Kyra Medical Inc.
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United States of America

KYRA® Stirrups

Instructions for Use

Kyra® Comfort™ Stirrups:

KYRA3000, KYRA3100
KYRA5000, KYRA5100
KYRA7100, KYRA7810
KYRA8100

Kyra® Clean™ Stirrups:

KYRA3200, KYRA5200

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:

Stirrups are used in a variety of surgical procedures including, but not limited to gynecology, urology, laparoscopy, colorectal, general, and robotic 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:

Stirrups are designed to position and support the patient's foot, lower leg and upper leg in a variety of surgical procedures including, but not limited to gynecology, urology, laparoscopy, general and robotic 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. Boot
2. Lithotomy Twist Handle
3. Boot Adjustment Handle
4. Gas Shock
5. Ball Joint
6. Locking Straps
7. Boot Pad

3.2 Product Specifications:

Mechanical Specifications	Description
Product Dimensions	40" x 11" x 16" (L x W x H) *approx.* 101.6cm x 28cm x 40.6cm
Material	Stainless Steel, Aluminum, and Low temperature Polymers.
Safe Working Load on the Device	• KYRA 350 Do not exceed 350 lbs. (159 kg) patient weight. • KYRA 500 Do not exceed 500 lbs. (227 kg) patient weight. • KYRA 800 Do not exceed 800 lbs. (363 kg) patient weight. • KYRA 250 Do not exceed 250 lbs. (113 kg) patient weight. • KYRA 400 Do not exceed 400 lbs. (181 kg) patient weight.
Overall Weight of Device	• KYRA 350 13.2lbs. (5.9kg) . • KYRA 500 & 800 14.6lbs. (6.6kg) . • KYRA CLEAN 350 13.2lbs. (5.9kg) • KYRA CLEAN 500 14.4lbs. (6.5kg) • KYRA 250 10.2lbs. (4.6kg) . • KYRA 400 12.2lbs. (5.5kg) .
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:	**Clamps:** • Secure-Release® Blade Clamp • Select Blade Clamp • Simple Blade Clamp • or equivalent clamps in correct rail size. **Pads:** • Kyra Stirrup Replacement Pads
Operating Room Table Compatibility	The Kyra Comfort stirrups are compatible with the following surgical table rail styles: US, UK, EU, DEN, JP, based on clamp selection.

3.3 System Setup and Use:

1. Prior to placing the Stirrups on the table, the patient should be examined and assessed for any pre-existing conditions that might prohibit the safe use of lithotomy positioning equipment.
2. Stirrups can be mounted to the table using the Secure-Lok™ clamps, the Select blade clamps, Simple blade clamp or a standard surgical table blade rail clamp.
3. Position the blade clamp adjacent to the patient's hip. The longer lateral fin of each stirrup boot should be positioned on the lateral side of the patient leg. Insert the blade of the stirrup fully into the table clamp. Tighten the clamp by turning the knob clockwise.
4. The curve in the stirrup support structure should be positioned parallel to the patient's femur and the stirrup ball joint should be in alignment with the femoral head.
5. WARNING: Once the stirrup is in the desired position, the blade clamps should be tightened in the clamping mechanism. It is important that the clamps be tightened and tested for security.
6. Loosen the boot adjustment clamp, to slide boot along support rod until the calf portion of the boot is located near the patient's calf. Tighten the boot adjustment clamp on the boot securely such that boot cannot be moved. Repeat for the opposite stirrup.
7. Position stirrups to be level with the table by turning the handle while moving the stirrups into place.

   For best results, the OR Table pad should be 3" (7.6cm) thick or more.

3.4 Patient Positioning:

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

1. Pre-position stirrup boots as described in Section 3.3 above. Confirm the boot-clamping mechanism is secure and the boot is positioned properly. Confirm stirrup blade clamp is secure to the OR rail.
2. Safe patient positioning requires at least two staff members. Each staff member will simultaneously place the patient's legs into a stirrup. Grasp the patient's heel in one hand and place the other hand under the patient's knee. Gently flex the patient's knee while supporting the leg with both hands. Each clinician should simultaneously transfer a leg into the stirrup boot.
3. Check that the patient's heels are fully seated into the heel section of the boot and the leg is securely in place. Close the boot pad by using the medial to lateral closure system with optional Secure-Lok™ Closure Straps or Velcro® straps. Confirm the pads are secured.
4. Perform a final check to ensure that the patient's heels are properly seated in the heels of the boots and that there are no pressure points on the calf. The leg must be centered in the boot to eliminate pressure on the peroneal nerve. There should be a 10-degree bend in the patient's knee.
5. Proper initial leg flexion includes the following safe guidelines:

   When using LOW LITHOTOMY, do not hyper-extend the leg while achieving desired abduction.

   When using MEDIUM OR HIGH LITHOTOMY, use minimal amounts of leg flexion/abduction initially as these will increase as the legs are moved into higher positions.

