Instructions For Use

1stInject P2.2 single use IOL injection system for implantation of 1stQ foldable hydrophilic preloaded intraocular lenses

IFU also available electronically on our website. Please visit: www.1stq.eu

Content:
One sterile single use disposable injection system for the implantation of 1stQ preloaded foldable hydrophilic intraocular lenses (IOLs).

Description:
The manufacturing and the quality management system of 1stQ is in accordance with international standards and is certified according to ISO 13485 and 93/42/EEC.

The injector contains the following parts:

- injector body
- pushing rod with a special soft plunger
- cartridge
- anchor (stopper)

The cartridge, injector body, pushing rod, plunger and the stopper are made of plastics of high durability.

The number given in the product code indicates the estimated corneal incision size.

Indications of use:
The **1stInject P2.2** injection system is indicated for implantation of foldable 1stQ preloaded hydrophilic intraocular lenses into the capsular bag of the adult eye after the removal of a cataractous lens by extracapsular cataract extraction including phacoemulsification.

Contraindications:
In case of implantation into the capsular bag there are no known contraindications.

Packaging:
The injection system is delivered in a sterile pouch / blister.

Sterilization:
This injection system is sterilized by ethylene oxide (ETO) after being packed under clean room conditions. Sterility is guaranteed only when the packaging is neither opened nor damaged.

Transportation, 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 in accordance with local/national regulations and requirements.

Expiration:
Do not use this medical device after the expiry indicated on the carton/pouch/blister. The expiry date refers to the last day of the month of expiry.

Warnings:
- Do not use if the sterilized package is 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.

Precautions:
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 all the material provided by 1stQ for the correct handling and insertion of this implant.

Interactions:
No direct interactions of the injector with drugs are known.

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.

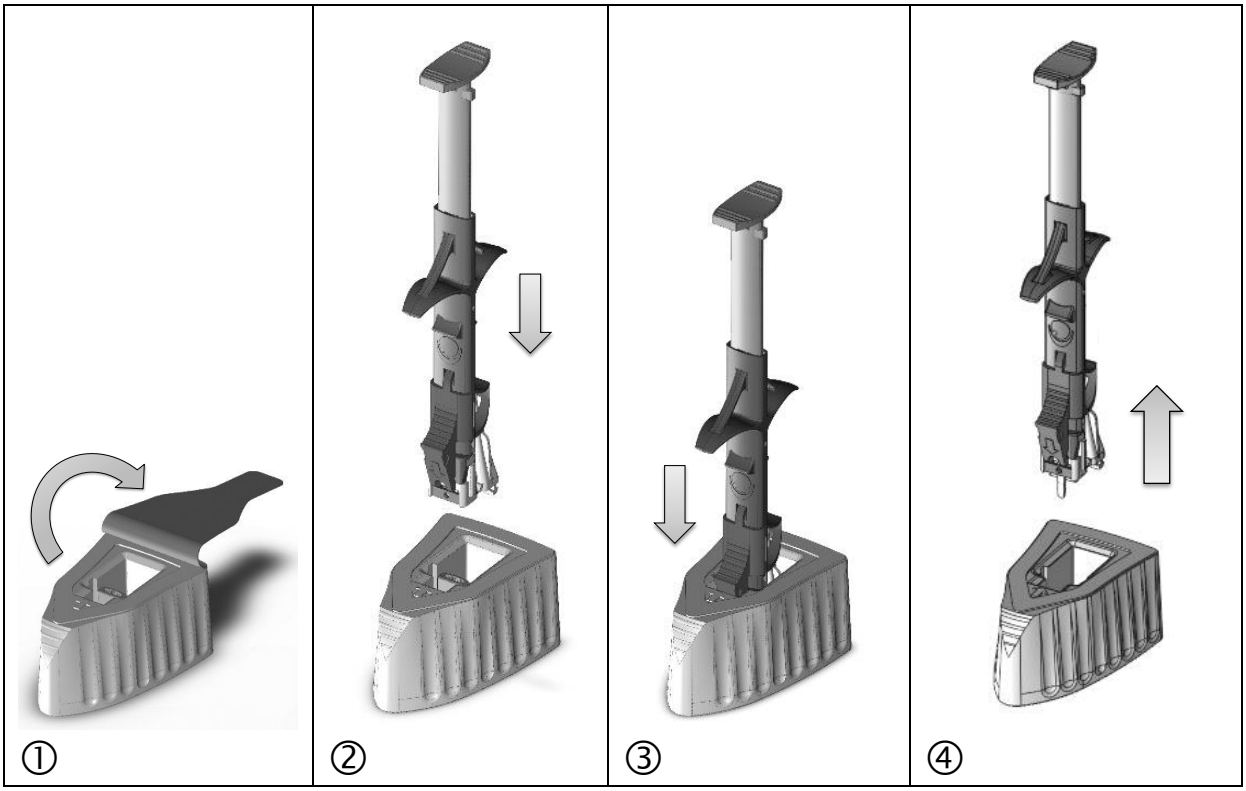
Patient information:
The surgeon performing the implantation must inform the patient about the implantation procedure and all its known side effects and risks. The patient should be instructed to inform the doctor in charge properly about any side effects after implantation.

