INSTRUCTIONS FOR USE

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eyeWatch implant and eyeWatch Pen single-use

DESCRIPTION

The eyeWatch system comprises the eyeWatch implant and the eyeWatch Pen single-use (Fig. 1). The eyeWatch system 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 or a Baerveldt Glaucoma Implant. It is not recommended to use the eyeWatch device 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.

eyeWatch implant eyeWatch Pen single-use

Figure 1: The eyeWatch system, comprising the eyeWatch implant (left) and its reading/adjustment device, the eyeWatch Pen single-use (right).

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 advantages of the eyeWatch technology are:

- Noninvasive adjustment of fluidic resistance of the shunt 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 resistance at longer term, to compensate for increased resistance due to fibrosis at the outlet port

INDICATIONS FOR USE

The eyeWatch system is indicated for patients suffering from glaucoma where medical and/or conventional surgical treatments have failed. The eyeWatch system is intended to drain aqueous humor from the anterior chamber to the subconjunctival space and to regulate non-surgically the intraocular pressure during the early post-operative period.

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. If the package is opened but not used, the implant should be returned to the manufacturer for exchange. The eyeWatch system, 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 implant shall not be dropped-off, the forceps used to grip the device should not have sharp teeth. The 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 device 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 eyeWatch implant and the eyeWatch Pen single-use are supplied sterile in two sealed separate bags. Both devices are sterilized by irradiation. 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. The eyeWatch implant as well as the eyeWatch Pen single use are intended for single use only. To prevent cross-contaminations and/or ineffective treatment, the eyeWatch implant and the eyeWatch Pen single use shall not be re-used and/or re-sterilized. The product box should be stored in a dry environment and at room temperature.

The needle used to create the corneo-scleral tunnel should have a 26G diameter. Prior to inserting the implant into the eye, care should be given to prevent possible hemorrhage (hyphema). The presence of blood into the tube of the 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 device.

The eyeWatch implant contains a magnet and thus tends to stick to ferromagnetic tools.

MRI INFORMATION

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

- Horizontal bore MRI system with a static magnetic field of 1.5 Tesla or 3 Tesla.
- Gradient magnetic fields lower or equal to 19 T/m.
- B0*IdB0/drl product lower or equal to 48 T^2/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.

KNOWN COMPLICATIONS / ADVERSE REACTIONS

The main known complications or adverse reactions are associated with the filtering surgery and might comprise (not an exhaustive list): prolonged IOP control troubles in the form of IOP spikes; flat or shallow chamber; ocular hypotony; leaks at the level of the filtering bleb; inflammation and/or infection of the filtering bleb (blebitis); filtering bleb fibrosis and encystment; increased risks of developing cataract; iritis associated with anterior uveitis; enhanced and accelerated fibrosis of the filtering bleb; extrusion of the implant; exposure of the draining tube; ocular movement limitation in lateral or upper/lower gaze; eye irritation; hyphema; choroidal or retinal detachment; endophthalmitis; tube erosion; tube touch to cornea; macular or corneal edema; tube block by iris; diplopia; vision alteration. Mechanical blockage of the eyeWatch's rotative system is rare but may occur, entraining higher IOP if the implant is in a relatively closed position.

LIFETIME

The eyeWatch device can be implanted during 5 years.

USER PROFILE

The eyeWatch is intended to be used by surgeons who have experience with drainage devices in glaucoma surgery.

PATIENT INFORMATION

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

IMPLANT CARD

An ID 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.

PREOPERATIVE ACTIVITIES

PREPARATION STEPS

The preparation for the filtering surgery using the eyeWatch system does not significantly differ from that of conventional filtering surgery, with or without

classical drainage tube. The anesthesia, the disinfection of the eye and the sterile draping are absolutely similar.

EQUIPMENT REQUIRED

The use of the eyeWatch system does not require any specific equipment, other than standard surgical equipment used in ophthalmic surgery.

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). A seton tube is placed under the conjunctiva. A 26-gauge needle is inserted into the anterior chamber through the center of the "blue line" at an angle parallel to the iris plane. The nozzle for the eyeWatch implant is inserted all the way into the anterior chamber through the ostium created by the needle. The device is secured in place within the sclera by stitching in the rear of the device through the two stitch holes using a 9-0 Prolene suture with a round needle. The tube of the seton tube is then connected to the rear end connector of the eyeWatch device (Figure 2). A scleral patch is then sutured in place using the same type of suture. Finally, the conjunctiva is carefully closed using an appropriate suturing technique.

