Carbon Fiber Butterfly 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 Carbon Fiber Butterfly Board (UTRT-7526) 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 Carbon Fiber Butterfly Board 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 Carbon Fiber Butterfly Board.

STORAGE

Store in a cool, dry environment.

ADVERSE REACTIONS

No adverse reactions have been identified for the use of the Carbon Fiber Butterfly Board.

WARNINGS

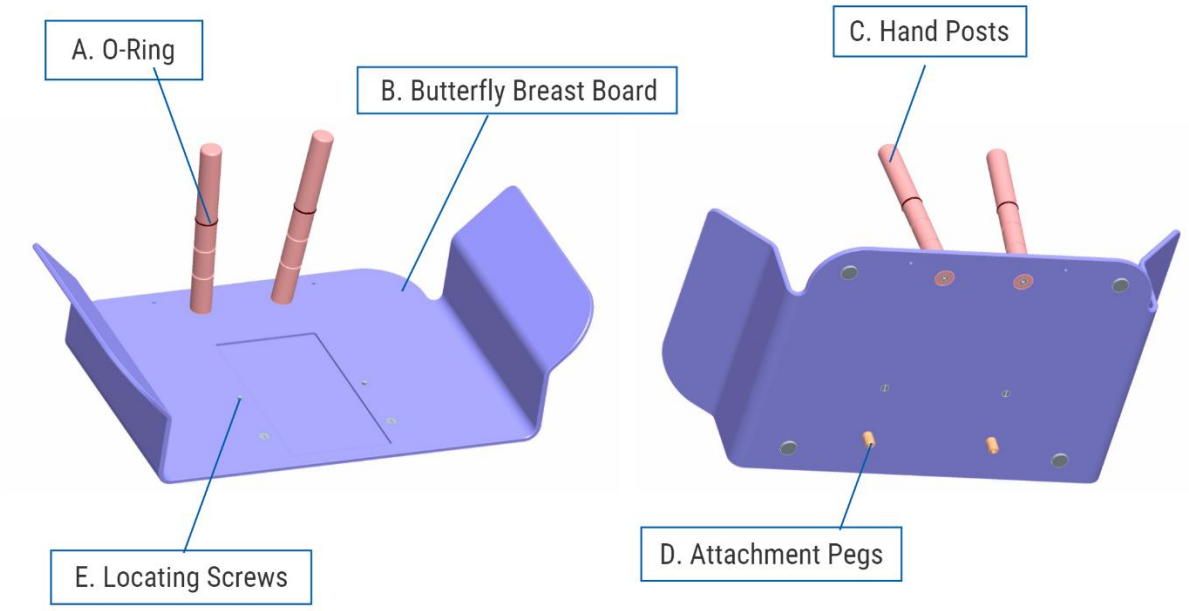
- Do NOT use the Carbon Fiber Butterfly Board if the package is damaged or open.
- Inspect the Carbon Fiber Butterfly Board.
- Do NOT attempt to sterilize the Carbon Fiber Butterfly Board. Attempts to sterilize the Carbon Fiber Butterfly Board may result in product damage and / or patient injury.

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.



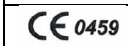
Note: Colors have been added to the illustration for clarity.

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

1. Position the Butterfly Breast Board (B) on the treatment table.
2. Position Punched Silverman hread cup on the Butterfly Board (D)
3. Position the patient on the Butterfly Board (D)
4. Move the O-Rings (A) on the hand posts to the desired position.
5. Optional: For attaching to a Bionix Breast Board: Remove the two Attachment Pegs (D) and place each peg into each of the larger holes located on the Butterfly Board (B). The Attachment Pegs (D) should be attached from the underside of the board (Figure 1). Secure the Attachment Pegs (D) to the Butterfly Breast Board (B). You can attached the Butterfly Breast Board (B) to any Bionix Breast Board.

Note: If you are using a SecureVac™ Cushion with the Narrow Extended Butterfly Board, first remove the two locating screws (located near the center of the Carbon Fiber Butterfly Board) so they do not puncture the SecureVac Cushion.

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
	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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