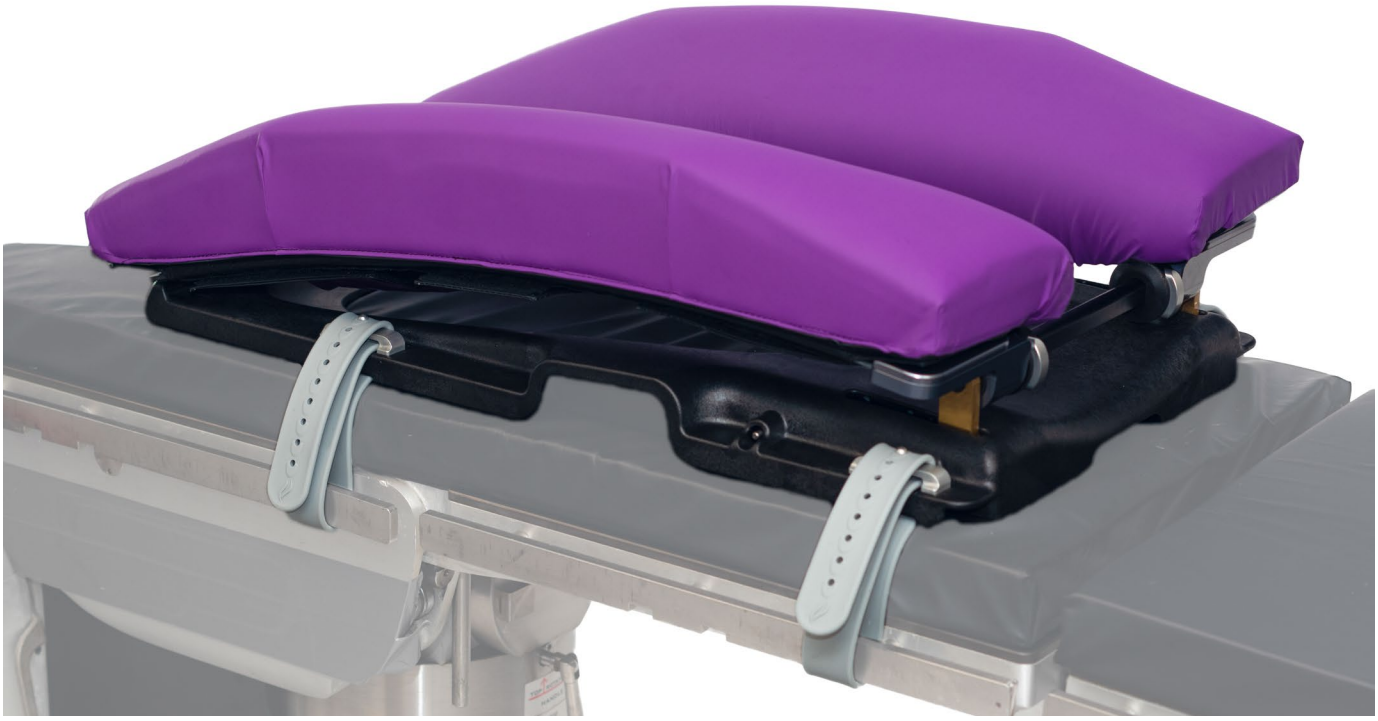
Kyra Medical Inc.
102 Otis St.
Northborough, MA 01532
United States of America

KYRA® Curve™ spine frame

Instructions for Use



Kyra® Curve™ Spine Frame:

KYRA9000

Prior to using this or any other type of medical equipment 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 physician.
- Device function should be checked prior to each usage.
- This device should only be operated by trained personnel.
- All modifications, upgrades, or repairs must be performed by an authorized specialist.
- 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.

NEVER EXCEED THE WEIGHT CAPACITY AND LOAD DISTRIBUTON OF THE OPERATING ROOM TABLE

1 Instructions for Use:

1.1 Indication for Use:

The Kyra Curve spine frame provides maximum lordosis in a variety of surgical spine procedures including, but not limited to Laminectomy, Decompression, Disc Surgery and Microdiscectomy surgery. These devices are capable of being used with a broad patient population as deemed appropriate by the caregiver or institution.

1.2 Intended Use:

The Kyra Curve spine frame is designed to position and support the patient's spine in a variety of surgical procedures including, but not limited to Laminectomy, Decompression, Disc Surgery and Microdiscectomy surgery. These devices are intended to be used by healthcare professionals within the Operating Room setting.