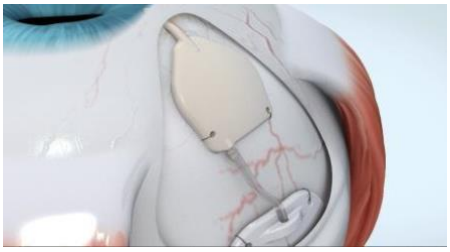

Figure 2: Schematic representation of the implant placement above the sclera and under the conjunctiva.

CONTROL PROCEDURE

After proper positioning of the device 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 device, at a distance of 1-2 mm while aligning the pointer of the compass with 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 implant drainage opening is indeed set at the fully open position (position 0)
4. Visually check the patency of the device, as evidenced by sufficient aqueous humor outflow from the distal end of the eyeWatch device.
5. Adjust the implant drainage opening using the eyeWatch Pen toward the fully closed position (position 6)
6. Verify with the eyeWatch Pen single use that implant drainage opening is indeed set at the fully closed position
7. Visually check the shut-off of the device seen by no further aqueous humor outflow from the distal portion of the eyeWatch device.
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 implant shall be exchanged for a new one and the test performed again. The malfunctioning eyeWatch device should be returned to the manufacturing for inspection.

ACCESSORIES

The eyeWatch implant and the eyeWatch Pen single use are delivered sterile inside a double Tyvek® pouch, guaranteeing sterility and integrity during storage and transport. Although the eyeWatch device is designed to sustain significant contact forces, it is recommended to handle it gently using standard blunt surgical equipment (forceps). No special delivery system is required for the surgical placement of the eyeWatch implant.

APPLICATION OF MEDICATION DURING OPERATION

No specific medication needs to be used or applied during the implantation of the eyeWatch device.

EXPLANTATION

In case of clinical emergency where the surgeon considers that the implant should be explanted, the procedure should include the following steps: Local anaesthesia (e.g. retrobulbar or peribulbar anaesthesia). Preparation of a paracenthesis and injection of viscoelastics to maintain the anterior chamber. Fornix based incision of the conjunctiva. Careful dissection of the scleral patch and the scarring tissue surrounding the device. Disconnection of the tube linked to the plate. Cutting of the Nylon sutures securing the eyeWatch onto the sclera. Gentle grasping the eyeWatch using the dedicated forceps and retrieval of the device. Depending on the clinical conditions, a new eyeWatch could be inserted to replace the initial device. Conversely, a seton tube or other draining system could be implanted instead.

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) 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 implant before adjustment. The physician who wishes to perform an adjustment (increase or decrease) of the hydraulic resistance of the implant needs first to determine the current angular position of the eyeWatch system. 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 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 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.

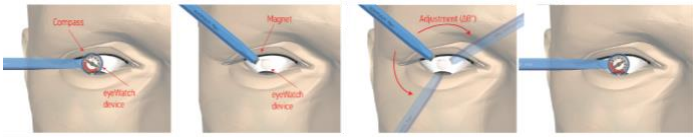

Figure 3: Sequence of steps necessary to adjust the eyeWatch device: 1) Read the angular position of the implant using the compass of the eyeWatch Pen. 2) Flip 180° the eyeWatch Pen and place the Pen's magnet near the periphery of the implant and at the position indicated by the compass. 3) Drag the 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 implant's internal magnetic disk and there is no interference problems with the much weaker geomagnetic field.

Note 2. The eyeWatch system allows for a relative adjustment of the fluidic resistance of the implant 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 system is intended to provide adjustability for the first 6 weeks 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), six 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.

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
	Sterilized Using Irradiation		Serial Number
	Double sterile barrier		Medical Device
	Do Not Reuse		Use by [YYYY-MM-DD]
	Do Not Resterilize		Manufacturing date [YYYY-MM-DD]
	Manufacturer		MR Conditional
	Catalogue number		European authorized representative
	Keep dry		Temperature limit

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