

# Patient Guide for the TrueTear<sup>®</sup> Intranasal Tear Neurostimulator



t r u e t e a r<sup>®</sup>

# Patient Guide for the TrueTear® Intranasal Tear Neurostimulator

Please read this entire guide. If you have any questions, discuss with your provider to make sure you understand how to use the TrueTear® Intranasal Tear Neurostimulator.

The TrueTear® Intranasal Tear Neurostimulator (TrueTear® device) provides a temporary increase in tear production during neurostimulation to improve dry eye symptoms in adult patients with severe dry eye symptoms.

**Rx Only**—Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

Proper patient training on use of the device is required before home use.



# The TrueTear® Intranasal Tear Neurostimulator Patient Guide

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# Glossary

Adverse event

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Base unit

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Cardiac demand pacemaker or defibrillator

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Clinical studies

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Contraindications

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Cornea

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Disposable tip

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Dry Eye symptoms

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Eligibility criteria

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Hypersensitivity

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Intranasal Tear Neurostimulator (TrueTear® device)

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Neurostimulation

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Precautions

---

Schirmer test

---

Temporary electrical discomfort

---

Warnings

---

An undesirable effect associated with use of a medical product.

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The base unit produces the neurostimulation and provides a connection to the charger.

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Device (cardiac demand pacemaker) placed in or in close proximity to (defibrillator) the heart to maintain cardiac rhythm.

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Clinical studies are conducted to evaluate the use of a drug or device.

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Cases where the TrueTear® device should not be used.

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Clear tissue located in the front of the eye covering the colored area of the eye.

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The disposable tip of the TrueTear® device connects to the base unit and is inserted into the nose.

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Dry eye symptoms may include, but are not necessarily limited to, sensitivity to light, grittiness, pain or soreness, blurred vision, and poor vision. Dry eye symptoms may be caused by advanced age, contact lens wear, certain medications, eye diseases, other medical conditions, or environmental factors.

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Characteristics or criteria used to determine whether a person can participate in a clinical study.

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Allergy or reaction to materials that may come into contact with the skin or to medications taken.

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A device that provides small electrical pulses to stimulate tear production.

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Delivery of small electrical currents to activate the nerves in the nose.

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A precaution provides information regarding any special care to be exercised by the provider and/or the patient for the safe and effective use of the device.

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A test in which a paper strip inserted inside the eyelid for several minutes to evaluate tear production.

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Temporary (short-term) discomfort resulting from electrical stimulation.

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A warning alerts the user about serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

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# Introduction

This guide is intended to help you decide whether to use and how to use the TrueTear® device to provide a temporary increase in tear production and improvement in symptoms. This device provides small electrical pulses to stimulate production of your own natural tears. The electrical pulses are delivered by a disposable tip attached to the TrueTear® device that you will place in your nose for short periods of time.

Your provider has determined that the TrueTear® device may work for you. Please read this entire guide and discuss your questions with your provider. You can then consider the expected benefits versus the risks and make an informed decision.

## Facts About Dry Eye Symptoms

Dry eye symptoms may include, but are not necessarily limited to, sensitivity to light, grittiness, pain or soreness, blurred vision, and poor vision. Dry eye symptoms may be caused by advanced age, contact lens wear, certain medications, eye diseases, other medical conditions, or environmental factors. In some people, dry eye symptoms may be improved by increasing the amount of tears produced.

## Indications for Use

The TrueTear® Intranasal Tear Neurostimulator provides a temporary increase in tear production during neurostimulation to improve dry eye symptoms in adult patients with severe dry eye symptoms.

## Potential Benefits of the TrueTear® Device

Use of the TrueTear® device will temporarily increase your tear production and improve your dry eye symptoms, though not all patients may respond to this device to the same degree.

## Potential Complications With Using the TrueTear® Device

Potential complications include the following:

- Nasal pain, discomfort, or burning sensation
- Short-term electrical discomfort
- Nosebleeds
- Trace blood in nostril
- Nose stuffiness (nasal congestion)
- Excessive sneezing
- Irritation or numbness of the nose

- Infection, scrape (abrasion), sore formation (ulceration) or inflammation inside the nose
- Irritation or sensitivity inside the nose
- Lightheadedness
- Headaches
- Sinus pain
- Sore eye
- Facial pain or pain around the eye
- Increased saliva production
- Sensation of teeth vibrating
- Excessive runny nose
- Temporary increase in symptoms associated with nasal allergies
- Allergic reaction to contact materials
- Potential permanent scarring of the inside of nose with prolonged use

## **Contraindications, Warnings, and Precautions**

### **CONTRAINDICATIONS**

Contraindications are situations where it is advisable not to use the TrueTear® device. If you have any of the following, you should NOT use the TrueTear® device:

- A cardiac demand pacemaker, implanted or wearable defibrillator, or other implanted metallic or electronic device (eg, cochlear implant) in the head or neck
- Chronic or recurrent nosebleeds, a bleeding disorder (eg, hemophilia), or another condition that can lead to increased bleeding
- A known hypersensitivity (allergy) to the hydrogel material that comes into contact with the inside of your nose

### **WARNINGS**

Warnings alert the user about serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur, as identified below:

- Follow the Instructions for Use when using the TrueTear® device.
- Do not use the TrueTear® device if electronic monitoring equipment is being used. This type of equipment includes heart monitors or electrocardiogram (ECG) alarms since this equipment may not operate properly when the TrueTear® device is being used.

