



## **Embrace™ Thermoplastic Masks 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 Embrace™ Thermoplastic Masks are 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.

**Embrace Thermoplastic Masks are intended to be used by a single patient during the course of treatment.**

This IFU applies to all product codes found at: <http://www.bionixrt.com/head-and-neck/embrace-thermoplastic/>

### **INDICATIONS**

Embrace™ Thermoplastic Masks are a single patient use device intended to immobilize a patient undergoing a course of external beam radiation therapy treatment.

### **CONTRAINDICATIONS**

No contraindications have been identified for the use of Embrace™ Thermoplastic Masks.

### **STORAGE**

Store in a cool, dry environment.

### **ADVERSE REACTIONS**

There are no known adverse reactions related to the use Embrace Thermoplastic Masks.

### **WARNINGS**

- Embrace™ Thermoplastic Masks must be used prior to the Use By date shown on the product label.
- Do NOT use Embrace Thermoplastic Masks if the package is damaged or open.
- Do not remove mask until the material cools completely. Removing the thermoplastic too soon may result in excess shrinkage and patient discomfort when refitting.
- Inspect the Embrace Thermoplastic Mask for damage prior to each patient use.
- Do NOT attempt to sterilize the Embrace Thermoplastic Mask. Attempts to sterilize the mask 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. Recommended cleaning procedures include:

1. Do not use alcohol based cleaners on this product.
2. Wipe thoroughly with water based antiseptic cleaner or foam.
3. Allow to dry before next patient use.

## U-Frame, S-Type and VersaFrame Thermoplastic Masks

**Instructions for Embrace Thermoplastic Masks when used with Bionix Radiation Therapy Dry Oven. To operate and use safely, follow all operating instructions that are supplied with the Dry Oven (KLSP-1604).**

**\*Note: The Bionix Radiation Therapy Dry Oven may take up to 7 minutes to reach desired temperature.**



1. Turn on power to the Dry Heat Convection Oven by using the main switch on the side.
2. Using the touch screen display, set the oven to 160°F (71°C)
3. Carefully position patient on immobilization device.
4. Once the oven has been heated to the desired temperature, open the drawer and place the Embrace Thermoplastic to be heated onto the non-stick tray.
  - a. VersaFrames & S-Type Frames- Make sure the black Bionix pins are in the unlocked position (i.e. held loosely by the black housing but still captured in the frame) prior to putting them into the oven.
  - b. If using a Head & Shoulder style frame, place the frame into the oven with the shoulder portion in first, making sure the black pins are facing down.
5. Close the drawer and use the touch screen display to set the timer to 10 minutes. Click 'restart button' to start timer. Allow for the mask to heat inside the oven for 10 minutes.
6. Once the time has elapsed, retrieve the Embrace Thermoplastic Mask.
7. Before placing the thermoplastic mask on the patient, feel thermoplastic with hand to ensure the mask is not too hot.
8. Center the mask over the area of the patient that is to be immobilized and press the thermoplastic firmly downward until the Embrace Frame is flush with your immobilization device.
  - a. **U-Frames-** Secure into place by twisting the swivel clamps inward so that the end of the clamp is pointing toward the thermoplastic mask.
  - b. **VersaFrames & S-Type Frames-** Secure into place by pushing the black Bionix pins downward until you hear them click into place. To release the mask, pull the black Bionix pins upward to unlock.
9. Gently mold the thermoplastic mask with your fingers to capture the contours of the body.

10. As thermoplastic cools, it becomes rigid and returns to its original white color. Do not remove mask until the material cools completely (about 5-10 minutes). Removing the thermoplastic too soon may result in excess shrinkage and patient discomfort when refitting.

**Instructions for Embrace Thermoplastic Mask when used with Bionix Radiation Therapy Water Bath. To operate and use safely, follow instructions for use that were supplied with the water bath.**

1. Adjust water bath temperature to 160°F (71°C).
2. Carefully position patient on immobilization device.
3. Place thermoplastic mask in the 160°F (71°C) water until the thermoplastic turns completely transparent (approximately 90 seconds).
  - a. VersaFrames & S-Type Frames- Make sure the black Bionix pins are in the unlocked position (i.e. held loosely by the black housing but still captured in the frame) prior to putting them into the water bath.
4. Lift the Embrace™ Thermoplastic Mask from the water bath and quickly remove excess water by patting the mask with a towel. Before placing the thermoplastic on the patient, feel the thermoplastic with your hand to ensure the material is not too hot.
5. Center the mask over the area of the patient that is to be immobilized and press the thermoplastic firmly downward until the frame of the thermoplastic is flush with the chosen positioning device.
  - a. **U-Frames-** Secure into place by twisting the swivel clamps inward so that the end of the clamp is pointing toward the thermoplastic mask.
  - b. **VersaFrames & S-Type Frames-** Secure into place by pushing the black Bionix pins downward until you hear them click into place. To release the mask, pull the black Bionix pins upward to unlock.
6. Gently mold the thermoplastic mask with your fingers to capture the contours of the body.
7. As the thermoplastic mask cools, it becomes rigid and returns to its original white color. Do not remove the mask until the material cools completely (about 5-10 minutes). Removing the thermoplastic mask too soon may result in excess shrinkage and patient discomfort when refitting.

