# RadTec Medical Devices Inc.

# Lollipop BiteBlocks Instructions for Use

Caution: Federal Law restricts this device to sale by or on the order of

a licensed Physician or Radiation Therapist

**If any questions arise contact RadTec Medical Devices**

**immediately at 1(844)Rad-Tec1 or email**

**Support@RadTecMD.com**

**DEVICE DESCRIPTION**

RadTec's Lollipop Bite Blocks (REF. "Lollipop BiteBlock Catalogue") are multi-configuration, single patient reusable devices intended to be used for the planning, positioning and re-positioning of a patient's oral cavity, undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

**INDICATIONS**

The Lollipop BiteBlock from RadTec Medical Devices Inc. is intended to be used for repeat positioning and immobilization of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

It is intended to be used by or under the direction of a licensed physician.

**CONTRAINDICATIONS**

No contraindications have been identified for the use of the RadTec Lollipop BiteBlocks.

MR SAFE

The Lollipop BiteBlocks are MR Safe (i.e., an item that poses no known hazards in all MR environments) because it is made from nonmetallic and nonconducting material.

**STORAGE**

Store in cool dry area. Do not expose to excessive heat or UV light.

ADVERSE REACTIONS

No adverse reactions have been identified for the use of the RadTec Lollipop BiteBlocks.

**WARNINGS**

- Do NOT use the Lollipop Bite Block if the package is damaged or open.
- Inspect the Bite Block before each use. If damaged, discontinue use
- Each device is solely intended to be used by one patient for the duration of treatment. Following use, discard the device following all local and state regulations.

**INSTRUCTIONS FOR DEPLOYMENT OF LOLLIPOP BITEBLOCKS**

Inspect for cracks or other defects. If defects are found, discontinue use.

**1.** If desired, the device may be sterilized prior to use. See validated sterilization parameters below.
**2.** Once inspected, place the device in the subject's mouth, fitting both upper and lower teeth into the appropriate positions.
**3.** Make sure the tongue is positioned, as needed, and inspect fitment.
**4.** If needed, prepare a thermoplastic mask and form it onto the patient with the Lollipop BiteBlock in place. Fitment of the positioning mask should leave enough room without putting pressure on the handle.
**5.** Have the patient verify that the position is comfortable, and they can maintain this position during treatment.
**6.** Once treatment session is complete, remove mask and bite block

Tips for ease of use:
- Instruct the patient to breathe through their nose, not mouth.
- Instruct the patient to minimize swallowing with Lollipop BiteBlock in place (suction may be applied if available).

**STERILIZATION INSTRUCTIONS**

**Sterilization:**

The Lollipop Biteblocks are supplied non-sterile and may be sterilized prior to use. The recommended sterilization method and parameters are listed in the table below. The device should be packaged in FDA-cleared pouch or wrap designed for autoclaving at the selected cycle and designed to maintain sterility after processing. The recommended sterilization method and parameters are listed in the table below.

| [illegible] | [illegible] | [illegible] | [illegible] |
|---|---|---|---|
| [illegible] | [illegible] | [illegible] | [illegible] |

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|---|---|---|---|
|  | Do Not Reuse | Indicates a medical device that is intended for use on a single patient. | xxxxxxxxx |
|   | Non-sterile | Indicates a medical device that has not been subjected to a sterilization process. | xxxxxxxxx |
|  | Do Not Use If Package is Damaged | Indicates a medical device that should not be used if the package has been damaged or opened | xxxxxxxxx |
|  | Biological Risks | Indicates that there are potential biological risks associated with the medical device. | xxxxxxxxx |
|  | Keep away from sunlight | Indicates product should be kept out of sunlight. | xxxxxxxxx |
|  | Fragile | Fragile, handle with care. | xxxxxxxxx |
|  | Keep Dry | Indicates the product should be kept dry. | xxxxxxxxx |
|   | MR Safe | Indicates the product safe to be in an MR env. | |