



# EzBite

## Oral Rehabilitation Device

ISO 13485 ISO 10993

### + Background

Head-and-Neck cancers (HNC) account for approximately 4% of all cancers in the United States (Ref: National Cancer Institute), and is the seventh most common cancer worldwide, that contributes to approximately 300,000 new cases per year in Asia Pacific Region. (Ref: Dr Makoto Tahara, chief, Department of Head and Neck Medical Oncology, National Cancer Centre Hospital East, Chiba, Japan).

Surgery, radiotherapy and chemotherapy are common therapeutic modalities used in HNC treatment which can lead to salivary dysfunction, oral many side effects such as mucositis, soft tissue fibrosis and trismus. Rehabilitation with mouth-opening exercise is mandatory for oral cleaning and speed recovery. The result of traditional methods by self-exercise or use of tongue depressors is unsatisfactory. EzBite Oral Rehabilitation Device is easy to use and portable, with only 78g, it can be easily stowed away and carried around by patients. It can improve jaw function, support oral cleaning, and alleviate post-surgical and post-radiation trismus, thus progress into a better quality of life.

### + Patents

EzBite Oral Rehabilitation Device is protected by Taiwan patent NO. M538380 and M543050, as well as by other patents pending worldwide.

### Please Note

Talk to your physician to develop rehabilitation plan for carrying out effective tracking of prognosis assessment.

We recommend EzBite Oral Rehabilitation Device is to be used under the guidance of a medical professional.

### + Benefits

- Easy to Use, Easy to Clean
- Durable, Lightweight and Easy to Carry
- Suitable for Progressive Mouth Opening Exercises
- Excellent Support for Oral Care
- Strengthen the Jaw Stretching and Swallowing Exercises
- Easy to Track with On Device Scale Display
- Assist Physician to Develop and Track Rehabilitation Program



### Award Winning

2016 Taipei International Invention Contest Gold medal.



## Product Detail



### Adjustment Knob Design

Supports Step by Step Passive Motion Rehabilitation



### Range Scale Display

5mm Interval Range-of-Motion Display for Ease of Track. Maximum Mouth-Opening to 70mm.



### Safety Limit Switch

Safety Control to Prevent Overstretching



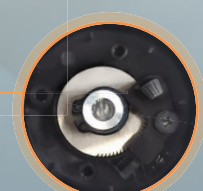
### None-Slip Design

Prevents In-Mouth Sliding



### Precision Sheet Metal Design

Strengthens In-Mouth Support



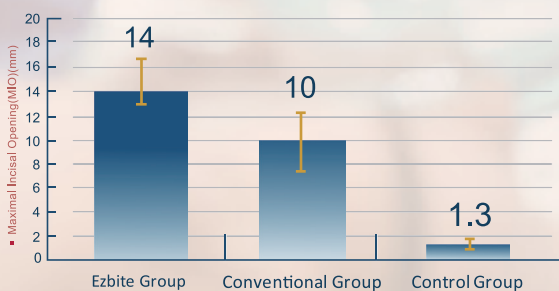
## + Clinical Study

The road to recovery with HNC can be complicated but is achievable with multidisciplinary rehabilitation. Ezbite Oral Rehabilitation Device plays an important role in HNC management for the patients. The device is clinically proven as more effective than traditional rehabilitation method, is proven to improve mouth-opening and trismus issue. Commitment to proper rehabilitation program at the earliest stage of post-surgery and post-radiotherapy with one effective tool will lead to a more successful recovery.

### Characteristics of the EzBite, conventional, and control group

	EzBite intervention Group n=20 Mean (range)	Conventional exercise Group n=20 Mean (range)	Control Group n=20 Mean (range)	p-value
<b>*Age mean(range)</b>	56.4(37-75)	54.2(30-67)	55.8(30-72)	ns
<b>*Gender</b>	n(%)	n(%)		
- Male	13(65)	12(60)	16(80)	
- Female	7(35)	8(40)	4(20)	
<b>*Treatment regimens</b>				ns
- Surgery only	7(35)	3(15)	6(30)	
- Radiochemotherapy	6(30)	7(35)	7(35)	
- Radiotherapy + surgery	7(35)	10(50)	7(35)	
<b>*Tumor location</b>				ns
- Buccal	6(30)	4(20.0)	5(25)	
- Lip	6(30)	6(30)	6(30)	
- Gingiva	5(25)	4(30)	5(25)	
- Retromolar area	3(15)	4(20)	4(20)	
<b>*Tumor staging</b>				ns
- I	4(20)	4(20)	5(25)	
- II	4(20)	4(20)	6(30)	
- III	6(30)	4(20)	6(30)	
- IV	6(30)	8(40)	3(15)	

Maximal interincisal opening (MIO) before and 3 months after intervention :  
Increase from 14 mm



### Maximal interincisal opening(MIO) before and 3 months after intervention

MIO(mm)	Before intervention Mean(CI)	3-months after treatment Mean(CI)	Change in MIO(mm) Mean(mm)(CI)	Change in MIO(%)
EzBite group	15.7(12.1-17.3)	29.7(27.1-32.5)	Δ 14(12.1-16.7)	Δ 89.2(70.1-93.5)
Conventional group	14.8(11.9-18.8)	25.3(19.7-27.1)	Δ 10.5(6.3-12.5)	Δ 70.9(55.3-89.9)
Control group	14.2(13.1-15.2)	15.5(12.9-17.3)	Δ 1.3(0.6-1.4)	Δ 9.2(5.5-11.6)
p-value	p=0.523	p<0.001	p<0.021	p<0.015

Data and images provided by Department of Oral and Maxillofacial Surgery, Tri-Service General Hospital, Taiwan



The clinical data indicates MIO of 29.7 mm after three months rehabilitation program by using EzBite device, has a significant increase of 14 mm on average; compare to MIO of 15.7 mm before use of the device.

Model No.	Dimension (L/W/H)	Material	Bite Force	Storage and Transportation Temperature	Storage and Transport Humidity	Minimum / maximum opening width	Scale / lattice
MGF-B16001-01	6.1cmx5.8cm x10cm/78(g)	Polycarbonate, Stainless Steel	25 kgf use or less	-20°C-60 °C, avoid direct sunlight	30% ~ 90% R.H	10mm / 70mm	5mm