



Frequently Asked Questions

Device Information

What are the Cerezen™ devices?

- The Cerezen™ devices are comprised of customized ear canal devices that reduce pain associated with temporomandibular joint disorder (TMJD).
- The devices conform to the shape of the ear canal when the jaw is in an open position.
- Cerezen™ devices have central hollow passageways so there is no interference with hearing.

Who are Cerezen™ devices suitable for?

Cerezen™ devices can benefit customers suffering from Jaw Pain, Facial Pain, Muscular Pain around the neck or shoulder area and Tension Headaches (all symptoms of TMJD).

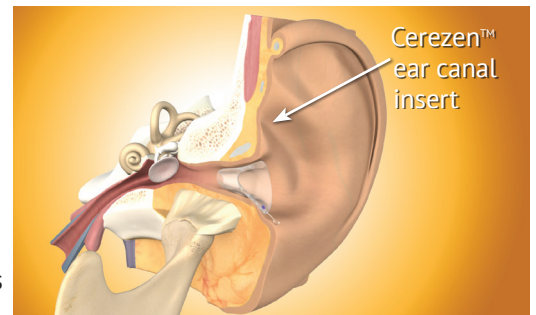
How do the devices alleviate TMJ pain?

There are two primary factors believed to be responsible for the clinically proven effectiveness of Cerezen™ devices:

- The ear canal devices support the temporomandibular joint and associated secondary musculature to reduce strain in the TMJ area.
- They provide “cognitive awareness” (consciously or subconsciously) to the wearer regarding para-functional habits (e.g. jaw clenching) that contribute to TMJ pain, relieving strain in the TMJ area. Both mechanisms function because of the proximity of the temporomandibular joint, and the ear devices maintain the shape and volume of the ear canal as the jaw opens and closes.

As can be seen in the figure to the right, the ear canal

(external auditory meatus) is located immediately posterior to the condyle and disc of the TMJ.



How long do the Cerezen™ devices last for?

Based on feedback and use of the devices, customers have reported that their Cerezen™ devices have continued to be effective for five years and longer.

Do the Cerezen™ devices lose effectiveness over time?

Every customer will have a different experience. Some customers do not experience a loss of effectiveness, whereas others may have an adaptive ear anatomy which may result in devices loosening and gradually losing benefit. We can then offer a refinement option to increase the size to regain effectiveness and clinical benefit.

How do I find a Cerezen™ devices prescriber?

Contact us and we can assist you in locating a Cerezen™ devices prescriber near you.

When can I be fitted for Cerezen™ devices?

Once a temporomandibular joint disorder (TMJD) diagnosis has been established, the prescribing health care provider can take the manual ear impressions or refer you to a participating impression provider.

How are the impressions taken?

Impressions are taken by a qualified Audiologist/certified ear technician. The impression process involves putting a foam barrier and a silicon material into the ear canal; this is pain free.

Do the impressions hurt?

No, some customers have referred to this procedure feeling like diving under water. It may tickle or make you cough slightly.

Can the devices be seen when wearing them?

No, the devices are very discreet and therefore can be worn during the day without being noticed by others.

Will wearing Cerezen™ devices affect my hearing?

No, because each device is hollow, sound waves can enter the ear as normal and hearing should not be diminished. There may be a slight alteration in tone, but not in volume. The ears will adapt to this and your hearing should not be affected.

Treatment Questions

Can I wear the Cerezen™ devices in conjunction with my mouth guard/bite splint?

Yes, if necessary, the Cerezen™ devices can be worn in conjunction with a mouth guard/bite splint. However, over time, customers may find they can effectively wear Cerezen™ devices alone and no longer require a mouth guard/bite splint. Customers are encouraged to consult with their dentist and/or prescribing physician.

I have/I'm going to get braces – will this affect anything? Should I wait until after they come off?

If braces are on the teeth this should not have an impact on your Cerezen™ devices. If they are any types of occlusion guard this may have some impact as anything that amends the bite this may the effectiveness of the Cerezen™ devices, but this would be a case by case issue. If the occlusion guard is in place at the time of impression taking there should be no impact on effectiveness. Customers are encouraged to consult with their orthodontist and/or prescribing physician.

Why hasn't my doctor heard of this treatment before?

Cerezen™ devices have been sold in Europe and are relatively new to the United States, many American doctors simply may not have information about the product. However, word is spreading fast. Providers can obtain information about the devices on our website <https://cerezen.com/providers/about-cerezen>

Is there any risk in this treatment?

You should not be fitted for Cerezen™ devices if you have active ear drainage, swelling, or redness; if you have an unresolved history of ear pain unrelated to TMJD, or if your ear canal anatomy does not allow for fitting of the device (i.e. too narrow or prolapsed canal, or a previous mastoid surgery).

If you experience some initial discomfort while wearing your Cerezen™ devices, it may simply represent a brief adjustment period as the ear tissue adapts to the Cerezen™ device. If, however, soreness, swelling, itchiness, or drainage occurs in either of the ears, then you should remove your devices and call your healthcare provider to discuss your condition and schedule an appointment if necessary.

Can using Cerezen™ devices make symptoms worse?

Cerezen™ devices should not increase symptoms. It may sometimes heighten the customer's awareness of their symptoms in the initial stages. We would always advise gradual build-up of wear and to remove if there is significant discomfort. Please refer to our Fitting Video to confirm how the devices should be inserted. If you are still experiencing issues with the fit, please contact Cerezen™ Customer Support at 855-303-4601 or customerservice@cerezen.com to determine if a refinement is needed.