## Contraindications, Warnings, and Precautions

### WARNINGS (continued)

- Do not use the TrueTear® device when in the bath or shower.
- Do not use the TrueTear® device while driving, operating machinery, or during any activity in which sneezing or watery eyes may put you at risk of injury.
- Do not apply the TrueTear® device to the neck, chest, or areas other than the nose.
- Do not continue using the TrueTear® device if your nose is irritated since further use may cause injury to the tissues inside your nose.
- Do not use the TrueTear® device within 3 feet of shortwave or microwave therapy equipment since this equipment may make the stimulation from the TrueTear® device unstable.
- Do not use the TrueTear® device in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide as there is a remote possibility (comparable to the risk of a mobile phone) it could ignite the gas.
- Use only manufacturer's supplied accessories.
- The TrueTear® device is limited only to the improvement in dry eye symptoms as the safety and effectiveness in the treatment of dry eye disease has not been established.
- In a clinical study, the safety and effectiveness of the TrueTear® device was evaluated over a 6-month period of time. The safety and effectiveness of the TrueTear® device for longer periods of use have not been established. Your provider may periodically check your nose if the TrueTear® device is used over a longer period of time.
- The clinical study was not designed to evaluate any changes in nerve sensitivity.
- The safety of the TrueTear® device has not been established in the following conditions and patient populations:
  - Pregnancy
  - Patients under 22 years of age
  - Nasal (nose) or sinus surgery, including a history of nasal cautery, or significant trauma
  - Severe nasal airway obstruction (such as severe septal deviation or inferior turbinate hypertrophy) or vascularized polyp (abnormal nasal mucosa with dense network of blood vessels)

## WARNINGS (continued)

- Disabling arthritis, neuropathy, severe dexterity impairment or limited motor coordination that would affect your ability to use or handle the TrueTear® device
- Active and severe:
  - Systemic allergy
  - Chronic seasonal allergies
  - Rhinitis or sinusitis requiring treatment such as antihistamines, decongestants, oral or aerosol steroids
  - Untreated nasal infection

## PRECAUTIONS

Precautions provide information regarding any special care to be exercised by the provider and/or patient for the safe and effective use of the TrueTear® device.

- Consult your provider before using the TrueTear® device.
- If you feel pain, discomfort, or numbness in your nose with higher levels of stimulation or a longer duration of stimulation, reduce the level and/or the number of times you use the TrueTear® device. If symptoms persist, discontinue use and contact your provider.
- Discard the disposable tip every 48 hours and replace with a new tip for proper operation and good hygiene.
- Remove any studs, nose rings, or other piercings from the nose prior to using the TrueTear® device as this could obstruct the device and/or cause discomfort if the electrical stimulation is conducted to surrounding areas.
- Do not use prescription eye medications (eye drops, gels, or ointments) or nasal sprays within 30 minutes before or after using the TrueTear® device.
- Consult your provider before use if you have suspected or diagnosed heart disease.
- The TrueTear® device should be kept out of the reach of children.
- If you have a severe fear of placing anything in your nose, you may not be able to use the TrueTear® device.
- Clean as directed.
- Failure to replace the tip as directed will cause the device to not work properly.

## Are You a Good Candidate for Use of the TrueTear® Intranasal Tear Neurostimulator?

You are a good candidate for the TrueTear® device if you:

- Are at least 22 years old.
- Have dry eye symptoms.
- Are able to use the TrueTear® Intranasal Tear Neurostimulator.
- Do not have a cardiac demand pacemaker, implanted or wearable defibrillator, or other implanted metallic or electronic device in the head or neck.
- Do not have a known hypersensitivity to the hydrogel material that contacts the nasal mucosa.
- Do not have chronic or recurrent nosebleeds, a bleeding disorder or another condition that can lead to increased bleeding.

## Questions to Ask Your Provider

You may want to ask your provider the questions below to help you decide if the TrueTear® device is right for you.

- What other options do I have for my dry eye symptoms?
- What are the benefits of the TrueTear® device?
- Can I use the TrueTear® device as often as I want?
- Will I be able to use artificial tears, gels and ointments in addition to using the TrueTear® device?
- Will I be able to use dry eye drugs in addition to using the TrueTear® device? Are there any risks if I use the TrueTear® device with dry eye drugs?

## Summary of Important Information

- The TrueTear® device provides a temporary increase in tear production during use resulting in an improvement in dry eye symptoms in adult patients with severe dry eye symptoms.
- You should not use the TrueTear® device if you have any of the following conditions:
  - A cardiac demand pacemaker, implanted or wearable defibrillator, or other implanted metallic or electronic device in the head or neck
  - Chronic or recurrent nosebleeds, a bleeding disorder or another condition that can lead to increased bleeding
  - A known hypersensitivity (allergy) to the hydrogel material that comes into contact with the inside of your nose
- You should follow all instructions to make sure you use the TrueTear® device correctly.
- Please call 1-800-433-8871 to report an adverse event.

# Instructions for Use

## OVERVIEW OF THE TRUETEAR® DEVICE COMPONENTS

The TrueTear® device consists of four components.  
These are:

- 1 A **disposable tip**, which is inserted into the nasal cavity and provides the contact surface for the stimulation of the target tissue in the nose
- 2 A reusable **base unit**, which produces the neurostimulation and enables the patient to control the neurostimulation
- 3 A reusable **cover** to protect the disposable tip
- 4 A **charger** to recharge the sealed battery inside the base unit

The disposable tip (tip) is connected to the base unit for stimulation. The tip contains a hydrogel material similar to materials used in contact lenses. The tip provides the contact for conducting the stimulation current, which is produced by the base unit, to the target site on the inside of the nose.

