MUNCHIES®

Instructions

HELLO

Thank you for purchasing Munchies[®], an orthodontic enhancement device designed to maximise the accuracy, fit and effectiveness of your clear aligner treatment and to provide relief from the discomfort of all forms of orthodontic treatment.

Munchies® devices help ensure that your aligners fit as intimately as possible against your teeth, increasing the likelihood that your treatment will progress as quickly as possible and minimising the chance of time-consuming and costly refinements and adjustments.

Munchies® devices deliver specific force profiles to ensure aligners or fixed braces move your teeth efficiently and comfortably as prescribed by your dental healthcare professional.

Munchies® devices are fabricated in 6 differing visco-elasticities (this refers to materials' ability to bend, flow and recover) that optimise forces appropriate for specific tooth movement and which are sympathetic to each stage of your treatment with clear aligners or fixed braces. These visco-elastic properties provide relief from the discomfort of orthodontic tooth movement, especially in the first 24 hours following new aligner insertion or orthodontic adjustments.

Patients can choose any of the Munchies® devices as a starting point and use in tandem with any other Munchies® device. Variations in the strength of the jaw muscles, size of the teeth, density of bone and tooth movement required will affect the comfort of each Munchies® device for each individual.

The Munchies® device has been designed by a prominent expert in aesthetic orthodontics and clear aligner therapy.

Indications for Use: Munchies® devices are used to assist in seating thermoplastic orthodontic aligners or retainers. Munchies® are also used to ensure that orthodontic tooth movements occur as predictably and comfortably as prescribed by your Doctor.

Contraindications: None known

Warnings: Use of excessive pressure to seat the aligners or retainers may cause damage to either the Munchies® device or aligners.

Precautions: Intermittent use for seating aligners or retainers and relief of discomfort caused by all forms of orthodontic treatment only.

Adverse Reactions: None known

Directions for Use:

- Place the aligner or retainer over the teeth by hand and apply slight pressure with your fingers until it is seated almost completely.
- Insert Munchies® device into your mouth and position it between the upper and lower arches. Insert your upper front teeth into the larger of the two grooves on the Munchies® device or your lower front teeth into the smaller groove.
- Gently bite down on the Munchies® device and work the aligner or retainer into place until fully seated.
- Focus on one tooth at a time and ensure that gentle forces are applied to all of your front teeth, both upper and lower.
- 5. Repeat the use of Munchies® device at least 3 times per day.

Get to know your Munchies device

Relieving discomfort

Discomfort is a common symptom of orthodontic treatment. Munchies® device usage induces the bite wafer effect^{1,2}, which has been shown to help relieve the discomfort associated with orthodontic movement.

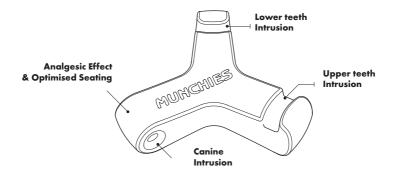
As a non-pharmacological option, this eliminates the possibility of side effects from the over-use of analgesics and can easily be used at home or school without supervision.

The most beneficial method to relieve discomfort is achieved when the Munchies® device is used by gently biting down in the posterior region (back teeth) for 3-4 minutes at 6-8 hour intervals for up to 1 week after new aligners are inserted or an orthodontic adjustment has occurred.

The use of varying hardness of Munchies® devices at different stages after new aligner insertion or orthodontic adjustment is critical to maximise your relief of discomfort.

The Munchies® device is available in 6 distinctive hardnesses/elasticities and can be purchased in a starter pack that has been specifically designed for you to get to know your preferred hardness.

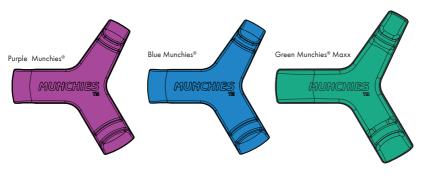
Each starter pack offers you the choice of the Gentle or Firm options. Both options contain 2 standard Munchies® devices and a Munchies® Maxx device, all of differing hardness. Munchies® Maxx is more robust in design and suited for patients who chew more aggressively and who may have deeper bites. Refill packs come in Gentle, Firm and Maxx options and Starter packs can be repurchased if you prefer to keep using the entire range of devices.



