

Klarity SBRT System

INSTRUCTIONS FOR USE

GENERAL INFORMATION

The Klarity® SBRT System is a medical device used for precise positioning and immobilization of patients undergoing radiation therapy treatments for tumors outside the CNS that require either a single high dose radiation treatment or a few fractionated radiation treatments.

PRODUCT DESCRIPTION

The Klarity® SBRT System is designed to be simple to use, highly indexable, and easily adjustable. The standard system has a streamlined design to allow for quick and easy set up with accurate reproducibility. Advanced indexing options are included in the standard system for treatments requiring high conformity and detail. Both standardized and customized indexing options are available in the form of Masks, Klarity Cushions™, and Vacuum Bags providing strong support, comfort, and accurate positioning.

STORAGE AND CLEANING

Store in a clean, dry place away from direct sunlight. Wipe thoroughly with a neutral antiseptic cleaner. Allow to dry thoroughly before next use.

PARTS INCLUDED	
R624-SCF1	Klarity SBRT Baseplate – Carbon Fiber
R632-BTCF	WingSpan Baseplate
R7641-25BC	SBRT Full Body Vacuum Bag
R624-SCF1-1	Belly Bridge
R624-SCF1-5	Respiratory Belt
R624-SCF1-2	Knee Bridge
R7131-5NLT	Knee Bridge Vacuum Bag
R624-SCF1-3	Knee Positioner Device
R624-SCF1-4	Foot Positioner Device
R634-LE	Knee and Foot Positioner Cushions: Knee Positioner Cushion (1), Knee Elevation Block (1), and Foot Positioner Cushion (1)
RE-15CF	SBRT Board Indexing Bars (2)
R624-SCF1-5	Respiratory Belt

INSTRUCTIONS FOR USE

BASEPLATE

The Klarity SBRT Board (R624-SCF1) can be attached to a couch top using standard indexing bars at the top and bottom of the board. Six holes are provided at both ends so the board can be secured in three different positions: in the Middle of the couch top, adjusted Left, or adjusted Right.



The Klarity SBRT System has a variety of positioning and indexing options for optimal patient set up and comfort. There are three regions in which positioning takes place; the upper body, the lower body, and the belly (for breath restriction).

UPPER BODY

WingSpan™ Baseplate: The Klarity WingSpan™ Baseplate (R632-BTCF) indexes to the SBRT Baseplate using one of the two SBRT Board Indexing Bars (RE-15CF) provided with the SBRT System and includes an adjustable T-grip handle that allows therapists to position patients' arms effectively and comfortably. The WingSpan™ Baseplate also features indexing points for optional headrests, as well as two black pegs near the middle of the board that allow for the SBRT Full Body Vacuum Bag (R7641-25BC) to be indexed directly to it.

T-Grip Handle: The handle has 12 indexing options (1-12) for the proximity to the patient's head and six (A-F) for the height of the handles. To index the handle to the board, first make sure the locking mechanism on the base is lifted, then slide the inverted T-shaped block

To be used by a qualified medical professional
IFU-B-002



EC REP

Lotus NL B.V
Koningin Julianaplein 10, le Verd, 2595AA
The Hague, Netherlands
T: +31645171879 (English)
T: +31626669008 (Dutch)

Klarity Medical Products, LLC
600 Industrial Parkway
Heath, OH 43056
T: 740.788.8107 F: 740-788-8109
info@klaritymedical.com
www.klaritymedical.com

under the overhangs (the green arrow should be pointing up, away from the patient's head), align the green line on the base of the handle with the lines of the desired indexing location, and engage the locking mechanism. To adjust the height of the handle, disengage the locking mechanism, either pull the handle up or push it down to the desired height, and reengage the locking mechanism.



Head Rests: The optional foam (R511) or Silverman (R507) headrests (sold separately) can both be used with the WingSpan™ Baseplate. The foam headrest simply sits in the shallow recess in the middle of the WingSpan™ Baseplate, while Silverman headrests can be indexed using the white pins to the sides of the recess.

