

Instruction For Use 1st Inject Instrument

Injector system for implantation of 1stQ foldable intraocular lenses

The IFU is available electronically on our website: www.1stq.eu

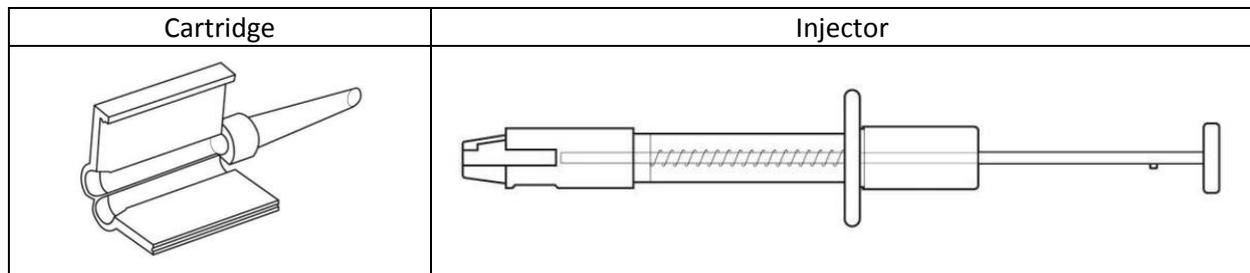
Content:

The package contains one sterile, single use disposable injection kit for the implantation of foldable hydrophobic or hydrophilic non-preloaded intraocular lenses (IOL) from 1stQ.

The numbers given in the product code indicate the estimated corneal incision size. The letters “HB” indicate that this injector model can also be used for the implantation of hydrophobic IOLs.

The assembled injector consists of two parts (cartridge and injector):

- The cartridge is a single piece device made up by two closeable winglets and the barrel. There is a groove towards the middle of the wings, forming the loading bay. The cartridge is packed separately in a small blister and is placed under the injector within the primary packaging.
- The injector body consists of the housing and a pushing rod with mounted plunger. It is packed together with the cartridge in one blister (primary package).



Transport, storage and waste management:

Handle with care.

Store at room temperature.

Do not expose to direct sunlight or extreme temperatures.

Do not freeze.

Keep dry, protect from moisture/water.

The product or its waste material should be disposed of in accordance with local/national regulations and requirements.

Sterilisation and expiration:

This injector has been sterilized with ethylene oxide after being packed under clean room conditions. Sterility is guaranteed only when the packaging is neither opened nor damaged. The applied sterilisation procedure is marked on the folding box. Do not use this product after its expiration date.

Indications:

The 1st Inject Instrument is indicated for implantation of foldable hydrophilic or hydrophobic 1stQ intraocular lenses into the posterior chamber of the adult eye (capsular bag or sulcus ciliaris) after surgical removal of a cataractous lens.

Contraindications:

There are no known contraindications to the use of the injector for implantation of a foldable intraocular lens into the posterior chamber.

Possible complications:

As with any surgical procedure, there is risk involved. The risk can be reduced significantly by attention to the instructions provided by the manufacturer. For the details please read the Instruction for use of the lens.

Interactions:

No direct interactions of the injector with drugs are known.

As the injector is used as a tool in a complicated surgical procedure, the use of antiplatelet and anticoagulant medications may increase the risk of hemorrhagic anesthetic or perioperative complications.

In reasonably foreseeable environmental conditions, no significant interaction or possible damage caused by exposition to magnetic fields, external electrical influences, electrostatic discharge, pressure or variation in pressure, thermal ignition sources, and acceleration is known.

Warnings:

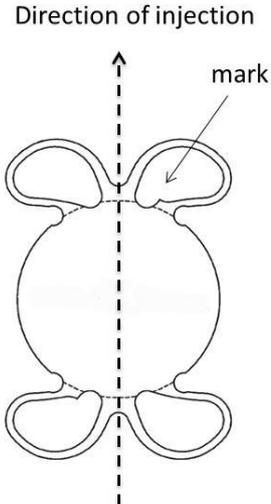
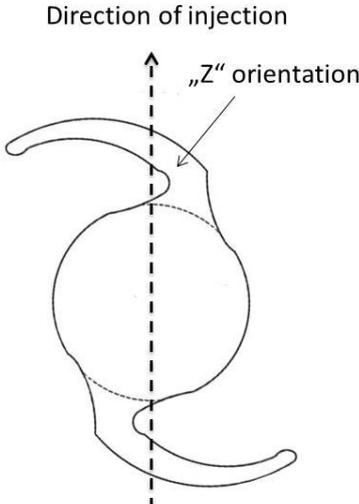
- Keep these Instructions for use and read it carefully before you apply this medical device.
- The surgeon performing the implantation must inform the patient about the implant and all known side-effects and risks.
- The patient should be instructed to inform the doctor in charge properly about any side-effects after implantation.
- Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or may necessitate additional surgical intervention.
- Do not use if the sterilized package is moist, open or damaged.
- Do not re-sterilize by any means.
- Do not use if expired.
- Do not re-use. Any occasional re-use must be avoided as it may pose serious health risk either by non-sterility or by any mechanical defect caused by the previous use.