The tip should be removed and replaced every 48 hours.  
The reusable cover can be used to protect the tip between uses.  
Once the tip is removed, the base unit can be placed onto the charger to recharge the battery in the base unit. Charge the base unit every 48 hours or when you change the tip.

All images shown in this guide are for referencing only.

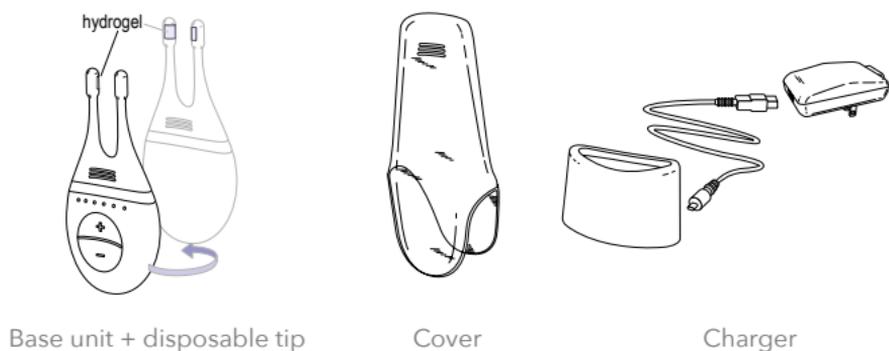


Figure 1. TrueTear® components.

## CHARGING THE BATTERY

NOTE: Only use the provided AC adapter for attaching the charger.

- 1 Ensure the base unit is fully charged when using the TrueTear® device for the first time.
- 2 Connect the charger to a wall outlet (120 to 240V) using the micro USB wall adapter and cable (Figure 2).

**CAUTION: The AC adapter provides protection from high voltages and should only be plugged into easily accessible outlets.**

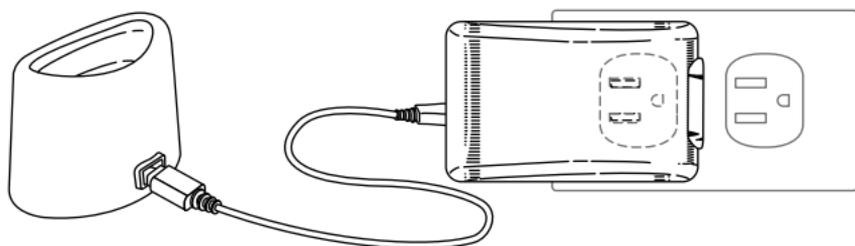


Figure 2. Connecting the charger.

- 3 If the tip is attached to the base unit, remove tip by rocking the tip away from the buttons—the disposable tip should disconnect easily. The base unit can then be placed on the charger. An LED light turns to a steady orange to indicate that the base unit is charging (Figure 3).

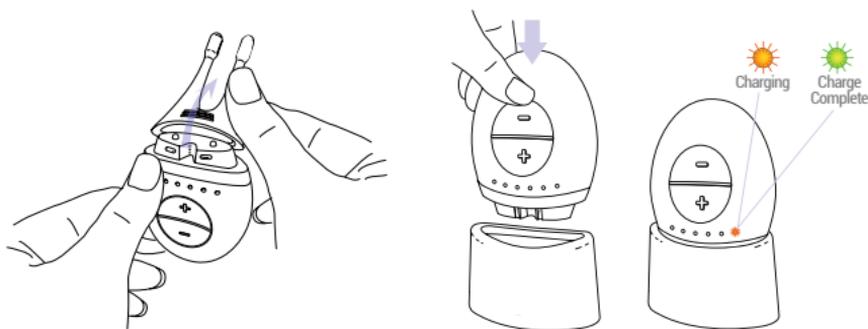


Figure 3. Placement of base unit on the charger.

- 4 Remember to charge the base unit every 48 hours or when you change the tip. The charging process should take less than 4 hours. An LED light turns green to indicate that charging is complete. The base unit may be removed or left on the charger when charging is complete (Figure 4).
- 5 If the TrueTear® device was fully charged and used briefly, it is not necessary to wait for the device to fully charge to use.



Figure 4. Remove or leave the base unit in the charger.

## ASSEMBLY

- 1 Ensure the base unit is fully charged if using the TrueTear® device for the first time (see CHARGING THE BATTERY).
- 2 Tear open the tip pouch at notch and remove the tip from the pouch by grasping the base (as shown in Figure 5). Avoid touching the hydrogel.

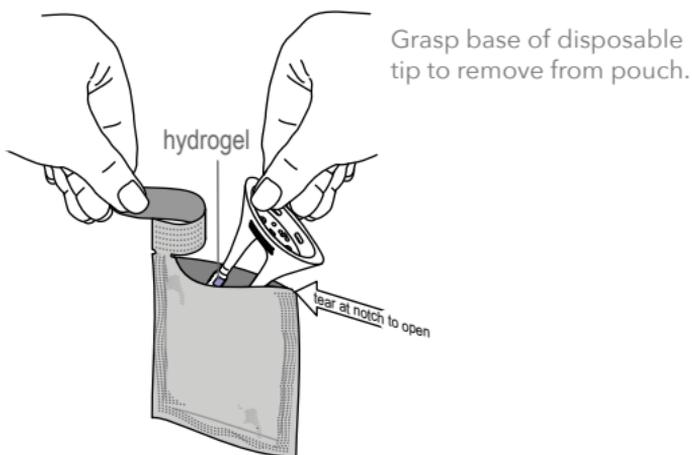


Figure 5. Remove the tip from the pouch.

