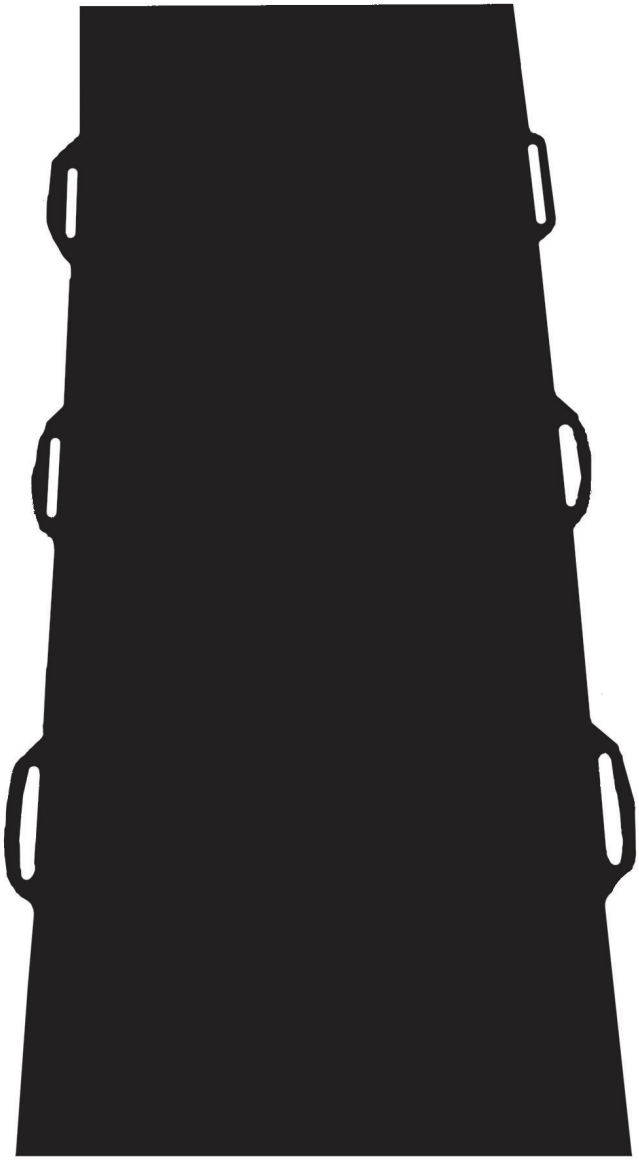

Gleiter

Instructions for Use

Product No. GLE04000

Contents

1 GENERAL INFORMATION 4
1.2 Safety Considerations 4

1.2.1 Safety hazard symbol notice 4
1.2.2 Equipment misuse notice 4
1.2.3 Notice to users and/or patients 4
1.2.4 Safe disposal 4
1.3 Operating the System 4
1.3.1 Applicable Symbols 4
1.3.2 Intended User and Patient Population 5
1.3.3 Compliance with medical device regulations 5
1.4 EMC considerations 5
1.5 Manufacturing Information 5
2 SYSTEM 5
..... 5
2.1 Product Code and Description 5
2.2 Indications for use 5
2.3 Intended use 6
3 EQUIPMENT SETUP AND USE 6
3.1 Prior to Use 6
3.2 Use Instructions 6
3.3 Storage, Handling and Removal Instructions 6
3.3.1 Storage and Handling 6
3.3.2 Removal Instructions 6
3.4 Troubleshooting Guide 6
3.5 Device Maintenance 6
4 SAFETY PRECAUTIONS AND GENERAL INFORMATION 7
4.1 General Safety Warnings and Cautions 7
4.2 Product Specifications 7
4.3 Sterilization Instruction 7
4.4 Cleaning and Disinfection Instruction 7
5 LIST OF APPLICABLE STANDARDS 8

IMPORTANT NOTICES

Prior to using this or any other type of medical apparatus with a patient, it is recommended that you read the Instructions for Use and familiarize yourself with the product.

- Read and understand all warnings in this manual and on the device itself prior to use with a patient.
- The symbol is intended to alert the user to important procedures or safety instructions regarding the use of this device.
- The symbol on the labels is intended to show when the IFU should be referenced for use.
- The techniques detailed in this manual are only manufacturer's suggestions. The final responsibility for patient care with respect to this device remains with the attending technician.
- Device function should only be operated by trained personnel.
- All modifications, upgrades, or repairs must be performed by an authorized specialist.
- Keep this manual available for future reference.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority listed in this document.

1 GENERAL INFORMATION

1.2 Safety Considerations

1.2.1 Safety hazard symbol notice

⚠	DO NOT USE IF PRODUCT SHOWS VISIBLE DAMAGE OR MATERIAL DEGREDATION

1.2.2 Equipment misuse notice

Do not use product if package is damaged or intentionally opened before use. All modifications, upgrades, or repairs must be performed by an authorized specialist.

1.2.3 Notice to users and/or patients

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Note: Refer to the MRI table manufacturer's user guide for instructions on use.

1.2.4 Safe disposal

Customers should adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories.

If in doubt, the user of the device shall first contact KyphoLift Technical Support for guidance on safe disposal protocols.