Handling:

High level of surgical skill is required for proper implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more appropriate courses before attempting to perform implantation. Before performing the implantation the surgeon must read these instructions for use.

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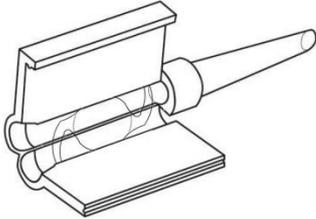
It is very important to ensure that the sharp edge of the optics of the lens implanted into the capsular bag is in contact with the posterior capsule, therefore the lens has to be properly positioned in the cartridge.

IOL with 4 loop haptics (1stQ Basis Q):	IOL with 2 haptics (1stQ Basis Z):
<p>The marked upper haptic is positioned to the right (small arrow). The large arrow shows the direction of the lens's movement during the injection.</p> 	<p>Position the lens in a "Z" or "reverse S" configuration, i.e. the end of the upper haptic is positioned to the left (small arrow). The large arrow shows the direction of the lens's movement during the injection.</p> 

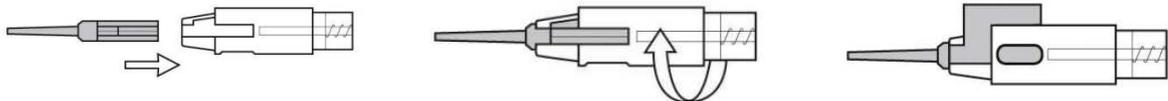
- Open the outer package to remove the blister containing the injector instrument and verify that the information on the blister is consistent with the outer package labelling (e.g. model, and lot number).
- Open the blister and remove the injector and the inner blister containing the cartridge in a sterile environment.
- Open the inner blister and remove the cartridge.
- Check the injector for free movement; use another one should you have concerns about its functionality.
- Pull the pushing rod completely to the back.
- Open the wings of the cartridge to an angle of 130°
- Fill the barrel and cover both grooves of the loading bay with a sterile viscoelastic solution. This ensures that the down side of the lens has the necessary lubrication during the injection. For implantation of a hydrophobic intraocular lens do not use cohesive viscoelastic solution.
- Balanced salt solution should not be used as a sole lubricant.
- Carefully remove the lens from its container. Handle lenses carefully to avoid damage to the lens optics or haptics. Non-toothed, polished instruments must be used when handling the IOL. Do not grasp the optical area with forceps.
- Thoroughly rinse the lens with a sterile intraocular irrigating solution (BSS).
- Examine the IOL for defects or foreign material.
- Grab carefully the root of the haptic and place the lens with proper orientation (see above) into the cartridge.
- Position the tip of the haptics under the edge of the grooves.

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- Keep the wings open at an angle of 130°, press down the lens with forceps and push the edges of the optic securely underneath the edges of the grooves.



- Cover the upper surface of the lens with the viscoelastic solution. In case the lens is made of hydrophobic material, carefully cover the full surface of the haptics with dispersive viscoelastic solution, as well.
- Close the wings of the cartridge to 90°.
- Check if the edges of the haptics and optic are completely positioned under the edges of the grooves. This will prevent that any part of the lens gets trapped between the wings when the cartridge is closed.
- Gently start closing the wings of the cartridge. Completing this step the two loading bays turn into a closed loading chamber filled up with the viscoelastic solution and the lens folds into a position ready for injection.
- Click the wings firmly together.
- The whole lens should be closed into the loading chamber. Visually observe that the lens is properly folded within the loading chamber.
- Insert the cartridge into the slot of the injector's body and lock the cartridge with a gentle rotation of the wings:



- Hydrophilic IOLs should not be kept in open air for longer than 1 minute. Neither type of IOL should be in folded condition for longer than 3 minutes. If these time limits have been exceeded the lens should be discarded.
- Inject the lens in a controlled manner. Do not use too much pressure. Anticipate a slight initial resistance. Excessive resistance could indicate a trapped lens. If the injector is blocked by the IOL, discard it.
- The entire injection should be one continuous process without interruption. Never pull the plunger back; otherwise the haptics might become damaged.
- When the lens exits the cartridge nozzle, stop pressing the plunger.
- The surgeon must achieve perfect placement, orientation and centration in the capsular bag for optimal results.
- Discard the injector after use.

Reporting customer complaints and return of product:

Customer complaints including quality complaints, adverse events and other medical device related observations should be reported to 1stQ without delay. A report is requested describing the details of the complaint/event, the applied therapy, the product type and LOT number of the medical device used.

If possible, return the medical device and/or its original container and/or any part of the packaging to 1stQ or to your local distributor.

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Symbols used:

	Do not resterilize		Serial number
	For single use		Sterilized using ethylene oxide
	Keep away from sunlight		Do not used if package is damaged
	Keep dry		Manufacturer
	Use by (date)		CE certified
	Consult Instructions for use		

Liability:

1stQ does not bear any responsibility for improper model selection by the physician, for improper handling, use, surgical technique applied or for any other iatrogenic error caused by the implanting surgeon.

This product is subject to change with or without prior notice. Improvement changes may be made in specification, shape and material.

All translations of this text are derived from the original English text. Should you face any discrepancy or problem in interpretation, please consult the English version for guidance.

The content of this document is subject to change without prior notice.

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