



# KyphoLift



**Instructions for Use**

**Product No. KYP02000**

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## 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 DEGRADATION
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### 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. Always refer to the MRI table manufacturer's weight limits.

	NEVER EXCEED THE WEIGHT CAPACITY OF THE MRI ROOM TABLE
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### 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
	<b>MR Conditional</b> Indicates the device is MR Conditional up to 3.0 Tesla.	N/A
	<b>Medical Device</b> Indicates the device is a medical device.	5.7.7 BS EN ISO 15223-1:2021
	<b>Date of Manufacture</b> Indicated the date when the medical device was manufactured.	5.1.3 BS EN ISO 15223-1:2021
	<b>Catalogue Number</b> Indicates the manufacturer's catalogue number.	5.1.6 BS EN ISO 15223-1:2021

	<p align="center"><b>Batch code</b></p> <p>Indicates the manufacturer's batch code so that the batch or lot can be identified.</p>	<p align="center">5.1.5 BS EN ISO 15223-1:2021</p>
	<p align="center"><b>Keep Dry</b></p> <p>Indicates that the product should be kept dry.</p>	<p align="center">5.3.4 BS EN ISO 15223-1:2021</p>
	<p align="center"><b>Do not use if packaged is damaged</b></p> <p>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.</p>	<p align="center">5.2.8 BS EN ISO 15223-1:2021</p>
	<p align="center"><b>Consult Instructions for use</b></p> <p>Indicated the need for the user to consult the instructions for use.</p>	<p align="center">5.4.3 BS EN ISO 15223-1:2021</p>
	<p align="center"><b>Manufacturer</b></p> <p>Indicates the medical device manufacturer</p>	<p align="center">5.1.1 BS EN ISO 15223-1:2021</p>
	<p align="center"><b>Temperature Limit</b></p> <p>Indicates the temperature limits to which the medical device can be safely exposed</p>	<p align="center">5.3.7 BS EN ISO 15223-1:2021</p>
	<p align="center"><b>Unique Device Identifier</b></p> <p>Indicates a carrier that contains unique device identifier information</p>	<p align="center">5.7.10 BS EN ISO 15223-1:2021</p>
	<p align="center"><b>Prescription Only</b></p> <p>Caution: Federal law restricts this device to sale by or on the order of a physician</p>	<p align="center">21 CFR 801.109</p>

### 1.3.2 Intended User and Patient Population

Intended User: MRI technicians or healthcare professionals involved in the device intended procedure. Not intended for Lay persons.

Intended Population: This device is intended to be used with kyphotic patients that do not exceed the weight in the safe working load field specified in the product specification section 4.2.

### 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 with the FDA database.

## 1.4 EMC considerations

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

## 1.5 Manufacturing Information

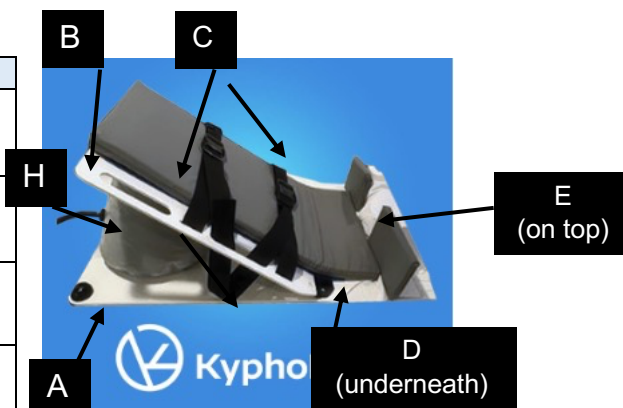


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## 2 SYSTEM

### 2.1 System components identification

	Description	Part Number
A	Bottom Board	KYP02002
B	Top Board	KYP02001
C	Straps (Webbing)	KYP02011
D	Gel Substrate Pad	KYP02010
E	Reusable Pads	KYP02038
F	Pump (Not Pictured)	KYP02015
G	Soft Rubber Tubing (Not Pictured)	KYP02007, KYP02008
H	Air Bladder	KYP02005



### 2.2 Product Code and Description

KXH– KyphoLift System

### 2.3 Indications for use

The KyphoLift device is used during MRI imaging of patients with kyphosis. This device is capable of being used with a range of adult patient populations with mild to severe kyphosis.

