INSTRUCTIONS FOR USE

EN

eyeWatch

DESCRIPTION

The eyeWatch implant is designed to allow physicians to adjust intraocular pressure in patients suffering from glaucoma. The eyeWatch implant contains a deformable drainage tube, which drains aqueous humor from the anterior chamber into a bleb formed under the conjunctiva. The eyeWatch should be always connected in series to an eyePlate. It is not recommended to use the eyeWatch implant as a stand-alone device. The eyeWatch encompasses a mechanism that permits the selective compression of its internal elastic tube, thus altering its fluidic resistance. The control of the fluidic resistance is performed noninvasively using the eyeWatch Pen single-use during the surgery or the eyeWatch Pen (office) post-operatively.

Figure 1: The eyeWatch implant (top left), its reading/adjustment device, the eyeWatch Pen single-use (top right), the eyeWatch Marker (bottom left) and the eyeWatch Tweezer (bottom right)

CONTENTS (QTY)

- eyeWatch implant (1)
- eyeWatch Pen single-use (1)
- eyeWatch Marker (1)
- eyeWatch Tweezer (1)

INDICATIONS FOR USE / INTENDED USE

The eyeWatch implant, when used in conjunction with a non-valved aqueous shunt, is intended to reduce intraocular pressure (IOP) by channeling aqueous humor out of the anterior chamber. The fluidic resistance of the eyeWatch implant can be adjusted non-invasively during the peri and early post-operative period.

INTENDED POPULATION

The eyeWatch is indicated for adults suffering from glaucoma where medical and/or conventional surgical treatments have failed.

EYEWATCH ACCESSORIES

The eyeWatch Pen single-use is intended to perform the adjustment and the reading of the eyeWatch implant's functional position, in a sterile environment.

The eyeWatch Pen has been designed to help the physician perform two essential functions:

1. Read the functional position of the eyeWatch implant.
2. Perform a noninvasive adjustment of this functional position, in order to adjust the drainage characteristics (fluidic resistance) of the implant.

The eyeWatch Pen exists in two versions: a polycarbonate sterile single-use version used during the surgery, and an aluminum version used for follow-up adjustments. The single-use version is provided in the same package as the eyeWatch implant.

The eyeWatch Marker is intended to outline the shape of the eyeWatch implant on the sclera to facilitate the realization of the scleral bed and the surgical positioning of the eyeWatch implant.

The eyeWatch Tweezer is intended to hold the eyeWatch implant for its insertion in the eye.

EYEWATCH ADVANTAGES

The advantages of the eyeWatch technology are:

- Noninvasive adjustment of the fluidic resistance of the device over a wide range of values, thereby enabling the intraocular pressure to be maintained within desired limits over extended periods
- Apply high fluidic resistance in the early days/weeks after surgery to prevent hypotony
- Lower fluidic resistance at longer term, to compensate for increased resistance due to fibrosis at the outlet port

EXPOSED MATERIALS

Implant materials to which patients are exposed: PEEK Optima (Long-term implantable synthetic polymer) $\simeq$ 75mm^2, Nusil MED-4830 (Long-term implantable biocompatible silicone) $\simeq$ 5mm^2, EPO-TEK MED 301-2 (Biocompatible medical-grade epoxy glue) $<$ 1 mm^2. Patients may have also transient contact with medical grade polycarbonate HP2REU.

CONTRAINDICATIONS

The implantation of the eyeWatch implant is contraindicated if one or more of the following conditions exist:

- Diagnosis of angle-closure glaucoma, neovascular glaucoma.
- Patient with ocular malformations such as microphthalmia.
- Patient with corneal opacifications or irregularities that may interfere with IOP measurements.
- History of previous corneal transplant surgery.
- Patient with concurrent inflammatory/infective eye disorder.

WARNINGS

The implanting surgeon should be familiar with the instructions for use. The integrity of the package, the eyeWatch implant and the eyeWatch Pen single use should be examined. Blister should be opened carefully and in a sterile environment. If the package is opened but not used, the implant should be returned to the manufacturer for exchange. The eyeWatch implant, like every other ophthalmic implant and filtering device, shall be handled with care. Especially the eyeWatch implant, due to its thin and curved geometry and fragile nature should be handled gently and with extreme care. The surgeon should not exert high forces during implantation. The eyeWatch implant shall not be dropped-off, the forceps used to grip the eyeWatch implant should not have sharp teeth. The eyeWatch implant shall not be handled in close vicinity of a source of strong magnetic field such as power units or strong permanent magnets. The surgery shall not be terminated without completion of a functional test to verify that the eyeWatch implant can be adjusted (ability to change the functional position of the implant with the eyeWatch Pen single-use) and that drainage (flow of aqueous humor through the device) is positively assessed when the implant is in an open position.

