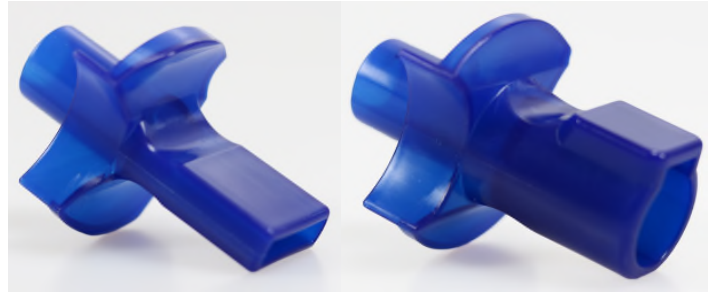


BITEFIX – BITE BLOCK WITH OR WITHOUT TONGUE DEPRESSOR



Article Nos. : 32788 & 32789

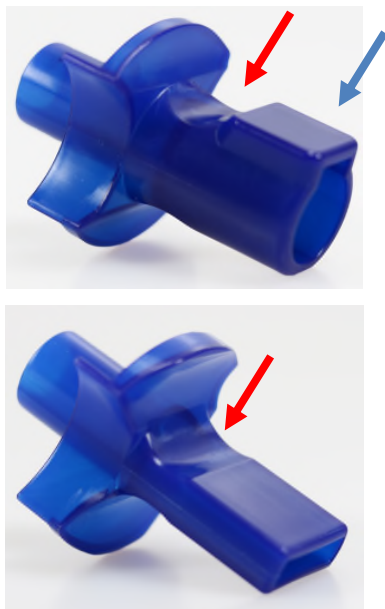
A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices, used for patient positioning and immobilisation in radiation therapy. The product can be used during both the simulation and the treatment stage, including MRI simulation.

To attain an optimal result, it is recommended to use this product in combination with Orfit immobilisation products.

B. PRODUCT DESCRIPTION

The BiteFix bite block is available in a version with (32789; figure 1) and without (32788; figure 2) tongue depressor.



The bite block without tongue depressor has a flat shape and the bite block with tongue depressor has a round shape containing a small block that is pushing down the tongue, away from the treatment field.

Each Efficast® thermoplastic mask can be moulded over the bite block. Both bite blocks have an airway opening that protrudes a hole in the mask for easy patient breathing. The outer contours of the bite blocks are visible in the mask making it a reproducible solution for increased patient immobilisation during head & neck treatments.

C. HOW TO USE

C.1. 32788 – BiteFix – Bite block without tongue depressor

1. Clean the bite block thoroughly (ref. paragraph F).
2. Position the bite block inside the patient's mouth so that the patient's teeth are positioned on the provided groove (figure 2; red arrow). The bite block is symmetric and can be used in either way (figure 3).



Figure 3

3. Mould the mask over the part of the bite block that protrudes from the patient's mouth. Make sure that the airway opening is protruding a hole in the mask (figure 4). If the mask doesn't contain a pre-punched hole, a hole can be cut at the desired position using a pair of scissors. Mould the mask on the nose bridge and below the

4. chin. Do not touch the bite block or other parts of the face (figure 5).



Figure 4

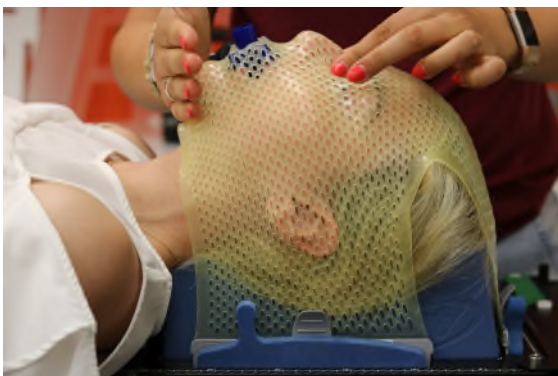


Figure 5

5. Leave the mask on the patient for at least 15 minutes to allow it to harden completely.
6. Remove the mask and the bite block from the patient. The bite block can be removed from the mask and stored in the provided plastic container.

Detailed instructions on how to mould the masks can be found in the respective instructions for use and on www.orfit.com.

C.2. 32789 – BiteFix – Bite block with tongue depressor

1. Clean the bite block thoroughly (ref. paragraph F.).
2. Position the bite block inside the patient's mouth so that the patient's teeth are positioned on the provided groove (figure 1; red arrow). The flat part (figure 1; blue arrow) of the bite block should face downwards (figure 6). Make sure that the patient's tongue is positioned below this flat part and doesn't fold backwards.



Figure 6

3. Mould the mask over the part of the bite block that protrudes from the patient's mouth. Make sure that the airway is protruding a hole in the mask (figure 4). If the mask doesn't contain a pre-punched hole, a hole can be cut at the desired position using a pair of scissors. Mould the mask on the nose bridge and below the chin. Do not touch the bite block or other parts of the face (figure 5).
4. Leave the mask on the patient for at least 15 minutes to allow it to harden completely.
5. Remove the mask and the bite block from the patient. The bite block can be removed from the mask and stored in the provided plastic container.

Detailed instructions on how to mould the masks can be found in the respective instructions for use and on www.orfit.com.

D. PRECAUTIONS FOR USE

- This product is intended for single patient use.
- Clean the bite block with water before and after each use.
- Do not sterilise the bite blocks.
- Do not use the product if it shows cracks, chipping or discoloration, or when the surface is brittle. This can prevent effective cleaning.
- Do not use when damaged. This could lead to ingestion of fragments.
- Verify that the bite block is correctly positioned in the patient's mouth before moulding or refitting the mask.
- Make sure that the tongue is positioned below the flat part of the bite block with tongue depressor.
- Leave the mask hardening on the patient for at least 15 minutes to prevent

pressure on the front teeth during treatment. Use a timer to check the hardening time.

- Write down the identification of the patient on the bite block storage container.

E. PROPERTIES

E.1. Physical properties 32788 & 32789

Dimensions: L 62 mm x W 35 mm x H 40 mm

Weight : +/- 15g

E.2. Material properties 32788 & 32789

Density: 0,9 g/cm³



These products are made entirely of electrically non-conductive, non-metallic and non-magnetic materials and are MRI safe.

F. MAINTENANCE AND WASTE MANAGEMENT

This product can be cleaned and disinfected by means of water and disposable wipes with alcoholic disinfectant, in case of re-usage for the same patient. The material is resistant to alcohols, esters, organic acids and ketones. **Never use chlorine-based or abrasive agents.** If unsure about the cleaning fluid, do not use. The bite blocks cannot be sterilised.

The product can be disposed of with household waste.

G. ADDITIONAL INFORMATION

For additional information such as distributor contact information, product brochures, Safety Data Sheets and regulatory information, please visit our website www.orfit.com.

Note:

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Ref. No. 50203
VERSION 5
LAST UPDATE: 14/02/2024
REVISION DATE: 14/02/2026