1.3 Intended User and Patient Population:

Intended User: Surgeons, Nurses, Doctors, Physicians and/or Healthcare professionals involved in the intended procedure utilizing the device. Not intended for lay persons.

Intended Populations:

This device is intended to be used with patients that do not exceed the weight in the safe working load field specified in the product specification section 3.2.

1.4 Residual Risk:

This product complies with relevant performance, safety standards. However, device harm from misuse, device damage, function or mechanical hazards cannot be completely excluded.

2 Safety Considerations:

2.1 Safety hazard symbol notice:

DO NOT USE IF PRODUCT SHOWS VISIBLE DAMAGE.

2.2 Equipment Misuse Notice:

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

2.3 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.

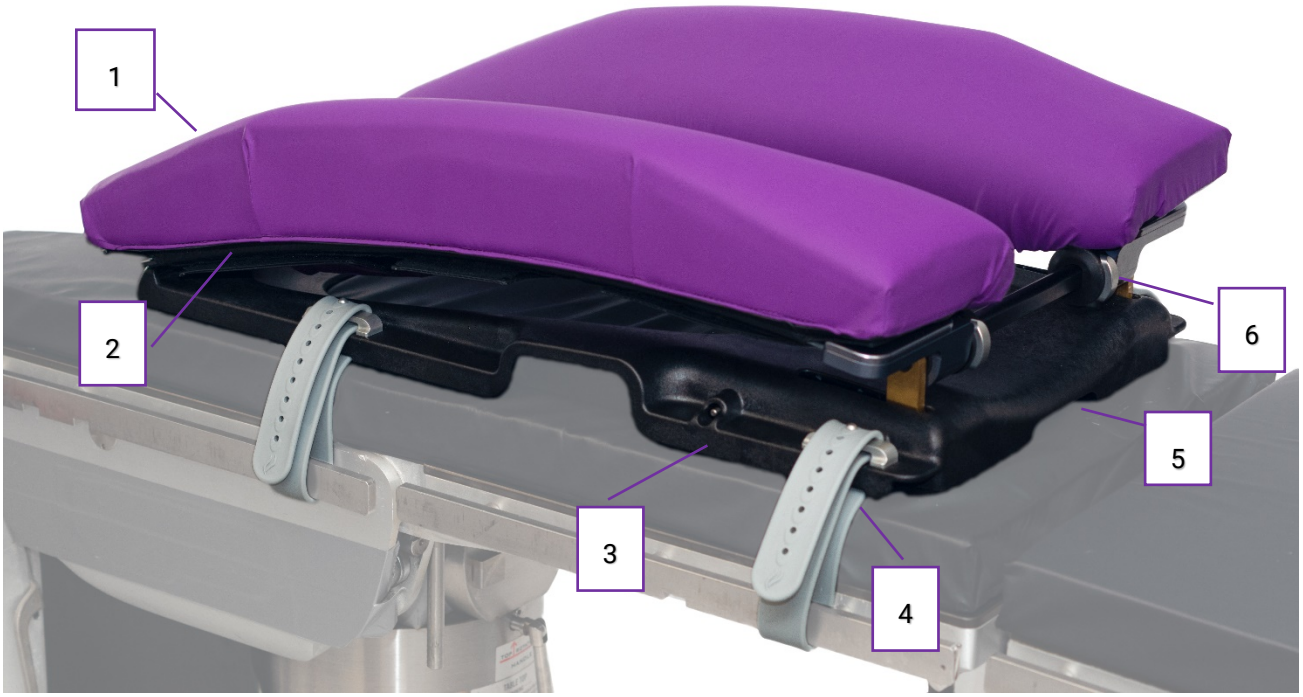
If in doubt, the user of the device shall first contact Kyra Medical Technical Support for guidance on safe disposal protocols.