- 3 Connect the tip to the base unit by aligning the post on the underside of the tip with notch on base unit, then rotate forward until the tip snaps into place, as shown in Figure 6.

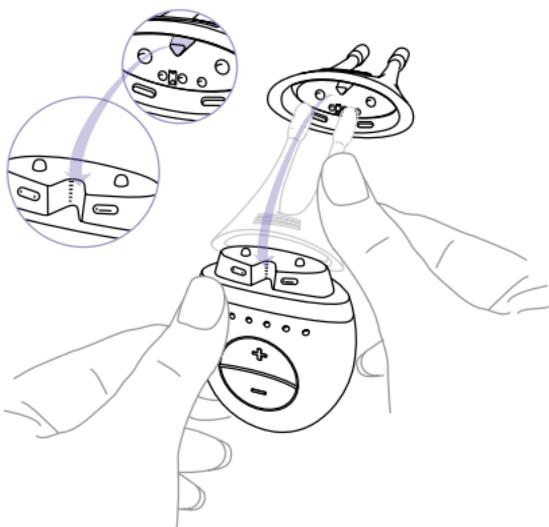


Figure 6. Align the tab to the notch for setup. The tip only fits one way.

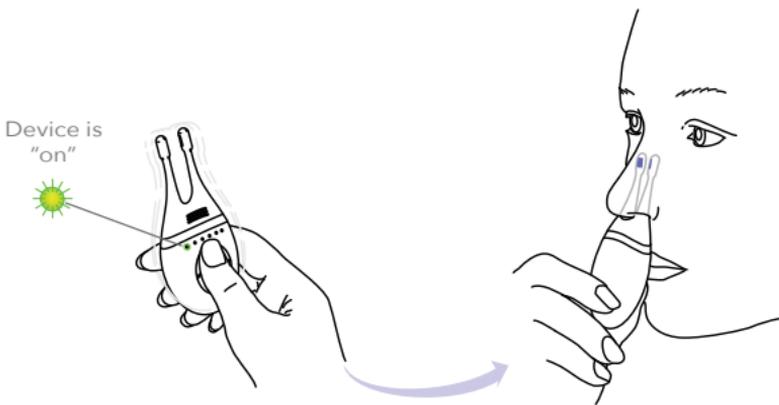
**IMPORTANT: DO NOT USE A DISPOSABLE TIP FOR MORE THAN 48 HOURS.** Tip should be replaced every 48 hours. Failure to replace the disposable tip causes the hydrogel to dry out and the TrueTear® device will not work properly.

## STIMULATION

There are 5 stimulation intensity levels. The base unit vibrates briefly when a button is pressed to indicate an increase or decrease in stimulation level. The blue LED light will be lit to indicate the stimulation level selected.

Your provider will confirm that you understand these instructions, including having you demonstrate the stimulation technique and the tearing response, prior to prescribing the TrueTear® device and, if necessary, at subsequent visits:

- 1 With the TrueTear® device fully assembled, hold the + button for 5 seconds to turn on the device. The LED indicator lights on the base unit flash, followed by a green LED light, which remains lit as shown in Figure 7.

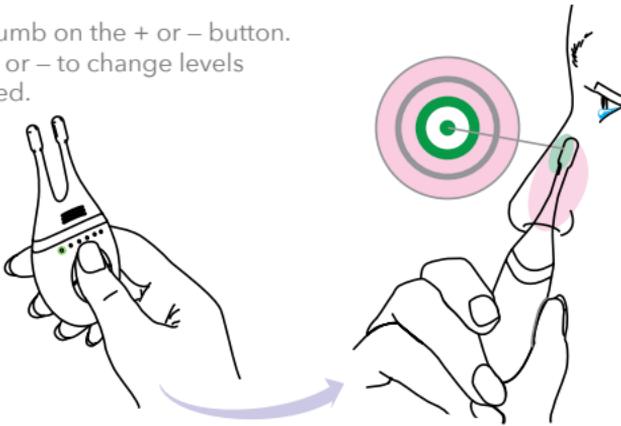


**Figure 7. Turning on the TrueTear® device and placing it into the nose.**

- 2 Press the + button to select a desired stimulation intensity level. Blue LED lights show the level selected.
- 3 Place thumb near buttons of base unit, then insert the tip into the nose with the buttons pointing towards your lips and face, as shown in Figure 7.
- 4 For effective stimulation, insert the tip all the way to the top and front of the nose, as shown in Figure 8.

Rest thumb on the + or - button.  
Press + or - to change levels  
if desired.

Insert tip into your nose,  
as far as is comfortable.



**Figure 8. Target zone for correct insertion of disposable tip.**

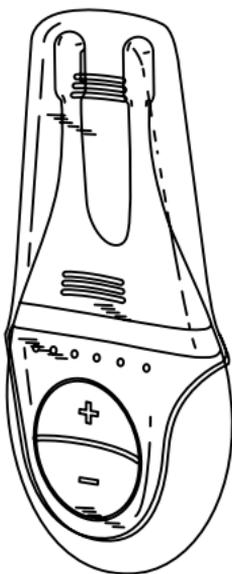
- 5 The + button is for increasing the intensity and the - button is for decreasing the intensity. You may gradually increase and adjust intensity (using the + and - buttons) until you feel a gentle tingling in your nose; this feeling lets you know that you are stimulating the correct tissue location and tears form. Stimulation should last no longer than 3 minutes (or 3 sequential cycles), but may be stopped sooner if you are satisfied with tear production.



