

EARMOLD

USER MANUAL

Index:

1.- Medical Devices	2
2.-Your Microson Earmold	2
3.- Description of your earmold	2
4.- Manufacturer	2
5.- Description of symbols	2
6.-Intended Purpose	3
7.-Operating principle	3
8.- Safety information	3
9.-Side effects	4
10.- Contraindications	4
11.- How to use your earmold	4
12.-Maintenance and cleaning	5
13.-Time life	5
14.-Troubleshooting Guide	5

1.- Medical Devices

Device name: Earmold

2.- Your Microson earmold

You have purchased a Microson earmold for RIC hearing aids manufactured by Sivantos, Starkey, GN, Oticon or Phonak, so first we would like to thank you for the trust you have placed in us and in our product.

The selection of the earmold will be made by the hearing health specialist taking into consideration the type of hearing instrument, hearing loss and canal morphology of the patient.

The earmold is shaped and formed by MICROSON to conform to your ear. This means that the earmold can only be used by you and not by others.

We hope that this product will be to your utmost satisfaction and meet all your expectations. The Microson team thanks you for your trust and wishes you every success in your fitting.

3.- Description of your earmold



4.- Manufacturer

This manual is valid for the earmolds to be connected to a RIC type hearing aid.



It is important that you read and follow the instructions in this manual for the proper use and maintenance of the device, as well as to avoid injury or damage.








The technical specifications can be downloaded from the website

<https://microsoncs.gaes.es/webMicrosondownloads/>, document ID: DS-0100-003-EN (RIC earmold).

Nm

5.- Description of symbols

	Indicates the need for the user to consult the information in the instructions for use, such as warnings and precautions
	Indicates the need for the user to consult the instructions for use.
	Indicates the date on which the product was manufactured. Identifies that the product was manufactured in Spain.

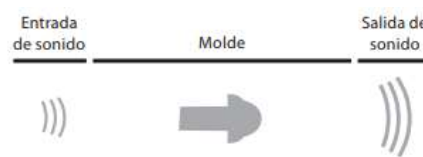
	Indicates the temperature limits within which the product may be safely exposed.
	The CE mark indicates compliance with the requirements of the medical device regulation 2017/745.
	Indicates the manufacturer's catalog number.
	Indicates the serial number.
	Indicates medical device product.
	Manufacturer of the product.
	Identifies a carrier containing the unique product information.

6. Intended Purpose:

Earmold is an adapted device that is intended to be placed into the patient ear canal natural orifice. The device combined with hearing aid permits to compensate for impaired hearing. The device is shaped and formed by MICROSON to conform to the patient's ear. This is a reusable device. The device is intended for adults and children. The device is not intended to be used by people with mental disability, due to the high risk of misuse of the device.

7. Operating Principle

The earmolds are responsible for conducting the sound and allowing the adaptation of the device to the patient ear. The device is compatible with RIC hearing aids.



RIC Hearing Aid is a type of hearing aid that can be partially adapted to the EEC (External Ear Canal). It is like a behind-the-ear hearing aid, but in this case the receiver goes inside the ECC, fitted via earmold.

8. Safety information

- The impression of the ear canal must be done by a hearing health specialist.
- The fitting of your earmold should be done by a medical professional or hearing health specialist.
- The prescription and adaptation of the hearing aids must be performed by a hearing health specialist.
- For child use, always handle and use under adult supervision.
- If you have any doubts or problems (i.e. fitting or removal of the earmold), please consult your hearing health specialist.
- If any part remains in the ear, only a medical professional can remove it.
- The earmold transmits the sound generated in the hearing aid, thus any excess of sound pressure will pass directly through the earmold to the user's eardrum.

- Protect your earmolds from moisture, heat sources.
- Do not use your earmolds to shower, bathe or spray your hair.
- Avoid heavy blows to the earmolds.
- Never use microwaves or other heat-emitting devices to dry the earmold.
- Do not use water, solvents or oil to clean your earmold.
- Do not ingest or deform.
- Under no circumstances modify or attempt to repair the device (e.g. if any part becomes detached), this will void the product warranty and Microson will no longer be responsible for the product for safety, reliability, and performance.
- For more information regarding your hearing aid and accessories, please refer to your hearing aid manual.
- In case of malfunction of the device, consult a hearing health specialist.
- The temperature limits within which the product may be exposed are between -20°C to 60°C.
- The maximum operating temperature limit (together with the hearing aid) will be 40°C.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- The device is not intended to be used with injured skin, just in intact skin.

9. Side effects

The product is made of silicone or acrylate and may contain nylon if it has a wire extractor. In case of allergic reaction/irritability do not use the device and consult your hearing center.

10. Contraindications

The device is not intended to be used by people with mental disability, due to the high risk of misuse of the device.

11. How to use your Earmold

11.1 Earmold connection with your RIC hearing aid



1. Be sure to attach the earmold and hearing aid on the same side

Right = earmold in dot red

Left = earmold in dot blue

2. Connect the earmold with your RIC hearing aid.

11.2 Placing the earmold in your ear



1. Hold the earmold by its outer part and insert the earmold into your ear canal
2. Move the earmold until it fits perfectly in your ear canal.
3. Place your RIC hearing aid behind your ear.

11.3 Remove the earmold from your ear

1. Remove your hearing aid from behind your ear.
2. Slightly pull your lobe to help dislodge your earmold and then slowly pull the earmold from the outside until the earmold is removed from your ear canal.
- 3.-Store the device in an appropriate box storage

12. Maintenance and cleaning



1. Clean the earmolds immediately whenever use with a soft cloth.
2. Use cleaning wipes intended for earmolds cleaning.
3. Use accessories provided by the hearing aid manufacturer, if needed.
4. In case of filter clogging (if present), go to your hearing centre for replacement,

13. Time Life

“Time life” means the projected time of proper functioning of the medical device, preserving its functional characteristics for which it was designed, without presenting potential risks for the operator and the patients.

The end of the life of your earmold will be when it has suffered deterioration due to aging, damage or any significant change that affects the adjustment of the earmold or hearing loss.

For disposal of the product at the end of its lifetime, please consult your professional store.

The life expectancy for an earmold is 1 year, with a special mention for children's earmolds where the recommendation to change the earmolds will be reduced to every 3-6 months.

14. Troubleshooting Guide

SYMPTOM	POSSIBLE CAUSES	SOLUTION
Hearing Aid not loud enough	1. Earmold/Tube covered or blocked	1. Remove obstruction and clean the earmold.
	2. Incorrect coupled with hearing aid	2. Re-couple the earmold with the hearing aid.
Intermittent output sound	1. Earmold/Tube covered or blocked	1. Remove obstruction and clean the earmold.
The earmold does not fit the ear	1. Change in the morphology of the ear (growth, weight gain, etc)	1. Visit your hearing professional store.

Información del fabricante

MICROSON S.A.U.

Tel. de contacto 900 303 304

NIF A08612079

C/ Pere IV, 160, 08005 Barcelona

Carsten Fusch

CE xxxx