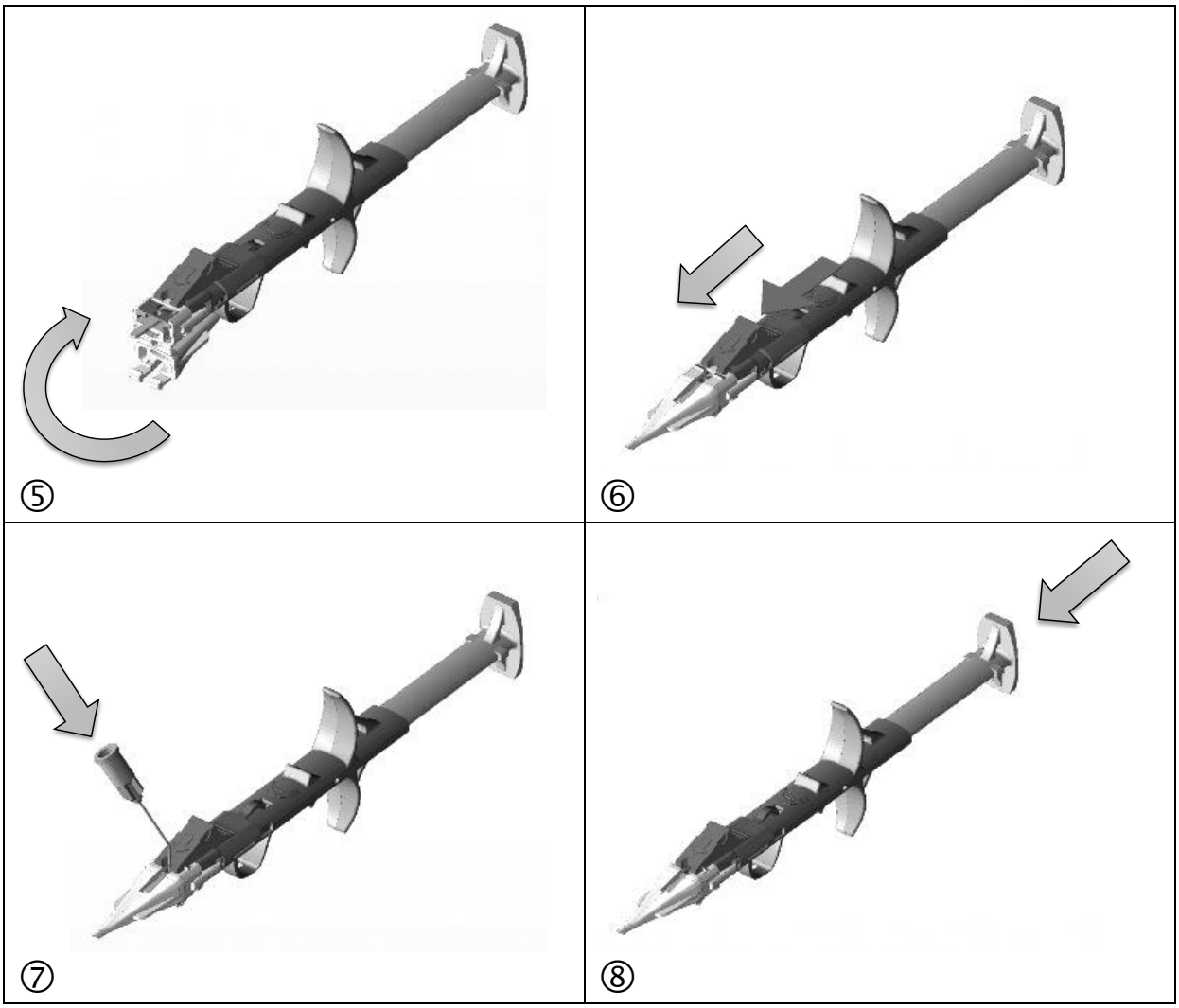
Handling:
- Check the label on the package to ensure that an unexpired, proper medical device is selected.
- Aseptically transfer the body of the injector, the relevant viscoelastic material and the sterile container with the preloaded lens inside to the sterile area of the operating theatre.
- Check the primary packaging of the injection system and wet container with preloaded lens.
- Check carefully the applicability of the injection system, use another one should you have concerns about its functionality.
- Anticipate an initial slight resistance. Significant resistance may indicate a trapped lens. (Stop the injection, do not try to implant the lens if it has been trapped.)
- Push the plunger of the injector forward in a slow controlled manner.
- In case of a smooth motion keep on pushing the plunger until the haptic reaches the nozzle.