## Open Face Embrace Thermoplastic Masks

**Instructions for Open Face Embrace Thermoplastic Mask when used with Bionix Radiation Therapy Dry Oven. To operate and use safely, follow all operating instructions that were supplied with the Dry Oven (KLSP-1604).**

**\*Note: The Bionix Radiation Therapy Dry Oven may take up to 7 minutes to reach desired temperature.**

1. Turn on power to the Dry Heat Convection Oven by using the main switch on the side.
2. Using the touch screen display, set the oven to 160°F (71°C)
3. Carefully position patient on immobilization device.
4. Once the oven has been heated to the desired temperature, open the drawer and place the Embrace Thermoplastic mask to be heated onto the non-stick tray.

- a. VersaFrames & S-Type Frames- Make sure the black Bionix pins are in the unlocked position (i.e. held loosely by the black housing but still captured in the frame) prior to putting them into the oven.
  - b. If using a Head & Shoulder style frame, place the frame into the oven with the shoulder portion first, making sure the black pins are facing down.
5. Close the drawer and use the touch screen display to set the built in timer to 10 minutes and click 'restart button' to start timer and allow for the material to heat inside the oven for the entirety of the given time.
6. Once the time has elapsed, retrieve the thermoplastic mask.
7. Before placing the thermoplastic mask on the patient, feel thermoplastic with hand to ensure the material is not too hot.
8. Optimal performance is best achieved with two people. Center the mask over the area of the patient that is to be immobilized. The open area of the mask should be between the patient's brow line and the bottom of the nose. Use one hand to hold the mask in place at the forehead and another to secure it to the patient's chin. The other individual forming the mask should press the thermoplastic firmly downward until the frame of the thermoplastic is flush with the chosen positioning device.
  - a. U-Frames- Secure into place by twisting the swivel clamps inward so that the end of the clamp is pointing toward the thermoplastic mask.
  - b. VersaFrames & S-Type Frames- Secure into place by pushing the black Bionix pins downward until you hear them click into place. To release the mask, pull the black Bionix pins upward to unlock.
9. Gently mold the thermoplastic mask with your fingers to capture the contours of the body. Avoid any gaps surrounding the mask opening by gently applying pressure around the opening.
10. As thermoplastic mask cools, it becomes rigid and returns to its original white color. Do not remove mask until the material cools completely (about 5-10 minutes). Removing the thermoplastic mask too soon may result in excess shrinkage and patient discomfort when refitting.

**Instructions with Embrace Thermoplastic Mask when used with Bionix Radiation Therapy Water Bath. To operate and use safely, follow instructions for use that are supplied with the water bath.**

1. Adjust water bath temperature to 160°F. (71°C.).
2. Carefully position patient on immobilization device.
3. Place thermoplastic mask in the 160°F (71°C) water until thermoplastic turns completely transparent (approximately 90 seconds).
  - a. VersaFrames & S-Type Frames- Make sure the black Bionix pins are in the unlocked position (i.e. held loosely by the black housing but still captured in the frame) prior to putting them into the water bath.
4. Lift Embrace™ Thermoplastic mask from water bath and quickly remove excess water by patting the mask with a towel. Before placing the thermoplastic mask on the patient, feel thermoplastic with hand to ensure the material is not too hot.
5. Optimal performance is best achieved with two people. Center the mask over the area of the patient that is to be immobilized. The open area of the mask should be between the patient's brow line and the bottom of the nose. Use one hand to hold the mask in place at the forehead and another to secure it to the patient's chin. The other individual forming the mask should

press the thermoplastic firmly downward until the frame of the thermoplastic is flush with the chosen positioning device.

- a. U-Frames- Secure into place by twisting the swivel clamps inward so that the end of the clamp is pointing toward the thermoplastic mask.
  - b. VersaFrames & S-Type Frames- Secure into place by pushing the black Bionix pins downward until you hear them click into place. To release the mask, pull the black Bionix pins upward to unlock.
6. Gently mold the thermoplastic mask with your fingers to capture the contours of the patient's anatomy. Avoid any gaps surrounding the mask opening by gently applying pressure around the opening.
  7. As thermoplastic mask cools, it becomes rigid and returns to its original white color. Do not remove mask until the material cools completely (about 5-10 minutes). Removing the thermoplastic mask too soon may result in excess shrinkage and patient discomfort when refitting.

## DISPOSAL INSTRUCTIONS

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

Visit [www.BionixRT.com](http://www.BionixRT.com). for Warranty information



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**Label Symbol Glossary (Note: not all symbols may be applicable to this product)**

<b>Symbol</b>	<b>Title of Symbol</b>	<b>Description of Symbol</b>	<b>Symbol Designation Number</b>	<b>Title of Symbol Standard Org. Standard</b>
	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