T-Form Extremity Immobilization Device 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 T-Form Extremity Immobilization Device (HNRT-6060A) is a reusable 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 Bionix T-Form Extremity Immobilization Device is 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.

CONTRAINDICATIONS

No contraindications have been identified for the use of the T-Form Extremity Immobilization Device.

STORAGE

Store in a cool, dry environment.

ADVERSE REACTIONS

No adverse reactions have been identified for the use of the T-Form Extremity Immobilization Device.

WARNINGS

- Do NOT use if the package is damaged or open.
- Inspect the T-Form Extremity Immobilization Device before each use.
- Do NOT attempt to sterilize the T-Form Extremity Immobilization Device. Attempts to sterilize the T-Form Extremity Immobilization Device 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.

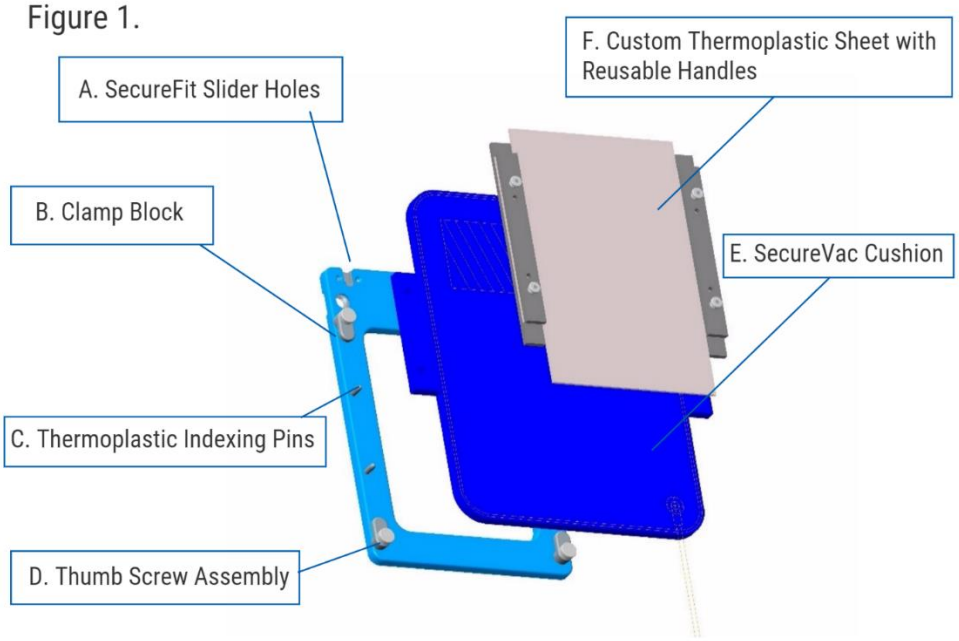
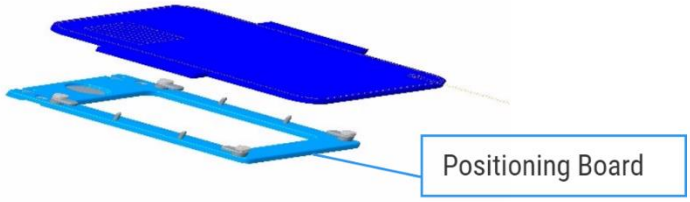


Figure 2.



1. Lock the T-Form Extremity Immobilizer onto the treatment table using the Bionix Radiation Therapy UTRT-5015 Slider (not included) using the desired SecureFit Slider Holes indicated in Figure 1.
2. Position the extremity using the SecureVac Cushion (E) as indicated in Figure 1. Be sure to have the end of the SecureVac Cushion (E) overhang the positioning board and the integrated indexing pins before evacuating in order to assist with locking the cushion in place (See Figure 2).
3. Loosen the Four Clamp Blocks (B) by turning the Thumb Screw Assemblies (D) counterclockwise.
4. Align the thermoplastic frame with the Indexing Pins (C) on the T-Form Extremity Immobilizer.
5. Position the Four Clamp Blocks (B) so the low melt thermoplastic sheet is held in place on the T-Form Extremity Immobilizer and tighten the Clamp Blocks (B) by tightening the Thumb Screw Assemblies (D) clockwise.
6. Form the low melt thermoplastic sheet to the patient's extremity. The low melt thermoplastic sheet can now be set onto the board.

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

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
	European Conformity	EC Declaration of Conformity by Notified Body	Annex XII	MDD 93/42/EEC:2007
	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

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