



KyphoLift™

A New Standard in Patient Positioning



A PROBLEM EVERY MRI TECH KNOWS-
A SOLUTION WE ALL NEEDED



Empowers a single technologist to deliver-

Safe, Efficient, No-Lift Care

FOR MORE INFO CONTACT US AT



WITHOUT KYPHOLIFT



WITH KYPHOLIFT



KyphoLift™

A New Standard in Patient Positioning

Difficulty in properly positioning kyphotic and obese patients can extend MRI scan times and reduce overall operational efficiency, creating scheduling delays and increased costs and liability for healthcare facilities.

WITHOUT
KYPHOLIFT



WITH
KYPHOLIFT



A New Standard in Patient Positioning

KyphoLift redefines patient positioning in radiology by streamlining workflows, eliminating manual lifting, and enabling a single technologist to safely manage even the most challenging cases—ideal for limited-staff or after-hours settings.

Designed for both stability and patient comfort, its ergonomic platform minimizes motion artifacts and injury risk while keeping the patient's center of gravity close to the table. By reducing delays and optimizing value-added time, KyphoLift enhances throughput, improves consistency, and supports more compassionate, predictable care—while also lowering physical strain and liability for healthcare teams.



KyphoWedge™

The First Height-Adjustable Knee Cushion

Offering interlocking precision, burn prevention, and personalized comfort, KyphoWedge is the ultimate leg positioning solution. Designed for seamless integration with KyphoLift or effective use on its own, its innovative 7-pad interlocking system provides adjustable height to achieve optimal leg elevation for any patient.

Engineered for both comfort and stability, the kit includes burn-prevention pads and secure leg-stabilizing straps—ensuring ideal positioning while minimizing patient movement and the risk of skin injury.



Gleiter

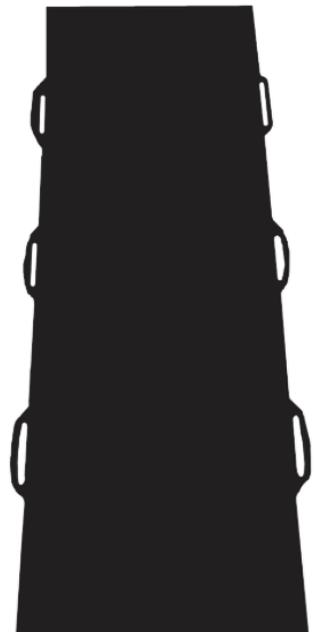
Imaging Transfer Pad

78" x 24" Radio-lucent Cross-Link Foam Pad with Reinforced Handles.

The Gleiter pad supports clear, artifact-free imaging across MRI, CT, and X-ray—without compromising comfort or image quality.

Made from high-density, cross-linked foam, it offers lightweight durability, full-body support, and insulation from cold imaging tables for a more stable, relaxed scan.

The waterproof, stain-resistant cover is easy to clean and features low-friction properties for smooth repositioning. Six reinforced handles ensure safe, controlled transfers—especially for patients with limited mobility. Ideal for technologists who prioritize safety, patient comfort, and workflow efficiency.



THE MOST OVERLOOKED COST IN MRI ISN'T THE SCANNER, IT'S THE PROCESS

Company Name: The Initiative, LLC dba KyphoLift
 UEI (SAM.gov): ZNVDTIFT9QS8
 EIN: 86-1730058

FDA Classification:

KyphoLift: Class I (lowest-risk medical device classification) 510(k)-Exempt | non-electric
KyphoWedge: Non-medical support accessory (general wellness exemption)

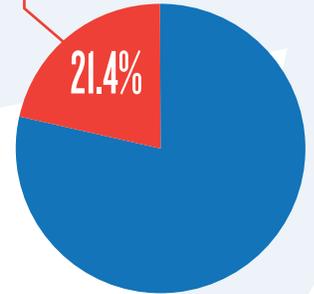
Regulatory Pathway:

FDA-registered establishment with fully documented Class I, 510(k)-exempt product pathway
 KyphoWedge classified as a non-medical accessory under FDA's general wellness exemption
 CE Mark pathway planned following establishment of EU distribution partner

Established Registration:

FDA Reg. #: 3027686079
 Owner/Operator #: IO088492 Commercially registered in USA, Canada, Australia, and New Zealand

PATIENTS THAT CREATE WORKFLOW BOTTLENECKS



Why KyphoLift?

KyphoLift addresses one of radiology's most persistent and costly workflow challenges—safe, reproducible patient positioning—without requiring power, scanner modification, or extensive staff training. It integrates seamlessly into any MRI workflow, delivering immediate safety, efficiency, and throughput benefits.