**Figure 9. Adjust stimulation by pressing the + or - buttons.**

- 6 There are 5 levels. The base unit vibrates briefly when a button is pressed to indicate an increase or decrease in intensity level. The blue LED lights are lit to indicate the stimulation level selected (Figure 9).

- 7 Reposition the tip inside the nose for desired stimulation. The feeling should be mild at its maximum intensity.
- 8 Use a new tip and try again if you do not feel any sensation.
- 9 Remove the tip from your nose at any time if you feel uncomfortable during stimulation.
- 10 The TrueTear® device automatically turns off at the one (1) minute session limit. The device may also be turned off by pressing the - button for 2 seconds. The device vibrates and the LED lights turn off to indicate that the power has been switched off.
- 11 If you prefer a longer stimulation time, turn on the TrueTear® device again if it automatically turns off.
- 12 When finished, clean the TrueTear® device with an alcohol wipe, if needed (see CARING FOR YOUR DEVICE), prior to placing the cover on to protect the tip between uses (Figure 10).



**Figure 10. Cover attached to base unit to protect disposable tip.**

## RECOMMENDED STIMULATION SCHEDULE

Use the TrueTear® device at least twice a day, as needed. Stimulation longer than 3 minutes (or 3 sequential cycles) is not recommended, and you should wait for at least 60 minutes before proceeding to the next application. The device may be used for up to 30 minutes per 24-hour period and has a built-in single-day usage limit of 30 minutes. If this daily limit has been reached, the TrueTear® device will turn on and then off immediately. The device will not deliver stimulation.

## CARING FOR YOUR TRUETEAR® DEVICE

- 1 Use alcohol wipes to clean the cover, disposable tip, and device between uses. Avoid damaging the hydrogel.
- 2 Use alcohol wipes to clean the durable parts of the device including the base, charger, and cover (including the interior of the cover), as shown in Figure 11. Clean the inside of the cover weekly or more often if needed to ensure proper hygiene.

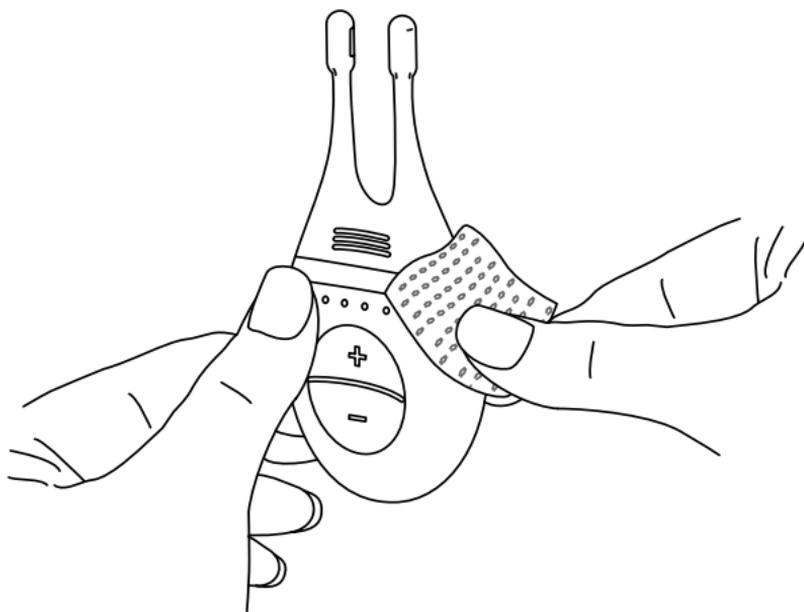


Figure 11. Cleaning with alcohol wipes.

- 3 Do NOT place or submerge the base unit, electrical plug, or charger in water or other liquid (Figure 12).

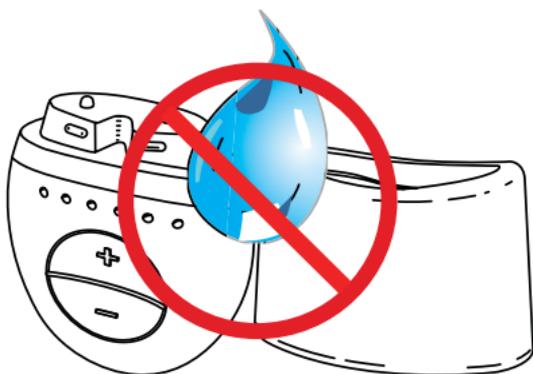


Figure 12. Do not rinse base unit or charger in water or any other liquid.

- 4 Handle with care. Store the TrueTear® device in a clean, cool, and dry location. Avoid exposure to extreme temperatures and humidity.

**CAUTION:** Exposure to direct heat can cause the hydrogel in the disposable tip to dry out and may result in ineffective stimulation. Avoid touching the metal contacts of the base unit or charger if either part is exposed to high temperature extremes (such as sitting in a hot car).

The expected service life for the base unit and charger is 3 years from the date of purchase. The expiration date of the disposable tips is provided on the product packaging.

## DISPOSAL AND REPLACEMENT

The base unit, charger, and AC adapter should be returned to the local distributor for recycling and disposal in accordance with any applicable local, state, and national regulations for disposal of electronic equipment, or otherwise returned to your provider or physician.

