Comfort Hold™ Thigh and Foot Positioner Instructions for Use

Caution: Federal Law restricts this device to sale by or on the order of a licensed Physician or Radiation Therapist.

DEVICE DESCRIPTION

Bionix Radiation Therapy Comfort Hold Thigh and Foot Positioner (PBRT-6030) is a reusable, customizable device intended to be used for the positioning and re-positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

INDICATIONS

The Comfort Hold Thigh and Foot Positioner (is intended to be used for the positioning and repositioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

CONTRAINDICATIONS

No contraindications have been identified for the use of the Comfort Hold Thigh and Foot Positioner.

STORAGE

Store in a cool, dry environment.

ADVERSE REACTIONS

No adverse reactions have been identified for the use of the Comfort Hold Thigh and Foot Positioner.

WARNINGS

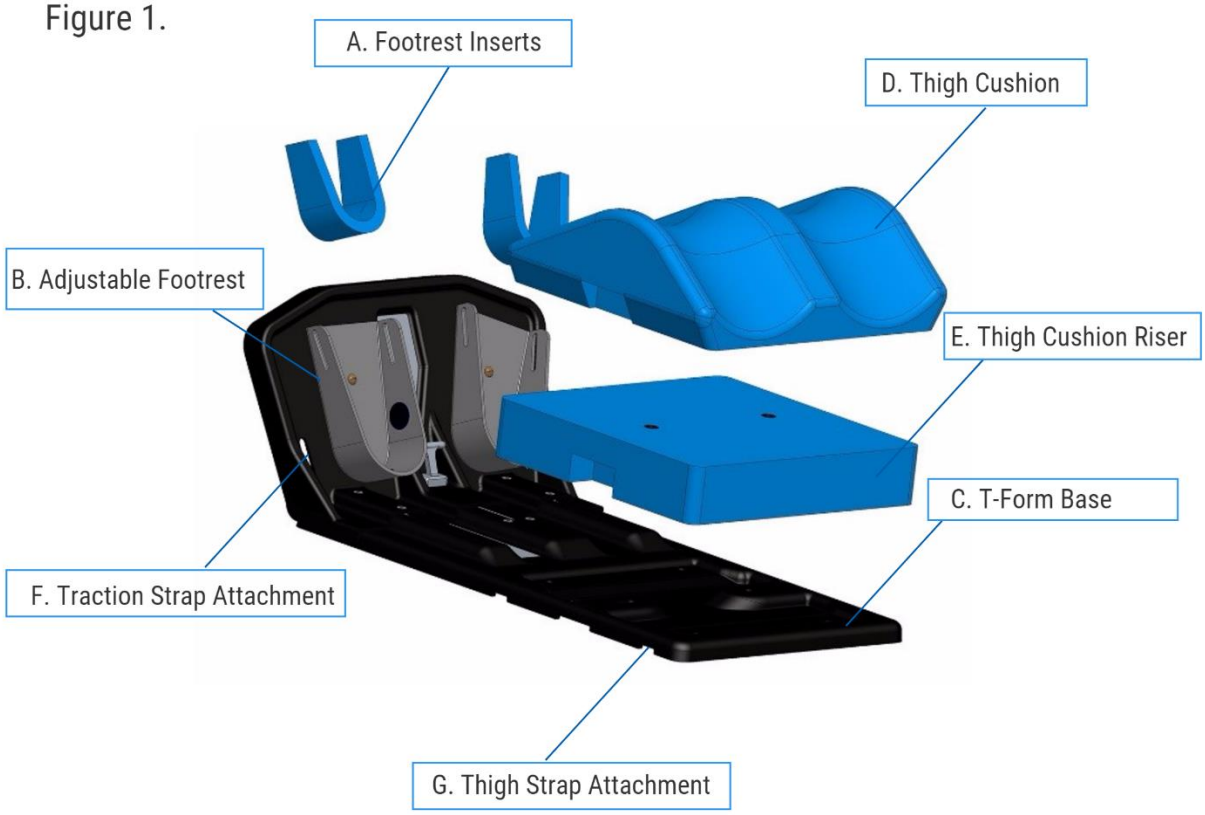
- Do NOT use the Comfort Hold Thigh and Foot Positioner if the package is damaged or open.
- Inspect the Comfort Hold Thigh and Foot Positioner before each use.
- Do NOT attempt to sterilize the Comfort Hold Thigh and Foot Positioner. Attempts to sterilize the Comfort Hold Thigh and Foot Positioner may result in product damage and / or patient injury.

