

The background is a repeating pattern of colorful Y-shaped objects (green, blue, pink) and wire cutters (black and silver).

**MUNCHIES<sup>®</sup>**

**WIRE**

**Instructions**

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**Intended User:** Any patient undergoing orthodontic treatment with braces.

**Indications for Use:** Munchies® WIRED devices are used to relieve discomfort associated with orthodontic treatment with braces.

**Performance Characteristics:** Munchies® WIRED devices are fabricated from medical grade, visco-elastic silicone that enables the device to compress when used and rebound afterwards to its original shape.

**Precautions:** For intermittent use for relief of discomfort caused by orthodontic treatment only.

**Warnings:** Use of excessive pressure when biting may cause damage to the Munchies® WIRED devices.

**Life Span:** Munchies® WIRED system, when used appropriately, should last approximately 2 months, that is, immediately after treatment or adjustment then periodically throughout the next 7 days.  
Overuse will lead to premature tearing, please discard if tearing occurs.

**Contraindications:** Do not use if you have an allergy or hypersensitivity to silicone.

**Adverse Reactions:** None known - any serious adverse incident experienced should be reported to the manufacturer and the relevant competent authority.

**Use in Children:** This device is safe for children to use with braces.

**Biocompatibility:** ISO 10933 Biocompatibility testing has been performed on the Munchies® WIRED with all tests passing the strict standards (tests performed cytotoxicity, skin sensitisation, irritation or subcutaneous reactivity, systemic toxicity and haemocompatibility).

**PFAS, PFOS & PFOA:** Munchies® WIRED does not contain PFAS, PFOS or PFOA

**US California Proposition:** Munchies® WIRED does not contain Phthalate, Lead or Cadmium.

**EU RoHS Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU:** Munchies® WIRED does not contain Lead, Mercury, Cadmium, Hexavalent chromium, PBBs, PBDEs, DEHP, BBP, DBP and DIBP.

# HELLO

Thank you for purchasing Munchies® WIRED, a series of orthodontic devices designed to relieve the discomfort associated with your orthodontic treatment.

## **PAIN FREE Fixed Braces, No Medication, No Side Effects and No Risks.**

Comfortable braces treatment for every patient is a reality with Munchies® WIRED. Research shows that biting on these remarkable devices regularly during fixed braces treatment is as effective as any over-the-counter medications in alleviating pain and discomfort<sup>3</sup>. Munchies® WIRED is the safest option for kids and adolescents by not using medication continually.

Munchies® WIRED devices are fabricated from specially sourced medical grade silicone and they are anatomically shaped to deliver correct forces to alleviate pain in all areas of the mouth. All Munchies® WIRED devices have visco-elastic properties, this means they have the ability to bend, flow and recover after each use.

Munchies® WIRED devices are manufactured in 5 different hardnesses to choose from, to suit varying degrees of discomfort.

Munchies® WIRED are packaged in a hygienic carrying cassette and box.

Designed by a prominent Australian expert in orthodontics.

## **MUNCHIES® WIRED - INDICATIONS FOR USE**

### **Discomfort Relief**

Munchies® WIRED devices have visco-elastic properties that provide relief from the discomfort felt during orthodontic tooth movement, especially in the first 24 hours after a wire placement & adjustment, separator insertion, elastic band application, palatal expander activation. Patients gain relief when biting initially into a soft device, followed by a firmer device, the phenomenon is called the Bite Wafer Effect<sup>1,2</sup>.

### **What part of my treatment will make me uncomfortable?**

Certain orthodontic procedures, such as the initial placement of your braces, insertion of small rubber separators between teeth, using elastics and the further activation of orthodontic wires are most likely to be painful and uncomfortable. Rapid palatal expanders, which help make upper jaws wider, are also quite painful when initially placed and are often uncomfortable after each screw activation.

### **When will I experience pain ?**

Generally, the sensation of discomfort and pain usually begins 2 to 4 hours following the placement of wires or expanders and peaks around 24 hours. The pain slowly disappears but can take up to 7 days to dissipate.