SBRT Full Body Vacuum Bag: The patient's torso can be immobilized from below using the large vacuum bag (R7641-25BC) included in the Klarity SBRT system. It has indexing locations at the bottom and top of the bag. The top location indexes directly onto the WingSpan™ Baseplate and should be done first, while the bottom location indexes to the board using one of the two SBRT Board Indexing Bars (RE-15CF) provided with the system. With the patient in place, remove air from the bag and form it around the patient.

NOTE: If an optional headrest is being used, index the vacuum bag over top of the headrest.

LOWER BODY

Knee and Foot Positioner: The Knee and Foot Positioner includes the Knee Positioner Device, the Foot Positioner Device, and their respective cushions.

Knee Positioner Device: The Knee Positioner Device (R624-SCF1-3) indexes to the SBRT board using the two locking clips on either side. To index, first make sure both clips are in the "Unlocked" position and place the device at the foot of the board with the clips toward the feet and hanging off the end. Slide the device up the board making sure that the clips go around the lip of the board. Move the device to the desired location, using the windows and indicator lines



above the locking clips for precise locating, and move the switch on both clips to the locked position.



To be used by a qualified medical professional
IFU-B-002



Keep in a cool and dry environment



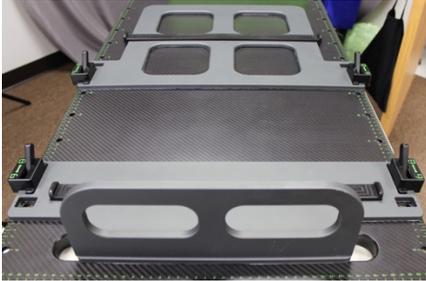
EC REP

Lotus NL B.V.
Koningin Julianaplein 10, le Verd, 2595AA
The Hague, Netherlands
T: +31645171879 (English)
T: +31626669008 (Dutch)

Klarity Medical Products, LLC
600 Industrial Parkway
Heath, OH 43056
T: 740.788.8107 F: 740-788-8109
info@klaritymedical.com
www.klaritymedical.com

Foot Positioner Device: The Foot Positioner Device (R624-SCF1-4) indexes to the SBRT board in the same manner as the Knee Positioner Device, with one small difference; this time the clips will go on first and be pointed toward the head so that the device is open to the rest of the board.

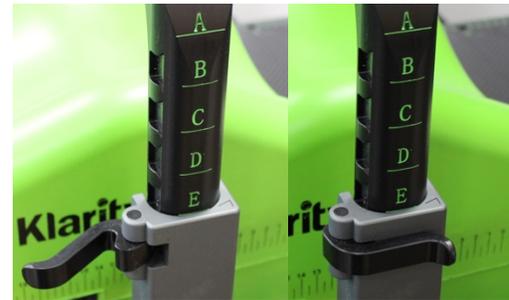
NOTE: The Knee Positioner Device must be indexed first, then the Foot Positioner Device.



Knee and Foot Positioner Cushions: The Knee and Foot Positioner Cushions (R634-LE) index to the Knee Positioner and Foot Positioner devices. Simply match up the channel on the cushions with the raised bars on the positioning devices and set them down. Make sure the Foot Positioner Cushion has the foot cups pointed up towards the body, so the patient's feet sit inside them. The elevation blocks for the Knee Positioner also have pegs on the raised bar for indexing to the Knee Positioner Cushion. Simply fit the pegs into the holes in the channel on the bottom of the next cushion. The Knee Positioner Cushion should be oriented, so the long side is toward the feet and the short side is toward the head.



Knee Bridge: The Knee Bridge (R624-SCF1-2) indexes to the SBRT board using locking clamps similar to the those on the Knee Positioner and Foot Positioner Devices; however, they can be indexed starting at any point and don't need to be slid on from the foot of the board. With the clamps in the "Unlocked" position and the green arrow on top pointing towards the head, place the bridge on the board in the desired location (usually this will line up with the crest of the Knee Positioner Cushion) and engage the locking mechanism of the clamps. The Knee Bridge is also height-adjustable with 5 height options (A-E). With the bridge attached to the board, undo the clips on the sides of the bridge and pull up or push down on it to change to the desired height, then reengage the clips.



