Neuro - Cochlear Implant System

Swim Kit Instructions for Use



CE 0459 (2020)



Swim Kit solutions



Thin Safety Line

Retention Tubing



"Note": Indicating a note/tip



"Caution": Potential hazard that could result in patient/user temporary injury or hospitalization if not avoided.



"Warning": Potential hazard that could result in patient/user serious injury or death if not avoided.

The statements of this instruction manual are believed to be true at the date of the publication. The pictures are not contractually binding. Availability of the products depends on the local registration.

Oticon Medical (In NEURELEC) reserves the right to make changes to the design, characteristics and models without prior notice. The only warranty Oticon Medical (In NEURELEC) makes, is the express written warranty extended on the sale or rental of its products.

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Introduction

The Swim Kit is a waterproof solution for Neuro 2 sound processor allowing water immersion for 2 hours at depths up to 3 metres. This accessory keeps your processor dry during water activities, such as swimming, boating or kayaking.

This is your guide on how to use the Swim Kit. We strongly recommend that you read it carefully before using the Swim Kit for the first time.

This document provides additional information in relation to the instructions for use of the Neuro 2 sound processor. It should complement and be read in conjunction with the instructions for use of the Neuro 2 sound processor (including warnings, cautions, disposal and environmental conditions), provided in the Neuro 2 packaging (in paper and electronic version) and available on the Oticon Medical website.

Intended Use

The Swim Kit is an accessory that provides extended protection to the Neuro 2 sound processor when used in water or humid and dusty environments.

Indications

As an accessory, the Swim Kit has no specific indication. Indication of the Neuro Cochlear Implant System applies.

Contraindications

As an accessory, the Swim Kit has no specific contraindication. Contraindications of the Neuro Cochlear Implant System apply.

Undesirable Side Effects

No undesirable side effects were associated with the Swim Kit use.

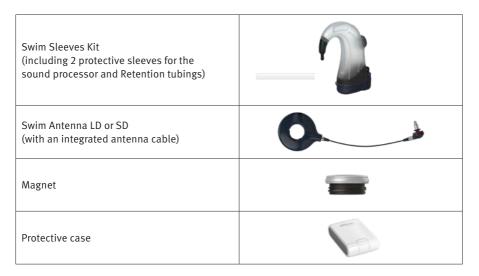
Intended User Profile

The device is operated by the patient, the caregiver and the audiologist. **Patient:** person implanted with a cochlear implant, non-healthcare professional, without relevant specialized training.

Caregiver: adolescent or adult with a minimum of 8 years of education, nonhealthcare professional, without relevant specialized training **Audiologist:** healthcare professional with at least 3 years of studies in audiology, with specialized training in the use of the device.

Packaging content

The Swim Kit consists of the following main parts:



Thin Safety Line	Č
Ear Plug Retention Kit	

Items ordered specifically to match your Neuro 2

When ordering a Swim Kit, make sure to select the variant that match your current Neuro 2 configuration:

- Magnet strength: The magnets for the Swim Kit are identical to those for the regular Neuro 2 antennas.
- Swim Antenna type: The Swim Antenna is marked with $\stackrel{\ref{eq:sense}}{\longrightarrow}$ and it comes in two variants like the regular Neuro 2 antenna: Zti SD or Zti LD.

Markings on the Swim Antenna





Caution: Make sure to use the same type of antenna (LD or SD) and magnet force as those vou use with your regular configuration.

Using the Swim Kit



Warning: The small parts may be a choking hazard if swallowed. In this case, immediately seek medical assistance.



Warning: Check all the parts of the Swim Kit before use and do not use it in case of damage.



Warning: The Swim Sleeve is designed to be used for one year or 50 times depending on which one is reached first. Always carefully inspect the Swim Sleeve before and after use. If you observe any changes to the sleeve material or tightness, stop using the sleeve and order new ones (Swim Sleeves Kit).



Caution: To avoid burns when using the Swim Kit in a bright sunlight, ensure that it has not overheated before putting it on the ear. Do not expose the sound processor to the temperatures outside the operating range (0°C to 50°C with Li-ion battery).



Caution: The Swim Sleeve and its dedicated Swim Antenna must always be used together. *If used separately, your sound processor will not be kept dry.*



Caution: Sound level can be slightly different when using the Swim Kit. This can typically be managed by adjusting the Neuro 2 volume. If this does not provide the desired audibility, please contact your hearing care professional.



