TruGuard™ Custom Tongue and Jaw 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 TruGuard Custom Tongue and Jaw Positioner (HNRT-3500 and HNRT-3501) 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 TruGuard Custom Tongue and Jaw 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 TruGuard Custom Tongue and Jaw Positioner.

MR SAFE

This product is MR safe.

STORAGE

Store in a cool, dry environment.

ADVERSE REACTIONS

No adverse reactions have been identified for the use of the TruGuard Custom Tongue and Jaw Positioner.

WARNINGS

- Do NOT use the TruGuard Custom Tongue and Jaw Positioner if the package is damaged or open.
- Inspect the TruGuard Custom Tongue and Jaw Positioner before each use.
- Do NOT attempt to sterilize TruGuard Custom Tongue and Jaw Positioner. Attempts to sterilize the TruGuard Custom Tongue and Jaw 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:

Instructions for TruGuard when used with a water bath:

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

Figure 1.

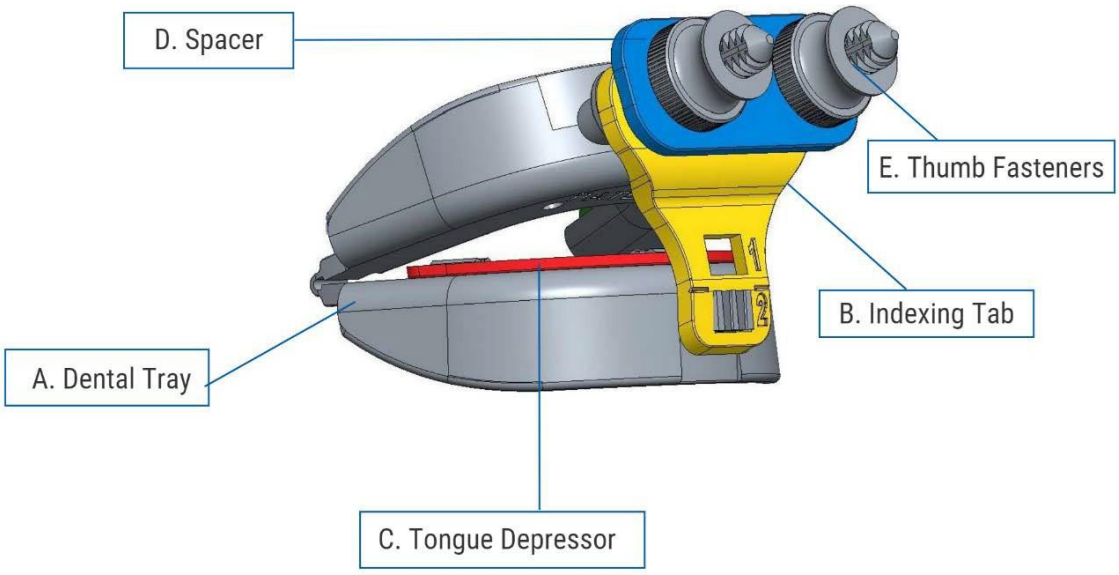


Figure 2.

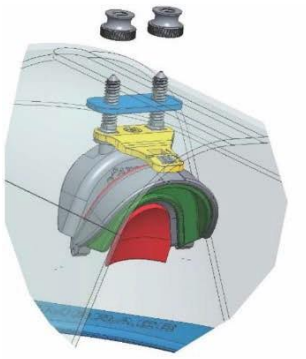
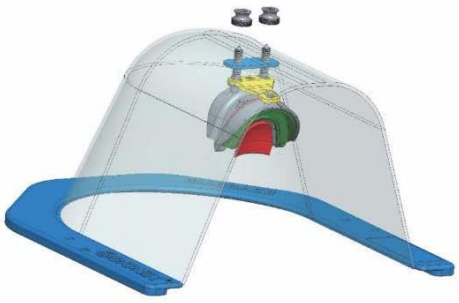


Figure 3.



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

1. If the Tongue Depressor (C) will be used, snap it on to the dental tray. Make sure it is securely fastened at the three snap locations.

2. Fold the Dental Tray (A)
3. Place the tray in hot water for 90 seconds (165 degrees F). Heat the water using a microwave, hot pot or equivalent.
4. Place heated dental tray into patient's mouth and instruct them to gently bite down for approximately two minutes until cool.
5. Once cooled, remove the patient's mouth.
6. Select the desired opening size and snap on the Indexing Tab (B) with the facing out. Cut off excess if applicable. Make sure the Indexing Tab is securely fastened at the three snap locations.
7. Place the Spacer (D) over the posts.
8. Prepare a thermoplastic mask and form it onto the patient with the TruGuard in place. Place the TruGuard by pushing the two posts through the mask and forming the mark around the spacer (Figure 2).
9. As the mask is cooling, fasten the two Thumb Fasteners (E) making sure the wide end is facing down.
10. Allow the mask to completely cool (Figure 3).
11. After treatment, remove the mask from the patient; it may be necessary to remove the mask from the patient; it may be necessary to remove the Thumb Fasteners from the posts and then remove the mask from the patient.

Instructions for TruGuard when used with a Bionix Radiation Therapy Dry Oven:

1. Turn on the power to the Dry Oven by using the main switch on the side.
2. Using the touch screen display, set the Dry Oven to 160°F (71°C).
3. Once the Dry Oven has been heated to the desired temperature, open the drawer and place the TruGuard onto the non-stick tray.
4. Close the drawer and use the touch screen display to set the timer to 6 minutes. Click the 'restart button' to start the timer. Allow the TruGuard to heat inside the oven for 6 minutes.
5. Retrieve the TruGuard, fold at the hinge and place in the subject's mouth.
6. Have the subject bite down gently, but with enough force to make an impression. Rinse the TruGuard in running water and let dry.

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
	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
	MR Safe	Indicates an item that poses no known hazards in all MR environments.	7.4.3.1 or 7.4.4.1	F2503-13

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