

CUSTOM EARMOLD USER MANUAL



- i. **INSERTION**
Rotate the mold slightly forward and place the tip (canal) of the mold into your ear canal. Then rotate the mold to the rear of your head, pushing the tip down your ear canal.



- ii. **REMOVAL**
Pull up gently on the top-rear of your ear to break the seal. Gently pull the earmold out from the rear. Then gently rotate the earmold forward, which removes the tip from your ear canal.



MANUFACTURED BY:

MICROSONIC, INC., AMBRIDGE, PA 15003, USA
1.800.523.7672 visit us www.microsonic-inc.com
FDA REGISTRATION NUMBER: 2523819
FDA DEVICE LISTING #D194890

IMPORTANT LEGAL NOTICE

THIS USER MANUAL SHALL BE PROVIDED TO THE PROSPECTIVE USER BY THE DISPENSER OF THE HEARING AID IN ACCORDANCE WITH CFR.21.801.421(C). REFER TO WARRANTY CARD TO LOCATE MANUFACTURING DATE AND SERIAL NUMBER

- INVOICE DATE IS THE MANUFACTURING DATE
- INVOICE NUMBER IS THE SERIAL NUMBER

KEEP WARRANTY CARD EVEN AFTER EXPIRATION. THE INFORMATION ON WARRANTY CARD MAY BE USED TO IDENTIFY PRODUCTS SUBJECT TO PRODUCT RECALL OR WITHDRAWAL

1 IMPORTANT SAFETY INFORMATION:

- i. Hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.
- ii. In most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.
- iii. Use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lip-reading.
- iv. The technical data for your hearing aid is provided in user manual accompanying the device.

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2 HAZARD WARNINGS

- i. Use hearing aids according to instructions provided with the device.
- ii. Modifications to the earmold that were not explicitly approved by Microsonic are not permitted. Such modifications may damage your ear.
- iii. Harmful if swallowed. Consult your physician immediately if swallowed. Children have to be supervised against swallowing small hearing aid parts including the earmold.
- iv. Consult your hearing care professional if:
 - You have pain, inflammation, or skin irritation in your ear
 - Frequent ear wax buildup occur

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3 PRODUCT DESCRIPTION

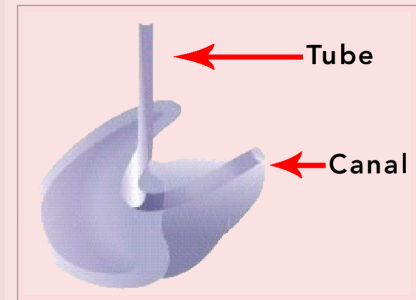
This custom earmold is manufactured to be used exclusively with air-conduction hearing aids. An earmold is the individually fabricated ear insert that channels the sound reproduced by a hearing aid through the ear canal to the eardrum. In most fittings and most configurations, custom earmolds have the following objectives:

- i. to provide a satisfactory acoustic seal to couple the hearing aid to the ear acoustically
- ii. to modify acoustically the signal produced by the hearing aid
- iii. to be comfortable to wear for an extended period of time

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4 INSTRUCTIONS FOR USE

The right fit is essential for best performance. Poorly fitted earmolds may also cause feedback or lack of comfort.



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5 CARE AND MAINTENANCE

- i. Cleaning
 - a. Spray Microsonic Earmold Cleaner on a facial tissue. Gently wipe the entire surface of earmold. Allow it to dry before wearing.
 - b. If there is a wax buildup in your earmold's sound channel and/or vent, have it cleaned by your hearing healthcare professional.
- ii. Storing

Keep the earmold in dryer cup or electric dryer when not in use. Refer to instructions provided with the dryer. The regular use of Microsonic Dehumidifier will extend the life of your earmold and hearing instrument.

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- (vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.
- (vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- (viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)



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NOTE: Always clean your earmolds thoroughly before storing for an extended period of time.

- iii. Changing the tube

If the earmold tubing is hard, cracked or discolored, it has to be replaced. Contact your hearing healthcare professional for replacement.

6 PRODUCT SAFETY

- i. Contact your hearing healthcare professional (or office where you purchased the earmold) if earmold is damaged or clogged.

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IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid.

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- ii. Never attempt to repair or modify. Your hearing healthcare professional will troubleshoot & repair, or initiate the remake process with us. Avoid excessive heat or direct sunlight. Such conditions may damage your earmold.
- iii. Never use harsh chemicals to clean your earmolds.
- iv. Never use a microwave or other household heating devices to dry your earmolds.



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The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician.

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WARNING TO HEARING AID DISPENSERS

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- (i) Visible congenital or traumatic deformity of the ear.
- (ii) History of active drainage from the ear within the previous 90 days.
- (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.
- (iv) Acute or chronic dizziness.
- (v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

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Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

CHILDREN WITH HEARING LOSS

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

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