1.3 Operating the System

1.3.1 Applicable Symbols

Symbol Used	Description	Reference
MD	**Medical Device** Indicates the device is a medical device.	5.7.7 BS EN ISO 15223-1:2021
	Date of Manufacture Indicated the date when the medical device was manufactured.	5.1.3 BS EN ISO 15223-1:2021
REF	**Catalogue Number** Indicates the manufacturer's catalogue number.	5.1.6 BS EN ISO 15223-1:2021
LOT	**Batch code** Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5 BS EN ISO 15223-1:2021
	Keep Dry Indicates that the product should be kept dry.	**5.3.4** BS EN ISO 15223-1:2021

	**Do not use if packaged is damaged** Indicated that the product should not be used if the package has damaged or opened, and that the user should consult the Instructions for Use for additional information.	5.2.8 BS EN ISO 15223-1:2021
	**Consult Instructions for use** Indicated the need for the user to consult the instructions for use.	5.4.3 BS EN ISO 15223-1:2021
	**Manufacturer** Indicates the medical device manufacturer	5.1.1 BS EN ISO 15223-1:2021
	**Temperature Limit** Indicates the temperature limits to which the medical device can be safely exposed	5.3.7 BS EN ISO 15223-1:2021
	**Unique Device Identifier** Indicates a carrier that contains unique device identifier information	5.7.10 BS EN ISO 15223-1:2021
	**Prescription Only** Caution: Federal law restricts this device to sale by or on the order of a physician	21 CFR 801.109

1.3.2 Intended User and Patient Population

Intended User: Healthcare professionals involved in the transfer of patients.

Intended Population: This device is intended to be used with any patient requiring transfer from gurney/bed to another gurney/bed.

1.3.3 Compliance with medical device regulations

This product is a non-invasive, Class I, 510(k) exempt Medical Device. The manufacturer and device is registered and listed within the FDA database.

1.4 EMC considerations

This is not an electromechanical device. Therefore, EMC Declarations are not applicable.

1.5 Manufacturing Information

The Initiative LLC, DBA KyphoLift

10352 S River Heights Dr, Suite 104

South Jordan, UT 84095

2 SYSTEM

2.1 Product Code and Description

FMR– Manual patient transfer device

2.2 Indications for use

The Gleiter device is used for bed to bed patient transfer.

2.3 Intended use

The Gleiter device is intended to serve patients within a hospital setting. The device is designed to be used to assist in the transfer of patients from one bed to another bed. This device is intended to be used by healthcare professionals within a hospital setting. Not to be used where there is a high potential for contact with bodily fluids. Must be used with appropriate sheet, chucks, or other appropriate PPE under the patient.

3 EQUIPMENT SETUP AND USE

3.1 Prior to Use

a. Ensure all surfaces and components of the device have been properly cleaned, disinfected, and wiped dry prior to each use. Safe to use all known common hospital wipes (Cavi-Wipes, Sani-Cloth, Super Sani-Cloth, Sani-Cloth Bleach).

3.2 Use Instructions

a. Ensure patient sheets, chucks, or other appropriate PPE is under patient.
b. Use appropriate number of personnel to lift patient without jeopardizing patient/personnel safety using the sheet, chuck, or other appropriate PPE onto Gleiter.
c. Use Gleiter handles to move patient.

3.3 Storage, Handling and Removal Instructions

3.3.1 Storage and Handling

Always store the product in its storage case to prevent it from getting damaged or falling onto other objects. Do not put heavy objects on the foam and prevent hard objects from falling on it to prevent permanent deformations. Avoid pressure points on the foam during storage as these can cause imprints in the foam.

Store the system between 10°C (50°F) and 40°C(104°F).

3.3.2 Removal Instructions

Not applicable.

3.4 Troubleshooting Guide

This device does not have a troubleshooting guide. For technical support user of the device shall first contact KyphoLift Technical Support.

3.5 Device Maintenance

Make sure that all labels are installed and can be read. Contact KyphoLift using the information from the contact details section (1.3) if you need to replace the device.

4 SAFETY PRECAUTIONS AND GENERAL INFORMATION

4.1 General Safety Warnings and Cautions

⚠ WARNING:

a. Do not use if product shows visible damage.
b. Prior to using the device, please read the instructions for equipment set up and use. Familiarize yourself with the product before application on a patient.
c. To prevent patient and/or user injury and/or equipment damage, examine the device and MRI table for potential damage or wear prior to use. Do not use the device is damage is visible, if parts are missing or if it does not function as expected.

⚠ CAUTION:

a. Damage may result if product is placed near extreme heat.
b. Damage may result if cleaning solution is used at full strength.
c. Damage may result if product is immersed in fluid during cleaning.
d. Do not exceed safe working load shown in the product specification table.

4.2 Product Specifications

Mechanical Specifications	Description
Product Dimensions	78” X 30” X 1”
Material:	Cover: Nylon Foam: Memory foam
Safe Working Load on the device	550 lbs. (226 kg)
Overall Weight of Completed Device	3 lbs. (1.4 kg)
Storage Specifications	Description
Storage temperature	10°C (50°F) - 40°C(104°F)
Storage Relative humidity range	<70%
Operating temperature	This device is intended to be used in a hospital setting.
Operating Relative humidity range	
Electrical Specifications	Description
Not applicable.	Not application.
Software Specifications	Description
Not applicable.	Not applicable.
Compatibility Specifications	Description
The Gleiter is compatible with:	This product does not have any magnetic materials. This device is MR safe.

4.3 Sterilization Instruction

This device is not intended to be sterilized. Equipment damage may occur.

4.4 Cleaning and Disinfection Instruction

⚠ WARNING:

- After each use, clean the device with alcohol-based wipes.
- Do not put the device into water. Equipment damage can occur.
- Use a cloth and a quaternary ammonium disinfecting/cleaning solution to clean and disinfect the device.
- Read and follow the cleaning product’s instructions.
- Wipe the device with a clean, dry cloth.

- Make sure that the device is dry before you store it or next use.

⚠ CAUTION: DO NOT IMMERSE FOAM IN ANY LIQUID

5 LIST OF APPLICABLE STANDARDS

Standard	Description
EN ISO 14971	Medical devices- Application of risk management to medical devices.
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process