CLEANING INSTRUCTIONS

Note: It is the user's responsibility to clean products according to hospital protocol / local regulations. Do not use alcohol-based cleaners on this product. Recommended cleaning procedures include:

1. Wipe thoroughly with water-based antiseptic cleaner or foam.
2. Allow to dry before next patient use.

Figure 1.



Note: Colors have been added to the illustration for clarity.

1. In order to begin using the Bionix Radiation Therapy Comfort Hold Thigh and Foot Positioner, you will need to have a SecureFit™ Bar (not shown/not included), which will need to be secured to the treatment couch.
2. Place the T-Form Base (C) onto the SecureFit Bar (not shown).
3. Continue by assembling the pad set as shown in Figure 1.
    a. Place the Thigh Cushion Riser (E) onto the T-Form Base (C). The Thigh Cushion Riser (E) is optiona for yse depending on the patient's size, comfort and optimum positioning.
    b. Place the Thigh Cushion (D) onto either the T-Form Base (C) or the Thigh Cusion Riser (E).
4. Slide the Adjustable Footrest (B) all the way out, and continue with positioning of the patient.
5. Posotion the patiet's knees first, then place the patients feet into the foot cups and secure with the foot straps (not shown). The Footrest Inserts (A) are optional for use when patients prefer not to wear their shoes during the procedure.

Figure 2.

6. Move the Adjustable Foot Rest (B) forward or backward by pulling straight up on the lock pin (I) (Figure 2), then moving the foot rest to the desired position. Then, place the lock pin down into the slot at the desired setting to lock in place (Figure 1).

Figure 3.

7. To adjust the angle of the foot (rotationalm straight or splayeD), loosen and adjust the screws on the back of the Adjustable Foot Rest (B)(Figure 1, adjust to the desired setting, then tighten (Figure 1).
8. Use the Traction Strap Attachment (F) to provide comfort and better immobilization for patients who require assistance in holding their arms down during treatment. (Optional).

9. Use the Thigh Strap Attachment (G) to provide comfort and better immobilization for patients who require assistance in holding their knees together during treatment. (Optional).

Label Symbol Glossary (Note: not all symbols may be applicable to this product)

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Symbol	Title of Symbol	Description of Symbol	Symbol Designation Number	Title of Symbol Standard

				Development Org. Standard
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1	ISO 15223-2012
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	5.1.2	ISO 15223-2012
	Date of manufacture	Indicates the date when the medical device was manufactured.	5.1.3	ISO 15223-2012
	Use-By Date	Indicates the date after which the medical device is not to be used.	5.1.4	ISO 15223-2012
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5	ISO 15223-2012
	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.	5.1.6	ISO 15223-2012
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	5.1.7	ISO 15223-2012
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	5.2.3	ISO 15223-2012
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4	ISO 15223-2012
	Do Not Resterilize	Indicates a medical device that is not to be resterilized.	5.2.6	ISO 15223-2012
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	5.2.7	ISO 15223-2012
	Do Not Use if Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8	ISO 15223-2012
	Biological Risks	Indicates that there are potential biological risks associated with the medical device.	5.4.1	ISO 15223-2012
	Do Not Reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2	ISO 15223-2012
	Consult Instructions For Use	Indicates the need for the user to consult the instructions for use.	5.4.3	ISO 15223-2012
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4	ISO 15223-2012
CE 0459	European Conformity	EC Declaration of Conformity by Notified Body	Annex XII	MDD 93/42/EEC:2007
CE	European Conformity	European Conformity	Annex XII	MDD 93/42/EEC:2007
℞ Only	By Prescription Only	Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.	N/A	FDA 81 Federal Register pg. 38911-38931

EC REP

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