
























TruGuard™

Custom Tongue and Jaw Positioner

INSTRUCTIONS FOR USE (IFU)

SYMBOL GLOSSARY

(Note: All symbols may not be applicable to this product)

	Medical Device		Do Not Use if Package is Damaged
	Manufacturer		Do Not Reuse Single- Use Device
	Date of Manufacture		Single patient- multiple use
	Use-By Date		Consult Instructions For Use (IFU)
	Lot Code		Caution
	Reorder Number		Warning
	Serial Number		Authorized representative in the European Community
	Sterilized using irradiation		European Conformity
	Do not resterilize		Prescription Only or "For Use by or on the order of a licensed medical professional"
	Non-sterile		Temperature limitation
	Biological Risks		MR Safe
	European Conformity		

CAUTION

Federal (United States) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

Bionix TruGuard™ Custom Tongue and Jaw Positioner (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.

PRODUCT OFFERING

REF **HNRT-3501**: 5 TruGuard™ Custom Tongue and Jaw Positioners

INDICATIONS FOR USE

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.

INTENDED USE

TruGuard Custom Tongue and Jaw Positioner is an all-inclusive, non-sterile mouth guard used to position and protect sensitive oral tissues. TruGuard™ Custom Tongue and Jaw Positioner is to be used on a single patient, for the duration of treatment.

CONTRAINDICATIONS

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

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.



WARNING

- 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.

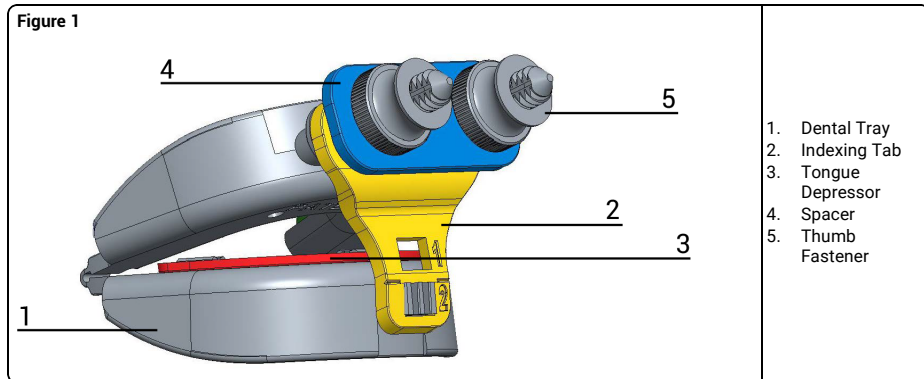
CLEANING INSTRUCTIONS

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.

1. Be sure to remember what position was used on the indexing tab.
2. To clean, use a non-alcohol based cleaner that is specifically formulated for cleaning either mouth guards or dentures.
3. Allow to dry prior to storage.

DISPOSAL INSTRUCTIONS

Dispose of properly in accordance with local regulations and standard or clinic procedures.

**INSTRUCTIONS FOR MOLDING TRUGUARD CUSTOM TONGUE AND JAW POSITIONER WHEN USING A WATER BATH:**

NOTE: Prior to forming, the patient should brush teeth and gums, then rinse mouth.

1. If the Tongue Depressor (3) 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 (1)
3. Place the tray in hot water for 90 seconds (165 degrees F). Heat the water using a microwave, hot pot or equivalent.

4. Select the desired opening size and snap on the Indexing Tab (2) with the indexing numbers facing out. Make sure the Indexing Tab is securely fastened at the three snap locations
5. Place the heated TruGuard Custom Tongue and Jaw Positioner into the patients mouth and instruct them to bite down gently, but with enough force to make an impression for approximately 2 minutes.
6. Once cooled, remove from the patient's mouth.
7. Follow cleaning instructions prior to storage.

INSTRUCTIONS FOR MOLDING TRUGUARD CUSTOM TONGUE AND JAW POSITIONER WHEN USED WITH A BIONIX RADIATION THERAPY DRY OVEN:

NOTE: Prior to forming, the patient should brush teeth and gums, then rinse mouth.

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. If the Tongue Depressor (3) will be used, snap it on to the dental tray. Make sure it is securely fastened at the three snap locations.
4. Once the Dry Oven has been heated to the desired temperature, open the drawer and place the TruGuard Custom Tongue and Jaw Positioner onto the non-stick tray.
5. 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 Custom Tongue and Jaw Positioner to heat inside the oven for 6 minutes.
6. Retrieve the TruGuard Custom Tongue and Jaw Positioner, fold at the hinge.
7. Select the desired opening size and snap on the Indexing Tab (2) with the indexing numbers facing out. Make sure the Indexing Tab is securely fastened at the three snap locations.
8. Place the heated TruGuard Custom Tongue and Jaw Positioner into the patients mouth and instruct them to bite down gently, but with enough force to make an impression for approximately 2 minutes.
9. Once cooled, remove from the patient's mouth.
10. Follow cleaning instructions prior to storage.

Figure 2

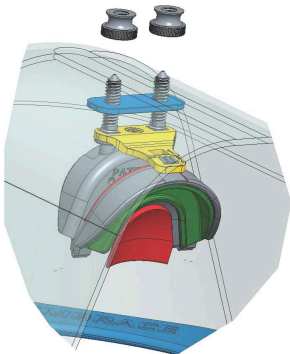
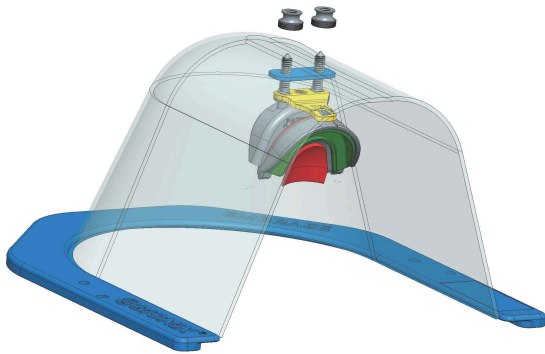


Figure 3



FORMING A THERMOPLASTIC MASK WITH THE MOLDED TRUGUARD CUSTOM TONGUE AND JAW POSITIONER:

1. Place the TruGuard Custom Tongue and Jaw Positioner in the patients mouth.
2. Place the Spacer (4) over the posts.
3. Prepare a thermoplastic mask and form it onto the patient with the TruGuard Custom Tongue and Jaw Positioner in place. Adhere the TruGuard Custom Tongue and Jaw Positioner to the mask by pushing the two posts through the mask and forming the mark around the spacer and posts (Figure 2).
4. As the mask is cooling, fasten the two Thumb Fasteners (E) making sure the wide end is facing down (Figure 3).
5. Allow the mask to completely cool.
6. After treatment, 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.
7. Follow cleaning instructions prior to storage.



Single Patient - Multiple Use



Rx ONLY

**MADE IN
THE USA**



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