



EarPopper Pro Order Information		
Product Number	Description	Sale Unit
EP-3000 Pro	EarPopper, Office Version Includes 10 disposable tips and 1 9-volt battery	1 Per Box
EP-1000	Disposable Tips	50 Per Box <i>Non-sterile, Single Use</i>

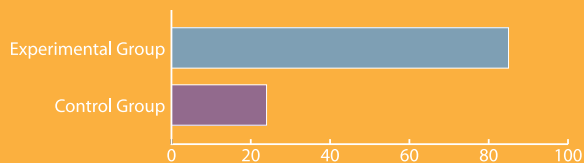
Healthcare providers interested in purchasing the EP-3000 Office Version should contact their medical supply company or Micromedics for additional information.

EarPopper Patient Order Information		
Product Number	Description	Sale Unit
EP-2100	EarPopper, Home Version Includes storage case and 4 AAA batteries	1 Per Box



The results are in...

In a four-year study sponsored by the National Institutes of Health involving children diagnosed with hearing loss from persistent Otitis Media with Effusion (OME), a few weeks of home treatment with the EarPopper restored hearing to normal in 85% of patients in the experimental group compared to 25% in the control group, without antibiotics or vent tubes.^[1]



The EarPopper can be used by both children and adults for such common conditions as:

- Middle Ear Effusion (Otitis Media with Effusion)
- Eustachian Tube Dysfunction
- Hearing loss
- Ear pain and pressure caused by airline travel
- Ear fullness caused by colds, allergies, sinusitis

The EarPopper... safe, simple, superior results.

About Micromedics

Micromedics, Inc. develops, manufactures and markets various proprietary medical devices, including ear, nose and throat products, Instru-Safe instrument protection trays, FibriJet® biomaterial applicators, the EarPopper® device for treating problems associated with Eustachian Tube Dysfunction and negative pressure in the middle ear, and Santa Barbara Medco/Physicians' Choice® ear protection and ear care products.



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treatment and prescribing guide



safe, simple, superior results



[1] "Non-Surgical Home Treatment of Middle-Ear Effusion and Associated Hearing Loss in Children. Part I: Clinical Trials" ENT JOURNAL Sept. 2005. ("Part II: Clinical Trials - Follow Up" ENT JOURNAL Oct. 2005)

What is the EarPopper™?

The EarPopper is a safe, simple, noninvasive, non-drug related prescription device for treating such common conditions as Otitis Media with Effusion, Aerotitis/Barotitis (caused by rapid elevation changes), and Eustachian Tube Dysfunction in children and adults.

Based on the Politzer Maneuver, the EarPopper delivers a safe, constant, regulated stream of air into the nasal cavity. During the moment of swallowing, the air is diverted up the Eustachian Tube, clearing and ventilating the middle ear. The EarPopper relieves negative ear pressure and allows accumulated fluids to drain.

Designed for treatment in the office with the professional model EP-3000 Pro or at home with the EP-2100 Home Version (Rx only), the EarPopper is the safe, simple solution with superior results.

Healthcare Provider Instructions

Treatment can be performed in the practitioner's office with the EP-3000 Office Version. Some situational conditions can be treated successfully in the office and may only require one or two treatments.

The following conditions require a prescription be written for the patient for the EP-2100 Home Version with specific treatment recommendations given by the provider based on the condition being treated.

- OME
- Eustachian Tube Dysfunction
- Serious Otitis Media
- Middle ear pressure from frequent airline travel, scuba diving, etc.

Using the EarPopper: It's as Quick as a Swallow!

(Always refer to instruction manual for proper use and care.)

1. Hold nosepiece firmly against nostril (creating a good seal is crucial). Press other nostril closed with finger.
2. Press button to begin airflow.
3. After 2–3 seconds of air flow, swallow with mouth closed while the motor is running. (Hint: holding a small amount of liquid in mouth prior to procedure may aid in swallowing.)
4. Repeat procedure for other nostril.
5. Wait 5 minutes then repeat steps 1–4.

