VersaBoard™ Ultra System 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 VersaBoard Ultra System (HNRT-7040-02) 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 VersaBoard Ultra System 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 VersaBoard Ultra System.

STORAGE

Store in a cool, dry environment.

ADVERSE REACTIONS

No adverse reactions have been identified for the use of the VersaBoard Ultra System.

WARNINGS

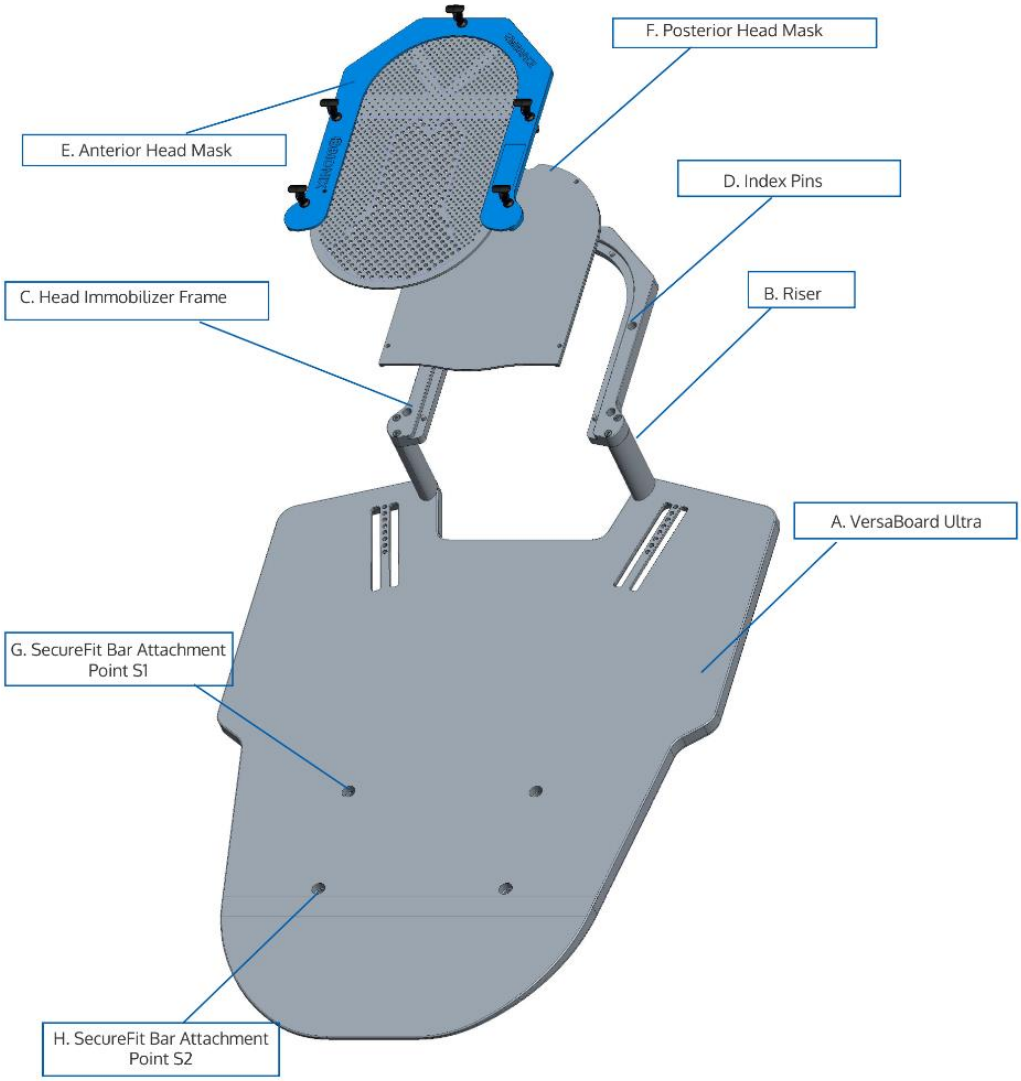
- Do NOT use if the package is damaged or open.
- Inspect the VersaBoard Ultra System before each use.
- Do NOT attempt to sterilize the VersaBoard Ultra System. Attempts to sterilize the VersaBoard Ultra System may result in product damage and / or patient injury.

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.



1. Position the Bionix VersaBoard Ultra System(A) on the treatment couch as desired using the Bionix Radiation Therapy SecureFit Bar. Bionix recommends using two bars (not shown) at preferred locations (G,H in Figure 2).
2. Position the VersaBoard Ultra at the line not to exceed the couch top. (See Figure 2 below).

Figure 2.

3. Place the patient on the VersaBoard Ultra and position them to determine head location. Allow the patient to sit up.
4. Warm the Posterior Head Mask (F) following manufacturer's instructions and position it on the Indexing Pins (D) in the Head Immobilizer Frame (C).
5. Make sure that the black frame for the posterior mask is facing down to facilitate a stronger bond when the posterior mask is attached.
6. Place the patient on the VersaBoard Ultra (A) to form the Posterior Mask (F). Form the mask to the patient by pinching and molding behind the neck and at the crown of the head.
7. Once the Posterior Mask (F) cools and is in place, warm the Anterior Mask (E) according to manufacturer's instructions.
8. Center the thermoplastic mask directly over the patient, draw the mask straight down towards the Index Pins (D), on the Head Immobilizer Frame (C).
9. Secure the mask to the Head Immobilizer Frame (C) with Index Pins (D).

Note: For patients with wider heads and short necks, be sure to

a) Have the patient slide all the way up so their shoulders slightly contact the risers of the VersaBoard Ultra and
b) Tuck their ears ino the frame.

Visit www.BionixRT.com for Warranty information

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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