2.4 Symbols:

Symbol used	Description	Reference
	Indicates the device is a medical device	MDR 2017/745
	Indicates the medical device manufacturer	EN ISO 15223-1
	Indicates the manufacturer's serial number	EN ISO 15223-1
	Indicates the medical device Global Trade Item Number	21 CFR 830 MDR 2017/745
	Indicates the manufacturer's lot code	EN ISO 15223-1
	Indicates the date when the medical device was manufactured	EN ISO 15223-1
	Indicates the manufacturer's catalogue number	EN ISO 15223-1
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions.	EN ISO 15223-1
	Indicates the device do not contain natural rubber or dry natural rubber latex	EN ISO 15223-1
	Indicates the authorized representative in the European Community	EN ISO 15223-1
	Indicates the Medical Device complies to REGULATION (EU) 2017/745	MDR 2017/745
	Indicates a Warning	IEC 60601-1
	Indicates the need for the user to consult the instruction for use	EN ISO 15223-1

3 System

3.1 System Components Identification:



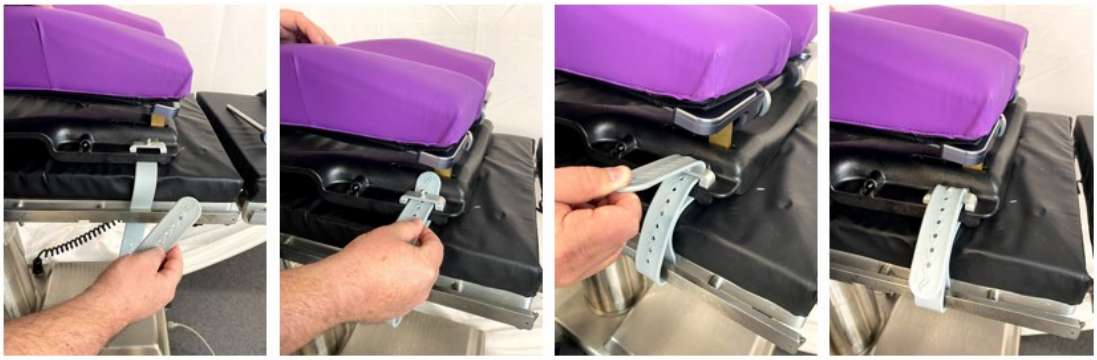
1. Gel Pads
2. Carbon Fiber Leafs
3. Crank Handle Connector
4. Secure-Lok® Straps
5. Base Handle
6. Medial/Lateral Slide Buttons

3.2 Product Specifications:

Mechanical Specifications	Description
Product Dimensions	30" x 17.5" x 10" (L x W x H) *approx.* 76.2cm x 44.4cm x 25.4cm
Material	Carbon Fiber, Stainless Steel, Aluminum, Brass and Polycarbonate.
Safe Working Load on the Device	• Do not exceed 600 lbs. (272kg) patient weight.
Overall Weight of Device	• 31.4lbs. (14.24kg)
Storage Specifications	**Description**
Storage Temperature	-20º F to 140º F (-29º C to +60º C)
Storage Relative Humidity Range	15% to 85%
Operating Temperature	This device is intended to be used in a controlled Operating Room environment.
Operating Relative Humidity Range	
Compatibility Specifications	**Description**
Compatible with:	• Curve Crank Handle • Curve Cart
Operating Room Table Compatibility	The Kyra Curve spine frame is compatible with the following surgical table rail styles: US, UK, EU, DEN, JP. The Kyra Curve spine frame is compatible with rails attachments of the OSI "Jackson" style tables and the Allen® Advance table and Flex frame.

3.3 System Setup and Use:

1. Center the Kyra Curve on the OR table or onto spine rail table connection.
2. Place Secure-Lok strap around the table rail, under and through the cleat and secure the strap hole into the stud. Repeat for all 4 straps.