### **How effective are Munchies® WIRED and what are the advantages?**

Biting regularly on the Munchies® WIRED device can provide significant relief from this pain and discomfort. Research confirms that this relief is as effective as over-the-counter medications, without the risks and side effects<sup>3</sup>.

In addition, use of anti-inflammatory medication<sup>4</sup> such as ibuprofen, naproxen sodium and aspirin during treatment can severely inhibit the effectiveness of orthodontic tooth movement and should be avoided.

4. Karthi M, Anbushevan GJ, Senthilkumar KP, Tamizharsi S, Raja S, Prabhakar K. NSAIDs in orthodontic tooth movement. J Pharm Bioallied Sci. 2012 Aug;4(Suppl 2):S304-6.

## **MUNCHIES® WIRED - HOW IT WORKS**

Pain and discomfort are often reported in patients undergoing fixed orthodontic treatment.

Patients complain of pain interfering with their normal activities like biting, chewing, and sleep and some even consider terminating their treatment.

Certain procedures like separator placement, placement and activation of arch wires and use of rubber bands are considered painful by the patients.

Pain sensation usually begins by 2 - 4 hours following these procedures, and peaks at 24 hours; it gradually disappears over the next 7 days.

Pain perceived by the patient during orthodontic treatment is often ignored by the orthodontist and the option of pain-free treatment is rarely considered.

Studies have shown that pain following arch wire placement is the response due to the combination of pressure, edema, inflammation and ischemia in compressed periodontal ligament (PDL).

Research<sup>3</sup> has shown that pain experienced by patients can be reduced by having them bite on the device repetitively, particularly for the first 24 hours following the insertion or activation of any orthodontic appliance.

Biting on the Munchies® WIRED temporarily induces micro movements of the teeth, allowing blood flow in the compressed areas of the PDL, which prevents the build-up of pain-inducing metabolites.

## MUNCHIES® WIRED RECOMMENDED USAGE

### Soft at first, then customize as you go.

As you progress through your treatment, you will find that different forces will be applied to your teeth at each stage, which leads to varying degrees of discomfort. The Munchies® WIRED system contains a series of devices in a variety of hardnesses, which allows you to customize which devices to use, to provide the most relief after each adjustment. We recommend starting with the softer devices and swap to harder as needed. Using the Munchies® WIRED devices is particularly important in the first 24 hours following any new treatment or adjustment and continuing as needed for up to 7 days.

## MUNCHIES® WIRED FEATURES





# MUNCHIES® WIRED RANGE

## MUNCHIES® WIRED

About 2 hours after treatment, relief is initially obtained by gently biting into the softest Munchies® WIRED devices (Purple or Blue).

As your treatment progresses many patients find that utilising the harder Munchies® WIRED devices (Green and W-Series) will bring the most significant relief.



## **SOFTEST**.....-> **FIRMER**

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.  
3. Murdock S, Phillips C, Khondker Z, Hershey HG. Treatment of pain after initial archwire placement: a noninferiority randomized clinical trial comparing over-the-counter analgesics and bite-wafer use. Am J Orthod Dentofacial Orthop. 2010 Mar;137(3):316-23.

## **MUNCHIES® W-SERIES**

The W-Series range of Munchies® WIRED are the firmest and longest lasting devices that help when pain and discomfort are at its worst. The W-Series has been manufactured in two hardnesses for patient choice as pain worsens.



Munchies®  
W-Series H1



Munchies®  
W-Series H2

**FIRM** .....> **FIRREST**

## **MUNCHIES® WIRED SYSTEM**

The Munchies® WIRED system contains a series of devices that have been designed to alleviate pain and discomfort in all fixed wired orthodontic treatments. The system includes the two packs shown below:

### **MUNCHIES® WIRED 3PC CASSETTE**



Product images are not to scale

### **MUNCHIES® WIRED W-SERIES 2PC PACK**

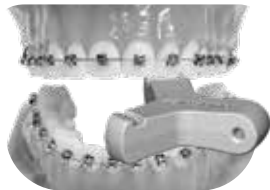


For more information and to reorder visit: [www.orthomunchies.com](http://www.orthomunchies.com)

## **MUNCHIES® WIRED INSTRUCTIONS: Purple, Blue and Green**

**Step 1.** About 2 hours after treatment, pain relief can be obtained using Munchies® WIRED, start by putting your upper front teeth into the larger groove and gently biting your lower teeth against it. Bite into the device with each of your upper front teeth for 2 to 3 minutes, repeating this step every 4 hours as needed.

