

Instructions for Use



Bite Fork

Indications for use:

The Oventus Bite Fork ("Bite Fork") is a single use disposable device that is intended to be used in a clinical setting to record a 5mm vertical bite registration for suitable O2Vent® oral appliance therapy.



Digital Workflow to Record Bite Registration

Step 1 Bite registration material is not required. Select the most appropriate Bite Fork for the patient's arch size.

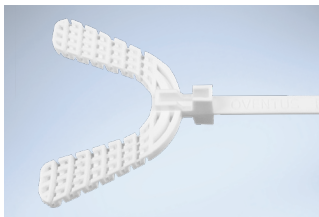
Step 2 Scan the patient's upper and lower arches up to 3mm above the gumline.

If using a **Double Sided** bite fork for edge to edge bite registration, place the Bite Fork in the patient's mouth and scan the bite position with the Bite Fork in place.

If using a **Single Sided** bite fork, insert it into a suitable bite measurement tool and record the ideal protrusive jaw position. Once the bite position has been recorded, scan the patient's upper and lower arches with the Bite Fork in place.

Step 3 Ensure scan files (upper arch, lower arch, oral bite) are all included and saved in STL format.

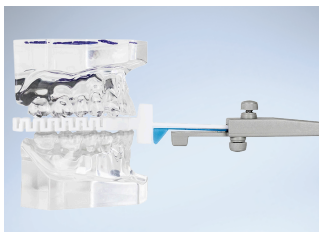
Step 4 Upload the files via the DDX.com device ordering page.



If using a Double Sided bite fork, scan the bite position with the Bite Fork in place.



If using a Single Sided bite fork, record the patient's ideal protrusive jaw position.



Once the bite position is recorded, scan the patient's upper and lower arches with the Bite Fork in place.

Bite Fork Variants

Bite Forks are available in two variants to record bite registrations with 5mm vertical clearance in the following ways:

1. **Double sided** – to be used to record an edge to edge bite registration.
2. **Single sided** – to record bite registration using a suitable bite measurement tool that will allow incremental and reversible advancement of the patient's mandible anteriorly, with respect to the maxilla.

Contraindications

- > Do not use when patient has a current or pre-existing oral condition likely to be aggravated by use of the Bite Fork.

Bite Fork Variants that can be ordered		Multipack Includes one each of the following Bite Fork arch sizes:		Pack of 5 Includes five of either of the following Bite Fork arch sizes:	
Arch Size	Type	Qty	Product Code	Qty	Product Code
M (Medium)	Double Sided	x 1	BFMP4	x 5	BFDM5
	Single Sided	x 1		x 5	BFSM5
L (Large)	Double Sided	x 1		x 5	BFDL5
	Single Sided	x 1		x 5	BFSL5

Instructions for Bite Fork Measurements

Select the appropriate type and arch size Bite Fork for recording the patient's bite registration. The Bite Fork should fit comfortably to the size of the upper and lower teeth.

Taking a Physical Bite Registration

Double Sided bite fork (for edge to edge bite registration)

Step 1 Attach PVS (polyvinyl siloxane) or suitable firm bite registration material on the upper and lower parts of the Bite Fork's occlusal surfaces.

Step 2 Immediately place the loaded Bite Fork in the patient's mouth, centering the handle under the patient's nose. Ask the patient to close their mouth around the impression material on the bite fork and bite down firmly. The Bite Fork should remain in place according to the manufacturer's recommended setting time for the impression material.

Step 3 Once the impression is complete, remove the Bite Fork from the patient's mouth.



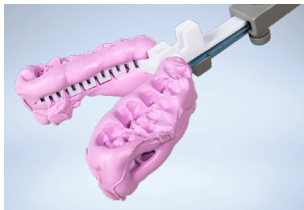
Step 4 Record the patient's facial midline in relation to their dental midline on the impression, using a permanent marker. This enables the centering of the O2Vent Optima® device's airway inlet to the patient's facial midline.



Single Sided bite fork (to be used in conjunction with a suitable measurement tool)

Step 1 Insert the Bite Fork into a suitable bite measurement tool.

Step 2 Follow the bite measurement tool's instructions to record the patient's ideal protrusive jaw position. The bite record is used by Open Airway Dental Solutions to set the level of protrusion and titration range of any Open Airway Dental Solutions oral device.



Step 3 Once the protrusive bite is recorded, follow steps one to four of the Double Sided bite fork instructions for recording edge to edge bite registration.

Upon Completion of Record Taking

Place your device order online via the DDX.com ordering site, including any additional specific clinical notes or requests in the comments section. Print the order form confirmation, decontaminate the records and package together. Place in protective packaging and ship to Open Airway Dental Solutions using the address provided.



MANUFACTURER AND AUSTRALIAN SPONSOR:

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UK/EU

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2 Bulgaria Street 2850 Petrich, Bulgaria



Precautions

- > May not be suitable for patients with a cross bite.
- > Do not use the Bite Fork in any way other than as instructed.



Do not re-use.
For single use only.