PRECAUTIONS

The opening of the packaging and the handling of the devices shall obey the Good Clinical Practice in surgery. The rules to keep the implant sterile throughout the entire surgery shall be strictly followed. The eyeWatch implant should not be used if sterility is compromised and should be replaced by a new one. The eyeWatch implant as well as the eyeWatch Pen single-use, eyeWatch Tweezer and eyeWatch Marker are intended for single use only. To prevent cross-contaminations and/or ineffective treatment, these devices shall not be re-used and/or re-sterilized.

The product box should be stored in a dry environment and at room temperature (15°C-25°C).

The needle used to create the corneo-scleral tunnel should have a 25G diameter. Prior to inserting the eyeWatch implant into the eye, care should be given to prevent possible hemorrhage (hyphema). The presence of blood into the tube of the eyeWatch implant could create clots, blocking the aqueous humor drainage and making the device non-functional. When necessary, a conventional space maintainer should be used instead of injecting viscoelastic in the anterior chamber to prevent such viscoelastic from entering and potentially clogging the eyeWatch implant.
The eyeWatch implant contains a magnet and thus tends to stick to ferromagnetic tools.

EXPECTED CLINICAL BENEFITS

The primary clinical benefit of the eyeWatch implant, when connected to a non-valved glaucoma drainage device (GDD), is that it can lower the IOP of the patient by at least 47% after 1 year follow-up. Evidence of such benefit is demonstrated in the Swiss clinical study (*NCT02554214*), which reported a 51% IOP reduction. The mean IOP in that study was reduced from 24.4mmHg to 11.2mmHg after 1 year. Additional evidence of IOP lowering is also demonstrated in two studies by Roy et al. from 2020 and 2021, demonstrating a mean IOP reduction of 56% and 55% at 1-year respectively.

Another clinical benefit that the eyeWatch implant brings to the patients, as it lowers the use of anti-glaucoma medications by at least 47%, when connected to a non-valved GDD. In the Swiss and United Kingdom clinical studies (*NCT03210571*), the use anti-glaucoma medications in patients decreased by 72% and 65% respectively. In the Swiss clinical study, patients which were taking in average 2.1 medications before eyeWatch surgery, reduced their use in average to 0.8 after 1 year. For the United Kingdom study, the anti-glaucoma medication use was reduced from 2.0 to 1.1 after 1 year. Such benefit is confirmed by the two published studies by S.Roy et al. (2022 and 2021) which demonstrated a reduction in medications of 93% and 73% respectively.

The summary of safety and clinical performance will be available on the EUDAMED database upon notify body approval on the following webpage: ec.europa.eu/tools/eudamed. It will also be available upon request.

COMPLICATIONS AND RESIDUAL RISKS
The main complications (side effects) that may happen during or after the implantation of the eyeWatch implant are similar to those encountered after any type of filtering surgery and might comprise (not an exhaustive list): suprachoroidal hemorrhage ; hyphema; choroidal effusion/detachment; flat/shallow anterior chamber; conjunctival erosion; wound leak; corneal edema; bleb encapsulation, dysesthesia; cystoid macular edema; aqueous misdirection; hypotony maculopathy; vitreous hemorrhage; retinal detachment; endophthalmitis or blebitis; iritis; tube erosion; tube-cornea touch; tube obstruction by blood clot, iris or vitreous; cataract progression; motility disorder; diplopia; malignant glaucoma; no light perception.
Residual effects include: high ocular pressure, cornea edema, choroidal effusion, flat/shallow chamber, conjunctival erosion, wound leak.
Adverse device events related specifically to the eyeWatch implant itself include: mechanical blockage of the eyeWatch implant's rotative mechanism.

