Stirrups

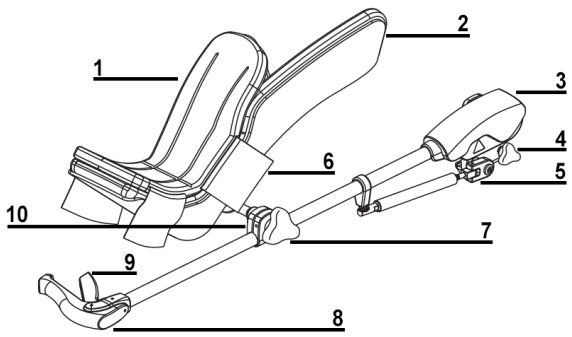
INSTRUCTIONS FOR USE (IFU)

CQ MEDICAL™

CE

STIRRUPS

Left Stirrup



Right stirrup not shown

1. Boot Pad
2. Boot
3. Knuckle Cover
4. Rail Knob
5. Rail Clamp
6. Velcro® Strap
7. Boot Knob
8. Handle
9. Handle Trigger
10. Boot Clamp

SPECIFICATIONS

MECHANICAL SPECIFICATIONS	
Overall Dimensions	38”L x 10”W x 18”H.
Patient Weight Limit Capacity	500lbs. (227 kg)
Overall Weight	9.7 lbs (4.40 kg) each
ENVIRONMENTAL CONDITIONS	
Operating	Temperature: 10°C To 40°C (50°F To 104°F) Humidity: 10% To 90% Non-condensing Atmospheric: 700–1060 HPa
Storage	Temperature: 0°C To 50°C (32°F To 122°F) Humidity: 0% To 95% Atmospheric: 700–1060 HPa

PARTS LIST

2009411	Knuckle Cover, Right
2009412	Knuckle Cover, Left
2009248	Boot, Right
2009249	Boot, Left
2009279	Boot Padding, Right
2009280	Boot Padding, Left
3002639	Boot Knob
2009416	Rail Knob Assembly

INTENDED USE

- The Symphony® Patient Transport System is indicated to aid in the support, positioning, and transfer of a patient for procedures involving imaging, including MRI; and external beam radiation therapy treatment with electrons, photons or protons; and other procedures requiring transfer of a patient. The Symphony® is designed to interface with other positioning devices, such as couchtops, inserts, thermoplastic masks, and positioning pads.
- The Lithotomy AirShuttle™ is for use as part of the AirDrive™ system to enable brachytherapy procedures, especially prostate and gynecological brachytherapy. The device is intended to support and transfer patients undergoing brachytherapy and related imaging procedures.

  Reference IFU RT-5100-05 Lithotomy AirShuttle™
- The Stirrups are accessories that will be used with the Lithotomy AirShuttle™ to position and support the patient's legs and feet during transfer and treatment of patients undergoing brachytherapy and related imaging procedures.

PATIENT TARGET GROUPS

Patients undergoing radiation therapy, diagnostic imaging procedures, or other procedures involving transfer of a patient.

INTENDED USERS

Person qualified in accordance with requirements of the regulatory region.

CAUTION

Federal (United States) law restricts this device to sale by or on the order of a physician.

⚠ WARNING

- *No modification of this equipment is allowed. If any part of this device experiences a catastrophic load, appears damaged or functions improperly, discontinue use immediately and contact CQ Medical at info@CQmedical.com.*
- *Patient should be examined for any pre-existing conditions that might prohibit safe use of device.*
- *To prevent patient injury, ensure device is positioned for proper patient positioning in accordance with facility, procedure, and provider requirements.*
- *When positioning patient for Imaging on MR and CT, ensure patient supporting device and stirrups are centered and lowered to prevent collision with imaging system.*
- *To prevent damage to stirrup function, do not try to move or adjust stirrup position, with or without a patient in the stirrup, without actuating release handle prior to movement.*
- *Using stirrup handles to position or transfer patient on procedural table can result in unintentional patient movement or position.*
- *Ensure all device knobs are securely tightened before activating AirDrive Trolley™ or AirDrive Caddie™ and transferring or moving of AirShuttle™.*
- *Use caution when moving stirrups to avoid patient or clinician injury. Extreme care has been taken to minimize trapping zones and other hazards associated with stirrups. However, potential trapping zones include but are not limited to:*
  - *Between stirrup and accessory rail*
  - *Between stirrup cover and rail clamp upright*
  - *Between stirrup tube and stirrup boot*
  - *Between stirrup tube and gas shock*

NOTE:
- If any serious incident occurs in relation to device, incident should be reported to manufacturer. If incident occurred within the European Union, also report to the competent authority of the Member State in which you are established.
- Refer to www.CQmedical.com for a listing of symbols and their definitions.

MRI SAFETY INFORMATION

Use only proven MR Safe or MR Conditional accessories, tested, and approved for your MR system. Consider MR compatibility of accessories prior to use on MR system.

⚠ WARNING

- *Use of unapproved MR accessories may result in:*
  - *Injury to Patient*
  - *Patient burns*
  - *Damage to equipment*
- *Recommended maintenance and service, as well as use of only CQ Medical-provided accessories, components, and replacement parts, are necessary to ensure safety, performance, and MRI compatibility of product(s), as well as to maintain applicable warranties.*

MR Conditional

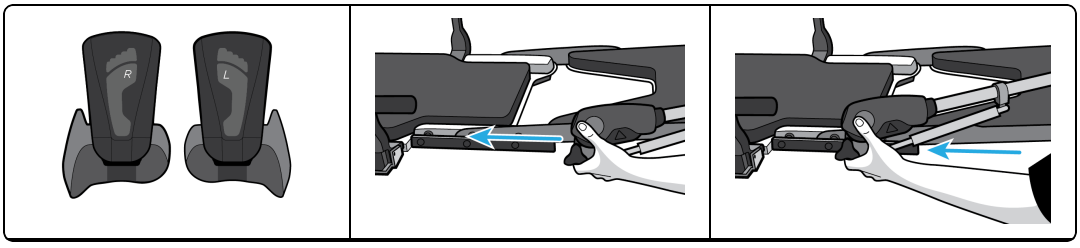
Non-clinical testing has demonstrated this device is MR Conditional and may be used with an MR system meeting the following conditions:
- Device may be placed in the bore of an MR system having a static magnetic field of 3T or less.
- Any attachments used with this device in an MR system must be MR Conditional or MR Safe for use in that system and used in accordance with their intended use.

