The MAX3™ Plus Breast Board 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 MAX3™ Plus Breast Board (UTRT-7020) 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.

INDICATIONS

The MAX3™ Plus Breast Board is intended to immobilize a patient undergoing a course of external beam radiation therapy treatment.

CONTRAINDICATIONS

No contraindications have been identified for the use of The MAX3™ Plus Breast Board.

ADVERSE REACTIONS

No adverse reactions have been identified for the use of The MAX3™ Plus Breast Board.

STORAGE

Store in a cool, dry environment.

WARNINGS

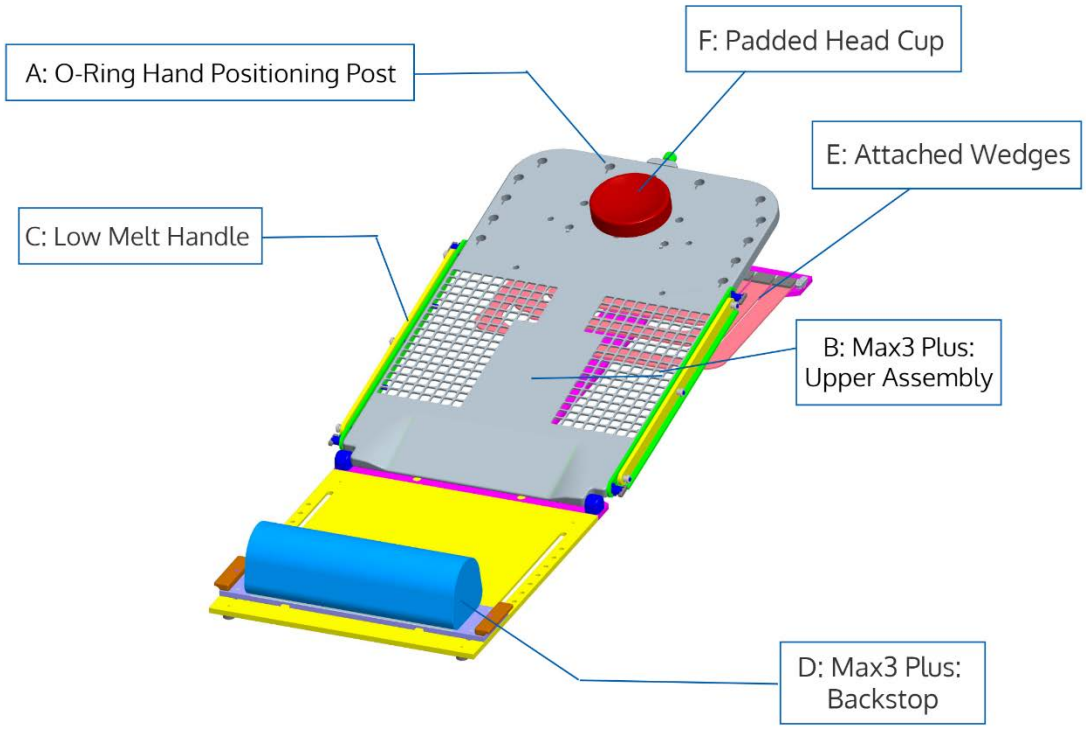
- DO NOT use if the package is damaged or open.
- Inspect the MAX3™ Plus Breast Board before each use.
- Do NOT attempt to sterilize the MAX3™ Plus Breast Board. Attempts to sterilize the MAX3™ Plus Breast Board may result in product damage and/or patient injury.

CLEANING INSTRUCTIONS

Note: It is the user's responsibility to clean products per 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.

INSTRUCTIONS



Note: The Silverman Head Cups must be punched to be used with the Locating Screws

1. Position the MAX3™ Plus Breast Board Upper Assembly (B) with backstop assembly on the treatment table (E) as shown in assembly diagram.

a. Note: The MAX3™ Plus Breast Board Upper Assembly (B) indexes on top of the Max3™ Plus Breast Board Backstop (D) to reduce movement.

b. Optional: Use the Bionix SecureFit Bar (F), UTRT-5010 or UTRT-7010 in Carbon Fiber.

2. Position Punched Silverman or Padded Head Cup (See holes labeled **1** through **9** in center of upper board) on the MAX3™ Plus Breast Board.

3. See the assembly diagram and "Figure 1", Position the attached wedges (G) of the MAX3™ Plus Breast Board to the desired angle, 7◦, 12◦, 17◦ or 23◦, pull the wedge release pin (I), lower the Upper Assembly (B) and Align the attached wedge into the "Wedge Slot".

