MigraineGuard®

Method of Action
Therapeutic Effects and Outcome

1. **Migraine pain is caused by a dysfunction of the Trigeminal cranial nerve,** a large, three-part nerve in your head that transmits primarily pain sensation.
(*Trigeminus* is Latin for "threefold", as the Trigeminal Nerve (TN) receives input from *three* divisions: 1) surface of the brain; 2) the sinuses; 3) the jaws and structures of the mouth).

2. Dysfunction of the Trigeminal Nerve is thought to be caused by **excessive nociceptive input** from one of the three divisions. (*Nocere* is Latin for "to harm". Nociception means "the receipt of harmful information").

3. **Pain is produced when the TN secrets an irritating amino acid** that may be received at any or all of the three divisions, resulting in: 1) migraine pain; 2) sinus pain; 3) jaw pain**.**

4. **Intense nocturnal Jaw Clenching** is of the most common and devastating of the *nociceptive* inputs, **while typically going completely undetected**. Migraine sufferers, on average, have developed the ability to clench with *twice the force* as non-sufferers.

5. **Minimizing the intensity of jaw-clenching with the MigraineGuard** dramatically reduces nociceptive input, thereby reducing migraine pain and episodes, while greatly improving disability.

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The MigraineGuard is an FDA cleared medical device for the reduction of migraine pain. The MigraineGuard's method of action is to minimize pathologic nocturnal clenching intensity, which when left unmanaged, can intensify and complicate subsequent migraine attacks.

Blinded, placebo-controlled, cross-over clinical trials shows that the MigraineGuard provides a profound improvement in the quality of life for 89% of Chronic Migraine suffers. ("Adjunctive treatment of chronic migraine using an oral dental device: overview and results of a randomized placebo-controlled crossover study." BMC Neurology, 22, #72, March 4 2022).

Minimizing the contraction intensity of the *temporalis* jaw-closing muscle thereby eliminates the chronic resistance encountered by the opposing *lateral pterygoid* jaw-opening muscle, allowing the *lateral pterygoid* to "normalize" and potentially lengthen from its chronically tensed state.

The lengthening of the *lateral pterygoid* may allow the lower jaw to settle more ideally into its socket, thereby changing the habitual relationship of the teeth of the lower jaw to the teeth of the upper jaw, which may be appreciated by a "change in the bite", as the posterior teeth contact more firmly than before. This is considered a "diagnostic event", revealing the subject's most optimal jaw relationship. In a study of 78,711 devices delivered, 1.6% reported a change in their bite. (Inside Dentistry, 2011, Volume 7, Issue 11).

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The degree of change can range from being practically unnoticeable to being readily identifiable. In rare cases, a significant improvement of symptoms can be accompanied by a significant change in the bite relationship. While the desire for symptomatic improvement be considerable, it must be weighed against the (potential) change in the bite. Resolving a change in the bite (if desired as it is not necessary) can range from simple recontouring of the contacting molars, to orthodontic treatment.

If the MigraineGuard user notices a change in their bite after 3 to 6 weeks of nightly use, they should note the degree of symptom improvement and discontinue use for one to two weeks, allowing their bite to return to its pre-use state, and then reevaluate.