Adverse events and/or complications that may reasonably be regarded as related to the eyeWatch and not previously expected in nature, severity or incidence must be reported to competent authority of the member state in which the user and/or patient is established and to Rheon Medical SA at:

E-mail: info@rheonmedical.com

MRI INFORMATION
A patient bearing one eyeWatch implant can be safely scanned in an MR system meeting the following conditions:

- Horizontal bore MR system with a static magnetic field of 1.5 Tesla or 3 Tesla.
- Gradient magnetic fields lower or equal to 19 T/m.
- Whole body averaged SAR (Specific Absorption Rate) limited to Normal Operating Mode (WB-SAR ≤2W/kg).
- The association eyeWatch + eyePlate is expected to produce a maximum temperature rise of 2°C at both 1.5T and 3T for a WB-SAR of 2W/kg after 1h of continuous scanning
- The MR image quality may be compromised if the imaging area of interest is in the exact same area of the implant. Some manipulation of scan parameters may be required to compensate for the artifact. In non-clinical testing, the image artifact caused by the device extends approximately 38 ± 3 mm from the device when imaged with a spin echo pulse sequence and 38 mm with a gradient echo, both at 1.5T.

If the patient undergoes an MR scan, it is highly probable that the functional position of the implanted eyeWatch is altered. It is therefore recommended that the patient gets the eyeWatch implant functional position checked by his/her ophthalmologist and re-adjusted, if necessary.

EXPIRATION DATE
The sterility expiration date is clearly labelled on the packaging. Sterility is assured until the expiration date, as long as the packaging is not damaged. The eyeWatch should not be used after the date indicated. If a device is expired, contact your local Rheon Medical customer service representative for instructions.

EXPECTED LIFETIME
The eyeWatch implant is intended for long-term use. The physician should monitor the patient postoperatively for proper maintenance of IOP as performance may change over time. If IOP is not adequately maintained, the physician should consider appropriate additional therapy to maintain the target IOP.

USER PROFILE
The eyeWatch implant and its accessories are intended to be used by surgeons who have experience with drainage devices in glaucoma surgery or after receiving a training from a Rheon Medical representative or a trainer designated by Rheon Medical.

DISPOSAL OF THE DEVICE
In the event of damaged/unsterile or defective explanted device, contact Rheon Medical for product return policy. Return the implant with proper identification and reason for return. Label return as biohazard.
After implantation is completed, the disposal of the eyeWatch accessories shall comply with biohazardous disposal practices of the healthcare facility.

PATIENT INFORMATION
It is recommended that each patient receive information regarding glaucoma implants prior to the decision to implant.

IMPLANT CARD
An implant card is supplied in the implant packaging. This card should be given to the patient with instructions to keep as a permanent record of the implant and to show the card to any eye care practitioner or physician that requests it in the future.

INSTRUCTIONS FOR USE
OPERATIVE ACTIVITIES
IMPLANTATION PROCEDURE
The eyeWatch implant is placed using a surgical technique analogous to the one used for other Glaucoma Drainage Devices (Fig. 2). After a proper opening of the conjunctiva (fornix or limbus based), the eyePlate is placed under the conjunctiva and sutured at 10-12 mm from the limbus. Once the sclera is exposed, the eyeWatch Marker can be used at 1 mm from the limbus to mark the sclera and outline the shape of the eyeWatch implant using commercially available ink. After proper dissection of the scleral bed, a 25-gauge needle is inserted into the anterior chamber at 1-1.5mm from the limbus at an angle parallel to the iris plane. The eyeWatch implant can be held with the eyeWatch Tweezer: the large part of the eyeWatch Tweezer go over the top part of the eyeWatch implant. Once the implant is flipped upside down, the nozzle of the eyeWatch implant is inserted with caution and without applying force, all the way into the anterior chamber through the ostium created by the needle. The eyeWatch implant is secured in place onto the sclera by stitching in the device through the two stitch holes using a 9-0 Prolene (or similar) suture with a round-shape needle. After trimming the tube of the eyePlate to the right length, the tube is then connected to the rear end connector of the eyeWatch device (Outlet, Figure 2). A scleral patch (or similar) is then sutured in place, covering the eyeWatch implant, using the appropriate type of suture. Finally, the conjunctiva is carefully closed using an appropriate suturing technique.

