

Retifix Vision Stim Mask (VSM)

Instructions for Use



Important: Please read

Disclaimer of liability: **Retifix Vision Stim Mask may only be used together with the Retifix Vision Enhancer (R-C101W) and in compliance with the manufacturer's instructions.** The use of non-compliant device might impair the function of the mask and consequently result in patient harm (burn, electric shock). Sole responsibility for correct application is assumed by the user and is beyond control of Retifix GmbH. Retifix GmbH do not assume any responsibility and liability for damage caused by misuse.

Description

The Retifix Vision Stim Mask is a mask with integrated electrodes, which transmit electrical microcurrents to the patient's skin around the eyes.

Intended Use

The Retifix Vision Stim Mask is intended to transmit electrical microcurrent to the patient's skin for use with Retifix Vision Enhancer, in order to support the management of Retinitis Pigmentosa.

Indications

The Retifix Vision Stim Mask is indicated for managing Retinitis Pigmentosa. The microcurrent electrical therapy stimulates retinal cells and improves blood flow.

Contraindications

CAUTION: Read also contraindications in the Retifix Vision Enhancer instruction manual.

- Do not use on cancerous lesions or other lesions in the treatment area.
- Do not use over swollen, infected, inflamed areas, or skin eruptions.
- Do not use on scarred areas for at least 10 months post-surgery.
- Do not use if you have had recent eye surgery, injuries, or active eye infections.

Side effects

- Possible skin irritation or hypersensitivity under the electrodes may occur.
- Possible allergic skin reaction to the electrodes may occur.
- Temporary (~10-15min) skin marks may occur due to mechanical pressure of the electrodes.

Warnings

- Apply only to normal, intact, clean, and healthy skin.
- This device cannot replace medication.
- Consult your doctor if you have any doubts.
- Discontinue use and do not increase the intensity level if you experience discomfort.
- For single patient use only.
- Mask has a limited lifetime: Replace the mask if you feel no more tingling during usage or not later than 12 months.
- Use only with Retifix Vision Enhancer (R-C101W) and accessories. Read the Retifix Vision Enhancer before operating the device.

Notice regarding serious incidents

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information of the manufacturer can be found at the end of this IFU.

Procedure

Preparation

CAUTION: It is recommended to wash and degrease the skin, and then dry it.

- Ensure the VSM is clean and dry before use.

Connection

CAUTION: Check electrode connections before each use.

- Attach the provided electrode wires to the designated ports on the VSM.
- Connect the opposite end of the electrode wire to the Retifix Vision Enhancer (R-C101W).
- Position the mask over your eyes, aligning it comfortably to cover the eye area completely.
- Adjust the elasticated strap, ensuring that all electrodes are in good contact with the skin.

Program Selection

CAUTION: Read Retifix Vision Enhancer instruction manual.

- Power on the Retifix Vision Enhancer (R-C101W).
- Select one of the 17 available treatment programs that best suits your individual needs.
- Increase the intensity of the selected treatment until a light, painless tingling is felt on the skin below the electrodes.

Usage

CAUTION: Do not exceed max daily usage: 20 minutes.

- Use the device twice daily for 10 minutes per session.

- During the session, you can perform other activities such as reading or watching television, thanks to the mask's design.

Post-use

- After the session, gently remove the VSM.
- Disconnect the electrode wire.
- Clean the VSM with a soft, slightly damp cloth. For heavier dirt build-up, use a mild detergent. Do not use aggressive or alcohol-based detergents.
- Place the VSM back into the box in its designated slot

Storage

CAUTION: Keep the device out of reach of children.

CAUTION: Keep the original packaging with label for product identification and traceability.

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight.

Disposal

Separation, re-cycling or disposal of device and packaging shall follow local country and government legislation, where applicable.

Manufacturer

 Retifix GmbH Mellingerstrasse 19, 5413 Birnenstorf AG, Switzerland, E-Mail: info@retifix.com



Batch code



Catalogue number



Caution



Medical device



Unique Device Identifier



Consult instructions for use



Keep away from sunlight



Keep dry



Temperature limit



Humidity limitation



Manufacturer



Date of manufacture



Authorized Representative in the European Union



CE marking