References: 1. Saloom, H. F. Pain intensity and control with fixed orthodontic appliance therapy (A clinical comparative study on Iraqi sample). Scientific Journal Published by the College of Dentistry-University of Baghdad, 122; 2. Farzanegan, F., Zebarjad, S. M., Alizadeh, S., & Ahrari, F. (2012). Pain reduction after initial archwire placement in orthodontic patients: a randomized clinical trial. American Journal of Orthodontics and Dentofacial Orthopedics, 141(2), 169-173.

Gentle Option

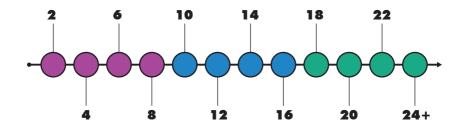
The "Gentle" pack has 2 Munchies® devices and one Munchies® Maxx device which are softer and more pliable. The gentle range is suited to patients who prefer minimal forces applied to their teeth after new aligner insertion or orthodontic wire adjustment.



(Colours may vary slightly)

Softest Firmer

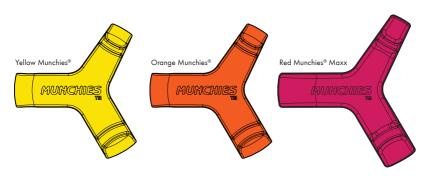
Follow the timeline below to aid minimising discomfort





Firmer Option

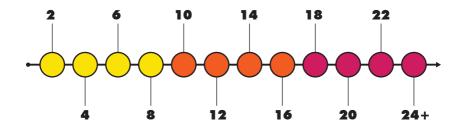
The "Firm" pack has 2 Munchies® devices and one Munchies® Maxx device which are less elastic and more viscous than the gentle devices. The Firm range is suited to patients who prefer to feel stronger forces acting against their teeth after new aligner insertion or orthodontic wire adjustment.



(Colours may vary slightly)

Firm •••••• Firmest

Follow the timeline below to aid minimising discomfort



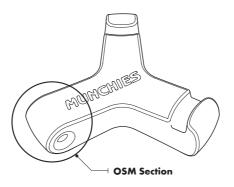


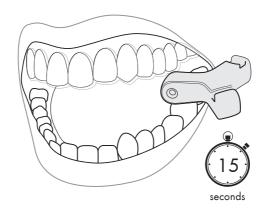
Modes of Use

Optimised Seating Mode

To ensure your aligner is seated intimately against your teeth and engaging the attachments which are critical for accurate movement, gently bite on the Optimised Seating Mode (OSM) section of the device, starting with your back teeth and moving completely around your mouth.

Select the Munchies® device that feels most comfortable to you.





Gently bite in a vertical (up and down) motion for 15 seconds on all teeth.

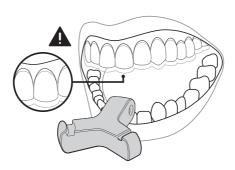
Repeat this process 3 times per day (morning, early afternoon and evening is ideal) for up to 3 minutes on each occasion.

Modes of Use

Recapture Mode

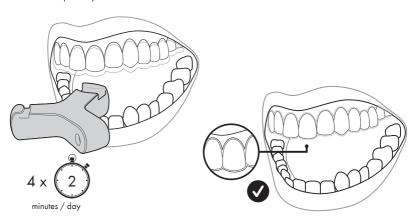
Sometimes during the course of treatment with clear aligners, your teeth do not move exactly as predicted. This results in a small space appearing between the biting edge of your teeth and the aligner. The Munchies® device can help recapture a perfect fit when used in the problematic area.

If you notice a gap appearing between the aligner and the biting edges of **many of your front teeth** (upper or lower) or your dental healthcare professional identifies an issue with your aligner fit, gently bite down repeatedly on the OSM end (rounded end) between the upper and lower teeth in the problem area.



Keep repeating this process 3 times daily until the space between the aligner and the biting edge disappears completely. If the space has not disappeared within two weeks, please consult your dental health care professional.