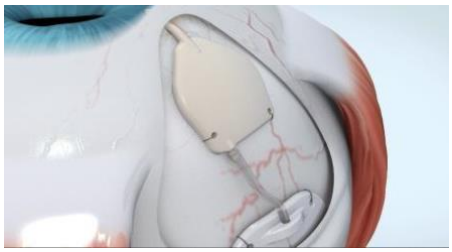

Figure 2: Schematic representation of the implant placement above the sclera and under the conjunctiva.

CONTROL PROCEDURE
After proper positioning of the eyeWatch implant into the eye, the surgeon should perform a functional test using the eyeWatch Pen single use the following way:

1. Read the actual position of the magnetic disk. This is done by placing the compass of the eyeWatch Pen single use centrally above the eyeWatch implant, at a distance of 1-2 mm while aligning the pointer of the compass (white arrow) within the direction of the eyeWatch's nozzle.
2. Adjust the implant drainage opening using the eyeWatch Pen single-use toward the fully open position
3. Verify with the eyeWatch Pen single-use that the eyeWatch implant mechanism opening is indeed set at the fully open position (position 0)
4. Visually check the patency of the eyeWatch implant, as evidenced by sufficient aqueous humor outflow from the distal end of the eyeWatch implant.
5. Adjust the eyeWatch implant drainage opening using the eyeWatch Pen single-use toward the fully closed position (position 6)
6. Verify with the eyeWatch Pen single-use that eyeWatch implant drainage opening is indeed set at the fully closed position
7. Visually check the shut-off of the eyeWatch implant seen by no further aqueous humor outflow from the distal portion of the eyeWatch implant.
8. Only upon achieving a satisfactory functional test may the surgical procedure be further performed until completion. Should the functional test not be satisfactory, the eyeWatch implant shall be exchanged for a new one and the test performed again. The malfunctioning eyeWatch implant should be returned to the manufacturer for inspection.

EXPLANTATION
In case of clinical emergency where the surgeon considers that the eyeWatch implant should be explanted, the procedure should follow the following steps: After a proper anesthesia, preparation of a paracenthesis and injection of an ophthalmic viscoelastic device into the anterior chamber to maintain the anterior chamber pressurized. Perform a fornix based incision of the conjunctiva. Careful dissection of the scleral patch and the scarring tissue surrounding the eyeWatch implant. Disconnection of the tube linked to the seton tube. Cutting of the sutures securing the eyeWatch implant onto the sclera. Gentle grasping the eyeWatch implant using adequate forceps and retrieval of the eyeWatch implant. Depending on the clinical conditions, a new eyeWatch implant may be inserted to replace the initial one. Conversely, a seton tube or any other draining system could be implanted instead. Finally, close carefully the conjunctiva using the appropriate sutures.

HOW SUPPLIED

Each eyeWatch box contains: one eyeWatch implant and one eyeWatch Pen single-use inside a sterile double blister and one eyeWatch Marker and one eyeWatch Tweezer inside a sterile blister (X-Ray irradiation) guaranteeing sterility and integrity during storage and transport.

POST-OPERATIVE ACTIVITIES

USE OF THE EYEWATCH PEN TO ADJUST THE IOP

The adjustment of the fluidic resistance of the eyeWatch implant is performed using the external adjustment device (eyeWatch Pen). The eyeWatch Pen (office version, non sterile) for post-operative adjustments is not delivered sterile because it is not intended to be in contact with exposed body tissues or fluids.

The adjustment procedure includes the following four sequential phases:

Step 1: Control of the functional position of the eyeWatch implant before adjustment. The physician who wishes to perform an adjustment (increase or decrease) of the hydraulic resistance of the eyeWatch implant needs first to determine the current angular position of the magnetic disk of the eyeWatch implant. The physician asks the patient to remain still and with the head in a vertical position. The physician then pulls on the eyelid, exposes the sclera and places the center of the compass flat at 1 to 2 mm from the eye, right above the center of the eyeWatch implant (see schematic in Fig. 3), while keeping the pointer of the compass aligned with the direction of the eyeWatch's nozzle. The magnetic needle is colored to indicate the "north pole" and the transparent cover slip or the outer rim of the compass housing contains graduations for easier reading of the angular position of the needle. The physician can thus read the angular position indicated by the compass (Fig. 3, step 1).