- Introduce the tip of the cartridge properly into the anterior chamber of the eye through a clear corneal incision.
- Do not stop if the injection of the lens is started. The whole process should be one continuous process without any interruption from this moment on.
- After the lens left the nozzle of the cartridge completely, stop pressing the plunger.
- The lens unfolds within the capsular bag.
- Remove the tip of the cartridge from the anterior chamber carefully.
- Continue the surgical procedure according to the accepted protocol.

Description of figures:

1. Open the wet container.
2. Insert the injector into the wet container.
3. Push the injector down with a firm motion (until the "click").
4. Pull out the injector and check if the lens holder is loaded in the injector.
5. Fold up the cartridge nozzle (second „click”).
6. Push the anchor to the end position (third “click”).
7. Fill the chamber with viscoelastic solution approximately to the half of the nozzle.
8. Push the rod forward until the lens exit the cartridge.





Possible pre-, peri- and postoperative complications and undesirable effects:
As with any surgical procedure, there is risk involved.
The most common potential complications and undesirable effects accompanying cataract or implant surgery – some of them may lead to a secondary surgical intervention – are referred in the relevant medical literature. These may include, but are not limited to the following

- corneal endothelial damage and/or oedema
- flat anterior chamber after lens extraction
- detachment of the Descemet's membrane
- wound leak/dehiscence
- thermal burns
- astigmatism, oedema/ bullous keratopathy
- uveitis
- haemorrhage in one or more segments of the eye
- radial tears of the anterior capsule
- rupture of the posterior capsule
- capsular phymosis and capsule block syndrome
- late tear of the capsule with posterior dislocation of the IOL
- posterior capsule opacification
- damage to the zonules with consequential IOL dislocation including the sunset syndrome
- wound gape/iris prolapse, iris trauma, seclusio pupillae, iris capture, epithelial ingrowth, pupillary block

- damage to the IOL during insertion
- postoperative opacification/calcification of the IOL
- incorrect positioning of the IOL during surgery
- retinal detachment
- vitreous loss
- raised intraocular pressure (angle closure/open angle glaucoma)
- cystoid macular oedema
- cyclitic membrane
- hypopyon
- endophthalmitis
- IOL dislocation
- pupillary block
- corneal (stromal) oedema
- iritis

The following complications (not limited to these) may lead to a secondary surgical intervention:

- dissatisfactory visual outcome, e.g. due to incorrect IOL refraction
- IOL dislocation (decentration, axial shift, rotation, tilt)
- pupillary block, iris capture
- wound leak
- retinal detachment

Reporting customer complaints including quality complaints, adverse events and other medical device related observations:
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/serial number of the medical device used.

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

<u>Contact details for complaints:</u>
1stQ GmbH
Quality Management
Harrlachweg 1
68163 Mannheim
Germany
Tel: +49 621 7895 3790
Fax: +49 621 7895 3791
E-Mail: info@1stq.de
Homepage: www.1stq.eu

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.

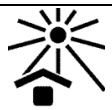
This product is subject to change with or without prior notice. Improvement changes may be made in specification, shape and material.

Please keep these instructions for use and read it carefully before you apply this medical device. IFU is also available electronically on our website: www.1stq.eu.

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

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.

Symbols used:

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

Manufacturer:

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www.1stQ.de