



## Frequently Asked Questions

### 1 What are the Cerezen™ inserts?

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

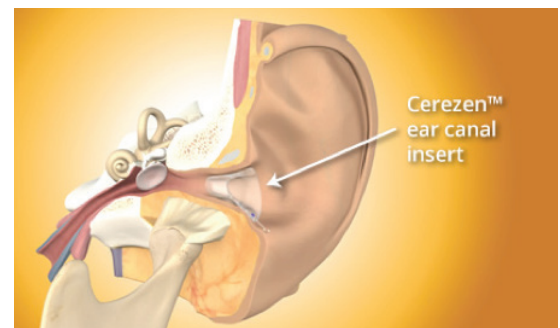
### 2 Who is Cerezen™ inserts suitable for?

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

### 3 How do the inserts alleviate TMJ pain?

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

- The ear canal inserts 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 inserts 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.



### 4 How do I find a Cerezen™ inserts prescriber?

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

### 5 When can I be fitted for Cerezen™ inserts?

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.

## 6 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.

## 7 Do the impressions hurt?

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

## 8 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 inserts.

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

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

## 10 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.

## 11 Do I have to wear the devices in both ears?

Yes. Wearing both devices simultaneously is recommended.

## 12 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.

## 13 Are the inserts 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.



## 14 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.

## 15 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.

## 16 What do I do if my devices are feeling a little loose?

Occasionally patients 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.

## 17 Why are my 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.

## 18 My 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 patients. It is recommended that the patient 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).

## 19 Will wearing Cerezen™ inserts 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.

## 20 What has been the patient response to Cerezen™ inserts?

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

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™ inserts.

## 21 What are some potential complications with this TMJ treatment?

No significant complications have been reported. This is not unexpected, because the Cerezen™ inserts are custom-fit to each patient's ear canal. The ear inserts 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™ inserts did include evaluation of patients for a range of potential complications. There were no unanticipated adverse effects or serious adverse events reported during the pivotal clinical trial. No study patients 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 patients treated with the Cerezen™ inserts.

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™ inserts.

## 22 Are my Cerezen™ inserts covered by insurance?

Cerezen™ inserts 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.

## 23 How much do Cerezen™ inserts 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.