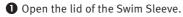
Note: The retention tubing will gradually change its mechanical properties over time. Make sure to replace it when it no longer provides sufficient retention.

Preparing the Swim Kit and the sound processor for use

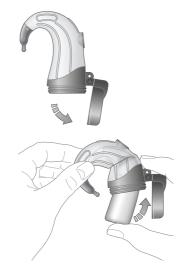
- Mount the magnet on the Swim Antenna. Refer to the "Placing and changing the magnet in the antenna" section in the sound processor Instructions for Use.
- **2** Mount a rechargeable battery on the sound processor. Refer to the "Connecting and changing the battery module" section in the sound processor Instructions for Use.
- **3** Activate the tamper-proof system to secure the battery module during the mounting of the Swim Kit. Refer to the "Locking and unlocking the battery module" section in the sound processor Instructions for Use.

Inserting the sound processor into the Swim Sleeve

Note: Always use rechargeable batteries to power the sound processor when using the Swim Kit. Zinc-Air batteries rely on fresh air supply to produce power and therefore can not he used inside a Swim Sleeve



- Inspect the Swim Sleeve to ensure it is free from any dirt, dust and hair fragments in the opening for the Swim Antenna connector, and the opening and lid for the processor insertion.
- **③** Insert the sound processor fully into the Swim Sleeve. During the insertion, bend the sleeve and carefully lead the sound processor hook to its place to avoid it is stocked to the sides



Ensure the sound processor is fully inserted so that its antenna connector is perfectly aligned with the opening in the Swim Sleeve.



Hold the angled Swim Antenna plug with the cable perpendicular to the Swim Sleeve and insert the plug fully into the sound processor and sleeve. The red seal ring must touch the sleeve.



 Rotate the plug 90 degrees clockwise to lock it in place. The antenna cable should end up being parallel to the sleeve.



Close the lid of the Swim Sleeve.

8 Place the system on your ear.



Removing the sound processor from the Swim Sleeve

1 Remove the system from your ear.

2 Disconnect the dedicated Swim Antenna.

3 Open the Swim Sleeve.

4 Remove the sound processor.

Care and maintenance

Caution: After each use of the Swim Kit, ensure to rinse the parts under fresh running water and shake off all water drops. Do not use any corrosive or abrasive substances to clean the accessory. Do not wipe it dry using a cloth that could potentially leave remnants on the sleeve as they may affect the tightness of the sleeve next time it is used. Let the parts dry fully and keep it stored in the protective case until the next usage.



Caution: Do not use the desiccation drying system for drying the Swim Kit.



Caution: Always remove the Swim Sleeve from the sound processor before drying and storage of the sound processor.



Caution: The Swim Antenna cable is permanently fixed to the Swim Antenna and cannot be disconnected.

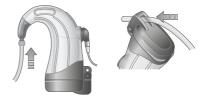
Securing the Swim Kit to the ear or your clothes

The Swim Kit provides three complementary ways of securing the Swim Kit to your ear or your clothes. It is recommended to use them individually or in combination.

Securing the Swim Kit with the retention tubing

To use:

Before placing the system on your ear, mount a retention tube: push one end of the tube onto the Swim Sleeve hook and then push the other end of the tube through the hole at the bottom of the lid.



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To remove:

Pull out the tube to remove it from the bottom of the lid and the Swim Sleeve hook.

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• Place the antenna in the correct position.

G If needed, cut the end of the tube with

2 Place the system on the ear.

Pull the free end of the tube to tighten the system to the ear.

a pair of scissors.





Securing the Swim Kit with the Ear Plug Retention Kit

Warning: Small parts may be a choking hazard if swallowed. In this case, immediately contact emergency medical services. The Ear Plug Retention Kit is not intended for use with children under 3 years old.

Users seeking better retention of their Swim Kit when worn on the ear are advised to use the Ear Plug Retention Kit. This is an instant fitting solution, and it could be replaced by a custom ear mould. The Ear Plug Retention Kit is used to prevent the sound processor from falling off the ear. It can be used during sports, lively activities or for everyday use. It fits both right and left ears.

The illustrations below are for left ear configuration. For right ear configuration illustrations please see page 23.

To fit the Ear Plug Retention Kit to your ear:

Select and mount an earpiece (A) on the adaptor (B) by first placing the pointed end of the earpiece over the rim of the adaptor opposite the tube adaptor part and then by pulling the other end (loop).