The tips may be discarded with regular trash. Contact your physician or the manufacturer if any portion of the device is not operating properly or if you need additional supplies.

## ***Bluetooth***<sup>®</sup>

The TrueTear<sup>®</sup> device includes *Bluetooth*<sup>®</sup> Smart wireless technology. This optional feature can be turned on to allow you to download your TrueTear<sup>®</sup> device data so you can view and track your usage on your smartphone via the TrueTear<sup>®</sup> mobile app. The *Bluetooth*<sup>®</sup> feature does not have to be on for you to use the TrueTear<sup>®</sup> device. For more information on using *Bluetooth*<sup>®</sup> and the TrueTear<sup>®</sup> mobile app, please visit [www.truetear.com/app](http://www.truetear.com/app).

The *Bluetooth*<sup>®</sup> word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Allergan is under license. Other trademarks and trade names are those of respective owners.

## **FCC COMPLIANCE**

This device contains FCC ID: T9JRN4020. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

## ELECTRICAL SPECIFICATIONS

Base unit output	Max current	5mA
	Max voltage	13V AC
	Max pulse width	300 $\mu$ s
	Frequency	30-60 Hz
Charger	Input	5V DC
	Output	6V AC
AC adapter	Input current	0.3A
	Input voltage	120-240V AC
	Output current	1.0A
	Output voltage	5.0V DC

## ELECTROMAGNETIC COMPATIBILITY

The TrueTear® device has been tested for immunity to electrostatic discharge, radio frequency interference, proximity RF fields from wireless equipment, and power frequency magnetic fields as specified in the table below. Emissions of energy are not likely to cause interference with nearby electrical equipment.

IEC 60601-1-2: 2014-02		
Basic Standard	Phenomenon	Test Specification
IEC 61000-4-2	Electrostatic discharge	Contact discharge: $\pm 8$ kV
		Air discharge: $\pm 15$ kV
IEC 61000-4-3	Radiated RF EM fields	10 V/m, 80-2700 MHz, 80% AM at 1 kHz
IEC 61000-4-6	Proximity fields from RF wireless communications equipment	3 Vrms, outside ISM bands between 0.15 MHz-80 MHz 6 Vrms, inside ISM bands between 0.15 MHz-80 MHz 80% AM (1 kHz)
IEC 61000-4-8	Power frequency magnetic fields	30 A/m at 50 Hz/60 Hz

## ENVIRONMENTAL OPERATING CONDITIONS

Ambient temperature range: 5°C-40°C (41°F-104°F)

Relative humidity range: 20%-90%

## SYMBOLS AND MARKINGS

Symbol	Description	Symbol	Description
	Type BF applied part	<b>R<sub>only</sub></b>	Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.
<b>IP22</b>	Base unit is protected against solid foreign objects of 12.5 mm $\varnothing$ and greater. Protection against vertically falling water drops when enclosure tilted up to 15°.	<b>IP21</b>	Charger is protected against solid foreign objects of 12.5 mm $\varnothing$ and greater. Protection against vertically falling water drops.
	Nonionizing electromagnetic radiation	 <b>Bluetooth®</b>	<i>Bluetooth®/Bluetooth®</i> Smart mark

# Summary of Clinical Studies

Two pivotal clinical studies have been conducted with the TrueTear® device. Both studies evaluated the device's safety and effectiveness in dry eye patients. Both pivotal studies (OCUN-009 and OCUN-010) demonstrated the device's capability temporarily to increase tear production during stimulation. OCUN-010 also demonstrated the TrueTear® device's capability to improve dry eye symptoms as a result of stimulation.

The next section summarizes both pivotal studies.

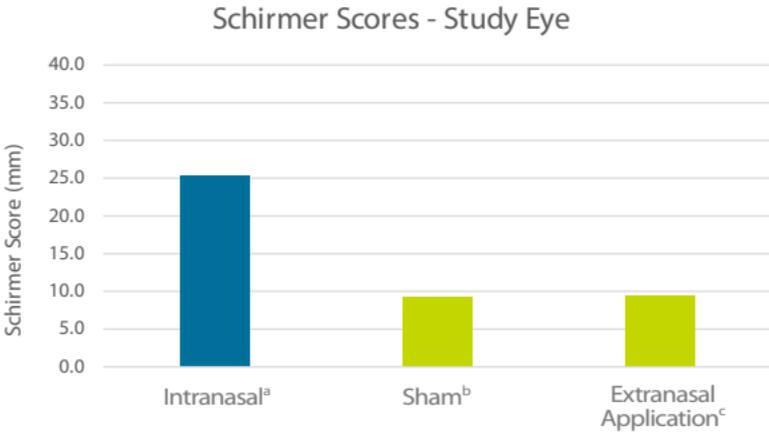
## **CLINICAL STUDY OCUN-009—SINGLE STUDY VISIT (ONE-TIME USE)**

This clinical study was designed to evaluate the effectiveness and safety of the TrueTear® device during use at a single study visit.

To qualify for enrollment in this study, potential participants were required to be 22 years of age or older and have dry eye symptoms based on the level of dryness in the eye(s) measured on a dry eye symptom scale. Potential participants were excluded from the study if the surface of the cornea had severe irregularities due to dry eye disease; if they had bleeding from the nose or previous sinus surgery or trauma; if they had coagulation problems (bleeding problems), a cardiac demand pacemaker, implanted defibrillator, or another implanted electronic device. Potential study participants with disabling arthritis or limited motor coordination were also excluded from participating in the study since these conditions could interfere with use of the TrueTear® device.