### 2.4 Intended use

The KyphoLift device is intended to serve kyphotic patient in radiology. The KyphoLift device is indicated for use as a tool in the fields of radiology. The device is designed to position and comfort a kyphotic patient appropriately while using a head and neck coil during MRI imaging. This device is intended to be used by healthcare professionals within the MRI imaging room setting.

## 3 EQUIPMENT SETUP AND USE

### 3.1 Opening the KyphoLift's Carrying Case

Place the carrying case onto the floor with the soft handles on top (KyphoLift logo is on the bottom right side and readable). Unzip the top zipper all the way around. Lift the KyphoLift out of the carrying case and place the KyphoLift onto the scanner. Ensure hinged portion of KyphoLift is firmly against MRI head and/or neck coil. **Keep carrying case and pump outside of the 200 Gauss line.**

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 Inspection**

Inspect the product looking for any visible damage or sharp edges that could be caused by a drop or impact during storage. Do not use if bladder or other damage is noted.

### **3.3 Hose-Pneumatic Attachment**

Attach the longer of the two hoses to the valve in the middle of the foot pump.

### **3.4 Positioning**

Place the KyphoLift directly centered on the imaging table with the top of the KyphoLift - bottom platform nested up against the base of the head and neck coil. Position gray multi-use pad over the gel substrate securing the pad to the top board.

### **3.5 Patient Safety**

Secure the patient with buckle straps prior to moving patient into scanning position and add any pads/pillows underneath patient's legs to desired comfort level to reduce pressure or discomfort at the patient's lower back.

Place pads/pillows underneath patient's legs to desired comfort level to reduce the pressure or discomfort of the patient's lower back.

As the patient is moving towards the isocenter or towards home position, ensure legs and patient anatomy is clear and free of obstacles that may cause pain or discomfort for entire range of table positions required for patient care.

### **3.6 Raise to Position**

Begin inflating the bladder using your foot until the patient is at the desired position. As the patient is moving toward isocenter or toward home position, ensure legs and patient anatomy is clear and free of obstacles that may cause pain) or discomfort for entire range of table positions required for patient care.

### **3.7 Before Scanning**

Disconnect the two hoses at the red attachment prior to starting scan/procedure.

### **3.8 Post Imaging**

When the scan is complete, remove any anterior coils, deflate KyphoLift by pressing valves on the valve connector housing (red), unbuckle the patient, and safely attend to the patient's mobility needs. Remove gray multi-use pads and clean/sanitize blue gel substrate pad/unit and multi-use pads prior to storage.

### **3.9 Storage, Handling and Removal Instructions**

#### **3.9.1 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).

#### **3.9.2 Removal Instructions**

Not applicable.

### **3.10 Troubleshooting Guide**

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

### **3.11 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:
  1. Examine the device and MRI table for potential damage or wear prior to use. Do not use the device if damage is visible, if parts are missing or if it does not function as expected.
  2. As the patient is moving towards the isocenter or towards home position, ensure legs and patient anatomy is clear and free of obstacles that may cause pain or discomfort for entire range of table positions required for patient care.



#### 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	Bladder volume (inflated): .792 ft <sup>3</sup> Reusable pads: 32" X 15.75" X 1" and (2) 8" X 5" X 1" Platform: 21" X 33" X 21"
Material:	Bladder: Rubber/Polyurethane Reusable pads: Memory foam covered in a polyurethane polyester fabric Platform: G10
Safe Working Load on the device	550 lbs. (226 kg)
Overall Weight of Completed Device	34 lbs. (15 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 controlled MRI imaging room environment.
Operating Relative humidity range	
Electrical Specifications	Description
Not applicable.	Not application.
Software Specifications	Description
Not applicable.	Not applicable.
Compatibility Specifications	Description
The KyphoLift is compatible with:	This product does have some magnetic materials and has been tested for MR compatibility. This device is MR conditional up to 3.0 Tesla.
The carrying case is compatible with:	This product does have some magnetic materials and has been tested for MR compatibility. This carrying case is MR

	conditional up to 3.0 Tesla but should remain outside the 200 gauss line.
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#### 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 manufacturer’s recommendation for low-level disinfection.
- Read and follow the cleaning product’s instructions. Use caution in areas where liquid can get into the mechanism.
- 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