Code Reference & Identifiers:

KyphoLift Product Code: KYPO2000	KyphoWedge Product Code: WEDG03000
GTIN: KYPO2000	GTIN: WEDG03000 CPT: 72148, 72158
CPT: 76018, 76019	HCPCS: E1399, E0197
HCPCS: E1399, E0197	Gleiter Product Code: GLED04000
UNSPSC: 42192202	GTIN: GLED04000
	HCPCS: E0705, E1399

US - NAICS Codes: 339113

Optional/ Relevant: 423450/ 339112/ 541690

SIC Codes: 3842

Optional/ Relevant: 5047/ 7389/ 8099/ 8742

UNSPSC Code: 42192202/ 42192200/ 42192109/ 42142701/ 42211503

These codes are provided as references and may require confirmation with payer or procurement systems.

Ready-to-Share Technical Documentation (upon request):

- MRI Safety Report / Tested Dr. Frank Shellock
- Conditional at 3T
- Design History File & Testing Protocols
- FDA Registration & Classification Summary
- Product Specs & Instructions for Use
- One-page product flyer and ROI summary
- Insurance coverage and liability documentation
- W-9, DUNS number, and tax ID info



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Key Use Cases:

- Safe positioning and stabilization of kyphotic, obese, and mobility-limited patients without manual lifting
- Enhanced image reproducibility and reduced motion artifact
- Enables single-technologist workflows, ideal for low-resource and after-hours environments
- Improves throughput efficiency while minimizing delays caused by complex setups or staff availability
- Promotes staff safety in settings affected by shortages or on-call coverage
- Expands access to care by enabling safer imaging for marginalized or mobility-limited patient groups
- Aligns with patient-centered care initiatives through tailored support and improved comfort



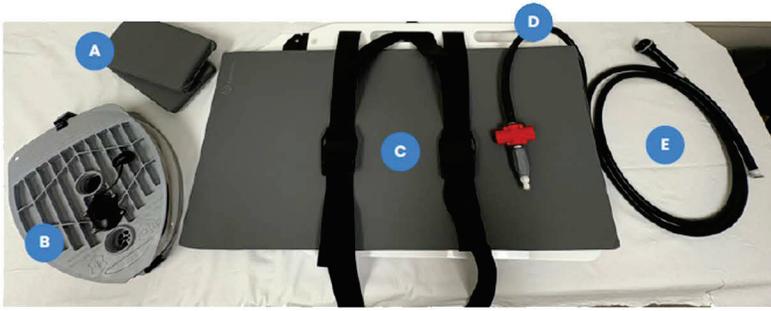
Market Adoption & Status:

KyphoLift and KyphoWedge are in clinical use across hospitals in the U.S., Canada, and Australia, with growing EU interest.



MRI KyphoLift Tech Guide

- MRI conditional 3T or less 
- *Foot pump & carrying case must remain outside of the 200 gauss line*
- Please see KyphoLift "Instructions for Use" for additional information.



- A** Shoulder Pads
- B** Foot pump
- C** KyphoLift
- D** Short hose *connected to KyphoLift*
- E** Long hose *connected to foot pump*



1. Remove KyphoLift from carrying case and place on table. KyphoLift should be flush with bottom of head/neck coil.
2. Place blue substrate pad on KyphoLift (white platform, under gray pad).
3. Push the narrow end of long hose into short hose until "clicked" in place. Attach end of hose to pump by turning threaded portion into middle receiver of pump.
4. Ensure all hose attachments are fastened securely and inspect KyphoLift system, prior to each use.
5. Position patient onto KyphoLift and secure strap as desired. Place additional padding as needed/ shoulder pad and lower leg cushion as needed to reduce strain/ provide comfort.
6. Use foot pump to inflate patient into acceptable position. Re-asses if any additional padding needed.
7. Disconnect long hose from short hose and observe patient's position, comfort, and extremities (relation to bore) while patient is moved to ISO center and/or when table position adjustment (z-axis)
8. After scan, remove anterior coils, deflate the KyphoLift by pressing the red valve on either side.
9. Unbuckle, and assist the patient off the table.
10. Clean the KyphoLift after use and return to case.

Mechanical Specification	Description
Product Dimensions:	Bladder volume (inflated): .792 ft ³ Reusable pads: 32" X 15.75" X 1" and (2) 8" X 5" X 1" Foam: 31" X 15" X 0.25" Platform: 21" X 33" X 21"
Material:	Bladder: Rubber/Polyurethane Foam: Flexible polyester polyurethane Platform: G10
Safe Working Load on the Device:	550 lbs. (226 kg)
Overall, Weight of Completed Device:	34 lbs. (15 kg)