Top Teeth



**Step 2.** Move to your bottom teeth by putting your lower front teeth into the smaller groove and gently biting your upper teeth against it. Bite into the device with each of your lower front teeth for around 2 to 3 minutes, repeating this step every 4 hours as needed.

Bottom Teeth



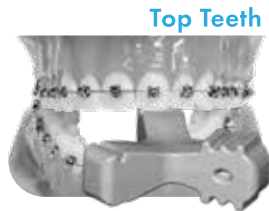
**Step 3.** Then move to your back teeth by putting the ridged arm of the device between your back teeth on one side of your mouth and bite up and down for around 2 to 3 minutes. Repeat on the other side of your mouth. Repeating this step every 4 hours as needed.

Back Teeth

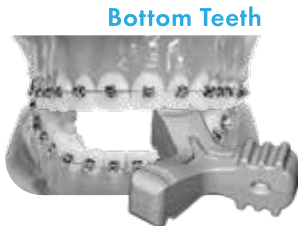


## MUNCHIES® WIRED INSTRUCTIONS: W-RANGE

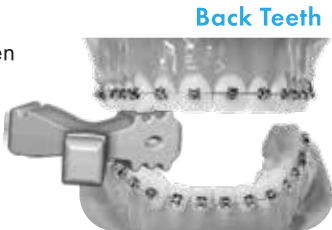
**Step 1.** About 2 hours after treatment, pain relief can be obtained using Munchies® WIRED, start by putting your upper front teeth into the larger groove and gently biting your lower teeth against it. Bite into the device with each of your upper front teeth for 2 to 3 minutes, repeating this step every 4 hours as needed.



**Step 2.** Move to your bottom teeth by putting your lower front teeth into the smaller groove and gently biting your upper teeth against it. Bite into the device with each of your lower front teeth for around 2 to 3 minutes, repeating this step every 4 hours as needed.



**Step 3.** Then move to your back teeth by putting the ridged arm of the device between your back teeth on one side of your mouth and bite up and down for around 2 to 3 minutes. Repeat on the other side of your mouth. Repeating this step every 4 hours as needed.



## **Maintenance, Cleaning & Storage**

Prior to use, rinse your Munchies® WIRED devices under warm water for at least 10 seconds. The most hygienic option to sanitize your Munchies® WIRED 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® WIRED carrying case/box. Munchies® WIRED devices can also be gently scrubbed with a toothbrush and toothpaste if any debris has become attached during use. Store Munchies® WIRED at ambient temperatures. (15-25°C)

## **Manufacturing Quality**

Munchies® WIRED devices are manufactured using Class VI medical grade silicones, and designed in Australia and manufactured in China.

Munchies® WIRED devices are listed as a Class I medical device on the TGA (ARTG Identifier: 237778), FDA and are CE marked. Free of Toxins, Phthalates, BPA, PFAS, PFOA, PFOS, Lead and Cadmium.

## **Wear & Lifespan**

Chewing too aggressively or too often can cause damage to your Munchies® WIRED device. The Munchies® WIRED systems will last about two months if the correct forces have been applied. You will notice significant indentation or deformation on the device when you use it, but these will generally rebound within 10 minutes due to the elastic 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® WIRED device 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!

## **Disposal**

Please dispose of your used Munchies® WIRED responsibly, we recommend discarding in the General Household waste bin.

For more information and to reorder visit:

**[www.orthomunchies.com](http://www.orthomunchies.com)**

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Revision Number : 2024.10.30