe the surface of the Glove Bolster Neck Pillow with an antibacterial or mild soap solution.
2. Allow to air dry.

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.

GBUK Group Ltd.
Woodland House,
Blackwood Hall Business Park,
North Duffield, Selby,
North Yorkshire,
Y08 5DD, UK.
T: EU: +44 (0) 1757 288587
E: info@gbukgroup.com
W: www.gbukgroup.com

GBUK GmbH
Wirtschaftsprüfungsgesellschaft
Im Klapperhof 7-23
50670 Köln, Germany

EU REP **QualRep Services BV,**
Utrechtseweg 310 B42,
6812 AR, Arnhem,
The Netherlands

CH REP **Swiss AR Services AG**
Industriestrasse 47,
6300 Zug, Switzerland

CE MD