Knee Bridge Vacuum Bag: The Knee Bridge Vacuum Bag (R7131-5NLT-0) indexes to the Knee Bridge. Start with some air in the vacuum bag, so it is easy to manipulate and will fit inside the arch of the bridge, with both locking pins on the top of the bridge disengaged (pulled up). Fit the holes in the indexing bar on the vacuum bag onto the indexing pegs and locking pins on the underside of the bridge and push down on the

To be used by a qualified medical professional
IFU-B-002

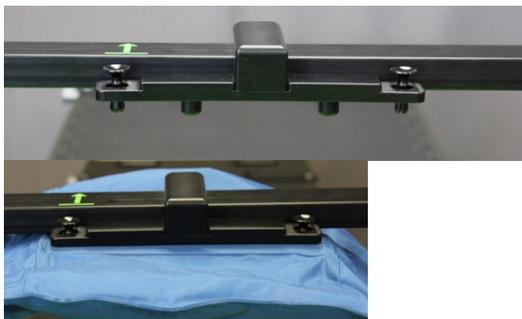


EC REP

Lotus NL B.V.
Koningin Julianaplein 10, le Verd, 2595AA
The Hague, Netherlands
T: +31645171879 (English)
T: +31626669008 (Dutch)

Klarity Medical Products, LLC
600 Industrial Parkway
Heath, OH 43056
T: 740.788.8107 F: 740-788-8109
info@klaritymedical.com
www.klaritymedical.com

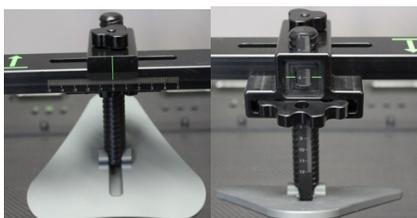
locking pins to engage them and lock the cushion in place. With the patient in place, remove air from the bag and form it around the patient.



BELLY

Belly Bridge: The Belly Bridge (R624-SCF1-1) is height adjustable and indexes to the SBRT board using locking clamps just like the Knee Bridge, as shown above. As with the Knee Bridge, the green arrow on top should be pointed towards the head of the board.

Belly Compression Paddle: The belly bridge comes with a Belly Compression Paddle which is used to restrict respiratory movement and is adjustable both laterally and vertically. The paddle is triangular and should be attached to the bridge so that the single corner of the triangle points to the patient's head, while the other two corners are pointed towards the patient's feet. To adjust the paddle laterally, loosen the set screw on the top of the bridge, shift the paddle assembly to the desired location using the indicator line and indexing scale, and retighten the set screw. To adjust the paddle vertically, turn the gear on the paddle assembly. Note the window with the indicator line that shows the paddles exact vertical location on another indexing scale.



Respiratory Belt: The Respiratory Belt (R624-SCF1-5) is another device to restrict the movement due to breathing. It indexes to the SBRT board using the same style of locking clips as the Knee Positioner and Foot Positioner Devices; however, due to its flexible nature, the clips do not need to be slid on from the foot of the board. After the patient is in place, index the loosened belt to the board, then tighten it using the Velcro strap on top. Attach the sphygmomanometer and inflate the belt to the desired amount, then detach the sphygmomanometer. Note the indexing scale on the strap to allow for a reproducible fit.



Thorax Mask: The optional SBRT thorax mask (R323-B2436) is another method of breath restriction. It indexes to the SBRT board using expansion pins and the indexing holes on the sides of the board. For heating instructions please refer to the Klarity Mask literature.

To be used by a qualified medical professional
IFU-B-002



Keep in a cool and dry environment



Lotus NL B.V
Koningin Julianaplein 10, le Verd, 2595AA
The Hague, Netherlands
T: +31645171879 (English)
T: +31626669008 (Dutch)

Klarity Medical Products, LLC
600 Industrial Parkway
Heath, OH 43056
T: 740.788.8107 F: 740-788-8109
info@klaritymedical.com
www.klaritymedical.com