There are four earpiece sizes, recognisable by the following markings on the ear moulds: Very Small: "-"; Small: "S"; Medium: "M" and Large: "L".



2 Push the tube firmly onto the adaptor.



Place the Ear Plug Retention Kit inside the ear with the loop of the earpiece pointing towards the back of the head.

Remove the Ear Plug Retention Kit and change the earpiece if the selected one does not fit well.



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5 With the Ear Plug Retention Kit placed in the ear, rotate the tube part to an upper vertical position.

6 Place the Swim Kit on your ear. Check the length of the tube and cut it if needed. The tube should cover 5–6 mm of the hook. If needed, request assistance to determine the appropriate tube length.









Firmly push the tube over the hook to finalise the setup.



Right ear configuration. See pages 19–22 for description of corresponding steps.



To remove the Ear Plug Retention Kit from your ear:

Pull the earpiece out of the ear and remove it together with the Swim Kit.

Securing the Swim Kit with the Thin Safety Line

The Thin Safety Line is designed to help you avoid dropping your sound processor during physical activity or in other situations where the device could fall off. It is intended to be used by adults and children older than 36 months.

To use:

• Remove the elastic ring from the Thin Safety Line by loosening the loop and by passing the clip through the loop.



2 Attach the open loop directly to the hole on the back of the Swim Sleeve. Push the loop through the Swim Sleeve hole.

- 3 Pass the clip through the loop and tighten the loop.
- 4 Place the Swim Kit on your ear.
- **5** Attach the clip to your swimwear.

To remove:

Release the clip and remove the Thin Safety Line from the Swim Sleeve hole.







Physical Characteristics

Swim Sleeve	Dimensions: 61 mm (Height) x 50 mm (Width) Weight (alone): 5.8 g
Swim Antenna	Dimensions: 30 mm (Diameter) x 5 mm (Height); 140 mm (Length) Weight (alone): 3.2 g
Lifetime Swim Sleeve	In normal conditions of operations, transportation and storage, the Swim Sleeve lifetime is 1 year or 50 times depending on which one is reached first.
Lifetime Swim Antenna	In normal conditions of operations, transportation and storage, the Swim Antenna lifetime is 2 years.
Lifetime Ear Plug Retention Kit	In normal conditions of operations, transportation and storage, the Ear Plug Retention Kit lifetime is 2 years.
Lifetime Thin Safety Line	In normal conditions of operations, transportation and storage, the Thin Safety Line lifetime is 2 years.
Swim Kit operating conditions	Temperature: 0°C to 50°C Relative humidity: waterproof, 2 hours at 3 meters Atmospheric pressure: 700 hPa to 1060 hPa (10.15 psi to 15.37 psi)
Swim Kit storage conditions	Temperature: -30°C to 60°C Relative humidity: 10% to 90% Atmospheric pressure: 700 hPa to 1060 hPa (10.15 psi to 15.37 psi)

Symbols

③	Refer to instruction manual
C€ 0459	Marking for European Community with notified body number
\triangle	Caution
Ĺ	Consult information for use
ww.oficonmedical.com	Electronic operating instructions
REF	Catalogue number
LOT	Batch code
~	Date of manufacture
	Manufacturer
Ŕ	Type B applied part

X	Dispose of electrical components in accordance with your local regulations
\bigotimes	Keep away from young children
Ť	Keep dry
X	Temperature limit
%	Humidity limitation
(¢+¢)	Atmospheric pressure limitation
8	Do not use if package is damaged
Ţ	Fragile, handle with care
IP68	IP6X: Dust-tight IPX8: Protected against the effects of continuous immersion in water
3	Waterproof

Warranty duration

All the elements of the Swim Kit have a one year warranty period except for the magnet, which is guaranteed for three years. Make sure to use the sound processor and its accessories according to the instructions. Any incorrect usage or modification of the equipment will lead to cancellation of the warranty.

For the warranty terms, please consult the Neuro 2 Warranty Certificate, provided in Neuro 2 packaging and on the Oticon Medical website (www.oticonmedical.com).

Swim Sleeve usage tracker

The Swim Sleeve is designed to be used for one year or 50 times depending on which one is reached first.

By using the following tables you can keep track by marking a box after each use.

Please replace the Swim Sleeve when all boxes in a Tracker are marked.

Tracker 1

Tracker 2

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