Step 2: Adjustment. Once the angular position is read, the operator flips the eyeWatch Pen 180 degrees to bring the eyeWatch Pen's magnet above the eyeWatch implant and magnetically couple the external magnet to the internal magnetic disk. The operator then pivots the eyeWatch Pen around the implant to any direction wished, thus forcing the internal magnetic disk to rotate accordingly (Fig. 3, step 2 & 3).

Step 3: Verification. The physician repeats Step 1 and obtains a reading of the new angular position of the implant. If unsatisfied, he can repeat Step 2 and 3 (Fig. 3, step 4).

Step 4: Validation of adjustment. The physician performs a measurement of the IOP using a tonometer or similar device. This can be done only after IOP has reached the new steady state (time estimated in the order of 15 – 30 minutes). If IOP is now within the physiological or desired range, the procedure is complete. Otherwise, further adjustment is required.

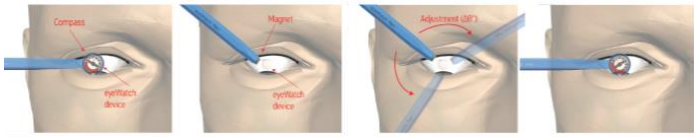

Figure 3: Sequence of steps necessary to adjust the eyeWatch implant: 1) Read the angular position of the implant using the compass of the eyeWatch Pen. 2) Flip 180° the eyeWatch Pen and place the Pen's magnet near the periphery of the implant and at the position indicated by the compass. 3) Drag the pen to the direction wished. 4) Read the new angular position of the implant using the compass of the eyeWatch Pen.

Note 1: The eyeWatch Pen's magnet generates a magnetic field in its vicinity, which is about 150 times higher than the magnetic field of the Earth. Such a strong magnet is necessary to be able to turn the eyeWatch implant's internal magnetic disk and there is no interference problems with the much weaker geomagnetic field.

Note 2. The eyeWatch implant allows for a relative adjustment of its fluidic resistance and by no means provides for a direct adjustment of the intraocular pressure of the patient. The physician needs to measure IOP before and after the adjustment, using appropriate means (i.e., tonometry) and, if necessary, repeats the adjustment until the desired IOP is achieved.

Note 3. The eyeWatch implant is intended to provide adjustability for the first 3 months post-operatively, where common complications due to hypotony often occur. To avoid excessive fluidic resistance in case the implant's rotative mechanism gets blocked, Rheon Medical recommends to set the eyeWatch implant in a 'open' fluidic position (i.e., position 0 or 1), from six to eight weeks after its implantation, if the condition of the patient allows it, for example when a resistive filtering bleb has formed.

Note 4. Rheon Medical recommends the consulting ophthalmologists to have two eyeWatch Pens in their office. In case of suspected damage of the eyeWatch Pen due to accidental drop or other environmental damage, the spare one can be used to test the functionality of the damaged eyeWatch Pen. To perform such test, the user shall approach the external magnet of the spare eyeWatch Pen close to the compass of the suspected non-functional one and move it circularly around the compass rim to check whether the compass is moving accordingly . If the compass moves and aligns with the external magnet, the eyeWatch Pen is functional. If not, it is recommended to send the non-functional eyeWatch Pen back to Rheon Medical for inspection.

Note 5: The final decision to use or not use the eyeWatch Marker and eyeWatch Tweezer is on the surgeon's responsibility and should be based on his/her own clinical judgment and experience.

Figure 4: The compass of the eyeWatch Pen with the different positions available. '0' defines the fully open position where the outflow is not restricted when '6' is the fully closed position where the eyeWatch is maximally restricting the outflow. A movement counterclockwise decreases the fluidic resistance (6 towards 0) or clockwise increases the fluidic resistance (0 towards 6).

Symbol	Meaning	Symbol	Meaning
	Consult Instructions for Use		Do Not Use if Damaged Package
STERILE R	Sterilized Using Irradiation	SN	Serial Number
	Double sterile barrier	LOT	Lot number
	Single sterile barrier	MD	Medical Device
	Do Not Reuse		Use by [YYYY-MM-DD]
	Do Not Resterilize		Manufacturing date [YYYY-MM-DD]
	Manufacturer	MR	MR Conditional
REF	Catalogue number	EU REP	European authorized representative
	Keep dry		Temperature limit

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