FlexSpace

Instructions for Use

Product No. FLEX2000

Contents

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 prior to use with a patient.
- The symbol is intended to alert the user to important procedures or safety instructions regarding the use of these pads.
- 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 foam pad set remains with the attending technician.
- Foam pad set function should only be operated by trained personnel.
- Keep this manual available for future reference.

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

1 GENERAL INFORMATION

1.1 Contact Details

Website: www.KyphoLift.com

Email: info@KyphoLift.com

Phone: (801) 946-7400

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 foam pad set should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

⚠ NEVER EXCEED THE WEIGHT CAPACITY OF THE MRI ROOM TABLE

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 foam pad set.

If in doubt, the user of FlexSpace 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
	**Keep Dry** Indicates that the product should be kept dry.	**5.3.4** 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
	**Temperature Limit** Indicates the temperature limits to which the medical device can be safely exposed	5.3.7 BS EN ISO 15223-1:2021

1.3.2 Intended User and Patient Population

Intended User: MRI technicians or healthcare professionals involved in imaging.

Intended Population: These foam pads are to be used to support a patient's legs during MR/CT scans or any other time support for a patient's legs is needed.

1.3.3 Compliance with medical device regulations

This product is not a medical device.

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

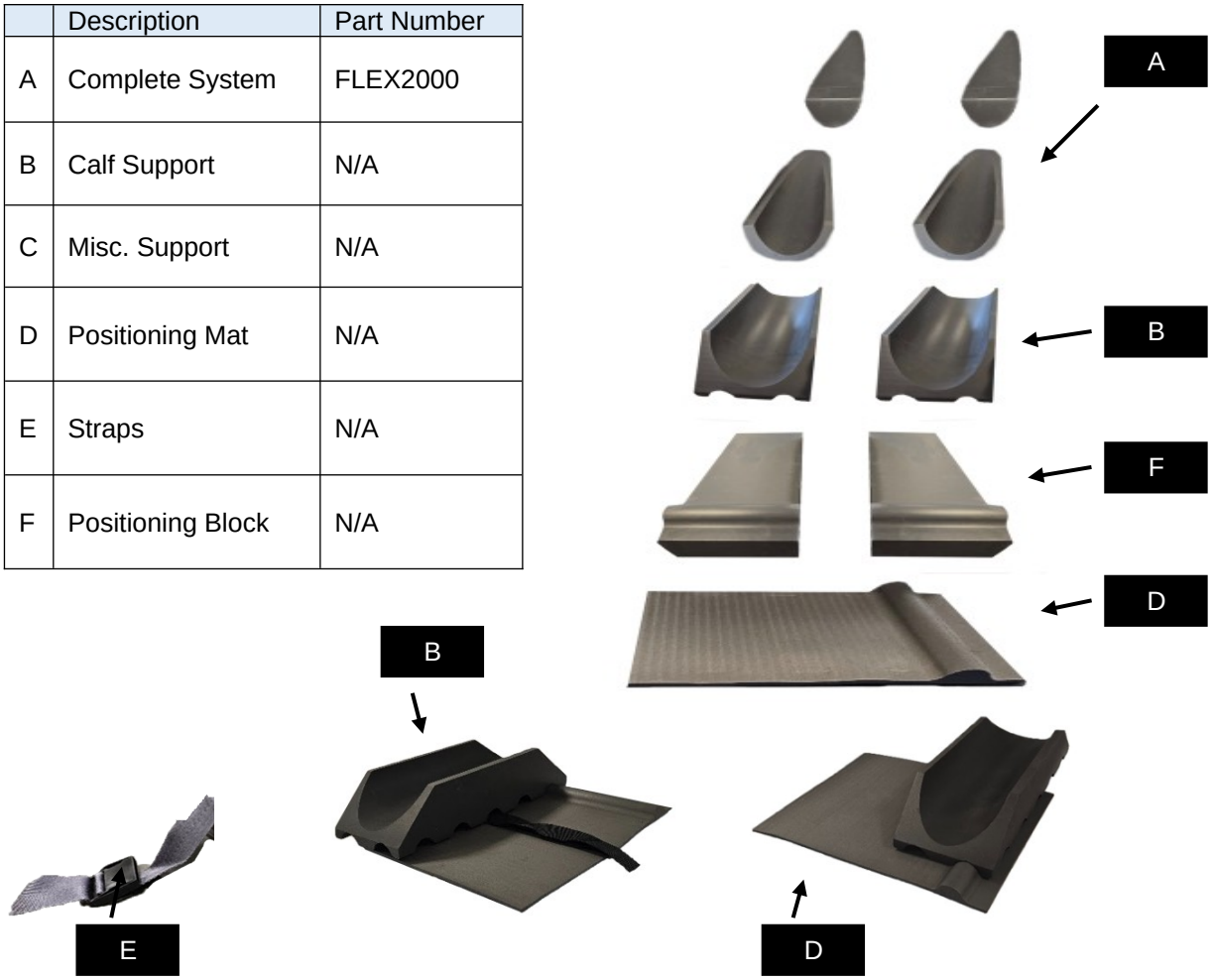
10352 S River Heights Dr, Suite 104

South Jordan, UT 84095

2 SYSTEM

2.1 System components identification

	Description	Part Number
A	Complete System	FLEX2000
B	Calf Support	N/A
C	Misc. Support	N/A
D	Positioning Mat	N/A
E	Straps	N/A
F	Positioning Block	N/A



2.2 Indications for use

FlexSpace is used to assist with patient comfort during scans or for other uses where the patient's limbs need to be lifted up and/or supported.

2.3 Intended use

FlexSpace is intended to serve any patient during scans or for other reasons where support of the patient's limbs is needed. FlexSpace is indicated for use during MR and CT scans or anywhere limb support is needed for a patient. FlexSpace contains no metal and is MR safe.

3 EQUIPMENT SETUP AND USE

3.1 Prior to Use

a. Ensure all surfaces and components of the pads 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. Maintain patient comfort while preparing to position.
b. Place foam limb support holder(s) under patient limb(s) for support as needed during procedure.

3.3 Storage, Handling and Removal Instructions

3.3.1 Storage and Handling

Always store the product in a safe and dry area 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

These pads do not have a troubleshooting guide. For technical support, user of the pads shall first contact KyphoLift Technical Support.

3.5 Maintenance

Contact KyphoLift using the information from the contact details section (1.3) if you need to replace the pads.

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 pads, 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 pads and MRI table for potential damage or wear prior to use. Do not use the pads 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 Sterilization Instruction

These pads are not intended to be sterilized. Damage may occur.

4.3 Cleaning and Disinfection Instructions

⚠ WARNING:

- After each use, clean the pads with alcohol-based wipes.
- Do not put the pads into water. Damage can occur.
- Use a cloth and a quaternary ammonium disinfecting/cleaning solution to clean and disinfect the pads.
- Read and follow the cleaning product’s instructions. Use caution in areas where liquid can pool within.
- Wipe the pads with a clean, dry cloth.
- Make sure that the pads are dry before you store it or next use.

⚠ CAUTION: DO NOT IMMERSE FOAM IN ANY LIQUID