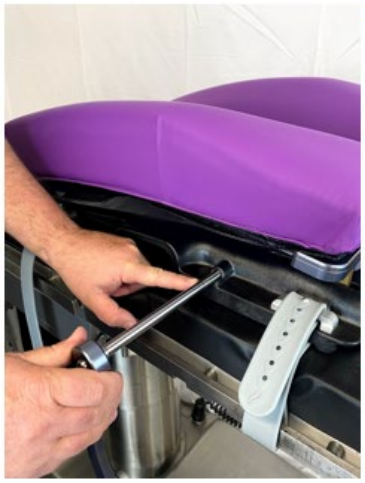
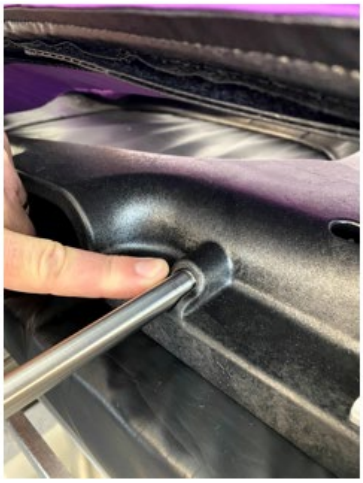
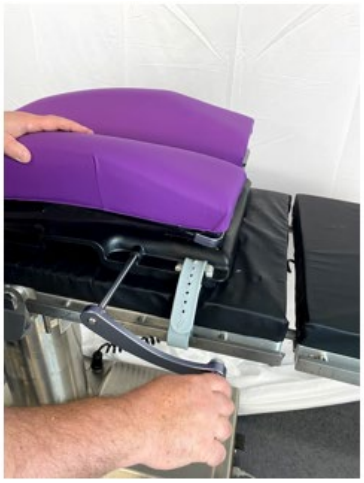
3. While pressing the button, slide the pad medially/laterally to provide patient support and provide space for the abdomen. Fit disposables as directed on its packaging.


4. Ensure the leafs are captured under the lower side edge of the frame.

3.4 Patient Positioning:

Position the patient onto the operating room table according to the requirements of the surgeon and facility protocol.

1. Connect the Crank Handle. Turn Clockwise to curve the pads. Turn Counter-clockwise to flatten the pads.

3.5 Device Maintenance:

Make sure that all labels are installed and can be read. Replace labels as necessary by using a plastic scraper to remove the label. Use an alcohol wipe to remove any adhesive residue.

Contact Kyra Medical, Inc. if you need to repair or replace the device contact us using the information from the contact details section.

3.6 Cleaning and Disinfection:

WARNING:

- After each use, clean the device as directed in this instruction for use.
- Do not submerge the device in liquid. Equipment damage can occur.
- Use caution in areas where liquid can get into the mechanism.
- Do not use bleach or products that contain bleach to clean the device. Injury or equipment damage can occur.
- Make sure that the device is dry before you store it or use it again.

After each use, clean the device. Clean and disinfect using a OR approved disinfecting/cleaning solution following the manufacturer's recommendation for achieving low-level disinfection and according to the facility protocol. After each use or exposure to a patient the equipment should be cleaned with disinfecting wipes or sprays; any organic material or residue should be removed completely from the surface of equipment.

- Wipes:
  - Wipes main contain up to 2% sodium hypochlorite.
  - Wipes may contain benzalkonium chloride (< or = 0.6% conc.) and didecyl dimethyl ammonium chloride (up to 0.6% conc.)
  - Wipes main contain benzalkonium chloride (up to 0.6% conc.), didecyl dimethyl ammonium chloride (up to 0.6% conc.) and may also contain polyhexamethylene biguanide (up to 0.6% conc.).
- Sprays:
  - Sprays main contain up to 2% sodium hypochlorite.
  - Sprays may contain up to .2% benzalkonium chloride and up to 0.2% didecyl dimethyl ammonium chloride (quaternary ammonium chloride solution (QACs) and may also contain polyhexamethylene biguanide (up to 0.6% conc.).
  - Sprays may contain up to 2% hydrogen peroxide.

Read the cleaning product's directions and follow the instructions on the label. Use caution in areas where fluid migration may occur:

Wipe device with a clean, dry cloth. Make certain the product is dry prior to reinstalling to avoid damage.

CAUTION: Damage may result if product is cleaned with caustic chemicals or harsh abrasives

ATTENTION: If any Kyra product is damaged or appears to be functioning abnormally, discontinue use and contact Kyra Customer Service at 1-508-936-3550

4 Compliance with Medical Device Regulations:

CE

This product is a non-invasive, Class I Medical Device and system is CE-marked according to Annex VIII, Rule 1, of the Medical Device Regulations (REGULATION (EU) 2017/745).

4.1 EC Authorized Representative:

EC REP

Emergo Europe
Prinsessegracht 20
2514 AP The Hague, Netherlands

4.2 Manufacturing Information:

KYRA MEDICAL, INC.
102 OTIS ST
NORTHBOROUGH, MA 01532 USA
888-611-KYRA (NORTH AMERICA)
508-936-3550 (INTERNATIONAL)

4.3 EU Importer:

Kyra Medical Europe Limited
69 Esker Woods Drive
Lucan Co Dublin
K78PX45
IRELAND