This study was conducted at two sites in the United States, and 48 people were tested. The study population, on average, was 57 years old. The majority of people who participated in the study were female. Each patient in the study underwent three applications of stimulation. On the study day visit, each subject received 3 applications in random order, with the TrueTear® device applied correctly, i.e., inside the nose, an inactive TrueTear® device applied inside the nose, i.e., no stimulation, and the TrueTear® device applied outside of the nose with stimulation.

In this study, the TrueTear® device used as intended resulted in a large increase in tear production. This is shown in the graph in Figure 13. The average Schirmer score (a standard measurement of Dry Eye that measures tear production) was approximately 25 mm during neurostimulation, compared with approximately 9 mm, i.e., less tear production, for the inactive control application and in people who used the TrueTear® device on the outside of the nose, where it would not be effective.



**Figure 13. Tear production score (Schirmer).**

<sup>a</sup> Intranasal = TrueTear<sup>®</sup> device applied correctly inside the nose    <sup>b</sup> Sham = Inactive TrueTear<sup>®</sup> device applied inside the nose  
<sup>c</sup> Extranasal = TrueTear<sup>®</sup> device applied outside of the nose with stimulation

The direct clinical benefit of temporarily increasing tear production as a therapy for patients with dry eye disease was not assessed as part of this clinical trial.

There were no adverse events that led to discontinuation from the study. Two adverse events were deemed related to or possibly related to the TrueTear<sup>®</sup> device. These included transient lightheadedness and intermittent nose itching. No changes of nasal tissue were observed with examination of the nasal cavity.

## CLINICAL STUDY OCUN-010–6-MONTH STUDY

This study was designed to evaluate the safety and effectiveness of the TrueTear<sup>®</sup> device to increase tear production at multiple time points during the study (Baseline and 7, 30, 90, and 180 days) for patients with dry eye symptoms.

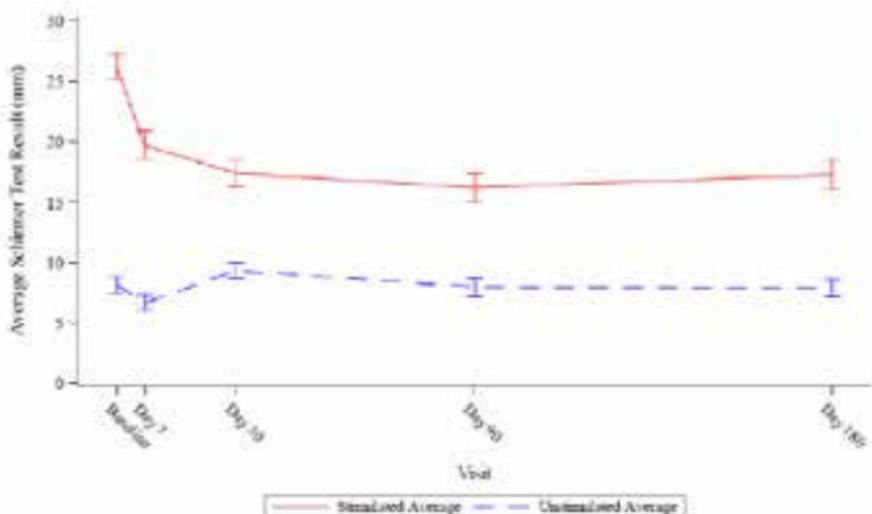
Eligibility for enrollment in this study required potential participants to be 22 years of age or older and have Dry Eye based on the level of dryness in the eye(s) measured on a dry eye symptom scale.

Potential participants were excluded from the study if the surface of the cornea had severe irregularities due to dry eye disease; if they had bleeding from the nose or previous sinus surgery or trauma; if they had coagulation problems (bleeding problems), a cardiac pacemaker, implanted defibrillators or another implanted electronic device. Potential study participants with disabling arthritis or limited motor coordination were also excluded from participating in the study since these conditions could interfere with use of the TrueTear<sup>®</sup> device.

Eligible participants were enrolled in the study and provided with a TrueTear® device for home use. Participants were instructed to use the TrueTear® device at least two times a day and as often as 10 times per day, as needed, and no more than three minutes per use. Study participants were examined at Baseline and days 7, 30, 90, and 180.

Ninety-seven (97) people with dry eye symptoms were enrolled at three sites in the U.S. The study population, on average, was 61 years old, and the majority of people who participated in the study were females.

Tear production at Baseline and each follow-up visit including 180 days (6 months) is shown in Figure 14. At 180 days, the study participants used the TrueTear® device with active stimulation and then without stimulation to evaluate whether there was a difference in tear production with and without active stimulation. In this study, tear production was much greater with active stimulation than without stimulation. In comparing the stimulated vs unstimulated tear production during the study, following the initial stimulation, there was a trend toward decreased effectiveness (tear production) with time with the use of the TrueTear® device; this trend appeared to plateau toward the end of the study. The mechanism for this decrease has not been identified and was not analyzed as part of the study. The average difference in Schirmer score (stimulated vs unstimulated) was 18.0 mm at Baseline (the first day of use), 13.1 mm at day 7, 8.1 mm at day 30, 8.3 mm at day 90, and 9.4 mm at day 180.