If your aligner is not seating in **one particular area** place the appropriate groove on the Munchies® device in the problem area and gently bite up and down repeatedly for 2 minutes at least 4 times per day.

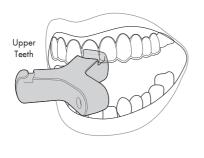


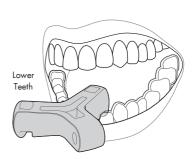
Modes of Use

Intrusive Mode

A common form of orthodontic tooth movement is called intrusion. This process involves a series of microscopic vertical movements to slowly and gently guide your teeth into your jaw bones. Intrusion, in particular of your front teeth, with both clear aligners or fixed braces can be challenging at times. The specially designed "intrusion grooves" on the Munchies® device individually engage each tooth (whether on the top or bottom jaw) aiding in the acceleration and predictability of the movement.

Patients can choose any of the Munchies® devices as a starting point and use in tandem with any other Munchies® device or Munchies® Maxx device.

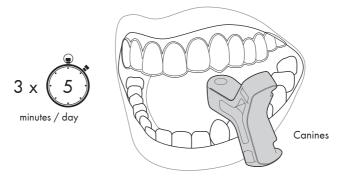




To intrude canines – rotate the Munchies® device by 90° to fit the sharp point of your canine snugly into the circular form. This will minimise any damage to the Munchies® device while delivering the correct forces.

This should be repeated 3 times per day for up to 5 minute intervals.

Variations in the strength of the jaw muscles, size of the teeth, density of bone and tooth movement required will affect the comfort for each individual and the choice of device should be customised accordingly.



Maintenance & Cleaning

Prior to use, rinse your Munchies® devices under warm water for at least 10 seconds. The most hygienic option to sanitize your Munchies® device is to immerse them in an ultrasonic bath for 5 minutes each day. After rinsing or an ultrasonic cleaning cycle, dry and place in your Munchies® devices carrying case. Munchies® devices can also be gently scrubbed with a toothbrush and toothpaste if any debris has become attached during use.

Manufacturing Quality

Munchies® devices are manufactured using FDA approved medical grade Dow Corning and Wacker silicones and pigments. Devices are designed in Australia and manufactured in China.

Munchies® devices are registered as a Class I medical device with the Therapeutic Goods Administration in Australia (ARTG Identifier: 237778)

Wear & Lifespan

Chewing too aggressively or too often can cause damage to your Munchies® device, especially in the intrusive mode. Most Munchies® devices last about two weeks if the correct forces have been applied.

You will notice significant indentations or deformation on the device when you use it, but these

will generally rebound within 10 minutes due to the unique nature of the material.

Premature tearing is generally due to overuse or too great a force being applied. To avoid this, simply use less force or use less frequently. Torn devices should be replaced immediately.



WARNING: Excessive chewing or bite forces will lead to your Munchies® devices tearing and should be avoided

Premature tearing in the device generally means that you have been biting down too hard or using your device too often!

Revision Number: 2015.06.1

Munchies® Product Range





Specially integral forgate with clear departs and fined functional Mandaus²⁸ halps.

Shares disconting

Recitle and occurred watering of oldparts

And in Sharps concentration of the Special Specia

For more information and to reorder visit: www.orthomunchies.com











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Manufacturer: EOCA MD Pty Ltd - 16 Transvaal Avenue, Double Bay NSW 2028 Australia

Sponsor: David Penn Consulting Pty Ltd - 16 Transvaal Avenue, Double Bay NSW 2028 Australia Distributors:

USA- Esthetic Orthodontic Company of America LLC - 4745 12th Avenue North, St Petersburg FL 33713 USA,

www.eocamerica.com

Australia- 1122Corp Ptv Ltd - 99/525 Illawarra Road, Marrickville NSW 2204, www.1122corp.com

EC REP EU Representative:

MDCRQ Solutions Ltd - 3 New Mill Court, Swansea Enterprise Park, Swansea SA7 9FG, UK, ph:+ 44 (0) 1685 874192

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