6. Ensure that the toe/ankle, knee, and opposite shoulder are maintained in alignment during positioning. The foot and thigh are typically abducted at the same angle. Use the alignment markings on the rod for assuring symmetry.
7. In order to adjust the boot position and change the flexion angle, the boot should be supported in one arm and with the other hand, or with the help of an assistant, the boot adjustment clamp should be loosened

by turning the handle on the boot clamping mechanism until the boot can be realigned to the proper position. Retighten the boot adjustment clamp securely to the rod.

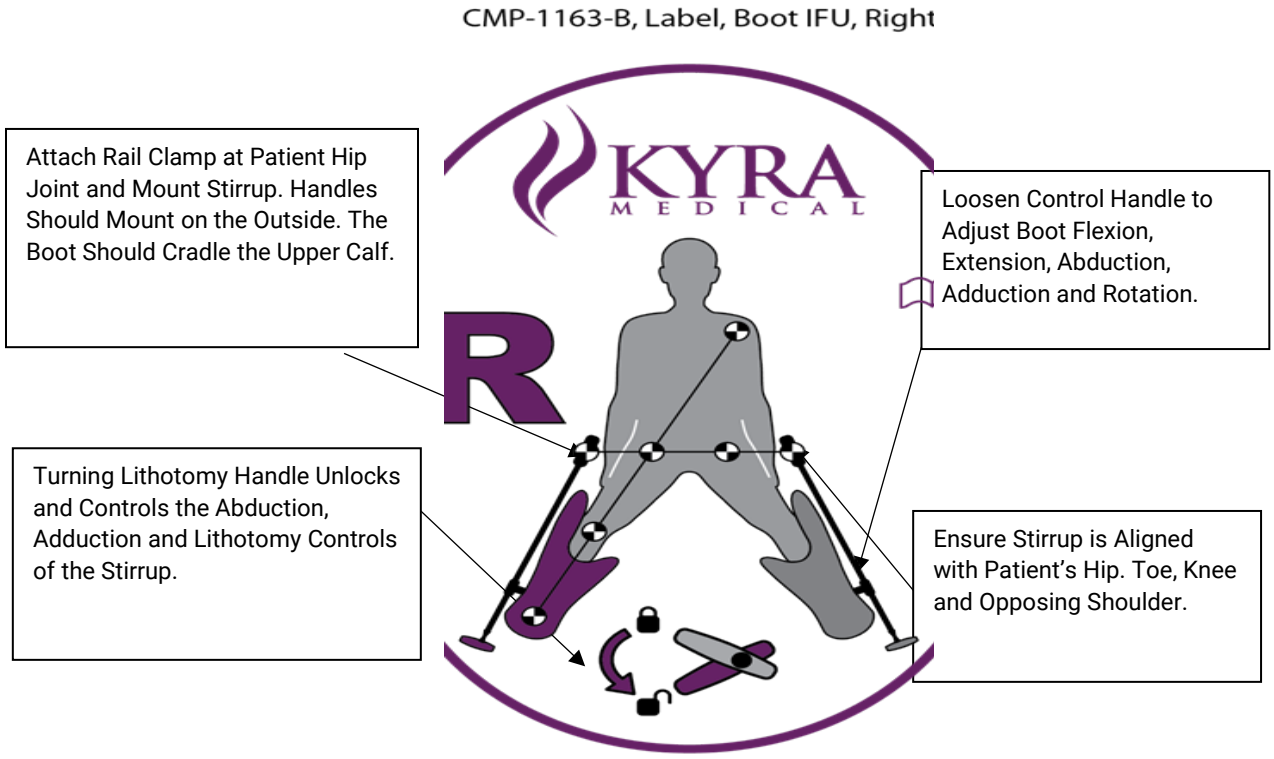
8. To articulate the patient's legs into high or low lithotomy, twist the handle at the distal end of the stirrup rod and raise or lower both legs simultaneously. Release the handle to lock the stirrups in place.
9. The boot has a self-adjusting design to protect the calf during raising or lowering of the legs. It is free floating and moves with the patient's leg as needed.

3.5 Removal Instruction

1. Raise/Lower stirrups by squeezing the release handles and simultaneously move the stirrups slowly to a horizontal level.
2. Gently remove patient's legs from stirrups.
3. Stirrups should be in a vertical position for removal from sockets. Loosen clamp/socket and remove stirrups.

WARNING: Additional positioning devices should be used when using the stirrup in Trendelenburg or reverse Trendelenburg.

3.6 Device Controls and Indicators:



This Symbol Represent the Patient's Right foot

3.7 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.

3.8 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:

Emergo Europe
Prinsessegracht 20
2514 AP The Hague, Netherlands

4.2 Manufacturing Information:

KYRA MEDICAL, INC.
100 OTIS ST, SUITE 1
NORTHBOROUGH, MA 01532 USA
888-611-KYRA (NORTH AMERICA)
508-936-3550 (INTERNATIONAL)

4.3 EU Importer:

Kyra Medical Europe Limited
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Lucan Co Dublin
K78PX45
IRELAND