Can I wear my Cerezen™ devices while showering, bathing, swimming or participating in contact sports?

It is not recommended to wear your devices while showering, bathing, swimming, or participating in contact sports. Please refer to the Precautions page for a complete list of warnings and precautions.

How long should I be wearing my Cerezen™ devices for?

The following sequence should be followed when you receive your Cerezen™ devices:

- **Days 1-3** (Day-time use only) 3 hrs / day.
- **Days 4-7** (Day-time use only) two lots of 4 hrs / day.
- **Week 2** (Day-time use only) If no problems in week one – full daytime wear.
- **Week 3** Introduce night-time wear. Only after follow up phone call.
- Thereafter, Cerezen™ devices can be worn up to 23 hours per day. However, if you experience any discomfort, you should remove the devices.

What are some potential complications with this TMJ treatment?

No significant complications have been reported. This is not unexpected, because the Cerezen™ devices are custom-fit to each customer's ear canal. The ear devices are constructed from medical-grade polymers and plastics that have been safely used in commercially available hearing aids for decades. The clinical trial of Cerezen™ devices did include evaluation of customers for a range of potential complications. There were no unanticipated adverse effects or serious adverse events reported during the pivotal clinical trial. No study customers were found to have ear drainage, allergic reactions, swelling or changes to the mouth, ear or jaw at any of the follow-up visits. There were no reports of diminished hearing acuity in customers treated with the Cerezen™ devices.

Tavera A, et al: Approaching Temporomandibular Disorders from a New Direction. A Randomized Controlled Clinical Trial of the TMDes* Ear System. J Craniomandibular Practice July 2012; Vol 30, No 3, 172-182. *TMDes is now called Cerezen™ devices.

Do I have to wear the devices in both ears?

Yes. Wearing both devices simultaneously is recommended.

Can the devices be worn at night?

Yes, Cerezen™ devices are designed for both day time and night time use. Once you get used to wearing the devices during the day, in accordance with the guidelines given, you can safely wear the devices at night.

Are the devices clearly marked as to which insert goes in each ear?

Yes. The right ear insert is marked with a ● red dot, while the left insert is marked with a ● blue dot.



How often should the devices be cleaned?

The devices need to be cleaned daily. Use the brush supplied to remove wax or soak in warm soapy water for 5-10 minutes. The devices must be completely dry before being put back into the ears.

What do I do if my Cerezen™ devices are feeling a little loose?

Occasionally customers will not fit the devices correctly. Go to the "User Guide" booklet and follow the instructions on how to fit your devices. If, however, you are still concerned with the fit, contact us so we can get you scheduled to get your devices checked by the audiologist at a review appointment.

If, at the review appointment, the fit looks correct but there is still looseness, this could be due to a reduction in swelling around the temporomandibular joint, creating more space in the ear canals. This means that the devices may not be as snug as they were when first fitted. You should still continue to wear your devices until your next follow up appointment.

Why are my Cerezen™ devices making my ears itchy?

This is normally due to your ear canal being dry. This can be solved by simply applying some of the lubricant provided onto your devices.

My Cerezen™ devices are uncomfortable, what should I do?

At first, it may not be comfortable to wear the Cerezen™ devices at night, this is common for customers. It is recommended that the customer allows time to adapt to their devices, by slowly building up their wear time during the day (even if your symptoms are worse at night).

Device Effectiveness

What has been the customer response to Cerezen™ devices?

Customer global satisfaction in the pivotal clinical trial was extremely high, with 100% of subjects in the Cerezen™ devices group indicating excellent (71%) or good (29%) overall satisfaction with their devices for TMJ pain relief. For more information on customer response, please view our customer testimonials.

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Pricing & Warranty

How much do Cerezen™ devices cost?

The price of treatment will depend on what best suits you - we will make an assessment and then provide you with detail of the cost, should Cerezen™ be a good fit for you.

Are my Cerezen™ devices covered by insurance?

Cerezen™ devices are not currently covered by insurance, however, deferred payment options can be made available. Flexible Spending Accounts (FSA)/Health Savings Plans (HSP) funds may qualify to cover Cerezen™ devices. Please check with your account administrator for eligibility.

Why do I need a prescription if Cerezen™ devices are not covered by insurance?

Cerezen™ devices are medical devices and require a Healthcare Practitioner to examine the customer and determine if Cerezen™ devices will work based on their TMJD symptoms.

Can replacements be ordered if devices are lost?

Replacement devices can be made without having to take the ear impressions again. There is a cost associated with replacing devices.

What happens if I lose the device or if it breaks?

Unfortunately, losing your Cerezen™ devices is not covered under a warranty. Should the device break we would need you to return the Cerezen™ devices to review the cause of the break to determine if this is covered under the product warranty. For more information on the warranty please go to: <https://cerezen.com/warranty-information/>

What is the warranty on the product?

Renew Health Ltd. warrants to the Prescriber ("Buyer") the "Product Warranty" on the terms of this Limited Warranty, that for a period of six (6) months from the date of shipment of a product (the "Warranty Period"), each product will materially conform to the ear impressions taken of the end-users ears and will be free from significant defects in material and workmanship. For more information please see the full warranty at <https://cerezen.com/warranty-information/>

How many Cerezen™ devices have been sold to date?

The approximately 3,700 Cerezen™ devices have been sold in Europe and the United States since 2014.