**Figure 14. Acute tear production at day 180.**

Symptom improvement from the start of the study was assessed at study day 7 and day 30 using a commonly used questionnaire called the Ocular Surface Disease Index (OSDI). Of the 97 subjects enrolled, 77 had severe dry eye symptoms at the start of the study and were seen following treatment. Of these subjects, between 18 (23%) and 33 (43%)

were shown to have meaningful improvement in their symptoms. There were more subjects with severe dry eye symptoms that had a meaningful improvement in symptoms from baseline as measured with the OSDI than the number with meaningful worsening of symptoms at day 7 and at day 30.

Safety and effectiveness of intranasal electrical stimulation was evaluated over a 6-month period of time. The safety and effectiveness of the TrueTear® device for longer periods of use has not been established.

In this study, safety was acceptable with no serious adverse events that were largely nasal in nature. The types and percentages for each type of AEs are presented in Table 1.

All device-related AEs (mostly mild discomfort or nosebleed) were evident to the patients and therefore self-limiting (with the exception of one case of chapped skin around the nostrils which resolved with over-the-counter medication) since patients could remove the device and discontinue stimulation at any time. The incidence of device-related AEs decreased over the course of the study, with the highest number occurring in the first month.

**Table 1. Proportion of Study Patients Experiencing Adverse Event Related or Possibly Related to TrueTear® Device**

Adverse Event Description	Number of Study Patients (Number of patients = 97)	Percentage
Nasal pain, discomfort, or burning	10	10.3%
Temporary electrical discomfort	5	5.2%
Nosebleed	5	5.2%
Nasal congestion	3	3.1%
Headaches	2	2.1%
Trace blood in nostril	2	2.1%
Facial pain	2	2.1%
Sore eye	1	1.0%
Sinus pain	1	1.0%
Pain around the eye	1	1.0%
Runny nose	1	1.0%
Nasal ulcers	1	1.0%
Lightheadedness	1	1.0%

\*Some patients had more than one adverse event.

The device was applied for an average of 1.7 times per day with an average daily application time of 130 seconds/day (2.16 minutes/day). Subjects applied the device a total of 27,338 times during the study, and the total device application time for the study was 34,726 minutes. Therefore, this small number of device-related mild AEs occurred in a large number of stimulation events. In all, 30 study patients (30.9% of those studied) had at least one of the adverse events listed in the above table.

# Warranty Information

Allergan warrants to the original purchaser of the TrueTear® device that your device is free from defects in materials and workmanship for three (3) years from the date of original purchase. This warranty extends to only the original purchaser and is not transferable. **Keep your invoice or receipt safe as this is your proof of purchase and the date marked on it shall be deemed the date of purchase.**

If during this three (3)-year period, the TrueTear® device does not function properly because of a defect in materials or workmanship, Allergan will replace it with a new device or equivalent product free of charge. The warranty of the replacement TrueTear® device will expire on the date of the original warranty expiration. The purchaser's exclusive remedy with respect to the TrueTear® device shall be replacement.

This warranty covers the original purchaser and cannot be transferred with sale or other transfer of the TrueTear® device to any other person or entity.

## EXCLUSIONS

**This warranty does not apply if the TrueTear® device has been:**

- Changed or modified by any person or entity other than Allergan.
- Serviced or repaired by any person or entity other than Allergan.
- Damaged by an act of God, external causes, misuse, abuse, negligence, accident, wear and tear, unreasonable use, use not in accordance with product instructions, failure to perform required maintenance, involvement of parts or components not supplied by Allergan or by other causes unrelated to defective materials or workmanship.

## **WARRANTY CLAIM PROCEDURE**

You must notify Allergan of the claimed defect within the warranty period by writing or calling: Allergan, 4410 Rosewood Drive, Pleasanton, CA 94588; Telephone: 1-866-502-TEAR (8327) and Fax: 1-855-637-4959.

The claim must include the date of purchase, model number, serial number, and a description of the claimed defect. Allergan's authorization must be obtained prior to returning the TrueTear® device. If authorized, the TrueTear® device must be properly packaged and returned in the TrueTear® Return Kit to Allergan. Allergan will pay all freight and transportation charges, where applicable, incurred in returning and replacing your TrueTear® device under this warranty.

## **MISCELLANEOUS**

REPLACEMENT AS PROVIDED UNDER THIS WARRANTY IS YOUR EXCLUSIVE REMEDY. ANY APPLICABLE IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO THE DURATION OF THIS WARRANTY. IN NO EVENT SHALL ALLERGAN, ITS SUPPLIERS, OR ITS DISTRIBUTORS BE LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES FOR BREACH OF ANY EXPRESS OR IMPLIED WARRANTY ON THE TrueTear® DEVICE. Some states do not allow limitation on how long an implied warranty lasts, and some states do not allow the exclusion or limitation of consequential or incidental damages, so the above limitations or exclusions may not apply to you.

This warranty gives you specific legal rights, and you may also have other rights, which vary from state to state. This warranty is valid only in the United States.

## NO OTHER WARRANTY

Unless modified in writing and signed by both parties, this warranty is understood to be the complete and exclusive agreement between the parties, superseding all prior agreements, oral or written, and all other communications between the parties relating to the subject matter of this agreement. No employee of Allergan or any other party is authorized to make any warranty in addition to those made in this warranty.

## Contact Information

If you wish to report a problem, please contact the provider who provided you with the TrueTear® device, or contact Allergan:

**Allergan, plc.**

4410 Rosewood Lane  
Pleasanton, CA 94588 USA  
1-866-502-TEAR (8327)  
TrueTear.com



t r u e t e a r ®

If your dry eye symptoms become intolerable or you experience any complications using the TrueTear® device, please contact your provider.



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