INSTALLATION

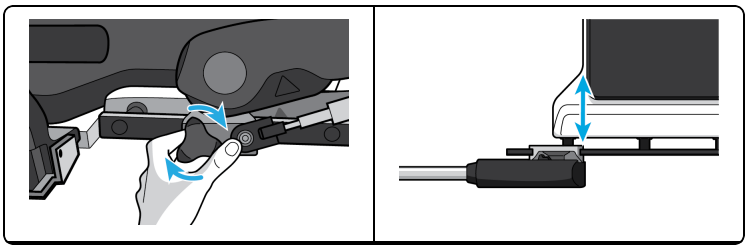
NOTE:
- At least two healthcare professionals are required to ensure safe stirrup installation and patient positioning.
- For best MR imaging results, position rear of stirrup clamp in line with edge of perineal cutout.
- Use two hands when handling stirrups to avoid dropping when carrying or attaching to device.

ATTACHING STIRRUPS

1. Identify left and right stirrup.
2. Slide rail clamps on accessory rail on both sides of lithotomy device.



3. Tighten rail knobs by turning clockwise.



⚠ WARNING

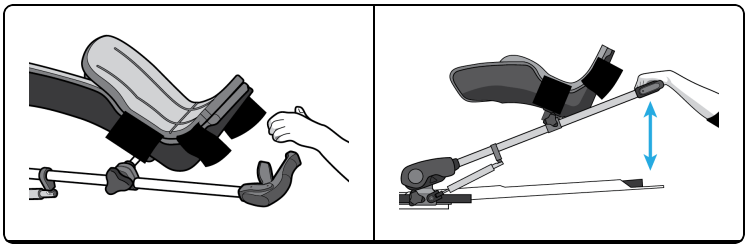
- *Securely tighten rail clamp along accessory rail before adjusting boot to prevent patient or operator injury from inadvertent stirrup movement.*

POSITIONING PATIENT AND STIRRUPS

⚠ WARNING

- *Do not place any extremities on or near stirrup mechanism when adjusting or moving Stirrup.*
- *To prevent damage to stirrup function, do not try to move or adjust the stirrup position, with or without a patient in the stirrup, without actuating release handle prior to movement.*

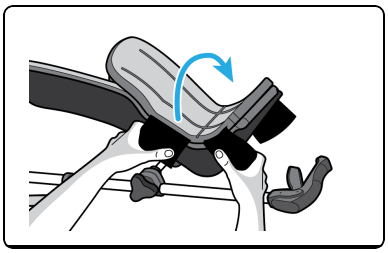
1. To position stirrup, squeeze handle trigger, adjust position, and release handle trigger to lock.



2. To position boot, loosen boot knob by turning counterclockwise. Adjust boot position and tighten boot knob by turning clockwise.

NOTE: Boot is designed to free float and not lock into rigid position.

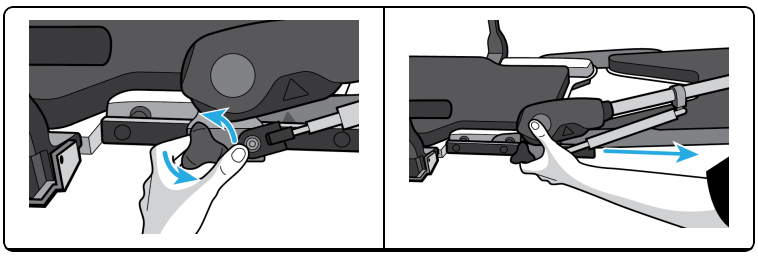
3. Tighten rail knobs by turning clockwise.
4. Pull lateral Velcro® straps to open boot padding to medial sides of patient.



5. Adjust Velcro® straps as needed.
6. Loosen and tighten boot knob as needed.
7. Adjust stirrups as needed with handle trigger.

REMOVING STIRRUPS

1. Loosen rail clamp knobs by turning counterclockwise.



MAINTENANCE

NOTE: Do not submerge device in liquid.

1. Device can be cleaned with a mild, non- abrasive cleaning or disinfecting solution. To clean, apply solution to clean cloth and wipe surface. Visually inspect device, if it is not clean, repeat previous cleaning steps until visually clean. Use a clean cloth moistened with water to wipe device to remove any cleaning agent residue. To dry, wipe device with a clean, dry cloth. The following cleaning material has been tested and found to be appropriate for cleaning device.
    - Water
    - Soap and Water
2. The following products are recommended. Refer to specific instructions from chemical agent manufacturer.
    - 10% Clorox® Bleach Solution
    - Isopropyl Alcohol

EC REP

Advena Limited
Tower Business Centre, 2nd Flr
Tower Street, Swatar BKR 4013
Malta

CH REP

Raditec Medical AG
Schlossberg 5a
5454 Bellikon
Switzerland

CQ MEDICAL™

QFix
440 Church Rd
Avondale, Pennsylvania
United States
info@cqmedical.com

www.CQmedical.com