One good indication that the procedure has been carried out successfully is to listen for a pitch change in the sound of the motor while swallowing. This is due to a temporary slowing of the motor due to back-pressure. You can experience this sound by plugging the hole with your finger while the device is running. This is the same sound you should hear when you swallow. If you don't hear the pitch of the motor change, you may not have a good seal with the nostril or the patient's mouth may be open.

NOTE: If the patient does not feel any change in the ear, repeat the procedure, making sure the EarPopper remains firmly against the nostril as the patient swallows with mouth closed.

Recommended Treatment Guidelines

Treatment of Otitis Media with Effusion (OME)

Treatment should be done twice a day, once in the morning and once in the evening, for 7 to 11 weeks — a protocol based on a clinical study. In this study group, hearing was restored to normal in 74% of patients after 7 weeks of treatment and 85% after 11 weeks of treatment^[1]. There appears to be no contraindication to extended use.

One treatment consists of four total swallows. Use the EarPopper once in each nostril, then repeat the procedure again in 5 minutes (in each nostril) for a total of four swallows.

Remember, the treatment only occurs at the moment of swallowing **while the device is running.**

Helpful hint: Where compliance could be an issue in young children, a step-wise approach is recommended:

1. Hold the EarPopper nosepiece beneath the nostril and push the power button, to allow the child to get used to the sensation of air entering the nose, as well as the sound of the device.
2. Hold the EarPopper nosepiece against one nostril and press the other nostril securely shut.
3. To encourage the child to swallow with his mouth closed, give the child a sip of water to hold in his mouth, repeat Step 2, and ask the child to swallow the water while the device is running.

Recommended Treatment Settings

In younger children (≤ 7 yr), use the low setting (I) for the first week. Use the high setting (II) for the remainder of the treatment. If the patient experiences discomfort using setting (II), then switch to setting (I).

For adults and older children (> 7 yr), the high setting (II) is the recommended treatment setting. If the patient experiences discomfort using setting (II), then switch to the low setting (I).

The EarPopper will not cause an ear infection. However, if the patient develops acute Otitis Media or other types of acute infection such as an upper respiratory infection during the treatment period, the EarPopper treatment can be temporarily suspended. Treatment can then be resumed after the infection resolves.

Treatment of Eustachian Tube Dysfunction and Aerotitis/Barotitis

A clinical study has demonstrated that negative pressure in the middle ear can be relieved by use of the EarPopper^[2]. Patients can use the EarPopper as needed. Often relief will occur after only one treatment.

Eustachian Tube Dysfunction can cause development of negative pressure in the middle ear due to a lack of ventilation and can lead to Otitis Media with Effusion, Ear Block or Aerotitis/Barotitis.

Aerotitis/Barotitis is a result of negative middle ear pressure caused by rapid elevation changes (airplane, diving, mountain climbing, etc.).

Recommended Treatment Settings

For children and adults use the low setting (I). If the negative pressure does not resolve, use the high setting (II). If the patient experiences discomfort using setting (II), then switch to setting (I).

Prescribing the EarPopper

1. The healthcare provider writes a prescription for "EarPopper" and gives it to the patient with the EarPopper **Patient Information** sheet.
2. The patient can fill their EarPopper EP-2100 prescription through most pharmacies. Purchasing information is provided in the **Patient Information** sheet.

CONTRAINDICATIONS

Patients who will be using the device at home should be instructed **not** to use the EarPopper in the presence of severe ear infection, upper respiratory infection, heavy nasal congestion or cold symptoms without first consulting their healthcare provider.

ADVERSE REACTIONS

Patients may feel a pressure change and/or "pop" in one or both ears after use of the EarPopper. The ears may feel temporarily "clogged" after inflation. This sensation is an indication that the procedure is working correctly and it should decrease within a few minutes.

[1] "Non-Surgical Home Treatment of Middle-Ear Effusion and Associated Hearing Loss in Children. Part I: Clinical Trials" ENT JOURNAL Sept. 2005. ("Part II: Clinical Trials – Follow Up" ENT JOURNAL Oct. 2005)

[2] "Efficacy of a Modified Politzer Apparatus in Management of Eustachian Tube Dysfunction in Adults" American Academy of Audiology Journal 10: 496-501 (1999)