4. Then press the Wedge Release Pin (I) in to secure the wedge in place.

Figure 1

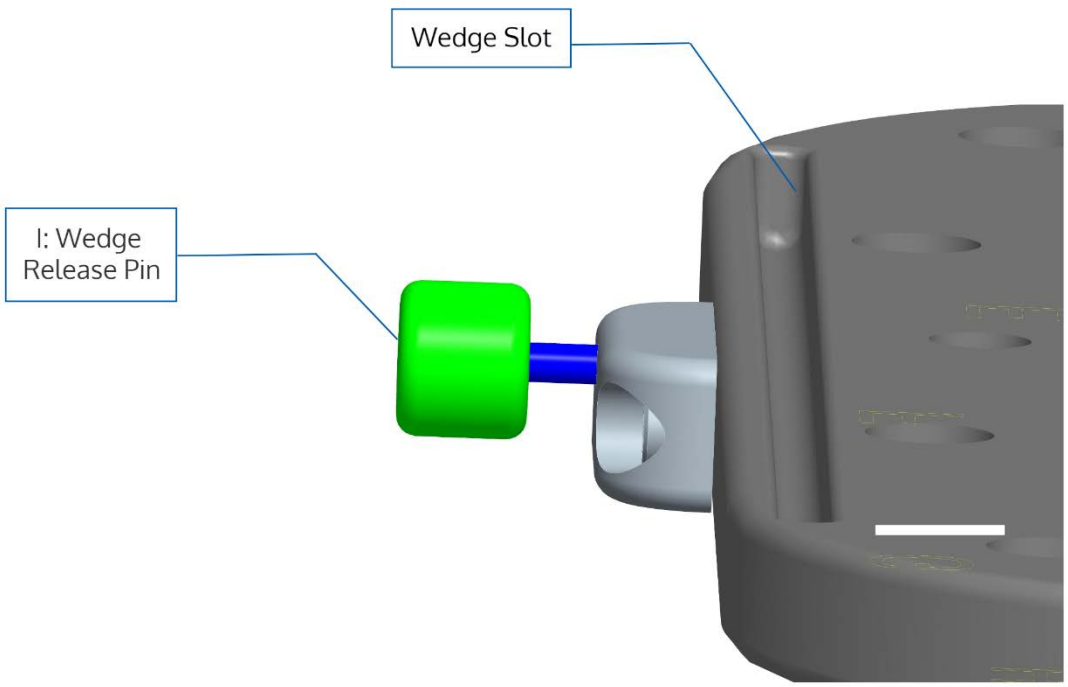


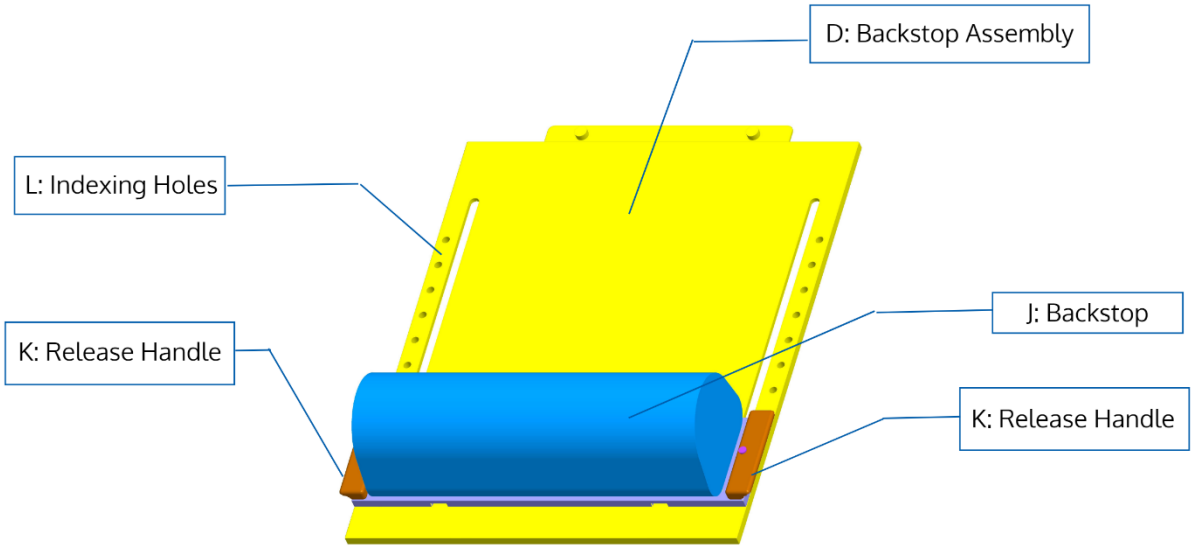
Figure 1- Wedge Release Close-up (from underside)

5. Move and Place O-ring hand positioning post (A) into the perimeter hole of your choice. These are labeled **A** through **H**.

6. Optional: The MAX3™ Plus Breast Board is designed to work with a variety of other Bionix Radiation Therapy products for added immobilization including, Butterfly Boards, SecureVac Bags, Disposable Low Melt Head Frames and Reusable Low Melt Handles. Contact customer service at 800.624.6649 for more details.

7. Move the Backstop Pad (J) to the desired position by lifting and holding the release handles, then move the backstop pad (J) to the desired indexing hole (L) and press the release handles down with a slight back and forth movement to lock the pad into place. **See Figure 2.**

Figure 2



Note: Refer to the instructions for the Hand post Assembly and Low Melt handle for further instruction on these products.

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	EC Declaration of Conformity by Manufacturer	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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