

Klarity BiteLok®



INSTRUCTIONS FOR USE

GENERAL INFORMATION

The Klarity BiteLok® is a one-per-patient medical device used with a thermoplastic mask as an aid for positioning the teeth and tongue for radiation therapy treatment.

PRODUCT DESCRIPTION

The Klarity BiteLok is an innovative design for simple positioning of the teeth and tongue. The BiteLok and its optional attachments can be easily removed from the mask for cleaning. The general size of the BiteLok allows it to fit various mouth sizes and offers an open airway for optimal patient comfort. The BiteLok is custom molded to the patient's dental anatomy as well as the thermoplastic mask, allowing for accurate reproducibility.

MAINTENANCE AND DISPOSAL

The Klarity BiteLok must be stored in a dry, clean place at temperatures between 50°F (10°C) and 95°F (35°C) and can be disposed of with normal facility waste.

PARTS INCLUDED

Klarity BiteLok®	Components
	BiteLok™ Mouthpiece
	Two-Part Dental Putty
	QuickFit™ Tool
	Long and Short Tongue Depressors
	Right and Left Tongue Diverters
	Tongue Device Removal Tool
	BiteLok™ Quick Instruction Card

INSTRUCTIONS

Determine Placement of the BiteLok:

1. Place the BiteLok mouthpiece in the patient's mouth. **The mouthpiece alone is not directional until putty has been formed by the patient's dental impression.*
2. If using one of the optional tongue depressors or diverters, insert the device into the BiteLok and test for desired length and placement. **The depressors and diverters are directional and are marked to show which side goes "up" or "down".*



Tongue Depressor inserting into the BiteLok™

**patent pending*

To be used by a qualified medical professional
IFU-A-011



EC REP

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Mixing and Forming the Putty:

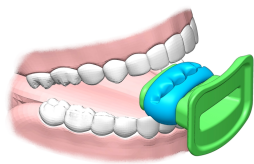
3. Before mixing the putty, you have the option to remove the tongue depressor or diverter from the BiteLok using the included tongue device removal tool. *This will allow a better impression of the teeth into the putty. If you choose to leave the tongue accessory intact, please be aware that the patient could cause the device to wiggle with their tongue, which could affect the impression in the putty made by the teeth.
4. Tear or cut the putty pouch and squeeze out the contents of both packets. Mix the two-part putty together thoroughly for 15-20 seconds. Roll the putty into a two-inch long cylinder. Pinch off a small amount of putty and set it aside (about 0.5cm) (See step 8).
5. Wrap the entire cylinder of putty around the “BITE” area of the BiteLok mouthpiece. Press the putty gently, but firmly, around the “Bite” area to ensure it will fill the bite region indentations.



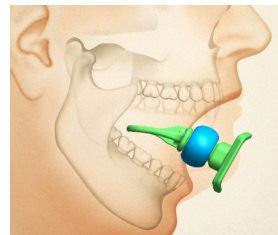
Putty wrapping around BITE region of BiteLok™ (shown with short tongue depressor)

Making the Impression:

6. While the putty is still soft, have patient gently bite into the putty until it hardens (about 2 minutes).
7. Instruct the patient to bite down with a “natural” bite, which will help relieve jaw fatigue during treatment.
8. Periodically check the 0.5cm piece you set aside earlier for firmness. This will help determine when the putty has fully set up.
9. Once the putty has set, verify that the hardened putty is fully secured to the BiteLok mouthpiece.
*If putty starts to harden before the impression was made, the putty may not fully secure to the mouthpiece.
10. If an optional tongue depressor or diverter is being used, insert it back into the BiteLok before making the mask and double check the attachment to ensure it is facing the correct direction.
11. Re-insert the BiteLok into the patient’s mouth.



BiteLok™ indexed to teeth



BiteLok™ with Tongue Depressor

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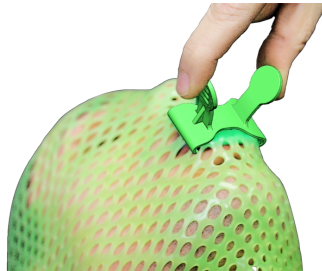
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Forming the Mask over the BiteLok:

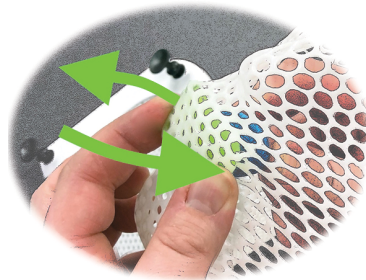
- 12. Form the mask according to the manufacturer’s instructions, placing the mask over the BiteLok.
- 13. While the mask is still warm, the QuickFit tool can be used for hands free indexing. Pinch the two QuickFit tool handles together, place the QuickFix™ tool over the BiteLok, and release. The QuickFit Tool will secure the mask over the BiteLok. Allow mask to fully cool.
- 14. Keep the QuickFit tool, mask, and BiteLok attached together as you remove the mask from the patient. It is recommended to leave the BiteLok indexed within the mask with the QuickFit tool attached for 12 hours. This will allow the mask to finish shrinking around the BiteLok for better re-indexing.
- 15. After 12 hours have passed, remove the QuickFit tool from the mask by pinching the two handles together and detaching from the mask. The BiteLok will remain indexed within the mask until removed



QuickFit™ Tool on top of mask

Removing the BiteLok from the Mask:

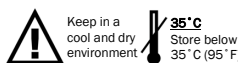
- 16. The BiteLok can be removed from the mask for easy cleaning. Once the mask is fully cured, hold onto the BiteLok with one hand. With your other hand, press on the outside of the mask at the corner of the BiteLok and push the BiteLok in on one side. This will allow the BiteLok to release from the mask. *Take care not to hold it by the putty or tongue depressor/diverter



Removing BiteLok

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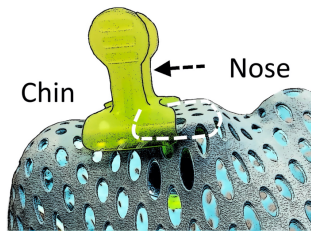


Cleaning the BiteLok:

- 17. Once removed from the mask, the BiteLok can be rinsed with water and cleaned with an antiseptic product such as mouthwash. Once clean, press the BiteLok back into the mask.

Extra Strong Thermoplastics and the Klarity BiteLok:

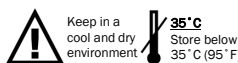
- 18. Form the upper mask according to the manufacturer's instructions, placing the mask over the BiteLok.
- 19. When using a strong thermoplastic mask, there are 2 options for using the QuickFit tool.
 - a. Option 1 - While the mask is still warm, pinch the two QuickFit tool handles together, place the QuickFit tool over the BiteLok and release. Allow mask to fully cool. *Please note: When using the BiteLok with stronger thermoplastic masks, take extra care when removing the mask. You may not be able to remove the BiteLok from the mask.*
 - b. Option 2 - While the mask is still warm, pinch the two handles together and align the QuickFit tool with the lower part of the BiteLok mouthpiece, toward the chin. You will only lock in the bottom half of the BiteLok. This will still allow you to re-index the BiteLok to the mask, while still being able to remove it for cleaning.



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Keep in a cool and dry environment
35°C Store below 35°C (95°F)



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